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Original Research Article

Tablet misoprostol as a cervical priming agent prior to surgical abortion

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ABSTRACT

Background: Every effort to promote effective contraceptive methods as well as emergency contraception is being made, still there would be a need and place for termination of pregnancy. Objective of present study was to evaluate and to know the efficacy and adverse effects of tablet misoprostol 400 micro gram as a cervical priming agent administered either by oral or vaginal route, 3 hours before MTP.
Methods: Prospective randomized not blinded study carried out for two years at Government Tertiary care level hospital, OBG Department, Mangalore on 100 women with gestational age up to 12 weeks requesting for surgical abortion.
Results: In both the groups there was no significant statistical difference with respect to age (p=0.44), parity and gestational age (p=0.59). With respect to baseline cervical dilatation significant statistical difference was not observed in both the groups. Baseline dilatation of the cervix was 8.0 mm versus 8.2 mm (p value=0.55). Baseline cervical dilatation was ≥7mm in 90% of women when tab misoprostol was given by oral route and 94% with vaginal route. There was no significant statistical difference with respect to side effects (p value>0.05) except nausea (p=0.01) found in both the groups. Gastro Intestinal side effects were more in oral misoprostol group, but it was not statistically significant.
Conclusions: Oral route is an effective alternative to vaginal route. Oral route is preferred over vaginal route because women can do self-administration at home and there was no internal examination discomfort.

Keywords: Cervical dilatation, Cervical priming, Misoprostol, Surgical abortion

INTRODUCTION

Every effort to promote effective contraceptive methods as well as emergency contraception is being made, still there would be a need and place for termination of pregnancy. One of the most import events in woman's life is child bearing and surely women would like to decide how many and when she should have children. Many contraceptive methods are now available to help her to meet her requirement. But contraceptive methods do fail sometimes, and then women find herself with an unwanted pregnancy. MTP act has legalized termination of such unwanted pregnancy in India in 1971.

The method generally used to do early abortion is mechanical dilatation of cervix followed by suction evacuation or dilatation and curettage. With surgical methods common complications associated with mechanical dilation are cervical laceration, uterine perforation, cervical incompetence and recurrent abortions.[1,2] Therefore, there is overwhelming urge to find a reliable and easier method for cervical dilatation.

The complications of surgical abortion were less when cervix was primed before surgical abortion. The RCOG also recommends cervical priming is useful before surgical abortion when the pregnant women are less than 18 years and pregnancy was more than 10 weeks.[3] Various studies conducted to search for appropriate technique and drugs for cervical priming, which should be cheap, easily available with minimal or no complications. At present a synthetic analogue of PGE_1 that is misoprostol is more useful as a cervical priming agent since it is freely available, no need to freeze it, ease of administration and cheap.[4,5]

Therefore, the purpose of this study was to use tab misoprostol 400 micro gram for priming of the cervix before MTP upto 12 wks.

METHODS

Prospective randomised not blinded study done at Govt. Tertiary Care Level Hospital, Mangalore Karnataka for two years.

Inclusion criteria

- Pregnant women upto 12 weeks of gestation for surgical abortion.

Exclusion criteria

- History of Heart disease
- History of Allergy to prostaglandins.

Period of gestation was calculated from LMP and confirmed by internal examination and if required by USG. Written informed consent, detailed history and examination was done. 100 pregnant women, were given tab. Misoprostol 400 microgram 3 hours prior to surgical abortion. 50 women were given orally and 50 women received tab Misoprostal vaginally. Dilatation and curettage was done under IV sedation. Dilation of the cervix was assessed by passing Hegar's dilator to start with number 12 size and the dilator which was passed through the os without any resistance was considered as baseline dilatation. Non-sensitized Rh-negative women were given 50 microgram Anti D injection intramuscularly. All adverse effects were noted.

Statistical analysis

Results were analyzed using SPSS version by Chi Square test, Fisher's exact test, ANOVA (Analysis of Variance). If p value was <0.05 it was considered statistically significant.

RESULTS

It is observed that in oral group, majority of patients 22 (40%) were 26-30 years, followed by 14 (28%) in 21-25 years. In vaginal group, majority of patients 20 (40%) in21-25 years, followed by 17 (34%) in26-30 years.

Table 1: Mean age with standard deviation.

Group	Mean age (yrs)	SD	t value	p value
Oral	28.16	5.32	0.77	0.443
Vaginal	27.36	5.06		NS

Mean age of the patients were 28.16 and 27.36 years for oral and vaginal groups respectively, which is not statistically significant difference (t=0.77, p=0.443). (Table 1).

Table 2: Mean period of gestation (weeks) with standard deviation.

	Mean GA	Standard deviation	t	p
Oral (n=50)	8.03	2.06	0.545	0.587
Vaginal (n=50)	8.08	1.97		NS

Distribution of patients according to gestational age is comparable in both the groups, majority of them 22 (44%) in the gestational age <8 weeks followed by 8-10 wks. Mean period of gestation is 8.03 and 8.08 weeks in oral and vaginal groups respectively, which is not statistically significant (p value= 0.545, p=0.587) (Table 2).

Distribution of patients according to gravidity is comparable in both groups. Majority of them were gravida 3.

Table 3: Distribution of patients according to cervical dilation (CD) (mm).

CD (mm)	Group				Total
	Oral (N=50)		VAG (N=50)		
	N	%	N	%	
3	2	4	0		2
4	3	6	1	2	4
5	0		2	4	2
7	8	16	9	18	17
8	21	42	20	40	41
9	6	12	9	18	15
10	8	16	8	16	16
12	2	4	1	2	3
	50		50		100

Distribution of patients according to cervical dilatation is comparable in both the groups. Majority of the patients had cervical dilatation of 8mm both in oral (42%) and vaginal group (40%) followed by 7mm (oral 16%, vaginal 18%) and 9 mm (Oral 12%, vaginal 18%) (Table 3).

Table 4: Mean and median cervical dilation (mm) with standard deviation/range.

	Mean (mm)	Standard deviation	Median (mm)	Range (mm)	T	P
Oral (n=50)	8.0	1.90	8.0	3-12	0.598	0.551 NS
Vaginal (n=50)	8.2	1.41	8.0	4-12		

Mean cervical dilatation in mm was 8.0 (1.9) and 8.2 (1.4) in oral and vaginal group respectively, which is not a statistically significant difference (t=0.598, p=0.55) (Table 4).

Table 5: Distribution of gestational age and mean cervical dilation (mm)–MCD.

Gestational age (wks)	Group					
	Oral (n=50)			Vaginal (n=50)		
	N	MCD	SD	N	MCD	SD
< 8	22	7.68	1.86	22	7.81	0.96
8 to < 10	17	8.11	1.83	15	8.26	1.62
10 – 12	11	8.45	2.11	13	8.76	1.69
P value		0.53 NS			0.16 NS	
	50	8	1.9	50	8.2	1.41

In oral misoprostal group, mean cervical dilatation was 8.45mm in patients with gestational age 10-12 weeks followed by 8.11 mm in 8-10 weeks and 7.68 mm in <8 weeks of period of gestation. Significant statistical difference was not seen (p=0.53).

Similarly, in vaginal group, mean cervical dilation was 8.76 mm in patients gestational age 10-12 weeks followed by 8.26mm in 8 - 10 weeks and 7.81 mm in <8 weeks of gestation (p=0.16). Significant statistical difference was not seen (Table 5).

GI side effects were more with oral misoprostol than vaginal misoprostol as shown in the table, but not statistically significant (p value >0.05) except nausea for which the difference is significant (p=0.01).

Table 6: Distribution of patients according to side effects.

Side effects	Group				Odds ratio	95% confidence interval	Chi square value (x^2)	'p' value
	Oral (50)		Vaginal (50)					
	N	%	N	%				
Nausea	22	44	10	20	0.32	0.13-0.76	6.62	0.01 NS
Vomiting*	3	6	0	0	0.49	0.40-0.60	*	0.24 NS
Diarrhea*	5	10	0	0	0.47	0.38-0.59	*	0.06 NS
Abdominal pain	35	70	28	56	0.55	0.24-1.20	2.10	0.15 NS
Vaginal bleeding	18	36	20	40	0.19	0.53-2.66	0.17	0.68 NS
Shivering	3	6	1	2	0.32	0.03-3.18	1.04	0.31 NS
Fever	2	4	2	4	1.00	0.14-7.40	0	1 NS
Total	50		50		*Fishers exact test			

Vaginal bleeding and shivering is slightly more in vaginal group than oral but there was no statistical significant difference found (p value >0.05) (Table 6).

DISCUSSION

In present study, we have selected pretreatment interval of 3 hours. Since when tablet misoprostol was given orally the plasma concentration increased rapidly and reached peak value between 12.5 minutes to 60 minutes and decreased steeply by 120 minutes and remained at lower concentration whereas when the same tablet was kept inside the vagina the peak level of the drug achieved between 60-120 minutes and decreased slowly.[5]

Table 7: Comparison of patients with respect to age, period gestation, parity and cervical dilation.

	Oral group (n=50)	Vaginal group (n=50)	P value
Age (years)	28.2 (5.3)	27.4 (5.1)	P-0.44 NS
Gestation (weeks)	8.0 (2.1)	8.1 (2.0)	P-0.59 NS
Primigravidae: n (%)	3 (6%)	3 (6%)	-
Multigravidae: n (%)	47 (94%)	47 (94%)	-
Cervical dilation (mm)	8.0 (1.9)	8.2 (1.4)	P-0.55 NS

Fong et al showed that misoprostol tablet given 3 hours before suction aspiration was sufficient for pretreatment dilatation of cervix (Table 7).[6]

In present study, majority of the women in the oral misoprostol group were 26-30 years and 21-25 years in vaginal misoprostol group. The mean age was 28.2 and 28.4 respectively (p=0.44), which is comparable to Oppegaard K et al, Lawrie et al and MacIsaac L et al studies.[7-9] But the mean age in Ashok PW et al and Ngai et al is not comparable because they selected only nulligravidae (Table 8).[10,11]

Table 8: Comparison of the age with other studies, values in mean (SD).

	Group			
	Oral		Vaginal	
	n	(Mean age years)	N	(Mean age years)
Present study.	50	28.2 (5.3)	50	27.4 (5.1)
Ashok et al, University Aberdeen, U.K.	32	20.1 (4.5)	32	20.4 (5.1)
Ngai SW et al, Queen Mary Hospital University of Honkong	40	23.4 (6.0)	37	22.2 (4.7)
Lawrie A et al, Aberdeen Maternity Hospital, U.K.	28	25.5 (16-40)	30	26.4 (17-37)
Oppegaard K et al, Ulleval University Hospital, Norway	158	27.7 (6.9)	163	28.1 (6.2)
Maclsaac L et al, University of California, California	45	23.0 (16-39)	47	25.0 (16-43)

Table 9: Comparison of mean cervical dilation (mm) with other studies.

Group	Ashok PW et al	Ngai SW et al	Lawrie A et al	Oppegard K et al	Present study	Fong YF et al
Oral	7.0	7.2	6.9	6.2	8.0	-
Vaginal	7.0	6.8	7.0	6.5	8.2	8.2
'p' value	P=0.87					

Table 10: Comparison of side effects experienced by patients with other studies, values in percentage.

	Ashok PW et al			Ngai SW et al		Present study		
	Oral	Vaginal	Odds ratio	Oral	Vaginal	Oral	Vaginal	Odds ratio
Nausea	56	25	3.86	5	0	44	20	0.01 sig
Vomiting	6	6	0.97	0	0	6	0	0.24 ns
Diarrhea	12	0	0.47	0	0	10	0	0.06 ns
Abdominal pain	69	62	1.21	20	21	70	56	0.15 ns
Vaginal bleeding	25	34	0.6	13	14	36	40	0.68 ns

Mean cervical dilatation in our study was slightly more than that of Ashok PW et al and Ngai SW et al.[10,11] No significant statistical difference was found in both groups of tablet misoprostol. Mean cervical dilatation in various studies ranges from 6.2 to 8.2mm (Table 9).

Tab misoprostol 400 microgram was given 3 hours prior to surgical abortion in both groups in present study, Ashok PW et al and Ngai SW et al where as it was 12 hours (oral group) and 3 hours (vaginal group) in Lawrie et al and Oppegaard K et al.[7,11] There was a satisfactory preoperative cervical dilatation of ≥7 mm.[11,8] In current study, 90% in oral route group and 94% in vaginal route group had preoperative satisfactory dilatation of cervix ≥7mm (Table 10). In present study nausea, vomiting, diarrhea and abdominal pain were more in oral than vaginal group but statistically not significant (p>0.05) except nausea which is statistically significant (p=0.01).

Vaginal bleeding and shivering is slightly more in vaginal group than oral but there was no significant statistical difference (p>0.05). Present study was comparable with Ashok PW et al. However, studies of Lawrie A et al, Carbonel JL et al and Oppegaard et al and women in the Lawrie et al, study experienced severe pain and excessive bleeding preoperatively and incomplete abortion compared to vaginal route, as pretreatment interval was 12 hours (oral) and 3 hours (vaginal) with 400 microgram

misoprostol.[7] In Carbonel JL et al study oral group experienced more gastrointestinal side effects as they gave 400 microgram misoprostal 8 hrs prior to surgical abortion in oral group, in contrast to 2-4hrs in vaginal group.[12]

Present study has showed that oral tab misoprostol 400 micrograms given orally 3 hours before surgical abortion has similar efficacy and no significant difference in the side effects compared to vaginal misoprostol with same pretreatment interval.

CONCLUSION

Present study concluded that either oral or vaginal tab misoprostol 400 microgram given 3 hours before as a priming agent was resulted in effective dilatation of the cervix. Oral route is an effective alternative to vaginal route. Oral route is preferred over vaginal route because women can do self-administration at home and there was no internal examination discomfort. For doctors and Nursing staff it reduces the work load especially in day care settings.

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