

Original Article

Efficacy of Mifepristone in induction of first-trimester miscarriage

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ABSTRACT:

Background: First trimester miscarriage, defined as pregnancy failure up to 13 completed weeks, affects nearly 25% of women in their reproductive age. The present study was conducted to assess efficacy of Mifepristone in induction of first-trimester miscarriage. **Materials & Methods:** 102 patients admitted to the department of Gynaecology & Obstetrics due to the first trimester miscarriage underwent repeatable doses of 800 mcg misoprostol vaginally. Type of miscarriage, gravidity, parity, time of drug administration were recorded. **Results:** BMI was 32.4 Kg/m² in successful and 32.1 Kg/m² in unsuccessful induction, time from previous delivery 3.61 years and 3.92 years respectively, History of miscarriages was 1 in 24 and 5 respectively, and >2 in 13 and 1 respectively, missed abortion was seen in 64 and 14 and blighted ovum in 18 and 6 respectively. Previous surgical interventions on uterus was seen in 11 and 5 in successful and in unsuccessful induction respectively. The difference was significant (P< 0.05). **Conclusion:** Pharmacological induction with Misoprostol is an effective and safe treatment method of first trimester abortion.

Key words: Abortion, Induction, Misoprostol

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INTRODUCTION

First trimester miscarriage, defined as pregnancy failure up to 13 completed weeks, affects nearly 25% of women in their reproductive age. Clinical presentation of spontaneous miscarriage most commonly includes bleeding from the genital tract and spontaneous expulsion of an embryo/fetus from the uterine cavity.¹ Expectant management is adequate in cases with small or moderate bleeding. However, in some cases - incomplete, inevitable, missed abortion - fetal or placental tissues may remain in the uterine cavity. In such conditions 3 different approaches are possible: expectant management, dilatation and curettage (D&C) and pharmacological induction of abortion with misoprostol.²

Mifepristone is costly and is unavailable in many settings. In the United States, although the drug is approved for marketing, the Food and Drug Administration has imposed restrictions on its distribution that substantially limit both patients' and providers' access to it.³ For women who cannot obtain

mifepristone, use of misoprostol alone, which is inexpensive and is widely used for various obstetric and gastrointestinal indications, can serve as an important alternative option.⁴ A systematic review published in 2007 found that the efficacy of misoprostol single-agent regimens at gestational ages ≤63 days ranged from 84% to 96%, but since then, additional studies have been published.⁵ The present study was conducted to assess efficacy of Mifepristone in induction of first-trimester miscarriage.

MATERIALS & METHODS

The present study comprised of 102 patients admitted to the department of Gynaecology & Obstetrics due to the first trimester miscarriage (prior to 14th week of gestation). Diagnosis was made by ultrasound with one of the following: an intrauterine sac with a diameter >20mm without a fetal pole or yolk sac, classified as anembryonic sac; the presence of fetal pole without heartbeat or crown-rump length (CRL) at

least 6mm with no cardiac activity and no change at the time of a second ultrasound one week later. All cases were included after obtaining their written consent.

Data such as name, age etc. was recorded. All patients underwent repeatable doses of 800 mcg misoprostol

vaginally. Type of miscarriage, gravidity, parity, number of doses, time of drug administration and side effects were recorded. Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

RESULTS

Table I Distribution of cases

| Total | Successful induction | Unsuccessful induction | P value |
|-------|----------------------|------------------------|---------|
| 102 | 82 | 20 | 0.01 |

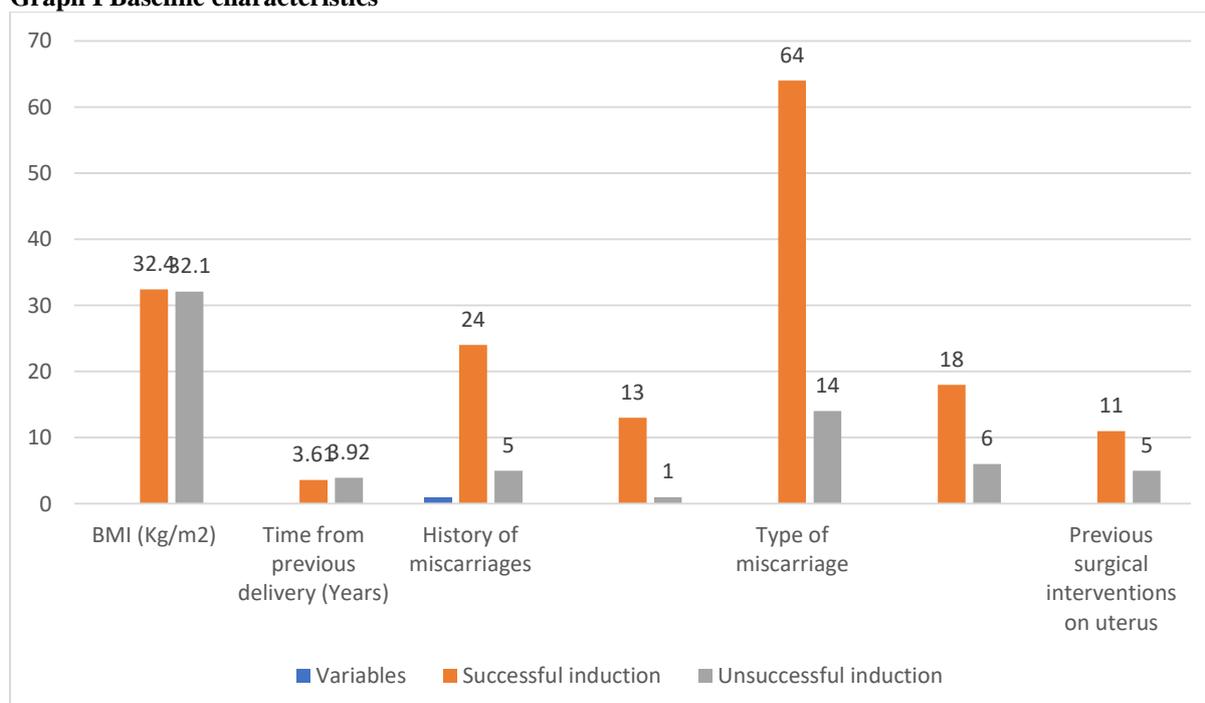
Table I shows that out of 102 cases, 82 showed successful induction and 20 had unsuccessful induction. The difference was significant (P< 0.05).

Table II Baseline characteristics

| Parameters | Variables | Successful induction | Unsuccessful induction | P value |
|---|-----------------|----------------------|------------------------|---------|
| BMI (Kg/m ²) | | 32.4 | 32.1 | 0.92 |
| Time from previous delivery (Years) | | 3.61 | 3.92 | 0.14 |
| History of miscarriages | 1 | 24 | 5 | 0.09 |
| | >2 | 13 | 1 | |
| Type of miscarriage | Missed abortion | 64 | 14 | 0.01 |
| | Blighted ovum | 18 | 6 | |
| Previous surgical interventions on uterus | | 11 | 5 | 0.02 |

Table II, graph I shows that BMI was 32.4 Kg/m² in successful and 32.1 Kg/m² in unsuccessful induction, time from previous delivery 3.61 years and 3.92 years respectively, History of miscarriages was 1 in 24 and 5 respectively, and >2 in 13 and 1 respectively, missed abortion was seen in 64 and 14 and blighted ovum in 18 and 6 respectively. Previous surgical interventions on uterus was seen in 11 and 5 in successful and unsuccessful induction respectively. The difference was significant (P< 0.05).

Graph I Baseline characteristics



DISCUSSION

Medical abortion with mifepristone 200 mg orally and misoprostol 800 mcg vaginally or buccally is highly effective through 63 days of gestation.⁶ In many countries, women use these medications on an outpatient basis and expel the pregnancy at home. A home-based model of medical abortion is as safe, effective and acceptable to women as in-clinic care.⁷ Recent research shows that the upper gestational age limit for outpatient regimens using mifepristone and buccal misoprostol may be extended to 70 days of gestation without a clinically significant reduction in effectiveness compared to 57–63 days of gestation.⁸ Similar efficacy is reported in a small number of cases with sublingual misoprostol. Few data are available to evaluate outcomes with mifepristone and a single dose of misoprostol vaginally beyond 63 days of gestation.⁹ The present study was conducted to assess efficacy of Mifepristone in induction of first-trimester miscarriage.

In present study, out of 102 cases, 82 showed successful induction and 20 had unsuccessful induction. Kobryn et al¹⁰ in their study 642 women diagnosed with first trimester miscarriage qualified for pharmacological induction with misoprostol were included in the study. Each patient underwent repeatable doses of 800mcg misoprostol vaginally. The endpoint was complete excretion of all tissues, with no need to perform surgical curettage. The percentage of successful miscarriage induction was 83.6%. Two main factors corresponded with successful pharmacological treatment in regression analysis: number of administered doses (adjusted OR 1.64; 95% CI 1.18–2.29) and week of gestation (aOR 1.22; 95%CI 1.03–1.44). The success of the pharmacological induction of miscarriage was significantly decreased if the woman had a history of caesarean section (aOR 0.34; 95% CI 0.2–0.57). 2.2% of patients experienced benign side effects of the therapy.

We found that BMI was 32.4 Kg/m² in successful and 32.1 Kg/m² in unsuccessful induction, time from previous delivery 3.61 years and 3.92 years respectively, History of miscarriages was 1 in 24 and 5 respectively, and >2 in 13 and 1 respectively, missed abortion was seen in 64 and 14 and blighted ovum in 18 and 6 respectively. Previous surgical interventions on uterus was seen in 11 and 5 in successful and in unsuccessful induction respectively. Raymond et al¹¹ among all 12,829 evaluable women, 2536 (meta-analytic estimate 22.0%, 95% CI 18.8%, 25.5%) had surgical uterine evacuation. Multiple factors were significantly associated with this proportion, including misoprostol amount per dose and route of administration, loss to follow-up rate, publication date, geographic region, number of misoprostol doses, duration of dosing, and time between dosing and evaluation. Of 6359 evaluable women, 384 (meta-analytic estimate 6.8%, 95% CI 5.3%, 8.5%) had ongoing pregnancy. At most 26 of

12,184 evaluable women (meta-analytic estimate 0.7%, 95% CI 0.4%, 1.0%) were transfused or hospitalized for abortion-related reasons. In trials that provided satisfaction data, most of women were satisfied or very satisfied with the treatment (meta-analytic estimate 78%, 95% CI 71%, 85%).

Hsia et al¹² found that of 2743 cases identified, we could not locate 40 charts and excluded 30 cases, leaving a final sample of 2673. Overall, 2538 women had a successful medical abortion. Reasons for failure included continuing pregnancy, retained nonviable pregnancy and incomplete abortion. Of those with continuing pregnancies, 81 underwent a uterine aspiration and 9 opted to continue the pregnancy. Thirty-five (1.3%, 95% CI 0.9–1.7) women had significant adverse events; 16 (0.6%, 95% CI 0.3–0.9) underwent an in-hospital aspiration. Pelvic infection (n=4, 0.2%) and transfusion (n=1, 0.03%) occurred rarely.

CONCLUSION

Authors found that pharmacological induction with Misoprostol is an effective and safe treatment method of first trimester abortion.

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