What Would Be the Appropriate Number of Clinical ERCP Cases for Trainees to Acquire Basic Competence? A Systematic Review and Meta-Analysis

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ABSTRACT

Endoscopic retrograde cholangiopancreatography (ERCP) is technically demanding and carries significant risks. It is performed by gastrointestinal and surgical endoscopists. There is no consensus on the minimum number of ERCPs required during training. This study was conducted to analyze the minimum number of clinical ERCPs that a trainee needs to perform to achieve competency. PubMed, Ovid-Embase, and the Cochrane library were searched systematically for prospective and retrospective studies reporting on trainees' ERCP performance. Mete-analysis was conducted to analyze the success rate of cannulation, other basic techniques, and adverse event rate, using the random-effect model with Review Manager 5.3. Thirteen studies met the inclusion criteria, with 149 trainees performing a total of 18 794 ERCP procedures. The pooled cannulation success rate was 85.7% (95% CI: 78.1%-91.0%) at completion of training. The cannulation success rate was 76.5% (95% CI: 69.2%-82.5%) when the trainees had completed 180 ERCPs, which increased to 81.8% (95% CI: 69.8%-90.6%) after 200 ERCP procedures. Adverse events and post-ERCP pancreatitis rates were 4.7% (95% CI: 2.9%-9.1%) and 2.0% (0.9%-3.9%), respectively. Achieving a cannulation success rate of >90% was considered a quality indicator for ERCP training by most societal guidelines. However, our retrospective analysis indicated that trainees only attained a pooled cannulation success rate of only 81.8% after 200 procedures. Therefore, the minimum number of ERCPs required to achieve competency during training may need to be redefined to meet the basic requirement.

Keywords: *Endoscopic retrograde cholangiopancreatography, trainee, competence, cannulation success rate*

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) was first described in 1968 as a diagnostic tool to assess pancreaticobiliary diseases. With improved diagnostic modalities including magnetic resonant cholangiopancreatography and endoscopic ultrasound, ERCP has evolved into mainly a therapeutic procedure.[1] Although majority of ERCPs are performed by gastroenterologists, a significant proportion of these procedures are done by surgeons. Emphasis is placed on trainees' performance to improve the success and safety of ERCP procedures.[2,3] Trainees are required to undergo supervised hands-on ERCP training in established and organized fellowship programs before performing these procedures individually.

Good clinical outcome of therapeutic ERCP depends on successful completion and absence of complications. Establishing a standard for ERCP training and assessment of competence has been a constant endeavor for many training programs, and different objective criteria have been used.[4] Many use the number of ERCP

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procedures performed as a surrogate of experience, but there is no real consensus regarding the absolute number of procedures needed for trainees to acquire their skills.[5] Besides, the trainer is often involved and the trainee may not be the only person performing the ERCP. In difficult cases, the trainer may offer hands-on assistance or even take over the procedure. Therefore, even for the same number of documented procedures, the skill acquired by individual trainees is not reflected uniformly.[2] There is also discrepancy in expectation between gastrointestinal and surgical societies in terms of the minimum number of procedures required to achieve competency.[6-8]

Traditionally, a successful selective cannulation rate is considered an objective surrogate marker for a successful ERCP procedure. This is because selective cannulation is pivotal to ensure completion of subsequent steps of a therapeutic ERCP procedure. However, different definitions of successful cannulation have been used in assessing competence ranging from successful deep cannulation to simply contrast injection into the desired duct. A complete ERCP procedure requires not only successful cannulation but also successful execution of other technical maneuvers including tissue sampling, sphincterotomy, stent placement, or stone extraction. The technical difficulty of an ERCP procedure can be divided into different grades thus requiring a varying level of expertise. A graduating trainee is expected to be capable in performing grade I and II procedures.[9] Given the limited value of using the total number of procedures performed as a surrogate of experience, we conducted a retrospective review of publications related to basic ERCP training. The aim of this meta-analysis is to determine the competence level attained by current trainees based on the reported number of ERCP procedures performed in training and to make a recommendation as to the appropriate number of supervised procedures required by future trainees to acquire basic procedural competence.

METHODS

Literature Review and Study Selection Criteria

A comprehensive literature search was performed by 2 of the authors using PubMed, Ovid-EMBASE, and The Cochrane Library. The following search criteria were used: ("Endoscopic retrograde cholangiopancreatography" OR "ERCP") AND ("trainee" OR "training" OR "fellows"). We also searched in the references quoted in selected studies, practice guidelines, and relevant review articles to identify any studies missed on the initial literature search.

Published papers were considered relevant if they assessed trainees' ERCP procedural competency. Studies were required to report trainees' cannulation success rate, preferably with procedural competency illustrated in the form of a learning curve. Studies were excluded if they were (1) non-English literature, (2) only abstracts without full-text articles, (3) review articles, letters, commentaries, or book chapters, or (4) do not provide trainee cannulation success rate.

Data Extraction and Analysis

Data extraction was carried out independently by 2 investigators. Any discrepancies were resolved by consensus of these 2 investigators. Any disagreement on a conflicting study was resolved by full discussion. The extracted information included author(s), year of publication, country of origin, study type, numbers of trainees, description of ERCP cases, and clinical outcome including ERCP competency. If a consensus could not be reached between the 2 study investigators, then the opinion of a third investigator was solicited to reach a final decision. The success rate was calculated by the number of successful cannulations divided by the total number of procedures. The meta-analysis of non-comparative binary data was performed using the software Review Manager 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration 2014).

We analyzed the pooled cannulation success rate in the included studies, and based on the learning curve, the training process was divided into subgroups according to the number of ERCPs performed at a certain increment of procedures (50, 100, 150, 180, 200, 250, 300, and >300 ERCPs, respectively) to calculate the cannulation success rate. Finally, we analyzed the reported incidence of all adverse events and in particular post-ERCP pancreatitis (PEP) rate.

RESULTS

Search Results and Study Description

The initial literature search identified 1351 studies based on inclusion criteria and 6 more based on review of the references in the reported studies included in the original search, guidelines, and relevant reviews. Of the total 1357 studies, 35 studies were selected for full-text review. Thirteen studies were eligible for inclusion in this meta-analysis.[2,10-21] Reasons for excluding the other studies are listed in Figure 1. There were 149 trainees involved in the 13 studies; and they performed a total of 18 794 ERCP procedures. Nine of the 13 studies

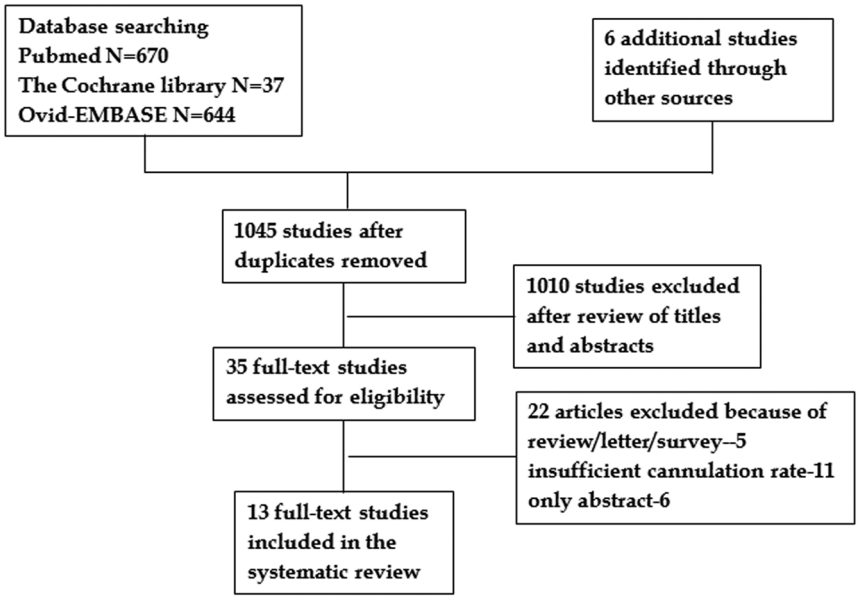

Figure 1. Flow diagram of the included and excluded studies.

were prospective studies, and 85% (11/13) involved gastrointestinal fellows in training, and 2 other studies involved general surgery trainees. Only 7 out of 13 studies included a description of the training protocol for the ERCP trainees during the study period with high variability, and before the ERCP procedure, trainees attended didactic lectures on ERCP, mastered the indications of ERCP, and practiced insertion of the duodenoscope and manipulation of accessories. Trainees then received supervised hands-on ERCP training in the intraprocedure period including cannulation and other maneuvers like sphincterotomy, stone clearance, and stent insertion. Five studies reported the average time allowed for the trainee to attempt cannulation of the desired duct, which varied between 5 and 20 minutes. Different endpoints were used in these studies to determine successful cannulation and assessment of trainees' procedural competency. Some studies used common bile duct cannulation, some used pancreatic duct cannulation, and others reported selective ductal (SD) cannulation. Only one study evaluated the trainees' cognitive skill as part of the competency assessment.[21] Cannulation success rates were reported between 80% and 90% and were used as the endpoint for competency assessment (Table 1). The total number of ERCPs performed per trainee ranged from 70 to 400. In general, the cannulation success rate of 90% was used as an indicator for competency in most guidelines, especially studies that documented supervised procedures in patients with a native papilla.[15,16]

Outcome Measure—Cannulation Success Rate

Good ERCP procedural outcome is defined as successful cannulation to facilitate subsequent maneuvers and therapies with a relatively low incidence of adverse events or complications. We analyzed the pooled cannulation success rate of the training procedure (Figure 2), and the pooled cannulation success rate was estimated at 85.7% (95% CI: 78.1%-91.0%).

Trainees undergo supervised hands-on ERCP training to acquire the basic skills and accumulate sufficient experience over time with practice. To determine the appropriate number of clinical ERCP procedures that a trainee should perform during training, we arbitrarily divided the training experience into different subgroups with increments of 50 procedures. As shown in Figure 3, the respective cannulation success rate was calculated at 53.5% (95% CI: 35.5%-70.6%) for the first 50 ERCPs, increasing to 81.8% (95% CI: 69.8%-90.6%) after 200 ERCP procedures, and subsequently leveling off to 81.4% (95% CI: 49.0%-95.3%) after 300 ERCPs. Although only a few studies documented more than 200 ERCP cases in trainees' learning experience, one study reported the experience of a single trainee who documented a cannulation success rate of >80% after performing 350-400 supervised procedures on a native papilla.[15] This suggested that more patients/procedures are required for training to meet the expected cannulation success rate of ≥90% because it could not be achieved after only 200 cases. As suggested by the data presented in Figure 4, the 95% CI

Table 1. Characteristics and Competency Outcomes of the Included Studies

Study	Country	Trainees (*n*)	Training Program, Duration	ERCPs (*n*)	Cannulation Success Rate	Competency
PD cannulation						
Jowell et al.	USA	17	Gastroenterology, expert endoscopic trainers supervised, 10 minutes	1796	80%	Achieved by 160 ERCPs
Watkins et al.	USA	20	Gastroenterology, University Training Program (1987-1993), 10-20 minutes	641	85%	Achieved by 70 ERCPs
SD cannulation						
Kowalski et al.	USA	69	Gastroenterology, University Training Program	9486	80%	Achieved by 180 ERCPs
Schlup et al.	New Zealand	1	Gastroenterology, through assisting other expert endoscopic trainer	532	90%	Achieved by 120-150 ERCPs
Vitale et al.	USA	13	General surgery, hands-on experiential training	2008	85%	Achieved by 102 ERCPs
Waller et al.	New Zealand	1	General surgery, expert endoscopic trainers supervised	238	80%*	Achieved by 100 ERCPs
Kwek et al.	Singapore	1	Gastroenterology, hands-on experiential training, 7 minutes	85	NA	NA
Frost et al.	UK	1	General surgery, expert endoscopic trainers supervised, 6 minutes	134	NA	NA
Pan et al.	China	4	Gastroenterology, hands-on experiential training, 5, 10, 15 minutes	256	NA	NA
Biau et al.	France	1	Gastroenterology, through assisting other expert endoscopic trainer	529	NA	Achieved by 79 ERCPs
CBD cannulation						
Ekkelenkamp et al.	Netherlands	15	Gastroenterology, training program in the Netherlands (2008-2013)	1541	80%	Achieved by 160 ERCPs
Verma et al.	USA	1	Gastroenterology, supervision and hands-on experience	499	80%*	Achieved by 350-400 ERCPs
Wani et al.	USA	5	Gastroenterology, hands-on experiential training	1049	90%	Achieved by 26-211 ERCPs^

Marker: the expected cannulation success rate. Competency results: the number of ERCP performed to achieve the expected cannulation success rate.
*Competency marker included native papilla; ^4 trainees achieved by 26, 104, 182, and 211 ERCPs, respectively.
CBD, common bile duct; PD, pancreatic duct; SD, selective duct cannulation; NA, not available; ERCP, endoscopic retrograde cholangiopancreatography.

upper limit for cannulation success rate can be used to demonstrate an improvement in successful cannulation after 200 cases.

Other Basic Techniques and Adverse Events Rate

Successful cannulation is only a part of therapeutic ERCP as other basic techniques are also important including papillotomy, stent placement, and stone extraction. There was only one study that assessed the trainee's competence with other techniques in our included studies[21]: 2 fellows achieved stone clearance competence after 19 and 70 procedures, respectively, and one fellow acquired competence after 19 stent insertion procedures. The learning curve reflects the performance of trainees over time and the success rates for stent placement and stone extraction were 84% and 72%, respectively, after approximately 160 ERCP procedures.[17]

In addition, adverse events or complications should be assessed objectively throughout the ERCP training. In this review, the included studies provided only a general description of adverse events and did not specify

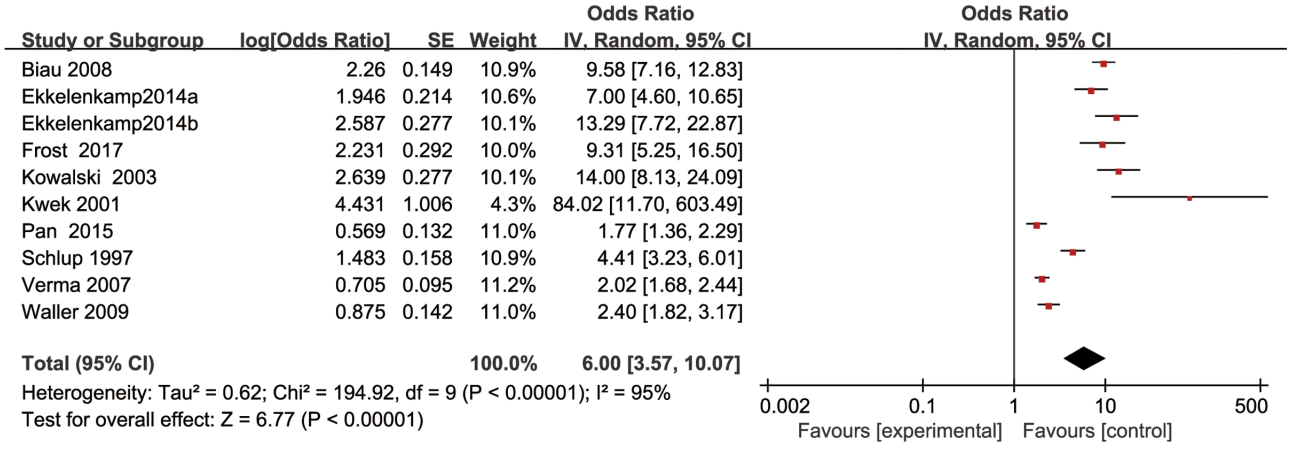

Figure 2. Forest plot of pooled trainee cannulation success rates for studies reported after ERCP procedures (Ekkelenkamp 2014a-patients with a native papilla, Ekkelenkamp 2014b-all patients).

an association between adverse events rate and the number of procedures performed. Only 5 studies documented the adverse events (Table 2) including PEP, bleeding, perforation, and biliary infection revealing a pooled adverse event rate of 4.7% (95% CI: 2.9%-9.1%), and the pooled estimated PEP rate was 2% (0.9%-3.9%) (Figure 5).

Publication Bias

The funnel plot (Figure 6) shows that there may be a publication bias (Begg's test z = 3.22, Pr > |z| = 0.001, Egger bias t = 9.07, *P* > |t| = 0.000).

DISCUSSION

ERCP is an established non-operative treatment option for pancreaticobiliary diseases since the early 1970s.[22] Therapeutic ERCP offers a range of therapies including papillotomy, stone extraction, dilation, and brushing cytology for bile duct strictures and plastic or metal stent placement for biliary drainage. ERCP is a risky procedure with complications including PEP, bleeding, perforation, and cholangitis with significant associated morbidity and even mortality.

ERCP consists of different techniques; while some are simple, others are technically demanding. During fellowship or advanced training, trainees learned to perform and become proficient with individual tasks and eventually become proficient in performing the entire procedure. In addition to technical skill, the cognitive aspect of ERCP training involves learning the clinical application of ERCP in patient management, including understanding the indication and contraindications, techniques involved, and the possible outcome in the overall planning of patient care. It is necessary for trainees to learn and practice with supervision to ensure success and to keep complications to a minimum. However, there are variations in trainees' supervision between different training programs. Currently, only the number of procedures performed by the trainee is used as a surrogate of experience. However, this metric only indicates the number of procedures the trainee has been involved in and may not reflect the trainees' experience because the learning experience gained can vary considerably between trainees. Analysis of success of the different aspects of ERCP could introduce certain flaws and biases. Confounding factors included potential trainer involvement which could affect the success and outcome than if the procedure was performed by the trainee alone. Therefore, using the cannulation success rate of a native papilla and limiting the assessment to trainee's performance would allow a more accurate determination of the trainee's basic skill and minimize the influence of the trainer.

Generally, the number of procedures performed by the trainee is used as a surrogate of procedural competency. The American Society of Gastrointestinal Endoscopy (ASGE) has increased in its guidelines the minimum number of ERCPs required for trainees to complete since it was first reported in 1996.[23] The early Gastroenterology Core Curriculum indicated that fellows required 100 ERCPs, of which 25 should be therapeutic (20 sphincterotomy and 5 stent placement) in 2007.[24] Realizing the complexity of training and learning experience, the ASGE increased the minimum number to 180 ERCPs, with at least half being therapeutic in a subsequent updated guideline. In 2017,

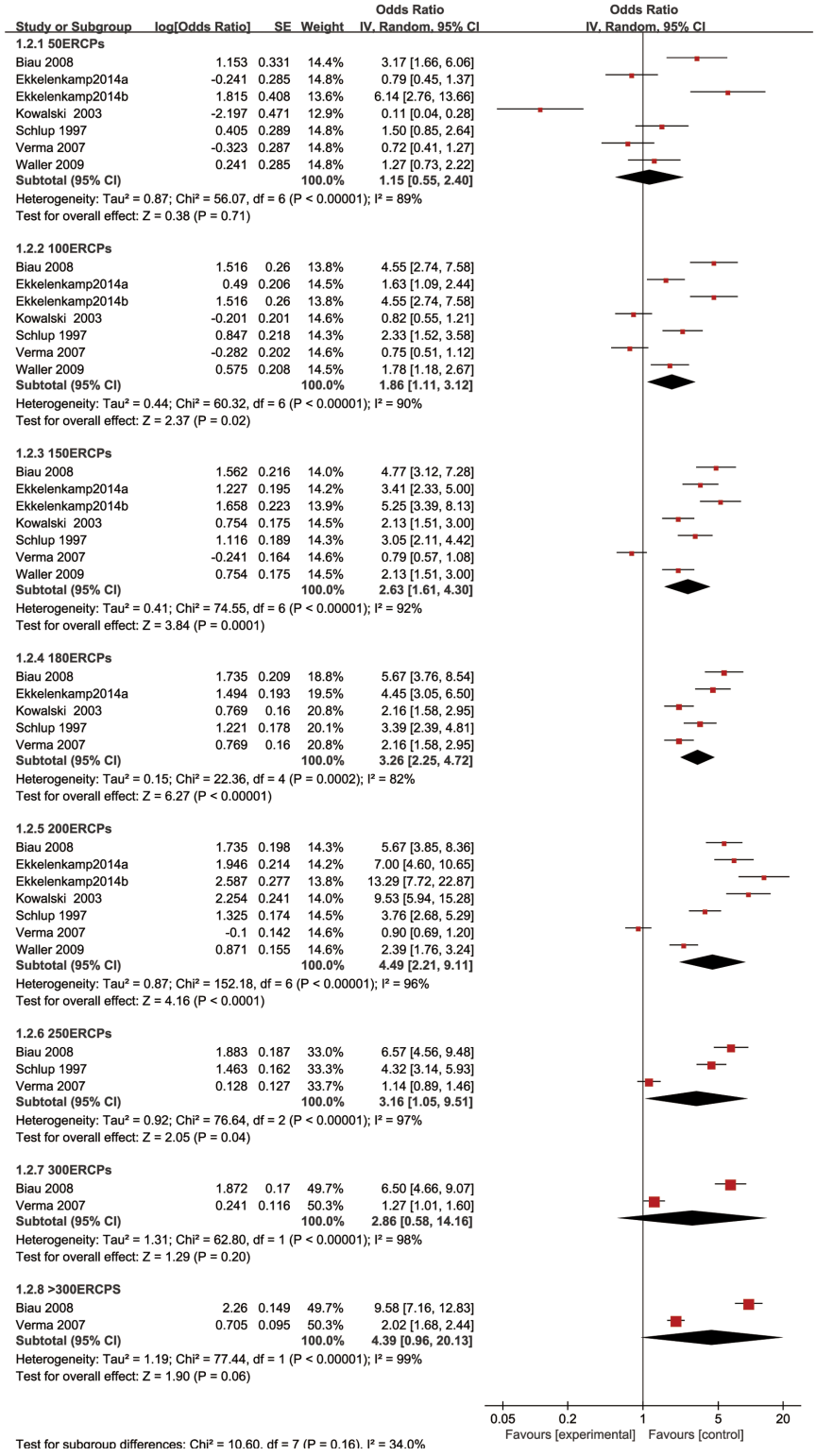

Figure 3. Forest plot of pooled cannulation success rates after 50, 100, 150, 200, 250, 300, and >300 ERCP procedures. ERCP, endoscopic retrograde cholangiopancreatography.

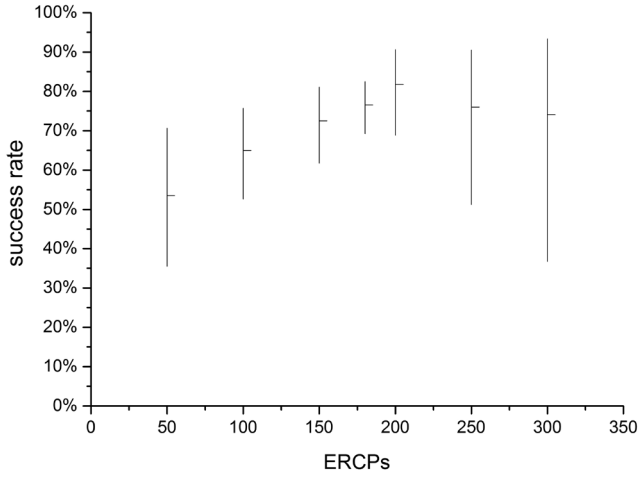

Figure 4. Successful cannulation rates according to the number of ERCP procedures. ERCP, endoscopic retrograde cholangiopancreatography.

the minimum number of ERCPs required for training was further increased to 200 cases.

Successful cannulation has been considered the endpoint for assessing trainees' basic skill in ERCP performance. In most settings, more than 90% success rate was set as an expectation to reflect skill and competency. In our retrospective analysis, the pooled cannulation success rate was 85.7% at the completion of training. When a trainee has completed 180 ERCP cases, the pooled cannulation success rate was only 76.5%, increasing to 81.8% after 200 ERCP cases. A more recent prospective study indicated that more practice was associated with further improvement in the trainee's skills (with an odds ratio of 1.1 for each additional 10 ERCPs performed).[25] However, because of the limited availability of clinical ERCPs for training, few studies were able to document more than 200 ERCP cases in the trainees' learning experience. In another study, a single trainee achieved a cannulation success rate of >80% only after performing 350-400 supervised ERCP procedures.[15] The 95% CI upper limit for pooled cannulation success rate continued to increase albeit slowly after 200 ERCP cases (Figure 3). If only 81.8% success rate was achieved with 200 ERCP cases, setting the expectation at 90% may seem unreasonable as shown in the retrospective analysis. Because of the heterogeneity of the selected studies in the current analysis, more prospective studies are needed to determine the appropriate number of ERCPs required for trainees to achieve competency. Recently, a prospective multicenter study showed that advanced endoscopy trainees of an advanced endoscopy training program achieved basic competency to perform ERCP after approximately 250 cases and to perform grade 2 ERCPs after 300 cases[26]; these findings were consistent with their previous prospective multicenter study which reported that a minimum number of 225 cases were required for training.[27] It is also important to stress the cognitive aspects of ERCP training including the application and safe use of fluoroscopy and real-time interpretation of the cholangiogram and/or pancreatogram during therapeutic intervention.[21]

Successful performance of the ERCP procedure and minimizing complications is part of quality assurance.[28] ERCP is not without risks, and complications can vary from PEP, bleeding, perforation, and cholangitis as well allergic reactions and cardiopulmonary complications. Proper documentation of these outcome measures is also a part of ERCP training. The incidence of PEP was 2.0% in our retrospective analysis, and this seems like an acceptable figure considering the varying experience of the trainees. While there is currently no consensus on the PEP rate for trainees, an Austrian nationwide benchmarking project reported a PEP rate of 5.1%.[29] Several issues deserve further discussion, especially the need for trainees to get more hands-on experience. Some training programs have limited number of clinical ERCP cases, and the total number of procedures available to individual fellows may not meet the expected minimum requirement. Despite being a training program, some faculty trainers are reluctant to

Table 2. Adverse Events Rates During ERCP Procedure

Study	Overall	PEP	Bleeding	Perforation	Biliary Infection
Vitale et al.	48/2008 (2.4%)	30/2008 (1.5%)	8/2008 (0.4%)	2/2008 (0.1%)	6/2008 (0.3%)
Wani et al.	50/1049 (4.8%)	16/1049 (1.5%)	7/1049 (0.7%)	4/1049 (0.4%)	–
Pan et al.	15/249 (6.0%)	12/249 (4.8%)	1/249 (0.4%)	–	1/249 (0.4%)
Kwek et al.	3/85 (3.5%)	3/85 (3.5%)	–	–	–
Frost et al.	16/134 (11.9%)	–	–	–	–

ERCP, endoscopic retrograde cholangiopancreatography; PEP, post-ERCP pancreatitis.

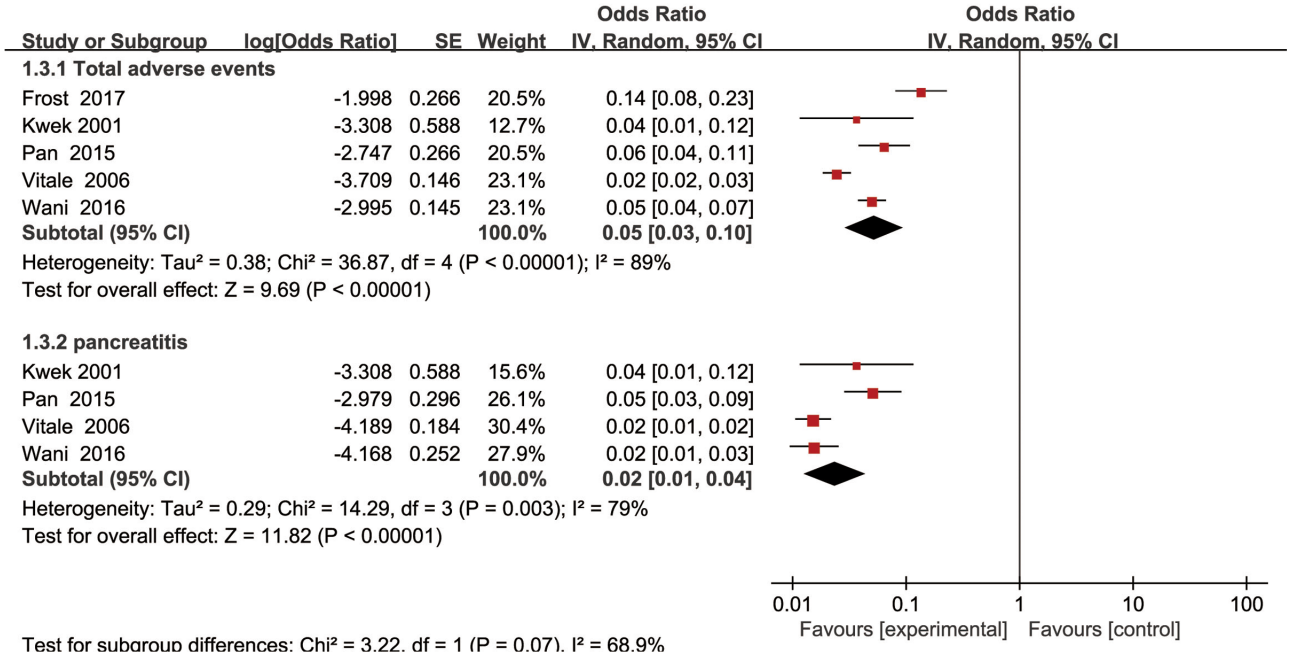

Figure 5. Forest plot of adverse event and PEP rates. PEP, post-ERCP pancreatitis.

allow trainees to perform high-risk procedures such as papillotomy because of liability issues, and this further limited the learning opportunity of the trainees. In a survey of graduating fellows, only 9% of trainees reported that they have performed the required 200 ERCPs.[30]

It is interesting to note that there is a new trend in using simulation devices for ERCP training, allowing trainees to acquire and master the basic ERCP skills without involving or risking a patient. Indeed, controlled randomized studies have shown a significant benefit in improving the biliary cannulation success rate of trainees receiving coached simulator practice when compared to those without simulation practice in the first 3 months of fellowship training.[31] The trainees can also practice different components of an ERCP procedure including simulation papillotomy using an artificial papilla[32] or perform multiple biliary stent placements.[33] The inclusion of simulation practice in a training program may confer benefits by improving the trainees' basic skills. This helps to shorten the learning curve while performing clinical ERCP and allows the trainees to focus on both cognitive and technical learning when they perform procedures on a patient.

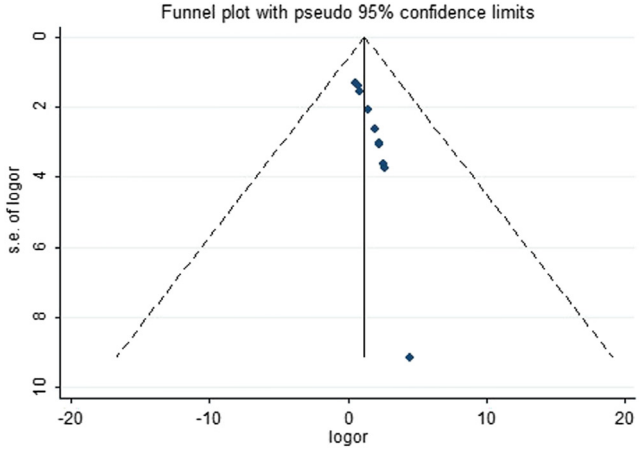

Figure 6. Bias assessment plot (Funnel plot) of pooled trainee cannulation success rates.

Our study has the same limitations as other meta-analysis which included the apparent heterogeneity of trainees' experience and training methods among the selected studies as well as the varying difficulty of the ERCP procedures. In addition, we have only included studies which were published in English, and it may be a potential source of publication bias.

In conclusion, successful cannulation is the most commonly used indicator to reflect trainee's ERCP skill and performance. However, setting the expectation of more than 90% successful cannulation rate seems unreasonable based on the reported studies. In this retrospective meta-analysis, trainees performing 200 ERCP cases

only achieved a cannulation success rate of 81.8%. Extrapolating the Society guidelines data, the number of ERCP procedures for trainees to acquire basic ERCP competency needs to be increased based on the existing guidelines. Other methods including simulation practice should be used to supplement trainee's early learning experience and help them acquire the basic skills with less clinical procedures.

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