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Surgeon-performed endoscopic retrograde cholangiopancreatography. Outcomes of 2392 procedures at two tertiary care centers

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Abstract

Background—Endoscopic retrograde cholangiopancreatography (ERCP) is a common procedure that, in the United States, is traditionally performed by gastroenterologists. We hypothesized that when performed by well-trained surgeons, ERCP can be performed safely and effectively. The objectives of the study were to assess the rate of successful cannulation of the duct of interest and to assess the 30-day complication and mortality rates.

Methods—We retrospectively reviewed the charts of 1858 patients who underwent 2392 ERCP procedures performed by five surgeons between August 2003 and June 2016 in two centers. Demographic and historical data, indications, procedure-related data and 30-day complication and mortality data were collected and analyzed.

Results—The mean age was 53.4 (range 7–102) years and 1046 (56.3%) were female. 1430 (59.8%) of ERCP procedures involved a surgical endoscopy fellow. The most common indication was suspected or established uncomplicated common bile duct stones ($n = 1470$, 61.5%), followed by management of an existing biliary or pancreatic stent ($n = 370$, 15.5%) and acute biliary pancreatitis ($n = 173$, 7.2%). A therapeutic intervention was performed in 1564 (65.4%), a standard sphincterotomy in 1244 (52.0%), stent placement in 705 (29.5%) and stone removal in 638 (26.7%). When cannulation was attempted, the rate of successful cannulation was 94.1%. When cannulation was attempted during the patient's first ERCP the cannulation rate was 92.4%.

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Compliance with ethical standards

Disclosures Mazen R. Al-Mansour, Eleanor C. Fung, Edward L. Jones, Nichole E. Zayan, Timothy D. Wetzel, Sara E. Martin del Campo, Anahita D. Jalilvand, Andrew J. Suzo, Rebecca R. Dettorre, James K. Fullerton, Michael P. Meara, John D. Mellinger, Vimal K. Narula, and Jeffrey W. Hazey have no conflicts of interest or financial ties to disclose.

94 complications occurred (5.4%); the most common complication was post-ERCP pancreatitis in 75 (4.2%), significant gastrointestinal bleeding in 7 (0.4%), ascending cholangitis in 11 (0.6%) and perforation in 1 (0.05%). 11 mortalities occurred (0.5%) but none of which were ERCP-related.

Conclusion—When performed by well-trained surgical endoscopists, ERCP is associated with high success rate and acceptable complication rates consistent with previously published reports and in line with societal guidelines.

Keywords

ERCP; ERC; Endoscopic retrograde cholangiopancreatography; Surgical endoscopy; ERCP outcomes

Endoscopic retrograde cholangiopancreatography (ERCP) is a common endoscopic procedure that transformed from a purely diagnostic tool to a highly effective technique for the treatment of a variety of biliopancreatic pathologies. When compared to other endoscopic procedures, ERCP is technically complex and is associated with relatively high rates of serious complications including pancreatitis, cholangitis, bleeding, and perforation. Therefore, it is essential to ensure that competent endoscopists with high success and low complication rates are performing the procedure.

The need to ensure procedural competency has lead several medical societies to publish credentialing guidelines for different endoscopic procedures including ERCP. These guidelines oftentimes rely on consensus statements, expert opinions, and previously published data looking at outcomes of ERCP performed by gastroenterologists. Both the American Society of Gastrointestinal Endoscopy (ASGE) and the Canadian Association of Gastroenterology (CAG) recommended trainees to perform 200 ERCP procedures as a guide for initial credentialing in ERCP [1, 2]. These recommendations were based on studies evaluating the learning curve in gastroenterology trainees to reach the threshold (often set at > 80%) of deep cannulation of the intended duct [3–5].

While, in the United States, most commonly performed by gastroenterologists, ERCP is also being performed by surgeons who are trained in advanced gastrointestinal endoscopy. The training pathways of gastroenterologists and surgical endoscopists are quite different. Gastroenterology training in the United States requires completion of an internal medicine residency or its equivalent followed by a 3-year gastroenterology fellowship accredited by the Accreditation Council for Graduate Medical Education (ACGME). ERCP exposure during gastroenterology fellowship varies by training program and therefore many fellows pursue additional training in advanced gastrointestinal endoscopy. On the other hand, the training pathway for surgical endoscopists in the United States includes the completion of an ACGME-accredited general surgery residency followed by an advanced gastrointestinal endoscopy fellowship many of which are administered through The Fellowship Council. Considering the differences in training pathways, the criteria for ensuring procedural competency may not be similar. Many skills can cross over from surgical training into the ERCP procedure including the ability to interpret cholangiograms and pancreatograms, safe

application of electrosurgical current, tissue handling and the recognition and management of complications.

Ensuring procedural competency allows the performance of ERCP with high success rate while minimizing complication risk regardless of the training pathway. The outcomes of ERCP procedures performed by gastroenterologists have been extensively studied. However, there are a limited number of studies evaluating the outcomes of ERCP when performed by surgeons. Our objectives were to evaluate the outcomes of ERCP procedure performed by fellowship-trained surgical endoscopists in two institutions and compare them to previously published studies and medical societal quality benchmarks.

Materials and methods

We retrospectively reviewed the charts of 1858 patients who underwent 2392 ERCP procedures at two academic tertiary care centers in the United States between August 2003 and June 2016 (2137 ERCP procedures from The Ohio State University and 265 procedures from Southern Illinois University). The respective Institutional Review Board approval was obtained. Inclusion criteria included patients who underwent a completed or attempted ERCP by a fellowship-trained surgeon. The data collected included demographic data, indications for the procedure, preoperative laboratory findings, procedure-specific data and 30-day complication and mortality data. Continuous variables were presented as mean (range), and categorical variables were presented as number (percentage). Statistical analysis was performed using Microsoft Excel 2013 (Microsoft, Redmond, WA, USA).

Results

1858 patients underwent 2392 ERCP procedures performed by five fellowship-trained surgical endoscopists between August 2003 and June 2016 at two centers. The demographic and historical characteristics of the patients are listed in Table 1. The mean age of the patient population was 53.4 (range 7–102) years and 56.3% of the patients were female. The most prevalent American Society of Anesthesiology (ASA) class was ASA 2 (62.1%) followed by ASA 3 (30.5%). Cirrhosis was present in 31 (1.8%), history of pancreatitis in 321 (19.0%), primary sclerosing cholangitis in 10 (0.6%), pancreatic divisum in 7 (0.4%) and 37 (1.5%) had a history of orthotopic liver transplantation with duct-to-duct anastomosis. 1430 (59.8%) of procedures involved a surgical endoscopy fellow. 1675 (70.0%) of ERCP were performed in patients who never had a prior ERCP. Transgastric access was required in 6 procedures due to surgically altered gastrointestinal anatomy (e.g., Roux-en-Y gastric bypass). The rendezvous technique was utilized in 14 ERCP procedures.

Table 2 reviews the indications for the procedure. The most common ERCP indication was suspected or established uncomplicated common bile duct stones in 1470 (61.5%). This was defined as abnormal liver function panel, abnormal biliary imaging or imaging evidence of bile duct stones without another established indication for ERCP. Other common indications included the management of existing biliary or pancreatic stent in 370 (15.5%) and acute biliary pancreatitis in 173 (7.2%).

1564 (65.4%) ERCP procedures included at least one therapeutic intervention. Table 3 shows the different therapeutic interventions utilized. Standard sphincterotomy was performed in 1244 (52.0%) and precut sphincterotomy was performed in 22 (0.9%). Balloon papillary dilation was performed in 219 (9.1%). Biliary or pancreatic temporary plastic stents were placed in 669 (28.0%). A metal stent was placed in 36 (1.5%). Retrieval of at least one stone was performed in 638 (26.7%).

Deep cannulation of the intended duct was attempted in 2331 cases (97.4%). In 57 ERCP procedures, cannulation was not attempted due to poor tolerance of sedation or altered proximal gastrointestinal tract anatomy precluding advancement of the duodenoscope to the second portion of the duodenum (e.g., large paraesophageal hernia, esophageal stricture, proximal duodenal stricture). In four patients, a procedure note was not available. When cannulation was attempted, successful cannulation of the intended duct was performed in 2193 (94.1%). In 1675 patients (70.0%), the index ERCP was their first ERCP. Cannulation was successful in 1499 of 1623 first ERCP procedures when cannulation was attempted at a rate of 92.4%.

Table 4 reviews the 30-day complication and mortality data of the ERCP procedures. A complication occurred within 30 days of the ERCP in 94 cases (5.4%). The most common complication was post-ERCP pancreatitis, which occurred following 75 procedures (4.2%). 11 patients (0.6%) developed post-ERCP ascending cholangitis.

Post-ERCP hemorrhage occurred in seven patients (0.4%). The bleeding was from the sphincterotomy site in two patients, hemobilia occurred in two patients, bleeding duodenal ulcer in one and the source of bleeding was not identified in two. Four of these patients were on antithrombotic drugs. Four patients needed blood product transfusion. Four patients required upper endoscopy for evaluation and/or hemostasis. One patient required angioembolization of the gastroduodenal artery.

In one patient perforation of the third portion of the duodenum occurred requiring operative exploration and primary repair along with concomitant cholecystectomy. The patient subsequently recovered without sequela.

A total of 11 patients died within 30 days of the procedure (0.5%). Five patients died from liver failure of either their native or transplant liver. Three patients died from sequelae of extensive metastatic cancer (colon, pancreas, and hepatocellular carcinoma). Two patients died from pneumonia and one patient died from respiratory failure complicating severe acute biliary pancreatitis. No mortalities were directly related to the ERCP procedure itself.

Discussion

Our study aims to evaluate the safety and efficacy of ERCP procedures performed by fellowship-trained surgical endoscopists. We used as a benchmark the 2015 communication letter published by ASGE describing the quality indicators for ERCP. This reports was endorsed by the American College of Gastroenterology. The statement describes process and outcome quality measures in the preprocedural, intraprocedural, and postprocedural ERCP settings. The reports names the following priority measures: deep cannulation rate of the

native papilla in patients with normal gastrointestinal tract anatomy of > 90%, extraction of common bile duct stones < 1 cm in patients with normal biliary anatomy of 90%, successful placement of biliary stent for obstructions below the biliary bifurcation of 90% and tracking of post-ERCP pancreatitis rates without describing a target rate. The target rates for significant hemorrhage and gastrointestinal perforation were set at 1 and 0.2%, respectively [6].

One of our objectives was to assess the 30-day complication and mortality rates. Our overall complication rate was 5.4%. The most common complication was post-ERCP pancreatitis (4.2%) followed by ascending cholangitis (0.6%), gastrointestinal hemorrhage (0.4%), and perforation (0.05%). 11 patients (0.5%) died within 30 days of the procedure but no mortalities were directly related to the ERCP. Our gastrointestinal hemorrhage and perforation rates are within the ASGE quality targets. Although ASGE considered post-ERCP pancreatitis a priority indicator, it did not set a target goal for post-ERCP pancreatitis rate. Our 30-day complication rate is in line with previously published data. Freeman et al. analyzed ERCP procedures performed on consecutive patients from 17 centers in the United States and Canada over 2 years. In 2347 patients, the complication rate was 9.8% including post-ERCP pancreatitis rate of 5.4% and hemorrhage rate of 2.0%. 55 deaths occurred within 30 days, of which ten were directly or indirectly related to the procedure [7]. Loperfido et al. prospectively analyzed 2769 consecutive patients undergoing ERCP at nine centers in Italy over a 2-year period. One hundred eleven major complications occurred (4.0%): moderate-severe pancreatitis rate was 1.3%, cholangitis 0.9%, hemorrhage 0.8% and duodenal perforation 0.6% [8].

After excluding the patients that did not tolerate sedation and those who had abnormal proximal gastrointestinal anatomy precluding access to the papilla our deep cannulation rate of the intended duct was 94.1%. Our cannulation rate for patients who had no previous ERCP (surrogate for native papilla cannulation rate) was 92.4%. This rate meets the ASGE goal of > 90% cannulation of the native papilla. The successful cannulation rate is also in line with previously published results. DeBenedet et al. published a meta-analysis of 52 articles published between 2006 and 2013. The primary aim was to assess intraprocedural performance of ERCP and the secondary aim was to assess variations in quality indicators across different practice settings (academic vs. community). The cumulative, weighted bile duct and pancreatic duct cannulation success rate was 89.3% (range 70.6–98.9) and 85.0% (range 84.1–87.1), respectively. Precut sphincterotomy utilization rate was 10.5%; common bile duct stone extraction rate was 88.3%, and the rate of successful biliary stenting below the level of the hepatic duct bifurcation was 97.5%. No statistically significant difference in success rate was noted between academic and community settings [9].

The American Board of Surgery (ABS) recognized the importance of ensuring that ABS-certified surgeons be competent in flexible gastrointestinal endoscopy. This is highlighted by the 2014 announcement that all ABS-certified surgeons need to complete a standard curriculum of endoscopic technique. The flexible endoscopy curriculum (FEC) is a step-wise curriculum designed to ensure that surgical residents acquire the knowledge and skills needed for the safe and competent performance of flexible endoscopy. This includes obtaining the flexible endoscopy skills (FES) certification developed by the Society of

American Gastrointestinal and Endoscopic Surgeons (SAGES). These requirements will apply to the ABS applicants who are completing their residency in the 2017–2018 academic year [10]. Studies confirming the safety and efficacy of surgeon-performed flexible endoscopy have been published for both colonoscopy and upper endoscopy. Wexner et al. published a prospective analysis of 13,580 colonoscopies performed by surgeons and entered into a database over a period of 18 months. The colonoscopy completion rate was 92% with a mean completion time of 22.7 min. The most common intraprocedural complications were hypoxia (5.6%) and hypotension (1.2%). Post-procedural complications occurred in 0.2%. A single mortality (0.007%) occurred. Completion rates and procedural times correlated positively with the level of experience, but the complication rate did not [11]. Reed et al. performed a prospective analysis of 3525 upper endoscopies performed by surgeons and entered into a database over a period of a year. Biopsies were performed in 59.0%, dilation in 7.2%, foreign body removal or removal/placement of percutaneous endoscopic gastrostomy tube in 5.4% and polypectomy in 1.7%. The procedure was completed to the duodenum in 93.1% and the mean procedural time was 9.2 min. The most common complication was hypoxia in 1.6%. No complications occurred in 97.8%. Completion rates and complications did not correlate with experience level but procedural time did [12].

There are a limited number of studies evaluating the outcomes of surgeon-performed ERCP. Meguid et al. evaluated a total of 193 ERCP procedures performed by surgical attendings and resident staff over a 6-year period. A success rate of 82.4% and a complication rate of 6.7% were reported. A surgical resident was the primary endoscopist in 51 procedures. There was no significant difference in success rates and complication rates between the attending and resident groups. They concluded that ERCP performed in the setting of surgical residency can be performed safely and successfully with outcomes comparable to those of gastroenterology [13]. Vitale et al. reported the outcomes of 13 surgical ERCP fellows who performed 2008 cases. An 85% cannulation rate was accepted as an indicator of ERCP success. All fellows reached the 85% cannulation rate with an average of 7.1 months and 102 ERCP procedures. Fellows with prior flexible endoscopy experience achieved their success rate faster [14]. Cooper et al. performed an analysis of the National Inpatient Sample database of ERCP procedures performed over a 2-year period. A total of 110,811 ERCP procedures were identified, of which 42,025 (37.9%) were performed by surgeons. The surgical ERCP group exhibited longer length of stay (8.7 vs. 7.2 days), overall cost (\$24,739 vs. 16,960), and mortality (3.9 vs. 1.2%) compared to the gastroenterology group. Cholecystectomy and laparotomy were more frequently performed in the surgical group (71.6 vs. 19.6%). The differences in outcomes persisted after propensity score matching was performed on the subsequent cholecystectomy group. A fivefold increase in mortality was found when < 5 ERCP procedures were performed annually regardless of the specialty. Due to the study design, it is unknown what proportion of the 80% of patients that did not undergo cholecystectomy during the index admission in the gastroenterology group underwent subsequent cholecystectomy during a different hospital encounter. The additional cost and morbidity of the second encounter may offset the outcome differences between the two groups [15]. In contrast to the study by Cooper et al., our study design allowed us to evaluate the indications, therapeutic interventions, success rates, and short-term

complications and mortality in a large number of ERCP procedures performed by fellowship-trained surgeons in both the inpatient and outpatient settings. In comparison, the surgeon-performed ERCP outcomes in our study are more favorable.

Our study has several limitations. The retrospective nature of the study limits our ability to consistently evaluate certain variables. This has limited our ability to determine the intent of the procedure (e.g., diagnostic vs. therapeutic intent). This also limited our ability to assess the success rates for stent placement and stone removal. The large number of procedures included helped offset some of these limitations. Despite some missing data, we maintained large numbers to allow for the statistical analysis. Another limitation of the study is that data on the surgeon experience and case volumes were not collected. This prevented us from correlating the surgeon level of experience with the success and adverse outcomes rates. However, the small number of surgeons performing these procedures would limit the generalizability of the correlation analysis. Our study highlights the need for a prospective database that evaluates the outcomes of surgeon-performed ERCP that factors in the experience and level of training of the endoscopist. This would help surgical and endoscopy societies and credentialing committees in hospitals ensure the competence of surgeons seeking ERCP privileges. The current guidelines are based on consensus statements, expert opinions, and published data evaluating the performance of gastroenterology trainees, and alternative criteria are needed for ERCP credentialing of surgeons considering the differences in training pathways.

Conclusion

Our study results show that when performed by fellowship-trained surgical endoscopists, ERCP is associated with high success rate and acceptable short-term complication and mortality rates consistent with societal guidelines and previously published data.

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Table 1

The demographic and historical characteristics of the patients

Age, mean (range)	53.4 (7–102)
Female, <i>n</i> (%)	1046 (56.3)
ASA class, <i>n</i> (%)	
ASA 1	92 (4.6)
ASA 2	1252 (62.1)
ASA 3	614 (30.5)
ASA 4	58 (2.9)
Comorbidities, <i>n</i> (%)	
Cirrhosis	31 (1.8)
History of pancreatitis	321 (19.0)
Primary sclerosing cholangitis	10 (0.6)
Pancreatic divisum	7 (0.4)
Orthotopic liver transplant	37 (1.5)

ASA American Society of Anesthesiology

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Table 2

Indication for ERCP procedures

Indication	<i>n</i> (%) ^a
Established/suspected uncomplicated choledocholithiasis	1470 (61.5)
Management of existing biliary/pancreatic stent	370 (15.5)
Acute biliary pancreatitis	173 (7.2)
Obstructing pancreaticoduodenal mass	143 (6.0)
Bile leak	113 (4.7)
Ascending cholangitis	41 (1.7)
Chronic/recurrent pancreatitis	40 (1.7)
Other ^b	58 (2.4)

ERCP endoscopic retrograde cholangiopancreatography

^aThe indications are not mutually exclusive

^bOther indications include sphincter of Oddi dysfunction, upper abdominal pain, biliary stricture, pancreatic pseudocyst

Table 3Interventions performed in therapeutic ERCP procedures ($n = 1564$)

Intervention	<i>n</i> (%)
Standard sphincterotomy	1244 (52.0)
Precut sphincterotomy	22 (0.9)
Balloon papillary dilation	219 (9.1)
Plastic stent placement	669 (28.0)
Metal stent placement	36 (1.5)
Stone removal	638 (26.7)

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Table 4

30-day complication and morality of the ERCP procedures

30-day outcome	n (%)
Post-ERCP pancreatitis	75 (4.2)
Significant hemorrhage	7 (0.4)
Ascending cholangitis	11 (0.6)
Perforation	1 (0.05)
Total complication	94 (5.4)
Mortality (all cause)	11 (0.5)
Mortality (ERCP-specific)	0 (0.0)

ERCP endoscopic retrograde cholangiopancreatography

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