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Original Article

Kidney transplantation in type 2 diabetic patients: a comparison with matched non-diabetic subjects

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Abstract

Background. Because they generally are older and frequently have co-morbidities, patients with type 2 diabetes mellitus and end-stage renal disease seldom are selected for renal transplantation. Thus, information on transplantation results from controlled studies in this high-risk category of patients is scarce. We have compared the results of kidney transplantations in type 2 diabetic patients with carefully matched non-diabetic subjects.

Methods. All first cadaveric renal transplants performed in type 2 diabetic patients from January 1, 1988 to December 31, 1998 in our centre were included. Non-diabetic controls were individually matched with diabetic patients with respect to year of transplantation, sex, age, selected immunological parameters, and graft cold ischaemia.

Results. We included 64 type 2 diabetic and 64 non-diabetic patients who were followed for a mean period of 37 ± 27 and 41 ± 31 months, respectively, after renal transplantation. Patient survival at 1 and 5 years post-transplant was 85 and 69 *vs* 84 and 74% ($P = 0.43$, NS), while graft survival rates censored for patient death were 84 and 77 *vs* 82 and 77% for diabetic and non-diabetic subjects, respectively ($P = 0.52$, NS). With graft survival results not censored for death with functioning graft, no significant change was seen (diabetic *vs* non-diabetic group: 77 and 54 *vs* 73 and 61%, $P = 0.19$, NS). Age, but not the presence of diabetes, was the only factor significantly affecting patient survival when both patient groups were pooled. With regard to post-transplant complications requiring hospitalization, there was a significant difference only in the number of patients who had amputations (diabetic *vs* non-diabetic group: 8 *vs* 0, $P = 0.01$).

Conclusions. Patient and graft survival after kidney transplantation was similar in type 2 diabetic and matched non-diabetic subjects, with more amputations occurring in the diabetic group. Thus, at a single-centre level renal transplantation results almost equivalent to those in non-diabetic patients may be achieved in type 2 diabetes mellitus.

Keywords: kidney transplantation; outcome; type 2 diabetes mellitus

Introduction

Diabetes mellitus represents the single most important cause of end-stage renal disease worldwide. The increasing proportion of patients with diabetes among those being treated for end-stage renal failure is also due to the rising number of type 2 diabetics with nephropathy [1–3]. However, although kidney transplantation has been firmly established as the best modality of renal replacement therapy in patients with type 1 diabetes and end-stage renal disease (currently often simultaneously performed with a pancreas transplant), for several reasons information concerning results of kidney transplantation in patients with type 2 diabetes is scarce. These mostly older-age patients with frequent co-morbidities are subject to a wide range of mainly vascular and infectious complications during treatment. This is reflected in their poor survival on dialysis and their rare selection for renal transplantation [4].

Additionally, the designation of the type of diabetes in many patients with end-stage renal failure often remains uncertain. In the past, many type 2 diabetics treated with insulin were wrongly classified as insulin-dependent or, even more commonly, no distinction of the type of diabetes would be made.

Significantly worse transplantation results in type 2 diabetic patients in comparison with other patient groups have been reported in the few available studies. However, while this undoubtedly reflects the high-risk nature of this population, several variables important for an analysis of graft and patient survival—in

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particular related to immunological status and graft harvesting—may have not been controlled sufficiently. This may be of particular importance since, due to the presence of several risk factors, vascular morbidity and mortality is substantially increased in the end-stage renal disease population as a whole. Therefore, the current study was undertaken to evaluate the results of kidney transplantation in type 2 diabetic patients in comparison with carefully matched non-diabetic controls.

Subjects and methods

This is a retrospective, case-control study from a transplant centre (Institute for Clinical and Experimental Medicine, IKEM) performing approximately 160 renal transplantations annually (which represents about 50% of all kidney transplantations in the Czech Republic). All consecutive first kidney transplants from non-related cadaveric donors to recipients with diabetes performed in the period from January 1, 1988 to December 31, 1998, in our centre were selected from the central Czech transplant registry. The presence and the type of diabetes mellitus was established using all IKEM hospitalization records from the time of or preceding transplantation, and all type 2 diabetic recipients were selected for the study. Diabetes was defined according to WHO 1985 criteria [5] or based on the use of anti-diabetic medication, and the following definition was used for type 2 diabetes: age at diagnosis over 30 years, no insulin treatment for at least 6 months after diagnosis, no history of ketoacidosis, lack of absolute insulin dependence and, when available, a fasting serum C-peptide level over 0.27 nmol/l (Immunoradiometric Assay Kit, Immunotech, Prague, Czech Republic).

Using the same transplant list which did not include information on transplantation results, non-diabetic controls who had had a first non-related cadaveric kidney graft in our centre were matched individually (first moving forward, then backward on the list) with the type 2 diabetic patients for the following criteria ranked in order of importance: year of transplantation (at most ± 1 year), sex, age (± 5 years), number of donor HLA A, B and Dr antigen mismatches (± 2 max.), pre-transplant recipient's highest historic level of pre-sensitization to HLA antigens expressed as panel reactive antibody percentage (PRA) (0–20, 21–79, 80–100%), duration of graft cold ischaemia (± 5 h), and duration of pre-transplant dialysis (± 12 months).

Additional information, when available, was obtained from pre-transplant hospitalization records for the diabetic patients: date of diagnosis of diabetes, type of pre-transplant treatment (diet, oral anti-diabetic drugs, or insulin), level of metabolic control as assessed by HbA_{1c} using ion exchange HPLC (BioRad Diamat Analyzer System, Bio-Rad Laboratories GmbH, Munich, Germany), and presence of background or proliferative diabetic retinopathy or blindness. Information on primary renal disease (whether biopsy-proven or not), time of initiation and the type of dialysis treatment, history of hospitalization for myocardial infarction or stroke, or of amputation was collected for all patients. Smoking status, results of extensive cardiovascular examinations (thallium-scintigraphy or coronary angiography), and the use of anti-hypertensive or hypolipidaemic treatments were also recorded for a comparison of cardiovascular risk in both groups. Pre-transplant clinical and laboratory data that were collected included: body mass index (BMI), blood pressure, haematocrit, albumin, cholesterol, and triglyceride levels.

Post-transplant information was obtained from standard transplantation follow-up protocols used in our institution and from all post-transplant hospitalization records until graft failure (initiation of dialysis) or death. This included: use of anti-T-cell induction therapy, the type of initial immunosuppressive regimen, creatinine, blood pressure, cholesterol and triglyceride levels at 1, 2, 3 and 5 years post-transplant, and the occurrence of complications requiring hospitalization—specifically, hospitalization for graft complications necessitating operative intervention, myocardial infarction, stroke, heart failure, pulmonary thromboembolism, infection, malignancy, any amputations and complete loss of sight. Patients were followed until death or December 31, 1999, so that a minimal 1-year follow-up would be ensured in all living patients.

Statistical analysis

Group differences in discrete variables were compared with the χ^2 test, with Yates' correction in case of expected values of less than 5. For continuous variables, Student's *t*-test or Mann–Whitney *U* test were used as appropriate. Patient and graft survival curves were calculated according to the Kaplan–Meier method. Patient deaths occurring 60 days or more after return to dialysis (in cases of graft failure) were censored, graft survival curves were calculated for death with functioning graft censored and without. The curves were compared using the log-rank test. Cox proportional hazards model was used to assess the effect of selected factors (presence of diabetes, sex, BMI, age, duration of dialysis, smoking status, and blood pressure pre-transplant) on patient and graft survival with the two patient groups pooled.

Means and standard deviations are presented unless otherwise stated. A P value <0.05 was considered statistically significant. We used BMDP 1990 software package for statistical calculations.

Results

Using the abovementioned criteria, 64 patients with type 2 diabetes (39 men and 25 women) with a mean diabetic history of 14 ± 7 years were selected for the study after kidney transplantation. At the time of transplantation, the treatment of diabetes consisted of insulin in 37 people (58%), oral anti-diabetic drugs in 14 (22%), and diet alone in 13 (20%). Basal C-peptide values were available only in 12 patients (median 1.69, range 0.31–4.92 nmol/l), HbA_{1c} values in 10 (median 7.76, range 7.1–9.9%), and retinal assessments in 47 (no retinopathy in seven (14%), background in 15 (31%), proliferative in 26 (53%), and blindness in 1 (2%)). Based on clinical data, diabetic nephropathy was considered the primary renal disease in 52 (83%) patients, although kidney biopsies had been performed in only seven (showing diabetic nephropathy in five and hypertensive renal disease and chronic glomerulonephritis in each of the remaining two).

An identical number of controls with the same male to female ratio were selected. Pre-transplant clinical

Table 1. Pre-transplant clinical and laboratory data of type 2 diabetic (DM 2) *vs* non-diabetic (Non-DM) transplant recipients

	DM 2	Non-DM	*P*
Age (years)	55.9 ± 7.9	55.4 ± 8.8	0.69
BMI (kg.m^{-2})	28.0 ± 3.9	26.2 ± 4.4	**0.016**
Smokers : non-smokers (*n*)	27 : 31 (6)	29 : 28 (7)	0.64
HD : CAPD (*n*)	56 : 6 (2)	62 : 2	0.25
Dialysis duration (months)	14.8 ± 12.1	21.8 ± 16.5	**0.007**
Past hospitalization due to MI (*n*)	7	4	0.54
Past hospitalization due to stroke (*n*)	6	2	0.28
With amputations (*n*)	4	0	0.12
With extensive CV examination (*n*)	3 (1)	3	1.00
With blood pressure treatment (*n*)	45	41	0.37
With hypolipidaemic treatment (*n*)	5 (1)	3 (1)	0.71
Systolic blood pressure (mmHg)	159 ± 23	154 ± 25	0.25
Diastolic blood pressure (mmHg)	87 ± 13	89 ± 14	0.41
Cholesterol (mmol/l)	5.7 ± 1.6 (14)	6.0 ± 1.1 (30)	0.24
Triglycerides (mmol/l)	2.6 ± 1.3 (32)	2.8 ± 1.3 (52)	0.72
Albumin (g/l)	42.0 ± 7.7 (12)	42.7 ± 8.4 (15)	0.67
Haematocrit	0.31 ± 0.06	0.33 ± 0.06 (3)	0.32
PRA (%)	23.8 ± 31.4	24.3 ± 30.4	0.42
Graft cold ischaemia (h)	19.5 ± 4.7	20.2 ± 4.0	0.36
No. of HLA mismatches	2.7 ± 1.1	2.8 ± 1.1	0.69

(*n*, number of patients; numbers in parentheses indicate number of patients with missing data). HD, haemodialysis; CAPD, continuous ambulatory peritoneal dialysis; MI, myocardial infarction; CV, cardiovascular; HLA, human leukocyte antigen. Bold signifies data that are significant at $P < 0.05$.

and laboratory data for both groups are shown in Table 1.

Both groups had similar age distribution; BMI was higher in the diabetic group. With regard to the cause of end-stage renal disease, in the control group chronic glomerulonephritis (22 patients, 35%), tubulo-interstitial nephritis (20 patients, 32%), and polycystic kidney disease (11 patients, 18%) were the most frequent primary renal diseases identified clinically (among the 12 recorded biopsies, chronic glomerulonephritis was present in seven, tubulo-interstitial nephritis and non-diabetic systemic disease in two, and hypertensive renal disease in one). The history of treatment of different dialysis modalities was similar between the two groups, with pre-emptive kidney transplantation having been performed in a single case in the diabetic group. However, matching was unsuccessful with regard to the duration of prior dialysis, which was significantly longer in the control group. There were no significant differences between the two groups in the number of smokers, previous hospitalization due to myocardial infarction or stroke, amputations, number of patients having undergone a more extensive cardiovascular examination, frequency of blood pressure and hypolipidaemic treatment, blood pressure levels, and in the selected laboratory parameters (pre-transplant cholesterol and triglyceride levels, however, were not available in a significant proportion of patients in both groups).

No difference was found between the groups also with regard to immunological and transplantation-associated variables (Table 1). Induction anti-T-cell therapy had been used with equal frequency in both groups (diabetic patients *vs* controls: 14 (22%) *vs* 13 (20%) patients, $P = 0.83$, NS) as had various types of initial immunosuppressive protocols—with an absolutely dominant combination comprising one of three available forms of cyclosporine A with azathioprine and prednisone (98% of patients in both groups).

Patient and graft survival

The mean duration of follow-up was 37 ± 27 and 41 ± 31 months in the diabetic and control groups, respectively. Patient survival in the diabetic group was 85, 84, 77, and 69% at 1, 2, 3, and 5 years post-transplant, respectively. The corresponding results for the control group were 84, 84, 82, and 74% and no statistical difference was found when survival curves of both groups were compared (Figure 1A).

When censored for deaths with functioning graft, there was a graft survival of 84, 80, 77, and 77% in the diabetic patient group. This was not significantly different from the control patients, where the graft survival at corresponding intervals was 82, 82, 77, and 77% (Figure 1B).

The results of comparison were unchanged even when deaths with functioning grafts were included and counted as cases of graft failure (graft survival of 77, 71, 62, and 54% *vs* 73, 73, 69, and 61% for the diabetic *vs* control group) (Figure 1C).

When adjusted for factors—sex, BMI, age, duration of pre-transplant dialysis, smoking status, pre-transplant systolic, and diastolic blood pressure—in the Cox proportional hazards model, no significant effect of diabetes on patient and graft survival was found with the two patient groups pooled ($P = 0.33$, $P = 0.36$, and $P = 0.35$ for patient, patient death censored, and non-censored graft survivals, respectively, NS). Of all the other factors, only advanced age had a significant negative effect on patient survival ($P = 0.004$).

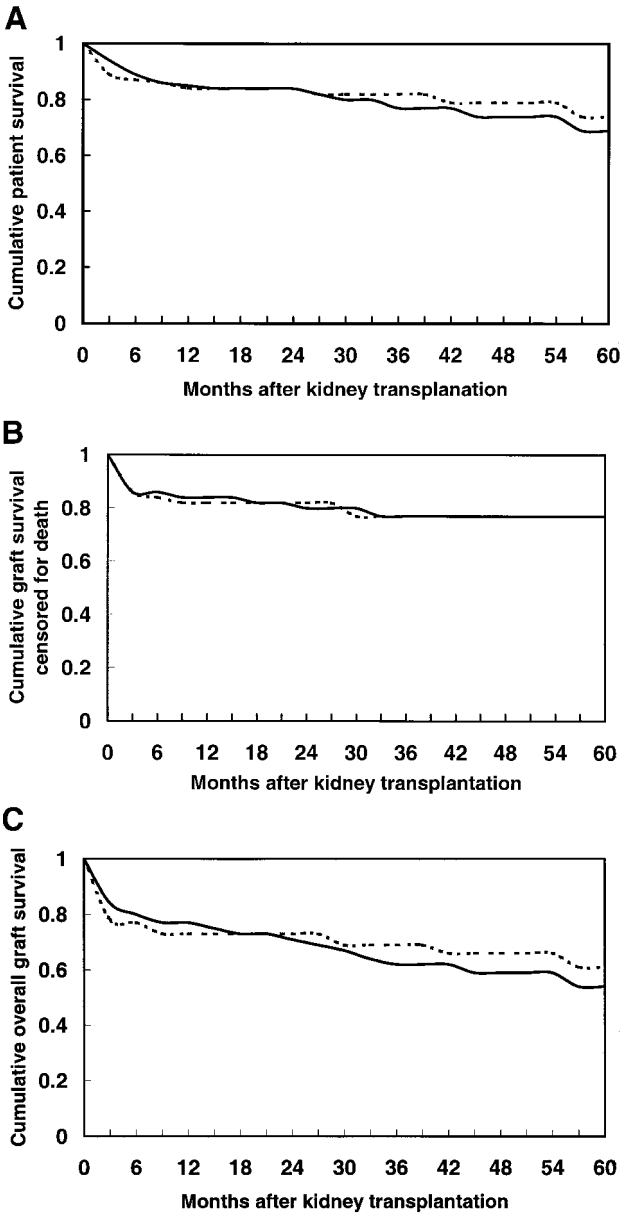

Fig. 1. Kaplan–Meier analysis of patient and graft survival after kidney transplantation. (**A**) Patient survival of type 2 diabetic patients (continuous line) and non-diabetic controls (dashed line) with death more than 60 days after return to dialysis censored ($P=0.43$, NS). (**B**) Kidney graft survival in type 2 diabetic patients (continuous line) and non-diabetic controls (dashed line)—patient deaths with functioning graft censored as transplantation failure ($P=0.52$, NS). (**C**) Kidney graft survival in type 2 diabetic patients (continuous line) and non-diabetic controls (dashed line)—patient deaths with functioning graft not censored as transplantation failure ($P=0.19$, NS).

Creatinine values increased similarly in both groups during the observation period, reaching 158 ± 65 and 140 ± 38 μmol/l (diabetic patients *vs* controls, $P=0.71$, NS) in 23 patients with a functioning graft at 5 years post-transplant (11 patients with type 2 diabetes and 12 non-diabetic controls).

There was no difference during the follow-up period between the groups in mean blood pressure (systolic blood pressure 147 ± 14 *vs* 144 ± 17 mmHg, $P=0.31$, NS, and diastolic blood pressure 84 ± 8 *vs* 86 ± 8 mmHg, $P=0.17$, NS, for the type 2 diabetic and non-diabetic groups, respectively) or lipid levels (cholesterol 6.1 ± 1.6 *vs* 6.4 ± 1.3 mmol/l, $P=0.36$, NS, and triglycerides 2.9 ± 1.6 *vs* 2.4 ± 0.9 mmol/l, $P=0.15$, NS, for the type 2 diabetic and non-diabetic groups, respectively). When comparing mean values at specific points of time, the only significant differences were higher systolic blood pressures at 5 years (153 ± 15 *vs* 136 ± 16 mmHg, $P=0.01$) and triglyceride levels at 3 years post-transplant (3.0 ± 1.5 *vs* 2.2 ± 0.8 mmol/l, $P=0.01$) in the diabetic patients.

Causes of patient death, graft failure, and post-transplant complications

During the follow-up period, 27 diabetic and 19 control patients died ($P=0.158$, NS), with 18 and 15 deaths in the respective groups occurring while the grafts functioned or within 60 days after return to dialysis (one patient in the control group was lost to follow-up after graft failure). In the type 2 diabetic group, deaths had occurred after a mean period of 34 ± 32 months post-transplant and at a mean patient age of 58 ± 8 years, the values being 25 ± 29 months and 59 ± 9 years for the control group. Vascular events (11 patients, 41%), malignancies (five patients, 18.5%), and infections (four patients, 15%) constituted the most frequent causes of death in the diabetic group. In the controls, patient death was most often due to vascular causes (eight patients, 42%) or infections (four patients, 21%).

Death with functioning graft represented the principal cause of graft function cessation in both groups (diabetic patients *vs* controls: 14 (47%) *vs* 10 (43%) patients, $P=0.817$, NS). The other single most important cause of graft failure was rejection (eight (27%) patients) in the diabetic group and primary non-function (four (17%) patients) in the control group (Table 2).

Amputations were required only in the diabetic patients (eight patients, $P=0.01$ for diabetic patients *vs* controls). The differences between the groups in the number of patients requiring hospitalization for all other complications did not attain statistical significance (Table 3).

In two diabetics patients, diabetic retinopathy progressed to total sight loss during the observation period. In the control group, five cases of post-transplant diabetes mellitus appeared *de novo* during follow-up.

Conclusions

The study shows that the outcome of kidney transplantation in non-diabetic subjects may almost be matched by type 2 diabetic patients, at least on a single-centre level. Patient and graft survival in the diabetic group was not significantly different from a carefully matched group of non-diabetic renal

Table 2. Causes of graft failure after kidney transplantation

	DM 2 *n* (%)	Non-DM *n* (%)
Rejection	8 (27)	3 (13)
Urinary fistula	1 (3)	1 (4)
Graft rupture	2 (7)	0 (0)
Graft vessel thrombosis	1 (3)	2 (9)
Infection	3 (10)	3 (13)
Primary non-function	0 (0)	4 (17)
Death with function	14 (47)	10 (43)
Other	1 (3)	0 (0)
Total	30 (100)	23 (100)

$P > 0.05$ for all differences between groups.

Table 3. Number of patients with complications requiring hospitalization after kidney transplantation

	DM 2	Non-DM	*P*
Surgical complications	10	18	0.09
Infections	16	22	0.25
Malignancies	6	3	0.49
Amputations	8	0	**0.01**
Vascular complications*	20	16	0.43

*Myocardial infarction, stroke, heart failure, and pulmonary thromboembolism.

transplant recipients. The overall higher number of deaths in the diabetic group may be explained by more deaths occurring in this group of patients after kidney graft failure, which confirms their well-known poor prognosis on dialysis treatment [4]. The number of diabetic patients who had died after returning do dialysis was more than double the number of such deaths among the controls.

The results add important evidence to previous information. In one of the first studies focusing on patients with type 2 diabetes, Hirschl *et al.* [6] reported in 1992 from Vienna that in patients without severe vascular complications, survival after kidney transplantation was better than on haemodialysis. However, Nyberg *et al.* [7] concluded that the high mortality and morbidity rates in their group of type 2 diabetic patients after kidney transplantation supported continued restriction of their acceptance for transplantation.

Kronson *et al.* [8] found a 5-year survival of 61% for patients and 53% for grafts in their recent analysis of kidney transplantation in type 2 diabetics. This was still significantly worse than the results obtained in the generally younger patients with type 1 diabetes or non-diabetic patients over 50 years old. In our opinion, this may have been due to—among other reasons, which of course include the deleterious effect of the diabetes *per se*—less rigorous matching of controls, e.g. in recipient age (the information about mean patient age in the non-diabetic control group is not available for the study by Kronson). In our study, age was the only factor having a significant negative effect on patient survival. Several other mainly immunologic and donor variables (e.g. pre-transplant PRA level or HLA matching) have also been shown consistently to influence the outcome of cadaveric kidney transplantation [9]. Additionally, as our study covered a slightly later period, the observed differences could reflect an improvement that may have occurred since.

On the other hand, very encouraging results of kidney transplantation in type 2 diabetic patients were reported recently from two transplant centres in Belgium [10]. Even though the small group (23 patients) and the lack of a control group are obvious limitations, an excellent patient survival (91 and 83% at 1 and 5 years post-transplant) and a relatively low complication rate are reported.

In our study, there was no significant difference in the proportion of patients experiencing post-transplant complications requiring hospitalization, apart from the number of amputations. This confirms information in other reports, that diabetic foot complications constitute one of the major problems of post-transplant care after kidney transplantation in diabetic patients [11]. Preventive podiatric care and regular post-transplant surveillance were in the past unavailable to many diabetic patients undergoing kidney transplantation at our institution. In accordance with reports that a reduction of gangrene and amputations in diabetic renal transplant patients can be achieved through attendance at a special foot clinic [12,13], such care is being provided currently at our centre to diabetic patients with end-stage renal disease.

When considering the results of our study, some reservations are inevitable. Undoubtedly, a prospective design would be more appropriate, to avoid possible sources of bias in the comparisons. Although the size of our group of type 2 diabetic patients after kidney transplantation was one of the two largest studied so far (alongside with the study by Kronson [8] which reported on an identical number of cadaveric transplant recipients), the slight tendencies towards worse patient and graft survival in the diabetic group (apparent in survival curve comparisons) could translate into significant differences if larger groups were analysed, in a multi-centre design, including several hundreds to thousands of subjects in each group.

A more restrictive selection process may have been applied in the case of our type 2 diabetic patients. They were referred after being selected by the staff of a number of external dialysis centres and a fixed set of examinations was not a prerequisite during the study period. The pre-transplant work-up included a standard ECG and echocardiography, with a more extensive cardiovascular examination performed in only a few cases in either group. However, due to substantial co-morbidities most type 2 diabetic patients probably were never considered for renal transplantation. The proportion of such patients on the transplant waiting list was much lower than their proportion among those treated by dialysis. According to the 1999 data of the Czech Nephrological Society, 33% of the dialysis population were diabetic patients, of whom at least half may be assumed to have had type 2 diabetes. However, only less than 3% of the transplant candidates on the

Czech waiting list in December 1999 were classified as type 2 diabetic (information from the Czech transplant registry).

Several major risk factors directly linked to cardiovascular disease (hypertension, hyperlipidaemia, smoking, etc.) are present in the end-stage renal failure population as a whole. Thus, as a result of a more rigorous selection of type 2 diabetic patients a group with a more favourable risk profile could have been created. However, as the occurrence of pre-transplant vascular disease and the levels of major risk factors were comparable in both groups, this probably was not the case. Moreover, some of the follow-up data suggest that the control of some major risk factors in the post-transplant period was similar in both groups of transplant recipients—e.g. no significant difference was found in overall mean blood pressure values, which in both groups were approaching levels currently considered as adequate.

Not all variables known to be associated with poorer long-term results (e.g. kidney donor status [14]) and increased mortality could be taken into account. The absence of conclusive biopsy information on the type of renal disease in most patients in the diabetic group probably is of little significance, for some data exists suggesting the primary importance of the diabetic state *per se*, and no effect of the primary renal disease, on the survival of diabetic patients with end-stage renal failure [15]. This may nevertheless be of certain importance in the non-diabetic group where an additional five cases of diabetes mellitus appeared in the post-transplant period. Post-transplant diabetes mellitus has been associated with worse patient survival [16], but perhaps it is confined to patients younger than 55 years [17]. There was also a significant difference between the groups in the duration of pre-transplant dialysis therapy with longer treatment in the non-diabetic patients. A long period on dialysis is an independent variable associated with poorer long-term results and increased mortality [18]. Although probably reflecting above all the higher age of our study subjects, our patient survival results in the non-diabetic group may have been influenced by some of these factors.

Still, this study—like some recent studies in patients with type 1 diabetes [19,20]—in our opinion, provides important additional evidence of a substantial improvement in the results of kidney transplantation in type 2 diabetic patients with end-stage renal failure that has occurred in recent years. Several reasons including more rigorous pre-transplant screening, new types of immunosuppressive therapy, improved metabolic control and better care of complications, probably are responsible. Although the presence of diabetes undoubtedly constitutes a very important risk factor, the study results do not provide support for a restriction of the access to kidney transplantation of patients with type 2 diabetes mellitus.

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