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
Laparoscopic radical nephrectomy was compared with open radical nephrectomy for renal cell carcinoma.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The intervention group comprised 32 men and 28 women who underwent 61 laparoscopic radical nephrectomies for suspected renal cell carcinoma.

The comparison group comprised all 33 patients with renal masses on radiograph of 10 cm or less, who underwent open radical nephrectomy for a renal tumour at the authors' institution between June 1990 and January 1999.

Setting
The setting was secondary care. The study was conducted in the USA.

Dates to which data relate
The effectiveness data were collected between June 1990 and June 1999. The resource use data appear to have been collected between July 1998 and January 1999 for the laparoscopic, group and between October 1998 and December 1999 for the open group. The prices used appear to have come from the same time period as the resource use data. The price year was not stated.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used in the effectiveness study, using the five most recent uncomplicated nephrectomy cases in each group. The authors did not state whether the costing was undertaken prospectively or retrospectively.

Study sample
Power calculations to determine the study sample size do not appear to have been performed either prospectively or retrospectively. In the early part of the laparoscopy sample, 15 patients underwent ureteral stent placement. The
The laparoscopy group was compared with a contemporary group of 33 patients who underwent open radical nephrectomy for a renal tumour with a renal mass of 10 cm or less. The control group was from the same institution. The authors justified the use of this particular study sample to answer the study question within their own institution. Ninety-three patients were included in the study. There were 60 patients in the laparoscopy group and 33 in the control group. No participants were reported to have refused to participate. No participants were excluded from the study. The mean age in the laparoscopic group was 63.5 years and the mean renal mass size was 5.3 cm. The mean age in the open radical nephrectomy group was 61.8 years and the mean renal mass size was 7.4 cm.

**Study design**
The study, although evaluating an intervention, was of an observational design. It best fits the description of a prospective cohort study with concurrent controls. The study was performed in a single institution. The mean duration of follow-up was 25 months in the laparoscopy group and 27.5 months in the control group. One patient (in the laparoscopy group) was lost to follow-up. The outcomes were not assessed blind.

**Analysis of effectiveness**
All patients who were included in the study appear to have been accounted for in the analysis. The clinical outcomes reported included:

- the operating time;
- the mean blood loss;
- intact specimen removal;
- analgesia;
- hospital stay;
- time to oral intake, ambulation, normal activity and 100% recovery;
- recurrence; and
- major and minor complications, categorised as intraoperative, early postoperative (if during hospitalisation) and late postoperative (if after discharged home).

The authors did not state which of these were the primary outcomes. The groups appear to have been similar in terms of their baseline characteristics. Confounding factors were addressed in terms of stratification according to tumour size (less than or equal to 4 cm versus more than 4 cm).

**Effectiveness results**
Significantly less estimated blood loss occurred in the laparoscopic group (172 mL) than in the open radical nephrectomy group (451 mL), (p<0.001).

The laparoscopic group also had significantly shorter hospital stay, 3.4 days versus 5.2 days, (p<0.001), and lower pain medication requirement, 28.0 mg versus 78.3 mg, (p<0.001). The laparoscopic group also had a significantly faster return to normal activity (3.6 weeks) than the open radical nephrectomy group (8.1 weeks), (p<0.001).

Sixty-five per cent of the laparoscopic specimens were not removed intact. Renal cell carcinoma recurred in three patients in each group (8% laparoscopy group versus 9% open group).

When the results were stratified by tumour size, similar benefits and results were seen in both tumour size groups.

There were no occurrences of trocar or intraperitoneal seeding in the laparoscopy group.
There were fewer complications in the laparoscopic group.

**Clinical conclusions**
Laparoscopic radical nephrectomy is a viable alternative to open radical nephrectomy for localised renal tumours of 10 cm or less. Patients undergoing the laparoscopic procedure have an improved postoperative course with less pain and faster recovery than patients undergoing the open procedure. The laparoscopic procedure provides similar efficacy at a mean follow-up of more than two years.

**Measure of benefits used in the economic analysis**
The authors did not develop a summary benefit measure for use in the economic analysis. A cost-consequences analysis was therefore performed. See the 'Effectiveness Results' section for the measures of health benefits.

**Direct costs**
The direct costs for each group were derived by calculating the mean values from the last five patients in each group (up to 1999). The hospital health care costs included the average operating cost, total hospital cost, operation cost per hour and operation cost per minute. The cost data appear to have been taken directly from the hospital records of the five most recent patients in each group. Discounting was not carried out and was not appropriate given the short period of analysis (less than one year). The costs were not adjusted for inflation. The costs and the quantities were not reported separately. The price year was not stated.

**Statistical analysis of costs**
The effectiveness results were not treated stochastically. No statistical tests were undertaken.

**Indirect Costs**
The indirect costs were reported in the discussion, which would have facilitated analysis from a societal perspective. However, only the direct costs were included in the overall calculation. In the discussion, the authors noted that the economic analysis failed to take convalescence expenses into account (time to return to normal activity). The daily earnings of the average American worker were then calculated on the basis of the median household income data from 1998. Discounting was not relevant.

**Currency**
US dollars ($).

**Sensitivity analysis**
A sensitivity analysis was not carried out.

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

**Cost results**
The average operative costs were higher for the laparoscopic group ($6,333) than the open nephrectomy group ($4,431). Laparoscopic nephrectomy resulted in operative charges of $1,793 per hour and $30 per minute, compared with $1,611 per hour and $27 per minute for open nephrectomy.

The total hospital costs were higher for the laparoscopic group ($15,816) than for the open nephrectomy group ($13,672).
The cost of convalescence, given the average earnings of $104.94 per day, was calculated to provide a saving of $3,305.61 in the laparoscopic group.

Synthesis of costs and benefits
Not applicable due to the cost-consequences approach.

Authors' conclusions
Laparoscopic radical nephrectomy is a viable alternative for managing localised renal tumours up to 10 cm. Compared with open nephrectomy, it affords patients an improved postoperative course with less pain and a quicker recovery, and is of similar efficacy at a follow-up of more than two years. Economically, open nephrectomy remains more cost-effective in the short term than laparoscopic nephrectomy, by about $2,000.

CRD COMMENTARY - Selection of comparators
The comparator used was justified on the grounds that, to the authors' knowledge, it was the best method of treating localised renal cell carcinoma, although it resulted in significant postoperative pain and a lengthy convalescence. You should decide if open radical nephrectomy is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
An observational study design (a cohort study with data collected prospectively, and with concurrent controls) was used. While the study design was not inappropriate to answer the research question, it has methodological limitations that may bias the results. The patients were not randomly allocated to open or laparoscopic nephrectomy. Therefore, there may have been important clinical differences between the groups that would influence the choice of treatment and also the treatment outcome (confounding factors). The average size of the tumour was reported to be 452 g in the laparoscopic group and 666 g in the open nephrectomy group. There may have been other clinical differences between the groups at baseline that could possibly have an effect on the treatment outcomes. No adjustment was made for potential confounding factors, other than stratification according to tumour size. It is not clear whether the study sample was representative of the study population.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
The categories of cost relevant to the stated perspective (i.e. operating room and total hospital charges) were included in the analysis. However, as the authors acknowledged, the research question would have been better answered by including convalescence expense (loss of productivity). Since this was not taken into consideration, the cost of laparoscopic nephrectomy in comparison with open nephrectomy may have been underestimated. The costs and the quantities were reported separately, although it is unclear whether costs or charges were reported. The authors did not state the source of the prices. The prices appear to have been derived from the actual costs or charges incurred by the last five uncomplicated cases in each group. No price year was given. The small sample size did not permit statistical analysis and it might not have produced results consistent with the whole sample. These factors hinder the internal and external validity of the cost results.

Other issues
The authors made appropriate comparisons of their results with the findings from other studies. The issue of generalisability to other settings was addressed only in terms of experience of the surgeons. The authors do not appear to have presented their results selectively. The study enrolled patients with tumours of 10 cm or less and this was reflected in the authors' conclusions. The authors acknowledged that their cost comparison failed to take productivity
losses into account. A societal perspective would have been informative for this patient group.

**Implications of the study**
The authors recommend that the indications for laparoscopic nephrectomy are expanded to include tumours up to 10 cm in size, double the cited limit of 5 cm. The results would have greater validity if supported by a randomised trial with a more rigorous economic analysis.

**Source of funding**
None stated.

**Bibliographic details**

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**Other publications of related interest**

**Indexing Status**
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