Pancreaticobiliary and Duodenal Perforations After Periampullary Endoscopic Procedures

Diagnosis and Management

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Objective: To review our experience with management of pancreaticobiliary and duodenal (PB/D) perforations after periampullary endoscopic interventions. Although pancreaticobiliary and duodenal perforations after periampullary endoscopic procedures are rare, their management has not been well described.

Patients: Individuals who experienced pancreaticobiliary and duodenal perforations.

Main Outcome Measures: Comorbidities, interventions performed, mechanism/site of perforation, management, and hospital morbidity/mortality.

Results: Seventy-five perforations (0.6%) occurred in 12,427 procedures; 20 perforations (27%) occurred during biliary stricture dilatation, 18 (24%) during diagnostic endoscopic retrograde cholangiopancreatography, and 15 (20%) during management of choledocholithiasis. Perforations were caused by guidewire insertion in 24 patients (32%), sphincterotomy in 11 (15%), passage of the endoscope in 8 (11%), or stent migration in 7 (9%) and were identified during the index procedure in 45 patients (60%). Delayed presentations included pain in 33 patients (44%), leukocytosis in 26 (35%), and/or fever in 13 (17%) and were diagnosed using computed tomography in 19 patients (25%) and abdominal radiography in 10 (13%); 9 cases (12%) were diagnosed more than 24 hours after the procedure. Indications for operative treatment were gaping duodenal perforations and perforations in patients with surgically altered anatomy. Indications for nonoperative management included contained bile duct perforations and focal duodenal perforations. Management was nonoperative in 53 patients (71%) and operative in 22 (29%). Patients with duodenal perforations, higher American Society of Anesthesiology status (P<.01 each), and older age (mean±SEM, 65±4 vs 55±2 years; P=.02) were more likely to require operative management. Hospital stay (mean±SEM, 16±4 vs 4±1 days; P<.05) and mortality (13% vs 4%; P<.05) were greater in operative patients (P<.05 each).

Conclusions: Most (70%) pancreaticobiliary and duodenal perforations secondary to periampullary endoscopic interventions can be managed nonoperatively. Most biliary perforations can be managed nonoperatively; a requirement for operative treatment increases the mortality rate.

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Endoscopic retrograde cholangiopancreatography (ERCP) has evolved from a diagnostic tool to a primarily therapeutic intervention in pancreaticobiliary disorders. This evolution has led to an increase in the volume and complexity of these procedures, and, consequently, complications have increased in number and spectrum. These invasive therapeutic procedures carry the risk of perforation of the bile duct, pancreatic duct, and/or duodenum.1-7 Duodenal perforations may be retroperitoneal (typically in the periampullary region and due to sphincterotomy) or intraperitoneal (typically in the lateral wall and due to endoscope passage). Although perforation as a result of ERCP is rare, the potentially serious nature of this complication, with a reported mortality of up to 25%, mandates a better understanding of the factors that predispose to this complication and the most appropriate management for perforations occurring after the various periampullary interventions.8-11 Multiple studies6,9,12,13 have reported an incidence of ERCP-related perforation of 0.3% to 1.0% and have examined the risk factors that predisposed to perforation. Some groups1,9 have attempted to stratify the features of perforation based on clinical and radiographic findings to help guide the course of management.

At our tertiary referral center, a high volume of diagnostic and therapeutic endo-

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scopically performed procedures are performed. Hence, the aim of this study was to determine the incidence of pancreaticobiliary and duodenal perforations after periampullary interventions, the risk factors predisposing to perforations, the operative and nonoperative management options, and their respective clinical outcomes.

METHODS

After approval from the Mayo Clinic institutional review board we queried our endoscopic database to identify all patients who underwent an endoscopic periampullary procedure that resulted in perforation of the duodenum, pancreatic duct, or bile duct between January 1, 1994, and December 31, 2004. Perforations resulting from transgastric manipulations were excluded from this study. Pertinent data were collected using the medical records of these patients regarding demographics, comorbidities, and history of a previous endoscopic or periampullary procedure. Indications for the procedure and the presence or absence of risk factors such as a periampullary diverticulum, precut sphincterotomy, and previous gastric, duodenal, or jejunal operations were assessed. The complexity of the periampullary endoscopic procedure, graded from 1 to 3 based on the degree of difficulty of therapeutic interventions, was evaluated.

Data were organized and are reported as mean±SEM or the median and range depending on the distribution of data. Statistical analysis included tests of association with operative vs nonoperative management using Wilcoxon and Kruskal-Wallis (rank sum) tests for continuous or ordinal variables. χ² and Fisher exact tests were used for nominal variables. Limited multivariate logistic regression modeling was then performed to adjust for confounding variables. A P<.05 was considered statistically significant.

RESULTS

During the 11-year period, 12 427 endoscopic periampullary procedures, including ERCP and endoscopic retrograde cholangiography, along with therapeutic endoscopic interventions, were performed at Mayo Clinic, Rochester, Minn. Seventy-five (0.6%) of these procedures resulted in pancreaticobiliary and duodenal perforations in 23 males and 52 females. The median age of patients was 56 years (range, 14-91 years). The incidence of perforation was 0.8% (n=70) during therapeutic procedures and 0.1% (n=5) during diagnostic procedures.

COMORBIDITIES

Almost half of these 75 patients with perforation had been treated previously for a chronic gastrointestinal disease, including primary sclerosing cholangitis (n=21), ulcerative colitis (n=16), and chronic pancreatitis (n=4). Six patients had pancreatic cancer, and 2 had cholangiocarcinoma. A history of upper gastrointestinal operations was common; 25 patients had undergone a cholecystectomy, and 50 had an additional abdominal operation in the past. Whereas 64 patients (85%) had normal gastroduodenal anatomic continuity, 11 (15%) had surgically altered anatomy: 6 had Billroth II–type anatomy (loop gastrojejunostomy), 3 had Roux-en-Y gastrojejunal anatomy, and 2 had a previous gastric resection. Thirty (40%) of the 75 patients had a history of previous ERCP or other periampullary endoscopic procedures. Twelve of these 30 had a postinterventional complication at the time of the previous endoscopic periampullary procedure.

Many of the patients who developed a perforation had substantial previous medical comorbidities. Thirteen patients were diabetic, 29 had clinically important cardiovascular disease, and 7 had underlying pulmonary disease. At the time of the procedure, 13 patients (17%) were identified as American Society of Anesthesiology (ASA) class 1, 24 (32%) as class 2, 36 (48%) as class 3, and 2 (3%) as class 4.

INDICATIONS FOR ENDOSCOPIC INTERVENTION

The most common indications for performing a periampullary procedure were dilatation of a biliary stricture in 20 patients (27%), diagnostic cholangiography in 18 (24%), and management of known or suspected choledocholithiasis in 15 (20%). Other less common indications included obstructive jaundice (n=9; 12%), sphincter of Oddi dysfunction (n=5; 7%), cholangitis (n=5; 7%), and various pancreatic abnormalities (pancreatic duct strictures, neoplasm, and ductal leak). The interventional procedures performed most commonly were sphincterotomy (biliary or pancreatic, n=43), placement of a bile duct or a pancreatic duct stent (n=22), and balloon dilatation of a bile duct stricture(s) (n=17). Other less commonly performed procedures included transampullary choledocholithotomy (n=4), cholangioscopy (n=2), and brushing or biopsy of a bile duct lesion (n=1). An exclusively diagnostic procedure with no additional intervention resulted in perforation in 5 patients. During the interventional procedure, 14 patients (19%) were found to have a periampullary diverticulum, 7 (9%) of whom required a precut sphincterotomy to allow the endoscopic intervention to be possible.

MECHANISM, SITE, AND IDENTIFICATION OF PERFORATION

Guidewire manipulation was the presumed cause of perforation in 24 patients (32%), and 11 (15%) were sphincterotomy-related perforations. Eight (11%) were related to difficulties in passage of the endoscope, 8 (11%) occurred during cannulation, 7 (9%) occurred in the process of stent insertion, and 5 (7%) occurred during stricture dilatation. The exact mechanism of perforation was unknown in 11 patients (15%). The duodenum and the bile duct were the most common sites of perforations (Table 1). Of the 75 perforations, 45 were identified immediately: 26 (35%) by direct endoscopic visualization and 19 (25%) by fluoroscopic identification of extravasation of contrast. Eight patients (11%) were suspected of having a perforation during the procedure, and it was confirmed using computed tomography (CT). Five other patients (7%) had the perforation diagnosed within 6 hours of the procedure, and...
requiring operative management (procedure was associated with the incidence of perforation increasing technical difficulty) of the interventional procedure performed was analyzed for the operatively and nonoperatively managed patients. Increasing grade (ie, increasing technical difficulty) of the periampullary interventional procedure performed was associated with the incidence of perforation during the procedure presented later with symptoms and signs of abdominal pain (44%), leukocytosis (39%), fever (17%), hypotension (3%), and chest pain (1%). The modalities used to identify and confirm the suspicion of a perforation in these delayed presentations included CT (n=19, 25%), abdominal radiographs showing free intraperitoneal or retroperitoneal air (n=10, 13%), and magnetic resonance imaging (n=1, 1%).

GRADE (COMPLEXITY) OF ERCP

Mean procedural complexity by grade was 1.5±0.1. The technical difficulty of the periampullary interventional procedure performed was analyzed for the operatively and nonoperatively managed patients. Increasing grade (ie, increasing technical difficulty) of the interventional procedure was associated with the incidence of perforation requiring operative management (P=.02).

MANAGEMENT

The pre-intervention plan was executed endoscopically with success in 45 patients (60%); however, 30 procedures (40%) were abandoned prematurely because of the perforation. After recognition of the perforation, overall, 53 patients (71%) were managed nonoperatively, and 22 (29%) were managed operatively. The mean hospital stay for the entire group was 8±1 days, with 5 deaths (7%).

Endoscopic management of the perforation was attempted in 27 (36%) of these 75 patients, including 14 with duodenal perforations, 12 with biliary perforations, and 1 with pancreatic duct perforation. Endoscopic treatments for perforation included biliary stents in 10 patients, a nasobiliary drain or nasogastric tube in 5 patients each, endoscopic placement of a clip(s) in an attempt to “close” the site of perforation in 8 patients, a nasoduodenal tube in 3 patients, and a pancreatic duct stent in the 1 patient with a pancreatic duct perforation. Five of these 27 patients failed endoscopic management and were transferred to the operating room immediately. Twenty-two (81%) of the 27 patients were admitted for observation, 18 of whom were managed successfully using a nonoperative approach; 4 required operative treatment eventually.

NONOPERATIVE GROUP

There were 53 patients (71%) in this group, 15 with duodenal perforations (11 intraperitoneal and 4 retroperitoneal perforations) and 32 with bile duct perforations. Most perforations in this group resulted from endoscopic instrumentation during the procedure. Nearly half were guidewire-related perforations. A combination of antibiotic drugs and intravenous hydration and, when possible, gastric or bile duct decompression was used to manage all of these patients; 8 patients had a nasobiliary or naso-duodenal drain, 9 had a bile duct stent, and 1 had a duodenal stent. An endoscopic clip device (Hemoclip; Olympus, Melville, NY) was placed in 6 of these 53 patients. The mean hospital stay was 4±1 days. Two patients with bile duct perforation died: 1 on postprocedure day 1 of a tension pneumothorax and the other on day 37 of multiorgan failure.

In 6 of the 53 patients, the site of perforation was unknown. The most common presentation was abdominal pain (n=5); 2 patients presented with fever. Computed tomography was used to diagnose the perforation in 5 patients, and an abdominal radiograph revealed free air in 1. All 6 patients had a biliary sphincterotomy performed during the procedure. The median hospital stay for this group of patients was 5 days (range, 2-13 days).

OPERATIVE GROUP

Of the 22 patients (29%) in this group, 19 had duodenal perforations (9 intraperitoneal and 7 retroperitoneal perforations), 2 had perforations in the bile duct, and 1 had a perforation in the pancreatic duct; 2 patients with Billroth II anatomy had jejunal (intraperitoneal) perforations. One patient had 2 perforations: a focal duodenal perforation and a bile duct perforation. Fifteen patients underwent immediate operative intervention on identification of the perforation during the index procedure, 7 of whom had periampullary duodenal diverticula. Seven

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Table 1. Mechanisms and Sites of Endoscopic Perforation*

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>Operative Group (n = 22)</th>
<th>Nonoperative Group (n = 53)</th>
<th>Total (N = 75)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidewire related</td>
<td>3</td>
<td>21</td>
<td>24</td>
</tr>
<tr>
<td>Passage of endoscope</td>
<td>7</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Cannulation</td>
<td>2</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Dilatation of stricture</td>
<td>0</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Sphincterotomy</td>
<td>4</td>
<td>7</td>
<td>11</td>
</tr>
<tr>
<td>Stent insertion</td>
<td>2</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>Difficult stone extraction</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Unknown</td>
<td>4</td>
<td>7</td>
<td>11</td>
</tr>
<tr>
<td>Site</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duodenum</td>
<td>19</td>
<td>15</td>
<td>34</td>
</tr>
<tr>
<td>Bile duct</td>
<td>2</td>
<td>32</td>
<td>34</td>
</tr>
<tr>
<td>Pancreatic duct</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Unknown</td>
<td>0</td>
<td>6</td>
<td>6</td>
</tr>
</tbody>
</table>

*Data are presented as number of patients.

Table 2. Time of Identification of Perforation and ICU Stay*

<table>
<thead>
<tr>
<th>Time of Identification After Procedure, h</th>
<th>Nonoperative Group, No. (n = 53)</th>
<th>Operative Group, No. (n = 22)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>With Prolonged ICU Course Total</td>
<td>With Prolonged ICU Course Total</td>
</tr>
<tr>
<td>During endoscopy</td>
<td>38</td>
<td>15</td>
</tr>
<tr>
<td>&lt;6</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>6-24</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>&gt;24</td>
<td>6</td>
<td>3</td>
</tr>
</tbody>
</table>
patients were managed nonoperatively for more than 6 hours before being taken to the operating room, resulting in 4 patients requiring intensive care unit admission with prolonged hospital stay and 1 death (Table 2). Seven of the duodenal perforations resulted from passage of the endoscope and were associated with large perforations that could not be managed endoscopically. Twelve patients underwent a primary duodenal repair, including 3 with an omental patch used to buttress the closure. Exploratory laparotomy with debridement and drain placement was performed in 7 patients. Three patients underwent a Roux-en-Y choledochojejunosometry, 2 with unresectable pancreatic cancer and 1 with a previous choledochocholedochostomy performed for biliary reconstruction as a part of orthotopic liver transplantation. The patient with pancreatic duct perforation underwent exploratory laparotomy on day 1 and had drainage of multiple intraperitoneal and retroperitoneal fluid collections. He developed severe necrotizing pancreatitis and cardiorespiratory complications that prolonged his hospital stay to 75 days. The mean hospital stay for patients who underwent operative management was 16±4 days. Three patients (all with duodenal perforations) died on postoperative days 10, 12, and 15 with an ASA status of 3 and had required intensive care unit care.

MORBIDITY AND MORTALITY

The overall mortality due to perforations resulting from periampanular procedures was 7% (n=5). Hospital mortality was greater in the operative group (13% vs 4%; P<.05). Four deaths were secondary to sepsis and multiorgan failure 10 to 35 days later. One patient, managed nonoperatively, died the evening of the endoscopic procedure from a tension pneumothorax. Complications after operative treatment included intra-abdominal abscess, hemorrhage, pancreatitis, and wound infection (n=1 each). Patients in the operative group were older than those in the nonoperative group (64±4 vs 55±2 years; P=.02). The median ASA status was also greater (3 vs 2; P=.003), with 18 patients (82%) in the operative group having an ASA status of at least 3, whereas only 22 nonoperative patients (42%) had an ASA status of 3 or greater.

Univariate analysis was performed to identify the association of variables such as age, sex, ASA status, grade of procedure, site of perforation, and duration of hospital stay between operative and nonoperative management. This analysis revealed that the mean age of patients requiring operative management was greater than that of those managed nonoperatively (65±4 vs 55±2 years; P=.02). An association was found between higher ASA status (≥3) and the need for an operative treatment (P=.003). Patients with duodenal perforations were more likely to require an operation than patients with bile duct perforations (P<.001). Increasing technical difficulty (grade) of the procedure was associated with requiring operative management (P=.02). The hospital stay was greater for patients requiring an operation vs those who could be managed nonoperatively (16±4 vs 4 ±1 days; P<.001). Sex difference and history of previous ERCP did not seem to predispose patients to require operative treatment; however, on applying the multivariate logistic regression model we found that the associations of ASA status and site of perforation with patients requiring operative management remained significant (P=.01 and .003, respectively).

Few studies have reported the incidence of perforation and its management, with no major series in the past decade.17 The retrospective review of 12 427 endoscopic periampanular procedures identified 75 perforations. The present major findings include an increase in the use of ERCP during the past decade, especially in terms of interventional procedures. This study identifies age, ASA status, site of perforation, and early recognition as critical factors in predicting patient outcome.

Between 1994 and 2004, we performed 12 427 endoscopic periampanular procedures. The total number of procedures performed in 2004 was nearly twice the number in 1994 (Figure 1). Although the yearly rate of per-
Perforation (range, 0.4%-0.7%) seems to have remained relatively unchanged during this period, the absolute numbers of pancreaticobiliary and duodenal perforations show a rising trend. Seventy-three percent (n = 9109) of the periampullary endoscopies were therapeutic procedures, and 27% (n = 3318) were performed with only a diagnostic intent. During the decade, the number of therapeutic procedures performed each year showed an increasing trend, with 53% of endoscopic periampullary procedures being therapeutic in 1994 and 89% in 2005, whereas the trend for diagnostic procedures declined, probably due to the advent of better, noninvasive imaging modalities, such as endoscopic ultrasonography and magnetic resonance cholangiopancreatography. Seventy of the perforations in this period occurred as a result of therapeutic procedures, translating to an incidence of perforation in the diagnostic group of 0.8%, which was 8 times greater than that of the therapeutic group of 0.1%. As expected, therapeutic procedures carry a much higher risk of perforation due to the invasive nature of the endoscopic procedure.

Patients who underwent operative management were older than those managed nonoperatively (65±4 vs 55±2 years; P = .02). Patients requiring operative treatment after a perforation were generally more ill, with multiple comorbidities, as indicated by the higher ASA status (median = 3), and required a longer hospitalization than patients requiring nonoperative management (12±4 vs 4±1 days); however, after adjusting for confounding variables, multivariate regression analysis demonstrated that greater ASA status (P = .001), higher grade (technical difficulty) of the endoscopic procedure (P = .06), and perforation in the duodenum (P = .003) were risk factors for the perforations requiring operative therapy. Associated medical illnesses and older age seem to be predictors of poor operative outcome.1,2

In the present study, approximately 20% of the patients with endoscopic perforations (14 of 75 patients) had a periampluillary duodenal diverticulum. Seven of the 22 patients requiring operative intervention had a periampullary diverticulum, in which the perforation was noted in 5. Because the extensive database used does not detail the presence of a periamplullary diverticulum, we cannot compare the presence or absence of a diverticulum and the association of a perforation in the entire experience. But, because the prevalence of periamplullary diverticula is much less than 20% in the general population, these findings suggest that interventional periamplular endoscopic procedures in patients with a peri-Vaterian duodenal diverticulum are undertaken with a greater risk of perforation than when a diverticulum is absent.

Early diagnosis and prompt treatment during the endoscopic procedure are vital for a better outcome.1,11,18-20 Suspicion and diagnosis of a procedure-related perforation can be facilitated greatly by clinical findings and especially radiographic imaging with contrast studies, CT, and even magnetic resonance imaging.13,21 Most important, suspicion of perforation should be high in patients with pain or fever after any periamplular endoscopic procedure. This concern is especially true when the procedure is therapeutic or technically difficult; the patient has local anatomic variations, such as periamplular diverticula22; strictures are dilated; there are changes in the usual anatomy related to previous operative interventions (eg, gastrectomy); or intubation is difficult. If there is any suspicion of perforation, prompt diagnosis and institution of systemic support with broad-spectrum antibiotics and intravenous resuscitation is mandatory; when perforation is confirmed, external biliary, duodenal, and/or pancreatic drainage may be indicated. Some patients could be managed by diversion or decompression of contents from the duodenum by placing a nasoduodenal tube alone or with

Figure 2. Proposed algorithms for the management of proven or suspected duodenal, biliary, or pancreatic perforations during (A) and after completing (B) an endoscopic periampullary procedure.
internal pancreaticobiliary drainage. The management of perforations after therapeutic periampullary endoscopic procedures has remained a major controversy. The present data indicate that most ductal perforations caused by guidewire passage (21 of 24) or during attempted cannulation (6 of 8) cause focal tears or perforations, which can be managed nonoperatively using sphincterotomy, nasobiliary drains, or endoluminal stents.\textsuperscript{23-25} Successful nonoperative management of sphincterotomy-related retroperitoneal perforations is also possible, despite extensive retroperitoneal air noted on CT, provided the patients remain nontoxic.\textsuperscript{26,27} In contrast, if patients develop abdominal pain or fever or appear toxic clinically, surgical consultation should be obtained, and operative evaluation for effective repair or drainage should be considered, especially in elderly or otherwise chronically ill patients less able to withstand the physiologic stress. We offer clinical management algorithms for patients noted to have a perforation either during or after completion of the procedure (Figure 2).

Duodenal perforations represent a different category of injury.\textsuperscript{10,21} Many of these are not truly periampullary but rather occur on the lateral duodenal wall, are rather large free tears into the peritoneal cavity, and seem to occur secondary to trauma from difficult passage of the endoscope. These types of perforations are often recognized by the endoscopist, are difficult or impossible (currently) to repair endoscopically, and require emergency operative intervention. Early operative intervention usually allows a primary repair, similar in principle to closure of duodenal perforations secondary to duodenal ulcers. Delayed recognition or repair after failure of an attempt at nonoperative management can be devastating, requiring drainage alone without repair of the actual perforation. Moreover, several of the prolonged intensive care unit admissions and deaths in the present series came from delayed intervention, with local sepsis leading to multiorgan failure. Seven patients in the operative group (6 with duodenal perforations and 1 with perforation at the junction of the pancreatic duct with the ampulla) had a delay in receiving operative treatment; 4 of these resulted in a prolonged intensive care unit course and the death of 1 patient (Table 2). Therefore, intraperitoneal duodenal perforations require an aggressive approach; simple nasogastric/nasoduodenal tube drainage seems unwise except for very limited, focal perforations (Figure 2). A delay in diagnosis of duodenal perforations can lead to severe morbidity. The ability of endoscopic repair with intraluminally applied clips is poorly defined and seems unwise in large, nonfocal tears using the current endoscopic technology. Recent studies\textsuperscript{28} using other modalities, however, show promise for allowing endoscopic closure.

Therefore, with the expanding spectrum of interventional ERCP procedures, the absolute number of resulting perforations has increased. Although it still is a rare entity, pancreaticobiliary and duodenal perforations can prove to be fatal, especially when the perforation occurs in the duodenum; operative treatment carries greater morbidity and mortality rates than perforations that can be contained nonoperatively.

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REFERENCES


DISCUSSION

Timothy Sielaff, MD, Minneapolis, Minn: This is an important data set for all of us who are involved in the management of patients with biliary tract and periampullary diseases and is important also as a description of the utilization of ERCP and the management of its complications. It is a single-institution experience, and that affords an opportunity to develop as uniform as possible a management approach to this very rare complication. The results, however, are broadly applicable to all of us who work in an institution where ERCPs are performed and for all of us who are called to help manage these complications.

I just have 3 relatively simple questions. Number 1, there is a striking trend away from diagnostic ERCP, and that is very useful for all of our practices during this period. What are the indications for diagnostic ERCP in the year 2006 in Rochester and what should they be generalized to in the nation as a whole?

Number 2, what are the predictors of perforation? We talked about those patients who had perforations, what their complicating factors were. But what is the denominator? What are the risk factors in the entire data set? Are there patients for whom the risk factors are so high that maybe endoscopic intervention should be avoided and other percutaneous interventions should be considered?

Last, could you stratify the risks associated with these patients? If we get a call from the endoscopy suite about a perforation, could you stratify these patients into those who are very low risk and we need not be terribly concerned about, which patients require very close observation, and what tests need to be done to help monitor those patients and confirm that nonoperative therapy is feasible? And probably most important from the manuscript, we see that there were patients who died as a result of these complications. Which patients do we take straight to the operating room to try to salvage?

Dr Farnell: The first question was, what are the indications for diagnostic ERCP in the year 2006? In our opinion, ERCP remains an important diagnostic tool. There are patients in whom there may be a suggestion of pancreatic malignancy on abdominal CT, magnetic resonance imaging, MRCP [magnetic resonance cholangiopancreatography], or endoscopic ultrasonography in whom the diagnosis remains unclear. A complementary or confirmatory ERCP in such patients may provide enough diagnostic information to achieve a clinical diagnosis and to plan operative therapy.

In patients who have pancreatitis of unknown etiology, an anomaly of the entry of the bile duct into the pancreatic duct may be present. While MRCP may be useful in such patients, in our hands an ERCP may be critically important in such patients with pancreaticobiliary malunion or a choledochal cyst. In patients with disconnected duct syndrome or those in whom operative intervention is being considered for chronic pancreatitis, our preference would be to perform ERCP for operative planning. In addition, sphincter of Oddi manometry can be useful in a selected subset of patients with equivocal symptoms of biliary pain. Our preference in many patients with intraductal papillary mucinous neoplasm is to get an ERCP because it gives me a road map for operative planning, particularly in those with multifocal side branch disease. While endoscopic ultrasonography is the preference of my gastroenterology colleagues, my own personal preference is to have an actual picture provided by ERCP for operative planning.

Dr Sielaff also asked about the predictors of perforation. Unfortunately, because of the design of the study, we were unable to address that. Dr Fatima is very industrious but she would have had to analyze over 12,000 charts in order to determine those factors predictive of perforation. We did analyze those factors that correlated with the need for operative intervention in those patients sustaining perforation, and those data were presented by Dr Fatima.

Dr Sielaff also asked about a management algorithm. While the care of each patient should be individualized, there are some generalizations that can be made. It is important to talk to your endoscopist and ask whether he or she noticed the complication at the time of the procedure or not. Was the perforation guidewire related? Was it a perforation of the bile duct? If it was a guidewire perforation of the bile duct, it is highly likely that it can be managed nonoperatively. A sphincterotomy perforation is a complication that can go either way. In such a patient, CT to determine if there is objective evidence of perforation and careful clinical monitoring of the patient to determine if toxicity is present would help to dictate the need for operative intervention. Last, those patients who have altered anatomy, such as prior gastrectomy and Billroth II gastroenterostomy, those patients with peri-Vaterian diverticula, and those in whom scope passage resulted in a gaping perforation visible to the endoscopist or associated with gross extravasation on contrast examination represent a group of patients that will probably need to be operated on straight away. In this subset of patients, we would not wait for them to deteriorate clinically before making a recommendation to intervene operatively.

Richard C. Thirlby, MD, Seattle, Wash: I have 1 comment and a question. I think I would quibble just a little bit with 1 of your conclusions, which I might paraphrase as “the majority of duodenal perforation should be operated on.”

At the Mayo Clinic, the majority of these were operated on; however, there is not a good nonoperated-on cohort to compare to the operated-on cohort. Please expand a little more on how the surgeon decides who gets operated on and who doesn’t.

You said a CT scan is essential. Would you require extravasation of contrast? Do you know how many patients were attempted to be managed medically who failed and subsequently went to operation? That might be helpful information.

Dr Farnell: Dr Thirlby is making the point that judgment may be appropriate in patients who have sphincterotomy perforation. The patients that we have recommended be operated
on immediately are those in whom passage of the endoscope results in an intraperitoneal gaping perforation.

For patients with biliary sphincterotomy-induced perforations, we would agree with you that the approach to these patients should be individualized. If there is evidence of a perforation after endoscopic sphincterotomy, both the clinical status of the patient and imaging are important. If the patient has a negative abdominal examination, does not have signs of systemic toxicity, and has minimal or no extravasation from the site of the sphincterotomy on abdominal CT with oral contrast, antibiotic therapy, fluid resuscitation, and careful observation would be appropriate. In contrast, if there is gross extravasation into the peritoneal cavity or retroperitoneum and if there is evidence of toxicity, operative intervention is our recommendation. Our endoscopists do have some experience using hemoclips to manage small endoscopic perforations; however, their use was so selective that I am unable to make generalizations about their use based on our data. Of 11 patients experiencing perforation as a result of sphincterotomy, 7 were managed nonoperatively and 4 were managed operatively.

Roger G. Keith, MD, Saskatoon, Saskatchewan: As an ERCPist, I think one of the problems that we encounter, and I think it is debated and you have mentioned it, is the presence of peri-Vaterian diverticula. There are numbers of interventional endoscopists who don’t consider that a contraindication to sphincterotomy, and there are those who do. I wondered if you had in your review any evidence of patients who you had to operate on who had been perforated through the diverticulum?

The second question is, more and more the interventional endoscopist is deploying metal stents for distal strictures, and perforation with a metallic stent, I think, creates a problem that one cannot avoid operating on. Perhaps you could comment on that.

Dr. Farnell: Indeed, there were patients who underwent sphincterotomy in spite of the presence of a peri-Vaterian diverticulum. Our experienced interventional endoscopists are willing to take on such patients for both diagnostic and therapeutic procedures selectively. In the majority of these patients, the procedures are performed safely. There were 14 patients in whom perforation occurred in the presence of a peri-Vaterian diverticulum. Seven were managed nonoperatively and 7 operatively. Of the 7 who were managed operatively, the perforation was at the site of the peri-Vaterian diverticulum in 5.

There were 7 patients in whom stent insertion resulted in perforation. Five were managed nonoperatively and 2 operatively. In none of the 7 patients were the stents of the expanding metal variety.

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