Research Article

Efficacy of misoprostol over dinoprostone gel and Foley's catheter as a cervical ripening agent

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Abstract

Background: Induction of labor is one of the most important and irrevocable interventions in obstetric practice. Timely induction could reduce maternal mortality and morbidity and assure a delivery of a healthy baby.

Objective: To evaluate the efficacy of misoprostol as a cervical ripening agent and its comparison with dinoprostone gel and Foley's catheter in terms of success rate, safety, side effects, patient's compliance, and cost factor.

Materials and Methods: A total of 175 pregnant women requiring induction of labor were recruited. Of the 175 cases, 75 were induced with 50 µg misoprostol, 50 cases with intracervical Foley's catheter No. 18, and 50 cases with 0.5 mg intracervical dinoprostone gel, selected by purposive sampling method during April to August 2002, at the Department of Obstetrics and Gynecology, Guru Gobind Singh Hospital, Jamnagar, and M.P. Shah Medical College, Jamnagar, Gujarat, India. Written and informed consent was taken from the patients. Outcome measures such as change in Bishop's score, need of augmentation, and induction delivery interval and complications such as hyperstimulation, fever, and meconium passage were compared between the three groups. Statistical analysis was performed by ANOVA test.

Results: The age range of the patients was 21 to 35 years; 76% of the patients were in the 21–25 years age group. Thirty-eight (50.6%) patients were multigravida, and 45 (60%) patients reported more than 37 weeks of pregnancy. Thirty-five (46.6%) of the patients showed premature rupture of membrane as indication of labor. The mean Bishop's score for induction was 3.20 in misoprostol group. Only 12% of the patients required augmentation in misoprostol group, while it was 48% in dinoprostone group and 72% in Foley's catheter group. Sixty-three (84%) patients in misoprostol group and 94% of patients in dinoprostone group delivered by vaginal delivery; 57.3% patients delivered within 6 h in misoprostol group (misoprostol: 57.3%, dinoprostone: 28%, Foley's catheter: 8%; $p < 0.001$). Incidence of thin meconium occurred in 12% in misoprostol group, 10% in dinoprostone group, and 18% in Foley's catheter group. In misoprostol and Foley's catheter groups, three patients developed fever after induction. No patient reported diarrhea and vomiting. Incidence of cervical tear and vaginal laceration was similar in all the groups. No case of hyperstimulation was observed in our study. Misoprostol is quite cheaper than dinoprostone gel and Foley's catheter.

Conclusion: Vaginal misoprostol is safe and effective for induction of labor with lesser need of oxytocin augmentation and shorter induction delivery interval and possess some advantages compared with dinoprostone and Foley's catheter including improved efficacy and lower cost of the drug.

KEY WORDS: Misoprostol, dinoprostone, Foley's catheter, cervical ripening, induction of labor, Bishop's score

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Introduction

Induction of labor is one of the most important and irrevocable interventions in obstetric practice. Induction is warranted when the benefits to either the mother or fetus are more important than those of continuing pregnancy.[1]

A perfect balance between the uterine activity, cervical dilatation rate, and response of the foetus is necessary to

achieve successful induction of labor. Timely induction could reduce maternal mortality and morbidity and assure a delivery of a healthy baby. Induction of labor involves a complete interaction between oxytocin and prostaglandins, and success of labor depends on cervical conditions such as dilatation, effacement, consistency, and position in the pelvis.[1]

Prostaglandins are in clinical use for more than 40 years. Prostaglandins are administered systematically or locally to induce biochemical changes in unripe cervix. Until now, two types of prostaglandins PGE_2 and PGF_2 were used in obstetrics. Recently, a new prostaglandin came into use in obstetrics for labor induction: PGE_1 methyl analog misoprostol. This was used initially for treatment of gastric ulcers caused by NSAIDS. Owing to its uterotonic effect and cervical ripening effect, its use in obstetrics for labor induction is increasing nowadays.

Our study is to evaluate the efficacy of misoprostol as a cervical ripening agent and its comparison against PGE_2 dinoprostone gel and Foley's catheter in terms of success rate, safety, side effects, patient's compliance, and cost factor.

Materials and Methods

This prospective study was carried out in 175 cases with gestational age equal to or greater than 28 weeks, no uterine activity at the time of induction, cervical dilatation should be less than 3 cm and effacement should be less than 50%, positive nonstress test without having history of antepartum hemorrhage, cesarean section, and allergy to prostaglandins selected by purposive sampling method during April to August 2002 at the Department of Obstetrics and Gynecology, Guru Gobind Singh Hospital, Jamnagar, and M.P. Shah Medical College, Jamnagar, Gujarat, India. The procedure, possible complications, and chances of failure of the procedure were explained to each patient in detail. Written and informed consent was taken from the patients.

Of the 175 cases, 75 were induced with 50 µg misoprostol, 50 cases with intracervical Foley's catheter No. 18, and 50 cases with 0.5 mg intracervical dinoprostone gel. Patients with cardiovascular disease, bronchial asthma, renal or hepatic disorders, cephalopelvic disproportion, low-lying placenta, acute local cervical lesion, and previous lower segment cesarean section or any scar over the uterus were excluded from the study.

Information regarding sociodemographic profile, duration of pregnancy, labor pain, leaking per vaginum, fetal movement, and any obstetric or medical disorders was collected using predesigned, pretested *per forma*. Patients were examined and evaluated using investigations such as hemoglobin, urine albumin and sugar, blood group, blood urea, plasma fibrinogen, bleeding time, and clotting time. Prophylactic antibiotics were given to all the patients. After induction, patient was monitored for vital signs, uterine activity, fetal heart sound, and progress of labor and development of any untoward reaction. Data were collected and analyzed statistically using SPSS 14 (trial version).

Table 1: Distribution of patients according their age groups

Age group (years)	Misoprostol (*n* = 75), *n* (%)	Dinoprostone gel (*n* = 50), *n* (%)	Foley's catheter (*n* = 50), *n* (%)
21–25	57 (76)	38 (76)	32 (64)
26–30	15 (20)	9 (18)	16 (32)
31–35	3 (4)	3 (6)	2 (4)
Mean age	24.32	24.64	24.44

Table 2: Distribution of patients according to gravidity and weeks of gestation

	Misoprostol (*n* = 75), *n* (%)	Dinoprostone gel (*n* = 50), *n* (%)	Foley's catheter (*n* = 50), *n* (%)
Gravidity			
Primigravida	37 (49.4)	24 (48)	20 (40)
Multigravida	38 (50.6)	26 (52)	30 (60)
Weeks of gestation			
<32	6 (8)	3 (6)	5 (10)
32–36	24 (32)	20 (40)	16 (32)
>37	45 (60)	27 (54)	29 (58)

Results

About 76% of the patients were in the 21–25 years age groups [Table 1]; 38 (50.6%) patients were multigravida. Forty-five (60%) patients reported more than 37 weeks of pregnancy.

Thirty-five (46.6%) patients showed premature rupture of membrane (PROM), followed by 18 (24%) with postmaturity as indication of labor [Table 2]. The mean Bishop's score for induction was 3.20 in the study group and was similar to that of control groups [Table 3]. Only 12% of the patients required augmentation in study group, while it was 48% in the dinoprostone group and 72% in the Foley's catheter group [Table 4].

Table 3: Distribution patients according to indication of labor

Indication	Misoprostol (*n* = 75), *n* (%)	Dinoprostone gel (*n* = 50), *n* (%)	Foley's catheter (*n* = 50), *n* (%)
Premature rupture of membrane	35 (46.6)	27 (54)	22 (44)
Postmaturity	18 (24)	12 (24)	11 (22)
Preeclamptic toxemia	10 (13.3)	6 (12)	8 (16)
Eclampsia	2 (2.6)	1 (2)	1 (2)
Intrauterine fetal death	3 (4)	2 (4)	2 (4)
Intrauterine growth retardation	4 (5.3)	1 (2)	4 (8)
Congenital anomalous baby	3 (4.1)	1 (2)	2 (4)

Table 4: Distribution of patients according to Bishop's score at the time of induction

Bishop's Score	Misoprostol (*n* = 75), *n* (%)	Dinoprostone gel (*n* = 50), *n* (%)	Foley's catheter (*n* = 50), *n* (%)
2	15 (20)	13 (26)	12 (24)
3	31 (41.4)	12 (24)	16 (32)
4	28 (37.3)	24 (48)	21 (42)
5	1 (1.3)	1 (2)	1 (2)
Mean Bishop's score	3.20	3.26	3.22

Sixty-three (84%) patients in the misoprostol group and 94% of patients in the dinoprostone group delivered by vaginal delivery. After application of intravaginal misoprostol (50 µg tablet), 57.3% patients delivered within 6 h [Table 5]. The minimum induction delivery interval was 2 h. In the dinoprostone gel group, maximum patients required 6–12 h for delivery after induction; minimum induction delivery interval was 3 h 40 min.

In the Foley's catheter group, 44% patients required 6–12 h for delivery and 36% required 12–24 h. Maximum induction delivery interval was 90 h 25 min, in which reinduction with dinoprostone gel was also done thrice [Table 6]. About 12% of patients showed thin meconium and 16% of patients demonstrated thick meconium compared with 10% thin meconium in dinoprostone group and 18% thin meconium in Foley's catheter group [Table 7]. In the study group and in Foley's catheter group, three patients developed fever after induction. There was a single spike of fever of 100°F, which responded to oral paracetamol and cold sponging. Fever in the Foley's group could be caused by oxytocin drip required for augmentation. No patient reported diarrhea and vomiting. Incidence of cervical tear and vaginal laceration was comparable in all the groups. No case of hyperstimulation was observed in our study [Table 8].

Table 8: Distribution of patients according to their complication

Complication	Misoprostol (*n* = 75), *n* (%)	Dinoprostone gel (*n* = 50), *n* (%)	Foley's catheter (*n* = 50), *n* (%)
Fever	3 (4)	—	3 (6)
Cervical tear	4 (5.3)	2 (4)	2 (4)
Vaginal laceration	2 (2.6)	1 (2)	—

Table 9: Cost factor

	Misoprostol (100 µg), 2 tablets	Dinoprostone gel (0.5 mg)	Foley's catheter (No. 18)
Total cost (Rs.)	18.00	183.00	75.00

Misoprostol is quite cheaper than dinoprostone gel and Foley's catheter. In our study, majority of patients were from rural areas; so, cost factor plays an important role. Table 9 suggests that total cost of the therapy with misoprostol (50 µg, 4 hourly total and doses) was only Rs. 18 when compared with dinoprostone gel, which was Rs. 183, and Foley's

Table 5: Distribution of patients according to their mode of delivery

Mode of delivery	Misoprostol (*n* = 75), *n* (%)	Dinoprostone gel (*n* = 50), *n* (%)	Foley's catheter (*n* = 32), *n* (%)	Foley's catheter followed by dinoprostone (*n* = 18), *n* (%)
Vaginal	63 (84)	47 (94)	30 (93.8)	14 (77.9)
Forceps/vacuum	3 (4)	2 (4)	1 (3.1)	1 (5.5)
LSCS	9 (12)	1 (2)	1 (3.1)	3 (16.6)

Table 6: Distribution of patients according to induction delivery interval

Hours	Misoprostol (*n* = 75), *n* (%)	Dinoprostone gel (*n* = 50), *n* (%)	Foley's catheter (*n* = 50), *n* (%)	*p*
0–6	43 (57.4)	14 (28)	4 (8)	<0.001 (highly significant)
6–12	28 (37.3)	23 (46)	22 (44)	
12–24	4 (5.3)	13 (26)	18 (36)	
>24	—	—	6 (12)	

Table 7: Distribution of patients according incidence of meconium in each group at the time of delivery

Meconium	Misoprostol (*n* = 75), *n* (%)	Dinoprostone gel (*n* = 50), *n* (%)	Foley's catheter (*n* = 50), *n* (%)	
			Foley's catheter (*n* = 32)	Foley's catheter followed by dinoprostone gel (*n* = 18)
Thin meconium	9 (12)	5 (10)	5 (15.6)	4 (22.3)
Thick meconium	12 (16)	8 (16)	4 (12.6)	6 (33.3)
No meconium	54 (72)	37 (74)	23 (71.8)	8 (44.4)

catheter of Rs. 75. Moreover, requirement of augmentation was also less in the misoprostol group compared with the other two groups. In Foley's catheter group, many of the patients required dinoprostone gel for augmentation, leading to total cost up to Rs. 258. In the dinoprostone gel group also, some patients required twice or thrice application, leading to total cost up to Rs. 366–549. Thus, misoprostol induction is 20–30 times cheaper than Foley's catheter and dinoprostone gel inductions [Table 9].

Discussion

Age definitely influence labor. Pregnancy below 20 years pose more complications as mother is also in developing phase. In contrast, increasing age increases the resistance of cervix for dilatation, and, so, ripening of cervix will be delayed or failed in case of primigravida women aged more than 35 years. Fortunately, in our study, no pregnancies were reported below 20 years and above 35 years of age, and maximum patients were in the age group of 20–30 years. In the study by Buser et al.,[2] 40.7% patients were aged older than 30 years compared with only 4% patients in this study. In this study, maximum patients (i.e., 46.6%) requiring induction showed PROM as an indication compared with 1.4% patients in the study by Blanchette et al.[3] In this study, 24% patients reported postdatism as indication of induction of labor, which was 35% and 57.9% in the studies by Blanchette et al.[3] and Kolderup et al.,[4] respectively.

Bishop's score at the time of induction is a very important factor in determining the successful outcome of labor. Increase in the Bishop's score increases the success of outcome of induction of labor. In the study group, maximum number of patients (41.3%) was induced in Bishop's score of 3. In the control group, maximum patients (45%) were induced in Bishop's score of 4. In the study group, 37.3% of patients were induced with Bishop's score of 4, 20% patients with Bishop's score 2, and only 1.3% patients with Bishop's score 5. The mean Bishop's score for induction was 3.20 in the study group and was similar to that of the control group.

In the studies by Buser et al.,[2] Blanchette et al.,[3] and Kolderup et al.,[4] the requirement of augmentation is less in the misoprostol group, that is, 50%–63%. In the study by Buser et al.,[2] 88% patients delivered within 24 h in the misoprostol group and 49.3% patients in the dinoprostone group. In the studies by Blanchette et al.,[3] Kolderup et al.,[4] and Wing et al.,[5] more than 70% patients in the misoprostol group delivered within 24 h and less than 50% patients in the dinoprostone group delivered within 24 h. In the study by Wing et al., 8.8% patients in the misoprostol group demonstrated thin meconium and 19.2% patients demonstrated thick meconium at the time of delivery. In the study by Garry et al., the interval from the start of induction to vaginal delivery (794.5 ± 408 min vs. 1005.3 ± 523 min; $p < 0.02$) was significantly shorter in the misoprostol group. Women receiving misoprostol were more likely to deliver vaginally both in <12 h (44% vs. 12%; $p < 0.0001$) and <24 h (68% vs. 38%; $p < 0.001$).[6] In the study by Agarwal et al., the Bishop score rise after 6 h of initiation of therapy was significantly higher in the misoprostol group than in the dinoprostone group (2.98 ± 2.57 vs. 2.05 ± 1.83; $p = 0.04$). The need of oxytocin augmentation was reduced in the misoprostol versus dinoprostone group (16.6% vs. 78.3%; $p < 0.001$). Induction delivery interval was shorter in the misoprostol group (12.8 ± 6.4 h) than in the dinoprostone group (18.53 ± 8.5 h; $p < 0.01$).[7] In the study by Ozkan et al., thetime interval from induction to vaginal delivery was found to be significantly shorter in the misoprostol group when compared with dinoprostone subjects (680 ± 329 min vs. 1070 ± 435 min; $p < 0.001$). Vaginal delivery rates within 12 h were found to be significantly higher with misoprostol induction [$n = 37$ (66%) vs. $n = 25$ (44.6%); $p = 0.02$], whereas vaginal delivery rates within 24 h did not differ significantly between groups [$n = 41$ (73.2%) vs. $n = 36$ (64.2%); $p = 0.3$]. More subjects required oxytocin augmentation in the dinoprostone group [$n = 35$ (62.5%) vs. $n = 20$ (35.7%); $p = 0.005$], and cardiotocography tracings revealed early decelerations occurring more frequently with the misoprostol induction (10.7% vs. 0%; $p = 0.03$).[8]

Conclusion

Vaginal misoprostol is safe and effective for induction of labor with lesser need of oxytocin augmentation and shorter induction delivery interval and may have some advantages compared with dinoprostone and Foley's catheter including improved efficacy, lesser adverse effect, and lower cost of the drug.

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