INTRODUCTION

Overview of Abortion World Wide

Abortions occur in all countries but ninety-five per cent (95%) of unsafe abortions occur in developing countries (World Health Organization 1998). Research has shown that about seventy thousand (70,000) women die from unsafe abortions per year worldwide (WHO, 1997). This means that close to 200 women die every day worldwide from unsafe abortions. Globally, unsafe abortion contributes to about thirteen percent (13%) of maternal deaths (WHO, 1998). In addition to these numbers tens of thousands of women suffer long-term health consequences including infertility. Major complications of abortion such as excessive hemorrhage and infection result from incomplete abortion. Therefore, finding affordable, effective and acceptable treatment of incomplete abortion can significantly help reduce morbidity and mortality from incomplete abortion.

Overview of Abortion in Zambia

Unsafe abortion is one factor contributing to the high maternal mortality ratio in Zambia. As reported in the 2007 Zambia Demographic and Health Survey, the maternal mortality ratio in Zambia is estimated at 591 per hundred thousand live births (ZDHS 2009). A hospital based study in 1983 by M'hango et al found that abortion contributes to about 15% of maternal mortality. Mati et al found that it contributed 30% (Situations Analysis UNICEF 1994). Therefore, addressing unsafe abortion can significantly reduce maternal mortality in Zambia.

While abortion complications are a common medical emergency in developing countries such as Zambia, care given to women with such conditions is often delayed due to critical shortage of health care workers and medical supplies. Realizing this problem, in 2002 Zambia embarked on a program to expand Post Abortion Care (PAC) services around the country. The PAC program anticipates the need for emergency treatment of post abortion complications; plans ahead to meet that need and provides family planning to prevent repeated abortions. The program has been successfully implemented and is being expanded to reach all districts of Zambia. It was aimed at using midlevel providers as a means of increasing access to PAC through training of nurses and midwives. This was brought about by the Nurses and Midwives act of 1997 which allows them a wide scope of practice, thereby ensuring that services are provided as close to the communities as possible (Kaseba et al, 1998). It was envisaged that the PAC services would provide such a service contributing to the reductions in the maternal mortality and morbidity (Kaseba et al, 1998).

Incomplete Abortion

Incomplete abortion is a major cause of morbidity and mortality among women that experience an abortion. Women with incomplete abortion present with varying clinical conditions. A typical clinical presentation of incomplete abortion is that of vaginal bleeding, lower abdominal cramps, and dilated cervix with partial expulsion of products of conception. However, some present with severe bleeding others with infected retained products of conception, or with injury to reproductive health organs and some just in poor general health and need immediate resuscitation and surgical evacuation of the uterus. Others come with retained products of conception but in good general condition.

Record inspections at the University Teaching Hospital, where this study was done, revealed that on average 430 Manual Vacuum Aspiration (MVA) procedures are performed per month for incomplete abortion. About 80% of these are for pregnancies 12 weeks or less as estimated by the last menstrual period. It was also found that abortion-related conditions accounted for about 30 to 50% of admissions to the gynecologic emergency ward at the UTH. Women often wait for hours before the vacuum aspiration is done due to the huge workload resulting from inadequate material resource, limited space and in some cases due to antiquated practices.

The treatment for incomplete abortion at the UTH is currently using manual vacuum aspiration (MVA) though before the 1990s management was by dilatation and curettage (D&C) under general anaesthesia. Finding safe, effective, acceptable, and affordable means of treating incomplete abortion is therefore a priority for low resource settings like the proposed study site.

LITERATURE REVIEW

The use of sharp curettage is discouraged by the World Health Organization (WHO), as it is considerably more painful for women than vacuum aspiration, and less safe (rates of major complications are two to three times higher than those of vacuum aspiration), (Grimes et al, 1979; Grimes et al, 1977).

Alternatives for Treatment of Incomplete Abortion

While both MVA and sharp curette are effective, they require specialized equipment and skills. Furthermore, they subject the woman to the dangers attendant on a surgical procedure such as trauma, perforations, infections, bleeding due to instrumentation, and reactions to anesthesia, among others. For these reasons, determining an effective nonsurgical approach to treatment is a priority

Misoprostol for Treatment of Incomplete Abortion

Misoprostol, a prostaglandin E1 analogue, is a medical alternative to manual vacuum aspiration and other uterine evacuation methods such as dilatation and curettage (D&C) for treatment of incomplete abortion. It is an orally active prostaglandin analogue that is widely available, inexpensive, easy to administer, and stable at room temperature. Initially registered for the prevention of gastric ulcers during long-term use of non-steroidal anti-inflammatory drugs, misoprostol is now registered and used in many countries for numerous obstetric and gynecologic indications including induction of labor, preparation of the cervix for surgical procedures, prevention or treatment of postpartum hemorrhage, and pregnancy termination (Winikoff B. 2006).

The World Health Organization expert committee on the selection and use of essential medicines has now recommended misoprostol for treatment of incomplete abortion and put the drug on the essential drugs list (WHO Technical Report Series, May 2009).The committee identified 22 relevant studies that directly compare the use of misoprostol with surgery for the treatment of incomplete first trimester abortion. Based on these data, there is no statistically significant difference between surgery and oral misoprostol in terms of uterine clearance up to 14 days after administration. Comparison of adverse effects showed that while misoprostol administration was associated with predictable adverse effects (such as bleeding and pyrexia) due to the pharmacological actions of the medicine, these effects generally did not require further interventions (such as blood transfusion) and were reported as acceptable by the women. The adverse effect profile of misoprostol needs to be compared with the potential risks of surgery in unsafe settings i.e settings with no staff trained in surgical uterine evacuation methods or settings that does not meet minimal medical standards (WHO Technical working group report 1992). With respect to use of misoprostol for the treatment of incomplete abortion, the Committee decided that the evidence showed that misoprostol is as effective as surgery and in some settings may be safer as well as cheaper and therefore recommended inclusion of the 200 micrograms tablet on the complementary list with a note indicating the appropriate use: "*for management of incomplete abortion and miscarriage"*. (WHO Technical Report Series, May 2009).

Management of incomplete abortion with misoprostol offers other advantages over surgical procedures and includes:

- Ease of use.

- Decreased complication rates compared to surgical uterine aspiration (Reproductive Health Technologies Project and Gynuity 2004).
- Potential use by a wider range of providers and facilities and gives women choice of the uterine evacuation method in any health faculty.
- High client satisfaction. In most studies, satisfaction with medical management is as high, or higher, than with surgical uterine aspiration (Bique et al, 2007*;* Dao et al 2007; Shwekerela et al 2007).

Many studies (Chung et al, 1995; de Jonge et al, 1995; Pandian et al, 2001; Sahin HG et al 2001; Bagratee et al 2004; Weeks A et al, 2005) have indicated that the uterotonic and cervical ripening properties of misoprostol make it a safe and highly effective method of evacuating the uterus in cases of incomplete abortion. Misoprostol's stability at room temperature and low cost makes it an ideal treatment in low-resource settings.

While some studies of misoprostol for incomplete abortion have employed the vaginal route of administration, (Demetroulis et al, 2001; Sahin et al, 2001, Ngai et al, 2001; Pang et al 2001), the majority of such studies that had high success rates have employed the oral route, (Chung et al, 1995; De Jonge et al, 1995; Pandian et al, 2001; Pang et al 2001; Sahin et al, 2001; Ngoc et al 2005; Weeks et al, 2005; Shwekerela et al 2007; Bique et al 2007; Dao et al 2007).

Dose finding studies conducted in Thailand and Vietnam (Blanchard et al, 2004; Zhang et al 2005; Moodliar et al 2005; Ngoc et al 2005) and a large study in Kampala, Uganda (Weeks et al, 2005) used 600µg dose and oral route of misoprostol for treatment of incomplete abortion. A number of studies which achieved the highest success rates of over

90% used a single 600 micrograms oral dose of misoprostol. (Weeks et al, 2005; Ngoc et al 2005, Shwekerela et al 2007; Bique, et al 2007; Dao et al 2007).

Previous studies on the use of misoprostol for incomplete abortion had a wide range of diagnostic criteria, doses, and routes and report success rates of between 13% and 100% (Creinin et al, 2001). This variation largely occurs as a result of the different ways in which previous studies have used ultrasonography. If ultrasonography is used before treatment, approximately 29% of women will be found to have an empty uterus and will therefore not require treatment (Chung et al, 1997). Conversely, if ultrasonography is used after treatment to assess success, a thickened endometrium is often seen in the first few days. This finding has been frequently misinterpreted as demonstrating "retained products," leading to unnecessary surgical intervention (Creinin et al, 2004). Hence the reported "success rate" in previous trials is closely related to the length of time after treatment at which the uterus is reassessed with an ultrasound examination (Weeks and Alia, 2001).

However, in women with prolonged bleeding following treatment, ultrasonography may have a role in distinguishing between retained products and endometritis, because those with a thin endometrium have been shown to have minimal tissue at evacuation (Chung et al, 1998). Therefore, the highest success rates (of 100%) are reported in situations where the passage of products before discharge from hospital is not a criterion for success, where endometrial thickness is not measured in clinically stable women following treatment, and where the final assessment of success is made 7 or more days post treatment (Ngai et al, 2001; Bagratee et al 2004).

Effects and side effects of misoprostol

Women taking misoprostol, which causes the uterus to contract, can expect to experience several effects and side effects of the medication, many of which are experienced during a spontaneous abortion. The most common are increased bleeding, cramping, nausea, vomiting and diarrhea, and fever. Generally, these occur within the first few hours after the medication is taken. Bleeding and cramping are generally greatest during completion of the abortion.

STUDY JUSTIFICATION

UTH has a high number of abortion-related admissions in the emergency gynecologic ward (30% to 50%) with a large number of patients treated for incomplete abortion (average 430 per month). Whilst MVA has been incorporated and has been shown to be very helpful in the treatment of incomplete abortion, there is need to explore other evidence based practices that will help in offering effective and acceptable treatment options for women.

There have been a number of patients that are reported to have refused MVA and made to write signed statements for deciding against medical advice. Whilst misoprostol has been studied in other countries and is now being used for the treatment of incomplete abortion, this has not yet been done for any health facility in Zambia. As a result there is no evidence on the safety and acceptability of the implementation of misoprostol for the treatment of incomplete abortion at the University Teaching Hospital and other health facilities in Zambia.

Being the largest health care and medical training institution in Zambia, and with the high numbers of patients with incomplete abortion, the UTH is well placed to take leadership in introducing this new technology.

Findings from this study will help in expanding uterine evacuations in incomplete abortions at sites without MVA facilities and expertise. The study will give women options for uterine evacuation in incomplete abortion. The results from this study will also inform authorities regarding the options for expansion of post-abortion programs.

AIM OF THE STUDY

To evaluate the safety, effectiveness, and acceptability of misoprostol for the treatment of incomplete abortion at the University Teaching Hospital, Lusaka, Zambia.

SPECIFIC OBJECTIVES

1. To determine the success rate of complete abortion at one and two weeks after administration of misoprostol in patients with first trimester incomplete abortion.
2. To document reported side effects (e.g. of abdominal cramping, vaginal bleeding, nausea, vomiting, diarrhea and fever).
3. To evaluate the acceptability of the intervention by the women
4. To evaluate patient satisfaction with the intervention

METHODOLOGY

I. Study Design

An open-label, single arm prospective study design was employed to recruit patients presenting at the University Teaching Hospital, gynecologic ward (ward CO3) in Lusaka for treatment of incomplete abortion between 31st October and 30th November 2009.

The study was designed to be a feasibility study since it introduces a different treatment option for incomplete abortion that is new to Zambia.

II. Hypothesis

Misoprostol is safe, effective and acceptable for uterine evacuation in incomplete abortion.

Eligibility (inclusion) Criteria

1. Patients with a diagnosis of incomplete abortion with gestational age of 12 weeks or less as established by a reliable menstrual history and/or pelvic examination on day one of study.
2. Woman in general good health (i.e. not needing resuscitation, and without chronic ill health).
3. No severe active bleeding (defined by change of two fully soaked sanitary pads hourly for two consecutive hours)
4. No signs of infection (temp >37.5°C, pulse >110 per minute, or foul smelling discharge)
5. No known hypersensitivity to misoprostol
6. Women coming from within Lusaka District
7. Women willing to return for follow up.

8. Able to give informed consent (at least 18 years old and of sound mind)

Exclusion criteria

1. Patients with incomplete abortion greater than 12 weeks gestation
2. Patients in poor general health (such as chronic ill health or patients needing resuscitation)
3. Patients with severe bleeding
4. Patients have signs of infection (Foul-smelling discharge, fever > 37.5°C, or pulse > 110/minute)
5. Known allergy to misoprostol.
6. Patient that require resuscitation
7. Women coming from outside Lusaka district
8. Women not willing to return for follow-up
9. Unable to give consent

SAMPLING:

The study population was that of women presenting to the University Teaching Hospital Gynecological emergency ward with incomplete abortion and the sample was from women with pregnancies in the first trimester who met the above eligibility criteria.

A total of 152 women with incomplete abortion seeking care at the University Teaching Hospital emergency gynecological ward and willing to take misoprostol treatment were recruited for the study. Because not many patients met the inclusion criteria, all those that met the criteria were purposively enrolled into the study.

SAMPLE SIZE CALCUALTION

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

n = the sample size; Z = the standard normal deviate (1.96), i.e. 95% confidence interval

P = Proportion of the target population estimated to have the variable of interest i.e. Success rate of uterine evacuation (at least 90%)

q = 1-P; d = degree of accuracy = 0.05

Therefore n= 138 patients, adjusted to 152 at 10% loss to follow-up

DATA COLLECTION AND CLIENT FOLLOW-UP PROTOCOL

A data entry clerk was trained on data entry. A doctor and nurse working in the gynecologic emergency ward were oriented about the study and they were trained on how to enroll patients on the study. The doctor and nurse followed and monitored events in the gynecology emergency admission ward and enrolled clients.

Patients on the study were recruited from the UTH emergency gynecologic admission ward. They were counseled and evaluated for eligibility using a client study ***eligibility check list form (appendix 1)*** and if eligible, consent obtained for follow up at the UTH. ***Once consent (appendix 2)*** *was* signed, the ***client interview day one form (appendix 3) was*** administered and then the woman was given 600µg misoprostol. They were required to swallow the pills in the presence of the study investigator and remained in the clinic for approximately one hour of observation. Antibiotics were prescribed routinely comprising metronidazole 400mg eight hourly for seven days and doxycycline 200mg start followed

by 100mg twelve hourly for seven days (erythromycin for those not eligible for doxycycline). Paracetamol 1g was provided to all women to be taken after the misoprostol was ingested at anytime they had pain but at least six hours apart.

Follow-up visits were done at one and/or two week intervals. The patients were advised to come back anytime they experience symptoms such as fever, foul smelling discharge, severe vaginal bleeding or when they were concerned about anything. All women were given a telephone number which they could reach in case they experience the aforesaid. They were also asked to give a telephone number (which was tested) for the follow-up in case they missed the follow-up appointment.

Women were asked to return to the hospital after one week to confirm the status of the abortion by clinical examination. Completion was determined clinically by cessation of vaginal bleeding, a closed cervical os and uterine size of almost normal size. If the abortion was still incomplete, women were given the option of waiting an additional week to see if the abortion would complete spontaneously, or immediately underwent a surgical evacuation by MVA. For those who elected to wait, they were evaluated again seven days later and, if there was still clinical evidence of substantial retained products of conception in the uterus, they had a surgical evacuation at that time. If the abortion was complete the women were discharged from the study.

Prior to being discharged from the study, all women answered a series of questions about the acceptability of the treatment and its side effects using ***client follow-up interview form (appendix 4).*** No monetary compensation was provided to the women, but those who

attended the follow-up visit received transport refund equivalent to the bus fares to the destination of their residence as documented on the hospital records.

Adverse events

In case of any adverse events, e.g. death, infection, severe bleeding (soaking for that two heavily soaked pad in an hour for two consecutive hours), vomiting causing body weakness, diarrhea causing body weakness, the following was to be done:

a. The adverse event form *(Appendix 5)* was to be filled in and the ethics review committee informed within 24 hours.
b. The patients were to receive immediate and expedited medical care within the UTH department of obstetrics and gynecology. The researcher was to ensure that the patient's medical expenses were met where needed and all information about the adverse event provided to the patient and her relatives as needed.

The following was the sequence of events in client enrolment and follow-up:

1. ***Patient eligibility assessment***
    a. *Client eligibility checklist form administered which captured demographic details.*
    b. *Eligibility criteria was assessed*
    c. *If patient eligible then consent form was administered*
2. ***Patient consent***
    a. *Consent form administered*
    b. *If patient consents, client interview day one is administered to obtain history and examination*

c. *If consent not given, patient not enrolled in study but allowed to access the services like any other patient*

3. ***Client interview day1 form***

   a. *The client interview day one form was administered*

   b. *Patient was then given 600µg misoprostol to swallow in the presence of the interviewer*

   c. *One week follow-up date was agreed and patient was given contact information in case of any adverse events*

4. ***Client follow-up interview (week one or two)***

   a. *Patient was reviewed at one week. If the abortion was found to be complete, the follow-up form was administered before the patient was discharged from the study*

   b. *If at first week the abortionwas not complete, the patient was given an option to either wait for one more week or had MVA done immediately.*

   c. *If they wish to wait for one more week then the client interview form was only administered at week two follow-up. If at week two the abortion was still incomplete then the patient was to undergo MVA and the follow-up interview form administered before discharge from study.*

OUTCOME VARIABLES

The primary outcome measure was complete uterine evacuation without recourse to additional surgical intervention at any point for any reason e.g. if a patient decided to have an MVA before the stipulated time for any reason, if there was a complication such as

excessive bleeding, infection and the follow-up was abandoned for MVA, etc. Other outcome measures included side effects, acceptability and satisfaction.

As the study assessed women's satisfaction with the treatment, each participant was asked the following: on how satisfied they were with the intervention (very unsatisfactory-1, unsatisfactory-2, satisfactory-3 and very satisfactory-4), to name the best and worst features of her treatment, to indicate whether she would select the treatment again, and if she would recommend it to a friend.

Abdominal cramping, if reported, was graded as follows: **mild: equal to menstruation; moderate: stronger than menstruation but tolerable**; and **severe: much stronger, inhibiting normal activities**. Vaginal bleeding was graded as follows: **mild: spotting, moderate: equal to menstrual flow, severe: heavier than menstrual flow.**

Some social demographic characteristics of the participants were collected such as age, marital status, education level, gravidity/parity, gestational age of the pregnancy, whether the abortion was reported to have been spontaneous or induced, previous use of a modern family planning method, whether the client was on a family planning method when she got pregnant, and how pregnancy was diagnosed (symptoms or gravindex).

Data analysis and presentation

Data was entered and analyzed using Epi Info which mimicked the study collection instruments.

Descriptive frequencies and proportions were computed for all variables and presented in form of tables.

Ethical considerations

Clearance was obtained from the Department of Obstetrics and Gynecology to conduct the study from the aforesaid ward, and ethical approval was obtained from the University of Zambia Ethics committee.

The study was conducted in compliance with the principles of the Declaration of Helsinki (World Medical Assembly, 1983).

RESULTS

Between 31st October and 30th November, 152 women were recruited into the study. Four (2.6%) were lost to follow-up and 148 returned for the follow-up visit. Two of those lost to follow-up were called on phone and said they had travelled out of Lusaka but said they were fine and felt that they didn't need to come for review. Data analysis for day one interview was done for 152 clients whilst that for the follow-up interview was done for 148 clients. Below is an account of the results.

PARTICIPANT'S DEMOGRAPHIC CHARACTERISTICS (Table 1 a and b)

The descriptive statistics of the study participants included, age, education level, marital status, cost of bus fares to the University Teaching Hospital, parity and gravidity. Other characteristics included whether abortion was reported by the patient to be Spontaneous or induced, the gestational ages, whether pregnancy test (Gravindex) was done or the patient relied on symptoms and whether the patient was referred from another health facility or not. Table 1 below shows the frequency and proportions of these variables.

It can be noted that most women were aged between 21 and 30 years old. This could be because most pregnancies occur during this period. Of note is the number of pregnancies among women aged between 18 and 20, despite only three age groups being included in this range, the number of pregnancies were second to that of women aged 20 to 30 years.
Married women were more likely to present with incomplete abortions more than other marital statuses combined and those with 2 to 4 pregnancies were more likely than primigravidas and those with 5 to 10 pregnancies combined.

More women reported spontaneous abortions than induced ones (86.8% and 13.2%). The mean gestational age of all the participants was 9.12 weeks. 48% women reported having

used symptoms to conclude about their pregnancies with 52% having done pregnancy tests.

Most of the women seen were referred from a local clinic (n=x, 98.7%) and the average cost of bus fare to UTH was about K 12,000.00.

Women who had used a modern contraceptive method before were 50.7% and 20% reported to have fallen pregnant whilst using a contraceptive method.

TABLE 1 (a): PARTICIPANT DEMOGRAPHIC CHARACTERISTICS (n=152)

Variable	Frequency	Percentage (%)
Age (years) – Mean 26.1		
• 18 to 20	26	17.1
• 21 to 25	48	31.6
• 26 to 30	50	32.9
• 31 to 35	20	13.2
• 36 to 40	7	4.6
• >40	1	0.7
Marital status		
• *Cohabiting*	1	0.7
• *Married*	100	65.8
• *Single*	47	30.9
• *Divorced/ Separated*	4	2.6
Education level (Mean 9.9)		
• *Primary*	***32***	***21.0***
• *Junior Secondary (grade 8-9 level)*	***46***	***30.3***
• *Senior Secondary (grade 10-12 level)*	***59***	***38.8***
• *Tertiary*	***15***	***9.9***
Gravidity (mean 3.01)		
• *Primigravida*	***37***	***24.3***
• *Gravida 2 to 4*	***91***	***59.9***
• *Gravida 5 to 10*	***24***	***15.8***
Abortion Reported Spontaneous	**132**	**86.8**
Abortion Reported Induced	**20**	**13.2**
Mean Gestational age	**9.12**	
Pregnancy test (Gravindex) done	**79**	**52**
Gravindex not done (Symptoms)	**73**	**48**
Referred patients	**150**	**98.7**
Average cost of bus fare to UTH	**K 11,990.00**	
Previous use of contraceptive method	**77**	**50.7**
Pregnant whilst using contraceptive method	**16 out of 77**	**20.8**

TABLE 1(b) GESTATIONAL AGE AT ENROLMENT

Gestation Age (Weeks)	Frequency	Percent
6	2	1.3%
7	15	9.9%
8	37	24.3%
9	39	25.7%
10	35	23.0%
11	15	9.9%
12	9	5.9%
Total	152	100.0%

CLINICAL OUTCOMES (See table 2)

Of the 148 women that returned to follow-up, 142 had successful uterine evacuations whilst 6 were not successful. Among the six patients with unsuccessful intervention, one had a wrong diagnosis of incomplete abortion when actually she had threatening abortion. An ultrasound scan done showed a continuing pregnancy at 12 week. The patient was counseled on the occurrence and advised to continue antenatal clinic visits at UTH. The five failed evacuations were due to patient's requests. One was not able to obtain permission from her employers for review dates or bed rest at home. Further, she was uncomfortable with abdominal cramps at the work place and on day two she came back and requested for MVA which was done. Another was a twenty year old who withdrew on day 2 due to severe bleeding and said that she was unhappy with the method. The third and fourth patients that requested MVAs were 20 years and 18 years old school going girls who withdrew on day two and indicated that they could not wait for the 7 to 14 days. The fifth still had an incomplete abortion on review at day 14 as noted by persistent vaginal bleeding, open cervix and bulky uterus and she had an MVA done as per protocol.

TABLE 2: CLINICAL OUTCOMES (n=152)

Variable	**Frequency**	**Percentage (%)**
Lost to follow-up	4	2.6
Returned for follow-up	148	97.4
Success rate (Evacuation Complete)	142	95.9
Total Failure rate (Evacuation not Complete)	6	4.1
• *MVA done on patients' request)*	5	3.4
• *Failure for medical reasons (misdiagnosis)*	1	0.7

SIDE EFFECTS (Table 3)

Women taking misoprostol, which causes the uterus to contract, can expect to experience several effects and side effects of the medication, many of which are experienced during a spontaneous abortion. The most common are increased bleeding, abdominal cramping, nausea, vomiting and diarrhea, and fever. Generally, these occur within the first few hours after the medication is taken and require no further treatment. Bleeding and cramping are generally greatest during expulsion of the returned products of conception.

Abdominal pain (cramps)

All the patients seen had complained of some level of abdominal cramps. Patients were more likely to have **moderate** abdominal cramps (67.6 %) which as defined above meant that the pain was more than pain due to menstruation but the patient continued with their normal daily activities (**mild** is like pain of menstruation and **severe** is more than menstruation and inhibiting normal activity).

Vaginal bleeding

All the patients reported some degree of vaginal bleeding bit patients were more likely to have **moderate bleeding** (76.3%) reported which, in this study, was defined as bleeding equivalent to normal menstrual flow (mild is equivalent to spotting and severe is defined as being much more than menstrual bleeding). The mean duration of bleeding among the participants was 4.7 days with a range of 1 to 11 days.

Other side effects

Diarrhea was the most frequently reported (68.2%) among other symptoms such as fever, nausea and vomiting. Some patients reported a combination of these symptoms such as fever with diarrhea and diarrhea with vomiting.

None of the patients experienced a **serious adverse event.** A serious adverse event is defined as events such as death, a life-threatening experience, prolonged inpatient hospitalization, persistent or significant disability or incapacity.

Among all the 148 patients that returned for follow-up, 95.3% reported having expelled tissue from the vagina a few hours after misoprostol administration. Others just reported the cramps and vaginal bleeding. This might be due to complete abortion even before taking misoprostol.

Table 3 (a): Side Effects

Variable	**Frequency**	**Percentage (%)**
Reported side effects	**146**	**98.6**
Pain	**148**	**100**
• *Mild Pain*	23	15.5
• *Moderate pain*	100	67.6
• *Severe pain*	*25*	*16.9*
Bleeding	**148**	**100**
• *Mild bleeding*	23	15.5
• *Moderate bleeding*	109	73.6
• *Severe bleeding*	16	10.8

Mean duration of bleeding (days)	**4.7 days**	
Tissue expelled	**141**	**95.3**
Fever	**6**	**4.1**
Diarrhea	**101**	**68.2**
Nausea	**28**	**18.9**
Vomiting	**37**	**25**
Serious adverse event	**0**	**0**

TABLE 3(b) SHOWING DURATION OF BLEEDING (Mean 4.67 days)

Number of days of bleeding	**Frequency**	**Percent** (%)
1	3	2.0
2	5	3.4
3	9	6.1
4	54	36.7
5	48	32.7
6	22	15.0
8	1	0.7
9	1	0.7
10	2	1.4
11	2	1.4
Total	147	100.0

SATISFACTION AND ACCEPTABILITY (Table 4 and 5)

Satisfaction was defined, in this study, by patients stating how satisfied they were on a scale of 4 (very satisfied, satisfied, unsatisfied, and very unsatisfied).

Acceptability as defined by patient stating that they would **choose the method again** if they had a miscarriage and would also **recommend the method to another person**.

Among the 148 patients that returned for follow-up of 98.7% (146 patients) of the patients indicated that they were satisfied with the intervention 81.1% very satisfied and 17.6% just satisfied). The remaining 1.4% (2 patients) indicated that they were unsatisfied with the method. No patient indicated being very unsatisfied with the method. Among the two patients who were unsatisfied, one was the patient who had a wrong diagnosis of incomplete abortion instead of threatening abortion. The other was the patient who reported severe abdominal cramping and severe vaginal bleeding and withdrew from the study on day 2 opting for MVA. Among the satisfied patients were 4 of the patients who did not have successful evacuation. They indicated that despite opting for MVA they were still satisfied that they had an option given to them for evacuation.

A total of 97.3% of the patients reported that they would choose the method if they had an incomplete abortion again whilst 99.3% indicated that they would recommend the method to a friend. These two numbers were different because some of the patients who said they would not choose the method again indicated that they would recommend it to others to judge for themselves. One of the patients indicated that she was satisfied with the method but would not choose the method again because she would want to experience MVA as well.

All the clients who received analgesia were given paracetamol, ibuprofen or diclofenac and 96.6% said they were satisfied with the prescribed analgesia.

Table 4: Satisfaction

Variable	Frequency	Percentage (%)
Very satisfied	120	81.1
Satisfied	26	17.6
Unsatisfied	2	1.4
Very unsatisfied	0	0
Satisfied with analgesic (NSAID)	141	96.6
Unsatisfied analgesic (others)	5	3.4

Table 5 Acceptability

Variable	Frequency	Percentage (%)
Would choose method again	144	97.3
Would not choose method again	4	2.7
Would recommend method to friend	147	99.3
Would not recommend method to a friend	1	0.7

DISCUSSION

The study showed a success rate of 95.7% complete uterine evacuation using Misoprostol for treatment of the incomplete abortion. Satisfaction and acceptability of the method was 99%. The study did not record any unexpected side effects and no patient experienced serious adverse events. The mean age of participants was 26.1, most were married (65.8%), majority of them having been only up to secondary school of education. Most of the women were in their 2^{nd} to 4^{th} pregnancy (59.9%) with mean gestational age being 9 weeks.

This study demonstrates that 600µg misoprostol given orally was effective in the treatment of incomplete abortion for pregnancies in the first trimester at the UTH. The success rate could have even been higher if three of the clients had not withdrawn for social reasons. These patients withdrew on day two and opted for MVA only for their convenience. The success rate of 95.9% is comparable to that reported in randomized trials conducted in similar clinical areas in Uganda, Tanzania, Mozambique and Burkina Faso (Weeks et al, 2005; Shwekerela et al 2007; Bique, et al 2007; Dao et al 2007).

The side effect profile showed these were not intolerable by the women and no unexpected side effects occurred. The study also showed that no serious adverse event occurred proving the safety of misoprostol for this indication.

The acceptability and satisfaction rate of close to 99% shows that women are comfortable with using this method for treatment of incomplete abortion. Although this was a single arm study, women indicated that they have about MVA is a surgical procedure and when it was explained to them they still felt that misoprostol was the better option. Even some of the women who did achieve completion felt satisfied and indicated that they would

recommend the method to others. The level of satisfaction and acceptability is also similar to that obtained in the studies done in similar settings mentioned above.

Some patients were lost to follow-up (2.6%) but this was within the projected rate of 10%. Half of these patients (two) were contacted and indicated that they were fine and did not see the need to come back for review. There is possibility that the abortions could have been complete for these patients and they had no problems or they may have gone to seek for treatment from other health care facilities. The high rate of return for follow-up could be because of emphasis put on return despite feeling well and that completion can be established by vaginal examination. In this study ultrasonography was not used to diagnose completion of the abortion. It was only used on one patient who turned out to have had continuing pregnancy. This was due to symptoms she presented with at one week review which were not consistent with incomplete abortion; she did not pass any clots before or after misoprostol administration and review of patient's file actually showed that the cervical os was closed at the time of recruitment. The patient was wrongly given diagnosis of incomplete abortion. The patient's pregnancy continued, and she was booked for antenatal but by the end of the study the patient was lost to follow-up and the outcome of the pregnancy is not known. This shows the need for very careful history taking, physical and pelvic examination, and documentation.

Future studies should address the use of misoprostol in primary health care facilities. As shown in this study, 98.7% patients were referred from primary health care facilities. Introduction of this service would help decongest the tertiary level facilities and make follow-up easier due to short distance. This may further reduce the rates of loss to follow-up. To some women, the cost of transport to the UTH which was on average K 11,990.00 could be significant to even contribute to their failure to return for follow-up. Rural

communities with no access to MVA facilities can benefit from this method of treating incomplete abortion. Training of providers in history taking and physical and pelvic examination may be needed but this may not take long since no further skills will be needed as is the case for MVA.

Study Limitations

One of the limitations of this study is that, the investigator could not know if the woman had taken misoprostol to induce the abortion and this may have had an additive effect on the outcome of this intervention since repeated doses of misoprostol are known to lead to completion of an abortion. In a similar way the investigators had no control of whether the patient had taken extra doses of misoprostol after living the hospitals as evidenced by wide use of unprescribed misoprostol in the community (Ministry of Health, Zambia Strategic Assessment, 2008 – unpublished manuscript). In a similar way, the investigator may not have had control on patient use of analgesia. The patient may have taken extra doses of stronger analgesia and not report and this may affect perception of pain.

Study Strengths

The strength of study is that the effectiveness of misoprostol has been studied by a number of randomized controlled trials and success rates for uterine evacuation have been found to be very high. The study was done at a site that has expertise already treating women with incomplete abortion and therefore staff training in the new technology was much easier.

CONCLUSION

Treatment of incomplete abortion using misoprostol is safe, effective and acceptable at the University Teaching Hospital in Lusaka, Zambia for pregnancies in the first trimester. There is need for training of providers in clinical skills and counseling.

RECOMMENDATIONS

1. A similar study should be conducted at primary health care facilities to demonstrate the feasibility of this intervention at that level of care.
2. Women seeking care for incomplete abortion at the University Teaching hospital should be given an option for uterine evacuation that could include misoprostol which is inexpensive and easy to store. MVA should not be mandatory for all the patients.
3. Patients who refuse MVA for fear of discomfort should not be made to sign against medical advice but should instead be offered the option of misoprostol.
4. Health care providers attending to women with abortion complications need further training in pelvic examination to ensure appropriate diagnosis of the state of an abortion and accurate estimation of uterine size.
5. The training package for post abortion care should not only include MVA but use of misoprostol as well.

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