

Post-ERCP Pancreatitis: Is the Endoscopist's Experience the Major Risk Factor?

Thomas Rabenstein¹, Eckhart G Hahn²

¹Department of Medicine II, Faculty of Clinical Medicine, Mannheim, Rupprecht-Karls-University Heidelberg. Mannheim, Germany. ²Department of Medicine I, Friedrich-Alexander-University. Erlangen, Germany

Summary

The assumption that the endoscopist is an important factor in outcome of ERCP is not easy to document. There are plenty of reasons for the difficulties in defining experience and skill of an endoscopist, and establishing suitable endpoints for their measurement. Suitable proxy variables are ERCP-frequency (ongoing volumes) and ERCP-experience (life-time volumes) of the endoscopist, as well as individual and institutional conditions. Important confounders are difficulty of ERCP, patient-related and procedure-related risk factors and risk-reducing factors. Endpoints should include success and (specific) complications of ERCP.

Only few studies are available that analyse the influence of the endoscopist's skills on post-ERCP pancreatitis. Studies with a high preponderance of dominating patient-related risk factors for post-ERCP pancreatitis, e.g. suspect of SOD and unexplained abdominal pain, failed to prove such a dependence. On the other hand, evidence increases from studies with patient populations of more traditional indications for ERCP that suggests the existence of an association between ERCP-frequency of the endoscopist or ERCP-frequency of the environment and the incidence of post-ERCP pancreatitis and other complications. ERCP-experience measured in overall live-time volumes, however, does not seem to influence the risk of pancreatitis due to ERCP, although the data are very limited.

During the ERCP-training of young endoscopists an impaired success rate appears more important than an increased complication rate. Nevertheless, all undesired outcomes of ERCP should be applied to the endpoints of quality assessment in ERCP-training.

Further studies on this topic are needed. Since many variables significantly interact with the endpoints post-ERCP pancreatitis and complications of ERCP, a special study design appears indispensable to conclusively prove a relationship between an endoscopist's expertise and specific complications of ERCP.

Background

"The assumption that the skill of the endoscopist is an important factor in safety is not easy to document". This statement, published in 1991 by Peter Cotton *et al.*, was one of the results of a workshop about complications of endoscopic sphincterotomy (EST) [1], but it also seems to be true for endoscopic-retrograde cholangiopancreatography (ERCP) without EST. There are plenty of reasons for the difficulties in defining the skill of an endoscopist, and establishing suitable endpoints for their measurement. They will be discussed as "background". Nevertheless, accumulating data that suggest a possible relevance of the "risk factor endoscopist" for ERCP in total and especially in post-ERCP pancreatitis are now available;

they will be presented in this article. These data directly lead to the problem of training, frequency of performance and certification in ERCP, which will be addressed here only insofar as training and frequency of performance are important determinants of skill and experience. Peter Cotton's question from the year 1974 "so who needs teaching" (in gastrointestinal endoscopy) [2] is obviously a current topic of today's ERCP, but unfortunately it will be left unanswered here.

Is the Endoscopist's Skill in ERCP a Banana Problem?

During our live-time work in endoscopy and gastroenterology we continuously accumulate a lot of skills and experiences. It is probably not possible to find a conclusive summary of single skills which easily and reliably determine a person's overall experience in ERCP. Additionally, we can lose former skills, if we discontinue or reduce to practise. Thus, comparisons between endoscopists, intra- and inter-individually or group-wise, are biased by a varying degree of skill with every procedure.

Two proxy variables appear to be practicable in addressing the problem of changing ERCP-skills in the course of time: cumulative life-time volumes ("ERCP-experience") and ongoing volumes per time-period ("ERCP-frequency").

In addition to that, the degree of ERCP-skill described by the proxy variables above also depends on other variables. Those can be divided into two major groups: individual conditions and institutional conditions, which are dependent on each other to a certain degree. Individual conditions contain personality, cognitive and manual ability, overall endoscopic capability, familiarity with analogue endoscopic techniques, pre-existing experience in ERCP-findings, experience in overall management of patients with biliopancreatic diseases, and others [3]. Those individual conditions can change extremely in the course of time and thus significantly

influence the outcome of ERCP. An experienced endoscopist of our department, for example, who showed significantly higher pancreatitis rates than others in a retrospective and a prospective study, was able to reduce pancreatitis to the institutional average value after being aware of the problem [4, 5, 6]. Institutional conditions cover environmental factors like speciality (academic, referral, community, private), ERCP-policy, ERCP-equipment, ERCP-frequency, ERCP-case-mix, ERCP-quality control, number or skill of ERCP-endoscopists, number or skill of endoscopy-nurses, and training conditions like autodidactic, supervision, training program, training on bench models, training case mix and others [7].

These four major variables, ERCP-experience, ERCP-frequency, individual conditions, and institutional conditions should offer a deemed-to-satisfy provision to assess an endoscopist's skill in ERCP. Their application to future studies will help to increase the validity and the transferability of the results [8].

Patient, ERCP-Technique or Endoscopist – Who Is the Bad Guy?

When discussing the skill of an endoscopist, we also have to consider the difficulty of the ERCP procedure. A difficult ERCP is not only a lame excuse in case of failure. To the contrary, the difficulty of ERCP is a major risk-factor for the success of the procedure and for the occurrence of complications [9, 10, 11]. The difficulty of ERCP, however, may interact with the experience and the practise of an endoscopist. On the other hand, difficult procedures may result in different technical approaches during ERCP, e.g. early access-needle-knife papillotomy (NKP) [5, 12] due to failed bile duct cannulation, or enforced cannulation attempts without NKP [10, 11], which might be associated with different specific outcomes. Only few studies have analysed the difficulty of ERCP so far, but interesting and practicable suggestions have already been made [9, 13, 14].

Moreover, several studies are being conducted at the moment to further quantify the degree of difficulty of ERCP-procedures. The occurrence of post-ERCP pancreatitis in individual patients is an almost unpredictable event. But statistically, only a few number of variables significantly increase the incidence of post-ERCP pancreatitis, and have to be considered as confounders in an analysis about the "risk factor endoscopist": patient-related risk factors and procedure-related risk factors [5, 10, 11, 15, 16, 17, 18, 19, 20, 21]. They are very important, since several studies have shown a significant correlation between the risk of post-ERCP pancreatitis and the number of present risk factors [5, 11, 15, 19]. Additionally, risk-reducing factors and prophylactic measures to anticipate complications may interact with outcomes [6, 19, 22].

Endpoints, Comparisons and Truth – How to Define Good or Bad Outcomes?

Next to the description of the major proxy variables of the endoscopist's skill in ERCP, the difficulty of the ERCP-procedure itself, and the known or suspected confounders, we have to think about suitable endpoints and their measurement [14]. Two major variables describe the overall outcome: the success of ERCP and complications due to ERCP. Both strongly depend on their definitions, on the methods of measurement used for assessment, and on the cognitive ability of the endoscopist, who mostly decides by himself if a procedure was technically successful or not. The overall clinical success of ERCP is usually the final result of our step-by-step efforts to solve a diagnostic or therapeutic problem. The index-ERCP may be completely successful, partly successful, or unsuccessful. A number of repeated ERCP or additional treatments like extra-corporeal-shockwave-lithotripsy (ESWL) or percutaneous-transhepatic-colangio-drainage (PTCD) may be necessary to finally achieve the technical success of ERCP. The overall clinical success of ERCP includes patient follow-up and clinical improvement; it is much more

difficult to assess and it depends many interactions. Therefore the overall clinical success of ERCP appears not suitable as an endpoint for the assessment of the endoscopist's impact on outcome. More specific information might be achieved and the chance for a meaningful interpretation will probably increase, if we look for the technical outcome of single procedures instead of final cumulative results.

In the context of the current topic, complications of ERCP and especially post-ERCP pancreatitis seem to be more important than success, and they are better defined. In an attempt on consensus, exact criteria for the definition and the grading of post-ERCP pancreatitis were published in 1991 [1]. The whole grading system uses a time scale together with major consequences for the patient to describe the severity of a complication. Post-ERCP pancreatitis is defined as clinical pancreatitis with amylase at least three times normal at more than 24 hours after the procedure, requiring admission or prolongation of planned discharge. A "mild" post-ERCP pancreatitis resolves within two to three days of medical therapy, while "moderate" pancreatitis requires hospitalisation and treatment of four to ten days. "Severe" post-ERCP pancreatitis is described as hospitalisation for more than ten days, or hemorrhagic pancreatitis, phlegmon, pseudocyst, or intervention (percutaneous drainage or surgery). The advantage of this easy-to-use system, which was applied to most of the published studies about post-ERCP complications during the last ten years, is the clinical impact due to the combination of laboratory findings and consequences for the patient. There are, however, several disadvantages, which one should consider when the reading results based on the "Cotton-criteria". These criteria are not applicable in case of acute pancreatitis at the time of ERCP and the system is probably associated with a low sensitivity in case of advanced chronic pancreatitis or in case of pancreatic involution of the elderly due to the inability of the pancreatic gland to react with hyperamylasemia. On the other hand, younger

patients and patients with sphincter or Oddi dysfunction may have a more sensitive pancreatic gland with an inadequate high short-term presence of pancreatic enzymes in the serum, which just persist the 24 hour cut-off interval and than quickly drop to normal values. Furthermore, "unplanned admission" is unsuitable in the predominant in-door-patient ERCP-policy in Europe. In studies about ERCP and EST from Erlangen, we therefore included "presence of new, moderate to severe pain lasting longer than 24 hours after ERCP" in the definition of post-ERCP pancreatitis, and the "duration of treatment" in the grading of severity [23].

When looking for differences between single endoscopists, groups of endoscopists, or institutions we should be aware that we are dealing with a very sensitive issue. Only few published studies provide a quality that allows far-reaching conclusions. Prospective studies usually demonstrate more complications than retrospective ones. Most of the available results were compared with historical controls. Thus, differences in those studies could be explained by the overall change of ERCP-technique, newly available instruments, increasing experience of endoscopy nurses, and a shift in the indications for ERCP rather than by the endoscopist's experience. Thus, we have to look at the details, if we want to know the truth.

Published Data on the Endoscopist's Skill and Post-ERCP Pancreatitis

Only few studies provide substantial information about a possible relation between the endoscopist's skill and post-ERCP pancreatitis. They will be discussed below. Several other papers focus rather on the success of ERCP or on the measurement of overall competence in ERCP during training and fellowship than on pancreatitis; they were not considered here. Neither were ERCP-studies included, which have been often cited in editorials and studies about outcomes in ERCP [4, 8, 21, 24] although they only described the problem of changing (mostly

improving) individual or institutional results over time by comparison with historic controls.

Freeman *et al.* published a prospective, multi-center study on risk-factors for complications after biliary sphincterotomy [10]. In addition to the assessment of technical and patient-related risk factors for complications, the results of five "higher-volume-centers" were compared to those of twelve "lower-volume-centers". Although a mean case volume of the endoscopist ≤ 1 EST per week was a significant risk factor for hemorrhage after multivariate analysis (Odds-ratio 2.17; $P=0.002$), the frequency of procedures was no risk factor for post-ERCP pancreatitis. The dominant risk factor for post-ERCP pancreatitis in this study was a suspected dysfunction of sphincter of Oddi (SOD; Odds-ratio 5.01; $P<0.001$). More than 40% of all cases of post-ERCP pancreatitis were associated with SOD. Since patients with suspect of SOD were usually treated by the most experienced endoscopist available [Martin L Freeman, personal communication], it might be possible that an association between low EST-frequency and an increased risk of pancreatitis was equalized by a high-risk case mix of endoscopists with a high EST-frequency. In fact, the five "higher-volume-centers" – compared to twelve "lower-volume-centers" – had significant more SOD-cases (13.1% vs. 10.1%, $P=0.02$). In centers with higher volumes, there were fewer difficult cannulations ($P<0.001$) and fewer inadvertent pancreatic injections ($P<0.001$). Both factors are certainly associated with the skill of the endoscopist, and both factors significantly increased the risk of post-ERCP pancreatitis in the multivariate analysis. The assumed risk factor "mean case volume of the endoscopist ≤ 1 EST per week", however, was not included into the multivariate model because of the missing significance in univariate testing. Thus, a possible interaction between procedure-related and patient-related variables, which increase the risk of pancreatitis and the EST-frequency of the endoscopist was not analysed. A correlation

between the incidence of post-ERCP pancreatitis and a low EST-frequency would not be surprising from the clinical point of view. The authors at least concluded that "the risk of pancreatitis was influenced by the technique of the endoscopist, and much of the injury to the pancreas appeared to result from the process of cannulating the bile duct rather than from the sphincterotomy itself" [10]. In an editorial about outcomes of ERCP Freeman concluded that the predominance of patient-related risk factors in determining the pancreatitis risk provides the clue as to why expert centers did not seem to have a substantially lower rate of pancreatitis; the effect of expertise is counterbalanced by the higher-risk case-mix of expert centers [24]. In a retrospective study about the impact of skill and experience of the endoscopist on the outcome of endoscopic sphincterotomy techniques [4] our group analysed 1,335 patients and found significant differences in the complication rates of eight major endoscopists of our department varying between 4.8% and 11.5%. The indication for the procedure of unexplained abdominal pain or suspected SOD, which five-fold increased the risk of pancreatitis in the former study [10], was irrelevant in ours; bile duct stones, malignant biliary obstruction and chronic pancreatitis were the major indications for EST. Cumulative live-time volumes of the endoscopists ("ERCP-experience") had no influence of the occurrence of complications, while a low ERCP-frequency (ongoing volumes of the endoscopist <40 EST per year) was the only significant risk factor for complications (9.3% vs. 5.6%; $P < 0.05$). Due to the low incidence of specific complications in this study - especially pancreatitis occurred only in 2.9% - it was not possible to analyse the influence of "ERCP-frequency" on post-ERCP pancreatitis. But we investigated that problem again in a prospective study about risk factors for complications after EST including 815 patients [5]. The indication spectrum for ERCP was similar to the retrospective one with the exception of more cases of chronic pancreatitis. Here we could demonstrate by use of multivariate analysis

that an EST-frequency ≤ 40 EST per year was the major risk factor for post-ERCP pancreatitis (Odds-ratio 2.9; $P = 0.001$) and for complications in total (Odds-ratio 2.1; $P = 0.003$). We therefore concluded that extensive and sustained practice of ERCP and EST significantly increases the safety of the procedure [5].

Loperfido *et al.* analysed the major early complications from diagnostic and therapeutic ERCP in an Italian prospective multicenter study [17]. In total, 3,356 ERCP-procedures were performed in 2,769 patients; 942 patients underwent diagnostic ERCP only, whereas in 1,827 patients therapeutic ERCP was performed including 419 precuts and 1,583 EST (320 EST after precut). Thus, there is a preponderance of therapeutic ERCP in the study, and almost two thirds of patients had either needle-knife papillotomy or sphincterotomy. One thousand and 66 patients were treated in small centers (less than 200 ERCP per year) and 1,703 in large centers (more than 200 ERCP per year). Although the indications for ERCP were not clearly listed, SOD seemed to be of no importance in this study population. The comparison of small and large centers showed significant differences in the outcome of ERCP. Large centers had significantly less overall complications (2.0% vs. 7.1%, $P < 0.001$) and less complication-related deaths (0.18% vs. 0.75%, $P < 0.05$). The risk of pancreatitis was significantly increased in small centers in the univariate analysis (relative risk 2.8), but the P value was only close to the limit of significance in the multivariate analysis. Due to the multicenter design and the high case-number, this study adds evidence to the assumption that a low ERCP-frequency increases not only the complication risk in total, but that it also increases the risk of post-ERCP pancreatitis. The ERCP-experience of the endoscopist measured in life-time volumes was not investigated in that study. A large US-multicenter study about post-ERCP pancreatitis was published in 2001 [11]. Eleven centers, six private and five university, included 1,963 ERCP-procedures, of which 353 (18.0%) were diagnostic, 97

(4.9%) diagnostic plus manometry, and 1,513 (77.1%) therapeutic. Sphincterotomy was performed in 932 ERCP (47.5%; biliary only 818, biliary plus pancreatic 51, pancreatic only 63). Neither a complete list of the indications for ERCP, nor a summary of the final diagnoses is given. According to the 32 potentially relevant risk factors of post-ERCP pancreatitis analysed in this study, however, it seems as if there was a high prevalence of patients with only a minor probability of structural biliopancreatic pathology before ERCP: suspect of SOD 12.2%, recurrent abdominal pain of unknown origin 28.9%, and serum bilirubin normal 35.7%. The frequency of diagnoses of definite pathology supports this assumption: common bile duct stones 21.3%, chronic pancreatitis 18.9%, cholangiogram normal 28.4%, pancreatogram normal 33.3%. The patient population of this US-trial is definitely not comparable to European or Eastern studies about EST and ERCP [16, 17, 18, 23, 25, 26]. Given this different population with a high preponderance of functional or missing biliopancreatic disease, the incidence of pancreatitis was relatively low (6.7%), and a lot of patient- and procedure-related risk factors for post-ERCP pancreatitis were found by univariate and multivariate analysis. But the model appears overloaded (131 events, 32 variables). ERCP case volumes of individual endoscopists in this study varied between 0.2 and 4.1 cases per week. The endoscopists, however, did not put all their ERCP-procedures into the study. Thus, the assessed ERCP-frequencies do not represent the entire ERCP case volume of the participating endoscopists. A higher case volume per endoscopist was unexpectedly associated with a higher rather than lower rate of pancreatitis by univariate analysis. However, after adjustment for case mix, there was no effect of the endoscopist's case volume in the multivariate model. The authors argued that possibly none of the participating endoscopists reached an ERCP-frequency above which pancreatitis rates would diminish, and that the reported pancreatitis rates from high-volume tertiary US-referral

centers are generally as high or even higher than those reported in the study. Although there was no significant result suggesting an association between the endoscopist's ERCP-frequency and risk of post-ERCP pancreatitis, the conclusion was that case mix is at least as important as expertise in determining the risk of pancreatitis. Another argument for the inability to demonstrate the assumed association has been given above: The predominance of patient-related risk factors in the participating centers probably counterbalanced the influence of ERCP-frequency on the risk of pancreatitis. The incidence of pancreatitis extremely increased in case of accumulation of more than one risk factor (over 40% in a female patient with normal bilirubin, suspect of SOD and difficult cannulation) [11].

The critical review of the two Freeman studies [10, 11], which more or less represent the overall ERCP and EST practise in North America, and the comparison to major studies from Europe and the Eastern World [16, 17, 18, 23, 25, 26], indicate an important association of institutional conditions and the risk of post-ERCP pancreatitis. If such an association is dominant, it could explain the inability to demonstrate a correlation between ERCP-frequency and post-ERCP pancreatitis. The principle of the pioneers of ERCP and EST was to select patients with strong predictors of structural biliary disease, usually increased serum bilirubin, dilated bile ducts, and related significant clinical symptoms. Under those circumstances, the risk of the procedure appeared acceptably low, and it included hemorrhage or perforation rather than incidental pancreatitis. Additionally, the technical success rates as well as the clinical benefit for the patient were very high, at least 90% and in some centers almost 100%. Two more indications for ERCP were added later on, for which a low risk and a high efficacy of ERCP is proven as well: severe biliary pancreatitis and chronic pancreatitis presenting with strictures or ductal stones [5, 23, 27]. The indication spectra for ERCP and EST in Europe and the Eastern World are still characterized by this traditional decision

making [16, 17, 18, 23, 25]. Institutional conditions in North America, in contrast, seem to be significantly different as far as ERCP-policy and ERCP-case-mix are concerned. The diagnostic and therapeutic approach to unexplained abdominal pain or suspect of SOD by means of ERCP and EST is a new and very frequent indication in the New World, but an infrequent indication in other regions. The risk of post-ERCP pancreatitis is extraordinarily high in this group of patients, a fact that has been proven in numerous studies [10, 11, 20]. Fogel *et al.* reported pancreatitis rates between 10.7% and 28.3% in SOD patients depending on the used technique of sphincterotomy, but the incidence of pancreatitis was only 1.7% for bile duct stones in the same institution during the same period of time [28]. The occurrence of pancreatitis almost seems to be an automatic response to ERCP in most patients with suspect of SOD, irrespective of the ERCP-experience or the ERCP-frequency of the endoscopist. The discussion about the degree of clinical benefit SOD-patients may expect after ERCP and EST has been excluded from this paper. Due to the high "penetrance" of the risk factors "suspect of SOD" and "unexplained abdominal pain", studies with a significant number of those indications for ERCP appear not suitable to contribute information about the impact of ERCP-frequency on the risk of post-ERCP pancreatitis.

ERCP-Training and Complications

Regulations for training in ERCP are a difficult issue. Current British [29] and American [30] guidelines state that it is not possible for all training programs to teach all endoscopic procedures to all fellows, nor it is necessary for optimal patient care. The successful performance of difficult procedures like ERCP requires fewer endoscopists with more skill and experience [30]. The British Specialist Advisory Committee in Gastroenterology has decided that ERCP will no longer be an essential requirement for a certificate of completion of

specialist training [29]. An endoscopy unit must undertake at least 250 procedures a year to register for ERCP training, and the trainee should carry out at least 100 procedures under supervision [29]. Cannulation of the desired duct of more than 90% of cases and the ability to provide biliary drainage is necessary for competence in ERCP [29]. The American guidelines demand that each program in advanced endoscopy should be able to provide sufficient numbers of endoscopic procedures; at least 50% of these procedures should contain a therapeutic component [30]. The desired endpoint of advanced training should be an advanced level of individual expertise; the trainee should demonstrate a substantial success rate (at least 80% selective deep cannulation) [30]. Available data suggest that the usual trainee will require a minimum of 180 cases to achieve this level of technical performance [31], but the guideline summarises that the use of threshold numbers of procedures might be misleading and should be employed with caution [30]. The British guideline states that reliable measurements of quality and competence are ultimately needed [29].

We can conclude that regulations for ERCP-training and ERCP-certification are changing quite quickly at the moment, and that there are no final recommendations for the assessment of individual expertise and skills in ERCP, neither in training nor in practise. Additionally, the impact of promising training models on future training programs cannot be estimated yet [32, 33]. Due to the most frequently used endpoints in studies about ERCP training - success of ERCP and frequency of selective deep cannulation - almost no data concerning complications and post-ERCP pancreatitis during training are available. These endpoints should be included in future guidelines, since they are an important outcome of ERCP.

In one prospective study about risk factors for post-ERCP pancreatitis, training fellows were involved in 526 of 1,963 procedures [11]. They faced almost the same rate of pancreatitis as experienced endoscopists (6.5% vs. 6.8%, P=0.82). The study, however,

provides no information about trainee case-mix and overall training-policy. In our institution, trainees begin with ERCP after being able to move the duodenoscope into the duodenum freely and safely. They start ERCP in selected cases, which are expected to be procedurally easy and of a low complication risk (biliary or pancreatic stent exchange, prior sphincterotomy [6, 9]). When the trainee is familiar with the technical basics and shows an acceptable hand-eye coordination, usually after 25 to 50 procedures, he is allowed to perform ERCP under supervision in previously untreated patients or in more difficult therapeutic cases for another 100 procedures [23]. Under these circumstances, trainees reached success rates of over 80% from the beginning, and the incidence of post-ERCP pancreatitis or other complications was comparable to experienced endoscopists [6, 9]. In a retrospective study about EST, all consecutive procedures of three endoscopists - from the very first to the last - were analysed according to complications [4]. These trainees had an EST-frequency of at least 25 EST per year. The complication rate was 16.7% during the first 10 EST, 12.2% between number 11 and 40, 6.4% between number 41 and 100, and decreased to 4.1% at numbers over 100. In all intervals the incidence of post-ERCP pancreatitis was about 50% of all complications and thus significantly decreased as well. Eighty percent of all ERCP in our institution are therapeutic [5, 6, 9, 23]. According to the overall frequency of more than 1,000 ERCP and about 200 EST per year, the same endoscopists performed a large number of additional ERCP without EST, estimated three to five times as many as EST-procedures. A cumulative experience of 40 EST therefore corresponds to an ERCP-experience of 160 to 240 ERCP, an equivalent number to the estimated necessary case volume for overall competence in ERCP [31]. It is worthy to note that other trainees within the same study period had a significantly lower EST-frequency (in part significantly <25 per year) [4]. These low-EST-frequency trainees showed no decrease of their complication rates over time.

While Canto *et al.* did not report complication rates in an abstract about outcome of training [7], Montes *et al.* found no difference in the pancreatitis rates between ERCP performed by trainees alone, attendings alone or trainees and attendings together [34]. Harewood and Baron published a study about the assessment of the learning curve for precut biliary sphincterotomy [35]. There was a slight improvement of success over the course of time, but no decrease of the complication rate. Although they used a needle-knife technique which is similar to suprapapillary fistulotomy and thus should avoid pancreatitis, they had confusingly an overall pancreatitis rate of 11%. Using the traditional needle-knife technique beginning at the papillary orificium, our group demonstrated lower complication and pancreatitis rates [12].

The result of training in ERCP seems to depend not only on absolute numbers of cases performed, but mainly on a minimum frequency of procedures. Endpoints for the assessment of expertise in ERCP should include parameters of successful implementation of ERCP and negative outcomes such as failure, need of assistance and complications. Insufficient data are available for the determination of the complication risk during training in ERCP, especially during the very first procedures. ERCP-training in high-frequency institutions with a predominance of therapeutic ERCP provide the opportunity of selecting easy and low-risk cases for the first steps of ERCP-trainees and guarantee an acceptably high training intensity (cases per period).

Conclusions

Only a few studies are available that analyse the influence of the endoscopist's skills on post-ERCP pancreatitis. Studies with a high preponderance of dominating patient-related risk factors for post-ERCP pancreatitis, e.g. suspect of SOD and unexplained abdominal pain, failed to prove such a dependence. On the other hand, evidence increases from studies with patient populations of more traditional indications for ERCP that there is

Table 1. Suitable proxy variables, confounders and endpoints for the assessment of the endoscopist's expertise and skill on the outcome of ERCP and EST.

Proxy variables	<ul style="list-style-type: none"> • ERCP/EST-experience (cumulative live-time volumes) • ERCP/EST-frequency (ongoing volumes per time-period) • Individual conditions • Institutional conditions
Confounders	<ul style="list-style-type: none"> • Difficulty of ERCP • Patient-related risk factors • Procedure-related risk factors • Risk-reducing factors and prophylactic measures
Endpoints	<ul style="list-style-type: none"> • Success of ERCP/EST • Complications of ERCP/EST

EST: endoscopic sphincterotomy

in fact an association between ERCP-frequency of the endoscopist or ERCP-frequency of the environment and the incidence of post-ERCP pancreatitis and other complications. ERCP-experience measured in overall live-time volumes, however, does not seem to influence the risk of pancreatitis due to ERCP, although the data are very limited. During the ERCP-training of young endoscopists an impaired success rate appears more important than an increased complication rate. Nevertheless, all undesired outcomes of ERCP should be applied to the endpoints of quality assessment in ERCP-training.

Further studies on this topic are needed. Since many variables significantly interact with the endpoints post-ERCP pancreatitis and complications of ERCP, a special study design appears indispensable for that purpose. Suitable proxy variables, confounders and endpoints for the assessment of the endoscopists expertise and skill on procedural outcome of ERCP are listed on Table 1.

Keywords Cholangiopancreatography, Endoscopic Retrograde /adverse effects /education /methods /trends /utilization; Education, Medical; Education, Professional; Professional Practice; Sphincterotomy, Endoscopic /adverse effects /methods /trends /utilization

Abbreviations EST: endoscopic sphincterotomy; ESWL: extra-corporeal-

shockwave-lithotripsy; NKP: needle-knife papillotomy; PTCD: percutaneous-transhepatic-colangio-drainage; SOD: dysfunction of sphincter of Oddi

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Correspondence

Thomas Rabenstein
 Department of Medicine II
 Faculty of Clinical Medicine, Mannheim
 Rupprecht-Karls-University Heidelberg
 Theodor-Kutzer-Ufer 1-3
 68167 Mannheim
 Germany
 Phone: +49-621-383.3284
 Fax: +49-621-383.3805
 E-mail: thomas.rabenstein@med.ma.uni-heidelberg.de

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