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Outpatient Pediatric Renal Biopsies: A Preferred Approach

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Abstract

Purpose: Healthcare providers continually seek ways to improve their practice while maintaining quality of patient care. An aspect that can be made more efficient is adjusting procedural protocols for prompt patient discharge. Historically, pediatric renal biopsies were performed following the established adult protocol. The purpose of this study is to evaluate the effectiveness of a 4-hour post-biopsy observation period for outpatient pediatric renal biopsies.

Material and Methods: This retrospective study was approved by the Investigational Review Board. Over a 7.5-year period from January 2011 to July 2018, all image-guided pediatric renal biopsies were reviewed. Patients were transferred to the recovery room for a 4-hour post-procedural observation period, after which outpatients were discharged home and inpatients were returned to their wards. All complications were recorded and classified using the Society of Interventional Radiology clinical practice guidelines.

Results: 798 biopsies were performed with 100% technical success as all biopsies yielded diagnostic sampling. 440 biopsies (55%) were performed as inpatients with 358 (45%) as outpatients. There were 58 (7.3%) total complications distributed as 51 minor and 7 major, with higher incidence among the inpatient group. All but 7 complications were identified within the post-procedural observation period of 4 hours, with 1 requiring intervention due to the patient restarting anticoagulation prematurely.

Discussion: To our knowledge, this is the largest, single institution renal biopsy experience in pediatrics using real-time ultrasound-guidance. The protocol utilized focused on a 4-hour post biopsy observation period. Our results support discharge after a 4-hour observation period for outpatients given that they have a pre-procedural Hgb ≥9 g/dL and are asymptomatic post-procedural with a Hgb decrease of <2 g/dL.

Keywords: Paediatric nephrology; Renal biopsy; Interventional radiology

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Introduction

Healthcare providers are continually seeking ways to improve their practice while maintaining or improving quality of patient care. One area that can be targeted is adjusting procedural protocols to allow for the prompt discharge of patients following routine procedures. For decades, pediatric renal biopsies were performed following the protocol established in the adult population (Tondel et al., 2012) [1]. The protocol mandated an overnight stay to monitor for post biopsy bleeding and other complications (Whittier and Korbet, 2004) [2]. More recently, the protocol has changed as studies have shown that in the adult population, biopsies can be performed safely and efficiently with an observation period of only 6 hours (Jiang, Karpe, and Talaulikar, 2011) [3].

Recognizing this research, we changed our post biopsy protocol in 2011 from a 23-hour to a 4-hour observation period. If, after the observation period, the child has normal or stable baseline vital signs, no pain or hematuria, and a "stable hemoglobin defined by a drop of less than 2g/dL", he or she is discharged to home. The purpose of this study is to evaluate the safety and cost effectiveness of this 4-hour post-biopsy observation period for outpatient pediatric renal biopsies and compare the complication rates and cost savings to a traditional observation period.

Materials and Methods

This study was approved by the Investigational Review Board. Over a 7.5-year period from January 1, 2011 to July 9, 2018, all pediatric renal biopsies performed in the Interventional Radiology Division were included in the analysis. Data was collected from the medical records of patients and included the following: patient demographics, pre- and post-biopsy laboratory values, indications

for biopsy, inpatient versus outpatient status, and the occurrence of minor and major complications. All patients were required to have their hemoglobin/hematocrit [H/H] levels checked pre- and post-procedurally as well as their coagulation factors [PT, PTT, INR, platelets] to assess for potential bleeding or hemorrhage within 24 hours of the procedure. Only children with normal or corrected coagulation studies were eligible for the renal biopsy protocol. Patients with a platelet count of 50,000 or greater were considered for a biopsy while children with fewer than 50,000 were administered a platelet transfusion. If abnormally elevated, PT, PTT and INR were corrected with infusion of Fresh Frozen Plasma [FFP] with an INR goal of <1.5.

All biopsies were performed using real-time ultrasound guidance by a fellowship-trained Pediatric Interventional Radiologist [PIR] or Pediatric Interventional fellow under the direct supervision of a PIR attending with the patient under general anesthesia or procedural sedation.

The PIRs had 3, 10, 26 and 38 years of experience.

Technique: Ultrasound Guided Renal Biopsy [UGRB]

Patient positioning varied depending on whether the kidney to be biopsied was a native kidney or transplanted kidney. For native kidneys, the patient was positioned prone on the procedural table, while patients with kidney transplants were positioned supine. All biopsies were guided with real-time ultrasound imaging with probe selection dependent on patient size and the operating physician's preference (Mahajan et al., 2010) [4]. The ultrasound transducer most frequently used was a Philips C8-5 curvilinear transducer in smaller patients and a Philips C5-1 curvilinear transducer in larger patients. The lower pole of the kidney was biopsied in all children with native kidneys. On occasion, in children with transplanted kidneys, the upper pole was sampled depending on the position of the transplanted kidney in the peritoneal cavity. Two sampling techniques were applied. One approach utilized a co-axial technique. The co-axial technique was reserved for high-risk patients mainly with vasculitides and other collagen-vascular diseases due to the ability for tract embolization (Table 1). A 17-gauge guide needle was advanced just deep to the renal capsule within the renal cortex and an 18-gauge BioPince biopsy needle [Argon Medical Devices, Frisco, Texas] was inserted into the renal cortex *via* the guide needle and a minimum of two specimens was obtained. Additional specimens were provided at the request of the pathologist who viewed the specimens in real-time. A technically successful renal biopsy was defined as a procedure yielding diagnostic specimens. At the conclusion of the procedure, tract embolization was performed utilizing a gelfoam slurry. The alternative, and more commonly utilized approach, was a direct puncture technique with an 18-gauge BioPince biopsy needle. Each specimen obtained required a separate US-guided pathway with inability for track embolization.

Immediate post-biopsy ultrasound including Doppler imaging was performed by the Interventional Radiologist to identify active bleeding or a perinephric hematoma. The protocolled post-procedural observation period was 4 hours. At approximately 3 hours after the procedure, a repeat hemoglobin/hematocrit level was obtained. Asymptomatic patients with stable hemoglobin levels of <2 g/dL from baseline were either discharged to home if they were outpatients or returned to their wards if they were inpatients. Intensive Care [ICU] patients were recovered in the ICU. Symptomatic patients complaining of severe pain, having gross hematuria, or demonstrating hemoglobin drops of >2 g/dL from baseline were examined with ultrasound to evaluate for active bleeding or an intrarenal or perinephric hematoma. If the ultrasound revealed no large hematoma, intrarenal bleed, or hemodynamically relevant Arteriovenous Fistula (AVF), the patient continued to be managed conservatively with pain control and follow-up H/H. If, however, hemodynamic instability or another major complication was identified, the patient was admitted to the hospital and prepared for red blood cell transfusion, if applicable, and angiography with potential embolization.

Table 1: Indications for use of the Co-Axial approach.

INDICATIONS	NUMBER OF PROCEDURES
Systemic Lupus Nephritis	17
Henoch-schonlein purpura	6
Wegener's granulomatosis	3
p-ANCA vasculitis	2
Other	2
Acute renal failure	1
Proteinuria	1
Renal Transplant	1

Table 2: SIR Classification system for Complications by Outcome [5].

Minor Complications
A. No therapy, no consequence.
B. Nominal therapy, no consequence; includes overnight admission for observation only.
Major Complications
C. Require therapy, minor hospitalization (<48 hours).
D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours).
E. Permanent adverse sequelae.
F. Death.

All major and minor complications were recorded and classified using the Society of Interventional Radiology (SIR) clinical practice guidelines (Table 2).

Results

A total of 798 biopsies were performed with 100% technical success as all biopsies yielded diagnostic specimens. 440 biopsies (55%) were performed as inpatients while 358 (45%) were outpatients presenting to the hospital for renal biopsy only. The gender distribution was 403 male (51%) and 395 female (49%) patients. Of the 798 biopsy specimens, 534 (67%) were from the native left kidney, 16 (2%) from the native right kidney, and 248 (31%) from kidney transplants. All patients were less than 18 years at the time of biopsy with a mean age of 11.1 years and an age range of 4 months to 18 years. Indications for biopsy are included in Table 3.

Overall, hemoglobin and hematocrit levels decreased post-biopsy. The mean pre-procedural hemoglobin and hematocrit levels were 11.7 g/dL and 34.7% respectively and 11.1 g/dL and 32.8% post-procedurally for an average difference of 0.6 g/dL and 1.9%. There were 72 patients (9%) who had a hemoglobin drop ≥2 g/dL and 724 patients (91%) who had a hemoglobin drop <2 g/dL. There were two patients who only received a post-biopsy H/H, and therefore, hemoglobin change could not be calculated. Of the 72 patients with a hemoglobin drop ≥2 g/dL, there were 17 complications (23.6%); 12 minor and 5 major. In patients with a post- procedure hemoglobin drop <2 g/dL, there were 41 complications (5.7%); 39 minor and 2 major.

Table 3: Indications for renal biopsy.

INDICATION	NUMBER OF PATIENTS
Transplant dysfunction	245 (30.7%)
Isolated proteinuria/previous history of nephrotic syndrome	201 (25.1%)
Lupus nephritis	81 (10.1%)
Hematuria and proteinuria (combined)	73 (9.1%)
Acute/chronic renal failure	72 (9%)
Previous history of nephritic syndrome	54 (6.7%)
Elevated creatinine (not else classified)	35 (4.3%)
Isolated hematuria (not else classified)	27 (3.3%)
Other*	10 (1.2%)

Other* includes the following: 2 patients with renal masses, 1 patient with glucosuria, 1 patient with microvillous inclusion disease, 1 patient with dermatomyositis, 1 patient with Fanconi Syndrome, 2 patients with abnormal appearance of kidney on a prior CT and a previous history of cancer, 1 patient with bilateral nephromegaly, 1 patient with Tuberous Sclerosis and multiple renal angiomyolipomas.

Note: Some transplant patients underwent biopsy for transplant dysfunction multiple times on separate occasions.

Of the 358 outpatient biopsies, 7 (2.0%) patients returned to the emergency department after the 4-hour post-biopsy observation period. 5 had persistent pain and two had hematuria that occurred after discharge. Of these 7 complications, 6 were considered SIR group A. The 1 remaining complication [SIR group D] was an outpatient who presented to the emergency department on post-biopsy day 3 secondary to pain. The patient resumed anticoagulation therapy less than 24 hours after the biopsy. The emergency visit work-up revealed a hemoglobin of 8.4 g/dL (down from 11.3 g/dL pre-biopsy) and the patient received a packed Red Blood Cell (pRBC) transfusion with elevation of medical care to ICU status.

There were a total of 58 (7.3%) recorded complications distributed as 51 (6.4%) minor and 7 (0.9%) major. There were 34 minor complications (4.2%) among the inpatient group as compared to 17 (2.1%) in the outpatient group. All but 1 of the major complications occurred in the inpatient cohort. All complications are classified using the 2017 Society of Interventional Radiology Guideline [5] (Table 2). Of the 51 minor complications, 47 were classified as SIR group A and 4 as SIR group B. None of the SIR group B patients received escalated therapy just overnight admission for observation. Of the 7 major complications, 5 were classified as SIR group C and 2 as SIR group D. 6 were inpatients with hematuria requiring pRBC transfusion. A single inpatient underwent a negative renal angiogram. The C sub-group received pRBC transfusions as inpatients without additional escalation of medical care. One inpatient in the D sub-group had a drop of Hgb from 9.6 to 3.4 g/dL and underwent angiography without need for embolization as no active bleeding was identified. The second member of the D sub-group was the patient restarted on anticoagulation prematurely. Neither of the D-subgroup suffered permanent sequelae.

Comparing transplanted to native kidney biopsies, there was a higher rate of complications with native kidney biopsies. Of the 248 transplanted kidney biopsies, there were 11 (4.4%) minor and 1 (0.4%) major complication. In contrast, of the 550 native kidney biopsies, there were 40 minor (7.3%) and 6 major (1.1%) complications. In the transplant group, the 1 major complication was a down-trending hemoglobin which dropped from 9.1 to 6.8 g/dL and was treated with 2 units of pRBCs (SIR group C). In the native group, the 6 major complications were sub-divided as 4 SIR group C and 2 SIR group D. Both complications were discussed above.

When comparing the two biopsy techniques, 765 (95.9%) procedures were performed *via* a direct puncture technique and 33 (4.1%) via a co-axial technique. Among the 33 co-axial biopsies, there were 3 minor [SIR A] complications; 2 patients reporting pain and 1 with a hemoglobin drop of 2.1 g/dL. There were no major complications.

The mean number of biopsy needle passes was 2.5, with a median of 2 and range of 2-7. In those biopsies resulting in complications, the mean number of passes was 2.7, with a range of 2-7. In the major complication group, the mean number of biopsy passes was 2.9, with a range of 2-5.

Discussion

In this single institutional study we used a standardized protocol, including identical imaging equipment, clinical practice, and laboratory values from a single laboratory. Remarkably, we were able to achieve 100% technical success regardless of minor individual technical variations. Therefore, we can conclude that the protocol utilized including the pre-procedural choices of laboratory tests and imaging and biopsy is appropriate for successful biopsy of native or transplanted kidneys.

Our null hypothesis that a Hgb drop of ≥2 g/dL was clinically significant led to this retrospective study. Analysis of this parameter demonstrates that only 2 major complications occurred in patients with a Hgb drop of <2 g/dL. One of these patients was discharged home but was prematurely re-started on their anticoagulation therapy. The patient subsequently presented to the emergency department with a significant Hgb drop [2.9 g/dL] requiring admittance to the intensive care unit for pRBC transfusion therapy. The second patient had a low pre-procedural Hgb (<9 g/dL) and therefore, despite a clinically insignificant Hgb drop of <2 g/dL, required pRBC transfusion due to low oxygen carrying capacity (Hgb <7 g/dL). A low oxygen carrying capacity is critical from an anesthesiology perspective as it increases the risk of hypoxemia under anesthesia which requires compensatory increased cardiac demands including tachycardia.

Historically, we have performed biopsies with pre-procedural pRBC transfusion if the Hgb is <8 g/dL. With a pre-procedural Hgb >8 g/dL, we routinely proceeded with the percutaneous biopsy without a red blood cell transfusion. This finding has led to a change in our practice so that children are now given a pRBC transfusion for a baseline Hgb of <9 g/dL to avoid a low oxygen carrying capacity post-procedurally. Otherwise, the threshold of a Hgb drop of <2 g/dL was demonstrated to be a safe parameter for patient discharge or no routine follow-up.

In general, renal biopsy in the IP population was riskier than in OP, as reflected in the rate of complications between the two. The complication rate was significantly higher in IPs, who suffered 34 of 440 (7.7%) minor and 6 of 440 (1.4%) major untoward events when compared to17 of 358 (4.7%) minor and 1 of 358 (0.3%) major complication in the OP group. This discrepancy may be related to inpatients being more likely to have other co-morbidities or lower baseline Hgb (anemia).

When comparing the risk of native versus transplanted kidney biopsy, we found a 10-fold difference in the rates of untoward effects. There was a 4.0% overall complication rate in the native kidney group

and only a 0.4% complication rate in the transplanted kidney group. We are uncertain of the reasons for this difference. However, the children with native kidneys have a more diverse set of indications including higher risk for bleeding related to their disease states than does the transplant group who are biopsied mainly to evaluate the possibility of transplant rejection that may result in less vascular renal parenchyma. In addition, we believe that the closer proximity of the transplanted kidney to the skin surface may facilitate sampling and reduce complication risks.

Technically, a co-axial biopsy technique with gelfoam track embolization helps further minimize the possibility of post biopsy bleeding. A co-axial technique was utilized in 33 cases, 21 IPs and 12 OPs (Table 1). There were 3 total complications, all classified as SIR A (Table 2). 2 children had pain and 1 developed a 2.1 gm/dL drop of Hgb with no clinical symptomatology. This data supports the use of a co-axial technique as an effective strategy in high-risk children.

Of the 348 OP biopsies, only 7 children [1.9%] returned to the Emergency Department post- biopsy. Of these 7 complications, 6 were minor with the patient having a negative US examination performed in the emergency department with subsequent discharge to home. The single major complication occurred in a child who had a substantial Hgb drop [SIR D] that was the consequence of prematurely resuming the patient's pre-procedural anticoagulation regimen by the caregiver, as discussed previously. This data supports our selection criteria for outpatient biopsy with a 4-hour observation period as a safe practice and this protocol for all image-guided percutaneous renal biopsies.

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