INPLASY PROTOCOL

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Conflicts of interest:

None declared.

Comparison of efficiency and safety of misoprostol and manual vacuum aspiration in treating first tremerster incomplete abortion: a systematic review and meta-analysis

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Review question / Objective: To comprehensively analyze the efficiency of misoprostol and MVA in accomplishing complete uterine evacuation in patients with incomplete miscarriage, the occurrence rate of adverse events following the two treatments, and patients' subjective evaluation towards the two treatments.

Condition being studied: To evaluate whether misoprostol use under strict surveillance could be used as an alternative of MVA in regions where the number of surgeons or equipment was insufficient.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 May 2023 and was last updated on 30 May 2023 (registration number INPLASY202350113).

INTRODUCTION

Review question / Objective: To comprehensively analyze the efficiency of misoprostol and MVA in accomplishing complete uterine evacuation in patients with incomplete miscarriage, the occurrence rate of adverse events following the two treatments, and patients' subjective evaluation towards the two treatments.

Rationale: To evaluate whether misoprostol use under strict surveillance could be used as an alternative of MVA in regions where the number of surgeons or equipment was insufficient.

Condition being studied: A large proportion of maternal morbidity and mortality from pregnancy failure could be attributed to severe complications of abortion, like intractable sepsis, uncontrollable vaginal or intra-abdominal bleeding, or uterine perforation. The detriment could be even more appalling in areas where standard and professional post-abortion care awere hardly accessible due to deficiency in equipment which were mandatory to perform the procedure and number and quality of personnel who were scrupulously trained for such purpose. As one kind of pregnancy failure, incomplete abortion was considered more treacherous since it might evoke various types of complications including intra-uterine infection and continuous bleeding because of unrepaired wound. Therefore, a rapid, safe, welladvised way which could achieve successful complete uterine evacuation in condition of incomplete abortion is called for, especially in low resources settings. Manual vacuum aspiration (MVA) arises as a replacement or supplement of curettage with benefits of less and more controllable bleeding as well as less pain. In addition, compared with other more complex technologies, MVA can be provided with verbal anesthesia without pharmacological anesthesia. Meanwhile, a series of clinical studies have pointed out MVA was able to promote successful uterine evacuation in over 85% of all cases, under the condition that it was carried out by experienced care providers having completed standard training process. Although MVA has been acknowledged as one of the first-line treatment for early-stage incomplete abortions, it is still inadequately and unprofessionally performed in places where socioeconomic development falls behind. It is also believed that popularization and standardization of MVA in these areas should be in consistency with sustainable enhancement of competence and increasing in number of care providers as well as promotion and upgrading of facilities and hygiene. In the past decade, an alternative medication called misoprostol gained attention and popularity for its potential to replace MVA as a much cheaper, safer, more available and easily accessible therapy in the treatment of early-stage incomplete abortion. While restricted in some conditions like hemorrhage of undetermined causes, misoprostol was found to achieve comparable uterine evacuation rate as MVA at a much lower cost. Moreover, the occurrence rate of adverse events following the treatment was also found to be lower in patients receiving optimal dose of misoprostol compared with those receiving MVA, especially the occurrence of bleeding andpain.

METHODS

Search strategy: ("incomplete abortion" OR "incomplete miscarriage" OR "abortion" OR "miscarriage" OR "miscarry) AND ("misoprostol" OR "medical treatment" OR "medication" OR "MVA" OR "manual vacuum aspiration" OR "vacuum aspiration" OR "uterine aspiration").

Participant or population: Patients with diagnosis of first trimester incomplete miscarriage.

Intervention: misoprostol vs MVA.

Comparator: The rate the successful complete uterine evacuation, the occurrence rate of adverse effects.

Study designs to be included: 1) having reported both the outcomes (rate of complete uterine evacuation, rate of adverse events, subjective evaluation from the patients) of misoprostol and MVA; 2) patients received only one treatment of MVA or misoprostol and did not receive other types of treatment or accessory treatment; 3) having reported adequate baseline characteristics of patients including age, parity, gestational age, marital status, etc; 4) gestational age less than 13 weeks (first trimester incomplete miscarriage).

Eligibility criteria: Main exclusion criteria were: 1) having reported patients who were accompanied by pelvic infection, severe anemia, renal failure; 2) having reported patients without detailed follow-up information; 3) gestational age over 13 weeks.

Information sources: PubMed, Medline, Embase, Ovid, and Web of Science.

Main outcome(s): Based on the number of event and total number of patients in both misoprostol and MVA group, we calculated the pooled RR (misoprostol vs MVA) of complete uterine evacuation, necessity for additional MVA, occurrence rate of adverse events (abdominal pain and rating of pain, bleeding, chills, fever, nausea, and vomiting), patients' satisfaction and possibility of recommendation of treatment using Stata 17MP (StataCorp LLC, Texas, The United States). With purpose to look for factors that might influence the pooled RR of successful complete uterine evacuation, we performed subgroup analysis including age, gestational age, parity, dosage of misoprostol, and marital status with the help of Stata 17MP (StataCorp LLC, Texas, The United States). **Credibility of Effect Modification Analyses** (ICEMAN) would be applied to consolidate the subgroup effect if positive correlation of subgroup was found. In order to determine heterogeneity between studies. we performed a meta-regression using Stata 17MP (StataCorp LLC, Texas, The United States). Besides, funnel plot and Egger's test were applied to look for potential publication with Stata 17MP (StataCorp LLC, Texas, The United States).

Quality assessment / Risk of bias analysis:

HJ and MZ evaluated the quality of the included studies and assessed the risk of bias using Review Manager 5.4 (Cochrane Collaboration, Copenhagen, Demark). Another reviewer YC consolidated the assessment individually. Studies with quality deficiency would be excluded from further data extraction and statistical analysis.

Strategy of data synthesis: Based on the number of event and total number of patients in both misoprostol and MVA group, we calculated the pooled RR (misoprostol vs MVA) of complete uterine evacuation, necessity for additional MVA, occurrence rate of adverse events (abdominal pain and rating of pain, bleeding, chills, fever, nausea, and

vomiting), patients' satisfaction and possibility of recommendation of treatment using Stata 17MP (StataCorp LLC, Texas, The United States). With purpose to look for factors that might influence the pooled RR of successful complete uterine evacuation, we performed subgroup analysis including age, gestational age, parity, dosage of misoprostol, and marital status with the help of Stata 17MP (StataCorp LLC, Texas, The United States). **Credibility of Effect Modification Analyses** (ICEMAN) would be applied to consolidate the subgroup effect if positive correlation of subgroup was found. In order to determine heterogeneity between studies, we performed a meta-regression using Stata 17MP (StataCorp LLC, Texas, The United States). Besides, funnel plot and Egger's test were applied to look for potential publication with Stata 17MP (StataCorp LLC, Texas, The United States).

Subgroup analysis: With purpose to look for factors that might influence the pooled RR of successful complete uterine evacuation, we performed subgroup analysis including age, gestational age, parity, dosage of misoprostol, and marital status with the help of Stata 17MP (StataCorp LLC, Texas, The United States).

Sensitivity analysis: None

Language restriction: English.

Country(ies) involved: China.

Keywords: first trimester incomplete miscarriage; misoprostol; MVA; efficiency; adverse effects

Contributions of each author:

Author 1 - Hongyu Jin - Author 1 conducted the initial search for related articles, screening of articles, quality assessment, and data extraction.

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