PERCUTANEOUS NEPHROSTOMY FOR UPPER URINARY TRACT OBSTRUCTION AT MUHIMBILI NATIONAL HOSPITAL: PATIENTS' PRESENTATION, CHALLENGES AND OUTCOME OF THE PROCEDURE

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By

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A Dissertation Proposal submitted in (Partial) fulfillment of the requirements for the Degree of Masters of Medicine in Urology

> Muhimbili University of Health and Allied Sciences. October 2021

CERTIFICATION

The undersigned certifies they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: "*Percutaneous Nephrostomy for Upper Urinary Tract Obstruction at Muhimbili National Hospital: Patients' Presentation, Challenges and Outcome of the Procedure*" in (partial) fulfillment of the requirements for the Master of Medicine in Urology of the Muhimbili University of Health and Allied Sciences (MUHAS).

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DECLARATION AND COPYRIGHT

I, Moses Mutua Francis declare that this **dissertation** is my original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

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My family has been the greatest source of inspiration throughout this period. My story would be incomplete without appreciating your special place in me. Thank you very much.

DEDICATION

This work is dedicated to my esteemed family. Elizabeth, my wife, and our beautiful daughter Marianne, I love you.

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ABBREVIATIONS

BOO	Bladder Outlet Obstruction
CBC	Complete Blood Count
СТ	Computer Tomography
DRE	Digital Rectal Examination
IR	Interventional Radiology
IV	Intravenous
LUTS	Lower Urinary Tract Symptoms
MMED	Master of Medicine
MNH	Muhimbili National Hospital
MUHAS	Muhimbili University of Health and Allied Sciences
PCN	Percutaneous Nephrostomy
PCS	Pelvicalyceal System
SPSS	Statistical Package for the Social Sciences
USG	Ultrasonography
UUO	Unlilateral Ureteric Obstruction
UUTO	Upper Urinary Tract Obstruction

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DEFENITION OF TERMS

Upper Urinary tract obstruction: Obstruction to urine flow occurring at any point from the Ureteric orifice up to the renal pelvis. It can be unilateral ureteric obstruction (UUO) or bilateral ureteric obstruction (BUO).

Percutaneous Nephrostomy: Image-guided placement of a catheter through a calyx into the renal collecting system. The collecting system can be localized by one or more cross-sectional techniques, such as ultrasonography, computed tomography (CT), or rotational fluoro-scopic acquisition (cone-beam CT).

Medical outcome: These are outcome of patients with upper urinary tract obstruction who have undergone Percutaneous nephrostomy. This can be treatment outcome either success, failure complication, treated as outpatient or inpatient, delay in reporting or treatment and investigation

ABSTRACT

Background: Upper Urinary tract obstruction is a common problem encountered by urologists, primary care physicians, and emergency medicine physicians. Percutaneous nephrostomy (PCN) is a widely used interventional procedure for upper urinary diversion and decompression of the renal collecting system in varied clinical settings. Despite it being a basic urological procedure, it remains technically challenging to perform.

Aim; This study assessed the clinical profile and characteristics of patients with upper urinary tract obstruction undergoing Percutaneous nephrostomy, including outcome and challenges related to the procedure at MNH.

Methodology: This was a retrospective cross sectional study, which was conducted at Muhimbili National Hospital from June 2020 to April 2021. Sociodemographic characteristics, Clinical presentation and underlying conditions were analysed by descriptive statistics using SPSS version 23 and then summarized into tables and figures. Categorical variables were analyzed in proportions while continuous variables were analysed into means. The means were compared by a paired t-test and a p-value of <0.05 was considered significant.

Results; The study involved 75 patients with mean age of 52.25 ± 11.74 years (33-79 years) who underwent PCN from January 2018 to June 2020. Amongst all patients 67 (89.3%) were female and 8 (10.7%) were male. The underlying conditions included cervical cancer (76%), bladder cancer (6.7%). Others were ureteric injury (5.3%), prostate cancer (4.0%), ovarian cancer (4.0%) and colorectal cancer (2.7%). Common clinical presentations were oliguria (90.7%), vomiting (77.3%) and flank pain (64%) others; were abdominal pain (44%), Confusion (30.7%) and hematuria (9.3). There was an improvement in creatinine and BUN levels, which occurred in 88% of patients after PCN. There was significant decrease in mean level of serum creatinine from 1100.02 ±73.10 µmol/l before PCN to 529.55 ± 54.46 µmol/l 2-4weeks after PCN (p < 0.01), Mean BUN dropped from 29.03 ± 1.51 mmol/l before PCN to 14.57 ± 0.91 mmol/l 2 to 4 weeks post PCN (p< 0.01). Short-term complications included tube dislodgement (40%), infection/sepsis (30.7%), pain (19%), urine leakage (8%) and tube

blockage (5.2%). Deaths occurred in 14.7% of patients within a month after PCN. Challenges reported in delivering PCN services included shortage of medical supplies and affordability of the services by patients.

Conclusion; Malignant causes of UUTO are among the commonest underlying conditions in patients undergoing PCN in our setting. Majority of patients undergoing PCN presents with early stage of kidney failure and uremia. PCN is a minimally invasive procedure for urinary diversion in UUTO with improved renal function and notable short-term complications. Inadequate medical supplies and affordability of the PCN were reported challenges.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Upper urinary tract obstruction (UUTO) is a common problem encountered by urologists, primary care physicians, and emergency medicine physicians. Obstruction can develop secondary to calculi, tumors, strictures, anatomical abnormalities, or functional abnormalities. Upper tract obstruction to urinary flow can occur at any point from the kidneys to the ureteric orifice, but certain sites are more susceptible to obstruction(1).

Causes of upper urinary obstruction in both males and females include neoplasm, trauma, strictures, valves, stones and acute inflammation. Damage to the nerves that supply the bladder, spinal cord trauma and neoplasm of the spinal cord either primary or secondary; will produce functional obstruction(2).

Urinary tract obstruction is a blockage that inhibits the flow of urine through its normal path (the urinary tract), including the kidneys, ureters, bladder, and urethra. Blockage can be complete or partial. Blockage can lead to kidney damage, kidney stones, and infection. Upper urinary tract obstruction is one of the most common conditions encountered in urological practice affecting people of all ages. Worldwide, prevalence was estimated to be around 90 million persons per year(3). In African countries, direct measures of the frequency and severity of upper urinary tract obstruction are lacking. Hence, the burden in Africa has had to be extrapolated from worldwide estimates, as is the case for many other diseases(4).

The health burden of urinary tract obstruction is high; many patients report poor quality of life and high cost of care, hence becoming hard to afford(5). With delayed or absent treatment through urinary diversion by PCN or otherwise, irreversible changes in the upper tract develop, which can lead to hydroureter, megaureter, **hydronephrosis**, renal scarring due to back pressure, renal failure, and premature death from uremia(6). Both surgical and nonsurgical therapies for upper urinary tract symptoms is becoming more available globally. However, barriers continue to limit patient access to therapies in low resource environments preventing a meaningful impact on mortality and morbidity(7).

Percutaneous nephrostomy (PCN) is a widely used interventional procedure for upper urinary diversion and decompression of the renal collecting system in varied clinical settings. Despite being a basic urological procedure, it remains technically challenging to perform. Most of the time challenges are due to lack of exposure of the urologist/interventional radiologist to correct technique of PCN placement in a stepwise manner (8). Goodwin and his colleagues reported the first placement of percutaneous trocar (needle) nephrostomy in a hydro nephrotic kidney. Since then, many direct and wire guided methods of PCN placement have been elucidated in literature(9). PCN can be done under fluoroscopy, ultrasound (USG) or computed tomography guidance. Lack of skilled personnel, cost and availability of supplies contribute to these challenges in developing countries. Since Percutaneous Nephrostomy procedure was introduced in 2018 at MNH, a limited number of this procedure have been conducted. Furthermore, there are no studies done at MNH concerning the patient characteristics and PCN procedure, its success, complications and challenges.

1.2 Literature Review

1.2.1 Clinical indications of Percutaneous Nephrostomy

Indications for this procedure range from relieving urinary obstruction from various causes to drainage of pyonephrosis. Several studies have documented the causes of urinary obstruction in patients undergoing PCN. In a study done in Singapore, in 190 patients who underwent PCN in a 3 year period, 77.7% of them had the procedure due to urinary obstruction. A further 18.3% had the procedure due to pyonephrosis and in the remaining 4% the procedure was done for urinary diversion SIM LS (19). Other investigators in another center in Singapore investigated the cause of obstruction in patients requiring PCN. In that study majority (77%) of patients had underlying obstructing urinary calculi. Other causes of obstruction included benign strictures (9%), papillary necrosis (7%), pelvi-ureteric junction obstruction(4%) and malignant stricture (3%) (10).

Another study that involved 100 participants undergoing PCN showed 35% of obstructions resulted from stones and 29% resulted from malignancies. Among the participants with malignancies, 30% had urinary bladder cancer, 45% had cervical cancer, 12% had prostate cancer, 7% had colorectal cancer and 6% had abdominal lymphomas and retroperitoneal tumors (2).

A study done in a tertiary hospital in India showed the commonest cause of obstruction to be urolithiasis (35%) followed by benign prostatic hypertrophy in 20.1%. Among the malignant causes of obstruction, 50% were caused by carcinoma of the cervix and 20% were due to bladder malignancies(11). These results are similar to those of a study done in Cameroon; in that study 35% of obstruction was due to urolithiasis, 27% due to BPE, 12% prostate CA, 16% due to cervical cancer and 5% was due to congenital malformations (12).

In another study in Sudan, causes of obstruction in patients undergoing PCN were urolithiasis in 51% of cases, tumor invasion 26%, ureteric strictures 12.5% and pelviureteric junction obstruction in 6.7% of the cases (13).

1.2.2 Outcomes of Percutaneous Nephrostomy

Chronically obstructed kidneys often suffer from loss of function. This raises the question whether relief of the obstruction will result in improvement of renal function. Several studies have investigated this issue.

In one study 36 obstructed kidneys were studied using nuclear medicine to determine their level of function before and after release of the obstruction. In the study, 20 out of 36 renograms were found to be abnormal before the relief of the obstruction. After the release of the obstruction all the 20 kidneys showed relief in their renograms(14).

In a study investigating recovery of renal function in patients with unilateral kidney obstruction, the study sought to establish the determinants of recovery of renal function post obstruction. The results were the preoperative selective renographic GFR and renal perfusion of the obstructed kidney were the significant determinants of recovery of renal function. A pre-operative GFR of 10ml/min.1.73m² was the estimated cutoff point that determined the best recovery of renal function post release of obstruction(15).

A more recent study sought to investigate the role of renal parenchymal volume (RPV) as a determinant of recovery of renal function post relief of upper urinary tract obstruction. In this study 82 patients with unilaterally obstructed kidneys were recruited. Renal function was measured before the relief of obstruction and 12 months after the release of obstruction. The results were, patients age, sex, pre relief renal parenchymal volume and pre-GFR were independent predictors of recoverability of renal function after release of obstruction. The cut-off point of pre-RPV to predict recoverability of renal function after the relief operation was 58.2 mL(16).

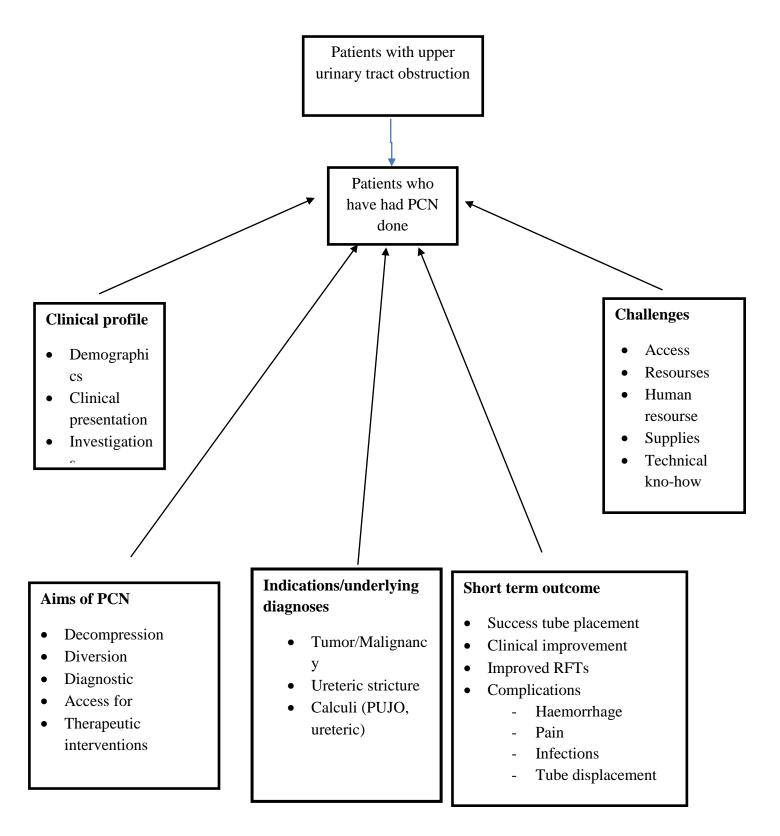
1.2.3 Complications of PCN

There are several complications associated with PCN. In a study in the United Kingdom, 66 patients undergoing emergency or elective PCN were studied. In this study three patients developed major complications which were septic shock in two patients and hemorrhagic episode requiring blood transfusion in the third patient. Four patients had nephrostomy catheter related complications which were blockage, leaking, fracturing and kinking. A majority of the complications (71.4%) occurred when the PCN was done outside the normal working hours(17).

In another study with data collected over a 10 years period, 341 patients who had indications of PCN were studied. Three patients (0.29%) had major complications in which two patients died within 30 days following the procedure, a third patient required open surgery due to retroperitoneal bleeding. Other complications of intermediate severity were catheter displacement in 3.57% of patients, catheter occlusion in 1.73%, hematuria in 1.16% and urinary tract infection in 0.87 of the patients. A common minor complication was inflammation of skin at the site of catheter insertion in 5.3% of the patients(8).

A one center audit observed complication in 318 patients who had undergone PCN. The study observed that 10 patients (3.1%) in that cohort, had major complications among which, 5 had sepsis, 2 had hemorrhage and 3 had major pelvic injury. Sepsis was the most serious complication leading to deaths of two patients. Complications were more common in procedures done after working hours (5.7%) compared to procedures that were done during normal working hours 1.8%(18).

1.3 Conceptual Framework



1.4 Statement of the Problem

An increasing number of patients with upper urinary tract obstruction is being observed at Muhimbili National Hospital. It is often a predicament encountered by urologists and emergency medicine physicians. UUTO is commonly secondary to calculi, tumors, strictures, anatomical, or functional abnormalities. Upper tract obstruction to urinary flow can occur at any point from the ureteric orifice to the renal pelvis, but certain sites are more susceptible to obstruction(1).

Several studies have shown that percutaneous nephrostomy is a very valuable radiologic procedure for providing temporary or permanent urinary diversion of an obstructed upper urinary tract. It is so often a lifesaving procedure that it deserves to be readily available at an affordable cost to patients at least in every regional hospital (19). At Muhimbili National Hospital this procedure was introduced to cope with the increasing levels of patients presenting with upper urinary tract obstruction. Since its inception, the rate of performing the procedures is still low, owing to likely challenges of access, failure to recognize the indications, limited resources or even technical know-how among the staff. Furthermore, there are no studies that have been conducted at MNH on patients who have had the procedure done, to demonstrate the demographic variations, causes of obstruction, successes or challenges of its utilization. Therefore, this study intended to assess the clinical profile and characteristics of patients with urinary tract obstruction undergoing PCN, its success and challenges encountered at MNH.

1.5 Study rationale

This study will generate knowledge on the clinical presentation, indications, complications and challenges of PCN among patients with upper urinary tract obstruction who underwent PCN procedure at MNH. It will stimulate further research on the subject. Further, it will identify challenges; inform SOPs, and resource allocation according to needs.

1.6 Research Questions

- 1. What is the clinical profile of patients with urinary tract obstruction undergoing Percutaneous nephrostomy at MNH?
- 2. What are the short-term outcomes of patients with upper urinary tract obstruction who undergo PCN at MNH?
- 3. What are the challenges faced by clinicians in performing PCN at MNH?

1.7 Research objectives

1.7.1 Broad Objectives

To **establish** the clinical profile, outcome and challenges of patients with upper urinary tract obstruction undergoing PCN at MNH

1.7.2 Specific Objectives

- 1. To establish the clinical profile of patients with upper urinary tract obstruction undergoing PCN.
- 2. To establish the short-term outcome of patients with upper urinary tract obstruction who have undergone PCN.
- 3. To determine the challenges of performing PCN at MNH

CHAPTER TWO

2.0 METHODOLOGY

2.1 Study design

This study was a Cross-sectional retrospective study where patients' files who underwent PCN between February, 2018 and December 2020 and met the criteria for this study were traced then clinical details in period of 4 weeks post stent placement were recorded.

Percutaneous nephrostomy tube insertion was either performed by an experienced interventional radiologist or a supervised trainee. As a primary procedure, PCN tubes were successfully inserted in all patients. In a well prepared and worked out patient, the degree of hydronephrosis was initially assessed. Then the puncture site determined under ultrasound guidance and with the patient in prone position. In most of the cases, to avoid vascular injury, percutaneous access through posterior, lower pole calyx was preferred. Access was done using a 21G micro puncture needle and into the selected calyx. If there was a return of urine following withdrawal, then the access was considered successful. The renal collecting system was then visualized via injection of 5-10 mL of iodinated contrast medium (Omnipaque 240 mg/mL). A guidewire was then inserted, followed by dilatation of the tract and then an 8F PCN catheter was placed over the guidewire under fluoroscopic guidance into the renal pelvis. The catheters were sutured to the skin at a distance of 1–2 cm from the site of insertion then secured by locking the C-lock on the shaft of the catheter. Finally, the catheter was connected to a drainage bag with a closed system and fixed to the skin with an adhesive patch.

2.2 Study Area

The study was conducted at Muhimbili National Hospital (MNH), a tertiary facility with over 1,500 bed capacity. The hospital is located in Ilala municipality, Dar es salaam, Tanzania. Focus was on patients attended at the urology and radiology departments, in the Interventional Radiology unit which was started in 2018. The unit runs one clinic day per week where patients are followed up. There is a special procedure room with a C-arm fluoroscopic machine and an ultrasound machine where PCN and other interventional procedures are done under imaging guidance

2.3 Study Population

All patients who had upper urinary tract obstruction and had underwent PCN between February 2018 and December 2020 done at the Intervention Radiology unit of Muhimbili National Hospital.

2.4 Inclusion and Exclusion Criteria2.4.1 Inclusion Criteria

1. All patients who have PCN done at the IR unit due to upper urinary tract obstruction between February 2018 and December 2020.

2.4.2 Exclusion Criteria

- 1. Patients who had PCN done elsewhere but being followed up at MNH.
- 2. Patients who had undergone PCN at MNH whose records were missing.

2.5 Sample size

Due to low levels of PCN among patients with upper urinary tract obstruction in the reviewed literatures; a 50% prevalence will be used.

Where; Z= 1.96 (at 95 confidence interval) $\epsilon = 5\%$ n = sample size Therefore: n = Z2 P(1-P)/E2 n = 384

However, this was further adjusted because of the finite population of these cases, with a presurvey at IR unit estimated at 70 cases in 24 months

Using formula nc = n/(1+n/N)

Therefore

Adjusted Sample size = 59 patients

• Adjusting for the non-response rate of 10%, the minimum sample size of patients to be considered is 64.

2.6 Study tool and Data collection

A structured checklist was used to collect data and pre-testing was done prior to data collection to assess its validity and reliability.

Case files of patients with characteristics of interest were traced and data extraction was done using the data collection tool, Cconsultation, clinic and procedure record books' search at the IR. The checklist had parts A and B. Part A contained patients' demographic information in which details of all patients listed for PCN on a particular day was filled. These included patient's background characteristics such as age, sex, residence and date of PCN procedure. Part B is for clinical profile including the presenting symptoms and signs; loin pain, hiccups, nausea & vomiting and altered mental status. Investigations done; serum creatinine, blood nitrogen and urea, and imaging studies like ultra sound of the kidney, ureter and bladder to demonstrate upper tract obstruction. The underlying diagnosis leading to obstruction; tumor/malignancy, ureteric calculi, ureteric stricture. Mechanism of obstruction; whether luminal, intramural, or extra-luminal. Indication and short term outcomes of PCN as either successful or complicated were also recorded in the same part. Renal functions tests results were obtained from JEVA system for patients who were attending follow up clinic. Challenges faced in performing the procedure was recorded in Likert scale as determined by the clinician after a short interview. After gaining consent pretested questionnaires were distributed to health care workers at the unit and each was required answer the questions with respect to human resource status, medical supplies, access of the service by patients, cost effective and challenges in technical know-how.

2.7 Variables

Independent variables: these were patient demographics including the Age, sex, and residence. The indications; Urethral stricture, tumor/malignancy or ureteric calculi, the clinical presentation which were loin pain, nausea/vomiting, hiccups or altered mental status

Dependent variables: The investigations which were creatinine, blood nitrogen urea, and imaging studies. The mechanism of obstruction; luminal, intramural or extra-luminal compression.

2.8 Data management and analysis

Data was managed and analyzed by using SPSS program version 23. Data quality was checked on daily basis, sorted, coded and entered into the program. An association with P-value less than 0.05 was considered statistically significant. Data presentation and interpretation were in form of one variable tables, two way tables, graphs and bar charts. Sociodemographic characteristics, clinical presentation and underlying conditions were analyzed by descriptive statistics and then summarized into frequency tables and figures. Categorical variables were analyzed in proportions while continuous variables were analysed into mean or median. The means were compared by a paired t test and a p-value of <0.05 was considered significant.

Objective one; clinical profile of patients undergoing PCN procedure was analyzed by using frequency distribution with patients being stratified according to age, sex, residence, indications for procedure and clinical presentation.

Objective two; outcome of PCN procedure was analyzed by using means. Means of renal functional tests (creatinine and BUN) before and after the procedure were compared by paired t-test before and after PCN with a p-value of <0.05 considered significant difference.

Objective three; challenges of performing the PCN as determined by the clinician in likert scale was analyzed by descriptive statistics and presented in frequency.

2.9 Ethical considerations

Ethical clearance **was obtained** from the Muhimbili University of Health and Allied Sciences' Research Ethics and Publication Committee. Permission to undertake the study at Muhimbili

National Hospital (MNH) **was obtained** from Teaching, Research and Consultancy Unit under the Executive Director.

High level of confidentiality was maintained; patients' names were not used, only registration numbers were recorded during data collection or analysis to ensure confidentiality. Consent was not sought from study participants since there were no direct interviews. Instead, the designed checklist was used to extract information from the theatre list. Therefore, this study was not expected to cause harm in anyway to study participants. The access to participants' information **was l**imited to the principal researcher only.

2.10 Study limitations and mitigation

2.10.21 Study limitations

- 1. Incomplete data from patients' case files considering the fact it was a retrospective study.
- 2. Short time follow up (4 weeks after the procedure)
- 3. The study was based on a single hospital

2.10.2 Mitigation.

- 1. Information was sought from the JEEVA software for missing data from the patients' files
- 2. Patient whose information on a particular variable was incomplete was excluded in the study.

CHAPTER THREE

3.0 RESULTS

3.1 Demographic characteristics

A total of 75 cases were included in this study, aged between 33 and 79 years and mean age of 52.25 ± 11.74 . Amongst the cases, 67 (89.3%) were female while 8 (10.7%) were male. Forty-four (58.7%) were living outside the city of Dar es salaam whereas 31 (41.3%) lived within the city.

Variable	n (%)	
Age (years)		
30-39	13 (17.3)	
40-49	21 (28.0)	
50-59	16 (21.3)	
60-69	18 (24.0)	
70-79	7 (9.3)	
Mean age (33-79)	52.25±11.74	
Sex		
Male	8 (10.7)	
Female	67 (89.3)	
Residence		
Within Dar es Salaam	31 (41.3)	
Outside Dar es Salaam	44 (58.7)	

Table 1: Demographic characteristics of patients who underwent PCN

3.2 Clinical presentation and indication of PCN

The indications for PCN was obstructive uropathy of which they had to undergo PCN for urinary diversion. The commonest underlying diagnosis was cervical cancer at 76% of all patients followed by bladder cancer in 6.7% and 5.3% had ureteric injury; other underlying conditions are given in table 2. Of all patients who underwent percutaneous nephrostomy, majority (90.7%) presented with oliguria followed by vomiting at 77.3% of patients and 64% presented with flank pain.

Prior to PCN the mean serum creatinine and BUN levels where $1100.02 \pm 73.10 \mu mol/L$ and $29.03 \pm 1.51 mmol/L$ respectively. On imaging, 94.7% of patients had done KUB ultrasound of which 81.7% had moderate hydronephrosis and 7 patients (9.3%) had done abdominal CT which showed moderate hydronephrosis in 6 patients and severe in one patient. On combining both USS and CT-scan findings, 81.3% had moderate hydronephrosis whereas 18.7% had severe hydronephrosis, none had mild hydronephrosis. table 2.

Variable	n (%)
Clinical indications	
Cervical cancer	57 (76)
Prostate cancer	3 (4.0)
Bladder cancer	5 (6.7)
Colorectal cancer	2 (2.7)
Ureteric injury	4(5.3)
Endometrial cancer	1 (1.3)
Ovarian cancer	3 (4.0)
Presenting symptoms	
Abdominal pain	33 (44.0)
Oliguria	68 (90.7)
Flank pain	48 (64.0)
Vomiting	58 (77.3)
Confusion	23 (30.7)
Hematuria	7 (9.3)
PV bleeding	36 (48)
Renal function tests (before PCN)	
Mean serum creatinine levels (µmol/L)	1100.02 ± 633.08
Mean serum BUN levels (mmol/L)	29.03 ± 13.07
KUB USS/CT degree of Hydronephrosis	
Moderate hydronephrosis	61 (81.3)
Severe hydronephrosis	14 (18.7)

Table 2: Clinical indications and presentation of PCN

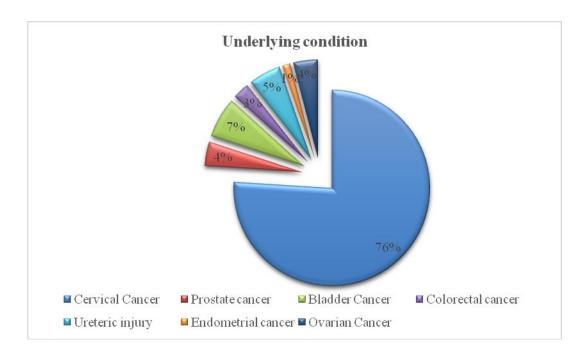


Figure 1: Pie chart showing indications for PCN among patients 3.3 Outcome of PCN

Post PCN; the mean serum creatinine levels dropped to $1022.82 \pm 73.10 \mu mol/L$ within 48 hours after the procedure, $747.19 \pm 57.18 \mu mol/L$ between 48hours and 2 weeks after the procedure and $529.55 \pm 54.46 \mu mol/L$ in 2 to 4 weeks after PCN. Serum urea dropped to $26.87 \pm 1.51 \text{ mmol/L}$ within 48 hours after PCN, $21.67 \pm 1.49 \text{ mmol/L}$ between 48 hours and 2 weeks and $14.57 \pm 0.91 \text{ mmol/L}$ in 2 to 4 weeks after the procedure.

The commonest complication was tube dislodgement which occurred in 30 patients (40%) of which most of tube dislodgement occurred more than 2 weeks after the procedure, other complications included; infection (sepsis) which occurred in 30.7%, pain per stoma site (18.7%), and urinary leakage (8%) others are given in table 3. Within 4 weeks after PCN, 88% of patients had reduced serum creatinine levels from their initial levels before PCN and 94.7% had reduced serum BUN levels. There was significant difference in mean levels of creatinine and BUN levels by paired t-test within 48hrs post PCN, 48hours to 2weeks and 2weeks to 4weeks, of which in all phases there was significant drop in their levels respectively, more details given in table 4.

Variable	\leq 48 hours	48hours to 2 weeks	>2 weeks	Overall
RFTs after PCN				
Serum Creatinine (µmol/L)	1022.82 ± 73.10	747.19 ± 57.18	529.55 ± 54.46	
Serum BUN (mmol/L)	$26.87{\pm}\ 1.51$	21.67 ± 1.49	14.57 ± 0.91	
Complications				
Hemorrhage	3(3.6)	-	-	3 (3.6)
Pain	10 (13.5)	4(5.2)	-	14 (18.7)
Infection/ sepsis	3 (4)	20 (26.7)	-	23 (30.7)
Tube dislodging	3 (4)	9 (12.0)	18 (24.0)	30 (40.0)
Urine leakage	-	2 (2.8)	4 (5.2)	6 (8.0)
Tube blockage	-	-	4 (5.2)	4(5.2)
Death	-	4 (5.3)	7 (9.3)	11 (14.7)

Table 3: Renal function tests and complications of Percutaneous nephrostomy

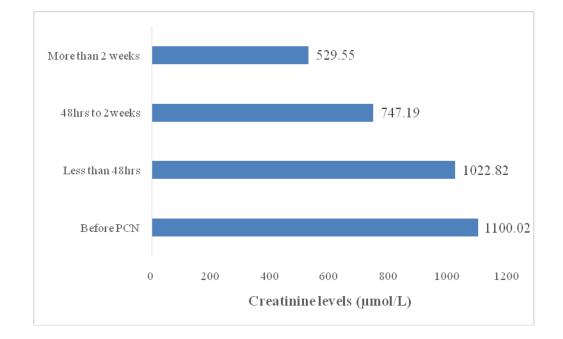


Figure 2: Bar graph showing mean creatinine level trends before and at different durations after PCN

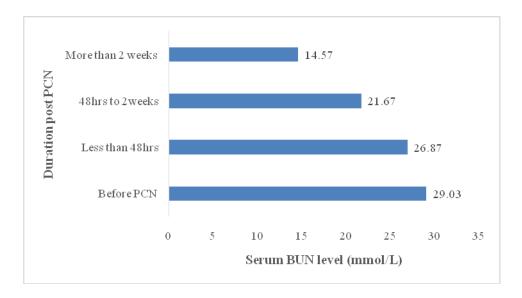


Figure 3: Bar graph with mean BUN level trends before and at different durations after PCN

Table 4: Serum Creatinine and BUN mean levels before and at different durations afterPCN

Mean differences between Serum Cr before PCN and serum Cr	Mean Difference	P-value
Within 48 hours post PCN	77.20	0.007
>48hours to 2 weeks post PCN	352.83	< 0.001
>2 weeks to 4weeks Mean differences between Serum BUN before PCN and serum BUN	570.47	<0.001
Within 48 hours post PCN	2.16	0.002
>48hours to 2 weeks post PCN	7.36	< 0.001
>2 weeks to 4weeks	14.46	< 0.001

3.4 Challenges by clinicians

A total of 10 healthcare workers from the sub-department of interventional radiology were interviewed, aged 30-41 years with mean age of 35.10 ± 3.18 years. Seven of them where male and three were female. Majority of them were radiologists (40%) by qualifications the rest being radiographers, fellow interventional radiologist, medical doctor, technologist and nurses. Six of respondents had worked for more than 2 years in the department.

Regarding challenges faced by clinicians in performing the procedure, five of the respondents reported on the scarcity in number of staffs whereas 4 of them denied the scarcity of human resource. However, all of the respondents reported a challenge on availability of medical supplies for the procedure. Seven of respondents disagreed on the patients having challenges in accessibility to the PCN procedure, whereas in terms of cost effectiveness and affordability of the PCN services 7 of respondents agreed on patients encountering such challenges. Majority (90%) of respondents reported no challenges in technical know-how or skills in performing PCN.

Variable	Number (Percentage)
Age range (years)	30-41
Mean age	35.10 ± 3.18
Sex	
Male	7 (70)
Female	3 (30)
Qualifications	
Nurse	1 (10)
Fellow IR	1 (10)
Radiographer	2 (20)
Radiologist	4 (40)
Medical doctor	1 (10)
Technologist	1 (10)
Duration of practice	
≤ 2 years	4 (40)
> 2 years	6 (60)

 Table 5: Health workers characteristics in the intervention radiology unit

Table 6: Challenges faced by health workers and patients in accessing PCN services

Variable	Frequency (%)	
Do you face challenges in terms of adequate human		
resources in performing PCN?		
Agree	5 (50)	
Disagree	4 (40)	
Neither agree nor disagree	1 (10)	
Do you face challenges in terms of medical supplies or		
equipments necessary for performing PCN?		
Agree	10 (100)	
Disagree	0 (0)	
Neither agree nor disagree	0 (0)	
Do patients have limited accessibility to undergoing		
PCN (in terms of the procedure to follow until it is		
done) ?		
Agree	3 (30)	
Disagree	7 (70)	
Neither agree nor disagree	0 (0)	
Are the costs effective and can be afforded by		
majority of patients in need of the procedure?		
Agree	7 (70)	
Disagree	2 (20)	
Neither agree nor disagree	1 (10)	
Do you face any challenges in term of technical know-		
how when performing the procedure?		
Agree	0 (0)	
Disagree	9 (90)	
Neither agree nor disagree	1 (10)	

I

CHAPTER FOUR

4.0 DISCUSSION

Among the common indications for patients to undergo Percutaneous nephrostomy is obstructive uropathy which to a large proportion is secondary to malignant causes and upper urinary tract stones. Such patients are being attended by urologists in our setting.

In this study clinical profile of patients undergoing PCN, short-term outcomes of PCN and challenges faced by clinicians involved in the procedure were assessed. The age of the patients involved in this study was between 33 and 79 with the mean age of 52.25±11.74 years, majority being female (89.3%). Of all the patients, 28% were aged between 40-49 years followed by age group 60-69 years which compised 24% of all patients. Khalaf in his study reported the mean age of 48±13 years for patients who underwent PCN, almost the same age (52-57 years) was reported in other studies(15,20). Lewis et al reported a range of 35 to 72 years(18). Few studies reported on higher proportion of female undergoing PCN as compared to male. Shuchi and his colleagues reported more than half (62%) were females similar to this study(20,21). However, in majority of studies it has been found that males outnumbered females which is different from this study(8,17,22,23). In this study female were more predominant than male, this could be associated with high prevalence of cervical cancer in our region of which majority of patients with advanced diseases have obstructive uropathy(24). On the other hand, majority of underlying condition that presented with UUTO were common in female (cervical cancer, bladder cancer, ovarian and endometrial cancers). only prostate and bladder cancers were the only cancers in male.

All of patients in the study underwent PCN for urinary diversion with majority being due to malignant causes as underlying condition. About three quarters (76%) had cervical cancer, followed by bladder cancer (6.7%) others were ureteric injury (5.3%), ovarian cancer (4%), prostate cancer (4%), colorectal cancer (2.6%) and endometrial cancer (1.3%). Such findings could be explained by high prevalence of cervical cancer as well as bladder cancer in our settings of which most of such patients present with advanced stage disease. Some of findings

are consistent with a study by Elseman and his colleagues in Sudan who found that bladder cancer comprised of 5.7% and prostate cancer by 3.8% among patients who underwent PCN(13). Shuchi et al reported cervical cancer being the most common cancer (48%) among the malignant causes followed by cancer of urinary bladder (20%), prostate (14%), colorectal (12%), ovarian (4%) and endometrial (2%)(20). Contrary to this study, majority of the studies have found non-malignant conditions such as ureteric stones, stricture, renal stones as causes of obstruction in patients undergoing PCN(8,16,23,25). There were no patients with stones neither strictures who underwent PCN in this study; this could be attributed to presence of other alternative interventions for such patients that are available which includes pyelolithotomy and ureterolithotomy. Also, considering the fact that many of patients with malignancy have obvious symptoms with non-specific symptoms in upper urinary tract stones hence subjected to misdiagnosis from the referring facilities. Ureteric strictures are rarely seen in our settings possibly with improved management of their underlying causes such as tuberculosis and schistosomiasis.

Majority of patients who had undergone PCN presented with oliguria (90.7%), vomiting (77.3%), and flank/loin pain (64%) others were abdominal pain, confusion and hematuria in lower proportions. To the best of our knowledge there are no published studies on the clinical presentation of patient undergoing PCN in both developed and developing countries however, Marie and her colleagues reported asthenia, anorexia, loin pain, vomiting edema and anuria as the common presentations among patients with obstructive uropathy(12). Barbaric et al reported azotemia, electrolyte imbalance, urosepsis with obstruction and impaired renal functional tests as emergency indications for PCN (26)

All patients in this study had deranged levels of creatinine and BUN prior to PCN with a mean a levels of 1100.02 μ mol/L and 29.03 mmol/L. These findings are consistent with a study among cervical cancer patients who underwent PCN where 96.4% had higher levels of creatinine with more than half (51.9%) of them having above 1000 μ mol/L. Similarly, 85.7% had raised BUN levels with 58.3% having levels above 30 mmol/L(27).

Out of 75 patients in this study, 81.3% had moderate hydronephrosis and 18.7% had severe hydronephrosis. Similar findings were reported by Lodh et al where 13% had mild (Grade I) hydronephrosis 68.2% had moderate hydronephrosis and 18.8% had severe hydronephrosis(25). There were conflicting results in a study by Elamin et al in which majority had severe hydronephrosis (45.2%) whereas, mild and moderate hydronephrosis occurred in 26.9% each The majority of patients in their study had ureteric stones (13).

In this study, 88% of patients had decreased serum creatinine levels within 4weeks after PCN as compared to their initial levels before PCN. Similarly, 94.7% of patients had their BUN levels decreased in 4weeks after the procedure compared to their initial levels. There was a significant difference in mean levels of creatinine and BUN levels within 48hours post PCN, 48hours to 2 weeks, and 2weeks to 4weeks after the procedure. Khalaf and his colleagues reported improvement in kidney function in 63.7% of patients after PCN while 4.3% remained stable after relief of obstruction (15). Most studies reported normalization of renal function (Creatinine and BUN) in all patients after the procedure. However, such findings are not comparable with this study since significant number of patients in such studies had normal levels before PCN compared to this study where all patients had their creatinine levels improved after PCN (28). Similar findings were reported by Shuchi et al who reported significant improvement in creatinine levels among 88% of patients (20). In a study by Yang et al who measured renal function in terms of GFR reported an increase in GFR by 57.3% whereas 39% had their GFR status deteriorated. However, this was 12 months after PCN (16).

In the literature the success rate of PCN tube placement ranges between 90% and 100% PCN has been associated with a number complications in which some may be short term complications (within a 1month after procedure) as well as long-term complications (more than a month) (12,27,29). In this study, PCN tube placement was successfully done by 100% which is comparable with other studies

The commonest complication of PCN in this study was tube dislodging which occurred in 30 (40%) patients, Similar findings were reported by Elsemani et al in Sudan in which 31.8% of patients had PCN tube dislodged(13). However most studies in developed countries report low incidences of tube dislodgement which ranges from 0.4 to 4.1% (8,25,30). Some conflicting results were reported in fewer studies. Carrafiello and his colleagues reported an incidence of 14.4% tube dislodgement whereas Turo et al reported overall PCN tube complications in 6.1% of all patients in the study (17,23). These variations could be attributed to low advancement in services provided in developing countries compared to developed countries as higher incidences were reported in low and middle income countries. In our setting, percutaneous nephrostomy under Intervention Radiology is a newly introduced intervention, which has been there for about 4 years with fewer skilled labour and faced by shortage of medical supplies to the extent that in some cases that improvisation is done. Therefore, limited experience, limited trained staff and inadequate medical supplies could be linked with high rates of tube dislodgement observed. Furthermore, patient's factors cannot be excluded; it has its own role in determining the outcome of PCN. If patients are not given proper education on how to take care of their nephrostomy tube, the chance of developing complications is higher.

The other described complication in this study was sepsis or infectious complications, which occurred in 30.7% of patients. The reviewed incidence of such complication is variable in different studies. This is due to different definitions of sepsis, septicemia, post procedural fever and septic shock which tends to describe infectious complications of PCN. Some studies have reported an incidence of septic shock between 4 and 10% with or without pyonephrosis while other studies reporting sepsis as a major complication in 0.7-3.6% patients(17,18,25,29).

The higher incidence in this study could be related to poor documentation on antibiotic prophylaxis or sepsis status before the procedure as well as septic status of patients before the procedure. Rafal et al reported that 48% of patients who develop septic shock were diagnosed with septicemia prior to PCN(17).

Pain is also common especially after the procedure. However, only fewer studies have looked into it and it has been reported to respond well to analgesics. In an experimental study by Shuchi and his colleagues; they reported an incidence of 17.4% which was the highest among all the minor complications(20). Other case reports have described pain post procedure being common; however, its exact proportion was not stated. In the current study, 18.7% of patients experienced pain after procedure similar to the findings of the study by Shuchi et al. In this study, there were limitations in availability of data and it was not documented whether pain was subjective or measured on visual scale from the patient's files. This could be the reason for deviations seen from other studies that presented pain as one of the complications of PCN.

Extravasation of urine was also among the reported complication in the current study which occurred in 6 (8%) patients and this was consistent with other studies despite its occurrence being not often reported(2). A prospective hospital based study by Elsemani reported urine leakage in 9% of patients post PCN(13). Another complication in this study was tube blockage (5.2%) whose incidences varies in different studies as some reported incidences above 15% and some less than 5%(13,20,31). Urine leakage and blockage depend on the correct choice of the tube size and availability of nephrostomy catheter. With limited medical supplies NGT have improvised in place of nephrostomy tube in our setting, which could be associated with the rate of complications seen. Moreover, patient factors together with skills and experience of the clinician cannot be ignored.

Minor bleeding post procedure is a common complication and has been regularly reported. Its incidence varies between 0.6 to 3% in most of the studies(17,18,20). In some cases, bleeding may be severe to the extent that blood transfusion is required. In the study the incidence was similar to other studies where 3.6% had bleeding post PCN within 48hours post procedure. However, none of them required transfusion. In addition, most of patients in this study had moderate and severe hydronephrosis which makes it easier to place the tube and avoid parenchymal injuries which is consistent with lower bleeding rates seen in this study.

Turo et al reported on an incidence of 13.6% deaths within 30 days after the procedure. However, it was not procedural related; rather it was secondary to septicemia prior to the procedure and underlying malignancy (17). A retrospective audit and some study reported death with prevalence of 4.3 to 10.7% secondary to the underlying disease and preexisting sepsis(12,30). In this study similar findings were reported where 14.7% of patients died within a month after the procedure this could also be attributed to advanced stage of malignancy such patients presented with rather than being related to the procedure.

Challenges faced by clinicians when providing PCN services were also assessed. One of the challenge reported was on inadequate human resource in terms of numbers which was reported by 50% of the interviewed health workers in the department responsible (Interventional Radiology) and 40% disagreed on facing that challenge. This could be attributed by the fact that department is new to the hospital and hospital management has not obtained clear data on burden of patients to the department. Another reason could be fluctuation in number of patients in which in sometimes the department is overloaded by large number of patients. To the best of my knowledge, there are no published studies that have looked into this challenge.

Another challenge was shortage of medical supplies as reported by all the respondents (100%) despite 90% of interviewed respondents denying technical know-how challenges. Such challenges could interfere with the quality of PCN services provided and there were no much details about which medical supplies were not adequate and to what extent and possibly could interfere with PCN outcome

Other challenges were accessibility and affordability of the service by the patients. More than two thirds (70%) of the respondents denied challenge of accessibility of the service to the patients. This could be supported by the fact that a large proportion of patients who underwent PCN were from out of Dar es Salaam city hence the service is accessible to people from any part of the country. On the other hand, there were reported challenges in affordability of PCN services by patients reported by 70% of respondents. This could be associated with the cost of the service offered or low economic status of the patients, hence further research is needed to study this challenge; moreover many of patients do not have health insurance which could be the contributing factor.

CHAPTER FIVE

5.0 CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

Malignant causes are among the commonest underlying conditions in patients undergoing PCN in our setting with cervical and bladder cancer being the leading causes. Majority of patients who undergo PCN present with early stage of kidney failure and uremia. PCN is a safe and minimally invasive procedure for urinary diversion in UUTO with improved renal function and notable short-term complications. Shortage of medical supplies, accessibility and affordability of the service have been identified as challenges facing clinicians and patients with regard to providing PCN. However, it is not clearly known whether they interfere with PCN outcomes.

5.2 Recommendations

- PCN is a safe with good outcome, thus it should be encouraged to be used as a palliative care for urinary diversion among patients with advanced malignant and nonmalignant obstructive uropathy of the upper urinary tract.
- 2. A prospective study to be done with thorough follow up so that details prior to the procedure, during and after the procedure are easily available
- 3. There is a need for a detailed study on challenges faced by clinicians so as to determine the extent to which they interfere with PCN outcome

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APPENDICES

Appendix I; Data collection tool one

Part A; Demographics

- a. Age_____(Years)
- b. Sex:
- c. Male
- d. Female
- e. Residential status:
 - a) Within Dar Es Salaam
 - b) Outside Dar Es Salaam

Part B; Patient characteristics

1.	PCN Date: Month Year
2.	Indication for PCN
	a) Decompression
	b) Diversion
	c) Diagnostic
	d) Access for therapeutic intervention
	Other
3.	Underlying diagnosis (Tumor, Stricture, Calculi)
	a) Benign
	If yes, what type
	b) Malignant
	If yes, what type
	c) Others (stricture, calculi)
4.	Mechanism of obstruction
	a) Luminal
	b) Intramural
	c) Extra-luminal compression

Part C; Clinical Profile

- 5. Common presenting symptoms
- a)
 b)
 c)
 d)
 e)
 6. Laboratory investigations before PCN
 - a) Serum Creatinineb) Serum BUN
 - c) Hemoglobin
- 7. Imaging
 - 1. USS KUB: Hydronephrosis;
 - a) Yes
 - b) No

Degree:

- a) Mild
- b) Moderate
- c) Severe
- 2. CT scan:

a)	Yes

b) No

Degree:

- a) Mild
- b) Moderate
- c) Severe

Other:

- 8. Laboratory investigation post PCN
 - ✓ Control Serum Creatinine level (within 48hrs):
 - ✓ Control Serum Urea Nitrogen level (within 48hrs):

Duration	48hrs to 2 weeks Post PCN	2 to 4 weeks Post PCN		
Creatinine				
BUN				

9. Complications of PCN

Complication	Yes	No	If yes, duration
Hemorrhage			
Pain			
Infection (sepsis)			
Tube dislodging			
Abscess			
Deep venous thrombosis			
Cardiac arrest			

Appendix II; Consent form for clinicians at intervention radiology unit

Greetings!,

I am Dr. Moses Mutua Francis, a third year resident pursuing master of medicine in urology of Muhimbili University of Health and Allied Science. I am hereby doing a study on clinical profile of patients undergoing percutaneous nephrostomy at Muhimbili National Hospital as partial fulfillment requariment for my master degree.

I would like to invite you to participate in my study; all the information collected from you will not be revealed to any unauthorized people neither will it display your identity. You are free to participate and stop anytime you wish from the study.

If you have questions about this study and if you need any information about your rights as a participant in this study, you can contact any of the following:

1. Dr. Bruno Sunguya,Director of Research and Publication MUHAS, P. O. Box 65001, Dar es Salaam. Tel: +255 22 2152489/03026.

 Dr. Obadia Nyongole, Head of department of Surgery, MUHAS P.O.Box 65001, Dar es Salaam.

 3. Dr. Mutua Moses F, Principal Investigator, P.O.Box 65001, Dar Es salaam Tel; +255 766 589 715
 Signature of the participant

Signature of the participant	
Signature of the investigator	Date
Signature of the investigator	Date

Appendix III; Interview form

INTERVIEW FORM;

SECTION A; Sociodemographic characteristics

- 1. Age (Years)
- 2. Sex a) Male b) Female
- 3. Qualifications.....
- 4. Number of years working under the unit (Intervention Radiology)...... (years)

SECTION B; Challenges faced by clinicians when performing PCN

To be filled by clinicians who are involved in performing PCN, for each question in the challenges section below the respondent should choose one of corresponding response by writing a tick sign ($\sqrt{}$)

	Challenges	Strongly Agree	Agree	Neither Agree nor disagree	Disagree	Strongly disagree
1.	Do you face challenges in terms of adequate human resources in performing PCN?					
2.	Do you face challenges in terms of medical supplies or equipments necessary for performing PCN?					
3.	Do patients have limited accessibility to undergoing PCN (in terms of the procedure to follow until it is done)					
4.	Are the costs effective and can be afforded by majority of patients in need of the procedure?					
5.	Do you face any challenges in term of technical know-how when performing the procedure?					