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Original Research Article.

Comparison of Safety and Efficacy of Intravaginal Misoprostol And Intracervical Dinoprostone in Induction of Labor at a Tertiary Care Hospital

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ABSTRACT

Background: Labor is a final consequence of Pregnancy and is inevitable. Misoprostol is a synthetic prostaglandin E_1 analogue used off-label for a variety of indications in the practice of obstetrics and gynaecology including induction of labor. Dinoprostone is a naturally occurring compound that is involved in promoting labor, though it is also present in the inflammatory pathway. Hence; the present study was conducted for comparing the safety and efficacy of intravaginal misoprostol and intracervical dinoprostone in induction of labor.

Materials & Methods: 52 subjects (within age range of 20 to 30 years and with gestational age of more than 37 weeks) were enrolled in the present study and were broadly divided into two study groups as follows: Group A: Subjects receiving tablet Misoprostol (25 microgram) vaginally four hourly to a maximum of three doses, and Group B: Subjects receiving Dinoprostone gel (0.5 mg) intracervically for six hours to a maximum of three doses. After drug insertion in their respective study groups, patients were assessed for signs and symptoms of labor. Maternal vital signs and fetal heart rate were continuously monitored. Outcome was assessed.

Results: Mean time of onset of labor among the subjects of Group A and Group B was 52.5 minutes and 84.7 minutes respectively. Significant results were obtained while comparing the mean time of onset of labor among the two study groups. Oxytocin augmentation was required in 15.38% and 19.23% of the patients of Group A and group B respectively. Non-significant results were obtained while comparing the incidence of complications among the two study groups.

Conclusion: Intravaginal misoprostol is significantly better in comparison to intracervical dinoprostone in induction of labor.

Key words: Induction, Intravaginal, Misoprostol, Dinoprostone.

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INTRODUCTION

Labor is a final consequence of Pregnancy and is inevitable. The timing of labor may vary widely but it will happen sooner or later. In some 5-25% of pregnancies, there comes a time when the fetus and/or mother would be better off if delivery was conducted.[1, 2]

Misoprostol is a synthetic prostaglandin E_1 analogue marketed as an oral preparation used to prevent and treat gastroduodenal damage induced by nonsteroidal anti-inflammatory drugs (NSAIDs). However, misoprostol is used off-label for a variety of indications in the practice of obstetrics and gynaecology, including medical abortion, medical management of miscarriage, induction of labor, cervical ripening before surgical procedures, and the treatment of postpartum hemorrhage.[3, 4] Prostaglandin E2 (PGE2), also known by the name dinoprostone, is a naturally occurring compound that is involved in promoting labor, though it is also present in the inflammatory pathway. Prostaglandin E2 is FDA approved for cervical ripening for the induction of labor in patients for which there is a medical indication for induction. When used as a vaginal suppository, it is indicated as an abortifacient from gestational week 12 to 20 or for the evacuation of uterine contents for the management of missed abortion and intrauterine fetal death up to 28 weeks.[5-7] Hence; the present study was conducted for comparing the safety and efficacy of intravaginal misoprostol and intracervical dinoprostone in induction of labor.

MATERIALS & METHODS

The present study was conducted in the Department of Obstetrics & Gynaecology, Rajshree Medical Research Institute & Hospital, Bareilly, Uttar Pradesh (India) for comparing the safety and efficacy of intravaginal misoprostol and intracervical dinoprostone in induction of labor.

A total of 52 subjects (within age range of 20 to 30 years and with gestational age of more than 37 weeks) were enrolled in the present study and were broadly divided into two study groups as follows:

Group A: Subjects receiving tablet Misoprostol (25 microgram) vaginally four hourly to a maximum of three doses, and

Group B: Subjects receiving Dinoprostone gel (0.5 mg) intracervically for six hours to a maximum of three doses.

Exclusion criteria for present study were as follows:

- Patients with history of previous cesarean section
- Contracted pelvis
- Antepartum hemorrhage
- Pelvis tumors
- Asthmatic patients

Continuous monitoring of all the patients was done. After drug insertion in their respective study groups, patients were assessed for signs and symptoms of labor. Maternal vital signs and fetal heart rate were continuously monitored. Outcome was assessed. All the results were recorded in excel sheet and were analyzed by SPSS software.

RESULTS

Mean gestational age among the subjects of group A and group B was 39.6 weeks and 39.1 weeks respectively. Mean time of onset of labor among the subjects of Group A and Group B was 52.5 minutes and 84.7 minutes respectively. Significant results were obtained while comparing the mean time of onset of labor among the two study groups. Oxytocin augmentation was required in 15.38% and 19.23% of the patients of Group A and group B respectively. Caesarean delivery was done in 2 patients of the Group A and 5 patients of Group B. NICU admission was done in 3 patients of the Group A and 1 patient of the Group B. Non-significant results were obtained while comparing the incidence of complications among the two study groups.

Graph 1: Mean gestational age

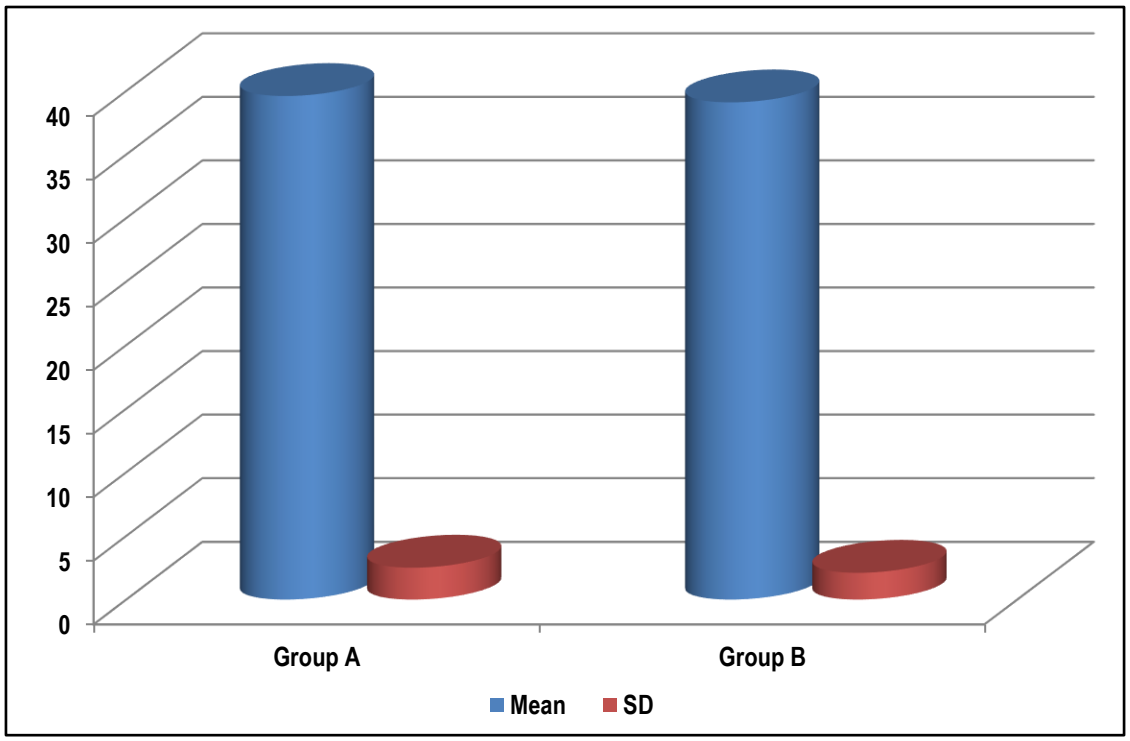

Table 1: Comparison of time of onset of labor

Time of onset of labor (minutes)	Group A	Group B
Mean	52.5	84.7
SD	8.6	15.9
p- value	0.001 (Significant)	

Table 2: Requirement of oxytocin augmentation

Variable	Group A		Group B	
	Number	Percentage	Number	Percentage
Requirement of oxytocin augmentation	4	15.38	5	19.23

Table 3: Incidence of Cesarean section and NICU admission

Variable	Group A		Group B	
	Number	Percentage	Number	Percentage
Cesarean section	2	7.69	5	19.23
NICU admission	3	11.54	1	3.85

DISCUSSION

Induction of labor at term with an intention of achieving a vaginal delivery is a common accepted obstetric intervention when continuation of pregnancy is deleterious for mother or fetus or both. It is an intervention that artificially stimulates uterine contractions leading to progressive dilation and effacement of cervix and expulsion of fetus prior to onset of spontaneous labor. In some 5-25% of pregnancies, there comes a time when the fetus and/or mother would be better off if the delivery was conducted. Advent of prostaglandins has revolutionized induction of labor.[7-9] Hence; the present study was conducted for comparing the safety and efficacy of intravaginal misoprostol and intracervical dinoprostone in induction of labor.

In the present study, 52 subjects were enrolled in the present study and were broadly divided into two study groups as follows: Group A: Subjects receiving tablet Misoprostol (25 microgram) vaginally four hourly to a maximum of three doses, and Group B: Subjects receiving Dinoprostone gel (0.5 mg) intracervically for six hours to a maximum of three doses. Mean time of onset of labor among the subjects of Group A and Group B was 52.5 minutes and 84.7 minutes respectively. Significant results were obtained while comparing the mean time of onset of labor among the two study groups. Oxytocin augmentation was required in 15.38% and 19.23% of the patients of Group A and group B respectively. Agarwal N compared the efficacy of 6-hourly vaginal misoprostol versus intracervical dinoprostone for induction of labor. A total of 120 pregnant women requiring induction of labor were recruited. Cases were randomized to receive either 50 microg vaginal misoprostol 6 hourly (group 1, n = 60) or 0.5 mg intracervical dinoprostone 6 hourly (group II, n = 60). The need of oxytocin augmentation was reduced in misoprostol versus dinoprostone group, 16.6% versus 78.3% (P = <0.001). Induction delivery interval was shorter in misoprostol; 12.8 +/- 6.4 h versus 18.53 +/- 8.5 h in dinoprostone group (P = <0.01). They concluded that vaginal misoprostol 50 microg 6-hourly is safe and effective for induction of labor with lesser need of oxytocin augmentation and shorter induction delivery interval.[2]

In the present study, Caesarean delivery was done in 2 patients of the Group A and 5 patients of Group B. NICU admission was done in 3 patients of the Group A and 1 patient of the Group B. Non-significant results were obtained while comparing the incidence of complications among the two study groups. Krithika KS et al, in another study compared the efficacy and safety of intravaginal Misoprostol with intracervical dinoprostone gel for induction of labor in cases of unfavourable cervix. One hundred women with an unfavourable cervix requiring induction of labor were randomised to receive either 25 microm vaginal Misoprostol 4-hourly or 0.5 mg of intracervical dinoprostone 12 hourly. Induction to delivery interval was shorter in the Misoprostol group, 16.59 +/- 5.13 h vs 27.77 +/- 12.71 h. The rate of complications was comparable.[10] In another study conducted by Raval BM et al, authors analysed compared effect of intra vaginal Misoprostol and intra cervical Dinoprostone gel for induction of labor. 100 patients who required labor of induction were included. 50 patients of them received 25mcg tablet misoprostol intravaginal and 50 patients of them required 0.5mg intracervical dinoprostone gel. The mean time taken for induction to active phase of labor (1hr 42min v/s 4hr 10min) and active phase to delivery (3hr 6min v/s 4hr54min) was less in Misoprostol than Dinoprostone group. The mean time required for induction to delivery was less in Misoprostol group (5hr 2min v/s 11hrs). Requirement of oxytocin for augmentation of labor was almost equal in both groups. They concluded that both Misoprostol and Dinoprostone gel are safe, effective for cervical ripening and induction but Misoprostol is more cost effective and stable at room temperature.[11] Agarwal et al have studied vaginal PGE1 50mg 6 hourly vs intracervial PGE2 gel, and have concluded that vaginal misoprostol is more effective and safer for labor induction at term.[2]

CONCLUSION

From the above results, the authors conclude that intravaginal misoprostol is significantly better in comparison to intracervical dinoprostone in induction of labor. However; further studies are recommended.

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