Prospective audit of the introduction of laparoscopic cholecystectomy in the west of Scotland

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Abstract

Although laparoscopic cholecystectomy has rapidly developed in the treatment of gall bladder disease in the absence of controlled clinical trial data its outcome parameters compared with open cholecystectomy remain unclear. A prospective audit of the introduction of laparoscopic cholecystectomy in the west of Scotland over a two year period was carried out to attempt to assess this new procedure. A total of 45 surgeons in 19 hospitals performing laparoscopic cholecystectomy submitted prospective data from September 1990-1992. A total of 2285 cholecystectomies were audited (a completed data collection rate of 99%). Laparoscopic cholecystectomy was attempted in 1683 (74%) patients and completed in 1448 patients (median conversion rate to the open procedure 17%). The median operation time in the completed laparoscopic cholecystectomy patients was 100 minutes (range 30-330) and overall hospital stay three days (1-33). There were nine deaths (0.5%) after laparoscopic cholecystectomy although only two were directly attributable to the laparoscopic procedure. In the laparoscopic cholecystectomy group there were 99 complications (5.9%), 53 (3%) of these were major requiring further invasive intervention. Forty patients (2.4%) required early or delayed laparotomy for major complications such as bleeding or bile duct injuries. There were 11 (0.7%) bile duct injuries in the laparoscopic cholecystectomy series, five were noted during the initial procedure and six were recognised later resulting from jaundice or bile leaks. Ductal injuries occurred after a median of 20 laparoscopic cholecystectomies. In conclusion laparoscopic cholecystectomy has rapidly replaced open cholecystectomy in the treatment of gall bladder disease. Although the overall death and complication rate associated with laparoscopic cholecystectomy is similar to open cholecystectomy, the bile duct injury rate is higher.

(Gut 1994; 35: 1121-1126)

Despite the widespread acceptance of this new technique there have been no formal comparisons of laparoscopic cholecystectomy with conventional cholecystectomy. Indeed the requirement for a controlled clinical trial of laparoscopic cholecystectomy and open cholecystectomy has been considered unethical.⁸

Only one controlled study with comparatively small numbers has compared laparoscopic with a small incision 'minicholecystectomy' and this study showed an advantage for the laparoscopic procedure in terms of more rapid return to normal activities.⁹ Initial uncontrolled reviews of laparoscopic cholecystectomy have shown significant patient benefit in terms of reduced wound pain and shortened hospital stay^{7 10-13} but at the expense of an increased bile duct injury rate^{7 10} compared with previous data from conventional cholecystectomy. These uncontrolled studies while accumulating large numbers of patients have been selective, assessing up to 88% only of all cholecystectomies performed.⁷ The outcome and safety of laparoscopic cholecystectomy in treating gall stone disease therefore remain unclear.

In this report we describe a prospective audit of the introduction of laparoscopic cholecystectomy in the west of Scotland. The main aim of this study was to examine the safety and efficacy of laparoscopic cholecystectomy in current surgical practice.

Methods

The west of Scotland serves a population of 2 422 130 and is covered by 15 NHS hospitals (six teaching, nine district general) and four private hospitals. A group of west of Scotland surgeons met in September 1990 and agreed to prospectively audit all laparoscopic cholecystectomies in the region over a two year period. After this meeting a total of 45 surgeons in 15 NHS and four private hospitals cooperated in the data collection as the west of Scotland laparoscopic cholecystectomy audit group. This represented 100% of the surgeons performing laparoscopic cholecystectomy in the participating hospitals. Individual surgeons contributed patient data from their first laparoscopic procedure until the study was terminated in September 1992. Each surgeon contributed patient data, however, on all cholecystectomies performed over the two year study period - that is, from day 1 (first laparoscopic procedure) to termination of

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Accepted for publication
30 November 1993

Laparoscopic cholecystectomy has rapidly emerged as the most popular treatment option for the patient with gall stones.¹⁻⁷

study in September 1992. Data were collected on a standard proforma but complete collection of audit data was achieved by a research nurse who visited all participating hospitals, reviewed the operating theatre record books, and completed the documentation from individual patient case sheets. The close cooperation between surgical units in the west of Scotland also facilitated data collection.

To ensure standardisation it was agreed that a complication should be defined as any postoperative problem that delayed hospital discharge or required further treatment, or both. These were further subdivided into: (1) major – a complication that required further open surgery or invasive intervention (radiological and/or endoscopic), or both; (2) minor – a complication that delayed discharge or required further non-operative treatment, or both.

A conversion from laparoscopic to open cholecystectomy was only regarded as a complication if this was performed for urgent reasons such as haemorrhage, bile duct or bowel injury. Overall complete data collection was achieved in 99% of all cholecystectomies performed over the study period.

PATIENTS

The 45 surgeons performed a total of 2285 cholecystectomies over the two year period. Laparoscopic cholecystectomy was started in 1683 patients, median age 48 years (range 16–87) and completed laparoscopically in 1448 patients (86%). For each surgeon the proportion of patients having laparoscopic cholecystectomy was 74% (median) (range 30–99). In the laparoscopic group 97% of patients had cholelithiasis, 2% had acalculous cholecystitis, 0.6% had gall bladder polyps, and 0.2% had suspected biliary dyskinesia. In 0.2% of cases the diagnosis before operation was not stated. The median conversion rate to open cholecystectomy was 17% (range 0–45).

Six hundred and two (26%) patients (median age 56 years (19–88)) had open cholecystectomy as the initial procedure. The commonest reason for patients having an open cholecystectomy was choledocholithiasis (27%), a requirement for other surgery (18%) followed by previous abdominal surgery (8%), laparoscopic equipment problems (5%), and obesity (4%). Sixteen per cent of patients were recruited to a concomitant 'mini'-cholecystectomy study. In 22% of cases the reason for open cholecystectomy was not stated.

Results

OPERATIVE TECHNIQUE

Laparoscopic dissection of the gall bladder bed was by diathermy in 95% of patients, 5% of patients had dissection by laser (one surgeon).

Of the 1448 completed laparoscopic cholecystectomies 133 (9%) had operative cholangiograms performed compared with

272 of 602 patients (45%) having open cholecystectomy.

OPERATIVE TIME

Of the 1448 patients completing laparoscopic cholecystectomy the median operation time was 90 minutes (range 30–330). In the 235 patients having open conversion from the laparoscopic procedure the median operation time was 105 minutes (30–270). The median operation time for open cholecystectomy in this series was 75 minutes (range 25–345).

OPERATIVE FINDINGS

Laparoscopic

Of the 1448 cases completing laparoscopic cholecystectomies, 46% had a normal looking gall bladder; 32% exhibited signs of chronic cholecystitis; 7% of gall bladders seemed contracted and fibrosed; 3.5% were acutely inflamed, 2.2% had mucocoeles, and 1% of patients had empyemata. In 8% of cases the operative findings were not described. In 10 cases there was unexpected pathology findings. These were cirrhosis (2), pelvic inflammatory disease (2), healed duodenal ulcer perforations (2), liver metastases (1), choledochal cyst (1), hepatic cyst (1), and a Morgagni hernia (1).

Common bile duct stones

Overall 151 (10%) of patients having laparoscopic cholecystectomy had an endoscopic retrograde cholangiopancreatography (ERCP) before operation and 42 had an endoscopic sphincterotomy for bile duct stones. Thirty one patients had a postoperative ERCP for suspected retained stones (n=22) or bile duct injuries (n=9).

At laparoscopic cholecystectomy nine patients had stones identified by operative cholangiography. Three patients had conversion to open cholecystectomy with duct exploration. Six patients had postoperative ERCP with four having stones confirmed by this examination and cleared after endoscopic sphincterotomy.

HOSPITAL STAY

The patients having completed laparoscopic cholecystectomy were discharged from hospital after three days (range 0–72) compared with nine days (range 1–177) in those having open cholecystectomy.

RETURN TO WORK OR NORMAL ACTIVITIES

Patients returned to work or normal activities at a median of 12 days (1–144) after laparoscopic cholecystectomy compared with 35 days (2–161) after open cholecystectomy.

REASONS FOR CONVERSION TO THE OPEN PROCEDURE (n=235)

The requirement for conversion to an open

TABLE I Reasons for conversion to open cholecystectomy (n=235) (%)

Urgent (n=29)		Elective (n=206)	
Haemorrhage	21 (72)	Adhesions	74 (36)
Bile duct damage	5 (17)	Acute inflammation	45 (22)
Bowel injury	3 (10)	Ill defined anatomy	45 (22)
		Obesity	12 (6)
		Insufflation problems	12 (5)
		Instrument failure	5 (2.5)
		Gall bladder leak	5 (2.5)
		Duct stones	3 (1.5)
		Others	5 (2.5)

cholecystectomy was divided into ‘urgent’ and ‘elective’ categories. ‘Urgent’ conversions were designated for laparoscopic procedures where a complication (bile duct damage, haemorrhage or trocar/instrument induced organ damage) had occurred necessitating immediate conversion. ‘Elective’ conversions were designated for laparoscopic procedures where it was deemed safer to convert to open procedure because of intra-abdominal adhesions, severe inflammation, access or instrument problems or the presence of bile duct stones on operative cholangiography.

Of the 29 patients having ‘urgent’ conversions, 21 had bleeding as the primary reason for conversion (Table I). Five patients had bile duct injuries and three had bowel injuries noted at the time of laparoscopic cholecystectomy leading to conversion.

There were 206 ‘non-urgent’ conversions to open cholecystectomy (Table I). The commonest reasons were intra-abdominal adhesions (36%), acute inflammation (22%), and ill defined anatomy (22%) (Table I).

MORTALITY

There were 14 deaths (0.6%) in the 2285 cholecystectomies performed over the study period. Nine deaths (0.5%) occurred after laparoscopic cholecystectomy although four of these occurred in patients who had conversions to the open procedure (Table II). Five patients (0.3%) died after laparoscopic cholecystectomy alone (Table II). Of these only one could be directly attributable to the laparoscopic procedure.

Five patients (0.8%) died after open cholecystectomy.

TABLE II Mortality after laparoscopic cholecystectomy (n=9) (0.5%)

Age	Days after operation	Cause of death
Laparoscopic (n=5)		
78	5	Left ventricular failure
60	6	Myocardial infarct, died 24 hours after emergency coronary artery bypass graft and mitral valve replacement
68	2	Myocardial infarct, gastric carcinoma
62	Operative	Trocar induced aortic perforation
71	44	Bile leak, pulmonary embolism
Conversion from laparoscopic to open (n=4)		
71	6	Conversion due to adhesions, peritonitis secondary to small bowel perforation
79	8	Conversion due to poorly visualised anatomy, pneumonia
65	3	Conversion due to poorly visualised anatomy, myocardial infarct
55	8	Conversion due to haemorrhage, acute pancreatitis secondary to impacted bile duct stone
Median		
68 (55–78)	6 (0–44)	

COMPLICATIONS

There were 99 complications (5.9%) noted in 1683 patients undergoing laparoscopic cholecystectomy (Table III). The complication was deemed major in 53 patients (3%) with 29 patients (1.7%) requiring urgent conversion for haemorrhage, bile duct or bowel injury (Table III). Of the remaining patients with major complications, 11 required delayed laparotomy for bile duct injuries (4), peritonitis secondary to bowel injury (3), haemorrhage (2), or strangulated incisional hernias (2). Overall, therefore, 40 patients (2.4%) required a laparotomy for complications developing during or after laparoscopic cholecystectomy. Forty six patients had minor complications (2.8%) after laparoscopic cholecystectomy (Table III).

SEX AND CONVERSION RATE

The overall conversion rate from laparoscopic to open cholecystectomy was higher in male patients 69/326 (21%) compared with female patients 166/1357 (12%) (p<0.002) (χ^2 test). The complication rates, however, after laparoscopic cholecystectomy were similar in women (6%) compared with men (5%).

BILE DUCT INJURIES

There were 11 (0.7%) bile duct injuries in this series of laparoscopic cholecystectomies (Table IV), five of these were recognised intraoperatively and this resulted in immediate conversion to the open procedure with either hepaticojejunostomy or primary duct repair and T tube drainage being performed. In six patients the bile duct injury was only recognised postoperatively by the development of a biliary fistula (n=4) or progressive jaundice (n=2). In four of these patients laparotomy was performed at a median of seven days (range 6–30), after initial cholecystectomy with either biliary-enteric bypass or simple repair being performed. Two patients with bile duct strictures were treated by endoscopic biliary stent insertion (Table IV).

The 11 bile duct injuries were incurred by 10 surgeons (nine consultants, one senior registrar) after a median of 20 laparoscopic cholecystectomies (range 3–51). Operative cholangiography was performed in two of these patients and this was after the ductal injuries had occurred. Two bile duct injuries (0.3%) occurred in patients having an open cholecystectomy.

Discussion

Laparoscopic cholecystectomy has been rapidly accepted by patients and surgeons as the preferred procedure for the treatment of gall stones.^{1–5 10–14} Its progression has been unchecked by the usual constraints of assessment by controlled clinical trial because of its widespread, largely unchallenged, acceptance by the surgical profession. The advantages of laparoscopic cholecystectomy include reduced wound pain, lack of scarring, and reduced

TABLE III Complications of laparoscopic cholecystectomy in 1683 patients

	No	% Incidence
<i>Major (n=53)</i>		
Urgent conversions:		
Haemorrhage	21	1.2
Bile duct injury	5	0.3
Bowel injury	3	0.2
Bile duct injuries	6	0.4
Bile collections	7	0.4
Incisional hernias	4	0.2
Peritonitis (bowel injury)	3	0.18
Haemorrhage	2	0.1
Subphrenic abscess	1	0.06
Cholangitis	1	0.06
<i>Minor (n=46)</i>		
Wound infection	8	0.5
Wound haematoma	7	0.4
Minor bile collections	7	0.4
Urinary retention	5	0.4
Urinary tract infection	5	0.4
Chest infections	4	0.2
Retained stones	4	0.2
Pneumothorax	3	0.18
Atrial fibrillation	3	0.18
Total	99	5.9

hospital stay with earlier return to work or normal activity. The major drawback of the laparoscopic procedure relates to its apparent higher bile duct injury rate compared with the open procedure.^{7 10}

In this large prospective audit of laparoscopic cholecystectomy in a defined west of Scotland population we hoped to answer some questions relating to the safety and efficacy of laparoscopic cholecystectomy. In this series we have collected data in 99% of all cholecystectomies performed by all the surgeons in the participating hospitals who undertake laparoscopic cholecystectomy. This is therefore a true reflection of cholecystectomy practice during each surgeons introduction to laparoscopic cholecystectomy. The data collection was aided by the close cooperation and geographical location of the surgical units in the west of Scotland.

It is clear from this study that the trend to laparoscopic surgery for gall stone disease is rapid and probably now unstoppable. Overall 74% of patients with gall bladder disease in this series had laparoscopic cholecystectomy with this figure rising to 88% in those surgeons with more than two years laparoscopic experience.

The benefits of laparoscopic cholecystectomy are clear from this audit. Most patients were discharged home from hospital after their laparoscopic cholecystectomy at three days

with most patients returning to work or normal activities by 12 days. We have recently shown that such clear patient benefits are accompanied by direct cost savings to hospitals by adopting laparoscopic cholecystectomy.¹⁵

The overall morbidity associated with laparoscopic cholecystectomy (6%) is similar compared with the open procedure, which has reported morbidity rates of 5–25%.^{16–19} In this series, 53% of our complications were important requiring therapeutic intervention with either further surgery or interventional radiology; haemorrhage being the commonest complication requiring urgent conversion to the open procedure. The commonest minor complication in this series was wound infection, which occurred despite antibiotic prophylaxis. Some complications noted are unique to laparoscopic surgery. Three patients in this study had visceral damage related to cannula insertion after induction of the pneumoperitoneum. These injuries may be avoided by the insertion of the initial port under direct vision as with the Hasson cannula – that is, open laparoscopy.²⁰ The four complications of incisional hernias through a cannula site can also be avoided by direct fascial closure at completion of laparoscopy.

The major concern relating to laparoscopic cholecystectomy has been the increased bile duct injury rate compared with the open procedure. Although this was higher at 0.5% in a large series of laparoscopic cholecystectomies⁷ compared with the figure for open cholecystectomy of 0–0.4%,^{18 19 21–23} the overall duct injury rate remains unknown but of concern.^{24–26} In our series the bile duct injury rate is also significantly higher than the previously established figure for open cholecystectomy. Bile duct injuries occurred during open cholecystectomy caused by dissection in poorly visualised areas with unclear anatomy^{27–29} and such factors seem to pertain in the laparoscopic procedure.

Certain patterns of bile duct injury during laparoscopic cholecystectomy are emerging. Firstly, excessive cystic duct traction may tent the common bile duct and lead to misidentification of this structure for the cystic duct with clipping or resection of the common bile duct and often right hepatic artery injury.³⁰ Secondly, inadvertent clipping of the bile duct may occur during hilar bleeding and thirdly thermal and ischaemic ductal injury through either injudicious use of diathermy or excessive dissection of the cystic/common bile duct junction.^{25 31} The requirement for surgeons to operate in a two dimensional field certainly contributes to misidentification of important structures and the recent development of three dimensional imaging may help reduce this risk.

With open cholecystectomy the risk of bile duct injury was highest between the surgeons 25th and 100th procedure²³ and this early period also seems to be the laparoscopists most vulnerable with a bile duct injury at a median of 20 procedures noted in the current study.

The role of operative cholangiography in prevention of bile duct injuries in open cholecystectomy is unclear although most

TABLE IV Bile duct injuries after laparoscopic cholecystectomy (n=11) (0.7%)

Age	Presentation	Duct injury	Treatment	Days after operation
37	Post operative jaundice	CHD transection	Hepaticojejunostomy	30
23	Post operative bile leak	CBD stricture	Choledochoduodenostomy	6
64	Post operative jaundice	CHD clipped	Hepaticojejunostomy	6
41	Post operative bile leak	CBD and right HD lacerations	Suture repair	7
50	Post operative bile leak	CBD stricture	Endoscopic stent	
54	Bile leak	CBD stricture	Endoscopic stent	
34	Intraoperative recognition	CBD transected	Hepaticojejunostomy	
38	Intraoperative recognition	CBD laceration	Repair with T tube drainage	
63	Intraoperative recognition	CBD laceration	Repair with T tube drainage	
26	Intraoperative recognition	CBD/cystic duct junction laceration	Repair with T tube drainage	
62	Intraoperative recognition	Minor CBD laceration	Drainage	

Median age 38 years (23–64). CHD=common hepatic duct, HD=hepatic duct, CBD=common bile duct.

authorities accept that an accurate biliary 'road map' is at least likely to offer some help in their prevention.^{24 25 32} In this series it is notable that operative cholangiography was performed in only 9% of patients having laparoscopic cholecystectomy compared with 45% of open cholecystectomy patients showing a change in surgical practice. In addition, of the 11 ductal injuries after laparoscopic cholecystectomy only two had operative cholangiography and this was performed after the injury had been produced. In a newly developing procedure such as laparoscopic cholecystectomy, which seems to carry an increased risk of bile duct injury it seems sensible that more frequent operative cholangiography should be performed particularly if the anatomy is in any way unclear.

The avoidance of bile duct injury during laparoscopic cholecystectomy may also require more closely regulated supervision of trainee laparoscopists particularly during their early 'learning curve' period. In addition patients with severe cholecystitis or previous abdominal surgery may be best treated by conventional open cholecystectomy from the outset. In difficult cases, however, where laparoscopy has been initiated perhaps a lower threshold for conversion to the open procedure would now seem appropriate. Retrograde dissection of the gall bladder in severe inflammation may also be helpful in decreasing the likelihood of ductal injuries.

The death rate in this unselected series of laparoscopic cholecystectomy stands at 0.5%, which is comparable with open cholecystectomy series. Of the nine deaths only the aortic perforation can be directly attributable to the laparoscopic procedure, although the small bowel perforation in the converted patient could have been a laparoscopic injury. Both aortic and bowel perforation are clearly technically avoidable complications especially if open laparoscopy is performed.

The treatment of bile duct stones with the advent of laparoscopic cholecystectomy remains controversial. At present the technique of laparoscopic common bile duct exploration and stone retrieval remains feasible in only a few highly experienced centres worldwide. With this proviso, surgeons in this study initially regarded choledocholithiasis as an indication for an open cholecystectomy. A significant number of patients with choledocholithiasis, however, have now been treated by a minimally invasive combination treatment of preoperative ERCP, endoscopic sphincterotomy, stone clearance, and subsequent laparoscopic cholecystectomy. Unless bile duct exploration techniques become clearly established this combination seems to be the most acceptable.

We conclude that laparoscopic cholecystectomy is rapidly replacing open cholecystectomy as the preferred treatment for patients with gall bladder disease. In this introductory period, although clear patient benefits exist, there is an increased risk of major bile duct injury with laparoscopic cholecystectomy. More judicious patient selection, increased use

of cholangiography, and earlier conversion to open procedure may be helpful in decreasing the ductal injury rate after laparoscopic cholecystectomy.

We wish to thank Mrs Helen Leslie, audit nurse, Inverclyde Royal Hospital, for help in this study and Mrs Annette Bowie for her secretarial assistance.

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