Comparison of laparoscopic versus open partial nephrectomy in a pediatric series

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 use of laparoscopic and open techniques for paediatric patients requiring partial nephrectomy, was studied.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised paediatric patients aged between 3 months and 15 years, who required partial nephrectomy. Specific inclusion and exclusion criteria were not reported.

Setting
The setting was tertiary care. The economic study was carried out in Utah, USA.

Dates to which data relate
The effectiveness and resource use data were gathered from March 1995 to May 2001. No price year was reported.

Source of effectiveness data
The effectiveness evidence came from a single study.

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

Study sample
Power calculations do not appear to have been conducted. A sample of 22 consecutive patients undergoing partial nephrectomy at the study centre was enrolled in the study, and 11 patients were included in each of the two study groups. However, one patient in the laparoscopic group was excluded due to an intraoperative complication and three patients in the open group were excluded because multiple procedures were performed at operation. Thus, there were 10 patients in the laparoscopic group (age range: 5 months - 15 years) and 8 in the open group (age range: 3 - 33 months). The laparoscopic group comprised all girls, while all but one patient in the open group were girls.

Study design
This was a retrospective cohort study. It was carried out in a single centre, the Division of Urology, University of Utah.
School of Medicine, Salt Lake City (UT), USA. The length of follow-up was not reported. Patient allocation to study groups was decided by the surgeon and the parents’ preferences. In the open group, heminephrectomy was performed in 6 cases and heminephrouretectomy in 5 cases. In the laparoscopic group, heminephrectomy was performed in 1 case and heminephrouretectomy in 10. The outcome assessment was conducted by retrospectively by reviewing patient charts.

**Analysis of effectiveness**

The analysis of the effectiveness was limited to those patients who were not excluded from the initial study sample. The primary health outcome measure used in the analysis was the number of complications. Potential health outcome proxies that were measured were blood loss, mean hospital stay and analgesic use. The mean operative time was also measured. No comment was made on the comparability of the study groups, but patient age appears to have been somewhat different between the two groups.

**Effectiveness results**

One intraoperative complication occurred in the laparoscopic group and one postoperative complication occurred in the open group.

The mean operative time was 200.4 minutes in the laparoscopic group and 113.5 minutes in the open group, (p<0.0005). Blood loss was 22.5 cm³ (range: 5 - 50) in the laparoscopic group and 12.5 cm³ (range: 5 - 30) in the open group, (non significant). The mean hospital stay was 25.5 hours (laparoscopic) and 32.6 hours (open), respectively, (non significant).

In the laparoscopic group, 3 of the 10 patients required continuous parenteral analgesia for an average of 15.7 hours, 4 required periodic parenteral analgesia, and 3 required oral medications. In the open group, 7 of the 8 patients required continuous parenteral analgesia for an average of 18.2 hours (range: 5 - 40) and one required only oral medication.

With respect to quantitative use, patients in the laparoscopic group required a lower mean number of analgesic doses than those in the open group, 10.9 doses versus 21 doses, (p=0.041).

**Clinical conclusions**

The effectiveness analysis showed that the laparoscopic approach for paediatric nephrectomy was associated with longer operative time than open surgery, but less analgesic use. The incidence of complications was similar in each group.

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

The health outcomes were left disaggregated and no summary benefit measure was used. A cost-consequences analysis was therefore conducted.

**Direct costs**

Discounting was not performed since the costs per patient were incurred in a short time period. The unit costs were not reported separately from the quantities of resources used. Also, a breakdown of the costs was not given. The cost/resource boundary adopted in the study was not explicitly reported. The evaluation of the costs referred to inpatient costs only. Resource use was estimated on the basis of actual data evaluated retrospectively using the same patients as those included in the effectiveness study. The source of the cost data was not given. Resource use was evaluated for March 1995 to May 2001. No price year was reported.

**Statistical analysis of costs**

Statistical analyses were conducted to test the statistical significance of the estimated difference in the total costs.
Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not conducted.

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

Cost results
The estimated costs per patient were $6,123 in the laparoscopic group and $4,244 in the open group, (p=0.016).

Synthesis of costs and benefits
Not relevant as a cost-consequences analysis was conducted.

Authors' conclusions
The study showed that increased operative time and costs were the main disadvantages of paediatric laparoscopic nephrectomy, compared with the open technique. However, there was a trend towards reduced hospital stay and lower analgesic use with the laparoscopic approach.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparators was clear. The laparoscopic and open procedures represent two alternative approaches for the treatment of paediatric patients requiring partial nephrectomy. You should decide whether they are widely used approaches in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness analysis used a retrospective cohort study, which was appropriate for the study question. However, the retrospective nature of the design and the small sample size represented a weakness of the study. The internal validity of the analysis was limited because power calculations were not performed and the power of the study was likely to have been low. Further, the study groups appear not to have been comparable at baseline. This may have confounded the results. The length of follow-up was not precisely defined and some patients excluded from the initial study sample were not included in the analysis. The measures of health outcome were limited in scope. There does not appear to have been any selection bias. However, it is uncertain whether or not the study sample was representative of the study population given the small sample size. The authors stated that some learning curve effect may have played a role in the analysis.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
Overall, only few details of the cost analysis were reported. The perspective adopted in the study was not mentioned and
a detailed breakdown of the cost items was not reported. The unit costs and the quantities of resources were not reported separately and the price year was not given. This makes the reproducibility of the study in other settings quite difficult. The costs were evaluated over a long period of time and it was unclear whether reflation was performed. Standard statistical analyses were conducted to test the statistical significance of the estimated difference in the total costs. However, no sensitivity analyses were conducted.

Other issues
The authors compared some of their findings with those from published studies. However, they did not address the issue of the generalisability of the study results to other settings. The study enrolled paediatric patients requiring nephrectomy and this was reflected in the conclusions of the study. The authors admitted that their study was likely to have been underpowered to detect statistically significant differences in the main outcome measures.

Implications of the study
The study highlights the advantages and disadvantages of the laparoscopic versus the open approach for nephrectomy. Such aspects should be considered when deciding the more appropriate approach for paediatric patients. However, caution is required when interpreting these conclusions, due to the limitations of the present study.

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