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Original Research

Assessment of efficacy of intravaginal misoprostol and intracervical dinoprostone in induction of labour: A comparative study

Dr Lalita Bansal[1], Dr Padam Negi[2],

[1]Gynecologist regional hospital Kullu Distt Kullu Himachal Pradesh
[2]Consultant Radiologist Shri Naina Diagnostic Centre Mandi Distt Mandi Himachal Pradesh

ABSTRACT:
Background: The present study was conducted for comparing the safety and efficacy of intravaginal misoprostol and intracervical dinoprostone in induction of labour. **Materials & methods:** 80 subjects were enrolled in the present study and were broadly divided into two study groups as follows: Group 1: Subjects receiving tablet Misoprostol (25 microgram) vaginally four hourly to a maximum of three doses, and Group 2: 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. Outcome was assessed. **Results:** Mean time of onset of labor among the subjects of Group 1 and Group 2 was 61.6 minutes and 88.4 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 12.5% and 20% of the patients of Group 1 and group 2 respectively. Caesarean delivery was done in 3 patients of the Group 1 and 4 patients of Group 2. NICU admission was done in 3 patients of the Group 1 and 2 patient of the Group 2. Non-significant results were obtained while comparing the incidence of complications among the two study groups. **Conclusion:** In comparison to intracervical dinoprostone, intravaginal misoprostol is significantly better in induction of labour.
Key words: Induction, Intravaginal, Misoprostol, Dinoprostone

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Corresponding author: Dr Lalita Bansal, Gynecologist regional hospital Kullu Distt Kullu Himachal Pradesh

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INTRODUCTION

Induction of labour (IOL) is the process of initiating contractions in pregnant persons who are currently not in labour, to help them achieve vaginal delivery within 24 to 48 hours.[1] Cervical ripening is one of the methods used for labour induction; it is "the use of pharmacological or other means to soften, efface, or dilate the cervix to increase the likelihood of a vaginal delivery."[1] The two major techniques for cervical ripening are mechanical interventions (e.g. insertion of balloon catheters), and application of pharmacological agents (e.g. prostaglandins).[2] Prostaglandins are one of the preferred methods for cervical ripening, including the agents dinoprostone and misoprostol.[3]

Misoprostol is a synthetic analogue of prostaglandin E1, which has gastric antisecretory and mucosal protective effects. The oral form is approved in Canada for the treatment and prevention of gastroduodenal ulcers caused by nonsteroidal anti-inflammatory drugs (NSAIDs), and for the treatment of duodenal ulcers caused by peptic ulcer disease.[4] The most common side effects with a single oral dose of misoprostol are diarrhea, abdominal pain, nausea, flatulence, and dyspepsia.[4]

Vaginal prostaglandin E2 (PGE2) (dinoprostone) has been shown to increase the chance of vaginal delivery in 24 h compared with a placebo. However, dinoprostone is costly and must be refrigerated or frozen during transportation and storage because of its thermal instability.[5, 6] Hence; the present study was conducted for comparing the safety and efficacy of intravaginal misoprostol and intracervical dinoprostone in induction of labour.

MATERIALS & METHODS

The present study was conducted for comparing the safety and efficacy of intravaginal misoprostol and intracervical dinoprostone in induction of labour. 80 subjects were enrolled in the present study and were broadly divided into two study groups as follows: Group 1: Subjects receiving tablet Misoprostol (25 microgram) vaginally four hourly to a maximum of three doses, and Group 2: Subjects receiving Dinoprostone gel (0.5 mg) intracervically for six hours to a maximum of three doses. 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. Outcome was assessed. All the results were recorded in excel sheet and were analyzed by SPSS software.

RESULTS

38.9 weeks and 39.5 weeks was the mean gestational age among subjects of group 1 and group 2 respectively. Mean time of onset of labor among the subjects of Group 1 and Group 2 was 61.6 minutes and 88.4 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 12.5% and 20% of the patients of Group 1 and group 2 respectively. Caesarean delivery was done in 3 patients of the Group 1 and 4 patients of Group 2. NICU admission was done in 3 patients of the Group 1 and 2 patient of the Group 2. Non-significant results were obtained while comparing the incidence of complications among the two study groups.

Table 1: Comparison of time of onset of labour

Time of onset of labor (minutes)	Group 1	Group 2
Mean	61.6	88.4
SD	7.3	14.8
p- value	0.000 (Significant)	

Table 2: Requirement of oxytocin augmentation

Variable	Group 1		Group 2	
	Number	Percentage	Number	Percentage
Requirement of oxytocin augmentation	5	12.5	8	20

Table 3: Incidence of Cesarean section and NICU admission

Variable	Group 1		Group 2	
	Number	Percentage	Number	Percentage
Cesarean section	3	7.5	4	10
NICU admission	3	7.5	2	5

DISCUSSION

Labour is a final consequence of Pregnancy and is inevitable. The timing of labour 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. 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). 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.[7- 10] Hence; the present study was conducted for comparing the safety and efficacy of intravaginal misoprostol and intracervical dinoprostone in induction of labour.

38.9 weeks and 39.5 weeks was the mean gestational age among subjects of group 1 and group 2 respectively. Mean time of onset of labor among the subjects of Group 1 and Group 2 was 61.6 minutes and 88.4 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 12.5% and 20% of the patients of Group 1 and group 2 respectively. Our results were in concordance with the results obtained by previous authors who also reported similar findings. Malik N compared the safety and efficacy of intravaginal misoprostol and intracervical dinoprostone gel (cervigel) for cervical ripening and induction of labour. 80 women were recruited in the study. 40 women were administered misoprostol tablet 25ug vaginally while the other 40 were given intracervical cervigel. A total of 85.1% (68 patients) delivered vaginally (33 in the misoprostol group and 35 in the cervigel group) i.e. spontaneous vaginal and assisted vaginal deliveries. The mean interval from start of induction to vaginal delivery was 707.63+146.511 minutes in the misoprostol group and 833.13 +144.36 minutes in the cervigel group with p=0.001 which was significant statistically. Though both the groups showed a favourable change in Bishop's score after induction but this was not statistically significant. However, the number of doses required in both the groups to produce an effect on cervical ripening and dilation was statistically significant p=0.001, cervigel group requiring lesser dose (42.5% in cervigel vesus 7.5% in the misoprostol group after administration of 1st dose). Both 25ug misoprostol intravaginal and dinoprostone gel intracervical are equally effective and safe for cervical ripening and induction of labour.[11]

Caesarean delivery was done in 3 patients of the Group 1 and 4 patients of Group 2. NICU admission was done in 3 patients of the Group 1 and 2 patient of the Group 2. Non-significant results were obtained while comparing the incidence of complications among the two study groups. In a similar study conducted by Nanda S et al, authors evaluated 100 pregnant women admitted for induction of labour. The patients were divided randomly into two groups of 50 each. Group I received 25 microg misoprostol

intravaginally every 3 h (maximum dose 200 microg), and Group II received 0.5 mg PGE(2) gel (dinoprostonev) intracervically every 6 h (maximum three doses in 24 h) until good uterine contractions started. The primary outcome measure was vaginal delivery occurring within 24 h of administration of the first dose of either study drug (successful induction). Statistical analysis were conducted using chi(2) test, Fisher exact test, Student's t-test and relative risk (RR) with 95% confidence interval (CI). In the misoprostol group, more patients achieved successful inductions as compared with the dinoprostone group, 80% vs. 62% (P = 0.0473, RR 1.63, 95% CI 0.95-2.81). The mean induction to delivery interval (IDI) was shorter in the misoprostol group, 13.30+/-8.74 (3-40.15) hours, as compared with the dinoprostone group, 18.53+/-11.33 (2-48.07) hours (P = 0.011). Misoprostol was associated with significantly less oxytocin use (18% vs. 50%) as compared with dinoprostone (P = 0.001 RR 0.36, 95% CI 0.19-0.69). In conclusion, although both misoprostol and dinoprostone appear to be effective agents for labour induction, misoprostol is cheaper, stable at room temperature, has shorter IDI and requires less oxytocin. These results make misoprostol superior to dinoprostone for induction of labour especially in developing and tropical countries.[12]

CONCLUSION

Intravaginal misoprostol is significantly better in comparison to intracervical dinoprostone in induction of labour.

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