Transampullary Septectomy for Post-cholecystectomy Pain

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Twenty-eight patients with chronic, incapacitating upper abdominal pain after cholecystectomy had excision of the common wall between the terminal bile duct and duct of Wirsung (ampullary septum). Twenty-two also had a sphincteroplasty; six had had this procedure previously. Pancreatic function studies, scintiscans, ultrasound and pancreatograms were non-diagnositc. Hyperamylasemia was an uncommon finding. Eight patients were found to have evidence of mild pancreatitis at exploration. There was gross scarring of the ampullary septum in 22 cases. Histologic examination revealed inflammation in 12 septa; the degree of fibrosis could not be assessed since 14 control septa from autopsy material free from biliary tract disease revealed a comparable degree of collagen and smooth muscle. There were no deaths, and minimal morbidity. In follow-up from seven to 59 months (mean = 26), 16 patients are relatively free of pain, five have occasional episodes which require non-narcotic analgesics, and seven have gained no relief from the operative procedure. A randomized controlled trial is recommended.

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PERSISTENCE OR RECURRENCE of symptoms after cholecystectomy is equally discouraging to patient and surgeon, and represents a relatively common, poorly defined problem.[5,8] An incapacitating variant of the so-called post-cholecystectomy syndrome is episodic, severe upper abdominal pain requiring potent analgesics for relief. Occasionally an overlooked or reformed stone within the common duct provides an explanation for the pain, and relief follows choledocholithotomy. More commonly, however, an etiologic agent is not revealed by extensive evaluation, including exploratory celiotomy. Inflammation and scarring of the papilla of Vater,[4] biliary dyskinesia,[14] and elongation or neuroma formation of a cystic duct remnant,[9,10] have been suspected to play a role in post-cholecystectomy pain, but conclusive evidence to support a role for these entities have not been forthcoming.

Acosta and Nardi[2] have provided convincing histologic evidence that the papilla of Vater becomes scarred and inflammed in some patients with chronic calcareous biliary tract disease. Unfortunately, an anterior 0.5 cm sphincterotomy or even a 2–3 cm sphincteroplasty does not always provide pain relief in patients with this problem.[3,7] The failure of this procedure would be predictable if the pain in this disease is pancreatic in origin, since anterior sphincteroplasty leaves the portion of the sphincter around the terminal end of the duct of Wirsung relatively intact (Fig. 1). Furthermore, inflammation of the papilla of Vater may render the ampullary septum, that thin veil of tissue between the duct of Wirsung and the terminal end of the bile duct, a thickened attachment for the undivided posterior aspect of the sphincter. Increased resistance to the outflow of pancreatic secretion could result from thickening of this tissue. It may be for this reason that Warren and Veidenheimer[15] reported improved results when dilatation of the opening of the duct of Wirsung is coupled with sphincterotomy in the treatment of mild pancreatitis.

In 1960, Bartlett and Nardi[3] described combined excision of the ampullary septum with sphincterotomy in a small number of patients with extensive scarring of the papilla of Vater. Others have also commented upon removal of the septum in selected cases.[15] A detailed analysis of patients so treated has not been reported. The following is a systematic prospective study of transampullary septectomy combined with sphincteroplasty in patients with severe, long standing post-cholecystectomy pain. A unique cultural taboo, abstinence from alcohol and tobacco, provided an ideal population for this study.

Material and Methods

Twenty-eight patients with intractable upper abdominal pain following cholecystectomy comprise the study group. Characteristics of this group are outlined in Table 1. Females outnumbered males by over four to one. Ages ranged from 23 to 60, with a mean of 40. Twenty-three were strict abstainers from alcohol and tobacco; three patients alluded to taking an occasional

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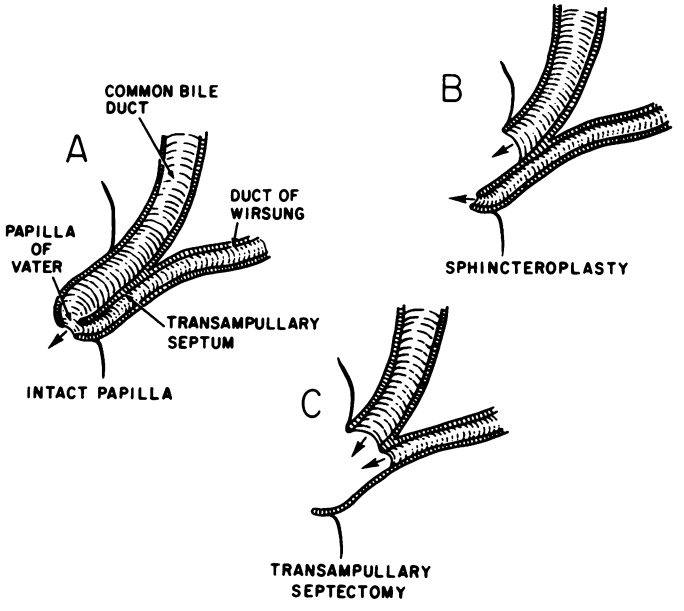

FIG. 1. Schematic of anatomical relationships within the papilla of Vater. Note the position of the ampullary septum forming the posterior wall of the bile duct and the anterior wall of the duct of Wirsung.

cocktail, and two were chronic alcoholics. Seven patients were chronic drug ingestors, and would be categorized as medical drug addicts by all standards. Only five patients were relatively free from the need of some form of analgesia on a regular basis. Four patients were judged to have a major psychiatric illness. Eight others had mild to moderate affective disorders.

All patients had undergone cholecystectomy from three months to 27 years in the past. Multiple gallstones were present in 21 cases; stones were not found in seven. The mean interval from cholecystectomy was 5.4 years. The onset of pain following cholecystectomy was variable. Some patients had persistence of the same pain that they had experienced prior to cholecystectomy; others developed pain years after gaining relief of this symptom following operation. Three patients had had a common duct exploration at the time of cholecystectomy; four patients had had a subsequent common duct exploration for stones. Six patients had a prior sphincteroplasty.

Abdominal pain represented the primary symptom which led these patients to seek medical attention. The mean duration of this symptom was 5.3 ± 1.0 (SEM) years. The pain was sudden in onset, usually epigastric in location, with referral to the right upper abdomen or back in about half the patients. Nausea and vomiting were a prominent feature of this illness. The pain was of such severity that the patient either employed self medication or visited a physician or an emergency room for injection of a narcotic for pain relief. Fever, chills, diarrhea, palpitations, and other systemic symptoms were unusual. Physical examination uniformly revealed mild epigastric tenderness with maintenance of bowel sounds, and absence of other remarkable physical findings. Hyperamylasemia was an infrequent finding. The illness was in most instances self limiting, lasting for 24 to 48 hours. Treatment was usually carried out on an ambulatory basis.

The study design consisted of admitting the patients to the University of Utah Medical Center for diagnostic workup. Preoperative assessment included consultation by members of the Division of Gastroenterology and Department of Psychiatry. Diagnostic workup included liver and pancreatic function studies, intravenous cholangiography, upper gastrointestinal endoscopy, and barium studies of the entire GI tract. Upper abdominal ultrasonography, pancreatic scintiscans, and endoscopic retrograde cholangiopancreatography were utilized when they became available. Visceral angiography was obtained in selected cases. In several instances the patient had already been extensively evaluated by a qualified gastroenterologist outside of the treatment center. Only selected studies such as retrograde pancreatograms were reattempted if previously unsuccessful.

The surgical procedures were all performed by one of us (FGM). The abdomen was entered through the incision previously employed for cholecystectomy. The large and small bowel were inspected throughout their entirety; adhesions were lysed as they were encountered. Exploration included examination of the pancreas through the gastrocolic omentum, mobilization of the second portion of the duodenum, and dissection of the cystic duct remnant and the scar tissue along the right lateral aspect of the common bile duct. An operative cholangiogram was obtained, either through the cystic duct remnant or by insertion of a #25 needle into the anterior wall of the common duct. The common duct was entered through a small choledochotomy and an exploration carried out. A 3 mm Ferris probe was passed through the papilla of Vater into the duodenum after attachment to a #5 French filiform catheter. The precise location of the papilla was iden-

TABLE 1. *Clinical Characteristics*

Females to males	23 to 5
Age (yrs)*	40
Duration of pain (yrs)*	5.3
Interval postcholecystectomy (yrs)*	5.4
Prior choledochotomy	7
Prior sphincteroplasty	6
Major psychiatric illness	4
Drug addiction	7
Alcoholism	2
Total abstinence (from alcohol)	23

* Mean.

tified by palpation through the anterior wall of the duodenum, and a two centimeter longitudinal duodenotomy was performed over the site. Insertion of small loop retractors into the duodenum provided a full view of the papilla of Vater in most cases. Occasionally it was necessary to locate the filiform and elevate the papilla by gentle traction on either end of this flexible instrument. Stay sutures of 4-0 silk were placed at three and nine o'clock on the lateral aspects of the papilla in order to allow further elevation to a position at or above the level of the duodenotomy. Inspection of the papilla at this point occasionally revealed the opening of the duct of Wirsung on its posterior lip. Four power ophthalmologic loops and a head lamp greatly facilitated this maneuver. An anterior three millimeter incision was then made in the opening of the papilla at a point just opposite the opening of the duct of Wirsung, or at a point precisely between the lateral stay sutures. The bile duct mucosa was secured to that of the duodenum with 5-0 Dexon. This procedure was continued until an opening of two to three centimeters was obtained. At this point the opening of the duct of Wirsung was always in full view on the inferior lip of the papilla or within a few millimeters of its opening. A prominent common channel was not encountered in this group of patients.

A pancreatogram was obtained if the pancreatic duct had not been previously visualized. This was accomplished by threading a #22 polyethylene catheter into the full length of the pancreatic duct. Two milliliters of 60 per cent Conray was injected into the ductal system as the catheter was withdrawn; an x-ray was taken as the catheter tip exited from the opening of the duct of Wirsung.

A 23 gauge needle or catheter was placed into the duct of Wirsung at a point proximal to its opening at the base of the ampullary septum. Placement of this catheter was facilitated by the insertion of a small probe into the duct of Wirsung. Secretin was then administered intravenously (one unit per kilogram body weight) in order to stimulate pancreatic secretion. When flow was constant pressures were taken before and following incision of the ampullary septum. It was possible to make this measurement in only half of the instances in which it was attempted. The septum was excised to a point deep within the cleft between the common bile duct and duct of Wirsung. This angle was closed when necessary with interrupted 7-0 chromic catgut sutures to approximate the bile duct and duct of Wirsung. The duodenotomy was closed in a transverse fashion with an inner row of 4-0 Dexon and an outer row of 4-0 silk, each placed in interrupted fashion. The closure was covered with an omental patch. A #12 French T-tube was secured in the common duct with 5-0 silk sutures placed in a closely spaced interrupted fashion to insure

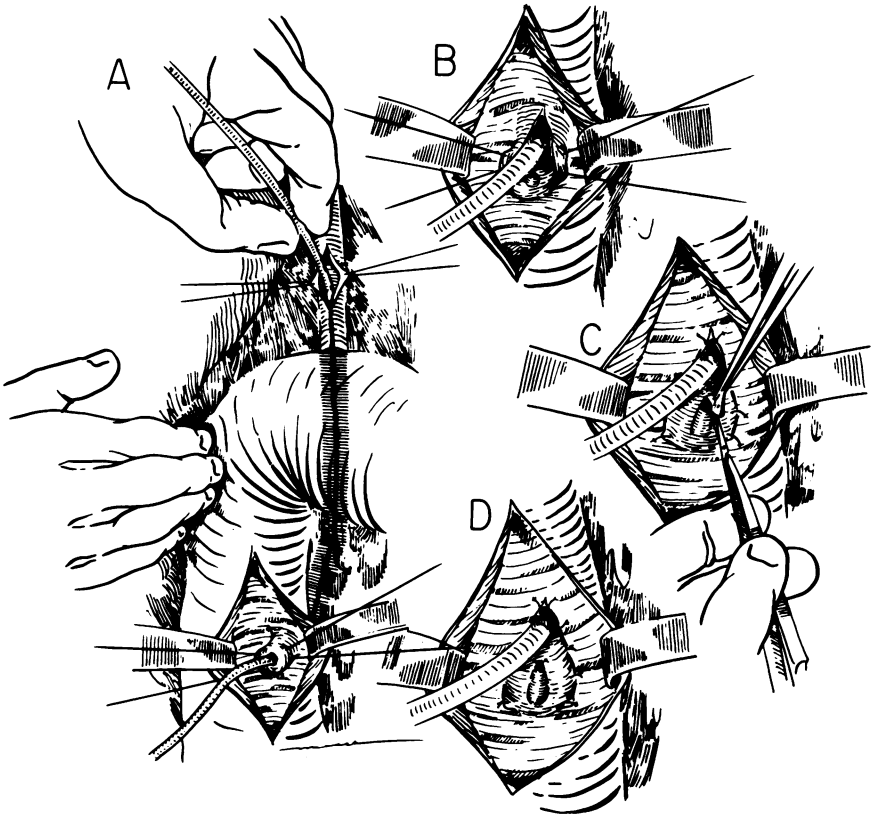

FIG. 2. (A) A filiform catheter is passed down through the papilla of Vater. The duodenum is opened for a distance of two centimeters over the papilla. (B) Traction sutures are placed on either side of the papilla. A small incision is initiated in the anterior surface of the papilla. The bile duct mucosa is secured to the duodenal mucosa with 5-0 polyglycolic suture material. These sutures provide further traction on the papilla. (C) The long sphincteroplasty has been completing revealing the full length of the anterior surface of the ampullary septum. (D) The septum has been excised, forming a direct communication between the duct of Wirsung and the posterior wall of the common bile duct. One or two sutures of 7-0 chromic catgut have been placed at the apex of this junction.

TABLE 2. *Laboratory Assessment of Pancreaticobiliary System*

Test	Patients	Abnormal	Percentage
Amylase	28	7	25.0
UGI Series	28	5	17.9
IV Cholangiography	28	4	14.3
Pancreatography	24	5	20.8
Pancreatic Echo	11	3	27.3
Secretin Test	12	3	25.0
Scintiscan	11	5	45.5
Angiography	7	1	14.3
Nardi Test	4	1	25.0

a bile tight closure. Two medium sized Penrose drains were placed into the operative site; drains and T-tube were brought out of the peritoneal cavity through openings separate from the incision The details of the operation are shown in Figure 2.

Postoperative management included nasogastric suction for 48 to 72 hours, parenteral fluid administration, Foley catheter drainage for 48 hours, T-tube drainage into a bile bag for eight to ten days, gradual removal of the drains beginning on the fifth day, and progressive oral alimentation as tolerated after removal of the nasogastric tube. The patients were discharged on the ninth to the nineteenth day after obtaining a normal cholangiogram and removal of the T-tube. All patients received preoperative antibiotics, either Ampicillin or Keflin, which was continued for five days post operation. Urinary and serum amylases were obtained on the evening of surgery and as indicated thereafter.

The initial follow-up was conducted by the operating surgeon Patients were returned to the care of their referring physicians following two or three postoperative ambulatory visits. An interval follow-up interview and examination was performed by a gastroenterologist (MMB) who was unfamiliar with the patient's prior history or operative findings. He was informed, however, as to the type of operation that had been performed. Some patients could only be contacted by telephone or by a written questionnaire, which included all the questions asked in the personal interview.

Material removed at operation was evaluated in a routine manner by the faculty of the Department of Pathology A second review was accomplished by a pathologist (DM) before and after an extensive histologic examination of ampullary septa obtained from 14 cadavers without biliary tract or gastrointestinal disease. This latter reviewer was not familiar with the case histories of the study patients.

Results

Results of special pancreatic studies are shown in Table 2. Elevated serum or urine amylase was present in seven of 28 (25%) patients. The elevations were, in general, of modest degree (less than 1,000 Somogyi units) and intermittent. Five patients had upper GI series demonstrating "pad" signs or other mucosal changes suggesting pancreatitis. Dilatation of the common bile duct or delay in emptying was present in four patients. Endoscopic retrograde or intraoperative pancreatography was successful in 24 of the 28 patients. Irregular duct margins, "beading" and other irregularities were documented in five patients. Echo pancreatography revealed enlargement of the pancreas in three of 11 patients so studied. No pseudocyts were detected. Three patients had abnormally low bicarbonate responses following stimulation with Secretin two units per kg. None of the patients had a significant rise in amylase following Secretin administration. Selenomethionine pancreatic scans were obtained in 11 patients. Inhomogenity and diminished pancreatic visualization was present in five studies. Visceral angiography was obtained in seven patients. One patient had changes suggesting pancreatitis. A Nardi test reproduced one patient's pain but was not associated with abnormal enzyme responses.

Gross inspection and palpation of the pancreas at the time of laparotomy revealed two patients with findings consistent with moderate pancreatitis and six with minimal pancreatitis; 20 were considered normal. On an individual basis, six patients had no abnormal pancreatic test, 15 had one abnormal study, two had two abnormalities and five had three abnormalities. Patients with or without pancreatitis had the same frequency of abnormal tests.

Intraductal pancreatic pressure during secretin stimulation was obtained in nine patients. Prior to septotomy this pressure ws 24.7 ± 3.3 cm of saline. Following septotomy the pressure decreased to 10.6 ± 3.4 cm of saline. Two of the patients had an insignificant drop in pressure.

Biopsies of the ampullary septum were handled in a routine manner by the Division of Surgical Pathology and examined by a staff pathologist unfamiliar with the patient's history, operative findings, or study design. Sixteen specimens were reported to be normal, and 12 revealed varying degrees of inflammation or fibrosis. Subsequently, a pathologist familiar with the goals and design of the study, but not acquainted with the operative findings or other characteristics of the study population reexamined 27 of the 28 specimens utilizing trichrome stain and polarized microscopy in addition to the usual hematoxylin eosin stains employed on routine histologic examination. His study confirmed that 16 of the septa were histologically similar to those obtained

FIG. 3. a (top) Histologic representation of a normal ampullary septum (H & E −160×). b (bottom) This photomicrograph of a septum removed from a study patient reveals glandular atypia, and chronic inflammation.

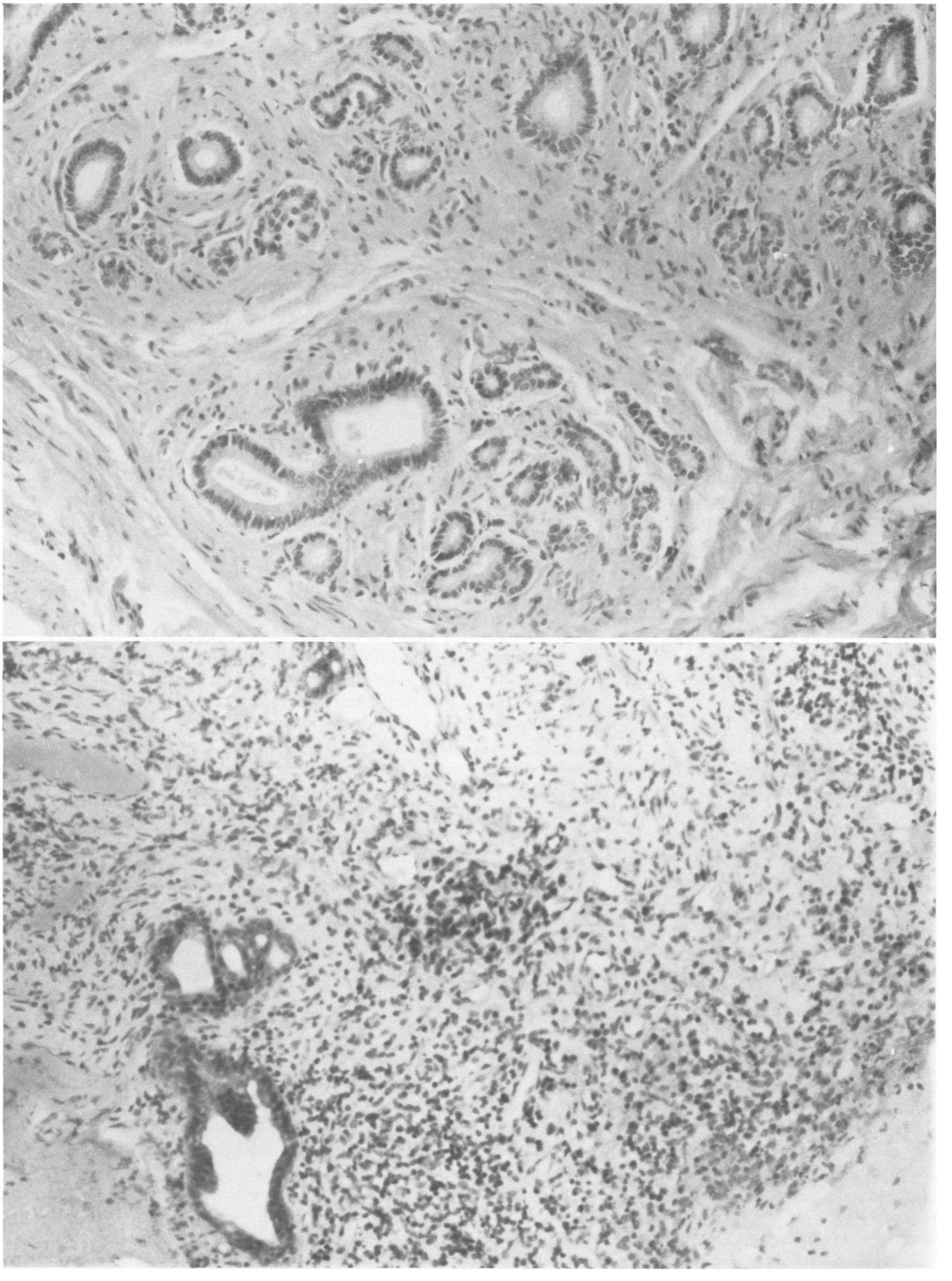

TABLE 3. *Outcome Following Sphincteroplasty with Septectomy*

Result	Relief of* Pain	Reduction in† Medication	Normal* Lifestyle	Overall* Benefit
Good	16	14	15	16
Fair	5	8	6	5
Poor	7	6	7	7

Degree of improvement:
* Good = > 75%, Fair = > 50% < 75%, Poor = < 50%.
† Good = 0 medication, Fair = non-narcotic medication, Poor = no change.

from 14 age matched autopsy control specimens and therefore considered to be normal. The autopsy material from patients without evidence of biliary tract disease revealed dense bundles of collagen and smooth muscle, interspersed with simple glands. Because of these findings it was difficult to assess in a meaningful way the degree of septal fibrosis in the study group. We, therefore, identified as abnormal only those septa which revealed a significant degree of inflammation. Eleven septa were abnormal: six had chronic inflammation, four had chronic and acute inflammation, and one had acute inflammation only. One specimen was not available for re-examination. The histologic features of normal and abnormal septa are compared in Figure 3.

The morbidity following operation was minimal. There were no deaths and one major complication, a pulmonary embolus. There were two cases of mild pancreatitis, two urinary tract infections, two undiagnosed fevers, one wound infection, one prolonged ileus, one injection site infection, one dislodged T-tube, one drug rash, and one instance of pulmonary atelectasis. Sixteen patients had an uncomplicated course. The length of hospitalization after operation was 12.0 ± 0.5 days.

Efficacy of surgery was assessed by personal interviews and questionnaires conducted by a gastroenterologist (MMB) unfamiliar with the cases. Patients were asked to rate their degree of pain relief, quantify reduction of narcotic and analgesic pain medication, estimate return to normal lifestyle, and evaluate overall benefit. The follow-up period ranged from seven to 59 months, with an average of 26 months. Results are presented in Table 3.

Relief of pain was fair to good in 21 of 28 patients. Seven patients had poor relief of pain: three men and four women. Of these, two were known to ingest alcohol and two were addicted to narcotics. Three of the seven had gross evidence of pancreatitis. Reduction of pain medication generally correlated with relief of pain. In most cases with good pain relief, all pain medications were discontinued; some patients required occasional non-narcotic analgesics. Fair pain relief was generally associated with discontinuation of narcotic analgesics and intermittent use of non-narcotic analgesics. Only a slight reduction in medication was noted in those individuals who had less than 50% relief of pain. A full return to normal lifestyle was achieved in most patients relieved of pain; those with poor relief maintained their disability and behavior characteristics of the chronic illness syndrome. Overall benefit was fair to good in 22 of the 28 patients (>50% improvement). One of these patients had only minimal pain relief, yet he had a significant reduction of pain medication and improvement of lifestyle.

Discussion

Post-cholecystectomy pain that cannot be ascribed to a specific cause even after intensive laboratory investigation is a difficult unresolved problem. Patients afflicted with this illness gradually withdraw from an active and productive life; many become addicted to narcotics. It is easy to appreciate why such individuals become estranged from the medical profession after years of failure to gain relief from their symptoms. The authors recognize the placebo effects of an operation employed in this setting, and the critical need for a control population. It appeared premature, however, to conduct a controlled trial until a conceptual approach to the problem had been established.

The rationale for excision of the ampullary septum and sphincteroplasty is based upon the hypothesis that post-cholecystectomy pain is of pancreatic origin and results from obstruction to the flow of pancreatic secretion. Inflammation and scarring of the ampullary septum may result from repeated passage of gallstones through the papilla of Vater, or from cholesterolosis of the ampulla of Vater (observed in two cases in this series). This hypothesis gains support from the observation of Acosta and his colleagues,[1] that gallstones can be recovered in the stools of the majority of patients with gallstones and pancreatitis.

Support for the obstruction hypothesis rests on three pieces of data: 1) 21 patients (77%) were improved after septectomy, 2) four of six patients with prior sphincteroplasty obtained a good reuslt, and 3) pressure within the pancreatic ductal system immediately decreased two fold following division of the ampullary septum during secretin activated pancreatic secretion.

There is, however, little objective evidence that pain in these patients was due to obstruction to the duct of Wirsung. For example, only 12 of 28 patients had histologic evidence of inflammation in the septum even though the surgeon interpreted that 23 had significant scarring in this area. Furthermore, gross evidence of pancreatic disease or hyperamylasemia were unusual findings, although most patients had one or more abnor-

mal test. The fact that only two of 12 patients had pain during their secretin test is also evidence against their pain being secondary to an obstruction to outflow of pancreatic secretion.

It is difficult to separate the role of septectomy from that of sphincteroplasty in these results. Sphincteroplasty was necessary in order to gain full visualization of the ampullary septum. That sphincterotomy or sphincteroplasty alone can provide pain relief in patients with stenosing papillitis has been well recorded.[4,6,11–13] None of the patients in this study had evidence of advanced fibrosis of the papilla of Vater. The fact that four of the six patients with unsuccessful prior sphincteroplasty had a good result lends further weight to the possibility that the septectomy may be the ciritical component of this procedure.

A search of the literature has not revealed a systematic assessment of ampullary septectomy and sphincteroplasty for post-cholecystectomy pain. Excision of the septum in cases where there is obvious stenosis of the opening of the duct of Wirsung is common practice. In this situation, there is usually overt evidence of chronic fibrosing pancreatitis. None of the patients in this series had evidence of advanced pancreatic disease. We have, however, performed this procedure on three alcoholic patients with fibrosing pancreatitis and normal gallbladders. All have continued to drink and have persistence of their pain. The fact that 23 of the patients in the present study were abstainers from alcohol may have contributed in some way to the relative success obtained in this series.

The reason for episodic pain in these patients is not known. We presume that it is pancreatic in origin, rather than arising from the biliary tree. A simple obstructive hypothesis is advanced to explain the syndrome, but unfortunately, methods to test this hypothesis are lacking. Furthermore, the physiology and hence the pathophysiology of the Vaterian system is complex and poorly understood. It is likely that the mechanisms of pain production involve a variety of neural and humoral influences. As these are being studied, the efficacy of ampullary septectomy should be tested by a controlled randomized trial in view of the encouraging preliminary results.

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Discussion

Dr. Marshall K. Bartlett (Boston, Massachusetts); A good many years ago we became interested in the work of Drs. Doubilet and Mulholland on sphincterotomy, and we began to select some patients, most of whom had had a previous cholecystectomy, and who were still having attacks of pain, which we thought might be due to some outflow obstruction to the pancreatic duct system. Selection of these patients to me has always been very difficult. Alcohol, drugs, emotional overlay—these may be present, some or all of them, to confuse the picture; and I think this really has been the crux of the problem over the years.

Our standard technical approach has been very much like the one you have heard described just now. We expose the papilla transduodenally, and try to standardize on a 15 mm sphincteroplasty. We have done several hundred of these operations at the Massachusetts General Hospital. They have been done by many surgeons and it is not possible to completely standardize any procedure when it is done by many people. As much as possible, we have kept to a 15 mm sphincteroplasty.

And then we identify the opening of the duct of Wirsung, and we believe that it normally should admit a three millimeter dilator without difficulty. If it will not, we incise the septum, as Dr. Moody has described, and continue until it is at least three millimeter in diameter. We have not attacked that septum quite as vigorously as Dr. Moody has.

We outline the pancreatic duct system, as he does, and as you know, sometimes the duct of Wirsung will not be the main drainage system. If it is not, we identify the papilla of the duct of Santorini, and do plastic procedure on it to provide an adequate lumen.

We have had reasonable success with this over the years, but certainly nowhere near 100%, and the difficulty of patient selection is still our greatest problem.