

Review Article

Native Kidney Biopsy: An Update and Best Practice Evidence

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Abstract

Objectives: To Provide up-to-date guidelines for medical and nursing staffs on the pre, during, and post care of a patient undergoing a percutaneous-kidney-biopsy-PKB.

Method: We review PKB procedures as performed at the Royal hospital by staff at the Renal Medicine Department since its establishment. The objective is to ensure the better care of our patients in providing a better diagnostic yields and hence proper management.

Results: PKB is obtained in 95%-99% of PKBs, with a typical yield of about 10-20 glomeruli when using 14- and 16- gauge needles. The diagnostic yield does not seem to differ significantly when comparing 14- and 16-gauge needles, but some (although not all) studies indicate lower yield with smaller (18-gauge) needles. Other factors, such as patient characteristics (e.g. kidney size) and operator experience, may also affect diagnostic yield.

Conclusion: PKB remains an essential component of nephrology diagnosis and management guidance. In training and practice, it may be better to use Semi-automated 18-gauge-15 cm-20 gauge needles. The procedure is a critically important component of the scope of practice of nephrologists, and all fellows should be competent to perform PKB independently and without direct supervision at the completion of fellowship are essential and urgently needed.

Keywords: Biopsy needle; Computerized Tomography (CT); Kidney biopsy; Percutaneous Kidney Biopsy (PKB); Systolic BP (SBP); Transjugular Kidney Biopsy (TJKB); Ultrasonography

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Introduction

The burden of non communicable diseases has been a worldwide public health challenge, as chronic diseases compose 61% of global deaths and 49% of the global burden of diseases. Currently, many countries are encountering a fast transformation in the disease profile from first generation diseases such as infectious diseases to the encumbrance of non communicable diseases. In addition, Chronic Kidney Disease (CKD) is increasingly recognized as a global public health challenge as 10% of the global population is affected [1,2].

The scarcity of well-trained renal pathologists, even in high-income countries, is a major obstacle to use of biopsy samples. The ISN is working worldwide to enhance development of local renal pathology expertise. Levin et al stated that analysis of kidney biopsy samples can be used to stratify CKD into distinct subgroups of diseases based on specific histological patterns, when combined with the clinical presentation [3]. Diabetes mellitus and hypertensive nephropathy are the commonly identified causes of End-Stage Kidney Disease (ESKD). Also, many patients with glomerulonephritis, systemic lupus erythematosus, and inherited kidney disease present with advanced CKD.

There is an intriguing relationship between kidney physiology and health and disease. The kidney's central role in the function of other organs and processes and its involvement in systemic diseases necessitate the performance of kidney biopsy for the purpose of diagnosis and prognosis and decision of intensity and magnitude of treatment delivery based upon patient's acceptance and agreement. This also affords the opportunity to be "hands on procedurally" by performing a kidney biopsy to inform clinicians decision-making by employing histological studies at various levels. However, Stuart J. Shankl and opined that patient safety is at risk because we lack adequate and standardized procedural training, and standards for procedural competence post-training and this may lead to high rate of complications after kidney biopsies [4].

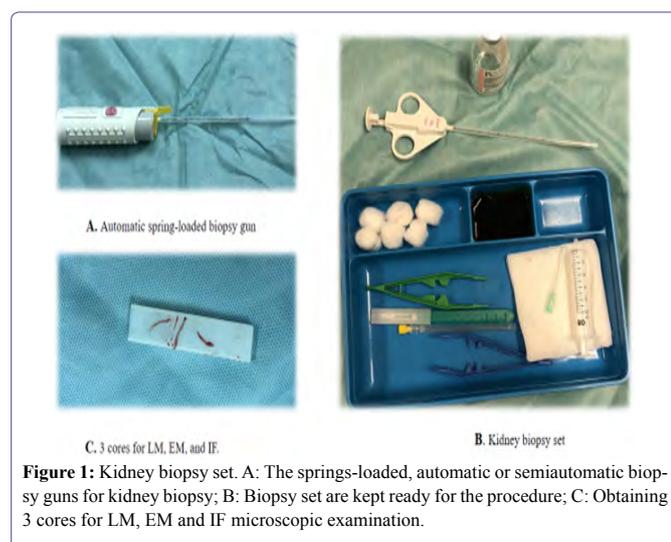
There is an increasing need to ensure that guidelines and treatment strategies are also tailored to low-income and middle-income countries, and that decision makers and funders understand the clinical and socioeconomic benefits of improving access to care [3]. Ferenbach DA and Bonventre stated that CKD can occur through diverse pathologic mechanisms injuring one or several of the compartments of the kidney: vasculature, the tubulointerstitium or the glomerulus. Several features are seen in the kidney regardless of the initiating insult and are known to be important for prognosis and progression to end stage renal disease. Although AKI is a common clinical problem with high levels of morbidity and mortality, renal biopsy is seldom undertaken in the acute phase of disease [5]. In addition, Chang and Chertow have elegantly stated that erroneously informing a patient that he or she has CKD could also lead to a host of adverse downstream consequences, including unnecessary office visits, blood tests, and interventions; difficulties obtaining health or life insurance; and undue anxiety, stress and worry [6]. Hence, making the utmost effort to delineate the actual disease process and the underlying diagnostic

and prognostic information is of paramount importance to patient, clinicians and the health system at large world-wide.

As an invasive diagnostic test, a kidney biopsy is recommended if the following criteria are met:

1. A kidney biopsy is required to make a diagnosis or provide information that guide treatment.
2. The natural history of suspected diseases is associated with significant morbidity and /or mortality.
3. The natural history of these diseases can be improved with therapy (i.e., if the natural history of these disorders could not be altered, then a biopsy would not be performed).
4. The treatment of these diseases differs between diagnosis that are made by kidney biopsy (i.e., one therapy does not exist for all renal diseases for which a biopsy is performed).
5. The treatments' adverse event profiles are acceptable to your patient in his/her current state of health.
6. The risk of the procedure is acceptable to your patient in his /her current state of health [7].

These criteria have been increasingly met for the kidney biopsy since its initial description after unpublished attempts by Alwall in Sweden in 1944 [8], Burn and Iversen of Copenhagen in 1951 [9], were the first to publish their experiences of aspiration biopsy with patients in the sitting position. However, the success rate in obtaining useful tissue remained low. It was Kark and Muehrcke in 1954 [10], who performed the first kidney biopsy in the prone position using Vim-Silverman needle. Finally, in 1961, the publication of CIBA foundation symposium of Kidney Biopsy registered the coming of age of a clinically useful and acceptable technique [11]. Today most nephrologists prefer to use one of the springs-loaded, automatic or semiautomatic biopsy guns for kidney biopsy, as shown in figure 1. The addition of ultrasonography and Computerized Tomography (CT) to locate the kidney as an aid in positioning of biopsy needle has simplified the technique.



As kidney transplant is significantly different from native kidney biopsy, transplant biopsy in not being discussed in this manuscript.

Potential contraindications for kidney biopsy in individual patients are listed in table 1.

1. Small kidneys or ESKD.
2. Abnormal coagulopathy / severe anemia.
3. Uncontrolled sever hypertension.
4. Hydronephrosis.
5. Inability to provide informed consent.
6. Multiple bilateral cysts.
7. Urinary tract infection, pyelonephritis, or perirenal abscess/infection.
8. Horseshoe kidney.
9. Uncooperative patient or inability to follow instructions during biopsy.

Table 1: Absolute and Relative contraindication to percutaneous kidney biopsy.

Pre-biopsy evaluation

Psychological preparation prior to procedure: All patients should receive general psychological preparation prior to the procedure. Psychological preparation should include specific interventions to provide needed information and to reduce anxiety. Information should be provided about:

- The procedure itself;
- The sensation the patient can expect to feel during and after the procedure;
- About how to cope with the procedure and post procedure recovery (e.g. Bed rest and when to mobilize).

Criteria to be met prior to admission:

1. The indications for biopsy are clearly stated.
2. Obtain complete blood count, international normalized ratio/ prothrombin time and activated partial thromboplastin time.
3. Formal recent ultrasound should be reviewed.
4. Appropriate informed consent should be obtained.
5. Medications should be reviewed for agents that may increase bleeding risk (anticoagulants, antiplatelet agents, and nonsteroidal anti-inflammatory drugs).
6. Blood pressure should be optimized and if Bp > 150/90 mmHg, anti-hypertensive medications should be reviewed and adjusted.
7. The urgency of the need for the procedure will depend on the clinical presentation, to give booked admission or to go for direct admission. If booked admission, ideally the Patient to be admitted early morning in the day of procedure through day care unit admission, or one day before the procedure in the nephrology ward if patient is not from Muscat catchment area or if the BP needs better control. Earlier admission may be appropriate if the patient is less fit or there are other concomitant medical problems that may interfere with performing the biopsy.

Per biopsy anticoagulation: Clinicians should adhere to evidence-based guidelines on the perioperative management of anti-thrombotic therapy, as shown in table 2 [12]. There are no data on the effect of newer anticoagulants on Percutaneous Kidney Biopsy (PKB) complication rate.

Criteria to be met on day of procedure:

Complete the admission Performa and Confirm that the patient has known about the procedure.

1. Seek or re-confirm and record patient's consent.

- Systolic Bp<150mmHg and diastolic Bp<90mmHg in recumbent position, from both arms for at least 2 readings, without augment Bp management on the day of the procedure.
- Recheck the result of needed investigations: CBC, Coagulation profile, INR and to be confirmed with the treating consultant.
- If serum creatinine is >300umol/L. consider use of Desmopressin (DDAVP), 20 micrograms in 50mls 0.9% sodium chloride to be given over 30 minutes prior to the procedure (this is contraindicated for patients with known IHD).
- Ensure that the histology technicians are aware about biopsy. If an infection risk e.g. blood borne virus positive or possible renal tuberculosis, the histology technicians should be clearly informed.
- Urgent biopsies should ideally be carried out early as possible and to finish it enough time before routine working hours.

Agent	Patient Population	Recommendation (Grade)
Aspirin	High risk for CV event	Continue aspirin (2C)
	Low risk for CV event	Stop 7-10 days before procedure (2C)
Vitamin K antagonist (e.g., warfarin)	High risk for thromboembolism	Use bridging anticoagulation (2C)
	Low risk for thromboembolism	Stop 5 days before procedure (1C); resume 12-24 h after procedure (2C)
Intravenous UFH as bridging anticoagulation	High risk for thromboembolism	Stop 4-6 h before procedure (2C)
LMWH as bridging anticoagulation	High risk for thromboembolism	Last therapeutic dose 24 h before procedure; for procedure at high risk of bleeding, resume 48-72 h after procedure (2C)

Table 2: Perioperative management of antithrombotic therapy.

Note: CV; cardiovascular, 2C weak recommendation on the basis of low-quality evidence, 1C; strong recommendation on the basis of low-quality evidence, UFH; unfractionated heparin, LMWH; low molecular weight heparin.

Biopsy technique and operator: The Percutaneous Kidney Biopsy (PKB) is the current standard of care, and most large case series describe ultrasound guided PKBs performed by nephrologist or radiologist [13]. PKBs are most commonly performed under local anesthesia with disposable, automatic, spring-loaded devices using 14-16 or 18-gauge needles (outer diameter of 2.11, 1.65 and 1.27 mm, respectively). Some but not all comparative studies have shown that automated needles provide superior yield (more glomeruli) [14] and lower major complications rates [15], than older hand-driven (trucut) systems. Although some operators use trocars to help guide the biopsy needle, most biopsy series do not describe using this technique.

Adequate Tissue (the criteria for which differs between diagnosis) [16], is obtained in 95%-99% of PKBs, with a typical yield of about 10-20 glomeruli when using 14- and 16- gauge needles [13]. The diagnostic yield does not seem to differ significantly when comparing 14- and 16-gauge needles, but some (although not all) studies indicate lower yield with smaller (18-gauge) needles [17-23]. Other factors, such as patient characteristics (e.g. kidney size) and operator experience, may also affect diagnostic yield. The use of 14-gauge needles has been associated with higher transfusion (2.1%) rates compared with 16-gauge (0.4%) and 18-gauge (0.6%) needles (P=0.05) [24]. Given these data, it is recommended to use Semi-automated 18-gauge-15 cm-20 T biopsy needles [25,26].

Kidney biopsies are performed at certain centres in each country world-wide. At our country, there are only done at two institutions in the whole country. At the Royal Hospital with electronic documentation started since 2006 till final review of this work at end of 2017, we had a total of 530 native kidney biopsies shown in figure 2. World-wide, there is variable number of biopsies performed per centre which is based on socio-economic and health system related strategies.

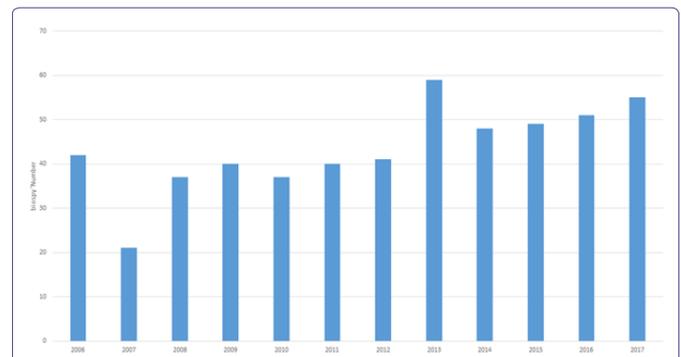


Figure 2: World-wide, there is variable number of biopsies performed per centre which is based on socio-economic and health system related strategies.

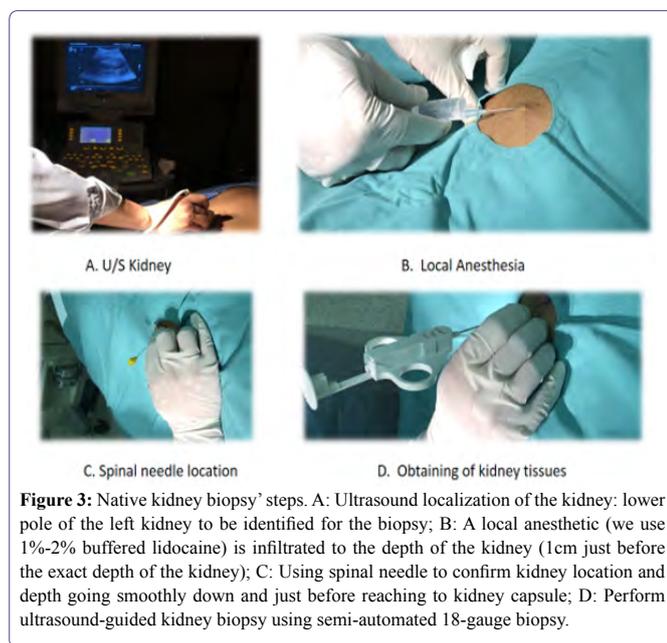
One retrospective study found no difference in diagnostic yield or complications (hematoma, need for transfusion, gross hematuria, pain, or infection) between ultrasound-marked, blind PKBs performed by nephrologist (n=271) and real-time/ultrasound-guided PKBs performed by nephrologists (n=170) or radiologists (n=217) [27]. It should go without saying that a kidney biopsy should only be done by someone skillful in performing the procedure and when the tissue can be processed and interpreted by those with the skills necessary to do [25]. Yet fellowship is needed to state process of training.

Biopsy protocol and specimen processing: Before shifting the patient to treatment room, Operator should review needed blood investigations: complete blood count, International normalized ratio/prothrombin time and activated partial thromboplastin. Medications should be reviewed for agents that may increase bleeding risk (anticoagulants, antiplatelet agents, and nonsteroidal anti-inflammatory drugs) and an appropriate informed consent should be confirmed. Adequate intravenous access is necessary to be secured before shifting the patient to treatment room and to be kept till discharge time (8 hours post biopsy).

Mild sedations to be given to the patient, 10-15 minutes before shifting the patient (Midazolam 3mg and Prometazine 12.5mg-Both are IM injection). Biopsy set are kept ready for the procedure, as shown in figure 1.

The kidneys are scanned as a routine with longitudinal and transverse images, with complete evaluation of the cortical and sinus echogenicity, looking for any structural abnormalities prior to the biopsy, as shown in figure 3. The lower pole of the left kidney to be identified for the biopsy. After ultrasound localization of the kidney, the overlying skin is prepped and draped in a sterile fashion and a local anesthetic (we use 1%-2% buffered lidocaine) is infiltrated to the depth of the kidney (1cm just before the exact depth of the kidney), as shown in figure 3B. We are using spinal needle to confirm kidney location and depth going smoothly down and just before reaching to kidney capsule we request the Patient to take deep inspiration and to hold it

while we push the spinal needle more down just ½cm after passing the kidney capsule then we ask the patient to release his breath and watching the swing movement of the spinal needle, as shown in figure 3. After confirming the exact position and depth of the kidney we pull out the spinal needle and measure the exact depth of the cortex marking it on the biopsy needle. We perform ultrasound-guided PKBs using semi-automated 18-gauge biopsy needle [13], as shown in figure 3, obtaining 3 cores for LM, EM and IF Microscopic examination. Each time, biopsy needle is going through the same direction and depth of the spinal needle. At the same time histopathology technician collects the 3 cores and start processing for LM, EM and IF examination, as shown in figure 1. By the end of the process wound dressing is applied.



Post-PKB, we prescribe bed rest for 8 hours, and we monitor vital signs every 15 minutes for 2 hours, every 30 minutes for 2 hours, and then, hourly for the remainder of the observation period. Each urine void is checked for hematuria visually and the result to be recorded. Post biopsy a complete blood count is not routinely checked, only in case of suspected complications.

All patients undergoing renal biopsy are to be evaluated for the development and timing of a post-biopsy complications. The timing of a complications is defined by the first clinical signs or symptom or a laboratory finding (i.e. gross hematuria, sever flank pain, hypotension or decrease in hemoglobin requiring transfusion) that a clinically relevant problem existed.

Nephrologist and biopsy operators should also be competent at biopsy specimen division (if needed) and processing [26,27]. Nephrologist' input on the basis of the biopsy indication is a must to ensure proper specimen division for optimum diagnostic and prognostic yield. Kidney biopsy should be accompanied by adequate clinical information to enable proper interpretation of findings. Statement that "one cannot feed in garbage and get out fruit juice" is most appropriate while providing information to the pathologist.

Expected discharge time:

A. 8 hours post biopsy in case of smooth recovery

Discharge Criteria:

- Post biopsy observation is stable for minimum 6-8 hours.
- Patient has voided clear urine with No macroscopic hematuria.
- No significant abdominal pain.
- Tolerating food and fluid.
- Patient has ward contact details if any problem.

B. After full stabilization in case of complications or after complete treatment course in case of need.

Return to work and other activities: A day or two off work is usually enough, heavy manual activities/Strenuous exercise should be avoided for one week.

Follow-up: Appropriate follow-up in clinic should be arranged (the time of the appointment will depend on the circumstances). We have a regular clinic-pathology meeting every month.

Biopsy results: For urgent biopsies and after discussion with pathologist we can get a preliminary report on the same day for light microscopy examination and 2-3 working days to get a full written report.

In case of routine elective biopsy, appointment will be fixed through outpatient clinic within two to four weeks. Sometimes, for patients from outside Muscat, they can follow with nephrologist at their regional hospitals with full referral including laboratory results and management strategies.

Complications of PKB: Complication rates after native kidney biopsy are delivered mostly from retrospective and prospective case series at individual centers. The strength of these studies includes the large patient numbers (500-2000) and uniform interinstitutional operators, expertise, and technique. Their limitation includes inter study heterogeneity in technique (blind/ultrasound guided), needle gauge and type (trucut/vim-Silverman/automated), operator (nephrologist/radiologist), and definitions of complications. In addition to reporting bias, these differences can confound the interpretation of the literature as a whole and may not reflect real-life practice.

Bleeding: Bleeding is the most common, clinically relevant complication after a kidney biopsy. Studies from 1970s and 1980s showed evidence of bleeding in 57%-91% of patients by utilizing CT scan [28-30]. A decrease in hemoglobin level after PKB is very common, but generalized bleeding rates after PKB are difficult to state given the heterogeneity in how bleeding is defined and diagnosed between studies. We consider a major bleeding complication as one that result in an alternation of clinical practice, leading to significant pain, extended hospital stays, urinary obstruction, requirement for blood transfusion, intervention (like Foley's catheter insertion and bladder irrigation), surgery, or death. Nephrologist should also be aware that postural changes may contribute to variations in hemoglobin levels commonly observed after PKB [31].

Corapi et al. [24], conducted a systemic review and meta-analysis of all adult PKB studies from 1980 to 2011 (34 studies with 9474 biopsies meeting inclusion criteria) and found the rates of complications as listed in table 3. Higher complications rates were observed when a 14-gauge needle (versus a 16- or 18-gauge needle) was used

for studies in which patients had a mean serum creatinine >2.0mg/dl (2.1% versus 0.4%; P=0.02), patients were >50% women (1.9% versus 0.6%; P=0.03), >10% kidney biopsies were done for AKI (1.1% versus 0.04%; P=0.001), and patients had a baseline hemoglobin <12 g/dl (2.6% versus 0.5%; P=0.001). Trends toward increased bleeding risk were observed in studies where mean age was >40 years old (1.0% versus 0.2%; P=0.20) and Systolic BP (SBP) was >130mmHg (1.4% versus 0.1%; P=0.09).

Complications	Incidence
Minor (%)	
Gross hematuria (95% CI)	3.5 (0.3 to 14.5) a
Hematoma on CT Scan	57-91 b
Major (%)	
PKBC transfusion (95% CI) C	0.9 (0.4 to 1.5) a
Intervention (95%)	0.6 (0.4 to 0.8) a
Nephrectomy	0.01 a
Bladder obstruction	0.3 a
Death	0.02 a

Table 3: Risk of complications after percutaneous kidney biopsy.

Note: 95% CI, 95% confidence interval; CT, computed tomography; PKBC, packed red cell.

a: Information from ref. [24].

b: Information from refs. [28-31]. Studies were conducted in the 1980s and 1990s using the CT scanners of that time; incidence may increasing using CT scanners with high sensitivities.

c: Other large series from academic centers observed transfusion rates as high as 5%-9% [18,23,32-35].

Other complications: Infection after kidney biopsy has been described in some case series [36], but if sterile technique is used and unless bowel perforation occurs, it is an extremely rare complication of PKBS.

Although the development of Page kidney after allograft biopsy has been described (0.8%) of patients in a case series [37], no patients with page kidney after native kidney biopsy have been reported [38]. The puncture of other organs is a rare complication of the PKB. In patients where other organs (such as bowel) are in close proximity to the kidney, CT imaging and/or another biopsy approach (TJKB, laparoscopic, or open) may be required to safely perform the procedure.

Timing of complications: Whitter and Korbet [39], found that 67% of major complications (need for transfusion or invasive procedure, acute renal obstruction or failure, septicemia, or death) occurred during the first 8 hours of observation, with 91% detected by 24 hours and 9% detected after 24 hours. In a smaller retrospective series, Simard-Meilleur et al. [34], found that 100% of complications in outpatients undergoing PKB occurred within 8 hours versus 72% of complications in inpatients and that 10% of inpatients had complications >24 hours after PKB. Another large biopsy series found that 91% of major complications occurred within 12 hours of PKB, with 7.4% occurring between 12 and 24 hours and 1.85% occurring after 24 hours [40]. On the basis of these data, our practice is to discharge uncomplicated outpatients who live close to the Royal hospital 8 hours after PKB and recommend an extended (24-hour) observation period for high-risk patients or those who live far from the hospital.

Post biopsy Imaging: Waldo et al. [41], analyzed 162 patients with native, ultrasound-guided PKBs (automated needle) who had an ultrasound 1 hour post-procedure, minor complications occurred in 8% of patients, and major complications occurred in 8% of patients (transfusion,

n=12; radiologic intervention, n=2); 69% of patients with minor complications (defined as those resulting in gross hematuria and /or a clinically symptomatic perinephric haematoma, but spontaneously resolving without the need for further intervention) and 87% of patients with major complications (defined as complications resulting in the need for intervention, such as a transfusion of blood products or invasive procedure, radiographic or surgical, those resulting in acute renal obstruction or failure, septicemia or those resulting in death) had a detectable hematoma. The size of hematoma did not predict complication, although there was a trend toward association with hematoma size >3 cm (55% versus 26%; P=0.06). The positive predictive value of a hematoma for developing a complication was 43%, whereas the negative predictive value was 95%. In another case series, Ishikawa et al. [42], retrospectively analyzed 317 PKBs at one center with an ultrasound performed 10 minutes after biopsy; 86% of patients had a detectable hematoma (13% hematoma >2cm). Although the presence of a >2cm hematoma was associated with a greater absolute decrease in hemoglobin (6.9% versus 2.9% for <2cm and 2.0% for no hematoma) and a hemoglobin decrease >10%, it was not associated higher rates of transfusion or intervention. These data and others [43], show that the presence of hematoma on post biopsy imaging does not predict clinically relevant complications, but the absence of hematoma has a high negative predictive value for complications and may be used to determine which patients can be discharged with a shorter observation period.

Were commend that post biopsy imaging be performed only when clinically indicated as development of hypotension, flank pain, gross haematuria and urinary obstruction.

The role of nephrologist in kidney biopsies

The Accreditation Council on Graduate Medical Education requires that nephrology fellow must be able to competently perform PKBs of both native and transplanted kidneys [44] and the American Board of Internal Medicine requires that competence in the performance of native and allograft PKBs be verified by the fellowship program director for initial certification in nephrology [45]. Requirements for training and determination of competence at the discretion of the individual training program and vary widely [46]. In one survey of nephrologists who completed their fellowship training from 2004 to 2008, 15%-20% indicated that they did not fell competent performing native and transplant PKBs [47]. Evidence-based standards for assessment and documentation of proficiency among nephrology fellows are needed [48] and use of simulation training may enhance competency [49,50].

It is a matter of ongoing debate as to whether nephrology fellowship programs should be required to provide sufficient training for graduates to independently and safely perform PKBs [51]. Some of the reasons cited for eliminating this requirement include time constraints, malpractice insurance costs, nephrologists do not do biopsies in practice, and inability to provide sufficient supervised experience. In fact, many nephrologists continue to perform kidney biopsies, and with proper training, nephrologists can become experts at ultrasound making for biopsy [52].

Kidney biopsy is an indispensable tool for current practice evidence-based medicine. Levin et al., stated that kidney biopsies can offer a valuable evidence on disease activity, its molecular mechanisms, and disease prognosis. Levin et al., emphasized that even in high-

income nations, kidney biopsy is only performed in a trivial percentage of patients with chronic kidney disease, typically in patients with assumed glomerular disease in whom knowledge of biopsy findings, such as endorsement of a precise cause, evidence for active inflammation and renal tubular damage, or sclerosis and fibrosis that might prompt a change in clinical management.

We believe that the PKB should remain an essential component of nephrology training and practice. Rather than giving up performance of a procedure long considered to be critically important component of the scope of practice of nephrologists, we believe that standards of establishing and documenting that all fellows are competent to perform kidney biopsies independently and without direct supervision at the completion of fellowship are essential and urgently needed. We are conducting an active fellow ship program in our department; 3 fellows finished their fellowship program last year and they can perform both native and transplant biopsies fully independent.

In the other hand, patient safety is of paramount importance in any procedure performed for diagnostic purposes. Stuart J. Shankland argued that "kidney biopsies should focus on patient safety first and foremost, which requires a group of very dedicated, qualified, and skilled operators who do this day-in and day-out, whether they are nephrologists or not. If a nephrologist fulfils these simple criteria, they should certainly participate in these two procedures. He argued strongly that if nephrology profession can stand up in the court of public opinion and defend the training of nephrology procedures to ensure the safest, highest quality patient care".

Increasing the use of kidney biopsies will require education, capacity building, and augmented hard work. Ideally, we will be able to compare biopsy findings across centres and settings and support the implementation of standards for kidney biopsy reporting. Regional centres for kidney biopsy procedures should be established worldwide, with appropriate access to expertise and supplies.

Compliance with Ethical Standards

Disclosure of potential conflicts of interest

The study did not require ethical approval from the Scientific Research Committee at the Royal Hospital, Muscat, Oman, Ministry of health.

Informed consent

Not needed for the present study but each participant was freely given, informed consent to undergo biopsy and blood collections.

Availability of data and material

Data of this paper is not available publicly but can be requested from the corresponding author in a reasonable time.

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Conflict of interest

Authors declare no conflict of interest.

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