

## Original Research Article

# Study of the efficacy of a single 600 µg oral misoprostol dose for full uterine evacuation in cases of blighted ovum and missed abortions

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## ABSTRACT

**Background:** Missed abortions are common and represent a significant gynaecological emergency workload. The conventional method of uterus evacuation by vacuum aspiration is associated with morbidity and mortality. The search for a non-invasive method with high success rate and patient acceptability has led to the use of prostaglandins in varied conditions.

**Methods:** Present study was conducted with 50 cases. Patients who complained of amenorrhoea lasting fewer than 12 weeks and had ultrasonographic evidence of blighted ovum and/or missed abortions were included in this prospective trial. The study comprised patients who had been diagnosed with blighted ovum or missed abortion by ultrasonography, had amenorrhoea for fewer than 12 weeks, and were willing to receive medical treatment. The trial excluded patients with undiagnosed vaginal bleeding, amenorrhoea lasting longer than 12 weeks, incomplete or inevitable abortion, asthma, a history of medication responses to prostaglandins, signs of pelvic infection and/or sepsis, haemodynamic instability, or shock.

**Results:** 24.8 years mean maternal age and 8.4 weeks mean gestational age was observed. 56% cases were observed with surgical evacuation. Most of the cases i.e. 84% cases were seen with lower abdominal pain. Statistically no significant difference was observed in Hb.

**Conclusions:** When treating a blighted ovum with oral misoprostol 600 µg, their efficacy is nearly the same. Oral misoprostol is a useful treatment for blighted ovum.

**Keywords:** Misoprostol, Miscarriage, Blighted ovum, Termination of pregnancy, Amenorrhoea

## INTRODUCTION

Miscarriage, often referred to as spontaneous abortion, is an early pregnancy termination that happens when the foetus or embryo cannot survive until the twentieth week of pregnancy. Miscarriage is by far the most common problem that can occur in the early stages of pregnancy.<sup>1</sup> Miscarriages that take place before the sixth week of a woman's most recent menstrual cycle are referred to in medicine as early pregnancy loss or chemical pregnancy. Medical practitioners refer to an abortion that takes place after six weeks of pregnancy as a clinical spontaneous

abortion. Early pregnancy failure, also referred to as a blighted ovum, an early foetal death, or a missed abortion, complicates 15 to 20 percent of pregnancies.<sup>2</sup>

Fertilised eggs that implant but fail to develop are known as blighted ova. The foetus does not grow together with the gestational sac. If the ovum is blighted, there will be no yolk or foetal pole. Some estimates indicate that miscarriages occur in 15% of all clinically confirmed pregnancies. According to current estimates, a blighted ovum causes miscarriage in just 45 to 55 percent of pregnancies.<sup>3</sup> It's amazing how little we know about the

blighted ovum. The blighted ovum is not the focus of many research articles, despite being often mentioned in medical literature. The widespread agreement is that a blighted ovary may be caused by an abnormality in chromosomes 16 or 22.<sup>4</sup> It is more prevalent in older women, and the blight is caused by the egg rather than the sperm. It is considered a freak accident when it occurs only once. However, any pregnancy carries the risk of miscarriage. Your risk of miscarriage is unaffected by a single blighted ovum as long as you are in good health.<sup>5</sup> As an alternative, medical management of miscarriage has recently been studied. Numerous studies have examined the effectiveness of prostaglandins with or without mifepristone. The differences in selection criteria, choice, and criteria for diagnosing complete miscarriage make it crucial to develop an alternative to mifepristone, which is costly and unavailable in many countries.<sup>6</sup>

The intrauterine death of an embryo or foetus that may go undetected without the products of conception (POC) being expelled is known as a missed abortion. It accounts for about 15% of pregnancies with a clinical diagnosis. Due to standard early screenings for cardiac activity, women who have missed an abortion may now present later since they do not exhibit any symptoms.<sup>7</sup> Pregnancy failure can now be accurately recognised at an earlier stage because to transvaginal sonography (TVS), which enables close monitoring of the intrauterine cavity. Another benefit of TVS is that it makes it easier to track how early pregnancy failure responds to medical treatment, which has become a viable substitute for surgical termination.<sup>8</sup> Surgical evacuation was once thought to be the earliest option for first trimester missed abortions. This was caused by two factors: the patient's motivated wish to terminate a nonviable pregnancy and the timely therapy intended to stop blood loss or infection.<sup>9</sup>

Surgical evacuation may have numerous problems in addition to the danger of anaesthesia. These days, medical management is taken into consideration because it is safe, effective, and accepted.<sup>10</sup> Mifepristone and misoprostol-based medical termination of pregnancy (MTP) is now widely used. High success rates of 90% to 95% have been repeatedly linked to this medication regimen.<sup>11</sup> However, misoprostol, a PGE1 analogue, has acquired widespread recognition as a medical treatment for pregnancy failure (blighted ovum or missed abortion). Misoprostol, a PGE1 analogue, has a number of benefits, including low cost, ease of storage, and accessibility. The variable success rates (62%–88%) when this prostaglandin regimen was administered could be explained by variations in patient selection, dosage schedules, administration routes, follow-up times, and success criteria.<sup>12,13</sup> Misoprostol is one of the most perplexing parts of the medical treatment of missed abortion; several regimens have been investigated and utilised more or less successfully. The purpose of the current study was to investigate the efficacy of a single 600 µg oral misoprostol dose for full uterine evacuation in cases of blighted ovum and missed abortions.

## METHODS

This was a prospective study conducted in Government Hospital Miraj during the study period of June 2013 to October 2015. Patients with 50 cases who complained of amenorrhoea lasting fewer than 12 weeks and had ultrasonographic evidence of blighted ovum and/or missed abortions during the study period were included in this prospective trial. The study comprised patients who had been diagnosed with blighted ovum or missed abortion by ultrasonography, had amenorrhoea for fewer than 12 weeks, and were willing to receive medical treatment. The trial excluded patients with undiagnosed vaginal bleeding, amenorrhoea lasting longer than 12 weeks, incomplete or inevitable abortion, asthma, a history of medication responses to prostaglandins, signs of pelvic infection and/or sepsis, haemodynamic instability, or shock. Following ethical committee clearance and patient informed agreement, participants in the trial received a single dosage of 600 µg of oral misoprostol. Patients were instructed to fill out a diary sheet detailing any side effects and to report any tissue passing vaginally after taking the medication. The entire history was recorded. Personal information was recorded, including name, age, occupation, marital status, unique habits, and address. The current history and complaint were noted. Obstetric history was recorded, including parity, gravidity, and the mode of prior deliveries or abortions. Menstrual history, such as the LMP (first day of the period). Diabetes mellitus (DM), hypertension, heart issues, kidney problems, bleeding tendencies, blood diseases, bronchial asthma, glucose, allergies, and prior surgeries (particularly uterine scare) were identified. Hypertension or diabetes run in the family. Blood pressure, pulse, and temperature measurements were recorded during the general examination. Pallor or jaundice, petichae or ecchymosis, A chest and cardiac examination was performed. Oedema was observed. Examining the abdomen revealed things like the existence of scars from prior surgeries. The liver, spleen, and kidney were examined for organomegaly. Bimanual and speculum examinations of the vagina were performed. To confirm the diagnosis, an ultrasound investigation was conducted. Laboratory tests, the majority of which are performed on a regular basis upon admission: Every patient's complete blood count and haemoglobin levels both before and after treatment. Rh type and blood group. coagulation profile (INR, activated partial thromboplastin time, and prothrombin time). fasting and blood glucose levels two hours after eating. Bilirubin and liver enzymes (SGOT, SGPT) were measured. Serum creatinine and blood urea were measured. Following admission, each patient underwent the following urine analysis: Misoprostol was administered three times every three hours for a total of three doses. The following adverse events were monitored for the patients: Fever (>38°C), chills, headaches, and lower abdominal pain are all signs of a serious sickness. Blood pressure, pulse rate, side symptoms such nausea, vomiting, diarrhoea, and fatigue, as well as body temperature, were recorded every hour. If the ladies reported significant pain, oral or parenteral

analgesics were given. After completing their misoprostol medication, women were permitted to return home as long as they were not experiencing discomfort or severe vaginal bleeding. The women were instructed to return and retrieve their belongings as they were leaving. the result of domestic conception. The product of conception underwent histological examination. Further surgical intervention is necessary: Patients with endometrial thickness of less than 11 mm will be considered to have had a complete abortion at 7-10 days after misoprostol treatment, while those with endometrial thickness larger than 15 mm will need surgical evacuation.<sup>14</sup>

### Statistical analysis

IBM SPSS Ver. 28 was used to calculate statistics. Microsoft Excelbook 2024 was used to prepare tables.

## RESULTS

In Table 1 of the present study, 24.8 years mean maternal age was observed and 8.4 weeks mean gestational age was seen.

In Table 2, of the present study, most of the cases i.e. 48% cases were observed with zero parity followed by 22% mothers with parity 1 and 20% cases with more than or equal to 2 parities.

In Table 3, of the present study, completed abortion was observed in 44% cases where 56% cases required Surgical evacuation.

In Table 4, of the present study, Lower abdominal pain was the most side effect observed in 84% cases followed by fever (70%), fatigue (62%), vomiting (48%), nausea (44%), diarrhea (21%) and chills (6%) respectively.

In Table 5, of the present study, before full uterine evacuation in cases of blighted ovum and missed abortions 9.48 mean Hb was observed and after 9.35 mean Hb was observed. Statistically no significant difference was observed in Hb during the study period.

**Table 1: Maternal and gestational age.**

| Maternal and gestational age | Mean±SD  |
|------------------------------|----------|
| Maternal age                 | 24.8±6.2 |
| Gestational age              | 8.4±9.2  |

**Table 2: Parity.**

| Parity | No. of cases | Percentage (%) |
|--------|--------------|----------------|
| P0     | 29           | 48             |
| P1     | 11           | 22             |
| P ≥2   | 10           | 20             |

**Table 3: Completed abortion and surgical evacuation.**

| Completed abortion and surgical evacuation | No. of cases | Percentage (%) |
|--------------------------------------------|--------------|----------------|
| Completed abortion                         | 22           | 44             |
| Surgical evacuation                        | 28           | 56             |

**Table 4: Side effects.**

| Side effects         | No. of cases | Percentage (%) |
|----------------------|--------------|----------------|
| Nausea               | 22           | 44             |
| Vomiting             | 24           | 48             |
| Diarrhea             | 21           | 42             |
| Lower abdominal pain | 42           | 84             |
| Fatigue              | 31           | 62             |
| Fever temperature    | 35           | 70             |
| Chills               | 3            | 6              |

**Table 5: Hemoglobin (Hb).**

| Hb        | Mean±SD   |
|-----------|-----------|
| Hb before | 9.48±1.11 |
| Hb after  | 9.35±1.09 |

## DISCUSSION

At some point in their life, one in four women will have an early miscarriage; the most common causes are spontaneous abortion, embryonic gestation, and embryonic or foetal death.<sup>15</sup> Surgery is a commonly acknowledged method of treating miscarriages in many parts of the world. It is an effective surgery with a success rate of up to 98%.<sup>16</sup> Asherman's syndrome, cervical injury, uterine perforation, and post-abortion pelvic infection are all potential outcomes. These issues may have a lasting impact on a woman's future fertility. A relatively recent breakthrough in the treatment of silent miscarriage is the use of expectant and medial management.<sup>17</sup> Controlling miscarriages during pregnancy is a desirable option. Compared to other treatment alternatives, it is therefore more likely to be safe and less likely to induce negative effects.<sup>18</sup> This study indicates that the duration of the study has an impact on the rate of complete abortions.

In the context of medical abortion, a few randomised trials have evaluated misoprostol dosages and intervals; the findings were conflicting. The objective of this study was to use repeated dosages of oral misoprostol in the medical treatment of blighted ovum.<sup>19</sup> The mean age in this study was 24.8±6.2 years (range: 17–31 years), the mean gestational age was 8.4±9.2 (range: 7–12 weeks) (Table 1), and the gravidity ranged from 1-3. In this study, 56% of patients underwent surgical evacuation and 44%

experienced a complete abortion (Table 3). Sublingual misoprostol was used by Tang et al to treat silent miscarriages in the first trimester. For a total of three doses, women were given 600 µg of misoprostol sublingually every three hours.<sup>20</sup> In a previous trial by Tang et al, the women were given 600 µg of misoprostol sublingually every three hours for a total of five doses.<sup>21</sup> 86% (95% confidence interval: 74-93) was the total abortion rate. There was a substantial difference between the two groups, with a higher proportion of patients in the oral group having side effects such diarrhoea and vomiting. 84% of the oral group experienced lower stomach pain, 70% experienced fever, 62% experienced exhaustion, 48% experienced vomiting, 44% experienced nausea, 42% experienced diarrhoea, and 6% experienced chills (Table 4). One of the most frequent side effects of early pregnancy is missed abortion. It occurs in 12% to 15% of pregnancies with a clinical diagnosis; of these, 2% to 6% of pregnancies may have had previously recorded foetal cardiac activity.<sup>22</sup>

ACOG and NICE recommendations do not advise using mifepristone before misoprostol in the medical management of missed abortions.<sup>23,24</sup> However, a number of studies employing this combination have demonstrated greater success rates.<sup>25-27</sup> Therefore, more research is required to assess the effectiveness of misoprostol alone against mifepristone followed by misoprostol. The MIFEMISO trial, a multicenter, double blind, placebo-controlled, randomised study, was conducted in 28 UK institutions between October 2017 and July 2019. Two groups of 711 women were randomly assigned. In their 2018 study, Schreiber et al. defined a successful treatment as the evacuation of the gestational sac using a single dose of misoprostol by the first follow-up appointment, with no further intervention for up to 30 days following treatment.

Out of the 148 women, 124 (83.8%) had successful treatment.<sup>27</sup> In a double blind, randomised, placebo-controlled experiment, Sinha et al. demonstrated a noteworthy success rate (no need for surgical evacuation) in the study group.<sup>28</sup> In both groups, retained products were the most frequent cause of surgical evacuation.<sup>29</sup> Similar to our analysis, the majority of studies have not reported any additional side effects with either of the regimens when it comes to medical management issues. More thorough research is needed to develop this regime in guidelines, even if the current study is a single-center study with a limited sample size.

### Limitations

Most of the cases were seen with heavy bleeding and undiagnosed pregnancy plocation. Some cases refused to participate or refused for medical management in study. Need more studies to be done for efficacy of a single 600 µg oral misoprostol dose for full uterine evacuation in cases of blighted ovum and missed abortions

## CONCLUSION

When treating a blighted ovum with oral misoprostol 600 µg, their efficacy is nearly the same. Oral misoprostol is a useful treatment for blighted ovum.

Misoprostol is inexpensive, has a long shelf life, doesn't require refrigeration, is readily available, doesn't require surgery and hence doesn't require anaesthesia, and is quite effective at evacuating the uterus in missed abortions. Therefore, even at the primary care level, it may be recommended for usage in an outpatient environment to treat early pregnancy failure.

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