

A randomized prospective clinical trial comparing intravaginal dinoprostone gel and misoprostol vaginal tablets as a method of induction of labour

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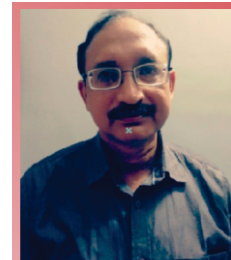
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Abstract: Induction of labour is the stimulation of uterine contractions before the spontaneous onset of labour with or, without ruptured membranes. In recent years, vaginal prostaglandins have become one of the most commonly used induction agents. These come with a variety of methods of administration, including gels, tablets, suppositories and pessaries. We conducted a randomized prospective clinical trial to compare the efficacy of intravaginal dinoprostone gel and misoprostol vaginal tablets in women undergoing induction of labour at term. 120 pregnant women were randomly chosen from our outpatients department and admitted during the period January 2011 to June 2012 as per the study protocol. Out of 120 pregnant women 60 subjects received dinoprostone gel and rest 60 received misoprostol vaginal tablets randomly as a method of induction of labour. The primary aim of this study was to compare the efficacy of intravaginal dinoprostone gel with misoprostol vaginal tablets in induction of labour and it was concluded that the administration of drugs and delivery interval was significantly higher in dinoprostone gel group than that of misoprostol tablets group and the mean duration of labour of misoprostol tablets group was significantly lower than that of dinoprostone gel group

Keywords: Induction of labour, Dinoprostone gel, Misoprostol tablets.

THESIS SUMMARY

Introduction

Induction of labour is the stimulation of uterine contractions before the spontaneous onset of labour with or, without ruptured membranes. An intervention designed to initiate uterine contractions artificially leading to progressive effacement and dilatation of the cervix and birth of the baby. It is a common obstetric intervention employed in response to a wide range of conditions in which prompt delivery may be achieved to reduce the risk of maternal and neonatal morbidity and mortality [1]. The physiological processes surrounding the initiation and promotion of labour are complex, but a successful vaginal delivery is less likely if the cervix is unfavorable. There are several methods of labour induction, including administration of oxytocin, prostaglandins, prostaglandin analogues and smooth muscle stimulants such as herbs or, castor oil, or mechanical methods such as digital stretching of the cervix and

sweeping of the membranes [2].

In recent years, vaginal prostaglandins have become one of the most commonly used induction agents. These come with a variety of methods of administration, including gels, tablets, suppositories and pessaries [2].

A successful induction is primarily dependent on the pre-induction condition of the cervix. When the cervix is favourable the usual method of induction is amniotomy and oxytocin, whereas with an unfavourable cervix vaginal prostaglandins are commonly used [6].

Dinoprostone is a synthetic analogue of ProstaglandinE2 (PGE2). It works by binding and activating the PGE2 receptor. The major clinical application of PGE2 relates to its effect on uterine smooth muscles. This property has led to its obstetrical use for term labour induction. Although the exact mechanisms are not fully understood, it is theorized

that the pharmacologic action of PGE₂ is related to its ability to regulate intracellular cyclic 3', 5'-cyclic adenosine monophosphate (cAMP) levels and cellular membrane calcium ion transport. It should be noted, however, that some effects of prostaglandins are independent of cAMP and are mediated through that of cGMP. Finally, Prostaglandins allow for an increase in intracellular calcium levels, causing contraction of myometrial muscle [7].

Misoprostol is a potential alternative to currently licensed labour induction agents. It is a prostaglandin E₁ analogue. Misoprostol has been widely used in the prevention and treatment of gastrointestinal ulcers for more than 20 years, but it also has uterotonic properties and there is a growing body of literature exploring its 'off-label' use for cervical ripening and labour induction [1].

Material And Methods

➤ STUDY DESIGN:

This was a hospital based observational comparative study.

SAMPLE SIZE:

This study was conducted on 120 indoor subjects. Sixty subjects were induced with intravaginal dinoprostone gel and rest were induced with misoprostol vaginal tablets on random basis.

INCLUSION CRITERIA:

- 1) Women with cephalic presentation
- 2) 37 to 42 week's period of gestation
- 3) Maternal medical conditions- diabetes mellitus, pregnancy induced hypertension

EXCLUSION CRITERIA:

- 1) Women who are hypersensitive to prostaglandins
- 2) Women with favourable cervix (modified bishop's score ≥ 8)
- 3) Certain circumstances where use is not recommended --
 - a) Multiple foetuses
 - b) Severe hydrocephalus
 - c) Malpresentation
 - d) Non reassuring fetal status
 - e) Prior uterine surgery (including caesarean section)
 - f) Contracted or distorted pelvic anatomy
 - g) Abnormal placentation (Placenta praevia, Vasa praevia)
 - h) Active genital herpes
 - I) Cervical cancer

METHODOLOGY

It was a randomized prospective clinical trial to compare the efficacy of intravaginal dinoprostone gel and misoprostol vaginal tablets in women undergoing induction of labour at term.

Women meeting the study criteria were approached for participation and an informed consent was obtained. Participants in the randomized trial were admitted to the antenatal ward. A 30 minutes admission cardiotocogram was recorded. Eligible patients were randomly assigned

by block randomization method to receive PGE₂ gel or misoprostol vaginal tablets.

PGE₂ vaginal gel contains 0.5mg of dinoprostone in 3 grams of thick clear gel in sterile translucent syringes stored at 2-8 degree Celsius. Misoprostol tablet contains 25mcg of misoprostol stored at room temperature.

Prior to the administration of the study drug, fetal heart sound was monitored for a period of 1 minute followed by vaginal examination if the FHR was within normal limits. The initial Bishop's score was recorded and the study drug (i.e. 1.5mg of PGE₂ gel or 25mcg misoprostol tablet) was administered into the posterior vaginal fornix.

Cardiotocography (CTG) was performed after 1 hour of administration of the medication. If normal, then patient was reviewed 6 hours after the first administration of inducing agent. A further dose of 0.5mg dinoprostone gel or 25mcg misoprostol was repeated if necessary. Patient was again reviewed after 24 hours of administration of first dose of the study drug and further dose of 0.5mcg dinoprostone gel or 25mcg misoprostol was administered, if necessary. And likewise, application of study drug was followed by CTG after 1 hour. No further dose of either agent was administered to women who experienced three or, more uterine contractions per 10 minutes, had a Bishop ≥ 8 or, spontaneous rupture of membranes. Subsequent management was taken thereafter.

Oxytocin augmentation was started in cases with unsatisfactory progress of labour or following amniotomy, at a rate of 1mU/minute. Oxytocin was not started for 6 hours following administration of vaginal prostaglandins and was increased at intervals of 30 minutes as needed to achieve an adequate contraction pattern. Surveillance of fetal heart rate and uterine activity was performed by CTG.

This study protocol includes a standardized Bishop's Scoring System used for assessment of inducibility. It is one of the quantifiable methods used to predict outcomes of labour induction described by Bishop in 1964.

A Bishop's score of 9 conveys a high likelihood for a successful induction. For research purposes, a Bishop score of 4 or less identifies an unfavorable cervix and may be an indication for cervical ripening.

The data regarding secondary outcome measures recorded were: requirement of oxytocin, mode of delivery, abnormal CTG recordings, incidence of uterine contraction abnormalities, any complications during labour. The newborn was examined immediately after birth, the Apgar score being determined at 1 and 5 minutes. Any fetal abnormalities occurring in hospital were noted. All maternal side-effects were recorded, as was the administration of all drugs including analgesics, tranquillizers, anesthetics and antiemetics.

Results

The specific objective of the study was to compare the efficacy of intravaginal dinoprostone gel with misoprostol vaginal tablets in induction of labour (vaginal delivery within 24 hours).

Having completed the result, analysis and the discussion on major issues, we finally present the following observations to arrive at a conclusion.

Overall views:

1. The mean age of Dinoprostone Gel group was 25.91 years with range 18-34 years and the median age was 26.0 years.

The mean age of Misoprostol Tablets group was 25.61 years with range 19-34 years and the median age was 25.5 years. Thus, in our study the subjects of the two groups are age matched.

2. In Dinoprostone Gel group 41.7% of the subjects whereas 26.7% of the subjects in Misoprostol Tablets group received education below higher secondary level. We observed that there is no significant association between level of education and groups.

3. The mean period of gestation on admission of the Dinoprostone Gel group was 272.53 days with range 259-280 days and the median was 276 days whereas in Misoprostol Tablets group it was 275.61 days with range 259-286 days and the median 278 days.

There is no significant difference between the mean period of gestation on admission of two groups ($p > 0.05$).

4. Majority of the subjects in this study were primigravida.

5. In Dinoprostone Gel group 26.7% of the subjects had an associated medical history however, only 11.7% had an associated medical history in Misoprostol Tablets group but it is not statistically significant ($p > 0.05$). Three subjects were β -thalassemia carrier, four individuals had a documented cholelithiasis, two subjects had a history of subfertility, four were HbE trait, two individuals contacted pulmonary tuberculosis and another two suffered from jaundice.

6. In Dinoprostone Gel group 23.7% of the subjects had a past surgical history however, only 16.7% had past surgical history in Misoprostol Tablets group but it is not statistically significant ($p > 0.05$).

7. Among the subjects taken in the study 41% had prior MTP in Dinoprostone Gel group whereas 58.3% of the individuals had prior MTP in Misoprostol Tablet group. Also two subjects underwent prior forceps delivery in Dinoprostone Gel group.

8. The following were the major complications noted in both the groups during their antenatal visits viz; bleeding per vaginum, fever, GDM on insulin, GDM on MNT, GGI, hypothyroid, ICP, IUGR, less fetal movement, PIH and UTI. These complications were evenly noted in both the groups and there was no significant association between these complications during antenatal visit and groups ($p > 0.05$).

9. We could not draw any significant difference between per abdomen findings of the subjects in the groups ($p > 0.05$).

10. The mean Bishop's score at admission of the Dinoprostone Gel group was 4.59 with range 3-6 and the median was 5 whereas it was 4.58 in Misoprostol group with range 2-7 and the median was 5. There was no significant difference between the mean Bishop's score at admission of the two groups ($p > 0.05$).

11. The mean period of gestation on day of induction of the Dinoprostone Gel group was 273.86 days with range 256-281 days and the median was 276 days however it was 276.78 days with range 260-287 days and the median was 279 days in Misoprostol Tablets group. There was no significant association between period of gestation on day of induction (in days) and groups ($p = 0.09$).

12. The mean Bishop's score before administration of drugs in the

Dinoprostone Gel group was 5.06 with range 3-6 and the median was 5 whereas it was 5.26 with range 3-8 and the median was 5.5 in Misoprostol Tablets group. There was no significant association between Bishop's score before administration of drugs and groups ($p = 0.12$). t-test showed that there was no significant difference between the mean Bishop's score before administration of drugs to the two groups ($p > 0.05$).

13. Several trials and study concluded that there was no significant difference in the incidence of abnormal fetal heart rate recordings [11, 12]. Whereas our study correlated similarly to their findings in the way that we also found no significant association between CTG abnormalities and groups. We found that in the Dinoprostone Gel group the CTG findings 1 hour after administration of drug was normal in 95%, pathological in 1.7% and suspicious in 3.3% of the cases whereas it was normal in 98.3% and suspicious in 1.7% of the cases in Misoprostol Tablets group.

14. A randomized study of vaginal misoprostol (PGE1) and dinoprostone gel (PGE2) for induction of labor at term concluded that in the Dinoprostone Gel group, more women required repeated doses of the inducing agent before achieving active labour and were less likely to deliver following administration of a single dose [6]. Our study too inferred the similar observation. The subjects in Misoprostol Tablets group requiring single repeat dose of drug for induction of labour in 60% of the cases whereas 70% of the subjects needed repeat dose of drugs in Dinoprostone Gel group. The subjects in Misoprostol Tablets group requiring twice repeat dose of drug for induction of labour in 8.3% of the cases whereas 15% of the subjects needed twice repeat dose of drugs in Dinoprostone Gel group. The above findings showed that there was significant association between requirement of repeat dose and groups ($p = 0.0001$). Test of proportion showed that subjects of the Dinoprostone Gel Group needed single as well as twice repeat dose significantly higher than the subjects of the Misoprostol Tablets Group ($p < 0.05$).

15. The CTG findings 1 hour after re-administration of drugs were normal in 63.3%, pathological in 1.7% and suspicious in 3.3% of the subjects in Dinoprostone Gel group and it was normal in 78.3%, pathological in 1.7% and suspicious in 3.3% of the subjects in Misoprostol Tablets group. The above findings shows that there is no significant association between CTG 1hr. after re-administration of drugs and groups ($p = 0.29$).

16. Several randomized studies opined that misoprostol may be more effective than other inducing agents, with a higher rate of vaginal delivery within 24hrs of induction [6].

Misoprostol is associated with a shorter duration of labour, higher rate of vaginal delivery within 24 hours from induction [6, 10].

Whereas in different studies, the number of women who delivered <24 hours was similar in both groups [11, 12]. In our study, the mean of administration of drugs and delivery interval in the Dinoprostone Gel group was 18.50 hours with range 5.0 – 56.0 hours and the median was 18.25 hours. The mean of administration of drugs and delivery interval of the Misoprostol Tablets group was 16.89 hours with range 4.5 - 41.08

hours and the median was 15 hours. There was a significant association between administration of drugs and delivery interval (in hours) and groups ($p=0.04$). t-test showed that the mean of administration of drugs and delivery interval (in hours) of Dinoprostone was significantly higher than that Misoprostol group ($p<0.01$).

17. In our study, the incidence of prelabour rupture of membranes was noted in 38.3% of subjects of Misoprostol Tablets group and 16.7% in Dinoprostone Gel group. Test of proportion showed that subjects of the Misoprostol Tablets group had prelabour rupture of membranes significantly higher than the subjects of the Dinoprostone Group ($Z=2.65$; $p<0.01$).

18. A comparative study on the efficacy of Dinoprostone versus Misoprostol found no significant difference between the two groups in mode of delivery [21]. Another study noted no significant difference in the rate of caesarean section between the two groups [10]. Few studies noted that there is no increase in the rate of caesarean section or maternal and neonatal morbidity between the Dinoprostone gel and Misoprostol Tablet group [6, 10]. Our study revealed that 65% of the subjects in the Dinoprostone Gel group and 75% of the subjects in the Misoprostol Tablets group underwent vaginal delivery respectively. The rate of caesarean section in our study in Dinoprostone Gel group and Misoprostol Tablets group was 31.7% and 25% respectively. 3.3% of the subjects had low forceps delivery in the Dinoprostone Gel group. The above findings in our study shows that there is no significant association between mode of delivery and groups ($p=0.23$), which corroborates with the above mentioned studies.

19. The mean duration of labour of the Dinoprostone Gel group was 5.06 hours with range 1-16 hours and the median was 4.0 hours whereas it was 3.22 hours with range 1-15 hours and the median was 4.5 hours in the Misoprostol Tablets group. The above findings inferred that there was no significant association between duration of labour and groups ($p=0.12$) although t-test showed that the mean duration of labour of Misoprostol Tablet group was lower than that of Dinoprostone Gel group.

20. Few studies reported that the number of women who delivered <24 hours was similar in both groups, as was the number requiring oxytocin augmentation [11, 12]. It was also concluded in some studies that a significantly smaller proportion of women in the misoprostol group required oxytocin augmentation during labour [6, 10]. In our study both the groups needed oxytocin augmentation for labour. It was needed in 60% subjects of Dinoprostone Gel group and in 58.3% of the subjects in the Misoprostol Tablets group. Hence, the requirement of oxytocin in both groups is similar with no significant association between the individual drugs.

21. There are studies that suggest that there is a role vaginal misoprostol for cervical ripening and induction of labour and found increased incidence of meconium-stained liquor [4]. However some other studies found no significant differences between the two groups in incidence of meconium [11, 12]. In our study, the incidence of meconium stained liquor was noted in 25% of the subjects of Dinoprostone Gel group and 45% of the subjects of Misoprostol Tablets

group. Test of proportion showed that subjects of the Misoprostol Tablets Group had meconium stained liquor significantly higher than the subjects of the Dinoprostone Gel Group ($Z=2.29$; $p<0.05$).

22. We found that the Intrapartum CTG was normal in 66.7%, pathological in 1.7% and suspicious in 3.3% of the subjects on Dinoprostone Gel group whereas it was normal in 65%, pathological in 6.7% and suspicious in 5% of the subjects in the Misoprostol Tablets group. Test of proportion showed that subjects of the Misoprostol Group had pathological Intrapartum CTG significantly higher than the subjects of the Dinoprostone Group ($Z=8.48$; $p<0.01$).

23. Shellhaas18 et al and Kastner19 et al described the association between increased incidence of postpartum atony and hemorrhage in women undergoing induction or augmentation. Intractable atony was the indication for a third of all caesarean hysterectomies. This indication was more prevalent in women with induced or augmented labor.

We could not find any significant association between the incidence of PPH and the use of individual drugs needed for induction of labor. In our study 6.7% of the subjects of Dinoprostone Gel group and 5% of the Misoprostol Tablets group suffered PPH. But there was no significant association between incidence of PPH and groups ($p=0.69$).

Among other observations, we noted equal number of subjects in both the groups whose fetus had one loose loop of cord around the neck, whereas two loose loop of cord around the neck was noted in two subjects of Dinoprostone Gel group and one subject of Misoprostol Tablets group. We noted an incidence of tight loop of cord around neck, vulval hematoma, scanty liquor in Dinoprostone Gel group. In Misoprostol Tablets group one subject delivered a newborn with CTEV. High intrapartum blood pressure was noted in one subject in each of the two groups.

24. In our study the indication of caesarean section in Dinoprostone Gel group and Misoprostol Tablets group was as follows: FIOL in 9.6% and 8% respectively, Suspicious CTG and unfavourable cervix in 6.4% and 4.8% of cases respectively, MSL with unfavourable cervix in 2% cases in both the group, pathological CTG in 3% of cases in both group and PROM in 1.6% of cases in both the groups. The conclusion is that the proportion of FIOL (9.6%) and suspicious CTG and unfavourable cervix (6.4%) were higher in Dinoprostone Gel Group than Misoprostol Tablets Group but it was not statistically significant ($p>0.05$).

25. There was significant association between Apgar score at 1 minute and groups ($p=0.03$). The mean Apgar score at 1 minute of the Dinoprostone Gel group was 6.46 with range 3-7 and the median was 7.0. The mean Apgar score at 1 minute of the Misoprostol Tablets group was 6.10 with range 3-7 and the median was 6.0. t-test showed that the mean Apgar score at 1 minute of Dinoprostone Gel group was significantly higher than that of Misoprostol Tablets group ($p<0.05$).

26. Sarah Gregson11 et al in a randomized study concluded that there were no significant differences between the two groups in incidence of Apgar scores below 8 at 5 minutes or admission to the neonatal unit.

We found no significant association between Apgar score at 5 minute and groups ($p=0.31$). The mean Apgar score at 5 minutes of the

Dinoprostone Gel group was 6.10 with range 6-9 and the median was 6.20. The mean Apgar score at 5 minutes of the Misoprostol Tablets group was 6.46 with range 6-9 and the median was 6.42. t-test showed that there was no significant difference in mean Apgar score at 5 minutes of Misoprostol tablets group and Dinoprostone Gel group ($p > 0.05$).

27. G. K. Pandis⁶ and Paul Bernstein⁹ in their randomized and multicenter trial concluded that there was no significant difference between the two groups in serious maternal morbidity or perinatal outcome.

G. K. Pandis⁶ and Marjorie Meyer¹⁰ concluded that there is no increase in the rate of maternal and neonatal morbidity in the two groups.

In our study the Newborns of 6.7% of subjects in Dinoprostone Gel group and 11.7% in Misoprostol Tablets group got admitted to NICU but there was no significant association between NICU admission of baby and groups ($p = 0.34$). The risk of NICU admission of baby was 1.84 times [OR-1.84(0.51, 6.68); $p = 0.34$] more in Misoprostol group in comparison with Dinoprostone group but the risk was not significant. Our study findings were in accordance to the results of the above investigators.

Three newborns of the Dinoprostone Gel group got admitted in NICU because of the delayed cry and respiratory distress and one newborn in the same group for poor feeding whereas four newborns with delayed cry after stimulation and needing assisted bag mask ventilation, one with low forceps delivery with MSL, other with delayed cry with MSL and one depressed baby delivered by caesarean section due to non-progress of labour in the Misoprostol Tablets group needed NICU admission.

Women whose labour is induced have an increased incidence of chorioamnionitis compared with those in spontaneous labor (American College of Obstetricians and Gynecologists, 1999a).

28. 18.3% of newborn in the Dinoprostone Gel group and 8.3% of newborn in Misoprostol Tablets group suffered from neonatal jaundice in our study. There was no significant association between neonatal jaundice and groups ($p = 0.10$). The risk of neonatal jaundice was 2.46 times ($p = 0.10$) more in Dinoprostone group in comparison with Misoprostol group but the risk was not significant.

29. 6.7% of newborn in the Dinoprostone Gel group and 3.3% of newborn in Misoprostol Tablets group suffered from neonatal sepsis in our study. There was no significant association between neonatal sepsis and groups ($p = 0.10$). The risk of neonatal sepsis was 2.11 times ($p = 0.39$) more in Dinoprostone group in comparison with Misoprostol group but the risk was not significant.

30. There was no significant association between hospital stay of mother after delivery (in days) and groups ($p = 0.27$). The mean hospital stay of mother after delivery (in days) of the Misoprostol Tablets group was 3.16 days with range 2-6 days and the median was 3.0 days. The mean hospital stay of mother after delivery (in days) of the Dinoprostone Gel group was 3.66 days with range 2-10 days and the

median was 3.0 days. t-test showed that there was no significant difference in mean hospital stay of mother (delivery) of Misoprostol Tablets group and Dinoprostone Gel group ($p > 0.05$).

31. The mean hospital stay of baby of the Misoprostol Tablets group was 2.98 ± 1.20 days with range 2-7 days and the median was 3.0 days. The mean hospital stay of baby of the Dinoprostone Gel group was 3.36 days with range 2-10 days and the median was 3.0 days. t-test showed that there was no significant difference in mean hospital stay of baby of Misoprostol Tablet and Dinoprostone Gel group ($p > 0.05$).

The mean total hospital stay of mother of the Misoprostol Tablets group was 5.10 days with range 3-10 days and the median was 4.5 days. The mean hospital stay of mother of the Dinoprostone Gel group was 5.90 days with range 3-16 days and the median was 5.0 days. t-test showed that there was no significant difference in mean hospital stay of mother of Misoprostol group and Dinoprostone group ($p > 0.05$).

Conclusion

The following inferences therefore can be clearly drawn from this study:

- Subjects of the Dinoprostone Gel group needed single as well as twice repeat dose which is significantly higher than subjects of the Misoprostol Tablets group.
- There is no significant association between CTG 1 hour after administration and 1 hour after re-administration of drugs and groups.
- Administration of drugs and delivery interval (in hours) in vaginal delivery in subjects of Dinoprostone Gel group is significantly higher than that of Misoprostol Tablets group.
- The incidence of prelabour rupture of membranes after administration of drugs is significantly higher in subjects of the Misoprostol Tablets group than Dinoprostone Gel group.
- There is no significant association between duration of labour and groups. However, the mean duration of labour of Misoprostol Tablets group is significantly lower than that of Dinoprostone Gel group.
- The incidence of meconium stained liquor is significantly higher in subjects of Misoprostol Tablets group than Dinoprostone Gel group in both vaginal delivery as well as caesarean section.
- The subjects of Misoprostol Tablets group have Pathological Intrapartum CTG significantly higher than the subjects of the Dinoprostone Gel group.
- There is no significant association between mode of delivery and groups.
- Proportion of FIOL necessitating caesarean section is higher in Dinoprostone Gel group than Misoprostol Tablets group but the comparison is not statistically significant.
- There is no significant association between the incidence of PPH and groups.
- There is an association between Apgar score at 1 minute and groups. The mean Apgar score at 1 minute of Dinoprostone Gel group is higher than that of Misoprostol Tablets group which is statistically significant.
- There is no significant association between NICU admission of baby and groups however; the risk of NICU admission of baby is 1.84 times

more in Misoprostol Tablets group in comparison with Dinoprostone Gel group.

- Neonatal jaundice is 2.46 times more observed in Dinoprostone Gel group than Misoprostol Tablets group but the observation is not significant.
- The incidence of neonatal sepsis is 2.11 times more in Dinoprostone Gel group in comparison with Misoprostol Tablets group but the risk is not statistically significant.
- There is no significant difference in mean hospital stay of mother after delivery and of baby in Dinoprostone Gel group and Misoprostol Tablets group.
- Therefore, both Misoprostol Tablets given per vaginam as well as Intravaginal Dinoprostone gel can be considered as a method of induction of labor and their respective advantages and drawbacks should be assessed for the better maternal and fetal outcome.

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