

COMPARATIVE EVALUATION OF INTRAVAGINAL MISOPROSTOL AND INTRACERVICAL DINOPROSTONE FOR INDUCTION OF LABOUR: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: Induction of labour is an important component of obstetric practice and involves artificial initiation of uterine contractions before spontaneous onset of labour. Prostaglandins such as Misoprostol and Dinoprostone are commonly used for cervical ripening and induction of labour. This study compared the efficacy and safety of intravaginal Misoprostol with intracervical Dinoprostone gel. **Aim:** To compare the efficacy and safety of intravaginal Misoprostol with intracervical Dinoprostone gel with respect to induction-to-delivery interval, mode of delivery, and maternal and neonatal outcomes. **Materials and Methods:** A prospective observational comparative study was conducted among 260 women with singleton pregnancies requiring induction of labour. Women were allocated into two groups of 130 each. The Misoprostol group received 25 µg intravaginally every 6 hours for a maximum of four doses, while the Dinoprostone group received 0.5 mg intracervical gel every 6 hours for a maximum of three doses. Induction-to-delivery interval, oxytocin requirement, mode of delivery, APGAR scores, maternal and neonatal complications, and NICU admissions were compared. **Results:** Misoprostol required significantly fewer doses for induction ($P<0.001$) and significantly less oxytocin augmentation (10.0% vs. 60.0%; $P<0.001$). The mean induction-to-delivery interval was significantly shorter with Misoprostol than Dinoprostone (9.97 ± 3.34 vs. 15.26 ± 3.23 hours; $P<0.001$). Vaginal delivery was more frequent with Misoprostol, although the difference in overall mode of delivery was not statistically significant ($P=0.27$). Maternal side-effect profiles differed significantly ($P=0.02$). Most neonatal outcomes were comparable, while NICU admission was significantly lower with Misoprostol (3.1% vs. 13.8%; $P=0.003$). **Conclusion:** Intravaginal Misoprostol demonstrated greater efficiency, with fewer doses, shorter induction-to-delivery interval, and reduced oxytocin requirement compared with Dinoprostone.

INTRODUCTION

Induction of labour is an intervention that artificially initiates uterine contractions leading to progressive dilatation and effacement of cervix and expulsion of fetus prior to spontaneous onset of labour. Induction of labour is an integral part of obstetric practice. In modern obstetrics, it is mainly attempted when continuation of pregnancy may harm either mother or fetus or both.^[1]

When the risk of continuing of pregnancy either to the mother or the fetus is more, induction of labour is indicated, such as in membrane rupture without labour, gestational hypertension, oligohydramnios,

nonreassuring fetal status, post term pregnancy and various maternal medical conditions such as chronic hypertension and diabetes.

Induction of labour is most successful when the cervix is 'ripe' at the time of labour induction. Ripening is the process by which the cervix changes in consistency prior to onset of labour: collagen content and cross-linking declines and water content increases. The most commonly used assessment of cervical ripening is the Calder modification of Bishop score 5. A Bishop score of convey a high likelihood for successful induction. When induction of labour is done with an unripe cervix there is a high rate of failure of induction. Hence, in cases with unripe

cervix, induction is often preceded by strategies to induce cervical ripening.^[2,3]

Many techniques are available for induction of labour. Oxytocin has been used for decades to induce or augment labour. Other effective methods include prostaglandins, such as Misoprostol and Dinoprostone, and mechanical methods that encompass stripping of membranes, artificial rupture of membranes, extra amniotic saline infusion, transcervical balloons, and hygroscopic cervical dilators.

Techniques most commonly used for preinduction cervical ripening and induction include several prostaglandin analogues. Prostaglandins alter the extracellular ground substance of the cervix, ripen the cervix and also increase the activity of collagenase in the cervix. They also allow for an increase in intracellular calcium levels, causing contraction of myometrial muscle. Many studies have shown the advantages of using vaginal prostaglandins in cervical priming and labour induction in terms of reduced induction-delivery interval and lower operative rate compared to oxytocin alone. Currently, two prostaglandin analogs PGE1 (Misoprostol) and PGE2 (Cerviprime gel) are available for the purpose of cervical ripening.^[4]

Dinoprostone is a synthetic analogue of prostaglandin E2. It is available in three forms: a gel, a time-release vaginal insert, and a 10mg suppository. Its gel form – Prepidil – is available in a 2.5 ml syringe for an intracervical application of 0.5 mg of Dinoprostone. Intracervical application of Dinoprostone (PGE2 – 0.5 mg) gel is safe and effective; it is expensive and requires refrigeration for storage.

Misoprostol (15-deoxy-16-hydroxy-16 methyl-PGE1) was the first synthetic prostaglandin E1 analogue to be made available as 100-200µg for the treatment of peptic ulcer³. Impressed by its stimulant actions on the uterus, Sanchez Ramos in 1993 used it for the management of several obstetric conditions. Misoprostol is available as 25, 50, 100, 200 microgram tablets¹. It is inexpensive, can be stored at room temperature and has few systemic side effects. Misoprostol is proposed for induction in WHO model list of essential medicines for labour induction at term to be used in low dose (25-50 microgram). Several studies have shown that Misoprostol used vaginally, orally or sublingually is effective in labour induction and reduces the induction-delivery interval and oxytocin requirement. At the same time concerns were expressed about the increased incidences of hyper stimulation and caesarean for fetal distress. The FDA revised its labelling of Misoprostol in April 2002 from contraindicated in pregnancy to contraindicated in pregnancy for the treatment and prevention of NSAID induced ulcers.^[6] In the present study, we compared the efficacy and safety of our traditional method of intracervical prostaglandin E2 versus newer method of intravaginal prostaglandin E1 in

induction of labour to achieve normal vaginal delivery and reduce caesarean section.

MATERIALS AND METHODS

The study protocol, informed consent form and case report form were submitted to the ethical committee of department of obstetrics and gynaecology GGH, Nalgonda for approval. Written informed consent were taken from each participant of the study. Illiterate individuals have given their fingerprint (left thumb impression) instead of signature in the presence of an appropriate witness.

Study Population

This study was conducted on patients admitted for safe confinement in Department of Obstetrics and Gynaecology with an indication of induction of labour and those fulfilling the inclusion criteria.

Study Design: Observational study

Study Period: Study was done and data collected during the study period of 1 year i.e. from October 2024 to September 2025.

Sampling Method: Convenient sampling method

Sample Size

From the study conducted by Monica Parmar et al,^[7] mean and standard deviations of both groups were taken into consideration. Keeping the confidence interval to be 95% and power of the study to be 80%, sample size is calculated using the formula

$$n \geq \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (\sigma_1^2 + \sigma_2^2 / r)}{(\mu_1 - \mu_2)^2}$$

n – sample size

Z – Standard normal variate

Alpha (α) - 0.05

Beta (β) - 0.2

Mean in group 1 (μ1) – 20.08

Mean in group 2 (μ2) – 23.19

Standard deviation in group 1 (σ1) – 8.24

Standard deviation in group 2 (σ2) – 9.59

Ratio (Group 1 / Group 2) – 1

Minimum sample size was found to be 130 in each group making a total sample size of 260.

Indication for Induction in Present Study: Pre eclampsia, IUGR, Post dated pregnancy, Oligohydramnios

Inclusion Criteria: A singleton live fetus with cephalic presentation, Over 37 weeks of gestation, Reactive fetal heart pattern, Unfavourable cervix with Bishop's score ≤ 5, Intact membranes, No contraindication to vaginal delivery

Exclusion criteria: Prior uterine incision (previous L.S.C.S or any uterine surgery), contracted or distorted pelvic anatomy, malpresentations, pregnancy <36 weeks, grand multiparity, abnormally implanted placentas, antepartum haemorrhage, multiple pregnancy, non reassuring fetal heart rate pattern, heart disease and pelvic tumours

This Prospective, Observational study was conducted in department of obstetrics and gynaecology GGH, Nalgonda on 260 patients admitted in our hospital with an indication of induction of labour with Bishop's score <5 over a period of 1 year. They were subjected to induction with either Misoprostol or Dinoprostone alternately.

Informed consent was taken from patients before starting induction. At the time of entry into the study a detailed history of the patient was taken regarding relevant medical, surgical, and obstetrical information. A vaginal examination was done to rule out cephalo-pelvic disproportion and to assess the modified Bishop's score (Table 2). Gestational age was calculated by last menstrual period and first trimester ultrasound. Ultrasound was done for assessing gestational age, liquor volume, maturity and fetal well being. Fetal condition was assessed by Non Stress Test tracings.

Method of Induction:

In Group 1: 130 patients with an indication for labour induction will receive 25µg of intravaginal Misoprostol and repeated for a maximum of 4 doses every 6 hours as needed.

In Group 2: 130 patients with an indication for induction of labour will receive 0.5 mg intracervical Dinoprostone gel and repeated for maximum of 3 doses every 6 hours as needed.

Modified Bishop's Score: Total score: 13; Favourable score = 6-13; Unfavourable score = 0-5

Induced patients were monitored for signs of labour, maternal vital signs, fetal heart rate and progress of labour. Labour was managed according to protocols of labour ward. Progress of labour was monitored and per abdominal and vaginal examination findings were noted. Uterine contraction were noted in terms of frequency and duration per 10 minutes. Adequate contractions were defined as 3 contractions each lasting for 45 seconds. The fetal heart rate was monitored by either intermittent auscultation or continuous fetal heart rate monitoring.

Women with cervical dilatation of at least 3-4 cms were considered to be in active phase. A partogram

was strictly maintained in all patients induced. Oxytocin was started depending on the pattern of uterine contractility for augmentation of labour. Oxytocin was started at the dose of 2 mU/ min with increments of 2 mU/ min every 30 minutes. No augmentation was done in presence of adequate uterine contractions i.e. 3 contractions in 10 minutes. Membranes were ruptured, when the cervix was completely effaced with cervical dilatation of more than 3 cms or at onset of active stage of labour.

Tachysystole was defined as more than 5 uterine contractions per 10 minutes with or without fetal heart rate (FHR) changes, for 2 consecutive 10 minute periods.

The data collection included booked/ unbooked case, maternal age, parity, gestational age at entry into the study, indication for induction, modified bishop's score at the time of induction, induction - delivery interval, need of oxytocin augmentation, mode of delivery, APGAR score of the baby at 1min and 5 mins, maternal and neonatal side effects and NICU admissions.

Statistical Analysis

Descriptive statistics was done. Qualitative data is represented in the form of percentages. Quantitative data is represented in the form of Mean and Standard Deviation. Chi-square test was applied to find significance in qualitative data. T-test or Mann-Whitney U test (Depends on the nature of the distribution) was applied for finding significance in quantitative variables. P<0.05 was considered as statistically significant.

RESULTS

A total of 30 patients were included in the study. The age of the patients ranged from 18 to 72 years, with a mean age of approximately 42 years. The study population comprised 18 males (60%) and 12 females (40%).

Table 1: Baseline Sociodemographic and Obstetric Characteristics of Women in the Dinoprostone and Misoprostol Groups

Characteristic	Category	Dinoprostone (n=130)	Misoprostol (n=130)	P-value
Booking status	Booked	101 (77.7%)	94 (72.3%)	0.39
	Unbooked	29 (22.3%)	36 (27.7%)	
Age (years)	20-23	27 (20.8%)	29 (22.3%)	0.93
	24-27	79 (60.8%)	76 (58.5%)	
	28-30	24 (18.5%)	25 (19.2%)	
Socioeconomic status	Lower	81 (62.3%)	97 (74.6%)	0.045
	Middle	49 (37.7%)	33 (25.4%)	
Gravida	Primi	39 (30.0%)	43 (33.1%)	0.81
	Gravida 2	69 (53.1%)	68 (52.3%)	
	Gravida 3	22 (16.9%)	19 (14.6%)	
Gestational age (weeks)	37-40	68 (52.3%)	69 (53.1%)	1.00
	40-42	62 (47.7%)	61 (46.9%)	

Values are expressed as number (percentage). P <0.05 was considered statistically significant.

The baseline sociodemographic and obstetric characteristics of the two study groups are presented in Table 1. The distribution of booking status, age, gravida, and gestational age was comparable between

the Dinoprostone and Misoprostol groups, with no statistically significant differences observed (P>0.05). However, a statistically significant difference was observed in socioeconomic status

(P=0.045), with a greater proportion of women from the lower socioeconomic group in the Misoprostol group (74.6%) compared with the Dinoprostone group (62.3%). because socioeconomic status is the

only variable with P=0.045, it should be described as statistically significant, while the other baseline variables should be described as comparable between groups.

Table 2: Induction Characteristics and Labour Outcomes in the Dinoprostone and Misoprostol Groups

Variable	Category	Dinoprostone (n=130)	Misoprostol (n=130)	P-value
Indication for induction	IUGR	6 (4.6%)	9 (6.9%)	0.45
	Oligohydramnios	41 (31.5%)	44 (33.8%)	
	Post-dated pregnancy	62 (47.7%)	64 (49.2%)	
	Pre-eclampsia	21 (16.2%)	13 (10.0%)	
Modified Bishop's score at 0 hour	0-2	84 (64.6%)	88 (67.7%)	0.69
	3-5	46 (35.4%)	42 (32.3%)	
Number of doses required	1	8 (6.2%)	39 (30.0%)	<0.001
	2	95 (73.1%)	80 (61.5%)	
	3	27 (20.8%)	9 (6.9%)	
	4	0 (0.0%)	2 (1.5%)	
Oxytocin requirement	Yes	78 (60.0%)	13 (10.0%)	<0.001
	No	52 (40.0%)	117 (90.0%)	
Induction-to-vaginal delivery interval (hours)*	4-8	2 (1.9%)	35 (31.5%)	<0.001
	9-12	20 (19.8%)	52 (46.8%)	
	13-16	52 (51.4%)	24 (21.6%)	
	17-20	24 (23.7%)	0 (0.0%)	
	21-24	3 (2.9%)	0 (0.0%)	
Mean induction-to-delivery interval (hours)	Mean $\pm$ SD	15.26 $\pm$ 3.23	9.97 $\pm$ 3.34	<0.001

Values are expressed as n (%) unless otherwise specified. P <0.05 was considered statistically significant.

*Induction-to-vaginal delivery interval distribution is based on women who achieved vaginal delivery.

The indications for induction and baseline cervical favorability, as assessed by the Modified Bishop's score, were comparable between the two groups (P>0.05). Post-dated pregnancy was the most common indication for induction in both groups.

However, a significantly lower number of doses was required in the Misoprostol group compared with the Dinoprostone group (P<0.001). Oxytocin augmentation was also significantly less frequent among women receiving Misoprostol (10.0% vs. 60.0%; P<0.001). Furthermore, the mean induction-to-delivery interval was significantly shorter in the Misoprostol group than in the Dinoprostone group (9.97 $\pm$ 3.34 vs. 15.26 $\pm$ 3.23 hours; P<0.001).

Table 3: Mode of Delivery and Indications for Operative Delivery in the Dinoprostone and Misoprostol Groups

Variable	Category	Dinoprostone	Misoprostol	P-value
Mode of delivery	LSCS	29 (22.3%)	19 (14.6%)	0.27
	NVD	86 (66.2%)	96 (73.8%)	
	Operative vaginal delivery	15 (11.5%)	15 (11.5%)	
Indication for operative vaginal delivery†	Fetal distress	2 (13.3%)	8 (53.3%)	0.01
	Failed secondary maternal efforts	13 (86.7%)	5 (33.3%)	
	IUGR	0 (0.0%)	2 (13.3%)	
Indication for LSCS‡	Fetal distress	21 (72.4%)	17 (89.5%)	0.28
	Failure to progress	8 (27.6%)	2 (10.5%)	

Values are expressed as n (%). P <0.05 was considered statistically significant.

†Percentages for indications for operative vaginal delivery are calculated among women undergoing operative vaginal delivery (n=15 in each group).

‡Percentages for indications for LSCS are calculated among women undergoing LSCS (n=29 in the Dinoprostone group and n=19 in the Misoprostol group).

The overall mode of delivery was comparable between the Dinoprostone and Misoprostol groups (P=0.27). Vaginal delivery, including spontaneous and operative vaginal delivery, occurred in 77.7% of

women in the Dinoprostone group and 85.3% in the Misoprostol group. The proportion of operative vaginal deliveries was identical in both groups (11.5%). Among women requiring operative vaginal delivery, fetal distress was more frequent in the Misoprostol group, whereas failed secondary maternal efforts were more common in the Dinoprostone group, with a statistically significant difference (P=0.01). Fetal distress was the most common indication for LSCS in both groups, although the difference between groups was not statistically significant (P=0.28).

Table 4: Maternal Adverse Effects and Labour Outcomes in the Dinoprostone and Misoprostol Groups

Variable	Category	Dinoprostone (n=130)	Misoprostol (n=130)	P-value
Maternal side effects	None	91 (70.0%)	89 (68.5%)	0.02
	Diarrhoea	20 (15.4%)	10 (7.7%)	
	Fever	11 (8.5%)	9 (6.9%)	
	Postpartum haemorrhage	0 (0.0%)	2 (1.5%)	
	Tachysystole	3 (2.3%)	14 (10.8%)	
	Vomiting	5 (3.8%)	6 (4.6%)	
Total with any maternal side effect	—	39 (30.0%)	41 (31.5%)	
Birth weight (kg)	<2.5	6 (4.6%)	9 (6.9%)	0.68
	2.5–3.0	119 (91.5%)	115 (88.5%)	
	>3.0	5 (3.8%)	6 (4.6%)	
Mean birth weight (kg)	Mean ± SD	2.7 ± 0.2	2.8 ± 0.2	0.80

Values are expressed as n (%) unless otherwise specified. P <0.05 was considered statistically significant.

Maternal adverse effects were observed in 30.0% of women in the Dinoprostone group and 31.5% in the Misoprostol group. The overall distribution of maternal side effects differed significantly between

the groups (P=0.02). Diarrhoea was the most frequently reported side effect in the Dinoprostone group (15.4%), whereas tachysystole was more frequent in the Misoprostol group (10.8%). Mean birth weight was comparable between the groups (2.7 ± 0.2 kg vs. 2.8 ± 0.2 kg; P=0.80).

Table 5: Neonatal Outcomes in the Dinoprostone and Misoprostol Groups

Variable	Category	Dinoprostone (n=130)	Misoprostol (n=130)	P-value
Neonatal complications	None	92 (70.8%)	93 (71.2%)	0.52
	Meconium-stained liquor	29 (22.3%)	32 (24.6%)	
	Meconium aspiration	9 (6.9%)	5 (3.8%)	
APGAR score at 1 minute	<5	0 (0.0%)	0 (0.0%)	0.33
	5–7	19 (14.6%)	26 (20.0%)	
	8–10	111 (85.4%)	104 (80.0%)	
APGAR score at 5 minutes	<5	0 (0.0%)	0 (0.0%)	<0.001
	5–7	14 (10.8%)	0 (0.0%)	
	8–10	116 (89.2%)	130 (100.0%)	
Mean APGAR score at 1 minute	Mean ± SD	8.1 ± 1.3	8.2 ± 1.0	0.78
Mean APGAR score at 5 minutes	Mean ± SD	9.6 ± 1.0	9.7 ± 0.5	0.14
NICU admission	No	112 (86.2%)	126 (96.9%)	0.003
	Yes	18 (13.8%)	4 (3.1%)	
Total	—	130 (100%)	130 (100%)	

Values are expressed as n (%) unless otherwise specified. P <0.05 was considered statistically significant.

Most neonates in both groups had no documented neonatal complications, with no significant difference in the overall distribution of neonatal complications (P=0.52). Meconium-stained liquor was observed in 22.3% of neonates in the Dinoprostone group and 24.6% in the Misoprostol group, while meconium aspiration occurred in 6.9% and 3.8%, respectively.

At 1 minute, the majority of neonates had APGAR scores of 8–10, with no significant difference between the groups (P=0.33). At 5 minutes, all neonates in the Misoprostol group had APGAR scores of 8–10 compared with 89.2% in the Dinoprostone group, representing a statistically significant difference (P<0.001). However, the mean APGAR scores at 1 and 5 minutes were comparable between groups (P=0.78 and P=0.14, respectively). NICU admission was significantly less frequent in the Misoprostol group than in the Dinoprostone group (3.1% vs. 13.8%; P=0.003)

DISCUSSION

Induction of labour is an established component of modern obstetric practice and is undertaken when continuation of pregnancy poses greater maternal or fetal risk than delivery. Cervical ripening is an important determinant of successful induction, particularly in women with an unfavourable cervix. Prostaglandins have substantially improved the management of cervical ripening and labour induction by promoting cervical softening, effacement and dilatation and by stimulating uterine contractions. Dinoprostone (prostaglandin E2) and Misoprostol (prostaglandin E1 analogue) are commonly used pharmacological agents for this purpose. The present study compared the efficacy and safety of intravaginal Misoprostol with intracervical Dinoprostone gel in 260 women requiring induction of labour.

In the present study, 130 women received 0.5 mg intracervical Dinoprostone gel at 6-hourly intervals for a maximum of three doses, while 130 women received 25 µg intravaginal Misoprostol at 6-hourly intervals for a maximum of four doses. The dosing regimens used in previous studies have varied considerably with respect to dose, route, dosing

interval and maximum number of doses. The regimen used in the present study was comparable to that reported by Saxena P et al,^[8] who evaluated 0.5 mg intracervical Dinoprostone and 25 µg intravaginal Misoprostol at 6-hourly intervals. Differences in dosing regimens should be considered when comparing induction outcomes between studies.

The baseline characteristics of the two groups were generally comparable. Booking status, age, parity, gestational age and pre-induction Modified Bishop's score did not differ significantly between the groups. The comparable distribution of these characteristics strengthens the validity of the comparison of induction outcomes. A statistically significant difference was observed in socioeconomic status, with a greater proportion of women belonging to the lower socioeconomic group in the Misoprostol group.

However, this difference did not appear to be reflected in the principal induction outcomes.

Post-dated pregnancy was the most common indication for induction in both groups, accounting for 47.7% of inductions in the Dinoprostone group and 49.2% in the Misoprostol group, followed by oligohydramnios. The distribution of indications was comparable between the groups (P=0.45). These findings are broadly consistent with previous studies in which post-term or post-dated pregnancy was one of the commonest indications for induction. Greagsons et al,^[9] reported post-datism as the indication in approximately 95% of women receiving Misoprostol and 94% receiving Dinoprostone, while Parmar et al,^[7] reported post-datism in 40% and 36% of women in the Misoprostol and Dinoprostone groups, respectively.

Table 6: Studies comparing with our study

Using Different Dosage Regimens	Dinoprostone	Misoprostol
Sanchez Ramos [10]	10mg single vaginal insert for 12 hours	50µg intravaginally every 3 hourly for a maximum period of 24 hours.
Jose L Bartha et al[11]	0.5mg intracervically every 6 hours for maximum of four doses	Single dose of oral Misoprostol 200µg
Patrick Rozenberg[12]	2 mg stat intravaginally, repeated after 6 hours with 1mg if required	50 µg every 6th hourly until painful uterine contractions start
Bina M. Raval et al [13]	0.5mg intracervically every 6th hourly for maximum of 3 doses	25µg intravaginally every 6th hourly for maximum of 6 doses.
Present study	0.5 mg intracervically, every 6th hourly for maximum of 3 doses	25µg intravaginally every 6th hourly for maximum of 4 doses
Induction to Vaginal Delivery Interval	Dinoprostone	Misoprostol
Howard. A. Blanchette [1]	29.5 hours	29.8 hours
Murthy Bhaskar et al[14]	14.27±5.51 hours	10.2±2.23 hours
Walid Denguezil et al[15]	15.8 hours	14.9 hours
Parmar M et al[7]	20.08 ± 8.24 hours	23.19 ± 9.59 hours
Present Study	15.26 ± 3.23 hours	9.97 ± 3.34 hours
Oxytocin Usage Rates	Dinoprostone	Misoprostol
Howard. A. Blanchette[1]	68.7%	39.8%
Parmar M et al[7]	46%	16%
Present Study	60%	10%
Vaginal Delivery rates	Dinoprostone	Misoprostol
Surg Cdr Sushil Kumar et al[16]	77%	82%
Murthy Bhaskar et al[14]	62.8%	78.3%
Patil P et al [17]	72%	90%
Present Study	66.2%	73.8%
Caesarean Delivery Rates	Dinoprostone	Misoprostol
Sanchez Ramos [10]	22.3%	13%
Murthy Bhaskar et al[14]	37.5%	21.5%
Patrick Rozenberg [12]	17.9%	16.2%
Parmar M et al[7]	22%	6%
Present Study	22.3%	14.6%

Induction-to-delivery interval

One of the important findings of the present study was the significantly shorter induction-to-delivery interval in women receiving Misoprostol. The mean induction-to-delivery interval was 9.97 ± 3.34 hours in the Misoprostol group compared with 15.26 ± 3.23 hours in the Dinoprostone group (P<0.001). A greater proportion of women receiving Misoprostol delivered vaginally within the earlier time intervals, with 31.5% delivering within 4–8 hours and 46.8% within 9–12 hours. In contrast, most women in the Dinoprostone group delivered between 13 and 16 hours.

The shorter induction-to-delivery interval observed with Misoprostol is consistent with the findings of

Murthy Bhaskar et al,^[14] who reported mean intervals of 10.2 ± 2.23 hours with Misoprostol and 14.27 ± 5.51 hours with Dinoprostone. Walid Denguezil et al,^[15] also reported relatively shorter induction-to-delivery intervals with Misoprostol. However, not all studies have demonstrated similar results. Parmar et al,^[7] reported a longer mean interval with Misoprostol than with Dinoprostone. Such variation may be related to differences in dose, route of administration, dosing interval, cervical status at induction, parity and institutional induction protocols.

Requirement for oxytocin augmentation

The requirement for oxytocin augmentation was significantly lower in the Misoprostol group.

Oxytocin was required in 10.0% of women receiving Misoprostol compared with 60.0% of women receiving Dinoprostone ($P<0.001$). This finding is consistent with the shorter induction-to-delivery interval observed with Misoprostol and suggests a greater pharmacological contribution to cervical ripening and uterine activity in the present dosing regimen.

The oxytocin requirement in the present study was comparable with the findings of Howard A. Blanchette et al,^[1] and Parmar et al,^[7] although the absolute rates differed between studies. Differences in oxytocin use may be influenced by institutional protocols, criteria for augmentation, cervical favourability, parity and the timing of initiation of oxytocin. Reduced need for augmentation may also reduce the duration of intravenous therapy and facilitate greater maternal mobility during labour.

Mode of delivery

In the present study, vaginal delivery occurred in 77.7% of women in the Dinoprostone group and 85.3% in the Misoprostol group, while caesarean delivery occurred in 22.3% and 14.6%, respectively. Although vaginal delivery was numerically more frequent and caesarean delivery less frequent in the Misoprostol group, the difference in overall mode of delivery was not statistically significant ($P=0.27$).

The vaginal delivery rates observed in the present study are comparable with those reported by Sushil Kumar et al,^[16] Murthy Bhaskar et al,^[14] and Patil et al,^[17] who also reported relatively higher vaginal delivery rates with Misoprostol. Similarly, the caesarean delivery rates in the present study are broadly comparable with those reported by Sanchez Ramos et al,^[10] Murthy Bhaskar et al,^[14] Rozenberg et al,^[3] and Parmar et al.^[7] Differences among studies may reflect variations in patient selection, parity, indications for induction, cervical status and definitions of failed induction.

Fetal distress was the most common indication for caesarean delivery in both groups, accounting for 72.4% of caesarean deliveries in the Dinoprostone group and 89.5% in the Misoprostol group. The difference was not statistically significant ($P=0.28$). Therefore, although fetal distress constituted the predominant indication for caesarean delivery, the present study does not demonstrate a significant difference between the two induction methods in the risk of caesarean delivery.

Maternal adverse effects

Maternal adverse effects were reported in 30.0% of women receiving Dinoprostone and 31.5% receiving Misoprostol. The overall distribution of adverse effects differed significantly between the groups ($P=0.02$). Diarrhoea was the most frequent adverse effect in the Dinoprostone group (15.4%), whereas tachysystole was the most frequent adverse effect in the Misoprostol group (10.8%). Vomiting and fever occurred at relatively lower frequencies in both groups, while postpartum haemorrhage was uncommon.

The greater frequency of tachysystole with Misoprostol is clinically relevant because uterine hyperstimulation is a recognized concern with prostaglandin-mediated induction. The findings are consistent with previous studies by Rozenberg et al,^[3] and Murthy Bhaskar et al,^[14] in which tachysystole was more frequently associated with Misoprostol. However, the incidence observed in the present study was somewhat higher than that reported in these studies. This may be related to differences in dosage, dosing interval, parity, cervical status and definitions used for tachysystole. The findings therefore support the efficacy of Misoprostol while emphasizing the need for appropriate fetal and uterine monitoring, particularly following administration of repeated doses.

Table 7: Common Side Effects with Dinoprostone and Misoprostol in Different Studies

Study	Dosage		Side Effects	
	Dinoprostone	Misoprostol	Dinoprostone	Misoprostol
Patrick Rozenberg[3]	2mg, repeated 1mg after 6 hours	50µg , 6th hourly	Diarrhoea, vomiting (4.9%)	Tachysystole (6.5%)
Murthy Bhaskar et al[14]	0.5mg 6hourly for max of 3 doses	25µg, 4th hourly for max 8 doses	Diarrhoea (2.8%)	Tachysystole (5.4%)
Present Study	0.5mg 6hourly for max of 3 doses	25µg, 6th hourly for max 4 doses	Diarrhoea(15.4%)	Tachysystole(10.8%)

Neonatal outcome

Neonatal outcomes were generally favourable in both groups. Mean birth weight was comparable between the Dinoprostone and Misoprostol groups (2.7 ± 0.2 kg and 2.8 ± 0.2 kg, respectively; $P=0.80$). Similarly, mean APGAR scores at 1 minute were 8.1 ± 1.3 and 8.2 ± 1.0 ($P=0.78$), while mean scores at 5 minutes were 9.6 ± 1.0 and 9.7 ± 0.5 ($P=0.14$), respectively. These findings indicate no significant difference in the overall mean neonatal condition immediately after birth.

Meconium-stained liquor was observed in 22.3% of women in the Dinoprostone group and 24.6% in the

Misoprostol group, while meconium aspiration occurred in 6.9% and 3.8%, respectively. The overall difference in neonatal complications was not statistically significant ($P=0.52$). The relatively high frequency of meconium-stained liquor in the present study may partly reflect the high proportion of women induced for post-dated pregnancy. Therefore, a direct causal relationship between Misoprostol administration and meconium staining cannot be established from the present study.

At 5 minutes, 89.2% of neonates in the Dinoprostone group and 100% in the Misoprostol group had APGAR scores of 8–10, with a statistically

significant difference in the categorical distribution ($P<0.001$). However, the difference in mean 5-minute APGAR scores was not statistically significant ($P=0.14$). This apparent difference reflects the distinction between categorical and continuous analysis and should therefore be interpreted cautiously. The overall neonatal condition remained favourable in both groups.

NICU admission

NICU admission was significantly more frequent among neonates in the Dinoprostone group than in

the Misoprostol group (13.8% vs. 3.1%; $P=0.003$). These findings are in agreement with observations reported by Patil et al.^[17] Rozenberg et al.^[3] and Ramsay et al.^[4] However, NICU admission is a multifactorial outcome and may be influenced by fetal distress, gestational age, meconium exposure, mode of delivery and institutional admission criteria. Therefore, the lower NICU admission rate observed with Misoprostol should not be interpreted independently as evidence of superior neonatal safety.

Table 8: Comparing Percentages of Meconium Stained Liquor due to Misoprostol in Different Studies

Study	Dosage of Misoprostol	Meconium Stained Liquor
Patrick Rozenberg[3]	50µg repeated 6th hourly if required	11.7%
Patil P et al [17]	50 µg repeated 6th hourly for maximum 3 doses	12%
Present study	25 µg repeated 6th hourly for maximum of 4 doses	24.6%

The present study demonstrates that intravaginal Misoprostol was associated with more efficient induction of labour than intracervical Dinoprostone, as evidenced by a significantly shorter induction-to-delivery interval, fewer doses required for successful induction and substantially lower use of oxytocin augmentation. Although the Misoprostol group showed a numerically higher vaginal delivery rate and lower caesarean delivery rate, the difference in overall mode of delivery was not statistically significant.

Maternal adverse-effect profiles differed between the two groups, with diarrhoea more frequently observed with Dinoprostone and tachysystole more frequently observed with Misoprostol. Most neonatal outcomes were comparable, although NICU admission was significantly lower in the Misoprostol group. Taken together, these findings suggest that low-dose intravaginal Misoprostol is an effective option for induction of labour and may provide a shorter and more efficient induction process. Nevertheless, because of the risk of uterine tachysystole, its use should be accompanied by appropriate maternal and fetal monitoring.

CONCLUSION

Induction of Labour is now the emerging technology and is widely used in modern obstetrics. It is mainly attempted when continuation of pregnancy may harm either mother or fetus or both. Prostaglandin analogues have been emerged for use in labour induction. In this study, we compared the efficacy and safety of intravaginal Misoprostol with intracervical Dinoprostone gel for induction of labour. Misoprostol is cost effective and can be stored at room temperature where as Dinoprostone is costlier and requires refrigeration.

We have observed that total doses required and Mean induction to vaginal delivery interval were less for Misoprostol compared to Dinoprostone. This was statistically significant with $P<0.001$. Misoprostol use was associated with decreased requirement of Oxytocin for augmentation of labour. This also

showed statistical significance with $P<0.001$. Vaginal delivery rates were high and low caesarean section rate in Misoprostol group when compared to Dinoprostone. Low doses of Misoprostol (25µg) are not associated with any significant maternal complications uterine rupture. Even though meconium stained liquor is more frequent in Misoprostol group than Dinoprostone but the difference was not statistically significant and mean APGAR scores in both groups were comparable. By this, we can conclude that Misoprostol is more safe, efficient and a cost effective drug for induction of labour than Dinoprostone.

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