The pros and cons of laparoscopic cholecystectomy and extracorporeal shock wave lithotripsy in the management of gallstone disease

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The recent introduction of laparoscopic cholecystectomy (LAPC) has revolutionised the surgical treatment of gallstone disease. However, it has also raised doubts about the future role of extracorporeal shock wave lithotripsy (ESWL) in the treatment of gallstones. In this study, we compared patients treated successfully with ESWL and dissolution therapy with patients treated by LAPC. Out of 67 patients, 50 had successful clearance with ESWL while 50 out of 54 had successful LAPC. We evaluate treatment duration, recurrence rate (ESWL) and cost of treatment in both groups. All patients had uncomplicated symptomatic gallstones. The inclusion criteria were similar in both groups with the exception of patients with non-functioning gallbladders who were excluded from ESWL.

The results of the study show that although ESWL is non-invasive and associated with minimal morbidity, it is also costly and has a high failure and recurrence rate. In contrast, laparoscopic cholecystectomy, while requiring short-term hospital stay and debility, seems to be a safe and effective alternative with an advantage in terms of cost and duration of treatment.

The introduction of extracorporeal shock wave lithotripsy (ESWL) has offered an alternative to the traditional treatment of gallstones (1). It is known that gallstone fragmentation and ultimately complete gallbladder clearance is possible with a combination of lithotripsy and oral bile salts (2–4). This form of therapy has many attractions as it avoids the need for surgery and general anaesthesia, and may be performed on an outpatient basis (2,3). The treatment duration of ESWL and dissolution therapy, however, is usually prolonged and patients may remain symptomatic before successful clearance is achieved. Furthermore, the risk of early gallstone recurrence is as high as 12% per annum, which is similar to other modalities of treatment in which the gallbladder is left in situ (5).

Cholecystectomy is the traditional method of treating gallstones, but is associated with a well-documented morbidity and mortality. Laparoscopic cholecystectomy is a less invasive procedure than conventional cholecystectomy and may be associated with a reduced complication rate, although there have been no controlled comparative trials (6–8). Laparoscopic cholecystectomy would also appear to have a number of advantages over ESWL in that treatment time is shortened and the possibility of gallstone recurrence obviated.

We have employed ESWL since August 1988 and laparoscopic cholecystectomy since May 1990. In this report we compare our experience with the first 50 patients treated successfully with each modality, looking at treatment duration, success rate and cost of each treatment.

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Patients and methods

ESWL and dissolution therapy

Extracorporeal shock wave lithotripsy was carried out on 67 patients (14 men, 53 women) with a mean age of 42 years (range 38–73 years). All patients had one or more attacks of biliary colic. Patients were selected if they met our extended selection criteria (Table I). Pretreatment assessment and exclusion criteria have been described previously (3,4).

Shock wave therapy

Lithotripsy was carried using the EDAP LT-01® lithotripter (Exploration Development Des Application de la Physique) which employs a piezo-electric system. This system has a focal area of 2.3 × 23 mm, a peak pressure at the focal region of 1031 atm and a rise time of 44 ns. All treatments were carried out as an outpatient procedure and patients were instructed to fast from midnight the night before. Each patient received 6000 shock waves per treatment session up to a maximum of six treatments at 1- to 4-weekly intervals. The endpoint of lithotripsy was to achieve gallstone fragment size less than 4 mm in diameter. None of the patients studied required any analgesia or sedation, thus allowing them to return to their normal daily activity after treatment.

Adjuvant oral dissolution therapy using a combination of ursodexoxycholic acid and chenodeoxycholic acid and terpenes, as described previously, was started 1 week before the first ESWL session and continued throughout the period of follow-up until complete clearance of the fragments, and then for a further 3 months to ensure clearance (3,4).

Follow-up after lithotripsy

All patients were followed monthly by clinical and ultrasonographic assessment. Two consecutive ultrasound examinations at a 1-month interval and an oral cholecystogram were required to establish total gallstone clearance. Time to clearance was measured from the date on which the first lithotripsy treatment was administered. Failure of treatment was defined as an absence of fragmentation or insignificant clearance of fragments after a maximum of six treatment sessions and follow-up of 6 months, or the development of gallstone complications.

Cost

In estimating the cost in Irish pounds (IR£) of ESWL and dissolution therapy, we have included the lithotripsy treatment cost, the cost of follow-up (Table II), as well as the cost of failures of treatment. The cost of treatment failure included the cost of subsequent cholecystectomy in this group. Extracorporeal shock wave lithotripsy was carried out by a trained registrar and specialist nurse who also monitored the patient’s progress. Each ESWL session lasted about 1 h at an estimated cost of IR£103. This figure takes into account the salaries of the medical personnel for this period and also includes the maintenance cost of the lithotripter. (This amounted to IR£2 000/annum and this figure was divided by the hourly usage for both gallstone and urinary stone lithotripsy). The total cost of oral dissolution therapy has fluctuated during our experience, but we estimate that this amounts to IR£94/month. The cost of radiological assessment after ESWL was estimated to be IR£180/patient. In addition, if the treatment failed the cost of further treatment was added to the financial estimate of each patient. Excluded from the cost estimation for ESWL and dissolution therapy was the capital cost of the lithotripter, the cost of the lithotripsy room usage, and the potential cost of future gallstone recurrence.

Laparoscopic cholecystectomy

Laparoscopic cholecystectomy was performed on 54 symptomatic gallstone patients. There were 42 females and 12 males whose mean age was 48 years (range 17–78

Table II. Itemised costing for ESWL and laparoscopic cholecystectomy

<table>
<thead>
<tr>
<th></th>
<th>IR£</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ESWL</strong></td>
<td></td>
</tr>
<tr>
<td>Maintenance + running</td>
<td>83/h</td>
</tr>
<tr>
<td>Operator and nursing fees</td>
<td>20/h</td>
</tr>
<tr>
<td>Oral dissolution therapy</td>
<td>100/month</td>
</tr>
<tr>
<td>Radiology*</td>
<td>180/patient</td>
</tr>
<tr>
<td><strong>LAPC</strong></td>
<td></td>
</tr>
<tr>
<td>Medical and nursing fees</td>
<td>61/h</td>
</tr>
<tr>
<td>Hospital stay</td>
<td>150/day</td>
</tr>
<tr>
<td>Cost of disposables</td>
<td>315/proc</td>
</tr>
</tbody>
</table>

* Radiology cost includes ultrasound and cholecystography before and during follow-up

ESWL, Extracorporeal shock wave lithotripsy

LAPC, Laparoscopic cholecystectomy
years). Preoperative assessment in all patients included biliary ultrasound and liver function tests. The selection criteria are given in Table I.

Laparoscopic cholecystectomy was carried out in a similar manner to that previously described by Reddick and Olsen (9).

Operative cholangiography was not performed. Disposable instruments included two 10 mm ports, a disposable Veress needle and an Endoclip® applier (AutoSuture® Company, Connecticut, USA). A saline irrigation solution was made up by adding tetracycline as an antibiotic and heparin to prevent clotting.

Cost

In estimating the cost of laparoscopic cholecystectomy we have included the following personnel: one consultant surgeon, two senior house officers, one consultant anaesthetist and two theatre nurses. Based on their annual salaries and assuming a 40-h working week for 48 weeks/year, we have calculated the salary cost of each hour of surgery at IR£61/h (Table II). Added to this there is a cost for each patient to include anaesthetic drugs, prophylactic antibiotics, and disposable instruments, which we have estimated at IR£315/patient. The cost of inpatient stay at our hospital was estimated at IR£150/day.

The cost of the operating theatre room usage and the capital costs of the laparoscopic cholecystectomy equipment were not included in the analysis, but the cost of the failures of treatment were assessed both in terms of prolonged operating time and prolonged hospital stay. Similarly, computations were made for complications that required further surgery or hospital stay.

Table III.

<table>
<thead>
<tr>
<th>Criteria for comparison</th>
<th>ESWL</th>
<th>LAPC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean duration of treatment (days) (range)</td>
<td>186 (30–540)</td>
<td>3 (2–6)</td>
</tr>
<tr>
<td>Mean time off work (days) (range)</td>
<td>3 (1–5)</td>
<td>18 (3–42)</td>
</tr>
<tr>
<td>Major complication rate (%)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Recurrence (number of patients)</td>
<td>6</td>
<td>N/A</td>
</tr>
<tr>
<td>Estimated cost per patient including the failures*</td>
<td>IR£1460</td>
<td>IR£1034</td>
</tr>
</tbody>
</table>

* There was a significant ($P<0.05$) difference in the cost of treatment (IRE) between ESWL and LAPC when the costs of failures were included.

ESWL, Extracorporeal shock wave lithotripsy
LAPC, Laparoscopic cholecystectomy
N/A, Not applicable

Results

ESWL and dissolution therapy

In all, 170 shock wave treatments were performed on 68 patients; successful clearance was achieved in 50 patients. Each patient required an average of three treatments (range 1–6). The mean duration of follow-up to achieve gallstone clearance was 6 months (range 1–20 months), during which all patients received oral dissolution therapy. There were 18 failures, and to date 14 of these have had a cholecystectomy. Of the patients, 17% had calcified stones, and the number of stones present was not a contraindication to ESWL. Fifteen patients (14%) complained of right upper quadrant discomfort after treatment but this settled spontaneously and required no analgesia. None of the patients had any evidence of skin ecchymosis or haematuria. Fourteen patients (13%) suffered an attack of biliary cholic during the follow-up period, but none required hospital admission.

Cost

The mean cost of ESWL treatment for the first 50 patients treated successfully was IR£1006 ± 69. However, the mean total cost of ESWL treatment per patient when the costs of failures were added was IR£1460 ± 116 (Table III). The lithotripter, which cost IR£600 000 was already available for use in the hospital as part of the renal lithotripsy programme.

Recurrence

Follow-up radiological examination of the patients with total gallstone clearance revealed recurrent stones in six of the 50 patients within 7–11 months after clearance. The recurrent stones were all multiple and occurred in patients with both solitary and multiple calculi.

Laparoscopic cholecystectomy

Laparoscopic cholecystectomy was completed successfully in 50 of 54 patients. The mean anaesthesia time was
139 ± 6.7 min with a postoperative hospital stay of 2.6 ± 0.2 days. The time of return to full activity after laparoscopic cholecystectomy was 13.7 ± 11.7 days.

Laparoscopic cholecystectomy was abandoned due to a perforated viscus in two patients. The first patient had a gastroscopy immediately after laparoscopic cholecystectomy, and the Veress needle was inserted into an incompletely deflated stomach. The second patient had a lower midline scar and required a formal laparotomy after the trocar perforated the jejunum when introduced at the umbilicus. The perforations were repaired in both cases and the patients made an uncomplicated postoperative recovery. There were no deaths after laparoscopic cholecystectomy in this series. Serious complications occurred in two patients. The first patient presented with biliary peritonitis 1 week postoperatively and a small hole was found in the right hepatic duct at laparotomy. The duct was sutured and the right subhepatic space drained. In the second patient laparotomy had to be performed after laparoscopic cholecystectomy because of bleeding from one of the trocar sites. Both patients made uneventful recoveries.

Cost

The cost of laparoscopic cholecystectomy for the 50 patients treated successfully was IR£908 ± 27. However, the cost of laparoscopic cholecystectomy per patient, including the cost of those failures who required open surgery and prolonged hospital stay was IR£1034 ± 105 (Table III). The equipment used for laparoscopic cholecystectomy cost IR£34 380.

The cost of laparoscopic cholecystectomy per patient was significantly lower than the cost of gallstone lithotripsy when the high cost of treating the failures in the ESWL group were included (IR£1460 ± 116 vs 1034 ± 105, P < 0.05). However, when the cost of treating the failures in the ESWL group were excluded, the cost of treatment in both modalities was similar (IR£1006 ± 69 vs 908 ± 27, P = NS).

Discussion

Open cholecystectomy has been the standard treatment in the management of gallstone disease. The presence of a well-documented morbidity with this procedure, however, has led to the development of less invasive techniques to treat patients with gallstones. Extracorporeal shock wave lithotripsy (1,2) and, more recently, laparoscopic cholecystectomy (6,7), are presently the two main 'less invasive' alternatives to standard cholecystectomy. The aim of the present study was to compare and contrast both forms of treatment when they were at comparable stages of development in a unit with a special interest in gallstone disease. The results show that while ESWL has minimal side-effects it is associated with more limited selection criteria, a more prolonged treatment time, a higher failure rate, and a higher recurrence rate when compared with laparoscopic cholecystectomy. This study also shows that ESWL is more costly when the endpoints of gallstone clearance and treatment failures are combined.

Laparoscopic cholecystectomy is now becoming the standard treatment for cholelithiasis. Several centres have shown that this procedure is associated with minimal morbidity and mortality, although more recent evidence suggests that the incidence of common bile duct injury may be higher than reported previously (10). Furthermore, mean postoperative stay in hospital and return to work time is considerably shortened. The present study confirms the latter finding, but also demonstrates that laparoscopic cholecystectomy can be associated with significant morbidity. The four complications of laparoscopic cholecystectomy in this study may reflect the early learning experience associated with any new technique. It is also possible, however, that the overall complication rate associated with this procedure has been understated, and perhaps more experience is needed before defining the complications of this procedure adequately.

The present study also assessed the financial implications of laparoscopic cholecystectomy and ESWL in treating gallstone disease. The study demonstrated no significant difference in the mean cost required for 50 patients treated successfully with both modalities, but that ESWL was more costly when treatment failures were included. Adjuvant dissolution therapy is a major cost burden and it has been suggested that such additional treatment is unnecessary. We have shown previously, however, that the addition of dissolution therapy to ESWL is required to achieve gallstone clearance (11).

The number of failures of ESWL in this study were greater than those reported by the Munich group (1). This discrepancy is due largely to our extended selection criteria for ESWL, which would have included up to 60% of the gallstone population as opposed to a 20% suitability rate in Munich.

The advent of laparoscopic cholecystectomy now suggests that we apply more rigid criteria for ESWL selection in order to achieve fewer failures of treatment and a consequent reduction in cost.

The one area not considered in the cost equation in the present study is the development of recurrent stones after successful gallstone clearance with ESWL. The recurrence rate of 12% within the first year in the present study, together with a well-documented cumulative recurrence rate, will add to the cost and further mitigate against the choice of ESWL as a means of treatment. Finally, the high capital cost of the lithotripter implies that this can be carried out only in hospitals where this equipment is already in place.

The ideal way to address the aims of the present study would be in the context of a controlled randomised trial. The diverse nature of both treatment modalities, however, makes such a trial impractical. Laparoscopic cholecystectomy offers advantages over open cholecystectomy in terms of reduced hospital stay and earlier return to work. It has largely replaced open surgery in centres where laparoscopic equipment is available. The key issue
is whether this procedure is sufficiently safe to replace ESWL in all patients. The present study shows that ESWL is safer but inferior to laparoscopic cholecystectomy with respect to recurrence rate, duration of treatment and cost. The natural history of patients undergoing laparoscopic cholecystectomy needs to be more clearly defined before it can replace ESWL in the management of all patients with gallstones, particularly those considered unsuitable for open cholecystectomy.

References


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