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Original Research Article

Induction of labour: a comparative study of dinoprostone gel versus vaginal misoprostol versus sequential intracervical Foley's catheter followed by vaginal misoprostol versus concurrent intracervical Foley's and dinoprostone gel

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ABSTRACT

Background: Induction refers to the stimulation of contractions prior to the spontaneous commencement of labour, whether or not the membranes have already ruptured. Induction of labour is needed when risks outweigh the benefits of pregnancy continuation and there is no contraindication for vaginal delivery.
Methods: This was a randomized control trial which included low risk pregnant women at term gestation. Eligible patients were divided into 4 groups by randomisation in ratio of 1:1:1:1 with 25 patients in each group i.e. vaginal misoprostol (25 µgm) (group A) versus intracervical dinoprostone gel (group B) versus sequential intracervical Foley's catheter followed by vaginal misoprostol (group C) versus concurrent intracervical Foley's and dinoprostone gel.
Results: Use of dinoprostone gel for cervical priming is a more efficacious method among women needing labour induction with bishop score <6 compared to vaginal misoprostol, concurrent intracervical foley's as well as sequential intracervical Foley's and vaginal misoprostol. It is associated with higher rates of vaginal delivery (84%, p value 0.001), shortened induction delivery interval (14.38±7.16 hours, p value 0.178) and least risk of fetal distress/MSL.
Conclusions: Use of dinoprostone gel for cervical priming is a more efficacious method as it is associated with higher rates of vaginal delivery, more predictable response, shortened IDI and least risk of fetal distress/MSL. It should be preferred over tablet vaginal misoprostol especially for nulliparous women.

Keywords: Bishop score, Fetal distress, Induction delivery interval, Induction of labour, Meconium-stained liquor

INTRODUCTION

Labour is the physiological process by which regular uterine contractions result in progressive effacement and dilatation of cervix leading to expulsion of foetus, placenta and membranes through the birth canal.[1] Induction refers to the stimulation of contractions prior to the spontaneous commencement of labour, whether or not the membranes have already ruptured. When the cervix is closed and uneffaced, cervical ripening- a procedure to soften and open the cervix is required before labour induction. Induction of labour is needed when risks outweigh the benefits of pregnancy continuation and there is no contraindication for vaginal delivery.[2] Various indications for induction of labour are FGR, hypertensive disorders of pregnancy, GDM/pregestational diabetes, PROM, chorioamnionitis, IUFD, post term pregnancy, obstetric cholestasis of pregnancy.[3] A BISHOP score >8 indicates a high probability of a successful induction, whereas a score <6 is deemed unfavourable, then preinduction cervical ripening needs to be done before induction of labor.[4]

Numerous factors, such as gestational age, maternal health and parity, indications for induction, any pregnancy

complications, any significant complication during previous delivery, fetal health, lie or presentation, cervical condition, maternal preference, and protocols of obstetric unit facilities, influence the decision regarding which method to use for induction of labor.[5] Phamacological methods are often deployed to conquer the most difficult inductions commonly using more than one drugs or combining pharmacologic and mechanical methods together for the same.

Aims and objectives

To compare the efficacy of four labour induction methods in achieving successful cervical priming, labour induction and vaginal delivery, induction delivery interval, maternal and neonatal outcome.

METHODS

This study was conducted at Government Medical College, Amritsar from September 2023 to December 2024 after approval from institutional ethical committee. This was a randomized controlled trial that included the low risk pregnant women who attended the antenatal clinic and labour room and were assessed for the following inclusion and exclusion criteria.

Inclusion criteria

Single live pregnancy more than or equal to 37 weeks gestation. Cephalic presentation. Intact membranes. Presence of valid obstetric/medical indication for induction of labour. Bishop score <6. Reactive NST.

Exclusion criteria

Pregnancy less than 37 weeks gestation. Multifetal pregnancy. Malpresentation. Ruptured membranes. Active genital infection, cervical malignancy. Cephalopelvic disproportion (CPD). Scarred uterus. Any acute fetal distress. Intrauterine fetal demise/major fetal malformation/evidence of fetal hypoxia. Severe oligohydramnios. Maternal medical disorders- severe pre-eclampsia/eclampsia, GDM/diabetes mellitus in pregnancy, HIV positive, ARDS or any acute maternal illness, jaundice or acute renal failure. Antepartum haemorrhage/placenta previa. Known uterine malformation/fibroid uterus.

Those fulfilling the inclusion criteria were informed about the nature of and were included in the study after taking written informed consent. The patients were divided into 4 groups i.e. group A, group B, group C and group D by randomisation and a computer-generated randomised table was made in ratio of 1:1:1:1. Detailed history was taken and general physical examination and obstetric examination was done for all patients along with Bishop scoring and NST.

Patient were said to have successful induction of labour when uterine contraction ≥2 in 10 minutes were established each lasting more than 20 second duration along with improvement in Bishop score. Preinduction ripening was abandoned once patient's bishop score was more than equal to 6 after which oxytocin was started if uterine contraction were inadequate (<3 contraction in 10 minutes each lasting 30-40 seconds).

Outcome

Primary outcome

Successful induction of labor followed by vaginal delivery. Rate of cesarean section. Percentage of caesarean section due to failed induction or non-progress of labor. Induction delivery interval.

Secondary outcome

Duration of oxytocin augmentation required. Rates of uterine tachysystole with fetal distress (>5 contraction in 10 minutes). Fetal distress. Meconium-stained liquor. Maternal complications. Neonatal complication

Data analysis

All the observations made were compiled in a proforma and were subjected to statistical analysis using appropriate tests including Chi-square test and Student "t" test. The data was documented, tabulated and analysed by using appropriate statistical methods, wherever applicable.

RESULTS

All the four groups were comparable in terms of maternal age (p value=0.785), gestational age (p value=0.451), parity (p value=0.931) and birthweight distribution (p value=0.74).

Table 1: Demographic profiles of participants in each group.

	Group A	Group B	Group C	Group D	P value
Age (years)	27.31±5.25	26±4.05	26.20±5.38	26.07±4.38	0.785
Gestational age (weeks)	38.93±1.36	37.21±6.63	38.99±1.30	37.77±1.40	0.451
Nulliparous	56%	52%	56%	48%	0.931
Parity 1	44%	48%	44%	52%	
Birthweight distribution (kg)	2.85±0.42	2.82±0.46	2.89±0.36	2.80±0.47	0.74

Table 2: Proportion of vaginal deliveries and cesarean section following induction of labor.

Method of induction	Vaginal delivery		Cesarean section	
	No. of cases	Percentage	No. of cases	Percentage
Vaginal misoprostol (25 µg)	12	48	13	52
Intracervical dinoprostone gel	21	84	4	16
Sequential intracervical Foley's catheter followed by vaginal misoprostol	15	60	10	40
Concurrent intracervical Foley's and dinoprostone gel	18	72	7	28
P value 0.001 (p<0.05; significant).				

Table 3: Time from induction to onset of regular uterine contractions.

Time from Induction to onset of regular uterine contractions	Number N=94/100	Mean (hours)	SD (hours)	P value	95% CI
Vaginal misoprostol (25 µg)	22	8.14	5.10	0.001	6.18-10.10
Intracervical dinoprostone gel	25	5.35	3.16		4.27-6.43
Sequential intracervical Foley's catheter followed by vaginal misoprostol	25	9.30	3.16		8.22-10.38
Concurrent intracervical Foley's and dinoprostone gel	22	6.11	2.44		5.09-7.13

Table 4: Time from induction to achievement of Bishop score ≥6.

Time from induction to achievement of BISHOP score 6	Number (n=72/100)	Mean (hours)	SD (hours)	P value	95% CI
Vaginal misoprostol (25 µg)	13	11.25	7.36	0.023	6.40-15.30
Intracervical dinoprostone gel	22	10.15	6.00		7.27-12.23
Sequential intracervical Foley's catheter followed by vaginal misoprostol	18	18.25	5.24		16.24-21.06
Concurrent intracervical Foley's and dinoprostone gel	19	12.11	7.12		9.08-15.54

Most common indication of labour was postdated pregnancy (33%) followed by hypertensive disorders of pregnancy (25%).

Participants in intracervical dinoprostone had maximum vaginal deliveries (84%) > concurrent intracervical Foley's and dinoprostone gel 72%) > sequential intracervical Foley's catheter followed by vaginal misoprostol (60%) > vaginal misoprostol (48%) and p value was 0.001 and hence the difference was statistically significant (Table 2).

Out of all 4 groups, regular uterine contractions were achieved earliest with intracervical dinoprostone gel (5.35±3.16 hours) followed by concurrent intracervical Foley's and dinoprostone gel (6.11±2.44 hours) followed by vaginal misoprostol (8.14±5.10 hours) followed by sequential intracervical Foley's followed by vaginal misoprostol (9.30±3.16 hours). There was statistically significant difference (p value 0.001) (Table 3).

The narrowest confidence interval was observed in sequential Foley's + misoprostol group, indicating higher consistency in the time to onset of regular uterine contractions. In contrast, the vaginal misoprostol group displayed a wider range, suggesting greater variability in response as shown in normal distribution curves as shown in Figure 1.

Amongst the four groups, maximum number of patients were able to achieve bishop score of 6 in intracervical dinoprostone group (88%) with the least time required amongst all the groups (10.15 hours) with narrowest 95% confidence interval (7.27-12.23 hours) suggesting more consistent responses. Maximum time taken to achieve Bishop ≥6 was in sequential intracervical Foley's + vaginal misoprostol and also had narrow 95% confidence interval (16.24-21.06 hours) suggestive of more consistent responses and 72% success rate. Least number of patients were able to achieve bishop score 6 in vaginal misoprostol (52%) and had wide confidence interval (6.04-15.30 hours) suggestive of considerable variability amongst patients. Concurrent intracervical Foley's + dinoprostone gel had the highest skew (right skew), indicating a few participants took considerably longer to reach bishop score 6 and 95% confidence interval was 9.08-15.54 hours and mean time 12.11±7.12 hours which is longer than intracervical dinoprostone group with a success rate of 76% (Figure 2).

Difference in number of doses of prostaglandins required (p value =0.35), requirement of oxytocin augmentation (p valuem=0.122) and hours of oxytocin augmentation required (p value =0.06) were statistically insignificant amongst the groups.

Differences in induction delivery interval were statistically insignificant amongst the groups (p value=0.178) with least IDI of intracervical dinoprostone group (14.38±7.16 hours) followed by concurrent intracervical Foley's and dinoprostone group (16.10±8.31 hours) and vaginal misoprostol (16.48±8.46 hours) and maximum with sequential intracervical Foley's followed by vaginal misoprostol (25.22±6.24 hours) (Figure 3).

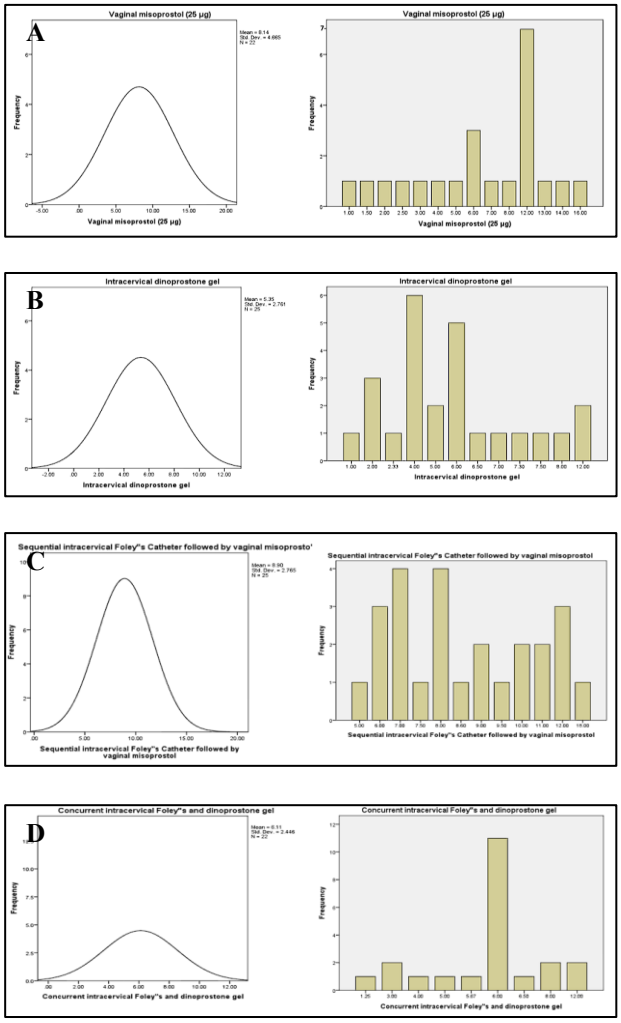

Figure 1: Time from induction to onset of regular uterine contractions.

(A) Confidence interval=6.18-10.10 (maximum amongst the four groups) indicating greater variability in response; (B)Confidence interval=4.27-6.43, right skewed data; (C) Confidence interval=7.82-9.98 (narrow) indicating high consistency to time to onset of regular uterine contractions, mildly right skewed data; (D) Confidence interval=5.09-7.13, Sharp peak at 6 hrs with more than 10 participants experiencing contraction onset around this time.

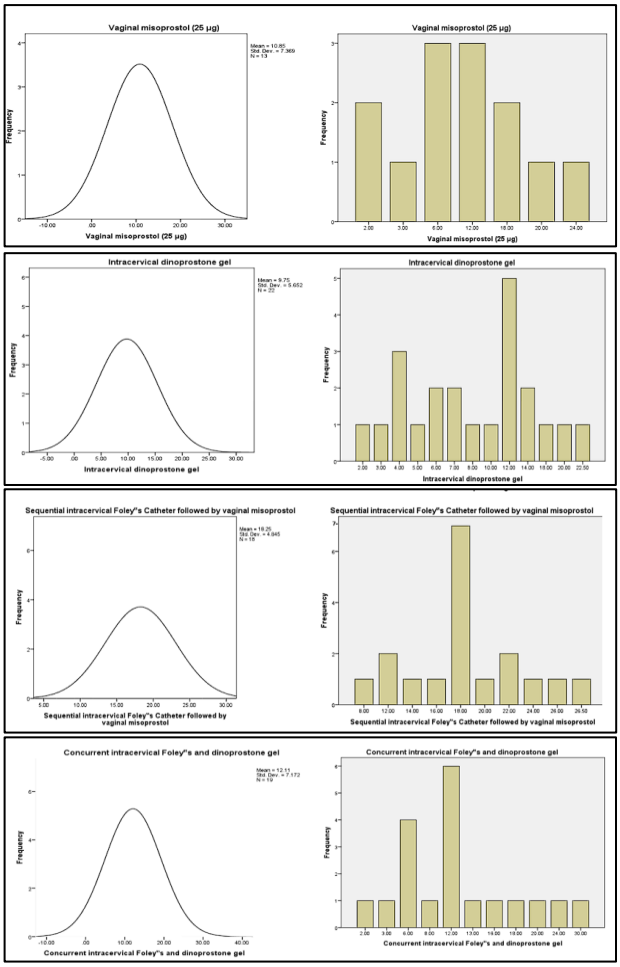

Figure 2: Time from induction to achievement of Bishop score ≥6.

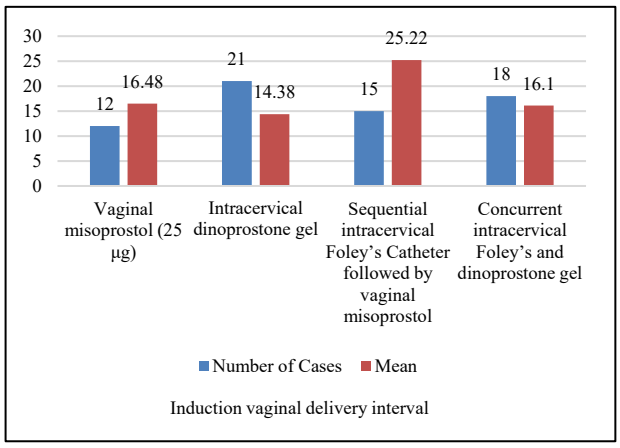

Figure 3: Induction delivery interval.

Table 5 indicates that concurrent intracervical Foley's and dinoprostone gel is likely the most favourable in terms of minimizing failed induction/NPOL risk. Vaginal misoprostol (both group A and D) carried double the risk than dinoprostone gel of caesarean section for failed induction or non-progress of labour although it is not statistically significant.

Table 5: Comparing risk of failed induction/non-progress of labour.

	Risk of failed induction/ NPOL	Relative risk (compared to intracervical dinoprostone)	P value
Vaginal misoprostol (25 µg)	6/25=0.24	2	0.28
Intracervical dinoprostone gel	3/25=0.12	1 (reference)	
Sequential intracervical Foley's catheter followed by vaginal misoprostol	6/25=0.24	2	0.28
Concurrent intracervical Foley's and dinoprostone gel	2/25=0.08	0.67	0.6404

Table 6: Comparing risk of foetal distress/meconium-stained liquor.

	Risk of FD/MSL	Relative risk (compared to intracervical dinoprostone)	P value
Vaginal misoprostol (25 µg)	7/25=0.28	7	0.05
Intracervical dinoprostone gel	1/25=0.04	1 (reference)	
Sequential intracervical Foley's Catheter followed by vaginal misoprostol	4/25=0.16	4	0.2
Concurrent intracervical Foley's and dinoprostone gel	5/25=0.20	5	0.15

Table 6 demonstrates that risk of fetal distress/MSL was maximum with vaginal misoprostol and it is statistically significant.

To assess the relationship between parity and route of delivery, participants were categorized into 4 groups based on parity: nulliparous (n=53), parity 1 (n=27), parity 2 (n=15), parity ≥3 (n=5). Incidence of caesarean sections and vaginal deliveries across the groups were analysed [p0.006], indicating the increasing parity was significantly associated with higher likelihood of vaginal deliveries. Among parity 2 and parity ≥3 females, vaginal deliveries were higher irrespective of the method of induction. In nulliparous and parity 1 females, intracervical dinoprostone was associated with least rates of caesarean section (23% and 14.2% respectively), intravaginal misoprostol with maximum percentage of caesarean section (71.4% and 50% respectively).

FGR and oligo/anhydramnios had no effect on outcome of induction of labour as p value is statistically insignificant (0.2821). Birth weight had no effect on route of delivery (p value =0.341).

There were no maternal deaths or perinatal mortality amongst the women studied. There was no incidence of uterine hyperstimulation, amniotic fluid embolism or uterine rupture in all the 4 groups. There was no statistically significant difference in postpartum complications like PPH, wound infection, puerperal sepsis.

DISCUSSION

Our study demonstrates that participants in intracervical dinoprostone had maximum vaginal deliveries (84%) > concurrent intracervical foley's and dinoprostone gel (72%) > sequential intracervical foley's catheter followed by vaginal misoprostol (60%) > vaginal misoprostol (48%) and p value was 0.001 and hence the difference was statistically significant. In a study conducted by Nimbalkar comparing intravaginal misoprostol and intracervical dinoprostone gel, caesarean section rate was 20% with misoprostol group and 2% with dinoprostone group.[6]

We compared the four methods for time taken to achieve regular uterine contractions and Bishop score >6 and found intracervical dinoprostone to be most quick and successful. Vaginal misoprostol took longer, had maximum failure rates. These differences were statistically significant and on analyzing the confidence intervals of these time durations, we also found that both groups with dinoprostone gel had a more predictable response whereas CI were widest for vaginal misoprostol indicating considerable variability in response which reduces in sequential foleys misoprostol group. Other contemporary studies didn't study these aspects.

Differences in IDI (induction delivery interval) were statistically insignificant amongst the groups (p value=0.178) with least IDI of intracervical dinoprostone group (14.38±7.16 hours) followed by concurrent intracervical Foley's and dinoprostone group (16.10±8.31 hours) and vaginal misoprostol (16.48±8.46 hours) and maximum with sequential intracervical Foley's followed by vaginal misoprostol (25.22±6.24 hours). Amongst all groups, least IDI (induction delivery interval) is of intracervical dinoprostone group and maximum IDI of sequential intracervical Foley's catheter followed by vaginal misoprostol with difference of 11.24 hours, but p value (0.178) was not statistically significant.

Thus, use of Foley's catheter before misoprostol resulted in increased induction delivery interval but improved

vaginal delivery rate. The use of Foley's catheter with dinoprostone gel resulted in increased induction delivery interval with no improvement in vaginal delivery rate.

In a study conducted by Shankarappa et al, comparing intracervical dinoprostone (n=52) and intracervical foley's+ dinoprostone gel (n=52), Group 2's mean IDI was higher (28.01±12.14 hours) compared to group 1 (13.56±7.1 hours) and was statistically significant (p value<0.0001).[7] In a study conducted by Bhatiyani et al, comparing intracervical Foley's + misoprostol (10.75 hours) versus misoprostol (8.15 hours), IDI was 3 hours shorter with vaginal misoprostol.[8]

Vaginal misoprostol has the highest relative risk of fetal distress/MSL (RR=7, p value- 0.05), with reference to intracervical dinoprostone group that had the least risk of FD/MSL. A comparative analysis of dinoprostone insert versus vaginal misoprostol tablet for labor induction by Unni et al also observed that, the vaginal misoprostol group had a higher prevalence of meconium-stained liquid (24.5%) than the dinoprostone group (11.3%).[9]

Difference in maternal outcomes (PPH, wound sepsis and postpartum pyrexia) and neonatal outcomes were statistically insignificant amongst groups, similar to observations in a study conducted by Shankarappa et al comparing intracervical dinoprostone gel with intracervical Foley's + dinoprostone gel, there was no difference in neonatal and maternal morbidity.[7]

Oligo/anhydramnios, FGR and birth weight had no impact on mode of delivery. In a study conducted by Upadhyay et al to assess association between neonatal birth weight and mode of delivery, the high birth weight group (≥3.8 kg) had a 45.2% cesarean delivery rate, while the lower weight group (2.5-3.79 kg) had a 28.8% rate. This difference was statistically significant (p<0.0001).[10]

Strength of this study are: the mean age of participants, gestational age and parity were comparable amongst the groups and were not the confounding factors in the study. Since all participants had relatively low risk pregnancies, it minimized other factors influencing induction delivery intervals, mode of delivery and maternal-neonatal outcomes.

However, there are some limitations also. Due to small sample size in all 4 groups, we didn't observe any of the known but rare adverse effects of any of the induction methods like uterine hyperstimulation, fever, rigors etc. The generalizability of the findings may be limited, as the study population was selected based on strict inclusion criteria, potentially excluding high risk or complex cases where induction of labor is often indicated.

CONCLUSION

Use of dinoprostone gel for cervical priming is a more efficacious method as it is associated with higher rates of vaginal delivery, more predictable response, shortened IDI and least risk of fetal distress/MSL. It should be preferred over tablet vaginal misoprostol especially for nulliparous women. Increasing parity was associated with significantly improved chances of vaginal delivery, regardless of the induction method used.

Use of Foley's catheter before vaginal misoprostol may improve the success of vaginal delivery rate, giving a more predictable response, but with a longer induction delivery interval. Addition of Foley's catheter to intracervical dinoprostone gel does not provide any added advantage in terms of vaginal delivery rates or decrease in induction delivery interval.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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