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Indian Journal of Obstetrics and Gynecology Research

Journal homepage: www.ijogr.org

Original Research Article

A prospective study to compare oral mifepristone and dinoprostone gel in induction of labour in primigravida

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ARTICLE INFO

Article history:
Received 20-05-2021
Accepted 13-01-2022
Available online 20-05-2022

Keywords:
Mifepristone
Dinoprostone gel
Labour

ABSTRACT

Introduction: Induction of labour is defined as the process of artificially stimulating the uterus to start labour. Mifepristone is a synthetic steroid hormone analogue that has both antiprogesterone and antiglucocorticoid activities. It increases the sensitivity of the uterus to prostaglandins and facilitates labour. 2 Dinoprostone, is a naturally occurring prostagladin that is involved in promoting labour. The aim of this study was to compare the safety and efficacy of oral mifepristone with dinoprostone gel in induction of labour in primigravidas.

Objectives: To compare the safety and efficacy of oral mifepristone with dinoprostone gel in induction of labour at term.

Materials and Methods: This was a hospital based prospective study conducted from August 2019 to January 2021.Group 1 involved primigravida who were given oral 200mg Mifepristone on an inpatient and primigravida in Group II were instilled with Dinoprostone gel 0.5mg without mifepristone ripening and further assessment were done in both groups. Progress of labour was seen and further augmentation done with oxytocin whenever required.

Results: 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 Bishop's score after administrating Mifepristone to the patients which was proved statistically significant (<0.004). Most of the patients delivered vaginally and was observed that there was 28% reduction in LSCS in Group I which was highly significant with p value < 0.004.

Conclusion: We concluded that Mifepristone is a safe and efficient agent for cervical ripening and for initiation of labour in term patients as it causes improvement in bishops score and increase in vaginal delivery.

1. 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 antiglucocorticoid activities. It increases the sensitivity of the uterus to prostaglandins and facilitates labour.[2]

Prostaglandin E2 (PGE2), also known by the name dinoprostone, is a naturally occurring compound that

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https://doi.org/10.18231/j.ijogr.2022.040

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. 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.

2. Materials and Methods

This study was conducted at the Obstetrics and Gynaecology department of a rural tertiary level institute of South India. This was a hospital based prospective study conducted from August 2019 to January 2021.

2.1. Study design

The following were the inclusion criteria in the study-

1. Primigravida with live singleton pregnancy in cephalic presentation and induced at term.
2. Ultrasonographically confirmed singleton pregnancy with no contraindications to vaginal delivery.
3. Bishop score <6 before induction.

Women with the following conditions were excluded from the study-

1. Previous scarred uterus.
2. Known hypersensitivity to prostaglandin or mifepristone
3. Major cephalopelvic disproportion.
4. Medical problems like impaired renal, hepatic or adrenal function.
5. Antepartum hemorrhage.

After detailed history, clinical examination, investigations and informed consent, the women were assigned one or the two treatment groups by random computer generated sequence. Group 1 involved cervical ripening with the use of oral 200mg Mifepristone on an inpatient basis, first assessment was done 24h after administration and later progress of labour was assessed. Induction of labour in Group II was done through endocervical instillation of Dinoprostone gel 0.5mg without mifepristone ripening.

A second dose of dinoprostone was used when the Bishop score was less than 6 at first assessment, 6h after instillation of first dose. If during labour, either of the groups, progress of labour was unsatisfactory or variable fetal heart rate patterns was observed, the participants underwent caesarean section or instrumental delivery as indicated.

Augmentation of labour was done with oxytocin in both groups with amniotomy when the Bishop score was 6 or more with oxytocin, wherever required.

3. Objectives

1. To compare the safety and efficacy of oral mifepristone with dinoprostone gel in induction of labour at term

The objectives were to be achieved by comparing the following outcomes:

1. Improvement in Bishop score
2. Induction to delivery interval
3. Duration between induction and the onset of active phase of labour
4. Mode of delivery

4. Statistical analysis

Qualitative baseline characteristics were compared in both groups using Fisher's exact test; continuous variables such as the gestational age, bishop scores, induction delivery interval and other outcomes of quantitative nature were compared using a two tailed Mann- Whitney test. Statistical analysis was carried out using SPSS version 19; statistical significance was set with a P value of 0.01.

5. Results

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.(Table 1)

Table 1: Distribution of cases according to age

Age in Yrs	Mifepristone Group	Dinoprostone Group	Total
≤ 20	6	10	16
21-25	27	17	44
26-30	6	8	14
31-35	0	4	4
Total	39	39	78

Chi Square Test P<0.01, Significant

Majority of the patients were between 39-41 weeks (74.3% in group I and 66.6% in group II) which shows almost equal distribution in both the group. (Table 2)

Mean Bishop's score at the time of admission observed in group I were 3.08 ± 0.70 and group II were 2.77± 0.74.

Mean Bishop's score at first post intervention assessment observed in group I were 6.4±0.91 and group II were 5.6±1.4. It was observed that there was significant improvement in the Bishop's score after administrating Mifepristone to the patients. This improvement was even proven statistically significant with p value <0.004.(Table 3)

Induction to delivery interval after priming cervix with mifepristone and misoprostol was definitely reduced, which is proven not much significant with p value = 0.597. (Table 4)

Table 2: Distribution of patients according to gestational age

Gestational age	Mifepristone group	Dinoprostone group	Total
37-37+6 wks	2	5	7
38-38+6 wks	8	8	16
39-39+6 wks	16	10	26
40-40+6 wks	13	16	29
Total	39	39	78

Chi Square Test P 0.039, Not Significant

Table 3: Bishop score in both the groups

Bishop score	Mifepristone group	Dinoprostone group	Unpaired t Test	
			P Value	Significance
At the time of admission	3.08 ± 0.70	2.77 ± 0.74	0.064	Not Sig
At first post intervension assessment	6.4 ± 0.91	5.6 ± 1.4	0.004	Highly Sig

Table 4: Induction delivery interval of both the groups

Parameters	Mifepristone group	Dinoprostone group	Unpaired t Test	
			P Value	Significance
Duration between induction to active phase of labour (in Hrs)	7.33 ±1.5	7.05 ± 3.5	0.650	Not Sig
Duration between active phase to delivery (only in vaginal) (in Hrs)	3.04 ± 1.62	3.08 ± 1.32	0.312	Not Sig
Induction to delivery interval (in Hrs)	10.9 ± 1.86	10.56 ± 3.79	0.597	Not Sig

Most of the patients delivered vaginally (89.7%) in Group I and (61.53%) in Group II. It was observed that there is 28% reduction in LSCS in Group I, and was highly significant with p value < 0.004.(Table 5)

Most common complication that required operative intervention was fetal heart variability more with Group II (73.3%).(Table 6)

6. Discussion

In this study, study population comprised of 78 patients with equal number of patients in the mifepristone and dinoprostone group. Few studies have been done where Mifepristone is used for induction of labour. Hapangama and Neilson reported that a single dose of 200mg mifepristone appears to be the lowest effective dose for cervical ripening.6In our study, Mifepristone 200mg was chosen for induction of labour.

Gupta et al. assessed the efficacy and safety of oral mifepristone for cervical priming and induction. They gave 400mg per oral dose to the study group and did no active intervention in the control group.[4] Yelikar et al., studied role of oral mifepristone and found statistically significant improvement in Bishop score after 24 h of administration in comparison to control.[5]

In our study, the Bishop score improved dramatically in both the treatment groups, however the improvement in Bishop's score was statistically significant in the mifepristone group.

In a study done by Sah et al, it was found that mifepristone was more effective in improving Bishop score as compared to dinoprostone as success rate was 76% in the former while 56% in the latter group.[6] The induction delivery interval in mifepristone group appears to be more because the drug takes at least 24-48 hours to have its priming effect on the cervix. Mifepristone exerts its effect by increasing uterine contractility and by increasing the sensitivity of the uterus to actions of prostaglandins. While, dinoprostone directly cause uterine smooth muscle contractility explaining the difference in the time of action of the two agents.

In present study patients included in Group I had mean Bishop score 3.08± 0.70 which were induced with mifepristone and outcome observed. In another group where Dinoprostone was used as pre induction drug for cervical ripening, mean Bishop's score observed was 2.77±0.74.

As expected after first post intervention assessment of mifepristone mean bishop's score observed was 6.4±0.91 and statistically proven significant with p value <0.004.

Table 5: Mode of delivery in both the groups

Mode of delivery	Mifepristone group	Dinoprostone group	Total
Vaginal delivery	35	24	59
LSCS	4	15	19
Total	39	39	78

Chi Square Test P< 0.004, Highly Significant

Table 6: Indication for LSCS in both the groups

Indication For LSCS	Mifepristone group	Dinoprostone group	Total
Fetal distress	3	11	14
Maternal desire	1	3	4
Uncontrolled BP readings	0	1	1
Total	4	15	19

Similar observations are with Wing D.A Fassett Michael J where Bishop's score before administration of mifepristone were unfavourable and almost 20% patients went in spontaneous labour with favourable Bishop's score. [7]

Shanitha Fathima et al observed the significant difference in Bishop's score pre and post administration of mifepristone as well as dinoprostone in their study as mean pre induction score 2.32 +-0.76 and mean post induction score as 7.25 +- 1.75 at 48 hours. [8]

Athawale R et al also observed pre induction Bishop's score <3 in 84% as compared to 58% in placebo group, where Bishop's score improved 24 hours after mifepristone upto >8 in 72% as compared to placebo where Bishop's score remain between 4-8 in 86% patients. [9]

In present study mode of delivery was affected much by the induction protocol used, 38.4% of Group I patients required LSCS whereas only 10.2% patients of Group II underwent LSCS.

7. Conclusion

From our study we conclude that Mifepristone is a safe and efficient agent for cervical ripening and for initiation of labour in term patients. Mifepristone causes a significant improvement in their Bishop score and is associated with an increase in the chance of vaginal delivery.

8. Source of Funding

None.

9. Conflict of Interest

The authors declare no conflict of interest.

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Cite this article: Gomathy E, Neha B S. A prospective study to compare oral mifepristone and dinoprostone gel in induction of labour in primigravida. *Indian J Obstet Gynecol Res* 2022;9(2):204-207.