Risk factors for complications after ERCP: a multivariate analysis of 11,497 procedures over 12 years CME

Peter B. Cotton, MD, FRCP, FRCS, Donald A. Garrow, MD, MS, Joseph Gallagher, MD, Joseph Romagnuolo, MD, FRCPC, MScEpid, FASGE

Charleston, South Carolina, USA

Background: Complications of ERCP are an important concern. We sought to determine predictors of post-ERCP complications at our institution.

Methods: GI TRAC is a comprehensive data set of patients who underwent ERCP at our institution from 1994 through 2006. Logistic regression models were used to evaluate 4 categories of complications: (1) overall complications, (2) pancreatitis, (3) bleeding, and (4) severe or fatal complications. Independent predictors of complications were determined with multivariable logistic regression.

Results: A total of 11,497 ERCP procedures were analyzed. There were 462 complications (4.0%), 42 of which were severe (0.36%) and 7 were fatal (0.06%). Specific complications of pancreatitis (2.6%) and bleeding (0.3%) were identified. Overall complications were statistically more likely among individuals with suspected sphincter of Oddi dysfunction (SOD) (odds ratio [OR] 1.91) and after a biliary sphincterotomy (OR 1.32). Subjects with a history of acute or chronic pancreatitis (OR 0.78) or who received a temporary small-caliber pancreatic stent (OR 0.69) had fewer complications. Post-ERCP pancreatitis was more likely to occur after a pancreatogram via the major papilla (OR 1.70) or minor papilla (OR 1.54) and among subjects with suspected SOD with stent placement (OR 1.45) or without stent placement (OR 1.84). Individuals undergoing biliary-stent exchange had less-frequent pancreatitis (OR 0.38). Biliary sphincterotomy was associated with bleeding (OR 4.71). Severe or fatal complications were associated with severe (OR 2.38) and incapacitating (OR 7.65) systemic disease, obesity (OR 5.18), known or suspected bile-duct stones (OR 4.08), pancreatic manometry (OR 3.57), and complex (grade 3) procedures (OR 2.86).

Conclusions: This study characterizes a large series of ERCP procedures from a single institution and outlines the incidence and predictors of complications. (Gastrointest Endosc 2009;70:80-8.)

ERCP has been widely practiced for more than 35 years, progressively evolving from a diagnostic to a therapeutic role. The risk of serious complications was recognized early and has been the focus of many studies and reviews.[1-9] In earlier years, a complication rate of about 10%, with a mortality of 1%, seemed acceptable, indeed, laudable, when alternative diagnostic techniques were limited and when surgery was clearly much more dangerous.

The situation is different now. Noninvasive imaging, such as MRCP and EUS, have largely superseded diagnostic ERCP, and the safety profile of surgery has greatly improved.[10] These facts are a stimulus to reduce the complication rate of ERCP to the bare minimum, by making sure that procedures are done well and done only when really indicated. Efforts to do so are helped by studying and understanding the factors that make complications more likely and less likely. Several studies document the complications of ERCP and analyze risk factors and predictors, but many of them are limited by nonuniformity of definitions[6,8,11] and by small sample sizes.[2,5,12,13] We sought to determine procedural and clinical correlates of post-ERCP complications at our institution with more than 11,000 individual procedural observations.

Abbreviations: ASA, American Society of Anesthesiologists; OR, odds ratio; SOD, sphincter of Oddi dysfunction.

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PATIENTS AND METHODS

Procedures

The ERCP procedures were performed by a total of 8 expert endoscopists, almost always with a trainee ''performing'' at least part of the procedure. The GI TRAC endoscopy database (Akron Systems, Charleston, SC) contains information regarding all ERCP procedures performed at our institution since 1994. Data were collected and entered immediately after each case. The database contains 105 categories and more than 1000 potential variables, including demographics, clinical history and context, blood test results, procedural details, technical procedures, procedural findings, diagnoses, and complications. Delayed complications were added systematically after a review of each case at 1 week or when we were notified by an outside physician. However, there was no routine follow-up patient contact. Deidentified data were provided by our information technologists to run our statistical analyses. Our institutional review board approved the study.

Variables

The variables documented for each case included the characteristics of the patients and the specifics of each procedure, as listed in Table 1. Of note, suspected sphincter of Oddi dysfunction (SOD) was defined by performance of biliary and/or pancreatic sphincter manometry on subjects who presented as outpatients. Obesity was documented by clinical observation at the time of the procedure. Previous upper-GI surgeries were those that involved biliary diversion, ie, Billroth II gastrectomy, Roux-en-Y bypass, and Whipple procedures.

The primary outcomes of interest in our analysis were overall complications, pancreatitis and bleeding, and complications graded as severe or fatal. We previously published (from this same data set) the occurrence and predictors of infection after ERCP and the role of prophylactic antibiotics.[14] We also identified the occurrence of other, less frequent, complications, including bowel-wall and sphincterotomy-related perforations, medication reactions, and cardiac and pulmonary events. Complications and their severity were defined by established consensus criteria (Table 2).[11] Procedural complexity was scored by an established grading scale. Grade 1 includes all standard biliary procedures; grade 2 includes minor papilla cannulation, large bile-duct–stones extraction, hilar strictures, and benign biliary strictures, whereas grade 3 are those procedures usually done only in tertiary-referral centers, such as pancreatic therapy, sphincter manometry, and procedures after biliary diversion.[15]

Analysis

To identify significant independent correlates of overall and specific complications, clinically relevant risk factors were dichotomized and compared with each complication variable in a univariate analysis (χ^2). Factors with a P value $<.10$ were considered in multivariate logistic regression models by using stepwise forward selection for each of 4 categories of complications: (1) overall complications, (2) pancreatitis, (3) bleeding, and (4) severe or fatal complications. Age, race, and sex variables were empirically included in each model, and interaction terms were considered. Adjusted odds ratios (OR) and their 95% CI were calculated. Analyses were performed (by author D.G.) with SAS version 9.1.3 (SAS Institute Inc, Cary, NC).

Capsule Summary

What is already known on this topic

- Despite its risk of complications, ERCP has been practiced widely for more than 35 years, evolving progressively from a diagnostic to a therapeutic role.

What this study adds to our knowledge

- Retrospective review of 11,497 ERCP procedures revealed 462 complications, 42 of which were severe and 7 were fatal, with complications occurring most commonly in suspected sphincter of Oddi dysfunction and after a biliary sphincterotomy.

RESULTS

Procedures

A total of 11,497 ERCP procedures were performed and documented over 12 years. The demographics, indications, and frequency of special interventions are outlined in Table 1.

Overall complications

There were a total of 462 complications (4.0%), 65% of which were pancreatitis in 304 cases (2.6%). The incidence of all complications and their severity grades are listed in Table 3. The multivariate analysis results for overall complications, pancreatitis, bleeding, and severe or fatal outcomes are shown in Tables 4, 5, 6, and 7, respectively. Univariate analysis revealed 21 potential risk factors for overall complications. Four factors were found to be independently associated with overall complications: (1) subjects with suspected SOD (OR 1.91 [95% CI, 1.37–2.65]) and (2) procedures (including a biliary sphincterotomy) (OR 1.32 [95% CI, 1.03–1.69]) were at increased risk, whereas (3) the presence of pancreatitis before the procedure (OR 0.78 [95% CI, 0.62–0.99]) and (4) placement of a small-caliber pancreatic-duct stent (OR 0.69 [95% CI, 0.50–0.95]) predicted significantly fewer complications (Table 4). Of note, the overall complication rate reduced with time when comparing the first 6 years of our data with the most recent 6 years (4.88% vs 3.26%, $P < .001$).

TABLE 1. Selected subject and procedural characteristics of patients who had ERCP

Variable	%
Subject	
Age	
18–50 y	43.2
51–65 y	29.6
66–80 y	21.1
>80 y	6.2
Race	
White	74.9
African American	20.2
Other	5.0
Sex	
Men	40.5
Context	
Jaundice	21.3
Abnormal liver function tests	4.8
Suspected or known stone	16.1
Suspected sphincter of Oddi dysfunction	25.4
Pancreatitis	
Historical	25.9
Active	1.4
Coagulopathy	4.6
Prior biliary diversion surgery	1.6
Prior ERCP	28.2
Prior ERCP complication	2.8
Inpatient	30.6
Procedural	
Antibiotics before the procedure	53.6
Fellow present	91.2
Pancreas divisum present	8.8
With dorsal cannulation	85.6
Without dorsal cannulation	14.4
Small pancreatic-duct stent placed	9.2
Anesthesia type	
General or propofol	19.8
Conscious sedation	80.0
None	0.2
Priority	
Urgent	1.7
Urgent on schedule	12.2
Elective	86.1
Difficulty grade	
3	40.1
2	16.7
1	43.2
Hilar tumor management	2.3
Biliary-stone extraction	11.1
Biliary-stent insertion	20.4
Biliary-stent extraction	13.7
Major pancreatogram	62.1
Minor pancreatogram	10.6
Biliary manometry	11.5
Pancreatic manometry	13.1
Biliary sphincterotomy	30.0
Pancreatic sphincterotomy	13.7
Biliary pre-cut	3.4

Pancreatitis

ERCP caused acute pancreatitis in 304 patients (2.6%). It was graded as mild in 229, moderate in 57, and severe in 17; there was 1 fatality (Table 3). Initial univariate analysis revealed 23 potential predictors of pancreatitis (Table 5). Variables that remained independently significant predictors of pancreatitis included the following: (1) performance of a pancreatogram at the major papilla (OR 1.70 [95% CI, 1.17–2.41]) or (2) at the minor papilla (OR 1.54 [95% CI, 1.06–2.24]) and (3) suspected SOD. Biliary-stent exchange predicted less-frequent pancreatitis (OR 0.38 [95% CI, 0.16–0.92]). With regard to suspected SOD, there was a significant interaction ($P = .0001$) among SOD and pancreatic stenting; patients being evaluated for SOD who received a small pancreatic-duct stent were at lower risk of pancreatitis (OR 1.45 [95% CI, 1.13–1.87]) than those who did not (OR 1.84 [95% CI, 1.55–2.18]).

Bleeding

Significant bleeding occurred in only 40 subjects; the only predictor in multivariable analysis was biliary sphincterotomy (OR 4.71 [95% CI, 2.33–9.50]) (Table 6). Mild coagulopathy (ie, slightly abnormal prothrombin time and/or

TABLE 2. Consensus criteria for ERCP complications*†

	Mild	Moderate	Severe
Bleeding	Clinical evidence of bleeding (ie, not just endoscopic); Hb level drop <3 g; no need for transfusion	Transfusion: ≤4 units; no angiographic intervention or surgery	Transfusion: ≥5 units or intervention (angiographic or surgical)
Perforation	Possible, or only very slight leak of fluid or contrast dye; treatable by fluids and suction for ≤3 d	Any definite perforation treated medically for 4–10 d	Medical treatment for more than 10 d or intervention (percutaneous or surgical)
Pancreatitis	Clinical pancreatitis; amylase at least 3 times normal at more than 24 h after the procedure requiring admission or prolongation of planned admission to 2–3 d	Pancreatitis requiring hospitalization of 4–10 d	Pancreatitis requiring hospitalization for more than 10 d, or hemorrhagic pancreatitis, phlegmon or pseudocyst, or intervention (percutaneous drainage or surgery)
Infection (cholangitis)	>38°C at 24–48 h	Febrile or septic illness requiring >3 d of hospital treatment or endoscopic or percutaneous intervention	Septic shock or surgery

*From Ref. 11.
†All other complications were graded for severity of the need for hospitalization and/or surgical treatment, ie, mild, unplanned hospital stay of 2–3 nights; moderate, 4–10 nights; and severe (>10 nights or intensive care or surgery).

TABLE 3. Complication frequency and severity

		Severity (% of complications)			
Complication	**Total (% of total procedures)**	**Mild**	**Moderate**	**Severe**	**Fatal**
Overall	462 (4.0)	335 (73)	78 (17)	42 (9)	7 (2)
Pancreatitis	304 (2.6)	229 (75)	57 (19)	17 (6)	1 (0.3)
Bleeding	40 (0.3)	22 (55)	9 (23)	9 (23)	0 (0)
Infection	38 (0.3)	29 (76)	5 (13)	2 (5)	2 (5)
Cardiac	10 (0.1)	5 (5)	0 (0)	2 (20)	3 (30)
Pulmonary	9 (0.1)	6 (67)	2 (22)	1 (11)	0 (0)
Bowel perforation	12 (0.1)	4 (33)	0 (0)	7 (58)	1 (8)
Sphincter perforation	4	0 (0)	1 (25)	3 (75)	0 (0)
Medication reaction	6	6 (100)	0 (0)	0 (0)	0 (0)
Phlebitis	2	2 (100)	0 (0)	0 (0)	0 (0)
Other	37 (0.3)	32 (86)	4 (11)	1 (3)	0 (0)

partial thromboplastin time) was recorded in 529 patients; only two (0.4%) had significant bleeding ($P = .90$). There were no significant predictors of bleeding in patients not undergoing biliary sphincterotomy.

Severe and fatal outcomes

There were 42 severe and 7 fatal outcomes in this series. Severe complications were because of the following: pancreatitis (n = 17), bowel perforation (n = 7), delayed bleeding (n = 7), sphincterotomy perforation (n = 3), immediate bleeding (n = 2), cardiopulmonary events (n = 3), cholangitis (n = 1), infection (n = 1), and other (n = 1). The 7 fatal outcomes were because of the following: cardiopulmonary events (n = 3), biliary sepsis (n = 2), pancreatitis (n = 1), and bowel perforation (n = 1). Fourteen potential predictors of severe or fatal outcomes were found in univariate analysis. With multivariate regression, 5 factors independently predicted severe or fatal complications: (1) poor health status (American Society of Anesthesiologists [ASA] III: OR 2.38 [95% CI, 1.14–4.97]; ASA IV or V: OR 7.65 [95% CI, 1.16–50.54]), (2) obesity (OR 5.18 [95% CI, 1.74–15.43]), (3) suspected or known biliary-duct stones

TABLE 4. Clinical and procedural predictors of post-ERCP overall complications (n = 462)

Variable*	n	OR	95% CI
Clinical			
Age			
>80 y	17	1.28	0.73-2.25
65–80 y	66	0.95	0.54–1.67
50–65 y	105	0.98	0.55–1.75
<50 y	274	Reference group	Reference group
Race			
African American	76	1.18	0.59–2.34
White	365	1.23	0.64–2.35
Other	21	Reference group	Reference group
Sex			
Men	174	1.23	0.99–1.53
Women	288	Reference group	Reference group
ASA grade			
IV and V	3	2.13	0.65–7.03
III	48	0.99	0.71–1.40
I and II	411	Reference group	Reference group
Liver transplant	29	1.58	0.97–1.57
Prior biliary diversion surgery	9	0.67	0.32–1.39
Prior pancreatitis	141	0.78	0.62–0.99†
Suspected SOD	250	1.91	1.37–2.65†
Prior ERCP complication	25	1.39	0.88–2.21
Suspected or known duct stone	51	1.22	0.76–1.94
Jaundice	58	1.11	0.76–1.61
Procedural			
Therapeutic procedure	388	1.21	0.88–1.67
Difficulty grade			
3	272	1.29	0.89–1.87
2	87	1.26	0.75–2.11
1	103	Reference group	Reference group
Biliary stone extraction	28	0.56	0.31–1.03
Major papilla pancreatogram	325	1.27	0.97–1.67
Minor papilla pancreatogram	65	1.33	0.77–2.31
Small pancreatic-duct stent	55	0.69	0.50–0.95†
Biliary sphincterotomy	189	1.32	1.03–1.69†
Pancreatic sphincterotomy	102	0.94	0.71–1.24
Biliary manometry	221	1.29	0.96–1.75
Pancreatic manometry	226	1.29	0.94–1.79

OR, Odds ratio; *ASA*, American Society of Anesthesiologists; *SOD*, sphincter of Oddi dysfunction.
*Included variables had $P < .10$ in univariate analysis, plus age, race, and sex.
†Significant at $P < .05$.

(OR 4.08 [95% CI, 1.75–9.48]), (4) pancreatic manometry procedures (OR 3.57 [95% CI, 1.19–10.65]), and (5) complex procedures (grade 3) (OR 2.86 [95% CI, 1.15–7.09]) (Table 7).

Perforation

Sixteen patients had perforations, too few to perform valid multivariable logistic regression. Eleven were treated surgically; 1 patient died. It is striking that there were more cases of bowel perforation (n = 12) than of sphincterotomy-related retroduodenal perforation (n = 4). Almost all of the bowel perforations occurred in patients with previous surgeries that involved biliary diversions (Billroth II gastrectomy, Roux-en-Y diversion, and Whipple procedure) (1.3% vs 0.1% in nonoperated patients, $P < .0001$).

DISCUSSION

This study of complications of ERCP and their correlates is the largest reported from a single center and reveals a number of clinical and procedural correlates for complications. The prevalence of overall complications was 4.0%, of which 72% were graded as mild (ie, requiring <3 days of hospital treatment). This prevalence is similar to 1 study[8] but lower than many others, which ranged from 4.0% to 15.9%.[2,5-8,12,13,16-19] The accuracy of the data and homogeneity in case definition are important issues. Because these data were captured at the time of each procedure, with mandatory fields, as part of the formal report, we were able to include 100% of our procedures. This may not be the case in studies in which the data were separately collected for research purposes.

TABLE 5. Clinical and procedural predictors of post-ERCP pancreatitis (n = 304)

Variable*	N	OR	95% CI
Clinical			
Age			
>80 y	5	1.97	0.78–4.96
65–80 y	30	1.27	0.50–3.25
50–65 y	62	1.11	0.42–2.90
< 50 y	207	Reference group	Reference group
Race			
African American	40	0.97	0.42–2.25
White	250	1.22	0.56–2.65
Other	14	Reference group	Reference group
Sex			
Men	93	1.06	0.80–1.40
Women	211	Reference group	Reference group
ASA class			
IV and V	1	1.90	0.25–14.37
III	16	0.64	0.36-1.13
I and II	287	Reference group	Reference group
Prior upper-GI surgery	3	0.55	0.08-4.03
Prior ERCP complication	22	1.52	0.92-2.51
Suspected SOD†	206	†	†
SOD with pancreatic-stent placement	32	1.45	1.13-1.87
SOD without pancreatic-stent placement	174	1.84	1.55-2.18‡
Liver transplant	8	0.95	0.39-2.27
Suspected or known duct stone	18	0.79	0.38-1.67
Prior pancreatitis	113	0.86	0.65-1.12
Jaundice	16	0.67	0.38-1.25
Procedural			
Therapeutic procedure	250	1.28	0.88-1.87
Antibiotics before procedure	144	1.24	0.95-1.63
Biliary-stone extraction	8	0.54	0.19-1.55
Biliary-stent insertion	23	5.01	0.62-40.73
Biliary-stent exchange	7	0.38	0.16-0.92‡
Major papilla pancreatogram	244	1.62	1.13-2.32‡
Minor papilla pancreatogram	53	1.48	1.01-2.17‡
Small pancreatic duct stent†	41	†	†
Biliary sphincterotomy	121	1.21	0.91-1.60
Pancreatic sphincterotomy	74	0.80	0.56-1.14
Biliary manometry	177	1.16	0.83-1.62
Pancreatic manometry	187	1.43	0.99-2.08

OR, Odds ratio; *ASA*, American Society of Anesthesiologists; *SOD*, sphincter of Oddi dysfunction.
*Included variables had $P < .10$ in univariate analysis, plus age, race, and sex.
†Significant interaction noted between SOD and 3F stents ($P < .0001$).
‡Significant at $P < .05$.

For example, a recent large audit from Britain captured only 80% of procedures.[19]

More difficult is the issue of delayed complications. We had a standard method (records review at 1 week) for collecting and adding data on all delayed complications of which we were aware but did not make routine follow-up calls to double-check. Although there are limitations with this approach, our system remained unchanged throughout the 12 years. It is also true that some studies used different definitions and thresholds for complications and their severity, especially those performed before the consensus criteria were reported.[20,21]

The factors likely to be associated with increased risk include the competence of the treating team (and their facilities and equipment), certain specific characteristics of the patients (eg, coagulopathy), and the precise type of manipulations (eg, sphincterotomy). Several studies demonstrated lower rates of complications, with greater experience[22,23]; others have not.[24] We cannot add data on this point, because all of the procedures were performed by experts, with excellent support staff. Although our complication rate significantly reduced with time when comparing the first 6 years of our data with the most recent 6 years (4.88% vs 3.26%, $P < .001$), there was a significant procedural change between the 2 eras, ie, the increasing usage of small-caliber temporary pancreatic-duct stents. The active presence of trainees did not appear to significantly affect outcomes. However, most cases involved a trainee, which limited the power of this analysis and raised the possibility of type II error.

The most prominent patient characteristic that correlated with complications was suspected SOD for any

TABLE 6. Predictors of post-ERCP bleeding (n = 40)

Variable*	N	OR	95% CI
Clinical			
Age			
>80 y	2	2.82	0.37-21.45
65-80 y	6	3.07	0.40-23.71
50-65 y	13	1.83	0.22-15.25
< 50 y	19	Reference group	Reference group
Race			
African American	12	1.80	0.23-14.12
White	26	1.04	0.14-7.77
Other	2	Reference group	Reference group
Sex			
Men	20	1.67	0.86-3.22
Women	20	Reference group	Reference group
Procedural			
Biliary sphincterotomy	25	4.71	2.33-9.50†
Pancreatic sphincterotomy	10	1.26	0.57-2.76

OR, Odds ratio.
*Included variables had $P < .10$ in univariate analysis, plus age, race, sex.
†Significant at $P < .05$.

complication and for pancreatitis specifically. SOD has repeatedly been shown to be a high-risk group, especially in studies by Freeman et al[24] and Freeman.[25] These studies convincingly showed that it is the patient type that increases the risk not the manometry procedure as was previously incriminated.[26,27] Manometry was not an independent predictor for any complication or for pancreatitis in our study, but pancreatic manometry was a significant predictor of severe or fatal outcomes. This is not surprising, because pancreatic manometry was previously associated with post-ERCP complications.[27] However, it is likely that the risk derives more from the pancreatic sphincterotomy that usually follows an abnormal manometry. Pancreatic manometry with sphincterotomy had a pancreatitis rate of 6.43% but was 4.48% without sphincterotomy ($P = .27$), comparable with the risk in all comers in our group.

Prior gastric surgery with biliary diversion increased the risk of bowel-wall perforation, which reflected the technical difficulties in accessing and traversing the afferent jejunal loop in patients likely to have adhesions. This difficulty was recognized before.[24] Among other patient characteristics, there was no evidence for increased risk in any specific indication (eg, jaundice), nor with procedures carried out as emergencies. Unlike the recent British audit[19] and studies by Freeman et al[24] and Freeman,[25] we found no significant increase in risk among younger patients or in women. Our findings in this regard are similar to the studies by Cheng et al[28] and Loperfido et al.[8] Patients with an established diagnosis of acute or chronic pancreatitis before ERCP were slightly less likely to have any complication. This is difficult to explain, because there was no difference in the risk specifically for postprocedure pancreatitis. Of note, our group only very selectively performs ERCP in active acute pancreatitis, as is recommended in the literature.

What exactly is done at ERCP should affect the risk. It is scarcely surprising that pancreatography increases the risk of producing pancreatitis. This has been documented repeatedly,[5,8,28] with increasing risk, with repeated cannulations and injections[19]; we also see an increased risk of overall complications and pancreatitis when pancreatography is performed. The effect of performing pancreatic manometry has already been mentioned. Most people assume that therapeutic procedures are more dangerous. Biliary sphincterotomy did increase the risk of bleeding (OR 4.71) and of overall complications (OR 1.32); however, it did not raise the risk of pancreatitis, which is similar to previous investigators' findings.[8,24,28] We showed that the overall complication rate for therapeutic procedures was no greater than for those ERCPs that involved no therapy (we did not count prophylactic temporary pancreatic stenting as ''therapeutic''). This finding is similar to those of some other studies,[5,29] but unlike other studies that found greater risk with therapeutic ERCP.[8,30] The more complex (grade 3) procedures carried a higher risk for severe or fatal complications. This was an important finding, because grade 3 procedures made up 40% of our cases.

Pancreatitis is the most common and feared complication after ERCP, with reported frequencies that generally range from 1% to 7%.[5-8,16,24,31-34] However, several higher figures were reported.[28,35,36] Our pancreatitis rate was 2.6%. We used the widely accepted consensus definition for pancreatitis,[11] which is a clinical illness associated with serum amylase or lipase at least 3 times normal at more than 24 hours after the procedure and requiring hospitalization or prolonging initial admission more than 1 day. Other studies on the topic used different definitions for post-ERCP pancreatitis,[6,37] which may affect reported prevalence.

Several studies showed that the risk of pancreatitis can be reduced, at least in higher-risk patients, by temporary placement of a small pancreatic stent (usually 3-5F) designed to pass spontaneously in a week or two.[38,39] We found a reduced risk of overall complications after prophylactic stent placement but, curiously, not specifically for pancreatitis. However, in the SOD subgroup, it did appear that those patients who did not receive a prophylactic stent had a higher risk of pancreatitis (OR 1.84 vs 1.45).

TABLE 7. Predictors of post-ERCP severe or fatal complications (n = 49)

Variable*	N	OR	95% CI
Clinical			
Age			
>80 y	5	0.35	0.12-1.05
65-80 y	7	0.58	0.20-1.68
50-65 y	17	0.35	0.11-1.14
<50 y	20	Reference group	Reference group
Race			
African American	16	0.86	0.23-3.23
White	29	0.41	0.12-1.45
Other	4	Reference group	Reference group
Sex			
Men	23	1.47	0.79-2.72
Women	26	Reference group	Reference group
ASA grade			
IV and V	2	7.65	1.16-50.54†
III	12	2.38	1.14-4.97†
I and II	35	Reference group	Reference group
Obese	4	5.18	1.74-15.43†
Suspected or known duct stone	13	4.08	1.75-9.48†
Suspected SOD	21	1.60	0.60-4.27
Procedural			
Therapeutic	37	1.58	0.78-3.19
Antibiotics pre-procedure	31	1.68	0.87-3.22
Priority			
Urgent	3	2.08	0.46-9.48
Urgent on schedule	4	0.48	0.14-1.70
Elective	42	Reference group	Reference group
Difficulty grade			
3	31	2.86	1.15-7.09†
2	6	1.94	0.68-5.55
1	12	Reference group	Reference group
Trainee involvement	48	3.90	0.53-28.58
Biliary-stone extraction	4	0.28	0.07-1.14
Biliary manometry	15	0.51	0.22-1.19
Pancreatic manometry	22	3.57	1.19-10.65†

OR, Odds ratio; *ASA*, American Society of Anesthesiologists; *SOD*, sphincter of Oddi dysfunction.
*Included variables had $P < .10$ in univariate analysis, plus age, race, and sex.
†Significant at $P < .05$.

The most striking correlations with risk (OR > 3) in this study were found when examining those complications graded as severe or fatal. These were more likely to occur in patients with extremely poor health status (OR 7.65), with obesity (OR 5.18), with a suspected or known ductal stone (OR 4.08), undergoing a complex grade 3 procedure (OR 2.86), or pancreatic manometry (3.57). These findings are not unexpected, nor were we surprised to find that patients with biliary sphincterotomy were at risk for bleeding (OR 4.71).

Predictors of complications found in other large ERCP data analyses (eg. women, younger age, biliary pre-cuts) were not found to be significant in our models. Our large sample size and inclusion of many different subject and procedural variables may have affected these results. There are limitations with our study. Our conclusions about severe and fatal complications should be weighed against the relatively small sample size for the model (n = 49) and for certain predictors (eg, obese patients [n = 4], and ASA grade IV or V [n = 2]). This model, therefore, should be interpreted with caution and may not predict future events. The generalizability of our conclusions can be questioned, because all of the procedures were performed at one institution, a large referral center for ERCP in southeastern United States, with high technical success rates. The lack of any routine system for checking may have resulted in missing some delayed complications. Certain predictors of pancreatitis in other series (eg, repeated cannulation attempts) were not included in our initial data set.

In conclusion, our data certainly show that low complication rates can be achieved by experienced endoscopists working on complex and high-risk subjects, even with trainee involvement. More prospective studies from both academic and community-based gastroenterologists should be encouraged, These will be helpful in further delineating the risk of complications and their predictors, and in guiding mechanisms for future reduction.

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Current affiliations: Department of Medicine (P.B.C., D.G., J.R.), Division of Gastroenterology and Hepatology, Digestive Disease Center, Medical University of South Carolina, Charleston, South Carolina, Department of Gastroenterology (J.G.), Wilford Hall Medical Center, Lackland Air Force Base, San Antonio, Texas, USA.

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Reprint requests: Peter B. Cotton, MD, Digestive Disease Center, Medical University of South Carolina (MUSC), 25 Courtenay Dr, ART 7100A, MSC 290, Charleston, SC 29425-2900.

If you want to chat with an author of this article, you may contact him at cottonp@musc.edu.