Prospective randomized trial comparing shock wave lithotripsy and ureterscopy for management of distal ureteral calculi

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The study compared shock wave lithotripsy (SWL) with ureterscopy for the treatment of distal ureteral calculi. Treatment with SWL was performed using an HM3 lithotriptor (Dornier MedTech) with the patient prone on a modified Stryker frame. Ureterscopy was performed with a 6.9F semi-rigid ureteroscope.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised adult patients with a solitary, radiopaque distal ureteral calculus below the bony pelvis, 15mm or less in diameter. Exclusion criteria were multiple ureteral calculi, solitary kidney, renal insufficiency, ipsilateral ureteral stricture, plan for simultaneous treatment of ipsilateral renal or contra lateral renal or ureteral calculi, active urinary tract infection, transplant kidney and uncorrected coagulopathy. In addition, women who were fertile and of childbearing age were also excluded from the study, owing to the risk of damage to the ovaries from SWL.

Setting
The setting was secondary care. The economic study was carried out in the USA.

Dates to which data relate
The study was undertaken between May 1995 and March 2000. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
Power calculations were performed to determine the sample size. Assuming a 10% difference in stone-free rate, and an alpha of 0.05, sample size calculations yielded a necessary 110 patients per group, allowing for a 10% dropout rate. However, an interim analysis at 30 patients per group revealed no difference in the stone-free rates. Therefore, nearly 300 patients per group would be required to notice a clinically less meaningful 5% difference in efficacy, which is itself
an unattainable sample size. Consequently, the authors elected to close the study and to further evaluate secondary outcome parameters. A total of 76 patients were randomised to SWL or ureteroscopy. Of these, 12 patients either passed the stone before treatment, or dropped out of the study after randomisation, leaving 32 patients in the SWL group and 32 in the ureteroscopy group. In the SWL group, the mean age was 41.2 (+/- 14.9) years and 26 patients were male. In the ureteroscopy group, the mean age was 41.2 (+/- 12.8) years and 25 patients were male.

Study design
The study was a multi-centre randomised controlled trial. Patients were randomised to undergo SWL or ureteroscopy in sets of 10, according to a random numbers table. The follow-up period for both groups appears to have been 3 months. Of the 76 patients randomised, 12 patients either passed the stone before treatment or dropped out of the study.

Analysis of effectiveness
The analysis of the study was conducted on the basis of treatment completers only. The primary health outcome used was the stone-free rate. Other outcomes included:

- procedural and operating room times;
- the rate of home discharge on the day of the procedure;
- the complication rates;
- postoperative symptoms including dysuria, haematuria and flank pain; and
- patient satisfaction.

At the initial follow-up, the patients were asked to rate postoperative symptoms from 0 (no symptoms) to 5 (severe symptoms). In addition, the patients were questioned about the procedure and their willingness to undergo the same procedure again if necessary. At analysis, both groups were shown to be comparable in terms of patient and stone characteristics, as well as the degree of ureteral obstruction. To determine if the difference between the two groups in procedural and operating room times was due primarily to differences in the treatment times for larger stones, each group was divided into smaller (7 mm or less) and larger (greater than 7 mm) stones.

Effectiveness results
Both treatment modalities were 100% successful as there was no stone recurrence.

Procedural times were statistically significantly shorter for the SWL group compared with the ureteroscopy group (34.1 +/- 8.2 minutes versus 64.7 +/- 37.1 minutes; p<0.001). Operating times were also statistically significantly shorter for the SWL group (71.8 +/- 22.4 minutes versus 96.6 +/- 43.2 minutes; p=0.04). For both small and large stones, the procedural and operating room times favoured SWL.

Of the patients who underwent SWL, 94% were discharged home after the procedure, compared with 75% of those who underwent ureteroscopy, (p=0.09).

Minor complications occurred in 3 patients (9%) treated with SWL and 8 patients (25%) treated with ureteroscopy, (p not statistically significant).

Postoperative flank pain and dysuria were more severe in the ureteroscopy group than the SWL group, although the differences were not statistically significant.

Patient satisfaction was high, 94% for SWL and 87% for ureteroscopy (p value not significant).

Clinical conclusions
Both treatment modalities were equally efficacious, with a 100% success rate in each. However, SWL was clinically and statistically better than ureteroscopy, as it required shorter operating time and showed a trend towards less flank pain and dysuria. It also resulted in fewer complications and quicker convalescence.

**Measure of benefits used in the economic analysis**

No summary measure of benefit was derived. The study was therefore categorised as a cost-consequences analysis.

**Direct costs**

The direct costs of the hospital were included in the analysis. These covered the costs of the operating room, supply, anaesthesia, stent removal and professional fees. The operating room cost was based on the mean procedural time for each group. The supply costs and charges assumed the use of routine disposable items. Anaesthesia charges were based on general anaesthesia in the ureteroscopy group and intravenous sedation in the SWL group. The cost of stent removal was added to the cost of ureteroscopy since the majority of patients underwent stent placement at the conclusion of the procedure. Professional fees were based on anaesthesiologist and urologist fees at the operating hospital. The cost of follow-up was excluded from the calculation since it was presumed to be identical in the groups. The estimated cost and charge for each procedure were calculated on the basis of cumulative costs and charges at one of the participating hospitals. The resource quantities and the costs were not reported separately. Discounting was not relevant, as the costs were incurred during a short time, and was not performed. The study reported the mean costs. The price year was not reported.

**Statistical analysis of costs**

The costs were treated as point estimates (i.e. the data were deterministic).

**Indirect Costs**

In accordance with the perspective adopted, the indirect costs were not included in the analysis.

**Currency**

US dollars ($).

**Sensitivity analysis**

No sensitivity analysis was performed.

**Estimated benefits used in the economic analysis**

See the 'Effectiveness Results' section.

**Cost results**

The cost to the hospital of providing lithotripsy was $7,343 per patient for the SWL group and $6,088 per patient for the ureteroscopy group.

The hospital charged $11,471 per patient in the SWL group and $9,879 per patient in the ureteroscopy group.

**Synthesis of costs and benefits**

The costs and benefits were not combined.

**Authors’ conclusions**
Shock wave lithotripsy (SWL) was clinically and statistically significantly better than ureteroscopy, despite the fact that both treatments were 100% successful. The authors also concluded that, it was only in the area of costs in which ureteroscopy was favoured over SWL.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used. Ureteroscopy is one of the most widely practised and highly successful procedures in urology. You should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a randomised controlled trial. This was appropriate for the study question since well-conducted randomised controlled trials are the ‘gold’ standard study design when comparing health technologies. The study sample appears to have been representative of the study population. The patient groups were shown to be comparable in terms of age, gender, stone characteristics, and degree of ureteral obstruction. Although a randomised controlled trial was conducted, the outcomes were analysed for treatment completers only. Despite this limitation, the study appears to have been handled credibly, as the randomisation method was carried in a purely random fashion and appropriate statistical techniques were undertaken to account for potential biases and confounding factors.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The reader is thus referred to the comments in the 'Validity of estimates of measure of effectiveness' field (above).

Validity of estimate of costs
All the categories of cost relevant to the hospital perspective adopted were included in the analysis. However, some relevant costs associated with follow-up were excluded from the analysis, because the authors believed they were common to both treatments. Hence, this omission is unlikely to have affected the authors’ conclusions. The costs and the quantities were not reported separately, which will limit the generalisability of the authors’ results. The unit costs and charges were derived from one of the participating hospitals. No statistical analyses of the costs or charges were performed, hence the uncertain reliability of the authors' conclusions. Discounting was unnecessary since all the costs were incurred during a short time. The date to which the prices related was not reported, which will hamper any future inflationary exercises of the authors' cost results.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. In particular, they compared their results with those from the only prospective study at the time, which also compared both treatment modalities. This study also found comparable stone-free rates of 90% and 100% for SWL and ureteroscopy, respectively. The issue of generalisability to other settings was partially addressed as the authors conducted a multi-centre study, although they did not report the number of hospitals included. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis. The authors reported as a limitation to their study, the fact that their small sample size might have precluded statistical significance in differences between the two groups.

Implications of the study
Based on their results, the authors believed that SWL was preferable over ureteroscopic manipulation since it was equally efficacious, significantly more efficient and clinically less morbid.

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None stated.
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Other publications of related interest


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