

Safety and efficacy of misoprostol versus manual vacuum aspiration in missed abortion up to 12 weeks

Badgire Swati, Deshpande Sonali, Gadappa Shrinivas, Patil Mohini
Government Medical College and Hospital, Aurangabad, Maharashtra, India

Received: August 1, 2020

Accepted: October 16, 2020

ABSTRACT

Aims: To compare the safety and efficacy of Misoprostol versus manual vacuum aspiration in missed abortion up to 12 weeks.

Methods: This is comparative study where Misoprostol 800 µg was administered sublingually four hourly till expulsion of products or maximum of three doses in one group and 400 µg misoprostol followed by manual vacuum aspiration 4 hours later was done under local anaesthesia in another group from October 2019 to March 2020 at Government Medical College and Hospital, Aurangabad, Maharashtra. Unpaired t-test and Chi squared test were performed with alpha-error set at 0.05.

Results: The success rate in Misoprostol group was 88 % and in the MVA group, it was 98%. Mean duration of hospital stay in Misoprostol group was 2.46±1.18 days and in MVA group was 1.55 ± 1.52 days (p= 0.3). Mean induction abortion interval in Misoprostol group was 8.125±3.29 and 4.46±0.44 hours in MVA group (p=0.000). One woman from MVA group had perforation of uterus which could be attributed to previous LSCS with tight os.

Conclusion: Single dose of Misoprostol followed by manual vacuum aspiration is better than the multiple dosage of Misoprostol for the treatment of first trimester missed abortion in terms of duration of treatment but not for the individual success rate. Hospital stay is similar.

Keywords: manual vacuum aspiration, misoprostol, missed abortion

Citation: Swati B, Sonali D, Shrinivas G, Mohini P. Safety and efficacy of misoprostol versus manual vacuum aspiration in missed abortion up to 12 weeks. Nep J Obstet Gynecol. 2020;15(31):73–76. DOI: <https://doi.org/10.3126/njog.v15i2.32910>

INTRODUCTION

Missed abortion is defined as intrauterine death of the embryo or fetus before the age of viability that is retained without expulsion of the products of conception.¹

Accepted treatment options for missed abortion include expectant management, medical treatment or surgical evacuation. With adequate time, expectant management is successful in achieving complete expulsion of products of conception in approximately 80 % of women.²

Surgical uterine evacuation remains the treatment of choice if there is excessive and persistent bleeding, if vital signs are unstable or in the presence of retained infected tissue. Study suggests that these complications affect less than 10 % of women who miscarry.³ Reported serious complications of surgical evacuation include perforation, cervical tear, intrauterine adhesions, hemorrhage and risk

of anesthesia. The incidence of serious morbidity is 2.1% with a mortality of 0.5/100000.^{4,5}

Many studies have proposed medical treatment with misoprostol as an effective alternative to conventional surgical treatment for missed abortion.⁶⁻¹² Misoprostol, due to the ease of handling and storing it, as well as its non-invasiveness and proven cost-effectiveness, offers several advantages within abortion care. It reduces the need for skilled surgical abortion providers, equipment, sterilization and anaesthesia, while offering a highly acceptable option to pregnant individuals. For these reasons, misoprostol is particularly useful in low-resource settings.¹³ Medical treatment is an alternative technique that complements but does not replace surgical evacuation.¹⁴

Though few studies have been conducted till date to evaluate and compare efficacy of misoprostol and MVA in missed miscarriage, very few researchers

CORRESPONDENCE

Dr Swati Badgire
Department of OBGYN
Government Medical College and Hospital, Aurangabad,
Maharashtra, 431005, India
Email: drswatibadgire@gmail.com; Mobile: +91-7448220988

have juxtaposed the drug at 800 mcg sublingual misoprostol¹⁵ doses with MVA, especially in India. Keeping in this mind, the present study was planned to compare safety, efficacy and acceptability of Misoprostol with MVA in missed abortion up to 12 weeks of gestation.

METHODS

This is the comparative study between two modalities of treatment from October 2019 to March 2020 at Government Medical College and Hospital, Aurangabad, Maharashtra. By comparison of proportion method at 95 % confidence interval and 80% power the minimum sample size is found to be 47 per group. Thus, 50 cases in each group were studied.⁶

Stable cases without further complications were include and cases having excessive uterine bleeding, haemoglobin concentration < 8 gm/dl, medical disorders, DIC, sepsis, known allergy to or contraindication to misoprostol use were excluded. After ethical approval, written informed consent was taken and structured format used for data collection. Study subjects identified clinically and confirmed by ultrasound.

The patients were divided in two groups where Misoprostol group received 800 µg of Misoprostol sublingually every four hours up to a maximum of three doses. The outcome was documented 12 hours after the last dose of Misoprostol to facilitate sufficient time for the drug to be effective. Surgical evacuation was performed in case of heavy vaginal bleeding, and in women who failed to abort. Women were allowed to request a surgical intervention at any time if they do not wish to continue or to wait for complete evacuation.

In another group, cervical ripening was done with 400mcg of Misoprostol four hours before the procedure; then underwent Manual Vacuum Aspiration under Local Anaesthesia (paracervical block).

Unpaired t-test and Chi squared test were performed with alpha-error set at 0.05.

RESULTS

Out of 114 cases 14 cases didn't provide consent, thus 100 cases were analysed. Baseline characteristics in each group were similar [Table-1].

Table-1: Baseline characteristics

Characteristics	Misoprostol group (n=50)	MVA group (n=50)	Total	Test	p-value
Age (years)	25.30±5.86	25.58±5.67		Unpaired t-test= 0.243	0.809
Parity	nullipara	14 (28%)	22 (44%)	Chi- square =2.7868	0.248
	Parity 1	15 (30%)	12 (24%)		
	Parity ≥2	21 (42%)	16 (32%)		
Residency	Rural	27 (54%)	22 (44%)	Chi-square =1.00	0.317
	urban	23 (46%)	28 (58 %)		
Previous history of LSCS	4 (8%)	4 (8%)	8 (8%)	Chi-square = 0	1
Weeks of gestation	8.626±1.22	8.694±1.37		Unpaired t test =-0.262	0.794

The induction to expulsion interval is significantly better with MVA group. There was one case of

incomplete abortion in MVA group who had previous 2 LSCS with adherent POCs [Table-2].

Table 2- Distribution according to outcome

Outcome	Misoprostol group	MVA group	P value	
Success	44 (88%)	49 (98%)	0.05	Not Significant
Failure	6 (12%)	1 (2%)		
Duration of stay in hospital (days)	1.82±1.18	1.55± 1.52	0.3	
Induction-abortion interval (hours)	8.125±3.29	4.46± 0.44	.000	Significant

There was no significant difference ($p = 0.065$) in complications like excessive bleeding, uterine perforation or incomplete expulsion. Six cases under misoprostol group required change of treatment modality as 3 women had excessive vaginal bleeding and 3 didn't respond even after complete dose of Misoprostol. One woman from MVA group had incomplete abortion requiring re-evacuation and one had uterine perforation that required laparotomy to repair.

As regards to side effects, there was no statistical difference in both groups. Frequency of side effects is not mutually exclusive [Table-3].

Table-3: Distribution of side effects (n=50 in each group)

Side effects	Misoprostol group	MVA group	p-value
Diarrhoea	11	1	0.100456
Fever	7	1	
Nausea	8	0	
vomiting	4	0	
Pain in abdomen	6	4	

DISCUSSION

In our study, success rate in Misoprostol group was 88 % and in MVA group, it was 98 %, the difference is not statistically significant. In similar studies^{6,11,12}, success rate was in the range of 83-97% in Misoprostol group and 95-99% in MVA group. Our results were comparable with these studies.

The wide variation (13-100%) in success rates and dose requirement of misoprostol may be attributed to several reasons: route of administration, different dose schedules, repeat dose schedule, stretching the follow

up (waiting for 3-15 days was found to be associated with higher success rates), patient selection, type of PG analogue used (like sulprostone or PGE2 analogue) along with misoprostol or simultaneous use of mifepristone in other studies, small sample size causing bias, use of USG before starting treatment is associated with higher success, criteria used to define success.⁹

As regards to induction-abortion interval, in our study, mean induction-to expulsion interval in Misoprostol group was 8.125 ± 3.298 hours. In a similar study by Sheeba Marwah et al,⁹ mean induction expulsion interval in misoprostol group was 10.87 ± 3.49 hours. These results were comparable to our study.

Similarly, 6 % women in misoprostol group had excess vaginal bleeding, and 12 % women required MVA for incomplete abortion. In MVA group, 1 woman had perforation requiring exploratory laparotomy. In a study by Kehinde et al,⁶ 29.2 % and 12.2 % women from misoprostol and MVA group had excessive vaginal bleeding while 17 % and 1 % women had incomplete abortion respectively. In a study conducted by Verma et al¹¹ no women had excessive bleeding, 1 % had uterine perforation in MVA group and 3 % and 5 % had incomplete abortion in misoprostol group and MVA group respectively. These complication rates were comparable with current study.

CONCLUSIONS

Our study shows that Misoprostol is a non-surgical method which is equally effective to the surgical method and it required the same duration of hospital stay as that of surgical method.

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