PERCUTANEOUS ANTEGRADE DOUBLE J URETERAL STENTPLACEMENT AT KENYATTA NATIONAL HOSPITAL: INDICATIONS, TECHNICAL SUCCESS RATE, COMMONLY ENCOUNTERED PROBLEMS AND SOLUTIONS

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DECLARATION

I declare that the work contained herein is my original work and has not been presented in anyother university or published anywhere to the best of my knowledge.

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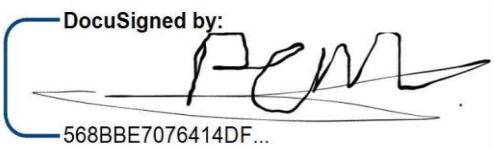

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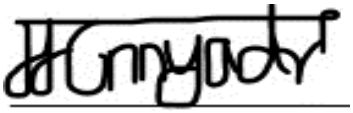
Signature:  **Date:** 02/11/2023

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ACRONYMS AND ABBREVIATIONS

DJ Stent-	Double J Stent
KNH-	Kenyatta National Hospital
Nbi-	Nairobi
P.I-	Principal Investigator
PAUS-	Percutaneous Antegrade Ureteral Stenting
UON -	University of Nairobi
VIR-	Vascular and Interventional Radiologist
IR-	Interventional Radiology
NACOSTI-	National Commission for Science, Technology and Innovation

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ABSTRACT

Background: Percutaneous ureteric stenting using image guidance is a safe method in treating obstructive ureteral pathology. This technique has showed higher technical success rates compared to the retrograde cystoscopic trans-vesicle approach in treatment of malignant ureteral obstruction. However, it is less well known and is usually requested after failure of retrograde ureteral stent placement by endo-urologists. Unlike the retrograde stenting, antegrade stenting does not require the use of either general or spinal anaesthesia. Due to development of nephrostomy services in many hospitals, antegrade stenting has become a common procedure in the radiology department. Despite improvement in the stent designs, percutaneous stent placement is challenging especially in cases of grossly dilated ureters and tight ureteral strictures.

Objective: This study sought to identify the indications, determine the technical success rate and identify the commonly encountered problems and their solutions during percutaneous antegrade double J ureteral stenting at a national referral institution.

Materials and Methods: Data of 53 patients who underwent 55 antegrade stenting procedures in the interventional radiology suite of Kenyatta National hospital between 1st June 2020 to 30th June 2022 was retrieved and retrospectively analyzed. Patient related variables included age and sex. Lesion related variables included causes of obstruction, laterality and site of obstruction. Technique related variables included site of calyceal access, severity of ureterohydronephrosis and shape of the ureters. Data on techniques modifications used to overcome the difficulties encountered like use of balloons to dilate a tight stricture and use of an introducer sheath to facilitate stent delivery was collected. Data of different indications for antegrade stenting was collected and analyzed using frequency statistics. Univariate analysis involved calculation of the measures of central tendency and dispersion which include: means, medians, standard deviations for continuous variables. For categorical variables, frequency distributions were determined and results presented using frequency tables and appropriate charts. Bivariate analysis was used to investigate any association between successful deployment of the stent and lesion related variables as well as stenting success and technique related variables. Relationships exhibiting P values of less than 0.05 were reported as statistically significant.

Results: A total of 55 procedures were done. Of these, seven procedures were performed in 7 patients with benign strictures while 48 procedures were done in 46 patients with malignant strictures. Among the malignant causes of ureteral obstruction, carcinoma of the cervix was the most common accounting for 79.17% of the procedures. Other malignant causes included prostate cancer (9%), bladder cancer (6%), retroperitoneal carcinoma (2%), endometrial cancer

(2%) and colon cancer (2%). Benign causes of ureteral strictures included post-surgical complications (42.85%, idiopathic (42.5%) and urolithiasis (14.29%).

There was high overall technical success rate of 90.91%. Technical success rate for malignant strictures was 91.6% and 85.71% for benign strictures. Majority of stenting failures occurred in malignant strictures (80%) and were caused by cancer of the cervix. The four procedures performed after failed retrograde stenting were all successful when subjected to antegrade stenting.

Common problems encountered during antegrade stenting included dilated and tortuous ureters, (47.42%), suboptimal calyceal access (20.62%), tight obstruction (18.56%) and difficulty in positioning the proximal pigtail loop of the ureteric stent (13.40%). Dilated and tortuous ureters were first decompressed by placement of nephrostomy tubes before antegrade stenting. Suboptimal calyceal access was overcome by use of a vascular sheath, stiff guidewire and change of calyceal access to a mid-pole calyx where necessary. For tight obstructions, use of a hydrophilic guide wire and vascular catheters were used to cross the lesion. Super stiff guide wire was used to facilitate the passage of the stent through the lesion. Balloon dilatation of a tight stricture was done to allow easy passage of the stent.

Conclusion: The study showed that the most common indication for antegrade ureteral stenting at KNH was malignant obstruction largely from carcinoma of the cervix. Antegrade stenting has high technical success rate for both benign and malignant ureteral obstruction. Among the commonly encountered problems, grossly dilated and tortuous ureters with Z and pigtail ureteric shapes were more challenging to stent. Though challenges are encountered during antegrade ureteric stenting, they can be overcome by various technique modifications.

1.0 CHAPTER ONE: INTRODUCTION

1.1 Background Information

The ureter is a paired fibromuscular tube which courses through the abdomen and pelvis to enter into the urinary bladder. Its long course and intimate relationship to the adjacent organs makes it prone to obstruction by both malignant and benign conditions thus interfering with urinary flow.

Malignant disease is by far the commonest cause of ureteral obstruction. Treatment of this condition has a higher likely hood of failure when subjected to retrograde ureteral stenting (1) Iatrogenic ureteral injuries may occur with gynecological surgery contributing to more than half of these injuries (2). Often times, draining of the system to facilitate ureteral healing through stenting is recommended.

Urinary decompression in malignant ureteral obstruction is key to maintain renal function, provide symptomatic relief and reduce the length of hospital stay (3,4).

There are no proper guidelines documented to show the most suitable method of decompressing the urinary tract in the setting of ureteral obstruction (5). Percutaneous nephrostomy is the method that is most frequently used to treat acute ureteral obstruction with the goal of preserving the renal function as well as draining of the infected urine (6). However, this method is complicated by the risk of infection, (7) tube dislocation, (8) and patient discomfort which can be at times severe.

Ureteral stenting by use of double pigtail catheters is usually recommended where long-term relief is indicated. These catheters are normally inserted via retrograde approach by endourologist using cystoscopic guidance (6). However, in patients with distorted anatomy of the urinary bladder wall and those with long segment malignant ureteral obstruction, this method can be challenging or even impossible (9,10). The only option in such cases is percutaneous nephrostomy with antegrade stenting.

Retrograde stenting technique in patients of renal transplant and ileal conduit urinary diversion is also challenging given their altered anatomy (6)

In addition, retrograde stenting especially in men is often done under spinal or general anaesthesia with attendant complications. Besides, general anaesthesia may be contraindicated for very sick patients.

In the light of the above shortcomings of the retrograde technique, antegrade double J stenting using ultrasound, fluoroscopy and local anaesthesia has been shown to be a viable and safe alternative.

1.2 Study Justification

Ureteric stent placement is routinely done by endourologists under cystoscopic guidance via the retrograde approach. Of late, this procedure is increasingly being performed percutaneously by interventional radiologists under image guidance with higher technical success rates over the retrograde technique. Moreover, this technique is preferred over retrograde approach in cases of malignant strictures and in cases of existing percutaneous nephrostomy tubes. In addition, where retrograde stenting has failed, antegrade stenting has shown significantly high technical success rates.

Despite registering high technical success rates overall compared to the retrograde ureteral stenting, antegrade stenting is less well established in many centers most likely because it has not been extensively studied. Furthermore, studies to identify the commonly encountered challenges and their solutions during antegrade stenting are rare in literature. No such studies have been conducted in our country or region. This study therefore seeks to identify the common indications, determine the technical success rate and identify challenges commonly encountered and their solutions during antegrade ureteric stenting at our institution.

Percutaneous antegrade ureteric stenting is now routinely performed at our institution, a national referral center, and a few other centers in the country but there is no data available to document our local experience. The results of this study will therefore help to bridge this gap and contribute to the general pool of knowledge regarding the management of ureteral obstruction. Identification of the most common challenges encountered during antegrade stenting and their solutions will help refine the technique leading to even better technical success rates in future.

Unlike retrograde ureteral stenting procedure, antegrade approach does not require spinal or general anesthesia. In addition, it is performed in the radiology department with no need for theatre space making it cost effective. Its most vital requirement is an experienced interventional radiologist. These features together with its higher technical success rates give it an edge over the retrograde technique especially in resource limited sets up like ours. The findings of this study will lay a good foundation for future studies on the various aspect of antegrade double J ureteral stenting. With increasing number of trained interventional radiologists and increasing number of radiology centers in the country, data from this study will help in creating awareness and training thus making this procedure available to more patients.

1.3 Research Question

What are the indications, technical success rate, commonly encountered problems and their solutions during percutaneous antegrade ureteral stenting procedure at KNH?

1.4 Objectives

1.4.1 Broad Objective

- To identify the indications, determine the technical success rate and identify the commonly encountered problems during antegrade ureteral stenting at KNH.

1.4.2 Specific Objectives

- Identify the indications of percutaneous antegrade ureteral stenting at KNH.
- Determine the technical success rate of antegrade ureteral stenting.
- Identify the commonly encountered problems during DJ stenting and their solutions.

2.0 CHAPTER TWO: LITERATURE REVIEW

Ureteral stent placement was first described by Zimskind et al in 1967(11). Since then, great improvement in stent material and technique modification has been made over time (12)

2.1 Technique of Percutaneous Antegrade Ureteral Stenting

The basic technique of internal percutaneous antegrade ureteral stent placement is described in literature by Mazer et al (36).

The procedure is done by an interventional radiologist in the radiology department using ultrasound and fluoroscopic guidance. Prior images are first reviewed to confirm the indication. Coagulations parameters are routinely checked with a cut off INR of >1.5 and platelet of <50000/mm^3. Informed consent is obtained. Prophylactic antibiotics are administered one hour before the procedure in line with the institutional protocol. Single stage or double stage procedure is then done. 18- or 21-gauge needle is used to access the calyceal system guided by ultrasound. 0.018 for micro-puncture or 0.035 guide wire is inserted into the pelvicalyceal system. After serial appropriate dilatation, a nephrostomy tube is first deployed into the renal pelvis for a few days in a two-stage technique and stenting done later. For stenting either in one stage or two stage technique, 0.035 hydrophilic wire and an angiographic catheter are usedto pass the ureteral obstruction. Once the angiographic catheter is safely in the urinary bladder,the hydrophilic wire is exchanged for a standard 0.035 guide wire. Over this stiff wire, ureteralstent is then passed through the obstruction into the urinary bladder with the aid of a pusher. The wire is then withdrawn slightly to allow for the formation of the distal loop of the stent. Once this loop is successfully formed, the wire is then withdrawn further beyond the proximalloop to allow for the formation of the proximal stent loop within the renal pelvis. Adjustment of proximal loop is done using the safety string. The wire is completely withdrawn and finallythe pusher is removed last to prevent backward retraction of the proximal loop.

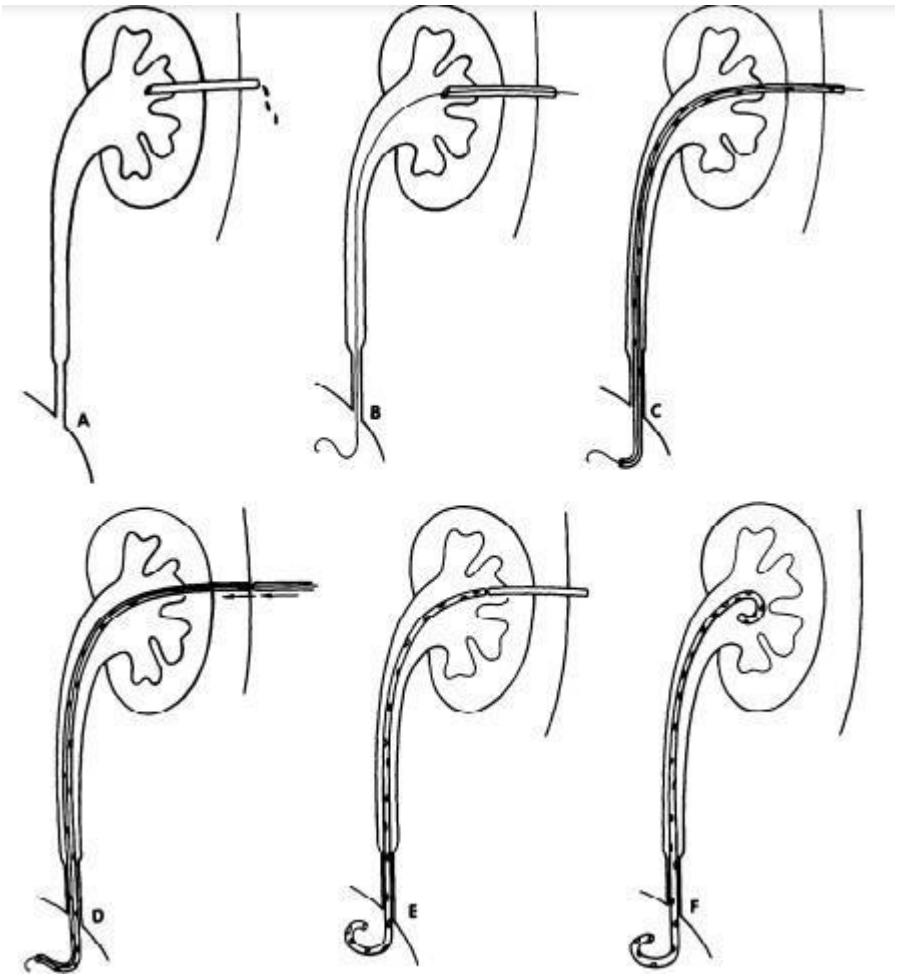

Figure 1: Line diagram showing the steps in standard antegrade stenting procedure (36)

A-Calyceal access

B- Guide wire through the obstruction

C- ureteral stent over the wire.

D- Stent being pushed into the bladder

E- Stent deployed with no wire.

F-final stent position

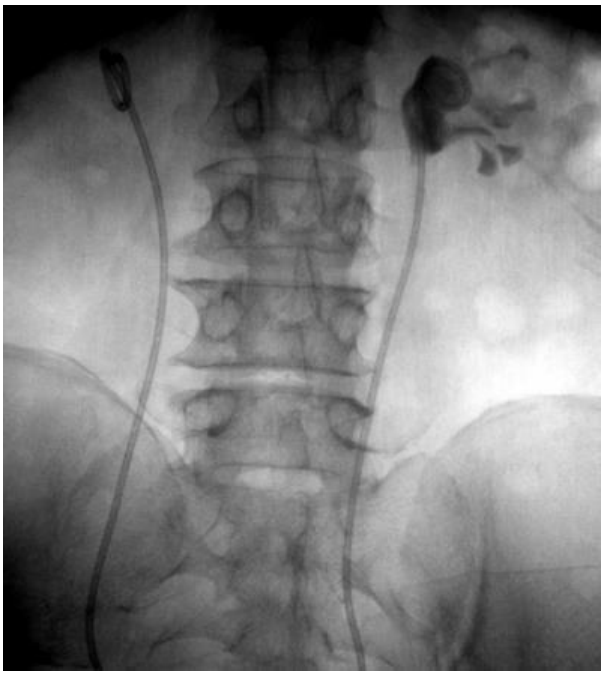

Figure 2: Spot film showing well deployed proximal pigtail loops in bilateral antegrade stenting done at KNH

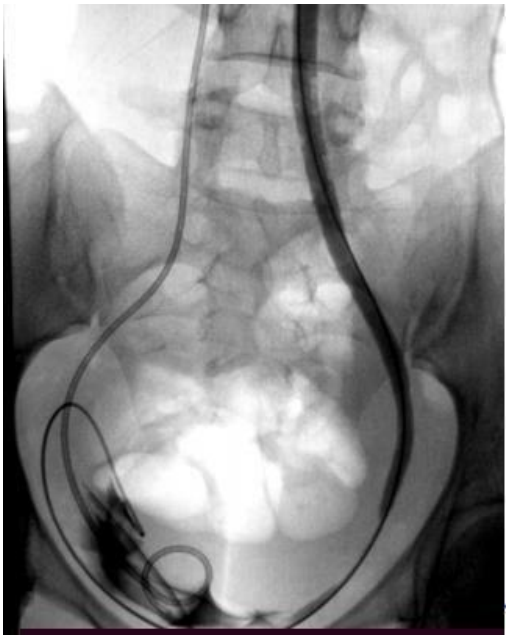

Figure 3: Spot film showing well deployed distal loop of the left stent in the bladder and a wire through the distal right ureteric stenosis (KNH)

2.2 Antegrade versus Retrograde Stenting Technique

Ureteral stent placement is done via retrograde approach by endourologists while interventional radiologists use the percutaneous antegrade route (13–17). Retrograde stenting is generally done using a rigid cystoscope under general anaesthesia in theatre while antegrade stenting is done in the interventional radiology suite under local anaesthesia using ultrasound and fluoroscopy. The use of local anaesthesia during antegrade stenting avoids the complications associated with general anaesthesia and affords a safe alternative for the critically ill patients who cannot withstand the effects of general anaesthesia. For antegrade stenting, the access is through the renal parenchyma into the collecting system and the stent is inserted through the renal pelvis and into the urinary bladder. Access for retrograde stenting is through the urethra and the double J stent is inserted from the bladder into the renal pelvis.

Retrograde route is considered the first line method over the antegrade approach especially in benign obstruction (16,17). This is because of the attendant complications of nephrostomy which is necessary for the antegrade approach (13). Besides, retrograde approach affords treatment of obstructive stones, biopsy sampling of endo-ureteral tumors and incision of strictures.

However, with regard to malignant obstruction, there is no consensus in literature as to which route is superior over the other. As a result, the choice of technique of stent placement should be determined by the patient's clinical status, patient's wishes, availability and competence of performing personnel, degree of urgency and availability of resources (5).

Retrograde stent insertion under cystoscopic guidance has technical limitations especially in malignant ureteral obstruction with high rates of failure. In these situations, antegrade approach which allows technical modifications including predilatation with a balloon provides better results and is thus preferred (1,5,6,18).

In addition, where a nephrostomy tube has been put previously, antegrade stenting is the route of choice since access to the collecting system is already secured with minimal complications during the procedure (6).

2.3 Indications of Stenting

The main cause of malignant ureteral obstruction according to Romulo et al (18) is cervical carcinoma seconded by urinary bladder cancer. Venyo et al (35) showed bladder carcinoma to be the leading cause of ureteral obstruction with regard to malignant disease seconded by prostatic carcinoma. A retrospective study by Ghassen et al (21) showed bladder cancer was the most predominant indication for antegrade ureteric stenting. This was followed by uterine

cancer, prostate cancer, colorectal cancer and retroperitoneal tumour respectively. The mostij prevalent benign cause of ureteral obstruction according to Rutger et al (6) was urolithiasis followed by surgical complications. A study by Guven et al (1) showed genitourinary tuberculosis, ureterovesical junction obstruction and neurogenic bladder as the most frequent indications of double J ureteral stenting. In the treatment of iatrogenic ureteral injuries, Dowling RA et al (2) recommended double J stenting to facilitate healing of the ureters. Koukouras D et al (22) showed percutaneous stenting to be safe and efficient in the management of a wide range of ureteral injuries.

2.4 Technical Success Rate

Studies have shown antegrade stenting to be safe and effective where failure of the retrograde approach has been encountered. In case of obstruction due to cancer, success rate of the retrograde approach has been reported as 50-88%(23–29). On the other hand, antegrade approach has been found to be superior with much higher rates of technical success ranging between 85 and 98%(1,9,29,30)

Similarly, in the treatment of the ureteric injury, percutaneous stenting has showed very high technical success rates of 100% according to Toporoff et al (31) and Liatsikos et al (32). However, Koukouras et al (22) reported lower technical success rates of 72% for the same indication in their study. With regard to ureteric injuries, retrograde approach technical success rate has been reported to range between 14 to 84%(30–34).

2.5 Technique Modifications for Commonly Encountered Problems

Technical difficulties are encountered in cases of suboptimal percutaneous access, grossly dilated and tortuous ureters, tight obstructions, stent assembly breakdown and deployment of the proximal end of the stent (37,38).

In their review of technical challenges of antegrade ureteral stenting, Papanicoloau et al (37) proposed various technique modifications to overcome the most commonly described challenges. In cases of suboptimal percutaneous access, they found the use Cobra one and two catheters to be particularly helpful when maneuvering at the pelviureteric junction. Super stiff guide wire and peel away sheath were useful in straightening the stent at the renal pelvis making it easy to pass down the ureter. The same study recommended the use of upper or mid pole calyx for fresh punctures to avoid the problem of suboptimal percutaneous access altogether. With regard to tortuous ureters, the study found the use of glide wire very helpful. Where sharp bends and kinks could not be negotiated through, their study recommended delayed stenting to

allow for decompression and thus easy passage of the catheter and glide wire in the subsequent attempts.

For tight obstructions, access from the upper or the mid calyx was found to be very helpful. An Angled tip catheter with high torque combined with a hydrophilic guide wire was very useful for negotiating through the ureter and passing through the obstruction. Combination of a sheath with a super stiff guide wire provided the necessary torque assisting the progression of stent through a tight obstruction and thus avoiding stent assembly breakdown.

A key advantage of percutaneous antegrade stenting is the ability to predilate a tight stricture. Rutger W van der Meer et al (6) found it necessary to dilate 13 tight ureteral strictures to allow the double J stent to pass. Similarly, Kahriman et al (1) performed 112 balloon dilatations just before ureteral stenting.

For very tight stenosis which only allow the guide wire to pass through, Papanicolou et al (37) recommended that the wire can be retrieved per urethral with subsequent stent placement either via retrograde or antegrade route.

For tortuous and dilated ureters Shreshta et al (39) proposed per urethra snaring of the guide wire and use of flexomettalic sheath to help traverse tortuous ureters with tight obstructions. Where the ureter is very tortuous, they suggested the technique of twisting and turning with retraction of the whole assembly to straighten the ureter.

2.6 Complications

Complications can occur either in the process of stent insertion or after stent insertion (1). They are broadly categorized as nephrostomy related and stent related (12,13).

Major complications are reported to occur in 4-8% of cases. They include heavy bleeding that may require angiographic embolization, pleural puncture, puncture to adjacent hollow and solid abdominal viscera and septicemia (35,40). Pleural puncture complications include pneumothorax, haemothorax and empyema. These complications are rare and approximate 0.2% of cases (5).

Minor complications such as urine extravasation, macroscopic haematuria and capsular haematoma are reported in 3-15% of cases (28).

UTI is the most frequently reported complication. This however, responds well with antibiotic treatment (6). Mild hematuria is common after stent placement either antegrade or retrograde ((6,41). This is attributed to either direct urothelial damage by the stent or it could be nephrostomy related due injury of the renal parenchyma. In most instances this hematuria is self-limiting.

A fistula between an artery and the ureter has been reported as a rare cause of significant hematuria. Hsu L et al (5) reported this rare phenomenon in patient of pelvic cancer treated with surgery or radiation. This would require a more aggressive treatment approach like angioembolization.

Stent malposition can also occur during antegrade placement. This however is mostly detected during the procedure and direct action is usually taken. Creation of a false tract is a rare finding during stent placement. However, this should always be considered with a malfunctioning stent (42). When this occurs, nephrostomy tube insertion is done to divert the urine and facilitate healing.

3.0 CHAPTER THREE: METHODOLOGY

3.1 Study Design

This was a retrospective study which involved analysis of data of patients who underwent PAUS at Kenyatta National hospital between 1ST June 2020 to 30TH June 2022.

3.2 Study Area

This research was conducted within the radiology department of Kenyatta National Hospital. A total of 73 patients underwent 83 antegrade ureteric stenting procedures between the 24th May 2019 to 30th June 2022. However, imaging data for 20 patients who underwent 28 antegrade ureteric stenting procedures was lost when the digital storage system of the angiography machine failed and was therefore not included in the study. The available data of 53 patients who underwent 55 antegrade stenting procedures between 1st June 2020 to 30th June 2022 was retrospectively analyzed.

3.3 Study Population

3.3.1 Inclusion Criteria

Patients referred to the interventional radiology suite of Kenyatta National hospital for percutaneous antegrade ureteral stenting between 1STJune 2020 to 30TH June 2022.

3.3.2 Exclusion Criteria

Patients whose imaging data and medical records could not be retrieved.

3.4 Sample Size Determination

This was a population survey where all patients referred for PAUS at the interventional radiology suite that satisfied inclusion criteria were included into the study. Sample size calculation was based on Cochran formula (1963).

$$n_0 = \frac{Z^2 * p(1-p)}{e^2}$$

Where;

n_0 was the sample size for target population> 10, 000

Z^2 was the abscissa of the normal curve that cuts off an area at the tails (1 - α equals the desired confidence level, e. g, 95%).

e was the desired level of precision,

p was the estimated proportion of an attribute that is present in the target population,

The study desired a 95% confidence level and ±5% precision.

The study assumed p=0.92. This p was obtained from technical success rate of percutaneous antegrade ureteral stenting in Harding et al

The sample size became

$$n_0 = \frac{1.96^2 * 0.92(1 - 0.92)}{0.05^2} = 114$$

Since the target population was less than 10,000 (i.e. target population of approximately 96 assuming 2 procedures per month during the study period) then the sample size was adjusted using finite population correction.

The sample size (n_0) was adjusted using:

$$n_1 = \frac{n_0}{1 + \left(\frac{n_0}{N} - 1\right)}$$

Where;

n1 was the adjusted sample size

N was the target population size

Therefore, the adjusted sample size became:

$$n_1 = \frac{114}{1 + \left(\frac{114}{196} - 1\right)} = 53$$

3.5 Data Collection Procedure

The data for those patients who underwent PAUS was obtained from medical records and images retrieved from the digital database of the fluoroscopic unit. Technique used during PAUS, problems encountered and solutions applied to mitigate the challenges were documented. The data collection tool (Appendix A) was used to extract the study data which was entered into a secure database accessible only by the principal investigator and the statistician.

Variables related to the patient, obstructing lesion and technique were collected

Patient related variables

- Age
- sex

Lesion related variables

- Cause of obstruction
- Laterality
- Site of obstruction
- Degree of hydronephrosis
- Shape of the ureter.

Technique related variables

- Calyceal access
- Challenges
- Solutions

Data on indications for stenting was collected. All entered data was reviewed prior to analysis for completeness, accuracy and consistency.

3.7 Data Management

Hard copy forms were securely stored in the principal investigators' office in secured cabinet before entry into a secure database. A backup copy of the data was stored in an external hard drive and a password protected internet cloud storage. Exploratory data analysis was conducted to determine the completeness, accuracy and consistency of the data and all issues arising were addressed to generate a clean dataset. Data coding and the creation of any composite variables from the cleaned data set was done.

3.7.1 Data Entry

The collected data was entered into password protected database by a trained research assistant in case the principal investigator was unavailable.

3.7.2 Data Cleaning

Integrity checks were done to detect outlier and invalid entries.

3.7.3 Quality Assurance and Control

All effort was made to implement quality assurance and control procedures throughout the entire study. Standardization and adherence to study protocol was maintained. The research assistants were trained on the study eligibility requirements and recruitment approaches.

3.7.4 Data Analysis

Technical success of the stenting procedure was defined by proper placement of the stent within the ureter through the point of obstruction. Statistical analysis was done using IBM Statistics, SPSS for Windows version 21 as follows;

3.7.5 Univariate Analysis

The univariate analysis involved calculation of the measures of central tendency and dispersion. Frequency distribution was determined and results presented using frequency tables and appropriate charts. Indications of the stenting procedure was analyzed using frequency statistics.

3.7.6 Bivariate Analysis

Bivariate analysis detected any association or difference between variables. Lesion related variables and those variables related to technique were correlated with successful deployment of the stent using Fischer's exact test. Relationships exhibiting p values of less than 0.05 were given statistical significance.

3.8 Ethical Considerations

Approval was sought from the local committee for ethics. Because this was a retrospective study that merely analyzed the medical records, request for waiver of written informed consent requirement was sought and granted. Research license was granted by the national commission for science, technology and innovation (NACOSTI).

3.9 Data Presentation

Frequency tables, graphs, appropriate charts, figures and textual description were used to present the results of the analyzed data. The study findings, conclusions and recommendations were made available to KNH and UoN.

4.0 CHAPTER FOUR: RESULTS

A total of 53 patients were included in the study. There were more females 44 (83.01%) than males 9(16.98%), with male to female ratio of 1:4.8. The mean age was 51.17% with an age range of 17 to 93yrs. The mean age of males was 51.22 while that of females was 51.16 years.

4.1 Indications of Antegrade Ureteric Stenting

A total of 55 procedures were done. The most common indication was malignant strictures accounting for 87% while benign strictures accounted for 13%.

Among the malignant causes of ureteral obstruction, carcinoma of the cervix was the most common accounting for 79.17% of the procedures (figures 4, 2). Other causes included prostate, bladder, retroperitoneal, endometrial and colon cancers.

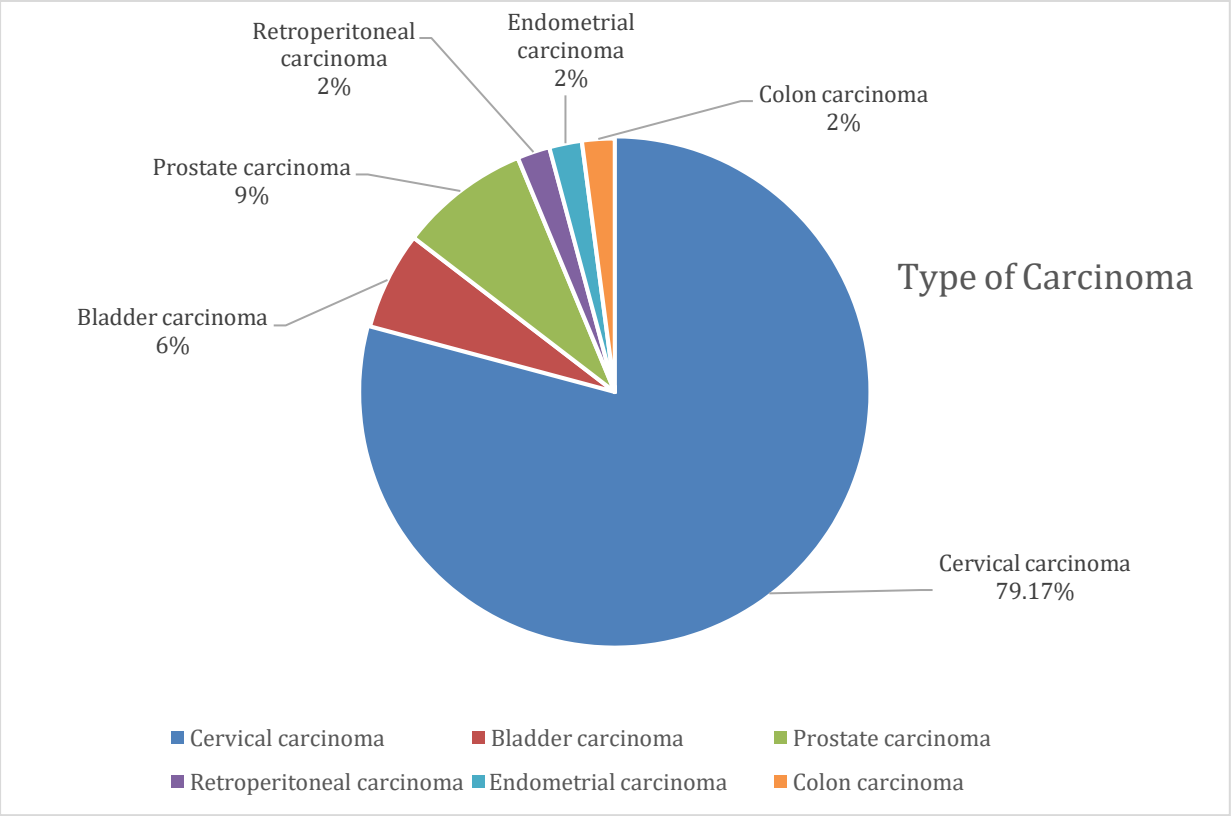

Figure 4: Pie chart showing causes of malignant ureteral obstructions. Cancer of the cervix was the leading cause (79.17%).

Benign causes of ureteral obstruction included urolithiasis (14.29%) and post-surgical fibrosis (42.85%). For the remaining three benign strictures, the cause could not be identified (table 1)

Table 1: Benign strictures

	n	%
Benign strictures N=7		
Post-surgical complications	3	42.85
Idiopathic	3	42.85
Urolithiasis	1	14.29

4.2 Technical Success Rate

This study showed a high technical success rate for both benign and malignant strictures (Table 2, figure 3).

Table 2: Technical Success Rate

Category	Technical success %
Malignant n=48	44 (91.67)
Benign n=7	6 (85.71)
Overall N=55	50 (90.91)

Four procedures were performed after failure of retrograde stenting and the cause was cancer of cervix. The five procedures that failed showed distal ureteral obstruction. Majority of the procedures (98%) underwent two stage technique with prior placement of nephrostomy tubes. One case (2%) underwent one stage technique.

4.3 Commonly Encountered Problems

Dilated and tortuous ureters was the predominant problem encountered during antegrade ureteric stenting (table 3). Other problems included suboptimal calyceal access, tight obstruction and difficulties in positioning the proximal pigtail loop of the stent.

Table 3: Commonly encountered problems during antegrade stenting

Challenges	
Dilated tortuous ureters	n=46 (47.42%)
Suboptimal calyceal access	n=20 (20.62%)
Tight obstruction	n=18 (18.56%)
Difficulty positioning the proximal pigtail loop	n=13 (13.40%)
Total	**N=97 (100.00%)**

4.4 Dilated and Tortuous Ureters

This was caused by distal ureteric strictures resulting in various degrees of hydronephrosis. Type three (severe) hydronephrosis was the commonest. Cases of severe hydronephrosis were more challenging to stent. Three shapes of the dilated ureters were observed. Normal ureter shape was seen in 43 cases, Z shape in 11 cases and pigtail shape in 2 cases (table 4, figure 4). It was more difficult to place a stent in those ureters that showed z and pigtail ureteric shapes (p value less 0.05).

Table 4: Shape of the dilated ureter

Shape of the dilated ureter N=55	n	Successful	Unsuccessful	P value
Normal	43	43 (100.00%)	0 (0.00%)	<0.001
Z	11	7(63.64%)	4(36.36%)	
Pigtail/corkscrew	1	0 (0.00)	1(100.00)	

The challenge of dilated and tortuous ureters was mitigated by placing nephrostomy tubes for decompression and use of a hydrophilic guide wire with angiographic catheter to negotiate through the ureter.

4.5 Suboptimal Calyceal Access

Suboptimal calyceal access was observed in 20 (20.62%) procedures. This resulted in a poor angle of entry towards the proximal ureter with subsequent looping of the stent in the renal pelvis. This problem was overcome by use of a vascular sheath, super stiff guidewire and change of calyceal access to a midpole calyx were necessary (figure 5).

4.6 Tight Obstruction

Tight obstruction was seen in 18(18.56%) cases. Hydrophilic guide wires and vascularcatheters were used to cross these lesions. Super stiff guide wires were used to facilitate the passage of the stent through the tight strictures. In one case dilatation with a 4mm balloon wasdone to allow the stent to pass. Distal ureteral obstruction was the most common (figure 6).

4.7 Difficulties in Positioning the Proximal Pigtail Loop of the Stent

Difficulties during positioning of the proximal pigtail loop occurred in 13(13.40%) procedures (table 3). This was seen as proximal pigtail loop flipping into mid or lower pole calycx and prolapse of the stent into the proximal ureter (figure 7). The pusher and the stent safety string mechanism was used to adjust the position of the proximal pig tail loop of the stent. Metallic marker on the distal end of the pusher facilitated ready identification of the proximal end of the stent and prevented engagement of the pusher catheter with the proximal end of the stent.

Images

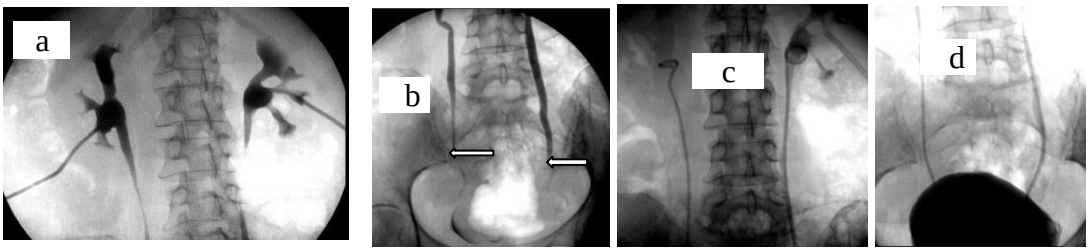

Figure 5: a-d: A 49-year-old female patient with carcinoma of the cervix, referred for bilateral antegrade ureteric stenting. Initial decompression nephrostomy tubes were placed(a). Nephrostograms show bilateral distal ureteric strictures (b, arrows). The strictures were successfully crossed and stents deployed (c, d).

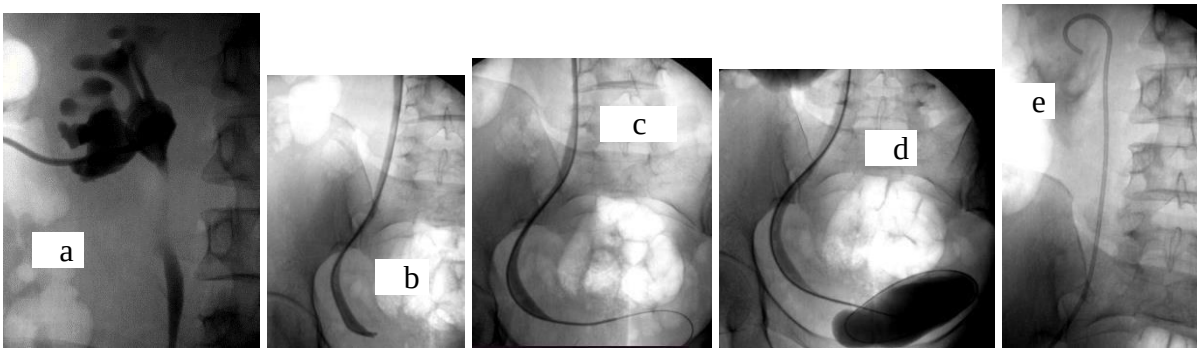

Figure 6: a-e: A 35-year-old female patient with carcinoma of the cervix, referred for unilateral left antegrade stenting. Two stage technique was used with placement of initial decompression nephrostomy tube (a). The stricture was crossed using an angiographic catheter and a hydrophilic guide wire (b, c). Confirmation of the bladder lumen was done by contrast injection (d) followed by successful stent placement (e).

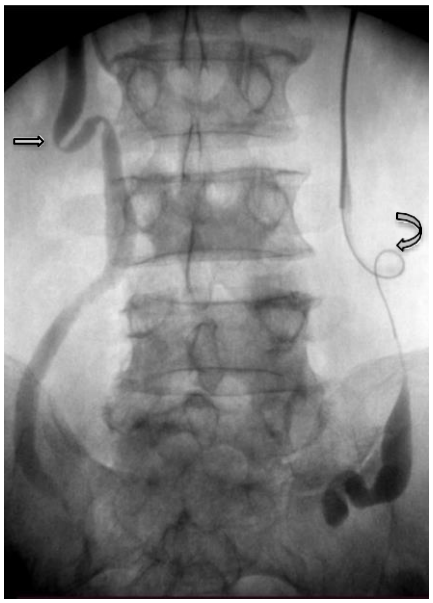

Figure 7: A 76year old male patient with prostate cancer. Antegrade stenting failed due to a large prostate tumor which obliterated the bladder lumen. Note the Z shaped ureteral tortuosity of the left ureter (straight arrow) and pigtail tortuosity of the right ureter with the guide wire forming a loop within the ureter (curved arrow).

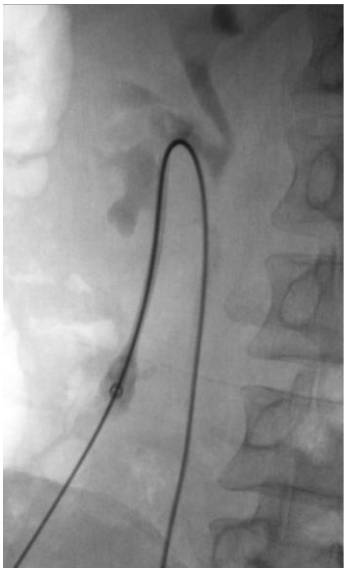

Figure 8: Suboptimal calyceal access in a 40-year-old female patient with cancer of the cervix. A vascular sheath and super stiff guide wire were used to help pass the stent down into the ureter.

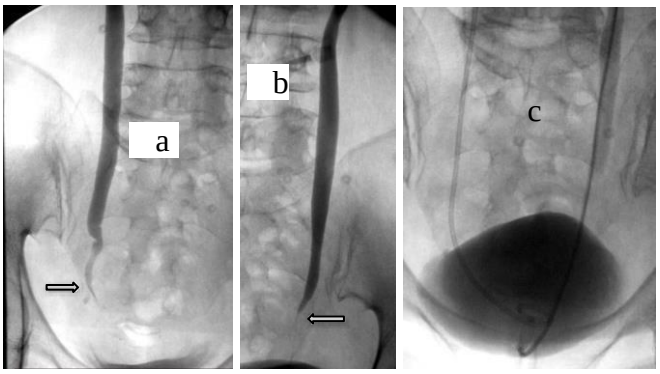

Figure 9: a-c: A 69-year-old female patient with carcinoma of the cervix. Bilateral distal ureteric strictures (straight arrows in a, b). Both strictures were crossed using an angiographic catheter and hydrophilic guide wire with successful stent placement bilaterally(c).

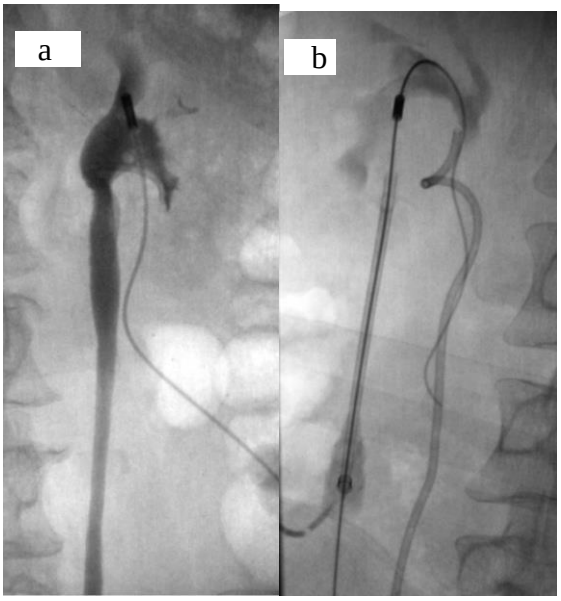

Figure 10: a, b: Difficulties in positioning the proximal pigtail loop of the double J stent. The proximal end of the stent is trapped in the lower pole calycx (a). The proximal end of the stent is seen in the upper ureter with resultant poor formation of the pigtail loop (b).

5.0 CHAPTER FIVE: DISCUSSION, CONCLUSION & RECOMMENDATIONS

5.1 Discussion

In this retrospective analysis we investigated the indications, technical success rate and identified the commonly encountered problems during antegrade double J stenting and their solutions. We found percutaneous antegrade ureteral stenting technique to be highly effective and safe for both malignant and benign causes of ureteral obstruction. For malignant extrinsic obstructions, antegrade stenting was found to be superior to retrograde cystoscopic ureteral stenting.

5.1.1 Indications of Antegrade Ureteric Stenting

In this study, antegrade stenting was indicated for both malignant and benign ureteral strictures. Malignant cause was the most prevalent indication accounting for 87% of the cases while benign strictures accounted for 13%. Similar findings were reported by Nunes et al (3) in their retrospective analysis of 150 procedures done in 90 patients. This study showed carcinoma of the cervix to be the leading cause of malignant ureteric stricture (79.17%). A study conducted by Macharia et al (43) showed cervical cancer as the most common cancer seen at KNH. This reflects the high number of malignant ureteral strictures due to carcinoma of the cervix as observed in this study. Other causes of malignant ureteric strictures in the current study included carcinoma of the prostate (9%), bladder cancer (6%) retroperitoneal cancer (2%), endometrial cancer (2%) and colon cancer (2%).

Nunes et al (3) also reported cervical carcinoma as the most prevalent cause of malignant ureteral obstruction accounting for 47% of the cases followed by prostate cancer at 32% and bladder carcinoma at 24%. Similar findings were also reported by Kahriman et al (1) in their retrospective review of 727 procedures. In their study, antegrade stenting was performed in 654 malignant strictures accounting for 90% of the cases and 73 non neoplastic strictures accounting for 10% of the cases. A study by van der Meer et al (6) also showed the most prevent indication for double J ureteric stenting was malignant obstruction.

5.1.2 Technical Success Rate

Several studies have reported high technical success rate for antegrade double J stenting with low complications rates compared to retrograde ureteric stenting. Chitale et al (9) performed 60 antegrade procedures out of which 59 (98%) procedures were successful. Uthappa et al (29)

succeeded in 24 out of 25 antegrade procedures in malignant ureteral obstruction giving a high technical success rate of 96%. Kahriman et al (1) succeeded in 654 antegrade stenting procedures done for malignant strictures achieving a high success rate of 97% and an even higher technical success rate in benign strictures of 100%. Turgut et al (44) reported a 95% technical success rate for antegrade ureteric stenting.

The present study compares well to these findings with a high overall technical success rate of 90.01%. Among the malignant strictures, this study recorded a technical success rate of 91.67% which compares favorably with the findings in literature varying between 85 and 98%. The study recorded a technical success rate of 85.71% among benign strictures which is in concordance with the documented rate in literature.

The three procedures done due to post-surgical fibrosis all succeeded giving a technical success rate of 100%. This compares favorably with findings of studies done by Toporoff et al (31), Liatsikos et al (32) and Kahriman et al (1).

Four strictures which were initially treated with retrograde stenting and failed were successfully treated by antegrade stenting. All the four strictures were caused by carcinoma ofthe cervix and affected the distal ureters. Similar findings were reported by van der Meer (6) where 21 strictures which failed during retrograde stenting were successfully stented via antegrade approach. Uthappa et al (29) succeeded in 24 (96%) out 25 procedures that had failedprior retrograde stenting attempt. It therefore appears that antegrade ureteric stenting is superiorto retrograde stenting in the setting of malignant distal ureteric strictures**.**

5.1.3 Commonly Encountered Problems

The problems encountered during antegrade stenting procedure in this study included suboptimal calyceal access, dilated and tortuous ureters, tight obstructions and difficulty in positioning the proximal pigtail loop of the stent. Similar problems are reported in literature by Lu et al (37) and Salazar et al (38).

In this retrospective series, the challenge of suboptimal calyceal access was observed in 20(20.62%) procedures. This was overcome by use of an angled angiographic catheter to negotiate through the pelviureteric junction and use of super stiff guidewire combined with a vascular sheath to reduce the looping of the stent at the renal pelvis. These measures were also found helpful by Lu et al (37) in their prospective study of 50 consecutive cases of antegrade ureteral stenting procedures. The same study recommended the use of upper or mid pole calyx to avoid this problem of poor angulation altogether. We also found it easier to stent through the mid pole calyx compared to the lower pole.

In the present study the challenge of grossly dilated and tortuous ureters was seen in 46 (47.42%) procedures. Two stage antegrade ureteral stenting was employed in 54(98.18%) out of 55 procedures where a nephrostomy tube was placed prior to stenting. We found this helpful in decompressing the ureters with sharp bends and kinks and thus easier negotiation of the glide wire and catheter down the ureter into the bladder. Similar recommendation was made for grossly dilated and tortuous ureters in the study by Lu et al (37). Shreshta et al (39) suggested the technique of twisting and turning with retraction of the assembly to straighten grossly dilated and tortuous ureters.

In the present study, very tight obstructions were recorded in 18(18.56%) procedures. To mitigate this challenge, use of a vascular sheath and a super stiff guide wire were found to be very helpful. In addition, the mid pole calyceal access was found to provide an easier angulation to pass the stent through the obstruction. Similar suggestions were made by Lu et al (37) with addition of per urethral snaring of the wire for very tight strictures and subsequent placement of the stent either via retrograde or antegrade route. Shreshta et al (39) also proposed per urethral snaring of the guide wire combined with the use of a flexometallic sheath to help place the stent through very tight obstructions. In one procedure in our study where the stent failed to pass through a tight stricture, dilatation using a 4mm balloon was done and the stent was placed successfully. Pre-stenting balloon dilatation to improve technical success is also recorded in studies by Kahriman et al (1) and Santos et al(18).

Difficulty in positioning the proximal pigtail loop of the stent was seen in 13(13.40%) procedures in this study. Where the stent was deployed too deep, the safety string was used to pull the stent upward into the renal pelvis. Flipping of the proximal end of the stent into a calyx during removal of the safety string was prevented by use of a vascular sheath or the pusher. This challenge was eliminated by Lu et al (37) by routinely using 9F peel-away sheath. Lu et al (37) further observed that use of a peel-away sheath facilitated deployment of a safety nephrostomy tube at the end of the procedure where necessary.

5.2 Conclusions

The study showed that the most common indication for antegrade ureteral stenting at KNH was malignant obstruction largely from carcinoma of the cervix. Antegrade stenting has high technical success rate for both benign and malignant ureteral obstruction. Among the commonly encountered problems, grossly dilated and tortuous ureters with Z and pigtail ureteric shapes are more challenging to stent. Though challenges are encountered during antegrade ureteric stenting, they can be overcome by various technique modifications including

balloon dilatation, use of vascular sheaths, hydrophilic guidewires, angiographic catheters and decompression of the ureters through nephrostomy tube insertion for a short period.

5.3 Recommendations

Studies with large sample sizes, possibly in many different centers with long follow up periods are required to improve the study power informing the use of antegrade ureteral stenting. Randomized trials between antegrade and retrograde ureteral stenting are required to determine which method should be adopted as first line. Cost analysis between antegrade and retrograde stenting should be carried out to determine which method is more cost effective especially in our resource limited setting.

5.4 Limitations

Due to the retrospective design of the study, the researcher had minimal control on the quality of data. The small sample size in this study affected the study power and inference. Being a single center experience, this study does not effectively document the local practice of antegrade ureteral stenting in our country.

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APPENDICES

Appendix A: Data Collection Form

BIODATA

Name:

Age:

Sex:

Date of procedure:

IP/OP Number:

Residence:

Occupation:

History of previous retrograde stent placement attempt

Yes	
No	

Indications of stenting/ cause of obstruction:

……

……

……

…….

Side of ureteral obstruction

Right	
Left	
Bilateral	

Site of ureteral obstruction

Proximal	
Mid	
Distal	

Hydronephrosis

Grade 0	
1	
2	
3	
4	

Shape of the ureter

Normal	
Z shaped	
Pigtail shaped	

Technique of stenting

Single stage	
Two stage	

Calyceal access:

Lower pole	
Mid pole	
Upper pole	

Challenges encountered	**Yes or No**	**Solution/devices used**
Suboptimal access		
Tight obstruction		
Dilated and tortuous ureters		
Stent assembly breakdown		
Difficulty positioning the proximal loop		
Others		
Others		
Others		

Procedure outcomes

	Successful
First attempt	
Second attempt	
Third attempt	

Failed:

Cause of failure……

……

……

……

Periprocedural complications

- ……

  ……

  ……

Urea and creatinine

- Preprocedure values:……....……
- Post procedure values:……..

Appendix B: Consent Waiver Form

UNIVERSITY OF NAIROBI (UoN) **COLLEGE OF HEALTH SCIENCES** **P O BOX 19676 Code 00202** **Telegrams: varsity** **(254-020) 2726300 Ext 44355**	**KNH-UoN ERC** **Email: uonknh_erc@uonbi.ac.ke** **Website: http://www.erc.uonbi.ac.ke** **Facebook: ttps://www.facebook.com/uonknh.erc** **Twitter: @UONKNH_ERC**	**KENYATTA NATIONAL HOSPITAL (KNH)** **P O BOX 20723 Code 00202** **Tel: 726300-9** **Fax: 725272** **Telegrams: MEDSUP, Nairobi**

(To be submitted with Application for ERC Review of Research)

Exempt studies to be defined

KNH-UoN ERC

REQUEST FOR WAIVER OF INFORMED CONSENT

(Not Required for Exempt Studies)

Project Title: "PERCUTANEOUS **ANTEGRADE DOUBLE J URETERAL STENT PLACEMENT AT KENYATTA NATIONAL HOSPITAL: INDICATIONS, TECHNICAL SUCCESS RATE, COMMONLY ENCOUNTERED PROBLEMS AND SOLUTIONS"**

Principal Investigator and Institutional affiliation: **JOHN MWANGI WANJIKU, UNIVERSITY OF NAIROBI**

Date: **/12/2022**

Under special circumstances, investigators may request one of three types of waivers to obtaining written informed consent from research participants.

1. **Alteration of informed consent.**

   With this waiver, the investigator may provide to the participants a consent which does not include or which alters one or all of the required elements. Examples of when this waiver might be applicable would be, when a researcher is conducting secondary data

analysis and the participants cannot be located or when requiring informed consent might somehow actually have negative consequences for research participants.

2. **Waiver of parental permission**.
   This waiver would be used in cases where something may be legal for a child to do (i.e. contraception) without parental permission and obtaining parental permission would violate that privacy. An example of this type of waiver would be a survey on children (which would require parental permission) but the survey is about their experience on contraception usage.
3. **Waiver of written documentation** that informed consent was obtained. With this waiver, the investigator would be required to read or provide the informed consent form to a participant, but would not need to obtain the participant's signature on the consent form. Examples of when this waiver might be applicable would be some internet or phone surveys or when signing the form might have some negative consequence for the participant. It must be emphasized that these waivers will be given only when there are compelling reasons for doing so.

The Ethics and Research Committee determines which type of consent applies to your research, but please indicate the type that you are requesting.

☐ **Waiver or alteration of the informed consent process.** *(Complete Section I)*

☐ **Request for waiver of parental permission.** *(Complete Section II)*

☒ **Waiver of written documentation of consent.** *(Complete Section III)*

I. Request for waiver or alteration of the consent process (Not required for Exempt studies)

I believe that this protocol is eligible for waiver or alteration of required elements of the informed consent process because the protocol meets all of the following criteria: (Provide protocol-specific supporting information for each criterion that justifies the findings for the following :)

1. The research presents no more than "minimal risk" of harm to participants.

This will be a cross sectional retrospective study which will involve analysis of data of patients who underwent PAUS at Kenyatta National hospital. There will be no direct contacts to with the participants and thus no risks.

2. The waiver or alteration will not adversely affect the rights and welfare of the participants.

This is a retrospective study that will merely analyze the medical records of participants. The collected data will be entered into password protected database accessed only by principal investigator and the statistician. Data sheets will be destroyed upon completion of the study. Hence not affecting the rights and welfare of the participants in any way whatsoever

3. The research could not practicably be carried out without the waiver or alteration.

Yes. Since the study does not deal directly with the participants. A waiver of consent was deemed necessary

4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

This won't be necessary because there will be no direct contact with the participants.

5. Elements of informed consent for which a waiver or alteration is requested and the rationale for each:

The waiver is requested in totality since there will be no direct contact with the participants but merely analyse their medical records.

6. The research does not involve non-viable neonates:

Not applicable

7. The research is not subject to FDA and/or national research regulation:

Not applicable

II. Request for waiver of parental permission (Not required for Exempt studies)

I believe that this protocol is eligible for waiver of parental permission because the protocol meets all of the following criteria: (Provide protocol-specific supporting information for each criterion that justifies the findings for one of the following two options :)

Option 1

1. The research presents no more than "minimal risk" of harm to participants.

_____

_____

_____

2. The waiver or alteration will not adversely affect the rights and welfare of the participants.

_____

_____

_____

3. The research could not practicably be carried out without the waiver or alteration.

_____

_____

_____

4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

_____

_____

_____

5. Elements of informed consent for which a waiver or alteration is requested and the rationale for each:

_____

_____

_____

6. The research does not involve non-viable neonates:

_____

_____

_____

7. The research is not subject to FDA and/or national research regulation:

_____

_____

_____

Option 2:

1. The research protocol is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (for example, neglected or abused children)

_____

_____

_____

2. An appropriate mechanism for protecting the children who will participate as participant in the research will be substituted

_____

_____

_____

3. The research is not subject to FDA and/or national research regulation:

_____

_____

_____

4. The waiver is consistent with international and national law:

_____

_____

_____

III. Request for waiver of written documentation of consent (Not required for Exempt studies and not required when the consent process is waived.)

I believe that this protocol is eligible for a waiver of written documentation of informed consent because the protocol meets one of the following criteria: (Provide protocol-specific supporting information for each criterion that justifies the findings for one of the following two options :) **(NOTE: Even when documentation of informed consent is waived, the investigator is required to give participants full consent information, and to obtain their voluntary consent orally.)**

Option 1

(Example: Conducting interviews with street children engaged in drug abuse. The only record of the name or other identifying information of the participants would be the signed consent form and knowledge of an individual's participation or information provided could lead to potential legal, social, or physical harm.)

Explain*:*

1. The only record linking the participant and the research would be the consent document.

_____

_____

_____

2. The principle risk would be potential harm resulting from breach of confidentiality.

_____

_____

_____

3. Each participant will be asked whether the subject wants documentation linking the participant with the research and the participant's wishes will govern.

_____

_____

_____

4. The research is not subject to FDA and / national research regulation.

_____

_____

_____

Option 2

(Example: Using an anonymous survey consent or conducting telephone interviews with politicians about how constitutional provision for funding of political parties will affecting the campaign process of smaller parties

1. The research presents no more than minimal risk of harm to participants.

_____

_____

_____

2. The research involves no procedures for which written consent is normally required outside of the research context.

_____

_____

_____

Approval (KNH-UoN ERC Chairperson: Check all that apply to indicate that the waiver or alteration is approved and to indicate agreement with the investigators protocol specific findings justifying the waiver.)

☐ Waiver or Alteration of the Consent Process

☐ Waiver of parental permission

☐ Waiver of Written Documentation of Consent

NOTE: To approve a waiver of written documentation of informed consent the investigator must provide a written document describing the information to be disclosed. This document has to include all required and appropriate additional elements of consent disclosure, unless the consent process has been altered.

Chose one of the following when approving a waiver of written documentation:

☐ The investigator must provide a written description of the information provided orally to the participant.

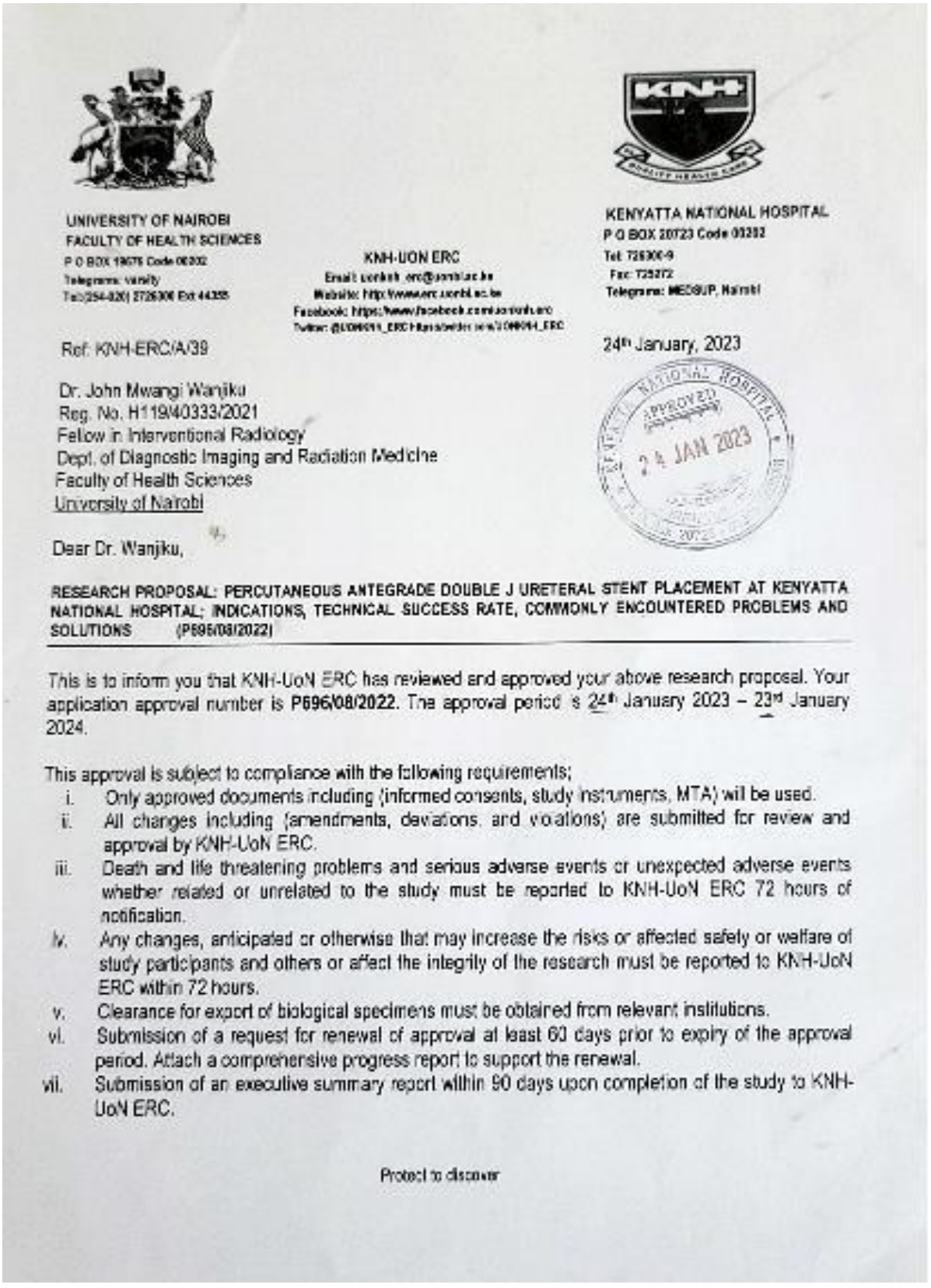
☐ The investigator does not have to provide a written description of the information provided orally to the participant.

APPROVED BY CHAIR KNH-UoN ERC:

Name:_____Signature _____

Date and Stamp:_____

Appendix C: KNH/UoN-ERC Letter of Approval



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KNH-UON ERC
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Facebook: https://www.facebook.com/uonknherc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/39

24th January, 2023

Dr. John Mwangi Wanjiku
Reg. No. H119/40333/2021
Fellow in Interventional Radiology
Dept. of Diagnostic Imaging and Radiation Medicine
Faculty of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 24 JAN 2023

Dear Dr. Wanjiku,

RESEARCH PROPOSAL: PERCUTANEOUS ANTEGRADE DOUBLE J URETERAL STENT PLACEMENT AT KENYATTA NATIONAL HOSPITAL; INDICATIONS, TECHNICAL SUCCESS RATE, COMMONLY ENCOUNTERED PROBLEMS AND SOLUTIONS (P696/08/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P696/08/2022**. The approval period is 24th January 2023 – 23rd January 2024.

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 KNH-UoN ERC.
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 KNH-UoN ERC 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 KNH-UoN ERC 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 KNH-UoN ERC.

Protect to discover

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

Yours sincerely,

DR. BEATRICE K.M. AMUGUNE
SECRETARY, KNH-UoN ERC

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Assistant Director, Health Information Dept., KNH
The Chairperson, KNH- UoN ERC
The Chair, Dept. of Diagnostic Imaging and Radiation Medicine, UoN
Supervisors: Dr. Peter Magabe Chacha, Dept. of Diagnostic Imaging and Radiation Medicine, UoN
Dr. Lawrence Mugambi M'Arithi, Consultant Vascular and Interventional Radiologist, KNH

Appendix D: NACOSTI Research Permit

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: 989149

Date of Issue: 01/March/2023

RESEARCH LICENSE

This is to Certify that Dr.. JOHN MWANGI WANJIKU of University of Nairobi, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Nairobi on the topic: PERCUTANEOUS ANTEGRADE DOUBLE J URETERAL STENT PLACEMENT AT KENYATTA NATIONAL HOSPITAL: INDICATIONS, TECHNICAL SUCCESS RATE,COMMONLY ENCOUNTERED PROBLEMS AND SOLUTIONS for the period ending : 01/March/2024.

License No: NACOSTI/P/23/23515

989149

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

See overleaf for conditions

THE SCIENCE, TECHNOLOGY AND INNOVATION ACT, 2013 (Rev. 2014)
Legal Notice No. 108: The Science, Technology and Innovation (Research Licensing) Regulations, 2014

The National Commission for Science, Technology and Innovation, hereafter referred to as the Commission, was the established under the Science, Technology and Innovation Act 2013 (Revised 2014) herein after referred to as the Act. The objective of the Commission shall be to regulate and assure quality in the science, technology and innovation sector and advise the Government in matters related thereto.

CONDITIONS OF THE RESEARCH LICENSE

1. The License is granted subject to provisions of the Constitution of Kenya, the Science, Technology and Innovation Act, and other relevant laws, policies and regulations. Accordingly, the licensee shall adhere to such procedures, standards, code of ethics and guidelines as may be prescribed by regulations made under the Act, or prescribed by provisions of International treaties of which Kenya is a signatory to
2. The research and its related activities as well as outcomes shall be beneficial to the country and shall not in any way;
    i. Endanger national security
    ii. Adversely affect the lives of Kenyans
    iii. Be in contravention of Kenya's international obligations including Biological Weapons Convention (BWC), Comprehensive Nuclear-Test-Ban Treaty Organization (CTBTO), Chemical, Biological, Radiological and Nuclear (CBRN).
    iv. Result in exploitation of intellectual property rights of communities in Kenya
    v. Adversely affect the environment
    vi. Adversely affect the rights of communities
    vii. Endanger public safety and national cohesion
    viii. Plagiarize someone else's work
3. The License is valid for the proposed research, location and specified period.
4. The license any rights thereunder are non-transferable
5. The Commission reserves the right to cancel the research at any time during the research period if in the opinion of the Commission the research is not implemented in conformity with the provisions of the Act or any other written law.
6. The Licensee shall inform the relevant County Director of Education, County Commissioner and County Governor before commencement of the research.
7. Excavation, filming, movement, and collection of specimens are subject to further necessary clearance from relevant Government Agencies.
8. The License does not give authority to transfer research materials.
9. The Commission may monitor and evaluate the licensed research project for the purpose of assessing and evaluating compliance with the conditions of the License.
10. The Licensee shall submit one hard copy, and upload a soft copy of their final report (thesis) onto a platform designated by the Commission within one year of completion of the research.
11. The Commission reserves the right to modify the conditions of the License including cancellation without prior notice.
12. Research, findings and information regarding research systems shall be stored or disseminated, utilized or applied in such a manner as may be prescribed by the Commission from time to time.
13. The Licensee shall disclose to the Commission, the relevant Institutional Scientific and Ethical Review Committee, and the relevant national agencies any inventions and discoveries that are of National strategic importance.
14. The Commission shall have powers to acquire from any person the right in, or to, any scientific innovation, invention or patent of strategic importance to the country.
15. Relevant Institutional Scientific and Ethical Review Committee shall monitor and evaluate the research periodically, and make a report of its findings to the Commission for necessary action.

National Commission for Science, Technology and
Innovation(NACOSTI),
Off Waiyaki Way, Upper Kabete,
P. O. Box 30623 - 00100 Nairobi, KENYA
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