Original Research Article

Comparison of efficacy and safety of intravaginal dinoprostone (PGE2) gel and intracervical dinoprostone (PGE2) gel for cervical ripening and induction of labour at term

Anjum Kekhashan[1*], Ismath Fatima[2]

[1]Associate Professor, [2]PG Student, Department of Obstetrics & Gynaecology, Deccan College of Medical Sciences, Hyderabad, Telangana.
Email: dranjumkehkashan@gmail.com

Abstract

Background: Induction of labor is the stimulation of uterine contractions before the spontaneous onset of labor, with or without rupture membranes. Invention of prostaglandin preparation have revolutionized the methods of induction especially in unripe cervix and today, prostaglandins in various forms are used mainly for induction of labour with low Bishop's score. Different preparations and different routes of administration of dinoprostone are used, for e.g. gels, tablets, pessaries, sustained release inserts. **Material and methods:** This prospective randomized control trial was carried out in the Department of Obstetrics and Gynecology at Princess Esra Hospital from 1/02/2017 till 30/07/2018 after obtaining permission from Institutional Ethics Committee. Accordingly 200 women who fulfilled inclusion/exclusion criteria and for induction of labour were enrolled in the study. These women were randomized into two groups, Group A and Group B. **Observation and Results:** With intracervical dinoprostone, early onset of labour pain was observed as compared to intravaginal dinoprostone gel. But at the end of 24 hours 99% in group A, 100% patients in group B started uterine contractions. With intracervical dinoprostone gel, active phase of labour was attained earlier as compared intravaginal route but, it was seen that at the end of 24 hours 88% in group A and 93% patient in group B went into active phase. The induction delivery interval was less with intracervical dinoprostone as compared to intravaginal dinoprostone. 63% women in group A and 61 % in group B delivered vaginally indicating effectivity of dinoprostone in vaginal delivery by both the groups. **Conclusion:** Intravaginal dinoprostone in the dose of 0.5 mg 8 hourly for induction of labour in unripe cervix should be considered as safe and effective method which is free of complication and has high success rate with minimal maternal and fetal morbidity.
Key Word: intravaginal dinoprostone.

***Address for Correspondence:**
Dr. Anjum Kekhashan, Associate Professor, Department of Obstetrics & Gynaecology, Deccan College of Medical Sciences, Hyderabad, Telangana.
Email: dranjumkehkashan@gmail.com
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INTRODUCTION

Induction of labor is the stimulation of uterine contractions before the spontaneous onset of labor, with or without rupture membranes. The success of induction of labour depends upon the status of cervix which is assessed objectively by cervical scoring system as designed by Bishop's EH *et al*[2]. Higher the score better is the prognosis of induction of labour. There are various methods of induction of labour – mechanical methods, medical methods, surgical methods and combinations. Medical methods include oxytocin infusion, locally or systemic PGE1 tablets, locally applied PGE2 gel, mifepristone and various others. Till the introduction of

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prostaglandins, Oxytocin infusion was widely used, universally accepted method for induction of labour. Invention of prostaglandin preparation have revolutionized the methods of induction especially in unripe cervix and today, prostaglandins in various forms are used mainly for induction of labour with low Bishop's score. Different preparations and different routes of administration of PGE2 are used, for e.g. gels, tablets, pessaries, sustained release inserts. Most centers use intracervical dinoprostone(PGE2) gel for induction of labour but RCOG guidelines recommends Vaginal PGE2 is the preferred method of induction of labour, unless there are specific clinical reasons for not using it (in particular the risk of uterine hyperstimulation) This prospective study is being carried out, in which induction of labour using intravaginal dinoprostone (PGE2) gel is being compared with intracervical dinoprostone (PGE2) gel to assess their efficacy and safety for induction of labour

OBJECTIVE

1. To Compare efficacy and safety of intravaginal Dinoprostone gel(PGE2) and intracervical Dinoprostone gel (PGE2) for cervical ripening and labour induction at term
2. To study maternal and fetal outcome in patient who are undergoing induction of labour by the two methods used in our institute.

MATERIAL AND METHODS

This prospective randomized control trial was carried out in the Department of Obstetrics and Gynecology at Princess Esra Hospital from 1/02/2017 till 30/07/2018 after obtaining permission by Institute Review Board of Deccan College of Medical Sciences. Accordingly 200 women who fulfilled inclusion/exclusion criteria and for induction of labour were enrolled in the study Randomization was done by using block randomization method. They were randomized into two groups, Group A and Group B.

Distribution of women in two groups

GROUP	Number
A -Control Groupwith **Intravaginal Dinoprostone gel** 0.5 mg8 hourly for maximum 3 doses for 24 hours	100
B – Test Group with **Intracervical Dinoprostone gel** 0.5 mg8 hourly for maximum 3 doses for 24 hours	100
Total	200

INCLUSION CRITERIA

1. Primigravida
2. Bishop's score less than or equal to 4
3. Gestation age between 37-42 weeks.
4. Reassuring fetal heart rate on Non-stress test (NST).
5. No Cephalo-pelvic disproportion.
6. Single live fetus.
7. Woman not in labour
8. Cephalic presentation, with favourable presenting part.

EXCLUSION CRITERIA

1. Parity more than or equal to 4
2. Patients with previous caesarean section
3. Malpresentation.
4. Cephalopelvic disproportion
5. Significant maternal or fetal compromise.
6. Multiple pregnancy
7. Hypersensitivity to prostaglandins
8. Polyhydramnios.
9. Placenta previa.
10. Premature rupture of membranes.
11. History of asthma, glaucoma or heart disease.

OBSERVATION AND RESULTS

Table 1: Distribution of women according to gravidity or parity

GRAVIDITY OR PARITY	Group A (n=100)	Group B (n=100)
Primigravida	64	60
Multigravida :	36	40
Para 1	28	35
Para 2	08	05

Table 1 shows that majority of the women in both groups were primigravida (64% in group A and 60% in group B). 36 patients in group A and 40 patients in group B were multigravida. The two groups were comparable, the statistical significance of gravity and parity was not significant by Chi square test (P = 0.56, Chi square – 0.33).

Distribution of women according to period of gestation: Majority of women were between 37-40 weeks of gestation (66% in group A and 64% in group B). Mean age of gestation in group A was 38.96 ± 1.68 SD days while in group B it was 39.04 ± 1.32 SD days. This difference was statistically insignificant**.** (P – 0.80, Chi sq. Test), hence the two groups were comparable.

Table 2: Distribution of women according to Indicationfor induction of labour

Indication	Group A	Group B	P value
Post-dated pregnancy	34	36	0.81
PIH	28	29	0.89
IUGR	16	18	0.73
Oligohydramnios	17	14	0.59
GDM	5	3	0.47

Table 2 shows that the commonest indication for induction of labour was postdate pregnancy 34% in Group Aand in 36%Group B. The next common indication was PIH, 28% in Group A and 29% in group B

Table 3: Distribution of patients according to Bishop's score at "0"hour

Bishop's score	Group A	Group B
0-2	66	63
3-4	34	37
Mean Score ± S.D	1.83 ± 1.3 SD	1.92 ± 1.28 SD

Table 3 shows that mean Bishop's score at 0 hrs, i.e. at the start of procedure in group A was 1.83 ± 1.3 SD while in Group B it was 1.92 ± 1.28 SD. Difference in Bishops score at 0 hour was not statistically significant (p- 0.68, one – tailed unpaired test). Hence the two groups were comparable.

Table 4: Distribution of women according to duration of interval Between induction of labour to onset of labour pain

Interval in hours	Group A (n =100)	Group B (n =100)
≤ 6	5	11
>6 to 12	6	12
>12 to 18	59	51
>18 to 24	29	26
No contractions	1	0

Table 4 shows that 11% of patients in Group A started contractions in 12 hrs where as in Group B 23% patients started contractions in 12 hours, but it is observed that at end of 24 hours 99% patients in Group A and 100% patients in Group B had started labour pain, thus showing that intravaginl dinoprostone takes longer time to start labour pains as compared to intracervical route where labour pains start early. 1 patient in intravaginal group had no uterine contraction for 24 hours after initiation of induction. The mean duration of induction to onset of labour pain in Group A, was 14.72 ± 4.56 SD hrs while in Group B, the mean duration of induction to onset of labour pain was 13.10 ± 4.82 SD hrs. There was statistically significant difference in induction to initiation of contractions interval in the two groups. (P = 0.016, t = 2.428).

Table 5: Distribution of women according to interval between induction to active phase

Interval in hours	Group A	Group B
≤ 6	1	5
>6-12	8	14
>12-18	42	46
>8-24	37	28
No active phase till 24 hrs	12	7

Table 5: active phase of labour was not achieved in 12% women in intravaginal group as compared to 7% patients in intracervical group thus showing that success of induction of labour with intracervical dinoprostone is more than intravaginal dinoprostone but the difference is not statistically significant (P = 0.22). It is also observed that majority of the patients in group B 65% were in active labour in 18 hours, as compared to 51% in group A, but at the end of 24 hours, 88% women in group A and 93% women in group B had reached active phase. The mean interval between induction to active phase of labour in 88 patients who reached active phase in group A was 17.71 ± 4.05 SD hours as compared to 15.12 ± 4.94 SD hours in 93 patients who reached active phase in group B. There was statistically significant difference in this interval between the two groups (P = 0.001. t = 3.87)

Table 6: Distribution of women according to route to delivery

Route of Delivery	Group A	Group B
Vaginal	63	61
LSCS	25	32
Failure of induction	12	7

Table 6 shows that, 63 patients in group A and 61 patients in group B delivered vaginally thus indicating comparable vaginal delivery rate in both the groups. (P -0.38, chi sq – 0.75) but at the same time it is observed that through number of patients with successful induction was high in intracervical group, vaginal delivery rate was less as compared to intravaginal route. Out of 88 women in group A in whom induction was successful that is who went in active phase of labour in 24 hrs, 71.61% patients delivered vaginally and 28.40% patients required LSCS. Out of 93 women in group B in whom induction was successful that is who went in active phase of labour in 24 hours, 65.60% patients delivered vaginally and 34.40% patients required LSCS.

Distribution of women according to doses of drug required: Total 242 doses of dinoprostone were required by group A as compared to 215 doses in group B Number of doses required by intravaginal route was more than number of doses required by intracervical route. Only one dose was required by 16 patients in group B whereas only 4 patient in Group A required one dose of dinoprostone. Similarly, 3 doses of dinoprostone were required in 46 patients in group A as against lesser patients, that is, 31 patients in group B thus indicating higher requirement of dinoprostone for induction of labour in women with intravaginal administration. Mean number of doses required in group A was 2.42 $\pm$ 0.573 SD and in group B was 2.15 $\pm$ 0.672 SD (P=0.002).

Table 7: Distribution of women according to indication for LSCS in Women with successful induction

Indication	Group A (n = 25)	Group B (n = 32)
Fetal distress	15	21
Protracted 1st stage	6	9
Deep transverse arrest	4	2
Total	25	32

Table 7: shows that fetal distress was the commonest indication of LSCS in both the groups. Amongst the 25 women from Group A who underwent LSCS, 15 women underwent LSCS for fetal distress. Protracted 1st stage as denoted on partogram was the indication of LSCS in 6 women and 4 patients went into DTA and underwent LSCS. Amongst 32 women from Group B who underwent LSCS, 21 women underwent LSCS for fetal distress, 9 patients had Protracted 1st stage of labour and 2 patients had DTA for which LSCS was done.

Distribution of women according to nature of augmentation given: Amniotomy for augmentation was done in all women who went into active labour in both the groups. Out of 88 women in group A who went into active phase, 46 women required oxytocin for augmentation of labour, majority of those who required oxytocin augmentation delivered vaginally and amongst them 11 women required LSCS. Out of 93 women from group B who went into active phase, 39 women required oxytocin for augmentation of labour, of which 13 ended in LSCS. There was no statistically significant difference in requirement of oxytocin augmentation in both the groups (p=0.31, Z score=1.01)

According to maternal complication: None of the women in Group A had tachysystole or shivering/hyperthermia, vomiting. One patient in Group B had tachysystole. This patient required LSCS for fetal distress.

Distribution of patients according to APGAR score: Apgar score was less than 7 at 1 min after birth in 6 babies in Group A as compared to 9 babies in Group B. None of the babies from both the groups had Apgar score less than 7 at the end of 5 min. There was no neonatal complications during hospital stay.

Table 8: Distribution of women according change in Bishop's score at 24 hours in cases of failed induction

Group (failedinduction)		Bishop's Score (0hr)	Bishop's Score (24hr)	Change in Bishop's Score
Group A	1st patient	2	8	6
	2nd patient	1	7	6
	3rd patient	1	5	4
	4th patient	1	7	6
	5th patient	1	6	5
	6th patient	1	8	7
	7th patient	1	6	5
	8th patient	1	8	7

	9th patient	2	7	5
	10th patient	2	7	5
	11th patient	3	6	3
	12th patient	1	1	0
Mean		1.42 ± 0.669SD	6.33 ± 1.932SD	4.92 ± 1.929SD
Group B	1st patient	1	7	6
	2nd patient	2	7	5
	3rd patient	1	7	6
	4th patient	2	6	4
	5th patient	2	7	5
	6th patient	1	6	5
	7th patient	1	6	4
Mean		1.43 ± 0.535SD	6.57 ± 0.535SD	5.14 ± 0.690SD

Table 8shows that 12 women in group A did not go in active phase of labour at the end of 24 hours. But all of them showed improvement in Bishop's score except one patient. In group B, 7 women did not go in active phase of labour at the end of 24 hours. But overall improvement in Bishop's score was comparable to group A. The mean change in Bishop's score was 4.92 ±1.92 SD in group A while in group B mean change in Bishop's score was by 5.14 ±0.690 SD This difference was not statistically significant. (P – 0.771, one-tailed unpaired t test).

Statistical Analysis: Statistical analysis was done by using open epi software version6. The mean SD and % was used. Chi square test, fisher exact test, proportion test, and unpaired 't' test was used. Level of significance is 0.05.

DISCUSSION

Over the last two decades, the incidence of induction of labour has increased dramatically. An ideal method must encompass its efficacy and safety for the mother and fetus, short induction- delivery interval, minimum side effects and convenience to women and medical staff It is well established that dinoprostone for cervical ripening and induction of labour in patients at term is beneficial. Different preparations and different routes of administration of dinoprostone are used. Most centres use intracervical dinoprostone gel for induction of labour but according to RCOG guidelines intravaginal dinoprostone gel is the ideal method for induction of labour. Intravaginal dinoprostone should be used in preference to intracervical preparations as they are equally effective and administration of vaginal dinoprostone is less invasive.[8] It has an added advantage of use in women with premature rupture of membranes, where use of intracervical gel is guarded (cunnigham *et al* Williams 24th edition page 527). Various studies are conducted in which dinoprostone is compared with its different forms like intracervical gel is compared with intravaginal pessary, intracervical gel is compared with intravaginal insert, intracervical gel is compared with intravaginal tablet[10]. Studies have also been conducted where intracervical and intravaginal preparations of same form have been studied for e.g. intracervical and intravaginal dinoprostone gel. In these studies higher doses of dinoprostone were used for intravaginal administration. There are very few studies where same dose of dinoprostone is used for intracervical and intravaginal administration e.g. dinoprostone sustained release inserts in the same dose, i.e. 10 mg sustained release dinoprostone inserts were used in the study done by M Perry. Until now exhaustive literature search failed to locate same dose of gel used by both the routes for induction of labour. The present randomized control study was conducted which was aimed at comparing the efficacy, safety and tolerance of intravaginal dinoprostone gel with intracervical dinoprostone gel for cervical ripening and labour induction at term in the same dosage. Among the 200 women divided into Group A and Group B.

- Period of gestation was 38-40 weeks in majority of the women in both the groups andMean gestational age was 38.96 ± 1.68 SDin group A and 39.04 ± 1.32 SD in group B. In study of Sibananda Nayak *et al* (2015), Joscha Reinhard *et al* (2014), M.Perry *et al* (2004), Stempel JE *et al* (1997), Hales KA *et al* (1994) the mean gestational age is similar to our study present study
- Majority of women in both the groups were primigravida 64% in Group A and 60% in Group B, In studies done by Sibananda Nayak *et al* (2015) and by Hales KA *et al* (1994) also percentage of primigravida was more than multigravida. This is in accordance with the present study. Once reason may be because PIH is one of the most common indication for induction of labour which is more common in primigravida.
- In present study, the most common indication of labour was post-dated pregnancy (group A 34% and group B 36%) and pregnancy induced hypertension (group A 28% and group B 29%).

In the study by Sibananda *et al* (2015), Stempel JE *et al* (1997), M. Perry *et al* (2004), Hales KA *et al* (1994) post-date and /or pregnancy induced hypertension was indication for induction in majority of cases which matches with the present study.

- The mean Bishop's score at 0 hours i.e. at the start of procedure in group A was 1.83 ± 1.3 SD and in group B was 1.92 ± 1.28 SD and was statistically comparable in both the groups.

In study done by Chyu JK (1997) *et al*, they used intravaginal dinoprostone controlled release pessary and intracervical gel. Each agent was administered according to manufacturer's recommendations. The induction to active phase interval in intracervical group was 25.5 hours and in intravaginal group was 18.3 hours. In study by M Perry *et al* (2007), they used intravaginal and intracervical sustained release dinoprostone insert. The dose used was same (10mg) in both the groups. The duration of induction to onset of labour was less in intracervical dinoprostone 8.25 hrs as compared to intravaginal dinoprostone 11.50 hrs. In present study also same dose of gel (0.5mg) was used by both routes and intravaginal group had longer induction-active phase interval as compared to intracervical route. In Group A, induction was successful in 88% women and in Group B, induction was successful in 93% of patients. In group A out of 88 women 71.60% delivered vaginally and 28.40% required LSCS and in group B out of 93 women 65.60% women delivered vaginally and 34.40% women required LSCS. And out of 88 women 63 women in group A delivered vaginally and 25 women required LSCS. Where as in group B, out of 93 women 61 patients delivered vaginally and 32 required LSCS. Thus vaginal delivery rate was same with both the routes of administration.

Most of the studies have shown higher number of vaginal deliveries with intravaginal dinoprostone as compared to intracervical dinoprostone. The studies by M Perry *et al* (2004), Grignafinni A *et al* (2004), Stempel JE *et al* (1997), Hales KA *et al* (1994) conclude that there are more number of vaginal deliveries with intravaginal dinoprostone as compared to intracervical dinoprostone within 24 hrs of induction of labour. This result was similar to our observation.

Only in the study Sibananda *et al* (2015), Joscha Reinhard el al (1994) showed that more number of vaginal deliveries with intracervical dinoprostone gel. Majority of the women delivered within 24 hours in both groups 76.20% in group A and 80.33% in group B. (P = 0.49) and the difference is not significant. 23.80% women in group A and 19.67% women required more than 24 hrs for vaginal delivery, these were the women who had gone in active phase of labour near the end of 24 hours and so though induction of labour was successful according to study criteria, they took more than 24 hrs after induction to deliver. Mean induction to delivery interval in patients who delivered vaginally was 20.23 ± 4.40 SD hrs in Group A while in Group B mean induction to delivery interval was 17.93 ± 5.92 SD hrs, thus indicating early delivery with intracervical dinoprostone as compared to intravaginal dinoprostone. In the studies by Chyu JK (1997) *et al*, Hales KA *et al* (1994), the induction to delivery interval was less in intravaginal dinoprostone as compared to intracervical dinoprostone In study bySibananda *et al* (2015), M. Perry *et al* (2004), Joscha Reinhard *et al* (2014), Stempel JE *et al* (1997), the induction to delivery interval was more in intravaginal dinoprostone as compared to intracervical dinoprostone In present study also,Induction to delivery interval was more in intravaginal group as compared to 39ntracervical group (20.23 ± 4.40 SD hrs and 17.93 ± 5.92 SD hrs) respectively similar to results by Perry el al, Sibananda *et al* (2015), Stempel JE *et al* (1997), Joscha Reinhard *et al* (2015). In the present study, number of doses required by intravaginal route was more than number of doses required by intracervical route. Total 242 doses of dinoprostone were required by group A as compared to 215 dosed in group B (p = 0.002). Only one dose of dinoprostone was required by 16 patients in group B whereas only 4 patients in group A required one dose of dinoprostone. Similarly, 3 doses of dinoprostone were required in 46 patients in group A as against lesser patients, that is 31 patients in group B thus indicating higher requirement of dinoprostone for induction of labour in women with intravaginal administration. In most of the studies where gel was used either as single dose or was repeated after 12 hours. In the randomized trial of one vs two doses of dinoprostone, (2 mg) for induction of labour conducted by Mackenzie *et al* (1997)[79], no difference were was observed in operative delivery rate but, reduction received 2 doses. In present study, initial dose was low and it was repeated 8 hourly for 3 doses. Thus overall requirement of intravaginal dinoprostone is more as compared to intracervical dinoprostone in all the studies including present study. In the present study, in Group, A 25 women underwent LSCS and in group B, 32 women underwent LSCS. Fetal distress was the most common indication in both the groups. Fetal distress was more common in group B65.62% as compared to group A 60% but the difference is not statistically significant. (P = 0.99)

In studies done by Sibananda *et al* (2015), Grignaffini A *et al* (2004), fetal distress was the most common indications for LSCS in both the groups which was similar to the present study. And study by M Perry *et al* (2004) the most common indication for LSCS was failure

to progress in both the groups. In study by Hales KA *et al* (1994) fetal distress was the most common indication for LSCS in Group A whereas failure to progress is the most common indication for LSCS in Group B.

APGAR SCORE: In the present study Apgar score was less than 7 at 1 min after birth in 6 babies in Group A as compared to 9 babies in Group B which was statistically insignificant. None of the babies from both the groups had Apgar score less than 7 at the end of 5 min. In the study done by Joscha Reinhard *et al* (2014)[70] Apgar score in intravaginal dinoprostone at 5 min was 9.8 $\pm$ 0. SD and 10 min was 10 $\pm$ 0 SD and in intracervical group at 5 min was 9.8 $\pm$ 0.5 SD and at 10 min was 10 $\pm$ 0.2 SD which was statistically insignificant. In study done by Stempel JE *et al* (1997)[64] Apgar score in intravaginal dinoprostone at 1 min was 7.36 $\pm$ 1.56 SD and at 5 min was 8.82 $\pm$ 0.6 SD in intracervical dinoprostone at 1 min was 7.87 $\pm$ 1.5 SD and at 5 min was 8.97 $\pm$ 0.48 SD which was statistically insignificant. In study done by Hales KA *et al* (1994)[62] Apgar score in intravaginal dinoprostone at 1 min was less than 6 in 18.8% and at 5 min in 4.2% and in intracervical dinoprostone at 1 min less than 6 was in 30.8% and at 5 min in 1.9% which was statistically insignificant. In studies by Irion O *et al* (1998)[65] and Perry *et al* (2004)[39], difference in Apgar score was statistically insignificant in both the groups though the exact value was not mentioned in the study. There was no neonatal complications both the groups during hospital stay.

CHANGE IN BISHOP'S SCORE AT 24 HRS IN WOMEN WITH FAILED INDUCTION: In present study, those women who did not go in active phase of labour at the end of 24 hours of initiation of labour have shown improvement in Bishop's score in both the groups. The mean change in Bishop's score at 24 hours in intravaginal dinoprostone Group was 4.92 $\pm$ 1.92 SD as compared to mean score of 1.42 $\pm$ 0.669 SD at '0' hours. In intracervical dinoprostone Group in mean change in Bishop's score was 5.14 $\pm$ 0.690 SD, whereas initial mean score at '0' hours was 1.43 $\pm$ 0.535 SD (P = 0.771). This improvement was not statistically significant. In study by Stempel JE *et al* (1997)[64], there was no tatistically significant difference observed in change in bishop's score with both the groups. In study by Sibananda Nayak *et al* (2015)[10], change in bishops score was more with intracervical dinoprostone as compared to intravaginal dinoprostone.

With intracervical dinoprostone, early onset of labour pain was observed as compared to intravaginal dinoprostone gel. But at the end of 24 hours 99% in group A, 100% patients in group B started uterine contractions

CONCLUSION

Intravaginal dinoprostone in the dose of 0.5 mg 8 hrly for induction of labour in unripe cervix should be considered as safe and effective method which is free of complication and has high success rate with minimal maternal and fetal morbidity In conclusion, both intravaginal dinoprostone gel and intracervical dinoprostone gel appear to be effective agents for induction of labour. There is no difference in rate of success of induction and vaginal delivery rate in both the groups. No significant difference is seen in incidence of LSCS and maternal and fetal complication in both the groups. Number of doses required for induction with intravaginal dinoprostone gel is slightly more as compared to intracervical dinoprostone, and induction to delivery interval and requirement of augmentation of labour with oxytocin is also slightly more in intravaginal administration as compared to Intracervcal administration but considering advantage of easy administration and no requirement of instrumentation for administration and minimal patient discomfort, intravaginal dinoprostone gel is recommended for induction of labour in unripe cervix. Thus intravaginal dinoprostone in the dose of 0.5 mg 8 hrly for induction of labour in unripe cervix should be considered as safe and effective method which is free of complication and has high success rate with minimal maternal and fetal morbidity.

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