

ORIGINAL RESEARCH

Comparative Study of the Safety and Effectiveness of Oral versus Vaginal Misoprostol for Induction of Midtrimester Abortions- A Retrospective Study

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ABSTRACT**Background:** To compare the safety and efficacy of oral versus vaginal misoprostol in induction of midtrimester abortions.**Methods:** We conducted a retrospective comparative study at the postpartum unit of the department of obstetrics and gynaecology, Government Medical College, Amritsar from January 2022 to September 2024. The available record of 125 patients who underwent termination of pregnancy between 13 and 24 weeks of pregnancy was analyzed. The outcome data of women undergoing midtrimester abortion (Group A) with vaginal misoprostol (n= 64) was compared with a contemporaneous cohort of women undergoing midtrimester pregnancy interruption (Group B) with oral misoprostol (n=61). The procedure efficacy and safety of the procedure were assessed. **Results:** There was complete foetal expulsion in all cases in Group A (100%) while the success rate was 90.16% with oral misoprostol in Group B. The median induction to abortion (IA) interval was significantly shorter in Group A (6.80 ± 1.1 versus 9.46 ± 2.69 hours; $p=.000$). The median amount of vaginal misoprostol (800ug) used in Group A was significantly less than the oral dose used in Group B (1200ug). The side effects in the vaginal group were less as compared to the oral group due to the higher dose of misoprostol used in the oral group. **Conclusion:** The present study confirmed that vaginal misoprostol is generally more effective than oral misoprostol hence should be the preferred method. Just resorting to the vaginal route reduces the total dosage of misoprostol required for termination and shortens the termination interval thereby increasing the patient comfort.**Keywords:** Foley catheter, Misoprostol, pregnancy termination, Oral, Vaginal.

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INTRODUCTION

The midtrimester abortions (13-24 weeks) contribute to about 10-15% of all induced abortions (WHO; 1997) but are responsible for two-thirds of abortion related complications. The complications related to abortions remain one of the major causes of maternal morbidity and mortality with midtrimester abortions being associated with 3-5 times higher maternal and morbidity compared to the first trimester. About 42 million legal abortions and 10 to 12 million clandestine abortions take place throughout the world every year. According to the central health management and information (HMIS) system of NRHM in India, 6.42 lakh abortions were recorded in the year 2006-07 and 11.06 lakh in 2008-09.

Antenatal screening techniques to detect severe foetal anomalies are accepted in modern obstetric practice, giving the woman an option to terminate pregnancy

leading to a gradual increase in midtrimester abortions.

The latest amendment in the MTP Act on 21st March 2021 has increased the age of wilful abortion to twenty four weeks of gestation and even beyond where such termination is necessitated by the diagnosis of substantial foetal abnormalities as recognised by the constituted medical board. Also, the approval of the use of pharmacological agents for medical abortion by the drug controller in 2002 has made the medical methods of midtrimester abortions safer and more acceptable.

No uniform consensus exists regarding the ideal method for induction of midtrimester abortions.^{1,2} Although the medical methods may be flaunted as the anchor of safe abortion care, the high cost of several pharmacological agents like mifepristone may be a deterrent in developing countries like India.³

Prostaglandins are commonly used to induce first and second abortions, with synthetic prostaglandin E1 analogue, misoprostol, getting increasing popular due to its low cost, ease of use and high efficacy. Being thermo and light stable with a long shelf life even in tropical countries, misoprostol is the drug of choice in induced midtrimester abortions. It has various routes of administration of misoprostol, namely oral, vaginal, sublingual, buccal and rectal route.

However, there is a lot of confusion regarding the ideal route of administration of misoprostol. Although most women preferred the oral route due to the ease of administration, the vaginal route gives optimal results due to better absorption of the drug through the vaginal mucosa and absence of salivary enzymes to affect the pharmacokinetics of misoprostol.

The aim of the present study was to retrospectively analyze all cases where misoprostol had been used for second trimester pregnancy termination either by oral route or the vaginal route to study the best route of action to achieve vaginal expulsion safely in an expeditious manner with least maternal complications.

MATERIAL AND METHODS

The study was conducted from January 2022 to September 2024 at Bebe Nanki mother and child care centre (BNMCCC), department of obstetrics and gynaecology, government medical college, Amritsar which is a tertiary care academic medical centre. We retrospectively analyzed the case files of all patients who underwent second trimester abortion, initiated after the approval of Institutional Ethics Committee vide No.GMC/IEC/24/HM/172. The cases were subdivided into subgroups based on the route of administration of misoprostol used.

The inclusion criteria of my study included 125 patients of age group of 18-35 years, singleton live intrauterine pregnancies of 13 to 26 weeks gestation terminating pregnancy for indication covered under the amended MTP Act, 1971 and had given informed written consent to participate in the study. Their detailed history, physical examination and confirmation of gestational age by clinical examination and ultrasound was evaluated from the available medical records. The included studies were pooled for meta-analysis and the results were presented in risk ratio at a 95% confidence interval. However, the exclusion criteria were the patients with pregnancy less than 13 weeks and more than 26 weeks, multiple pregnancies, grand multipara, scarred uterus, severe anaemia, cervical incompetence, genital infections, with underlying medical conditions like cardiac disease, diabetes mellitus, bronchial asthma, epilepsy, disseminated intravascular coagulation or liver disease, an intrauterine contraceptive device in utero, any contraindications to the use of misoprostol like uncontrolled bronchial asthma, with known allergy to prostaglandins, carrying a dead foetus or already in the process of abortion.

The sample size selected was 125 with Group A including 64 patients induced with intracervical Foley's catheter and vaginal misoprostol for midtrimester abortion. Group B had 61 patients induced medically with combination of intracervical Foley's catheter and oral misoprostol.

Group A: Induction was done with intracervical foley's catheter followed by intravaginal misoprostol 400mcg after 24 hours of insertion. The size 14 or 16 Foley's catheter was inserted 3-4 cm into the cervix under proper antiseptic conditions and inflated with 25ml of distilled water. Intravaginal misoprostol 400mcg was inserted into the posterior fornix every 4 hours upto a maximum of 5 doses.

Group B: Induction with intracervical foley's catheter was followed by 400mcg of oral misoprostol 24 hours later and repeated every 4 hours upto a maximum of 5 doses.

After misoprostol administration, pulse, blood pressure and temperature were recorded fourly. The procedure efficacy (defined as complete abortion performed on site) was assessed. The primary endpoint was complete foetal expulsion with no subsequent intervention needed and induction-abortion interval (AI). The critical outcome reported was ongoing pregnancy. The 'efficacy' was analyzed on the basis of completeness of procedure, total number of doses of misoprostol required, need for surgical evacuation of the retained products of conception in cases of incomplete abortion and evidence of other complications among the two routes of administration being studied. The other parameters studied were complications (uterine rupture or cervical laceration, pelvic infection), patient acceptability (whether patients would opt for the same method again), satisfaction (whether patients were satisfied with the method) and side effects (e.g., nausea, vomiting, diarrhoea and fever). If the patient did not abort after five doses, 4hr after the last dose, she was labelled as 'failure' and alternative methods including use of oxytocin drip or surgical evacuation were used for abortion. The statistical analysis was applied to study the demographics and the efficacy of the chosen method. The descriptive statistics was used to calculate the mean, frequencies, standard deviation and Chi square test was used to compare the categorical variables of significance.

RESULTS

During the twenty-one month study period, a total of 351 females in the reproductive age group underwent wilful pregnancy termination in the first and second trimesters of pregnancy for well defined indications permitted under the amended MTP Act, 2021. The sample size of 125 was used in this study of oral or vaginal misoprostol induction of midtrimester abortions.

The socio-demographic of the patients under study was determined by modified BG Prasad classification(2008).The median age of the study

group was 26-30years and 85% of the women were multigravidae. There was no statistical difference in any of these parameters (age, parity, previous obstetrical history, mean gestational age between the two groups).

Table 1: Comparative study of the demographic and obstetric data of Groups A and B:

	Group A(n=64)	Group B(n=61)	Total(n=125)
Age(Years)			
16-20	04(6.25%)	07(11.48%)	11(8.80%)
21-25	19(29.69%)	17(27.87%)	36(28.80%)
26-30	31(48.43%)	25(40.98%)	56(44.80%)
31-35	07(10.94%)	07(11.48%)	14(11.20%)
>36	03(4.69%)	05(8.19%)	08(6.40%)
Parity			
Primigravida	10(15.63%)	24(39.34%)	34(27.20%)
G2	24(37.50%)	16(26.23%)	40(32.00%)
G3	22(34.38%)	17(27.87%)	38(30.40%)
G4	08(12.49%)	04(6.56%)	13(10.40%)
Previous abortions	19(29.69%)	15(24.59%)	34(27.20%)
Mean body mass index(kg/m2)	25.8±1.2	26.2±1.3	25.98±1.25
Gestational age at delivery(weeks)			
13-15wks6days	25(39.06%)	24(39.34%)	49(39.20%)
16wks-19wks6days	28(43.75%)	26(42.62%)	54(43.20%)
20wks-21wks6days	6(9.38%)	7(11.48%)	13(10.40%)
22wks- 23wks6days	5(7.81%)	4(6.56%)	9(7.20%)
Total	64(100%)	61(100%)	125(100%)
Mean	18.62±2.20	17.92±2.10	18.27±2.15
Indications for midtrimester abortion			
Contraception failure	15(23.44%)	17(27.87%)	32(25.60%)
Congenital malformations	38(59.38%)	36(59.02%)	74(59.20%)
Anhydramnios	7(10.94%)	6(9.84%)	13(10.40%)
Unwed	4(6.25%)	2(3.28%)	06(4.80%)
Total	64	61	125

Table 2: Cervical dilatation and mean induction abortion interval in both the groups:

Cervical dilatation	Group A(n=64)		Group B(n=61)	
	No.	Mean IAI	No.	Mean IAI
Closed	11(17.19%)	7.5	10(16.39%)	10.2
Tip	31(48.44%)	6.6	32(52.46%)	9.8
Upto 1.5cm	19(29.69%)	3.7	15(24.59%)	7.5
1.5-2.5cm	03(4.69%)	3.4	04(6.56%)	7.2

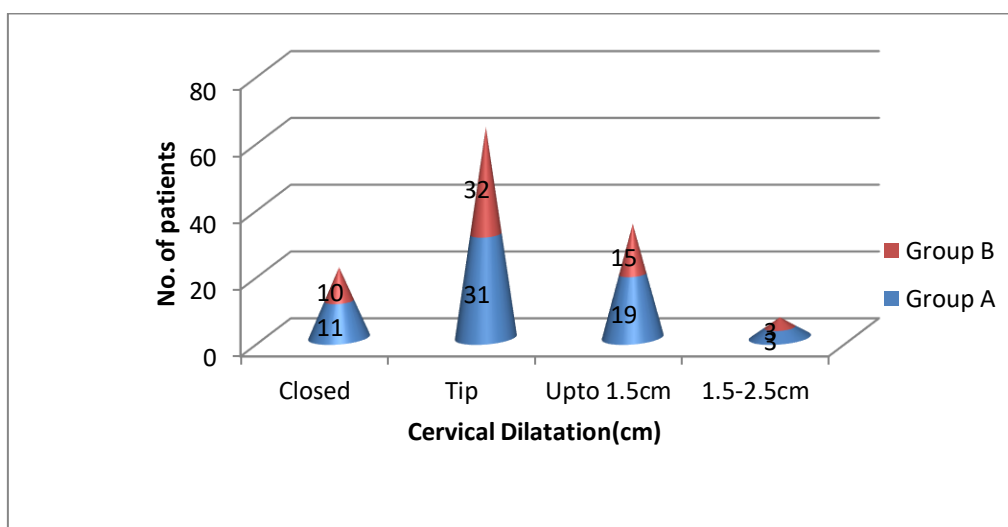


Fig 1 shows the cervical dilatation prior to induction in Group A and B:

The mean induction-to-abortion interval in Group A was 6.80±1.1 h (range: 2.4-43.8 h). Nulliparous women took significantly longer time to abort (6.5 h in multiparous women compared to 7.6 h in nulliparous women; p<.0001). The mean induction to abortion interval in Group B was 9.46±2.69h (range: 4.1-65.5h). In Group B, six women (9.84%) failed to abort within 48 hours and surgical evacuation of the uterus was performed in five women (8.19%) for

incomplete abortion or retained placenta. Multiparous women were less likely to need analgesic administration for pain relief, and to experience vomiting and diarrhoea than nulliparous women. Overall, 97.1% of the women in Group A and 90% of the women in Group B aborted within 24 hours. 100% of the women in Group A and 89.47% of the women in Group B aborted within 36 hours respectively.

Table 3: Comparative study of the mean misoprostol dosage in relation to parity in Groups A and B:

Mean dose of misoprostol (mcg)	Group A(n=64)			Group B(n=61)		
	Primigravida	Multigravida	Total(n=64)	Primigravida	Multigravida	Total(n=61)
400	1(1.56%)	6(9.38%)	7(10.93%)	0	0	0
800	6(9.38%)	24(37.50%)	30(46.88%)	2(3.28%)	16(26.23%)	18(29.51%)
1200	6(9.38%)	18(28.12%)	23(35.94%)	5(8.19%)	23(37.70%)	28(45.90%)
1600	2(3.12%)	1(1.56%)	4(6.25%)	4(6.56%)	6(9.84%)	10(16.39%)
2000	0	0	0	3(4.92%)	2(3.28%)	5(8.20%)

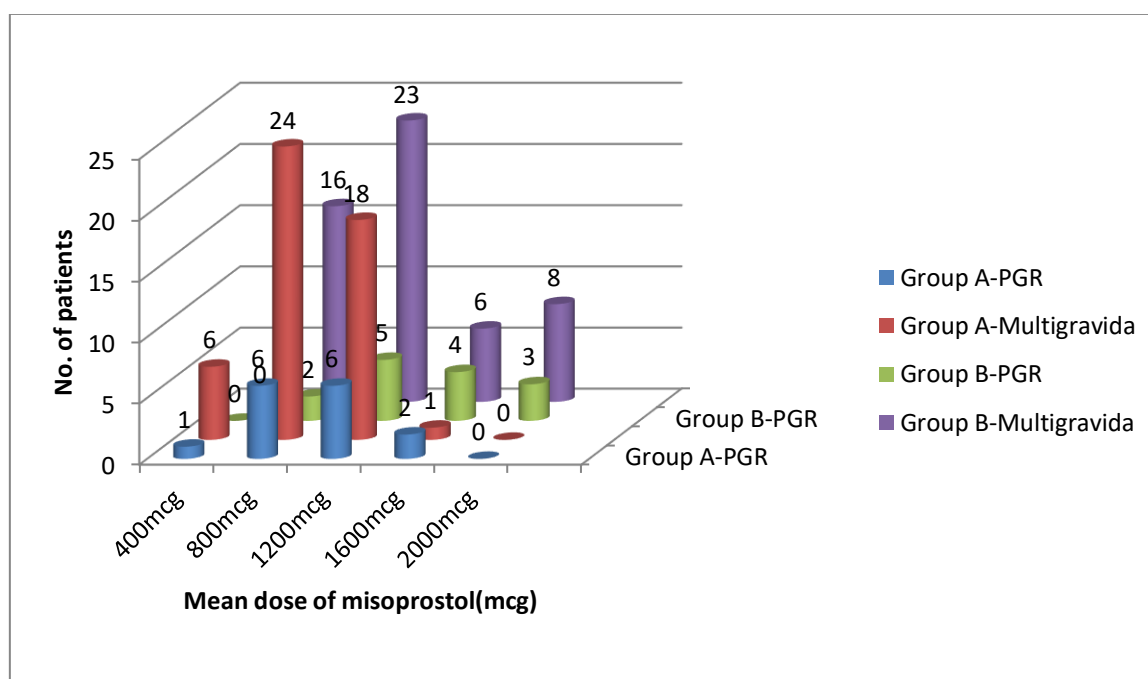


Fig 3 shows mean dose of misoprostol needed for termination in Group A and B:

Table 4: Comparative study of gestational age on induction to abortion interval and completeness of abortion in Groups A and B:

Characteristics	Descriptive Statistics(n=125)			
	Group A(n=64)	IAI	Group B(n=61)	IAI
Gestational Age				
13-15wks6days	24	6.84±1.88	23	10.76±2.96
16wks-19wks6days	20	5.86±0.36	22	7.77±2.71
20wks-21wks6days	12	6.78±0.96	11	8.28±2.56
22wks-23wks6days	08	8.76±1.60	05	11.88±1.68
Completeness of abortion	64(100%)		55(90.16%)	
Mean IAI		6.80±1.1		9.46±2.69

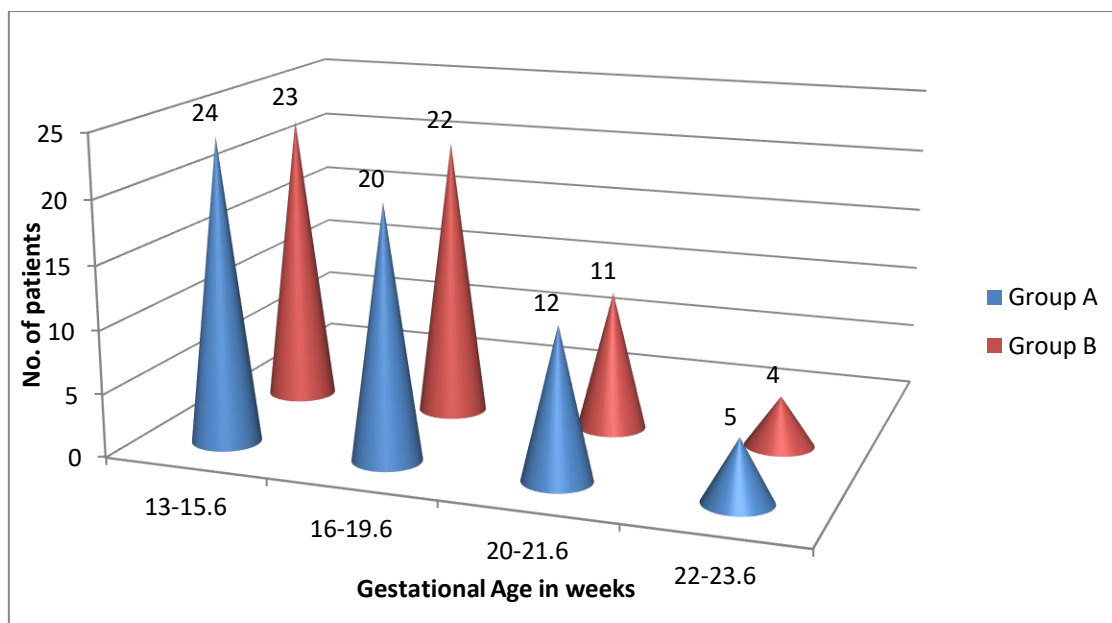


Fig 4a and b: showing the comparative study of gestational age on induction to abortion interval in Group A and B:

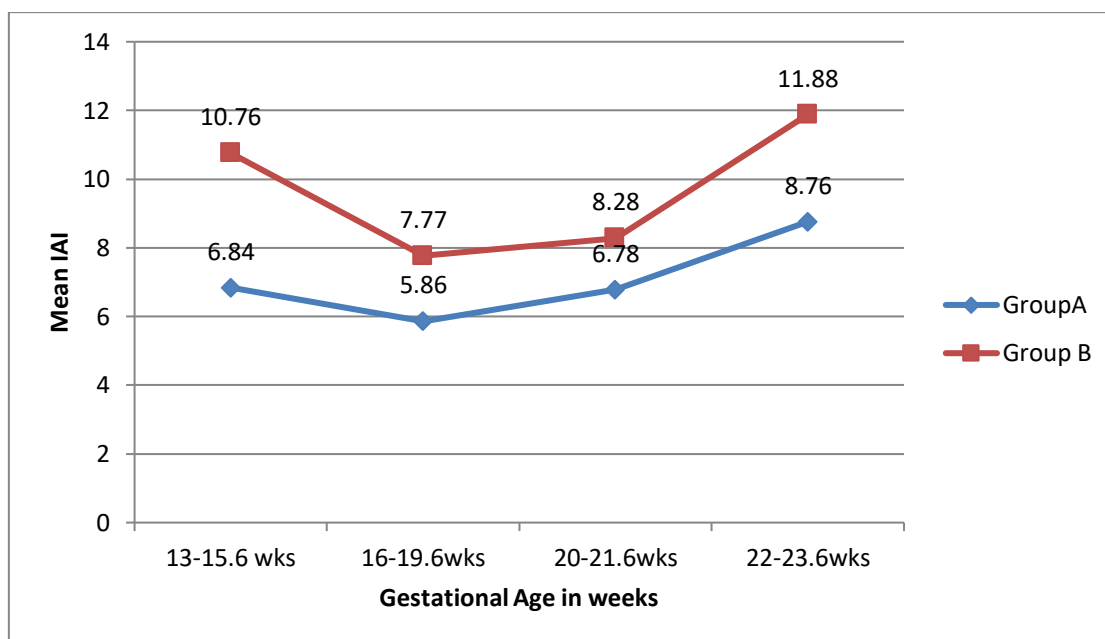


Table 5: Comparative study of the complications of the procedure adopted in Groups A and B:

Complications of the adopted procedure	Group A(n=64)	Group B(n=61)	Total(n=125)
Severe abdominal pain	08(12.50%)	13(21.31%)	21(16.80%)
Fever with rigors and chills	11(18.03%)	05(7.81%)	16(12.80%)
Shivering	03(4.69%)	10(16.39%)	13(10.40%)
Nausea/Vomiting	08(12.50%)	14(22.95%)	22(17.60%)
Diarrhoea	07(10.93%)	12(19.67%)	19(15.20%)
Sepsis	0	04(6.56%)	04(3.20%)
Cervical lacerations	0	1	1
Incomplete abortion	0	08(13.11%)	08(6.40%)
Haemorrhage	07(10.94%)	10(16.39%)	17(13.60%)
Failure of the method	0	06(9.84%)	06

Women in Group B needed more doses of misoprostol and were more likely to experience diarrhoea (p < 0.01), vomiting (p < 0.01) and shivering. (p < 0.01).

DISCUSSION

Unsupervised midtrimester abortions continue to be major cause of maternal morbidity and mortality. Misoprostol, a synthetic prostaglandin E1 (PGE1) analog has revolutionized the success rate of midtrimester abortions. Combining the pharmacological and mechanical methods in the form of intracervical Foley's catheter and misoprostol combination gives very good results.^{3,4} Misoprostol can be used by various routes namely, orally, vaginally or sublingually with varying degree of success. Although different doses, time interval between doses and route of administration are used, a definite consensus is yet to be reached⁴.

Most of the women in both groups were in the age group of 26-30 years (44.80%) which was comparable to the results by Holla R et al⁵ which showed mean age as 27.96±5.41 years. The study conducted by Fathalla MM et al⁶ showed the mean age to be 25.9 years.⁸ In the present study, 36(28.80%) cases were in the age group of 21-25 years which was comparable to the study by Maninder K et al which showed 30% of the cases in the same age group. 22(17.6%) cases were above the age group of 30 years which was comparable to the study by Maninder K et al which showed 18.75% cases to be older than 30 years.

In this study, most patients were third and fourth gravid (40.80%) in both groups. This was comparable to the study by Veena et al⁷ where most of the women were third gravid and above (53%). 27.20% patients were primigravida similar to the study by Veena et al⁷ which had 23.8% cases as primigravidae. 32% patients were second gravid as compared to the same study which had 28% second gravidae.

In the present study, 42(33.60%) patients were in the gestational age of 16-20 weeks while the study conducted by BalaSubramanian SR et al⁸, 56% patients were in the age group of 13-16 weeks.

Studying the outcome variable of the misoprostol dose required in Group A, 10.93% patients expelled with only 400 mcg of misoprostol, 46.88% with 800 mcg of misoprostol, 35.94% expelled with 1200mcg and only 6.25 % with 1600 mcg of misoprostol. This is comparable to the study by Fathalla MM et al⁶, 13.4% expelled with 400mcg of misoprostol, 35.8% with 800mc, 19.4% with 1200mcg and 28.4% with 1600mcg dose of misoprostol. However, in Group B, no case expelled with dose less than 800mcg. 29.51% expelled with dose of 800mcg and 45.90% cases expelled with dose of 1200 mcg. 16.39% needed 1600mcg for foetal expulsion while 8.20% required 2000mcg for expulsion.

In the present study, the induction to abortion interval in Group A was 6.8±1.1 hrs which is comparable to the study by Rezk MA et al⁹ which showed the average induction to abortion interval as 7.5±1.25 hrs. The study by Balasubramanian SR et al⁸ also showed a comparable induction to abortion interval of 7 hours. Also, Desai et al reported a similar induction abortion interval of 7.9 h. However, the induction to abortion

interval in Group B was 9.46±2.69 hrs which was comparable to the study by Rezk MA et al⁹ which showed the induction to abortion interval in the similar group as 11.76±1.63h. Nautiyal et al⁹ also reported a similar induction abortion interval of 10.6±2.9 h in the vaginal group which was less than that in the oral group (14.3±3.3 h), but there were no significant differences in failure rate and need for surgical intervention.

The present study showed a success rate of 100% in Group A which is comparable to the study by Patel U et al and Sharma N et al.^{10,11} However, the study group using oral misoprostol as abortifacient showed a success rate of 90.16%.

In the group using vaginal misoprostol, severe abdominal pain occurred in 12.50% cases, fever with rigors and chills in 7.81 % cases, nausea and vomiting in 12.50% and diarrhoea in 1.93% cases. This is comparable to the study by Mohamed Rezk et al which showed fever with rigors and chills in a similar study group in 13% cases and vomiting in 4% cases. The vaginal insertion of misoprostol resulted in more cases of fever as highlighted by Rahimi-Sharbat et al and Nautiyal et al¹². In Group B, severe abdominal pain occurred in 21.31% cases, fever with rigors and chills in 18.03% cases and vomiting in 22.95% cases which is comparable to the study by Balasubramanian SR et al, severe abdominal pain occurred in 28% cases and vomiting in 4% cases.

In our study, no case reported uterine rupture, avulsion of the cervix or sepsis in either group which is similar to the study by Mohamed Rezk et al⁹. Sajjan et al¹³ have reported complete avulsion of the cervix from the lower part of the uterus as a rare complication with intravaginal misoprostol. Failure of method occurred in no case in Group A which is similar to the study by Mohamed Rezk et al which showed 100% success rate without any failure. However in Group B, women (9.84%) failed to abort within 48 hours and needed other methods for completing the evacuation.

The nulliparity, longer interpregnancy interval (>22months),^{14,15} smaller gestational age (<14 weeks)¹⁶ and lower Bishop score before insertion (<2)^{17,18} were significantly associated with a lesser likelihood of abortion within 24 hours.^{19,20} This compared favourably with the study by Ali MK et al which showed similar results²²

However, there were certain limitations in the present study. The nulliparous women, the women with longer interpregnancy interval or previous uterine surgery faced certain complications inherent to these factors which could not be segregated from the complications due to the procedures of induction of abortion while drawing conclusions and may have affected the results.

CONCLUSION

The given trial highlights the importance of improving outcome and safety of induced midtrimester abortions

by just adjusting the route of administration of misoprostol to optimise the results. Vaginal misoprostol is generally more effective than oral misoprostol hence should be the preferred method. Use of misoprostol is more affordable in the low resource countries. Preferring the vaginal route of its administration reduces the total dosage of misoprostol required for termination, shortening the induction abortion interval, thereby increasing the patient's comfort by minimising the side-effects of the prostaglandin analogue. However, it has been noted that the patients prefer the oral route.

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DECLARATIONS

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Conflict of interest: There is no conflict of interest, financial or otherwise.

Ethical approval: The study was approved and was in accordance with the ethical standards of the Institutional Ethics Committee vide No.GMC/IEC/24/HM/172.

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