INDICATIONS, IMMEDIATE COMPLICATIONS AND TISSUE ADEQUACY OF ULTRASOUND GUIDED PERCUTANEOUS RENAL BIOPSY AT MOI TEACHING AND REFERRAL HOSPITAL- ELDORET KENYA

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THIS RESEARCH THESIS IS SUBMITTED IN PARTIAL FULFILMENT FOR THE AWARD OF MASTER OF MEDICINE IN RADIOLOGY AND IMAGING OF MOI UNIVERSITY SCHOOL OF MEDICINE

DECLARATION

Declaration by the Candidate

This thesis is my original work and has not been presented for a degree or any academic credit in any other University or examining body. No part of this work may be reproduced without the author and/or Moi University's prior written permission.

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DEDICATION

I would like to dedicate this work to my God, who has made it possible. To my wife, Mrs Hamdi Mursal, for her undying support and my parents, whose constant encouragement has given me the strength to press on. I am grateful.

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LIST OF ABBREVIATIONS

AVF	Arteriovenous Fistula
BP	Blood Pressure
DBP	Diastolic Blood Pressure
HB	Hemoglobin
INR	International Normalized Ratio
IQR	Interquantile range
IR	Interventional Radiology
MTRH	Moi Teaching and Referral Hospital
PPT	Partial Thromboplastin Time
PR	Pulse Rate
PRB	Percutaneous Renal Biopsy
RR	Respiratory Rate
SBP	Systolic Blood Pressure.
SD	Standard Deviation
USG PRB	Ultrasound-guided percutaneous renal biopsy

DEFINITION OF TERMS

Immediate complication: PRB related complications that occur within 24 hours.

Major complications: Includes AVF, hypotension, perirenal hematoma more than 5cm, which may require intervention, such as (blood transfusion, embolization, nephrectomy), and death(Azmat, Siddiqui, Khan, Sunder, & Kashif, 2017).

Minor complications: Includes pain lasting more than 24 hours, macrohaematuria, perinephric hematoma less than 5cm but spontaneously resolving without the need for further intervention.

Renal masses: These are abnormal growth in the kidney which can be benign or malignant.

Renal parenchymal disease: These are renal medical conditions that include various disorders of the glomeruli, interstitium, tubules, and small blood vessels of the kidneys.

Tissue adequacy: Biopsy tissues were considered adequate if they contained at least eight glomeruli as seen under light microscopy for renal parenchymal diseases, at least one core tissue length more than 10mm for renal masses and a histopathologist can make a diagnosis(Fogo, 2003) (Obiagwu, Abdu, & Atanda, 2014) (Wang et al., 2018).

Ultrasound-guided percutaneous renal biopsy: This is a procedure of acquiring renal tissue for histopathological analysis using ultrasound.

ABSTRACT

Background: Ultrasound-guided percutaneous renal biopsy (USG PRB) is a minimally invasive procedure involving real-time ultrasonographic guidance, a spring-loaded biopsy gun, and with or without a coaxial needle. However, a wide range of complications has been reported, such as arteriovenous fistulas, small perirenal hematomas, large actively bleeding perirenal hematomas, which might require intervention like blood transfusion, embolization and nephrectomy. In some cases, death was reported.

Objective: To assess the indications, immediate complications and tissue adequacy of Ultrasound-guided percutaneous renal biopsy at Moi Teaching and Referral Hospital-Eldoret Kenya.

Methods: This was a census, a prospective descriptive study conducted among 48 adult patients scheduled for USG PRB from November 2019 to October 2020.

A data collection form was utilized to record age, gender, pre-biopsy laboratory findings, renal biopsy indications, post-biopsy complication findings and tissue adequacy. Biopsies were taken by the consultant radiologist under ultrasound guidance using a 3.5-5MHZ curvilinear transducer of Mindray M7 (ultrasound machine with exquisite Doppler and greyscale capability), coaxial needle and biopsy gun. A two to five core tissues were obtained. Biopsy tissues were considered adequate if they contained at least eight glomeruli for native kidneys. One core tissue length more than 10mm for renal masses and a histopathologist can make a diagnosis. Continuous variables were summarized using means and standard deviations. Categorical variables were summarized in frequency, percentages and bar graphs. Fisher's exact test was done to assess the relationship between complications and associated factors. A p-value of less than 0.05 considered significant.

Results: The mean age was 34.8 years (SD=13.1). The majority of the participants (52.1%) were females. Nephrotic syndrome was the commonest indication for renal biopsy (45.8%) followed by renal masses (25.0%), SLE (20.8%) and nephritic syndrome (8.3%). The overall complications were 8(16.7%). Seven patients (14.6%) developed minor complications, namely, macrohematuria (n=5) and perirenal hematoma less than 5cm (n=2). One participant (2%) developed a major complication (perirenal hematoma >5 cm and hypotension) where transfusion and gelfoam embolization was done. The number of biopsy passes had a statistically significant association with the complications (p-value < 0.001). However, gender, creatinine and indications for PRB were not associated with complications. The majority of the participants (95.8%) whose tissue specimens were obtained were declared adequate by the histopathologist.

Conclusions: Nephrotic syndrome was the most common indication for Ultrasound-guided PRB. Macrohematuria was the commonest complication of USG PRB. More than four biopsy passes were significantly associated with post PRB complications. Up to 95% of the biopsy tissues were adequate.

Recommendations: Close monitoring for patients done more than 4 biopsy passes is recommended After USG PRB.

CHAPTER ONE

1.1 Introduction

Ultrasound-guided percutaneous renal biopsy is a diagnostic method used over many years in the diagnosis of focal and non-focal renal diseases, assess prognosis, decide treatment strategy, and evaluate response to treatment(Manno et al., 2004). The technique has evolved over the years to improve diagnostic accuracy and patients safety(Bagga, 2005). The improvement in biopsy needles and imaging technique has increased the ability to obtain adequate renal tissue for diagnosis by over 98%(Maya, Maddela, Barker, & Allon, 2007).

The kidney is bean-shaped with a superior, midpole and inferior pole and has a fibrous capsule, which is surrounded by perirenal fat and Gerota's fascia(Macchi et al., 2017). The kidney is subdivided into renal parenchyma, comprising of renal medulla and cortex, and the renal sinus containing renal pelvis, lymphatic's, renal vessels nerves and calyces(Macchi et al., 2017).

The kidneys are supplied by renal arteries that originate from the abdominal aorta and enter renal hila. It subdivides into the anterior and posterior division which further subdivides into segmental, interlobar, arcuate and interlobar branches(Klatte et al., 2015).

The venous drainage is by peritubular capillary venous plexus that drains through venae rectae into the arcuate veins which in turn drains to interlobar veins and continues as renal vein. Renal vein drains to IVC (Klatte et al., 2015).

Brodel bloodless line is an avascular plane of renal parenchyma between anterior 2/3 and posterior 1/3 on cross-section which represents a plane where posterior and anterior segmental artery branches meet(Macchi et al., 2017).

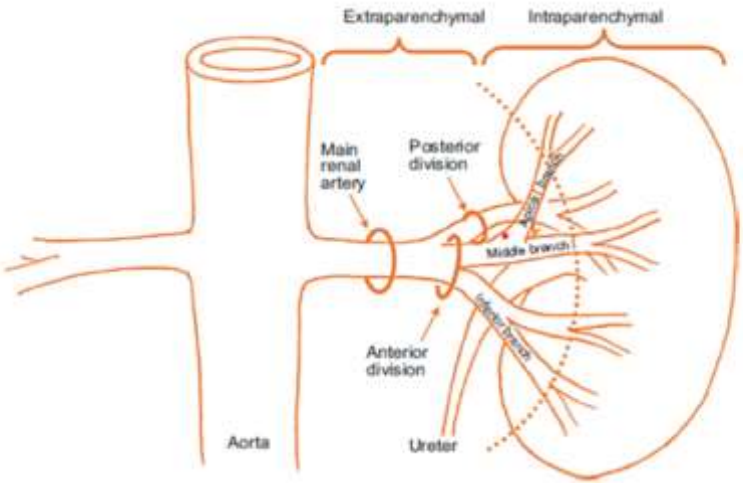

Figure 1:Renal Artery Anatomy
Adapted from (Klatte et al., 2015).

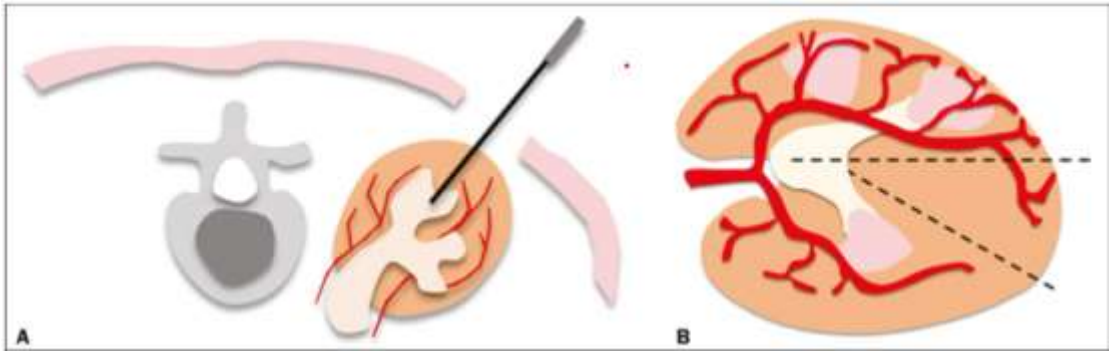

Figure 2: Brodel bloodless line
Adapted from (Macchi et al., 2017).

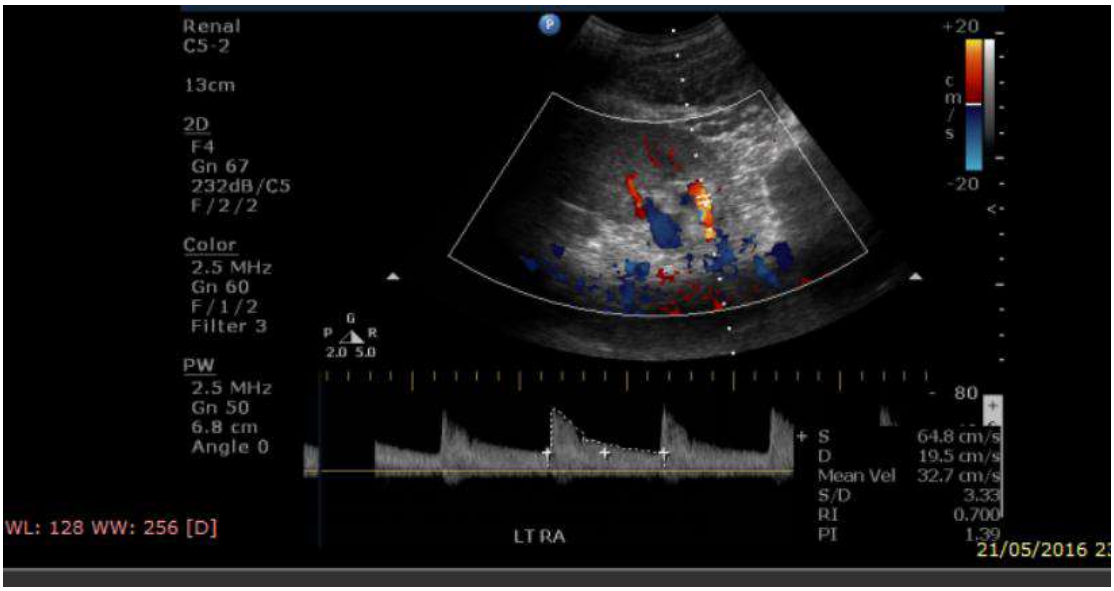

Figure 3: Normal Renal Arterial Dopler and waveform
Adapted from (M, Alungat 2019)

The common indications for renal biopsies include nephrotic syndrome, nephritic syndrome, acute and chronic renal failure of unknown aetiology, systemic lupus erythematosus, evaluation of renal transplant rejection and renal masses(Obiagwu et al., 2014)(Bakdash et al., 2019)(Agarwal, Sethi, & Dinda, 2013)(Airapetian et al., 2015)(Vermeulen et al., 2019)(Lemrabott et al., 2019).

Nephritic syndrome is characterized by abrupt macroscopic hematuria, oliguria, acute renal failure, manifested by edema and hypertension. Urinary protein varies widely in this syndrome and is generally less than 3g of protein per day(Lemrabott et al., 2015). Nephrotic syndrome is characterized by “heavy” proteinuria (protein excretion, >3 g per day), hypoalbuminemia, edema, and varying degrees of hyperlipidemia and lipiduria(Lemrabott et al., 2015).

A wide range of complications has been reported in PRB. These complications range from small perirenal hematomas to a large actively bleeding hematoma that requires intervention like blood transfusion, embolization, nephrectomy and some reported death (Bagga, 2005).

Bleeding is the primary complication of renal biopsy in about 30%. It may be macroscopic hematuria, small perirenal hematoma detected on ultrasound or blood loss requiring transfusion emergency angiographic intervention or nephrectomy(Ishikawa et al., 2009).

About 7% of these complications are life-threatening and need urgent intervention(Whittier & Korbet, 2004). But there is a variation in the incidence of complications across different studies.

The current diagnostic PRB involves the use of a spring-loaded biopsy gun and real-time ultrasonographic guidance. Though this has lowered the post kidney biopsy

complications with life-threatening complications resulting in death decreasing from 0.12 to 0.02%, still significant complications have been reported (Whittier & Korbet, 2004).

The other fewer complications that were also reported in some studies include infection, arteriovenous fistula, adjacent organ damage, low back pain and even death, although rare(Manno et al., 2004)(Ishikawa et al., 2009)(Gervais, 2010).

Several factors are associated with an increased rate of post-PRB complications, i.e. prolonged bleeding time, increased partial thromboplastin time, elevated serum creatinine, repeated punctures, thrombocytopenia, coagulation factor abnormalities, amyloidosis and uncontrolled hypertension(Stratta et al., 2007).

The basis of diagnostic yield for the PRB is the number of glomeruli per specimen. A successful biopsy is considered by the presence of adequate tissue in the renal sample biopsy with at least 8-10 glomeruli in non-focal biopsies (Al Rasheed, Al Mugeiren, Abdurrahman, & Elidrissy, 1990)(Geldenhuys et al., 2015).

Most of the studies reported over 85% post-percutaneous renal biopsy tissue adequacies(Franke, Kramarczyk, Taylan, & Maintz, 2014) (Bakdash et al., 2019)(Esposito et al., 2018)(Whittier, Gashti, Saltzberg, & Korbet, 2018)(Kruger & Loggenberg, 2011)(Chung et al., 2014)(Obiagwu et al., 2014).

The purpose of this study is to assess the indications, the incidence of immediate complications (both major and minor) and tissue adequacy of Ultrasound-guided percutaneous renal biopsy.

1.2 Problem Statement

Renal disease is on the rise globally, currently estimated at 10% of the world population, and responsible for 1 million deaths annually(Kaze, Ilori, Jaar, & Echouffo-Tcheugui, 2018).

The overall prevalence of renal disease in Africa is 15.8%, sub-Saharan Africa 17.7%, while in Kenya, the prevalence is 2.05%(Abd Elhafeez et al., 2018)(Kaze et al., 2018)(Stanifer et al., 2014)(Cherono, 2017).

30% of USG PRB complicate (Ishikawa et al., 2009) and about 7% of these complications are life-threatening and need urgent intervention (Whittier & Korbet, 2004).

No data is available on the indications, immediate complications and tissue adequacy of percutaneous renal biopsy in this institution.

There is a need to ascertain the burden of immediate complications locally to inform practice.

1.3 Justification

Due to the increase of non-communicable diseases such as diabetes and hypertension in Kenya, renal disease is on the rise in our region. Cherono et al. reported 6040 cases in 2017.

Different renal disease causes cannot be differentiated using clinical presentation and laboratory findings and therefore ultimately needs percutaneous renal biopsy for histopathological diagnosis.

Percutaneous renal biopsy is minimally invasive, relatively accessible and is undoubtedly the gold standard for obtaining tissue in diagnosing renal diseases,

whether focal or parenchymal(Bakdash et al., 2019). It is, however, associated with life-threatening but reversible complications such as haemorrhage requiring urgent and timely interventions such as transfusion, embolization or even nephrectomy (Whittier & Korbet, 2004).

Previous observational studies revealed that time is an integral and most important component in evaluating complications following Ultrasound-guided PRB. Hogan et al. showed that with 24 hours follow up, up to 90% of the complications can be detected in contrast to 8 hours, where only 70% of the complications were noted.

Percutaneous renal biopsy is fairly/relatively common in our setup, with 55 cases done in the year 2018 (IR room record). Despite this significant number of cases, no data is available on the type of complications, indications and tissue adequacy. This study, therefore, aims to address the gap in the lack of data on the potential complications following PRB and will aid policymakers, interventional radiologists, nephrologists and urologists to formulate standard patient care.

1.4 Research question

What are the indications, immediate complications and tissue adequacy of Ultrasound-guided percutaneous renal biopsy at Moi Teaching and Referral hospital-Eldoret Kenya?

1.5 Objective

1.5.1 Broad objective

To assess the indications, immediate complications and tissue adequacy of Ultrasound-guided percutaneous renal biopsy at Moi Teaching and Referral Hospital-Eldoret Kenya.

1.5.2 Specific objective

1. To describe the indications for Ultrasound-guided percutaneous renal biopsy.
2. To determine Ultrasound-guided percutaneous renal biopsy immediate complications and associated factors.
3. To determine the adequacy of the renal biopsy tissue.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

Percutaneous renal biopsy is a relatively safe procedure used in the diagnosis, prognosis and treatment response evaluation(Obiagwu et al., 2014).

Real-time ultrasound is widely used in renal biopsy to get adequate tissue for pathology and minimizes post-procedural complications, but a certain rate of complications have been reported; therefore, due diligence has to be done during the procedure(Maya et al., 2007).

Post renal biopsy complications can be classified as minor complications(gross hematuria, small hematoma less than 5cm, pain lasting more than 24 hours), major complications(AVF, perirenal hematoma more than 5cm, perirenal hematoma requiring embolization, transfusion and nephrectomy or death though rare) (Mendelssohn & Cole, 1995). However, the classification of renal biopsy complications varies across the literature.

2.2 Indications of percutaneous renal biopsy

The clinical presentation and expert opinion are used for the indication of renal biopsy(Bomback, Herlitz, & Markowitz, 2012).

The common indications for renal biopsies include nephrotic syndrome, acute and chronic renal failure, systemic lupus erythromatosus, HIV and evaluation of renal transplant rejection(Eshed, Elias, & Sidi, 2004)(Bomback et al., 2012)(Obiagwu et al., 2014)(Bakdash et al., 2019)(Agarwal et al., 2013)(Airapetian et al., 2015)(Vermeulen et al., 2019)(Lemrabott et al., 2019)(Niang et al., 2008)(Zajjari et al., 2015)(Nadium, Abdelwahab, Ibrahim, & Shigidi, 2013)(Van Rensburg, Van Staden, Rossouw, &

Joubert, 2010)(Okpechi et al., 2011)(Okpechi, Duffield, & Swanepoel, 2012)(Vermeulen et al., 2019)(Kanjanabuch et al., 2005)(Bernieh, Sirwal, & Abbadi, 2000).

Simard-Meilleur et al reported that renal biopsy's most common indications are nephrotic syndrome, acute kidney injury, renal masses, and rapidly progressive renal insufficiency(Simard-Meilleur, Troyanov, Roy, Dalaire, & Brachemi, 2014).

In contrast to the studies mentioned above, unexplained elevation of renal parameters such as non-nephrotic range proteinuria, hematuria was reported to be a common indication of renal biopsies in some studies(Manno et al., 2004)(Manganelli & Iannaccone, 2016)(Stratta et al., 2007).

Renal masses are also a common indication for renal biopsy to determine whether the mass is benign, primary malignancy, or metastasis from extrarenal malignancy(Simard-Meilleur et al., 2014) (Isah, Sahabi, Adamu, Muhammad, & Mungadi, 2013)(Klufio, 2004).

2.3 Complications of percutaneous renal biopsy.

The detection of post renal biopsy complications depends on the quality of post-biopsy follow-up. Doppler ultrasound is necessary for post-renal biopsy assessment to detect AV fistula since many of them are asymptomatic(Franke et al., 2014).

Post-percutaneous renal biopsy complications are classified as minor and major complications(Ishikawa et al., 2009) (Whittier & Korbet, 2004).

The minor complications are perirenal hematoma less than 5cm spontaneously reabsorbed, gross hematuria (Ishikawa et al., 2009) (Whittier & Korbet, 2004).

The major complications include arteriovenous fistula, hematoma requiring blood transfusions, hematoma requiring drainage, post-procedural hypotension, nephrectomy and death(Ishikawa et al., 2009) (Whittier & Korbet, 2004)(Azmat et al., 2017).

The overall complication frequency associated with renal biopsies ranges from 8-34%(Esposito et al., 2018)(Azmat et al., 2017)(Hughson et al., 2009)(Sosa-barrios et al., 2017)(Manno et al., 2004).

Major complication frequency requiring intervention such as transfusion or other intervention range 0.4-6%(Eiro, Katoh, & Watanabe, 2005),(Shidham et al., 2005)(Hergesell, Felten, Andrassy, Kühn, & Ritz, 1998)(Esposito et al., 2018)(Bakdash et al., 2019)(Tøndel, Vikse, Bostad, & Svarstad, 2012). While the mortality from percutaneous renal biopsies is usually less than 1%.(Smith, 1991) (Maya & Allon, 2009).

The minor complication frequency associated with PRB ranges between 4- 33%. (Esposito et al., 2018) (Franke et al., 2014) (Stratta et al., 2007)(Obiagwu et al., 2014)(Shidham et al., 2005)(Esposito et al., 2018)(Maya et al., 2007)(Hughson et al., 2009)(Maya & Allon, 2009)(Azmat et al., 2017)(Manno et al., 2004).

More than 90% of Perinephric hematoma was demonstrated 24 hours post kidney biopsy and was present in less than 6% of the cases was clinically significant but the majority of them are asymptomatic 50%, as a result 24 hours bed rest and patient observation are advised(Rosenbaum, Hoffsten, Stanley, & Klahr, 1978).

7.4% of post renal biopsy complications occur in between 12-24hours after biopsy(Hogan, Mocanu, & Berns, 2015).

Roccatello et al reported no difference in complication rate between inpatient 24hours observation and 6hours post-biopsy observation(Roccatello et al., 2017).

Frequent vital monitory, Doppler ultrasound post-biopsy observation and haemoglobin monitoring is recommended in outpatient renal biopsy where monitoring is only 8 hours(Maya & Allon, 2009)

2.3.1 Hemorrhage

Haemorrhage during the renal biopsy is usually assessed one hour post-biopsy. It is classified as uncomplicated if the bleeding is less than 5cm, and in case it is more than 5cm, it is complicated (Hughson et al., 2009).

Hemorrhage from PRB can be in the collecting system or in the peri-nephric areas (Lechevallier et al., 1997). Nearly a quarter of the non-focal renal biopsies develop macrohematuria, and almost a third develop a peri-nephric hematoma(Walker, 1901(Rosenbaum, Hoffsten, Stanley, & Klahr, 1978) (Rocco & Berns, 2012).

The major complications such as AVF and peri-renal hematoma requiring interventions like transfusion and embolization account for less than 13% (Al Rasheed et al., 1990) (Tondel et al., 2012)(Rocco & Berns, 2012) (Hughson et al., 2009). While minor complications account for 15%(Bakdash et al., 2019)(Manno et al., 2004)(Esposito et al., 2018)(Bakdash et al., 2019).

Other common complications include gross hematuria, flank pain, and drop in hemoglobin requiring transfusion, abdominal pain, hypotension and macro-hematuria and the need for embolization (Hughson et al., 2009). (Manno et al., 2004),(Mendelssohn & Cole, 1995). (Ishikawa et al., 2009)(Whittier et al., 2018). Hematuria is the most common minor complication and accounts for between 1 -

8%(Bakdash et al., 2019) (Tondel et al., 2012)(Whittier & Korbet, 2004)(Azmat et al., 2017).

A fifth of the hematomas is seen in the first one hour of post renal biopsy(Hughson et al., 2009), while peri-nephric bleeding is noted between 24-72 hours (Rosenbaum et al., 1978).

An arteriovenous fistula is more common in kidney transplant biopsies. A-V fistula may decompensate after many years and bleed, causing hemodynamic instability; thus important to detect early(Franke et al., 2014).

2.3.2 Adjacent Organ Injury

Pneumothorax is common in the biopsy of upper pole renal tumours. Proper positioning of the patient by placing the patient ipsilateral side down position minimizes the amount of pleura traverse during the biopsy and accounts for less than 1%(Rocco & Berns, 2012)(Gervais, 2010).

Other commonly injured adjacent organs include the liver, spleen, pancreas, and colon(Gervais, 2010).

2.3.3 Tumor Seeding

The occurrence of tumour seeding through percutaneous biopsy is rare(Chang, Sur, Lozinskiy, & Wallace, 2015).

2.4 Factors associated with complications

The risks that predispose patients to complications after PRB are prolonged bleeding time, poorly controlled hypertension, patients with coagulopathy state and renal insufficiency(Hughson et al., 2009).

The risk of bleeding is two-fold more in patients with BP greater than 160/100mmhg and risk increases by 3 times in patients with a serum creatinine of more than 2mg/dl(Hughson et al., 2009).

Contrary to the studies that reported uncontrolled hypertension as a risk factor for post PRP bleeding, Esposito et al found patients with normal blood pressure have more post-renal biopsy complications as compared with patients with hypertension (Esposito et al., 2018), however, Simard- Meilleur, found uncontrolled hypertension, and renal insufficiency are not associated with increased risk of post renal biopsy bleeding (Simard-Meilleur et al., 2014).

Patients with an estimated GFR of less than 40ml/min(advanced renal failure) have a six-fold increased risk of post-PRB bleeding. (Winkelmayer, Levin, & Avorn, 2003), (Whittier & Korbet, 2004).

The biopsies performed by trainees have major complications compared to the trained and experienced staff. (Abdurrahman & Elidrissy, 1990). High mortality predictors include metastasis, liver disease, acute renal failure, and coagulopathy (Al Turk, Estiverne, Agrawal, & Michaud, 2018). (Karafin, Kendall, & Fleisher, 1970).

Patients with Anemia and thrombocytopenia have a significant risk of developing post renal biopsy hematoma(Simard-Meilleur et al., 2014). Simultaneously, the needle gauge and female gender are also associated with an increased risk of bleeding. The higher the needle size, the more the risk of bleeding (Manno et al., 2004, (Corapi, Chen, Balk, & Gordon, 2012), (Esposito et al., 2018). However, according to Tondel Vikse et al and Simard-Meilleur et al reported the number of passes and size is not associated with major complications(Tondel et al., 2012) (Simard-Meilleur et al., 2014) (Roccatello et al., 2017a).

Bakdash et al. and Roccatello et al. found no significant association between age, gender, diagnosis, and complications (Bakdash et al., 2019)(Roccatello et al., 2017b).

Biopsy passes more than 5 have been associated with post-percutaneous renal biopsy complication risk (Eiro et al., 2005).

The biopsies done with a coaxial needle is associated with lesser complications as compared with biopsies done without a coaxial needle(Babaei Jandaghi et al., 2017)

The number of samples taken determine sample adequacy but increases the risk of bleeding and other complications (Gervais, 2010).

Most of the major complications like Anemia requiring transfusion, acute obstruction, nephrectomy or death occur within the first eight hours post percutaneous renal biopsy(Whittier & Korbet, 2004)**.**

Women were observed to have an increased risk of bleeding due to a greater percentage of fat mass that could increase the bleeding into perirenal tissues(Manno et al., 2004).

Patients with 24 hours post renal biopsy bed rest have fewer complications compared to those without complete rest. (Rosenbaum et al., 1978), this is contrary to Roccatello et al who reported no difference in complication rate between inpatient 24hours observation and 6hours post-biopsy observation(Roccatello et al., 2017b) (Hogan, Mocanu, & Berns, 2015).

When performing an Ultrasound-guided renal biopsy in the outpatient department, it is important to monitor the vital signs, the hemoglobin level and Doppler ultrasound post-biopsy observation is recommended for four to eight hours. (Maya & Allon, 2009) (Franke et al., 2014).

2.5 Tissue adequacy

Currently, there is no agreement among researchers on the definition of tissue adequacy; for renal parenchymal disease Fogo and Obiagwu reported a successful biopsy is considered by the presence of adequate tissue in the renal sample biopsy with at least eight glomeruli seen under a light microscope and histopathologist can make a histological diagnosis(Fogo, 2003) (Obiagwu et al., 2014).

However, Geldenhuys et al defined adequacy for native kidneys by the presence of at least ten glomeruli in light microscopy and one glomerulus in electron microscopy

and immunofluorescence. For transplant kidneys, biopsy tissue should contain at least ten glomeruli on light microscopy, at least one glomeruli in electron microscopy and one artery(Geldenhuys et al., 2015).

Biopsy from a renal mass is considered adequate if at least one core tissue length is more than 10mm and inadequate if the sample contains blood, necrotic tissue or normal renal parenchyma where histopathologist is not able to make a histological diagnosis(Wang et al., 2018).

The success of renal mass biopsy is classified as technical success and histologic success. Technical success is defined by the insertion of the biopsy needle into the target lesion with tissue present in the specimen, while histological success is defined as the presence of adequate tissue for histological analysis(Lee et al., 2019).

Over 85% of post-percutaneous renal biopsy tissue adequacies has been reported(Al Rasheed et al., 1990) (Franke et al., 2014) (Karafin et al., 1970)(Bakdash et al., 2019)(Esposito et al., 2018)(Whittier et al., 2018)(Kruger & Loggenberg, 2011)(Chung et al., 2014)(Obiagwu et al., 2014).

Biopsy gun g14 and g16 produce bigger and wider tissues hence contain more glomeruli, while biopsy gun g18 produces small and narrow tissues(Peters, Mölne, Hadimeri, Hadimeri, & Stegmayr, 2017).

CHAPTER THREE

3.0 METHODS

3.1 Study site

The study was conducted at the Moi Teaching and Referral Hospital, in the main X-Ray unit.

The hospital is located in Eldoret town. The headquarter of Uasin Gishu county. It is 350km North-West of the Kenyan capital Nairobi. It's the second-largest national referral hospital which also serves as a teaching hospital for Moi University School of Medicine (MUSOM), School of Nursing, School of Public Health, and the School of Dentistry and Kenya Medical Training Centre (KMTC). MTRH is an internship Centre for medical, nursing and clinical officers.

Its catchment includes the western part of Kenya and the North Rift, about 20 million people. The hospital has a bed capacity of over 700 patients, with several departments, which include surgery, paediatrics, medicine, obstetrics and gynaecology, radiology and imaging, accident and emergency department, among others.

3.2 Study Design

This was a prospective descriptive study design and was carried out within one year-from November 2019 to October 2020.

3.3 Study Population

Patients aged 18 and above booked for Ultrasound-guided percutaneous renal biopsy.

3.4 Eligibility Criteria

3.4.1 Inclusion criteria

Patients aged 18 years and above scheduled for ultrasound-guided percutaneous renal biopsy in the main X-Ray unit.

3.4.2 Exclusion criteria

Patients with previous percutaneous renal biopsy.

Patients with previous percutaneous renal surgeries.

Critically ill patients.

3.5 Sampling and Sampling Procedures:

3.5.1 Sample Size

This was a census study done over one year to recruit all adult patients scheduled for Ultrasound-guided percutaneous renal biopsy. This was reached owing to the number of Ultrasound-guided percutaneous biopsies done in the year 2018. According to MTRH records, 55 renal biopsies were performed in MTRH in 2018, and so based on these numbers, we set out to recruit all patients that were scheduled for ultrasound-guided percutaneous renal biopsy. The number of patients was limited by the study period of 1 year.

3.5.2 Study procedure

Pre-biopsy tests were conducted a day before the procedure, and these included full blood counts, coagulation profile, creatinine and abdominal ultrasonography.

All adult patients reported to the ultrasound unit radiology department on the morning of the procedure after having fasted for at least six hours and intravenous access was established, usually on the dorsum of the hand. Blood pressure and heart rate were checked before the procedure.

Recruitment of patients was done at interventional radiology unit MTRH. The principal investigator explained the study objective to the patients in a simple and plain language that they could comprehend. Those who met the inclusion criteria and accepted were recruited into the study and signed the consent form for both PRB and study. The investigator recorded the patient's age, sex, hemoglobin level, serum creatinine, baseline coagulation parameters and indications for renal biopsy were obtained from the patient's hospital file. This information was recorded in the questionnaire.

All Patients were placed in a prone position with a pillow under the abdomen to reduce lumbar lordosis.

The kidneys were scanned as a routine with longitudinal and transverse images, with a complete evaluation of the cortical and sinus echogenicity, looking for structural abnormalities before the biopsy. The retroperitoneum (psoas areas) were also evaluated.

The transducer was draped with probe cover and skin disinfected with 10% povidone-iodine, the kidney's biopsy site (focal lesion or lower pole of either kidney in renal parenchymal disease) identified and assessed for accessibility and vascularity. Then local anaesthesia 1% infiltrated. Finally, all biopsies were performed using a coaxial technique with semi-automated biopsy gun G18, coaxial needle G17 and real-time ultrasound guidance (Mindray7 US machine).

All biopsies were performed by the interventional radiologist assisted by the principal investigator.

The coaxial needle was advanced under ultrasound guidance until it reached the lower pole of the kidney or the focal lesion. The biopsy gun is inserted, deployed and removed 2 to 5 times to obtain adequate tissues for histopathological analysis. Each core tissue biopsy was inserted in a sample bottle containing 10% buffered formalin solution for analysis in the hospital's pathology laboratory.

Immediately after the biopsy procedure, an ultrasound evaluation is done to check for any early complications. A firm occlusive dressing was then placed on the biopsy site, and patients were observed in the interventional radiology recovery room where they remained supine, flat on the bed, and closely monitored for one hour.

Vital signs were checked every 15 min for the first one hour, each urine void was checked for the sign and symptoms of post-ultrasound-guided percutaneous renal biopsy complications such as gross haematuria visually; flank pain or hypotension and the results were recorded.

For outpatients, they were continuously monitored at interventional radiology observation for 8 hours. a repeat ultrasound was performed at 1^{st} hour and 8^{th}-hour post-biopsy to check for any complication, and patients were discharged home if they were stable and came back for reevaluation after 24 hours. Post-procedure unstable outpatients were admitted to the ward for 24 hours observation.

For inpatient after 1^{st}-hour post-biopsy monitoring, the biopsied kidney was again examined with ultrasound. Then the patients were taken to the respective wards for 24 hours of observation. Patients were monitored for signs or symptoms of post-biopsy complications, such as gross haematuria, flank pain or hypotension. The principal investigator did additional follow-up studies (repeat ultrasound at 8 hours and 24 hours post-ultrasound-guided PRP). Samples were taken to the MTRH histopathology

laboratory. The total number of glomeruli, maximum core tissue length, inadequate and adequate samples were recorded.

Adequacy of the tissue biopsy was defined as one in which the histopathologist could make a histopathological diagnosis. It included visualization of more than eight glomeruli on light microscopy for native kidney biopsy and at least one core tissue length, more than 10mm for renal masses.

There were three follow-up points; the first follow-up on 1st hour, the second follow up 8th-hour post-percutaneous renal biopsy and the third follow up on 24 hours post-ultrasound-guided PRB at the interventional radiology department and any complications noted were recorded in the data collection sheet.

Detailed ultrasound-guided percutaneous renal biopsy protocol is in appendix VI.

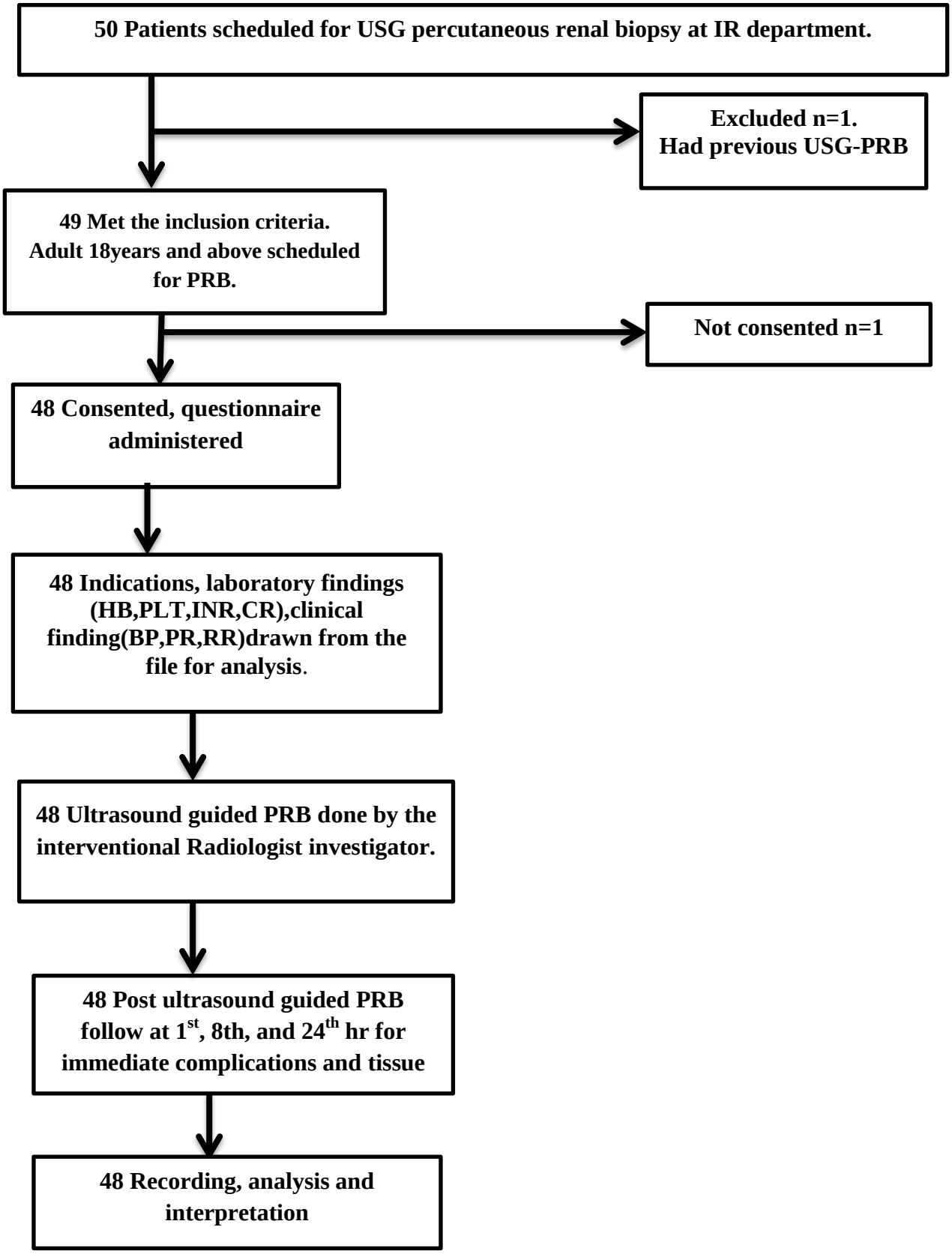

Figure 4: study procedure

3.6 Data Collection, Entry and Management

Data were collected using a structured questionnaire. Information on the socio-demographic characteristics, clinical, laboratory data and indications for renal biopsy were obtained from the patient's hospital file and collected. Any risk factor for post-renal biopsy complications was collected. 1st, 8th and 24th-hour post-biopsy complications were collected.

The filled questionnaires were checked for completeness every day before being kept in a safe cabinet under lock and key kept by the investigator.

Data entry was done into a standard database created using Microsoft Access. The participant's data was de-identified of the patient identifying information and the database was encrypted with a password to ensure that confidentiality is maintained. The password was accessible to the investigator alone. The entered data were checked for consistency, missing data, among other integrity issues, and cleaned appropriately. After data entry and data cleaning were finalized, encrypted backups of the database were created using removable storage devices such as memory sticks and hard drives stored in separate safe locations. This cushioned against data loss.

The cleaned copy of the database was then available for analysis.

3.7 Statistical Data Analysis

Data was imported into STATA/MP version 13, where coding, cleaning and analysis were done. Descriptively categorical data such as sex, indication for percutaneous renal biopsy, biopsy adequacy, and post renal biopsy complications were summarized through frequencies and proportions. While numerical data such as age were summarized through measures of central tendencies (mean/median) and dispersion (standard deviation/interquartile range). Most of the laboratory findings and clinical

findings were captured as numeric variables such as haemoglobin level, INR level, pulse rate, blood pressure were transformed into categorical variables and summarized as a categorical variable. A composite variable, such as "complications", was created by combining several variables capturing complications. This assisted in the test of association between outcome and pre-percutaneous renal biopsy assessment and intra-procedure findings.

Fisher's exact test was done to assess the relationship between complications and associated factors (indication, gender, high creatinine, and the number of biopsy passes). A p-value of less than 0.05 is considered significant.

3.8 Data Presentation and Dissemination

The data was presented in the form of charts, tables and graphs. The results will be disseminated through the presentation department of radiology and imaging, Moi University School of medicine, thesis defense, conferences and publishing in a reputable journal.

3.9 Ethical Considerations

Written informed consent was sought directly from the respondents and information gathered was kept confidential.

Patient names or other identifying characteristics were not used in the study to maintain anonymity.

Respondents were free to withdraw from the study anytime without the need to seek prior authorization or consequences for doing so.

This proposal was submitted for prior approval by the Hospital management and IREC before commencing the study.

CHAPTER FOUR

4.1 Results

4.2 Demographics

A total of 48 participants were recruited for the study. In terms of demographics, the mean age was 34.8 years (std=13.1); the median was 32 (IQR: 23,47.5). 25 (52.10%) were female while the rest were male 23 (47.9).

4.3 Objective 1: Indications for ultrasound-guided percutaneous renal biopsy.

Nephrotic syndrome was the commonest indication of renal biopsy 22(45.8%), followed by renal masses 12(25.0%). Those who had systemic lupus erythematosus (SLE) as an indication were 10(20.8%) and 4(8.3%) had nephritic (figure 2).

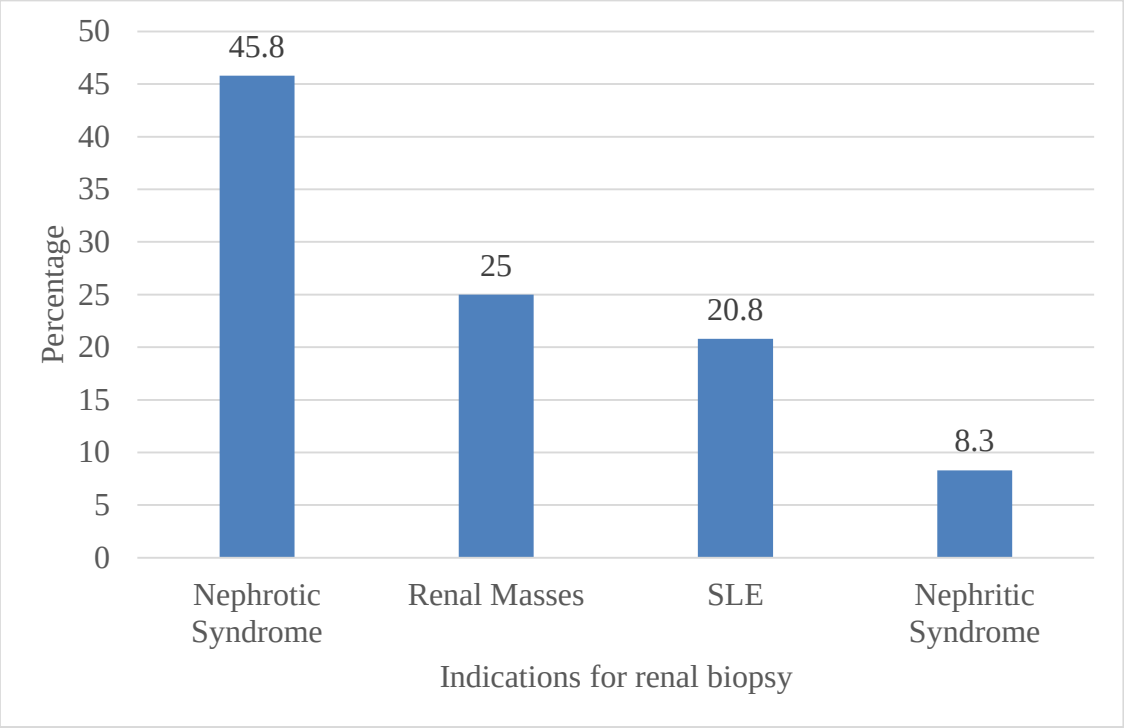

Figure 5: Indications for renal biopsy

4.4 Pre- Percutaneous Renal Biopsy Assessments

We observed that all participants had normal HB, INR, platelets and vitals. Table 1 shows the laboratory and clinical findings before the renal biopsy.

Table 1: Laboratory and clinical findings

Variable	Mean	Std	Median	IQR
Hb	12.01	0.71	12	(11.8,12)
INR	0.98	0.04	1	(1,1)
Creatinine	111.65	35.10	108	(90,120)
SBP	128.54	12.75	130	(120,140)
DBP	79.73	10.23	80	(72.5,85.5)
PR	77.47	6.95	78	(72,82)
Platelets	208.1	39.6	200	(179.5, 227.5)
RR	14.9	2.1	14	(14,16)

4.5 Objective 2: Immediate complications of Ultrasound-guided percutaneous renal biopsy and associated factors.

A total of 8(16.7%) participants developed immediate complications, with 7(14.6%) reporting minor complications and 1(2.1%) reporting major complications. Of those who had minor complications, 5(10.4%) had macrohematuria and 2(4.2%) had Hematomas less than 5 cm. 1 participant who reported major complications had a hematoma greater than 5 cm, had hypotension, required a blood transfusion and gealfoam embolization.

Table 2: Post Renal biopsy immediate complications

Complications		Frequency	Percentage
Overall		8	16.7
Minor		7	14.6
	Macrohematuria	5	10.4
	Perirenal hematoma(<5 cm)	2	4.2
Major		1	2.1

4.5.1 Objective 2: Factors associated with ultrasound-guided percutaneous renal biopsy immediate complications.

There was a significant association between immediate complications and the number of passes done ($p<0.001$).

Age, gender, creatinine and indication for biopsy were not associated with complications ($p>0.05$).

Table 3: Factors associated with immediate complications

	Immediate complications		
	No	Yes	
Variable	**Freq (row %)**	**Freq (row %)**	**p-value**
Creatinine			
Normal	21 (87.5)	3 (12.5)	0.701[1]
High	19 (79.2)	5 (20.8)	
Gender			
Female	20 (80.0)	5 (20.0)	0.710[1]
Male	20 (87.0)	3 (13.0)	
Indication			
Nephrotic syndrome	18 (81.8)	4 (18.2)	0.096[1]
Renal masses	12 (100)	0 (0)	
Nephritic syndrome	2 (50.0)	2 (50.0)	
SLE	8 (80.0)	2 (20.0)	
Number of biopsy passes			
2 – 3	38 (100)	0	<0.001[1]
4 – 5	2 (20)	8 (80)	

[1] Fishers exact test

4.6 Objective 3: Adequacy of the renal tissue biopsy.

We observed two core tissue biopsies (4.17%) of patients with renal parenchymal disease had less than seven glomeruli; therefore were declared inadequate by the histopathologist, while 34(70.83%) core tissue biopsies had more than eight glomeruli.

All patients with renal masses 12(25%) had at least one core tissue length measuring more than 1cm and were all adequate.

We observed 46 (95.8%) out of 48 participants had adequate tissue for biopsy.

Table 4: Tissue adequacy

Variable	Category	Frequency	Percentage
No. of glomeruli for renal parenchymal disease.	0-7	2	4.17%
	≥8	34	70.83%
Maximum core tissue length in renal masses. (cm)	<1	0	0%
	≥1	12	25%

SAMPLE IMAGES

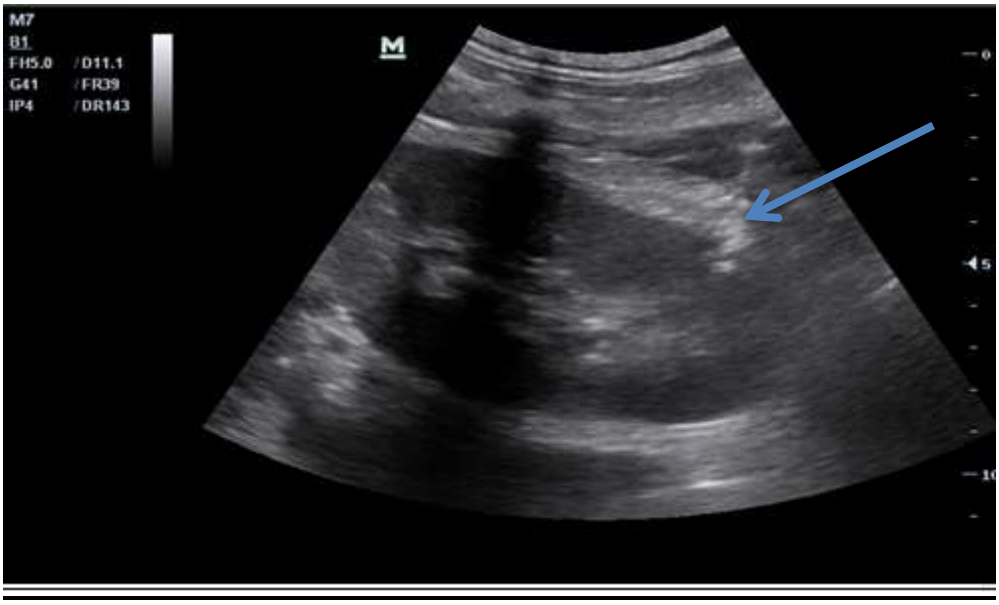

Image 1: 26-year-old male with nephrotic syndrome. Axial transabdominal ultrasound image showing ongoing USG PRB with a coaxial needle in situ in the lower pole of the left kidney.

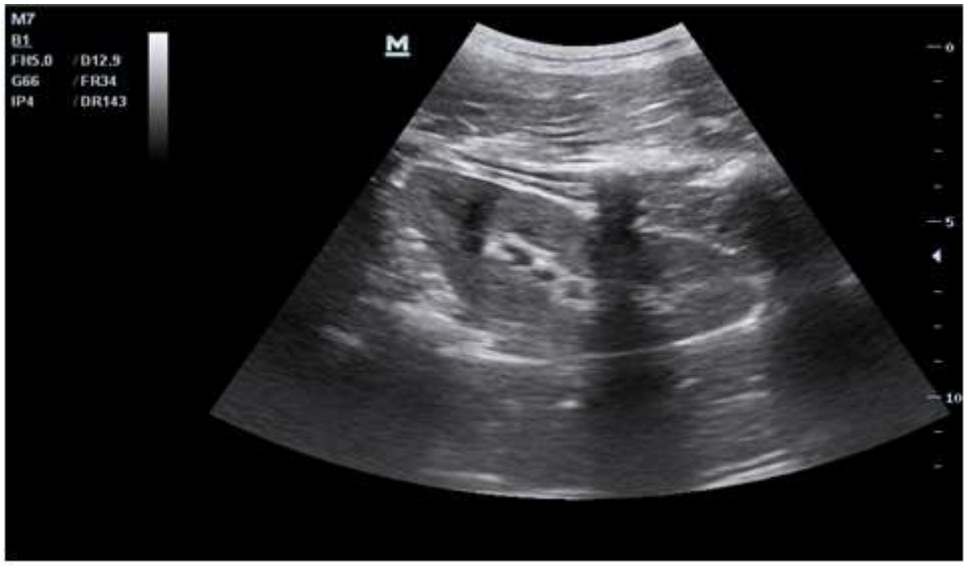

Image 2: 45-year-old male with nephritic syndrome. Post USG PRB follow up was unremarkable.

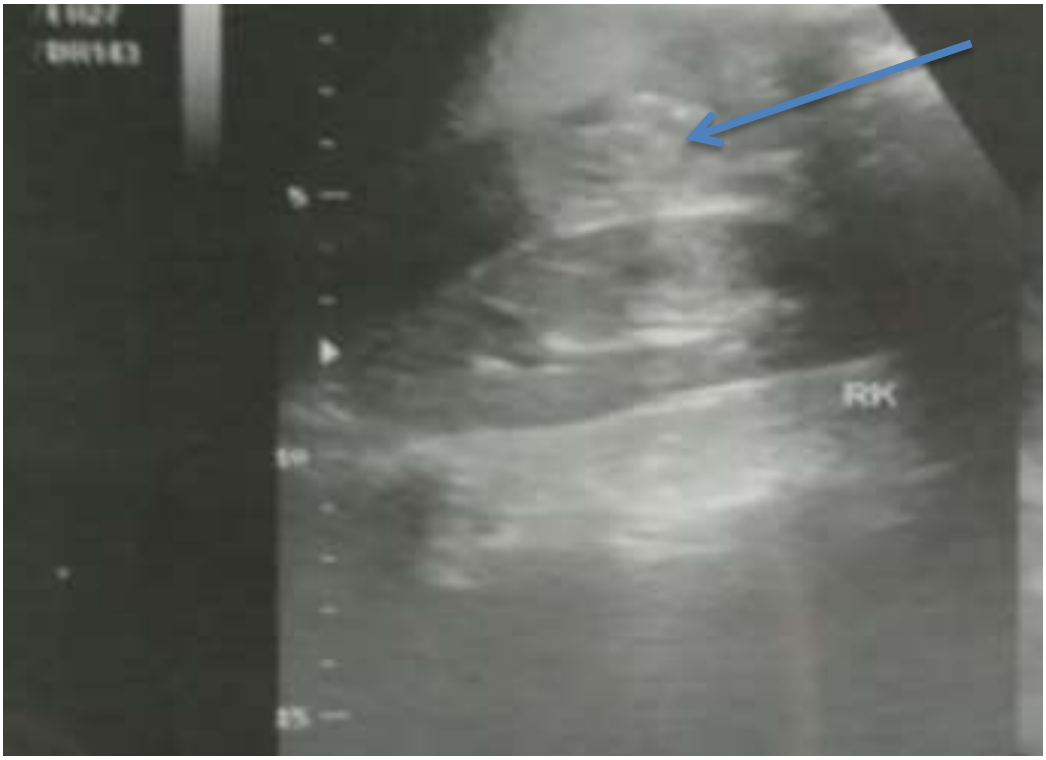

Image 3: 32-year-old female with nephrotic syndrome, axial abdominal ultrasound showing hematoma collection in the Morison's pouch.

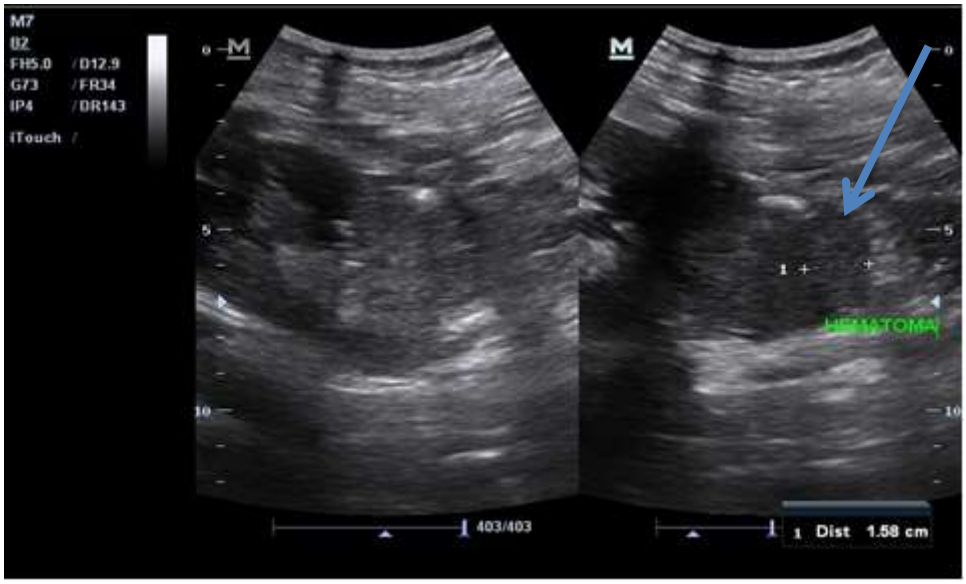

Image 4: 42 year female with SLE. Post USG PRB axial abdominal ultrasound image showing perirenal hematoma less than 5cm detected at 8th hour but resolved spontaneously in the subsequent follow-up.

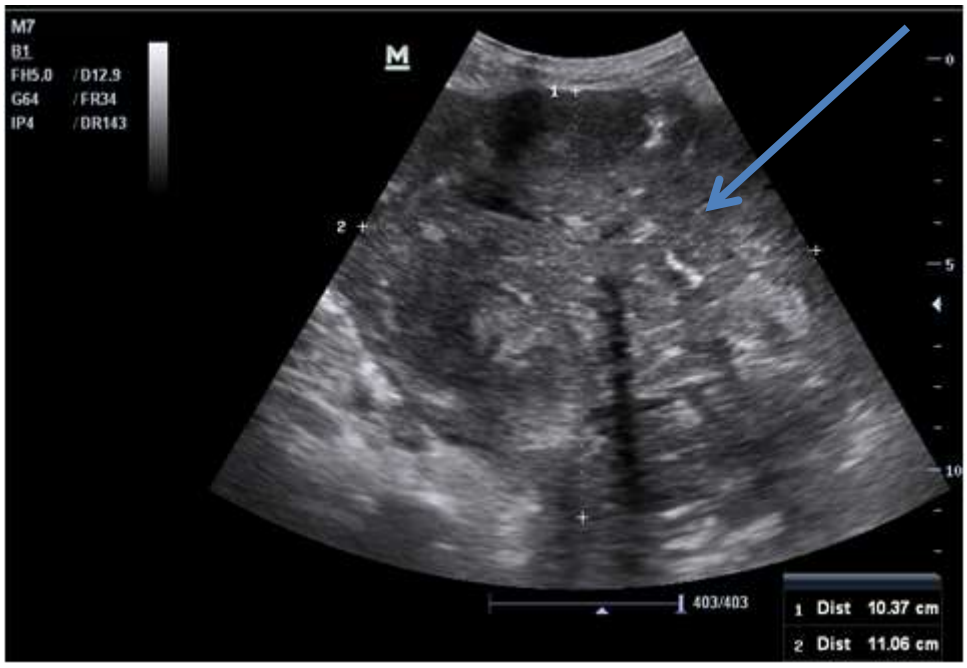

Image 5: 50-year-old male with soft tissue mass involving lower pole of left kidney measuring 10.4cm x 11.06cm.

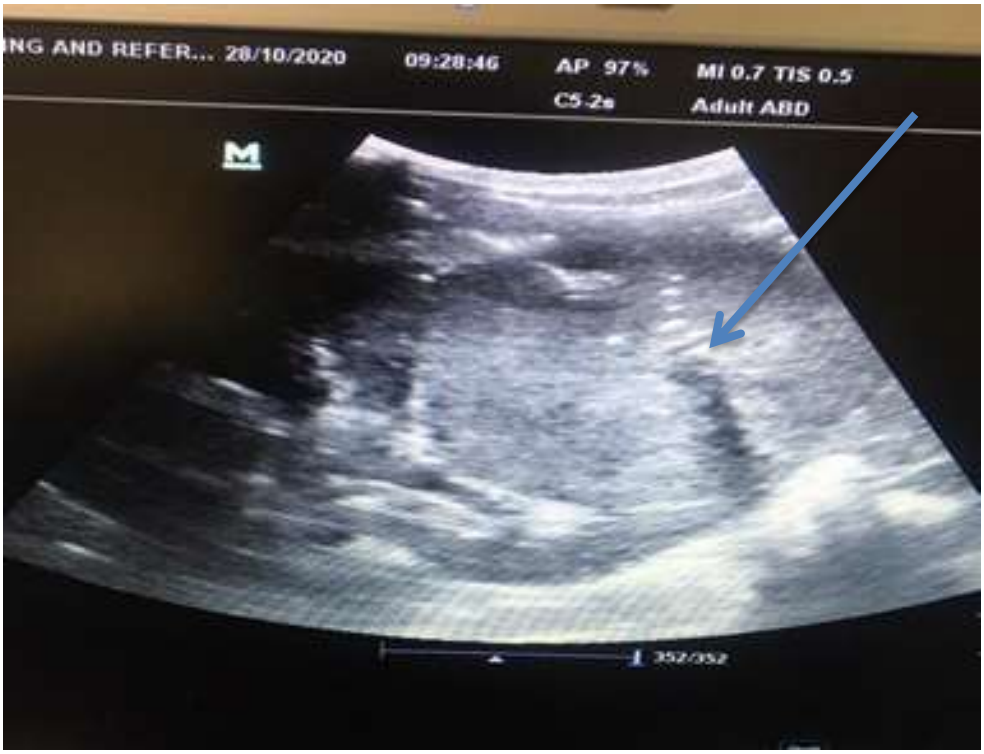

Image 6:60-year-old female with soft tissue mass involving the lower pole of the right kidney

CHAPTER FIVE: DISCUSSION

5.1 Introduction

Percutaneous renal biopsy (PRB) is an important diagnostic method used in diagnosing focal and non-focal renal diseases. PRB can cause severe complications that may result in loss of kidney and rarely, even death. Proper selection of patients is required to avoid complications.

5.2 Objective 1: Indications for Ultrasound-guided percutaneous renal biopsy.

Nephrotic syndrome was the commonest indication for USG percutaneous renal biopsy 22(45.8%) in this study. Similar findings were found by Nadium et al study done in Sudan who reported nephrotic syndrome as the commonest indication of renal biopsy at 46.5% (Nadium et al., 2013).

Multiple studies Manno et al., 2004, Manganelli & Iannaccone, 2016, done in Europe reported the most common indication for percutaneous renal biopsy as unexplained elevation in renal parameters(Manno et al., 2004) (Manganelli & Iannaccone, 2016). This glaring difference to our study can be explained by better health-seeking behaviours among citizens of the developed world, increasing interest among health care providers towards identifying the underlying cause of renal impairment and patients with atypical presentation and early referrals of patients to nephrology specialists.

Most of the studies that published indications for renal biopsy were focusing on medical conditions, but in our study, all indications for renal biopsies were included.

Renal masses were the second commonest indication for renal biopsy at 12(25%), in contrast with Simard-Meilleur et al study in Canada who found a frequency of 7%

(Simard-Meilleur et al., 2014). The difference can be explained by the fact that it was a retrospective study with a possibility of selection bias.

SLE nephritis was the third commonest indication for renal biopsy representing 10(20.8%). This was comparable to Bernieh, Sirwal, & Abbadi study done in Saudi Arabia who reported similar findings with lupus nephritis as the third commonest indication for renal biopsy representing 15.3% (Bernieh et al., 2000).

However, this was in contrast to Niang Abdou et al in Senegal found SLE nephritis at 10%(Niang et al., 2008). The difference can be explained by the fact that their study was a retrospective study with large sample size.

Nephritic syndrome was the least indicated at 4(8.3%) in this study. Similar findings were reported by Nadium et al in Sudan reported nephritic syndrome at 7% (Nadium et al., 2013).

Zajjari et al in Morocco found a lower proportion of nephritic syndrome at 2.3% (Zajjari et al., 2015). The difference can be explained by the fact that this study was a retrospective study that went 5 years back.

5.3 Objective 2: Immediate complications of Ultrasound-guided percutaneous renal biopsy and associated factors.

The overall complication frequency in this study was 8(16.8%). This is comparable to that reported by (Azmat et al., 2017) (Esposito et al., 2018) (Hughson et al., 2009)(Sosa-barrios et al., 2017), in which their overall complication ranged between(16-19.9%). However, it is much less than 34.1% reported by (Manno et al., 2004) in a prospective study involving 471 participants. The large complication frequency can be explained by the use of a G14 biopsy gun which is associated with

more complications as compared to the biopsy gun G18 used in our study(Simard-Meilleur et al., 2014).

The overall minor complication frequency in our study was 7(14.6%), with macrohematuria and perirenal hematoma less than 5cm as the most common minor complications, which were similar to studies by (Hughson et al., 2009)(Azmat et al., 2017)(Maya & Allon, 2009) and (Esposito et al., 2018) with overall minor complication frequency of 8%, 11.8%, 13% and 17.5% respectively.

Macrohematuria and perirenal hematoma less than 5cm were the most common minor complications with a frequency of 5(10.4%) and 2(4.2%), respectively. This was comparable to the Whittier & Korbet study in the USA who reported macrohematuria frequency of 7.5% and perirenal hematoma less than 5cm frequency of 2%(Whittier & Korbet, 2004). Azmat et al study in Pakistan also reported macrohematuria and perirenal hematoma less than 5cm, frequencies of 10% and 1.8%, respectively(Azmat et al., 2017), which is comparable to our findings.

Stratta et al in Italy and Manno et al in Italy reported higher minor complication frequency of 24.2% and 32.9%, respectively (Stratta et al., 2007)(Manno et al., 2004). This can be explained by the fact that both studies were retrospective studies with larger sample sizes, different sizes of biopsy guns (G14 and G16) and a non-coaxial technique was used(Babaei Jandaghi et al., 2017).

One patient (2.08%) had a major complication (perirenal hematoma more than 5cm and hypotension) where transfusion and gelfoam embolization was done. This was consistent with major complications reported by (Esposito et al., 2018) 1.2%, (Manno et al., 2004)1.2% and (Bakdash et al., 2019) 1.7%. However, this was less than 6.7% and 13% major complication incidence reported by (Whittier & Korbet, 2004) and

(Hughson et al., 2009), respectively. This can be explained by the larger sample size and use of biopsy gun G14, which was associated with more complications (Corapi et al., 2012).

The number of biopsy passes was significantly associated with immediate complications with a p-value less than 0.001. Where those with 2 or 3 passes, none had complications, while 80% of those with 4 or 5 passes developed complications.

A similar prospective study by Eiro et al in Japan reported more than five passes were significantly associated with post percutaneous renal biopsy immediate complications with a p-value of 0.0433(Eiro et al., 2005).

In contrast to our findings, Simard-Meilleur et al in Canada found no significant association between the number of biopsy passes and post percutaneous renal biopsy immediate complications with a p-value of more than 0.05(Simard-Meilleur et al., 2014). This could be attributed to him doing a retrospective study with a possibility of selection bias.

Bakdash et al in Macedonia also reported no association between the number of biopsy passes and post-percutaneous renal biopsy complications with a p-value of more than 0.05(Bakdash et al., 2019). This can be explained by the fact that they only did two to three biopsy passes since they had an on-site laboratory technician to confirm the tissue adequacy unlike in our setup where tissue can only be confirmed at the histopathology laboratory.

There was no significant association between gender, creatinine, indications for percutaneous renal biopsy, and post percutaneous renal biopsy complications with $p>0.05$.

Similar findings were found by Roccatello et al in Italy and Bakdash et al in Macedonia. They reported no significant association between gender, creatinine,

indications for percutaneous renal biopsy, and percutaneous renal biopsy complications with a p-value of more than 0.05(Roccatello et al., 2017a & Bakdash et al., 2019).

Stratta et al in Italy found elevated serum creatinine was associated with increased post renal biopsy complication with a p-value of 0.0004(Stratta et al., 2007).

The difference can be explained by it was a retrospective study, went 36 years back and larger sample size (11542). Strata had more participants with chronic kidney failure which is associated with an increased risk of bleeding (Ocak et al., 2018).

5.4 Objective 3: Adequacy of the renal biopsy tissue.

Our study observed that in 46 out of the 48 participants (95.8%), their tissue biopsy was adequate. The other 2 patients had glomeruli less than 7, and the histopathologist could not make a diagnosis. The inadequate biopsies were subsequently repeated.

This finding resonates well with an outcome of a similar study done in 2018 by Esposito et al in Italy, who reported tissue adequacy of 97.3 %(Esposito et al., 2018).

Similar findings were also reported by Chung et al in South Korea and Kruger & Loggenberg et al in South Africa, who found tissue adequacy of 98.2% and 93.5%, respectively(Chung et al., 2014) & (Kruger & Loggenberg, 2011).

In contrast to this study, Whittier et al in USA found a higher biopsy tissue adequacy of 99.5%(Whittier et al., 2018). The higher frequency can be explained by the use of biopsy guns g14 and g16, which was different from that used in our study g18. g14 and g16 produce bigger and wider tissues hence contain more glomeruli, while biopsy gun G18 produces small and narrow tissues.

5.5 Limitations of this study

The small number of patients referred for ultrasound-guided percutaneous renal biopsy.

CHAPTER SIX: CONCLUSION AND RECOMMENDATION

6.1 Conclusion

The most common indication of PRB in this study was nephrotic syndrome.

Macrohematuria was the commonest complication of USG PRB.

More than 4 biopsy passes were significantly associated with post PRB complications.

Up to 95% of the biopsy tissues were adequate.

6.2 Recommendations

Close monitoring for patients done with more than four biopsy passes is recommended After USG PRB.

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APPENDICES

APPENDIX I: CONSENT FORM
English Version

Investigator: My name is Dr Adan Abdi Ukure. I am a qualified doctor registered by the Kenya Medical Practitioners and Dentists Board. I am currently pursuing a Masters degree in Radiology and Imaging at Moi University. I would like to recruit you into my research which is indication and outcomes of percutaneous renal biopsy among patients with renal parenchymal disease at Moi Teaching and Referral Hospital- Eldoret Kenya.

Percutaneous renal biopsy is a minimally invasive procedure that entails the removal of a small piece of kidney tissue using ultrasound guidance and an automatic biopsy gun and is sent to a pathologist to be examined under a microscope for signs of damage or disease.

Purpose: To assess the indication and outcomes of percutaneous renal biopsy among patients with renal disease at Moi Teaching and Referral Hospital- Eldoret Kenya.

Procedure: the patients who consent will be enrolled in the study. The investigator will record patients age, sex, Hemoglobin level, serum creatinine, baseline coagulation parameters (prothrombin time, partial thromboplastin time, bleeding time, INR), and indications for renal biopsy will be obtained from the patient's hospital file.

Patients will be placed in the prone position with a pillow under the abdomen to reduce lumbar lordosis (transplanted patients were placed supine). The kidneys will be scanned as a routine with longitudinal and transverse images, with a complete evaluation of the cortical and sinus echogenicity, looking for any structural abnormalities before the biopsy. The retroperitoneum (psoas areas) and bladder will also be imaged.

The lower pole of the left kidney will be located by ultrasound. Subsequently, the skin will be disinfected with 10% povidone-iodine before injecting local anaesthesia with 1% lidocaine. A small incision will be made to facilitate the introduction of the biopsy needle. All biopsies will be performed using a Bard automated biopsy gun loaded with an 18 Gauge tru-cut needle. Under real time-ultrasound guidance, the needle will

be advanced by the second operator until reaching the lower pole of the kidney and subsequently fired and removed. Adequate material for the diagnosis will be obtained.

Immediately after the biopsy procedure, patients will be observed in the interventional radiology recovery room, where they remained flat on the bed and were closely monitored for 8 hours.

Each urine void will be checked for haematuria visually, flank pain or hypotension and the results will be recorded. Repeat ultrasound will be performed at 30minute, 1 hour and 8-hour post-biopsy to check for any complication. For the outpatient procedure, the patient will be discharged home if there will be no complications and comes back for reevaluation after 24 hours.

The data gathered from the clinical and ultrasound examination will be entered in a structured data entry form.

Confidentiality: The data gathered will be stored safely under lock and key and will only be accessed by the principal investigator and his two supervisors.

Benefits: There will be no direct benefits of participating in this study

Risks: There are no anticipated risks to the participants attributable to this study.

Rights to Refuse: Participation in this study is voluntary. There is the freedom to refuse to take part or withdraw at any time. This study has been approved by the Institutional Research and Ethics Committee (IREC) of Moi University/Moi Teaching and Referral Hospital.

Sign or make a mark if you agree to take part in the study

Participant's Signature_____Date _____

I certify that the patient has understood and consented to participate in this study.

Dr Adan Abdi Ukure

Signature _____Date _____

APPENDIX II: KISWAHILI VERSION

Mpelelezi: jina langu ni Daktari Adan Abdi Ukure. Mimi ni daktari aliyehitimu na kusajiliwa na bodi ya Kenya ya Madaktari na Madaktari wa meno. Mimi sasa natafuta shahada ya uzamili katika Radiology na Imaging katika Chuo Kikuu cha Moi. Ningependa kukuhusisha katika utafiti wangu ambao ni wa dalili na matokeo ya biopsy ya figo kwa kutumia chombo cha ultrasound katika hospitali ya mafundisho na ya rufaa ya moi.

Kusudi: Utafiti huu utajaribu kujua dalili na matokeo ya biopsy ya figo kwa kutumia chombo cha ultrasound katika hospitali ya mafundisho na ya rufaa ya moi.

Utaratibu:

wagonjwa watakaotoa kibali kuhusika katika utafiti huu Data ya umri, ngono, (shinikizo la damu, kiwango cha vurugu, zitaandikwa. Kiwango cha hemoglobin, seramu creatinine, vigezo vya msingi vya mwako wa kimsingi (wakati wa prothrombin, wakati wa sehemu ya thromboplastin, wakati wa kutokwa na damu, INR) na dalili za ugonjwa wa figo zitapatikana kutoka faili ya hospitali ya mgonjwa.

Wagonjwa watapelkwa kwenye chumba cha kufanyiwa biopsy na biopsy zitachukuliwa kutumia Chombo cha ultrasound.

baada ya biopsy mgonjwa atazingatiwa kwa masaa 8 kwenye chumba cha interventionali radiolojia ya kawaida kwa hematuria, hypotension na hematoma na arteriovenus fistula.

Data zitakusanywa kwenye fomu za ukusanyaji data. Hifadhi zitakazo tumika katika ukusanyaji wa data zitawekwa katika kabati iliyofungwa katika nyumba ya mpelelezi mkuu katika kipindi cha utafiti.

Faida: Kutakuwa hakuna faida moja kwa moja ya kushiriki katika utafiti huu. Wanaofanyiwa utafiti watakuwa nahaki nakupewa ubora sawa na wale ambao hawatofanyiwa utafiti huo.

Hatari: Hakuna hatari ya kutarajia kwa washiriki inatokana na utafiti huu.

Usiri: habari zote zilizopatikana katika utafiti huu wa kutibiwa zitawekwa kwa usiri mkubwa na wala haitatolewa kwa mtu yeyote asiye husika na utafiti.

Haki ya kukataa: Kushiriki katika utafiti huu ni hiari yako, kuna uhuru wa kukataa kuchukua sehemu au kutoka wakati wowote. Utafiti huu umeidhinishwa na Utafiti wa Taasisi na Kamati ya Maadili (IREC) ya Chuo Kikuu cha kufundisha cha Moi na Hospitali kuu ya Rufaa.

Weka sahihi au kufanya alama kama unakubali kushiriki katika utafiti

Mgonjwa: ..... Tarehe: .....

Mpelelezi: ..... Tarehe: .....

APPENDIX III: QUESTIONNAIRE
STUDY NUMBER……

SECTION A: DEMOGRAPHIC DATA

AGE…….

GENDER: MALE ☐ FEMALE ☐

SECTION B: INDICATIONS FOR RENAL BIOPSY

WHAT IS/ARE THE INDICATIONS OF PERCUTANEOUS(S) RENAL BIOPSY?

NEPHROTIC SYNDROME: YES ☐ NO ☐

ACUTE RENAL FAILURE: YES ☐ NO ☐

CHRONIC RENAL FAILURE: YES ☐ NO ☐

RENAL MASSES: YES ☐ NO ☐

OTHERS SPECIFY…….

SECTION C: PRE- PERCUTANEOUS RENAL BIOPSY ASSESSMENTS

ARE/IS THERE RISK FACTOR(S) FOR POST-RENAL BIOPSY IMMEDIATE COMPLICATIONS?

BLEEDING DISORDER: YES ☐ NO ☐

UNCONTROLLED HYPERTENSION: YES ☐ NO ☐

SEVERE ANEMIA: YES ☐ NO ☐

OTHERS SPECIFY……

LABORATORY FINDINGS

HEMOGLOBIN LEVEL……

PLATELET LEVEL……

INR LEVEL…….

CREATININE LEVEL……

CLINICAL FINDINGS

BLOOD PRESSURE: SBP ☐ DBP ☐

PULSE RATE…….

RESPIRATORY RATE……

SECTION D: INTRA-PROCEDURAL FINDINGS.

NUMBER OF BIOPSY PASSES……

SECTION E: POST PERCUTANEOUS RENAL BIOPSY COMPLICATIONS

WHAT IS/ARE THE COMPLICATION(S) OBSERVED FROM 0 to 1ST HOUR OF POST-PERCUTANEOUS RENAL BIOPSY?

MINOR COMPLICATIONS

MACROHEMATURIA: YES ☐ NO ☐

PERIRENAL HEMATOMA LESS THAN 5 CM: YES ☐ NO ☐

OTHERS SPECIFY……

MAJOR COMPLICATIONS

HAS THE PATIENT DEVELOPED A PERIRENAL HEMATOMA OF MORE THAN 5 CM?

YES ☐ NO ☐

DOES THE PATIENT REQUIRE TRANSFUSION: YES ☐ NO ☐

DOES THE PATIENT REQUIRE EMBOLIZATION: YES ☐ NO ☐

DOES THE PATIENT REQUIRE A NEPHRECTOMY: YES ☐ NO ☐

ARTERIOVENOUS FISTULA: YES ☐ NO ☐

HYPOTENSION: YES ☐ NO ☐

OTHERS SPECIFY……..

WHAT IS/ARE THE COMPLICATION(S) OBSERVED FROM 2nd to 8th HOUR OF POST-PERCUTANEOUS RENAL BIOPSY?

MINOR COMPLICATIONS

PERIRENAL HEMATOMA LESS THAN 5 CM YES ☐ NO ☐

MACROHEMATURIA: YES ☐ NO ☐

OTHERS SPECIFY…….

MAJOR COMPLICATIONS

HAS THE PATIENT DEVELOPED A PERIRENAL HEMATOMA OF MORE THAN 5 CM?

YES ☐ NO ☐

DOES THE PATIENT REQUIRE TRANSFUSION: YES ☐ NO ☐

DOES THE PATIENT REQUIRE EMBOLIZATION: YES ☐ NO ☐

DOES THE PATIENT REQUIRE A NEPHRECTOMY: YES ☐ NO ☐

HYPOTENSION: YES ☐ NO ☐

ARTERIOVENOUS FISTULA: YES ☐ NO ☐

OTHERS SPECIFY……..

WHAT IS/ARE THE IMMEDIATE COMPLICATION(S) OBSERVED FROM 9TH to 24th HOUR OF POST-PERCUTANEOUS RENAL BIOPSY?

MINOR COMPLICATIONS

MACROHEMATURIA: YES ☐ NO ☐

PERIRENAL HEMATOMA LESS THAN 5 CM: YES ☐ NO ☐

OTHERS SPECIFY……..

MAJOR COMPLICATIONS

HAS THE PATIENT DEVELOPED A PERIRENAL HEMATOMA OF MORE THAN 5 CM?

YES ☐ NO ☐

DOES THE PATIENT REQUIRE TRANSFUSION: YES ☐ NO ☐

DOES THE PATIENT REQUIRE EMBOLIZATION: YES ☐ NO ☐

DOES THE PATIENT REQUIRE NEPHRECTOMY: YES ☐ NO ☐

HYPOTENSION: YES ☐ NO ☐

ARTERIOVENOUS FISTULA: YES ☐ NO ☐

OTHERS SPECIFY……..

SECTION F: ADEQUACY OF THE TISSUE BIOPSY AS REPORTED BY PATHOLOGIST

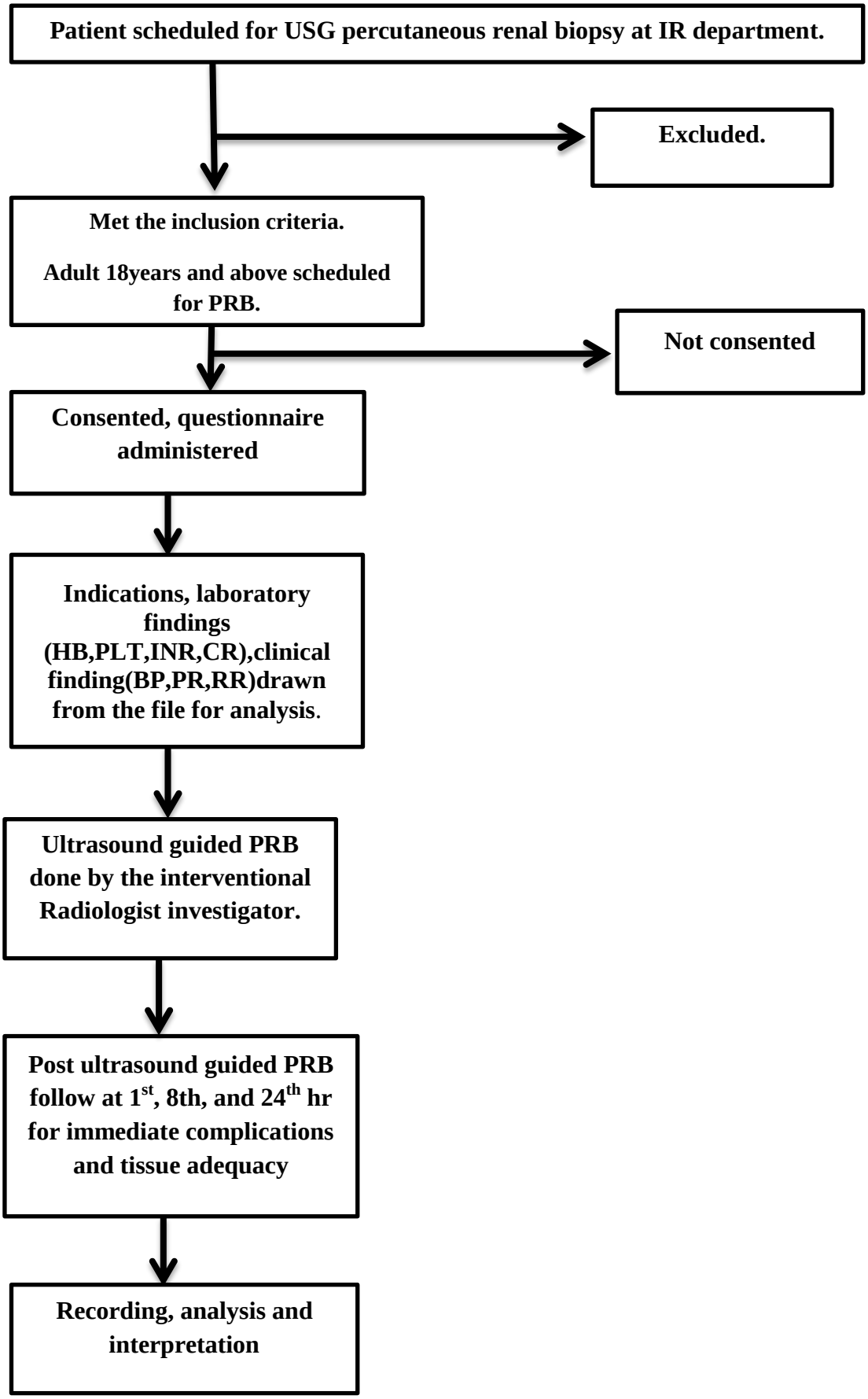
1. RENAL PARENCHYMAL DISEASE. YES ☐ NO ☐
   NUMBER OF GLOMERULI IN RENAL……

2. RENAL MASS YES ☐ NO ☐

   MAXIMUM CORE TISSUE LENGTH…….

3. IS THE BIOPSY TISSUE ADEQUATE? YES ☐ NO ☐

APPENDIX IV RECRUITMENT SCHEMA



APPENDIX V: CONSENT FOR DOING A BIOPSY

I……..having been explained to the procedure of doing a Renal biopsy, its advantages and possible complications do hereby agree to undergo the procedure at my own free will.

Name:…….

Signature:…….

Witness……

Name……..

Signature…….

APPENDIX VI: ULTRASOUND-GUIDED PERCUTANEOUS RENAL BIOPSY PROTOCOL.

Patient preparation

- Inform the patient about the procedure
- Seek consent
- Maintain confidentiality and privacy

Equipment required.

Pre-warmed coupling gel

3.5-5 MHz Curvilinear transducer.

Biopsy gun g18.

Coaxial needle g17.

Lignocaine.

Sample Bottle containing 10% formalin.

Positioning

- The patient wears a hospital gown
- The patient lies prone on the examination couch.
- The lumbar region was disinfected with 10% iodine and draped.
- The interventional radiologist and principal investigator were standing on both sides of the patient.

Percutaneous renal biopsy procedure

The procedure was conducted using either of the two Minday M7 ultrasound machines in the radiology department.

Patients were placed in a prone position with a pillow under the abdomen to reduce lumbar lordosis.

The kidneys were scanned as a routine with longitudinal and transverse images, with a complete evaluation of the cortical and sinus echogenicity, looking for structural abnormalities before the biopsy.

The transducer was draped with probe cover and skin disinfected with 10% povidone-iodine, the kidney biopsy site (focal lesion or lower pole of either kidney in renal parenchymal disease) was identified and assessed for accessibility and vascularity. Local anaesthesia 1% infiltrated.

Finally, all biopsies were performed using a coaxial technique with semi-automated biopsy gun G18, coaxial needle G17 and real-time ultrasound guidance (Mindray7 US machine curvilinear transducer 3.5-5MHZ).

All biopsies were performed by the interventional radiologist assisted by the principal investigator.

The coaxial needle was advanced under ultrasound guidance until it reached the lower pole of the kidney or the focal lesion. The biopsy gun is inserted, deployed and removed 2 to 5 times to obtain adequate tissues for histopathological analysis.

Each core tissue biopsy was inserted in a sample bottle containing 10% buffered formalin solution for analysis in the hospital's pathology laboratory.

Immediately after the biopsy procedure, an ultrasound evaluation is done to check for any early complications.

A firm occlusive dressing was then placed on the biopsy site, and patients were observed in the interventional radiology recovery room where they remained supine, flat on the bed, and closely monitored for one hour.

Post-procedure care plan

1. The patient is advised bed rest mostly supine for 18-24 hours.

2. Blood pressure monitoring is done as follows:

 Every 15 mins for one hour.

 Every 30 mins for one hour

 Every 1 hour for four hours then

 4 hourly for the next 24 hours

3. Ultrasonographic follow up at 1st hour, 8th hour and 24th hour done after procedure.

4. Patients' urine was collected in a clear container to examine any gross hematuria at 1st hour, 8th hour and 24 hours.

5. patients with suspected macrohematuria were confirmed dipstick urinalysis.

5. Analgesics and antibiotic was prescribed.

Anticipated complications shall be documented

APPENDIX VII: MACROHEMATURIA ASSESSMENT
Visual assessment

Urine was collected in a sterile sample bottle that was given to every patient. The urine sample was collected before the procedure to make it the baseline. 3 sample bottles were given to each patient after the procedure to collect urine at 1st hour, 8th hour and 24 hours to check for macrohematuria. Red colour or frank hematuria was considered positive for macrohematuria. 2 observers will read the colour and a third person acts as a tie-breaker if there is disagreement.

APPENDIX VIII: PROCEDURE FOR FOLLOW UP ABDOMINAL ULTRASOUND

Equipment

3.5–5-MHz transducer.

Imaging procedure

The examination was conducted using either of the two Minday M7 ultrasound machines in the radiology department.

The patient lies supine abdomen is exposed and a paper towel is used to protect the patient's clothes.

Pre-warmed coupling gel is applied to the 3.5-5 MHz curvilinear transducer and abdominal ultrasound is conducted.

The patient turned right (RAO) and left anterior oblique (LAO) positions or lateral for kidneys. The kidneys are scanned longitudinally in an oblique coronal plane supplemented by transverse sections perpendicular to the axis.

The perinephric space, renal capsule, renal parenchyma were assessed for hematoma collection. The largest diameter of any hematoma was measured in centimetres and recorded.

Minor calyces, major calyces and renal pelvis were assessed for hematoma collection and hydronephrosis. Ureters were checked for any hydroureter.

Doppler ultrasonography was done (angle <60 degrees) and various parameters of renal doppler were assessed for arteriovenous fistula (AVF).

The liver size, echo pattern and hepatic borders were assessed. Any injuries or hematoma recorded.

The hepatorenal interface (Morison pouch) is first identified, with subsequent assessment of the more cephalad subphrenic and pleural spaces.

The pancreas was assessed for injuries and hematoma. Any injuries and hematoma were recorded. The splenic was assessed for injuries, hematoma. Splenorenal interface checked for hematoma.

The bladder is scanned suprapubically in transverse and longitudinal planes to check for any hematoma collection. The pouch of Douglas or rectovesical space is explored for free fluid.

APPENDIX IX:IREC APPROVAL

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

4th November, 2019

Reference: IREC/2019/245
Approval Number: 0003478

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
04 NOV 2019
APPROVED
P. O. Box 4606-30100 ELDORET

Dr. Adan Abdi Ukure
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Adan

THE INDICATIONS AND COMPLICATIONS OF PERCUTANEOUS RENAL BIOPSY AT MOI TEACHING AND REFERRAL HOSPITAL-ELDORET

This is to inform you that ***MU/MTRH-IREC*** has reviewed and approved your above research proposal. Your application approval number is ***FAN: 0003478*** The approval period is **4th November, *2019 – 3rd November, 2020.***

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by ***MU/MTRH-IREC***.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to ***MU/MTRH-IREC*** within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to ***MU/MTRH-IREC*** within 72 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to ***MU/MTRH-IREC.***

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and also obtain other clearances needed.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc CEO - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

APPENDIX X:HOSPITAL APPRVAL (MTRH)

An ISO 9001:2015 Certified Hospital

MOI TEACHING AND REFERRAL HOSPITAL

Telephone :(+254)053-2033471/2/3/4
Mobile: 722-201277/0722-209795/0734-600461/0734-683361
Fax: 053-2061749
Email: ceo@mtrh.go.ke/directorsofficemtrh@gmail.com

Nandi Road
P.O. Box 3 – 30100
ELDORET, KENYA

Ref: ELD/MTRH/R&P/10/2/V.2/2010

7th November, 2019

Dr. Adan Abdi Ukure,
Moi University,
School of Medicine,
P.O Box 4606-30100
ELDORET-KENYA

APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"The Indications and Complications of Percutaneous Renal Biopsy at Moi Teaching and Referral Hospital".

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

MOI TEACHING AND REFERRAL HOSPITAL
CEO
APPROVED
07 NOV 2019
SIGN
P.O. Box 3 - 30100, ELDORET

DR. WILSON K. ARUASA, *MBS*
CHIEF EXECUTIVE OFFICER
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