Single-center comparison of purely laparoscopic, hand-assisted laparoscopic, and open radical nephrectomy in patients at high anesthetic risk


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 laparoscopic radical nephrectomy (LRN), hand-assisted LRN and open RN for renal tumours in a population of patients at high risk of perioperative complications.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised all patients undergoing radical nephrectomy for presumed renal-cell carcinoma (RCC) between August 1999 and August 2001 at Vanderbilt University Medical Center, who had an American Society of Anesthesiologist (ASA) score of greater than or equal to 3. Patients with known metastasis, local invasion, caval thrombi, or additional simultaneous surgical procedures were excluded.

Setting
The setting was a university medical centre (it is assumed this represents tertiary care). The economic study was carried out at the Vanderbilt University School of Medicine, Nashville (TN), USA.

Dates to which data relate
The effectiveness and resource use data were collected between August 1999 and August 2001. 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 appears to have been performed on the same sample population as that used in the effectiveness analysis, with the data used being collected retrospectively from a patient database.

Study sample
No sample size calculations appear to have been performed in the planning phase of the study in order to assure a certain power. A retrospective chart review of all 149 patients undergoing nephrectomy at Vanderbilt University Medical Center between August 1999 and August 2001 was performed. Of the 149 kidneys removed, 76 patients
underwent RN for presumed RCC. From this population, all patients who were at high risk for perioperative complications, as determined by an ASA score of 3 or more, were reviewed in detail. Patients with known metastatic disease at the time of diagnosis, grossly evident local invasion, known nodal disease, caval thrombi, a tumour size of at least 3 cm, or additional simultaneous procedures were excluded. Using these inclusion and exclusion criteria, 47 high-risk patients were identified. Of these, 13 were treated with LRN, 8 with hand-assisted LRN and 26 with open RN. The authors did not report any evidence that the study sample was representative of the study population.

Study design
The study design was not explicitly reported. However, the study was a single-centre comparison.

Analysis of effectiveness
The basis of the effectiveness analysis was "treatment completers only". This involved 13 patients treated with LRN, 8 patients treated with hand-assisted LRN, and 26 patients treated with open RN. The primary health outcomes used to assess the three treatments were length of hospital stay operative time, pain medication required, and complication rate. The authors reported that the patient demographics in the three groups were similar.

Effectiveness results
The patients with an ASA score of 3 had 1.3 hospital days with LRN, 2.6 hospital days with hand-assisted LRN, and 3.75 hospital days with open RN.

The mean operative time in these patients was 2.8 hours (LRN), 2.8 hours (hand-assisted LRN), and 2.5 hours (open RN), respectively.

The time to oral intake was 7.3 hours for patients in the LRN group, 9.4 hours for those in the hand-assisted LRN group, and 54 hours for those in the open RN group.

Both the LRN patients (22.9 mg of morphine sulphate equivalent) and the hand-assisted LRN patients (42.1 mg) required less pain medication than open RN patients (97.7 mg).

The difference between LRN and open RN was significant, (p<0.001).

Clinical conclusions
Both LRN and hand-assisted LRN can be performed safely in patients with significant co-morbid conditions. They also resulted in a lower requirement for pain medication and a faster return to oral intake than open RN. LRN resulted in fewer perioperative complications than hand-assisted LRN or open RN in patients at high perioperative risk.

Measure of benefits used in the economic analysis
No summary measure of benefit was used in the economic analysis. The study was, in effect, a cost-consequences analysis.

Direct costs
The cost estimates were based on actual costs to the institution and not charges billed to the patient. The direct costs were for operating room supplies, anaesthesia, recovery room stay, operating room time, total operating room and total hospital charges. The price year was not identified. Discounting was not performed.

Statistical analysis of costs
The costs were treated stochastically since the mean and ranges of the total costs were reported.
Indirect Costs
The indirect costs were not reported.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were reported.

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

Cost results
The operation costs for patients with an ASA score of 3 were $4,913 with LRN, $5,008 with hand-assisted LRN, and $3,846 with open RN.

The total hospital costs for these patients (ASA 3) were $6,089 with LRN, $7,678 with hand-assisted LRN, and $7,694 with open RN.

Compared with ASA 4 patients, the ASA 3 patients had lower anaesthetic costs ($297 versus $435; p=0.007), operating room time costs ($2,521 versus $3,378; p=0.03), and total hospital costs ($7,215 versus $11,429; p=0.002).

Synthesis of costs and benefits
Since a cost-consequences analysis was undertaken, the estimated health benefits and costs were not combined. The authors reported that the LRN technique had a 21% lower total cost than both hand-assisted LRN and open RN.

Authors' conclusions
The hand-assisted and purely laparoscopic radical nephrectomy (LRN) techniques can be performed safely and cost-effectively in patients with significant co-morbid conditions. Pure LRN performed in patients with an ASA score of 3 resulted in significantly lower analgesia requirement, time to oral intake and length of stay, as well as a $1,605 total hospital cost reduction, in comparison with open RN performed in ASA 3 patients. LRN appeared to result in lower morbidity than both hand-assisted LRN and open RN.

CRD COMMENTARY - Selection of comparators
The authors did not provide a justification for their choice of the comparator.

Validity of estimate of measure of effectiveness
The study was based on a retrospective review of patient data from a single centre. An analysis was performed on the basis of treatment completers only. The sample size was rather small. As the authors acknowledged, their results probably reflected the selection biases of the referring physicians. It was unclear whether the results of this study were internally valid and, since the authors did not report any evidence that the study sample was representative of the study population, it cannot be stated whether the study findings were externally valid.

Validity of estimate of measure of benefit
No summary measure of health benefit was used in the economic analysis. The study was, in effect, a cost-consequences analysis.
Validity of estimate of costs
The perspective adopted in the analysis was unclear. The resource quantities used and the unit costs were not reported separately. Means and ranges for the final costs were presented, which reduce some of the uncertainty surrounding the cost estimation. The price year was not reported, which will limit any future inflation exercises. Discounting was not performed, which was appropriate since the period considered for the estimation of costs was less than 2 years.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. However, the issue of the generalisability of the results to other settings was not addressed. The authors reported several limitations of the study, such as the small sample size and its retrospective nature.

Implications of the study
The authors recommended that larger multi-centre studies comparing LRN, hand-assisted LRN and open RN would be necessary to confirm the findings of this study. Future studies comparing the costs and recovery of open and laparoscopic surgery patients should consider the ASA score as a significant factor in the analysis.

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