

Safety And Efficacy Of Intra Vaginal Misoprostol Tablet Versus Intra Cervical Dinoprostone Gel For Cervical Ripening And Induction Of Labour

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Abstract:

Objective of the study: To compare the safety and efficacy of intra-vaginal Misoprostol with intra-cervical Dinoprostone gel for induction of labour.

Materials and Methods: 120 Patients who required labour induction were included in this prospective cross sectional study from January 2017 to December 2017 at Department of Obstetrics and Gynaecology, Patliputra Medical College, Dhanbad, Jharkhand. 60 of them received 0.5mg intra-cervical Dinoprostone gel (PGE2) and 60 patients received 25 mcg of intra-vaginal Misoprostol tablet and dose was repeated every 4 hours for up to maximum of 3 doses. Factors such as parity, GA, induction to delivery time, indication for induction, No. of doses required, need of Oxytocin, MBS prior to induction, mode of delivery, indication for C- section, side effects, No. of NICU admissions and indication, MSL were studied in detail.

Results: 120 antenatal women requiring induction of labour were followed 60 patients received 25 g misoprostol 4th hourly, 60 patients received 0.5 mg of intracervical dinoprostol gel 12 hourly. The result of the study shows induction delivery interval was significantly shorter in misoprostol group than dinoprostone group. Caesarean section rate is low in misoprostol group compared to dinoprostone group. With the lower dosage of misoprostol, no maternal complications were observed and foetal complication i.e., meconium stained liquor was seen in 8% of misoprostol group, but Apgar score was good in both group.

Conclusion: Both Misoprostol and PGE2 are safe and effective drugs for cervical ripening and labour induction but Misoprostol is more cost effective and stable at room temperature and induction to delivery time was significantly less with it but more side effects were seen. No. of doses required were less with PGE2. Failure of induction was more with PGE2 and fetal distress was more with Misoprostol. These findings suggest that Misoprostol is safe, effective and less expensive drug for cervical ripening and induction of labour.

Keywords: Dinoprostone; Misoprostol; Induction of labour; Modified Bishop score; vaginal delivery; C- section.

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I. Introduction:

Labour is a final consequence of Pregnancy and is inevitable. The timing of onset of labour may vary widely, but it will happen sooner or later. Induction of labour implies the artificial initiation of uterine contractions after period of viability for the purpose of vaginal delivery where as augmentation of labour is a process of stimulation of uterine contractions that are already present but found to be inadequate [1]. Induction of labour is indicated when continuation of pregnancy risks the life of mother or fetus. The baby should be delivered in a good condition, in an acceptable time frame and with minimum maternal discomfort and least side effects.

In order to be successful, induction of labour must lead to adequate uterine contractions which increases in frequency, duration and progressive dilatation of cervix. It should result in vaginal delivery, as there is little purpose in bringing about labour as a mere preparation for caesarean section [1]. The aim is to achieve vaginal delivery with minimal risk to mother and fetus. Induction of labour is common procedure of obstetric practice [2]. It is indicated in 10% - 15% [2] of pregnant women.

The cervix is an organ of diverse properties. Ripening of the cervix takes place before the onset of labour resulting in increased softening, effacement. Pharmacologically and physiologically prostaglandins have two direct actions associated with labour. They are ripening of the cervix and myometrial contractility.

The method of administration that has been well known is endocervical Dinoprostone or prostaglandin E2. Though this is widely used, the disadvantage is that it is expensive and required refrigeration for storage

with warming before use. Later, a comparably cheap, safe and effective vaginally administered Prostaglandin, which claims to have limited side effects available with the name Misoprostol or PGE1 in tablet form. It does not need any refrigeration. A number of recently published clinical trials abroad and in India have shown that intravaginal Misoprostol is an effective agent for induction of labour and cervical ripening at term, when compared to other methods of labour induction.

In this study, intracervical dinoprostone (PGE2) gel is compared to intravaginal misoprostol in the induction of labour and its efficacy and safety for the mother and fetus.

II. Material And Methodology:

After taking informed consent, 120 patients who have completed 37 weeks of gestation are selected from antenatal ward of OBG department of Department of Obstetrics and Gynaecology, Patliputra Medical College, Dhanbad, Jharkhand, during the period January 2017 to December 2017. Indications for induction of labour were varied. Among the 100 patients half of them were induced with intra vaginal misoprostol of 25 g kept in the posterior fornix of the vagina every 4 hourly for a maximum of 6 doses. In 50 cases induction was carried out by single application of 0.5 g dinoprostone gel.

In some dinoprostone gel instilled cases supplementation was done with oxytocin or misoprostol and results were compared. The inclusion criteria of patients for induction are, women not in active labour with intact membranes and should be

Inclusion Criteria:

1. singleton pregnancy patient,
2. cephalic presentation,
3. completed 37 wks gestation,
4. bishop score less than or equal to 4,
5. contraindications for vaginal delivery like CPD, contracted pelvis and abnormal lie, no contraindications for usage of prostaglandins and no lower genital tract infection.

Exclusion Criteria For Induction:

1. Non reassuring foetal heart pattern.
2. Malpresentations.
3. Multiple pregnancy.
4. Cephalo pelvic disproportion.
5. History of previous caesarean section or scar on the uterus.
6. Antepartum haemorrhage.
7. Grand Multi paras.
8. Allergy to prostaglandins.

The indications for induction taken in this study are (1) Past dates (2) Preeclampsia (3) Oligohydromnios (4) Polyhydromnios.

III. Materials And Methods:

Misoprostol after taking informed consent the 100 g or 200 g tablets were divided into 25 g bits and under aspects precautions, 25 g misoprostol kept in the posterior fornix of vagina, the drug was repeated every 4th hourly until delivery occurs or within 24 hours (up to 6 doses) after starting of induction or method was terminated when the foetal distress or uncontrolled PIH warranted immediate termination by abdominal delivery. PGE2 (Dinoprostone) Gel: dinorpostone gel, in a special syringe with a catheter containing 0.5mg of dinoprostone per 2 gms of gel is instilled into the cervical canal. Following application patient should remain supine position for at least 15-30 minutes to prevent leakage of gel.

Monitoring: The treatment was considered successful if the patient delivered spontaneously within 24 hours. In failed cases the cervical scores were recorded at the end of the study and compared with initial scores. The type of delivery and induction – delivery interval were recorded.

The weight of baby Apgar score at 1 min and 5 min were recorded and neonatal complications were noted.

IV. Results:

120 antenatal women were followed in this study among them 60 were induced with 25 µg misoprostol intra vaginal tablets and rest of the 60 we induces with dinoprostone intra cervical gel.

The demographic features of women, i.e., age, gravidity and parity were similar.

	Misoprostol		Dinoprostone	
	No of cases	Percentage	No of cases	Percentage
Preeclampsia	16	32%	18	30
Oligo and Polyhydromnios	9	18%	10	16
Post dated pregnancy	27	50%	32	54

* P value is <0.9999 (by chi square test) statistically not significant.

The major percentage 52% in misoprostol group, 60% in dinoprostone group had 41-42 weeks of gestational age needed induction for post-dates, 16% in both groups needed induction for oligo and polyhydromnios. 32% in misoprostol group, 24% in Dinoprostone group had need induction for preeclampsia. The prior Bishop Score in both groups were almost similar.

Time in hours	Misoprostol		Dinoprostone	
	No of cases	Percentage	No of cases	Percentage
<0-6	10	16	5	8
7-12	25	41	15	25
13-18	14	23	25	41
19-24	10	16	10	16
>24	1	4	5	10

Table 2: Induction delivery Interval

*P value is 0.0020 (by chi square test) statistically significant.

In this study maximum no of women i.e., (84% in misoprostol group, 68% in dinoprostone group) delivered within 18 hours of induction. No women in misoprostol group >24 hours, where as in dinoprostone group 12% patients took >24 hours for delivery after induction. It is a statically significant, p value: 0.0020.

Time (Hours)	Average Induction delivery interval (hours)		
	Misoprostol group Mean ± SD	Dinoprostone Mean ± SD	Statistical value (p Value)
All patients	(N=60) 11.60+4.769	(N=60) 16.80+5.216	<0.0001 Significant
Primi gravida	(N=38) 12 +4.968	(N=35) 18.46+5.622	<0.0001 Significant
Multi Gravida	(N=22) 9.621+3.077	(N:25) 14.16+3.032	<0.0001 Significant

Table 3: Average induction delivery interval in relation with parity

*P value is 0.0001 (by chi square test) statistically significant.

The induction – delivery interval was significantly shorter in all pregnant women in misoprostol group than in dinoprostone group. In both primigravida and multigravida the observed difference in the induction – delivery interval was statistically significant.

Parameters	Misoprostol		Dinoprostone	
	No of cases	Percentage	No of cases	Percentage
Success rate vaginal delivery	56	93	52	86
Failure rate (caesarian section)	4	7	8	14

Table 4: Success and Failure Rates

*P value is 0.2184 (by chi square test) statistically not significant.

The percentage of women who had vaginal delivery taken as a criteria for success rate, and who had caesarean section taken as a criteria for failure rate, the percentage of success rate is 92% in misoprostol group, 84% were dinoprostone group, caesarean section rate 8% in misoprostol group, 16% in dinoprostone group. But the difference was not statically significant. The indication for caesarean section in both groups was for failed induction, for foetal distress, and for failure to progress.

The foetal complications like meconium stained liquor has occurred in misoprostol group was 8% in dinoprostone group was 4%, but they were not significant.

Apgar		Misoprostol		Dinoprostone	
		No of cases	Percentage	No of cases	Percentage
1 min	<8	0	0	0	0
	>8	60	100%	60	100%
2 min	<8	0	0	0	0
	>8	60	100%	60	100%

Table 5: Foetal Outcome

Apgar scoring in both the groups was same. Even though meconium stained liquor noticed little high in misoprostol group, but APGAR score was same. It is not significant.

Statistical Analysis: The collected data was entered into Microsoft Office Excel - 2007 and date analysis was performed by using the statistical software Graph pad prism - 6. The analyzed data was presented as Mean, Standard deviation (SD) and percentages. Data between misoprostol group and dinoprostone gel group was analyzed by using unpaired t test to find out the differences between the two means and by Chi square t test.

V. Discussion:

Induction of labour with prostaglandins offers the advantage of promoting both cervical ripening and myometrial contractility. The use of prostaglandins for this purpose had been extensively reported. Prostaglandin E1 i.e., misoprostol in this group is compared with the PGE2 Gel.

The present study was undertaken to compare the efficacy of intra vaginal misoprostol tablet with intra cervical dinoprostone gel for cervical ripening and induction of labour. 100 Antenatal women who were having indications for induction, divided into two groups. 50 cases were induced with 25 µg of misoprostol kept in the vagina repeated every 4th hourly for a maximum of 6 doses.

In 50 cases induction was carried out by single application of dinoprostone gel. The dose was repeated only if the patient could afford another dose, otherwise she was supplemented with oxytocin or misoprostol and results were compared. The study group consists of primi gravid to multi gravid. In majority of cases the indication was done past dates. The Bishop Score was almost same in the both groups. 84% in misoprostol group and 68% in dinoprostone group delivered within 18 hours of induction, no women are seen in misoprostol group >24 hours. Where as in dinoprostone group 12% of patients, took >24 hours for delivered of induction.

In the present study the average induction delivery interval was 13± 4.997. in primi's, 8.75±3.06 in multi's in misoprostol group, where as it was 16.98 ± 5.511 in primi's, 14.22 ± 3.02 in multi's in dinoprostone group respectively. It was statistically significant and was in accordance with the study by Nanda et al.[7] The no of vaginal deliveries are 92% in misoprostol and 84% in dinopostone group. Gupta N et al [8] have also reported that vaginal deliveries were 86% in misoprostol, 68% in dinoprostone group.

Foetal complications were less in dinoprostone gel group but there was no significant difference (8% vs 4%). Chuck et al also reported that no significant difference was noted in maternal and foetal effects. Rates of caesarean section were less in misoproto group (8% vs 16%) but statistically insignificant. Jouatte et al[9] stated that, there was no significant difference in the rates of caesarean section.

In this study there was no significant statistically difference apgar score at 1 min and min between both group similar to the study by Daniel et al [10] and Herabutya et al Van Gemund et al [11]. In this study with this lower dosage 25 g of misoprostol lesser neonatal complications and maternal complication were noted.

VI. Conclusion:

For induction of labour in obstetrics indications, prostaglandins are effective agents to achieve successful outcome on the basis of our study misoprostol appears effective agent for indication of labour as compared to dinoprostone. The result shows that successful outcome was more and caesarean section rate was less in misoprostol group. Induction deliver interval was shorter compare to Dinoprostone group. Coming to cost wise misoprostol is cheaper than dinoprostone, easy to administer by intra vaginal route and does not require refrigeration.

Hence the intra vaginal misoprostol for induction of labour is a better, effective and safe alternative drug for induction of labour, in a women belonging to resource constrained developing countries.

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