

Cost Utility Analysis of Treatment Options for Gallstone Disease: Final Report

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ABSTRACT

An economic evaluation was conducted of treatment options for patients with symptomatic gallstone disease, namely open cholecystectomy, laparoscopic cholecystectomy and extra corporeal shockwave lithotripsy (ESWL). Because of the importance of quality of life following treatment, a cost utility analysis was selected as the appropriate method for the evaluation.

Information was obtained from a clinical trial at St Vincent's Hospital in Melbourne. Further information on the outcomes of treatment were sought from clinical staff, the literature, and patients themselves. The utility associated with being in each post-treatment health state was assessed by presenting descriptions of these health states to members of the general public and asking them to evaluate each using the time trade-off technique.

Data on resource use was derived from patient protocols devised by hospital staff and from a patient questionnaire. The cost analysis included hospital costs, costs borne by patients and care-givers, and the indirect costs of lost time to productive activity.

The three treatments were compared in terms of their costs and outcomes, and the results subjected to sensitivity analysis. It was found that laparoscopic cholecystectomy was unambiguously superior to open cholecystectomy, and would generally be preferred to ESWL. In the absence of laparoscopic cholecystectomy, ESWL is unambiguously the preferred option if (1) indirect costs are included in the analysis or (2) when patients presenting with a small single stone.

The present paper provides an overview of the study, its methods and it reports, in full, the results of the sensitivity analysis conducted. More detailed discussion of particular aspects of the study are presented in Cook and Richardson (1993a,b), Street (1993) and Cook, Richardson and Street (1994).

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Cost Utility Analysis of Treatment Options for Gallstone Disease: Final Report

1 Introduction

Open cholecystectomy, the conventional treatment for symptomatic gallstone disease, is one of the most commonly performed operations in Australia (Hailey & Hirsch 1991). In recent years two new options have been developed to treat gallstone disease, ie laparoscopic cholecystectomy and extra corporeal shockwave lithotripsy (ESWL). Laparoscopic cholecystectomy is a minimally invasive surgical procedure which, like open cholecystectomy, entails removal of the gallbladder. In contrast, ESWL leaves the gallbladder intact. Gallstones are fragmented by means of shockwaves and cleared from the body using litholytic (bile salt) therapy. The medication may result in significant side effects, particularly nausea and diarrhoea.

An economic evaluation was conducted on the basis of information gained from a clinical trial of the treatment options at St Vincent's Hospital, Melbourne (*Section 2*). Because of the importance of the effect on quality of life (QoL) of each treatment, a cost utility analysis (CUA) was selected as the appropriate framework for an economic evaluation of the three options. CUA evaluates treatment outcomes, not only terms of the quantity of life obtained, but also in terms of the 'quality of life' gained from the intervention. The desirability or otherwise of an intervention from the patient's point of view is measured by the number of Quality Adjusted Life Years (QALYs) that are 'produced' by the intervention. The QALY provides the common unit by which different outcomes may be compared.

The stages of the analysis were as follows:

Outcome Measurement:

The identification of relevant outcomes from the epidemiological evidence and the calculation of utility values for these (*Section 3*).

Cost Measurement:

The calculation of direct and indirect costs associated with each procedure (*Section 4*).

Comparison of Treatment Options:

The comparison of the three treatments in terms of their costs and outcomes, and the exploration of the robustness of the conclusions to changes in the underlying assumptions (*Section 5*).

2 The Clinical Trial

The study was based upon a clinical trial of the three treatment options that was conducted at St Vincent's Hospital, Melbourne where Australia's first publicly owned lithotripter was put to clinical use in September 1989. While this trial was originally conducted to evaluate ESWL it resulted in the collection of information on a comparable sample of patients undergoing each of the treatment options, ESWL, open cholecystectomy and laparoscopic cholecystectomy.

The design of the St Vincent's trial is described in both the first interim report of the St Vincent's Hospital Biliary Lithotripsy Evaluation Sub-Committee (1991) and in Hailey and Hirsch (1991). A randomised control trial was not employed because of the difficulty in obtaining agreement from patients and referring specialists, doubts as to whether randomisation criteria would be consistently followed, and the potential difficulty with numbers of patients in each of the arms of the trial.

As a second best approach the clinical trial employed clinical selection criteria to ensure that patients assigned to each arm of the trial were comparable, ie their prior medical condition would not bias the outcome of the trial. Patients in the ESWL arm of the trial were given the procedure if they had a functioning gall bladder, if they had no more than three stones with a total volume not exceeding 3 cm, and if they were willing to accept the treatment. Pregnancy, jaundice and the presence of acute cholecystitis, acute pancreatitis, and acute cholangitis were all contra-indications for the procedure. The application of these criteria result in about 15-20 percent of all patients presenting with symptomatic gallstone disease being suitable for ESWL (Vellar et al. 1993).

When laparoscopic cholecystectomy became available at St Vincent's Hospital at the end of 1990, patients were normally offered and selected the laparoscopic procedure as the treatment of choice. As a consequence there have been few uncomplicated open cholecystectomy patients at the hospital since 1991. For comparative purposes only uncomplicated open cholecystectomy patients could be included in the trial. This meant that open cholecystectomy patients in the study were chosen retrospectively and pre-date laparoscopic patients by up to 30 months. The selected uncomplicated open cholecystectomy patients were matched as far as possible by age and sex to patients in the ESWL and laparoscopic cholecystectomy arms of the trial. While the selection criteria eliminated the most obvious sources of systematic difference between the three groups, the trial permits the possibility that patients undergoing the three procedures may have varied systematically in some respect. Characteristics of the patient samples are summarised in *Table 1*.

| TABLE 1 PATIENTS IN THE ST VINCENT'S HOSPITAL TRIAL | | |
|--|------|--------|
| | Male | Female |
| Procedure | | |

| | Open Cholecystectomy | Laparoscopic Cholecystectomy | ESWL | Open Cholecystectomy | Laparoscopic Cholecystectomy | ESWL |
|-------------|----------------------|------------------------------|-----------|----------------------|------------------------------|-----------|
| Sample size | 25 | 26 | 128 | 74 | 72 | 326 |
| mean age | 53 | 47 | 53 | 46 | 49 | 49 |
| range age | (20 - 79) | (19 - 79) | (28 - 80) | (18 - 72) | (14 - 77) | (16 - 81) |

3 Measuring Quality Adjusted Life Years (QALYs)

In cost utility analysis the common unit of outcome is the quality adjusted life year or QALY. The adjusted life year is achieved by assigning weights to different health states on a scale from 0 (dead) to 1 (healthy).

All three treatments of gallstones usually result in a return to normal health. The conversion of temporary ill health states into QALYs differs from the measurement of QALYs for chronic (or permanent) conditions in two respects. First, rather than measuring QALYs *gained* as a result of an intervention, the QALY loss associated with the post procedural period is estimated. The marginal benefit (loss) of QALYs resulting from a new procedure may be calculated by comparing the QALY loss after the new treatment with the loss following the more conventional treatment. Secondly, following Torrance (1986) the temporary health state is measured on a 0-1 scale where the lowest reference point is the health state identified as the worst health state by the individual who is being asked to evaluate the treatment outcomes. Subsequently, the values of the temporary health states are rescaled into utilities on a 0-1 (death-normal health) scale using the value of the worst health state when measured as a chronic condition.

The steps in the QALY analysis were as follows:

- i) The construction of outcome trees for each intervention based upon a review of the clinical literature, discussions with clinical staff at St Vincent's Hospital, open ended qualitative patient interviews, and a patient questionnaire;
- ii) The construction of health state scenarios which were used in subsequent interviews with the general public to evaluate the utility of the different health states described by the scenarios;
- iii) Calculation of QALY losses attributable to each intervention by weighting the outcome utilities by the probability and duration of their occurrence.

3.1 Identifying Outcomes

The first step in calculating QALYs is to determine relevant outcomes; their probabilities and transitional probabilities into subsequent health states. Determining the outcomes for the patients in the trial was seriously hindered by the lack of comprehensive information. Limited follow up data was available for ESWL patients. A total of 454 ESWL patients were recruited into the trial between August 1989 to April 1992. At the time of the economic evaluation 199 patients had had the procedure 12-24 months earlier. Little or no follow up information was available for laparoscopic cholecystectomy and open cholecystectomy patients. To overcome the gaps in the protocol data, further outcome data were sought from the literature, from discussions with clinical staff at St Vincent's Hospital and from patient interviews and questionnaires. The resulting outcome trees are reproduced in Appendix 1.

The information collected directly from the patients was crucial to the constructions of the outcome trees. An implicit assumption often made in the CUA literature is that the patient experience is a function of the clinical state of the patient. That is, while it is emphasised that the patient experiences, perspectives and preferences provide the relevant values for measurement of post treatment quality of life, these are assumed to vary systematically with the clinical state. However, if the assumption is unwarranted then the various health outcomes found in a clinical trial may only be of limited assistance in the measurement of QALYs.

The initial work of Daly (1990) questioned the validity of the assumption that the patient experience is closely correlated with the clinical state in the case of gallstone disease. This conclusion was reinforced by a study by Nicholl et al. (1992) in which it was found that biliary pain experience after ESWL did not depend on whether or not stones were cleared. A further confounding factor, and one well documented in the literature, is the so-called 'post cholecystectomy syndrome'. Long term follow up of cholecystectomy patients suggests that patients continue to experience symptoms following removal of the gallbladder. In some cases these symptoms can be attributed to physical problems or complications of the procedure. However, in other cases no explanatory physiological symptoms can be found.

Patient Interviews

A series of open ended patient interviews were conducted using the approach advocated by Glaser and Strauss (1987). The nature of the interview was largely unstructured to allow all aspects of the patient's experience to be explored. Subjects were recruited into the study up to a point where each major outcome dimension was judged to be saturated. This resulted in a total sample of 20 ESWL patients to identify the major outcomes of ESWL. Similarly, the typical post laparoscopic cholecystectomy health state was identified from a sample of 11 patients.

Because of the time since treatment it was not feasible to interview open cholecystectomy patients and the description of the immediate post-operative experience of the typical patient was based, in the first instance, on expert judgment. As the procedure has long been established and is well understood this was judged to be a reliable approach.

Patient Questionnaire

The postal questionnaire had two objectives in terms of assessing health outcomes. First, it sought to validate the result of the patient interviews and to ensure that no major category of symptoms or patient experience had been overlooked. Secondly, as clinical data could not be used to group patients into the relevant outcome categories, it sought information on the distribution of patients between the common health states, and information for the calculation of the probability of transition between health states. Patients were asked about the severity and frequency of their symptoms after treatment. Open ended questions allowed patients to report any other post-treatment symptoms which had not been identified by the previous methods.

Questionnaires were sent to all open cholecystectomy patients in the trial and to a sample of ESWL and laparoscopic cholecystectomy patients. Excluding those who were known to have died or for whom there was no current address, questionnaires were sent to 369 ESWL, 79 laparoscopic cholecystectomy and 89 open cholecystectomy patients. The response rate from the three groups was 73, 82 and 69 percent giving an overall response rate of 74 percent from the 537 patients approached.

Since people have imperfect recall, the information collected in the survey was limited to the experience in the first six months after the procedure and in the one month immediately prior to receipt of the questionnaire. This latter information was designed to allow estimation of the prevalence of symptoms beyond the initial six months and up to the 18 months when litholytic therapy for ESWL ceased. As pain was the dominant symptom, the standard health state outcomes were determined by combining pain with degrees of diarrhoea and nausea. Pain, if it existed, was the most persistent and important symptom and it was the pre-cursor to subsequent treatment. Diarrhoea can be, and was, controlled over time through a reduction in the dosage of medication and by the ability of the body to adjust to the litholytic therapy. The standard states and the probabilities of their occurrence are given in Table 2. For example, the probability of an open cholecystectomy patient experiencing health state 1 (HS1) in the first month following treatment is 0.467. These probabilities were used to estimate 'base values' for each of the treatment options. If symptoms persisted beyond this initial period they were to be primarily attributed to post-cholecystectomy syndrome.

TABLE 2
PROBABILITIES USED IN THE OUTCOME TREE

| Time (Months) | HSe | HS1 | HS2 | HS3 | HS4 | HS5 | HS6 | HS7 |
|---|---|--|---------------------------------|---|----------------|---------------------|--|-----------------------------|
| | Severe Post Operative Symptoms | Normal Post Operative Open Cholecystectomy | Post Operative Discomfort | Strong Pain/Severe Diarrhoea/ Nausea | Severe Pain | Severe Diarrhoea | Moderate Pain/ Severe Diarrhoea | Moderate to Mild Pain |
| Open Cholecystectomy | | | | | | | | |
| 0 - 1 | .35 | .467 | .183 | | | | | |
| 1 - 7 | | | | | .115 | | | .524 |
| 7 - 18 ⁺ | | | | | .04 | | | .30 |
| Laparoscopic Cholecystectomy | | | | | | | | |
| 0 - .5 | .246 | | .323 | | | | | .431 |
| .5 - 6.5 | | | | | .108 | | | .292 |
| 6.5 - 18 ⁺ | | | | | .02 | | | .29 |
| ESWL | | | | | | | | |
| 0 - 2 | | | | .168 | .130 | .073 | .100 | .302 |
| 2 - 6 | | | | .080 | .123 | .073 | .038 | .322 |
| 6 - 18 ⁺ | | | | .02 | .04 | | | .30 |

Source: Patient Questionnaire

Low Probability and Long Term Outcomes

The patient interviews and questionnaires identified the common outcomes of treatment. Low probability and long term outcomes were identified from the literature and from advice from clinical staff at St Vincent's Hospital. Full details are given in *Appendix 2*. Not all symptoms were included in the outcome analysis. Most are minor or have no long term effect and are treated during the normal hospital stay (extra time in hospital being included in the cost of the procedure). *Table 3* reports the symptoms that were included in the outcome evaluation.

Common Bile Duct Damage

Other than death, the most serious complication arising from open or laparoscopic cholecystectomy occurs when there is damage to the common bile duct (CBD). Repair of a duct transection is a complicated procedure and for maximum probability of satisfactory long term results needs to be carried out by an experienced surgeon. Repeat procedures reduce the chances of successful outcome; stricture may become irreversible and liver failure may occur after many years. In the young this may ultimately lead to a liver transplant. Detailed probabilities of the consequences are reported in *Appendix 1, Figure 4*.

| TABLE 3 LOW PROBABILITY AND LONG TERM OUTCOMES INCLUDED IN THE ANALYSIS | | | |
|--|-----------------------------------|---|---|
| Complication | Open Cholecystectomy | Laparoscopic Cholecystectomy | ESWL |
| Death (from a variety of causes) | 0.1 - 0.2% | 0.12 - 0.22% <i>St Vincent's</i> 0.1 - 0.2% | 0.01% |
| Conversion to Open Cholecystectomy (depends on selection criteria) | Not Applicable | 10 - 15% <i>St Vincent's</i> 5% | Not Applicable |
| Subsequent Cholecystectomy (due to a variety of causes) | Not Applicable | Not Applicable | <i>St Vincent's</i> 20.0% |
| CBD damage (including transection) | 0.2 - 0.4% | 0.2 - 0.5% | Not Applicable |
| Transection | 0.1 - 0.2% | 0.1 - 0.3% <i>St Vincent's</i> 0.1% | |
| Retained stone requiring ERCP Sphincterotomy (depends on use of Operative Cholangiography) | 1-5% <i>St Vincent's</i> 1% | 1-5% <i>St Vincent's</i> 1% | 1-2% <i>St Vincent's</i> 4/454 or 0.9% |
| Recurrence of stones | Not Applicable | Not Applicable | 10% per year for first 5 years with few further recurrences after 5 years for bile salt therapy alone |

3.2 Valuing Outcomes

Interviews with the General Public

The health state scenarios reported in Table 4, were used in the interviews with the general public to obtain utility values for the common outcomes of treatment. On the basis of the anticipated standard error, a target sample of 96 was sought to obtain utility values. Sampling was designed to obtain the same socio-economic status (SES), age and sex profile as the patients in the trial. SES profiles based on the indicators of socio-economic disadvantage by Ross, et al. (1988) were drawn up from

postcodes of patients. To simplify the sampling procedure these profiles were divided into upper and lower SES groups and the median SES value in each group was used to identify the area from which to recruit members of the general public. The educational status of respondents was used as an indicator of SES. Women were over sampled to reflect the gender difference in the incidence of gallstone disease and in the trial.

Interviewing was carried out, by appointment, in the respondent's home. Three experienced interviewers were employed and trained to use the measurement techniques and visual aids. Subsequent interviews were observed to ensure quality control. The interview schedule is reproduced in Cook and Richardson 1993(b).

The health states were scaled using both the rating scale (RS) and time trade off (TTO) procedures. A detailed analysis and comparison of these is given in Cook and Richardson (1993a). The final analysis employed only the results from the TTO instrument. The reasons for this preference are also discussed in Cook and Richardson (1993a), and Cook, Richardson and Street (1994).

Conversion of Temporary Health State Values into Utility Scores

Eighty percent of respondents nominated HS3 as the worst health state scenario, the remainder nominating either HS1 or HS6. The value of the worst health as chronic health states for 12 months were used to convert other health states into utilities on a 0-1 scale. As the utility values for the chronic health state could be subject to serious bias arising from the assumed life expectancy they were compared with values obtained from the same health state and an assumed life expectancy of twelve years. No significant difference was found. The correlation between the two was 0.83 and the mean values were 0.45 (months) and 0.41 (years). The mean values would have been identical if a 2 percent discount rate was applied over the 12 years. Results from the shorter time period were used for utility calculations as they are the theoretically correct values for the calculation of health state preferences if Torrance's method is used (*Torrance, 1986*).

TABLE 4
HEALTH STATE SCENARIOS

| Health State | Category | Scenario |
|--------------|---|---|
| HS1 | Open Cholecystectomy <i>(normal)</i> | You have had a successful operation. You get tired very easily and you don't sleep very well at night. The wound gives you a continuous dull sort of pain. You find that you cannot carry out most of your normal activities. |
| HS2 | Laparoscopic Cholecystectomy <i>(normal)</i> | You have had a successful operation. You feel a little tired. It is uncomfortable for you to move. You cannot exercise or lift heavy things. You find that you can do most of your normal activities. |
| HS3 | Severe pain Severe diarrhoea Nausea | You are having specialist medical treatment. Your treatment gives you 2 or 3 attacks of continuous agonising pain in your chest and back. The pain can last from half an hour to 4 hours. You can do nothing to relieve the pain. When the pain goes you can return to your normal activities. The treatment also gives you uncontrollable diarrhoea 2 or 3 times a week. You need to be near a toilet most of the time. About once a week the diarrhoea is very painful. About once a week you feel a bit nauseous for a few hours. |
| HS4 | Severe pain <i>(periodically)</i> | You are having specialist medical treatment. Your treatment gives you 2 or 3 attacks of continuous agonising pain in your chest and back. The pain can last from half an hour to 4 hours. You can do nothing to relieve the pain. When the pain goes you can return to your normal activities. |
| HS5 | Severe diarrhoea | You are having specialist medical treatment. You have uncontrollable diarrhoea 2 or 3 times a week. You need to be near a toilet most of the time. About once a week the diarrhoea is very painful. |
| HS6 | Moderate pain Sever diarrhoea | You are having specialist medical treatment. The treatment gives you an uncomfortable heavy feeling in your stomach most of the time. About once a month you also have a cramping pain in your chest and back. You have uncontrollable diarrhoea 2 or 3 times a week. You need to be near a toilet most of the time. About once a week the diarrhoea is very painful. |
| HS7 | Moderate pain | You are having specialist medical treatment. The treatment gives you an uncomfortable heavy feeling in your stomach most of the time. About once a month you also have a cramping pain in your chest and back. |

Utility Values for the Health States

Utility values for the health states derived from interviews with the general public are presented in Table 5. In all cases the mean values differ significantly from full health (1.00). Confidence intervals were comparatively narrow indicating a degree of concurrence between respondents about the value of the health states. The striking result is the importance of the symptoms that are unique to litholytic therapy following ESWL. The loss of utility from moderate pain plus severe diarrhoea is almost double the loss from pain alone and the loss from severe pain/severe nausea is almost three times

as great as the loss from severe pain.

| TABLE 5 UTILITY VALUES: MEANS AND CONFIDENCE INTERVALS | | | |
|---|--|------|----------------------------------|
| Health States | | Mean | Confidence Interval [*] |
| HS2 | Laparoscopic cholecystectomy (<i>normal</i>) | 0.90 | 0.87-0.93 |
| HS7 | Moderate pain | 0.90 | 0.87-0.92 |
| HS4 | Severe pain (<i>periodically</i>) | 0.88 | 0.86-0.90 |
| HS5 | Severe diarrhoea | 0.81 | 0.78-0.85 |
| HS1 | Open cholecystectomy (<i>normal</i>) | 0.81 | 0.77-0.86 |
| HS6 | Moderate pain/severe diarrhoea | 0.68 | 0.63-0.74 |
| HS3 | Severe pain/severe diarrhoea/nausea | 0.47 | 0.40-0.54 |

^{*} Confidence interval at 95 percent level.

To reduce the interview burden and the likelihood of cognitive overload not all health states identified in the outcome trees were included in the interview but were estimated from the values directly obtained from respondents as follows. The loss of utility associated with moderate to mild pain following laparoscopic cholecystectomy was set equal to HS7 (moderate pain) while the loss of utility associated with post-operative discomfort following open cholecystectomy was set equal to HS2. Assuming an additive model, the loss of utility associated with the most severe post operative health state (HSe) were determined in the following manner. For open cholecystectomy, loss of utility in the severe post operative state was set equal to the loss of utility of the `normal' post operative health state (HS1) plus the loss of utility associated with severe pain alone (HS4). For laparoscopic cholecystectomy, the loss of utility in the severe post operative state was calculated as the loss of the moderate to mild pain following laparoscopic cholecystectomy (HS7) plus the loss of utility associated with severe pain alone (HS4).

An estimate of the order of magnitude of the QoL loss due to CBD damage was based upon the following assumptions:

- The probabilities of different consequences are as shown in *Appendix 1, Figure 4*.
- The average life expectancy of patients is 25 years, the average for the respondents to the survey.
- The disutility of the repair of a stricture is equal to the loss of utility associated with the post-operative health state for open cholecystectomy.
- The loss of utility associated with permanent CBD damage is equal to the loss from the worst health state (0.53) and the loss continues for the rest of life.

The Effect of Litholytic Therapy

Two forms of litholytic therapy are available to assist with the dissolution and clearance of stone fragments following ESWL, chenodeoxycholic acid (Cheno) and ursodeoxycholic acid (Urso). The latter is not permitted in Australia at present despite evidence that it is associated with less diarrhoea and nausea. To investigate the effect of Urso on quality of life following ESWL we have assumed that patients who suffered from pain and other symptoms when taking Cheno would only experience pain when on Urso. Utility losses for ESWL were recalculated assuming no diarrhoea or nausea, ie HS3 and HS6 were equal to HS4 and HS7 respectively, while the utility of HS5 was set equal to 1.0.

Calculating QALYs Losses

Finally, the QALY loss associated with each procedure was calculated by combining the loss of utility associated with each health state with the probability of the patient experiencing the outcome and its duration, according to the following formula:

$$\text{QALY Loss} = \sum_{i=1}^n p_i D_i (1 - U_i)$$

where P_i = Probability of entering State i
 D_i = Average duration of State i
 U_i = Utility Value for State i
 n = Number of health states.

Total QALY losses for each procedure are presented in *Table 6*. Because there was insufficient information to calculate the standard error of the mean utility values, upper and lower estimates were constructed by aggregating the disutility associated with each treatment option using (1) the upper and lower value of the 95% confidence interval where the health state is measured directly and (2) an upper and mean estimate based on the literature and expert advice where health states are not measured directly. Subsequent analysis is based on the means as the best estimate of the QALY losses associated with each treatment option. In terms of outcome alone, procedures are to be preferred when they result in lower post-treatment disutility and/or speedier recovery, and therefore lower QALY losses. As expected, the effect of an open cholecystectomy on QoL is larger than the effect of an uncomplicated laparoscopic cholecystectomy. The poorer result from ESWL shown in Row A when Cheno is the adjuvant bile salt reflects the disutility of the side effects associated with this treatment option. The poorer outcome from uncomplicated ESWL is partly offset when the results included the likelihood of complications and death. ESWL is unambiguously the preferred option when estimate of QALY losses are based on the use of Urso. Despite the evidence that it is associated with less diarrhoea and nausea Urso is not available in Australia. The most unreliable estimate in *Table 6* relate to the outcome of common bile duct damage. However, the very small probability of its occurrence reduces its importance.

| TABLE 6 LOSS OF QALYS PER 100 PATIENTS | | | | | |
|---|-------------------------|---------------------------------|-------|------|--|
| QALY LOSS | Open Cholecystectomy | Laparoscopic Cholecystectomy | ESWL | | |
| | | | Cheno | Urso | |
| A 18 mths post procedure | | | | | |
| 1 Lower estimate | 6.59 | 4.5 | 10.31 | 5.66 | |
| 2 Mean estimate | 8.25 | 5.67 | 11.42 | 6.98 | |
| 3 Upper estimate | 10.47 | 7.22 | 14.94 | 8.78 | |
| B Death¹ | | | | | |
| 1 Mean estimate | 2.5 | 3.0 | - | - | |
| 2 Upper estimate | 5.0 | 5.5 | - | - | |
| C CBD Damage¹ | | | | | |
| 1 Mean estimate | .17 | .17 | - | - | |
| 2 Upper estimate | .52 | .66 | - | - | |
| D Full Procedure² | | | | | |
| 1 Lower estimate | 9.26 | 7.83 | 10.31 | 5.89 | |
| 2 Mean estimate | 10.92 | 9.05 | 11.75 | 7.47 | |
| 3 Upper estimate | 15.99 | 13.64 | 15.28 | 9.39 | |

1 Mean estimates regarding death and CBD damage associated with the surgical procedures were based on clinical advice and have been used in calculating both the mean and lower estimates of the QALY loss associated with the full procedure. These assumptions have been changed in the upper estimates to test the sensitivity of the results to increases in complication rates.

2 Adjusted for conversions: 10 percent of laparoscopic become open cholecystectomies; 20 percent of ESWL patients receive laparoscopic cholecystectomy after 13 weeks (median time experienced) during which the average utility experienced was assumed equal to the average for patients in the first 3 months following ESWL.

4 Measuring Costs

4.1 Economic Costs

The economic cost of treatment includes the direct cost to the health system, the patient and their families, and the indirect cost arising from the loss of (paid or unpaid) productive activity. Details of the costing methods are reported in Street (1993).

Hospital data were collected by the St Vincents' biliary lithotripsy unit which recorded patient specific treatment details. This allowed investigation of cost variation between patients as well as between treatments. This information was supplemented by data from the patient questionnaires described earlier. Among other things, patients were asked about the time lost, number of journeys made to hospital, and amount of additional care received because of their treatment and recovery.

Accordingly, estimates were made of the following:

- 1 Hospital costs; including medical, theatre, diagnostic tests, nursing, overheads, capital and pharmacy;
- 2 Patient costs; including transport and travel time, and costs borne by carers; and
- 3 Indirect costs; including the loss of paid and unpaid activity.

4.2 Hospital Costs: Open and Laparoscopic Cholecystectomy

The direct costs of open and laparoscopic cholecystectomy were calculated using individual patients' data. The patient protocols recorded details including the number of diagnostic tests, the type and dosage of medication received, and the main indicators of resource use for these patients, operation time and length of stay. Laparoscopic cholecystectomy patients typically had a longer operation than those who had open surgery, the operation lasting 82 minutes (± 32) compared to 70 minutes (± 22) with the open procedure. This difference was significant ($p < 0.01$). The costs of the surgeon and theatre staff were allocated according to operating time. Nursing costs, ward and hospital overheads were estimated on the basis of length of stay. On average, open cholecystectomy patients were in hospital for 8.8 days (± 2.2) compared to 5.6 days (± 2.8) for laparoscopic cholecystectomy patients. This difference was significant ($p < 0.001$).

Medical and theatre costs

The cost of the surgeon and post-operative medical care was calculated on the assumption that doctors were paid a standard sessional rate. Inter-patient variation primarily reflects differences in operating time, but is also a result of differences in length of stay. The average cost of the surgeon amounted to \$191 (± 23) for open cholecystectomy and \$187 (± 33) for laparoscopic cholecystectomy. Differences between the cost of theatre staff are fully explained by differences in the length of the operation. The average cost of theatre staff was \$291 (± 52) and \$318 (± 75) for open and laparoscopic cholecystectomy respectively.

Details of anaesthetics, consumables and instruments were provided by theatre staff, and their costs amounted to \$255 and \$319 for open and laparoscopic cholecystectomy respectively. The capital cost of the theatre was estimated as \$69 per operation.

The cost of diagnostic and laboratory tests

A variety of tests were conducted on patients undergoing the two procedures. Details were recorded in the protocols and costed using the benefit rate of 75% of the schedule fee in the Commonwealth Medical Benefits Schedule (CMBS). The average cost was estimated as \$180 (± 75) and \$182 (± 96) for open and laparoscopic cholecystectomy respectively.

Nursing costs

Two methods could be used to estimate the cost of nursing staff. The first would be to calculate a per diem cost, by dividing the nursing salary bill by the total number of bed days for a given period, and multiplying by the length of stay for each patient in the study. However, nursing costs vary both by length of stay and the intensity of care required. For any given day in hospital, cholecystectomy patients might require different amounts of nursing time than patients admitted with other conditions.

To account for this, estimates of nursing costs were calculated using the hospital's patient dependency system. For each shift spent at a particular dependency level, the patient's time requirement of each category of nursing staff was multiplied by the hourly employment cost for that shift and nursing category. When the costing was conducted the actual dependencies of patients in the study were no longer available, so the shift specific dependency level costs were applied to more recently treated open and laparoscopic cholecystectomy patients to derive an average daily nursing cost. These average daily nursing costs were then applied to patients in the study, according to their lengths of stay.

The difference in average daily nursing costs for open compared to laparoscopic patients was not marked. However, because open cholecystectomy patients spent longer in hospital, total nursing costs were greater for this procedure than for laparoscopic cholecystectomy. Total nursing costs amounted to \$984 (\pm 241) for open cholecystectomy and \$588 (\pm 290) for laparoscopic cholecystectomy.

Overheads

Ward overheads include nursing allowances, consumables, laundry, and floor space. The costs of catering, cleaning, electricity, and administration were included in the estimate of hospital overheads. Average total overhead costs were calculated as \$1,286 (\pm 314) for open cholecystectomy and \$814 (\pm 402) for laparoscopic cholecystectomy, the difference attributable to differences in average length of stay for the two procedures.

Pharmacy costs

The patient protocols recorded information on the type and amount of medication prescribed for each patient. Costs were estimated using the buying guide of the Victorian Hospital's Association (VHA). Pharmacy overheads were assigned on the basis of length of stay.

Total hospital costs

Average total hospital costs amounted to \$3,366 (\pm 603) for open cholecystectomy and \$2,581 (\pm 820) for laparoscopic cholecystectomy. However, it was estimated that 10% of patients undergoing laparoscopic cholecystectomy would have to convert to open cholecystectomy during the course of the operation for technical reasons. After adjustment for the higher cost of converted patients, the average hospital cost of laparoscopic cholecystectomy was estimated as \$2,699 (\pm 738). The cost difference between the surgical interventions was significant ($p < 0.001$).

4.3 Hospital Costs: ESWL

ESWL patients were treated as out-patients. Following their initial consultation, patients received a variable number of treatments on the lithotripter. They returned to the biliary lithotripsy unit periodically for follow-up, where the size of the stone was monitored and further treatments may have been recommended. Patients were prescribed litholytic therapy to facilitate the dissolution and removal of stone fragments.

ESWL Treatment Costs

The costs of the physician, ultrasonographer and nurse were estimated according to the time each

typically spent with the patient, and assuming treatment time on the lithotripter was the same for all patients. Staff costs were estimated as \$185 per session on the lithotripter.

The costs of diagnostic tests, medication and floor space were calculated as they were for the surgical treatments. The cost of hospital overheads was estimated as approximately 20% of the cost of a per bed day, on the basis of the average time it takes to perform an episode of ESWL.

The lithotripter and colour doppler cost \$2,056,538 when purchased in 1989. There was an associated maintenance charge of \$227,218 per annum. In calculating the equipment cost per operation it was assumed that the lithotripter had a useful life of five years, two electrodes were used per treatment, there was a throughput of 1000 treatments per year, and the discount rate was 7%. The equipment cost per treatment session amounted to \$1,284. If the purchase of the machine could be independently justified by its use for other conditions, the cost of capital need not be attributed to ESWL. The equipment cost per treatment session would then amount to \$731. The effect of excluding capital costs is discussed in the sensitivity analysis.

The treatment cost per patient varied according to the number of treatment sessions necessary. On average patients required 1.5 sessions. The average treatment cost amounted to \$2,406 (\pm 1,074).

ESWL patients returned for follow-up examinations in the first two weeks after treatment, six weeks later, and thereafter at intervals of approximately three months. Follow-up continued until the patient was declared stone free or surgery was recommended. Patients had an average of five follow-up sessions. The cost of follow-up was calculated according to the number of sessions attended and the tests conducted during the examination, and amounted to an average \$370 per patient.

Litholytic therapy

Litholytic therapy represents a significant proportion of the cost of ESWL. The medication was taken to dissolve the fragments which remain after stones have been shattered by the lithotripter shockwaves. Patients were prescribed Cheno or Urso, either alone or in combination, according to their body weight. Protocols recorded dosages and time spent on the medication. A number of patients (8.4%) did not return for follow-up and the time spent on medication for these is unknown. Although a proportion of patients were prescribed Urso the drug had not been granted regulatory approval and was withdrawn during the trial. The cost estimates of litholytic therapy have, therefore, been based on the cost of Chendol, supplied through the VHA at a price of \$0.43 per 125 mg. Excluding those lost to follow-up, the cost of litholytic therapy amounted to an average of \$1,094 (\pm 769). Urso causes significantly fewer adverse reactions than does Cheno, but is more expensive at \$0.67 per 125 mg. The effect of using Urso in terms of quality of life and cost is explored in the sensitivity analysis.

Total hospital costs

The average total hospital cost of ESWL was estimated as \$4,007 (\pm 1,471). Of the 454 patients who received ESWL, 20% were subsequently admitted for surgery. It has been assumed that patients having surgery had laparoscopic cholecystectomy with a 10% probability of conversion to the open procedure. The average hospital cost of ESWL for all patients including those who have subsequent surgery was estimated as \$4,617 (\pm 1869).

4.4 Patient Costs

Travel costs

In the postal questionnaire patients were asked about the number of trips made to hospital, and the mode of transportation used. Travel costs included the cost of transportation and time spent travelling. Transportation costs were estimated assuming journeys were undertaken by private car as this was the mode most commonly used. The cost of travel time was estimated at 40% of average weekly earnings (Sharp 1988). Average travel costs amounted to \$97 (\pm 74), \$81 (\pm 55), and \$175 (\pm 116) for open cholecystectomy, laparoscopic cholecystectomy, and ESWL respectively. ESWL mean costs were significantly higher than the mean costs of the surgical patients reflecting the greater number of trips needed for multiple treatment and follow up sessions ($p < 0.001$).

Costs borne by carers

Patients were asked whether they had been assisted and cared for after discharge from hospital. Very few patients required additional professional care, and the cost of this care was minimal for each treatment. However, many patients indicated that they were cared for by relatives and friends. The cost of days lost by carers was calculated using the opportunity cost and replacement cost approaches although only the latter are reported here. On average, the cost of additional care amounted to \$881 (\pm 2,066) for open cholecystectomy, \$307 (\pm 662) for laparoscopic cholecystectomy, and \$69 (\pm 145) for ESWL. Between group differences were significant ($p < 0.001$), with the mean cost of care for open cholecystectomy significantly different to that for both laparoscopic cholecystectomy and ESWL.

Total patient costs

After adjusting for conversion, average total patient costs amounted to \$992 (\pm 2108) for open cholecystectomy, \$455 (\pm 569) for laparoscopic cholecystectomy, and \$345 (\pm 199) for ESWL. Analysis of variance revealed significant between group differences ($p < 0.001$), subsequent multiple comparison testing using Tukey's HSD test showing that mean patient costs were significantly higher for open cholecystectomy patients, but that the difference between laparoscopic cholecystectomy and ESWL was not significant.

4.5 Indirect Costs

Indirect costs are defined as the production losses resulting from treatment because the patient is unable to return to normal activity. It is important to identify those costs arising as a result of treatment, rather than those which would have occurred anyway because the patient was ill. In other words, the objective is to evaluate the consequences of treatment, not the costs of illness. Strictly, indirect costs are not a cost of treatment at all, in that they do not represent a contribution to the production of health, and it would be more accurate to consider them to be a (negative) benefit of treatment. However, because the measurement of outcome in this study did not incorporate consequences for production these have been included on the cost side of the equation to produce an overall 'net resource cost' associated with treatment. The effect of ignoring production losses altogether is explored in the sensitivity analysis.

The cost of days lost to paid activity was estimated using average weekly earnings for those in the

paid work force. A number of patients estimated that no time was lost to paid activity because they were financially compensated for their time off work. However, because the loss of production is borne somewhere in the economy, if not to the patients directly, cost estimates have been attributed to these patients to account for this misunderstanding. The productive loss associated with time lost to home duties was also estimated using both the replacement cost and opportunity cost methods although only the former are presented here. No productive value was attributed to those categorised as unemployed or retired, as the effects of treatment on non-productive time are subsumed in the outcome measure.

The occupational status of patients who received open cholecystectomy differed from the status of the other treatments. This could introduce bias to the cost estimates which should be based upon perfectly matched samples as would occur in a randomised control trial. Consequently, the same work force composition was assumed for open cholecystectomy patients as for the other two treatment categories and open cholecystectomy costs were adjusted accordingly. On average, indirect costs amounted to \$2,564 (\pm 3,869) for open cholecystectomy, \$1,123 (\pm 1,338) for laparoscopic cholecystectomy, and \$321 (\pm 503) for ESWL. After adjusting for the possibility of conversion from laparoscopic to open cholecystectomy, and from ESWL to surgery, the average indirect cost of laparoscopic cholecystectomy amounted to \$1,267 (\pm 1204) and of ESWL to \$574 (\pm 504). These differences were significant for each treatment group ($p < 0.001$).

4.6 Summary

The cost analysis is summarised in *Table 7*. Mean cost estimates include adjustment for the possibility of conversion to other treatments, and were calculated by summing the mean costs of the components incorporated in the broad categories of hospital, patient and indirect costs. This preserves data from cases which did not have full information. Confidence intervals, however, were calculated using reduced samples. Consequently mean costs may not be at the midpoint of the confidence interval. For hospital, patient and indirect costs taken separately, few cases had incomplete information and were omitted from the calculation of the confidence interval. However, because some 35% of patients did not return questionnaires, the confidence intervals around hospital plus patient costs, and around total costs were approximated using an estimate of the standard error based on complete subsamples.

On average, the total cost of treatment was \$6,922 for open cholecystectomy, \$4,422 for laparoscopic cholecystectomy and \$5,536 for ESWL. The sensitivity of these results to the capital cost of the lithotripter, the use of Urso rather than Cheno, and the inclusion of indirect costs, is explored in *Section 4*.

| TABLE 7 MEAN COST ESTIMATES | | | | | |
|--------------------------------|--------------------------------|--|---|--------------------------------|---|
| | Hospital Costs (a) \$ | Patient Costs ¹ (b) \$ | Total Direct Costs ² (a & b) \$ | Indirect Costs (c) \$ | Total Costs ² (a & b & c) \$ |
| <i>Open Cholecystectomy</i> | | | | | |

| | | | | | |
|-------------------------------------|-----------|----------|-----------|-----------|-----------|
| Mean | 3366 | 992 | 4358 | 2564 | 6922 |
| 95% CI | 3246-3476 | 448-1557 | 3799-4917 | 1528-3600 | 5666-8328 |
| Laparoscopic Cholecystectomy | | | | | |
| Mean | 2699 | 455 | 3154 | 1267 | 4422 |
| 95% CI | 2552-2848 | 275-566 | 2992-3386 | 948-1587 | 3917-4619 |
| ESWL | | | | | |
| Mean | 4617 | 345 | 4962 | 574 | 5536 |
| 95% CI | 4427-4787 | 309-359 | 4854-5070 | 508-641 | 5336-5736 |

1. Patient costs are the sum of the costs of professional and informal care and travel costs. A number of patients had missing data for one or more of these variables. Data were also trimmed if values were more than three standard deviations from the mean. The mean patient costs reported are the sum of the means for each variable, including patients who may have had missing data or who were trimmed from other variables. The confidence intervals, however, are derived from only those patients who had complete data for all variables. ($n = 58, 61, 253$ for open cholecystectomy, laparoscopic cholecystectomy and ESWL respectively).

2. Mean total direct costs are the sum of the means of hospital and patient costs, while mean total costs are the sum of the means of hospital, patient and indirect costs. However, because questionnaire data was missing for approximately 35% of cases, confidence intervals for total direct costs and total costs were approximated based on the variance and co-variance of hospital and patient and indirect costs, using the following formula:

$$SE(\text{Total}) = \sqrt{\frac{\sigma_H^2}{n_H} + \frac{\sigma_P^2}{n_P} + \frac{2\rho\sigma_H\sigma_P}{n_H}} \quad \text{where } n_H > n_P$$

where σ is the standard deviation, n sample size, H hospital cost sample, P patient and indirect cost sample, and ρ the correlation between hospital costs and patient and indirect costs.

5 Comparison of Treatment Options

Treatment options for gallstone disease are compared under 2 main scenarios. The first considers only direct hospital and patient costs (*Scenario 1*). The second includes indirect costs in the assessment (*Scenario 2*).

In addition, the relative advantage of ESWL is explored to determine the effects on outcomes and/or costs of the following: (1) excluding the capital cost of the lithotripter; (2) using Urso rather than Cheno as bile salt therapy; and (3) subsequent stone recurrence. These forms of sensitivity analysis are all presented as changes from the base estimates of the costs and QALY losses associated with ESWL.

Table 8 presents lower, mean and upper estimates of the outcomes and costs under various assumptions. For every assumption considered, lower and upper estimates of the outcomes and costs allow assessment of the stability of the results based on mean estimates. The calculation of the lower and upper estimates was described previously.

Table 9, presents the policy implications of the information presented in *Table 8*, by ranking the three treatment options according to both outcome and cost under each form of the sensitivity analysis. Higher ranked options on both outcome and cost are unambiguously superior to those ranked below, using mean values as best estimates. Where an option ranks higher when considering outcomes (i.e. is associated with a lower QALY loss than the alternatives) but is ranked lower on cost, preference for the procedure must be based on how much it costs to acquire the additional benefits it promises over its rivals. Figures showing the cost per QALY gained when such trade-offs arise are presented beneath the relevant rankings. Finally, the table indicates when the policy choice based on mean estimates is altered when upper or lower estimates are used.

Finally, differences in the costs and outcomes of ESWL are presented according to the size or number of gallstones. Details of this stage of the analysis are provided in *Table 10*.

TABLE 8
COSTS AND QALY LOSSES OF THE TREATMENT OPTIONS
Lower, Mean and Upper Estimates

| | | <i>Scenario 1</i> | <i>Scenario 2</i> |
|---|-------|--------------------------|----------------------------------|
| QALY Loss per 100 Patients | | Total Direct Costs \$ | Direct & Indirect Costs \$ |
| Open Cholecystectomy: base estimates | | | |
| Lower | 9.26 | 3799 | 5666 |
| Mean | 10.92 | 4358 | 6922 |
| Upper | 15.99 | 4917 | 8328 |
| Laparoscopic Cholecystectomy: base estimates | | | |
| Lower | 7.83 | 2992 | 2917 |
| Mean | 9.05 | 3154 | 4422 |
| Upper | 13.64 | 3386 | 4619 |
| ESWL: base estimates | | | |
| Lower | 10.31 | 4854 | 5336 |
| Mean | 11.75 | 4962 | 5536 |
| Upper | 15.28 | 5070 | 5736 |
| ESWL : Excluding Capital Costs of Lithotripter | | | |
| Lower | 10.31 | 3884 | 4388 |
| Mean | 11.75 | 4039 | 4564 |
| Upper | 15.28 | 4194 | 4741 |
| ESWL : Use of Urso | | | |
| Lower | 5.89 | 5299 | 5932 |
| Mean | 7.47 | 5502 | 6152 |
| Upper | 9.39 | 5705 | 6372 |
| ESWL : 50% Recurrence | | | |
| Lower | 12.96 | 5310 | 5946 |
| Mean | 14.81 | 5420 | 6179 |
| Upper | 19.46 | 5540 | 6368 |

TABLE 9
RANKING OF TREATMENT OPTIONS AND COST PER QALY GAINS

| Rank | Scenario 1 | | | Scenario 2 | | |
|---|---|------|------|---|------|------|
| | Total Direct Costs | | | Direct & Indirect Costs | | |
| | 1 | 2 | 3 | 1 | 2 | 3 |
| 1. Base Estimates | | | | | | |
| Rank: · QALY loss | LC | OC | ESWL | LC | OC | ESWL |
| · Cost | LC | OC | ESWL | LC | ESWL | OC |
| | Upper: ESWL preferred to OC \$21,549 per QALY gained | | | OC preferred to ESWL \$166,988 per QALY gained | | |
| Sensitivity to lower/upper estimation | Upper: ESWL preferred to OC \$21,549 per QALY gained | | | Upper: ESWL dominates OC | | |
| 2. Exclusion of Capital Cost of Lithotripter | | | | | | |
| Rank: · QALY loss | LC | OC | ESWL | LC | OC | ESWL |
| · Cost | LC | ESWL | OC | LC | ESWL | OC |
| | OC preferred to ESWL \$38,434 per QALY gained | | | OC preferred to ESWL \$284,096 per QALY gained | | |
| Sensitivity to lower/upper estimation | Lower: OC dominates ESWL Upper: ESWL dominates OC | | | | | |
| 3. Use of Urso | | | | | | |
| Rank: · QALY loss | ESWL | LC | OC | ESWL | LC | OC |
| · Cost | LC | OC | ESWL | LC | ESWL | OC |
| | ESWL preferred to LC \$148,608 per QALY gained ESWL preferred to OC \$33,159 per QALY gained | | | ESWL preferred to LC \$109,494 per QALY gained | | |
| Sensitivity to lower/upper estimation | | | | Lower: ESWL preferred to OC \$7,893 per QALY gained | | |
| 4. ESWL: 50% Stone Recurrence | | | | | | |
| Rank: · QALY loss | 1 | 2 | 3 | 1 | 2 | 3 |
| · Cost | LC | OC | ESWL | LC | OC | ESWL |
| | LC | OC | ESWL | LC | ESWL | OC |
| | | | | OC preferred to ESWL \$19,100 per QALY gained | | |
| Sensitivity to lower/upper estimation | | | | Lower: OC dominates ESWL | | |

Using the mean QALY loss associated with each procedure as the best estimate *Table 9* demonstrates that laparoscopic cholecystectomy is generally the first ranked procedure, entailing lower costs and QALY losses than the alternatives. The only exception to this clear dominance appears where the sensitivity of the results to the use of Urso is explored. When Urso is used as bile salt therapy for ESWL patients, the procedure is associated with the lowest QALY loss (7.47 QALYs per 100 patients compared to 9.05 for laparoscopic cholecystectomy and 10.92 for open cholecystectomy). However, laparoscopic cholecystectomy is less expensive than both ESWL and open cholecystectomy, with the procedures costing an average of \$3,154, \$5,502 and \$4,358 respectively. If ESWL were to be preferred to laparoscopic cholecystectomy on the basis of its having a better outcome under this scenario, the additional QALYs gained would be attained at a cost of \$148,608 per QALY gained if only direct hospital and patient costs are included in the estimation and \$109,494 per QALY gained if indirect costs are included. These figures are calculated by dividing the difference in cost by the difference in QALY loss (per 100 patients) for the procedures for which the trade-off exists. It is doubtful that any authority would consider purchasing QALYs at the costs reported under this scenario. Hence, it can be concluded that the dominance of laparoscopic cholecystectomy is not sensitive to the assumptions investigated here.

The comparison of open cholecystectomy and ESWL is less clear cut, and applicable only when laparoscopic cholecystectomy is unavailable. When base estimates are considered open cholecystectomy would be preferred to ESWL if indirect costs are excluded from the assessment (*Scenario 1*). However, there is a trade-off if upper rather than mean estimates are used to calculate costs and outcomes. When upper estimates are used, the greater benefit secured by ESWL (which has a QALY loss per 100 patients of 15.28 compared to 15.99 for open cholecystectomy) comes at a cost of \$21,549 per additional QALY gained.

Because indirect costs are considerably higher for open cholecystectomy, their inclusion results in ESWL being the less costly of the two treatments (*Scenario 2*). Based on mean estimates, open cholecystectomy results in fewer QALY losses (10.92 as compared to 11.75 per 100 patients). The marginal cost per QALY gain of choosing open cholecystectomy over ESWL amounts to \$166,988. ESWL dominates open cholecystectomy if upper estimates are used.

Exclusion of the capital cost of the lithotripter can be justified if spare capacity is available on multi-purpose machines. The exclusion of the capital cost of the lithotripter reduces the direct costs of ESWL by \$923 to \$4,039. Open cholecystectomy is then associated with a lower QALY loss, but is more expensive. If open cholecystectomy were to be preferred, the additional benefit would cost \$38,434 per QALY gained. This result is sensitive to the basis for estimation with open cholecystectomy dominating ESWL when lower estimates are considered, and ESWL dominating on upper estimates.

The use of Urso as litholytic therapy for ESWL patients significantly reduces the QALY losses associated with the treatment. However, because Urso is more expensive than Cheno, the cost of ESWL increases. The additional QALYs gained by opting for ESWL instead of open cholecystectomy cost \$33,159 per QALY gained when direct costs are considered. When indirect costs are included, ESWL entails both better outcomes and lower costs than open cholecystectomy, although the conclusion is sensitive to the basis of estimation. Based on the lower estimate open

cholecystectomy is cheaper than ESWL and the cost of choosing ESWL as the preferred option amounts to \$7,893 per QALY gained.

Unlike the surgical procedures ESWL does not entail removal of the gallbladder. Hence there is a possibility that stones would re-occur after the original treatment. At present, the probability of recurrence is unknown. Recurrence would increase the cost and QALY loss associated with ESWL.

We modelled the effect of recurrence, assuming all those requiring later treatment would receive laparoscopic cholecystectomy (including the possibility of conversion to open cholecystectomy) with costs and outcomes discounted at 5% over 15 years. *Table 8* presents the results of this analysis. Lower, mean and upper estimates of both costs and outcomes are provided. The figures for ESWL assume that 50% of those who do not immediately convert to laparoscopic cholecystectomy because of a failure to clear stones by ESWL, will subsequently require surgical intervention because of stone recurrence. *Table 9* shows the rankings which result at this recurrence rate when indirect costs are excluded or included.

Inclusion of the effects of stone recurrence serves merely to emphasise the dominance of the laparoscopic cholecystectomy over ESWL, as was found when comparing base estimates. Nor does stone recurrence have a great influence on whether ESWL should be preferred to open cholecystectomy. The rankings remain the same but the cost per QALY gained by preferring open cholecystectomy to ESWL falls from \$166,988 to \$19,100. Hence, our conclusions are not sensitive to stone recurrence.

Stone size

The effect of stone size on the costs and benefits of ESWL treatment was also investigated. Stone size was categorised on the basis of clinical advice. The resulting costs and QALY losses associated with ESWL are shown in *Table 10* under Scenarios 1 and 2.

In general, the findings from the previous analysis still hold. Laparoscopic cholecystectomy remains the cheapest option for all categories of stone size whether or not indirect costs are included, and this is not sensitive to lower and upper estimates. Only for ESWL patients with single small stones were QALY losses less than for laparoscopic cholecystectomy and then only when these losses are based on upper estimates. In this case, the marginal QALY gain from choosing ESWL over laparoscopic cholecystectomy may be achieved at a cost of \$61,470 when only direct costs are included in the comparison (*Scenario 1*) or \$16,941 when indirect costs are included (*Scenario 2*). For all other stone categories, the QALY loss associated with ESWL exceeds that of laparoscopic cholecystectomy, and the latter procedure is clearly to be preferred.

The comparison of ESWL and open cholecystectomy is less straightforward. ESWL dominates open cholecystectomy for patients with single small stones under both scenarios, but the reverse is the case for patients with single large stones. For those with medium sized or multiple stones neither procedure clearly dominates.

| TABLE 10 COSTS AND QALY LOSSES OF ESWL PATIENTS BY STONE SIZE | | | |
|--|----------------------------------|--|---|
| | QALY Loss per 100 patients | Scenario 1 Total Direct Costs \$ | Scenario 2 Direct & Indirect Costs \$ |
| ESWL by Stone Size | | | |
| Single Small Stone ≤ 10 mm | | | |
| · Lower | 7.85 | 3717 | 4135 |
| · Mean | 9.69 | 4074 | 4521 |
| · Upper | 11.95 | 4431 | 4907 |
| Single Medium Stone > 10 mm ≤ 20 mm | | | |
| · Lower | 10.01 | 4439 | 4983 |
| · Mean | 12.2 | 4712 | 5295 |
| · Upper | 14.77 | 4985 | 5607 |
| Single Large Stone > 20 mm ≤ 30 mm | | | |
| · Lower | 14.87 | 5495 | 6222 |
| · Mean | 17.98 | 6062 | 6865 |
| · Upper | 21.51 | 6629 | 7508 |
| Multiple Stone with volume ≤ 30 mm | | | |
| · Lower | 8.63 | 4866 | 5249 |
| · Mean | 12.3 | 5190 | 5737 |
| · Upper | 14.93 | 5514 | 6225 |

6 Conclusion

The original intent of the clinical trial, on which this economic evaluation was based, was a comparison of open cholecystectomy and ESWL. Subsequently, laparoscopic cholecystectomy became available at St Vincent's Hospital and was included in this analysis because of its potentially significant effect on QoL and costs. This analysis has show that, although ESWL results in better treatment outcomes, as measured by QALYs, than does the open procedure, it is not necessarily less expensive. The additional QALYs made available by the new technology are generally to be gained at a prohibitive cost. The exceptions to this rule are when indirect cost are included in the cost analysis, or when patients present with a small single stone. In these cases ESWL is clearly preferable to open cholecystectomy both in terms of health gains and costs.

Laparoscopic cholecystectomy offers a stronger challenge to the established technique than ESWL. Entailing both better treatment outcomes and lower costs, laparoscopic cholecystectomy is clearly preferable to open cholecystectomy for those patients for whom both treatments might be options, ie

upwards of 85% of patients presenting with symptomatic gallstone disease. This conclusion is not sensitive to the various assumptions used in the measurement of QALYs or costs.

When compared with laparoscopic cholecystectomy, the case for ESWL is considerably weaker than it was in comparison with open cholecystectomy. Under all scenarios examined in the sensitivity analysis, ESWL is more expensive than laparoscopic cholecystectomy. Under those scenarios where ESWL does afford a greater treatment benefit, this is achieved at a substantial cost.

REFERENCES

- Cook, J. & Richardson, J. 1993(a), Quality of life during the treatment of gallstone disease: Issues in the development of health state scenarios, Working paper 32, NHMRC National Centre for Health Program Evaluation, Melbourne.
- Cook, J. & Richardson, 1993(b), Quality of life measurement of patients receiving treatments for gallstone disease: options, issues and results, Working paper 33, NHMRC National Centre for Health Program Evaluation, Melbourne.
- Cook, J., Richardson, J. & Street, A. 1993, Cost utility analysis of treatments for gallstone disease: Interim results, Working paper 28, NHMRC National Centre for Health Program Evaluation, Melbourne.
- Cook, J., Richardson, J. & Street, A. 1994, 'A cost utility analysis of treatment options: methodological issues and results', *Health Economics*, forthcoming.
- , Daly, J. 1990, *The Patient Experience of Gallstone Lithotripsy*, paper presented to the Annual Conference of the British Sociological Association, Manchester, March 1990.
- Dubois, F., Icard, P., Berthelot, G. et al. 1990, 'Coelioscopic cholecystectomy: Preliminary report of 36 cases', *Annals of Surgery*, vol. 211, pp. 60-62.
- Drummond, M.F., Stoddart, G.L. & Torrance, G.W. 1987 *Methods for the Economic Evaluation of Health Care Programs*, Oxford Medical Publications, Oxford.
- Glaser, E.G. & Strauss, 1987, *The Discovery of Grounded Theory: Strategies for Qualitative Research*, New York, Aldine Publishing Company.
- Hailey, D.M. & Hirsch, N. 1991, 'Options for the treatment of gallstones', *Hospimedica*, vol. 9, pp. 36-42.
- Nicholl, J.P., Brazier, J.E., Milner, P.C. et al. 1992 'Randomised controlled trial of cost-effectiveness of lithotripsy and open cholecystectomy as treatments for gallbladder stones', *Lancet*, vol. 340, pp. 801-7.

Ross, K.N., Farish, S. & Plunkett, M. 1988, Indicators of socio-economic disadvantage for Australian schools, Deakin Institute for Studies in Education, Geelong, Victoria.

Sharp, C. 1988, 'The value of time savings and of accident prevention', *Journal of Transport Economics and Policy*, May, pp. 235-238.

Street, A. 1993, Gallstone disease: The cost of treatment, Working paper 29, National Centre for Health Program Evaluation, Melbourne.

Torrance, G.W. 1986, 'Measurement of health state utilities for economic appraisal: A review', *Journal of Health Economics*, vol. 5, pp. 1-30.

Vellar, I., Desmond, P.V., Pritchard, C.P., Bunting, S.W. et al. 1993 'Extracorporeal shockwave lithotripsy combined with litholytic therapy in the treatment of patients with symptomatic gallstones - the Melbourne experience', *Medical Journal of Australia*, vol. 158, pp. 94-97.

APPENDIX 1

FIGURE 1: OPEN CHOLESCYSTECTOMY

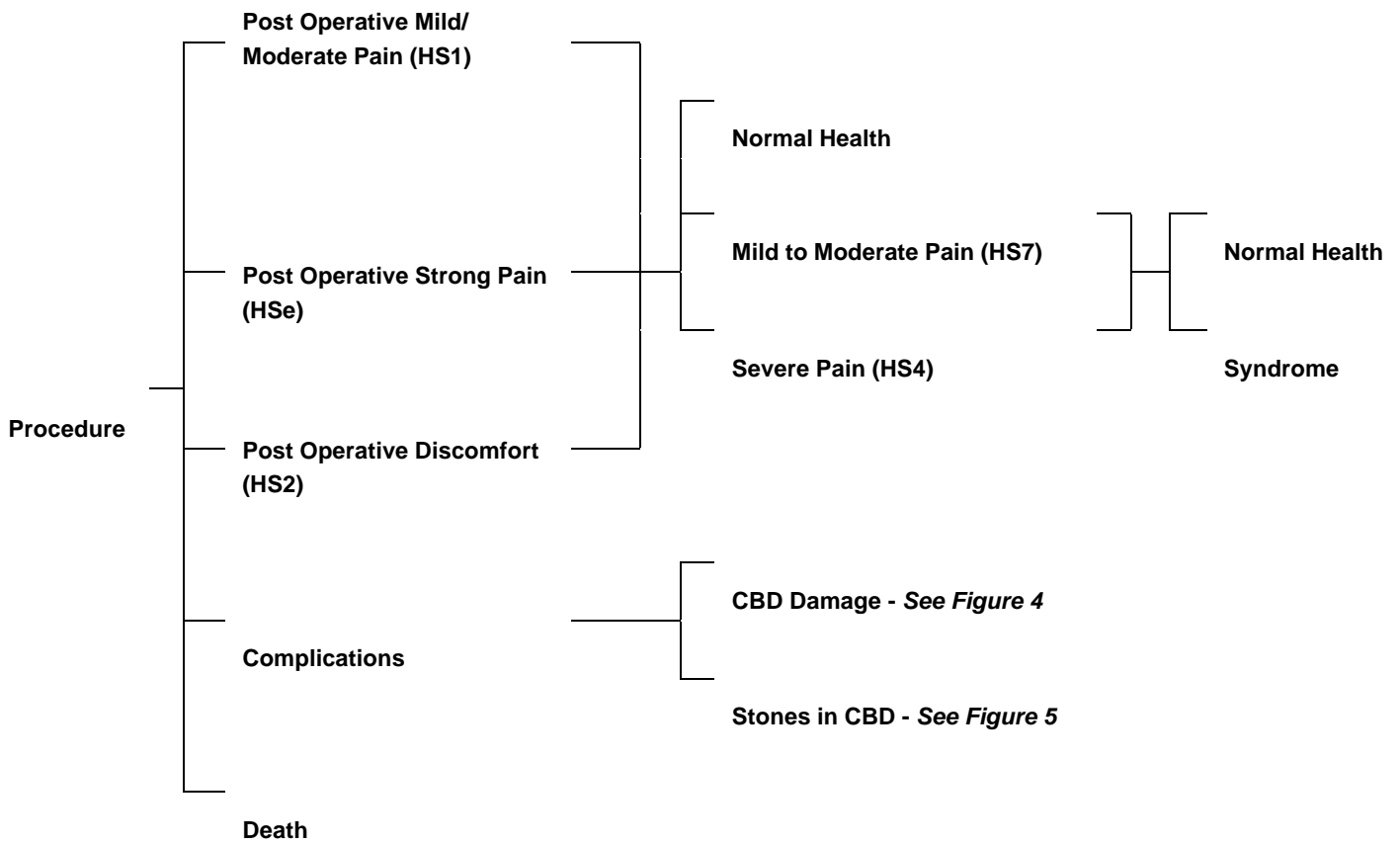


FIGURE 2: LAPAROSCOPIC CHOLECYSTECTOMY

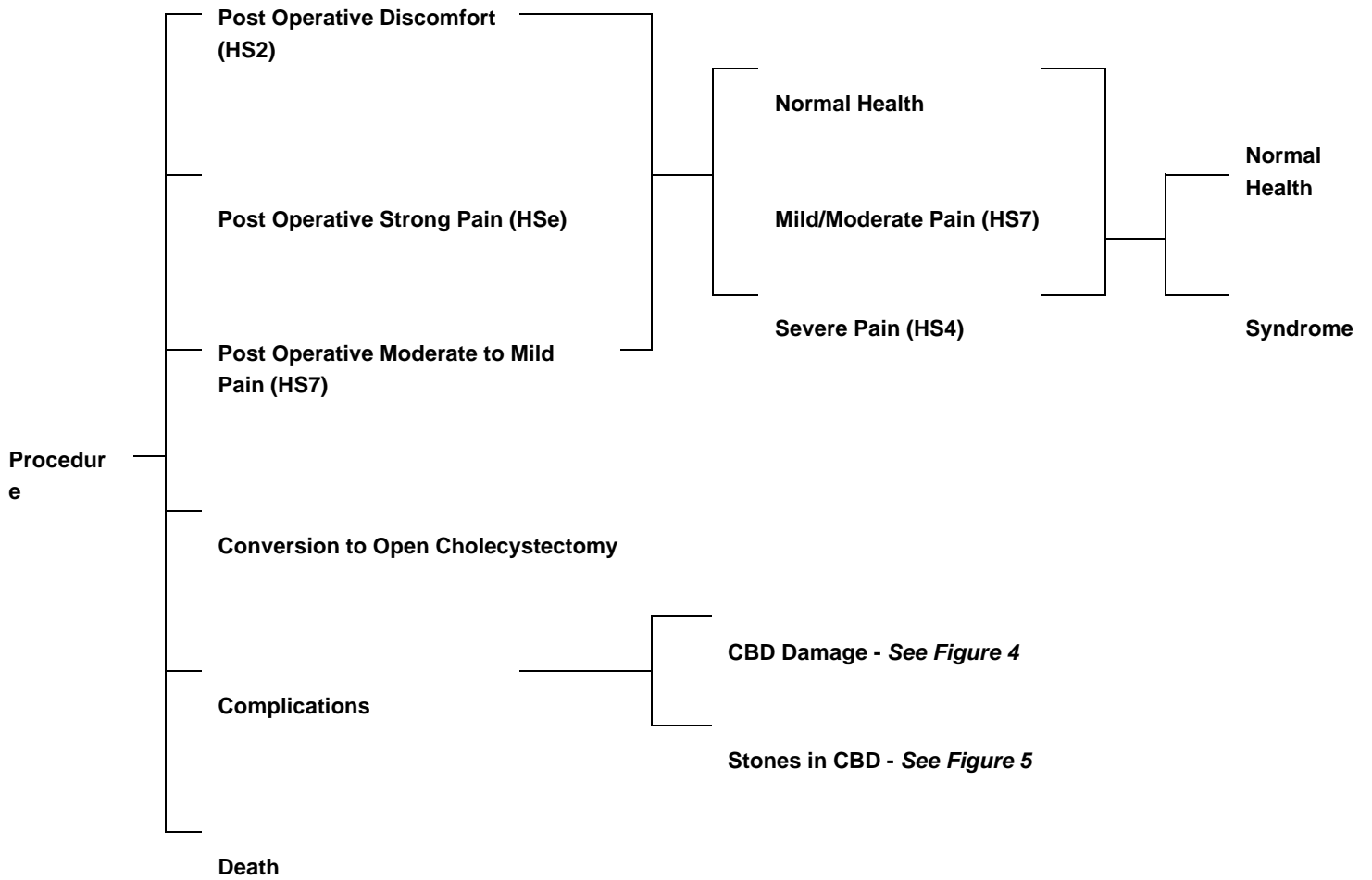
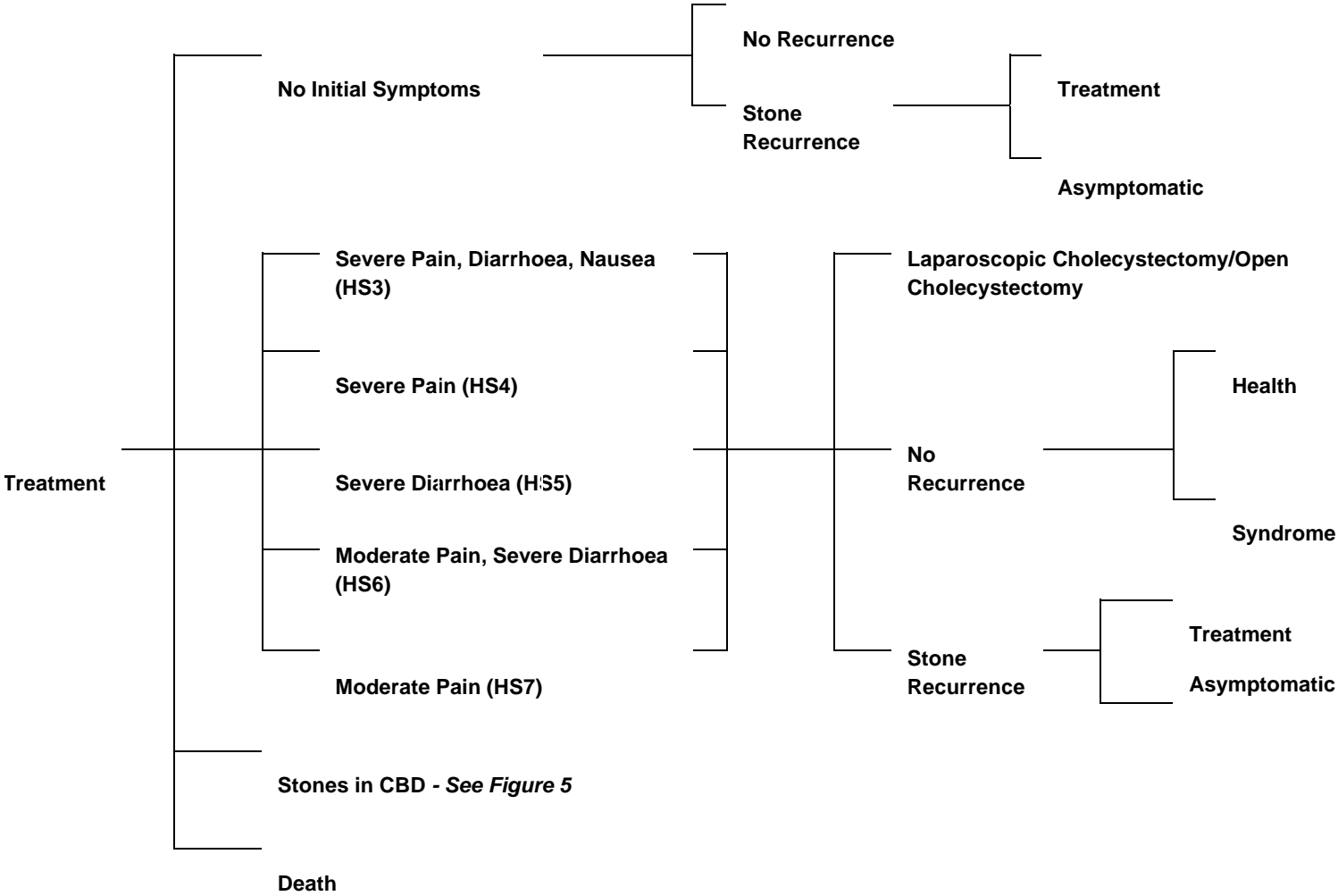


FIGURE 3: ESWL



**FIGURE 4:COMMON BILE DUCT DAMAGE :
OUTCOME PROBABILITIES: OPEN AND LAPAROSCOPIC
CHOLECYSTECTOMY**

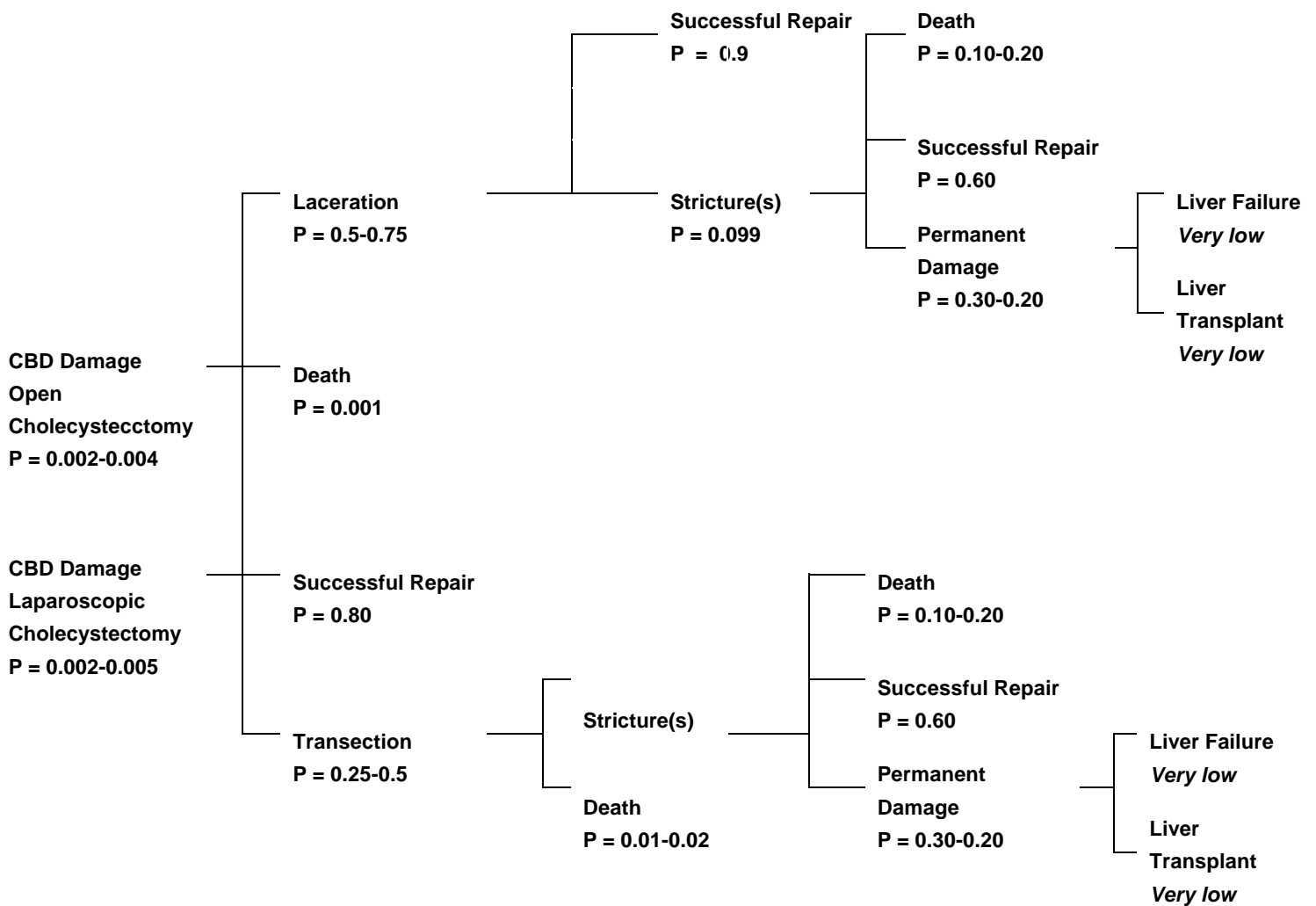
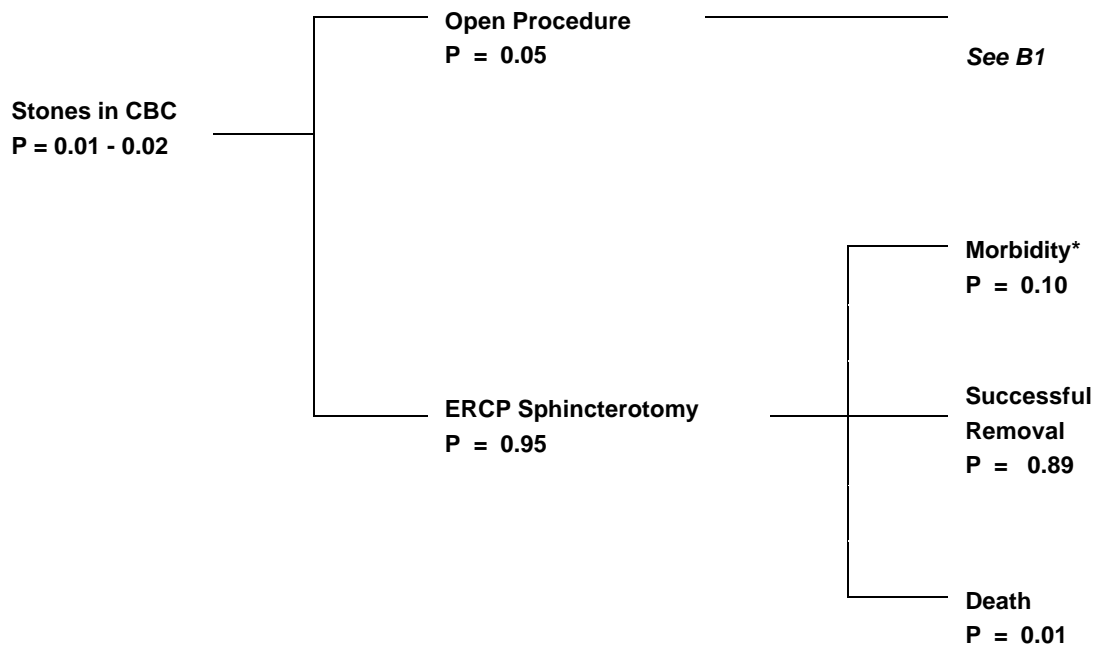


FIGURE 5: STONES IN CBD FOLLOWING TREATMENT



- * *haemorrhaging self-limiting or may require open procedure*
- * *perforated duodenum - requires open procedure*
- * *pancreatitis can only treat complications - if severe can result in death*
- * *cholangitis*
- * *jaundice*

COMPLICATIONS OF TREATMENTS FOR GALLSTONE DISEASE

Complications of treatments for gallstone disease for patients in the study were arrived at in consultation with Mr Ivo Vellar, Clinical Supervisor, Biliary Lithotripsy Unit, St Vincent's Hospital Melbourne. Where possible a worldwide estimate based on an assessment of the literature and known practice has also been included.

ESWL

Death

The one related death in the Melbourne series is thought to have been caused by pancreatitis. It is unlikely to represent the true mortality rate in a Centre such as St Vincent's Hospital where patients have access to ERCP sphincterotomy. Worldwide the death rate is estimated as 1/10,000 but the real incidence is not known.

Self-limiting Complications

Most complications of ESWL are self-limiting and include cutaneous petechie (bruising of the abdominal wall), phlebitis (irritation of the vein caused by the administration of intravenous drugs) and haematuria (microscopic blood particles in the urine). There is no evidence the hypertension is induced but the possibility has been discussed.

Pain or Biliary Colic

The majority of patients experience pain or biliary colic after ESWL. This is due to fragments leaving the gall-bladder. For most the symptoms will be mild lasting from a few minutes to several hours. Mild cases are defined as those where pain is controlled by oral analgesics. Severe cases are defined as those needing medical help or a hospital stay. These symptoms usually occur in the first two months after treatment but may occur at any time.

Pancreatitis

Serious long term complications are rare, the most serious being severe pancreatitis which sometimes can result in death. Pancreatitis is caused by stones fragments passing through the bile duct. Sometimes this produces severe necrotising pancreatitis. The mortality rate of this complication is as high as 20% and is age related. In certain cases it is possible to remove the stone with an ERCP sphincterotomy.

Cholangitis

Cholangitis is caused by fragments of stone obstructing the common bile duct. The treatment for this condition is antibiotics and/or use of an endoscope to remove the obstruction. The incidence at St Vincent's Hospital is ERCP 10/454 or 2.2% and ERCP sphincterotomy 4/454 or 0.9%.

Acute Cholecystitis

Acute cholecystitis is associated with pain due to fragments occluding the cystic duct. Patients with this condition are treated by cholecystectomy at St Vincent's Hospital. The incidence of cholecystectomy at St Vincent's is 9/454 or 2.0%.

OPEN CHOLECYSTECTOMY

Death

Death may be due to a variety of causes (see notes under complications below). Death rates vary in sub-sets of patients:

- Elective patients with uncomplicated cholecystectomy - 0.1%
- Elective patients with co-morbidity - 0.1% - 0.2%.
- Elective patients aged 65 and over with uncomplicated cholecystectomy between 1.0% - 2.0%.
- Acute (emergency) patients with complicating medical diseases - 5.0%.

For 'good risk' patients under 65 years of age the risk of death is estimated to be 0.2%.

Persisting Symptoms ('Post-Cholecystectomy Syndrome')

No follow up data were available for patients in the St Vincent's trial. The literature suggests that 90% of patients have a long term satisfactory outcome. The remaining 10% of patients are thought to fall into a number of sub-groups:

- (a) those whose symptoms were never due to gallstone disease e.g. those with peptic ulcers as pancreatic disease;

(b) patients whose symptoms have a non-organic cause; and

(c) patients with an incisional hernia or pain in the area of the incision.

Post Cholecystectomy Symptoms

If symptoms remain after an uncomplicated cholecystectomy they are usually due to other causes, most commonly peptic ulcers or chronic pancreatitis. Other causes such as cancer of the pancreas are possible but uncommon. Symptoms may also be due to an overlooked stone in the Common Bile Duct but rarely to a stricture. We have assumed a random occurrence of post-cholecystectomy syndrome across the three treatment modalities.

Anaesthetic

All open cholecystectomy patients are treated under general anaesthetic. Complications are the usual complications of anaesthetic and include pulmonary and cardiac complications. (See notes below). Complications are usually proportional to time under anaesthetic.

Cardiac Complications

Cardiac complications rarely occur in healthy patients but patients who are classified ASA3-4 (having significant medical problems) are at risk.

Persons who are classified ASA-4 who present with acute cholecystitis may be treated conservatively (a hospital stay with administration of antibiotics and/or pain killers). Symptoms will settle down in about 90% of cases. These patients are often older and they may never suffer another attack. If necessary, a percutaneous puncture to drain the gall bladder can solve the problem in the short term. The stones are left *in situ*.

Pulmonary Complications

Pulmonary complications are not uncommon and are related to age, smoking habits and obesity. Collapse is easily treated with physiotherapy and has no long term effects.

Post-Operative Bleeding

Reactionary haemorrhage, although uncommon usually occurs immediately after the operation. Bleeding is usually from the liver, and if it continues a return to operating theatre may be necessary. Reactionary haemorrhage has no long term effects.

Secondary haemorrhage is also very uncommon. At St Vincent's Hospital only two cases have been recorded in the last 5-7 years. It is usually associated with infection and requires a further operation. It has no long term effect.

Biliary Leak

- (a) A biliary leak can emanate from the gall-bladder bed if the ducts of Luschka are damaged. The incidence is estimated to be 1/500. If the bile is drained the condition is usually self-limiting. The condition becomes a problem if the bile collection becomes infected and cause peritonitis. It usually requires an additional two to seven days in hospital but it has no long term effect on the patient. Biliary leaks can be controlled by insertion of a drain tube at the time of the operation. Bile collection can also be drained percutaneously even if infected.
- (b) Biliary leaks can also develop as a result of clips not occluding the cystic duct. Again this causes no problem if drain tubes are *in situ*. Otherwise the condition may be controlled by a further procedure, usually a laparotomy.

Some Centres have a policy of always inserting drain tubes after cholecystectomy while others do according to need. St Vincent's Hospital policy dictates that drain tubes are used for all laparoscopic patient and for open cholecystectomy patients according to need.

Damage to Common Bile Duct

Transection of Common Bile Duct

Transection of the Common Bile duct by experienced surgeons is relatively rare, between 1/1000 and 1/500. If duct lacerations are included Common Bile Duct damage is estimated to be 1/500, in centres of excellence. Outside centres of excellence it may be 1/250.

Repair of a duct transection is a complicated procedure and needs to be carried out by experienced surgeons for maximum probability of satisfactory long term results. Repeat procedures minimise changes of successful outcome, strictures may become irreversible and liver failure occurs after many years. In the young this may lead to a liver transplant ultimately.

With use of the appropriate technique 80% of Common Bile Duct repairs give good results. However, the procedure is not without risk. The mortality rate is estimated to be:

- Less than 1% in Centres of Excellence for first time repair.
- Subsequent attempts at repair 10-20%. (In Centres of excellence 10%).
Complicating factors are portal hypertension and biliary cirrhosis.

Morbidity as a result of failed repairs and subsequent strictures occurs in 20% of cases. With repeat procedures the chances of a long term satisfactory outcome diminish. Permanent strictures can occur and ultimately liver failure.

Laceration of Common Bile Duct

Lacerations of the common bile duct are very uncommon and can be repaired. It is possible to suture a tear using a laparoscope (surgeons need to be highly experienced). But in most cases, including St Vincent's, there would be a conversion into an open procedure. Undiagnosed bile duct damage can result in peritonitis

Ileus

Paralytic bowel obstruction is rare. Some need to be treated by intravenous therapy. The condition has no long term effects.

Wound Infection

With the routine administration of antibiotics the wound infection rate at St Vincent's Hospital is about 5%. The complication increases hospital stay up to 2 weeks and may be important in producing an incisional hernia. Otherwise it has no long term effects. The wound requires daily dressing and the infection may last for weeks.

Delayed wound infection occurs in about 2% of cases. It is usually due to the use of non-absorbable sutures.

Retained Stone

The percentage of patients who are left with a stone in the common bile duct after cholecystectomy ranges from less than 1.0% to 5.0%. This rate depends on use of operative cholangiography as most stones are diagnosed in this way. Stones can be removed during an open cholecystectomy but otherwise the stones are moved by ERCP sphincterotomy. If patients are young an open procedure is preferred. The mortality rate of the procedure is about 1%. Morbidity is about 10% and includes:

- haemorrhaging which can be self-limiting or may require an open procedure
- perforated duodenum which requires an open procedure
- pancreatitis where only complications can be treated. Severe pancreatitis can result in death.
- cholangitis
- jaundice

Confusion

In the elderly, disorientation can occur and may last for up to two weeks, but which has no long term effects. In rare cases elderly persons may suffer a CVA.

Urinary Retention/Infection

Urinary retention is self limiting. To avoid urinary retention a catheter may be used during the procedure which is removed when the patient wakes up. This results in the bladder being deflated during the procedure and the chance of accidental puncture is also virtually eliminated.

Use of catheter is by clinician's choice. More recently use of the Hasson cannula has dispensed with the need for a catheter with a resulting reduction in the incidence of urinary infection. If urinary infection occurs it is either self limiting or treated by antibiotics. There are no further complications after hospital discharge.

Renal Failure

Renal failure is virtually unknown in an uncomplicated cholecystectomy, now that intravenous therapy is available.

Phlebitis

Inflammation of the vein as a result of the drip is not uncommon. The vast majority of cases consist of a localised area of tenderness which disappears as the drip is removed. More severe cases have more extensive area of tenderness and they take longer to settle. Severity is related to lengths of intravenous therapy. Phlebitis has no long term effects.

Hernia

It is difficult to estimate the incidence of hernias. The literature is not very helpful and patients may be treated anywhere so estimates are hard to make. It is possible that 5% will produce incisional hernia which produces discomfort and pain. Most cases that produce symptoms are repaired. Repair of a large hernia is a complicated procedure and patients may still complain of discomfort.

Scar

Patients can develop scar keloid which is unsightly. Some patients complain of a numb area beneath the incision. This sensation reduces in time but about 1% - 2% continue to be bothered by it.

LAPAROSCOPIC CHOLECYSTECTOMY

Death

Death from gynaecological laparoscopic procedures is very low and is estimated to be 1/50,000. Laparoscopic extraction of the gall-bladder has resulted in some death although a figure can not be substantiated.

In two overseas cases, death was thought to be the result of inadequate post-operative care after day surgery. In Australia, only one death in 3,500 can be attributed to the laparoscopic procedure. However, precise figures are not available and it is thought that inexperience may possibly have resulted in death in a few more cases, i.e. with experienced surgeons a death rate of perhaps 1 - 5000 may be assumed.

Other deaths are as for open cholecystectomy. (Refer to notes under complications of cholecystectomy above).

Conversion to Open Cholecystectomy

Conversion to open cholecystectomy depends on patient selection and experience of the operating surgeon.

The St Vincent's Hospital Biliary Unit estimates that with an optimum selection policy about 5% of elective laparoscopic cholecystectomies will be converted to open cholecystectomies. If all-comers are taken this percentage would rise to between 10%-15%, with the major reasons for conversion being obesity and acuity.

The long term effects on the patient health state as a result of the laparoscopic procedures is limited to a possible umbilical hernia the incidence of which is not known as the procedure is too recent to permit an adequate follow up.

Punctured Blood Vessel

One death from a punctured blood vessel has been reported in Australia. Usually, if a blood vessel is punctured the laparoscopic cholecystectomy is converted into an open cholecystectomy and the damage repaired without any long term effect on the patient. With the use of the Hasson cannula, which is routinely used at St Vincent's Hospital the risk of injury has practically been eliminated.

Gas in Blood Vessel

There has been one reported case of death due to a gas embolism in Melbourne in relation to a gynaecological laparoscopic procedure. In gynaecology the incidence is estimated to be 1:50,000.

Gas in Thoracic Cavity

Extremely low probability. No figure known.

Punctured Organ

Puncture of the gut

A puncture of the gut which resulted in peritonitis was the reported reason for the death of the two laparoscopic day cases in the U.S.

From the gynaecological literature the incidence of visceral damage appears to be extremely low and to some extent is related to case selection. Patients with previous abdominal surgery are more likely to be at risk due to lesions which have developed as a result of the previous operation. In this case, safe practice dictates that a Hasson cannula is used instead of a Veress needle. Complications can occur but are either self limiting or treated during hospital stay.

Hernia around Stab Wound

It is not clear to what extent this may be a problem. Follow up time required has not been sufficient. The incident in the gynaecological area has been very low up to now. There may, however, be a difference post laparoscopic cholecystectomy as the incision required to remove a gall-bladder is slightly larger; i.e. 2 cm - 2.5 cm instead of 1 cm. If an umbilical hernia does manifest itself it can be repaired.

Wound Infection around Umbilical Stab Wound

Wound infection can develop around the stab wound if contaminated material needs to be removed through it. If wound infection occurs the wound needs to be drained for a couple of weeks but there are no long term effects. Wound infection following laparoscopic cholecystectomy tends to be less severe than for open cholecystectomy.

Transection of Common Bile Duct

It is debatable whether the risk of transection of the Common Bile Duct is greater for laparoscopic removal of the gall-bladder than it is with the open procedure. In the laparoscopic procedure any possible additional risk is off-set if the operation is carried out by two experienced clinicians, both of whom have a clear view of what is happening via the television monitors. The risk may be slightly larger if only one surgeon is present. At St Vincent's there has been one case of bile duct damage in 700 laparoscopic procedures. This is equivalent to about 0.1%. The worldwide estimate is between 0.2 and 0.5%.