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EFFICACY AND SAFETY OF MIFEPRISTONE FOR INDUCTION OF LABOUR IN POST TERM PREGNANCY

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ABSTRACT

Aims and objective: The aim of our study was to evaluate the efficacy and safety of single dose oral mifepristone 200mg use for cervical ripening and initiation of labor in women with normal pregnancies beyond term.

Material and methods: This is a prospective study conducted in the department of obstetrics and gynecology at Patna Medical College and Hospital, Patna. 200 women with post term pregnancy who fulfilled the inclusion and exclusion criteria were included in our study over a period of 2years. A written informed consent was taken from all women who entered the study. Ethical committee approval was also taken.

Result:84 out of 104 of primigravida and 92 out of 96 of multigravida showed improvement in the Bishop score post induction with the single dose oral mifepristone of 200mg.81 out of 84 primigravida who showed improved Bishop score delivered vaginally and 90 out of 92 multigravidas with improved Bishop score had vaginal delivery successfully. Induction delivery interval was less than 48hour for 16 primigravida and 72 multigravida women of the study group.

Conclusion: Mifepristone as labor induction agent in post term pregnancies causes improvement in Bishop score and thereby increases rate of successful vaginal deliveries both in primigravids as well as multigravidas with no increased risk of maternal or fetal morbidity.

KEYWORDS : Mifepristone, post-term pregnancy, Bishop score, vaginal delivery, induction of labor (IOL).

INTRODUCTION

Any pregnancy which has crossed the expected date of delivery is called a postdated or post term pregnancy. In our study we have included all pregnancies of gestational age between 41 weeks 0 days to 41 weeks 6 days as post term pregnancies.

The incidence of post term pregnancy is between 4-14%, an average of 10%. Perinatal morbidity and mortality are increased when pregnancy continues beyond 41 weeks [1]. Induction of labour (IOL) may be considered at or beyond 41 weeks if cervix is favourable to prevent maternal morbidity and increased fetal morbidity and mortality. ACOG concludes that "induction of labour between 41 0/7 and 42 0/7 weeks can be considered given evidence of an increase in perinatal morbidity and mortality" [2].

Induction of labour however is associated with risks of uterine hyperstimulation, chances of failed induction thereby increasing caesarean section rates. A recent Cochrane registry report suggests that induction of labour at 41 completed weeks of gestation is associated with fewer perinatal deaths, and significantly fewer caesarean deliveries compared with expectant management [3].

Multiple agents are used for pre-induction cervical ripening and induction of labour. One of them is mifepristone. The role of mifepristone for cervical ripening and labour inducing agent in second trimester termination of pregnancy is well established. However, the role of mifepristone for labour induction in term as well as post term pregnancies is not well established.

Progesterone is responsible for uterine quiescence. Mifepristone is an antiglucocorticoid and antiprogesterone with higher affinity to progesterone receptors thereby causing initiation of labour by causing cervical effacement and dilatation and improving Bishop score. Mifepristone is characterized by rapid absorption and a long half-life of 25-30 hours [4]. Mifepristone is not an oxytocic therefore does not increase uterine activity and therefore does not causes over/hyper stimulation of the uterus. Cochrane collaboration published in 2012 is of the opinion that there is insufficient information available from clinical trials to support the use of mifepristone to induce labour [4]. We therefore conducted this study to find out safety and efficacy of single dose oral mifepristone for labour induction in normal post term pregnancies and also assess the induction delivery interval in our study population.

MATERIAL AND METHODS

This is a prospective study conducted in the department of obstetrics and gynaecology at Patna medical college and hospital, Patna over a duration of 2 years. This study included 200 women who have crossed their expected date of delivery and came to labour room emergency or antenatal out patient department with period of gestation between 41 weeks 0 days to 41 weeks 6days. All these women had normal pregnancies with no associated risk factors or comorbidities were taken for study.

The women who fulfilled inclusion and exclusion criteria were included in study. Written informed consent was taken from all patients prior to induction. All benefits and risks associated with induction of labour with mifepristone were explained to patients and relatives. Ethical committee approval was taken for the study. Pre induction modified Bishop's score was calculated for all patients.

INCLUSION CRITERIA-

a) women with post term pregnancy with maternal age >18years.
B) singleton pregnancy with live fetus in cephalic presentation
c) reactive fetal heart rate
d) intact membranes
e) preinduction Bishop's score <5.

EXCLUSION CRITERIA-

a) pregnancies with comorbidities or high-risk pregnancies like gestational diabetes mellitus, gestational hypertension.
b) pregnancies with intrauterine fetal demise
c) multiple pregnancy
d) antepartum haemorrhage, chorioamnionitis
e) previous caesarean section
f) estimated fetal weight >4000grams or <2000grams.

All women in the study group were given oral tablet of mifepristone of 200mg after preinduction Bishop scoring at the time of enrolment. Repeat scoring was also done at 24hours and then at 48hours.

Induction was considered successful if women showed improvement in Bishop's score and progressed to active labour within 48hours of induction. If the women do not show improvement in Bishop's score even after 48hours of induction, they were categorised as cases of failed induction. Women with failed induction, fetal distress underwent caesarean section. Women who entered active labour were augmented if required and progressed was watched and delivery was conducted according to our labour room protocols.

STATISTICAL ANALYSIS

In this study continuous variables were presented as mean with standard deviation. The Chi square test, unpaired test and fisher exact test was applied for statistical analysis. The statistical significance was considered as <0.05.

RESULT

Our study included 200 women who fulfilled inclusion and exclusion

criteria. Out of 200 women with single live fetus and post term pregnancy, 104 were primigravida and 96 women were multigravida. All women were between the age group of 19 years to 38 years.

Table 1: Age distribution of women in study group

Sl.no	Age Group	Study Population(n=200)
1	19-24	64(32%)
2	25-30	110(55%)
3	31-35	22(11%)
4	36-38	4(2%)

The study showed that majority of the women that is 55% of the women with post term pregnancy were of the age group 25 to 30years. 32% were of the age group 19-24 years,11% were of the age group 31-35 years and only2% were of the age group 36-38 years as shown in the table 1.

Table 2: Gestational age of women in study group

Sl. no.	Gestational age in weeks.	Study population N=200
1.	41 weeks 0days	62(31%)
2.	41 weeks 1 day	10 (5%)
3.	41 weeks 2 days	18(9%)
4.	41 weeks 3 days	24(12%)
5.	41 weeks 4 days	42(21%)
6.	41 weeks 5 days	39(19.5%)
7.	41 weeks 6 days	5(2.5%)

According to table 2, majority of women entered the study at the gestational age of 41 weeks which was 31% and only 2.5% of the study group women were of the gestational age 41 weeks and 6days.21% women were of gestational age of 41 weeks 4 days ,19.5 % were of gestational age 41 weeks 5 days,12% were of gestational age 41weeks 3 days and about 9% were of the gestational age 41 weeks 2 days.

Table3: Mean maternal age and mean gestational age of the women of the study group.

Mean maternal age(years)	25.79
Mean gestational age ($\pm$2SD)	41weeks $\pm$1 days

The mean age of the women in the study group was 25.79 years and the mean gestational age of the women was 41weeks and 1 day as shown in table3.

Our study included 200 women out of which 104 women were primigravida and 96 were multigravida as shown in table 4.

Table 4: Obstetric index of the study population

Obstetric index	Percentage (%)
Primigravida	52%
Multigravida	48%

Out of 104 primigravida women of the study population, 84 women showed improvement in bishop score within 48hours of induction of labour with oral mifepristone. 20 primigravida women showed no improvement in bishops score even after 48 hours of induction. Out of 96 multigravida women, 92 women showed improvement in bishops score within 48hours of induction and only 4 women failed to show improvement in the bishops score even after 48hours of induction with mifepristone. This is shown in table 5.

Table5: Bishops score analysis in study population

Bishops score	Primigravida (104)	Multigravida (96)
Improvement in Bishops score (0-24hours)	14	72
Improvement in Bishops score (24-48hours)	70	20
No improvement in Bishops score > 48 hours	20	4

Of the 84 primigravida who showed improvement in bishops score 81 delivered vaginally and 3 women underwent caesarean section due to fetal distress and arrest in second stage of labour. 20 primigravida who showed no improvement in bishops score even after 48 hours of induction underwent caesarean section due to failed induction. In the multigravida group, out of 92 who showed improvement in bishop score, 90 were delivered vaginally and 2 had to undergo caesarean section due to fetal distress.4 multigravida who did not show improvement in bishops score also underwent caesarean section due to failed induction.

Table6: Final outcome after induction

Bishops Score	Primigravida (104)	Multigravida (96)
Improvement in Bishops score<=48hours	84	92
Vaginal delivery after Bishop improvement	81	90
Caesarean section despite bishop improvement due to fetal distress	3	2
Caesarean section due to failed induction	20	4

Majority of multigravida women, 95.8% of the study group went into spontaneous labour within 48 hours of induction with mifepristone and 93.7% delivered vaginally. Only 4.1 % of multigravida women showed no improvement in the bishops score even after 48 hours of induction and were labelled as cases of failed induction and had to undergo caesarean section. 2 multigravida women had to undergo caesarean section due to fetal distress despite improved bishops' score. Amongst the primigravida 80.7 % went in spontaneous labour within 48 hours of induction and77.8 % delivered vaginally, some needed augmentation of labour as well.19.2% of primigravida had failed induction and had to undergo caesarean section.3 primigravida women had to undergo caesarean section despite improvement in bishops score due to fetal distress. These are shown in table 6.

DISCUSSION

There are different modalities available for induction of labour with the main aim of successful vaginal delivery with least maternal as well as fetal morbidity and mortality. In our study we used oral mifepristone tablets of 200mg for cervical ripening and labour induction in cases of post term pregnancies. Single dose of mifepristone of 200mg was found to be effective for cervical ripening at 72 hours (RR 2.13, 95% CI 1.15-3.97) as reported by Hapangame and Neilson [4]. Similar finding was also reported by Yelakar et al and Atawale et al [5,6]. Study by Wing et al however did not find significant cervical changes with the use of mifepristone. In our study however we found significant changes in the Bishop score within 48 hours in both multigravida as wellas primigravida women. Our study corroborates the finding of Hapangama and Neilson wherein they recorded high incidences of women going in spontaneous labour and having favourable cervix after 48 hours. More women went into spontaneous labour in our study without requiring oxytocin for induction. The incidence of caesarean section was also reduced and was comparable to the earlier study reported by Hapahgama and Neilson and Fathima et al [8]. There was minimal NICU admission and meconium stained liquor and was not so significant in our study. Even abnormal fetal heart rate pattern as shown in Hapangama and Neilson study was not found in our study after giving mifepristone.

Induction of labour with mifepristone in multigravida resulted in less interval in less time interval for spontaneous onset of labour from the time of induction. Majority of primigravida showed favourable response to induction with mifepristone though the time interval for spontaneous onset of labour was comparatively more than multigravidas.

Mean induction delivery interval was 35hours 4mins which was comparable to Sterlund and Wing study [9,10]. Mifepristone is an efficient drug for induction of labour in late term pregnancies. In our study primigravida resulting in vaginal delivery was 77.8 % and primigravida leading to caesarean section was 22.1 %. In case of multigravida 93.75% had vaginal delivery and 6.25% ended up in caesarean section.

Majority of the women of the study group (77.8% primigravida and 93.7% multigravida) had vaginal delivery. Induction of labour with mifepristone in late term pregnancy results in significant vaginal deliveries.

Only total of 29 women out of 200 women of the study group underwent caesarean section which was comparable to Sterlund study. Majority of primigravida that is 77.8% had vaginal deliveries. 93.7% of multigravida had vaginal delivery. 22.1%primigravida and 6.25% of multigravida had caesarean section.

CONCLUSION

Amongst various labour inducing agent mifepristone can be considered as cervical ripening and labour induction agent to achieve successful vaginal delivery.

Mifepristone an antiprogesterone causes a significant improvement in the Bishops score and is associated with an increase in the chances of vaginal delivery with minimal maternal and neonatal morbidities in the late term pregnancy. Mifepristone can be considered as an efficient drug for induction of labour in late term pregnancy.

Mifepristone in multigravida improved Bishops score and also resulted in less induction delivery interval compared to primigravida. Majority of primigravida also showed improvement in Bishop score and had vaginal deliveries.

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