The Auckland experience with laparoscopic donor nephrectomy

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 kidney transplantation. Laparoscopic donor nephrectomy (DN) was compared with open DN.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised donors and recipients of kidney grafts who underwent either laparoscopic or open DN. Donors all met the standard selection criteria used by the Auckland Renal Transplant Group. The vascular anatomy of the donors was examined preoperatively using either catheter angiography or computed tomography angiography. No further inclusion or exclusion criteria were provided for the recipients.

Setting
The setting was secondary care. The study was conducted at Auckland Hospital, New Zealand.

Dates to which data relate
The effectiveness data related to a period from 1998 to 2002 (June 2000 to June 2002 for laparoscopic DN and 1998 to 2002 for open DN). The resource data referred to the same period. The price year was not stated.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The cost data were collected retrospectively from the same sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. The study sample comprised the first 35 consecutive donors who underwent laparoscopic DN at the hospital and 35 consecutive donors who underwent open DN.

The median age of the donors was 39 (range: 24 to 56) for the laparoscopic DN group and 46 (range: 23 to 67) for the open DN group. The gender ratio (male:female) was 14:21 for the laparoscopic group and 20:15 for the open group. The ethnicity ratio (European: Pacific people: Others) was 30:3:2 for the laparoscopic group and 25:5:5 for the open group. Five kidneys procured by open DN and one procured by laparoscopic DN had multiple renal arteries. The ratio...
of left:right kidney was 35:0 for the laparoscopic group and 21:11 for the open group.

The median age of the recipients was 37 (range: 1 to 66) for the laparoscopic DN group and 43 (range: 19 to 69) for the open DN group. The gender ratio (male:female) was 26:9 for the laparoscopic group and 20:15 for the open group. Ethnicity ratio (European: Pacific people: Others) was 30:3:2 for the laparoscopic group and 26:5:4 for the open group.

Study design
This was a non-randomised trial that was carried out at a single centre. The median follow-up period was 13 months (range: 3 to 27) for the laparoscopic DN group and 35 months (range: 6 to 49) for the open DN group. No loss to follow-up was reported.

Analysis of effectiveness
The analysis of effectiveness was conducted on the basis of treatment completers only. The outcomes assessed were operating time, length of inpatient stay, recovery time and morbidity rate of the donors, and graft function of the recipients at one month and one year. In terms of the baseline characteristics, no significant differences in the donors’ and recipients’ age, gender and ethnicity ratio were observed between the laparoscopic and open groups. The only significant difference observed was in the ratio of left and right kidney use between the two groups, (p=0.0004).

Effectiveness results
The mean operating time was 257.6 minutes (standard deviation, SD=61.8) for laparoscopic DN and 169.6 minutes (SD=38.2) for open DN. The difference was significant, (p<0.0001).

The median length of donor inpatient stay was 3 days (range: 1 to 9) for the laparoscopic DN group and 6.5 days (range: 4 to 10) for the open DN group. The difference was significant, (p<0.0001).

The median length of donor recovery time was 3 days (range: 1 to 6) for the laparoscopic DN group and 6 days (range: 2 to 10) for the open DN group. The difference was significant, (p<0.0001).

The donor morbidity rate was 26% for the laparoscopic DN group and 31% for the open DN group. The difference was not significant.

Graft function (mean serum creatinine) of recipients at one and 12 months was not significantly different.

Clinical conclusions
The operating times were longer in the laparoscopic DN group than in the open DN group. However, operating times in the laparoscopic group lessened through the series of operations. The inpatient stay and recovery time were shorter in the laparoscopic group than in the open group.

Measure of benefits used in the economic analysis
The authors did not develop a summary benefit measure in the economic analysis. As such, a cost-consequences analysis was undertaken.

Direct costs
The direct costs included were for the ward (e.g. medical, nursing, pharmacy, hotel services), operating room, disposables (equipments used during surgery), radiology and laboratory. The unit costs and the resource quantities were not reported separately. Discounting was not carried out. The use and cost of services were based on Auckland District Health Board databases. The price year was not stated.
Statistical analysis of costs
The cost data were treated stochastically. Student’s t-test (parametric data) and the Mann-Whitney U test (non-parametric data) were used to examine the differences in costs between the laparoscopic and open DN groups.

Indirect Costs
The indirect costs were not included.

Currency
New Zealand dollars (NZD).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
Due to the cost-consequences approach, the reader is referred to the effectiveness results (see ‘Effectiveness Results’ section).

Cost results
The mean total costs were NZD 13,357.02 (SD=1,436.28) for the laparoscopic DN group and NZD 6,712.83 (SD=1,083.30) for the open DN group. This difference was significant, (p<0.0001).

Laparoscopic DN was significantly more expensive because of the significantly higher costs associated with extra operating time and disposable operating equipment.

Synthesis of costs and benefits
The costs and benefits were not combined because of the cost-consequences approach taken.

Authors’ conclusions
"LDN (laparoscopic donor nephrectomy) in the New Zealand setting provides effective grafts for renal transplant recipients, and it is safe for the donor. Advantages for the donor are a shorter hospital stay and convalescence period. The major disadvantage of LDN is its higher cost compared with ODN (open DN)."

CRD COMMENTARY - Selection of comparators
The authors clearly described the rationale behind their choice of the comparator. Open and laparoscopic surgical procedures are valid alternatives in most settings.

Validity of estimate of measure of effectiveness
The validity of the effectiveness data is likely to be high, although it may have been compromised to some extent by the non-randomised study design (consecutive patients for each alternative were used) and the sample size (which was not determined by a power calculation). However, appropriate statistical analyses were conducted and p-values were reported. The patients were shown to be similar at baseline and none were lost to follow-up. The effectiveness data were reported in a disaggregated form which meant that a cost-consequences analysis was performed; this is a common approach for surgical procedures with several clinical outcomes of interest to the study.

Validity of estimate of measure of benefit
Due to the cost-consequences approach, the reader is referred to the comments in the 'Validity of estimate of measures of effectiveness' field (above).

Validity of estimate of costs
The authors provided a clear breakdown of the overall costs, as well as a clear explanation of the factors that influenced the higher cost of laparoscopic DN. For example, the operating time costs reduced with increasing experience in performing laparoscopic DN (later times in the study were lower than earlier procedures). The higher cost of disposable equipment was cited as the most significant factor between the two procedures. Appropriate statistical analyses were performed. Discounting was not performed, but this might have been appropriate given the short period of analysis.

Other issues
The authors made reference to other studies where relevant and other initiatives of this nature were undertaken in Australia. However, this was reported to be the first study of its type in New Zealand. It is the case that laparoscopic practices have been introduced without the benefit of randomised controlled trials. In terms of limitations, the authors mentioned that the cost to the community of prolonged convalescence in otherwise healthy donors was not assessed in the present study, but pointed to the results of a randomised controlled trial that showed no significant difference in global costs between laparoscopic DN and open DN. In terms of generalisability, the authors linked results in Australia with the New Zealand setting, but did not discuss the issue further.

Implications of the study
The results indicate that laparoscopic DN in New Zealand provides effective grafts for renal transplant recipients and is safe for the donor. The advantages of a shorter hospital stay and convalescence period for the donor are important benefits. The main disadvantage of laparoscopic DN is its higher cost in comparison with open DN, but this may reduce with surgical experience. Within the stated caveats of this study, the results are likely to be relevant and valid for the UK National Health Service. Future randomised controlled trials comparing laparoscopic DN with open DN may be difficult in terms of recruiting participants: the authors emphasised the importance of research on audit in assuring future quality control for both donors and recipients.

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