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A prospective comparison of laparoscopic *versus* open cholecystectomy

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In one surgical unit, 115 patients undergoing cholecystectomy were studied to compare patient recovery, subjective and objective pain experienced and complications after laparoscopic and open cholecystectomy. The data were collected prospectively where allocation to open or laparoscopic cholecystectomy was by consecutive attendance. Laparoscopic cholecystectomy was feasible in 90% of patients presenting with symptomatic gallstones. Compared with the open operation, laparoscopic cholecystectomy was safe with less peroperative and postoperative morbidity, was more cost-effective and was associated with faster patient recovery as documented by less postoperative pain, earlier return to diet, earlier full mobilisation and discharge home. Laparoscopic cholecystectomy is superior to open cholecystectomy and should be available to all patients requiring elective cholecystectomy.

Over the past 2 years there has been an enormous increase in the popularity of the new operative technique of laparoscopic cholecystectomy. Cholecystectomy is the most common major general surgical operation performed in the developed world, with more than 40 000 performed every year in England and Wales and 500 000 performed every year in the United States of America *(1)*. This has allowed pioneers to perform huge personal series, such as Olsen with 800 laparoscopic cholecystectomies performed in less than 2 years *(2)*. Despite the large number of publications on the subject, the majority of papers make no scientific comparisons with the open operation but make presumptive claims of the benefits of the laparoscopic approach. In the few articles that do give comparative data, the information has been collected retrospectively and no attempt has been made to randomise *(3–5)*.

One study set out to perform a randomised, controlled trial but had to abandon the attempt because of 'ethical constraints' *(6)*. They concluded that the only way to assess the new technique was to use 'comprehensive surveillance'.

When we realised that this new technology was going to have a major impact on our own practice, we set up a prospective data collection protocol. While we waited for our new instruments to arrive we continued to perform open cholecystectomies and collected information on patient recovery, postoperative pain and complications. On arrival of the new instruments we set out to perform all cholecystectomies using the laparoscope. Thus, allocation was by the chronological order of patient arrival. This study was applied to all patients and there were no exclusions other than those specifically described. As the study included our initial experience, which involved a learning curve, we expected that any advantages of the new procedure were unlikely to be overestimated.

Patients and methods

A total of 115 consecutive cholecystectomies were performed by one surgical team over a 10 month period (Table I). The age and sex distribution were similar as was their average weight, cardiorespiratory fitness and medical and surgical history. The first 52 operations were performed by open cholecystectomy and all of the next 63 patients were considered for laparoscopic cholecystectomy. All except one of the 52 patients who had open cholecystectomy would have been suitable for a laparoscopic cholecystectomy. The one possible exception was a patient with a previous partial gastrectomy. Three of

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Table I. Age and sex distribution of patients considered for laparoscopic and open cholecystectomy

	Laparoscopic ($n=63$)	*Open* ($n=52$)
Female:Male	5:1	5:1
Age (SD)	52 (13)	51 (11)
Body mass (kg (SD))	72.3 (16.7)	66.7 (9.3)
Cardiac/respiratory status ASA score* (SD)	1.5 (0.8)	1.2 (0.4)

* American Society of Anaesthesia score

the latter 63 patients were regarded as unsuitable for laparoscopy because of previous right-sided upper abdominal surgery, where adhesions might limit access or provide an increased risk of complication during introduction of the instruments. We no longer consider this an absolute contraindication as our experience has grown. All operations were performed by the consultant or registrar and each performed a similar number of both techniques.

The open cholecystectomy was performed through a 12–15 cm right subcostal incision which involved cutting the rectus muscle to give access to the peritoneal cavity. In the laparoscopic approach we insufflated the peritoneum through a Veress needle placed below the umbilicus and then introduced a 10 mm trocar to allow insertion of a telescope carrying a video camera. We then placed instruments through three further points, one under the xiphisternum, one under the costal margin in the midclavicular line and another on the anterior axillary line. Positions varied depending on the size and shape of the patient and on the relative position of the gallbladder.

The operative technique was very much the same for each procedure. The anatomy of Calot's triangle was clearly identified, the cystic duct and artery isolated separately, clipped and divided, and the gallbladder was then dissected from the liver with diathermy and removed via the umbilical stab incision. We did not perform routine operative cholangiography in laparoscopic cholecystectomy during this trial, but in four patients preoperative endoscopic cholangiography was performed for a history of jaundice in three and pancreatitis in one. In two patients cholangiography revealed stones which were cleared endoscopically and the other two were normal.

The factors recorded during the study were recovery, pain perceived and complications. Recovery was measured by recording the duration of intravenous fluids, the time to oral fluids and diet and the number of days to discharge home. Postoperative pain was assessed by measuring the duration of intramuscular narcotic analgesia and subjectively using a visual analogue scale preoperatively and at 1 week postoperatively. The mark drawn by the patient on the horizontal line (Fig. 1) was scored using a linear scale of 1–10. This linear analogue score was recorded preoperatively (expected pain) and postoperatively (experienced pain) and compared between the laparoscopic and open groups. Comparisons were made using non-parametric statistics using the Wilcoxon rank sum test for groups and Fisher's exact test for proportions.

Results

In all, 57 laparoscopic cholecystectomies were performed successfully. Operative difficulties were few. In three of 60 operations (5%) a decision was made to convert the operation from laparoscopy to the open method. One was to facilitate the dissection of a large empyema, which was difficult even through the open wound. In one patient who had had previous upper abdominal surgery with adhesions, there was a perforation of the small intestine which was recognised and dealt with at the time of surgery. The third patient had abnormal anatomy and after a successful laparoscopic cholecystectomy we elected to open the abdomen to ensure that there was no ductal injury. No duct injury was found. The recovery of all three of these patients was uneventful. The laparoscopic technique gave excellent exposure, which was often superior to that achieved in open surgery, particularly in the obese patient. Blood loss during laparoscopic surgery was minimal with no patient requiring transfusion.

Table II shows the recovery and pain after open and laparoscopic cholecystectomy. Patients who had laparoscopic cholecystectomy started oral fluids and diet earlier than after open cholecystectomy. Discharge home was most dramatically improved by laparoscopy. These differences were statistically significant using the Wilcoxon rank test. Objective measurement of pain showed that patients required significantly less narcotic analgesia after laparoscopy than after open cholecystectomy. Using the visual analogue pain score, the preoperative pain expectation was no different in patients in either group. Postoperatively measurement of pain perceived was significantly less after laparoscopic cholecystectomy compared with the open approach ($P<0.05$).

The complications are listed in Table III. In the open group there were four patients who had exploration of

Prospective audit of biliary surgery:

Linear analog scale for expected post-operative pain

(none) | ---------- | (very severe)

At one month:

Linear analog scale for post-operative pain actually experienced.

(none) | ---------- | (very severe)

Figure 1. The visual analogue scale used to evaluate patients' subjective feeling of pain experienced by cholecystectomy. Before the operation the patient was asked to mark the position on the scale which represented the pain which he or she expected to experience. At 1 month after the operation the patient was asked to mark the position on the scale of the pain that they actually experienced postoperatively.

Table II. Patient recovery and pain experienced after open and laparoscopic cholecystectomy (medians)

	Open ($n=51$)	*Laparoscopic* ($n=57$)
Patient recovery		
Start oral fluids (h)	24	8*
Start diet (h)	40	19**
Discharge home (days)	6	2**
Postoperative pain		
Subjective (visual analogue scale)	4	2**
Objective (narcotic analgesia) (h)	28	16**

* $P<0.05$, ** $P<0.01$ (Wilcoxon Rank Sum)

Table III. Complications after open and laparoscopic cholecystectomy

Complications	*Open* ($n=51$)	*Laparoscopic* ($n=60$)
Common duct exploration	4	0
Duct injury	1	0
Wound infection	2	2
Respiratory infection/atelectasis	3	0
Small bowel perforation	0	1
Conversion to open	–	3

the common bile duct; exploration was not performed in any of the laparoscopic patients. There was one duct injury in the open group, repaired successfully, and none in the laparoscopic group. One patient required drainage of a subphrenic collection after laparoscopy. This was done under ultrasound control and the patient was discharged the next day. There were two wound infections in each group, but the morbidity attached to the infection of the 15 cm subcostal incision was much greater than that related to a discharge from the 1-cm stab wound below the umbilicus. Three patients had respiratory complications after open cholecystectomy and none after laparoscopy. The costs of laparoscopic cholecystectomy at £1030.00 (disposables, outlay on new technology, 2 days hospital stay) were cheaper than open cholecystectomy at £1450.00 (standard operation cost, 6 days hospital stay).

Discussion

The introduction of a new therapy into modern medical practice requires careful assessment in order to ensure its safety and efficacy. There are strict regulations set by law for a new drug. This is not the case for new techniques in surgery, but it behoves the surgical community to monitor their own endeavours. The introduction of laparoscopic surgery, especially in cholecystectomy, where it is being applied so enthusiastically, is a vitally important area for surgeons to assess carefully.

Few attempts have been made to carry out prospective randomised trials of the laparoscopic and open approach to cholecystectomy, and no such study has been completed. The authors of the attempt that failed described problems with randomisation, when patients or their surgeons perceived a great benefit from the new procedure and it was felt unethical to place patients in the control arm *(3)*. In fact, randomised trials are not impossible in surgical practice as we have recently successfully completed a fully randomised, prospective trial of laparoscopic *versus* open appendicectomy *(7)*, but during the latter study laparoscopic appendicectomy had not gained popular acclaim with either patients or surgeons, in contrast to the almost universal application of laparoscopy to cholecystectomy that has taken place in our region.

Our study of the technique of cholecystectomy has attempted to make a valid comparison between the new laparoscopic approach and the traditional open laparotomy procedure used since its introduction in 1888. Because of the difficulties of prospective randomisation as described above, we achieved unbiased groups by consecutive attendance. This study performed over a 10-month period compares both techniques and has not used data collected retrospectively. Also, because the procedures were performed by one surgical team, this lessened the chance of interoperator bias. Indeed, since the laparoscopic technique was only being introduced, any advantage reported is likely to be underestimated.

This study has been able to show that laparoscopic cholecystectomy allows faster patient recovery, earlier full mobilisation and discharge home than after open cholecystectomy. The speed of recovery is similar to that reported by other European studies for laparoscopic surgery *(2–4)*, but in our study recovery has been compared prospectively with the open operation. We have not studied return to work but note that on return to the outpatients department at 5–7 days after surgery, most patients were leading an active life. The advantage of this rapid recovery is the single most attractive feature of the laparoscopic technique both from the patient's viewpoint and for hospital cost-effectiveness.

The reduction of postoperative pain experienced by the patients has been documented in this study using both objective and subjective criteria. The disturbance to the abdominal musculature is much less with trocar stabs than with muscle-cutting incisions and the patients are able to mobilise fully immediately after surgery, in dramatic contrast to the open technique where mobilisation returns gradually over a number of weeks. A lesser degree of early activity has been shown after the technique of minilaparotomy for cholecystectomy, where a small incision is made and the muscle split lateral to the rectus rather than through the rectus *(8,9)*, but this latter technique provides a limited access compared with the standard open approach, and has not been shown to allow recovery at rates similar to laparoscopy. With such a clear view of the operative field provided by modern

colour video equipment, it is likely that any form of open keyhole surgery where the exposure is not enhanced will not gain popularity *(10)*.

The complications after open cholecystectomy are greater both in relation to the operative field and in the other systems, especially the respiratory system. Reductions in wound infection would be expected given that only one pass of a stainless steel trocar is required at each site and the small wounds are effectively closed during the operation. Restriction to respiratory function has been well documented after open cholecystectomy in studies that compare the midline laparotomy with the subcostal incision *(11)*. Although we have not examined specific respiratory function tests, our results have shown a lower incidence of atelectasis and lower respiratory tract infection. This may be due to the reduced postoperative pain and lack of diaphragmatic splinting postoperatively. We have not seen any cardiorespiratory problems related to the creation of the pneumoperitoneum.

There is concern about the possibility of an increased incidence of bile duct injury with laparoscopic cholecystectomy. Our study is too small to provide any conclusive evidence on safety. A series of 1000 cases would need to be studied in order to compare with the previous incidence of 1 in 300–500 for open cholecystectomy estimated by Baer and Blumgart for populations in Europe and Australia *(12)*.

The question of how to manage common bile duct stones has not been considered in this study. We chose to perform preoperative endoscopic cholangiography only when indicated by the presence of jaundice, abnormal liver function tests, pancreatitis or a dilated biliary tract on ultrasound examination. It is possible that stones in the common bile duct may have been missed, but in our study these were asymptomatic preoperatively and may remain so. Since there is a definite increase in morbidity after exploration of the common bile duct at the open cholecystectomy, we elected only to treat common duct stones if symptomatic. In our series to date no stones have become symptomatic.

Laparoscopic cholecystectomy is more cost-effective than open cholecystectomy. However, in a system of free health care the effect of the new technology does not directly reduce the resources used by the hospital. In fact, because the efficiency is so much improved it allows the hospital to treat more patients and the end result is an increase in the total resource used while the cost per patient is reduced. The biggest impact of the new technology is that it has allowed many patients to have their operation who would otherwise have stayed on a long waiting list.

In conclusion, we have shown that in a prospectively performed study where allocation was by consecutive attendance, laparoscopic cholecystectomy is feasible in 90% of patients and compared with the open operation is safe with less peroperative and postoperative morbidity, and associated with faster patient recovery because of less postoperative pain, earlier return to diet and earlier full mobilisation and discharge home. We would suggest that this study indicates that laparoscopic cholecystectomy is superior to open cholecystectomy and should therefore be available to all patients requiring elective cholecystectomy.

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