Leading Article

Endoscopic removal of common duct stones: current indications and controversies

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Introduction

Endoscopic sphincterotomy (ES) is now the method of choice for removing common bile duct stones in most situations. First described 15 years ago,^{1,2} ES, a therapeutic development of endoscopic retrograde cholangiopancreatography (ERCP) has replaced surgical exploration of the common bile ducts. Large series report the success rate and complications of ES. Formal trials, to evaluate the indications for and benefits of this technique, however, have only started to appear recently and some areas of its use remain controversial. This paper reviews the state of the art of ES in current clinical practice. There are few specific contraindications to endoscopic removal of common duct stones (Table I). We shall discuss ES for stones causing duct obstruction, cholangitis and pancreatitis separately. The efficacy of sphincterotomy in patients with a gall bladder *in situ* remains controversial. Risk-benefit evaluation has to start with an assessment of complications.

Complications of endoscopic sphincterotomy

The major complications may be classified as early or late. Early complications include haemorrhage, cholangitis, pancreatitis and perforation. Haemor-

rhage is usually self-limiting and rarely serious enough to require transfusion, provided there is no bleeding diathesis. In the largest series of endoscopic sphincterotomies reported in the UK³ the incidence of haemorrhage was 3.9% with transfusion required in 0.6%. It is probable that the size of sphincterotomy correlates with risk of haemorrhage although no data exist to support this hypothesis. Risks of cholangitis, pancreatitis and perforation were 1.6%, 0.9% and 0.5% respectively in the Middlesex Hospital series.³ Retroperitoneal perforation generally heals spontaneously with conservative treatment. Overall mortality of ES is approximately 1.2%, but it is clear that in higher risk patients it may be greater. Thus, while sphincterotomy may be regarded as less interventional than surgery, it is not without significant morbidity and mortality. The principle long term complications include stone recurrence and stenosis of the sphincterotomy. One study has assessed stenosis in detail. Rosseland and Solhaug⁴ measured sphincterotomy size prospectively in 68 of 75 patients with a gall bladder *in situ*. The mean diameter was 12.8 mm. In 11 patients there was a reduction of 20% in sphincterotomy diameter during a follow-up of up to 5 years but all patients were asymptomatic and

Table I Removal of duct stones by ES

i.	<i>Contraindications</i>	
	No clear contraindication except coagulopathy	
ii.	<i>Indications</i>	
	a) Definite:	Acute obstructive suppurative cholangitis Acute cholangitis Duct stones after cholecystectomy
	b) Probable:	Duct stones in elderly patients (gall bladder <i>in situ</i>) Acute pancreatitis
	c) Controversial:	Duct stones in young patients with gall bladder <i>in situ</i>

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hence the clinical relevance of this is probably marginal.

Failure of duct clearance occurs in 6% of cases and patients at particular risk can be identified before the procedure.⁵ Predisposing factors include post-operative strictures, periampullary diverticula, previous Billroth II gastroenterostomy and the presence of large, irregularly shaped, multiple stones. Treatment may be by endoprosthesis, dissolution therapy or lithotripsy. Where a large stone is impossible to remove the risk of subsequent cholangitis is high and endoprosthesis insertion, successful in up to 85% of patients, is the immediate treatment of choice.

Contraindications to ES and stone removal

The only clear contraindication to ES is severe coagulopathy. It is generally accepted practice that if the platelet count is less than $70 \times 10^9/l$ or the prothrombin time prolonged by more than 3 seconds, ES should be performed under cover with platelet transfusion or fresh frozen plasma. Alternatively, nasobiliary drainage can be done to relieve obstruction with later elective ES after coagulation status has returned to normal.

Indications for ES and stone removal

Acute obstructive suppurative cholangitis

Reynold's pentad (pain, jaundice, fever, confusion and hypotension) is the classical presentation of stone impaction at the ampulla with purulent bile above, under pressure. This is a medical emergency. Appropriate antibiotic therapy (aminoglycoside, ureidopenicillin and metronidazole) is given and followed by emergency biliary decompression. Although no controlled trials of ES versus percutaneous drainage or surgery exist, the results of ES⁶ are superior to other techniques and ERCP with ES and stone removal is the treatment of choice.

Acute cholangitis

Gall stones are the cause of cholangitis in over 80% of cases. Leese *et al.*⁷ have now reported a retrospective series of 81 patients with gallstone-related cholangitis and have clearly shown both the efficacy and safety of endoscopic sphincterotomy as initial management. Comparing sphincterotomy with surgery both complications (27.9 vs 57.1%) and mortality (4.7 vs 21.4%) were significantly lower using an endoscopic approach.

Empyema of the gall bladder following sphincterotomy for cholangitis occurs in approximately

5% of cases and particularly in those with an obstructed cystic duct. This risk is minimized by ensuring adequate biliary decompression combined with prolonged antibiotic cover.⁸ Despite this complication, long term follow-up demonstrates the safety of bile duct clearance by ES alone, only 7.0% requiring later cholecystectomy.⁸ Thus, endoscopic sphincterotomy provides the definitive therapy for acute cholangitis although corroborative prospective data would be valuable.

Duct stones without cholangitis

The two most important factors in planning treatment of these patients are, first, the general fitness of the patient to undergo surgery and second, the presence or absence of the gall bladder.

Endoscopic sphincterotomy is generally regarded as the treatment of choice for elderly patients with accompanying medical risk factors who are consequently unfit for general anaesthesia, independent of whether they have had a previous cholecystectomy. Overall, clearance rates of 85–90% are common. However, this group remains at particularly high risk from ES, with a recent series reporting an overall mortality of 11.3%.⁸ The need for successful drainage of the biliary tree has been emphasized in this group of 106 patients with the gall bladder *in situ*. A complication rate of 30.4% was reported in those with failed drainage compared with 11.7% when the duct was cleared. This was a highly significant difference.

In younger patients with a previous cholecystectomy, an endoscopic procedure is appropriate rather than surgical exploration on the basis of lower mortality and morbidity, albeit based on studies in older patients.^{9–12}

The management of young, fit patients with a gall bladder *in situ* is as yet unclear with little published data to go on. Reported studies are retrospective reviews of heterogeneous populations of patients – no randomized controlled trials have been described although they are under way. Can the existing published data give any guidelines?

Table II summarizes the published data on a predominantly elderly population group and gives a brief meta-analysis.^{4,8,13–25} Procedural success is over 90% and common bile duct clearance approximately 72–100%. Complication rates are seen in about 10% of this group and mortality is variable. Clearly these patients – mainly elderly – would be at greater risk than younger patients whether ES or surgery is performed. Later cholecystectomy is needed in approximately 10% of patients indicating that successful clearance of the common duct alone is sufficient treatment for most patients. These data confirm the efficacy of ES alone in this predominantly elderly group.

Table II Retrospective studies of endoscopic sphincterotomy for common duct stones with gall bladder *in situ*

Study	Number	Mean age (years)	Mean follow-up (months)	Procedure success (%)	CBD clearance (%)	Total complication rate (%)	Early mortality (%)	Late cholecystectomy (%)
Cotton ¹³	71	72	19	99	86	8.5	1.4	10.4
Cotton ¹⁴	118	78	40	—	—	5.9	0	5.3
Escourrou ¹⁵	234	79	22	92	72	—	—	5.3
Solhaug ¹⁶	22	74	28	95	82	18.2	0	18.2
Moss ¹⁷	33	72	15	91	77	15.2	6.6	9.5
Duron ¹⁸	33	83	1	94	76	0	6.1	—
Tanaka ¹⁹	162	69	36	—	—	10	0.6	3.2
Martin ²⁰	81	76	24	99	86	7.5	1.2	6.1
Rosseland ⁴	75	77	5–8 years	100	95	13.3	2.7	15
Davidson ⁸	106	79	30	99	81	19.8	4.7	7.0
Siegel ²¹	1272	73	8–13 years	100	—	14.6	0.15	8.5
Miller ²²	54	75	28	—	89	9.0	3.7	21
Worthley ²³	20	80	8	100	100	—	0	30
Hansell ²⁴	121	80	24	100	96	4.1	5	18
Ingoldby ²⁵	186	80	32	99	93	4.8	1.6	9.6
Total	2588	76	34	97	86	10.1*	2.4	11.9

CBD – common bile duct; *Including cholecystitis (1.2%).

The extension of sphincterotomy to a younger population with gall stone disease remains an untested idea, the chief concern being the lack of data on the natural history of biliary tract problems following ES. Nevertheless, as Cotton has written . . . ‘few would advise (sphincterotomy) for fit patients under the age of 60 years; the expectation of life is substantial, and the risk of long term complication is much greater . . . further data would clarify the situation; randomized studies would be welcome but are difficult to mount’.²⁶

The place of ES followed by elective cholecystectomy versus surgery alone remains an open question. Theoretically, the mortality of surgical common duct exploration is higher than sphincterotomy (2–8% *vs* 1%) and so use of ES to clear ducts before cholecystectomy would be expected to improve outcome. The first prospective randomized study to test this hypothesis was reported by Neoptolemos *et al.*²⁷ In a study of 115 patients with known common duct stones, there was no significant difference in major (16.4% *vs*; 8.5%) and minor (16.4% *vs* 13.6%) complication rates between surgical and ES groups. This study has been criticized however for excluding the most ill patients who might have shown particular benefit from sphincterotomy.²⁸ However, Heinerman *et al.*²⁹ have recently reported a prospective non-randomized study of 728 patients. Preoperative ES reduced the post-operative complication rate from 21.8% to 2.1% and mortality from 3.8 to 1%. Unfortunately, no statistical analysis of their data was given. A long term, prospective clinical trial of

ES alone versus ES or surgical removal of common duct stones followed by cholecystectomy would be difficult to perform, but is the only way forward for this controversial issue.

Despite all precautions some patients have retained duct stones after cholecystectomy. If a T-tube has been inserted in the bile duct, is of sufficient size (> 14 FG) and can be left long enough to form an adequate tract (greater than 4 weeks) then the percutaneous trans-T-tube tract approach can be used for stone removal. This technique has a lower complication rate than ES and is the method of choice. Often, however, the diameter of the T-tube inserted is too narrow to allow this approach and ES is indicated.

Acute pancreatitis

Gallstones are the most frequent (50%) underlying cause of acute pancreatitis in the UK. Mortality in this group is approximately 10% and it is hypothesized that the cause of the pancreatitis is gallstone impaction at the junction of the pancreatic and common bile ducts. Circumstantial support for this finding is provided by the fact that stones are found in the bile ducts in up to 60% of patients with pancreatitis but the incidence falls as the pancreatitis subsides.³⁰ However, it is not known whether the continued presence of gallstones is responsible for progression of an attack from mild to severe. Would all patients benefit from endoscopic decompression of the biliary tract or are there particular high risk groups?

Having confirmed the safety of sphincterotomy in 107 patients with gallstone pancreatitis³¹ Neoptolemos *et al.* reported a prospective randomized trial in 121 patients who received either sphincterotomy within 72 hours of admission or conventional resuscitative treatment only.³² They stratified patients within 48 hours of admission into mild or severe groups based on the modified Glasgow criteria³³ and found that complications (particularly respiratory and heart failure, pseudocysts and pleural effusions), mortality and length of hospital stay were significantly lower in the group having ES. Moreover, there were no procedure-related complications in this group. It would therefore appear that early sphincterotomy may be the treatment of choice in severe gallstone pancreatitis. This represents approximately 25% of all admissions for pancreatitis.³² However, opinions differ as to exactly which patients should receive ERCP and ES since there is a high rate of spontaneous recovery.³⁴

Failed endoscopic removal of common duct stones: options

Failure to clear the common duct occurs in only 10% of cases following successful ES. The principle reasons for failure of duct clearance will be that stones are too large (> 1.5 cm) or too numerous. The main adjuvant treatments available are lithotripsy, dissolution therapy and stenting.

Mechanical lithotripsy (stone crushing) has a role³⁵ but is now being supplemented by extracorporeal shock wave techniques and lasers. Shock wave lithotripsy may be most appropriate for large stones^{36,37} with clearance rates of up to 86% and may become the treatment of choice where available. Pulsed laser lithotripsy also has potential using an endoscopically placed laser fibre.³⁸ Complications appear minimal to date but the potential for tissue damage requires a time consuming and sophisticated system to prevent tissue contact.

Dissolution therapy with methyltertbutyl ether, though successful,³⁹ again requires technically demanding systems of delivery and its widespread application will be limited.

Endoprosthesis insertion is quick, usually easy and prevents subsequent duct obstruction and sepsis. Early studies demonstrating the feasibility of stents⁴⁰ have now been followed by larger studies⁴¹ which show successful drainage of the

biliary tract in over 90% of cases with a 1 to 5 year follow-up.

Risk factor assessment in patients undergoing ES

With these expanding indications for ES, is there any way of identifying preprocedural risk factors which would help the (referring) clinician to choose the best approach for a particular patient?

Neoptolemos *et al.*⁴² have shown that only serum bilirubin and albumin were of independent significance in predicting morbidity after ES. Medical conditions were not predictive of risk. Interestingly, they identified ES itself as a risk factor for complications after surgery. This group advocates further non-surgical procedures when possible, rather than operation, if there are ES-related complications.

In elderly patients with gall bladders *in situ* there is a risk of cholecystitis and empyema after ES for duct stones. Davidson *et al.*⁸ reported that the only factor predicting complications was the presence of pre-existing cholangitis. This emphasizes the requirement for complete clearance of duct stones as discussed above. Furthermore, non-filling of the gall bladder at cholangiography, implying an obstructed cystic duct, is associated with persistent symptoms and raised mortality.²³ However, patient numbers are small in this study and are not supported by other, larger series.⁸

Conclusion

Endoscopic removal of common bile duct stones is now a routine procedure available in many district general hospitals as well as teaching centres. In general, it is the procedure of choice to remove common duct stones in the elderly and those with cholangitis. ERCP and ES is probably appropriate in patients with severe pancreatitis, particularly when not resolving. Retrospective analysis, however, reveals areas of considerable uncertainty, for example, its use in younger patients with intact gall bladders. Therapeutic ERCP carries with it complications and further effort is needed to precisely define risk factors for ES. Prospective studies of stone number and size, sphincterotomy diameter, non filling gall bladder, pre-existing cholangitis and laboratory criteria are difficult, but are needed to improve the management and outcome of patients with common bile duct stones.

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