Choledochoscopy

A Cost-minimization Analysis

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Although choledochoscopy for the prevention of retained bile duct stones has been postulated as cost effective, no economic evaluation exists to substantiate this claim. We performed a cost-minimization analysis on 287 patients who underwent choledochoscopy during operations for biliary tract calculi between 1981 and 1987 to assess the economic impact of choledochoscopy *versus* noncholedochoscopic alternatives in obtaining a stone-free duct. Common duct exploration was positive for calculi in 75% of patients. Choledochoscopy detected residual stones after duct exploration in 10% of patients. Residual stones were more frequent after positive (12.5%) than negative (2.7%) duct explorations. Retained stones occurred in 4.5% of patients after operation. Sensitivity, specificity, and negative predictive values of choledochoscopy were 67%, 100%, and 95%, respectively. Cost-minimization analysis showed that total cost of either selective ($75,250) or routine ($110,450) choledochoscopy significantly exceeded the total cost of obtaining a stone-free duct for patients with retained stones *via* either extraction through a T-tube tract ($17,545) or by endoscopic papillotomy ($45,675). Because choledochoscopy was not economically competitive with noncholedochoscopic, nonoperative alternatives, reduction of choledochoscopy fees was implemented to economically justify continued use of choledochoscopy. We conclude that choledochoscopy is clinically efficacious in obtaining a stone-free duct, but endorsement of either routine or selective choledochoscopy by cost-minimization analysis requires careful assessment of fee structure to make choledochoscopy competitive economically.

INTRAOPERATIVE CHOLEDOCHOSCOPY HAS become a widely accepted adjunct to common duct exploration. Its value in the detection and extraction of unsuspected bile duct calculi,[1-12] reduction of retained calculi,[13] and localization and biopsy of bile duct neoplasms[14-18] has been proved. Furthermore choledochoscopy potentially may reduce the average operating time of common duct exploration by expediting calculi retrieval and, if accurate, by eliminating postexploratory intraoperative cholangiography. Despite these benefits, it is unclear whether choledochoscopy should be used as a routine adjunct to common duct exploration. To advocate routine choledochoscopy, a high diagnostic accuracy and clinical utility must be consistently attainable and cost effective. Although diagnostic accuracy of choledochoscopy after standard bile duct exploration has been demonstrated,[1-12] no cost analysis has been reported. Indeed, although choledochoscopy has been postulated as cost effective[8,10] and economically justifiable,[11] actual analysis of its economic impact is strikingly absent. To evaluate choledochoscopy as a routine adjunct to common duct exploration, a procedural cost-minimization analysis of choledochoscopy was performed based on the results of a recent experience.

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Patients and Methods

The records of all patients undergoing choledochoscopy during operations for calculus disease of the bile ducts or gallbladder at the Mayo Clinic-affiliated hospitals between July 1981 and December 1987 were reviewed. Patients who had choledochoscopy aborted during operation because of technical problems due to common duct size or equipment malfunction were excluded. Choledochoscopy was performed with either a Storz rigid or an ACMI flexible choledochoscope (American Hospital Supply Corp., Stanford, CA). Choice of scope was determined by the preference of the operating surgeon. Choledochoscopy was preceded by a standard common duct exploration. After a vertical choledochotomy, scoops or stone forceps were inserted into the common duct to remove stones. The common duct was then lavaged liberally with warm 0.9M sodium chloride solution to remove any residual stones or debris. After duct exploration, choledochoscopy was performed. Although the extent of the ductal visualization was generally greater for flexible than for rigid choledochoscopy due to instrument differences, choledochoscopy was considered technically successful if the operative records stated that the extrahepatic bile duct was visualized completely. Passage of the scope through the ampulla into the duodenum was not routinely done. Choledochoscopy was concluded when the visualized ductal system was judged free of stones. Unsuspected stones were defined as those stones identified during operation by choledochoscopy after standard common duct exploration. Retained stones were defined as stones identified after operation by cholangiography.

Patient demographic data, type of choledochoscope, operative procedure, indications for common duct exploration, operative, choledochoscopic, and postoperative cholangiographic findings, and morbidity and mortality rates were recorded. Cost analysis was based on our 1989 charge for operative choledochoscopy ($350), stone extraction through a T-tube tract ($605), and endoscopic papillotomy ($1575), although procedure costs escalated during the study period. Procedural costs included the physician's fee. The sensitivity, specificity, and positive and negative predictive values of choledochoscopy were defined as shown in Table 1. The calculations of sensitivity and positive predictive value assumed that all unsuspected stones (a) would have been identified on postoperative cholangiography as retained stones.

Results

Choledochoscopy was performed successfully in 287 patients. There were 122 men (43%) and 165 women (57%). The mean age and age range of men (66; 24 to 90 years) and women (60; 20 to 92 years) were similar.

The indications for common duct exploration are listed in Table 2. An operative cholangiogram preceded common duct exploration in 244 patients. Common duct exploration was positive for calculi in 215 patients (75%). Additional bile duct pathology included strictures in eight patients and bile duct cysts in two patients.

Overall choledochoscopy detected unsuspected stones after common duct exploration in 29 patients (10.1%).

TABLE 1. *Method for Calculating Specificity, Sensitivity, and Predictive Value of Choledochoscopy*

Choledochoscopy	Postoperative Cholangiography: Positive	Postoperative Cholangiography: Negative	Total
Positive	a	b	a + b
Negative	c	d	c + d
Total	a + c	b + d	

Sensitivity, a/a + c; specificity, b/b + d.
Positive predictive value = a/a + b; negative predictive value = c/c + d, where "a" represents unsuspected stones and "c" represents retained stones.

TABLE 2. *Primary Indications for Common Bile Duct Exploration*

Indication	Patients
Operative Cholangiogram	
Stone(s)	195
Large duct >10 mm	14
Ampullary obstruction	6
Ampullary distention	4
Stone *vs.* debris	5
Indeterminate cholangiogram with clinical suspicion	6
Negative	14
Total	244
Stones by preoperative ERCP	9
Stones by preoperative THC	2
Palpable stone at operation	8
Clinical criteria alone*	24
Total	287

* Clinical criteria included jaundice, history of pancreatitis, dilated common duct, cystic duct size, or debris.

Choledochoscopy was positive in 27 patients in whom common duct exploration was positive for calculi and in two patients in whom common duct exploration was negative. Thus unsuspected stones were detected significantly more often in patients with positive than negative common duct exploration (12.5% *vs.* 2.7%, respectively, $p < 0.02$). Retained common duct stones were detected after operation by cholangiography in 14 patients (4.5%). Postoperative cholangiography was performed in 93% of the patients. Cholangiography was not performed in 18 patients after choledochoduodenostomy and in two patients after Roux-Y choledochojejunostomy. The relationship of biliary pathology to bile duct calculi, unsuspected stones, and retained stones is shown in Table 3.

Flexible choledochoscopy was used in 170 (59%) patients, rigid choledochoscopy in 95 (33%) patients, both flexible and rigid in two (0.7%) cases, and the type of scope was indeterminate in 20 (7%). Unsuspected stone rate was 10.6% for flexible (18 of 170) and 9.4% for rigid (9 of 95) choledochoscopies. In patients in whom the type of scope could not be ascertained, 10% (2 of 20) had unsuspected stones.

Retained stones were detected in 14 patients. Flexible choledochoscopy was used in 9 patients, rigid choledochoscopy in 2, and scope type was indeterminate in 3. All patients with retained stones had had a positive common duct exploration. Five of 14 (36%) patients with retained stones also had unsuspected stones at duct exploration. Three of these 14 patients had had cholecystectomy at the time of the common duct exploration. Two had a choledochoduodenostomy done at the time of the common duct exploration because of recurrent common bile duct stones, and one had a left hepatectomy for intrahepatic stones and hepatic abscess.

The disposition of the 14 patients with retained stones was variable. In six patients retained stones were extracted

TABLE 3. *Relationship of Biliary Tract Pathology, Ductal Stones, and Unsuspected and Retained Stone Rate*

Pathology	Total Pts.	Ductal Stones (%)	Unsuspected Stones (%)	Retained Stones (%)
Chronic cholecystitis	187	129 (69.0)	13 (7.0)	5 (3.0)
Acute cholecystitis	60	49 (81.7)	5 (8.3)	4 (6.7)
Choledocholithiasis PC/BD	32	29 (90.6)	5 (15.6)	2 (6.3)
Hepaticolithiasis	5	5 (100)	4 (80)	1 (20)
Choledochal cysts	2	2 (100)	2 (100)	2 (100)
Primary sclerosing cholangitis	1	1 (100)	0	0
Total	287			

via the T-tube tract. In one patient the stone actually consisted of mucous debris that was aspirated through the T tube. In one patient an asymptomatic stone was left *in situ*, anticipating spontaneous passage through a choledochoduodenostomy. In the remaining six patients no intervention was needed because these retained stones passed spontaneously without precipitating symptoms during the interval of T-tube tract maturation as documented by subsequent T-tube cholangiography.

The diagnostic discrimination of both rigid and flexible choledochoscopy is shown in Table 4. The sensitivity of choledochoscopy, that is the number of patients with unsuspected stones divided by the number of patients with unsuspected plus retained stones, was greater for rigid than for flexible choledochoscopy. The specificity and positive predictive value of both rigid and flexible choledochoscopy was 100% because there were no false-positive findings on choledochoscopy. Importantly the predictive value of a negative flexible and rigid choledochoscopy was 94% and 98%, respectively.

Two patients died after operation (mortality rate was less than 1%). The cause of death in both patients was delayed multiorgan failure from abdominal sepsis after cholecystectomy and common duct exploration for acute cholecystitis with cholelithiasis. Thirty patients encountered postoperative morbidity (10.4%). There were nine minor and 21 major complications, which are detailed in Table 5. No patient had a complication directly attributable to choledochoscopy. Although seven patients had distal common bile duct irregularities identified on postoperative cholangiography that may have resulted from choledochoscopy, these cholangiographic findings were not clinically significant.

TABLE 4. *Diagnostic Discrimination of Choledochoscopy (%)*

Type of Choledochoscopy	Sensitivity	Specificity	Predictive Value Positive	Predictive Value Negative
Total	67	100	100	95
Rigid	82	100	100	98
Flexible	67	100	100	94

The cost of choledochoscopy based on procedure fee and the clinical findings of this study are shown in Table 6. The cost of routine choledochoscopy was based on the total number of patients and selective choledochoscopy on only those patients with common duct calculi found on common bile duct exploration. Although all retained stones were extracted through the T-tube tract or passed spontaneously in this study, the cost of endoscopic papillotomy was included to compare the current, most expensive nonoperative alternative for the treatment of retained stones. The treatment cost of retained stones was added to the cost of choledochoscopy because of its adverse financial impact, *i.e.*, additional treatment cost to compensate for a failed diagnostic procedure. The cost of retrieving all unsuspected stones, if left *in situ*, was calculated for both T-tube extraction and endoscopic papillotomy to provide a cost comparison of treatment alternatives if choledochoscopy had been completely withheld, which is inherent in the cost-minimization analysis

TABLE 5. *Postoperative Mortality and Morbidity Rates*

Complication	Patients
Deaths	
Multiple organ failure with sepsis	2 (0.7%)
Minor	
Wound infection	8
Urinary tract infection	1
Major	
Pancreatitis	3
Pneumonia	3
Major arrhythmias	2
Myocardial infarction	2
Bile leak/subhepatic abscess	2
Subphrenic abscess	1
Wound dehiscence	1
Pancreatic fistula/abscess	1
Congestive heart failure	1
Severe bleeding requiring reoperation	1
Prolonged respiratory insufficiency	1
Subcapsular hematoma requiring reoperation	1
Renal failure with sepsis	1
Pulmonary embolus	1
Total	30 (10.4%)

TABLE 6. *Cost-minimization Analysis of Choledochoscopy*

Treatment Scenario	Cost ($)
Routine choledochoscopy ($350)	
Total cost (287 pts.)	100,450
Cost per unsuspected stone (29 pts.)	3464
Total cost if all retained stones (14 pts.)	
removed *via* T-tube tract*	108,920
removed *via* endoscopic papillotomy†	122,450
Selective choledochoscopy	
Total cost (215 pts.)	75,250
Cost per unsuspected stone (27 pts.)	2787
Total cost if all retained stones (16 pts.)	
removed *via* T-tube tract*	84,930
removed *via* endoscopic papillotomy†	100,450
No choledochoscopy (287 pts.)	
Total cost—T-tube tract extraction (29 pts.)*	17,545
Total cost—endoscopic papillotomy (29 pts.)†	45,675

* 1989 cost for T-tube tract extraction: $605.
† 1989 cost for endoscopic papillotomy: $1575.

design. Cost-minimization analysis does not account for added expenses such as extended hospitalization as a result of retained stones or related complications, further diagnostic studies such as T-tube cholangiograms, absence from employment, and travel and lodging expenses.

Discussion

Choledochoscopy as an adjunct to common bile duct exploration developed as an intraoperative aid to reduce the incidence of retained stones during the 1960s and 1970s with the concurrent refinement of fiberoptics.[1] In fact choledochoscopy evolved as a diagnostic tool to eliminate a major cause of reoperative biliary tract surgery (retained stones) which, at that time, was approachable only by reoperation. The clinical and economic advantages were self evident. Many studies have confirmed the value of choledochoscopy for the identification of unsuspected stones and other intraductal pathology and, consequently, routine use during common duct exploration has been advocated. Interestingly, because the diagnostic efficacy of choledochoscopy has been widely accepted, cost-effectiveness has been assumed. However no study has focused on the economic impact of choledochoscopy. Furthermore, because choledochoscopy predated the development of effective nonoperative alternatives such as stone extraction through a T-tube tract or by endoscopic sphincterotomy, the question of its economic value in the current climate of cost containment remains unclear.

Our findings further confirm the clinical value for choledochoscopy in the diagnosis of unsuspected stones. Detection of unsuspected stones in 10% of our patients after standard bile duct exploration is similar to other large experiences with choledochoscopy (Table 7). These data emphasize that choledochoscopy is consistently productive regardless of institution. The detection rate of unsuspected stones did not differ between flexible and rigid choledochoscopy (10.6% *versus* 9.4%) and the diagnostic accuracy of choledochoscopy, *i.e.*, sensitivity, specificity, and negative predictive value, has remained high. Only 2.7% of our patients had unsuspected stones after negative duct exploration, compared to 12.5% of patients after positive bile duct exploration. The disparity in the detection rate of unsuspected stones between negative and positive common duct exploration has been recognized previously by Rattner and Warshaw.[5] These findings support a role for selective choledochoscopy in patients with only positive common duct exploration. Finally the rate of retained stones or false-negative choledochoscopy was low and did not significantly differ from that of other series. These findings attest to the clinical efficacy of choledochoscopy.

We used cost-minimization analysis as the method of economic evaluation in this study. This method requires a discrete outcome of interest, that is a stone-free bile

TABLE 7. *Unsuspected and Retained Stone Rates with Choledochoscopy—Selective Literature Review*

Author	Year	Scope Flexible/Rigid	Patients	Unsuspected Stones (%)	Retained Stones (%)
Nora et al.[1]	1977	R	208	25	1.9
Kappas et al.[2]	1979	R	121	18	6.6
Feliciano et al.[3]	1980	R	140	14	8.9
Yap et al.[4]	1980	F	149	14	1.3
Rattner/Warshaw[5]	1981	R	144	24	4
Kappas et al.[6]	1981	R	148	—	1.6
Chen et al.[7]	1983	F	339	24	4.4
Escat et al.[8]	1984	R	380	12	2
Dayton et al.[9]	1984	R	121	—	5.7
Escat et al.[10]	1985	R	441	10	2
Jakimowicz et al.[11]	1986	F	320	7.1	1.6
Markowitz et al.[12]	1987	F	102	—	0
Present series	1989	F & R	287	10.1	4.9

—, Rate undefined.

duct, which can be achieved using two or more alternatives. Choledochoscopy affords a stone-free duct by concurrent detection of stones and removal during operation, while stone extraction through a T-tube tract or extraction by endoscopic papillotomy permits a similar goal after operation. Cost-minimization analysis simply seeks to determine the least expensive alternative that provides identical results.[19,20]

Our study clearly showed that the overall procedural costs for routine choledochoscopy clearly exceeded that of either selective choledochoscopy or the nonoperative treatment alternatives for retained stones (Table 6). This difference persisted whether the calculations included the adverse financial impact of retained stones, *i.e.*, false-negative choledochoscopy. Given our current fee structure, these data suggest that routine choledochoscopy may not be justified economically. Furthermore routine use of a diagnostic procedure that is negative in nearly 90% of patients warrants more selective use on a procedural-cost basis alone. Indeed our data could be interpreted to suggest that routine or selective choledochoscopy are too expensive from an economic viewpoint and thus surgeons should accept a finite retained stone rate and treat with less expensive nonoperative methods after operation.

How can an apparent paradox between clinical efficacy of choledochoscopy and economic inefficiency be resolved? Translation of the clinical value of choledochoscopy into economic value is viewed differently by patient, physician, and third party payor health care. The surgeon bears the responsibility of obtaining a stone-free duct and, therefore, of using a proved diagnostic tool to obtain this goal. The patient, in essence, views choledochoscopy as biliary tract insurance to avert further biliary tract intervention. The third party health care payor wants safe, effective treatment at minimal dollar cost. Acceptance of a diagnostic procedure by the surgeon would seem reasonable if the cost of detecting an event in a patient did not greatly exceed procedural cost. In our study, however, the cost of detecting an unsuspected stone per patient was $3464, which greatly exceeded the procedural cost of $350. Selective choledochoscopy only partially compensates for this significant difference. Although the cost per patient for an unsuspected stone remains high, this figure is far less than the cost of a repeat common duct exploration and compulsory hospitalization, although not estimated herein. Thus choledochoscopy, as initially designed, remained competitive with its operative alternative. However as seen in Table 6, this figure is not competitive with current nonoperative alternatives.

The calculated difference in overall cost between choledochoscopy *versus* other treatment alternatives is obviously dependent on the base fee for each respective procedure. If the base fee of choledochoscopy decreases or the fee for nonoperative alternatives of bile duct stone extraction increases, cost differential would decrease or possibly reverse. Given the proved clinical utility of choledochoscopy, the appropriate response by surgeons to the present cost disparity should not be to abandon the procedure, but rather reduce fees. To reasonably establish fees for choledochoscopy and make them competitive with nonoperative alternatives, fees can be estimated by multiplying the expected percentage yield of unsuspected stones by choledochoscopy times the expected total cost of a similar number of patients treated by nonoperative alternatives. Therefore the appropriate reduction of choledochoscopy fees should equal 10% (percentage of unsuspected stones detected by choledochoscopy herein) of the total fee of patients treated by T-tube or endoscopic stone extraction in our study population. This fee reduction allows either routine or selective employment of choledochoscopy at acceptable cost to both patient and health care provider and thereby economically supports use of the efficacious procedure by the surgeon. As a consequence of our recognition of the excessive cost differential between alternatives that evolved in our own practice, we have recommended and subsequently implemented a reduced fee for choledochoscopy based on this cost-minimization analysis (our current charge is $150).

Several potential problems exist in this economic analysis. The cost of all procedures escalated during the study period and the actual individual yearly fees were not incorporated in our calculations. Because we used our 1989 fee schedule, the differences in absolute procedural costs would have varied. However choledochoscopy fee escalated disproportionately to both nonoperative alternatives during the study period and, therefore, use of actual fees throughout the study period would not have changed our conclusion. In retrospect we found that escalated choledochoscopy fees paralleled fee changes for other institutional endoscopic procedures, but the increase for choledochoscopy did not account for concurrent escalation of operative fees during the study period, thus yielding a disproportionate increase. The length of hospitalization and the cost of additional diagnostic tests incurred in the management of retained stones was also not considered. Furthermore time missed from work and travel and lodging expense for the patients with retained stones were not accounted for in our analysis. Given the economic complexities of these variables, we limited our study to a cost-minimization analysis considering only alternative approaches in achieving a stone-free duct. Other economic models are required to assess these other factors. Our findings support either routine or selective choledochoscopy on a procedural-fee basis if choledochoscopy fees are competitive. This study identified a negative economic aspect of choledochoscopy and led to a fee change that made choledochoscopy cost acceptable. Until more extensive economic evaluations are done that assess variables other than procedural costs, we favor selective choledochoscopy as a more optimal means to reduce the rate of retained stones and limit the total cost of choledochoscopy. Further cost analyses directed at cost benefit, cost utility, or cost-effectiveness are necessary to address issues not incorporated in our cost-minimization study.

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