



## Comparative study of induction of labor with oral mifepristone and intracervicaldinoprostone in primigravida

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### Abstract

**Background:** To evaluate the comparison of oral mifepristone and intracervicaldinoprostone in primigravida for induction of labour

**Material and methods:** Overall 100 subjects were enrolled in this research. The subjects were randomised into two cohorts: group 1 and group 2. Group 1 involved subjects who were given oral 200mg Mifepristone and Group 2 included subjects who were instilled with Dinoprostone gel 0.5mg without mifepristone ripening. Progress of labour was seen and further augmentation done with oxytocin whenever required. SPSS software was used for evaluation of results.

**Results:** It was observed that there was significant improvement in the APGAR score after administering Mifepristone to the patients which was proved statistically significant. Most of the patients delivered vaginally and was observed that there was 30% reduction in LSCS in Group 1 which was highly significant.

**Conclusion:** Mifepristone is a safe and efficient agent for cervical ripening and for initiation of labour in term patients.

**Key words:** Mifepristone, Dinoprostone, Labour

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### INTRODUCTION

Induction of labour is defined as the process of artificially stimulating the uterus to start labour. 1 Labour induction is required in 10-20% of the women near term. Medication that ripen the cervix play important role in modern obstetrics. Progesterone inhibits myometrial contractility, and its ongoing secretion during pregnancy ensures cervical competence. This is the rationale for attempting to use a progesterone receptor antagonist as a cervical ripening agent. Mifepristone is a synthetic steroid hormone analogue that has both antiprogesterone and anti-glucocorticoid activities.<sup>1</sup>

It increases the sensitivity of the uterus to prostaglandins and facilitates labour. Prostaglandin E2 (PGE2), also known by the name dinoprostone, is a naturally occurring compound that is involved in promoting labour. PGE2 is administered vaginally as a suppository, gel or insert.

Many studies have reported the efficacy of dinoprostone gel and misoprostol in induction, but the effectiveness of oral mifepristone lacks sufficient data relatively.<sup>2</sup>

Only a few studies have been reported so far where in the efficacy and safety of oral mifepristone have been assessed. 3–5 The aim of this study was to compare the safety and efficacy of oral mifepristone with dinoprostone gel in induction of labour in primigravidas.<sup>3,4</sup>

## MATERIALS AND METHODS

Overall; 100 subjects were enrolled in this research. The subjects were randomised into two cohorts: group 1 and group 2. Group 1 comprised primigravida who were given oral 200mg Mifepristone and Group 2 subjects were administered with Dinoprostone gel 0.5mg without mifepristone ripening. Advancement of labour had been observed as well as subsequent augmentation was done with oxytocin whenever needed. In the event of unsatisfactory labor progress or the presence of variable fetal heart rate patterns during labor in either group, the participants underwent a caesarean section or instrumental delivery as needed. Oxytocin was used to augment labor in both groups, along with amniotomy when the Bishop score was 6 or higher with oxytocin, as required. SPSS software was used for evaluation of results.

## RESULTS

Table 1 illustrates that majority of the women enrolled in both the groups were from same age group (21-25); only upto 10% of patients were elderly (>30 years) in the dinoprostone group. Majority of the patients were between 39-41 weeks which shows almost equal distribution in both the group. It was observed that there was significant improvement in the APGAR score after administering Mifepristone to the patients. This improvement was even proven statistically significant with p value <0.004. Most of the patients delivered vaginally in Group 1 and in Group 2. It was observed that there is 30% reduction in LSCS in Group 1, and was highly significant with p value < 0.004.

Table 1: Age wise distribution of cases.

| Age in years | Mifepristone Group | Dinoprostone Group | Total     |
|--------------|--------------------|--------------------|-----------|
| <20          | 6(12%)             | 8(16%)             | 14(14%)   |
| 21-25        | 37(74%)            | 27(54%)            | 64(64%)   |
| 26-30        | 7(14%)             | 9(18%)             | 16(16%)   |
| 31-35        | 0(0%)              | 6(12%)             | 6(6%)     |
| <b>Total</b> | 50(100%)           | 50(100%)           | 100(100%) |

Table 2: Need for oxytocin augmentation

| Oxytocin augmentation | Mifepristone Group | Dinoprostone Group | p-value             |
|-----------------------|--------------------|--------------------|---------------------|
| Required              | 28                 | 33                 | 0.001 (Significant) |
| Not required          | 22                 | 17                 |                     |

Table 3: Outcome variables

| Outcome variables          | Mifepristone Group | Dinoprostone Group | p-value             |
|----------------------------|--------------------|--------------------|---------------------|
| Mean APGAR Score at 5 mins | 7.51               | 8.38               | 0.001 (Significant) |
| NICU admission             | 2                  | 5                  | 0.001 (Significant) |

## DISCUSSION

The incidence of labor induction has continued to rise over the past several decades. The survey found that African countries have lower rates of induction of labor (Nigeria 1.4%) compared with Asian and Latin American countries (highest: Sri Lanka 35.5%). Induction can be defined as an intervention intended to artificially initiate uterine contractions resulting in the progressive effacement and dilatation of the cervix which will result in the birth of the baby by vaginal route.<sup>7-10</sup> Hence the present study was conducted to evaluate the comparison of oral mifepristone and intracervical dinoprostone in primigravida for induction of labour.

Majority of the patients were between 39-41 weeks which shows almost equal distribution in both the group. It was observed that there was significant improvement in the APGAR score after administering Mifepristone to the patients. This improvement was even proven statistically significant with p value <0.004. Most of the patients delivered vaginally in Group 1 and in Group 2. It was observed that there is 30% reduction in LSCS in Group 1, and was highly significant with p value < 0.004. Kumari S et al compared the effectiveness and safety of mifepristone with PGE2 gel for cervical ripening and induction of labor. 191 patients were included and divided into 94 patients in group A (mifepristone) and 97 patients in group B (PGE2 gel). Tablet mifepristone 200 mg orally was given in group A, and intracervical PGE2 gel was given in group B. Preinduction Bishop's score was noted at beginning to compare the improvement in Bishop's score after induction. Mode of delivery and induction to delivery interval, complication, and neonatal outcome were noted in both groups. Change in Bishop's score was noted after 24 hours, and it was comparable in both groups. Induction to delivery interval was significantly less in group B (29 hours) as compared to group A (34 hours). The rate of vaginal delivery was 62.5% in group A and 55.4% in group B. In group A 10.2% and 16.3% in group B required NICU admission. Mifepristone is more effective than PGE2 gel for cervical ripening as it has high rate of vaginal delivery and good neonatal outcome.<sup>10</sup> Jindal Net al evaluated the efficacy and safety of mifepristone for cervical ripening and induction of labor. A total of 100 patients were enrolled in a prospective study and assigned to one of two treatment protocols. After the exclusion of 10 patients, there were 46 patients in the mifepristone group and 44 in the dinoprostone group. Outcome was evaluated using the improvement in Bishop score, admission delivery interval, duration between induction and the onset of active phase of labor and the mode of delivery. The improvement in Bishop's score at first post-intervention assessment was significantly better in dinoprostone group. Duration between instillation and active phase assessment was significantly lesser in dinoprostone group while the admission delivery interval was lesser in mifepristone group. There was no difference in mode of delivery between the two groups. The results of the study

suggested that oral administration of 200 mg mifepristone in term patients is an effective method of labor induction; and is more convenient and equally safe as compared to intravaginal instillation of dinoprostone.<sup>11</sup>

## **CONCLUSION**

Mifepristone is a safe and efficient agent for cervical ripening and for initiation of labour in term patients.

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