



Assessment of the endoscopic retrograde cholangiopancreatography grading system: A prospective study from a tertiary care center

LIVER/BILIARY

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ABSTRACT

Background/Aims: The American Society for Gastrointestinal Endoscopy (ASGE) endoscopic retrograde cholangiopancreatography (ERCP) grading system was proposed but has not been fully evaluated with prospective clinical studies. In this study, we aimed to evaluate the effectiveness of the ERCP difficulty grading system for predicting success and adverse event rates related to the procedure.

Materials and Methods: A total of 1057 ERCP procedures performed on 752 patients were included in the present study. The complexity grades of the procedures were recorded according to the ASGE grading system. Specific complications of ERCP (pancreatitis, cholangitis, bleeding, and perforation) were also defined and graded.

Results: The procedure difficulty was determined as 1st degree in 153 patients (14.4%), 2nd degree in 498 patients (47.1%), 3rd degree in 271 (25.6%), and 4th degree in 135 patients (12.7%). The success rate for the entire procedures was 88.4%. The success rate for 1st degree procedures was 99.3%, 97.2% for 2nd degree procedures, 86.7% for 3rd degree procedures, and 46.7% for 4th degree procedures ($p < 0.005$). When the difficulty of the procedures increased from 1 to 4, the adverse event rates increased from 1.3% to 10.4%.

Conclusion: The findings support the evidence that the difficulty degrees of ERCP procedures can help predict the success and complication rates of the procedure. Because of the increased rates of failure and complications in more difficult cases, the procedures should be performed by experienced endoscopists in advanced centers.

Keywords: Adverse events of ERCP, difficult cannulation, success of ERCP

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a comparatively complicated endoscopic procedure that has been performed for more than 40 years (1). It requires specific equipment and a long learning period and causes a higher rate of and more severe complications than other standard endoscopic techniques. The risk of serious complications is perhaps the procedure's most important feature, and ERCP has been the subject of many studies concerned with complications (2,3).

The technical success rate and the complication rate vary greatly in studies related to ERCP. The success rates vary between 76% and 95%, and severe complication rates range between 1% and 16% (4-6). Such degrees of variation in rates are far from acceptable. Although the

reason for this variation originates in the differences in the definition of success and complication, the level of difficulty in these patients could also affect the success and complication rates.

Skill and experience have a major effect on ERCP results (7,8). However, the effect on the results of the technical difficulty of the procedure is also indisputable. A working party of the American Society for Gastrointestinal Endoscopy (ASGE) recently published a grading system for the complexity of endoscopic procedures to provide rankings for the complexity of all major endoscopic procedures, including ERCP (9). This scale, which is expected to provide information to patients about the difficulty of the planned procedure, the expected technical success, in addition to providing information

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to endoscopists regarding which patients should undergo the procedure and which patients should be referred, was created via a voting procedure by endoscopists who are highly experienced in their fields.

The objective of our study was to evaluate the relationship of the ASGE ERCP difficulty grading system, which was created as a result of voting, on the other hand, evidence level C, with ERCP procedure success and complications in clinical practice.

MATERIALS AND METHODS

A total of 887 patients who had undergone 1213 procedures between October 2012 and March 2013 at the Türkiye Yüksek

İhtisas Training and Research Hospital ERCP unit, a tertiary care hospital that performs more than 2000 ERCP procedures annually, were enrolled in the study prospectively. Of these patients, 156 ERCP procedures performed in 135 patients who lacked data were excluded from the study, and 1057 ERCP procedures performed on 752 patients were included in the study. The demographic characteristics of the study participants are presented in Table 1. The study was approved by the ethics committee of Türkiye Yüksek İhtisas Hospital.

All procedures were performed by three pancreaticobiliary endoscopists (very similar levels of experience and expertise) using the Olympus video duodenoscope [(Olympus TJF 240,

Table 1. Demographic features and procedure indications of study participants

| | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
|---|-----------------|-------------------|-------------------|-----------------|
| Age (years) | 57.1±18.3 | 57.8±17.2 | 57.8±18.9 | 59.9±17.5 |
| Gender | 69 (45)/84 (55) | 252 (51)/246 (49) | 127 (47)/144 (53) | 76 (56)/59 (44) |
| Indications | | | | |
| Biliary stent removal/exchange | 153 | | | |
| Biliary stone extraction (<10 mm) | | 253 | 12 ^{ab} | |
| Stents for bile leaks | | 52 | | |
| Extrahepatic benign and malignant strictures | | 170 | | |
| Prophylactic pancreatic stents | | 23 | | |
| Biliary stone extraction (>10 mm) | | | 72 | 72 ^c |
| Minor papilla cannulation in divisum, and therapy | | | 6 | |
| Remove of internally migrated biliary stents | | | 5 | |
| Intraductal imaging, biopsy, FNA | | | 2 | |
| Management of acute or recurrent pancreatitis | | | 4 | |
| Management of pancreatic strictures | | | 13 | |
| Removal of pancreatic stones (<5 mm) | | | 6 | |
| Hilar tumors | | | 67 | 7 ^d |
| Treatment of benign biliary stricture, hilar, and above | | | 78 | 6 ^d |
| Suspected SOD (with or without manometry) | | | 6 | |
| Removal of internally migrated pancreatic stents | | | | 2 |
| Pancreatic stones, impacted and/or >5 mm | | | | 14 |
| Intrahepatic stones | | | | 14 |
| Pseudocyst drainage, necrosectomy | | | | 2 |
| Ampullectomy | | | | 5 |
| ERCP after Whipple or Roux-en-Y bariatric surgery | | | | 13 |
| Deep cannulation of duct of interest, main papilla, sampling | | | | 0 |
| Intraductal image-guided therapy e.g.; photodynamic therapy, electrohydraulic lithotripsy | | | | 0 |

SOD: sphincter of oddi dysfunction; ERCP: endoscopic retrograde cholangiopancreatography; FNA: fine-needle aspiration

^aBillroth II+ <1 cm biliary stone

^bAge <3 years+<1 cm biliary stone

^cBillroth II+Previous failed/incomplete procedure+Emergency case (outside of normal hours)

^dPrevious failed/incomplete procedure

4.2 mm working channels with the Olympus 240 and 3.8 mm working channel, particularly for undergone surgery undergone patients such as billroth II (Olympus Corporation; Tokyo, Japan)]. Before the ERCP procedure, all enrolled patients signed an informed consent. Premedication was provided with 2 mg midazolam and 25 mg meperidine. Duodenal peristalsis was inhibited using intravenously administered hyoscine n-butylbromide. In all patients with naïve papilla, cannulation was performed using a sphincterotome (Ultratome, Boston Scientific; Marlborough, MA, USA) loaded with a guide wire Jagwire 0.035 inch (Boston Scientific, Marlborough, MA, USA).

The success of the procedures performed was evaluated and determined at the end of each day by the three endoscopists who performed the procedures. Development of complications was recorded for up to 1 week after the procedure.

Following discharge, patients were informed about returning to the hospital or calling by phone if abdominal pain, high fever, hematemesis, or melena developed. Antibiotic prophylaxis was administered with ciprofloxacin to patients with primary sclerosing cholangitis, hilar cholangiocarcinoma, and liver transplantation, and a prophylactic pancreatic stent was inserted in patients with repetitive guide-wire insertion in the pancreas (≥ 5 times). In addition, 100 mg of rectal indomethacin was administered to high-risk patients just after the procedure for pancreatitis prophylaxis.

Specific complications of ERCP (pancreatitis, cholangitis, bleeding, and perforation) were defined and graded as designated by Cotton et al. (10). Pancreatitis was defined as at least a three-fold increase in amylase levels together with typical abdominal pain 24 h after the procedure. Hemorrhage was defined as a >2 g/dL reduction in hemoglobin levels together with hematemesis and/or melena. Cholangitis was defined as a $>38^{\circ}\text{C}$ fever lasting for longer than 24 h together with cholestasis. Complications of the ERCP procedure were detected as follows: plain X-ray of the abdomen or computed tomography (CT) scan for post-ERCP abdominal pain was performed to detect perforation. The patients with naïve papilla were followed up for at least 24 h. Complete blood count (CBC) and amylase levels were tested postoperatively at 4 h and 24 h, and patients' vital signs were monitored before and after the procedure. The success of the procedure was defined as completing the targeted therapeutic intention during the first procedure (for example, complete removal of stones and successful stenting of the obstruction). Repetitive procedures were recorded as unsuccessful even if they were successful in the second procedure. The complexity grades of the procedures were recorded according to the ASGE grading system.

Statistical analysis

Statistical analysis of the data was performed using the Statistical Package for the Social Sciences (SPSS) version 18 (SPSS Inc.; Chicago, IL, United States). Continuous data were presented

as mean (\pm standard deviation) and as median value when necessary (inter-quartile range; 25th–75th percentiles), and the categorical data were presented as frequency and percentage (n, %). Student's t-test was used to compare groups with continuous variables, and the Pearson chi-square test and Fisher's exact test were used for categorical variables to compare the distribution of the groups. When the p value was smaller than 0.05, it was accepted as statistically significant.

RESULTS

A total of 1057 ERCP procedures were performed on 752 consecutive patients between October 2012 and March 2013. Of the patients, 373 were female (49.6%) and 379 were male (50.4%). The mean age was 58 ± 17 years.

The degree of procedure difficulty was 1st degree in 153 patients (14.4%), 2nd degree in 498 patients (47.1%), 3rd degree in 271 patients (25.6%), and 4th degree in 135 patients (12.7%). The success rate for all procedures was 88.4%. The success rate for 1st degree procedures was 99.3%, 97.22% for 2nd degree procedures, 86.7% for 3rd degree procedures, and 46.7% for 4th-degree procedures ($p=0.001$) (Figure 1). Because procedure success was defined as completion of the therapeutic aim during the first procedure during the course of planning the study, the success rate of repetitive procedures was not considered. A total of 54 (5.1%) complications developed in 51 patients. The most common complication was pancreatitis, which de-

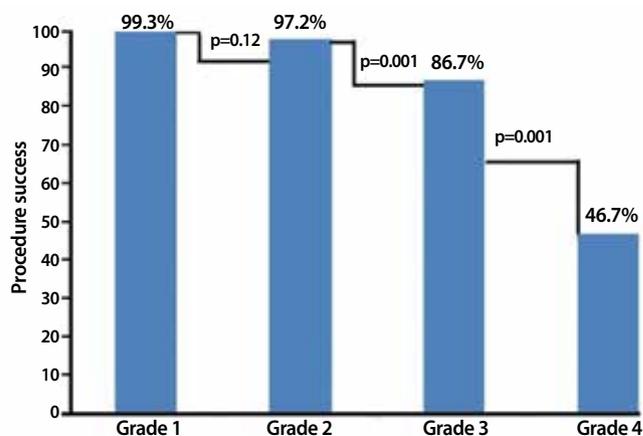


Figure 1. Success rates according to procedure difficulties.

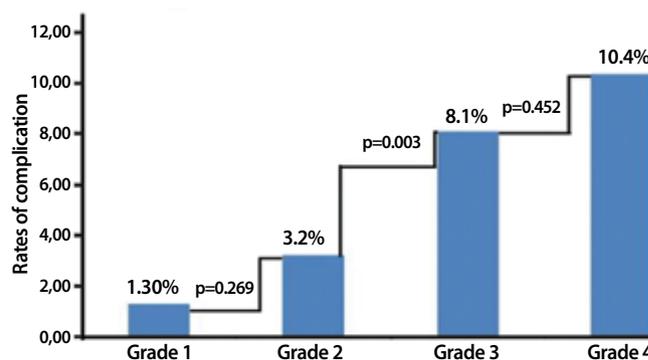


Figure 2. Complication rates according to procedure difficulties.

Table 2. Complication numbers of the procedures according to the difficulty

| Complication | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Total |
|--------------|---------|---------|---------|---------|-------|
| Pancreatitis | 1 | 12 | 7 | 3 | 23 |
| Bleeding | 1 | 3 | 7 | 3 | 14 |
| Cholangitis | - | 1 | 6 | 7 | 14 |
| Perforation | - | - | 2 | 1 | 3 |
| Total | 2 | 16 | 22 | 14 | 54 |

veloped in 23 (2.2%) patients. Bleeding developed in 14 patients (1.3%), cholangitis developed in 14 patients (1.3%), and perforation developed in 3 patients (0.28%). More than one complication developed in 3 (0.28%) patients. The complication rate was 1.3% in 1st-degree procedures, 3.2% in 2nd-degree procedures, 8.1% in 3rd-degree procedures, and 10.4% in 4th-degree procedures (Figure 2).

In our study, bleeding in 1 patient and pancreatitis in 1 patient developed in 1st-degree procedures. Pancreatitis in 12 patients, bleeding in 3 patients, and cholangitis in 1 patient developed in 2nd-degree procedures. Pancreatitis in 7 patients, bleeding in 7 patients, cholangitis in 6 patients, retroperitoneal duodenal perforation in 1 patient, and bile duct perforation in 2 patients developed in 3rd-degree procedures. Pancreatitis in 3 patients, bleeding in 3 patients, cholangitis in 7 patients, and retroperitoneal duodenal perforation in 1 patient developed in 4th-degree procedures (Table 2).

Of the three perforations, two were retroperitoneal duodenal perforations, and one was a bile duct perforation; they were moderate. All three patients were treated with conservative methods. Hypoxia that recovered with flumazenil developed in one patient on whom a 4th-degree procedure was performed. During the study period, mortality related to the ERCP procedure was seen in one patient (0.09%). A 61-year-old male patient underwent a procedure for portal vein thrombosis, portal biliopathy, and common bile duct stone (approximately 2 cm in diameter). On development of hemobilia during the procedure, stone removal was abandoned, and the patient was transferred to the intensive care unit after a nasobiliary drain was installed. However, although the bleeding did not continue, the patient died because of the development of cholangitis and sepsis.

DISCUSSION

The difficulty scale recommended by Cotton et al. (9) seems to be convenient; however, it has not been confirmed clinically. In this study, we aimed to evaluate the effectiveness of the system in terms of predicting the success and complications of the procedure. Our study has demonstrated that as the degree of the procedure increased, the technical success rate decreased and the complication rate increased. The success rate linearly decreased from 1st degree to 4th degree, and the complication rate increased. When the complication rates of

3rd- and 4th-degree procedures were compared with those of 1st- and 2nd-degree procedures, a sharp increase was observed, particularly in 4th-degree procedures; the complication rate increased to 10.4% and the success rate decreased to 46.7%. There was nearly an eightfold difference between the complication rates of 4th-degree and 1st-degree procedures. Furthermore, all three perforations, which are accepted as the most feared complication of ERCP, developed in 3rd- and 4th-degree procedures. Perforations in 2 patients were of Type 2, and the perforation was Type 3 in 1 patient. They were moderate and treated with conservative methods.

In modern medicine, the importance of using evidence-based procedures and predicting the clinical effectiveness and results of a planned procedure has gradually increased. ERCP is one of the most difficult endoscopic procedures, comprising a wide range of procedures ranging from diagnostic imaging to difficult and vital procedures that can be an alternative to large open surgery; thus, differentiation and grading the procedure diversity are important.

When the studies in the literature related to ERCP complications were reviewed, in a pilot study, Schutz et al. (11) developed a 5-stage difficulty scale as follows: 1st-degree simple diagnostic ERCP, 2nd-degree simple therapeutic ERCP, 3rd-degree complex diagnostic ERCP, 4th-degree complex therapeutic ERCP, and 5th-degree very advanced ERCP. Prior to this, a B subgroup was created in the case of an unsuccessful procedure. Consequently, discordant findings were obtained between the difficulty degree of the procedure and the technical success and the complication rates. Furthermore, the number of cases in the study (n=231) was considered insufficient. Therefore, no practical use in the field of clinical practice was found. In the study conducted by Ragunath et al. (12), which included 259 patients, the ERCP procedures were divided into four degrees, and the success and complication rates between experienced endoscopists and trainee endoscopists were compared. Eventually, discordant results were found between the technical difficulty of the procedures and the success and complication rates. Zuber-Jerger et al. (13) also conducted a similar study. They divided the ERCP procedure into five difficulty scales. According to this scale, stage A included the diagnostic procedures in patients with no naïve papilla, stage B comprised therapeutic procedures in patients with no naïve papilla, stage C comprised diagnostic procedures in patients with naïve papilla, stage D included therapeutic procedures in patients with naïve papilla, and stage E included specific procedures (sphincterectomy with anterior incision, intrahepatic stricture dilation, and pancreatic therapeutic procedures). This study on 526 patients demonstrated that the complication rates increased linearly from stage A to stage E (stage A 1.9%, stage B 3.0%, stage C 6.3%, stage D 11.6%, and stage E 13.3%). However, the effect of the stage of the procedure on the technical success of the procedure was not evaluated.

This scoring system can be used as part of gradual ERCP training in endoscopy units in different countries. Furthermore, this staging system may be considered by healthcare providers for performance scoring and billing because high-degree processes take a longer duration and additional accessories such as stents are used. One of the benefits of this study was the introduction of the ERCP difficulty grading scale. This scale is extremely convenient for the objective evaluation of the difficulty of the process and probable results and for the comparison of the success and complication rates of ERCP procedures performed in different centers. It is not ideal to compare endoscopists and endoscopy units without comparing the technical difficulties of the procedures because the success and complication rates may vary. Moreover, this scale can predict the success and probable complications of the planned procedure, which can provide quantitative information to the healthcare provider, patient, and patient's relatives.

The study has several limitations. It was conducted in a single center, and the sample size was small. Because the procedures were performed by experienced endoscopists, the relationship between experience and success and complication rates could be predicted. In addition, there may be inter- and intra-observer variability, although the three endoscopists working in our clinic have similar levels of experience. Finally, predicting the success of the applied procedures before the procedure and grading of the procedures by an unbiased endoscopist could have added value in interpreting the resulting data.

In conclusion, the ERCP difficulty grading system can be used in clinical practice. According to this scale, as the difficulty of the procedure increases, the technical success rate decreases and the complication rate increases. Performing 1st and 2nd degree procedures by endoscopists who do not have sufficient experience and referring the 3rd and 4th degree procedures to more experienced advanced centers will assist in maintaining the success rates higher and in avoiding complications. These findings are valuable for predicting the success and complication rates of ERCP procedures and for providing quantitative information to the healthcare provider, patient, and patient's relatives about the probable results of the procedure. Further studies based on an improved design are required to confirm whether this grading system will demonstrate more accurate results in predicting technical success and adverse events.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Türkiye Yüksek İhtisas Hospital.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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Author Contributions: Concept - S.T., E.P.; Design - S.T., B.Ö.; Supervision - N.Ş., E.K.; Materials - S.D., E.P., B.Ö.; Data Collection and/or Processing - S.T., H.Y.; Analysis and/or Interpretation - S.T., H.Y.; Literature Review - S.T.; Writer - S.T.; Critical Review - S.D., E.P., B.Ö.

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