Extracorporeal shock wave lithotripsy in the treatment of renal pelvicalyceal stones in morbidly obese patients

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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 examined extracorporeal shock-wave lithotripsy (ESWL), using a Siemens Lithostar Plus third-generation lithotripter, in the treatment of renal pelvicalyceal stones. There was no comparison technology.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised morbidly obese patients with renal pelvicalyceal stones. Criteria for ESWL were symptomatic stone size between 6 and 20 mm, without evidence of active urinary tract infection, and good renal function. Morbidly obese patients were defined as patients with a body mass index of more than 40 kg/m2, according to the World Health Organization classification.

Setting
The setting was secondary care (the Moscow Regional Scientific Research Clinical Institute). The economic study was carried out in Moscow, Russia.

Dates to which data relate
The effectiveness data were collected for patients treated between 1995 and 2002. Resource use was measured between 1990 and the time of the study. The price year was 1990.

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

Link between effectiveness and cost data
The costing was carried out retrospectively on the same sample of patients as that used in the effectiveness study.

Study sample
The study sample comprised all patients with morbid obesity who were treated with the Siemens Lithostar Plus third-generation lithotripter by a single urologist at the study setting between 1995 and 2002. This method of sample selection identified an appropriate set of patients to address the clinical study question. Over the study period, 37 cases were identified. They were aged from 18 to 72 years, 20 were male, and they weighed from 123 to 179 kg (mean 143 kg).
The patients were stratified by stone location (pelvic, low caliceal, and middle and upper caliceal) and by distance between the lithotripter blast path and the stone.

**Study design**
The analysis followed a case series study with a single group of patients treated by a certain clinician at a single centre. The patients were followed for 3 months and they were all available for the full period. Blinding would not have been possible within this study.

**Analysis of effectiveness**
The analysis was based on those patients receiving treatment. The primary outcome was the success rate of treatment. The secondary outcomes were the rates of hospitalisation and complications. Despite there being a single group of patients, stratification made some within-group comparisons possible: 15 patients had pelvic, 10 patients had low caliceal, and 12 patients had middle and upper caliceal stones; 9 stones were within 1 cm of the blast path, 14 stones were within 1 - 2 cm, and 14 stones were within 2 - 3 cm.

**Effectiveness results**
The success rate was:

- 3 out of 3 (100%) for pelvic stones within 1 cm of the blast path;
- 6 out of 7 (85.7%) for pelvic stones 1 - 2 cm of the blast path;
- 4 out of 5 (80%) for pelvic stones 2 - 3 cm of the blast path;
- 2 out of 2 (100%) for low caliceal stones within 1 cm of the blast path;
- 2 out of 4 (50%) for low caliceal stones 1 - 2 cm of the blast path;
- 2 out of 4 (50%) for low caliceal stones 2 - 3 cm of the blast path;
- 3 out of 4 (75%) for middle and upper caliceal stones within 1 cm of the blast path;
- 2 out of 3 (75%) for middle and upper caliceal stones 1 - 2 cm of the blast path; and
- 3 out of 5 (60%) for middle and upper caliceal stones 2 - 3 cm of the blast path.

Overall, the success rate was lower in the patients treated with the blast path between 2 and 3 cm (64.3%) than in the patients treated with the blast path less than 1 cm (89%), (p<0.01).

Overall, pelvic stones had a success rate of 13 out of 15 (87%) and required an average of 1.6 treatments per stone.

Overall, middle and upper stones had a success rate of 8 out of 12 (67%) and required an average of 2.1 treatments per stone.

Overall, low caliceal stones had a success rate of 6 out of 10 (60%) and required an average of 2.9 treatments per stone.

The author reported that the overall stone-free rate at 3 months was 73%.

Two (5.4%) patients required hospitalisation for post-ESWL pain.

No complications, such as acute pyelonephritis, perirenal or subcapsular haematoma, were recorded.

**Clinical conclusions**
The author concluded that ESWL is most effective in obese patients with pelvic stones sized between 6 and 20 mm. So long as the stone is positioned in the focal point or within 3 cm of the blast path, the increased distance from the skin surface to the stone does not decrease the success rate.

Measure of benefits used in the economic analysis
There was no summary measure of health benefit. In effect, the author carried out a cost-consequences analysis.

Direct costs
The author estimated the expected cost per treatment by taking the initial cost of the Siemens Lithostar Plus and dividing by the total number of treatment sessions obtained from the machine in its 12-year working life. This cost included the cost of equipment and its maintenance. The author reported that the salary of the Russian medical staff and engineers, as well as the cost of supplementary medication, "hardly contribute to overall treatment expenses". These aspects were therefore excluded from the analysis. The treatment cost was estimated in 1990 prices and was not inflated to 2005 prices (the date of the study).

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
No indirect costs were included.

Currency
German marks (DM) converted in to US dollars ($). However, no conversion rate was reported.

Sensitivity analysis
There was no report of a sensitivity analysis being carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The average cost of treatment was $393 for stones within 1 cm of the blast path, $437 for stones within 1 - 2 cm, and $524 for stones within 2 - 3 cm.

The average cost of treatment was $349 for a pelvic stone, $633 for a low caliceal stone, and $458 for a middle and upper caliceal stone.

Synthesis of costs and benefits
The costs and benefits were not combined as the study was, in effect, a cost-consequences analysis.

Authors' conclusions
Extracorporeal shock-wave lithotripsy (ESWL) is most effective and cost-efficient in obese patients with pelvic stones sized between 6 and 20 mm. ESWL should not be considered as the first line of treatment for patients with low caliceal stones where the stone is positioned more than 1 cm from the focal point on the extended shock pathway.
CRD COMMENTARY - Selection of comparators
There was only a single technology of interest, namely ESWL. ESWL was proposed as a treatment that may help to overcome some issues that arise when treating obese patients for renal pelvicalyceal stones. For example, patients exceeding the weight limits of surgical tables, and the extended distance between the skin surface and the stone. However, because other treatment alternatives for renal pelvicalyceal stones were available (e.g. percutaneous nephrolithotomy and retrograde intrarenal surgery), it would have been more appropriate to include these alternatives as the comparators. You should decide if ESWL represents a widely used technology in your own setting, or whether other comparators could also be relevant.

Validity of estimate of measure of effectiveness
The case series design was appropriate for observing the impact on the patients and stones of treatment using ESWL. This helped answer the study question of whether ESWL is an effective treatment in the study population. The study sample contained morbidly obese patients and so was an accurate reflection of the study population. This suggests that the results and conclusions could be generalised to the study population. Further work on effectiveness could compare ESWL with alternative technologies or within different samples of patients.

Validity of estimate of measure of benefit
The author did not derive a summary measure of health benefit as this was a cost-consequences analysis.

Validity of estimate of costs
Although the perspective from which costing was carried out was not specified, it appears to have been that of the direct health care provider. A very simple costing exercise was carried out in which the cost per treatment was estimated. This gave an indication of the cost. The author suggested technology costs were the main cost driver and that salaries have only a minor impact. It would have been useful had the author presented salary data in order for the reader to confirm this assertion. The analysis carried out used the number of sessions provided by the technology in its useful life to date, but it was unclear whether the technology was at the end of its working life. A further 2 years' working life treating many more patients would affect the productiveness of the technology and so influence the average cost per treatment and also cost-effectiveness.

The quantities and the unit costs were reported separately, thus enhancing the reproducibility of the study in other settings. Discounting was not necessary as the costs were incurred during less than 2 years. The price year was reported, which will aid any future reflation exercises. The conversion rate used was not reported.

Other issues
The author cited an earlier study that reported comparable success rates, thus reinforcing the author's own results and conclusions. Differences in the study that might have contributed to the slightly higher success rate were also discussed. The author did not address the issue of generalisability to other settings and populations. It would seem that the effectiveness results might well transfer to other settings, although it would be unwise to generalise to broader populations given the specific issues involved with treating obese patients, as acknowledged by the author as a major aim for this study. The cost and usage data would need to be re-estimated for alternative settings. The conclusions drawn are an accurate reflection of the results presented and relate well to the study question and design. No limitations were reported.

Implications of the study
The author did not make any recommendations for policy or practice following this work, except to say that ESWL should not be used as the first line of treatment for patients with low caliceal stones positioned more that 1 cm from the focal point on the blast path. No suggestions for further work were made, although this might include further analysis in sub-populations and a more detailed cost-effectiveness estimate carried out from a broader perspective.
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None stated.

Bibliographic details

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Other publications of related interest


Indexing Status
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MeSH
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