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Comparative Study between PGE1 Misoprostol and PGE2 Dinoprostone in Preinduction Cervical Ripening.

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ABSTRACT

Background: Prostaglandin E2(cerviprime gel), an inducing agent is instilled intracervically or placed high in the posterior fornix of the vagina and may need to be re-in- stilled after 6 h if required. Another alternative is misoprostol (15-deoxy-16-hydroxy-16-methyl prostoglandin E1) which is used in various dosages. **Methods:** This was a prospective observational study of nulliparous women undergoing labor induction for one year, 100 womens, in a tertiary care center. Participants were then randomly assigned to pre-induction cervical ripening with a dinoprostone vaginal insert (0.5mg) (group I), and with misoprostol (50 microg) intravaginally(group II). **Result:** From our study observation, maximum patients delivered normal vaginal delivery. Of the vaginal deliveries six (18%) of PGE2 group and five patients(10%) of PGE1 having meconium stained liquor after ARM or spontaneous rupture of membrane, fetal heart was reassuring i.e, no fetal distress was there. The caesarean section rate in both groups nine (18%) and (10%) was statistically insignificant. Mean change in bishop score was also not significant in both groups. Need for oxytocine after 8hrs of induction between both group was significant, 84% in dinoprostone group and 56% in misoprostol group. Gastrointestinal side effects, uterine tacchysystole, uterine hyperstimulation was more common in misoprostol group than dinoprostone group, that is statistically significant. Induction to delivery time was shorter in misoprostol group that is statistically significant. No adverse neonatal outcomes that can directly be related with both drugs. Both agents are equally efficacious in causing cervical repining and almost equal changes in mean bishops. **Conclusion:** Misoprostol is an excellent labour-inducing agent and can be used liberally for labour induction, unlike PGE2 gel, is comparatively cheaper and is stable at room temperature; thus, it could be an ideal inducing agent in poor resource settings. Local application of misoprostol tablet in posterior vagina is easier method than dinoprostone insertion. Intravaginal insertion of misoprostol tablet is superior to dinoprostone gel in inducing labour and shorter interval between induction and delivery.

Keywords: Misoprostol, Cervical Ripening.

INTRODUCTION

WHO defines IOL as the initiation of labour by artificial means prior to its spontaneous onset at a viable gestational age, with the aim of achieving vaginal delivery in a pregnant woman with intact membranes. In developed countries, IOL accounts for about 25 % of all deliveries. In developing countries, the rates vary.[1] Prostaglandins have evolved as the most popular and frequently used pharmacologic agents for IOL, owing to their dual action of cervical ripening and uterine contraction inducing effect. Prostaglandin E2 (cerviprime gel), a registered inducing agent in many countries is expensive and needs to be refrigerated due to its sensitivity to temperature changes. It is instilled intracervically or placed high in the posterior fornix of the vagina and may need to be re-in- stilled after 6 h if required. Another alternative is misoprostol (15-deoxy-16-hydroxy-16-methyl prostoglandin E1) which is used in various dosages. It is stable at room temperature, comparatively cheaper and can be given via several routes (oral, vaginal, sublingual, buccal and rectal). The use of sublingual misoprostol also offers high effi- cacy as it bypasses gastrointestinal and hepatic metabolism and also lowers hyperstimulation of uterus by avoiding direct effect on the cervix. Moreover sublingual route, having the added advantage of easier administration, is less invasive and therefore obviates the need for repeated per vaginal examinations. However, prostaglandins being powerful uterotonics can lead

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to adverse maternal and perinatal outcomes. Researchers in the past have compared efficacy of vaginal and oral PGE1 with intracervical PGE2 and proved that PGE1 is as effective as PGE2 except for increased incidence of caesarean rate and hyperstimulation.[2,3]

MATERIALS AND METHODS

This was a prospective observational trial of nulliparous women undergoing labor induction for one year in a tertiary care center. Inclusion criteria were: gestational age between 36 to 42 weeks, singleton cephalic presentation of the fetus, intact membrane and unfavorable cervical Bishop score < 6, and absence of spontaneous uterine contractions, no contraindication to vaginal delivery and allergy to drug. Participants were then randomly assigned to pre-induction cervical ripening with a dinoprostone vaginal insert (0.5mg) administered into the posterior fornix for a total of 8 hours without oxytocin (group I); with oxytocin (group II), and with misoprostol (50 microg) intravaginally in the posterior fornix.

Clinically monitoring of labour done, hourly BP, PR and temperature monitoring. Uterine contraction monitoring for frequency , intensity and duration by external palpation, FHR monitoring every 30 min in First stage of labour and every 5 min in second stage of labour, P/V examination every 2hrly, amniotomy done at 4-5 cm dilatation of cervix and progress of labour was monitored by Partogram.

Following observation were made out, like change in Bishop Score, need for oxytocin for augmentation, induction to delivery time, mode of delivery(vaginal, caesarean or instrumental) and side effects of drugs.

RESULTS

Mode of delivery	Dinoprostone N=50		Misoprostol N=50		Significance
	No	%	No	%	
Vaginal	37	78	38	76	NS
Caesarean section	9	18	10	20	NS
instrumental	4	8	2	4	NS

From above observation, maximum patients delivered normal vaginal delivery. Of the vaginal deliveries six (18%) of PGE2 group and five patients (10%) of PGE1 having meconium stained liquor after ARM or spontaneous rupture of membrane, fetal heart was reassuring i.e, no fetal distress was there.

The caesarean section rate in both groups nine (18%) and (10%) was statistically in significant.

Out of nine cases in Dinoprostone group 5 were taken for LSCS, because of secondary arrest of dilatation leading to non-progress of labour, 4 were taken for LSCS due to foetal distress (non-reassuring of fetal heart), out of which 2 were having thick msl.

Out of 10 cases of LSCS in Misoprostol group, 5 pts were taken for non-progress of labour, and 5 cases for foetal distress due to Msl.

However incidence of fetal distress in both groups was statistically insignificant.

Four pts (8%) of Dinoprostone groups having instrumental deliveries.. 3 were vaccume delivery, one forceps delivery. Two pts (4%) of Misoprostol group had instrumental deliveries, one vaccume delivery. Indication for instrumental deliveries in both group due to poor maternal bearing down efforts in second stage of labour without fetal distress.

S NO	Parameters	Dinoprostone PGE2	Misoprostol PGE1	significance
1	Mean Bishop score	3.66+1.30SD	4.14+ 1.21SD	NS
2	Mean change in bishop score	3.74+1.06SD	4.14+1.32 SD	NS
3	Need of oxytocine after 8 hrs of induction (%)	84	56	P<0.002
4	Cesearean section rate (%)	18	20	NS
5	Induction to delivery time (hrs)	17.35+2.96SD	12.96+2.83SD	P<0.001
6	Gastrointestinal sideffects(%)	24	40	P<0.04
7	Uterine tachysystole(%)	2	16	P<0.01
8	Uterine hyperstimulation(%)	0	8	P<0.02

DISCUSSION

Herabutya et al,[4] in a similar study 110 study subjects had similar initial bishop score in both groups, there was no significant changes in mean bishop score in both groups. In the study of Buser et al,[5] and wing et al,[6] Misoprostol is more powerful drug in inducing labor than Dinoprostone. Since in most studies, the misoprostol group caused the same mean change in Bishop score or significantly more changes in mean Bishop score after instillation as compared to Dinoprostone gel as seen in our study.

In the present study a significantly lesser patients in misoprostol group (36%) required oxytocine after 8hrs for augmentation of labour, as compared to Dinoprostone group (84%) (p<0.002). and 44% pts went in to spontaneous labour in misoprostol group than 22% in Dinoprostone group. Gottschall et al6 in similar study had 58% patients in Misoprostol group going into spontaneous labour and 24% in Dinoprostone group (p<0.04)

Three fourth of patients in both groups in both groups had normal vaginal delivery 74% in Dinoprostone group and 76% in misoprostol group.

The caesearen rate was 20% in misoprostol group and 18% in Dinoprostone group, there were no statistically significance. In Gottschall6 et al had cesearen section rate of 18% misoprostol group and 27% in Dinoprostone group (not significant)

Induction to delivery mean time was significant shorter in misoprostol group (12.96hrs) as compared to (17.35hrs) in Dinoprostone group (P<0.001). Wing5 et al 1995 had significantly lower induction delivery time with misoprostol (mean time 15.09hrs) as compared to Dinoprostone (23.9hrs) (P<0.001).

Srisomboon7 et al had induction delivery time 12hrs with misoprostol and 25.5 hrs with Dinoprostone (P<0.001). Gottschal6 et al had significantly lower induction delivery time in misoprostol group (14.7hrs) as compared to Dinoprostone group (20.4hrs) (P<0.005)

in present study it was seen that gastrointestinal symptoms in form of nausea, vomiting and diarrhea(single or in combination) was commonly encountered with both groups but it is two times more common with use of misoprostol (40%) than with Dinoprostone (24%)(p<0.01).

Uterine tachysystole (six or more than six contraction in 1 min) was significantly higher in misoprostol group (16%) as compared to Dinoprostone group (2%)(p<0.01).

Hyper stimulation syndrome (tachysytole with non-reassuring FHR changes like bradycardia, late deacceleration, and variable deceleration etc.) was higher with misoprostol (8%) vs Dinoprostone (%) (p<0.02)

Studies of Wing et al,[5] showed no significant difference in GI syndrome in both drugs, tachysystole was seen more with misoprostol (36.7%) vs Dinoprostone (11.9%) (p<0.001). no significant difference in rates of hyperstimulation syndrome and hypertonus. Gottschall et al,[7] had uterine tachysytole in (15.8%) patients Vs (2.7%) in misoprostol and Dinoprostone groups respectively (not significant).

CONCLUSION

Misoprostol is an excellent labour-inducing agent and can be used liberally for labour induction, as long as proper patient selection and vigilant labour monitoring are done. Misoprostol (PGE1), unlike PGE2 gel, is comparatively cheaper and is stable at room temperature; thus, it could be an ideal inducing agent in poor resource settings. Strict adherence to asepsis and minimal use of invasive procedures are essential steps to avoid infections, local application of misoprostol tablet in posterior vagima is easier method than Dinoprostone insertion. Both agents are equally efficacious in causing cervical repining and almost equal changes in mean bishops.Dinoprostone gel is more ideal for cervical ripening because it induces uterine contraction significantly less number of patients than misoprostol.Single dose of 50 microgram misoprostol is more efficacious than single dose of .5mg Dinoprostone gel in inducing labour along with cervical ripening.

LSCS rate after induction with both misoprostol and Dinoprostone are not significant. Intravaginal insertion of misoprostol tablet is superior to Dinoprostone gel in inducing labour and shorter interwal between induction and delivery.

Gastrointestinal side effects are more common with misoprostol than Dinoprostone. Uterine tachysystole is more commonly seen with tab misoprostol than Dinoprostonegel.

No adverse neonatal outcomes that can directly be related with both drugs.

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