

Gut

Leading article

Laparoscopic cholecystectomy

What is the role of laparoscopic cholecystectomy with its 'appealing modern technology'?¹ There has been an explosion of interest in this operation throughout the world and many medical journals include at least one article on its value or hazards in each issue. In 1992 *MEDLINE* listed 230 published articles: this rose to 557 in 1993, and 197 have appeared between January and September 1994. New societies and new journals based on the technology are being spawned at an alarming rate, and international 'state of the art' meetings are advertised regularly. The national press, too, ever ready to report critically on medical progress, has carried a spate of articles with 'terrifying' headlines such as 'Keyhole Surgeons. Crackdown on safety after hospital deaths' (*Sunday Express*, 2 May, 1993).

Historical perspective

Laparoscopy is not new but has been practised for decades – enthusiastically by gynaecologists but less so by general surgeons. Gynaecologists led the way to laparoscopic surgery by carrying out relatively minor procedures during the endoscopy.² There was no general enthusiasm for expanding the technique by the surgical community, however, and so development of appropriate instrumentation was slow.

Although it is generally believed that laparoscopic cholecystectomy was 'born in secret' in France seven years ago,³ the procedure was probably undertaken first in Germany in 1985 using a modified laparoscope without television attachment.⁴ This early experience demonstrated dramatically that gall bladders could be removed without the need for a formal laparotomy and many advantages over the conventional operation were reported. Although a few surgeons were excited by this in continental Europe^{3,4} the UK,⁵ and the United States, however,⁶ traditional surgical caution and scepticism reigned for a short while.

The surgical instrument industry, on the other hand, speedily recognised the financial potential and rapidly invested in the design and production of laparoscopic tools. These range from simple forceps to complex stapling devices, both re-usable and disposable, from new designs of electrocautery to lasers, and from TV cameras and dedicated video recorders to electronically controlled peritoneal insufflation apparatus.

Several manufacturers arranged for some of the still

conservative but leading European surgeons to visit America to witness this new surgical millennium. The industry realised the potential profit if laparoscope surgery could be generally practised, especially in relation to cholecystectomy, one of the commonest general surgical operations.

The procedure

The operation is carried out using general anaesthesia and the peritoneal cavity is inflated with CO₂. Four trocars are inserted: one 10 mm diameter through the umbilicus, one 10 mm diameter in the epigastrium, and two 5 mm diameter in the right subchondral region. Through these are introduced a laparoscope with an attached television camera and the operating instruments. The operation is viewed on television screens. The gall bladder is visualised and its duct and artery identified, dissected, ligated, and divided. Operative cholangiography is routinely carried out at this time by some practitioners. The gall bladder is removed from its bed in the liver using electro-cautery or occasionally laser coagulation to achieve haemostasis. The area is flushed with saline which is then aspirated and the gall bladder is removed through one of the larger ports.

Training courses, mainly industry-sponsored, started in the United States and shortly afterwards in the UK. All the places on the courses were eagerly filled by surgeons not wishing to be left behind. They returned home after a weekend of viewing operations, live or on video, and a few minutes playing on a simulator, ready to start practising the technique clinically.

Although the £25 000–30 000 needed to purchase the basic equipment⁷ was difficult to find from NHS hospital funds, it was readily forthcoming from private charities and in the private sector. The surgeons' new enthusiasm for the technique persuaded potential donors that acquiring the instruments would constitute a major advance in surgical treatment which would be cost effective.

The popular press, and thus the public at large, learnt of the new 'keyhole' techniques for removing gall bladders. Hospital stays of only 24 to 48 hours, were reported with minimal patient discomfort and rapid return to work within a few days. This compared favourably with the conventional operation which incurred a hospital stay of 10–14 days followed by up to two months off work. Patients, oblivious of any problems, started demanding



Figure 1: Lower abdominal bruising appearing four days after a laparoscopic cholecystectomy and associated with a fall in the haemoglobin concentration.

this new operation. Problems did, however, occur. The instrument manufacturers, taken by surprise, found they could not match the volume of demand and there were often long delays before essential instruments could be delivered. Surgical complications were observed and patients expecting four tiny abdominal scars, each between 0.5 and 1 cm long, sometimes ended up with multiple scars and extensive bruising (Figs 1 and 2), sometimes after multiple further surgical procedures to correct major problems (Fig 3).

The current situation

It is now appropriate to review critically the current 'state of the art'. The indications for laparoscopic cholecystectomy are the same as for the conventional open procedure and preoperative assessment needs to be just as rigid.^{7 8}

The procedure is without doubt a feasible and effective way of removing the gall bladder, not only in uncomplicated situations but also when there are coexistent complications. In experienced hands it is possible after previous abdominal surgery, in morbidly obese,⁹ anticoagulated,¹⁰ paediatric,¹¹ or pregnant patients,¹⁴ when the gall bladder is acutely inflamed,^{12 13} in patients with sickle haemoglobinopathies,¹⁵ and the rare patient with situs inversus.^{16 17}

The exact technique varies slightly in unimportant details from centre to centre but perhaps the major controversy involves the need for intraoperative cholangiography. Some surgeons advocate that it should be used

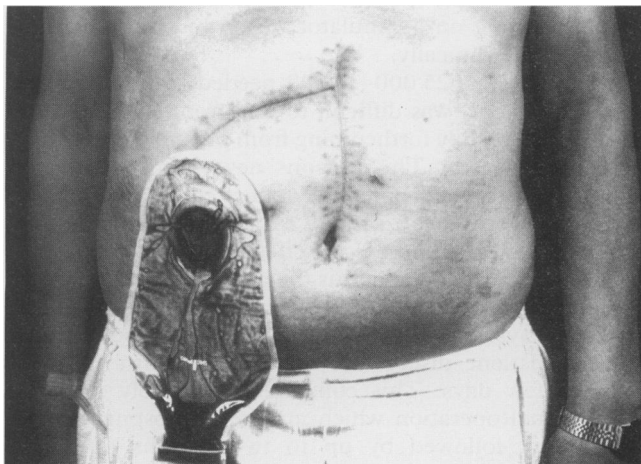


Figure 2: Scars and a haemobiliary fistula six weeks after a laparoscopic cholecystectomy which had to be formally re-explored, initially for jaundice and then for internal haemorrhage.

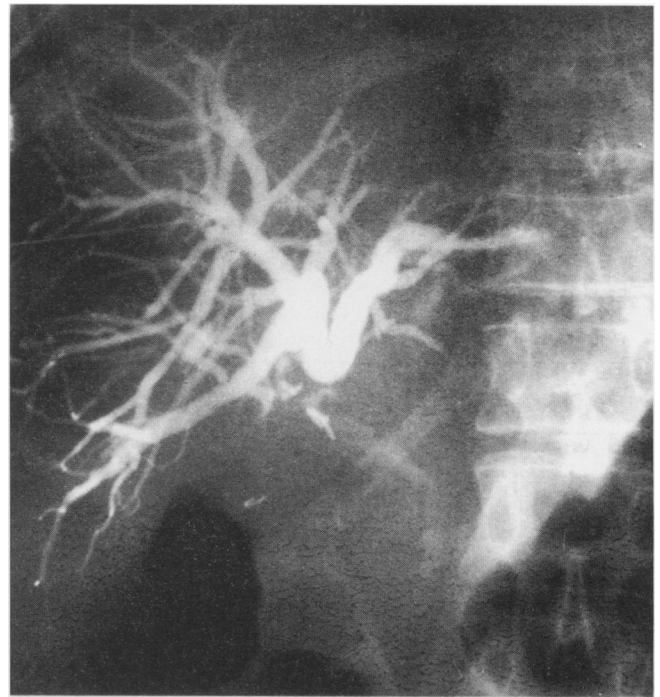


Figure 3: Percutaneous cholangiogram of a patient who became jaundiced after laparoscopic cholecystectomy. Staples totally occluded the common bile duct

routinely during conventional open cholecystectomy as well as during the laparoscopic procedure. They argue that this allows accurate identification of the anatomical variants of the extrahepatic bile ducts and so reduces the risk of damage to them.¹⁸⁻²⁰ Others, minimising this need but concentrating on the value of the technique for identifying stones in the common bile duct, argue that preoperative ultrasound evaluation²¹ or ERCP²² in selected patients make routine cholangiography unnecessary. This argument has raged for years in relation to its use during open cholecystectomy and has still not been resolved. However, the argument for the need to identify anomalous biliary anatomy before serious life threatening irreversible damage occurs is, I believe, a strong one. Unexpected bile duct stones will be visualised and can be removed laparoscopically or at later ERCP before they cause problems later on.

Those who advocate selective cholangiography only when clinical criteria suggest the presence of common bile duct abnormalities²³ are usually very experienced hepatobiliary surgeons who can make such value judgements and their arguments should not apply to everyone.

Postoperative pain is minimal and, at most, patients need only one injection of an opiate. Any pain is usually at the site of one of the incisions or occasionally referred to the right shoulder, probably due to slight biliary irritation of the peritoneum in the right upper quadrant of the abdomen. Some patients experience transient nausea but the metabolic response to the procedure is less^{24 25} and most patients can expect to leave hospital between six hours and three days after the operation and to return to work between seven and 16 days later.²⁶⁻³⁰ One report claims that 90% of patients treated (319 patients) were discharged within 24 hours of surgery.³¹

Complications

Complications of the operation are related both to the surgical procedure in general and more specifically to the laparoscopic technique.

The general complications of surgery – postoperative

chest problems, wound infections, and deep venous thrombosis – are less than those observed after conventional surgery due to the use of smaller incisions, less need for strong analgesic drugs,^{7 27 28} and a more rapid return to normal activities. However, the incidence of complications related specifically to the technique are often serious and if not immediately recognised may be fatal. The bowel can be perforated either with the Veress needle at the time of CO₂ insufflation²⁸ or by cautery or laser during the surgical procedure. Bile duct damage can result from inadvertent cutting, total occlusion, or stenosis by clips. Major haemorrhage can follow vascular damage and post-cholecystectomy bile leakage because of division of an unrecognised accessory duct can lead to peritonitis or abscess formation.³² Seeding of previously undiagnosed gall bladder or pancreatic cancer can occur along the ports of entry.^{33 34} The incidence of these problems, between 0.5% and 2% of all cases, is higher than after conventional surgery, and varies between centres, and becomes less with increasing experience.^{27 35 36}

To avoid major problems, the operating surgeon must be aware of these potential dangers, be totally confident about the biliary anatomy before cutting any structure, and avoid the arrogant complacency of 'it can't happen to me'.³⁷ One clear lesson is that if any difficulty is encountered during surgery or any problem recognised, the surgeon should without hesitation convert to an open procedure. Furthermore if a major bile duct is injured the patient should have any further formal surgery carried out only by an experienced hepatobiliary surgeon if later problems are to be avoided.³⁸

A poor press

It is inevitable that complications are widely reported in the press, especially when a patient dies or needs a liver transplant. It is these alarming isolated reports which have precipitated the need for a review of training and certification of surgeons practising these new techniques.

'Between August 1990 and June 1992, 99 hospitals in New York reported 192 laparoscopic cholecystectomies that resulted in temporary or permanent injury to patients, seven of the patients died. The highest percentage of complications involved bile leaks, common bile duct ligation, haematoma or haemorrhage'.³⁹ This report continues: 'studies show that the majority of complications in laparoscopic cholecystectomy have occurred in cases where the surgeon has very little experience with the procedure; incidence of complications has dropped drastically as surgeons gain experience'.

Addressing the problems

The State of New York has published *Guide lines for determining credentials for performing laparoscopic cholecystectomy*, and now only properly trained and certified laparoscopic surgeons are allowed to carry out this operation.⁴⁰ Similar certification is likely to be introduced in the United Kingdom. Already several of the major private hospitals in London are demanding such guidelines. We, as clinicians, perhaps through our surgical royal colleges, should introduce appropriate assessment and certification without delay. Professor Frederick Green, President of the Society of American Gastrointestinal Endoscopic Surgeons has said, 'Unless we act responsibly ... and demand that the highest principles be used in ... developing competency amongst ourselves ... the State and Federal Governments will take over this activity for us'.⁴⁰

Training in laparoscopic surgical techniques should consist of a formal 'hands on' course. This should begin with practice using a simulator, a 'black box' with holes, to gain expertise with the unfamiliar techniques. Ideally the trainee should next gain further practical experience in an animal laboratory. Unfortunately this is not possible under current Home Office rules in the United Kingdom, although it is allowed in the Republic of Ireland, some parts of continental Europe, and in the USA. This should be followed by a probationary period as an assistant in the operating room.⁴¹⁻⁴³ In many centres such training is already integrated into formal surgical registrar training programmes and no doubt the younger surgeons, used to playing computer games, will adapt to the technique very readily.⁴⁴ This training coupled with the new and carefully researched instruments will contribute to the safer, controlled development of this area of surgery.⁴⁵

Is it worthwhile

In an attempt to investigate whether laparoscopic cholecystectomy really is a major advance and the 'gold standard',⁴⁶ several studies have attempted to compare the technique with the open operation. These have mostly used retrospective data relating to the conventional procedure which have drawn critical comments in the correspondence pages.^{47 48} Despite this criticism, it is quite clear that the operating time is longer, especially during the 'learning' phase of the surgeon's experience, surgical cost is higher,⁴⁹ and the incidence of major duct injury is marginally greater with the laparoscopic approach. These problems are well compensated for, however, by the facts that the patient suffers less postoperative discomfort, enjoys a shorter hospital stay and a more rapid return to work,^{1 28 50-52} and the overall cost difference is probably not significant.⁴⁹ Because of these observations it is probably too late now to carry out any properly controlled prospective studies.⁷

When compared prospectively with a mini-cholecystectomy (conventional open operation carried out through a tiny incision) the laparoscopic approach seems to enjoy only marginal advantages^{1 53} but we do not yet know the full spectrum of hazards attached to the mini-open operation. Prospective studies of these two procedures are indicated and the results of trials currently underway are awaited with interest.

There is no doubt that laparoscopic cholecystectomy represents a major advance in the management of patients with gall stone disease when it is carried out by a surgeon properly trained and aware of the potential hazards. If any problems are encountered during the operation the surgeon should not hesitate to convert the procedure to an open exploration. It is inevitable that even in the most experienced hands major problems will occur from time to time and careful audit of each individual surgeon's results is essential to ensure his or her track record is acceptable. Any major duct injuries must be recognised and repaired by a surgeon skilled in such techniques.

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