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Original Research Article

A comparative study on the role of oral mifepristone and endocervical prostaglandin as preinduction cervical ripening agent

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ABSTRACT

Background: Induction of labour is one of the most common interventions practised in modern obstetrics with up to 20% of pregnant women having labour induced in some countries. Induction rates have been influenced by several reports worldwide, which claimed that an active induction policy, led to substantial reduction in perinatal and maternal morbidity and mortality. A ripe or favourable cervix is a pre-requisite for successful vaginal birth. This study is conducted with an aim to compare the efficacy of mifepristone and dinoprostone as a cervical ripening and priming agent for induction of labour and their safety and fetomaternal outcome.

Methods: It was a prospective comparative study in the Department of Obstetrics and Gynecology, M.K.C.G. Medical college, Berhampur from October 2017 to October 2019. 100 cases with bishop score less than 6 were subjected for pre induction ripening. These cases were assigned at random either to study group, who were given single dose oral mifepristone 200 mg and control group with single dose intracervical E2 gel. All the cases were examined to check the bishop score. In cases of control cases, second dose was given after 6 hours, if there was no improvement in bishop score. At the end of 24 hour if bishop score <6, it was called as failed induction.

Results: 90% of mifepristone gr and 56% of dinoprostone gr had improved Bishop score >6 after 6hr. 32 cases required oxytocin augmentation in mifepristone gr where as it was 57 in dinoprostone. Drug administration to delivery interval was 19.40 hour in mifepristone gr and 15 hour in dinoprostone gr. More vaginal delivery and less fetal distress in mifepristone gr.

Conclusions: Mifepristone is an effective agent for cervical ripening with better fetomaternal outcome compared to dinoprostone.

Keywords: Dinoprostone, Mifepristone, Preinduction cervical ripening

INTRODUCTION

Human parturition has been termed 'labour' in recognition of the hard work that the parturient as well as the uterine myometrium have to perform in order to deliver the fetus. Labour refers to the onset of effective uterine contractions leading to progressive effacement and dilatation of the cervix resulting in the expulsion of the fetus, placenta and the membranes.¹ Cervical ripening is a process by which the cervix becomes soft, compliant

and partially dilated. It is due to a combination of biochemical, endocrine, mechanical and possibly inflammatory events.

In the present world, there is a spectrum of valid indications for induction of labour. The concept of elective induction for the convenience of the obstetrician and the patient, is not recommended by the ACOG at present, but this practice is recommended or indicated when the benefits for the mother and fetus outweigh

those of continuing the pregnancy and to achieve vaginal delivery, thus avoiding an unnecessary caesarean section.² Favourability of the cervix is a need for labour induction. Research in this direction has helped in the development of various methods to 'ripen' the cervix prior to uterine contractions. The discovery of prostaglandins, and lately the antiprogesterones, have made labour induction at the disposal of the obstetrician, enabling the delivery of the patient as and when required, thus allowing a carefully planned active management, and in bringing down the trauma of a prolonged or protracted and painful labour for the patient, to give her a healthy baby without compromising her.

Mifepristone is a 19 nor Steroid with a greater affinity for the progesterone receptor and thus blocks the action of progesterone at a cellular level. As a fall in the level of progesterone considered one of the important events in the onset of spontaneous labour, it therefore seems likely that this drug may be useful on induction.³ The pharmacokinetics of mifepristone is characterized by rapid absorption and a long half-life of 25-30 hour.⁴ Dinoprostone is a naturally occurring prostaglandin E2 (PGE2). Prostaglandins allow for an increase in intracellular calcium levels, causing contraction of myometrial muscle. Dinoprostone Gel (cerviprime gel) is a prostaglandin E2. Fetal membranes (amnion) produce prostaglandin E2. It acts mainly on the cervix due to its collagenolytic property and has an oxytocic effect on the pregnant uterus when used in appropriate dose, stimulates labour and delivery and thus terminates pregnancy. Dinoprostone also is capable of stimulating the smooth muscles of gastrointestinal tract. Objective was to compare the efficacy of mifepristone and dinoprostone as a cervical ripening and priming agent for induction of labour and to study safety and fetomaternal outcome after the use of mifepristone versus dinoprostone.

METHODS

This prospective comparative study was done in the Department of Obstetrics and Gynecology, M.K.C.G. Medical College, Berhampur from October 2017 to October 2019. 100 antenatal women were selected for study 50 women received oral mifepristone 200mg and 50 women received endocervical PGE2 gel 0.5mg.

Inclusion criteria

Singleton pregnancy with cephalic presentation and intact membranes if labour induction was indicated and delivery could be postponed for 24 hours. Women with unfavourable cervix (Bishop score less than 6). Valid indication for induction of labour.

Exclusion criteria

Known hypersensitivity to prostaglandins or mifepristone. Medical problems like impaired renal,

hepatic or adrenal function. All cases where vaginal delivery is not indicated.

On admission, a detailed history, and complete general and obstetric examination was carried out. Vaginal examination was done under strict aseptic precautions and the cervical status, fetal station were assessed. Gestational age calculated by Naegle's rule and a routine obstetric scan for fetal maturity and well-being was done. Once the inclusion criteria were fulfilled and cephalopelvic disproportion was ruled out.

Out of 100, 50 pregnant women were given tablet mifepristone 200mg orally and other 50 were instilled endocervical PGE2 gel 0.5mg. They were observed for maternal vitals, uterine activity, bleeding or draining pv and fetal heart rate. After the wait period of 24 hours or when the Bishop score was ≥ 6 or when the membranes ruptured or when the patient was well in labour whichever is earlier labour was accelerated with oxytocin drip. 2nd dose of PGE2 will be given after 6 hours, if there will be no improvement in bishop's score.

The efficacy was assessed by favourability of Bishop score at 24 hours, need of oxytocin for augmentation, duration of 1st, 2nd and 3rd stage of labour, drug administration to delivery interval, mode of delivery, C-section rate, Apgar score, neonatal complications, maternal complications.

Success of induction was assessed by the following criteria

Bishop score of ≥ 6 at the end of 24 hours

Failure of induction was assessed by the following criteria

Bishop score of < 6 at end of 24 hours

RESULTS

Most of the cases were 20-29 years of age and least were ≥ 35 year in both groups. Age and parity distributions of women included in this study were comparable in both mifepristone and PGE2 gel group. In maximum cases, induction was done at > 40 week (56% in group I verses 60% in group II). The major indication for induction was post-dated pregnancy without any risk factors, 16 cases (32%) in gr-I and 17 cases (34%) in gr-II. For oligohydramnios, 15 and 13 cases were induced in gr-I and gr-II respectively. Other indications for induction were FGR, twin (1st twin vertex), IUFD, GDM with controlled sugar, PIH and congenital anomaly (Table 1).

Maximum mothers in both the groups had initial bishop's score of 2 to 5 before preinduction cervical ripening. Only 1 primi in gr-I had 0 Bishop score. P-value for Bishop's score at start 0.169 which is not significant (Table 2). After 6 hour 5 cases in gr-I and 22 cases in gr-

II still had Bishop's score <6. So, in 90% of gr-I and 56% of gr-II have improved Bishop score >6 (Table 3).

In gr-I, the rate of improvement in Bishop's score was satisfactory, i.e. 6.24 at 6 hour, 9.43 in 12 hour and 10 in 24 hour. Only 1 patient was having Bishop's score 5 at 24 hour undergone CS due to failed induction in gr-I. In gr-II, the mean Bishop's score at 6 hour, 12 hour and 24 hour were 5.96, 9.93 and 5 respectively. In 2 patients having Bishop's score 5 LSCS was done due to failed induction. P-Value for Bishop's score at 6 hour, 12 hour was 0.025 and 0.134 respectively which is not significant. P-Value for Bishop's score at 24 hour is 0.007, which is significant (Table 4).

In the mifepristone group among 17 primigravida who required oxytocin, 15 delivered vaginally. LSCS done in 2 cases due to failed induction. Rest 5 delivered vaginally without oxytocin augmentation. In PGE2 gel 18 primigravida required oxytocin. 13 delivered by normal labour and 5 undergone LSCS.

Table 1: Baseline characteristics of study population.

Parameter	Group-I	Group-II
Age(years)		
<20	3 (6%)	2 (4%)
20-24	20 (40%)	20 (40%)
25-29	22 (44%)	26 (52%)
30-34	4 (8%)	3 (6%)
≥35	1 (2%)	0 (0%)
Parity		
Primi	22 (44%)	24 (48%)
Multi	28 (56%)	26 (52%)
Gestational age		
37-40 week	22 (44%)	20 (40%)
>40 week	28 (56%)	30 (60%)
Indication for induction		
Postdated, uncomplicated pregnancy with CPD ruled out	16 (32%)	17 (34%)
Oligohydramnios	15 (30%)	13 (26%)
FGR (mild)	5 (10%)	4 (8%)
Twin (1 st twin vertex)	2 (4%)	3 (6%)
IUFD (41 weeks)	4 (8%)	5 (10%)
GDM with controlled sugar	2 (4%)	2 (4%)
PIH (GHTN)	4 (8%)	3 (6%)
Others (congenital anomaly)	2 (4%)	3 (6%)

In mifepristone group, 13 multipara not required oxytocin, 12 delivered by labour natural. Only 1 case undergone CS due to fetal distress out of 15 multi requiring oxytocin. In PGE2 gel, 7 multigravida delivered vaginally without oxytocin augmentation. Out of 19, who required augmentation with oxytocin 3 undergone LSCS due to fetal distress and rest delivered vaginally. In mifepristone and PGE2 group, both primi multi require oxytocin for vaginal delivery. In PGE2 gel group, 12

primi and 10 multi received repeat PGE2 gel, among which 4 had cesarean section because of fetal distress (2 cases) fetal distress and failed induction (2 cases) (Table 5).

Table 2: Bishop score at the start of study.

Score	Group-I		Group-II	
	Primi	Multi	Primi	Multi
0	1 (2%)	-	-	-
1	2 (4%)	1 (2%)	4 (8%)	4 (8%)
2	4 (8%)	6 (12%)	5 (10%)	5 (10%)
3	3 (6%)	5 (10%)	5 (10%)	5 (10%)
4	6 (12%)	8 (16%)	6 (12%)	7 (14%)
5	6 (12%)	8 (16%)	4 (8%)	5 (10%)

Shortest drug administration to delivery interval in mifepristone group was 13hours 30 min and in PGE2 gel group was 11 hours 48 min (Table 6).

Duration of 2nd and 3rd stage of labour were all most same in both group with statistically not significant. Duration of 1st stage was shorter in PGE2 gel group with statistical significance. Drug administration to delivery interval was shorter with PGE2 gel group with statistical significance (Table 7).

In mifepristone group 36% of primi and 46% of multi delivered by natural labour. 1 patient in each delivered by outlet forceps. 2 multi and 1 primi delivered by vacuum application and rest undergone LSCS (8%). In PGE2 gel group, 17 (34%) primi and 20 (40%) multi were delivered vaginally. 1 patient in each parity delivered by outlet forceps. vacuum application was as gr-I. Total 8 (16%) undergone LSCS (Table 8).

In the mifepristone group 2 (4%) primigravida were delivered by cesarean section of which 1 (2%) was done for failed induction and another 1(2%) for fetal distress whereas in multigravida 2 (4%) were delivered by caesarean with indication of fetal distress.

In the PGE2 gel group among 5 (10%) primigravida delivered by cesarean, 2 (4%) were done for failed induction and 3 (6%) were done for fetal distress whereas in multigravida 3 (6%) were delivered by cesarean section out of which 2 (4%) were done for fetal distress and other 1 (2%) for failed induction (Table 8).

Maternal complications like fever was more in cerviprime group 10% compared to 4% in mifepristone group. 4 (8%) cases had abdominal cramp in mifepristone group whereas 2 cases developed tachysystole in cerviprime group. There was no PPH or puerperal sepsis in both group (Table 9).

NICU admission was 16% in PGE2 gel as compared to 8% in mifepristone group. In PGE2 gel 5 (10%) neonate were found to have fetal distress where as it was 4% in

mifepristone group. But there was no neonatal mortality were similar in both groups (Table 9).
in both groups. APGAR score at 1 minute and 5 minutes

Table 3: Favourability of Bishop’s score at 6 hour.

Score at 6 hr	Group-I			Group-II		
	Primi	Multi	Total	Primi	Multi	Total
<6	5 (10%)	0	5 (10%)	12 (24%)	10 (20%)	22 (44%)
≥6	17 (34%)	28 (56%)	45 (90%)	12 (24%)	16 (32%)	28 (56%)

Table 4: Favourability of Bishop Score.

Bishop Score	Group	Number	Mean	Std. deviation	Std. error mean	P-value
Bishop score at start	Group-I	50	3.46	1.358	0.192	0.169 (NS)
	Group-II	50	3.08	1.383	0.196	
Bishop score at 6 hour	Group-I	50	6.24	1.041	0.147	0.256 (NS)
	Group-II	50	5.96	1.384	0.196	
Bishop score at 12 hour	Group-I	47	9.43	1.395	0.203	0.134 (NS)
	Group-II	43	9.93	1.765	0.269	
Bishop score at 24 hour	Group-I	9	10	1.936	0.655	0.007 (S)
	Group-II	2	5	0.000	0.000	

Table 5: Augmentation with oxytocin.

Augmentation	Group-I			Group-II		
	Primi	Multi	Total	Primi	Multi	Total
Required	17 (34%)	15 (30%)	32 (64%)	18 (36%)	19 (38%)	37 (74%)
Not required	5 (10%)	13 (26%)	18 (36%)	6 (12%)	7 (14%)	13 (26%)

Table 6: Drug administration to delivery interval.

Drug administration to delivery interval (hours)	Group-I	Group-II
10-12.59	0	11
13-15.59	12	12
16-18.59	12	7
19-21.59	7	9
22-24.59	7	3
25-27.59	8	0

Table 7: Comparison of duration of labour between the PGE2 and Mifepristone group at various stages.

Duration of Labour	Group-I (46) Mean+SD	Group-II (42) Mean+SD	P-value
1st stage (hr)	11.6124±2.43722	9.2236±1.24753	0.0002 (S)
2nd stage (min)	26.67±4.926	26.71±5.584	0.971 (NS)
3rd stage (min)	5.030±0.9789	5.186±1.0094	0.466 (NS)
DD Interval (hr)	19.4065±4.30411	15.9769±3.50301	0.0002 (S)

Table 8: Mode of delivery.

Mode of delivery	Group I			Group II		
	Primi	Multi	Total	Primi	Multi	Total
Labour natural	18 (36%)	23 (46%)	41 (82%)	17 (34%)	20 (40%)	37 (74%)
Outlet forceps	1 (2%)	1 (2%)	2 (4%)	1 (2%)	1 (2%)	2 (4%)
Vacuum delivery	1 (2%)	2 (4%)	3 (6%)	1 (2%)	2 (4%)	3 (6%)
LSCS	2 (4%)	2 (4%)	4 (8%)	5 (10%)	3 (6%)	8 (16%)
Indication of LSCS						
Failed induction	1 (2%)	0	1(2%)	2 (4%)	2 (4%)	4(8%)
Fetal distress	1 (2%)	2 (4%)	3(6%)	3 (6%)	1 (2%)	4(8%)

Table 9: Complications.

Complications	Group I	Group II
Maternal complications		
Fever	2 (4%)	5 (10%)
GI symptoms	3 (6%)	3 (6%)
Abdominal cramps	4 (8%)	-
Tachysystole	-	2 (4%)
PPH	-	-
Puerperal sepsis	-	-
Neonatal complications		
Respiratory distress	1 (2%)	3 (6%)
Meconium aspiration syndrome	2 (4%)	5 (10%)
Transient tachypnoea of newborn	1 (2%)	-

DISCUSSION

Research continues to invent and modify doses of different drugs for cervical ripening. Mifepristone has been used to induce labour or to allow pregnancy to be terminated. In present study, we opted for 200mg mifepristone as a tablet and observation period was of 24 hours similar to the Wing et al, Arumugalselvi et al study and Salitha et al.⁵⁻⁷ In Wing et al mifepristone was compared with placebo whereas in others with PGE2 gel like in our study.

42 (84%) and 46 (92%) both primi and multigravida were between the age group of 20-29 years in mifepristone group and dinoprostone group respectively accounting for 88% in our study (Table 1). This study correlates with randomized controlled trial conducted by Wing et al in which 88% of the patients were in the age group of 21-30 years.⁵ It also correlates with a randomized controlled trial by Saranya et al 85% of the patients were in 21-29 years.⁸

Although term gestation between (37-42) weeks were included but maximum cases were of GA between 40-42 weeks (Table 1) in our study which is similar to study of Fathima et al and Su et al in 1996.^{9,10}

Patients with bishop's score less than 6 were included in the study group (Table 2). Similar study was done by Bashutheen et al in which Bishop's score of 1-6 were included.¹¹ According to another study by Deepika et al 400 mg mifepristone was given with Bishop's score <6.¹² In our study, mean Bishop's score at start of the study was 3.27, which was comparable with Saranya study, where mean bishop's score at start was 2.72 and Yellikar et al with mean bishop's score 2.02.^{8,13}

Favourable Bishop score of 6 or more at augmentation was seen in 90% in Group-I and 56% in Group-II (Table 3) which was consistent with Sah et al, Saranya et al, Arumugaselvi.^{6,8,13} Study done by Sah et al in 2018 with 76% in mifepristone gr and 56% in PGE2 gr with 200mg mifepristone. It was 96.6% in mifepristone gr and 76.6%

in PGE2 gr according to the study done by Gaikwad et al.¹⁵ This was contrary to study done by Sailatha et al in which improvement in Bishop score was significantly better with dinoprostone group as compared to mifepristone group.⁷

The need for augmentation with oxytocin was 64% in the mifepristone group and 74% in PGE2 group (Table 5) which was similar with Arumugaselvi et al where 66% in mifepristone gr and 78% in PGE2 gr required oxytocin. Similar study was done by Wing et al where 67% in mifepristone group required oxytocin for augmentation as compared to placebo.^{6,5} According to Salitha et al oxytocin requirement was less in mifepristone group (24%) as compared to cerviprime group (38%).⁷

Shortest drug administration to delivery interval in our study was 13 hours 30 min in mifepristone gr and 11 hour 48 min in PGE2 gr (Table 6) which was consistent with Arumugaselvi et al.⁶ In that study, shortest drug administration to delivery interval was 12 hour 5 min and 5 hour 54 min in mifepristone and PGE2 gr respectively.

In our study the mean induction delivery interval in Mifepristone group was 19.40 hours and PGE2 15.97 (Table 7) which is comparatively less than the randomized controlled trial conducted by Sailatha et al, in which mean induction delivery interval was 20.3 hours for mifepristone and 11.5 hours in PGE2 gr.⁷ The induction to delivery interval in mifepristone group was more as it takes about 24-48 hours for the drug to have priming effect on the cervix. According to Arumugaselvi et al, it was 18.73 hours and 11.47 hours in mifepristone and PGE2 respectively.⁶ A study was done by Bama et al in which 28.6 hour in mifepristone group and 35.44 hour in placebo group.¹⁶ Induction to delivery interval was shorted in mifepristone group compared to dinoprostone group in Sah et al study which was contrast to all above study.¹⁴

The criteria taken for the success of induction was vaginal delivery. In our study the rate of vaginal delivery was 92% in Mifepristone group (40% primigravida and 52% multigravida) and 84% in PGE2 gr (38% primi and 46%) (Table 8). The results were consistent with Bama et al study where the vaginal delivery is 96% in mifepristone gr and 72% in PGE2 gr.¹⁶ Success rate was 87.5% in mifepristone group in Wing et al study.⁵

Rate of LSCS in mifepristone group in our study was 8% and 16% in dinoprostone group (Table 8). Similar findings were noted by Sah et al and Shanitha et al.^{9,14} In this aspect our study is consistent with Sailatha et al study in which LSCS was done for failed induction (4%) in mifepristone gr and 10% in PGE2 gr.⁷ Gaikwad et al was also found higher of LSCS in dinoprostone group.¹⁵ According to Hapangama and Neilson, mifepristone treated women are less likely to undergo CS as a result of failed induction.¹⁷ The most common indication for LSCS was fetal distress in mifepristone group (6%)

where as both fetal distress (8%) and failed induction (8%) in dinoprostone group (Table 8). Fetal distress was most common indication for LSCS in the study of Shanitha et al and Sah et al.^{9,14} Gaikwad et al in their study found that the most common indication for LSCS was fetal distress in mifepristone group (8%) and most common indication for LSCS was failed induction in dinoprostone group (28%).¹⁵

None of the patient of mifepristone gr had hypertonus or tachysystole which was comparable with Wing et al.⁵ 2 patient in PGE2 gr had tachysystole (Table 9). This was in contrast to study conducted by Giacalone et al, in which Mifepristone treated group had higher rates of uterine hyperstimulation and tachysystole.¹⁸

In our study, none of our study population had major complications like rupture uterus, chorioamnionitis, postpartum hemorrhage, puerperal sepsis (Table 9). Only minor side effect like nausea, vomiting, abdominal pain which is similar to Elliot et al and Lelaideir et al.^{19,20} A total of 18% study population had minor complications like nausea, vomiting, abdominal cramps in mifepristone group and 8% in PGE2 group. In this aspect our study is consistent with the study conducted by Stenlund et al study.²¹

Meconium passage was encountered in 4% and NICU admission was 8% in mifepristone group and meconium passage was 10% and NICU admission was 16% in PGE2 gel group. APGAR score at 1 minute and 5 minute were similar in both groups. But there was no neonatal mortality in both groups (Table 9). In this aspect, our study is consistent with study conducted by Gaikwad et al, in which 6% and 14% babies admitted in mifepristone and PGE2 gr respectively.¹⁴ It was contrast to study by Sah et al where five neonate (10%) in mifepristone group one (2%) cases in dinoprostone group required NICU admission.¹³

Limitations

Limitations of this study is 24 hour study for induction is very lengthy process and only limited indicated cases are taken for induction.

CONCLUSION

The safety and efficacy of oral mifepristone as a preinduction cervical ripening agent is assessed in this study and compared with PGE2 gel. 100 antenatal mothers admitted at MKCG Medical College Hospital, who needed elective induction, satisfying the inclusion criteria were recruited into two groups and each were given oral mifepristone 200 mg or endocervical PGE2 gel 0.5 mg for cervical ripening and augmented with oxytocin. This study documents the success of induction, details of parturition, maternal and neonatal outcome. This study revealed that mothers in both groups had Bishop score of 0 to 5 at the start of study. 90% (42%

primigravida and 48% multigravida) had favourable Bishop score in mifepristone group whereas only 56% (28% primigravida and 28% multigravida) in PGE2 gel group. Duration of 1st stage and DD interval is shorter in PGE2 gr which is not significant.

Duration of 2nd and 3rd stage is shorter in mifepristone gr which is not significant. The outcome of induction in this study reveals that the mifepristone was successful in 82% in achieving vaginal delivery whereas PGE2 gel was successful in 74%. Cesarean section rate was 8% in mifepristone group whereas 16% in PGE2 gel group. 2% of failed induction in mifepristone gr where as it was 8% in PGE2 gr. Another indication of CS in both groups was fetal distress which comprises 6% and 8% in mifepristone and PGE2 gr respectively. Maternal complications were similar in both groups. Neonatal complications and neonatal admissions were lesser in mifepristone group.

Oral mifepristone is very safe and an effective drug for preinduction cervical ripening. It has an added advantage of ease of administration, better patient compliance and acceptance, reduced oxytocin requirement, shorter duration of II, III stages of labour with an overall success rate of 82%. The drug has no untoward side effects on uterine contraction and no major maternal complications and safe in neonatal outcome. Hence mifepristone offers advantages over PGE2 gel which is currently used for preinduction cervical ripening.

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

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