SCIE DOI: 10.14744/scie.2024.04810
South. Clin. Ist. Euras. 2025;36(1):29-34

Original Article

Assessment of the First 30 Cases Following the Turkish Surgical Association's Basic ERCP Training: Challenges and Success Criteria of a Complex Procedure in a Public Hospital Setting

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Submitted: 28.10.2024
Revised: 28.10.2024
Accepted: 10.12.2024

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Keywords: ERCP; learning curve; procedural success; structured training.

ABSTRACT

Objective: Endoscopic retrograde cholangiopancreatography (ERCP) is a challenging procedure that requires high-level skills, especially because the risks associated with performing ERCP in patients with altered anatomy are increased. In order to safely and effectively perform ERCP, specialized training and experience are important.

Methods: This is a retrospective study on the outcome of the first 30 ERCP cases performed by a surgeon newly trained in a public hospital. Patients were divided into two sets of 15 cases in order to evaluate the development of the skill. Data are analyzed regarding success rates, procedure duration, and complications.

Results: Technical success and clinical improvement were achieved in 76.7% each. First-attempt success improved from 46.7% in Group 1 to 86.7% in Group 2, showing skill maturation. Procedure time was significantly shorter in Group 2, at 31.67 vs 50.33 minutes in Group 1 ($p<0.001$). Complications were rare, in one patient with bleeding and one patient with pancreatitis (3.3%).

Conclusion: The data indicates that the success rate and efficiency of ERCP rise with experience, demonstrating the need for recently trained surgeons to attend structured training courses. There is minimal complication incidence that puts in view the importance of protocols and experience in safeguarding patients. It has also brought challenges identified, including anesthesia and equipment problems, that indicate a need for procedural support to enhance success. Advanced ERCP training courses that emphasize technical and cognitive skills can optimally prepare surgeons, especially in resource-constrained settings, to safely and effectively carry out these complex interventions.

INTRODUCTION

ERCP is a complex endoscopic procedure applied in the diagnostic and therapeutic management of biliary and pancreatic duct diseases.[1-3] The success rates of ERCP in patients with normal anatomy are quite high, usually ranging from 90-95%. In patients with surgically altered anatomy, there is a significant decrease in these success rates.[4-7] Anatomical changes, such as long intestinal loops and reconstructions, after surgeries cause technical difficulties and hence reduced access to the biliary tree, leading to a decrease in the success rate of the procedure.[8,9] Such post-surgical anatomic alterations make ERCP more difficult and hence increase the complication rate.[10,11]

With such technical challenges, ERCP is a high-risk procedure that requires tremendous experience for effective and safe conduction. Consequently, experienced surgeons have an important role in conducting ERCP safely. The American Society for Gastrointestinal Endoscopy recommends at least 200 ERCPs be performed before independent competence in patients with normal anatomy is achieved, although no specific case number is established for anatomically altered cases. These technical challenges and increased risks make it clear why specialized training in ERCP is recommended.[12,13]

Traditional ERCP training has been performed on live patients under supervision, with the learning curves closely monitored through continuous assessment by instructors. It translates to a strong correlation existing between the number of procedures and the procedural success rate; variability regarding case number for surgeons to reach expertise in ERCP.[3,6,11]

The aim of this study was to review the outcomes of the first 30 ERCP cases performed by a surgeon in a public hospital after undifferentiated basic ERCP training. We expect improvement in the rate of success, reduction in procedure time, and complication rates with increasing experience. We will also assess the impact of altered anatomy-specific challenges, namely, technical difficulties pertaining to anesthesia and equipment issues, on the outcome of procedures.

MATERIALS AND METHODS

This is a retrospective analysis of the first 30 ERCP cases at a public hospital. ERCP is an advanced endoscopic procedure with a very important role in diagnosing and treating diseases of the bile ducts and pancreas. Effective and safe performance of ERCP procedures, especially in a public hospital setting, poses specific difficulties for less-experienced surgeons. Consequently, the study aims at success criteria and surgical adaptation of newly qualified surgeons performing ERCP. This study includes patients to whom ERCP was applied in İzmir Bakıçay University Hospital between January 2022 - May 2022. The procedures were performed by a surgeon who just completed all prerequisites of Turkish Surgical Association's Basic ERCP Training and obtained a certificate after finishing this training program.

Patient Selection and Grouping

This study included 30 patients with the diagnosis of cholangitis and choledocholithiasis as indications for ERCP. The patients were divided into two groups to observe experiential progress of the surgeon more properly. The initial 15 patients, representing cases immediately following the training of the surgeon, were regarded as "Group 1". The second set of 15 patients was taken as "Group 2", representing procedures after more experience was gained by the surgeon.

To compare the groups, differences in demographic characteristics, gender distribution, mean age, ERCP indications, procedure times, and complication rates between and within the groups were evaluated.

Data Collection and Evaluation Criteria

For each patient, the procedure time, complications occurring during or after the procedure, including bleeding or pancreatitis, and clinical improvement rates were also recorded. Procedure time was considered as the time between the insertion of the endoscope and the end of the procedure. Clinical improvement was defined as a decrease or total resolution of clinical symptoms after ERCP.

The primary success rate reflected the surgeon's ability to achieve the principal objective of the intervention, while the technical success rate represented the thorough and protocol-compliant performance of the procedure. The reasons for procedural failure included lack of surgeon experience, poor administration of anaesthesia or sedation, inappropriate maintenance of patient positioning, and failure of the electrosurgical device.

Ethical Approval and Institutional Protocols

Ethics committee approval was obtained for this study (2024/1783/1763). ERCP interventions made in public hospitals were planned to protect the safety and privacy of the patients. Additionally, before participation in the study, all participants were provided with adequate detail about the procedures that would be used in their treatment, and adherence to all national and international endoscopic standards was ensured throughout the process, also focusing on patient privacy.

ERCP Procedure

During ERCP procedures, routine biochemical evaluations were performed, including tests for coagulation and electrolyte status. Sedation and anesthesia were provided based on the facilities of the instituting hospital, and all procedures were performed under the supervision of a specialist. Procedures were performed with sedation, and patients maintained in the appropriate position within the operating room setting. The facilities and instruments of intervention during endoscopy were provided according to the availability in the hospitals and were planned based on the ability and expertise of the surgeon. The patients

were followed up for at least 24 hrs post-operatively for any complications and clinical recovery.

Statistical Analysis

Data were analyzed using SPSS version 22.0. The demographic data and ERCP results are presented as mean ± standard deviation for the continuous variables, and the categorical variables, such as gender, are described as counts (percentage). Comparison of the continuous variables, for instance, age and duration of the procedure between both groups, was done by the Student's t-test. The difference among categorical variables was analyzed using the chi-square test or Fisher's exact test. A p-value of <0.05 was considered to represent statistical significance in both groups and as the main factor in deciding whether the differences are statistically significant. In this study, a p-value of <0.05 represented statistical significance.

RESULTS

The present study is a retrospective analysis of the initial 30 ERCP procedures performed by a recently trained surgeon in a public hospital setting; demographic features, clinical indications, success rates, and complications are highlighted. Data is presented as cumulative information for all 30 patients and comparative studies between Group 1 (first 15 cases) and Group 2 (next 15 cases). The specific findings for each group are reported below and summarized in Tables 1, 2 and 3.

The cohort of 30 patients showed a mean age of 63.97 years (SD: 12.72), indicating an older population more commonly associated with the indications of ERCP, such as choledocholithiasis and cholangitis. In terms of gender distribution, there were 12 males (40%) and 18 females (60%), reflecting a modest preponderance of female individuals. The main indications for ERCP were choledocholithiasis in 22 patients (73.3%) and cholangitis in 8 patients (26.7%), with the former taking up the highest percentages. The mean procedure time for all cases was 41 minutes (SD: 15.55). In terms of the success rate regarding the procedure, 20 (66.7%) were successful at the first attempt. When technical success is considered, defined as complete protocol-compliant performance of the procedure, success was achieved in 23 cases (76.7%). Clinical improvement, defined as the resolution of symptoms following ERCP, was also experienced by 23 patients (76.7%) and closely matched the rate of technical success. In terms of complications, two adverse events were documented: One episode of bleeding (3.3%) and one episode of pancreatitis (3.3%). These complications were graded as mild and managed conservatively without any further surgical intervention (Table 1).

A comparative analysis of demographic and clinical outcomes between Group 1 and Group 2. To assess the effect of experience of the operator on the outcomes of the procedures undertaken, patients were grouped into two. Group 1 included the initial 15 cases following the completion of training in ERCP and group 2 included the subsequent 15 cases in which superior experience was expected. The mean age of Group 1 was 60.93 years (SD: 16.55) and that of Group 2 was 67 years (SD: 6.45), with no statistically significant difference between the two groups (p=0.197). The gender distribution was unchanged between the groups, each having 9 males (60%) and 6 females (40%), and this yielded no statistically significant difference (p=0.859). The indications for ERCP were similar in both groups, though with minor variations. In Group 1, there were 5 patients (33.3%) diagnosed with cholangitis and 10 (66.7%) with choledocholithiasis. In Group 2, 3 patients had cholangitis (20%), and 12 (80%) had choledocholithiasis. This difference was not statistically significant (p=0.341). The only finding of any great importance was that the duration of procedures was shorter with growing experience. The mean procedure time for Group 1 was 50.33 minutes (SD: 11.56), compared with a significantly shorter mean duration for Group 2 of 31.67 minutes (SD: 13.45), of statistical significance, p<0.001. This reflects a great improvement in efficiency with experience of the surgeon. First-attempt ERCP success rates also improved substantially between groups. In Group 1, 46.7% (7 cases) were successful at the first pass, while in Group 2, the success rate was obviously higher, reaching 86.7% (13 cases), and the difference was statistically significant (p=0.025). The technical success rates were also more obvious in Group 2 (86.7%) than those in Group 1 (66.7%); however, this difference was not statistically significant (p=0.195). Clinical improvement was noted in 10 (66.7%) of Group 1 and in 13 (86.7%) of Group 2, with no statistically significant difference between them (p=0.195).

Table 1. Demographic characteristics and ERCP outcomes of the first 30 patients

Age	
Mean ± SD	63.97±12.72
Sex (n)	
Male (%)	12 (40)
Female (%)	18 (60)
Ercp indication (n)	
Cholangitis (%)	8 (26.7)
Choledocholitiazis (%)	22 (73.3)
Procudure Duration (min.)	
Mean ± SD	41±15.55
Succesful ERCP in First Attempt	
(n) (%)	20 (66.7)
Technically Successful ERCP	
(n) (%)	23 (76.7)
Clinical Improvement Post-Procedure	
(n) (%)	23 (76.7)
Complications (n)	
Bleeding (%)	1 (3.3)
Pancreatitis (%)	1 (3.3)

ERCP: Endoscopic Retrograde Cholangiopancreatography

Table 2. Comparison of demographic and clinical outcomes between group 1 and group 2

	Group 1 (n=5)	Group 2 (n=15)	P value
Age			
Mean ± SD	60.93±16.55	67±6.45	0.197
Sex (n)			
Male (%)	9 (60)	9 (60)	0.859
Female (%)	6 (40)	6 (40)	
Ercp Indication (n)			
Cholangitis (%)	5 (33.3)	3 (20)	0.341
Choledocholitiazis (%)	10 (66.7)	12 (80)	
Procedure Duration (min.)			
Mean ± SD	50.33±11.56	31.67±13.45	<0.001
Succesful ERCP in First Attempt			
(n) (%)	7 (46.7)	13 (86.7)	0.025
Technically Successful ERCP			
(n) (%)	10 (66.7)	13 (86.7)	0.195
Clinical Improvement Post-Procedure (n) (%)	10 (66.7)	13 (86.7)	0.195
Complications (n)			
Bleeding (%)	0	1 (6.7)	0.368
Pancreatitis (%)	1 (6.7)	0	

ERCP: Endoscopic Retrograde Cholangiopancreatography; SD: Standard Deviation.

Table 3. Causes of unsuccessful ERCP procedures

Causes of Unsuccessful ERCP Procedures	n (%)
Lack of Surgical Experience	2 (6.6)
Inadequate Anesthesia/Sedation and Position Loss	5 (16.6)
Electrocautery Device Malfunction	1 (3.3)

ERCP: Endoscopic Retrograde Cholangiopancreatography,

Taken all together, this may be interpreted as a trend toward increased technical success rate and better clinical benefits with increasing experience, although some of the discrepancies were not statistically significant. Complications were infrequent in both groups, without a significant difference between them (p=0.368). Group 1 had one case of pancreatitis (6.7%) and no bleeding, while in Group 2, there was one case of bleeding (6.7%) and no pancreatitis (Table 2).

Causes of Unsuccessful ERCP Procedures Failure of procedure was reviewed for possible contributing factors with certain causes compiled in Table 3. The major causes for failure of ERCP included inexperience of surgeons, incomplete anesthesia or sedation leading to movement of the patient, and failure of electrocautery device. Inexperience accounted for 2 cases (6.6%) of failed ERCP, implying that experience is a crucial factor in success, especially in the initial cases. The most common cause was inadequate anesthesia or sedation that made it impossible to maintain the patient in the optimal position, responsible for 5 failed procedures (16.6%). It really underlines the necessity of effective anesthesia and sedation protocols that can support the success of the procedure. Lastly, one case (3.3%) had a complication due to the malfunction of an electrocautery device, hence the importance of good maintenance and functioning equipment to ensure effectiveness and efficiency during any procedure (Table 3).

DISCUSSION

This is a retrospective analysis of the first 30 ERCP cases performed by a newly trained surgeon in a public hospital, and it goes to show parallelism of findings with other studies in the literature. In the case of complex endoscopic procedures like ERCP, it was realized that with increased experience on the part of the surgeon, there is a higher success rate and a lower number of hours taken to complete the procedure. The results are in line with the findings elicited from learning curve analysis, as obtained in the studies by Chen & van der Wiel et al.,[6] which stress the positive effect that institutionalized training programs have on success rates.[13]

Its first results in 30 cases revealed a technical success rate of 76.7% and a clinical improvement rate of 76.7%. Notably, the initial ERCP success rate increased from 46.7% to 86.7%, hence showing that with experience, the technical prowess improves. In a study by Ekkelenkamp et al.,[14] it was demonstrated that an experienced endoscopist would have a lower complication rate and that technical competence is acquired over a period of time. In a multicenter

study on ERCP training, Wani et al.[3] found a strong association of case volume with success rates but also underlined that more experience is associated with a decrease in complication rates.

One of the major findings is the reduction in procedural time associated with experience accumulated. The mean duration of surgery for the first 15 was 50.33 minutes, which then decreased to 31.67 minutes for the second set of 15 ($p<0.001$). This clearly demonstrates a significant gain in efficiency and an inverse relationship between experience and duration of surgery. Moreover, multiple studies support this result, suggesting that increased experience is associated with reduced surgical time, positively impacting the learning curve and correlating with improved patient outcomes and decreased procedural complications.[15-17]

Analysis of complication rates showed that, in addition to adherence to strict protocols, the build-up of experience has played an important role in ensuring continuing low-complication rates. In the present study, there was only one case of bleeding (3.3%) and one case of pancreatitis (3.3%), which is within the complication rate found in previous studies. According to a review done by Borrelli de Andreis et al.,[8] complication rates related to ERCP vary between 5-10%, and experience plays a major role in curtailing these complications. The very low complication rates in this study suggest that newly trained surgeons should be guided carefully and supported while attempting complex procedures such as ERCP.[17]

Review of the failed procedures showed that the commonest complications encountered during ERCP were problems related to anesthesia and equipment. The inability to properly position the patient, due to insufficient anesthesia or sedation, was identified as a contributing factor in the high rate of failure. Van der Wiel et al.[13] have underlined the importance of simulation-based learning in overcoming these technical challenges. Optimal levels of anesthesia and sedation might be vital in affording the surgeon an adequate level of proficiency and in obtaining optimal results. Thus, supportive approaches must be strengthened, such as simulation training and controlled applications, until complex endoscopic procedures like ERCP can be performed with good results.[3,15] Well-structured teaching programs do seem to play a very important role in allowing trainee surgeons to become proficient in the performance of highly complex endoscopic procedures like ERCP. Chen and Wang emphasized the need for ERCP training programs to include not only technical skills but also cognitive competence, hence calling for a curriculum framework that fully ensures the safe and efficient execution of procedures. The need for integrating theoretical knowledge with practical competencies in ERCP training is thus the reason associated with better outcomes in this particular procedure.[6] This study highlights the need to acquire technical competence and stresses the importance of having adequate knowledge to ensure patient safety.

This study is limited by its small sample size, analyzing only the first 30 ERCP cases done by a newly trained surgeon, which may not give the real dimension of procedural complexities, especially in patients with altered anatomy. This is a single-center retrospective analysis in a public hospital; the findings may reflect conditions and resources that may not be generalizable. In addition, the lack of long-term follow-up precludes an understanding of the durability of experience in terms of both safety and effectiveness and lacks objective assessment of the learning curve beyond the measures of procedure time and early outcome.

Conclusion

The present study shows that experience significantly improves ERCP success rates and also reduces procedural time, indicating the important role of structured training programs in skill acquisition. Moreover, low complication rates may point out the fact that protocol adherence and experience are paramount for the protection of patients. These findings give credence to supportive training approaches, which can be used to improve outcomes in complex procedures such as ERCP, especially among newly trained surgeons in resource-constrained settings within hospital frameworks.

Ethics Committee Approval

The study was approved by the the İzmir Bakırçay University Non-Interventional Clinical Research Ethics Committee (Date: 02.10.2024, Decision No: 1783).

Informed Consent

Retrospective study.

Peer-review

Externally peer-reviewed.

Authorship Contributions

Concept: N.S.P., S.C.E.; Design: N.S.P., S.C.E.; Supervision: N.S.P., S.C.E., E.K., M.O., M.U., Y.B.K, W.A.; Materials: N.S.P.; Data Collection and /or Processing: N.S.P., S.C.E.; Analysis: S.C.E.; Literature Review: N.S.P., S.C.E., E.K., M.O., M.U., Y.B.K, W.A.; Writinging: N.S.P., S.C.E., E.K., M.O., M.U., Y.B.K, W.A.; Critical Review: N.S.P., S.C.E., E.K., M.O., M.U., Y.B.K, W.A.

Conflict of Interest

None declared.

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İlk 30 Vakanın Değerlendirilmesi: Türk Cerrahi Derneği Temel ERCP Eğitimi Sonrası Bir Kamu Hastanesinde Karmaşık Bir İşlemin Zorlukları ve Başarı Kriterleri

Amaç: Endoskopik retrograd kolanjiyopankreatografi (ERCP), özellikle anatomisi değişmiş hastalarda uygulanırken artan riskleri nedeniyle yüksek düzeyde beceri gerektiren zorlu bir işlemdir. ERCP'nin güvenli ve etkili bir şekilde yapılabilmesi için özel eğitim ve deneyim önemlidir.

Gereç ve Yöntem: Çalışmaya biyopsi ile tanı konulan 30 NASH hastası ve kontrol koluna da 21 sağlıklı vaka dahil edildi. Her iki gruba dahil olan bireylerin serum FGL-2 düzeyleri karşılaştırıldı. Yine her iki gruba dahil edilen bireylerin klinikopatolojik özellikleri ile FGL-2 düzeyleri arasındaki ilişki incelendi.

Bulgular: Teknik başarı ve klinik iyileşme oranları her iki grupta %76.7 olarak elde edilmiştir. İlk denemede başarı oranı, 1. grupta %46.7'den 2. grupta %86.7'ye yükselmiş ve becerinin gelişimini ortaya koymuştur. İşlem süresi, 2. grupta anlamlı ölçüde kısalarak 1. grupta 50.33 dakika iken 2. grupta 31.67 dakikaya düşmüştür ($p<0.001$). Komplikasyonlar nadir olup bir hastada kanama, bir hastada pankreatit (her biri %3.3) görülmüştür.

Sonuç: Veriler, ERCP'nin başarı oranının ve verimliliğinin deneyimle arttığını göstermekte ve yeni eğitim almış cerrahların yapılandırılmış eğitim kurslarına katılmalarının gerekliliğine işaret etmektedir. Komplikasyon oranının minimal olması, hasta güvenliğini sağlamak için protokoller ve deneyimin önemini vurgulamaktadır. Ayrıca, başarıyı artırmak için anestezi ve ekipman sorunları gibi zorluklar belirlenmiş olup, bu da prosedürel desteğe ihtiyaç olduğunu göstermektedir. Teknik ve bilişsel becerilere odaklanan ileri düzey ERCP eğitim kursları, özellikle kaynak kısıtlı ortamlar için cerrahları bu karmaşık işlemleri güvenli ve etkili bir şekilde gerçekleştirmeye en iyi şekilde hazırlayabilir.

Anahtar Sözcükler: ERCP; işlem başarısı; öğrenme eğrisi; yapılandırılmış eğitim.