

Endoscopic sphincterotomy for common bile duct calculi in patients with gall bladder *in situ* considered unfit for surgery

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SUMMARY Endoscopic sphincterotomy (ES) was attempted in 106 patients with common bile duct (CBD) calculi and gall bladders present, who were considered unfit for surgery on the grounds of age and frailty alone (35%) and/or the presence of major medical problems (65%). Endoscopic sphincterotomy was successful in 105 patients (99%). Early ES related complications occurred in 21 patients (19.8%). Twelve hospital deaths occurred (11.3%), although this was due to biliary causes in only five (4.7%) and one of these was moribund on admission. Complications were more frequent in those in whom initial ES did not clear the common bile duct (30.4%) compared with those in whom this was (11.7%; $p=0.0164$). The mortality was also greater in patients in whom there was no ERCP proof of CBD clearance ($p=0.01$) unless operated upon. Twelve patients developed gall bladder complications (11.3%) including five with empyema (4.7%). Analysis of clinical, haematological, and biochemical factors together with ERCP findings showed that the only factor which had any value in predicting gall bladder complications was pre-existing cholangitis. The present series was compared with another using ES as a definitive procedure, and with a surgical series. Although there were significant differences in outcome, differences with respect to medical risk factors and the incidence of complications of CBD stones (jaundice, cholangitis, and acute pancreatitis) were striking. Further analysis of these factors may allow a clearer definition of patients most likely to benefit from either ES or surgery.

Endoscopic sphincterotomy (ES) is a safe and effective method of managing common bile duct (CBD) calculi. From major centres clearance of the common bile duct is achieved in greater than 85% with an early complication rate of 10% and a mortality rate of less than 2%.¹⁻³ The established role of ES for retained stones postcholecystectomy has been extended in recent years to the management of the early retained stones post cholecystectomy in patients with T-tube *in situ*,^{5,6} and the management of acute cholangitis.⁷ The role of ES for the removal of CBD calculi before cholecystectomy⁸ and in acute biliary pancreatitis⁹ remains under evaluation.

Many patients with gall bladder and CBD calculi

are elderly and often have major medical problems making them unsuitable candidates for surgery. In these patients ES may be used as a definitive procedure with the gall bladder being left *in situ* but significant complications may develop as a result of remaining gall bladder stones. A method of predicting those patients at a high risk of developing complications would be of value. Moreover a clearer definition is required of those patients with CBD stones who are indeed most likely to benefit from treatment by ES alone as compared with surgery alone.

This study represents our initial attempts to examine these problems and includes a comparison with two other studies of patients with CBD calculi in which sufficient information was available to allow statistical analysis.

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Methods

PATIENTS

Between August 1978 and December 1985 106 patients from our local referral population with intact gall bladders who were considered at high risk for surgery on the grounds of age and/or associated medical problems had ES for CBD calculi with the intention of not proceeding to elective cholecystectomy. Patients referred from outside the Leicester area were excluded. Short and long term outcome was analysed together with various clinical and laboratory variables and the findings at ERCP in an attempt to predict which patients might develop significant complications of gall bladder disease. A comparison was then carried out between this group of patients and another undergoing ES as a definitive procedure¹⁰ and a surgical series⁸ with respect to factors potentially important in the prediction of outcome.

ENDOSCOPIC SPHINCTEROTOMY

Diagnosis of CBD calculi was by ERCP in all cases. This was carried out using pharyngeal topical anaesthesia and intravenous sedation. All patients received prophylactic antibiotics before ES. Stone extraction after sphincterotomy was carried out as previously described^{11,12} using Fujinon DUO-X and DUO-XL side viewing duodenoscopes and a Classen-Demling sphincterotome with an Erbotom T175D diathermy unit. Basket and/or balloon extraction was used in an attempt to clear the CBD in all cases (Olympus FG18Q dormia basket, Medi-Tech OB/5/2/200 balloon, KeyMed Ltd, Southend, Essex). In selected patients where removal of CBD calculi proved impossible a nasobiliary catheter was inserted at the time of ES and dissolution therapy was attempted by instilling mono-octanoin (Moctanin T^m, Capital City Products Company, Columbus, Ohio, USA) into the CBD through the catheter at 2–3 ml/h.

Of the 106 patients 40 were male and 66 female with a median age of 79 years (range 47–92). Forty five patients (42%) were 80 years or over. Presentation was pain and jaundice in 80 cases (75.5%), pain alone in 19 (18%), and jaundice alone in seven (6.5%). Twenty nine patients (27%) had acute cholangitis on admission and 19 cases had acute pancreatitis (18%). The diagnosis of acute cholangitis was based on the findings of a temperature of greater than 38°C with a history of rigors, clinically apparent jaundice and upper abdominal pain or tenderness. The diagnosis of acute pancreatitis was based on a serum amylase value of greater than 1000 IU/l with a compatible clinical picture.

Thirty seven patients were selected for ES as a definitive procedure on the grounds of age and frailty alone (35%). The median age in this group was 80 years (range 61–92). Sixty nine patients were selected on the grounds of major medical problems (65%). The median age of this group was 76 years (range 47–88), 38% of whom were 80 years or over. The age distribution of the two groups is shown in Figure 1 and the major medical problems in Table 1. A combination of major medical problems was present in 15 patients. Additional medical problems not considered to be major were present in 16 patients; these were peptic ulceration in eight, a history of malignant disease in four, chronic pancreatitis in three and chronic osteomyelitis in one.

STATISTICAL ANALYSIS

Continuous variables were analysed using the Mann Whitney U test (Minitab computer package) and discrete variables were analysed using X² test and X² test with Yates correction for small expected numbers.

Results

Endoscopic sphincterotomy (ES) was successfully carried out in all but one of the 106 patients (Fig. 2). The failure was an 84 year old lady with severe angina

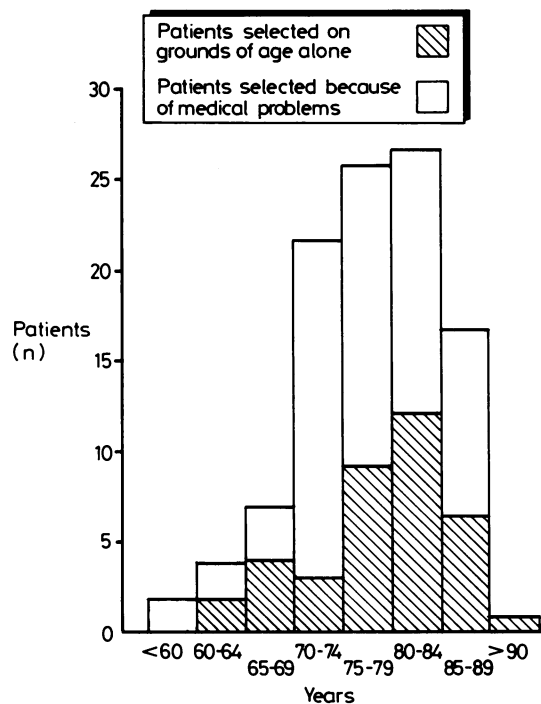
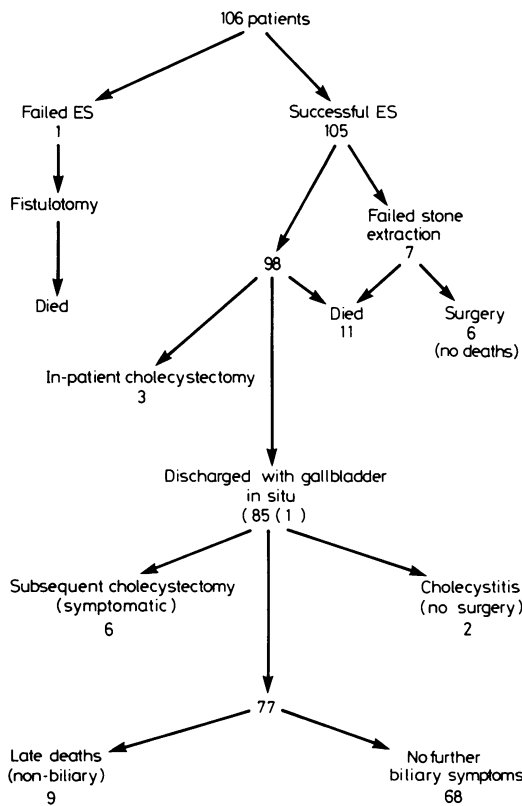


Fig. 1 Age group of patients undergoing ES.

Table 1 Medical risk factors in the 69 patients selected for ES principally on medical grounds

Cardiovascular (History of MI, severe angina, congestive cardiac failure or hypertension)	46
Diabetes mellitus	9
Chronic obstructive airways disease	8
Previous cerebrovascular accident	6
Severe psychiatric disorders	4
Morbid obesity	3
Haemolytic anaemias	3
Hypothyroidism	2
Previous pulmonary embolism	2
Lobar pneumonia	1
Multiple sclerosis	1
Polymyalgia rheumatica	1

who died from acute haemorrhagic pancreatitis after a needle knife choledochoduodenostomy for impacted stones at the ampulla of Vater. Seven patients (aged 72–86 years) had successful ES but failure to remove large CBD calculi. One of these



*One patient had percutaneous aspiration of gall bladder empyema
Fig. 2 Outcome of patients undergoing ES for CBD stones.

Table 2 Details of all inpatient deaths (n=12)

Age	Sex	Medical problems	Retained CBD stones*	Cause of death
Deaths directly related to ES				
84	F	Angina, CCF	Yes	Acute pancreatitis
85	F	Hypertension	Yes	Septicaemia
76	M	Nil major	Yes (A)	Septicaemia/empyema of the gall bladder
84	M	Hypertension	Yes	Septicaemia (awaiting surgery)
71	F	Angina, CCF, Diabetes, Renal Failure†	Yes (A)	Septicaemia/liver abscess/multisystem failure
Deaths remotely related to ES				
68	M	Angina, CCF, Hypertension	?	Cardiac and respiratory failure
86	F	Nil major	No	Myocardial infarct
84	M	CVA	No	Aspiration pneumonia
81	F	CCF	No	Haematemesis from gastric erosions
89	M	CCF	No	Pancreatic carcinoma‡/ septicaemia/empyema of gall bladder
65	M	CCF, COAD	No	Bronchial carcinoma‡
85	F	Nil major	No	Ovarian carcinoma‡

*Status of CBD as shown by ERCP or autopsy (A); †moribund on admission; ‡malignant disease diagnosed at autopsy; F/M=female/male; CCF=congestive cardiac failure; CVA=cerebrovascular accident; COAD=chronic obstructive airways disease.

patients aged 85 years was considered unfit for surgery and died from cholangitis. Six patients were referred for surgery and had cholecystectomy and CBD clearance carried out. Despite four having major medical problems all survived although two patients developed wound and chest infections, one patient developed septicaemic shock which responded to fluids and antibiotics, and another had a wound infection.

Of the remaining 98 patients confirmation of CBD clearance was obtained in 79 patients (81%). Complete clearance was determined at the time of initial ERCP in 60 cases. Seventeen other patients had confirmation at a repeat ERCP and two additional patients had two further ERCP's. Nine patients required a further ES to allow CBD clearance and two patients had two further ES's. The remaining 19 patients (19.4%) were felt to have had a sphincterotomy adequate to allow spontaneous clearance of the CBD. Ten of these 98 patients died and details are given in Table 2.

DISSOLUTION THERAPY

Three patients had attempted dissolution of CBD stones and this was successful in two. The one patient who failed dissolution had an endoprosthesis inserted and remains well two years later.

OUTCOME OF PATIENTS PRESENTING WITH ACUTE CHOLANGITIS AND PANCREATITIS

Of the 29 patients presenting with cholangitis four had a further episode of cholangitis post-ES. Four of the group developed an empyema of the gall bladder one of whom died (*vide infra*). A further death was from cholangitis and liver abscess in a patient with failed CBD clearance. Three patients in this group had retained CBD stones post-ES and underwent surgery as previously mentioned. The overall mortality of patients presenting with cholangitis was 6.9%.

All 19 patients with acute pancreatitis had successful ES and stone extraction with only one ES related complication in a patient with concomitant cholangitis (included in the above).

EMPYEMA OF THE GALL BLADDER

Five of the 106 patients with CBD stones developed an empyema of the gall bladder after ES (4.7%) and two had this before ES. One patient had had cholecystostomy for empyema of the gall bladder and subsequently underwent elective cholecystectomy post-ES. The other patient had an empyema of the gall bladder and choledochoduodenal fistula at the time of ES and underwent an emergency cholecystectomy. Four of the five patients who formed an empyema of the gall bladder after ES, had presented with cholangitis (14%) ($p=0.036$). One of the five patients responded to ultrasound directed aspiration of the gall bladder. Two other patients had urgent cholecystectomy with no complications. In the remaining two patients with empyema of the gall bladder, the diagnosis was only made at autopsy. One of these patients died from septicaemia shortly after readmission to hospital and was found to have CBD stones as well as an empyema. The other patient had carcinoma of pancreas and liver secondaries in addition to the empyema. Overall two of the seven patients with empyema of the gall bladder died (29%).

OVERALL INPATIENT COMPLICATIONS AND MORTALITY

Twenty one of the patients had early complications related to attempted ES (19.8%) (Table 3). Nine of these patients (42.9%) had more than one complication. Twelve of the 21 patients (57.1%) had retained CBD stones; six of the 12 patients underwent further ES with complete clearance, four had surgery with a successful outcome, one died after a needle fistulotomy, and another died having been considered unfit for surgery. In total 12 patients (11.3%) died during their hospital admission although this was from biliary causes – all associated with retained stones – in only five (4.7%) and one of these was

Table 3 Early complications related to attempted ES in all 106 patients (1–30 days)

Complication	Number	
Acute cholangitis	11 (4*)	10.4%
Post-ES bleeding	7	6.6%
Septicaemia	5	4.7%
Empyema of gall bladder	5 (4*)	4.7%
Acute pancreatitis	2	1.9%
Patients with complications (n)	21	19.6%
Deaths (n)	5	4.7%

*Number with pre-existing cholangitis.

moribund on admission. Excluding patients who died of malignant disease there was a higher mortality in the group who did not have confirmation of CBD clearance by ERCP (6/27 or 22%) compared to those who did (3/79 or 4%) ($p=0.01$). Furthermore in patients without ERCP proof of CBD stone clearance, five of the six deaths were related to retained CBD stones, whereas the three non-cancer related deaths in patients who did have CBD clearance confirmed were from non-biliary causes. Complications after ES were greater in patients in whom initial ES did not result in CBD clearance (14/46 or 30%) compared to those in whom this was (7/60 or 12%) ($p=0.0164$).

LONGTERM OUTCOME

Eighty five patients with gall bladder *in situ* were discharged from hospital after ES and were followed up for 1–8 years (mean 29.6 months). Eight patients developed symptoms referable to the gall bladder (9.4%) of whom six had cholecystectomy. Two patients represented with cholangitis and were found to have retained CBD stones at operation. Neither patient had had confirmation of CBD clearance at the time of ES. Surgery was undertaken in two patients because of repeated episodes of biliary colic and in one because of acute cholecystitis. An elective cholecystectomy was performed in another patient who had had cholecystostomy for empyema of the gall bladder before ES.

None of the 79 patients who had had confirmation of CBD clearance subsequently presented with retained or recurrent CBD calculi, although two of these patients had had an episode of cholecystitis but were not considered for surgery. Nine patients died from unrelated causes: myocardial infarction in four cases, pneumonia in three instances and pulmonary tuberculosis and pulmonary embolism in one each. Sixty eight patients did not report any further biliary tract symptoms. None of the 19 patients who presented with acute pancreatitis have had a further episode of pancreatitis during a mean follow up period of 39 months.

PREDICTION OF POST-ES GALL BLADDER COMPLICATIONS

None of the factors analysed in an attempt to define at the time of admission the group of patients who might subsequently develop significant gall bladder pathology (empyema, acute cholecystitis or recurrent biliary colic) were found to be significant (Table 4).

COMPARISON WITH ANOTHER SERIES OF DEFINITIVE ES AND A SURGICAL SERIES

Table 5 shows a statistical comparison of the presenting features and mortality for the present group of patients together with those of a Manchester series of definitive ES¹⁰ and a Leicester series of surgery for CBD stones.⁸

Discussion

Cholecystectomy is an operative procedure with a low mortality rate of 1%.¹³⁻¹⁶ In contrast when CBD exploration is required the risk is greatly increased, especially in elderly patients in whom mortality rates of 9-30% have been reported.^{17,18} Endoscopic sphincterotomy with a mortality of less than 2% has obvious advantages for managing CBD calculi in elderly patients if cholecystectomy is avoided.^{19,20} Previously published series have suggested that approximately 10% of patients eventually require

Table 4 Comparison of patients developing and those not developing significant gall bladder complications

	Complications (n=12) (empyema, cholecystitis or biliary colic)	No Complications (n=86)
Age (years)	75.5 (58-89)	79 (47-92)
Sex male/female	7/5	30/56
Acute pancreatitis	1 (8%)	18 (21%)
Acute cholangitis	5 (42%)	21 (24%)
White cell count	9.6 (4.7-20.6)	8.8 (1.2-40)
Bilirubin ($\mu\text{mol/l}$)	103 (14-425)	71 (5-491)
Alkaline phosphatase (IU/l)	331 (89-834)	456 (85-3047)
Gamma glutamyl transpeptidase (IU/l)	283 (47-734)	313 (22-1164)
Alanine transaminase (IU/l)	146 (17-313)	114 (10-1114)
ERCP findings		
CBD diameter	12.5 (8-20)	13 (5-26)
Gall bladder filling	6 (50%)	46 (53%)
Gall bladder		
No filling	6 (50%)	40 (47%)
Filling No stones	1/6 (17%)	7/46 (15%)
Single stones	1/6 (17%)	6/46 (13%)
Multiple stones	4/6 (67%)	33/46 (72%)

Median values (range). None of these values was significantly different.

cholecystectomy^{2,20} and the incidence of 7% in the present series is in accordance with this.

Although ES was achieved in all but one patient (99%) confirmation of CBD clearance by ERCP was obtained in only 81%. This is somewhat lower than that in previously reported series from Leicester^{7,8,20} and other centres.^{3,3} There are two possible explanations for this difference. Firstly, in some series CBD clearance may be assumed when ES is followed by resolution of symptoms rather than being confirmed by repeat ERCP or nasobiliary cholangiography. Secondly, this figure may reflect a reluctance to have ERCP repeated in elderly and frail patients, often with major medical problems, when symptoms have subsided.

The overall hospital mortality was significantly higher in patients having either failed stone extraction or no confirmation of CBD clearance compared with those patients having confirmation of CBD clearance. Complications after ES were also increased if CBD clearance was not achieved at initial ERCP and ES. All five deaths caused by post-ES complications were associated with retained stones. The remaining seven deaths were because of malignancy or other intercurrent medical problems; six of these patients had successful stone clearance and in one cases this was uncertain. Surgery should be seriously reconsidered at an early stage for patients with incomplete stone clearance - indeed six patients were operated on without mortality - but it may not be feasible. Endoscopic insertion of a nasobiliary catheter followed by dissolution therapy,²¹ or placement of a biliary endoprosthesis²² may, however, improve the prognosis of this group of patients.

Seven patients (6.6%) had an empyema of the gall bladder and in five cases this followed ES which was done in the presence of acute cholangitis in four. As preoperative ES results in a higher incidence of positive gall bladder bile cultures,⁸ it seems likely that ES in the presence of marked biliary tract sepsis predisposes to the development of empyema of the gall bladder. The mortality rate for patients with empyema of the gall bladder was 29% in this series. Previously mortality rates of 15-25% have been reported and has been highest in those in whom treatment was delayed.²³ The recent introduction of ultrasound directed percutaneous gall bladder catheterisation, as used in one case in this series, may improve the prognosis for high surgical risk^{24,25} patients. Dissolution therapy *via* the catheter may avoid the need for subsequent cholecystectomy.²⁶

After an initial attack of acute biliary pancreatitis early cholecystectomy is usually recommended to prevent further episodes.²⁷⁻²⁹ None of the patients who presented with acute pancreatitis and in whom the gall bladder remains *in situ* have had a further

Table 5 Comparison of the present and Manchester ES (10) series with a Leicester surgical study (8)

	Series A present ES study (n=106)		Series B Manchester ES study (n=81)		Series C Surgical study (n=59)		p values		
	n	(%)	n	(%)	n	(%)	A v B	A v C	B v C
Jaundice	87	(82)	56	(69)	52	(88)	0.036	NS	0.008
Acute cholangitis	29	(27)	15	(19)	9	(15)	NS	NS	NS
Acute pancreatitis	19	(18)	5	(6)	1	(2)	0.018	0.005	NS
Age >60 years	105	(99)	74	(91)	30	(51)	NS	0.001	0.001
Major medical problems	69	(65)	32	(40)	15	(25)	0.001	0.001	NS
Mortality	9/103*	(8.7)	1	(1.2)	1	(1.7)	0.038	NS	NS

*Three patients with previously undiagnosed carcinoma not included; NS=not significant.

episode. It seems likely, therefore, that ES alone has a role in elderly patients with acute biliary pancreatitis.

Prediction of gall bladder complications after ES would be valuable in allowing early therapeutic radiological intervention or reconsideration of surgical options. Only the presence of cholangitis indicated an increased risk of gall bladder complications. The presence or absence of gall bladder filling on ERCP as suggested by Cotton³⁰ has not been found to be a useful indicator.

The comparative study with the Manchester ES series¹⁰ and the surgical series⁸ has provided some insight into the factors which are responsible for the morbidity and mortality in patients presenting with CBD stones. Their outcome will be dependent on the techniques used, the skill of the endoscopist and the type of patient involved. In comparing the present series with that from Manchester (Table 5) it has been shown that despite similar age ranges in both groups being managed by ES the mortality was significantly different. The contrast between these series with respect to the incidence of jaundice, acute pancreatitis and intercurrent medical problems was, however, even more striking. The mortality of a surgical series from Leicester was less than that of the present series of patients undergoing ES but they were younger and had fewer major medical problems. Furthermore the mortality in the Manchester ES series and the Leicester surgical series was not significantly different, nor was their incidence of major medical problems. Although the patients in the Manchester series were older the Leicester surgical patients more commonly presented with jaundice.

Cotton has drawn attention to the difficulties faced in attempting to draw conclusions from the results of surgical and ES series because of the different make up in these groups.³⁰ Adverse risk factors in biliary tract disease have been derived from surgical series largely composed of patients with malignancy.³¹⁻³³ The use of medical risk factors as used here has been

shown to be of importance in determining mortality from acute cholangitis as a result of choledocholithiasis.⁷ Determination of specific risk factors which can be applied to all patients with CBD stones ought to be a major goal now as a means of furthering progress in defining the optimum management of these patients.

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