# Competence development in ERCP: the learning curve of novice trainees

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**Background and study aim:** Measures for competence in endoscopic retrograde cholangiopancreatography (ERCP) during training are poorly defined. Currently, various training and accreditation programs base verification of competence on performance of a minimum number of procedures. There is a general awareness that procedural competence certification should be based on objective performance criteria. Continuous self-assessment using a Rotterdam Assessment Form for ERCP (RAF-E) can provide insight into trainee performance. The study aim was to express development in ERCP competence as a learning curve.

**Methods:** ERCP trainees at a tertiary referral center in the Netherlands were invited to participate. Performed procedures were appraised using RAF-E. Indication for each ERCP and presence of a virgin papilla were documented. Complexity was graded on a 3-point scale. The primary outcome parameter was common bile duct (CBD) cannulation success rate. Success of the intended therapeutic interventions was additionally expressed as a learning curve.

**Results:** 15 trainees were included. 1541 ERCPs (624 procedures in native papillary anatomy) were assessed through RAF-E. Unassisted CBD cannulation success rate improved from 36% at baseline to 85% after 200 procedures ($P<0.001$), and in 624 patients with a virgin papilla from 22% at baseline to 68% after 180 procedures ($P<0.001$). Learning curves for therapeutic interventions showed significant improvements for successful sphincterotomy ($P=0.01$) and stent placement ($P<0.001$).

**Conclusions:** Learning curves are a valuable means for assessing competence in ERCP. Differences in learning curves can be shown with RAF-E. Verification of competence should be based on actual performance, instead of minimum numbers.

## Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is considered to be one of the most challenging procedures in gastrointestinal endoscopy. In order to attain competence in performing this procedure, extensive training is necessary. Trainees differ considerably in the rates at which they acquire their endoscopy skills [1]. Moreover, methods of measuring ERCP competence are lacking and poorly defined. At present, competence is merely assumed on the basis of performance of a minimum number of ERCP procedures, ranging in various training programs mostly from 100 to 200. The American Society for Gastrointestinal Endoscopy (ASGE) recognized that 180–200 ERCPs were required for competence, based on the first study regarding this subject [1]. This important study used a composite endpoint for procedure success, and evaluated a relatively small number of procedures per trainee (average 85), with only three trainees reaching the level of 180 procedures. The evaluation of trainee performance was carried out by trainers. Additional data are scarce and threshold numbers do not necessarily reflect competence. Various guidelines state that competence should be verified by objective performance criteria [2–4]. Outcome measures such as common bile duct (CBD) cannulation rates and therapeutic success give insight into performance. The ASGE guidelines state that a trainee should be able to reach an 80%–85% CBD cannulation success rate at the end of ERCP training [3]. There is however no standardized method to assess such criteria.

Continuous self-assessment may be one way to gain insight into the performance of trainees. This method has already proven its value for competence measurement in colonoscopy. We have previously developed and assessed the Rotterdam

Assessment Form for Colonoscopy (RAF-C), with which learning curves can be plotted and individual as well as group performance analyzed and followed [5]. A similar method can be used for competence assessment in ERCP.

The aim of this study was to express competence development as a learning curve for different types of procedures and to assess the performance of residents who are commencing ERCP training.

## Methods

### Training program

From January 2008 to March 2013 we performed a prospective evaluation of individual and group ERCP performance in our academic medical center. The gastroenterology training program in the Netherlands starts with a 2-year residency in internal medicine followed by a 4-year program in gastroenterology. Trainees participate in endoscopy throughout these 4 years. After reaching competence in upper gastrointestinal endoscopy and colonoscopy, residents begin ERCP training. All successive trainees performing ERCP in our department were included in this study. They were in years 4 to 6 of their training and had reached competence in basic endoscopic procedures. Trainees were supposed to complete a newly developed self-assessment form after every ERCP.

### Self-assessment form

For this program, the Rotterdam Assessment Form for ERCP (RAF-E) was used. This form is in itself an unvalidated assessment instrument, but it is partly based on previously validated assessment tools [5–8]. Also, it has been used to assess the performance of experienced endoscopists [9]. The assessed items in the RAF-E comprise the proposed quality indicators for ERCP [3]. **Fig. 1** shows the form, which consists of three parts. The first part covers objective parameters such as procedural indication, degree of technical difficulty, based on Schutz & Abbott's classification [10] (**Table 1** shows the modified classification), and previous ERCP failure.

The second part of the form contains success or failure options for different parts of the procedure such as cannulation of the CBD or pancreatic duct, stent placement, sphincterotomy, or stone extraction. These parameters can be scored as successfully completed, partial success, or failure. Regarding cannulation, successful completion was defined as deep cannulation of the desired duct, partial success was defined as opacification of the duct or passing of a guidewire, but without deep cannulation with a catheter. Partially successful stenting was defined as achievement of partial or incomplete drainage of the desired segments. However, in the analysis all partially successful aspects of the procedure were considered to be failures, in order to avoid debate on definitions of partial success.

In the third part of the form, these various aspects of the procedure are followed by the request to complete an improvement plan after every 10 procedures, with a four-step approach. This is based on the Osborn–Parnes creative problem solving process, developed in the 1950s [11]. An example of such a plan would include the detailed responses to questions on identifying the problem, on solutions, and on improvement strategy. The subjective visual analogue scores shown on the form were not taken into account in the statistical analysis, nor was the outcome of the improvement plan. The value of the subjective assessment was in creating self-awareness to enable reflection on performance rather than in providing evidence for quality measurements.

Trainees registered only the parts of the procedure where they were actively involved.

### Patients

All ERCPs performed in this study were part of the regular training program, supervised by a staff endoscopist. Patients were referred for ERCP for a broad range of indications such as gallstones, benign or malignant strictures, and stent placement. Patients were routinely sedated using fentanyl and midazolam.

### Main outcome measures

The primary outcome measure was the rate of successful CBD cannulation. This parameter was used to create individual and group learning curves. Success of therapeutic interventions such as stone extraction or stent placement was also calculated.

Since all procedures performed during a training period have an effect on the learning process, we first evaluated all procedures combined for each endoscopist, irrespective of their degree of technical difficulty. If the supervisor had to intervene in the procedure for any reason, that part of the intervention counted as failure, and the subsequent part of the procedure was considered not applicable for the trainee. When CBD cannulation was successfully performed by the trainee, and stone extraction failed, only this last part counted as a failure.

Procedures performed in patients with a virgin papilla were analyzed separately regarding CBD cannulation, since this is the step that an endoscopist performing ERCP in an average practice should be able to achieve.

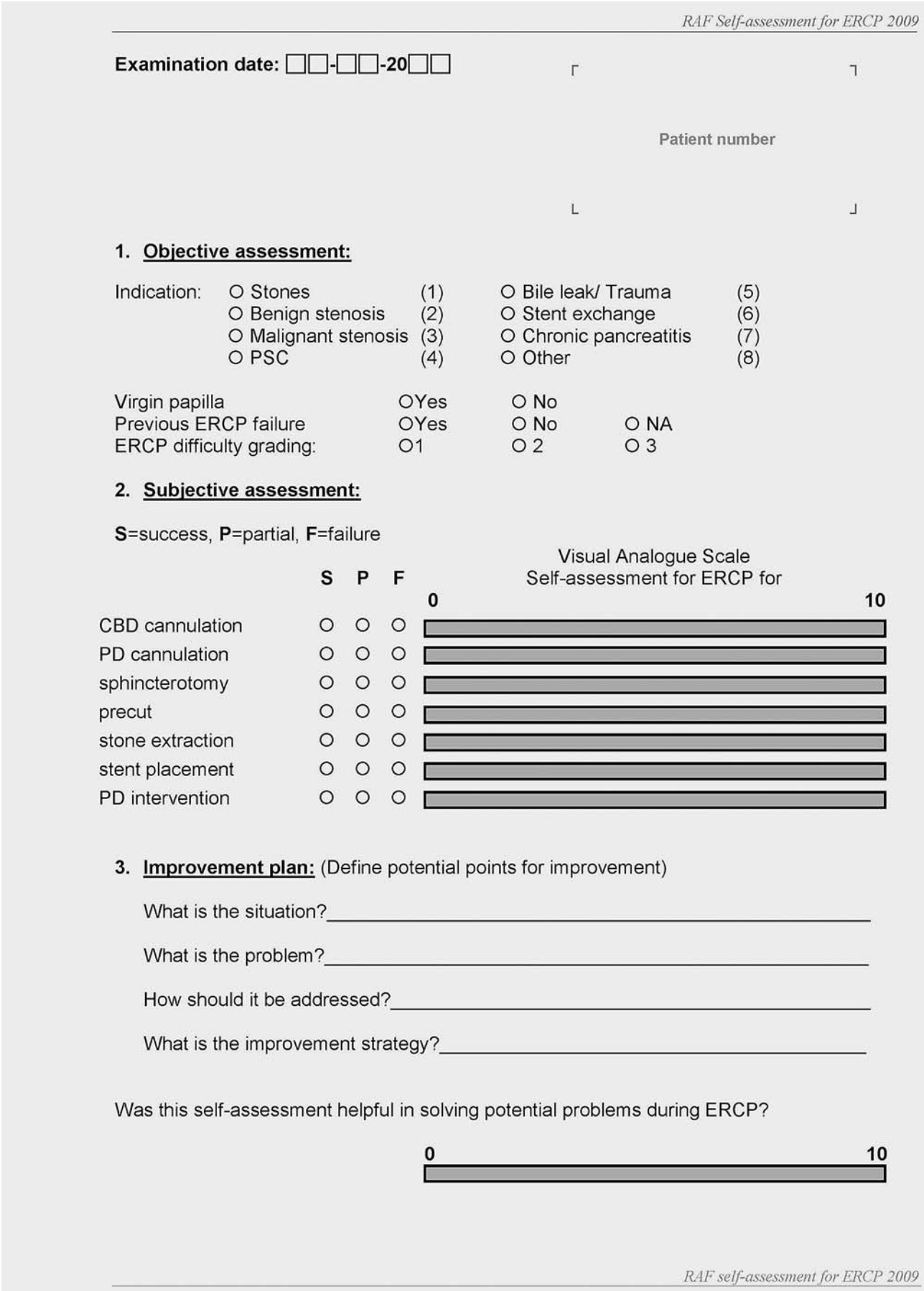
### Statistical analysis

For all analyses, we used binary outcome measures (success vs. failure). Partial success was regarded as failure. We plotted the probability of a successful common bile duct cannulation against number of ERCPs with 95 % confidence intervals (95 %CI), obtained from a generalized linear mixed model (logistic regression for longitudinal data) and we analyzed the significance of the increment in the learning curve in this way. The probability was modeled with a cubic spline having two interior knots equally spaced over the available range of ERCP numbers. Correlations between the repeated measurements of the individual endoscopists were accounted for by including a random intercept term for the endoscopists in these models. Similar analyses were performed for therapeutic interventions such as stone extraction and stent placement. Differences in proportions were analyzed using chi-squared tests. A two-sided $P$ value of $<0.05$ was considered significant. Analyses were carried out using SAS version 9.2.

## Results

A total of 15 trainees were included in this study. Between January 2008 and March 2013 they filled out 1541 RAF-E forms. Three trainees had already started ERCP training before January 2008, but the number of ERCPs performed before participating in this study was taken into account in the analysis. The median number of RAF-Es filled out per trainee was 90 (range 20–218). Adherence to completion of the forms was 82.9 %.

**Table 2** gives an overview of the different indications for which the ERCPs were performed. **Table 3** shows the distribution of



RAF Self-assessment for ERCP 2009

**Examination date:** □□-□□-20□□

Patient number

**1. Objective assessment:**

| | | | | |
|---|---|---|---|---|
| Indication: | ○ Stones | (1) | ○ Bile leak/ Trauma | (5) |
| | ○ Benign stenosis | (2) | ○ Stent exchange | (6) |
| | ○ Malignant stenosis | (3) | ○ Chronic pancreatitis | (7) |
| | ○ PSC | (4) | ○ Other | (8) |

| | | | |
|---|---|---|---|
| Virgin papilla | ○Yes | ○ No | |
| Previous ERCP failure | ○Yes | ○ No | ○ NA |
| ERCP difficulty grading: | ○1 | ○ 2 | ○ 3 |

**2. Subjective assessment:**

**S**=success, **P**=partial, **F**=failure

| | S | P | F | Visual Analogue Scale Self-assessment for ERCP for 0 — 10 |
|---|---|---|---|---|
| CBD cannulation | ○ | ○ | ○ | |
| PD cannulation | ○ | ○ | ○ | |
| sphincterotomy | ○ | ○ | ○ | |
| precut | ○ | ○ | ○ | |
| stone extraction | ○ | ○ | ○ | |
| stent placement | ○ | ○ | ○ | |
| PD intervention | ○ | ○ | ○ | |

**3. Improvement plan:** (Define potential points for improvement)

What is the situation?_____

What is the problem?_____

How should it be addressed?_____

What is the improvement strategy?_____

Was this self-assessment helpful in solving potential problems during ERCP?

0 — 10

RAF self-assessment for ERCP 2009

**Fig. 1** Trainee self-assessment for endoscopic retrograde cholangiopancreatography (ERCP). The Rotterdam Assessment Form for ERCP (RAF-E). PSC, primary sclerosing cholangitis; NA, not applicable; CBD, common bile duct; PD, pancreatic duct.

**Table 1** Degrees of difficulty of endoscopic retrograde cholangiopancreatography (ERCP) procedures, based on the classification of Schutz & Abbott [10].

| Degree of difficulty | Biliary procedures | Pancreatic procedures |
|---|---|---|
| Grade 1 | Diagnostic cholangiography<br>Biliary cytology<br>Stone extraction ≤ 10 mm<br>Dilation of stenosis/stent placement/ nasobiliary drain in extrahepatic strictures | Diagnostic pancreatography<br>Pancreatic cytology |
| Grade 2 | Stone extraction > 10 mm<br>Dilatation of stenosis/stent placement/nasobiliary drain in hilar tumors or benign intrahepatic strictures | Cannulation of minor papilla |
| Grade 3 | Billroth II anatomy<br>Intrahepatic stone extraction<br>Stone extraction with lithotripsy | Therapeutic pancreatic procedures including pseudocyst drainage |

**Table 2** Overview of indications for 1541 ERCPs performed by 15 trainees.

| Indication | Number of procedures, n (%) |
|---|---|
| Stones | 361 (23.5) |
| Stenosis (benign or malignant) | 730 (47.6) |
| Primary sclerosing cholangitis | 63 (4.1) |
| Biliary leakage or trauma | 71 (4.6) |
| Endoprosthesis change | 43 (2.8) |
| Chronic pancreatitis | 172 (11.2) |
| Other | 101 (6.2) |

**Table 3** Distribution according to degree of difficulty of 1511 endoscopic retrograde cholangiopancreatographies (ERCPs) performed by trainees.

| Degree of difficulty | Number of procedures, n (%) |
|---|---|
| 1 | 1029 (68.1) |
| 2 | 222 (14.7) |
| 3 | 260 (17.2) |

the procedures according to degree of difficulty (this information was available for 98.1 % of the procedures).

## Learning curves

When the data for all the individual endoscopist assessment periods were combined, the overall CBD cannulation success rate was seen to gradually increase with the total of ERCPs performed (**Fig. 2a**). This increment in the learning curve was significant ($P<0.001$). We also analyzed differences between individual performances. One trainee with below-average performance achieved a CBD cannulation success rate of 60 % after 100 procedures, while another with above-average performance attained a percentage success of 84 % after 100 ERCPs (chi-squared test; $P<0.005$). **Fig. 2b** illustrates the learning curve of two other randomly selected trainees plotted against the group average.

We separately analyzed CBD cannulation success in patients with a virgin papilla, meaning that no previous sphincterotomy had been performed. The number of ERCPs performed in patients with native papillary anatomy was 624 (40.5 %). **Table 4** gives an overview of the CBD cannulation success rate per block of 20 ERCPs in patients with native papillary anatomy. The group learning curve obtained in these patients is shown in **Fig. 3**. The improvement over time was significant ($P<0.001$). However, the success rates for CBD cannulation in this subgroup of patients were remarkably lower than those for patients overall.

The learning curves for therapeutic interventions were also addressed (**Fig. 4a, b, c**). The increments in the learning curve for sphincterotomy and stent placement were also significant ($P=0.01$ and $P<0.001$, respectively). The success of stone extraction did not significantly increase over time ($P=0.44$).

## Discussion

In this prospective study, the performance of gastroenterology residents in their ERCP training was evaluated by means of their self-assessment recorded on a standard form. With this relatively simple method we were able to provide insight into the learning curve of trainees for CBD cannulation as well as for other ERCP outcome parameters such as success of therapy. The self-assessment form allowed determination of the progress of every individual trainee with regard to these different aspects of the procedure, but simultaneously gave information about average group progression.

In this study, all trainees followed the same program regarding endoscopy training. All trainees started with a basic course in flexible endoscopy, which is a theoretical and hands-on training for esophagogastroduodenoscopy (EGD) and colonoscopy. Subsequent endoscopy training consisted of performing EGD and sigmoidoscopy procedures. After this period, trainees began to perform colonoscopies. When they were considered to be competent in these 'basic' procedures after extensive exposure, they entered the ERCP training program.

Until now, as in most countries worldwide, training and certification for ERCP in the Netherlands is based on a performance of a minimum number of procedures. There is however growing awareness that unvalidated threshold numbers are an inadequate method for determining competence and awarding certification. The assessment of procedural competence by means of individual learning curves is likely a more thorough method. Regarding procedural competence, the ASGE recommends a CBD cannulation success rate of 80 %–85 % after completion of ERCP training [3]. This number has no real scientific basis but seems intuitively correct [12]. In our study, trainees had not reached this success rate after performance of the 100 ERCPs required for certification in the Netherlands. However, since performance obviously varies with each trainee, an assessment of individual performance is more robust than the use of minimum numbers for defining competence. The Rotterdam Assessment Form for ERCP is useful for monitoring competence development and can show the point at which objective performance standards are met.

Only a few studies have addressed the development of technical competence in ERCP [1, 13–16]. Our results showed a CBD cannulation success rate of > 80 % after approximately 160 procedures; other findings range from a CBD cannulation success rate of 85 % after 148 ERCPs to 80 % success after 300–400 procedures [14, 15].

The study of Jowell et al. was the first to provide evidence about trainees' learning curve for ERCP [1]. Based on this study, several guidelines were adopted regarding training and threshold numbers. There are nonetheless important differences between that study and ours, the main dissimilarity being the involvement of trainers in performance evaluation as opposed to the self-assessment and development of learning curves used in our study. In

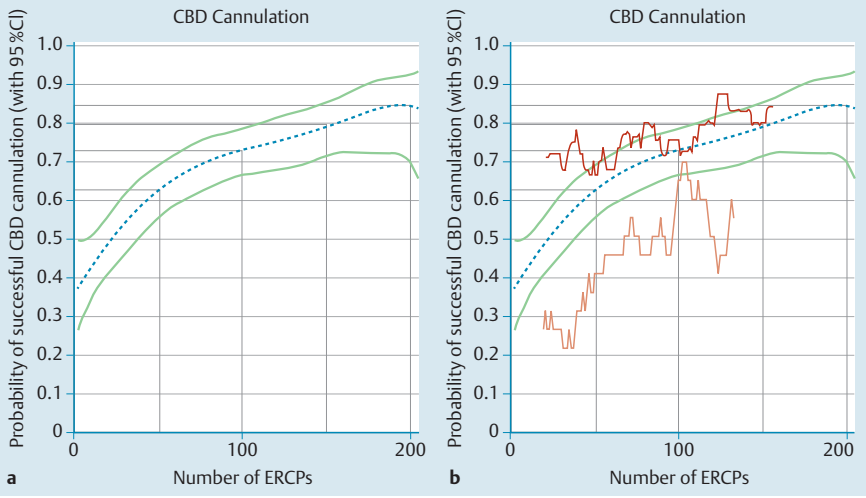



**Fig. 2** Trainee performance in endoscopic retrograde cholangiopancreatography (ERCP). **a** Probability of achieving a successful cannulation of the common bile duct (CBD) plotted against the number of ERCPs performed. The figure shows the group curve (blue line) with 95 % confidence interval (CI) (green lines). **b** Learning curves of two randomly selected trainees plotted against the group curve, illustrating individual versus group performance.

**Table 4** Success of cannulation of the common bile duct (CBD) by trainees for successive groups of 20 procedures in patients with a virgin papilla (n = 624 endoscopic retrograde cholangiopancreatographies [ERCPs]).

| Successive ERCP blocks | Trainees, n | Successful CBD cannulation, % | Range |
|---|---|---|---|
| 1 to 20 | 12 | 26.7 | 0 % – 40.0 % |
| 21 to 40 | 11 | 23.4 | 0 % – 50.0 % |
| 41 to 60 | 11 | 30.0 | 0 % – 60.0 % |
| 61 to 80 | 10 | 36.0 | 0 % – 60.0 % |
| 81 to 100 | 8 | 52.6 | 0 % – 70.0 % |
| 101 to 120 | 8 | 57.0 | 20.0 % – 80.0 % |
| 121 to 140 | 4 | 56.5 | 25.0 % – 80.0 % |
| 141 to 160 | 4 | 58.6 | 33.0 % – 86.0 % |
| 161 to 180 | 2 | 60.7 | 50.0 % – 71.0 % |
| 181 to 200 | 1 | 87.5 | Not applicable |

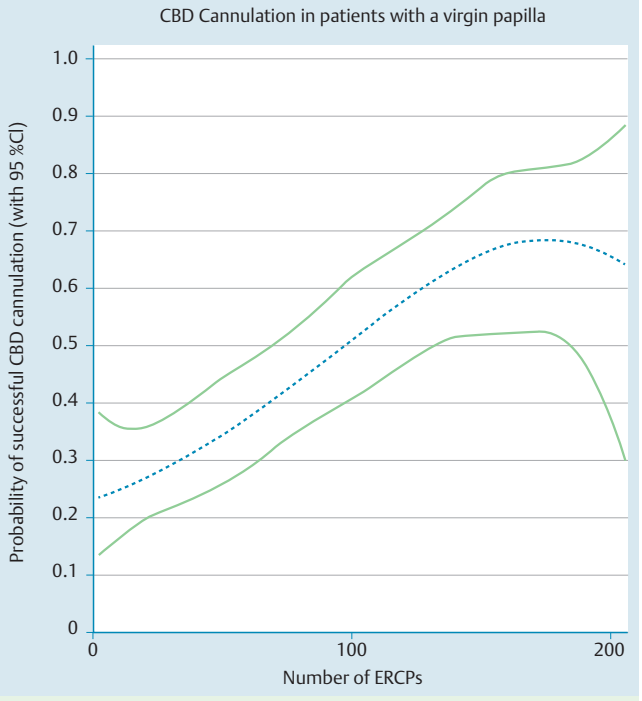



**Fig. 3** Probability of a successful common bile duct (CBD) cannulation in patients with a virgin papilla, by trainees in endoscopic retrograde cholangiopancreatography (ERCP).

current training, we feel that assessment of individual performance by means of learning curves, as shown in our study, is much more robust and relevant for the individual trainee than simple threshold numbers. This can easily be monitored through self-assessment and we were able to follow quite a number of trainees from the beginning of their training. Since adequate experience is also essential for becoming competent, we would advocate that competence criteria should be based on both numbers and success.

CBD cannulation can be regarded as a surrogate marker for procedural competence. The curve for CBD cannulation was comparable to those for therapeutic interventions such as stent placement and sphincterotomy. This means that the learning curve for overall CBD cannulation success can be used for quick information on whether an individual trainee is progressing according to the expected group learning curve or not. It will, to some extent, reflect the corresponding learning curves for therapeutic interventions.

Stent placement showed an 84 % success rate after 160 ERCPs. This curve revealed a slight decline around this number of procedures.

The learning curve for stone extraction did not significantly increase over time. After approximately performance of 160 ERCPs, stone extraction was successful in 72 % of patients. We can only speculate about reasons for this flattening of the learning curve, especially at around 100 ERCPs. The curve was created for all degrees of difficulty in extraction combined, and might have been better if only level 1 stone extractions were analyzed. However, numbers were too small to perform the analysis for this subgroup. Most learning curves show such a decrease at some point. A possible explanation is that trainees are getting overconfident and want to act more independently, with a slight decline in performance as a result; however, there is no real scientific evidence for this theory.

It is important to note that the success rate for CBD cannulation in patients with a native papilla was remarkably lower than the overall success rate. This is not an unexpected finding: a previous successful sphincterotomy often makes cannulation much easier. The number of patients with a virgin papilla was also relatively small; that must be taken into account when drawing conclusions. We do recognize that a successful CBD cannulation in a patient with a virgin papilla is one of the basic steps in ERCP that every endoscopist should be able to execute.

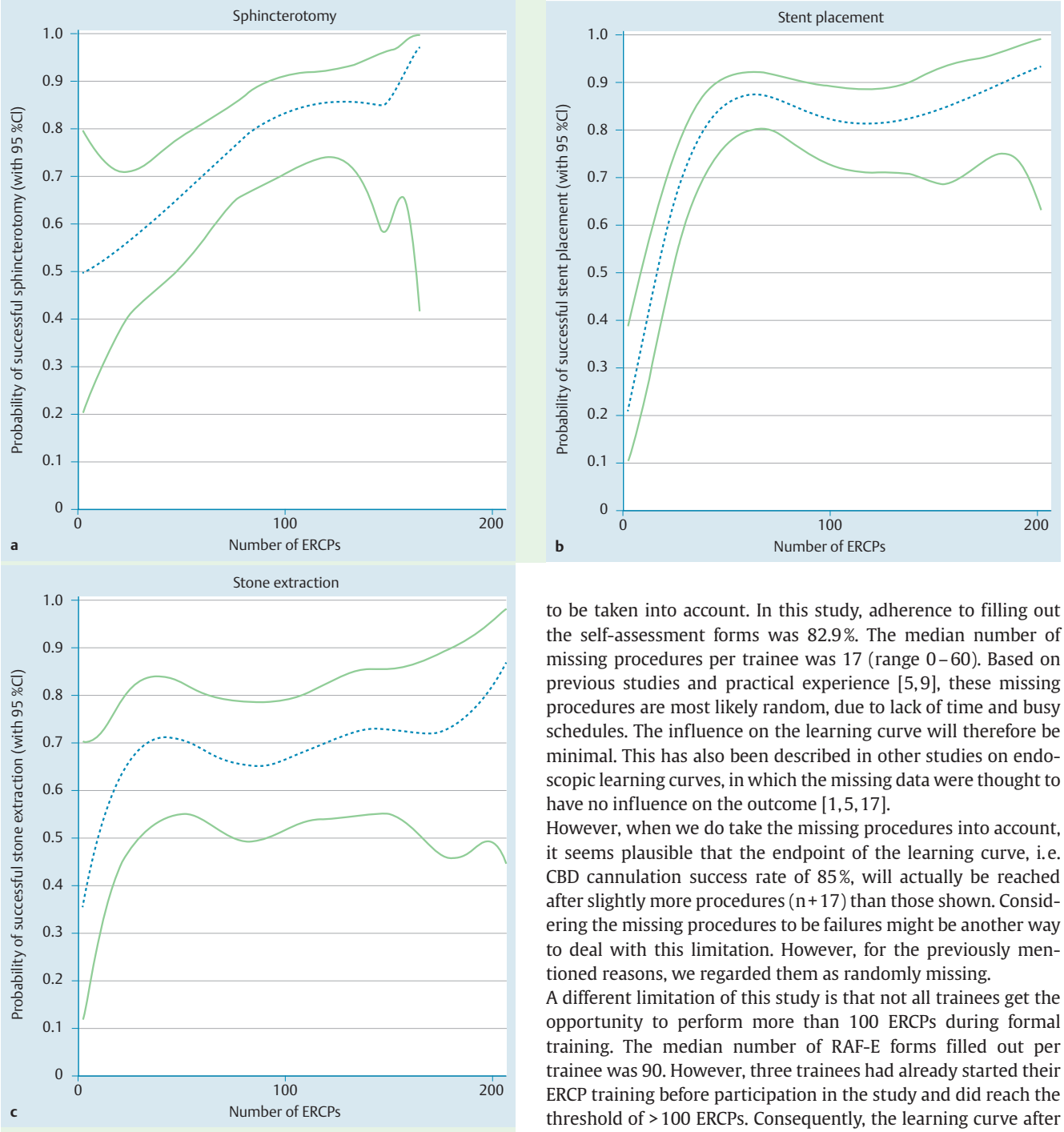



**Fig. 4** Learning curves for success in therapeutic interventions by trainees in endoscopic retrograde cholangiopancreatography (ERCP). The *x*-axis represents the number of ERCPs performed, the *y*-axis is the probability of achieving a successful intervention: **a** sphincterotomy; **b** stent placement; **c** stone extraction.

With continuous assessment using RAF-E, in the near future, real-time feedback can be provided on a trainee's performance in comparison with peers. When a trainee's performance then deviates from the group curve, an intervention such as additional training is possible. This system provides trainers with solid evidence for assessment of performance.

When procedural success is evaluated in relation to numbers of procedures performed, adherence to completing the forms has to be taken into account. In this study, adherence to filling out the self-assessment forms was 82.9 %. The median number of missing procedures per trainee was 17 (range 0 – 60). Based on previous studies and practical experience [5, 9], these missing procedures are most likely random, due to lack of time and busy schedules. The influence on the learning curve will therefore be minimal. This has also been described in other studies on endoscopic learning curves, in which the missing data were thought to have no influence on the outcome [1, 5, 17].

However, when we do take the missing procedures into account, it seems plausible that the endpoint of the learning curve, i. e. CBD cannulation success rate of 85 %, will actually be reached after slightly more procedures (n + 17) than those shown. Considering the missing procedures to be failures might be another way to deal with this limitation. However, for the previously mentioned reasons, we regarded them as randomly missing.

A different limitation of this study is that not all trainees get the opportunity to perform more than 100 ERCPs during formal training. The median number of RAF-E forms filled out per trainee was 90. However, three trainees had already started their ERCP training before participation in the study and did reach the threshold of > 100 ERCPs. Consequently, the learning curve after 100 ERCPs is based on smaller numbers. This limitation is a direct result of the present design of the training program for ERCPs in the Netherlands. Until recently, most gastrointestinal fellows were enrolled in the ERCP training program, which created a capacity problem. However, gastrointestinal teaching programs are changing and shifting from a broad, relatively superficial training to specific focus areas such as interventional endoscopy or gastrointestinal oncology. Consequently, fewer residents will enter the ERCP training program and, it may be hoped, those who will be doing ERCPs will have the opportunity to participate in a sufficient number of procedures to gain competence.

Furthermore, complications were not taken into account in this study. The focus of this study was to gain insight in procedural competence, given the ultimate aim of the best overall outcome and patient safety. In the Netherlands, registration of complica-

tions is already compulsory. The relation between good performance and occurrence of complications is likely to be inverse. As yet, however, there are no data to support this.

This self-assessment program was used as an addition alongside the traditional master–apprentice model. The method is subject to the knowledge of the trainee and therefore might be biased. On the other hand, the trainer might influence the evaluation. Moreover, self-reflection is more likely to raise the trainee's awareness of their own performance, and thereby enhance and optimize the learning process. There was no predetermined protocol regarding the involvement of the supervising senior clinician. As noted, the self-assessment program was an addition to the regular training program for ERCP. It is very difficult to implement a standardized protocol for the whole ERCP training program, which still largely consists of the master–apprentice model. A strict protocol is therefore not feasible in practice. Trainer assessment using the RAF-E was not a part of this project, but would be an interesting follow-up study. We would propose an extended form for trainers, with room for feedback. Furthermore, the comparison of subjective scores given by trainees and trainers may provide additional insight on the value of self-reflection. We evaluated the RAF-E in a post-training setting also, where it proved its value for assessment of performance of experienced endoscopists [9].

In agreement with ASGE, we believe that in current training, competence should be based on learning curves rather than threshold numbers alone [18]. The RAF-E is an easily used device for monitoring the development of competence in ERCP in individuals as well as groups. This form is now available in an electronic portfolio for all gastroenterology residents in the Netherlands. We believe that with the further development of the e-portfolio, where real-time feedback can be provided regarding the trainee's own performance compared with the peer group, assessment of performance through RAF-E enhances quality in ERCP training.

**Competing interests:** None

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