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Induction of Labour by Intravaginal Misosprostol and Intracervical Dinoprostone: A Comparative Study.

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ABSTRACT

Background: Induction of labour is indicated when the benefits to either the mother or foetus outweigh those of continuing the pregnancy. Many drugs or methods have been tried for the purpose, the latest addition being prostaglandins. Objective: The present study was taken up to compare the safety and efficacy of 50 µg intra-vaginal Misoprostol and a single dose of 0.5 mg intra-cervical Dinoprostone in induction of labour. **Methods:** 220 women admitted in RIMS during the period Jan 2003-Aug 2004 and needing induction of labour were randomly allocated into two groups, each group consisting of 110 women. To one group Misoprostol was given while the other group got Dinoprostone. These two groups were followed up up-to the perinatal period. **Result:** The mean Bishop's score at 4th hour were found to be significantly increased in both the groups, the mean score at 4th hour being significantly higher in Misoprostol group as compared to Dinoprostone group (5.77 Vs 4.83). The need for oxytocin augmentation was significantly less in Misoprostol group. The induction-delivery period was also found to be much shorter in this group when compared to Dinoprostone group (10.8±4.8 hours Vs 12.0±7.7 hours). The proportion of vaginal delivery was comparable in the two groups. Apgar scores of babies in the two groups also were comparable. Maternal and perinatal complications were very less in both the groups. **Conclusion:** Both intra-vaginal Misoprostol and intra-cervical Dinoprostone were found to be effective and safe for induction of labour. However, Misoprotol is less expensive, easy to administer and more effective than Dinoprostone with minimal side effects when cases are monitored properly.

Keywords: Dinoprostone, Efficacy, Induction of labour, Misoprostol, Safety

INTRODUCTION

The aim of successful induction is to get a healthy baby where continuation of pregnancy presents a threat to the health of the mother or her unborn child. Hence, it is indicated when the benefits to either the mother or the foetus outweigh those of continuing the pregnancy. Common indication for induction include rupture of membrane without spontaneous onset of labour, maternal hypertension, non-reassuring foetal status and post-term gestation.[1]

In the beginning, methods like artificial rupture of the fore-water and hind-water were deployed which were gradually phased-out as they were uncertain, dangerous and bizarre.[2] In recent years, modern methods of induction by using Oxytocin, Prostaglandins (E1 and E2), Amniotomy have greatly increased the safety, reliability and success of induction of labour. But induction of labour still remains as one of the challenges in obstetric practice as each method is not without risks and hazards and resultantly, requires intense intra-partum monitoring.

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The use of Misoprostol, a synthetic PGE1 analogue was first reported in 1987 for induction of labour in cases of intra-uterine foetal death and has been shown to be superior to the conventional methods of induction.[3] Prostagladins play a key role in the cervical ripening at cellular level and lead to a series of biochemical effects on the cervix that increase cervical compliance. Apart from the local effect, prostaglandin also induces "gap junctions" intra-myometrial cellular connections that are believed to be responsible for the propagation of coordinated myometrial contractions.[4] The ideal method of prostaglandins will maximize the local effect and minimize systemic side effects. Indeed, since the introduction into clinical use, routes of delivery have evolved from oral/systemic to intra-vaginal and intra-cervical routes.

Objective:
The present study was done to compare the safety and efficacy of intra-vaginal Misprostol with that of intra-cervical Dinoprostone for induction of labour.

MATERIALS AND METHODS

The present study was done among all women admitted in the Obstetric Ward of the Regional Institute of Medical Sciences (RIMS), Imphal during the period Jan 2003 – Aug 2004. The study subjects included all singleton pregnancy women with

cephalic presentation with a Bishop's score of 4 or less who required induction of labour at or near term due to medical and obstetric reasons. Women younger than 20 years or older than 35 years, placenta praevia, post-caesarean pregnancy and having history of allergy to prostaglandin were excluded. In this way, a total number of 220 eligible women could be found during the study-period.

On the first day of admission after obtaining informed verbal consent a detailed history was taken which was followed by general, systemic and pelvic examinations. Routine investigations like Hb%, TLC, DLC, ESR, Blood grouping, typing and Urine R/E were done for all cases supplemented with ultrasound scanning in indicated cases so as to avoid any possible premature induction.

On the day of induction reassessment was done and the initial Bishop's score was noted. Following this, by using lottery method, the 220 study-subjects were allocated into two groups namely Group 1 and Group 2. Under aseptic and antiseptic precautions, in Group 1 patients 50µg of tablet Misoprostol was manually placed digitally in the posterior fornix of vagina whereas in Group 2 patients the catheter of a pre-filled syringe containing PGE2 (Dinoprostone) 0.5 mg was gently pushed and the syringe was gradually withdrawn to ensure deposition of the entire content of gel into the cervical canal. The patients were then let to remain in recumbent position for 30 minutes. All the patients were monitored half-hourly for uterine contraction, foetal heart rate and maternal vital signs. The change in the cervix was also monitored after 6 hours of induction or whenever clinically indicated.

In both the two groups, when the cervical dilatation was 4-5 cm., artificial low rupture of membrane (ARM) was done to assess the colour of liquor and also to accelerate the labour. Oxytocin drip was then started for acceleration in the absence of adequate uterine contraction after ARM. Once the patient was in active labour, the progress of labour was assessed by noting the strength of uterine contraction, descent of presenting part, dilatation and effacement of the cervix. Appropriate intervention was carried out when indication arose during labour in both the groups. Those patients who did not have improvement of Bishop's score and labour did not progress significantly within 24 hours were considered as failed to induction. They were allowed to take rest.

Information on intra-partum course regarding Bishop's score, colour of liquor, cord prolapsed, mode of delivery, indication of operative interference, induction-delivery interval, foetal outcome and any maternal or foetal complications were obtained. The results were compared by using appropriate statistical tests of significance (chi-square for comparison of proportions and t-test for comparison of means). A p-value of less than 0.05 was considered as statistically significant.

RESULTS

Out of the total 220 study-subjects, 89 (41%) were from the age-group of 20-25 years, 93 (42%) belonged to 26-31 years and the remaining 38 (17%) were from the age-group of 31-35 years. The proportions were comparable between the two intervention groups. Similar proportions of women with different parities were also seen among the two groups (45% primi, 32% para 1 and 23 para 2). The commoner indications of labour-induction were premature rupture of membranes (85; 39%), post-dated pregnancy (63; 29%) term pregnancy (55; 25%) and pre-eclamptic toxaemia (12; 5%) although there were differences in the proportions between the two groups.

The Bishop's scores for both the group 1 and group 2 patients were almost comparable at "0" hour at around 3.4. However, at 4th hour the Misoprostol group had a significantly higher mean score (5.77) than that of the Dinoprostone group (4.83). Again, test values suggest that those women who received Misoprostol had significantly higher Bishop's score than those who received Dinoprostone at 4th hour. Further, it was observed that in both the groups, mean Bishop's scores at 4th hour were found to be highly significantly higher than the corresponding mean scores at "0" hour [Table 1].

Table 1: Comparison of Bishop's score at 0 and 4 hours between Group 1 and 2.

Time	Mean Bishop's score (SD) in		t-value	p-value
	Group 1	Group 2		
0 hour	3.436±0.74	3.418±0.76	0.180	>0.05
4 hours	5.773±2.20	4.827±2.33	3.112	<0.01
t-value	10.623	6.073		
p-value	<0.001	<0.001		

By mode of delivery, out of all the study-subjects 174 (79.1%) women had spontaneous vaginal delivery, 19 (8.6%) had instrumental delivery and the remaining 27 (12.3%) culminated in Caesarean section (CS). There was no statistically significant difference in the mode of delivery between the two intervention groups. The indications for CS were cervical dystocia (8), fail to induction (7) persistent occiput-posterior (6), foetal distress (5) and APH (1). The proportions were comparable between the two groups.

When all the vaginal deliveries were analyzed by mode of induction a variation could be observed. Induction with Misoprostol resulted to less than half (44%) of the vaginal deliveries. There was slightly higher proportion (56%) when oxytocin was added. Dinoprostol only resulted to one-fourth of the vaginal deliveries in the Group 2 patients. Its combination with oxytocin resulted to the remaining three-fourths of the vaginal deliveries. This difference between the two groups was found to be statistically significant [Table 2].

Table 2: Comparison of vaginal deliveries by mode of induction

Group 1 (n=96)		Group 2 (n=97)		X2 value	p-value
Misoprostol only	42 (43.8%)	Dinoprostol only	24 (24.7%)	7.796 at d.f.=1	<0.01
Misoprostol + oxytocin	54 (56.2%)	Dinoprostol + oxytocin	73 (75.3%)		

Out of all the 96 patients in Group 1 who had vaginal delivery, 94 (97.9%) had delivery within 24 hours of induction whereas out of the 97 patients in Group 2, 86 (88.7%) had delivery within 24 hours of induction. The difference between the two was found to be statistically significant (x2 value at 1 d.f. =6.592; p<0.01) implying that the induction-delivery interval was shorter with Misoprostol induction compared to Dinoprostone group. When the induction-delivery interval was analyzed by parity, no significant difference could be seen between the two types of induction in primi and Para 2 patients. But it was significantly shorter in the Misoprostol group in Para 1 (t-value = 4.089; p >0.001).

When the mean Apgar scores at 1st minute and 5th minute were compared between the two intervention groups no statistically significant difference could be detected.

Out of all the 110 patients in Group 1 patients, the maternal complications seen were Mild PPH (4; 3.6%), 10 perineal tear (3; 2.7%) and one case each of cervical tear and vaginal wall tear. In Group 2 patients, the maternal complications were mild PPH (2; 1.8%) and one case each of cervical tear and atonic PPH [Figure 1]. There was no maternal death.

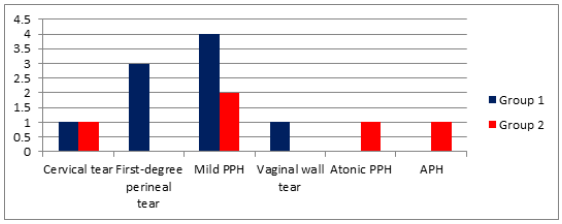

Figure 1: Maternal complications

[Figure 2] shows the distribution of perinatal complication in the two groups. Its incidence in the two intervention groups was found to be comparable.

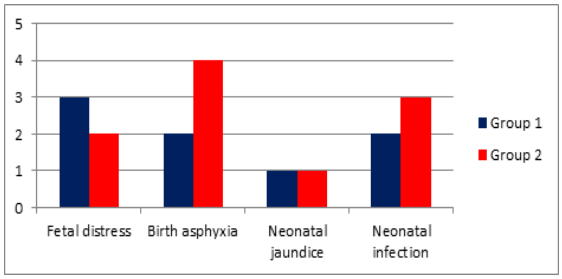

Figure 2: Perinatal complications

DISCUSSION

Earlier studies by Kore S et al and Buser D et al showed that majority of patients who needed labour-induction belonged to the age-group of 20-25 years.[5,6] They also showed that the patients were more or less equally distributed among the primi-gravidae and multi-gravidae. In the present study women from the age-group of 20-25 years constituted only 41%, the majority (42%) being from the age-group of 26-30 years. This disparity may be because of difference in the study-setting. The present-study composition of patients in terms of gravida is similar to the aforementioned earlier studies.

In earlier studies done by Mackenzie IZ et al, Bhatla N et al and Rozenberg P et al post-dated pregnancy (PDP) was the main indication for induction of labour.[7-9] In the present study, the main indication was PROM (38.6%) followed by PDP (28.6%). The reason may be that after reaching term, the efficiency of placenta starts to diminish and the foetus suffers increasingly from anoxia.

Buser D et al in their study found that Misoprostol was more effective than Dinoprostone in causing cervical ripening, inducing labour, shortening the duration of labour and decreasing the need for oxytocin augmentation.[6] Ozan H et al also found that, 50 µg intra-vaginal misoprostol combined with oxytocin augmentation when necessary, was an effective and safe method of labour-induction.[10] The current study findings corroborate with their study finding.

Many researchers have shown that the mode of delivery differed greatly among the method or drugs used for induction of labour. Spontaneous vaginal delivery ranges from 67% to 88%.[5,11-13] The current study finding of 79% being spontaneous vaginal delivery lies within this range. The proportion of CS in the two groups in the present study was found to be comparable (12.7% in Misoprostol and 11.8% in Dinoprostol group). Buser D et al in their study found greater CS rate in Misoprostol group (35.5% versus 21.5%).[6] Sanches-Ramos L et al, too found higher CS rate in Misoprostol group (22.2% versus 13%).[14]

Regarding induction-delivery interval, Sahu L et al and Fernandez E et al found it to be shorter in Misoprostol group.[15,16] Similar result was seen from our study.

No difference in Apgar score could be seen between the Misoprostol and Dinoprostone groups. Similar finding was made by Mackenzie IZ et al.[7]

Nunes F et al could detect any significant difference in the incidence of maternal and perinatal complications between Misoprostone and Dinoprostone groups. The present study finding reaffirmed this.

CONCLUSION

50 µg of intra-vaginal Misoprostol and a single dose of intra-cervical Dinoprostone 0.5 mg are effective in initiation of labour with a ripening effect on an unfavourable cervix. Both shortened the duration of labour and have low incidence of Caesarean section. Both are simple, safe and convenient with less discomfort to patients as they can remain ambulant. Both are effective for induction of labour. But the induction-delivery period is shorter with Misoprostol. Misoprostol is relatively cheaper, stable at room temperature and easy to administer with minimal side-effects. Therefore, it can be concluded that, Misoprostol augmented with oxytocin when necessary, appears to be more effective and safer method of labour-induction when compared to Dinoprostone.

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