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Results of endoscopic retrograde cholangiopancreatography procedures at surgical clinics: A multicenter observational study in Türkiye

Yilmaz S *et al*. Yılmaz S,Uğurlu ET hiç ERCP sonuçları

Abstract

BACKGROUND

Endoscopic retrograde cholangiopancreatography (ERCP) is an invasive endoscopic procedure used mainly to treat the hepato-pancreato-biliary (HPB) diseases. The need for ERCP has increased with the rising of HPB diseases over the past decade. So increased demand made ERCP to be performed at more centres. Currently, it is performed by general surgeons, gastroenterology and invasive radiology specialists in United States and Europa as recommended by British Society of Gastroenterology (BSG).

AIM

To present the results of ERCP procedures of fourteen surgical centres in Türkiye.

METHODS

Fourteen surgical centres performing ERCP were included into the present study. The age, gender, ERCP indication, success status, post-ERCP complications, ERCP reports and patient files of 66993 patients who underwent ERCP were collected from the data of the centres participating in the study. The results were discussed according to the targets declared by BSG. They were; volume load per annum, proportion of successful cannulation (> 85%), bile duct clearance rate (> 75%), stenting rate for strictures (> 80%) and complications (< 6%).

RESULTS

A total of 66993 ERCP procedures were performed in the centres included in the study till the August 2024. 29250 (43.6%) of the procedures were performed urgently, especially for suppurative cholangitis, biliary tract injuries, *etc.* The remaining 37743 (56.4%) cases were performed electively. 50.2% of the patients were female and 49.8% were male. The average ages were 56.5 for women and 55.9 for men. General anesthesia was used for 84.1% of the while sedation was used for 15.9%. The indications were bile

duct stone (78.7%), pancreatic tumor (3.9%), papillary tumor (3.3%), cholangiocarcinoma (2.6%), Oddi sphincter dysfunction (2.4%), bile leakage after cholecystectomy (2%), bile leakage after hydatid cyst surgery (1.9%), biliary stricture (1.7%), and other diseases (3.1%). Hyperamylasemia and the post-ERCP pancreatitis were the most common complication as observed at 8.1% of the patients. They were usually self-limited and responded to supportive measures. The frequency of the other complications was also consistent with the literature.

CONCLUSION

There is a huge shortage of ERCP endoscopists throughout the world due to insufficient ERCP training and centres especially in developing or underdeveloped countries. Since the patients requiring ERCP usually present to surgical practitioners, the incorporation of surgeons into this training programmes is effective and reliable solution. BSG recommends to incorporate the surgeons and radiologists besides the gastroenterology specialists. This study is the first to present the results of ERCP procedures of fourteen surgical centres through the Türkiye. The results suggest that surgical centres involved were able to achieve the targets set by BSG. This study demonstrated that the surgical ERCP units in the present work have reached satisfactory results and provided reliable and successful ERCP service. Nowadays there is no hesitation on the validity and appropriateness of the surgeons to perform ERCP. So ERCP training should be encouraged to surgeons and more surgical ERCP centres should be provided.

Key Words: Endoscopic retrograde cholangiopancreatography; General surgeon; Education; Endoscopic retrograde cholangiopancreatography training; Surgical centres; Endoscopic retrograde cholangiopancreatography endoscopist

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Core Tip: Sunulan makalede, çalışmaya dahil edilen on dört genel cerrahi merkezinde gerçekleştirilen tüm ERCP prosedürlerinin sonuçları gösterilmiştir. Retrospektif, çok merkezli ve gözlemsel bir çalışma olarak tasarlanmış olup istatistiksel değerlendirme yapılmamıştır. Çalışmaya katılan merkezlerden ERCP uygulanan 66993 hastanın yaşı, cinsiyeti, ERCP endikasyonu, başarı durumu, ERCP sonrası komplikasyonlar, ERCP raporları ve hasta dosyaları toplanmıştır. Sonuçlar BSG tarafından açıklanan hedeflere göre tartışılmıştır. Bunlar; yıllık hacim yükü, başarılı kanülasyon oranı (% >80), safra yolu temizlenme oranı (% >75), darlıklar için stent oranı (% >85) ve komplikasyonlar (% <6). Çalışmaya dahil edilen merkezlerde ERCP uygulanan tüm hastalar çalışmaya dahil edilmiştir. Hem elektif hem de acil prosedürler kaydedilmiş olup hiçbir dışlama kriteri yoktur. Çalışmaya dahil edilen on dört merkezin yıllık ERCP vaka yükü 70-500 ERCP prosedürüdür. Bu merkezler yaklaşık 20 milyonluk bir nüfusa sağlık hizmeti sunmaktadır. Tüm merkezlerden iki sorumlu yazar belirlendi ve veriler bireysel yazarların sorumluluğu altında elde edildi. Merkezlerden elde edilen veriler bir excel dosyasında birleştirildi ve kümülatif sonuçlar hesaplandı.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is an invasive endoscopic procedure used mainly to treat the hepato-pancreato-biliary (HPB) diseases. Although developing imaging methods such as magnetic resonance imaging, magnetic resonance cholangiopancreatography (MRCP) replaced the role of ERCP, it is still used for diagnostic purposes rarely. Since the diagnostic value of magnetic resonance imaging/MRCP is low especially in patients with bile duct stones ≤ 5 mm in size and patients with dysfunction of Oddi sphincter and benign strictures, ERCP is used for diagnosing also[1]. The need for ERCP has increased with the rising incidence of HPB

diseases over the past decade[2]. So increased demand made ERCP to be performed at more centres. It is a technically challenging procedure which requires an intensive training process mainly under the vision of an experienced endoscopist mentor[3].

It is used for elective treatment of certain diseases as well as urgent situations. Bile duct stones and malignant biliary stenoses are the most commonly seen indications for elective ERCP procedures. The bile duct clearance is extremely high following ERCP for the patients with biliary stone; De'Ath *et al*[3] reported in a recent work that bile duct clearance was achieved in 80% of patients with ERCP. Additionally, ERCP has a superior role to decompress the malignant obstructions over the percutaneous transhepatic cholangiography since the latter has higher infectious complications and mortality rates[4]. The emergency cases are mainly cholangitis, certain cases of biliary pancreatitis and surgical bile duct injuries (bile fistulas or jaundice after cholecystectomy) but sporadic cases like biliary system parasites or T-tube breakage may be encountered[5-7]. ERCP may sometimes be valuable for bridging to subsequent cholecystectomy in patients with severe cholecystitis or Mirizzi syndrome[8,9].

Since it has a significant morbidity and mortality (up to 1%) rates, several precautions have been recommended to decrease the adverse events and to improve the procedure success. The experience of endoscopist, ERCP volume of the center, technical facilities and the patient related conditions are the proposed factors to affect the morbidity and mortality. There are some targets to be achieved related for both endoscopist and center to provide the optimal results. Endoscopist and center volume should be above 75 and 200 yearly, successful cannulation rate should be above 85%, stone clearance of bile duct should be above 85% and complication rates should be less than 6%[10].

There are numerous complications up to 15% after the ERCP, 1%-2% of which are serious. Ugurlu[11] has reported an overall complication rate of 17.4% including the patients with hyperamylasemia. When the hyperamylasemia cases were excluded, the complication rate was 8.1%. Pancreatitis, ascending cholangitis/sepsis, bleeding and perforation are well described complications after ERCP. However, the unusual and unexpected complications related with basket stuck, stent migration or duodenoscope

itself may be detected in which the management is difficult[12,13]. There are also non-procedural complications like cardiopulmonary depression, hypoxia, aspiration and adverse drug reactions. European Society of Gastrointestinal Endoscopy described the ERCP-related complications as follows: (1) Pancreatitis: Newly or worsened abdominal pain combined with amylase or lipase values (> three times the normal) more than 24 hours and requirement of hospital admission or prolongation; (2) Cholangitis: New onset of temperature > 38 °C for more than 24 hours combined with cholestasis; (4) Cholecystitis: Right upper quadrant signs of inflammation, images demonstrating the findings of acute cholecystitis, systemic signs of inflammation; (5) Bleeding: Hematemesis and/or melena or Hb decrease > 2 g/dL; and (6) Perforation: Presence of gas or any GIS content outside of the gastrointestinal lumen depicted by radiological methods[14]. Close monitorization and repeat abdominal examinations are important to detect and manage the post-ERCP complications.

Although ERCP is a technically challenging procedure and associated with potentially severe complications there are several studies reporting that it can be safely performed even in elderly patients, childhood and also pregnancy once the specific precautions are ensured[9,15-17]. The clinician should evaluate and re-check the indication and potential benefit of ERCP in this group in which the certain anatomical and physiological differences may be observed. Anesthesia plays an important role at the beginning step of ERCP to ensure optimal papilla positioning and eventual successful cannulation. However, despite the increased number of ERCP performed thoroughly, anesthesia type and protocols are not still standardized. The collaboration of anesthetist/endoscopist and the clinical status of the patient will determine the type of anesthesia. Nowadays general anesthesia and deep sedation are usually used depending on the center's preference[18].

The selective cannulation of the bile duct is the main crucial step for a successful ERCP and also a prerequisite to obtain maximum benefit. Despite the advances in ERCP devices including specific guides, rotable sphincterotomes and stents, even experienced endoscopists may fail to cannulate the papilla due to several reasons. Diverticular

papilla, ectopic placement, ampullary tumor and the deranged anatomy due to gastric surgery are the examples resulting failure[19]. Repeating the procedure within a few days after the initial failed ERCP is recommended before contemplating more invasive interventions[20]. ERCP procedure which was first developed by a surgeon McCune in 1968 nowadays is performed by general surgeons, gastroenterology and invasive radiology specialists in United States and Europa. The issue of who performs ERCP is determined by national laws, rules of professional associations, legislations of Ministry of Health and patients demand[21].

Although ERCP has achieved great progress over the last years, there is a still a shortage of both ERCP-endoscopists (ERCPist) and centres throughout the world especially in developing countries. So, there are several training programmes to supply this demand. In these programmes, there are several types of training periods (one year, half year, 4-months). Following the training courses there are follow-up targets to evaluate the adequacy of programme with the help of feedback responses[22]. In Türkiye ERCP is performed mainly by general surgeons in addition to gastroenterology specialists. ERCP training is provided through a 6-month one-by-one training program during general surgery residency. There is also another education programme directed by Turkish Surgical Society (TSS) for the general surgeons after residency as post graduate education. The present study investigated the results of ERCP procedures carried out in fourteen general surgery departments in Türkiye with the guidance of British Society of Gastroenterology (BSG) ERCP standards framework[10].

MATERIALS AND METHODS

Study centres

The present paper showed the results of all ERCP procedures performed at the fourteen general surgery centres included in the study. It was designed as a retrospective, multicenter and observational study and no statistical evaluation was made. The age, gender, ERCP indication, success status, post-ERCP complications, ERCP reports and patient files of 66993 patients who underwent ERCP were collected from the centres

participating in the study. The results were discussed according to the targets declared by BSG. They were volume load per annum, proportion of successful cannulation (> 80%), bile duct clearance rate (> 75%), stenting rate for strictures (> 85%), and complications (< 6%). All patients who had an ERCP in the centres involved were included into the study. Both elective and urgent procedures were recorded and there was no exclusion criteria. The annual ERCP case load of all fourteen centres included in the study was 70-500 ERCP procedures. These centres provide health services to a population of about 20 million people. Two responsible authors were identified from all centres and the data were obtained under the responsibility of individual authors. The data obtained from the centres were combined in an excel file and the cumulative results were calculated.

ERCP clinicians

All ERCPs were performed mostly by general surgeons and rarely by gastrointestinal surgeons. The centres have been performing ERCP for 2-15 years. The clinicians usually received their ERCP training during residency or by postgraduate training organized by TSS and rarely training from an abroad country. Twenty-seven of the participants were academicians, while the others were general surgery specialists working in a public and private hospital.

ERCP procedure

ERCPs were routinely performed under general or deep sedation anesthesia, depending on the preference of the center, anesthesiologist, and ERCPist. The patients were routinely placed in the left lateral decubitus position except one with situs inversus. The routine antibiotic use and rectal diclofenac administration varied between centres.

RESULTS

A total of 66993 ERCP procedures were performed in the centres included in the study till the August 2024. 65747 (98.1%) of them were performed by using Fujinon, 920 (1.4%) using Olympus and 326 (0.5%) using Pentax imaging systems. 29250 (43.6%) of the procedures were performed urgently. especially with suppurative cholangitis, biliary tract injuries, *etc.* The remaining 37743 (56.4%) cases were performed electively. 50.2% of the patients were female and 49.8% were male. The average ages were 56.5 for women and 55.9 for men. There were additional comorbidities in 48% of the patients. The average length of hospital stay was 8.91 days. General anesthesia was used for 84,1% of the while sedation was used for 15,9%. The general features of the patients and the procedures were depicted in Table 1.

The hemogram-biochemistry studies, ultrasonography, computed tomography and MR/MRCP images were obtained to get the clinical diagnoses of the patients. The indications were bile duct stone (78.7%), pancreatic tumor (3.9%), papillary tumor (3.3%), cholangiocarcinoma (2.6%), Oddi sphincter dysfunction (2.4%), bile leakage after cholecystectomy (2%), bile leakage after hydatid cyst surgery (1.9%), biliary stricture (1.7%) and other diseases (3.1%) (Table 2). Hyperamylasemia and post-ERCP pancreatitis (PEP) were the most common complication as observed at 8.2% consistent with the literature. They were usually self-limited and responded to supportive measures. The other complications encountered were listed at Table 3.

DISCUSSION

There is a huge shortage of ERCP endoscopists throughout the world due to insufficient ERCP training and centres[22]. Since the patients requiring ERCP usually present to surgical practitioner and eventually undergone to surgical resection or palliation, the incorporation of surgeons into this training programmes is effective and reliable solution. BSG recommends to incorporate the gastrointestinal surgeons and radiologists besides the gastroenterology specialists. This study is the first to present the results of ERCP procedures of fourteen surgical centres through the Türkiye. The results suggest that surgical centres involved were able to achieve the targets set by BSG[10]. There is a

significant increase in demand of ERCP due to gradually rising health problems related with hepatopancreatobiliary diseases. In Türkiye, ERCP which was first performed in 1977 has also been performed by general surgeons besides the gastroenterology specialists as of 1993. Nowadays nearly two hundred general surgeons are carrying out ERCP procedure. Between 15000-20000 patients require ERCP and the number of ERCP procedures performed by general surgeons is around 9500-10000 annually[21].

In developed countries the ERCPist-to-population ratio is 20-50 per 1000000 inhabitants, so there is a shortage in Türkiye in terms of ERCPist and new ERCP training programmes and centres should be arranged to overcome this problem[22]. The apprenticeship model is the basis of ERCP training but simulation-based programmes are also recommended to accelerate the learning curves and to decrease the procedural risks[23]. However, they aren't available everywhere. Although the training programmes are held as fellowship after specialization in Western countries, general surgery residents are able to get it during residency in some centres in Türkiye. There is also another training programme organized by TSS as a postgraduate fellowship programme. Of the 29 ERCP specialists included in this study, 15 of them have received ERCP training and certification from this program organized by TSS. Others received their training during their general surgery residency or abroad education program.

ERCP training in Türkiye lasts six months and is basically held upon on hands-on training. In the first two months, the trainee is acknowledged about the pre-procedural preparation of the patient and theoretical training and observes the ERCP procedures carried out by the mentor. Next two months trainees should achieve competence of basic ERCP procedures and cannulation of post sphincterotomy papilla. Finally, the remaining skills including cannulation of native papilla, stenting, biopsy and stone extraction are acquired through one-on-one training under the supervision of mentor. ERCP providing centres and ERCPists should ensure acceptable target points to deliver reliable health services. There should be minimum of 75 procedures for ERCPist per year and 150 procedures minimum for center. Individual ERCPist in a center should be

able to cannulate the virgin papilla > 85%, extract the common bile duct stone > 75% and place the stent successfully through the extrahepatic stricture and to provide the cytology > 80% of cases[10].

Considering the results of the centres included in this study, it is seen that the cannulation success rate is 90.8% and these rates are in line with the rates determined by BSG. ERCP referral centres should be integrated with HPB sections that can access to HPB surgeon, invasive radiologist and intensive care unit. These are actually the advantages of general surgeons performing ERCP, because many of them are HPB surgeons and have close relationships with invasive radiologists and intensivists. We believe that the surgeon-lead ERCP also accelerates the surgical treatment process in occasional cases. The present study revealed that 24 out of 28 participants in the present study are HPB surgeons and they perform intervention themselves in case of a surgical complications after ERCP.

Although ERCP has a strong therapeutic potential, it carries a risk of significant complications, some of which can be serious. The complication rate should be below 6% according to BSG and it is 10.1% in this study (Table 3). Hyperamylasemia and the PEP were the most common complication as observed at 8.2% consistent with the literature. They were usually self-limited and responded to supportive measures. Although it isn't within the scope of this article, female gender, previous pancreatitis, previous PEP, suspicion of Oddi sphincter dysfunction, younger age, non-dilated common bile duct, normal bilirubin values, ERCPist's experience and the anatomical derangement of papilla are the factors developing PEP[11,23]. The rate of hyperamylasemia in this study is 4.7% and is consistent with the literatures. Ascending cholangitis is one of the infectious complications following ERCP and is observed between 0.4% and 10%. They usually respond to antibiotic therapy. In this study, 0.9% of the patients developed cholangitis after the procedure.

Bleeding is rarely seen after ERCP (0.3%-2%) and usually result from sphincterotomy. Fortunately, it doesn't produce serious hemodynamic consequences and respond to local measures as balloon pressure, adrenalin injection, *etc.* In this study, 346 (0.5%)

patients developed bleeding in the patient and laparotomy was performed in only two patients. The most feared complication of ERCP is perforation, fortunately most of them may be treated without surgery. Although the incidence ranged from 0.3% to 1.3%, the mortality may be as high as 37.5%. Conservative treatment is emphasized in post-ERCP perforations and surgery is required only in highly selected group[24,25]. In this study, perforation was observed in 0.15% of patients. This result is consistent with the literature.

The procedure volume of both center and endoscopist significantly impact the results and high volume for center > 200/year and endoscopist > 75/year are associated with increased success and lower complications[2]. In this study, the volume of the centres varied between 70-500 (twelve centres were high volume while two centres were low volume centres), however, the rate of successful cannulation and complications in these centres were close to others. But it should be reminded that, in addition to the endoscopist and center volume, patient-related factors and technical developments are also among the factors affecting cannulation success and complication rates. For example, it is known that more complex and previously unsuccessful cases are referred to tertiary centres thus decreasing the procedure success. We consider that the acceptable rates of complications in the present study are closely related with center/endoscopist volume, anesthesia management and the staff experience.

CONCLUSION

This study demonstrated that the surgical ERCP units in the present work have reached satisfactory results and provided reliable and successful ERCP service. Nowadays there is no hesitation on the validity and appropriateness of the surgeons to perform ERCP and enough data is available confirming this. So ERCP training should be encouraged to surgeons and more surgical ERCP centres should be provided.

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