Implementation and Results of a Percutaneous Renal Allograft Biopsy Protocol to Reduce Complication Rate

Charles H Li BS¹, Laura E Traube MD MPH¹, David S Lu MD¹, Steven S Raman MD¹, Gabriel M Danovitch MD², Hans A Gritsch MD³, Justin P McWilliams MD¹

UCLA Departments of Radiology¹, Nephrology², and Urology³, UCLA David Geffen School of Medicine

Contact Info: JuMcWilliams@mednet.ucla.edu
Percutaneous renal transplant biopsy (PRTB) is the gold standard for evaluating allograft rejection after renal transplant.

Hemorrhage is the predominant complication.

We describe the implementation of a standardized protocol for PRTB at a single institution, with the aim of reducing bleeding complications.

Utilizing the plan-do-study-act model for quality improvement, we created and deployed a protocol centered on controlling patient’s hypertension, platelet function, and anticoagulation status.

- The 4-year study encompassed a total of 880 PRTBs, before and after implementation of the protocol.
- Total complication rate, which was 5.8% in the 2 years leading up to implementation of the protocol, was reduced to 2.9% after the protocol was introduced (P = .04).

A standardized approach to PRTB can potentially lower complication rates; we present a framework for implementing a quality improvement protocol at other institutions.
Introduction

• 12,000 patients undergo renal transplants annually

• Percutaneous renal transplant biopsies (PRTB) is gold standard for evaluation of allograft rejection

• Major vs Minor Complications (SIR Definitions)
  • Major:
    • Requires therapy, increased level of care, or hospitalization
  • Minor:
    • Clinically inconsequential or nominal therapy
PDSA: Plan, Do, Study, Act

• Plan: Defining the Scope of the Problem
  • Reviewed complications and known risk factors for biopsy
  • Historic biopsy complication rate at our institution shown in Table 1
  • A protocol was developed jointly between radiologists and transplant nephrologists

• Do: Implementation of the Protocol
  • Guidelines provided to all departmental staff and radiologists performing PRTB
  • Printouts of protocol posted in control area of procedure rooms

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of Renal Biopsy Complications Reported to the QOC Committee</th>
<th>No. of Renal Biopsy Procedures Performed</th>
<th>Estimated Complication Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>1</td>
<td>141</td>
<td>0.7</td>
</tr>
<tr>
<td>2006</td>
<td>5</td>
<td>238</td>
<td>2.1</td>
</tr>
<tr>
<td>2007</td>
<td>7</td>
<td>258</td>
<td>2.7</td>
</tr>
<tr>
<td>2008</td>
<td>3</td>
<td>271</td>
<td>1.1</td>
</tr>
<tr>
<td>2009</td>
<td>7</td>
<td>307</td>
<td>2.3</td>
</tr>
<tr>
<td>2010</td>
<td>5</td>
<td>352</td>
<td>1.4</td>
</tr>
<tr>
<td>2011</td>
<td>5</td>
<td>360</td>
<td>1.4</td>
</tr>
<tr>
<td>2012</td>
<td>13</td>
<td>380</td>
<td>3.4</td>
</tr>
</tbody>
</table>

Note: The estimate of complication rate differs slightly from the actual complication rate based on our rigorous chart review, because not all complications were submitted to the QOC committee. QOC = Quality of Care.
Study: Comparison of Complication Rates Before and After Implementation

Table 2. Patient demographics and percutaneous renal transplant biopsy complication rate

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Before Implementation of Protocol (n = 502)</th>
<th>After Implementation of Protocol (n = 378)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male gender</td>
<td>304 (60)</td>
<td>239 (63)</td>
<td>.42</td>
</tr>
<tr>
<td>Age (y)</td>
<td>50.4 ± 14.4</td>
<td>51.5 ± 13.6</td>
<td>.65</td>
</tr>
<tr>
<td>Major complications</td>
<td>8 (1.6)</td>
<td>2 (0.5)</td>
<td>.14</td>
</tr>
<tr>
<td>Minor complications</td>
<td>21 (4.2)</td>
<td>9 (2.4)</td>
<td>.15</td>
</tr>
<tr>
<td>Total complications</td>
<td>29 (5.8)</td>
<td>11 (2.9)</td>
<td>.04</td>
</tr>
</tbody>
</table>

Note: Values are n (%), or mean ± standard deviation, unless otherwise indicated.
Feedback was elicited from referring physicians and nephrologists

Changes included:

- Recommendations for when discussion should occur with referring clinicians
- Allowability of moderate hypertension in low risk patients with superficial, compressible kidney
- Effective BP reduction agents
- Caution in use of DDAVP in patients with cardiac issues
- Expansion of anticoagulation cessation recommendations
- Adoption of new technique to reduce further needle passage into the medulla
- Post-procedure guidelines added, including instructions for compression, post-procedure ultrasound, and time in recovery
Limitations

- Biopsies were performed at a single center

- Study was done at a tertiary care hospital with higher risk factors and bleeding risk

- Gelfoam usage wasn’t studied
Protocol Summary

• Hypertension Goals
  • Goal Blood Pressure <140/90, defer if SBP > 180
  • Sedation to help lower BP. Use midazolam (1-2mg IV)

• Uremia/Renal Failure: Higher bleeding risk due to platelet dysfunction
  • Consider DDAVP if BUN > 50. Dose 0.3 ug/kg at least 30 minutes prior to biopsy

• Platelet/Anticoagulation
  • Correct if platelets <75 or INR >1.5, using platelets or FFP
  • Stop anticoagulants per SIR guidelines (detailed in full protocol).
  • Restart warfarin and aspirin 12-24 hrs after biopsy. Restart heparin and NOACs 48-72 hrs after biopsy.
Take-Home Points

• Implementation of a protocol for standardized screening and management of patients undergoing PRTB was associated with a decrease in total complication rate.

• A standardized protocol should serve as a framework to guide decision making, but should not be used inflexibly such that appropriate patient access to procedures is blocked.

• QI projects based on the PDSA model are achievable and can lead to meaningful change.


1. **Recommend discussion with referring clinician for consideration of risk versus benefit in select situations:**
   a. If the indication for biopsy seems inappropriate or uncertain
   b. Deep, noncompressible renal transplant in high risk patients:
      a. ICU and critically ill patients, especially if in organ failure
      b. Patients with hematologic disorders or cirrhosis

2. **Hypertension (HTN):** Hypertensive patients are high risk. However, risk vs. benefit depends on individual patient factors such as degree of hypertension, depth of kidney, ability to compress, and urgency of biopsy.
   a. Patients who are hypertensive in clinic or on the ward should have their blood pressure controlled before being sent to the radiology suite. Goal blood pressure for renal transplant biopsy is <140/90.
   b. In most cases, severe HTN (>180 mmHg systolic) will require that the biopsy be deferred and the patient returned to clinic or admitted for blood pressure control.
   c. For less severe HTN, whether to proceed depends on level of concern and urgency on a patient-to-patient basis. Patients with a superficial transplant kidney that is easily compressed and no other risk factors may be biopsied safely even if moderately hypertensive, particularly if biopsy is urgent.
   d. Sedation will help lower blood pressure. Midazolam (1-2 mg IV) is often sufficient.
   e. Helpful blood pressure medications include hydralazine 10 mg IV (repeat if needed); labetalol 10-20 mg IV (repeat if needed); nitro paste 1 inch to skin; clonidine 0.2 mg PO.
3. **Uremia or renal failure:** Uremic patients are higher bleeding risk due to platelet dysfunction.
   a. Consider DDAVP for BUN >50 particularly if the kidney is deep, or there are other risk factors.
   b. DDAVP dose is 0.3 ug/kg IV at least 30 minutes prior to biopsy (effect lasts at least 8 hours).
   c. DDAVP should be given prior to bringing patient to the radiology suite whenever possible.
   d. Caution in CAD/CHF.

4. **Abnormal platelets/clotting factors or on antiplatelet/anticoagulation medication:**
   a. Should correct if platelets <75 or INR >1.5, using platelets or FFP. These patients remain high risk.
   b. Aspirin should be held 5-7 days if biopsy is not urgent. If biopsy is urgent, proceed at the discretion of the radiologist.
   c. Clopidogrel should be stopped 7 days prior to biopsy.
   d. Warfarin should be stopped 5 days prior to biopsy, check INR.
   e. Heparin should be stopped 6 hours prior to biopsy.
   f. Enoxaparin should be stopped 24 hours prior to biopsy.
   g. Fondaparinux should be stopped 48 hours prior to biopsy.
   h. Apixaban, dabigatran, and rivaroxaban should be stopped 3 days prior to biopsy.
   i. After biopsy: Clopidogrel, heparin, enoxaparin, fondaparinux, apixaban, dabigatran, and rivaroxaban can be restarted 48-72 hours after biopsy. Warfarin and aspirin can be restarted 12-24 hours after biopsy.