

Original Research Article

A comparative study of mifepristone with dinoprostone for induction of labor in third trimester

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ABSTRACT

Background: Success of labor induction depends upon favourability of the cervix at the time of induction. Various methods have been tried for labor induction but the search for ideal induction agent continues. There is a paucity of literature regarding the safety and efficacy of Mifepristone as induction agent in live pregnancies. Our aim was to study the efficacy of tablet Mifepristone as a cervical ripening agent and to compare the feto-maternal outcome with Dinoprostone gel.

Methods: A total of 100 patients who required labor induction were enrolled and randomized to receive mifepristone and dinoprostone. 50 patients were given oral tablet Mifepristone 200mg and 50 patients were instilled with intracervical Dinoprostone 0.5mg gel. The outcome was assessed by improvement in bishop's score, induction delivery interval, requirement of oxytocin, mode of delivery, and feto-maternal complications.

Results: The improvement in mean Bishop's score after 24hours was more in Mifepristone group (2.78 ± 1.28 to 7.22 ± 2.02) than in Dinoprostone group (2.64 ± 1.29 to 6.70 ± 1.75) ($p=0.173$). The incidence of vaginal delivery and LSCS were 86% and 14% in Mifepristone group and 72% and 28% in Dinoprostone group, respectively ($p=0.227$). The requirement of mean dosage of oxytocin was lesser in Mifepristone group (2.26 ± 0.71) as compared to Dinoprostone group (3.29 ± 1.35) ($p=0.001$). NICU admission was required in 26% neonates in Dinoprostone group and 16% neonates in Mifepristone group ($p=0.220$).

Conclusions: Mifepristone is a safe and efficient cervical ripening agent with no significant adverse effects to both mother and fetus.

Keywords: Mifepristone, Dinoprostone, Induction of labor, Bishop's score

INTRODUCTION

Induction of labor is an active intervention and it is indicated when continuation of pregnancy poses risk either to mother or the fetus. Induction of labor is defined as the process of artificially stimulating the uterus to start labor. As per latest studies, the induction rate varies from 9.5 to 33.7 percent of all pregnancies annually.¹ Success of induction primarily depends on the pre-induction Bishop's scoring of the cervix. Commonly used methods for cervical ripening are Dinoprostone, Misoprostol and

intracervical foley's insertion. Constant efforts are made in search of an ideal induction agent that reduces the load of uterotonics and minimizes adverse effect on mother and baby.

The fall in the level of progesterone is one of the important events in the onset of spontaneous labor, which leads to experimenting antiprogesterone in the field of labor induction.² Mifepristone is also called as RU (Roussel Uclaf)-486. It is a 19 nor-steroid with potent competitive anti- progesterone and significant anti-glucocorticoid

activity.³ It acts on the progesterone receptors (PR), with a greater affinity than that of progesterone itself and effectively blocks the action of progesterone at the cellular level.⁴ Mifepristone also increases the sensitivity of the uterus to prostaglandins and facilitates labor.⁵ It is approved by the FDA for termination of pregnancy in early trimesters. Limited literature is available about the efficacy and safety of oral Mifepristone in live pregnancies and so it remains a dilemma.^{6,7} So, we planned this study on use of oral Mifepristone as a cervical ripening and labor induction agent in live pregnancies.

Aims and objectives

To study the efficacy of Mifepristone as a cervical ripening agent for induction of labor in third trimester and compare it with Dinoprostone. To study the maternal and neonatal outcome in Mifepristone group v/s Dinoprostone group.

METHODS

This was a hospital based prospective study conducted in the Department of Obstetrics and Gynecology, Guru Gobind Singh Medical College and Hospital, Faridkot, Punjab over a period of one year from June 2019 to May 2020. The study was approved by Institutional Ethics Committee, GGSMCH, Faridkot. Study population comprised of one hundred antenatal women, of >28 weeks' gestation, who required induction of labor.

Inclusion criteria

Patient with single live intrauterine pregnancy with cephalic presentation and intact membranes with gestation >28 weeks. Unfavourable cervix (Bishop's score <6). No contraindication for vaginal delivery or induction with mifepristone, oxytocin or dinoprostone.

Exclusion criteria

Patients who didn't gave consent for the study. Estimated fetal weight >4000g. Parity >3. Eclampsia. Previous caesarean. Antepartum hemorrhage. Intrauterine fetal demise. PROM. Any contraindication to vaginal delivery

Methodology

One hundred eligible patients were enrolled for the study. After a written informed consent, detailed demographic particulars of the patients were noted according to the self-structured proforma. Routine investigations were done. Pre-induction Bishop's score and fetal wellbeing was recorded. The patients were divided into two groups, Group A and group B.

Group A

The patients of group A were given tablet Mifepristone 200 mg orally and they were monitored for uterine contractions (UC) and fetal heart rate (FHR) (Figure 1).

First bishop's score assessment was made at 12 hours or when patient went into labor, whichever was earlier. If Bishop's score was six or more, patients were augmented with Oxytocin. The active stage of labor was monitored using Partograph. UC and FHR were monitored every half-an-hour. Per Vaginal examination (PV) was done every four hourly till delivery. If patient do not get any contractions for 24 hours, PV was done to see the change in Bishop's score and then the patients were induced with Oxytocin/Misoprostol.

Group B

The patients in group B were instilled with intracervical Dinoprostone gel 0.5mg, under aseptic precautions and they were asked to lie in left lateral position for thirty minutes (Figure 2). FHR and UC were checked immediately and then every hour. PV for Bishop's score was done after 6 hours. If Bishop's score was six or more labor was augmented with Oxytocin. Partograph was maintained in active stage of labor. UC and FHR were monitored every half-an-hour. PV was done every four hourly till delivery. If the cervix was still unfavourable after 6 hours, a second dose of Dinoprostone gel was instilled and was monitored for UC and FHR. Maximum 3 doses were given. Duration of latent phase of labor was measured and patients with inadequate uterine contractions were augmented with ARM and oxytocin drip. The course of labor in all patients was recorded on partogram.

Decision on course of labor was made on clinical grounds. Inference was noted based on induction delivery interval (IDI), interventions required, mode of delivery and foeto-maternal outcome.

Success of induction was assessed as follows

Primary outcomes

Bishop's score of >6 at the end of 24 hours. Patients who deliver vaginally within 48hours of the start of the induction. Uterine hyperstimulation with FHR changes. Vaginal delivery/assisted delivery/lower segment caesarean section (LSCS). APGAR score <7 at 5minute.

Secondary outcomes

Cervix unfavourable after 24hours / Patient fails to go into active labour within 48hours of induction. Adverse maternal outcomes (uterine rupture, postpartum haemorrhage (PPH), admission to intensive care unit, septicaemia). Adverse neonatal outcomes (birth asphyxia, admission in neonatal intensive care unit (NICU), sepsis, perinatal death).

Statistical analysis

Data was entered in excel sheet and analyzed using IBM SPSS® v 20.0. The results observed were subjected to

statistical analysis by appropriate test and a p-value of <0.05 was considered as significant.

RESULTS

In our study, age of the patients ranged from 18-33 years. The mean age in Mifepristone group was 23.90 ± 3.30 years and in Dinoprostone group was 23.44 ± 3.35 years ($p=0.711$). Primigravida were 27 (54%) and multigravida 23 (46%) in Mifepristone group and in Dinoprostone group, primigravida were 29 (58%) and multigravida were 21 (42%) in our study ($p=0.687$). In our study, 32 (64%)

patients were at gestational age of more than 40 weeks in both the groups. About 10 (20%) patients in Mifepristone group and 9 (18%) patients in Dinoprostone group were at 37-40 weeks and 8 (16%) of patients in Mifepristone group and 9 (18%) in Dinoprostone group were at less than 37 weeks of gestation ($p=0.946$). The most common indication for induction in our study was prolonged pregnancy (64%) followed by hypertensive disorders (24%) and gestational diabetes mellitus (12%) in both the groups ($P=1.000$). Patients were comparable in both groups with no statistical difference with regards to demographic parameters (Table 1).

Table 1: Demographic characteristics of both the groups.

Demographic parameter		Group A	Group B	P value (chi square)
Age (18-33 yrs)	Mean age	23.90 ± 3.30	23.44 ± 3.35	0.711
	Primigravida	27	29	0.687
Gravida	Multigravida	23	21	
Gestational age	<37 wks	8	9	0.946
	37-40 wks	10	9	
	>40 wks	32	32	
Indication for induction	Prolonged pregnancy	32	32	1.000
	HDP	12	12	
	GDM	06	06	

Table 2: Bishop's score before induction and after 24 hours.

Preinduction Bishop's score	Group A (n=50) (%)	Group B (n=50) (%)	Statistical analysis(Chi square test)
0	3 (6)	3 (6)	P=0.966
1	6 (12)	8 (16)	
2	11 (22)	11 (22)	
3	9 (18)	10 (20)	
4	21 (42)	18 (36)	
Bishop's score after 24 hours			
>6	39 (78)	35 (70)	P=0.362
<6	11 (22)	15 (30)	

Table 3: Gain in Bishop's score with time.

Bishop's score	Group A (n=50) (Mean±SD)	Group B (n=50) (Mean±SD)	Statistical analysis (Unpaired t test)
Pre-induction Bishop's score	2.78 ± 1.28	2.64 ± 1.29	P=0.587
Bishop's score after 12 hours	4.24 ± 1.80	4.94 ± 1.38	P=0.242
Bishop's score after 24 hours	7.22 ± 2.02	6.70 ± 1.75	P=0.173
Difference in Bishop's score	4.44 ± 1.34	4.06 ± 1.33	P=0.158

Most of the patients in both groups had pre-induction Bishop's score of 2 to 4. After 24 hours, 78% patients in Mifepristone group and 70% patients in Dinoprostone group had Bishop's score >6 (Table 2). Comparing the mean gain in Bishop's score after 24 hours, Mifepristone group had better gain (4.44 ± 1.34) as compared to patients in Dinoprostone group (4.06 ± 1.33) with p value of 0.158 (Table 3). However, the difference was not statistically significant. The mean duration of labor was longer in Dinoprostone group as compared to Mifepristone group

($p=0.246$). However, the induction delivery interval (IDI) was lesser in Dinoprostone group (12.28 ± 6.75) as compared to Mifepristone group (14.00 ± 7.00) (Table 4). Half of the patients in group A (48%) and two-third of the patients in group B (70%) required oxytocin for labor induction or augmentation. The mean dose of oxytocin (units) required was higher in Dinoprostone group (2.26 ± 0.17) and lesser in Mifepristone group (3.29 ± 1.35) with p-value of 0.001. This difference was highly significant statistically (Table 5).

Table 4: Duration of different stages of labor.

Duration of different stages of labor	Group A (n=50) Mean±SD	Group B (n=50) Mean±SD	P value (Chi square value)
Stage I (hours)	4.90±1.77	5.47±2.34	P=0.216
Stage II (minutes)	20.86±6.23	24.31±6.29	P=0.017
Stage III (minutes)	4.15±1.20	4.82±1.93	P=0.066
Induction to delivery interval (IDI) (hours)	14.00±7.00	12.28±6.75	P=0.273

Table 5: Requirement of oxytocin for augmentation.

Oxytocin requirement	Group A (n=50) (%)	Group B (n=50) (%)	*= Chi square test #= Unpaired t test
Yes	24 (48)	35 (70)	P=0.025
No	26 (52)	15 (30)	
Dosage of oxytocin requirement (units) (Mean±SD)	2.26±0.17	3.29±1.35	P=0.001

Table 6: Mode of delivery.

Mode of delivery	Group A (n=50) (%)	Group B (n=50) (%)	P value (Chi square test)
NVD	42 (84)	5 (70)	P=0.227
Instrumental delivery	1 (2)	1 (2)	
LSCS	7 (14)	14 (28)	
Indication for LSCS			
Failed Induction	3 (6)	5 (10)	P=0.813
FHR abnormalities	2 (4)	3 (6)	
Meconium-stained liquor (MSL)	2 (4)	6 (12)	

Table 7: Maternal and fetal complications.

Complications	Group A (n=50) (%)	Group B (n=50) (%)	Statistical Analysis (Chi-square test)
Maternal complications			
Fever	2 (4)	4 (8)	P=0.570
GI symptoms	1 (2)	3 (6)	
Abdominal cramps	2 (4)	2 (4)	
Hypertonic uterine contractions	1 (2)	0 (0)	
PPH	0 (0)	1 (2)	
Fetal complications			
Birth asphyxia	1 (2)	1 (2)	P=0.328
MSL	2 (4)	6 (12)	
Transient tachypnoea of newborn (TTN)	1 (2)	2 (4)	
NICU admission	8 (16)	13 (26)	
APGAR <7 at 5 minute	8 (16)	10 (20)	

Majority of the patients in both groups (86% in Mifepristone and 72% in Dinoprostone) had vaginal delivery. Failed induction and meconium-stained liquor were the commonest indications for caesarean section (Table 6).

Comparing the feto-maternal outcome, none of the groups had serious complications. All the mothers and babies were discharged in healthy condition. However, minor complications like fever, GI symptoms, cramps were comparable in both groups (Table 7). Higher rate of complications was reported in Dinoprostone group. NICU admission was required by 26% neonates in Dinoprostone

group and 16% in Mifepristone group. The mean APGAR at 5 min was <7 in 20% neonates in Dinoprostone group and 16% neonates in Mifepristone group. The difference among two groups was not statistically significant ($p=0.328$).

DISCUSSION

In the present study, the usefulness of tablet Mifepristone for labor induction was evaluated. The rationale behind our study was to utilize the anti-progesterone activity of mifepristone at term and to find out whether it is a suitable and effective labor inducing agent and to compare it with Dinoprostone gel. Tablet mifepristone 200mg was administered and there was an observation period of 24 hours. This methodology was similar to the study conducted by Arumugalselvi et al and Salitha et al.^{8,9} In a double blinded placebo-controlled dose finding study conducted by Berkane et al, 50, 100, 200, 400 and 800mg of oral Mifepristone was used for induction of labor and the patients were reassessed at 12th, 45th and 54th hour for changes in Bishop's score.¹⁰ In the case control study of Sharma et al patients were treated with 400mg Mifepristone orally and were reassessed after 48hours.¹¹

In our study, most of the patients had pre-induction Bishop's score of 2 to 4. The mean Bishop's score at the start of induction was 2.78 ± 1.28 in Mifepristone group and 2.64 ± 1.29 in Dinoprostone group which was comparable with the study conducted by Yelikar et al where the mean pre-induction Bishop's score was 2.02 ± 0.749 in the study group and 2.16 ± 0.7 in the control group.¹²

The mean Bishop's score after 24 hours improved to 7.22 ± 2.02 in Mifepristone group and 6.70 ± 1.75 in Dinoprostone group, but it was not statistically significant. Similar changes in the mean Bishop's score (7.33 ± 3.53) were obtained after 48hours of Mifepristone induction in the study by Chourasia et al.¹³ However, Sailatha et al in their study found that the mean improvement in Bishop's score was more in Dinoprostone group (4.7 ± 1.49) than Mifepristone group (4.0 ± 1.49) after 24hours of induction, which was different from our results.⁹

In our study, the gain in mean Bishop's score after 24hours in Mifepristone group (4.44 ± 1.34) was better as compared to Dinoprostone group (4.06 ± 1.33). Similar findings were obtained in the study conducted by Arumugaselvi et al, and the gain in mean Bishop's score over 24hours was 5.0 ± 1.55 in Mifepristone group and 3.64 ± 2.14 in the Dinoprostone group.⁸ It was to be noted that in our study, the improvement in Bishop's score after 24hours of induction was with single dose of oral Mifepristone 200mg in group A and with maximum of two doses of Dinoprostone in group B. The study of Gaikwad et al concluded that single dose of tablet Mifepristone produced significant improvement in Bishop's score than a single dose of Dinoprostone at any given point of time.¹⁴

The mean duration of second and third stage of labor was significantly shorter in Mifepristone group when compared to Dinoprostone group in our study. Similar results were obtained in the study conducted by Dhillon et al, where the mean duration of second and third stage of labor was significantly shorter in the patient treated with Mifepristone than the patients treated with endocervical PGE2 gel.¹⁵ However, Deshmukh et al in their study observed that duration of second stage of labor didn't differ much in duration but the duration of third stage of labor was relatively shorter in mifepristone group (4.32 min) with p-value of 0.002.1.

The mean IDI in Dinoprostone group was 12.28 ± 6.75 hours which was shorter than Mifepristone group (14.00 ± 7.00 hours), but the difference was not statistically significant. This can be explained due to longer half-life of Mifepristone, to reach a steady state plasma concentration. Comparable results were also obtained in the study of Arumugaselvi et al where the mean induction IDI in Dinoprostone group was 11.47 ± 3.8 hours and 18.73 ± 10.0 hours in Mifepristone group.⁸ Ankitha et al also reported shorter IDI in dinoprostone group (5.21 hours) when compared to mifepristone group (9.61 hours), which was statistically significant ($p < 0.001$).¹⁶ Sah et al found a different observation in their RCT, where the mean IDI in Mifepristone group (39.06 ± 15.00 hours) was shorter than Dinoprostone group (41.30 ± 17.41 hours) with no statistical significance.¹⁷

Out of 43 (86%) patients who delivered vaginally in Mifepristone group, 26 (52%) patients delivered without need for oxytocin. The mean dosage of oxytocin required for augmentation in Mifepristone group was significantly lesser than Dinoprostone group in our study. Frydman et al, in their clinical trial concluded that the patients who delivered vaginally required less amount of oxytocin for augmentation, when Mifepristone has been given for pre-induction cervical ripening.¹⁸ Our study correlates with the data obtained by Hapangama et al in their systematic review available in Cochrane database and study by Priyanka et al on the effect of mifepristone in induction of labor at term which stated that the women treated with Mifepristone were less likely to need augmentation with oxytocin and were less likely to have caesarean delivery.^{19,20}

The incidence of LSCS was lower in Mifepristone group (14%) compared to Dinoprostone group (28%), but was not statistically significant. The rate of LSCS in Mifepristone group was 12% and 24% in endocervical PGE2 group in the studies of Arumugaselvi et al and Dhillon et al, which were comparable with our study.^{8,15} When compared the indication for LSCS in our study, the incidence of failed induction and MSL was higher in Dinoprostone group and incidence of fetal heart abnormalities were comparable in both the groups. In the study of Gaikwad et al, fetal distress (8%) was the most common indication for induction in Mifepristone group and failed induction (28%) was the most common

indication for LSCS in Dinoprostone group.¹⁴ In the study of Sailatha et al, where the incidence of LSCS for fetal distress was more in Mifepristone group (75%) compared to Dinoprostone group (41.67%).⁹ We also observed in our study that the lower segment of the uterus in mifepristone treated patient was well formed and stable as compared to uterus of dinoprostone treated patient, where the lower segment was thinned out and friable.

The mean blood loss in Mifepristone group was 278±162ml which was significantly lesser than Dinoprostone group 402±284ml with $p=0.009$. This can be explained due to incidence of lesser number of LSCS in Mifepristone group in our study. Comparable result was also obtained in the study of Dhillon et al, where the mean amount of blood loss in Mifepristone group was 248±160 ml and 368±222ml in Dinoprostone group.¹⁵ In our study, one patient in Mifepristone group had hypertonic uterine contractions, which was treated with analgesics and hydration. Atonic postpartum hemorrhage was noted in one patient of Dinoprostone group, which was managed successfully with uterotonics and blood transfusion. Kumari S et al reported that complications were more common in Dinoprostone group. Hyperstimulation and postpartum hemorrhage was reported in 4 patients each (4.35%) in dinoprostone group and one patient each (1.14%) in mifepristone group.²¹ Baev et al in their study observed higher proportion of cephalo-pelvic disproportion in patients treated with 200mg of Mifepristone (9 cases) compared to expectant management (2 cases). The spastic response of the lower uterine segment and pelvic muscles to the more pronounced and painful uterine contractions caused malpositioning of the fetal head in the patients treated with Mifepristone.²² Two patients had abdominal cramps in both the groups. The incidence of other minor complications in Mifepristone and Dinoprostone group respectively were; fever in 2 and 4 patients and gastrointestinal symptoms like nausea, vomiting and diarrhea in 1 and 3 patients. There was no significant difference with respect to the incidence of maternal complications between two groups. Lelaider et al in their study observed that, two patients had fever and no patient had uterine bleeding on induction with Mifepristone.²³ These observations were in comparison with our results. In the study of Giacalone et al, 12.1% induced with Mifepristone had uterine hypertonia during oxytocin infusion.²⁴ We didn't observe such correlation between uterine hypertonia and oxytocin augmentation in our study. This might be due to the difference in our induction and oxytocin infusion protocol.

Among the fetal complications, one baby in both the groups had birth asphyxia. One baby in Mifepristone group and two babies in Dinoprostone group had TTPN. The incidence of MSL was more in Dinoprostone group (6 babies) compared to Mifepristone group (2 babies). Similar results were obtained in the studies of Dhillon et al and Mohapatra et al where 2 (4%) babies in Mifepristone group and 5 (10%) babies in Dinoprostone group had MSL.^{15,25}

About 8 (16%) babies in Mifepristone group and 10 (20%) babies in Dinoprostone group had APGAR score less than seven at 5 minutes with no statistical significance. The mean APGAR score at 5 minutes in Mifepristone group was 8.20±0.86 and 7.76±0.98 in Dinoprostone group. Similar results are obtained by Sah et al in their comparative study of Mifepristone versus intracervical PGE2 gel for cervical ripening in primigravida patients at term.¹⁷ The mean birth weight in Mifepristone group was 2.74±0.32 and 2.73±0.30 in Dinoprostone group, which was comparable between both the groups ($p=0.821$). Among 8 babies of Mifepristone group admitted in NICU, 5 babies were admitted for low birth weight and among 13 babies of Dinoprostone group, 3 neonates were admitted for low birth weight. Even though, there were more NICU admission was found in Dinoprostone group (26%) as compared to Mifepristone group (16%), but was no statistical significance. In this aspect our study was comparable with the study of Dhillon et al, where 5 (10%) babies in Mifepristone group and 9 (18%) babies in Dinoprostone group required NICU admission.¹⁵

Additional advantages of Mifepristone were

Mifepristone administered orally was found convenient by the patients whereas endocervical Dinoprostone gel was inconvenient, required strict asepsis and technically skilled persons for instillation.

Post instillation, patient needed observation in left lateral position whereas patients can be ambulant after taking Mifepristone.

Mifepristone is not a direct inducer of uterine contractions but by its action as cervical ripening agent; decreases the discomfort of the mother due to painful uterine contraction and prolonged labor. The main goal of Mifepristone is to prepare of uterus for natural start of labor, to decrease the induction to delivery duration and to reduce the dose of direct inducers (Misoprostol, Oxytocin) of uterine contractions.²²

Mifepristone can be stored at room temperature whereas Dinoprostone gel needs cold chain maintenance.

The cost of single dose of Mifepristone is comparable to Dinoprostone gel as Dinoprostone requires multiple dose instillations.

The further need of Oxytocin for augmentation could be reduced with Mifepristone when compared with Dinoprostone gel.

Limitations of the study

Unblinded study. Limited sample size. Limited time period.

CONCLUSION

Mifepristone is an effective cervical ripening agent; capable of inducing labor in viable pregnancies with improved overall induction outcome. Also, being orally administered and one dose regimen has better patient compliance. It increases the number of vaginal deliveries with reduced duration of second and third stages of labor and lesser oxytocin augmentation. There were no adverse effects on mother or fetus. Thus, Mifepristone can be a safe and better alternative for labor induction when compared to Dinoprostone.

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

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