IMPACT OF PERCUTANEOUS NEPHROSTOMY ON CLINICAL OUTCOME IN ADVANCED CERVICAL CARCINOMA WITH OBSTRUCTIVE UROPATHY AT KENYATTA NATIONAL HOSPITAL FROM 2016-2019:

A DESCRIPTIVE RETROSPECTIVE COHORT STUDY

A dissertation submitted in partial fulfillment of the requirements for the award of degree of Masters of Medicine (MMed) in Obstetrics and Gynecology

University of Nairobi.

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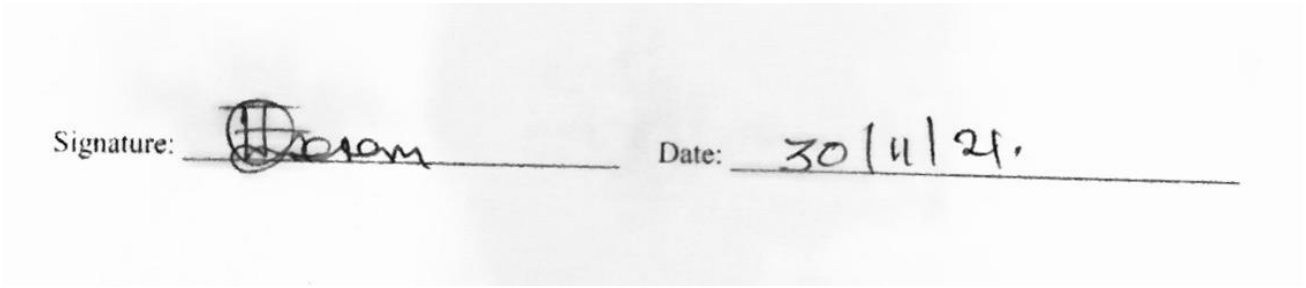

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DEDICATION

I would like to dedicate this work to my family for their understanding and support through my studies and work on this project. My mother Dr. Nelly Gacheri Mutua who crafted my path to this noble profession, I am eternally indebted, and my sister Dr. Yvonne Mukiri for the support.

LIST OF ABBREVIATIONS

ABBREVIATION	MEANING
PCN	Percutaneous Nephrostomy
FACT-Cx	Functional assessment of cancer therapy- cervix
Hb	Haemoglobin
HPV	Human Papilloma Virus
HIV	Human Immuno-deficiency Virus
HTN	Hypertension
AKI	Acute Kidney Injury
CKD	Chronic Kidney Disease
DVT	Deep Vein Thrombosis
VVF	Vesico-vaginal Fistula
RVF	Recto-vaginal Fistula
QOL	Quality of life
PWB	Physical Well Being
SWB	Social/family Well Being

EWB	Emotional Well Being
FWB	Functional Well Being
CxCs	Additional concerns
KNH	Kenyatta National Hospital
UoN	University of Nairobi
WHO	World Health Organization
GFR	Glomerular filtration rate
ERC	Ethics and Research Committee

DEFINITION OF TERMS

Quality of life: is an assessment of an individual's perception in life in context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns; with subsets such as physical well-being, social/family well-being, emotional well-being, functional well-being and additional concerns

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ABSTRACT

Introduction: Cervical carcinoma is one of the main causes of mortality with a mortality rate of 22.8% in Kenya and most frequent among women between the ages of 15 and 44 years. It can cause obstructive urinary complications, either due to local expansion or pelvic metastases. Percutaneous nephrostomy can be performed to relieve the urinary obstruction. There is limited local and regional studies on the impact the percutaneous nephrostomy has on the quality of life of the patient and the renal function of the patient. This study will use hospital data and records to evaluate survival and performance status among patients with advanced cervical carcinoma after palliative urinary diversion.

Objective: To determine the impact of percutaneous nephrostomy on the quality of life of the patient and the renal function of the patient.

Methodology: The study design was a descriptive retrospective cohort study, conducted in the gynaecological wards 1B and 1D in the Department of Obstetrics and Gynaecology at Kenyatta National Hospital (KNH) from 2016-2019. Records of the women with cervical carcinoma and obstructive uropathy, and who met the inclusion criteria, were evaluated and data relevant for the study was collected by filling a pre-coded form and entered into an MS excel database. The impact on quality of life was assessed and scored by the FACT-Cx tool, and analysed and presented as frequencies and proportions. The impact on renal functions, by assessing the change in urea/creatinine/Haemoglobin (Hb) levels before and, 72 hours, 1 month and 3 months after the procedure, was analyzed by using a paired sample t-test and presented as mean with standard deviation and with median with interquartile range.

Results: Records of 58 women who were managed in KNH between the years 2016 and 2019 for advanced cancer of the cervix and obstructed uropathy and had a PCN inserted, were retrieved and analysed. General sociodemographic and clinical characteristics were analysed further to assess the

impact of PCN in their quality of life before and after the procedure, and renal functions before, 72 hours, 1 month and 3 months after the procedure.

Insertion of PCN was found to improve the QOL (p=0.041), mainly in the aspects of PWB (p=0.018) and CxCs (p=<0.001) whereas SWB (p=0.666), EWB (p=0.454) and FWB (p=0.200) had no improvement.

Insertion of PCN improved the renal functions slightly. There was an improvement of urea levels in 62% of the patients (72 hours p=0.029; 1 month p=0.139; 3 months p=0.099). There was an improvement of creatinine levels in 64% of the patients (72 hours p=<0.001; 1 month p=<0.001; 3 months p=0.003). There was a slight improvement of Hb levels in 48% of the patients but with no statistical significance (72 hours p=0.276; 1 month p=0.555; 3 months p=0.444).

Conclusion: The insertion of PCN had minimal added value in management to women with obstructed uropathy in advanced cervical cancer as only two aspects of their QOL improved slightly, while urea and creatinine levels improved slightly before worsening and Hb levels had almost no improvement.

Recommendations: Women with advanced cervical cancer and obstructive uropathy would not benefit from the added financial cost of the insertion of a PCN. Other alternative modes of management such as dialysis in addition to chemotherapy and radiotherapy would be more beneficial to the patient.

Key words: Quality of life, cervical cancer, Percutaneous Nephrostomy

1: INTRODUCTION

Cervical carcinoma is a major cause of mortality worldwide , and even more so in developing countries with an incidence of 3.2% in 2018 worldwide[1]. In Africa, cervical cancer has an incidence rate of 20.9% and a mortality rate of 26.2%, of which 40.1% and 30.0% are in Eastern Africa[2] and 33.8% and 22.8% in Kenya[3]. Among women in Kenya, it is the 2nd most frequent cancer second to breast cancer[4], and the most prevalent among women between 15 and 44 years of age[5].

Despite achievements in the prevention and management of cervical cancer, it can progress to obstructive urinary complications as a result of metastases to the pelvis or local expansion. It can also be the result of iatrogenic injury or treatment toxicity[6]. If the obstruction is not relieved, the patient's clinical conditions will deteriorate due to uremia, water-electrolyte abnormalities, urinary infections, and subsequently death.

There is lack of consensus of the most preferable approach in management of malignant ureteral obstruction which remains unclear. One of the recognized methods for improving renal function in the obstructed urinary system for its association with low morbidity and improvement of QOL, is palliative decompression. The procedure may involve PCN, ureteric stent or a combination of both[6].

Urinary diversion performed presents with an ethical dilemma for the patients. Evidence indicates that the procedure undermines the quality of life in relation to pain and physical performance which may outweigh the benefits of the procedures to patients[9]. The limitations of inserting PCN include no improvement, lifespan limitations of nephrostomy stomas and catheters, urinary tract infection. Also, the procedure is contestably argued to prolong patient's suffering, increasing cost while offering no guarantees to improvement on quality of life. Since this procedure is a terminal intervention as a

palliative measure, the true benefit of the procedure, which is significantly invasive, needs to be well documented.

The purpose of this study is to evaluate survival and performance status after palliative urinary diversion in patients with advanced cervical carcinoma. This was done by assessing the quality of life and the changes in renal function after PCN.

2: LITERATURE REVIEW

2.1 Background

Cancer of the uterine cervix occurs from metaplastic changes of the squamocolumnar junction of the cervical epithelium. One of the most important causative factor is HPV infection, which is transmitted through unprotected penetrative intercourse or close skin-to-skin physical contact with an infected area[41]. High risk variants are HPV types 16, 18, 31 and 33; whereas low risk variants are HPV types 6, 11, 40 and 42. HPV types 16 and 18 are the most commonly isolated HPV types in cervical cancer, with type 16 found in approximately 50% of patients[42].

The diagnosis of cervical cancer is made based upon histologic evaluation of a cervical biopsy. Early clinical manifestations of cervical cancer are frequently asymptomatic, but for those with symptoms, the most common one is irregular or heavy vaginal bleeding[11]. Advanced cervical cancer is that which is from FIGO classification stage III (Figure 1).

Figure 1: 2018 FIGO classification of cervical cancer

Stage	Description
I	The carcinoma is strictly confined to the cervix (extension to the uterine corpus should be disregarded)
IA	Invasive carcinoma that can be diagnosed only by microscopy, with maximum depth of invasion <5mm[a]
IA1	Measured stromal invasion <3mm in depth
IA2	Measured stromal invasion ≥3mm and <5mm in depth
IB	Invasive carcinoma with measured deepest invasion ≥5 mm (greater than Stage IA), lesion limited to the cervix uteri[b]
IB1	Invasive carcinoma ≥ 5mm depth of stromal invasion, and < 2cm in greatest dimension
IB2	Invasive carcinoma ≥ 2cm and < 4cm in greatest dimension
IB3	Invasive carcinoma ≥ 4cm in greatest dimension
II	The carcinoma invades beyond the uterus, but has not extended onto the lower third of the vagina or to the pelvic wall
IIA	Involvement limited to the upper two-thirds of the vagina without parametrial involvement
IIA1	Invasive carcinoma < 4cm in greatest dimension
IIA2	Invasive carcinoma ≥ 4cm in greatest dimension
IIB	With parametrial involvement but not to the pelvic wall
III	The carcinoma involves the lower third of the vagina and/or extends to the pelvic wall and/or causes hydronephrosis or nonfunctioning kidney and/or involves pelvic and/or para-aortic lymph nodes[c]
IIIA	The carcinoma involves the lower third of the vagina, with no extension to the pelvic wall
IIIB	Extension to the pelvic wall and/or hydronephrosis or nonfunctioning kidney (unless known to be due to another cause)
IIIC	Involvement of pelvic and/or para-aortic lymph nodes, irrespective of tumor size and extent (with r and p notations)[c]
IIIC1	Pelvic lymph node metastasis only
IIIC2	Para-aortic lymph node metastasis
IV	The carcinoma has extended beyond the true pelvis or has involved (biopsy proven) the mucosa of the bladder or rectum. (A bullous edema, as such, does not permit a case to be allotted to Stage IV)
IVA	Spread to adjacent pelvic organs
IVB	Spread to distant organs

Reproduced from Bhatla N., Aoki D., Sharma DN., Sankaranarayanan R. Cancer of the cervix uteri. Int. J Gynecol Obstet. 2018;143(Suppl 2):22-36.
When in doubt, the lower staging should be assigned.
[a]Imaging and pathology can be used, where available, to supplement clinical findings with respect to tumor size and extent, in all stages.
[b]The involvement of vascular/lymphatic spaces does not change the staging. The lateral extent of the lesion is no longer considered.
cAdding notations of r (imaging) and p (pathology) to indicate the findings that are used to allocate the case to stage IIIC.

Obstructive uropathy is due to an obstruction of flow of urine due to obstruction in the either upper or lower urinary tracts. It could be acute or chronic, partial or complete, unilateral or bilateral. Obstruction at or distal to the renal pelvis causes diffuse caliectasis or hydronephrosis. Cervical cancer can cause obstruction due to tumor extension to the bladder and ureter, enlarged lymph nodes or metastases.

The clinical presentation depends upon the site of obstruction and the rapidity with which obstruction occurs. The obstruction presents with a myriad of symptoms, the most critical being due to the resultant uremia. Pain is frequently absent, and when present is usually as a result of bladder distension, secondary infection or obstructing masses. Generally, patients present with change in urine output, blood pressure, hematuria or increased serum creatinine. Patients with chronic obstruction often have a hyperkalemic renal tubular acidosis[12]. The diagnosis of urinary obstruction is made by imaging with the presence of hydronephrosis; which has been found to be a poor predictive factor in overall survival in cervical cancer patients[13]. The obstruction is often noted clinically though presents after signs of uremia or frank anuria manifest. Brin et al., in their study found that development of severe ureteral obstruction appeared to be a sign of an extremely late stage of disease[14], with it being most worthwhile in patients with prostatic carcinoma.

Decompression by 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.

PCN was first described by Goodwin and Casey in 1955[7]. The procedure is performed with the patient in prone, prone oblique or lateral position. Using aseptic technique and following infiltration of local anesthetic agent, the calyx is punctured with an 18-gauge, two-part needle under ultrasound guidance. A guidewire is used to exchange the needle for a dilator and an 8 French pigtail drain catheter is placed within the renal pelvis over the guidewire. Once the position of the catheter is confirmed with the use of contrast material, it is tied to the skin with suture (2-0 silk or 2-0 polypropylene) and attached to an external drainage bag.

Large number of studies that have reviewed PCN are mainly retrospective, with data defined in either terms of survival benefit or quality of life. A study by Shoshany O. et. al showed there was no clinically significant difference in patient's recovery after insertion of a ureteral stent and a PCN tube in acute ureteral obstruction[15].

In 1995 the first PCN was performed in the Department of Radiology at KNH by Millward[8], a visiting Professor from the University of Western Ontario, Canada. In the Department of Obstetrics and Gynecology at KNH, PCN is performed to patients who meet the surgical criteria. There is no definite data on the statistics; but the number of procedures done are few.

2.2 Impact on the quality of life

By definition, quality of life is rather a broad multidimensional concept, which incorporates both subjective and objective findings on patient's aspects of life. Health related quality of life and its determinants on the individual level includes the physical and mental health perceptions and their correlates- including health risks and conditions, functional status, social support, and socioeconomic status[10]. Quality of life is commonly self-reported, and interviews with the patients are commonly considered the best method to capture the patient's perceptions.

Prior studies measuring quality of life include the study by Emmert et al., 64.7% of patients had an acceptable quality of life for 2 months or more while the mean survival was 5.6 months[16]. Rasijidi et al., in their study found a 56.9% survival in the 6th month and 31.1% survival in the 12th month after undergoing percutaneous nephrostomy[17].

The QOL in this study will be assessed using FACT-Cx (appendix 1/2) which consists of the Functional Assessment of Cancer Therapy- General (FACT-G) and a cervix cancer-specific subscale. It assesses the physical well-being, social/ family well-being, emotional well-being, functional well-being and sexual well-being.

It is a universally applied measure developed and licensed by FACIT.org (Functional Assessment of Chronic Illness Therapy) and has been used in prior studies. This includes studies to determine the difference in different chemotherapy drugs. McQuellon et al., in their study found that there was no significant difference in overall QOL between treatment arms or serially[18]. Monk et al., in their study found that despite its increased toxicity, Topotectan did not significantly reduce patient QOL when compared with Cisplatin alone. They also concluded that patient reported QOL measures may be an important prognostic tool in advanced cervical cancer. It was also used in study by Santos et al., where QOL seemed to improve after radiotherapy after six months[19].

In this study, the FACT-Cx questionnaire has been translated to Kiswahili language for easy understanding to Kenyan women. There is an available licensed Kiswahili version but no journaled use in any prior study. The Chinese version was used in the study by Y. Ding et al. where it was concluded that the Chinese version of FACT-Cx covered major areas perceived as important and was regarded as easy to understand and administer and in comparison to other tools, was found it to be the best instrument for measuring health related QOL in women with cervical cancer in mainland

China[20]. The Portuguese version was used in study by Fernandes et al. where FACT-Cx was found to be a valid and reliable measurement of health status[21].

For purposes of this study, permission has been acquired from FACIT.org to use the licensed English and Kiswahili versions of FACT-Cx (Appendix VII).

2.3 Impact on renal function

Studies have shown improvement in renal function after performing PCN. This includes a study by Texeira et al., where they showed an improvement in renal parameters in majority of patients with advanced cervical cancer in addition to an improved quality of life[22].

Aardt et al., in their study found that 50% of their patients had an improved renal function[23]. They also found age to be a significant factor, with a better survival and lower hospital mortality rates in patients aged 52 years and less.

Misra et al., found in their study that despite having additional morbidity, PCN was effective in improving renal function. They however were unable to determine the duration in which the improved renal function remains[24].

In the study by Souza A.C, Souza A.N et. al, there was a recovery of renal function in 61.7% of patients, leading to interruption of renal replacement therapy[25]. There was also an association between an increase in hemoglobin (Hb) to levels >8.7g/dL and hematocrit (Ht) levels >27% with a greater survival rate.

The study of Hosseini SR, Mohseni MG, Roshan H and Alizadeh F found that the mean creatinine level started to reduce 72 hours after the procedure, with an improved glomerular filtration rate on the 3rd post-operative day as well[26]. They found an increase in urea levels and a decrease in Hb levels after the operation.

2.4 Study significance

Some studies have analyzed the benefit of PCN in a terminally ill patient as it is unclear whether percutaneous urinary diversion provides significant improvement. There have been some ethical concerns arising during the management due to the question of prolonging the patient suffering. Dienstmann et al., in their study found that 80% of malignant uropathy patients with nephrostomy tubes had cancer-related symptoms despite implementation of the diversion and concluded that most patients with advanced cervical cancer had poor performance status and short survival after PCN[27]. They therefore recommended that the indication for urinary diversion in terminal cancer patients should be individualized based on expectations for prolonged palliation.

Wilson et al., in their study showed that palliative percutaneous urinary diversion has significant benefits in managing malignant ureteric obstruction. However, the benefits had limited long-term survival[28]. The study showed a median survival after PCN placement to be 87 days and spent up to one third of the patients' subsequent life as in-patients.

Shekarriz et al., in their study found that despite patients with advanced cancers undergoing PCN, majority of them had poor performance status, poor survival rate of just 5 months, and with 86% having cancer-related pain. Besides, 50% of the five months survival time was spent in the hospital[4].

However, several studies have been done with results showing the procedure has a good survival benefit.

Lapitan et al., in their study got an overall median survival of 21 weeks and a 12-month survival rate of 22%, which was associated with a reduction of creatinine levels after the urinary diversion[29], however there was no significant difference in the quality of life scores.

Mishra et al., in their study found that in 85% of patients, PCN provided the benefit of administering either curative/palliative radiotherapy or chemotherapy[30].

It is therefore necessary to identify those who would benefit from the procedure so as to advice the patients adequately.

It was observed by Alawneh et al., in their study which found that patients with two or more risk factors have a short expected survival time with poor survival after PCN[31].

Cordeiro et al., concluded in their study that patients with an ECOG (Eastern Cooperative Oncology Group) index of >2, and four or more events related to malignant dissemination are possible indicators of poor prognosis among patients who underwent urinary diversion for malignant obstruction[32].

This study therefore aims to assess the need to perform a PCN and the impact it has on the patient.

2.5 Conceptual Framework

2.5.1 Narrative

In the late stages of cervical carcinoma, due to pressure effects of the tumor or metastasis, patients could develop renal failure as a result of obstruction of urinary flow. They then present with features of renal failure, most critical being uremia. This is marked by elevated concentrations of urea in the blood and associated with fluid, electrolyte and metabolic abnormalities. This could complicate further to life-threatening conditions as uremic encephalopathy, cardiovascular abnormalities, such as anemia and pericarditis, and possibly death.

Despite this presenting in the terminal stages of the disease, alleviating the progression of the uremic complications could improve the quality of life of the patient as a form of palliative management. The patient would be too sick to perform usual daily activities and distort their perceptions of themselves. This is well detailed in the QOL questionnaire (Appendix 1).

Palliative urinary diversion could be done by insertion of a percutaneous tube through PCN. This allows flow of urine from the renal pelvis to an exteriorized urinary catheter on the back or flank and drain into a urine bag.

The expected outcome after a successful PCN would be an improvement of renal function, which would reflect in a normalized blood urea level, as well as the serum fluid and electrolyte levels and an improved metabolic function. This therefore reduces the risk of uremic complications, and ultimately improve the QOL of the patient.

With the investigation of the effect of PCN, recommendations will be given to make policies that could be developed to improve the life of the patient in the palliative management of the advanced cervical carcinoma by recommending timely urinary diversion. This therefore results in better outcome in the palliative care.

2.5.2 Schematic

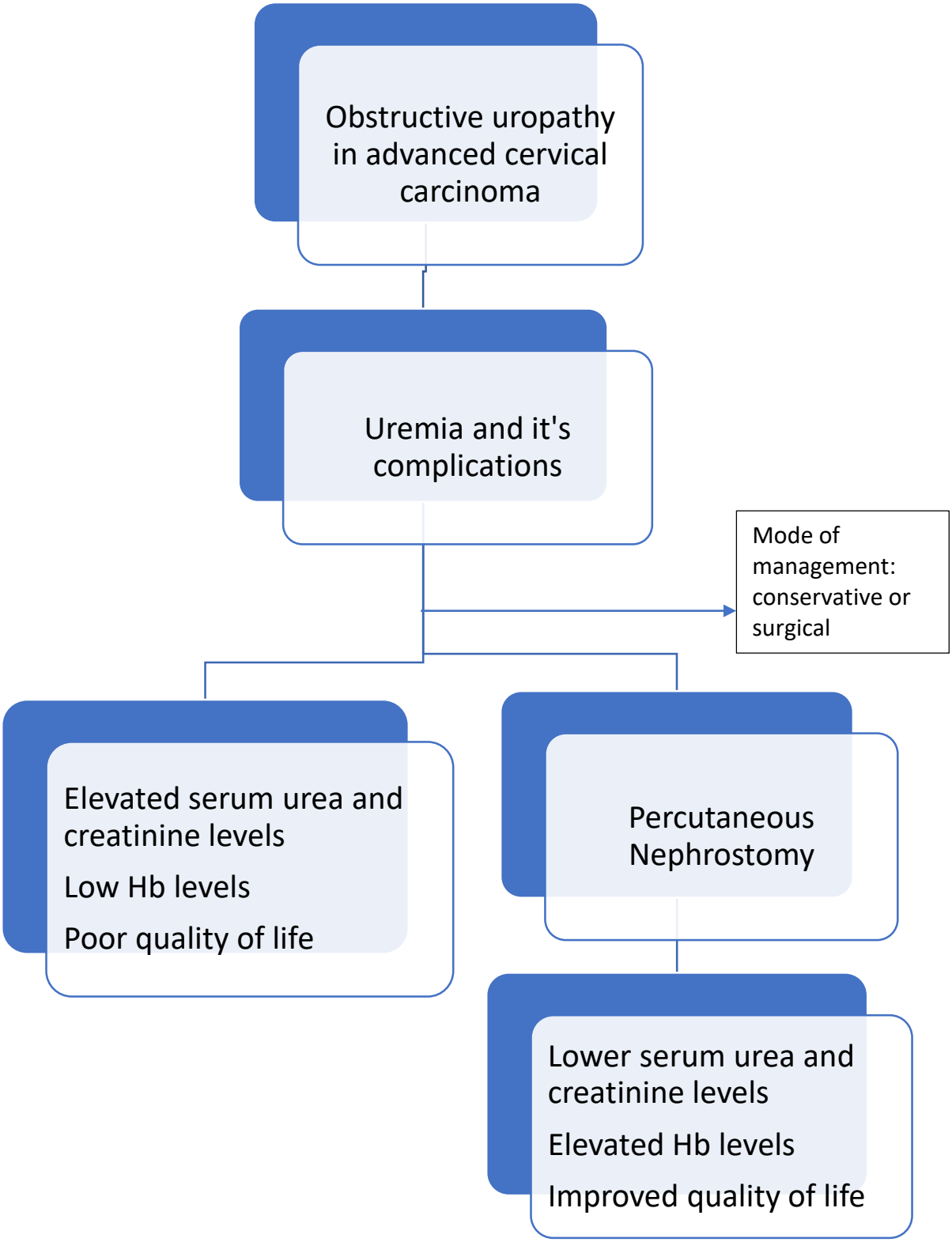


Figure 2

2.6 Problem Statement

Most of the admissions in the gynae-oncology wards of 1B in KNH tend to be women in the late stage of gynecological cancers. Those with late stage cervical carcinoma are admitted for management of complications arising from metastasis of the disease. This includes, but not limited to, complications of obstructed uropathy. However, not all patients qualify or benefit from the surgical procedure of percutaneous nephrostomy. The admission of such patients can therefore be an additional yet unnecessary financial burden, as well as a burden to the health facility.

2.7 Rationale

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, including Kenya in relation to gynecological malignancies.

There have been few studies done on the effect of percutaneous nephrostomy to the survival of late-stage cervical cancer patients with impaired renal function in Kenya. Therefore, by extension, there are no effective programmes and interventions that include the QOL in palliative care.

Strengths of the study is that it is one of the few of its kind in the oncology unit of KNH. Another would be that since it is a retrospective study, the quality of life after the PCN insertion is better assessed months after. The recommendations of this study will provide a chance to come up with guidelines that could help in decision making processes of management of cervical cancer patients with urinary obstruction and adequately advice the patients on other forms of palliative management. If found to be beneficial, PCN will therefore be recommended to the institution (KNH) and government for timely management in palliative care of patients with advanced cervical carcinoma. This study will also lay a platform on which more studies will be conducted in a bid to improve care of cervical cancer patients.

2.8 Research Question

Does percutaneous nephrostomy have any impact on the quality of life and renal function in advanced cervical carcinoma with obstructive uropathy?

2.9 Objectives

2.9.1 Broad Objective

To determine the impact of percutaneous nephrostomy in patients with obstructive uropathy in advanced cervical carcinoma at Kenyatta National Hospital.

2.9.2 Specific Objectives

Among patients with obstructive uropathy due to cervical cancer managed in KNH from 2016 to 2019:

- ⇒ To determine the impact of percutaneous nephrostomy on the quality of life using the FACT-Cx questionnaire tool.
- ⇒ To determine the impact of percutaneous nephrostomy on renal function.

3: METHODOLOGY

3.1 Study design

This was a hospital based descriptive retrospective cohort study, conducted in gynecological wards of 1B and 1D in the Department of Obstetrics and Gynecology at Kenyatta National Hospital (KNH). The descriptive design quantified the problem in a poorly studied area forming a foundation for further studies. The longitudinal flow of the design allowed to identify the changes before and after the PCN. It was a retrospective review of patients admitted in the period of 2016-2019. The study period was chosen as there is no available data digitalized in the admissions records department system before the year 2016.

3.2 Study site

This study was conducted at Kenyatta National Hospital (KNH) health records department.

KNH is a national referral, teaching and research hospital within Nairobi, Kenya, which has been in existence since 1901.There is an Accident and Emergency department, 22 outpatient clinics, 50 wards, and 24 theatres (16 of which are specialized). The total bed capacity is 1800 beds, with 209 in the private wing. The hospital serves an average of 80,000 inpatients and > 500,000 outpatients yearly.

The Department of Obstetrics and Gynecology consists of antenatal wards, maternity theatres, specialized clinic and gynecology/oncology wards. The oncology wards have a bed capacity of 30 patients each.

Being the national referral hospital, it receives patients with advanced cases of cervical carcinoma from other hospitals locally and regionally for further specialized management. This was beneficial in acquiring statistically significant numbers for inclusion in the study.

KNH also has Interventional Radiologists skilled to perform PCN. This was necessary as the main component of this study was patients who had undergone this specialized procedure.

3.3 Study Population

Study participants were women regardless of age with a confirmed diagnosis of cervical carcinoma managed in KNH during the study period. They were identified from the ward registers as those who had undergone PCN placement during the years of 2016-2019 due to obstructive uropathy secondary to malignant ureteric obstruction in cancer of the cervix. Medical records were then retrieved from the hospital's records registry for all such patients who met the study criteria.

3.4 Target Population

3.4.1 Inclusion criteria

Women with confirmed histology diagnosis of cancer of the cervix.

Women with obstructive uropathy as determined by ultrasound findings of hydronephrosis and hydroureter, associated with high serum creatinine and urea levels.

Women who had undergone PCN placement from 2016-2019.

3.4.2 Exclusion criteria

Patients with incomplete investigations before and after the procedure.

Missing files or files with incomplete data. Data extraction forms missing ≥80% of data will be excluded from the study.

3.5 Sample Size Determination

Kenyatta National Hospital performs on average 1 procedure per month for gynae oncologic purposes, this translates to approximately 48 women who have undergone such procedure within the study period. Due to the few numbers and nature of outcomes related to the procedure such as mortality, missing data and lab reports, lost to follow-up of patients, including the exclusion criteria for potential study participants the number might be less. A census method was therefore employed

where all women that fit the criteria and whose records were complete were included in the study, and therefore forming the final sample size.

The sample size was calculated using the Fischer's formula as:

$$n=\frac{Z^2P(1-P)}{I^2}=\frac{1.96^2 0.5(0.5)}{0.1^2}=96$$

where:

Z= 95% confidence interval of 1.96

P= 50% (proportion of unknown population with desired effect)

Q= 50% (proportion of unknown population without desired effect)

I= 10% degree of precision

Sample adjustment for a population of 118 women formed an adjusted sample size of:

$$nf= n/1+\frac{n}{N}=96/1+\frac{96}{118}=53$$

The adjusted sample size after adding 10% contingency for missing data was 58.

3.6 Variables

The outcome is the recorded changes in the quality of life and renal functions.

Independent variables are the factors stemming from the urinary obstruction caused by the advanced cervical carcinoma.

3.7 Data collection

After ethical clearance from the KNH/UON ERC, administrative approval from the KNH/UON Obstetrics and Gynecology department as well as the KNH health records department was sought and obtained to conduct the study. Files of patients who met the eligibility criteria were retrieved from the medical records department after attaining permission from the departmental head. Data was abstracted from the retrieved files by the principal investigator and trained assistants. Two

research assistants from the medical field were trained in use of the questionnaire off-site before interviews were conducted.

Data collection was done using a structured questionnaire (Appendix 1). The questionnaires were coded to make the data entry easy. The filled questionnaires were kept in a safe and confidential cabinet that was accessible only to the principal investigator and research assistants, ready for the data entry.

Sociodemographic data (such as age), primary diagnosis (histological reports that were available in the patients' file) and prior imaging studies to confirm obstruction were collected from the patients' registers. This also included the changes of serum urea levels, serum creatinine levels, and Hb levels before PCN and after PCN, 72 hours after, 1 month after the procedure and 3 months after the procedure. These were documented on a data abstraction form (appendix 3). Any co-existing co-morbidities were also documented.

Impact on quality of life was assessed by calling the patients using the phone number in patient's file, called and asked the FACT-Cx (appendix 1/2) questionnaire in either English or Kiswahili, depending on the preference of the patient. This was done from a personal phone, registered to the assistants, who received airtime to do so. Verbal consent was acquired from the patient before administering the questionnaire, in either English or Kiswahili, depending on the client's preference (appendix 5/6). Some patients were not able to be reached by phone and hence not interviewed, disqualifying them from being included in the final data analysed.

This questionnaire is a pre-structured questionnaire whose questions were directed to the patient and/or care givers, who gave their observations where applicable. They gave the responses of their perceptions before and after PCN. It consists of 42 items, grouped into the domains: physical well-being, social/family well-being, emotional well-being, functional well-being as well as additional concerns which assess symptoms of gynecologic area, urinary and bowel problems, vaginal changes, and concerns about the treatment, diet, sexuality and self-image. Each has a score of 0-4 and a total

score range of 0-168. Higher values represent better health related QOL. The responses were scored using the FACT-Cx Scoring Guidelines (appendix 3).

3.8 Data Management and Analysis

All data abstraction forms were checked for completeness prior to entry into an MS Excel database and later analyzed using Statistical Package for Social Scientists (SPSS).

Demographic and clinical characteristics of the patients were analyzed and presented as mean with standard deviation or with median with interquartile range for continuous data, and as frequencies with proportions for categorical data.

The impact of percutaneous nephrostomy has on quality of life in patients with advanced cervical carcinoma with obstructive uropathy was assessed and scored by the FACT-Cx tool which was analyzed and presented as frequencies and proportions.

The impact of percutaneous nephrostomy has on renal functions in management of advanced cervical carcinoma with obstructive uropathy was assessed by analyzing the urea, creatinine and Hb levels before and after PCN using a paired sample t-test and presented as mean with standard deviation or with median with interquartile range.

Statistical significance was set at 95% and used to test the strength of association between the two groups. $p<0.05$ was considered statistically significant. Data presentation was in form of tables and graphs.

3.9 Study Results Dissemination Plan

The results of this study were shared transparently via PowerPoint presentation with the Department of Obstetrics and Gynecology, University of Nairobi, and thereafter it will be published in peer reviewed journals, and also be presented in medical conferences. A report will also be sent to the department of Obstetrics and Gynecology, gynae-oncology unit, in Kenyatta National Hospital.

3.10 Research Ethics

The principal investigator instituted all measures to ensure that the ethical rights of the study participants were safeguarded. The following measures were put into place:

1. Ethical approval was obtained from the KNH-UON Ethics and Research Committee and administrative approval sought from Kenyatta National Hospital.
2. Informed comprehensive and voluntary consent from the participants prior to recruitment by qualified investigators. Only willing participants were included in the study, and in accordance with the Belmont Principles of 1979[33], the autonomy of all participants of this study was respected.
3. No procedures were done to the study participants as the study was retrospective in nature.
4. There was no identifying features used for the patients, as each was assigned a unique study number to maintain confidentiality. The privacy of all study participants was maintained, and they were all treated equally.
5. Data collected remained confidential, accessed only by the PI and the statistician to achieve set objectives.

3.11 Study Limitations and Limitation Minimization

The sample was derived from a single site, KNH, and may reflect patterns and characteristics unique to KNH, thus making it difficult to generalize the findings.

The retrospective nature of this study made it difficult to collect data that was not documented in the files.

It was difficult to differentiate the effect or patient improvement is solely attributed to the PCN and not due to other additional management plans such as radiotherapy or dialysis. This could possibly have altered the outcome.

Some patients also had some co-morbidities such as hypertension or HIV infection which could have led to worsening prognosis altering the outcome.

Most of the information was retrieved from patient records and that led to non-response and selection bias in the study.

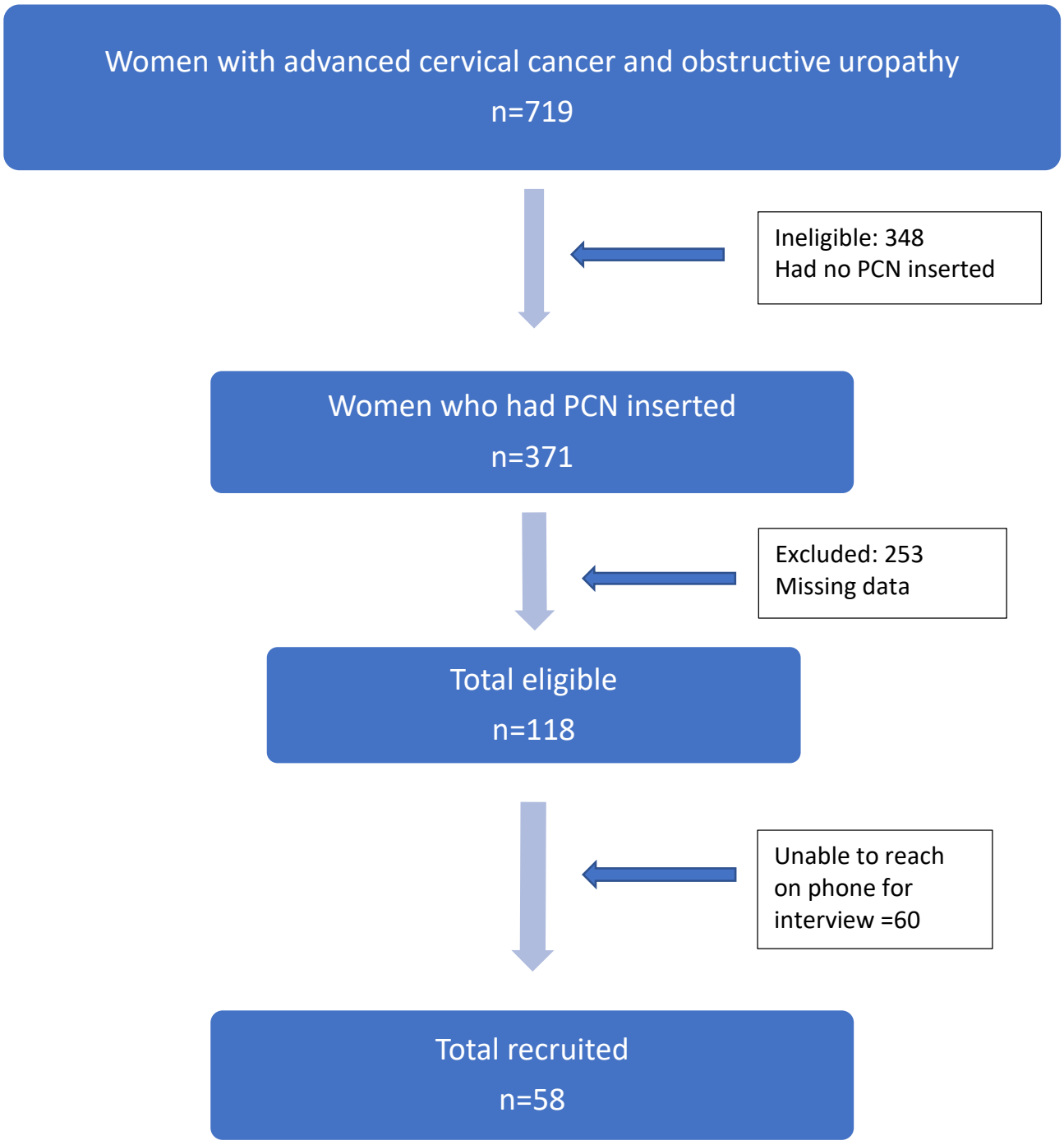
There was also loss to follow-up of some of the patients. Some of them were too sick to respond, or dead, while some had no form of contact.

There could also have been recall bias due to the lapse in time in question.

4: STUDY FLOW CHART

4.1 Diagrammatic

Figure 3



4.2 Narrative

Records of women who were managed in KNH for advanced cervical cancer with obstructed uropathy between 2016-2019 were retrieved from the department of records KNH. Out of those, 371 had a PCN inserted. Out of those files, 118 had all the necessary data and were deemed eligible for the study. The achieved sample size of 58 were reachable on phone and consented for the verbal interview. The data collected from them, in addition to the laboratory findings of the renal functions from their files, was then analyzed.

5: RESULTS

5.1 Bio-demographic characteristics of study participants

Table 1: Bio-demographic characteristics of study participants

Variable	Frequency	Percent
Age *(n=58)*		
<30	2	3.4
30 – 39	5	8.6
40 – 49	16	27.6
50 – 59	19	32.8
60 – 69	13	22.4
≥70	3	5.2
Marital status		
Single	13	23
Married	35	61
Separated	2	4
Not documented	8	12
Religion		
Christian	56	98
Muslim	1	1
Not documented	1	1
Comorbidity		As % of comorbidities
Yes	39	67.2
• Hypertension	10	17.2
• Human Immuno-virus	9	15.5
• Anaemia	8	13.9
• Vesicovaginal fistula	3	5.2
• Deep Vein Thrombosis	3	5.2
• Acute Kidney Injury	2	3.4
• Chronic Kidney Disease	2	3.4
• Rectovaginal fistula	1	1.7
• Other	1	1.7
No	19	32.8

Table 1 shows the bio-demographic characteristics of the participants for the study. The mean age was 51.6 (SD 11.2) years, and the median age was 50.5 (IQR 44.0- 60.0) years. The minimum observed age was 28.0 years while the maximum was 78.0 years. The modal age group was 40-59 years at 62.5% of the participants. 85% of the participants were in the age group 30-69 years. With regards to marital status, majority were married (61%). Majority of the women were Christian (98%). 67.2% of the women had co-morbidities, majority of them having hypertension (17.2%).

5.2 Impact of Percutaneous Nephrostomy on the Quality of life

Table 2: Impact of PCN on the QOL using the FACT-Cx questionnaire tool

QOL Indicator	**FACT-Cx score**		
	before PCN	**after PCN**	**p-value**
Physical well being	13.3±4.9	18.6±5.8	0.018
Social/ family well being	19.1±4.1	18.1±4.0	0.066
Emotional well being	14.9±4.8	14.4±4.8	0.454
Functional well being	16.3±4.3	14.4±5.5	0.200
CxC[1]	28.0±8.1	39.4±9.3	<0.001
FACT-Cx Total	91.5±19.5	105.0±23.0	0.041

[1] CxC: Additional concerns such as sexual function, self-esteem and appearance, urinary function, appetite and gastrointestinal function

Table 2 shows that PCN had an overall improvement in the QOL of the study participants, though slight (p=0.041). PCN had a significant improvement in CxC (p=<0.001) and physical well-being (p=0.018). There was no statistical improvement in the social well-being (p=0.066), emotional well-being (p=0.454) and functional well-being (p=0.200) of the study participants before and after insertion of the PCN.

5.3 Impact of Percutaneous Nephrostomy on renal function

Table 3: Impact of Percutaneous Nephrostomy on renal function

	Mean values + SD						
			(p-value)		**(p-value)**		**(p-value)**
Duration	**At Admission**	**72hrs**		**1month**		**3 months**	
Lab indicators							
Urea	20.5 ± 16.6	14.1 ± 8.2	0.029	14.8 ± 13.8	0.139	11.6 ± 10.3	0.099
Creatinine	848.2 ± 878.8	379.0 ± 358.2	<0.001	327.9 ± 298.2	<0.001	272.0 ± 251.3	0.003
Hemoglobin	8.7 ± 2.0	8.3 ± 1.5	0.276	8.9 ± 1.9	0.555	9.0 ± 2.2	0.444

Table 3 shows a significant improvement in urea (p=0.029) 72 hours after the procedure but progressively worsened as time progressed. creatinine levels improved significantly maintaining its significance 1 month after the procedure (p=<0.001). There was no statistical improvement in Hb levels at any time variation.

Further analysis however indicates that there was a gradual reduction in levels of urea and creatinine as time progressed. However, it was noted that the levels began to worsen within 3 months after the procedure in urea levels. This has been represented below in Figure 4 for urea levels and 5 for creatinine levels. Figure 6 illustrates Hb had no change in progression with time.

Figure 4: Box plot showing progression of urea levels vs change in time after PCN insertion

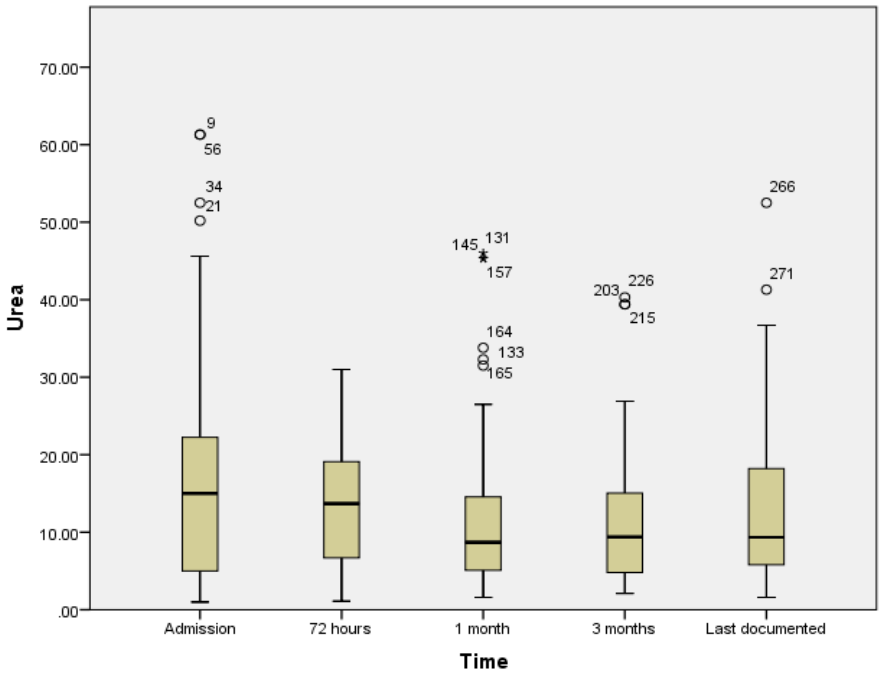


Figure 5: Box plot showing progression of creatinine levels vs change in time after PCN insertion

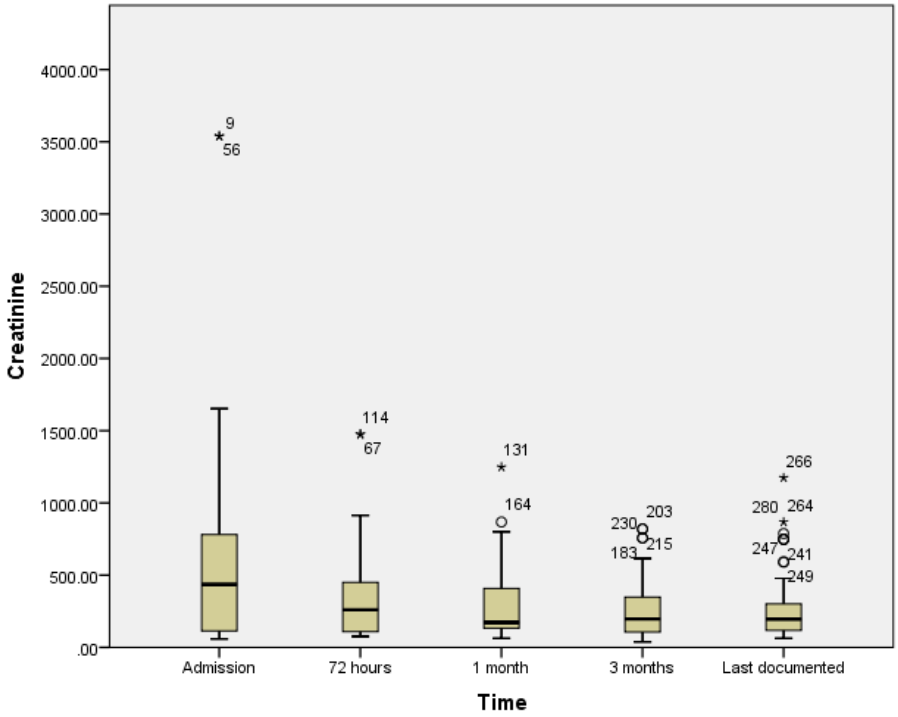
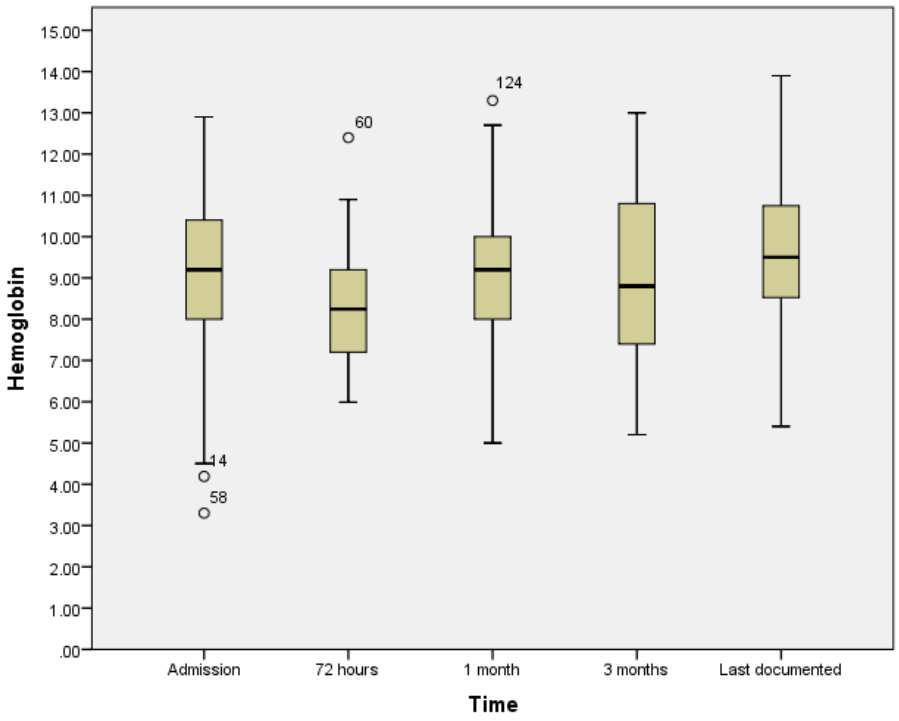


Figure 6: Box plot showing progression of Hb levels vs change in time after PCN insertion



6: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

6.1 Discussion

In regards to the sociodemographic characteristics of the study participants, 15% of the patients were found to have HIV. This was in keeping with a local study by Gichangi P. et al who found 15% of the patients with cervical cancer had HIV[34]. Innocent M et al also conducted a study locally and found a 27.5% prevalence of HIV in cervical cancer[35]. This discrepancy could be due to the inclusion of other stages of cervical cancer and not just those in advanced stages.

In this study, 17.2% of the women with co-morbidities had HTN. This was in keeping with the study by Lapitan et al who found that the most common co-morbidity was HTN (21%)[29].

In this retrospective cohort study, there was an improvement in the QOL in women with advanced cervical cancer and obstructed uropathy who have had an insertion of the PCN tube. However, the noted improvement was slight (p=0.041) with the improvement mainly in their physical well-being and additional concerns including sexual function, self-esteem and appearance, urinary function, appetite and gastrointestinal function. This was in keeping with findings from a study by M.C.M Lapitan in Philippines which showed that the QOL did not significantly differ across the diversion groups over the entire study period[29] and the study by Shoshany O. et. al which showed there was no clinically significant difference in patient's recovery after insertion of a ureteral stent and a PCN tube in acute ureteral obstruction[15].

In India, L. Texeria et al also found that QOL improved at the 1st week and 1st month but was not sustained at 3rd month[22].

The PWB aspect in the QOL of patients improved significantly, one of the determinants being pain. Shekarizz et al in Michigan found little benefit and has a poor performance status in asymptomatic patients as 86% of their study participants presented with pain after urinary diversion[9]. The

difference could be as the study included other malignancies other cervical cancer altering the outcome.

The impact of PCN on renal function was found to improve initially before worsening with a 62% improvement in urea levels, 64% improvement in creatinine levels and 48% improvement in Hb levels. This was in keeping with a study by Souza A.C in Brazil that found a 61.7% improvement in renal function[25], in the study by M.C van Aardt et al in South Africa that found 50% of patients had an improvement in renal function[23] and in the study by Rodrigo D. MD et al in Brazil that found 60% of patients had an improvement in renal function[36].

At the end of the 4 year analysis, it was noteworthy that there was a 43.1% survival. I. Rasjidi in Jakarta found that probability of survival in 6th month was 56.9% and 12 month was 31.1%[17].

The renal failure in cervical cancer is mainly due to hydronephrosis at 23% according to a study by Krishna et al[37]. The renal collecting system is blocked by either the tumour or lymph node encroachment. This leads to distension of renal calyces. Prolonged obstruction can lead to tubular atrophy, interstitial fibrosis and eventually irreversible renal injury. There is an increase in pressure proximal to the obstruction due to glomerular filtration and eventually being responsible for the dilatation of the collecting ducts. The elevation in pressure is transmitted back to the proximal tubule, thereby lowering the GFR by counteracting the high intraglomerular pressure that normally drives glomerular filtration. As the GFR, the serum creatinine concentration increases.
Most of the functional recovery will be seen in the first 7 to 10 days after relief after the obstruction, though in severe renal failure the relief could take months and may even require dialysis[38].

This would explain why there was a brief improvement in serum creatinine levels in this study 1 month after insertion of the PCN. The improvement however progressively reduced as most patients had no co-current management like dialysis or radiotherapy.

Iron deficiency and tumour bleeding are common causes of anaemia in cervical cancer with a haemoglobin level of <12g/dL in 33% of patients in a study by Krystyna Serkies et al[39]. The best mode of management is blood transfusion, but even then a study by Andrew J.B et al showed there was an association between Hb level <10g/dL and no benefit in blood transfusion[40].

In this study, the mean Hb level was 8.7g/dL and that would explain why despite management by insertion of the PCN, there was no added benefit to the improvement of the Hb level.

6.2 Conclusions

There is transient improvement in QOL in some aspects in spite of late interventions. This allows return of some renal functions in this terminal phase of the disease, in keeping with the goals of palliative care.

The observed amelioration of renal biochemical indicators of function implies that there is transient recovery of function in the nephrons which in turn may allow mental renal function improvement in terminal care where communication is often very important.

In conclusion, there seems to be no prolonged significant positive impact PCN has on both the QOL and renal function in women with advanced cervical cancer and obstructed uropathy.

6.3 Recommendations

- In women with advanced cervical cancer and obstructed uropathy, other forms of management would be a better option as PCN bears a financial strain and increases hospital stay with no long-term major benefit to said patient and family, especially in our low resource setting. The patients could consider dialysis in combination with other palliative measures such as radiotherapy, blood transfusion, chemotherapy and hospice care. Based on physiology of the effect of the obstruction, radiotherapy or chemotherapy could be used to reduce the tumour size and lymph nodes that would block the renal collecting system.
- Early diagnosis and intervention before the disease process is too advanced is key to enable higher possibility of care in relation to renal function and QOL, before renal function is irreversible.
- Large volume of missing data is indicative of lack of protocol of care, and hence the full advantage accrual becomes elusive. Hence there is need for standardized protocols in provision of the service. Standardizing the recorded information would enable appropriate impact of evaluation. Structured protocol of care would enable an efficient treatment and availability of data.

STUDY TIMELINES

	Aug 2019	Sept 2019- Nov 2020	Dec 2020- Mar 2021	April 2021- Sept 2021	Oct 2021- Nov 2021
Concept development					
Proposal development					
Ethical approval					
Data collection					
Data analysis					
Results presentation, dissemination and close out					

STUDY BUDGET

	Item	Amount (Ksh)
Proposal Development	Proposal: 6 copies (initial +corrected): 300 pages @10 Kshs per page Binding @100Ksh per book	3,600
	Opaque envelopes	1000
	Printing: 50 Questionnaires+ Consent forms: each 4 pages @10 Kshs per page	26,000
	KNH-UoN ERC Application costs	2,000
Data Collection	Training and use of 2 research assistants: Each @ Ksh. 500/day for 60days + Hospital fee access to patient records 1500	61,500
	Stationary: Pens, diaries, file tags, notebooks, counter books, posters.	1,500
	Airtime: 1000 per person per month	2,000
	Transport/Meetings	2,000
Data Analysis	Statistician	30,000
Thesis write up	Printing drafts	5,000
	Printing thesis	6,000
	Contingency	20,000
	TOTAL	160,600

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[updated 2018]

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APPENDICES

Appendix I: FACT-Cx Version 4 Questionnaire (Kiswahili)

Date of collection: _____

Serial No: _____

IP Number: _____

Hapa chini kuna orodha ya taarifa ambazo watu wengine walio na ugonjwa kama wako wamesema ni muhimu. Tafadhali duru au alama nambari moja kwa kila mstari kuashiria majibu yako kwa siku saba zilizopita.

	USTAWI WA MWILI	Hapa na	Kidogo	Kwa kiasi	Kiasi	Sana
GP1	Nina ukosefu wa nguvu	0	1	2	3	4
GP2	Nina kichefuchefu	0	1	2	3	4
GP3	Kwasababu ya hali yangu ya mwili, nina shida ya kukidhi mahitaji ya familia yangu	0	1	2	3	4
GP4	Nina maumivu	0	1	2	3	4
GP5	Nina wasiwasi na athari za matibabu	0	1	2	3	4

GP6	Ninahisi mgonjwa	0	1	2	3	4
G	Ninalazimishwa ktumia wakati kitandani	0	1	2	3	4

	USTAWI WA KIJAMII/ FAMILIA	Hapana	Kidogo	Kwa kiasi	Kiasi	Sana
GS1	Ninahisi karibu na marafiki wangu……..	0	1	2	3	4
GS2	Napata msaada wa kihemko kutoka kwa familia yangu	0	1	2	3	4
GS3	Napata msaada kutoka kwa marafiki wangu	0	1	2	3	4
GS4	Familia yangu imekubali ugonjwa wangu	0	1	2	3	4
GS5	Nimeridhika na mawasiliano ya kifamilia juu ya ugonjwa wangu	0	1	2	3	4
GS6	Ninajiskia karibu na mwenzi wangu (au mtu ambaye ndiye msaada wangu mkuu)	0	1	2	3	4
Q1	Kama hungependa kujibu swali hili la ngono, tafadhali weka alama [ ].					
G	Nimeridhika na maisha yangu ya ngono	0	1	2	3	4

Tafadhali duru au alama nambari moja kwa kila mstari kuashiria majibu yako kwa siku saba zilizopita.

	USTAWI WA KIHEMKO	Hapana	Kidogo	Kwa kiasi	Kiasi	Sana
GE1	Ninahisi huzuni	0	1	2	3	4
GE2	Nimeridhika na jinsi ya kukabiliana na ugonjwa wangu	0	1	2	3	4
GE3	Nina poteza tumaini katika vita dhidi ya ugonjwa wangu	0	1	2	3	4
GE4	Nahisi wasiwasi	0	1	2	3	4
GE5	Nina wasiwasi juu ya kufa	0	1	2	3	4
G	Nina wasiwasi kuwa hali yangu itazidi kuwa mbaya	0	1	2	3	4

	USTAWI WA KAZI	Hapana Kabisa	Kidogo	Kwa kiasi fulani	Kiasi	Sana
GF1	Nina uwezo wa kufanya kazi (pia kazi za nyumbani)	0	1	2	3	4
GF2	Kazi yangu (pamoja na kazi za nyumbani) inatimiza	0	1	2	3	4
GF3	Nina uwezo wa kufurahia maisha	0	1	2	3	4

GF4	Nimekubali ugonjwa wangu	0	1	2	3	4
GF5	Nalala vizuri	0	1	2	3	4
GF6	Ninafurahia mambo ambayo mimi hufanya kujifurahisha	0	1	2	3	4
G	Nimeridhika na ubora wa maisha yangu hivi sasa	0	1	2	3	4

Tafadhali duru au alama nambari moja kwa kila mstari kuashiria majibu yako kwa siku saba zilizopita.

	WASIWASI MWINGINE	Hapana	Kidogo	Kwa kiasi	Kiasi	Sana
Cx1	Nina shida na kutokwa na kutokwa kwa damu kutoka kwa uke wangu	0	1	2	3	4
Cx2	Nina shida na harufu mbaya inayotoka kwa uke wangu	0	1	2	3	4
Cx3	Ninaogopa kushiriki ngono	0	1	2	3	4
B4	Ninahisi kuvutia kijinsia	0	1	2	3	4
Cx4	Uke wangu unahisi mwembamba au mfupi	0	1	2	3	4
BMT7	Nina wasiwasi juu ya uwezo wangu wa kupata watoto	0	1	2	3	4

Cx 5	Ninaogopa matibabu yanaweza kuumiza mwili wangu	0	1	2	3	4
BL 4	Ninavutiwa na ngono	0	1	2	3	4
C7	Ninapenda muonekano wa mwili wangu	0	1	2	3	4
Cx 6	Nina wasiwasi na kuvumbiwa	0	1	2	3	4
C6	Nina hamu ya kula	0	1	2	3	4
BL 1	Nina shida ya kudhibiti mkojo wangu	0	1	2	3	4
BL 3	Hua nachomeka wakati nakojoa	0	1	2	3	4
Cx 7	Nina usumbufu wakati nakojoa	0	1	2	3	4
H N1	Nina uwezo wa kula vyakula ambavyo napenda	0	1	2	3	4

Appendix II: FACT-Cx version 4 questionnaire (English)[43]

Date of collection: _____

Serial No: _____

IP Number: _____

Below is a list of statements that other people with your illness have said are important. Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	PHYSICAL WELL-BEING	Not at all	A little bit	Some -what	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
G	I am forced to spend time in bed	0	1	2	3	4
___	SOCIAL/FAMILY WELL-BEING					

GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box ☐ and go to the next section.					
G	I am satisfied with my sex life	0	1	2	3	4

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	EMOTIONAL WELL-BEING	Not at all	A little bit	Some -what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4

GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
G	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	Not at all	A little bit	Some -what	Quite a bit	Very much
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4

G	I am content with the quality of my life right now	0	1	2	3	4

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	ADDITIONAL CONCERNS	Not at all	A little bit	Some -what	Quite	Very much
Cx 1	I am bothered by discharge or bleeding from my vagina	0	1	2	3	4
Cx 2	I am bothered by odor coming from my vagina	0	1	2	3	4
Cx 3	I am afraid to have sex	0	1	2	3	4
B4	I feel sexually attractive	0	1	2	3	4
Cx 4	My vagina feels too narrow or short	0	1	2	3	4
B M T7	I have concerns about my ability to have children	0	1	2	3	4
Cx 5	I am afraid the treatment may harm my body	0	1	2	3	4
BL 4	I am interested in sex	0	1	2	3	4
C7	I like the appearance of my body	0	1	2	3	4
Cx 6	I am bothered by constipation	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
BL 1	I have trouble controlling my urine	0	1	2	3	4
BL 3	It burns when I urinate	0	1	2	3	4

Cx 7	I have discomfort when I urinate	0	1	2	3	4
H N1	I am able to eat the foods that I like	0	1	2	3	4

Appendix III: FACT-Cx Scoring Guidelines (Version 4)[44]

Instructions: * 1. Record answers in "item response" column. If missing, mark with an X

2. Perform reversals as indicated and sum individual items to obtain a score.

3. Multiply the sum of the item scores by the number of items in the subscale, then divide by the

number of items answered. This produces the subscale score.

4. Add subscale scores to derive total scores (TOI, FACT-G & FACT-Cx).

5. **The higher the score, the better the QOL.**

Subscale	Item Code	Reverse item?		Item response	Item Score
PHYSICAL	GP1	4	-	_____	=_____
WELL-BEING	GP2	4	-	_____	=_____
(PWB)	GP3	4	-	_____	=_____
	GP4	4	-	_____	=_____
Score range: 0-28	GP5	4	-	_____	=_____
	GP6	4	-	_____	=_____
	GP7	4	-	_____	=_____

Sum individual item scores: _____
Multiply by 7: _____
Divide by number of items answered: _____=**PWB subscale score**

SOCIAL/FAMILY	GS1	0	+	_____	=_____
WELL-BEING	GS2	0	+	_____	=_____
(SWB)	GS3	0	+	_____	=_____
	GS4	0	+	_____	=_____
	GS5	0	+	_____	=_____
Score range: 0-28	GS6	0	+	_____	=_____
	GS7	0	+	_____	=_____

Sum individual item scores: _____
Multiply by 7: _____
Divide by number of items answered: _____=**SWB subscale score**

EMOTIONAL	GE1	4	-	_____	=_____
WELL-BEING	GE2	0	+	_____	=_____

(EWB)	GE3	4	-	_____	=_____
	GE4	4	-	_____	=_____
Score range: 0-24	GE5	4	-	_____	=_____
	GE6	4	-	_____	=_____

Sum individual item scores: _____
Multiply by 6: _____
Divide by number of items answered: _____ **=EWB**

subscale score

FUNCTIONAL	GF1	0	+	_____	=_____
WELL-BEING	GF2	0	+	_____	=_____
(FWB)	GF3	0	+	_____	=_____
	GF4	0	+	_____	=_____
	GF5	0	+	_____	=_____
Score range: 0-28	GF6	0	+	_____	=_____
	GF7	0	+	_____	=_____

Sum individual item scores: _____
Multiply by 7: _____
Divide by number of items answered: _____ **=FWB**

subscale score

FACT-Cx Scoring Guidelines (Version 4) – Page 2

Subscale	**Item Code**	**Reverse item?**		**Item response**	**Item Score**
CERVIX	Cx1	4	-	_____	= _____
CANCER	Cx2	4	-	_____	= _____
SUBSCALE	Cx3	4	-	_____	= _____
(CxCS)	B4	0	+	_____	= _____
	Cx4	4	-	_____	= _____
Score range: 0-60	BMT7	4	-	_____	= _____
	Cx5	4	-	_____	= _____
	BL4	0	+	_____	= _____
	C7	0	+	_____	= _____
	Cx6	4	-	_____	= _____
	C6	0	+	_____	= _____
	BL1	4	-	_____	= _____
	BL3	4	-	_____	= _____
	Cx7	4	-	_____	= _____
	HN1	0	+	_____	= _____

Sum individual item scores: _____
Multiply by 15 : _____
Divide by number of items answered: _____ **=CxC**

Subscale score

To derive a FACT-Cx Trial Outcome Index (TOI):
Score range: 0-116

_____ + _____ + _____=_____=**FACT-Cx TOI**
(**PWB** score) (**FWB** score) (**CxCS** score)

To Derive a FACT-G total score:
Score range: 0-108

_____ + _____ + _____ +_____=_____=**FACT-G Total score**
(**PWB** score) (**SWB** score) (**EWB** score) (**FWB** score)

To Derive a FACT-Cx total score:
Score range: 0-168

_____+ _____ + _____ + _____ + _____ =_____=**FACT-Cx Total score**
(**PWB** score) (**SWB** score) (**EWB** score) (**FWB** score) (**CxCS** score)

*For guidelines on handling missing data and scoring options, please refer to the Administration and Scoring Guidelines in the manual or on-line at www.facit.org.

Appendix IV: Data abstraction form

Date of collection: _____

Serial No: _____

1. IP number……
2. Age…….
3. Verbal consent acquired:……from:……
4. Cervical cancer stage…….
5. Obstructive uropathy diagnosed: ultrasound…….

   Date:…….
6. Urea blood levels at time of admission…….
7. Creatinine blood levels at time of admission…….
8. Hemoglobin (Hb) levels at time of admission…….
9. FACT-Cx questionnaire filled in retrospect based on condition at time of admission….

   (attached)

   Questionnaire answered by: (patient)……. (caregiver)……
10. Date of procedure: Percutaneous Nephrostomy……
11. Urea blood levels at least 72 hours after

    procedure……
12. Creatinine blood levels at least 72 hours after

    procedure……
13. Hemoglobin (Hb) levels at least 72 hours after

    procedure……
14. FACT-Cx questionnaire filled in retrospect after procedure……. (attached)

    Questionnaire answered by: (patient)……. (caregiver)……

15. Urea blood levels at least 1 month after procedure…….

16. Creatinine blood levels at least 1 month after procedure…….

17. Hemoglobin (Hb) levels at least 1 month after

    procedure……

18. Urea blood levels at least 3 months after procedure…….

19. Creatinine blood levels at least 3 months after procedure…….

20. Hemoglobin (Hb) levels at least 3 months after

    procedure……

21. Date of discharge from the ward…….

22. How many clinic follow-ups……

23. Was the patient re-admitted?.....

    If so, re-admission diagnosis:…….

24. In the event of death, date of death…….

25. Last documented urea blood levels:……Date:…….

26. Last documented creatinine blood levels…….

    Date:……

27. Last documented Hemoglobin (Hb) levels…….

    Date:……

28. Co-morbidities

Illness…….

Duration……

On management?.....

Appendix V: Verbal consent form (English)

Hello, my name is …….…… research assistant to Dr. Brenda Kiende, a Senior House officer pursuing Masters in Obstetrics and Gynaecology in the University of Nairobi. You have been chosen to be in a study about how having Percutaneous Nephrostomy affects your quality of life and renal function as a patient with advanced cervical carcinoma. This study involves research whose purpose is to determine whether the procedure is beneficial to patients with advanced cervical carcinoma. This will take a few minutes of your time. If you choose to be in the study, I will ask you a few questions and you will be expected to answer them. I will then note down your responses on a questionnaire tool to determine the responses in relation to your quality of life.

There are no foreseeable risks or benefits to you for participating in this study. There is no cost or payment to you. If you have questions while taking part, please stop me and ask. We will do our best to keep your information confidential, but we cannot guarantee absolute anonymity. We will link your answers to you initially by assigning reference serial numbers, but this link will be removed later in order to protect you.

If you have questions about this research study you may contact Dr. Brenda Kiende at 0713338504. If you feel as if you were not treated well during this study or have questions concerning your rights as a research participant call The Secretary/Chairperson KNH-UoN ERC on Tel. No. 2726300 Ext 44102.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop. May I continue?

I certify that I have consented the participant (code no.) _____

Researcher's name: _____

Signature: _____

Date: _____

Appendix VI: Verbal consent (Kiswahili)

Jambo, jina langu ni ……. msaidizi wa utafiti wa daktari Brenda Kiende, daktari mwanafunzi wa shahada ya uzamili kwa uzazi na magonjwa ya wanawake katika Chuo Kikuu ya Nairobi. Umechaguliwa kama mshiriki kwa utafiti wake wa kisomo. Hii ni sababu ulifanyiwa upasuaji wa kuwekewa mpira kwenye mishipa ya figo katika matibabu yako ya saratani ya kizazi. Utafiti huu ungependa kujulisha jinsi upasuaji huo umeathiri ubora wa maisha yako na jinsi figo yako inavyofanya kazi. Ningependa kukuuliza maswali machache ukikubali kushuriki katika utafiti huu. Nitakuuliza maswali haya na nitayaandika majibu yako kwenye dodoso.

Hakuna hasira ama faida utakayopata ukishiriki katika utafiti huu. Hakuna malipo utakayopewa. Ukiwa na maswali katikati ya uhoji, tafadhali nisimamishe na uniulize. Tutafanya chochote tutakachoweza ili habari utakayotupea itawekwa kwa siri. Tutaunga majibu yako na dodoso na nambari itakayotolewa baadaye ili kulinda habari yako ya kibinafsi.

Ukiwa na maswali yoyote kuhusu utafiti huu, unaweza pigia daktari Brenda Kiende kwa simu 0713338504. Ukiona kama hutibiwi vyema, ungepeleka wasiwasi na maswala kwa katibu was KNH-UoN ERC kwa simu 2726300.

Ushiriki wako ni kwa hiari yako, na hutaadhibiwa ama kupoteza faida yoyote ukikataa kushiriki ama kuamua kuachia katikati. Naomba kuendelea.

Nathibitisha nimechulua kibali kutoka mshirika (nambari)……

Jina ya msaidizi……

Sahihi…….

Tarehe…….

Appendix VII: FACIT License

PROVIDING A VOICE FOR PATIENTS WORLDWIDE

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Name ("Licensee"): DR. BRENDA KIENDE NYAMU

Measurement: FACT-Cx

Language(s): English and Swahili

Study Title ("Study"): IMPACT OF PERCUTANEOUS NEPHROSTOMY ON CLINICAL OUTCOME IN ADVANCED CERVICAL CARCINOMA WITH OBSTRUCTIVE UROPATHY AT KENYATTA NATIONAL HOSPITAL

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