Laparoscopic vs open donor nephrectomy: a cost-utility analysis
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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 the use of laparoscopic nephrectomy (LapDN) for living donors.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised adults who were considered to be candidates for a left living donor nephrectomy, who had single renal vessels (one renal artery and vein) on preoperative imaging, were donating a kidney to recipients with end-stage renal disease, and who were suitable for both LapDN and OpenDN.

Setting
The setting was a hospital. The economic study was performed at St. Michael's Hospital, Toronto, Canada.

Dates to which data relate
The effectiveness data were derived from studies published between 1992 and 2001. The cost data were collected from publications published between 1996 and 2001, and from a study sample corresponding to 2000. The price year was 2001.

Source of effectiveness data
The effectiveness data were derived from a review of the literature and institutional records.

Modelling
A decision tree was constructed to identify the important factors to consider in the analysis of LapDN versus OpenDN, and to estimate the health benefits and costs of these alternative strategies. It was considered in the model that patients could have either LapDN or OpenDN, and those donors undergoing LapDN could cross over to OpenDN. In any event, patients could present either serious perioperative complications or no serious perioperative complications. The donor was considered to have either pain during the 4 weeks after the surgery or no pain after 4 weeks. Finally, the donor was considered to be able or not able to return to work 4 weeks after the surgery.

The period of follow-up was modelled as 3 months because the authors assumed that patients would have recovered completely 3 months after the intervention.
Outcomes assessed in the review
The outcomes assessed in the review were:

- the probability of conversion to OpenDN in the LapDN arm;
- the probability of major donor perioperative complications with OpenDN and LapDN (i.e. death, bleeding necessitating transfusion, major cardiac event and pneumonia);
- the probability of the donor requiring narcotic analgesics 4 weeks after surgery with OpenDN and LapDN;
- the probability of the donor not returning to work 4 weeks after surgery with OpenDN and LapDN;
- the relative risk reduction (RRR) in LapDN for a donor not working at 4 weeks;
- the RRR in LapDN arm for a donor with pain at 4 weeks after surgery;
- the RRR in OpenDN arm for severe operative complications;
- the decreased risk (relative risk, RR) of the donor not returning to work in the absence of pain.

Study designs and other criteria for inclusion in the review
The authors reported that the studies included in the review were non-randomised trials, with the best evidence obtained mainly from prospective case series studies. However, the probabilities for LapDN were derived from 5-year observational studies, and the probabilities for OpenDN were derived from the largest published retrospective studies.

Sources searched to identify primary studies
The authors reported that MEDLINE was searched from 1966 to 2001.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
About five studies were included in the review to provide evidence for different parameters.

Methods of combining primary studies
Some parameters were taken from one study, whilst others were weighted averages of the largest published retrospective studies and institutional records.

Investigation of differences between primary studies
The authors reported the lowest and highest values of the different outcomes assessed in the review.

Results of the review
The probability of conversion to OpenDN in the LapDN arm was 0.05 (lowest value 0; highest value 0.2).

The probability of major donor perioperative complications was 0.073 (lowest value 0.05, highest value 0.11) with
OpenDN and 0.085 (lowest value 0.07; highest value 0.13) with LapDN.

The probability of the donor requiring narcotic analgesics because of pain 4 weeks after surgery was 0.11 (lowest value 0.05; highest value 0.35) with OpenDN and 0 (highest value 0.16) with LapDN.

The probability of the donor not returning to work 4 weeks after surgery was 0.54 (lowest value 0.28; highest value 1) with OpenDN, and 0.28 (lowest value 0.15; highest value 0.32) with LapDN.

The RRR in the LapDN arm (when compared with OpenDN) for a donor not working at 4 weeks was 0.48 (lowest value 0.46; highest value 0.68).

The RRR in the LapDN arm (when compared with OpenDN) for a donor without pain at 4 weeks after surgery was 1 (lowest value 0.69).

The RRR in the OpenDN arm (when compared with LapDN) for severe operative complications was 0.34 (lowest value 0.15; highest value 0.79).

The decreased risk of the donor not returning to work in the absence of pain was 0.99 (lowest value 0.8; highest value 1).

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

The outcome measures used in the economic analysis were the quality-adjusted life-years (QALYs). The authors reported that no relevant utilities for the postoperative health states of the donors were identified in the literature. Therefore, a panel of 25 experts in transplantation was created to derive these utilities, using time trade-off techniques.

The authors reported that, in order to adjust the utilities of the different health states that the donors could experience, the model was adjusted for the length of time the individual was in that state. The three time periods considered were inpatient phase (length 1 week), where severe complications could occur; early outpatient phase (length 4 weeks), where pain and work-related complications could occur; and late outpatient phase, where pain and work-related complications could occur again.

**Direct costs**

The resource quantities and the costs were reported separately. The direct costs considered at analysis were those of the health service. These included inpatient costs, the costs of complications and outpatient costs. The inpatient costs covered the costs per LapDN or per OpenDN, disposable instruments (e.g. pneumosleeve, endoshears, endoGIA handle and cartridge), surgeon fee and anaesthetic fee). The costs caused by complications were those of the intensive care unit. The outpatient costs covered clinic visits, physician fee for clinic visit, outpatient dispensing fee and drug costs (including Colace, Tylenol plain, Tylenol ES, Endocet and Tylenol 3).

The decision analytic model was used to extrapolate the costs for the whole period of follow-up of the patients (3 months). The estimation of the costs was based on actual data. The costs of surgical procedures, inpatient hospital stay, complication, clinical space and visits were obtained from St. Michael's Hospital Decision Support Department, using the cost-per-weighted case (with data from 2000). OpenDN costs and outpatient resource consumption were estimated from a sample of 61 patients who received either LapDN or OpenDN in St. Michael's Hospital. Fee-for-service surgeon charges, charges for anaesthetic services and physician charges were obtained from the Ontario Health Insurance Plan Schedule of Benefits (2001). The drug costs were obtained from Ontario Drug Benefit formulary charges. Discounting was not carried out, which was appropriate as the follow-up period considered at analysis was less than 2 years. The study reported the average costs. The price year was 2001.

**Statistical analysis of costs**

No statistical analysis of the costs was reported.
Indirect Costs
Given the perspective adopted (societal), the costs derived from the loss of employment and caring for children were included in the analysis. The indirect costs included in the study were the lost income costs, and opportunity and replacement costs for household and childcare. The authors reported that Ontario earnings data (Statistics Canada, 1996) were used to estimate lost income costs, inflated to year 2001 using the Consumer Price Index (Statistics Canada, 2001) and using the minimum Ontario hourly wage rate. Replacement costs were estimated using survey data from 5 physicians who used a nanny to provide child care services. The weights applied for the proportion of people either working or caring for children were obtained from the sample of 21 patients from the centre where the study was performed in the year 2000 (as reported in the 'Direct Costs' section).

Currency
Canadian dollars (CAD).

Sensitivity analysis
Sensitivity analyses were performed to assess the robustness of the model. The areas of uncertainty investigated were variability in the data and the perspective adopted. The authors used one-way sensitivity analyses, varying the probabilities, RRR, RR, lengths of time used in the model to estimate the QALYs, utilities and costs, using a range of 1 standard deviation or alternative ranges determined by clinical experts where appropriate. Best- and worst-case analyses were also performed from a societal perspective in order to obtain confidence intervals around the baseline cost-effectiveness ratio obtained at analysis. The authors also considered an alternative perspective in the sensitivity analysis, the payer perspective (i.e. the Ministry of Health), which did not consider the indirect costs reported previously.

Estimated benefits used in the economic analysis
The number of QALYs experienced during the 3-month follow-up considered at analysis was 0.7247 with LapDN, and 0.6585 with OpenDN. The incremental QALYs gained with LapDN in comparison with OpenDN were 0.0662.

Cost results
The total costs were CAD 12,631.91 for OpenDN and CAD 11,170.10 for LapDN. The incremental cost of OpenDN in comparison with LapDN was CAD 463.70.

Synthesis of costs and benefits
No incremental cost-effectiveness ratio was calculated since the OpenDN intervention was dominated by the LapDN intervention. This means that LapDN was both cheaper and more effective than OpenDN.

The only sensitivity analysis that altered the dominance of LapDN over OpenDN was when the LapDN hospital costs were significantly higher than expected and the OpenDN costs were significantly lower than expected.

Authors' conclusions
Laparoscopic nephrectomy (LapDN) is "a cost-effective alternative to OpenDN, particularly once the learning curve of the procedure has been ascended".

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used. OpenDN was the current and most used practice in the authors' setting. You should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The authors did not state whether a systematic review of the literature had been undertaken. Moreover, only one source
(MEDLINE) was searched for primary studies. It was unclear whether the authors used data from the available studies selectively. These facts introduce uncertainty into the reliability of the effectiveness results. However, sensitivity analyses of health outcomes were conducted within ranges that seemed appropriate according to the clinical evidence the authors reported in the review. This may have helped to counter the uncertainty previously commented on.

**Validity of estimate of measure of benefit**

The measure of benefit was the QALYs. The authors adequately described the derivation of the utility values for health states a donor could experience. The authors assumed that these utilities, which were derived from an expert panel, reflected the utilities of the general population or of patients in these health states. Community or patients' views are regarded as the best source of utilities and it was not clear how accurately the experts' views used in this study reflected the community or patients' views.

**Validity of estimate of costs**

All the categories of costs relevant to the perspective adopted seem to have been included in the analysis. The fact that the resource quantities and the costs were reported separately and that the price year was given facilitate reflation exercises to other settings. The authors reported the costing in detail, and two perspectives were considered at analysis. The societal perspective was considered as the base-case, while a perspective of the Ministry of Health was considered in the sensitivity analysis. The authors did not provide evidence that the sample used in the costing (in order to calculate some of the direct costs and the weights applied in the calculation of the indirect costs for people working or caring for children) was representative of the study population. Therefore, there is uncertainty about the accuracy of the estimation of these costs and weights.

**Other issues**

The authors published an almost identical paper in a different journal a few months before the present paper (Pace et al. 2002, see 'Other Publications of Related Interest' below for bibliographic details. The NHS EED abstract of that paper can be found at:

http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?View=Full&ID=22002001745

The results of this study were significantly different from those of the previous study, and it seems strange that the authors did not compare the results of their studies. There was no reference in the present paper to the other publication.

The authors did not report their results selectively and their conclusions reflected the scope of the analysis. The only 'limitation' that the authors mentioned was that the study was biased against LapDN.

**Implications of the study**

The authors are mistaken in suggesting that QALYs cannot account for changes in utility over time. If you measure the patients' utility or the patients' health status using, for example, the EQ-5D form on a regular basis during the follow-up of a trial, you will record the change. The problem only arises if you choose to derive utility values from experts and apply them for the entire period in question.

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**Bibliographic details**

Other publications of related interest

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Indexing Status
Subject indexing assigned by NLM

MeSH
Cohort Studies; Confidence Intervals; Cost Control; Health Care Costs; Humans; Kidney Transplantation /economics /methods; Laparoscopy /economics; Nephrectomy /economics /methods; Ontario; Prospective Studies; Quality-Adjusted Life Years; Sensitivity and Specificity; Tissue Donors

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