Figure 1: Consolidated flow chart of *participants* randomized to early versus standard insertion of IUDs after medical management of first trimester incomplete abortion

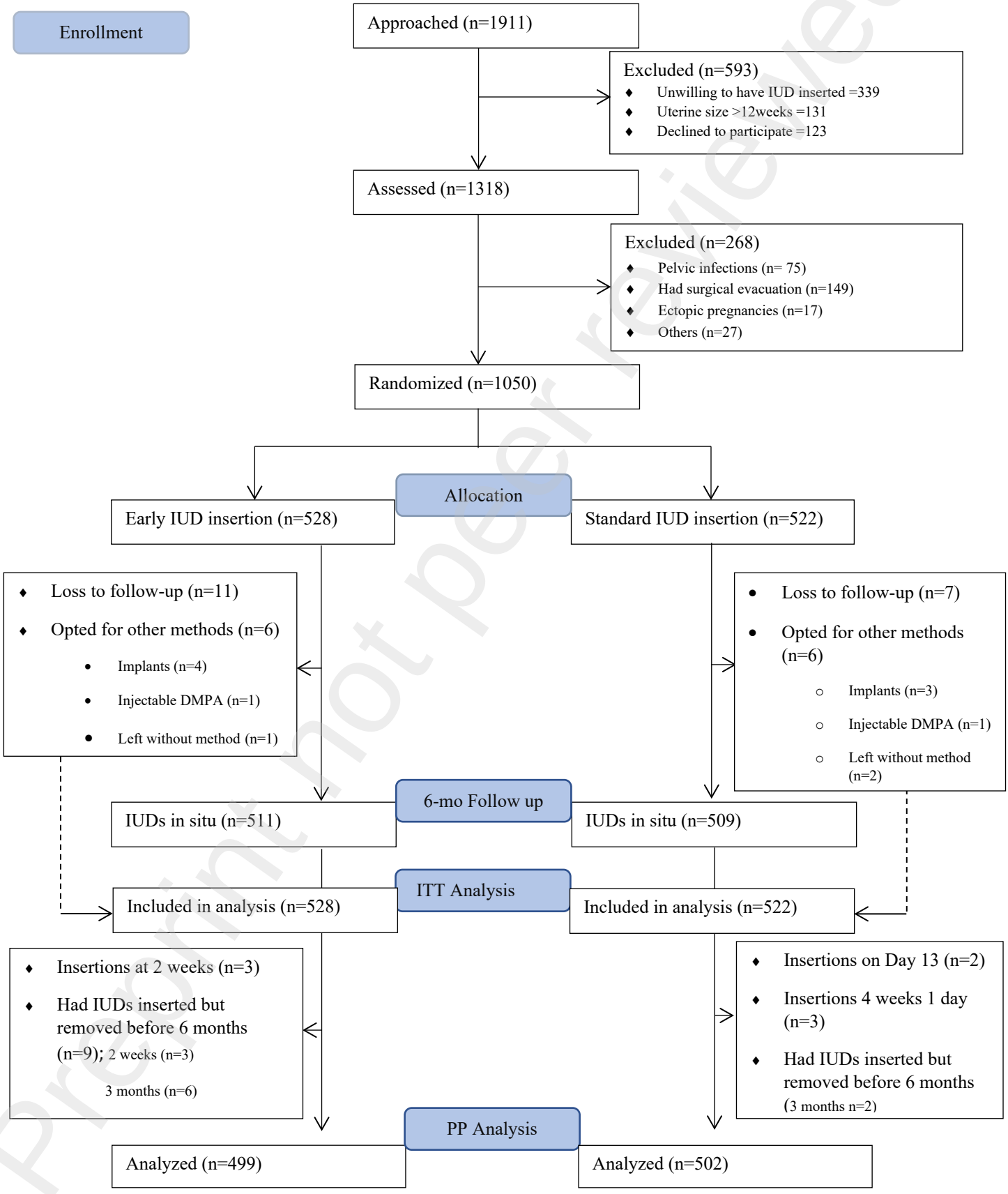

Figure 2: Kaplan-Meier plot of trends of IUD expulsions over six months in early vs. standard insertion of Intrauterine contraception after medical management of First Trimester incomplete abortions

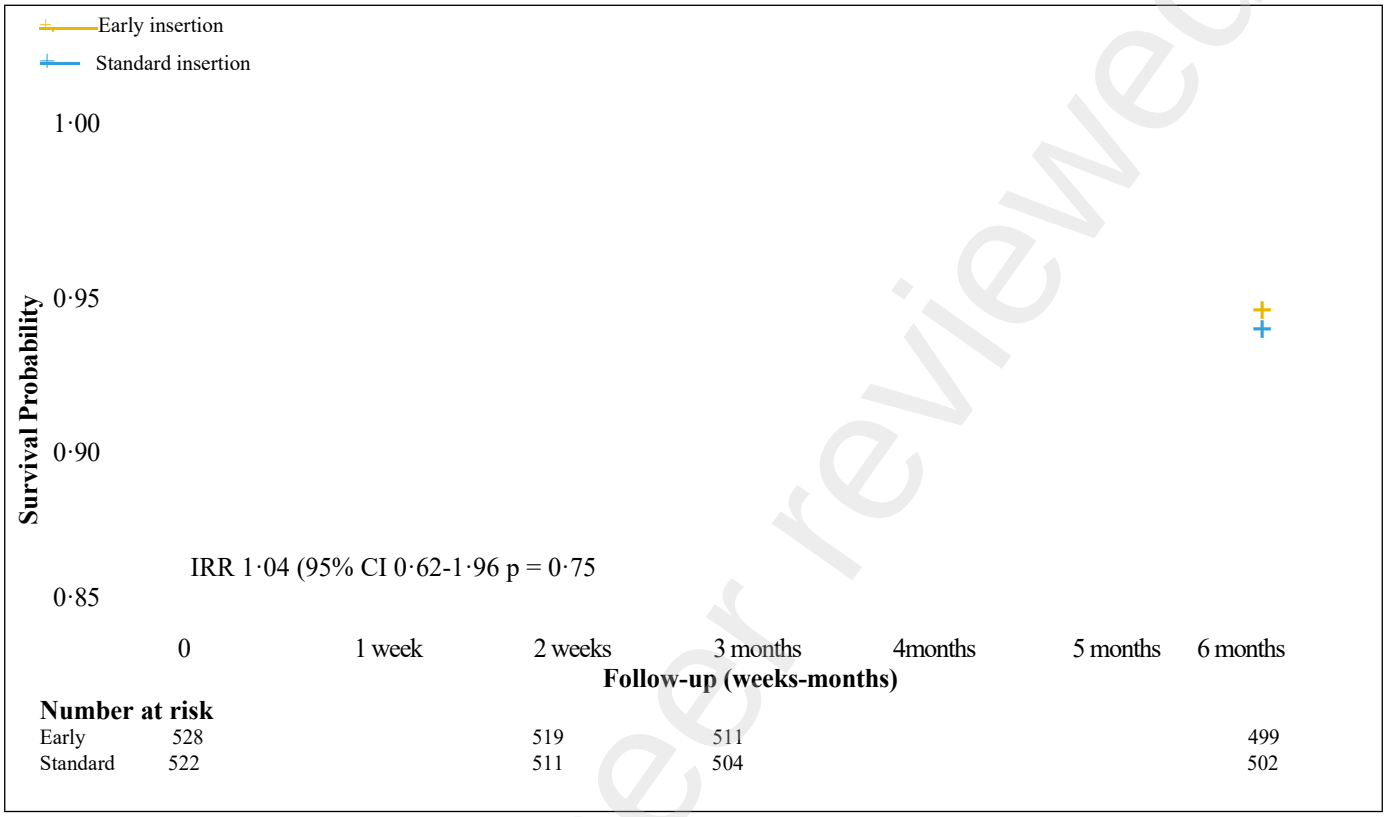

Table 1: Characteristics of the 1050 participants enrolled at the five health facilities in central Uganda:

Characteristic	Early insertion (n=528) Number (percentages)	Standard insertion (n=522) Number (percentages)
Age		
<20	47 (4·5%)	49 (4·7%)
20-24	132 (12·6%)	119 (11·3%)
25-29	172 (16·4%)	174 (16·6%)
30-35	117 (11·1%)	121 (11·5%)
>35	60 (5·7%)	59 (5·6%)
Mean (SD)	27·5 (6·1%)	27·6 (6·0%)
Marital status		
Married	418 (39·8%)	418 (39·8%)
Single	110 (10·5%)	104 (9·9%)
Type of IUD inserted		
Levonorgestrel IUDs	265 (25·2%)	267 (25·4%)
Copper IUDs	246 (23·4%)	242 (23·0%)
Education level		
Never attended school	16 (1·5%)	17 (1·6%)
Primary level	224 (21·3%)	217 (20·7%)
Secondary level	245 (23·3%)	243 (23·1%)
Tertiary (or University)	43 (4·1%)	45 (4·3%)
Number of births		
Nulliparous	76 (7·2%)	77 (7·3%)
1-4	385 (36·7%)	380 (36·2%)
.>5	67 (6·4%)	65 (6·2%)
Currently breastfeeding		
Yes	55 (5·2%)	50 (4·8%)
No	473 (45·0%)	472 (45·0%)
HIV status		
Positive	26 (2·5%)	22 (2·1%)
Negative	491 (46·8%)	489 (46·6%)
I don't know	11 (1·0%)	11 (1·0%)
What happened with the pregnancy?		
I had a miscarriage	459 (43·7%)	472 (45·0%)
I had an induced abortion	69 (6·6%)	50 (4·8%)

Table 2: Expulsions of Post abortion IUDs as per the different Insertion Arms using the GEE model

Variable	Expulsion (n=47)	No Expulsion (n= 973)	Adjusted RR (95% CI)	Risk difference (95% CI)	IRR (95% CI)
Date of Insertion	Number (percentages)	Number (percentages)			
Early Insertion	23 (2·3%)	488 (47·8%)	1		
Standard insertion	24 (2·4%)	485 (47·5%)	1·02 (0·58 - 1·82)	-0·00006 (-0·0008 - 0·00066)	
Type of Analysis					
ITT					1·05 (0·59 - 1·86)
Per Protocol					1·04 (0·62 - 1·96)

Table 3: Secondary outcomes

Characteristic	Early insertion (n=528) Number (percentages)	Standard insertion (n=522) Number (percentages)	P-value
Continuation rates			0·71
Yes	481 (91·1%)	471 (90·2%)	
No	47 (8·9%)	51 (9·8%)	
IUD removals before 6 months			0·06
Yes	9 (1·7%)	2 (0·4%)	
No	519 (98·3%)	520 (99·6%)	
Pregnancies			0·45
Yes	5 (0·9%)	2 (0·4%)	
No	523 (99·1%)	520 (99·6%)	
Insertion Experiences			
Ease of IUD insertion			0·76
Very easy	356 (67·4%)	342 (65·5%)	
Somewhat easy	148 (28·0%)	156 (29·9%)	
Difficult	5 (0·9%)	6 (1·1%)	
Pain on IUD insertion			0·97
No pain	137 (25·9%)	140 (26·8%)	
Mild	346 (65·5%)	340 (65·1%)	
Moderate	22 (4·2%)	21 (4·0%)	
Severe	4 (0·8%)	3 (0·6%)	

Effectiveness of Early versus Standard Intrauterine Contraception following Medical Management of First Trimester Incomplete Abortions: A Non-Inferiority Open-Label Randomized Control Trial in central Uganda

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Summary

Background With paucity of information on ideal timing for intrauterine contraception placement, we set out to determine the effectiveness of early insertion (within one week) versus standard insertion (two-four weeks) of intrauterine contraception after medical management of first trimester incomplete abortions in central Uganda.

Methods In a multicenter non-inferiority trial at five public health facilities in central Uganda, 1,050 women with first trimester incomplete abortions managed by sublingual misoprostol, were recruited upon giving informed consent. After selecting either Copper or Levonorgestrel intrauterine devices (IUDs), participants were randomly assigned to early or standard insertion arms in a ratio of 1:1. The primary outcome was IUD expulsion rates at six-months. The non-inferiority margin was set at 5% for the upper limit of the confidence interval (CI) for the absolute risk difference. The trial was registered at ClinicalTrials.gov NCT05343546.

Findings Between 8th July 2023 to 31st May 2024, 528 (50·3%) participants were assigned to early and 522 (49·7%) participants to standard insertion arms. About 531 (50·6%) participants chose Levonorgestrel IUDs, 489 (46·6%) participants chose copper IUDs, while 30 (2·9%) participants opted against IUDs. In an intention-to-treat analysis, expulsion occurred in 23 (4·4%) of 528 participants in the early insertion arm and in 24 (4·6%) of 522 participants in the standard arm; Adjusted Risk Difference (standard-early) was -0·00006 (95% CI: -0·0008 to 0·00066, p = 0·93). No serious adverse events occurred in both arms. The IUD continuation rates at six-months were 91·1% in the early and 90·2% in the standard insertion arms.

Interpretation Early IUD insertion after medical treatment of first trimester incomplete abortions was non-inferior to standard IUD insertion with respect to expulsion. Early IUD insertion may help to prevent unintended pregnancies.

Funding The Swedish Research Council in partnership with Makerere University and MakRif project.

Keywords: First Trimester- incomplete abortion, Post abortion care, Intrauterine contraception, Misoprostol, Uganda

Introduction

Unintended pregnancies continue to be a global threat to maternal health especially in low and middle income countries.[1] Every year, 73 million unintended pregnancies occur in low-resource countries, nearly half (49%) of which end up as induced abortions.[2] In the face of restrictive abortion laws in many sub-Saharan Africa (SSA) countries, the issue of unintended pregnancy is a major contributor to unsafe abortion, maternal morbidity and mortality.[3] In East Africa, women have a lifetime risk of 1 in 16 of dying as a result of abortion-related complications.[3] The unmet need for contraception, is one of the drives of the high burden of unintended pregnancies.[1] In SSA, contraceptive knowledge gaps among women, low skillsets among the healthcare providers and limited access to effective contraceptive methods, contributes to the high unmet need for contraception exceeding 30% among sexually active women.[4]

Provision of post abortion care (PAC), is an effective intervention proposed to reduce the morbidity and mortality associated with unsafe abortion.[5] PAC entails providing emergency treatment of the abortion-related hemorrhage and sepsis using either medical evacuation with misoprostol, or surgical evacuation and post abortion contraception as recommended by the World Health Organization (WHO) for first trimester incomplete abortions.[6] With increased access to misoprostol and approval of midwives and other cadres to manage abortion complications, misoprostol use has had a major impact in PAC in SSA.[7]

As fertility can return within two-weeks of first trimester abortions, it's critical that women have access to effective post abortion contraception.[8] Whereas the WHO recommends use of intrauterine contraception (IUC) immediately after surgical evacuation, placement of intrauterine contraception after medical management with misoprostol has been between two-four weeks post first trimester abortions.[9] There is limited evidence on the safety and effectiveness of early (within one) post abortion contraception after medical management for incomplete abortion.[10] Evidence shows higher expulsion rates with early (within one week) IUD placement after medical post abortion care though with high continuation rates.[10]Other studies have reported no difference in the expulsion rates, perforation, or discontinuation rates between early versus standard post abortion intrauterine contraceptive insertion.[11, 12] With more than 50% of the women resuming sexual intercourse within two-weeks after first trimester pregnancy losses, the risk of early repeat pregnancies is high.[13] Early repeat pregnancies are associated with adverse maternal and fetal outcomes such as repeat miscarriages, preterm labour, preeclampsia and fetal demise.[14]

Uganda has a high unmet need for contraception at 27·7%[15] as compared to the whole East African region at 24·66%,[16] hence the high unintended pregnancy rate of 56%.[16] Long acting reversible contraceptives (LARCs) methods such as IUDs are underutilized in SSA and Uganda in particular.[15] Uganda has a low IUD user rate of two percent among married women.[15] Provision of early post abortion IUDs could be one of the strategies to increase the contraceptive prevalence rate and reduce the unintended pregnancy rate in Uganda. This study was undertaken to guide in formulation of evidence-based practices on placement of IUDs after medical management of first trimester incomplete abortion.

Methods

Study design

Using a non-inferiority open-label randomized controlled study design, we compared the expulsion rates following early insertion (within one week) versus standard insertion (within two-four weeks) after medical management of first trimester incomplete abortion in central Uganda, with the ultimate aim of determining the effectiveness and safety profile for post abortion IUD placement. The trial and study protocol followed the CONSORT guidelines for reporting equivalence and non-inferiority randomized trials.[17]

The Uganda central region was selected due to the high abortion rate compared to the national average (62 vs. 39 per 1,000 live deliveries) and the subsequent huge case load of women treated for abortion complications.[16] Initially the study was meant to run at 15 study sites, but two months into the study, an amendment was done to continue the study at only five sites; reasons being staff rotations at the remaining sites which made participant recruitment impossible or very slow. The remaining five sites were; a national referral hospital, a regional referral hospital, a general hospital, a health centre IV and a health centre III. All sites were equipped to provide comprehensive emergency obstetric and gynecological services in rural, peri-urban and urban areas and were located within one-two hours from Kampala, the capital city of Uganda. (See Appendix 1)

Participants

Women 15 years and above, medically treated for first trimester incomplete abortion, staying within ten kilometers from the health facility, opting for post abortion IUDs with no intention of conceiving within one year, able and willing to comply with the planned follow up visits, were included into the study. Women with contraindications for medical PAC, or surgically evacuated, fevers above 38·5ºC, suspected pelvic infections, ectopic pregnancy, confirmed breast cancer, known allergies to study medications, confirmed cervical cancer or with atypical Pap smear cytology results, or known uterine anomalies, were excluded.

Semi-structured case report forms (CRF) were used to collect data from the participants; on their first contact visits, on the scheduled IUD insertion visits based on the group allocation, then at two-weeks, three-months and six-months follow-up visits. When deemed eligible, participants signed the informed consent in the presence of the attending healthcare provider at that consultation.

Randomization

The randomization sequence was generated using STATA 12 software package (Stata Corporation, College Station, TX, USA) in a ratio of 1:1 allocation using permuted block size of 4, that was varied randomly. The randomization was performed by a biostatistician otherwise not involved in the study before the study started. Group assignments were kept in sealed envelopes, that were only opened by the study nurse after obtaining informed consent. The randomization list remained with the biostatistician throughout the study period. Intermittent check-ups that ensure that the intervention procedures were adhered to, were routinely performed.

Allocation concealment

Sequentially numbered, identical, opaque, sealed envelopes prepared by staff otherwise not involved in the trial, were used to conceal the pre-specified allocation from clinicians, research personnel, and participants.

Blinding

Blinding of the primary outcome (IUD expulsions) to outcome assessors (healthcare providers) and to study participants, was not possible. The study therefore was an open-label design.

Trial process and data collection

Enrolment

All women with incomplete first trimester abortions managed medically with misoprostol opting for post abortion IUDs, were invited to be included in the study at the initial outpatient consultation. The women received detailed oral and written information regarding the study. An informed consent was signed by the research assistant and the woman before randomization or any other study related activity.

Allocation and treatment

Designated research assistants who were midwives, were assigned to recruit and examine study participants at the outpatient clinics. Eligible participants who chose to participate in the study and who had signed informed consent forms, were randomized into either: Arm 1; early insertion (insertion within one week of PAC) or Arm 2; standard insertion (insertion two-four weeks post PAC).

Participants chose between the Copper IUDs (Nova T®, Bayer AG, Berlin, Germany) and the Levonorgestrel (LNG) IUDs (Mirena®, Bayer AG, Berlin, Germany). The diagnosis of first trimester incomplete abortion, was made based on history taking and clinical examination. Participants were then given misoprostol 400 mcg sublingually as a single dose.[18] Oral ibuprofen and paracetamol were administered for analgesia.[19] As prophylaxis against post abortion endometritis, oral metronidazole and doxycycline were administered to all participants.[20]

After receiving PAC, the participants were discharged unless they had medical reasons for hospitalization. All efforts such as phone calls, text messages and home visits were made to reach the participants in case they failed to return to the health facility for the different interventions. Transport reimbursements were provided to encourage return for the scheduled visits.

Ultrasonography was not done routinely and only used in cases where incomplete expulsion of products of conception was suspected from the clinical evaluation after misoprostol administration.[21] If a participant was diagnosed with an

incomplete abortion at the insertion visit, the healthcare provider had options of either surgically evacuating the uterus or giving another dose of misoprostol. Participants who were identified to have developed clinical presentation suggestive of sepsis, were managed as per the local clinical guidelines. All participants in the standard insertion arm were encouraged to abstain from unprotected sexual intercourse for two weeks prior to insertion of the IUDs to prevent unintended pregnancies. Participants' safety was ensured throughout the trial according to the GCP guidelines. Measures were undertaken to minimize risk to participants through regular monitoring and prompt adverse events reporting.

Follow up

All participants were followed up at two weeks, three, and six months after IUD insertion. At each scheduled visit, the participants undertook standardized history and physical examination including general, abdominal and pelvic examinations. If a participant missed a scheduled visit by two weeks, she was contacted by phone, reminded of the missed visit and had rescheduling of her appointment within the time frame of the study. At every visit, the participants were assessed clinically for pelvic inflammatory diseases and asked about complications and whether they received any medication from other sources. Participants with complications or in need of further counselling, were seen at unscheduled visits. Information about IUD removal, IUD expulsion, heavy or prolonged menstrual bleeding or missed menstrual periods and hormonal side effects related to LNG, was collected.

Outcomes

The primary outcome was effectiveness measured as IUD expulsion rates at six months. Our secondary outcome was safety measured in adverse events (AEs) and serious AEs (SAEs) occurring by the six-months follow-up. AEs included cervical tears, infections requiring treatment with antibiotics, or prolonged bleeding after misoprostol. SAEs were defined as uterine perforation, need for exploratory laparotomy after post abortion IUD insertions, need for blood transfusion following severe hemorrhage, hospitalization, anaphylactic reaction after IUD insertion, life threatening sepsis, or deaths. Other secondary outcomes included unscheduled visit attendance, pregnancies, IUD removal and continuation rates measured at the six months.

Statistical Analysis

We assumed that early insertion of post abortion IUDs would be non-inferior to the standard insertion following medical management of first incomplete abortion within a non-inferiority margin of -5% in regard to effectiveness measured in number of IUD expulsions at six months.[22] With an assumed 95% "success" (non-expelled IUDs) in both arms with a power of 90% and an alpha of 0·05, we needed to randomize 500 participants in each group. Compensating for 20% loss to follow up which is commonly seen in studies on abortions, we randomized 1,050 participants.

The primary outcome, expulsion rates at six months was analyzed by a generalized estimating equation with trial center treated as a random factor. Univariate analysis was done using frequencies and percentages for categorical variable and mean and standard deviation for continuous variables. Independent variables between the early versus standard insertion arms, were assessed to determine whether they were similar. Type of IUD inserted, was also analyzed by proportions and Chi^2-test for the two different types of IUD used. Expulsion rates were analyzed using Chi^2-test or Fisher´s exact test depending on cases. IUD removals for any other reason and subsequent contraceptive method prescribed was shown as proportions and analyzed by Chi^2-test. An intention-to-treat (ITT) analysis was used to compare the expulsion rates between the two arms regardless of whether the participants had the IUDs removed before the six-months follow up. Per-protocol (PP) analysis was used for all participants included in the ITT excluding those who had their IUDs removed before six months or were lost to follow up before the six months. Data were analyzed using STATA version 15.0 software (Stata Corporation, College Station, TX, USA).

The Principal Investigator carried out a trial run for a month to pre-test all study instruments, so as to streamline the process of enrolment, allocation and follow up at the health facilities prior to starting data collection.

A multidisciplinary committee formed the Data Safety and Monitoring Board (DSMB). DSMB had access to the study findings and reported interim analysis results with recommendations on whether to halt or continue with the study.

An interim analysis of results was performed when 50 percent of the participants had been recruited. The expulsion rates were then at five percent. If expulsion rates had exceeded 20 percent, the study was meant to be stopped.[23]

All filled or recorded CRFs were checked on a daily basis for completeness. The trial was registered at ClinicalTrials.gov NCT05343546.

Role of the funding source

The funders had no role in the study inception, data collection, analysis and manuscript preparation. All authors had full access to the study data materials and take collective responsibility for the submitted manuscript. The corresponding author had the mandate to submit the manuscript for publication.

Results

Between 8th July 2023 and 31st May 2024, 1,191 women medically managed for first trimester incomplete abortion, were screened for eligibility during the study period. A total of 528 participants were assigned to the 'early insertion' arm and 522 participants to the 'standard insertion' arm (figure 1).

The socio-demographic characteristics were generally comparable between the two arms. Of the 1,050 participants who were randomized, 1,020 (97·1%) participants had IUDs inserted. The majority 531 (50·6%) of the participants chose LNG-IUDs, while 489 (46·6%) participants chose copper IUDs in both arms. A total of 30 (2·9%) participants opted against IUDs. Among those who received IUDs, 511 (50·1%) participants were in the early insertion arm, and 509 (49·9%) were in the standard insertion arm (Table 1).

In the per-protocol analysis, 1,011 participants had IUDs inserted. Of the 511 participants in the early insertion arm, 499 participants made it to the final analysis. Three participants had their IUD insertion at two weeks. Nine participants had their IUDs removed before six months (three at two weeks and six at three months due to either IUD related side effects or desire to conceive). In the standard arm of 509 participants, 502 participants were in the final analysis. Two participants had their IUDs inserted on day 13, three participants had their insertion at four weeks and one day and two participants had their IUDs removed at three months due to a wish for pregnancy.

Expulsion of IUDs, either partial (within the cervix) or complete, was assessed by clinical evaluation and/or pelvic ultrasound at the different follow up visits or unscheduled visits. There were 47 (4·5%) IUD expulsions by the end of six months; 30 (63·8%) were reported as partial expulsions while 17 (36·2%) were complete expulsions. After adjusting for study sites, the risk difference (RD) of expulsion between the early insertion and standard insertion arms, was -0·00006 (95% CI: -0·0008 to 0·00066, p = 0·93). This RD is below the pre-specified -5% non-inferiority margin, demonstrating non-inferiority between the two arms (Table 2).

In the intention-to-treat (ITT) population, the rate of expulsion at six months was 1·05 times higher in the standard insertion arm compared to the early insertion arm (IRR = 1·05; 95% CI: 0·59 - 1·86, p = 0·87). Using per-protocol, 45 expulsions were analyzed (unadjusted IRR = 1·04; 95% Cl: 0·62 - 1·96, p = 0·75). One participant with expulsion was excluded in the early insertion arm following an MVA done for pelvic infection but later on had the IUD inserted. Another participant in the standard arm was excluded following IUD removal resulting from prolonged bleeding and pelvic infection. She had a re-insertion and partial IUD expulsion at three months. She opted for an implant thereafter.

Half of the partial expulsions 15 (50%) occurred by the second week of insertion, eight (26·7%) occurred by the three-months follow up and seven (23·3%) occurred by the six-months follow up visit. As per the complete expulsions, four (23·5%) occurred by the second week, eight (47·1%) occurred by the three-months follow up and five (29·4%) by the six-months follow up visit. The majority of the partial expulsions; 17 (56·7%), occurred in the early insertion arm while the majority of the complete expulsions; 12 (70·6%), occurred in the standard insertion arm.

The Kaplan-Meier survival analysis shows a higher cumulative expulsion rate in the standard insertion arm compared to the early insertion arm across all follow-up periods (two weeks, three months, and six months), though the difference is not statistically significant (p = 0·75) (figure 2).

After administration of misoprostol 400mcg sublingually, 98% of participants had complete expulsion of the products of conception by the insertion visit and 100% by scheduled follow up after two weeks using clinical evaluation. About 204 (19·4%) of participants needed pelvic ultrasound evaluation to ascertain complete expulsion. Additional doses of misoprostol were required for 120 (11·4%) participants to complete the expulsion of the products of conception.

In regard to Adverse Events (AEs), a total of 18 (1·7%) participants developed pelvic infections with eight participants (0·8%) in the early insertion arm and ten (1·0%) participants in the standard insertion arm. The infection rates were

comparable between the two study groups (p=0.069). No other AEs or Serous Adverse Events (SAEs) occurred in the two groups. Five pregnancies (0·5%) occurred in the early insertion arm while two pregnancies (0·2%) occurred in the standard insertion arm. Five pregnancies occurred after IUD removal and two pregnancies occurred with the copper IUD in situ in the standard insertion arm. The IUD continuation rates at six months in both early and standard insertion arms were above 90%. Secondary outcomes are summarized in Table 3.

Discussion

The expulsion rate following early insertion (within one week) was non-inferior to standard insertion (two-four weeks) of intrauterine devices after medical management of first trimester incomplete abortions. The safety profiles in both arms were similar at six months.

The expulsion rate of 4·5% in our study is lower than what has been previously reported among women who had medical abortions up to 63 days of gestation in Sweden by Sääv et al[24] and among women with spontaneous first trimester abortions in Egypt.[25] Our study expulsion rate is however comparable to the 4·1% reported by the three-month follow up after medical first trimester abortion.[26] In contrast, findings from a systematic review on immediate and delayed placement of IUDs after abortion by Ying Lou et al,[27] showed that expulsion rates were higher in the early insertion groups as compared to the standard insertions. The explanation for this discrepancy could be our large sample size and high follow up rates as compared to the pooled sample size of 745 from the five sub-studies included in the meta-analysis by Lou et al.[27]

Our continuation rates of over 90% in both arms at six months, are higher than the 80% continuation rates reported by Betstadt et al.[26] The high continuation rates could be due to the fact that healthcare providers in this study were provided with training on post abortion IUD insertion and removal and had significant experience on contraceptive counselling and provision prior to the study. Given the prevalence of first trimester incomplete abortion with 25% of the pregnancies (39 per 1000) ending in abortion[16] in central Uganda and the access of IUDs, healthcare providers in this setting could have gained more confidence in managing the abortions and inserting the IUDs, thus the more trust earned from the participants and the minimal loss to follow up.

Our study demonstrates that early insertion of post medical PAC IUDs is safe and reduces missed opportunities of using an effective family planning method. Early IUD insertion fronts the advantages of women being motivated to take on the method, the assurance that they are not pregnant, reduces chances of early conception and results in higher continuation rates.[10]

Strengths and limitations

The strength of our study relies on the fact that our sample size of 1,050 participants was large and included women from rural, urban and peri-urban areas in central Uganda, giving us the ability to generalize our findings. Women were comprehensively counseled on a wide range of contraceptive methods and voluntarily adopted methods of their choice freely thereby minimizing social desirability bias. The healthcare providers had extensive training in post abortion family planning counselling and provision prior to the study. The acquired knowledge and skillsets in post abortion contraception was a backbone that could have motivated women to participate until the end of trial. There were no serious adverse events in the study. We were able to follow up 98·3% of the participants from enrolment to completion of the study.

We were unable to assess the satisfaction rates in the current study though it would have been informative in making client-based recommendations on the utilization of post abortion intrauterine contraception. Factors associated with IUD expulsions after medical management of first trimester incomplete abortions are not explored in the current study but can be an interesting area for future research to streamline policies in post abortion care.

Interpretation

Our study demonstrates that early insertion of IUDs is non-inferior to standard insertion after first trimester medical PAC with regard to expulsions, showing that women are safe to have their preferred IUDs inserted as early as within one week after their treatment. The continuation rates in both arms were above 90% at six months, emphasizing the need to integrate IUD services in PAC.

Research in context

Evidence before this study

Prior to the current study, clinical guidelines recommended IUD insertion immediately after surgical evacuation. However after medical management with misoprostol, placement of IUD has been between two-four weeks post first trimester abortion.[9] Evidence on the safety of early post abortion contraception after medical management for first trimester incomplete abortion, is scarce.[10] With more than 50% of the women resuming sexual intercourse within two weeks after first trimester abortions, the risk of early repeat pregnancies is high.[13] There was a need to assess the safety and effectiveness of early (within one week) post abortion contraception to prevent subsequent unintended pregnancies.[8]

Added value of this study

Our study demonstrates that early insertion of post abortion IUDs is non-inferior to the standard insertion after first trimester medical management of incomplete abortions. Women can safely utilize early insertion of IUDs after medical management of their abortions.

Implications of all the available evidence

With return to fertility as early as within two weeks after treatment of first trimester incomplete abortion, women should be encouraged to utilize early insertion of IUDs to prevent subsequent unintended pregnancies. Measures should be underway to update policies and pre- and in-service training in post abortion counselling and family planning provision after medical management of first trimester abortions.

Other information

Contributors

KGD conceptualized the study, developed the protocol, received funding for the study, supervised the study conduct, data analysis and editing of the manuscript.

HK contributed to the conceptualization, data curation, data analysis, investigation, methodology, and writing of the original report. ELT contributed to the conceptualization, Data curation, formal analysis and software, review and editing of written original report. OK, MS, JR, NT, JB, AC also contributed conceptualization, methodology, supervision, review & editing of original draft.

Trial registration

The trial was registered at ClinicalTrials.gov, number NCT05343546.

Protocol

The full protocol can be accessed from the corresponding author on request.

Ethical approval

Ethical approvals were obtained from the Makerere University School of Medicine Research and Ethics Committee, (Mak-SOMREC-2021-131), Stockholm Regional Ethical Committee (2023-01263-01) and Uganda National Council for Science and Technology (HS2111ES). Administrative clearances were also obtained from the five implementing health facilities.

Declaration of interests

We have none to declare.

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Data sharing statement

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

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