CT FINDINGS IN SUSPECTED RENAL COLIC PATIENTS UNDERGOING UNENHANCED LOW-DOSE MULTI-DETECTOR COMPUTED TOMOGRAPY.

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DECLARATION

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

Signature…… Date…….....

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This research has been submitted with my approval as a University supervisor;

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DEDICATION

This research is dedicated to my late mum; Grace Wairimu who passed in my first year of the master's program.

"To my loving and caring mum; your embodiment of grace and faith in god helped you build an outstanding family amidst great odds. You left a legacy borne of sacrifice and hard work and taught us to believe in ourselves and be the best."

ACKNOWLEDGEMENTS

I am grateful to God for giving me the power, courage and knowledge to pursue this study.

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ABBREVIATIONS

- **CT** Computed tomography
- **CT KUB** Computed tomography of the kidneys ureters and bladder.
- **IVU** Intravenous Urogram
- **IV** Intravenous
- **CM** Contrast Media
- **KNH** Kenyatta National Hospital
- **MDCT** Multidetector computed tomography scanner.
- **NCCT /NECT** Non contrast enhanced computed tomography
- **PU**J Pelvi-ureteric junction
- **U/S** Ultrasound.
- **A-P** Antero-posterior
- **UON** University of Nairobi
- **VUJ** Vesico-ureteric junction
- **U.T.I** Urinary tract infection
- **AAA** Acute aortic aneurysm
- **AEC** Automatic exposure control
- **AKUH** Agha Khan University Hospital
- **PID** Pelvic inflammatory disease.

ABSTRACT

Background

Acute flank pain is one of the most painful events one can be involved in. The most common cause for this is usually urinary tract calculi also known as urolithiasis. There is a global rise in urolithiasis incidences and the same trend is being seen in Kenya with diagnostic tools awareness and use being a challenge in the emergency departments. However other non-genital urinary conditions and non-calculus causes can have similar presentation.

Due to the nature and acuteness of the presentation of suspected renal colic as an emergency a diagnostic tool that is highly sensitive, specific and rapid is required in such incidences.

CT-KUB has a high accuracy in detecting ureteric stones and plays a vital role in identifying significant alternative diagnoses therefore guiding the proper management of the patient.

Aim

The goal of this study was to determine the CT findings in patients undergoing unenhanced CT KUB for suspected renal colic.

Methodology

Prospective cross-sectional descriptive study was done at the MP Shah hospital and the Kenyatta national hospital department of radiology.

The study was carried out over a period of 6 months, from October 2019 to March 2020.

Patients who visited the emergency department or referred by the urologist with suspected renal colic to undergo unenhanced low dose CTKUB and fit the inclusion criteria for the duration of the study were included in this study.One hundred and two patients meeting the inclusion criteria were selected for this study.

Results

One hundred and two patients underwent unenhanced low dose MDCT KUB.All this patients were included in the statistical analysis. These were 55 male and 47 female with age range of 19 -72 years. The mean age was 41.7 (SD 12.5) years and the median age was 40 (IQR 33-49) years.

Thirty six of the patients [35%] had ureteric calculi, Thirty five [34%] were normal studies with 31 [31 %] patients having alternative diagnosis.

The study demonstrated that unenhanced low dose MDCT is the imaging of choice for evaluation of suspected renal colic as it is able to correctly identify ureteric calculi and also identify alternate diagnoses for the proper management of the patients.

Conclusion.

- Unenhanced low dose MDCT is the imaging of choice for evaluation of suspected renal colic as it can correctly identify urolithiasis and is able to significantly identify other causes of acute pain that may mimic renal colic.
- Presence of secondary radiological signs which was positive in 78% of the positive cases for urolithiasis is a strong correlation and a significant finding in aiding the reporting radiologist in making and confirming the diagnoses. They also give the confidence that obstruction is caused by a calculus therefore an important diagnostic clue.

Recommendations.

- Adoption of Low dose Multidetector CT KUB as the first line imaging of choice for evaluation of suspected renal colic patients as its able to correctly identify urolithiasis and other alternate diagnosis with reduction of radiation dose exposure to the patient.
- Proper and comprehensive clinical history and examination from referring clinician can help in improve on discriminating the patients to undergo CT KUB and utilization of other modalities like ultrasound especially on female patients as demonstrated by the high number of female patients with gynecological alternate diagnosis in this study.
- Future studies involving the dual energy MDCT to determine calculus composition is warranted for future utilization of CT IN urolithiaisis imaging.

CHAPTER 1

1.1 Introduction

Urolithiasis [calculi/stone forming in the urinary tract] has a prevalence of 5-15% of the world population. It occurs commonly in the mountainous, desert and tropical regions(1,2). Geographical variations depend on food, water drinking habits and environmental factors. The M: F ratio is 3:1 and is more prevalent in the young adult patients.

In renal colic, patients typically present with colicky pain radiating to the groin with or without associated haematuria. This presentation is not specific and a wide range of other medical conditions can present likewise including but not limited to gynaecological emergencies, appendicitis, bowel pathologies, diverticulitis and acute pyelonephritis (3). Imaging therefore has become an important tool in triaging the patient into the correct path of management.

Evaluation of suspected renal colic has often in the past included the use of ultrasonography [US] or intravenous urography [IVU] as first line imaging tools.US can detect intrarenal stones and secondary changes due to ureteric obstruction(4). However the major impediment with US is the difficulty in directly imaging ureteric calculi. IVU is valuable in identification of urolithiasis and establishing hydroureteronephrosis secondary to calculi but it requires the use of intravenous [IV] contrast media [CM], multiple exposure and is time consuming(5),(6).

Magnetic resonance imaging [MRI] use in the evaluation of urinary tract stones is limited. MRI is not able to directly visualize calculi but it is able to detect obstruction and can identify other causes of renal colic.(7). However despite its safety it is infrequently used in the emergency department as it is not readily available, is time consuming and expensive compared to other modalities.

Unenhanced CT KUB [NECT- KUB] recently has become the imaging of choice in screening for urolithiasis(5),(8). It is able to demonstrate stones < 1 mm in diameter and has the advantage of direct imaging of secondary obstructive features like hydroureter, hydronephrosis, and periureteric/renal oedema(8,9) It is a rapid investigation and takes less

than 5 minutes to scan and do computer reconstruction. No IV CM is required and the scan has the ability to demonstrate other conditions that may mimic renal colic and therefore is a useful tool to the patient as it puts him in the right path of management.

The demonstration of ureteric and intrarenal collecting system dilatation even when is mild can be a useful clue for very small calculus lodged in the distal ureters. Peri ureteric fat stranding or soft tissue oedema are some of the indirect signs of acute obstruction(10) . This gives CT the upper hand compared to the other modalities.

Due to its high tissue contrast resolution CT allows for the detection of stones the size of 1-2mm.Plain radiography can equally demonstrate the same but not with confidence compared to CT as this can be confused with a phlebolith or are difficult to visualize if bone or dense soft tissue are overlying.

Though US is safe as it does not use ionizing radiation the user dependency variability is high. A comparative study done by Douglas and Sheafor showed the sensitivity for the detection of ureteral calculi was 83%–91% for CT and 39%–61% for US(8).

Therefore due to high sensitivity of NECT KUB scan in detecting ureteric and renal calculi it is now used in many emergency departments as imaging of choice in patients presenting with renal colic(3).

CHAPTER 2

2.0 Literature Review

2.1 Anatomy

The kidneys are situated in the paravertebral gutters in the retro peritoneum. They have an oblique lie and the upper poles are more medial and posterior than the inferior poles. The adult kidney in males is 10-15cms long and 9-13 cms long in females, 3-5 cm wide, and 3 cm in A-P thickness. The approximate weight is 150-260 grams(11).

Production of urine happens in the renal lobes from where it drains at a papilla which in turn drains into a minor calyx. Four or five minor calyx joins and forms a major calyx which in turn joins to make the renal pelvis.

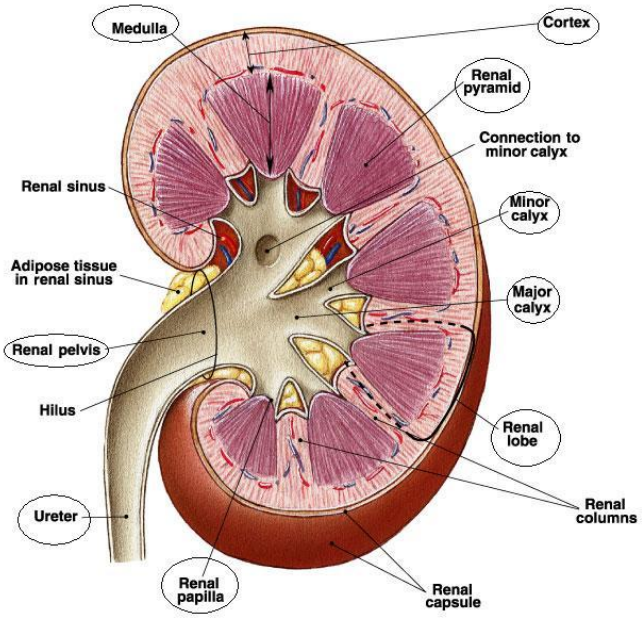


FIG 1; Renal Anatomy(12)

FIG 2;Ultrasound image of the kidney.(12)

Renal pelvis at the pelvi-ureteric junction [PUJ] drains into the ureter. The ureter is a tubular muscular structure that drains via peristalsis into the urinary bladder. It measures 25cms in length and is divided into the proximal, middle, distal and the vesicoureteric junction [VUJ] (11,13) The proximal two-thirds of the ureter crosses within the abdomen, and lies anterior to the psoas muscle which overlies the tips of the transverse processes of the lumbar vertebral bodies from L2-L5(10,13)

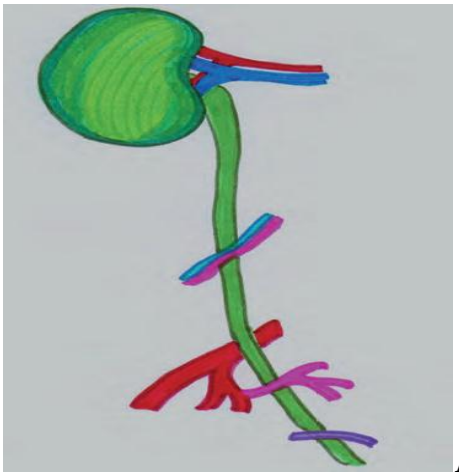
 A

FIG 3; Anatomy of the ureter in relation to other structures(10)

It enters the pelvis anterior to the sacroiliac joint at the level of bifurcation of the common iliac artery. It then lies on the pelvic side wall anterior to the internal iliac artery to a point just anterior to the ischial spine.

The ureter passes above the seminal vesicles and is crossed by the vas deferens in males and in the female this part of the ureter runs through the stiff band of fibrous tissue on either side of the cervix under the uterine artery at the base of the broad ligament(10)

There are three recognized locations where the ureter is anatomically narrowed and it is in this areas stones may be impacted. This are the PUJ, the pelvic brim and the VUJ(10).

There are normal anatomical variants of the collecting system that can predispose to stone formation. This include duplex kidney, ureterocele and a defective VUJ valve mechanism(14)(15)

2.1.1 Renal stone formation pathophysiology.

Stone formation mainly begins by crystals forming in supersaturated urine which in turn adheres to the urothelium. This forms a nidus for crystal collection and formation of a stone. Low fluid intake and output can cause accumulation of stone forming materials in urine which include organic and inorganic substances, salts, compounds like calcium, phosphate, oxalate, and uric acid(16)(17).

Recent concepts are based on the role cell surface molecules that cause or inhibit adhesion of crystals on the urothelium. Injury of the urothelium by a stone and its subsequent repair may lead to the rise in expression of this molecules which favours crystal adhesion .(16,)

The risk factors include(16)

- dehydration
- hypercalciuria
- primary hyperparathyroidism
- high salt intake
- hypocitraturia.
- hyperuricuria

- urinary tract malformation
- urinary tract infections.
- hyperoxaluria

2.1.2 Kidney Stone Composition

The radiographic features of stone are dependent on the composition and this is important in their visualization as they are radio-opaque and radio-lucent stones. Urinary tract stone composition will depend on the metabolic changes in the body, the location geographically and if there is presence of infection. There are three major types of kidney stones:

- Calcium, which can be oxalate or phosphate-75% of all stones
- Struvite-15%
- Uric acid-5-8 %

Others include indanavir medication stones

Calcium stones usually contain calcium oxalate and calcium phosphate stones. Most patients with these stones have idiopathic hypercalciuria without hypercalcemia but others can have hypercalcemia from metabolic disorders

Struvite stones occur mainly when urinary tract infection [U.T.I] is caused by certain bacteria that are urease producing and result in increase in the urinary PH by hydrolysing urea into ammonia.(3) . This stones can develop into a large stone which forms a cast in the renal pelvis and calyces largely known as the staghorn calculi. Due to association with UTI, women and patients with anatomic malformation of the urinary tract have increased incidence(3).

Acidic urine and hyperuricosuria influences uric acid stone formation (3,16). These include patients with acid-base imbalances , obese, diabetics and hypertensive patients on thiazide diuretics(3,19)

2.2 Imaging Modalities

As discussed earlier renal colic can present as many other diseases. Imaging plays major role in confirmation of urolithiasis and in ruling out other pathologies that can mimic renal colic(4).

The composition of the calculi mainly divided into calcium containing and non –calcareous will determine the selection of the imaging modality to be used. However this composition is not usually known by the clinician therefore the radiological study must be carefully chosen to ensure correct diagnosis is arrived at. The available imaging modalities include KUB X-ray, IVU,KUB ultrasound , MRI and CT KUB(20).

The modality with high sensitivity will provide the confidence in the requesting doctor that the probable cause of the patients symptoms are from alternative diagnosis when no urolithiasis is visualized(3,4,20)

Imaging also plays the 1st step in the management of the urolithiasis as the stone size, number and location can be determined allowing for risk stratification.

This determines the intervention to be taken including conservative management, allowing for spontaneous stone passage or invasive interventions. The overall sensitivity, specificity, radiation dose, and relative costs vary between modalities(4)

Table 2.1: Comparison of different imaging modalities for kidney stones(4)

Imaging modality	**Sensitivity*(%)**	**Specificity*(%)**	**Radiation exposure (mSv)[25]**	**Cost multiple relative to that of KUB[25]**
CT	95 (REF [12])	98 (REF [12])	10.0	10
Low-dose CT	95 (REF [12])	97 (REF [12])	~3.0	10
Ultrasonography	84 (REF [25])	53 (REF [25])	None	5
KUB	57 (REF [25])	76 (REF [25])	0.7	1
MRI	82 (REF [25])	98 (REF [25])	None	30

*Published sensitivity and specificity vary widely in the literature for some modalities; therefore, these values are derived from values published by the American College of Radiography and American Urological Association, who have obtained them from pooled data analysis

Discussed below are the imaging modalities available and their specificity and use in renal colic.

2.2.1 KUB X-ray

Plain KUB radiograph was previously used as the initial imaging tool in patients with flank pain. This method uses ionizing radiation x-rays to visualize bones, gas and internal structures on an image receptor.

Although about 75% of stones are calcium-based and should be visible on a plain film, due to varying radiographic technique and other factors, only about 60% are found to be visible on plain films(3,21). Of note is that the non calcerous stones are not visible on plain KUB radiograph(3).

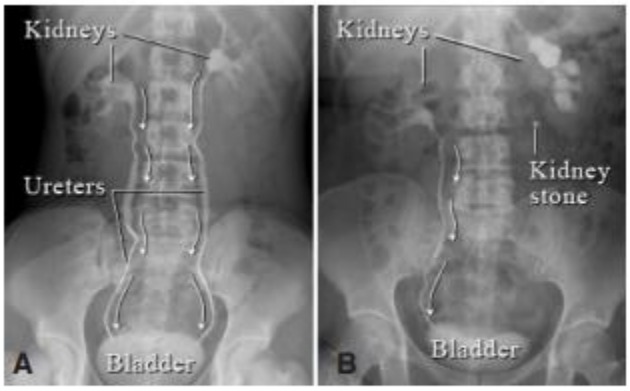
Levine study of 178 patients with renal colic found sensitivity of KUB radiograph is 45%-59% and a specificity of 77% in diagnosing urolithiaisis(22).

KUB radiograph due to low sensitivities and specificities is not adequate in detecting urolithiasis. Therefore other methods are used or paired to it to increase the sensitivity.

2.2.2 Intravenous Pyelogram

Intravenous pyelogram/urogram [IVP/IVU] is able to demonstrate the anatomy of the entire urinary tract. It involves the use of intravenous contrast media which is excreted into the renal collecting system and images acquired at various intervals(3).

FIG 4 ; IVP demonstrating a kidney stone



View A shows normal flow of urine (white arrows). View B shows kidney stone blocking the normal flow of urine.
Reprinted courtesy of Intermountain Medical Imaging.

IVP was the method of choice in finding urolithiasis prior to the discovery of CT scan. A study by Fister showed it has a sensitivity of 94.2% and specificity was 90.4%, which was within 5% of the results for CT(6). Calculi is identified as a filling defect in the contrast filled collecting system. However it has serious limitations to its use due to the use of iodinated CM which carries the risk of CM induced reactions, nephrotoxicity and also small tumours seen as filling defect can be interpreted as calculi(21).Also is the risk of radiation from exposure to X-rays.(23).

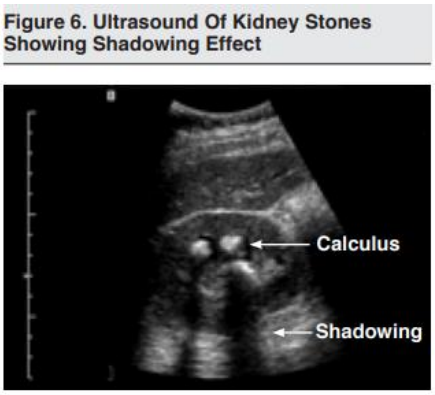
IVP use has now fallen out of favour with the advent of newer imaging modalities.

2.2.3 Ultrasonography

Ultrasound uses sound waves and is therefore the imaging of choice in pregnant women and children as no radiation is involved. It is a real time and can be performed as bed side procedure(3)(24) .

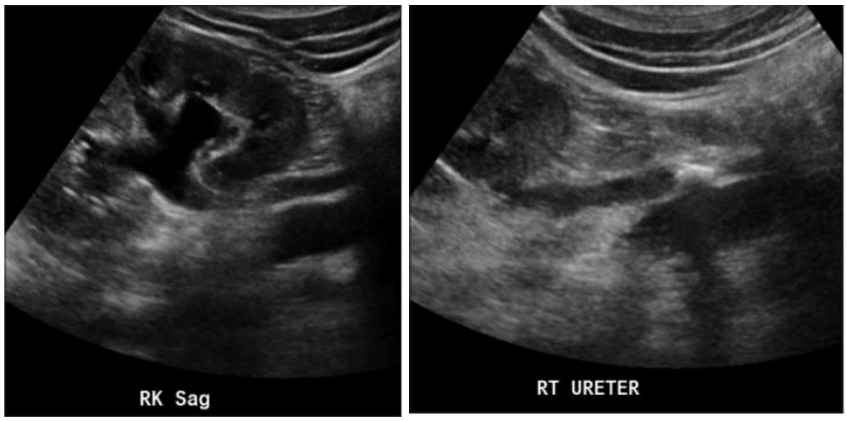
Renal calculi are normally seen as a hyperechoic with posterior shadowing.

FIG 5; Renal stones.(4)



Also secondary signs like hydronephrosis can be seen(3)(21).

FIG 6;Hydronephrosis(4)



Midureteral calculus. A, Sagittal image of the right kidney shows moderate hydronephrosis and dilatation of the proximal ureter in this 24-year-old woman presenting with right flank pain. B, More distal image shows an echogenic shadowing calculus in the mid ureter with dilatation of the proximal ureter

Sensitivity is varied and ranges from 29-81% and is determined by the size of the calculi,,the site and also the skill of performer (25).

However stones > 5mm are well seen with ultrasound but stones < 3mm and those impacted in the ureters are difficult to visualize(4)

2.2.4 MRI and MR Urogram.

MRI use in the evaluation of urinary tract stones is limited. MRI is not able to directly visualize calculi but is able to detect obstruction and can identify other causes of renal colic.(7).

On T2W images perirenal oedema presence and ureteral dilatation has a sensitivity and specificity of 93 % and 95 % in finding urolithiasis(25,26).

The 3D FLASH sequence together with T2- weighted images have demonstrated a similar sensitivity and specificity for the diagnosis of ureteral stones as NCCT(26)

Due to its safety MRI would be a better option however it is infrequently used due to issues of availability ,high cost compared to the other modalities and it is time consuming to completely scan the patient (23).

2.2.5 CTKUB

This method was first used in 1970 for evaluation of urolithiasis. It was initially mainly used to image suspected radiolucent stones (25).

CT KUB also referred to as non-contrast CT scan of the kidneys ureters and bladder [NECT KUB] has now become the gold standard in the clinical presentation of acute loin pain for the diagnosis of urolithiasis(27).

NECT KUB is the most reliable in evaluation of urolithiasis due to its sensitivity of 95-98% and specificity of 96-98%(28) . It is superior as it is able to assess the stone location, size and amount(25).

Apart from calculi identification CT KUB is able to identify obstructive signs secondary to urolithiasis like hydroureter in 82.7%, hydronephrosis in 80% of cases, Periureteric oedema in 59% of cases, and unilateral renal enlargement in 57.2% of cases(29).

As the rest of the abdomen and pelvic is also imaged and as alluded earlier CT KUB has the added advantage of identifying alternative diagnosis and also to rule out pathology with a higher degree of confidence(30) .

For the purpose of this study the in-depth description of the technique and the salient imaging features in urolithiasis is carried out below.

2.2.6 CT KUB TECHNIQUE

CT KUB is type of CT scan that is different in image acquisition from the routine non contrast abdominal pelvic CT study. CT KUB is tailored for the diagnosis of urinary stone disease. In CT KUB unenhanced scans [meaning no oral or IV CM is given] are acquired from the lung bases to the base of the bladder (20)

CT uses the diverse grades to which tissues absorb radiation. Numerous data points are attained by rotating a radiation source and contralateral detector around the patient, these data are processed by a computer into 3D images. Urinary calculi has different composition from the kidney, ureter and urine as they absorb more radiation and can be easily identified as hyperdense without the use of contrast. In view of this for CT detection of calculi dose reduction is possible owing to the great contrast difference between most urinary calculi and surrounding tissues. Thus CT KUB is also referred to low dose non enhanced CT.(31) Therefore there is no need for IV or oral contrast as these themselves are dense and can obscure the stones and make them non visible.(20)

CT Urogram also known as excretory urogram [EU] demonstrates the collecting systems, ureters and bladder with the use of intravenous contrast media with images acquired at different times including arterial phase and delayed phases and is such different from CT KUB. CT urography is used mainly to evaluate patient with haematuria or suspected urologic disease including infections and tumours.

Following studies especially the one done in 1995 by Smith et al comparing CT KUB with CT urogram in evaluating patients with acute flank pain in the emergency set up many centres have since replaced CT Urogram with unenhanced CT KUB .(32)

In order to reduce the radiation dose and maintain the diagnostic quality of CTKUB a low dose technique has been developed and is currently recommended (33) This technique has a comparable diagnostic accuracy with sensitivity of 97% and specificity 95% .This is done by increasing the beam width and pitch and reducing exposure factors. The dose can be reduced by 0.5 mSv for men and for women by 0.7mSv(33).

There is no patient preparation required and the scans are acquired in the supine position. The setback with low dose technique is that its sensitivity is low in detecting stones <3mm, VUJ stones and in obese patients. However this is in a minority of cases and further imaging can be recommended if need be. The prone position can be used if VUJ stone is suspected as this allows for better localization of stones at the VUJ(10)

FIG 7; stone impacted at the VUJ(10)

Figure 5. Prone CT of the kidneys, ureters and bladder shows that the nondependent stone is impacted at the vesico–ureteric junction (arrow).

For the purpose of this study KNH and MP shah hospital uses a low dose technique for CT KUB imaging.Both centers use Siemens somatom 128 slice MDCT scanner.The images were acquired using a this multidetecter CT scanners [MDCT] with the patient in the supine position.Both institutions use a protocol with the scans covering between the lung bases and pubic symphysis. The tube voltage was between 120 Kvp and the tube current reduced to 100Ma.

Axial source images 5mm thick are acquired with 1-2 mm reconstruction of the images in the coronal and saggital planes.The CT images are interpreted in a work station with 3D reconstruction and multiplanner reformating capability.

With the use of dual energy CT it has the ability to characterize stone composition differentiating low molecular weight stone like uric acid stone from the dense calcium oxalate or cysteine stones. This uses energy values at 80 kV and 120–140kV(34).

This dual energy CT technique is however recommended for targeted patients with stone detected on the low dose CT KUB and not for initial screening of patients with renal colic as it is associated with high radiation doses.

2.2.7 Image review via PACS

The review of images was done at a picture archiving and communication system [PAC] workstation as compared to hard copy films as this permited the reviewer to trail the passage of the ureter in a continuous sweep.

The ureters were followed and viewed in turns then assessment of the rest of the abdomen and pelvic was done.

Multiplanner reformatting is important especially in the coronal views as this allows the estimation of the location and maximum width of the stone using electronic calliper as this are important in the subsequent management(10)(35).

2.2.8 CT KUB Radiological findings

Urolithiasis appears as high attenuation focus within the kidney or in the ureters and is the most important primary sign in diagnosis of renal colic. Most stones apart from indinavir crystals are visualized on CT HU+200-600 against the soft tissue density of ureterwall(10,36)

Calculi identification on the kidney or ureter on the side with renal colic is positive of urolithiaisis.However this is not short of challenges as extra urinary calcifications like phlebolith and calcifications in veins can mimic ureteric calculi(10).

Figure 7. CT of the kidneys, ureters and bladder shows a phlebolith (arrow) in the left pelvic side wall.

FIG 8 ; Showing a phlebolith(10)

Therefore due to these shortcomings there are well described imaging signs on CT KUB that can assist with the diagnosis in ureteric calculi. These are direct signs from the calculi and indirect sign that result from ureteric obstruction.

2.2.8 [1] Direct sign: soft tissue rim sign

Impacted stone in the ureteric lumen causes oedema of the ureteric wall and is seen as 1–2 mm rim of soft tissue measuring 20–40 HU(37)

This sign is however not reliable for stones >6mm and those impacted at the VUJ(37). The sensitivity and specificity of the soft tissue rim sign are 77 and 92%, respectively in differentiating stones from phleboliths(38)

2.2.8 [2] Direct sign: comet tail sign

This is the conical soft tissue mass of a non calcified portion of a pelvic vein associated with a phlebolith and has a positive predictive value of 100% in differentiating phlebolith from a ureteric calculi (10)

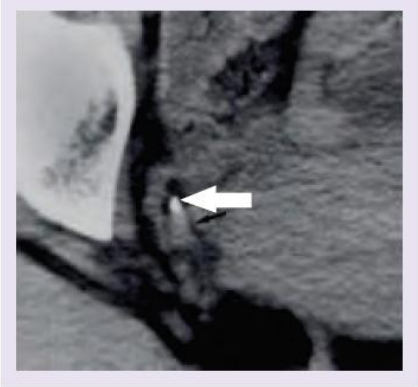


Figure 15. CT of the kidneys, ureters and bladder shows a classic comet tail sign in a phlebolith (arrow) at the right pelvic side wall.

FIG 9; comet tail sign(10)

2.2.8 [3]Indirect secondary signs.

The secondary sign result from urinary tract obstruction include hydroneproureter,nephromegaly and peinephric stranding. The sensitivity and specificity are: nephromegaly 71 and 89%, hydronephrosis 69–83 and 94%,hydroureter 67–90 and 93% and perinephric edema 65–82 and 93%(30)(39).

Passage of stone through the ureter can be suspected if hydroureter in absence of calculi(10).Obstruction causes increased back ward pressure causing perinephric edema though its quite non specific but it is related to the time of onset of renal colic which is maximum after 8 hours.

Figure 16. Axial and coronal reformat CT of the kidneys, ureters and bladder. Demonstrates a small stone **(A)** impacted at the left upper ureter causing mild left hydronephrosis (arrow) and **(B & C)** perinephric edema (arrows).

FIG 10; showing hydronephrosis due to calculi (10)

Occasionaly the pale kidney sign is seen where there is a difference in attenuation of about <5 HU in the renal parenchyma between the obstructed kidney and the normal kidney.This is due to renal edema(40)

Figure 17. Coronal reformat of a CT of the kidneys, ureters and bladder shows a small left distal ureteric stone (short arrow) obstructing the left kidney and the dominant secondary sign is the pale kidney sign (long arrow) displayed by the left kidney.

FIG 11; Pale kidney sign(10)

2.2.8 [4] Extra-urinary pathology

CTKUB is considered the best modality in imaging patient with acute renal colic as it is able to detect alternative diagnosis.This include common causes like gallstones,acute appendecitis and ovarian pathologies.

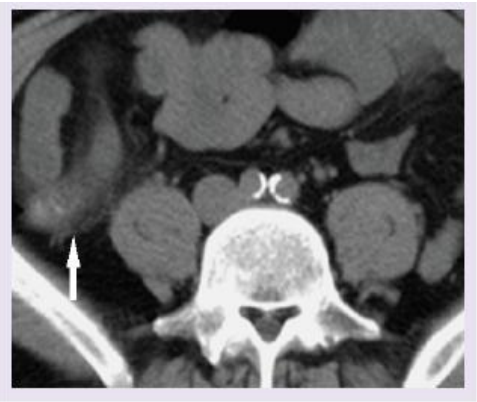


Figure 19. Acute appendicitis (arrow) is detected on the CT of the kidneys, ureters and bladder examination.

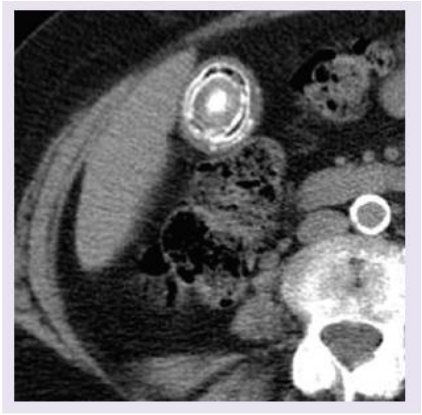


Figure 18. CT of the kidneys, ureters and bladder shows a large laminated gallstone in the gallbladder.

FIG 12; showing acute appendecities and gall stone(10)

Other patholigies like pyelonephritis,diverticulitis and life threatening condition like acute aortic aneurysm [AAA] and tumours can de diagnosed.

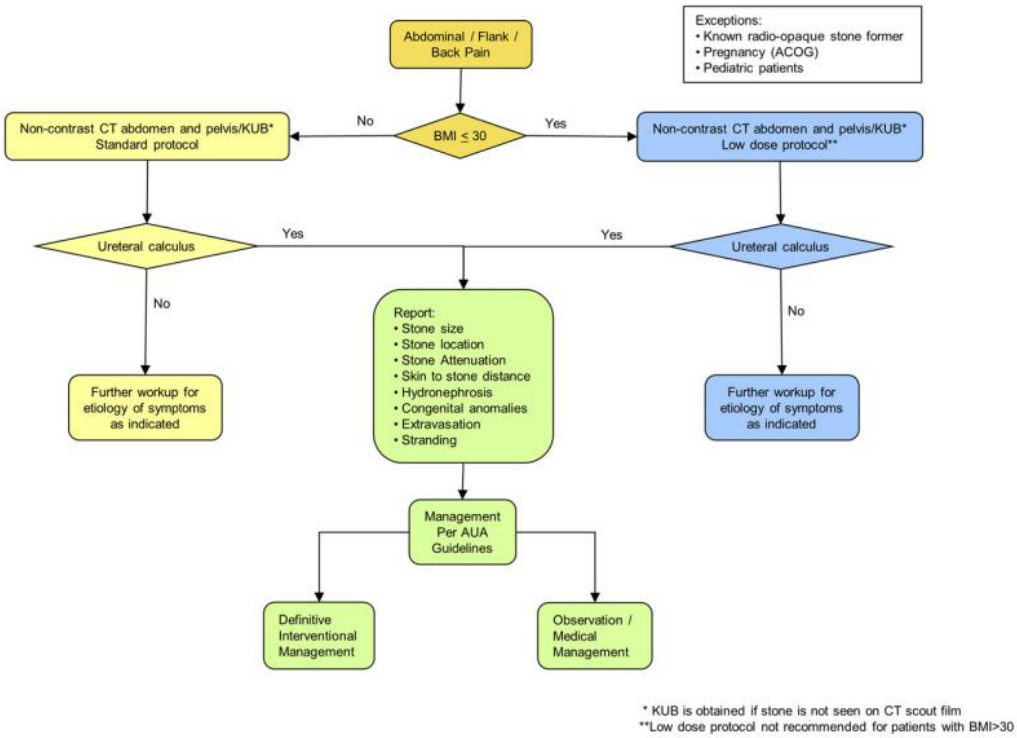
About 30% of patient being investigated for renal colic have alternative diagnosis for the cause of their pain(28)(3)(10)

2.2.9 Current Practice Guidelines

Patients with renal colic and abdominal pains and are suspected to have renal/ureteral stones,CT KUB is the first line imaging of choice based on the ureteral calculi detection median sensitivity of 98% and 95 % specifity. For patients with a BMI > 30 kg/m2 for ureteral stone detection it is not recommended as it has a lower sensitivity and specificity.(41)

However this does not apply to paediatric,pregnant patients and those on follow –up whom ultrasound may be used as the imaging of choice.

This is demonstrated in the flow chart below(41)



2.3 Study Justification

Imaging is the investigation of choice in investigating renal colic. It plays a major role in planning management and predicting the outcome. The rising prevalence of urolithiasis and its associated morbidity is a growing concern both locally and globally

The commonest cause of acute renal colic cases is an obstructing ureteric calculus however non calculus and other abdominal pelvic pathologies can exhibit similar features.

No Kenyan studies have been done to analyse the CT findings in patients undergoing CT KUB to establish the positive outcomes and the common radiological alternative diagnoses.

This study aims to provide local data on the use of CT KUB investigating renal colic and establish its use and importance in patient management.

Therefore this study is purposed to evaluate the diagnosis of urolithiasis and other possible differential diagnosis using the low dose MDCT.

2.4 Study Objectives

2.4.1 Broad Objectives

Determining the proportion of patients positive for urolithiasis and those with alternate diagnoses using unenhanced low dose multidetector CT KUB in patients presenting with suspected renal colic.

2.4.2 Specific Objectives

i.To establish the percentage of Participants positive for urolithiasis in patients undergoing non enhanced CT KUB for suspected renal colic.

ii.To establish the percentage of participants demonstrating secondary radiological signs associated with urolithiaisis.

iii.To establish percentages of the most common alternative diagnoses in patients presenting with suspected renal colic.

2.4.3 Research question

What are the CT KUB findings for patients presenting with renal colic.

CHAPTER 3

3.0 Study Design And Methodology

3.1 Study Design
The study design was Prospective cross-sectional descriptive study

3.2 Study Area
The study was conducted at the radiology department of KNH and MP Shah hospital.

3.3 Study Population
This study relied on the patients who visited the emergency department or were referred by the urologist with symptoms of renal colic and who upon the assestement by the primary physician urolithiasis was suspected and CTKUB is requested and met the inclusion criteria.

3.4 Inclusion Criteria
- All patients presenting renal colic or suspected urolithiasis and referred to the radiology department for CT KUB
- Patients who have given informed written consent

3.5 Exclusion Criteria
- Patient with known or on follow up for urolithiasis

Patient with pre-existing known abdominal pelvic pathology.

Patients with fevers or unstable vital signs

3.6 Sample Size
The sample size was calculated based on the equation applied in descriptive studies designed to measure characteristic in relation to proportion.

Sample size was calculated using the Cochran's formula

$n= (z/d)^2 X \rho(1- \rho)$

Where:

z= 1.96

d= 0.05(margin of error)

ρ=0.05

Sample size = 101

The assumption is that 93% of ureteric calculi would be detected with a confidence interval of ±10% and a significant p-value of 0.05.

3.7 Methodology

This was a prospective cross-sectional descriptive study involving 102 patients who visited the emergency department or referred by the urologist with suspected renal colic and were referred for CT KUB and fit the inclusion criteria.

The partcicipants were not required to undergo any additional Laboratory tests as the clinical suspicion by the referring doctor of renal colic and requesting CT KUB was only required. The clinical information and laboratory test requested by the primary physician were accesible during interpretation of the patients images.

Consent to be included in the study was sought by filling and signing the consent form.Only participants who were above 18 years of age were included in the study.

The patients clinical history and biodata was extracted from the request form and filled into a structured questionaire by the principle investigator.

The patient then underwent CTKUB in the Radiology department.

3.8 CT protocol and radiation dose

The scans in both centers were conducted using Siemens somatom 128 slice MDCT scanner.Patient preparation only included filling their bladder just before CT examination,however no oral or IV contrast media was given .

The patient were placed in the CT gantry in supine position and the scanning was done with the scan area covering from the lung bases to the pubic symphysis.A low dose technique was applied with exposure factors of 120 kVp with the tube current reduced to

100 mA. 5mm thick source images and 1-2 mm reconstruction in multiplanner reformation done.

This examinations were carried by the radiographers under this agreed and recommended protocols.

3.9 CT KUB interpretation and results.

The interpretation of the patients images acquired was carried out by the principal researcher and verified and supervised by the consultants in the MPshah, KNH and UON radiology department.

The source images were 5 mm thick with a 1-2 mm reconstructed images.The CT KUB examinations were interpreted at the work station where multiplanner reformating and 3D reconstruction was done. The patients clinical and laboratory findings were accessed to aid in reaching at a diagnosis with consultation with the referring physician where necessary.

The CT finding were reported on a a predefined structured format which included.

- Positive for urolithiasis indicating the presence ,location ,number and size of calculi.
- Presence of secondary features which include pyeloureterectasis, perinephric and periureteral soft tissue standing, soft tissue rim sign.
- Normal scans.
- Those with alternate diagnosis with note on the pathology/diagnoses..

To ensure quality control and reproducibility the primary researcher carried out the initial interpretation of the images and the results were discussed and verified by a senior consultants from MP shah, KHN or UON radiology department.

The final findings as discussed and agreed upon were the one included in the study.

3.10 Ethical Consideration

Ethical approval was obtained from the KNH – UON ERC. The study started once approval was received.Patient's personal information were not used in the study for confidentiality.

The examination commenced once informed consent was obtained and only the requested examination by the primary physician was conducted.Information acquired was not used for any other purpose besides in the clinical management of patients and academics.

The data obtained was securely stored electronically and protected through the use of password.

3.11 Data collection

Data was collected at the end of each examination on a specially designed form (appendix 1) for this study.

3.12 Statistical analysis

Data was recorded and analyzed with the use of Statistical Package for Social Sciences version 21.A describtive analysis of each variable outcome was done.The main outcome were the presence of urolithiasis ,presence of secondary features with urolithiasis ,normal scans and the presence of alternative diagnosis.

The data was tabulated using pie charts, frequency tables and bar graphs.

CHAPTER FOUR

4.1 Results and Statistical analysis

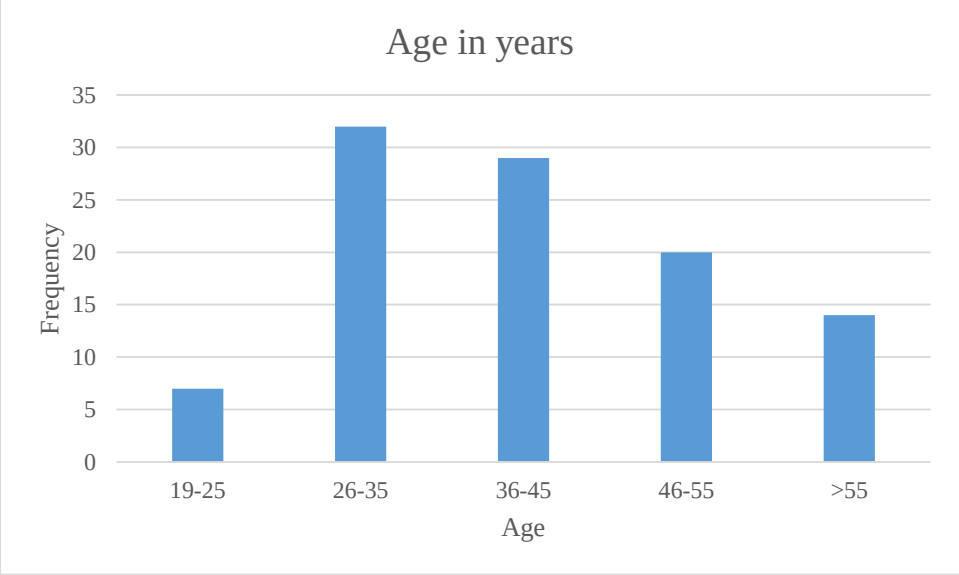
4.1.1 Socio-demographic characteristics

A total of 102 patients consented for the study and consequently underwent low dose un enhanced MDCT KUB. There were 55 male and 47 female patients with age range of 19-72 years who met the inclusion criteria and were part of the statistical analysis. Eighty one of the patients were between 26 and 55 years ,with 14 above 55 years and only 7 patients between the ages of 28 and 25 year [Bargraph 1].The mean age was 41.7 (SD 12.5) years and the median age was 40 (IQR 33-49) years

Table 4.1: Gender

	Frequency	**Percentage**
Male	55	53.9
Female	47	46.1
Total	**102**	**100.0**

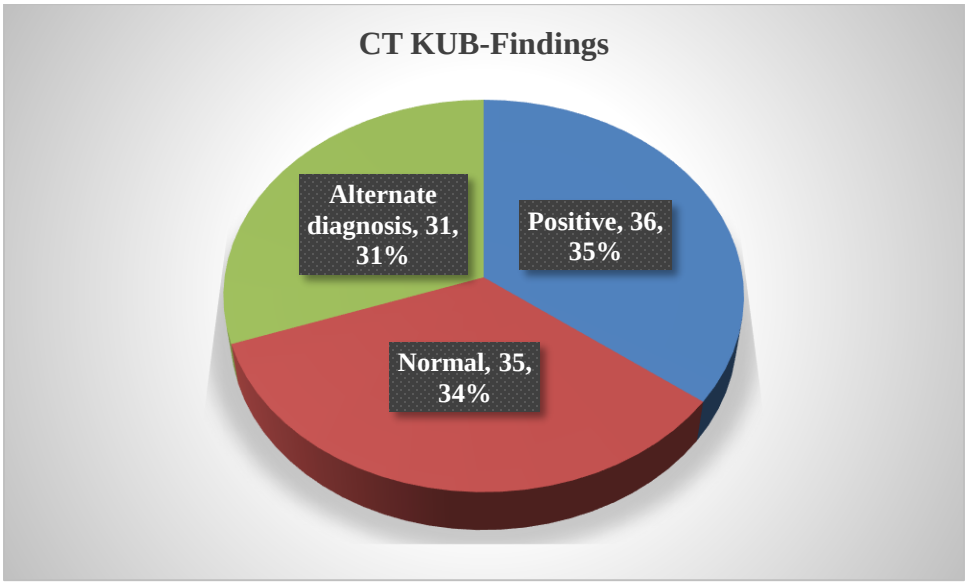
Figure 1; Age in Years



4.1.2; Unenhanced low dose MDCT-KUB findings

Thirty six (35%) out of the one hundred and two patients had positive for ureteric calculi ,31/ 102 [31%] patients underwent alternative diagnosis made on the unenhanced low dose MDCT while 35/102 [34%] patients were normal scans with no pathology identified.[as shown in the Piechart below]

Figure 2; Unenhanced low dose MDCT-KUB findings.



Unenhanced low dose MDCT-KUB findings gender and age distribution

In terms of gender distribution the majority of patients who were positive for urolithiasis were male with 27/35 [75%] of the patients and only 9/35 [25.%] of the patients were female. There were more females 25/31 [80.6%] patients compared to male patients with alternate diagnosis as shown in the bar graph below.

Majority of the patients with ureteric calculi detected in both genders were between the ages of 26 and 55 years as shown in Table 2 below.

Figure 3;Gender distribution of CT KUB findings.

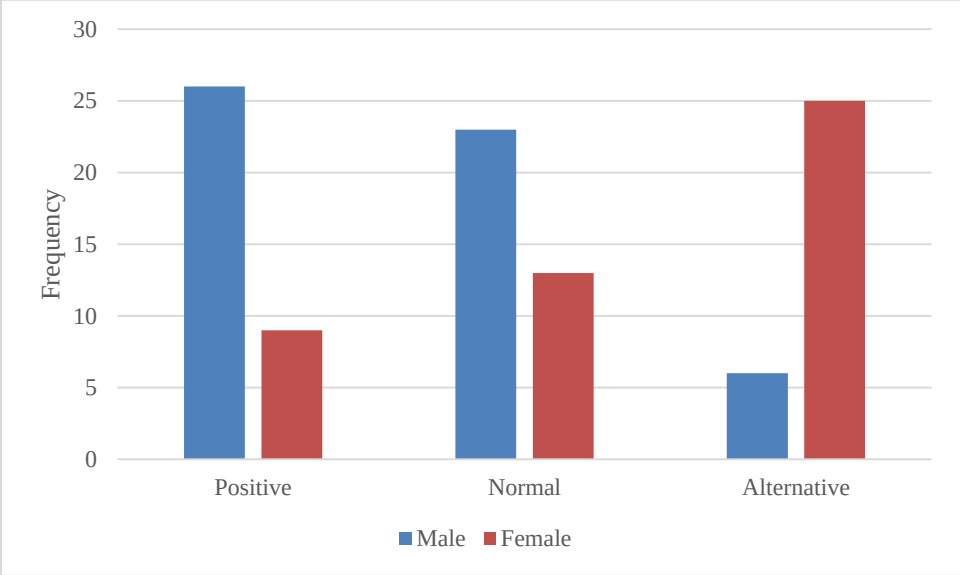


Table 4.2: Showing findings based on the gender and age

	Gender	**19-25**	**26-35**	**36-45**	**46-55**	**>55**	**Total n (%)**
Positive	Male	1	9	7	4	6	27 (75)
	Female	0	2	3	4	0	9 (25)
Normal	Male	3	5	6	7	1	23 (62.9)
	Female	1	6	4	0	2	13 (37.1)
Alternative	Male	0	1	1	3	1	6 (19.4)
	Female	2	9	8	2	4	25 (80.6)

4.1.3; Calculi size and location.

Among the patients whose findings were positive for urolithiasis , the size and location of the calculus was analysed and the location grouped in categories of those who only had ureteric calculus, those with renal or calyceal calculus and those with calculi in both the ureter and in the kidneys .

Majority 25/35 of the patients had calculus on the right ureter as compared to 12/35 patients who had calculus on the left urinary system.

Table 4.3: Location

	Frequency	**Percent**
Ureteric	19	54.3
Renal	7	20.0
Ureteric and Renal	9	25.7
Total	**35**	**100.0**

	Right	**Left**
Ureteric	12	7
Renal	5	2
Ureteric and Renal	6	3
Total	**23**	**12**

Table 4.4: Demonstrating the location of the calculi in the ureter.

Location 1 Ureteric	Frequency	Percentage
Distal Ureter	1	3.6
Mid Ureter	15	53.6
Prox Ureter	1	3.6
PUJ	1	3.6
VUJ	10	35.7
Total	**28**	**100.0**

Figure 4; Low dose unenhanced MDCT KUB ,axial and reformatted coronal images of a 34 year male with 3mm mid right ureteric calculus.

Figure 5; Low dose unenhanced MDCT KUB ,axial and reformatted coronal images of a 30 year male with three non-obstructing left lower pole calyceal calculi measuring between 3-9 mm.

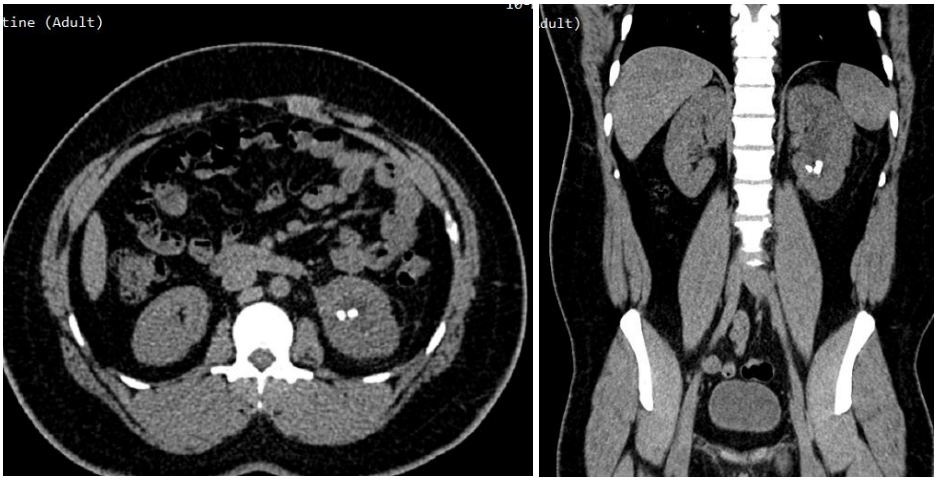
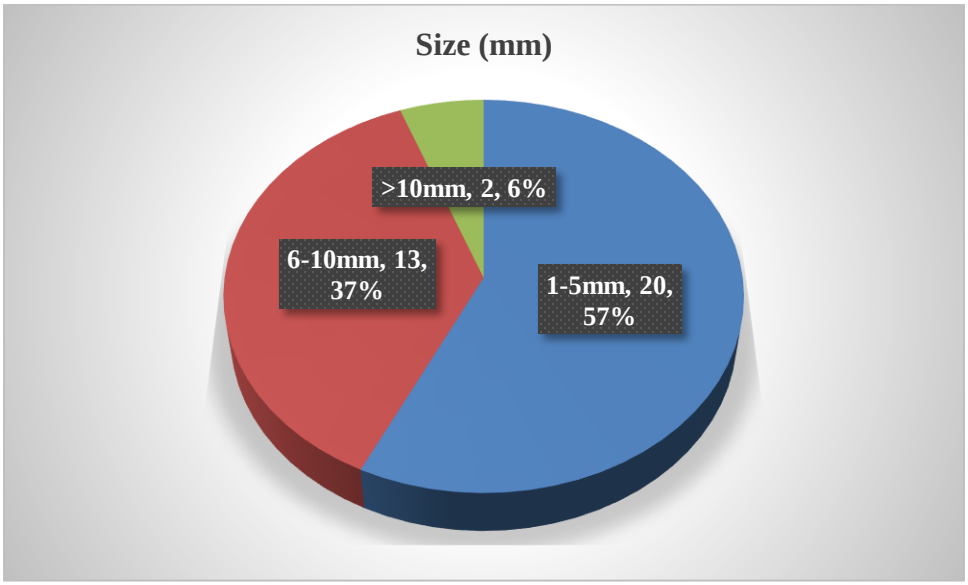


Figure 6; Pie chart showing the different sizes of the calculi .



4.1.4;Presence of secondary signs.

Presence of secondary signs formed of hydronephrosis ,perinephric stranding and the rim sign were an important clues in predicting presence of an obstructing calculus.This signs were a common findings nad were identified in 78% of all the cases with calculus reported. Hydroneproureterosis was present in 28/35 [77.8 %] of the patients with calculus ,perinephric stranding was present in 17/35 [47.1%] and the Rim Sign in 7/35 [20.6%].Of note is that some of the patients had only one two or all the present as shown below.

Figure 5; Secondary signs individual prevalence.

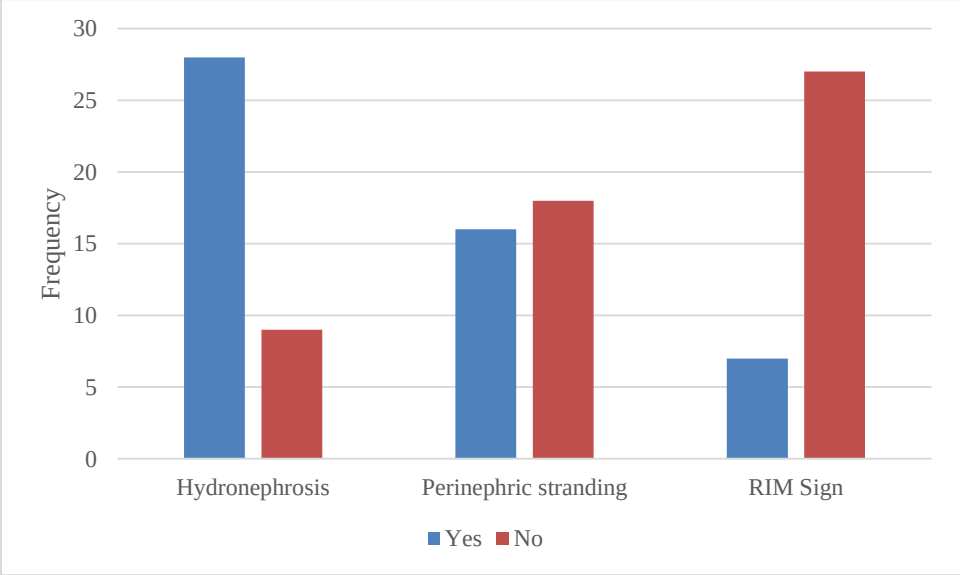


Table 4.5: Presence of secondary signs.

	Frequency	Percentage of patients
	(N=36)	%
Positive for any or all	28	77.8
Absent in all	9	25.0
Positive with all three	5	13.9
Hydronephrosis and Perinephric stranding	11	30.6

Figure 6; Low dose unenhanced MDCT KUB, Axial and reformatted coronal images of a 45 year female with 5.3mm mid right ureteric calculus with right proximal hydroureter and hydronephrosis

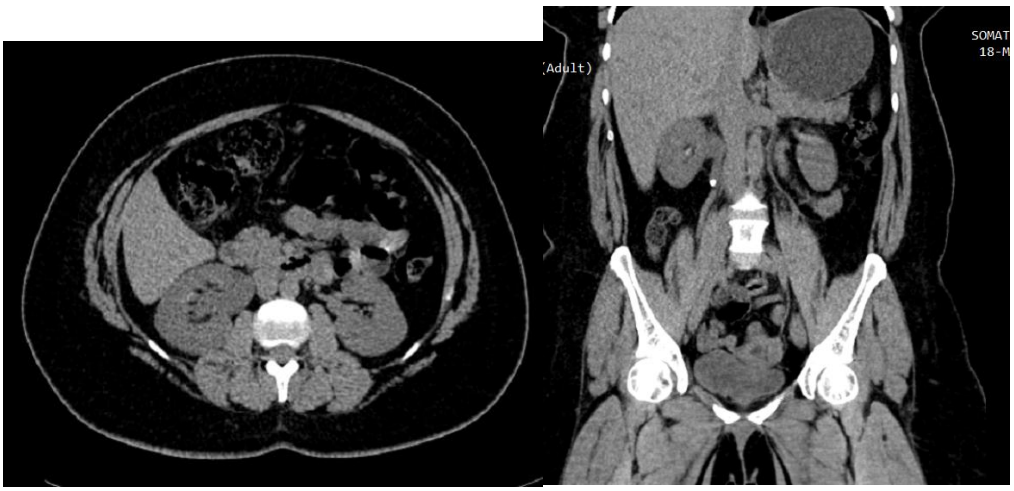


Figure 7; Low dose unenhanced MDCT KUB ,Axial and reformatted coronal and sagittal images of a 40 year male with 5 mm mid left ureteric calculus and a 3mm calculus in the left lower calcyx demonstrating proximal hydroureter , hydronephrosis with associated perinephric stranding.

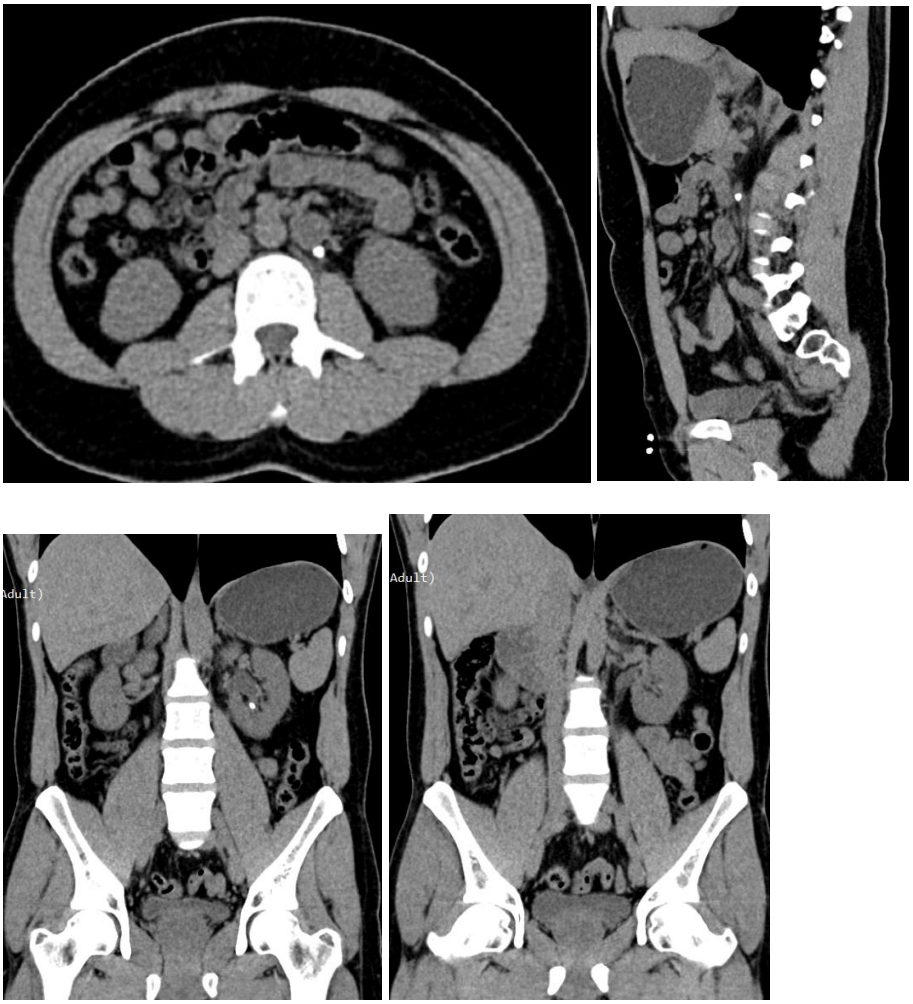
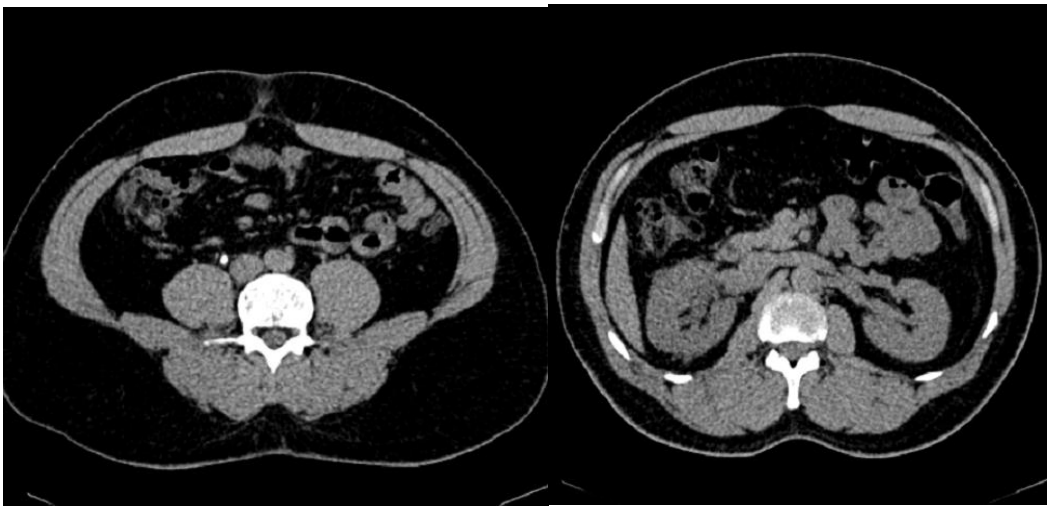


Figure 8; Low dose unenhanced MDCT KUB Axial NECT images of a 34 year male with 5 mm mid right ureteric calculus causing proximal hydronephrosis and perinephric fat stranding.



4.1.5 ; Alternate diagnosis.

A wide range of alternative diagnoses were identified during this study with a prevalence of 31/102 [31%] of the total number of patients.11/31 [28.5 %]patients had acute appendicitis as this was the most common alternative diagnoses.

The table below gives the various alternative diagnoses picked on the unenhanced CT KUB having initially being suspected clinically of renal colic**.**

Table 4.6: Alternate Diagnosis

	Frequency	Percent
Adhesions	8	25.8
AML	1	3.2
Appendicitis	11	35.5
Cholelithiasis	2	6.5
Colitis	1	3.2
Dermoid Cyst	1	3.2
Fibroids	2	6.5
Hydronephrosis	1	3.2
Peritonitis-Sub	1	3.2
PID	1	3.2
Sacral Lesion	1	3.2
Vertebral Lesion	1	3.2
Total	**31**	**100.0**

Figure 8; Low dose unenhanced MDCT KUB axial and reformatted coronal images of 35 year female patient demonstrating a dilated appendix with a 15mm appendicolith in it. Extensive surrounding fat stranding is present, acute appendicitis was confirmed intra-op.

Figure 9 A; Low dose unenhanced MDCT KUB ,axial and reformatted corona MDCT KUB images of a 29 year female patient with right lumbar region pains demonstrating a 15 mm solitary right lower renal pole well defined lesion with soft tissue and fat density areas.

FIGURE 9 B;On contrast administration the lesion demonstrated an enhancing soft tissue part with fat areas non enhancing.

A diagnosis of right renal Angiomyolipoma was made.

5.1 Discussion

This study demonstrated that unenhanced low dose CT KUB is an effective technique for the evaluation of patients with suspected renal colic as it is able to effectively pick ureteric calculus and other alternate diagnosis.

CT-KUB fast image acquisition and retrospective reconstruction using thin sections provides comprehensive evaluation of the entire urinary tract. CT has superior tissue contrast resolution compared to other modalities like IVU and ultrasound and this allows detection of calculi as small as 1 mm as well as calculus lodged in difficult areas like in the distal ureter.In this study the smallest calculi picked was 2 mm.

A study by smith et al in 1995 comparing non contrast enhanced CT with IVU showed that unenhanced CT is superior to IVU which was previously used to image patients with suspected renal colic as it is more sensitive in identifying ureteric stones, in identifying ureteric obstruction and picking other alternate diagnosis.(39)

A total of 102 patients consented for this study out of this 36 [35%] were positive for urolithiasis of which 26 were male and 9 were female. The male to female ratio was 2.8, this follows similar trends in other countries . A study done by Sietz et al in 2013 on Epidemiology and gender-specific aspects of urolithiasis in USA and Europe found the ratio at 2.28 (42)

The recent worldwide trend shows increasing cases of urolithiasis. A similar local study done on evaluation of renal colic patients using low dose NECT by Twahirwa et al in 2009 at AKUH on 90 patients had 18/90 [20%] positive for urolithiasis(9).In this study 35% of the patients were positive for urolithiasis and this demonstrates the increasing prevalence of urolithiasis in Kenya which is similar to reported increasing prevalence of urolithiasis world wide.

Calcification within the ureteric lumen is the utmost direct sign of ureteral stone . Once in a while, however, differentiating a phlebolith from a stone in the ureter can be challenging. A study by Rucker et al demonstrated that in cases like these secondary signs of obstruction, including hydroureteronephrosis ,perinephric stranding and nephromegaly are useful in aiding the radiologist in giving the correct diagnosis(43).

Hydronephrosis and hydroureter were the most common secondary sign present with 28/35 [75.5%] of the patients. These two carry a 99% positive predictive value in predicting an ureteric stone causing obstruction(10).In all the patients who had ureteric calculi proximal ureteric dilatation and hydronephrosis were present though in some cases dilatation was to a mild degree. Perinephric stranding was found in 16/35 [47%].This is usually due to Perinephric edema,though on its own is a nonspecific sign ,in the presence of urolithiasis it can help in predicting the degree of obstruction. This carries a sensitivity and specificity of 65–82 and 93% respectively.

Hydronephrosis and hydroureter even when mild can be easily picked on unenhanced CT KUB. This gives a clue to the reporting radiologist to look for an otherwise unapparent small calculus in the ureter or bladder. Periureteral and perirenal stranding is usually due edema or urine resorption and is a sign of acute obstruction likely caused by a calculi (44).

This signs form important clues for the reporting radiologist in diagnosing urolithiasis and would be difficult to appreciate in IVU and ultrasound.

Alternate diagnosis was identified in 31/102 (31%) of the total patients. Studies done previously have reported prevalence of 30 to 38%.A local similar study done by Twahirwa et al at AKUH reported a prevalence rate of 32 %(9).

In this study acute appendicitis was the most prevalent with 11 [35.5%] patients, followed by nonspecific adhesions with 8 patients. Others included cholelithiasis, colitis, fibroids, dermoid cyst, PID and vertebral lesions. This spectrum of alternate diagnosis is similar to those reported in literature and as described by Rucker et al (43).

Of major concern is that majority of the patients with alternate diagnosis were female with 85.4% of the patients in this category. This was mainly due to gynecological conditions and nonspecific adhesions. This raises the question of use of CT KUB as compared to other modalities especially ultrasound in female patients(3).

Most times it's difficult to discriminate symptoms related with other illnesses from those of acute renal colic. Therefore CT KUB in this area has a strong advantage over the other modalities in its capacity to diagnose alternate diagnoses. It has been shown that urolithiasis may be detected in as few as 33% of patients presenting with acute flank pain and that alternative diagnoses can be identified in as many as 45%(45)(43) .

This study demonstrates that there were almost equal number of patients positive for urolithiasis and for alternate diagnosis. This can be explained by the use of CT KUB for lumbar pains and the manageable cost of examination compared to the standard CT abdomen, also its faster to acquire as no preparation is required.

Follow-up standard CT with iv and oral contrast was occasionally recommended for the further characterization of the patients already diagnosed with alternative diagnosis if necessary like in a case of a 29 year old female who had well defined renal mass with fat and soft tissue density on NECT and contrast administration was recommended and a diagnosis of renal angiomyolipoma made.

Unenhanced low dose MDCT KUB was adequate in evaluating cases of renal colic patients in this study. This emphasizes a fact that low dose CT KUB is sensitive and specific in identifying ureteral stones. A study done by Tack et al on low dose versus

standard dose showed low dose to have an accuracy rate of more than 93%, and performance was similar to that of standard CT(46).

In this study low dose protocol was used to acquire the images with reduction of the mA from 200mA for standard dose to 100 mA. Post-acquisition processing was done with Multiplaner and 3 D reconstruction ,this aided and enhanced interpretation confidence. This technique greatly reduced the radiation dose exposure to the patient which was an important goal in this study.

International Committee on Radiation Protection (ICRP) has made recommendations based on the ALARA principle, which stands for "As low as reasonably achievable".

This study provides evidence that use of the low dose protocol MDCT provides a high diagnostic accuracy in patients presenting with acute renal colic and is applicable in our Kenyan set up and African population at large .

5.2 Conclusions

- Lack of enhanced low dose MDCT is the imaging of choice for evaluation of suspected renal colic as it can correctly identify urolithiasis and is able to significantly identify other causes of acute pain that may mimic renal colic.
- Presence of secondary radiological signs which was positive in 78% of the positive cases for urolithiasis is a strong correlation and a significant finding in aiding the reporting radiologist in making and confirming the diagnoses. They also give the confidence that obstruction is caused by a calculus therefore an important diagnostic clue.

5.3 Limitations

- No follow up done on the patients was done to further confirm stone retrieval or passage therefore possibility of false positive or negative.
- Study was conducted in referral Facility therefore not a true representation of the Kenyan population.
- Relative small sample size.

5.4 Recommendations

- A Adoption of Low dose Multidetector CT KUB as the first line imaging of choice for evaluation of suspected renal colic patients.
- Due to the significant number of patients with normal findings and alternate diagnosis its necessary to develop clinical guideline for likely renal colic to necessitate MDCT KUB to avoid unnecessary radiation exposure.
- A study comparing the diagnostic performance of Ultrasound compared to MDCT KUB especially in female patients with suspected renal colic.

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APPENDICES

APPENDIX 1; Timeline

	May to June 2019	July to August 2019	Sept to Nov 2019	Dec to Jan 2019	Feb to March 2019
Proposal Write up	✔				
Submission To ERC and corrections		✔			
Data collection			✔		
Data entry and analysis				✔	
Report writing and dissertation submission					✔

APPENDIX 2: Budget

ITEMS	QUANTITY	UNIT PRICE(KSHS)	TOTAL COST (KSHS)
Note books	4 pcs	60.00	240.00
Printing paper	3 packets	550.00	1650.00
Files	3 pcs	90.00	270.00
Cartridge	1 pc	15,000	15,000.00
Internet surfing	50 GB	120 per GB	6000.00
Writing pens	20 pcs	20	400.00
Telephone airtime			5000.00
Flash discs	2 pcs	1500	3000.00
Photocopies of data collection tool	20 copies	5.00 per page	1000.00
Photocopy of final proposal	6 copies	5.00 per page(47 pages)	1260.00
Binding copies of proposal	6 copies	50.00	300.00
Ethical review fees	1	2000.00	2000.00
Miscellaneous			4,000.00
Biostatistician	1		30,500.00
Contingency (10% of total cost)			10,000.00
Total			80,620.00

APPENDIX 3: Data collection tool

PIN;

AGE; SEX; WT;

CT KUB FINDINGS

POSITIVE FOR CALCULUS ……

Location	
Size [mm]	
Number of stones	

PRESENCE OF SECONDARY FEATURES

TYPE OF SECONDARY FEATURE	CALCULUS PRESENT	CALCULUS ABSENT
1.hydronephroureter		
2.perinephric soft tissue stranding		
3.soft tissue rim sign		

NO CALCULUS PRESENT

Normal CT KUB	
Alternate diagnoses present	1. 2. 3.

APPENDIX 4: Consent form to participate in research study.

Research title:

CT findings in suspected renal colic patients undergoing unenhanced low-dose multi-detector computed tomography

This consent form has three parts:

- Statement by the researcher/research assistant.
- An Information sheet.
- Consent certificate.

Investigators statement

I am Dr. Bernard Kuria Njau a postgraduate student pursuing a Masters in Medicine Degree in Diagnostic Imaging and Radiation Medicine at the University of Nairobi **.**I am conducting a study on CT findings in suspected renal colic patients undergoing unenhanced low-dose multi-detector computed tomography.

CT scan imaging will be used for the study. It is a safe imaging modality and no pain will be experienced during the procedure. The study will be conducted as requested by the primary doctor and no additional imaging will be conducted.

This consent form is to help you decide whether you want to be part of the study or not. I will be delighted if you agree to take part in this study.

Please feel free to ask any questions before, during and after the study.

Kindly read through the form.

INFORMATION SHEET

Background

Acute flank pain is an excruciating event one can be involved in. This is usually typical for urinary tract calculi also known as urolithiasis. There is a global rise in urolithiasis incidences and the same trend is being seen in Kenya with diagnostic tools awareness and use being a challenge in the emergency departments. Urolithiasis and non-genital-urinary conditions can have similar presentation and CT KUB is one vital radiological test that offers more precise and rapid evaluation of patients with renal colic giving precise information on the size , location of calculi and any other alternate diagnoses the patient have.

Study purpose

The aim of this study is to determine the percentage of the number of patients with urolithiasis and alternate diagnoses in patient presenting with renal colic and to establish the radiological signs associated with urolithiasis.

Risks and benefits

Following participation in this study the participant will benefit from having his CT KUB images being looked by more than one participant therefore improving on the diagnostic accuracy and more information will be given in the report therefore improving on management.

CT scan carries the risk of radiation to the participant however this study does not influence whatsoever on whether the patient will undergo the examination or not as this will be a preserve of the primary doctor.

During this study there are no additional investigation or imaging that would be carried other than the one requested by the primary doctor and the set hospital protocol on carrying out the said CT scan will be adhered to.

Also of note is that no laboratory tests will be done for the purpose of this study and as such no blood samples will be taken from the participants.

Study Procedures

The patient will undergo CT scanning as requested by the care-giver. During the scanning the patient lies down supine in the CT scanner gantry. No contrast material that is given and there are no side effects. There is no recovery period required and the patient is free to leave as soon as the procedure is complete.

Voluntariness of participation or withdrawal

Participation in this study is entirely voluntary and you will not be denied medical care in case you refuse to participate. If you do decide to take part you shall be expected to sign the underlying consent form. You may withdraw from participating in the study at any time with no consequence whatsoever.

Confidentiality

All information will be treated with confidentiality and any relevant medical information regarding the CT findings results and the data collected will be accessible only to persons authorized to handle it. This will include the researcher, their supervisors and the patient's primary caregiver, if so required.

All patients personal information collected will be destroyed at the end of the study.
No records of names of the patients/ relatives will be kept in the data collection.

Compensation

No compensation, financial or otherwise, will be offered to the participants. Neither will any preferential treatment, gift or reward, be awarded to the participants during or after the duration of the study.

Contact information

Should you require any further clarification regarding the study please feel free to contact the principal researcher:

Dr. Benard Kuria Njau
Radiology resident, University of Nairobi
Telephone Number: 0723749253
Email address; njaukuria15@gmail.com

Supervisor:

Dr Timothy Musila Mutala,
Consultant Radiologist and Lecturer,
Department of Diagnostic Imaging and Radiation Medicine,
University of Nairobi.
Email address; musilamutala@gmail.com

For queries concerning your rights as a research participant you may contact the Kenyatta National Hospital Ethics and Research Committee. It is the mandate of this committee to protect you, if you chose to participate, from harm.

KNH-UoN Ethics and Research Committee,
P.O. Box 19676-00202 OR P.O Box 20723-00202, Nairobi.
E-mail: uonknh_erc@uonbi.ac.ke
Tel number 726300-9 Ext.44102 44355.

Consent form

I, the undersigned, have read and fully understood the explanation given to me regarding the above mentioned study. I have been given the opportunity to ask questions which have been answered satisfactorily by the investigators.

I understand that my participation is voluntary and that I have not been forced to take part in the study and that I can decline on my own accord without my medical care being affected.

I understand that I will not receive any form of remuneration or preferential treatment for taking part in the study.

I understand that my personal information will be kept confidential, but that any pertinent medical information obtained from CT scan imaging and the data collected therefrom may be accessible to the principal investigator and their supervisors.

I hereby consent to my participation in this study.

SIGNED: …… (Patient)

Date: …….

Unique Patient ID: …….....

SIGNED: ……. (Witness)

Statement by the researcher

I hereby confirm that I have adequately explained the contents of the information sheet to the participant; and that they understand the voluntary nature of their participation in the study as well the confidentiality with which their information will be treated; and their right to refuse or withdraw from the study without fear of compromise to their quality of care.

Name……..

Signature……

Date……....

Kiambatisho 2: Fomu ya idhini ya kushiriki katika utafiti.

Kichwa cha utafiti: Matokeo ya CT kwa watu wanaoshukiwa wa ugonjwa wa figo wanaopatwa na kipimo cha chini cha kipimo cha kiwango cha chini cha uchunguzi

Njia ya idhini hii ina sehemu tatu:

Taarifa ya mtafiti / msaidizi wa utafiti

Karatasi ya Habari

Cheti cha idhini

Taarifa ya wachunguzi

Mimi ni Dr. Bernard Kuria Njau mwanafunzi wa kuhitimu akifuatilia Shahada ya Uzamili ya Tiba katika Tiba ya Utambuzi na Ugonjwa wa Mionzi katika Chuo Kikuu cha Nairobi .Nafanya uchunguzi juu ya matokeo ya CT kwa watu wanaoshuhudia ugonjwa wa figo wenye kidato cha chini wenye kipimo cha chini cha kipimo tomografia.

Utaftaji wa uchunguzi wa CT utatumika kwa utafiti. Ni njia ya kufikiria salama na hakuna uchungu wowote utakaopatikana wakati wa utaratibu. Utafiti huo utafanywa kama ulivyoombewa na daktari wa msingi na hakuna fikira za ziada zitakazofanywa.

Njia hii ya idhini ni kukusaidia kuamua ikiwa unataka kuwa sehemu ya utafiti au la. Nitafurahi ikiwa utakubali kushiriki katika utafiti huu.

Tafadhali jisikie huru kuuliza maswali yoyote kabla, wakati wa na baada ya masomo.

Soma kwaheri kupitia fomu

Karatasi ya habari

Asili

Maoni ya maumivu ya papo hapo ni tukio kubwa mtu anaweza kuhusika .. Hii kawaida ni kawaida kwa calculi ya njia ya mkojo pia hujulikana kama urolithiasis. Kuna kuongezeka kwa ulimwengu kwa matukio ya urolithiasis na hali hiyo hiyo inaonekana nchini Kenya na ufahamu wa zana za utambuzi na matumizi ya kuwa changamoto katika idara za dharura. Urolithiasis na hali zisizo za ukeni-mkojo zinaweza kuwa na uwasilishaji sawa na CT KUB ni mtihani mmoja muhimu wa kiinolojia ambao hutoa tathmini sahihi zaidi na ya haraka ya wagonjwa walio na figo ya colic inayotoa habari sahihi juu ya saizi na eneo la calculi.

Kusudi la kusoma

Madhumuni ya utafiti huu ni kujua asilimia ya idadi ya wagonjwa walio na urolithiasis na utambuzi mbadala katika kuwasilisha mgonjwa na colic ya figo na kuanzisha ishara za radiolojia zinazohusiana na urolithiasis.

Kujitolea kwa ushiriki

Ushiriki katika utafiti huu ni wa hiari kabisa na hautakataliwa huduma ya matibabu ikiwa utakataa kushiriki. Ukiamua kuchukua sehemu utatarajiwa kusaini fomu ya idhini ya msingi. Unaweza kujiondoa kutoka kushiriki katika masomo wakati wowote bila matokeo yoyote.

Hatari na faida

Kufuatia kushiriki katika utafiti huu mshiriki atafaidika kutokana na picha zake za CT KUB kutazamwa na mshiriki zaidi ya mmoja kwa hivyo kuboresha juu ya usahihi wa utambuzi na habari zaidi atapewa ripoti hiyo ikiboresha usimamizi. Scan ya uchunguzi inachukua hatari ya mionzi kwa mhusika lakini wakati wa uchunguzi huu hakuna uchunguzi wa ziada au fikira ambazo zingechukuliwa isipokuwa ile iliyoombewa na daktari wa msingi na itifaki ya hospitali ya kutekeleza Scan itafuatwa. Pia kumbuka ni kwamba hakuna majaribio ya maabara ambayo yatafanywa kwa madhumuni ya utafiti huu na kwa hivyo hakuna sampuli za damu zitakazochukuliwa kutoka kwa washiriki.

Taratibu za Kujifunza

Mgonjwa atapitia skanning ya CT kama ilivyoombewa na mtoaji. Wakati wa skanning mgonjwa amelala chini juu katika vifaa vya skana ya scanner ya CT.Hakuna tofauti ya vifaa ambavyo hupewa na hakuna athari mbaya. Hakuna kipindi cha kupona kinachohitajika na mgonjwa yuko huru kuondoka mara tu utaratibu utakapokamilika

Usiri

Habari zote zitatibiwa kwa usiri na habari yoyote muhimu kuhusu matibabu kuhusu matokeo ya matokeo ya CT na data iliyokusanywa itapatikana tu kwa watu walioidhinishwa kuishughulikia. Hii itajumuisha mtafiti, wasimamizi wao na mlezi wa mgonjwa wa kwanza, ikiwa inahitajika.

Wagonjwa wote habari ya kibinafsi iliyokusanywa itaharibiwa mwishoni mwa utafiti.

Hakuna rekodi za majina ya wagonjwa / jamaa zitahifadhiwa kwenye mkusanyiko wa data.

Fidia

Hakuna fidia, kifedha au vinginevyo, itapewa kwa washiriki. Wala hakuna matibabu ya upendeleo, zawadi au tuzo, itakayopewa washiriki wakati wa au baada ya masomo.

Habari ya mawasiliano

Ikiwa utahitaji ufafanuzi zaidi kuhusu utafiti tafadhali jisikie huru kuwasiliana na mtafiti mkuu

Dkt. Benard Kuria Njau
Mkazi wa radiology, Chuo Kikuu cha Nairobi
Nambari ya simu: 0723749253
Email address; njaukuria15@gmail.com

Msimamizi:

Dkt. Timothy Musila Mutala,
Mshauri wa radiolojia na Mhadhiri,
Idara ya Utambuzi wa Utambuzi na Tiba ya Mionzi,
Chuo Kikuu cha Nairobi.
Anwani ya barua pepe; musilamutala@gmail.com

Kwa maswali kuhusu haki zako kama mshiriki wa utafiti unaweza kuwasiliana na Maadili na Kamati ya Maadili ya Kitaifa ya Hospitali ya Kitaifa ya Kenya. Ni jukumu la kamati hii kukulinda, ikiwa umechagua kushiriki, kutokana na madhara.

Kamati ya Maadili na Utafiti ya KNH-UoN,
P.O. Sanduku 19676-00202 AU Box Box 20723-00202, Nairobi.
Nambari ya simu; 726300-9 Ext.44102 44355.
Barua-pepe: uonknh_erc@uonbi.ac.ke

Fomu ya idhini

Mimi, waliosajiliwa, nimeisoma na kuelewa kwa undani maelezo niliyopewa kuhusu utafiti uliotajwa hapo juu. Nimepewa nafasi ya kuuliza maswali ambayo yamejibiwa kwa kuridhisha na wachunguzi.

Ninaelewa kuwa ushiriki wangu ni wa hiari na kwamba sijazimishwa kuchukua sehemu kwenye masomo na kwamba naweza kupungua kwa hiari yangu bila huduma yangu ya matibabu kuathirika.

Ninaelewa kuwa sitapokea malipo ya aina yoyote au matibabu ya upendeleo kwa kushiriki katika utafiti.

Ninaelewa kuwa habari yangu ya kibinafsi itatunzwa kwa siri, lakini kwamba habari yoyote inayofaa ya matibabu inayopatikana kutoka kwa uchunguzi wa skirini ya CT na data iliyokusanywa hapo inaweza kupatikana kwa mpelelezi mkuu na wasimamizi wao.

Kwa hivyo nakubali kushiriki kwangu katika utafiti huu.

Iliyodhibitishwa: …… (Mgonjwa)

Tarehe: …….

Kitambulisho cha Mgonjwa wa kipekee: …… ....

Iliyodhibitishwa: ……. (Shahidi)

Taarifa ya mtafiti

Kwa hivyo ninathibitisha kwamba nimeelezea vya kutosha yaliyomo kwenye karatasi ya habari kwa mshiriki; na kwamba wanaelewa asili ya hiari ya ushiriki wao katika masomo na usiri ambao habari zao zitatibiwa; na haki yao ya kukataa au kujiondoa kutoka kwa masomo bila kuogopa kupatana na ubora wao wa utunzaji.

Jina …… ..

Sahihi……

Tarehe……....

APPENDIX 5: KNH Ethical Approval Letter

Turnitin Originality Report

CT FINDINGS IN SUSPECTED RENAL COLIC PATIENTS UNDERGOING UNENHANCED LOW-DOSE MULTI-DETECTOR COMPUTED TOMOGRAPY. by Dr. Benard Kuria Njau

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