To Pedro

SUMMARY OF THE THESIS

In this doctoral thesis, the primary objective is to advance the landscape of advanced digestive endoscopy, specifically focusing on ERCP and EUS procedures. The imperative for precise and effective care is addressed through a comprehensive exploration of ERCP/EUS training and performance, with the aim of contributing to the improvement of standards in the endoscopic approach to biliopancreatic diseases.

The initial foray into ERCP and EUS training underscores the inherent complexity and risks associated with these procedures. Positions statements regarding European curriculums obtained through collaborative discussion and included in this thesis advocate for a formalized and standardized training approach, recognizing the necessity of rigorous quality standards. This evaluation then connects to insights derived from worldwide ERCP experts, shedding light on their journeys to success in these techniques. They emphasized the importance of specific training, dedicated to achieving competence through continuous, supervised work guided by mentors. Furthermore, specific certain qualities crucial for trainee success were identified, leading to a dedicated evaluation in a separate chapter outlining the significance of cognitive and personality traits alongside technical skills.

Additionally, a critical assessment of the adoption of proposals in European training centers reveals gaps in implementing recommended standards. This observation serves as a crucial link to the discussion on simulation training, a fundamental aspect in optimizing basic ERCP training. One of the most well-known prototypes of ERCP simulation training, Boškoski-Costamagna ERCP Trainer, has been enhanced through the incorporation of a biological papilla, providing realistic training in sphincterotomy, precut and papillectomy. Moreover, evidence from a randomized controlled trial substantiates the benefits of simulation training with this simulator, particularly its potential to expedite competence attainment among trainees.

Transitioning from training to ERCP performance, the study explores the correlation between ERCP volume, endoscopist experience, and procedural outcomes. These findings emphasize the paramount importance of conducting ERCP procedures in high-volume centers, a theme further reinforced in an economic analysis showcasing the cost-effectiveness of centralizing ERCP in such settings.

In conclusion, this thesis provides evidence supporting standardized training programs, comprehensive trainee selection, and the integration of simulation into ERCP training. Additionally, the consideration of centralizing ERCP in high-volume centers for its cost-effectiveness is explored. The overall impact of these findings on clinical practice and their potential to drive advancements in the field of endoscopic procedures, with a focus on specific training strategies and restructuring of ERCP services, are evident. As future projects, this thesis outlines an exploration of alternative training methods beyond simulation, such as teletraining, and a detailed analysis of specific country's ERCP performance, incorporating real-world data assessing outcomes, costs, and environmental impact. Collectively, these initiatives aim to continuously enhance healthcare standards and improve patient outcomes within the realm of ERCP and EUS.

RESUMÉ DE LA THÈSE

Dans cette thèse de doctorat, l'objectif principal est de faire progresser le domaine de l'endoscopie digestive avancée, en mettant particulièrement l'accent sur les procédures de CPRE et d'EUS. L'impératif d'une prise en charge précise et efficace est abordé à travers une exploration approfondie de la formation et de la performance en CPRE/EUS, dans le but de contribuer à l'amélioration des normes dans l'approche endoscopique des maladies bilio-pancréatiques.

La première analyse de la formation en CPRE et EUS souligne la complexité inhérente et les risques associés à ces procédures. Les *guidelines* européens, basées sur des réunions de consensus après analyse de la littérature, soulignent la nécessité d'une approche de formation structurée, reconnaissant la nécessité de normes de qualité rigoureuses. Cette évaluation est ensuite complétée par des opinions recueillies auprès d'experts mondialement reconnus en CPRE, qui partagent leur parcours personnels vers le succès dans ces techniques. Ils ont souligné l'importance d'une formation spécifique, dédiée à l'acquisition de compétences par un travail continu et supervisé, guidé par des mentors. De plus, certaines qualités cruciales pour le succès des résidents en formation ont été identifiées, soulignant l'importance de l'approche clinique raisonnée au-delà de la performance technique. De plus, une évaluation critique des programmes de enseignements actuels dans les centres de formation européens révèle des lacunes dans la mise en œuvre des normes recommandées. Une observation est l'usage limité des simulateurs, un aspect fondamental pour optimiser la formation de base en CPRE. L'un des prototypes les plus connus de simulateurs mécaniques en CPRE, le simulateur Boškoski-Costamagna ERCP trainer, a été amélioré par l'incorporation d'une papille biologique, offrant une formation plus réaliste en sphinctérotomie, précoupe et papillectomie. De plus, des preuves issues d'un essai contrôlé randomisé étayent les avantages de la formation par simulation avec ce type de simulateur, en particulier son potentiel à accélérer l'acquisition de compétences chez les résidants.

Passant de la formation à la performance en CPRE, une étude type revue systématique et meta-analyse explore la corrélation entre le volume de CPRE, l'expérience de l'endoscopiste et les résultats procéduraux. Ces résultats soulignent l'importance primordiale de la réalisation des procédures de CPRE dans des centres de référence, à haute volume par des médecins expérimentés, une observation renforcée dans une analyse économique complémentaire démontrant le bénéfice en termes de coût-efficacité de la centralisation de la CPRE dans de tels établissements.

En conclusion, cette thèse fournit des évidences supplémentaires soutenant des programmes de formation structurés, une sélection exhaustive des résidents et l'intégration des outils de simulation dans la formation en CPRE. De plus, la considération de la centralisation de la CPRE dans des centres à fort volume en vue d'un coût-efficacité est explorée. L'impact global de ces résultats sur la pratique clinique et leur potentiel à stimuler les progrès dans

le domaine des procédures endoscopiques, en mettant l'accent sur des stratégies de formation spécifiques et la restructuration des services de CPRE, est évident. Concernant des projets futurs, cette thèse propose d'explorer des méthodes de formation alternatives de l'enseignement en CPRE, telles que le télé-enseignement, ainsi qu'une analyse détaillée de la performance en CPRE dans le cadre d'un pays spécifique, en incorporant des données du monde réel évaluant les résultats, les coûts et l'impact environnemental. Globalement, ces initiatives visent à améliorer continuellement les normes des soins de santé dans le domaine de la CPRE et de l'EUS et in fine, d'optimaliser l'impact clinique sur les patients.

ACKNOWLEDGEMENTS

I would like to express my sincere gratitude to those whose support and guidance have been instrumental throughout my doctoral journey. Their unwavering encouragement and contributions have enriched my academic experience and made this achievement possible.

> My first expression of gratitude is extended to Professor Jacques Devière, who provided me with the most significant professional opportunity of my career so far. Having the chance to work closely with one of the foremost figures in the field of endoscopy, a reference not only as an endoscopist but, above all, as a physician and as a leader. My initial impression of Professor Devière was during a live procedure when, during a ductal cannulation attempt, he repeatedly emphasized the words "gentle, gentle, gentle." His unwavering respect for patients is his guiding principle. It's a motto that should underlie every endoscopic procedure, medical action, or research project, and it is according to this principle that I strive to shape my practice. Thank you for all the lessons, for making me see beyond standardized approaches, for encouraging thinking outside the box, yet always within the bounds of patient safety.

> When I entered the world of biliopancreatic endoscopy, I stepped into a predominantly male domain. At a conference, I met Professor Marianna Arvanitakis, the first woman I saw speaking eloquently in this field, and I thought that one day I would like to be like her. Little did I know that she would eventually become my doctoral supervisor. A thank you for demonstrating that a woman can succeed in this area!

> In the realm of biliopancreatic endoscopy, I cannot overlook the acknowledgment to those who introduced me to this field. A thank you to Professor Marco Bruno and Dr. Jean-Werner Poley for instilling in me a passion for this area and providing the fundamental groundwork for working rigorously, methodically, and safely.

> To my parents, my best friends, my greatest sources of confidence. Thank you for all the efforts to provide the best education possible. Thank you for always being present and available to offer a word of encouragement and strength, even when it seemed they had run out.

> To my Pedro, my dearest love, my life partner, my source of inspiration for this PhD. The person most present in my life and especially during this doctoral journey. Thank you for showing me the beauty and the importance of the research world, a space where we can pause to reflect. Reflect on what we do and how we can do it better. I cannot thank you enough for all the days and nights spent reflecting together!

> Finally, to my dear Francisco, my sweetest baby, my reason to keep wanting to do more and be better to one day be an example for his future.

TABLE OF CONTENTS

ABBREVIATIONS

AE	Adverse Events
AGIE	Advanced Gastrointestinal Endoscopy
ASGE	American Society of Gastrointestinal Endoscopy
BESAT	Bethesda ERCP Skills Assessment Tool
CEA	Cost-Effectiveness Analysis
CH-EUS	Contrast Harmonic EUS
CV	Curriculum Vitae
DOPS	Direct Observation of Procedural Skills
EASIE	Erlanger Active Simulator for Interventional Endoscopy
EBGH	European Board of Gastroenterology and Hepatology
EDGE	Endoscopic-Directed transGastric ERCP
EI	Extremely important
EMR	Endoscopic Mucosal Resection
EMS	ERCP Mechanical Simulator
EO	Expert Opinion
ERCP	Endoscopic Retrograde CholangioPancreatography
ESCP	EndoSonographic CholangioPancreatography
ESGE	European Society of Gastrointestinal Endoscopy
EUS	Endoscopic Ultrasound
EUS-E	EUS-Elastography
EUS-GE	EUS-GastroEnterostomy
FNA	Fine-Needle Aspiration
FNB	Fine-Needle Biopsy
GAPS-EUS	Global Assessment of Performance and Skills in EUS
GI	GastroIntestinal
GESAP	Gastrointestinal Endoscopy Self-Assessment Program
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HRQoL	Health-Related Quality of Life
HV	High-Volume
ICC	Intraclass Correlation Coefficient
ICER	Incremental Cost-Effectiveness Ratio
IQR	Interquartile Range
LV	Low-Volume
MBO	Malignant Biliary Obstruction
MGOO	Malignant Gastric Outlet Obstruction
MRCP	Magnetic Retrograde CholangioPancreatography
NA	Not Applicable
NS	Not Significant

NTS	|	Non-Technical Skills
OR	|	Odds Ratio
PEP	|	Post-ERCP Pancreatitis
PFC	|	Pancreatic Fluid Collection
PICO	|	Population, Intervention, Comparator, Outcome
PSA	|	Probabilistic Sensitivity Analysis
PTC	|	Percutaneous Transhepatic Cholangiography
QALY	|	Quality-Adjusted Life-Year
RAF-E	|	Rotterdam Assessment Form for ERCP
TPD	|	Training Program Directors
TEESAT	|	The EUS and ERCP Skills Assessment Tool
TIERS	|	Trainee Involvement in ERCP Risk Score
UGI	|	Upper Gastrointestinal
WTP	|	Willingness-To-Pay

SECTION I

Conceptualization

CHAPTER 1

General introduction and outline of the thesis

INTRODUCTION

The intertwined role of ERCP and EUS

Since its introduction in 1968 [1], endoscopic retrograde cholangiopancreatography (ERCP) has evolved from a diagnostic tool to a therapeutic modality for biliopancreatic conditions. Initially used with diagnostic purposes, ERCP's therapeutic potential expanded significantly after the introduction of sphincterotomy [2], followed by techniques for stone extraction and stenting. Today, it stands as a minimally invasive procedure for complex biliopancreatic endotherapy, relying on precise indications and patient selection [3].

Similarly, endoscopic ultrasound (EUS) was introduced in the 1980s after modifying a side viewing scope to include an ultrasound probe at its tip [4]. Initially used as a diagnostic modality for pancreatic pathology, EUS evolved into an interventional procedure [5] with the introduction of the linear echoendoscope, which allowed for EUS-guided puncture [6].

Over the years, the clinical demand and utilization of ERCP and EUS have surged [7,8]. These techniques have become complementary tools in managing biliopancreatic conditions, sharing common indications, equipment, and technical skill sets [9]. This synergy unfolds in four distinct dimensions [10].

Firstly, EUS can determine the need for ERCP, particularly in cases with an intermediate risk of choledocholithiasis. In such situations, EUS or Magnetic Resonance Cholangiopancreatography (MRCP) should be performed before ERCP to confirm the presence of biliary stones [11]. When the pretest probability of choledocholithiasis is high, performing EUS in the same endoscopic session as ERCP could be considered, whenever possible [12]. A meta-analysis found that EUS had similar sensitivity and specificity for diagnosing choledocholithiasis, compared to MRCP (97% versus 87% and 90% vs 92%, respectively), but EUS was found to have a significantly higher diagnostic odds ratio than MRCP due to its superior sensitivity, especially for small stones [13]. Additionally, a systematic review showed that performing EUS beforehand avoided the need for ERCP in 67% of patients by confirming the absence of choledocholithiasis [14], significantly reducing overall adverse events (AE) (6,6% versus 19%) and post-ERCP pancreatitis (PEP) (1.39% versus 7.85%).

Secondly, EUS can complement ERCP. In jaundice secondary to biliopancreatic neoplasm, EUS can provide a diagnosis through tissue-guided sampling, while ERCP can offer treatment. Performing both procedures in a single session can be advantageous, particularly regarding the dose of propofol [15–17]. Pancreatic collections associated with ductal pathology secondary to acute or chronic pancreatitis can also be addressed through EUS-collection drainage, which is superior to percutaneous and surgical treatments [18,19]. Additionally, EUS can complement ERCP in managing pain due to inoperable pancreatic cancer. EUS-guided celiac plexus neurolysis has been shown to achieve pain control in approximately 73% of cases [20], with better responses when performed early [21].

Thirdly, EUS can facilitate ERCP. In patients with normal anatomy, bile duct cannulation should be achieved in at least 90% of cases [22]. In expert centers, the failure of cannulation may be significantly reduced to around 5%, depending on the patient's condition and local expertise. In situations where papillary cannulation fails but the papilla is endoscopically accessible, EUS-guided rendezvous technique can be used. This involves using EUS to guide a wire through the duct, facilitating ERCP. The technical success rate of EUS-guided biliary rendezvous ranges from 70% to 100%, with an AE rate of approximately 15% [23,24]. For EUS-guided pancreatic rendezvous, the clinical success rate is about 80%, with an AE rate of around 20% [25]. EUS-directed transgastric ERCP (EDGE) is another technique, which can be used for patients with gastric bypass. Studies comparing EDGE versus laparoscopy-assisted ERCP found no significant differences in technical success, therapeutic success, or adverse event rates but noted shorter procedure times (73 versus 184 minutes) and hospital stays (0.8 versus 2.65 days) for EDGE [26].

Finally, EUS can substitute ERCP, especially valid when the papillary area is unreachable. In such cases, EUS can offer transmural biliary or pancreatic drainage solutions.

In patients with concomitant malignant biliary obstruction (MBO) and malignant gastric outlet obstruction (MGOO), double stenting (biliary and duodenal) is considered the standard for palliative treatment, while surgical biliary and gastrojejunostomy is adopted for patients with higher life expectancy. While endoscopic stenting and surgical gastrojejunostomy have similar rates of technical success, clinical success, and reintervention, patients undergoing surgical bypass have longer mean patency duration (193.4 versus 169.2 days) and survival lengths (119.9 versus 96.5 days) [27]. However, open surgical bypass has significant morbidity (25%) and mortality (2.5%) [28]. Growing evidence supports the better efficacy of EUS-guided gastroenterostomy (EUS-GE) over enteral stenting in terms of clinical success (91% versus 75%; $p = 0.008$) and stent dysfunction (1% versus 26%; $p < 0.001$) due to tumor ingrowth or overgrowth [29]. Its combination with EUS-biliary drainage might become the main palliative treatment strategy for concurrent MBO and MGOO in the near future [30].

In patients with altered anatomy due to previous surgery, such as Roux-en-Y reconstruction, the papillary area can also be difficult to reach, reducing the cannulation rate to about 60% even in expert centers [31]. Two meta-analysis showed that EUS-guided transmural biliary drainage achieved high technical and clinical success rates, between 91% and 95.68% and 87% and 90.32%, respectively, with AE rates between 17.9% and 24.41%, and a re-intervention rate of 6.5% [32,33]. When traditional ERCP fails, EUS-biliary drainage may be preferred over percutaneous transhepatic cholangiography (PTC). A recent meta-analysis [34] demonstrated that, while technical success rates were similar, EUS-biliary drainage resulted in better clinical success (OR, .45; 95% CI, .23-.89; I2 = 0%), a lower rate of AE (OR, .23; 95% CI, .12-.47; I2 = 57%), reduced need for reintervention (OR, .13; 95% CI, .07-.24; I2 = 0%), and it was more cost-effective. Consequently, various scientific societies have integrated this EUS approach into therapeutic algorithms ahead of PTC, provided that advanced endoscopy expertise and logistics are available [35–37].

Even in cases where papilla is reachable, the use of EUS as primary treatment for MBO instead of ERCP has already been noted [38–40] and is currently being investigated in ongoing randomized trials [NCT04099862, NCT03870386, NCT04898777].

These scenarios highlight the importance of combining EUS and ERCP for effectively managing biliopancreatic diseases. The intertwined role of EUS and ERCP in patient care have led to the creation of the concept known as endosonographic cholangiopancreatography (ESCP) [41]. Formally proposed in 1996 by Wiersema et al. [42], ESCP represents a paradigm shift in the endoscopic treatment of biliary and pancreatic diseases, addressing many limitations of ERCP.

However, due to the technical and cognitive complexity involved, skilled endoscopists proficient in both techniques and working under optimal conditions are essential to ensure effective and safe patient management, which may not be feasible in all centers. Moreover, logistical and financial considerations are crucial. As mentioned earlier, evidence suggests that combining ERCP and EUS, when clinically appropriate, can be a cost-effective strategy [15]. This approach not only leverages the strengths of each technique but also optimizes resource utilization.

Training in ERCP and EUS

Given the expanding array of therapeutic indications, the technical complexity and high risk of AE associated with ERCP and EUS, as well as their operator-dependent nature, achieving proficiency in these procedures require thorough training. Efforts are underway to establish standardized training programs for advanced biliopancreatic endoscopy [43]. These training programs should be well-structured and encompass the definition of appropriate training conditions (including qualified trainers and well-equipped training facilities), the inclusion of a wide range of procedures volumes and complexities and complementary training models, and the adoption of validated competence assessment tools. Despite increasing awareness of the importance of developing these programs, they remain lacking. This absence can be attributed to several factors, such as the infrequency of certain procedures, the unpredictable mix of clinical cases, the lack of validation for complementary training tools, and the extended and varying learning curves required for trainees to achieve competence, among others [44–47].

Traditionally, training programs have relied on procedure volume as an indicator of competence, as endoscopists' experience with specific procedures correlates with their performance [48]. In ERCP, the success rate for selective cannulation without assistance is another commonly used measure of competence [49–52]. However, many training programs are not able to meet the established cut-offs [53], and even when they do, it does not always guarantee trainee competence. Trainees develop skills at different rates, and the learning curves in ERCP and EUS vary considerably [46,47,54–56]. This variability can be attributed to several factors, such as the trainee's skills, the trainer's teaching abilities, the intensity e comprehensiveness of the training program, and access to complementary training models. Consequently, the current trend is moving away from a purely volume-based approach towards a competence-based model, emphasizing other measures of competence beyond just the number of completed procedures [57].

Apart from procedure volume, trainees should gain experience in ERCP and EUS across various indications and levels of complexity. To standardize the measurement of complexity, a scale predicting or expecting difficulty should be adopted. Apart from advising patients about the likelihood of technical success and assisting endoscopists in deciding which cases to attempt and which to refer elsewhere, such a scale can aid in structuring training phases and credentialing stages.

Schutz and Abbott were the pioneers in ranking the difficulty of ERCP procedures on a five-point scale based on common perceptions of endoscopists and success rates [58]. Schutz's complexity grading scale correlated with procedural success but showed no variation in AE rate [58,59]. Furthermore, this grading system includes diagnostic ERCP, largely abandoned in favor of MRCP and EUS, rendering it somewhat outdated.

In 2011, the American Society of Gastrointestinal Endoscopy (ASGE) published the Cotton's classification, a grading system for the complexity of major endoscopic procedures, including ERCP and EUS. This system focus on predicting difficulty before the procedure begins [60]. Scoring on a four-point scale and considering additional aggravating factors, it includes not only technical difficulty (e.g., patients with surgically altered anatomy), but also clinical difficulty and perceived risk parameters, such as performing procedures outside normal working hours, on very young children, or after previous unsuccessful attempts. This classification has significantly influenced global benchmarks for ERCP procedures. The EUS and ERCP Skills Assessment Tool (TEESAT), widely used to assess competence in ERCP and EUS, documents the indication and the grade of difficulty using the ASGE degree of difficulty grading system [44]. In 2016, the ASGE ERCP Core Curriculum simplified the existing system to a three-grade scale for ERCP complexity [49].

In 2017, Olsson et al. introduced the H.O.U.S.E. classification [61], which consists of three different classes based on perceived procedural complexity of ERCP. There is a clear correlation between grading and procedure duration, and to some extent, with AE. However, the score might be biased as the data is monocentric and originates from Karolinska University Hospital, a tertiary referral center and major teaching institute for ERCP, potentially contributing to higher AE rates [62]. Additionally, this score includes peri-procedural criteria, making it unsuitable for directing ERCPs to referral centers.

Competence gained with a comprehensive training should be monitored regularly during the training period and also before commencing independent practice. Competence in endoscopy is defined by the ASGE as the "minimum level of skill, knowledge, and/or expertise derived through training and experience that is required to safely and proficiently perform a task or procedure" [43]. To independently carry out successful and safe procedures, endoscopists should master not only specific technical skills, but also cognitive and integrative skills [63]. While motor skills include hand-eye coordination, agility and dexterity, cognitive skills include patient selection, procedural indications and contraindications, knowledge of equipment, clinical assessment, adverse event management and knowledge of sedation protocols. Integrative skills include situational awareness, ethical and professional behavior, self-development, teamwork and decision-making and problem-solving (clinical reasoning and integrating data into a management plan).

Adopting a competence-based model in ERCP and EUS training requires accurate measurement of competence. Observational competence assessment tools with strong evidence of validity can provide an objective, reliable, standardized, and comprehensive evaluation of trainees, supporting feedback and decisions regarding progression and certification. To achieve this, these tools should include the evaluation of trainee's learning curves, which are the best-suited benchmark for assessing competence [55]. By comparing individual skills to generic learning curves, it is possible to project each trainee's improvement over time. In addition to measuring technical skills, these tools should also assess cognitive and integrative skills. A recent systematic review of validity evidence for ERCP assessment tools [64] identified three tools that effectively integrate the assessment of all these skills needed for safe and effective practice while also having the strongest validity evidence: TEESAT, the ERCP Direct Observational Performance Score (ERCP-DOPS), and the Bethesda ERCP Skills Assessment Tool (BESAT). Self-assessment tools like the Rotterdam Assessment Form for ERCP (RAF-E) [55] can provide further insight into the trainee's performance evolution during the training period. Both TEESAT [65] and DOPS [66] are also validated for EUS competence assessment, as well as Global Assessment of Performance and Skills in EUS (GAPS-EUS) [67].

The conventional training strategy typically followed the master-apprentice model, where a trainer demonstrates a technique, and the trainee practices on patients with subsequent feedback. This method is a highly effective way of teaching due to its high realism, low cost, direct mentorship, and immediate feedback [68]. However, it also has several drawbacks, such as limited hands-on exposure for trainees (due to rising complexity of procedures, the absence of evidence linking trainee involvement and clinical outcomes, and increasing legal and ethical issues related to training with actual patients), variability in training experiences [69,70], and the potential for prolonged procedure times and increased precut rates in ERCP [71,72].

Simulation-based training is gaining traction as a complementary training model due to its several advantages. Firstly, "safety": trainees can build their skills at a pace that suits them, without the risk of harming patients. This removes the pressures associated with live patient procedures, fostering an ideal training atmosphere. Secondly, "repetition": trainees can repeatedly practice incremental steps or specific scenarios until they achieve mastery. Thirdly, "feedback": simulation training can provide immediate feedback, facilitating quicker learning and correction of mistakes. Fourthly, "consistency": it ensures a comprehensive, effective and standardized training experience, regardless of the variability in clinical case availability. Different clinical and anatomical conditions can be simulated to expose the trainee to a broader clinical case-mix. Finally, "assessment": it may enable objective assessment of trainee skills through performance metrics. Significant progress has been made with the introduction of simulators for training, which have had a striking impact on the learning curve of novice endoscopists [63].

The beginnings of endoscopic simulation training can be traced back to 1969 with the use of mechanical models, when the first basic mannequin for sigmoidoscopy training was created [73]. Since then, a variety of simulators have been designed for endoscopy training, particularly for basic gastrointestinal (GI) procedures [74]. These include mechanical models, live and ex vivo animal models, and the latest virtual reality simulators, each with unique advantages and limitations [75,76].

Mechanical simulators are physical models made of non-tissue materials designed to mimic anatomic structures for practicing endoscopic maneuvers. Although they lack realistic tissue properties and cannot simulate dynamic physiological responses such as bleeding or peristalsis, they generally offer benefits such as low costs, easy assembly, good haptic feedback, and the ability to use the same equipment as in real-life situations. The X-Vision ERCP system [77] and the ERCP Mechanical Simulator (EMS) Trainer [78] were the first mechanical simulators developed for ERCP training. The X-Vision ERCP system is a custom-defined simulator that includes four models, each weighing under 3kg, with a chassis that directly exposes the ductal systems and eliminates the need for fluoroscopy. Made of aluminum, plastic, and rubber, it features exchangeable or fixed organic tissue papillae for various training purposes. The duodenum can be intubated with an endoscope via a curved tube, and the system mounts on an endoscopy trolley below the monitor displaying the endoscopic image. To date, this simulator has been subjected only to face and construct validity testing [79]. The EMS simulator, on the other hand, features a model of the upper GI tract with a soft rubber duodenum, foam papilla, and detachable bile duct for practice scenarios. It uses an external video camera for simulated fluoroscopy instead of radiologic contrast, activated by a foot switch to display images on a monitor. Both models allow visualization of the pancreaticobiliary ductal system and the simulation of selective ductal cannulation, sphincterotomy, stricture dilation, brush cytology, stone extraction, and stent placement. Three randomized controlled trials have demonstrated that EMS reduces procedure times, increases success rates, and lowers adverse events, proving its effectiveness in training programs [80–82].

More recently, Boškoski-Costamagna ERCP Trainer (BCT) was designed to train residents on proper endoscope positioning, which is crucial for successful ERCP. It consists of a metal framework with plastic esophagus, stomach, and duodenum, and latex papillae with varied papillary anatomy and biliopancreatic junction. The model supports the use of a real endoscope and equipment and can be placed on a table with real-time fluoroscopy displayed via a small camera. The BCT simulates different patient positions (prone, oblique, supine) and various ERCP steps (selective cannulation, stone extraction and stent placement), with adjustable difficulty based on anatomical variations. Although the original latex papilla did not support biliary sphincterotomy, a new synthetic papilla now enables this training [83]. Face and construct validity has already been proved [84–86].

Considering the previous models, Jirapinyo et al. created the latest ERCP mechanical model based on a training box that includes six different silicone papillae, each with a bile duct and pancreatic duct. These vary based on factors such as the angles or axes of the papilla, common channel length, angle between biliary and pancreatic ducts, and location within the duodenum. The primary purpose of this simulator is to train ductal cannulation, for which content validity has been established [87]. However, it lacks capabilities for sphincterotomy and fluoroscopy.

Mechanical simulators for EUS have also been developed but are not widely used in training. The EUS Phantom (Olympus, Tokyo, Japan) is a simple, easy to use, and conveniently stored and transported box with a central orifice that mimics the esophageal lumen [88]. Structures within the box produce sonographic images that replicate human anatomical structures such as hypoechoic masses and lymph nodes. EUS tissue sampling can also be practiced with the Phantom model [89].

In vivo models involve using live animals, typically swine, which provide the most realistic simulation with tactile feedback identical to human tissue and include dynamic physiological responses, such as GI peristalsis, respiratory motion, presence of luminal fluid and bleeding and perforation risks [90]. Gholson et al. [91] introduced the first live porcine model for ERCP in 1990, although anatomical differences in the bile and pancreatic ducts have been demonstrated. Dogs are also sometimes used for research and training purposes [92]. In EUS, Bhutani et al [93] studied the effectiveness of using a swine model for EUS training [94], including teaching interventional EUS by creating pseudo-lesions through saline injection. Trainees practicing on animal models have gained confidence in performing endoscopic procedures, though not significantly more than those using mechanical models [95]. Additionally, their use is limited by high cost, the need for specialized facilities and equipment, limited availability and reusability, and ethical considerations and regulations.

Ex-vivo animal organ simulators combine plastic models with explanted animal organs and can be modified to simulate various pathological conditions. The Erlanger Active Simulator for Interventional Endoscopy (EASIE) model by Hochberger et al. allows practice of therapeutic maneuvers for ERCP [96], EUS, and EUS-FNA [97–101] using porcine organs on a mannequin with arteries sewn into their linings and an electric pump to simulate pulsatile bleeding. The Neo-papilla by Cotton et al. [102], made of chicken heart tissue, can be added to the EASIE model for a more realistic result and to enable fluoroscopy. Rustemovic et al. developed another simple, reproducible, easy-to-build, ex-vivo ERCP model for training sphincterotomy and precut, also incorporating a chicken heart into a pig stomach to simulate the papilla of Vater [103]. In EUS, Fukushima model [104] uses fresh chicken tenderloins embedded as target lesions in the submucosal layer of an isolated porcine stomach for EUS-FNA training. Additionally, a porcine model was developed to train EUS-biliary drainage, where dilation of the biliary system is achieved by applying over-the-scope clips to the major papilla [105]. Although useful, it takes about ten days for common bile duct (CBD) to dilate after clipping of the papilla, and the dilation of intrahepatic biliary radicals may be erratic. To address this, the Mumbai EUS bile duct prototype [106,107] was developed, using stereolithography/3-dimensional printing technology to create a polycarbonate bile duct. Multiple procedures can be performed on a single model, with or without X-ray. All these ex-vivo models offer intermediate costs and realism in terms of feel and anatomy compared to live animal use. However, they are limited in replicating physiological responses, require careful preparation, specific equipment, and disposal of biological materials. Additionally, tissue characteristics can degrade over time, limiting reusability and making this option challenging to adopt in practice.

Virtual Reality simulators, introduced in the 1980s, were the latest advancement in endoscopic simulation training. The GI Mentor (Simbionix), with special models for ERCP and diagnostic EUS with linear and radial imaging, the EndoVR Simulator [108–110], and EUS Meets Voxel-Man [111] use computer-generator environments to simulate endoscopic procedures. These systems incorporate haptic and visual interfaces to practice cognitive and technical skills across a wide range of procedures, from diagnostic to complex treatments, including rare complications. They provide a customized educational environment tailored to individual trainees' needs, offering real-time feedback along with objective performance metrics assessment, and tracking their progress, all without the need for a trainer. They are easy to incorporate into training programs, standardizing the training experience. However, the high initial cost of equipment and software, the need for regular updates and maintenance, the lower realism index (particularly the tactile feel of live tissue, as they do not use real endoscopes or accessories), and the limited role in advanced training preclude their wide adoption. Few validation studies exist [95,108,112,113], and more rigorous research on their effectiveness is needed.

Despite significant advancement in the variety and quality of simulators over the years, none can match the realism of human cadaver models [114]. Cadavers offer the closest replication of clinical and anatomical conditions, as well as accurate tactile and spatial sensations [115]. However, they have several drawbacks, including limited availability, storage challenges, legal and ethical issues, and high costs [116,117]. Currently, there is no literature on the use of human cadaver models specifically for ERCP or EUS training.

Despite significant advancements in simulators, particularly in ERCP, their widespread integration into clinical practice is impeded by insufficient validation [118]. Validity, in essence, is defined as "the extent to which a test, model, measurement, simulation, or other reproduction provides an accurate representation of its real equivalent" [119]. Ensuring the validation of any simulation platform before its inclusion it into training programs or introduction to the market is paramount. This validation process encompasses several stages to furnish evidence of the simulator's performance across different levels [119–121].

The initial stage is "face validity" answers the question "does the simulator look and feel realistic?". It gauges the extent to which a simulator appears effective in fulfilling its intended purpose. Fundamentally, it assesses whether the simulator is realistic and representative of the skills acquired in the real environment. This validity type is typically evaluated through expert feedback, soliciting assessments from experienced endoscopists. If they affirm that the simulator accurately replicates real-life procedures and environments, the simulator is deemed to possess high face validity.

Subsequently, "content validity" tackles the question, "does the simulator encompass all relevant skills essential as a learning tool?". This validity type ensures that the simulator offers a comprehensive representation of the procedural steps that a trainee may encounter in real life. It is usually evaluated by comparing the simulator's attributes and functionalities against a checklist of required competencies and procedural elements, often involving a panel of experts in GI endoscopy.

The third stage, "construct validity", addresses the question "can the simulator discriminate between different levels of expertise?". This type of validity is crucial for training programs because it confirms that the simulator can be used to assess the progression of a trainee's skills over time. Construct validity is assessed by having participants of differing expertise levels use the simulator, followed by a comparison of their performance. The simulator should show clear performance differences between novices and experts.

The final and most critical stage is "predictive or transfer validity", which answers the question "does performance on the simulator predict actual clinical performance?". It measures the extent to which performance on the simulator predicts future performance in actual clinical settings. It evaluates whether the skills acquired and demonstrated on the simulator translate to real-world competence. Predictive validity holds paramount importance as it determines the ultimate effectiveness of simulation training. It ensures that time and resources invested in simulation training lead to enhanced clinical outcomes. This validity is evaluated through longitudinal studies where trainees' performance on the simulator is monitored and compared to their subsequent performance in real endoscopic procedures. Successful predictive validity implies that high simulator performance correlates with high performance in the clinical setting.

Each validity type plays a vital role in ensuring that GI endoscopic simulators serve as effective educational tools that provide realistic, comprehensive, and transferable training experiences. Simulation in ERCP demonstrates adequate face and construct validity and proves beneficial for acquiring gross motor skills early in training, with benefits extending to clinical procedure success [86]. Nevertheless, its effectiveness in skill transfer to trainees (predictive validity) still needs thorough evaluation for formal training integration. Ultimately, high-quality education is key in clinical practice [122], emphasizing the need for further research to substantiate training program recommendations and to standardize ERCP and EUS training practices within evidence-based curricula [123].

Performance in ERCP

High quality endoscopy leads to improved health outcomes and enhances the patient experience [124]. However, there is considerable clinical variation in the quality of ERCP currently performed in endoscopy units, both in terms of success rates and AE rates [70,125–130].

Performance measures, defined as "measurements that are used to assess the performance of a service or aspect of a service", have been widely recommended and implemented in endoscopy to set benchmarks for acceptable performance [131]. By establishing minimum and target standards, these measures drive continuous improvement. When clinicians and healthcare services examine their performance data, they are incentivized to improve their results. These measures help identify, evaluate, and monitor critical steps and key outcomes in the procedure, revealing areas where systems may be deficient and whether the service is providing high-quality, patient-centered care. They enable providers to identify and rectify specific shortcomings in their service, ultimately leading to improved patient outcomes. Performance measures can be applied during the pre-, intra- or post-procedural periods. They can be "structural", reflecting the conditions under which providers care for patients or aspects of healthcare infrastructure, such as the procedural volumes performed by a provider. They can also be "process measures", indicating whether actions known to benefit patients are being performed (e.g. the percentage of patients needing pre-procedure antibiotics who receive the correct antibiotic at the right time) and "outcome measures", which analyze the actual results of care, such as the percentage of patients readmitted to the hospital for complications within 30 days of an endoscopic procedure. In 2018, Domagk et al. introduced performance metrics for ERCP and EUS as part of the European Society of Gastrointestinal Endoscopy (ESGE) quality improvement initiatives [22]. Specifically for pancreatobiliary endoscopy, these performance measures include: adequate antibiotic prophylaxis before ERCP ≥ 90% of cases, adequate antibiotic prophylaxis before EUS ≥ 95% of cases, bile duct cannulation rate ≥ 90% of cases, diagnostic tissue sampling during EUS ≥ 85% of cases, documentation of EUS landmarks ≥ 90% of cases, clearance of common bile duct stones ≥ 90% of cases, stent placement in case of biliary obstruction ≥ 95% of cases, safety of ERCP, with a PEP rate < 10%.

Since ERCP is an invasive procedure, it entails notable risks of AE, ranging from mild to life-threatening [132,133]. PEP is the most frequent AE (3.5-9.7%), followed by bleeding (0.3-9.6%), cholecystitis (0.5-5.2%), cholangitis (0.5-3%) and perforation (0.08-0.6%). Ensuring optimal ERCP performance requires a deep comprehension of these AEs and identifying related risk factors. These factors are broadly categorized into patient-related (including patient age and gender, bilirubin level, previous history of post-ERCP pancreatitis, among others) and procedure-related (including ERCP indication and complexity, difficult cannulation, among others) [132,133]. Bridging this understanding to preventive strategies, several measures have shown efficacy. For instance, utilizing rectal non-steroid anti-inflammatory drugs, administering with high-volume hydration with lactated Ringer and employing pancreatic stenting, whenever indicated, have proven successful in reducing both the frequency and severity of PEP [132].

Additionally, operator-related factors, such as the center and operator's case volume, may also influence ERCP success and AEs, as in other fields.

Outside medicine, this observation is consistent with the broader understanding that achieving and maintaining proficiency in any skill requires extensive, deliberate practice, as seen in professional athletes or musicians. Malcolm Gladwell's "10,000 hours rule", popularized in "Outliers" [134], posits that achieving mastery in any field typically requires about 10,000 hours of focused, structured practice aimed at improving specific skills. While this rule underscores the importance of extensive practice, it also acknowledges the critical roles of individual differences, quality of practice, and the learning environment.

In surgery, the relationship between volume and outcomes has been a subject of study since 1979 [135]. Over the years, numerous publications have demonstrated that outcomes are generally better when procedures are performed by high-volume (HV) surgeons [136] and in HV surgery departments [137,138]. Both surgeon and center volumes impact patient outcomes, although the extent of this relationship varies depending on the type and complexity of the surgery and the scope of specific hospital-based services [139]. For instance, in lung resection, where complications such as cardiac events, pneumonia, and respiratory failure, have a greater impact on outcomes than direct technical complications of the procedure itself (such as bleeding or leakage from a bronchial stump), the superior results of HV centers are better justified by their more extensive services (e.g., intensive care, respiratory care, and nursing care). Conversely, for procedures like aortic-valve replacement, technical skills have a higher direct impact on outcomes. This means that the surgeon's volume plays a more significant role, and the positive effect observed in HV hospitals are primarily due to having more experienced surgeons for these specific procedures.

In digestive endoscopy, similar trends are observed. Higher volumes of procedures correlate with better outcomes in managing acute nonvariceal upper-GI hemorrhage [140], diagnostic colonoscopy [141], upper GI endoscopic mucosal resection [142], endoscopic drainage of pancreatic fluid collections [143] or gastric endoscopic submucosal dissection [144].

As a result of these findings, the concept of centralization has gained traction. By concentrating resources such as infrastructure, staff, equipment, knowledge, and research in certain centers [145], centralization aims to improve healthcare quality and increase financial efficiency.

Besides improving outcomes, centralization aims to be cost-neutral, or even cost-saving by reducing severe complications, which significantly increase procedure costs. Severe complications are the single most important factor affecting the total cost of a surgical procedure [146]. For instance, in pancreatic surgery, severe postoperative complications can lead to a five-fold increase in costs compared to uneventful courses [147]. Therefore, preventing complications is a significant economic target.

High-quality performance also offers important advantages in long-term, usually oncologic, outcomes such as disease-free survival and quality of life, which should dramatically affect indirect costs. However, data on economic evaluation on centralization of specialized healthcare services is lacking [148].

There are some successful examples of centralization in surgery, with The Netherlands serving as a prime example in pancreatic surgery [149]. Starting in 1994 in response to high mortality rates, several centers cooperated to introduce centralization regionally and published their promising improvement of outcomes, creating pressure on health policy makers. After introduction of a minimum annual caseload, further research was conducted, showing a remarkable improvement in resectability rates [150,151] and decrease in in-hospital mortality from 9.8% to 3.6% [152,153] from 2004 to 2015, as the number of hospitals performing these surgeries drastically decreased and the percentage of patients treated in high-volume facilities increased.

United Kingdom (UK) adopted a top-down approach by setting strict thresholds for pancreatic surgery centers. In 2001, the Association of Upper Gastrointestinal Surgeons and the UK Health Department mandated that pancreatic cancer patients be treated in specialist units for populations of 2 to 4 million. This centralization improved outcomes: from 1999 to 2005, the number of hospitals performing resections decreased from 101 to 73, and 30-day mortality dropped from 6.2% to 5.7% [154]. This policy effectively concentrated expertise, improving patient care and outcomes in pancreatic surgery.

Similarly, centralization in the case of esophageal surgery has also shown to be advantageous not only in the Netherlands [155], but also in the UK [156] and in Belgium [157]. In the United States, centralization of transplantation surgery, rectal cancer surgery, complex pancreatic, cardiac and aortic surgery, has shown superior results and cost-effectiveness for patients and providers [145].

However, a widespread implementation of this type of policy faces several challenges due to a complex interplay of healthcare policies shaped by various stakeholders, including politicians, insurers, hospitals, physicians, and national medical societies [145,149].

Challenges to centralization at the healthcare provider level include the potential for inadequate infrastructure and equipment, a shortage of specialized staff, long waiting times, limited access to centers, and restrictions on working hours. Additionally, the structure of healthcare systems and the uneven distribution of HV centers in some countries further complicate centralization efforts.

For patients, obstacles include reluctance to travel longer distances, limited access to centers, long waiting times and not being aware of the benefits of centralized care. In countries with low population densities, the vast distances to HV centers make access difficult. Socioeconomic factors also play a role, with patients from lower socioeconomic backgrounds facing greater difficulties in affording and managing travel to these centers.

From the payer's perspective, concerns about increased costs or charges are significant. Furthermore, if regulatory bodies or insurers do not effectively enforce minimal caseload regulations, centralization efforts can be undermined.

Politically, barriers include the failure to properly implement decisions, regional interests that conflict with centralization policies, differences in regulations between publican and private hospitals, conflicts between specialized and general physicians, and extensive bureaucracy. In some countries, healthcare providers' concerns about maintaining status and reputation also hinder centralization. Additionally, the absence of specialization boards and mutual recognition of qualifications between centers and countries complicates the process.

A common argument against centralization is the lack of reliable national data to show the link between center volume and outcomes.

In ERCP, the potential association between performance quality and the operator's experience or center volume has been scrutinized since Freeman et al. suggested lower complications with endoscopists performing more than one sphincterotomy per week [158]. However, subsequent research has yielded inconsistent results due to methodological variations and discrepancies across studies [159]. While volume may not be the only factor influencing ERCP outcomes, it warrants further investigation. Cost-effectiveness studies in this regard are also lacking.

If this hypothesis is validated and significant costs disparities are identified based on these outcomes, reconsidering the structure of healthcare services could be necessary. This might entail centralizing ERCP procedures in HV centers staffed by HV endoscopists, potentially enhancing the likelihood of patients receiving the most optimal care.

AIMS AND OUTLINE OF THE THESIS

This Ph.D. thesis sought to contribute to the advancement of evidence in the fields of ERCP and EUS, aiming to enhance the quality of care for patients with biliopancreatic diseases.

In *SECTION I*, **Chapter 1** provides a broad overview of advanced biliopancreatic endoscopy, identifying particular gaps in the existing literature. These gaps served as the basis for formulating several research questions that guided the structure of this thesis, dividing it into two distinct areas of research: ERCP and EUS training, detailed in *SECTION II*, and ERCP performance, covered in *SECTION III*.

Chapters 2 to **4** in *SECTION II* aimed to address the research question of how training in ERCP and EUS should be conducted. **Chapter 2** and **Chapter 3** had the goal of providing European curricula for ERCP and EUS training in Europe, with recommendations for standardizing learning practices. This was achieved through collaborative efforts with various experts in the field and following an extensive literature review. **Chapter 4** supplemented these insights by incorporating a more personalized perspective from global experts on succeeding in advanced biliopancreatic endoscopy, including soft skills.

Chapter 5 sought to scrutinize the question of how ERCP and EUS training is currently being conducted across European training centers, employing a survey-based study to evaluate the extent of their adherence to European training curricula recommendations.

Chapter 6 delved into the identification of the most suitable trainees for advanced biliopancreatic endoscopy, exploring the personal attributes they need to excel and elucidating the criteria and perceptions involved in the selection of these trainees, from the standpoint of program directors and experts.

Chapters 7 and **8** intended to propose interventions to enhance training quality through simulation training with Boškoski-Costamagna ERCP Trainer. **Chapter 7** reported the development of a novel tool used in this mechanical simulator, a biological papilla, designed to improve ductal access and sphincterotomy training. **Chapter 8** aimed to validate the Boškoski-Costamagna ERCP Trainer simulator in a comparative manner, assessing its impact on trainees' skills and learning curves (predictive validity evaluation).

Beyond training analysis, it was crucial to address the question of where ERCP should be performed, considering the potential outcome variations among centers with different case volumes, a focus that *SECTION III* explored. **Chapter 9** conducted a systematic review and meta-analysis on ERCP outcomes related to endoscopist and center volumes. Building on these findings, **Chapter 10** delved into a comprehensive cost-effectiveness analysis of current ERCP practices across varying volume centers. This is particularly pertinent in the context of escalating healthcare costs and resource constraints, underscoring the importance of cost-effective care in healthcare provision.

Finally, *SECTION IV* (**Chapter 11**) integrated the results from all conducted studies, offering a thorough discussion and recommendations to enhance training and practices in biliopancreatic endoscopy. This section concludes by presenting perspectives for clinical implementation, as well as future research.

STRUCTURE OF THE THESIS

This thesis is organized in the four sections detailed above. A schematic representation of its organization, outlining the sections, corresponding research questions and chapters, can be found in *TABLE 1* .

TABLE 1

Schematic representation of this thesis' structure, regarding research questions.

SECTION	RESEARCH QUESTION	CHAPTER
I: Conceptualization		1: General introduction and outline of the thesis
II: ERCP and EUS training	*How should ERCP and EUS training be?*	2: Curriculum for ERCP and EUS in Europe: ESGE Position Statement 3: Curriculum for diagnostic EUS in Europe: ESGE Position Statement 4: Vade Mecum in ERCP, a roadmap to achieve success: Tips from Experts to those who want to excel in advanced endoscopy
	How is ERCP and EUS training currently being performed?	5: A portrait of ERCP and EUS training programs in Europe: current practices and opportunities for improvement
	Who should enter in a ERCP and EUS fellowship?	6: Who will excel in advanced endoscopy? A study assessing Experts' criteria and perceptions regarding selection of ERCP and EUS trainees
	Which interventions could improve ERCP training?	7: Face and content validity of a biological papilla designed for the Boškoski-Costamagna ERCP simulator 8: Fast-tracking ERCP learning with the Boškoski-Costamagna Trainer: results of a multicenter randomized clinical trial
III: ERCP performance	*Where should ERCP be performed?*	9: The impact of ERCP volume per center and endoscopist on ERCP outcomes: a systematic review and a meta-analysis 10: Assessing the impact of center's volume on cost-effectiveness of centralizing ERCP
IV: General discussion		11: Summary of the chapters, conclusions and future perspectives

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SECTION II

ERCP and EUS training

How should ERCP and EUS training be?

How is ERCP and EUS training currently being performed?

Who should enter in a ERCP and EUS fellowship?

Which interventions could improve ERCP training?

How should ERCP and EUS training be?

Chapter 2: Curriculum for ERCP and EUS in Europe: ESGE Position Statement

Chapter 3: Curriculum for diagnostic EUS in Europe: ESGE Position Statement

Chapter 4: Vade Mecum in ERCP, a roadmap to achieve success: Tips from Experts to those who want to excel in advanced endoscopy

CHAPTER 2

Curriculum for ERCP and EUS in Europe: Endoscopy Society of Gastrointestinal Endoscopy Position Statement

Adapted from:

Johnson G, Webster G, Boškoski I, Teles de Campos S, et al. Curriculum for ERCP and EUS in Europe: ESGE Position Statement. Endoscopy 2021 Oct; 53(10): 1071-1087; doi 10.1055/a-1537-8999.

KEY POINTS

Objective of Position Statement: Chapter 2 by the ERCP and EUS Curricula working group of the European Society of Gastrointestinal Endoscopy established guidelines for ERCP and EUS training in Europe, aiming to enhance trainee proficiency based on current evidence.

Methodology: Developed through consensus among diverse ERCP/EUS practitioners, using the PICO format where applicable, a Delphi process for evidence review, and the GRADE framework for evidence-based statements.

Training Prerequisites: Prior competence in upper gastrointestinal endoscopy was considered required for ERCP/EUS training.

Structured Training and Courses: ERCP/EUS training should be systematic and supplemented with formal courses and other learning resources.

Simulation-Based Training: Recommended for accelerating the learning curve before hands-on training, although the quality of evidence and strength of recommendation for this approach was limited.

Training Duration and Volume: At least 12 months of high-volume training was advised for basic ERCP and diagnostic EUS, with additional training for advanced procedures.

Training Centers: Training should be in high-volume centers offering comprehensive learning opportunities, including simulation, multidisciplinary meetings, and research.

Trainer Experience: Trainers must be highly experienced in ERCP/EUS and continuously maintain their skills.

Competence Assessment: Regular, formal assessments using validated tools like TEESAT, focusing on both procedural numbers and performance measures. Self-assessment was also encouraged.

Continuous Learning: Competence in ERCP/EUS is an ongoing process, with continued mentorship advised in the early stages of independent practice.

Research and Development: Continuous research in training methods is encouraged for increasing evidence of statements and enhancing service quality, safety, and training effectiveness.

INTRODUCTION

The European Society of Gastrointestinal Endoscopy (ESGE) has identified quality in endoscopy as a major priority [1]. It is recognized that there continues to be an accelerated development of new and complex diagnostic and therapeutic endoscopic interventions and a lack of specific guidance for providing high quality training for many of these techniques has been identified in many countries [2]. Of all the commonly performed endoscopic procedures, endoscopic retrograde cholangiopancreatography (ERCP) is associated with the highest risk of serious complications and with a recognized mortality [3]. Furthermore, endoscopic ultrasound (EUS) is an important adjunct to ERCP, and also continues to evolve as a therapeutic modality in its own right. Therefore, ESGE has identified the requirement for a consensus on how to optimize training in ERCP and EUS as an important part of improving the quality of endoscopy [1].

In 2017, the ESGE board convened the Curricula Working Group, which was responsible for developing curricula that defined the minimum training standards for more advanced and therapeutic endoscopic practice that may often go beyond the core endoscopy training curricula in each country. This process has been outlined previously [2] and position statements on three endoscopy topics have already been published [4–6].

AIMS

The aim of this position statement is to recommend best practice to optimize ERCP and EUS training in Europe, based on the currently published evidence and knowledge. This paper focuses on training and aims to help trainees develop, evidence, and maintain their skills in ERCP and EUS.

METHODS

In 2019, R.B. invited G.J. to develop a working subgroup of ERCP and EUS practitioners with an open call via ESGE communications. The curriculum was developed using consensus methodology, so the constitution of this working party was selected by G.J. and R.B. to ensure that the group was broadly representative in terms of a wide range of nationalities, levels of clinical experience, and clinical backgrounds, and also included trainee representation.

The first meeting of the subgroup was in April 2019. At this meeting, the overall aims of the project were defined and the methodology was agreed. At this kick-off meeting, three principal topics were identified, as previously defined by the ESGE [2]; from these, specific questions were developed using the Population, Intervention, Comparator, Outcome (PICO) format where possible:

a) Pre-adoption requirements to start training (skills required prior to engaging in ERCP/EUS training);

b) Training/learning steps (the steps to achieve competence in ERCP and EUS, including requirements for training programs);

c) Definition and assessment of trainee competence (the ESGE definition of competence for ERCP and EUS, and the evidence of competence in terms of prior training and performance measures to be attained before certification for independent ERCP/EUS practice).

Two subgroup members were nominated as the leads for each topic. A Delphi process was then used to review the evidence and develop consensus statements for each topic. Each topic was the subject of a systematic literature review using major databases (PubMed, Embase, and the Cochrane Library) from 1990 to April 2019. Any publications emerging during the Delphi process and manuscript writing were also considered for inclusion. Statements were drafted based on this evidence and subjected to an appraisal using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework [3, 7]. In situations where there was a paucity of evidence in an aspect of training that was deemed important, the groups drew upon expert opinion to develop statements that went forward into the Delphi process.

The statements were distributed electronically in August 2019. In October 2019, there was a second face-to-face meeting where the statements and supportive evidence were discussed in turn, resulting in further modification of the statements. The first round of anonymous electronic voting took place in November 2019 and was based on a 5-point Likert scale, ranging from "Strongly Disagree," through to "Strongly Agree." Any statement receiving at least an 80 % level of "agreement" or "strong agreement" was accepted.

Thereafter G.J. modified any statements based on feedback to improve their acceptability. The new statements were discussed in a teleconference in January 2020, before a second electronic vote between February and July 2020. Owing to the paucity of evidence, all statements should be considered GRADE weak, with low or very low-quality evidence or based on expert opinion, with the exceptions of recommendations that consider the learning curves for ERCP and diagnostic EUS, which are based on moderate quality evidence.

SUMMARY OF RECOMMENDATIONS

The recommendations presented in this curriculum, a total of 31, are given along with their quality of evidence and strength of recommendation in *TABLE 1*. They are based on a consensus among experts in ERCP and EUS who are involved in training.

TABLE 1

Summary of recommendations, with quality of evidence and strength of recommendation. Abbreviations: ERCP, endoscopic retrograde cholangiopancreatography; ESGE, European Society of Gastrointestinal Endoscopy; EUS, endoscopic ultrasound; FNA, fine-needle aspiration; FNB, fine-needle biopsy; PFC, pancreatic fluid collection; UGI, upper gastrointestinal.

NUMBER	RECOMMENDATION	QUALITY OF EVIDENCE	STRENGTH OF RECOMMENDATION
	ERCP and EUS training in general		
1	Every endoscopist should have achieved competence in UGI endoscopy before commencing training in ERCP or EUS (i.e. having personal experience of at least 300 gastroscopies and meeting the ESGE quality measures for UGI endoscopy).	Low	Strong
2	Simulation-based training represents a positive development to accelerate the trainee's learning curve and should be encouraged. When available, trainees should start training by undertaking structured supervised ERCP/EUS simulator-based training before commencing hands-on training on endoscopy training.	Very low	Weak
3	Where it is available, simulation-based training should evolve in a stepwise approach for training: virtual reality and mechanical simulators should be used during early training, followed by hands-on endoscopy training.	Very low	Weak
4	Trainees should undertake formal courses to complement ERCP/EUS training.	Low	Strong
5	ERCP and EUS trainees should engage with a range of learning resources to supplement formal courses and experiential learning.	Very low	Strong
6	ERCP and EUS training should follow a structured syllabus to guide what is covered in workplace learning, formal training courses, and self-directed study.	Very low	Strong
7	A minimum training period of 12 months of high-volume training is likely to be required to obtain minimum proficiency in both ERCP and diagnostic EUS. At least a further year of dedicated training is likely to be required for trainees to reach competence in advanced ERCP (Schutz 3 and 4) and therapeutic EUS. Should there be an interruption to training, a longer period may be required.	Very low	Strong
8	A significant proportion of ERCP and EUS training should be based in high volume training centers that are able to offer trainees a sufficient wealth of experience for at least 12 months.	Very low	Strong

TABLE 1 | CONTINUATION

NUMBER	RECOMMENDATION	QUALITY OF EVIDENCE	STRENGTH OF RECOMMENDATION
9	An ERCP/EUS training center should ideally be able to provide: - facilitation of trainee involvement in multidisciplinary meetings; - onsite hepaticopancreaticobiliary surgery and interventional radiology; - ERCP and EUS simulation; - support for trainee involvement in research and service improvement initiatives.	Very low	Strong
10	A trainee's principal trainer should ideally have more than 3 years' experience of independent ERCP and/or EUS practice.	Very low	Strong
11	A trainee's principal trainer should be performing adequate volumes of EUSs and/or ERCPs to demonstrate maintenance of their own competence.	Very low	Strong
12	ERCP and EUS competence should be defined as the ability to independently assess the need for and carry out successful and safe procedures, with good patient satisfaction across a range of case difficulties and clinical contexts.	Low	Strong
13	Formal assessments tools (e. g. Direct Observation of Procedural Skills [DOPS] and The EUS and ERCP Skills Assessment Tool [TEESAT]) should be used regularly during ERCP and diagnostic and therapeutic EUS training to track the acquisition of trainees' competence and to support trainee feedback.	Moderate	Strong
14	Trainees should be encouraged to undertake self-assessment and keep a contemporaneous logbook of all cases, which includes the degree of trainer support that was needed for each aspect of the procedure.	Low	Strong
15	A trainee should undergo a formal summative assessment process prior to commencing independent practice in ERCP and EUS.	Low	Weak
16	The attainment of competence in ERCP and EUS is not a single event, but a career-long process. It is recommended that, once competent in ERCP and EUS, endoscopists should be supported to continue a period of mentored practice with an experienced colleague.	Very low	Strong
	ERCP training		
17	ERCP competence should be considered in two stages: - basic ERCP (Schutz level 1 and 2 procedures); - advanced ERCP (Schutz level 3 and 4 procedures).	Low	Strong

TABLE 1 | CONTINUATION

NUMBER	RECOMMENDATION	QUALITY OF EVIDENCE	STRENGTH OF RECOMMENDATION
18	Competence in ERCP should take account of predicted procedure complexity. All those delivering independent ERCP practice should achieve competence in basic ERCP (i. e. Schutz 1 and 2 levels of complexity).	Low	Strong
19	Competence in advanced procedures (Schutz level 3 and 4) may be achieved after reaching competence in basic ERCP and requires additional formal training following the commencement of independent practice.	Low	Strong
20	The number of ERCPs performed may be a surrogate marker of competence, but in isolation is an inexact means to demonstrate competence. Most trainees are likely to need to have performed > 300 ERCPs to be in a position to demonstrate competency.	Moderate	Strong
21	The following performance measures should be used to indicate a trainee's competence in basic ERCP to continue to independent mentored practice: - selective native papilla cannulation rate of ≥ 80 % as an intention to treat[1]; - complete stone clearance (< 10 mm) in ≥ 85 % cases following successful selective cannulation[2]; - successful stenting of distal biliary strictures of ≥ 90 % of cases following successful selective cannulation[2] Following a period of mentored independent practice, to bring these performance measures into line with the ESGE Quality Improvement Initiative for ERCP and EUS, they should be: [1] at least 10 % higher [2] 5% higher	Moderate	Strong
22	An individual undertaking ERCP independently should be able to demonstrate an overall post-ERCP pancreatitis rate of ≤ 10 %.	Low	Weak
	EUS training		
23	Competence in radial EUS is not a prerequisite to commence linear-array EUS.	Low	Weak
24	Competence in diagnostic EUS is a prerequisite for therapeutic EUS. Competence in ERCP is mandatory for therapeutic EUS, and competence in therapeutic luminal endoscopy is advantageous.	Very low	Strong
25	EUS training should be defined as two stages: diagnostic EUS, including tissue acquisition, and therapeutic EUS.	Very low	Strong

TABLE 1 | CONTINUATION

NUMBER	RECOMMENDATION	QUALITY OF EVIDENCE	STRENGTH OF RECOMMENDATION
26	EUS-guided FNA/FNB can be commenced early in training once safe handling and stable positioning of the echoendoscope has been accomplished.	Low	Weak
27	Once competent in diagnostic EUS, training in therapeutic EUS may commence with less complex procedures (such as EUS-guided drainage of PFCs) and, when competence has been achieved, may progress to more advanced interventions (including EUS-guided gallbladder or biliary drainage, or EUS-guided anastomosis creation).	Very low	Weak
28	The number of EUSs performed may be a surrogate marker of competence, but in isolation is an inexact means to demonstrate competence. Trainees are likely to need to have performed > 250 diagnostic EUSs to be able to demonstrate competency.	Moderate	Strong
29	The following performance measures should be used to indicate a trainee's competence in diagnostic EUS: - successful documentation of anatomical landmarks in ≥ 90 % of cases; - EUS-guided FNA/FNB accuracy rate of ≥ 85 %.	Low	Strong
30	Trainees are likely to need to have performed 75 EUS-guided FNA/FNBs to be able to demonstrate competency in tissue acquisition.	Low	Strong
31	Until more robust data are available, an endoscopist can be considered competent to undertake therapeutic EUS when they can demonstrate acceptable rates of clinical success and adverse events that equate to the rates described in published case series. It is recommended that at least the first 25 cases of any intervention should be performed under the supervision of an endoscopist experienced in that intervention.	Low	Weak

CONCLUSIONS

As part of the mission of the ESGE to identify quality in endoscopy as a major priority, we present this Position Statement on training in ERCP and EUS. The working group included representation from across Europe and included different backgrounds in training and a range of career experience. Standard Delphi methodology was used to propose and agree statements pertaining to the prerequisites for ERCP and EUS training; the steps in training and the quality of training; and the definition and assessment of competence in ERCP and EUS prior to independent practice. These proposals have no legal implication but serve to recommend best practice in training. It is hoped they will be of use to National Societies, program directors, and trainees in improving the provision and standard of ERCP and EUS training.

Many of the statements are drawn from low or very low-quality evidence, so are derived from the expert opinion of the curriculum working group through consensus. Arguably the best quality evidence is that related to learning curves and the rate at which competence is attained in terms of procedure numbers. However, this is a source of controversy as there has been an understandable move away from competence being measured solely on the basis of the procedure volume of the trainee. ESGE has proposed that procedure numbers are retained as they serve as guidance to lead trainers responsible for organizing training programs, as well as to trainees who will benefit from a benchmark to determine when full competence in ERCP and EUS is likely to be attained. ESGE emphasizes however that the procedure volume of a trainee is no longer sufficient evidence of competence and recommends that key performance measures are attained, and that consideration is given by national institutions to a formal summative assessment process prior to independent practice.

There remain major challenges to delivering effective ERCP and EUS training. It has been proposed that simulation forms a central part of training, although access to effective simulation is highly variable. There is also inconsistent availability of formal endoscopy courses and "train the trainer" workshops, both of which have been shown to benefit training. Given the paucity of evidence behind many of the statements, ESGE encourages further study into all facets of training in ERCP, diagnostic EUS, and therapeutic EUS in particular. *TABLE 2* lists potential research questions that should be prioritized by investigators with an interest in enhancing ERCP and EUS services, safety, and training quality.

TABLE 2

Potential research questions to be prioritized. Abbreviations: ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound.

a) To what degree can trainee learning curves and recommended minimum case volumes be improved with greater focus on: - Formal courses - Simulation - Trainer expertise - "Immersion training" (greater intensity of case experience)?
b) What levels of objective performance measures for ERCP and EUS are fair and attainable for trainees to attain prior to independent practice (e. g. cannulation rates)?
c) What effects do breaks in training have on ERCP and EUS learning curves?
d) What are the most valid and feasible ways to assess a trainee's competence prior to independent practice?
e) What constitutes ideal training for an endoscopist in lower volume, more complex, advanced therapeutic ERCP and EUS procedures, and how should competence be determined?
f) What is the suggested format for effective ERCP and EUS mentoring once independent practice has commenced?

Training in therapeutic EUS remains a particular challenge. Even in specialist centers, the procedure numbers for therapeutic EUS are much lower than for ERCP and diagnostic EUS. The evidence with regard to learning curves for therapeutic EUS is less robust than the equivalent data for ERCP and diagnostic EUS. Furthermore, endoscopists training in these procedures may already be experienced practitioners of ERCP and EUS, so ensuring their appropriate supervision can be particularly difficult if the individual is already an independent endoscopist. The solutions to these problems will vary between nations, but may include access to simulation, a mentoring network, and robust ongoing audit of performance. ESGE discourages unsupported endoscopists learning new therapeutic procedures on patients.

For national societies and program directors to meet the proposals in this position statement will be challenging, but there is enough evidence to suggest that, if these recommendations are delivered, the objective of the ESGE to enhance quality in ERCP and EUS will have been furthered. Training in ERCP and EUS is long and challenging but very rewarding and ESGE hopes that this position statement benefits trainees embarking on this process and helps to produce independent endoscopists capable of delivering a safe and effective service for their patients.

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CHAPTER 3

Curriculum for diagnostic endoscopic ultrasound in Europe: Endoscopy Society of Gastrointestinal Endoscopy Position Statement

Adapted from:

Badaoui A, Teles de Campos S, Fusaroli P, Gincul R, et al. Curriculum for diagnostic EUS in Europe: ESGE Position Statement. Endoscopy 2024 Mar;56(3):222-240.
doi: 10.1055/a-2224-8704.

KEY POINTS

Position Statement Scope: Chapter 3 by the European Society of Gastrointestinal Endoscopy's diagnostic EUS Curricula working group set out to define training standards for diagnostic EUS, guiding National societies, directors, and trainees towards improved training and potential standardization and certification.

Methodology: Developed using a Delphi consensus among participants, it involved formulating key questions in the PICO format where possible, and systematic literature reviews. It used the GRADE framework for evidence-based statement drafting.

Pre-Adoption Requirements: Prior competence in upper gastrointestinal endoscopy and familiarity with related imaging techniques were prerequisites. Additional skills, like competence in sigmoidoscopy and experience in ERCP, were also considered beneficial.

Trainer and Center Requirements: Trainers should have extensive experience in diagnostic EUS, and training centers should offer a high volume of procedures and multidisciplinary interaction opportunities.

Training Modules and Approach: The curriculum advocated a blend of formal training and diverse learning resources, including simulators. It recommended a structured syllabus, starting with observation and simulation and leading to hands-on training. Linear echoendoscope training should be mandatory, and EUS-tissue sampling training should begin after mastering basic skills.

Competence Assessment: Criteria include minimum procedure volumes, accurate documentation of anatomical landmarks, and achieving high accuracy rate in EUS-FNA/FNB, along with technical, cognitive, and integrative skills assessments using reliable valid tools. Regular self-assessment is encouraged.

Maintaining Competence: Emphasized continuous practice, early independent activity supervision, multidisciplinary collaboration, and adherence to minimum yearly examination thresholds and performance measures.

Future Directions: Aims towards standardizing diagnostic EUS training and developing tools for performance measurement and certification.

INTRODUCTION

Over the three last decades, endoscopic ultrasound (EUS) has become an indispensable tool in the management of pancreaticobiliary, gastrointestinal (GI), and mediastinal diseases. Training in endoscopic ultrasound is considered a long and challenging process, requiring optimal training conditions and a major personal investment. Many factors can influence the learning curve and the quality of training.

Training in EUS requires a standardized approach, which the European Society of Gastrointestinal Endoscopy (ESGE) has tried to define through the development of curricula. A curriculum in endoscopic retrograde cholangiopancreatography (ERCP)/EUS training in Europe has already been developed and was published in 2021 [1]. Therefore, ESGE next decided to focus specifically on diagnostic EUS training in developing a curriculum that will guide endoscopists in becoming competent in this field. Guidance for standardized training in diagnostic EUS for trainees and trainers, respecting the quality indicators, is essential and of paramount importance.

In 2017, the ESGE board convened the Curricula Working Group, which was responsible for developing curricula that defined the minimum training standards for more advanced and therapeutic endoscopic practice that may often go beyond the core endoscopy training curricula in each country. This process has been outlined previously [2] and Position Statements on six endoscopy topics have been already published [1, 3–7].

AIMS

The aim of this position statement is to recommend best practice to optimize diagnostic EUS training in Europe, based on the currently published evidence and knowledge. This paper focuses on training, and aims to help trainees develop, evidence, and maintain their skills in diagnostic EUS.

METHODS

This curriculum was developed through a Delphi consensus process among international experts in diagnostic EUS [8].

In October 2021, T.T. (Chair of the Curricula Working group) invited A.B. to be the section chair for the diagnostic EUS training curriculum. After an open call via ESGE communication in November 2021, T.T. and A.B. selected a working group of 14 EUS practitioners among more than 50 applicants to ensure that they were broadly representative in terms of their wide range of expertise in diagnostic EUS training, level of clinical experience, clinical background, sex, and nationality.

The first meeting of the working group was in January 2022. At this meeting, the overall aims of the project were defined, and the methodology was agreed.

From three principal domains, previously defined by the ESGE [9], specific questions were developed using the Population, Intervention, Comparator, Outcome (PICO) format where possible:

a) preadoption requirements to start diagnostic EUS training;

b) training modules and learning methods to achieve competency in diagnostic EUS;

c) definition and assessment of competence in diagnostic EUS, including maintaining competence after training.

The group was organized into five sub taskforces that covered the above domains, and one or two group members were nominated as the leads for each subgroup. A Delphi process was then used to review the evidence and develop consensus statements for each domain.

Each domain was the subject of a systematic literature review. Any publications emerging during the Delphi process and manuscript writing were also considered for inclusion. Statements were drafted based on this evidence and subjected to an appraisal using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework [1,3– 7,10]. When a paucity of evidence was noted in an aspect of training that was deemed important, the groups relied on expert opinion to develop statements that were then fed into the Delphi process.

Two rounds of anonymous online voting on the categorized statements were necessary and took place in December 2022 and March 2023. In addition to the 16 working group members, 18 of the initial applicants to the curriculum who were not part of the working group also participated in the voting rounds. All of the rounds of anonymous electronic voting were based on a 5-point Likert scale, ranging from “Strongly disagree” through to “Strongly agree.” Any statement that received at least an 80 % level of “agreement” or “strong agreement” was accepted.

Taskforce meetings were held after each voting round to allow the statements to be discussed and modified based on the feedback in order to improve their acceptability without altering their sense.

SUMMARY OF RECOMMENDATIONS

The 30 recommendations presented in this curriculum are based on a consensus among endoscopists considered to be experts in diagnostic EUS who are strongly involved in training. These recommendations are given along with their quality of evidence and strength of recommendation in *TABLE 1*.

NUMBER	RECOMMENDATION	QUALITY OF EVIDENCE	STRENGTH OF RECOMMENDATION
Preadoption requirements for training in diagnostic EUS			
A. Preadoption requirements for trainees			
1	Trainees should have achieved competence in upper gastrointestinal endoscopy before training in diagnostic EUS.	Moderate	Strong
2	Competence in sigmoidoscopy is desirable for training in rectal EUS.	Low	Weak
3	Experience in the interpretation of abdominal imaging such as transabdominal ultrasonography and other imaging modalities is advisable, but not mandatory, prior to commencing training in diagnostic EUS.	Low	Weak
4	The development of diagnostic EUS skills by methods that do not involve patients is advisable, but not mandatory, prior to commencing formal training in diagnostic EUS.	Low	Strong
5	Experience in ERCP is helpful, but not mandatory, prior to commencing training in biliopancreatic diagnostic EUS.	Low	Weak
B. Preadoption requirements for trainers and training centers			
6	A trainee's principal trainer should ideally have more than 3 years' experience of independent diagnostic EUS practice.	Very low	Weak
7	A trainee's principal trainer should be performing adequate volumes of diagnostic EUSs to demonstrate maintenance of their own competence.	Very low	Strong
8	A trainee's principal trainer should be aware of the current management protocols in digestive neoplasms, should be involved in the multidisciplinary teams of their institution for decisions regarding the management of GI and pancreaticobiliary diseases, and should have a good knowledge of diseases managed with diagnostic EUS.	Very low	Strong
9	Training centers for diagnostic EUS should offer expertise, as well as a high volume of procedures per year, to ensure an optimal level of quality for training. Under these conditions, training centers should be able to provide trainees with a sufficient wealth of experience in diagnostic EUS for at least 12 months.	Very low	Strong
10	Training centers for diagnostic EUS should ideally be able to facilitate trainee involvement in multidisciplinary meetings and provide support for trainee involvement in research, and service and quality improvement initiatives.	Very low	Strong

TABLE 1

Summary of recommendations, with quality of evidence and strength of recommendation. Abbreviations: EUS, endoscopic ultrasound; ERCP, endoscopic retrograde cholangiopancreatography; GI, gastrointestinal; AE, adverse event.

TABLE 1 | CONTINUATION

NUMBER	RECOMMENDATION	QUALITY OF EVIDENCE	STRENGTH OF RECOMMENDATION
Training/learning steps in diagnostic EUS: training modules and learning methods			
11	Trainees should engage in formal training and supplement this with a range of learning resources for diagnostic EUS, including EUS-guided fine-needle aspiration and biopsy (FNA/FNB).	Moderate	Strong
12	Training in diagnostic EUS should start first with the observation of EUS procedures on patients and, when available, training on simulators should begin with computer-based and mechanical models in the early phases, followed by ex vivo or in vivo animal simulators for more advanced training.	Low	Weak
13	Training with a linear echoendoscope should be mandatory, and this may be complemented by training with a radial echoendoscope when available.	Low	Strong
14	EUS-FNA/FNB should be included early in training as soon as the basic skills for safe and stable scope handling have been achieved.	Low	Strong
15	Adequate competence in diagnostic EUS is a prerequisite before training in EUS image-enhancement techniques, such as elastography (EUS-E) and contrast harmonic EUS (CH-EUS).	Low	Strong
16	Diagnostic EUS training should follow a structured syllabus to guide the learning program.	Moderate	Strong
Assessment criteria for diagnostic EUS proficiency			
A. Definition and assessment of trainee competence in diagnostic EUS			
17	Competence in diagnostic EUS should be defined as the ability to independently assess the need for and carry out successful and safe EUS procedures, with good patient satisfaction across a range of case difficulties and clinical contexts.	Low	Strong
18	The following performance measures should be used to indicate a trainee's competence in diagnostic EUS: - successful documentation of anatomic landmarks in ≥ 90 % of cases; - an EUS-FNA/FNB accuracy rate of ≥ 85 %.	Low	Strong
19	A minimum procedure volume should be offered to trainees during diagnostic EUS training to ensure that they have the opportunity to achieve competence in the technique. To evaluate competence in diagnostic EUS, trainees should have completed a minimum of 250 supervised EUS procedures: 80 for luminal tumors, 20 for subepithelial lesions, and 150 for pancreaticobiliary lesions. At least 75 EUS-FNA/FNBs should be performed, including mostly pancreaticobiliary lesions.	Moderate	Strong

TABLE 1 | CONTINUATION

NUMBER	RECOMMENDATION	QUALITY OF EVIDENCE	STRENGTH OF RECOMMENDATION
20	Competence assessment in diagnostic EUS should take into consideration not only technical skills, but also cognitive and integrative skills. A reliable valid assessment tool should be used regularly during diagnostic EUS training to track the acquisition of competence and to support trainee feedback.	Moderate	Strong
21	Trainees should undertake regular self-assessments and record all cases performed in a contemporaneous logbook. The logbook should include information on the type of procedure performed and the support given by the trainer for each aspect of the procedure.	Very low	Strong
22	A trainee should undergo a formal summative assessment process prior to commencing independent practice in EUS.	Low	Weak
	B. Maintaining competence after training in diagnostic EUS		
23	Newly trained endosonographers should start diagnostic EUS practice immediately after training. If a relevant delay occurs, making the endosonographer less confident, retraining should be considered.	Low	Strong
24	A period of supervised practice should follow the start of independent activity. Supervision can be delivered either on site if other colleagues are already practicing EUS or by maintaining contacts with the training center and/or other EUS experts.	Moderate	Strong
25	Significant efforts must be devoted to establishing a multidisciplinary collaboration with colleagues in order to obtain feedback from other imaging techniques, pathology, and surgery results. This is particularly important when EUS is a new practice for the center.	Low	Strong
26	While it is expected that the number of diagnostic EUS procedures will gradually increase after the initiation of a new practice, a minimum number of 100 yearly examinations per endosonographer should be established to maintain proficiency.	Very low	Weak
27	Key performance measures including the annual number of procedures, frequency of obtaining a diagnostic sample during EUS-FNA/FNB, and AEs should be recorded within an electronic documentation system and evaluated.	Moderate	Strong
28	Any relevant deviation from major diagnostic standards (i. e. the successful documentation of anatomic landmarks in ≤ 90 % of cases and/or an EUS-FNA/FNB accuracy rate of ≤ 85 %) should be promptly acknowledged and countermeasures should be undertaken.	Low	Strong

TABLE 1 | CONTINUATION

NUMBER	RECOMMENDATION	QUALITY OF EVIDENCE	STRENGTH OF RECOMMENDATION
29	Any significant increase in rates of AEs compared with the published literature should be promptly acknowledged and countermeasures should be undertaken.	Low	Strong
30	Endosonographers should demonstrate ongoing competence in the form of continuing cooperation with former EUS mentors/other more experienced colleagues, consulting dedicated literature and other online content, and attendance at focused courses to maintain EUS privileges.	Low	Weak

CONCLUSION

This ESGE Position Statement on training in diagnostic EUS was developed by a working group made up of experts from all over Europe and the USA, having different backgrounds in training and professional experiences.

The statements were proposed and agreed using a standard Delphi methodology. They concern the requirements for diagnostic EUS training, the steps in training and the quality of training, and the definition and assessment of competence prior to independent practice including maintenance of competence after training. While these suggestions have no legal implication, they are still used to recommend best practice in training. It is hoped they will assist national societies, program directors, and trainees in improving the standards of diagnostic EUS training.

This curriculum in diagnostic EUS training in Europe aims to guide training by defining minimum standards, specific end points, and thresholds for competence in diagnostic EUS. The next steps beyond this curriculum might be to define a proposal for standardized training, and ultimately to provide a tool for performance measurement and ESGE certification in diagnostic EUS.

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CHAPTER 4

Vade Mecum in ERCP, a roadmap to achieve success: Tips from Experts to those who want to excel in advanced endoscopy

Published as:

Teles de Campos S, Arvanitakis A, Boškoski I, Devière J. Vade Mecum in ERCP, a roadmap to achieve success: Tips from Experts to those who want to excel in advanced endoscopy. Endoscopy International Open 2024 Apr,12(4): E613-E620. doi: 10.1055/a-2290-1479.

KEY POINTS

Expert-Driven ERCP Training Guidance: Chapter 4 compiles expert tips to guide trainees in ERCP, based on a survey that included a significant participation rate from 53 experts across 24 countries worldwide.

Survey Results Overview: The web-based survey intended to capture the professional trajectories of ERCP experts, including their training investments and challenges faced, and the strategies they employed for success.

Early Start and Comprehensive Training: Most experts started their ERCP training at an average age of 31 (range: 42-52 years old), often in combination with EUS. A long training period, averaging 21 months (range: 3-120 months), was common and frequently complemented with active engagement in research in the field (76.5%).

Key Investments for Success: "Time and practice" were highlighted as critical investments for achieving success in ERCP, aligning with guidelines discussed in Chapters 2 and 3. Selecting and appropriate mentor was often highlighted, emphasizing the significant role of mentorship in fostering ERCP expertise. Sports and other skill-building activities outside endoscopy were also considered beneficial.

Facing Obstacles in Professional Development: The most significant obstacles encountered by the majority of experts were the scarcity of dedicated training time and the competitive nature among peers.

Valuable Expert Advice: Experts emphasized the importance of resilience, carefulness, patience, responsibility, and hard work as essential qualities in mastering ERCP.

Balancing Personal and Professional Life: Maintaining a healthy balance between personal life and professional commitments was identified as crucial for long-term success in this demanding field.

Concluding Insights for Trainees: The chapter provides a unique look into the professional journeys of renowned ERCP experts, offering valuable recommendations and practical tips for trainees to excel in ERCP.

ABSTRACT

Background & Aims: ERCP training is an operator-dependent procedure that traditionally adopts the apprenticeship model, in which Experts are considered to be role models. This paper aimed to develop a practical guide compiling tips from Experts to help guide Trainees to succeed in ERCP.

Methods: A web-based survey was created to understand the professional development of ERCP Experts, the investments they made, the obstacles they overcame and the quotes that guided their professional life. ERCP experts worldwide were invited to participate.

Results: Fifty-three experts (of 71; 74.6%) from 24 countries answered the survey. Experts started early (average age 31 years; range 24-52) and it was frequently combined with training for EUS. A long training period (average 21months; range 3-120 months) was needed to achieve competence, frequently in another department, and it was commonly complemented with research in the field (76.5%). "Time and practice" were the most worthwhile investments they made to achieve success. "Sports" were an area outside endoscopy frequently considered to be important to acquire the necessary skills to excel in ERCP. "Lack of dedicated time for training" and "peer competition" were the biggest obstacles the experts faced. Several pieces of advice were given, such as to be resilient, careful, patient, responsible and hard-working. "Personal life" was mentioned as an undeniably crucial factor for achieving long-term success that should not be forgotten.

Conclusion: This survey is the first to provide insight regarding the professional trajectory of renowned ERCP Experts worldwide, providing valuable recommendations to help Trainees excelling in ERCP.

INTRODUCTION

In the specialized domain of endoscopic retrograde cholangiopancreatography (ERCP), proficiency demands a skill set that is intricately tied to the operator's technical, cognitive, and integrative abilities [1]. The demanding nature of ERCP arise from the protracted learning curve essential to achieve competence [2,3] and the heightened occurrence of associated adverse events (AEs) [4].

An Expert is defined as an individual who has achieved mastery in a particular area of knowledge or skill, consistently demonstrating a performance level surpassing the average. Given the traditional adherence of ERCP to the apprenticeship model, it is rational to seek guidance from these experts and consider them as role models. The comprehension of ERCP experts' professional trajectory, their strategic investments, and their success in overcoming professional challenges serve as a substantive example for trainees aspiring to follow a similar path toward success in this area.

The Latin term "*Vade Mecum*", literally translating to "go with me", historically refers to a guide carried for immediate reference. In this context, our *vade mecum* aimed to compile practical insights from ERCP experts, providing trainees with a valuable compendium of knowledge to facilitate their journeys toward proficiency in this field.

METHODS

Study design and participants

A web-based survey was developed to gather insights into the professional development and experience of ERCP experts, by identifying key milestones in their career advancement and assembling recommendations for trainees striving for excellence in this field (*SUPPLEMENTARY MATERIAL*).

The questionnaire was then distributed to 71 ERCP experts from high-volume training centers worldwide. These experts were identified based on their recognized expertise and peer acknowledgment. Selection criteria included reputation and contributions to the field, to ensure a diverse and knowledgeable sample.

Development and content of survey instrument

An online Google form survey instrument was created, consisting of 24 open-ended questions covering various aspects of training, career progression and personal reflections. It was organized into the following 5 domains: specifics in ERCP-EUS training, investments, advice to be (or not to be) followed, obstacles and quotes to guide professional life. The final survey version was distributed after pilot testing among the authors.

Survey distribution and collection of data

The survey was distributed to experts via email. A brief statement describing the goal of the study and informing respondents that their participation constituted their voluntary consent to the study were included in the invitation, as well as a link to the survey. Two mailing reminders were sent to non-respondents to maximize participation.

As this study did not involve sharing of patient data, ethics committee approval was not attained.

Questionnaire answers were voluntary and individual responses stayed confidential and only assessed by the researchers. Published data is reported as average or as totals from the group, no individual responses were reported, and data is not directly traceable to participants.

Study endpoints

The primary endpoint was to determine important points in experts' professional development. Secondary endpoints included capturing experts' recommendations to excel in ERCP.

Data analysis

All data provided per user was automatically documented in a software database (Microsoft Excel). Questions 2,3,5-7,10,12-13 were then structured as binary (yes/no) responses for ease of quantitative analysis. Questions 4,8-9, which sought information on timings, and questions 10-11, which gathered numerical data, were aggregated, summarized, and presented quantitatively. Questions 14-15,18-19 and 24 revealed recurring patterns and similarities in responses and were subject to thematic analysis. Questions 17, 20, 23 were approached using a qualitative methodology.

Quantitative data from binary and numerical responses were subjected to descriptive analysis, and mean values and ranges, numbers, and percentages were used where applicable. All calculations were made using Microsoft Excel.

Thematic analysis was applied in the questions abovementioned to enhance clarity and readability of the results. In this regard, similar or identical responses were identified and grouped into themes, in order to facilitate a more concise presentation of the qualitative data and allow for a clearer identification of prevalent ideas. These themes were then reviewed and adjusted through collaborative discussions among the research team members, for optimal accuracy in presenting the results.

RESULTS

Fifty-three experts (74.6%) from 24 countries answered the questionnaire. The geographical distribution of respondents to the survey is shown in *FIGURE 1*.

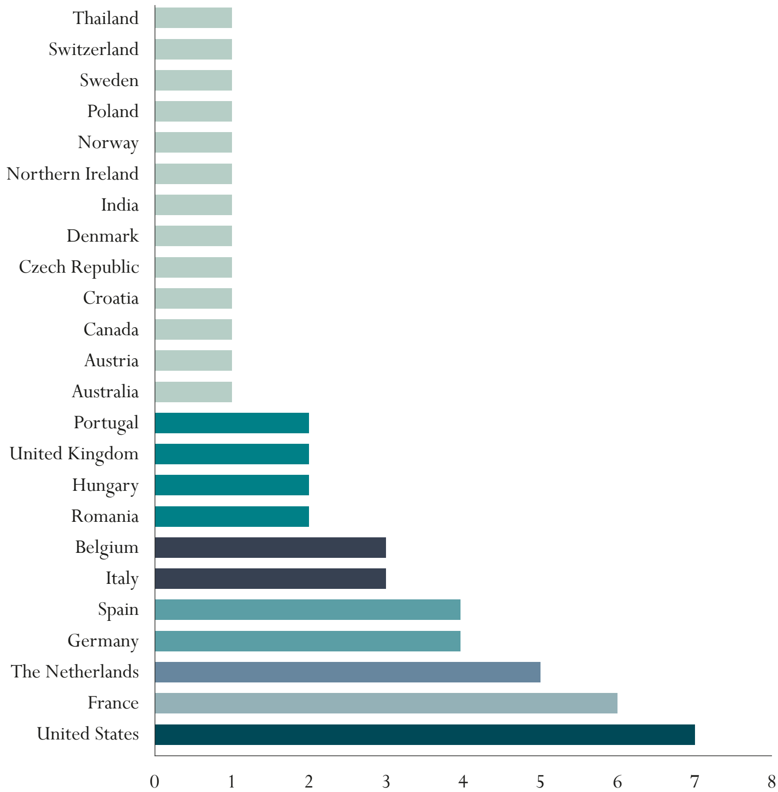

FIGURE 1

Geographical distribution of respondents to ERCP/EUS training survey: Australia (n=1), Austria (n=1), Belgium (n=3), Canada (n=1), Croatia (n=1), Czech Republic (n=1), Denmark (n=1), France (n=6), Germany (n=4), Hungary (n=2), India (n=1), Italy (n=3); Northern Ireland (n=1), Norway (n=1), Poland (n=1), Portugal (n=2), Romania (n=2), Spain (n=4), Sweden (n=1), Switzerland (n=1), Thailand (n=1), The Netherlands (n=5), United Kingdom (n=2), United States (n=7)

Training in ERCP and EUS

FIGURE 2 provides the specifics regarding their ERCP training experience.

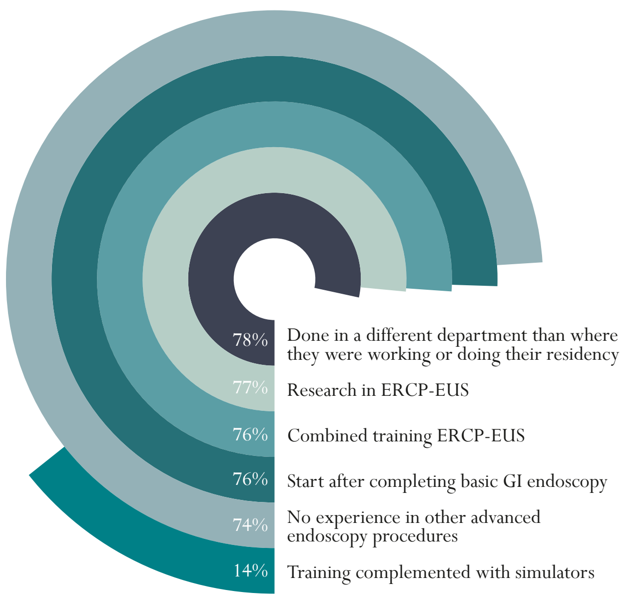

FIGURE 2

Specific aspects of Experts' ERCP training experience.

ERCP training was started early (average age of 31 years old; range: 24-52 years old), following training in basic gastrointestinal endoscopy, and demanded a rather long period of training (average duration of 27 months; range: 3-120 months). Most of the experts followed a specific period for ERCP training (81%), which often required moving to another department (78%). ERCP was learned in combination with EUS in most cases (76%), either sequentially (ERCP was frequently learned first) or simultaneously. Following these principles, experts took an average of about 1.5 years (range: immediately after training - 5 years) to start performing ERCP/EUS independently and about 4 years (range: 1-10 years) to accomplish a total of about 1000 ERCP/EUS procedures (each).

In addition, training was frequently complemented by research, with the goal of going beyond and expanding the limits of knowledge in a certain field. In fact, most experts (77%) developed research projects in ERCP/EUS while in training, with 72% having completed a Ph.D. thesis (most from European departments) by the age of 34 years old (23-49 years old). While most of these Ph.D. theses were done in the field of advanced endoscopy and/or biliopancreatic diseases, some were also done in other subjects, such as clinical gastroenterology, hepatology, basic science, or even in experimental ophthalmology or in regenerative stem cells.

Investments

When enquired about the best and most worthwhile investments experts made to develop their skills, "time and practice" (n=11) were essential for the majority, followed by "observing other experts" (n=10), "maintaining continuous learning" and "doing a fellowship" (n=8 each), "choosing the right mentor" (n=7) and "being involved in research" (n=6) as the most frequently cited.

Additionally, more than half of the experts developed certain areas outside endoscopy/medicine that they felt were also important to acquire ERCP/EUS technical skills. "Sport" (e.g., sailing, fencing, climbing) (n=10) was the most frequently mentioned, followed by "research" (e.g., translational, clinical, or bioengineering) (n=8).

Advice to be (or not to be) followed

Throughout their path to success, experts were given lot of suggestions, some were considered useful to be followed, others not so much. Experts recalled the best and the worst advice they were given, discriminated in *TABLES 1* and *2*, respectively.

BEST ADVICE GIVEN TO EXPERTS	N
"Be careful and concerned with patient safety" "Be resilient and don't give up"	n=10 each
"Observe others"	n=9
"Be patient and take your time"	n=7
"Be responsible and know your limits"	n=6
"Work hard"	n=5
"Keep on learning" "Follow your passion and enjoy what you do" "Check all conditions before starting"	n=4 each
"Learn from your experience and mistakes" "Get support and create your network" "Stay curious and enthusiastic" "Be competent and diligent" "Get involved in academics, teaching, and research"	n=3 each
"Be modest and don't let your ego go too far" "Believe in yourself" "Know your team and be a team player" "Think before you act"	n=2 each
"Less is more" "Be systematic" "Make your practice your research" "Listen" "Start early" "Stay yourself" "Be committed" "Limit your commitments" "Be positive" "Try to do the best possible" "Dedicate to not only technical but also cognitive ERCP aspects" "Change the strategy after adequate time if your approach has no success" "Focus on the question which has to be answered"	n=1 each

TABLE 1

Best advice given to experts when they were Trainees.

WORST ADVICE GIVEN TO EXPERTS
"You are a woman, should you continue?"
"Don't consult, you can manage it without help"
"Go with the flow"
"This is not a job for you", "You will never succeed", "Give up"
"Don't take risks"
"Why spend more time in endoscopy, do surgery instead"
"Never mind"
"I give you 5 minutes for cannulation"
"Don't bother putting in pancreatic stents for protection against pancreatitis"
"Don't learn to scope, you are an academic"
"Just stick to the endoscopy room"
"You will never become as good as the one who was really good at ERCP when I started training so deal with it"
"Choose Internal Medicine instead"
"It would be better if you do colonoscopy"

TABLE 2

Worst advice given to experts when they were Trainees.

Obstacles

The negative comments that some experts received during their training are a glimpse into the reality that it is not easy to get to the top. Indeed, expanding upon this idea, several obstacles to the entry of these experts into the ERCP field were listed. "Lack of dedicated time for training" (n=11) and "peer competition" (n=10) were the biggest obstacles, followed by "lack of resources" (n=8), "lack of procedure volume" (n=7), "lack of support" and "time constraints with family" (n=5 each), "lack of opportunity", "gender issues", "lack of structured training", "procedures complexity" and "difficulty developing research" (n=3 each), "difficult relation with surgeons", "bureaucracy issues", (n=2 each) and "lack of funding" (n=1).

Once more, certain attitudes, such as "keeping motivation and resilience", "humbleness and modesty", "maintaining training" and "observing and discussing with colleagues" and having critical thinking skills (e.g., "reflecting, discussing and understanding the failure and learning from it", "reassessing indications and technique", "reviewing registered procedures"), helped these experts to overcome these obstacles.

Quotes to guide professional life

Work life is tough, no doubt about it. To help in guiding professional life, the favorite quotes mentioned by the experts were summarized in *TABLE 3*.

TABLE 3
Favourite experts quotes to guide professional life.

FAVORITE EXPERTS QUOTES TO GUIDE PROFESSIONAL LIFE
"Enjoy each day"
"Learning is a continuous process"
"Keep trying" or "Never give up"
"Always be careful"
"Strive on and trust!"
"Failure is not an option" (but can be a decision)
"*Primum non nocere*"
"When sailing aimlessly, no wind is favourable"
"Who does not risk, does not win"
"Medicine is not a science; it is an art and an imperfect one"
"I am not what happened to me, I am what I choose to become"
"The value of case for the individual patient should be given the highest priority"
"The failure is when we do not even try it"
"To someone with a new hammer, everything looks like a nail"
"Well done is better than well said"

TABLE 3 | CONTINUATION

FAVORITE EXPERTS QUOTES TO GUIDE PROFESSIONAL LIFE
"You are most likely to be good at what you enjoy"
"There is no worse teacher than the one who is not overwhelmed by his student"
"It is not because things are difficult that we do not dare, it is because we do not dare that things are difficult"
"Do not take yourself too seriously"
"Cannulate the papilla with the care you would like to get a Foley catheter placed"
"Hard work pays off"
"Persistence wears down resistance"
"To thine own self be true"
"If you learn, teach; if you get, give"
"Patients who need ERCP the least are most likely to suffer a complication"

Beyond all the above mentioned advice, it should also be taken into account that "personal life", "having the possibility of teaching", "providing high work quality", "optimizing your patients' outcomes" and "developing a good relation with them and your team" and/or "collaborating in GI societies", which are frequently forgotten at more initial stages of professional life, constitute, undeniably, important factors to achieve long-term success in ERCP career.

DISCUSSION

This study results first provide insight regarding the professional trajectory of renowned worldwide ERCP experts, giving valuable advice to help trainees to excel in this field.

Training in ERCP entailed a formal and focused training for most of the experts, often incorporating a comprehensive strategy that involved both ERCP and EUS learning and was complemented by active engagement in research activities. The experts demonstrated a significant commitment by dedicating a considerable duration to their training and completing a substantial number of procedures to achieve competence. This commitment aligns with recent guidelines [5] emphasizing the importance of adopting effective and thorough training programs to fulfil the performance measures that have also been launched [6] to ensure that ERCP is performed in a standardized manner and with the appropriate quality it demands. However, it is crucial to acknowledge the evolving landscape of ERCP training. Despite the opportunities and commitment demonstrated by these experts, accomplishing all the requirements of the ERCP training curriculum [5] has become increasingly challenging in the current settings [7]. Legal considerations around training on actual patients, alongside increasing procedural complexities due to technological advancements, long learning curves to achieve competency in ERCP [3,8,9] and lack of validation regarding the relationship between trainee involvement and clinical outcomes in ERCP [10], contribute to these difficulties. Acknowledging these challenges, simulation training, though underutilized by experts, may emerge as a promising solution. Simulator-based education is increasing to complement and facilitate this supervised training process, at the same time as it obviates potential patient-related AEs. In a dedicated learning environment and maintaining the feedback from the trainers, this type of training allows the acquisition of skills and competencies at the trainee's own pace, without increasing procedure times or risks for the patient. Furthermore, simulators can permit the adoption of a "deliberate" practice, a practice that focuses on tasks beyond the trainee's current level of competence and comfort [11]. As stated by the top psychologist Anders Ericsson, "it is only by working at what you can't do that you turn into the expert you want to become" [12]. In fact, contrary to commonly held misconceptions, training should entail specific, considerable, and sustained efforts in skills/steps that the trainee can't do well, or even at all. In ERCP, although several types of simulator models have been developed [13], they still have limited formal implementation in training programs, due to their specific limitations (anatomical characteristics, price, ethical and logistical demands) [5] and lack of proper validation. The Boškoski-Costamagna ERCP Trainer, which is one of the most appreciated simulation prototypes for ERCP training [14–16], is currently being validated (ClinicalTrials.gov Identifier: NCT05533944).

Regarding the most valuable investments experts made, "time and practice" were pointed out by the majority. "Practice isn't the thing you do once you're good. It is the thing you do that makes you good" [17]. Indeed, it takes time to become an expert. Research has shown that "the most gifted performers need at least ten years (or 10,000 hours) of intense training in a given field before winning international competitions. Specifically in the field of music, the apprenticeship may be even longer, and most elite musicians will need 15 to 25 years of steady practice, on average, before they succeed at the international level" [17]. ERCP is surely no exception. Another crucial investment was the choice of a mentor. Training in ERCP has traditionally adhered to the apprenticeship model, a method rooted in experiential learning on actual patients [7]. First described by Pratt and Johnson [18], this model, especially prevalent in teaching motor skills, is characterized by the principle of "learning by doing". It is a common approach in vocational training, where a seasoned endoscopist, designated as the trainer, serves as a model for behavior. The trainee, in turn, attempts to replicate the demonstrated skills, receiving constructive feedback from the trainer. In ERCP, the importance of "choosing the right mentor", highlighted in survey responses, is pivotal. The mentor shapes not only technical expertise, but also cognitive and integrative skills, guiding decision-making, procedural intricacies, and nuanced patient care. Emphasizing "choosing the right mentor" underscores the profound impact of mentorship on ERCP expertise development. A mentor providing targeted, constructive feedback becomes a vital asset, significantly influencing the trainee's professional trajectory.

Concerning areas outside endoscopy, the importance of sports on skills development should be highlighted. As one of the experts explained, "sports teach you to manage performance anxiety and stress, change in tactics, and mental flexibility". Indeed, sports can mean much more than physical development. They can help you learn to focus and create a positive attitude towards life and its struggles, and build character traits such as perseverance, determination, commitment, equanimity, fair play and team spirit, leadership skills, strategic and analytical thinking, goal setting and risk taking [19]. As also observed in the section on "advice to be followed", these are just the same characteristics that experts consider to be crucial for excelling in a complex field like ERCP, which is also demanding, involves high pressure situations and deals the unforeseen. Interestingly, several experts have also engaged in research spanning translational, and bioengineering domains. Translational research facilitates the seamless integration of bench-to-bedside knowledge, bridging the gap between scientific discoveries and practical applications in patient care. The incorporation of bioengineering reflects a commitment to advancing technologies and methodologies. This holistic research endeavour aligns with the experts' aspiration to continually elevate the standards of care in ERCP, contributing to both the scientific understanding and the practical advancements in this field.

The insights gleaned from experts' experiences as trainees offer additional valuable guidance for those navigating in the field of ERCP. The "best advice" emphasizes fundamental principles crucial for professional growth. The best advice experts can give to their trainees was "be careful and concerned with patient safety". The patient should always be the focus. For the specific purpose of exceling in ERCP, the preparation for this kind of procedure should start, ideally, the day before the procedure, by talking to the patient, and, if necessary, the relatives. It is essential to create a good doctor-patient relationship, and to ensure that all technical conditions, such as checking the indication and reviewing all the clinical history, blood tests and imaging, are satisfied. "Make a plan, check the devices and be prepared" [20]. Planning the procedure and checking the availability and proper functioning of the devices should be done routinely. ERCP is a risky procedure with several potential related AEs that could potentially be severe [4]. It is important to be aware of AEs, adopt all recognized preventive measures, and know how to act accordingly to treat them, when needed. As mentioned by one of the experts, "ERCP is an opportunity to analyze a clinical history and provide an advice or a plan for future management". Furthermore, being in the ERCP room should not be reduced to "simply watching a procedure". We can learn a lot from assuming an active presence in the room and asking reasonable questions, watching the hands of the operator (not only the screen!), learning how to use the accessories and reviewing ERCP imaging, amongst others. After the procedure, and as experts well recalled, you should take your time to carefully reflect on the successes, but also on the failures. It is important to devise plans to keep improving. David Allen Kolb, a well-known American educational theorist, argues that "learning is the process whereby knowledge is created through the transformation of experience" [21]. Kolb's experiential learning style theory is characterized by a four-stage learning cycle in which the learner "touches all the bases". In the case of ERCP, the trainee is primarily subject to a new and unknown situation in the ERCP room. This novel and "concrete experience" should be followed by a time for reflection, a "reflective observation of the new experience", so that the trainee can reach the third stage, the so called "abstract conceptualization" stage. In other words, it is the possibility of developing critical thinking that will enable the construction of new connections between different concepts and the interconnection of knowledge. In the end, it is this type of experience that will enable the trainee to succeed when faced with different circumstances, the "active experimentation" stage. In the end, "always be responsible"! The day after the procedure, it is mandatory to check on how the patient is doing, whether there have been any AEs and, if so, trainees should be involved in the treatment.

Besides prioritizing patient safety, other recommendations given by the experts, such as cultivating resilience, underscore the core values integral to mastering ERCP. Observational learning, responsibility awareness, and continuous self-improvement are recurrent themes and have been already acknowledged recently [22]. Indeed, this study published by our team underscores the high importance of a trainee possessing non-technical skills to achieve success in ERCP, in additional to the technical skills traditionally associated with the high performance of an endoscopist. Conversely, the worst advice, marked by gender bias and discouragement, reveals the resilience exhibited by our experts, defying these challenges, as well as the need to overcome stereotypes and create an inclusive environment for learning that ensures equal opportunities for trainees to thrive in this field. The dichotomy between constructive and detrimental advice served as a compelling reflection on the varied experiences encountered during the formative stages of ERCP training.

"Personal life" was, undoubtedly, the factor most frequently mentioned by the experts, and this in line with Gladwell's [17], who argues that it is the supportive relationships people build and who they are outside our job, that defines the future professionals they will become. Expert opinion!

The study type is one of the study limitations. An analysis based on experts' opinion has low grade of evidence. However, the objective of the study was precisely to collect personal accounts, in an open-answer format, on the choices, believes and experiences of those who excelled in this field. It is a natural curiosity of those striving for success, and, from the authors knowledge, there are no papers in this regard. This methodology was chosen because, in the absence of previous studies in this field restraining the option to create a multiple-choice survey (e.g.), this format allowed the experts to better express their ideas and to capture as many information as possible. Moreover, we acknowledge that the thematic grouping linked to some of the answers, while enhancing readability, may also potentially lead to a reduction of detailed nuances within individual responses; is inherent to a subjectivity, that was reduced with performing collaborative discussions within the research team to minimize individual biases; and has potential implications for data interpretations. An additional limitation was that there were no objective criteria to define expertise in ERCP. Instead, experts were suggested by peer recognition. This method of experts' identification introduces inherent subjectivity. Additionally, despite intentional efforts to include a broad spectrum of expertise, there might be a bias in the representativeness of expertise. Finally, a consideration in the expert selection process is the potential bias in peer recognition, where some experts may be more widely acknowledged than others, which may impact the diversity of perspectives reflected in the survey responses.

Despite these limitations, this ERCP *vade mecum* constitutes a valuable resource for individuals seeking success in the field. ERCP is a technically demanding procedure, and a long process is required to develop competence. There are no shortcuts. Trainees who train in ERCP should be selected from among those who are likely to achieve proficiency and will make good use of the valuable skills. Adopting a structured and rigorous ERCP training program, engaging in deliberate practice, and following good examples, such as the ones discussed in this paper, will surely contribute to your success in performing ERCP. In the end, "Experts are always made, not born" [23] !

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How is ERCP and EUS training currently being performed?

Chapter 5: A portrait of ERCP and EUS training programs in Europe: current practices and opportunities for improvement

CHAPTER 5

A portrait of ERCP and EUS training programs in Europe: current practices and opportunities for improvement

Published as:

Teles de Campos S, Arvanitakis M, Devière J.
A portrait of ERCP and EUS training programs in Europe: current practices and opportunities for improvement. United European Gastroenterology Journal 2023 May;11(4):350-360.
doi: 10.1002/ueg2.12377.

KEY POINTS

Examination of ERCP and EUS Training Practices: Chapter 5 offers a survey of 41 experts and 30 trainees, representing the first international effort to comprehensively evaluate ERCP/EUS training across in European high-volume centers and examine adherence to the curricula recommended in Chapters 2 and 3.

No Standardized Application: The application process relied heavily on subjective evaluation of the application (individual application in 87.8%).

Well-Equipped Training Centers: All surveyed centers offered combined ERCP/EUS training, with the majority equipped with the necessary facilities and staffed by experienced trainers.

Constraints in Hands-on Trainee Experience: Despite long-term fellowships in high-volume centers, trainee involvement was, with only 43% expecting to perform 100–150 ERCPs and 69% up to 150 EUSs. Factors like extended learning curves, procedural complexity in HV centers, and legal considerations in training may contribute to these limitations.

Curriculum Implementation: About about half of the training centers (53.7%) had formalized their training curricula.

Limited Simulation Training: Utilized by only 27.3% of centers, simulation training, as suggested in Chapters 2 and 3, faced limitations probably due to its scarce availability, questions about clinical validation impacting its perceived value, and cost factors.

Competence Assessment Practices: While competence was assessed in approximately two-thirds of centers (65.9%), the adoption of validated assessment tools was limited, with only 25.9% implementing such methods.

Guideline Adherence and Gaps: Training programs generally adhered to European standards. However, there were notable discrepancies, in the application processes, the use of training tools, the curricula implementation, and the methods of performance assessment.

Proposals for Future Enhancement: Addressing these identified gaps offers a pivotal opportunity to significantly advance the quality and effectiveness of ERCP/EUS training throughout Europe.

ABSTRACT

Background & Aims: ERCP and EUS are challenging procedures requiring a high level of expertise to provide effective and safe patient care. Thus, high-quality training is needed to achieve competence. We aimed to evaluate the status of European ERCP/EUS training programs, to evaluate adherence to international recommendations, and to propose possible solutions for future improvements.

Methods: A web-based survey was developed and ERCP/EUS experts and trainees across Europe were invited to participate.

Results: Forty-one experts (out of 50; 82%) and 30 trainees (out of 70; 42.9%) from 18 countries answered the questionnaire. The training program application process is mainly driven by individual requests (87.8%). All surveyed departments offer combined ERCP/EUS training, and the majority have adequate facilities and trainers. Although centers are high-volume and provide long-term fellowships, trainee hands-on exposure is not very high (43% expect to do (or did) 100–150 ERCPs and 69% up to 150 EUSs). A formal curriculum is in place in 53.7% centers, including simulation-training in 27.3%. Competence is assessed in 65.9% of centers, but validated tools are applied in only 25.9%.

Conclusions: This survey first provides an overview of ERCP/EUS training programs across Europe. It shows that there is adherence to international guidelines to a certain degree, but several gaps in the application process, use of simulators for training, training curriculum and assessment of performance have been recognized. Overcoming these shortcomings could serve as a basis for further improvement in ERCP/EUS training.

INTRODUCTION

Digestive endoscopy is becoming more complex and subspecialized, with a growing number of different advanced gastrointestinal endoscopy procedures available, such as endoscopic retrograde cholangiopancreatography (ERCP) and interventional endoscopic ultrasound (EUS). However, these challenging procedures raise the risk of adverse events and because they are highly operator-dependent, require a high level of endoscopic expertise comprised of unique technical, cognitive, and integrative skills [1].

Quality in endoscopy is highly dependent on the quality of training [2]. Consequently, there is an increasing need for dedicated ERCP/EUS training to develop these specialized competencies, reflecting the growing number of training programs in the United States and Europe [3]. However, we must also consider the potential additional impact of trainee participation in critical outcomes of already risky procedures such as ERCP and EUS [4–7], further raising the requirement for high standards of quality in these programs.

To reduce the variation in the quality of endoscopy procedures, which significantly impacts patient outcomes [8], international societies, such as the European Society of Gastrointestinal Endoscopy (ESGE), have increasingly embraced the quality improvement paradigm. This initiative involves the development of evidence-based reviews, issuing fundamental recommendations that should be followed to standardize and optimize quality in ERCP/EUS performance [9] and curriculum training [10] and ensuring patients are optimally managed. Nonetheless, despite the publication of these ERCP/EUS training and credentialing recommendations, the capability of European fellowships to meet these guidelines has not been adequately assessed [11].

The current study aimed to evaluate the status of European ERCP/EUS training programs, analyze adherence to international recommendations, and propose possible solutions for future improvements.

METHODS

Study design and participants

A cross-sectional web survey examining the status of European ERCP/EUS training programs, current infrastructures and competence assessment, and adherence to ESGE guidelines was conducted from January to March 2022.

Training Program Directors (PD) and Experts from a list of 50 European ERCP and EUS training centers, recognized by ESGE and/or other national organizations, were invited to answer the survey. Experts were also asked to name up to three trainees that would be willing to participate, and an invitation was also sent to them.

Development and content of survey instrument

Two online Google form survey instruments were developed, one for PD/Experts and the other for trainees (*SUPPLEMENTARY MATERIAL 1S, 2S*). The five-part survey items consisted of 37 and 27 questions, respectively, organized into the following domains: characterization of the current process for ERCP/EUS training application; characterization of ERCP/EUS training departments; characterization of ERCP/EUS trainers; evaluation of departments' adherence to ESGE Curriculum; evaluation of PD/experts and trainees' overall opinions regarding the current ERCP/EUS training and determination of opportunities for improvement.

The questions were formatted as open-ended, check all that apply, multiple-choice, yes or no, 5-point Likert scales (anchors ranging from "strongly agree" to "strongly disagree"; or from "Extremely important (EI)" to "not important") and boxes for free-text comments.

The final survey version was distributed after pilot testing among the authors.

Survey distribution and collection of data

The survey was disseminated to experts and trainees via email. The email invitation was introduced by a brief statement describing the purpose of the data and informing respondents that their participation constituted their voluntary consent to the study, and a link to the survey was included. Two mailing reminders were sent to non-respondents to encourage maximum participation. All information provided per user was automatically recorded in a software database (Microsoft Excel).

Ethics committee approval was not obtained since this study involved no sharing of patient data.

Survey responses were voluntary and individual answers remained confidential and only seen by the researchers. Published data is reported as average or as totals from the group, no individual responses were reported, and data is not directly traceable to participants.

Study endpoints

Primary endpoint: assess the organization of current ERCP/EUS training programs.

Secondary endpoints: document endoscopist adherence to current recommendations and determine possible improvement solutions.

Data analysis

Quantitative data are expressed as mean and standard deviation and categorical data as number and percentage. All calculations were performed using Microsoft Excel.

RESULTS

The response rate was 82% from the experts (from 41 departments out of 50) and 42.9% from the trainees (30 out of 70) from 18 European countries (*FIGURE 1*).

FIGURE 1

Geographical distribution of respondents to Endoscopic retrograde cholangiopancreatography (ERCP)/endoscopic ultrasound (EUS) training survey: Austria (n = 1), Croatia (n = 1), Czech Republic (n = 1), Denmark (n = 1), Northern Ireland (n = 1), Norway (n = 1), Poland (n = 1), Sweden (n = 1); Hungary (n = 2), Portugal (n = 2), Romania (n = 2), United Kingdom (n=2); Belgium(n=3), Italy(n=3); Germany(n=4), Spain(n=4); The Netherlands (n = 5), France (n = 6).

Application process

Twenty-five centers (out of 37; 67.6%) accept 50% or less than the total number of applications received.

The application process has been conducted through individual request (n = 36; 87.8%), Curriculum Vitae (CV) (n = 17; 41.5%), formal interview (n = 16; 39%), recommendation letter (n = 12; 30%), society endoscopy fellowship grant (n = 11; 29.3%), motivation letter (n = 12, 29.3%), payment of an application fee (n = 3, 7.3%), practical evaluation (n = 3, 7.3%), and theoretical evaluation (0%). A request from another Institution (n = 2) was also mentioned as a method for the application process.

Criteria for trainee acceptance in the ERCP/EUS training program were rated according to the PD/experts' opinion (*TABLE 1*).

TABLE 1

PD/Experts opinion on trainees' criteria for acceptance in AGIE fellowships. Abbreviations: EI = Extremely important; VI = Very important; MI = Moderately important; SL = Slightly important; NI = Not important; EBGH = European Board of Gastroenterology and. Hepatology

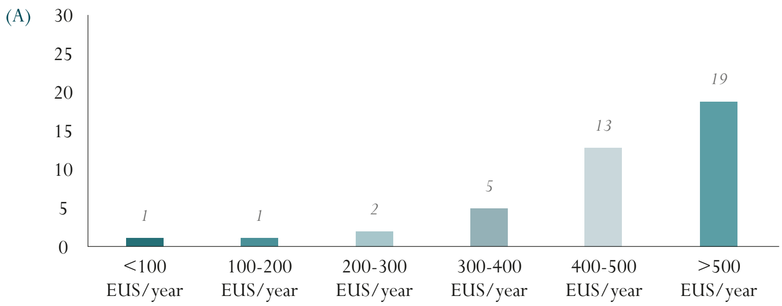
CRITERIA EVALUATED FOR TRAINEE ACCEPTANCE	EI	VI	MI	SI	NI
Endoscopic skills	46.3%	46.3%	7.4%	0	0
Appreciation in the interview	22%	46.3%	22%	7.3%	2.4%
Curriculum Vitae	17.1%	41.5%	36.6%	2.4%	2.4%
Recommendation letter	12.1%	22%	46.3%	9.8%	9.8%
Motivation letter	9.8%	36.5%	22%	19.5%	12.2%
Theoretical knowledge	9.8%	56.1%	24.4%	7.3%	2.4%
EBGH test score	0	4.9%	22%	26.8%	46.3%
Membership of endoscopy societies	4.9%	12.2%	17.1%	36.6%	29.2%
Age	2.4%	22%	34.1%	26.8%	14.7%
Research experience	2.4%	22%	43.9%	26.8%	4.9%
Gender	0	0	4.9%	2.4%	92.7%
Honours awarded	0	0	34.1%	34.1%	31.8%
Others (mentioned in free-text box)	- Trainee's speciality (Gastroenterology) (n=1) - Completion of a preliminary 1-2 months training (n=1)				

Among all the criteria considered to be "extremely important" to be evaluated before acceptance in the training, "endoscopic skills" were considered to be the most crucial ones (31 out of 38; 81.6%), followed by "appreciation in the interview" and "CV" (n = 13 each; 34.2%).

Characteristics of ERCP/EUS training departments

Volume of procedures per center

All the departments provide training in ERCP and EUS. Data related to case volume per year across centers can be found in *FIGURE 2*.



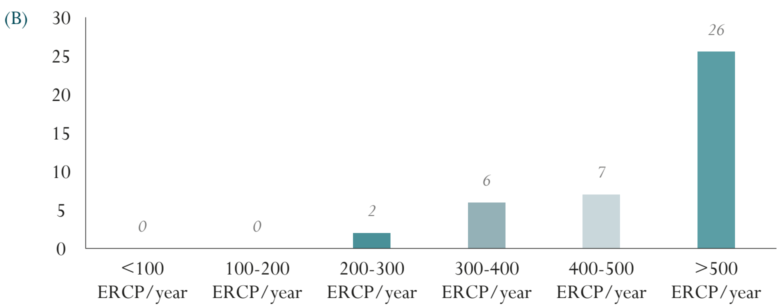


FIGURE 2

Average number of procedures per year in each center: EUS (A) and ERCP (B).

Per year, the majority of departments accept 1–2 trainees for EUS (n = 29, 70.7%) and for ERCP (n = 35, 85.4%).

Most of the trainees (n = 25; 83.3%) do combined ERCP/EUS training and expect to do (or did) 100–150 ERCPs/year (43%) and up to 150 EUSs/year (69%); only 3% (n = 1) expect to do more than 300 ERCPs and 250 EUSs (*FIGURE 3*).

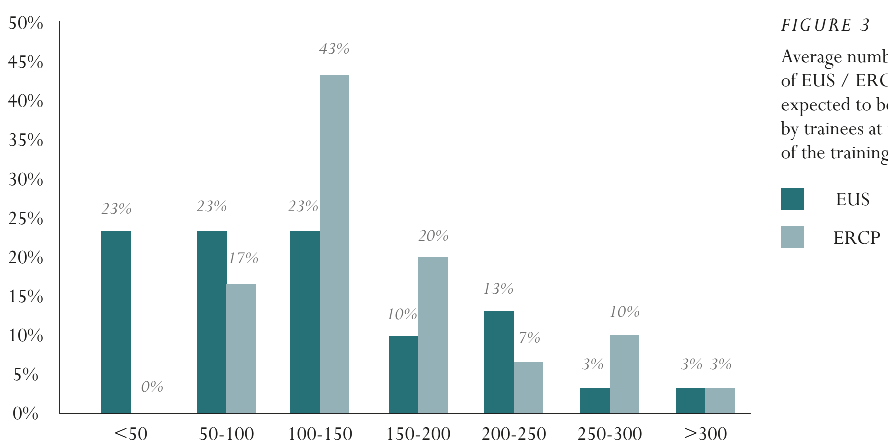


FIGURE 3

Average number of EUS / ERCP expected to be done by trainees at the end of the training.

Facilities of ERCP/EUS training centers

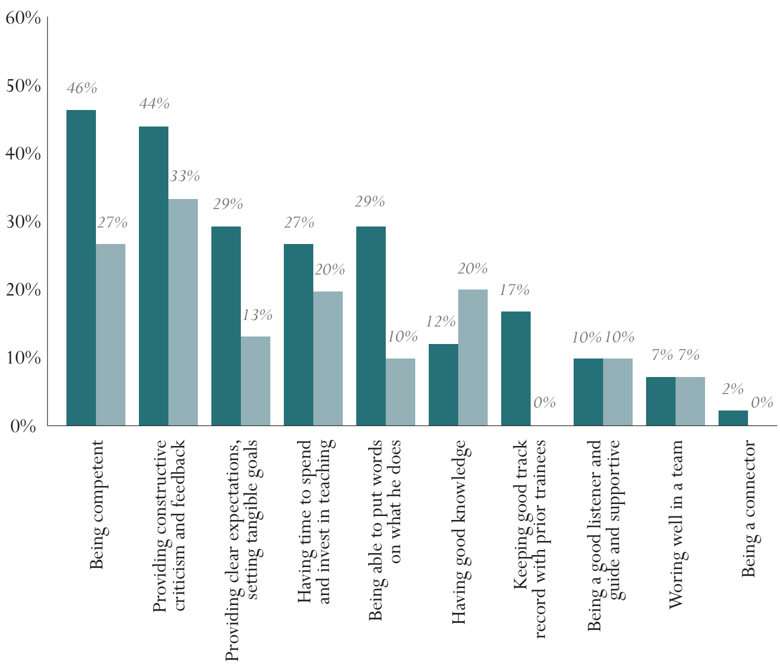
Training centers provide the following facilities: multidisciplinary hepaticopancreaticobiliary meetings (n = 37; 90.2%), onsite hepaticopancreaticobiliary surgery (n = 37, 90.2%), onsite interventional radiology (n = 39, 95.1%), trainee involvement in research and service improvement initiatives (n = 36, 87.8%), ERCP and EUS simulation training (n = 21, 51.2%).

Characteristics of ERCP/EUS trainers

Twenty-seven departments (65.9%) designate specific trainers to teach ERCP/EUS. The majority have 2–3 EUS trainers (n = 23, 56.1%) and 1–3 ERCP trainers (n = 25, 60.9%).

There is agreement between trainers and trainees regarding trainer characteristics considered to be "extremely important" to excel in ERCP/EUS (*FIGURE 4*).

FIGURE 4 Trainer's characteristics considered to be "extremely important" according to the experts' opinion (darker columns) and trainees' opinion (lighter columns) – exceptions: "keep good track record with prior trainees" and "being a connector" were mentioned only by experts.



Trainers have been performing ERCP/EUS independently for less than three years in 19.5% (n = 8), between 3 and 10 years in 39% (n = 16), and more than 10 years in 41.5% (n = 17). Program Directors/Experts took an average of 18 months (range: 3–60 months) to start performing ERCP/EUS independently and 4 years to perform 1000 ERCPs/EUSs each (range: 2–10 years).

Most of the experts (n = 40; 97.6%) consider training courses on how to teach ERCP/EUS to be beneficial, but the majority (n = 29; 70.7%) do not have access to them.

ERCP/EUS training program structure

Duration of training

Most departments provide at least 12 months of specific ERCP/EUS training (n = 22; 53.7%) and trainees plan to have, on average, an 18-month fellowship (range: 3–36 months). Twenty-four months is the longest duration for an ERCP/EUS fellowship (n = 7; 17.1%).

There is wide variation (between 1 and 24 months) between departments regarding the minimum duration for a hands-on ERCP/ EUS fellowship.

Training curriculum

Approximately half of the training programs (n = 22; 53.7%) have a formal ERCP/EUS curriculum, which includes dedicated "hands-on" training (100%; n= 22), didactic sessions / courses (n=14; 63.6%), endoscopy simulator training (n=6;27.3%), and participation in clinical research (n = 3; 13.6%).

Simulation-based training

Although PD/Experts mentioned the availability of endoscopy simulators in 53.7% (n = 22) of departments, only six respondent trainees from 5 departments referred to having access to them during their training.

Different types of simulators are available: mechanical simulators (n=16; 53.3%); a virtual reality simulator (n = 9; 30%); animal models (ex vivo) (n = 9; 30%); and animal models (in vivo) (n = 3; 10%).

Trainees use simulators at different stages of training: before (n = 10; 45.5%), at the beginning (n = 7 ; 31.8%), or during the whole hands-on training period (n = 5; 22.7%).

Competence assessment

Twenty-seven departments (65.9%) perform a formal assessment during ERCP/EUS training programs, which is done: at set intervals throughout the fellowship (n = 12; 44.4%); randomly throughout the fellowship (n = 7; 25.9%); at the end of the fellowship (n = 8; 29.6%).

The method(s) used to assess whether the trainee achieved endoscopic competence in ERCP/EUS are adequate performance on specific quality metrics, for example, cannulation rate or documentation of EUS landmarks (n = 15; 55.6%); the achievement of certain benchmarks (e.g., procedure volume) (n = 14; 51.9%); verbal attending evaluations (n = 11; 40.7%); adequate performance on a skills assessment tool, for example, TEESAT and DOPS (n = 7; 25.9%), written attending evaluation (n = 3; 11.1%).

Specific parameters of the ERCP/EUS trainee's competence assessment were rated according to PD/expert opinion (*TABLE 2*).

TABLE 2

Criteria evaluated by Program Directors (PD)/Experts for trainee's assessment of ERCP/EUS competence.

Abbreviations: EI = Extremely important; VI = Very important; MI = Moderately important; SL = Slightly important; NI = Not important

CRITERIA EVALUATED FOR TRAINEE'S ASSESSMENT OF COMPETENCE	EI	VI	MI	SI	NI
Knowledge of procedure indications and contraindications	75.6%	19.5%	4.9%	0	0
Recognition of pathology	68.3%	29.3%	2.4%	0	0
Appropriate selection of therapeutic manoeuvres/tools	68.3%	31.7%	0	0	0
Recognition of anatomic landmarks	61%	39%	0	0	0
Complication rates	53.7%	24.3%	22%	0	0
Correct surveillance/follow-up recommendations	43.9%	43.9%	12.2%	0	0
Appropriate informed consent discussion	34.1%	46.4%	19.5%	0	0
Independent procedure completion rates	34.1%	53.7%	12.2%	0	0
Procedures volume	31.7%	51.3%	14.6%	2.4%	0
Monitoring patient discomfort/ experience	22%	53.7%	14.6%	7.3%	2.4%
Appropriate selection and use of sedation	17%	53.7%	22%	4.9%	2.4%
Appropriate antibiotic prophylaxis before ERCP/EUS	19.5%	46.3%	29.3%	4.9%	0
Reporting	24.4%	61%	14.6%	0	0

Self-assessment tools

Although only 2 PD/Experts recommend using self-assessment tools, such as the ERCP Rotterdam Assessment Form (RAF-E) and GESAP Self-Assessment tool, 11 trainees (36.7%) maintain a dedicated notebook to register completion rates and complications.

Adherence to ESGE recommendations

Based on all gathered data from PD/Experts and trainees, we summarized the department adherence rates to the ESGE Curriculum for ERCP/EUS training (*TABLE 3*).

NUMBER	ESGE RECOMMENDATION	NUMBER POSITIVE ANSWERS	NUMBER NEGATIVE ANSWERS	% ADHERENCE TO THE RECOMMENDATION
1	Every endoscopist should have achieved competence in UGI endoscopy before commencing training in ERCP or EUS, i.e. having personal experience of at least 300 gastroscopies and meeting the ESGE quality measures for UGI endoscopy.	24	6	80%
2a	Simulation-based training represents a positive development to accelerate the trainee's learning curve and should be encouraged.	22	19	53.7%
2b, 3	When available, trainees should start training by undertaking structured supervised ERCP/EUS simulator-based training before commencing hands-on training in the workplace. Where it is available, simulation-based training should evolve in a stepwise approach for training: virtual reality and mechanical simulators should be used during early training, followed by hands-on endoscopy training.	10	12	45.5%
4, 5	Trainees should undertake formal courses to complement ERCP/EUS training. ERCP and EUS trainees should engage with a range of learning resources to supplement formal courses and experiential learning.	14	8	63.6%
6	ERCP and EUS training should follow a structured syllabus to guide what is covered in workplace learning, formal training courses, and self-directed study.	22	19	53.7%
7	A minimum training period of 12 months of high volume training is likely to be required to obtain minimum proficiency in both ERCP and diagnostic EUS.	22	19	53.7%
8	A significant proportion of training should be based in high volume* training centers that are able to offer trainees a sufficient wealth of experience for at least 12 months:			
	8a ERCP	39	2	95.1%
	8b EUS	37	4	90.2%
9	An ERCP/EUS training center should ideally be able to provide:			
	9a Multidisciplinary hepaticobiliary meetings	37	4	90.2%
	9b Onsite hepaticopancreaticobiliary surgery	37	4	90.2%
	9c Onsite interventional radiology	39	2	95.1%
	9d ERCP and EUS simulation	21	20	51.2%
	9e Involvement in research, service improvement initiatives	36	5	87.8%
10, 11	A trainee's principal trainer should ideally have more than 3 years' experience of independent ERCP and/or EUS practice.	33	8	80.5%

TABLE 3

Adherence rate to ESGE Recommendations on ERCP/EUS Training.

*High-volume training centres defined as performing > 300 EUS/ERCPs per year.

TABLE 3 | CONTINUATION

NUMBER	ESGE RECOMMENDATION	NUMBER POSITIVE ANSWERS	NUMBER NEGATIVE ANSWERS	% ADHERENCE TO THE RECOMMENDATION
13	Formal assessments tools should be used regularly during ERCP and EUS training to track the acquisition of trainees' competence and to support trainee feedback.	7	20	25.9%
14	Trainees should be encouraged to undertake self-assessment and keep a contemporaneous logbook of all cases, which includes the degree of trainer support that was needed for each aspect of the procedure.	11	19	36.7%
15	A trainee should undergo:			
	15a Formal summative assessment process	27	14	65.9%
	15b Prior commencing independentpractice in ERCP/EUS	8	19	29.6%
20, 28	The number of ERCP/EUS performed may be a surrogate marker of competence, but in isolation is an inexact means to demonstrate competence. Most trainees are likely to need to have performed > 300 ERCPs / > 250 diagnostic EUSs to be in a position to demonstrate competency.	1	29	3%

General opinion regarding ERCP/EUS training

The feelings experts and trainees have concerning the current ERCP/ EUS training programs provided by their department are shown in *TABLE 4*.

TABLE 4

Experts (TR) and trainees (TE) opinions regarding ERCP/EUS training programs. Abbreviations: ES = Extremely satisfied; VS = Very satisfied; MS = Moderately satisfied; SS = Slightly satisfied; NS = Not satisfied.

OPINION ABOUT TRAINING PROGRAM	ES		VS		MS		SS		NS	
	TR	TE	TR	TE	TR	TE	TR	TE	TR	TE
Overall quality of endoscopy training	7.3%	40%	63.4%	46%	24.4%	10%	4.9%	4%	3.3%	0
Trainee's selection process	2.4%	16.7%	51.2%	33.3%	36.6%	33.3%	9.8%	13.4%	0	3.3%
Environment/ facilities of institutions	4.9%	36.7%	68.3%	53.3%	19.5%	6.7%	7.3%	3.3%	0	0
Overall competence assessment	0	26.7%	70.7%	43.3%	22%	26.7%	7.3%	3.3%	0	0

For some trainees, training is hampered by having too many trainees simultaneously, lack of procedure volume, or trainer's inability to let the trainee touch the scope. On the other hand, for some PD/experts, training is hampered by lack of time and a very heavy clinical burden on trainers, with competing clinical and bureaucratic requirements. Additionally, there is a lack of formal support from national societies and no remuneration for training included in the reimbursement systems. There is no actual auditing or performance evaluation.

DISCUSSION

This web-based survey represents the first international attempt to obtain a comprehensive "portrait" regarding ERCP and EUS training program structures by capturing data from facilities in Europe. This study presents data on a significant part of European countries.

The majority of the centers have an application acceptance rate of 50% or less, which shows a high demand for ERCP/EUS training programs that is currently unmet. In addition, the number of applications per year is increasing in some regions (33.3% of cases). Nonetheless, it should be noted that it is not possible to assess whether applicants rejected at one center were accepted at another one. Thus, the actual rejection rate may be lower than shown here.

As suggested in the literature [12] and confirmed in our results, there is no standardized application process in these training programs, and the application process relies heavily on subjective evaluation of the applicants (e.g., individual application, interview). An application selection method that could be uniformly applied across centers could minimize application selection biases. Endoscopic skills were considered the most important criterion for acceptance into training programs. Thus, it would make sense to include a formal evaluation of these skills in the application process, especially given that there are currently available validated assessment tools for endoscopy performance, such as DOPS [13–15]. It should be noted that good performance in basic endoscopy may not translate to good performance in ERCP/EUS as no relationship between basic handling skills and therapeutic skills has been demonstrated [16]. In addition, it can be questionable to perform this kind of practical evaluation on actual patients due to safety and legal concerns. Endoscopy simulators could play a role in this trainee screening process [17]. The importance of certain non-technical skills has been recently acknowledged [18] and, while being incorporated in assessment tools such as DOPS, should also be considered during the trainee selection process.

One interesting and somewhat contradictory finding is that, despite theoretical knowledge being considered by a large percentage of experts to be a very important parameter to be evaluated in this process, the EBGH score was only slightly to moderately valued for the majority. Possible explanations could be the lack of knowledge about the EBGH examination or the preference of the PD to conduct their own theoretical evaluations (which may hamper the standardization needed for training).

Another parameter not considered to be important to experts for trainee acceptance was gender, although 70% of the respondent trainees were male. Available data do not allow assumptions regarding trainee gender distribution from the PD responses, but it can be assumed that the large percentage of selected male trainees is not gender related. Although it was not possible to obtain a justification for this result, it is true that women remain underrepresented in Gastroenterology, especially in ERCP/EUS. A recent study [19] confirmed that women represent a minority in this field, corresponding to 14% of current ERCP/EUS fellows and to 13.2% of endoscopy chiefs. Inflexible hours and calls, exposure to fluoroscopy during childbearing age, lack of women endoscopists at conferences/courses, and lack of mentorship for female trainees were perceived barriers to recruitment. To strive toward equity in ERCP/EUS, the number of women being recruited to these fellowships should increase, and structural changes and policies should be implemented to aid the development of women during their career in this field.

Some trainers considered the "perspective of continuing ERCP/ EUS after training" as a valuable criteria worth mentioning before acceptance into the fellowship. Given the limited number of training vacancies available, it makes sense to attribute these to those with the highest likelihood of continuing their ERCP/EUS practice. Furthermore, and has already suggested [16], it would make sense to have national and international institutions determining beforehand the need for additional human resources for centers/countries, which could be better accomplished based on predefined criteria. These criteria could consider several parameters, such as the forecasted number of ERCPs to be performed [20], case volume per endoscopist, procedure complexity, academic setting, and availability of support from other specialties.

To ensure good training, a good trainer is mandatory [21]. Nonetheless, objectively, clinical and teaching prerequisites for an ideal trainer are not determined. This study determined the best qualities that a trainer should have for interviewing ERCP/EUS PD/experts and trainees. From the PDs' point of view, the three most important characteristics of a trainer are being competent (46%), providing constructive criticism and feedback (44%), and having clear expectations and tangible goals (32%). Surprisingly, trainees, comparatively, undervalued the trainer's competence and correct setting of expectations, which could be a manifestation of the Dunning-Kruger effect [22], a form of cognitive bias where those with low skills overestimate their ability (expecting to attain a good level of performance regardless of the trainer's skills). High variability in teaching methods was mentioned by those having different trainers. Nonetheless, as trainees also agree, having more than one trainer may be beneficial to take advantage of all the possible qualities good mentors have [21].

The threshold for defining a low volume (LV) center in the included centers ranged from 87 to 200 annual ERCPs per center [23]; therefore, we defined a high volume (HV) center as one with more than 200 procedures per year. The majority of the departments surveyed are considered to be very HV. High volume centers are considered to be better fit to handle complex cases as they have better outcomes than LV centers [23], providing an ideal setting for learning ERCP/EUS, specifically the clinical decision-making process and the steps to avoid complications. In addition, the HV of procedures available may provide ample opportunities for hands-on practice of these procedures, parameters considered to be EI to both PD/experts and trainees, in line with results from other surveys in other medical specialities [24]. Accordingly, a large percentage of centers will only accept 1–2 trainees per year, which can be assumed to be an effort to provide an adequate case load for the trainees.

Nonetheless, the expected number of procedures performed during training is lower than the recommended minimum for independent practice. This may be due to the complexity of the cases in HV academic centers. For a trainee starting the technique, it may take a couple of months to build up a fair number of relatively simple cases for practice leading to more complex cases. Clinical-based predictive tools, such as the TIERS risk score, could improve ERCP training through an individualized selection of cases for hands-on training without exposing patients to higher risks (Voiosu et al., unpublished data). In addition, trainees could be exposed to other forms of training, such as simulators, to try to overcome this issue. Another possible takeaway is that formal fellowship programs in HV centers may only be the first step toward independent practice and should probably be complemented with a period of supervised performance of ERCP/EUS in LV centers. Although these centers have lower volumes, cases will typically be less complex, providing a suitable environment for the reinforcement of the theoretical and practical principles acquired during training in HV centers. Of note, PD/experts took an average of 18 months to start performing ERCP/EUS independently. In this regard, Voiosu et al [25] described the evolution of ERCP practice of an advanced endoscopist at the beginning of this independent practice. It was interesting to confirm that, beyond the training period, it is expected that the learning curve keeps evolving as experience increases.

Although around half of the departments have endoscopy simulators available, they are not part of the regular formal training programs. Possible explanations for this underuse of the simulators might be lack of permanent availability (only during workshops), lack of clinical validation of their role leading to a lower perceived value of this training modality, and the price.

However, around 50% of departments do not have a formal ERCP/EUS curriculum and around one third do not perform any kind of formal assessment of trainee performance. Although validated assessment tools are formally used in only 25.9% of those who do, more than half of the training programs measure traditional benchmarks and performance metrics. Such practice is following the shift away from the absolute number of procedures performed as the only measure of competence to a more tailored and milestone-based training and assessment [3], since learning curves among individual trainees can be substantially different [26–30]. Regarding specific quality metrics, one interesting finding is that to know on “whom” should we perform the procedure (or do not) (“knowledge of procedure indications and contraindications” and “recognition of pathology”) and “how” (“appropriate selection of therapeutic manoeuvres and tools") are more valued than "independent procedure completion rates" or "complication rates". Although case volume and opportunities for hands-on practice are very much appreciated, PD/experts attribute high importance to the correct framework for decision-making rather than solely technical skills.

Taking into account adherence rates to ESGE guidelines and global PD/expert and trainee opinions regarding ERCP/EUS training programs, some specific aspects can still be improved, such as:

a) Standardizing the trainee selection process, while considered to be essential, is still performed in a very subjective manner;

b) Optimizing training structure, assuring that the aims of the fellowship are explicit, and all domains and skills required to achieve competence are communicated to trainees;

c) Assessing the real impact of simulation training on achieving better clinical performance to optimize its use in regular ERCP/ EUS training programs;

d) Adopting a systematic assessment of competence, using standardized and validated tools, may allow the identification of specific skill deficiencies and individualized strategies to overcome them; and

e) Granting privileges to trainers, endoscopy departments, and hospitals by institutions or societies, including improving facilities and providing dedicated time and remuneration for those who truly can and are willing to teach.

The main limitation of this study is related to the fact that this is a survey-based analysis. Although the trainer response rate was relatively high (82%), there is no objective manner to confirm the information provided in the responses. On the other hand, the trainee response rate was rather low, despite the mailing reminders. Reasons for non-participation can only be speculated (lack of motivation, concern over PD reactions to answers). Nonetheless, trainers and trainees agreed on most of the common questions, which is reassuring regarding the quality of their answers. Self-reporting bias should also be considered when analyzing this kind of survey.

Another limitation is related to the fact that this questionnaire was developed specifically for this study and did not make use of a validated training quality assessment instrument. A pilot evaluation by two experienced GIs was undertaken to minimize issues related to the questionnaire itself. The main issue regarding this point is that adherence to ESGE recommendations was made based on a subjective evaluation of the responses. This was done to avoid duplication of the questions since some were already asked to characterize the training center.

Finally, this study is limited by the number of specific centers included, which may represent a selection bias and underrepresentation of the general European panorama. As there is neither a centralized updated database of training centers for ERCP/EUS in Europe nor a formal list of requisites to recognize a center as a training center, the centers contacted for this study were selected based on recognition by ESGE and/or other national organizations. Future endeavors aimed at the development of centralized registry of ERCP/EUS training centers could serve as a stimulus toward the uniformization of training center recognition criteria and training protocols.

This survey is the first to provide an overview of ERCP/EUS training programs across Europe. Additionally, it showed that there is adherence, to a certain degree, to international guidelines on ERCP/ EUS training. However, several gaps, in the standardization of the application process, the number of procedures performed, use of simulators for complementing training, and in the adoption of a formal ERCP/EUS training curriculum and assessment of trainee performance, have also been recognized. Overcoming these shortcomings could serve as a basis for further improvement in ERCP/EUS training.

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Who should enter in a ERCP and EUS fellowship?

Chapter 6: Who will excel in advanced endoscopy? A study assessing Experts' criteria and perceptions regarding selection of ERCP and EUS trainees

CHAPTER 6

Who will excel in advanced endoscopy? A study assessing Experts' criteria and perceptions regarding selection of ERCP and EUS trainees

Published as:

Teles de Campos S, Devière J, Arvanitakis M.
Who will excel in advanced endoscopy?
A study assessing Experts' criteria and perceptions
regarding selection of ERCP and EUS trainees.
Endoscopy International Open 2023 Mar 23;11(3):
E268-E275; doi: 10.1055/a-2017-3827.

Best moderated poster presentation prize
in Education in GI at UEG Week 2022

KEY POINTS

Investigation of Key Criteria and Perceptions for ERCP/EUS Trainee Selection: Chapter 6 provides a comprehensive analysis of a web-based survey involving 36 Training Program Directors (TPDs) and experts from eighteen European countries, alongside 25 trainees. This survey represents an initial study offering valuable insights into the selection criteria and perceptions guiding the process of selecting ERCP/EUS trainees.

Individual-Requested Application Process: The majority (86.1%) of the application process for ERCP/EUS training was driven by individual requests, heavily relying on a subjective assessment of applicants. Concerningly, nearly half (38.9%) of TPDs/experts expressed only moderate satisfaction with the current application process, indicating potential shortcomings in ERCP/EUS candidate selection quality.

Importance of Non-Technical Skills: Non-technical skills such as honesty, teamwork, and self-awareness (72.2% each) were highly prioritized by TPDs and experts over technical expertise, emphasizing their significance in excelling in advanced biliopancreatic endoscopy. Notably, technical skills ranked seventh as considered "extremely important".

Common Reasons for Training Disqualification: Trainee disqualification occurred in 22.2% of cases, primarily due to disregard for patient welfare and lacking work ethic. This indicates a correlation between key attributes for trainee excelling in ERCP and reasons for disqualification.

Alignment between Perspectives: There was notable alignment between the perspectives of TPDs/experts and trainees regarding critical trainee characteristics essential for success in ERCP/EUS.

Collaboration for Improvement: Collaborative efforts among stakeholders are necessary to address identified gaps in the selection process, standardize practices, and enhance the quality and effectiveness of ERCP/EUS training throughout Europe.

Recommendations for Future Improvement: By refining the selection process and emphasizing both technical and non-technical skills in ERCP/EUS candidate selection, the quality of endoscopy practice can be elevated.

ABSTRACT

Background & Aims: Training program directors (TPDs) and experts play a crucial role in selecting ERCP/EUS trainees and determining the workforce in endoscopy. Additionally, prospective trainees should know what TPDs/experts expect from them. Nonetheless, the criteria and perceptions used in this selection have not been clarified. With this study, we aimed to identify TPDs/experts values/beliefs regarding personal attributes needed for selecting trainees that can excel and those which may lead to disqualification; compare perspectives between TPDs/experts and trainees regarding the selection process and critical trainee characteristics; and investigate the general approach and satisfaction regarding current application process for ERCP/EUS training.

Methods: We conducted a web-based survey to collect general opinion and data regarding the application process and trainee selection and disqualification from training. European TPDs/experts and trainees were invited to participate.

Results: Thirty-six TPDs/experts and 25 trainees from 18 countries responded. The application process is mainly driven by individual request (86.1%). Almost half of TPDs/experts felt only moderately (38.9%) to slightly (8.3%) satisfied with the current application process. TPDs/experts value a diversity of trainee characteristics, but mainly traits such as "honesty", "being a team player", and "self-awareness" (72.2% each). Technical skills ranked seventh as considered "extremely important". "Disregard for patient welfare" and "lack of work ethic" were the most common reasons for disqualification. TPDs/experts and trainees agreed in most questions.

Conclusions: This survey outlines trainee selection criteria for ERCP/EUS training. Non-technical skills are the most valued by TPDs/experts. While knowledge and technical expertise are clearly important, understanding that professional attitudes are highly regarded may help direct the application process more effectively.

INTRODUCTION

Advanced gastrointestinal endoscopy (AGIE) encompasses an increasing number of different procedures for which high complexity is the common denominator. In this context, there is growing demand for dedicated subspecialty training, namely in endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasound (EUS) [1], to deepen the knowledge and acquire the skills needed to achieve competence [2]. Due to the fact that these therapeutic procedures are not only complex but are also associated with severe complications more frequently in non-expert hands [3], proper training and selection are paramount.

To ensure high-quality training in ERCP/EUS, it is fundamental to determine who should be trained. Trainee selection should be fair and based on predefined criteria to predict future performance. However, subjective factors, such as the selector's personal opinion, may affect this process. Consequently, training program directors' (TPDs) personal values and beliefs involved in selection of a trainee should be better clarified to improve the selection of the future AGIE workforce.

The current literature reports fellowship selection criteria and methods used in various medical fields, including gastroenterology [4–8], but there is lack of data in the AGIE field. Additionally, there is also little information about the particular influence of selectors' personal values and beliefs on the judgment and decision-making process. For example, there are publications focused on other medical specialties [9], but there are no specific reports in ERCP/EUS, an area where most guidelines agree nowadays that both techniques should be taught together at least for therapeutic purposes [10].

Which tools are used for selecting ERCP/EUS trainees? What do TPDs/experts value, believe, and consider when judging a potential candidate interested in training in ERCP/EUS? These questions are still to be answered. Clarifying the factors involved in this process is important because selectors decide who will be admitted to AGIE training programs and have an essential role in ensuring that future advanced endoscopists are skilled enough to provide quality, safe, and effective care. Furthermore, young physicians applying for these training programs should know what TPDs/experts are expecting from them.

In this study we aimed:

a) First, to identify TPDs/experts values and beliefs regarding the critical personal attributes used for selecting AGIE trainees that are likely to excel in ERCP/EUS, as well as those that may lead to a training disqualification;

b) Second, to compare perspectives between TPDs/experts and trainee opinions regarding the training selection process and personal characteristics needed to be selected as a trainee. In addition, to investigate the general approach and satisfaction regarding the current trainee application process for ERCP/EUS training.

METHODS

Study design and participants

We developed an online survey instrument that merged topics from an earlier international survey (unpublished data). A list of potential trainee characteristics which could influence selection and training in ERCP/EUS programs was compiled from the answers to this previous survey and from the literature [4, 8, 9, 11, 12] and used as a starting point. An invitation was sent by e-mail to TPDs/experts from a list of 45 European ERCP/EUS training centres. In addition, a request was made to each TPDs/experts to provide up to three AGIE trainee contacts who could participate in the survey and an invitation was also sent to them to complete a trainee-specific form. Participants were contacted to participate in the study between January and March 2022.

Development and content of survey instrument

Two electronic survey instruments were prepared, one for TPDs/experts and the other for trainees (*SUPPLEMENTARY MATERIAL, APPENDIX 1*). The available version of Google forms was used to conduct the survey. Data on individual participants were not collected. The four-part surveys comprised 50 and 33 questions, for TPDs/experts and trainees, respectively, structured into the following categories: Section 1, enquiring about general opinion regarding application process and trainee selection; Section 2, evaluating the current application process for ERCP/EUS training programs; Section 3, defining trainee qualities needed to excel in ERCP/ EUS; and Section 4, defining trainee characteristics that could justify disqualification from ERCP/EUS training.

The question format varied and included open-ended, check all that apply, multiple-choice, yes or no, and 5-point Likert scale (anchors ranging from "strongly agree" to "strongly disagree"; or from "extremely important" to "not important") questions. The surveys also included boxes for free-text comments.

The final survey version was revised and distributed after pilot testing among the authors.

Survey distribution and collection of data

The online survey was sent to TPDs/experts and trainees via email. The survey was presented with a short introduction explaining the purpose of the collected information and acknowledging the contribution of the participants. Participation constituted voluntary consent to the study. Additionally, a link to the survey was added. Two direct mailing reminders were sent to non-respondents to maximize participation in the study. All data per user was automatically recorded into a software database (Microsoft Excel).

Ethics committee approval was not obtained since no patient data were collected for the study.

Answers to the questionnaire were voluntary and individual responses stayed confidential and were only seen by the investigators analyzing the data.

Therefore, published data are described as averages or as totals from the group, no individual responses were reported, and the data is not directly traceable to the contributors.

Study endpoints

The primary outcome was to ascertain TPD/expert values and beliefs regarding the critical personal attributes used for selection of AGIE trainees (ERCP/EUS programs), including those that indicate a trainee is likely to be successful and those that may lead to training disqualification.

The secondary outcomes were to compare perspectives between TPDs/experts and trainees regarding the selection process and personal characteristics needed to be selected as a trainee; and to evaluate the general approach and satisfaction regarding current selection process for AGIE training programs.

Data analysis

A descriptive analysis was conducted on all study variables. Categorical variables were described through absolute and relative frequencies, and continuous variables were described using mean and standard deviation, quartiles, minimum and maximum values. Frequencies of answers were compared between trainees and trainers with Pearson's Chi-squared or Fisher's exact test, depending on expected frequencies. The statistical significance level was set at 0.05. The analyses were performed with Stata/SE 17.0.

RESULTS

Eighty percent (36 of 45) TPDs/experts answered the questionnaire. Among the trainees, the response rate was 38.5% (25 of 65 invited). Trainees were from 17 different departments. The 18 European countries represented in the survey are shown in *FIGURE 1*.

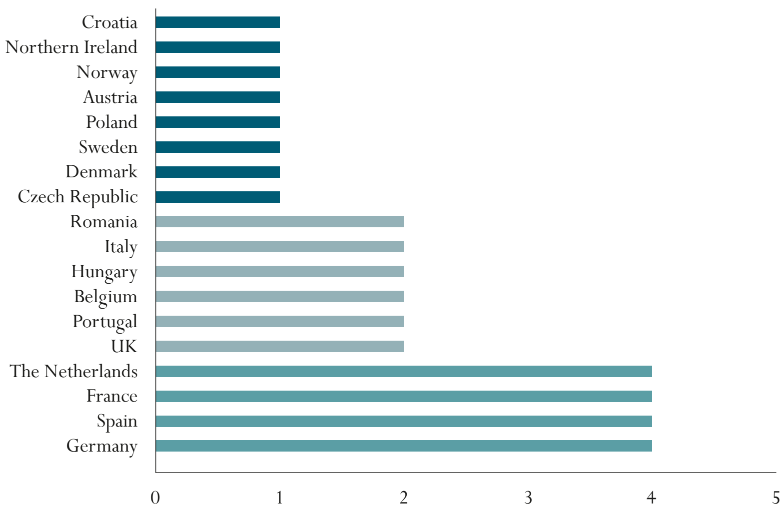


FIGURE 1

Geographical distribution of both TPDs/experts and trainees respondents to survey on ERCP/EUS training.

ERCP/EUS trainee selection

The evaluation of TPDs/experts and trainees concerning the current selection process for ERCP/EUS training is shown in *FIGURE 2*.

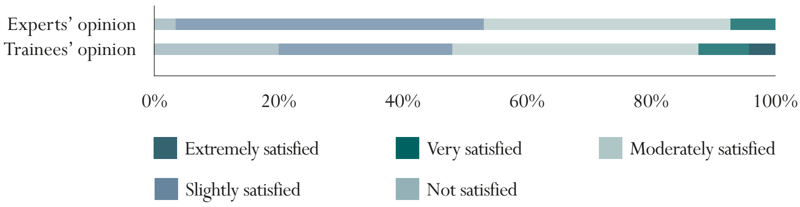


FIGURE 2
TPDs/experts and trainees opinions regarding current ERCP/EUS trainee selection process.

There is a general agreement between TPDs/experts and trainees regarding the selection process (p=0.08) (*SUPPLEMENTARY MATERIAL, APPENDIX 2, TABLE 1*).

Past ERCP/EUS trainee evaluations

The majority of the TPDs/experts were either "very satisfied" (n = 26; 72.2%) or "extremely satisfied" (n=5; 13.2%) with the trainees who graduated from their fellowship program in the last five years. Five of them (13.9%) were "neutral" and none were "somewhat unsatisfied" or "not at all satisfied." Those who were "neutral" explained their reasoning further: "time allowed for the training is limited and is standardized based on very inadequate criteria at a national level, getting trainees to have an inadequate period for training."

Current process for trainee selection in ERCP/EUS training

The application process was conducted through: individual request, 86.1% (n = 31); curriculum vitae (CV), 41.7% (n = 15); formal interview, 38.9% (n = 14); recommendation letter, 30.6% (n = 11); endoscopy society fellowship grant, 27.8% (n = 10); motivation letter, 27.8% (n = 10); payment of an application fee, 8.3% (n = 3); practical evaluation, 8.3% (n = 3); theoretical evaluation, 0 cases.

A request from another institution (n = 2) was also mentioned as a method for the application.

Ideal trainee characteristics needed to excel in ERCP/EUS training

The value of the following ERCP/EUS trainee characteristics was rated according to TPDs/experts and trainee opinions, as shown in *FIGURE 3*.

There is a general agreement between TPDs/experts and trainees regarding the importance of the abovementioned trainee characteristics to excel in ERCP/EUS (*SUPPLEMENTARY MATERIAL, APPENDIX 2, TABLE 2*), with the exception of "honesty", which is considered to be slightly more important for trainers than for trainees (e. g. extremely important rates of 72.2% versus 44.0%, respectively; p = 0.032).

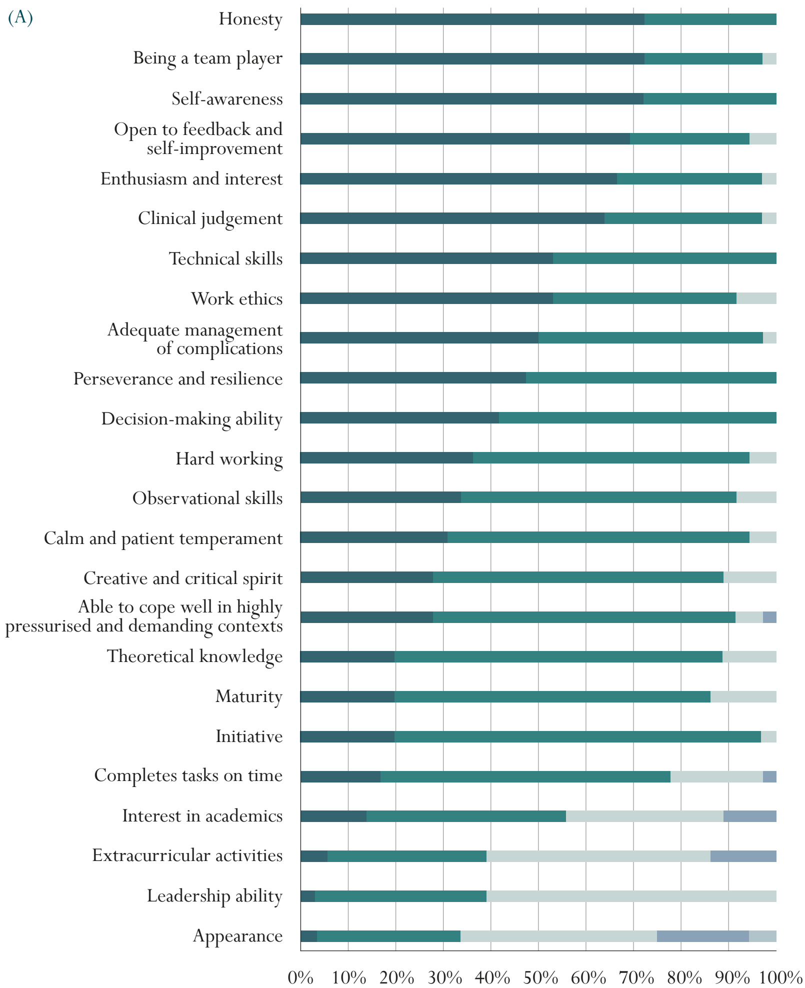
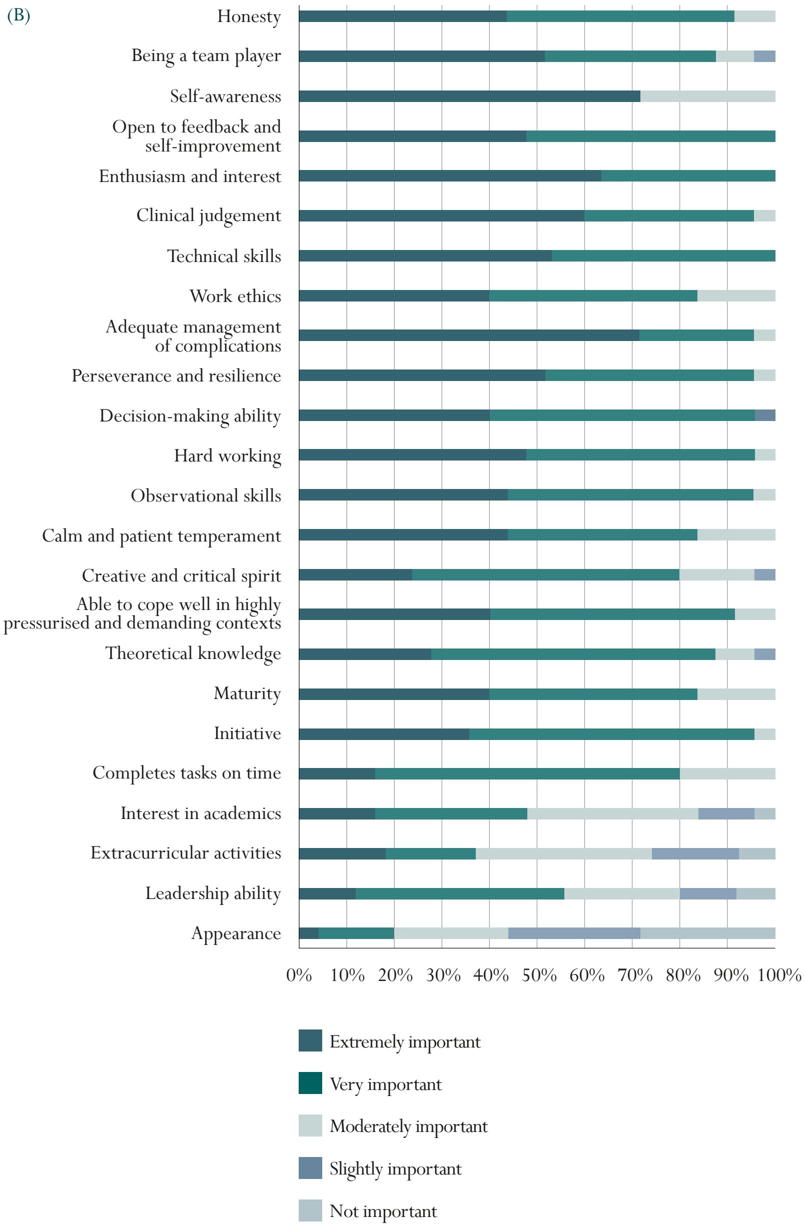


FIGURE 3
Rating of trainee characteristics regarding their importance to TPDs/experts (A) and trainees (B).

FIGURE 3 | CONTINUATION



Moreover, all participants were asked to select the three most crucial trainee characteristics from all the ones they had previously considered to be "extremely important" to excel in ERCP/EUS (*FIGURE 4*).

There is a general agreement between TPDs/experts and trainees regarding their opinions about the characteristics of trainees considered to be "extremely important" (*SUPPLEMENTARY MATERIAL, APPENDIX 2, TABLE 3*), the only exception being "to be a team player", considered extremely important by eight TPDs/experts but by no trainees (22.2% versus 0%, respectively; $p = 0.017$).

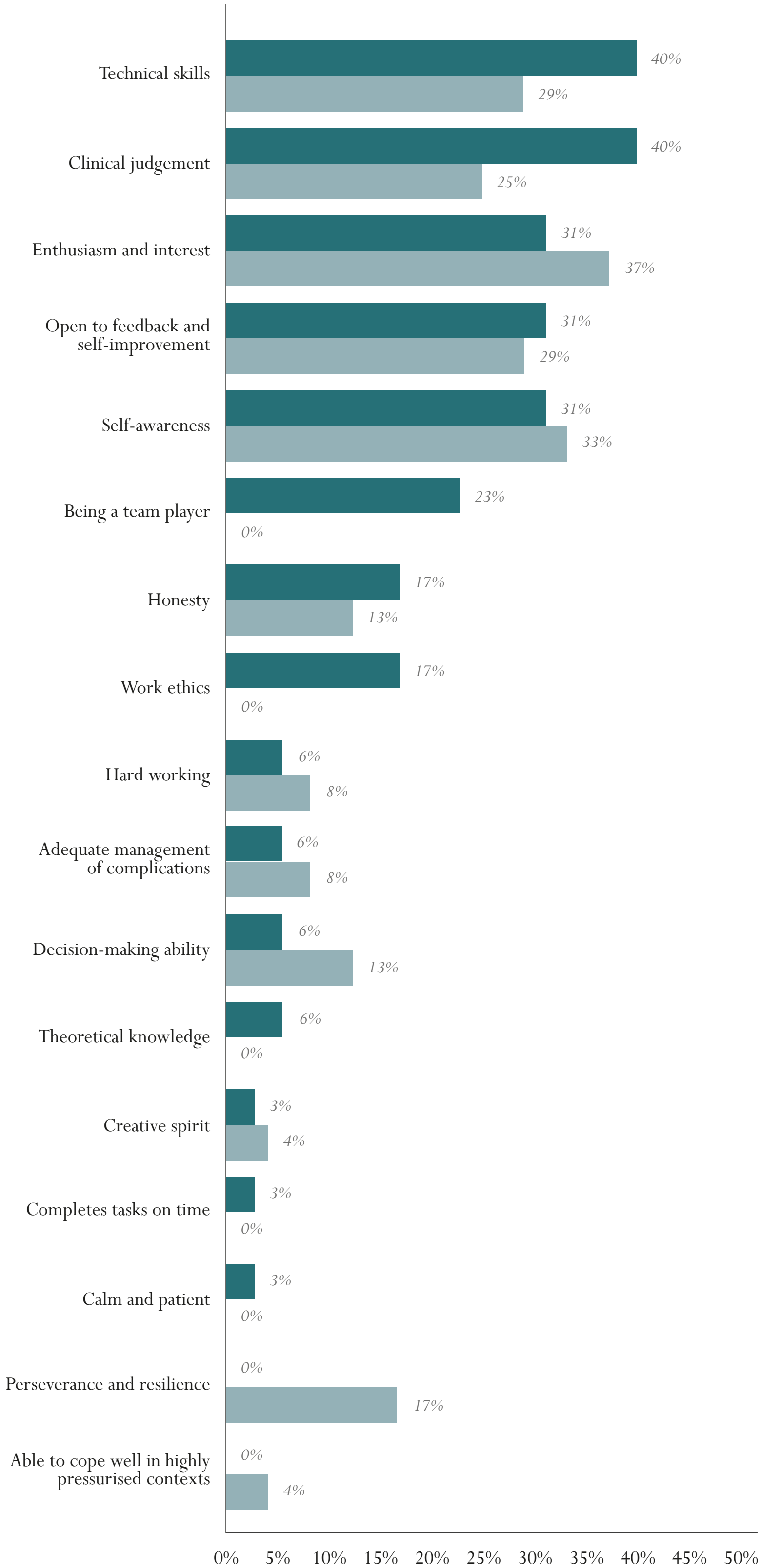


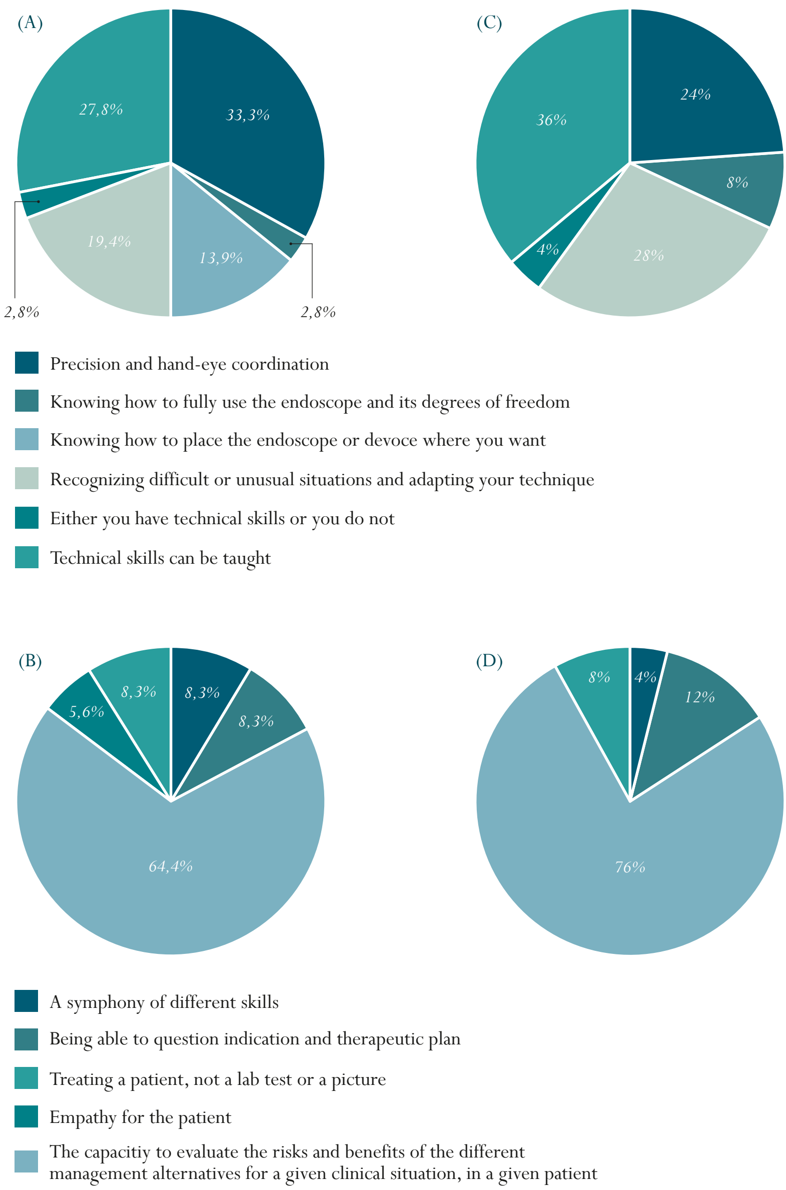
FIGURE 4

Trainee characteristics considered to be "extremely important" according to TPDs/experts (darker columns) and trainees opinion (lighter columns).

Definition of technical skills and clinical judgement

The importance of technical skills and clinical judgement, as characteristics for a trainee to excel in ERCP/EUS training, was defined by both TPDs/experts and trainees and is shown in *FIGURE 5*.

FIGURE 5 Definitions for "technical skills" according to (A) TPDs/experts and (C) trainees opinion; and "clinical judgement" according to (B) TPDs/experts and (D) trainees opinion.



None believed that clinical judgement could not be taught (*FIG. 5B* and *FIG. 5D*) and trainees did not consider clinical judgement to be "empathy for the patient" (*FIG. 5D*). One trainee defined technical skills differently, as "Precise maneuvering of endoscope and equipment, tip control as well as recognizing and acting on scope positions and situations" and clinical judgement, as "Thoroughly study the individual case and evaluate the patient. Know the indications of the technique to be applied and the risk-benefit balance. Establish a therapeutic plan."

There is general agreement between TPDs/experts and trainees regarding their opinion about definition of both "clinical judgement" ($p = 0.837$) and "technical skills" ($p = 0.308$) (*SUPPLEMENTARY MATERIAL, APPENDIX 2, TABLE 4*).

Criteria for ERCP/EUS trainee disqualification

Twenty-six TPDs/experts (72.2%) had identified fellows who performed below the expected level of competence for ERCP/ EUS procedures. This determination was made by:

a) Inadequate performance on specific quality metrics, 51.9% (n = 14)
b) Inadequate performance on a skills assessment tool, 37% (n = 10)
c) Inadequate procedure volume, 25.9% (n = 7)
d) Inadequate verbal attending evaluations, 18.5% (n = 5)
e) Inadequate fellow self-reporting, 11.1% (n = 3)
f) Inadequate written attending evaluations, 3.7% (n = 1)

Other features that were also used to identify trainees performing below the expected level of competence were: failure to follow institutional protocol/ instructions repeatedly, inadequate clinical judgement or negative input from the trainers and from colleagues, and overall impression of competence.

Twenty-five TPDs/experts (of 28; 89.3%) reported that they provided this feedback directly to their trainees. The following interventions were employed to overcome these issues:

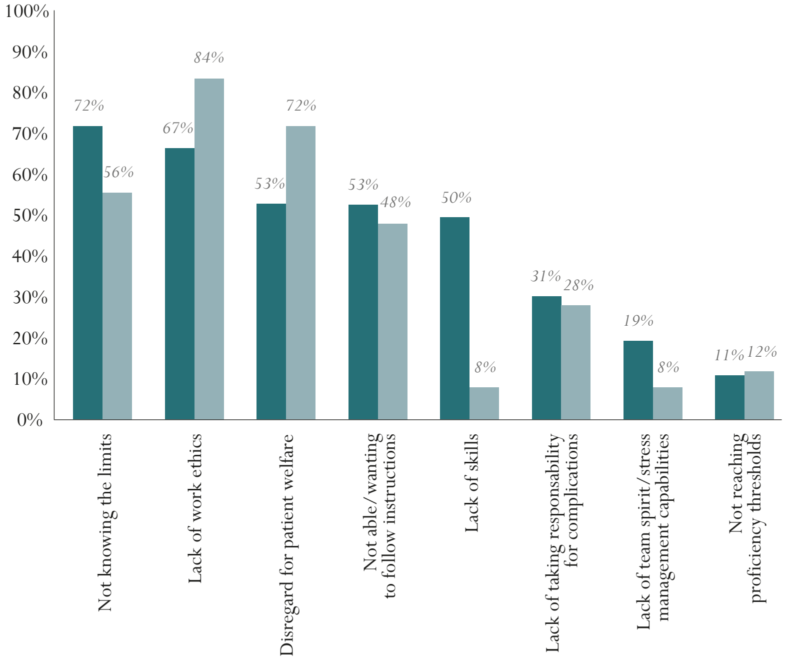
a) Ensure increased procedure volume in 41.7% (n = 10)
b) Set up procedure blocks with specific educational focus in 41.7% (n = 10)
c) Provide didactic theoretical sessions in 16.7% (n = 4)
d) No specific intervention was set up in 12.5% (n = 3)

None chose to provide simulator training as a rescue solution for improving the trainee's performance. Other interventions were also mentioned to overcome this problem: transfer to another unit more suitable to the trainee's situation, suggest training program interruption, re-explain the principle of training, intensified training of the items below par, and ensure appropriate supervision and feedback.

In this regard, eight TPDs/experts (of 36; 22.2 %) have disqualified a trainee from an ERCP/EUS training program, due to: not fulfilling minimum theoretical and technical capabilities, could not understand the limits of their skills/high complication rate, lack of honesty, inadequate progression, no adequate technical skills, insufficient overall involvement, and technical level despite corrective measures.

From a list of eight potential reasons to disqualify trainees in an ERCP/EUS training program, all participants were asked to select the 3 most relevant ones in their opinion (*FIGURE 6*).

FIGURE 6
Most relevant reasons for trainee disqualification according to TPDs/experts opinions (darker columns) and trainees opinions (lighter columns).



Lack of enthusiasm/interest/motivation was also considered extremely important to be added to the disqualification reasons (n = 2).

There is general agreement between TPDs/experts and trainees regarding the most relevant reasons for trainee disqualification (*SUPPLEMENTARY MATERIAL, APPENDIX 2, TABLE 5*), with the exception of "lack of skills" (P = 0.006), which, in the opinion of trainees, was not considered to be an important motive for disqualification, in opposite of TPDs/experts.

DISCUSSION

To our knowledge, this is the first study to provide an insight of the criteria and perceptions of TPDs/experts regarding the selection of ERCP/EUS trainees. This study presents a wide range of data gathered from multiple training centers across Europe.

A high response rate (80 %) from the TPDs/experts was obtained, allowing analysis of practices in a wide range of countries across Europe. However, despite receiving up to three reminders, the response rate from the trainees was relatively low (38.5%), possibly due to a lack of incentive.

Despite a large percentage of TPDs/experts being very (72.2%) or extremely (13.9%) satisfied with trainees in their programs, almost half of them felt only moderately (38.9%) to slightly (8.3 %) satisfied with the current application process. In addition, there was a significantly lower rate of extreme satisfaction (2.8%) with the application process. The rate of satisfaction with the application process is also shared by the trainees (P = 0.08). These data raise concerns over the perceived quality of the current process of selecting candidates for ERCP/EUS Training.

As suggested in the literature [13], our results confirm that there is no standardized trainee application process in these AGIE training programs. The selection process depends greatly on an applicant's subjective assessment (e. g., individual application, CV, interview), as in other medical specialties [4–8]. We found noteworthy that "payment of an application fee" is part of the application process in three centers. We do understand that a proper training involves extra efforts, not only from Trainer's point of view, but also from the department and Institution involved in this process. But at the same time, it may be a constraint to some promising trainees. A solution could be granting privileges to trainers, endoscopy departments and hospitals, by institutions or societies, including improving facilities and providing dedicated time and remuneration for those who truly can and are willing to teach. Moreover, it was interesting to observe that there is no reported theoretical evaluation at the start of training, a feature that contrasts with the lack of theoretical knowledge appearing in trainees with difficulties or even in rare disqualifications. The low importance of theoretical knowledge in the trainee's selection process, suggests that current ERCP/EUS training is based on an apprenticeship model. However, a major endeavor should be pursued to certify this aspect is acquired as the lack of theoretical knowledge in this complex area may rapidly appear as problematic.

When asked to rate a series of trainee attributes, there was a high diversity of selection criteria, but TPDs/experts most highly valued characteristics related to personality traits, such as "honesty," "being a team player," and "self-awareness." Indeed, these are considered non-technical skills (NTS) and examples of social and cognitive skills, that influence quality and safety outcomes, respectively [14]. The importance of such NTS has been acknowledged previously in other areas such as high-risk industries (e. g., aviation [15]) and healthcare practice (e. g., anesthesiology [16] and surgery [17]). Furthermore, being transferable by nature, NTS is also becoming increasingly recognized in endoscopy (so-called ENTS) [18] and integrated into gastrointestinal endoscopy training [19] and as an evaluation item in endoscopy competence assessment tools, such as DOPS [20]. In addition, TPDs/experts highly valued "honesty," which is a fundamental characteristic of integrity in the workplace and medical professionalism. Being upfront about one's actions and consequences is essential to good medical conduct and effective teamwork.

"Interest in research/academics" was rated as an extremely important feature only by a minority. Our findings are in line with others [6] that also reported less emphasis on research. It is well recognized that research is a major element in the development of any medical field [21] and is also needed to provide better care for our patients. However, in the present context, where trainees are at the beginning stage in AGIE, attaining an acceptable level of competence is prioritized and pushing the boundaries of knowledge in the topic is of secondary importance.

"Leadership ability" was comparatively undervalued by TPDs/experts, despite being considered an ENTS in assessment tools [20]. Of note, some of the characteristics that define good leadership can be found elsewhere in the list, such as "being a team player," "being able to make decisions" or "being calm and having patient temperament," with higher ratings.

TPDs/experts and trainees agreed regarding the relative importance of these characteristics to a high degree in most characteristics. Of note, trainees most valued two somewhat interrelated characteristics, "self-awareness" and "adequate management of complications." This may reflect their perception of the complexity and risks of AGIE procedures.

"Technical skills" came up seventh with regard to being considered "extremely important" by TPDs/experts. Interestingly, even when asked to select only three extremely important characteristics, technical skills were selected by less than half of the participants. Clearly, TPDs/experts placed a higher priority on various cognitive or personality traits, such as "clinical judgement," "enthusiasm/interest," and "openness to feedback," as hallmarks of a good prospective trainee. On the other hand, AGIE is a demanding area of endoscopy and requires specific and significant training to reach a level of competence and life-long training to reach and maintain expertise. In this matter, technical skills are a crucial characteristic. Nonetheless, when we asked for a definition, opinions were divided between several options. These options were taken from a previous questionnaire developed by our group and sent to another list of TPDs/experts (unpublished data). From the options provided, there were definitions related to purely motor skills ("precision and hand-eye coordination") and others integrative of both motor and cognitive skills ("knowing how to fully use the scope and its degrees of freedom" or "how to place the scope or device where you want" or "recognizing difficult or unusual situations and adapting your technique"). Remarkably, a similar number of TPDs/experts chose an integrative option (36.1%) over a purely motor skill definition (33.3%). This agrees with the general trend towards selecting personality or cognitive based options as key attributes to succeed in ERCP/EUS.

"Clinical judgement" was mainly defined by both TPDs/experts and trainees as the "capacity to evaluate the risks and benefits of the different management alternatives for a given clinical situation, in a given patient." This increased agreement between responders can be attributed to a more discrete distribution of categories and less overlap between them. Regardless, it is interesting to note that many of the trainee characteristics highly-rated by both TPDs/experts and trainees needed to excel in ERCP/EUS can be considered interrelated with the definition of sound clinical judgment. Specifically, "honesty," "self-awareness," and "adequate management of complications" are integral parts of personalized care for patients, in which the potential benefits and risks of the procedures, and the recognition of our limitations, need to be weighted.

Although a large proportion of TPDs/experts identified underperforming trainees at some point, only 22.2% had to disqualify a trainee. Several reasons were mentioned as justifying a trainee's disqualification from an AGIE program, with "disregard patient welfare" and "lack of work ethic" (dishonesty, misconduct, untrustworthiness) being the most commonly stated. Of note, in general terms, there was agreement between the most important characteristics for trainee selection and reasons for disqualification, according to TPDs/experts. Also, there was general agreement between TPDs/experts and trainees regarding reasons for disqualification. One notable exception was the percentage of TPDs/experts and trainees selecting "lack of skills" as a reason for disqualification (50% vs 8 %, respectively; $P = 0.006$). It is possible that this reflects the trainee's perception that technical skills should be taught and lack of them cannot be considered a reason for disqualification from a training program. It may also reflect a lack of self-awareness of the trainee as well as a lack of clear communication from the trainer.

This study carries an inherent risk of selection bias due to the selective invitation of certain centers. However, it should be noted that a high number of respondents was obtained for TPDs/ experts and a wide range of countries was included. Another limitation is related to the questionnaire development process. For example, no validity or reliability evaluations were performed. In addition, some overlap may exist between some of the characteristics, which may make the interpretation of some of the results more difficult. In particular, it is not easy to adequately rank domains or make inferences between the relative importance of certain characteristics. It should be noted, however, that other studies [4, 8] have attempted to evaluate trainee characteristics in other specialties using similarly formulated questions or using similar Likert rating scales. The scale was rated up to 5 points, instead of 10 points used in the other studies [4], to reduce constraints in the data evaluation. In addition, the questions meant to select the 3 most crucial trainee characteristics from all the ones they considered to be extremely important to excel in ERCP/EUS or to be disqualified in training, had the specific purpose of ensuring that the most important characteristics would be captured in a context where potentially all could be very important. Another limitation is the fact that ERCP and EUS were not considered separately. Indeed, there might be variation between the personality of an EUS endoscopist and an ERCP endoscopist, as, traditionally, EUS is more of a diagnostic tool and ERCP is a therapeutic procedure. Nonetheless, ERCP is increasingly being linked to simultaneous EUS training as these techniques are very complimentary when approaching patients with hepatobiliary diseases [10]. In this sense, it makes sense to evaluate ERCP and EUS trainee characteristics together. Finally, no definitive assumptions can be made about the true value of these characteristics with regard to outcomes as no correlations between TPD/expert opinion on ideal trainee characteristics and performance after training were evaluated. Therefore, as is in other specialties [11], future studies may address this research issue specifically in AGIE.

In summary, these results highlight the importance of ENTS to excel in AGIE, and specifically in ERCP/EUS. As highly regarded by TPDs/experts, the process of selection and evaluation of an ERCP/EUS trainee should take into consideration, apart from knowledge and skills, professional attitudes not directly related to the technical aspect itself. Ultimately, it is the set of effective teamwork, self-awareness, openness to feedback and self-improvement, enthusiasm and interest, clinical judgement, technical skills, and work ethics that will enable an advanced endoscopist to perform high-quality and safe endoscopy.

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Which interventions could improve ERCP training?

CHAPTER 7

Face and content validity of a biological papilla designed for the Boškoski-Costamagna ERCP simulator

Published as:

Teles de Campos S, Boškoski I, Voiosu T, Arvanitakis M, Costamagna G, Devière J et al. Face and content validity of a biological papilla designed for the Boškoski-Costamagna ERCP simulator. Gastrointestinal Endoscopy 2023 Nov; 98(5):822-829.e1. doi: 10.1016/j.gie.2023.06.014.

KEY POINTS

Novel ERCP Training Tool Evaluation: Chapter 7 evaluated a newly designed biological papilla, crafted from chicken heart tissue, incorporated into the mechanical Boškoski-Costamagna ERCP Trainer (BCT) simulator. The study assessed the face and content validity of this new tool specifically for training sphincterotomy.

Study Participants and Tasks: Nineteen participants, comprising 10 non-experienced and 9 experienced individuals, were included in the study. They were tasked with standardized assignments on the model, including sphincterotomy and precut for both groups, and with papillectomy additionally for the experienced group.

Methodological Approach: Post-task completion, all participants provided feedback through a questionnaire, evaluating the model's realism. Experienced endoscopists further assessed its didactic value using a 5-point Likert scale.

Positive Realism Ratings: Participants consistently rated the biological papilla as realistic across various parameters, including general appearance, sphincterotomy, precut, and papillectomy, with an overall rating of 4 out of 5. Furthermore, there was good agreement on the overall realism between participating groups.

Endorsement by Experienced Endoscopists: Experienced endoscopists endorsed the use of the biological papilla from training sphincterotomy, precut and papillectomy, particularly for novice and intermediate trainees. Their strongly agreement rates on its didactic value (≥ 4 out of 5) underscores its potential for enhancing procedural skills.

Training Practice Implications: This biological papilla, combined in the BCT, showed good face validity and excellent content validity. Its affordability, versatility, low cost, and ease of use make it a valuable for sphincterotomy, precut, and papillectomy training – procedures often challenging to train due to their complexity and associated risks.

Enhancements in Simulator Training: The additional of the new biological papilla to the BCT represents a significant advancement over the previous synthetic model, enabling training across all ERCP interventions and offering improved therapeutic training capabilities.

ABSTRACT

Background & Aims: A biological papilla made of chicken heart tissue, incorporated into the Boškoski-Costamagna ERCP Trainer simulator, was recently designed to allow training in sphincterotomy. This study aimed to evaluate the face and content validity of this tool.

Methods: Participants from two groups (non-experienced and experienced, with less or more than 600 ERCPs performed lifetime, respectively) were invited to perform standardized assignments on the model: sphincterotomy and precut for both groups and papillectomy for the experienced group. Following these assignments, all participants filled out a questionnaire to rate their appreciation of the realism of the model and experienced endoscopists were also asked to evaluate its didactic value using a 5-point Likert scale.

Results: A total of 19 participants were included: non-experienced=10, experienced=9. Parameters regarding the realism of the tool in terms of general appearance, sphincterotomy, precut, and papillectomy were overall considered realistic (4/5), with good agreement rates in terms of overall realism between groups. Experienced operators reported the highest realism for "positioning the scope and needle-knife in the field of view" and "during precut", "cutting in small increments during precut" and "controlling the scope during papillectomy" and highly agreed that this papilla should be included for training novice and intermediate trainees in sphincterotomy, precut, and papillectomy.

Conclusions: Our results demonstrate good face validity and excellent content validity of this biological papilla combined with the Boškoski-Costamagna ERCP Trainer. This new tool provides a useful, inexpensive, versatile, and easy tool to train sphincterotomy, precut, and papillectomy. Future studies should explore whether including this model in real-life training improves the learning curve of endoscopy trainees.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is one of the most challenging and complex endoscopic procedures with a steep learning curve [1]. Therefore, proper training is essential to achieve competence and to accomplish these procedures safely and with efficacy. To limit the exposure of patients to performer-related risk factors such as operator experience, simulator-based endoscopy education has been increasingly advocated as a potential solution to accelerate trainee learning curves. Several training models have been developed so far, including in vivo and ex vivo models, mechanical simulators, and virtual reality simulators [2]. The Boškoski-Costamagna ERCP Trainer is one of the most highly valued simulation prototypes for ERCP training in ductal cannulation, stent placement, and stone extraction. It has already been demonstrated to have a good face and construct validity [3] and it is currently being evaluated for its predictive validity in a randomized prospective study (ClinicalTrials.gov Identifier: NCT05533944).

The Boškoski-Costamagna ERCP Trainer has been optimized over time. The original version of the simulator was equipped with a papilla composed of latex and sphincterotomy on this iteration of the model was not possible. However, endoscopic sphincterotomy constitutes a key therapeutic step of ERCP [4] and it is also considered to be one of the high-risk components of this procedure that is associated with the endoscopist's experience [5]. As such, it became crucial to develop a tool to ensure training on this aspect. To accomplish this goal, a single-use synthetic papilla was developed by COOK Medical (Cook Medical, Limerick, Ireland) for the Boškoski-Costamagna ERCP Trainer and later evaluated for its face validity [6]. Although the COOK Medical synthetic papilla was found to be satisfactory in terms of overall realism for performing a sphincterotomy, the level of haptic feedback was limited by the cutting effect, which was "not perceived as expected" [6]. To overcome the limitations inherent to a synthetic tissue, a biological papilla, made of chicken heart tissue, has been recently created, with the aim of enabling a more realistic training experience.

There are different levels of assessment used to test the validity of a simulator, with the initial steps being the face validity and the content validity. Face validity is defined as the extent to which a simulator's content is representative of the skills that are learned in the real environment, which, in this case, addresses the question of how realistic the simulator is [7–9]. Content validity answers the question of how useful the simulator is for learning relevant skills, which, in the context of the biological papilla, refers to the assessment of its suitability as a learning tool for both achieving ductal access and performing sphincterotomy.

The aim of the current study was to evaluate the realism (face validity) and didactic value (content validity) of this biological papilla.

METHODOLOGY

Biological papilla

The biological papilla is a newly developed insertable component in the previously described mechanical Boškoski-Costamagna ERCP Trainer that can be used to simulate the selective ductal cannulation process and the techniques of ductal access, namely sphincterotomy.

The use of chicken heart tissue in ERCP simulators has been previously reported [10–12], and it was selected as it resembles a real major papilla in terms of size, shape, and color (*FIGURES 1, 2A, 2B*).

FIGURE 1

Schematic figure of anatomical representation – Legend: (A) chicken heart; (B) papilla of Vater. LV = Left Ventricle. LA = Left Atrium. CBD = Common Bile Duct. PD = Pancreatic Duct.

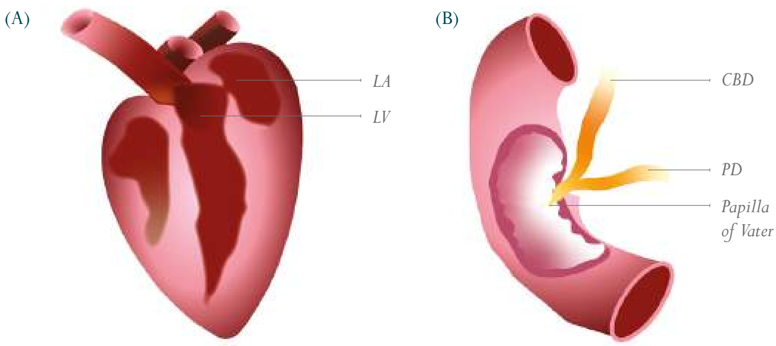
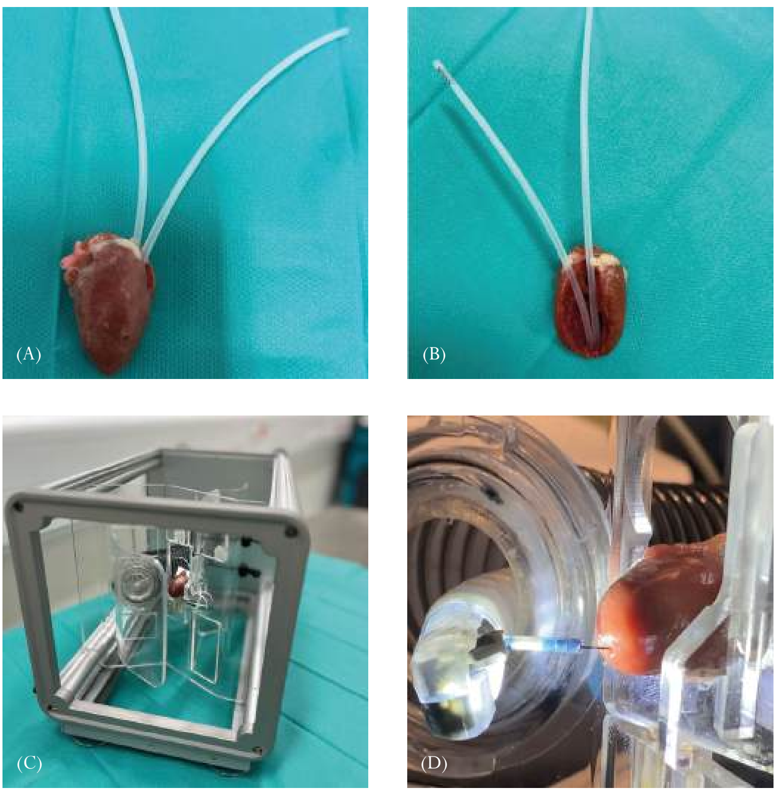


FIGURE 2

(A) Frontal view of the chicken heart specimen; (B) Chicken heart with the plastic tubes inserted into the chambers to resemble biliary and pancreatic ducts to allow cannulation; (C) Frontal view of the chicken heart papilla attached to the model; (D) Lateral view of the chicken heart papilla attached to the model.



The chicken heart tissue papilla can be easily manually inserted into the ERCP Trainer (*FIGURE 2C*), and rapidly exchanged. A millimeter-sized hole is artificially created at the apical wall of the left ventricle to allow ductal cannulation through one of the chambers (*FIGURE 2D*). The biological papilla is a disposable tool that allows for electrical conduction and cutting of the material with all commercially available sphincterotomes and needle knives.

Ethics committee approval

Because the study involved no human or live animal subjects, it was exempt from review by the institutional review board.

Participants

Participants were divided into two study groups based on their self-reported lifetime ERCP experience: non-experienced (up to 600 lifetime ERCPs performed) and experienced (more than 600 lifetime ERCPs performed). Because there is no formal definition of an "experienced" ERCP endoscopist, we adopted the same definition as has been previously reported in the literature for the same purposes [3,6].

Simulation setting

Simulator sessions were organized at the participating institutions (Fondazione Policlinico Gemelli, Rome, Italy; Erasme Medical Center, Rotterdam, the Netherlands; Institute de Recherche contre les Cancers de l'Appareil Digestif, Strasbourg, France) either to perform general ERCP simulation-training using Boškoski-Costamagna simulator (for the non-experienced group) or to specifically target the aim of this study (for the experienced group). All participants were invited to perform up to three standardized assignments: sphincterotomy and precut for both groups, and papillectomy for the experienced group. A DASH Sphincterotome DASH-35-48 (Cook Medical) and a guidewire Acrobat2 (Cook Medical) were used to perform sphincterotomy; a Huibregtse Precut Knife HPC-2 (Cook Medical) was used for precut; and an ACU Snare AS-1-S (Cook Medical) was used for papillectomy. An ERBE VIO 200D (Erbe Elektromedizin GmbH, Tübingen, Germany) electrosurgical system was used, with the following settings: ENDO CUT I, effect 2 for sphincterotomy and precut; and ENDO CUT Q, effect 2 for papillectomy. The cutting length of the sphincterotomy was considered optimal when the cutting reached the rubber edge of the simulator.

Following these assignments, the participants were invited to fill out a questionnaire on demographics, endoscopy experience, and previous simulator training experience. They were also asked to rate their appreciation of the realism of the cutting papilla. Appreciation was expressed on a 5-point Likert scale, varying from very unrealistic (1) to very realistic (5). Questions included the realism of anatomical representation, simulator setup, endoscopic/device control, the actual cutting, and the achieved cutting result and haptic feedback. Furthermore, the experienced group was also asked to evaluate the didactic value of the cutting papilla on a 5-point Likert scale, varying from strongly disagree (1) to strongly agree (5). The questionnaire is further detailed as *SUPPLEMENTARY MATERIAL*.

Data analysis

Statistical analyses were performed using SPSS version 28 (IBM SPSS Statistics, IBM Corporation, Armonk, NY, USA). Face validity was stratified by non-experienced and experienced groups, whereas content validity data were only collected in the experienced group. Data were tested for normality using the Shapiro-Wilk test and expressed as median and interquartile range (IQR). In addition, differences between non-experienced and experienced ratings for each face validity statement were analyzed with the Mann-Whitney U test, with a p value ≤0.05 indicating significance. Inter-rater agreement and reliability were evaluated by computing the intraclass correlation coefficient (ICC) in a 2-way mixed model.

RESULTS

Demographic characteristics

A total of 19 participants (17 male subjects [89.5%]) from 9 different countries and with different levels of ERCP expertise agreed to participate in this study. Based on the lifetime number of ERCPs performed, 10 were included in the non-experienced group and 9 in the experienced group. Participants' baseline characteristics are presented in *TABLE 1*.

TABLE 1

Baseline characteristics of participants.

Abbreviations: IQR = Interquartile range, GE = Gastroenterology, No. = Number

CHARACTERISTIC	NONEXPERIENCED (N=10)	EXPERIENCED (N=9)
Sex, male	8 (80%)	9 (100%)
Age, median (IQR), y	31 (7)	49 (8)
No. of nationalities	7	4
Medical background		
GE resident	6 (60%)	0
GE specialist	4 (40%)	9 (100%)
Workplace		
Academic hospital	8 (80%)	9 (100%)
Regional hospital	2 (20%)	0
ERCP experience, median (IQR), y	2 (3)	14 (14)
Previous simulator experience	5 (50%)	6 (66.7%)

Face validity

Participants rated the biological papilla according to several parameters of face validity (Q1-Q25), which are described in *TABLE 2*.

FACE VALIDITY PARAMETERS	MEDIAN (IQR) SCORE ACCORDING TO LEVEL OF ERCP EXPERTISE			P VALUE
	TOTAL	NONEXPERIENCED OPINION	EXPERIENCED OPINION	
General appearance				
Q1. Resemblance to the real papilla	4 (0)	4 (0)	4 (1)	NS
Q2. Positioning in front of the papilla	4 (0)	4 (1)	4 (0)	NS
Sphincterotomy				
Q3. Positioning of the sphincterotome during cannulation	4 (1)	5 (1)	4 (1)	NS
Q4. Controlling the direction of the sphincterotome during cutting	4 (1)	5 (1)	4 (1)	NS
Q5. Controlled cutting in small increments	4 (1)	4 (1)	4 (1)	NS
Q6. Cutting/ coagulation effects	4 (1)	4 (1)	4 (1)	NS
Q7. Controlling guidewire introduction	4 (0)	4 (1)	4 (0)	NS
Q8. Controlling the scope during procedure	4 (1)	4 (1)	4 (1)	NS
Q9. Overall appreciation in comparison to real situation	4 (1)	4 (1)	4 (1)	NS
Precut				
Q10. Positioning of the needle-knife in the field of view	5 (1)	5 (1)	5 (1)	NS
Q11. Positioning of the needle-knife during cutting	5 (1)	5 (1)	5 (1)	NS
Q12. Cutting slowly with small increments	4 (1)	4 (1)	5 (1)	NS
Q13. Cutting control "layer-by-layer", exposing deeper layers	4 (1)	4 (0)	4 (1)	NS

TABLE 2

Items used to determine face validity, rated by the participants with different level of ERCP expertise, on a 5-point Likert Scale. Abbreviations: IQR=Interquartile range. Q=Question. NS=Not Significant.

TABLE 2 | CONTINUATION

FACE VALIDITY PARAMETERS	MEDIAN (IQR) SCORE ACCORDING TO LEVEL OF ERCP EXPERTISE			p VALUE
	TOTAL	NONEXPERIENCED OPINION	EXPERIENCED OPINION	
Q14. Cutting/ coagulation effects	4 (1)	4 (1)	4 (1)	NS
Q15. Controlling guidewire introduction	4 (1)	4 (1)	4 (0)	NS
Q16. Controlling the scope during procedure	4 (1)	4 (2)	4 (1)	NS
Q17. Overall appreciation in comparison to real situation	4 (1)	4 (1)	4 (1)	NS
Papillectomy				
Q18. Positioning of the snare in the field of view	4 (1)	-	4 (1)	NS
Q19. Controlling the scope during the procedure	5 (1)	-	5 (1)	NS
Q20. Overall appreciation in comparison to real situation	4 (0)	-	4 (1)	NS
Overall realism				
Q21. Anatomical representation	4 (0)	4 (1)	4 (0)	NS
Q22. Simulator setup	4 (1)	4 (1)	4 (0)	NS
Q23. Endoscopic and devices control	4 (1)	4 (1)	4 (1)	NS
Q24. Haptic feedback	4 (1)	4 (1)	4 (1)	NS
Q25. Difficulty	4 (1)	4 (0)	4 (1)	NS

Practically all of the parameters were rated as "realistic", with a few exceptions for "positioning of the sphincterotome during cannulation" and "controlling the direction of the sphincterotome during cutting" for the non-experienced group; "cutting slowly with small increments during precut" and "controlling the scope during papillectomy" for the experienced group; and "positioning of the needle-knife in the field of view" and "during cutting" for both groups, which achieved the highest scores ("very realistic"). There were no significant differences in ratings between groups.

For validity content, the ICC demonstrated a good agreement rate and reliability between both groups concerning the overall realism of the tool [ICC= 0.743; 95% CI (0.237-0.969)].

Content validity

Median scores of statements of experienced participants regarding chicken heart papilla as a learning tool (Q26-Q31) are shown in *TABLE 3*.

CONTENT VALIDITY PARAMETERS	EXPERIENCED OPINION
Q26. Expertise gained with this papilla is transferrable into clinical setting	5 (0)
Q27. Useful tool to be included in an ERCP training curriculum	5 (0)
Q28. Useful tool to be included in the training of novice endoscopists (<50 ERCPs lifetime)	5 (0)
Q29. Useful tool to be included in the training of intermediate endoscopists (50-600 ERCPs lifetime)	5 (1)
Q30. Useful tool to be included in the training of experienced endoscopists (600-2500 ERCPs lifetime)	3 (1)
Q31. Useful tool for (re) certification in ERCP	3 (2)

TABLE 3
Items used to determine content validity, rated by the experienced participants, on a 5-point Likert Scale. Values are median (interquartile range). Abbreviation: Q=Question.

For content validity, the ICC demonstrated a high overall agreement and reliability between experienced participants [ICC= 0.858; 95% CI (0.555-0.977)], indicating that the "expertise gained with this papilla can be transferrable into clinical setting" and that it is a useful tool to be included "in an ERCP training curriculum" for "novice and intermediate endoscopists", despite having a limited role for "training of experienced endoscopists" or "(re)certification in ERCP".

DISCUSSION

Our results demonstrate good face and content validity of this hybrid model, consisting of a new biological papilla adapted to the mechanical Boškoski-Costamagna ERCP Trainer simulator, for endoscopic sphincterotomy, precut and papillectomy training. The latter 2 situations are those in which clinical training is particularly difficult to obtain during ERCP fellowships, either because it comes late after starting the ERCP procedure or because it is potentially associated with severe adverse events. All experienced ERCP operators strongly agreed on the didactic value of this tool, which goes beyond the novice trainees and extends to intermediate ERCP operators, and on its incorporation into the ERCP training curriculum. The Boškoski-Costamagna ERCP Trainer, a mechanical simulator which has been proven to have good face and construct validity for basic ERCP training [3], offers better therapeutic training capabilities with this biological model, even when compared with the synthetic papilla which was available previously [6].

Teaching endoscopic sphincterotomy traditionally involves supervised hands-on clinical practice, in a master/apprentice model. However, sphincterotomy and precut techniques are high-risk components of ERCP because they can be associated with several adverse events (AEs) including perforation, pancreatitis, and bleeding [5]. Proper positioning of the scope (to allow a correct orientation towards the papilla) and appropriate cutting along the correct axis, while adjusting and controlling the cutting devices, the scope, its wheels, and elevator [13], are crucial to reducing complications and optimizing results. Because most AEs have been systematically associated with endoscopist experience [14], training for this step in real-life situations can be limited. In addition, because it is recommended that training is performed in tertiary high-volume centers [15], the training opportunities for novice ERCP endoscopists can be limited [16,17]. At referral centers, the number of complex procedures tends to be high, and the number of naïve papillae to be relatively low, as previously reported [18], resulting in a reduced exposure of trainees to potential cases of native papilla anatomy. This is even more clear for the indications related to precut, which is often decided at a time when the master has already taken over, or for the rare indication of papillectomy. Taking all these aspects into account, there is an urgent need to develop alternatives for complementing traditional ERCP training programs. The possibility of using simulators to provide training in an optimal risk-free environment with supervisor feedback is, therefore, highly appealing.

This biological papilla design incorporated into the ERCP Trainer has multiple advantages. Chicken hearts are inexpensive (the price of a twenty-five chicken hearts pack is $2.56, in opposition to a synthetic papilla that costs $.80 per unit) and available in local grocery stores and can be easily prepared and attached to the simulator. This results in a versatile cutting model since it can be rotated manually to allow further cuts along different axes, before exchanging it for a new papilla (an average of two to three attempts in each papilla can be performed to train sphincterotomy/precut). To train ductal access, the traditional plastic tubes used in this mechanical simulator can be easily mounted on this tissue (*FIGURES 2A, 2B*) and both the common bile duct and pancreatic ducts can be cannulated, separately or simultaneously. Apart from enabling training of conventional sphincterotomy using a pull-type sphincterotome and precutting by using a needle knife, this tool also allows teaching of endoscopic papillectomy with diathermy snares, a seldom available feature when comparing to other simulators. As a result, this new tool incorporated in the Boškoski-Costamagna ERCP Trainer, makes it now feasible to perform all ERCP interventions with this simulator. In fact, apart from enabling the scope to freely move in the duodenum and be correctly positioned, while also enabling to handle the wheels and the elevator, targeting the papilla with different grades of complexity (due to different levels of patient position and papilla orientation) and attaining the proper axis to selectively cannulate the biliary and pancreatic ducts, extract stones, and place plastic, and metal stents [3,19], it is now possible now possible to perform sphincterotomy, precut and papillectomy in a very simple and realistic way.

For face validity, parameters regarding the realism for general appearance, sphincterotomy, precut, and papillectomy were overall rated as "realistic" (median score of 4/5), with good agreement rates between all participants for the overall realism of the tool. The minor differences in realism in comparison to human papilla tissue may be accounted for by the lack of clear papillary complex landmarks, the lack of respiratory variation and bowel wall peristalsis, and the lack of intraprocedural bleeding, as reported in the individual comments from the experienced group.

Agreement rates regarding content validity were high for using this tool "in the ERCP training curriculum" and for "training novice and intermediate endoscopists" as the "expertise gained with this papilla can be transferrable into clinical setting". Nonetheless, its role for "training of experienced endoscopists" or "(re)certification in ERCP" is limited.

Although the goal of this study was validation of this biological model, without comparison with other teaching models, it offers obvious advantages over its former synthetic version constructed out of rubber. The major advantage is the cutting effect itself, which seems to be more realistic than the previous version for which the "cutting process" was only rated as 6 in a 10-point Likert scale [6]. In fact, the cutting settings on the electrosurgical generator are the same as the ones used in real-life situations. In addition, in comparison to the synthetic papilla, this new version enables the performance of other ERCP procedures, namely papillectomy, the performance of which requires specific procedures to ensure en-bloc non superficial resection. The complexity associated with papillectomy, a grade IV procedure according to the Schutz classification [20], is partially due to its associated risks [5]. As such, all training opportunities in ex vivo models should be explored before attempting such procedures in real-life patients.

Currently there are several other ERCP simulators available [2]. Mechanical simulators, such as X-Vision ERCP Training System [21] and ERCP Mechanical Simulator (EMS) [22], use nonbiological casted organic rubber and foamy soaked conducting gel, respectively, to train endoscopic sphincterotomy, with its inherent limitations mentioned above. Live anesthetized pig models, although shown to be adaptable to all procedural aspects of ERCP, are currently underused due to high costs, logistical demands (specialized personnel), and the need for bioethics committee approval. Furthermore, anatomical differences between porcine and human anatomy, including the unusual location of the major papilla (rather difficult to localize because of its more proximal location compared with human papilla), tight angulation of the bile duct, and the lack of the pancreatic duct adjacent to the bile duct orifice and sphincter, render this model impractical for standard training programs. Itoi et al [23] reported a in vivo and ex vivo model using a porcine stomach and rectum using a simulated papilla, by submucosal injection of hyaluronate solution into the porcine mucosa to make it swell and allow endoscopic sphincterotomy and papillectomy. This model requires the preparation of a porcine stomach, is limited by the maneuverability of the scope, and does not allow the cannulation and placement of a guidewire to perform sphincterotomy. Ex vivo porcine simulators offer the same advantages as a live animal and are easier to use, less costly, and eliminate ethical concerns, but the issue regarding the anatomy of a porcine papilla remains. As such, alternatives have been developed to overcome this limitation, and chicken heart explants have been used. The artificial Neo-papilla model by Matthes-Cohen [10], uses a modified chicken heart, that is more visible because of its increased prominence, and is attached to the porcine ex-vivo model, such as the Erlanger Active (Erlanger Active Simulator for Interventional Endoscopy). However, the protocol for preparation and attachment of this tissue to a porcine duodenum is rather cumbersome and time-consuming (preparation time: 75 minutes).

More recently, another version has been developed [11] with two main advantages over the Matthes-Cohen model: the formation of a duodenal sweep by using the pig stomach, which overcomes the complex and different pig stomach anatomy and allows focused training in sphincterotomy and biliary cannulation; and the development of an easily exchanged neo-papilla, made from chicken heart and trachea tissue that is more easily obtained than previously reported neo-papillae. Similar to the other ex-vivo porcine simulators, including Artifon et al [12], the protocol for preparing the model is rather complex. A Japanese dry model, specific for sphincterotomy and needle knife precut, was designed by Katanuma et al [24] using a piece of rolled uncured ham mimicking the ampulla of Vater. Although easy to prepare and use, the duodenum simulator is rather expensive, and the reproduction of scope operability is rather poor. Virtual reality simulators, such as GI Mentor II (Simbionix Ltd., Airport City, Israel) have the possibility of treating complications, such as bleeding or perforation; however, they have a high start-up cost and a low perceived realism due to lack of tactile feedback and control of handling real equipment [25], and thus they are not frequently used in this manner.

In conclusion, this pilot study showed the good face and content validity of a real tissue papilla combined with a mechanical simulator. It provides a useful, inexpensive, versatile, and easy tool for endoscopic sphincterotomy, precut, and papillectomy training. Experienced operators strongly agreed that this tool should be included in ERCP training programs for novice and intermediate trainees. Although a prospective randomized study is underway to clinically validate the usefulness of this new simulator tool for teaching ERCP and a comparative evaluation with other simulators should be performed in the near future, this initial assessment of our biological papilla shows promise for training all ERCP steps in a simple and realistic manner.

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CHAPTER 8

Fast-tracking ERCP learning with the Boškoski-Costamagna Trainer: results of a multicenter randomized clinical trial

Submitted for publication in Endoscopy journal as:

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Accepted for poster presentation in UEG Week 2024

KEY POINTS

Simulator Integration in ERCP Training: Chapter 8 focused on the impact of incorporating the Boškoski-Costamagna ERCP Trainer (BCT) in the performance of novice ERCP trainees starting their training.

Trial Design and Participants: It was a one-year, multicenter, randomized controlled trial involving 16 ERCP novice trainees, divided into two groups: a control group (CG) receiving traditional hands-on training and a study group (SG) receiving additional simulator training during the first three months of training.

Outcome Measures: The primary outcome was the overall competence rate of trainees. Secondary outcomes included the rates of successful biliary cannulation and adverse events (AEs). Learning curves were generated cumulatively based on these parameters. Mixed-effect logistic regression models were used.

Performance Assessment Strategy: Trainees performance was assessed using TEESAT score to provide a comprehensive evaluation of their skill development. All ERCPs with any degree of trainee involvement were included, until each trainee completed a minimum of 60 procedures.

Comparative Performance Analysis: In 1,106 ERCPs (SG=562, CG=544) included, the SG outperformed the CG in native biliary cannulation success rate (SG=52%, CG=42%, $p<0.001$) and biliary cannulation time (SG=3(6)min, CG=5(8)min, $p<0.001$) and showed faster evolution on overall performance, native biliary cannulation, and sphincterotomy. AE did not significantly differ, an expected finding likely due to experience supervision during procedures.

Study Conclusions and Educational Implications: Constituting the most extensive validation study for an ERCP simulator to date, it concluded that early training with BCT can accelerate learning curves, advocating for its incorporation into ERCP education.

ABSTRACT

Background&Aims: Achieving ERCP competence requires prolonged training. Recognizing simulator-based education's potential for safe, effective skill development, we aimed to assess whether ERCP training with an initial period using the Boškoski-Costamagna ERCP Trainer (BCT) is beneficial over conventional training.

Design: A prospective, multicenter, randomized trial involved 16 ERCP novice trainees randomly assigned to study (SG) and control (CG) groups. Both underwent hands-on training. Additionally, SG received simulator-training during the first three months. A minimum of 60 ERCPs per trainee in up to 1 year was required. TEESAT score was used to evaluate overall competence rate (primary outcome), biliary cannulation and adverse event (AE) rates (secondary outcomes). Learning curves were generated cumulatively over the training period. Mixed-effect logistic regression models (MELR) were adopted to assess both outcomes and specific ERCP steps predictors of overall competence. The most effective predictive model of overall competence was identified using a stepwise backward procedure. MELR was employed to investigate potential confounding factors.

Results: In 1,106 ERCPs (SG=562, CG=544), SG demonstrated higher success in native biliary cannulation (SG=52%, CG=42%, p<0.001), faster biliary cannulation [SG=3(6) min, CG=5(8) min, p<0.001], and a faster evolution on overall performance, native biliary cannulation, and sphincterotomy. Successful biliary cannulation [OR=10.10, 95% CI (5.15-19.83)] and sphincterotomy [OR=7.71, 95% CI (3.77-15.76)] were the most important steps associated with the overall ERCP competence. No confounding factors were identified.

Conclusion: Early simulator training with BCT improves technical competence and accelerates the learning curve of trainees in performing key steps of the ERCP procedure.

INTRODUCTION

Traditional endoscopy teaching typically follows an apprenticeship model, occurring in the endoscopy unit with the trainees undergoing supervised hands-on training on patients. However, the prolonged learning curve required before reaching competency poses challenges for both endoscopists and patients, potentially exposing the latter to additional risks. To address this, various gastrointestinal endoscopy simulators [1,2] have been developed with the aim of accelerating this learning curve [3–5]. Simulator-based education aims to enhance the efficiency and effectiveness of endoscopy training by providing a dedicated learning environment where trainees can acquire skills at their own pace without increasing procedural time and risk.

Endoscopic retrograde cholangiopancreatography (ERCP) is among the most challenging endoscopic procedures and requires a long learning curve to achieve competence [6,7]. Simulator-based training appears well-suited for ERCP, as several models have been developed [1,2,8,9] and are suggested by the European Society of Gastrointestinal Endoscopy (ESGE) guidelines [10]. The Boškoski-Costamagna ERCP Trainer (Cook Medical, Limerick, Ireland) (BCT) [11,12] offers an ERCP mechanical simulator with a simulated patient, and features portability, varied patient positions, and realistic papillary anatomy. Unlike biological models, the simulator avoids ethical concerns and additional material costs. This simulator has demonstrated good face and construct validity and is endorsed by ERCP experts [13]. The next validation step is to assess the ability of the simulator to transfer skills to trainees (i.e., predictive validity) [14].

The hypothesis of this study was that early ERCP simulator-based training with the BCT can enhance clinical performance in novice ERCP trainees. This prospective, randomized, multicenter study, aimed to analyze the impact of ERCP Trainer simulation training on the basic skills of novice ERCP trainees by assessing its additional benefit compared to standard training for achieving technical competence.

METHODS

Study design and participants

This prospective, multicenter, parallel arm randomized controlled trial (RCT) involved gastroenterology trainees without prior ERCP experience who had completed basic endoscopy training (i.e. having personal experience of at least 300 gastroscopies and meeting the ESGE quality measure for UGI endoscopy [15]), have participated in fewer than 30 ERCPs (with no hands-on experience in ERCP) and were prepared to start their advanced endoscopy training modules in recognized high-volume ERCP training centers. Informed consent from the participants was obtained. The study protocol was registered with ClinicalTrials.gov (Identifier: NCT05533944) and adhered to the Helsinki Declaration and Good Clinical Practice guidelines. It was approved by the Ethics Committee at the coordinating Institution (N2022/034, Erasme Hôpital, Brussels, Belgium) and at each participating unit according to local regulation. All patients in the participating centers provided informed consent before undergoing ERCP. Anonymity and

General Data Protection Regulation compliance while collecting patients' data were ensured. Moreover, no intervention regarding patient care was performed during the study and all patients received the exact same routine care they would receive regardless of the current study.

Participants were randomly assigned to the Study Group (SG) or the Control Group (CG), using a 1:1 ratio. Randomization was stratified by study site, to avoid bias created by site-specific differences, both trial arms had the same number of participants, and, in the centers with two participants, trainees were equally distributed between the SG and CG.

The study was designed with a 1-year duration for each trainee to participate in a minimum of 60 procedures. A systematic evaluation of trainee's performance was conducted for each ERCPs with any degree of trainee hands-on involvement. If a trainee achieved 60 ERCPs before the end of the study, further participation up to completing 1 year of training was encouraged, but not required. *FIGURE 1* summarizes the study protocol.

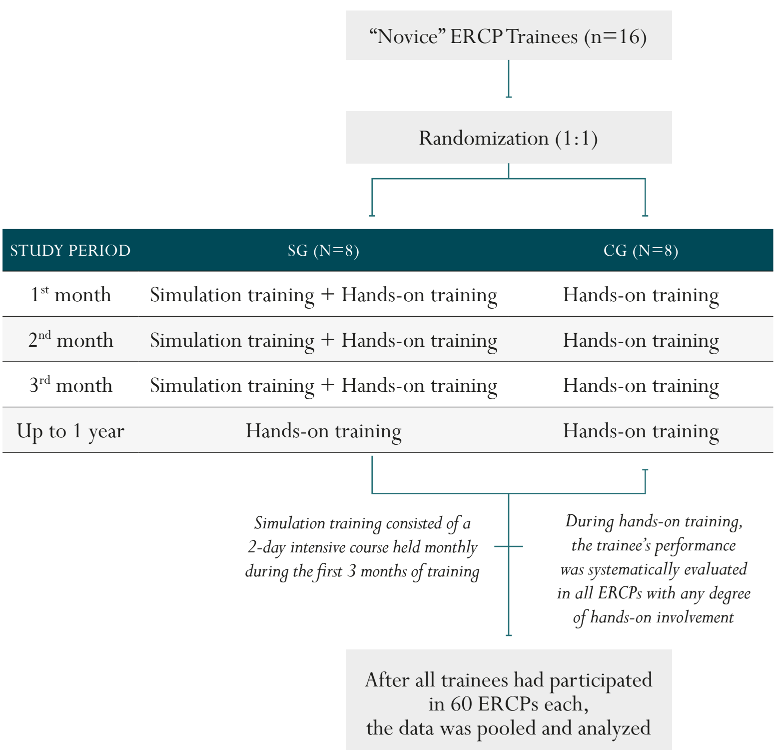


FIGURE 1

Study flowchart for training in ERCP with or without using the BCT. Consolidated Standards of Reporting Trials (CONSORT) Flow Diagram [29]. CG, control group; SG, study group.

Training protocol

All participants completed a basic theoretical ERCP course immediately before beginning the study. The course included video presentations prepared by the research team, covering fundamental aspects of ERCP, such as basic concepts of the procedure, biliary cannulation, sphincterotomy, stone extraction, and stent placement. This course was designed to ensure the trainees had the necessary foundational knowledge to safely begin their ERCP training, regardless of the study group to which they were allocated.

Both groups underwent traditional hands-on clinical ERCP training at their respective institutions. The training followed the established educational practices and was supervised by an expert endoscopist that intervened as required.

Trainees in the SG received additional structured simulator-based training sessions to practice using the BCT (*FIGURE 2A*) [11,12]. A recently validated biological papilla made of chicken heart tissue incorporated into the BCT [16] was available to train on sphincterotomy (*FIGURE 2B-D*).

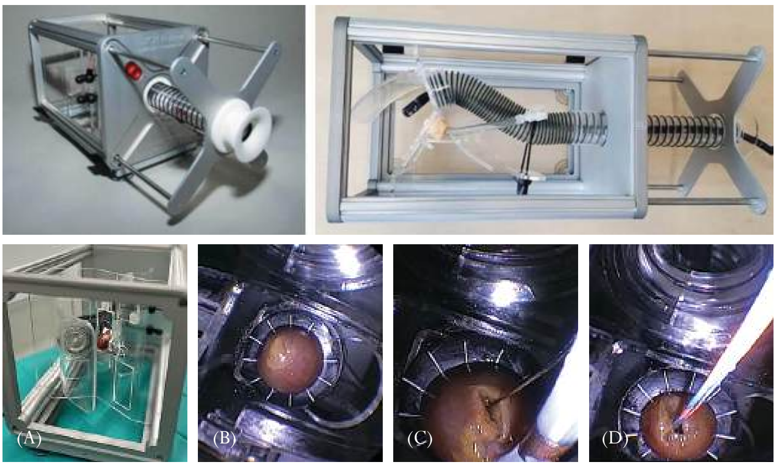


FIGURE 2
Boškoski-Costamagna ERCP Trainer with specific papilla to train on ERCP steps: biological papilla made out of chicken heart tissue (A); sphincterotomy (B); cannulation (C)

Simulation training occurred over two full days supervised by senior ERCP trainers, at Fondazione Policlinico Gemelli, Rome, with monthly sessions in the first three months of structured step-by-step training program that gradually covered different aspects of ERCP: scope handling, positioning, cannulation, sphincterotomy, stone removal, and stent placement. The training protocol was developed by a team of ERCP experts with long-standing experience in ERCP training.

Performance evaluation

Trainee performance was assessed after each individual procedure using the ERCP TEESAT score [6] endorsed by ESGE [10] and ASGE [7]. The ERCP TEESAT questionnaire allows the assessment of trainees, evaluating them on basic maneuvers as well as technical and cognitive aspects of ERCP through a 4-level of supervision scoring system. In this system, technical and cognitive competence in ERCP is defined as successful with a TEESAT score of 1 or 2, while a score of 3 or 4 is considered a failure. Furthermore, in the 4-level trainees' global overall performance (GOA) assessment after each ERCP, a score of 3 or 4 indicates competence, while a score of 1 or 2 indicates non-competence. This dichotomization into competent/non-competent and success/failure was defined in the TEESAT score validation study [6].

Successful biliary cannulation was defined as deep guidewire placement into the common bile duct (CBD) with contrast visualization. Cannulation time was measured from the first attempt to successful cannulation (minutes) and procedural total time was measured from initial scope insertion until final scope withdrawal (minutes). Time taken to achieve each step was monitored by either the ERCP trainer, gastrointestinal nurse, or technician involved in the procedure. Adverse events (AEs), defined based on the ESGE [17], were assessed up to 72 hours after the procedure by the attending physician.

The supervising trainer collected performance and complication data using REDCap®, a secure electronic online database system.

Study outcome measures

The primary outcome was overall trainee competence rate, measured by the GOA in the ERCP TEESAT score.

Secondary outcomes included biliary cannulation performance and AE rates.

Statistical analysis

A power analysis was conducted for a logistic regression using $\alpha = 0.05$ and a power of 80%, assuming a 15% difference between the groups in terms of GOA. Considering an Intra-Class Correlation (ICC) of 3%, 60 procedures per trainee and 16 trainees in total (8 per group) were required.

Trainee characteristics are presented as continuous variables with medians and interquartile ranges (IQRs), categorical variables as counts and percentages.

Primary and secondary analyses

Mixed effect logistic regression univariate models were employed to assess the differences in ERCP procedure competence and success between the study groups. In mixed-effect logistic analyses, each trainee was treated as a random effect within the mixed-effect model to account for the trainee as a grouping factor for the procedures.

To assess the learning progress of trainees in both the study and control groups, learning curves were graphically designed based on the accumulation of competence and successes in each group from procedure one to 60. In addition, the probability to observe a positive outcome (e.g. competence in GOA or success in biliary cannulation or stent placement) in the CG and in the SG were inferred based on mixed effect logistic regression models.

These predictive probabilities, and 95% confidence intervals (CIs) were generated for each outcome focusing on the initial 60 procedures for each trainee.

A comprehensive analysis of potential confounding factors was conducted to evaluate their influence on the observed differences in success and failure between the groups. This analysis focused on key study outcomes, including GOA, biliary cannulation, and AEs. The variables included trainee-specific attributes (years of experience and expertise in other endoscopic procedures), patient-related variables (i.e., patient age), and clinical parameters (i.e., bilirubin level), as well as procedural factors (i.e., ERCP setting, level of difficulty [18], and presence of native papilla and peri-ampullary diverticulum). This thorough analysis was performed using a mixed-effect logistic model for each specified variable.

Supplementary analyses

Supplementary analyses were performed to identify factors associated to the GOA. Mixed effect logistic regression models were used with the study group included as a covariate.

Multiple testing was accounted for by using the Sidak method and the statistical threshold was set to 0.007.

RESULTS

Baseline trainee characteristics

Sixteen trainees (SG=8, CG=8) were included, and their characteristics are detailed in *TABLE 1*.

BASELINE TRAINEE CHARACTERISTICS	SG (N=8)	CG (N=8)	TOTAL
Male, n (%)	5 (63%)	5 (63%)	10 (63%)
Age in years, median (IQR)	30.5 (3.5)	32.5 (4.5)	31.5 (4)
Number of nationalities	4	4	4
Number of departments	8	8	10
Medical career stage Gastroenterology fellow in training Gastroenterologist	 8 (100%) 0	 7 (88%) 1 (13%)	 15 (94%) 1 (6.3%)
Years of GI endoscopy experience, median (IQR)	2 (2)	2 (1.5)	2 (2)
Previous experience in other advanced endoscopy procedures, n (%)	2 (25%)	3 (38%)	5 (31%)

TABLE 1

Baseline characteristics of the study population.

Legend:
CG = control group; IQR = interquartile range; SG = study group.

Primary outcome - ERCP overall performance

Out of a total of 1,174 registered ERCPs, 1,106 (SG=562, CG=544) were included in the study. Sixty-eight were excluded due to unassessed GOA: 46 for ductal cannulation not achieved, 17 for no trainee hands-on participation, and 5 for major papilla not reached/identified. We recorded a median of 79 procedures per trainee (range:17-106) in the SG and 75.5 procedures (range:41-85) in the CG. During the 1-year study period, one trainee from each group did not achieve the predefined threshold of 60 ERCPs.

TABLE 2 shows ERCP performance (complete descriptive analysis provided in Supplementary Material).

TABLE 2

Boškoski-Costamagna ERCP Trainer with a specific papilla (a) to train on ERCP steps: biological papilla made out of chicken heart tissue (b); sphincterotomy (c); cannulation (d).

Legend: AE = adverse event; CG = control group; CI = confidence interval; ERCP = endoscopic retrograde cholangiopancreatography; GOA = global overall assessment; IQR = interquartile range; N/V = not valid, model failed to converge; OR = odds ratio; SG = study group.

ERCP OUTCOMES	SG (N=562)	CG (N=544)	TOTAL (N=1,106)	OR (95% CI)	p-VALUE
Global overall assessment (GOA), n (%)					
- Competent (TEESAT score 3-4)	274 (49%)	173 (33%)	447 (40%)	1.47	0.903
- Non-competent (TEESAT score 1-2)	288 (51%)	371 (68%)	659 (60%)		
Biliary cannulation achieved - yes, n (%)					
- Success, according to TEESAT (score 1-2)	358 (71%)	327 (65%)	685 (68%)	1.11	0.973
- Failure, according to TEESAT (score 3-4)	149 (29%)	176 (35%)	325 (32%)		
Native biliary cannulation achieved – yes, n (%)					
- Success, according to TEESAT (score 1-2)	115 52%)	96 (42%)	211 (47%)	1.05 (1.0-1.1)	<0.001*
- Failure, according to TEESAT (score 3-4)	105 (48%)	132 (58%)	237 (53%)		
Time (min) for biliary cannulation, median (IQR)	3 (6.0)	5 (8.0)	4.0 (6.0)	0.99 (0.98-0.99)	<0.001*
Time (min) for native biliary cannulation, median (IQR)	6.0 (7.0)	8.0 (6.3)	7.0 (7.0)	0.99 (0.98-1.00)	0.201
Biliary sphincterotomy, n (%)					
- Success, according to TEESAT (score 1-2)	111 (66%)	91 (60%)	202 (62%)	1.63	0.877
- Failure, according to TEESAT (score 3-4)	54 (26%)	65 (33%)	119 (37%)		

TABLE 2 | CONTINUATION

ERCP OUTCOMES	SG (N=562)	CG (N=544)	TOTAL (N=1,106)	OR (95% CI)	P-VALUE
Stone removal					
- Success, according to TEESAT (score 1-2)	178 (86%)	158 (81%)	336 (84%)	1.00	0.999
- Failure, according to TEESAT (score 3-4)	29 (14%)	37 (19%)	66 (16%)		
Stent Placement					
- Success, according to TEESAT (score 1-2)	172 (70.2%)	157 (68.6%)	329 (69.4%)	N/V	0.985
- Failure, according to TEESAT (score 3-4)	73 (29.8%)	72 (31.4%)	145 (30.6%)		
Overall AEs					
- No	501 (89%)	491 (90%)	992 (90%)	1.08	0.986
- Yes	61 (11%)	53 (9.7%)	114 (10%)		
Total procedure time (min), median (IQR)	30 (23)	28 (28)	30.0 (26.8)	1.01 (1.01-1.02)	<0.001*

The results did not reveal a significant difference in terms of GOA between the groups (OR=1.47, 95% CI [0.0-692.0], p=0.903).

Notably, a high level of heterogeneity was observed between the trainees in the SG group in terms of GOA. The proportion of procedures where trainee performance was graded as overall competent varied between 13% and 88% within the SG. In the SG, the IQR was 36.5 (variance equal to 698.2) compared to 12.6 in the CG (variance equal to 575.7).

Secondary outcomes

These results highlight a statistical difference towards improved native biliary cannulation (SG=52%, CG=42%, p<0.001) and faster biliary cannulation in the SG [SG=3(6) min, CG=5(8) min, p<0.001] (*TABLE 2*). Additionally, a longer total procedure time was observed for the SG. No statistical difference was found in terms of grade of difficulty (OR=0.65, 95% CI [0.0-764], p=0.904).

Overall, AE rates did not achieve a statistically significant difference between groups (OR=1.08, 95% CI [0.0-8325.2], p=0.986).

Effect of simulation training on key outcomes

Based on the mixed effect logistic regression models, probabilities to observe a positive outcome (e.g. competence in GOA or successful biliary cannulation) were inferred depending on the study group.

Mixed-effect models predicted the following probabilities in the first 60 procedures. However, in the study group, one trainee performed less than 60 procedures (n = 17) whereas in the control group, one trainee performed

41 procedures. For these two trainees, 17 and 41 procedures, respectively, were included as observations in the analyses. The results showed the probability: SG=38% (95% CI [17%-59%]) vs CG=18% (95% CI [6%-39%]) competent procedures by GOA rate; SG=46% (95% CI [32%-60%]) vs CG=37% (95% CI [20%-51%]) successful native biliary cannulations; SG=67% (95% CI [42%-82%]) vs CG=42% (95% CI [20%-67%]) successful biliary sphincterotomies; SG=79% (95% CI [61%-90%]) vs CG=76% (95% CI [58%-88%]) successful stone removals; SG=69% (95% CI [52%-82%]) vs CG=58% (95% CI [41%-74%]) successful stent placements.

The progressive accumulation of overall competence and success in specific ERCP steps is shown in *FIGURE 3* through learning curves depicting the learning progression within both the SG (red lines) and the CG (blue lines). As shown, trainees from the SG learned faster to perform native biliary cannulation and biliary sphincterotomy and achieved faster overall competence in ERCP.

FIGURE 3

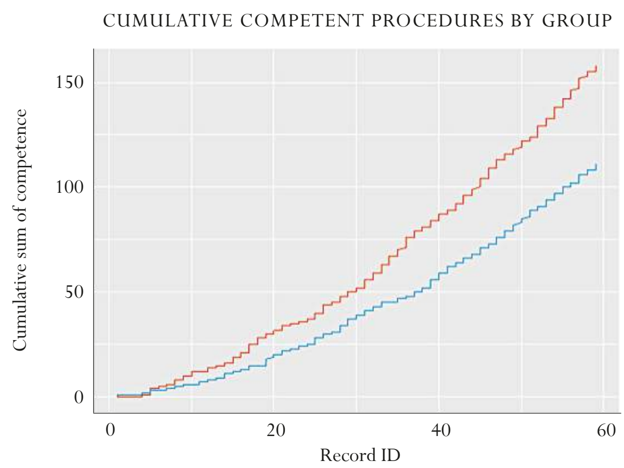
Learning curves for: (A) global overall assessment, (B) successful CBD cannulation in native papilla), (C) biliary sphincterotomy, (D) stone removal, (E) stent placement. Red line = study group; Blue line = control group.

Study group

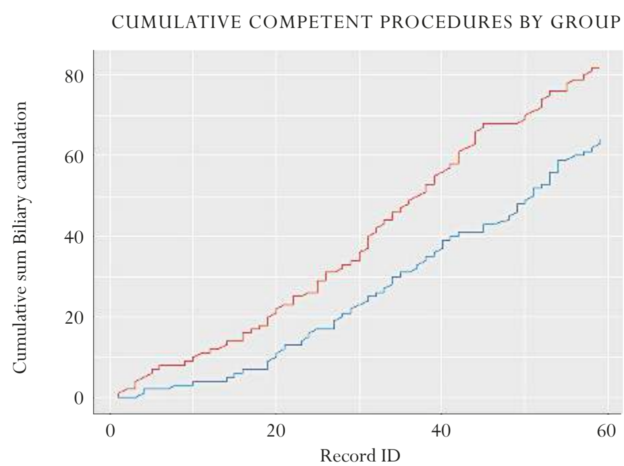
Study group

Control Group

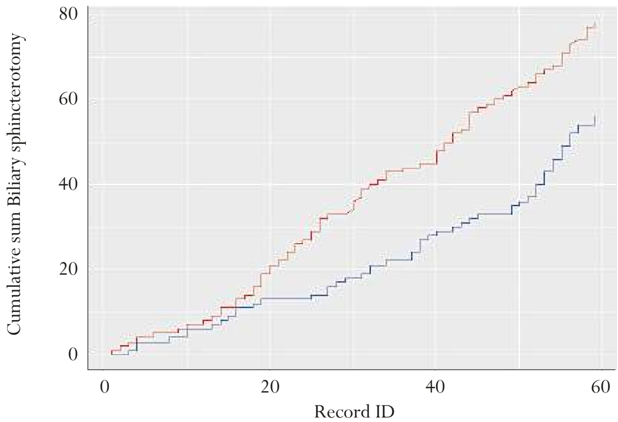
(A)



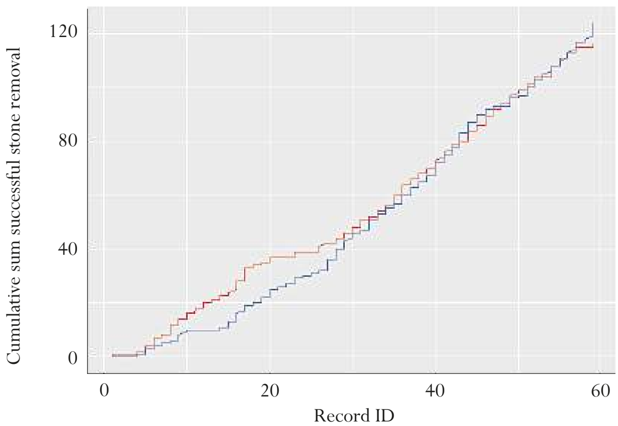
(B)



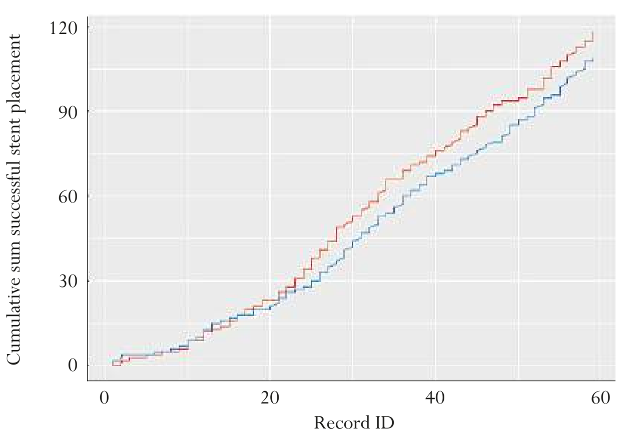
(C) CUMULATIVE SUCCESSFUL PROCEDURES BY GROUP



(D) CUMULATIVE SUCCESSFUL STONE REMOVAL PROCEDURES BY GROUP



(E) CUMULATIVE SUCCESSFUL STENT PLACEMENT PROCEDURES BY GROUP



Analysis of study confounders

For GOA, no factors were found to be confounders as they have not influenced the observed absence of difference between the groups. The effect of simulation practice in native biliary cannulation was maintained after adjustments with study confounders, meaning no other parameters were found to influence the observed results for the groups' successes. Finally, for AEs, no confounders were found to influence the observed results for the groups' successes.

Supplementary analyses - predictors of overall competence by TEESAT score

Univariate analyses revealed that successful native biliary cannulation, biliary sphincterotomy, stone removal, and stent placement were all associated with the GOA ($p<0.001$). In univariate analysis, the results showed that trainers valued success on stone removal highest (OR=22.37, 95% CI [7.99-62.67]) for determining the trainee's overall competence by GOA, followed by success on biliary cannulation (OR=15.29, 95% CI [10-24.82]), biliary sphincterotomy (OR=7.38, 95% CI [4.01-13.61]) and, lastly, stent placement (OR=5.76, 95% CI [3.16-10.49]).

DISCUSSION

This RCT is the first multicenter, prospective trial that assessed the impact of simulator-based training using the BCT on the performance of novice ERCP trainees starting their advanced endoscopy training. The results revealed a significant increase in technical performance based on the TEESAT score. This improvement was particularly evident in the performance of biliary cannulation in native papilla cases, with 52% of attempts graded as technically competent for trainees in the SG compared to only 42% in the CG. Furthermore, SG trainees demonstrated a faster overall acquisition of specific technical skills, such as biliary cannulation and biliary sphincterotomy, which are key steps in conducting a successful ERCP procedure. These advancements are substantiated by the corresponding learning curves, although cumulative differences between groups did not attain statistical significance. These findings highlight the potential of simulator-based training to fast-track ERCP learning, a critical consideration given the procedure's inherent complexity requiring prolonged training and large caseload volumes to achieve competency [6,7].

The primary outcome measure of this study was the GOA of trainee competence as assessed by the TEESAT score. The SG demonstrated a higher percentage of procedures in which trainees were considered competent (49% in the SG versus 33% in the CG). However, the difference between groups did not reach statistical significance in the univariate mixed-effect logistic regression model. This lack of statistical significance may be attributed, in part, to the inherent limitations of the outcome measure itself, which is subjective in nature.

The BCT enables learning all steps of an ERCP procedure, and the GOA was chosen to provide a comprehensive evaluation of trainees' performance with simulation-training. Additionally, we adopted the TEESAT score due to its robust validity evidence [19]. Nevertheless, we acknowledge the inherent subjectivity of an "global overall assessment", which could only be mitigated if a single trainer assessed all trainees in all ERCPs, a scenario that is impossible in real life. Furthermore, the lack of statistical difference might be also attributed to the substantial heterogeneity in the hierarchical structure of the study. In this approach, groups were assessed based on procedure outcomes, yet each group comprised a diverse set of trainees with heterogenous performances, posing a challenge to drawing robust conclusions from statistical assessments.

The success rate of biliary cannulation, a secondary outcome, revealed a statistically significant difference favoring simulation training, particularly in cases involving native papillae. The emergence of differences solely in the analysis of native papillae cases may be attributed to the inherent simplicity of non-native papilla cases in comparison. Combining both native and non-native papilla cases dilutes the impact of simulation training, as non-native papillae cases were more numerous and usually present fewer challenges for cannulation. Native biliary canulation, a relatively objective parameter (even considering that, in some cases, trainer input may have been necessary for success) compared to the GOA, was extensively practiced during simulation training courses. It stands out as a critical step in ERCP, a performance measure acknowledged by ESGE [20]. Arguably the most challenging step in ERCP, native biliary cannulation, is considered a key metric for assessing ERCP competence in the current literature [21].

The time required to complete each step of the procedure serves as a performance indicator in simulation training. In the context of overall biliary cannulation, the time was observed to be lower in the SG, which highlights a small but positive impact of simulation training on technical skills. The lack of statistical significance in the subgroup of native papillae may be attributed to the smaller sample size, in comparison to the overall number of biliary cases.

Adverse events rates did not achieve a statistically significant difference between groups, which has also been reported in other simulator-based training studies as well as in large cohort studies of real-life training [22,23]. This is to be expected considering that these procedures, albeit being at least in part performed by novice endoscopists, were constantly supervised by experienced ERCP performers. The apprenticeship model, on which current training is based, has proved, for the most part at least, safe and reliable [24], and thus, no differences between groups were to be expected. Furthermore, to avoid the "training center" being a potential confounding factor, trainees were paired by study site and for all departments with two trainees, they were allocated to both study groups. The similarity in AE rates between groups highlights the fact that training settings provided an equally high standard of practice for all trainees, although the study was not specifically powered for detecting potential differences in AEs.

A small, but statistically significant, longer total procedure time was observed in the SG compared to the CG. This difference could be due to the fact that trainers would be more inclined to allow additional time to more competent trainees in order to allow them to complete the procedure before intervening (i.e., an increased "perception of competence").

Analysis of the plotted learning curves, further supported by predicted probabilities in the first 60 procedures using mixed effect models, showed that trainees in the SG accumulated successful procedures at a higher rate regarding GOA, native biliary canulation, and biliary sphincterotomy than trainees in the CG, which further reinforces the positive effect of simulator-based training on acquisition of skills in ERCP, as was also observed in studies evaluating the impact of the ERCP Mechanical Simulator (EMS) on trainee performance [22,25]. The observed difference in learning biliary sphincterotomy can be attributed to the recent modification of the BCT, which now includes a biological papilla, allowing for a more realistic training experience in this step [16]. This holds particular significance considering that sphincterotomy is considered a high-risk component of ERCP that is associated with various AEs such as perforation, pancreatitis, and bleeding [17]. Moreover, differences in learning curves in the stent placement procedures and stone placement procedures were minor or became almost non-existent after a certain number of procedures, which may signify that, for these components, simulation training does not provide, or ceases to provide, additional benefit past a certain point.

The study's limitations should be acknowledged. First, despite all efforts, two trainees (one in each group) were unable to complete the target of 60 procedures. The lack of statistical significance in the differences in GOA between groups may be attributed to heterogeneity in the data. Although trainees were selected based on similar experience levels in ERCP, and evaluations were conducted by trainers rather than through self-assessment, we observed high variability within the study groups. High-performing trainees in either group may have disproportionately influenced the overall results. Future research may be aimed at developing personalized training programs focused on tasks and steps in which the trainee is underperforming or showing difficulties. Differences in the rates at which procedures were performed across various training centers, potentially impacting distinct opportunities, and learning paces, along with diverse evaluators and the subjective nature of GOA measurement, might have contributed to statistical heterogeneity. This heterogeneity may have prevented the analysis from reaching statistical significance despite the numerical differences, suggesting that a more homogenous study group could have yielded different results. From a statistical perspective, this limitation could have been mitigated by increasing the number of trainees in each group. However, in practice, achieving this is challenging due to the logistical constraints with organizing simulation courses. To minimize this limitation, we employed a mixed-effects logistics regression model, which is more robust than straightforward statistical analyses. Additionally, we accounted for varying trainee opportunities by creating learning curves and making predictions for the 60 first procedures. Secondly, it was also not possible to perform formal comparisons between specific AEs due to statistical restrictions related to multiple comparisons, which limit the number of comparisons performed to avoid increasing the risk of

Type I error. Another limitation is that, while an ideal scenario would involve a blinded study for trainer evaluations, this was not feasible due to the protocol of simulation-training courses and the involvement of multiple training centers and trainers. To overcome this limitation, we used a validated competence tool, which was fully explained and discussed with the trainers prior to the start of the study to standardize the evaluation of the trainees' performance. This TEESAT score, despite having GOA as a potentially subjective parameter, includes a long list of measures that are objective and independent of the trainers' opinion or potential preferences for the trainees in the study group (e.g. rate of successful of biliary cannulation or time for biliary cannulation). This confirms that the conclusions of our study are valid and robust, providing valuable insights into the effectiveness of simulation-based training. Additionally, it would be helpful to investigate the long-term effects of simulator-based training, determining whether the initial competence gain translates into sustained clinical proficiency and improved patient outcomes over extended periods of time, even beyond the formative period. Nevertheless, and as previously noted [21,26], trainees often face difficulties in meeting the procedure volume requirements during ERCP training. In our study, 12.5% of trainees did not achieve 60 ERCPs within one year, requiring an amendment to the initial study timeline and protocol, to ensure that the study objectives remained achievable. The low trainee exposure to hands-on training observed in our study reinforces the need for simulator-based training. The last limitation concerns the optimal methodology of simulation training, which remains undetermined, presenting an avenue for future research.

Few studies have sought to validate simulation training for ERCP [27], with existing research focusing on the impact of the ERCP Mechanical Simulator (EMS) [22,25,28], demonstrating improvements in successful cannulation rates [22,25,28], reduced cannulation times [22,25], and enhanced overall performance [22,28] in the SG. Our study stands out as the largest validation study for an ERCP simulator to date and, as such, we believe that our findings carry significant implications for the training of gastroenterology fellows. First, integrating simulator-based training in ERCP could reduce the time required for trainees to become competent, thereby enhancing patient safety. Accelerated skill acquisition may also optimize the utilization of training resources. Secondly, our study, employing a multivariate random-effects model, identifies specific ERCP steps where simulation training yields the greatest benefits, namely biliary cannulation (OR=10.10, 95% CI [5.2-19.8], p-value<0.001) and biliary sphincterotomy (OR=7.71, 95% CI [3.8-15.8], p-value=0.001). These skills are pivotal, and enhancing proficiency in these areas through simulation training could lead to improved patient outcomes, particularly given the association of these steps with higher complication rates.

In conclusion, this multicenter, randomized study demonstrates that simulator-based training is a valuable addition to traditional hands-on clinical training for ERCP. Simulator training accelerates the acquisition of critical skills and improves technical trainee competence. Specifically, simulation training increases the performance of biliary cannulation, especially in cases of native papilla, reduces the time required for biliary cannulation, and accelerates the learning curve for overall competence, biliary cannulation, and biliary sphincterotomy.

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SECTION III

ERCP performance

Where should ERCP be performed?

Where should ERCP be performed?

Chapter 9: The impact of ERCP volume per center and endoscopist on ERCP outcomes: a systematic review and a meta-analysis

Chapter 10: Assessing the impact of center's volume on cost-effectiveness of centralizing ERCP

CHAPTER 9

The impact of ERCP volume per center and endoscopist on ERCP outcomes: a systematic review and a meta-analysis

Published as:

Teles de Campos S, Papaefthymiou A, Florou T, Facciorusso A, Arvanitakis M, Devière J, Gkolfakis P et al. The impact of ERCP volume per center and endoscopist on ERCP outcomes: a systematic review and a meta-analysis. Gastrointestinal Endoscopy 2023 Sep; 98(3):306-315.e14. doi: 10.1016/j.gie.2023.05.045.

Presentation as free-paper session in Prevention and Treatment of ERCP related adverse events in ESGE 2023

KEY POINTS

Systematic Review and Meta-analysis of ERCP Volume and Outcomes: Chapter 9 presents a in-depth examination of the relationship between endoscopists' and centers' volume and ERCP outcomes. Synthesizing data from 31 studies, identified from a comprehensive literature search of 6,833 publications in PubMed, Web of Science and Scopus, up to March 2022.

Research Methodology: Volume classification categorized endoscopists and centers into high- and low-volume (HV and LV) groups. The quality of the studies was assessed using the Newcastle-Ottawa scale. Additionally, a sensitivity analysis evaluated the potential impact of volume threshold on the results. Data synthesis utilized direct meta-analyses with a random-effects model, presenting results as odds ratios (OR) along with 95% confidence intervals (CI).

Impact of Volume on ERCP Success: ERCP success, defined as deep bile duct cannulation, was the primary outcome. HV endoscopists and centers showed significantly higher success [OR = 1.81 (95% CI: 1.59-2.06); I^2=57% for endoscopists; and OR = 1.77 (95% CI: 1.22-2.57); I^2=67% for centers]. Heterogeneity in findings may stem from the absence of uniform HV and LV thresholds. A sensitivity analysis using a 200-procedure cutoff confirmed HV endoscopists' superior performance with acceptable heterogeneity (I^2=23%, p=0.27).

Complications and Volume Thresholds: Secondary outcomes included overall complication rates and specific complications. Overall complications were less prevalent in HV settings [OR = 0.71 (95% CI: 0.61-0.82); I^2=38% for endoscopists; and OR = 0.70 (95% CI: 0.51-0.97); I^2=92% for centers], with lower bleeding rates observed among HV endoscopists [OR = 0.67 (95% CI: 0.48-0.95); I^2=37%]. No statistically significant differences were observed in rates of post-ERCP pancreatitis, cholangitis, or perforation based on volume thresholds.

Implications for Practice and Patient Care: These findings underscore the importance of endoscopists' and centers' volume in achieving optimal ERCP outcomes. By emphasizing the significance of volume in procedural success and safety, this analysis highlights opportunities to enhance patient care through improved volume-based practices.

ABSTRACT

Background & Aims: Endoscopist experience and center volume might have a relation with ERCP outcomes, as in other fields of endoscopy and in surgery. An effort to assess this relationship is important to improve practices. This systematic review with meta-analysis aimed to accumulate these comparative data and elucidate the impact of endoscopist experience and center volume on ERCP procedure outcomes.

Methods: We performed a literature search in PubMed, Web of Science, and Scopus until March 2022. Volume classification included high- and low-volume (HV and LV) endoscopists and centers, respectively. The primary outcome was the impact of endoscopists' and centers' volume on ERCP success. Secondary outcomes were the overall adverse event (AE) rate and the specific AE rate (pancreatitis, cholangitis, bleeding and perforation). The quality of the studies was assessed using the Newcastle-Ottawa scale. Data synthesis was obtained by direct meta-analyses using random-effects model and the results are presented as odds ratios (OR) with 95% confidence intervals (CI).

Results: Of 6,833 relevant publications, 31 studies met the inclusion criteria. Procedure success was higher among HV endoscopists (OR, 1.81; 95% CI, 1.59-2.06; I^2 = 57%) and in HV centers (OR, 1.77; 95% CI, 1.22-2.57; I^2 = 67%). The overall AE rate was lower for procedures performed by HV endoscopists (OR, .71; 95% CI, .61-.82; I2 = 38%) and in HV centers (OR, .70; 95% CI, .51-.97; I^2 =92%). Bleeding was less frequent in procedures performed by HV endoscopists (OR, .67; 95% CI, .48-.95; I^2 =37%) but did not differ based on center volume (OR, .68; 95% CI, .24-1.90; I^2 = 89%). No statistical differences were detected concerning pancreatitis, cholangitis, and perforation.

Conclusion: High-volume endoscopists and centers provide higher ERCP success rates with fewer adverse events, especially bleeding, compared with respective low-volume comparators.

INTRODUCTION

ERCP is essential in the management of biliopancreatic disease, and the annual clinical need and use of this procedure have continued to rise over the past decade [1]. Nevertheless, ERCP represents one of the most challenging endoscopic procedures, with high complexity because of the need for a set of advanced endoscopic skills and because of the related adverse events (AEs) [2,3]. In accordance with this, it has been shown that a long learning curve is required to achieve the expertise needed to perform these procedures with safety and efficacy [4,5]. ERCP also has one of the highest AE rates among all performed endoscopic procedures, accounting for a total AE rate of above 10% [6], including post-ERCP pancreatitis (PEP), bleeding, cholecystitis, cholangitis, and perforations [2]. Despite recommended prophylactic measures [2], the incidence rates, hospital (re)admissions, and mortality associated with AEs, such as PEP, appear to be increasing, suggesting that further preventive approaches need to be developed [7].

Currently, ERCP is performed across high-volume (HV) and low-volume (LV) centers and by endoscopists with various levels of experience. This difference in procedure volumes between different centers and operators might have an impact on the quality and safety of ERCP, as described in other fields of endoscopy, for example, in GI bleeding [8], colonoscopy [9], EMR [10], drainage of pancreatic fluid collections with lumen-apposing metal stents [11],and surgery [12].

A previous meta-analysis from 2017 reported an association between ERCP success and endoscopist and center volumes and an association between overall AEs and endoscopist volume [13]. Since then, although further studies have been published to deepen this subject, there are still no clear recommendations to suggest a minimum endoscopist and center volume threshold to perform and maintain expertise in ERCP. Therefore, this study aimed to conduct an updated systematic review and meta-analysis to evaluate any potential associations between center and endoscopist ERCP volume and ERCP success and AEs.

METHODS

Protocol design and registration

This review was conducted according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses guidelines for systematic review and meta-analysis [14] and is registered in the International Prospective Register of Systematic Reviews (registration no. CRD42022318744).

Eligibility criteria

The PICO framework was adopted in this review to investigate ERCP success and AE rates based on center and endoscopist ERCP volume [15]. Comparative studies including at least 1 group (endoscopists or centers) were included if the following criteria were met: *Patients*: adult patients (≥ 18 years old) with normal anatomy and an indication for conventional ERCP performed with duodenoscopes; *Interventions*: ERCP using a side-viewing duodenoscope; *Comparators*: at least 1 comparison between LV and HV endoscopists or centers should be presented for ERCP success and/or AEs; and *Outcomes*: ERCP success, defined as at least deep cannulation of the desired duct; AEs related to the procedure. Studies that did not report outcomes of interest or only included outcomes in 1 arm with no volume comparison were excluded, as well as those that reported results in the pediatric population or using instruments other than a duodenoscope to perform ERCP (eg, enteroscope). Publications in languages other than English were also excluded. Additionally, guidelines, position statements, reviews, systematic reviews, meta-analyses, and expert opinions were excluded, but reference lists of potentially relevant systematic reviews and meta-analyses were checked for any missed studies.

Search strategy

A comprehensive computerized literature search was performed in the PubMed/MEDLINE, Web of Science, and Scopus databases to identify eligible published articles. No time frame restrictions were applied. Searches were conducted from inception until March 5, 2022.

The search strategy (*APPENDIX 1*, available online at www.giejournal.org) was performed including the terms "endoscopic retrograde cholangiopancreatography," "high volume," "low volume," "volume," "outcomes," and "adverse events," both as medical subject headings and free-text terms combined with the Boolean set operator "AND." Three reviewers (S.C., A.P., and T.F.) independently performed the search. Duplicates were removed, and then the titles and abstracts of all search results were evaluated for eligibility by 4 reviewers (S.C., A.P., T.F., and P.G.). Predesigned electronic forms were used to assess eligibility for each selected article, whereas any disagreement was settled by discussion and consensus. Reference lists of all eligible studies and previous publications reporting on this issue were hand-searched as well to identify potentially eligible studies missed during the first search. When data were not available, the corresponding author was contacted via email to provide further information.

Data extraction and methodologic quality assessment

For each study included in the analysis, the following data items were collected: authors, year of publication, number of ERCPs, number of endoscopists, number of centers, threshold for defining LV and HV center and endoscopist volume, native papillary anatomy, trainee involvement, gender, age, indication for ERCP (biliary stone extraction, stent placement for malignant or benign biliary stenosis, other), procedure success rate (defined as the completion of all intended therapeutics during ERCP or, if not reported, successful cannulation of the duct of interest or not requiring to repeat biliary drainage procedure within 1 week [13]), and post-ERCP AE rate (any ERCP-related AEs including PEP, bleeding, cholangitis, cholecystitis, and perforation or any ERCP-related AEs requiring extraordinary therapeutic measures, namely endoscopic, surgical, medical, emergency readmission, or hospitalization [13]). The methodologic quality of the studies was assessed using a customized Newcastle-Ottawa scale for observational studies, including a semiquantitative score for each item considered for evaluation of eligibility [16].

Outcomes

The primary outcome was the comparison of overall procedure success rate according to endoscopist and center volume. Secondary outcomes were the comparison between overall and specific post-ERCP AE rates in HV centers and endoscopists compared with LV centers and endoscopists. Specific AEs were PEP, bleeding, cholangitis, and perforation, and their pooled rates were calculated for both subgroups.

Quality of evidence assessment

The Grading of Recommendations Assessment, Development and Evaluation framework was used to summarize the quality of evidence [17]. Inconsistency, indirectness, imprecision, and risk of bias were judged by 2 authors (S.C. and A.P.) independently for an overall quality assessment of very low, low, or moderate using the Grading of Recommendations Assessment, Development and Evaluation pro tool [18].

Data synthesis and statistical analysis

All outcomes were assessed by direct meta-analyses to estimate odds ratio (OR) and 95% confidence interval (CI). A random-effects model (DerSimonian and Laird method) was used for analysis of outcomes to allow a more conservative estimate of the measured effect [19]. Heterogeneity was assessed using the I^2 statistic, with values exceeding 50% showing presence of significant heterogeneity, whereas small study effects were assessed by examining funnel plot asymmetry [20]. All direct analyses were carried out in Review Manager 5.4.1 (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark), and pooled rates were calculated using OpenMetaAnalyst [21].

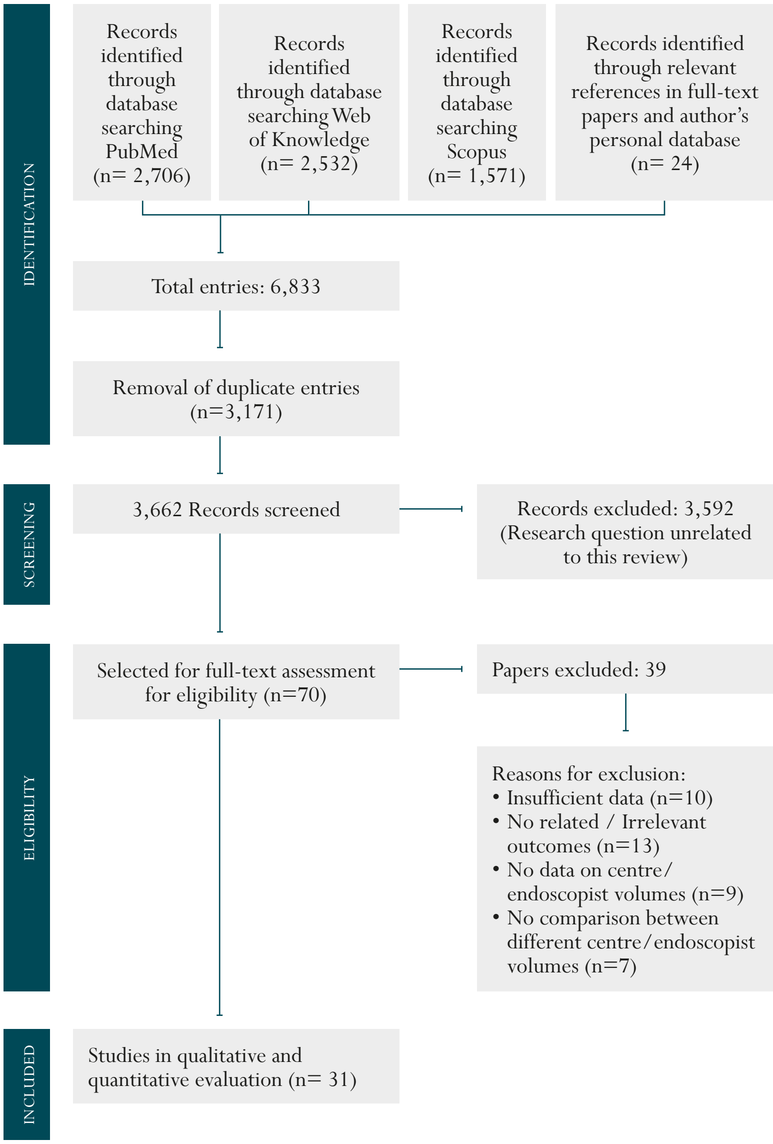
RESULTS

Study selection

After initial identification of 6,833 relevant publications by the electronic literature search, 31 studies [7,22-51] finally met the inclusion criteria and were included in the systematic review and meta-analysis. The study selection Preferred Reporting Items for Systematic reviews and Meta-Analyses flowchart is illustrated in *FIGURE 1*.

FIGURE 1

Preferred Reporting Items for Systematic reviews and Meta-Analyses flowchart for study selection.



Characteristics of included studies

SUPPLEMENTARY TABLE 1 (available online at www.giejournal.org) summarizes the basic patient- and procedure-related characteristics of the included studies.

Overall, 31 studies were included in our review and analyzed. The recruitment period ranged from 1992 to 2019, with 38.7% of the studies conducted after 2017. The female-to-male ratio was 17:7, and the mean patient age ranged between 50.1 and 75 years. The most common indication for ERCP was biliary stone disease (52.9%), followed by benign (18.8%) and malignant strictures (6.8%). Fifteen studies [22-36] provided information about previous ERCPs, and the percentage of native papilla was 96.7% among those reports.

Individual study outcomes are summarized in *SUPPLEMENTARY TABLES 2* (available online at www.giejournal.org). Studies had either prospective (n = 14) [22-27,30,33,35,38,40,42,45,46] or retrospective (n = 17) [7,28,29,31,32, 34,36,37,39,41,43,44,47-51] cohorts, and procedures ranged between 75 and 1,222,467 per study. The threshold for defining HV or LV endoscopists and centers varied among studies, whereas the threshold to define LV endoscopists ranged from 25 [48] to 204 [37] procedures per year. Similarly, the cut-off for LV centers ranged from 16 per 9 months [44] to 500 per year [41]. Intermediate volumes, defined in some studies, were not included in this analysis because the primary goal of this study was to compare HV and LV endoscopists and centers, and intermediate volume was only mentioned in a few studies.

Methodologic quality and risk of bias

Six studies [26,35,42-45] were rated as high quality (low risk of bias), whereas 11 [25,27,29,31,32,36-41] were considered as having a high risk of bias according to the Newcastle-Ottawa scale. Fourteen studies [7,22-24,28,30,33,34,46-51] had an intermediate risk of bias. The most common reason for down-rating was missing data about the follow-up period. A detailed assessment of study quality is shown in *SUPPLEMENTARY TABLE 8* (available online at www.giejournal.org).

Primary outcome: ERCP success rates

FIGURE 2A and *B* show the meta-analysis results for the primary outcome considering endoscopist and center volume, respectively.

(A)

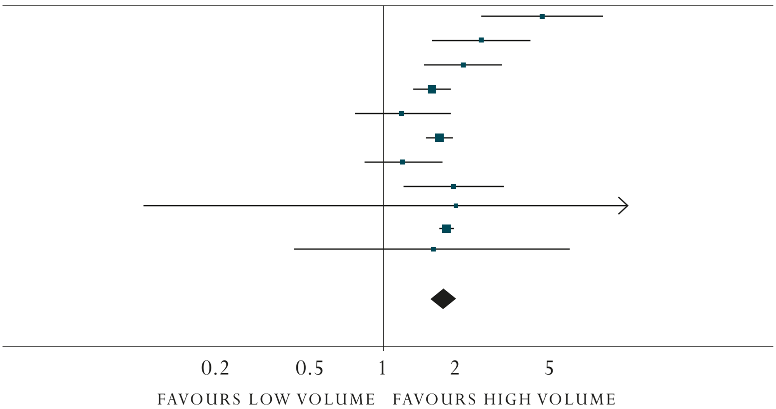
	HIGH VOLUME		LOW VOLUME			ODDS RATIO	
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Random, 95% CI**	**Year**
Freeman 1996	1144	1158	1125	1189	4.1%	4.65 [2.59, 8.34]	1996
Freeman 2001	637	660	1192	1303	6.0%	2.58 [1.63, 4.08]	2001
Vitte 2007	919	971	644	722	8.4%	2.14 [1.49, 3.08]	2007
Kapral 2008	2126	2447	976	1215	16.5%	1.62 [1.35, 1.95]	2008
Wang 2009	1948	2015	649	676	6.1%	1.21 [0.77, 1.91]	2009
Cotè 2013	7574	8030	6777	7484	20.3%	1.73 [1.53, 1.96]	2013
Voiosu 2018	957	1021	760	822	8.5%	1.22 [0.85, 1.75]	2018
Mariani 2019	1114	1197	169	194	5.7%	1.99 [1.23, 3.19]	2019
Han 2019	68	69	67	69	0.3%	2.03 [0.18, 22.92]	2019
Harvey 2020	38896	41492	11380	12790	23.1%	1.86 [1.73, 1.99]	2020
Caglar 2020	49	59	12	16	0.9%	1.63 [0.44, 6.12]	2020
Total (95% CI)		59119		26480	100.0%	1.81 [1.59, 2.06]	
Total events	55432		23751				

Heterogeneity: $Tau^2 = 0.02$; $Chi^2 = 23.26$, df = 10 (p = 0.010); $I^2 = 57\%$
Test for overall effect: Z = 8.95 (p < 0.00001)

FIGURE 2
Forest plots of the pooled odds ratios of primary outcomes reflecting the comparison on ERCP success between high- and low-volume (A) endoscopists and (B) centers. CI = Confidence interval.

FIGURE 2 | CONTINUATION

ODDS RATIO
M-H, Random, 95% CI

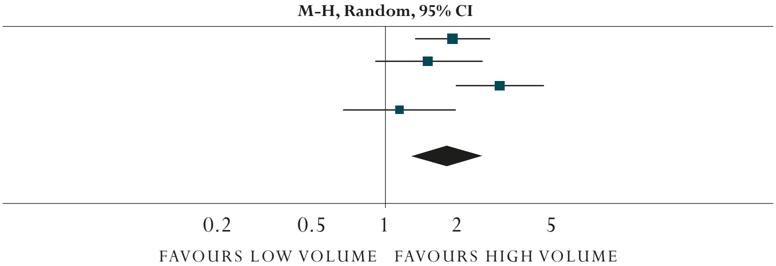


(B)

	HIGH VOLUME		LOW VOLUME			ODDS RATIO	
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Random, 95% CI**	**Year**
Loperfido 1998	1636	1703	991	1066	28.9%	1.85 [1.32, 2.59]	1998
Masci 2006	344	389	160	191	22.8%	1.48 [0.90, 2.43]	2006
Vitte 2007	779	812	826	927	26.2%	2.89 [1.93, 4.33]	2007
Mariani 2019	1136	1185	452	474	22.1%	1.13 [0.67, 1.89]	2019
Total (95% CI)		4089		2658	100.0%	1.77 [1.22, 2.57]	
Total events	3895		2429				

Heterogeneity: $Tau^2 = 0.10$; $Chi^2 = 8.99$, df = 3 (p = 0.03); $I^2 = 67\%$
Test for overall effect: Z = 3.00 (p = 0.003)

ODDS RATIO
M-H, Random, 95% CI



Based on endoscopist volume

Eleven studies [24-26,30,32,33,36-38,42,48] assessed ERCP success rates based on endoscopist volume: 59,119 ERCPs were performed in the HV group and 26,480 ERCPs in the LV group. The comparison between HV and LV endoscopists regarding ERCP success demonstrated a higher success rate when the procedure was performed by HV endoscopists (94.4%; 95% CI, 92.8-96) compared with LV endoscopists (90.7%; 95% CI, 88.6-92.7) (OR, 1.81; 95% CI, 1.59-2.06; $I^2 = 57\%$, p = .01).

Based on center volume

Four studies [22-24,33] with 4,089 procedures in the HV group and 2,658 in the LV group assessed ERCP success rates according to center volume. Differences in success rates between HV (94.8%; 95% CI, 92.9-96.6) and LV (89.3%; 95% CI, 84-94.7) centers were also statistically significant (OR, 1.77; 95% CI, 1.22-2.57; $I^2 = 67\%$, $p = .03$) in favor of HV centers.

Secondary outcomes: ERCP AE rates

Based on endoscopist volume: overall AE rates

Twelve studies [24-26,29,30,32,33,35,36,38,39,47] assessed overall AEs by endoscopist volume, including 10,071 ERCPs for the HV group and 5,601 for the LV group. HV endoscopists had a significantly lower rate of overall AEs (9.5%; 95% CI, 7.2-11.8) compared with LV endoscopists (12.7%; 95% CI, 9.8-15.9) with an OR of .71 (95% CI, .61-.83) and nonsignificant heterogeneity among studies ($I^2 = 38\%$, $p = .09$) (*FIGURE 3A*).

Based on center volume: overall AE rates

Similarly, 8 studies [22,24,33,35,40,44,46,50] assessed overall AE rates by center volume (40,828 and 12,883 ERCPs for HV and LV groups, respectively). The assessment of AEs revealed a significantly lower incidence of AEs among HV versus LV centers (7.4% [95% CI, 5.2-9.6] vs 9.4% [95% CI, 6.2-12.5]; OR, .70; 95% CI, .51-.97; $I^2 = 92\%$, $p < .001$) (*FIGURE 3B*).

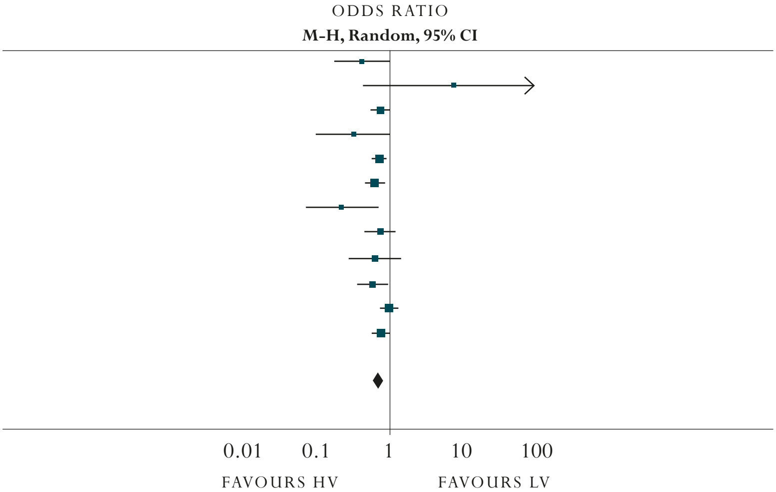
(A)

	HV		LV			ODDS RATIO
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Random, 95% CI**
Alkhatib 2011	11	115	15	73	3.0%	0.41 [0.18, 0.95]
Caglar 2020	11	59	0	16	0.3%	7.82 [0.44, 140.23]
Freeman 1996	97	1158	132	1189	14.5%	0.73 [0.56, 0.96]
Han 2019	4	69	11	69	1.6%	0.32 [0.10, 1.08]
Kapral 2008	250	2447	165	1215	18.0%	0.72 [0.59, 0.89]
Lee 2020	123	702	121	489	14.2%	0.65 [0.49, 0.86]
Liao 2009	9	101	7	23	1.8%	0.22 [0.07, 0.69]
Mariani 2019	101	1197	21	194	7.2%	0.76 [0.46, 1.25]
Saito 2017	14	216	11	113	3.2%	0.64 [0.28, 1.47]
Vitte 2007	33	971	41	722	7.8%	0.58 [0.37, 0.93]
Volosu 2020	149	1021	121	822	15.3%	0.99 [0.76, 1.28]
Wang 2009	150	2015	63	676	13.1%	0.78 [0.58, 1.06]
Total (95% CI)		10071		5601	100.0%	0.71 [0.61, 0.83]
Total events	952		708			

Heterogeneity: $Tau^2 = 0.02$; $Chi^2 = 17.64$, $df = 11$ ($p = 0.09$); $I^2 = 38\%$
Test for overall effect: $Z = 4.29$ ($p < 0.00001$)

FIGURE 3

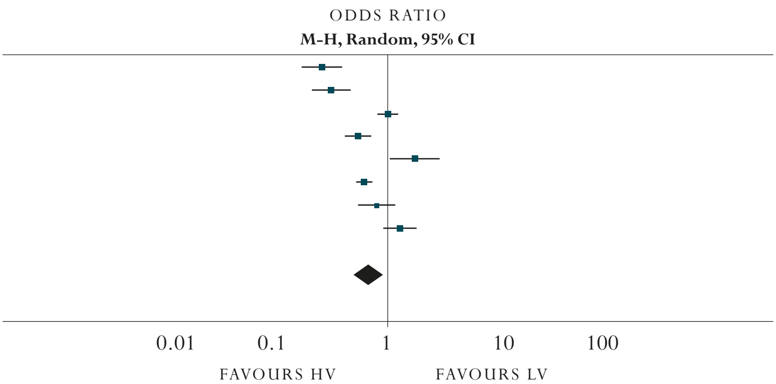
Forest plots of the pooled odds ratios regarding the comparison of overall adverse events rates between high- and low-volume (A) endoscopists and (B) centers. CI = Confidence interval; HV = High-volume; LV = Low-volume



(B)

	HV		LV			ODDS RATIO	
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Random, 95% CI**	**Year**
Loperfido 1998	35	1703	76	1066	11.7%	0.27 [0.18, 0.41]	1998
Vitte 2007	37	812	116	927	12.0%	0.33 [0.23, 0.49]	2007
Enochsson 2010	323	2436	316	2436	13.8%	1.03 [0.87, 1.21]	2010
Murata 2010	91	2840	165	2941	13.1%	0.56 [0.43, 0.72]	2010
Glomsaker 2013	42	1393	25	1415	10.7%	1.73 [1.05, 2.85]	2013
Huang 2019	1617	29613	275	3279	14.0%	0.63 [0.55, 0.72]	2019
Mariani 2019	104	1185	50	474	12.2%	0.82 [0.57, 1.16]	2019
Lee 2020	183	846	61	345	12.6%	1.29 [0.93, 1.77]	2020
Total (95% CI)		40828		12883	100.0%	0.70 [0.51, 0.97]	
Total events	2432		1084				

Heterogeneity: $Tau^2 = 0.19$; $Chi^2 = 86.67$, df = 7 ($p < 0.00001$); $I^2 = 92\%$
Test for overall effect: Z = 2.13 (p = 0.03)



Based on endoscopist volume: PEP rate

Regarding individual AEs, PEP was recorded more commonly among LV endoscopists (5.9%; 95% CI, 4.6-7.2) compared with HV endoscopists (5.0%; 95% CI, 4.1-6.0). However, the difference was not significant (OR, .76; 95% CI, .53-1.09; $I^2 = 85\%$, $p < .001$) (*SUPPLEMENTARY FIGURE 1A*, available online at www.giejournal.org).

Based on center volume: PEP rate

With respect to PEP, 4.7% (95% CI, 3.4-5.9) and 5.9% (95% CI, 4.9-6.9) of ERCPs were complicated with PEP in HV and LV centers, respectively, with an OR of .84 (95% CI, .63-1.12; $I^2 = 99\%$, $p < .001$) (*SUPPLEMENTARY FIGURE 1B*, available online at www.giejournal.org).

Based on endoscopist volume: cholangitis rates

Post-ERCP cholangitis was diagnosed at a rate of 1.7% (95% CI, .6-2.7) and 2.2% (95% CI, 1.4-2.8) in procedures performed by HV and LV endoscopists, respectively, without a statistically significant difference (OR, .77; 95% CI, .37-1.61; $I^2 = 63\%$, $p = .04$) (*SUPPLEMENTARY FIGURE 2A*, available online at www.giejournal.org).

Based on center volume: cholangitis rates

Although cholangitis was recorded more frequently in LV centers (1.2%; 95% CI, .1-2.4) compared with HV centers (.5%; 95% CI, .1-1.0), this difference did not reach the level of statistical significance (OR, .51; 95% CI, .11-2.29; $I^2 = 83\%$, $p = .003$) (*SUPPLEMENTARY FIGURE 2B*, available online at www.giejournal.org).

Based on endoscopist volume: bleeding rates

The prevalence of post procedure bleeding was 3.3% (95% CI, 1.6-5.1) and 4.7% (95% CI, 2.0-7.4) among cases treated by an HV or LV endoscopist, respectively, with an OR of .67 (95% CI, .48-.95; $I^2 = 37\%$, $p = .16$) (*SUPPLEMENTARY FIGURE 3A*, available online at www.giejournal.org).

Based on center volume: bleeding rates

Interestingly, the rate of post-ERCP bleeding was higher in HV centers (3.0%; 95% CI, 1.4-4.7) versus LV centers (2.3%; 95% CI, 1.0-3.5), but this difference was not statistically significant (OR, .68; 95% CI, .24-1.90; $I^2 = 89\%$, $p < .001$) (*SUPPLEMENTARY FIGURE 3B*, available online at www. giejournal.org).

Based on endoscopist volume: perforation rates

Perforation rates were similar in both groups (HV vs LV: .5% [95% CI, .2-.7] vs .5% [95% CI, .2-.8)], with an OR of .88 (95% CI, .44-1.74) and null heterogeneity ($I^2 = 0\%$, $p = .71$) (*SUPPLEMENTARY FIGURE 4A*, available online at www.giejournal.org).

Based on center volume: perforation rates

Similarly, both HV and LV centers presented equivalent frequencies for this outcome (.3% [95% CI, .1-.5] and .3% [95% CI, .1-.5], respectively), with an OR of 1.10 (95% CI, .43-2.82; $I^2 = 0\%$, $p = .69$) (*SUPPLEMENTARY FIGURE 4B*, available online at www.giejournal.org).

Sensitivity analysis

The analysis of studies using the 200 procedures as a threshold to differentiate HV from LV endoscopists resulted in a similar outcome in terms of success (OR, 1.50; 95% CI, 1.59-2.06), albeit with lower heterogeneity (I^2 = 23%, p = .27) [30,33,36]. Similarly, the respective sensitivity analysis for center volume improved heterogeneity (I^2 = 58%, p = .09) to a nonsignificant extent without also affecting the success rate of the meta-analysis (OR, 2.02; 95% CI, 1.40-2.91) [22-24]. Moreover, in the meta-regression analysis, there was a trend for correlation between the rate of procedure success and the rate of AEs but without statistical significance (p = .14) (*SUPPLEMENTARY FIGURE 5*, available online at www.giejournal.org).

The analysis of studies using solely those that included the number of ERCPs performed per year (and excluding those evaluating lifetime experience) resulted in similar outcomes for success (OR, 1.87; 95% CI, 1.63-2.14; I^2 = 62%, p = .01) [24-26,33,36-38,42,48] and overall AEs (OR, .68; 95% CI, .55-.83; I^2=37%, p = .15) [24-26,33,35,36,38,39,47]. The sensitivity analysis performed including studies evaluating ERCPs performed from 2010 onward showed a similar endoscopist success rate with lower heterogeneity (OR, 1.72; 95% CI, 1.44-2.07; I^2 = 22%, p = .27) [30,32,33,36,37]. Regarding overall AEs, a similar OR was found but without a statistically significant difference (OR, .76; 95% CI, .56-1.02; I^2 = 48%, p = .09) [29,30,32,33,35,36]. For centers, this analysis was not done because of the reduced number of studies available.

Additionally, an analysis was conducted with studies defining therapeutic success as the achievement of all intended targets, without changes in findings (OR, 1.72; 95% CI, 1.49-1.97; I^2 = 68%, p = .003) [24,25,30,33,36-38,48].

A sensitivity analysis including only "prospective" studies did not modify the results, neither for success rates, according to endoscopist volume (OR, 1.9; 95% CI, 1.45-2.51; I^2= 73%, p = .001) [24-26,30,33,38,42] or center volume (OR, 1.77; 95% CI, 1.22-2.53; I^2=67%, p =.003) [2,22-24], nor for overall AE rates, according to endoscopist volume (OR, .75; 95% CI, .67-.85; I^2=11%, p < .001) [24-26,30,33,35,38] or center volume (OR, .75; 95% CI, .45-1.24; I^2=93%, p = .26) [22,24,33,35,40,46].

Finally, a subgroup analysis was completed to evaluate bleeding rates including solely native papilla, with similar results (OR, .66; 95% CI, .47-.93; I^2 = 0%, p = .74) [32,35,36].

Quality of evidence

The initial quality of evidence value for all included studies was low because they were observational. Nevertheless, no reasons for further downgrading were recognized. Therefore, based on the meta-analysis, the low quality of evidence supported the comparisons among the presented groups.

Publication bias

Funnel plots that consider the primary outcomes and overall AEs are presented in *SUPPLEMENTARY FIGURE 6* (available online at www.giejournal.org). The visual assessment of the funnel plots indicates symmetry for all outcomes, thus precluding the absence of significant publication bias.

DISCUSSION

This study indicates that the success rate of ERCP is higher if performed by HV endoscopists or in HV centers. More specifically, the odds of ERCP success are 81% higher when performed by HV endoscopists compared with LV endoscopists (OR, 1.81; 95% CI, 1.59-2.06; I^2 = 57%) and 77% higher in HV centers than in LV centers (OR, 1.77; 95% CI, 1.22-2.57; I^2 = 67%), with statistically significant differences between HV and LV groups in both analyses. Furthermore, the volume of ERCPs performed by an endoscopist can also impact the rate of AEs. Indeed, AE rates after procedures performed by HV endoscopists were 29% lower compared with LV endoscopists (OR, .71; 95% CI, .61-.82; I^2 = 38%). A similar pattern was detected when comparing HV with LV centers, with 30% less AEs in the HV center group (OR, .70; 95% CI, .51-.97). A particular parameter that could affect the results, although it was not possible to assess it in any study, was the level of complexity of the recorded ERCP. HV experienced endoscopists and tertiary centers accumulate a higher percentage of difficult ERCPs, including failed cannulation elsewhere, large stones, and complex strictures, compared with conventional departments, thus impacting the ERCP success rates and the possibility of severe AEs [52].

In 2017, a meta-analysis was performed analyzing 13 studies [13]. Keswani et al [13] concluded that increased ERCP volume was associated with significantly higher procedure success per endoscopist (OR, 1.6; 95% CI, 1.2-2.1) and per center (OR, 2.0; 95% CI, 1.6-2.5) and with lower AE rates only when considering endoscopist volume (OR, .7; 95% CI, .5-.8). These results are similar to ours, despite the fact that more than one-third of the studies were added to the literature since then, thus implying the stable impact of procedure volume, at least on success-related outcomes. Indeed, the heterogeneity found in Keswani et al's study regarding the primary outcome of success based on endoscopist volume (I^2 = 82%) has improved with this review (I^2=57%). Moreover, we considered the absence of a uniform cut-off number among included studies to distinguish LV from HV endoscopists and centers as a possible reason for heterogeneity. Therefore, as an addendum to the basic analysis, we performed a sensitivity analysis by using a threshold of 200 procedures, because this was common among several studies. Interestingly, this analysis maintained the superiority of HV endoscopists over LV endoscopists (OR, 1.50; 95% CI, 1.59-2.06) considering ERCP success and yielded an acceptable heterogeneity (I^2 = 23%, P = .27). Similarly, HV centers, defined by a threshold of >200 procedures per year, provided significantly optimal results (OR, 2.02; 95% CI, 1.40- 2.91) with nonsignificant heterogeneity (I^2 = 58%, P = .09). Although this threshold is arbitrary, it could be a reasonable minimum annual pace for endoscopists and centers to preserve competency and guide further studies to produce homogenously designed results. Technical developments that occurred over the last decade in this field (in instruments, with monofilament and smaller tipper sphincterotomes, improved electrosurgical generators, and smaller, hydrophilic, tipped guidewires that can be physician-controlled; and in techniques, as with the evolution from contrast-guided to wire-guided cannulation [53]) could also account for the heterogeneity found, as shown in the subgroup analysis performed taking this fact into consideration. Another novel finding of this review is the overall AE rate, which was not determined to be related to center volume in the previous review (OR, .72; 95% CI, .51-1.5) and was detected in this study as occurring at a lower rate in HV centers (OR, .70; 95% CI, .51-.97).

Specific AEs were also assessed. The difference in PEP incidence between HV and LV endoscopists or centers did not reach statistical significance (OR, .76; 95% CI, .53-1.09; and OR, .84; 95% CI, .63-1.12), respectively), although there was a slight predominance of PEP in LV comparators. This observation could reflect a plethora of potential confounders implicated in PEP. Considering the investigators' expected compliance with the guidelines [2] the steps for prophylaxis and safe approach were probably followed in the included studies regardless of the experience or volume of procedures. Moreover, the provision of additional measures, apart from standard-of-care nonsteroid anti-inflammatory drug suppositories, including the low threshold for placing pancreatic stent among LV endoscopists, after unintentional pancreatic duct cannulation, may have impacted the results. Those potential differences in practice are also reflected in the heterogeneity observed for this outcome. Patient factors may also have a predominant role in PEP risk over endoscopist or center volume [2], and more difficult or risky cases (referred patients, pancreatic endotherapy) might be more frequent in HV centers. Similarly, perforation and cholangitis rates were tested de novo but did not differ significantly among assessed subgroups (for perforation: OR, .88 (95% CI, .44-1.74) and 1.10 (95% CI, .43-2.82); for cholangitis: OR, .77 (95% CI, .37-1.61) and .51 (95% CI, .11-2.29); for endoscopists and centers, respectively). From a statistical point of view, both outcomes occurred at a low frequency, thus warranting high-powered studies to produce significant results, if they exist. However, it is reasonable for LV endoscopists to be more hesitant, avoiding perforations, and to treat simpler ERCP cases, thus keeping this ratio low [54]. On the other hand, the rate of bleeding related to ERCP was 33% lower among HV endoscopists compared with LV endoscopists (OR, .67; 95% CI, .48-.95) accompanied by low heterogeneity (I^2 = 37%, p = .16), a novel finding of this review that persisted after performing a sensitivity analysis with studies including only native papilla. Because ERCP related bleeding usually occurs after sphincterotomy, it is self-evident that the technique affects the outcome [55]. The comprehension of the vascular anatomy along the bile duct and at the level of Oddi's sphincter and the perception of the correct cutting angle and appropriate and stable sphincterotome positioning represent skills that require experience, advanced endoscopic handling, and reasonable ERCP volume [5]. These prerequisites also limit the impact of further patient-, device-, and procedure-related variables, at least in patients with normal anatomy, on PEP, thus providing reliable and homogenous results.

Despite the significant addition to existing knowledge, this study also has some persistent limitations. First, the quality of the included studies is debatable because of the retrospective design and the absence of randomization. Nevertheless, although prospective cohorts are feasible to be conducted, randomized studies in this field seem impossible, given the nature of outcomes and the investigated parameters. Another drawback, as mentioned before, is the broad range of volume thresholds. Although we incorporated the distributions of included studies for the basic analysis, we performed a sensitivity analysis using the most recorded cut-off (200 procedures), thus achieving homogeneity. This cut-off is arbitrary and could be further assessed by future studies, based on our outcomes. A third limitation is the remarkable variability of successful ERCP definitions among the included studies. Some of them considered success as the deep cannulation of the desired duct, whereas others required the achievement of the intended therapeutic manipulations. To overcome this variability, we considered the biliary cannulation rate as a marker of success, because it is the most substantial step before proceeding with further operations [56]. Additionally, we conducted a sensitivity analysis considering only those that defined therapeutic success without changing the meta-analytic findings. Another unsolved question is the impact of endoscopist volume over hospital volume. It was impossible to state a possible independent significance of endoscopist volume over center volume because the value of HV endoscopists in LV centers or LV endoscopists in HV centers was not assessed in any of the studies.

Furthermore, we must consider that expertise in ERCP does not rely exclusively on case volume. Apart from other endoscopist-related factors (combination of technical and nontechnical skills [57], training background, and lifetime experience) and center-related factors (available resources), other factors that can be involved in achieving high outcomes, namely procedure-related factors (complexity of case mix) and patient-related factors (age and gender, among others) [2], were not possible to evaluate because of the lack of study details.

The results of this study highlight the need for improving future standards of ERCP practice. Although at this point it is only possible to speculate, because of an absence of data, several solutions could be considered to overcome the worse outcomes experienced by LV endoscopists and LV centers. Those measures could potentially involve developing official databases and ensuring a mandatory and continuous registry of ERCP quality indicators and outcomes [58], which is indeed already a reality in countries such as The Netherlands [59]. Moreover, more efforts should be pursued to establish an appropriate method of credentialing and privileging endoscopists performing ERCP, as has being attempted in the United Kingdom [60]. Although increasing LV experience is important (eg, through maintaining regular training and continuous mentorship with HV endoscopists and centers, developing standardized protocols, joining multidisciplinary meetings with HV centers, having HV endoscopists assisting LV endoscopists and centers in more complex cases or transferring these cases, and improving or setting up complementary services), a major shift in the organization of healthcare services, with centralization of ERCPs in HV centers performed by HV endoscopists, might have to be weighed in the near future to guarantee high-quality performance in ERCP.

In sum, ERCP is a demanding endoscopic procedure, and all efforts should be conducted to minimize AEs and optimize the quality associated with this technique [58]. As an operator-dependent technique, ERCP should be performed by endoscopists and in centers most capable of delivering high-quality care, as indicated by our results. This systematic review and meta-analysis confirmed that success and overall safety in ERCP are dependent on endoscopist and center volume.

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CHAPTER 10

Assessing the impact of center's volume on cost-effectiveness of centralizing ERCP

Accepted for publication:

Teles de Campos S, Diniz P, Castelo-Ferreira F, Voiosu T, Arvanitakis M, Devière J et al. Assessing the impact of center's volume on cost-effectiveness of centralizing ERCP. Gastrointestinal Endoscopy 2024 Jun; 99(6): 950-959.e4. doi: 10.1016/j.gie.2023.11.058.

KEY POINTS

ERCP Cost-Effectiveness Based on Center Volume: Chapter 10 examines whether high-volume (HV) centers perform ERCP more effectively and economically compared to low-volume (LV) centers. Prior economic analyses in this context were lacking.

Analytical Approach: This analysis established a baseline case by comparing the current distribution of ERCP procedures between HV and LV centers to a hypothetical scenario where all ERCPS are centralized in HV centers. This comparison was conducted through a cost-effectiveness analysis using the ICER and sensitivity analyses (one-way, two-way, and PSA) using Monte Carlo simulations. A conceptual model incorporating probabilities and utilities related to ERCP outcomes based on center volume, alongside the associated costs, was designed for these analyses and integrated data from the systematic review and meta-analysis included in Chapter 9 and from a broad literature review.

Baseline Case Insights: The baseline case revealed a significant cost-effectiveness in favor of centralizing ERCP procedures in HV centers, with an ICER of -151,270€/year, indicating lower costs and marginally higher Quality-Adjusted Life Years in HV centers.

Sensitivity Analysis Findings: The model was particularly sensitive to changes in the transportation costs (109.34%), the likelihood of significant adverse events (AEs) after successful ERCP at LV centers (42.12%) and at HV centers (23.53%), but only transportation cost above 3,407€ changed the study outcome.

Performance Metrics of LV Centers: For LV centers to be cost-effective, they would need to substantially enhance their procedural success rates (≥ 92.4% vs. 89.3%) and significantly decrease AE occurrence (≤ 0.5% vs 6.7%) - a highly improbable scenario not yet attained even by HV centers.

Advantages of Centralization: The data strongly supports centralizing ERCPs in HV centers, indicating potential enhancements in quality of care alongside cost reductions. The cumulative expertise gained from higher annual caseloads, coupled with overall periprocedural management, may justify the observed improved outcomes in HV centers.

Healthcare Policy Implications: The findings make a compelling case for healthcare policymakers to consider the centralization of ERCP procedures into HV centers as a strategy to optimize healthcare resources while improving patient outcomes.

ABSTRACT

Background & Aims: ERCP is a complex endoscopic procedure in which the center's procedure volume influences outcomes. With the increasing healthcare expenses and limited resources, promoting cost-effective care becomes essential for healthcare provision. This study was a cost-effectiveness analysis to evaluate the hypothesis that high-volume (HV) centers perform ERCP with higher quality at lower costs than low-volume (LV) centers.

Methods: A baseline case compared the current distribution of ERCPs among HV and LV centers with a hypothetical scenario in which all ERCPs are performed at HV centers. A cost-effectiveness analysis was constructed, followed by one-way and two-way sensitivity analyses and probabilistic sensitivity analysis (PSA) using Monte Carlo simulations.

Results: In the baseline case, the ICER was -151,270€/year, due to the hypothetical scenario's lower costs and slightly higher QALYs. The model was most sensitive to changes in the transportation costs (109.34%), probability of significant adverse events (AEs) after successful ERCP at LV centers (42.12%), utility after ERCP with significant AEs (30.10%), and probability of significant AEs after successful ERCP at HV centers (23.53%); only transportation cost above 3,655€ changed the study outcome. The current ERCP distribution would only be cost-effective if LV centers achieved higher success (≥ 92.4% vs. 89.3%) with much lower significant AEs (≤ 0.5% vs 6.7%). The study's main findings remained unchanged while combining all model parameters in the PSA.

Conclusions: Our findings show that HV centers have high-performance rates at lower costs, raising the need to consider the principle of centralization of ERCPs into HV centers to improve the quality of care.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a complex procedure for managing biliopancreatic diseases. However, although ERCP is highly effective, adverse events (AEs), including post-ERCP pancreatitis (PEP), bleeding, perforation, infection, and cardiopulmonary events, occur at a higher rate with ERCP than with other endoscopic techniques, with an overall AE rate higher than 10% [1,2].

It has recently been shown in a systematic review and meta-analysis [3] that clinical outcomes, both ERCP success and overall AEs, are improved by increasing a center's annual caseload, i.e., when ERCP is performed in HV centers. Higher procedure volume, associated with higher endoscopists' experience, namely dealing with more complex ERCPs, and improved resources, may justify these better outcomes in HV centers [4]. However, ERCP is performed in high-volume (HV) and low-volume (LV) centers. The lack of structured referral systems and financial incentives for providers, in addition to the lack of data regarding the costs related to the quality of care in ERCP and the expenses resulting from adverse outcomes, may contribute to the present organization of the healthcare provider system for ERCP.

Promoting cost-effective and quality care constitutes a vital component of healthcare provision in the context of increasing healthcare expenses and limited resources. However, despite the publication of several studies that have examined the costs associated with ERCP in different scenarios [5–17], no specific economic analyses comparing clinical outcomes between HV and LV centers have been reported. We hypothesized that HV centers perform ERCP with better clinical quality at lower costs. Thus, this study aimed to measure the economic impact of quality-of-care delivery in ERCP and explore the relationship between center volume, clinical outcomes, and ERCP costs by performing a complete cost-effectiveness analysis comparing ERCP in HV and LV centers.

MATERIALS AND METHODS

This research was carried out considering published guidelines [18,19].

Study context

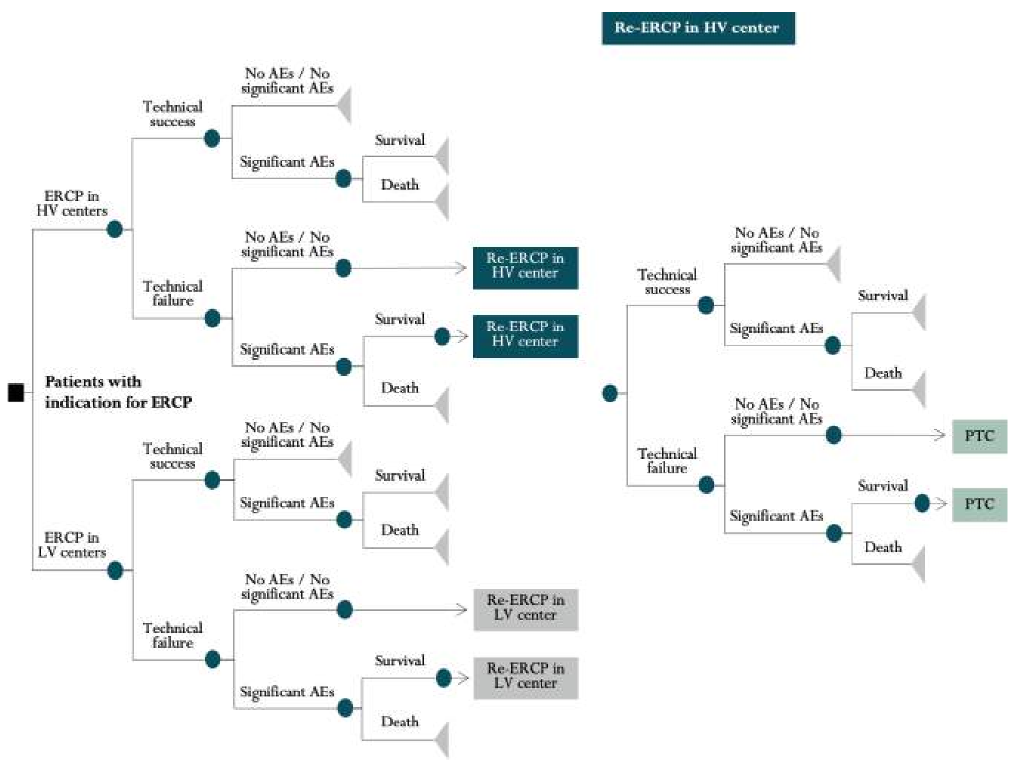
First, a baseline case and a cost-effectiveness analysis (CEA) were constructed using the Incremental Cost-Effectiveness Ratio (ICER) to investigate whether a center's ERCP volume has cost implications. Cost-effectiveness measures how efficiently resources are utilized to improve patient well-being by comparing gained utilities and associated costs [20]. The methodology used to assign values to costs and utilities is discussed below. Second, one-way and two-way sensitivity analyses were performed to identify the parameters to which the model was most sensitive and to establish threshold values, or combinations of values, that would cause a significant change in study outcomes. Finally, a probabilistic sensitivity analysis (PSA) was conducted using Monte Carlo simulations to evaluate model robustness.

Conceptual model

The target population was adult patients (≥ 18 years old) with a formal indication for conventional ERCP, i.e., a biliopancreatic procedure performed with a duodenoscope in a patient with normal anatomy. ERCPs performed in HV and LV centers were compared. The evaluation time frame was one year, as most outcomes relevant to an ERCP procedure, namely the sequelae of severe PEP, present themselves within this period [17]. Comparisons were made concerning incremental utilities and costs. Utilities were measured in terms of quality-adjusted life-years (QALYs).

The conceptual model, devised through a decision tree (*FIGURE 1*), sought to delineate the primary potential health events during ERCP and the necessary subsequent steps. ERCPs were assumed to be performed without substantial delays. Moreover, ERCPs were not separated by etiology due to a lack of specific data. The model considered, with different probabilities and utilities, the events described below:

1. Admission to an HV or an LV center: as there is no standardized threshold for defining HV and LV centers [3], we refrained from selecting a strict cut-off point between HV and LV centers. Instead, we used data from the literature in which higher volume centers are compared to lower volume centers regarding outcome rates.



2. Procedure success: regardless of center type, two main events during treatment were considered, as the procedure either technically succeeded or failed. Biliary cannulation rate was used as a technical success indicator (or completeness of the procedure), according to the European Society of Gastrointestinal Endoscopy (ESGE) key performance measures [21].

3. Possible AEs: regardless of procedure success, AEs may occur. However, as further specified below, different probabilities of AEs were assigned according to the success or failure of the procedure. Only significant AEs (classified as "moderate" or "severe" AEs, according to Cotton's classification [1,22]), which could potentially lead to morbidity or mortality and represent a significant increase in hospital admission costs, were included in the decision tree. These were not separated by type (e.g., PEP, bleeding, perforation) to standardize the costs related to the episode.

4. Patient re-direction when treatment fails: although, in a clinical setting, patients may be directed toward different treatment modalities in case of ERCP failure (e.g., percutaneous transhepatic cholangiography [PTC], endoscopic ultrasound [EUS], or surgery), for the sake of simplicity, and following the current literature [23], we assumed a second attempt at ERCP and then, in case of failure of the second ERCP (Re-ERCP), PTC as salvage therapy.

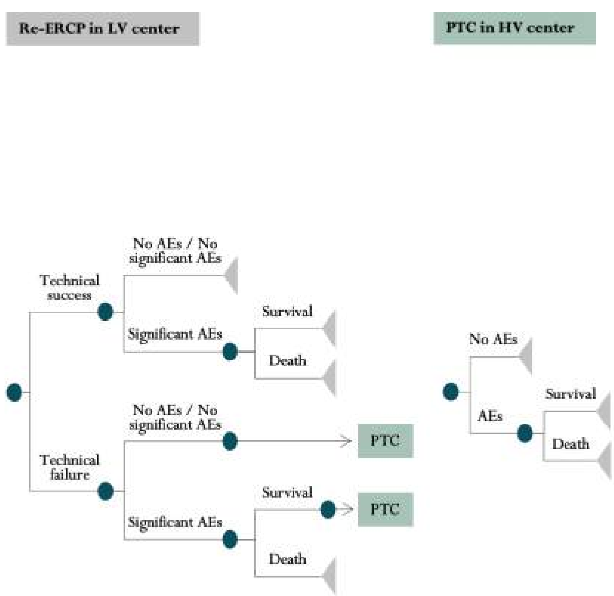


FIGURE 1

Schematic representation of the decision tree. Squares, circles, or triangles represent nodes, indicating a decision point, an uncertain event, or an endpoint, respectively. Lines between or after a node, representing branches, denote clinical or health events. Legend: ERCP = Endoscopic retrograde cholangiopancreatography. PTC = Percutaneous transhepatic cholangiography. AEs = Adverse events. HV = High-volume. LV = Low-volume

This conceptual model was developed into a Markov model, using MATLAB Release 2019 (MathWorks, Inc., Natick, Massachusetts) to examine the distribution of a simulated cohort of 100,000 patients.

Baseline case

The model was parameterized using secondary data from a systematic review and meta-analysis recently published by our team [3] and further supplemented with data from an exhaustive literature review. When multiple sources were available for the same parameter, they were combined using weighted averages. In case of an absence of data in the literature, parameters were defined based on the researchers' expertise.

Model input probabilities

Transition probabilities are shown in *TABLE 1*.

For index, i.e., initial ERCPs, these include the percentage of index ERCPs allocated to each type of centre [24], respective rates of procedure success [3], and probabilities of significant AEs, including death [16,25,26]. Difficult cannulation, often associated with the need for advanced cannulation techniques (e.g., precut), is considered a risk factor for AEs [1]. As no specific data were available, we assumed a higher probability of significant AEs, including death-related, in cases of failed ERCP over cases with successful cannulation (with 0.02 and 0.002 added to these probabilities, respectively) for both HV and LV centers.

As previously mentioned, the model assumed that a repeat ERCP was attempted when an index ERCP failed. For the reference case, if the index ERCP was performed in an HV center, the second ERCP was considered to be performed at the same HV center; if the index ERCP was performed at an LV center, the second attempt had a 50% possibility of being performed at an HV center. Other scenarios, including the possibility of attempting all second ERCPs at HV centers when ERCPs failed at LV centers, were analyzed in the sensitivity analyses. A subgroup analysis using data from Voiosu et al. [27] revealed a 3.3% decrease in technical success rates for second ERCP attempts compared to index procedures, which was considered in this model. The same AEs and death rate probabilities were attributed to the second ERCP attempt for both LV and HV centers [28].

Patients were always referred for PTC at an HV center after a second ERCP failure. A 100% success rate was assumed, and the AE rate was retrieved from the literature [23].

VARIABLE	CENTER VOLUME	BASE VALUE	RANGE	DISTRIBUTION	SOURCE
For index ERCP					
Allocation of index ERCP	HV	0.3256	NA	NA	[24]
	LV	0.6744	NA	NA	[24]
Probability of ERCP success	HV	0.9480	0.9290-0.9660	Beta	3
	LV	0.8930	0.8400-0.9470	Beta	3
Probability of significant AEs after a successful ERCP	HV	0.0220	0.0050-0.0700	Beta	[25,26], EO
	LV	0.0670	0.0050-0.1000	Beta	[25,26], EO
Probability of significant AEs after a failed ERCP	HV	0.0420	0.0250-0.0900	Beta	[25,26], EO
	LV	0.0870	0.0250-0.1200	Beta	[25,26], EO
Probability of successful ERCP-related death	HV	0.0018	0-0.0200	Beta	16,25
	LV	0.0075	0-0.0300	Beta	16,25
Probability of failed ERCP-related death	HV	0.0038	0-0.0400	Beta	[16,25], EO
	LV	0.0095	0-0.0500	Beta	[16,25], EO
For 2nd attempt of ERCP					
Probability of 2nd ERCP attempt in HV center after failed ERCP in LV center	-	0.5000	0-1	Beta	[24], EO
Probability of success in 2nd attempt of ERCP	HV	0.9150	0.8960-0.9330	Beta	[27], EO
	LV	0.8600	0.8070-0.9140	Beta	[27], EO
Probability of significant AEs after a successful ERCP	HV	0.0220	0.0050-0.0700	Beta	[25,26], EO
	LV	0.0670	0.0050-0.1000	Beta	[25,26], EO
Probability of significant AEs after a failed ERCP	HV	0.0420	0.0250-0.0900	Beta	[25,26], EO
	LV	0.0870	0.0250-0.1200	Beta	[25,26], EO
Probability of successful ERCP-related death	HV	0.0018	0-0.0200	Beta	16,25
	LV	0.0075	0-0.0300	Beta	16,25
Probability of failed ERCP-related death	HV	0.0038	0-0.0400	Beta	[16,25], EO
	LV	0.0095	0-0.0500	Beta	[16,25], EO

TABLE 1

Transition probability data from included studies. Legend: ERCP = Endoscopic retrograde cholangiopancreatography. PTC = Percutaneous transhepatic cholangiography. AEs = Adverse events. HV = High-volume. LV = Low-volume. EO = Expert opinion. NA = Not applicable

TABLE 1 | CONTINUATION

VARIABLE	CENTER VOLUME	BASE VALUE	RANGE	DISTRIBUTION	SOURCE
For PTC					
Probability of PTC success	-	1.0000	-	Beta	EO
Probability of AEs after PTC	-	0.0500	0.0170-0.0830	Beta	[23]
Probability of PTC-related death	-	0.0032	0.0028-0.0036	Beta	[23]

Utilities

Quality-adjusted life-year (QALY) is a metric that quantifies utility and disease impact by integrating health-related quality of life (HRQoL) and life expectancy. The Tufts Medical Center CEA Registry [29] was used, complemented with a literature search, to identify studies reporting relevant utilities for the conditions mentioned in *TABLE 2*.

TABLE 2
Utilities included in the economic model. Legend: ERCP = Endoscopic retrograde cholangiopancreatography. AEs = Adverse events.

VARIABLE	BASE VALUE	RANGE	DISTRIBUTION	SOURCE
Utility before ERCP	0.800	0.608-0.990	Triangular	[15,30]
Utility after ERCP without or with non-significant AEs	0.885	0.810-0.990	Triangular	[12,15], EO
Utility after ERCP with significant AEs	0.760	0.660-0.860	Triangular	[12,15]

Considering several studies on ERCP [10–13,15,23,30–39], and in the absence of data to establish a specific QALY before ERCP that combined all indications for this procedure, we considered it reasonable to assume the utility for choledocholithiasis (0.8000), the most frequent indication for ERCP regardless of center volume [3], to be the value for the initial utility before ERCP procedure in the baseline case. The possible values range in sensitivity analysis from 0.608 (cholangitis) to 0.990 (incidental finding of CBD stones). The studies from Almario et al. [12] and Howard et al. [15] were selected to determine post-treatment utilities, as they were the only studies found to have utility values that differentiated the severity of AEs after ERCP. Because our study cohort was followed up over one year, no further discounting in utilities for patient age or life expectancy was performed. In the specific case of "utility after ERCP without or with non-significant AEs", we calculated an average of "no AEs" and "minor AEs". Furthermore, during the 1-year study timeline, it was assumed that there was no mortality from competing but unrelated causes.

Regardless of center volume, ERCPs were assumed to produce similar utilities. For the sake of simplicity and in line with other studies [12,23], we also assumed the utilities after PTC to have the same values as the ones after ERCP.

Costs

After conducting a literature review on costs in ERCP, several papers were identified [7,10–12,14,16,17,23,34,36] and reviewed. For this study, our health economic model considered only direct medical costs, from the health care provider's perspective (*TABLE 3* and *SUPPLEMENTAL MATERIAL – TABLES 2* and *3*). Data from Brinne Roos et al. [23] were selected, as only this study incorporated the costs of both ERCP and PTC (aggregated costs of procedures, supplies, medications, and salaries of doctors and nurses according to the number of professionals and length of procedure); as well as admission costs; these costs were discriminated according to the grade of AEs and including death (1-day admission was assumed for no/non-significant AEs and 4 days for significant AEs; aggregating costs of admission/day, medications/day, AEs and death). Because the costs were in 2016 Swedish Krona, they were converted into euros (€) [40] and updated to 2022 considering the inflation rate [41]. We only considered a 1-year time horizon in the model and thus no discount rates were applied to cost values.

TYPE OF PROCEDURE AND ADMISSION		BASE VALUE (2023 €)	SD / RANGE (€)	DISTRIBUTION	SOURCE
Admission for ERCP	without or with non-significant AEs	2,535€	209€	Log-normal	[23]
	with significant AEs	12,624€	1,207€	Log-normal	[23]
	with significant AEs and death	13,312€	1,275€	Log-normal	[23]
Admission for PTC	without or with non-significant AEs	1,655€	164€	Log-normal	[23]
	with significant AEs	11,743€	1,161€	Log-normal	[23]
	with significant AEs and death	12,432€	1,229€	Log-normal	[23]
Transportation from LV to HV center		139€	73 to 4,678€	Triangular	[23], EO

TABLE 3

Base-case cost estimates used throughout the analysis. Legend: ERCP = Endoscopic retrograde cholangiopancreatography. PTC = Percutaneous transhepatic cholangiography. AEs = Adverse events. SD = Standard Deviation. LV = Low-volume. HV = High-volume.

The same costs for HV and LV centers were assumed for the baseline case. This assumption was tested in one-way and probability sensitivity analyses, using a cost-coefficient applied to HV centers, signifying a decrease/increase in HV center costs of up to 25%. Moreover, we considered the possibility of requiring ambulance transportation to HV centers for the hypothetical scenario where all ERCPs were performed in HV centers. We assumed that approximately two-thirds of patients require this type of transportation (in line with the reference case), having a base value of 139€ (ranging from 73€ and 4,678€) [23] .

Cost-effectiveness analysis

The primary measurement used to ascertain the optimal strategy was the ICER, which is defined as the proportion of differences in costs and utilities between two treatments and is calculated as follows:

$$\text{ICER} = \frac{\text{Cost}_{\text{hypothetical}} - \text{Cost}_{\text{reference}}}{\text{QALY}_{\text{hypothetical}} - \text{QALY}_{\text{reference}}}$$

Where costs and QALY in the "reference" scenario were calculated for the group of 100,000 patients considering the current distribution of ERCPs between LV (67.44%) and HV (32.56%) centers [24], the "hypothetical" scenario corresponds to the new distribution in which all ERCPs are performed in HV centers. A willingness-to-pay (WTP) threshold of ICER of 53,635€ up to 107,271€ per QALY gained was used to determine whether the ICER of a given intervention is worth the investment by decision-makers.

Sensitivity analysis

Considering the degree of uncertainty, variability, and reliability inherent in a decision analytical model, several sensitivity analyses were performed to determine whether changes in input parameters could cause significant divergence from the baseline case results and allow the presentation of the results in an appropriate and robust way [42].

A *one-way sensitivity analysis* was conducted by sequentially varying each model parameter within a given range, defined from the literature search or the research team's opinion, to identify critical parameters of the model that could significantly change the final result. Model parameters used in this analysis are those in *TABLES 1-3*. The model was considered sensitive to a given parameter if the ICER shifted more than 10% from the baseline value; or the performance's ranking between the two ERCP distribution approaches ("hypothetical" versus "reference") was reordered concerning values obtained for cost-effectiveness, QALY or overall costs. Model sensitivity to a parameter was calculated as the absolute mean percentage change in the ICER from the baseline case divided by the absolute change in the parameter values. Additionally, only parameters that showed more than 0.5% sensitivity were considered. The outcomes of this analysis are the model's sensitivity to a specific parameter, along with the threshold values and ICERs for each parameter under the previously mentioned conditions, if applicable.

A two-way sensitivity analysis assessed the combined effect of changing the success rate and significant AEs for the index ERCP in LV centers. These parameters were changed in 1/100 increments of the value range. Thus, a total of 1,000 additional simulations were conducted.

A *probabilistic sensitivity analysis* (PSA) was conducted considering all model parameters to explore their uncertainty and impact on the final result. Hence, Monte Carlo simulations were utilized to study the model's response to randomly generated multiple input variables across 100,000 iterations. For each iteration, the model input parameters were randomly selected from probabilistic distributions, which were derived either from literature-based data or the clinical experience of our research team. One hundred thousand simulations were conducted for the PSA. Random data sets were generated from probability distributions and incorporated into the model during each iteration. Success and AE rates used beta distributions, utility metrics used triangular distributions, and cost data used log-normal or triangular distributions (*TABLES 1-3*).

RESULTS

Baseline case

As shown in *TABLE 4*, in the baseline case, the ICER was negative (-151,270€/year), benefiting from lower costs and slightly higher QALYs of the hypothetical scenario of having all ERCPs performed in HV centers, compared to the current distribution of patients for ERCP care described by the reference case.

This result's two main cost drivers were the costs related to repeating ERCPs due to technical failure, followed by costs related to significant AEs.

ASSUMPTION	QALYS	AVERAGE COST PER ERCP	ICER
ERCPs under current patient distribution model (performed in HV and LV centers – "reference" scenario)	0.0763	3,859€	-151,270€/year
ERCP under hypothetical patient distribution (performed only in HV centers – "hypothetical" scenario)	0.0819	3,014€	

TABLE 4

Results of the baseline case analysis. Legend: ICER: calculated using the current LV/HV centers distribution as "reference". Legend: ERCP = Endoscopic retrograde cholangiopancreatography. HV = High-volume. LV = Low-volume. QALYs: quality-adjusted life-years.

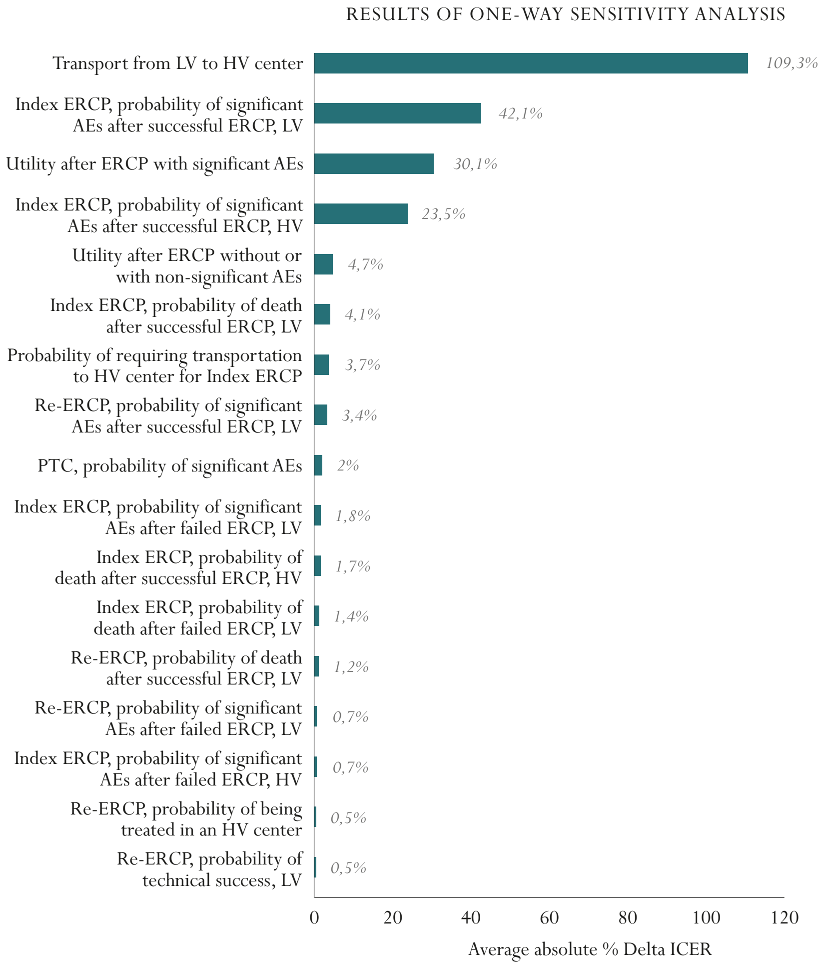
One-way and two-way sensitivity analyses

The different sensitivity percentages for parameters to which the model was determined to be sensitive are depicted in *FIGURE 2*.

SUPPLEMENTAL MATERIAL - TABLE shows the parameters to which the model was sensitive, the threshold values with corresponding ICERs, and the average model sensitivity percentages.

FIGURE 2

Results of one-way sensitivity analysis. Sensitivity was calculated as the percentage change in the ICER from the baseline case and presented as the average across the input value range. The ICER variations introduced by the parameter changes are summarized in the Supplemental Material - Table. Legend: ERCP = Endoscopic retrograde cholangiopancreatography. PTC = Percutaneous transhepatic cholangiography. AEs = Adverse events. HV = High-volume. LV = Low-volume.



The model was most sensitive to changes in the price of transportation (109.34%), followed by the probability of significant AEs after a successful ERCP at LV centers (42.12%), utility after ERCP with significant AEs (30.10%), and probability of significant AEs after a successful ERCP at an HV center (23.53%). Transportation cost changed the study outcome (centralization not cost-effective) if more than 3,655€. In addition, centralization would be more costly, but still cost-effective, if transportation costs more than 2,212€. The remaining parameters elicited a change in the ICER above 10% but did not change the cost-effectiveness profile of centralization or produce changes in the costs or utility ranking between the two approaches.

The results of the two-way sensitivity analysis comparing concurrent variations in the probability of technical success for the index ERCP and the significant AE rate at LV centers are represented in *SUPPLEMENTAL MATERIAL - FIGURE*. This analysis showed that the current approach to ERCP distribution (reference case) would only be cost-effective in the specific scenario of combined higher success rates (≥ 92.4% vs. 89.30% reference case) with a much lower significant AE rate (≤ 0.5% vs 6.7% in the reference case).

Probabilistic sensitivity analysis

FIGURE 3 shows a scatter plot of the PSA results. The plot shows the incremental costs versus the incremental QALYs for each iteration, comparing the hypothetical approach where the ERCP takes place at an HV center against the current approach in which some ERCPs are performed on patients at HV centers and others at LV centers, according to the probabilities shown in *TABLE 1*. For most of the iterations, there is a benefit of the centralized model, with all patients being directed to undergo ERCP at HV centers, with this strategy leading to lower costs, higher QALYs, or simultaneously lower costs and higher QALYs in 88.3%, 97.5%, and 87.1%, respectively, of the cases. At a WTP threshold of 53,635€ per QALY, performing ERCPs at centralized HV centers (T_1) was cost-effective in 87.1% of the simulations. At a WTP threshold of 107,271€ per QALY, this percentage was 94.12%.

RESULTS OF PROBABILISTIC SENSITIVITY ANALYSIS

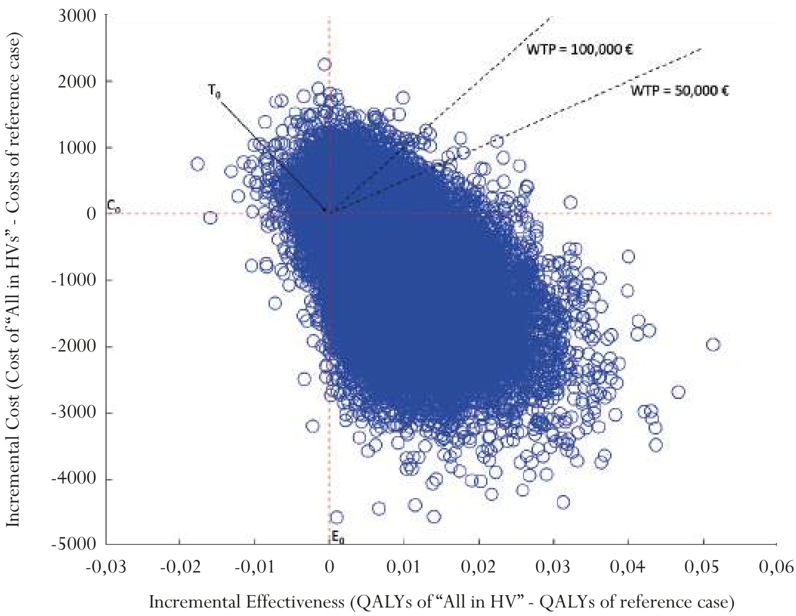


FIGURE 3

Scatter plot showing the results of the probabilistic sensitivity analysis.

Legend: NV = Not Valid; WTP = Willingness-To-Pay; T_0 = point of balance between current and hypothetical ERCP distributions, with a null incremental cost (C_0) and effectiveness (E_0); T1 = cost-effective iterations of hypothetical ERCP distribution, with ERCP centralization in HV centers, to the right of E0 and below the WTP thresholds.

DISCUSSION

The current study results indicate that centralizing ERCPs at HV centers is more cost-effective than distributing them across both LV and HV centers. This is due to reduced costs, increased QALYs, and a favorable ICER (ICER=-151,270€/year), primarily attributed to fewer repeated ERCPs following failures and significant AEs in HV centers. To our knowledge, no prior economic analyses have compared these settings, and the fact is that this centralized approach is not currently widely adopted, as, despite the existence of several LV centers that refer cases to HV centers, the rate of referral is low [24]. The one-way sensitivity analysis highlighted the significant economic impact of transportation and costs. The two-way analysis revealed that only if LV centers had a success rate of ≥ 92.4% and an AE rate of ≤ 0.5% would their distribution approach be cost-effective, a very improbable scenario, as even HV centers do not achieve such low AE rates. In the PSA, the primary conclusions remained consistent despite uncertainty regarding some values in our model.

Apart from higher endoscopist annual caseloads and cumulative experience at performing the procedure itself, overall periprocedural management can also be performed more efficiently due to the greater availability of resources and multidisciplinary teams, all justifying improved ERCP success and reduced AEs in HV centers [3].

While there are concerns about centralization [43,44], such as increased travel distances and patient waiting times, these may not be significant issues in many countries. Most countries have relatively compact sizes and efficient transport systems, and many LV centers are urban-based. Additionally, surveys indicate patients are open to longer travel distances for better healthcare quality [43]. Resource reorganization and incentives for HV centers could be introduced to mitigate potential waiting times due to centralization. Of note, as shown, increased procedural costs from such incentives could be offset by cost savings associated with improved outcomes associated with performing ERCPs at HV centers. Some may also assume that a limited spectrum of procedures in peripheral hospitals could lead to problems in allocating staff in LV hospitals, but LV centers could also focus on those services that they can deliver with high quality, considering their caseloads. Furthermore, for patients presenting in LV centers with cholangitis complicated by septic shock, the solution could pass by first stabilizing and posteriorly transferring them to an HV center where ERCP and all the periprocedural management could be better offered. Finally, in light of growing environmental concerns, it is also essential to consider the carbon footprint of centralizing ERCPs, as endoscopy procedures are known to be significant contributors to a hospital's CO^2 equivalent [45]. Notably, transportation using fossil fuels constitutes a significant portion of this carbon footprint. Balancing this against the CO^2 emissions related to hospital materials, medications, and energy consumption during hospitalization while accounting for the improved efficiency of HV centers is essential. Future research evaluating these environmental impacts alongside the cost-effectiveness can provide a more comprehensive understanding of the ecological implications of centralization.

Despite the added value of these results, some limitations must be addressed. First, as occurs in any decision analytic model, there is an intrinsic level of uncertainty and variability due to the need for using several data sources with different grades of methodological quality and the choices made concerning the inclusion of certain data. We attempted to overcome this drawback by performing sensitivity analyses, allowing us to draw more robust conclusions. Nonetheless, further studies are needed to define the criteria for LV and HV centers, update data on AE rates [25,26], and compare outcomes between successful and failed ERCPs and between ERCP attempts.

Moreover, data were collected from various literature sources, precluding the model from being specific to a single country's situation. Although the probabilities derive from countries with similar clinical resources, making them relevant for Europe and the United States, universal generalization is challenging since there cannot be a single centralization method suitable for all healthcare systems [44]. For example, transportation costs may significantly vary among countries. Once more, the sensitivity analyses enabled us to represent a wide range of clinical practices better.

Furthermore, due to data unavailability, other variables that surely contribute to the outcomes, such as the ERCP indication and grade of ERCP complexity [1], were not included in the model. As such, it was impossible to weigh the possibility of considering how less complex ERCPs might impact LV centers. Despite this possibility, and as mentioned above, we must consider that outcomes are influenced not only by the procedure performance *per se* but also by the overall patient management, which may not always be achieved at LV centers.

Another consideration is that only direct medical costs were retrieved, focusing especially on real-world healthcare scenarios as they pertain to the context of Sweden [23]. Although there is a shift towards patient-centered care [46], our study could not capture the patient's perspective, such as out-of-pocket expenses or societal costs like lost work hours, due to data constraints. Considering the burden for these patients and their families, possible solutions could include providing funding from the authorities or ensuring adequate mobility to reach these centers, which might be easily provided with the savings gained with this centralized service. It is worth noting potential extra costs in ERCP care reorganization, which were impossible to evaluate with the current data and should be further researched.

Finally, this is an analytical model, and population-based studies should be done to confirm this hypothesis.

Despite these limitations, this is the first study, to our knowledge, to evaluate ERCP cost-effectiveness based on center volume. Centralization has been shown to improve overall results in several fields, namely in pancreatic surgery [24,44,47]. In ERCP, foundational steps, the first steps are being established, such as the publication of guidelines for training, and credentialing [48], and quality assessment [21], as well as the implementation of mandatory ERCP registration [49]. These actions will offer insights into ERCP performance across countries, highlighting potential areas for service reorganization and possible implementation of ERCP centralization where warranted.

In sum, the robustness of our findings, associated with current increased healthcare restraints, supports the need to weigh the principle of ERCP centralization into HV centers with high-performance rates and lower costs, to increase the likelihood that patients are treated at appropriate hospitals and to improve quality of care.

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SECTION IV

General Discussion

CHAPTER 11

Summary of the chapters, conclusions and future perspectives

SUMMARY OF THE CHAPTERS

As digestive endoscopy becomes increasingly specialized, incorporating a growing array of complex procedures like ERCP and EUS, the imperative to deliver precise and effective care becomes more pronounced. In this context, attaining proficiency through specialized training and sustaining expertise by adhering to stringent high-performance standards is crucial. Through the several chapters detailed below, this Ph.D. thesis endeavored to assess the current landscape of ERCP/EUS training (Section II) and ERCP performance (Section III), proposing strategies to improve the effectiveness and standards of care in the endoscopic management of biliopancreatic diseases.

In Chapters 2, 3 and 4, this thesis began with an exploration of ERCP and EUS training, recognizing these procedures as some of the most intricate and high-risk within GI endoscopy. Establishing rigorous quality standards in training programs is crucial due to the complexity and potential risks involved [1,2]. Through collaborative discussions and consensus within a working group comprising experts in ERCP and EUS training across Europe, European curricula for ERCP and for EUS training were proposed (**Chapter 2** and **Chapter 3**). These curricula outline prerequisites before training, a stepwise training approach and finally incorporate quality measures and assessment tools for pre-independent practice evaluation and competence assessment. In essence, these statements advocate for a formal and standardized ERCP/EUS training, emphasizing the necessity of prior basic GI endoscopy competence. The recommended training duration is a minimum of twelve months in HV training centers that provide a multidisciplinary approach to pancreaticobiliary diseases and actively engage in research and service improvement initiatives. The training should be complemented with various learning resources, including simulation-training where feasible. Certification of competence before independent practice initiation is paramount, and this assessment should extend beyond the completion of a specific number of procedures and include a formal competence assessment, evaluating multiple performance quality criteria, both technical and cognitive. However, it is crucial to acknowledge the limited level of evidence supporting many of the formulated statements, emphasizing the need for further studies to comprehensively address all aspects of ERCP/EUS training and determine optimal strategies for delivering effective training in these advanced endoscopic techniques.

The position statements published in Chapters 2 and 3 were further complemented in **Chapter 4**, by compiling specific tips from ERCP experts to guide trainees towards success. Given that experts are acknowledged for their mastery of the technique and superior performance, understanding their professional path, and leveraging their advice becomes invaluable for trainees aspiring to follow a similar trajectory. A web-based survey was conducted, gathering responses from fifty-three experts worldwide, to pinpoint pivotal aspects of their professional development. The survey revealed that ERCP training, often in conjunction with EUS, frequently occurred in a department different than the one where the initial internship was completed. Experts typically commenced their training early, undergoing an extensive training lasting an average of twenty-seven months, complemented by active involvement in research within the field. The critical investments for success in ERCP were identified as time and consistent practice, and the choice of a suitable mentor. Experts consistently stressed the importance of qualities such as resilience, attentiveness, and a commitment to patient safety in their advice to trainees. Despite inevitable obstacles, such as the challenge of finding dedicated time for training and facing peer competition that may impact motivation and resilience, experts highlighted the significance of maintaining humility and modesty, sustaining ongoing training, fostering connections with colleagues, and cultivating critical thinking skills to overcome these challenges.

Conversely, it was crucial to assess the adoption of the requisites proposed in Chapters 2 and 3 and identify potential limitations to their implementation. Employing the same methodology as previously outlined in Chapter 4, **Chapter 5** delved into this inquiry by reaching out to various training centers across different countries. This provided an initial overview of ERCP/EUS training programs in Europe. The study confirmed a substantial demand for ERCP/EUS training programs, with the current application process being primarily driven by subjective evaluations based on individual requests. Notably, all surveyed departments were HV centers, equipped with adequate facilities, competent trainers, and offering long-term fellowships with combined ERCP/EUS training. However, the hands-on exposure for trainees was found to be relatively low. Additionally, only around half of the centers adopted a formal curriculum with a structured guiding syllabus, and there was limited exposure to simulation-training. Furthermore, competence was not formally assessed uniformly across all departments. These findings underscore that, despite increased awareness and efforts to enhance the quality of training through the development and dissemination of international guidelines, the ability of European fellowships to adhere to these standards remains insufficient in relation to the parameters mentioned above.

Considering the operator-dependent nature of ERCP/EUS procedures [3], identifying the ideal candidates to enter this field is of utmost importance, a topic explored in **Chapter 6**. Given that the current selection process heavily relies on subjective assessment by program directors, as stated in Chapter 5, we conducted a study using a questionnaire to uncover the values and beliefs of training program directors regarding the personal attributes they prioritize in trainee selection. Both experts and trainees were invited to participate, allowing us to compare perspectives. The key qualities highly valued in ERCP/EUS trainees include honesty, teamwork, self-awareness, openness to feedback, enthusiasm, clinical judgement, technical skills, work ethic, perseverance, decision-making ability, willingness to work hard, having a calm and patient temperament, as well as being capable of creative and critical thinking. Notably, cognitive and personality traits were deemed more crucial than technical skills. The findings from this study are important for developing effective and standardized application processes that consider both technical skills and non-technical skills and ensuring the selection of trainees with the right attributes to perform high-quality and safe ERCP.

Acknowledging the need for a specific training in these advanced endoscopic techniques, as specified in Chapters 2 and 3, and the inherent difficulties, it is essential to seek improvement measures. Addressing a key research question identified in the ERCP/EUS curriculum, the potential enhancement of learning through the integration of simulation-training, emerges as a focal point. Chapter 5 underscored the discrepancy between the expected number of procedures during training and the recommended minimum for independent practice. Simulation-training could offer a promising solution, allowing trainees to acquire skills at their own pace, and providing the opportunity for repetitive practice without extending procedure time. Despite these advantages, endoscopy simulators have not been seamlessly integrated into regular formal training programs. This may be attributed to the limited access to biological ex-vivo simulators, the scarcity of realistic mechanical simulators and their insufficient validation in clinical practice [4]. To address the realism concern, **Chapter 7** presented a face and content validation study on a biological papilla composed of chicken heart tissue, incorporated into the Boškoski-Costamagna ERCP Trainer for sphincterotomy training. The Boškoski-Costamagna ERCP Trainer simulator training model [5–7] stands out as one of the most esteemed prototypes for ERCP training. In its earlier version, the simulator utilized a single-use synthetic papilla. While this synthetic papilla was considered satisfactory in terms of overall realism for sphincterotomy, it encountered limitations in haptic feedback of the cutting process, which was not perceived as expected [8]. Recognizing the high-risk nature of sphincterotomy [1], addressing its training in the most effective way is crucial. This necessity justified the enhancement of the simulator. The newly introduced chicken-heart tissue papilla closely mirrors a real major papilla in size, shape, and color. Our results showed a high realism, not only for sphincterotomy training but also for precut and papillectomy procedures. With its affordability, ready availability, versatility, and user-friendly design, this tool now enables training for ERCP interventions on a simulator in a realistic manner. According to experts' opinion, this novel tool should be incorporated into the curriculum for novice and intermediate trainees. The present work was also an example of how educational tools, such as mechanical simulators, can be developed, progressively improved, and assessed by both trainers and trainees.

Simulation training was further addressed in **Chapter 8**, through a prospective, multicenter, parallel-arm, randomized controlled trial, aimed to evaluate the clinical impact of Boškoski-Costamagna ERCP Trainer, specifically investigating whether training with it confers additional benefits beyond standard training. This novel study, the largest of its kind, involved 1.106 ERCPs performed by sixteen trainees across ten different departments in four European countries. The simulation group exhibited a higher success rate in native biliary cannulation and demonstrated a faster overall performance acquisition, particularly in native biliary cannulation and biliary sphincterotomy. These outcomes carry profound implications for ERCP training. The incorporation of simulation training into ERCP programs has the potential to shorten the time required for trainees to attain competence, thereby optimizing the efficient utilization of training resources. Moreover, the identification of specific ERCP steps, such as biliary cannulation and sphincterotomy, where simulation training yields substantial benefits is crucial, given their association with higher AEs rates. Strengthening proficiency in these areas through simulation training holds promise for potentially enhancing patient outcomes. In conclusion, this study provided a rationale to consider the integration of initial simulation training with Boškoski-Costamagna ERCP simulator in ERCP training programs.

In addition to training, Section III of this thesis addressed factors related to ERCP performance. **Chapter 9** undertook a systematic review and meta-analysis to assess the potential influence of ERCP volume per center and endoscopist on ERCP outcomes. A thorough literature search spanning from inception to March 2022, incorporating 31 studies, was conducted. The results suggested that ERCP success is higher and adverse events (AE) rates lower when performed by high-volume (HV) endoscopists or in HV centers. Specific AEs were also examined, revealing a slight predominance of post-ERCP pancreatitis in low-volume (LV) centers, with no significant differences in perforation or cholangitis among assessed subgroups. Notably, bleeding related to ERCP was found to be lower in HV endoscopists compared to LV endoscopists. Furthermore, a sensitivity analysis using a threshold of 200 procedures to differentiate HV from LV endoscopists and centers helped mitigate result heterogeneity. These findings align with the notion that ERCP outcomes are operator-dependent, emphasizing the importance of performing the procedure in HV-centers and by experienced endoscopists capable of delivering optimal care.

To complement this assessment, it was essential to consider the associated costs. The promotion of cost-effective and quality care is a critical aspect of healthcare provision amid rising healthcare expenses and limited resources [9]. In **Chapter 10**, an economic analysis was conducted to measure the impact of quality-of-care delivery in ERCP. The study explored the relationship between center volume, clinical outcomes, and ERCP costs, performing a comprehensive cost-effectiveness analysis to explore the hypothesis that HV centers performing ERCP may deliver higher quality at lower costs than LV centers. Despite evidence supporting the improvement of overall outcomes through centralization in various fields, such as pancreatic surgery, the ERCP landscape lacked sufficient data. Our study found that, indeed, the hypothetical scenario of all ERCPs being performed in HV centers proved to be a cost-effect approach. To the best of our knowledge, this study marks the first attempt to evaluate ERCP cost-effectiveness based on center volume. While acknowledging the considerations of the potential burden on patients and the healthcare system posed by centralization, as recognizing scenarios where centralization may not be feasible or necessary, the principle of centralization of ERCPs into HV centers with superior performance rates and lower costs should be weighed for future implementation. This approach aims to increase the likelihood that patients receive treatment at appropriate hospitals, ultimately enhancing the overall quality of care.

CONCLUSIONS

Considering the comprehensive data presented in this Ph.D. thesis, several key conclusions can be drawn:

> The introduction of curriculums for ERCP and EUS training in Europe has been a positive initiative aimed at enhancing knowledge and skills acquisition and standardization of clinical practices.

> Despite the acknowledged importance of standardized trainee selection process, it remains predominantly subjective.

> The selection process for ERCP/EUS training should not only assess technical endoscopic skills but also incorporate a focus on non-technical cognitive and soft skills.

> Gaps persist in meeting recommendations for ERCP/EUS training programs in Europe. These gaps include insufficient hands-on exposure to simulators and to real-life procedures, a lack of adoption of a structured curriculum, and a deficiency in adopting formal competence assessments.

> The updated Boškoski-Costamagna ERCP Trainer model simulator, featuring a biological papilla made of chicken heart tissue, has proven beneficial with good face and content validity.

> The integration of ERCP simulators, particularly the Boškoski-Costamagna ERCP Trainer simulator, optimized basic training. This simulator has demonstrated improvements in native biliary cannulation rates and in learning curves for overall performance, as well as for specific ERCP steps, such as native biliary cannulation and sphincterotomy.

> The recommendation that ERCP should be conducted by HV endoscopists in HV centers holds true for improving success rates and reducing associated AE.

> Centralizing ERCP procedures in HV centers emerges as a cost-effective approach, as these centers tend to demonstrate superior performance at lower costs.

FUTURE PERSPECTIVES

To further enhance the quality of ERCP/EUS services in Europe, ongoing efforts are essential to continuously elevate healthcare standards across multiple dimensions. In line with this commitment, the following projects are envisioned to build upon the foundation laid by this doctoral research, addressing specific aspects of ERCP practices:

Assessing ERCP in Belgium: Center Volume Impact on Performance, Costs, and Carbon Footprint

Teles de Campos, S, Arvanitakis M, Devière J, Lemmers A

The systematic review and meta-analysis detailed in Chapter 9 revealed a correlation between ERCP clinical outcomes and the annual caseload of the performing center. Chapter 10 emphasized the superior performance and cost-efficiency of HV centers, sparking considerations about ERCP centralization to enhance quality of care. However, it is crucial to acknowledge that the decision analytic model used various data sources and relied on certain assumptions, introducing some uncertainty, and limiting the model's specificity to the circumstances of a specific country. Furthermore, ERCP training challenges identified in Chapter 6, are possibly influenced by the current distribution of ERCP procedures. Beyond performance and cost data limitations, environmental impact, particularly in the case of ERCP, has not been studied extensively [10].

This project aims to assess the economic and environmental impact of ERCP across different center volumes in Belgium. The current reality in Belgium will be compared with a hypothetical ERCP centralization in HV centers. We hypothesize that HV centers may demonstrate distinct outcomes, costs, and environmental impact. To achieve this, a prospective, observational, multicenter trial involving all ERCP performing centers in Belgium will be conducted. The study will assess ERCP performance, through a specific questionnaire, quality of life in patients undergoing ERCP through the EuroQol survey [11], ERCP costs through collaboration with the billing department of Erasme Hospital, Belgium, and carbon footprint in ERCP, through collaboration with a specialized company. Primary outcomes include the average cost-effectiveness ratio and the estimated quantity of CO_2 equivalent per ERCP in HV centers and LV centers in Belgium. Secondary outcomes involve the incremental cost-effectiveness ratio comparing the current scenario of ERCP in Belgium across HV and LV centers with a hypothetical situation where ERCP would be centralized in HV centers.

Advancing ERCP Skills by Tele-mentoring: the ADVERT study

Voiosu T, Boškoski I, Teles de Campos S, Voiosu A, Bengus A, Diaconu C, Birligea M

In addition to simulation training, the implementation of other strategies is essential to facilitate trainee competence in ERCP. Telemedicine serves as a noteworthy example of how developments in information technologies may bridge competence transfer across geographically distant institutions. A parallel study conducted during the Ph.D. period focused on volunteer work done in Sao Tome and Principe, Africa, addressing the establishment of a GI endoscopy department in a lower middle-income country [12]. While outlining the blueprint for creating a GI department to meet basic GI needs, the study emphasized the integration of telemedicine. This web platform was purposefully designed to provide consistent support to local teams and enhance their capacity. Through features like videoconferencing and real-time sharing of endoscopy images and clinical data, telemedicine has facilitated remote assistance during endoscopy procedures. This pioneering project sparked the idea of extending its application to teleguide other endoscopic procedures, such as ERCP, and supporting professionals in LV centers.

The ADVERT study aims to assess the feasibility, safety and efficacy of a tele-training intervention designed to enhance the technical skills and performance of non-expert ERCP endoscopists. Consecutive ERCP procedures conducted in a training center (Colentina Clinical Hospital, Romenia) by independent operators with a total experience of < 500 ERCPs will be randomly assigned in a 1:1 ratio to an active group and a control group. Procedures in the active group will involve supervision and verbal instructions from an expert trainer connected remotely through a web-based application providing live video streaming from the endoscopy suite, including endoscopy and fluoroscopy images. All study procedures will be recorded in both groups and subsequently edited to enable blinded assessment of technical performance by independent experts using the validated Bethesda ERCP Skill Assessment Tool [13]. The results of this study could offer insights on how to maintain a mentoring setting, even after training, during the first period of independent practice.

Validation of a simple clinical risk score (TIERS) for prediction of ERCP-related adverse events in a training setting

Voiosu T, Teles de Campos S, Boškoski I, Voiosu A, Arvanitakis M, Devière J

The limitation of attaining the thresholds outlined in the ERCP European curriculum, Chapter 2, using the current training models has been established in Chapter 6, revealing a relatively restricted hands-on involvement for ERCP trainees. For an ERCP novice, it may take several months to accumulate a sufficient number of relatively simple cases before progressing to more complex ones. Clinical-based predictive tools, such as the Trainee Involvement in ERCP Risk Score (TIERS), could offer potential enhancements to ERCP training by facilitating the personalized selection of cases for hands-on training, mitigating patient exposure to higher risks. TIERS was developed by identifying specific pre-procedural clinical predictors (ERCP indication, bilirubin level, previous ERCP failure, native papilla), enabling the classification of patients into low or high risk for ERCP-related AEs in a training environment [14].

Our objective is to validate the TIERS score in a real-life setting to customize ERCP training, enabling novice endoscopists to initiate training with selected, low-risk cases, thereby enhancing patient safety. To achieve this, a post-hoc analysis of data collected in the simulation trial (Chapter 8) will be undertaken. Procedure-related and safety outcome data from ERCP procedures with varying degrees of trainee hands-on involvement will be extracted from the prospectively updated database. Procedures will be categorized as high-risk (TIERS > 1 point) or low-risk (TIERS 0 or 1) based on predefined criteria. Subsequently, we will compare the occurrence rates of procedure-related AEs, as defined by the ESGE guidelines [1], between the high and low-risk groups.

In conclusion, the findings elucidated and discussed in this Ph.D. thesis provide valuable insights into enhancing the endoscopic care of patients with biliopancreatic diseases. The presented results offer several avenues for future research, with the ongoing goal of continuously advancing performance within the realms of ERCP and EUS.

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Appendix

Appendix I:
Supplementary material for Chapter 4

Appendix II:
Supplementary material for Chapter 5

Appendix III:
Supplementary material for Chapter 6

Appendix IV:
Supplementary material for Chapter 7

Appendix V:
Supplementary material for Chapter 8

Appendix VI:
Supplementary material for Chapter 9

Appendix VII:
Supplementary material for Chapter 10

Appendix I

Supplementary material for Chapter 4

APPENDIX I
Supplementary material for Chapter 4

Web-based survey to the ERCP Experts

ERCP is one of the most challenging advanced endoscopy procedures. It is an operator-dependent technique that requires unique technical, cognitive and integrative skills.

As ERCP training traditionally adopts the apprenticeship model, it makes sense to follow the advice from Experts and take them as role models.

Indeed, understanding the professional trajectory of ERCP Experts, the investments they made and the obstacles they overcame can serve as a good example for the younger ones who ambition to follow the same success path in this area.

In this regard, being an ERCP Expert, we would kindly ask your participation in the following questionnaire:

1. In which hospital and city do you work?
2. Did you do your specific ERCP/EUS training? If yes, for how long? And where (institution, city)?
3. Did you learn ERCP and EUS at the same time or sequentially? Please specify the training time-frame for each technique.
4. How old were you when you began your advanced endoscopy training?
5. At that time, had you already finished your basic GI endoscopy training or did you learn basic and advanced endoscopy simultaneously?
6. Did you have any previous experience in another advanced endoscopy procedures before starting ERCP/EUS training (e.g., EMR, ESD)? If yes, please specify the techniques and tell us if it helped you.
7. Besides apprenticeship model on patients, did you have any other modalities for deepening your training? If yes, please specify which ones (e.g., simulators).
8. How long (number of years) did it take for you to start performing ERCP/EUS independently?
9. How long (number of years) did it take for you to accomplish a total of around 1000 ERCP/EUS procedures (each)?
10. When you started performing ERCP/EUS independently, how many colleagues also did these procedures in your department?
11. When you started performing ERCP/EUS independently, how many procedures were done, in average, in your department?
12. Have you completed a Phd thesis? If yes, at what age? In which area?
13. Did you develop research studies in ERCP/EUS while performing training?

14. What was the best and most worthwhile investments have you made to develop these techniques?
15. Which areas outside endoscopy / medicine have you developed that you consider have contributed to your technical development in ERCP/EUS?
16. What are the 3 most determining factors to get where you've arrived?
17. What were the 3 best advices you received as a trainee to accomplish the same goals as you did?
18. What were the 3 biggest obstacles to your training and how did you overcome them?
19. How has a "failure" set you up for later success?
20. What is the worst advice anyone gave you in your area of expertise?
21. Please name three sources or people you've learned from, or followed closely, during your path:
22. What is the best decision you have made in your career?
23. Is there a quote that guides your professional life?
24. What has become more important to you in the last few years and what has become less important and why?

Thank you very much for your time and contribution!

Appendix II

Supplementary material for Chapter 5

APPENDIX II
Supplementary material for Chapter 5

1s.Web-based survey to the ERCP Experts

The following questions concern ERCP/EUS training programs carried out in your department:

1. In which **department** do you work?
2. Which type of **procedures** do you offer in your advanced endoscopy fellowship programs:
    a) ERCP
    b) EUS
    c) ERCP and EUS
    d) Other
    2.1 If you answered "Other" in question 2, please specify which type of procedures are also offered:
3. What is the average duration of the AGIE fellowship in your department (in months)?
    3.1 Is there a minimum **duration** for a hands-on ERCP/EUS fellowship in your department (in months)?
4. What is the approximate annual **volume** of the following AGIE procedures in your centre?

PROCEDURES	<100/Y	100-200/Y	200-300/Y	300-400/Y	400-500/Y	>500/Y
EUS						
ERCP						

5. For EUS, how many AGIE **trainees**, in average, are accepted at your department per year?
6. For ERCP, how many AGIE **trainees**, in average, are accepted at your department per year?
7. How many EUS **trainers** do you have at the moment in your department?
8. How many ERCP **trainers** do you have at the moment in your department?
9. How many years, in average, have your **trainers** been performing ERCP/EUS independently (<3y, 3-10y, > 10y)?

10. How is the **application process** conducted in your department (Select all that apply)?

   a) Through individual application
   b) Through a Society endoscopy fellowship grant
   c) Through payment of an application fee
   d) Through a CV
   e) Through a motivation letter
   f) Through a recommendation letter
   g) Through a formal interview
   h) Through a theoretical evaluation
   i) Through a practical evaluation

   10.1 If there is any other method you use for the application process, please specify it:

11. According to your opinion, please indicate the importance of the following criteria for **trainee acceptance in your AGIE training program:**

   11.1 You may further comment your opinion regarding any of the options discussed in question 11:

CRITERIA EVALUATED FOR TRAINEE ACCEPTANCE	EXTREMELY IMPORTANT	VERY IMPORTANT	MODERATELY IMPORTANT	SLIGHTLY IMPORTANT	NOT IMPORTANT
Age					
Gender					
Motivation letter					
Recommendation letter					
Curriculum Vitae					
Research experience					
European Board of Gastroenterology and Hepatology examination score					
Honours awarded					
Membership of endoscopy societies					
Appreciation in the interview					
Theoretical knowledge					
Endoscopic skills					

11.2 From all the criteria you considered to be "extremely important" to be evaluated before acceptance in the training in question 11, please select the 3 you consider to be the most crucial ones:

11.3 Are there any other valuable criteria that you consider to be worth mentioning for trainee's evaluation before acceptance in an AGIE training program?

12. Does your training program have a formal ERCP/EUS **curriculum**? Yes / No

12.1 If "yes" to question 13, does this ERCP/EUS curriculum formally include (Select all that apply)?

a) Observation only

b) Dedicated "hands-on" training

c) Didactic sessions/courses

d) Endoscopy simulator training

12.1.1 If there is any other parameter(s) included in your endoscopy curriculum, please specify it:

13. Does your training centre provide any of the following **facilities** (Select all that apply):

a) Multidisciplinary hepaticopancreaticobiliary meetings

b) Onsite hepaticopancreaticobiliary surgery

c) Onsite interventional radiology

d) Trainee's involvement in research and service improvement initiatives

e) ERCP and EUS simulation

14. Please select the 3 institutional facilities you consider the most important for the development of trainees' ERCP/EUS endoscopic skills:

INSTITUTIONAL FACILITIES FOR DEVELOPMENT OF TRAINEES' SKILLS	RATING (FROM 1 TO 8)
Department dedication to teaching (Vs throughput/efficiency/service)	
Volume of procedures	
Diversity of cases and procedures	
Dedicated time for fellowship without interruption	
Availability of endoscopy simulators	
Didactic sessions	
Dedicated trainers	

14.1 You may further comment your opinion regarding any of the option discussed in question 16:

14.2 If there is another institutional facility that you consider important for the development of ERCP/EUS endoscopy trainees' skills, please specify it:

15. Does your training program make available the use of endoscopy **simulators**? Yes / No

15.1 If you replied "yes" to question 17, please specify what type of simulators do you use:

a) Mechanical simulators

b) Virtual reality simulator

c) Animal models (*in vivo*)

d) Animal models (*ex vivo*)

15.1.1 Please specify name(s) of the simulator(s) used in your department:

15.2 If you replied "yes" to question 17, please indicate at what stage of the training do your trainees train in simulators:

a) Before starting hands-on training

b) At the beginning of hands-on training, to complement

c) During all hands-on training period

16. Do you perform any formal **assessment** during your ERCP/EUS training programs? Yes / No

16.1 If you replied "yes" to question 18, please specify when do you perform the assessment:

a) At set intervals throughout fellowship

b) Randomly throughout fellowship

c) At the end of fellowship

d) Other timing

16.1.1 If you replied "Other timing" in question 18.1., please specify when:

16.2 If you replied "yes" to question 18, please specify what is the method(s) used to assess whether the trainee achieved endoscopic competence in ERCP/EUS (Select all that apply)?

a) Achievement of certain benchmarks (e.g. procedure volume)

b) Written attending evaluations

c) Verbal attending evaluations

d) Adequate performance on a skills assessment tool - if yes, please specify which:

e) Adequate performance on specific quality metrics (e.g. cannulation rate, stone removal, stent placement, safety of ERCP, tissue sampling in EUS-FNA, documentation of EUS landmarks)

16.3 Is it recommended the use of a self-assessment tool in your department? If yes, please specify which one:

16.4 According to your opinion, please indicate the importance of the following parameters in assessing ERCP/EUS trainee's competence:

CRITERIA EVALUATED FOR TRAINEE'S ASSESSMENT OF COMPETENCE	EXTREMELY IMPORTANT	VERY IMPORTANT	MODERATELY IMPORTANT	SLIGHTLY IMPORTANT	NOT IMPORTANT
Procedures volume					
Knowledge of procedure indications and contraindications					
Appropriate informed consent discussion					
Appropriate selection and use of sedation					
Monitoring patient discomfort/experience					
Appropriate antibiotic prophylaxis before ERCP/EUS					
Recognition of anatomic landmarks					
Recognition of pathology (e.g. identification of a suspicious mass in EUS)					
Appropriate selection of therapeutic manoeuvres/tools					
Independent procedure completion rates					
Reporting					
Complication rates					
Correct surveillance/follow-up recommendations					

16.4.1 You may further comment your opinion regarding any of the option discussed in question 18.4.

16.4.2 Is there any other valuable parameter that you consider to be worth mentioning while assessing ERCP/EUS trainee's competence?

17. What are your feelings regarding the current ERCP/EUS training programs provided by your department?

Opinion regarding parameters of your training program	Extremely satisfied	Very satisfied	Neutral	Somewhat unsatisfied	Not at all satisfied
Overall quality of endoscopy training					
Trainee's selection process					
Environment/Facilities of your institution					
Overall competence assessment					

17.1 You may further comment your opinion regarding any of the options discussed in question 19:

Thank you for your time and contribution!

2s. Web-based survey to ERCP and EUS Trainees

The following questions concern ERCP/EUS training programs carried out in your department:

1. In which **country** are you doing your ERCP/EUS training fellowship?
2. When did you **start** your ERCP/EUS training program (DD-MM-YY)?
3. What is the **duration** of your ERCP/EUS fellowship (months)?
4. How many **procedures**, in average, have you done thus far in this EUS/ERCP fellowship?

AGIE PROCEDURES DONE SO FAR	<50/Y	50-100/Y	150-200/Y	>200/Y
EUS				
ERCP				

5. How many procedures, in average, do you expect to have completed by the end of your AGIE training?

AGIE PROCEDURES EXPECTED TO BE DONE	<50/Y	50-100/Y	150-200/Y	200-250/Y	250-300/Y	>300/Y
EUS						
ERCP						

6. How many total EUS **trainees** are also training at your department, at the moment?
7. How many total ERCP **trainees** are also training at your department, at the moment?
8. With how many EUS **trainers** are you learning in your department?
9. With how many ERCP **trainers** are you learning in your department?
10. How did you **apply** for this ERCP/EUS training program (Select all that apply)?
    a) Through individual application
    b) Through a Society endoscopy fellowship grant
    c) Through payment of an application fee
    d) Through a CV
    e) Through a motivation letter
    f) Through a recommendation letter
    g) Through a formal interview

h) Through a theoretical evaluation

i) Through a practical evaluation.

10.1 If there is any other method that have been used for the application process, please specify it:

11. Does your ERCP/EUS training program have a formal **curriculum**? Yes / No

11.1 If you replied "yes" to question 18, does this ERCP/EUS curriculum formally include: (Select all that apply)

a) Observation only

b) Dedicated "hands-on" training

c) Didactic sessions/courses

d) Endoscopy simulator training

11.1.1 If there is any other parameter(s) included in your endoscopy curriculum, please specify it:

12. Does your training centre provide any of the following facilities (Select all that apply):

a) Multidisciplinary hepaticopancreaticobiliary meetings

b) Onsite hepaticopancreaticobiliary surgery

c) Onsite interventional radiology

d) Trainee's involvement in research and service improvement initiatives

e) ERCP and EUS simulation

13. Please select the 3 institutional **institutional facilities** you consider the most important for the development of trainees' ERCP/EUS endoscopic skills:

INSTITUTIONAL FACILITIES FOR DEVELOPMENT OF TRAINEES' SKILLS	RATING (FROM 1 TO 8)
Department dedication to teaching (Vs throughput/efficiency/service)	
Volume of procedures	
Diversity of cases and procedures	
Dedicated time for fellowship without interruption	
Availability of endoscopy simulators	
Didactic sessions	
Dedicated trainers	

13.1 You may further comment your opinion regarding any of the options discussed in question 20:

13.2 If there is another parameter that you find very important in the development of trainees' ERCP/EUS endoscopic skills, please specify it:

14. Does your training program make available the use of ERCP/EUS simulators? Yes / No

14.1 If you replied "yes" to question 21, please specify what type of simulators?

a) Mechanical simulators

b) Virtual reality simulators

c) Animal models (*in vivo*)

d) Animal models (*ex vivo*)

14.1.1 Please specify the name(s) of the simulator(s) used in your department:

14.2 If you replied "yes" to question 21, please indicate at what stage of your training do/did you use simulators:

a) Before starting hands-on training

b) At the beginning of hands-on training, to complement

c) During all hands-on training period

15. Do you have any formal **assessment** during the ERCP/EUS training program? Yes / No / I don't know

15.1 If you replied "yes" to question 22, please specify when are you evaluated?

a) At set intervals throughout fellowship

b) Randomly throughout fellowship

c) At the end of fellowship

d) Other timing

e) Not sure

15.1.1 If you replied "Other timing" in question 22.1, please specify when:

15.2 If you replied "yes" to question 22, please specify what is the method used to assess whether you have achieved competence in ERCP/EUS:

a) Achievement of certain benchmarks (e.g. procedure volume)

b) Written attending evaluations

c) Verbal attending evaluations

d) Adequate performance on a skills assessment tool - if yes, please specify which:

e) Adequate performance on specific quality metrics (e.g. cannulation rate, stone removal, stent placement, safety of ERCP, tissue sampling in EUS-FNA, documentation of EUS landmarks)

15.3 Do you use any self-assessment tool? If yes, please specify which one:

16. What are your feelings regarding your current AGIE training program?

OPINION REGARDING PARAMETERS OF YOUR TRAINING PROGRAM	EXTREMELY SATISFIED	VERY SATISFIED	NEUTRAL	SOMEWHAT UNSATISFIED	NOT AT ALL SATISFIED
Overall quality of endoscopy training					
Trainee's selection process					
Environment/Facilities of your institution					
Overall competence assessment					

16.1 You may further comment your opinion regarding any of the options discussed in question 23:

Thank you for your time and contribution!

Appendix III

Supplementary material for Chapter 6

APPENDIX III
Supplementary material for Chapter 6

1a. Web-based survey to the ERCP and EUS Training Program Directors

Section 1: General data and opinion regarding application process and trainees selection

1. In which hospital and city do you work?
2. Please rate your **satisfaction with the current process of ERCP/ EUS trainee selection** in your department:
   a) Extremely satisfied
   b) Very satisfied
   c) Moderately satisfied
   d) Slightly unsatisfied
   e) Not satisfied
3. Please rate your **satisfaction with the trainees** who graduated from your ERCP/EUS fellowship program in the last 5 years:
   a) Extremely satisfied
   b) Very satisfied
   c) Neutral
   d) Somewhat unsatisfied
   e) Not at all satisfied

   3.1 If you answered "neutral" or less in question 3, please explain further your opinion:
4. How is the application process conducted in your department (Select all that apply)?
   a) Through individual application
   b) Through a Society endoscopy fellowship grant
   c) Through payment of an application fee
   d) Through a CV
   e) Through a motivation letter
   f) Through a recommendation letter
   g) Through a formal interview
   h) Through a theoretical evaluation
   i) Through a practical evaluation

Section 2: Current application process for ERCP/EUS training programs

5. How is the **application process** for ERCP/EUS fellowship conducted in your department (Select all that apply)?

   a) Through individual application

   b) Through a Society endoscopy fellowship grant

   c) Through payment of an application fee

   d) Through a CV

   e) Through a motivation letter

   f) Through a recommendation letter

   g) Through a formal interview

   h) Through a theoretical evaluation

   i) Through a practical evaluation

   5.1 If there is any other method you use for the application process, please specify it:

Section 3: Qualities for trainees to excel in ERCP/EUS training

6. According to your opinion, please rate how much you value the following trainee's **characteristics to excel in ERCP/EUS training:**

CHARACTERISTICS OF AGIE TRAINEES	EXTREMELY IMPORTANT	VERY IMPORTANT	MODERATELY IMPORTANT	SLIGHTLY IMPORTANT	NOT IMPORTANT
Enthusiasm and interest					
Clinical judgement (patient-oriented clinical practice)					
Technical skills					
Able to cope well in highly pressurised and demanding contexts					
Open to feedback and self-improvement					
Maturity					
Initiative					
Completes tasks on time					
Honesty					
Perseverance and resilience					
Hard working					

TABLE | CONTINUATION

CHARACTERISTICS OF AGIE TRAINEES	EXTREMELY IMPORTANT	VERY IMPORTANT	MODERATELY IMPORTANT	SLIGHTLY IMPORTANT	NOT IMPORTANT
Creative and critical spirit					
Work ethics					
Being a team player					
Self-awareness (knowing your limits)					
Calm and patient temperament					
Adequate management of complications					
Observational skills					
Interest in academics					
Theoretical knowledge					
Ability to decision-making					
Extracurricular activities					
Leadership ability					
Appearance					

6.1 If there is any other valuable characteristic of the trainee that you consider to be worth mentioning, please specify it:

6.2 From all the trainee's characteristics you consider to be "extremely important" to excel in ERCP/EUS, please select the most crucial ones (up to 3 characteristics):

7. How would you best describe "**technical skills**" as characteristic for a trainee to excel in ERCP/EUS training (only one option will be accepted):

a) Precision and hand-eye coordination

b) Knowing how to fully use the endoscope and its degrees of liberties

c) Knowing how to place the endoscope or device where you want

d) Recognizing difficult or unusual situations and adapting your technique

e) Either you have technical skills, either you do not

f) Technical skills can be taught

7.1 If you consider there is a better definition for "technical skills" than the ones mentioned above, please specify it:

8. How would you best describe "**clinical judgement**" as a characteristic for a trainee to excel in ERCP/EUS training (only one option will be accepted):

   a) A symphony of different skills

   b) Being able to question indication and therapeutic plan

   c) The capacity to evaluate the risks and benefits of the different management alternatives for a given clinical situation, in a given patient

   d) Technical skills can be taught, but not clinical judgment

   e) Empathy for the patient

   f) Treating a patient, not a lab test or a picture

   8.1 If you consider there is a better definition for "technical skills" than the ones mentioned above, please specify it:

Section 4: Criteria for ERCP/EUS trainee disqualification

9. Have you ever identified fellows who perform **below the expected** level of competence for ERCP/EUS procedures?

   9.1 If you replied "yes" to question 9, how did you make this determination (Select all that apply)?

      a) Inadequate procedure volume

      b) Inadequate written attending evaluations

      c) Inadequate verbal attending evaluations

      d) Inadequate performance on a skills assessment tool

      e) Inadequate performance on specific quality metrics

      f) Inadequate fellow self-reporting

   9.2 If you replied "yes", did you provide this feedback directly to your trainee?

      9.2.1 If you replied "yes" to question 9.2., please explain the reasons for it:

   9.3 If you replied "yes" to question 9, what intervention(s) did you employ to overcome the issue(s) (Select all that apply)?

      a) Ensure increased procedure volume

      b) Set up procedure blocks with specific teaching attending's

      c) Provide simulator training

      d) Provide didactic theoretical sessions

      e) No specific intervention was set up

10. Have you ever **disqualified** a trainee from an ERCP/EUS training program?

 10.1 If you replied "yes" to question 10, please specify the reason(s) for disqualification:

 10.2 From the following reasons that may justify a trainee disqualification in an ERCP/EUS training program, please select which, in your opinion, are the 3 most relevant:

  a) Disregard for patient welfare

  b) Lack of work ethics (dishonesty, misconduct, untrustworthiness)

  c) Lack of taking responsibility for complications

  d) Not able / wanting to follow instructions

  e) Lack of team spirit / stress management capabilities

  f) Not knowing the limits (arrogant, dare-devil)

  g) Lack of skills

  h) Not reaching proficiency thresholds

 10.3 If there is another motive that you consider to be extremely important to be added in the disqualification motives, please specify it:

Thank you for your time and contribution.

1b. Web-based survey to the ERCP and EUS Trainees

Section 1: General data and opinion regarding application process and trainees selection

1. In which hospital and city do you work?

2. From which country are you?

3. Please rate your **satisfaction with the current process of ERCP/ EUS trainee** selection in your department:

   a) Extremely satisfied

   b) Very satisfied

   c) Moderately satisfied

   d) Slightly unsatisfied

   e) Not satisfied

Section 3: Qualities for trainee to excel in ERCP/EUS training

4. According to your opinion, please rate how important you believe the following **characteristics are for a trainee to excel in ERCP/EUS training:**

CHARACTERISTICS OF AGIE TRAINEES	EXTREMELY IMPORTANT	VERY IMPORTANT	MODERATELY IMPORTANT	SLIGHTLY IMPORTANT	NOT IMPORTANT
Enthusiasm and interest					
Clinical judgement (patient-oriented clinical practice)					
Technical skills					
Able to cope well in highly pressurised and demanding contexts					
Open to feedback and self-improvement					
Maturity					
Initiative					
Completes tasks on time					
Honesty					
Perseverance and resilience					
Hard working					
Creative and critical spirit					

TABLE | CONTINUATION

CHARACTERISTICS OF AGIE TRAINEES	EXTREMELY IMPORTANT	VERY IMPORTANT	MODERATELY IMPORTANT	SLIGHTLY IMPORTANT	NOT IMPORTANT
Work ethics					
Being a team player					
Self-awareness (knowing your limits)					
Calm and patient temperament					
Adequate management of complications					
Observational skills					
Interest in academics					
Theoretical knowledge					
Ability to decision-making					
Extracurricular activities					
Leadership ability					
Appearance					

4.1 If there is any other valuable trainee's characteristic(s) that you consider to be worth mentioning, please specify it:

4.2 From all the trainee's characteristics you considered to be "extremely important" to excel in ERCP/EUS, please select the most crucial ones (up to 3 characteristics):

5. How would you best describe "**technical skills**" as a characteristic for a trainee to excel in ERCP/EUS training (only one option will be accepted):

a) Precision and hand-eye coordination

b) Knowing how to fully use the endoscope and its degrees of liberties

c) Knowing how to place the endoscope or device where you want

d) Recognizing difficult or unusual situations and adapting your technique

e) Either you have technical skills, either you don't

f) Technical skills can be taught

5.1 If you consider there is a better definition for "technical skills" than the ones mentioned above, please specify it:

6. How would you best describe "**clinical judgement**" as a characteristic for a trainee to excel in ERCP/EUS training (only one option will be accepted):

a) A symphony of different skills

b) Being able to question indication and therapeutic plan

c) The capacity to evaluate the risks and benefits of the different management alternatives for a given clinical situation, in a given patient

d) Technical skills can be taught, but not clinical judgment

e) Empathy for the patient

f) Treating a patient, not a lab test or a picture

6.1 If you consider there is a better definition for "clinical judgement" than the ones mentioned above, please specify it:

Section 4: Criteria for ERCP/EUS trainee disqualification

7. From the following **reasons that may justify a trainee disqualification** in an ERCP/EUS training program, please select which, in your opinion, are the 3 most relevant:

a) Disregard patient welfare

b) Lack of work ethics (dishonesty, misconduct, untrustworthiness)

c) Lack of taking responsibility for complications

d) Not able / wanting to follow instructions

e) Lack of team spirit / stress management

f) Not knowing the limits (arrogant, dare-devil)

g) Lack of skills

h) Not reaching proficiency thresholds

7.1 If there is another motive that you consider to be important to be added in the disqualification motives, please specify it:

Thank you for your time and contribution.

2. Agreement between Experts and Trainees

QUESTION	TRAINERS (N = 36)	TRAINEES (N = 25)	P-VALUE
Opinion trainees' selection process, n (%)			0.08
Not satisfied	0 (0.0)	1 (4.0)	
Slightly unsatisfied	3 (8.3)	2 (8.0)	
Moderately satisfied	14 (38.9)	10 (40.0)	
Very satisfied	18 (50.0)	7 (28.0)	
Extremely satisfied	1 (2.8)	5 (20.0)	

SUPPLEMENTARY TABLE 1

Agreement rate between Trainers and Trainees regarding their opinions about current trainee selection process.

QUESTION	TRAINERS (N = 36)	TRAINEES (N = 25)	P-VALUE
Rate enthusiasm and interest, n (%)			0.873
Extremely important	24 (66.7)	16 (64.0)	
Very important	11 (30.6)	9 (36.0)	
Moderately important	1 (2.8)	0	
Rate clinical judgement. n (%)			0.935
Extremely important	23 (63.9)	15 (60.0)	
Very important	12 (33.3)	9 (36.0)	
Moderately important	1 (2.8)	1 (4.0)	
Rate technical skills. n (%)			0.09
Extremely important	19 (52.8)	14 (56.0)	
Very important	17 (47.2)	8 (32.0)	
Moderately important	0	3 (12.0)	
Rate able to cope. n (%)			0.629
Extremely important	10 (27.8)	10 (40.0)	
Very important	23 (63.9)	13 (52.0)	
Moderately important	2 (5.6)	2 (8.0)	
Slightly important	1 (2.8)	0	
Rate open to feedback. n (%)			0.052
Extremely important	25 (69.4)	12 (48.0)	
Very important	9 (25.0)	13 (52.0)	
Moderately important	2 (5.6)	0	
Rate maturity. n (%)			0.165
Extremely important	7 (19.4)	10 (40.0)	
Very important	24 (66.7)	11 (44.0)	
Moderately important	5 (13.9)	4 (16.0)	
Rate initiative. n (%)			0.322
Extremely important	7 (19.4)	9 (36.0)	
Very important	28 (77.8)	15 (60.0)	
Moderately important	1 (2.8)	1 (4.0)	
Rate completes tasks on time. n (%)			1.0
Extremely important	6 (16.7)	4 (16.0)	
Very important	22 (61.1)	16 (64.0)	
Moderately important	7 (19.4)	5 (20.0)	
Slightly important	1 (2.8)	0	

SUPPLEMENTARY TABLE 2

Agreement rate between Trainers and Trainees regarding the importance of several trainee characteristics to excel in ERCP/EUS.

QUESTION	TRAINERS (N = 36)	TRAINEES (N = 25)	P-VALUE
Rate honesty. n (%)			0.032
Extremely important	26 (72.2)	11 (44.0)	
Very important	10 (27.8)	12 (48.0)	
Moderately important	0	2 (8.0)	
Rate perseverance. n (%)			0.499
Extremely important	17 (47.2)	13 (52.0)	
Very important	19 (52.8)	11 (44.0)	
Moderately important	0	1 (4.0)	
Rate hard working. n (%)			0.685
Extremely important	13 (36.1)	12 (48.0)	
Very important	21 (58.3)	12 (48.0)	
Moderately important	2 (5.6)	1 (4.0)	
Rate creative. n (%)			0.713
Extremely important	10 (27.8)	6 (24.0)	
Very important	22 (61.1)	14 (56.0)	
Moderately important	4 (11.1)	4 (16.0)	
Slightly important	0	1 (4.0)	
Rate work ethics. n (%)			0.498
Extremely important	19 (52.8)	10 (40.0)	
Very important	14 (38.9)	11 (44.0)	
Moderately important	3 (8.3)	4 (16.0)	
Rate team player. n (%)			0.234
Extremely important	26 (72.2)	13 (52.0)	
Very important	9 (25.0)	9 (36.0)	
Moderately important	1 (2.8)	2 (8.0)	
Slightly important	0	1 (4.0)	
Rate self-awareness. n (%)			0.637
Extremely important	26 (72.2)	18 (72.0)	
Very important	10 (27.8)	6 (24.0)	
Moderately important	0	1 (4.0)	
Rate calm. n (%)			0.144
Extremely important	11 (30.6)	11 (44.0)	
Very important	23 (63.9)	10 (40.0)	
Moderately important	2 (5.6)	4 (16.0)	
Rate management of complications. n (%)			0.155
Extremely important	18 (50.0)	18 (72.0)	
Very important	17 (47.2)	6 (24.0)	
Moderately important	1 (2.8)	1 (4.0)	
Rate observational skills. n (%)			0.283
Extremely important	12 (33.3)	11 (44.0)	
Very important	21 (58.2)	13 (52.0)	
Moderately important	3 (8.3)	0	
Slightly important	0	1 (4.0)	

QUESTION	TRAINERS (N = 36)	TRAINEES (N = 25)	P-VALUE
Rate interest academics. n (%)			0.830
Extremely important	5 (13.0)	4 (16.0)	
Very important	15 (41.7)	8 (32.0)	
Moderately important	12 (33.3)	9 (36.0)	
Slightly important	4 (11.1)	3 (12.0)	
Not important	0	1 (4.0)	
Rate theoretical knowledge. n (%)			0.620
Extremely important	7 (19.4)	8 (28.0)	
Very important	25 (69.4)	15 (60.0)	
Moderately important	4 (11.1)	2 (8.0)	
Slightly important	0	1 (4.0)	
Rate decision making. n (%)			0.580
Extremely important	15 (41.7)	10 (40.0)	
Very important	21 (58.3)	14 (56.0)	
Moderately important	0	1 (4.0)	
Rate extracurricular activities. n (%)			0.325
Extremely important	2 (5.6)	3 (12.0)	
Very important	12 (33.3)	5 (20.0)	
Moderately important	17 (47.2)	10 (40.0)	
Slightly important	5 (13.9)	5 (20.0)	
Not important	0	2 (8.0)	
Rate leadership. n (%)			0.067
Extremely important	1 (2.8)	3 (12.0)	
Very important	13 (36.1)	11 (44.0)	
Moderately important	19 (52.8)	6 (24.0)	
Slightly important	3 (8.3)	3 (12.0)	
Not important	0	2 (8.0)	
Rate appearance. n (%)			0.067
Extremely important	1 (2.8)	1 (4.0)	
Very important	11 (30.6)	4 (16.0)	
Moderately important	15 (41.7)	6 (24.0)	
Slightly important	7 (19.4)	7 (28.0)	
Not important	2 (5.6)	7 (28.0)	

SUPPLEMENTARY TABLE 3

Agreement rate between Trainers and Trainees regarding their opinions about trainee characteristics considered to be "extremely important".

QUESTION	TRAINERS (N = 36)	TRAINEES (N = 25)	P-VALUE
Ideal technical skills. n (%)			0.379
Yes	14 (38.9)	7 (28.0)	
No	22 (61.1)	18 (72.0)	
Ideal clinical judgement. n (%)			0.223
Yes	14 (38.9)	6 (24.0)	
No	22 (61.1)	19 (76.0)	
Ideal enthusiasm. n (%)			0.495
Yes	10 (27.8)	9 (36.0)	
No	26 (72.2)	16 (64.0)	

QUESTION	TRAINERS (N = 36)	TRAINEES (N = 25)	P-VALUE
Ideal open to feedback. n (%)			0.830
Yes No	11 (30.6) 25 (69.4)	7 (28.0) 18 (72.0)	
Ideal self-awareness. n (%)			0.830
Yes No	11 (30.6) 25 (69.4)	7 (28.0) 18 (72.0)	
Ideal team player. n (%)			0.017
Yes No	8 (22.2) 28 (77.8)	0 25 (100)	
Ideal honesty. n (%)			1.00
Yes No	6 (16.7) 30 (83.3)	4 (16.0) 21 (84.0)	
Ideal work ethics. n (%)			0.073
Yes No	6 (16.7) 30 (83.3)	0 25 (100)	
Ideal hard working. n (%)			1.00
Yes No	2 (5.6) 34 (94.4)	2 (8.0) 23 (92.0)	
Ideal adequate management. n (%)			1.00
Yes No	2 (5.6) 34 (94.4)	2 (8.0) 23 (92.0)	
Ideal decision making. n (%)			0.392
Yes No	2 (5.6) 34 (94.4)	3 (12.0) 22 (88.0)	
Ideal theoretical knowledge. n (%)			0.508
Yes No	2 (5.6) 34 (94.4)	0 25 (100)	
Ideal creative spirit. n (%)			1.00
Yes No	1 (2.8) 59 (96.7)	1 (4.0) 24 (96.0)	
Ideal tasks on time. n (%)			1.00
Yes No	1 (2.8) 35 (97.2)	0 25 (100)	
Ideal calm. n (%)			1.00
Yes No	1 (2.8) 35 (97.2)	0 25 (100)	
Ideal perseverance. n (%)			0.112
Yes No	2 (5.6) 34 (94.4)	5 (20.0) 20 (80.0)	
Ideal able to cope. n (%)			0.410
Yes No	0 36 (100)	1 (4.0) 24 (96.0)	

QUESTION	TRAINERS (N = 36)	TRAINEES (N = 25)	P-VALUE
Clinical judgement definition			0.837
Technical skills definition			0.308

SUPPLEMENTARY TABLE 4

Agreement rate between Trainers and Trainees regarding their opinions about definition of both “clinical judgement” and “technical skills”.

QUESTION	TRAINERS (N = 36)	TRAINEES (N = 25)	P-VALUE
Disqualif not knowing limits. n (%)			0.730
Yes	20 (55.6)	15 (60.0)	
No	16 (44.4)	10 (40.0)	
Disqualif lack work ethics. n (%)			0.194
Yes	25 (69.4)	21 (84.0)	
No	11 (30.6)	4 (16.0)	
Disqualif disregard patient welfare. n (%)			0.086
Yes	18 (50.0)	18 (72.0)	
No	18 (50.0)	7 (28.0)	
Disqualif not able to follow instructions. n (%)			0.510
Yes	16 (44.4)	9 (36.0)	
No	20 (55.6)	16 (64.0)	
Disqualif lack skills. n (%)			0.006
Yes	12 (33.3)	1 (4.0)	
No	24 (66.7)	24 (96.0)	
Disqualif lack responsability. n (%)			0.574
Yes	11 (30.6)	1 (24)	
No	25 (69.4)	19 (76.0)	
Disqualif lack team spirit. n (%)			0.640
Yes	4 (11.1)	1 (4.0)	
No	32 (88.9)	24 (96.0)	
Disqualif not reaching thresholds. n (%)			0.392
Yes	2 (5.6)	3 (12.0)	
No	34 (94.4)	22 (88.0)	

SUPPLEMENTARY TABLE 5

Agreement rate between Trainers and Trainees regarding the most relevant reasons for trainee disqualification.

Appendix IV

Supplementary material for Chapter 7

APPENDIX IV
Supplementary material for Chapter 7

Survey on the face and content validity of biological papilla in ERCP training

We kindly invite you to provide us your feedback on your experience regarding the new biological papilla of the Boškoski-Costamagna ERCP Trainer. Please fill out the short questionnaire below and help us validating the ERCP Trainer.

1. Demographics
   a) Gender:
   b) Age:
   c) Country:
   d) Medical background (GE specialist, GE resident – year, other):
   e) Working place (academic hospital, regional hospital, other):
2. Exposure to endoscopic interventions and learning methods in endoscopy
   a) Number of years of ERCP experience:
   b) Average number of ERCPs performed per year:
   c) Estimated lifetime number of ERCPs performed:
   d) Previous experience in other medical simulators (no, yes):
   e) If simulator familiarity:
   f) Please state how many times (0-5, 6-10, > 10 times):
   g) Please state which simulator(s):
3. Adequacy and realism of the novel biological papilla (5-point Likert scale; varying from very unrealistic (1) to very realistic (5))

   Realism of the novel biological papilla compared to patient-based ERCP.

   3.1 General appearance - opinion regarding the level of realism:

   Q1. Resemblance to the real papilla:

   Q2. Positioning in front of the papilla:

   3.2 Sphincterotomy - opinion regarding the level of realism:

   Q3. Positioning of the sphincterotome (tip control and wire deflection and angulation into intended position) during cannulation:

   Q4. Controlling the direction of the sphincterotome (tip control and wire deflection and angulation into intended position) during cutting:

   Q5. Controlled cutting in small increments:

Q6. Cutting/coagulation effects:

Q7. Controlling guidewire introduction:

Q8. Controlling the scope during procedure (considering the several known dimensions for movement control):

Q9. Overall appreciation in comparison to real situation:

3.3 Precut - opinion regarding the level of realism:

Q10. Positioning of the needle-knife in the field of view:

Q11. Positioning of the needle-knife (tip control, deflection, and angulation into intended position) during cutting:

Q12. Controlled cutting in small increments:

Q13. Cutting control "layer-by-layer", exposing deeper layers:

Q14. Cutting/coagulation effects:

Q15. Controlling guidewire introduction:

Q16. Controlling the scope during procedure:

Q17. Overall appreciation in comparison to real situation:

3.4 Papillectomy - opinion regarding the level of realism:

Q18. Positioning of the snare in the field of view:

Q19. Controlling the scope during the procedure:

Q20. Overall appreciation in comparison to real situation:

3.5 Overall realism:

Q21. Anatomical representation:

Q22. Simulator setup:

Q23. Endoscopic and devices control:

Q24. Haptic feedback:

Q25. Difficulty:

4. Appreciation of the novel biological papilla as a learning tool (5-point Likert scale; varying from strongly disagree (1) to strongly agree (5)).

4.1 Your opinion about using novel biological papilla as a learning tool:

Q26. Expertise gained with this papilla is transferrable into clinical setting?

Q27. Useful tool to be included in an ERCP training curriculum?

Q28. Useful tool to be included in the training of novice endoscopists (< 50 ERCPs lifetime)?

Q29. Useful tool to be included in the training of intermediate endoscopists (50-600 ERCPs lifetime)?

Q30. Useful tool to be included in the training of experienced endoscopists (600-2500 ERCPs lifetime)?

Q31. Useful tool for (re) certification in ERCP?

5. Are there any other potential benefits of this teaching tool?

In case of publication of the results of this study, we would like to acknowledge those who contributed to the results. Please let us know if you have any objections against stating your name in the acknowledgements.

□ *I have no objection.*

□ *I rather not have my name stated in the acknowledgements.*

Thank you for your collaboration.

Appendix V

Supplementary material for Chapter 8

APPENDIX V
Supplementary material for Chapter 8

SUPPLEMENTARY TABLE

Descriptive analysis of ERCP pre-procedure, procedure, and post-procedure data.

*Refers to number of patients with AEs.
**11 patients had more than 1 AE.
***cholecystitis, ischemic colitis, fever, abdominal pain, stent migration.

Legend: AE, adverse event; ERCP, endoscopic retrograde cholangiopancreatography; IQR, interquartile range

ERCP DATA
Pre-procedure data
Male patient, n (%)
Patient's age in years (median IQR)
ERCP setting, n (%) Elective Urgent
Indication for ERCP, n (%) Deep cannulation of duct of interest or sampling Biliary stent removal / exchange Biliary stone extraction ≤ 10mm Biliary leak treatment Extrahepatic stricture treatment Prophylactic pancreatic stent placement Removal of CBD stone > 10mm Hilar tumor treatment Benign biliary stricture, hilum and above, treatment Removal of internally migrated biliary stents Intraductal imaging and biopsy Pancreatic stricture treatment Removal of pancreatic stones mobile and <5mm Minor papilla cannulation and therapy Removal of intrahepatic stones ERCP after Whipple's or Roux-en-Y bariatric surgery Papillectomy Removal of pancreatic stones impacted and/or >5mm Intraductal image-guided therapy N/A
Degree of difficulty, n (%) Grade 1 Grade 2 Grade 3 Grade 4 N/A
Bilirubin level (mg/dL) at the time of ERCP (median - IQR)
Native papillary anatomy, n (%) Yes No
Periampullary diverticulum, n (%) Yes No
Previous ERCP failure, n (%) Yes No
Procedure data
Achievement of short positioning in duodenum, n (%)
Papilla major reached / identified, n (%)

SG (562 ERCPs)	CG (544 ERCPs)	TOTAL
Pre-procedure data		
296 (53%)	278 (51%)	574 (52%)
67 (21)	65 (20)	65.0 (20.0)
436 (78%) 126 (22%)	437 (80%) 107 (20%)	873 (79%) 233 (21%)
17 (2.8%) 128 (21%) 172 (29%) 16 (2.7) 131 (22%) 1 (0.2%) 26 (4.3%) 38 (6.3%) 21 (3.5%) 5 (0.8%) 1 (0.2%) 24 (4.0%) 5 (0.8%) 3 (0.5%) 3 (0.5%) 1 (0.2%) 2 (0.3%) 2 (0.3%) 6 (1.0%) 0 (0.0%)	8(1.6%) 63 (13%) 179 (36%) 12 (2.4%) 171 (34%) 1 (0.2%) 13 (2.6%) 23 (4.6%) 17 (3.4%) 1 (0.2%) 0 (0%) 13 (2.6%) 1 (0.2%) 0 (%) 0 (0%) 0 (0%) 1 (0.2%) 0 (0%) 0 (0%) 1 (0.2%)	25 (2.3%) 191 (17%) 351 (32%) 28(2.5%) 302 (27%) 2(0.2%) 39 (3.5%) 61 (5.5%) 38 (3.4%) 6 (0.5%) 1 (<0.1%) 37 (3.3%) 6 (0.5%) 3 (0.3%) 3 (0.3%) 1 (<0.1%) 3 (0.3%) 2 (0.2%) 6 (0.5%) 1 (<0.1%)
133 (24%) 298 (53%) 117 (20%) 14 (2.3%) 0 (0.0%)	83 (15%) 385 (71%) 74 (14%) 1 (0.2%) 1 (0.2%)	216 (20%) 683 (62%) 191 (17%) 15 (1.4%) 1 (<0.1%)
1 (3.8)	1.2 (3.1)	1.1 (3.5)
238 (42%) 324 (58%)	246 (54%) 298 (46%)	484 (44%) 622 (56%)
58 (10%) 504 (90%)	64 (12%) 480 (88%)	122 (11%) 984 (89%)
31 (5.5%) 531 (94%)	28 (5.1%) 516 (95%)	59 (5.3%) 1047 (95%)
Procedure data		
592 (98%)	496 (99%)	1,088 (98%)
562 (100%)	544 (100%)	1,106 (100%)

ERCP DATA
Biliary cannulation achieved - yes, n (%) Success, according to TEESAT (score 1-2) Failure, according to TEESAT (score 3-4)
Native biliary cannulation achieved - yes, n (%) Success, according to TEESAT (score 1-2) Failure, according to TEESAT (score 3-4)
Time (min) for biliary cannulation, median (IQR)
Time (min) for native biliary cannulation, median (IQR)
Biliary sphincterotomy, n (%) Success, according to TEESAT (score 1-2) Failure, according to TEESAT (score 3-4)
Sphincteroplasty, n (%) Success, according to TEESAT (score 1-2) Failure, according to TEESAT (score 3-4)
Tissue sampling, n (%) Success, according to TEESAT (score 1-2) Failure, according to TEESAT (score 3-4)
Stone removal, n (%) Success, according to TEESAT (score 1-2) Failure, according to TEESAT (score 3-4)
Stricture dilation, n (%) Success, according to TEESAT (score 1-2) Failure, according to TEESAT (score 3-4)
Stent removal, n (%) Success, according to TEESAT (score 1-2) Failure, according to TEESAT (score 3-4)
Stent Placement Success, according to TEESAT (score 1-2) Failure, according to TEESAT (score 3-4)
Total procedure time (min), median (IQR)
Post-procedure data
Global overall assessment, n (%) Competent (TEESAT score 3-4) Non-competent (TEESAT score 1-2)
Overall AEs* No Yes
AEs specified by type**: Bleeding (immediate and post) Perforation (immediate and post) Sedation-related adverse events Post-ERCP pancreatitis Cholangitis Death Other***

	SG (562 ERCPS)	CG (544 ERCPS)	TOTAL
	358 (71%) 149 (29%)	327 (65%) 176 (35%)	685 (68%) 325 (32%)
	115 (52%) 105 (48%)	96 (42%) 132 (58%)	211 (47%) 237 (53%)
	3.0 (6)	5.0 (8.0)	4.0 (6.0)
	6.0 (7.0)	8.0 (6.3)	7.0 (7.0)
	111 (66%) 54 (26%)	91 (60%) 65 (33%)	202 (62%) 119 (37%)
	14 (83%) 3 (17%)	7 (60%) 4 (40%)	21 (75%) 7 (25%)
	12 (67%) 6 (33%)	17 (89%) 2 (11%)	29 (36%) 8 (10%)
	178 (86%) 29 (14%)	158 (81%) 37 (19%)	336 (84%) 66 (16%)
	53 (91%) 5 (8%)	26 (76%) 8 (24%)	79 (86%) 13 (14%)
	193 (91%) 19 (9%)	106 (83%) 22 (17%)	299 (81%) 41 (11%)
	172 (70.2%) 73 (29.8%)	157 (68.6%) 72 (31.4%)	329 (69.4%) 145 (30.6%)
	30 (23)	28 (28)	30.0 (26.8)
	274 (49%) 288 (51%)	173 (33%) 371 (68%)	447 (40%) 659 (60%)
	501 (89%) 61 (11%)	491 (90%) 53 (9.7%)	992 (90%) 114 (10%)
	20 (29.41%) 0 (0%) 4 (5.9%) 21(30.9%) 10 (14.71%) 0 (0%) 13 (19.12%)	14 (24.56%) 1 (1.75%) 2 (3.51%) 20 (35.1%) 11 (19.3%) 4 (7.02%) 5 (8.8%)	34 (27.2%) 1 (0.8%) 6 (4.8%) 41 (32.8%) 21 (16.8%) 4 (3.2%) 18 (14.4%)

Appendix VI

Supplementary material for Chapter 9

APPENDIX VI
Supplementary material for Chapter 9

The following search string was used for both PubMed/Medline and Web of Science:

SUPPLEMENTARY TABLE 1
Detailed search terms in the analysis

SEARCH TERMS IN THE ANALYSIS
(“ERCP” or “Endoscopic Retrograde Cholangiopancreatography” or “Endoscopic Retrograde Cholangiopancreatographies”) AND
(“Volume*” or “High-Volume” or “Low-Volume” or “Experience” or “Number*” or “Workload” or “Caseload” or “Case Load”) AND
(“Outcomes” or “Success” or “Complications” or “Adverse Events” Or “Failure” or “Pancreatitis” or “Bleeding” or “Perforation” or “Cholangitis”)

SUPPLEMENTARY TABLE 2

Patient and procedure data regarding the studies included in the primary analysis

STUDY	AGE [MEAN ± SD; MEDIAN (RANGE)]	SEX [FEMALE (N, %)]	INDICATION FOR ERCP				
			BILIARY STONE DISEASE (N, %)	BENIGN STRICTURE (N, %)	MALIGNANCY (N, %)	OTHER (N, %)	NATIVE PAPILLA (N, %)
Freeman, 1996	N/A	N/A	1600 (68.2%)	98 (4.2%)	310 (13.2%)	456 (19.4)	N/A
Loperfido, 1998	66 (6-93)	1493 (54%)	N/A	N/A	N/A	1270 (45.9%)	2541 (91.7%)
Freeman, 2001	N/A	1083 (55.17%)	N/A	N/A	N/A	N/A	N/A
Varadarajulu, 2006	59.4 ± 20.1	125764 (63%)	50543 (39.7%)	N/A	21180 (16.6%)	55578 (43.6)	N/A
Masci, 2006	65.9 ± 16.4	389 (55.6%)	700 (100%)	0	0	N/A	700 (100%)
Vitte, 2007	70.1 ± 17	1516 (56%)	1697 (62.5%)	N/A	610 (22.5%)	587 (21.6%)	2211 (81.6%)
Kapral, 2008	66 (4-99)	1359 (51.9%)	1231 (39.3%)	N/A	N/A	1901 (60.7%)	2330 (74.4%)
Wang, 2009	57.88 ± 17.43	1238 (46%)	1893 (70.3%)	191 (7.1%)	442 (16.4%)	461 (17.1%)	2691 (85%)
Liao, 2009	N/A	16 (12.9%)	N/A	N/A	N/A	N/A	N/A
Enochsson, 2010	67.6	4448 (55%)	2926 (26.4%)	N/A	1140 (10.3%)	7008 (63.2%)	N/A
Murata, 2010	75 ± 12.9 LV centres; 72.4 ± 13.3 HV centres	2474 (89%)	5238 (90%)		497 (8%)	116 (2%)	N/A
Testoni, 2010	N/A	1825 (50.2%)	1656 (45.5%)	128 (3.5%)	715 (19.7%)	1136 (31.3%)	N/A
Alkhatib, 2011	50.1 (15-82)	17 (22.7%)	N/A	179 (96.8%)	6 (3.2%)	N/A	N/A
Glomsaker, 2013	70	1546 (55.1%)	1359 (48.4%)	N/A	N/A	892 (31.8%)	N/A

Coté, 2013	51.5 ± 19.4	10842 (66.9%)	5137 (33.1%)	N/A	684 (4%)	9693 (62.5%)	N/A
Peng, 2013	N/A	N/A	4791 (36.8%)	N/A	N/A	8227 (63.2%)	13018 (100%)
Kalaitzakis, 2015	67 ± 18	7345 (58%)	9119 (72%)	N/A	N/A	3576 (28%)	12695 (100%)
Hu, 2016	N/A	N/A	129124 (66%)	N/A	35216 (18%)	31303 (16%)	N/A
Saito, 2017	74.6 ± 14.1	200 (47.3%)	425 (100%)	N/A	N/A	N/A	424 (100%)
Voiosu, 2020	66.8 ± 14.5	896 (48.7%)	862 (46.8%)	98 (5.4%)	562 (30.5%)	305 (16.6%)	1318 (71.6%)
Saito, 2019	N/A	516 (46.1%)	1113 (100%)	N/A	N/A	N/A	1113 (100%)
Hudhud, 2019	59.7	78422 (56.9%)	N/A	N/A	N/A	N/A	N/A
Han, 2019	72 ± 10.8	28 (30.3%)	N/A	N/A	N/A	N/A	293 (100%)
Mariani, 2019	N/A	N/A	1407 (59%)	143 (6%)	571 (23.9%)	1346 (56.5%)	1765 (73.9%)
Huang, 2019	62.3 ± 17	38338 (55.9%)	21812 (31.8%)	16074 (23.7%)	6138 (8.9%)	24618 (35.9%)	N/A
Zheng, 2020	N/A	1099 (46.1%)	1754 (73.5%)	479 (20.1%)		8 (0.34%)	2385 (100%)
Langerth, 2020	67 ± 17	28.070 (54%)	16828 (32%)	N/A	4957 (10%)	19379 (37.2%)	N/A
Lee, 2020	71 (19-101)	501 (42.1%)	856 (71.9%)	N/A	N/A	N/A	1191 (100%)
Caglar, 2020	71.18 ± 10.39	17 (22.7%)	47 (62.7%)	16 (21.3%)	8 (10.7%)	4 (5.3%)	75 (100%)
Harvey, 2020	75 (66-88)	20089 (50.6%)	N/A	N/A	39702 (100%)	N/A	N/A
Mutneja, 2020	61 (60.6-61.4)	718694 (58.8%)	706531 (60.5%)	227644 (18.6%)	12655 (10.4%)	196697 (16.1%)	N/A

SUPPLEMENTARY TABLE 3

Studies included in the Primary analysis assessing Procedure Success as an outcome

STUDY FIRST AUTHOR, YEAR OF PUBLICATION	COHORT STUDY DESIGN	TOTAL NUMBER OF ERCPS	DEFINITION OF PROCEDURE SUCCESS
Procedure success as outcome, by Endoscopist Volume			
Mariani, 2019	Prospective	2388	Cannulation, visualization of the desired duct and achievement of the therapeutic/diagnostic target
Freeman, 1996	Prospective	2347	No failure of biliary access or drainage after ST
Coté, 2013	Retrospective	15514	No need for repeat ERCP/PBD or surgical duct exploration within 7 days
Vitte, 2007	Prospective	2708	Selective catheterization and opacification of the targeted biliary and/or PD (1) and therapeutic goal achieved / no complementary procedure was needed to complete the procedure (2)
Wang, 2009	Prospective	3178	Successful deep cannulation of the first-only ERCP
Freeman, 2001	Prospective	1963	Successful deep cannulation
Kapral, 2008	Prospective	3132	Achievement of therapeutic/ diagnostic target
Han, 2019	Retrospective	293	CBD cannulation completed in one ERCP session
Voiosu, 2020	Prospective	1843	Ability to achieve the planned diagnostic and/or therapeutic procedure in each individual case
Caglar, 2020	Retrospective	75	(1) Selective cannulation; (2) Technical success = access to papilla + selective cannulation; (3) Therapeutic success = extraction of stone, placement of stent in stricture, and clinical and lab improvement
Harvey, 2020	Retrospective	39702 (patients)	No need to undergo PTC or further ERCP within 30d of index ERCP
Peng, 2013	Prospective	13018	(1)"Conventional" deep biliary cannulation rate (use of precut considered as failure); (2)"Overall" biliary cannulation rate (allowing precut if success occurred in the same procedure)

NUMBER OF ENDOSCOPISTS	NUMBER OF CENTERS	CUT-OFF (LOW VS HIGH)	SUCCESS RATE, HV	SUCCESS RATE, LV	P VALUE AND/OR ODDS RATIO
Procedure success as outcome, by Endoscopist Volume					
38	18	200 lifetime and/or 50 per year	1114 (93.1%)	169 (87.2%)	0.001
N/A	17	1 per week	1144 (98.8%)	1125 (94.6%)	<0.001
130	NA	25 per year	7574 (94.3%)	6777 (90.5%)	<0.001
41	28	<40 or > 80 per year	919 (94.6%) 809 (84.2%)	644 (89.2%) 547 (79.3%)	e (2) <0.001
NA	14	3 per week	1948 (96.7%)	649 (96%)	1.000
26	11	2 per week	637 (96.5%)	1192 (91.5%)	0.0001
89	28	50 per year	2126 (86.9%)	976 (80.3%)	<0.001
2	1	experienced >5000 lifetime Vs beginner, completed 1y supervised training, >100 supervised, no independent	68 (98.6%)	67 (97.1%)	NA
37	6	supervision and/or <200 independently Vs experienced	957 (93.7%)	760 (92.4%)	0.3
2	2	200 per year	49 (92%); 49 (83%); 39 (66.1%)	12 (92%); 12 (75%); 10 (62.5%)	0.98 0.59
NA	NA	<204 Vs > 318 per year; 40 ERCP per year malignant obstruction	38896 (93.74%)	11380 (89%)	<0.001
NA	85	≤ 90 Vs > 239 per year	? (90.6%); ? (97.1%)	? (87.9%); ? (92.2%)	<0.53; 0.01

STUDY FIRST AUTHOR, YEAR OF PUBLICATION	COHORT STUDY DESIGN	TOTAL NUMBER OF ERCPS	DEFINITION OF PROCEDURE SUCCESS
Procedure Success as outcome, by Center Volume			
Mariani, 2019	Prospective	2388	Cannulation (1), visualization of the desired duct and achievement of the therapeutic/diagnostic target (2)
Varadarajulu, 2006	Retrospective	199625	No need to perform PTBD or open CBD exploration after ERCP
Vitte, 2007	Prospective	2708	Selective catheterization and opacification of the targeted biliary and/or PD and therapeutic goal achieved (no complementary procedure was needed to complete the procedure)
Kalaitzakis, 2015	Retrospective	12695	No need for PBD and/or CBD exploration during the same hospital episode
Loperfido, 1998	Prospective	3356	No need for repeat ERCP ("no failure ERCP = no cannulation or no ductal opacification")
Masci, 2006	Prospective	2919	Complete removal of stones in the biliary tree

NUMBER OF ENDOSCOPISTS	NUMBER OF CENTERS	CUT-OFF (LOW VS HIGH)	SUCCESS RATE, HV	SUCCESS RATE, LV	P VALUE AND/OR ODDS RATIO
Procedure Success as outcome, by Center Volume					
38	18	< 100 Vs > 250 per year	1136 (95.9%) 1081 (91.2%)	452 (95.3%) 427 (90%)	0.6 0.6
NA	2629	<50 Vs >300 per year	? (95.3%)	? (94%)	OR 0.87
41	28	<100 Vs >200 per 18 months	779 (95.9%) 713 (86.9%)	826 (89.1%) 670 (79.3%)	<0.01
NA	66	87 per year	? (99.8%)	? (99.5%)	0.007
NA	9	200 per year	1636 (96.1%)	991 (93%)	<0.0001
NA	14	200 per year	344 (88.4%)	160 (83.7%)	0.324

SUPPLEMENTARY TABLE 4

Studies included in the Primary analysis assessing Adverse Events as an outcome

STUDY FIRST AUTHOR, YEAR OF PUBLICATION	COHORT STUDY DESIGN	TOTAL NUMBER OF ERCPS	DEFINITION OF ADVERSE EVENTS
Adverse Events as outcome, by Endoscopist Volume			
Lee, 2020	Prospective	1191	Included PEP, bleeding, perforation, cholangitis - similar to those reported by Cotton et al
Mariani, 2019	Prospective	2388	Defined and graded according to consensus criteria proposed by Cotton et al
Freeman, 1996	Prospective	2347	Complications of ST (any AE related to ERCP during which ST was performed and that required more than one night of hospitalization) - similar to Cotton et al (included PEP, bleeding)
Vitte, 2007	Prospective	2708	Any unexpected event first 30d after ERCP and requiring >1d hospitalization
Wang, 2009	Prospective	3178	Overall complications after ERCP (PEP, cholangitis, bleeding, perforation, cholecystitis, basket trapping, pulmonary infection, hepatic encephalopathy, acute renal failure)
Liao, 2009	Retrospective	124	PEP, bleeding, perforation, cholangitis
Alkhatib, 2011	Retrospective	185	Any ERCP related AE within 30 days
Kapral, 2008	Prospective	3132	Bleeding, perforation, PEP, post-ERCP cholangitis, cardiopulmonary complications, pain before and after the day after ERCP
Han, 2019	Retrospective	293	Included bleeding, PEP and perforation
Voiosu, 2020	Prospective	1843	Any procedure-related complications that prolonged hospital stay and/or required additional medical or surgical interventions
Saito, 2017	Retrospective	425	Any AE occurring after ERCP procedure that required more than 1 night of hospitalization

NUMBER OF ENDOSCOPISTS	NUMBER OF CENTERS	CUT-OFF (LOW VS HIGH)	AE RATE, HV	AE RATE, LV	P VALUE AND/OR ODDS RATIO
Adverse Events as outcome, by Endoscopist Volume					
18	6	200 therapeutic per year	123 (17.5%)	121 (24.7%)	0.003
38	18	200 lifetime and/or 50 per year	101 (8.4%)	21 (10.8%)	0.6
NA	17	1 per week	97 (8.4%)	132 (11.1%)	0.03
41	28	<40 or > 80 per year	33 (3.3%)	41 (5.5%)	0.03
NA	14	3 per week	150 (7.4%)	63 (9.3%)	0.115
NA	7	200 per year	19 (8.9%)	7 (30.4%)	0.015
7	NA	28 lifetime	11 (9.6%)	15 (20.5%)	0.05
89	28	50 per year	250 (10.2%)	165 (13.6%)	0.007
2	1	>5000 lifetime Vs completed 1 year supervised training, >100 supervised, no independent	4	11	NA
37	6	supervision and/or <200 independently Vs experienced	149 (14.6%)	121 (14.7%)	>0.99
15	2	<200 lifetime or could only perform procedures grade 1 regardless assistance Vs grade 3 without assistance	14 (3.3%)	11 (2.6%)	0.57

STUDY FIRST AUTHOR, YEAR OF PUBLICATION	COHORT STUDY DESIGN	TOTAL NUMBER OF ERCPS	DEFINITION OF ADVERSE EVENTS
Caglar, 2020	Retrospective	75	Included PEP, bleeding, cholangitis, cholecystitis, perforation, cardiopulmonary complications, death
Adverse Events as outcome, by Center Volume			
Lee, 2020	Prospective	1191	Included PEP, bleeding, perforation, cholangitis - similar to those reported by Cotton et al
Mariani, 2019	Prospective	2388	Defined and graded according to consensus criteria by Cotton et al
Huang, 2019	Retrospective	68642	Unplanned hospital admission/ED visit related to ERCP AE (included PEP, bleeding, perforation, infection, CP events at 7d, 15d, 22d, 30d)
Hu, 2016	Retrospective	195643	Included PEP, bleeding, perforation, cholangitis - similar to those reported by Cotton et al
Murata, 2010	Retrospective	8698	Included bleeding/hematoma, iatrogenic perforation during endoscopy, perforation bile duct, PEP
Vitte, 2007	Prospective	2708	Any unexpected event first 30d after ERCP and requiring >1d hospitalization
Loperfido, 1998	Prospective	3356	Any AE causing death or requiring surgery / endoscopy or other extraordinary therapeutic measures such as resuscitation, blood transfusion, admission for outpatients or readmission for discharged patients
Enochsson, 2010	Prospective	11074	Perioperative complications; (2) Postoperative AE (including pancreatitis, bleeding, perforation)
Glomsaker, 2013	Prospective	2808	Severe complications as condition or event unfavorable to the patient's health, causing irreversible damage, or requiring a change in therapeutic policy that occurred in relation to the procedure and during the dirst 30d after ERCP (namely PEP)
Masci, 2006	Prospective	2919	N/A

NUMBER OF ENDOSCOPISTS	NUMBER OF CENTERS	CUT-OFF (LOW VS HIGH)	AE RATE, HV	AE RATE, LV	P VALUE AND/OR ODDS RATIO
2	2	200 per year	13 (22.0%)	1 (6.25%)	0.230
Adverse Events as outcome, by Center Volume					
18	6	200 therapeutic per year	183 (21.6%)	61 (17.7%)	0.133
38	18	< 100 Vs > 250 per year	104 (8.8%)	50 (10.6%)	0.1
NA	635	<50 Vs ≥ 300 per year	1617 (5.5%)	275 (7.7%)	<0.001
NA	1156	500 per year	? (5.79%)	? (5.64%)	0.43
NA	654	< 16 Vs > 32 per 9 month	91 (3.2%)	165 (5.6%)	<0.001
41	28	<100 Vs >200 per 18 months	37 (4.4%)	116 (12.1%)	0.001
NA	9	200 per year	35 (2%)	76 (7.1%)	RR 2.9
177	51	< 200 Vs > 1000 per 2 years	52 (2.1%); 272 (11.2%)	77 (3.1%); 239 (9.6%)	0.0255; NS
48	11	150 per year	42 (3.02%)	25 (1.77%)	0.043
NA	14	200 per year	? (88.4%)	? (83.7%)	NA

SUPPLEMENTARY TABLE 5

Studies included in the Primary analysis assessing PEP as an outcome

STUDY FIRST AUTHOR, YEAR OF PUBLICATION	COHORT STUDY DESIGN	TOTAL NUMBER OF ERCPS	NUMBER OF ENDOSCOPISTS
PEP as outcome, by Endoscopist Volume			
Zheng, 2020	Retrospective	2385	NA
Lee, 2020	Prospective	1191	18
Mariani, 2019	Prospective	2388	38
Freeman, 1996	Prospective	2347	NA
Wang, 2009	Prospective	3178	NA
Freeman, 2001	Prospective	1963	26
Testoni, 2010	Prospective	3635	NA
Kapral, 2008	Prospective	3132	89
Han, 2019	Retrospective	293	2
Voiosu, 2020	Prospective	1843	37
Saito, 2019	Retrospective	1113	32
Caglar, 2020	Retrospective	75	2
PEP as outcome, by Center Volume			
Lee, 2020	Prospective	1191	18
Mariani, 2019	Prospective	2388	38
Hu, 2016	Retrospective	195643	NA
Vitte, 2007	Prospective	2708	41
Enochsson, 2010	Prospective	11074	177
Glomsaker, 2013	Prospective	2808	48
Testoni, 2010	Prospective	3635	NA
Hudhub, 2019	Retrospective	137825	NA
Mutneja, 2020	Retrospective	1222467	NA

NUMBER OF CENTERS	CUT-OFF (LOW VS HIGH)	PEP RATE, HV	PEP RATE, LV	P VALUE AND/ OR ODDS RATIO
PEP as outcome, by Endoscopist Volume				
NA	200 lifetime and/or 50 per year	148 (7.6%)	47 (10.8%)	0.019
6	200 therapeutic per year	43 (6.8%)	52 (12%)	0.004
18	200 lifetime and/or 50 per year	51 (4.3%)	12 (6.2%)	0.3
17	1 per week	64 (5.5%)	63 (5.3%)	0.81
14	3 per week	80 (4.85%)	36 (6.79%)	0.102
11	2 per week	60 (9.1%)	70 (5.4%)	NS
21	200 lifetime and/or 40 per year	125 (3.8%)	9 (5.5%)	0.345
28	50 per year	120 (4.9%)	68 (5.6%)	0.014
1	>5000 lifetime Vs completed 1y supervised training, >100 supervised, no independent	3 (4.3%)	9 (13%)	NA
6	supervision and/or <200 independently Vs experienced	27 (2.6%)	25 (3%)	0.58
3	<200 lifetime or G1 Vs experienced	40 (76.9%)	12 (23.1%)	0.53
2	200 per year	3 (5%)	0	NA
PEP as outcome, by Center Volume				
6	200 therapeutic	69 (9.4%)	26 (8%)	0.560
18	< 100 Vs > 250 per year	53 (4.7%)	21 (4.5%)	0.2
1156	500 per year	? (4.65%)	? (4.18%)	0.26
28	<100 Vs >200 per 18 months	19 (2.2%)	234 (3.5%)	0.3
51	< 200 Vs > 1000 per 2 years	90 (3.7%)	60 (2.4%)	0.0123
11	150 per year	54 (3.88%)	34 (2.4%)	0.023
21	200 per year	112 (3.9%)	25 (3.1%)	0.379
NA	200 per year	3825 (7%)	5158 (6.2%)	<0.01
NA	200 per year	40058 (4.2%)	15167 (5.8%)	<0.01

SUPPLEMENTARY TABLE 6

Studies included in the Primary analysis assessing Bleeding as an outcome

STUDY FIRST AUTHOR, YEAR OF PUBLICATION	COHORT STUDY DESIGN	TOTAL NUMBER OF ERCPS	NUMBER OF ENDOSCOPISTS
Bleeding as outcome, by Endoscopist Volume			
Lee, 2020	Prospective	1191	18
Freeman, 1996	Prospective	2347	NA
Kapral, 2008	Prospective	3132	89
Han, 2019	Retrospective	293	2
Voiosu, 2020	Prospective	1843	37
Caglar, 2020	Retrospective	75	2
Bleeding as outcome, by Center Volume			
Lee, 2020	Prospective	1191	18
Hu, 2016	Retrospective	195643	NA
Vitte, 2007	Prospective	2708	41
Loperfido, 1998	Prospective	3356	NA
Enochsson, 2010	Prospective	11074	177

SUPPLEMENTARY TABLE 7

Studies included in the Primary analysis assessing Cholangitis as an outcome

STUDY FIRST AUTHOR, YEAR OF PUBLICATION	COHORT STUDY DESIGN	TOTAL NUMBER OF ERCPS	NUMBER OF ENDOSCOPISTS
Cholangitis as outcome, by Endoscopist Volume			
Lee, 2020	Prospective	1191	18
Kapral, 2008	Prospective	3132	89
Voiosu, 2020	Prospective	1843	37
Caglar, 2020	Retrospective	75	2
Cholangitis as outcome, by Center Volume			
Lee, 2020	Prospective	1191	18
Hu, 2016	Retrospective	195643	NA
Vitte, 2007	Prospective	2708	41
Hudhud, 2019	Retrospective	137825	NA

NUMBER OF CENTERS	CUT-OFF (LOW VS HIGH)	BLEEDING RATE, HV	BLEEDING RATE, LV	P VALUE AND/ OR ODDS RATIO
Bleeding as outcome, by Endoscopist Volume				
6	200 therapeutic per year	70 (10%)	71 (14.5%)	0.018
17	1 per week	13 (1.1%)	34 (2.9%)	0.002
28	50 per year	78 (3.2%)	57 (4.7%)	NS
1	>5000 lifetime Vs completed 1y supervised training, >100 supervised, no independent	1 (1.4%)	2 (2.9%)	NA
6	supervision and/or <200 independently Vs experienced	14 (1.4%)	6 (0.7%)	0.26
2	200 per year	3 (5%)	0	NA
Bleeding as outcome, by Center Volume				
6	200 therapeutic per year	117 (3.8%)	24 (7%)	0.001
1156	500 per year	? (0.38%)	? (0.59%)	0.08
28	<100 Vs >200 per 18 months	4 (0.5%)	24 (2.5%)	0.001
9	200 per year	7 (0.4%)	14 (1.3%)	RR 2.945
51	< 200 Vs > 1000 per 2 years	27 (1.1%)	22 (0.9%)	NS

NUMBER OF CENTERS	CUT-OFF (LOW VS HIGH)	CHOLANGITIS RATE, HV	CHOLANGITIS RATE, LV	P VALUE AND/ OR ODDS RATIO
Cholangitis as outcome, by Endoscopist Volume				
6	200 therapeutic per year	4 (0.7%)	7 (1.8%)	0.216
28	50 per year	37 (1.5%)	34 (2.8%)	0.007
6	supervision and/or <200 independently Vs experienced	29 (28.8%)	16 (1.9%)	0.29
2	200 per year	3 (5%)	0	NA
Cholangitis as outcome, by Center Volume				
6	200 therapeutic per year	7 (1.1%)	4 (1.3%)	0.751
1156	500 per year	? (0.69%)	? (0.64%)	0.54
28	<100 Vs >200 per 18 months	1 (0.1%)	21 (2.2%)	<0.001
NA	200 per year	383 (0.7%)	416 (0.5%)	<0.01

SUPPLEMENTARY TABLE 8

Studies included in the Primary analysis assessing Perforation as an outcome

STUDY FIRST AUTHOR, YEAR OF PUBLICATION	COHORT STUDY DESIGN	TOTAL NUMBER OF ERCPS	NUMBER OF ENDOSCOPISTS
Perforation as outcome, by Endoscopist Volume			
Langerth, 2020	Retrospective	52410	NA
Lee, 2020	Prospective	1191	18
Kapral, 2008	Prospective	3132	89
Han, 2019	Retrospective	293	2
Voiosu, 2020	Prospective	1843	37
Caglar, 2020	Retrospective	75	2
Perforation as outcome, by Center Volume			
Langerth, 2020	Retrospective	52410	NA
Lee, 2020	Prospective	1191	18
Hu, 2016	Retrospective	195643	NA
Enochsson, 2010	Prospective	11074	177

SUPPLEMENTARY TABLE 9

Risk of bias assessment using the Newcastle-Ottawa scale

STUDY	REPRESENTATIVENESS OF THE EXPOSED COHORT	NON-EXPOSED COHORT	ASCERTAINMENT OF EXPOSURE	DEMONSTRATION THAT OUTCOME OF INTEREST WAS NOT PRESENT AT START OF STUDY
Freeman, 1996				
Loperfido, 1998	*		*	
Freeman, 2001	*			*
Varadarajulu, 2006	*	*	*	*
Masci, 2006	*		*	
Vitte, 2007	*			
Kapral, 2008	*			
Wang, 2009	*		*	*
Liao, 2009			*	
Enochsson, 2010	*		*	
Murata, 2010	*	*	*	*
Testoni, 2010	*	*	*	*
Alkhatib, 2011			*	

NUMBER OF CENTERS	CUT-OFF (LOW VS HIGH)	PERFORATION RATE, HV	PERFORATION RATE, LV	P VALUE AND/ OR ODDS RATIO
Perforation as outcome, by Endoscopist Volume				
51	83	100 (?%)	276 (?%)	0.042
6	200 therapeutic per year	2 (0.3%)	3 (0.6%)	1.000
28	50 per year	12 (0.5%)	7 (0.6%)	NS
1	>5000 lifetime Vs, completed 1 year supervised training, >100 supervised, no independent	0	0	NA
6	supervision and/or <200 independently Vs experienced	6 (0.6%)	3 (0.4%)	0.74
2	200 per year	2 (3.3%)	1 (6.25%)	0.6
Perforation as outcome, by Center Volume				
51	10-320 Vs 380-780 per 8 years	120 (?%)	256 (?%)	0.028
6	200 therapeutic per year	4 (0.5%)	1 (0.3%)	1.000
1156	500 per year	? (0.23%)	? (0.16%)	0.09
51	< 200 Vs > 1000 per 2 years	7 (0.3%)	7 (0.3%)	NS

COMPARABILITY OF CASES AND CONTROLS ON THE BASIS OF THE DESIGN OR ANALYSIS	ASSESSMENT OF OUTCOME	WAS FOLLOW-UP LONG ENOUGH FOR OUTCOMES TO OCCUR	ADEQUACY OF FOLLOW UP	TOTAL SCORE
		*	*	2
*	*	*		5
**	*	*	*	7
**	*	*		8
*	*	*	*	6
**		*	*	5
*				2
*	*	*	*	7
*	*			3
*	*	*		5
*	*	*		7
*	*	*		7
*	*	*		4

STUDY	REPRESENTATIVENESS OF THE EXPOSED COHORT	NON-EXPOSED COHORT	ASCERTAINMENT OF EXPOSURE	DEMONSTRATION THAT OUTCOME OF INTEREST WAS NOT PRESENT AT START OF STUDY
Glomsaker, 2013	*			
Coté, 2013	*		*	*
Peng, 2013				*
Kalaitzakis, 2015	*		*	*
Hu, 2016			*	
Saito, 2017			*	
Voiosu, 2018	*	*	*	
Saito, 2019			*	
Hudhud, 2019	*	*	*	
Han, 2019			*	
Mariani, 2019	*		*	*
Huang, 2019	*		*	*
Zheng, 2020	*		*	
Langerth, 2020	*		*	*
Lee, 2020	*		*	*
Caglar, 2020			*	
Harvey, 2020				*
Mutneja, 2020	*			*

COMPARABILITY OF CASES AND CONTROLS ON THE BASIS OF THE DESIGN OR ANALYSIS	ASSESSMENT OF OUTCOME	WAS FOLLOW-UP LONG ENOUGH FOR OUTCOMES TO OCCUR	ADEQUACY OF FOLLOW UP	TOTAL SCORE
*				2
*	*	*		6
	*			2
	*	*		5
	*			2
*	*			3
**	*			6
*	*			3
*	*			5
*	*			3
	*			4
	*			4
*	*	*		5
		*	*	5
**	*	*		7
*				2
	*	*		3
	*	*	*	4

Appendix VII

Supplementary material for Chapter 10

APPENDIX VII
Supplementary material for Chapter 10

SUPPLEMENTARY TABLE 1

Results of threshold analysis, in which each input parameter's is varied over a range, to determine the level ("threshold") above or below which the conclusion changes [1]. Legend: ERCP = Endoscopic retrograde cholangiopancreatography. PTC = Percutaneous transhepatic cholangiography. AEs = Adverse events. HV = High-volume. LV = Low-volume. ICER = Incremental Cost-Effectiveness Ratio. Min = Minimum. Max = Maximum

PARAMETER	BASELINE	MIN. THRESHOLD	MAX. THRESHOLD
Transport from LV to HV center	130,000	68,000	4361,000
Transport from LV to HV center	130,000	3407,000	4361,000
Transport from LV to HV center	130,000	2062,727	4361,000
Index ERCP, probability of significant AEs after successful ERCP, LV	0,067	0,005	0,100
Utility after ERCP with significant AEs	0,760	0,660	0,860
Index ERCP, probability of significant AEs after successful ERCP, HV	0,022	0,005	0,070
Utility after ERCP without or with non-significant AEs	0,885	0,810	0,990
Index ERCP, probability of death after successful ERCP, LV	0,008	0,000	0,030
Probability of requiring transportation to HV center for Index ERCP	0,674	0,000	0,674
Re-ERCP, probability of significant AEs after successful ERCP, LV	0,067	0,005	0,100
PTC, probability of significant AEs	0,050	0,017	0,083
Index ERCP, probability of significant AEs after failed ERCP, LV	0,087	0,025	0,120
Index ERCP, probability of death after successful ERCP, HV	0,002	0,000	0,020
Index ERCP, probability of death after failed ERCP, LV	0,010	0,000	0,050
Re-ERCP, probability of death after successful ERCP, LV	0,008	0,000	0,030
Re-ERCP, probability of significant AEs after failed ERCP, LV	0,087	0,025	0,120
Index ERCP, probability of significant AEs after failed ERCP, HV	0,040	0,025	0,090
Re-ERCP, probability of being treated in an HV center	0,500	0,000	1,000
Re-ERCP, probability of technical success, LV	0,860	0,807	0,914

MIN. ICER	MAX. ICER	EFFECT	% SENSITIVITY
-145603,231	171930,659	Change in ICER > -14102 EUR	109,33
101367,572	171930,659	Centralization is not cost-effective	109,33
1937,769	171930,659	Change in total costs order	109,33
-620102,739	-118929,117	Change in ICER > -14102 EUR	42,12
-553788,597	-80795,631	Change in ICER > -14102 EUR	30,10
-291771,120	-127843,836	Change in ICER > -14102 EUR	23,53
-324034,384	-78748,523	Change in ICER > -14102 EUR	4,75
-147679,100	-124078,542	Change in ICER > -14102 EUR	4,10
-151589,623	-141017,370	Change in ICER > -14102 EUR	3,75
-161682,137	-133363,838	Change in ICER > -14102 EUR	3,35
-150075,435	-140918,357	Change in ICER > -14102 EUR	2,01
-149974,318	-137392,846	Change in ICER > -14102 EUR	1,78
-146605,440	-140451,711	Change in ICER > -14102 EUR	1,74
-142365,123	-135705,721	Change in ICER > -14102 EUR	1,43
-142449,829	-136337,468	Change in ICER > -14102 EUR	1,23
-149950,362	-140819,641	Change in ICER > -14102 EUR	0,69
-143851,177	-140113,428	Change in ICER > -14102 EUR	0,68
-191289,442	-80010,491	Change in ICER > -14102 EUR	0,55
-147214,261	-138497,235	Change in ICER > -14102 EUR	0,52

SUPPLEMENTARY TABLE 2

Base-case cost estimates for ERCP admission [22]

Legend: ERCP = Endoscopic retrograde cholangiopancreatography.

AEs = Adverse events. HV = High-volume. LV = Low-volume. SD = Standard Deviation

*Considering: the salary of doctor and nurse per hour (568 SEK and 218 SEK), the number of doctors and nurses per procedure (2 doctors and 2 nurses, either for ERCP or PTC) and 0.9480 hours per procedure.

TYPE OF ADMISSION	ASSOCIATED COSTS	BASE VALUE (2016 SEK)	SD (2016 SEK)	BASE VALUE (2023 €)	SD (2023 €)
Admission for ERCP without or with non-significant AEs	ERCP procedure	3,066	-	-	-
	ERCP supplies	7,760	776	-	-
	ERCP procedure medication	64	6	-	-
	ERCP medication/day	50	5	-	-
	Salary doctor*	1,077	112	-	-
	Salary nurse*	413	42	-	-
	Hospital admission (1day)	6,000	600	-	-
	TOTAL	**18,430**	**1,541**	**2,364**	**195**
Admission for ERCP with significant AEs	ERCP procedure	3,066	-	-	-
	ERCP supplies	7,760	776	-	-
	ERCP procedure medication	64	6	-	-
	ERCP medication/day	50	5	-	-
	Salary doctor*	1,077	112	-	-
	Salary nurse*	413	42	-	-
	Hospital admission (4 days)	24,000	2,400	-	-
	Complication	55,312	5,531	-	-
	TOTAL	**91,742**	**8,872**	**11,768**	**1,125**
Admission for ERCP with significant AEs and death	ERCP procedure	3,066	-	-	-
	ERCP supplies	7,760	776	-	-
	ERCP procedure medication	64	6	-	-
	ERCP medication/day	50	5	-	-
	Salary doctor*	1,077	112	-	-
	Salary nurse*	413	42	-	-
	Hospital admission (1day)	24,000	2,400	-	-
	Complication	55,312	5,531	-	-
	Death	5,000	500	-	-
	TOTAL	**96,742**	**9,372**	**12,410**	**1,189**
Transportation from LV to HV center		**34,000**	**-**	4,361	**-**

TYPE OF ADMISSION	ASSOCIATED COSTS	BASE VALUE (2016 SEK)	SD (2016 SEK)	BASE VALUE (2023 €)	SD (2023 €)
Admission for PTC without or with non-significant AEs	PTC supplies	4,438	443	-	-
	PTC procedure medication	50	5	-	-
	PTC medication/day	50	5	-	-
	Salary doctor*	1,077	112	-	-
	Salary nurse*	413	42	-	-
	Hospital admission (1day)	6,000	600	-	-
	TOTAL	**12,028**	**1,207**	**1,543**	**153**
Admission for PTC with significant AEs	PTC supplies	4,438	443	-	-
	PTC procedure medication	50	5	-	-
	PTC medication/day	50	5	-	-
	Salary doctor*	1,077	112	-	-
	Salary nurse*	413	42	-	-
	Hospital admission (4days)	24,000	2,400	-	-
	Complication	55,312	5,531	-	-
	TOTAL	**85,340**	**8,538**	**10,947**	**1,083**
Admission for PTC with significant AEs and death	PTC supplies	4,438	443	-	-
	PTC procedure medication	50	5	-	-
	PTC medication/day	50	5	-	-
	Salary doctor*	1,077	112	-	-
	Salary nurse*	413	42	-	-
	Hospital admission (4 days)	24,000	2,400	-	-
	Complication	55,312	5,531	-	-
	Death	5,000	500	-	-
	TOTAL	**90,340**	**9,038**	**11,589**	**1,146**

SUPPLEMENTARY TABLE 3

Base-case cost estimates for PTC admission [22]

Legend: PTC = Percutaneous transhepatic cholangiography.

AEs = Adverse events. HV = High-volume. LV = Low-volume. SD = Standard Deviation

*Considering: the salary of doctor and nurse per hour (568 SEK and 218 SEK), the number of doctors and nurses per procedure (2 doctors and 2 nurses, either for ERCP or PTC) and 0.9480 hours per procedure.

SUPPLEMENTARY FIGURE

Results of two-way sensitivity analysis comparing the success and significant AEs for the index ERCP at LV centers.

Legend: The blue-colored area corresponds to situations where the “current scenario” is not cost-effective; The green-colored area corresponds to the situations where the “current scenario” is cost-effective.