# INDICATIONS,OUTCOMES AND COMPLICATIONS OF PERCUTANEOUS NEPHROSTOMY AT MOI TEACHING AND REFERRAL HOSPITAL,ELDORET,KENYA.

**KIMUTAI NICHOLAS KIMETO.**

**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.

**KIMUTAI NICHOLAS KIMETO**

**SM/ PGR/11/2017,**

**Department of Radiology and Imaging, Moi University.**

**Signature: _____ Date: _____**

**SUPERVISOR'S DECLARATION**

**This research proposal has been submitted for consideration with our approval as university supervisors**

**1. Dr. LOICE SITIENEI,**

**Consultant Radiologist**

**Department of Radiology and Imaging,**

**Lecturer Moi University.**

**Signature: _____ Date:_____**

**2. Dr. KIPCHIRCHIR C. KOECH,**

**Consultant Radiologist**

**Department of Radiology and Imaging,**

**Moi Teaching and Referral Hospital.**

**Signature: _____ Date: _____**

## ACKNOWLEDGEMENT

I would like to thank The Almighty God for the gift of life and health.My sincere gratitude goes to my supervisors Dr. Loice Sitienei and Dr. Kipchirchir for their guidance and support during writing of this thesis.I would also like to acknowledge the staff at Department of Diagnostic Imaging at Moi Teaching and Referral Hospital and my biostastistician for their help and encouragement. I also thank my family for being supportive at all times

Finally, the Ministry of Health and West Pokot County government for facilitating my education.

## DEFINITION OF TERMS

- Percutaneous Nephrostomy-An interventional radiology procedure whereby a catheter is inserted through the skin and into the renal pelvis using image guidance.
- Hydronephrosis- Distention of the renal calyces and pelvis with urine as a result of obstruction of the outflow of urine distal to the renal pelvis.
- Uraemia- Higher than normal upper limit of urea and other nitrogenous waste compounds in blood.
- Obstructive uropathy-A general term that refers to structural or functional hindrance of normal urine flow, sometimes leading to renal dysfunction (obstructive nephropathy).
- Outcomes-Are the changes we expect to result from PCN in terms of clinical,radiological and laboratory parameters.
- Cortical thickness: Shortest distance from the base of the medullary pyramid to renal capsule.
- Corticomedullary differentiation: The ability to clearly delineate the renal medulla from the renal cortex, absence of which can indicate possible nephropathy (Faubel *et al.*,2014)
- Parenchymal echogenicity:Refers to how bright or dark the kidney parenchyma appears in sonography in comparison to the liver or spleen and increase is associated with CKD (Lockhart *et al.*,2014).

- Major complication: Require major therapy, unplanned increase in level of care, prolonged hospitalization or leading to permanent adverse sequelae/death.(SIR-ACR,2016)
- Minor complications: Require no therapy, nominal therapy or require overnight admission for observation only.(SIR-ACR,2016).
- Normal serum potassium:3.5 - 5.1 (mmol/L)
- Normal creatinine: Females 44-80 umol/L,Males 62-106 umol/L.
- Normal urea 0.0-8.3 mmol/L

## ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| **ACR** | American College of Radiology |
| **AKI** | Acute kidney injury |
| **CMD** | Corticomedullary differentiation |
| **CKD** | Chronic kidney disease |
| **INR** | International Normalised Ratio |
| **IREC** | Institutional Research and Ethics Committee |
| **MTRH** | Moi Teaching and Referral Hospital |
| **PCN** | Percutaneous Nephrostomy |
| **PUJ** | Pelvi-ureteric junction |
| **SIR** | Society of Interventional Radiology |
| **UEC** | Urea, Electrolytes, Creatinine |
| **VUJ** | Vesicoureteric junction |

# TABLE OF CONTENTS

# LIST OF TABLES

## LIST OF FIGURES

## LIST OF IMAGES

## ABSTRACT

**Background:**Percutaneous nephrostomy (PCN) is an interventional radiology procedure whereby a flexible catheter is placed in the renal pelvis through the skin using image guidance.PCN is commonly performed for various benign and malignant indications and affords immediate decompression of the obstructed renal collecting system but can also be done for temporary urinary diversion in indications like urinary fistula,ureteric leaks and haemorrhagic cystitis.Laboratory,clinical and radiological outcomes post PCN placement are variable and influenced by several factors such as duration and extent of obstruction and status of contralateral kidney.

**Objective:**To describe the indications, clinical,radiological and laboratory outcomes and complications of PCN at Moi Teaching and Referral Hospital,Eldoret Kenya.

**Methods:** A prospective study was conducted on all 68 patients undergoing ultrasound guided PCN between June 2019 to May 2020.A census methodology was used. All patients who met the eligibility criteria and gave informed consent were enrolled in the study.Data collection form was used to record demographic and clinical data, renal ultrasonographic findings and laboratory investigations results, as well as complications. Data analysis done using SPSS software. Continuous variables were summarized using means and standard deviations, median and inter-quartile ranges (IQR) while categorical variables were summarized using frequencies and percentages. McNemar's test was used to determine the differences in proportion in categorical data pre and post PCN while Wilcoxon Ranked test was used to determine differences pre and post PCN for continuous variables. All P values were two-sided at a 0.05 significance level.

**Results:** PCN placement was successful in all the 68 patients.The mean age of the 68 patients included in the study was 37.62 ±12.5. (SD) years. A total of 38 (55.9%) of the patients were female. Malignancy was the most common indication for PCN n=55 (80.8%).Inflammatory indications and calculi were the second most common indications each constituting 4(5.8%).Cancer of the cervix was the commonest malignancy (32.7%) followed by prostate cancer.There was clinical improvement with reduction in degree and number of patients with oedema and flank pains 2 weeks post PCN.1(8.3%) patient discontinued dialysis two weeks post PCN.There was significant reduction in Urea,Creatinine and Potassium levels post PCN (P-value< 0.05). The study found a statistically significant increase in renal cortical thickness post PCN.There was no statistically significant change in parenchymal echogenicity and corticomedullary differentiation post PCN.15(22%) of the participants developed complications after PCN, of which major were 5(7.5%) and minor complications 10(14.5%).No deaths resulted from the procedure.

**Conclusion:** Malignancy was the main indication for PCN in this study.PCN was associated with improved clinical and laboratory outcomes. Majority of the patients did not have any complications post PCN with most of the complications being minor.

# CHAPTER ONE: INTRODUCTION

## 1.1 Background

One of the common interventional radiology procedures done at MTRH is Percutaneous nephrostomy or nephropyelostomy. This procedure is currently done under ultrasound guidance at MTRH but the procedure can also be done under fluoroscopy guidance. PCN affords immediate decompression of the obstructed renal collecting system in conditions such pelvic malignancy and ureteric stricture and can also be done for temporary urinary diversion in certain indications such as urinary bladder fistula.

The procedure involves the placement of a flexible rubber catheter under either fluoroscopy or ultrasound guidance into the renal pelvis.The advantage of ultrasound over fluoroscopy is that ultrasound does not use ionizing radiation.In a randomized clinical trial of 100 patients,Abbas Basiri and his colleagues in 2008 found that ultrasound guided PCN is an acceptable alternative to fluoroscopy guieded PCN and decreases radiation hazards (Basiri *et al*., 2008).

Interruption of urinary flow may result in pain, infection, sepsis, and loss of renal function. It is a potentially life threatening condition and immediate measures are required to decompress the kidneys.The various modalities available are retrograde stenting,open drainage of kidneys and percutaneous nephrostomy (Sood *et al.*,2006).Since the publication of the first report describing this procedure in 1955, percutaneous nephrostomy catheter placement has been the primary option for temporary and at times long term drainage of an obstructed collecting system or in case of ureteric injury in which primary ureteric surgery is considered injudicious or impossible (Almgard & Fernstrom, 1974).

With the development of percutaneous puncture of the renal pelvis for antegrade pyelo-ureterography in the 1950's,the idea of renal drainage by a similar technique came up (Goodwin *et al.*, 1954). Since then,there has been a tremendous advancements in the technique,equipment and catheters used for PCN.

The earliest decription of the techniques and results of PCN was by Goodwin and Casey in 1955.They published the results of 16 trochar nephrostomy performed by percutaneous lumbar puncture of the renal pelvis under x-ray guidance on patients who had hydronephrosis,for temporary drainage of the collecting system (Goodwin *et al*., 1955).

Later on in 1965,Bartley using the seldinger technique,was able to introduce a permanent drain to drain the renal pelvis and relieve pressure in the renal pelvis.This marked a major improvement in the technique of PCN (Seldinger, 1953).

The thin-walled,narrow-bore arterial catheters then in use were however unsuitable,being easily b1ocked, kinked,or broken. To avoid these disadvantages, a technique for percutaneous nephrostomy has been devised which uses a wide-bore replaceable catheter.Successive modifications have resulted in a safe and reliable technique which can be learned quickly (Conor *et al*.,2017).

With the correct technique,PCN can be performed under local anesthesia and will not cause undue distress to the often critically-ill patient.Since 2016,500 PCN procedures have been successfully carried out by interventional radiologists at MTRH.

Ureteric obstruction is a common presenting symptom in patients with advanced malignancy and other benign diseases that cause obstruction in the renal collecting

system and without timely intervention can progress quickly to renal failure and uraemia regardless of the cause of obstruction.

Indications of PCN include obstruction proximal to the vesicoureteric junction by conditions such as pelvic and abdominal malignancies,ureteric stones,ureteric stricture,pregnancy,fibrosis involving the ureters and iatrogenic injury. PCN offers a quick way of decompressing or diverting urine from the obstructed renal collecting system and often results in improvement of renal function and reduces mortality and morbidity if done in a timely manner (Faubel *et al*.,2016).

Indications for PCN have evolved over time to include access for therapeutic interventions, diagnosis and urinary diversion (Nasir *et al.*,2009).Malignant obstructive uropathy remains the leading indication for PCN in most studies(Farrell *et al.*,2013;Chalmers *et al*., 2008;Mouton *et al*.,2017).

The indications for percutaneous nephrostomy in renal transplants is largely the same as in native kidneys (Bennett *et al*.,1996). Occasionally, percutaneous nephrostomy drainage may be performed as a therapeutic trial to differentiate renal failure caused by urinary obstruction from that related to other causes. Percutaneous nephrostomy can be performed on an outpatient basis in selected patients. Patients who live alone or in whom the risk of complications is high, such as in those with staghorn calculi, uncorrected hypertension, or a coagulopathy, are best treated in an inpatient setting so they can be appropriately monitored (Cochran *et al*.,2007). In patients with severe uncorrected metabolic imbalance such as hyperkalemia or metabolic acidosis, correction of these imbalances may be necessary before the percutaneous nephrostomy to decrease the risk of complications such as arrhythmias or cardioplegia related to the profound electrolyte abnormality(Connor et al.,2017). The indications

for percutaneous nephrostomy can therefore be broadly categorized into the following groups: obstruction with infection, obstruction without infection, stone disease, prelude to endoscopic/interventional procedures, delivery of medications/ chemotherapy, urinary leaks, and urinary diversion for hemorrhagic cystitis.

**1.2 Problem Statement**

The outcomes in terms of patient clinical status, renal biochemical and radiological parameters and complications after PCN are variable (Halle *et al.*,2016).Studies done in different countries showed 6-38% no recovery of renal function after PCN (Stravodimos *et al*.,2000; Souza *et al*.,2016).Patients present for PCN in different stages of obstructive uropathy with associated complications and some already on dialysis (Farrel *et al*.,2007).Patients with no recovery of renal function after PCN require chronic dialysis and have increased morbidity and mortality (Jeremy *et al.*,2019).The outcomes and complications of PCN locally is unknown.

The most important factors determining extent of recovery of renal function are extent and duration of obstruction,intrapelvic pressure ,renal morphological factors,the status of contralateral kidney and the presence of renal infection(Turka *et al*.,2008).Some kidneys fail to recover even after PCN placement due to irreversible permanent damage.However,partial recovery that allowed discontinuation of dialysis has been reported even after 7 months of complete obstruction in other studies (Cohen *et al*.,2012).

Delay in referral of patients for PCN greatly affects the recoverability of renal function.This can occur due to late diagnosis of patients with hydronephrosis or delay in referring these patients.In other cases,the patients themselves present to hospital when it is too late to save their renal function through urinary diversion using

PCN.No local study has been done to determine the indications, clinical,radiological,laboratory outcomes and complications of PCN.

**1.3 Justification**

PCN is an interventional radiology procedure that relieves renal pelvic pressure dramatically and improves renal function if done in a timely manner and using the right techniques (Elamin *et al*.,2017).MTRH being a regional referral hospital for Western,Southrift and Northrift regions of Kenya has been receiving several patients annually with various indications for PCN.The number of patients presenting for PCN at MTRH has increased from 40 patients in 2017 to 80 patients in 2019.Some of these patients present with deranged kidney function and some already on renal replacement therapy.A study in Cameroon reported that 76% of patients presenting for PCN had AKI or CKD and 41% required emergency dialysis (Ekane *et al.*, 2016).PCN can potentially modify the outcomes in these patients if done in a timely manner.There is also need to place local practice within SIR-ACR guidelines for complications.

There has not been any local study describing the different indications for percutaneous nephrostomy encountered at MTRH and the immediate clinical,laboratory and radiological outcomes of patients reffered for PCN at MTRH.

Renal failure and dialysis are associated with increased morbidity and mortality and portends a poor prognosis especially in cancer patients (Chapman *et al*.,2018).There is increasing incidence of patients requiring PCN placement at MTRH and majority of these patients are cancer patients with advanced disease presenting with urinary obstruction and various levels of impairment in renal function.PCN is an expensive procedure but potentially life saving and can preempt the need for dialysis if done

early before the onset of irreversible renal damage(ESRD). There is therefore need to describe the indications,radiological,laboratory and clinical outcomes and complications of PCN in order to guide planning for interventions aimed at improving outcomes in this referral facility

## 1.4 Research Questions

1. What are the indications of PCN at Moi Teaching and Referral Hospital?
2. What are the outcomes of PCN at MTRH
3. What are the complications of PCN at MTRH?

## 1.5 Research Objectives

### 1.5.1 Main objective

To describe the indications,outcomes and complications of PCN at Moi Teaching and Referral Hospital.

### 1.5.2 Specific Objectives

1. To describe the indications of PCN at MTRH
2. To describe the short term clinical,radiological and laboratory outcomes of PCN at MTRH
3. To describe the immediate and intermediate complications of PCN at MTRH

# CHAPTER TWO: LITERATURE REVIEW

## 2.1 Background of Percutaneous nephrostomy

Percutaneous nephrostomy (PCN) has come a long way from the times of William Goodwin,who inadvertently punctured the renal pelvis attempting a translumbar aortogram.Although percutaneous nephrostomy was developed using fluoroscopic guidance, ultrasound guided procedures are now safe and effective. Ultrasound guided PCN has gained popularity among interventional radiologists because of its high success rate of up to 92% (Verma *et al*.,2006). The advent of the high resolution ultrasound machines has enabled accurate viewing of the pelvicaliceal system with high accuracy in identifying hydronephrosis as a hypoechoic cavity surrounded by a central echo complex. The principles of a successful ultrasound-guided PCN do not differ from those of the fluoroscopic guided PCN.With proper training, technical success is achieved in more than 95% of cases (Lee, Mond, Patel, & Pillari, 1994). Advancement in imaging,equipment and techniques of percutaneous nephrostomy has enabled removal of calculi from the kidney or proximal ureter through a percutaneous tract that is dilated to sufficient size to allow placement of a rigid nephroscope so that large stones can be fragmented under direct vision (with ultrasonic, electrohydraulic or laser lithotripsy) before removal. Smaller stones may be amenable to extraction without fragmentation. The targeted stones should be successfully removed through the percutaneous access tract. The placement of multiple nephrostomy tracks and the use of flexible instruments is often necessary for complete removal of stone material (Pellegrini *et al*.,2019). Although practicing physicians should strive to achieve perfect outcomes (100% success, 0% complications), in practice, all physicians will fall short of this ideal to a variable extent. Therefore, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs.Practice guidelines

set by the Society of Interventional radiology and American College of Radiology provide a benchmark of best practice threshold for percutaneous nephrostomy (SIR-ACR,2016). A threshold is a specific level of an indicator that should prompt a review. Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a (minimum) threshold, or when complication rates exceed a (maximum) threshold, a review should be performed to determine causes and to implement changes, if necessary. Thresholds may vary from those listed in the SIR guidelines; for example, patient referral patterns and selection factors may dictate a different threshold value value for a particular indicator at a particular institution.(SIR-ACR,2016).Therefore, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to higher or lower values to meet its own quality improvement program needs. Complications can be stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation(SIR-ACR,2016).

**2.2 Indications of percutaneous nephrostomy.**

Currently PCN has a wide range of indications in both malignant and benign conditions. First described in 1955 by Goodwin *et al* as a minimally invasive treatment for urinary obstruction causing marked hydronephrosis (Goodwin *et al.*, 1955), PCN has become uselful in management of various clinical conditions presenting with dilated and nondilated systems. Although the advancement of modern endourological techniques has led to a decline in the indications for primary

nephrostomy placement, PCNs still play an important role in the treatment of multiple urologic conditions.

Currently PCN is a prelude to more complex procedures such as stenting,laser lithotripsy, antegrade endopyelotomy, and resection of abdominal and pelvic tumors and tumors of the upper urinary tract.

The Society of Interventional Radiology(SIR.,2016) has grouped the indications for PCN into the following three broad categories:

**Diversion:**

- Urinary obstruction due to kidney or ureteric stones.
- Obstructon of the ureters due to tumors
- Postsurgical fibrosis associated with urinary obstruction
- Ureteric fistula and/or leaks either due to trauma,as a result of medical procedures, tumors, inflammation or hemorrhagic cystitis
- Pregnancy associated urinary obstruction with hydronephrosis
- Post renal transplant urinary obstruction.
- Drainage of fluid collection around the kineys for example abscesses and cysts.

**Direct access to renal collecting system:**

- For intervention radiology procedures for example dissolution of kidney and ureteric stones, chemotherapy for malignancy,antibiotics or antifungals
- For procedures such as antegrade ureteral stent placement, stricture dilatation, stone retrieval, pyeloureteroscopy, or endopyelotomy

**For diagnostic procedures:**

- Whitaker test, antegrade pyelography or biopsy

Relief of urinary obstruction represents the most common indication for PCN placement representing 85 to 90% of patients (Dagli & Ramchandani, 2011).

The three most common causes of renal obstruction in adults are urinary stones, malignancy, and iatrogenic benign stricture. In one large series,26% of all nephrostomy tubes were placed because of calculus disease and 61% due to malignancy (Ramchandani *et al*., 2001).

Malignant indications for PCN are common.There are certain malignancies that are more likely to involve the renal collecting system and these include bladder cancer,ureteral cancer,colorectal cancer,cervical cancer,uterine cancer,prostatic cancer,testicular cancer, lymphoma and metastatic tumors.

Involvent of the renal collecting system can be either from direct tumor invasion,extrinsic compression or due to compression of the ureters or base of bladder by the enlarged lymph nodes as a result of the tumor.

Benign indications for PCN include renal and ureteric calculi,renal cysts,ureteral stricture,retroperitoneal fibrosis and compression of the ureters by aortic or iliac artery aneurysms.In these benign indications,PCN can be a temporary relief of the obstruction to allow for definitive management (Verma *et al*.,2006). Ureteral calculi can be associated with urinary drainage blockage, requiring urinary diversion with percutaneous nephrostomy (PCN) or retrograde ureteral stent (RUS). Currently no evidence exists to support the superiority of one method over the other (Pereira *et al*.,2018). In some cases, drainage of an obstructed kidney is necessary and stent

placement is inadvisable or impossible. In particular, such cases include patients with pyonephrosis who have a UTI or urosepsis exacerbated by an obstructing calculus. In these patients, retrograde endourological procedures such as retrograde pyelography and stent placement may exacerbate infection by pushing infected urinary material into the obstructed renal unit. Percutaneous nephrostomy is useful in such situations (Schwartz *et al*.,2020).If retrograde stent placement is determined to be more appropriate, attempts to minimize additional pressurization of the collecting system by using minimal contrast and or decompressing prior to contrast administrating should be employed.Frequently,due to an obstruction in the renal collecting system,infection sets in and antibiotics are unable to penetrate the kidney. In these cases, percutaneous nephrostomy is an attractive treatment alternative. It allows decompression of the obstructed system, permits specimen collection, and creates a route for antibiotic instillation if needed. This procedure decreases the risk of urosepsis associated with acute open surgical intervention which carries the risk of peritonitis and septicaemia (Kumar *et al*.,2015).In obstructive uropathy due to ureteric calculi,PCN can be used to relieve the obstruction and allow the edema to subside after obstructing calculus spontaneously passes (Verma *et al*.,2006). For an obstructed and infected collecting system secondary to stone disease, virtually no contraindications exist for emergency surgical relief either by ureteral stent placement (a small tube placed endoscopically into the entire length of the ureter from the kidney to the bladder) or by percutaneous nephrostomy.

Many urologists and interventional radiologists have a preference for one technique or the other. In general, however, patients who are acutely ill, who have significant medical comorbidities, or who harbor stones that probably cannot be bypassed with

ureteral stents undergo percutaneous nephrostomy, whereas others receive ureteral stent placement (Chirag *et al*.,2020).

In patients who are floridly septic or hemodynamically unstable, a percutaneous nephrostomy can be a faster and safer way to establish drainage of an infected and obstructed kidney, though airway concerns and other complicating factors such as anticoagulant use or sepsis-associated thrombocytopenia may sway providers towards retrograde stent placement (Philippe *et al*,2016). Ultimately when dealing with seriously ill patients requiring urologic decompression, discussion between urology, anesthesia and interventional radiology is key to determine the best course of treatment based on positioning and comorbid conditions. Broad spectrum antibiotics which are then tailored to sensitivities is also paramount whenever a UTI is suspected in conjunction with hydronephrosis or renal colic a septic patient.

The vast majority of symptomatic urinary tract calculi are now treated with noninvasive or minimally invasive techniques. Open surgical excision of a stone from the urinary tract is now limited to isolated atypical cases (Verma *et al*.,2018).

If the obstruction is the result of postoperative edema, percutaneous nephrostomy can be used to relieve the obstruction and allow the edema to subside. Percutaneous nephrostomy may similarly facilitate the management of urinary fistulas by facilitating urinary diversion away from the urinary bladder to allow healing of the fistula to take place.

Various studies have come up with contrasting results in terms of indications of PCN.

In a study in Sudan in 2007, The majority (51%) of patients had underlying obstructive urinary calculi followed by obstruction due to tumor invasion (26%).

Other causes were ureteric stricture (12.5%), pelvi-ureteric junction obstruction (6.7%) and ureteric ligation (3.8%) (Elamin, Taha, & Ahmed, 2017).

In another study in Cameroon,main indications for PCN were urolithiasis (35%), benign prostatic hypertrophy (27%), prostatic cancer (12%), cervical cancer (16%), and congenital malformations (5%) (Halle *et al*., 2016).

Farrell and his colleagues in a review of radiologically guided percutaneous nephrostomies in 303 patients reported that 26% of all nephrostomy tubes were placed because of calculus disease and 61% due to malignancy (Farrell & Hicks, 1997).

Locally in Kenya,a study done in Kenyatta National Hospital found malignancy to be the most common indication.The commonest malignancies necessitating PCN were cancer of the cervix(94%),ovarian cancer(3%) and bladder cancer(3%) (Masaki, 2015).

In terms of demographic distribution,the indications are largely determined by the patient's age and  can be benign or malignant. In children the main indications are uretero-pelvic junction obstruction,congenital urethral stenosis and urethral strictures (Mandeep *et al*.,2014).

In young adults, calculus or urinary stones is the primary indication while in older patients benign prostatic hyperplasia, calculi and malignancy are the common indications. Hydronephrosis is a usual situation in the course of advanced malignancies(cervical, bladder, prostate, or colorectal cancer)in adults and the cause of obstruction may be invasive-infiltration of the ureters by tumor,extrinsic compression by a retroperitoneal primary or metastatic neoplasia, and this may be

aggravated by periureteral fibrosis, secondary to previous chemotherapy and radiation therapy.

In a study on patients with obstructive uropathy in Sudan, renal function recovery was 100% in patients with acute obstruction and was stabilized in 90% of patients with chronic obstruction and 4 patients had end-stage renal failure and therefore still required chronic dialysis (El Imam *et al*., 2006). The indications for percutaneous nephrostomy in renal transplants is largely the same as in native kidneys (Bennett *et al*.,1996). Occasionally, percutaneous nephrostomy drainage may be performed as a therapeutic trial to differentiate renal failure caused by urinary obstruction from that related to rejection. Percutaneous nephrostomy can be performed on an outpatient basis in selected patients. Patients who live alone or in whom the risk of complications is high, such as in those with staghorn calculi, uncorrected hypertension, or a coagulopathy, are best treated in an inpatient setting so they can be appropriately monitored (Cochran *et al*.,2007).In patients with severe uncorrected metabolic imbalance such as hyperkalemia or metabolic acidosis, correction of these imbalances may be necessary before the percutaneous nephrostomy to decrease the risk of complications such as arrhythmias or cardioplegia related to the profound electrolyte abnormality. The indications for percutaneous nephrostomy can therefore be broadly categorized into the following groups: obstruction with infection, obstruction without infection, stone disease, prelude to endoscopic/interventional

## 2.3 Outcomes of PCN

### 2.3.1:Clinical outcomes

The presence of pain symptoms radiating to the T11 to T12 dermatomes is common in obstructive uropathy. Patients may present with abdominal and/or flank pain.Studies have shown that these symptoms are less likely to occur in chronic obstruction in which symptoms and signs of obstruction are often mild, occurring over long periods of time and requiring a high index of suspicion for diagnosis(Sood *et al.*,2014) Early recognition and treatment are the keys to preventing renal loss.

Pain is common when obstruction acutely distends the renal collecting system (ie, the ureter, renal pelvis, and renal calyces), or renal capsule. Upper ureteral or renal pelvic lesions cause flank pain or tenderness (Patti & Leslie, 2017).

In a retrospective study 1152 children with abdominal pain,Zhang and his colleagues in 2015 found 14 of them had hydronephrosis due to ureteropelvic junction obstruction (UPJO) (Chen *et al.*, 2019).

Fluid overload and weight gain can occur as a result of renal impairement following obstructive uropathy and acquired tubular resistance to antidiuretic hormone and aldosterone (Policastro *et al*.,2016).Following placement of PCN,studies have shown that there is post obstructive dieresis characterized by a marked natruresis and diuresis with excretion of large amounts of sodium and water with resultant decrease in edema and weight (Scallan, Huxley, & Korthuis, 2010).

### 2.3.2 Laboratory outcomes

The outcomes in terms of renal function after placement of PCN has been found to be variable and influenced by several factors such as duration and extent of obstruction,underlying cause of obtruction and status of contralateral kidney (Halle *et al*., 2016).

Some patients dont recover their renal function even after PCN placement due to irreversible permanent damage and therefore dont show clinical improvement (Pietrow *et al.*, 2003). Percutaneous nephrostomy is a procedure that has significant implications for the treatment of obstructictive uropathy.Studies have been done to determine significant independent predictors of renal function recovery like renal cortical thickness, corticomedullary differentiaton, echogenicity, pre-PCN creatinine along with renal intrapelvic pelvic pressure (IPP) which can provide an index to evaluate residual renal function before deciding to perform PCN procedures (Sharma *et al*.,2015).

The most important factors determining extent of recovery of renal function are extent and duration of obstruction (Turka & Rose, 1988). The best evaluation of the capacity of a kidney to recover after obstruction is a period of therapeutic trial and PCN has been recommended for this purpose. More recent studies however, have reported no significant improvement of RF after PCN drainage (Dhillon *et al*.,2018).The use of PCNs should be limited to evaluate the recoverability of poorly functioning obstructed kidneys with Split renal function(SRF) of about 10% before any nephrectomy(Rahman *et al.*,2017). (Irving *et al*.,2016) in their short series of 9 cases showed recovery after trial of PCN in 4 cases.But (Singh *et al*.,2018) showed in their 29 cases series, only 7(24.1%) cases were functionally improved.

In a study by Kamlesh Mishra and his colleagues,of 15 patients with cervical cancer with obstructive uropathy and deranged renal functions,there was symptomatic improvement and significant fall of mean serum creatinine value from 7.5 mg/dl to 0.9 mg/dl over a period of 1-3 weeks post PCN.Out of 12 patient with primary untreated advanced disease, curative treatment was possible in 3, palliative radiotherapy/chemo-therapy in 7 and only symptomatic treatment in 2 cases after obstructive uropathy was managed with PCN insertion.Out of the 3 already treated patients, 2 were disease free after curative radiotherapy/surgery (Mishra, Desai, Patel, Mankad, & Dave, 2009).

In another study in Cameroon of 229 patients with obstructive uropathy who underwent PCN, Drainage was effective in 45% of the patients and 28% had a complete recovery of renal function (Halle *et al.*, 2016).

Various factors predict recoverability of renal function post percutaneous nephrostomy.The underlying cause of obstruction,duration of obstruction,intrapelvic pressure (IPP),renal morphological factors,the status of contralateral kidney and the presence of renal infection are some of the factors postulated to determine the recoverability of renal function post PCN insertion (Sharma, Yadav, & Tomar, 2015). Some kidneys fail to recover even after PCN placement due to irreversible permanent damage.However,partial recovery that allowed discontinuation of dialysis has been reported even after 7 months of complete obstruction in other studies (Cohen *et al.*,1992).

After PCN placement in patients with azotemia secondary to obstruction, renal function has been noted to normalize in two-thirds of patients within 15 days, with a mean of 7.7 days (Pabon-Ramos *et al*., 2016).

Despite the fact that various studies have shown significant improvement in ranal function post PCN,in malignant cases of obstructive uropathy,some studies have shown renal function improvement is possible only if the procedure is carried out at an early stage. **(**Sood *et al*.,2006).

A prospective study done in Greece on outcomes of PCN in patients with cervical cancer showed that 6% of the patients had no significant renal function improvement 2 weeks after PCN placement (Stravodimos *et al.*,2000).

Another study in Brazil showed that 38% of the patients who underwent PCN due to malignant obstructive uropathy had no recovery of renal function 3 weeks after the procedure and still require renal replacement therapy (Souza *et al*.,2016).

The mechanism involved in irreversible renal damage,among many other factors include increased intratubular pressure, local ischemia, and, often, urinary tract infection (UTI) (Preminger *et al*.,2020). If obstruction is bilateral, nephropathy may result in renal insufficiency. Renal insufficiency may rarely occur when obstruction is unilateral because autonomic-mediated vascular or ureteral spasm may affect the functioning kidney.The time and rate at which irreversible damage to the kidney (or kidneys) develops after obstruction depends on so many factors that it is hard to predict (Preminger *et al*.,2020).To prevent irreversible damage, obstruction of the urinary tract should be diagnosed and treated as promptly as possible. Before planning of nephrectomy in poorly functioning kidneys with split renal function of < 10% due to unilateral ureteropelvic junction obstruction(UPJO), PCN drainage should be done to asses improvement of renal function because in many studies, most of the poorly functioning kidneys show significant improvement in renal function after PCN drainage ( Hossain *et al*.,2017).

### 2.3.3 Radiological outcomes

Kidney length, volume,corticomedullary differentiation,echogenicty and cortical thickness are parameters that are usually considered when doing an ultrasonographic examination of the kidneys. Length is feasible to measure, but is not necessarily diagnostic, as it is not always measured using a standardized approach and is related to body size (Korkmaz, Aras, Guneyli, & Yılmaz, 2018).

Increased echogenicity of the kidney parenchyma results from the increased presence of material that can reflect sound waves back, thus increasing its brightness on the ultrasonography image.

Although clinically relevant kidney diseases may be present without changes in echogenicity, if increased parenchymal echogenicity is noted (echogenicity is greater than a normal liver) it is usually abnormal (except in neonates). For example, increased echogenicity was reported to have a 96% specificity (and 67% positive predictive value) for the presence of parenchymal kidney disease (Riccabona, Mache, & Ring, 2008).

Renal cortical thickness is measured over a medullary pyramid, perpendicular to the capsule as the shortest distance from the base of the medullary pyramid to renal capsule. Reduced renal cortical thickness <6 mm has been found to be amore reliable measure of renal functional status than length in some studies.A study done by (Megally *et al*., 2020) concluded that renal cortical thickness was correlated with renal function, and therefore, measuring renal cortical thickness using US is an important method in the follow-up care of patients with CKDs.

Corticomedullary differentiation (CMD) is defined radiologically as the ability to clearly delienate the renal medulla from the renal cortex,absence of which can indicate possible nephropathy(Faubel *et al.*,2014).

Studies have shown outcomes in radiological parameters of cortical thickness and corticomedullary differentiation after relieve obstruction in the renal collecting system.A study done by (Shehab *et al*., 2013) in which 138 patients with obstructive uropathy with age ranged from 2 months to 73 years who underwent ureteral stenting due to obstructive uropathy secondary to ureteral stricture showed a statistically significant relation between cortical thickness and recovery ( $P < 0.0002$), and a statistically significant relation between degree of corticomedullary differentiation and recovery ( $P < 0.0003$).

(Ebisuno *et al*., 1986) in retrospective study of 145 PCN patients also found a correlation between cortical thickness before preliminary nephrostomy and the renal function after the nephrostomy.Angelelli *et al*.,2007) in Italy also showed that the mean cortical thickness increased significantly after PCN.

The same conclusion was arrived at by a study by (Estroff *et al*., 1991) who found that the presence of normal parenchymal echogencity is a good prognostic parameter in patients with obstructive uropathy.

Another study relating to the changes in renal morphology on ultrasound was done by Angelelli and his colleagues and contrasted the above study as regards parenchymal echogenicity.The results of a prospective evaluation of the alterations in the morphology and vascular resistance of the renal parenchyma after percutaneous nephrolithotomy showed that the mean cortical thickness increased significantly while no statistically significant change was recorded in parenchymal echogenicitiy (Angelelli & Macarini, 1987).

However a study in India found no significant change in cortical thickness post PCN among patients who had PCN placement as a palliative management for malignant obstructive uropathy (Surajit *et al.*,2017).

**2.4 Complications of Percutaneous nephrostomy**

Two systems currently is use for reporting PCN complications are the Modified Clavien Classification System and the SIR-ACR Practice Guidelines.The SIR-ACR classification is a reproducible system and has been adopted widely (Degirmenci *et al*.,2013).It has set recommended 30 day threshold for major complications 4-8%, and minor complications <15%.The rates of PCN-related major complications vary in literature from 0 to 7% (Agistini *et al.*,2003).In one of the largest reported series of 454 PCNs by (Farrell *et al*.,2007) the incidence of major and minor complications was 5.2% and 14.4% respectively.

Specific complications related to PCN are uncommon, and may include hemorhage, perforation of the pelvicaliceal system,leakage of urine into the abdomen and infection.The complications related to the catheter include blockage and dislodgement of the catheter.Failure of the placement of PCN is uncommon.

Society of Interventional Radiology (SIR) has come up with a commonly used classification related to the complications of PCN.The complications are classified as minor complications (A) no therapy, no consequences, or (B) nominal therapy, no consequences.

Major complications are (C): complications requiring therapy and minor hospitalisation (<48h), (D) major therapy, and associated with unplanned increase in level of care, prolonged hospitalisation (>48 h), (E) permanent adverse sequel, or (F)

resulting in death. The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high-quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed toward the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high-quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure.(SIR-ACR.,2016).

The rate of minor complications range from 0.4-10% in most literature. In 2007, the suggested standard set by the Royal college of Radiologists(RCR) in the UK was ≤15%. The UK group of investigators proved this to be an achievable target and demonstrated the rate of minor complications to be as low as 12% (Chalmers *et al*.,2008).

The total rate of minor complications in one series was 6.1% and were catheter-related problems,most frequently catheter dislodgment (Carrafiello *et al*., 2006) reported 43 [43/299 (14.4%)] cases of dislodgements.Other commonly reported minor complications included transient hematuria and catheter site infection/inflammation, catheter blockage,pain (common) and extravasation of urine (< 2%)

The most significant major complications related to PCN in most studies included severe sepsis and septic shock. A study done by (Agostini *et al.*, 2003) reported sepsis as a major complication in 0.7–3.6% of cases. Other major complications reported in other studies include massive hemorrhage requiring transfusion, surgery, or embolization (1-3%),Pneumothorax (< 1%).

When minor and major complications are considered together, they occur in approximately 10% of patients (Miller *et al*.,2008). The departmental thresholds apply to all complications that occur in the department. The individual thresholds apply to all complications that each practitioner encounters. Published rates for individual types of complications are highly dependent on patient selection and are, in some cases, based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs in a small volume of patients (Miller *et al*.,2008).

In a study of 30 day outcomes of percutaneous nephrostomy in post renal transplant patients by (Jeon *et al.*,2015) early complications were observed in three patients within 24 hours of catheter insertion and were related to bleeding. In two cases, the bleeding was sufficient to cause bladder clots, and a urinary catheter was inserted. Both patients required bladder washouts for 1 day and the bleeding stopped spontaneously, without recurrence. Neither patient required blood transfusion or additional treatment, so these events were graded as SIR grade B and Clavien grade I. One of these patients had the lowest platelet level (84 × 109 cells/L). In the third patient, bleeding via the nephrostomy catheter occurred immediately after percutaneous nephrostomy catheter insertion. This was treated expectantly with blood transfusion but because it continued beyond 24 hours, angiography and embolization

were undertaken (SIR grade D). At angiography, transection of a segmental branch of the renal artery was discovered and successfully treated by selective coil embolization. There were no other major complications, including bowel injury, giving a major complication (defined as SIR grade C or higher or Clavien grade II or higher) rate of 1.4% (1/73 percutaneous nephrostomy episodes).

Two more patients were noted to have an asymptomatic perirenal hematoma (SIR grade A or Clavien grade I) on ultrasound at days 9 and 27 after percutaneous nephrostomy, respectively.Both patients were asymptomatic and had undergone uncomplicated balloon dilation and stent insertion.Six patients had positive urine cultures before percutaneous nephrostomy catheter insertion and were successfully treated with continued antibiotics. There were no cases of septicemia and no new cases of urinary tract infection within 30 days of the nephrostomy catheter insertion. There were no late cases of pseudoaneurysm or major bleeding. Thus, the overall complication rate in this study (any grade) was 6.8% (5/73), and the major complication rate was 1.4% (1/73) (Jeon *et al.*,2015).

## 2.5 The technique of percutaneous nephrostomy

### 2.5.1 Equipment

- High resolutions Ultrasound machine
- Initial puncture needle G21
- Guidewire(0.038-inch diameter)
- Pigtail catheter gauge 8 or 10F 30-45cm long with self retaining mechanism
- Dilators ranging from 8-12 French
- Urine bag connector
- Two way stop cock

### 2.5.2 Patient preparation

1. The procedure is explained to the patient in detail and informed consent is obtained.
2. Coagulation parameters should be within normal limits. International normalized ratio is obtained and should be within the normal range of below 1.5.Platelets of atleast 100000/microliter and Hemoglobin >10g/dl.
3. Intravenous (IV) access is established.Antibiotics may or may not be given depending on the likelihood of urosepsis. For uncooperative but willing patient, procedure may be performed under sedation. Relevant radiological images should be reviewed again in order to check for variant anatomy and decide on the optimal approach for renal access.

### 2.5.3 Patient positioning

Patient is positioned in prone position,prone oblique or lateral position and lumbar region disinfected with 10% povidone iodine and draped.The affected side is brought to the edge of operating table.Disinfection of the operation site with povidone and draping is done.In case of relative contraindication to prone position for example compromised cardiopulmonary status,bone deformity and morbid obesity,lateral position can be used.

### 2.5.4 Surface marking

There is less likelihood of injury to intra-abdominal viscera and organs if PCN is inserted in the quadrangle of safety formed by posterior axillary line as lateral limit, upper margin of iliac crest as lower limit, lateral margin of paraspinous muscle as medial limit, the 11th and 12th rib border as upper limit.

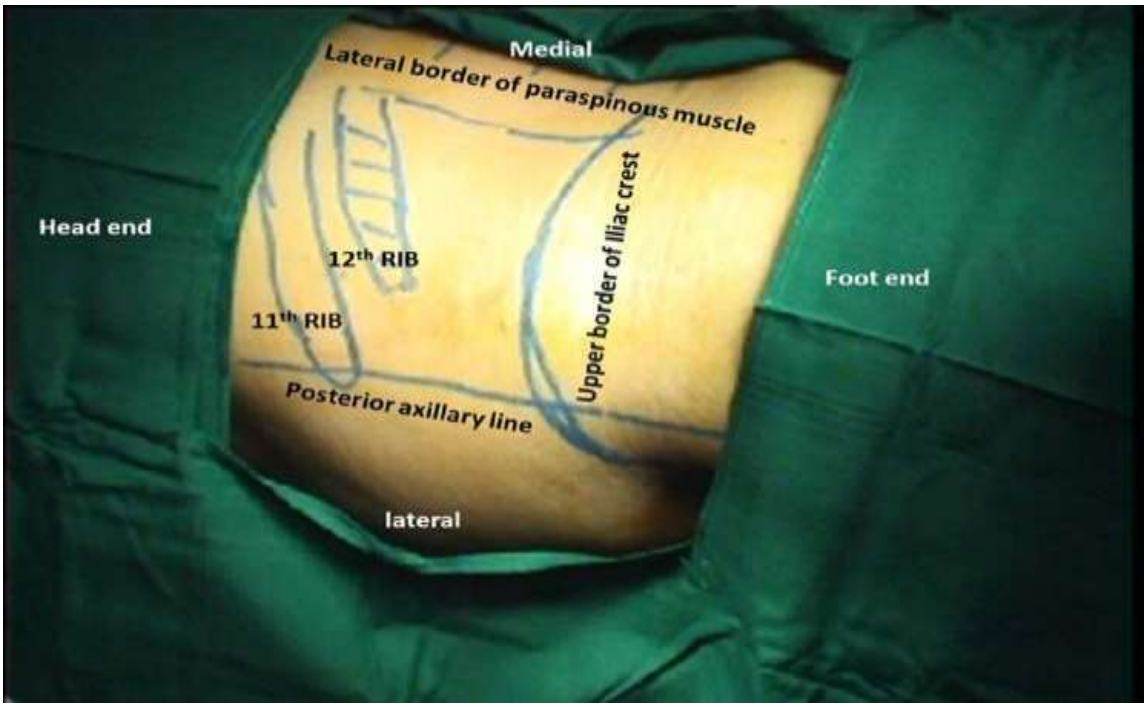


**Figure 1:The quadrangle of safety(Desai et al.,2017)**

Bleeding complications can be minimized by entering the kidney in a relatively avascular zone created by branching of the renal artery (Cavanagh *et al*.,2002). The specific site of renal entry is dictated by the indication for access with consideration of the anatomic constraints. Familiarity with renal anatomy is necessary for selection of a safe route through the kidney for percutaneous nephrostomy (Regan *et al*.,2008). The renal artery divides into major ventral and dorsal branches, which creates a zone of relative avascularity between the divisions . This zone known as the Brodel bloodless line of incision lies just posterior to the lateral convex border of the kidney (Chen *et al*.,2004).Bleeding complications related to percutaneous nephrostomy can be minimized by traversing this avascular region. The optimal entry plane lies posterolaterally, at the junction of the anterior two-thirds and posterior one-third of the renal parenchyma.

Because of the normal renal rotation about its horizontal axis, the posterior calices are usually oriented with their long axis pointing to this watershed territory. The anteriorly and posteriorly directed calices can be identified fluoroscopically by using iodinated contrast material and air.With the patient prone, urine containing iodinated contrast material opacifies dependent, anteriorly directed calices, which are usually seen tangentially.Air introduced into the collecting system accumulates in the posteriorly directed (nondependent) calices.

Oblique fluoroscopy with the image intensifier angled 20 °–30° from the vertical toward the side of the kidney to be punctured can be used for entry into the collecting system, along the fluoroscopic axis. Alternatively, when vertical fluoroscopy is used, the patient may be placed in an oblique position with the side of the kidney to be punctured elevated 20°–30°.

Successful percutaneous nephrostomy requires visualization of the collecting system for selection of an appropriate entry site. The definitive entry site is then selected; ideally, the entry site should be subcostal and lateral to the paraspinous musculature. Small-bore nephrostomy tracks can be created over a guide wire coiled in the renal pelvis. A large-diameter track may be necessary for percutaneous stone therapy, nephroscopy, or antegrade ureteroscopy. The most common extension of percutaneous nephrostomy is placement of a ureteral stent for treatment of obstruction. Transient hematuria occurs in virtually every patient after percutaneous nephrostomybut severe bleeding that requires transfusion or intervention is uncommon (Zagoria *et al*.,2002) In patients with an obstructed urinary tract complicated by infection, extensive manipulations pose a risk of septic complications (Raymond *et al*.,2005).

### 2.5.5 Ultrasound guided entry

Using aseptic technique,A 3.5 MHz convex transducer focused at 5-9 cm for adults and 5 MHz transducer focused at 5-7 cm for children is used to examine the diseased kidney starting from medial aspect (Para spinal), advancing laterally until the posterior axillary line so as to see posterior calyces first followed by lateral calyces thereafter and thus to have an idea of degree of hydronephrosis.

Local anesthesia in the form of 10mls 2% lignocaine is infiltrated under ultrasound guidance at the site chosen for percutaneous access and directed along intended tract of tube catheter placement. Exact site of puncture depends primarily on the cause of hydronephrosis and anatomic landmarks. For simple urinary drainage a lower pole posterior calyx is usually best which can be easily accessed via subcoastal approach.For accessing pelvic-ureteric junction (PUJ) or upper ureter, upper or middle posterior calyx provides easy access and may require supracoastal puncture. Whenever possible aim should be to puncture posterior calyces and to avoid direct pelvic puncture especially in case of hydronephrosis due to stone disease.

Small incision is made with a scalpel.A 15-cm, diamond-tipped, 18-gauge two-part trocar needle is then engaged in needle attachment connected with the probe .The tip of the needle should be introduced first through the incision site and then advanced into deeper plane with needle guide.When the needle has entered the collecteting system,needle stellate is removed and urine will flow through the needle.If no urine flow is observed,aspiration is done while withdrawing the needle from the renal system until urine is observed.Some urine sample is collected for appropriate tests.

Once position of needle in the collecting system is confrmed, a 0.038-inch diameter guide wire is introduced through the needle under ultrasound guidance.

Tract then is dilated from 8 up to 14 French size using single step fascial dilator over the guide wire using rotatory screw movements of hands.

In a similar fashion and direction as used during tract dilatation nephrostomy tube is inserted with screwing movement of hands (avoid pushing) over the guide wire until it reaches well into the pelvis.Free flow of urine through nephrostomy tube conforms the tube in correct position.Guidewire is withdrawn.

The nephrostomy tube is anchored in position on the skin using non-absorbable suture material and adhesive strapping.

### 2.5.6 Postoperative Care

Frequent vital signs should be obtained to evaluate for the potential of ongoing blood loss or for the development of septic complications in those at risk (Robero *et al*.,2013). Careful charting of the nephrostomy tube output to assess adequacy of drainage should also be performed. Hematuria, which is initially present in virtually all patients in whom percutaneous renal entry is performed, should diminish gradually over 24–48 hours (Preminger *et al*,2016). Narcotics may be required for pain relief, especially in patients with intercostal entries. Arrangements should be made for ongoing tube care and maintenance if long-term drainage is anticipated. In most institutions, patients will be admitted overnight after initial nephrostomy tube placement. In some patients, it may be appropriate to place a nephrostomy tube in an outpatient setting.

# CHAPTER THREE: METHODOLOGY

## 3.1 Study design

This study was a prospective study at MTRH spanning a period of one year from the time approval by IREC

## 3.2 Study Site

The study site was at the interventional radiology section at the department of Radiology in MTRH. This is a referral facility located in Eldoret town,Kenya. It is the second largest referral facility in Kenya. Eldoret town is roughly 350 Kilometres west of Nairobi, the capital city of Kenya. Its a tertiary health facility with a catchment area of about 24 million people.The hospital has a fully equiped and staffed radiology department. The Interventional radiology department has modern ultrasound machines.

## 3.3 Study Population

All patients undergoing percutaneous nephrostomy at Moi Teaching and Referral Hospital.

**3.4 Study period** –June 2019 to May 2020.

## 3.5 Sampling technique

This study was a census study.A total of 68 cases was attained during study period.

## 3.6 Eligibility criteria

### 3.6.1 Inclusion criteria

All patients undergoing ultrasound guided PCN at the radiology department at MTRH were included in the study.

### 3.6.2 Exclusion criteria

Patients undergoing re-insertion of nephrostomy tubes after a previous successfull insertion.

### 3.7 Data collection and management

#### 3.7.1 Study procedure

Data was collected between June 2019 to May 2020 at the Interventional radiology room at the radiology department at MTRH. Clinical team at IR department were sensitized to inform the Principal investigator(P.I) on receiving request for assessment for PCN insertion.P.I assessed all the patients referred by the primary doctor for PCN and assessed the symptoms,weight,indication,previous imaging and histopathological diagnosis.The P.I did an abdominal ultrasound on all the patients and recorded the radiological findings.If PCN was indicated,the procedure was explained to the patient and informed consent to be enrolled in the study was obtained.

The patient was booked and lab request forms for INR,HB,platelet count,and tripple serology test filled and given to the patient to be done on the day before procedure.The lab results were reviewed by the P.I as as per the MTRH interventional radiology protocol,the parameters are required to be above the following limits: Platelet(>100,000/microliter),INR(<1.5) and HB(>10g/dl).

On the day of the procedure,the principal investigator assisted the interventional radiologist in the procedure.The P.I reviewed the patients 24 hours after PCN for radiological and clinical evaluation.The patients were followed up for 14 days and repeat renal function test (Urea and creatinine) and elctrolytes was done and recorded on the14th post operative day during followup at I.R department

All the data was entered into a data sheet and then transferred to a Microsoft access data base and double entry was used to increase the accuracy of the data entered. Patients were assigned serial numbers to protect their identity and only the supervisors and the investigator was allowed access through password protected documents.

### 3.7.2 Recruitment procedure and schema

Recruitment was done at Interventional radiology room at the radiology department at MTRH. The principal investigator assessed every patient who has been referred to the department for possible PCN placement.This was done from Monday to Friday for the entire study period. Previous images were reviewed by the P.I with the help of the interventional radiologist.

The ultrasound assessment was carried out to confrm the indication,degree of hydronephrosis and if unilateral or bilateral PCN was indicated. In some cases where the ultrasound examination was insufficient, further imaging using Computerised tomography(CT) was done.

If PCN was indicated,the procedure was explained to the patient including the risks and benefits of the procedure. The patient was booked for the procedure or if an emergency PCN was deemed necessary, the procedure was done on the same day after some baseline laboratory tests have been carried out. The cost of these tests was paid by the patient.

On the day of the procedure,informed consent was obtained from patients who were above 18 years. For the children between the ages of 7-18 years,assent was obtained from them in the presence of their parents or guardians. For children below the age of 7 years,the parents or guardians consented on their behalf.

For the consenting patients, demographic and clinical data was recorded in the data collection form..

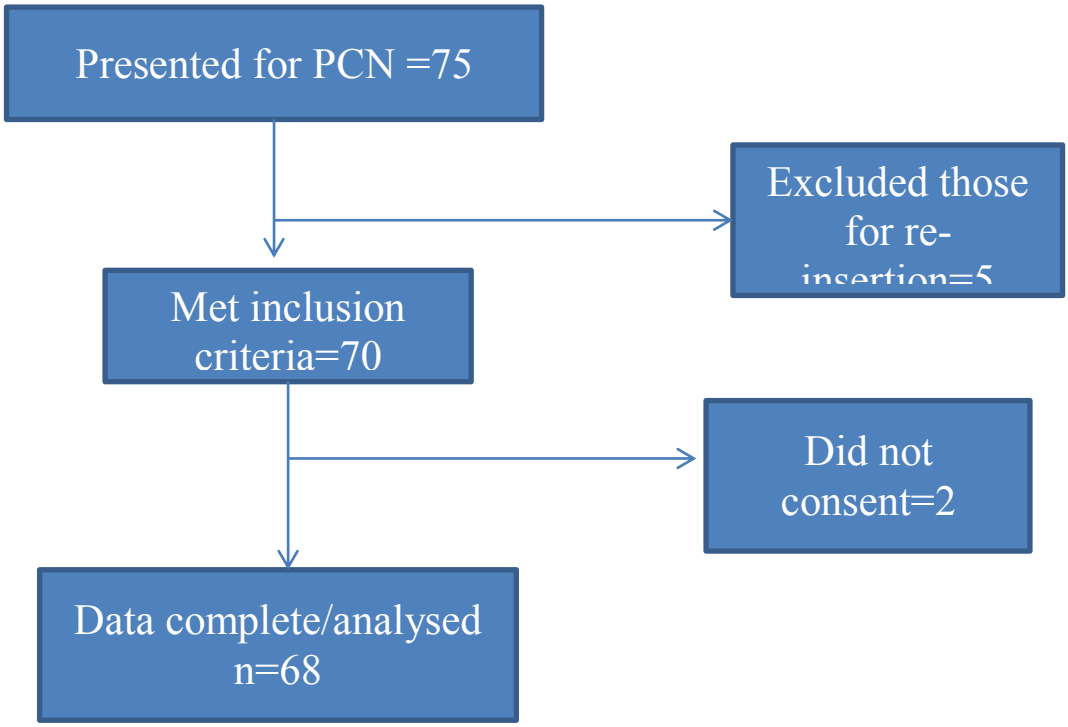


**Figure 2:Recruitment schema**

### 3.7.3 Quality control

The data collection form was pretested with 5 random patients and validated before administration in order to determine the completeness of the form.The data collection forms was cross-checked for completeness at the end of each day and securely kept by the Principal Investigator. Each data collection form was assigned a specific code that was maintained for each patient to ensure that patients were not recruited more than once.Samples collected were analysed within 24hrs to minimise deterioration of samples. All blood samples were analysed at Moi Teaching and Referral Hospital laboratory for reproducibility of the results.

### 3.7.4 Data analysis

Data collected was coded and entered in Microsoft Excel spreadsheet and thereafter cleaned before exporting to SPSS for statistical analysis. The study population was described by summarizing demographic and clinical data into percentages and means for categorical and continuous variables respectively.

### 3.7 Ethical considerations

Approval of the research proposal was sought and granted by the Ethical and Resarch Committee(IREC).Permission to carry out the study was obtained from CEO,MTRH

The patients who met the eligibility criteria were informed fully about the procedure and informed consent was obtained. For the children between the ages of 7-18 years, assent was obtained from them in the presence of their parents or guardians. For children below the age of 7 years, the parents or guardians consented on their behalf.

All data was collected anonymously and confidentiality observed. A code was used instead of the patients' names for confidentiality. Data was stored in password protected computer.

# CHAPTER FOUR: RESULTS

## 4.1 Introduction

In this chapter, the results of the study are presented. The chapter is organized into three main sections. The first section is on the indications for PCN, the second part is on the clinical,radiological and laboratory outcomes of PCN while the last part is on the complications associated with PCN procedure.

## 4.2 Demographic information

The mean age of the 68 patients included in the study was 37.62 ±125.00 (SD) years. The youngest was 3 months old while the oldest patient was 89 years.

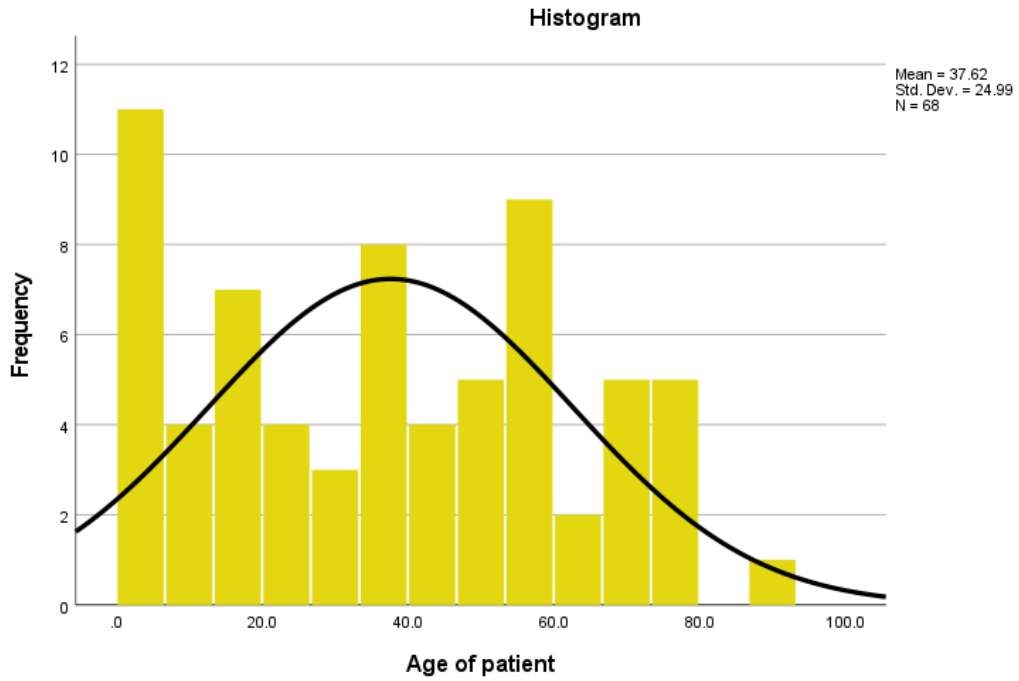


**Figure 3 :Age distribution in years**

A total of 38 (55.9%) of the patients were female while the rest (30; 44.1%) were male.

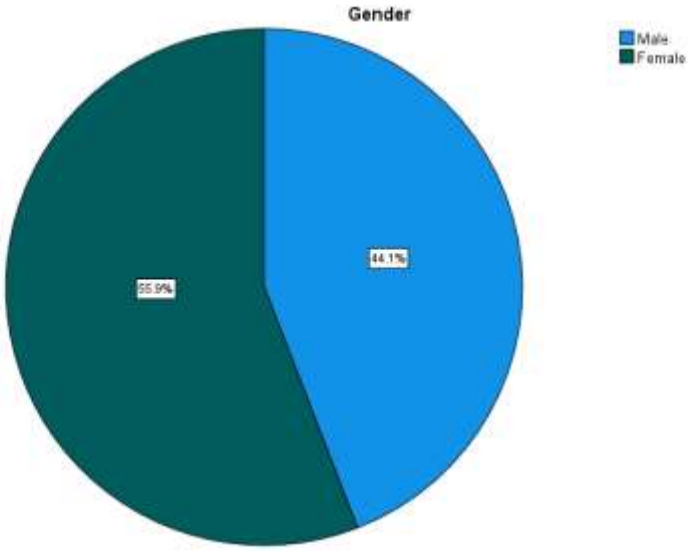


**Figure 4: Gender of the patients**

The mean period from  assessment to PCN insertion was 24.18 ± 10.77 days.

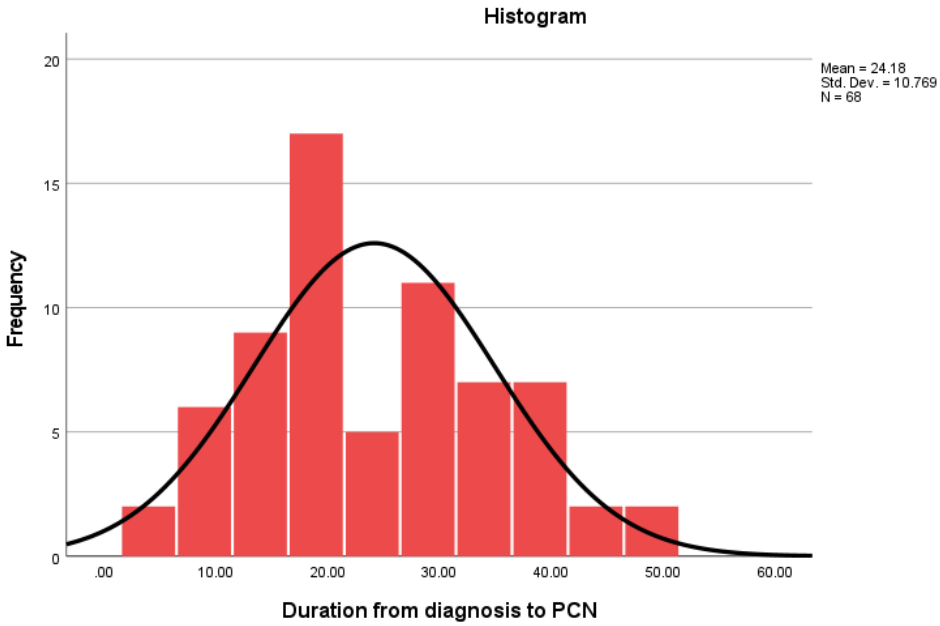


**Figure 5:Duration from diagnosis to PCN placement( days )**

### 4.2 Indications for PCN

The most common indication for PCN placement was malignant disease constituting 55 cases(80.8%)

**Table 1 :Indications for PCN**

| Indications | n | Percentage |
|---|---|---|
| **Malignancy** | **55** | **80.8** |
| **Inflammatory** | **4** | **5.8** |
| **Diversion**<br>Traumatic fistula<br>Iatrogenic | <br>**1**<br>**1** | <br>**1.5**<br>**1.5** |
| **Urinary calculi** | **4** | **5.8** |
| **Perinephric fluid collection**<br>Abscess<br>Urinoma | <br>**1**<br>**2** | <br>**1.5**<br>**3** |
| **Total** | **68** | **100** |

Most common malignancy indication was carcinoma of the cervix constituting 18(32.7% )of all malignant indications.Second most common malignancy was cancer of the prostate 11(20%)

**Table 2: Malignant indications for PCN**

| | Frequency (n) | Percent (%) |
|---|---|---|
| Abdominal Lymphoma | 5 | 9.0 |
| Bladder Cancer | 2 | 3.6 |
| Cervical cancer | 18 | 32.7 |
| Ovarian Cancer | 6 | 10.9 |
| Prostate Cancer | 11 | 20.0 |
| Colorectal Cancer | 2 | 3.6 |
| Endometrial Cancer | 3 | 5.4 |
| Gastic Cancer | 1 | 1.8 |
| Neuroblastoma | 6 | 10.9 |
| Paraspinal Rhabdomyo Sarc | 1 | 1.8 |
| TOTAL | 55 | 100 |

### 4.3 Clinical outcomes pre and post PCN

**Table 3: Clinical outcomes pre and post PCN**

| **Sign/Symptom** | **Pre PCN** | | **Post PCN** | | **% Change** |
|---|---|---|---|---|---|
| **Oedema** | n | | n | | |
| Grade 0 (No edema) | 25 | | 38 | | 19.1 |
| Grade 1 | 12 | | 10 | | 2.9 |
| Grade 2 | 12 | | 8 | | 5.9 |
| Grade 3 | 11 | | 6 | | 7.3 |
| Grade 4 | 8 | | 6 | | 2.9 |
| **Wilcoxon signed rank test** | Mean | Median | Mean | Median | P Value |
| **Weight** | 58.68± 25.15 | 65.85 (55.85-75.25) | 57.3618 ±24.96 | 65.00 (54.93-74.60) | <0.001 |
| **Flank pain (McNema's test** | n | | n | | P Value |
| Present | 27 | | 11 | | 0.003 |
| Absent | 41 | | 57 | | |

**Table 4: Clinical outcomes**

| **Pre PCN** | **Post PCN** | | **McNemar's test exact sig** |
|---|---|---|---|
| **Patient on dialysis** | **post operative dialysis** | | |
| **preoparative** | Yes | No | |
| Yes | 12 | 1 | 1.000 |
| No | 1 | 54 | |

The non-parametric Wilcoxon signed rank test was used to compare the mean weight pre and post PCN.

There was reduction in mean weight of patients after PCN from a mean of 58.68± 25.15 pre PCN to a mean of 57.3618 ±24.96 post PCN

This reduction in weight was statistically significant with a P value of <0.001

The McNema's test was used to compare the number of patients reporting flank pains pre and post PCN.

There was reduction in the number of patients reporting flank pain from 27(39.7%) to 11(16.1%)

This reduction was statistically significant with a P value of 0.003

There was an increase in the number of patients with no pitting edema from 25(36.7%) to 38(55.8%) after PCN.There was also a 2.9%,5.9%,7.3% and 2.9% decrease in number of patients with grade 1,2,3 and 4 edema respectively.

A total of 12 patients who were on dialysis before PCN were also on dialysis post-operative, one patient who was not on dialysis pre-operative was put on dialysis post-operative (after PCN) and one patient discontinued dialysis post PCN. A total of 54 patients were not on dialysis both pre- and post-operative. An exact McNemar's test determined that there was no statistically significant difference in the proportion of patients on dialysis pre and post-operative (P value = 1.00).

### 4.5 Radiological outcomes post PCN

#### 4.5.1 Parenchymal echogenicity

Before PCN placement,parenchymal echogenicity was normal in both kidneys in 45 (66.2%) of the patients , while in 23 (33.8%) parenchymal echogenicity was abnormal in one or both kidneys.

**Table 5:Parenchymal echogenicity**

| Characteristic | Pre PCN | Post PCN |
|---|---|---|
| **Parenchymal echogenicity** | | |
| Normal | 45 (66.2%) | 49 (72.1%) |
| Abnormal | 23 (33.8%) | 19 (27.9%) |

Only 4 patients who had abnormal parenchymal echogenicity pre PCN had a reversal of echogenicity to normal post PCN

An exact McNemar's test determined that there was no statistically significant difference in the proportion of patients with normal parenchymal echogenicity in the pre and post-operative periods(P value = 0.125)

**Table 6: McNemar's test parenchymal echogenicity**

| Characteristic | Parenchymal echogenicity | | |
|---|---|---|---|
| Parenchymal echogenicity | **POST PCN** | | **P Value** |
| **PRE PCN** | Normal | Abnormal | |
| Normal | 45 | 0 | 0.125 |
| Abnormal | 4 | 19 | |

### 4.5.2 Cortical thickness

The mean cortical thickness before PCN was 6.68±2.76 .After PCN the mean cortical thickness was 8.44 ±3.42

**Table 7:Cortical thickness**

| **Characteristic** | **Pre PCN** | **Post PCN** |
|---|---|---|
| **Cortical thickness** | | |
| Mean | 6.68±2.76 | 8.44 ±3.42 |
| Median | 6.00, IQR(4.00-8.00) | 8.00,IQR(6.00-10.75) |

**Comparison of pre and postoperative Cortical thickness**

The non-parametric Wilcoxon signed rank test was used to compare cortical thickness pre and post PCN. The results showed that there was a significant increase in cortical thickness after PCN.

**Table 8: Wilcoxon signed rank test cortical thickness.**

| Wilcoxon Signed Ranks Test | Median | Z | P value |
|---|---|---|---|
| Cortical thickness post PCN | 8.00 | -6.325 | .000 |
| Cortical thickness pre-PCN | 6.00 | | |

**4.5.3 Corticomedullary Differentiation**

Before PCN,corticomedullary diferentiation was normal in 42(61.7%) of the patients while in 26(38.3%) the CMD was lost

Post PCN the number of patients with normal CMD increased to 44(74.7%)

McNemar's test was used to determine the significant of this increase and it was found not to be significant with a P value of 1.

**Table 9:Corticomedullary differentiation**

| | 14 days post PCN | | McNemar's test |
|---|---|---|---|
| **Pre PCN** | **Normal** | **Abnormal** | **P value** |
| **Normal** | **42(74.7%)** | **0** | **1** |
| **Abnormal** | **2(2.9%)** | **24(35.3%)** | |

### 4.6 Laboratory Outcomes

#### 4.6.1 Urea and Creatinine

The mean preoperative urea and creatinine were 25.61±11.95 mg/ll and 595.25± 600.13 mmol/L, respectively while the median preoperative urea and creatinine levels were 26.20 (18.60-33.93) mg/dl and 394.00 (92.25-985.75) mmol/L respectively. A total of 22 (32.4%) patients had normal creatinine and urea pre-PCN.

**Table 10 :Preoparative parameters**

| **Preoperative characteristics** | **Frequency (n)** | **Percent (%)** |
|---|---|---|
| **Variable** | **Mean (sd)** | **Median (IQR)** |
| Preoperative urea (mg/dl) | 25.61 (11.95) | 26.20 (18.60-33.93) |
| Preoperative creatinine (mmol/L) | 595.25 (600.13) | 394.00 (92.25-985.75) |
| **Preoparative urea** | | |
| Normal | 22 | 32.4 |
| High | 46 | 67.6 |
| **Preoprative creatinine** | | |
| Normal | 22 | 32.4 |
| High | 46 | 67.6 |

The mean postoperative urea and creatinine was 19.50±10.42 mg/dl and 329.2118±426.96 mmol/L respectively while the median post-operative urea and creatinine levels were 18.40 IQR(14.00-25.48) mg/dl and 174.00 IQR(79.0-378.98) mmol/L respectively. A total of 41 (60.3%) patients had nomal urea postoperatively while 27 (39.7%) had high level of urea. Postoperatively, 30 (44.1%) had normal creatinine levels while 38 (55.9%) had high level of creatinine.

**Table 11: Post-operative urea and creatinine**

| Post-operative characteristic | Frequency (n) | Percent (%) |
|---|---|---|
| **Urea and creatinine** | **Mean (sd)** | **Median (IQR)** |
| Post-operative urea (mg/dl) | 19.50 (10.42) | 18.40 (14.00-25.48) |
| Post-operative creatinine (mmol/L) | 329.2118 (426.96) | 174.00 (79.0-378.98) |
| **Post operative urea** | **Frequency (n)** | **Percent (%)** |
| Normal | 41 | 60.3 |
| High | 27 | 39.7 |
| **Post operative creatinine** | | |
| Normal | 30 | 44.1 |
| High | 38 | 55.9 |

### 4.4.3 Relationship between preoperative and post-operative outcomes

A total of 22 patients had normal creatinine pre PCN increasing to 30 post PCN while 22 patients had normal urea levels pre-PCN increasing to 41 post PCN. An exact McNemar's test determined that there was a statistically significant difference in the proportion of urea pre- and post-intervention (P<0.001), and creatinine pre and post intervention (p = .021).

**Table 12: McNemar's test of differences between Pre and Post PCN Urea and Creatinine**

| Pre PCN | Post PCN | | McNemar's test exact sig |
|---|---|---|---|
| **Preoperative creatinine level** | **Post operative creatinine** | | |
| | Normal | High | |
| Normal | 21 | 1 | 0.021 |
| High | 9 | 37 | |
| **Preoperative urea levels** | **Post operative urea** | | |
| | Normal | High | |
| Normal | 21 | 1 | <0.001 |
| High | 20 | 26 | |

The non-parametric Wilcoxon signed rank test was used to compare the urea and creatinine levels pre and post-operative. The results showed that there was a significant reduction in urea (average rank of 38.42 verses average rank of 20.63) (Z= -5.27, P-value< 0.001) and creatinine levels (average rank of 36.59 verses average rank of 18.81) (Z= -6.248, P-value< 0.001) from the preoperative levels to post-

operative levels (. Hence a significant reduction in urea and creatinine levels from preoperative period to post-operative period (P- value<0.001).

**Wilcoxon signed rank test for differences in creatinine and Urea between pre and post PCN**

**Table 13: Wilcoxon signed rank test urea and creatinine**

| Variables | | N | Mean Rank | Sum of Ranks | Z | P value |
|---|---|---|---|---|---|---|
| Post-operative urea - preoperative urea | Negative Ranks | 53 | 38.42 | 2036.50 | -5.277 | <0.001 |
| | Positive Ranks | 15 | 20.63 | 309.50 | | |
| Post-operative creatinine - preoperative creatinine | Negative Ranks | 60 | 36.59 | 2195.50 | -6.248 | <0.001 |
| | Positive Ranks | 8 | 18.81 | 150.50 | | |

**Table 14:Potassium**

| **PRE PCN** | **n** | **Percentage** | **Mean** |
|---|---|---|---|
| Potassium(K+) | | | |
| Normal | 53 | 78% | 4.88 mmol/L |
| High | 15 | 22% | 6.41mmol/L |
| **14 days POST PCN** | **n** | **Percentage** | **Mean** |
| Normal | 57 | 83.9% | 4.91mmol/L |
| High | 11 | 16.1% | 5.62mmol/L |

The non-parametric Wilcoxon signed rank test was used to compare potassium in patients with hyperkalaemia pre and post PCN. The results showed that there was a significant decrease in Potassium after PCN .

**Table15: Wilcoxon signed rank test on Potassium**

| **Potassium in patients with hyperkalaemia** | **PRE PCN** | **14 DAYS POST PCN** |
|---|---|---|
| **MEAN** | 6.41±1.24 | 5.62±1.42 |
| **MEDIAN** | 6.50, IQR(4.00-8.00) | 5.8800,IQR(5.3.00-5.75) |
| **Z of MEDIAN** | -5.243 | |
| **P VALUE** | .00125 | |

### 4.8 Complications post PCN

Among the participants, 15 (22%) developed complications after the PCN procedure.53(78%) did not have any complications .Majority of the complications were minor 10 (14.5% ) and No therapy or only nominal therapy was required.Major complications were few and constituted 5(7.5% ).The commonest minor complication was tube blockage 8(11.7) which was managed successfully by flushing tube with saline.There was no death that resulted from the procedure

**Table 16:Complications**

| **Grading** | **Management** | **Complication, *n* (%)** |
|---|---|---|
| **Minor Complications A/B** | | |
| Tube blockage | Flushing tube with saline | 8(11.7) |
| Transcient haematuria<24hrs | conservative | 1(1.4) |
| Infection at insertion site | Cleaning and dressing | 1(1.4) |
| | **Minor complications** | **10(14.5)** |
| **MajorComplicationsC/D** | | |
| Pyelonephritis | antibiotics | 1(1.4) |
| Tube Dislodgement | reposition/change/reisertion | 2(2.9) |
| Urinoma | Percutaneous drainage | 1(1.4) |
| Perirenal abscess | Percutaneous drainage | 1(1.4) |
| E/F permanent adverse sequelae/Death | | 0 |
| | **Major complications** | **5(7.5)** |

## SAMPLE IMAGES

**Image 1: Longitudinal ultrasound image showing hydronephrosis in a patient with an acute ureteral stone.**

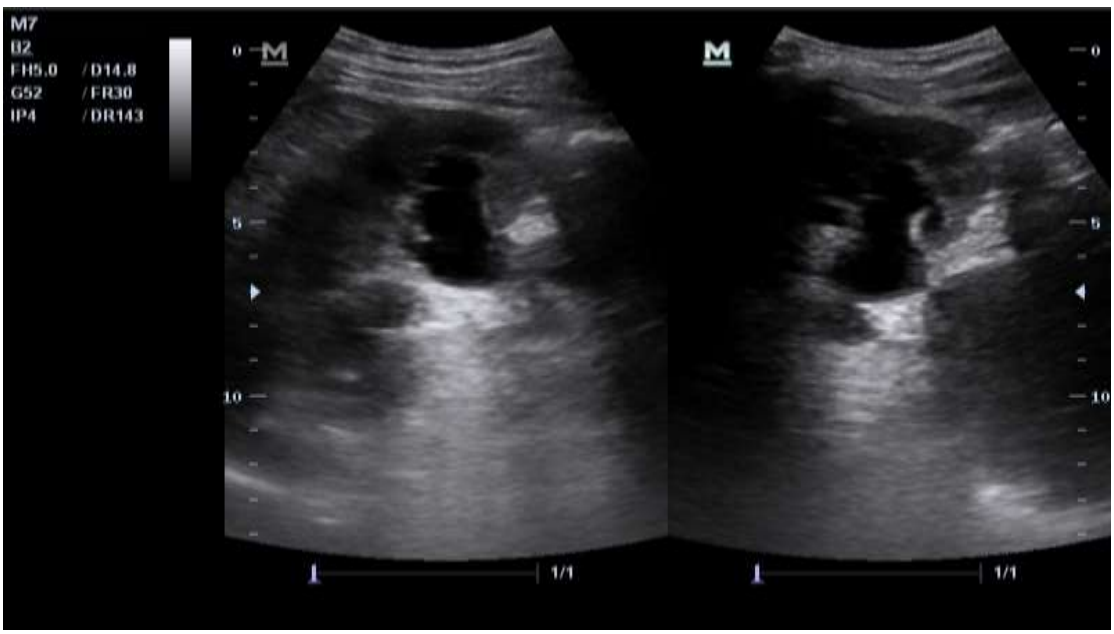


**Image 2:Longitudinal ultrasound images showing PCN placement using Single step technique in a 37 year old male with pelvic lymphoma and grade 3 hydronephrosis.**

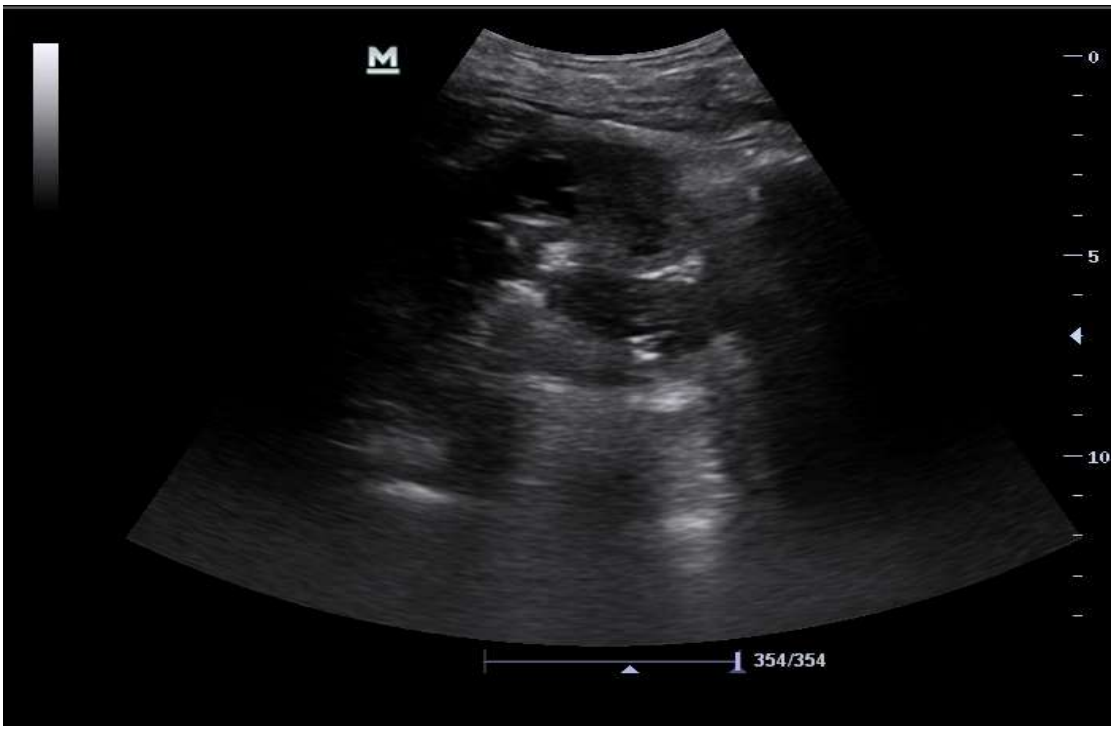


**Image 3: Longitudinal ultrasound image showing PCN procedure with correct placement of pigtail in the renal pelvis in a 41 year old female with post inflammatory ureteral stricture.**

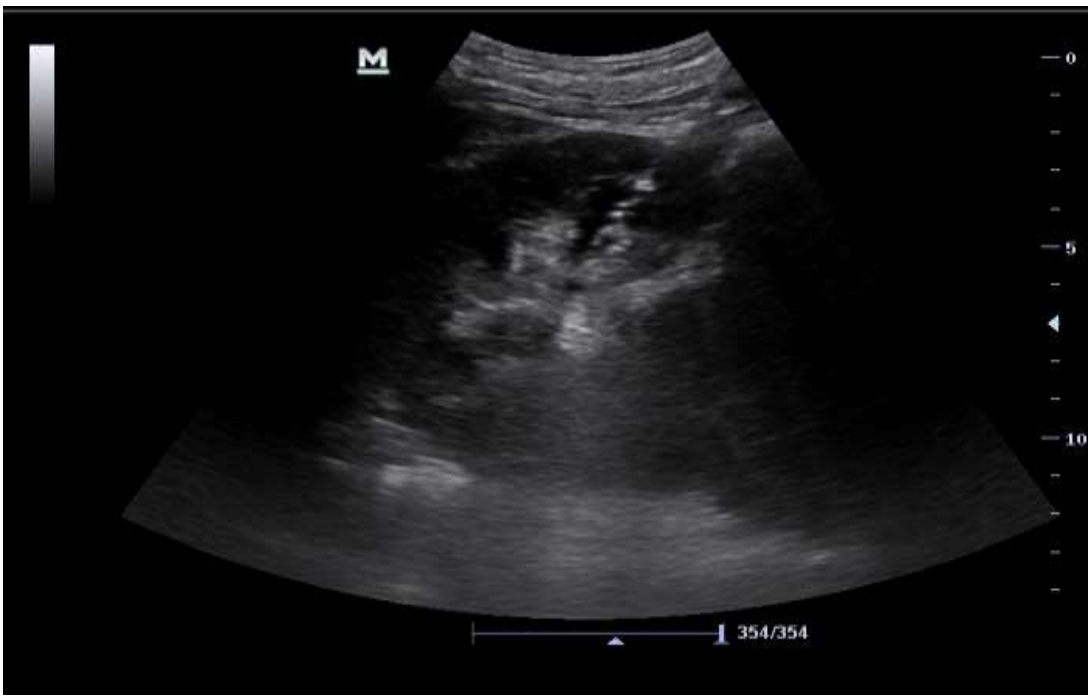


**Image 4: Longitudinal ultrasound image showing PCN coaxial needle entry in a posterior calyx in a 46 year old female with stage 4 ca cervix and grade 3 hydronephrosis**

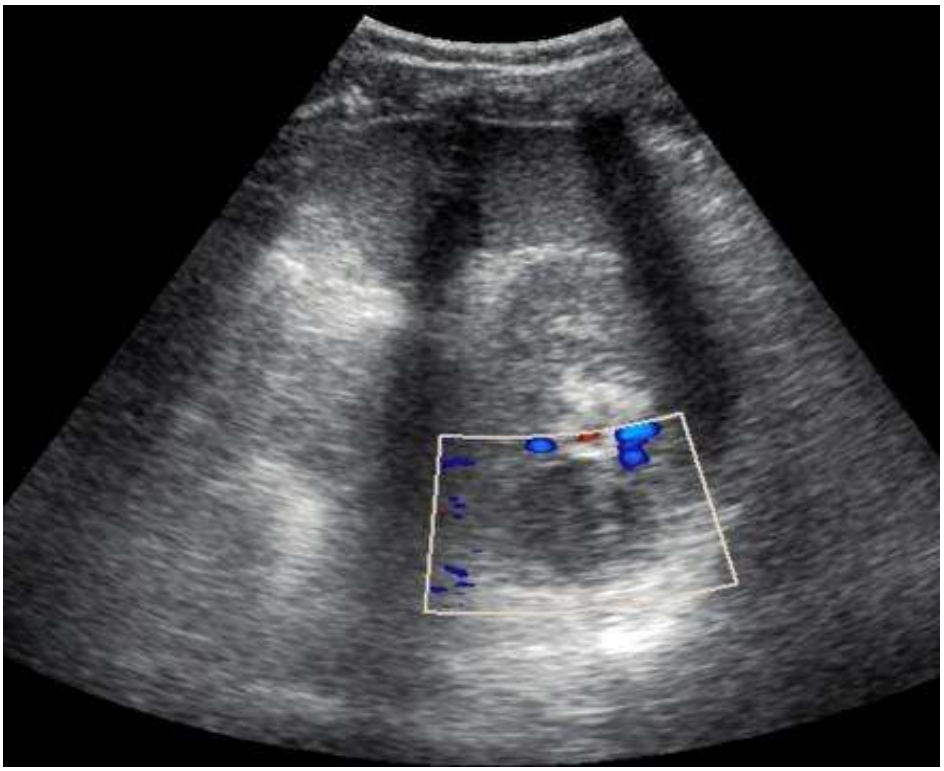

**Image 5:Transverse Ultrasound image showing perirenal abscess post PCN with multipurpose catheter pig-tail size 10 French tip inside the abscess cavity**

# CHAPTER FIVE: DISCUSSION

## 5.1 Objective 1:Indications for PCN

Malignancies were the most common reason for the placement of PCN.A study by Farrel and his colleagues reported that 26% of all nephrostomy tubes were placed because of calculus disease and 61% due to malignancy (Farrell *et al*., 1997) which is consistent with this study findings. Similar to this study findings, malignancy was also found to be the main indication for 60% of all nephrostomies (Better *et al*., 1973). In UK a review of PCN found malignancy to be the main indication for PCN (Chalmers *et al.*, 2008).

However, contrary to this study finding where malignancy was the main cause of obstruction necessitating PCN, in a study conducted in Sudan, stones disease was the main cause of obstruction accounting for half of the patients undergoing PCN. The high proportion of patients with stone disease was justified by the fact that most of them presented late hence PCN being the preferred procedure for them rather than ureteric stenting or stone removal by medical or surgical methods (Elamin *et al*., 2017). Obstructing ureteric stone was also the main indication for PCN associated with 163 of the 401 reviewed patients in the study conducte in Sweden (Radecka & Magnusson, 2004).

## 5.2 Objective 2:Clinical outcomes

There was improvement in the clinical outcomes in this study.There was a 13(19.1%) increase in the number of patients with no pitting edema and a significant decrease in flank pain and weight in patients after PCN.

This finding Compares well with a study in Greece where 28 % of patients reported no flank pain 10 days after PCN, significant reduction in oedema and weight was seen in 22% of patients presenting with post renal anuria (Stravodimos *et al.*,2000).

These findings are also consistent with a study in Slovenia which concluded that PCN was associated favorable maternal and fetal clinical outcomes in the pregnant cohort studied who had PCN due gestational hydronephrosis.The study evaluated weight,blood pressure,pedal edema and pain associated with urinary obstruction (Pirnovar *et al*., 2020),

Another study of outcomes after PCN in patients with malignant obstructive uropathy by (Tan *et al*.,2018) in Singapore found a significant reduction in fever and abdominal pains post PCN.

Our findings however contrast with a study done of post PCN patients with pelvic malignant disease which showed poor clinical outcomes and survival (Lau *et al*., 1995). The difference could be due to the long follow-up period of 2 years in this study and also patients with benign indications were excluded.

Dialysis was discontinued in 1( 8 % ) of patients two weeks post PCN.This finding compares with a study in Egypt where 13.2% of patients discontinued dialysis 10 days post-PCN (Baishya *et al*.,2009).However,a two and half year prospective study of PCN in patients with cancer of cervix reported that 61.7% of patients discontinued dialysis during the study period (Kirsztajn *et al*.,2016). This is a much higher rate than our study and this may be due to the fact that the two studies differed markedly in duration of follow up of the patients.

### 5.3 Objective 2: Radiological outcomes

#### 5.3.1 Cortical thickness

There was statistically significant increase in renal cortical thickess post PCN in this study.This is Consistent with a study by (Lu *et al*., 2013) who found a correlation between urine output with every millimeter increase in cortical thickkess in patients

who had PCN placement.However this contrasts with a study by (Surajit *et al.*,2012) who found no significant change in cortical thickness in patients with ESRD post PCN.This can be attributable to the fact that the study excluded patients with normal renal function.Another study by (Grover *et al*., 2017) in India found no statistically significant increase in cortical thickness post PCN.This study only included patients with malignant disease on palliative PCN and that could explain the contast in the findings with this study which included both malignant and benign indications.

A study done by (Shehab *et al*., 2013) in which 138 patients with obstructive uropathy with age ranged from 2 months to 73 years who underwent PCN before ureteral stenting showed a statistically significant increase in cortical thickness and this was associated with recovery of renal function.( $P < 0.0002$).

### 5.3.2 Objective 2: Parenchymal echogenicity and corticomedullary differentiation

This study found no significant changes in parenchymal echogenicity and corticomedullary differentiation pre and post PCN.

These findings are consistent with a study done by (Marcia *et al*.,2000).The study include forty-two patients presenting with chronic renal failure secondary to obstructive uropathy.The study found that the increased echogenicity of kidneys was not specific to any renal parenchymal diseases, and there was no definite correlation between the echogenicity of the kidneys, kidney size, and the degree of decrease of renal function.Although our study did not try to correlate kidney function and echogenicity,the findings of the above study can explain the lack of any significant change in renal parenchymal echogenicity post operatively.

Another study relating to the changes in renal morphology on ultrasound was done by Angelelli and his colleagues.This study also agreed with our study as regards parenchymal echogenicity.The results of a prospective evaluation of the alterations in the morphology and vascular resistance of the renal parenchyma after percutaneous nephrolithotomy showed that the mean cortical thickness increased significantly while no statistically significant change was recorded in parenchymal echogenicitiy (Angelelli & Macarini, 1987).

A prospective study done by Sharma and his colleagues which included a hundred and sixty patients with supravesical obstruction from various causes who needed PCN found that there was significant changes in cortical thickness,corticomedullary differentiation and parenchymal echogenicity post PCN and this correlated well with renal function.(Sharma *et al*.,2015).This study contrasted with our study.This could be attributable to the fact that this study had a larger sample size of 160 and longer follow up period of 4 weeks.In our study we followed up the patients for only two weeks.

**5.4 Objective 2:Laboratory outcomes**

There was significant increase in number of patients with normal electrolytes level, reduced creatinine and urea levels after PCN compared to the preoparative period. Similar trend was observed in previous study in Sudan where the proportion of patients with normal serum creatinine was observed to increase postoperative (Elamin *et al*., 2017). Improvement in renal functions after PCN has also been reported previously by (Efthymiou, Cheng, & Tapping, 2017) where electrolytes levels returned to baseline levels after 24 hours of the PCN in 54% of the patients and in all patients within 48 hours.

In a study among cervical cancer patients in Mexico, there was improvement in creatinine level among the patients who underwent PCN from a median of 3.5 mg/dL (IQR 7.5) to 1.0 (IQR 0.7) after 30 days from intervention ($p< 0.001$) with 62.4% of the patients having normalized renal functions by day 30. The findings of the study in Mexico concurs well with this study finding despite differences in study population characeteristics (Morales-Vasquez et al., 2016).

However, the improvement in laboratory renal functions criteria does not necessarily lead to better quality of life (Hoe, Tung, & Tan, 1993). Besides, it has previously been shown that a number of patients who showed early improvement after PCN later deteriorated and developed renal dysfunction resulting in mortality within three months in some of the cases as was the case in the study in India (Sankhwar *et al*., 2019). This makes it difficult to appropriately infer factors associated with improvement in PCN patients despite renal functions and laboratory parametres being used widely. This necessitates further studies especially well designed randomized trials. However, other measures such as dialysis are essential in managing patients who have PCN placement done but continue to have poor significant impairment in renal function.

**Objective 2: Laboratory Outcomes**

**Potassium**

There was significant reduction in Potassium in patients who had hyperkalaemia from a mean of 6.41mmo/l to 5.62mmol/l.

Consistent with study by (Kumar *et al*.,2014) to assess the outcomes of early percutaneous nephrostomy in hydronephrosis and hyperkalaemia from ureteric obstruction.The study include 61 patients who underwent 69 PCN procedures.Forty

(58%) had nephrostomy without prior medical treatment of the hyperkalaemia. The mean serum potassium in these patients reduced from 6.7 mmol/L to 5.8 mmol/L after PCN (Kumar *et al*,2014).

Another study on outcomes in emergency PCN was done on 100 consecutive patients who have underwent PCN between May 2014 and September 2016.Out of the 12 cases of hyperkalemia, 75% (9/12) normalized within 24h, and all patients' potassium levels normalized within 48h of the PCN(Chang *et al*,2017).This higher rate of normalization of Potassium may be due to the fact that all the cases were emergency cases due to acute urinary obstruction and therefore the PCN intervention was done before the onset of permanent renal impairment.

**5.5 Objective 3: Complications of PCN**

Major complications were 5(7.5%).Minor complications were 10(14.5%) in this study.Combined major and mi nor was 22%.Most patients (78%) who underwent PCN did not develop any complication in our study concurring with findings in several previous studies where majority of the patients did not have any complications after PCN. In the study in Sudan, (78.8%) of the patients did not develop any complications after PCN (Elamin *et al*., 2017).

In this study, 22% of the patients developed some form of complications. Contrary to this study findings, a study in India, among bladder carcinoma patients with obstructive uropathy reported a lower proportion of patients (16.6%) who developed complications after PCN (Garg *et al.,* 2019). However, other studies in patients with cervical cancer reported a high proportion of patients developing complications associated with PCN ranging from 62-83% (Cohen *et al*., 1992); (Harris,

McCullough, & Talner, 1976). The prevalence of complications seems to vary with the indication with some malignancies indications likely to be associated with more complications. However, this needs to be evaluated further.

The society of Interventional radiology recommends a threshold of 4-8% major complication and <15% minor complications rates.The findings of our study are withing this threshold.

(Romero *et al*.,2005) in Brazil reported 17.7% major complications and 42.3% Combined complication rate in a study of cervical cancer patients who had PCN placement.This much higher rate could be atrributable to the fact that patients with benign indications were excluded and the study was also for a longer period of 2 years.

A study in sudan found similar findings where by hemorrhage, sepsis, catheter blockages, and leakages of urine to be the the minor commplications associated with PCN procedure. Blockage and infections at the insertion site were the main occurring complications (Elamin *et al*., 2017) as was the case in this study. Similarly, a retrospective study in Sweden reported urinary tract infection, leakage of urine, catheter dislodgement in 38% of the PCN cases reviewed (Radecka & Magnusson, 2004).

Catheter dislodgement and infection at the insertion site was also found to be the most occurring complications associated with PCN in the study among cervical cancer patients in Mexico (Morales-Vasquez *et al*., 2016).

### 5.6 Study Limitations

The study was limited by shortage of supplies required for PCN and this caused a delay between booking of patients for the procedure and carrying out the procedure

# CHAPTER SIX: CONCLUSION AND RECOMMENDATION

## 6.1 Conclusion

1. Obstruction due to malignancy was the main indication for PCN in this study.
2. There was significant improvement in the clinical, and laboratory outcomes post PCN whereas radiological outcomes were variable.
3. Complications rates in this study were within SIR-ACR recommended threshold.

## 6.2 Recommendations

1. Timely referral of patients with obstructive uropathy secondary to abdominal and pelvic malignancy for PCN placement.
2. Further studies to correlate the radiological and laboratory outcomes of PCN and to evaluate long term outcomes.

## REFERENCES

Agostini, S., Dedola, G. L., Gabbrielli, S., & Masi, A. (2003). A new percutaneous nephrostomy technique in the treatment of obstructive uropathy. *Radiol Med, 105*(5-6), 454-461.

Almgård, L. E., & Fernström, I. (1974). Percutaneous nephropyelostomy. *Acta Radiol Diagn (Stockh), 15*(3), 288-294. doi:10.1177/028418517401500307

Angelelli, G., & Macarini, L. (1987). [Difficulty in the differentiation of renal parenchymal hyperechogenicity]. *Radiol Med, 74*(1-2), 88-92.

Basiri, A., Ziaee, A. M., Kianian, H. R., Mehrabi, S., Karami, H., & Moghaddam, S. M. (2008). Ultrasonographic versus fluoroscopic access for percutaneous nephrolithotomy: a randomized clinical trial. *J Endourol, 22*(2), 281-284. doi:10.1089/end.2007.0141

Bhatt, S., Verma, P., Grover, R. K., Sharma, P., & Rajaram, S. (2017). Success, Effectiveness, and Safety of Combined Sonographic and Fluoroscopic Guided Percutaneous Nephrostomy in Malignant Ureteral Obstruction. Int J Radiol Radiat Ther 3(1): 00048.. Int J Radiol Radiat Ther. 3. 10.15406/ijrrt.2017.03.00048.

Carrafiello, G., Laganà, D., Mangini, M., Lumia, D., Recaldini, C., Bacuzzi, A., . . . Fugazzola, C. (2006). Complications of percutaneous nephrostomy in the treatment of malignant ureteral obstructions: single-centre review. *Radiol Med, 111*(4), 562-571. doi:10.1007/s11547-006-0051-2

Chalmers, N., Jones, K., Drinkwater, K., Uberoi, R., & Tawn, J. (2008). The UK nephrostomy audit. Can a voluntary registry produce robust performance data? *Clin Radiol, 63*(8), 888-894. doi:10.1016/j.crad.2007.10.021

Chen, J. C., Zhang, Q. L., Wang, Y. J., Cui, X., Chen, L., Zhang, J. Q., & Zhou, C. (2019). Laparoscopic Disconnected Pyeloplasty to Treat Ureteropelvic Junction Obstruction (UPJO) in Children. *Med Sci Monit, 25*, 9131-9137. doi:10.12659/msm.918164

Cohen, E. P., Sobrero, M., Roxe, D. M., & Levin, M. L. (1992). Reversibility of long-standing urinary tract obstruction requiring long-term dialysis. *Arch Intern Med, 152*(1), 177-179.

Dagli, M., & Ramchandani, P. (2011). Percutaneous nephrostomy: technical aspects and indications. *Semin Intervent Radiol, 28*(4), 424-437. doi:10.1055/s-0031-1296085

Ebisuno, S., Morimoto, S., Yoshida, T., Kumeda, K., Ohkawa, T., Kitagawa, M., . . . et al. (1986). [An experience of percutaneous nephro-ureterolithotomy]. *Hinyokika Kiyo, 32*(8), 1099-1104.

Efthymiou, E., Cheng, X., & Tapping, C. (2017). *Should percutaneous nephrostomy be performed as an emergency?*

El Imam, M., Omran, M., Nugud, F., Elsabiq, M., Saad, K., & Taha, O. (2006). Obstructive uropathy in Sudanese patients. *Saudi J Kidney Dis Transpl, 17*(3), 415-419.

Elamin, E., Taha, S., & Ahmed, M. (2017). Outcome and Complications of Percutaneous Nephro-stomy: Single Center Experience. *Sudan Medical Journal, 53*(2), 69-75.

Estroff, J. A., Mandell, J., & Benacerraf, B. R. (1991). Increased renal parenchymal echogenicity in the fetus: importance and clinical outcome. *Radiology, 181*(1), 135-139. doi:10.1148/radiology.181.1.1887022

Farrell, T. A., & Hicks, M. E. (1997). A review of radiologically guided percutaneous nephrostomies in 303 patients. *J Vasc Interv Radiol, 8*(5), 769-774. doi:10.1016/s1051-0443(97)70658-4

Garg, G., Bansal, N., Singh, M., & Sankhwar, S. N. (2019). Role of Percutaneous Nephrostomy in Bladder Carcinoma with Obstructive Uropathy: A Story Revisited. *Indian J Palliat Care, 25*(1), 53-56. doi:10.4103/ijpc.Ijpc_102_18

Goodwin, W. E., Casey, W. C., & Woolf, W. (1955). Percutaneous trocar (needle) nephrostomy in hydronephrosis. *J Am Med Assoc, 157*(11), 891-894. doi:10.1001/jama.1955.02950280015005

Halle, M. P., Toukep, L. N., Nzuobontane, S. E., Ebana, H. F., Ekane, G. H., & Priso, E. B. (2016). The profile of patients with obstructive uropathy in Cameroon: case of the Douala General Hospital. *Pan Afr Med J, 23*, 67. doi:10.11604/pamj.2016.23.67.8170

Harris, R. D., McCullough, D. L., & Talner, L. B. (1976). Percutaneous nephrostomy. *J Urol, 115*(6), 628-631. doi:10.1016/s0022-5347(17)59315-5

Hoe, J., Tung, K., & Tan, E. (1993). Re- evaluation of indications for percutaneous nephrostomy and interventional uroradiological procedures in pelvic malignancy. *British journal of urology, 71*(4), 469-472.

Ključevšek, T., Pirnovar, V., & Ključevšek, D. (2020). Percutaneous Nephrostomy in the Neonatal Period: Indications, Complications, and Outcome-A Single Centre Experience. *Cardiovasc Intervent Radiol, 43*(9), 1323-1328. doi:10.1007/s00270-020-02528-z

Korkmaz, M., Aras, B., Güneyli, S., & Yılmaz, M. (2018). Clinical significance of renal cortical thickness in patients with chronic kidney disease. *Ultrasonography, 37*(1), 50-54. doi:10.14366/usg.17012

Lau, M. W., Temperley, D. E., Mehta, S., Johnson, R. J., Barnard, R. J., & Clarke, N. W. (1995). Urinary tract obstruction and nephrostomy drainage in pelvic malignant disease. *Br J Urol, 76*(5), 565-569. doi:10.1111/j.1464-410x.1995.tb07779.x

Lee, W. J., Mond, D. J., Patel, M., & Pillari, G. P. (1994). Emergency percutaneous nephrostomy: technical success based on level of operator experience. *J Vasc Interv Radiol, 5*(2), 327-330. doi:10.1016/s1051-0443(94)71496-2

Lu, C. H., Liu, Y. S., Tsai, H. M., Chuang, M. T., Chen, C. Y., & Tsai, Y. S. (2013). Percutaneous nephrostomy performed on kidneys with a thin renal cortex: a retrospective study of daily urine output in 46 nephrostomy procedures. *Radiol Med, 118*(6), 909-916. doi:10.1007/s11547-013-0969-0

Masaki, M. S. (2015). *The role of percutaneous nephrostomy in the management of obstructive uropathy secondary to pelvic malignancies at Kenyatta national hospital.* University of Nairobi.

Megally, H. I., Mohamed, M. Z., Mohamed, W. H., & Mohamed, M. A. D. (2020). Renal cortical thickness as an indicator of renal insufficiency in chronic kidney disease. *Journal of Current Medical Research and Practice, 5*(3), 268.

Mishra, K., Desai, A., Patel, S., Mankad, M., & Dave, K. (2009). Role of percutaneous nephrostomy in advanced cervical carcinoma with obstructive uropathy: a case series. *Indian J Palliat Care, 15*(1), 37-40. doi:10.4103/0973-1075.53510

Morales-Vasquez, F., Caballero, H. M., Lopez-Basave, H. N., Cabelle, E., & Cano Blanco, C. (2016). Percutaneous nephrostomy drainage to improve renal function in patients with advanced versus recurrent or progressive disease in cervical cancer with similar complications: American Society of Clinical Oncology.

Ng, C. K., Yip, S. K., Sim, L. S., Tan, B. H., Wong, M. Y., Tan, B. S., & Htoo, A. (2002). Outcome of percutaneous nephrostomy for the management of pyonephrosis. *Asian J Surg, 25*(3), 215-219. doi:10.1016/s1015-9584(09)60178-0

Pabon-Ramos, W. M., Dariushnia, S. R., Walker, T. G., d'Othée, B. J., Ganguli, S., & Midia, M. (2016). Quality improvement guidelines for percutaneous nephrostomy. *J Vasc Interv Radiol, 27*(3), 410-414.

Patti, L., & Leslie, S. W. (2017). Acute renal colic.

Pietrow, P. K., Auge, B. K., Lallas, C. D., Santa-Cruz, R. W., Newman, G. E., Albala, D. M., & Preminger, G. M. (2003). Pain after percutaneous nephrolithotomy: impact of nephrostomy tube size. *J Endourol, 17*(6), 411-414. doi:10.1089/089277903767923218

Radecka, E., & Magnusson, A. (2004). Complications associated with percutaneous nephrostomies. A retrospective study. *Acta Radiol, 45*(2), 184-188. doi:10.1080/02841850410003671

Ramchandani, P., Cardella, J. F., Grassi, C. J., Roberts, A. C., Sacks, D., Schwartzberg, M. S., & Lewis, C. A. (2001). Quality improvement guidelines for percutaneous nephrostomy. *J Vasc Interv Radiol, 12*(11), 1247-1251. doi:10.1016/s1051-0443(07)61546-2

Riccabona, M., Mache, C. J., & Ring, E. (2008). Renal parenchymal disease *Pediatric uroradiology* (pp. 355-383): Springer.

Scallan, J., Huxley, V. H., & Korthuis, R. J. (2010). *Capillary fluid exchange: regulation, functions, and pathology*. Paper presented at the Colloquium Lectures on Integrated Systems Physiology-\nl\hspace* 18pt From Molecules to Function.

Seldinger, S. I. (1953). Catheter replacement of the needle in percutaneous arteriography; a new technique. *Acta Radiol, 39*(5), 368-376. doi:10.3109/00016925309136722

Sharma, U., Yadav, S. S., & Tomar, V. (2015). Factors influencing recoverability of renal function after urinary diversion through percutaneous nephrostomy. *Urol Ann, 7*(4), 499-503. doi:10.4103/0974-7796.157960

Shehab, M., El Helali, A., Abdelkhalek, M., Abdelshafy, M., Mourad, M., El Helaly, H., & Zikry, M. (2013). Role of ureteric stents in relieving obstruction in patients with obstructive uropathy. *Urol Ann, 5*(3), 148-151. doi:10.4103/0974-7796.115731

Turka, L., & Rose, B. (1988). Clinical aspects of urinary tract obstruction. *acute renal failure, 2*.

Wickbom, I. (1954). Pyelography after direct puncture of the renal pelvis. *Acta Radiol, 41*(6), 505-512. doi:10.3109/00016925409170694

# APPENDICES

## Appendix I:Data Collection form

### Socio –Demographic data

Date DD/MM/YYYY Patients number:

Serial Number D.o.B DD/MM/YYYY

Age

Gender Male Female

### Symptoms

Flank pain

Abdominal pain

Painful Micturation

Bloody urine

Fever

Facial swelling

Abdominal swelling

Others specify

Creatine level at booking 14 days Post PCN levels

Urea Level at booking 14 days Post PCN levels

Electrolytes Normal range Deranged

Levels

Sodium

Pottassium

Chloride

Is the Patient on dialysis

Yes ☐

No ☐

If yes:How many sessions/week

Did the patient still require dialysis 10 days post PCN

Yes ☐

No ☐

If yes how many sessions

Cause of obstruction

Cancer

Type of cancer

Cervical ☐

Endometrial ☐

Prostate ☐

Colorectal ☐

Kidney ☐

Ureter ☐

Others specify ☐

Calculi ☐

Ureteric stricture ☐

Iatrogenic ☐

Pregnancy ☐

Congenital ☐

Others-specify ☐

**Ultrasound Examination Finding**

**Renal Morphology**

Cortico-medullary differentiation

Normal ☐

Poor CM differentiation ☐

**Cortical thinning**

No thinning ☐

Mild ☐

Moderate ☐

Severe ☐

Cortical thickness mm ☐

Parenchymal echogenicity

Increased ☐

Normal ☐

**Ascites**

Yes ☐

No ☐

**Degree of hydronephrosis**

**Moderate** ☐

**Severe** ☐

**Massive** ☐

**Duration from time of diagnosis of hydronephrosis to PCN insertion**

Months ☐

Days ☐

Duration of Procedure (Minutes) ☐

Did the patient have any complications after PCN procedure?

Yes ☐

No ☐

If yes;

Specify complication

Dislodgement of tube ☐

Blockakge of tube ☐

Leakage of urine ☐

Infection ☐

Bleeding ☐

Others Specify

**Appendix II:Consent form**

**English Version**

**Investigator:** My name is Dr.Kimutai Nicholas. I am a qualified doctor, registered with 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 to study the indications and outcomes of Percutaneous nephrostomy at Moi Teaching and Referral hospital.

**Purpose:** To investigate the indications of percutaneous nephrostomy and the outcomes at MTRH

**Procedure:** All patient with Obstructive uropathy who undergo percutaneous nephrostomy at MTRH who will give informed consent will be included into the study. Demographic data,clinical and radiologic data will be obtained and recorded on data collection forms. Confidentially of the patients data will be observed by keeping the records in a locked cabinet and in password protected

**Benefits:** There will be no direct benefits of participating in this study. Study subjects will be accorded same quality of management as non-study subjects

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

**Confidentiality:** All information obtained in this study will be treated with utmost confidentiality and shall not be divulged to any unauthorized person

**Rights to Refuse:** Participation in this study is voluntary, there is 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 ReferralHospital

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

Parent/Guardian: ..... Investigator:..... Date: .....

**Appendix III:Assent form for children 7-18 years.**

Name of child giving assent……

Signature/*Sahihi*……. Or/*Ama* Thumb print *(Left)/Alama ya kidole*

*Gumba (kushoto)*

Date/*Tarehe*……

**Name of the person taking assent**……

*(Jina la anayetoa idhini*

Signature/*Sahihi*…..**.....**Date/*Tarehe* ……

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

Parent/Guardian: …… Investigator: …….. Date:

**Consent Form**

**Kiswahili Version**

Mimi ni daktari Kimutai Nicholas.Nimehitimu na kusajiliwa na bodi ya madaktari nchini Kenya.( Kenya Medical Practitioners and Dentists Board).

Natarajia kufanya utafiti wa Kujua ni magonjwa gani yanasababisha kuwekwa kwa mipira ya kupitisha mkojo (percutaneous nephrostomy tubes) na matokeo yanayojiri baada ya kuwekwa mipira haya.

Wagonjwa ambao watakuja kutibiwa kwa shida hii ya kuziba mipira yanayopitisha mkojo watasajiliwa ikiwa watapeana hiari yao.

Hakutakuwepo na manufaa yoyote zaidi na yale ya kawaida kwa wale watakao kubali kusajiliwa katika utafiti huu. Majibu ya upelelezi huu yatawekwa katika hospitali na hakuna yeyote isipokuwa mgonjwa ambaye atapewa majibu haya.

Kila mgonjwa ako na haki ya kukataa kujumuishwa katika utafiti huu.

Utafiti huu umeidhinishwa na kitengo cha upelelezi cha hospitaliya MTRH.

Nakubali kujumuishwa kwa upelelezi huu:

Mgonjwa /Mzazi…….. mpelelezi:..... Tarehe:……...

**Appendix IV.Society of Interventional Radiology Standards of Practice Committee Classification of Complications by Outcome.**

**Minor Complications**

A.No therapy, no consequence, or

B.Nominal therapy, no consequence; includes overnight admission for observation only.

**Major Complications**

C. Require therapy, minor hospitalization (< 48 h)

D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 h)

E. Have permanent adverse sequelae, or

F. Result in death.

## Appendix V: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

Reference: IREC/2019/39
***Approval Number: 0003358***

27th June, 2019

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
27 JUN 2019
APPROVED
P. O. Box 4606 - 30100 ELDORET

Dr. Kimutai Nicholas Kimeto,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
**ELDORET-KENYA.**

Dear Dr. Kimutai,

**INDICATIONS AND OUTCOMES OF PERCUTANEOUS NEPHROSTOMY AT MOI TEACHING AND REFERRAL HOSPITAL**

This is to inform you that ***MU/MTRH-IREC*** has reviewed and approved your above research proposal. Your application approval number is ***FAN:0003358.*** The approval period is ***27th June, 2019 – 26th June, 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 VI:Hospital Approval (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

28th June, 2019

Dr. Kimutai Nicholas Kimeto,
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:-

***"Indications and Outcomes of Percutaneous Nephrostomy 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
01 JUL 2019
P.O. BOX 3 - 30100, ELDORET

01/07/2019

**DR. WILSON K. ARUASA, *MBS***
**CHIEF EXECUTIVE OFFICER**
**MOI TEACHING AND REFERRAL HOSPITAL**

cc - Senior Director, (CS)
- Director of Nursing Services (DNS)
- HOD, HRISM