

**OUTCOME OF TRANS-RADIAL UTERINE ARTERY FIBROID EMBOLISATION:  
A KENYAN EXPERIENCE.**

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A thesis submitted as Partial Fulfillment of the Requirements for the Award of a Fellowship  
in Interventional Radiology Degree from the University of Nairobi

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**DECLARATION**

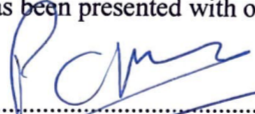
I declare that this thesis is my original work and has not been presented anywhere else for academic purposes.

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## **List of Abbreviations**

UAE	Uterine artery embolization
UFE	Uterine fibroid embolization
QOL	Quality of life
IR	Interventional radiologist.
UF	Uterine fibroids
MRI	Magnetic Resonance Imaging
BMI	Body mass index
TKH	The Karen Hospital
KNH	Kenyatta National Hospital
TRA	Trans radial approach
TFA	Trans femoral approach
SPSS	Statistical Package for Social Sciences
SIR	Society of Interventional Radiology
GOPC	Gynaecologic outpatient clinic
Fr	French

### Operational Definition of Terms

An Interventional Radiologist (IR)	A physician that uses imaging guidance to perform minimally invasive, targeted procedures and treatments with quicker recoveries.
Uterine fibroid embolization	Uterine fibroid embolization is a non-surgical interventional radiology procedure that is minimally invasive, used to treat symptomatic uterine fibroids. It uses fluoroscopy to show where to deliver the embolic agents into the uterine arteries and fibroids.
Uterine myomas or fibroids or leiomyomas	Firm round, white growths within the uterus. Though fibroids are not cancerous, they can cause a significant detriment to a woman's reproductive health causing problems such as heavy periods, anaemia, infertility, or pregnancy complications.

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## Abstract

**Background:** Uterine leiomyomas are the most frequent cause of non-cancerous pelvic tumours in women. In Kenyatta National Hospital and the Karen Hospital, most patients are treated medically and surgically with myomectomy or hysterectomy. However, for cases where surgery is contraindicated, Uterine fibroid embolization (UFE), a minimally invasive interventional radiology procedure, is used to treat symptomatic uterine fibroids. Using the trans-radial approach (TRA) instead of the femoral approach for UFE, there is a significant reduction in hospital stay, complications, and patient comfort. However, the evidence of the technical success rate and complications of TRA UFE has not been evaluated locally.

**Broad objective:** The study sought to determine the characteristics, technical success rates and complications in patients undergoing trans-radial UFE at Kenyatta National Hospital and Karen Hospital.

**Participants and methods:** This was a retrospective and prospective cross-sectional study carried out at Kenyatta National Hospital and Karen Hospital. Medical records of patients who underwent trans-radial UFE at Kenyatta National Hospital and Karen Hospital were retrieved. The Census sampling approach was used with a sample of 48 TRA UFE required. Data was extracted from the patients' records. Information collected included the patient's age, parity, last menstrual period, symptomatology – bleeding, cramps, bloating, pelvic fullness, urinary tract symptoms, MRI – fibroids, and Haemoglobin level, INR, working diagnosis and management undertaken, data on the trans-radial access UFE including the technical outcome of uterine fibroid embolization, complications related to uterine artery embolization, and access. The data was entered into Epi Info software, from where it was cleaned and coded, and any missing data was sought from the files. The hard copies were stored in a lockable file cabinet while the soft copies were entered into a password-protected laptop. Frequencies and percentages were used for categorical data analysis, while mean and standard deviation or median and interquartile ranges were used for continuous variables.

**Results:** A total of 48 patients underwent UAE at the two facilities with a mean age of 43.3 (SD= 6.8) years. Half, 24 (50.0%), had anaemia. Only 5 (10.4%) had received prior treatment for the condition. On imaging, the mean number of fibroids was 5.4 (SD=2.8). The procedure was technically successful in all 48 (100%) patients. All the patients had pain and cramping with some degree of post embolization syndrome, consisting of the following symptoms (nausea, fever, headache, and malaise). From the trans-radial approach, access site complications included hematoma (3; 6.3%), pain (2;4.2%) and bleeding from the puncture site (1; 2.1%). After the procedure, all the patients were discharged after monitoring.

**Conclusion:** Trans radial uterine artery embolization is a viable and successful treatment option for fibroids with few complications. TRA is a feasible, effective, and safe approach to UAE. Besides, it has the advantage of same-day discharge from the hospital. Randomised studies are needed to validate its effectiveness and clinical benefits compared to existing approaches such as TFA.

## CHAPTER ONE: INTRODUCTION

### 1.1 Background information

Uterine myomas or fibroids, or leiomyomas are firm, round, white growths within the uterus. Though fibroids are not cancerous, they can cause a significant detriment to a woman's reproductive health, causing problems such as heavy periods, anaemia, infertility, or pregnancy complications. They are the most frequent non-cancerous tumour of the female pelvis and affect 20–40% of women in their reproductive years (1). Myomas are the reason for approximately 67% of all hysterectomies performed in middle-aged ladies (2). Uterine fibroids affect the quality of life (QOL) in the affected ladies. The related health care burden and morbidity are significantly high. Uterine fibroids are prevalent benign tumours in gynaecology and are associated with severe menstrual bleeding with or without consequences of abdominal pain, urinary tract infections, pelvic pain, and bowel compression (3).

Uterine artery embolization (UAE) or Uterine fibroid embolization (UFE) has been utilised to manage Uterine myomas, fibroids, or leiomyomas. The UAE procedure was first described and utilised by Meland in 1974 to manage uterine fibroid tumours in a life-threatening haemorrhage context (4). The UFE involves the delivery of an embolic agent via uterine arteries directly in fibroids and the uterus. It is commonly utilised in women in whom surgery is contraindicated or who decline surgery (hysterectomy or myomectomy) which is usually the standard treatment of choice (3). The procedure was reported in a number of cases in Paris as effective and safe, involving less invasiveness and hence an alternative for fibroid tumours management (5).

With improvement and refinement of the procedure over time, transfemoral access (TFA) technical variations, including utilising the bilateral femoral access, have led to the minimization of fluoroscopy time and the time the procedure takes (6). However, over the last decade, trans-radial access (TRA) for coronary procedures has increased promoted by mounting evidence favouring TRA over TFA as TRA was found to be associated with patient comfort, less costs and more minor complications of access site in studies among cardiac patients (7). A feasibility assessment of TRA in UAE involving 29 consecutive patients who underwent the procedure in a single centre in the USA found it to have a 100% technical success rate with no immediate minor or major complications even within one month of follow up hence an indication of its safety and feasibility in those settings (8).

A recent systematic review on the approach found 10 studies and the synthesis of the evidence concluded the approach to be comparable to TFA when used for arterial embolism. It was also concluded to be an efficient and safe procedure as is the case with TFA. Besides TRA was considered advantageous as it was associated with minimal complications and shortened period of hospitalization (9).

Related evidence regarding effectiveness and safety of TRA use in UAE interventions has been documented mainly in developed countries but there exists a huge gap in knowledge on the intervention as documented in a recent review (9). Besides, evidence on the approach locally remains scanty and TRA remains underused by the interventional radiologists. Hence this study seeks to fill the existing knowledge gap on the same.

## **1.2 Problem statement**

There is paucity of data regarding the technical success rates and complications associated with TRA UFE in Kenya. This is despite it being utilised in several facilities in patients with fibroids. At Kenyatta National Hospital and Karen Hospital, the procedure is increasingly being used in patients contra-indicated or who object to surgical uterine fibroids management. However, its wide application is hampered by lack of shared knowledge and understanding of its efficiency, effectiveness, and success.

## **1.3 Study Justification**

The current management practice of fibroids at the Kenyatta National Hospital (KNH) and Karen Hospital does not routinely include UFE or interventional radiology consults. This is despite most embolization requests being on an emergency basis for intractable bleeding and patient with low haemoglobin unsuitable for surgery. While TRA UFE is an effective and technically successful alternative, there is a lack of local evidence to inform policies and guidelines for its wider adoption. With the growing application of this approach, local studies are warranted. Evidence from such studies will inform the increased utilisation in the country. It will also help generate new hypotheses for further research on the subject hence growing the local body of knowledge on the same.

## **1.4 Research Question**

What are the characteristics, technical success rates and complications in patients undergoing trans radial UFE at Kenyatta National Hospital and Karen Hospital?

## **1.5 Objectives**

### **1.5.1 Broad Objective**

To determine the characteristics, technical success rates and complications in patients undergoing trans radial UFE at Kenyatta National Hospital and Karen Hospital.

### **1.5.2 Specific objectives**

1. To describe the clinical characteristics of patients undergoing trans radial UFE at Kenyatta National Hospital and Karen Hospital.
2. To determine the technical success rate of trans radial UFE at Kenyatta National Hospital and Karen Hospital.
3. To evaluate the immediate (immediately after TRA UFE) and post-intervention complications (at 2 weeks follow-up) of trans radial UFE at Kenyatta National Hospital and Karen Hospital.

## CHAPTER TWO: LITERATURE REVIEW

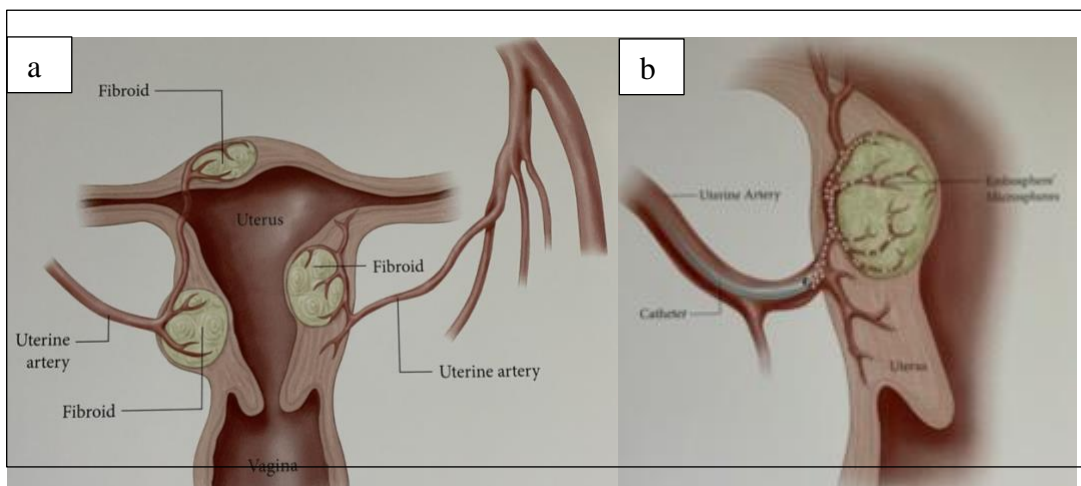
### 2.1 Literature review

#### 2.1.1 Aetiology and management of fibroids

The precise aetiology of myomas is not well known, but the working hypothesis is that prenatal hormone exposure, genetic predisposition, and the effects of growth factors, hormones, and xenoestrogens cause myoma growth. Known risk factors are polycystic ovary syndrome, African descent, obesity, nulliparity, diabetes, and hypertension.

Although hysterectomy has been thought to be the definitive treatment for symptomatic leiomyomas and remains a frequent treatment option for myomas, there is an increased interest in less invasive interventions that avoid loss of the uterus, including medical treatment, laparoscopic myomectomy, endometrial ablation, focused ultrasound and UFE. UFE has come out as one of the most important of these options.

UFE is done by selective catheterization of the uterine arteries and blocking the peri fibroid plexi with embolic particles (Image 1a, Image 1b). The resultant effect is ischemia and infarction of the myomas. It is a different treatment to myomectomy or hysterectomy for many ladies afflicted by leiomyomas.



**Image 1: a) An illustration showing peri fibroid plexi. b) Shows the particles being injected into the uterine artery**

An interventional radiologist (IR) and a gynaecologist ideally, should evaluate the patients considered for UFE. To assess if UFE is the appropriate treatment choice an IR should at a minimum evaluate any woman considered for UFE. That discussion should include a complete history with gynaecologic history, general medical history to determine comorbidities and a thorough physical examination. Gynaecologic history includes any gynaecologic surgeries, reproductive history, likely future pregnancies, previous gynaecologic diseases, and a menstrual cycle history. The discussion also allows the IR to talk about embolization in the context of the client's preferred treatment outcomes. It is important for the gynaecologist to

ensure no other pathologic diseases and to discuss other possibilities such as myomectomy or hysterectomy.

Post procedure management must be well laid out because majority of clients will have moderate discomfort or pain for a couple of hours post UFE. The discomfort is due to ischemia. Post embolization syndrome i.e., low-grade fever, fatigue, nausea, malaise loss of appetite is also experienced by patients and may necessitate readmission in 10% of patients (10)

Uterine myomas, fibroids or leiomyoma are firm round, white growths within the uterus. Uterine fibroids (UF) are the most common benign pelvic tumour in women affecting 20 – 40% of women in their reproductive years. Recent systematic reviews have shown that the prevalence estimates vary depending on the study population and methodology. This range has been estimated to be between 4% - 68.6% (2). Notably this prevalence has been shown to be higher in women of African descent. A United States Census Bureau and Population estimates report extrapolated that the prevalence of myomas was at 1,649,105 cases (approximately 10-20% of the female population) in Kenya (11). The higher prevalence rate of myomas in African ladies may be owed to the gene encoding leiomyoma development or a positive family history of myomas, myometrial irritation following a pelvic disease resulting in irregular uterine growth, or higher levels of oestrogen (12). It was also noted to be higher in women with conditions such as hypertension (13), breast cancer or ovarian cancer (14). Despite such high prevalence the underlying pathogenesis remains poorly understood. The working hypothesis is that prenatal hormone exposure, genetic predisposition, effects of growth factors, hormones and xenoestrogens have been linked to leiomyomas. Known risk factors include polycystic ovarian syndrome, African descent, obesity, nulliparity and diabetes (15). The disease burden of uterine fibroids cannot be underplayed. The direct costs of management remain high and has been estimated to be as high as 35 billion US dollars annually in the United States of America (USA) (16). Other indirect costs such as loss of work which translates to loss of manpower notwithstanding (17). Symptoms associated with UF also negatively impacts on the daily living of an individual and the quality of life. Symptoms such as heavy menses with menorrhagia, which is the most common, can result in life threatening anaemia (18). 10% of infertility has been associated with fibroids and pregnancy related complications such as spontaneous abortions and preterm deliveries (19).

Several other papers have reported an increased incidence of myomas in African ladies (12, 14, 15). Some evidence also shows that African females are more likely than Caucasian women to have more symptomatic and larger leiomyomas at the time of intervention (1, 15). After including other known risk factors and the body mass index (BMI), African ladies show a higher incidence and relative risk of leiomyomas than other racial and ethnic groups including Hispanic, Caucasian, and Asian ladies.

Hysterectomy has been thought to be the definitive treatment for symptomatic leiomyomas and remains the most frequent treatment for myomas. None the less there are several other treatment options. Treatment for fibroids should be tailored to the size, location of the tumours, patient age and desire to maintain fertility, symptoms, and access to treatment (20). The various options available include both medical and surgical therapy. None the less there is increased interest in less invasive interventions that avoid loss of the uterus. Interventional procedure such as UFE is one of these options. UFE is done by selective catheterization of the uterine arteries and blocking the peri fibroid plexi with embolic particles. The resultant effect is ischemia and infarction of the myomas. It is a different treatment to myomectomy or hysterectomy for many ladies afflicted by leiomyomas (21). Post procedure management must be well laid out because majority of clients will have moderate discomfort or pain for a couple

of hours post UFE. The discomfort is due to ischemia. Post embolization syndrome i.e., low-grade fever, fatigue, nausea, malaise loss of appetite is also experienced by patients and may necessitate readmission in 10% of patients (10).

Though UFE has been done for a long time in the treatment of symptomatic myomas in the first world (22, 23), it is a relatively new intervention choice for myomas in Kenya. Minimal local data exists on both the imaging and clinical results of this treatment option. J.K. Mutai in a study, Uterine Fibroid embolization for symptomatic fibroids: study at a teaching hospital in Kenya, showed UFE culminated in statistically significant reduction ( $P < 0.001$ ) of dominant myoma, uterine volumes, and reduction of symptom severity scores, which were 43.7%, 40.1%, and 37.8%, respectively (24).

C. Mariara in another study in Kenya, One year symptom severity and health related quality of life changes among black African patients undergoing UFE, showed a mean decrease in symptom severity score was 29.6 [95% CI 23.6 to 35.6,  $P < 0.001$ ] and the mean increase in health related quality of life (HRQOL) score was 35.7 [95% CI 28.4 to 42.9,  $P < 0.001$ ] (25).

Thomas J Kroencke et al showed that two years after UAE 50 % of patients with partial infarction and 80 % with almost complete infarction required no reintervention. Infarction was based on contrast enhanced MRI post UAE. There were significant differences between patients with partial and those with complete infarctions for persistence or recurrence of menorrhagia and bulk-related symptoms (26).

Complications of UFE though rare include infection, ovarian embolization leading to ovarian failure, permanent amenorrhea, passage of submucosal fibroids, uterine ischemia (10).

Anatomic variations of the Uterine Artery play a major role in the success of uterine embolization. It affects the ease of cannulating the uterine artery and the catheter selection.

There is a classification of the origin of the uterine artery: type I which is the most common and accounts for 45%, the origin of the uterine artery as a branch of the inferior gluteal artery, type II the uterine artery is part of a bifurcation with the inferior gluteal artery and occurs in 6%, type III the uterine artery arises from the internal iliac artery as a trifurcation, with the upper and lower gluteal artery. This is the second most common type and occurs in 43%. The last is type IV where the uterine artery arises proximal to the origin of the superior and inferior gluteal arteries. (27-31).

Trans radial arterial access (TRA) has been used for transcatheter coronary procedures for more than 25 years, with many studies showing better patient safety as compared with transfemoral arterial access. However, TRA remains underused by the interventional radiologists.

Trans radial access technique was started in the late 1980's by interventional cardiologists and was in response to risk of vascular and bleeding complications during percutaneous cardiac interventions. There are many advantages of TRA over trans-femoral arterial access (TFA).

Advantages of TRA over transfemoral arterial access include easier accomplishment of post procedure haemostasis, reduced risk of bleeding complications, shorter patient recovery leading to quicker ambulation and reduced hospital-related costs, and improved patient satisfaction.

The radial artery is a superficial compared to the femoral artery and has no surrounding critical structures that maybe injured during cannulation. Injury to the artery like dissection or thrombosis, is significantly less harmful to the patient because of the dual blood supply to the



hand (32). The radial artery is also easily compressible, which reduces the incidence of bleeding complications after most procedures (33). Haemostasis can be achieved without the introduction of a vascular closure device, which is common in many interventional suites that use TFA.

Following TRA, patients can sit up in bed, walk and ambulate immediately and are discharged home faster. In a randomized trial, Cooper et al demonstrated improved quality-of-life metrics, a strong patient preference, and decreased hospital costs for TRA over TFA during cardiac catheterization (34)

There is a reduced likelihood of vascular complications in TRA as compared to TFA though minor and major access site complications can still occur. There has therefore been a shift in the use of trans radial approach in majority of vascular intervention procedures.

### **2.1.2 Imaging of Uterine fibroids**

Radiologic imaging is extremely useful in diagnosis, management and follow up of myomas. Ultrasound is the tool of choice for imaging the female pelvis. Either trans abdominal or trans vaginal scans can be used. The trans vaginal scans are more sensitive in diagnosing small fibroids, but when the uterus is large then the trans abdominal scan is used. Ultrasound unfortunately very user dependent and may not be reproducible. CT scan is not used in investigating fibroids as it may not characterize the fibroids well and uses ionizing radiation. The favoured choice for characterizing accurately pelvic masses is Magnet Resonance Imaging (MRI). It does not use ionizing radiation and is not operator dependent like ultrasound and is easily reproducible. MRI is helpful in looking at the response to UFE. On T2W images fibroids are low signal compared to myometrium and iso intense on T1W images. They enhance on gadolinium scans, and this is used to assess suitability of embolization. On post UFE scans successfully embolized fibroids do not enhance on gadolinium scans.

### **2.1.3 Technical success rate and complications of trans radial access in UAE/UFE**

In a study conducted in USA that assessed the feasibility of use of uterine artery embolization (UAE) via trans radial access (TRA), among 29 cases, of which 26 had bleeding while 3 had bulk symptoms attributed to uterine fibroid tumours. The intervention was found to have 100% technical success rate. All the 29 UAE performed via left TRA was technically successful. with no complications reported. There were no cases of access site complication in all the cases and normal radial pulse was noted in all patients. All the patients were discharged on the same day the procedure was carried out with no overnight admissions. Besides, none of the patients required Foley catheterization. Post intervention and clinical evaluation at follow up of one month found normal left radial artery pulse. No further follow up imaging was done to assess cerebral infarction as the possibility of any risks was rated very low with no issues reported (8).

In another retrospective study that assessed the safety and efficacy of trans radial uterine fibroid embolization which was done via small calibre arterial access in USA settings targeting patients with RA calibres of 2 to 3 mm. Potency of RA was assessed post-operatively, at the time of discharge, and at 5-weeks based on the pulse rate palpation. The satisfaction of the patients at 5-weeks of follow up was also assessed. Of the 60 UFE procedures performed during the study period, technical success rate of 100% was reported. No major adverse events were reported while there were two cases of minor events including ecchymosis at the puncture site and intra-operative RA vasospasm. No other adverse events were found at 5 weeks of follow up. RA



remained patent at all assessment periods. Marked improvement in the patient's satisfaction and wellbeing was reported at 5 weeks of follow-up (35).

In the retrospective study conducted in a single centre in the Republic of Macedonia assessing the results of Uterine Fibroid Embolization via Trans radial compared to Transfemoral Arterial Access, 11 TRA and 13 TFA cases were compared. There was achievement of technical success in all the cases where TRA or TFA was used. The mean procedure time for TRA was lower (60.3 minutes) compared to mean procedure time for TFA (72.4 minutes). In addition, the mean fluoroscopy time was lower in TRA group (21.1 minutes) compared to 25.3 minutes in TFA group. No significant differences in adverse events were noted in the two approaches (3).

## CHAPTER THREE: METHODOLOGY

### 3.1 Study Area

The study was conducted at the gynaecology outpatient clinic, interventional radiology outpatient clinic and gynaecology inpatient wards in Kenyatta National Hospital and any patient undergoing UAE at the Karen Hospital. KNH is the biggest and oldest government, tertiary teaching, and referral hospital in Kenya, with a bed capacity of 2000. The hospital is located immediately West of the Upper Hill business hub in the capital city Nairobi. Approximately two patients undergo UFE at the two facilities weekly.

### 3.2 Study Design

This was a retrospective and prospective cross-sectional study. Cross-sectional design is where data on the outcome and exposures is collected at one instant in time.

### 3.3 Study Population and target population

The study population consisted of women with uterine fibroids undergoing UAE. Included in the study were women with uterine fibroids undergoing UAE at Kenyatta National Hospital and the Karen Hospital.

### 3.4 Eligibility criteria

#### 3.4.1 Inclusion Criteria

To enter the study each participant had to meet the following criteria:

- Have symptomatic or asymptomatic uterine fibroids.
- Have undergone trans radial access uterine fibroid embolization

#### 3.4.2 Exclusion Criteria

- Uterine artery embolization done for any other indication other than fibroids
- Clients on whom Trans femoral uterine fibroid embolization was done.

### 3.5 Sample Size and Sampling Methods

The sample size for the study was calculated using Cochran's formula:

$$n = \frac{z^2 pq}{d^2}$$

Where:

n = is the needed sample size

z = confidence interval at 95%, 1.96 according to the normal distribution table.

p = 0.5. (With no local studies, a prevalence of technical success rate of TRA UFE is assumed to be 50%).

q = 1 - p

d = error tolerated q, 0.05

$$n = \frac{z^2 pq}{d^2} = \frac{1.96^2 \times (0.5 \times 0.5)}{0.05^2} = 384$$

According to data at the two facilities, approximately 2 trans radial access UFA were conducted every month. With the study covering the period January 2019 to April 2022, approximately 56 UFE would have been conducted within the period. Hence, Cochran's correction formula for finite population was used to reduce the sample size proportionate to the total population (in cases where total population <50,000):  $n_1 = n/1+n/N$

$$: n_1 = 384 / (1 + 384/56) = 48.8$$

Hence a sample of 49 was needed in the study.

Considering the small number of such procedures within the 28 months study period, all the eligible participants were included in the study, hence a census sampling approach.

### 3.6 Data Collection

#### 3.6.1 Trans radial UFE procedure

For all participants, trans radial uterine artery embolization was performed at the interventional radiology suite at KNH or Karen Hospital. Embospheres of 700-900 and 500-700 micrometres were used. Any supplemental embolic was recorded.

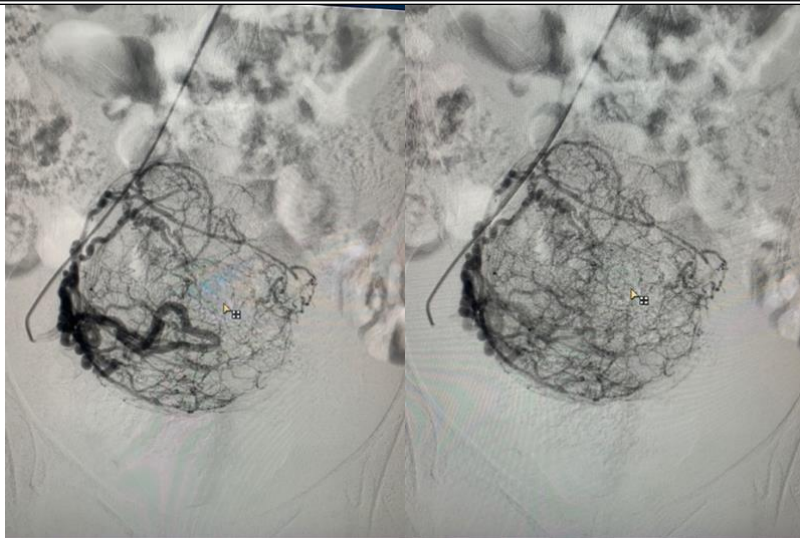
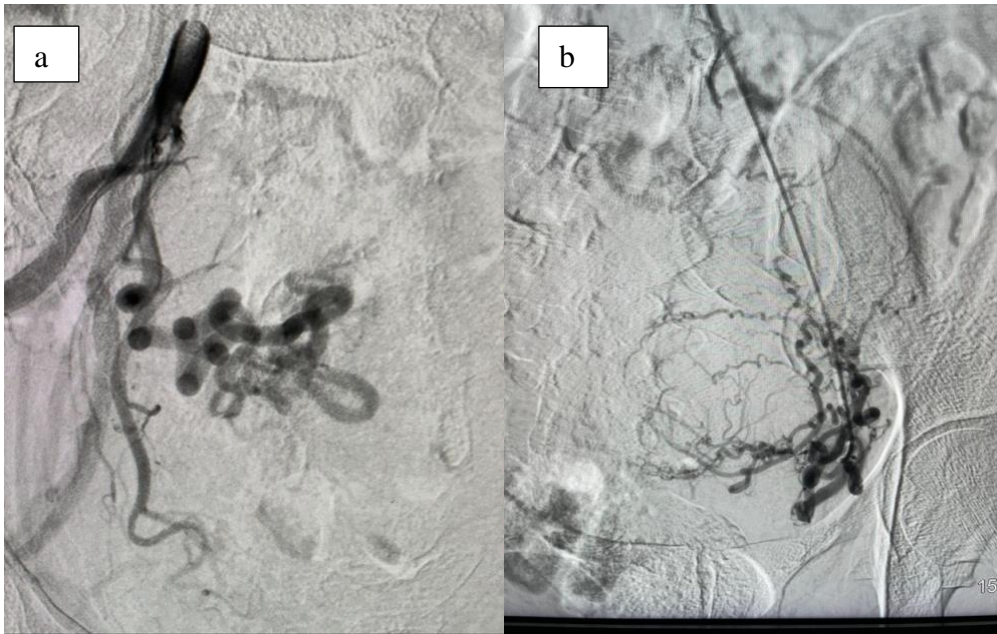
Equipment: Radial sheath kit of 5 or 4 French (Fr) was used. The kit includes an introducer needle, a nitinol guide wire 0.014, dilator and a vascular sheath. The catheters used for UFE will either be Bernstein or ultimate 5 or 4Fr, length of 125cm from Merit. If required a microcatheter 2.7Fr with a 0.018 hydrophilic guide wire was used for small uterine arteries. Angiographic machine: Both Kenyatta and Karen hospitals used Phillips angiographic machines. Ultrasound Machine: Philips at KNH and Sonoscape at Karen. High frequency linear transducer was used to interrogate the radial arteries.

Procedure: Patient was placed supine. Vitals (BP, pulse, SpO<sub>2</sub>) were monitored. Regional ultrasound of the left radial artery was done to assess its diameter to select size of the catheter. The left forearm and wrist were cleaned using povidone iodine then draped with sterile drapes leaving the palmar aspect of the wrist exposed. Local anaesthesia (2% lidocaine) mixed with 1ml (100mcg) of Nitro-glycerine was injected above and around the radial artery. Under ultrasound guidance the introducer needle was used to gain access to the radial artery and guide wire inserted. The needle was removed and over the guide wire the radial sheath with preloaded dilator was inserted. Guide wire was removed and antispasmodic cocktail of nitro-glycerine 200µg, verapamil 2.5mg and heparin 2000 units injected through the radial sheath after flushing in with normal saline. Once the catheter size had been decided, either the Bernstein or ultimate, the catheter was used over a hydrophilic guide wire 150cm. Under fluoroscopic guidance the catheter over the guide wire was tracked down the aorta then into each common

iliac artery successively and the internal iliac artery was selectively catheterized. An angiographic run was done at this point to study the uterine anatomy (Image 2a). The uterine artery was then cannulated (Image 2b) and embolised using Embospheres to near stasis. Embolization was deemed successful when both uterine arteries were closed. Haemostasis was achieved at the puncture site by 30min compression using a preludeSYNC compression device from Merit.

Patients were monitored after the procedure in the post op area for an hour before being transferred to the ward. In the ward, they were given intravenous analgesic consisting of paracetamol 1g 4-6 hourly and tramadol 100mg 12hourly with metochlopromide 10mg. They were discharged from the ward 6hours after the procedure.

Image 2: Internal iliac angiogram showing the anterior division branches (Right). Selective catheterization of the left uterine artery(left).



**Image 3: Selective catheterization of the right uterine artery showing a solitary fibroid**

### 3.6.2 Data collection procedure

Files and medical records of all the patients who underwent UFE at the two facilities over the 28 months study period were retrieved from GOPC or IRC at Kenyatta National hospital and at Karen Hospital and those who underwent trans radial access UFE selected. The process of retrieving these files was done by the principal investigator. The required data was extracted from the files/medical records into the hard copy data extraction form by the principal investigator. Angiographic images of the UFE procedure were analysed by the principal investigator in assessing technical success. The reporting standards of the Society of

Interventional Radiology (SIR) for uterine artery embolization for the treatment of uterine leiomyomata and the SIR complications classification (36) was applied.

### **3.6.3 Study tools**

A pre-prepared data extraction form was used to gather data from the patients' files/medical records. Information collected included the age of the patient, parity, last menstrual period, symptomatology – bleeding, cramps, bloating, pelvic fullness, urinary tract symptoms, MRI – fibroids, Haemoglobin level, INR, working diagnosis and management undertaken.

Data on the trans radial access UFE was also gathered including, technical outcome of uterine fibroid embolization, minor and major complications related to uterine artery embolization and those related to access i.e., using trans radial approach and any complication management procedure instituted.

### **3.7 Study Variables**

The study variables included prior use of medical management in treatment of the fibroids, haemoglobin level, INR, symptoms, embolization complications and their treatment, imaging done, trans radial access site complications and their treatment, procedure success rate and duration of hospitalisation.

### **3.8 Data Analysis & Management**

#### **3.8.1 Data management**

The data obtained from the patients' records was entered manually into pre-prepared data extraction form. The data was entered into Epi Info software where it was cleaned and coded and any missing data sought from the files. The hardcopies were stored in a lockable file cabinet while the soft copies were entered into a password protected laptop.

#### **3.8.2 Data analysis**

The data was imported into Statistical Package for Social Sciences (SPSS) version 27.0 for analysis. Descriptive statistics was used for the analysis. Frequencies and percentages were used to analyse categorical variable data such as complications, management outcomes and symptoms. For continuous variables such as haemoglobin level, and age, mean and standard deviation were used. The results are presented in form of tables, figures, radiographic images, and prose format.

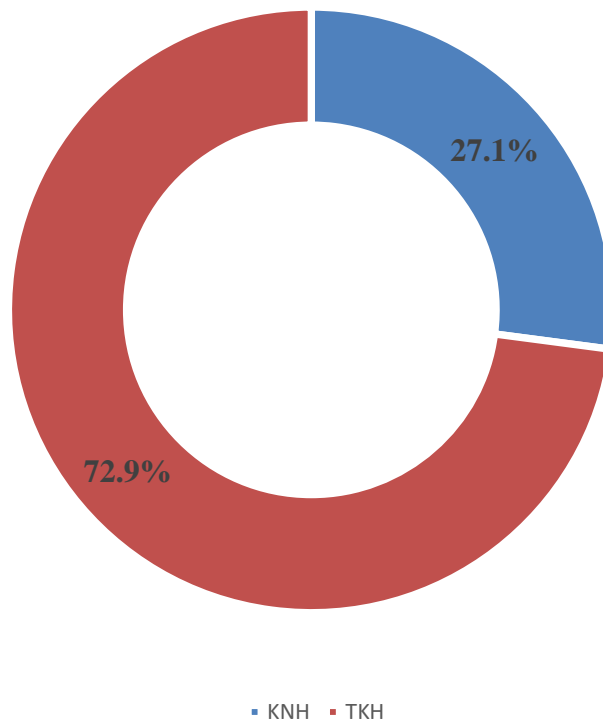
### **3.9 Ethical Considerations**

Ethical review and approval for the study, including informed consent waiver were granted by the Kenyatta National Hospital-University of Nairobi Ethics, Research and Standards Committee. Strict confidentiality was observed in the entire study period, kept in trust by participating research staff, investigators, and the study institutions. The study participants were assigned unique study identification numbers with no personal identification data taken. All study materials are kept under lock and key with only specific study personnel who have signed confidentiality agreement forms allowed access to the study materials.

## CHAPTER FOUR: RESULTS

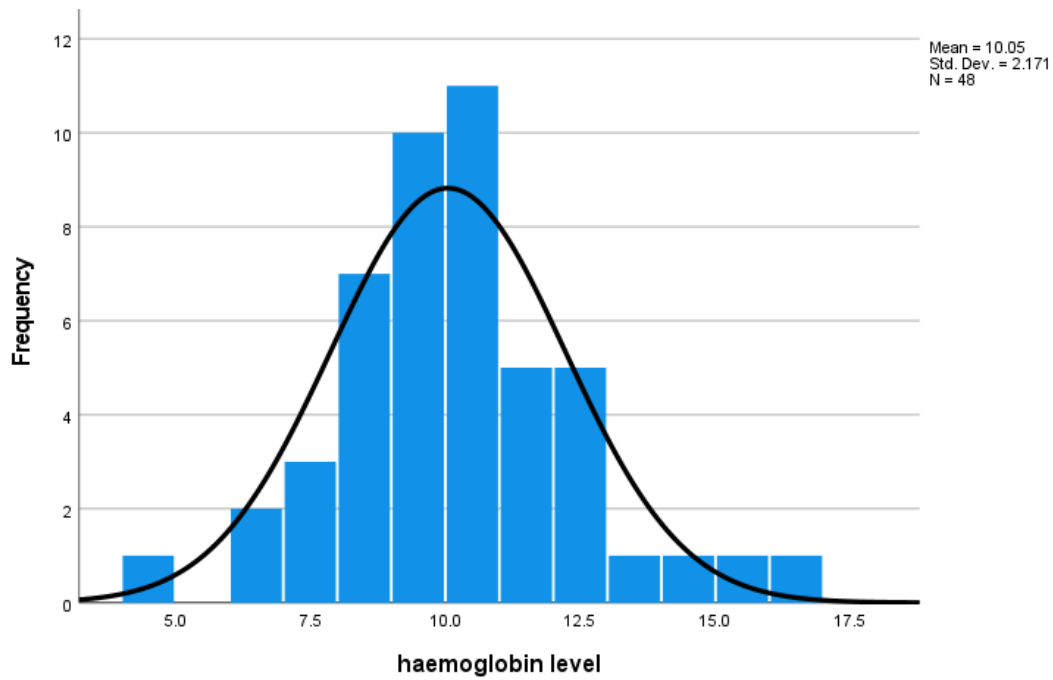
### 4.1 Patient characteristics

A total of 48 patients underwent UAE at the two facilities, 35 (72.9%) at the Karen Hospital and 13 (27.1%) at Kenyatta National Hospital. (Figure 1)

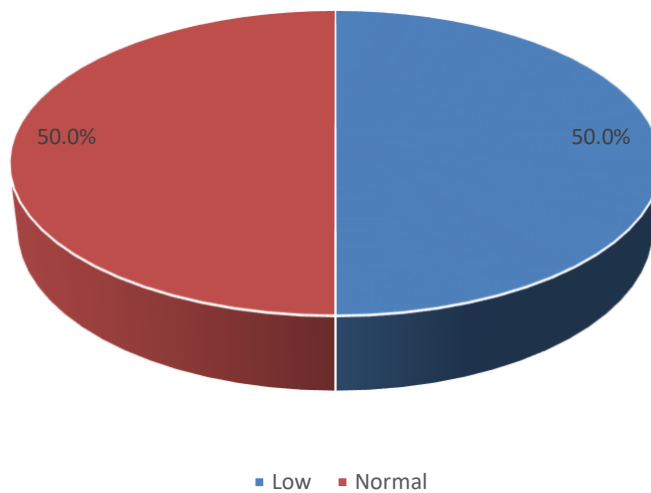


**Figure 1: Facility**

The mean age of the patients was 43.3 (SD= 6.8) years. The mean INR and haemoglobin levels were 1.2 (SD=0.2) and 10.1 (SD=2.2), respectively. Half, 24 (50.0%), had low haemoglobin levels. (Figure 3)



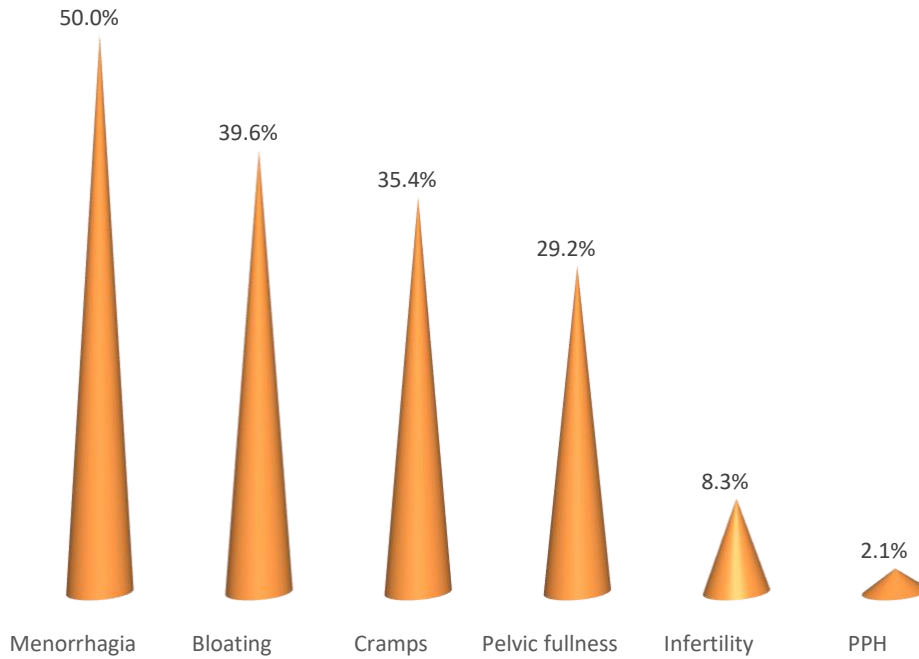
**Figure 2: Distribution of haemoglobin levels among the patients**



**Figure 3: Haemoglobin levels**

With regards to the symptoms among the patients, 24 (50.0%) had menorrhagia, 19 (39.6%) had bloating, 17 (35.4%) cramps, 14 (29.2%) pelvic fullness, 4 (8.3%) had infertility while 1 (2.1%) had PPH. (Figure 4).





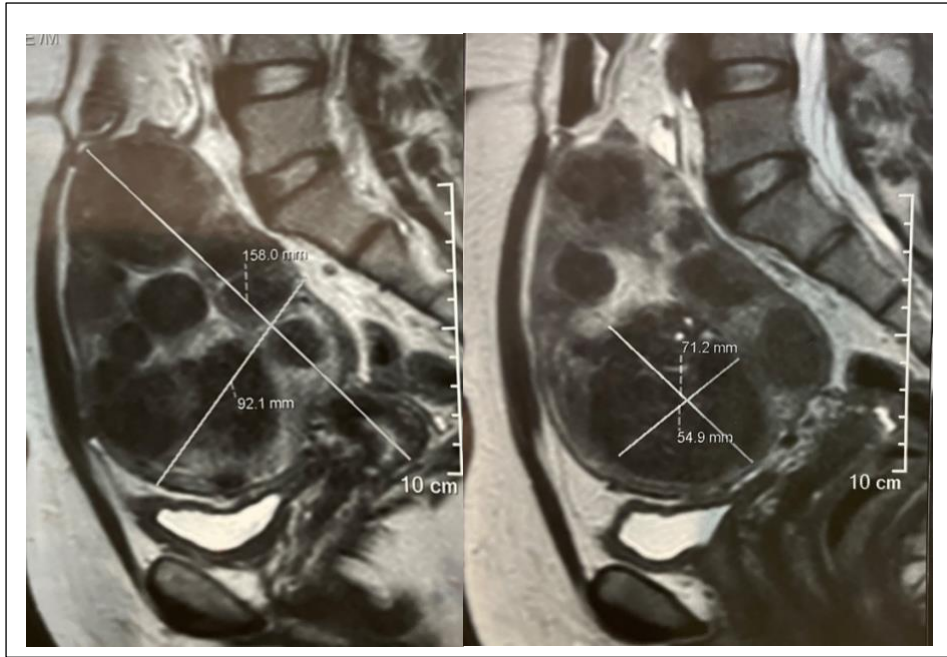
**Figure 4: Symptoms**

#### 4.2 Treatment and technical success rates

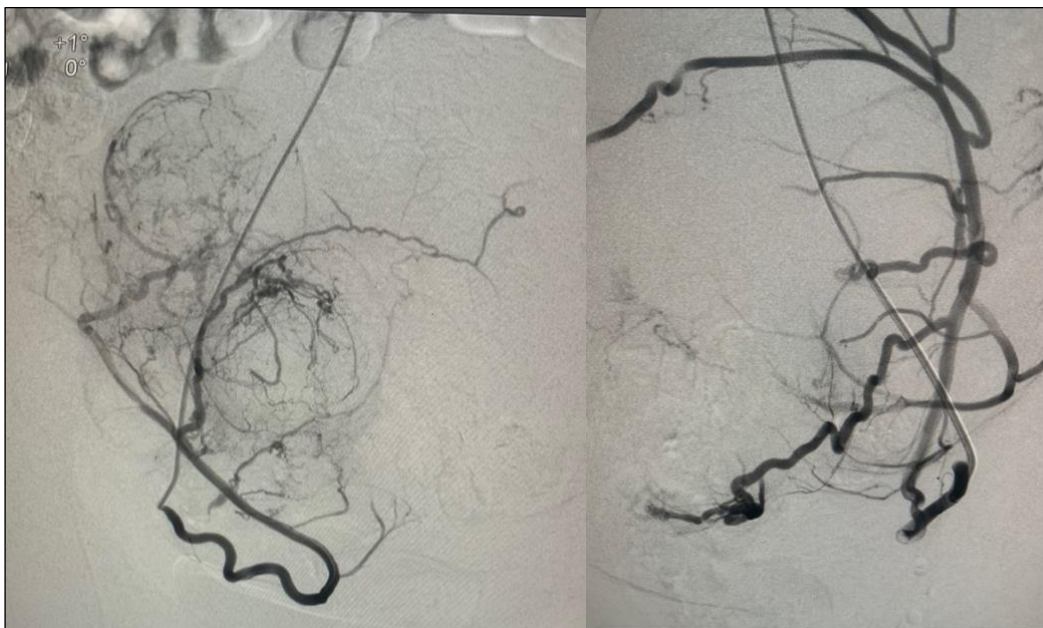
Only 5 (10.4%) had received prior treatment for the condition (myomectomy). MRI was done in 39 (81.3%), while ultrasound was done in 9 (18.8%). The mean number of fibroids was 5.4 (SD=2.8). Most, 26 (54.1%) had 1-5 fibroids (Image 4 and Image 6), 20 (41.7%) had 6-10 fibroids while 2 (4.2%) had between 11-15 fibroids (Image 5 and Image 7). The procedure was successful in all 48 patients.



**Image 4: Sagittal MRI showing two fibroids**



**Image 5: Sagittal MRI showing multiple fibroids and a bulky uterus**

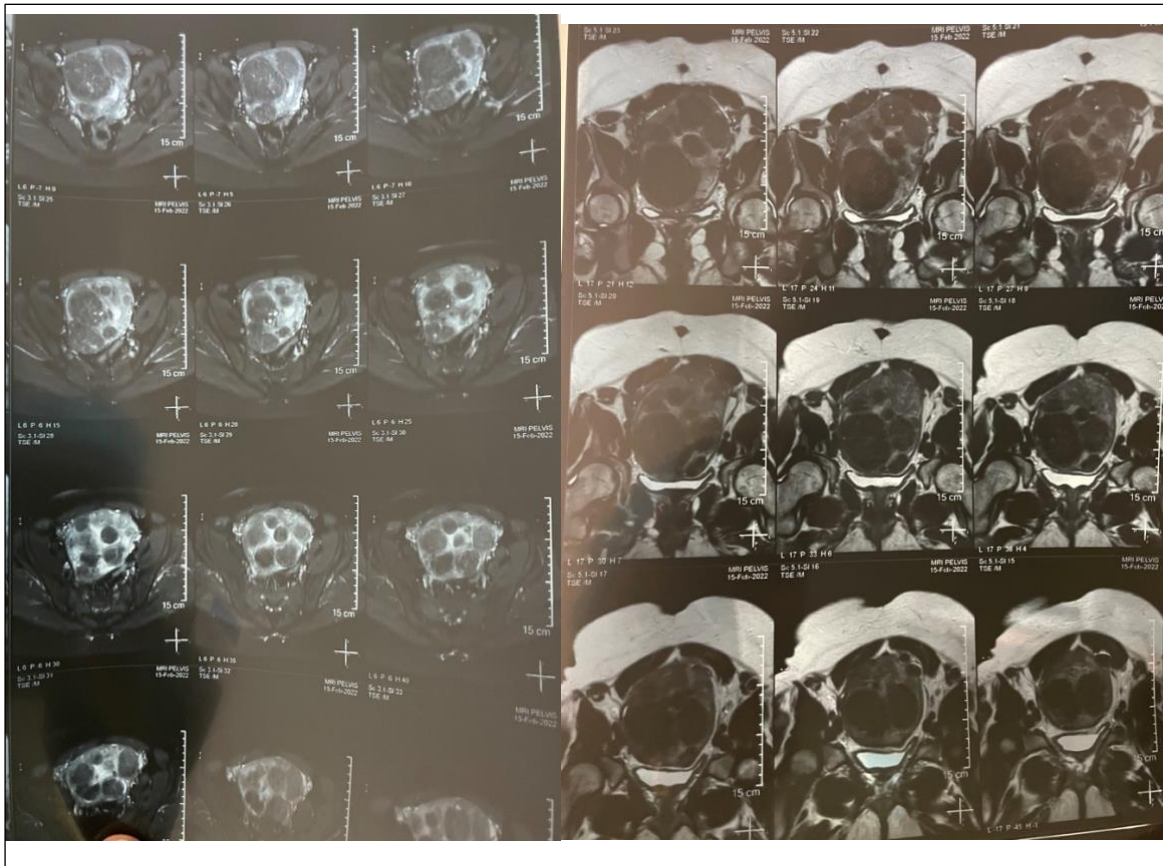


**Image 6: Bilateral uterine artery angiograms showing multiple fibroids on the left**

**Table 1: Imaging and treatment**

<b>Imaging and treatment</b>	<b>Frequency (n)</b>	<b>Percent (%)</b>
<b>Prior treatment</b>		
Yes	5	10.4
No	43	89.6
<b>Imaging</b>		
MRI	39	81.3
Ultrasound	9	18.8

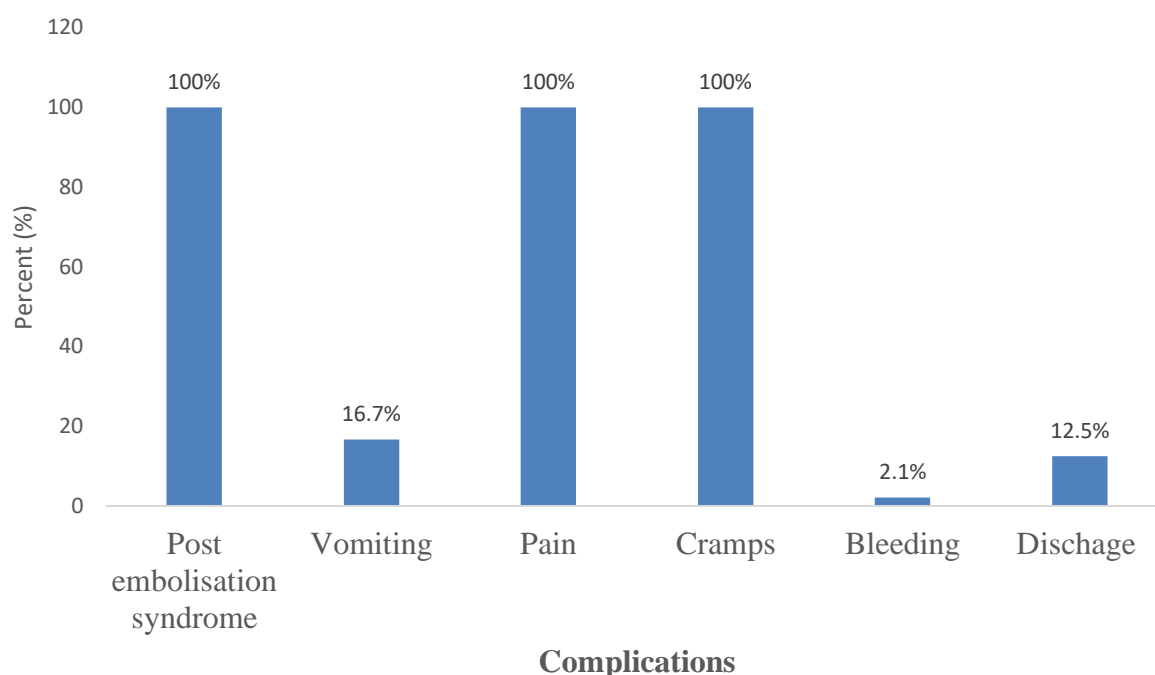
<b>No of fibroids</b>		
1-5	26	54.1
6-10	20	41.7
11-15	2	4.2
<b>Success rate</b>		
Successful	48	100.0



**Image 7: Axial MRI with contrast and T2W axial MRI showing multiple fibroids**

### **4.3 Complications associated with TRA UFE and their management**

The patients had several complications, including post embolization syndrome, which consists of one or more of the following symptoms (nausea, fever, headache, and malaise), pain and cramps in all the 48 patients, vomiting in 8 (16.7%), discharge in 6 (12.5%) and bleeding in 1 (2.1%).



**Figure 5: post-procedure complications**

After embolization, the following treatment was given to manage complications.

**Table 2: Treatment post embolization**

Treatment post embolization	Frequency (n)	Percent (%)
Analgesics, buscopan	40	100
Hematinic	2	4.2
Transfusion	1	2.1
Dilation and curettage	2	4.2

From the trans-radial approach, access site complications included hematoma (3; 6.3%), pain (2;4.2%) and bleeding from the puncture site (1; 2.1%).

**Table 3: Trans radial approach complications and their management**

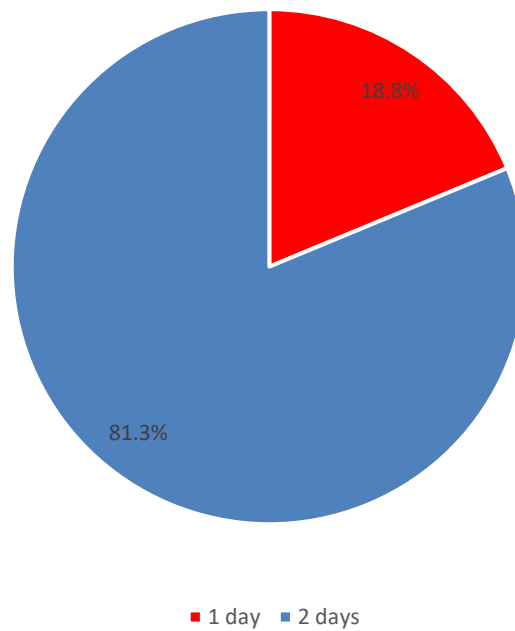
Access site complications and their management	Frequency (n)	Percent (%)
<b>Access site complications</b>		
Hematoma	3	6.3
Bleeding from the puncture site	1	2.1
Pain	2	4.2
None	42	87.5
<b>Treatment for access site complications</b>		
Analgesics	1	

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Pressure applied	1
Re-assured	3

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After the procedure, all the patients were discharged after monitoring. However, 39 (81.3%) spent two days in the hospital, choosing to go home on the second day after the procedure, while 9 (18.8%) were left on the same day.



**Figure 6: Duration of hospitalization**



## CHAPTER FIVE: DISCUSSION

### 5.1 Summary of findings

This study is among the first to evaluate the technical success rate of embolization in patients undergoing TRA UFE in Kenya. From the study, most of the patients (72.9%) underwent the procedure at a private hospital (TKH). Half had a low level of haemoglobin. The common symptoms among the patients included menorrhagia (50.0%), bloating (39.6%), cramps (35.4%) and pelvic fullness (29.2%). Only 5 (10.4%) had myomectomy performed as prior treatment for the fibroids. There was a 100% technical success rate for the TRA UFE. The most common post-procedure complication was pain and cramping, seen in all participants (100%). All the patients had some form of post embolization syndrome after the procedure. Access site complications included hematoma (3; 6.3%), pain (2; 4.2%) and bleeding from the puncture site (1; 2.1%). After the procedure, all the patients were discharged after monitoring. However, 39 (81.3%) spent two days in the hospital, choosing to go home on the second day after the procedure, while 9 (18.8%) left on the same day.

### 5.2 Patient characteristics

The majority of the TRA UFE procedures in the study (72.9%) were conducted at a private health facility (TKH). This indicates the low utilization of the procedure in the public health facilities in Kenya. Besides, it might be due to the limited capacity to carry out the procedure locally in public health facilities, frequent machine downtime, stock outs, and the high costs involved, which are prohibitive to most patients seeking services in the Kenyan public health facilities.

Most of the patients were of middle age, above 40 years, with a mean age of 43 years. This was in line with findings from a previous study in India which found the majority (46%) of those with UF undergoing UFE to be between 40-45 years (37), and another in Chinese women whose mean age was 42.9 years (SD=3.9 years) (38). This is a likely reflection of the population burdened by UF, which has been shown in the literature to be of middle age, considering age is a crucial risk factor for fibroids development. The condition is highly prevalent in the middle age to elderly, with the incidence of those pathologically diagnosed with the condition increasing with age and peaking at 50 years (39). By age 30, fibroids incidence was found to be 60% in African American population, increasing to more than 80% by age 50 (40). Besides, uterine fibroids hospitalization rates have increased with age, peaking at age 45-49 with 62.7 per 10,000 women (41). Hence, the number and incidence of fibroids increase with advancing age (15).

Half of the patients had anaemia. Uterine fibroids result in heavy loss of blood, resulting in reduced haemoglobin levels. Heavy and sometimes prolonged bleeding is a common symptom associated with uterine fibroids (42), leading to anaemia, as found in this study. Such was the case among the patients in this study, where menorrhagia was the most common symptom. Pelvic pain and infertility are also other symptoms of uterine fibroids (43), observed in 20-50% of these patients (44).

In concurrence with this study, a study conducted in Islamabad, Pakistan, found heavy menstrual bleeding and pelvic pain, menorrhagia alone and pain to be common symptoms in the patients with Uterine fibroid who underwent UFE (45). Such was the case in Slovakia, where menorrhagia in 78.8% of the patients and secondary and primary fertility were key symptoms and indications for UFE (46). In the study conducted on Chinese women, most

(82%) had menorrhagia. Others included pelvic pain, dysmenorrhea, and abdominal mass (38). Such symptoms can play a key role in identifying patients at risk for fibroids needing further investigation to diagnose fibroids.

### 5.3 The technical success rate of trans-radial UFE

The uterine artery embolization procedure has mainly been done via the common femoral artery access. Over the last two decades, TRA use for coronary interventions has significantly increased, driven by growing evidence that supports TRA use over TFA to conduct percutaneous coronary intervention (PCI). The TRA approach has been associated with comfort, early ambulation, lower costs, and fewer access site complications. However, TRA is a relatively new approach in intervention radiology despite being predominantly used in interventional cardiology over the last decade. The few recent studies on the utilisation of TRA in UFE have shown it to be highly successful and safe with good feedback from patients ((3).

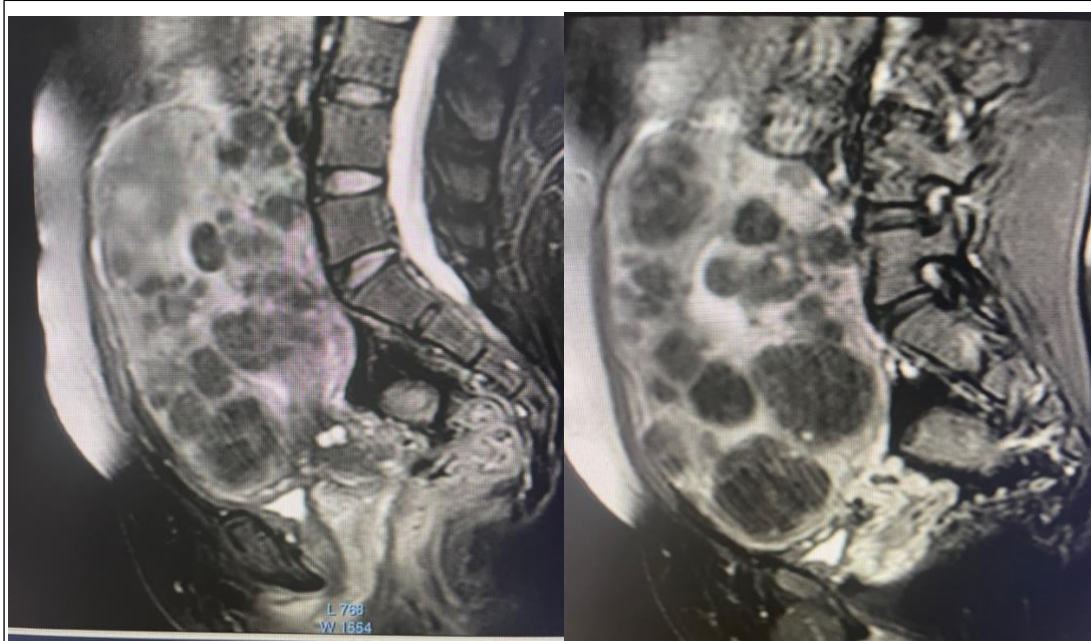
Despite the few available studies assessing the UFA success rate using the TRA approach, it is evident that high success rate cuts across the different settings where it was applied. As was the case in this study, a previous study in the USA among 29 cases reported a 100% technical success rate for UAE TRA (7). Another study in the USA consisting of 60 UFE procedures reported a technical success rate of 100% (34). A similar technical success rate was also reported in the retrospective study conducted in a single centre in the Republic of Macedonia, assessing the results of Uterine Fibroid Embolization via Trans radial compared to Transfemoral Arterial Access, where all 11 TRA and 13 TFA cases were compared. There was the achievement of technical success in all the cases where TRA or TFA was used (3). Regardless of the small sample sizes associated with these studies, the high success rate cannot be by chance, and we expect the same trend to be observed in the longer term in future studies involving large sample sizes.

### 5.4 Complications associated with TRA UFE

Pain and cramping are the immediate complications of embolization. This begins as soon as the embolic is injected and the uterine artery is closed. Though all participants were premedicated with analgesics, they still suffered from severe cramping in the first 12 hours and started subsiding after 24hr of the procedure with the use of intravenous analgesics. As was the case in this study, a study in India among women who had undergone UFE found pain in the abdomen to be the most common symptom seen in 74% (37). Similarly, in the study by Jawad and colleagues, all patients who underwent UFE experienced varying levels of post-procedure pain, which was managed using opioids and oral medication post-discharge (45). It is evident that pain is a common post-procedure complication in patients who undergo UFE. This makes it essential to provide analgesia. This pain has been associated with fibroid necroses which are common post-procedure (47, 48). In several patients, the experienced ischaemic pain makes it essential to offer opioid analgesia for up to 4 days post-procedure (49)

All the patients had some form of post embolization syndrome after the procedure. This included one or more of the following symptoms headache, fever, and general malaise. However, the fever was subjectively reported by patients as the majority did not have access to a thermometer with them. Fever was also a common occurrence in the patient's post-procedure, as highlighted previously (37, 38). Fever has also been found to be a common post-procedure in a systematic review looking at complications associated with UFE conducted by Martin and colleagues (50).

Only one patient reported vaginal bleeding post embolization, which resulted from her menses. 6 patients reported a vaginal discharge consisting of brown fluid or altered blood. Two patients had a foul-smelling discharge necessitating dilatation and curettage. These two patients had submucosal fibroids that may have undergone necrosis and caused the discharge (**Image 8**).



**Image 8: Sagittal MRI scans showing submucosal fibroids**

A rare complication in patients who have undergone UFE is death. In this study, no mortality case was reported. However, other studies have reported such procedures as in India, where 5 (2.6%) death cases were reported post-procedure (37). However, similar to this study's findings, most earlier studies did not report any cases of mortality post-procedure. (50). Other rare complications in patients who have undergone UFE include septicaemia (0.009 %), Asherman syndrome (0.018 %), and cardiopulmonary arrest or resuscitation (0.045 %). However, none of these was observed in our study (50). It is essential to note that the small sample size in this study and most previous studies make it challenging to determine the true complications and risks due to such a procedure.

Failure of embolization occurs when fibroids are found to be still viable and are enhancing on MRI done during routine follow up. Failure may also be seen as persistence of symptoms like menorrhagia and associated cramping even after embolization. While a review of randomising clinical trials found a 4% failure rate in UFE, no failure was found in our study (50). However, the review generally found a low likelihood of significant complications with UFE (50), backing our findings, indicating high safety levels of the procedure. In the review, there was a ten times increase in the risk of re-intervention in the patients who underwent UFE (50). However, the likelihood of this occurring in our setting remains unclear due to the short follow up period. Studies with long term follow up of these patients are needed locally to understand the likelihood of the need for re-intervention in our settings.

One key advantage of the TRA approach in the UAE is patients' comfort after the procedure and minimal or no complications. Besides, patients can move freely in bed without the



restriction of flexing the hip, as seen in TFA. Similar to the findings of this study, few or no complications have been associated with the TRA approach in previous studies. In the study conducted in the USA involving 29 cases, no complications were found. There were no access site complications in all the cases, and normal radial pulse was noted in all patients. All the patients were discharged on the same day the procedure was carried out with no overnight admissions. Post-intervention and clinical evaluation at one-month follow-up found normal left radial artery pulse. No further follow up imaging was done to assess cerebral infarction as the possibility of any risks was rated very low with no issues reported (8). In another USA study involving 60 cases, no major adverse events were reported, while there were two cases of minor events, including ecchymosis at the puncture site and intra-operative RA vasospasm. No other adverse events were found at five weeks of follow up. RA remained patent at all assessment periods. Marked improvement in the patient's satisfaction and wellbeing was reported at five weeks of follow-up (35).

The TRA approach had been demonstrated to be preferred by patients, being associated with improved quality of life and reduced hospitalisation costs in cardiac catheterization (33). While this was not assessed in this study, we believe that such advantages also apply to patients undergoing UAE. The patients were discharged on the same day as reported in similar studies in other settings, being highlighted as another advantage of TRA over TFA (3). Hence the procedure can be performed as an outpatient without patient hospitalization.

## **CHAPTER SIX: CONCLUSION AND RECOMMENDATION**

### **6.1 Conclusion**

The study assessed the technical success rate and complications associated with TRA UFE. From the study findings, it is evident that uterine artery embolization is a viable and successful treatment option for fibroids with few complications. TRA is a successful approach with few complications, as previously highlighted in studies conducted in other settings. However, UFE is associated with considerable analgesic requirements. From the study experience, UFE promises to provide a keyless invasive alternative treatment of uterine fibroids, while the TRA approach is a highly promising option for UFE procedures associated with same-day hospital discharge. Subject to further effectiveness studies, the approach shows indication of being highly effective, feasible and safe. However, providers must educate patients about the likely complications and the potential for reintervention, which helps the patients and the service provider come to a reasonable decision on whether to go for the UFE.

### **6.2 Recommendations**

Further studies with larger numbers of patients with follow-ups on longer intervals are necessary to provide statistically significant evidence to inform TRA use.

Randomised trials are needed to determine the effectiveness and clinical benefits of TRA compared to existing approaches such as TFA. Besides, cost-effectiveness analysis needs to present an economic case for its adoption instead of the other used approaches.

### **6.3 Limitations of the study**

The study was retrospective; hence the researcher had minimal control over the data quality. The study was only conducted in two facilities hence not representative of the practice in the country, considering practices at other facilities not included in the study where the procedure is conducted. Considering the few cases due to the limited number of procedures conducted, the sample size was small, affecting the study power and inference.

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## APPENDICES

### Appendix I: Data Collection Tool

<b>PARTICIPANT IDENTIFICATION NUMBER (PIN)</b>			
<b>DATE (dd/mm/yyyy)</b>			
<b>SECTION I: PATIENT DETAILS</b>			
<b>INITIALS</b>		<b>DATE OF ADMISSION (dd/mm/yy)</b>	
<b>LAST MENSTRUAL PERIOD (dd/mm/yy)</b>		<b>AGE (years)</b>	
<b>Any prior treatment</b>		<b>YES [ ] NO [ ]</b>	
<b>SECTION II: PRE EMBOLIZATION</b>			
<b>INR</b>		<b>Haemoglobin (g/dL)</b>	

<b>SECTION III: IMAGING</b>	
<b>ULTRASOUND SCAN</b>	
<b>PELVIC MRI</b>	
<b>NUMBER OF FIBROIDS</b>	
<b>SECTION IV: POST EMBOLIZATION IMAGING</b>	
<b>OUTCOME</b>	
<b>COMPLICATIONS FROM EMBOLISATION</b>	<b>Pain Cramps Vomiting Nausea Fever Headache Malaise Others:</b>
<b>COMPLICATIONS FROM TRANS RADIAL APPROACH</b>	<b>Pain Hematoma Active bleeding from puncture site</b>



	<b>Numbness</b> <b>Tingling sensation in the thumb/index finger</b> <b>Others:</b>
<b>Treatment:</b>	
<b>Remarks</b>	
<b>Date of discharge:</b>	

## Appendix II: KNH/UON ERC approval letter



UNIVERSITY OF NAIROBI  
FACULTY OF HEALTH SCIENCES  
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Telegrams: varsity  
Tel:(254-020) 2726300 Ext 44355

**KNH-UON ERC**  
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Website: <http://www.erc.uonbi.ac.ke>  
Facebook: <https://www.facebook.com/uonknh.erc>  
Twitter: @UONKNH\_ERC [https://twitter.com/UONKNH\\_ERC](https://twitter.com/UONKNH_ERC)



**KENYATTA NATIONAL HOSPITAL**  
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Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/60

Dr. Jasper Muruka  
Reg. No. H117/38308/2020  
Fellowship in Interventional Radiology  
Dept. of Diagnostic Imaging and Radiation Medicine  
Faculty of Health Sciences  
University of Nairobi

22<sup>nd</sup> February, 2022



Dear Dr. Muruka,

**RESEARCH PROPOSAL: OUTCOME OF TRANSRADIAL UTERINE ARTERY FIBROID EMBOLISATION; A KENYAN EXPERIENCE (P748/09/2021)**

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P748/09/2021**. The approval period is 22<sup>nd</sup> February 2022 – 21<sup>st</sup> February 2023.

This approval is subject to compliance with the following requirements;

- i. Only approved documents including (informed consents, study instruments, MTA) will be used.
- ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
- iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
- iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
- v. Clearance for export of biological specimens must be obtained from relevant institutions.
- vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
- vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Protect to discover

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) <https://research-portal.nacosti.go.ke> and also obtain other clearances needed.

Yours sincerely,





**DR. BEATRICE K.M. AMUGUNE**  
**SECRETARY, KNH-UoN ERC**

- c.c.    The Dean, Faculty of Health Sciences, UoN  
          The Senior Director, CS, KNH  
          The Chairperson, KNH- UoN ERC  
          The Assistant Director, Health Information, KNH  
          The Chair, Dept. of Diagnostic Imaging and Radiation Medicine, UoN  
Supervisors: Dr. Peter Magabe Chacha, Dept. of Diagnostic Imaging and Radiation Medicine, UoN  
               Dr. Mugambi Lawrence, Consultant Interventional Radiologist, Radiology Department, KNH

Protect to discover


### Appendix III: research license from National Commission for Science, Technology and Innovation (NACOSTI)

  
**REPUBLIC OF KENYA**

  
**NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY & INNOVATION**

Ref No: **288805** Date of Issue: **29/March/2022**


**RESEARCH LICENSE**




**This is to Certify that Dr.. Jasper Simeon Muruka of University of Nairobi, has been licensed to conduct research in Nairobi on the topic: Outcome of Transradial uterine artery fibroid embolisation; A Kenyan experience for the period ending : 29/March/2023.**

License No: **NACOSTI/P/22/16626**

**288805**  
Applicant Identification Number

  
Director General  
**NATIONAL COMMISSION FOR SCIENCE, TECHNOLOGY & INNOVATION**

Verification QR Code



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