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A COMPARATIVE STUDY OF INTRAVAGINAL MISOPROSTOL WITH INTRACERVICAL DINOPROSTONE GEL FOR INDUCTION OF LABOR AT TERM

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ABSTRACT

AIM & OBJECTIVE: Labor is the final consequence of pregnancy and is an inevitable event. The aim of this study is to compare efficacy and safety of low dose vaginal misoprostol with dinoprostone gel for induction of labor at term.

METHODS: The study was conducted at AVBRH, DMIMS on 262 pregnant women with term pregnancy after application of inclusion and exclusion criteria. The study was divided into two groups on the basis of induction drug given to the patient. Group A received Misoprostol 25 µg at every 6 hours to a maximum of five doses; while Group B received 0.5mg dinoprostone gel every six hourly for a maximum of three doses. Outcome such as mode of delivery and induction delivery interval; side effects of drug were assessed in both the groups.

RESULT: There was no significant difference in the mode of delivery between the groups. Incidence of Vaginal delivery, LSCS and instrumental delivery were similar in both the groups (70.23% & 67.18%, 22.90% & 26.72%, 6.87% & 6.11%). The mean induction delivery interval is less in misoprostol group (13.83±5.41 hours & 18.29±6.17, p-0.0001). Requirement of oxytocin augmentation was less in Misoprostol group (44.27% & 72.52% in group A & B respectively). No significant difference was observed in indication of caesarean section and side effects in both the groups (p-0.23, 0.16)

CONCLUSION: Low dose vaginal Misoprostol is as efficacious than Dinoprostone gel for induction of labor at term.

KEYWORDS : Misoprostol tablet, Dinoprostone gel

INTRODUCTION:

In the past decades there has been an increase in the incidence of induction of labor. Data collected from WHO global survey on maternal and perinatal heath has shown that 9.6% of deliveries all around the world required induction of labor.[1] incidence of labor induction in developed countries is as high as 25%.[1]

To be successful, induction of labor must fulfill three aims. Firstly, it should result in labor i.e. adequate uterine contractions with progressive dilatation of cervix. Secondly, this onset of labor should result in vaginal delivery. Third, in viable pregnancies, these aims must be achieved with minimum discomfort and risk to both mother and fetus. Commonly available drugs for this purpose are Misoprostol, Dinoprostone and oxytocin.[2]

Dinoprostone, a PGE2 analogue has been in use for cervical ripening and labor induction since a long time. It is a very efficacious drug with a good safety profile. But it is an expensive drug and requires refrigeration for storage.

Misoprostol, a PGE1 analogue has also been shown to be effective in cervical ripening and labor induction. It is an inexpensive drug and can be stored at room temperature with few systemic side effects. Misoprostol was originally approved for use in prevention and treatment of peptic ulcer. FDA in 2002 finally approved a new label for use of Misoprostol in pregnancy.[3] This revises its labelling from "contraindicated in pregnancy" to "contraindicated in pregnancy with peptic ulcers." Misoprostol is now a part of the FDA approved regime for use with mifepristone to induce abortion in early pregnancy and is also recognized for its use in labor induction.

A large data exists in literature regarding the use of Misoprostol by vaginal, oral or sublingual routes for induction of labor in various doses. ACOG has recommended the use of vaginal Misoprostol of 25 µg every three to six hourly.[4] WHO has recommended its use six hourly.[1]

With the lowest effective dose of Misoprostol and the optimal dosing interval, that achieves a balance between high doses, which result in rapid delivery but cases of hyperstimulation are seen. With lower doses which takes longer time to achieve delivery but have a better safety profile is under investigation. People are using different protocols of low dose vaginal Misoprostol with Dinoprostone gel for induction of labor in term pregnancies.

MATERIAL AND METHODS:

The study was conducted in Department of Obstetrics and Gynaecology at Acharya Vinobha Bhave Rural Hospital, DMIMS, Sawangi (Meghe), Wardha, Maharashtra from August 2016 to June 2018. It is a comparative interventional study. A total of 262 patients with obstetrical and medical indication for labor induction, who met the inclusion and exclusion criteria of the study were enrolled. The inclusion criteria were singleton pregnancy more than 37 weeks, Bishop score of 5 or less, oligohydramnios, medical indication for labor induction, cephalic presentation and a reactive non stress test. The exclusion criteria include evidence of cephalopelvic disproportion, women with previous uterine scar, multiple pregnancy, placenta previa, non-reactive NST, severe IUGR, estimated fetal weight more than 4 kg and pelvic dystocia. The study was approved by Institutional Ethical Board.

After getting consent from the patient, a detailed history and examination including vaginal examination was performed to assess the initial Bishop score. NST was done in all eligible candidates. Randominsation was done using envelope method. Patients who chose A envelope were given Misoprostol and those who chose B envelope were given Dinoprostone gel. Patients in Group A received 25 µg Misoprostol placed in the vagina every six hourly up to maximum of five doses. The women in Group B received intracervical Dinoprostone 0.5mg six hourly up to maximum of three doses. All the patients were monitored clinically under close supervision. Fetal heart rate monitoring was done every hour in latent phase and when patient goes into active stage of labor continuous FHR monitoring was done. Bishop score was reassessed at six hours and whenever required. If patient did not enter into active phase of labor in 24 hours of induction, it was labelled as failed induction. Subsequent doses of the drugs were withheld if the woman went into established labor or with non-reassuring fetal heart rate. The outcome measures assessed were induction delivery interval.

STATISTICAL ANALYSIS:

Data analysis was done using descriptive and inferential statistics using ^{2} test. The software using analysis were SPSS version 22.0 and Graphpad prism 6.0 version. P<0.05 is considered as level of significance.

TABLE 1: Demography (age, gestation age)

Mean ±SD	GROUP A	GROUP B	P value
Age (years)	24.69±3.67	25.51±3.47	0.43,NS
Gestation Age (weeks)	38.73±1.09	39.02±1.12	0.36,NS

Table 2: Distribution According to Parity

Gravida	Misoprostol GROUP A	Dinoprostone GROUP B	p-value
Primigravida	55(41.98%)	65(49.62%)	0.21,NS, p>0.05
Multigravida(G2+G3)	76(58.02%)	66(50.38%)	
Total	131(100%)	131(100%)	

Table 3: Indication of Induction

Indication of induction	Misoprostol GROUP A	Dinoprostone GROUP B	p-value
GDM	12(9.16%)	9(6.87%)	0.29,NS, p>0.05
Polyhydramnios	7(5.34%)	8(6.11%)	
Oligohydramnios	30(22.90%)	34(25.95%)	
PIH	59(45.04%)	44(33.59%)	
Postdate pregnancy	21(16.03%)	31(23.66%)	
Hypothyroidism	2(1.53%)	5(3.82%)	
Total	131(100%)	131(100%)	

Table 5: Induction to onset of labor

	GROUP A	GROUP B	p-value
Mean±SD	1.51±0.69 hrs	2.26±1.61 hrs	0.652,NS

TABLE 6: Induction delivery interval

Induction delivery interval	Group A	Group B	P value
Mean ±SD	13.83±5.41	18.29±6.17	0.0001, S

RESULTS:

There were 131 women enrolled in each group. Both the groups were comparable as regards to demographic characteristics (age, parity and period of gestation). In Misoprostol group, 45.04% patients had PIH, 22.90% had Oligohydramnios,16.03% were Postdate. In Dinoprostone group, 33.59% had PIH, 25.95% had oligohydramnios, 23.66% were postdate pregnancy. Other causes of induction were GDM, polyhydramnios and hypothyroidism. Indication of induction were similar in both the groups(p-0.29).

The mean duration of induction to onset of labor was less in Misoprostol group but the difference between the groups is statistically not significant (1.51±0.69 hrs & 2.26±1.61 hrs in Group A & B respectively, p =0.652). The mean induction delivery interval is less in Misoprostol group (13.83±5.41 hours & 18.29±6.17 hours in Misoprostol and Dinoprostone

DISCUSSION:

The result of the study shows a comparable efficacy of low dose vaginal misoprostol when compared with Dinoprostone gel for induction of labor at term. Similar results were obtained by Cranes et al[5] in 2006 showed that misoprostol has less induction delivery interval and is more effective than Dinoprostone. But since the dosage schedule are different it is difficult to make direct comparisons.

In our study the administration of two prostaglandin resulted in a similar induction-delivery interval. Similar results have been shown by Shivarudraiah G et al[6] by using the same regime. However, in the study conducted by Nanda et al [7] but the dose of 25 µg was used three hourly.

CONCLUSION:

Low dose vaginal Misoprostol 25 µg six hourly is as efficacious and has shorter induction delivery interval than Dinoprostone gel for induction of labor at term

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