Laparoscopic v open donor nephrectomy: a cost-utility analysis of the initial experience at a tertiary-care center
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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, who were donating a kidney to recipients with end-stage renal disease (ESRD), and who were suitable for both LapDN and OpenDN.

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

Dates to which data relate
The effectiveness data were derived from 2 studies published between 1999 and 2000. The cost data were collected from publications published between 1996 and 2001, and from a study sample corresponding to 2000. The price year was 2000.

Source of effectiveness data
Effectiveness data were derived from a review of the literature and estimates of effectiveness based on an expert panel.

Modelling
A decision analytic model 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 peri-operative complications or no serious peri-operative complication. The donor was considered to have either pain during 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 peri-operative 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 the surgery with OpenDN and LapDN; the relative risk reduction (RRR) in LapDN for donor not working at 4 weeks; the RRR in LapDN arm for donor with pain at 4 weeks after surgical intervention; 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, although 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 2000.

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
Two studies were included in the review.

Methods of combining primary studies
The method used by the authors to combine the results from the primary studies included in the review was not stated.

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 results of the review were as follows:

The probability of conversion to OpenDN in the LapDN arm was 0.1 (with 0 as the lowest value and 0.2 as the highest value).

The probability of major donor peri-operative complications with OpenDN and LapDN, respectively, were 0.073 (with 0.015 as the lowest value and 0.11 as the highest value) and 0.11 (with 0.07 as the lowest value and 0.13 as the highest value).

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

The probability of the donor not returning to work 4 weeks after the surgery was 0.54 (with 0.28 as the lowest value and 1 as the highest value) with OpenDN, and 0.28 (with 0.09 as the lowest and 0.54 as the highest values) with LapDN.
The relative risk reduction (RRR) in LapDN (when compared to OpenDN) for donor not working at 4 weeks was 0.48 (with 0.46 as the lowest and 0.68 as the highest values).

The RRR in LapDN arm (when compared to OpenDN) for donor with pain at 4 weeks after surgical intervention was 1 (with the lowest value equal to 0.69).

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

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

**Methods used to derive estimates of effectiveness**
The authors reported that no relevant utilities for the post-operative health states of the donors were identified in the literature and, therefore, a panel of 14 experts in transplantation was created to derive these utilities, using time-trade off techniques.

**Estimates of effectiveness and key assumptions**
The utilities for donor events were estimated as follows:

the utility of a donor not working at 4 weeks was estimated as 0.67 (with the lowest value equal to 0.4 and the highest value equal to 1);

the utility of a donor who experienced pain at 4 weeks after the intervention was 0.76 (with the lowest value equal to 0.5 and the highest equal to 1); and

the utility of a donor experiencing severe complications was valued as 0.18 (with the lowest value equal to 0.04 and the highest equal to 0.33).

These utilities were assumed to be independent of the treatment arms. The authors assumed that these utilities reflected the utilities of the general population or of patients in these health states.

**Measure of benefits used in the economic analysis**
The outcome measures used in the economic analysis were quality-adjusted life-years (QALYs). Utilities for health states were derived from an expert panel (see 'Methods Used to Derive Estimates of Effectiveness' and 'Estimates of Effectiveness and Key Assumptions' sections, reported above). 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. Three time periods were considered: 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. The authors assumed that any complication occurring within a period would last for the whole period.

**Direct costs**
Resource quantities and costs were reported separately. The direct costs considered at analysis were those of the health service, and included: the inpatient costs (i.e. costs per LapDN or per OpenDN, disposable instruments such as pneumosleeve, endoshears, endoGIA handle and cartridge, surgeon fee and anaesthetic fee); the costs caused by complications (i.e. the intensive care unit costs); and the outpatient costs (i.e. 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 (three months). The estimation of the costs was based on actual data. The costs of surgical procedures, inpatient hospital stay, complication costs, clinical space and visits were obtained from St. Michael's Hospital Decision Support Department, using cost-per-weighted case (with data from 2000). A sample of 21 patients who received either LapDN or OpenDN in
St. Michael's Hospital was used to estimate OpenDN costs and outpatient resource consumption. Fee-for-service surgeon charges, charges for anaesthetic services and physician charges were obtained from the Ontario Health Insurance Plan Schedule of Benefits (2001). Drug costs were obtained from Ontario Drug Benefit formulary charges. Discounting was not carried out which was appropriate as the period of follow-up considered at analysis was less than 2 years. The study reported average costs. The price year was 2000.

**Statistical analysis of costs**
No statistical analysis of costs was reported.

**Indirect Costs**
The costs derived from the loss of employment and caring for children were included in the analysis due to the perspective adopted (societal). The indirect costs included in the study were: lost income costs, and opportunity and replacement costs for household and childcare. The authors reported that Ontario earnings data (Statistics Canada, 1996) were used as source to estimate lost income costs, inflated to year 2000 using the Consumer Price Index (Statistics Canada, 2001), and using the minimum Ontario hourly wage rate. As the authors reported, 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 during the year 2000 (as reported in the 'Direct Costs' section).

**Currency**
Canadian dollars (Can$).

**Sensitivity analysis**
Sensitivity analyses were performed to assess the robustness of the model. The areas of uncertainty investigated were variability in 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 (SD) or alternative ranges determined by clinical experts where appropriate. Best-case and worst-case analyses were also performed from a societal perspective in order to obtain confidence intervals around the baseline cost-effectiveness ratio (CER) 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 gained during the 3-month period of follow-up considered at analysis was 0.7683 with LapDN, and 0.7062 with OpenDN. The incremental QALY gained with LapDN, when compared to OpenDN, was 0.0621.

**Cost results**
The total costs were: Can$9,853.70 for OpenDN, and Can$10,317.40 for LapDN. The incremental cost of LapDN when compared to OpenDN was Can$463.70.

**Synthesis of costs and benefits**
The estimated benefits and costs were combined in CER, reporting the cost per QALY for each of the interventions considered at analysis. The incremental CER (ICER) of LapDN, when compared to OpenDN, was also reported.

The CER for OpenDN was Can$13,952.21 per QALY, while for LapDN this CER it was Can$13,428.66 per QALY. The ICER for LapDN when compared to OpenDN was Can$7,471.11 per QALY.

The results from the one-way sensitivity analyses showed that the model was robust to variations in most of the
variables (within the clinically significant ranges), and only 5 variables proved to be sensitive: the inpatient costs of LapDN, the inpatient costs of OpenDN, the probability of an OpenDN patient not working 4 weeks after the intervention, the RRR of a LapDN patient not working compared with OpenDN, and the length of time. The ICER never exceeded Can$34,765.03 per QALY from the societal perspective. The best-case and worst-case analyses showed that LapDN was a dominant strategy under the best scenario, while the ICER was $13,710 per QALY under the worst scenario. When the perspective of the Ministry of Health was considered, the CER for OpenDN was Can$6,378.71, and for LapDN it was Can$8,028.04. The ICER for LapDN compared to OpenDN was Can$26,796.65.

Authors' conclusions
The authors conclude that LapDN offers improved donor outcomes (in terms of quality of life) when compared to OpenDN, but at higher costs, independently of the perspective adopted (either societal or Ministry of Health). The model used to estimate health benefits and costs was robust, and results from the sensitivity analyses showed that the ICER never exceeded Can$34,765.03 per QALY.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used, namely that OpenDN was the current and most used practice in the authors' setting. You, as a user of this database, 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 was searched to identify primary studies (MEDLINE) and only 2 studies were included as primary studies. It was not clear if 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 to be appropriate according to the clinical evidence the authors reported in the review. This may have helped to counter the uncertainty previously commented on. An expert panel was used to estimate utilities to assign to the alternative health states that the donors could experience. Time-trade off techniques were used to estimate these utilities. The authors did not report the process by which the physicians were selected.

Validity of estimate of measure of benefit
The estimation of benefits was modelled by means of assigning utilities to the alternative 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, therefore, it is 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 resource quantities and 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 show evidence that the sample used in the costing (in order to calculate some of the direct costs and the weights applied in the calculus of the indirect costs for people working or caring for children) was representative of the study population. Therefore, there is uncertainty regarding the accuracy of the estimation of these costs and weights.

Other issues
The authors compared the ICER generated by the model with those obtained for other interventions to conclude that the ICER obtained with LapDN is within the range that is considered to be cost effective for an intervention. The issue of
the generalisability of the results to other settings was not addressed.

**Implications of the study**
The authors raise the question of whether additional people would be willing to donate a kidney if the surgical intervention could be performed with LapDN rather than OpenDN (as evidence from the USA suggests) and whether LapDN may become a dominant strategy with further donations by living donors.

**Source of funding**
Supported in part by a Biomedical Research Grant from the Kidney Foundation of Canada.

**Bibliographic details**

**PubMedID**
12396443

**DOI**
10.1089/089277902760367467

**Other publications of related interest**


**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Aftercare; Cost of Illness; Cost-Benefit Analysis; Decision Trees; Health Care Costs; Hospitals, University; Humans; Kidney Transplantation /economics; Laparoscopy /economics; Living Donors; Models, Economic; Nephrectomy /economics /methods; Quality of Life; Risk

**AccessionNumber**
22002001745

**Date bibliographic record published**
31/07/2003
Date abstract record published
31/07/2003