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ORIGINAL ARTICLE

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A randomized clinical trial comparing misoprostol and dinoprostone for cervical ripening and labor induction

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OBJECTIVE(S) : To compare the efficacy and safety of vaginal dinoprostone with misoprostol for induction of labor in women with unfavourable cervix.

METHOD(S) : A progressive randomized comparative study was carried out. Two hundred pregnant women with unfavourable cervix were alternately assigned to two groups of 100 each for dinoprostone (Group A) and misoprostol (Group B) administration. Success of induction, mean induction delivery internal, uterine contractions, and apgar score were analyzed. Statistical evaluation was done by student t test and chi square test.

RESULTS : The mean induction delivery interval was 12.34 hours in Group A and 9.8 hours in Group B, spontaneous vaginal deliveries were 86% in Group B in contrast to 68% in Group A ($P<0.01$). Uterine contraction abnormalities were more in Group B than in Group A (12% vs 4%; $P>0.10$). Failure of induction was 8% and 2% in Group A and B respectively ($P>0.10$). Apgar scores at 1 and 5 minutes in Group A and B were 7.2 and 7.74 vs 7.15 and 7.59 respectively.

CONCLUSION(S) : Misoprostol is more efficacious for cervical ripening and labor induction than dinoprostone as seen by shorter induction delivery interval, greater number of vaginal deliveries, and good perinatal outcome.

Key words : dinoprostone, misoprostol, induction of labor

Introduction

Induction of labor is an elective procedure at a predetermined time after 28 weeks of gestation, which demands continuous monitoring, as it usually deals with a pregnancy at risk. Many medical and obstetrical complications of pregnancy where continuing pregnancy outweighs risk of delivery, require labor induction. Induction of labor is required in 16% of deliveries [1].

The success of induction of labor is influenced by a combination of events existing prior to initiation of labor, such as Braxton Hicks contractions, ratio of estrogen to progesterone, prostaglandin synthesis, and the state of cervical collagen matrix. Labor induction in presence of unfavorable cervix is often prolonged, tedious, and may lead to induction failure. The failure rate with an unfavourable cervix ranges from 25 to 50% [2]. Hence cervical ripening is required before induction of labor to achieve more successful outcome.

Prostaglandins have a very important therapeutic role in induction of labor and cervical ripening. Dinoprostone (DNP) is an effective and established agent for cervical ripening and labor induction. It is a naturally occurring form of PGE_2 having site specific action [4]. Misoprostol (MSP), the synthetic analog of PGE_1, commonly used as a gastric cytoprotective agent, was first reported in 1987 for induction of labor in case of intrauterine fetal death (IUF) in 3rd trimetster [3]. Nowadays it is used as an effective agent for labor induction. The present study was aimed to compare the efficacy, safety and complications of DNP and MSP for cervical ripening and induction of labor in women with unfavorable cervix.

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Methods

Two hundred antenatal women, who required induction of labor for different indications, were enroled in the study.

Inclusion criteria were singleton viable pregnancy of ≥37 weeks, pregnancies soon after the diagnosis of IUFD and congenital fetal malformations at any gestational age, premature rupture of membranes (PROM), cephalic presentation, and Bishop, score of 5 or less.

Exclusion criteria were, pregnancy with heart disease, bronchial asthma, glaucoma, multiple gestation, cepholopelvic disproportion, placenta previa, allergy to prostaglandins, previous cesarean section, and grand multiparity.

The women were alternately assigned to one of the two groups.

Group A : Women were given intracervical DNP gel (0.5 mg 6 hourly, upto a maximum of four doses)

Group B : Women were given intravaginal MSP tablet (25µg 6 hourly, upto a maximum of five doses)

All women were studied for demographic profile, gestational age, improvement in Bishop score, latent period, induction delivery interval, mode of delivery, 3rd stage blood loss, and fetomaternal outcome. Dose repetition was withheld when women had any complication like hyperstimulation, and tachysystole or hypersystole. The need for augmentation was assessed and implemented by other methods such as artificial rupture of membranes and syntocinon. When women did not achieve the active phase even after receiving the maximum dose of the drug, induction was considered to have failed and other measures under taken.

Student t test and chi square test were used to compare the significance of parameters between the two groups.

Results

Obstetric characteristics of the two groups are given in Table 1.

Improvement in Bishop score was seen in significantly greater number of women in Group B than in Group A (Table 2). Augmentation was needed in 40% and 8% subjects in Group A and B respectively (P<0.001). Uterine contraction abnormalities were more in Group B in comparison to Group A but not statistically significantly so (tachysysloly 8 % v/s 2%, P>0.1 and hyperstimulation 4% vs 2%, P>0.5). Mean induction delivery interval was significantly shorter in Group B than in Group A (Table 3). Significantly more number of spontaneous vaginal deliveries (SVD) occurred in Group B than in Group A viz., 86% vs 68% (P<0.01) (Table 4). Cesarean deliveries were more, but not significantly so in Group A than in B (26% vs 12%,P> 0.05). Cesarean section was done mainly for fetal distress in Group B and for fetal distress, failure of induction, and non-progress of labor in Group A. There was no statistically significant difference between Group A and B in the incidences of cervical tears (0% vs 4%, P> 0.10) and postpartum hemorrhage (8% vs 2%, P>0.10). One of the cervical tears was due to forceps delivery. Third stage blood loss was 477 mL vs 369 mL in Group A and B respectively (P > 0.05). Apgar scores at 1 and 5 minutes were slightly less in Group B than in Group A (7.15 vs 7.2 at 1 minutes and 7.5 vs 7.74 at 5 minutes). Fetal heart rate anomalies and nursery admissions were more in Group B, whereas meconium staining was observed more often in Group A (Table 5).

Table 1. Obstetric characteristics.

		Group A n=100	Group B n=100
Age (years)		24.8	24.0
Nulliparas		64	42
Gestational age (weeks)		38.94	38.0
Bishop score (Mean ± SD)		2.71±1.34	3.02±1.39
Indications for induction			
Fetal compromise	Postterm	30	18
	IUGR	8	12
Nonfetal indications	Elective induction	34	32
	Pregnancy induced hypertation	24	14
	Oligohydramnios	0	4
	Premature rupture of membranes	0	10
	Others	4	10

Table 2. Improvement in Bishop score.

Assessment after	Improvement seen		
	Group A n=100	Group B n=100	P value
12 hours	42	60	< 0.05
18 hours	34	34	> 0.05
24 hours	16	4	< 0.001

In Group A, 8 women and in Group B, 2 women showed no improvement in Bishop score.

Table 3. Induction delivery interval.

Induction delivery interval hours	Group A n=100		Group B n=100		P value
	Number	Mean ± SD Hours	Number	Mean ± SD Hours	
≤ 12	56	7.51 ± 1.02	62	6.55 ± 1.39	< 0.001
≤ 24	92	11.02 ± 1.62	98	9.56 ± 1.75	< 0.001
> 24	8	27.50 ± 1.40	2	30.00 ± 0.00	< 0.001

Table 4. Mode of delivery.

Spontaneous	Group A n=100	Group B n=100	P value
Spantaneous vaginal delivery	68	86	< 0.01
Forceps delivery	6	2	> 0.10
Cesarean section	26	12	
Fetal distress	12	10	
Failure of induction	4	0	
Nonprogress of labor	4	0	
Deep transverse arrest of the head	2	2	
Premature rupture of membranes	2	0	
Accidental hemorrhage	2	0	

Table 5. Fetal and neonatal results.

	Group A n=100	Group B n=100
Meconium staining of liquor	12	8
Cesarean section for fetal distress	12	10
1 min apgar < 7	14	22
5 min apgar <7	6	8
Nursery admission	10	14
Perinatal mortality	1	2

No case of rupture uterus occurred in the study. No major side effect of the drug was observed in any of the two groups. Shivering and pyrexia were more in (4% vs 2%) Group B.

Discussion

The latent period was shorter and improvement in Bishop score was earlier and better in group B as compared to those in Group A (Table 2). This was statistically significant (P<0.001). Similar were the observations of Fletcher et al [4], Wing et al [5] and Gottschall et al [6]. Requirement for augmentation of labor was more in Group A than in Group B. Some women of Group A had premature rupture of membranes. Hence, dinoprostone had to be stopped and augmentation carried out by other methods. Chuck and Huffaker [7] and Subrek et al [8] had also reported greater need for augmentation with DNP than that with MSP. Uterine contraction abnormalities were more in Group B than in Group A. Similar were the observations of other authors [5,6]. Statistically significant greater number of women had spontaneous vaginal deliveries in group B than in Group A (P<0.01).

Cesarean section rate was not significantly more in Group A than in Group B (26% vs 12% P >0.05). The main indication for cesarean section was fetal distress in group B but the apgar scores of all the babies were satisfactory. Previous studies have also reported an increased incidence of fetal heart rate abnormalities with misoprostol, but the interpretation of abnormal traces remains controversial [9,10].

Perinatal asphyxia as considered by 5 minute apgar score of <7, and meconium aspiration, were almost similar in the two groups. These results contrast with the higher rate of fetal distress observed with misoprostol in other studies. This may be because we used a lower 25 µg dose of MSP. This discrepancy in results (fetal distress associated with healthy babies) has also been reported previously [9]. Total cost of drug was much less in MSP group than in DNP group.

Our results confirm that the efficacy of MSP was better than that of DNP, considering induction delivery intervals and vaginal deliveries. Other authors have also reported similarly [5-8].

Conclusion

Misoprostol is more efficacious for cervical ripening and labor induction than dinoprostone as the former has better improvement in Bishop scores, lesser requirement of other oxytocics for labor augmentation, shorter induction delivery interval, greater number of vaginal deliveries, reduced cesarean section rates and less amount of bleeding in 3rd stage of labor. Misoprostol is inexpensive and stable at room temperature.However, uterine contraction abnormalities, fetal heart irregularities and meconium staining of liquor should be carefully assessed in a subset of potentially compromised fetuses.

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