

Effectiveness of Percutaneous Nephrostomy: A Prospective Institution Based Assessment in a Tertiary Teaching Hospital in Addis Ababa, Tikur Anbessa Specialized Hospital, Ethiopia, 2023-2024

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INTRODUCTION

Majority of percutaneous drainage are done for the purpose of draining an obstructed upper system be it sterile or septic obstruction. The procedure might be done for the obstruction caused by either a benign or malignant condition. Most of patients who undergo this procedure are its mainly done as a permanent and is part of palliative care given for them. As an objective of this study, we are going to explore the safety and efficacy of our procedures done to alleviate the renal upper system obstruction in a wide variety of causes.(1)

RESEARCH CONCEPT AND OBJECTIVES

The efficacy and safety of percutaneous nephrostomy procedure is a paramount to deal with in a high burden setting in which we are practicing. So, the research will answer weather we are doing a such effective procedure from this point of view.

METHODOLOGY

This prospective institutional study included all patients undergoing therapeutic ultrasound-guided PCN between January 1 and April 30, 2024. Effectiveness was assessed using a transparent outcomes framework: technical success, early clinical response (24–48 hours), and a primary biochemical endpoint defined as achieving the expected creatinine drop by day 7.

RESULTS

One hundred fifty patients underwent PCN, predominantly female (83.3%), with mean age 50.0 ± 12 years and most aged 40–59 (43.3%); 52.7% were from Addis Ababa. Clinical features included flank pain in 64.4% (mostly bilateral), decreased urine output in 69.3%, and fever in 20.7%. Hydronephrosis was mainly moderate-to-severe, and obstruction was predominantly malignant (85.3%), largely gynecologic. Early outcomes showed marked clinical improvement, and bleeding events were self-limited with no transfusions or interventions. Follow-up creatinine documentation was incomplete (available for 63/150 at 24 hours, 68/150 at day 7, and 31/150 at day 30).

CONCLUSION

Percutaneous nephrostomy in our setting showed high effectiveness with rapid clinical improvement and no major complications. Effectiveness appeared better in mild-to-moderate hydronephrosis and benign obstruction, while higher baseline creatinine predicted slower biochemical response. Standardized follow-up laboratory capture is needed to strengthen long-term effectiveness estimates.

Keywords: Percutaneous nephrostomy, obstructive uropathy, nephrostomy tube, urine out put , malignant and benign obstruction

Acronyms and Abbreviations

AAU _Addis Ababa University

PCN- percutaneous nephrostomy

UAA-urinealaysis

CVAT-costvertebral angle tenderness

ECOG-eastern cooperative oncology group

TASH-tikur anbessa specialized hospital

EC-ethiopian calender

ETB-ethiopian birr note

SPSS-statistical package for social sceinces

PCS-pelvicalyceal system

OR-operation room

UPJ-ureteropelvic junction

CT-computed tomography

CHAPTER ONE: - INTRODUCTION

Background

A percutaneous nephrostomy is one of the drainage mechanisms in the renal upper tract for the purpose of alleviating obstruction, for drainage of infected system and or the therapeutic and diagnostic purposes of the kidney. It's obvious that all surgical procedures should fulfill all necessary steps in preventing introduction of infections , further trauma and subsequent unwanted complications associated with the mere intervention of the procedure.

Percutaneous nephrostomy should attain its goals with less discomfort, iatrogenic incidents or complications so as to consider it as a safe procedure.(1) The best measure of safety and efficacy of this procedure by both process and outcome indicators and follow up steps we did on our life.(2)

All nephrostomy procedures are not of post operative complications and long term sequele which may affect both the kidney anatomy and function ,as well as skin and subcutaneous tissue long term physical impacts. In general, the effectiveness and safety profile of our procedure will be evaluated based on the spectrum of preoperative preparation , intraoperative techniques and incidents and post operative outcomes that will affect both the patients life and subsequent impacts on the disease process.

Statement of the Problem

Purpose wise, this study is meant to investigate the factors that determine the safety and efficacy of our nephrostomy procedures among patients undergoing the procedure in TASH. Nephrostomy is an essential intervention for relieving obstruction in the urinary tract, which is often caused by all types of pelvic tumors ,kidney stones , or strictures. Despite its clinical importance, the effectiveness, patient outcomes, and complication rates of PCN can vary significantly across different healthcare settings. This variation raises

concerns about the influence of institutional practices and procedural expertise on the success of the treatment. In general, critical for facilitating renal drainage and preserving kidney function.

Literatures indicate discrepancies in success rates and patient outcomes associated with nephrostomy, suggesting a potential gap in uniformity of care and procedural steps. This our institution-based evaluation focusing on how PCN approaches, patient management strategies, and available resources affect the outcomes of PCN is clearly absent. Prospective assessment done within our institution intends to address these gaps, thereby enhancing the understanding of factors that contribute to the effectiveness PCN. After this study practice improvements and influence training programs and significantly optimize patient care in urinary tract obstructions

Research question

In the four months starting from January, we are going to assess the effectiveness of our nephrostomy procedures in the set up where we are practicing with respect to techniques we use, sterility of the procedure and the extent of post operative complication both on the patients life and the disease process as well.

Significance of the Study

Safety and efficacy of nephrostomy procedure is highly important to have and overview of the impact of the procedure on our patients and their disease process. Its clear that assessment of effectiveness on this line has never been studied in the setup we are aiming to get detailed insight in the topic.

While using a preset format of questioners included in a template which is going to be attached to patients charts and direct interview during the clerking and while undergoing the procedure. The final result of the study is expected to show us how we are practicing in the set up specifically and the country wide in general which has great impact in the revision and reassessment of the practice we are using literally.

As a pioneer study in this concept of day to day activity it is used as an eye opener to conduct plenty of researches on the topic and some related concepts. It will open a wide range of study insights concerning all percutaneous procedures(3). The impact it has in questioning urologic clinicians to rethink their common practices and the health policy makers to review their knowledge and budget allocations concerning the procedure and its impact on clients life is area of future concentration after finishing this research

CHAPTER TWO: OBJECTIVES OF THE STUDY

General Objective

- To determine the effectiveness and safety of percutaneous nephrostomy procedures we are exercising in Tikur Anbessa Specialized hospital in the period of January 1 to April 30, 2024 GC

Specific Objectives

- To describe the patient's profile, clinical presentation, and the procedures done and related situations
- To know the success rate of nephrostomy procedure with respect to clinical and laboratory parameters
- To determine the factors that affect procedure outcome and complications happening due to the procedure

Operational definitions

Effective nephrostomy procedure :-

Cambell-Walsh urology and some modifications

- the percutaneous placement of a catheter directly into the renal pelvicalyceal system to ensure urinary drainage from the kidney, bypassing obstructions with minimized complications till the intended period of time..

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- a nephrostomy that successfully achieves its intended clinical outcomes, such as alleviating hydronephrosis, reducing renal pressure, managing urinary tract infections, and preserving renal function by providing an alternative pathway for urine drainage from the kidney.

Dislodgement of PCN – it's the presence of all of the fenestra of the tube outside the calyces .

Nonfunctional PCN- its when the tube remains fixed to the skin with th adequate length to the PCS is maintained but doesn't have out put with or with out paratube urine leak

Pyonephrosis – this is diagnosed by looking at the first aspirated out put from the collecting system or that comes out while removing the stylet of a needle

Permanent nephrostomy – a nephrostomy tube which cannot be changed in to other mode of drainage due to a pathology causing permanent untreatable obstruction.

Nephrostomy exchange- exchange of nephrostomy tube usually at the end of the third month from insertion.

PCN reinsertion- done for exchange or dislodgement or for unalleviated blockage in non functional PCN.

Scope of the study

It is to evaluate the effectiveness and safety of percutaneous nephrostomy within a single healthcare institution, analyzing success rates, complication incidences, and both short-term and long-term patient outcomes. Furthermore, it will assess procedural techniques, physician expertise, and compare these findings against national and international standards to identify actionable improvements

CHAPTER THREE: LITERATURE REVIEW

Introduction--Background and procedure

As a matter of fact, percutaneous nephrostomy is a routine activity in the urological unit with the aim of both therapeutic and diagnostic results . Historically it traces back to the midst of 20th century when a urologist Dr Willard Goodwin accidentally entered into a calyx of hydronephrotic kidney while doing arteriogram. He is credited to describe nephrostomy procedure for the first time [1]. Nephrostomy tube was actually first inserted by Thomas Hiller in 1865 when he has frequently aspirated a hydronephrotic kidney for a four years old child over the period of four years to relief pain [2] [3]

First described in 1955 by Goodwin et al as a minimally invasive treatment for urinary obstruction causing marked hydronephrosis, percutaneous nephrostomy (PCN) placement quickly found use in a wide variety of clinical indications in both 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. In this article, the indications, placement, and postprocedure management of percutaneous nephrostomy drainage are described (4)

The procedure of percutaneous nephrostomy is done for different purposes ranging from drainage of an obstructed system to a simple antegrade diagnostic work ups. It includes a temporizing urinary diversion, treatment of sepsis and access for upper tract urinary procedures endo urologically (5) Despite the CT guided approach is valuable in difficult collecting system, an ultrasound becomes the cheapest and easily accessible imaging modality during PCN puncture and access . PCN was successfully performed under combined image guidance and it effectively drained the obstructed kidney. It is a safe procedure but has a high minor complication rate leading to patient morbidity(6). A step wise approach towards accessing the renal calyceal

system is applied to have purposeful procedure , less eventful and a procedure of decreased post operative complications . A proper patient positioning ,surface marking and assessing with US image is crucial. A puncture to a calyx and placing GW with serial dilations are of paramount essentiality .after tube sized dilation placement of a nephrostomy tube with fixation commences the procedure (7)

In a randomized controlled trial to compare emergency percutaneous nephrostomy and nephrolithotomy in Brazil revealed a complication rate of both. A significant difference was clearly visible from the point of both lab results normalization and clinical improvements timing in the post operative period(8)

Clinical applications and outcomes

We reviewed different and plenty amount of papers in multiple parts of the world with respect to the topic at varying levels of institutions. We searched at the online materials like in google scholar, the pub-med and open online searches using the Microsoft-bing tool and different AI generated outputs

Percutaneous nephrostomy is a gentle procedure associated with high technical success and low morbidity. However, the risk of the procedure has to be weighed against the expected benefit (9). Trial of PCN before definite surgery in young adult patients with poorly functioning kidney due to UPJO prevents unwanted renal loss in addition to prediction of renal function recovery(10). Bearing the techniques applied in mind, insertion of nephrostomy tube has been done either using ultrasound guidance or fluoroscopic assisted ones.

A prospective randomized study to assess safety of PCN on different modes of guidance by ultrasound or fluoroscopy in a university hospital in Egypt revealed that a certain degree of pain hematuria trial repetition were found to be best factors of concern to assess efficacy and safety. The degree of presence of these parameters were so less in the ultrasound guided puncture and dilation.

From among world wide papers a evaluating technical efficacy of a percutaneous drainage of an obstructed hydronephrotic kidney small number of failures encountered in this respect . a review of nephrostomy insertion in about 47 patients there has been no failed attempts except a septic complication encountered.. In this practical review the success rate to drain the upper tract was more than ninety five percent.(11)

A PCN care has a relative paucity of infectious complications, which represents an excellent marker for patient care, the low rate of infection dictates a large sample size for sufficiently-powered research studies to be able to find a significant impact of interventional measures. In this review article, we discuss various aspects of pathogenesis and treatment of the different subtypes of PCNC-associated infections.(12)

We got a study to assess ultrasound guided PCN insertion in patients while they are kept in the lateral positions in al azhar university ,cairo ,Egypt. In this study out of 50 patients who undergo PCN insertion in lateral positions the success rate was more than 90% with different degree of hydronephrosis. Complications of varying degree have been encountered, even if it has special recommendation in certain group of patients generally it is said of equal efficacy to the standard technique of PCN insertion(13)

A study was conducted KH Gebreselassie et al as a retrospective analysis on 110 patients who underwent emergency percutaneous nephrostomies (PCN) between October 2019 and September 2020. The group comprised 70% females and 30% males, with an average age of 48 years. The majority, 60%, had bilateral obstructions, primarily occurring in the ureter, which accounted for 77.3% of cases. Over 80% of the patients were suffering from malignancies, and acute kidney injury (AKI) was noted in 70% of the cases. The success rate post-PCN stood at 75.5%, although complications arose in 41.8% of the patients. Key predictors of complications were male gender, severe pre-operative hydronephrosis, and the use of combined imaging for guidance. Notably, the occurrence of postoperative complications was associated with poorer outcomes(14).

Marie et al. did a review at Douala General Hospital in Cameroon between January 2004 and December 2013 involved 229 obstructive uropathy patients, of whom 69% were men with an average age of 50. Common comorbidities in these patients included hypertension, diabetes, and HIV. About 41% of the patients required dialysis, presenting symptoms such as asthenia, anorexia, and loin pain. The major causes of obstructive uropathy were identified as urolithiasis (35%), benign prostatic hypertrophy (27%), and cancers, with prostate

cancer accounting for 12% and cervical cancer for 16%. Despite effective in 45% of cases; only 28% of the patients fully recovered. A significant portion, 41%, were lost to follow-up, and 22% died. Mortality was notably associated with prostatic and cervical cancers, particularly in those who underwent radiotherapy(15).

In a study by CE de Wet et al conducted at Groote Schuur Hospital in South Africa from 2015 to 2017, the impact of percutaneous nephrostomy (PCN) on patients with malignant ureteric obstruction was evaluated, focusing particularly on the estimated glomerular filtration rate (eGFR) and the influence of urinary tract infections (UTIs) over six months. The study involved 90 patients (54 male, 36 female) with a mean age of 56. It observed an initial improvement in eGFR from a median of 9 ml/min/1.73 m² pre-PCN to 48 ml/min/1.73 m² post-PCN. However, eGFR declined to 23 ml/min/1.73 m² within six months. Patients who developed UTIs post-PCN had a significantly lower eGFR of 6.15 ml/min/1.73 m². The conclusion drawn was that while PCN can temporarily improve renal function in patients with malignant obstructions, this benefit diminishes over time, particularly in the presence of UTIs, emphasizing the need for selective decision-making in PCN interventions(16)

A paper by P PAPPAS et al assessed the safety and efficacy of percutaneous nephrostomy (PCN) for urinary diversion in patients with obstructive uropathy. It involved 159 patients ranging in age from 18 to 94 years, undergoing 206 PCNs. Obstructions were primarily due to malignancy in 125 patients, benign causes in 30, and were unknown in 4 cases. With the guidance of both ultrasound and fluoroscopy, a 99% success rate was achieved. Post-procedure, there were significant reductions in urea and creatinine levels, with 66% of patients regaining normal renal function, 28% showing improvement without the need for dialysis, and 6% exhibiting no improvement. Negative predictors of outcome included advanced age and prostate cancer. However, pre-procedure blood urea nitrogen (BUN) and creatinine levels, and whether the nephrostomies were unilateral or bilateral, did not significantly impact outcomes. Minimal severe complications were reported, and patients with malignancy had a median survival of 227 days. This underscores the effectiveness and safety of PCN in managing obstructive uropathy(17).

Ivan rukundo and colligues fellows in Tanzania by interventional radiology fellows to evaluate the benefits of percutaneous nephrostomy (PCN) for patients with late-stage cancer-induced obstructive uropathy. A retrospective analysis was performed on patients at Muhimbili National Hospital and Ocean Road Cancer Institute from October 2018 to May 2021. A total of 62 patients were analyzed, with an additional 14 follow-up procedures carried out. The evaluation primarily focused on changes in patients' creatinine levels before the procedure and at 7 and 30 days post-procedure. The success rate of the PCNs was 98.7%. There were complications in eight cases. The average pre-procedure creatinine decreased by 59% at 7 days post-procedure and by 77% at 30 days post-intervention. Post-procedural clinical information was obtained for 28 (45.2%) patients, and 18 of these patients were able to restart chemotherapy following the nephrostomy (18)

Ahmed R.G et al. in BMC urology did a prospective study from August 2019 to March 2022 and assessed serum creatinine trajectory (SCr-Tr) in 102 patients with bilateral malignant ureteral obstruction. The average age was 59.6 years. The primary finding was that SCr-Tr varied non-linearly, averaging 0.5 mg/dl/day. Multivariate analysis showed that female gender, higher body mass index (BMI), and initial SCr were significant predictors of rapid SCr-Tr during the time-to-nadir. Conversely, older age and low urine output were linked to slower SCr-Tr. The lateral drainage and parenchymal thickness did not generally affect SCr-Tr, except that parenchymal thickness alone predicted rapid SCr-Tr when exceeding 0.5 mg/dl/day. Additionally, low BMI and bilateral drainage correlated with higher SCr normalization rates, whereas unilateral drainage was linked to a lower rate[19].

CONCLUSION

In a sum up fashion of literatures show technical aspects of upper tract percutaneous drainage. The literature on upper tract obstruction and the use of nephrostomy underscores its critical role in the management of obstructive uropathy, particularly in acute and complex cases. Nephrostomy provides an effective and minimally invasive means of relieving obstruction, thereby preserving renal function and preventing further complications such as infection and permanent kidney damage. It is used in both benign and malignant obstructions, offering symptomatic relief and serving as a bridge to definitive surgical treatment. Advances in

imaging and interventional techniques have enhanced the safety and efficacy of nephrostomy procedures, highlighting their essential place in the contemporary urological practice.

Clinical presentation of patients in need of percutaneous nephrostomy

Benign

A benign renal obstruction, occurs when non-cancerous conditions cause a blockage in the urinary tract, impeding the flow of urine from the kidneys to the bladder. Common causes include kidney stones, strictures (narrowing) of the ureter, and congenital abnormalities such as ureteropelvic junction (UPJ) obstruction. Flank pain, hematuria (blood in urine), recurrent urinary tract infections, and decreased kidney function were symptoms and signs . Early diagnosis and intervention are crucial to prevent potential kidney damage, often involving imaging studies and surgical or minimally invasive procedures to remove the obstruction and restore normal urine flow.

Malignant

Malignant obstruction might be gynecologic or non gyneco but all are known to hinder urine flow out of the PCS. This obstruction can lead to severe complications, including hydronephrosis (swelling of the kidney due to urine buildup), pain, hematuria (blood in urine), and impaired kidney function. Common causes include cancers of the bladder, prostate, cervix, and colon that invade or compress the ureters. Both relieving the obstruction to preserve kidney function and addressing the underlying malignancy are focuses of PCN , often through a combination of surgery, PCN , radiation therapy, and chemotherapy. Early detection and intervention are critical to managing symptoms and improving patient outcomes.

Non septic upper system blockage

Aseptic urinary obstruction means where there is an obstruction in the upper urinary tract without an accompanying infection. Causes can include kidney stones, strictures, tumors, or congenital abnormalities like ureteropelvic junction (UPJ) obstruction. This blockage can lead to hydronephrosis, where urine accumulates in the kidney, causing swelling and potential kidney damage if left untreated. Symptoms may include flank pain, nausea, and reduced urine output. Diagnosis typically involves imaging studies such as ultrasound or CT scans. Treatment aims to remove the obstruction through procedures like lithotripsy, ureteroscopy, or surgical intervention, thereby relieving symptoms and preventing long-term kidney damage.

Septic upper tract obstruction

An obstruction in the upper urinary tract is accompanied by a bacterial infection. This combination can lead to pyonephrosis, where pus accumulates in the renal pelvis, causing severe pain, fever, chills, and systemic signs of sepsis such as low blood pressure and rapid heart rate. Common causes include kidney stones, strictures, and tumors obstructing the flow of urine. Immediate medical attention is crucial to manage both the obstruction and the infection. Treatment typically involves urgent drainage of the infected urine, often using percutaneous nephrostomy or ureteral stenting, along with broad-spectrum intravenous antibiotics to control the infection and prevent sepsis-related complications. Rapid intervention is essential to preserve kidney function and prevent severe systemic illness.

CHAPTER FOUR: RESEARCH METHODOLOGY

Study area and period

The study setting is Tikur Anbessa Specialized Hospital ,Addis Ababa University , Addis ababa , Ethiopia in the study period of this research is starting from January 1,2024 and ending at the 30th of April 2024 .

Research design

A prospective, institution-based study at Black Lion Specialized Hospital during the specified study period will enable us to systematically collect and analyze data on patients diagnosed with upper tract obstructions as

they present to the hospital. We aim to ensure consistency in diagnostic and treatment protocols, thereby providing reliable and comprehensive insights into the management and outcomes of upper tract obstructions in this setting. This approach will allow us to monitor patient progress in real-time and gather detailed information to support our research objectives.

Study population

The study population encompasses all patients who have been diagnosed with upper tract obstructions during the specified study period within the research settings. Individuals presenting with various forms of obstruction, whether benign or malignant, and irrespective of underlying etiology are included. Comprehensive demographic, ensuring a thorough analysis of patient characteristics, treatment outcomes, and the effectiveness of nephrostomy procedures are all assessed. The research seeks to provide a detailed understanding of the incidence, management strategies, and clinical outcomes associated with upper tract obstructions, thereby contributing valuable insights to the field of urology.

Source population

Our review will concentrate on all urologic patients presenting to the Department of Surgery and the Nephrology Unit at Black Lion Specialized Hospital in Addis Ababa. By encompassing this specific patient population, we aim to capture a comprehensive dataset that reflects the full spectrum of upper tract obstruction cases managed within these specialized units. This approach ensures that our findings will be robust and applicable to the clinical practices and patient demographics unique to this hospital, providing valuable insights into the epidemiology, treatment strategies, and outcomes associated with upper tract obstructions in this setting.

Sample size and sampling procedures

Sample size determination

The sample size for this cross-sectional study will be calculated according to the Cochran and William guidelines (26), using the single proportion and correction formula by assuming a 5% marginal error, 95% confidence interval, and in the absence of prior information we take the population proportion as 0.5.

The required sample size of the study participants will be determined by infinite population formula first.

$$n_0 = \frac{Z^2 \cdot p \cdot (1 - p)}{E^2}$$

Where

n: the desired sample size

z: the standard normal deviate usually set at 1.96 (which corresponds to the 95% confidence level)

p: the population proportion which we don't know and used 50%, hence 0.5

E: the margin of error, normally set at 0.05.

$$n_0 = \frac{1.96^2 \times 0.5 \times (1 - 0.5)}{0.05^2}$$

$$n_0 = \frac{0.9604}{0.0025} = 384.16 \implies \underline{\underline{384.16}}$$

Hence, the calculated sample size for infinite population became 384.16, correction formula will be used to adjust the sample size, for an estimated finite population using the formula :

$$\text{Adjusted Population Correction : } n = \frac{n_0}{1 + \frac{(n_0 - 1)}{N}}$$

Where

n.= is required sample size

N= is estimate finite population be it 250

n,0= calculated sample size for infinite population 384.16

$$\text{hence } n = \frac{384.16}{1 + \frac{384.16 - 1}{250}} = \frac{384.16}{2.53264} = 150.13$$

Therefore our sample size is **150**

Sampling procedures

Having obstructive uropathy be it by benign or malignant obstruction requiring diagnostic or therapeutic decompression , all patients will be included in this prospective study. A method of taking all patients will be employed to include the sample (n=150), using patients presentation to the procedure room or major OR . In general all patients appearing at the procedure room or major OR will be included in the study.

Data collection procedure

Data will be collected by using structured questionnaires prepared in English and reviewed by a research adviser before the actual study. The contents of the questionnaire include socio-demographic characteristics, information on the clinical presentation of patients, procedure and technique related questions and outcome variables will be also assessed . The questionnaire will be pretested on the first 5 participants to ensure the questions are balanced, correctly constructed, and able to obtain crucial information. Clarity and other issues will be fixed based on the comments gained from advisors/

A registered nurses from the urology unit of TASH will be recruited and trained to assist with data collection under the supervision of the principal investigator. A one-day training session will be provided for data collectors, covering the study's objectives, methodology, sampling technique, ethical issues, data collection instrument, and data collection procedure. The principal investigator also will give awareness to the residents in the duty times to fill the questionnaires with greatest possible accuracy. Outcome portion of the questionnaires will be filled by the investigator himself every post procedure day.

Inclusion and exclusion criteria

Inclusion criteria

All patients who has undergone percutaneous nephrostomy procedure in the urology dept procedure room or major operation room

Exclusion criteria

All patients who has undergone stenting

All patients with any procedure to alleviate upper tract obstruction other than nephrostomy

All patients in whom accessing the PCS was not successful.

Study variables

Dependent variables

- ✓ Effective nephrostomy procedure

Independent variables

- ✓ Socio-demographic variables include
- ✓ Age
- ✓ Place of residency
- ✓ Marital status
- ✓ Higher level of education level
- ✓ Occupation.
- ✓ Patient-related factors
- ✓ Family history
- ✓ Presence comorbidity
- ✓ Clinical conditions of patients
- ✓ Causes of obstruction
- ✓ Preprocedure imaging and lab results
- ✓ Procedure techniques
- ✓ Patient nephrostomy care

Outcomes framework and endpoint definitions

Primary endpoint (biochemical effectiveness). The primary outcome was biochemical response at day 7 after PCN, defined as achieving the prespecified expected creatinine drop (average 0.4 mg/dL/day, corresponding to a 2.8 mg/dL reduction from baseline by day 7) in patients with available baseline and day 7 creatinine measurements.

Secondary endpoints. (i) Technical success: successful ultrasound-guided access to the collecting system with placement of a nephrostomy catheter and immediate drainage. (ii) Early clinical response within 24–48 hours: improvement in fever, flank pain, urine output, vital signs, and urine/urinalysis clearance where documented. (iii) Longer-term biochemical response at day 30 where available.

Complications. Post-procedure adverse events were categorized using a standardized minor/major framework consistent with Society of Interventional Radiology (SIR) and Clavien-Dindo concepts. In particular, self-limited hematuria/bleeding not requiring transfusion or intervention was treated as a minor complication, whereas clinically significant bleeding was defined as bleeding requiring transfusion, endovascular/surgical intervention, ICU care, or resulting in prolonged hospitalization.

Missing data and attrition

The study prespecified a complete-case strategy for analyses requiring laboratory follow-up. For each end

point, we report the available denominator and the number of missing observations. No imputation was performed. Missing follow-up creatinine values occurred when testing was not performed after discharge/transfer or results were not captured in the study records, and this limitation was considered when interpreting biochemical outcomes and multivariable modeling.

Methods of data analysis

Data were collected prospectively using a structured questionnaire and supplemented from the electronic medical record (Iwket care). Completed questionnaires were checked, coded, entered in Epi Info, and exported to SPSS version 26 for analysis. Continuous variables are summarized using mean (standard deviation) or median (interquartile range) as appropriate, and categorical variables using frequency and percentage.

For the primary biochemical endpoint (expected creatinine drop achieved by day 7), univariate and multivariable logistic regression were performed among complete cases with baseline and day 7 creatinine values. Candidate predictors were selected a priori based on clinical plausibility (age, baseline creatinine, cause of obstruction, hydronephrosis severity, repeat vs new PCN, decreased urine output, and presence of pus at first aspirate). Adjusted odds ratios (AOR) with 95% confidence intervals were reported, and $p \leq 0.05$ was considered statistically significant. Given the limited number of complete cases, the multivariable model was kept parsimonious and interpreted cautiously.

Data quality management

The gathered data will be checked for completion and processed using SPSS version 26. To minimize measurement error, a color-coding system was implemented to prevent case and data duplication by marking the front cover of a participant's case record for easy identification. The questionnaire's content validity was ensured by adapting it from by comments from advisors, and it was reviewed and approved by the Addis Ababa University College of Health Sciences research committee, the urology unit of the Department of Surgery, and an advisor.

A pilot study was conducted with the first 5 participants to ensure the questions were balanced and correctly constructed, and that crucial information would be obtained. The 5 piloted questionnaires were included in the study since no significant changes were necessary.

Ethical clearance

The proposal will be reviewed and approved by Addis Ababa University College of Health Sciences research committee and urology unit of department of surgery of Addis Ababa University. Permission letter for study will be obtained from Addis Ababa University College of Health Sciences research committee and urology unit of department of surgery of Addis Ababa University. Verbal consent will be obtained from each study subject before review of patients chart. Patients will be informed about the objective of the study that it will contribute necessary information for policy makers and other concerned bodies. If unwilling to participate in the study patient will not be forced to participate. They will be also informed that all data obtained from them would be kept confidential by using codes instead of any personal identifiers and is meant only for the purpose of the study

Dissemination plan of results

The obtained results of this study will be disseminated through publication, presentation on annual scientific meeting, conferences, seminars etc. A copy of it will be offered to Addis Ababa University College of Health Sciences research directorate and urology unit of department of surgery of Addis Ababa University

CHAPTER FIVE: RESEARCH FINDINGS

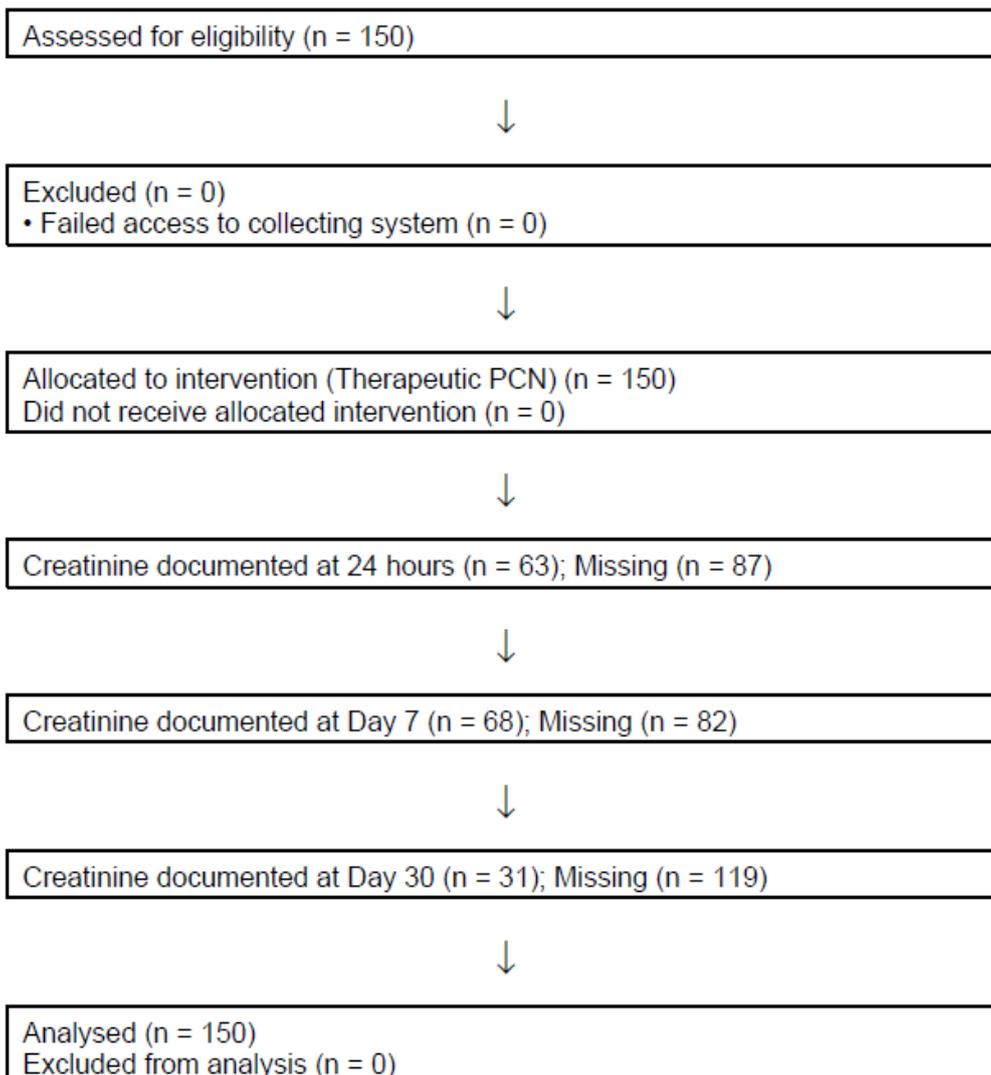
Results

Participant flow and data completeness

During January 1 to April 30, 2024, all consecutive therapeutic PCN procedures performed at Tikur Anbessa Specialized Hospital were assessed and included (n=150). Patients treated with alternative diversion (e.g., ureteral stenting) were outside the sampling frame, and prespecified exclusions included cases in which access to the pelvicalyceal system was not successful; no failed accesses were documented during the study period. Because follow-up laboratory testing and documentation varied, the denominator differs across outcome measures. Post-PCN serum creatinine was available for 63/150 at 24 hours, 68/150 at day 7 (primary biochemical endpoint), and 31/150 at day 30, and these missing values were handled using a complete-case approach for analyses that required creatinine.

Figure . CONSORT-like flow of included cases and creatinine follow-up completeness.

- Eligible therapeutic PCN procedures during the study period: n=150
- Excluded after eligibility assessment (failed access to collecting system): n=0
- Included in the study (procedures analyzed): n=150
- Creatinine documented post-PCN: 24 hours n=63; day 7 n=68; day 30 n=31



Socio demographic characteristics

During the study period, 150 patients underwent percutaneous nephrostomy (PCN). The female-to-male ratio was 5:1 (83.3% female). The mean age was 50.02 ± 12 years, and most patients were 40–59 years old (43.3%) (Figure 1). Slightly over half resided in Addis Ababa (52.7%), while 47.3% came from outside Addis Ababa (Table 1).

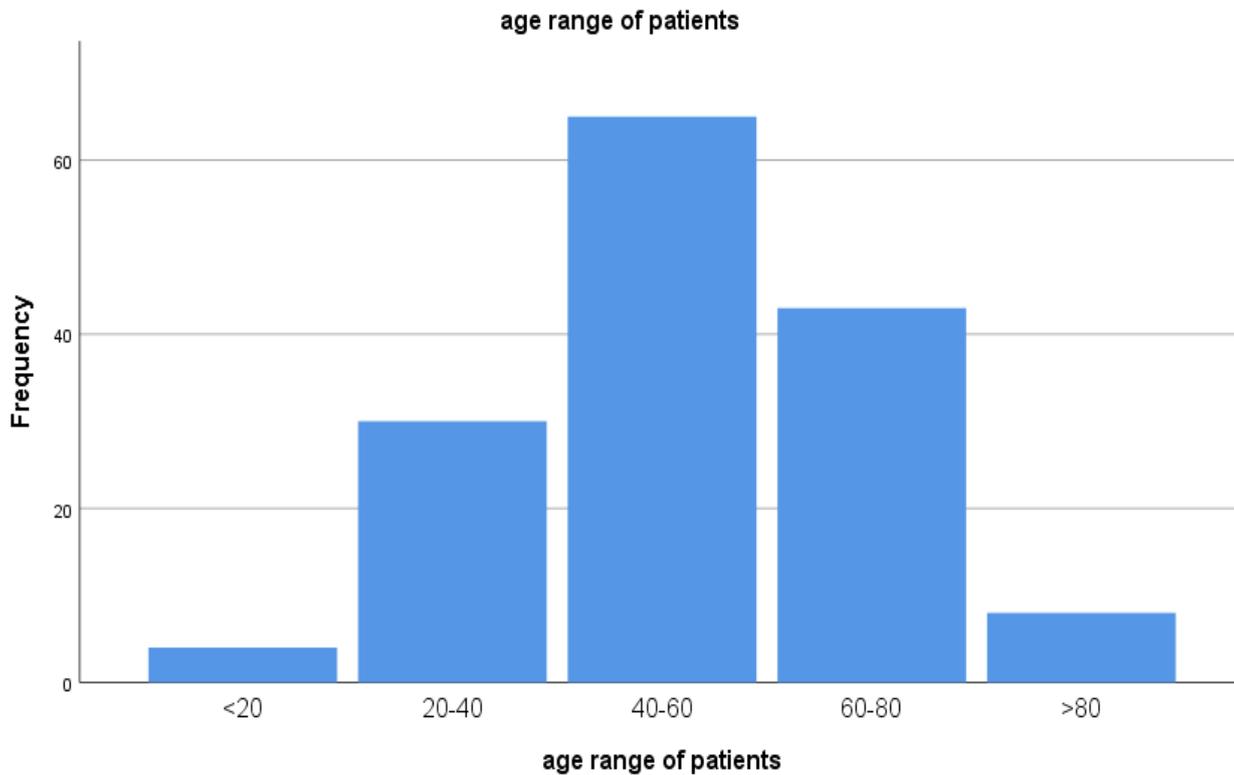


Figure 1 distribution of patients by age

Table 1- Distribution of sociodemographic data

Variables	Categories	Column N %	Count
gender of the patients	Female	83.3%	125
	Male	16.7%	25
age range of patients	<20	2.7%	4
	20-40	20.0%	30
	40-60	43.3%	65
	60-80	28.7%	43
	>80	5.3%	8
educational status of clients	Illiterate	53.3%	80
	primary education	15.3%	23
	secondary education	21.3%	32

	higher education	10.0%	15
residential area of the patient	Addis Ababa	52.7%	79
	outside AA	47.3%	71
religious affiliation of clients	Muslim	22.7%	34
	Orthodox	71.3%	107
	Protestant	6.0%	9

Baseline clinical characteristics and preoperative parameters

As a baseline assessment most of the patients have either bilateral or unilateral flank pain (64%) with 67pts bilateral and 29 patients unilateral flank pain . as an indicative of suspicious septic process Fever was there in in only 1/5th of patients in the study list . More than 2/3rd of patients presented with recent decreament in urine out put hence acute obstruction process. Most of our patients are of good physical performance with ECOG value of 1 .

More over the patients presented with normal vital signs in about ¾ of them and costovertebral angle tenderness was not elicited in more than 60% of them . (table 2)

Variable	Category / value	Count	Column N %
Presence of flank pain due to obstruction	No	53	35.6%
	Yes	96	64.4%
Laterality of flan pain	Unilateral	29	30.2%
	Bilateral	67	69.8%
Presence of fever	No	119	79.3%
	Yes	31	20.7%
Nausea and vomiting	No	123	82.0%
	Yes	27	18.0%
Decreament in urine output	No	46	30.7%
	Yes	104	69.3%
Change in mentation	No	143	95.3%
	Yes	7	4.7%
Performance status of patients as scaled by ECOG	0	20	13.3%
	I	115	76.7%
	II	14	9.3%
	III	1	0.7%

	IV	0	0.0%
Presence of tachycardia	Normal	108	72.0%
	<100	14	9.3%
	>100	28	18.7%
Presence of costovertebral angle tenderness	No	85	57.0%
	Yes	64	43.0%
Laterality of CVAT	Unilateral	41	64.1%
	Bilateral	23	35.9%

Table 2 –Distribution by the symptoms and signs at presentation

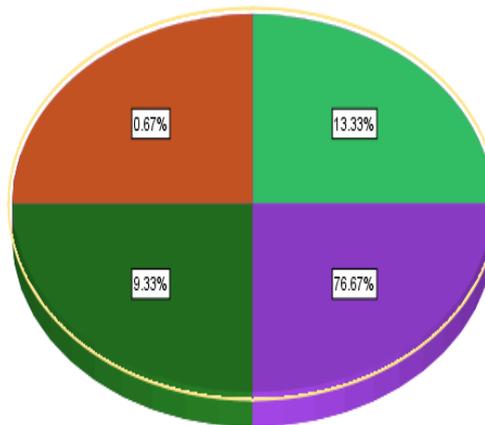
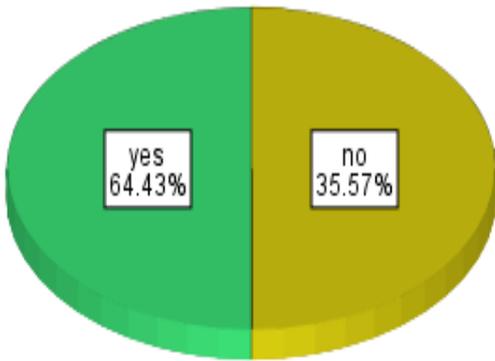


Figure 2- Flank pain

Figure 3- Performance status ECOG score

Imaging of the kidneys was done using bedside ultrasound at the procedure room and operation theater and the procedure was totally ultrasound Guided. About 44% Of patients have moderate hydronephrosis while nearly 40% were severely hydronephrotic in one or both kidneys . Most of the patients have no laboratory derangements leukocytosis was in ¼ of them and 25% have positive urinalysis result (table 3)

Variables	Categories	Count	Column N %
level of WBC count at lab investigation	Normal	110	73.3%
	<15,000	18	12.0%
	>15,000	22	14.7%
finding in the urine analysis	Negative	108	72.0%
	Positive	42	28.0%
degree of hydronephrosis on the right kidney	Mild	22	14.8%
	Moderate	64	43.0%

	Severe	63	42.3%
degree of hydronephrosis on the left kidney	Mild	23	15.3%
	Moderate	68	45.3%
	Severe	59	39.3%
presence of perinephric collection	No	144	96.0%
	Yes	6	4.0%

Table 3 Distribution of investigation parameters

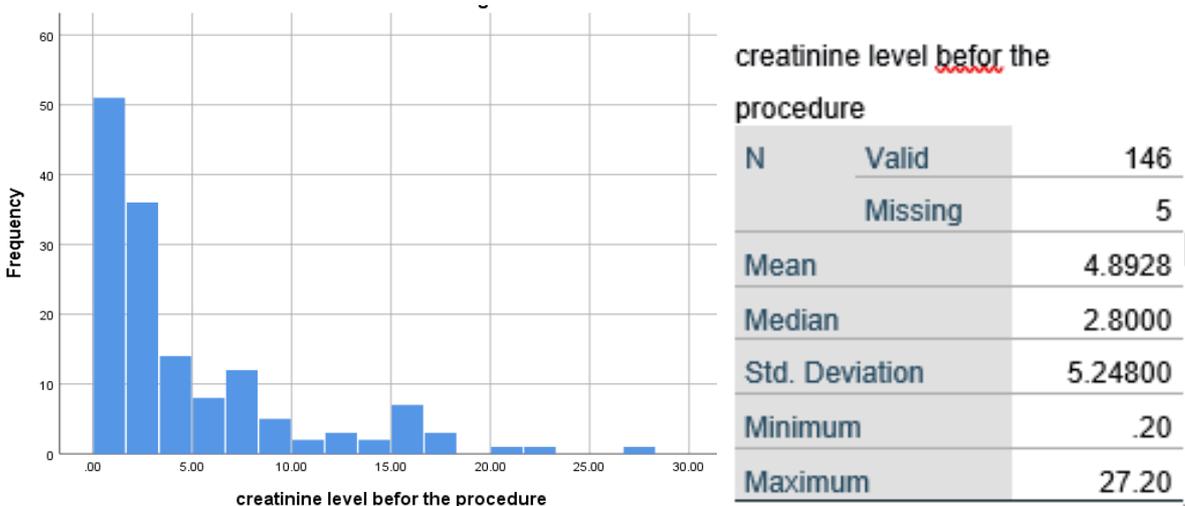


Table 4 creatinine level preoperatively

Procedure related findings

Considering the conditions and reasons prior to the procedure, most of the obstructions were caused by malignant conditions 85% of which were cervical cancer patients and urolithiasis (91%) was the commonest cause of obstruction from the benign group. Almost all benign obstructions were admitted and interventions were done. (Table 4)

Variables	Category	Count	Column N %
Indications for PCN	Therapeutic	150	100.0%
	Diagnostic	0	0.0%
Causes of obstruction	Malignant	128	85.3%
	Benign	22	14.7%
Category of malignancy	gynecologic	108	85.0%
	non gynecologic	19	15.0%
Benign condition causing	Stone	10	41.7%

obstruction	postop stricture	3	12.5%
	inflammation	9	37.5%
	Others	2	8.3%
Admission for benign	not admitted	2	8.7%
	Admitted	21	91.3%
why were not admitted to manage	no bed	0	0.0%
	social reason	2	100.0%
	Others	0	0.0%

Table 5 -distribution of patients based on cause of obstruction

Status of PCN	New	82	54.7%
	Repeat	68	45.3%
The reason for repeated PCN	dislodgement	35	50.7%
	Nonfunction	3	4.3%
	Exchange	31	44.9%
The reason for exchange	Palliative	30	96.8%
	delayed dx and mx	1	3.2%
The reason for dislodgement	technical in 7 days	6	18.2%
	Obstructed	10	30.3%
	improper care	17	51.5%
Time presentation after dislodgement	in 12hrs	10	30.3%
	12-48hrs	17	51.5%
	>48hrs	6	18.2%

Table 6- distribution of patients based on recurrence of the procedure

In our study period more than half of patients had new PCN insertion while 50% of patients with nephrostomy insertion the reason was dislodgment of PCN due to loose placement or debris obstruction or improper patient care . Patients with dislodged PCN present in 12 to 48 hrs in more than 50%. About 45 % of repeated nephrostomy was for exchange of PCN . (table 6)and (table 7)

Variables	Category	Count	Column N %
size of nephrostomy tube used	10F	126	84.0%

	12F	24	16.0%
The kidney PCN inserted in	Rt	55	36.9%
	Lt	89	59.7%
	Both	5	3.4%
The calyx PCN inserted	Lower	53	35.3%
	Mid	96	64.0%
	Upper	1	0.7%
Presence of blood in first aspirate	No	72	48.3%
	Yes	77	51.7%
Presence of pus in first aspirate	No	93	62.8%
	Yes	55	37.2%
Antibiotics given/not	No	8	5.3%
	Yes	142	94.7%
fixation of the tube to the skin	No	0	0.0%
	Yes	150	100.0%

Table 7-distribution showing intraoperative and procedure related findings

Outcome parameters and finding

All clinical outcome parameters were readily attained while 90% of patients with fever got improved in the first 24 hrs. Most of the improvement (both subjective and objective) parameters were more than 50%successful after the procedure in the first 24-48 hours. Ninety percent of patients were having successfully improved quality of life after the nephrostomy was inserted and the obstructed system was drained. The creatinine level was recorded at first seventh and thirty days and the seventh day creatinine was selected for the searching for the predictor independent variables so as to decide the factors affecting outcome and see the effectiveness .(Table 8).

Variables	Category	Count	Column N %
fever improvement	No	3	7.5%
	Yes	37	92.5%
Time needed for fever to decrease	in 24hrs	29	82.9%
	>24hrs	6	17.1%
Flank pain improvement	No	2	2.2%
	Yes	91	97.8%

UOP adequacy after PCN	No	2	1.8%
	Yes	108	98.2%
quality of life improvement after PCN	No	1	0.9%
	Yes	105	99.1%
Time for normalization of pulse rate after PCN	in 24 hrs	34	75.6%
	>24hrs	11	24.4%
time for urine to clear	in<24hrs	64	88.9%
	in>24hrs	8	11.1%
time to have negative UAA	in 48hr	30	60.0%
	>48hrs	20	40.0%

Table 8- frequency description of post operative evaluation

Cr level at first ,7 th and 30 th post op day				
		creatinine level in one day after PCN	creatinine level in seven day after PCN	creatinine level in thirty day after PCN
N	Valid	63	68	31
	Missing	88	83	120
Mean		5.4692	3.0294	2.5129
Median		3.9000	1.6000	1.5000
Std. Deviation		5.35909	3.77011	2.60253
Minimum		.20	.40	.60
Maximum		23.80	18.80	13.70

Complications were recorded after PCN placement and categorized as minor versus major events (see standardized definition in the Methods). Hematuria/bleeding was the most frequent event (60.0%, n=90) but was self-limited in all cases; bleeding stopped within 24 hours in 67.8% and no patient required transfusion or additional intervention, indicating no clinically significant bleeding.

Post-procedure pain was common (48.7% reported severe pain, grade 7–10). Para-tube urine leakage (3.3%), new-onset illness (4.0%), and early tube blockage within 48 hours (2.7%) were uncommon, and no wound infections were documented (Table 9).

Variables	Category	Count	Column N %
presence of post procedure hemorrhage	No	60	40.0%
	Yes	90	60.0%
when does hemorrhage stopped	<24hr	61	67.8%

	>24hrs	29	32.2%
subjective grading of pain after procedure	mild(grade 1-3)	23	15.3%
	moderate(grade 4-6)	54	36.0%
	severe (grade 7-10)	73	48.7%
post op wound infection	No	150	100.0%
	Yes	0	0.0%
New onset of illness at post operative period	No	144	96.0%
	Yes	6	4.0%
was there para tube urine leakage	No	145	96.7%
	Yes	5	3.3%
was there any tube blockage	in 48hrs	4	2.7%
	>48hrs	146	97.3%

Table 9- complication PCN procedure

Factors associated with biochemical effectiveness (day 7 creatinine response)

Predictors of the primary biochemical endpoint (expected creatinine drop achieved by day 7) were evaluated using logistic regression among complete cases with baseline and day 7 creatinine measurements. Predictors were chosen a priori based on clinical relevance, including age, baseline creatinine, cause of obstruction (benign vs malignant), hydronephrosis severity, repeat versus new PCN, decreased urine output, flank pain, and presence of pus in the initial drainage.

In multivariable analysis, higher baseline creatinine was associated with lower odds of achieving the expected day 7 creatinine drop (AOR 0.809; 95% CI 0.674–0.971; p=0.023). Other predictors were not statistically significant and had wide confidence intervals, although benign obstruction and moderate hydronephrosis tended to show higher odds of response compared with malignant obstruction and severe hydronephrosis, respectively (Table 11).

		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
								Lower	Upper
	age pf patients undergoing nephrostomy	0.029	0.024	1.456	1	0.227	1.029	0.982	1.078
	presence of flank pain due	-0.255	1.852	0.019	1	0.890	0.775	0.021	29.213

	to obstruction								
	decrement in urine output	-0.128	1.597	0.006	1	0.936	0.880	0.038	20.136
	Status of PCN	-0.840	1.141	0.543	1	0.461	0.432	0.046	4.037
	Presence of pus in first aspirate	0.381	0.898	0.180	1	0.671	1.464	0.252	8.508
	Causes of obstruction	1.737	1.089	2.542	1	0.111	5.678	0.671	48.022
	rt kidney hydronephrosis	0.676	1.085	0.388	1	0.533	1.966	0.234	16.491
	lt kidney hydronephrosis	1.657	1.082	2.345	1	0.126	5.244	0.629	43.728
	creatinine level before the procedure	-0.212	0.093	5.184	1	0.023	0.809	0.674	0.971
	Constant	-1.863	2.056	0.821	1	0.365	0.155		

		expected creatinine drop at 7 day (at rate of 0.4mg/dl/day =2.8 from baseline)		
		expected drop reached	expected drop not reached	AOR (95% CI)
presence of flank pain due to obstruction				
	no	9(60%)	6(40%)	1
	yes	32(60%)	22(40%)	0.775 (0.021, 29.213)
decrement in urine output				
	no	8(57%)	6(43%)	1
	yes	33(58%)	22(42%)	0.880 (0.038, 20.136)
Presence of pus in first aspirate				
	no	27(63%)	16(37%)	1
	yes	13(52%)	12(48%)	1.464 (0.252, 8.508)

Status of PCN				
	new	26(59%)	18(41%)	1
	repeat	15(60%)	10(40%)	0.432 (0.046, 4.037)
Causes of obstruction				
	malignant	36(64%)	20(36%)	1
	benign	5(38%)	8(62%)	5.678 (0.671, 48.022)
hydronephrosis on the right kidney				
	Severe	17(63%)	10(37%)	1
	moderate	18(55%)	15(45%)	1.966 (0.234, 16.491)
hydronephrosis on the left kidney				
	Severe	20(77%)	6(23%)	1
	Moderate	15(48%)	16(52%)	5.244(0.629,43.728)
Age of patients		Mean +SD =49.49±1.35	Mean +SD =49.18±1.45	1.029 (0.982, 1.078)
Preoperative creatinine		Mean=7.37	Mean= 3.56	0.809 (0.674, 0.971)

Table 11: Factors affecting outcome of nephrostomy

CHAPTER SIX: DISCUSSION AND CONCLUSION

Discussion

This study has revealed in assessing the effectiveness and determining factors of percutaneous nephrostomy in about 150 patients appearing at Black Lion Hospital . Upper tract obstruction of unilateral or bilateral kidney has created a huge sociomedical challenge world wide. This medical entity has affected all age groups and both sexes at any cause and any site of ureteric obstruction .

Strengths of this work include prospective data capture and use of an explicit primary biochemical endpoint. However, outcome documentation was incomplete for several variables, particularly follow-up creatinine (available for 63/150 at 24 hours, 68/150 at day 7, and 31/150 at day 30), which may reflect tests not obtained after discharge or loss to follow-up. Accordingly, the primary biochemical analyses and multivariable model were complete-case and may be underpowered and susceptible to selection bias. Future studies should ensure systematic laboratory follow-up and longer-term outcome capture. If additional follow-up creatinine results exist in the electronic record but were not captured in the dataset, re-extraction and re-modeling are recommended to improve power and the stability of multivariable estimates.

Different literature has been published and researches have been made world wide on assessing the degree and intervention of obstructive uropathy . when we consider the gender distribution of this disease most of them are females(70%) which can be correlated to the occurrence of cervical cancer and commonest age group is in

forties via sixties with mean age of 50.2 ± 14.2 SD which is consistent with the findings in different articles. All of the have undergone ultrasound guided nephrostomy insertion to divert the obstruction they have .

Age of patients was almost not affecting the improvement in renal function AOR= 1.061 and was found not to affect . This small percentage of positive effect can be explained by increased number of respondents from higher level of ages of patients.

All of the nephrostomies were done for therapeutic purposes and we didn't have a single case whom undergone nephrostomy for diagnostic intention. Considering indications for PCN insertion most of the literatures described malignant obstruction primary due to pelvic malignancies ,cervical cancer being in the first place. In our the finding on the causes of obstruction was the same to the articles circulating in the Literatures. More than 83% of the cases who undergone nephrostomy procedure was due to malignancies an 80 % of which was due to advanced cervical cancer. In the background of high prevalence of malignant obstructions the most effective procedure of PCN was found in the benign obstruction in decreasing creatinine postoperatively.[AOR=2.88(0.671,48.022)at 95% ci ;p=0.111].

Multiple researches have shown the propensity of bilateral renal obstruction as common as in the 40-55% of patients . In our study the prevalence of bilateral obstruction is as high as 85% with different degree of hydronephrosis in both kidneys . This can be easily explained by the causes of obstruction being cervical cancer as high as in 80% of the cases and this definitely will affect both distal ureters leading to bilateral obstruction. The mean creatinine level at the time of the procedure was 4.8 with SD of ± 5.6 in the finding .this in turn can outstandingly explain the bilaterality of the obstruction.

Apart from being an effective procedure in improving quality of life ,nephrostomy diversion of upper tract obstruction has revealed a new deviation of expert thinking in further treating patients with malignancy with chemotherapy and so on. A literature from Tanzania , Most patients were sent for home as end stage illness ,however about 35% of patients have returned to chemotherapeutic intervention after they got PCN diversion. Most literatures describe effectiveness of PCN depending on preoperative level of creatinine, degree of hydronephrosis and comorbid medical illnesses.

In our study success rate of the procedures was assessed based on the average drop of creatinine in the seventh day post nephrostomy . different factors were found to be determinant of such effectiveness. Most of our patients have moderate hydronephrosis (44%) and in accordance with our practice the better kidney id meant to undergone PCN insertion to effect better result. Therefore, patients with moderate hydronephrosis undergoing nephrostomy had revealed a better result than those with severe hydronephrosis with respect to functional improvement in kidneys. Moderate hydronephrosis has successful and effective nephrostomy as compared to severely hydronephrotic kidney as high as a two fold and above positive impact in creatinine improvement postoperatively [AOR=1.966 (0.234,16.491 at 95% ci p=0.245]. This result has cleared out that good parenchyma of the kidney is of effective PCN procedure than those with thinned out cortex.

As a matter of fact, baseline creatinine is a good determinant factor for post operative creatinine improvement in patients undergoing nephrostomy. Different literatures also have shown BMI ,age baseline creatinine as predictor parameters for renal function return to low. In our study creatinine levels were recorded at the first ,seventh and thirtieth day post operatively . Based on a study to determine serum creatinine trajectory and rate of creatinine drop after PCN one study showed that the above parameters were determinant for creatinine drop .[19]

In this study the average cr drop rate was 0.5mg/dl/day for those high preop creatinine . hence based on this concept a creatinine drop was at the seventh day was determined by baseline serum creatinine i.e. the higher the baseline creatinine the lower creatinine drop rate was observed and an increase of creatinine by 1.0 will negatively affect creatinine drop at seventh day by 20% and so on [AOR=0.809(0.629,43.728) at 95% ci ;p=0.012] .

When considering clinical outcome of patients after PCN insertion most literatures describe a good improvement after it. Most of the clinical outcome were showing effective nephrostomy procedure with a

cumulative effectiveness being around 75% Of the cases . this will be more effective PCN procedure than the studies done in st PMMC 73%% and Cameron 45% studies .

Conclusion

In conclusion, ultrasound-guided percutaneous nephrostomy at our institution demonstrated high effectiveness, with rapid clinical improvement and no evidence of major procedure-related complications. Effectiveness appeared better in patients with mild-to-moderate hydronephrosis, benign causes of obstruction, and those with pus in the initial drainage, while higher baseline creatinine predicted a lower likelihood of achieving the expected biochemical response by day 7.

The overall success rate can be improved through strengthened patient education and catheter-care practices to reduce dislodgement, earlier health-seeking behavior, and timely treatment of obstructive nephropathy. Because follow-up creatinine data were missing for many patients, a longitudinal study with standardized follow-up timepoints, explicit endpoint definitions, and standardized complication grading is recommended.

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ANNEXES

Annex I: Consent for Participation on study about effectiveness of nephrostomy procedure done at Tikur Ambessa Specialized Hospital (TASH), Addis Ababa, Ethiopia from January 1,2024-april 30,2024

Consent form

Hello! My name is _dr ahmed abebe , a principal investigator and member of a team that is collecting some information on surgical outcome of adult hypospadias repair at Tikur Ambessa Specialized Hospital (TASH), are kindly requested to be included in the study, which will have importance in understanding effectiveness of nephrostomy procedur in our Hospital, which may take less than 15 min . No information concerning you, as individual will be passed to another individual or institution without your agreement. Your participation is voluntary and you have the right to not participate fully or partially. If you agree to be included in the study, I will start my questions by asking general identification points. Only honest answers would contribute to improvement in existing knowledge gap on surgical outcome of adult hypospadias repair.

The study has approval from Addis Ababa University, college of Health Sciences, department of surgery.

“My I continue?”

If yes, continue interviewing

If No, thank and stop interviewing

Annex 2:

Questionnaires to be filled by operating physician and on phone call for percutaneous nephrostomy procedures effectiveness assessment