

# Comparison of endoscopic sphincterotomy and laparoscopic exploration of the common bile duct

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**Background:** Laparoscopic exploration of the common bile duct is becoming more popular, although endoscopic sphincterotomy remains the usual treatment for bile duct stones. However, loss of the biliary sphincter causes permanent duodenobiliary reflux, and recurrent stone disease and biliary neoplasia may be a consequence.

**Methods:** A systematic literature review was conducted to compare laparoscopic exploration with endoscopic sphincterotomy. A text word search of the Medline, Pubmed and Cochrane databases, and a manual search of the citations from these references, was used.

**Results:** Endoscopic sphincterotomy is associated with a median (range) mortality rate of 1 (0–6) per cent, compared with 1 (0–5) per cent for laparoscopic bile duct exploration. The median (range) rate of pancreatitis following endoscopic sphincterotomy is 3 (1–19) per cent; this is a rare complication after laparoscopic duct exploration. The combined morbidity rate for laparoscopic cholecystectomy and endoscopic sphincterotomy is 13 (3–16) per cent, which is greater than 8 (2–17) per cent for laparoscopic bile duct exploration. Randomized trials are few and contain relatively small numbers of patients. They show little overall difference in rates of duct clearance, but a higher mortality rate and number of hospital admissions are noted for endoscopic sphincterotomy compared with laparoscopic bile duct exploration. Endoscopic sphincterotomy is associated with recurrent stone formation (up to 16 per cent) with associated cholangitis. It is also associated with bacterobilia and chronic mucosal inflammation. The late development of bile duct cancer has been reported in up to 2 per cent of patients.

**Conclusion:** Laparoscopic exploration of the common bile duct may be a better way of removing stones than endoscopic sphincterotomy plus laparoscopic cholecystectomy.

Paper accepted 13 August 2002

British Journal of Surgery 2002, 89, 1495–1504

## Introduction

The advent of endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic sphincterotomy has dramatically changed the management of bile duct stones. Mortality in elderly patients fell from reported rates of up to 7.4 per cent for open bile duct exploration to 0.2–2.3 per cent<sup>1,2</sup>. The value of endoscopic sphincterotomy was particularly obvious in those who were unfit for general anaesthesia, in whom it was, and still is, accepted that bile duct stones may be removed with the gallbladder left *in situ*<sup>3–5</sup>. Since its inception, ERCP with sphincterotomy has been used increasingly in elderly patients with bile duct stones and serious co-morbidity, who would otherwise have posed a therapeutic problem – often insuperable. Conversely, young healthy patients were still treated by

open operation without much mortality<sup>6</sup> and with preservation of the biliary sphincter.

The second revolution in the management of bile duct stones came with the development of laparoscopic cholecystectomy<sup>7,8</sup>. Suddenly, gallbladder stones could be treated surgically without laparotomy. By this time, however, endoscopic sphincterotomy was in widespread use, and many surgeons favoured this endoscopic method of treating bile duct stones rather than continuing with open operation. An added advantage is that endoscopic sphincterotomy can be performed before or after laparoscopic cholecystectomy, depending on the circumstances. Consequently, a group of young and fit patients, previously treated by bile duct exploration at open operation following a positive finding on operative cholangiography, could now undergo sphincterotomy.

ERCP with sphincterotomy is quick and often painless; it is usually successful. However, there are reports of adverse effects of endoscopic sphincterotomy in the short, medium and long terms. These include pancreatitis, duodenal perforation and bleeding, and failure to clear the duct in the short term. In the medium term cholangitis and recurrent stone formation may occur, and in the longer term bile duct malignancy. Recently, laparoscopic exploration of the common bile duct has been described, with apparently good results<sup>9,10</sup>. The aim of this review of the available literature was to try to determine the appropriate management of bile duct stones.

## Methods

An electronic search of the Medline and Pubmed databases and the Cochrane Controlled Trials Register was conducted using the following keywords: common bile duct stones, common bile duct calculi, endoscopic cholangio-pancreatography, ERCP, endoscopic sphincterotomy, ES, laparoscopic cholecystectomy, cholecystectomy, laparoscopic common bile duct exploration, common bile duct exploration. These terms were mapped to Medline Subject Headings (MESH) terms as well as being searched for as text items. The titles and abstracts of 'hits' were assessed and the relevant articles were acquired. The references cited in retrieved articles and review articles were cross-checked manually to locate other relevant papers. Studies in all languages were considered. The relevance and validity of each article was assessed and included if it reported a series of 50 or more patients. All randomized trials were included, irrespective of sample size. Papers published before 1990 and those with fewer than 50 patients were excluded because of a desire to include only those studies for which reasonable experience in either technique could be assumed, in order to minimize any effect of technical inexperience. The end-points of the study were short-term efficacy, mortality, complications, and long-term results.

## Results

Published data on endoscopic sphincterotomy are shown in *Tables 1* and *2a*. The reported success rates for sphincterotomy vary from 79 to 98 (median 92) per cent and duct clearance from 75 to 96 (median 91) per cent respectively. These rates do not improve in larger or more recent studies. Total complication rates vary from 2 to 24 (median 8) per cent and mortality rates from 0 to 6 (median 1) per cent. Pancreatitis occurs after diagnostic ERCP and this complication is increased after sphincterotomy. Reported incidences following sphincterotomy vary from 1 to 19 (median 3) per cent, but associated deaths are not usually

reported separately. The data of Deans *et al.*<sup>17</sup> appear to show that age has no influence, but patients aged less than 55 years were six times more likely to suffer this potentially serious complication than older patients. Tham *et al.*<sup>29</sup> and Freeman *et al.*<sup>13</sup> recorded a similar but less marked bias towards increased risk in younger patients. Cholangitis occurs in up to 4 per cent of patients, and haemorrhage has an overall incidence of 1–6 per cent, with a mortality rate of about 2 per cent. Duodenal perforation occurs in 1–2 per cent, also resulting in a high mortality rate. The overall mortality rate following endoscopic sphincterotomy is 0–6 per cent. There has been little change in the rate of complications over the decades; indeed the rate of postprocedure pancreatitis appears to have risen, from a median (range) of 1 (1–4) per cent in the 1980s to 3 (1–19) per cent in the 1990s.

Medium-term results are now increasingly available, and are summarized in *Table 3*. The rate of late biliary symptoms varies from 7 to 11 per cent. Reported complications consist mainly of recurrent stones (2–16 per cent) with or without sphincterotomy stenosis (1–7 per cent) and cholangitis (1–6 per cent). The recurrent stone rate increases according to the length of follow-up. These tabulated studies have a median follow-up of 8 (range 1–15) years from the initial sphincterotomy. Ikeda *et al.*<sup>42</sup> reported a recurrent stone rate of 6 per cent after a mean of 2.4 years, even though the mean follow-up period in this study was only 3.7 years. Recent data from Japan show a continuing accrual of recurrent stones up to 25 years after sphincterotomy, with no sign of a plateau<sup>37</sup>. *Table 4* summarizes reports in the literature describing further long-term sequelae of sphincterotomy or biliary bypass procedures. Bacterobilia, mucosal hyperplasia and bile duct cancer have been recorded, including two reports of cancer after endoscopic sphincterotomy<sup>26,37</sup>.

Laparoscopic common bile duct exploration was started in the early 1990s and several reports are available. These are summarized *Tables 2b* and *5*. Some describe the early and later experience of the same authors; all have been included. Bile duct clearance rates are over 90 per cent in 70 per cent of reports, with a median retained stone rate of 5 (range 0–19) per cent and a median rate of conversion to open operation of 4 (range 1–20) per cent. The median mortality rate is 1 (range 0–5) per cent and the complication rate 8 (range 2–17) per cent. The success, mortality and morbidity rates show no improvement with the number of patients in the series.

The results of randomized trials comparing ductal exploration with endoscopic sphincterotomy and subsequent laparoscopic cholecystectomy are shown in *Table 2a,b*. When these studies alone are summated, the rates of duct clearance and length of stay are similar for both

**Table 1** Success rates and early complications of endoscopic sphincterotomy

Reference	Year	No. of patients	CBD stones (%)	Age (years)	Successful sphincterotomy (%)	Successful duct clearance (%)	Morbidity (%)	Pancreatitis (%)	Haemorrhage (%)	Cholangitis (%)	Duodenal perforation (%)	Mortality (%)
Siefert <i>et al.</i> <sup>11</sup>	1982	9041 (25 centres)	84				8	1	2	1	1	
Safrany <i>et al.</i> <sup>12</sup>	1978	3853 (15 centres)	85		93*	90	7	1	2	1	1	1
Freeman <i>et al.</i> <sup>13</sup>	1996	2347	68				8	5				2
Geenan <i>et al.</i> <sup>14</sup>	1981	1250 (21 centres)	88				9	3	2	2	1	
Sherman <i>et al.</i> <sup>15</sup>	1991	1204	97	55			5					1
Vaira <i>et al.</i> <sup>16</sup>	1989	1000				87	7					1
Deans <i>et al.</i> <sup>17</sup>	1997	958		73			2	1				0
Lambert <i>et al.</i> <sup>18</sup>	1991	602		76	91†		10	3	5	2	1	2
Wojtun <i>et al.</i> <sup>19</sup>	1997	483	100		96*		7	3	2	1	1	
Escourrou <i>et al.</i> <sup>20</sup>	1984	443	100		92*	96	7	1	4		1	
Leese <i>et al.</i> <sup>21</sup>	1985	394	81	67	98*	92	10	3	6	2	1	1
Welbourn <i>et al.</i> <sup>22</sup>	1995	306	53	50	79*							
Viceconte <i>et al.</i> <sup>23</sup>	1981	296	86	62	86*	82	7		5	2		1
Siegel <sup>24</sup>	1981	267	87	66	98*		6	1	3	1	1	1
Boender <i>et al.</i> <sup>25</sup>	1994	242	100	70	94*	82	14	2	6	4	2	
Prat <i>et al.</i> <sup>26</sup>	1996	169	100	< 70		90	6		1	3	1	
Sugiyama and Atomi <sup>27</sup>	1998	115	100	50 (< 60)	97†	96	8	4	3	1	1	
Bergman <i>et al.</i> <sup>28</sup>	1997	101	100	71		92	24	7				
Tham <i>et al.</i> <sup>29</sup>	1994	45	58	44 (< 55)			10		4			

CBD, common bile duct. \*Mean; †median

**Table 2a** Summary of randomized controlled trials: endoscopic sphincterotomy

Reference	Year	No. of patients	No. with CBD stones	Mean age (years)	Cannulation success (%)	Cholangiogram success (%)	Stones (%)	Therapeutic success (%)	Missed stones (%)	Duct clearance (%)	Retained stones (%)	Morbidity (immediate) (%)	Pancreatitis (%)	30-day morbidity (%)	Mortality rate (%)	Length of stay (days)
Neoptolemos <i>et al.</i> <sup>30</sup>	1987	55		61				96		91		16	4			9
Hammerstrom <i>et al.</i> <sup>31</sup>	1995	39		75				90			10	3	3	28	0	13
Targarona <i>et al.</i> <sup>32</sup>	1996	50	25	79	94	94	50	88	2	88		16	2	16	6	5
Sees and Martin <sup>33</sup>	1997	31	8	54				90					19			14
Rhodes <i>et al.</i> <sup>34</sup>	1998	40	40	68			100	75						15	2	4
Suc <i>et al.</i> <sup>35</sup>	1998	97						95			16	13			3	12
Cuschieri <i>et al.</i> <sup>9</sup>	1999	150	98		95		72	84		84		13	4		2	9

CBD, common bile duct

**Table 2b** Summary of randomized controlled trials: duct exploration

Reference	Year	No. of patients	Mean age (years)	Laparoscopic or open	Success rate (%)	Conversion rate (%)	Retained stones (%)	Morbidity rate (%)	Mortality rate (%)	Length of stay (days)
Neoptolemos <i>et al.</i> <sup>30</sup>	1987	60	59	Open	92		8	7	2	11
Hammerstrom <i>et al.</i> <sup>31</sup>	1995	41	74	Open	90		2	7	5	16
Targarona <i>et al.</i> <sup>32</sup>	1996	48	80	Open	96		2	8	4	11
Sees and Martin <sup>33</sup>	1997	51	51	Laparoscopic	100	20				10
Rhodes <i>et al.</i> <sup>34</sup>	1998	40		Laparoscopic	75	2		10	0	1
Suc <i>et al.</i> <sup>35</sup>	1998	105		Laparoscopic	100		6	4	1	16
Cuschieri <i>et al.</i> <sup>9</sup>	1999	150		Laparoscopic	83	13		16	1	6

**Table 3** Medium-term complications of endoscopic sphincterotomy

Reference	Year	No. of patients	Length of follow-up (years)	Symptom-free (%)	Biliary symptoms (%)	Recurrent stones (%)	Papillary stenosis (%)	Ascending cholangitis (%)	Bile duct cancer (%)	Mortality rate (%)
Bergman <i>et al.</i> <sup>36</sup>	1996	94	15.0†			14	10			1
Sugiyama and Atomi <sup>27</sup>	1998	103	14.2*	90		8	7	5		
Tanaka <i>et al.</i> <sup>37</sup>	1998	410	10.1*			12	1	5	2	
Prat <i>et al.</i> <sup>26</sup>	1996	154	9.6*	88		2	2		2	
Hawes <i>et al.</i> <sup>38</sup>	1990	115	8.0*	83	11					
Tham <i>et al.</i> <sup>29</sup>	1994	30	8.0*	87	10		6	3		
Hammarstrom <i>et al.</i> <sup>39</sup>	1998	64	7.0†			5				
Wotjun <i>et al.</i> <sup>19</sup>	1997	483	6.0*		10	6	1	1		
Jacobsen and Matzen <sup>40</sup>	1987	96	4.1*	93	7	3		6		2
Testoni and Tittobello <sup>41</sup>	1991		4.0*	86		10				
Ikeda <i>et al.</i> <sup>42</sup>	1988	408	3.7*			6	7			
Greenfield <i>et al.</i> <sup>43</sup>	1985	25	3.0*	76						
Siefert <i>et al.</i> <sup>11</sup>	1982	9041		82		6	3			
Geenan <i>et al.</i> <sup>44</sup>	1998	2096	1.0*			2				

\*Mean; †median

**Table 4** Long-term complications of endoscopic sphincterotomy and biliary–enteric anastomosis

Reference	Year	Complication
Bergmann <i>et al.</i> <sup>45</sup>	1997	Permanent loss of sphincter function, bacterobilia and chronic inflammation
Sand <i>et al.</i> <sup>46</sup>	1992	Bacterobilia resulting in deconjugation of bile and formation of pigment stones
Kurumado <i>et al.</i> <sup>47</sup>	1994	Bacterobilia resulting in deconjugation of bile and formation of pigment stones
Gregg <i>et al.</i> <sup>48</sup>	1985	Bacterobilia resulting in deconjugation of bile and formation of pigment stones
Kurumado <i>et al.</i> <sup>47</sup>	1994	Biliary hyperplasia or atypia
Eleftheliadis <i>et al.</i> <sup>49</sup>	1988	Biliary hyperplasia or atypia
Tanaka <i>et al.</i> <sup>37</sup>	1998	Bile duct cancer
Prat <i>et al.</i> <sup>26</sup>	1996	Bile duct cancer
Strong <sup>50</sup>	1999	Bile duct cancer following biliary–enteric anastomosis
Hakamada <i>et al.</i> <sup>51</sup>	1997	Bile duct cancer following transduodenal sphincteroplasty
Tocchi <i>et al.</i> <sup>52</sup>	2001	Bile duct cancer following biliary–enteric drainage

methods, but with a slightly higher morbidity and significantly higher mortality rate (2 *versus* 1 per cent;  $P = 0.03$ ) for endoscopic sphincterotomy compared with laparoscopic exploration. No long-term results are yet available for laparoscopic bile duct exploration.

**Discussion**

A major difficulty in considering the literature reports is that there are frequently no clear definitions of patient popula-

tions, therapeutic success and complication rates. This means comparisons can be only approximate. Many trials involving laparoscopic surgery have been undertaken while the participating surgeons were relatively inexperienced and their methods have varied. This has probably also happened in some of the studies of laparoscopic bile duct exploration, including the randomized trials. The larger series of laparoscopic bile duct exploration including all-comers describe a consistent duct clearance rate of over 90 per cent; the randomized trials do not achieve this value.

**Table 5** Summary of bile duct explorations

Reference	Year	No. of patients	Age (years)	Laparoscopic or open	Unsuspected CBD stone (%)	Success rate (%)	Conversion rate (%)	Retained stones (%)	Morbidity rate (%)	Mortality rate (%)	Length of stay (days)
Roukema <i>et al.</i> <sup>53</sup>	1986	1007		Open (1971–1980)				0	14	2	
Martin <i>et al.</i> <sup>54</sup>	1998	300	51†	Laparoscopic		90	4		7	0	2.0
Millat <i>et al.</i> <sup>55</sup>	1997	236		Laparoscopic	25	88	10	5	13	0	
Berci and Morgenstern <sup>56</sup>	1994	226	54‡	Laparoscopic	41		7	3	6	0	
Berthou <i>et al.</i> <sup>57</sup>	1998	220		Laparoscopic		95	1	3	9	2	7.8
Giurgiu <i>et al.</i> <sup>58</sup>	1999	217		Laparoscopic		97		4			
Millat <i>et al.</i> <sup>59</sup>	1996	189	68‡	Laparoscopic		81	10	4		0	
Paganini and Lezoche <sup>60</sup>	1998	161		Laparoscopic		98	2	8	9	1	
Drouard <i>et al.</i> <sup>61</sup>	1997	161		Laparoscopic		92		4	7	0	7.6
Dorman <i>et al.</i> <sup>62</sup>	1998	148	53‡	Laparoscopic		97	3	2	4	1	
Snow <i>et al.</i> <sup>63</sup>	1999	136		Laparoscopic	31	84	8		8	1	
Phillips <i>et al.</i> <sup>64</sup>	1994	130		Laparoscopic	37	93		3	17	1	3.7
Rhodes <i>et al.</i> <sup>65</sup>	1995	129	47†	Laparoscopic		96			5		
Phillips <i>et al.</i> <sup>66</sup>	1995	129		Laparoscopic		90	3	5	13	1	3.4/9.5*
Keeling <i>et al.</i> <sup>67</sup>	1999	120		Laparoscopic		89					
Millat <i>et al.</i> <sup>68</sup>	1995	115	69‡	Laparoscopic		87	10	3			
DePaula <i>et al.</i> <sup>69</sup>	1994	114		Laparoscopic		90	3	1	6	1	1.7
Paganini <i>et al.</i> <sup>70</sup>	1995	110	57‡	Laparoscopic	39	96	4	5	8	1	
Pappas <i>et al.</i> <sup>71</sup>	1990	100	53‡	Open (1982–1986)				5		0	
Lezoche <i>et al.</i> <sup>72</sup>	1996	100		Laparoscopic		96	4	5	7	1	
Petelin <sup>73</sup>	1993	86		Laparoscopic		97	1	2	9	1	1.9
Swanstrom <i>et al.</i> <sup>74</sup>	1996	77		Laparoscopic				1	5		
Petelin <sup>75</sup>	1993	77		Laparoscopic		96	1	3			1.9
Hawasli <i>et al.</i> <sup>76</sup>	2000	73		Laparoscopic		85		11			
Ido <i>et al.</i> <sup>77</sup>	1996	73		Laparoscopic		93	0	19	5	0	9.4
Stoker <sup>78</sup>	1995	64		Laparoscopic		94	6	5	9	0	2.8
Franklin <i>et al.</i> <sup>79</sup>	1994	60		Laparoscopic		97	3	0	2	2	2.8
Dion <i>et al.</i> <sup>80</sup>	1992	59		Laparoscopic			7	10	15	0	6.5/12.0*
Lieberman <i>et al.</i> <sup>81</sup>	1996	59		Laparoscopic		86	2	12	12	2	6.1
Khoo <i>et al.</i> <sup>82</sup>	1996	51		Laparoscopic		75	2	14	16	0	3.0

CBD, common bile duct. \*Transcystic *versus* transduced exploration; †median; ‡mean

Better randomized trials are needed with a clear statement that results are based on an intention-to-treat basis; so far this has not usually been the case.

This review shows that endoscopic sphincterotomy has three main disadvantages. First, rates of stone clearance may be as low as 75 per cent, with a median of 91 per cent (although several centres report higher rates of up to 100 per cent). This failure rate is clinically significant, although it may not be noticeable as an average UK general surgical practice would experience only one or two failures each year. Second, although the complication rate of the procedure has decreased with greater experience, pancreatitis continues to be a problem in most series, with an incidence of up to 7 per cent and a mortality rate of 0.2–2.3 per cent<sup>13,17,28</sup>. This complication rate depends more on technical factors than on concurrent medical risk<sup>16,83</sup>. Preliminary results of a recent trial from Arnold *et al.*<sup>84</sup> show a 10 per cent incidence of pancreatitis, which accounts for most of the sphincterotomy-related complications. In an average district hospital performing 200 cholecystectomies

per year this would result in one or two cases of pancreatitis per year, and possibly one death from this complication in 7–10 years. (This assumes that 10 per cent of patients undergoing laparoscopic cholecystectomy have bile duct stones.) Another report<sup>11</sup> demonstrates a higher risk of pancreatitis among young and otherwise healthy patients, although this is challenged by a report from Cetta *et al.*<sup>85</sup> refuting such risk when the sphincterotomy is performed by experts. Several attempts have been made to prevent pancreatitis, but with little success<sup>86</sup>. Laparoscopic bile duct exploration does not avoid pancreatitis, although this complication occurs only when instruments are passed through the sphincter of Oddi. To date, only a few cases have been reported, suggesting an incidence of about 1 per cent. Most series do not report pancreatitis as a problem.

As endoscopic sphincterotomy enters its third decade, medium- and longer-term results are now available and the third disadvantage is becoming apparent. Several centres have now published 10-year follow-up data. The late biliary complications include a disappointing rate of recurrent duct

stones some years after sphincterotomy, without evidence of a plateau effect<sup>37</sup>. Endoscopic sphincterotomy alone produced inferior results when subjected to a randomized trial against open cholecystectomy and bile duct exploration<sup>32</sup>, despite all the patients in the trial being at increased risk for open operation because of older age or coexistent medical conditions. The surgically treated patients had fewer late biliary complications. The retained gallbladder may have contributed to the biliary complications in the endoscopic group. A preliminary communication from Peppelenbosch *et al.*<sup>87</sup> described a 2 per cent bile duct stone rate at 10 years after open cholecystectomy with bile duct exploration, compared with a rate of 19 per cent after endoscopic sphincterotomy.

The sphincter of Oddi provides a barrier that prevents reflux from the duodenum into the bile duct, and biliary sphincter function is permanently lost after sphincterotomy<sup>45</sup>. A high rate of bacterobilia occurs after endoscopic sphincterotomy (up to 60 per cent), the result of duodenobiliary reflux<sup>46,48</sup>. Recurrent bile duct stones are soft brown calcium bilirubinate stones resulting from bacterial infection<sup>88,89</sup>. Confirmed duodenobiliary reflux and bacterial contamination of the bile ducts are responsible for the continuing duct stone formation with time<sup>90</sup>. The resultant clinical problem has led both Geenen *et al.*<sup>44</sup> and Ikeda *et al.*<sup>42</sup> to recommend annual ERCP and stone extraction in patients who have undergone sphincterotomy.

These circumstances are similar to those pertaining in the presence of duodenal diverticula, where an incompetent sphincter results in bacterial contamination of the bile ducts and formation of pigment stones due to bacterial deconjugation of bilirubin<sup>91,92</sup>.

Once the barrier provided by the sphincter of Oddi is abolished, duodenobiliary reflux causes the biliary epithelium to adapt to a new environment. Kurumado *et al.*<sup>47</sup> produced varying degrees of bacterobilia in rodents by constructing biliary–enteric anastomoses. Examination of the mucosa showed hyperplasia in almost all cases, and epithelial atypia in two of six patients with a choledochojejunostomy. Eleftheliadis *et al.*<sup>49</sup> took gastroscopic biopsies of the bile duct mucosa 1–12 years after choledochoduodenostomy, and detected hyperplasia and intestinal metaplasia of the bile duct epithelium in all nine patients. Hyperplasia and intestinal metaplasia have been found frequently in the epithelium adjacent to gallbladder cancer<sup>93</sup>. The above studies raise the possibility that chronic bacterobilia may lead to neoplastic change in the biliary epithelium. Bile duct cancer rates as high as 7.4 per cent have been reported in several studies 10–30 years after biliary–enteric anastomosis and transduodenal sphincteroplasty<sup>50,51</sup>. Surgeons from Japan<sup>37</sup> and France<sup>26</sup> have recently reported cases of bile duct cancer occurring

about 10 years after endoscopic sphincterotomy. Cholecyst-ectomy alone may protect against the development of bile duct cancer<sup>94</sup>, so any rise noted after sphincterotomy must be taken seriously.

An anomalous pancreaticobiliary junction is present in nearly all patients with congenital choledochal cysts<sup>95–97</sup>, a condition with a high incidence of malignancy<sup>98</sup>. The anatomical anomaly is frequently associated with biliary cancer without coexistent cyst formation. Abnormal reflux of pancreatic juice into the biliary tract occurs, reflected by the high amylase content of gallbladder bile in these cases. This enzymatic refluxate is activated in the bile ducts. Activated phospholipase A<sub>2</sub> has a directly proliferative effect on the gallbladder mucosa and, once activated, produces lysophosphatidylcholine, which has a cytotoxic effect. Both may cause mucosal hyperplasia and carcinoma of the gallbladder<sup>95</sup>. It is possible that destruction of the biliary sphincter by sphincterotomy may allow reflux of pancreatic juice into the bile duct, producing mucosal changes; further study is required.

It seems, therefore, that there is a good case for preserving the biliary sphincter in young patients with bile duct stones. If dividing the sphincter is to be avoided in order to preserve the physiological status of the biliary system, what reasonable alternatives are available? Endoscopic balloon sphincteroplasty has been used<sup>99,100</sup> with the hope that sphincter of Oddi function may recover, in contrast to the permanent destruction caused by sphincterotomy<sup>101,102</sup>. The reported incidences of postsphincteroplasty pancreatitis and persistent bacterobilia suggest no improvement over those for endoscopic sphincterotomy<sup>48</sup>.

The alternative of supraduodenal exploration of the bile duct at open operation is safe and effective in fit patients<sup>6</sup>. Recent experience with laparoscopic common bile duct exploration outside randomized trials has demonstrated initial bile duct clearance rates consistently above 90 per cent; a few of the larger series are based on ‘all-comers’. There is a consistently lower incidence of pancreatitis after laparoscopic exploration, compared with open exploration<sup>103–105</sup> which, when applied to larger numbers, should reduce the mortality rate in young fit patients. This would render the laparoscopic approach the preferred option, even after previous cholecystectomy<sup>106</sup>. For older or less fit patients the choice is more difficult and randomized trials are required to determine any advantage of one treatment over the other. The National Institutes of Health in the USA has examined the role of endoscopic sphincterotomy in the management of choledocholithiasis, and concluded that laparoscopic common bile duct exploration is more efficient and is preferable when surgical proficiency in this technique is available.

If such proficiency is not available, is open bile duct exploration to maintain a competent sphincter a good alternative? The results reported by Vellacott and Powell<sup>1</sup> in 1979 were poor: a 51 per cent negative exploration rate, 9 per cent retained stone rate and 7 per cent mortality rate. However, these results were achieved by inexperienced surgeons more than 20 years ago. Ten years later better results were reported: a negative exploration rate of 29 per cent, retained stone rate of 3 per cent and a mortality rate of 3 per cent<sup>107</sup>. Results from recent randomized trials with one arm as open duct exploration have suggested a 6 per cent retained stone rate and 1 per cent mortality rate for all age groups<sup>108</sup>, and a 6 per cent retained stone rate and 4 per cent mortality rate for high-risk patients<sup>32</sup>. The results of both trials slightly favour open operation over endoscopic treatment. A population-based study from Pennsylvania completed in 1989 reported a mortality rate of 3.5 per cent in 5530 patients over 65 years old undergoing open cholecystectomy and exploration of the common bile duct; 28 per cent of these patients were over 80 years old<sup>109</sup>. High rates of duct clearance are required, avoiding surgical sphincterotomy or choledochoduodenostomy; choledochoscopy is probably the best method of achieving this objective<sup>110</sup>.

Taking all the evidence into account, the authors conclude that laparoscopic exploration of the bile duct appears to be the best option overall for young fit patients. There may be a marginal advantage over endoscopic sphincterotomy in terms of mortality risk in the short term and possibly fewer late sequelae, although long-term follow-up studies are required to confirm any such effect. No such judgement can be made in respect of patients with co-morbidity adding to the operative risk; randomized trials are required to address the management of this group of patients.

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