

**THE ROLE OF PERCUTANEOUS NEPHROSTOMY IN THE MANAGEMENT OF
OBSTRUCTIVE UROPATHY SECONDARY TO PELVIC MALIGNANCIES AT
KENYATTA NATIONAL HOSPITAL**

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Award of the Degree of Master's in Medicine in Diagnostic Radiology.

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1 DECLARATION

I, **Dr. Masaki Shila Moraa**, declare that the work contained herein is my original idea and has not been presented at any other place in Kenya to the best of my knowledge.

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DEDICATION

This work is dedicated to my parents for their love, undying support and prayers.

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3 LIST OF ABBREVIATIONS

- BUN - Blood Urea Nitrogen.
- ESRD - End Stage Renal Disease.
- CT - Computer Tomography.
- GFR - Glomerular Filtration Rate.
- Hb - Haemoglobin.
- IVU - Intravenous Urography.
- INR - International Normalised Ratio
- KNH - Kenyatta National Hospital.
- KUB - Kidney Ureter Bladder.
- MRI - Magnetic Resonance Imaging.
- PCN - Percutaneous Nephrostomy.
- U/S - Ultrasound or Ultrasonography.
- UTI - Urinary Tract Infection.
- WHO - World Health Organisation.

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5 ABSTRACT

5.1 Background

Ureteric obstruction is an unpromising sign in patients who have advanced malignancy, and can progress into uraemia and quickly become a terminal event if no intervention is undertaken. Decompression by percutaneous nephrostomy (PCN) placement provides a direct access to the urinary tract and allows for drainage of renal tract contents thus improving renal function and reverse metabolic derangements with presumed low morbidity.

5.2 Objective

The aim of the study is to assess renal function improvement among patients with obstructive uropathy due to pelvic malignancies after percutaneous nephrostomy placement, by comparing pre and post procedure levels of urea and creatinine.

5.3 Study setting

Kenyatta National Hospital

5.4 Study design

A descriptive retrospective study

5.5 Methodology

A data collection sheet was used to manually record demographic data, type of pelvic malignancy, prior radiological imaging, pre drainage by PCN urea and creatinine levels and 10 days post insertion renal function parameters by evaluating the urea/creatinine level from the records available in the patient's files, of those who had undergone PCN within the previous two years from January 2013 to December 2014. The data was entered into an MS Excel database and analyzed using the Statistical Package for Social Scientists (SPSS™) version 22. Patients' longevity was not evaluated, as this was beyond the scope of this study.

5.6 Results

A total of 72 patient files were enrolled into the study. The average age of the study subjects was 47.4 years (SD =10.3 years). Majority of the study participants were female 70 (97%) and 2 (3%) were male. The median duration of illness was 8 months; ranging from 2 to 48 months. The most common malignancy was cancer of the cervix (94%) followed by cancer of the ovary 2 (3%) and cancer of the urinary bladder 2 (3%). The most commonly reported co-

morbidity was hypertension (26%), followed by sero-reactive (24%) and a combination of hypertension and diabetes mellitus (14%).

Almost all the patients had an ultra-sound investigation (91.7%). None of the patients had been diagnosed using other tests such as IVU and MRI to diagnose hydronephrosis. The most common form of therapy that patients received was radiotherapy (69%) compared to other forms of therapy. The median age of the time taken from the radiological diagnosis of obstructive uropathy to the PCN insertion was 14 days (Range of 1 to 120 days).

Mean creatinine and urea levels, were higher pre PCN compared to post PCN. This difference was statistically significant. Fifty four (75%) of the patients underwent bilateral nephrostomies and 18 (25%) underwent unilateral nephrostomy. The p values in both groups approached statistical significance but were slightly more significant in the group who had bilateral insertions.

5.7 Conclusion

The results of this study show that PCN, though it is expensive is effective as an initial palliative or temporary means of saving renal function in patients with malignant pelvic ureteric obstruction. However this will depend on the physician for timely referrals and thus early intervention. The patient and family need to know and understand the disease, its complications and the available therapeutic options.

6 INTRODUCTION AND LITERATURE REVIEW

Obstructive Uropathy due to pelvic malignancies is increasingly becoming a challenge, and is one of the major emergencies seen in various departments such as gynaecology, urology and oncology. The obstruction may be caused by prostate cancer, bladder cancer, colorectal cancer, cervical cancer, uterine cancer, ovarian cancer, testicular tumors, lymphoma and other metastatic deposits.

Malignant obstruction may develop over a short or long period of time usually within a month and it can be either due to extrinsic tumor compression, direct tumor invasion, or due to enlarged metastatic lymph nodes close to the ureters, or base of the bladder. If the obstruction occurs gradually and over a long period of time, then cortical thinning and atrophy of the affected kidney ensues, resulting in deterioration of renal function and uremia.

There have been many breakthroughs in the treatment of pelvic malignancies, such as surgery, chemotherapy and radiotherapy. Despite the advancements, these neoplasms often progress insidiously, and the patients seek medical help late, presenting with obstructive uropathy. If the obstruction is not relieved, the patient's clinical condition often deteriorates at a rapid pace through uremia, water-electrolyte imbalances, urinary tract infections and subsequent death. Urinary decompression and diversion by PCN is a recognized method of improving renal function, with presumed low morbidity and improved quality of life (1).

Ultrasound (U/S) and fluoroscopic guidance has made PCN quite a safe procedure thus attaining improvement in the biochemical parameters of renal function (blood urea and serum creatinine). It is known that PCN can be associated with complications such as: dislodgment, kinking, blockage and infection of the nephrostomy tubes, bleeding at the nephrostomy site and even haemorrhagic shock which can lead to significant morbidity (2). However the benefits outweigh the complications, which are usually controlled and minimized, in experienced hands.

7 PERCUTANEOUS NEPHROSTOMY

7.1 Background

In 1955 Goodwin and Casey described the indications, technique and results of trocar nephrostomy performed by percutaneous lumbar tap of the renal pelvis for temporary urinary drainage in 16 selected cases of hydronephrosis under roentgenographic control(3). Ten years later in 1965, Bartley described a technique for the application of a permanent drain, he used a modified Seldinger technique and relieved the pressure on the renal pelvis using an angiography catheter (4) .

The procedure became more acknowledged when Almgard and Fernstrom in 1974 (5) described a technique using a polyethylene catheter on a trocar introduced into the renal pelvis under fluoroscopy guidance. They used a dilatation technique in which the nephrostomy channel was dilated by gradually increasing the size of the catheter, it was however noted to be time consuming as it would take upto a week from the time of the first puncture to the time of the foley catheter placement.

The first U/S guided PCN was reported in 1974 by Pedersen (6) and this has since become an established technique. In 1980 Lindgren and Hemmingsson introduced the coaxial dilatation technique whereby, the puncture was performed under ultrasound guidance with the needle guide unit fitted to the transducer,after the puncture, a steel braided polyethylene catheter is inserted into the renal pelvis and secured on the skin. After a period of two days the steel braided catheter could then be replaced by a soft balloon catheter for temporary or permanent drainage, thus reducing the overall mobilization time required (7).

Constatin Cope introduced a crossed-limb loop anchor in 1980 which has a distal loop that configures to the renal pelvis, perforations that provide unobstructed drainage and minimal chance of migration into the renal pelvis thus it can be retained for a longer period of time (8). These various experiences that were previously gained with percutaneous techniques combined with upcoming technological advances in instrumentation, is continuously broadening the indications for percutaneous renal entry, and therefore by applying this new technologies to difficult management cases appears to be promising (9).

In 1995 the first PCN was performed in the radiology department at KNH by Millward (10) who was a visiting professor. There was a lapse of time from then due to lack of trained personnel and difficulty in procuring the catheters due to international sourcing. The procedure was then recommenced from the year 2000 by Dr Wanga followed by Dr Tata, Dr Kibaya and Dr Mugambi and colleagues. From the records about 200 cases have been performed at KNH, despite the difficulties in obtaining the nephrostomy tubes.

7.1.1 Indications for percutaneous nephrostomy

- Drainage of the renal collecting system due to intrinsic or extrinsic obstructive factors such as stones, malignancy, pregnancy or iatrogenic disorders which may cause urinary tract obstruction.
- Diversion of urine after iatrogenic injuries, urinary leakage or fistulas.
- Access to the collecting system as a prelude for further interventional procedures like; ureteral stent placement, foreign body retrieval such as migrating stents, or as a way to deliver medication such as chemotherapy.

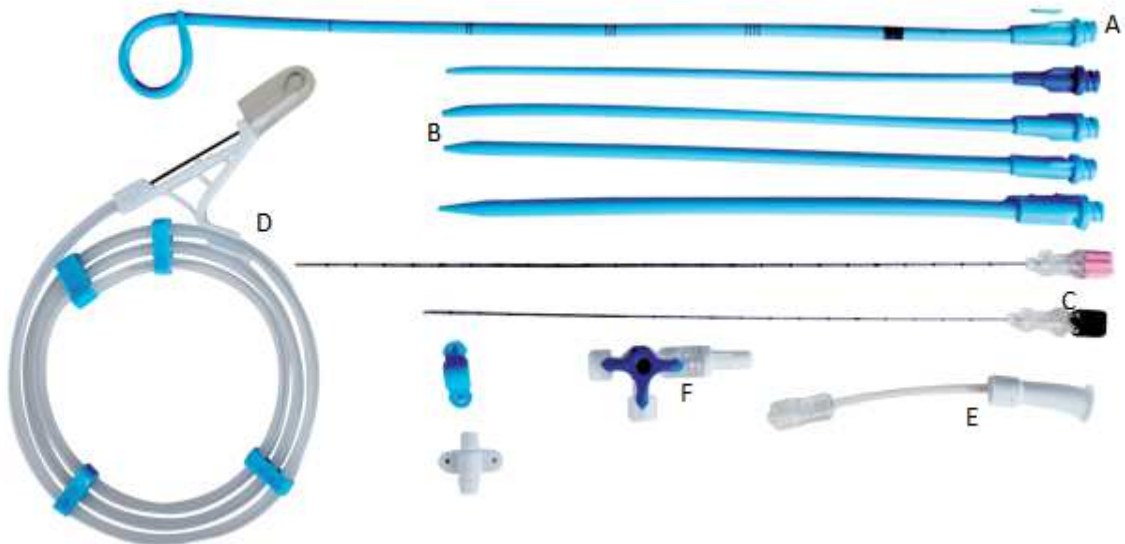
7.1.2 Relative contraindications

- Uncorrectable severe coagulopathy and terminal illness.

7.2 Equipment and Technique

7.2.1 Equipment

1. Needles: 21G Chiba needle, 18G initial puncture needle .
2. Guide wires: “0.018” Cope mandril wire, “0.035” hydrophilic wire, “0.035” stiff Amplatz wire.
3. Catheters: 8F or 10F pigtail drainage catheters, 30–45 cm long, preferably with self retaining mechanism.
4. Water soluble contrast media.
5. Dilators ranging from 7-9 French.



A-PIG TAIL DRAINAGE CATHETER

B-FASCIAL DILATORS

C-INITIAL PUNCTURE NEEDLE-2 PART

D-J TIPED GUIDE WIRE TEFLON COATED

E-URINE BAG CONNECTOR

F-2 WAY STOP COCK

7.2.2 Patient Preparation and Technique

Depending on the local setting this intervention is performed either by an interventional radiologist or a urologist. At KNH the procedure is performed by an interventional radiologist usually under U/S and/or flouroscopy guidance by a single-stick or double-stick technique (11).

Pre –procedure evaluation

Prior imaging is reviewed to confirm the indication for the procedure and assess renal anatomy, so as to establish a safe access route. The patient’s current physical status and presence of any comorbidities are thoroughly assessed as they may affect the risk of developing complications following the procedure.

Haemoglobin (Hb), platelet and INR (International Normalised Ratio) levels are pre-assessed. Informed consent is obtained to undergo the procedure. The patient should adequately fast.

Technique

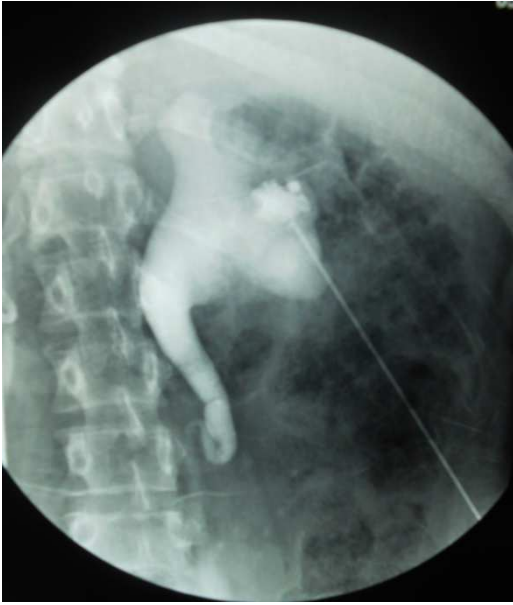
In relation to the side that is being intervened, the patient is positioned 30° prone oblique cleaned and draped, the puncture site and tract ideally should be below the twelfth rib, to minimize the risk of intra thoracic complications, is infiltrated with 1% plain lignocaine. The kidney is first visualised with U/S such that the lower, mid and upper pole posterior calyces are in the field of view. A small stab incision is made at the site of the puncture and if the target calyx is well visualised, an 18 gauge trocar needle or 21-gauge Chiba needle can be used to make the puncture, entering the skin at an angle of 20-30 degrees to the saggital plane and ideally traversing the renal fornix to enter acalyx.

Once the needle is inserted into the calyx, urine drains out spontaneously or is aspirated with a disposable syringe and a sample is sent to the laboratory for culture and sensitivity and this also assists in decompressing the system. Under fluoroscopic guidance contrast equal in amount to the aspirate is used to opacify the collecting system and confirm puncture of an appropriate calyx .

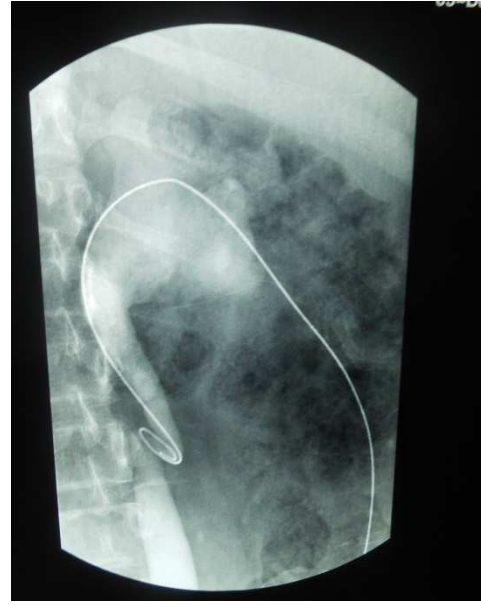
A stiff 0.035-inch guide wire can be advanced through the 18-gauge needle and guided into the proximal ureter or upper pole calyx. Once the wire is appropriately positioned, the tract is then gradually dilated with Teflon dilators up to 2Fr more than the diameter of the nephrostomy tube.

After tract dilatation, an 8Fr or 10Fr pig tail nephrostomy tube is passed over the guide wire into the renal pelvis and once its confirmed to be in the correct position the nephrostomy tube is anchored securely on the skin using 2/0 nylon suture.

STAGES OF NEPHROSTOMY TUBE PLACEMENT



Lower pole puncture and opacification of renal tract .



Introduction of the guidewire(0.035 inch) through the needle into the renal pelvis distally.



8Fr pig tail is threaded over the 0.035 inch guide wire and secured in place.



(Diagnostic Imaging Department, KNH, Nairobi Courtesy of Dr Mugambi)

7.2.3 Complications (12, 13)

Minor complications

These complications occur in relation to the procedure. They are of no clinical consequence and can be managed conservatively. They include:

- Transient haematuria.
- Perinephric hematoma.
- Catheter kinking, obstruction or dislodgement.
- Urine leaks.
- Fever.
- Pain.
- Contrast extravasation.

Major complications

These complications do require urgent intervention or hospitalization. They include:

- Haemorrhage, especially intraperitoneal, this can lead to haemorrhagic shock.
- Sepsis.
- Pleural complications; haemothorax or pneumothorax .
- Bowel perforation.
- Intra-abdominal visceral injury

- Death can occur in severe complications.

7.2.4 Review of Studies on Percutaneous Nephrostomy in Malignant Ureteric Obstruction

Large number of studies that have been reviewed on PCN are mainly retrospective and have generally small sample sizes. The scope of the data analysed was defined either in terms of survival benefit or quality of life.

Grabastald and Mcphee in their study defined quality of life as having fulfilled the following main criterias (14):

1. A minimum of 8 weeks at home with minimal or no pain.
2. Few complications related to PCN insertion.
3. Satisfactory mental status.

However renal function improvement is mentioned as an important factor that contributes to the quality of life by Jalbani MH, Deenari RA, Dholia KR ...et al in their study on the role of percutaneous nephrostomy in malignant ureteral obstruction, which showed that this is a variable that contributes to the quality of life (15) .

The critical length of time a kidney can withstand obstruction, and recover its renal function after relief of the ureteric obstruction, was studied by Pridgren WR, Woodhead DM and Younger RK, using kidneys of healthy mongrels as study subjects, in 1966 (16). This study showed that recovery of renal function depended on the duration and the extent of the obstruction. Extrapolating these findings, this can be applied to the human renal system, where the extent and duration of ureteric obstruction would determine the recovery of the renal function.

Later in 2006, this was shown to be true by G.Sood, A.Sood, A. Jidal et al... in a prospective study that showed renal fuction compromise was in direct proportion to the duration of the ureteric obstruction (17). In time the ureteric obstruction leads to irreversible renal damage. In this study it was observed that patients who presented early benefitted from PCN placement, with notable change in their renal biochemical parameters, while those who presented late in the course of the disease, renal function

could not be recovered due to irreversible damage, In this study 29 (58%) of the malignant cases only 6 patients showed definite improvement.

Similar observations were shown in another study by Samarsinghe UC, Perera ND in Sri Lanka. All patients with terminal malignancies who had chronic ureteric obstruction, did not show any improvement in renal function assessment post PCN, as a result of irreversible renal damage due to the chronic obstruction (18).

In view of this Malik Hussain, Rajib Deenari, Kheo Dholia et al... confirmed similar findings in another prospective study (15), In this study 75% of the patients who presented in early stages of disease and their malignancies were urogenital in origin showed significant improvement in renal function. Out of these, 62.5% their blood urea and serum creatinine levels gradually decreased to normal levels. However those who were in advanced stages or those who had non urogenital malignancies, showed a poor outcome. This may have possibly been due to the advanced primary disease before it caused obstruction of the ureter. Hence there was no change in renal function post PCN placement.

Muhammad Naeem, Mir Alam, Anayat Ullah et al... in 2011, demonstrated similar findings, in 200 patients. Majority of the patients, 188 (94%) showed notable improvement in both clinical and renal biochemical parameters post PCN insertion. The rest of the 12 patients (6%), who had End Stage Renal Disease showed no renal function improvement after a period of two months, and had to be referred further for dialysis (19).

Pappas P, Stravodimos KG, Mitropoulos D et al reported high success rates of 99% in renal decompression in patients with malignant obstructive nephropathy following PCN (20). The mean urea and creatinine concentrations, showed a significant decline, 15 days post procedure (mean drop creatinine from 160.6 mg/ml to 63 mg/ml and urea from 6.9 mg/dl to 2.2 mg/dl respectively). There was normalisation of renal function in 66% of the patients, within the same period. One of the conclusions from this study was that PCN proved to be a useful procedure that can be used to assess the recoverable functions of an obstructed kidney.

In another retrospective study, Chapman M.E and Reid J.H, observed that there was improved renal function in 88% of their patients with malignant ureteric obstruction, with normalization of blood urea and creatinine levels within 10 days post PCN placement (21). In this study they also evaluated benefits of single or bilateral nephrostomy tubes. There was no significant difference observed, in the time to achieve the renal function improvement in the two groups of patients. In conclusion there was no significant benefit in renal function improvement by use of either bilateral or unilateral tubal insertion.

Similar findings were shown in another study by J Nariculam, D G Murphy, N Sellars et al.....(22). In this study patients with bilateral ureteric obstruction and acute renal failure due to advanced prostate cancer, the mean creatinine levels post PCN showed no significant difference whether one or two nephrostomy tubes had been inserted. Despite the improvements in renal function parameters in these patients post tubal insertion, survival depended on the aggressive nature of the disease and not on the number of nephrostomies inserted.

Despite the advantages of PCN in restoring or improving renal function parameters, it is a temporary measure. The underlying obstruction may not be treatable but can be amenable to palliative urinary diversion. This however should be individualised, factors such as the stage of the primary tumor, presence of metastasis and the period from diagnosis to the diversion should not play a significant role in deciding whether a patient should benefit from diversion(23, 24).

Watkinson AF, A Hern RP, Jones A et al.....(25) in a retrospective study in 1993, concluded that for PCN to be performed in patients with abdominal-pelvic malignancies, it should involve an accurate evaluation of the type of the tumor and the stage, as well as in the patients management, there should be an intention of treating the primary disease. Thus it would be legitimate to refuse to perform a nephrostomy in patients who have no available treatment options. This would specifically be in the interest of the patient and also prevent wastage of the hospitals resources.

Consistent with the above observations, Dr Kamlesh Misra in his case study (26), concluded that by correcting deranged renal function via PCN (significant fall of serum creatinine from 7.5 to 0.9 mg was noted) it enables patients to undergo further therapeutic management such as: chemotherapy, radiotherapy, surgery, and all in all this may improve the patients outcomes(2, 15, 26). Consequently there is a need to properly outline the role of PCN in the management of malignant obstructive uropathy in a more precise manner in terms of either survival benefit or quality of life improvement by more large randomized sample sized prospective studies.

7.3 STUDY OBJECTIVES

7.3.1 Primary Objective

To assess the renal function improvement (pre and post blood urea and serum creatinine levels) among patients with malignant obstructive uropathy after successful PCN insertion. The effect of improvement in quality of life was not evaluated, since it was not one of the objectives of this study.

7.3.2 Secondary objective

To determine factors associated with renal function improvement following PCN insertion. These are; Type of obstruction whether intrinsic or extrinsic and level of obstruction; Age; Gender; Duration of obstruction; Any associated management procedure for example radiotherapy, chemotherapy or surgery, other associated comorbidities for example hypertension or diabetes mellitus.

7.4 STUDY RATIONALE AND JUSTIFICATION

Despite the documented evidence of improved renal function post PCN insertion in obstructive uropathy secondary to pelvic malignancies, few studies have been done in Africa and currently to the best of my knowledge no study has been done in Kenya to document the same.

The study is therefore designed to assess the improvement in renal function in patients with pelvic malignancies who have undergone PCN in Kenyatta National Hospital due to obstructive uropathy. The study will provide a basis for the expansion of the procedure in the palliative management of malignant ureteric obstruction in our set-up and also form a base line for further studies on the survival benefit and quality of life improvement post PCN insertion.

7.5 RESEARCH QUESTION

1. Is there any improvement in renal function in regard to serum creatinine and blood urea levels post PCN insertion in patients with obstructive uropathy secondary to pelvic malignancies?

8 STUDY DESIGN AND METHODOLOGY

8.1 Study site and design

This was a descriptive retrospective study, conducted at the Angiography unit in the Radiology Department at KNH, between October and December, 2014

8.2 Study population

Study participants were identified from the Angiography Unit registers as those who had undergone PCN placement within the last two years i.e January 2013 to December 2014 due to obstructive uropathy secondary to malignant ureteric obstruction. A participant list was drawn up and used to create a link log. Medical records were consecutively sampled for all the patients who had undergone PCN placement within the two year period.

The need for PCN placement as evaluated from the patients file was purely a sole decision of the attending physician, in consultation with the interventional radiologist, in view of the patients' clinical condition and high urea and creatinine levels.

Only improvement in the urea/creatinine levels, were evaluated. Other factors such as quality of life and longevity were beyond the scope of this study.

8.3 Sampling and sample size

The following sample size formula (27) was applied :

$$n = \left(\frac{SD}{SE} \right)^2$$
$$n = \left(\frac{3.71}{0.525} \right)^2$$

n = 50 records

Where :

n = sampe size

SD = standard deviation

SE = standard error

Based on assessment of sample sizes from various studies on the effect of PCN in malignant pelvic obstructive uropathy, a minimum sample size of 55 records was sufficient to estimate the post insertion Urea and Creatinine levels of patients who had undergone PCN at KNH with a 95% level of confidence.

It was anticipated that 10% of the records may have had incomplete information, thus this was adjusted by sampling a total of 55 records.

Medical records were consecutively sampled from the Angiography Unit in the Radiology Department until the sample size was attained.

8.4 Inclusion criteria

All patients with diagnosis of pelvic malignancies such as cancer of the cervix, cancer of the ovary, endometrial carcinoma, prostate cancer, cancer of the urinary bladder, colorectal carcinoma, retroperitoneal tumors and others, with secondary obstructive uropathy judged by ultrasound findings of hydronephrosis and hydroureter, associated with high serum creatinine and BUN levels who have undergone PCN placement within the last two years.

8.5 Exclusion criteria

- Patients undergoing repeat PCN placement because we could not determine the reasons for failure in the first attempt and effects of renal improvement when the catheter was insitu..
- Patients with no pre or post procedure renal function assesment tests.
- Patients having PCN sited for benign clinical reasons (e.g obstructing ureteric calculi or pelvo-ureteric kink, iatrogenic following pelvic/ureteric surgical procedures).

9 DATA MANAGEMENT

9.1 DATA COLLECTION

Data abstractions from the eligible medical records were conducted by the principal investigator and the trained assistants. The following data was collected from the patient registers: social demographic data (age and sex), primary diagnosis (histological reports that were available in the patients file) and prior imaging studies (e.g renal ultrasound) to confirm obstruction. Laboratory tests - serum creatinine and blood urea - were verified from the patients' files and documented on a data abstraction form. Files of patients who had died were also collected, if they had satisfied the inclusion criteria.

9.2 DATA ANALYSIS

All data abstraction forms identified with an inpatient number were entered into an MS Excel database and analysed using the Statistical Package for Social Scientists (SPSS™) version 22.

9.2.1 Descriptive analysis;

Descriptive analysis of data obtained from the study was summarized and presented in the form of proportions and measures of central tendencies (mean or median). Descriptive data such as Demographic data, primary malignancy, duration of renal obstruction prior to PCN placement, other associated co-morbidities, prior radiological investigations to diagnose hydronephrosis i.e U/S/IVU/CT, prior therapeutic management i.e surgery or radiotherapy, biochemical parameters i.e blood urea and serum creatinine pre and post PCN insertion, were presented in tabular and graphical format.

A linear relationship between the creatinine and urea levels and the duration of renal obstruction was determined using the Pearson correlation (r) test. Associations between categorical data was determined using the Pearsons chi-square test, and those that were statistically significant (<0.05) were modelled using the binary logistic regression to determine the strength of their association.

9.3 ETHICAL CONSIDERATIONS

- Kenyatta National Hospital ethical and research committee approved the research.
- The patient's personal information e.g. names were not used in the study in order to uphold confidentiality.
- The study commenced after approval by the ethical and research committee.
- Confidentiality and care was upheld when handling the patient's files.
- Information acquired was used for the intended purpose.

9.4 RESULTS

A total of 150 files were reviewed and 72 eligible patient files who met the inclusion criteria, were enrolled into this study. Table 1. below illustrates the patient demographic and clinical characteristics.

Table 1: Participant demographic and clinical characteristics (n=72)

| Participant characteristics | N(%) |
|------------------------------------|-------------|
| Age groups | |
| 20-30 years | 1(2.3%) |
| 31-40 years | 20 (28.6%) |
| 41-50 years | 28 (40%) |
| 51-60 years | 16 (22.9%) |
| Above 60 years | 4 (5.7%) |
| Type of malignancy | |
| Ovarian tumors | 2 (3%) |
| Cancer of the cervix | 68 (94%) |
| Cancer of the urinary bladder | 2(3%) |

The average age of the study subjects was 47.4 years (SD =10.3 years).

9.4.1 Radiological investigations to diagnose hydronephrosis.

Table 2: radiological investigations (n=72)

| Radiological investigation | n(%) |
|-----------------------------------|-------------|
| Ultra sound | 66 (91.7%) |
| CT scan | 6 (8.3%) |

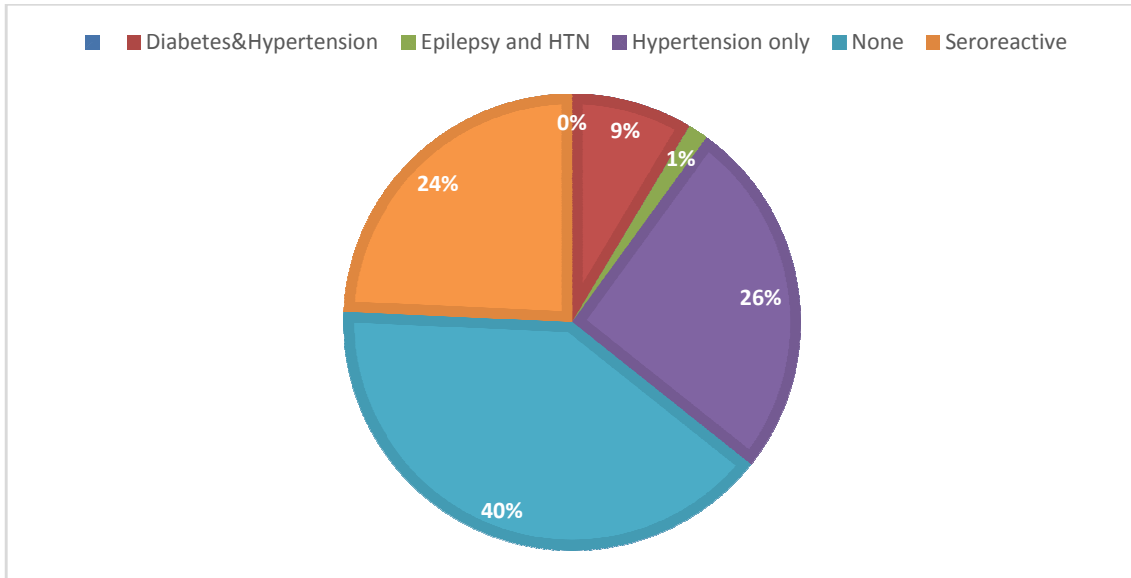


Figure 1: Reported co-morbidities

The most common form of therapy that patients underwent pre and post PCN insertion was radiotherapy compared to other forms of therapy (figure 2).

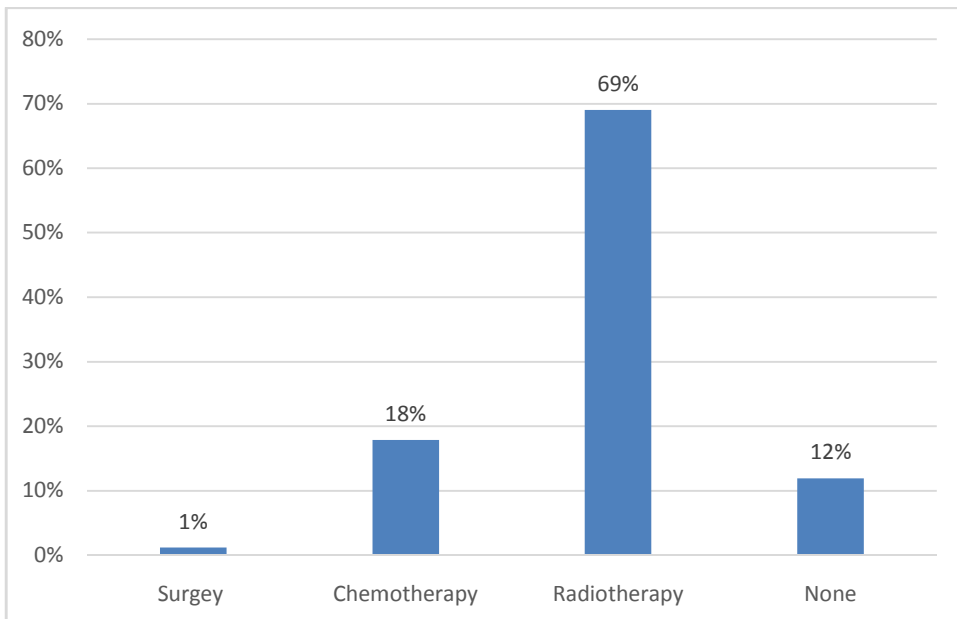


Figure 2: Forms of therapy that patients underwent

The median age of the time taken before PCN insertion was 14 days (Range of 1 to 120 days).

9.4.2 Comparison of pre and post PCN means of urea and creatinine.

Table 3: Mean differences between the urea and creatinine levels pre and post PCN in the same individuals (n=72)

| | Pre-PCN mean (SD) | Post PCN mean (SD) | Difference in mean | P value |
|-------------------|---------------------------|---------------------------|--------------------|---------|
| Creatinine levels | 762.9(581.8)umol/L | 400.5(379.2)umol/L | 362.4mmol/L | <0.0001 |
| Urea levels | 31.9 (63.1)mmol/L | 19.3 (12.3)mmol/L | 122.6mmol/L | 0.1043 |

Notes:
 The paired t test was applied to determine the means of the creatinine and urea levels in the same individuals
 Creatinine and urea levels were the dependent variables. Pre/post PCN variables were the independent variables .
 A p-value of less than 0.05 was considered statistically significant.

(Normal levels: Creatinine- Males- 71-124 umol/L, Females 53-97umol/L.

Urea- 1.7-8.3 mmol/L)

9.4.3 Correlation between duration before PCN and urea and creatinine levels.

Table 4: Pearson correlation between duration of before PCN and urea and creatinine levels

| | Pearson co-relation (r) | p-value |
|---------------------------------|-------------------------|---------|
| Cervical cancer pre-creatinine | -0.039 | 0.748 |
| Cervical cancer post-creatinine | 0.039 | 0.752 |
| Cervical cancer pre-urea | -0.094 | 0.443 |
| Cervical cancer post-urea | 0.012 | 0.921 |

Nephrostomy

Fifty four (75%) of the patients underwent bilateral nephrostomy and 18 (25%) underwent unilateral nephrostomy. The decision for a unilateral or bilateral insertion was determined by the interventional radiologist, depending on the side with worse hydronephrotic features on imaging and as was indicated in the patients notes and also the cost of the tubes.

9.4.4 Differences between the urea and creatinine levels among patients who underwent bilateral and unilateral nephrostomies

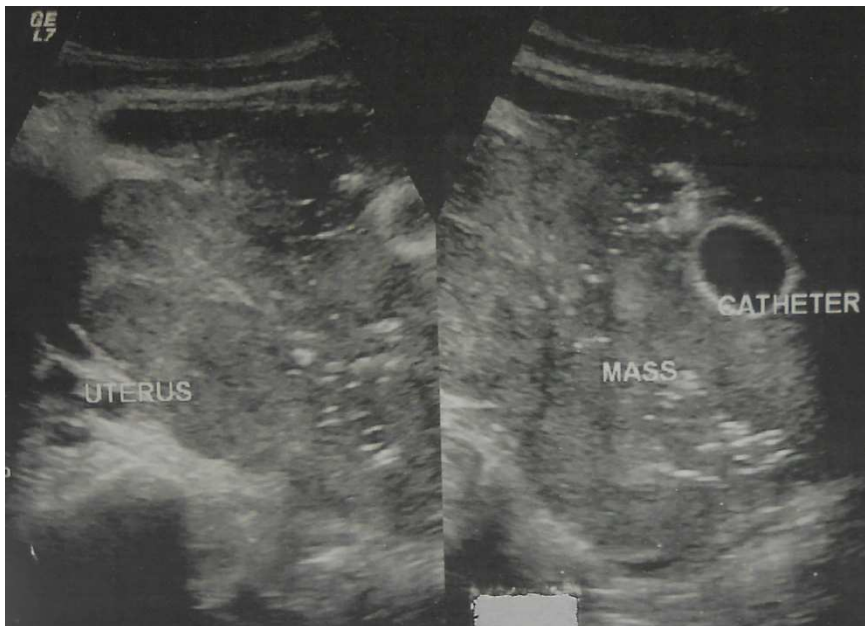
The Mann-Whitney U test was applied to test the difference in medians between the pre and post creatinine and urea levels among patients who underwent the two different forms of nephrostomy as illustrated in the table 5 below.

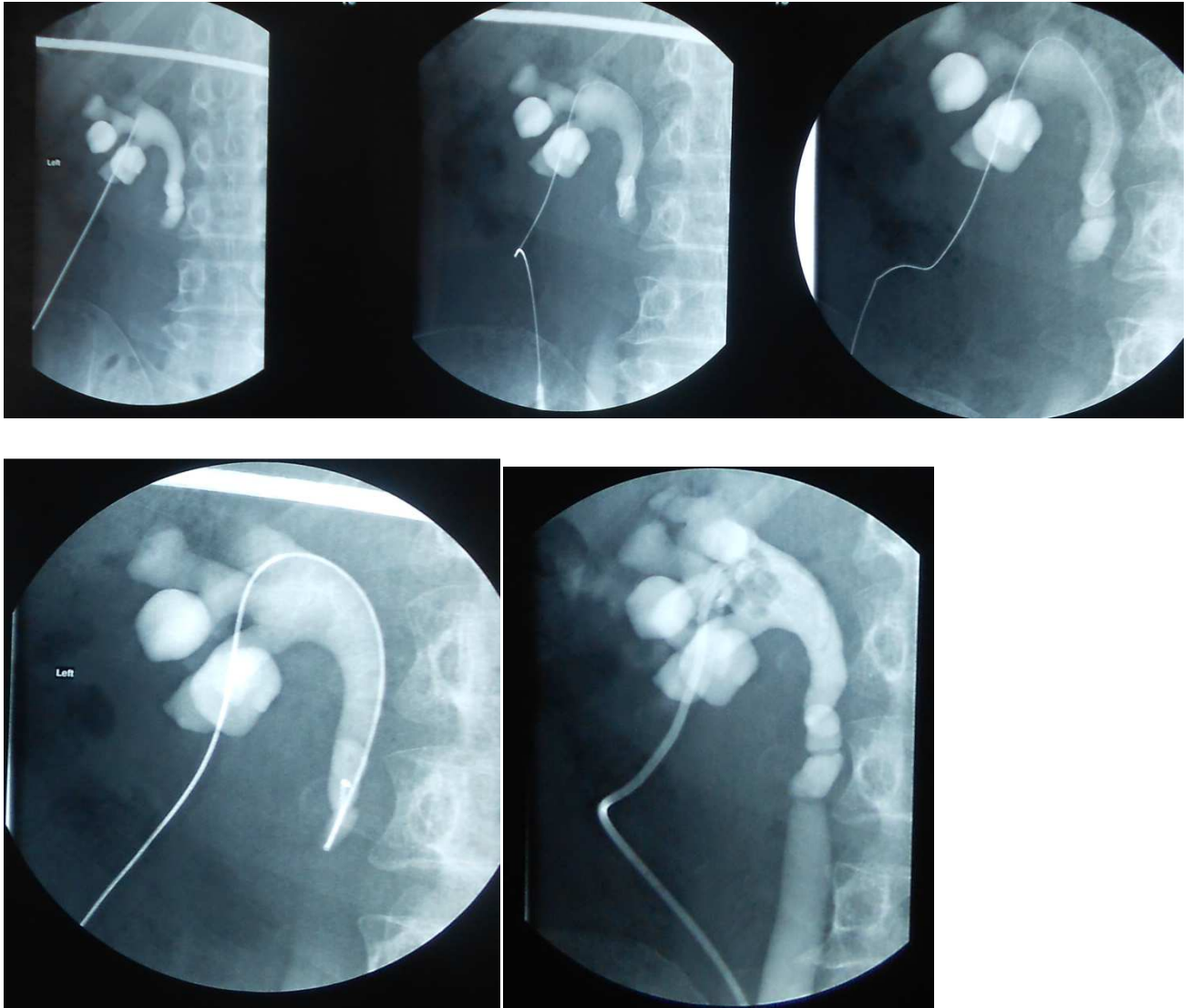
Table 5: Differences between the urea and creatinine levels among patients who underwent bilateral and unilateral nephrostomies

| Nephrostomy | | Median levels | p-value |
|-------------|-----------------|---------------|---------|
| Unilateral | Pre-creatinine | 379.5umol/L | 0.00445 |
| | Post-creatinine | 180.5umol/L | |
| | Pre-urea | 19.35mmol/L | 0.2613 |
| | Post-urea | 11.65 mmol/L | |
| Bi-lateral | Pre-creatinine | 738.5 umol/L | <0.0001 |
| | Post-creatinine | 341.5umol/L | |
| | Pre-urea | 24.3 mmol/L | 0.0023 |
| | Post-urea | 19.2 mmol/L | |
| | | | |

9.4.5 PLATES

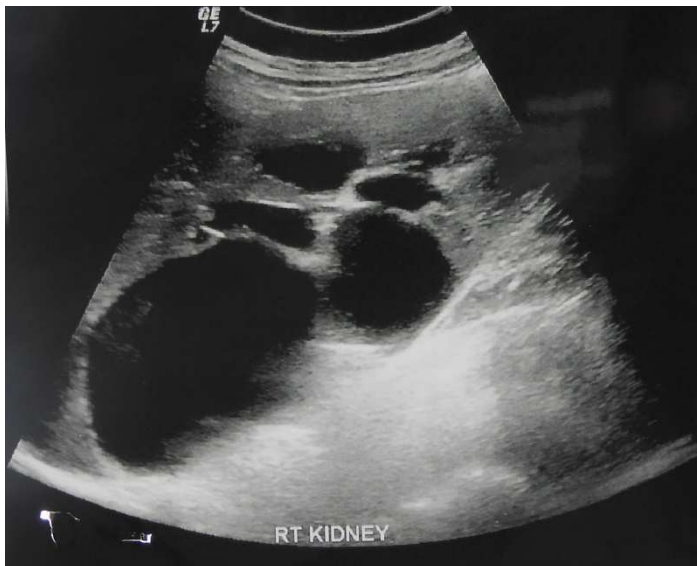
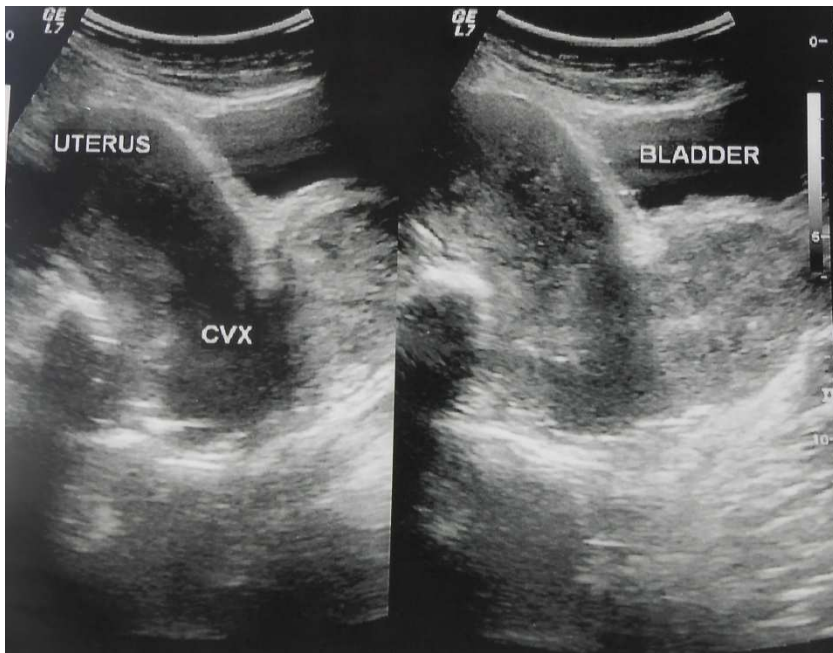
Case 1

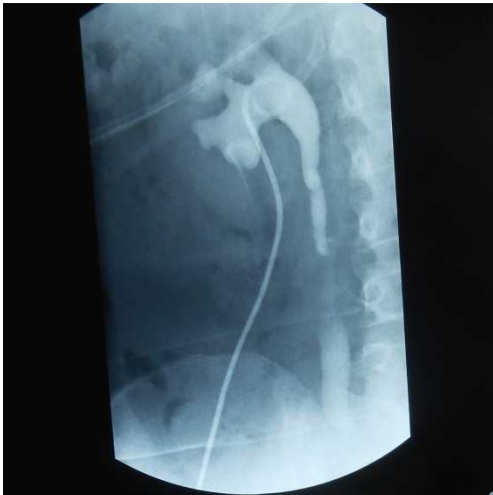




The above are images from a 32 year old female patient, who had presented with a 8 month history of per vaginal discharge, post coital bleeding, weight loss, low urine output and confusion. Clinical examination revealed a cervical mass that was later histologically proven to be cancer of the cervix stage 3a. Renal function tests revealed high creatinine and urea levels (905umol/L and 28mmol/L), abdominal/pelvic ultrasound showed bilateral hydronephrosis with a distal obstruction due to a cervical mass. Unilateral PCN was performed on the left with subsequent improvement of the renal function parameters 10 days post PCN(creatinine-492umol/L, urea-8.3mmol/L).

Case 2





27 year old sero-reactive female patient, who had presented with a 12 month history of per vaginal discharge, weight loss, seizures and chronic fatigue. Patient had been diagnosed with a cervical mass 6 months prior to presentation. EUA and histology later revealed cancer of

the cervix stage 3b. Renal function tests showed elevated creatinine and urea levels (1004 $\mu\text{mol/L}$ and 18.4mmol/L), abdominal/pelvic ultrasound showed severe bilateral hydronephrosis with a distal obstruction due to a cervical mass. Bilateral PCN were performed. Renal function parameters subsequently improved post PCN(creatinine- $184\mu\text{mol/L}$, urea- 3.76mmol/L).

(Diagnostic Imaging Department, KNH, Nairobi Courtesy of Dr Mugambi / Dr Kibaya)

10 DISCUSSION

A total of 150 files were reviewed and 72 eligible patients were enrolled into the study having fulfilled the inclusion criteria of initial PCN insertion that is having a pelvic malignancy with the presence of obstructive uropathy associated with high serum creatinine and urea levels and radiologically proven hydronephrosis. The average age of the study subjects was 47.4 years (SD =10.3 years) and there was a female predominance with 70 (97%) females and 2 (3%) male patients. The median duration of illness was reported to be 8 months; ranging from 2 to 48 months.

The commonest type of malignancy seen in this study was cancer of the cervix 68 (94%) followed by ovarian carcinoma 2 (3%) and cancer of the urinary bladder 2 (3%). Cervical cancer is the most common cancer in developing countries. In a report published in 2010, World Health Organization (WHO) estimated that cervical cancer was the second most common cancer among women in Kenya in 2008 (28), and there is an association in increased incidence in younger patients who are sero- reactive (29, 30). We found similar findings in this study as the commonest cancer in our female study subjects was cancer of the cervix at 94% with sero- reactivity being the second commonest co morbidity at 24% in this study group. In the associated co morbidities hypertension 26% preceded and a combination of hypertension and diabetes mellitus was at 14%.

In the male patients, 2 (3%) had cancer of the urinary bladder. A local retrospective study done in 1990 by Ndaguatha PL on the clinical presentation of urinary bladder cancers in Kenya, showed an incidence of 0.75% of all reported cancers at Kenyatta National Hospital (KNH), which was lower than the European and American statistics (31). In the male population, cancer of the prostate is high in our setup, with a crude hospital incidence at KNH of 76.5/100,000 as reported in 2007 by Wasike and Magoha for Prostate cancer Africa (32). Although management of obstructive uropathy secondary to advanced prostate carcinoma with PCN placement has been a source of debate over the years (33, 34), some studies have shown its benefit in short term relief of patients who present in acute renal failure (1, 21, 22). In our study it was noted from the records that most of the prostate cancer patients presented late with obstructive uropathy and in established renal failure. They were primarily managed by dialysis and no data was available to show if PCN was ever considered in the management of these patients.

Majority of the patients presented in advanced stages of their malignancies (histology results of the various carcinomas ranged from Stage 3-4) with radiotherapy being the commonest form of therapy (69%) as compared to the other forms including: chemotherapy (18%) and surgery (1%), of note 12% of the patients had no form of therapy and presented with advanced stage of the disease with uremic symptoms.

The primary imaging tool used to establish the diagnosis of hydronephrosis was ultrasound with majority of the study subjects 91.7% having had been performed one. The rest of the patients were diagnosed with CT (8.3%). On imaging all the patients had obstruction in the distal ureter and none was noted to be in the proximal ureter. As compared to the other imaging modalities ultrasound had higher usage in these patients due to the fact that it is readily available, affordable, fast and noninvasive as a first line radiological investigation in our setup.

Following PCN insertion renal biochemical parameters were assessed within 10-14 days. There was a significant decline in the mean creatinine and urea levels (from 762 to 400 $\mu\text{mol/L}$ and from 31 to 19 mmol/L), respectively. The difference in the mean creatinine levels was statistically significant ($P < 0.0001$) as compared to the urea levels. This was seen in 67 (93%) of the patients but 5 (7%) patients did not show any improvement in their renal parameters post PCN insertion (mean creatinine from 1621 to 1591 $\mu\text{mol/L}$ and urea from 48 to 42 mmol/L). This finding possibly may be attributed to a prolonged period of time before insertion post diagnosis of obstructive uropathy or late presentation (the patients had an average of 30-120 days before PCN insertion) and also the contribution of secondary confounding factors such as hypertension, diabetes and advanced age (one patient was 84 years). In majority of our patients (93%), our findings of the change in renal biochemical parameters post insertion is comparable to all other studies reviewed in the literature (1, 15, 19-21, 23, 24, 26).

For the 5 (7%) patients in our study who did not show any improvement in their renal biochemical parameters post insertion, they were further referred for dialysis. The study by Muhammad Naeem, Mir alam, Ullah A et al..... confirmed similar findings, that there was notable improvement in majority of their study subjects, but those who were declared to have End Stage Renal Disease their renal function did not drop thus they had to be referred for dialysis (19).

Not much difference was noted in the renal biochemical parameters in patients who had bilateral PCN insertions as compared to unilateral insertion. The patients with bilateral PCN had median creatinine levels from 738.5 to 341.5 $\mu\text{mol/L}$ and urea from 24.3 to 19.2 mmol/L , while in the unilateral group the difference in the median creatinine was 379.5 to 180.5 $\mu\text{mol/L}$ and urea levels from 19.3 to 11.6 mmol/L . The p values in both groups approached statistical significance but were slightly more significant in the group who had bilateral insertions. This is consistent with the findings in two other retrospective studies, whereby it was noted that there was not much significant difference in the mean creatinine levels post PCN whether one or two nephrostomy tubes are inserted (21, 22).

The known median time taken before PCN insertion from the time of diagnosis of obstructive uropathy by imaging was 14 days (Range 1 to 120 days). The patients who were in the extreme end of the time period such as 120 days come from low socio-economic status and have poor health seeking behavior, thus presenting at advanced stages of the disease with already established complications such as acute/chronic renal failure.

The cost of the procedure ranges from 20,000 to 38,000 Kenya Shillings which is out of reach for majority of the patients. This is a major factor which contributes to delays in seeking medical help and in management. Lately the hospital has started providing catheters at a subsidized cost when available. However the hospital procurement procedure in attaining the nephrostomy sets is lengthy and can take up to 4 months, or more. It becomes easier for the patients who can afford to get a prescription and acquire the tubes privately from local established suppliers. This reduces the delay in intervention, and may contribute to preserving renal function in an already compromised system.

The current study showed a weak linear correlation between the time period before insertion and the change in urea/creatinine levels. This could have been attributed to inadequate knowledge of the time period of obstruction prior to patient presentation. Despite this lapse, there was significant change in the renal function parameters post PCN that was statistically significant. This is contrary to a number of studies that showed no improvement in renal function in advanced disease despite timely intervention (15, 17, 18).

From the records ureteric stents were subsequently inserted in 4 patients in this study, whose renal function improved with PCN, in order to provide a more optimal method for long-term relief of obstruction. The low numbers of further intervention in this study is attributed to the

fact that majority of the patients could have died due to the advanced stage of the disease, or the ureter/bladder tumor invasion was beyond stenting.

10.1 Conclusion

PCN is effective as an initial palliative or temporary means of saving renal function in patients with malignant pelvic ureteric obstruction, despite the fact that it is an invasive and expensive procedure. However the procedure improves renal function and renders the patient relatively fit for further therapeutic management, thus improving the patients' outcome, and possible better quality of life. The decision for PCN insertion depends on the physician for timely referrals and thus early intervention. The physician needs to be aware of the benefits of PCN and advice the patient accordingly. The patient and family members need to know and understand the nature of the disease, its complications, especially the effects to the urinary system, the ensuing compromise to patient's wellbeing, and the available therapeutic options. The healthcare providers especially in public hospitals where the majority of the population are attended to, need to know the prevalence of malignant pelvic obstructive uropathy and make available the necessary equipment and subsidize the cost of the procedure.

10.2 Recommendations

1. There is a need to create awareness on early diagnosis of obstructive uropathy in relation to pelvic malignancies so as to prevent patients from presenting in End Stage renal disease with unsalvageable kidneys.
2. A protocol should be set up for these patients so that initial work-up should include a renal ultrasound and urea/creatinine levels.
3. Clinicians need to be aware of the availability of Percutaneous Nephrostomy and its various indications. This will ensure early referrals for a larger spectrum of conditions and better outcomes following the procedure
4. There is need for the government to subsidize the cost of the nephrostomy sets and the procedure so as to be affordable to the patients in public hospitals and also prevent delay in timely intervention.
5. There is need for a further large sample sized prospective study to assess if there is any survival benefit and improvement in the quality of life post PCN insertion in patients with advanced pelvic malignancies.

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APPENDIX

QUESTIONNAIRE: DATA COLLECTION FORM

Form No ----

Participant ID: _____ Date: ___/___/___

Age (years): _____ Sex: Male Female

Disease leading to renal obstruction:

- Ca Endometrium
- Ovarian tumors
- Ca cervix
- Ca urinary bladder
- Ca rectum

Duration of disease in months: _____

Any other co-morbidities: _____

Investigation: U/S [] IVU [] CT []

Period before PCN after diagnosis of renal obstruction: _____

Prior therapeutic management: Surgery [] Chemotherapy [] Radiotherapy []

| | Primary malignancy | Percutaneous nephrostomy | | Creatinine (mol/ml) | | Urea (mmol/ml) | |
|--|-----------------------|--------------------------|-----------|---------------------|------|----------------|------|
| | | single | bilateral | pre | post | pre | Post |
| | Ca Bladder | | | | | | |
| | Ca Prostate | | | | | | |
| | Ca Cervix | | | | | | |
| | Ca Ovary | | | | | | |
| | Colorectal | | | | | | |
| | Malignant lymphoma | | | | | | |
| | Retroperitoneal tumor | | | | | | |
| | Others | | | | | | |

Informed Consent Document for Hospital Administrators and Section Heads

Title of Research: The role of Percutaneous Nephrostomy in the management of obstructive uropathy secondary to pelvic malignancies at Kenyatta National Hospital.

Investigators: Principal investigator: Dr. Masaki Shila Moraa, Department of Diagnostic Imaging and Radiation Medicine, University of Nairobi.

Study location: Kenyatta National Hospital, Nairobi, Kenya.

Purpose of Research: To assess improvement of renal function in patients with obstructive uropathy secondary to pelvic malignancies who have undergone PCN insertion.

Description of Research: The study involves an analysis of patient records for pre and post blood urea and serum creatinine levels in patients with advanced pelvic malignancies who have undergone PCN during a specific time period due to obstructive uropathy. Data will be destroyed after a period of 2 years (at the end of the study).

Potential harm: There is a risk of breach of the of participants' privacy. However, study records will be de-identified, anonymized and stored securely in a password protected file.

Potential benefits: Results from this study will provide a basis for the expansion of the procedure in the palliative management of malignant ureteric obstruction and also form a base line for further studies on the survival, benefit and quality of life improvement post PCN insertion.

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Confidentiality: The records will remain anonymous, access to research data will be restricted, as hard copies of records will be stored in locked cabinets while soft copies will be encrypted and password protected.

Reimbursements: None

Contacts: For any concerns about the study contact Dr. Masaki Shila Moraa, DDIRM, University of Nairobi, P.O. Box 300197 Nairobi: Telephone Number +254722936230. Email address: masakishila@yahoo.com

Should you have any questions pertaining to your rights as a research participant, kindly contact, The Secretary to the KNH/UON Ethics Review Committee, P.O. Box20723, Nairobi.

Informed Consent Form

This study is an analysis of renal function improvement in patients who have undergone PCN placement due to obstructive uropathy secondary to advanced pelvic malignancies at KNH. Should you agree for this review to be conducted at your facility, you will be asked to allow the researcher access to patient records and images at your angiography unit in the radiology department as well as the medical records department.

All data collected will be coded in order to protect patients' identities, if applicable. Only the research study staff will have access to the information. At the end of the study, there will be no way to link patients' names with their data (where applicable).

Your facility/institution is free to withdraw or refuse to participate at any time without consequences. Should you agree to be part of this study, please sign your name below, indicating that you have read and understood the nature of the study, your responsibilities as a participating institution, the inconveniences associated with voluntary participation in the study and that all your questions and concerns concerning the study have been answered satisfactorily.

Name of hospital staff _____

Designation _____

Signature _____

Date _____

Name of Investigator _____

Signature _____

Date _____

BUDGET

| ITEM | QUANTITY | UNIT PRICE (Ksh) | TOTAL (Ksh) |
|--|------------|------------------|---------------|
| WRITING PENS | 1 BOX | 200 | 200 |
| NOTEBOOKS | 5 PIECES | 60 | 300 |
| FILES | 8 PIECES | 50 | 400 |
| PRINTING PAPER | 5 RIMS | 400 | 2000 |
| CARTRIDGE | 1 PC | 6000 | 6000 |
| INTERNET SURFING | 200 HRS | 60 | 12000 |
| FLASH DISCS | 2 PCS | 2000 | 4000 |
| PRINTING DRAFTS AND FINAL PROPOSAL | 10 COPIES | 500 | 5000 |
| PHOTOCOPIES OF QUESTIONNAIRES | 300 COPIES | 10 | 3000 |
| PHOTOCOPIES OF FINAL PROPOSAL | 6 COPIES | 100 | 600 |
| BINDING COPIES OF PROPOSAL | 6 COPIES | 60 | 360 |
| ETHICAL REVIEW FEE | 1 | 2000 | 2000 |
| SUBTOTAL | | | 35860 |
| PERSONNEL | | | |
| RESEARCH ASSISTANT | 2 | 10000 | 20000 |
| BIostatistician | 1 | 30000 | 30000 |
| SUBTOTAL | | | 50000 |
| DATA COLLECTION, DATA ANALYSIS AND THESIS DEVELOPMENT | | | |
| PRINTING OF THESIS DRAFTS | 10 COPIES | 1000 | 10000 |
| PRINTING FINAL THESIS | 6 COPIES | 1000 | 6000 |
| BINDING OF THESIS | 6 COPIES | 300 | 1800 |
| DISSEMINATION COST | | | 10000 |
| SUBTOTAL | | | 27800 |
| CONTINGENCY (10% OF TOTAL BUDGET) | | | 9266 |
| GRAND TOTAL | | | 122926 |