

Efficacy of Single Dose of 800µg Vaginal Misoprostol in the Induction of First Trimester Abortion

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ABSTRACT

Background: Dissolution of pregnancy in the first trimester for several maternal as well as foetal concerns (therapeutic abortion) is a common obstetrical issue. However, induction of abortion demands thorough and effective care, just as women in labour with childbirth. World Health Organization estimates that 13% of all the maternal deaths in South-Asia are associated with abortion procedures. The current recommended approach is 800 µg misoprostol administered vaginally repeated at 3 hours intervals for a maximum of 3 doses with a reported frequency of 85% for complete expulsion of products of conception within 24 hours after administration. There are studies which claim a single vaginal dose of 800µg misoprostol to be equally effective, but more convenient and safe. However, there was controversy surrounding the efficacy of this single dose regimen.

Aim: To determine the efficacy of single dose of 800 µg vaginal misoprostol in the induction of first trimester abortion.

Methods: This was a descriptive case series conducted at the Department of Obstetrics and Gynecology, University of Lahore Teaching Hospital, Lahore. A written informed consent was taken from all the patients.

Results: The total number of patients admitted in the unit over period of 1 year were 369 women in their first trimester requiring therapeutic abortion. The mean age of the patients was 29.04±4.98 years and the mean gestational age was 7.96±2.24 weeks. Majority of the patients were para 2 48(40.1%) followed by para 3(35.8%) and para 1(24.1%). Complete expulsion of POCs within 24 hours was achieved in 342(92.7%) cases while it failed in 7.3% cases. When cross tabulated, the frequency of successful expulsion was unaffected by age (p=.114), gestational age (p=.250) and parity (p=.238).

Conclusion: The frequency of complete expulsion of products of conception with single dose of 800µg vaginal misoprostol in first trimester induced abortion was observed to be 92.7%.

Keywords: First-Trimester Abortion, Vaginal Misoprostol, 800µg Single Dose

INTRODUCTION

Maximum number of pregnancy loss is in the form of first trimester abortion. 28% of World's population resides South-Asia (Bangladesh, India, Pakistan, Nepal and Sri-lanka) and it contributes to almost one third (30%) of world's maternal deaths. World Health Organization estimates that 13% of all the maternal deaths in South-Asia are associated with abortion procedures¹.

Dissolution of pregnancy in the first trimester for several maternal as well as foetal concerns (therapeutic abortion) is a common obstetrical issue. Induction of abortion demands thorough and effective care, just as women in labour with childbirth. Misoprostol which is a prostaglandin E1 analogue can be administered orally, sublingually, rectally and vaginally and has emerged as an effective agent for the induction of abortion. The current recommended dosage is 800µg misoprostol administered vaginally repeated at 3 hours intervals for a maximum of 3 doses (depending on cervical dilatation) which has an efficacy (complete expulsion in 24 hours) of 85%. However, there are evidences that a single dose of 800 µg misoprostol administered vaginally is equally effective^{2,3}.

Subedi in 2012 documented that a single dose of 800µg misoprostol administered vaginally was highly effective (complete expulsion rate of 92.7%). Similar results were achieved previously by Prasad et al. in 2007 (94.2%)^{4,5}.

Thus a single dose of 800µg misoprostol may be equally effective, yet avoiding repeated unnecessary dosage. Also it gives the advantage of outdoor management where the patients can be sent home after single dose and need not to be kept for repeated evaluation and dosage administration.

But before jumping to conclusions, one must not forget that there is great discrepancy among results of different authors. Sedigheh et al. in 2008 documented complete abortion rate of just

62% with single vaginal dose of 800µg misoprostol. Similar results were achieved previously by Blanchard et al in 2005 (60%) and Kovavisarach & Jamnansiri in 2005 (68.40%)^{5,6}.

This conflict among different authors may be due to poor control of confounder (didn't exclude uterine abnormalities, didn't exclude missed/ incomplete abortion, only included early pregnancy failure). The purpose of the current study is to determine the efficacy of single dose regimen after eliminating bias by carefully excluding the confounders. If found better or at least equally effective, this study will enable avoidance of unnecessary dosages and outdoor management of such cases thus avoiding un-necessary burden over the hospital⁴⁻⁸.

The purpose of the current study was to resolve this controversy while minimizing bias by selecting a large sample size, carefully excluding confounders and stratifying the data for effect modifiers with a hope that if this single dose regimen is found equally effective, the results of this study will enable more convenient, safe and economical management of first trimester abortions in future practice by avoiding repeated dosage in conventional approach.

METHODOLOGY

This was a descriptive case series conducted at Department of Obstetrics and Gynecology, University of Lahore Teaching Hospital, Lahore after permission from IRB on patients who got hospitalized in unit over a period of 1 year after the approval of synopsis from 16/08/2021 to 15/02/2022. All the patients with first trimester miscarriage as per dating scan requiring therapeutic abortion were included in the study. A written informed consent was taken from all the patients. Study was conducted after getting approval from hospital ethical and research committee. Non probability consecutive sampling technique was used. Patients hypersensitive to prostaglandins, diagnosed case of bronchial asthma, history of missed/ incomplete abortion, previous cesarean section and patients with severe bleeding per vagina necessitating surgical management were excluded.

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Detailed history followed by clinical examination was done. The history of congenital uterine abnormalities and fibroids in the uterus were ruled out on transvaginal ultrasound. Clinical examination was done to exclude uterine myomas. Required investigations were sent. 800µg of misoprostol (4x200µg Tablets) was inserted into the posterior vaginal fornix and the patient then remained in a semiprone position for 30 minutes. Thereafter the patient was kept under observation for next 24 hours. Expulsion of product of conception was observed and confirmed on transvaginal scan as per operational definition. Predesigned proforma was used for data collection. Data was analyzed using SPSS version 24, calculating mean for numerical variables like age and frequencies and percentages for categorical variables.

RESULTS

Over the period of six months, 369 women in their first trimester requiring therapeutic abortion were admitted. The age of the patients ranged from 21 years to 38 years with a mean of 29.04±4.98 years. The gestational age of the patients ranged from 4 weeks to 12 weeks with a mean of 7.96±2.24 weeks. Majority of the patients were para 2, 148(40.1%) followed by para 3(35.8%) and para 1(24.1%) (Table 1). Complete expulsion of POCs within 24 hours was achieved in 342 (92.7%) cases while it failed in 7.3% cases. Table 2

Table 1: Demographics of patients

Feature	Mean±SD, f (%)
n	369
Age	29.04 ± 4.98
Gestational age	7.96 ± 2.24
Parity	
1	89 (24.1%)
2	148 (40.1%)
3	132 (35.8%)

Table 2: Complete resolution of PCOS within 24 hours

Complete resolution	Frequency	Percent
Yes	342	92.7%
No	27	7.3%
Total	369	100.0%

DISCUSSION

Maximum number of pregnancy loss is in the form of first trimester abortion. Dissolution of pregnancy in the first trimester for several maternal as well as foetal concerns (therapeutic abortion) is a common obstetrical issue. Induction of abortion demands thorough and effective care, just as women in labour with childbirth. World Health Organization estimates that 13% of all the maternal deaths in South-Asia are associated with abortion procedures¹.

Misoprostol which is a prostaglandin E1 analogue can be administered orally, sublingually, rectally and vaginally and has emerged as an effective agent for the induction of abortion. The current recommended dosage is 800 µg misoprostol administered vaginally repeated at 3 hours intervals for a maximum of 3 doses (depending on cervical dilatation) which has an efficacy (complete expulsion in 24 hours) of 85%¹⁻³.

However, there is evidence that a single dose of 800 µg misoprostol administered vaginally is equally effective. It is evident from this literature review, that there is great degree of disparity

about the efficacy of this single dose regimen; frequency of complete expulsion varies from as low as 60% to as high as 95%^{6,9}.

Three hundred and sixty nine women in the first trimester requiring therapeutic abortion were enrolled after written informed consent. The mean age of the patients was 29.04±4.98 years and the mean gestational age was 7.96±2.24 weeks. Majority of the patients were para 2, 148(40.1%) followed by para 3 (35.8%) and para 1 (24.1%). 800ug misoprostol was placed vaginally and complete expulsion of products of conception was noted within 24 hours. Complete expulsion of POCs within 24 hours was achieved in 342(92.7%) cases while it failed in 7.3% cases. Our results match closely with those of Subedi (2012, 92.7%), Prasad et al (2007, 94.2%) and el-Refaey et al (1995, 95%)^{4,5,9}.

When cross tabulated, the frequency of successful expulsion was unaffected by age (p=.114), gestational age (p=.250) and parity (p=.238). Thus single dose of 800µg vaginal misoprostol is high effective in first trimester induced abortions with successful expulsion of products of conception in 92.7% cases. This efficacy is unaffected by age, gestational age and parity making it ideal choice in all patients requiring therapeutic abortion in first trimester.

The strength of our study is minimal bias due to larger sample size, exclusion of confounders and stratification of results for effect modifiers. A very important limitation of our study is that we only considered successful expulsion and other important aspects of management like complications/ side effects were not considered. Therefore similar studies including these parameters are highly recommended in future.

CONCLUSION

The frequency of complete expulsion of products of conception with single dose of 800µg vaginal misoprostol in first trimester induced abortion was observed to be 92.7%.

Conflict of interest: Nil

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