# INDICATIONS AND EARLY COMPLICATIONS OF DOUBLE – J URETERIC STENTS AS SEEN AT KENYATTA NATIONAL HOSPITAL

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## DECLARATION

CANDIDATE

I declare that this dissertation is the result of my original work and has not been submitted or presented either wholly or in part in any other university or elsewhere for any award/degree.

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## DEDICATION

This dissertation work is dedicated to all my urology teachers, colleagues, and patients; with love and gratitude for making this possible.

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## ABBREVIATIONS

ACTD – AXIAL CT DISTANCE

AP – ANTEROPOSTERIOR

BH – BODY HEIGHT

CHS – COLLEGE OF HEALTH SCIENCES

CT – COMPUTERIZED TOMOGRAPHY

DJ – DOUBLE ‘J’

ERC – ETHICS AND RESEARCH COMMITTEE

IVU – INTRAVENOUS UROGRAPHY

KNH – KENYATTA NATIONAL HOSPITAL

KUB – KIDNEY URETER BLADDER

MRI – MAGNETIC RESONANCE IMAGING

PCNL – PERCUTANEOUS NEPHROLITHOTOMY

SEM - STANDARD ERROR OF THE MEAN

SPSS – STATISTICAL PACKAGE FOR THE SOCIAL SCIENCES

UON – UNIVERSITY OF NAIROBI

UPJ – URETEROPELVIC JUNCTION

UPJO – URETEROPELVIC JUNCTION OBSTRUCTION

UTI – URINARY TRACT INFECTION

VS – VERSUS

## OPERATIONAL DEFINITIONS

**Complications** - A surgical complication is any undesirable, unintended and direct result or outcome of an operation or a procedure affecting the patient which would not have occurred had the operation/procedure gone a success as could reasonably be hoped. 'any deviation from the ideal postoperative course.'

**DJ ureteric stent** - This is a slender tube that is inserted into the ureteral lumen to prevent or treat urine obstruction from the kidney to the urinary bladder.

**Early –** within the first 6 (six) weeks post DJ ureteric stenting

**Outcome** - result or effect of an action, situation activity, or process at the end of it

**Ureter -** the conduit in which urine passes from the kidney to the urinary bladder

## ABSTRACT

***INTRODUCTION*:** Double - J ureteric stents have been in use in urological practice to facilitate drainage of urine to the bladder since the 1960s. The benefits of DJ ureteric stents in individual patients are clear, but indwelling stents still have problems to the patients while being placed, while in situ and subsequently during their removal. Early DJ ureteric stenting complications include urinary tract infections, fevers, hematuria, ureteric stent migration, irritative urinary symptoms loin and suprapubic discomfort to name just but a few.

***STUDY OBJECTIVES*:** The study objectives were to establish the indications, early complications, and factors associated with development of early complications of DJ ureteric stents as seen in Kenyatta National Hospital.

***METHODOLOGY***

***Study design*:** This was a hospital based prospective cohort study among patients undergoing DJ ureteric stenting in Kenyatta National Hospital.

***Study setting:*** The study was carried out at Kenyatta National Hospital department of surgery (both adults and pediatrics), department of obstetrics & gynaecology, department of microbiology and department of radiology

***Study Population*;** This involved all patients in Kenyatta National Hospital undergoing DJ ureteric stenting, who consented for the study or whose parents/guardians consented for the study having met the inclusion criteria.

***Materials and Method:*** Categorical and Non-Categorical data from 32 patients was collected clinically, from laboratory and radiology departments by use of pre-prepared and a pre-tested data collection tool. Patients were followed for six weeks post DJ ureteric stenting and reviewed and evaluated every two weeks in order to establish any early complication.

***Data analysis:*** Data was entered and managed in Microsoft Excel spread-sheet. The captured raw data was entered into a password protected database, and correlated with hard copies of the same

to ensure accuracy. Data entry and analysis was done using SPSS version 23.0,Chicago Illinois. Upon completion of entry, the hard copy forms were used to clean and verify correctness of the entered data and then stored safely in the lockable cabinet.

***RESULTS:*** The major indications for ureteric stenting in Kenyatta National Hospital were adjunct to surgery – secondary to renal calculi and in PUJO at 21.9%. The early complications of DJ ureteric stenting were minimally evident as all our patients; 100%, got grade-1Clavien-Dindo complication. Univariate and multivariate data analysis with calculation of p-value to establish the factor(s) associated with early complication was not done for all our patients developed complications.

***SIGNIFICANCE OF THE STUDY*:** The study will be useful to the urologist locally, regionally and internationally on what to expect in terms of early complications of DJ ureteric stents and will enable better characterization of DJ ureteric stenting morbidity associated with various DJ stents designs and biomaterials, give an idea of the possible factors associated with early complications of DJ ureteric stenting and how to overcome them. The study will also allow comparison of various different surgical techniques (stenting methods), which is very vital due to the relative lack of randomized trials in the urological armamentarium of literature.

## INTRODUCTION AND BACKGROUND

There are various types of ureteric stents available for urological use in the market currently(2). It is essential that the urologist using them be very conversant with their overall characteristics and properties, design, merits, and demerits. Despite the tremendous improvement in stent biomaterials, characteristics and design, DJ stents are not free of urological complications and problems hence the scientific search for an ideal DJ stent remains a challenging topic in the world of urological practice. (3)

DJ Ureteric stents are used in urological practice to prevent renal damage from the urinary obstruction that results from ureteric obstruction, treat blockage of the urine flow from the kidney to the urinary bladder or to allow proper healing of the ureter, renal pelvis or kidney post organ procedure, (4). When all the principles of DJ ureteric stents placement are followed, this procedure is in most circumstances a simple process with very minimal or no complication(s) at all (5).

DJ ureteric stents can be inserted either by retrograde approach up the ureter or through percutaneous ante-grade approach down the ureter to the urinary bladder(6). DJ ureteric stents are usually made of a synthetic material with molecular memory that uncurl during insertion but recoils back in the human body after they had been placed, and this helps in preventing migration of the stent either up the ureter or down into the urinary bladder(1). DJ ureteric stents have a predictably short stay life when inserted into the ureter for various indications(7).

Similar to other surgical or medical instruments and equipment, DJ ureteral stents are a fundamental innovation for the daily practice of urological practice and have been through a long history of development and improvement(8).

As the practice of medicine and surgery keeps on changing with the ever-evolving world of technology, different technologies that are modern have been implemented in the ureteric stent industry to improve on its biomedical properties with the sole aim of decreasing the overall complications hence resulting in an improvement on patient health related to quality of life impact(9).

**Indications of double J ureteric stenting.**

Broadly, the known indications for DJ ureteral stenting may be considered to fall into three main categories,

- For managing ureteral obstruction which can be both extrinsic and/or intrinsic; for example, ureteral obstruction caused by ureteric calculi stones, ureteric strictures, ureteric oedema, , ureteric tumours, in tuberculosis of the ureter, and in retroperitoneal fibrosis or tumours.(16).
- As a pre and/or postoperative adjunct to Ureteral surgery. For example adjunct to percutaneous nephrolithotomy, extracorporeal shock wave lithotripsy, URS, upper tract endopyelotomy, open or laparoscopic ureteric surgery, iatrogenic or non-iatrogenic ureteric injury and post-renal transplantation(17).
- In management of ureteric injuries. For example; iatrogenic ureteric injuries during total abdominal hysterectomies and colon surgeries.

**DJ ureteric stent complications.**

For more than two decades now, DJ ureteric stents have been in use in the urological world for various uses. However, they have not been free of complications.(18).

The complications associated with the use of DJ stents can be classified as either early or late complications as indicated below. The common established problems and difficulties experienced with the use of indwelling DJ ureteric stents include the following and can be divided into early vs. late complications for the purpose of this study(5).

- *Early DJ ureteric stenting complications include,* lower urinary tract irritative symptoms, urinary tract infections, fevers, ureteric stent migration or dislodgement, hematuria, loin and suprapubic discomfort, (19).
- *Late DJ ureteric complications include,* ureteric stent fracture, visical-ureteric reflux, ureteric stent encrustation, ureteric stent blockage, ureteral-vascular fistulae, ureteral-intestinal fistulae etc (20).

There are no standardized guidelines currently or in the past or criterion that exists in the urological arena for reporting surgical complications in the area of urology. It will be very essential that the urological practicing community creates a local, regional and even globally universal acceptable criterion for documenting and reporting urological complications.

## LITERATURE REVIEW

Since the introduction of DJ stent in 1978, by Finney, Hepperlen and colleagues for the urological practice, DJ ureteral stents have become a daily bread for all urological surgeon(12). DJ ureteric stent use has various several associated complications which include stent associated urinary tract infections, stent encrustation, stent dislodgement or migration, patient's discomfort in the loins and suprapubic regions that lowers the value as a modality for both short term and long term ureteric stenting as a means of urinary drainage(12). The super ideal stent which combines perfect longterm efficacy with none or very minimal ureteric stent associated and related morbidity is still yet to be released for use in urology practice(13)

A 5 years review was done on Longterm complications of DJ ureteric stent and its management by Rajkumar Singha Mahapatra, Rajendra Prasad Ray, , and Dilip Kumar Pal where they had Nineteen patients with indwelling Double-J stent for more than six months. They were assessed with X-ray KUB, USG KUB, blood urea, creatinine, and DTPA renogram. Out of 19 patients, 7 (36.84%), were female and 12 (63.16%) were male. The mean age was, 39.78 ± 13.69 years., the mean duration for which the stent was in situ was 29.56 months. The most common complication was a fractured stent, in 11 cases (57.89%). Other complications were encrustation in 2 (10.52%)a migration in 5 (26.32%), and 1 case of (5.26%) stone formation. Eighteen cases were managed by endoscopic approaches. A single procedure handled eleven cases, and eight patients required multiple procedures. All were managed successfully with no death reported, and Post-operative complications were seen in eight cases (42.11%).

A single-centre experience on Complications and outcomes of JJ stenting of the ureter in urological practice by Mohammed S. Al-Marhoon, Omar Shareef, and Krishna P. Venkiteswaran where they included 220 patients (87 females and133 males, mean age 39.5 years, SD 15.4) who had self-retaining JJ ureteric stents placed while in the authors' institution, Using the modified Clavien classification, there were grade I, II, IIIa, IIIb complications in 67 (30.4%), 39 (17.7%),

2 (0.9%) and 23 (10.5%) patients, respectively, and none of the patients had grades IVa, IVb and V. Loin colic (10.9%) and UTI (10.9%) were the very most common complications, followed by dysuria at 7.7%. There were significant complications requiring treatment in about 29% of patients, & 71.4% of patients were reported to have improved after stenting. Following multivariate analysis, it was shown that the significant independent factor that affected the complication rate was the stent length, and the significant independent factor affecting the ‘improved' outcome was age (P = 0.014).

In 2014, Umut Gönülalan, Murat Akand, Eray Hasırcı, and Murat Koşan reported on an unusual complication of a double-J ureteral stent (renal parenchymal perforation in a solitary kidney) where they declared their patient being the third presented in the literature with a renal parenchymal perforation and hematoma after DJ stenting in a single kidney.

**The ideal stent.**

The ideal ureteral stent that is the one that is expected to remain in position, drain well and keep the ureteral passage open has not yet been designed(12). A typical DJ ureteric stent ought to be patient/tissue friendly in its qualities, very free of early or late complications even with longstanding and prolonged indwelling times(12). It should also combine the aspects of biocompatibility and bio-durability on top of being radio-opaque(14). Thus, the sole goal of ureteral stenting is to have a ureteric stent that will easily slide up the ureter, stay in position, drain the urine well, be comfortable to the patient while in-situ, be visible easily on fluoroscopic studies and be economical to the patient and the hospital(15).

**Stent size selection.**

DJ ureteral stenting is a fundamentally important part of the various urological procedures that involve the kidney and the ureter. Choosing an optimal length of a ureteral stent depending on the patient is very important for lowering the incidences of associated early or late

complications. Placement of a DJ stent that is too long compared to the ureter often causes complications, such as frequency or urgency in urination, bladder pain, urinary incontinence, flank discomfort or pain hematuria, negatively impacts on quality of life for patients undergoing DJ ureteric stenting. A short ureteral stent increases the risk of stent migration, resulting in complications that require redo of the entire procedure for replacement of the DJ ureteric stent, hence choosing a stent of optimal and proper length remains important for lowering the incidences of stent migration/dislodgement and other complications(21) Specific and actual ureteral length measurement and calibration remains the most accurate method for measuring the ureteric stent but the very actual specific stent measurement involves radiation exposure to the patient and lengthens the procedural time(21).

Direct ureteric measurement with a ureteral catheter in assessment of the actual ureteral length has been reported previously. Other previous studies have shown the reliability of multiple modalities for approximating the ureteral length in a cohort of patients undergoing DJ ureteric stents, this includes, the length from renal vein to the ureteric orifice in the urinary bladder, measured by ACTD has been shown to have a very stronger association than any other variables which includes body height and intravenous urogram measurement. Precisely and accurately predicting the ureteric length is necessary for determination of the optimal stent length.(21)

**Guidelines & precautions to note before usage of ureteric stents.**

The urologist anticipating to perform DJ ureteric stenting should discuss with patient the indication of ureteric stent and take an informed written consent. This is because DJ ureteric stenting is not usually complication free and has even been associated with escalation of complications which has even included raising the cost of the procedure. Proper patients follow up plan which should include diaries should be put in place.

Correct ureteric sizing should always be done to prevent or reduce irritative urinary tract symptoms. Stent material selection should also been considered for polyurethane ureteric stent are best suited for short term use though prone to migration and dislodgement. They are also prone to encrustation and should be changed every three months or earlier in recurrent stone formers.

It is agreeable that all patients should be kept on a Foleys catheter for the first 24-48 hours post ureteric stenting to reduce the chances and occurrences of VUR. Prophylactic antibiotics should also be used and this should be guided by the hospital antimicrobial protocols.

**Stent insertion and removal procedure.**

The ideal ureteric stent set comprises the DJ stent which is usually calibrated, a guide wire, a stent pusher and a clip.(22) The ureteric stent is opened and prepared under sterile and aseptic conditions, and keenly assembled over an aseptic guide wire. If it is a close-ended (blind) ureteric stent the tough end of the guide wire can be safely inserted into the leading end of the ureteric stent. The ureteric stent is then made taut over the guide wire and held in position with a clip. The stent pusher is then placed over the guide wire and flushed to the distal end of the DJ ureteric stent and held in place with another clip. For an open-ended ureteric stent, the floppy soft end of the guide wire should be obviously deployed at the leading side/end(23). The now assembled DJ ureteric stent is then inserted urethero-cysto-ureteroscopicaly up into the ureter under fluoroscopic guidance in cases of retrograde stenting. Once the ureteric stent negotiates successfully into the distal ureter, the upper clip is then removed, and the DJ ureteric stent is advanced slowly and carefully into the kidney by using the stent pusher. The lower clip is now disengaged and removed carefully, and the guide wire is then withdrawn partially until the proximal renal coil of the DJ ureteric stent is safely visualized in the pelvis of the kidney. Now, the pusher and guide wire are now gently withdrawn until the distal/lower coil of the DJ ureteric

stent is seen in the urinary bladder. Most DJ ureteric stents have markings on them at calibrated intervals of 5 cm and this greatly aids in confirmation of precise ureteric stent placement(24).

Antegrade ureteric stenting is performed in a similar manner using fluoroscopic guidance. This uses a nephroscope where the sliding of the ureteric stent is done antegrade (from kidney down to the ureter then into the urinary bladder) over a pre-placed open (through and through) guide wire post percutaneous nephrolithotomy. (23). Most ureteric stents are safely removed as day case under local/topical anesthesia using a rigid or semi.semi rigid or flexible cystoscope with a two-prongs rigid or flexible tissue biopsy forceps(25).

**Stent monitoring.**

This includes regular urine culture and sensitivity analysis, ideally on monthly basis, serum urea, creatinine and electrolytes and a plain KUB X-ray(1). Where renal function compromise is suspected, there is a role for specific renal scans. However this scans should and must be done with a draining indwelling urethral Foleys catheter, to avoid diagnosing a pseudo-obstructive pattern on the scan, to keep the urinary bladder empty, (36).

Internal ureteric stent patency may be evaluated and confirmed by color-coded Doppler sonography (CCDS) or by a micturating cystourethrography (MCU). CCDS generally have a sensitivity of upto almost 100% on top of being completely a non-invasive procedure. A simultaneous KUB ultrasound scan should be considered and done in order to detect or confirm any hydroureter or hydronephrosis(24),(13). To establish ureteric patency before considering ureteric stent removal, retrograde pyelography should be entertained and also attempted via the ureteric stent(37). Patients who are at risk of, or known ‘stone formers’ should be considered for additional screening for other metabolic abnormalities(38).

**Duration of safe ureteric stenting.**

The ideal safe time for ureteric stenting has not been agreed or described locally, regionally or globally(29). Irrespective of what the ureteric stenting duration is, it should be noted that nearly all ureteric stents will form a bacterial bio-film with resultant degree of bacterial adherence(30),(31). If ureteric stenting are left for a significantly sufficient long duration, almost all ureteric stents will form encrustation(20). The safe documented window period, of ureteric stenting, is probably 6-8 weeks(32).

Specific scenarios for stenting following various procedures like URS or SWL for ureteric stones is generally 2 to 3 weeks(33). A challenging and difficult PCNL or ECSWL associated with a risk of developing a significant "steinstrasse" may necessitate or warrants ureteric stenting for up to 2 to 3 months.(34),(35). Patients known to have CKD due to ureteric obstructive uropathy or other ureteric obstruction due to various malignant conditions may need a lifelong ureteric stenting, either done by antegrade or retrograde routes, with a three monthly serial change hence need for proper patient ureteric stenting(13).

**Potential risk factors for developing early DJ ureteric stenting complications.**

It has been shown that not all patients can tolerate indwelling DJ ureteral stents, and some have been shown to be more prone to develop complications directly attributable to them[32]. For the patients with already known and established metabolic problems like recurrent stone formers, chronically compromised kidney, congenital anomalies of the kidney, patients with abdominal and pelvic organs pathologies like tumors are also at a very high risk of getting ureteric stenting early complications, are some of the `at risk' groups hence it is very essential to identify and closely monitor these patients keenly[19].

Ureteric stents bio materials, correct sizing and other stents qualities and characteristics like recoil or coiling memory are additional factors that can lead to early complications of ureteric stents.

Other patient factors like bleeding diathesis, chronic co-morbidities like diabetes mellitus, hypertension, ascites and recurrent urinary tract infections can be potential factors for early or late complications of DJ ureteric stenting.

**Early DJ ureteric complications.**

- ***Failure to successfully negotiate the vesical - ureteric orifice***

This is usually or may be due to over-distension of the urinary bladder, abnormal anatomy of the ureter or a too rigid ureteric stent or guide-wire being used. This is successfully overcome by placement of a guide wire through a ureteral access catheter and then sliding an open-ended ureteric stent retrogradely using a pusher over it under fluoroscopic monitor. This can also be overcome by injecting more water soluble lubricant into the ureteral opening/orifice through a ureteral catheter and re-attempt the DJ ureteric stenting.(26)

- ***Guide wire is stuck***

The most obvious likely cause of a stuck guide wire is an incorrect size (gauge) of the guide-wire being used and is corrected by removing and reinserting a smaller gauge the guide wire. (22)

- ***Failure of proximal coil to open***

This is most obvious likely caused by the stent being in the ureter or PUJ; this is managed by trying to push the guide wire which will straighten the coil then advancing it further followed by pushing the stent further up and then removing the guide wire or by removing everything and reinserting afresh(27).

- ***Distal coil fails to open(recoil)***

It is most probably and likely due to over-insertion of the DJ stent up into the ureter. To overcome this, it requires repositioning with a ureteroscope under sedation if the guidewire had already been removed. Spontaneous DJ ureteric migration or dislodgement may allow the distal end of the ureteric stent to pout out where it can be gently pulled out partially(28).

- ***Hematuria***

Hematuria is usually defined as presence of blood in urine, it can be visible with naked eyes (macroscopic hematuria) or invisible (microscopic) with naked eyes. Immediately after Dj ureteric stenting, microscopic hematuria is an expected finding but macroscopic hematuria is usually an early complication and may require a further and through work up in order to save a patients life.

- ***Flank pain***

Usually due to the incorrect positioning of the proximal ureteric coil in the ureter rather than the renal collecting system or pelvis. When the proximal coil stretches the ureteric wall, pain results at the flanks.

- ***Suprapubic pain***

It is usually due to the distal portion of the ureteric stent, Incorrect positioning, either too low into the urinary bladder or too high in the distal ureter. Patients complain of severe pain or discomfort of the lower abdomen.

- ***Urinary frequency and Urinary urgency***

This is usually due to the irritative feeling when the distal coil of the ureteric stents is lying on the trigonal area of the urinary bladder. The patients become unable to hold urine for long because of the bladder ‘sensing being full’ and this is accompanied by the urge to mictrurate often and urgently.

- ***Urinary incontinence***

This is usually caused by the distal part of the ureteric stent either being at the bladder outlet or urethral opening causing spasms of the bladder neck leading to urinary incontinence.

- ***Stent migration***

Stent migration is referred to as the dislodgement of the ureteric stent from its intended location/position to unwanted or unintended position.

The stent can either migrates upwards into the kidney and distal ureter or downwards in the urinary bladder or proximal ureter. This might present with pain or difficulty to retrieve the stent.

It is either due to technicality challenges when placing the stent or due to stent qualities and characteristics.

- ***Stent fracture***

This is usually breakage of ureteric stent either because of poor ureteric stents quality, biomaterial used or secondary to insertion technicalities leading to breakage. Stent fracture can also be secondary to associated metabolic complications leading to excessive encrustation with subsequent fracturing.

- ***Urinary tract infection and fever***

Urinary tract infection is a common early complication, entry point can be either during ureteric stenting procedure itself, when the ureteric stent is insitu or during the removal of the stent.

Prophylactic antibiotics using local antibacterial protocols should be entertained and put in place.

- ***Ureteral arterial fistula***

This is usually due to difficulties in insertion of ureteric stent. The guide wire can perforate the ureteric wall and goes into the gonadal vessels or the reanl vein or renal artery.

**Managing stent complications.**

Stents that are heavily encrusted are a challenge to the endo-urologist, this is especially when the practioner is confronted with a very long overdue and forgotten ureteral stent. Multimodal approaches using endo-urology has been and will remain the fundamental cornerstone of managing such complications. Most ureteric stents that have mild encrustations or those that have stuck on ureter usually respond to 1 or 2 shockwave lithotripsy sessions. The patients with known significant proximal ureter including the renal pelvis or kidney stone burden usually require a PCNL[21].

Ureteric stents that have undergone fragmentation and fracture can also be considered safely for removal by using PCNL approach using image intensifier, or still the ureteric stent fragments can also be managed successfully by use of the minimally invasive procedures and techniques such as the ureteroscopy and the intracorporeal lithotripsy approaches. Forgotten ureteric stents should be carefully managed by endoscopic approach by the endo urologist who are well trained and versed and have sufficient advanced skills in endourology. Where endourology technology fails, Open surgical techniques have a role, but the urologist must remember that this is not an easy task and has the attendant risks and caveats that can lead to further renal or ureteric impairment, destruction and end up even with sepsis[30]. It should be over emphasized that a stent diary or a computerized stent log in system be established and maintained with periodic updating by the urologist in order to track down overdue ureteric stents and hence remind the patients for removal at the earliest convenience to avoid concomitant complications[11,31.] There have been documented two established strategies in order to reduce and minimize ureteric stent encrustation that comes with association of, and, with bio-film formation. This includes, use of ureteric stents that are coated with surface active antimicrobials and also the use of some hydrophilic compounds[12].

It has been documented that patients with severe urosepsis associated with ureteric stents should prompt them removed and percutaneous nephrostomy done [30.]

**Reporting surgical morbidities and outcomes.**

Having an integrated and exhaustive method of grading, characterizing and communicating morbidities associated with surgery has the potential of improving patient care on many levels and has several advantages which include but not limited to the following. This enables better characterization of morbidities associated with various several surgical methods and techniques; Allows for relative comparison of various and different surgical procedures, which is essential due to the relative lack (< 1%) of randomized trials in the armamentarium of urological literature. It also allows the urologist or surgeon to highlight more precisely to the patients the dangers of a certain surgical procedure vs. other several surgical options. This also allows for better sequencing of various multimodality approaches. It still allows for earlier and timely recognition of several patterns of complication, henceforth allow for pre-emptive changes in patients' care with an effort to significantly decline the incidences. It also allows for much better comparison of different individual specific surgeons or between specific institutions' experiences. Last but not least, it enables identification of quality of care measures for benchmarking.

In order to minimize DJ ureteric stents complications in the current and future urological practice, researchers are busy experimenting with new stent designs with an aim to make them more comfortable to the patients. Currently new stents designs in the market, they are impregnated with medications directly that can relieve discomfort, prevent infections.

Modern ureteric stents that are biodegradable over time in order to eliminate the complication of a forgotten ureteric stent are also in the market(10),(11). Various procedural and post-procedural complications of ureteric stent placement include, UTI, hematuria, irritative urinary symptoms, encrustation, stent migration, forgotten stent unless there is a tracking diary to record and remind patients of the due date of ureteric stent removal[8]. Urological complications just like any other surgical complication should be reported and graded as per the Clavien-Dindo grading system for the surgical complications classification.

**Clavien-Dindo Grading system for the classification of complications of surgery**

Just like any other surgical complications, urological complications can also be reported using the Clavien-Dindo grading system as shown below. This allows and ensures global uniformity of reporting surgical morbidity and complications.

**Table 1: Clavien-Dindo Grading system for the classification of complications of surgery**

| Grades | Definition |
|---|---|
| Grade I | Any deviation from the ordinary post-operative course without the need for pharmacological treatment or surgical, endoscopic and radiological intervention.<br>Allowed treatment regimens are drugs as antiemetics, antipyretics, analgesics, thiazides or loop diuretics, electrolytes & physiotherapy. This grade also includes the wound infections opened at the bedside setting. |
| Grade II | this Requires pharmacological treatment with drugs other than such allowed for grade I complications.<br>Blood transfusions and total parenteral nutrition also included. |
| Grade III | Requiring surgical, endoscopic or radiological intervention |
| IIIA | Intervention not under general anesthesia |
| IIIB | Intervention under general anesthesia |
| Grade IV | Life-threatening complication (including CNS complications)* requiring IC/ICU-management |
| IVA | single organ dysfunction (including dialysis) |
| IVB | Multi organ dysfunction |
| Grade V | Death of a patient |

## STATEMENT OF PROBLEM.

DJ ureteric stents are used in management of urinary obstruction or as an adjunct to ureteric or kidney procedures. Urinary bladder irritative or storage symptoms, loin or suprapubic pain, hematuria, urinary tract infections and fevers are early signs of DJ ureteral stents complications in a patient. In a patient undergoing DJ Ureteric stenting, such complications need to be anticipated so that they can be picked on time and timely revision of the procedure or removal of the DJ stent be done on time as well.

Lack of specific, clear indications for the use of DJ ureteric stenting in our set up present a whole problem by itself and clear guidelines need to be put in place to aid the practicing urologist and residents in training so that they can know of what to expect after DJ stenting, avoid unnecessary DJ ureteric stenting or come up with policies of how to monitor patients post DJ ureteric stenting.

The statistics in health information department at KNH indicates that 140 DJ ureteric stenting was done in 2013, 138 in 2014, 142 in 2015, and 139 in 2016 but there is no documented indication of or outcome of DJ ureteric stenting, procedural or post-procedural DJ ureteric stent complication. Also, no factors that affect the development of early complications of DJ ureteric stents in KNH have been documented locally or regionally.

## STUDY JUSTIFICATION/RATIONALE.

There has been paucity of local data on indications, early complications, and factors that affect the development of early complications of DJ ureteric stents in patients undergoing various ureteric and kidney procedures at Kenyatta National Hospital. Still, there have been no local, current or past standardized guidelines or criterion that have been in existence for reporting urological complications in the area of endo-urology.

This was the first study conducted locally and regionally looking at indications, early complications, and factors that affect the development of early complications of DJ ureteric stenting which has become a standard procedure at Kenyatta National Hospital. The findings in this study will, therefore, serve as a baseline for future studies, and contribute to the armamentarium of resources available and be utilized in the formulation of policies regarding DJ ureteric stenting which will entail earlier and faster recognition of the pattern of early complications, thereby ensuring early pre-emptive care changes in an effort to lower the incidence.

The study results discussed will enable better characterization of DJ stenting morbidity associated with various DJ stents designs. The study results will also allow comparison of various several stenting methods, which is vital due to the relative lack of randomized trials in the armamentarium of urologic literature.

The findings of the study will in depth help in categorizing early ureteric stents complications and will be useful in development of local, regional and worldwide protocols in order to aid the urologists in follow up of patients post DJ ureteric stenting.

## RESEARCH QUESTIONS

The study questions were;

1. What are the indications of DJ ureteric stenting in Kenyatta National Hospital, (KNH)?
2. What are the complications seen within 6 (six) weeks after DJ ureteric stenting in KNH?
3. What are the factors associated with the development of early complications of DJ ureteric stents in KNH?

## STUDY OBJECTIVES

Broad Objective

To establish the indications, early complications, and factors associated with development of early complications of DJ ureteric stents as seen in Kenyatta National Hospital.

Specific Objectives

*1.* To establish the indications of DJ ureteric stenting in Kenyatta National Hospital.

*2.* To establish the complications seen within 6 (six) weeks after DJ ureteric stenting in KNH.

*3.* To establish the factors associated with the development of early complications of DJ ureteric stents in KNH.

## STUDY DESIGN AND METHODOLOGY.

### Study design.

The study was a hospital-based prospective cohort study that was conducted over duration of eighteen weeks (four and a half months), after approval by KNH-UON/ERC. Patients who underwent DJ stenting were recruited once they agreed and consented to participate in the study. The first twelve weeks (three months) were used for data collection and the last six weeks (one and a half month) were used for following up the last recruited study participant, for each study participant was to be followed up for six weeks once they have consented and recruited to the study.

Literature from previous studies looking at early complications and early outcome of double J ureteric stenting done in several urological centers worldwide had been conducted in a duration of three months and had concluded that the average minimal duration of ureteric stenting is usually six weeks and this sufficed for this study which aimed to look at indications and early complications of DJ ureteric stent in patients at the Kenyatta National Hospital.

All patients were followed up for 6 weeks post DJ ureteric stenting to establish the indications, early complications and factors associated with the development of early complications of DJ ureteric stents as seen in Kenyatta National Hospital.

### Study setting/area.

This study was carried out at the Kenyatta National Hospital. Data was collected in urological theatres (adults and pediatrics), gynecological theatres, wards, urological outpatient clinics, gynecological outpatients' clinic, interventional radiology department, cancer treatment centre and minor theatre. More information especially pertaining microbiology and stent location/position were obtained from the Kenyatta National Hospital and the University of Nairobi Microbiology laboratories and radiology department respectively.

Patients who underwent DJ ureteric stent were evaluated for early complications such as irritative urinary bladder symptoms (frequency, urgency, nocturia, and incontinence) pain, hematuria, fevers, urinary tract infections, and stent migration, among others, within the first six weeks post-DJ ureteric stenting.

**Study population and sampling technique.**

The study population were all patients (adults and paediatrics) undergoing DJ ureteric stenting in Kenyatta National Hospital who had voluntarily consented to participate in the study. This included all adults and children in all departments (adults' and pediatrics' urological theatres, maternity and gynecological theatres, wards, urological outpatient clinics, gynecological outpatients' clinic, interventional radiology department, cancer treatment centre and minor theatre.) who had a clear indication of ureteric stenting, who had undergone the procedure of the ureteric stenting and recruited into the study.

Consecutive non-random sampling and recruitment technique was used with Consecutive enrolment of every possible patient who met the inclusion criteria and agreed to be recruited to the study by signing the consent.

**Recruitment and consenting of study participant.**

The principal investigator discussed the consent form with the intended study population, scheduled to undergo DJ ureteric stenting in Kenyatta National Hospital who had voluntarily agreed to participate in the study. This included all adults and children, through their next of kin or guardians, in all departments and units (adults' and pediatrics' urological unit, obstetrics and gynecological unit, medical wards, urological outpatient clinics, obstetrics and gynecological outpatients' clinic, medical outpatients' clinics, interventional radiology department, cancer treatment centre.).

The principal investigator took  through the consent form to the study participants who met the inclusion criteria in a language which they best understood and incase of language barrier; a translator (upon patient agreeing and consenting) was used to translate the message between the researcher and the study participant.

The principal investigator demystified to the study participant the topic of the study to ensure they understood it before they agreed or disagreed to participate to the study. The sole aim of the study, risks & benefits of participating into this study was discussed to the study participant.

The study participant was informed by the principal investigator that Kenyatta National Hospital being a teaching and referral hospital, the DJ ureteric stenting could be done by consultants' urologists or specialist trainee doctors who will be under strict supervision of consultants' urologist; in addition the study participant was informed that medical students may be in theatres to observe the procedure.

The principal investigator also informed the study participant of the clinical, laboratory, imaging and radiological data that will be collected in theatres, wards, clinics, laboratory and radiology department. The principal investigator reassured the study participant that all the collected data will be handled with utmost privacy and confidentiality; this included informing the study participant of the scheduled post procedural reviews which entails clinical, laboratory and radiological evaluations.

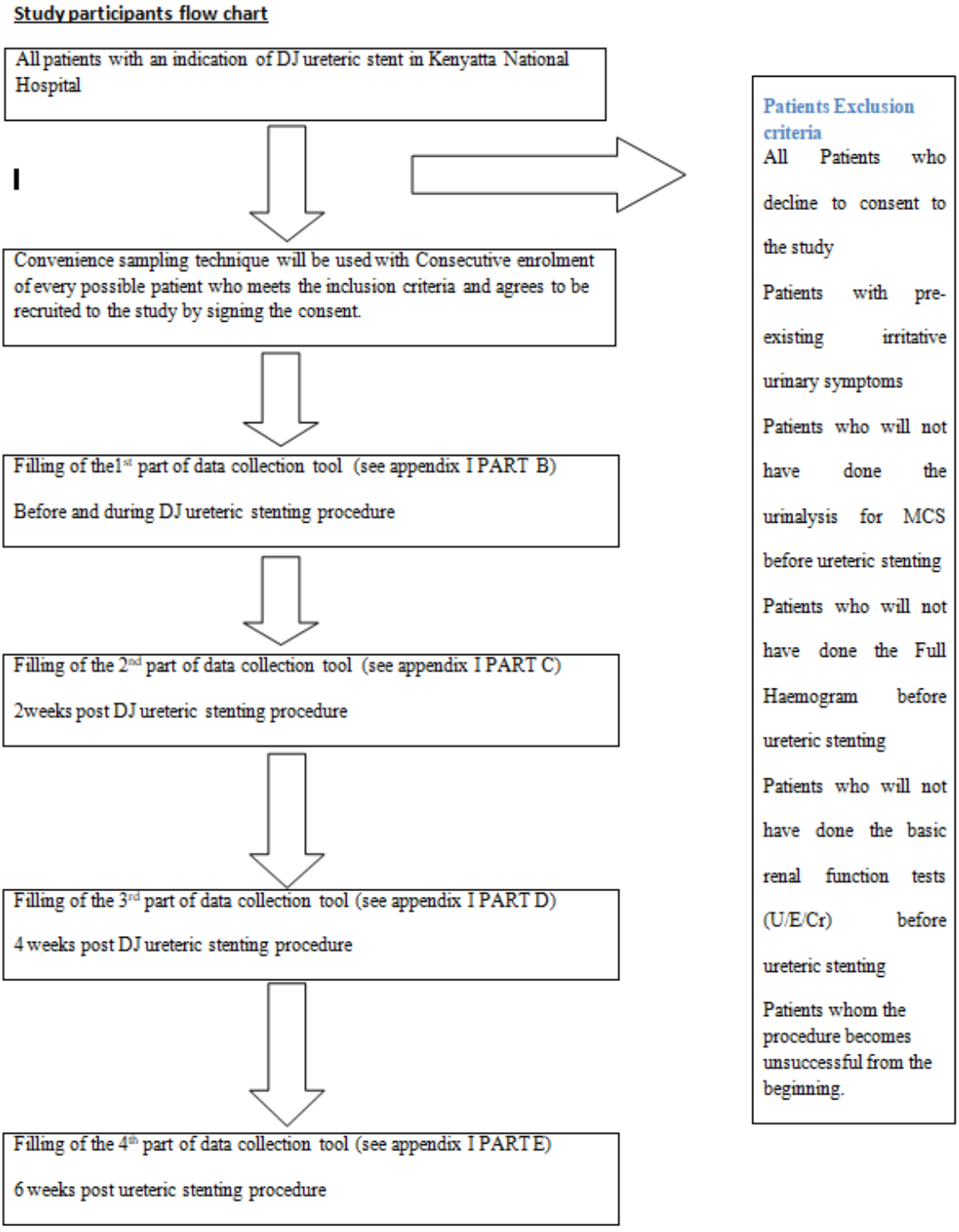
The principal investigator further informed the study participant of the benefits and risks of agreeing and consenting to participate in the study; this was done when the patient/study participant is diagnosed with a disease that falls under the indications of DJ ureteric stenting.

This was done either in the clinics, wards, cancer treatment centre and department of radiology in a secure quite environment/room where the patient and the researcher were comfortable and secure.

The principal investigator requested the study participant whether they had understood the entire process being discussed and whether they had any question(s) to ask before they agreed or disagreed to consent to participate in the study.

The principal investigator without coercion allowed the study participant to make an informed decision on the spot or after sometime to allow further consultation and information seeking.

**Flow chart 1: The study population flow chart**



**Sample size (41)**

The Fischer's sample size formula was used in calculation of the population sample size.

$$n_r = \frac{z^2\, p\,(1-p)}{d^2}$$

Where:

- $n_r$ is the sample size,
- Z is the standard deviation value, (1.96), corresponding to a 95% level of confidence (1.96)
- P is expected prevalence i.e. expected proportion in a population based on other previous studies. (42)
- d is absolute error or precision (corresponding to effect size) – has to be decided by the researcher. For this study, I will calculate the sample size with the precision/absolute error of 5%.

$$nr = \frac{1.96^2\ 0.6\ (1-0.6)}{0.05^2}$$

$$nr = 369$$

- The statistics in the health information department at KNH indicated that 140 DJ ureteric stenting were done in the year 2013, 138 in the year 2014, 142 in the year 2015, and 139 in the year 2016. This meant that on average, 140 DJ ureteric stenting are done in a year. After the discussion with my supervisors, we agreed to collect the data for three months based on the prevalence of the procedure being studied. This translated to 35 ureteric stenting in every three months or every quarter of a year.
- This was arrived to by dividing the stents done in a year by four (140÷4) in order to get the 3 monthly average ureteric stenting in KNH.

- Other reasons of specifying the study duration to be three months included the following. One, referenced published scientific literature from previously conducted studies looking at early complications and early outcome of double J on ureteric stenting done in several urological centers worldwide had been conducted in a duration of three months and had concluded that the average minimal duration of ureteric stenting is usually six weeks and this sufficed for the purpose of this study which aimed to look at indications and early complications of DJ ureteric stent in patients at the Kenyatta National Hospital. (7) Two, this study being conducted in three months was to be used in future as feasibility/pilot study or a pilot study, where the principal investigator or other future scientific researchers wanting to look at long-term complications and outcome of DJ ureteric stents or any other related topic of interests involving DJ ureteric stents could use the study as baseline.(1) Thirdly, for the purpose of reproducibility by other researchers who may wish to conduct a similar study in a limited time frame, the study duration was restricted to three months. Since this study population was finite, the finite population correction formula for proportions was applied for calculation of the study sample size.

$$n_a = \frac{n_r}{1 + ((n_r - 1)/N)}$$

Where:

- na=adjusted sample size
- nr=original required sample size
- N = population size

$$= \frac{369}{1 + ((369 - 1) / 35)}$$

$$na = 32$$

**Patients inclusion criteria.**
The study participants' inclusion criteria include;

- all Patients undergoing DJ ureteric stenting for various indications at Kenyatta National Hospital and who agreed to consent to the study and had done the basic urine analysis, full Haemogram and basic renal function tests (U/E/Cr)

**Patients exclusion criteria.**
The study participants' exclusion criteria included the following;

- All Patients who declined to consent to the study
- Patients with pre-existing irritative urinary symptoms
- Patients who had not have done the urinalysis for MCS before ureteric stenting
- Patients who had not have done the Full Haemogram before ureteric stenting
- Patients who had not have done the basic renal function tests (U/E/Cr) before ureteric stenting
- Patients whom the procedure became unsuccessful from the beginning

**Data collection.**

After obtaining informed consent (Appendix II) from the participants, a study questionnaire (Appendix I) was administered for data collection over a duration of eighteen weeks (four and a half months), after approval by KNH-UON/ERC. Data was collected using Clinical, laboratory and radiological methods.

Patients who had met the study inclusion criteria and had given informed written consent were assigned a unique patient serial number and their information which included demographic factors, indication for DJ ureteric stenting, and date of ureteric stenting among others were entered in a pre-prepared and pre-tested data sheet as a research instrument.

All departments were informed by the writing of posters which were pinned in the wards, clinics, theatres, and other patients' points requesting the consultants and resident doctors in training to inform the researcher of a patient scheduled for DJ ureteric stenting. This was done after authorization from Kenyatta National Hospital Maintenance Department.

This was followed by frequent reminders so that all patients could be captured and evaluated for inclusion in the study. Data collection was divided into 5 (five) parts - data prior to the procedure, data during the procedure itself, data two weeks post procedure, data 4 weeks post procedure and data six weeks post procedure.

Part one of the data collection involved capturing and documentation of the data before the DJ stenting, findings during the procedure itself and findings within the first 24 hours post procedure as per the data collection tool. The dates of the DJ ureteric stenting as well us subsequent revisits for reviews will be captured. The diagnosis and indications of DJ ureteric stenting were captured into the data collection tool. The cadre of the doctor performing the procedure was documented, e.g., consultant urologist, consultant general surgeon, resident in training, etc. whether urine analysis had been done pre DJ stenting and the Urine analysis findings pre-procedural was documented and whether prophylactic antibiotics pre-stenting were given was captured. The blood investigations like full Haemogram, urea, creatinine levels and electrolytes before the procedure was captured and documented. The size and material of DJ ureteric stent was documented. The method of approach, whether antegrade or retrograde were noted and documented. The ureter side done stenting was documented as left or right side. The immediate intra-procedural and, within the first 24 hours complications were captured and documented. Radiological and imaging modality used within the first 24 hours as well as the findings were captured into the data collection tool. The site of the upper ureteric coil, whether in the calyx, renal pelvis or proximal ureter as well as the lower coil shape – complete circle vs

incomplete circle of DJ ureteric were documented post imaging and/or radiological examination. The site of the lower coil, whether on the same side or crossing the midline was documented post imaging and/or radiological examination.

Part two, of the data collection involved capturing and documentation of the data during the first visit/review (two weeks) post DJ ureteric stenting, second visit/review (three weeks) post DJ ureteric stenting, and third visit/review (four weeks) post DJ ureteric stenting. This involved collecting and documentation of urine and blood (full haemogram and renal function tests) analysis findings, imaging and radiological modality used and the findings, The site of the upper ureteric coil, whether in the calyx, renal pelvis or proximal ureter as well as the lower coil shape – complete circle vs incomplete circle of DJ ureteric was documented post imaging and/or radiological examination. The site of the lower coil, whether on the same side or crossing the midline was documented post imaging and/or radiological examination., complications reported and identified in that visit/review and documentation of the complication as per The Clavien-Dindo grading system.

**Quality control.**

The principal investigator recruited the patients himself; obtained informed written consent from the patients and in case of a language barrier, a translator was invited to assist in the filling of the questionnaire after the patient consented. The principal investigator collected, counterchecked and recorded the data himself.

**Data management.**

The collected Data was entered and managed in Microsoft Excel spreadsheet which was password protected for patients' information confidentiality. Standards to protect personal data were followed. Data collection instruments with minimum possible subject identifiers; only the a serial number were entered in the study questionnaire and specimen labels.

**Data entry and analysis.**

Data was entered into a password protectable database, which was correlated with hard copies of the same to ensure accuracy. The data forms were stored in a secure lockable cabinet only accessible by the principal investigator and the statistician. The indications and early complications of DJ ureteric stenting were analyzed using SPSS version 23,Chicago Illinois and presented as frequency tables and proportions. The factors associated with development of early complications of DJ stenting were analyzed using chi-square and factors which were found to be significant ($p < o.1$) were taken to multivariate analysis using logistical regression.

Categorical variables were presented as frequencies and percentages and continuous data summarized into means (standard deviations) or medians (inter-quartile ranges). Data summary was presented in tables and graphs. Univariate and multivariate analysis were not done to identify the significant factors affecting the complication rate like gender, stenting duration, stent length and a positive urine culture before and after stenting, this is because all the patients recruited into the study developed complications and calculation of p-value was also not done.

**Data presentation.**

Results were presented in the form of tables and bar graphs, for knowledge and information consumption.

**Data sequestration.**

The Collected data was confidentially stored for further reference in both hard and soft copies in lockable safes and in password protected software programs

**Dissemination of results.**

The results, findings, and recommendations from this study were presented to the Department of Surgery, University of Nairobi, shared with the UoN /KNH Ethics and Research Committee and

with the University of Nairobi library in both soft and hard copies. The results of the study will also be published in a reputable journal for global consumption.

**Results utility.**

The results of the study will bridged the academic knowledge gap on complications of ureteric DJ stenting locally.

## ETHICAL CONSIDERATION

Ethical approval was sought from the KNH/UON Ethics and Research Committee and permission was sought from Kenyatta National Hospital administration.

Patients who voluntarily agreed to participate to the study and consented were recruited into the study and were guaranteed the utmost observance of confidentiality and were allowed to drop out at any time during the study period.

The study participants will did not incur any extra financial costs

The principal investigator did not benefit in monetary terms from this study

## STUDY DURATION

The study commenced after the approval by KNH-UON/ERC and run for 18 weeks (4.5 months) from the date of approval.

## CONFLICT OF INTEREST

There was no conflict of interest

## STUDY LIMITATIONS

There was basically no study limitation encountered that had an effect to the study outcome

## RESEARCH FINDINGS/RESULTS.

Table 2: Table showing patient characteristics.

| | Frequency (n) | Percent (%) |
|---|---|---|
| **Gender** | | |
| Male | 15 | 46.9 |
| Female | 17 | 53.1 |
| **Age** | | |
| 29-38 | 9 | 28.1 |
| 39-48 | 8 | 25.0 |
| 49-58 | 8 | 25.0 |
| 59+ | 7 | 21.9 |

Table 3: Table showing cadre of healthcare worker performing the DJ ureteric stenting.

| | Frequency (n) | Percent (%) |
|---|---|---|
| **Cadre** | | |
| Consultant urologist | 11 | 34.4 |
| Consultant interventional radiologist | 7 | 21.9 |
| Resident doctor in training | 14 | 43.8 |

Table 4: Table showing size (length) of DJ ureteric stent used

| | Frequency (n) | Percent (%) |
|---|---|---|
| **Ureteric stent length** | | |
| 14 | 3 | 9.4 |
| 24 | 11 | 34.4 |
| 26 | 18 | 56.3 |

The Size (diameter) of DJ Ureteric Stent was 6.0, while the Size (material) of DJ Ureteric Stent was Polyurethane for all.

Table 5: Table showing pre-procedural antibiotics given.

| | Frequency (n) | Percent (%) |
|---|---|---|
| **Antibiotics Administered** | | |
| No Antibiotic | 1 | 3.1 |
| IV Augmentin | 8 | 25.1 |
| IV Ceftriaxone | 23 | 71.9 |

Table 6: Table showing DJ ureteric stenting approach methods.

| Route | Frequency (n) | Percent (%) |
|---|---|---|
| Retrograde route | 25 | 78.1 |
| Antegrade route | 7 | 21.9 |

Table 7: Table showing indications for DJ ureteric stenting.

| Diagnosis | Indication DJ Stenting | Frequency | |
|---|---|---|---|
| | | (n) | (%) |
| Cervical Cancer | Obstructive uropathy | 3 | 9.4% |
| Renal Calculi | Adjunct to surgery | 7 | 21.9% |
| Post Renal Transplant | Adjunct to surgery | 3 | 9.4% |
| Ureter Injury | Adjunct to surgery | 2 | 6.3% |
| PUJO | Adjunct to surgery | 7 | 21.9% |
| | Obstructive uropathy | 3 | 9.4% |
| Renal Pelvis Staghorn Calculi | Post laser lithotripsy | 1 | 3.1% |
| Ureteric Calculi | Post-surgery | 1 | 3.1% |
| | To dilate the ureteric before laser lithotripsy | 1 | 3.1% |
| Urinary Bladder Malignancy | Obstructive uropathy | 4 | 12.5% |

Table 8: Table showing the proportion of patients who had urinalysis and culture done before DJ ureteric Stenting

| | **Frequency (n) Percent (%)** | **Results of urinalysis and culture** |
|---|---|---|
| URINALYSIS DONE | 27<br>84.4% | Normal findings<br>No positive cultures |
| URINALYSIS NOT DONE | 5<br>15.6% | |

Table 9: Table showing complications that were encountered during DJ stenting (intra-procedural complications).

| | **Frequency (n)** | **Percent (%)** |
|---|---|---|
| **Complication** | | |
| Difficult to identify ureteric orifice | 2 | 6.3 |
| Difficult to negotiate ureteric orifice | 4 | 12.5 |
| No complication | 26 | 81.3 |

Table 10: Table showing outcomes/complications of DJ ureteric stents in specific durations of follow up

| OUTCOMES IN SPECIFIC DURATION OF FOLLOW UP | **Symptom/sign present -** first 24 hours) after DJ stenting | **Symptom/sign present** – 2 weeks after DJ stenting | **Symptom/sign present -** 4 weeks after DJ Stenting | **Symptom/sign present -** 6 weeks after DJ Stenting |
|---|---|---|---|---|
| **FREQUENCY** / **SYMPTOM/SIGN** | **(%) (n)** | **(%) (n)** | **(%) (n)** | **(%) (n)** |
| **Microscopic Hematuria** | 78.1% 25 | 37.5% 12 | 43.8% 14 | 43.8% 14 |
| **Macroscopic Hematuria** | 25.0% 8 | 3.1% 1 | 3.1% 1 | 12.5% 4 |
| **Flank Pain** | 71.9% 23 | 46.9% 15 | 46.9% 15 | 56.3% 18 |
| **Suprapubic Pain** | 75.0% 24 | 59.4% 19 | 50.0% 16 | 50.0% 16 |
| **Urinary Frequency** | 34.4% 11 | 25.0% 8 | 25.0% 8 | 43.8% 14 |
| **Urinary Urgency** | 18.8% 6 | 12.5% 4 | 25.0% 8 | 34.4% 11 |
| **Urinary Incontinence** | 9.4% 3 | 3.1% 1 | 0.0% 0 | 6.3% 2 |
| **Stent Migration** | 6.3% 2 | 6.3% 2 | 6.3% 2 | 9.4% 3 |
| **Stent Fracture** | 0.0% 0 | 0.0% 0 | 0.0% 0 | 0.0% 0 |
| **Urinary Tract Infection** | 0.0% 0 | 3.1% 1 | 15.6% 5 | 40.6% 13 |
| **Uretero-Arterial Fistula** | 0.0% **0** | 0.0% 0 | 0 0.0% | 0.0% |
| **Fever** | 0.0% 0 | 6.3% 2 | 9.4% 3 | 40.6% 13 |

Table 11: Table showing check imaging done & findings in specific durations of follow up post DJ ureteric stenting

| CHECK IMAGING DONE & FINDINGS IN SPECIFIC DURATION OF FOLLOW UP | First 24 hours after DJ stenting **Percent (%) Frequency (n)** | 2 weeks after DJ stenting **Percent(%) Frequency( n)** | 4 weeks after DJ stenting **Percent(%) Frequency( n)** | 6 weeks after DJ stenting **Percent(%) Frequency(n)** |
|---|---|---|---|---|
| **Plain KUB XRAY** | | | | |
| Abnormal | 9.4**%**<br>3 | 6.2%<br>2 (upper stent coil in ureter) | 6.2%<br>2( Stent migration) | 6.2%<br>2( Stent migration) |
| Normal | 90.6**%**<br>29 | 93.8%<br>30 | 93.8%<br>30 | 93.8%<br>30 |
| **Ultrasound** | | | | |
| Abnormal | 3.1**%**<br>1 (pyelonephritis) | N/A | N/A | 3.1**%**<br>3 (pyelonephritis) |
| Normal | 5 | N/A | N/A | N/A |
| **CT Scan Urogram** | | | | |
| Abnormal | 3.1%<br>1 (upper coil in the ureter) | N/A | N/A | N/A |

Table 12: Table showing urine analysis findings in specific durations of follow up post DJ ureteric stenting

| WEEK 2 | Abnormal | Normal | Absent | Present |
|---|---|---|---|---|
| **Color** | 4 (12.5%) | 28 | | |
| **Dipstick** | | | | |
| Ph | | 32 | | |
| Specific Gravity | | 32 | | |
| **Laboratory** | | | | |
| **Microscopy** | | | | |
| Casts | | | 28 | 4(12.5%) |
| White Blood Cells | | | 28 | 4(12.5%) |
| Red Blood Cells | | | 29 | 3(9.4%) |
| **Biochemistry** | | 32 | | |
| **WEEK 4** | | | | |
| **Color** | 9(28%) | 23 | | |
| **Dipstick** | | | | |
| Ph | | 32 | | |
| Specific Gravity | | 32 | | |
| **Laboratory** | | | | |
| **Microscopy** | | | | |
| Casts | | | 23 | 9(28%) |
| White Blood Cells | | | 24 | 8 (24%) |
| Red Blood Cells | | | 28 | 4 (12.5%) |
| **Biochemistry** | | 32 | | |
| **WEEK 6** | | | | |
| **Color** | 15 (46.9%) | 17 | | |
| **Dipstick** | | | | |
| Ph | | 29 | | |
| Specific Gravity | | 29 | | |
| **Laboratory** | | | | |
| **Microscopy** | | | | |
| Casts | | | 17 | 15(46.9%) |
| White Blood Cells | | | 17 | 15(46.9%) |
| Red Blood Cells | | | 28 | 4(12.5%) |
| **Biochemistry** | | 32 | | |

Table 13: Table showing urine cultures & findings in specific durations of follow up post DJ ureteric stenting

| URINE CULTURES & FINDINGS IN SPECIFIC DURATION OF FOLLOW UP | **Positive urine cultures 2 weeks after DJ stenting**<br><br>***Percent (%) Frequency(n)*** | **Positive urine cultures 4 weeks after DJ stenting**<br><br>***Percent (%) Frequency(n)*** | **Positive urine cultures 6 weeks after DJ stenting**<br><br>***Percent (%) Frequency(n)*** |
|---|---|---|---|
| **URINE CULTURE/SENSITIVITY RESULTS** | 4(12.5%) | 6(18.8%) | 13(40.6%) |

## DISCUSSION

A total of 32 patients were recruited into the study. Female patients were the majority at 53%, (n=17), while the males were 47 %,( n=15). The age ranged from 29 years to 59+ years. **Table 2**

Most of the ureteric DJ stenting was done by resident doctors in training at 44%, while the consultant urologists and interventional radiologists performed 34% and 22% respectively. This could be explained by the fact that Kenyatta National Hospital being a teaching and tertiary hospital, houses the University of Nairobi School Of Medicine (CHS), which offers a post graduate teaching hence the resident doctors in training get the chance to perform some of urological procedures. **Table 3**

The DJ ureteric stents done used at KNH were all made of polyurethane and the sizes used were 6 x 14F, (9.4%). 6 x 24F (34.4%) & 6 x 26 F (56.3%). The small sized stents were used during kidney transplants. The other sizes were used depending on the patients' height approximation. **Table 4**

A total of 23 (72%) patients received intravenous Ceftriaxone, 25% (n=8), received intravenous Augmentin. Only 1 patient did not receive any antibiotic before the procedure. **Table 5**

Retrograde approach was the most commonly used route, 78% (n=25). This was mainly done by the consultant urologists and resident doctors in training where-as antegrade approach was done during pyeloplasty surgeries and by the interventional radiologist, 22% (n=7). **Table 6**

The most common indication for DJ ureteric stenting was adjunct to surgery – secondary to renal calculi and in pelvi-ureteric junction obstruction at 21.9%, Post Renal Transplant at 9.4%, and Ureter Injury at 6.3%. All the antegrade ureteral DJ stenting by the interventional radiologist were secondary to hydronephrosis in urinary bladder malignancies and cervical cancer at 12.5%

and 9.4% respectively. Post laser lithotripsy, post ureteral calculi surgery and to dilate the ureter before laser lithotripsy were the least frequent indications for ureteric DJ stenting at 3.1% each. **Table 7**

A total of 27 (84.4%) patients had a pre-procedural urinalysis done while only 15.6% (n=5) did not have a pre-procedural urine analysis done. This included patients who underwent emergency ureteric stenting. **Table 8**

Difficulty to negotiate ureteric orifice and difficulty to identify ureteric orifice was only in 12.5% and 6.3% respectively while 81.3% of patients did not have any intra-procedural complication. **Table 9**

All the patients underwent a check KUB X-Ray within the first 24 hours post ureteric stenting. A total of 29 patients (91%), had a normal scan while 9%, (n=3), had an abnormal scan. The abnormal findings were; proximal coil being in the upper ureter and lower coil crossing the midline. A total of 6 patients underwent KUB Ultrasound because of severe loin pain but only one patient had pyelonephritis. Only 1 patient had a CT-SCAN urogram which showed upper ureteral coil being in the upper ureter rather than the pelvis. **Table 11**

Within the first 24 hours post procedure, 78.1% and 25% of the patients had microscopic and macroscopic hematuria respectively. Other complications encountered included; flank pain (71.9%), suprapubic pain (75%), urinary frequency (34.4%), urinary urgency (18.8%), urinary incontinence and stent migration in 9.4% and 6.3% respectively. There were no stent fractures, urinary tract infections, ureteral arterial fistula or fever identified within the first 24 hours post procedure. **Table 10**

On week 2 of follow-up, 12.5% (n=4), of  patients had an abnormal urine color, casts, and white cells but only 3 had red blood cells picked on urinalysis. All the 4 patients had positive urine culture. All 32 patients underwent KUB X-ray. 2 patients had the upper stent coil being in the

ureter. The rest had normal findings. By week 2 (14 days) post procedure, 37.5% and 3.1% of the patients had microscopic and macroscopic hematuria respectively. Other complications encountered included; flank pain (46.9%), suprapubic pain (59.4%), urinary frequency (25%), urinary urgency (12.5%), and urinary incontinence 3.1% and stent migration in 6.3%, UTI in 3.1% and fevers in 6.3%. There were no stent fracture and ureteral arterial fistula identified within the first 24 hours post procedure. **Tables 10 - 13**

On week 4 post ureteric stenting, 28%, (n=9), patients had an abnormal urine color and casts detected on urine analysis. A total of 8(24%) patients had white cells detected in urine and 4(12.5%) had red cells detected in urine. Only 6 (18.8%) patients had a positive urine culture. all 32 patients underwent KUBP X-ray. A total of 2 patients (those diagnosed earlier on week 2) still had the upper stent coil being in the ureter. The rest had normal findings. By week 4 post procedure, 43.8% and 3.1% of the patients had microscopic and macroscopic hematuria respectively. Other complications encountered included; flank pain (46.9%), suprapubic pain (50%), urinary frequency (25%), urinary urgency (25%), stent migration in 6.3%, UTI in 15.6% and fevers in 9.4%. There were no urinary incontinence, stent fracture and ureteral arterial fistula identified within the first 4weeks post procedure. **Tables 10 - 13**

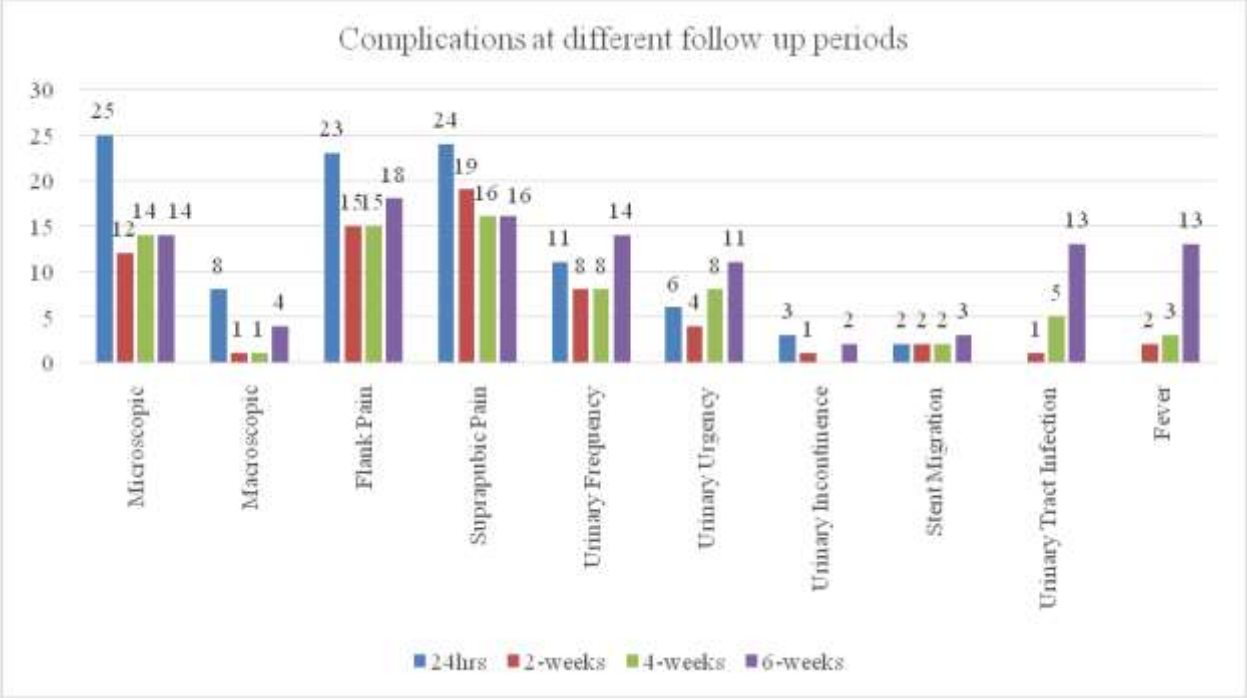
By 6 weeks of follow-up post procedural, 46.9%, (n=15), patients had an abnormal urine color, casts and white cells detected in urine and 4(12.5%) had red cells detected in urine on urine analysis. 1 patient had urine PH elevated, 1 patient had urine specific gravity elevated, 2 patients had urine PH reduced and 2 patients had urine specific gravity reduced. A total of 13 patients (40.6%) patients had appositive urine culture. All the 32 patients underwent KUB X-ray. Two (2) patients (those diagnosed earlier on week 2 and 4) still had the upper stent coil being in the ureter. The rest had normal findings on KUBP X-ray. Three (3) patients were diagnosed of pyelonephritis on KUB Ultrasound which was done due to persistent loin pain. By week 4 post

procedure, 43.8% and 12.5% of the patients had microscopic and macroscopic hematuria respectively. Other complications encountered included; flank pain (56.3%), suprapubic pain (50%), urinary frequency (43.8%), urinary urgency (34.4%), urinary incontinence (6.3%), and stent migration in 9.4%, UTI in 40.6% and fevers in 40.6%. There were no stent fracture and ureteral arterial fistula identified by week 6 post-procedure. **Tables 10 - 13**

All patients had Clavien-Dindo grade 1 surgical complication from the time of the procedure to 6 weeks post ureteric stenting.

The average ureteric stenting duration was 47.93 days with a median of 47.00 and standard deviation of 4.719.

**Graph 1: Graph showing complications at different follow up periods.**




From the graph above, it can be seen that microscopic hematuria was evident in almost all patients (n=25) within the 1st 24 hours post ureteric stenting and continued all through up-to 6 weeks post ureteric stenting. Macroscopic hematuria was higher in the immediate post procedure duration but in a very small proportion of patients.

Flank pain and suprapubic pain were higher in the initial 24 hours post procedure but reduced in the subsequent follow-ups.

Urinary frequency and urgency rates were noted to be going higher from the first 24 hours to six weeks of follow-up and this corresponds to increasing rates of urinary tract infections and fevers as well as stent migrations.

Factors affecting complication rate in the 32 patients could not be assessed by assessed by univariate analysis because all patients had complications hence there was no single factor that could be taken or exposed to multivariate analysis.

## CONCLUSION.

The major indications for ureteric stenting in Kenyatta National Hospital were well demonstrated in the study as described in the discussion section above with the most common indication for DJ ureteric stenting being adjunct to surgery – secondary to renal calculi and in PUJO at 21.9%.

The early complications of DJ ureteric stenting have been discussed above and it is evident that Ureteric stenting is a fairly safe procedure as all our patients; 100%, got grade-1Clavien-Dindo complication.

There was no obvious single or multiple factor that could be associated with the early outcomes of DJ ureteric stenting as all our patients developed complications hence univariate and multivariate analysis could not be run on the data.

## RECOMMENDATIONS.

Most procedures, (44%), were done by resident doctors training in urology under supervision of a consultant urologist, this is commendable bearing in mind KNH is a teaching and referral hospital for specialty training.

Need to continue with the above principle for good training and good patient outcome.

The stent material available in KNH is only one type, polyurethane. The department of procument needs to be advised to have other types of ureteric stents with makes of other bio-materials for comparison studies.

Almost all patients received pre-procedural antibiotics; this can be associated with the lower rates of urinary tract infections. There is a need to ensure that 100% of the patients receive antibiotics before the procedure hence need to come up with a protocol and standard operating procedures of ureteric stenting.

Pre- procedural Urine analysis should be recommended to all patients, 16% of patients did not have a urine analysis done. This opens a room for a comparison study to compare rates of urinary tract infections between patients who have a urine test and those without a urine test pre-procedure (ureteric stenting). The number in the current study may not be enough for an exhaustive comparison and conclusion whether urine test should be mandatory before ureteric stenting.

Antegrade stenting was only done in 22% of the patients; need to increase the number for training purposes.

Need to come up with a post ureteric stenting follow up protocols as it is evident that almost all patients develop complications with increasing frequencies as time elapses. Two weekly follow –up is recommended hence a diary to be established and started for constant reminders. Examples; Protocol for post stenting urine for MCS and other post procedural complication as per table 10.

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**APPENDIX I – DATA COLLECTION TOOL**

**TOPIC**: INDICATIONS AND EARLY COMPLICATIONS OF DOUBLE – J URETERIC STENTS AS SEEN IN KENYATTA NATIONAL HOSPITAL

**NOTES**

This questionnaire is divided into 6 (SIX) parts

- **PART A: DATES OF DJ URETERIC STENTING AND FOLLOW UPS**
- **PART B: GENERAL PATIENT INFORMATION**
- **PART C: FINDINGS ON 1ST POST-OP VISIT - WEEK 2 (TWO) OF FOLLOW UP**
- **PART D: FINDINGS ON 2ND POST-OP VISIT WEEK 4 (FOUR) OF FOLLOW UP**
- **PART E: FINDINGS ON 3RD POST-OP VISIT WEEK 6 (SIX) OF FOLLOW UP**
- **PART F: OTHER INFORMATION/FINDINGS**

**PART A: DATES OF DJ URETERIC STENTING AND FOLLOW-UP**

**1. INDICATE THE DATES OF PATIENT ATTENDANCE IN THE TABLE BELOW**

| | |
|---|---|
| DATE OF DJ URETERIC STENTING | …… |
| DATE OF 1ST POST OP VISIT (WEEK 2) | …… |
| DATE OF 2ND POST OP VISIT (WEEK 4) | …… |
| DATE OF 3RD POST OP VISIT (WEEK 6) | …… |

**PART B: GENERAL PATIENT INFORMATION**

2. FILL IN THE PATIENT'S BIODATA IN THE SPACES PROVIDED IN THE TABLE BELOW.

| | |
|---|---|
| QUESTIONNAIRE SERIAL NO. | |
| GENDER | |
| AGE | |

3. TICK THE CADRE OF THE HEALTH CARE PROVIDER WHO PERFORMED DJ URETERIC STENTING.

| | | |
|---|---|---|
| i. | CONSULTANT UROLOGIST | |
| ii. | CONSULTANT GENERAL SURGEON | |
| iii. | CONSULTANT INTERVENTIONAL RADIOLOGIST | |
| iv. | CONSULTANT PAEDIATRIC SURGEON | |
| v. | RESIDENT DOCTOR IN TRAINING | |
| vi. | OTHER ***(SPECIFY)*** | |

***4.*** WHAT IS THE SIZE AND MATERIAL OF DJ URETERIC STENT USED? ***(Indicate clearly in the spaces provided in the box below)***

| | | |
|---|---|---|
| SIZE | *Length* | |
| | *diameter* | |
| MATERIAL | | |

5. WERE ANTIBIOTIC PROPHYLAXIS GIVEN BEFORE DJ STENTING? ***(tick accordingly)***

| | |
|---|---|
| YES | |
| NO | |

6. IF THE ANSWER TO *QUESTION 6* (SIX) ABOVE IS 'YES,' LIST THE ANTIBIOTIC THAT WAS GIVEN. **(Example iv/im ceftriaxone, im/iv penicillin, im/iv gentamycin, im/iv meropenem, iv/im amikacin etc)**

……..

7. WHAT IS THE DJ URETERIC STENTING APPROACH METHOD USED? ***(tick accordingly)***

| | |
|---|---|
| RETROGRADE ROUTE | |
| ANTEGRADE ROUTE | |

***8.*** IN WHICH URETER WAS THE DJ URETERIC STENTING DONE? ***(tick accordingly)***

| | |
|---|---|
| LEFT URETER | |
| RIGHT URETER | |
| BOTH URETERS | |

9. WHAT WAS THE DIAGNOSIS AT PRESENTATION PRE DJ URETERIC STENTING?

**(Examples PUJO, ureteric calculi, kidney calculi, post pyeloplasty, post laser lithotripsy, cervical malignancy, urinary bladder malignancy, prostate malignancy, post ureteric injury repair, post renal transplant etc)**

***(Write clearly in CAPITAL LETTERS in the spaces provided)***

i. ……

ii. ……

iii. ……

***10.*** WHAT WAS/WERE THE INDICATION(S) FOR DJ URETERIC STENTING? ***(write clearly in CAPITAL LETTERS in the spaces provided)***

i. ……

ii. ……

iii. ……

iv. ……

v. ……

11. WAS URINALYSIS DONE BEFORE DJ URETERIC STENTING? ***(tick accordingly in the table below)***

| | |
|---|---|
| YES | |
| NO | |

***12.*** IF **YES** TO QUESTION 11 ABOVE, WHAT IS THE URINE ANALYSIS RESULTS BEFORE DJ STENTING ***(document the findings as negative or positive or not done)***

**Key: normal=expected finding/ present= positive finding/ absent=negative or no finding**

| TEST DONE | RESULTS<br>***(document the findings accordingly)*** |
|---|---|
| | N – NORMAL/A-ABSENT/P-PRESENT or POSITIVE/E-ELEVATED/R-REDUCED/N-NEGATIVE |
| URINE COLOUR | |
| DIPSTICK | |
| i. PH | |
| ii. SPECIFIC GRAVITY | |
| LABORATORY | |
| MICROSCOPY | |
| i. CASTS | |
| ii. WHITE BLOOD CELLS | |
| iii. RED BLOOD CELLS | |
| BIOCHEMISTRY | |
| CULTURE/SENSITIVITY | ***(document the findings)*** |
| OTHERS(SPECIFY) | |

13. WAS BLOOD STUDIES DONE BEFORE DJ URETERIC STENTING? ***(tick accordingly in the table below)***

| | |
|---|---|
| YES | |
| NO | |

14. IF **YES** TO QUESTION 13 ABOVE, WHAT IS THE BLOOD STUDIES FINDINGS BEFORE DJ STENTING?

| TEST | RESULTS ***(document the findings)*** |
|---|---|
| | N - NORMAL<br>E – ELEVATED<br>R - REDUCED |
| i. WHITE CELL COUNT | |
| ii. RED CELL COUNT | |
| iii. HAEMOGLOBIN LEVEL | |
| iv. HAEMATOCRIT LEVEL | |
| v. UREA LEVEL | |
| vi. CREATININE LEVEL | |
| vii. BLOOD UREA NITROGEN LEVELS | |
| viii. SODIUM LEVEL | |
| ix. POTASSIUM LEVEL | |
| x. OTHERS (SPECIFY) | |

*15.* WHICH COMPLICATION(S) WAS/WERE ENCOUNTERED DURING DJ STENTING? **(PROCEDURAL COMPLICATIONS) -** ***(write clearly in capital letters in the spaces provided)***

i. ……

ii. ……

iii. ……

iv. ……

iv. ……

16. WHAT IMAGING AND RADIOLOGICAL INVESTIGATIONS/STUDIES WERE DONE IMMEDIATELY POST DJ STENTING **(WITHIN THE FIRST 24 HOURS)**

| INVESTIGATIONS/STUDIES | FINDINGS (tick accordingly and document the findings) | |
|---|---|---|
| PLAIN KUB XRAY | | |
| ULTRASOUND | | |
| CT SCAN UROGRAM | | |
| IVP/IVU | | |
| OTHERS (SPECIFY) | | |

***17.*** WHAT IS THE SITE OF UPPER COIL IMMEDIATELY (WITHIN THE FIRST 24 HOURS) AFTER STENTING? ***(tick accordingly)***

| | |
|---|---|
| CALYX | |
| PELVIS | |
| URETER | |

***18.*** WHAT IS SITE OF THE LOWER COIL IMMEDIATELY (WITHIN THE FIRST 24 HOURS) AFTER STENTING? ***(tick accordingly)***

| | |
|---|---|
| SAME SIDE | |
| CROSSING MIDLINE | |

***19.*** WHAT IS THE LOWER COIL SHAPE IMMEDIATELY (WITHIN THE FIRST 24 HOURS) AFTER STENTING? ***(tick accordingly)***

| | |
|---|---|
| COMPLETE CIRCLE | |
| INCOMPLETE CIRCLE | |

***20.*** WHICH COMPLICATION(S) WAS/WERE ENCOUNTERED IMMEDIATELY (WITHIN THE FIRST 24 HOURS) AFTER DJ STENTING? (WITHIN THE FIRST 24 HOURS)- ***(write clearly in CAPITAL LETTERS in the spaces provided)***

| COMPLICATION | (document the findings accordingly) |
|---|---|
| | P-PRESENT/ A-ABSENT/ |
| i. HEMATURIA | |
| a. microscopic | |
| b. macroscopic | |
| ii. FLANK PAIN | |
| iii. SUPRAPUBIC PAIN | |
| iv. URINARY FREQUENCY | |
| v. URINARY URGENCY | |
| vi. URINARY INCONTINENCE | |
| vii. STENT MIGRATION | |
| viii. STENT FRACTURE | |
| ix. URINARY TRACT INFECTION | |
| x. URETERO-ARTERIAL FISTULA | |
| xi. FEVER | |
| xii. OTHERS (SPECIFY) | |

21. WHAT EARLY COMPLICATION DOES THE PATIENT HAVE AS PER THE CLAVIEN-DINDO GRADING SYSTEM FOR THE CLASSIFICATION OF SURGICAL COMPLICATIONS? (fill in the space provided in the table below - indicate ‘O’ if none)

| |
|---|
| |

**PART C: FINDINGS ON 1ST POST OP VISIT - WEEK 2 (TWO) OF FOLLOW UP**

22. WHAT IS THE URINE ANALYSIS RESULTS ON 1ST POST OP VISIT - 2 (two) WEEKS AFTER DJ STENTING? (document the findings as negative or positive or not done)

**Key: normal=expected finding/ present= positive finding/ absent=negative or no finding**

| TEST | INTERPRETED RESULTS<br><br>(document the findings ACCORDINGLY) |
|---|---|
| | N – NORMAL/A-ABSENT/P-PRESENT or POSITIVE/E-ELEVATED/R-REDUCED/N-NEGATIVE |
| COLOUR | |
| DIPSTICK | |
| i. PH | |
| ii. SPECIFIC GRAVITY | |
| LABORATORY | |
| MICROSCOPY | |
| i. CASTS | |
| ii. WHITE BLOOD CELLS | |
| iii. RED BLOOD CELLS | |
| BIOCHEMISTRY | |
| CULTURE/SENSITIVITY | |
| OTHERS(SPECIFY) | |

23. WHAT IS THE BLOOD STUDIES FINDINGS ON 1ST POST OP VISIT - 2 (TWO) WEEKS AFTER DJ STENTING?

| TEST | RESULTS (document the findings)<br><br>N - NORMAL<br><br>E – ELEVATED<br><br>R - REDUCED |
|---|---|
| WHITE CELL COUNT | |
| RED CELL COUNT | |
| HAEMOGLOBIN LEVEL | |
| HAEMATOCRIT LEVEL | |
| UREA LEVEL | |
| CREATININE LEVEL | |
| BLOOD UREA NITROGEN LEVELS | |
| SODIUM LEVEL | |
| POTASSIUM LEVEL | |
| Others (specify) | |

24. WHICH IMAGING AND RADIOLOGICAL INVESTIGATIONS/STUDIES WERE DONE ON 1ST POST OP VISIT - 2 (TWO) WEEKS AFTER DJ STENTING?

| INVESTIGATIONS/STUDIES | FINDINGS | |
|---|---|---|
| | ***(tick and document the findings)*** | |
| PLAIN KUB XRAY | | |
| ULTRASOUND | | |
| CT SCAN UROGRAM | | |
| IVP/IVU | | |
| OTHERS (SPECIFY) | | |

**25.** WHAT IS THE SITE OF UPPER COIL ON 1ST POST OP VISIT - 2 (TWO) WEEKS AFTER DJ STENTING? ***(tick accordingly)***

| | |
|---|---|
| CALYX | |
| PELVIS | |
| URETER | |

26. WHAT IS THE SITE OF THE LOWER COIL ON 1ST POST OP VISIT - 2 (TWO) WEEKS AFTER DJ STENTING? ***(tick accordingly)***

| | |
|---|---|
| SAME SIDE | |
| CROSSING MIDLINE | |

27. WHAT IS THE LOWER COIL SHAPE ON 1ST POST OP VISIT - 2 (TWO) WEEKS AFTER DJ STENTING? ***(Indicate YES or NO accordingly)***

| | |
|---|---|
| COMPLETE CIRCLE | |
| INCOMPLETE CIRCLE | |

28. WHICH COMPLICATION(S) WAS/WERE ENCOUNTERED BY 1ST POST OP VISIT - WEEK 2 AFTER DJ STENTING? ***(write clearly in capital letters in the spaces provided)***

**Key: normal=expected finding/ present= positive finding/ absent=negative or no finding**

| COMPLICATION | (document the findings accordingly )<br>P-PRESENT/ A-ABSENT/ |
|---|---|
| i. HEMATURIA | |
| a. microscopic | |
| b. macroscopic | |
| ii. FLANK PAIN | |
| iii. SUPRAPUBIC PAIN | |
| iv. URINARY FREQUENCY | |
| v. URINARY URGENCY | |
| vi. URINARY INCONTINENCE | |
| vii. STENT MIGRATION | |
| viii. STENT FRACTURE | |
| ix. URINARY TRACT INFECTION | |
| x. URETERO-ARTERIAL FISTULA | |
| xi. FEVERS | |
| xii. Others (specify) | |

29. WHAT EARLY COMPLICATION DOES THE PATIENT HAVE AS PER THE CLAVIEN-DINDO GRADING SYSTEM FOR THE CLASSIFICATION OF SURGICAL COMPLICATIONS ON 1ST POST OP VISIT? (fill in the space provided in the table below - indicate ‘O’ if none)

**PART D:FINDINGS ON 2ND POST OP VISIT - WEEK 4 (FOUR) OF FOLLOW UP**

30. WHAT WAS THE URINE ANALYSIS RESULTS ON 2ND POST OP VISIT - 4 (FOUR) WEEKS AFTER DJ STENTING?

**Key: normal=expected finding/ present= positive finding/ absent=negative or no finding**

| TEST | RESULTS (document the results accordingly) |
|---|---|
| | N – NORMAL/A-ABSENT/P-PRESENT or POSITIVE/E-ELEVATED/R-REDUCED/N-NEGATIVE |
| COLOUR | |
| DIPSTICK | |
| i. PH | |
| ii. SPECIFIC GRAVITY | |
| LABORATORY | |
| MICROSCOPY | |
| i. CASTS | |
| ii. WHITE BLOOD CELLS | |
| iii. RED BLOOD CELLS | |
| BIOCHEMISTRY | |
| CULTURE/SENSITIVITY | |
| OTHERS(SPECIFY) | |

31. WHAT WAS THE BLOOD STUDIES FINDINGS ON 2ND POST OP VISIT - 4 (FOUR) WEEKS AFTER DJ STENTING?

| TEST | RESULTS (document the findings) |
|---|---|
| | N - NORMAL<br>E – ELEVATED<br>R - REDUCED |
| WHITE CELL COUNT | |
| RED CELL COUNT | |
| HAEMOGLOBIN LEVEL | |
| HAEMATOCRIT LEVEL | |
| UREA LEVEL | |
| CREATININE LEVEL | |
| BLOOD UREA NITROGEN LEVELS | |
| SODIUM LEVEL | |
| POTASSIUM LEVEL | |
| Others (specify) | |

32. IMAGING AND RADIOLOGICAL INVESTIGATIONS/STUDIES DONE ON 2ND POST OP VISIT - 4 (FOUR) WEEKS AFTER DJ STENTING

| INVESTIGATIONS/STUDIES | FINDINGS (tick and document the findings) | |
|---|---|---|
| | POST DJ STENTING DAY 14 (2 WEEKS) | |
| PLAIN KUB XRAY | | |
| ULTRASOUND | | |
| CT SCAN UROGRAM | | |
| IVP/IVU | | |
| Others (specify) | | |

***33.*** WHAT WAS SITE OF UPPER COIL ON 2ND POST OP VISIT - 4 (FOUR) WEEKS AFTER DJ STENTING? ***(tick accordingly)***

| | |
|---|---|
| CALYX | |
| PELVIS | |
| URETER | |

34. WHAT WAS SITE OF THE LOWER COIL ON 2ND POST OP VISIT - 4 (FOUR) WEEKS AFTER DJ STENTING ***(tick accordingly)***

| | |
|---|---|
| SAME SIDE | |
| CROSSING MIDLINE | |

**35.** WHAT WAS THE LOWER COIL SHAPE ON 2ND POST OP VISIT - 4 (FOUR) WEEKS AFTER DJ URETERIC STENTING? **(tick accordingly)**

| | |
|---|---|
| COMPLETE CIRCLE | |
| INCOMPLETE CIRCLE | |

36. WHICH COMPLICATION(S) WAS/WERE ENCOUNTERED BY ON 2ND POST OP VISIT- WEEK 4 AFTER DJ URETERIC STENTING? ***(write clearly in capital letters in the spaces provided)***

**Key: normal=expected finding/ present= positive finding/ absent=negative or no finding**

| COMPLICATION | (document the findings as negative or positive )<br>P-PRESENT/ A-ABSENT/ |
|---|---|
| HEMATURIA | |
| i. microscopic | |
| ii. macroscopic | |
| FLANK PAIN | |
| SUPRAPUBIC PAIN | |
| URINARY FREQUENCY | |
| URINARY URGENCY | |
| URINARY INCONTINENCE | |
| STENT MIGRATION | |
| STENT FRACTURE | |
| URINARY TRACT INFECTION | |
| URETERO-ARTERIAL FISTULA | |
| FEVERS | |
| Others (others) | |

37. WHAT EARLY COMPLICATION DOES THE PATIENT HAVE AS PER THE CLAVIEN-DINDO GRADING SYSTEM FOR THE CLASSIFICATION OF SURGICAL COMPLICATIONS ON 2ND POST OP VISIT? (fill in the space provided in the table below - indicate ‘O’ if none)

**PART E: FINDINGS ON 3RD POST OP VISIT - WEEK 6 (SIX) OF FOLLOW UP**

38. WHAT WAS THE URINE ANALYSIS RESULTS ON 3RD POST OP VISIT - 6 (SIX) WEEKS AFTER DJ URETERIC STENTING?

**Key: normal=expected finding/ present= positive finding/ absent=negative or no finding**

| TEST | RESULTS **(document the results accordingly)** |
|---|---|
| | N – NORMAL/A-ABSENT/P-PRESENT or POSITIVE/E-ELEVATED/R-REDUCED/N-NEGATIVE |
| COLOUR | |
| DIPSTICK | |
| i. PH | |
| ii. SPECIFIC GRAVITY | |
| LABORATORY | |
| MICROSCOPY | |
| i. CASTS | |
| ii. WHITE BLOOD CELLS | |
| iii. RED BLOOD CELLS | |
| BIOCHEMISTRY | |
| CULTURE/SENSITIVITY | |
| OTHERS(SPECIFY) | |

39. WHAT WAS BLOOD STUDIES FINDINGS ON 3RD POST OP VISIT - 6 (SIX) WEEKS AFTER DJ URETERIC STENTING?

| TEST | RESULTS (document the findings accordingly)<br>N - NORMAL<br>E – ELEVATED<br>R - REDUCED |
|---|---|
| WHITE CELL COUNT | |
| RED CELL COUNT | |
| HAEMOGLOBIN LEVEL | |
| HAEMATOCRIT LEVEL | |
| UREA LEVEL | |
| CREATININE LEVEL | |
| BLOOD UREA NITROGEN LEVELS | |
| SODIUM LEVEL | |
| POTASSIUM LEVEL | |
| WHITE CELL COUNT | |
| Others (specify) | |

40. IMAGING AND RADIOLOGICAL INVESTIGATIONS/STUDIES DONE ON 3RD POST OP VISIT - 6 (SIX) WEEKS AFTER DJ URETERIC STENTING?

| INVESTIGATIONS/STUDIES | (tick and document the findings) | |
|---|---|---|
| | POST DJ STENTING 6 WEEKS | |
| PLAIN KUB XRAY | | |
| ULTRASOUND | | |
| CT SCAN UROGRAM | | |
| IVP/IVU | | |
| Others (specify) | | |

41. WHAT WAS SITE OF UPPER COIL ON 3RD POST OP VISIT - 6 (SIX) WEEKS AFTER DJ URETERIC STENTING? **(tick accordingly)**

| | |
|---|---|
| CALYX | |
| PELVIS | |
| URETER | |

42. WHAT WAS SITE OF THE LOWER COIL ON 3RD POST OP VISIT - 6 (SIX) WEEKS AFTER DJ URETERIC STENTING? **(tick accordingly)**

| | |
|---|---|
| SAME SIDE | |
| CROSSING MIDLINE | |

43. WHAT WAS THE LOWER COIL SHAPE ON 3RD POST OP VISIT - 6 (SIX) WEEKS AFTER DJ URETERIC STENTING? **(tick accordingly)**

| | |
|---|---|
| COMPLETE CIRCLE | |
| INCOMPLETE CIRCLE | |

44. WHICH COMPLICATION(S) WAS/WERE ENCOUNTERED BY ON 3RD POST OP VISIT - 6 (SIX) WEEKS AFTER DJ URETERIC STENTING? **(write clearly in capital letters in the spaces provided)**

**Key: normal=expected finding/ present= positive finding/ absent=negative or no finding**

| COMPLICATION | (document the findings accordingly)<br>P-PRESENT/ A-ABSENT/ |
|---|---|
| HEMATURIA | |
| i. microscopic | |
| ii. macroscopic | |
| FLANK PAIN | |
| SUPRAPUBIC PAIN | |
| URINARY FREQUENCY | |
| URINARY URGENCY | |
| URINARY INCONTINENCE | |
| STENT MIGRATION | |
| STENT FRACTURE | |
| URINARY TRACT INFECTION | |
| URETERO-ARTERIAL FISTULA | |
| FEVERS | |
| Others (specify) | |

**45.** WHAT EARLY COMPLICATION DOES THE PATIENT HAVE AS PER THE CLAVIEN-DINDO GRADING SYSTEM FOR THE CLASSIFICATION OF SURGICAL COMPLICATIONS ON 3RD POST OP VISIT? (**fill in the space provided in the table below - indicate 'O' if none)**

**PART F: OTHER INFORMATION**

*46.* WHAT WERE THE FINDINGS OR STATUS OF THE STENT DURING REMOVAL ***(tick accordingly)***

| | |
|---|---|
| STENT FRACTURE | |
| STENT ENCRUSTRATION | |
| OTHERS (SPECIFY)<br>----------<br>---------- | |

*47.* WHAT WAS THE DJ STENT DURATION IN DAYS? *(fill in the space provided in the table below)*

| |
|---|
| |

48. WHAT WAS THE STENT MICROBIOLOGICAL PROFILE? (fill in the spaces provided)

| PARAMETER | FINDINGS/RESULTS |
|---|---|
| ORGANISMS GROWN | i. ……...<br>ii. ……<br>iii. ……<br>iv. ……. |
| SENSITIVITY<br>**(list the drugs)** | |
| RESISTANCE<br>**(list the drugs)** | |
| | |

**APPENDIX II - CONSENT FORM**

**English version**

This is an informed consent form for persons aged 18 years and above as well as those below the age of 18 whose guardians/ next of kin/ parents allow to be included in the study whose title is

'INDICATIONS AND EARLY COMPLICATIONS OF DOUBLE – J URETERIC STENTS AS SEEN IN KENYATTA NATIONAL HOSPITAL'

Principal investigator: Dr. Joshuah Mburu Kairu

Institution: School of Medicine, Department of surgery, University of Nairobi

Supervisors: Prof. Oliech J. S, Prof Ndaguatha, P.L.W., Dr. Ikol A. J.

My name is Dr. Joshuah Mburu Kairu, a Postgraduate student at the School of medicine, University of Nairobi. I am conducting a research study titled 'INDICATIONS AND EARLY COMPLICATIONS OF DOUBLE – J URETERIC STENTS AS SEEN IN KENYATTA NATIONAL HOSPITAL.'

I would like to invite you to take part in this study sincerely. Participation is purely voluntary, and you are allowed to consent either immediately after getting this information or after a period of consultation.

You are free to ask questions at any time regarding this study, or to seek any clarification from either me or any doctor you are comfortable with. If you consent to participate in the study, you will be recruited into the study consecutively. Some personal details, as well as information concerning your condition, will be sought and this will be handled with utmost confidentiality and will not be accessed whatsoever by anyone other than the researchers and any other person authorized by the KNH/UON Ethics and research committee. This information will be coded with numbers such that only the researchers can identify you.

Participation in this study will be through a clinical interview which will involve the recording of your Imaging and operative findings. Withdrawal from this study can be done at any stage and will not affect your treatment at this hospital.

**Benefit(s) of getting into this study**

The benefit of getting into this study is that you will be part and parcel of the general population that will add knowledge locally, regionally and even globally in understanding of the topic being studied which is very important for current and future patient's management. However there is no financial benefit in agreeing to participate in this study.

**Risk(s) of getting into this study**

There are no additional risks involved during your participation in this study. The general protocols of anesthesia and surgical principles of management in ureteric stenting will be strictly followed and adhered to minimize and if possible to eliminate any complication that might be associated with the procedure you are about to undergo.

This study proposal has been reviewed and approved by the KNH/UON ERC which is a body that ensures the protection of persons like yourself that take part in research studies.

This approval has been granted after the submission of the study proposal to the committee by the Chairman of the Department of Surgery, School of Medicine, University of Nairobi with the approval of my University and Kenyatta National Hospital supervisors.

In the very event that you require any additional information or for any other purpose regarding this study, relevant contact details are listed below:

1. Dr. Joshuah Mburu Kairu

   Department of Surgery

   School of Medicine

   University of Nairobi

   P.O. Box 19676-00202

   KNH, Nairobi

   Mobile No. 0722717714

2. The Secretary

   KNH/UON Ethics and Research Committee (ERC)

   Tel no: +2542726300-19 Ext.44102

   P O BOX 20723-00202, Nairobi, Kenya

   Email: uonknh_erc@uonbi.ac.ke

3. Prof. Oliech J. S, & Prof Ndaguatha, P.L.W.

   Department of Surgery

   School of Medicine,

   University of Nairobi

   Tel: 020-2726300

4. Prof Ndaguatha, P.L.W.,

   Department of Surgery

   School of Medicine,

   University of Nairobi

   Tel: 020-2726300

5. Dr. A. J. Ikol

   Department of surgery

   Kenyatta National Hospital

   KNH Research and Programs Department

   Tel: 020 2115953

**CONSENT CERTIFICATE**

I……..freely give consent of myself /my proxy…… to take part in the research study carried out by Dr. Joshuah Mburu Kairu, the nature of which he has explained to me. I also understand that my participation in the study is purely voluntary and that I am free to withdraw this study consent at any time. I also understand that withdrawing my consent will not affect the quality of care given to myself/my proxy at the Kenyatta National Hospital.

Left thumbprint if participant illiterate (witness to

Signature of participant/Guardian/Next of kin……

Date……

I certify that the above consent has been freely given in my presence

Left thumbprint if the witness is illiterate)

Witness Name…….

Witness Signature……..

Date…….

**STATEMENT BY THE RESEARCHER**

I confirm that the information relating to this study as contained in the information sheet has been accurately read to the participant. I confirm that I have ensured the understanding of its contents by the participant who understands that:

1. Declining to give consent or otherwise participate in this study will not affect the quality of care offered at this institution
2. All information provided by the participant will be kept strictly confidential
3. The conclusions from this study may be used to influence local, regional and global clinical practice of patients undergoing DJ ureteric stenting.

I further confirm that the participant has been allowed to seek clarification of all aspects of this study and that he/she has freely and willingly given consent. The participant has also been provided with a copy of the Informed consent form.

Name of researcher ……

Signature…….

Date…….

**Kiswahili version**

Jina langu ni Dkt. Joshuah Mburu Kairu, mwanafunzi katika Kitivo cha masomo ya Udaktari, Chuo kikuu cha Nairobi. Ninafanya utafiti kuhusu 'INDICATIONS AND EARLY COMPLICATIONS OF DOUBLE – J URETERIC STENTS AS SEEN IN KENYATTA NATIONAL HOSPITAL'

Umechaguliwa kushiriki katika utafiti wa utafiti, kwa kibali chako, tukiangalia 'INDICATIONS AND EARLY COMPLICATIONS OF DOUBLE – J URETERIC STENTS AS SEEN IN KENYATTA NATIONAL HOSPITAL'

Hakikisha kusoma fomu hii vizuri na ujisikie huru kuuliza maswali / ufafanuzi wowote wakati wowote, kabla ya kwenda mbele na kushiriki katika utafiti huu.

ukikubali kushiriki katika somo tutakuuliza maswali machache kulingana na proforma ya kujifunza ili kutusaidia kujua zaidi kuhusu wewe na kisha tutakuandikisha kama mshiriki wa utafiti huu .

Ningependa kukualika kujumuishwa kwenye utafiti huu. Kujumuishwa kwako ni kwa hiari na unayo haki kujiondoa kwenye utafiti huu wakati wowote. Idhini yako ya kujumuika unaweza kuipa maramoja baada ya kusoma nakala hii ama baada ya muda wa kufikiria. Unao uhuru wa kuuliza maswali yoyote kuhusu utafiti huu kutoka kwangu ama msaidizi wangu.

Ukikubali kujumuishwa kwenye utafiti,maelezo yako binafsi pamoja na maelezo ya ugonjwa wako yatachukuliwa. Unapewa hakikisho ya kwamba maelezo yote utakayotoa yatawekwa siri wala hakuna atakayeoona maelezo haya isipokuwa watafiti na watu waliokubaliwa na kamati ya uadilifu ya Hospitai kuu ya Kenyatta ikishirikiana na Chuo kikuu cha Nairobi. Nambari zitatumiwa badala ya majina ili kukinga maelezo yako.

Maelezo yatachukuliwa kwa njia ya maswali. Kujiondoa kwako hakutaadhiri kiwango cha matibabu utakachopatiwa katika hospitali hii.

**Je! Ni faida gani ya kuingia katika somo hili?** Faida ya kuingia katika utafiti huu ni kuwa utakuwa sehemu ya idadi ya jumla ya watu ambayo itaongeza ujuzi ndani ya nchi, kanda na hata duniani kwa kuelewa mada ambayo ni muhimu sana kwa matibabu ya mgonjwa wa sasa na wa baadaye. Hata hivyo hakuna faida ya kifedha kwa kukubali kushiriki katika utafiti huu.

**Ni hatari gani ya kuingia katika somo hili?** Hakuna hatari zinazohusika wakati wa ushiriki wako katika utafiti huu. Protokta ya jumla ya anesthesia na kanuni za upasuajina usimamizi katika upepo wa dj ureteric stenting zitafuatishwa kwa ukamilifu na kuzingatiwa ili kupunguza na iwezekanavyo ili kuondoa matatizo yoyote ambayo yanaweza kuhusishwa na matibabu ulioelekea kupata.

Ruhusa ya kufanya utafiti huu imepatiwa kutoka Kamati ya Uadilifu wa Utafiti ya Hospitali kuu ya Kenyatta ikishirikiana na Chuo Kikuu cha Nairobi, kupitia Mwenyekiti wa Idara ya Upasuaji, Kitivo cha Masomo ya Udaktari, Chuo Kikuu cha Nairobi.

Ikiwa unahitaji maelezo zaidi kuhusu utafiti huu, tafadhali wasiliana na wafuatao

1. Dr. Joshuah Mburu Kairu
   Department of Surgery
   School of Medicine
   University of Nairobi
   P.O. Box 19676-00202
   KNH, Nairobi
   Mobile No. 0722717714

2. The Secretary

   KNH/UON Ethics and Research Committee (ERC)

   Tel no: +2542726300-19 Ext.44102

   P O BOX 20723-00202, Nairobi, Kenya

   Email: uonknh_erc@uonbi.ac.ke

3. Prof. Oliech J. S, & Prof Ndaguatha, P.L.W.

   Department of Surgery

   School of Medicine,

   University of Nairobi

   Tel: 020-2726300

4. Prof Ndaguatha, P.L.W.,

   Department of Surgery

   School of Medicine,

   University of Nairobi

   Tel: 020-2726300

5. Dr. A. J. Ikol

   Department of surgery

   Kenyatta National Hospital

   KNH Research and Programs Department

   Tel: 020 2115953

***Sehemu ya pili: Idhini***

6. Mimi…….nimekubali kwa hiari yangu/hiari ya mgonjwa niliyemsimamia……..kujumuishwa kwenye utafiti unaoendeshwa na Dkt. Joshuah Mburu Kairu, baada ya kupewa maelezo kamili na yeye. Ninaelewa kuwa kujumuika kwangu ni kwa hiari na nina uhuru wa kujiondoa wakati wowote. Naelewa kwamba kujiondoa kwangu hakutaathiri kwa vyovyote kiwango cha huduma nitakayopokea katika Hospitali Kuu ya Kenyatta.

Jina la mgonjwa/Msimamizi wa mgonjwa……

Sahihi……

Tarehe……

| **Alama ya kidole gumba cha kushoto**(mgonjwa asiyejua kuandika – sharti shahidi kutia sahihi kando) |
|---|
| |

Nimeshuhudia ya kwamba idhini ya mhusika imetolewa kwa hiari yake mwenyewe

Jina la shahidi……

Sahihi ya shahidi……

Tarehe……

| **Alama ya kidole gumba cha kushoto**(shahidi asiyejua kuandika) |
|---|
| |

***Sehemu ya tatu: Idhibati ya Mtafiti mkuu***

Ninatoa idhibati ya kwamba maelezo kuhusu utafiti huu yametolewa kikamilifu kwa mhusika, na kwamba nimemsaidia kuelewa kwamba:

1. Kutotoa idhini ama kujiondoa kwenye utafiti huu hautaathiri kwa vyovyote kiwango cha matibabu atakayopata katika hospitali hii.
2. Maelezo yote yatakayotolewa yatawekwa siri.
3. Matokeo ya utafiti huu yanaweza kutumiwa katika kuchangia ujuzi wa kubaini ugonjwa unaochunguzwa.

Ninatoa idhibati pia ya kuwa mhusika amekubaliwa kuuliza maswali yoyote kuhusu utafiti huu na kwamba ametoa idhini kwa hiari bila kulazimishwa. Mhusika pia amepewa nakala ya stakabadhi ya idhini.

Jina la mtafiti ……

Sahihi…….

Tarehe…….

**APPENDIX III - POSTER**

**EXAMPLE OF A POSTER THAT WILL BE USED TO REQUEST THE DOCTORS IN VARIOUS DEPARTMENTS IN KNH TO INFORM THE RESEARCHER OF A PATIENT SCHEDULED FOR DJ URETERIC STENTING**

**ATTENTION! ATTENTION! ATTENTION!**

**DEAR, COLLEAGUES**

**MY NAME IS DR. JOSHUAH MBURU KAIRU, A 5TH YEAR POSTGRADUATE STUDENT IN THE UNIVERSITY OF NAIROBI, PERSUING MASTERS OF MEDICINE IN UROLOGY.**

**I AM CARRYING OUT A STUDY ON 'INDICATIONS AND EARLY COMPLICATIONS OF DJ URETERIC STENTS AS SEEN IN KENYATTA NATIONAL HOSPITAL'**

**KINDLY INFORM ME BY EITHER A PHONE CALL OR SMS, ON ANY PATIENT IN YOUR DEPARTMENT SCHEDULED FOR DJ URETERIC STENTING**

**MOBILE PHONE NUMBER: 0722717714**

**THANKYOU**

**APPENDIX IV - STUDY BUDGET**

The study budget was as follows,

| ITEM | COST (KSHS) |
|---|---|
| KNH-ERC fee | 2,000 |
| Statistician | 30,000 |
| Stationery and printing | 50,000 |
| Imaging (plain abdominal x-ray/ultrasound) | 90,000 |
| Laboratory investigation | 90,000 |
| Contingencies | 35,000 |
| TOTAL | 300,000 |

**APPENDIX V - TIME FRAME/ IMPLEMENTATION TIMETABLE**

The study time frame was as tabulated below

| | DECEMBER 2018 - JANUARY 2019 | JANUARY - APRIL 2019 | MAY – JULY 2019 | AUGUST 2019 | |
|---|---|---|---|---|---|
| PROPOSAL WRITING AND PRESENTATION | | | | | |
| PRESENTATION/ETHICAL APPROVAL | | | | | |
| DATA COLLECTION | | | | | |
| DATA ANALYSIS | | | | | |
| PRESENTATION OF RESULTS/SUBMISSION | | | | | |