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Prognostic value of the Banff classification

J. Waiser
M. Schreiber
K. Budde
T. Böhler
W. Kraus
I. Hauser
R. Riess
H-H Neumayer

J. Waiser (✉) · K. Budde · T. Böhler · H.-H. Neumayer
Department of Internal Medicine-Nephrology, Charité Campus Mitte, Humboldt-University, Schumannstrasse 20/21, D-10117 Berlin, Germany
e-mail: johannes.waiser@charite.de
Tel.: + 49-30-2802-5865
Fax: + 49-30-2802-8471

M. Schreiber
Department of Internal Medicine II, University of Regensburg, Franz-Josef-Strauss-Allee 11, D-93042 Regensburg, Germany

W. Kraus
Department of Internal Medicine-Nephrology, Friedrich-Alexander-University Erlangen-Nuremberg, Breslauerstrasse 201, D-90471 Nuremberg, Germany

I. Hauser
Department of Nephrology, Medical Clinic IV, University of Frankfurt/Main, Theodor-Stern-Kai 7, D-60590 Frankfurt, Germany

R. Riess
Department of Pathology, Hospital of Nuremberg South, Breslauerstrasse 201, D-90471 Nuremberg, Germany

Abstract We evaluated whether classification of renal allograft biopsies according to the Banff schema is a predictive parameter for graft survival. All patients who received renal transplants between 1980 and 1994 at the University of Erlangen-Nuremberg ($n = 1141$) were included. Patients who had undergone a renal biopsy ($n = 306$) were divided into groups according to the Banff classification. We observed a correlation ($P < 0.05$) between biopsy findings and the following patient characteristics: donor/recipient age, donor/recipient gender, panel reactive antibodies, maintenance immunosuppression, and primary renal disease. Compared to patients who did not undergo renal biopsy (55.9%), 5-year graft survival was reduced in patients with moderate acute rejection defined by tubulitis (20.6%, $P = 0.03$) or arteritis (0%; $P < 0.0001$) and in patients with severe acute rejection (24.4%, $P < 0.0001$). Conclusions: (1). The Banff classification is a predictive parameter for renal allograft survival. (2). Certain characteristics predispose patients to certain biopsy findings.

Key words Banff classification · Graft survival · Prognostic value · Rejection

Introduction

Core needle biopsy is the "gold standard" by which to establish the correct diagnosis of clinically apparent renal allograft dysfunction [1]. However, when the diagnosis of rejection is based on histological criteria alone, acute rejection may be overdiagnosed [8] or underdiagnosed [12]. For this reason, renal allograft pathology must be seen in the context of the patient's clinical situation.

Until 1991, there was no standardized schema for the nomenclature and classification of renal allograft pathology. In August 1991, the Banff working classification of kidney transplant pathology was established in Banff, Canada [13]. This was a major step towards international uniformity. The refinement of definitions and the standardization of terms have markedly eased the dialogue between transplant physicians, allowing a more reliable comparison of different treatment modalities. The high grade of reproducibility [3, 7, 15] has made rejection as defined by the Banff schema an internationally accepted primary endpoint in large multicenter trials [4]. The sensitivity and specificity of the Banff classification in indicating acute rejection episodes range between 83% and 67%, and 71% and 94% respectively, depending on whether "borderline cases" are assumed to indicate rejection or not [2]. Since 1991, several modifications have been incorparated into the original Banff classification [11, 14]. Additional modifications, such as the adoption of immunohistochemical markers, are currently being discussed [10]. To date, however, the clinically relevant question of whether the Banff classification is a useful tool for predicting renal allograft survival has not been sufficiently addressed. We investigated whether renal allograft pathology classified according to the Banff criteria is a predictive parameter of renal allograft survival.

Subjects and methods

Patients and immunosuppression

In a retrospective single-center analysis, data from 1141 cadaveric renal allograft recipients, who underwent transplantation between 1980 and 1994 at the University of Erlangen-Nuremberg, were evaluated. Patients, who had had one renal core biopsy or more ($n = 306$) were compared to a control group of patients ($n = 835$) who had had no renal biopsy. All patients received standard double immunosuppression therapy. Patients transplanted between 1980 and 1984 ($n = 75/306$, $n = 352/835$) received methylprednisolone plus azathioprine, whereas patients transplanted between 1985 and 1994 ($n = 231/306$, $n = 483/835$) received methylprednisolone plus cyclosporine. Methylprednisolone was given as a bolus of 250 mg i.v. before transplantation, 100 mg on day 1, 60 mg for the next 3 days, and 40 mg within the 1st week. Thereafter, the drug was tapered in a stepwise procedure to 4 mg/day, 6 months after transplantation. Azsthioprine was dosed according to body weight (1–3 mg/kg) and adjusted to the white blood cell count such that the latter ranged between 4000 and 8000 cells/μl. The dose of cyclosporine was adjusted to maintain stable whole-blood monoclonal trough levels in the target range of 100–150 ng/ml (TDX, Abbott Co., Wiesbaden, Germany).

Formation of patient groups

Patients, who had undergone a renal allograft biopsy were divided into nine different groups according to the 1991 Banff classification [13]: group 1, normal or other (nonspecific) changes; group 2, borderline changes; group 3, mild acute rejection (grade 1); group 4.1, moderate acute rejection defined by tubulitis (grade 2A); group 4.2, moderate acute rejection defined by arteritis (grade 2B); group 5, severe acute rejection (grade 3); group 6, cyclosporine toxicity; group 7, acute tubular necrosis (ATN); group 8, chronic transplant nephropathy. As proposed at the Third Banff Conference on Allograft Pathology [14], patients with grade 2 rejection were subdivided into two groups depending on the presence or absence of arteritis. In some cases, the histological patterns of different diagnoses were present in a single biopsy specimen. Other patients underwent more than one renal biopsy with differing results (altogether 362 biopsies were performed in 306 patients). When more than one diagnosis was established, the diagnosis corresponding to the most severe changes was used. All diagnoses were therefore ranked according to their severity and their potential impact on renal allograft survival, as follows: 5 > 4.2 > 4.1 > 3 > 6 > 8 > 7 > 2 > 1.

Diagnosis and treatment of acute rejection episodes

Allograft rejection was suggested by a rise in serum creatinine (≥ 0.4 mg/dl), decreased urine volume, fever, swelling and tenderness of the graft, and reduced graft blood flow, as determined by duplex ultrasonography, in the absence of other causes of graft dysfunction. Core needle biopsy was required to confirm the diagnosis of acute rejection in each patient. Histological diagnosis was standardized according to the Banff criteria. First-line treatment for acute rejection episodes was high-dose intravenous methylprednisolone (250 mg/day for 3 days). If the initial therapy failed to maintain or reduce serum creatinine levels, patients were rebiopsied after 1 week. If acute rejection was still apparent, these rejection episodes were defined as corticoid-resistant and treated with a course of antilymphocyte globulin (ATG, Fresenius, Bad Homburg, Germany: 5 mg/kg i.v. for 10 days).

Statistics

Renal allograft survival was defined as the interval (in days) between transplantation and resumption of dialysis, retransplantation, or death with functioning graft. Kaplan-Meier analysis was used to calculate graft survival. The log-rank test was employed to compare survival between groups. Continuous variables were compared among groups using the Mann-Whitney U-test. The χ^2-test was used to compare categorical variables between groups. All data are expressed as mean ± standard deviation of the mean (SEM). Differences were considered as statistically significant when P was less than 0.05.

Results

Histological diagnosis

In patients who had undergone renal biopsy, the most common diagnoses were mild acute rejection (group 3: 28.1%), severe acute rejection (group 5: 17.0%), and chronic transplant nephropathy (group 8: 15.0%). These were followed by moderate acute rejection defined by tubulitis (group 4.1: 9.1%), moderate acute rejection defined by arteritis (group 4.2: 8.2%), ATN (group 7: 6.9%), borderline changes (group 2: 5.6%),

Table 1 Characteristics of biopsied patients grouped according to the Banff classification compared to those of patients who did not undergo biopsy (CMV^+ cytomegalovirus-positive, *PRA* panel reactive antibodies, *CIT* cold ischemia time, *WIT* warm ischemia time)

	Banff group								All ($n = 306$)	No biopsy ($n = 835$)
	1 ($n = 16$)	2 ($n = 17$)	3 ($n = 86$)	4.1 ($n = 28$)	4.2 ($n = 25$)	5 ($n = 52$)	6 ($n = 15$)	7 ($n = 21$)	8 ($n = 46$)		
Donor age (years)	37.9 ± 4.6	36.3 ± 4.4	36.8 ± 1.8**	40.0 ± 3.1**	36.6 ± 3.6	36.5 ± 2.7	37.3 ± 4.9	38.1 ± 4.1	36.8 ± 2.5*	37.2 ± 1.0***	31.1 ± 0.6
Male donor (%)	56.2	52.9	60.5	78.6	76.0	65.4	40.0*	52.4	50.0*	60.5	66.5
Donor CMV^+ (%)	69.2	53.8	57.7	69.2	61.9	61.2	70.0	73.7	64.3	62.8***	55.4
Recipient age (years)	42.7 ± 3.3	42.6 ± 3.1	45.1 ± 1.3***	46.4 ± 1.7*	40.9 ± 2.6	44.1 ± 1.8*	46.9 ± 2.1*	48.5 ± 2.7**	37.6 ± 1.5	44.1 ± 0.7***	40.3 ± 0.5
Male recipient (%)	62.5	52.9	58.1	60.7	64.0	67.3	86.7*	76.2	76.1*	65.7	61.5
PRA > 5% (%)	20.0	20.0	5.2*	8.0	13.6	18.0	13.3	10.0	11.6	11.7	15.7
CIT > 24 h (%)	50.0	66.7	58.5	39.3*	70.8	42.0*	53.3	31.6**	65.1	53.8*	60.9
WIT > 35 min (%)	43.8	33.3	41.0*	60.7	29.2**	49.0	46.7	42.1	46.5	44.2**	54.2
1st transplant (%)	75.0	82.3	93.0	92.9	76.0	84.6	80.0	85.7	87.0	86.6	84.8
2nd transplant (%)	25.0	5.9	7.0	7.1	24.0	11.5	13.3	14.3	8.7	11.1	14.0
3rd transplant (%)	0	11.8	0	0	0	3.9	6.7	0	4.3	2.3	2.1
Cyclosporine + methylprednisolone (%)	87.5*	76.5	89.5***	78.6*	60.0	38.5*	100.0*	100.0***	80.4**	75.5**	57.8

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$ vs no biopsy

normal or other (nonspecific) changes (group 1: 5.2%), and cyclosporine toxicity (group 6: 4.9%). The overall incidence of acute rejection was 62.4%. The incidence of "interstitial rejection" episodes (groups 3 + 4.1: 37.2%) was higher than the incidence of "vascular rejection" episodes (groups 4.2 + 5: 25.2%).

Relevant patient characteristics

Table 1 compares the relevant patient characteristics of the nine patient groups according to the Banff schema compared to those of patients who had not undergone renal biopsy. With respect to the primary renal disease, only two parameters turned out to be statistically significant. First, the incidence of glomerulonephritis was elevated in patients with severe acute rejection (group 5 vs others: 61.5% vs 44.5%, $P = 0.04$). Second, the incidence of autosomal dominant polycystic kidney disease (ADPKD) was elevated in patients with moderate acute rejection defined by arteritis (group 4.2 vs others: 20.0% vs 5.0%, $P = 0.01$). For all other parameters, there were no significant differences between groups.

Intervals and frequencies of renal biopsies

The mean time interval between renal transplantation and renal biopsy was 13.1 ± 1.4 months. Compared to the other groups, the interval was shortest in group 7 (1.1 ± 0.1 months, $P = 0.001$). Concerning acute rejection episodes, the interval increased with decreasing severity of rejection (group 5: 1.8 ± 0.3 months, $P = 0.0001$; group 4.2: 3.7 ± 1.3 months, $P = 0.02$; group 4.1: 5.1 ± 1.9 months, $P > 0.05$; group 3: 9.4 ± 2.3 months, $P > 0.05$; group 2: 11.4 ± 4.2 months, $P > 0.05$). The longest intervals were found in group 6 (39.9 ± 11.2 months, $P = 0.03$), in group 8 (38.2 ± 4.6 months, $P < 0.0001$), and in group 1 (17.8 ± 5.6 months, $P = 0.03$). The percentage of patients who underwent two renal biopsies was significantly higher in group 1 than in all other groups (37.5% vs. 13.8%, $P = 0.03$). Between all other groups, there was no significant difference in the frequency of renal allograft biopsy.

Renal allograft survival

Renal allograft survival was significantly lower in patients who had undergone renal biopsy than in those who had not (Table 2). Statistically, this was mainly due to a significant reduction of graft survival in patients with moderate acute rejection (groups 4.1 and 4.2) and severe acute rejection (group 5). In all other groups, there were no significant differences as compared to patients who had not had a renal biopsy.

Table 2 Renal allograft survival according to the Banff classification

	Banff group										
	1 ($n = 16$)	2 ($n = 17$)	3 ($n = 86$)	4.1 ($n = 28$)	4.2 ($n = 25$)	5 ($n = 52$)	6 ($n = 15$)	7 ($n = 21$)	8 ($n = 46$)	All ($n = 306$)	No biopsy ($n = 835$)
A: From the date of transplantation											
1 year (%)	93.8	82.4	91.9	78.6	56.0	36.5	86.7	90.5	89.1	77.1	72.6
3 years (%)	65.0	64.9	68.7	46.3	26.9	24.4	80.0	90.5	71.3	57.5	62.4
5 years (%)	65.0	64.9	52.0	20.6	0	24.4	58.2	90.5	59.8	44.9	55.9
P_A[a]	0.38	0.87	0.33	0.03	0.0001	0.0001	0.83	0.10	0.80	0.02	–
B: From the date of biopsy											
1 year (%)	87.5	76.5	83.5	75.0	44.0	30.8	86.7	90.5	59.5	68.7	–
3 years (%)	61.0	52.1	59.6	37.7	23.3	20.2	46.8	90.5	42.0	46.7	–
5 years (%)	0	52.1	44.2	19.8	0	20.2	0	90.5	33.0	34.2	–
P_B[b]	0.24	0.34	0.001	0.52	0.002	0.0001	0.89	0.003	0.61	–	–

[a] P_A: Graft survival (from the date of transplantation) according to the Banff classification compared to that in patients who did not undergo renal biopsy

[b] P_B: Graft survival (from the date of biopsy) according to the Banff classification compared with all other patients who had undergone renal biopsy

Table 3 Graft survival according to the modified Banff classification[a] [25]

Time since transplantation	Group			No biopsy ($n = 835$)
	I ($n = 33$)	II ($n = 114$)	III ($n = 77$)	
1 year (%)	87.9	88.6	42.8	72.7
3 years (%)	65.5	62.9	23.6	62.4
5 years (%)	65.5	42.5	14.2*	55.9

[a] Group I: no rejection, borderline changes; group II: mild to moderate acute rejection, tubulitis, no arteritis; group III: moderate to severe acute rejection with intimal arteritis

* $P < 0.0001$ vs groups I, II, and no biopsy

In addition, we analyzed renal allograft survival according to a modified form of the Banff classification, which was adopted from Solez et al. [15]. Patients were divided into four groups: group I: no rejection, borderline changes; group II: mild to moderate acute rejection, tubulitis, no arteritis; group III: moderate to severe acute rejection with intimal arteritis; not classified (NC): all other patients. In this analysis, graft survival turned out to be reduced in group II as compared to all other groups (Table 3). All other group comparisons revealed no significant differences.

As mentioned above, the time interval between transplantation and renal biopsy was significantly different between the nine patient groups. For this reason we assessed graft survival starting from the date of renal biopsy (Table 2). Comparison of each group with all other groups of patients who had undergone renal biopsy showed that graft survival was significantly reduced in patients with moderate acute rejection defined by arteritis (group 4.2) and in patients with severe acute rejection (group 5). In contrast, graft survival was significantly better in patients with mild acute rejection (group 3) and in patients with ATN (group 7).

Discussion

The Banff classification was introduced in 1991 in order to standardize the interpretation of renal allograft biopsy [13]. Since then, several modifications have been included [11, 14]. So far, it has not been investigated sufficiently whether renal allograft pathology according to the Banff classification is a predictive parameter for renal allograft survival. In a retrospective single-center study we analyzed whether classification of renal allograft biopsies according to the Banff criteria is a useful tool for predicting renal allograft survival. In addition, we investigated whether a correlation exists between relevant patient characteristics and histological diagnosis according to the Banff classification.

All patients who underwent kidney transplantation between 1980 and 1994 at the University of Erlangen-Nuremberg were included. Patients who had undergone a renal biopsy were divided into groups according to the 1991 Banff criteria [13]. Following the proposals of the Third Banff Conference in 1995 [14], moderate acute rejection (grade 2) was further subdivided into moderate acute rejection defined by tubulitis (grade 2A) and moderate acute rejection defined by arteritis (grade 2B). The patient characteristics and graft survival in the nine resulting groups were compared to those of a group of patients who had not undergone renal biopsy.

Among the group of all patients who had undergone renal allograft biopsy, donor and recipient age was higher, more patients had received kidneys from cytomegalovirus-positive donors, and more patients received cyclosporine than in the group who had not undergone renal biopsy. Surprisingly, fewer of all biopsied patients had prolonged cold or warm ischemia times. The mean donor age was higher in each of the nine biopsied groups than among patients who had not had a renal biopsy. The mean recipient age was highest in patients

with ATN (group 7). These results confirm previous studies showing that kidneys from older donors are generally more susceptible to pathogenic processes following transplantation [18]. Concerning recipient age, it is well established that the incidence of ATN in older patients is increased [18]. The percentage of male recipients who had received kidneys from female donors was highest in patients with cyclosporine toxicity (group 6) and chronic transplant nephropathy (group 8). This gender-related phenomenon may reflect differences in susceptibility to cyclosporine nephrotoxicity. A mismatch between female donor kidney nephron supply and male recipient functional demand may also result in hyperfiltration-mediated glomerular injury. Neugarten et al. observed that graft survival of female donor kidneys in cyclosporine-treated recipients was lower than that of male donor kidneys [9]. The severity of rejection increased with panel reactive antibody titers, supporting the thesis that elevated HLA-antibody titers correlate with the severity of vascular lesions during acute rejection [17]. Cyclosporine treatment was associated with a marked reduction in the severity of rejection, but also with an increased incidence of cyclosporine nephrotoxicity, ATN, and chronic transplant nephropathy. The combined effect of cyclosporine treatment and elevated recipient age on the incidence of ATN even abolished the beneficial effect of relatively short cold ischemia times in these patients. Concerning the primary renal disease, we found an elevated percentage of patients with ADPKD in group 4.2 (moderate acute rejection defined by arteritis) and an elevated percentage of patients with glomerulonephritis in group 5 (severe acute rejection).

Graft survival in patients who had undergone renal biopsy was lower than that in patients who had not. This finding was mainly attributable to patients who suffered from moderate or severe acute rejection. Interestingly, graft survival was significantly reduced in both patients with moderate acute rejection defined by tubulitis and patients with moderate acute rejection defined by arteritis. In order to investigate whether a modified form of the Banff classification, introduced by Solez et al. [15], provides different results, we compared graft survival between this classification and the original Banff classification. In this modified Banff classification, which resembles the pre-Banff classification of acute rejection, patients with no rejection or borderline changes were placed together in group I, patients with interstitial rejection were placed together in group II, and patients with vascular rejection were placed in group III, while patients with all other diagnoses were not classified (see Table 3). As expected, graft survival in group III ("vascular rejection") was significantly lower than in all other groups. However, no significant differences were found between group I, group II, and patients who had not undergone renal biopsy. This is especially important since group II contained patients in Banff group 4.1 (moderate acute rejection defined by tubulitis), who were shown to have significantly reduced graft survival in the previous analysis. Thus, this modified Banff classification missed relevant differences between mild acute rejection and moderate acute rejection defined by tubulitis.

The time interval from the date of transplantation to the date of biopsy varied considerably depending on the histological diagnosis. TherFor this reasonefore, we also analyzed renal allograft survival starting from the date of biopsy. As before, graft survival was significantly lower in patients with moderate acute rejection defined by arteritis and in patients with severe acute rejection. By contrast, graft survival was significantly better in patients with ATN and in patients with mild acute rejection. It is known that ATN does not per se negatively influence renal allograft survival [5, 6, 16]. However, ATN may predispose the patients to develop subsequent acute rejection episodes. When ATN and rejection are both present, renal allograft survival is significantly reduced [16]. Owing to the ranking process, patients with ATN did not have any other severe biopsy findings including rejection. Our results are therefore in agreement with the existing literature. The fact that graft survival in patients treated for mild acute rejection was better than in patients with moderate acute rejection defined by tubulitis, emphasizes that these two groups should not be collectively classed as "interstitial rejection."

In sum, we found a significant correlation between several patient characteristics and certain histological diagnoses classified according to the Banff criteria. In addition, there was a significant correlation between biopsy findings classified according to the Banff criteria and renal allograft survival. The difference in graft survival between patients with mild acute rejection and patients with moderate acute rejection defined by tubulitis ceased to be apparent when the two groups were classed together. Thus, the classical Banff classification seems to be a predictive parameter for renal allograft survival, whereas a simplification of this schema may overlook significant differences. These results suggest that it may be useful to adapt the immunosuppressive therapy to the characteristics of the individual patient and to the biopsy findings classified according to the Banff criteria.

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