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Original Research Article

A comparison of buccal versus vaginal misoprostol administration for induction of first and second trimester abortion

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ABSTRACT

Background: Aim of study was to compare effectiveness, adverse effects and patient's acceptability of buccal and vaginal routes of administration of misoprostol in 1st and 2nd trimester abortion, type of study-randomized control trial
Methods: A total of 200 women with indications for abortion up to 20 weeks of pregnancy were enrolled over a period of 1 year and received misoprostol either through buccal (Group A) or vaginal (Group B) route. Each group containing 50 patients of first trimester and second trimester.
Results: Incomplete abortion rate (25%) was significantly higher in vaginal group while drug related side-effects (47%), patients' satisfaction and acceptability (82%) was higher in buccal group respectively.
Conclusions: Buccal route may be preferred owing to a better complete abortion rate, better patient satisfaction and acceptability as compared to vaginal route.

Keywords: Misoprostol, Abortion, First trimester, Second trimester

INTRODUCTION

A WHO defines abortion as "termination of pregnancy before 20 weeks of gestation/fetus less than 500 gm of weight.[1] In India, statutory control on abortions is exercised through medical termination of pregnancy act, 1971 (also called as "MTP act of 1971") which was implemented in 1972. In 2021, amendment in act was made which legalized pregnancy termination upto 20th week of gestation based on judgement of only one medical practitioner and upto 24th week of gestation with consent of 2 medical practitioners. For serious fetal abnormalities,

a state-level medical board may permit abortions after 24 weeks of gestation.[2] Globally, nearly 73 million abortions are performed each year.[3] As per data available for year 2015, total of 15.6 million abortions carried out in India, however only approximately 1/5th of these were performed in formal healthcare units while nearly three-quarter performed in facilities other than formal healthcare units.[4]

Reasons to terminate pregnancy often reflect social and economic circumstances of women. In India, limiting family size emerges to be commonest reason for this (Table 1).[5-7]

Misoprostol is a synthetic prostaglandin E1 analogue that has capacity to bind with smooth muscle cells. When it does so with the muscle cells in uterine lining it aggravates the power and number of contractions. At the same time, it degrades the collagen and diminishes the cervical tone. It can be used to reduced the risk of NSAID related ulcers, manage miscarriages, prevent PPH and for first trimester abortions.[8-10] The route of elimination is through urine.

Side effects

The side effects associated with Misoprostol are abdominal pain and tremors apart from other side effects like sedation, diarrhoea and fever. Some patients may experience hemodynamic events like hypotension and bradycardia.

Table 1: WHO recommendations on medical management of induced.

Recommendation (weeks)	Combination regimen (recommended)		Misoprostol alone (alternative regimen)
	Mifepristone	Misoprostol	
Induced abortion <12	200 mg oral once	800 µg buccal, vaginal/ sublingual	800 µg buccal, vaginal/ sublingual
Induced abortion ≥12	200 mg oral once	400 µg buccal, vaginal or sublingual every 3 hours	400 µg buccal, vaginal or sublingual every 3 hours

The current study is targeted to compare the efficacy of buccal and vaginal routes of misoprostol for first and second trimester abortions in terms of complete abortion rates, adverse events and acceptability by the patient.

METHODS

We carried out a prospective randomized control study at department of obstetrics and gynaecology of Swaroop Rani Nehru hospital which is an affiliate hospital to Motilal Nehru medical college in Prayagraj, India, over a period of 1 year (July 2021 to June 2022).

Patient selection

Patients presented to antenatal OPD or labour room for termination of pregnancy in first trimester or history of fetal anomaly or maternal risk up to 20 weeks, were selected for the purpose of study. The inclusion criteria of the study permitted inclusion of women aged 18 years or more, who opted for elective termination of pregnancy in compliance with MTP act stated earlier, sonographically confirmed intrauterine pregnancies of up to 12 weeks for first and 13-20 weeks for second trimester abortion. Only women consenting to undergo surgical procedure in case of failure of medical method and those available for follow-up were included in the study. Women having conditions like glaucoma, uncontrolled seizure disorder, mitral stenosis or allergy to prostaglandins were excluded from the study. Patients known to have clotting defect or those placed on anticoagulants, having cardiovascular disease, previous history of lower segment caesarean section (LSCS) and those having undiagnosed adnexal mass were also excluded from the study.

Data collection method

A total of 200 patients (100 each in first and early second trimester respectively) falling in the sampling frame and providing informed consent were enrolled in the study. Age, demographic information, socioeconomic status, weight, height and body mass index (BMI), obstetric history including gestational age, indication for abortion, history of systemic and chronic illnesses, personal habits, drug history were noted. Routine blood investigations were done to rule out exclusion. The patients were then grouped by stratified block randomization technique into the following two groups:

Group A (n=100)

The 50 first trimester (<12 weeks) and 50 second trimester (12.1-20 weeks). Abortion was induced by misoprost given by buccal route as per WHO recommendations 3A and 3B.

Group B (n=100)

The 50 first trimester (<12 weeks) and 50 second trimester (12.1-20 weeks). Abortion induced by misoprost given by vaginal route as per WHO recommendations 3A and 3B.

Follow up

Subjects were asked to return for examination on 2nd, 14th days and after 6 weeks or after menses or in between if they had any complaints. USG was done at 14 days to look for any RPOCs. The outcomes noted were: Interval between administration of drug and abortion, blood loss (amount and duration), side-effects-GI side effects like nausea, vomiting requiring antiemetics and diarrhea. Other side effects like fever, chills, alteration in taste and abdominal cramping and patient satisfaction scores for the method used. Patient coming with incomplete abortion were offered immediate surgical evacuation.

Assessment

Assessment of study was done in form of: Induction to abortion time, efficacy as judged by complete abortion, drug related adverse effects and patient's acceptability and satisfaction that was measured on a three-point scale as follows: Score 1: Very satisfied, comfortable, likely to recommend. Score 2: Neutral. Score 3: Very unsatisfied, unlikely to recommend.

Ethical issues and approvals

We obtained the approval for the study from ethics committee of our institution. Patients were well informed. Approval for the study was obtained from the institutional ethics committee. We also provided the patients/their spouses or legal guardians full information regarding procedures carried out and risks involved and obtained their consent for participation in the study.

Data analysis

Data analysis was done using IBM SPSS Stats 21.0 version. For categorical assessments, chi-square test was used. Parametric assessments were done using student's t test. Non-parametric data like patient's acceptability and satisfaction were compared using Mann-Whitney U test. The confidence level of the study was kept at 95% and hence p value less than 0.05 was considered to be statistically significant.

RESULTS

A randomized-controlled study was planned in which a total of 200 women falling in sampling frame were enrolled in the study and were randomized to one of the following two groups as shown in (Table 2).

Table 2: Group-wise distribution of study population.

Group	Description	N	Percent (%)
A	Women in whom abortion was induced by misoprost given by buccal route	100	50
B	Women in whom abortion was induced by misoprost given by vaginal route	100	50

In group A, age of women ranged from 19 to 40. Mean age of women in group A was 26.03±4.32 years. Compared to this, in group B age of women ranged from 20 to 40 years. Mean age of women in group B was 26.00±4.31 years (Table 3).

Table 3: Comparison of demographic profile of two study groups.

Variables	Group A (n=100)	Group B (n=100)	Results
Age (years)	26.03±4.32 (19-40)	26.00±4.31 (20-40)	T=0.049; p=0.961(NS)
BMI (kg/m²)	22.64±2.20 (18.5-30)	22.31±2.14 (18.20-30.1)	T=1.058; p=0.296
Gravida (%)			
G1	28	28	$\chi2$=3.254; p=0.354
G2	29	34	
G3	35	25	
G4	8	13	
Abortion history			
No	67	60	$\chi2$=3.226; p=0.199
One	31	33	
Two	2	7	

Body mass index (BMI) of women enrolled in the study ranged from 18.2 to 30.1 kg/m^2. Mean BMI of group A women was 22.64±2.20 and that of group B women was 22.31±2.14 kg/m^2.

In group A, there were 57% gravida 1/2 and 43% gravida 3/4 whereas in group B, 62% were gravida 1/2 and 38% were gravida 3/4.

In group A, 31% had history of one and 2% had history of two abortions as compared to 33% having history of one and 7% having history of two abortions in group B (Table 4), $\chi2$=0; p=1.00.

In both the groups, half (50 percentages) women each had gestational age ≤12 weeks at presentation and remaining half (50 percentages) women had gestational age >12 weeks (Figure 1).

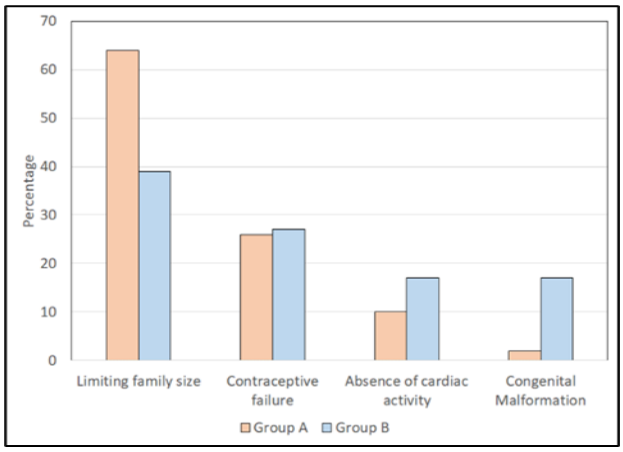

Figure 1: Comparison of women in two study groups for indications for abortion.

Proportion of those reporting desire to limit family size was significantly higher in group A (64%) whereas proportion of those reporting congenital malformation as the indication for abortion was significantly higher in group B (17%) (Table 5).

Induction to abortion time ranged from 5.5 to 14 hours in the first trimester abortions. Mean induction to abortion time was 9.76±2.18 hrs in group A as compared to 10.42±1.80 hrs in group B. Rate of incomplete abortion was higher in group B (22%) as compared to that in the group A (14%). In both group, nausea was the most common side effect (24%) (Table 6).

Induction to abortion time ranged from 10 to 24 hours in the second trimester abortions. Mean induction to abortion time was 16.54±2.09 hrs in group A as compared to 15.89±4.02 hrs in group B. Rate of incomplete abortion were significantly higher in group B (28%). In group A, nausea was the most common side effect (28%) while in group B, vomiting was the most common side effect (10%) (Figure 2).

Z=2.323; p=0.020 (Mann-Whitney U test).

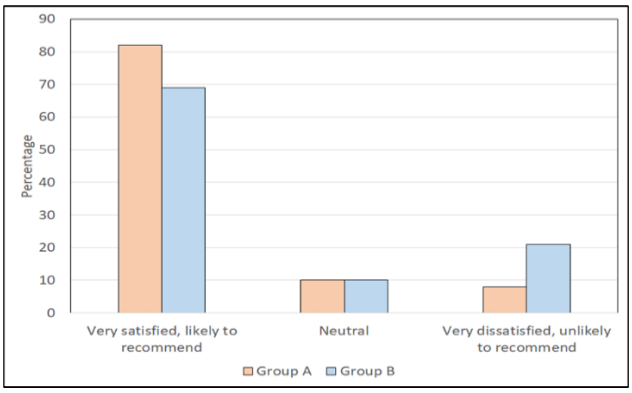

Figure 2: Comparison of patient acceptability and outcome between the two groups.

The 82% women were very comfortable with buccal route while 69% women with vaginal route.

Table 4: Comparison of women in two study groups for gestational age at presentation.

GA at presentation (Weeks)	Group A, (n=100)	Group B, (n=100)	Total, (n=200)	
			N	%
First Trimester (≤12)	50	50	100	50
Second trimester (12.1-20)	50	50	100	50

Table 5: Comparison of time taken and associated outcomes between the two groups for first trimester pregnancies.

Outcome	Group A, (n=50) (%)	Group B, (n=50) (%)	Statistical significance	
			T/χ2	P
Mean induction to abortion time ±SD (Range) (hours)	9.76±2.18 (5.5-14)	10.42±1.80 (6.0-14)	1.656	0.101
Incomplete abortion	7 (14)	11 (22)	1.084	0.298
Drug related side effects	24 (48)	20 (40)	0.649	0.420
Nausea	12 (24)	16 (32)	0.794	0.373
Vomiting	0	0	-	-
Altered taste	9 (18)	0	9.890	0.002
Fever	2 (4)	3 (6)	0.211	0.646
Shivering	1 (2)	1 (2)	0	1
Diarrhea	0	0	-	-

Table 6: Comparison of time taken and associated outcomes between the two groups for second trimester pregnancies.

Outcome	Group A, (n=50) (%)	Group B, (n=50) (%)	Statistical significance	
			T/χ^2	P
Mean Induction to abortion time ±SD (range) (hours)	16.54±2.09 (12.0-20.5)	15.89±4.02 (10.0-24)	1.015	0.312
Incomplete abortion	5 (10)	14 (28)	5.263	0.022
Drug related side effects	23 (46)	8 (16)	10.52	0.001
Nausea	14 (28)	2 (4)	10.71	0.001
Vomiting	9 (18)	5 (10)	1.329	0.249
Altered taste	0	0	-	-
Fever	0	0	-	-
Shivering	0	0	-	-
Diarrhoea	0	1 (2)	1.010	0.315

DISCUSSION

In the present study, the women enrolled were aged between 19 and 40 years and mean age of women was 26.02±4.30 years which was close to 26.7 years as reported by Bhandekar et al while Mukherjee et al.[11,12] Reported it to be less than 25 years. Majority of women (86%) were in normal BMI category, multigravida (72%) and did not have an abortion history (63.5%). There was no statistically significant difference between the two groups with respect to age, BMI and gravida.

In both the groups limiting family size and contraceptive failure were the most common indications, however, in buccal group, the indication limiting family size (64%) was seen in significantly higher number of cases while

congenital malformation was significantly higher in vaginal group (17%). There was no significant difference between the two study groups with respect to induction to abortion time. Overall mean induction to abortion time in buccal group was 13.15±4.01 hours as compared to 13.16±4.14 hours in vaginal group which was comparable to that reported by Khan et al.[13] While et al reported induction to abortion time to be significantly longer in buccal group (40±29 hours) as compared to present study.[14] However, we found complete abortion rate to be significantly higher in buccal (88%) as compared to vaginal group (75%) while in Khan et al.[13] They reported higher complete abortion rate in both buccal (96%) as well as in vaginal (98%) group. Young et al found that buccal administration of misoprostol resulted in higher success rate before 64 days of gestation whereas vaginal misoprostol had a higher success rate through 70 days of gestation.[15]

Although overall adverse drug effects were significantly higher in buccal group as compared to vaginal route. A better patient satisfaction and acceptability was seen for buccal as compared to vaginal route which as compared to Garg et al who did not find a significant difference between two groups with respect to patients' satisfaction.[16]

The findings in turn indicated that although both the routes were similar in terms of induction to abortion interval for both combined and trimester wise evaluation, however, with respect to complete abortion rate and patient satisfaction in overall assessment and in second trimester, buccal route had an edge over vaginal route, though it accompanied short term adverse effects.

Limitations

For assessment of patient's acceptability and satisfaction better method can be used. The use of mifepristone 24-48hrs before misoprostol can have better outcome in terms of shorter induction to abortion interval.

CONCLUSION

The performance of two routes was comparable for first trimester abortions, however, for second trimester and overall evaluation between the two, buccal route may be preferred owing to a better complete abortion rate and better patient satisfaction and acceptability.

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