Choledocholithiasis

Endoscopic Sphincterotomy or Common Bile Duct Exploration

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A prospective randomized trial was conducted of preoperative endoscopic sphincterotomy and surgery (ES&S) or surgery alone (SA) in 52 patients with cholecystolithiasis and choledocholithiasis that were candidates for elective surgery. After ES&S 65% of patients were stone free. Eighty-eight per cent of patients with SA were stone free after surgery ($p < 0.05$). Three patients in each group had residual stones at the completion of the operation. Five of these six had more than 20 common bile duct (CBD) stones. There was one episode of major hemorrhage in a patient in each group and no deaths. Costs were essentially equal for the individual patient with a successful ES as compared to SA. Societal costs of a program of preoperative endoscopic retrograde cholangiopancreatography and ES would be higher because of the cost of screening for patients with CBD stones. These results do not support preoperative ES as a technique for clearance of the CBD of stones on the basis of efficacy, morbidity rate, or cost.

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CHOLECYSTECTOMY, FIRST PERFORMED by Karl Langenbuch in 1882, has become the standard therapy for symptomatic cholecystolithiasis.[1] Newer options available for treatment of cholecystolithiasis include laparoscopic,[2] lithotriptic,[3] and endoscopic techniques[4] and chemical dissolution.[5] Common bile duct (CBD) stones present or suspected at the time of cholecystectomy traditionally have been treated by choledochotomy, common bile duct exploration (CBDE), stone retrieval, and T-tube placement. The newer techniques mentioned above also can be used in the management of choledocholithiasis.[4,6,7]

This report will concern a prospective randomized study of preoperative endoscopic sphincterotomy (ES) in conjunction with surgery (ES&S) or surgery alone (SA) in patients with chronic cholecystitis with cholecystolithiasis and choledocholithiasis who were candidates for elective surgery. Whether, in such patients, ES is as effective as CBDE in retrieval of CBD stones and what is the relative morbidity of these two approaches have not been established. Costs will be compared.

Methods

Patients admitted to the Los Angeles County—University of Southern California Medical Center with a diagnosis of cholecystolithiasis and possible choledocholithiasis and who were candidates for elective surgery were considered for entry into the study. Cholecystolithiasis was documented by ultrasound in all patients and choledocholithiasis was suspected on the basis of a serum bilirubin level greater than 2 mg/100 mL, previous hyperamylasemia, or ultrasound examination that revealed either a CBD larger than 1 cm in diameter or probable CBD stones, or both. The study was approved by the Institutional Review Board and informed consent was obtained from each participant. All patients underwent endoscopic retrograde cholangiopancreatography (ERCP). Those with CBD stones were assigned randomly to one of two groups, preoperative ES and surgery (ES + S; group 1), or surgery alone (SA; group 2). A computer-generated randomization sequence was used. The endoscopist who made the decision to enroll the patient was blinded as to the treatment that would be assigned. The sphincterotomy was performed immediately after ERCP. Clearance of the CBD stones by basket retrieval or by subsequent spontaneous passage was left to the discretion of the endoscopist. Cholecystectomy was scheduled electively. Surgeons were not blinded as to the group to which the patients had been randomized. The decision to perform CBDE during the operation was based on all relevant

Presented at the 102nd Annual Scientific Session of the Southern Surgical Association, Boca Raton, Florida, December 3–6, 1990.

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Reprints will not be available.

Accepted for publication January 3, 1991.

considerations, including operative cholangiography. A CBDE was performed in all patients without a technically satisfactory intraoperative cholangiogram that did not show CBD stone(s). T-tube cholangiograms were performed in the early postoperative period in all patients who had CBDE. For purposes of this paper, innumerable CBD stones are defined arbitrarily as more than than 20. The accuracy of numeration beyond that point becomes questionable.

Duration of surgery in minutes and days of hospitalization from the day of surgery until hospital discharge were calculated for all patients. The cost of professional services at the adjusted prevailing rate was calculated based on Medicare allowable charges for the endoscopist, surgeon, and anesthesiologist for our Medical Service Area. Actual median duration of operation in our patients was used to calculate anesthesiology fees. Radiologist charges were not determined. The fee for interpretation of radiograms associated with ES would be approximately balanced by the additional fees for postexploration cholangiogram in patients with CBDE.

Results

Fifty-two patients completed the study. Twenty-six patients were randomized to ES&S (group 1) and 26 to SA (group 2). The patients in the two groups were comparable as to age, sex, and indication for ERCP. Multiple indications for ERCP were present in several patients. The patients were predominantly young Hispanic women without significant comorbidity. Relevant data are listed in Table 1.

The interval from ERCP to operation varied. The interval in group 1 ranged from 0 to 213 days and in group 2 from 0 to 24 days. Five patients in group 1 and four patients in group 2 underwent surgery within 48 hours of ERCP. The median time from ERCP to operation was 4 days in each group. Delays of 48 hours to 1 week after ERCP usually were due to scheduling problems. Longer delays were a result of patient refusal to proceed with surgery.

TABLE 1. *The Demographics of the Patients and the Indications for ERCP*

	ES and Surgery (26 cases)	Surgery Alone (26 cases)
Demographics		
Male:female	6:20	3:23
Mean age (years)	48.4 (31–78)	42.4 (20–86)
Indication for ERCP		
Jaundice (bili. > 2 mg. %)	17	18
Hyperamylasemia	6	3
Ultrasound positive CBD: stones or > 1 cm	14	13

Bili., bilirubin.

Exact data were not available concerning the number of cases of suspected CBD stones screened by ERCP who would have been asked to participate in the study had a CBD stone been demonstrated. A review of the endoscopy log suggests that about three patients were screened for each patient who was randomized.

Group 1: Endoscopic Sphincterotomy and Surgery

Endoscopic sphincterotomies were performed in 24 of the 26 patients. Sphincterotomy was not technically feasible in two patients. A CBDE was not performed in 14 patients with a normal intraoperative cystic duct cholangiogram. A CBDE was performed in the remaining 12 patients. These included the two patients with an unsuccessful attempt at ES. Stones were retrieved in 9 of the 12, or 35%, of the original 26 patients. In seven of these nine patients with persistent stones after ES, an attempt at clearance of the CBD by basket retrieval of CBD stones had been made during the endoscopic procedure. Operation was performed on these 9 patients from 1 to 213 days after sphincterotomy, with a median of 4 days.

Stones were not found in 3 of the 12 patients with a CBDE. In two of these three patients the surgeon did not perform a pre-exploration cholangiogram. His reasons were a serum bilirubin of 6 mg/100 mL with previous cholangitis in one patient and a common bile duct that measured 1.5 cm in diameter in the other. Regardless of the result of the cholangiogram, he intended to explore the duct. These operations were performed 5 and 12 days after ES, respectively. In the final patient with a negative CBDE, blood clots were found as an explanation for an abnormal cholangiogram. Because of scheduling feasibility, this operation was performed on the same day as the endoscopic sphincterotomy.

Three patients in group 1 had persistent stones after CBDE. In two patients the stones were documented by postoperative T-tube cholangiogram. A 21-year-old woman with innumerable CBD stones and hepatic duct stones required an emergent operation for postsphincterotomy hemorrhage from the ampulla. A duodenotomy was performed and hemostasis was secured by transduodenal sutures. The CBD was explored but the surgeon did not persist in an attempt to remove all of the intrahepatic stones in this seriously ill patient. A second patient had innumerable stones removed from the CBD and hepatic ducts at operation performed 24 hours after sphincterotomy. Completion cholangiogram was normal. The surgeon decided to rely on the sphincterotomy for passage of any residual covert stone rather than to perform a choledochoenteric anastomosis. Postoperative cholangiogram revealed a persistent stone. The third patient, also with innumerable stones in the CBD, had a normal postoperative T-tube cholangiogram. She returned several months after removal of the T tube with jaundice. Resid-

ual stones were documented by ERCP. The residual stones in all three patients were managed successfully by basket retrieval or endoscopic clearance.

Group 2: Surgery Alone

Cystic duct cholangiogram was normal in three patients and a CBD exploration was not performed. Common bile duct exploration was performed in the remaining 23 patients. Common bile duct stones were present in 19, or 73%, of the original 26 patients. Stones were not found in four patients at CBDE. The surgeon decided against pre-exploration cholangiogram in two of these four patients because of the positive ERCP that was performed 4 and 6 days earlier, respectively. A third patient had a total bilirubin level of more than 10 mg/100 mL immediately before operation and the final patient had a CBD that measured 2 cm in diameter. In both of the latter patients, the surgeon was unwilling to omit common bile duct exploration, regardless of the results of cholangiography.

Three of the twenty-six patients (12%) in group 2 had persistent stones after CBDE. This represented 16% of the patients with stones in group 2. Two of these three patients had innumerable stones removed from the common bile duct and hepatic ducts during the operation. Completion cholangiograms were negative in both of these patients. The surgeon elected not to perform an operative choledochoenteric drainage but rather to rely on radiologic or endoscopic intervention after operation for any residual covert stones. A postoperative T-tube cholangiogram revealed residual stones in each patient. These were successfully managed by basket retrieval or endoscopic clearance. A third patient with 12 stones at operation had a normal postoperative T-tube cholangiogram. At the time of his death 18 months later from colon cancer, autopsy revealed a CBD stone.

Data regarding status of stones in the CBD at various times in the study are depicted in Table 2. The end point of the study was designed to be stones present at operation in group 1 and after the operation in group 2. The 35% incidence of persistent stones after ES as compared to a 12% incidence after CBDE in group 2 is significant by Fisher's exact test, with a p value less than 0.05. For purposes of statistical analysis, patients were left in the original group to which they were randomized.

Complications

Hyperamylasemia developed in three patients in group 2 after ERCP but resolved in each patient within 72 hours. There was one episode of major hemorrhage in each group. The case of hemorrhage after ES in group 1 that required emergency celiotomy has already been discussed. A patient in group 2 had a dense inflammatory process with a cholecystoduodenal fistula identified during operation. The fistula was not seen during endoscopy. The fistula was closed. The patient bled after operation and required re-exploration with religation of the cystic artery.

TABLE 2. *The Number of Cases with Stones in the CBD at Various Times During the Study*

	ES and Surgery No. Pts. (%)	Surgery Alone No. Pts. (%)
At ERCP	26 (100%)	26 (100%)
	|	
	Sphincterotomy	
	|	
At operation before CBDE	9 (35%)*	19 (73%)
At follow-up	3 (12%)	3 (12%)*

* $p = <0.05$.

There were no deaths in either group. Other complications were one minor hemorrhage from the papilla in one patient from group 1 and one from the wound in one patient in group 2, a minor wound infection that occurred in a patient in each group, a sacral decubitus in a patient in group 1, and a forearm rash in a patient in group 2.

A major complication occurred in a patient being screened for participation in the study, but not as yet randomized. A 50-year-old woman had been admitted to the hospital with gallstone pancreatitis. After the serum amylase returned to normal and clinical manifestations of pancreatitis resolved, she underwent ERCP. A duodenal perforation occurred and emergency celiotomy was performed with closure of a 15-mm perforation. Cholecystectomy and CBDE were performed. One stone was retrieved from the CBD.

Endoscopic Sphincterotomy Versus *CBDE*

The success of ES or CBDE in clearing the CBD of stones was calculated by comparing the result of ES in patients with CBD stones documented by ERCP immediately before ES with that of CBDE that was performed in cases with proved stones during operation from either group. Seventeen of twenty-six patients (65%) were stone free after ES as documented by subsequent intraoperative cholangiography. Seventy-nine per cent of the 28 patients with documented stones at the time of operation were stone free after operation. Five of the six patients with residual stones after CBDE had innumerable CBD stones (Fig. 1). The above calculations represent cross-over from original randomization and two disparate populations of patients. It was concluded that a study of a statistical difference between these two populations would not be valid.

Time Considerations

The median duration of operation in patients randomized to group 1 (ES&S) was 151 minutes, with a range from 80 to 300 minutes. The median duration of hospi-

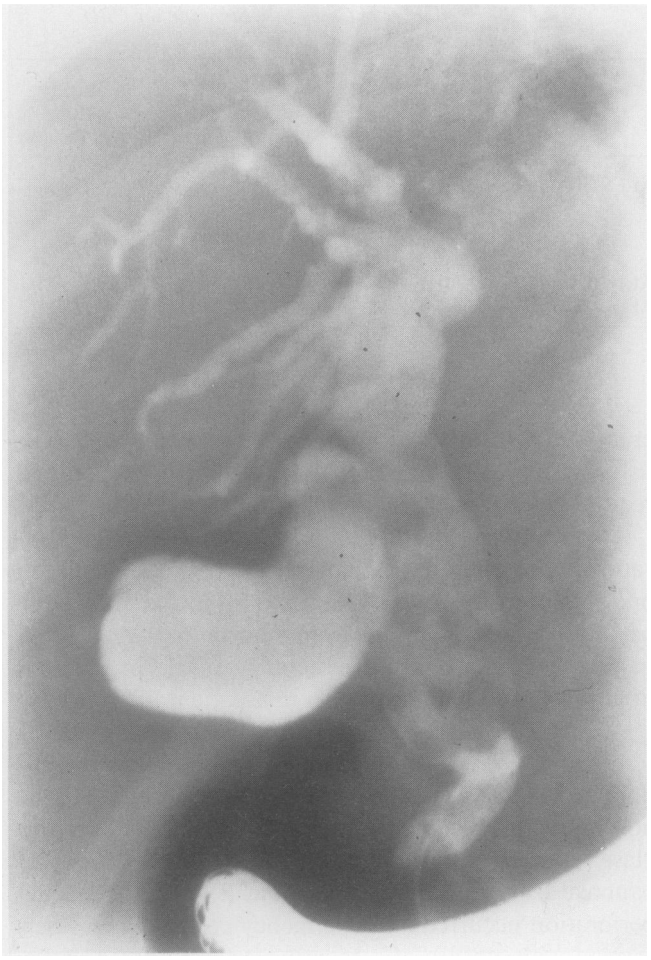

FIG. 1. This cholangiogram was obtained at the time of ERCP and reveals innumerable CBD stones. The patient was randomized to ES. There were two residual stones in the CBD at the time of the operation, which was performed 48 hours later.

talization in group 1, beginning with the day of surgery, was 5 days, with a range from 2 to 19 days. The median duration of operation in patients randomized to group 2 (SA) was 214 minutes, with a range from 115 to 420 minutes. The median duration of hospitalization in this group was 6 days, with a range from 4 to 22 days.

The duration of hospitalization from the day of surgery in patients with successful ES and who did not require CBDE ranged from 2 to 12 days, with a median of 5 days. The comparable figures for patients from either group who underwent CBDE were a range of 4 to 22 days and a median of 7 days.

Professional Cost

Professional fees for the endoscopist, surgeon, and anesthesiologist as calculated for Medicare reimbursement for a typical case are depicted in Table 3. For a patient with successful ES who did not require CBDE, the professional fees totaled $2952.00 and those for a patient undergoing cholecystectomy and CBDE the fees were $2740.00.

Discussion

Endoscopic sphincterotomy was first described in 1974 independently by Classen and Demling in Germany,[8] and Kawai from Japan.[9] Sphincterotomy initially was used for patients with recurrent or retained CBD stones after cholecystectomy with or without CBD exploration.[10,11] As experience grew the application of sphincterotomy in the management of CBD stones was advocated in high-risk patients,[12] patients with cholangitis,[13] and patients with acute biliary pancreatitis.[14] Endoscopic sphincterotomy to permit stone passage has been suggested as an alternative to cholecystectomy in patients with cholecystolithiasis with or without choledocholithiasis and with or without a patent cystic duct[4,15-18] or as a method for managing choledocholithiasis before elective surgery in patients with synchronous cholecystolithiasis and choledocholithiasis.[19,20] The latter indication is the subject of this study and has been the basis for one previous randomized study.[21]

Reports of the efficacy of ES in clearing the CBD of stones are as high as 90%.[22] Cases with basket retrieval or the use of other techniques for clearance of stones as well as those with spontaneous passage are included. Most studies report a percentage of clearance at the completion of the initial procedure, whereas others calculate the percentage based on multiple endoscopic procedures.[20,21] Few studies have verified that the ducts are stone free by subsequent cholangiography. Surgeons are well aware that cholangiography at the completion of CBDE may not reveal calculi, whereas the postoperative cholangiogram will reveal residual stone.

The literature on the efficacy of CBDE in clearance of CBD stones is also somewhat confusing. Reports may state the percentage of residual stones by postoperative cholangiogram of all patients who had a CBDE or only among those with a CBDE whose ducts harbored stones. Way and associates[23] reported a 7% incidence of retained

TABLE 3. *The Cost of Successful ES and Cholecystectomy Compared to that of Cholecystectomy and CBDE*

Successful ES and Surgery			Cholecystectomy and CBDE
Hospital			
>Preop. Days for ES		=	>Postop. Days for CBDE
Endoscopy Suite		=	>OR Time
Professional fees			
Endoscopist	$800		
Surgeon	$1312		$1680
Asst. surgeon	$328		$420
Anesthesiologist	$512		$640
Total	$2952		$2740

stones, a rather typical figure. This was for all cases of CBD exploration. The incidence among cases with choledocholithiasis was 10%. In a series reported subsequent to the introduction of intraoperative choledochoscopy, Felliciano and associates[24] reported a 8.9% incidence of retained stones in patients with CBDE who had ductal stones. Glenn,[25] in a collected series from various clinics of 16,700 cases of CBDE, reported a 4.3% incidence of retained CBD stone. The rate among cases from whom stones were removed was 9.5%. Thus a figure of about 10% for the incidence of retained stones by postoperative cholangiogram among patients with CBD stones at operation probably is a reasonable estimate.

Experienced surgeons know that the risk of retained stones is vastly increased in patients with innumerable stones in the common and hepatic ducts. A negative completion cholangiogram too often fails to reveal a covert stone lurking in an hepatic duct that is demonstrated on a postoperative cholangiogram. Cotton[22] has emphasized the hazards inherent in attempting to compare reported results within and between groups of patients treated by ES or CBDE.

In this study a significantly greater number of CBD stones were present at surgery in cases randomized to preoperative ES than in patients randomized to surgery alone. This was the intended end point of the study. The incidence of residual stones among patients undergoing ES also was higher than that of all patients in the study who underwent a CBDE and in whom stones were present.

There are hazards in interpretation of this data with respect to residual stones. Seven patients in whom stones were documented at the time of ERCP and who were randomized to surgery alone did not have stones in the CBD at the time of operation. Presumably the stones were passed spontaneously between ERCP and the day of operation. Credit is given to ES for clearance of stones in all patients undergoing ES and in whom stones were not present at the time of operation (17 patients). A number of these patients might have passed these stones spontaneously without endoscopic sphincterotomy. Finally stones present in the CBD after sphincterotomy could represent stones that passed from the gallbladder to the CBD after ES and successful clearance of the CBD and in the interval between ES and surgery. We assumed that all CBD stones present at surgery and after ES were failures of ES.

This study demonstrates the challenge in management of innumerable CBD stones. Three patients from each group had residual stones at the completion of the study. Five of these six patients had innumerable CBD stones. When 20 or more stones are removed from the CBD, one or more additional stones are likely to be present. Formerly such cases were considered during the first operation for a drainage procedure to permit subsequent passage of residual stones. Controversy existed as to whether the preferable procedure was a choledochoduodostomy, choledochojejunostomy, or transduodenal sphincteroplasty. With the advent of basket retrieval and ES, such drainage procedures are less frequently used at the first operation.[22,26] As in the cases in this study, the surgeon is more prone to rely on postoperative basket retrieval or transduodenal endoscopic procedures for retrieval of residual stones. Such procedures were successful in our patients with retained stones after surgery.

Complications of ES were significant. They included three instances of hyperamylasemia, one episode of major hemorrhage, and one episode of duodenal perforation in a patient screened but not randomized to the study. Conversely there was one major episode of hemorrhage in the SA group.

There were no deaths among our patients. This is consistent with experience with either cholecystectomy and CBDE or ES in good-risk patients. With either of these procedures the mortality risk should not exceed 1%.[19,22,27,28] A policy of ES before surgery could not be expected to effect favorably this low mortality rate from cholecystectomy and CBDE in good-risk patients, and indeed the cumulative mortality from both procedures might be higher than that for either alone.

Our results must be compared with those reported by Neoptolemos and associates[21] in their randomized study of ES and surgery or surgery alone in cases similar to ours. They randomized twice as many cases. The interval between endoscopy and surgery varied widely as in our patients. The definition of successful ES and stone clearance was a clear duct, as judged by the endoscopist, at the end of the endoscopic procedure rather than findings at subsequent operation, the end point of our study. Cholangiograms performed at the time of ES were assumed to be 100% accurate, a most questionable assumption. Five patients refused surgery after ES and had no further objective confirmation of the success of ES. One patient, defined as a success for ES, required more than one endoscopic procedure for stone clearance. The paper does not state whether at operation every case had either a negative cholangiogram or a CBDE. In two 'successful' cases of ES, CBD stones were present at the time of operation. The stones in these patients were assumed to have passed from the gallbladder to the common duct in the interval between ES and surgery. We considered all CBD stones at surgery to represent failure of ES. Thus their figure of 91% success for ES cannot be compared with our figure of 65%, and such an attempt would epitomizes Cotton's[22] caution of comparing "apples and oranges."

Major complications reported by Neoptolemos[21] were more frequent in patients with ES than in those with SA. A review of their data leads to the conclusion that the severity of the major complications also was greater with

ES. This is consistent with our experience, although our overall rate of complications was low in both groups.

The actual costs of all hospitalization were not compared among the patients randomized to the two arms of this study. Variations in duration of hospitalization that were due to nonmedical reasons, such as scheduling for endoscopy and surgery, surgeon and endoscopist availability, and patient vacillation to accept surgery, would make such determinations meaningless. The duration of hospitalization from the day of surgery was compared between the two randomized groups as well as between those patients who did and did not require CBDE. The median duration of additional hospitalization in patients randomized to SA was 1 day and in all cases of CBD exploration was 2 days. The additional postoperative hospitalization with CBDE would be offset in a patient with ES&S by the preoperative hospitalization associated with the endoscopic procedure. The added operating room charges for a CBDE would be offset by the facility fee for the endoscopy suite used for the ERCP and ES. Our estimate of professional fees for these two approaches to the management of synchronous cholecystolithiasis and choledocholithiasis on an elective basis reveal that the charges would be marginally greater for the endoscopist, surgeon, and anesthesiologist in patients undergoing successful ES followed by cholecystectomy then would be true of the patient undergoing cholecystectomy and CBDE. In conclusion, for an individual patient who underwent a successful ES before surgery, the facility and professional costs would be about equal for the two approaches. Van Stiegman and associates[29] compared two groups of nonrandomized and questionably comparable cases and concluded that preoperative ES would be cost-effective. Their cases with CBDE were hospitalized an additional 4.4 days at $1085.00 per day. If this seemingly excessive duration of hospitalization had not occurred there would not have been a cost benefit.

Despite the above conclusion regarding an individual case of successful ES&S, a general policy of ERCP and ES before elective surgery in the management of patients with cholecystolithiasis and suspected choledocholithiasis would be much greater than that for SA because of the screening costs necessary to identify patients with CBD stones. An extensive literature exists with respect to the yield in identification of CBD stones that may be anticipated at elective surgery based on various indicators such as jaundice, previous pancreatitis, dilated duct, or palpable stones.[23] These studies establish that a minority of patients with other than a palpable stone will harbor a CBD stone at the time of operation. Thus if one were to screen patients using our indications, namely, a serum bilirubin level greater than 2 mg/100 mL, a dilated duct by ultrasound, and a history of hyperamylasemia, one would predict confidently that not more than one in three patients would be identified with CBD stones. In addition CBDE would still be required for those patients in whom ES failed to clear the ducts. The total cost of the program would be much greater.

The results of this study do not support the routine use of ES as a preoperative procedure for removal of CBD stones in patients with cholecystolithiasis and choledocholithiasis who are candidates for elective surgery. Neither efficacy in clearing the CBD of stones, morbidity of the procedure, nor cost would favor a preoperative endoscopic sphincterotomy. These conclusions are similar to those of Neoptolemos and associates[21] based on their randomized study. These conclusions should not be applied to other indications for ES. The results of our study are not relevant to the role of ES in patients with severe acute gallstone pancreatitis, cholangitis, retained stone after previous biliary surgery, or to the treatment of patients with high surgical risk. They should not be applied to a patient with obstructive jaundice who undergoes an ERCP to determine whether obstruction is due to stone or tumor. A stone may be identified in the common bile duct. It is reasonable under such circumstances for an ES to be performed to permit passage of the stone. Preferably 48 hours should lapse between ES and surgery to allow the passage of any residual stone(s). The result of a cholangiogram performed at the time of ES should not be accepted. The surgeon should perform an intraoperative cholangiogram. Finally there is current intense interest in laparoscopic cholecystectomy.[2] The management of CBD stones in patients selected for that procedure has not been standardized. The results in clearance of the CBD of stones that we report can be a part of the debate that will occur as to whether laparoscopic cholecystectomy might be preceded or followed by ES.

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Discussions

Dr. Ronald K. Tompkins (Los Angeles, California): Dr. Donovan and his coauthors are to be congratulated for designing a prospective randomized trial comparing endoscopic papillotomy to operation for the treatment of patients with common duct stones.

Their findings were that 35% of the patients treated by endoscopic papillotomy had residual common duct stones, proved at operation, a median of 4 days after procedure, compared to the 12% of surgically treated patients who had residual common duct stones at the time of postoperative T-tube cholangiogram.

Clearly, in the author's institution, a patient with common duct stones who is treated by operation is three times less likely to have residual common duct stones than the patient treated by endoscopic papillotomy.

However, if the patient treated by endoscopic papillotomy for common duct stones then undergoes subsequent cholecystectomy and is found to have common duct stones, that patient has a 33% chance of having postoperative retained stones. That is, three of nine of their patients with stones in group 1 had retained stones at the end of the operation. Why should the residual postoperative stone rate be twice as high in that group as it was in group 2, which was only 16%; 3 of 19 patients who underwent operation with stones in the common duct?

The authors suggested that complications of papillotomy and unwise reliance by the surgeon on previous ERCP and papillotomy may be major factors. The question logically arises as to whether biliary endoscopy was used in all these patients, and in both groups was completion T-tube cholangiography performed at the end of the procedure?

Studies from a number of institutions, our own included, have demonstrated the ability of operative choledochoscopy or cholangioscopy and completion cholangiography to reduce residual common bile duct stones to less than 2%, often to zero.

Undoubtedly the endoscopists who read this paper will argue that more time should have been given to the papillotomy patients to pass their stones before operation. However some of the patients, as Dr. Donovan has noted, went as long as 213 days before operation after the papillotomy was done. So I do not think that is a very good argument.

The real question is whether in nonemergent patients with common duct stones it makes sense to subject them to a preoperative ERCP and papillotomy before removing their gallbladders. It does not make sense to compound the risk to the patient by performing two procedures, that is, endoscopic papillotomy and then adding cholecystectomy and common duct exploration when the latter procedure has a better success rate as demonstrated by the authors.

They have presented a wealth of data in their manuscript and, like all good studies, it raises more questions for future work. I would ask them, in addition, if they had any patients with unusual biliary problems in this series, such as the oriental cholangiohepatitis patients that they have described before, and what were their exclusion criteria for this study.

Also how many endoscopists and how many surgeons participated in the procedures?

Dr. Talmadge Bowden (Augusta, Georgia): I find this to be a very well-designed study that, unfortunately, in view of recent endoscopic advances, may be a bit obsolete.

I agree with Dr. Tompkins that the 65% stone clearance rate by endoscopic papillotomy is too low. As you know, you should expect an 80% to 90% clearance rate.

I, too, want to know if you, in your hospital routine, do intraoperative choledochoscopy, which is clearly an additional marriage of endoscopy to surgery that is very worthwhile?

Dr. Donovan, in reviewing your bibliography, I noted that there were three studies that you did not reference. Because these studies do support the thesis that preoperative endoscopic sphincterotomy may be of benefit, let me briefly summarize them.

Worthley from Australia compared common duct exploration in 102 patients with endoscopic sphincterotomy and 50 patients with surgery and found 26% fewer complications after sphincterotomy than after common duct exploration. He also showed a clear difference in mean hospital stay, with sphincterotomy being 3 days and surgery alone 7 days.

Heinerman studied 728 patients in whom ERCP and stone extraction were performed 2 to 4 days before cholecystotomy. These authors reduced