Laparoscopic cholecystectomy in England and Wales: results of an audit by The Royal College of Surgeons of England

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The results of an audit of open and laparoscopic cholecystectomy conducted by the Comparative Audit Service of The Royal College of Surgeons of England are presented. Data were submitted by 124 consultant surgeons on 3319 attempted laparoscopic and by 227 consultant surgeons on 8035 open cholecystectomies performed in England and Wales during the 2 years 1990 and 1991. These were contrasted with 9322 attempted laparoscopic cholecystectomies reported in 21 series reported in the world literature between 1991 and 1992, and with five other nations' audit studies. Among attempted laparoscopic cases, conversion to an open procedure was necessary in 175/ 3319 (5.2%) of cases and overall mortality was 0.15% (5/3319). Major complications were reported in 2.1% and minor complications in 5.9% of cases. Bile duct injury was reported to be significantly more common after attempted laparoscopic cholecystectomy (11/ 3319, 0.33%) than after open cholecystectomy (4/8035, 0.06%) (95% confidence intervals -0.48 to 0.08), but it was not significantly different from that reported for laparoscopic cholecystectomy in the combined world literature (28/9322, 0.3%) (95% confidence intervals -0.19 to 0.25). Most systemic complications were significantly more common after open cholecystectomy. For open cholecystectomy, the mortality was 55/8035 (0.76%), with major complications reported in 3.2% and minor complications in 9.8% of patients. Adoption of the laparoscopic approach was associated with a four-fifths reduction in the mortality of cholecystectomy, and a 40% reduction in the overall complication rate when compared with the open operation. While laparoscopic cholecystectomy has an impressively low mortality and morbidity profile during the first 2 years of its introduction into the UK, prevention of bile duct injury is the most important issue to be addressed in all laparoscopic cholecystectomy training programmes.

The first laparoscopic cholecystectomy in England was performed in February 1990, and in 1992 it is estimated that 10 000 cholecystectomies (about 25% of the national total) were done laparoscopically (1). The rapid adoption of laparoscopic cholecystectomy by a large number of surgeons worldwide has focused the attention of regulatory bodies and the lay public alike on issues relating to quality control. The demand for a prospective controlled trial of laparoscopic versus open cholecystectomy has never really been fulfilled, with only three small trials having been reported in the world literature (2-4). The main problem in recruiting patients for such trials is difficulty in obtaining informed consent (5). In the absence of such controlled trials, a careful prospective audit of large numbers of laparoscopic and open cholecystectomies performed contemporaneously seems the best way to document the results of this relatively new operation. National audit studies have been reported from Belgium (6), France (7), Scotland (8), Switzerland (9) and the USA (10). The task of organising a similar audit project in England and Wales was taken up by The Royal College of Surgeons of England Comparative Audit Service in 1991. This service has previously reported the results of its audit performed in England and Wales (11,12) in which its methodology has been successfully tested.

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Material and methods

The Comparative Audit Service of The Royal College of Surgeons of England was established in 1990 to enable surgeons to compare their results confidentially. In all, 1025 general surgical Fellows of The Royal College were circulated by letter asking them if they wished to participate in such a project by submitting data about their surgical activity to the Comparative Audit Service. Data to be submitted included details of surgical workload, case mix, number of operations performed, deaths and complications. Participation was voluntary, and all potential participants were assured that the data submitted by them would remain confidential. A total of 227 surgeons agreed to participate and had sufficient access to data to be able to do so. Each one was allotted a unique number by a member of The Royal College office staff. Analysis of the data submitted for this study was performed by the authors who had access to the numbers but not the names of the participating surgeons. The surgeons who participate have regular access to comparison of their own results with the pooled results of others. Thus, they are able to recognise areas of poor performance, and hopefully take the appropriate remedial action. An advantage of voluntary participation is that those who do submit data are likely to be interested in the result of the audit and therefore to submit complete and truthful accounts of their results and complications. Compulsory participation would only encourage the submission of inaccurate data. Keeping the audit confidential ensured that there was nothing to be gained by falsifying data so as to make exaggerated claims to excellence.

Surgeons who had agreed to participate in this study were mailed a booklet proforma in March 1991 requesting details of their surgical activity during 1990. Separate data were requested for cholecystectomies (open and laparoscopic), and these are listed in Table I. The proforma was intentionally kept simple and surgeons were encouraged to complete them and return them within 1 month. A complicated proforma would have made available more data for statistical analyses, but would have discouraged many surgeons from replying. Complications were classified according to the system involved, and as 'major' if they were life-threatening or significantly prolonged the patient's hospital stay. Otherwise, they were classified as 'minor'. Another booklet proforma was mailed in March 1992 requesting data for 1991.

For the purpose of comparison, data from major world series of laparoscopic cholecystectomy reported in the world literature and indexed in *Index Medicus* were used.

Table I. Data requested in proforma sent by the Comparative Audit Service to consultants

Number of cholecystectomies—open, laparoscopic, converted
Number of common bile duct explorations
Duration of postoperative stay and range
Complications—total number, major and minor, and by system
Deaths

Only those series which included at least 50 cases, and gave full details of mortality, complications and rates of conversion to open cholecystectomy were selected. In all, 21 series published between 1991 and 1992, and involving 9322 cases were compared with cases reported to the comparative audit service. These studies mainly represent the results of 'centres of excellence' or leaders in the field, while the data reported to the Comparative Audit Service is from a wide range of participating surgeons. Comparisons have also been drawn with results of audit studies from other nations (6–10).

Results

During the years 1990 and 1991, data on 8035 open cholecystectomies were reported by 227 surgeons (Table II) and data on 3319 attempted laparoscopic cholecystectomies by 124 surgeons (Table III).

Of the laparoscopic cases, 175 had to be converted to an open operation (5.2%). There were five reported deaths, including one that occurred in a converted case, giving an overall mortality of 0.15%, significantly lower than that reported for open surgery (55/8035, 0.76%) (95% confidence intervals, -0.86 to -0.35). Major non-fatal complications were reported in 56 patients (2.05%), and minor complications in 161 (5.9%) of laparoscopic cases. At open cholecystectomy, major complications were reported in 203 patients (3.2%) and minor complications in 614 (9.8%). Most systemic complications were significantly more common at open cholecystectomy, compared with laparoscopic cholecystectomy (Table IV). Bile duct injury occurred in 7/3144 cases (0.26%) of cases completed laparoscopically, and if bile duct injuries reported in the converted cases are added to this, the total bile duct injury rate for attempted laparoscopic cholecystectomy was 11/3319 cases (0.33%). This is significantly higher than the bile duct injury rate

Table II. The Royal College of Surgeons of England Comparative Audit Service. Audit of open cholecystectomy 1990–1991. Complications in 8035 cases.

	Deaths	Wound infections	Respir- atory	Haemor- rhage	Cardio- vascular		Urolo- gical	Meta- bolic	CNS	Retained stone	Bile duct injury	Bile leak	Other
n	55	145	170	32	81	55	134	20	20	32	4	65	105
%	0.76	2.31	2.7	0.51	1.29	0.87	2.13	0.32	0.32	0.51	0.06	1.03	1.67

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Year l	Attempted !aparoscopic	Attempted Converted to Completed aparoscopic open laparoscopic	Completed laparoscopic Deaths	Deaths	Wound infection	Respir- atory	Haemor- rhage	Cardio- vascular	15	GI Urological	Metabolic (SNS	Retained stone	Bile duct Injury	Bile leak	Other
1990	364	23	341	00	6	0.3	6	0 0	1 0.3	4	00	00	00	3	4	7 2.11
1991 %	2955	152 5.1	2803 94.9	5 0.17*	32 1.34	19 0.79	22 0.92	11 0.46	5 0.21	22 0.92	00	5 0.21	6 0.25	8 0.27*	31 1.29	30
1990 + 1991	3319	175	3144	2	38	70	28	=	9	56	0	2	9	11	35	37
comonied %		5.2	94.8	0.15*	1.39	0.73	1.03	0.4	0.22	0.95	0	0.18	0.22	0.33*	1.28	1.36

^{*} Denominator includes converted cases

Table IV. Comparison of the results of laparoscopic versus open cholecystectomy, The Royal College of Surgeons of England Comparative Audit Service 1990-1991

	Mortality	Total complications	Wound infections	Respir- atory	Haemor- rhage	Cardio- vascular	IÐ	Urological	CNS	Retained Stone	Bile duct injury
Open cholecystectomy 1990–1991 $(n = 8035)$ Laparoscopic cholecystectomy 1990–1991 $(n = 3144)$ Observed difference 95% Confidence intervals	55 (0.76%) 5* (0.15%) -0.61 -0.86-	817 (13.0%) 217 (7.95%) -5.0 -6.3-	145 (2.31%) 38 (1.39%) -0.92 0.43	170 (2.7%) 20 (0.73%) -1.97 -2.5- -1.5	32 (0.51%) 28 (1.03%) 0.52 0.1– 0.9	81 (1.3%) 11 (0.4%) -0.88 -1.2- -0.52	55 (0.87%) 6 (0.22%) -0.65 -0.94-	134 (2.13%) 26 (0.95%) -1.2 -1.7- -0.7	20 (0.32%) 5 (0.18%) -0.13 -0.35- 0.07	32 (0.51%) 6 (0.22%) -0.29 -0.54-	4 (0.06%) 11* (0.33%) 0.28 -0.48-
orginicant: yes/mo	2	3	2	3	S	2	C	S	2	I CS	I CS

^{*} Includes converted cases: denominator = 3319

Table V. Major world series of laparoscopic cholecystectomy 1991–1992

	4			7.77									7.7.4	7.6	
Author (reference no)	Allempleu laparoscopic	converted	Deaths	Wound Deaths infection	atory	naemor- rhage	vascular	$I\mathcal{D}$	Urological Metabolic	Metabolic	CNS	retained stone	stone injury	Dile leak	Other
Spaw et al. (13)	200	6	0	0	0	1	-	2	40	0	0		0	1	
Fitzgibbons et al.	350	12	0	7	6	7	2	2	0	0	-		0	7	60
(14)															
Schirmer et al. (15)	152	13	0	5	-		7				_		-		0
Corbitt and Cantwell	400	9	0	-		60						7	0	0	
(16)															
Haicken (17)	135	œ	-	0	0	-	-	0	-				-	_	-
Wilson et al. (18)	180	10	0	7	0	1	0	7	0	0	0	6	-	_	7
Peters et al. (19)	283	œ	7	7	0	1	0	7	0	0	0	3	4	7	-
Bailey et al. (20)	375	20	-	_	0	7	7	0	7	0	0	7	6	-	7
Hershman and Rosin	195	ю	0	0	0	7	0	_	0	0	0	2	-	3	0
(21)															
Scott et al. (22)	210	4	0	=======================================	3	60			7			1	1	7	
Rees and Williams	155	œ	0	0									-	7	7
(23)															
South. Surgeons (24)	1518	72	-	16	4	2	7	9	9			4	7		9
Cuschieri et al. (25)	1236	45	0	7	0	3	0	7	0	0	0		-	7	∞
Voyles et al. (26)	453	24	0	0	0	7						7	0	_	_
Stoker et al. (2)	280	14	0	_	3	1	0	7	7	0	0	3	0	-	3
Larson et al. (27)	1983	88	7	5	7	7	7	9	0	-	0	9	Ŋ	7	3
Meador et al. (28)	82	6	0	10	7	0	0	0	0	0	0		0	0	7
Neugebauer et al. (5)	100		0	0	0	0	0	6	0	0	0	0	1	0	0
Grace et al. (29)	20	9	0	7	0	_	0	_	0	0	0	1	0	7	2
Graves et al. (30)	304	21	0	0	0	0	0	7	0	0	0	0	1	0	0
Wolfe et al. (31)	381	12	6	7	2	-	_	-	4	_	7	7	0	10	7
Total n	9322	386	10	29	23	36	13	20	57	7	4	34	28	38	46
%		4.15	0.11	0.73	0.27	0.41	0.16	69.0	0.71	0.03	90.0	0.53	0.3	0.53	0.5

Table VI. Comparison of audit data on laparoscopic cholecystectomy with major world series

		Wound							Retained	Bile duct	
	Deaths	infections	Deaths infections Respiratory Ha	Haemorrhage	Cardiovascular	$I\mathcal{D}$	Urological	CNS	stone	injury	Bile leak
Current study 1990–1991 $(n = 3144^*)$	5	38	20	28	11	9	26	5	9	11	35
` *	0.15	1.39	0.73	1.03	0.4	0.22	0.95	0.18	0.22	0.33	1.28
Major world series $1990-1992$ ($n = 9174^*$)	10	29	23	36	13	20	57	4	34	78	38
·	0.11	0.73	0.27	0.41	0.16	69.0	0.71	90.0	0.53	0.34	0.53
Observed difference	-0.05	99.0-	-0.47	-0.62	-0.24	0.47	-0.24	-0.12	0.31	0.03	-0.87
95% confidence	-0.22-	-1.1-	-0.84-	-1.02-	-0.5-	0.21 -	-0.65-	-0.29-	0.05	-0.19-	-1.3-
interval	0.12	-0.19	-0.13	-0.22	0.014	0.73	0.17	0.05	9.0	0.25	-0.43
Significant? yes/no	No	Yes	Yes	Yes	No	Yes	No	No	Yes	No	Yes

^{*} Includes only those cases completed laparoscopically. † Includes converted cases: denominator = 3319. ¶ Includes converted cases: denominator = 9322

Table VII. Complications in cases converted from laparoscopic to open cholecystectomy

i		Wound						Retained	Bile duct		
	Deaths	infection	Deaths infection Respiratory Hae	Haemorrhage	morrhage Cardiovascular	GI	GI Urological	stone	injury	Bile leak	Other
Royal College CAS $1990-1991$ ($n = 175$)	1	7	0	8	1	1	2	2	4	0	5
%	0.64	2	0	5.7	0.7	0.2	1.4	1.4	2.8	0	2.86
Major world series	7	7			1	7			1		
1991–1992 ($n = 148$)	1.35	1.35 1.35	:		0.68	1.35			0.68		

Table VIII. England and Wales data compared with other nations' results of laparoscopic cholecystectomy

Country (ref no)	Number of cases	Conversions	Bile duct injuries	Complications	Deaths
England and				1,100	
Wales	3319	175 (5.2%)	11 (0.33%)	217 (8%)	5 (0.17%)
(current study)					
Belgium (6)	3244	6.5%	16 (0.5%)	6.4%	3 (0.09%)
France (7)	2955	4.8%	18 (0.6%)	3.4%	1 (0.03%)
Scotland (8)	1655	228 (14%)	11 (0.7%)	98 (5.8%)	8 (0.5%)
Switzerland (9)	1091	8.1%	5 (0.5%)	2.8%	0 `
USA (10)	77604	3–8%*	459 (0.6%)	1586 (2%)	33 (0.04%)

^{*} Conversion rate varied in different centres

reported for open cholecystectomy (4/8035, 0.06%) (95% confidence intervals -0.48 to -0.08). Exploration of the bile duct was carried out laparoscopically in 20/3144 patients (0.73% of cases), compared with 681/8035 patients undergoing open cholecystectomy (13.4%). The median of the mean hospital stays reported was 2.7 days for laparoscopic cases and 7.4 days for the open cases.

If the data reported to the Comparative Audit Service for 1990 and 1991 for laparoscopic cholecystectomy are considered separately, the reported total complication rate fell significantly from 11.5% to 7.5% (95% confidence intervals 0.42 to 7.6). The conversion rate fell from 6.3% in 1990 to 5.1% in 1991, and the bile duct injury rate fell from 0.82% to 0.27%, but these differences were not significant (Table III). This is probably related to surgeons' increasing experience of laparoscopic cholecystectomy, and suggests a 'learning curve' during this period.

In comparison, data reported in the combined world literature studied (2,5,13-31), show that 386 of 9322 attempted laparoscopic cholecystectomies had to be converted to open operations (4.15%) (Table V). Ten deaths were reported, giving an overall mortality of 0.11%. The mean stay was 1.76 days. Major complications were reported in 156/9174 patients (2.3%) and minor complications in 242/9174 (3%) of cases. Bile duct exploration was carried out in 49 patients (0.53% of cases). These data are compared with the data reported from England and Wales in Table VI. There are remarkable similarities in the incidence of various complications.

Converted cases

Complications reported in the small number of converted cases were higher than for those which were completed laparoscopically, and rates approached those occurring at open cholecystectomy. Out of 21 series in the world literature that were studied, only seven series specifically mentioned the complications occurring in converted cases separately (Table VII).

Laparoscopic cholecystectomy in England and Wales compared with audit studies from other nations

These are shown in Table VIII. The results of laparoscopic cholecystectomy in England and Wales are

compared with those from Belgium, France, Scotland, Switzerland and the USA. Bile duct injury rates for laparoscopic cholecystectomy in England and Wales are the lowest reported among national audit studies, but other complications appear to have a higher incidence.

Discussion

This is the first national audit study of laparoscopic cholecystectomy reported from England and Wales. It represents parallel audits of laparoscopic and open cholecystectomy. Comparison of these two groups are of interest, but does not represent a trial. The participation of 124 surgeons who reported 3319 laparoscopic cholecystectomies makes this study more representative of British surgery than single institution reports from the 'centres of excellence'. Since the data in this audit cover approximately one-third of all laparoscopic cholecystectomies undertaken in England and Wales during 1990 and 1991, the figures for mortality and morbidity represent the best estimate available to date of the outcome of the introductory phase of laparoscopic cholecystectomy in England and Wales. It is probably the biggest study reported in Europe, and is second only to the US study reported by Deziel et al. (10). The close similarities between this study and other world series (Table VI) and other national audits (Table VIII) suggest that, overall, British surgeons have been successful in introducing laparoscopic cholecystectomy safely.

In this study, it is clear that the effort to convert to laparoscopic surgery is worthwhile in terms of diminished danger to the patient, but further improvements in technique are necessary to lower the incidence of bile duct injuries.

As in other national audit studies (10), it is true that there are many surgeons who have not submitted data. Furthermore, an inherent limitation of this method of data collection is that the completeness and accuracy of data submitted cannot be verified. Another criticism is that surgeons would select the 'easy' cases and those without common bile duct stones for the laparoscopic approach early on in their learning curve, leaving the 'difficult' ones and those with common bile duct stones for the open approach. On these three counts, the figures reported in this study must be taken to represent at least the minimum incidence of complications of laparoscopic cholecystectomy and the patients from the laparoscopic and open operation audits cannot be considered directly comparable.

As is inevitable with any new surgical procedure, there is an element of 'case selection' with surgeons choosing straightforward 'good risk' patients for the laparoscopic approach early in their learning curve. This may partly be responsible for the better results seen for laparoscopic cholecystectomy. As surgeons' skill improves, more and more will adopt an 'all-comers' policy for laparoscopic cholecystectomy. It remains to be seen if such a policy has any influence on the complication rate. This is a topic that should be addressed in future audit studies of laparoscopic cholecystectomy.

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