

Justification for Living Donor Kidney Transplantation

Date written: June 2007

Final submission: July 2007

Author:

GUIDELINES

No recommendations possible based on Level I or II evidence

SUGGESTIONS FOR CLINICAL CARE

(Suggestions are based on level III and IV evidence)

From the perspective of a potential kidney transplant recipient:

- **Kidney transplantation using either live or deceased donors, is worthwhile for an individual with renal failure if it significantly improves their quality of life and/or long-term survival.**
- **The potential benefit of live donor transplantation needs to be weighed up against the likely outcome with the alternative options. For the individual recipient, factors to consider include the eventual or continuing need for dialysis, the suitability and possible outcome of deceased donor transplantation, as well as the likely waiting time for a deceased donor organ.**
- **When compared to deceased donor transplantation, living donor kidney transplantation is associated with similar or even superior recipient outcomes. Living donor kidney transplantation therefore represents an excellent option for many individuals requiring renal replacement therapy.**
- **In Australasia, while there is a short supply of deceased donor kidneys, live donation can be justified if the risk of harm to an individual donor is very low and there is the likelihood of a benefit for the individual recipient.**
- **For some individuals (older recipients, those with multiple co-morbidities, the immunologically sensitised) live donor kidney transplantation may provide significant benefits over deceased donor transplantation. In some cases, live donation may be the only reasonable transplant option available.**
- **Pre-emptive (prior to dialysis) live donation is associated with excellent recipient outcomes and should be strongly considered in appropriate recipients who have suitable live donors.**

From the perspective of a potential kidney donor:

- To justify live kidney donation, the risk of harm to the individual donor should be very low and the potential benefit to the recipient should be significant with a reasonable likelihood of success. Each case needs to be assessed individually with the potential risks and benefits being carefully examined.
- There is a general lack of data regarding the overall safety and long term outcome for donors who fail to meet the strict criteria for suitability (eg. donors who are overweight, mildly hypertensive, smokers, and those with minor urinary abnormalities). As part of the informed consent process, it is essential that these potential donors be made aware of this lack of data regarding long term safety and outcomes.
- There is a very strong desire to donate in some individuals despite the risks involved (eg. parents, partners). These individuals may experience significant psychological and personal gains when donation has been successful in improving the life of their intended recipient. In these situations, special care is required during the informed consent process to ensure that donors are fully aware of the potential risks involved.
- Failure to donate (for eg. on medical or psychological grounds) may result in psychological harm (guilt, depression) and efforts must be made to provide or arrange appropriate support and education in these cases (see guideline on Psychological care of the Live Donor).
- Live donation can only be justified if general ethical principles arising from the assessment and care of the donor are not compromised. High ethical standards need to be maintained throughout the process and the rights of the donor should be strongly considered at all times. Important elements of this include:
 - **Donor autonomy**: Donors should be as fully informed as possible regarding the risks they are undertaking. Consent should be freely given by the donor, without pressure, coercion or inducement from medical personnel, the family, or the recipient. Donors should be seen separately, in the absence of the potential recipient and their family and their expectations and willingness should be gauged as early as possible in the assessment process.
 - **Confidentiality**: The principle of confidentiality implies that efforts will be made for this to be maintained between the donor and recipient. It is accepted that some information will always be shared (eg. CMV status, HLA issues, renal vascular anatomy and functional results) however the need for sharing information that is potentially sensitive in nature should be made explicit to each individual and consent obtained.
 - **Donor advocacy**: Independence between the clinicians or team members responsible for the donor, and those responsible for the recipient is highly recommended. This will help minimise concerns regarding a

conflict of interest between the care of the recipient and the care of the potential donor.

From the perspective of the transplant team:

- **There should be general agreement between team members regarding a decision to proceed with a particular live donor transplant. Where there is a conflict, additional independent assessments of donor/recipient suitability should be sought.**
- **The transplant team has rights and responsibilities also. Although donors and recipients may be fully aware of their risks and accept these, the team has the right to refuse to perform a transplant if it feels the risk is unacceptable. Once again, additional independent assessments of donor/recipient suitability should be sought in these circumstances.**

Background

The key objective of this guideline was to examine the evidence that the practice of living kidney donation in Australia and New Zealand, is an acceptable and justifiable option for those with kidney disease. In defining what is “acceptable”, the medical and psychological impact on the donor was seen to be of paramount importance as was the outcome for recipients, relative to their alternative options of dialysis and/or deceased donor transplantation.

To justify living donation as an option in the care of those with kidney disease the situation would ideally satisfy the following criteria:

- i) There would be no risk to the living kidney donor
- ii) The transplant recipient would benefit significantly
- iii) Dialysis or waiting for a deceased donor kidney would be much worse alternatives.

If all these conditions could be clearly met, then live donation would be very easily justifiable. Unfortunately, even in the simplest or least complicated of situations, none of these three criteria can be absolutely achieved or completely and accurately quantitated. In practice, if conditions go to a reasonable extent to satisfying the above criteria, then live donation has usually been deemed acceptable to potential donors, recipients and transplant teams.

From the perspective of the recipient, it is well established that transplantation is associated with significant benefits. Furthermore, live donation is clearly very successful and may present several benefits over deceased donor transplantation. There is little dispute over these “recipient” issues and data can be obtained from registries including ANZDATA and from cohort studies that strongly support these statements (even though it is not Level I or II evidence). Furthermore, in the presence of a significant shortage of deceased kidney donors and the likelihood of otherwise

waiting for several years for a deceased donor, it becomes very easy to justify live donor kidney transplantation – for the recipient.

When we consider the live donor, things are not quite as clear. Although live donation has been occurring for some decades and the practice is generally perceived to be very safe for most individuals in Australia, New Zealand and other developed countries, it is not without some risk. The direct benefit to the donor is either non-existent or often much harder to perceive. However, in some cases a benefit to the donor is clearly present and may be an important consideration (eg. the partner who will benefit their whole family by donating; or the parent who benefits psychologically from helping their child). In most cases the justification rests on the perception of safety for the donor. Is this safety clearly established - particularly long term? Probably - but one could argue that this is only with fairly strict adherence to the donor acceptance criteria. We must also consider, what degree of risk is “acceptable” for a donor as opposed to that for a recipient? As would be expected, the criteria for each are very different. For some donors that fall out of the usual limits for acceptance and are perceived as being “marginal”, ethical issues become a very major part of the assessment process, particularly when the desire to donate is very strong. The data helping us to justify live donation in these “marginal” situations is particularly lacking and requires much more study. The perceived safety of live donation in a general sense does not mean that it is necessarily safe for all potential donors.

Long-term follow up studies of donors are generally lacking and those that exist are often flawed to some extent (eg. lack of an appropriate control group, loss to follow up). The recent establishment of the ANZDATA Live Donor Registry should help significantly in further assessing long-term donor outcomes.

Search strategy

Databases searched: MeSH terms and text words for kidney transplantation were combined with MeSH terms and text words for living donors and combined with MeSH terms and text words for mortality, prognosis, graft survival, survival analysis and cohort studies. The search was carried out in Medline (1966 – September Week 2 2006).

Date of searches: 26 September 2006

What is the evidence?

Waiting list and number of kidney transplants performed

From the 2006 ANZDATA report (1), the number of patients on the kidney transplant waiting list at the end of 2005 was 1365 in Australia and 240 in New Zealand. In that year, the deceased donor transplants performed were 377 in Australia and 47 in New Zealand. Live donor transplants performed were 246 in Australia and 46 in New Zealand. Thus, in Australia and New Zealand in 2005, live donor transplants accounted for 41% of the total transplants performed.

By comparison 10 years earlier in 1995, although the number of deceased donor transplants performed was similar (348 in Australia and 70 in New Zealand), much fewer live donor transplants were performed (94 in Australia and 24 in New Zealand) accounting for only 22% of the total transplants performed (1).

This progressive increase in the number of live donor transplants performed is indicative of the overall success of kidney transplantation as well as the increased confidence in using live donors. However, it also reflects the continued shortage of deceased donor organs.

Recipient and Graft Survival - Australia and New Zealand

In Australia and New Zealand since 2000, 12 month primary deceased donor recipient survival has been approximately 96%. 12 month primary deceased donor graft survival has been approximately 92% (1). By comparison for live donation, 12 month primary live donor recipient survival has been approximately 99%. 12 month primary live donor graft survival has been approximately 96% (1).

Examining longer term results: recent 5 year primary deceased donor recipient survival has been approximately 87% with 5 year primary deceased donor graft survival being approximately 80%. By comparison for live donation, 5 year live donor recipient survival has been approximately 94% with 5 year live donor graft survival being approximately 86%.

These recipient and graft survival outcomes for both deceased and live donation are excellent. Unadjusted figures show superior outcomes for live donor transplantation relative to deceased donor transplantation.

Recipient and Graft Survival – recipient and donor factors influencing outcome

Various studies have assessed the success of live donor kidney transplantation relative to the donor source (eg. related, unrelated, spousal). In general, graft survival is excellent and equivalent regardless of whether the donor is related or unrelated (2-5). Unmatched, unrelated live donor transplants show similar or superior results compared to deceased donor transplants (2-5). Gjertson and Cecka analysed UNOS Registry data and found that 5 year graft survival rates for spousal, living unrelated and parental donation were all similar (75%, 72% and 74% respectively) (5). Graft half-lives were 14, 13 and 12 years respectively (5).

In considering transplantation for recipients over 60 years of age, Mandal et al performed an analysis of the USRDS data and compared primary deceased donor vs primary live donor transplantation for this subgroup (6). The outcomes for 5142 recipients over 60 years old were analysed. The findings were that live donation was always associated with a better outcome. Comparing deceased donor to live donor

renal transplant in this subgroup, the relative risk of death was 1.72 and the relative risk of graft failure was 1.64.

From the same USRDS based analysis, in considering transplantation for recipients aged 18 - 59 years, Mandal et al reported that living donor renal transplantation was also generally associated with better outcomes compared to deceased donor renal transplantation (6). However in some instances deceased donor renal transplant was associated with a better outcome. This occurred when all of the following criteria were met: recipient age 18-59 years; deceased donor age less than live donor age; deceased donor HLA match better than live donor HLA match. The impact of waiting on dialysis was not taken into account.

The impact of waiting time on the success of transplantation has been examined in several studies. Meier-Kriesche et al analysed USRDS data from 73,103 primary adult renal transplants performed between 1988-1997 (7). There was a progressive rise in the risk of death and of death-censored graft loss with increasing time on dialysis prior to transplantation. The increases in mortality risk for waiting relative to pre-emptive transplantation were as follows: 6-12 month wait, 21%; 12-24 month wait, 28%; 24-36 month wait, 41%; 36-48 month wait, 53%; >48 month wait, 72%. In another manuscript, Meier-Kriesche and Kaplan reported that waiting >2 years on dialysis for a live donor transplant, had the effect of reducing the graft survival to the same level as that for deceased donor transplants performed within 6 months of commencing dialysis (8). Using UNOS Registry data, Gjertson reported that pre-transplant dialysis time accounted for 12-13% of the variation seen in one year graft survival rates for both live and deceased donor transplantation (9). Also using UNOS Registry data, Kasiske et al reported that the relative risk of death or of graft failure, was lower in deceased donor and live donor recipients who were transplanted preemptively, when compared to those transplanted following dialysis commencement (10). Racial minority groups and those with a lower level of education were less likely to be transplanted preemptively.

With regards to recipients who are less than 18 years old, a study by Ishitani et al examined the success of living related transplantation in paediatric recipients using UNOS Registry data (11). When compared to pre-emptive transplantation, there was a relative risk of graft failure of 1.77 in those transplanted following the commencement of dialysis. Kennedy et al, used ANZDATA to examine graft outcomes in transplanted adolescents, and also reported improved outcomes with preemptive transplantation (12).

Patient Survival – comparison between dialysis and transplantation

Wolfe et al have compared the survival of subjects on the waiting list to those that received a primary deceased donor transplant (13). Standardised mortality ratios were derived from an analysis of 228,552 subjects on dialysis. 46,164 were on the waiting list of which 23,275 received a primary deceased donor transplant over a 7 year period of observation. The annual death rate for those on the waiting list was 6.3 per 100 patient-years. By comparison, those transplanted had a long-term annual death rate of 3.8 per 100 patient years. The improvement in relative risk of mortality was most pronounced for young, white recipients (20-39 years old) and for diabetics.

It should be pointed out that there was an initial elevation in the relative risk of mortality related to the early transplant period. The mortality risk was equal in the two groups by day 106 of follow up and improved in the transplanted group thereafter.

McDonald and Russ have reported similar findings using ANZDATA (14). An analysis of the period between 1991-2000, found an 80% lower long-term risk of mortality between those transplanted and those remaining on the waiting list.

Quality of Life – comparison between dialysis and transplantation

Cameron et al have performed a meta-analysis examining the effect of transplantation on overall quality of life (15). Successful kidney transplantation was associated with improved general well being and less distress, when compared to continued haemodialysis or peritoneal dialysis. There are several individual studies that have examined quality of life issues in more detail. Evans et al reported that 79.1% of transplant recipients describe near normal physical function compared to only 50% of dialysis patients (16). Mental function scores were also higher in transplant recipients. Studies by both Gorlen et al (17) and Laupacis et al (18) found that the quality of life improvements associated with transplantation were sustained long term. However, transplantation continued to effect quality of life relative to normal (18). This was attributed to side effects of immunosuppression, co-morbid conditions and the stress associated with the possibility of losing graft function.

Cost effectiveness of transplantation

A detailed analysis of the relative costs of dialysis and transplantation has been performed by Kidney Health Australia (19). Estimates for the cost of home or satellite based dialysis (haemodialysis and peritoneal) for an individual are approximately \$45,000-\$60,000 per year. Hospital-based haemodialysis is estimated to cost approximately \$83,000 per year. Although the initial cost of transplanting an individual is estimated to be relatively high (\$62,000 for the first year) the cost falls significantly thereafter (approximately \$11,000 per year, year 2 and onwards). The estimated costs associated with an individual live donor transplant are similar to those for an individual deceased donor transplant (19). A Canadian report estimated that transplanting an individual would result in savings of \$104,000 CAN over a 20-year period (20).

Overall safety for live donors

Only a brief account of the overall safety data will be summarised here. A much more detailed analysis of the literature regarding donor safety will follow in subsequent sections of these Live Donor Guidelines (see later).

By and large, live kidney donation is considered to be safe for the majority of healthy donors. This contention however, is based predominantly on large retrospective studies, which demonstrate that unilateral nephrectomy in healthy subjects is generally associated with a very low level of long-term risk (21-27). It is important to point out that the absence of any large prospective, well-controlled, long-term follow up studies on live donors is seen as a significant deficiency (27-29). Furthermore,

long-term studies regarding live donors with isolated abnormalities (for example hyperlipidaemia, mild hypertension, obesity) are also lacking and the long-term risks in these subjects remain particularly ill defined. It is hoped that the recently established ANZDATA Live Donor Registry, will help in further clarifying the true long-term donor outcomes in Australia and New Zealand.

With regards to the short-term risks, these are predominantly related to the surgical procedure. The risk of peri-operative mortality is generally regarded as being approximately 1 in 3,000 – a figure derived from large American surveys and several single centre reports (see later section for detailed account of the literature). Although Australian and New Zealand registry data is currently lacking, out of approximately 4,000 live kidney donations that have occurred in Australia and New Zealand to date, the transplant community is currently aware of one perioperative death (anecdotal report).

The risk of non-fatal major perioperative complication is also generally felt to be low, approximating 2-4% in most published series (see later section for a detailed account of the supportive literature). The majority of these complications have been haemorrhagic episodes, although a variety of other events have been reported including bowel obstruction, bowel injury, thromboembolic events, pneumothoraces, hernia development and rhabdomyolysis.

Summary of the evidence

Most of the data presented here comes from Registries and from large retrospective cohort studies. There is a lack of prospective long-term data regarding live donor safety, particularly in relation to consequences of donation in certain donor subgroups.

To summarise this guideline topic:

- Live kidney donation is currently justifiable in Australia & New Zealand based on:
 - i) The current overall success of kidney transplantation,
 - ii) The demand for donor organs, which far outweighs the supply from deceased donors,
 - iii) The detrimental effects of waiting on dialysis for several years,
 - iv) The apparent low level of risk to the majority of healthy donors.

- It is acknowledged that there is a need for more precise information regarding long-term risks faced by donors. This would ideally be obtained from prospectively collected live donor registry data.

What do the other guidelines say?

Several documents exist outlining similar issues:

NHMRC:

There are two recently published documents, which cover various aspects of the information presented here (28, 31). The first document - for health professionals - outlines important ethical principles, and details the rights and responsibilities of donors, health professionals and institutions (28). The second document - for potential donors - provides information regarding the assessment, a discussion of the risks and also outlines important ethical issues (31). Both discuss the rationale behind live kidney donation. These are available at: www.nhmrc.gov.au/publications/subjects/organ.htm

British Transplant Society / British Renal Association:

An extensive, 100-page document has been produced outlining similar issues to those discussed here (32). Full version of these British Live Donor Guidelines available at: www.bts.org.uk and at www.renal.org

The Canadian Council for Donation and Transplantation:

A 70-page document has been produced outlining similar issues to those discussed here (33). Full version of these guidelines available at: www.ccdt.ca

The Amsterdam Forum:

A short manuscript outlining similar issues to those discussed here (34).

Implementation and audit

Short and long term live donor outcomes need to be closely monitored.
Live donor transplant outcomes need to be closely monitored.
Deceased donor rates and transplant list waiting times, need to be close monitored.

Suggestions for future research

1. Assessment of long-term donor risks: Medical and Psychosocial. Prospective studies are required. The risks in various donor sub groups to be better assessed (eg. those with isolated abnormalities, eg. mild hypertension, obesity etc.)
2. Survey of Australian and New Zealand transplant centres regarding live donor outcomes to date. Known major adverse events to be collated and reported.
3. An examination of the barriers to donation for live donors in Australia and New Zealand (eg. financial, social, community attitudes and awareness).
4. Cost-effectiveness of kidney transplantation in Australia / New Zealand.
5. An examination of Australian and New Zealand transplant centre practice regarding live donor assessment (handling of ethical issues, informed consent process).

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Appendices

Table 1: Summary table of included studies

Study ID	N	Study methods	Data sources	Results	Main findings
Feheman-Ekholm et al 1997	430	Donor survival (Kaplan Meier analysis)	1964-1994, national registry, Sweden	Survival: donors 85%, expected survival (Hakulinens method) 66%	No long term risk to live kidney donors (better survival likely due to health persons accepted for donation)
Gjertson and Cecka 2000	117 239	Survival analysis (Kaplan Meier analysis)	1970-1998, United Network for Organ Sharing Renal Transplant Registry	5 year graft survival: spouse donor 75%, LRD 72%, parent donor 74%, cadaver 62%.	Living unrelated kidney donors provide excellent long-term results.
Goldfarb et al 2001	70	Donor renal outcome – cross sectional, test for creatinine, protein, albumin, serum creatinine, blood pressure, GFR, medical questionnaire)	1963-1975, single centre, US	24 hr creatinine clearance: 72% of pre-nephrectomy value, 24 hr protein excretion >0.15 gm/24hrs 19%.	Renal function well persevered after donor nephrectomy.
Kasiske et al 2002	38 836	Analysis of cadaver and living donor transplants (Chi-squared, logistic regression, Kaplan Meier analysis)	1995-1998, USRDS	Preemptive transplantation on delayed graft function compared with non preemptive transplantation: cadaver (8.4 vs 25.6%) and living donor (2.6 vs 6.1%).	Preemptive transplantation is associated with improved patient and graft survival.

Table 1: Summary table of included studies cont...

Study ID	N	Study methods	Data sources	Results	Main findings
Mandal et al 2003	31 909	Cox proportional hazards model to approximate risk associated with CRT, LRT.	1995-1998, United States Renal Data System Registry	Cadaveric vs live donor (younger patients): graft failure uncensored for death RR 1.49 (95%CI: 1.41-1.61), risk of death 1.64 (95%CI: 1.49, 1.82) Cadaveric vs live donor (elderly patients): graft failure uncensored for death RR 1.64 (95%CI: 1.41-1.89), risk of death 1.72 (95%CI: 1.45, 2.04)	Elderly recipients with an imminent LRT should not be offered CRT, CRT may be preferable in younger recipients.
Matas et al 2003	10 828	Survey sent to transplant centers listed with UNOS	1991-2001 171/234 UNOS-listed kidney transplant programs	Death from surgical complications 0.02%, mortality rate 0.03%.	Morbidity and mortality for living kidney donor nephrectomy is low
Najaran et al 1992	57	Comparison of donors and their siblings	20 years, single centre, US	Hypertension drugs: donors 32%, siblings 44%; proteinuria: donors 23%, siblings 22%	Peri operative mortality after living donor nephrectomy is low.
Ramcharan and Matas 2003	464	Living donor outcomes – cross sectional	1963-1979, single centre, US	Survival 89.9%, normal kidney function in surviving donors 99.2%	Most kidney donors have normal renal function >20 years follow up
Rizvi et al 2005	736	Retrospective analysis of living related kidney donation	2000-2004, single centre, Pakistan	Creatine clearance: 87% of pre-nephrectomy value, hypertension 10.3%, proteinuria > 150mg/24hr 24.3%, ESKD 1 donor.	Donor nephrectomy has minimal adverse effect on overall health status.

Table 1: Summary table of included studies cont...

Study ID	N	Study methods	Data sources	Results	Main findings
Simforoosh et al 2006	2155	Survival analysis (Kaplan Meier analysis)	1984 – 2004 transplant data, single centre, Iran	15 year graft survival: LRD 48.4%, LURD 53.2%; 15 year patient survival: LRD 73.9%, LURD 76.4%.	Long term results for living unrelated kidney transplantation comparable with living related kidney transplantation
Terasaki et al 1995	47206	Graft survival rates (Kaplan-Meier analysis)	United Network for Organ Sharing Renal Transplant Registry	3 year survival rate: spouse donor 85%, living unrelated 81%, parents 82%, cadaveric 70%.	High rate of graft survival rate in kidney donations from spouses and parents.
Voiculescu et al 2003	62	Transplant data (Fisher's exact test, Mann-Whitney test)	Transplant data from single centre, Germany	Acute rejection: LRD 52.2%, LURD 54.2%; delayed graft function: LRD 15.8%, LURD 4.2%; number of patients with rejection: LRD 52.5%, LURD 54.2%	Kidney transplantation from emotionally related living donors is a valuable option.