

**OUTCOMES OF MEDICAL VERSUS SURGICAL MANAGEMENT OF FIRST
TRIMESTER INCOMPLETE ABORTION AMONG WOMEN ADMITTED
AT KAMPALA INTERNATIONAL UNIVERSITY
TEACHING HOSPITAL**

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OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY OF
KAMPALA INTERNATIONAL
UNIVERSITY**



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DECLARATION

I, **Victor Tetty Otieno**, hereby declare that the work here in this report is out of own effort through literature search from publications but not necessarily full texts from those sources and has never been submitted for award of any degree in this University.

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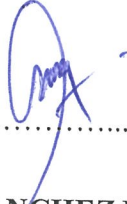
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APPROVAL

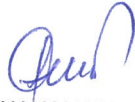
We have supervised **Dr. VICTOR TETTY OTIENO** in the process of developing this report entitled **outcomes of medical versus surgical management of first trimester incomplete abortion among women admitted at Kampala International University Teaching Hospital** and we hereby approve this work to be forwarded to the postgraduate department for consideration.

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DEDICATION

A great deal of time has been incurred in the course of developing this report. I dedicate this work to my grandmother Melenia and parents Dan Onyango, Rose Nyambura and Rose Auma. I also dedicate this work to my siblings Evans sandley Otieno, Emmaculate Tatu Otieno and Melanie Munyori. To the rest of my family members especially my grandfather (Sir John), my uncle (Henry), Aunties (Janet, Mercy and Lilly) and my cousins, this work is dedicated to you as a result of how much you put in to get me here.

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OPERATIONAL DEFINITIONS

Medical management of abortion: Use of misoprostol (PGE1 analogue) to manage abortion.

Surgical management of abortion: Use of Manual Vacuum Aspiration to achieve complete uterine evacuation.

Induction – abortion time: Refers to the duration between initiation of medical management of abortion and the time it takes for complete uterine evacuation to occur.

Expectant management of abortion: Refers to watchful waiting for the body to exclude the remaining products of conception without intervening.

Incomplete abortion: Part of products of conception have been expelled leaving part of the products within the uterine cavity at time of presentation to hospital.

Spontaneous abortion: Abortion occurring without human intervention.

Missed abortion: Foetal cardiac activity is absent but all products of conception are still within the uterine cavity.

Threatened abortion: Refers to when the process of abortion has started but still the pregnancy can be salvaged with appropriate interventions.

Primary outcome (effectiveness): Ability of a given method to achieve completion of uterine evacuation within 48 hours evidenced by volume of retained products of conception of <30mls on trans abdominal pelvic ultrasound scan.

Secondary outcomes: Other factors to be analysed apart from effectiveness. These include bleeding duration, misoprostol side effects, infections, pain level, trauma to genito-urinary tract and hospital stay.

LIST OF ACRONYMS

ANC	Antenatal care
ACOG	American College of Obstetrics and Gynaecologists.
BT	Blood transfusion
CBC	Complete blood count
D&C	Dilatation and curettage
FP	Family planning
GUT	Genitourinary tract
HCG	Human chorionic gonadotropin
ICU	Intensive care unit
KIU – TH	Kampala International University Teaching Hospital
MVA	Manual vacuum aspiration
OPD	Outpatient department
PGE1	Prostaglandin E1
SPSS	Statistical package for the social sciences.
UDHS	Uganda Demographic and Health survey
W.H.O	World Health Organisation.

ABSTRACT

Background: Outcomes of surgical versus medical management of first trimester incomplete abortion are poorly documented in Uganda and it is important to guide clinical practice.

Objectives: To compare the effectiveness, secondary outcomes and satisfaction level between surgical and medical management of first trimester incomplete abortion among women admitted at Kampala International University Teaching Hospital.

Methodology: Prospective open labelled randomized clinical trial of 100 consecutively recruited participants, using investigator administered questionnaire conducted from June to September, 2018. Ethical clearance was obtained from Research and Ethics Committee of Kampala International University Teaching Hospital (UG REC O23).

Results: The effectiveness of surgical management was statistically significant higher than that of medical management (RRR=11.7%; $p=0.043$). Majority in the medical arm reported mild pain (64% versus 4%; $p<0.01$) while most of those in surgical arm reported severe pain (78% versus 8%; $p<0.001$). Bleeding was prolonged in the medical arm method with majority of those in surgical arm reporting bleeding for <6hours (94% versus 46%; $p=0.0002$). Although medical method had longer bleeding, it was associated with lesser symptoms of headache, dizziness, syncope and blood transfusion. 90% of those in medical arm and only 50% of those in surgical method would recommend the method assigned ($p<0.001$). Fever, chills and nausea were more common in medical method. Average hospital stay was longer in medical method ($p=0.03$). Only 1 participant in surgical arm developed infection while no patient had genitourinary trauma. Participants reported more satisfaction with medical as compared to surgical management.

Conclusions: Surgical management is more effective than medical management. Although Medical management has prolonged expulsion bleeding, prolonged hospital stay and increased fevers, chills and nausea that are self-limiting, it has reduced pain. Most patients are satisfied with and would recommend medical management.

Recommendations: Although surgical method has a short term higher effectiveness, more studies are needed to ascertain long term effectiveness. Medical management can be used as an alternative especially to patients who want to avoid anaesthesia and surgery in low socioeconomic settings. Patients should be allowed autonomy to make the decision on which method they would be satisfied with.

Key words: Incomplete abortion, effectiveness, secondary outcomes, satisfaction.

CHAPTER ONE

INTRODUCTION

1.1 Background

Abortion refers to termination of pregnancy before viability. Viability varies from place to place but in Uganda it is considered at 28 weeks of amenorrhea. First trimester abortion refers to abortion occurring within the first 12 weeks of amenorrhea (Shokry *et al*; 2014). Abortion may be spontaneous without human intervention or may be induced. In some countries, abortion is legalized while in others, like Uganda, it is considered unlawful unless it is for medico - legal reasons (Larsson *et al*; 2015). Estimation of abortion incidences in the world is not conclusive but currently the rates have been falling in the developed countries while it has remained constant in developing countries in the last decade (W.H.O, 2014). According to World Health Organization, the rate currently is at 27 per 1000 women in developed countries while in the developing countries is at 34 per 1000 women (Department of Reproductive Health and Research WHO, 2012) . This study further found out that up to 88% of spontaneous abortions occur in developing countries. In Africa, abortion incidence is at 34 per 1000 women annually as stated above. The greatest incidence is found in Eastern Africa at 2.5 million cases annually (Guttmacher, 2013). Abortion is the most common early pregnancy complication occurring in about 54 women per 1000 pregnant women in Uganda (Guttmacher, 2013). This is higher than the average rate in East Africa of 34 abortions per 1000 pregnancies (Department of Reproductive Health and Research WHO, 2012). Maternal mortality rate in Uganda is among the highest in the world, with 336 maternal deaths per 100,000 live births, 26% of which are attributed to abortion (Uganda Bureau of Statistics, 2016).

Out of all the abortion types, incomplete abortion is the most common presenting type to gynaecology outpatient department and wards. In this type, part of the products of conception are still within the uterine cavity at the time of presenting to the hospital. Incomplete abortion is closely related to unsafe abortion especially in countries where abortion is restricted, with women seeking pregnancy termination from unskilled providers, where procedures are performed in environments lacking minimal medical standards or both. These conditions increase the likelihood of abortion complications and mortality. At Kampala International University Teaching Hospital (KIU-TH),

medical records data suggest that incomplete abortion accounts for up to 40% of total gynaecology admissions (October – December, 2016).

Safe and effective treatment of incomplete abortion is an effective way of reducing abortion related mortality particularly in areas where legal abortion is restricted. Whether spontaneous or induced, management involves uterine evacuation either through expectant management or active management. Although expectant management allows for spontaneous evacuation of the uterus, it is not preferred by most of the women and providers due to its low efficacy and the unpredictable interval of spontaneous expulsion (Odland *et al*; 2018). Active management may be through medical or surgical intervention. For optimal management, women should be provided with a choice between the two methods (W.H.O, 2014). Surgical management has been readily acceptable since early 19th century when first curettage was described and performed worldwide. This was later adopted as the first line treatment for evacuating the uterus worldwide including in Uganda (W.H.O, 2014). The procedure is believed to reduce hemorrhage and infection while providing immediate evacuation up to 100% (Yonke & Leeman, 2013). However, surgical methods are believed to be associated with many immediate complications including, but not limited to, cervical trauma, uterine perforation, endometritis, injury to bladder, gut, rectum and anesthesia complications. Some of the remote complications are uterine synachiae, subfertility, ectopic pregnancy, morbid placenta adherence, placenta previa, preterm labor, spontaneous abortion and low birth weight (Ilboudo *et al*; 2015). The other rate limiting step in having surgical method used universally is that it requires skilled health workers specifically trained, special equipment, sterilizing equipment and anesthesia that may not be readily available (Panta *et al*; 2013).

Currently, management of first trimester abortion is mainly by medical or surgical methods. World Health Organization recommends use of Dilatation & curettage (D&C) or Manual Vacuum Aspiration (MVA) for surgical management but MVA is preferred to D&C. Medical management in first trimester as per W.H.O guidelines depends on whether mifepristone is available or not. If mifepristone is available an oral dose of 200mg then followed 24 – 48 hours later by misoprostol 800micrograms vaginally, buccal or sublingual or 400micrograms orally is the recommended treatment. If mifepristone is unavailable then misoprostol 400micrograms repeated 3hourly up to 5 doses can be given (W.H.O, 2014).

The W.H.O in April 2009 included the use of prostaglandin E1 (PG E1) analogue for medical management of abortion that is a safe effective alternative up to 99% effective (Taylor *et al*; 2011). Prior to this, other medical regimes like methotrexate and mifepristone were being used in different ways. This method can be administered by low and middle providers. Medical method is thought to work well especially in areas lacking skilled personnel, uterine abnormalities, areas with no surgical instruments or anesthetic capability and patients already with established complications of surgical method like Asherman syndrome, subinfertility, ectopic pregnancy and morbid placenta adherence. Also, the ability of misoprostol to be kept at room temperature, being inexpensive and being widely available and easier to administer, makes it favorable in resource - limited areas (Dah *et al*; 2011). Use of misoprostol would reduce the healthcare burden by probably limiting the burden of highly skilled surgical workers, reducing the need for surgical supplies, surgical wards, sterilization and anesthesia (Ilboudo *et al*; 2015). Misoprostol also has the added advantage of being readily acceptable to women as it is less medicolised and less invasive (Gerds *et al*; 2013). However, this method is not without its inherent complications like need for emergency surgical evacuation at 2%, hemorrhage, pain, increase in induction – abortion time and increase in analgesia requirement (Bhadra & Deb, 2013). Unlike surgical evacuation, the risk of perforation, cervical trauma, synachiae, placenta previa and accreta are reduced if not absent as per the same study.

No study has been done in Bushenyi district which is a rural setting comparing the outcomes of medical and surgical management of first trimester incomplete abortion. This study is therefore meant to find the practicality of using either of the methods exclusively or interchangeably.

1.2 Problem Statement

Incomplete abortion is a common complication affecting about 20% of pregnancies in the world (W.H.O, 2012) . In the world, 13% and East Africa, 18% of maternal deaths are attributed to abortion (W.H.O, 2012). Abortion is a major cause of maternal mortality in Uganda accounting for 26% of all maternal deaths (Guttmacher, 2013). This therefore means that the maternal deaths in Uganda are higher as compared to East Africa and the world. The demand for abortion is high due to unintended or unwanted pregnancy yet abortion is prohibited by law in Uganda unless it is done to save the life of the mother. One in two pregnancies in Uganda is unintended and about one in three of this pregnancies end up in abortion (Guttmacher, 2013).

Management decision on whether to use medical or surgical methods has been a controversial topic in Uganda and the world in general with no local studies comparing effectiveness and secondary outcomes between the two methods. There is also a debate on whether these methods can be used interchangeably or exclusively (Kim *et al*; 2016).

In KIU-TH, up to 98% of patients are managed surgically locking out those that would benefit from medical management (KIU- TH hospital records between September and December 2017). Those who would benefit from medical more than surgical management include; those with history of sub infertility, ectopic pregnancy, morbidly adhered placenta, immunosuppressed, bad obstetric history and those who prefer less invasive procedure. By exclusively managing these patients surgically, they fail to get the best available treatment option.

Use of surgical method exclusively up to 98% of the cases in KIU-TH may also be expensive due to the need for surgical ward, presence of skilled surgical providers, administration of anaesthesia and use of special equipment in each case (KIU-TH records and finance rates). This cost is passed down to the women thereby causing inflated public health accounts. This would not be the case probably with medical management of abortion.

Due to absence of studies done comparing the two methods in Gynaecology ward in KIU – TH including while using our own available brand of misoprostol, we set out to determine the outcomes of medical management as compared to surgical management of first trimester incomplete abortion in a teaching hospital in rural Uganda.

1.3 Objectives

1.3.1 General Objective

To compare the effectiveness, secondary outcomes and satisfaction level between surgical and medical management of first trimester incomplete abortion among women admitted at KIU-TH.

1.3.2 Specific Objectives

- i. To determine the comparative effectiveness of medical and surgical management of first trimester incomplete abortion among women admitted in KIU-TH.

- ii. To compare the secondary outcomes encountered among women admitted in KIU-TH when first trimester incomplete abortion is managed using medical or surgical methods.
- iii. To compare the level of satisfaction with the method of management assigned to women with first trimester incomplete abortion admitted in KIU-TH.

1.4 Hypotheses

1.4.1 Null Hypothesis

Surgical management of incomplete abortion by MVA is not more effective than medical management of incomplete abortion using 800 microgram of misoprostol in the posterior vaginal fornix to maximum of 3 doses 6 hourly.

1.4.2 Alternative Hypothesis

Surgical management of incomplete abortion by MVA is more effective than medical management of incomplete abortion using 800 microgram of misoprostol in the posterior vaginal fornix to maximum of 3 doses 6 hourly.

1.5 Justification of the study

Most of the studies done comparing use of medical versus surgical management of first trimester incomplete abortion have shown that medical use is mostly done in urban centers where there is good patient follow up and higher spending power unlike in rural settings where follow up and compliance to instructions including on antibiotic prophylaxis is a challenge (Chigbu *et al*; 2012). This has been attributed to different factors but mainly due to health workers concerns of perceived reduced efficacy of medical management, the need for more follow up and the need for second surgical method for those on medical management with primary failure. This therefore means that any method employed in rural settings should achieve evacuation of retained products of conception as early as possible since follow up is not readily feasible. This study was done in rural setting with review of completion within 48 hours unlike prior studies with longer duration of review and so will help in confirming the practicality of either using both of the methods or inability to use any of the methods in a rural setting.

At KIU –TH, results of this study shall highlight the suitability or drawbacks of medical and surgical methods and therefore form the basis for recommending implementation of either surgical

or medical methods. This can be used interchangeably or exclusively to specific cases depending on prevailing conditions like lack of enough skilled medical personnel, shortage of surgical equipment, those with established sub-infertility, those with history of ectopic pregnancy or uterine abnormalities, management of incomplete abortion in hospitals with no theatres or no good follow up and hospitals with strained facilities. It was therefore important that the study be undertaken to ascertain what is envisaged above.

1.6 Significance of Study

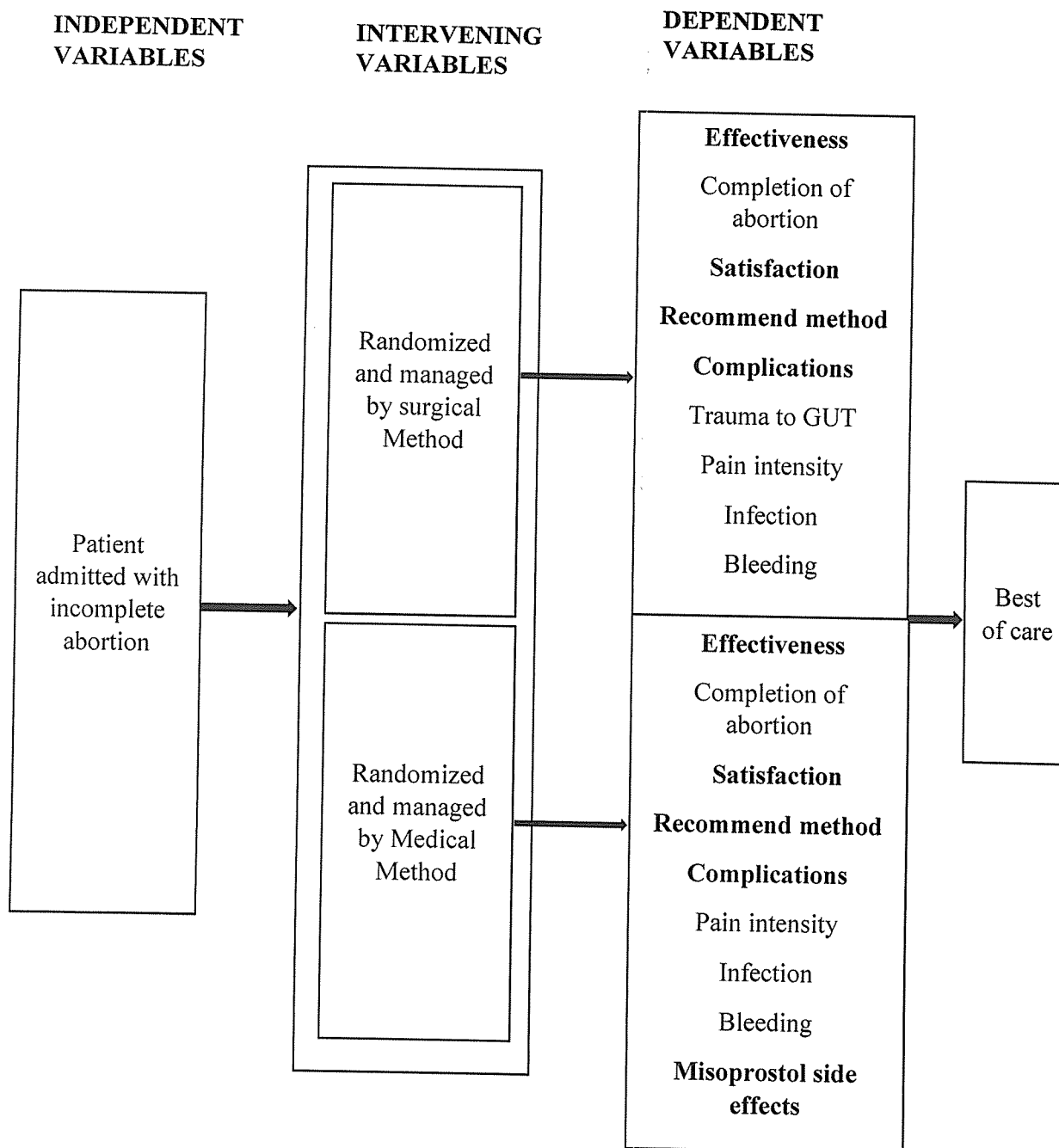
At the community level, this study will impart knowledge to the community at large when it comes to management of abortion when using both medical and surgical methods and form the basis for decision - making by the community. The findings of this study regarding the effectiveness and common complications can also form the basis for policy formation and implementation at the regional level.

Abortion commonly affects younger women who are at the peak of their reproductive life, therefore, offering the best available method of management chosen by the mothers themselves is paramount. With this study mothers will be able to make an informed choice on the method of management they consent for.

The information gathered from this study will also form the basis for future research being undertaken along the same topic.

1.7 Conceptual Framework

Figure 1: CONCEPTUAL FRAMEWORK



1.8 Scope of Study

1.8.1 Geographical scope

The study was conducted at KIU-TH that is found in Ishaka-Bushenyi Municipality, Western Uganda. It is a private, not - for - profit hospital, approximately 5 kilometres from Bushenyi district headquarters as well as Bushenyi Health Centre IV which is a government unit. The hospital is close to Ishaka Adventist and Comboni Hospitals in the west which are church founded hospitals run by general practitioners. In the South, it is bordered by Kitagata hospital in Shema district also run by general practitioners. KIU-TH therefore acts as a referral centre for these neighbouring hospitals.

1.8.2 Content scope

The study included women admitted at gynaecology ward in KIU -TH with a confirmed diagnosis of first trimester incomplete abortion whether spontaneous or induced. This is because clinically it's very difficult to determine whether the abortion is induced or spontaneous.

1.8.3 Time Scope

The study was limited to eligible women from the time of diagnosis of incomplete abortion and initiation of specific management to 48hours (successful evacuation) or 72 hours (primary failure) post initiation of management. Study was conducted between June and September 2018 and therefore lasted for a period of 4 months.

CHAPTER TWO

LITERATURE REVIEW

2.1 Effectiveness of Medical and Surgical Procedures

Effectiveness of a given method is the ability of the method to cause complete expulsion of all products of conception without a second method being employed. There is a large variation in success rate of medical in comparison with surgical management of first trimester abortion (Shochet *et al*; 2012). However, the effectiveness of both methods is generally considered high. There is strong evidence to suggest that the primary success rate of surgical method is slightly higher but not statistically significant being given at 100% and 94.4% for surgical and medical management respectively (Shochet *et al*; 2012). Several factors have been postulated as to why there is great variability in the above results. Some of these factors include; brand of PGE1 used and route of administration with vaginal route thought to be superior to oral route of administration (Nautiyal *et al*; 2015). Also, successful evacuation varies depending on gestation and parity with the success of medical treatment regarded as higher in nulliparous than multipara women (Yonke & Leeman, 2013). Regarding routes of administration, vaginal and sublingual routes are generally considered to achieve higher bioavailability than oral route. Vaginal administration results in greater contractility and the intensity continues to rise for at least four hours. It has been suggested that adding water to misoprostol would increase absorption. However, no confirmation of this has been found. Sublingual route leads to initial high intensity contractions but they diminish within 2-3 hours (Yonke & Leeman, 2013).

A review of several studies of misoprostol use in management of incomplete abortion shows varying effectiveness with dosages ranging from 400 – 1200 micrograms. Chung studied 400µg orally every 4 hours to a maximum of 1200µg and reviewed the success on the same day. Overall success with misoprostol use was at 50% requiring additional surgical method in over 50% of participants. Other studies compared oral and vaginal misoprostol with 800µg repeated doses and effectiveness assessed on the same day and this higher doses slightly showed an increase of up to 60% (Diop & G.A, 2012).

Studies in which the efficacy was assessed later (3-15 days) following initial treatment have shown considerably higher rates ranging from 65% - 95%. Gronlund *et al*; (2012) compared 400µg

vaginal misoprostol to expectant management and achieved a 90% success rate on assessment on day 8 – 14. Another study compared single dose 600µg to two doses 600µg 4 hours apart and it showed no difference in effectiveness. Although use of misoprostol promises to have an impact on public health, it cannot be used in some patients and in others it requires caution. Absolute contraindications of misoprostol use in incomplete abortion include known allergy to misoprostol and other prostaglandins, unstable haemodynamic status and signs of pelvic infection. It should be used with caution in those with coagulation disorders and those on anticoagulation treatment. Misuse of misoprostol to procure illegal abortion is also a challenging factor.

Surgical methods of abortion include vacuum aspiration and D&C. Vacuum aspiration involves use of electrical or manual vacuum. It is generally considered safer and less painful than D&C and it is widely used in many countries in first trimester incomplete abortion management (W.H.O, 2014). Usually, surgical method is performed under anaesthesia that may be general anaesthesia, Para cervical block and conscious sedation. This may lead to anaesthetic complications in up to 2% of cases. Royal College of Obstetrics and Gynaecology considers suction curettage to be safer under local anaesthesia than under general anaesthesia.

2.2 Secondary Outcomes of Medical and Surgical Management of First Trimester Abortion

2.2.1 Bleeding

Most clients report some form of bleeding during the first 48 hours after initiation of treatment; 100% for medical and 56.3% for surgical (Chigbu *et al*; 2012). Further bleeding after 48 hours of initiation of treatment is reported commonly in medical treatment as compared to surgical treatment and even recurrent bleeding may occur with both treatment 50% vs. 6.3% (Chigbu *et al*; 2012). After 2 weeks however, no client expresses bleeding in both groups. Generally the incidence of severe bleeding is more in medical than surgical method (Shokry *et al*; 2014).

With surgical management, most clients report excessive bleeding during evacuation that may complicate the procedure (Niinimäki *et al*; 2009). Bleeding occurs because the procedure involves mechanical evacuation and therefore causes bleeding from raw sites in the endometrium. Bleeding may also occur due to perforation of the uterus or injury to GUT (Odland *et al*; 2018). It is also common for these patients to have hypovolemic shock due to sudden abrupt loss of blood unlike

in medical management. However, with medical management they have protracted minimal menstrual like bleeding and therefore it is devoid of hypovolaemic shock (Odland *et al*; 2018).

2.2.2 Trauma to Genitourinary Tract (GUT)

This commonly occurs with surgical management and never with medical management. The most frequently injured organs include vagina, perineum, bladder, urethra, cervix, uterus and rectum (Gerdtz *et al*; 2013). These injuries can vary from simple laceration to perforation with fistula formation. The incidence of the above injuries is variable and determinants include the clinician's skill, uterine position since a retro-verted uterus is commonly injured and gestation. Usually, uterine perforations are recognised when you pass a uterine sound deep into the pelvis without resistance. For small perforations, expectant management is preferred with antibiotics cover and close monitoring preferably in the ward. Large, extensive and wide perforations may warrant laparotomy plus repair of the uterus or hysterectomy. This not only increases morbidity and mortality but also increases hospital stay. It also increases cost of management and in case hysterectomy is done, it then prevents further conception that may be a challenge to a young mother.

Generally, surgical methods have high tendency of trauma about 5.6% (Kapp *et al*; 2013) as compared to medical that is insignificant since it is not invasive. With medical method however, some instances of uterine rupture have been reported with excessive doses of misoprostol, previous scarred uterus, poorly monitored medical abortion and higher gestation. However, this is very rare (W.H.O, 2014).

2.2.3 Infection

There is a wide variation in infection rates depending on different factors. However, many researchers have shown that the incidence is higher in developing countries as compared to developed areas (Moreau *et al*; 2011). Because medical method is non-invasive, there is an expectation that infection may be less in medical than surgical methods. Still the risk is present in medical management due to retained products of conception for a longer period than in surgical management which acts as a fertile ground for bacteria to thrive. The incidence in medical management is less than 1% and in surgical worldwide it is about 0.1 – 4.7% (W.H.O, 2014). The most common infection that occurs usually is endometritis accounting for 49% of all infections as

per the same study. These infections are mainly bacterial but may also be viral, fungal or protozoal (Melese *et al*; 2017). Other factors include surgical technique, antiseptic used, induction – abortion time, use of prophylactic antibiotics, duration before presenting to hospital and clients immune system (Melese *et al*; 2017).

If prophylactic antibiotics are given, it reduces the incidence of pelvic infection by 40-90% (Cunningham *et al*; 2014). In our setting, women who undergo surgical management are likely to receive antibiotics for suspected endometritis than those on medical management. However, most studies have not found statistical significance between infection rates in incomplete abortion managed by medical or surgical methods (Jones *et al*; 2010). Other studies though, have found that rates of infection may be higher in either medical or surgical methods. Rarely, distant infections following sepsis like endocarditis and meningitis that are potentially fatal may develop. Fatal septic shock syndrome may also occur with organisms like clostridia and Gram - positive bacilli with an incidence of 1/100,000 (Ashok *et al*; 2002).

2.2.4 PGE1 Side Effects (Fever, Diarrhoea, Vomiting, Chills)

These are commonly associated with misoprostol. They are usually mild and self-limiting. However, they may affect patients to an extent of declining or stopping the medical method as a whole (Diop & G.A, 2012). Irritation of the GIT in the surgical method and infections may also give the same symptoms and these are usually picked up with proper physical examination, laboratory investigations and imaging studies. Patients on any of the treatments may experience the above symptoms: fever occurs in 15% versus 9%, nausea in 8% versus 7%, vomiting in 6% versus 6%, diarrhoea in 3% versus 0% in medical and surgical treatment respectively (FCRA, 2010). Apart from this, there are women who may not be able to use misoprostol including those with misoprostol or other prostaglandins allergy thereby locking them out (Ngoc *et al*; 2013).

2.3 Satisfaction and Recommendation for Use

When choosing a method of management of incomplete abortion, being given a choice as discussed earlier is perceived as extremely important by majority of women (Moreau *et al*; 2011). Previous studies have also shown that women are more likely to be satisfied by a method if they personally choose it. Studies have indicated levels of satisfaction at 84.3% and 55.6% for medical

and surgical participants respectively with up to 90% recommending medical management and only 54% recommending surgical management (Ngoc *et al*; 2013).

In a different survey, the main reasons given as to why medical method is preferred includes avoiding anaesthesia, the method being perceived to be safer and more natural, as well as providing more privacy and autonomy and being less invasive (Niinimäki *et al*; 2009). A Danish partially randomised study found that medical method was regarded as being more painful and satisfaction with care was relatively inversely related to the level of pain.

2.4 Outcome of Medical versus Surgical Management of First Trimester Incomplete Abortion

With regards to various studies, except from injury to GUT that is commonly found in surgical management, all the other dependent variables may be low or high in any of the methods (Shokry *et al*; 2014). With this study, the results found will then help paint a picture of the local statistics on effectiveness, bleeding, pain intensity, infection, satisfaction, hospital stay and need for readmission and whether patients would recommend a given method or not.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Study Design

An open labelled prospective randomised clinical trial was carried out where the participants (women) were randomised to surgical and medical management arms. On each arm, women were managed with either method and followed up for outcomes.

3.2 Selection Criteria

3.2.1 Inclusion Criteria

Women with first trimester incomplete abortion admitted in gynaecology ward who are;

1. Hemodynamically stable with no signs of hypovolaemia or shock due to excessive bleeding.
2. In first trimester of pregnancy with weeks of amenorrhea at ≤ 12 weeks.
3. Having per vaginal bleeding with retained products of conception suggestive of incomplete abortion.
4. No contraindication for misoprostol use like allergy to prostaglandins and previous uterine scars.
5. No major organ disease like renal, cardiovascular, nervous, liver, hematological or immunosuppressive disease.

3.2.2 Exclusion Criteria

1. Women with evidence of infection: temperature < 36 or > 38 degrees celsius, Pulse Rate > 100 , Respiratory rate > 20 respirations/min and offensive per vaginal discharge.
2. Women with structural uterine abnormalities like unicornuate or bicornuate uterus and uterine septum as this complicates surgery.
3. Women with previous fresh uterine scars (less than 18 months) since they are at increased risk of uterine rupture
4. Patients with ≥ 2 previous scars as this increases the risk of uterine rupture.

5. Patients with more than three abortions as this would alter the findings on satisfaction and secondary outcomes.

3.3 Study Area

The study was conducted in the gynaecology ward at KIU-TH. KIU-TH is located in Ishaka-Bushenyi municipality, Bushenyi District, 5 Kilometres from Bushenyi town along Ishaka-Mbarara highway. Ishaka is found in Igara County, Bushenyi District, approximately 62 kilometers (39 mi) from and west of Mbarara district. Bushenyi District is found in western Uganda latitude 0.541667; longitude: 30.187778 and has a population of 41063 according to Uganda Bureau of Statistics, (2014). The hospital neighbours Bushenyi Health Centre IV in the North and Kitagata Hospital in the South (government owned) while Ishaka Adventist and Comboni hospitals are in the West (church founded) all managed mainly by general practitioners.

The hospital has a bed capacity of approximately 700 beds. The department has outpatient section offering antenatal care (ANC), postnatal care, gynaecological care, family planning (FP) and health education. It is the immediate referral point for the above general hospitals. Apart from the outpatient department (OPD), the hospital has inpatient services in obstetrics and gynaecology, medicine, paediatrics including a neonatal unit and surgery. The obstetrics and gynaecology inpatient services are further divided into first stage section for monitoring labour, delivery room for delivering and gynaecology examining room for patient's examination. There is a minor theatre for minor surgeries like D&C and MVA. There is also an antenatal ward for pregnant mothers, postnatal ward for mothers who have delivered and gynaecology ward for gynaecological admissions. The department uses 2 theatres, one exclusively for obstetric emergencies that is operational daily and one for gynaecology cases that the department is assigned to use two days a week for elective cases but in case of an emergency gynaecology case it can be accessed. Apart from the emergency care given to mothers in abortion, other services offered that are related to abortion include counselling, FP, sexually transmitted disease testing and community integration services.

The hospital also has a 5 bed intensive care unit (ICU) for adults and a 7 bed Neonatal Intensive Care Unit for the newborns. It also has a well-equipped laboratory for blood transfusion and investigations like CBC and urinalysis. There is a fully functional ultrasound machine.

3.4 Study Population

All consented women presenting with incomplete abortion within the first trimester of gestation admitted at gynaecology ward who met the eligibility criteria.

3.5 Study Procedure

The study was done at KIU-TH Gynaecology ward involving all patients who met the inclusion criteria and consented irrespective of whether it was spontaneous or induced abortion. Diagnosis was done by history of amenorrhea not exceeding first trimester, low abdominal pain and vaginal bleeding. Physical examination of the abdominal to confirm fundal height and abdominal tenderness and pelvic examination with Cusco's speculum to confirm open cervix with bleeding and retained products of conception was done. Confirmation was by urine qualitative human chorionic gonadotropin (hCG) and trans abdominal pelvic ultrasound scan that were mandatory to all patients. Other investigations like complete blood count (CBC), malaria parasite, urinalysis, blood grouping and cross matching were done if deemed necessary but not routinely. CBC was done in patients with signs of anemia due to bleeding, signs of infections or those with signs suggestive of thrombophilia or thrombocytopenia. Malaria test was done to those with fevers, chills, joint pains or any other symptoms suggestive of malaria. Urinalysis was done to those who reported dysuria, urgency and frequency. Blood grouping was done in those who required blood transfusion (BT). Pre-procedure counselling with information on success rates, complications, advantages and disadvantages of each method was given. Where a woman consented, simple randomisation using sealed envelopes as detailed below was done to one of the treatment groups.

Surgical management was done immediately in the minor theatre with MVA and para cervical block at 4 and 8 o'clock cervical position with lidocaine as soon as feasible. After the procedure, the patient was admitted for 48 hours for observation as bed facilities are free in KIU-TH with regular review for any complications including hemorrhage, infection, trauma to GUT, failure of a method and pain severity.

Medical management was according to American college of obstetrics and gynaecologists (ACOG) involving giving misoprostol tablets that are initially made moist with water for injection 800µg in the posterior fornix of the vagina and patient made to lie still for 2 hours to allow for absorption of the same. This could be repeated to a maximum of 3 doses 6 hourly. All these patients

were put on the same brand of misoprostol available at the institution's pharmacy for uniformity purposes. Patients were then admitted for 48 hours just like their counterparts in surgical management. Assessment of the cervix and vaginal bleeding by speculum examination, vitals and medications given including add-on stronger analgesics was assessed hourly or 4 hourly depending on the patient in both treatment.

Pain control by Paracetamol tablets 1 gram 3 hourly in both groups post initiation of management was given. Broad spectrum prophylaxis antibiotics given was oral doxycycline 200 milligrams single dose before initiation of management and if allergic to doxycycline, oral azithromycin 1 gram single dose was given (W.H.O, 2014). At 48 hours, participants in both groups were reviewed for primary outcomes, secondary outcomes and satisfaction. Those with evidence of incomplete evacuation confirmed by trans-abdominal scan with a volume of more than 30mls of retained products underwent a mandatory surgical evacuation (dilatation and curettage) under para cervical block and remained admitted for one more day as recommended by W.H.O. All patients were discharged after 48hours unless there was a complication or primary failure warranting further hospital stay. Before discharge, the questionnaire was filled and patients released from the study. They then continued with routine post abortion care including scheduled reviews at the hospital, FP services, counselling and community integration that are all offered at KIU-TH.

3.6 Outcomes

3.6.1 Primary outcome

Primary outcome (effectiveness) was assessed by complete uterine evacuation within 48 hours. This was done by history of no vaginal bleeding or abdominal pain, physical exam of the abdomen to rule out tenderness and pelvic exam by speculum to check for no retained products. Trans-abdominal ultrasound scan was used to confirm complete evacuation by ruling out retained products of >30mls(W.H.O, 2014). If the retained products was >30mls, this was captured as failure of the primary method to cause complete evacuation.

3.6.2 Secondary outcomes

1. Duration of bleeding while on the ward.

Mild - less than 6 hours of bleeding

Moderate - between 7- 12 hours of bleeding

Severe – more than 12 hours.

2. Infections using temperature, pulse rate, pelvic examination by speculum and digital examination, laboratory findings of CBC and imaging studies with abdominal pelvic ultrasound.

Temperature <36 or >38 degrees Celsius, Pulse rate $>100/\text{min}$, offensive smelling yellowish or pus like vaginal discharge, adnexal tenderness, cervical motion tenderness, elevated white blood cells and pelvic abscess pointed towards an infection.

3. Pain using Likert scale (Bhardwaj & Yadav; 2015)

Use of seven circles progressively increasing in size for the patient to pick the circle that is proportionate to her pain. Smallest being the least pain while greatest maximum pain.

Mild pain – Likert scale between 1-3

Moderate – Likert scale between 4-5

Severe – Likert scale between 6-7

4. If they would recommend the method determined by interview.

5. Hospital stay or need for readmission if admitted for more than 48 hours.

6. Need for second method if there is primary failure.

7. Trauma to genitourinary tract evidenced by abdominal examination, pelvic examination and trans-abdominal pelvic ultrasound scan.

3.6.3 Satisfaction

Satisfaction with the method determined through satisfaction tool (Powell; 2010).

The parameters used to assess this were:

- a) Level of pain of less than 3 on Likert scale (1 point)
- b) If they recommended the method (1 point)
- c) Completion of abortion (1 point)

- d) Any complications (syncope, blood transfusion, severe headaches and dizziness, infection, genitourinary trauma). 1 point if there was no any complication.

This was then awarded scores between 0/4 to 4/4 and this determined satisfaction.

≤1/4 – very dissatisfied

2/4 – somewhat dissatisfied.

3/4 – somewhat satisfied

4/4 –very satisfied

3.7 Sample Size

Sample size determination was based on the null hypothesis that surgical management of abortion is not more effective than medical management of abortion; Surgical abortion is 100%- p_1 effective and medical abortion is 85.0% - p_2 effective (Moodliar *et al*; 2005). p_1 And p_2 reflect the effectiveness of 100% and 85% for surgical and medical management respectively.

Using sample size estimation formula for proportions in parallel design clinical trials over null hypothesis of equality, statistical power of 80% allowed us to detect 8.5% difference in efficacy between surgical and medical approaches of abortion (Tushar, 2010). Taking type I error as 0.05.

$$n = \frac{(z_{\alpha} + z_{\beta})^2 x [p_1 x (1 - p_1) + p_2 x (1 - p_2)]}{(p_1 - p_2)^2}$$

$$n = \frac{(1.96 + 0.84)^2 x [1.0 x (1 - 1.0) + 0.85 x (1 - 0.85)]}{(1.0 - 0.85)^2}$$

$$n = 45$$

Taking 10% dropout rate/loss to follow up into consideration;

$$n = 50$$

A sample size of 100 women, 50 in each arm, was sufficient to detect a clinically important difference of 8.5% and more in a successful outcome of abortion using a Z-test of proportions between the medical and surgical group with 80% power and 5% level of significance.

3.8 Sampling Techniques

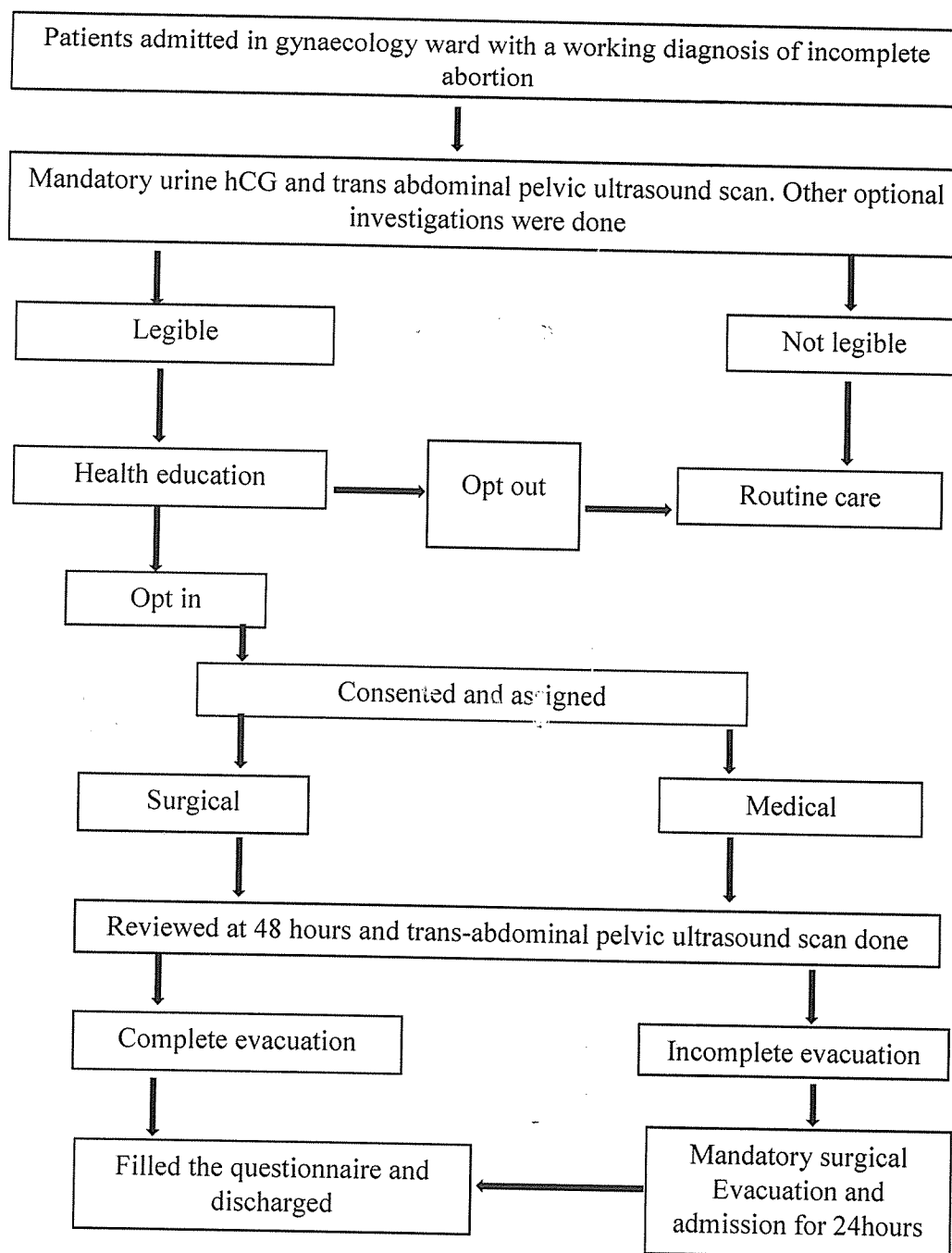
Participants were consecutively enrolled until the target number was attained. Simple randomization in the two arms was exercised to avoid bias. The attending doctor opened a randomly selected sealed numbered envelope that contained the management method to be assigned and allocated the patient to one of the two methods depending on the envelope content.

The envelope also contained questionnaire allocated a dummy number to be used in the study of that patient. Allocation was in the ratio of 1:1. No blinding was done but allocation concealment was exercised.

3.9 Feasibility

KIU-TH gynaecology department provide services to 50 - 60 patients with incomplete abortion per month (KIU-TH gynaecology ward records). This was therefore adequate presentation of the population.

Figure 2: FLOW OF PARTICIPANTS IN GYNAECOLOGY WARD



3.10 Data Collection Tools

Data was collected by use of an investigator administered questionnaire that was designed in simple English and based on the problem statement and objectives. For all objectives, questionnaire was used after pre testing from KIU - TH prior to data collection to check relevance and validity and thereafter editing was done. Researcher was keen to ensure that the questionnaires were properly filled.

Other tools included laboratory request forms and scan reports.

3.11 Data Collection Methods

Data regarding incomplete abortion was collected using face to face interview and all women enrolled were physically examined for clinical diagnosis of incomplete abortion. Trans abdominal ultrasound and urine qualitative hCG was done routinely to confirm diagnosis. Other tests that were done although not routinely include CBC, urinalysis, Malaria Parasites and blood grouping. Data on CBC, urinalysis, malaria parasites, blood group and evidence of infection were obtained from lab requests that accompanied samples to the lab. Data on satisfaction was collected using in-depth interviews.

3.12 Data Quality Control

Inclusion and exclusion criteria was strictly adhered to. The study groups were comparable in terms of age, reproduction, medical and surgical history. A common pretested questionnaire that had been edited prior was used. The principal researcher supervised the procedure to ensure accuracy and smooth running of the research. A senior specialist in the department supervised the procedure on each 5th patient to ensure protocol is adhered to. Weekly meetings were held to rectify any errors. The study was also carried out with the help of pre – trained research assistant.

3.13 Data Analysis and Interpretation

Data from questionnaires were entered into Microsoft Excel version 2010 checked for completion and cleaned. It was then transported to STATA version 14.2 (Statacorp, Lakeway Drive, USA Texas). Baseline demographic and clinical characteristics were assessed using Univariate analysis. Statistical difference was considered when $p \leq 0.05$. Numerical variables were summarized using means, medians (for non-normally distributed variables) and frequencies/proportions for categorical variables.

Objective1: Primary end point outcome (effectiveness) was analyzed using Intention to Treat Analysis (ITT). Loss to follow up was catered for in analysis not to lose any statistically significant difference that there might be.

Objective2: Secondary outcomes were analyzed across medical and surgical arms through Univariate analysis. Statistical difference was considered when $p \leq 0.05$.

Objective3: Satisfaction with the method of management was analyzed across medical and surgical arms through Univariate analysis. Statistical difference was considered when $p \leq 0.05$.

All statistical analysis was carried out in Statistical Package for the Social Sciences (SPSS) 23.0.

3.14 Ethical Considerations

3.14.1 Informed Consent

Adequate explanation was made to the participants in english and local languages and informed consent sought from those women who were eligible. Copy of consent is attached at appendix. Minors (emancipated minors under the age of 18) did not require presence of their guardians to consent. This is because the study carried negligible added risks which are the usual risks involved in abortion management.

3.14.2 Risks and Benefits

The study was more beneficial with minimal risks but no added risks than the risks in routine management of incomplete abortion. The study was also to prove the practicality of using surgical or medical methods of managing abortion exclusively or interchangeably in different situations in our setting.

3.14.3 Confidentiality and Privacy

Confidentiality of participants was ensured by using dummy number on questionnaires and limiting access to data from non- research members and other clinicians not involved in study or who were not helping participants in one way or the other. Details of respondents were kept under lock and key for privacy and confidentiality purposes throughout the course of research. There was no disclosure of participants' information to the public without their consent.

3.14.4 Selection of Participants

Recruitment was after voluntary acceptance and signing of consent form. Each research participant was handled as an individual with uttermost respect for her participation and was free to withdraw from the study any time she wished without coercion or compromise of care given thereafter.

3.14.5 Community Involvement

Our study findings will be communicated to the head of Obstetrics and Gynaecology ward at KIU-TH as a form of feedback. Communication will also be given to Bushenyi Municipality Health office and the library at K.I.U – TH.

3.14.6 Competence of Researcher

The principal investigator is a senior resident in Obstetrics and Gynaecology. He's therefore well-skilled and knowledgeable in diagnosis and management of abortions and their complications. The research assistants were also well trained in this area by the principal investigator. Patients enjoyed close monitoring from the research team who were trained to handle any complications that may have come up.

3.14.7 Approval Procedure

Approval to carry out the study was sought from the department of obstetrics and gynaecology, the faculty and post graduate school and finally the Research and Ethics Committee of Kampala International University. The approval letter was presented to the hospital administration of the hospital (KIU-TH). Consent was sought from the administration of the hospital before the study was conducted. The study was also registered with Uganda National Council for Science and Technology and also in the Pan African Clinical Trial Registry (PACTR201810731753052). There were no complaints arising from the study. However in case of such an incidence, the REC at KIU was fully accessible to the participants with their contacts on the consent form given to participants.

3.14.8 Incentives and Reimbursement

Maximal ethical norms were adhered to for participants. No monetary or any other form of incentives were offered to the participants but compensation and reimbursement was offered where applicable.

3.15 Dissemination of Results

The final report will be submitted to the department of obstetrics and gynaecology as well as the University Library, Post graduate Directorate and District health officer.

The manuscript will be submitted for publication by end of November through Clinical Gynaecology- Journal-Elsevier (www.journal.elsevier.com)

CHAPTER FOUR

PRESENTATION AND INTERPRETATION OF RESULTS

4.1 Baseline characteristics of study participants

4.1.1 Socio-demographic characteristics of study participants

Table 1. The total number of participants enrolled was 100 participants with no loss to follow up. Study population consisted of 50 women in each arm aged between 17 to 39 years having a median age of 24.0 and 24.5 years in medical and surgical arms respectively. The majority were Christians in both medical (90%) and surgical (98%) arms with more Muslims being significantly enrolled in the medical as compared to surgical arm ($p < 0.001$). Of those enrolled, most of them were Banyankole by tribe in both arms (80% of medical and 84% of surgical) and married (84% of medical and 92% of surgical). Most of them (50% of medical and 62% of surgical) had attained primary level of education and (50% of medical and 70% of surgical) were peasant farmers.

Table 1: Socio-demographic characteristics of study population

Variable	Intervention		p-value
	Medical n=50	Surgery n=50	
Median age (IQR)	24(21-28)	24.5(22-30)	0.55
Religion n (%)			
Christian	45(90.0)	49(98.0)	0.09
Muslim	5(10.0)	1(2.0)	<0.001
Tribe n (%)			
Munyankole	40(80.0)	42(84.0)	0.82
Mukiga	4(8.0)	4(8.0)	1.00
Mufumbira	-	1(2.0)	-
Others	6(12.0)	3(6.0)	0.74
Marital status n (%)			
Married	42(84.0)	46(92.0)	0.55
Widow	1(2.0)	-	-
Single	7(14.0)	3(6.0)	0.55
Divorced	-	1(2.0)	-
Separated	-	-	-
Education n (%)			
None	2(4.0)	1(2.0)	0.89
Primary	25(50.0)	31(62.0)	0.41
Secondary	18(36.0)	16(32.0)	0.78
Tertiary	4(8.0)	1(2.0)	0.68
University	1(2.0)	1(2.0)	1.0
Occupation n (%)			
peasant	25(50.0)	35(70.0)	0.30
Self employed	14(28.0)	10(20.0)	0.68
Student	6(12.0)	3(6.0)	0.75
Civil servant	3(6.0)	2(4.0)	0.92
others	2(4.0)	-	-

4.1.2 Obstetrics and gynaecology characteristics of study participants

Table 2. The median parity of the patients managed medically was 1(IQR=0-2) and surgically was 2(IQR=0-3) which was statistically significant ($p=0.004$). In relationship to the parity, the difference in gravidity was also statistically significant with median gravidity of 2 (IQR=1-3) and 3 (IQR=2-4) in medical and surgical arms respectively ($p=0.001$). The two groups were comparable in terms of median weeks of amenorrhea and history of previous abortions. The median weeks of amenorrhea was 10.42 weeks in medical and 10.43 weeks in surgical with 16% ($n=8$) and 20%

(n=10) of participants enrolled in medical and surgical arms having a prior history of 1 to 2 abortions but not ≥ 3 abortions as stipulated in the exclusion criteria.

Table 2: Obstetrics and gynaecology characteristics of study participants

Variable	Intervention		p-value
	Medical n=50	Surgery n=50	
Median parity (IQR)	1(0-2)	2(0-3)	0.004
History of abortions n (%)			
No	42(84.0)	40(80.0)	0.60
Yes	8(16.0)	10(20.0)	0.60
Median gravidity (IQR)	2(1-3)	3(2-4)	0.001
Median weeks of amenorrhea (IQR)	10.42(8.71-11.29)	10.43(9.86-11.29)	1.00

4.2 Comparative effectiveness of medical and surgical management of first trimester incomplete abortion among women admitted at KIU-TH

Table 3. Out of the 50 participants enrolled in surgical arm, 96% (n=48) had successful evacuation of the uterus using MVA. Of those in the medical arm, 84% (n=42) had successful evacuation of the uterus. Out of the 100 participants enrolled 10% (n=10) of patients across both arms of management had primary failure. Of this primary failure, 80% (n=8) and 20% (n=2) were on medical and surgical arms respectively. When the two methods were therefore compared, surgical method significantly reduces the risk of primary failure by 11.7% as compared to medical method (RRR=11.7%, p value=0.043).

Table 3: Comparative effectiveness of medical and surgical management of first trimester incomplete abortion among women admitted at KIU-TH

intervention	Yes (n=10)	Primary failure		
		RRR (efficacy)	95% CI	p-value
Medical n (%)	8 (80.0)	Ref	-	-
Surgical n (%)	2 (20.0)	11.7%	0.4% - 21.0%	0.043

4.3 Comparative secondary outcomes encountered among women admitted in KIU-TH when first trimester incomplete abortion is managed using medical or surgical methods.

Table 4. The mean length of hospital stay was longer in medical management as compared to surgical management ($p=0.03$) which was statistically significant. Duration of bleeding varied across the different hours. 94% ($n=47$) of participants in surgical arm and 46% ($n=23$) of the participants in medical arm bled for less than 6 hours that was statistically significant. This in comparison, showed that patients in surgical management experienced few hours of bleeding as compared to those in medical management ($p=0.0002$). Majority of those who bled for 7-12 hours were from medical arm with 32% ($n=16$) being the percentage as compared to only 2% ($n=1$) in surgical management which was statistically significant ($p=0.02$). There was 22% ($n=11$) of participants who had bleeding for >12hours in medical arm while only 4% ($n=2$) in surgical arm had bleeding for >12hours which was statistically insignificant ($p=0.16$). Of participants enrolled, 64% of those on medical arm reported mild pain as compared to only 4% in the surgical arm ($p=<0.01$). However, 78% of those allocated to surgical arm reported severe pain as compared to only 8% of those in medical arm ($p=<0.001$). Majority of the participants 90% ($n=45$) managed medically would recommend the same method as compared to only half ($n=25$) of those enrolled in surgical management ($p=0.01$). This was quite significant statistically. Fever, chills and nausea were significantly more common in medical arm than surgical arm however this were self-limiting and no intervention was required. There was no statistical significance between the two arms in regards to those who had severe headache, severe dizziness and those who required blood transfusion post initiation of treatment even though the absolute numbers were higher in surgical arm. Of all the 100 participants enrolled, only one participant had evidence of infection, 1 participant had diarrhea and 3 patients had syncope in those who underwent surgical management.

None of the participants had evidence of trauma to genito-urinary tract in both management groups.

Table 4: Comparative secondary outcomes encountered among women admitted in KIU-TH when first trimester incomplete abortion is managed using medical versus surgical method

Variable	Intervention		p=
	Medical (n=50)	Surgical (n=50)	value
Mean length of hospital stay (Sd)	2.18(0.39)	2.04(0.04)	0.03
Duration of bleeding post treatment initiation n (%)			
≤6 hours	23(46.0)	47(94.0)	0.0002
7-12 hours	16(32.0)	1(2.0)	0.02
>12 hours	11(22.0)	2(4.0)	0.16
Syncope			
Yes	-	3 (6.0)	-
Severe dizziness			
Yes	11 (22.0)	13 (26.0)	0.64
Severe headache			
Yes	11 (22.0)	10 (20.0)	0.81
Blood transfusion			
Yes	2 (4.0)	5 (10.0)	0.24
Diarrhoea			
Yes	-	1 (2.0)	-
Fever			
Yes	19 (38.0)	3(6.0)	<0.001
Chills			
Yes	19 (38.0)	5 (10.0)	0.001
Nausea			
Yes	11 (22.0)	4 (8.0)	0.047
Infection			
Yes	-	1(2.0)	-
Pain level			
Mild	32 (64.0)	2 (4.0)	<0.01
Moderate	14 (28.0)	9 (18.0)	0.39
Severe	4 (8.0)	39 (78.0)	<0.001
Recommend the method			
No	5 (10.0)	25 (50.0)	<0.001
Yes	45 (90.0)	25 (50.0)	<0.001



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4.4 Comparative level of satisfaction with the management method assigned to women with first trimester incomplete abortion admitted at KIU-TH

Table 5. Of the 50 participants enrolled in medical management, 48% (n=24) were very satisfied as compared to only 2% (n=1) in the surgical arm. This was statistically significant with a p value of 0.0001. Of the participants managed surgically 98% (n=49) of them were not very satisfied with the method of management.

Table 5: Comparative level of satisfaction with the management method assigned to women with first trimester incomplete abortion admitted at KIU-TH

Satisfaction	Medical n=50	Surgical n=50	P value
Very satisfied	24 (48.0)	1 (2.0)	0.0001
Others	26 (52.0)	49 (98.0)	

CHAPTER FIVE

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Comparative effectiveness of medical and surgical management of first trimester incomplete abortion

The present study aimed at finding the outcomes of medical versus surgical management of incomplete abortion that included effectiveness, secondary outcomes and satisfaction level. In this study, out of the 50 participants enrolled in surgical arm, 96% (n=48) had successful evacuation of the uterus using MVA. Of those in the medical arm, 84% (n=42) had successful evacuation of the uterus. This meant that 2 patients on the surgical arm and 8 patients on the medical arm had primary failure that required a second surgical method for evacuation of retained products of conception. This interpreted in a different way, is that 80% (n=8) of all those with primary failure were from medical arm and only 20% (n=2) were from surgical arm. Of the two patients that were re evacuated, both of them were uncooperative due to pain despite para cervical block and verbal reassurance. Also, both patients had previous uterine scars due to caesarean section. This made it difficult for the doctors to achieve complete evacuation in the first procedure. The patients were both stable after first evacuation but a trans abdominal pelvic scan done after 48 hours showed retained products of conception exceeding 30mls. D&C was done after the initial MVA. This therefore meant that surgical method significantly reduces the risk of primary failure by 11.7% as compared to medical method (RRR=11.7%, p value=0.043).

The effectiveness of surgical method on management of incomplete abortion has been studied in various parts of the world. In the present study, the effectiveness was 96%. This is generally a mild lower success rate of the method as compared to other previous studies that showed 100% success rate (Shochet *et al*; 2012) and (Shokry *et al*; 2014). The minimal difference between the current studies and the previous studies maybe explained by the fact that KIU-TH is a teaching hospital and most of the doctors in the current study are still undergoing some form of training, either to become specialists in obstetrics and gynaecology or some doing their internship. This has been shown to affect effectiveness of surgical management as surgical skill is a determining factor (Gerdtts *et al*; 2013). Moreover, in Africa, surgical intervention by most of the population is

considered as too invasive and most patients would be apprehensive to have the procedure which may lead to lack of cooperation and failure of the method (Gerdtts *et al*; 2013).

The effectiveness of medical method in the present study was at 84% which was comparable to a study done in a Yemen hospital that had an effectiveness of 83% using misoprostol 400µg in the posterior fornix and 200µg 4 hourly for 3 doses and review was done after 7 days (Shuaib *et al*; 2013). It was found to be less as compared to a previous study done in India with an effectiveness of 97% using misoprostol 600µg orally and review after 3 days (Bhadra *et al*; 2013). The current effectiveness was higher than a study done in Senegal with effectiveness of 50% - 60% using misoprostol 400µg as a single dose and review done after 7 days (Diop & G.A; 2012). The difference in the effectiveness can be explained by the brand of misoprostol used and the route of administration used with vaginal and sublingual route considered superior to oral route. Also, the higher the dose, the more the effectiveness (Nautiyal *et al*; 2015). Apart from this, different definition of success including how many days after initiation of treatment the patient waits for the method to be declared a failure and the volume of retained products that is considered unsuccessful was different. The longer the duration and the more the volume, the higher the success rate (Nautiyal *et al*; 2015)

The present study showed that surgical management of first trimester incomplete abortion by MVA is more effective than medical management of first trimester abortion using misoprostol 800 microgram in the posterior fornix 6 hourly with a maximum of 3 doses and reviewed after 48hours. This was in keeping with a study done in South Sudan with success rates of 100% and 93.5% for surgical and medical methods respectively (Bray *et al*; 2016). Other studies have shown higher effectiveness with surgical method as compared to medical method although this were not statistically significant. This studies were done in Iran (Dastgiri *et al*; 2017) and Nepal (Panta *et al*; 2013) with effectiveness of 97% and 95% for surgical and medical management respectively. In East Africa, recent studies are missing with the latest studies being in Uganda with effectiveness of 96.3% versus 91.5% with a review after 1 week (Weeks *et al*; 2005) and Tanzania with effectiveness of 100% versus 99% for surgical and medical management respectively with a review after 2 weeks (Shwekerela *et al*; 2007). The higher effectiveness of medical method in the Tanzania and Uganda study is probably due to prolonged duration that the participants waited before a method was declared a failure. However, a study done in India showed a higher success

rate of 97% in medical management as compared to 95% for surgical management using single dose 600µg vaginally and review after 2 weeks (Verma *et al*; 2016). The higher effectiveness of medical management in the study done in India can be explained by the difference in brand of misoprostol used and the definition of success which was reviewed after 15 days as compared to the present study of which review was after 48 hours only. The longer the duration you wait to declare medical method a failure the higher the success rates (Nautiyal *et al*; 2015).

Given the higher effectiveness of surgical method including need for surgical method in case of failure of medical method, it is mandatory to train as many personnel as possible and provide this services to most if not all health facilities because if done properly then it is very effective.

5.2 Comparative secondary outcomes encountered when first trimester incomplete abortion is managed using medical or surgical methods.

In this present study, the mean length of admission to the hospital was longer in medical 2.18 days (sd=0.39) than surgical 2.04 days (sd=0.04) arm that was statistically significant ($p=0.03$). As regards bleeding duration, most of the patients (54%) in medical arm had moderate and severe bleeding in terms of hours of bleeding (>7 hours of bleeding) while most of those in surgical arm (94%) reported mild bleeding that lasted <6 hours. This was statistically significant. In this present study, majority of the participants (64%) in medical arm experienced mild pain ($n=32$) while 78% ($n=39$) of those managed surgically reported severe levels of pain that was statistically significant. 90% ($n=45$) of those who underwent medical management would recommend the method while only 50% ($n=25$) on surgical method would ($p=<0.001$). Those randomized in the medical arm had increased incidences of fever, chills, nausea that was statistically significant as compared to surgical method. Although there were more participants having syncope, dizziness, headache, and requiring blood transfusion in the surgical arm, this was not statistically significant. Only 1 case of infection was reported in the surgical arm and there was no case of trauma to GUT.

The present study showed that the participants on medical arm had longer stay in the hospital than their counterparts in surgical arm. In our study, this was explained by the fact that as compared to surgical management, 80% of the patients who had failure of the method were from medical arm while only 20% were from surgical arm. This therefore meant that they had to be kept in hospital for 1 more day as compared to those who had expulsion of all retained products of conception.

The other possible explanation was that because of prolonged bleeding, participants in medical method had to be kept in the ward till the bleeding was minimal. This present study findings are similar to a study done in chad (Bray *et al*; 2016) and Nigeria (Lamina, 2015) which showed that surgical management required less hospital stay (<6 hours) as compared to medical management (>12hours). This was due to immediate completion of uterine evacuation with surgical management. This therefore means that in patients on medical management there is strict need for follow up to confirm completion of abortion and if need be re – evacuation and monitoring bleeding. Health providers need to Emphasize and judge patient's ability to come for follow up before initiating medical management.

The present study demonstrated that bleeding in surgical arm was of a shorter duration as compared to medical arm. The prolonged duration of bleeding in medical management was probably associated with prolonged period before complete expulsion of products of conception. This is because for bleeding to stop, all the products of conception have to be evacuated. This would also explain why surgical management had few hours of bleeding with most of them reporting stoppage of active bleeding immediately after completion of the procedure. Of importance to note is that although surgical management had few hours of bleeding, most of the symptoms associated with loss of excessive blood like syncope, dizziness, severe headache and blood transfusion were more common in the surgical arm. This is in agreement with previous study in middle East where bleeding duration in medical was more than in surgical management with all participants having some form of bleeding within the first 24 hours of which after 24 hours, no participants in surgical reported bleeding (Shokry *et al*; 2014). Another study done in Nepal showed that 91.6% of participants managed medically had bleeding while none in surgical management had bleeding after evacuation (Panta *et al*; 2013). The reason why this symptoms of blood loss are common in the surgical arm than medical arm is that in surgical arm, there is sudden excessive loss of blood unlike in medical arm where bleeding is not more than menstrual flow (Odland *et al*; 2018). It is therefore paramount to have surgical procedure done in units that have access to some form of blood transfusion services and during the procedure to have capability to resuscitate patients in terms of airway, breathing and circulation. Proper training on how to carry out the procedure is a must to avoid excessive bleeding. Use of oxytocin and other drugs that cause uterine contractions post evacuation should also be emphasized.

The present study showed that majority 64.0% (n=32) of the patients in the medical arm reported mild pain while the majority 78.0% (n=39) in surgical arm reported severe pain that was statistically significant. This was consistent with findings in a study done in Nepal where 77% of the patients managed surgically reported severe pain (Panta *et al*; 2013). Another study in India also showed that up to 98% of patients managed surgically experienced excruciating pain while only 28% of those managed medically reported pain that was cramp like in nature (Verma *et al*; 2016). According to the same study, the pain during MVA can be so severe to cause vasovagal syncope that may lead to irreversible shock if not rectified early as it was experienced in 1 of the participants in the same study. The excessive pain in surgical management in our study and other studies quoted is due to the fact that MVA involves mechanical evacuation as opposed to medical of which evacuation is due to uterine contractions. However, a study done at N'Djamena hospital in Chad showed no statistically significant difference between the pain level experienced in use of misoprostol or surgical evacuation of the uterus (Bray *et al*; 2016). This was probably due to the fact that although surgical method is associated with high intensity of pain that is short lasting, medical method is associated with low intensity pain but it is prolonged. According to the present study, pain control especially in the patients managed surgically is paramount to avoid vasovagal syncope. Excessive pain may also reduce patient's satisfaction with surgical method and may lead to lack of cooperation that may result in GUT injury, incomplete evacuations and other adverse effects. In our study, we used para cervical block and verbal assurance during the procedure but still had patients reporting severe pain. Therefore, more analgesia like a systemic opioid or conscious sedation should be used as an add-on to para cervical block to reduce the pain level. Another important factor is to use verbal reassurance and pre procedure counselling on what to expect during the procedure that may help in reducing the pain level.

The present study determined that 90% (n=45) of those managed medically would recommend the method to other patients while only 50% (n=25) would recommend surgical evacuation. The above finding is consistent with a study done in Tanzania where 95% of participants would recommend medical method while only 75% would recommend surgical method (Shwekerela *et al*; 2007). Other studies have found that surgical is preferred to medical (Bray *et al*; 2016), while others report no statistically significant difference between the two methods (Shokry *et al*; 2014). The main reason why participants did not recommend surgical method was because of increased pain. Other

reasons included invasive nature of surgical method, use of anaesthesia, fear of trauma to GUT and negative psychological perceptions. However, participants that recommended surgical method did so mainly because of immediate evacuation with higher success rate and less duration of bleeding. Participants who recommended medical method reported that the main reason was not only because of less pain, but also because of the less nature of invasiveness, no anaesthesia and the general acceptability of drug use as compared to surgery. The main reason why participants did not prefer medical method was because of the failure of the method with all the 8 participants who had primary failure opting for alternative method. Other reasons included prolonged hospital stay and prolonged bleeding. These same reasons for and against medical and surgical intervention are similar to findings of analyzed studies by American college of obstetrics and gynaecologists (ACOG, 2009). With this present study findings, pain management is an important factor in determining recommendation of a given method and so pain levels have to be suppressed to ensure patients recommendation. Pre procedure counselling should also be given to every patient.

This current study showed higher incidences of fever, chills and nausea in medical arm as compared to surgical arm. Fever in 38% versus 6% ($p < 0.001$), chills in 38% versus 10% ($p = 0.001$) and nausea in 22% versus 8% ($p = 0.047$) for medical versus surgical management respectively which were all significant. Finding is similar to a study done in Vietnam where 82.7% of patients managed medically reported this effects but they were self-limiting (Ngoc *et al*; 2013). A study done in Chad showed the same findings as regards to fever, chills and nausea (Bray *et al*; 2016). Even though this may be constitutional symptoms, they may point towards an infection especially fever. In the present study, this was mainly due to side effects of misoprostol. This side effects were however mild and self-limiting and no extra medication apart from those on the research protocol were added to treat them as demonstrated by earlier studies (Ngoc *et al*; 2013). The presence of this side effects did not affect the participants' recommendation of the method. This knowledge should be known to all providers and should be passed to patients undergoing medical management. This will ensure no anxiety on the patient's side when this self-limiting side effects arise and avoid irrelevant medical tests and costs. However, if there is any sign of infection associated with this symptoms then urgent intervention should be instituted.

In the present study, only 1 participant developed infection in those assigned to surgical management and none in medical management. This was a 24 year old para 1+0 gravida 2 at

11 weeks of amenorrhea who presented with incomplete abortion but had stayed home for 4 days bleeding hoping for spontaneous abortion and only came to hospital on the 5th day. However, on arrival, she did not have any signs of infection and was enrolled in the study. 24 hours after MVA, she was noted to have signs of endometritis but was successfully treated on intravenous antibiotics. Prolonged retention of products of conception is a risk factor for infection (Cunningham *et al*; 2014). This most likely played a role in this patient. Generally no consensus has been found between which method has more risks for infection than the other (Jones *et al*; 2010). Due to the invasive nature of surgical management some studies have found higher infection rates in this group like a study done in Mulago hospital in Uganda (Weeks *et al*; 2005). The study in Mulago reported 10 incidences of infection and this might be explained by the fact that unlike KIU –TH, Mulago hospital is the National Referral Hospital. Other studies argue that longer induction - abortion time may lead to higher occurrence of infections (Shuaib & Alharazi, 2013). There are other factors that determine infection rates including; surgical technique, antiseptic used, use of prophylactic antibiotics and clients immune system (Melese *et al*; 2017). In the present study doxycycline 100mgs orally as a single dose or azithromycin 1gram orally single dose was effective as prophylactic antibiotic. To avoid infections, providers should stick to standard operating procedures, maintain aseptic techniques, use prophylactic antibiotics and empower patients to seek medical attention with the earliest warning signs like increasing lower abdominal pain and offensive vaginal discharge.

Present study did not have any trauma to GUT in both groups which was contrary to a study in Mulago hospital Uganda where 5 patients had trauma to the cervix although none of them required more than one suture knot on the cervix (Weeks *et al*; 2005). Generally surgical methods have higher rates of trauma about 5.6% (Kapp *et al*; 2013) as compared to medical management that is insignificant. With medical method however, rupture of uterus may occur if larger doses are used in patients with previous uterine scars (Kapp *et al*; 2013). Therefore, provided proper training is given surgical method can be carried out without any trauma. Also periodic refresher courses would help review and update knowledge on surgical technique. Patients with previous uterine scars should be assessed and benefits against risks weighed before initiating misoprostol as this can lead to uterine rupture. Initiation should only be done at centers where monitoring and comprehensive care is available in this group of patients (Nouhjah *et al*; 2017).

5.3 Comparative levels of satisfaction between medical and surgical management of first trimester incomplete abortion

In the present study 50 participants were randomized in each arm. 24 participants (48%) in medical management reported to be very satisfied while only 2% (n=1) in surgical management reported the same. This contrasts with a study done in Uganda that showed no statistical difference in the satisfaction between the two groups (Weeks *et al*; 2005). The study in Uganda reported that the reasons why participants were satisfied with medical management was because of less pain, effectiveness, non-invasiveness and lack of anaesthesia use. It also reported participants were satisfied with surgical method because of high effectiveness, short duration of treatment, less hours of bleeding and reduced hospital stay. A previous study by Shochet and others also found similar outcomes regarding satisfaction (Shochet *et al*; 2012).

Other earlier studies found more satisfaction levels with surgical management as compared to medical management (Shokry *et al*; 2014). The reason why participants were more satisfied with surgical method was because of high effectiveness, short duration of treatment and shorter duration of bleeding.

This study results are in line with a study that found more satisfaction in medical arm 84% as compared to only 16% in surgical arm (Ngoc *et al*; 2013). Some of the reasons given for this was that medical management had less pain, high effectiveness, lack of surgery and lack of anaesthesia (Ngoc *et al*; 2013).

Patients should be offered a method that gives maximum satisfaction as this will encourage health seeking behaviour and avoid unsafe abortion services which will lead to reduced abortion related complications.

5.4 Strength and Weaknesses

5.4.1 Strength

Non co-operation of some participants in the course of study was solved by comprehensive counselling of participants with regards to the participation. Patients' preferred method of management that would have caused difficulty in assigning them to medical or surgical arms was solved by comprehensive counselling about the advantages, disadvantages, effectiveness and

complications of each method. Providing visual aids on each procedure was also done to overcome this. Medical personnel perception that a patient would benefit more from one method as compared to the other was solved by randomisation and allocation concealment. The study being done in a private-public partnership health facility might not have reflected what is in purely public health facility. However, data collection spread out over a period of 4 months with different variations of the sample was captured in the study to overcome this. This was the first study in a rural setting in western Uganda comparing the two methods of management. There was no loss to follow up.

5.4.2. Weaknesses

Lack of blinding which might have caused bias and lack of a parallel comparable group of both medical and surgical management.

5.5 Conclusion(s)

- I. Surgical management of first trimester incomplete abortion by manual vacuum aspiration is more effective than medical management of first trimester abortion using misoprostol 800 microgram in the posterior fornix 6 hourly maximum of 3 doses when reviewed after 48 hours.
- II. Medical management of first trimester incomplete abortion is associated with reduced pain than surgical management and this makes most patients recommend it. However, medical management has prolonged menstrual like expulsion bleeding, prolonged hospital stay and increased fevers, chills and nausea than surgical method. The fevers, chills and nausea are however self-limiting.
- III. Many participants are satisfied with medical management of first trimester incomplete abortion due to high effectiveness, less pain, non-invasiveness and lack of anaesthesia as compared to surgical management.

5.6 Recommendation(s)

- I. Surgical management of first trimester incomplete abortion by MVA has higher effectiveness in short term. However, further studies are needed to compare long term outcomes of surgical and medical management of first trimester incomplete abortion.
- II. Given that medical management with misoprostol 800micrograms in the posterior fornix 6 hourly to maximum of 3 doses of first trimester incomplete abortion is associated with high success rates within 48 hours, less pain, gives patients more satisfaction and most patients would recommend it, it can be used as an alternative especially to patients who want to avoid

anaesthesia and surgery in low socioeconomic settings with no surgical services and who have no contraindication for misoprostol use. .

- III. Patients should be provided with all the information regarding both medical and surgical procedures and outcomes of each of the two procedures and allowed autonomy to make the decision on which method they would be satisfied with since all the methods have high effectiveness.

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APPENDICES

APPENDIX I: INFORMED CONSENT DOCUMENT



KAMPALA INTERNATIONAL UNIVERSITY (KIU) WESTERN CAMPUS (WC)

RESEARCH ETHICS COMMITTEE (REC)

PO Box 71, Bushenyi, Uganda; Tel: +256 758 096 775

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Study Title:

Outcomes of medical versus surgical management of first trimester incomplete abortion among women admitted at Kampala International University Teaching Hospital.

Principal Investigator(s): Dr. Victor Tetty Otieno a postgraduate student at the department of Obstetrics and Gynaecology in Kampala International University Teaching Hospital Western Campus. **Qualifications:** Bachelor of medicine and surgery (University of Nairobi 2011).

INTRODUCTION

What you should know about this study

- You are being asked to join a research study;
- This consent form explains the research study and your part in the study;
- Please read it carefully; and take as much time as you need;
- You are a volunteer. You can choose not to take part; and if you join, you may quit at any time. There will be no penalty if you decide to leave the study

Leave blank (for REC Office only): KIU WC REC Stamp:	For REC Office use only: APPROVAL DATE: APPROVED CONSENT REC VERSION NUMBER: PI's NAME: REC NO:
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Background of the study:

Incomplete abortion is among the most common complications of pregnancy affecting about 54 pregnancies per 1000 in Uganda (C, 2013). This is higher than the average rate in E.A of 34 abortions per 1000 pregnancies (Department of Reproductive Health and Research WHO, 2012).

Maternal mortality rate in Uganda is among the highest in the world. 336 maternal deaths per 100,000 live births is the current figure of which 26% are attributed to abortion. (Uganda Bureau of Statistics, 2016). The management involves removal of all products of conception medically or surgically. Each of these methods has variable success rates and different complications that all contribute to either wellbeing or death of mothers.

Purpose of the research project

The study will provide data on success rates and complications which will in turn aid in decision making whether to use them interchangeably or exclusively. The findings of this study will also aid in decision making by the patient on which method they prefer.

The study will aim at determining the outcomes of medical versus surgical management of first trimester incomplete abortion. The study will involve a total of 100 participants and the study will run from time of diagnosis of incomplete abortion and admission till 48 hours (complete evacuation) or 72 hours (primary failure)

Why you are being asked to participate

You have been chosen randomly to participate in this study because you meet the designed inclusion criteria of the study. All women with incomplete abortion have been given an equal chance to participate. When u take part in the study information generated will be used to determine whether to use medical or surgical method in the management of incomplete abortions in different hospitals settings.

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Procedures:

If you agree to participate in the study you will be given more information regarding the study and asked to sign a consent form. A unique dummy number will be assigned to you for identification purposes and you will be enrolled in your assigned management plan and monitored adequately for results. A questionnaire will be administered to you at the end of research.

Risks/Discomforts

There are minor risks anticipated with no added risks than in routine management of incomplete abortion with standard available care in Uganda both medically and surgically. This risks are very rare and the doctors attending should be able to identify and manage them appropriately.

Benefits

Participant will be educated on first trimester abortion treatment methods and complications of each method. This will lead to mass sensitization and thus reduce deaths arising from abortion. The efficacy and complications collected will be used to draft policies on management of incomplete abortion. You will also enjoy close monitoring by assigned health worker during the period of study to readily and appropriately handle any complications and answer your concerns.

Incentives/Rewards for Participating

There shall be no incentives like meals, transport refunds or gifts awarded to participants. Any appreciation given to you will be part of research protocol.

Protecting data confidentiality:

Access to data will be strictly limited to those involved in the study. All data collected will be locked in a cabinet in the gynaecology ward. However, university ethics and internal review board may have to review data collection tool to cross check how we shall have handled them but will not be able to correlate your response with your name. We shall ultimately use your response only for the study.

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Protecting subject privacy during data collection

During the process of obtaining data dummy numbers and not participants initials will be used. Other identifying patient details will not be used.

Right to refuse/withdraw

Your participation in the study is purely voluntary, and refusal to participate will involve no loss of benefits that you are entitled to.

What happens if you leave the study?

You are invited to participate in the study. Note that it is your right to accept or not to accept and that your refusal shall not interfere with the services provided to you at Kampala International University Teaching Hospital.

Who do I ask/call if I have questions or a problem?

In case of any matters which are not clear, please contact; Dr.Victor Tetty Otieno a student at Department of Obstetrics and Gynaecology, Kampala International university, Tel. +256750813662 or Prof. Bonet Ivan Tel +256772 387977

What does your signature (or thumb print/mark) on this consent form mean?

Your signature on this form means that you have:

- Been informed about this study's purpose, procedures, and possible benefits and risks;
- Been given the chance to ask questions before you sign; and
- Voluntarily agreed to be in this study.

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-----	-----	-----
Print name of adult participant	Thumb print/Signature of participant/legally Authorized representative	Date
-----	-----	-----
Print name of person obtaining Consent	Signature	Date
-----	-----	-----
Print name of witness	Thumb print/Signature of witness	Date

PART 2: CONSENT FOR MEDICAL OR SURGICAL MANAGEMENT OF ABORTION

I..... is due to undergo medical/surgical
.....as a management method of first trimester abortion after being educated
and counseled. I have understood the explanations and hereby give my consent in the form of a
signature/thumb print, for the said procedure to be carried out on me.

-----	-----	-----
Name of participant	Signature/thumbprint of participant.	Date
-----	-----	-----
Name of witness	Signature/thumbprint of witness	Date

Leave blank (for REC Office only): KIU WC REC Stamp:	For REC Office use only: APPROVAL DATE: APPROVED CONSENT REC VERSION NUMBER: PI's NAME: REC NO:
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APPENDIX II: TRANSLATED CONSENT FORM



**KAMPALA INTERNATIONAL UNIVERSITY (KIU) WESTERN CAMPUS (WC)
RESEARCH ETHICS COMMITTEE (REC)**

PO Box 71, Bushenyi, Uganda; Tel: +256 758 096 775

E-mail: kiurec2017@kiu.ac.ug; Website: www.kiu.ac.ug

**EBARUHA YO'KWIKIRIZANA NAIWE NAN'OKUKUMANYISA EBIRAKORWE
OMUKUCONDOOZA OKU.**

Omutwe gw'okucondooza:

EBIRIKURUGA OMUKUJANJABA ORIKUKUGYERAGYERANISA NANA
OMURINGO GW'OKUSHEMEZA ABAKYARA ABARUGIRWEMU ENDA
HAKATSIGARA EBICHWEKA OMURINYINENDA OMU MYEZI ESHATU
Y'OKUBANZA AHAKWIHAMU EBIRIKUBA BISIGAIRE OMURI NYINENDA
OMUBAKYARA ABAINA ENDA OMWIRWARIRO ERIKUSHOMERWAMU
ABASHAHO AHITENDEKYERO ERIKURU ERYA KAMPALA INTANASHONOLO
EITAGI ERYA ISHAKA.

Mukuru w'okucondooza: Dr. Victor Tetty Otieno omwegi aharurengo rwakabiri rwemishomo
aha itagi ryokuzarisa omwirwariro erikushomerwamu abashaho ahitendekyero erikuru erya
Kampala Intanashonolo eitagi erya Ishaka.

Emishomo: Diguri y'ebyobushaho (Dikita) okuruga omu itendekyero erikuru erya Nairobi.

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Entandikiri:**Ebi'oshemereire kumanya aha kucondooza oku:**

- Noshabwa kwetaba omu kucondooza oku
- Ekihandiko eki neshoboorora aha kucondooza kwitu hamwe nanobuhabuzi bwaawe ahamushomo ugu.
- Noshabwa okugishoma okagyetegyereza kurungi orikukozesa obwire bwoona obworikenda.
- Ori omuyambi omumushomo ugu. Nobaasa kusharamu obuteetaba omukukucondooza oku Kandi watwegeitaho, noyikirizibwa kuruga omukukyondoza oku ohorikwendera otaferirwe kintu kyoona.

Ebikwatirine nanokukyondoza kandi nan'ekirikutuma twakora oku kucondooza:

Enda ezirikuremwa kurugamu nizimwe ahabirikukira kuteganisa abakazi benda kandi nizeyongyera munonga kuteganisa abakazi abeine enda kuhika ebicweeka 54 ahari 1000 omwihanga rya Uganda (C, 2013). Ekyagambwa aharuguru nikikiraho ahabwingi waba okwatirine amahanga ageterine agabugwizooba bwa Afrika ahabikwatirine nokwihamu enda oburikwingana obuchweka 34 ahari 1000 ahabakazi abarikwihamu enda. ((Department of Reproductive Health and Research WHO, 2012).

Eihanga rya Uganda nirimwe omumahanga againe enamba mpango yabakazi abarikufa barikuzara omunsi yona. Omubaro gukuhika 336 gwabakazi nibafa barikuzara kandi pasenti ya 26 nibafa ahabwokwihamu enda. (Uganda Bureau of Statistics, 2016). Abebyobureberezi nibafayo kukozeza burikimwe ahabikwatirine nemibazi nanokushemeza kurebeka ngu bayihamu ebirikuba bisigaire omurinyinenda. Burimuringo gwine ekigurikuyamba kandi nigukiza nigashi gubase kuretera okufa kwabakazi.

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Emigasho y'okucondooza oku:

Okucondooza oku nikuza kuyamba kumanya nibusinguziki narishi niburemeziki obwakubasa kuruga omukukozesa omuringo gumwe narish okugikozesa yona hamwe ekirayambe omusaramu. Ebibirarugye omukucondooza oku nabyo nibizakuyamba abarwire omukusharamu omuringo ogubarikukunda kukozeza. Enda ezirikiurugamu zitakarengize emyezi eshatu nizo zirakorweho omukucondooza oku.

Okukuchandoza oku nikuza kufayo omukusaramu ebirikuga omukwejuninisa emibazi orikukugyeragereranisa nanokushemeza ahakwihamu ebisigarira omuri nyinenda.

Ahabwenkyi orikuhabwa kwetaba omu'mushomo ugu?

Otoreinwe kwejumba omu kucondooza oku ahabwokuba oine ebisanizo ebirikwetagisa. Abakazi boona abaine enda ezirigimu ebichweka bahairwe omugisha gurikwingana kwetaba omukuchondooza narishi omumushomo ugu. Kwerayetabe omumushomo, ebirarugyemu nibiza kwejunisibwa kusharamu kukozeza emibazi narishi okushemeza ahabikwatirine no'kureberera enda ezirugiremu ebichweka.

Engyendererwaho:

Ku'orayikirize kwetaba omu kucondooza oku, noyija kuheebwa omuhuure ogukwatirine no'mushomo ugu kandi noshabwa kutaho omukono ahabaruha egi. Bwanyima, noyija kuheebwa enamba yabantu eratoranwe yona reero abashaho bakukoreho kurungyi obwe barikukozesa omuringo ugu enamba erikugamba. Ekipapura kyebibuzo nikijja kukuheebwa ahamuheru gwomushomo ugu.

Ebyaakubasa kukuteganiisa omukucondooza oku

Hariho ebizibu bikye munonga ebyakubaasa kukuteganiisa ahanda ezirugiremu ebichweka kurugirira aharurengo rwokujanjaba kwa ihanga rya Uganda orikukozesa omuringo gwe emibazi yonka narishi okusemeza.

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Ebi okucondooza oku kurayambe:

Abarayetabe omumushomo barayegyesibwa emiringo y'okureberera enda ezeihirwemu eziri ahansi yamyenzi eshatu. Eki kiraretera okumansisibwa kandi nan'okwegyesibwa ekirakyeendeze ahanamba yabakazi abarikufa ahabwokwihamu enda.

Ebirungi nana ebibi ebirarugye omukuchondooza nibyija kwejunisibwa omukubaga engyenderwaho ahabikwatirine nenda zirugiremu ebichweka.

Ebiraakuheebwe ahabwokwetaba omu kucondooza oku:

Tihariho bicoonco byoona nka sente nginga ebyokurya ebiriije kukuheebwa.

Okubiika kurungi ebi'oragarukemu kugira ngu abandi batabimanya:

Toriije kushabwa amaziina gaawe kwiyaho noyija kuheebwa enamba kandi abashaho abarikukora oku'kucondooza nibo boonka abariije kureeba ebiragarukwemu. Nibyiija kubiikwa kurungyi omu ward yabakyara konka akakiiko k'okucondooza nikatasa kushaba kwikirizibwa kubireebaho.

Okwanga / okuruga omu kucondooza oku:

Noobasa kwanga kwejumba omuri'oku kucondooza nginga osahbe kurugamu akiire koonka.

Wayanga nginga okaruga omu kucondooza oku nihabaho kyi?

Ekyi tikirikwiija kuteganisa omu muringo gweena kandi nabwe noyija kukorwaho nkabandi barweire boona omu'irwariro hatarimu kucwamu.

Nobuuzza oha wakuba oine ekwetombeitwa?

Okwetombeitwa kwena, nobaasa kwebuuzaho ahari;

Dr.Victor Otieno, Department of Obstetrics and Gynaecology, Kampala International university,
Tel. +256750813662 or Prof. Bonet Ivan Tel +256772 387977

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Okuta omuhuure gwawe nginga ekinkumu aha baruha egyi nikimanyisa kyi?

- Noshoborokyerwa ebiriije kukorwa omu kucondooza oku n'ebirikubaasa kurugamu byona.
- Noikirizibwa kubuuza ebi'otarikukyenga otakatiireho ekinkumu.
- Watwara obwiri bwoona obwokenda obuwakubasa kukozesa kwetegyereza ahabikwatirine nana omushomo ogu.
- Waikiriza batakugyemire kwetaba omu kucondooza oku.

.....		
Eizina rya orikugarukamu	Omuhuure/Ekyinkumu	Ebiro
.....		
Eizina rya orikubuuza	Omuhuure/Ekyinkumu	Ebiro
.....		
Eizina ry'owaaba ariho	Omuhuure/Ekyinkumu	Ebiro

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	NUMBER:
	PI's NAME:
	REC NO:

EKICHWEKA KYAKABIRI: EBARUHA YO'KWIKIRIZANA YABEBYOKWERINDA ABEMIBAZI (EBIJUMA) NANA ABOKUSHEMEZA.

Nyowe Ninyikiriza kwetaba omukucheberwa/okushemezazibwa.....nkomuringo gwebyokwerinda gwokujanjaba enda zirikwihwamu eziri ahansi yemwezi eshatu bwanyima yokwegyesibwa. Nayetegyereza byoona ebibanshobororora kandi ninyikiriza ndikutekaho omukono gwangye narishi ekinkumu ahabwa omuringoogubagamba kunkozesaho.

.....		
Eiziina ryomurwire	Omukono/siyini/ Ekinkumu	Ebiro
.....		
Eiziina ry'omwema	Omukono/siyini/ Ekinkumu	Ebiro

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APPENDIX III: INVESTIGATOR ADMINISTERED QUESTIONNAIRE

Patient serial number..... Date.....

Telephone contact.....

This will be necessary for the purpose of communication

Address.....

Date of admission.....

Date of discharge.....

Length of hospital stay (days).....

Parity.....

Gravidity.....

Last normal menstrual period.....

Expected date of delivery.....

Weeks of amenorrhea.....

Short history

.....

Abdominal and pelvic examination findings

.....

.....

INTERVENTION GIVEN (medical vs surgical)

.....

EXTRA MEDICATION GIVEN APART FROM THOSE ON RESEARCH PROTOCOL

.....

.....

1.0. DEMOGRAPHIC DATA.

1.1. Age of the respondents

.....

1.2. Religion

- a. Christians ()
- b. Muslim ()
- c. Others (specify)..... ()

1.3. Tribe.

- a. Munyankole. ()
- b. Mukiga. ()
- c. Mufumbira. ()
- d. Others (specify)..... ()

1.4. Marital status.

- a. Married. ()
- b. Widow. ()
- c. Single ()
- d. Divorced. ()
- e. Separated. ()

1.5. Education status.

- a. None ()
- b. Primary ()
- c. Secondary ()

- d. Tertiary. ()
- e. University. ()

1.6. Occupation.

- a. Peasant farmer. ()
- b. Self-employed ()
- c. Student ()
- d. Civil servant. ()
- e. Others (specify)..... ()

1. For how many hours did you bleed after initiation of treatment?

.....

2. During the period of bleeding did you experience any of the following? (Tick as necessary)

- a) Syncope
- b) Dizziness to inhibit daily functions
- c) Severe headache
- d) Blood transfusion
- e) None of the above

3. Are you experiencing any of the following? Tick as necessary

- a) Fever
- b) Chills
- c) Foul smelling vaginal discharge
- d) Nausea and vomiting

e) Diarrhea

4. Can you rate the pain level you felt (use Likert scale of pain)

.....

5. Rank the level of fulfillment on the method used. Tick one (use satisfaction tool)

a) Very satisfied

b) Somewhat satisfied

c) Somewhat dissatisfied

d) Very dissatisfied

6. Give reasons for the response given above (invasiveness, anaesthesia, failure of method, excessive bleeding, hospital stay, pain level, etc.)

.....
.....
.....
.....

7. Would you recommend the method to anyone?

a) Yes

b) No

8. After the 1st method assigned to you, was there another intervention method used? (Primary failure)

a) Yes

b) No

9. If yes which method was used?

a) D&C /MVA

b) Medical treatment

c) Hysterotomy

d) Exploratory laparotomy.

APPENDIX IV: TRANSLATED INVESTIGATOR ADMINISTERED QUESTIONNAIRE

Enamba yo'mubaro yomurwire..... Ebiro

Enamba yesimu

Eki nikiza kwetagwa omukuhurizana kurungi

Obuzaarwa.....

Eizooba/ebiro ebiwagyerireho omwirwariro.....

Eizooba/ebiro byokusibuza.....

Enaku/ebiro ebiwamazire omwirwariro.....

Amazaara

Emirundi yogizire enda.....

Obwohereruka (ekiro) kuza omumichwe.....

Ebiro ebyorikutekateka kuzariramu.....

Esanda ezihingwireho kwiiha oza omumicwe.....

Ebikwatirine nebyaharuguru omubufunze

.....

Ebyarugire omukyebera enda

.....

.....

Obuhabuzi obwahairwe ahabikwatirine nomuringo gwokukozesa (Okukozesa ebijuma/emibazi narish okushemeza).

.....

Obuzanjabi obukukiraho obwahairwe obwabiire butagambirweho omumushoomo

.....

.....

1.0. Ebikukukwataho

1.1. Emyaka

.....

1.2. Ediini

- a. omukurasi wa kurisitu ()
- b. Omusiramu ()
- c. ebindi (yoreka) ()

1.3. Orurimi

- a. Runyankole. ()
- b. Rukiga. ()
- c. Rufumbira. ()
- d. Ebindi (yoreka) ()

1.4 Ebikwatirine no'bushwere

- a. Omufumbo ()
- b. Efakazi ()
- d. Owayangaine ()
- e. Omurekwa ()

1.5. Ebikwatirine nemishomo

- a. Tindashomire ()
- b. Purayimare ()
- c. Siniya ()

- d. Obwegyese obwahiguru ()
- e. Yunivasite (ahakasozi) ()

1.6 Omurimo

- a. Ndyomuhingi ()
- b. Ninyekozesa ()
- c. Ndi omwegi ()
- d. Ndi omukozi wa gavumenti ()
- e. Ebindi (yoreka)..... ()

1. Okamara ebiro bingahi orikujwa eshagama bwanyima yokukujanja? (yoreka omubaro gwa padizi eziwakozise omukiro kimwe)

.....

2. Obuwabiire nojwa eshagama, haine ekyakuhikireho ahabiri ahaifo? (Kyebera ahikirikwetagisa)

- a. Nkagwa kihumura
- b. Okubura amani
- c. Okuteerwa omutwe mwingi
- d) Okukutamu eshagama
- e. Tihaine nakimwe ahabyayorekwa aharuguru

3. Obwahati haine ekyorikwehuriramu ahabyayorekwa ahifo? (Kyebera ahikirikwetagisa)

- a. Omuriro (oruswijaswija)
- b. Orubuho omunda
- c. Ekinuko
- d. Nohurira noyenda kutanaka

e. Ekirukano

4. Nobasa kupimapima obusaasi obuwapunire (Kozesa lickert scale kupima obuhurizi/obusaasi)

.....

5. Gamba obwesigye obuwapunire bwanyima yokukozesa omuringo ogubakukoziseho. Kyeberaho kimwe

a. Nkahirira namarwa

b. Nkahirira mazirwegye

c. Tindafunire kumarwa kwoona

d. Nkahirira ntamazirwe

e. Tindamazirwe nakakye

6. Hereza enshonga ahabwa ekigarukamu kyawe ekayaharuguru (Ahakibuuzo kya 5)?

.....
.....
.....
.....

7. Kurugirira aha muringo gubakukoziseho, nobasa kuhabura omuntu ondijo kugukozesa?

a. Ego

b. Ngaha/apaana

8. Bwanyima yo'muringo gwokubanza ogubayejunise, heine omuringo ogundi ogwakukozesibweho?

a. Ego

b. Ngaha/Apana

9. Kuharabe hariho omuringo ogundi nomuringo guha? Torana ahiifo.

a. Okwoja omuri nyinenda

- b. Okukozesa emibazi narishi ebijuma
- c. Okusemeza kwihamu nyinda
- d. Okusemeza omunda

