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Nature, timing, and severity of complications from ultrasound-guided percutaneous renal transplant biopsy

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Summary

We sought to review our kidney transplant biopsy experience to assess the incidence, type, presenting symptoms, and timing of renal transplant biopsy complications, as well as determine any modifiable risk factors for postbiopsy complications. This is an observational analysis of patients at the University of Wisconsin between January 1, 2000, and December 31, 2009. Patients with an INR ≥1.5 or platelet counts less than 50 000 were not biopsied. An 18-gauge needle was used for biopsy. Over the study period, 3738 biopsies were performed with 66 complications (1.8%). No deaths occurred. A total of 0.7% were mild complications, 0.7% were moderate complications, 0.21% were severe complications, and 0.19% were life-threatening. Most complications occurred within the 4-h postbiopsy period, although serious complications were often delayed: 67% of complications requiring surgical intervention presented greater than 4 h after biopsy. Biopsy within 1 week of transplant had a 311% increased risk of a complication. Postbiopsy reduction in hematocrit and hemoglobin at 4 h was associated with a complication. In conclusion, life-threatening complications after renal allograft biopsy occurred in 0.19% of patients. Most complications occurred within 4 h postprocedure; however, many serious complications occurred with a time delay after initially uneventful monitoring. The only clinically significant laboratory predictor of a complication was a fall in the hematocrit or hemoglobin within 4 h. Patients biopsied within a week of transplant were at the highest risk for a complication and should therefore be most closely monitored.

Introduction

Percutaneous core needle biopsy is the gold standard for assessing and diagnosing renal dysfunction in the transplanted kidney. First developed over 50 years ago [1], and with the advent of automated, smaller gauge biopsy instruments, there has been an improvement in the rate of complications [2–5]. This has made biopsy as an outpatient procedure feasible [6–10]. Safer than a native renal biopsy [11], the safety and cost–benefit as an outpatient procedure has been well described [12–15]. Indications for this procedure vary; however, clinical criteria alone have been found to be inadequate for diagnosis in 50–70% of cases. In these scenarios, histopathology has been required [12,16,17].

We sought to investigate the nature and risk factors for postbiopsy adverse events in our patient population at the University of Wisconsin. We defined adverse event as any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medical procedure or treatment [18]. We graded them according to the

Common Terminology Criteria for Adverse events, with a grading scale of 1–5 (mild to death) (see Table 1, for examples). Our ultimate goal was to determine the appropriate risk stratification to determine postprocedure monitoring.

Methods

This study represents a retrospective chart review of percutaneous core needle biopsies performed at the University of Wisconsin between January 1, 2000, and December 12, 2009. This study was approved by the Institutional Review Board. This comprised of 3738 consecutive biopsies. These biopsies were performed in 1951 patients over the study period in 2065 transplants. For laboratory comparisons, available laboratories and clinical characteristics were abstracted for all biopsies with a complication ($n = 63$) and the first biopsy for patients with no complications ($n = 1807$). Patients were kept on clear liquids the evening prior to the biopsy and then kept nil per os (NPO) the morning of the biopsy. Preprocedure vitals were obtained and included coagulation parameters (INR/platelets), hematocrit, and serum Cr. Patients with an INR > than 1.4 or platelets <50 000/mm^3 were not biopsied unless they corrected with transfusion of fresh frozen plasma or platelets. Other coagulation parameters including partial thromboplastin time, fibrinogen, and factor VIII were not performed. Patients on aspirin, plavix, or warfarin were instructed to hold at least 5 days prior to biopsy. Patients with a blood pressure greater than 160/90 were treated until the blood pressure was less than 160/90 prior to biopsy. All patients were counseled of risk prior to the procedure and gave their informed consent. All biopsies were performed using real-time ultrasound guidance and an 18-gauge automated biopsy device. A single core biopsy was the standard. The approach was practitioner dependent, but the primary aim was performing the safest core biopsy of the renal cortex through the available ultrasound window. Often times, it is the upper or lower pole, but the mid-kidney is used if felt to be the safest approach. Ultrasound was used immediately after the biopsy to confirm no immediate bleeding diathesis. Most were for cause biopsies, but the exact number was not available for analysis. An adverse event was defined as any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medical procedure or treatment. These events were then graded on a scale of 1–5 (mild to death) based on the Common Terminology Criteria for Adverse Events [18] (see Table 1 for examples).

Postbiopsy monitoring protocol

We kept our patients for 4 h postbiopsy with vital sign monitoring every 15 min × 4, then every 30 min × 2, and then every hour × 2. Patients who were required to remain supine in bed during this period, however, had bathroom privileges. While on bed rest, a 5-pound sandbag was placed over the biopsy site. A postprocedure hematocrit was obtained at 4 h. If they were asymptomatic with a stable hematocrit and vital signs, they discharged home. Patients did not routinely get a postbiopsy ultrasound unless clinically indicated. Patients underwent a noncontrast CT scan of the abdomen or ultrasound if hematocrit dropped by four or more points and if they had pain or other symptoms. Patients who were admitted to the hospital had daily laboratories drawn including hematocrit, hemoglobin, blood urea nitrogen (BUN), and creatinine. For bleeding complications requiring intervention, surgical exploration was performed. At our institution, radiological intervention with coiling and glue was not performed.

Results

Incidence of Complications. Of the 3738 biopsies performed, there were 66 complications (1.8%; Table 2). A total of 48.5% were documented by ultrasound, and 51.5% were documented by CT scan. Mild complications were found in 0.7% of our population. Postprocedure

Table 1. Common Terminology Criteria for Adverse Events (CTCAE).

Severity	CTCAE Grade	Description	Example
Mild	Grade 1	-Asymptomatic or mild symptoms requiring observation. -Intervention not indicated	-Mild pain -Small asymptomatic hematoma
Moderate	Grade 2	-Minimal, local, or noninvasive intervention indicated. -Hospitalization.	-Large perinephric hematoma not requiring operation. -Decreased hematocrit -Transfusion of Blood Products
Severe	Grade 3	-Severe or medically significant -Requiring intervention or intensive care hospitalization	-Page Kidney
Life-threatening	Grade 4	-Intraperitoneal hemorrhage requiring ex-lap	
Death	Grade 5		

hematoma made up the majority of this group, occurring in 18/25 patients. The remaining 7/25 had either an arteriovenous fistula (AVF) (4/25) or (3/25) abdominal pain not requiring intervention. Gross hematuria after biopsy was not observed. Forty-one of the 66 patients suffering complication had a moderate (0.7%), severe (0.21%), or life-threatening complication (0.19%). All of these complications were related to bleeding. For patients with moderate, severe, or life-threatening complications, 30 of 41 (73%) presented with decreased hematocrit or abdominal pain. The remaining 11 patients presented initially with either hypotension, decreased urine output/elevated creatinine, or abnormalities on postprocedure U/S. No one in the mild complication cohort required intervention other than observation. Intervention in the moderate group included admission with serial hematocrits and transfusion of blood product. All severe and life-threatening complications required surgical intervention. We had no deaths occur in our cohort and no graft loss secondary to biopsy complications.

Time to Presentation (Table 3). Average presentation time of moderate complications was 5 h 37 min (range 0–72 h, standard deviation ± 13.8 h) with the majority of moderate complications (20/26) presenting within 4-h postbiopsy (77%). However, average presentation time of severe complications was 12 h 22 min (range 0–48 h, standard deviation ± 12.1 h) with the minority of severe complications (5/15) presenting within 4 h postbiopsy (33%) and greater than half (8/15) presenting greater than 8 h postbiopsy. One patient with a moderate complication and one patient with a severe complication developed bleeding after discharge while at home.

Baseline Demographics (Tables 4 and 5). There was no significant difference in age, BMI, gender, or race between those patients that had a complication and those that did not. A higher percentage of patients who were biopsied within 1 week of transplant were found to have a complication compared to those that did not (14.3% vs. 5.1%, $P = 0.002$). Furthermore, there was no statistically significant difference in any of the prebiopsy laboratory parameters between those patients that had a complication and those that did not.

Table 2. Number of complications in 3738 post-kidney transplant biopsies.

Severity	CTCAE grade	# of patients	% of total
Mild	1	25	0.7
Moderate	2	26	0.7
Severe	3	8	0.21
Life-threatening	4	7	0.19
Death	5	0	0
Total		66	1.8

Changes in laboratory values as predictor of postbiopsy complications are shown in Table 6. We examined changes in preprocedure and postprocedure laboratory values to determine their association with complications. Mean changes in hematocrit/hemoglobin within 4 h, and serum creatinine and BUN within 24 h were associated with complications.

Table 3. Timing of presentation for complications.

Time period	Number of complications	Percent of complications
Moderate complications		
0–4 h	20	77
4–8 h	4	15
>8 h	2	8
Severe/life-threatening complications		
0–4 h	5	33
4–8 h	2	13
>8 h	8	54

Mean Presentation Time 5 h 37 min, 20/26 (77%) presented within 4 h (Moderate Complications).
Mean Presentation Time 12 h 22 min, 5/15(33%) presented within 4 h (Severe/Life-threatening Complications).

Table 4. Basic demographics.

	No complication	Complication	*P*-value
Age, years	49.2 (12.4)	50.5 (13.4)	0.44
BMI, kg/m^2	26.9 (5.5)	26.1 (4.4)	0.20
Non-white, %	14.0	15.9	0.67
Female, %	39.7	49.2	0.13
Months since transplant	40.5 (52.5)	28.6 (41.3)	0.08
≤1 week post-transplant, %	5.1	14.3	0.002

Table 5. Laboratory values in patients with and without complications.

	No complication	Complication	*P*-value
Prebiopsy			
Hematocrit, %	33.6 (5.6)	32.9 (6.1)	0.29
Hemoglobin, g/dl	11.4 (2.8)	11.4 (2.1)	0.96
White Blood Cell, ×10^3/μl	8.1 (3.9)	7.6 (3.2)	0.65
Platelets, × 10^9/l	219.5 (90.4)	201.6 (83.0)	0.12
INR	1.06 (0.15)	1.09 (0.19)	0.12
Creatinine, mg/dl	3.1 (2.0)	2.9 (1.6)	0.37
BUN, mg/dl	47.7 (23.9)	48.2 (23.3)	0.86
Postbiopsy			
Hematocrit, %	32.5 (5.3)	30.5 (6.3)	0.003
Hemoglobin, g/dl	10.9 (1.8)	10.3 (2.1)	0.007
White Blood Cell, × 10^3/μl	8.5 (4.5)	8.4 (3.7)	0.78
Platelets, × 10^9/l	215.8 (98.9)	191.8 (70.3)	0.11
INR	1.16 (0.27)	1.14 (0.19)	0.69
Creatinine, mg/dl	3.2 (2.0)	3.0 (1.4)	0.49
BUN, mg/dl	50.4 (24.9)	53.0 (25.6)	0.42

Table 6. Mean changes in laboratory values in patients with and without complications.

Laboratory parameter	No complication	Complication	*P*-value
Hematocrit, % (SD)	−1.14 (0.06)	−2.41 (0.44)	<0.001
Hemoglobin, g/d (SD)	−0.43 (0.03)	−0.87 (0.20)	<0.001
White Blood Cell, $\times 10^3/\mu l$ (SD)	0.30 (0.83)	0.53 (0.36)	0.56
Platelets, $\times 10^9/l$ (SD)	0.36 (1.80)	−1.70 (6.90)	0.80
INR (SD)	0.11 (0.01)	0.02 (0.02)	0.87
Creatinine, mg/dl (SD)	−0.11 (0.02)	0.20 (0.09)	0.004
BUN, mg/dl (SD)	0.14 (0.28)	4.12 (1.75)	0.005

Discussion

Percutaneous core needle biopsy of the transplanted kidney is a common procedure that is generally performed successfully with minimal risk of complications. Alternatives to an invasive procedure have been explored [19,20], but core needle biopsy remains the gold standard approach. A major component for the diagnosis of rejection, by the Banff criteria, is histologically defined [21]. In general, the community has probed to seek out which populations represent an increased risk. Complications relating to bleeding appear to dominate, with perinephric hematomas (0.5–11%) and macroscopic hematuria (1–9%) being the most common complications [7,22–25]. Bleeding rates have also been reported as high as 10–13% in extraperitoneal kidneys [7,24,25]. Risk factors for these complications have previously been noted to be an inadequate platelet count (<60 000) [26] or elevated INR (>1.3) [27]. Elevated serum Cr at time of biopsy has also been suggested as a risk factor for suffering a complication [28]. Attempts to decrease the complication incidence have been twofold: (1) patient selection to minimize risk factors and (2) changes in the technique. Preprocedure assessment of coagulation parameters and correction versus aborting the procedure has been recommended and practiced. At our center, we require a minimum platelet count of 50 000 and INR <1.5. Alternations in the biopsy needle caliber and added automated needles have also decreased complications rates [4,5]. The length of postprocedure monitoring has been debated [28] and was one of our goals of examination here.

In our experience, we found complications after percutaneous renal core needle biopsy to be rare, occurring in 1.8% of biopsies. Although we did experience a variety of mild complications, all of our moderate to life-threatening complications were hemorrhagic in nature. They presented predominately with decreasing hematocrit or abdominal pain. The 77% of the moderate, or medically managed, complications were discerned within the 4-h observation period. Unfortunately, the same could not be said for our severe to life-threatening complications with the average presentation being 12 h and 22 min. Ultimately, 67% of those patients requiring surgical intervention presented after the 4-h mark. The surgical intervention consisted of evacuation of hematoma and cauterizing or suture ligating a bleeding point if present. In response to this finding, it is our practice to follow up after discharge all patients with a phone call the following day to ensure clinical stability. We provide extensive patient education of signs and symptoms of complications. This practice of aggressive outpatient surveillance, assessment, and referral through outpatient transplant coordinators ultimately ensured proper care for these patients with no deaths in our patient cohort.

In our patient cohort, we identified biopsy with 1 week of transplant as a significantly associated with postbiopsy complications. These patients may be best monitored in the hospital as the recent transplant may be less likely to tamponade any bleeding that may arise from a biopsy. We speculate that in this early postoperative period, the surgical field has not scared in and therefore is less able to tamponade any biopsy bleeding. A drop in hematocrit and hemoglobin is associated with a biopsy bleeding complication and is rather self-evident. However, we identified a mean increase in BUN and serum creatinine within 24 h to also be associated with complication. Uremia is known to cause platelet dysfunction and could explain the increase in bleeding complications. However, hemorrhage itself can lead to hemodynamic changes and compression of the kidney that can impair function and lead to an increase in BUN and creatinine. It is unclear from our data whether this increase is causative or, rather, a result of the biopsy complication itself. Additionally, patients early postoperatively may have persistent uremia which could lead to increase bleeding risk.

Limitations of this study include that it was a retrospective chart review and is limited by the granularity of documentation. Interestingly, we did not observe any cases with gross hematuria or pyeloureteral obstruction following renal transplant biopsies. Compared to the available literature, this incidence appears to be low and raises a question of whether such data were underreported. It is possible that such complications failed to be adequately captured in our data set. The incidence of clinically significant gross hematuria has been reported to occur in 1–9% of patients [3,28–30]. Similarly, we noted a low incidence of AVF in our data, 0.11%, requiring no interventions. The incidence of AVF postbiopsy has been estimated to occur in up to 7.6% of patients [24]. We observed only 4 cases, which were diagnosed on ultrasound immediately postbiopsy. Because each patient undergoes real-time ultrasound during the biopsy procedure, a large AVF would be expected to be detected at this time. A small asymptomatic AVF may have formed in some patients, which was not immediately detected on ultrasound. Because we do not routinely perform a repeat postbiopsy ultrasound in asymptomatic patients, we may

have failed to detect small asymptomatic AVFs. Thus, it is likely that our data underestimates the true incidence of AVF postbiopsy. Even though our data does not support the routine surveillance by ultrasound postbiopsy, as none of the AVF discovered required intervention, we recognize that while many AVFs will remain small or disappear spontaneously, some increase may contribute to further deterioration of the graft function and consequently could require treatment. Therefore, further ultrasound examinations in the short-term follow-up after biopsy might detect a larger number of delayed significant AVFs. In many institutions, follow-up ultrasound is an inherent part of the postbiopsy monitoring protocol (e.g., at some institutions an ultrasound is performed 4 h and 24 h postbiopsy). Such a protocol of further routine postbiopsy ultrasound examinations, exclusive of laboratory and vital sign monitoring, maybe of value. In particular, in light of the delayed bleeding complications, we observed in our cohort such a protocol could prove to be beneficial to our patients and warrants further study. Additionally, we acknowledge an inherent selection bias as we already aggressively screen patients ensuring adequate coagulation parameters and is thus likely why INR and platelet count were not found to be significant in our data set.

In conclusion we validate that percutaneous transplant kidney biopsy is safe with a low frequency of complications. The majority of complications are found within the post-procedural observation time; however, complications can present later, especially severe to life-threatening ones. The only clinically significant laboratory predictor of a complication is a fall in the hematocrit or hemoglobin and increase in postbiopsy BUN and creatinine. Patients who were biopsied within a week of transplant were at the highest risk for a complication and should therefore be most closely monitored.

Authorship

RRR: performed research/study, collected and analyzed the data, and wrote the manuscript. KRM: analyzed data and wrote the manuscript. AR: collected the data. ES, MH, KG, and BCA: designed and performed research/study, analyzed and collected the data, and wrote the manuscript. AJK and JR: designed and performed research/study, and analyzed and collected the data. MM, SP, and DA: performed research/study, analyzed data, and wrote the manuscript. AD: designed and performed research/study, analyzed data, and wrote the manuscript.

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