Laparoscopic cholecystectomy

Naarilla A Hirsch

Health Technology Unit
Australian Institute of health

November 1990

LAPAROSCOPIC CHOLECYSTECTOMY

A discussion paper

Naarilla A Hirsch

Comments on the material in this report would be welcome and should be forwarded to:

The Head
Health Technology Division
Australian Institute of Health
GPO Box 570
CANBERRA CITY ACT 2601

ISBN 0 642 15830 4

November 1990

LAPAROSCOPIC CHOLECYSTECTOMY

CONTENTS

SUMMARY

- Laparoscopic cholecystectomy is a new procedure for removal of the gallbladder that does not involve open surgery. It is diffusing rapidly in Australia. Indications for the procedure are still evolving, but it could potentially replace at least 80 per cent of open cholecystectomies.

- Laparoscopic cholecystectomy promises low morbidity and mortality, short hospital stays, and reduced convalescence periods and patient discomfort. The decreased hospital stay and convalescence could result in large savings to the health care system and to the community as a whole.

- Specialised equipment is needed, costing between $55,000 and $70,000. Specialised surgical instruments are also needed. Some are available as disposable or re-usable instruments; the total cost of disposable instruments per patient is about $510. Cost per patient for re-usable instruments is less. The relative merits of disposable versus re-usable instruments need to be resolved.

- A preliminary estimate of the total cost per patient of a laparoscopic cholecystectomy is $3,650.

- The safety of laparoscopic cholecystectomy is not yet well documented. There are little or no published data available on complications, morbidity and long-term effects, but the potential for serious complications exists. There is an urgent need for studies to establish its success rate, complications, morbidity, mortality, long-term effects, and its cost-effectiveness, in comparison with those for open cholecystectomy and gallstone lithotripsy. It would be desirable to include laparoscopic cholecystectomy in the trial comparing gallstone lithotripsy and surgery, currently in progress at St. Vincent's Hospital, Melbourne.

- The procedure is being performed largely by biliary surgeons specially trained in the procedure. There is a learning curve and early in the surgeon's experience complications and conversions to open cholecystectomy are likely to be more frequent. If the procedure diffuses too rapidly there is a danger that training of surgeons and assistants will be inadequate and complication rates will be high. Steps will need to be taken to ensure that the procedure is performed only by fully trained teams and that case load is sufficiently high for expertise to be maintained.

INTRODUCTION

It has been suggested that 25 per cent of women and 20 per cent of men in developed countries will have gallstones at some time in their lives (1). While many gallstones are asymptomatic, some lead to problems such as cholecystitis, acute obstruction of the bile duct, biliary colic and flatulent dyspepsia. Cholecystectomy removes the gallbladder and has been the treatment of choice for symptomatic gallstones, with over 23,000 cholecystectomies being performed annually in Australia (2). Other therapies for treating gallstones leave the gallbladder intact. These include oral bile acid dissolution therapy, direct dissolution therapy with methyl tertiary-butyl ether, percutaneous cholecystostomy and cholecystolithotomy, and extracorporeal shock wave lithotripsy (ESWL).

A laparoscopic alternative to the open surgical procedure of cholecystectomy has been developed recently from principles used in gynecology. The laparoscopic procedure is diffusing very rapidly since it promises low morbidity, short hospital stays and convalescence, and much improved patient comfort. This paper has been prepared to provide a basis for comment and discussion by health authorities, professional bodies and other organisations with an interest in this procedure.

NATURE OF LAPAROSCOPIC CHOLECYSTECTOMY

Description of the procedure

The laparoscopic procedure is done under general anesthesia (3,4). The peritoneum is inflated with carbon dioxide. A 10 mm diameter trocar is inserted through the umbilicus, and a telescope introduced. A video camera is attached to the telescope, which allows inspection of the gallbladder and intra-abdominal structures on a video monitor. Under direct vision three more small incisions are made in the upper abdomen for the introduction of various instruments. The liver is retracted, and the gallbladder, cystic duct and cystic artery are dissected free using diathermy, laser (e.g. KTP, CO_2, argon or Nd:YAG) or laparoscopic scissors (5). The cystic artery and cystic duct are clipped and, if necessary, intraoperative cholangiography can be performed to evaluate the common bile duct. The gallbladder is dissected out from its bed, grasped externally through the umbilical cannula, and removed through the small opening. If it is too large, stones and bile can be removed externally with forceps and suction.

Learning the procedure

Surgeons accustomed to open cholecystectomy need to make several adjustments to perform laparoscopic cholecystectomy. They need to learn to work from an image, to develop the eye/hand co-ordination needed to use laparoscopic instruments, and to learn to recognise the anatomy from the new perspective (Hugh, personal communication). Once these adjustments are made, the surgical skills required are similar

to those used for open cholecystectomy. Two assistants are essential when the surgeon is learning the procedure. Both need laparoscopic skills. One also needs camera skills whereas the other needs general surgical skills. Once experienced in the procedure, some surgeons dispense with one assistant. With an experienced operating team, the length of the procedure is similar to that for open cholecystectomy. The time taken usually ranges from 30 minutes to two hours, with a mean of about 80 minutes (Bursle, Hugh, personal communications).

Diathermy or laser?

The dissection requires the same skills as for open cholecystectomy. The Institute has been advised that lasers do not offer any particular advantage over diathermy (Bursle, Fletcher, Hugh, personal communications), and have the disadvantage of being more costly. Another disadvantage is that, if lasers are used, diathermy is still needed to control any bleeding that occurs (Bursle, personal communication).

Conversion to open cholecystectomy

Laparoscopic cholecystectomies are converted to open operations in a small number of cases. Reddick converted two in the last 100 patients of a series of 500 procedures (6). Operations are converted more frequently early in the surgeon's experience with the procedure; Reddick converted two in an early series of 27 laparoscopic cholecystectomies (7). Reasons for converting operations include the gallbladder not being intact, dense inflammatory changes around the gallbladder, and technical difficulties early in the surgeon's experience. This is not a problem if the surgeon is a biliary surgeon and the operating theatre is prepared for open cholecystectomy should it be needed.

EQUIPMENT AND COSTS

Equipment

Laparoscopic cholecystectomy has been made possible by recent advances in the equipment available, in particular by development of high resolution sterile video cameras with high powered light sources, and of specialised clip appliers. The equipment needed for laparoscopic cholecystectomy comprises:

- two 10 mm or 11 mm, and two 5 mm or 5.5 mm trocars, with converters to convert the 10 mm/11 mm ports to 5 mm instrumentation;
- telescope, 10 mm diameter;
- high flow carbon dioxide gas insufflator with automatic monitoring of the gas pressure;
- insufflation needle and tubing;
- high resolution video camera with two monitors;
- high powered light source with fibre optic light transmission;
- diathermy unit and suitable cables;

- laser and suitable accessories (optional);
- suction/irrigation pump with suitable accessories;
- specialised suction and irrigation tube with hook for diathermy or central tube for laser fibre;
- set of endoscopic instruments, e.g. 5 mm grasping and dissecting forceps and scissors;
- clip applier and clips;
- cholangiography fixation clamp and guide tube.

Cost of equipment

Some of this equipment (TV monitors, diathermy units or lasers, and suction/irrigation pumps) is the same as that already used for other procedures, although specialised cabling and tubing to connect it to the field of operation are needed. Other items are not already available in hospitals. The insufflator needs to be high flow with automatic monitoring of gas pressure; those used for gynecological procedures are low flow and so are not suitable. High resolution video cameras and high powered light sources are also not in common use. The once-off costs for these specialised items of equipment lie between $55,000 and $70,000 (Table 1).

TABLE 1: ESTIMATED COSTS OF EQUIPMENT FOR LAPAROSCOPIC CHOLECYSTECTOMY

Type of Equipment (a)	Estimated Cost ($)
Telescopes	6500
Insufflator	13000-17000
Video camera	19000-28000
Light source and accessories	14300
Endoscopic instruments (b)	3600
Total	56400-69400

(a) TV monitors, suction/irrigation pumps, diathermy units and lasers have been omitted since they are already available in many hospitals.
(b) Includes instruments for cholangiogram; excludes instruments available as disposables (see below).

Source: N Stenning and Co.

Cost of instruments

The trocars, clip appliers, converters and insufflator needles are available as disposable or re-usable instruments. Disposable instruments can be bought as a kit, at a cost per patient of $510 (Nielsen, personal communication). Disposable instruments are also available individually, but are more expensive purchased this way. The cost per patient is considerably lower if re-usable instruments are used. A complete set of re-usable instruments costs about $3100 (Hugh, personal communication).

Disposable instruments have several advantages over re-usable instruments (Fletcher, Hugh, personal communications). Placing the insufflation needle and first trocar with disposable instruments is safer since re-usable instruments become blunt and require more force to insert. Disposable instruments are easier to use, and less gas escapes when instruments are inserted into or removed from the ports, shortening the operation time. They also eliminate any risk of transfer of infection. Radiolucent disposable instruments are available, which is useful if cholangiograms are done routinely. Re-usable instruments place demands for cleaning and sterilising on nursing staff (Fielding, personal communication). A combination of disposable and re-usable instruments might be a compromise between the above factors and the higher cost of disposable instruments. Safety does not appear to be compromised if, for instance, the 5 mm trocars and the second of the 10 mm trocars are re-usable.

Cost of procedures

Table 2 gives preliminary estimates of the public hospital costs of laparoscopic cholecystectomy, open cholecystectomy and gallstone lithotripsy. The assumptions made in deriving these costs are listed in the Appendix.

TABLE 2: PRELIMINARY ESTIMATES OF COSTS OF LAPAROSCOPIC AND OPEN CHOLECYSTECTOMY, AND GALLSTONE LITHOTRIPSY

Item	Estimated Cost ($)		
	Laparoscopic cholecystectomy	Open cholecystectomy	Gallstone lithotripsy
Surgeon's fee	740	465	435
Assistant's fee	148	93	-
Anesthetist's fee	126	126	138
Radiologist's fee	-	-	27
Hospital costs	555	3700	370
Theatre costs	700	600	-
Medication	60	120	40
Diagnostic procedures	477	477	477
Equipment costs	54	-	300-600
Instrument costs	510	-	-
Post-operative treatment	-	-	638-4268
Conversion to open surgery	279	-	-
Total	3649	5581	2425-6355

Laparoscopic cholecystectomy costs will be a little higher when two assistants rather than one are used, and lower if re-usable instruments are used instead of disposable instruments. Gallstone lithotripsy costs vary considerably depending on the length of post-operative treatment, the type of bile salt used for this treatment, the type of lithotripter and the re-treatment rate.

Comparison of costs

Laparoscopic cholecystectomy has a decided advantage over open cholecystectomy in terms of direct costs. Savings result from the dramatic decrease in length of hospital stays, since the operation itself is more expensive. Indirect savings to the community are also large. The reduction of convalescence from at least four weeks to one week or less results in savings in terms of time lost from work or other normal life-style activities. Since over 23,000 open cholecystectomies are performed each year, replacing 80 per cent with laparoscopic cholecystectomies could result in enormous savings to both the health care system and the community. Fletcher and associates have suggested possible savings of $10.8M to the State and Federal governments of replacing about 80 per cent of open cholecystectomies with laparoscopic cholecystectomies (using a marginal bed cost) (8). They estimate a further saving of 156,855 days productivity per year. These estimates may be conservative.

In terms of costs, gallstone lithotripsy has a small advantage over laparoscopic cholecystectomy provided post-ESWL treatment is not extended and chenodeoxycholic acid is used. Convalescence is also a little shorter after ESWL, reducing the time lost from work, although this may be offset in some cases by the side-effects of the bile salts used. Gallstones could be expected to recur in 27 to 50 per cent of patients (9,10) and re-treatment would substantially add to the cost. Taking all these factors into consideration, gallstone lithotripsy may not be cost-effective compared with laparoscopic cholecystectomy.

INDICATIONS

The indications and contraindications of laparoscopic cholecystectomy are still evolving. Absolute contraindications include pregnancy, severe general anesthesia risk and active intraperitoneal sepsis (4,11; Hugh, personal communication). Relative contraindications include coagulation defects, massive obesity and previous upper abdominal surgery. Portal hypertension is regarded by some as a contraindication (Bursle, personal communication). Large gallstones need not be regarded as a contraindication, since they can be crushed before being extracted (Hugh, personal communication). Acute cholecystitis and empyema were regarded as contraindications, but many of these cases can be treated by laparoscopic cholecystectomy with only a few needing to be converted to an open operation, although the incidence of conversion to open operations will be greater. The presence of common bile duct stones was originally regarded as a contraindication, since they could not be removed by this procedure.

These stones are no longer considered an absolute contraindication, since many can be removed, by a pre- or post-operative endoscopic procedure (ERCP) rather than by an open operation. Common bile duct stones have been removed during laparoscopic cholecystectomy using flexible instruments (Fletcher, personal communication). This procedure is still investigative and its safety and efficacy remain to be determined.

ESWL can be used on patients at risk for open surgery, such as elderly patients with underlying cardiac or pulmonary disease. Indications for safe and effective treatment are a solitary radiolucent stone ($\leq$30 mm), or up to three stones with similar total volume, together with gallbladder visualisation by oral cholecystography and the shock wave avoiding lung and bone (12). Contraindications include acute cholecystitis or pancreatitis, biliary obstruction, known bile duct stone, gastroduodenal ulcers, pregnancy, bleeding diathesis, and aneurysms or cysts in the shock wave path. Currently, only about 25 per cent of patients can be treated safely and effectively with ESWL (13).

Open cholecystectomy is the current treatment of choice for symptomatic gallstones. At least 80 per cent could be treated by laparoscopic cholecystectomy (4). With the emergence of laparoscopic cholecystectomy, it is possible that fewer gallstone patients will need lithotripsy, with some estimates being as low as 1 to 2 per cent (14).

EFFICACY AND COMPLICATIONS

Laparoscopic cholecystectomy

Laparoscopic cholecystectomy is effective in treating gallstone disease since it removes the gallbladder. Post-operative pain and discomfort are considerably reduced, and patients are allowed oral fluids immediately on awakening. They can be discharged from hospital 24-48 hours after the procedure, and return to work within a week (7).

The complications of laparoscopic cholecystectomy are those of laparoscopy plus those specific to cholecystectomy. Complications specific to cholecystectomy include bile leaks, injury to the bile duct, and hemorrhage. Complications of laparoscopy are more frequent when the surgeon is inexperienced. They include puncturing blood vessels or the diaphragm with the insufflation needle and pumping gas into either a blood vessel or the thoracic cavity, and puncturing an organ with either the insufflation needle or a trocar leading to injury of the organ (Hugh, personal communication).

Reported complication rates are low to date. Dubois and associates reported two complications in their first 36 patients, and five major complications in 600 patients (3; Hugh ,personal communication). Hugh (personal communication) reports two minor complications and no major complications in his first 50 patients. Reddick and Olsen report only

one death in over 700 laparoscopic cholecystectomies (15). Any long term effects of laparoscopic cholecystectomy are unknown at present. Possible long term complications include strictures due to bile duct injury, and hernias around the stab wound (Bursle, personal communication).

The safety of laparoscopic cholecystectomy remains to be proved. Surgeons using the procedure consider it safe provided training is adequate and guidelines such as those being prepared by the Royal Australasian College of Surgeons (Fletcher, personal communication) are adhered to. However, the procedure has the potential for serious complications. Data about the success, complication and mortality rates of laparoscopic cholecystectomy are urgently needed in view of the rapidity with which the procedure is being adopted.

Open cholecystectomy

Open cholecystectomy has a mortality rate of 0.6 to 1.3 per cent, and a morbidity rate of 10 to 33 per cent (12). Complications include choleperitonitis, pancreatitis, injury to the bile duct and hemorrhage, together with those common to all open surgery such as pneumonia, infected wound and blood clots (16). In Australian hospitals the average length of stay for open cholecystectomy ranges from 8.7 days (private hospitals) to 12.6 days (males in public hospitals) (17). Convalescence usually requires a month. Indications to date are that laparoscopic cholecystectomy achieves the same result as open cholecystectomy with significant decreases in morbidity, length of hospital stay, length of convalescence, patient discomfort and scarring.

Gallstone lithotripsy

Biliary lithotripsy is considered more effective if followed by adjuvant treatment, the most usual being oral dissolution therapy with bile acids (12). Overall success rates vary enormously with different studies, from 22 to 99 per cent (12,13). Re-treatment rates also cover a considerable range, from 5 to 66 per cent (13). Complications from ESWL include transient hematuria, cutaneous petechiae, mild leucocytosis and mild biliary pain. The oral bile-acid treatment can cause diarrhea in some patients. Compliance may be a problem with some patients as the bile-acid treatment must continue for some months. Depending on the type of lithotripter, ESWL can be done on an out-patient basis or followed by one to three days in hospital. Recovery is very rapid, with a return to work possible in a few days.

One of the major disadvantages of ESWL over both forms of cholecystectomy is the recurrence of gallstones. The recurrence rate is thought to be similar to that of gallstone dissolution therapy alone i.e. 8 to 10 per cent per year for the first three to five years (10). Another disadvantage is the long period for which bile salts must be taken following lithotripsy. On the other hand, it has the advantage of being less invasive with faster recovery times than open cholecystectomy, and is suitable for patients who cannot undergo

open surgery. However, little data are available yet on the long-term cost-effectiveness of gallstone ESWL. When compared with laparoscopic cholecystectomy, ESWL appears to lose most of its advantages; hospital stays are comparable and recovery after laparoscopic cholecystectomy is not much slower than recovery after ESWL.

There appears to be no role for ESWL as an adjunct to laparoscopic cholecystectomy. Stones do not need to be fragmented prior to laparoscopic cholecystectomy since they can be easily crushed externally before being extracted through the umbilical port. In addition, pre-operative ESWL could lead to fragments lodging in the common bile duct, necessitating further intervention.

INTRODUCTION INTO AUSTRALIA

Once they become aware of the procedure, most patients are likely to prefer to have their gallbladders removed with laparoscopic cholecystectomy rather than an open operation because of shorter hospital stay, reduced convalescence and cosmetic benefits. Since cholecystectomy is one of the most common surgical operations in Australia, those slow in introducing the procedure may find it making an impact on their practice. Laparoscopic cholecystectomy is also proving popular with surgeons overseas due to the decreased morbidity and post-operative care required. Consequently there is a sudden high demand for training in the procedure and for the equipment needed which may not be able to be met in the short term.

There is a danger that this sudden high demand for laparoscopic cholecystectomy may compromise its safety. Use of inappropriate equipment will compromise the safety of the procedure, as will inadequate training. Guidelines for the procedure are being prepared by the Royal Australasian College of Surgeons, but there are no controls or credentialling bodies to ensure that such guidelines are adhered to. It should be borne in mind that there have been no studies on the safety, efficacy and long-term effects of the procedure. This raises the question of whether the procedure should be restricted to tertiary institutions until the procedure is proven to be safe and effective compared with the alternative of open cholecystectomy. Assuming it is proven, the question that will then arise is how acquisition and distribution of the specialised equipment can be arranged so that it is adequately used and so that all gallstone sufferers have access to the procedure.

Laparoscopic cholecystectomy is being presented overseas by some as a new laser procedure. Since diathermy is at least as effective as lasers (Bursle, Fletcher, Hugh, personal communications), it should not be taken up as a specific laser procedure in Australia.

Laparoscopic cholecystectomy has already been introduced to several Australian hospitals, including the Austin, Sydney, St. Vincent's (Sydney), Royal Brisbane and Calvary (Adelaide) Hospitals. In their early experience at the Austin Hospital, Jones and associates

successfully removed gallbladders laparoscopically in 18 of 25 patients (17). They report a reduction in complications with experience and strict adherence to their operative technique, and note a significant learning curve and a need to audit results prospectively to ensure that the long term adverse effects do not outweigh the immediate benefits.

CONCLUSIONS

While the indications for laparoscopic cholecystectomy are still evolving, the procedure appears to be likely to make a major impact on current treatments for gallstones. If, as is predicted, the laparoscopic procedure replaces over 80 per cent of open operations, it will significantly decrease hospital stays and convalescence after cholecystectomy, with consequential decreases in health care costs and productivity losses. The procedure also seems likely to reduce future demand for gallstone lithotripsy. It is being taken up with great rapidity and enthusiasm both overseas and in Australia. However, its safety and effectiveness have not yet been fully documented, and there are a number of issues that need to be addressed.

The appropriate equipment and instruments need to be used if safety is not to be compromised. Some of the instruments are available as disposable or re-usable versions. The effect on safety of each instrument being disposable or re-usable should be determined and clearly stated, together with any differences that might occur early in the surgeon's experience. Any advantages or disadvantages of diathermy over lasers also should be defined. The question of acquisition and distribution of equipment in both the short and long term needs to be addressed.

While the surgical skills are similar, the surgeon needs to develop laparoscopic skills to perform the procedure. Two assistants with laparoscopic skills are essential when learning the procedure, with at least one having general surgical skills. Training must be adequate since the possibility of a major mishap exists. Standard surgical guidelines are needed, with some mechanism (such as accreditation) to ensure that they are adhered to.

Complications are those of laparoscopy and those specific to cholecystectomy. While laparoscopic cholecystectomy is considered to have a low complication rate, there is little data available on complication rates, and none on long-term effects. The potential for serious complications exists, and the safety of the procedure needs to be documented. There is an urgent need for information on the success rate, complications, morbidity, mortality, long-term effects and cost-effectiveness of the procedure, and comparisons of these data with those from open cholecystectomy and gallstone lithotripsy. It would be desirable to include laparoscopic cholecystectomy in the trial comparing gallstone lithotripsy and surgery, currently in progress at St. Vincent's Hospital, Melbourne.

Ideally, introduction of the procedure should occur in a controlled way until the results of such studies are available. However, the procedure is already spreading rapidly. There is a need to develop procedures/mechanisms to ensure that use of the technique is undertaken only by those with appropriate training, and at institutions with adequate facilities.

REFERENCES

1. Harding Rains AJ. "Gallstones and cholecystitis" in Smith, Lord, Sherlock S.(eds) "Surgery of the gallbladder and bile ducts". Butterworths, London, 1981.

2. National Health Technology Advisory Panel. "Gallstone lithotripsy". Australian Institute of Health, Canberra, December 1988.

3. Dubois F, Icard P, Berthelot G et al. "Coelioscopic cholecystectomy: preliminary report of 36 cases". Ann Surg 1990;211:60-62.

4. Hugh TB "High-tech solution to gallstones". Aus Dr Weekly; Aug 1990 26-31 supplement:18

5. Wallace C. "Laparoscopy: a new era in general surgery?". Health Tech Trends 1990;2:2.

6. Hugh TB. "Laparoscopic cholecystectomy". Med J Aust 1991 (in press).

7. Reddick EJ, Olsen DO. "Laparoscopic laser cholecystectomy: a comparison with mini-lap cholecystectomy". Surg Endosc 1989;3:131-133.

8. Fletcher DR, MacLellan DG, Jones RM. "Percutaneous cholecystectomy - Australian cost implications" (unpublished paper).

9. Gibney RG, Chow K. So CB et al. "Gallstone recurrence after cholecystolithotomy". AJR August 1989;153:287-289.

10. Thistle JL "Pros and cons of the nonsurgical treatments for gallbladder stones". Hepato-gastroenterol 1989;36:327-329.

11. Picus D. "Percutaneous gallbladder intervention". Radiology July 1990;176:5-6.

12. Vergunst H, Terpstra OT, Brakel K et al. "Extracorporeal shockwave lithotripsy of gallstones: possibilities and limitations". Ann Surg 1989;210:565-575.

13. Barkun ANG, Ponchon T. "Extracorporeal biliary lithotripsy". Ann Int Med 1990;112:126-137.

14. ECRI. "Is the biliary lithotripter becoming a 'stone age' technology?". Health Tech Trends 1990;2:4-6.

15. Way LM. "Changing therapy for gallstone disease". N Eng J Med 1990;323:1273-1274

16. McSherry CK, Glenn F. "The incidence and causes of death following surgery for nonmalignant biliary tract disease". Ann Surg 1980;191:271-275.

17. Mathers C, Harvey R. "Hospital utilisation and costs study volume 2: survey of public hospitals and related data". Australian Institute of Health, Canberra, 1988.

18. Jones RM, Fletcher DR, MacLellan DG et al. "Laparoscopic cholecystectomy: initial experience". Aus NZ J Surg 1991 (in press).

ACKNOWLEDGEMENTS

The Institute is grateful for the advice and comments from the following:

- Dr T Hugh, St. Vincent's Hospital, Sydney
- Dr G Bursle, Sydney Hospital
- Professor D Fletcher, Austin Hospital, Melbourne
- Dr J Duggan, Royal Newcastle Hospital
- Mr P Nielsen, Auto Suture, Adelaide

APPENDIX 1: ASSUMPTIONS USED TO DERIVE PROCEDURE COSTS

The assumptions used to estimate the cost of laparoscopic cholecystectomy are:

- the procedure is performed by a specialist surgeon who receives a fee equivalent to that for open cholecystectomy plus that for laparoscopy;
- the surgeon has one assistant (although two are needed while the surgeon is gaining experience in the procedure) and an anesthetist;
- bile duct exploration or stone extraction is not performed;
- diagnostic procedures used are plain film x-ray, oral cholecystography, operative cholangiogram, ultrasound, and urine and blood analyses (pre- and post-treatment);
- there are no complications requiring additional procedures;
- 1.5 days in hospital are required at a cost per bed day of $370;
- theatre costs include setting up for open cholecystectomy in case it is required;
- five per cent of laparoscopic procedures are converted to open operations;
- equipment costs are amortised over five years, and assume 300 patients treated per year;
- instrument costs are the costs of specialised instruments needed for the procedure and only disposable instruments are used.

Operation costs will be a little higher when two assistants are used, and lower if re-usable instruments are used.

The assumptions used to estimate the costs of open cholecystectomy are:

- the procedure is performed by a specialist surgeon with an assistant and an anesthetist,
- bile duct exploration is not performed;
- diagnostic procedures used are plain film x-ray, oral cholecystography, operative cholangiogram, ultrasound, and urine and blood analyses (pre- and post-treatment);
- 10 days in hospital are required at a cost per bed day of $370.

The assumptions used to estimate the costs of gallstone lithotripsy are:

- the lithotripter is operated by a gastroenterologist who receives a fee equivalent to that for renal stone ESWL;
- the diagnostic procedures required before treatment are plain film x-ray, oral cholecystography, cholangiogram, abdominal ultrasound, and urine and blood analyses;
- after treatment abdominal ultrasound and blood analyses are required at 3 month intervals until fragments have cleared (assumed to take an average of 6 months);

- medication with chenodeoxycholic acid is required for an average of six months to clear fragments. Costs based up are those found in the gallstone lithotripsy trial at St. Vincent's Hospital, Melbourne;
- one day in hospital is required;
- lithotripter costs include capital costs amortised over seven years, maintenance, insurance and space maintenance costs, and assume that 1000 patients a year are treated on the lithotripter.

The cost range of gallstone ESWL varies depending on the lithotripter used. There is a wide range of capital costs for the lithotripters suitable for treating gallstones, from $427,000 for the Direx Tripter X1 (cost of localisation unit is additional) to $2.2M for the Dornier MPL9000. The cost per patient ranges from $150 to $480 if 1000 patients are treated each year. If fewer patients are treated annually, the cost will rise.

Costs of gallstone ESWL are even more sensitive to the post-operative oral bile salt treatment. The length of this treatment varies considerably, and can often be as long as two years. A two year treatment regime makes a significant impact on the cost of the procedure, increasing it to $4268. High re-treatment rates due to stone recurrence increase the cost further. In addition, ursodeoxycholic acid (or a combination of the two) is preferred to chenodeoxycholic acid because it has fewer side effects, but it is more expensive and there are availability problems in Australia.