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A retrospective analysis of the utility and safety of kidney transplant biopsies by nephrology trainees and consultants

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ABSTRACT

Background and aims: Dysfunction of a kidney transplant often requires histological sampling by percutaneous ultrasound-guided core needle biopsy. Transplant biopsy is more specialized than native kidney biopsy, the indications and complications are less well defined and in England are performed mainly by nephrologists. The aims of the study were to evaluate the adequacy and complication rate in living and deceased donor recipients according to training status of the nephrologist, assess the accuracy of physicians in predicting rejection, the threshold creatinine rise for biopsy, and the change in drug management post-biopsy.

Materials and methods: We performed a retrospective analysis of all adult patients undergoing a kidney transplant biopsy in 2015 at a major teaching hospital in the UK as part of a service evaluation program. The primary outcome measure was the rate of major complications and secondary measures included sample adequacy, seniority of operator, clinician-predicted diagnosis, biopsy diagnosis and change in drug management.

Results: One hundred and seven (n = 107) transplant biopsies were performed across 27 living donor (LD) recipients and 57 deceased donor (DD) recipients. LDs were statistically less likely to have diabetes, more likely to take azathioprine. Biopsies were performed by trainees rather than consultants at a ratio of 3:1. The complication rate was low with no major bleeding complications. Visible haematuria occurred in 4.7% and 2.8% of patients developed transplant pyelonephritis. 3.7% of biopsies contained no glomeruli. There was no effect attributed to training status. The pre-biopsy rise in creatinine was significantly less for LD compared to DD recipients (45% vs 70%). A clinician-suspected diagnosis of rejection was confirmed on biopsy in 42.9% of cases and overall about 47.9% of biopsies led to a change in drug management.

Conclusions: Kidney transplant biopsies were safe, performed adequately by trainee nephrologists and were often associated with a change in drug management.

1. Introduction

Kidney transplantation is the optimal treatment for many patients with end-stage renal failure [1]. Episodes of renal dysfunction are common during the lifetime of a transplanted kidney and often mandate histological sampling of the organ [2]. A percutaneous ultrasound-guided kidney transplant biopsy is the 'gold standard' method for determining the cause of allograft dysfunction after obstructive and major vascular causes have been excluded [3].

The indications for transplant biopsy are divided between protocol biopsies that are performed at defined time points and those that are performed for acute or chronic graft dysfunction [3]. The threshold reduction in kidney function leading to a non-protocol biopsy is largely unknown and may vary across different transplant units and for donor types. Information on the reasons for initiating a biopsy could be helpful for developing more standardized guidelines for transplant biopsy. Percutaneous kidney transplant biopsies in England are performed predominantly by nephrologists and not radiologists or surgeons. The extent to which biopsies are performed by trainees versus certified consultants in nephrology is unknown and could impact on biopsy quality and safety. In England, competency with renal transplant biopsy is an optional part of the nephrology training program (https://www.jrcptb.org.uk/specialties/renal-medicine).

Percutaneous kidney transplant biopsy is an invasive procedure that confers a risk of major and minor complications. Major complications of transplant biopsies are variously described in the literature but predominantly comprise haemorrhage requiring transfusion, radiological intra-arterial embolization or surgical intervention. Recent studies of native kidney biopsies have described the risk of such bleeding complications as 2.2 to 7.4% [4–6]. Fewer data exist for transplant biopsies. One study described a composite major complication rate of 1.9%, comprising predominantly a need for transfusion due to bleeding [7].

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Another study described a composite severe or life-threatening complication rate of 0.4% and that the risk of bleeding was 311% higher for biopsies within the first week after transplantation [8]. In addition to complications, biopsy adequacy is a major factor in the overall utility of performing a biopsy [9]. Although precise criteria for an adequate biopsy are difficult to define the Banff criteria recommend several parameters such as a minimum of 10 glomeruli [10].

We conducted a service evaluation to analyse the utility and safety of kidney transplant biopsies performed over 12 months at a major kidney transplant centre in England. We examined the complication and adequacy rate stratified by donor status and biopsy operator grade. We also examined the value of biopsies with regards confirming the clinicians' suspected diagnosis of rejection and effect on drug treatment.

2. Methods

We evaluated all percutaneous inpatient and outpatient renal transplant biopsies for patients aged > 16 years old performed from 1st January 2015 to the 31st of December 2015 at the Oxford Kidney and Transplant Unit. Data were collected in January 2017 allowing at least 1 year of follow-up for each patient. Data were obtained from the local online renal patient database (Proton), from the electronic patient record (EPR) and where available from the paper medical notes. A list of patients having undergone a biopsy was ascertained by examining the local paper biopsy diary, and electronic annotation of biopsies on Proton and EPR. Transplant biopsies were performed under ultrasound guidance with 18 gauge needles and a spring loaded re-usable biopsy gun. Biopsies were performed in the supine position and all patients had laboratory blood tests within 2 weeks prior and following the biopsy. All anti-coagulants were stopped prior to biopsy with a suitable washout period but continuation of aspirin was permitted. Our protocol recommended patients receive Desmopressin 0.4 mcg/kg (max dose 28 mcg) intravenously prior to the biopsy if the creatinine was more than 250 μmol/L unless there was active coronary artery disease or recent stroke. Biopsies were performed on the renal day-case unit with 6 h post-biopsy observation or on the renal/transplant wards. The data were entered into an Excel Spreadsheet and analysed using the R software environment. The rise in creatinine from baseline to the time of biopsy was based on a comparison of the nadir creatinine within the last 6 months and last creatinine preceding or on the biopsy date. Statistical tests were conducted within R using default software parameters. A Fisher's exact test was used to compare count data between groups with a P value threshold for significance of 0.05. Alternatively, a Student's *t*-test, with a threshold for significance of 0.05, was used to compare means for the following data variables: age (at first biopsy), time from transplant to first biopsy, baseline creatinine, proportion globally sclerosed glomeruli, change in haemoglobin post-biopsy, absolute rise in creatinine prior to biopsy, fold change in creatinine rise prior to biopsy, and differences in sampled glomeruli numbers. The project and manuscript were evaluated by the Oxford University Hospitals NHS Trust Research and Development department and the work deemed a 'service evaluation' and that further external ethical permissions were not required. Where applicable the study format adheres to the STROCSS guideline (https://www.strocssguideline.com).

3. Results

3.1. Baseline characteristics of patients undergoing renal transplant biopsy

We analysed 107 (100%) kidney transplant biopsies that were performed in 84 patients during the 1 year study period. The majority of patients had a deceased donor kidney that was biopsied (57, 67.9%) and two of these patients had a simultaneous kidney-pancreas transplant. Biopsies were predominantly performed on an outpatient basis with 66 (61.7%) biopsies occurring on the renal day-case unit. Several patients underwent more than one biopsy of the same kidney transplant within this year – 66 (62%) patients underwent 1 biopsy, 14 (13.1%) patients underwent 2 biopsies, 3 (2.8%) patients under went 3 biopsies and 1 (0.9%) patient underwent 4 biopsies. The baseline demographic and clinical details are shown on a per patient basis comparing deceased donors and living kidney donors (Table 1). DD recipients undergoing a biopsy were more likely than LD recipients to have diabetes and to have diabetes as their primary renal diagnosis whereas LD recipients were more likely to be taking azathioprine.

Table 1
Baseline demographic and clinical parameters of patients with living or deceased donor kidneys who underwent a kidney transplant biopsy during the evaluation period (HLA = human leucocyte antigen, NA indicates missing data).

Variable	Living Donor (%)	Deceased Donor (%)	P value
Number of patients	27	57	
Number of biopsies	38 (35.5)	69 (64.5)	
Gender male	19 (70)	30 (52.6)	0.16
Age (mean)	48.78	54.37	0.06
HLA mismatches			0.87
0	1 (3.7)	3 (5.3)	
1	1 (3.7)	2 (3.5)	
2	4 (14.8)	7 (12.3)	
3	8 (29.6)	20 (35.1)	
4	8 (29.6)	9 (15.8)	
5	2 (7.4)	2 (3.5)	
6	0 (0)	1 (1.8)	
NA	3 (11.1)	13 (22.8)	
Comorbidity			
Cardiovascular	4 (14.8)	12 (21.1)	0.57
Respiratory	2 (7.4)	5 (8.8)	1.00
Diabetes	2 (7.4)	19 (33.3)	0.014
Other	4 (14.8)	11 (19.3)	0.76
Ethnicity			
White	23 (85)	39 (68.4)	0.12
Asian	2 (7.4)	8 (14)	0.49
Black	0 (0)	2 (3.5)	1.00
Other	2 (7.4)	8 (14)	0.12
Primary renal disease			
Diabetes	1 (3.7)	13 (22.8)	0.03
Hypertension	3 (11.1)	4 (7)	0.66
Polycystic Kidney Disease	2 (7.4)	6 (10.5)	1.00
Glomerulonephritis	7 (25.9)	18 (31.6)	0.80
Reflux Nephropathy	4 (14.8)	2 (3.5)	0.08
Other	10 (37)	14 (24.6)	0.20
Time from transplant to first biopsy (days)			
Min	4	4	
Median	160	536	
Mean	969	1368	
Max	6218	10067	0.39
Baseline creatinine (μmol/L, mean)	194	238	0.19
Mortality (at last follow-up)	0 (0)	7 (12.3)	0.09
Immunosuppression			
Tacrolimus	23 (85.2)	50 (87.7)	0.74
Ciclosporin	2 (7.4)	7 (12.3)	0.71
Sirolimus	1 (3.7)	0 (0)	0.32
Mycophenolate	15 (55.6)	40 (70.2)	0.22
Azathioprine	12 (44.4)	11 (19.3)	0.02
Prednisolone	11 (40.7)	15 (26.3)	0.21

3.2. Baseline haematological parameters in living and deceased donor recipients at the time of biopsy

To begin to assess the safety of kidney transplant biopsy we ascertained the baseline haematological profile of patients using blood tests performed within 2 weeks preceding the biopsy (Table 2 - data are shown on a per biopsy basis). We also assessed the number of patients who continued on aspirin and the use of desmopressin. Patients were generally permitted to continue aspirin at the clinician's discretion, but other anticoagulants or anti-thrombotic agents were discontinued. Our policy was to give desmopressin pre-biopsy if the creatinine was more

Table 2
Haematological and clotting parameters prior to biopsy in LD and DD kidney transplant recipients (analysed on a per biopsy basis, NA indicates data not available).

Variable	Living Donor (%) n = 38	Deceased Donor (%) n = 69	P value
Haemoglobin (mean g/L)	107.3	103.2	0.34
Prothrombin time (mean seconds)	11.33	11.27	0.84
Activated partial thromboplastin time (mean seconds)	26.96	26.79	0.82
Platelets $x10^9$/L (mean)	232.3	267.6	0.09
Number of patients with aspirin not stopped for biopsy	10/11 (91), NA = 27	12/19 (63), NA = 50	0.20
Number of patients given Desmopressin pre-biopsy (in patients with creatinine > 250 and no contraindication)	6/13 (46.2), NA = 2	17/32 (53.1), NA = 13	0.75

than 250 μmol/L and there was no contraindication. Overall about one quarter of patients were taking aspirin at the time of biopsy and about a quarter of patients received pre-biopsy desmopressin. The majority of patients also had normal clotting parameters and the mean haemoglobin was over 100 g/L in LD and DD recipients.

3.3. Training status of biopsy operator

We then ascertained whether the biopsies were performed by a trainee or by a Consultant nephrologist. The operator was infrequently recorded on the hospital electronic record or separate renal electronic Proton database and the data was sought from the paper medical notes where available. The grade of the operator was determined for 39 biopsies and 30 of these were performed by trainees. Trainees were junior doctors on a specialty training program in nephrology and have typically been qualified as doctor for a minimum of 4 years. The complications and adequacy of biopsies has been analysed and stratified by operator status in the sections below.

3.4. Biopsy complications in living and deceased donor recipients performed by consultants and trainees

We first studied whether biopsies without an overt bleeding complication were nevertheless associated with a fall in haemoglobin (Hb) since a previous study had reported a modest post-biopsy drop in Hb [8]. We compared the Hb antedating the biopsy (most recent Hb within 2 weeks before the biopsy) with the post-biopsy Hb (most recent Hb within 2 weeks after the biopsy). There was no significant change in Hb in the LD group, or in the DD group (p value = 0.13 and 0.16).

Macroscopic haematuria occurred in 5 biopsies (4.7%). These 5 biopsies comprised 5 male patients of whom 2 (1.9%) patients had a living donor kidney and 3 (2.8%) a deceased donor kidney. There was no significant difference in the rate of macroscopic haematuria between male and female patients (p value = 0.07) or between living and deceased donor recipients (p value = 1.00). The clotting profile was normal in all patients and one patient was continued on aspirin prior to the biopsy. One patient had received desmopressin prior to the biopsy. In all cases the biopsy yielded a diagnostic sample and none of the patients required a blood transfusion, angiography or operation. In all cases the haematuria resolved spontaneously. For three of these biopsies data was available on the grade of operator—trainee for 2 biopsies and consultant for one biopsy with no significant difference in the bleeding rate between grades (p value = 0.56).

Overall, there were no radiological interventions or operations required for post-biopsy bleeding. A blood transfusion was administered at the time of the biopsy in 3 patients—in 2 of these patients it was given pre-biopsy because of a Hb less than 80 g/L and it was unclear why the third patient received a transfusion (pre-Hb 96 g/L).

Three patients developed transplant pyelonephritis within 48 h of the transplant biopsy. In one of these cases the biopsy showed pyelonephritis. In all 3 cases a urine dipstick had been performed that was negative for nitrites but positive for leucocytes in 2 patients. There was no significant difference in the rate of pyelonephritis between trainees and consultants (p = 0.56).

None of the biopsies resulted in clinically apparent injury to other organs and no biopsy samples contain non-renal tissue other than fibroadipose tissue (7 biopsies) or skeletal muscle (4 biopsies).

3.5. Quality of biopsy samples performed by consultants and trainees

All biopsies were performed using a re-usable automatic biopsy gun deploying 18-gauge needles under ultrasound guidance. The mean number of glomeruli per biopsy in LD kidney biopsies was 16.0 and in DD was 15.6 (p value 0.83). The mean number of biopsy cores taken was 2.5 in LD and 2.3 in DD kidney transplants (p value = 0.40, data was not available for 65 biopsies). Four biopsies (3.7%) contained no glomeruli and were consequently non-diagnostic. Three of the four non-diagnostic biopsy samples contained non-renal tissue including skeletal muscle and adipose tissue. Of the non-diagnostic biopsies, 1 occurred in a LD recipient and 3 in DD recipients (p value = 1.0). Operator seniority data were not available for 2 of the non-diagnostic biopsies and in the other two cases the biopsies were performed by trainees (p value = 1.0 comparing trainees and consultants). The Banff '97 criteria for transplant biopsy adequacy recommend an arbitrary threshold of 10 or more glomeruli for an adequate biopsy [10]. For living recipients and deceased donor recipients 11 (28.9%) and 23 (33.3%) biopsies contained fewer than 10 glomeruli, respectively (p value 0.67). There was no significant difference between the number of Banff 'inadequate' biopsies for trainees compared with consultants (10/30 vs 1/9 respectively, p value = 0.40).

3.6. The accuracy of clinician suspected diagnosis, threshold for biopsy and associated change in drug management

We ascertained the rise in creatinine from baseline prior to the kidney biopsy since this rise is likely to have informed the decision to undertake a biopsy. The mean absolute rise in creatinine from baseline was 45.33 μmol/L and 79.91 μmol/L in LD recipients and DD recipients, respectively (p value 0.018). The fold change in creatinine over baseline prior to biopsy was 1.45 and 1.72 for LD and DD kidneys recipients, respectively (p value 0.047). Overall, 12% of patients were in a period of delayed graft function following transplantation.

We then ascertained the clinician suspected diagnosis at the time or preceding the biopsy although data were not available specifically describing this for 47 biopsies. The specific indications for performing the biopsies were suspected rejection in 35 cases, recurrent glomerulonephritis in 10, calcineurin-inhibitor toxicity in 10 and 4 biopsies were performed as part of a research protocol (for some biopsies clinicians queried more than one diagnosis). We then ascertained the histological outcome of the biopsies (Table 3). Finally, we compared the clinician suspected diagnosis of rejection to the biopsy diagnosis (we arbitrarily defined rejection as the overriding query when there were multiple queried diagnoses). Of the 35 patients in which rejection was suspected 15 of the patients (42.9%) had rejection on their biopsy.

We next surveyed the changes in drug management after the biopsy result was obtained for living and deceased donor recipients (Table 4). To ascertain changes in management we examined the electronic drug records for changes that occurred within 2 weeks after the biopsy result. These changes were likely to have occurred in response to the biopsy. Overall, a biopsy was associated with a change in drug management in 47.9% of cases and there was no significant difference between management changes in LD or DD recipients.

Table 3
Biopsy Histological findings.

Parameter	Living donor (%) N = 38	Cadaveric (%) N = 69	P value
T cell rejection	11 (28.9)	8 (11.6)	0.03
T cell with vascular rejection	2 (5.3)	2 (2.9)	0.61
Acute antibody mediated rejection (AMR)	2 (5.3)	2 (2.9)	0.61
Mixed T cell/AMR	2 (5.3)	2 (2.9)	0.61
Acute tubular injury	31 (83.7)	54 (78.3)	0.80
Calcineurin inhibitor Toxicity:			
Acute	2 (5.3)	5 (7.2)	1.00
Chronic	3 (7.9)	13 (18.8)	0.16
Recurrent disease	5 (14)	9 (13.0)	1.00
BK nephropathy	2 (5.3)	1 (1.4)	0.29
Interstitial fibrosis/tubular atrophy (mean percent)	19.8	31.3	0.05
Proportion globally sclerosed gloms (mean)	14.0	23.5	0.03

Table 4
Change in drug management after transplant biopsy.

Management	Living N = 32 (%)	Deceased N = 62	P value
Methylprednisolone	10 (31.3)	10 (16.1)	0.11
Reduced tacrolimus	4 (12.5)	9 (14.5)	1.00
Alemtuzumab	0	2 (3.2)	0.55
Plasmapheresis	1 (3.1)	0 (0)	0.34
Sirolimus	0 (0)	2 (3.2)	0.55
Other	5 (15.7)	6 (9.7)	0.50
Nil	12 (37.5)	33 (53.2)	0.19

4. Discussion

We found that kidney transplant biopsy was a safe procedure with no major bleeding complications in our cohort of biopsies performed during 1 calendar year.

The lack of major bleeding complications in this study is consistent with the low rate reported in the literature of 0–2.2% [7–9]. As in other studies, macroscopic haematuria was the most frequent complication [9]. We were surprised to find that 3 patients developed clinical signs of graft pyelonephritis within 24 hours of the transplant biopsy and in one case the biopsy demonstrated pyelonephritis. Previous studies have, however, demonstrated a relatively high rate of biopsy proven transplant pyelonephritis—up to 25%—in patients where it was not suspected [11]. The authors noted that even on retrospective review 5 of 26 of these pyelonephritis cases had no clinical signs of urinary tract infection.

In our unit, the majority of biopsies are performed by trainees and this did not adversely impact on the complication rate. Given the safety and success rate of these biopsies the present approach to biopsy training appears acceptable. Another group has reported that a porcine simulation model of kidney biopsy can be helpful, particularly for trainees who lack confidence in this procedure [12].

Most of the biopsies contained glomeruli but using the relatively strict Banff criteria about a third of biopsies contained a technically inadequate number of glomeruli [10]. A quality improvement project aimed at improving transplant biopsy adequacy noted a biopsy inadequacy rate of about 25–30% that was not improved by restricting biopsies to a smaller number of radiologists, labelling biopsy reports with specimen adequacy or immediate examination of cores at the bedside by microscopy [13]. Another study of transplant biopsy adequacy attained a lower mean number of glomeruli per biopsy (9) with 70% of biopsy containing more than 7 glomeruli and 1 artery [9]. Although we did not count the number of arteries included in our biopsies, our results are broadly similar to these studies.

Our results suggest that there may have been a lower threshold for biopsies of living donor kidneys given the significantly lower rise in creatinine from baseline prior to biopsy. Nevertheless in both groups the biopsies occurred after a rise in creatinine of more than 25% which is generally taken as a threshold for biopsy [14].

Rejection was the most commonly anticipated diagnosis and clinicians were correct in their suspicion of this diagnosis in nearly half of cases. On the one hand this finding emphasizes the overarching importance of a renal biopsy in establishing a firm diagnosis of transplant dysfunction. On the other hand, the relatively common strategy of giving empirical intravenous steroids for suspected rejection prior to a biopsy may lead to patients receiving or not receiving steroids erroneously. Our data is broadly in line with other studies that show a biopsy changes the clinician diagnosis in about 39% of cases [3]. T cell-mediated rejection occurred significantly more commonly in LD recipients and was relatively uncommon in DD recipients. Although azathioprine use was more common in LD recipients we did not assess other important factors, such as induction immunosuppression, that could have influenced rejection risk.

About half of kidney transplant biopsies were associated with a change in drug management and the commonest changes were either a reduction in tacrolimus dose or a course of intravenous steroids. We believe this finding underscores the usefulness of biopsies in our patient population but there can be a number of reasons why a biopsy does not lead to a change in drug management. Possible reasons include the lack of specific treatment for delayed graft function or recurrent disease and the use of protocol biopsies in normally functioning kidneys. In this retrospective analysis, we may not have identified changes that were not apparent on the electronic drug record and did not ascertain certain management changes such as intravenous fluid use or bladder catheterization. It is also possible that changes in drug management occurred after the 2 week period we reviewed following the biopsy. Finally, a biopsy finding of acute tubular injury may have led to other interventions such as an angiogram to exclude renal artery stenosis that we did not record. It is likely that in our retrospective analysis our study underreports the true extent of management changes following a biopsy. Overall, our data are in line with existing studies that show a rate of change in management of 59% after a biopsy [3].

Our study has a several limitations including its retrospective nature, and the relatively small number of patients undergoing a transplant biopsy within one calendar year. We also did not assess a number of factors that have been associated with the risk of complications in other studies. For example, with native kidney biopsy there is a higher risk of complications when performing a biopsy of the right kidney [15]. It is possible that the position of a kidney transplant also influences biopsy safety. For example, some patients with simultaneous kidney-pancreas transplants may have intra-abdominal placement of the kidney and this could be more technically challenging. Another limitation is that because the majority of data was gathered from the electronic record there is likely under-ascertainment of information pertaining to, for example, comorbidity.

One of the main aims of our service evaluation was to assess the impact of trainee status on biopsy safety and adequacy. However, we were not able to identify when trainees were performing the biopsy independently and when under supervision. Also, a consultant may be expected to have a higher complication rate if they are secondarily called in to assist a trainee for a difficult biopsy. Further prospective evaluations may be helpful in addressing these questions further and designing the optimal training program.

Overall our report indicates that percutaneous ultrasound guided renal transplant biopsy was used safely during the observed period and that it frequently yielded a diagnosis such as rejection, mandating significant changes to immunosuppression. Trainees performed most biopsies, and this does not appear to adversely affect safety or quality of our biopsies.

Ethical approval

The study was approved by the local renal unit clinical governance department and the Oxford University Hospitals NHS Foundation Trust Research and Development department who advised that further external ethical approval was not required.

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Author contribution

Michael Reschen, Andrea Mazzella and Edward Sharples designed the study. Andrea Mazzella and Michael Reschen collected and analysed the data. Michael Reschen wrote the manuscript. Andrea Mazzella, Edward Sharples and Michael Reschen edited the manuscript.

Conflicts of interest

We have no conflicts of interest to declare.

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