Acute Biliary Pancreatitis: When Should the Endoscopist Intervene?

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Clinical Case
A 63-year-old woman is admitted to the hospital with acute pancreatitis of presumed biliary origin. Laboratory results include white blood cell count (WBC) 18,500; hemoglobin 13.0; platelets 191,000; alanine aminotransferase (ALT) 330; aspartate aminotransferase (AST) 260; alkaline phosphatase 250; bilirubin 1.4; glucose 225; blood urea nitrogen (BUN) 47; creatinine 1.4; and prothrombin time 12 seconds. Ultrasound shows gallstones in the gallbladder; the common bile duct is 5 mm without stones identified.

Background
In 1901, Opie described a patient who died of hemorrhagic pancreatitis. At postmortem examination, a small stone was found impacted at the ampulla. Opie postulated that this obstruction allowed reflux of bile into the pancreatic duct, initiating a cascade of events resulting in pancreatitis. More recent studies have suggested alternative pathogenetic mechanisms. Regardless, we know that at least half of all cases of pancreatitis are caused by the passage of small stones. Gallstones have been recovered in the stool of 85%–95% of patients with acute pancreatitis, compared with a 10% recovery rate in patients with symptomatic cholelithiasis without pancreatitis. Furthermore, earlier surgical series have demonstrated a high incidence of common bile duct stones and impacted ampullary stones (63%–78%) at surgery performed within 48 hours of admission to hospital.

Diagnosis of Gallstone Pancreatitis
Distinguishing biliary pancreatitis from other causes may be difficult, often requiring an extensive biochemical and radiologic evaluation. Finding gallbladder stones is suggestive but not conclusive of a biliary origin. When cholangitis complicates pancreatitis, the likelihood of finding an obstructing stone is certainly raised. Serum amylase levels tend to be higher in patients with gallstone pancreatitis than in those with alcoholic pancreatitis. In a recent review, Frakes suggested that an amylase level greater than 1000 IU/L should suggest a biliary tract origin, although some overlap exists with other causes.

Abnormal serum liver biochemistries may be useful in diagnosing pancreatitis of biliary origin, and several well-designed studies have evaluated these, with conflicting results. However, a meta-analysis by Tenner et al. has suggested that a 3-fold or greater elevation in ALT in the presence of acute pancreatitis has a positive predictive value of 95% in diagnosing acute gallstone pancreatitis. The same meta-analysis found that elevations of AST, alkaline phosphatase, and bilirubin are supportive of this diagnosis but are less useful. Even at values 3 times the upper limit of normal, all have positive predictive values less than 90%, and therefore cannot be used with confidence to make the diagnosis. More recently, Stimac et al. found that serum amylase, ALT, AST, alkaline phosphatase, and urinary amylase are all higher in gallstone pancreatitis than alcoholic pancreatitis.

Abdominal ultrasonography is the diagnostic study of choice for the detection of stones in the gallbladder, with a sensitivity and specificity of 95% to 98%. The offending stone may be visualized, with or without a dilated common bile duct. However, ultrasound (US) has been shown to have only a 60%–80% sensitivity in the diagnosis of gallbladder stones during an acute attack of pancreatitis. Furthermore, this imaging technique detects stones less readily in the bile ducts, with a sensitivity of 25%–90% and a specificity of 90%–95%. The lack of biliary dilation on ultrasound should not dissuade one from making a diagnosis of...
biliary pancreatitis, particularly in the acute setting (less than 48 hours from symptom onset).

Endoscopic ultrasound and magnetic resonance cholangiopancreatography (MRCP) are evolving techniques which are being used with increasing frequency to assess for the presence of choledocholithiasis, without the inherent risks of endoscopic retrograde cholangiopancreatography (ERCP). At the recent NIH State-of-the-Science conference on ERCP, it was noted that several studies have found EUS to have comparable accuracy to that of ERCP for the diagnosis and exclusion of common bile duct (CBD) stones.26 A review from the same meeting noted that with recent technical improvements, studies with magnetic resonance cholangiopancreatography (MRCP) have found sensitivities of 90% to 100%, specificities of 92% to 100% and positive predictive values of 93% to 100% in the setting of suspected choledocholithiasis.27 However, both EUS and MRCP are operator dependent, and may not be available in smaller centers. Furthermore, performance of MRCP may be difficult in an ill patient with pancreatitis. It is frequently the case, therefore, that the diagnosis of biliary pancreatitis is based on clinical suspicion with supporting biochemical data, in the absence of radiologic confirmation.

Outcome of Gallstone Pancreatitis

When biliary sepsis accompanies gallstone pancreatitis, the mortality rate ranges from 13%–50%.28–30 Early surgical opinion, therefore, advocated urgent intervention and removal of the offending stone(s) in all patients with biliary pancreatitis.31 It was hoped that early intervention would prevent progression of a mild attack of pancreatitis to a more severe case. However, many of these studies found that urgent surgery was accompanied by an increased mortality rate,8,26,32 and this approach was abandoned.

Although ERCP and endoscopic sphincterotomy have been performed for approximately 30 years, the application of this technique in the setting of acute biliary pancreatitis lagged behind, principally due to the fear of exacerbating the pancreatitis. Anecdotal reports began surfacing in the 1980s documenting the rapid improvement in some patients after endoscopic establishment of biliary drainage.33 The majority of patients with pancreatitis, however, continue to follow a benign course without intervention. It is now clear, however, that some patients do require biliary drainage, and indeed, may not survive without it. The challenge to endoscopists is to determine which subset of patients will benefit from early ERCP and sphincterotomy.

The outcome of patients presenting with acute pancreatitis depends on the disease severity. Most patients with gallstone pancreatitis present with mild disease, follow a benign course and recover quickly, responding to conservative therapy. However, up to 25% of patients will develop severe pancreatitis, with significantly increased morbidity and mortality.34–39 Early recognition of the severity of the attack, therefore, is of paramount importance, as therapy may be altered. Frequently used severity-of-illness classification systems include the Ranson criteria score40 and (its modified version) the Glasgow score,41 as illustrated in Tables 1 and 2. An attack is predicted to be mild if 0–2 features are present, and severe if 3 or more features are present. Patients with a score of 5 or greater almost always require intensive care unit monitoring.42 If the episode of pancreatitis is known to be associated with cholelithiasis, these prognostic indicators vary slightly (Table 3).40 Another clinical scale, the acute physiology and chronic health evaluation score (APACHE II), is based on several physiologic variables and is frequently used in intensive care unit (ICU) patients.43 This scale has the advantage of allowing for frequent reassessment during the course of the disease. An APACHE II score ≥8 on admission suggests a severe attack. Other systems or markers that are available but are not in widespread use include the Hong Kong scoring system, the New Haven scoring system (BUN/glucose), obesity, polymorphonuclear granulocyte elastase/alpha antiprotease complex, and C-reactive protein.44–46

As defined in the Atlanta Symposium on pancreatitis in 1992,47 the presence of organ failure and pancreatic necrosis also represents severe pancreatitis.

An intervention that potentially may alter the course of severe pancreatitis would be of great interest. The role of ERCP in biliary pancreatitis in this setting remains controversial. However, in a landmark study, Neoptolemos et al.48 found that patients with severe gallstone pancreatitis were more likely to have CBD stones at the time of early ERCP (with 72 hours of admission) when

### Table 1. Adverse Prognostic Factors in Acute Pancreatitis: Ranson’s Criteria

<table>
<thead>
<tr>
<th>At admission</th>
<th>During initial 48 hours</th>
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<tbody>
<tr>
<td>Age &gt; 55 years</td>
<td>Hematocrit decrease of &gt;10%</td>
</tr>
<tr>
<td>White blood cell count &gt; 16,000/mm³</td>
<td>Blood urea nitrogen increase of &gt;5 mg/dL</td>
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<tr>
<td>Blood glucose &gt; 200 mg/dl</td>
<td>Serum calcium &lt; 8 mg/dL</td>
</tr>
<tr>
<td>Serum LDH &gt; 350 mg/L</td>
<td>Arterial oxygen tension &lt; 60 mm Hg</td>
</tr>
<tr>
<td>AST &gt; 250 U/L</td>
<td>Base deficit &gt; 4 mEq/L</td>
</tr>
<tr>
<td></td>
<td>Fluid sequestration &gt; 6 L</td>
</tr>
</tbody>
</table>

LDH, lactate dehydrogenase; AST, aspartate aminotransferase.
Table 2. Adverse Prognostic Factors in Acute Pancreatitis: Glasgow Criteria

<table>
<thead>
<tr>
<th>Criterion</th>
<th>P Value</th>
<th>Significance</th>
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</thead>
<tbody>
<tr>
<td>Within 48 hours of hospitalization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age &gt;55 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White blood cell count &gt;15,000/mm³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucose &gt;180 mg/dL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood urea nitrogen &gt;45 mg/dL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactate dehydrogenase &gt;600 U/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albumin &lt;3.3 g/dL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium &lt;8 mg/dL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arterial oxygen tension &lt;60 mm Hg</td>
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Compared with patients with predicted mild disease (63% vs. 25%, P = 0.03). Including this British study, there are now 4 prospective randomized trials in the literature that have attempted to determine the role of ERCP in gallstone pancreatitis.48–51

**Recommended Management Strategies**

**Endoscopic Therapy of Acute Biliary Pancreatitis**

**British study.** Neoptolemos et al. randomized 121 patients with suspected acute biliary pancreatitis and cholelithiasis on ultrasound to urgent ERCP and endoscopic sphincterotomy (ES) if common duct stones were visualized (ERCP ± ES) within 72 hours of admission or conventional medical management.48 Patient stratification was based on the modified Glasgow criteria. Overall, performance of ERCP ± ES was associated with a reduction in morbidity (12%) compared with conventional treatment (24%). While no decrease in morbidity was noted in those patients suspected to have a mild attack (12% both groups), the outcome was significantly improved in patients with a predicted severe attack (24% vs. 61%, P < 0.01). Mortality was not significantly lower with endoscopic therapy than with conventional management (2% vs. 8%). All deaths occurred in patients predicted to have a severe attack. The length of hospital stay was also significantly shorter for those patients with severe attacks who underwent ERCP ± ES than for those who received conservative treatment (median 9.5 vs. 17.0 days). This study further demonstrated that ERCP could be performed safely in the setting of acute pancreatitis by an expert endoscopist.

**Hong Kong study.** Fan et al.49 randomly assigned 195 patients with acute pancreatitis of any cause to receive ERCP within 24 hours of admission or conservative therapy. Severity of pancreatitis was determined by serum urea and plasma glucose levels on admission, and Ranson’s score. Although patients with pancreatitis of any etiology were included in this study, a subgroup analysis of patients with gallstones and CBD stones confirmed the results of the British study. One hundred twenty-seven patients were found to have gallstones. Of the 97 patients randomized to early ERCP, 64 patients had gallstones, and a biliary sphincterotomy was performed in the 37 patients who had CBD stones. Sixty-three patients with gallstones were randomized to conservative therapy. Twenty-two of these patients deteriorated, and then underwent ERCP; bile duct and gallbladder stones were identified in 10 patients. While there was no difference in morbidity or mortality of patients with mild pancreatitis treated with ERCP or conservative therapy, patients who were predicted to have severe disease clearly benefited from endoscopic intervention. Morbidity was significantly reduced in the ERCP ± ES group (15% vs. 54%, P = 0.003), and there was a trend toward a decrease in mortality with endoscopic therapy (3% vs. 18%, P = 0.097). The incidence of biliary sepsis, in particular, was not significantly reduced in the ERCP ± ES group in patients who were predicted to have mild pancreatitis (0 of 34 vs. 4 of 35 patients, P = 0.114), but the difference was significant in the group predicted to have severe pancreatitis (0 of 30 vs. 8 of 28, P < 0.001).

The most appropriate conclusion from this study is that urgent ERCP with sphincterotomy for common bile duct stones is beneficial in patients predicted to have severe pancreatitis. Although the patient population and study methodology were somewhat different, the results of the Hong Kong study were consistent with those of the British study.

**Polish study.** In the largest series to date, Nowak et al.50 prospectively evaluated 280 patients with suspected acute gallstone pancreatitis, all of whom underwent ERCP within 24 hours of admission. Seventy-five patients with a stone impacted at the papilla underwent endoscopic sphincterotomy. The remaining patients, with a normal-appearing papilla, were randomized to ERCP ± ES or conservative management. Patients treated endoscopically were found to have a statistically significant reduction in morbidity (22% vs. 36% with conservative therapy, P = 0.0003). Mortality was not significantly different (5% vs. 9%). The incidence of biliary sepsis was significantly lower in the ERCP ± ES group (1% vs. 18% with conservative therapy, P = 0.0001). The incidence of post-ERCP pancreatitis was significantly lower in the ERCP ± ES group (7% vs. 35% with conservative therapy, P = 0.0001). The incidence of persistent biliary sepsis was significantly lower in the ERCP ± ES group (4% vs. 18% with conservative therapy, P = 0.0001). The incidence of post-ERCP pancreatitis was significantly lower in the ERCP ± ES group (7% vs. 35% with conservative therapy, P = 0.0001). The incidence of persistent biliary sepsis was significantly lower in the ERCP ± ES group (4% vs. 18% with conservative therapy, P = 0.0001).

**Table 3. Ranson’s Criteria for Pancreatitis Associated With Cholelithiasis**

<table>
<thead>
<tr>
<th>Criterion</th>
<th>P Value</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt;70 years</td>
<td></td>
<td>Hematocrit decrease &gt;10%</td>
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<tr>
<td>Blood glucose &gt;220 mg/dL</td>
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<td>Serum calcium &lt;8 mg/dL</td>
</tr>
<tr>
<td>White blood cell count &gt;15,000/mm³</td>
<td></td>
<td>Base deficit &gt;5 mEq/L</td>
</tr>
<tr>
<td>LDH &gt;400 IU/L</td>
<td></td>
<td>Blood urea nitrogen increase &gt;2 mg/dL</td>
</tr>
<tr>
<td>AST &gt;250 U/dL</td>
<td></td>
<td>Fluid sequestration &gt;4 L</td>
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</table>

LDH, lactate dehydrogenase; AST, aspartate aminotransferase.
significant reduction in complications (17% vs. 36%, $P < 0.001$) and mortality (2% vs. 13%, $P < 0.001$). Moreover, in this study the benefits of ERCP ± ES were seen in patients predicted to have either mild or severe disease. However, as this study has been published only in abstract form to date, inclusion/exclusion criteria remain unavailable. Extensive analysis, therefore, is limited and requires its full report.

**German study.** In contrast to the other 3 single-center studies, Fölsch et al.\(^5^1\) reported a multicenter trial in which 238 patients with suspected biliary pancreatitis were randomized to either conservative treatment or ERCP ± ES within 72 hours of symptom onset. The severity of the pancreatitis was classified before treatment according to the modified Glasgow criteria. Because of the concern that benefit from ERCP ± ES in the prior studies was due to treatment of biliary obstruction and cholangitis, these authors excluded patients with cholangitis or a serum bilirubin $\geq 5$ mg/dL. One hundred twenty-six patients were randomized to receive endoscopic therapy; 58 had bile duct stones. Of the 112 patients who were treated conservatively, 20 subsequently underwent ERCP, and 13 of these had CBD stones identified. Total complications were similar in the treatment and control groups (46% vs. 51%, respectively). Subgroup analysis according to severity of disease (mild and severe) also revealed no benefits of endoscopic therapy. However, patients in the ERCP ± ES group had more severe complications, including respiratory failure. Furthermore, the treatment group had twice as many deaths than the control group, leading to premature termination of the study. The authors concluded that early ERCP and sphincterotomy in patients with acute biliary pancreatitis without cholangitis or biliary obstruction were not beneficial. However, this study has been criticized for randomizing significantly fewer patients with severe pancreatitis than the other 3 trials noted previously. Moreover, 19 of the 22 institutions contributed less than 2 patients per year to the trial,\(^5^2\) raising into question the level of ERCP expertise available. The increased incidence of respiratory failure (defined as an inability to maintain a partial pressure of oxygen above 60 mm Hg) in the ERCP group is also concerning. While hypoxemia is not uncommon in patients with pancreatitis, early ERCP did not lead to this complication in the other 3 studies. The reason for this increased incidence noted in the German trial remains unclear.

### Summary of the Four Randomized Controlled Trials

The 4 prospective trials described above suggest that while certain patients with biliary pancreatitis benefit from early intervention with ERCP ± ES, others do not and may even suffer a worse outcome. Establishing a set of recommendations for intervention is difficult, however, due to significant differences between studies with respect to patient characteristics, definitions of severity, presence of organ failure, and incidence of necrosis. A meta-analysis by Sharma and Howden\(^5^3\) has attempted to address this issue (Tables 4 and 5). The authors recommended that endoscopic therapy be performed in all patients with biliary pancreatitis, particularly in those patients with severe disease. However, this meta-analysis presented just the pooled results from the 4 trials discussed previously. The greatest weight was given to results from the largest study (i.e., the Polish study), despite the fact that this study has only been presented in abstract form, and it has not been published in a peer-review journal 8 years after its presentation. The lack of publication and the inability to adequately appraise the

<table>
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<tr>
<th>Reference</th>
<th>Complications ERCP+ES</th>
<th>Complications Control</th>
<th>RRR</th>
<th>ARR</th>
<th>NNT</th>
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<tbody>
<tr>
<td>Neoptolemos(^4^8)</td>
<td>16.9%</td>
<td>33.9%</td>
<td>50.2</td>
<td>17.0</td>
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<td>Fan(^4^9)</td>
<td>17.5%</td>
<td>28.6%</td>
<td>38.8</td>
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<td>9</td>
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<tr>
<td>Nowak(^5^0)</td>
<td>16.9%</td>
<td>36.3%</td>
<td>53.4</td>
<td>15.9</td>
<td>6.3</td>
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<tr>
<td>Fölsch(^5^1)</td>
<td>46.0%</td>
<td>50.9%</td>
<td>19.6</td>
<td>4.9</td>
<td>20.4</td>
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ERCP, Endoscopic retrograde cholangiopancreatography; ES, endoscopic sphincterotomy; RRR, % relative risk reduction; ARR, % absolute risk reduction; NNT, number needed to treat. Table modified from Sharma et al.\(^5^3\).

<table>
<thead>
<tr>
<th>Reference</th>
<th>Death ERCP+ES</th>
<th>Death Control</th>
<th>RRR</th>
<th>ARR</th>
<th>NNT</th>
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<td>Neoptolemos(^4^8)</td>
<td>1.7%</td>
<td>8.1%</td>
<td>79</td>
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<tr>
<td>Fan(^4^9)</td>
<td>5.2%</td>
<td>9.2%</td>
<td>43.5</td>
<td>4.0</td>
<td>25</td>
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<tr>
<td>Nowak(^5^0)</td>
<td>2.3%</td>
<td>12.8%</td>
<td>82</td>
<td>10.5</td>
<td>9.5</td>
</tr>
<tr>
<td>Fölsch(^5^1)</td>
<td>11.1%</td>
<td>6.3%</td>
<td>-77.4</td>
<td>-4.8</td>
<td>-20.8</td>
</tr>
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</table>

ERCP, endoscopic retrograde cholangiopancreatography; ES, endoscopic sphincterotomy; RRR, % relative risk reduction; ARR, % absolute risk reduction; NNT, number needed to treat. Table modified from Sharma et al.\(^5^3\).
study design and analysis limit the utility of the Polish study. Greater weight therefore should be given to the other 3 trials in drawing overall conclusions. At the State-of-the Science Conference of ERCP recently held at the NIH, the role of ERCP in pancreatitis was specifically examined. It was concluded that ERCP plays a distinct role in the very ill patient with acute biliary pancreatitis.52

Endoscopic Sphincterotomy If Stones Are Not Visualized?

When an ERCP is performed in the setting of acute biliary pancreatitis, a biliary sphincterotomy is typically fashioned when a common bile duct stone is identified. However, a sphincterotomy may also be indicated if a stone is not found in certain settings. Some patients with acute gallstone pancreatitis may not be considered candidates for cholecystectomy due to comorbid medical illnesses. Further episodes of gallstone pancreatitis may be prevented by biliary sphincterotomy, without the attendant risks of operative intervention,54–56 including during pregnancy.57,58

Recommended Approach

When confronted with a patient presenting with acute pancreatitis, we attempt to establish the etiology and severity of the episode, as therapy will vary. In the case presented here, the initial question is whether this episode is biliary in origin. The serum ALT is 330 U/L, or 10-fold elevated. With this degree of elevation, the positive predictive value for a biliary etiology is 95%. While her AST, alkaline phosphatase, and bilirubin are all elevated as well, at the levels found here, all have positive predictive values less than 90%, and therefore cannot be used with confidence to make the diagnosis. Our patient has gallstones identified on abdominal ultrasonography. While the finding of cholelithiasis on ultrasound alone is suggestive but not conclusive of a biliary origin, this finding in association with a markedly elevated ALT is highly suggestive of gallstone pancreatitis.

A fundamental question remains regarding subsequent management: will she benefit from ERCP and biliary stone removal if this is identified, and when should the ERCP be performed if this strategy is chosen? Using Ranson’s criteria, this episode of pancreatitis in our 63-year-old patient is predicted to be a severe attack (the patient has at least 3 criteria, including elevated WBC, serum glucose, and AST). However, the clinical picture is not suggestive of significant biliary obstruction (i.e., the bile duct is normal diameter, and there is no evidence of cholangitis), which if present, would argue for performance of urgent ERCP with sphincterotomy and stone extraction. The available literature, although somewhat contradictory, provides us with an approach that will hopefully maximize a favorable patient outcome. Despite the absence of biliary obstruction, we would proceed with early ERCP (within 72 hours of admission), and perform a biliary sphincterotomy if a common bile duct stone is identified. In patients presenting with mild nonobstructive biliary pancreatitis, however, we would not proceed with ERCP but rather suggest performance of cholecystectomy with intraoperative cholangiogram once the pancreatitis resolves.

Evolution of the Case

The patient undergoes an ERCP that demonstrates a single 0.5-cm stone in the common bile duct. Sphincterotomy with balloon extraction of the stone is performed. The patient’s abdominal pain slowly resolves over the next 3 days.

Subsequent Management

Need for Follow-Up Cholecystectomy

The Amsterdam group recently reviewed their experience with 120 surgically fit patients with documented gallbladder stones who had undergone ES and stone extraction and were randomized to laparoscopic cholecystectomy within 6 weeks after ERCP or a wait-and-see approach.59 During a median follow-up of 30 months, 47% of patients in the wait-and-see group experienced biliary-related events, compared with 2% in the cholecystectomy group (relative risk 22.4; P < 0.0001). Twenty-two (37%) of the 27 patients in the wait-and-see group with recurrent biliary events underwent cholecystectomy, and 6 patients (10%) required repeat ERCP for bile duct clearance of stones, whereas none were needed in those patients undergoing surgery. There was a trend to higher rates of postoperative complications (32% vs. 14%) and longer hospital stays (9 vs. 7 days) in the wait-and-see group, but these differences were not significant.

These results suggest that a wait-and-see policy is associated with a high frequency of biliary symptoms postsphincterotomy. In the era of laparoscopic cholecystectomy, it seems reasonable to recommend cholecystectomy in surgically fit patients after clearance of the bile duct. Following an episode of gallstone pancreatitis, one should proceed with surgery during the initial episode of pancreatitis (assuming that ERCP and biliary sphincterotomy are not done), once the acute symptoms have resolved. Performance of an intraoperative cholangio-
gram should be obtained, particularly if a preoperative sphincterotomy has not been performed.

**Conclusions**

While the role of ERCP in all patients with biliary pancreatitis remains controversial, current evidence supports a distinct role for endoscopic intervention in patients with a severe episode. Further study is needed to clarify the role of other imaging modalities, such as EUS and MRCP, in patients with severe biliary pancreatitis, with the goal of selectively performing ERCP in patients with documented bile duct stones.

**References**


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