TUBAL RECANALIZATION SUCCESS RATE AND COMPLICATIONS OF FLUOROSCOPY GUIDED TRANSCERVICAL FALLOPIAN TUBE CATHETERIZATION IN TREATMENT OF PROXIMAL TUBAL OBSTRUCTION

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I, **Dr. Violet Wangui Kabute**, do declare that the work contained herein is my original work and has not been presented at any other university or institution of higher learning to the best of my knowledge.

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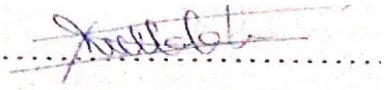
Signature:  1st September 2023

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DECLARATION

To my beloved husband and best friend, Dr. Njoroge Murigi for being the wind beneath my wings and my greatest supporter.

To my daughters Mbula and Mwihaki. May you always dream big.

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS AND ACRONYMS

ART	Assisted reproductive technique.
CT	Computerized tomography
FT	Fallopian tube(s)
FTC	Fallopian tube catheterization
FTR	Fallopian tube recanalization
HSG	Hysterosalpingography
HyCoSy	Hysterosalpingo-contrast sonography
IVF	In-vitro fertilization
KNH	Kenyatta National Hospital
MRI	Magnetic Resonance Imaging
NICE	National Institute for Health and Care Excellence
NSAID	Non- Steroidal anti-inflammatory drugs
PACS	Picture-archive and communications systems
PID	Pelvic Inflammatory disease
PTO	Proximal tubal obstruction
PV	Per vaginal
SIS	Saline infusion sonography
T-FTC	Trans-cervical fallopian tube catheterization
UON	University of Nairobi
US	Ultrasound

OPERATIONAL DEFINITIONS

Selective Salpingography: Is a diagnostic procedure carried out under fluoroscopic image guidance in which the fallopian tube is directly opacified after injection of radio-opaque contrast medium through a catheter placed at the tubal ostium. It has been used to distinguish tubal spasm from true obstruction and to clarify equivocal findings from other tests.

In fallopian tube catheterization: A coaxial system (including a catheter and guide wire) is used to clear proximal tubal obstructions. The recanalization procedure is simple for interventional radiologists to perform under fluoroscopic image guidance and is successfully completed in most patients. It is performed after pre-procedure HSG as an alternative treatment of tubal blockage.

Hysterosalpingography (HSG): Refers to the radiographic evaluation of the uterine cavity and fallopian tubes after injection of a radio-opaque medium through the cervical canal. It is commonly used in the investigation of infertility or recurrent abortions. Fluoroscopy with image intensification is performed to improve the quality of the radiographic images as well as help guide the procedure.

Infertility: Is the inability to conceive after at least 12 months of regular unprotected intercourse.

In-vitro fertilization (IVF): Is a form of assisted reproductive technique (ART) used to help a woman with infertility become pregnant. It is a medical procedure in which mature ova are removed from a woman, fertilized with male sperm outside the body (in-vitro) and inserted into the uterus of the same or (not of) another woman for a normal gestation.

ABSTRACT

Background: Infertility is a relatively common condition with crucial medical and socioeconomic implications, and it affects 10 to 15% of couples worldwide in the reproductive age group. A third of the cases of infertility in women are of tubal origin, with 20% of these attributed to isolated proximal tubal obstruction (PTO). The unique anatomy of the proximal fallopian tube is relevant in preventing vaginal bacteria from gaining access to the peritoneum but also predisposes it to obstruction. Fluoroscopy-guided transcervical selective salpingography and fallopian tube recanalization by use of a coaxial system of guidewires and catheters has been universally accepted as an alternative treatment for this condition. Despite its good technical success rates, confirmed feasibility and safety it has been slow to become adopted since the advent of assisted reproductive techniques (ART) such as in vitro fertilization (IVF).

Study Objective: To evaluate the tubal recanalization success rate and complications of fluoroscopic trans-cervical fallopian tube catheterization (FTC) in patients with proximal tubal obstruction.

Materials and Methods: A cross-sectional study was carried out at the interventional radiology suites of Kenyatta National Hospital and The Karen Hospital in Nairobi, Kenya from July 2020 to October 2021. Female patients in the reproductive age group with documented tubal infertility referred for FTC who fulfilled the inclusion criteria were enrolled into the study. A structured data collection tool was used to document demographic data, clinical and imaging findings of the study participants. The proportion of patients who had PTO on pre-procedure HSG, subsequently underwent fluoroscopic T-FTC and the tubal recanalization success rate and complications of the procedure determined. Data was analyzed using SPSS version 23 and Microsoft Excel and represented in tables and charts. HSG and FTC findings were presented as proportions with 95% confidence intervals and further association with other patient characteristics will be tested using Fischer's exact test of associations. Significance was defined as $p< 0.05$.

Results: A total of 37 participants were recruited into the study. Their ages ranged from 24 years and 47 years. The mean age was 34.3years and the median age was 35 years. 7 patients (18.9%) had primary infertility while 30 patients (81.1%) had secondary infertility. We successfully recanalized 46 of the 56 proximal fallopian tube obstructions with guidewire and catheter at a technical success rate of 82%. There was statistically significant association between uterine cavity abnormalities with cannulation success with a p value of 0.021.

Conclusion: In our experience, fluoroscopy guided T-FTC is a safe treatment option in appropriately selected patients with infertility from PTO, associated with high technical success rate at relatively low cost and morbidity. We established an association between acquired uterine cavity abnormalities seen on HSG and the success rate of T-FTC, which can be subjected to larger study evaluations. It therefore merits to be recommended for patients with PTO, prior to more invasive and costly treatments.

1.0 CHAPTER ONE: INTRODUCTION AND BACKGROUND

1.1 Introduction

Infertility is a relatively common condition with important medical and socioeconomic implications. It is the inability to conceive after at least 12 months of regular unprotected intercourse. Infertility can either be primary or secondary. Primary infertility refers to inability in a woman who has had no previous pregnancy to achieve pregnancy after one year of regular unprotected sexual intercourse while secondary infertility refers to inability in a woman who has previously achieved a pregnancy, regardless of outcome, to achieve pregnancy after one year of regular unprotected intercourse. Infertility affects 10 to 15% of couples worldwide in the reproductive age group (1). WHO estimates that infertility affects 50-80 million women worldwide and 11.3% of married women with only 35% of these seeking medical interventions. 30% of these patients are attributable to tubal subfertility or infertility (2). The exact magnitude in Kenya is not known but according to the Kenya Demographic and Health Survey of 2014 the prevalence of primary infertility is almost 2% of women (3).

Causes of infertility include tubal disease, especially from pelvic infection, endometriosis and prior pelvic surgery. Approximately one third to one fourth of all infertile women are diagnosed with tubal disease in developed countries. In the United States, the commonest cause of tubal disease is infection with *C trachomatis* or *N gonorrhoeae.* in contrast, in developing countries, genital tuberculosis may account for 3-5% of infertility cases (1). A local retrospective study carried out in 2014 at the Kenyatta National Hospital, Kenya revealed that the main laparoscopic findings of women with infertility were tubal blockage (74.40%), endometriosis (11.20%) and genital tuberculosis (5.22%) (4).

Fallopian tube obstruction is among the leading causes of female infertility. Tubal obstruction occurs more commonly at the distal and proximal segments of the FT. It is estimated that PTO occurs in up to 25% of women with tubal pathology (5)(6). PTO is commonly caused by a transient phenomenon known as tubal spasm or intra-luminal filling defects such as mucus plugs, debris, blood products, adhesions or salpingitis isthmica nodosa. These are easily treated by fallopian tube recanalization (FTR). On the other hand, distal tubal obstruction is commonly because of pelvic inflammatory disease (PID) and is often associated with considerable inflammation around the FT, adhesions and hydrosalpinx. This is not perfect for FTR and is also challenging to treat by other available modalities (5).

The key initial diagnostic methods for tubal obstruction are hysterosalpingography (HSG) and or laparoscopic tubal dye perfusion. Although laparoscopy is considered superior to HSG

in the assessment of pelvic pathology and adnexal factors of infertility, HSG is more affordable and less invasive. Treatment for tubal obstructions was traditionally by tubal reparative surgery until the advent of in-vitro fertilization (IVF) which is now more often offered by reproductive health specialists and gynecologists. Both options are risky. Each type of tubal reparative surgery is associated with surgical and anesthetic risks and is also costly due to the requirement of specialized personnel and theatre time. As a treatment modality, IVF is financially and emotionally demanding, with the potential to instigate a myriad of complications such as ovarian hyperstimulation syndrome and multiple gestation with its attendant neonatal and maternal sequelae (6).

Fluoroscopy guided, selective salpingography with fallopian tube recanalization has greatly improved treatment of tubal infertility. Results from many centers across the world have demonstrated that recanalization using a catheter is achievable in majority of women with proximal tubal obstruction (PTO) by use of typical angiographic techniques which all interventional radiologists are acquainted with; moreover, several studies have revealed its feasibility and safety (7)(8). Consequently, the American Society for Reproductive Medicine as well as the Royal College of Obstetricians and Gynecologists have suggested that women whose hysterosalpingogram (HSG) reveals PTO should undergo fallopian tube catheterization with selective salpingography before more aggressive and expensive infertility treatments (6)(7).

No local data is recorded evaluating the success rate of this procedure in achieving tubal recanalisation. This study aims to form a standard baseline and add to the scientific knowledge on the subject as well as developing local data-driven clinical guidelines for infertility treatment.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Fallopian Tube Anatomy

The fallopian tubes are slender muscular conduits extending laterally to the upper free edge of the broad ligament. These hollow paired structures are approximately 10-12cm in length and 1-4mm in diameter. They originate posteriorly from the uterine fundus and extend into the peritoneal cavity. They convey ova from the ovaries and open into the uterine cornua, allowing transportation of the embryo to the uterine cavity for implantation (11).

The fallopian tube has 4 main anatomical parts namely, the infundibulum, ampulla, isthmus and interstitial segment from distal to proximal. The most proximal part of FT is the interstitial segment which is around one-centimeter-long, located within the wall of the uterus and opens to it. The isthmus is the narrow medial part spanning 3cm, immediately after the interstitial segment. The ampulla is a wide, dilated tortuous outer portion, approximately 5cm long, which curves over the ovary and where fertilization of the ovum usually happens. The most distal part of the FT is the infundibulum which is funnel shaped and with a fimbriated rim. The infundibulum extends out beyond the broad ligament through the abdominal ostium, opening into the peritoneal cavity. (12) (11). Fimbriated end of the infundibulum opens into the peritoneal cavity and passes superior to the ovary. This allows the ovum to be drawn into the FT after ovulation for fertilization to occur.

Courtesy of https://www.tubal-reversal.net/blog/fallopian-tube-anatomy-function/

Figure 1:Fallopian Tube Anatomy

The luminal diameter in the proximal interstitial and isthmic parts of the FT closest to the uterus is nearly 1 mm, with a linear or relatively curled course in about 60%, and a tortuous passage in about 40%. This anatomical appearance prevents vaginal bacteria from gaining access to the peritoneum. Similarly, this dainty configuration, its thick muscular wall and fewer cilia in its epithelium make it susceptible to spasm, buildup of secretions, occlusion by mucus and disfigurement from inflammatory processes, resulting in obstruction and sterility (13)(10).

2.2 Imaging Techniques in Fallopian Tube Disease

The imaging techniques employed in the assessment of FT disease and patency range from HSG, ultrasonography, CT, and MRI to more advanced tools such as hysterosonography with the aid of contrast agents. In the basic evaluation of presumed FT anomalies and related pathology of the female pelvis, the preferred initial imaging modality is sonography. It is also useful in providing surveillance and visual guidance during infertility treatment as well as in follow up after other imaging. Gray scale US is useful in evaluation of morphologic changes such as dilated tubes, thickened tubes, wall nodularity, mass, cystic changes, and fluid collections. Evaluation of FT perfusion, hyperemia, waveform patterns as is the case of infection, torsion and neovascularity instances of tubal mass is further done using Doppler US examinations. Recent technologic advances in US such as contrast-enhanced hysterosonography which involves injection of contrast material (microbubbles) and combined HSG-contrast-enhanced US which involves saline into the FTs through US direction, have transformed the capability to evaluate tubal patency, eliminating exposure to radiation as well as possible allergic reactions to iodinated contrast media. Previously, a fallopian tube could be detected with sonography only when distended by fluid, such as with obstruction. Three-and four-dimensional US are essential in evaluation of fallopian tube shape and configuration as well as associated anomalies (11).

HSG is a radiographic imaging technique used in preliminary infertility evaluation to assess the endocervical canal, the endometrial cavity and the FT lumina via fluoroscopic guidance after injecting water-soluble iodinated contrast media through the cervix. It is also indicated in assessing patency of the FT preceding and after reversal of tubal ligation. An average study is conducted in 10 minutes, involves roughly 90 seconds of fluoroscopic time and has a mean radiation exposure of 0.01 to 0.02 Gy to the ovaries. HSG is performed between days 5 and 10 of the menstrual cycle during which, cessation of menstrual flow reduces infection risk and probability of flushing an ovum from the FT after ovulation is low. The procedure causes cramping and an NSAID administered 30 minutes prior may reduce discomfort. Rapid contrast

injection is discouraged as it may cause tubal spasm (1). It is contraindicated in pregnancy, active bleeding and or pelvic infection. Complications include pain, pelvic infection, hemorrhage and vasovagal attacks.

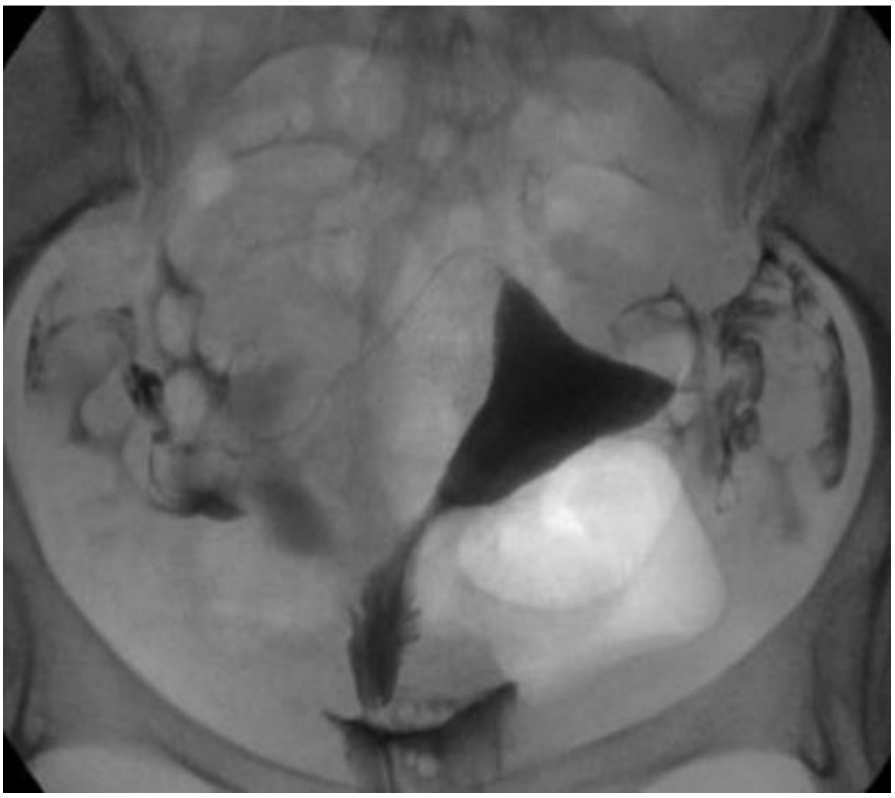

Figure 2:Normal HSG image demonstrating patent fallopian tubes with peritoneal spill

CT of the pelvis and abdomen is not the go-to modality for imaging the fallopian tubes and is mostly earmarked for staging of a tumor affecting the fallopian tubes or in assessing the extent or complications of known tubal pathology. With the increased availability of CT and the upsurge of its use in emergent pelvic and/ or abdominal evaluation for non-specific symptoms, abnormalities of FT may be seen on CT images. It is therefore important to be conversant with these findings. MRI is routinely used as a problem-solving tool when a diagnosis is inconclusive using US alone or with other imaging examinations. It is considered superior to other modalities given its high soft tissue resolution, accessibility of various tissue-specific sequences and use of contrast media in precisely ascertaining the nascency of adnexal pathology, its characteristics and tissue viability (11).

2.3 Spectrum of Fallopian Tube Disease

A variety of conditions can affect one or both FTs. Commonly encountered ones include pelvic inflammatory disease which particularly presents with pyosalpinx and hydrosalpinx, ectopic

pregnancy, isolated tubal torsion as well as ovarian torsion with FT involvement, endometriosis presenting with hematosalpinx and pelvic adhesions, and malignant lesions. Some of these conditions are self-limiting; however, others lead to infertility or worse still, potentially fatal infections or hemorrhage especially if not treated (11).

Anatomical and physiological factors are believed to contribute to PTO. Particularly, the thick muscle wall and low number of cilia in the proximal tube epithelium renders this segment susceptible to spasm. Additionally, physiologic obstruction may be observed in the follicular phase of the menstrual cycle due to accumulation of secretions within the FT, primarily at the isthmus and uterotubal junction. This aggregation of secretions normally resolves during the luteal phase of the menstrual cycle. However, if this fails, it leads to prolonged stasis of uterine contents leading to incomplete or complete occlusion. Fluoroscopy guided selective FTC using coaxial system of guidewires and catheters has been used from the late 1980s with improved imaging of tubal anatomy and treatment of PTO(5).

2.4 Evolution of FTC techniques

Fallopian tube catheterization (FTC) is a technique uses small catheters and guide-wires to cannulate the fallopian tubes and establish patency if there is cornual occlusion in an otherwise normal pelvis (14). It was first performed in 1966 using a curved metallic cannula and due to technological advances major improvements in the design of cannulas have been witnessed. This can be performed under endoscopic, sonographic, fluoroscopic or tactile guidance with catheters, and flexible atraumatic guide-wires or inflatable devices (13). FTC is used in treatment of infertility triggered by PTO, and where available, FTC has replaced surgical interventions for PTO (10). Recent developments in the field of assisted reproduction have led to renewed interest in the diagnosis and treatment of PTO under fluoroscopic guidance which is a non-surgical procedure and allows the patient to conceive naturally(15). This is a safe treatment option in a developing country like Kenya, where the access to assisted reproductive techniques (ART) such as IVF is still a challenge.

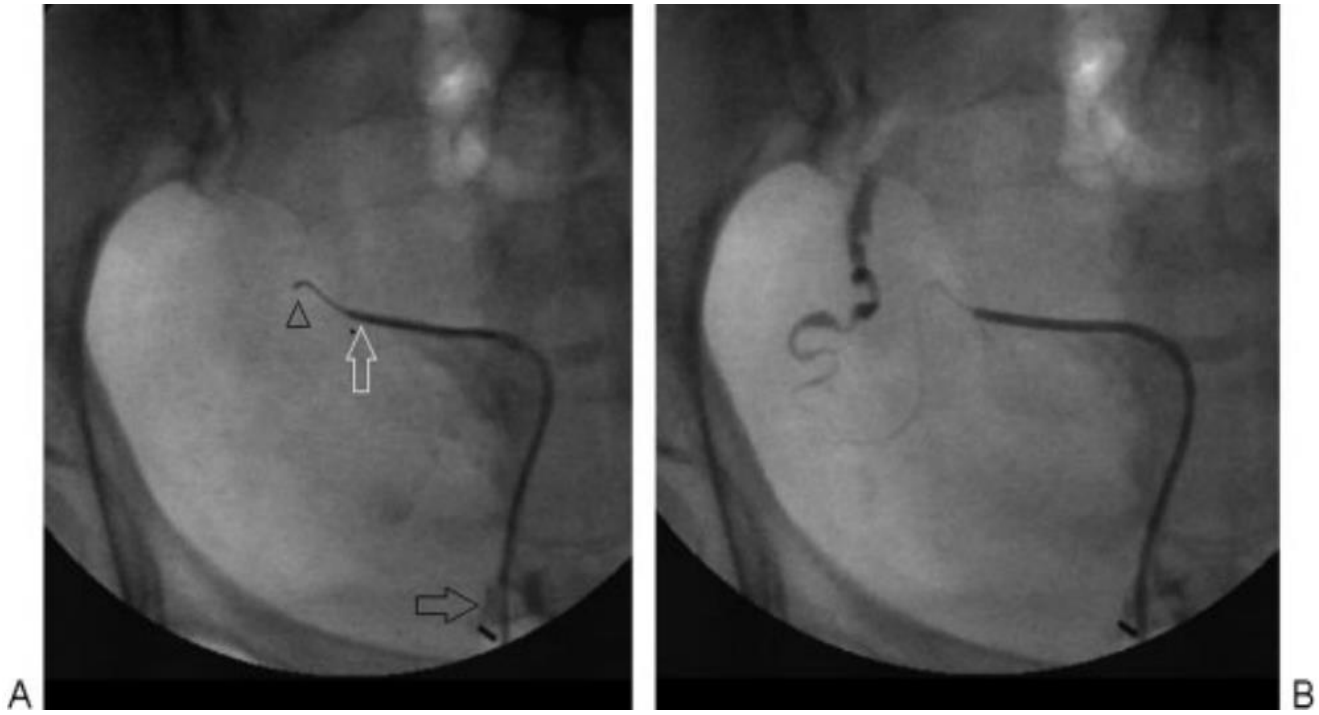

Figure 3:FTC images with successful recanalization of the right fallopian tube

(A) 9-Fr balloon catheter is inflated in the cervix (open black arrow), a 5-Fr catheter tip is lodged in the tubal ostium (open white arrow), and a 0.035-inch hydrophilic guidewire (arrowhead) is passed into the proximal right fallopian tube. (B) After removal of the guidewire, contrast material is injected through the 5-Fr catheter revealing a patent normal tube**.**

2.5 Patient Preparation and FTC Technique

FTC is performed as an outpatient procedure during the follicular phase (first 10 days) of the menstrual cycle provided the bleeding has stopped. During this time, the endometrium is thinnest which improves visualization of the uterine cavity and minimizes the possibility that the patient may be pregnant(7)(16). After written consent has been obtained, patients will be premedicated with 100mg of intra-muscular tramadol and 20mg of intra-venous buscopan 30 minutes prior to the procedure.

A single operator (interventional radiologist) will perform the procedure in the interventional radiology suite under strict aseptic conditions with a dedicated FTC kit. The patient will lie supine on the table, with knees flexed and legs abducted. The vulva will be cleaned with chlorhexidine and a lubricated self-retaining vaginal speculum will be inserted exposing the cervix. The cervical os will be identified and a Margolin or Leech-Wilkinson HSG cannula will be inserted into the cervical canal after taking care to expel all air bubbles from the cannula and adjoining syringe. A conventional HSG with diluted water-soluble contrast media (e.g., Omnipaque 180mg/ml equivalent) will be performed using a fluoroscopy unit with spot film

device to confirm tubal blockage and the blocked tube will then be cannulated using an angled-tip 5-Fr multipurpose catheter. A hydrophilic guidewire (0.035-inch Roadrunner® PC; Cook Medical Inc.) will then be inserted into the blocked tube(s) all the way until the wire can move freely within the peritoneal cavity. Finally, a post recanalization HSG will be done to confirm tubal patency and peritoneal spillage.

All women will be admitted to the day care for pre-procedure preparation and post-procedure observation. Analgesics and prophylactic antibiotics will be prescribed to all women. It will be ensured that no patient is in any serious discomfort or significant bleeding before she leaves.

2.6 Complications

PV bleeding and mild uterine cramping are commonly experienced after FTC. Analgesics administered pre- and post-procedure and usually adequate for pain control and intravenous sedation is usually unnecessary. Tubal perforation has been reported in less than 4% of FTC patients especially associated with severe tubal disease. However, this has extremely low morbidity hence additional monitoring or treatment is not necessary after perforation has occurred.

Radiation to the ovaries during fluoroscopic transcervical FTC is documented as less than 1 rad (10Gy) which is equivalent to the dose delivered during a barium enema or intravenous pyelogram. The radiation dose is dependent on the equipment, amount of fluoroscopy and number of radiographs exposed. The procedure typically takes less than half an hour and fluoroscopy time is less than 10 minutes (7)

2.7 Efficacy of FTC

Several studies have proven FTC as a worthy and safe treatment option for patients with infertility due to PTO with high pregnancy rates after the procedure when the recanalized tube is found to be normal with no prior tubal disease. A retrospective study done in a multi ethnic south-east Asian population over 9 years in 78 patients who underwent FTC for documented PTO revealed the technical success rate was 86.8 % and post-FTC pregnancy rates at 36.8% after approximately 1 year of follow-up with no major post-procedure complications (16). Another retrospective study in 36 patients who underwent the procedure, revealed the success rate of the catheterizations was 88.8% with 40% pregnancy rate there-after.

According to NICE guidance, fallopian tube recanalization by atraumatic guidewire is a treatment for infertility triggered by blocked fallopian tubes, particularly when the blockage is in the proximal fallopian tubes. FTC is done at the same treatment session with diagnostic HSG, involving insertion of a catheter into the fallopian tube. Injection of radiopaque dye may clear the blockade. However, if this strategy is unsuccessful, a guidewire may be passed up into the fallopian tube through the catheter and manipulated to clear the obstruction. Successful recanalization has been reported in 77% of cases of proximal tube obstruction of 302 patients in a single study (17).

2.8 Conceptual Framework

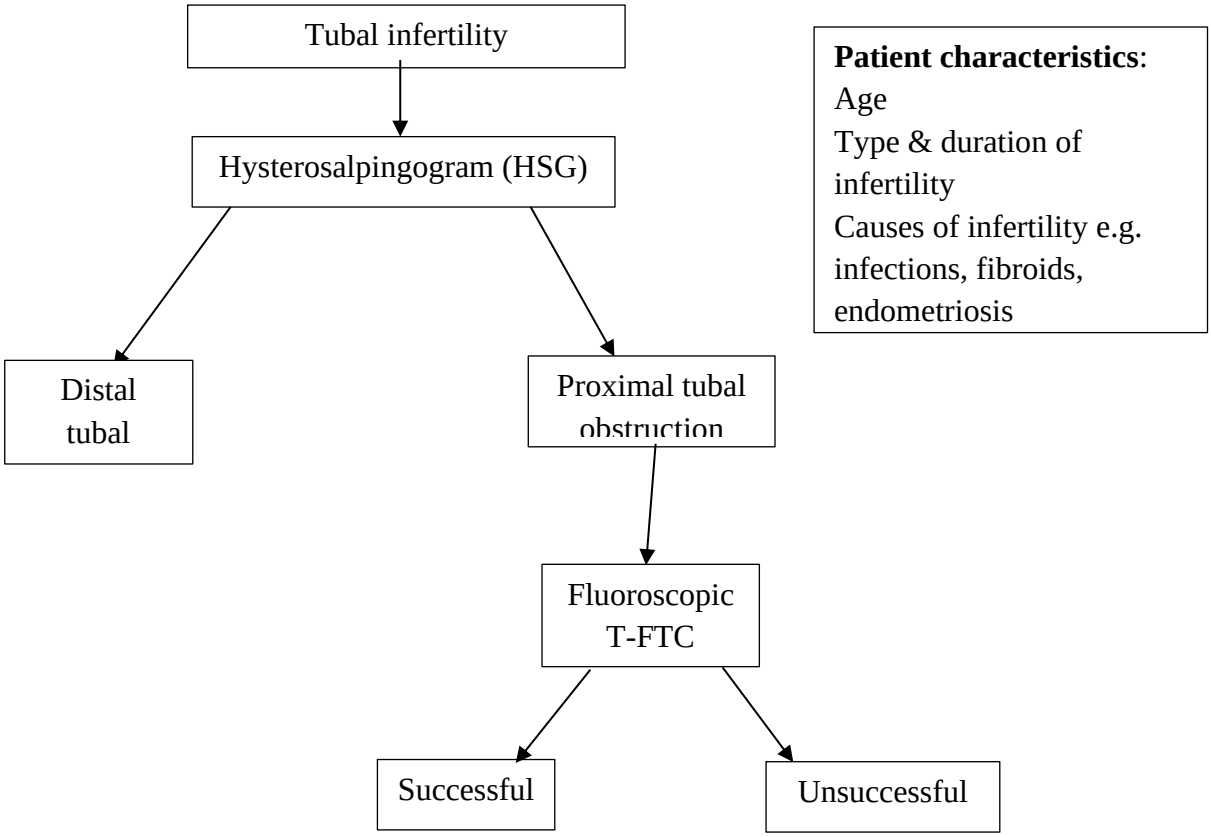

Figure 4:Conceptual Framework

The investigators intend to determine the success rate of fluoroscopy guided T-FTC in achieving tubal patency and complications of the procedure in a sample of Kenyan women with documented proximal tubal infertility from prior HSG. The patients will have been referred by their primary physician for the procedure. HSG findings have been known to influence the

technical success rate of FTC as PTO are easier to treat and more amenable to FTC unlike DTO. Patient age, number of recanalized tubes, type and duration of infertility are critical factors known to impact pregnancy rate following FTC. Only patients who consent to participate in the study will be sampled in those found to have proximal tubal obstruction based on the patient attributes.

2.9 Study Justification

Since advent of ART, especially IVF, tubal catheterization has fallen out of favour and is now not commonly performed. Absence of comparative studies between the reproductive outcomes of tubal catheterization versus IVF in treatment of PTO has resulted in inadequate evidence to suggest that tubal catheterization is effective in treating PTO (9). Inequitable access to ART to treat infertility remains a challenge for people living in resource-poor settings especially in sub-Saharan Africa. Even where the services are available, they are prohibitively expensive hence accessible to a select few.

Fallopian tube catheterization is used for treatment of infertility caused by proximal tubal occlusion and where accessible has replaced surgical treatment for this condition. However, the more recently trained gynecologists and fertility specialists are prone to treating most couples with procedures that bypass the fallopian tubes all together such as IVF and embryo transfer due to their perceived higher "take home baby rate". These are still expensive, time consuming and require hormonal stimulation and other maneuvers to which some couples object. It is important to remind gynecologists and fertility specialists about catheter recanalization, which is a cost-effective, safe and minimally invasive treatment option advocated before IVF. Additionally, it is essential to initiate a close working relationship with other specialists to help a couple once the FTs are open after FTC, achieve their goal of having a baby as some may need additional fertility treatments which are out of a radiologist's field of expertise (10).

No local data exists to assess the success rate of TFTC in achieving patency or associated complications in patients with proximal tubal obstruction. Findings from this study will set pace for this as well as contribute to scientific knowledge. This study will be aimed at developing local evidence-based clinical guidelines for the management of infertility that can be used by the Kenya Association of Radiologists and Kenya Obstetrical and Gynecological Society.

2.9 Study Objectives

2.9.1 Main Objective

To assess tubal recanalization and complications after fluoroscopic transcervical fallopian tube catheterization in patients with proximal tubal obstruction on HSG

2.9.2 Specific Objectives

a) To evaluate the HSG findings in women undergoing fluoroscopic transcervical fallopian tube catheterization

b) To derive the success rate of transcervical fallopian tube catheterization in achieving tubal recanalization in patients with PTO on HSG

c) To assess the complications of fluoroscopic transcervical fallopian tube catheterization

3.0 CHAPTER THREE: STUDY METHODOLOGY

3.1 Study Design

A hospital based retrospective and prospective cross-sectional study was employed. For the retrospective study, all patients who underwent T-FTC from July 2020 in both facilities as recorded from health management information systems in the study areas who met the inclusion criteria were included. Stored images from the image intensifier in KNH and Picture-Archive and Communications Systems (PACS) at The Karen Hospital were retrieved.

3.2 Study Area

This study was carried out at Interventional radiology suites at KNH and The Karen Hospital-Nairobi branch. KNH is a National Teaching and Referral hospital located in Nairobi, Kenya. It is the teaching hospital of University of Nairobi, College of Health Sciences. It is one of the two tertiary referral facilities in the entire country and as such it serves majority of the Kenyan population requiring specialised health care. The Karen Hospital is a privately owned hospital located in Karen, Nairobi. It is also a multi-specialty hospital with modern state-of-the art amenities and 8 branches country-wide.

In 2019, the number of FTC cases done at KNH and Karen Hospital where 30 and 20, respectively. Being a non-emergency procedure however, the number of cases dropped drastically due to the COVID-19 global pandemic and an average of 2 cases per month are now conducted in both facilities. Patients are referred for fluoroscopic trans-cervical FTC by gynaecologists, reproductive health specialists or primary care physicians who diagnose tubal infertility.

3.3 Study Population

All patients with documented tubal infertility confirmed on HSG referred for fluoroscopic trans-cervical FTC at Kenyatta National Hospital and The Karen Hospital.

3.3.1 Inclusion Criteria

a) All patients who had documented tubal infertility confirmed on HSG referred for fluoroscopic trans-cervical FTC in the study sites.

b) All patients who suspected tubal infertility within the follicular phase of the menstrual cycle, preferably days 5 -10. Similar to the scheduling of HSG, FTC is performed during the follicular phase in which the endometrium is thinnest which improves visualization of the uterine cavity and also minimizes the possibility that the patient may be pregnant.

c) Patients who grant informed consent.

d) Patients who are 18 years and above.

3.3.2 Exclusion Criteria

a) All patients with contraindications for HSG i.e., during menstruation, are pregnant, have a purulent discharge on inspection of the vulva or cervix, or diagnosed PID 6 months prior to the procedure, have sensitivity to contrast.

b) Patients who declined to consent.

c) Patients who were 18 years and below.

3.4 Sample Size Determination

Sample size was calculated using the Fisher's formula.

$$n = \frac{Z^2 x\ P(1-P)}{d^2}$$

Were,

n = Desired sample size

Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

P = expected true proportion (estimated at 80.0%, from a study conducted by Kabute V. et al (2021) at the Kenyatta National and Karen Hospitals, Nairobi, looking at success rate of fluoroscopic trans-cervical FTC in achieving tubal patency in patients with proximal tubal obstruction. ..... cases, found 80.0% of them were .....)

d = desired precision (0.05)

$$n_0 = \frac{1.96^2 x\ 0.80(1-0.80)}{0.05^2} = 246$$

The estimated accessible population is 35 patients. Adjusting the sample size for finite populations less than 10,000 the resulting sample size will be.

$$nf = \frac{n_0}{1 + \frac{n_0 - 1}{N}} = \frac{246}{1 + \frac{246 - 1}{35}} = 31$$

A minimum sample size of 31 patients will be required for the study (18)

3.5 Sampling Procedure

This was done using consecutive sampling (total enumerative) method, where every patient who meets the inclusion criteria was selected until the required sample size was achieved.

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3.6 FTC Procedure

Patients were booked for the procedure where all relevant medical history, explanation of the procedure and ruling out of any contraindications were done. These patients had documented tubal infertility confirmed on prior HSG and were within the follicular phase of their menstrual cycle. The procedure was explained to the patient and written informed consent obtained. Patients were premedicated with 100mg of intra-muscular tramadol and 20mg intra-venous buscopan 30 minutes prior to the procedure.

A single operator interventional radiologist, scrub nurse and radiographer performed the procedure in the interventional radiology suite under strict aseptic conditions with a dedicated FTC kit. The patient lay supine on the table, with knees flexed and legs abducted. The vulva was cleaned with chlorhexidine and a sterile speculum was inserted into the vagina using sterile gel and exposing the cervix. The cervical os was identified and a Margolin or Leech-Wilkinson HSG cannula was inserted into the cervical canal after taking care to expel all air bubbles from the cannula and adjoining syringe. A conventional HSG with diluted water-soluble contrast media (e.g., Omnipaque 180mg/ml equivalent) was performed using a fluoroscopy unit with spot film device to confirm tubal blockage and the blocked tube was then cannulated using an angled-tip 5-Fr multipurpose catheter. A hydrophilic guidewire (0.035-inch Roadrunner® PC; Cook Medical Inc.) was then inserted into the blocked tube(s) repeatedly by gentle probing until the wire could move freely within the peritoneal cavity. Finally, a post recanalization HSG was done to confirm tubal patency and peritoneal spillage.

All women were admitted to the day care for pre-procedure preparation and post-procedure observation. A 5-day course of analgesics and prophylactic antibiotics was prescribed to all women after the procedure. It was ensured that no patient was in any serious discomfort or significant bleeding before she left. Patients were cautioned that some cramping and mild bleeding may occur in 3-5 days post procedure. The patients were also advised to avoid sexual intercourse for a few days, especially if bleeding or vaginal spotting occurred and referred to the primary physician for pre-conception care and further management. Follow-up calls 1 week post procedure were made to access for complications.

3.7 Data Collection Procedure

The principal investigator used a pre-designed data collection tool (Appendix V) organized in sections distinct groups of data that mirror the study objectives. Medical records and imaging data of all women included in the study were reviewed for extracting demographic and clinical information such as patient's age, duration, and type of infertility. Imaging findings were

discussed with the interventional radiologist. The following imaging characteristics were evaluated: uterine and FT findings on HSG, tubal patency achieved after FTC and immediate complications seen such as features of tubal perforation. Patient feedback on the assessment of intermediate complications such as prolonged PV bleeding, pelvic pain and PV discharge were ascertained on follow-up calls 1 week after the procedure and documented.

3.8 Quality Assurance Protocol

Only patients who met the inclusion criteria were recruited into the study.

A single operator (interventional radiologist) performed the procedure in the interventional radiology suite under strict aseptic conditions with a dedicated FTC kit and imaging findings discussed post procedure. Proximal tubal obstruction was confirmed on pre-procedure hysterosalpingogram and selective salpingography performed just prior to FTC, thereby reducing the risk of a false positive finding of PTO related to tubal spasm or inadequate tubal filling (5). A standardized data collection tool was used for all patients. Daily review of the data collected during the study was done by the principal investigator. Representative spot images and cine clips of the procedures were recorded and stored in a password protected laptop and offsite back up device accessible only to the principal investigator.

3.8.1 COVID-19 Safety measures

To prevent the transmission of COVID-19:

a) All patients were booked to allow social distancing of patients in the waiting lobby.
b) All patients and personnel were required to wear masks throughout the procedure.
c) A single operator (interventional radiologist), scrub nurse and radiographer were in the interventional suite during the FTC procedure.

3.9 Ethical Consideration

Permission and ethical clearance was sought from the KNH/UON Ethics Review Committee prior to commencement of the study. Participation in the study was voluntary and the participants were free to pull out of the study at any juncture during the study. Informed consent was sought from all eligible study participants prior to any data collection. The participants were not subjected to any harm and were treated with respect and dignity during the study. All the data collected was coded and stored in an encrypted storage device to maintain patient's privacy and anonymity. Works of other authors used during the study was acknowledged using a referencing system.

3.10 Data Management

Data was captured using standardized Microsoft Excel data collection tool. Statistical calculations were performed with use of SPSS version 23.0 software. During analysis, demographic and clinical characteristics were summarized by using means and medians for continuous variables and proportions for categorical variables. HSG and FTC findings was presented as proportions with 95% confidence intervals and further association with other patient characteristics were tested using Chi square test of associations. All statistical tests were performed at 5% level of significance (p value of ≤ 0.05)

3.11 Study Results Dissemination plan

After completion of the study, the final report shall be presented to the Department of Imaging and Radiation Medicine at the University of Nairobi. The results will be published in a peer reviewed journal of Radiology.

4.0 CHAPTER FOUR: RESULTS

37 patients who met the inclusion criteria were recruited into the study. The mean age was 34.3 (SD 6.2) years, where the minimum recorded age was 24.0 years and the maximum being 47.0 years old. The median age was 35.0 (IQR 30.0 – 38.0) years. The mean duration of infertility was 6.5 (SD 4.1) years, where the minimum was 2.0 years and the maximum being 20.0 years. The median was 6.0 (IQR 4.0 – 7.0) years.7 patients (18.9%) had primary infertility while 30 patients (81.1%) had secondary infertility The demographic patterns of the study population are shown in Table 1 below.

Table 1:Demographic patterns of T-FTC patients

		Frequency	Percent
Age (years), *(n=37)*	≤30	11	29.7
	31 – 35	12	32.4
	36 – 40	7	18.9
	41 – 45	5	13.5
	>45	2	5.4
Duration of infertility (years), *(n=37)*	<5	11	29.7
	5 - 9	19	51.4
	≥10	7	18.9
Type of infertility, *(n=37)*	Primary	7	18.9
	Secondary	30	81.1

From the 37 patients initially referred for T-FTC, only 30 patients (81%) required FTR. These were female patients in the reproductive age group with documented tubal infertility confirmed on HSG referred for fluoroscopic T-FTC who met the inclusion criteria in the study sites. (See table 2 below)

Following pre-procedure HSG, 3 out of the 37 patients (8%) had patent tubes as well as normal uterine and pelvic findings and no further intervention was performed. Meanwhile, the remaining 34 patients (92%) revealed pathology in the uterus, fallopian tubes, adnexa or combination of gynecologic pathology. Fallopian tube occlusion was the most common finding identified on HSG in 92% of patients with majority of the occlusions noted bilaterally than unilaterally. Pelvic adhesions seen as loculated spill were observed on only 1 patient while 5 patients (14.7%) had irregular uterine and cervical outline coexistent with tubal occlusion noted on HSG (see Table 2 below). Of the 34 patients, 26 (76.5%) had bilateral PTO, 4 (11.8%) had unilateral PTO, 3 (8.8%) had bilateral DTO and 1 (2.9%) had unilateral DTO. Only those with PTO were included in the study analysis. (See Figure 5 flow chart below)

Table 2:HSG findings

		Frequency	Percent
Tubal status, *(n=37)*	Blocked	34	91.9
	Patent	3	8.1
Tubal occlusion, *(n=34)*	Bilateral DTO	3	8.8
	Bilateral PTO	26	76.5
	Unilateral DTO	1	2.9
	Unilateral PTO	4	11.8
Pelvic adhesions, *(n=34)*	Yes	1	2.9
	None	33	97.1
Uterine and cervical	Irregular	5	14.7
Outline, *(n=34)*	Normal	29	85.3

We successfully recanalized 46 of the 56 proximal fallopian tube obstructions with guidewire and catheter at a technical success rate of 82% (95% CI, 70.2% - 90.0%). Excluding 5 patients i.e., 1 with bilateral PTO that we failed to recanalize and 4 with DTO, the remaining 32 of the 37 referrals were eligible for conception.

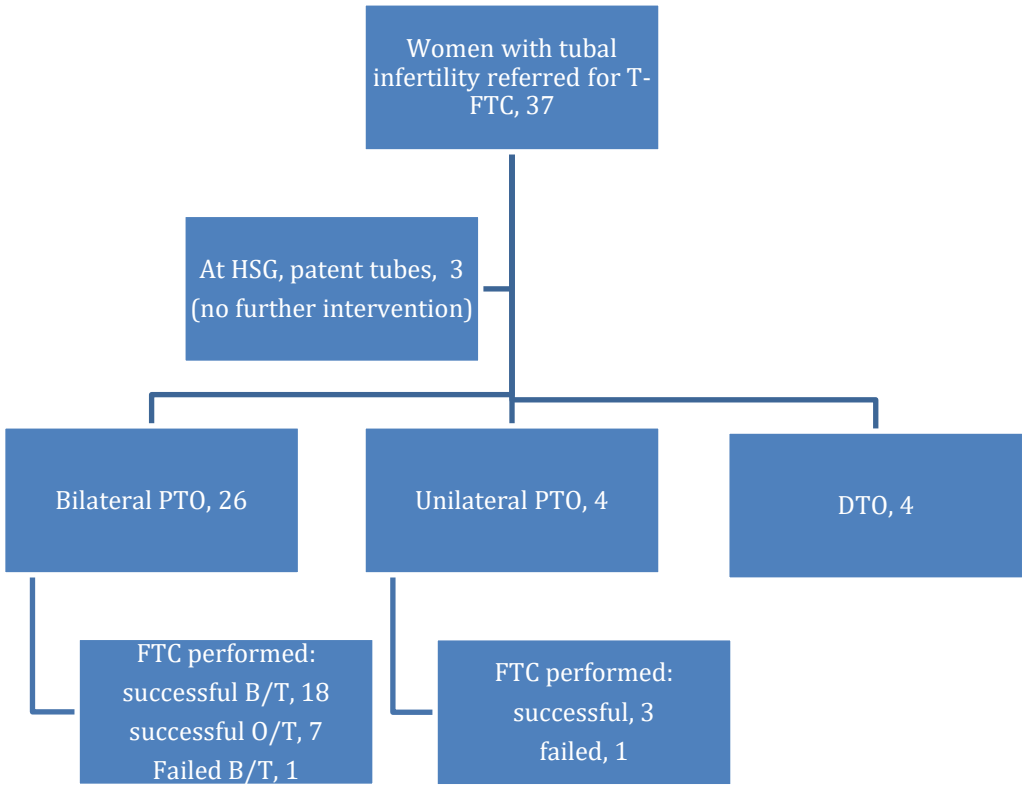
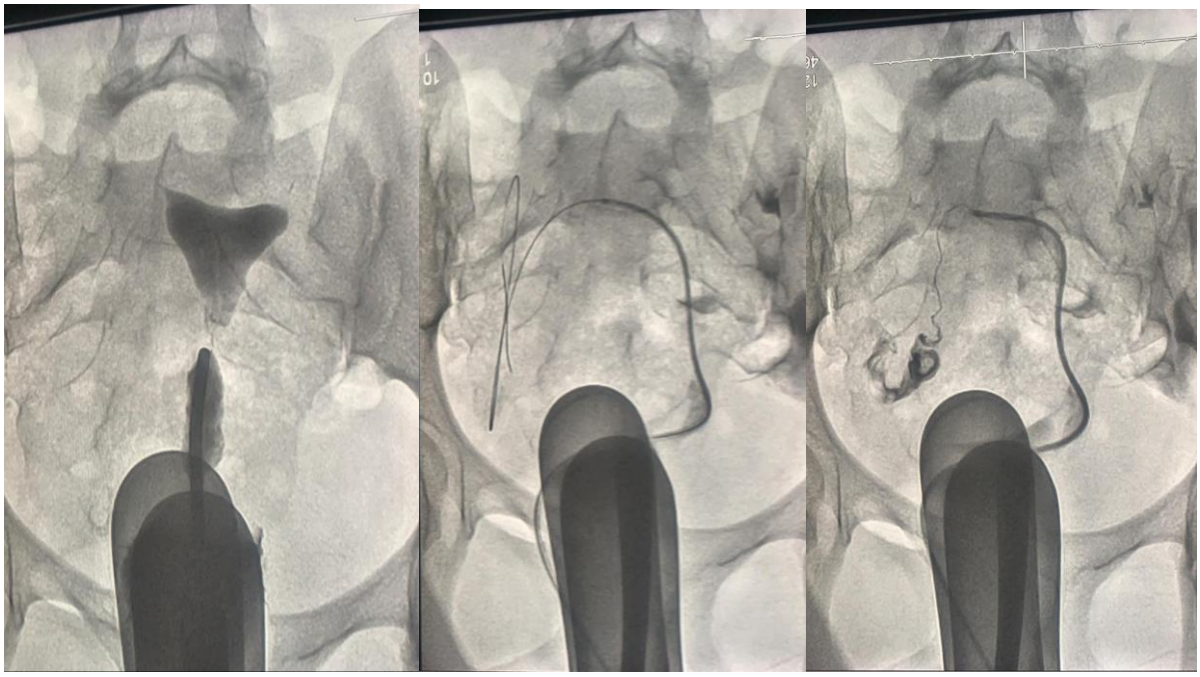


Figure 5:Flow Chart



a) b) c)

Figure 6:Patient with bilateral PTO, with successful bilateral tubal catheterization

a) Pre-procedure HSG showing non-filling of both tubes with a regular uterine outline.
b) Spot radiograph shows right uterine cornu engaged with a 5-french multi-purpose angiographic (MPA) catheter. A 0.035-in curved tip guidewire has been advanced beyond the mid portion of the right tube. Peritoneal spill is noted in the left adnexa from successful catheterization of the left tube.
c) Follow-up salpingogram through the 5-F MPA catheter confirms patency of the right tube with normal outline.

The post-procedure follow-up period varied from 4 days to 14 days. There were two (5.8%) instances of tubal perforations. However, none of them required any additional monitoring or intervention. 1 patient had pelvic pain 2 weeks post procedure. Majority of the patients experienced mild PV spotting and cramping for 3-5 days after the procedure and did not require additional treatment of these symptoms. No patients reported PV discharge or PV bleeding more 5 days after the procedure

Table 3:FTC complications

		Frequency	Percent
Tubal perforation, *(n=34)*	Yes	2	5.9
	No	32	94.1
Prolonged PV	No	34	100
Bleeding, *(n=34)*			
Pelvic pain, *(n=34)*	Yes	1	2.9
	No	33	97.1
PV discharge, *(n=34)*	No	34	100

Table 4:Crosstabulation of relationship of canalization success against uterine abnormalities using Fishers exact test

		Canalization Success		Total
		Yes	**No**	
Uterine abnormality	**Yes**	3	2	5
	No	25	0	25
Total		28	2	30

Fischer's exact test value, p = 0.021 i.e., significant association

Table 5:Crosstabulation of relationship of canalization success against laterality of PTO using Fishers exact test

		Canalization Success		Total
		Yes	**No**	
Laterality	**Unilateral**	3	1	4
	Bilateral	25	1	26
Total		28	2	30

Fischer's exact test value p = 0.235 i.e., association not significant.

Table 6:Crosstabulation of relationship of canalization success against laterality of unilateral PTO using Fishers exact test

		Canalization Success		Total
		Yes	**No**	
Laterality	**Right unilateral**	1	1	2
	Left unilateral	2	0	2
Total		3	1	4

Fischer's exact test value p = 1.000 i.e., association not significant.

Table 7:Crosstabulation of relationship of canalization success against laterality of unilateral PTO and bilateral PTO using Fishers exact test

		Canalization Success		Total
		Yes	**No**	
Laterality	**Right unilateral**	1	1	2
	Left unilateral	2	0	2
	Bilateral	25	1	26
Total		28	2	30

Fischer's exact test value = 0.253 i.e., association not significant.

5.0 CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECCOMMENDATIONS

5.1 Discussion

Tubal blockage is a common cause of infertility among women in the reproductive age group. Fluoroscopic-guided transcervical selective salpingography and fallopian tube recanalization by use of a coaxial system of guidewires and catheters is an established technique for the diagnosis of the precise site(s) of tubal disease and treatment for proximal tubal occlusion (PTO). In appropriately selected patients, it is effective in establishing patency and is less invasive and costly than surgical alternatives. Despite its good technical success rate and confirmed feasibility and safety it has been slow to become adopted since the advent of ART such as IVF.

Our study demonstrated that majority of the patients (88%) with tubal infertility had proximal tubal occlusion. This pattern was similar to other previous studies carried out by Dwivedi et al, Anil et al and Badawy et al (15,16,19).

The causes are varied and are associated to anatomical and physiological factors. These include tubal spasm, secretion accumulation, mucus plugging and scarring from inflammation, leading to obstruction and infertility. Other causes include endometriosis, salpingitis isthmica nodosa and uterine fibroids

3 patients from our study showed normal tubal patency, despite prior HSG showing PTO. Similar characteristic seen in a study by Anil et al where 4 out of 100 patients had patent tubes at pre-procedure HSG. These false positive cases of PTO may be attributed to spasm of the utero-tubal sphincter or mucus plugs that might have been cleared during initial HSG.

Tubal spasm can result from multiple factors such as anxiety, cervical irritation or increase in intrauterine pressure. Therefore, pre-procedure communication with the patient to allay her anxieties with or without use of sedatives and anxiolytics is common. Pain control, slow and gentle injection of contrast media into the uterine cavity to avoid abrupt increase in intrauterine pressure as well as use of antispasmodic like hyoscine-N-butyl bromide are useful to avoid tubal spasm (16)

1 patient was noted to have pelvic adhesions seen as loculated spill while 5 patients had irregular uterine and cervical outline coexistent with tubal occlusion noted on HSG. Submucosal leiomyomas which presented with uterine outline irregularity prevented instrumentation of the tubal ostia in 3 patients with known uterine fibroids who were subsequently referred for myomectomy.

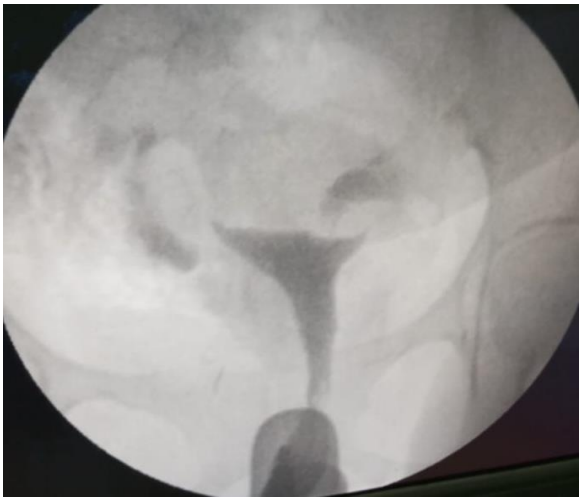


Figure 7:Spot HSG image of patient with pelvic adhesions seen as bilateral loculated spill

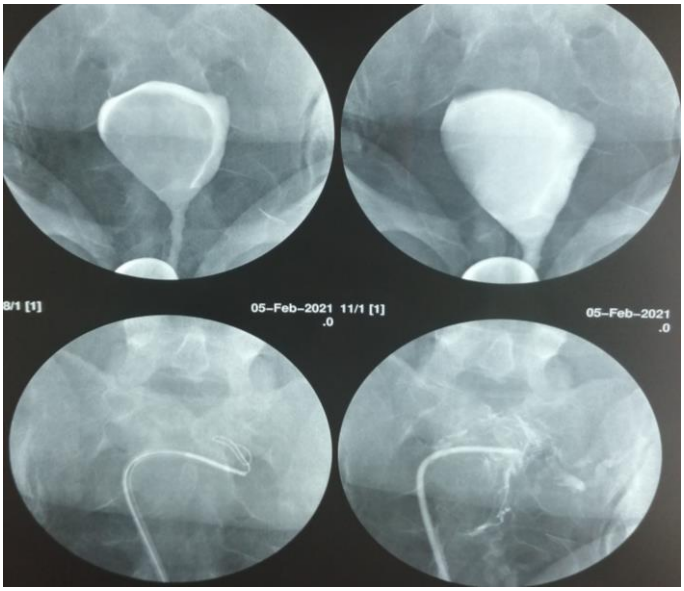


Figure 8:HSG image of patient with uterine fibroids seen as a large intrauterine filling defect and bilateral cornual blockage. On FTC attempt, unsuccessful catheterization of the left cornua is noted

We successfully recanalized 46 of the 56 proximal fallopian tube obstructions with guidewire and catheter at a technical success rate of 82%. This was comparable by similar studies done by Badawy et al in 2019, Anil et al in 2011and another by Rawal et al in 2005 with success rates of 88.8%, 86.8% and 78% respectively (Anil et al., 2011; Badawy & Singer, 2019; Rawal et al., 2005)

Excluding 5 patients i.e., 1 with bilateral PTO that we failed to recanalize and 4 with DTO, the remaining 32 of the 37 referrals were eligible for conception

Selective salpingography (SS) and T-FTC techniques characterized obstructive lesions by location, proximal/distal or both and by probable cause. After recanalization of proximal segment of the tubes, SS made possible detailed assessment of the distal end of the tube.

On crosstabulation of the relationship of success against uterine cavity abnormalities and laterality of unilateral or bilateral PTO using Fisher's exact test, we found significant association between uterine cavity abnormalities and cannulation success with a p value of 0.021. No significant association between laterality of PTO and canalization success was observed. No comparative studies were identified to further evaluate these associations.

In this study, the 5.8% incidence of tubal perforation by guidewire, the most common complication of FTC, is within the 0-10% range reported by Kumpe et al and Lang et al in 1990(20,21). These could be attributed to fibrosis or scarring from chronic inflammation as they occurred in patients with history of infertility for longer than 10 years. There was no significant morbidity or mortality from any of these perforations.

Patients undergoing T-FTC need to be appraised of the risk of infection, post-procedure lower abdominal cramps, vaginal spotting and contrast reactions. Cervical cannulation and uterine injections can occasionally cause vasovagal syncope. Performing the procedure under strict aseptic conditions, with a dedicated FTC kit and proper technique as well as prescribing pre- and post-procedure analgesic and antibiotics will prevent these complications.

5.2 Conclusion

In our experience, fluoroscopy guided T-FTC is a safe treatment option in patients with infertility from PTO, associated with high technical success rate at relatively low cost and morbidity. Our study also concluded that the procedure could be performed during HSG with significant saving in terms of time and cost. It therefore merits to be recommended for patients with PTO, prior to more invasive and costly treatments.

5.3 Limitations

Loss of imaging data of several women treated in KNH during the study period due to machine maintenance and lack of PACS

5.4 Recommendations

- 1 year follow-up studies to confirm pregnancy outcomes of study population or re-occlusion rates
- Multicenter comparative studies on varied techniques of T-FTC

STUDY TIMELINE

Activity	Action by	Sept 20	Oct 20	Nov 20	Dec 20	Jan 21	Feb 21	Mar 21	Apr 21	May 21	Jun 21	Jul 21	Aug 21	Sept 21
Writing Research Proposal	Student													
Revising and Finalizing proposal	Student and Supervisor													
Ethical Approval and correction	KNH-ERC													
Data Collection	Student													
Data Checks and Cleaning	Student													
Data Analysis and Interpretation	Student and Biostatistician													
Writing up	Student and Supervisor													
Dissertation submission	Student													

STUDY BUDGET

ITEM	QUANTITY	UNIT PRICE	TOTAL
PRINTING PAPER	5 RIMS	500	2500
NOTEBOOKS	2 PIECES	100	200
FILES	1 PIECES	90	90
PRINTER CATRIDGE	1 PIECES	2400	2400
INTERNET	50GB DATA BUNDLE	4000	4000
FLASH DISK	32GB – 1 PIECE	900	900
PHOTOCOPIES OF QUESTIONAIRES	50 COPIES	10	500
PHOTOCOPIES OF FINAL PROPOSAL	6 COPIES	100	600
BINDING OF FINAL PROPOSAL	6 COPIES	60	360
AIRTIME	1	3000	3000
ETHICAL REVIEW FEE	1	2000	2000
SUBTOTAL			16550
BIOSTATICIAN	1		40000
SUB TOTAL			25000
DATA COLLECTION, DATA ANALYSIS AND THESIS DEVELOPMENT			
PRINTING OF THESIS DRAFTS	10 COPIES	1000	10000
PRINTING OF FINAL THESIS	6 COPIES	1000	6000
BINDING OF THESIS	6 COPIES	400	2400
SUBTOTAL			18400
CONTINGENCY (10% OF TOTAL BUDGET)			5995
GRAND TOTAL			80945

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APPENDICES

Appendix I: Patient Information Document

TITLE OF STUDY: TUBAL RECANALIZATION SUCCESS RATE AND COMPLICATIONS OF FLUOROSCOPY-GUIDED TRANSCERVICAL FALLOPIAN TUBE CATHETERIZATION IN TREATMENT OF PROXIMAL TUBAL OBSTRUCTION

Principal Investigator and institutional affiliation: Dr Violet Wangui Kabute, University of Nairobi

Co-Investigators and institutional affiliation:

1. **Dr Jasper Muruka**, Kenyatta National Hospital
2. **Dr Timothy Musila Mutala,** Department of Diagnostic Imaging and Radiation Medicine University of Nairobi

Introduction

My name is Dr Violet Wangui Kabute, I am a resident at the University of Nairobi in the Department of Diagnostic Imaging and Radiation Medicine. I am carrying out the above study. I am requesting you to participate in this study. The aim of this consent form is to assist you in deciding whether to be included in the study or not. Kindly read through this form and feel free to ask any questions about this study. The principal investigator will be available to answer all and any questions that you may have at any point in this study and thereafter.

Even before you are enrolled into the study, your primary doctor will have already referred you to have fallopian tube catheterization for the treatment of blockage in your fallopian tubes. The researcher will have access to and will analyze your clinical information and imaging findings. No additional costs or risks except those involved in the procedure will be incurred.

Study Background

This study involves assessing Fallopian Tube Catheterization, an X-ray (fluoroscopy) guided procedure carried out on women to treat blocked fallopian tubes and documenting the outcomes at the end of the procedure.

Study Objective

The goal of this study is to assess how successful fluoroscopy guided Fallopian Tube Catheterization is in treating women with blocked fallopian tubes and extent of associated complications.

Study Procedures

Prior to the procedure you will be required to answer a few questions related to your condition e.g., your age, duration and type of infertility, prior pelvic intervention. The procedure is short and moderate discomfort may be experienced. You will lie on your back on an X-ray table. Medication to help you relax and keep you from feeling pain will be administered through an IV (intravenous) line put into a vein in your arm or hand. A speculum will be put into your vagina to hold it open, and a small metal tube (HSG cannula) will be put through your cervix into your uterus. X-ray dye (contrast media) will be injected through the cannula which will flow up to your fallopian tubes and will help your tubes be seen clearly on the X-ray images. It will show any blockage that may be in your fallopian tube and guide the rest of the procedure. A thin, flexible tube (catheter) with a guidewire inside it will be put through your cervix into the uterus and up to the opening of your fallopian tube. This guidewire is then carefully used to unblock the tube by gentle probing. A dye is then introduced into the fallopian tubes to check whether the procedure was successful. Since we are keen to evaluate the outcome of the procedure, would be grateful if you would agree to be contacted in the future for follow up by providing your telephone number.

Voluntariness of Participation

Enrollment in the study is purely voluntary and you are free to withdraw from the study at any point during the study without injustice or fear of repercussions.

Confidentiality

Confidentiality will be observed within the extent allowed by law as all your information will be encoded and all recorded data obtained will be secured.

Benefits of the Study

The study will enable creation of local data to assess the success rate of fallopian tube catheterization for the treatment of tubal infertility. Findings from this study will also provide evidence-based guidelines for the management of infertility in our region. No additional cost will be incurred apart from what has been recommended by the primary physician.

Risks of the Study

No additional costs or risks will be incurred for participating in the study except those involved in the procedure itself.

Possible risks of fallopian tube catheterization include:

1. Mild to moderate discomfort during the procedure which will be alleviated by medication given during and after the procedure.
2. Small hole (perforation) in the fallopian tube

3. Pelvic infection which will be minimized by use of prophylactic antibiotics.
4. Problems due to X-ray dye, including allergic reaction or kidney damage.
5. Tubal pregnancy, where a fertilized egg stays and grows in a fallopian tube.
6. Radiation exposure to your reproductive organs, although the risk from this is low.
7. Your fallopian tubes may become blocked again. If this happens, you will need to have the same or a different procedure in the future.

Right of Withdrawal

You are free to decline to give consent and to withdraw from participating in this study at any juncture. There will be no repercussions to you as a person, nor will it affect your medical care.

Appendix II: Hati ya Habari ya Mgonjwa

MADA YA UTAFITI: KIWANGO CHA MAFANIKIO NA SHIDA ZINAZOAMBATANA NA UKAGUZI WA MIRIJA YA UZAZI KWA KATHETA NA FLUOROSCOPY KATIKA MATIBABU YA UJENZI WA MISHIPA YA UZAZI ILIYOZIBA.

Mchunguzi mkuu\mshirika wa taasisi: Dkt. Violet Wangui Kabute, Chuo Kikuu cha Nairobi

Wasaidizi wa Mchunguzi mkuu\mshirika wa taasisi:

- Dkt. Jasper Muruka, Hospitali kuu ya Kenyatta
- Dkt. Timothy Musila Mutala, Kitengo cha Uchunguzi na Dawa ya Mionzi, Chuo Kikuu Cha Nairobi.

Utangulizi

Jina langu ni Dkt. Violet Wangui Kabute, mimi ni mwanafunzi wa uzamili katika chuo kikuu cha Nairobi kitengo cha Uchunguzi na Dawa ya Mionzi. Naendeleza mafunzo yaliyoko hapo juu. Nakuomba uweze kushiriki katika mafunzo haya. Umuhimu wa hii fomu ya idhini nikukusaidia kuamua kama utajihusisha na haya mafunzo au la. Tafadhali isome fomu hii na kuielewe na kama una maswali yoyote kuhusu haya mafunzo unaweza uliza. Mchunguzi mkuu atakuwa na nafasi ya kujibu maswali yote.

Hata kabla hujajihusisha na utafiti huu, daktari wako ameshakuagiza kufanya ukaguzi wa mirija ya uzazi kwa katheta (Fallopian Tube Catheterization) na utaratibu wa X-ray (Fluoroscopy guided) kwa kutibu mirija ya uzazi iliyozibwa. Mchunguzi mkuu ataweza kuona na kuchambua habari ya klinki na matokeo ya picha yatakayoambatana na matibabu haya. Hakuna gharama za ziada au hatari zinginezo zitapatikana kwa kushiriki katika utafiti huu ila zinazohusika na matibabu haya.

Asili Ya Mafunzo

Mafunzo haya yanahusisha kukaguliwa kwa mirija ya uzazi (Fallopian tube) kwa katheta (Catheterization), na utaratibu wa X-ray (fluoroscopy) uliofanywa kwa wanawake kutibu mirija ya uzazi iliyoziba na kuandika matokeo mwishoni mwa utaratibu.

Lengo La Mafunzo

Lengo la utafiti huu ni kutathmini jinsi mafanikio na shida zinazoambatana na ukaguzi wa mirija ya uzazi kwa katheta na fluoroscopy katika matibabu ya ujenzi wa mishipa ya uzazi iliyoziba.

Taratibu Za Mafunzo

Kabla ya utaratibu utahitajika kujibu maswali machache yanayohusiana na hali yako kwa

mfano; umri wako, muda na aina ya utasa, matibabu yoyote ya njia ya uzazi. Utaratibu ni mfupi na usumbufu wa wastani. Utalala chali kwenye meza ya X-ray. Dawa za kukusaidia kupumzika na kukuepusha na maumivu zitatolewa kupitia njia ya IV (intravenous) iliyowekwa kwenye mshipa mkononi mwako. Speculum itawekwa ndani ya uke wako kuishika wazi na bomba ndogo ya chuma (HSG cannula) itawekwa ndani ya kizazi (uterus) chako. Dawa ya X-ray itakayosaidia mirija yako ya uzazi kuonekana wazi kwenye picha ya X-ray itaingizwa kupitia bomba hilo. Itaonyesha uzuizi wowote ambao unaweza kuwa kwenye mrija wako wa uzazi na kuongoza utaratibu wote. Bomba nyembamba, rahisi kubadilika (catheter) iliyo na waya wa mwongozo ndani yake itawekwa kupitia kizazi chako ndani ya uterasi na hadi ufunguzi wa mrija wako wa fallopian. Mwongozo huu hutumiwa kwa uangalifu kufungua bomba. Rangi huletwa ndani ya mirija ya fallopian ili kuangalia ikiwa utaratibu ulifanikiwa. Kwa kuwa tunatamani kutathmini matokeo ya utaratibu, tutashukuru ikiwa utakubali kuwasiliana baadaye kwa kutoa nambari yako ya simu.

Kujitolea Kwa Kushiriki

Uandikishaji katika utafiti ni wa hiari tu na uko huru kujiondoa kutoka kwa utafiti wakati wowote wakati wa utafiti bila udhalimu au hofu ya athari.

Usiri

Usiri utazingatiwa kwa kiwango kinachoruhusiwa na sheria kwani habari yako yote itasimbwa na data zote zilizorekodiwa zitapatikana.

Faida Za Mafunzo.

Utafiti huo na kuwezesha uundaji wa data za mitaa kutathmini kiwango cha mafanikio ya catheterization ya mrija wa uzazi kwa matibabu ya utasa wa neli. Matokeo kutoka kwa utafiti huu pia yatatoa miongozo inayotokana na ushahidi kwa usimamizi wa utasa katika mkoa wetu. Hakuna gharama ya ziada itakayopatikana isipokuwa ile iliyopendekezwa na daktari wa msingi.

Hatari Za Mafunzo

Hakuna gharama za ziada au hatari zinginezo zitapatikana kwa kushiriki katika utafiti huu ila zinazohusika na matibabu haya.

Hatari zinazowezekana za catheterization ya mrija wa uzazi ni pamoja na:

1. Usumbufu wa wastani hadi wastani wakati wa utaratibu ambao utapunguzwa na dawa inayotolewa wakati na baada ya utaratibu.
2. Shimo ndogo (utoboaji) kwenye bomba la mrija wa uzazi.
3. Maambukizi ya pelvic ambayo yatapunguzwa kwa matumizi ya dawa za kuzuia

maambukizi.

4. Shida kwa sababu ya rangi ya X-ray, pamoja na athari ya mzio au uharibifu wa figo.
5. Mimba ya Tubal, ambapo yai lililorutubishwa hukaa na kukua katika mrija wa uzazi.
6. Mionzi yatokanayo na viungo vyako vya uzazi, ingawa hatari ya hii ni ndogo.
7. Mirija yako ya uzazi inaweza kuzuiwa tena. Ikiwa hii itatokea, utahitaji kuwa na utaratibu sawa au tofauti katika siku zijazo.

Haki ya Kujiondoa

Uko huru kukataa kutoa idhini na kujiondoa kushiriki katika utafiti huu wakati wowote. Hakutakuwa na athari kwako kama mtu, wala haitaathiri huduma yako ya matibabu.

Appendix III: Informed Consent Certificate

I hereby confirm that the above-named doctor has explained the study to me in a language that I understand, and the benefits and risks involved.

I understand that my participation is voluntary, and I have not been forced or coerced to participate.

I understand that I can refuse to participate or opt out of the study at any point without any effect to my medical care.

I understand that I will not receive neither I am entitled to any compensation monetary or otherwise for taking part in this study.

I understand that all personal information availed for purposes of this study will be kept confidential.

I do hereby consent to take part in the above study.

Patient number _____ Signature _____

Date _____

I certify that the patient has understood and consented to participate in the study.

Dr Violet Wangui Kabute

Signature _____ Date_____

In case of any queries or if you require further information, please contact any of the following contacts:

Contacts:

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KNH-UON Secretariat

Kenyatta National Hospital and University of Nairobi

Ethics and Research Committee

College of Health Sciences

Telephone Number: (254- 020) 2726300 EXT 44355

Email: uonknh_erc@uonbi.ac.ke

Appendix IV: Hatua ya ukubali

Ninathibitisha kuwa daktari aliyetajwa hapo juu amenielezea utafiti huo kwa lugha ambayo ninaelewa na faida na hatari zinazohusika.

Ninaelewa kuwa ushiriki wangu ni wa hiari, na sijalazimishwa au kulazimishwa kushiriki.

Ninaelewa kuwa ninaweza kukataa kushiriki au kuchagua kutoka kwa utafiti wakati wowote bila athari yoyote kwa huduma yangu ya matibabu.

Ninaelewa kuwa sitapokea wala sina haki ya kulipwa fidia yoyote au vinginevyo kwa kushiriki katika utafiti huu.

Ninaelewa kuwa habari zote za kibinafsi zinazopatikana kwa madhumuni ya utafiti huu zitahifadhiwa kwa siri.

Ninakubali hivi kushiriki katika utafiti hapo juu.

Nambari ya simu ya mgonjwa_____ Sahihi_____

Tarehe_____ Sahihi_____

Ninathibitisha kwamba mgonjwa ameelewa na kukubali kushiriki katika utafiti.

Dkt.Violet Wangui Kabute

Sahihi_____ Tarehe_____

Kwa maswali au mawasiliano zaidi unaweza kuwasaliana na wafuatao:

Mtafiti Mkuu:

Dkt. Violet Wangui Kabute

Idara ya Uchunguzi wa Uchunguzi na Dawa ya Mionzi

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Sekretarieti ya KNH-UON

Hospitali ya Kitaifa ya Kenyatta na Chuo Kikuu cha Nairobi.

Kamati ya Maadili na Utafiti

Chuo cha Sayansi ya Afya

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Appendix V: Data Collection Tool

TUBAL RECANALISATION SUCCESS RATE AND COMPLICATIONS OF FLUOROSCOPY GUIDED TRANSCERVICAL FALLOPIAN TUBE CATHETERIZATION IN TREATMENT OF PROXIMAL TUBAL OBSTRUCTION

Section 1: Demographic data

Unique number ……

Age/ Year of birth …….

Section 2: Clinical summary

Duration of infertility ……

Type of infertility:

- Primary infertility
- Secondary infertility

Section 3: Spectrum of pre-procedure HSG findings

Abnormality	**Right FT**	**Left FT**
Fallopian tube patency		
Tubal occlusion site -Proximal		
-Distal		
Pelvic adhesions		
Uterus & cervix outline		

Impression: …….

Section 4: Fallopian Tube Catheterization

Was FTC attempted:

- Yes
- No

Indication for FTC

- Bilateral PTO
- Unilateral PTO
- Others ……

Tubal patency achieved:

- Bilateral patency
- Unilateral patency
- None / unsuccessful catheterization

Section 5: FTC complications

Immediate:

- Tubal perforation Yes/ No

Subacute:

- Prolonged PV bleeding Yes/No
- Pelvic pain Yes/ No
- PV discharge Yes/ No

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Ref: KNH-ERC/A/228

28th June, 2021

KENYATTA NATIONAL HOSPITAL
APPROVED
28 JUN 2021
KNH/UoN-ERC
P. O. BOX 20723 - 00202, NAIROBI

Dr. Violet Wangui Kabute
Reg. No.H58/10686/2018
Dept of Diagnostic Imaging & Radiation Medicine
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Kabute

RESEARCH PROPOSAL: **TUBAL RECANALIZATION SUCCESS RATE AND COMPLICATIONS OF FLUOROSCOPY GUIDED TRANSCERVICAL FALLOPIAN TUBE CATHETERIZATION IN TREATMENT OF PROXIMAL TUBAL OBSTRUCTION (P73/02/2021)**

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 28th June, 2021 – 27th June, 2022.

This approval is subject to compliance with the following requirements:

i. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
ii. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
iii. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affect 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 KNH- UoN ERC for each batch of shipment.
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.

This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M. J. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chair, KNH- UoN ERC
The Dean, School of Medicine,UoN
The Chair, Dept of Diagnostic Imaging & Radiation Medicine, UoN
Supervisors: Dr. Timothy Musila Mutala, Dept.of Diagnostic Imaging & Rad. Medicine, UoN
Dr Jasper Muruka, Dept.of Diagnostic Radiology, KNH