



The ASGE grading system for ERCP can predict success and complication rates in a tertiary referral hospital

Nadav Sahar¹ · Danielle La Selva¹ · Michael Gluck¹ · S. Ian Gan¹ · Shayan Irani¹ · Michael Larsen¹ · Andrew S. Ross¹ · Richard A. Kozarek¹

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Abstract

Background The utility of the American Society for Gastrointestinal Endoscopy (ASGE) grading scale assessing complexity of endoscopic retrograde cholangiopancreatography (ERCP) has not been evaluated in clinical practice.

Methods Patients that underwent ERCP between January 2015 and December 2015 were included. Procedural difficulty was graded according to the grading system proposed by the ASGE workshop. Technical success rates and complications were recorded.

Results A total of 1355 ERCPs were performed on 934 patients. Patients were equally divided with respect to gender and had a mean age of 58 years (range 29–86). 391 cases were grade 1, 2 (29%), 695 were grade 3 (51%), and 269 were grade 4 (20%). Altered anatomy was observed in 88% of grade 4 patients. Cannulation was achieved in 98% of cases graded 1–3 and in 88% of cases graded 4 ($p < 0.05$). Complications were recorded in 10% of all cases with post-ERCP pancreatitis (5.4%) and procedure-related bleeding (1.5%) being the more common ones. No statistically significant difference was noted between the groups with regard to complications. Three perforations were seen in grade 1–3 cases (0.3%) compared to 4 cases in grade 4 cases (1.5%), ($p = 0.01$).

Conclusion The grading system proposed by the ASGE workshop can aid in predicting cannulation success and perforation rates in ERCP. Based on this retrospective study, the most complex ERCP procedures can be achieved with encouraging rates of success. There is a need to validate our study with prospective ones performed in other high-volume centers.

Keywords ERCP · Grading · Complications

Endoscopic retrograde cholangiopancreatography (ERCP) has evolved into a leading modality in the treatment of the pancreas and biliary tract since its introduction nearly 50 years ago. With the integration of advanced non-invasive imaging techniques such as magnetic resonance cholangiopancreatography (MRCP), the role of ERCP has shifted from a diagnostic tool to a predominantly therapeutic procedure [1, 2]. Nevertheless, ERCP is still considered a challenging procedure with a steep learning curve, adverse events, and severe complications [3, 4]. Subsequently, several scoring systems grading the difficulty levels of ERCP have been published in an attempt to serve as a standardized platform

for endoscopists, notably the Schutz score and Morrision score [5, 6].

Historically, the Schutz and Morrision scores were the first to be tested in the clinical setting in an attempt to lead to their universal adoption. More recently, the American Society for Gastrointestinal Endoscopy (ASGE) proposed a scoring system based on comments and votes collected from a representative group of experienced endoscopists [7]. A validated scoring system for grading the complexity of ERCP procedures has the potential to become an important tool in daily practice; however, the new scoring system has yet to be evaluated in clinical practice and older scoring systems have become outdated due to technological advancements.

The objective of our study was to assess success and complication rates for ERCP in the setting of a large-volume tertiary center utilizing the proposed ASGE grading system. We hypothesized there would be a correlation between the

✉ Nadav Sahar
nadav.sahar@virginiamason.org

¹ Digestive Disease Institute, Virginia Mason Medical Center, 1100 Ninth Avenue, C3-GAS, Seattle, WA 98101, USA

degree of difficulty of the procedure and the therapeutic success rates and documented complications.

Materials and methods

We conducted a retrospective analysis of all ERCP procedures performed between January 1, 2015 and December 31, 2015 at Virginia Mason Medical Center. Patients under the age of 18 were excluded. Review of electronic medical records was performed for a minimum of 30 days after the procedure. Procedural details extracted included patient demographics, indications for the procedure, endoscopes used, and interventions that were performed. The difficulty of procedures was graded according to the system proposed by the ASGE workshop (Table 1) [7].

Procedural success rates and complications were recorded. Procedural success was defined as completion of the intended procedure, such as retrieval of a migrated pancreatic duct stent or cannulation of the bile duct in order to remove biliary stones. Complications that occurred in the

30-day time frame after the procedure were categorized and graded according to ASGE criteria defined by Cotton et al. [8].

Pancreatitis was defined as typical abdominal pain for more than 24 h after the procedure with levels of serum pancreatic enzymes three times above normal.

Post-procedural bleeding was defined as hematemesis and/or melena or a > 2 g/dL reduction in hemoglobin levels.

Perforation was defined as evidence of air or luminal contents outside the gastrointestinal tract as detected using abdominal X-ray or computed tomography (CT).

Cholangitis was defined as a > 38 °C fever lasting longer than 24 h in patients with cholestasis.

All procedures were performed under monitored anesthesia, either with propofol-based sedation or general anesthesia. Olympus video duodenoscopes were used for all patients with conventional anatomy (Olympus Medical Systems; Center Valley, PA). Double-balloon enteroscopes (Fuji Film Co., Japan), single balloon enteroscopes (Olympus), and pediatric colonoscopes (Olympus) were used in cases with altered surgical anatomies, to include post-pancreaticoduodenectomy patients. Cannulation systems used for procedures were Cook long-wire (Cook Medical, Winston-Salem, NC).

All procedures were performed by six experienced endoscopists who perform a minimum of 200 yearly procedures. Two providers have more than 25 years of experience performing ERCPs, three others have been performing ERCPs for 12+ years, and the sixth provider—6 years. The senior endoscopist has performed more than 20,000 ERCPs to date.

The study was approved by the Institutional Review Board of the Virginia Mason Medical Center.

Statistical analysis

Continuous variables were expressed as means and categorical variables were expressed as percentages. Categorical variables were compared with the Chi-square and Fisher's exact tests and continuous variables were compared using the unpaired *t* test. A *p* value < 0.05 was regarded as statistically significant.

STATA/IC software version 13.1 for Windows was used for all statistical analysis (StataCorp LP, College Station, TX).

Results

During the study period of January 1, 2015 to December 31, 2015, a total of 1355 ERCPs were performed on 934 patients. Patients were equally represented by sex with a mean age of 58 years (range 29–86).

Table 1 Proposed ASGE grading system for complexity of ERCP procedures [7]

| Types of procedures |
|---|
| Grade 1 |
| Deep cannulation of duct of interest, main papilla, sampling Biliary stent removal/exchange |
| Grade 2 |
| Biliary stone extraction < 10 mm Treat biliary leaks Treat extrahepatic benign and malignant strictures Place prophylactic pancreatic stents |
| Grade 3 |
| Biliary stone extraction > 10 mm Minor papilla cannulation in divisum, and therapy Removal of internally migrated biliary stents Intraductal imaging, biopsy, FNA Management of acute or recurrent pancreatitis Treat pancreatic strictures Remove pancreatic stones mobile and < 5 mm Treat hilar tumors Treat benign biliary strictures, hilum, and above Manage suspected sphincter of Oddi dysfunction (with or without manometry) |
| Grade 4 |
| Remove internally migrated pancreatic stents Intraductal image-guided therapy Pancreatic stones impacted and/or > 5 mm Intrahepatic stones Pseudocyst drainage, necrosectomy Papillectomy ERCP after Whipple or Roux-en-Y bariatric surgery |

Increase 1 level (to a maximum of 4) when the patient has had Bill-
roth II gastrectomy

Table 2 Quality measures for ERCP procedures

| | All cases (%) | Grades 1, 2 (%) | Grade 3 (%) | Grade 4 (%) | <i>p</i> value |
|---|---------------|-----------------|-------------|-----------------|----------------|
| Successful cannulation | 97.3 | 98.3 | 98.2 | 88 ^a | 0.01* |
| Use of pre-cut sphincterotomy | 8.9 | 6.5 | 9.3 | 11.1 | 0.14 |
| Successful extraction of biliary duct stones | 98.2 | 99.1 | 97.6 | 93.1 | 0.18 |
| Successful biliary stent placement | 98.7 | 99.2 | 97.8 | 94.7 | 0.12 |
| Successful extraction of pancreatic duct stones | 97.4 | N/A | 97.0 | 100.0 | 0.98 |
| Pancreatic stent placement | 96.9 | 97.9 | 97.1 | 93.0 | 0.11 |
| Rectal indomethacin use | 12 | 6.5 | 16.4 | 9.4 | 0.11 |

p value represents Grade 1–3 compared to Grade 4

*Statistically significant at $p < 0.05$

^aGrade 4 success rates when converting to EUS-guided rendezvous procedure or laparoscopic-assisted ERCP-93%

Table 3 ERCP Grade 4—procedural indications

| Indication | Percentage of patients (%) |
|--|----------------------------|
| Biliary obstruction | 23.3 |
| Cholangitis | 20.8 |
| For treatment of chronic or acute pancreatitis | 18.2 |
| Afferent limb syndrome | 8.2 |
| Other pancreatic indication (pancreas divisum, pancreatic duct leak, pancreatoscopy) | 7.8 |
| Abnormal imaging/labs in altered anatomy patient | 5.6 |
| Papillectomy | 5.6 |
| Biliary leak | 5.2 |
| Post-operative follow-up | 4.5 |
| Migrated stent retrieval | 1.9 |

88% of grade 4 patients with altered anatomy

The distribution of cases was the following: 391 cases were grade 1, 2 (29%), 695 were grade 3 (51%), and 269 were grade 4 (20%) (Table 2). The overall procedural success rate was 97%. Successful cannulation was achieved in 98% of cases graded 1–3 and in 88% of cases graded 4 ($p < 0.05$). There was no statistically significant difference between operators when considering success rates and adverse events.

Focusing on grade 4 procedures, 88% of patients had altered anatomy leading to their score. Indications for ERCP in these patients included biliary obstruction (23% of cases), cholangitis (20%), chronic pancreatitis (18%), afferent limb syndrome (8%), and planned papillectomy (6%) (Table 3).

Biliary duct (BD) stones were successfully extracted in 98% of cases graded 1–3 and 93% of cases graded 4 ($p = 0.18$). Pancreatic duct (PD) stones were extracted with 97% success in grade 3 procedures and 100% in grade 4. Biliary stents were successfully placed in 98% of cases graded 1–3 and 94% graded 4 ($p = 0.12$). PD stent placement was achieved in 97.5% of cases graded 1–3 and 93% of cases graded 4 ($p = 0.1$).

A total of 714 repeat procedures (52.7% of all cases) were performed on 290 patients (Table 4). There was a statistically significant difference in the frequency of repeat procedures between grade 4 procedures (65% repeat procedures) and grade 1–3 procedures (49% repeat procedures), ($p = 0.01$), and also between grade 1 and 2 procedures and grade 3. The most common indications for repeat grade 4 procedures were biliary indications, therapy of chronic pancreatitis, and treatment of afferent limb syndrome.

Table 4 Repeat ERCP procedures

| | All cases ($n = 1355$) | Grades 1, 2 ($n = 391$) | Grade 3 ($n = 695$) | Grade 4 ($n = 269$) | <i>p</i> value |
|--|--------------------------|---------------------------|-----------------------|-----------------------|----------------|
| All indications | 714 (52.7%) | 152 (39.0%) | 414 (59.6%) | 175 (65.0%) | $< 0.01^*$ |
| Biliary indications | | 142 (93.8%) | | 72 (26.7%) | < 0.01 |
| Therapy of chronic or acute pancreatitis | | | 508 (73.1%) | 62 (22.9%) | < 0.01 |
| Afferent limb syndrome/cholangitis | | | | 72 (26.7%) | |
| Anastomotic leak/stricture | | | | 21 (7.6%) | |

714 procedures performed on 290 patients representing 52.7% of all procedures

**p* value applies to comparison between each group and also Grades 1–3 compared to Grade 4

Adverse events

Adverse events occurred in 9.9% of all procedures with no statistically significant difference between the groups (Table 5). The most common adverse events seen were post-ERCP pancreatitis (5.4% of procedures) and procedure-related bleeding (1.5%).

There were seven perforations diagnosed during the study period (0.005%), of which four perforations were in the grade 4 procedure group ($p = 0.01$ in comparison to grades 1–3). All three perforations in the grade 1–3 procedures were retroperitoneal and were diagnosed 1–2 days after the procedure. Two of these procedures were graded 3 for treatment of suspected type 2 sphincter of Oddi dysfunction with a diagnosis of papillary stenosis and another procedure was graded 2 for treatment of cholangitis secondary to biliary stones. In all three procedures, a biliary sphincterotomy and balloon sphincteroplasty were performed. No patient required surgical intervention.

In the four perforations that took place in the grade 4 procedures, 2 cases were graded 4 due to altered anatomy (post-pancreaticoduodenectomy with Roux construction and post-Roux-en-Y gastric bypass); another case was retrieval of a migrated PD stent and the fourth case was a papillectomy. All four perforations were in female patients with a mean age of 70 years and 3 out of the 4 were diagnosed during ERCP. Two perforations were seen in the post-surgical afferent loop and both were repaired surgically. The remaining two perforations were contained duodenal perforations and treated conservatively with no need for operative intervention.

There were 2 cases of death within 30 days of the procedure, neither related to the procedure itself. Both deaths occurred in post-pancreaticoduodenectomy female patients on supportive hospice care for complications of recurrent metastatic pancreatic cancer. Both procedures were graded 4 and no adverse events were noted in either procedure.

Discussion

ERCP is the standard procedure for managing pancreaticobiliary disorders, including biliary obstruction, cholangitis, and chronic or acute pancreatitis. It is still considered the most difficult and demanding technique in the practice of gastroenterology with rates of complications that cannot be overlooked and are higher than all other gastrointestinal procedures. As such, several scoring systems have been developed in an attempt to grade the technical difficulty of ERCP procedures.

Two scoring systems and classifications that were first to grade ERCP complexity were the Schutz score and the Morrison score [5, 6]. Both proposed scoring systems were potentially useful objective tools and were tested in two European studies that tried to evaluate the success of ERCP [9, 10]. The two studies reported a good correlation between the degree of procedural difficulty and the likelihood of success. However, a major drawback of both studies was that the proportion of complex procedures was relatively low and ranged between 5 and 10% of all procedures. Also, the success rate for the most difficult exams according to each scoring system was not higher than 50–75%. Furthermore, the technological advancements in the field of gastroenterology have made both scoring systems somewhat obsolete, leading to the drafting of novel grading scores [8, 11].

Following the most recent ASGE publication of a lexicon for defining ERCP complexity and difficulty, we sought to examine the success and complication rates of this modified grading system in a tertiary center clinical practice. We conducted a detailed chart review of patients who underwent ERCP at our institution within a 12-month time frame. The difficulty of each procedure was graded according the ASGE scale. Technical success rates and all complications were recorded. Of the 1355 ERCPs performed, more than 70% were classified as a grade 3 or grade 4 procedure, the most complex procedures according to this scoring system. The spectrum of procedures we treat was also a consequence of our multi-state referral pattern. We found that the success and complication rates were equivalent in grades 1–3 procedures. For the more advanced and challenging grade 4

Table 5 Adverse event rates for ERCP procedures

| | All cases (%) | Grades 1–2 (%) | Grade 3 (%) | Grade 4 (%) | <i>p</i> value |
|------------------------|---------------|----------------|-------------|-------------|----------------|
| Overall | 9.9 | 6.1 | 10.5 | 11.9 | 0.15 |
| Post-ERCP pancreatitis | 5.4 | 2.6 | 7.3 | 4.5 | 0.45 |
| Bleeding | 1.5 | 1.8 | 1.0 | 1.9 | 0.56 |
| Perforation | 0.5 | 0.3 | 0.3 | 1.5 | 0.03* |

p value represents Grades 1–3 compared to Grade 4

*Statistically significant at $p < 0.05$

procedures, which comprised a fifth of all procedures done at our institution and consisted of predominantly patients with surgically altered anatomy, the success rate was 88% and calculated as an even higher 93% when including EUS-guided and laparoscopic-assisted procedures. Although the procedural success for these most difficult procedures was measured as statistically inferior in comparison to procedures performed for the less-demanding lower graded procedures, the rate accomplished (88%) seems satisfactory based on benchmarks that were previously suggested, such as >90% cannulation rate for mild to moderately difficult procedures [12].

Another important finding is that there was no statistically significant difference in overall complication rates regardless of the degree of difficulty. Interestingly, rectal indomethacin usage was not higher than 12% of procedures, yet the frequency of post-ERCP pancreatitis approximated 5% of total cases, despite variable levels of procedural difficulty. We do not routinely use prophylactic NSAIDs in several situations, to include low-risk procedures, procedures when a biliary sphincterotomy had been previously performed, biliary procedures not involving the pancreatic duct, and procedures when a pancreatic stent is used for prophylaxis. There was, however, a statistically significant difference in the rate of perforation between grade 4 patients with post-surgical anatomy and all other grades. The perforations requiring surgical repair were in patients with Roux anatomy and occurred in the afferent limb in patients with retrocolic reconstructions, a site known to be associated with limited mobility and not an infrequent site of afferent limb obstruction. Therefore, endoscopists need to be aware of the elevated risk of perforation in procedures considered to be of the highest degree of difficulty and emphasize this to patients in advance. Knowing the expected level of difficulty beforehand can aid in adequate preparation for each procedure, including selective consultation with surgery and interventional radiology, and has the potential to minimize adverse events.

Validating the complexity of practice in a specialized tertiary referral center and the degree of success confirm that the most complex procedures may not be suited for low-volume centers with limited procedural expertise. One primary limitation of this study is that our results do not necessarily apply to other centers practicing ERCP and extrapolation may not be valid. Readers must interpret success rates with caution when attempting to reproduce them in other centers where the level of expertise may be different. The study is also limited by its retrospective design with potential confounders we are unaware of or did not measure, such as presence of trainees in the procedures or whether ERCP was done in the emergency setting or as outpatient cases. Nevertheless, the latest grading score introduced by the ASGE seems to be a promising, useful tool that can also be applied for educational purposes.

In summary, we have found that the grading system proposed by the ASGE is useful in predicting technical success and complication rates of ERCP in a high-volume specialized institution. Even the most difficult procedures can be completed with high rates of success. The grading system is a potentially convenient tool that helps stratify procedures by difficulty and aids in decision making, to include possible referral on alternative diagnostic or therapeutic procedures. Future prospective studies are needed to further validate our results.

Compliance with ethical standards

Disclosures Dr. Nadav Sahar, Daniella La Selva, Dr. Michael Gluck, Dr. S. Ian Gan, Dr. Shayan Irani, Dr. Michael Larsen, Dr. Andrew S. Ross, and Dr. Richard A. Kozarek have no conflicts of interest or financial ties to disclose.

References

1. Yachimski PS, Ross A (2017) The future of endoscopic retrograde cholangiopancreatography. *Gastroenterology* 153:338–344
2. Ahmed M, Kanotra R, Savani GT, Kotadiya F, Patel N, Tareen S, Fasullo MJ, Kesavan M, Kahn A, Nalluri N, Khan HM, Pau D, Abergel J, Deeb L, Andrawes S, Das A (2017) Utilization trends in inpatient endoscopic retrograde cholangiopancreatography (ERCP): a cross-sectional US experience. *Endosc Int Open* 5::E261–E271
3. Chandrasekhara V, Khashab MA, Muthusamy VR, Acosta RD, Agrawal D, Bruining DH, Eloubeidi MA, Fanelli RD, Faulx AL, Gurudu SR, Kothari S, Lightdale JR, Qumseya BJ, Shaikat A, Wang A, Wani SB, Yang J, DeWitt JM (2017) Adverse events associated with ERCP. *Gastrointest Endosc* 85:32–47
4. Anderson MA, Fisher L, Jain R, Evans JA, Appalaneni V, Ben-Menachem T, Cash BD, Decker GA, Early DS, Fanelli RD, Fisher DA, Fukami N, Hwang JH, Ikenberry SO, Jue TL, Khan KM, Krinsky ML, Malpas PM, Maple JT, Sharaf RN, Shergill AK, Dominitz JA (2012) Complications of ERCP. *Gastrointest Endosc* 75:467–473
5. Schutz SM, Abbott RM (2000) Grading ERCPs by degree of difficulty: a new concept to produce more meaningful outcome data. *Gastrointest Endosc* 51:535–539
6. Ragnath K, Thomas LA, Cheung WY, Duane PD, Richards DG (2003) Objective evaluation of ERCP procedures: a simple grading scale for evaluating technical difficulty. *Postgrad Med J* 79:467–470
7. Cotton PB, Eisen G, Romagnuolo J, Vargo J, Baron T, Tarnasky P, Schutz S, Jacobson B, Bott C, Petersen B (2011) Grading the complexity of endoscopic procedures: results of an ASGE working party. *Gastrointest Endosc* 73:868–874
8. Cotton PB, Eisen GM, Aabakken L, Baron TH, Hutter MM, Jacobson BC, Mergener K, Nemcek A Jr, Petersen BT, Petrini JL, Pike IM, Rabeneck L, Romagnuolo J, Vargo JJ (2010) A lexicon for endoscopic adverse events: report of an ASGE workshop. *Gastrointest Endosc* 71:446–454
9. Ekkelenkamp VE, de Man RA, Ter Borg F, Borg PC, Bruno MJ, Groenen MJ, Hansen BE, van Tilburg AJ, Rauws EA, Koch AD (2015) Prospective evaluation of ERCP performance: results of a nationwide quality registry. *Endoscopy* 47:503–507

10. Williams EJ, Ogollah R, Thomas P, Logan RF, Martin D, Wilkinson ML, Lombard M (2012) What predicts failed cannulation and therapy at ERCP? Results of a large-scale multicenter analysis. *Endoscopy* 44:674–683
11. Olsson G, Arnelo U, Swahn F, Tornqvist B, Lundell L, Enochsson L (2017) The H.O.U.S.E. classification: a novel endoscopic retrograde cholangiopancreatography (ERCP) complexity grading scale. *BMC Gastroenterol* 17:38
12. Adler DG, Lieb JG, Cohen J, Pike IM, Park WG, Rizk MK, Sawhney MS, Scheiman JM, Shaheen NJ, Sherman S, Wani S (2015) Quality indicators for ERCP. *Am J Gastroenterol* 110:91–101