GUIDELINES FOR LIVING DONOR KIDNEY TRANSPLANTION IN HIGH-RISK ADULT RECIPIENTS

Introduction

In response to concerns about variations in practice and policy about transplantation of recipients deemed to be of “high risk”, of kidney transplants from living related donors, the British Transplantation Society (BTS) asked a small group of clinicians, nurses and patients to consider the issues and propose guidelines. This group met on two occasions. The composition of the group and the method of developing the Guidelines are described in the Appendix. The Renal Association was represented on this group and the Guidelines have been reviewed by its Clinical Affairs Board. The BTS approved this final version of the Guidelines for publication in May 2008. The views of the National Kidney Federation have also been sought.

There are three particular reasons that issuing of guidelines will be helpful.

1. High risk patients should not be denied consideration of the option of transplantation because of local policies or prejudices. Patient survival is superior in subjects treated by transplantation compared to those treated by dialysis.
2. The overall results of units undertaking transplantation of high risk recipients will be worse than average. This should be recognised and results described with, and without this subset.
3. Failure of a living related donor transplant, either graft loss or death of the recipient, is always deeply disappointing and has a marked impact on the donor and the clinical team. When risk is higher all parties must be prepared by prior recognition of the possibility of an adverse outcome.

Definition:

At one extreme, a high risk candidate could be defined as one who would not, on utilitarian grounds, be considered suitable for the deceased donor waiting list.

For the purposes of this guideline a high-risk recipient is defined as a potential recipient of a kidney transplant who is at a ***significantly*** higher risk of death, complications or graft failure because of pre-existing co-morbidity or immunological status. Statistically this would be an outcome that is outside the 95% CI for graft and patient survival for the UK. We recognise that there is no agreed precise definition of high risk; nor are there robust clinical criteria or outcome data to inform the definition. The BTS is at present developing a definition but until then reliance on the judgement of transplant teams will have to suffice

Measuring Success

We recognise that the expectations of patients and the views of donors will vary. However transplantation should only proceed if there is a realistic expectation of the patient surviving with a functioning transplant for at least 2 years. We do not believe that the cost of the procedure (compared to dialysis treatment) or the risk to the donor could be justified if survival of the graft or the recipient was any less.

Pre-transplant agreement/understanding.

There must be a clear agreement between the clinical team and the donor and recipient of their expectations of the procedure, a realistic prediction of possible success, and recognition of the risks of failure (death of the recipient or failure of the graft). Although such agreements are applicable to living donation in general they are particularly important for the high risk recipient group in whom expectations will be case specific. Although there is a paucity of information on the balance of risks and benefits in "high risk" recipients, the clinical team should do their best to describe the best and worst case scenarios. The timing and content of these discussions must be documented in the medical notes.

The following process is recommended:

- The multiprofessional clinical team should first establish what the recipient wants and expects from the transplant in terms of quality and extension of life.
- Consideration of the option of living donor transplantation should be started early enough for the procedure to be performed pre-emptively i.e. before dialysis becomes essential. The trigger for initiation of discussion will be at an eGFR of ~20ml/min but this will vary, depending on the rate of decline of renal function, and the time at which Stage 5 CKD will be reached.
- The risks and benefits of living donor transplantation should be described but so should the other options including: maximal conservative care of Stage 5 CKD (neither dialysis nor transplantation); reliance on dialysis; transplantation from a deceased donor.
- The details of the final understanding must be recorded and signed by both the recipient and the donor, and to be compliant with the NHS consent process, the consultant transplant surgeon taking responsibility for the recipient operation. Copies of the agreement which will be filed in the notes must be given to both the donor and the recipient with the consent form. This agreement would serve as part 1 of the consent for transplantation surgery in the two-part consent process.
- If an agreement cannot be achieved within a particular transplant centre e.g. because of differences in opinion on the degree of risk, the option of referral to another transplant centre for a second opinion should be discussed with the potential recipient and donor.

- There should be no disincentive to the referral of high risk recipients to transplant centres with greater experience of managing such patients.

Process Standards

- In the course of pre-dialysis counselling the option of living donor transplantation should be discussed with all patients unless it is unlikely that the criteria for success (see above) could be achieved.
- A *decision* about transplantation should be reached within three months of the initiation of discussion.
- The procedure should be performed pre-emptively whenever possible.

Further recommendations

It is recommended that these guidelines are reviewed 3 years following implementation.

The BTS should through UK Transplant and the Renal Registry conduct a prospective audit of outcomes in high risk patients undergoing living donor transplantation.

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APPENDIX

Developing Guidelines for High-Risk Recipients of Living Donor Kidney Transplants: Background Paper

Participants in the Consensus Meeting 3/10/2006

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Ms Rose Elwell
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Ms Andrea Louis
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APPROACH AND METHODOLOGY

A Consensus Meeting was planned as a joint initiative between the BTS and RA and in conjunction with the Kidney Disease Modernisation Initiative (KDMI) funded by Guy's & St. Thomas' Charity. The meeting mirrored a format that has been successful within the KDMI and representation from the key stakeholders, healthcare professionals and previous living donors and recipients of living donor kidney transplants and their family members were invited in order to reflect a range of opinion. (Appendix 1). The objective of the meeting was to produce a draft document for wider consultation and debate at the meeting of the Living Donor Renal Transplantation Forum in Bristol on Wednesday December 6th 2006.

Prior to the meeting, a contemporary literature review and evidence base was collated and circulated to all participants to inform the discussion (Appendix 2). This included consultation with UK Transplant and The Renal Registry to establish the availability of UK data to compare with worldwide practice. This highlighted some key issues

- There is little comparative UK data available on outcome for patients who are not listed for deceased donor transplantation but who receive a living donor transplant. There is also little comparative UK data for patients who remain on dialysis and are not on the transplant list.

- There is limited UK data available about the benefits of pre-emptive kidney transplantation.

- There is data that stratifies risk of death for patients who remain on dialysis (1)

Participants were divided into three facilitated discussion groups for the morning session

1. Healthcare professionals (HCP)

2. Transplant recipients and family members (TR)

3. Living donors and family members (LD)

Discussion within each group focused upon the same key questions, viewed from the perspective of the constituency represented within each group

1. What do/did you need to make the decision to proceed to living donor transplantation?

2. What support and information did you need/should provide to support and inform the decision-making process?

3. What level of risk for the recipient is acceptable?

4. What equals success?

A spokesperson was nominated from each group to feedback in a plenary session.

Key themes across all groups were identified and further discussed in mixed focus groups with representation from each constituency. The outcome of these discussions would provide the basis for establishing some key recommendations. The key themes identified were

1. Pre-transplant agreement between healthcare professionals and the recipient

2. Information and support: How? When? Where? By Whom?

3. Measuring success

LIMITATIONS

Existing evidence base to inform discussion.

The patient groups were smaller than anticipated and a degree of bias may exist as each donor or recipient only represents as sample of one and each scenario is unique.

KEY ISSUES

The structure of the meeting encouraged each constituent group to discuss and develop opinion independently prior to sharing ideas with the wider plenary group. This highlighted a number of key differences between the three groups and variations in practice between different transplant centres. The key issues could be broadly categorised as follows:

1. Equity of Access

In the context of the high-risk recipient, there was disparity in

- The practice of listing patients for transplantation and discussion about the options that might be available, either deceased or living donation. The healthcare professionals agreed that approximately 50% of patients on renal replacement therapy in the UK may not be listed for transplantation.

- The practice of listing patients on the deceased donor list if a living donor kidney transplant is anticipated.

- The provision, timing and cascade of information for patients and their families in order to facilitate decision-making and optimise transplant planning. This was often limited by the healthcare professional's view about viability rather than offering all patients the same information and allowing them +/- the family to make a decision.

- The HCP group as to whether all patients who may need renal replacement therapy should be given information about living kidney donation.

- The practice of referring recipient/donor pairs to another centre with greater expertise and capability if considered appropriate to do so.

2. Criteria for Success

- A successful outcome following transplantation is difficult to define and is viewed differently by each constituent group.

- Perception of a successful outcome is influenced by personal experiences and individual situations.

- Donors and recipients are prepared to accept a greater level of risk than healthcare professionals. Within reasonable economic constraints, both donors and recipients will accept a higher risk of transplant failure and death in the recipient than healthcare professionals.

- Donors were unanimously agreed that, having made the decision to donate, it is for the recipient to decide if he/she is prepared to take the risk to proceed to transplantation. In their view, success is defined by the recipient's perception of a good outcome.

- Recipients have a range of expectations about acceptable risk depending upon individual circumstances. Influences include comparative quality of life on dialysis, experience and cause of previous transplant failure and family/lifestyle issues.

- Recipients have anxieties about the welfare of their donors but respect the autonomy of their decision to donate, even in the context of higher risk scenarios.

- There was a general consensus of opinion amongst recipients that a year of good health, excluding the initial period of multiple clinic visits, would constitute a successful outcome for the majority. The time taken to achieve this goal may differ between individual patients according to their pathway to recovery.

- Healthcare professionals expressed higher expectations of acceptable outcome than donors and recipients with greater emphasis upon longevity of graft and patient survival rather than quality of life, particularly if this period is 'time limited' either by graft failure or patient death.

- Healthcare professionals have competing considerations that extend beyond individual patient outcome when measuring criteria for success. These include local expertise and capability and interpretation of outcome data that reflects upon the morale and performance of individual transplant centres and impacts upon the viability and external perception of the programme.

3. Process Management

- There was a clear consensus that living donor transplantation should be addressed at an early stage in the process of planning renal replacement therapy for high-risk patients.

- In order to offer realistic choices for both patients and healthcare teams, HCPs have a part to play in facilitating referral of recipient/ donor pairs to another centre with greater expertise and capability if it is considered appropriate (see above).

- There was agreement that the management of expectation and the transplant process itself should be a joint enterprise between the recipient and

healthcare team. Transparency and clarity were considered to be important in achieving a realistic agreement between both sides about reasonable outcome prior to transplantation. Protocols for managing challenging transplant scenarios were considered helpful and reassuring for patients, particularly if they formed part of the discussions prior to transplantation. These aspects were considered to be part of an on-going consent process on behalf of the recipient to proceed to transplantation.

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