VOLUME-7, ISSUE-6, JUNE-2018 • PRINT ISSN No 2277 - 8160

Original Research Paper

Gynaecology

A CLINICAL TRIAL COMPARING INTRA VAGINAL MISOPROSTOL (PGE1) AND INTRA CERVICAL DINOPROSTONE (PGE2) FOR CERVICAL RIPENING

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ABSTRACT In the present trial, Misoprostol(PGE1) and Dinoprostone(PGE2) are compared for their efficacy in pre - induction cervical ripening. After informed consent, 100 patients were randomized to receive either Dinoprostone gel int0.5mg inracervically or Misoprostol tablet 25 mcg intravginally. After 8 hrs, change in Bishops score recorded. During the study it is found that, change in Bishops score is significantly more and induction to delivery interval is significantly less in Misoprostol group. The incidence of side effects is similar in both the groups. It is concluded that a single dose of intravaginal Misoprostol is an efficacious, convenient and inexpensive medication for ripening the unfavourable cervix.

KEYWORDS : Misoprostol, Dinoprostone, Cervical ripening, Induction.

INTRODUCTION

In numerous circumstances, labour and vaginal delivery is indicated when a cervix is unprepared to respond to uterine contraction. If the cervix is not prepared, it is unlikely to respond favorably to uterine activity. Many methods of cervical ripening have been described,but the search for the ideal cervical ripening agent continues. For some years now, PGE2 (Dinoprostone) has been the preferred cervical ripening agent. Most recently PGE1 (Misoprostol) has been found to be an interesting alternative to PGE2 for cervical ripening. Oral use of misoprostol is less effective due to first pass hepatic circulation(1). Aim of the present study is to compare and evaluate the efficacy of intracervical application of 0.5 mg Dinoprostone gel (ProstaglandinE2), and intravaginal application of 25 mcg misoprostol Prostaglandin E1), in a randomized trial, for pre - induction cervical ripening. And to compare the side effects of both the drugs.

MATERIAL AND METHODS

This study was done at Government General Hospital, Nellore from March to May 2018. After informed consent, 50 patients were selected at random to receive the commercially available 'Dinoprostone' gel – CERVIPRIME (0.5 mg) intra cervically, and the other 50, in a random selection received 'Misoprostol' tablets – CYTOTECH (25 mcg) intra vaginally placed in the posterior fornix.

Selection criteria

A. Singleton fetus with cephalic presentation.
B. Over 37 weeks gestation.
C. Reactive foetal heart pattern.
D. Unfavorable cervix (Bishops score <4)
E. Intact membranes.
F. No contraindications to vaginal delivery.

Exclusion criteria

A. Previous uterine surgery.
B. Non vertex presentation.
C. With preexisting foetal distress.
D. Known allergy to prostaglandins.
E. Grand multiparity.

Bishop score of the cervix was recorded, before the placement of the study agent. The study agent was placed intracervically (dinoprosto ne gel) or intravginally (misoprostol tablet) – eight hours before the planned time of induction of labour. However, if the patient was already found to be in labour, due to labour induction caused by the study agent itself, Oxytocin drip was not started and labour let to proceed till delivery. Bishop score of cervix was again recorded, eight hrs after placement of study agent. Clinical monitoring of labour was done.

RESULTS

1.Change in Bishop score (Table 1)

	PGE 2 (n=46)	PGE 1 (n=45)	Significance
Mean change in Bishop score	4.67 +/- 1.78	5.75 +/- 2.22	Significant (p=0.0121)
Median change in Bishop score	4	5	

2.Need of Oxytocin after 8 hrs (Table 2)

	PGE 2 (n=50)		PGE 1 (n=50)		
	No	**%**	**No**	**%**	**Significance**
Oxytocin needed At 8 hrs	46	92	42	84	NS (p=0.2183)
Already in Labour	4	8	8	16	NS

From the above observations, it is seen that 8 hrs after instillation of the study agent, 46 (92%) of the patients in Dinoprostone group required Oxytocin drip for induction of labour after cervical priming, whereas 42 (84%) in Misoprostol group required Oxytocin for labour induction. The study agent itself was responsible for labour induction in 4 (8%) cases in Dinoprostone group and 8 (16%) cases in Misoprostol group. The difference seen in the observations is statistically not significant.

3. Mode of delivery (Table 3)

	PGE 2 (n=50)		PGE 1 (n=50)		
Mode of delivery	**No**	**%**	**No**	**%**	**Significance**
Vaginal	36	72	40	80	NS (p=0.6039)
Cesarean section	12	24	8	16	NS
Instrumental	2	4	2	4	NS

From the above observations it is seen that maximum number of cases had a normal vaginal delivery. Of the vaginal deliveries 5 in Dinoprostone group and 6 in Misoprostol group had meconium stained liquor after 'ARM' or spontaneous rupture, without any abnormal changes in FHR i.e., no foetal distress. The cesarean section rate in both the groups (24% in PGE2 and 16% in PGE1) is statistically insignificant.

4.Induction to delivery time (Table 4)

	PGE 2	PGE 1	
Time (minutes)	**N=38**	**N=42**	**Significance**
Mean +/- SD	847 +/- 237	734 +/- 239	Significant (p=0.0372)

(*Excluding those cases that were subjected to emergency cesarean section for developed indications.)

Induction to delivery time was significantly reduced in the Misoprostol group (734 +/- 239 minutes), as compared to the Dinoprostone group (847 +/- 237 minutes). The calculated 'p'value (p=0.0372), is statistically significant.

The systemic effect of the drugs are mainly Gastrointestinal symptoms which include Nausea, vomiting. The incidence of side effects is similar in both the groups (p=0.6816).Uterine tachysystole is seen in 2 cases of Dinoprostone group and in 3 cases of Misoprostol group. Uterine hypertonus is seen in 1 case of Dinoprostone group and in 2 cases of Misoprostol group. Both these uterine contractile abnormalities are seen when augmented with Oxytocin.

There is no difference in the neonatal outcome in both groups as per Apgar score at one minute and five minutes (Median 7/10 and 9/10 ; respectively)

DISCUSSION

1. Change in Bishop score

In the present study (Table 1), the mean change in Bishop score was significantly less in PGE2 group (4.67) as compared to PGE1 group (5.75) , (p=0.0121). Fletcher et al (2)1994 in a similar study on 63 women had mean change in Bishop score was significantly higher in those receiving Misoprostol (5.0 vs 3.3) (p=0.008). In studies by Buser et al (3) and Wing et al (4), Misoprostol was more effective in causing cervical ripening, than Dinprostone gel.

2. Need for oxytocin augmentation for labour

In the present study (Table 2), 46 (92%) patients in PGE2 group and 42 (84%) patients in PGE1 group required oxytocin after 8 hrs for augmentation or induction of labour (Table 7). The difference in both groups is statistically not significant (p=0.2183).Daniel V. Surbek et al (5), who used 50 mcg Misoprostol and 0.5mg Dinoprostone had 32% patients in Misoprostol group and 48% patients in Dinoprostone group required oxytocin augmentation. From the present study and the above studies it is evident that Misoprostol in a dose of 25 mcg is equally effective in causing spontaneous labour (8% in PGE2 group and 16% in PGE1 group).

3. Mode of delivery

Most of the patients in both groups had vaginal delivery (72% in PGE2 group and 80% in Misoprostol group). The caesarean section rate was 24% in PGE2 group and 14% in PGE 1 group with no statistical significance in the difference. In numerous studies compared with oxytocin or with intravaginal or intracervical dinoprostone, misoprostol increased the vaginal delivery rate within 24 hours.(6) Gotschall et al (7) had caesarean section rate of 18% in Misoprostol group and 27% in Dinoprostone group (not significant). Wing et al (4) had caesarean rate of 14.7% in misoprostol and 19.4%in dinoprostone group (not significant). From the present study and those mentioned above it is seen that there is no difference in the caesarean section rate in either of drug groups.

4. Induction to delivery time.

In the present study (Table 4), the induction to delivery time was significantly shorter in the misoprostol group (734min) as compared to (847min) in dinoprostone group(p=0.0372). Wing et al 1995 (4) had a significantly lower induction delivery time with misoprostol (mean 15.09hrs) as compared to Dinoprostone (23.9hrs) (p<0.001). Gotschall et al (7) had a significantly lower induction to delivery time in misoprostol group (14.7hrs) as compared to dinoprostone group (20.4hrs) (p<0.005).From the present study and most of the other studies, it can be seen that misoprostol is superior to Dinoprostone in causing delivery in short period after its instillation in the vagina.

5. Side effects

In the present study it was seen that gastrointestinal symptoms in form of nausea and vomiting was the most commonly encountered side effect in both groups of drug. It was seen equally in frequency in both the groups (24%in PGE2 group and 20% in PGE1 group) (p=0.6816). Uterine tachysystole (4% in PGE2 group and 6% in PGE1 group) and uterine hypertonus (2% in PGE2 group and 4% in PGE1 group) were not significantly different in both groups. Gotschall et al (7) had uterine tachysystole in 15.8% patients vs 2.7% in Misoprostol and Dinoprostone groups respectively, which was statistically not significant. Deborah A. Wing et al (8) had uterine tachysystole in 17.4% cases of Misoprostol group and 10.2% cases in Dinoprostone group (not significant), and Hyper stimulation in 5.8% cases of Misoprstol group and 2.2% cases of Dinoprostone group (not significant). From the studies above and the present study it is seen that Misoprostol (in a dose of 25 mcg) had maternal side effects equal in frequency to that of Dinoprostone (0.5mg) group.

6. Neonatal outcome.

No major adverse neonatal out come, which could directly be attributed to the drug was noticed in the present study. The mean Apgar score in both groups was 7/10 at 1 minute and 9/10 at 5 minutes. Similar studies Fletcher (2), Wing et al (4), Gotschall (7), Buser et al (3) show no significant difference in neonatal out comes, as seen in the present study.

CONCLUSION

A single dose of intravaginal Misoprostol is an efficacious, convenient and inexpensive medication for ripening the unfavourable cervix. Some serious side effects like tachysystole and hyperstimulation, associated with application of Misoprostol are not seen with 25 mcg dose. A single 25 mcg intravginal dose of Misoprostol is equally effective as a single 0.5 mg dose of intracervical dinoprostone gel for cervical ripening.

Induction to delivery time is significantly less in Misoprostol group compared to Dinoprostone group. Overall side effects are equal in frequency in both the groups. No adverse neonatal outcomes that can directly be related with local application of the drug intravginally or intracervically, are seen with either of the drugs.

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