Outcomes of Medical versus Surgical Management of Incomplete Abortion in Uganda. an Open Labeled Randomized Clinical Trial

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Abstract

Background: Management decision on whether to use medical or surgical method in women diagnosed with incomplete abortion particularly in the first trimester has been a controversial topic in Uganda and the world in general with no local studies comparing effectiveness and secondary outcomes between the two approaches. This has posed a big challenge to the attending clinicians as regards making informed management options when encountered with such cases.

Methods: A five months prospective open labeled randomized clinical trial involving 100 consecutively recruited participants was conducted from June 1st, 2018 to October 30th, 2018. Ethical clearance was obtained from KIUREC and UNCST. Data collection was achieved using an investigator administered questionnaire; in-depth face to face interviews as well as laboratory and ultrasound scan report forms. 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 or proportions for categorical variables. All statistical analysis was carried out using IBM SPSS Statistics software version 23.0.

Results: The effectiveness of surgical management was higher than that of medical management (RRR=11.7%; p=0.043). Majority in the medical arm reported mild pain (64% *vs* 4%; p<0.001) while most of those in surgical arm reported severe pain (78% *vs* 8%; p<0.001). Bleeding was prolonged in the medical arm method with majority of those in surgical arm reporting bleeding for less than six hours (94% *vs* 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 one participant in surgical arm developed infection while no patient had genitourinary trauma. There was no statistical significant difference between the satisfaction levels in the two arms.

Conclusion: 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.

Background

Abortion remains one of the leading devastating early pregnancy complications in the world with about 20% of all pregnancies affected world over. About 13% of all maternal deaths in the world, and up to 18% of all maternal deaths in East Africa are attributed to abortion (1). Abortion is a major cause of maternal mortality in Uganda accounting for 26% of all maternal deaths (2). Incomplete abortion continues to be the most common cause of admitted cases of abortion in most settings, more so in the resource constrained nations. Management decision on whether to use medical or surgical methods in women

diagnosed with incomplete abortion particularly in the first trimester 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 (3). At KIUTH, our routine observation can reveal that close to 100% of patients are managed surgically, locking out those that would benefit from the medical management. This leaves patients who would strongly benefit from medical more than surgical management such as those with history of sub fertility, morbidly adhered placenta, the severely immunosuppressed, those with poor obstetric history and those who prefer less invasive procedure marginalized. By exclusively managing these patients surgically, they fail to get the best available treatment option. Use of surgical method exclusively 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. Paucity of published literature comparing the two methods in this setting continues to pose a big challenge to the attending clinicians as regards making informed management options when encountered with such cases.

Methods

An open labeled prospective randomized clinical trial was carried out over a period of five months, from June 1st, 2018 to October 30th, 2018. The study was conducted in the gynaecology unit of Kampala International University Teaching Hospital in South-western Uganda. KIUTH is located in Bushenyi- Ishaka municipality, Bushenyi district about five kilometres from Bushenyi town along Mbarara-Kasese highway. It is approximately 62 kilometers to the west of Mbarara town and about 370 kilometers from Kampala, Uganda's capital city. The hospital serves a large catchment population of about 41,063 people (4) and is a referral point for all the neighboring health facilities such as Kitagata Hospital, Ishaka Adventist Hospital, Comboni hospital, Kabwohe Intgrated Community Based Initiative Hospital, Kabwohe health centre IV, Bushenyi health centre IV, Lugazi health centre IV, Buwhezu health centre IV and several others, with a bed capacity of 700. The gynaecology unit where this study was conducted comprises of one of the obstetrics and gynaecoloy department units of the hospital and operates both outpatient and inpatient services with a capacity of 85 beds. The unit is fully equipped to handle all gynaecologic cases both outpatient and inpatient. It has a minor theatre for minor surgeries such as D&C and MVA as well as a major theatre for major gynaecology operations such as hysterectomy, myomectomy, fistula repairs and so forth. The unit provides emergency abortion care services as well as all post abortion care services such as counselling, family planning, sexually transmitted disease testing, and special clinic linkages such as adolescent and cervical cancer screening as well as community integration services.

Patients were extensively educated and counseled about the study in English and Runyankore-Rukiga, the local language for those who did not understand English language and a written consent to participate in the study was sought accordingly. Our inclusion criteria was all women with incomplete abortion in first trimester of pregnancy (that is, below 12 weeks of amenorrhea) admitted in the gynaecology unit who were haemodynamically stable with no signs of hypovolaemia or shock due to excessive bleeding, with no known history of any contraindication to misoprostol or any other prostaglandins use such as allergy, and with no any known major organ disease. Women with evidence of infection basing on history of

symptoms suggestive of an infectious process such as fever, headache, nausea and vomiting, abnormal discharge from the vagina, dysuria, urinary frequency, among others; coupled with evidence of infection on physical examination which included a body temperature of less than 36^{o}C or more than 38^{o}C, pulse rate of more than 100 beats per minute, respiratory rate of more than 20 respirations per minute among others were however excluded from the study. Women with structural uterine abnormalities such as unicornuate or bicornuate uterus and uterine septum; women with previous fresh uterine scar of less than 18 months, and those with two previous scars or more were also excluded from the study because of associated risk of uterine rupture when subjected to prostaglandin agents such as misoprostol. All patients who met the inclusion criteria and consented for the study were considered irrespective of whether it was spontaneous or induced abortion. A diagnosis of incomplete abortion was achieved by specifically basing on history of amenorrhea not exceeding 12 weeks, per vaginal bleeding and/or lower abdominal pain. Physical examination including per abdominal examination to assess for the fundal height and lower abdominal tenderness as well as pelvic examination using a Cusco's bivalve vaginal speculum to confirm the presence of an open cervical os, and/or per cervical bleeding and/or any popping products of conception through the cervical os were done under clear light. Thereafter, a rapid qualitative urine human chorionic gonadotropin (hCG) pregnancy test and a trans abdomino-pelvic ultrasound scan were done. Other investigations such as complete blood count (CBC), blood smear (BS) for malaria parasites, urinalysis and blood grouping and cross matching were done for selected cases if deemed necessary. CBC was particularly done for patients with signs of anaemia due to bleeding, signs of infections or those with signs suggestive of thrombophilia or thrombocytopenia. A blood smear for malaria parasites was done for the patients with fevers, chills, joint pains or any other related symptoms to rule out a malaria infection. Urinalysis was done to those who reported dysuria, urgency and frequency and/or fever to rule out a possible mimicking urinary tract infection.

Participants were randomized to two arms of first trimester incomplete abortion management, that is; the surgical arm and the medical arm. On each arm, the participants were managed with either method and followed up for 48 hours for outcome. Pre-procedure counselling with information on success rates, complications, advantages and disadvantages of each method was given. Where a woman consented, simple randomization using sealed envelopes as detailed below was done to one of the treatment groups. A broad spectrum prophylactic antibiotic of per oral doxycycline 200 milligrams single dose before initiation of management was administered. Per oral azithromycin tablets one gram single dose was given for those with history of allergy or intolerance to doxycycline capsules (5). Surgical management was done immediately in the minor theatre with MVA under cervical block as soon as possible. After the procedure, the patient was admitted for 48 hours for observation with regular review for any complications including haemorrhage, infection, trauma to the genitor-urinary tract, presence of pain and its severity as well as for failure of the method. Medical management was according to the ACOG criteria which involved administering 800µg of misoprostol tablets that were initially moistened with about 2 ml of sterile water for injection in the posterior fornix of the vagina (6). The patient was then requested to lie in bed for about two hours to allow for absorption of the drug. This could be repeated to a maximum of three doses every six hours. We strictly ensured that the same brand of misoprostol (that is,

cytotek® UK brand) and which is readily accessible and affordable on the Ugandan market was used for every randomized patient for the medical arm. Pain control using tablets of paracetamol one gram every eight hours in both groups post initiation of management was administered. Every patient was then admitted for 48 hours just like her counterpart in the surgical management arm. At 48 hours, participants in both groups were reviewed for primary outcomes, secondary outcomes and satisfaction. Those with evidence of incomplete evacuation after medical management confirmed by a trans abdomino-pelvic scan with a volume of more than 30 mls of retained products underwent a mandatory surgical evacuation (MVA) under cervical block and the patient remained admitted for one more day as recommended by ACOG. Otherwise all patients were discharged after 48 hours unless there was a complication or primary failure warranting further hospital stay. Before discharge, a pre-tested structured investigator administered questionnaire was filled and the patient released from the study. She then continued with routine post-abortion care including scheduled reviews at the hospital, family planning services, counselling and community integration which are all offered at this facility.

The primary outcome (effectiveness) of the method was assessed by evidence of a complete uterine evacuation within 48 hours. This was done by history of no vaginal bleeding or abdominal pain, physical examination of the abdomen revealing absent or mild tenderness and a speculum vaginal examination showing a closed cervical os with no bleeding and/or any popping products of conception. Accordingly, a mandatory trans abdomino-ultrasound scan was done to confirm this. If retained products were noted, this was considered as failure of the primary method. The secondary outcomes included the duration of bleeding while on the ward which was categorised as mild if it was less than 6 hours of bleeding, moderate if it was between 7 hours and 12 hours of bleeding and severe if it was more than 12 hours of bleeding; infections-basing on physical examination for any signs suggestive of infection (such as temperature of less than 36^0C or more than 38^0C, pulse rate of more than 100 beats per minute, offensive smelling yellowish or pus like vaginal discharge, adnexial tenderness, cervical motion tenderness), CBC and abdomino-pelvic ultrasound scan findings suggestive of infection (elevated white blood count, features of endometritis or pelvic abscess). Pain was assessed using the Likert scale (7). This involved 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 being maximum pain. Likert scale between 1 and 3 was classified as mild pain, between 4 and 5 as moderate pain, and between 6 and 7 as severe pain. Assessed also was if the patient would recommend the method as determined by interview; hospital stay or need for re-admission if admitted for more than 48 hours; need for second method if there was primary failure; trauma to the genito-urinary tract which was evidenced by both abdominal and pelvic examination and a trans abdomino-pelvic ultrasound scan. Satisfaction with a particular method was determined using the satisfaction tool by (8). The parameters used to asses this were: level of pain of less than 3 on Likert scale (1 point). If they recommended the method (1 point), completion of abortion (1 point), 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 between0/4 to 4/4 and this determined satisfaction, ≤ 1/4 –very dissatisfied, 2/4 –somewhat dissatisfied, 3/4 –somewhat satisfied, 4/4 –very satisfied.

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.$p_1$andp_2 reflected 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. Taking type I error as 0.05,

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

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

$$n = 45$$

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. 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 a 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. KIUTH gynaecology unit provide services to 50 to 60 patients with incomplete abortion per month according to the KIUTH gynaecology ward records at the time. This was therefore adequate presentation of the population.

Data was collected by use of an investigator administered questionnaire that was designed in simple English and Runyankore-Rukiga, the local language for those who did not understand English language. The researcher was keen to ensure that questionnaires were properly filled. Other tools included laboratory request forms and abdomino-pelvic ultrasound scan reports. Data on satisfaction was collected using in-depth interviews. The study groups were comparable in terms of age, reproduction, medical and surgical history. A common investigator administered pre-tested questionnaire was used. A senior specialist in the department supervised the procedure on each 5th patient to ensure protocol was adhered to. Weekly meetings were held to rectify any errors. 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 and proportions for categorical variables. All statistical analysis was carried out in IBM SPSS Statistics version 23.0.

Results

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 arm compared to the 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. Either arms, majority were peasant farmers (50% for the medical arm and 70% for the surgical arm). This is shown in Table 1.

Table 1

Socio-demographic characteristics of the study participants

	Intervention		
Variable	**Medical (n=50)**	**Surgery (n=50)**	***p*-value**
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)	-	-

Obstetric and gynaecologic characteristics of the study participants

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 arm and 10.43 weeks in surgical arm 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. This is shown in Table 2.

Table 2

Obstetric and gynaecologic characteristics of the study participants

	Intervention		
Variable	**Medical (n=50)**	**Surgery (n=50)**	***p*-value**
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

Comparative effectiveness of medical and surgical management of first trimester incomplete abortion among women admitted at KIUTH

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

Table 3

Comparative effectiveness of medical and surgical management of first trimester incomplete abortion among women admitted at KIUTH

		Primary failure		
Intervention	**Yes (n=10)**	**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**

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

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 more than 12 hours in medical arm while only 4% (n=2) in surgical arm had bleeding for more than 12 hours 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 4% of those in medical arm (p<0.001). Majority of the participants 90% (n=45) of those 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 these 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. This is shown in Table 4.

Table 4

Comparative secondary outcomes encountered among women admitted in KIUTH when first trimester incomplete abortion is managed using medical versus surgical method

	Intervention		
Variable	**Medical (n=50)**	**Surgical (n=50)**	***p*-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)	**<0.001**
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**

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

Of the 50 participants enrolled in medical management, majority of the patients 48% (n=24) were very satisfied while 26% (n=13) were somewhat satisfied. Only 20% (n=10) and 6% (n=3) were somewhat dissatisfied and very dissatisfied respectively. On surgical arm majority of participants 42% (n=21) were somewhat dissatisfied while 18% (n=9) were very dissatisfied. Only 2% (n=1) and 38% (n=19) were very satisfied and somewhat satisfied respectively. This was however not statistically significant. This is shown in table 5.

Table 5

Comparative level of satisfaction with the management method assigned to women with first trimester incomplete abortion admitted at KIUTH

Satisfaction	Medical (n=50)	Surgical (n=50)	*p*-value
Very satisfied	24 (48.0)	1 (2.0)	0.07
Somewhat satisfied	13 (26.0)	19 (38.0)	0.64
Somewhat dissatisfied	10 (20.0)	21 (42.0)	0.39
Very dissatisfied	3 (6.0)	9 (18.0)	0.64

Discussion

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 two patients on the surgical arm and eight 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 the surgical arm. Of the two patients that were evacuated, both of them were uncooperative due to pain despite the cervical block and verbal reassurance. Also, both patients had previous uterine scar 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 30 mls. Dilatation and Curettage 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*=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 by Shochet et al., (9) and Shokry et al., (10) that noted 100% success rate. The minimal difference between the current study and the previous studies may be explained by the differences in the surgical skills among the different healthcare providers for the different settings. The fact that KIUTH is a teaching hospital with majority of the attending doctors residents could explain the discrepancy. This has been shown to affect effectiveness of surgical management as surgical skill is a determining factor. 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 (11).

The effectiveness of medical method in the present study was at 84% which was comparable to a study done in Yemen Shuaib et al., (12) 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. It was however found to be less as compared to a previous study done in India where an effectiveness of 97% using misoprostol 600µg orally and review after 3 days was reported Bhadra et al., (13). The current effectiveness was higher than one reported by in Senegal (50%-60%) using misoprostol 400µg as a single dose and review done after 7 days (14). 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 (15). 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 (15)

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 48 hours. This was consistent with several other studies done in South Sudan with success rates of 100% and 93.5% for surgical and medical methods respectively (16). Other studies have shown higher effectiveness with surgical method as compared to medical method although these were not statistically significant. For example Dastgiri et al., (17) in Iran and Panta et al., (18) in Nepal 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 one week (19) and Tanzania with effectiveness of 100% versus 99% for surgical and medical management respectively with a review after two weeks (20). The higher effectiveness of medical method in Tanzania and Uganda studies 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 (21). The higher effectiveness of medical management in the study done in India can be explained by the differences in the 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 as failure the higher the success rates (15). Therefore, given the higher effectiveness of surgical method including the need for surgical method in case of failure of the medical method, it is mandatory to train as many personnel as possible and provide this service to most, if not all, health facilities because if done properly, it is very promising.

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

In the 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 (more than 7 hours of bleeding) while most of those in surgical arm (94%) reported mild bleeding that lasted less than 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 genito-urnary tract.

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 (16) and Nigeria (22) which showed that surgical management required less hospital stay (less than 6 hours) as compared to medical management (more than 12 hours). 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 (23). Another study done in Nepal showed that 91.6% of participants managed medically had bleeding while none in surgical management had bleeding after evacuation (18). 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 (24). 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 (18). 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 (21). 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 (16). 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 genito-urinary tract 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 counseling 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 (20). Other studies have found that surgical is preferred to medical (16), while others report no statistically significant difference between the two methods (23). 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 genito-urinary tract and negative psychological perceptions. However participants that recommended surgical method did so mainly because of immediate evacuation with higher success rate and less bleeding. Participants who preferred 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 (25). 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 counseling 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 (26). A study done in Chad showed the same findings as regards to fever, chills and nausea (16). 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 (26). The presence of these 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 these self-limiting side effects arise and avoid irrelevant

medical tests and costs. However, if there is any sign of infection associated with these 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 (27). 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 (28). 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 (19). The study in Mulago hospital reported ten incidences of infection and this might be explained by the fact that unlike KIUTH, Mulago hospital is the National Referral Hospital. Other studies argue that longer induction-abortion time may lead to higher occurrence of infections (12). There are other factors that determine infection rates including; surgical technique, antiseptic used, use of prophylactic antibiotics and clients immune system (29). 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.

The present study did not register any trauma to the genito-urinary tract in both groups which was contrary to a study conducted in Mulago hospital in Uganda where five patients had trauma to the cervix although none of them required more than one suture knot on the cervix (19). Generally, surgical methods have higher rates of trauma (about 5.6%) (30) as compared to medical management that is generally insignificant. With medical method however, rupture of uterus may occur if larger doses are used in patients with previous uterine scars (30). 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. As suggested by Nouhjah et al., (31), initiation should only be done at centers where monitoring and comprehensive care is available in this group of patients.

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. Most of the participants 48% (n=24) in medical management reported to be very satisfied while only the minority 2% (n=1) in surgical management reported to be very satisfied. Although this was not statistically significant (p=0.07), the

difference in numbers was absolute. Those who reported to be somewhat satisfied with each method were 26% and 38% for medical and surgical management respectively. 30 participants which is more than half of the patients in surgical arm reported to be dissatisfied with surgical management (n=21 for somewhat dissatisfied and n=9 for very dissatisfied). Only 13 participants in the medical arm reported dissatisfaction (n=10 for somewhat dissatisfied and n=3 for very dissatisfied). In this study, although the most number of participants in medical arm were satisfied and the opposite was true for surgical method, there was no statistical significance between the two groups' satisfaction level. This is in line with a study done in Uganda (19). The study in Uganda reported that the reasons why participants were satisfied with medical management were 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. This was in keeping with the present study. A previous study by Shochet and colleagues also found similar outcomes regarding satisfaction (9). Other earlier studies found more satisfaction levels with surgical management as compared to medical management (23). The reason why participants were more satisfied with surgical method was because of high effectiveness, short duration of treatment and shorter duration of bleeding. Some studies have also found more satisfaction in medical arm 84% as compared to only 16% in surgical arm (26). Some of the reasons given for this was that medical management had less pain, high effectiveness, lack of surgery and lack of anaesthesia (26). Patients should therefore 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.

Conclusion

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. 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. Although many patients are satisfied with medical management of first trimester incomplete abortion due to less pain, non-invasiveness and lack of anaesthesia, this was not statistically significant as compared to surgical management.

Abbreviations

D&C: Dilatation and Curettage; KIUREC: Kampala International University Research Ethics Committee; KIU-TH: Kampala International University Teaching Hospital; MVA: Manual Vacuum Aspiration; UNCST: Uganda National Council for Science and Technology

Declarations

Ethics approval and consent to participate in the study

Adequate explanation was made to the participants in English and the local language (Runyankore-Rukiga) and an informed consent sought from those women who were eligible. Minors (emancipated minors under the age of 18) did not require presence of their guardians to consent. 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. Approval to carry out the study was sought from the department of obstetrics and gynaecology, the faculty and post graduate school, Kampala International University Research Ethics Committee and the Uganda National Council for Science and Technology. Approval was sought from the administration of the hospital before the study was conducted. Recruitment of participants into the study was after voluntary acceptance and signing of KIUREC approved informed consent form written in both English and Runyankore-Rukiga for those who did not understand English. Each research participant was handled with uttermost respect for her participation and was free to withdraw from the study any time she wished to without coercion or compromise of care given thereafter.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

We bear no any competing interests to declare

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No funding was obtained for this study.

Authors' contributions

VTO was involved in conceptualization and design of the study, sample collection, processing and report writing. SB contributed towards study design, methods, drafting of the manuscript and submission. IB and SE participated in conceptualization, data collection, and its processing. CA made substantial contribution towards study design, study methods and statistical analysis of this research. All the authors had sufficient time to read and approve the final manuscript.

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