



Effectiveness, safety and acceptability of self-assessment of the outcome of first-trimester medical abortion: a systematic review and meta-analysis

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Background For many women, the need for multiple clinical visits is a barrier to medical abortion.

Objectives We assessed the effectiveness, safety, and acceptability of self-assessment of the outcome of medical abortion completed at home versus routine clinic follow up after medical abortion.

Search strategy We searched databases such as MEDLINE, Embase, and CENTRAL to find studies published in 1991–2018.

Selection criteria Eligible studies included women of reproductive age who had undergone a medical abortion that was completed at home. The intervention and self-assessment of the outcome of medical abortion done by urine pregnancy tests kits by women at home was compared with routine medical follow up at a clinic.

Data collection and analysis Two researchers completed the study selection, data extraction, critical appraisal, and assessment of the evidence. The outcomes were successful complete abortions, side effects and complications, and acceptability. We performed meta-analyses when possible and GRADE to ascertain the certainty of the evidence. The protocol was registered in PROSPERO (CRD42017055316).

Main results Four randomised controlled trials (RCTs; $n = 5493$) met our inclusion criteria. The pooled analysis from all studies showed no significant difference in complete abortion rates between self-assessment and routine clinic follow up: RR = 1.00, 95% CI 0.99–1.01. The ongoing pregnancy rates were similar and the pooled results for the safety outcomes showed no significant differences between the groups. There was a significantly greater preference for self-assessment as the follow-up method.

Conclusions The effectiveness, safety, and acceptability of self-assessment of the outcome of medical abortion completed at home are not inferior to routine clinic follow up.

Keywords Abortion, home, pregnancy test, self-assessment, systematic review.

Tweetable abstract The effectiveness, safety, and acceptability of self-assessment of the outcome of medical abortion are not inferior to routine clinic follow up.

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Introduction

Medical abortion is increasingly being used for early termination of pregnancy.¹ The World Health Organization (WHO) recommends the mifepristone–misoprostol combination regimen for medical abortion^{2,3} because it works faster than a misoprostol-only regimen and is approximately 98% effective up to 9 weeks (63 days) of gestation.^{4,5} It can

be performed either at a clinic or at home,⁶ providing women with options based on their choice.⁷

Despite excellent effectiveness and safety, the procedure remains inaccessible for many women, especially in low-resource settings.^{6,8} The required clinic follow-up visit to ensure the termination of pregnancy in medical abortion is one of the most important barriers affecting access and acceptability. Many women, especially those with low

autonomy and limited financial resources, perceive clinic visits as burdensome, and the long travel time required for clinic visits results in lost wages and difficulties in ensuring privacy.⁶ Administration of misoprostol at home and subsequent self-assessment of the outcome of the abortion help to de-medicalise abortion and provide more privacy to women. The assessment to detect the absence of ongoing pregnancy can be performed by health personnel at a clinic or can be self-assessed by women themselves at home with a Urine Pregnancy Test (UPT) kit, typically a Low Sensitivity Urine Pregnancy Test (LSUPT), Semi-Quantitative Urine Pregnancy Test (SQUPT) or High Sensitivity Pregnancy Test (HSPT).⁷

Recently, studies have shown that the self-assessment of outcome of medical abortion done by UPT kits with a follow-up telephone call, text message or online conversation can be an alternative to clinical follow up after medical abortion. A study has shown that a telephone follow up with self-test is a feasible and accurate method of determining the outcome of medical abortion.⁹ While evidence seems to support the benefits of self-assessment of the outcome of medical abortion, efforts are needed to optimise clinical recommendations for self-assessment compared with routine clinic follow-up visits. The objective of this systematic review was to assess the effectiveness, safety, and acceptability of self-assessment of the outcome of medical abortion compared with routine clinic follow up after medical abortion at home.

Methods

We conducted a systematic review in accordance with the Cochrane Handbook for Systematic Reviews of Interventions,¹⁰ with at least two researchers involved in the study selection, data extraction, assessment of risk of bias (RoB) of the included studies, data extraction, and Grading of Recommendations Assessment, Development, and Evaluation (GRADE). The study protocol was registered *a priori* in PROSPERO (CRD42017055316).¹¹ Patients were not involved in the development of the review.

Search strategy and selection criteria

We collaborated with two search librarians in developing the search strategy, which incorporated subject headings and text words, in title and abstract, for 'Abortion' AND 'Pregnancy Test' AND 'Home' (the full search strategy is available in Appendix S1). In February 2018, we searched in the following databases: MEDLINE, Embase, Cochrane Central Register of Controlled Trials, Web of Science, Cumulative Index to Nursing and Allied Health Literature, British Nursing Index and Archive, Scopus, and Google Scholar. We searched from year 1991 up to February 2018 because medical abortion with mifepristone and

prostaglandin was licensed for the ending of pregnancy up to 9 weeks of gestational age in 1991.^{12,13} We filtered the search to identify studies on humans in English language. We also searched in ClinicalTrials.gov and WHO International Clinical Trials Registry Platform for ongoing studies. Further, we screened the reference lists of systematic reviews and literature reviews to identify any other relevant publications.

Studies eligible for inclusion were randomised controlled trials (RCTs) and, in the event we had not identified high-quality RCTs, also non-RCTs, interrupted-time-series, controlled before/after studies, and prospective cohort studies with a control group. The population was women of reproductive age (≥ 15 years) who had a confirmed pregnancy, the confirmation of which was done by ultrasound, clinically, or by a positive urine or serum human chorionic gonadotropin (hCG) test, and who had requested a medical termination of pregnancy up to 9 weeks of gestation age, which they performed at home (i.e. mifepristone was administered in the clinic, whereas the women administered misoprostol at home and expelled the embryo at home). The intervention was self-assessment of the abortion outcome done using UPTs such as LSUPT, SQUPT or HSPT by women themselves at home, combined with a follow up by home visit or telephone call or a combination of these to confirm the complete termination of pregnancy. Self-assessment by women at home was compared with assessment by medical/healthcare personnel during routine clinic follow-up visit. Our primary outcome was successful complete abortion, i.e., complete evacuation of the uterine contents with no requirement for surgical or repeat medical intervention within 3 months of complete abortion. The secondary outcomes were medical abortion failure such as ongoing pregnancy¹⁴ and/or side effects and complications, such as pain, haemorrhage (excessive bleeding), endometritis, gastrointestinal side effects (e.g. nausea, vomiting, diarrhoea), headache, dizziness, and thermoregulatory changes, loss to follow up, number of clinic visits or number of telephone consultations, and acceptability of the technique. We excluded studies conducted retrospectively. We also excluded clinical practice guidelines, conference abstracts and proceedings, books, chapters, animal and modelling studies, reviews, protocols, and publications containing only qualitative information or written in a language other than English.

We imported the results from all the searches into ENDNOTE X8 to manage bibliographies and remove duplicates. Next, screening of literature was carried out in a two-stage procedure whereby each level consisted of increasing scrutiny of the studies based on the inclusion criteria of the systematic review. The reviewers (N.B., R.B., F.D.) independently assessed all titles and abstracts first, and then the full texts of the potentially relevant studies. At each level, the

authors compared their judgements and excluded studies that did not meet all inclusion criteria. The reviewers were not blinded to the authors or other information about the publication when assessing the studies. We recorded the reasons for exclusion of full texts (Table S1). Two independent reviewers (N.B., F.D.) extracted data from the published sources using a pre-designed data recording form, related to setting, population, intervention, comparator, and outcomes. Differences in opinion in either the screening or data extraction processes were few and were resolved by re-examination of the publication and consensus; no authors had to be contacted. Two independent reviewers (N.B., A.C.) appraised the included studies using the Cochrane RoB tool,¹⁰ independently and then jointly.

Data analysis

All outcomes were dichotomous and we estimated effect by the relative risk (RR) and 95% confidence interval (CI). We also decided, *a priori*, if studies were sufficiently similar, to pool those that could be grouped together and use the statistical technique of meta-analysis to estimate effect, using REVIEW MANAGER 5.3 (RevMan 2014). We used

Mantel–Haenszel random effects meta-analysis for dichotomous outcomes and examined between-study heterogeneity with the chi-square (χ^2) test and *I*-square (I^2) statistic. Lastly, to assess the certainty of the evidence, we performed a GRADE assessment for the primary outcome and selected secondary outcomes.^{15,16}

Results

The search resulted in 1478 individual records (Figure 1). After screening the titles and abstracts, we obtained and read the full text for 132 publications, of which four studies (presented in five publications) met the inclusion criteria (Table 1).^{6,7,17–19}

Our RoB assessment of the included studies shows that all studies had low risk of bias in all the domains except for two domains with unclear risk (blinding of participants, blinding of outcome assessment) (Figure 2). Because we deemed the risk of bias to vary across outcomes, we assessed biological outcomes separately from self-reported outcomes (Figure S1, Table S2).

The four included studies were carried out between 2010 and 2014 in low-resource to high-resource settings: India,⁶

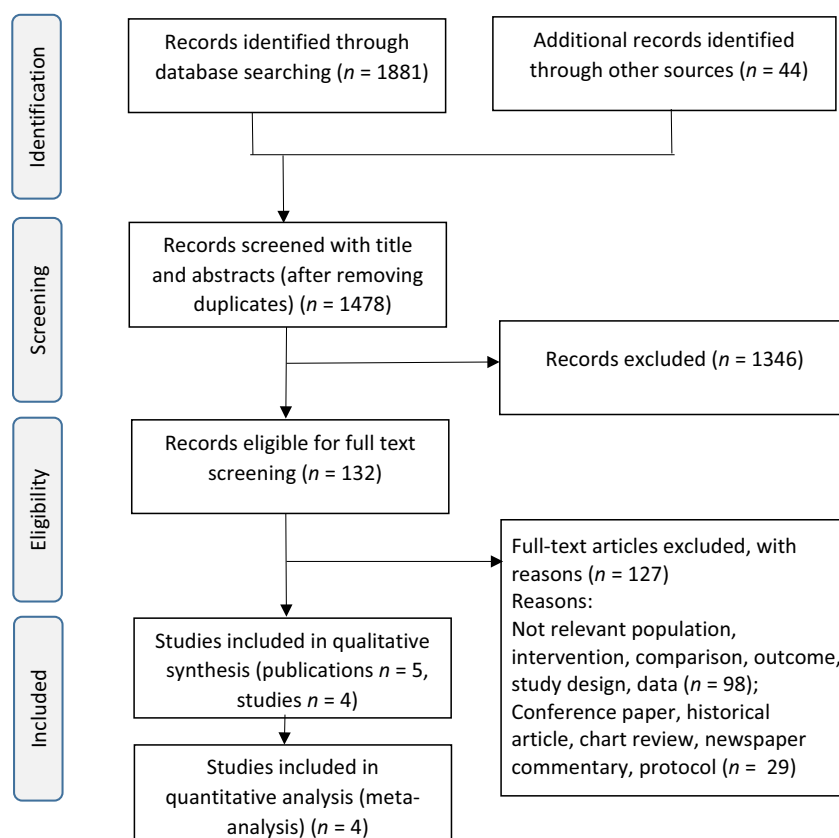


Figure 1. PRISMA flow diagram for selection of studies for the systematic review.

Table 1. Characteristics of the included studies ($n = 4$)

Study	General features	Population	Intervention	Comparison	Outcome
Iyengar et al. (2015) ⁶	Study design: RCT (non-inferiority) Country: India $n = 731$ (baseline) Mean age: 27.1 years Education: 45% literate	Women above 18 years with unwanted pregnancies opting for medical abortion with gestational age 9 weeks or less	Self-assessment of outcome at home with an LSUPT and pictorial instruction sheet. Follow-up after 2 weeks by home visit or telephone call	Routine clinic follow up	Primary outcome: Complete abortion without continuing pregnancy or need for surgical evacuation or additional mifepristone and misoprostol. Secondary outcomes: Safety (no adverse events or side effects) and feasibility of home assessment
Oppegaard et al. (2015) ⁷	Study design: RCT (non-inferiority) Country: Austria, Finland, Norway, Sweden $n = 929$ (baseline) Mean age: 25.97 years Education: Not stated	Women aged 18 years and above who requested medical termination of pregnancy up to 63 days of gestational age	Self-assessment of outcome at home with a semi-quantitative urine hCG test. Follow up after 1–3 weeks by telephone consultation	Routine clinic follow up	Primary outcome: Complete abortion with no requirement for further surgical or medical intervention within 3 months of completing the abortion. Secondary outcomes: Clinical efficacy (adverse events and complications), loss to follow up, additional visits, additional telephone consultations, acceptability, and initiation of agreed contraception
Ngoc et al. (2014) ¹⁷	Study design: RCT Country: Vietnam $n = 1433$ (baseline) Mean age: 27 years (SD 5.7) Education: 99.95% literate	Women opting for early medical abortion with gestational age 63 days or less	Self-assessment of outcome at home with an SQUPT in combination with self-administered checklist. Follow up after 2 weeks by telephone call	Routine clinic follow up	Primary outcome: Complete abortion without continuing pregnancy or need for surgical evacuation. Secondary outcomes: acceptability of phone follow up
Platais et al. (2015) ¹⁸	Study design: RCT Country: Moldova & Uzbekistan $n = 2400$ (baseline) Median age: 27 years Education: 100% literate	Women with pregnancies less than or equal to 63 days of gestational age who wanted a medical abortion	Self-assessment of outcome at home with a semi-quantitative pregnancy test in combination with symptom checklist. Follow-up after 2 weeks by telephone call	Routine clinic follow up	Primary outcome: Complete abortion without continuing pregnancy or need for surgical or medical intervention. Secondary outcomes: acceptability of telephone follow up

Vietnam,¹⁷ Moldova and Uzbekistan,¹⁹ and Austria, Finland, Norway, and Sweden⁷ (Tables 1 and S2). All four included studies were RCTs, with two classifying their studies as a non-inferiority RCT.^{6,7} In total, 5493 women, with a mean age of about 27 years, were randomised. The intervention in all studies was self-assessment with a pregnancy test (LSUPT or SQUPT) in combination with a pictorial instruction sheet, symptom checklist or no checklist. Follow up was 1–3 weeks later by telephone call^{7,17,19} or 2 weeks by home visit or telephone call.⁶ In all studies, the comparison was routine medical follow up at a clinic. All reported

on successful complete abortions, ongoing pregnancy, safety,^{6,7,17,19} and acceptability.^{7,17–19}

All four studies included the same primary outcome and were sufficiently similar to warrant pooling of effect sizes in a meta-analysis. Likewise, we could pool individual study results for ongoing pregnancy and safety outcomes. Study results that could not be combined in meta-analyses are shown in Tables S4–S6. The tools for assessing the main outcome at home and measurement techniques at clinics varied across studies.^{6,7,17,19} Thus, we used random effect models.

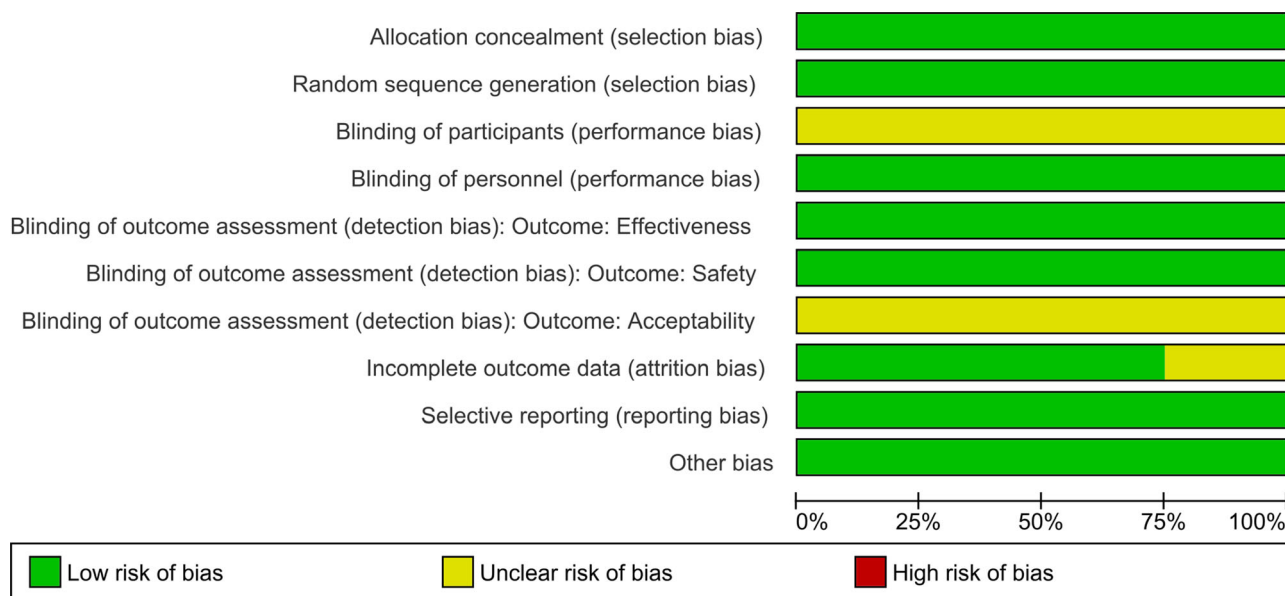


Figure 2. Risk of bias (RoB) assessment graph: Review authors’ judgements about each RoB item presented as percentages across all included studies.

Effectiveness

Effectiveness was measured in terms of complete termination of pregnancy. The meta-analysis result showed there was no statistical significant difference between self-assessment and routine clinic follow up regarding complete termination of pregnancy (RR = 1.00, 95% CI = 0.99–1.01; $I^2 = 0\%$) (Figure 3). Our GRADE assessment for the primary outcome found there was high certainty of the evidence (Table S3).

Safety

The studies reported on ongoing pregnancy and safety in terms of need for surgery, occurrence of haemorrhage, occurrence of fever and infections, and rates for drug administration for haemorrhage. Operationalisations of safety outcomes were not given in the study publications (Table S2). We were able to conduct meta-analyses for four safety outcomes. There were no statistically significant

differences between the two groups with regard to need for surgery (RR = 0.92, 95% CI = 0.70–1.21, $I^2 = 0\%$), occurrence of haemorrhage (RR = 1.48, 95% CI = 0.84–2.60, $I^2 = 43\%$), fever and infections (RR = 0.41, 95% CI = 0.08–2.12, $I^2 = 62\%$), rates of drug administration for haemorrhage (RR = 1.80, 95% CI = 0.60–5.39, $I^2 = 0\%$) or ongoing pregnancy (RR = 0.90, 95% CI = 0.50–1.62, $I^2 = 7\%$) (Figure 4). Drugs administered for haemorrhage were intravenous fluids, blood transfusion, and iron supplements (Table S2). Our GRADE assessments for these secondary outcomes found that the certainty in the safety estimates ranged from moderate to low (Table S3). Outcomes on safety reported in only one study could not be pooled and are reported in Table S4. There were no statistically significant differences between the self-assessment group and the routine clinic follow-up group with regard to these safety outcomes (need for blood transfusion, admission to hospital, pain, additional phone consultation, clinic visit).

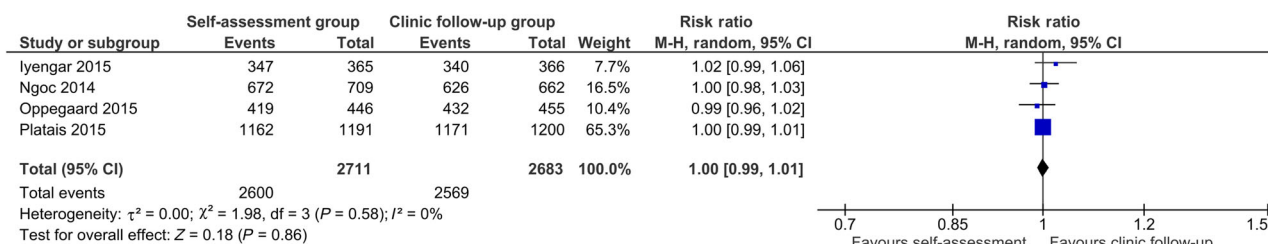


Figure 3. Forest plot, effectiveness of the outcome of medical abortion (complete termination of pregnancy). Self-assessment of the outcome of medical abortion at home was compared with routine clinic follow up.

Acceptability of self-assessment

Acceptability was measured in terms of preference for assessment in the event of a future medical abortion. All four studies found that the acceptability of follow-up technique was significantly greater for self-assessment than for routine clinic follow up (Table S5).

Our final outcome of interest was loss to follow up. The percentage of women lost to follow up was slightly lower in the self-assessment group than in the clinic follow-up group (Table S6).

Discussion

Main findings

In this systematic review of four well-conducted RCTs, we found that for both effectiveness and safety, self-assessment of

the outcome of medical abortion at home is not inferior to routine clinic follow up. There is high-quality evidence that complete abortion rates do not differ between the two conditions. The meta-analyses results also showed that there are no serious complications related to self-assessment at home and ongoing pregnancy rates are not higher compared with clinic follow up. With moderate- to low-quality evidence for the safety outcomes, self-assessment at home appears to be as safe as routine clinic follow up. Furthermore, our results shed light on the acceptability of follow-up method, showing that the preference of follow-up technique is significantly greater for self-assessment than for routine clinic follow up.

Strengths and limitations

We conducted the review in accordance with the criteria in the Cochrane Handbook for Systematic Reviews of

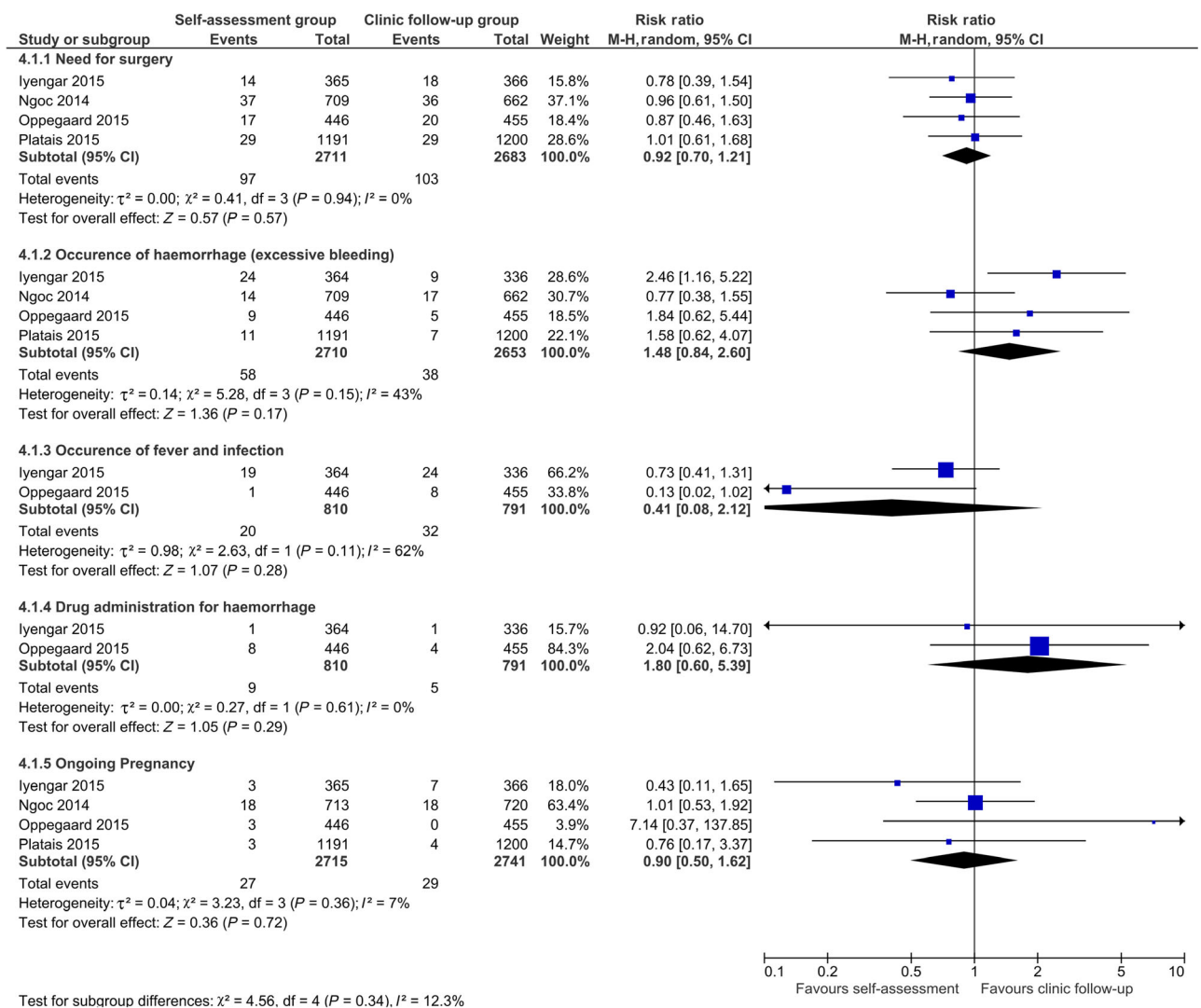


Figure 4. Forest plot, ongoing pregnancy, and safety of the outcome of medical abortion (need for surgery, haemorrhage, fever and infections, drug administration for haemorrhage). Self-assessment of the outcome of medical abortion at home was compared with routine clinic follow up.

Interventions. The searches covered a range of databases and ran up to February 2018. We conducted meta-analyses and assessed the certainty of the evidence. We could not statistically assess the possibility of publication bias because of the low number of included studies. However, it is unlikely that studies have been missed, as a thorough search was performed in different databases. Similarly, although the meta-analyses revealed moderate heterogeneity for the safety outcomes, we could not explore reasons for heterogeneity through sub-group analyses because of the low number of studies included. Due to a lack of resources, publications in languages other than English were not considered eligible. To the best of our knowledge, there is no core outcome set for self-assessment of the outcome of first-trimester medical abortion, thus we were inclusive in our review outcomes. The definition of outcomes, including treatment success, is a recognized problem in publications related to abortion.¹⁹ Despite these limitations, this review is able to draw strong conclusions about the effectiveness and safety of the outcome of assessment of medical abortion at home.

Interpretation

Home self-administration of misoprostol for medical abortion has been suggested to be safe, efficient, feasible, and acceptable by a handful of studies from the USA.^{20–24} Studies have shown it to be highly acceptable and the majority of women specified that they would prefer home administration of medical abortion again in the hypothetical situation of needing another abortion.¹³ Women reported that it is much easier to tolerate the side effects in the known, comfortable environment of their homes with someone familiar nearby to support them, which ultimately prepares them for any problems that could arise later.²⁵ Correct diagnosis of ongoing pregnancy is an important aspect of follow up after medical abortion. The Royal College of Obstetricians and Gynaecologists (RCOG) in its recent guidance has advised that telephone follow up and urine pregnancy testing may be considered appropriate in the absence of evidence to recommend one particular procedure for routine follow up to exclude ongoing pregnancy after medical abortion.⁹ Although ultrasound examination is the only sure way to confirm ongoing pregnancy, our review results support the RCOG recommendation, as the rates of complete abortion, ongoing pregnancy, and other complications were similar irrespective of whether the assessment of outcome was performed by women themselves or healthcare professionals. Grossman et al.²⁵ in their review in 2010 stated that alternatives to routine in-person follow-up visits after medical abortion, such as women's self-assessment without using any tests, clinician's assessment, serum hCG measurements, UPT, or a combination of these techniques are accurate at diagnosing the complete

termination of pregnancy. However, the researchers emphasised that there is a need for additional research to determine the accuracy, acceptability, and feasibility of alternative follow-up modalities in practice, particularly of home-based urine testing with self-assessment.

To the best of our knowledge, our review is the first systematically to evaluate effectiveness, safety, and acceptability of self-assessment of the outcome of medical abortion at home compared with routine clinic follow up. Concerning generalisability, Ngo et al.²⁶ found that there was no difference in effectiveness or acceptability and safety between medical abortion performed at home and clinic across countries, a finding that is supported by the results on follow-up assessment in this review.

Conclusion

This review offers encouraging evidence of the effectiveness, safety, and acceptability of self-assessment of the outcome of medical abortion at home combined with telephone follow up or home visit. It demonstrates that there is high-quality evidence that the effectiveness of self-assessment of the outcome of medical abortion at home is not inferior to routine clinic follow up. It also shows that self-assessment at home appears to be as safe as routine clinic follow up and is preferred by women from both high- and low-resource countries.

In low-resource settings, where access to health facilities or ultrasound examination is limited or abortion services are socially sanctioned, the self-assessment of the outcome of medical abortion with UPTs and a simple follow-up technique such as a telephone call or home visit is a viable option. Furthermore, in all resource settings, self-assessment at home helps to shorten the waiting times for patients and reduces the need for medical resources. It also saves time and energy for women who travel, sometimes long distances, to clinics, who have to arrange childcare or take time off from household or work duties. Moreover, this technique provides women with a confidential and friendly environment to confirm the outcome of abortion at home, and it may encourage women to access abortion at an early gestational age (because they know there is no clinic follow up), which helps to reduce risks and complications related to abortion at later gestational ages.

Although high-quality evidence is drawn from this review, regarding especially the effectiveness of self-assessment of abortion at home, researchers are encouraged to conduct further research on different aspects of this topic in various study areas. Studies should be conducted to investigate the long-term safety outcomes of self-assessment of the outcome of medical abortion, such as fertility, and effectiveness and safety among vulnerable groups, such as women living with HIV, teenagers, and immigrants.

Likewise, studies should analyse reasons for follow-up preferences among both women themselves and patients' partners or family members, as this would give a broader and stronger evidence base concerning the attitude and acceptability of communities towards self-assessment.

There is a rapid rise in healthcare costs in the present world. Therefore, it is essential that healthcare policy makers focus on developing interventions that are not only effective but also cost-effective and affordable. Self-assessment of medical abortion is one of the interventions that may be both effective and affordable. However, due to complete lack of economic evaluation in the included studies, it is impossible to draw any conclusions on the cost-effectiveness of self-assessment. Thus, there is a clear need for further research evaluating the economics of the assessment.

In sum, self-assessment of the outcome of medical abortion at home is a simple follow-up technique which is comparable in effectiveness and safety to routine clinic follow up, acceptable to women, and feasible to implement regardless of resource settings, giving women the choice to carry out the assessment themselves or in clinics. This does not prevent women from selecting routine clinic follow up. Rather, it gives women greater choice in abortion care, facilitating access to safe and acceptable abortion options.

Disclosure of interests

The authors declare they have no conflicts of interests. Completed disclosure of interest forms are available to view online as supporting information.

Contribution to authorship

NB: led the concept of the review; drafted the protocol, and was involved in formulating the search strategy, running the searches, selecting studies, extracting data, and assessing risk of bias of the included studies, analysing data, and performing the GRADE assessment. NB drafted and revised the manuscript with input from RB. RB supervised and helped develop the research protocol and search strategy, selection of studies, assessment of risk of bias of the included studies, data analysis, and the GRADE assessment; contributed to writing and revising the manuscript. GA supervised and helped to develop the research protocol and search strategy, and contributed to reviewing the manuscript. FD contributed in selection of the studies, verifying the data extraction, and reviewing the manuscript.

Details of ethics approval

Not applicable.

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Figure S1. Risk of bias (RoB) assessment summary

Table S1. Reasons for exclusion of full text

Table S2. Characteristics of the included studies and RoB assessment

Table S3. GRADE assessment

Table S4. Safety outcomes

Table S5. Preferences of follow-up technique

Table S6. Loss to follow up

Appendix S1. Search strategy in electronic databases. ■

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