GUIDELINES

a. We recommend that diabetes should not on its own preclude a patient from being considered for kidney transplantation (1D).
b. We recommend that potential renal transplant candidates with diabetes are screened for cardiovascular disease in accordance with the “Cardiovascular Disease” sub-topic guidelines (1D).
c. We suggest that renal transplant candidates with diabetes be considered for preemptive transplantation due to better patient and graft survival compared to transplantation after the commencement of dialysis. (2C)
d. We suggest that, following screening for cardiovascular disease, Type 1 diabetic transplant candidates should be considered for referral for simultaneous pancreas and kidney transplantation (SPK) or live donor renal transplantation. (2B)

UNGRATED SUGGESTIONS FOR CLINICAL CARE

The “Cardiovascular Disease” sub-topic should be referred to for all renal transplant candidates with diabetes.

- Kidney transplantation generally offers longer survival than remaining on dialysis for patients with diabetes who have historically been wait-listed for transplantation. (ungraded)
- Diabetes is a multi-system disease, and some of the complications of diabetes can directly impact on the success of transplantation:
  - Consideration should be given to the possibility of diabetic enteropathy, which can reduce the oral absorption of immunosuppressive medications. Patients should be monitored carefully for immunosuppressive drug concentrations and for rejection. (ungraded)
  - Consideration should be given to the urological implications of potential neuropathic bladder. (ungraded)

IMPLEMENTATION AND AUDIT

Very general audit would be feasible through ANZDATA, but would not allow detailed case analysis without much more detailed information.

BACKGROUND

Diabetes mellitus is an increasingly common disease in Australia and New Zealand. It is an important cause of renal failure, and a common comorbidity among dialysis and transplant patients. It is associated with increased rates of cardiovascular disease and premature mortality. These factors make diabetes an important consideration in the assessment of patients for renal transplantation. The “Cardiovascular Disease” guidelines present recommendations and suggestions in relation to screening and testing for cardiovascular disease.

Suitability for transplantation is a difficult and sometimes imprecise concept. Studies to demonstrate which patients will live longer after a transplant, compared to remaining on dialysis are difficult. Randomization is impossible, inherent biases are inevitable and transplant outcome data can only be
obtained for patients who are being transplanted under current acceptance protocols. Furthermore, the potential for an improved quality of life means that there are patients who would enthusiastically embrace an opportunity to attempt transplantation even if the statistics were against their success.

This guideline reviews the available data about the impact of diabetes mellitus on the outcomes of renal transplantation. The most frequently studied outcomes are patient and graft survival. This guideline will not specifically look at the cardiac assessment of these patients, which will be covered in another section.

SEARCH STRATEGY

Databases searched: Databases searched: MeSH terms and text words for kidney transplantation were combined with MeSH terms and text words for Type 1 Diabetes Mellitus, Type 2 Diabetes Mellitus, and then combined with MeSH terms and text words for prognosis, survival analysis, graft rejection, graft survival, mortality, incidence and diagnosis. The search was carried out in Medline (1950 – September Week 4, 2009). The Cochrane Renal Group Trials Register was also searched for trials not indexed in Medline.

Date of search: May 2011

WHAT IS THE EVIDENCE?

There is little prospect of any studies that will accurately measure the benefit or otherwise of renal transplantation compared to remaining on dialysis, for diabetic patients. Prospective randomised trials are impractical, and retrospective analyses are potentially limited by the under-diagnosis of diabetes among wait-listed patients [1], and by differences between wait-listed patients who either do or do not receive transplants [2].

The most informative studies available are a number of retrospective cohort studies, taken from a number of databases, that compare patients who are transplanted with those who are wait listed, but not transplanted, and/or those who are not waitlisted. [3-5] A systematic review of these studies [6] these studies demonstrate that across a wide range of subgroups, including patients with diabetes, survival is better for patients who are transplanted, than for patients who remain on dialysis. Clearly these studies have considerable potential for bias, and only allow analysis of transplant outcomes for patients who are actually transplanted under contemporary or historical acceptance processes. A single centre case-control study of 46 type 2 diabetics transplanted between 1978 and 1997 showed that renal transplantation conferred a significant survival advantage compared with remaining on dialysis [3].

An early analysis from the UNOS Registry [4] showed that for patients receiving a kidney alone transplant between 1991 and 1995, overall 5-year patient survival was 60%, but the figure was just 54% for diabetic recipients. A multivariable registry analysis of American diabetics transplanted between 1995 and 2002 showed that donor and recipient ages have increased with time, and that both are associated with poorer patient and graft outcomes [5].

There are numerous, single centre, retrospective reviews of outcome data from renal transplants performed in diabetic patients. One such review from Malmo, Sweden [6] showed similar rates of cardiovascular and cerebrovascular death in their 189 diabetic renal transplant recipients, compared to non-diabetic recipients transplanted after 1988.

Kronson et al showed that at 5 years, transplanted type 2 diabetics had significantly lower patient and graft survival than either type 1 diabetics or non-diabetic patients over 50 years old [7].

A Kuwaiti study showed 10-year survival was significantly worse in diabetics (58%) compared to non-diabetics (86%), mainly as a result of cardiovascular disease and infections [8]. Ten-year death-censored graft survival was similar, 76% v 80%.

Orsenigo et al showed that the 5-year patient survival was lower in diabetics who received a kidney only (60%), compared to non-diabetics (82%) or diabetics who received a SPK (82%) P = 0.02 [9]. There was less of a difference in death-censored graft survival at 5 years between non-diabetics (82%), diabetics after SPK (77%) and diabetics after kidney only (68%). In a multivariate analysis [10], the
same unit showed that the survival of transplanted non-diabetics or diabetics who received a SPK, was significantly better than diabetics who received a kidney alone.

Two further retrospective analyses showed small differences in patient and graft survival favouring non-diabetics over diabetics [11, 12], but failed to demonstrate statistical significance other than for 10-year patient survival [12].

A number of retrospective case-control studies have been performed. These are generally small and despite an overall trend of lesser outcomes in diabetic patients across most of the studies, they generally lack the power to show significant differences in outcome. One such study of 78 type 1 diabetics with matched controls showed lower patient, graft and death-censored graft survival at 5 and 10 years for type 1 diabetics, but because of the small numbers, only the 10-year patient survival was significantly different [13].

A similarly small case-control study of 64 type 2 diabetics with matched controls, showed lower patient, graft and death-censored graft survival at 5 years for the type 2 diabetics, but only the graft survival reached statistical significance18.

A case-control study of both type 1 and type 2 diabetics with controls showed lower patient and graft survival for type 1 and 2 patients, at either 1 or 3 years [14]. Age was a further independent predictor in this study.

A further case-control study of 77 type 1 diabetics, compared to non-diabetic controls showed that diabetes carried an odds ratio of 4.38 for death, and of 4.47 for cardiovascular death [15].

A case control study of 78 type 1 diabetics matched with 78 non diabetic kidney transplant recipients, showed a significantly (P<0.05) lower 10 year patient survival of 86% in diabetics compared to 95% in the controls. Patient 5-year survival and graft survival at 5 and 10 years were not significantly different between diabetic recipients and the control group. [16]

A case-control series of 35 type 1, and 20 type 2 diabetics showed that the diabetics had more rejection (P = 0.049), more delayed graft function (P = 0.03), better patient survival (P = 0.03) and better graft survival (P = 0.04) [17].

A cohort study of 798 diabetic, renal transplant recipients in Vienna demonstrated that maximal glucose level (but not HbA1c), was predictive of patient survival; none of the studied parameters of glycaemic control were predictive of death censored graft survival [23].

Unpublished data from ANZDATA for the recipients of first deceased donor renal transplants in Australia and New Zealand from 1998-2003, shows that for the recipients of first deceased donor renal transplants, 5-year patient and graft survival are reduced in diabetic recipients (see Table 1) Whilst the 5-year unadjusted graft survival for all first deceased donor transplants was 80.0%, it was 65.7% for type 2 diabetics. There was a trend towards graft survival being further modified by the presence or absence of vascular disease. For diabetics without vascular disease the 5-year graft survival was 69.2%, but for those with vascular disease, it was 60.5%.

A number of different analyses have been undertaken of the UNOS Registry. Reddy et al. looked at 18,549 patients with type 1 diabetes mellitus transplanted between 1987 and 1996 [24]. They showed that the 8 year survival of patients who received a simultaneous pancreas-kidney transplant (SPK) was superior to that of patients who received a cadaveric transplant (72 v 55%), but that the benefit was reduced when adjustment was made for donor and recipient factors. They also found no difference in the 8 year survival of patients undergoing either SPK transplantation or live donor kidney transplantation (72 v 72%), with the SPK patients having a higher early mortality, and the live donor recipients a higher late mortality.

Bunnapradist et al. looked at 6016 patients from the UNOS database transplanted between 1994 and 1997 [25]. They also found that patients did better after SPK compared to deceased donor renal transplantation alone, but found that the short term benefit in renal allograft and patient survival could be explained by favourable donor and recipient factors in the SPK transplants. In the most recent of these analyses, Young et al. looked at type 1 diabetic patients transplanted between 2000 and 2007 [26]. On multivariate analysis they found that over 72 month follow-up, live donor renal transplantation was associated with lower adjusted risks of graft failure (HR 0.71; 95% CI 0.61 to 0.83) and patient
death (HR 0.78; 95% CI 0.65 to 0.94), compared with SPK transplantation. Live donor transplantation was also associated with a shorter period of time on dialysis.

A smaller series of 101 type 1 diabetic patients, by Mohan et al. also showed a survival advantage for SPK transplantation compared to deceased donor, kidney alone transplantation [27]. Rayhill et al. have also shown while the survival for 379 recipients of SPK transplants were better than 296 deceased donor renal transplants, they were similar to the outcomes of 130 live donor renal transplants [28].

Diabetes is a multi-system disease, and some of the complications of diabetes can directly impact on the success of transplantation. Diabetic gastroparesis can slow gastric emptying, and delay or reduce the absorption of immunosuppressive medication [18, 19]. This could potentially increase the risk of rejection in certain individuals. A small study of 49 diabetics [20] showed a rejection rate of 16.3% versus 7.1% in non-diabetics (P = 0.11; ns). Furthermore, diabetes can lead to neuropathic changes affecting the bladder, with the potential for post-transplantation urological problems [21].

**SUMMARY OF THE EVIDENCE**

Numerous studies suggest that patients with either type 1 or type 2 diabetes have lower patient and graft survival than non-diabetic recipients. This reduction in graft survival is less pronounced if death-censored graft survival is considered. There is a higher rate of cardiovascular death in particular among diabetic renal transplant recipients, and this probably explains a significant part of the difference in outcomes.

Diabetes is a multi-system disease, and some of the complications of diabetes can directly impact on the success of transplantation. It makes intuitive sense to screen diabetic transplant candidates carefully for evidence of cardiac or other vascular disease, either to inform peri-operative risk and management, to allow pre-emptive treatment, or to exclude on the basis of poor outcome (refer to “Cardiovascular Disease” guidelines).

Patients with Type 1 diabetes mellitus are best served where possible, by simultaneous pancreas and kidney transplantation (SPK), or by live donor renal transplantation.

**WHAT DO THE OTHER GUIDELINES SAY?**

**Kidney Disease Outcomes Quality Initiative:** No recommendation.

**UK Renal Association:** No recommendation.

**Canadian Society of Nephrology:** No recommendation.

**European Best Practice Guidelines:**

1. **I.5.3 Guideline N. Recurrence of Diabetes Mellitus:** Renal Transplantation should be considered as the treatment of choice for many patients with diabetes mellitus despite the almost inevitable histological recurrence a few years after renal transplantation. However, overt clinical nephropathy leading to late graft loss occurs in only a minority of patients. (Evidence Level B)

2. **I.5.5 Comorbid Conditions – Diabetes Mellitus:**
   - Kidney Transplantation should be considered as the first therapeutic choice for all suitable patients with end-stage renal disease (ESRD) due to diabetes mellitus, because kidney transplantation is able to significantly extend survival compared to dialysis. (Evidence Level B)
   - Diabetic ESRD patients should be considered for an early and pre-emptive transplantation of either a simultaneous pancreas-kidney transplantation (SPK), a living related donor graft, or an early cadaver graft early when residual glomerular filtration rate (GFR) decreases to <20 mls/min. (Evidence Level B)
   - Diabetes mellitus should be considered as a serious co-morbid condition affecting transplant success and patient morbidity/mortality, mainly because of increased cardiovascular and infectious risks. (Evidence Level B)
   - Therefore, a thorough evaluation of diabetic transplant candidates is recommended with particular attention to the cardiovascular risk. (Evidence Level C)

**International Guidelines:** No recommendation.
SUGGESTIONS FOR FUTURE RESEARCH

Conduct an analysis of the predictive value of pre-operative comorbidities and risk factors for renal transplant graft and patient survival in Australia. This should include the impact of diabetes, and the interaction of other comorbidities with diabetes.

CONFLICT OF INTEREST

Scott Campbell has no relevant financial affiliations that would cause a conflict of interest according to the conflict of interest statement set down by CARI.

REFERENCES

APPENDICES

Table 1. 5 Year Patient and Graft Survival from ANZDATA (95% Confidence Intervals in parentheses)

<table>
<thead>
<tr>
<th></th>
<th>Graft Survival</th>
<th>Patient Survival</th>
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</thead>
<tbody>
<tr>
<td>All DD1 transplants</td>
<td>80.0% (78.2 – 81.6%)</td>
<td>88.4% (87.0 - 89.7%)</td>
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<tr>
<td>Non-Diabetic</td>
<td>81.4% (79.6 – 83.1%)</td>
<td>89.8% (88.3 – 91.1%)</td>
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<tr>
<td>Type II Diabetes</td>
<td>65.7% (58.5 – 71.9%)</td>
<td>74.1% (67.2 – 79.7%)</td>
</tr>
<tr>
<td>Diabetes + any Vascular Disease</td>
<td>60.5%</td>
<td>69.1% (57.1 – 78.4%)</td>
</tr>
<tr>
<td>Diabetes but no Vascular Disease</td>
<td>69.2%</td>
<td>77.0% (67.5 – 84.0%)</td>
</tr>
</tbody>
</table>

Table 2. Characteristics of included studies

<table>
<thead>
<tr>
<th>Study ID (author, year)</th>
<th>N</th>
<th>Study Design</th>
<th>Setting</th>
<th>Participants</th>
<th>Outcomes</th>
<th>Results</th>
<th>Follow up (months)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hergesell and Zeier, 2003 [1]</td>
<td>377</td>
<td>Retrospective review</td>
<td>Single centre</td>
<td>377 patients on the waiting list, 9 with Type 1 diabetes and 37 with Type 2 diabetes.</td>
<td>How many diabetics are actually listed?</td>
<td>Only 20 of 37 with Type 2 diabetes were initially listed as such.</td>
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<tr>
<td>Kyllonen and Salmela, 2004 [2]</td>
<td>405</td>
<td>Retrospective review</td>
<td>Single centre</td>
<td>Are transplanted patients the same as non-transplanted, wait-listed patients?</td>
<td></td>
<td>They are not the same; those not transplanted have more diabetic complications.</td>
<td></td>
<td></td>
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<tr>
<td>Cecka, 1996 [4]</td>
<td></td>
<td>Retrospective review</td>
<td>UNOS database</td>
<td>1991-1995</td>
<td>1 and 5 year graft survival</td>
<td>1 year graft survival: All deceased donors = 84% Diabetics = 81% 5 year graft survival: All deceased donors = 60% Diabetics = 54%</td>
<td></td>
<td>Old data</td>
</tr>
<tr>
<td>Waki, 2004 [5]</td>
<td>99933</td>
<td>Retrospective review</td>
<td>US database</td>
<td>Patients transplanted from 1995-2002.</td>
<td>Multi-variable analysis</td>
<td>Donor and recipient ages for Type 1 and Type 2 diabetic patients have increased over the years. These ages were associated with lower patient and graft outcomes in type 1 and Type 2 diabetics.</td>
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<td>Study ID (author, year)</td>
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<tr>
<td>Kronson et al, 2000 [7]</td>
<td></td>
<td>Retrospective review</td>
<td>Single centre, University of Minnesota</td>
<td>90 Type 2 diabetics.</td>
<td>5 year patient survival</td>
<td>5 year patient survival for Type 2 diabetics = 61%</td>
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<td></td>
<td>5 year graft survival for Type 2 diabetics = 53%</td>
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<td></td>
<td>Graft survival was lower than Type 1 diabetics or non-diabetics who were over 50</td>
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</tr>
</tbody>
</table>
| Nampoory et al, 2002 [8] | 631 | Retrospective review    | Single centre in Kuwait                      | 79 with pre-transplant diabetes 117 with post-transplant diabetes (excluded from comparison) 435 non-diabetics | Patient survival and death-censored graft survival.                      | 1 Year patient survival: Non-diabetics = 97%  
Diabetics = 84%                  |                   |                             |
|                         |     |                         |                                              |                                                                              |                                                                           | 5 Year patient survival: Non-diabetics = 93%  
Diabetics = 65%                  |                   |                             |
|                         |     |                         |                                              |                                                                              |                                                                           | 10 Year patient survival: Non-diabetics = 86%  
Diabetics = 58%                  |                   |                             |
|                         |     |                         |                                              |                                                                              |                                                                           | 10 Year death-censored graft survival: Non-diabetics = 80%  
Diabetics = 76%  
P=ns                  |                   |                             |
After SPK = 82%  
After kidney = 60%  
P = 0.02                  |                   |                             |
|                         |     |                         |                                              |                                                                              |                                                                           | 5 year graft survival: Non-diabetics = 82%  
After SPK = 77%  
After kidney = 68%                  |                   |                             |
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<th>Follow up (months)</th>
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<tbody>
<tr>
<td>Orsenigo et al, 2005 [10]</td>
<td>361</td>
<td>Retrospective review</td>
<td>Single centre</td>
<td>189 diabetics with SPK, 81 diabetics receiving a kidney only and 91 non-diabetics receiving a kidney only.</td>
<td>Multi-variable analysis</td>
<td>Survival was significantly better in non-diabetics (0.002), or diabetics receiving a SPK, compared to diabetics who received a kidney alone.</td>
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<tr>
<td>Romming et al, 2006 [12]</td>
<td>498</td>
<td>Retrospective review</td>
<td>Single centre</td>
<td>68 transplants in 62 patients with diabetes. 498 transplants in 399 patients without diabetes.</td>
<td>Patient and graft survival at 1, 5 and 10 years.</td>
<td>1 Year patient survival: Non-diabetics = 91% Diabetics = 88% P = ns 5 Year patient survival: Non-diabetics = 73% Diabetics = 68% P = ns 10 Year patient survival: Non-diabetics = 52% Diabetics = 31% P &lt; 0.05 1 Year graft survival: Non-diabetics = 72% Diabetics = 72% 5 Year graft survival: Non-diabetics = 52% Diabetics = 52% 10 Year graft survival: Non-diabetics = 33% Diabetics = 27%</td>
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<tr>
<td>Revanur et al, 2001 [13]</td>
<td>939</td>
<td>Retrospective review</td>
<td>Single centre in Glasgow</td>
<td>First grafts in the cyclosporine era 1984-1999. 66 (7%) with renal failure due to Type 1 diabetes. 7 (0.8%) with renal failure due to Type 2 diabetes. 10 (1.1%) with co-</td>
<td>Patient survival</td>
<td>Mean survival was: PTDM = 10.3 years Type 1 = 8.4 years Type 2 = 3.7 years Non-diabetic = 12.8 years</td>
<td></td>
<td>Very few diabetics, so difficult to draw conclusions.</td>
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<td>Study ID (author, year)</td>
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<tr>
<td>Boucek et al, 2002 [22]</td>
<td>128</td>
<td>Retrospective case-control study</td>
<td>Single centre</td>
<td>64 Type 2 diabetics With 64 matched controls.</td>
<td>Patient, graft and death-censored graft survival.</td>
<td>1 Year patient survival: Non-diabetics = 84% Type 2 diabetics = 85%</td>
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<td>Type 2 diabetics:</td>
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<td>5 Year patient survival: Non-diabetics = 74% Type 2 diabetics = 69% P = 0.43</td>
<td>1 Year graft survival: Non-diabetics = 73% Type 2 diabetics = 77%</td>
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<td>Too few patients.</td>
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<td>5 Year graft survival: Non-diabetics = 61% Type 2 diabetics = 54% P = 0.19</td>
<td>1 Year death-censored graft survival: Non-diabetics = 82% Type 2 diabetics = 84%</td>
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<td></td>
<td>5 Year death-censored graft survival: Non-diabetics = 77% Type 1 diabetics = 77% P = 0.52</td>
<td></td>
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</tr>
<tr>
<td>Fernandez-Fresnedo, 2002 [14]</td>
<td>107</td>
<td>Retrospective case-control study</td>
<td>Single centre</td>
<td>31 with Type 1 diabetes. 25 with Type 2 diabetes. 51 age matched non-diabetics with nephrosclerosis.</td>
<td>1 and 3 year graft and patient survival.</td>
<td>1 Year patient survival: Non-diabetics = 88% Type 1 diabetics = 73% Type 2 diabetics = 69%</td>
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<td>3 Year patient survival: Non-diabetics = 80% Type 1 diabetics = 69% Type 2 diabetics = 60%</td>
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<td>Study ID (author, year)</td>
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<td>Study Design</td>
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<td>Kim et al, 2001[16]</td>
<td>156</td>
<td>Retrospective case-control study</td>
<td>Single centre</td>
<td>78 Type 1 diabetics with 78 matched non-diabetics.</td>
<td>Patient and death-censored graft survival at 5 and 10 years.</td>
<td>5 Year patient survival: Non-diabetics = 97% Type 1 diabetics = 86% 10 Year patient survival: Non-diabetics = 95% Type 1 diabetics = 74% P&lt;0.05 5 Year graft survival: Non-diabetics = 80% Type 1 diabetics = 71% 10 Year graft survival: Non-diabetics = 72% Type 1 diabetics = 58% P=ns</td>
<td></td>
<td>Trends limited by small numbers.</td>
</tr>
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<td>Study ID (author, year)</td>
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<td>Study Design</td>
<td>Setting</td>
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<td>Follow up (months)</td>
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<tr>
<td>Bittar et al, 2006 [11]</td>
<td>523</td>
<td>Retrospective review</td>
<td>Single centre</td>
<td>35 diabetics and 488 non-diabetics</td>
<td>Graft survival at 1, 3 and 5 years.</td>
<td>1 Year graft survival: Non-diabetic = 87.6% Diabetic = 82.7% 3 Year graft survival: Non-diabetic = 79.0% Diabetic = 70.9% 5 Year graft survival: Non-diabetic = 72.5% Diabetic = 63.0%</td>
<td>3.3 +/- 1.5 years</td>
<td></td>
</tr>
<tr>
<td>Einollahi et al, 2008 [17]</td>
<td>222</td>
<td>Retrospective case-control study</td>
<td>Single centre</td>
<td>111 diabetics and 111 random non-diabetic recipients. 36 had Type 1 diabetes, 20 had Type 2 diabetes and 55 had post-transplant diabetes.</td>
<td>Acute rejection, delayed graft function, patient and graft survival.</td>
<td>Diabetic patients had: More acute rejection; ( P = 0.049 ) More delayed graft function; ( P = 0.03 ) Worse patient survival; ( P = 0.03 ) Worse graft survival; ( P = 0.04 )</td>
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<tr>
<td>Schiel et al, 2005 [20]</td>
<td>302</td>
<td>Retrospective review</td>
<td>Single centre</td>
<td>Patients transplanted since 1992. Type 1 diabetes; ( n=3 ) Type 2 diabetes; ( n=46 )</td>
<td>Acute rejection</td>
<td>8 Diabetics (16.3%) and 18 without diabetes (7.1%); ( P = 0.11 )</td>
<td></td>
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</tbody>
</table>