ORIGINAL RESEARCH

Comparative Evaluation of Safety and Efficacy of Intravaginal Misoprostol and Intracervical Dinoprostone in Induction of Labor: An Institutional Based Study

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ABSTRACT

Background: The present study was conducted for comparing the safety and efficacy of intravaginal misoprostol and intracervical dinoprostone in induction of labor. **Materials & Methods:** A total of 100 subjects were enrolled and were broadly and randomly divided into two study groups with 50 subjects in each group as follows: Misoprostol group and Dinoprostone group. Complete demographic and clinical details of all the subjects were obtained. Subjects of Misoprostol group received 50 µg misoprostol tablet vaginally while subjects of Dinoprostone group received 0.5 mg dinoprostone gel. In most cases the fetal heart was auscultated every fifteen minutes until the onset of labor. Surveillance by continuous palpation for uterine hypertonicity and auscultation after each contraction were started as soon as labor was established. Cardiotocography was reserved for cases with signs of fetal distress. All the results were recorded in Microsoft excel sheet followed by statistical analysis using SPSS software. **Results:** Need for second dose among Misoprostol group and Dinoprostone group was in 8 percent and 16 percent of the subjects respectively. Need for oxytocin infusion among Misoprostol group and Dinoprostone group was in 16 percent and 38 percent of the subjects respectively. Vaginal delivery occurred in 98 percent of the subjects of the Misoprostol group and in 88 percent of the subjects of the Dinoprostone group. **Conclusion:** Misoprostol should be preferred to intracervical dinoprostone in induction of labor.

Key words: Misoprostol, Dinoprostone, Labor.

INTRODUCTION

Induction of labor (IOL) is a common obstetric intervention that stimulates the onset of labor using artificial methods. Rates of labor induction have nearly doubled since 1990. There is substantial variation in IOL rates worldwide, and this can be attributed to variability in the guidelines and lack of consensus on the clinical practice guidelines on IOL.[1-3] The indications are maternal, most commonly hypertensive disorders, or fetal, when the risk of stillbirth or cesarean delivery is raised beyond 41 weeks of gestation. Together with growth restriction and diabetes, these are the most common indications; there is little research published about induction on request.[3-5]

Misoprostol is a methyl ester of prostaglandin E1 additionally methylated at C- 16 and is marketed for use in the prevention and treatment of peptic ulcer disease caused by prostaglandin synthetase inhibitors. The reported mean peak serum misoprostol acid following oral administration was 227 pg/ml versus vaginal route 165 pg/ml; the times to peak levels were 34 versus 80 minutes.[6] Prostaglandin E2 (PGE2), also known by the name dinoprostone, is a naturally occurring compound 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.[7- 9] 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 comparing the safety and efficacy of intravaginal misoprostol and intracervical dinoprostone in induction of labor. A total of 100 subjects were enrolled and were broadly and randomly divided into two study groups with 50 subjects in each group as follows: Misoprostol group and Dinoprostone group. Complete demographic and clinical details of all the subjects were obtained. Subjects of Misoprostol group received 50 µg misoprostol tablet vaginally while subjects of Dinoprostone group received 0.5 mg dinoprostone gel. In most cases the fetal heart was auscultated every fifteen minutes until the onset of labor. Surveillance by continuous palpation for uterine hypertonicity and auscultation after each contraction were started as soon as labor was established. Cardiotocography was reserved for cases with signs of fetal distress. All the results were recorded in Microsoft excel sheet followed by statistical analysis using SPSS software. Chi-square test and student t test were used for evaluation of level of significance.

RESULTS

Mean age of the subjects of Misoprostol group was 28.3 years while among Dinoprostone group was 29.1 years. Mean parity among Misoprostol group and Dinoprostone group was 1.8 and 1.5 respectively. Mean infant weight during delivery among Misoprostol group and Dinoprostone group was 2.79 Kg and 2.84 Kg respectively. Need for second dose among Misoprostol group and Dinoprostone group was in 8 percent and 16 percent of the subjects respectively. Need for oxytocin infusion among Misoprostol group and Dinoprostone group was in 16 percent and 38 percent of the subjects respectively. Vaginal delivery occurred in 98 percent of the subjects of the Misoprostol group and in 88 percent of the subjects of the Dinoprostone group.

Table 1: Variables

Variable	Group Misoprostol	Group Dinoprostone	p-value
Mean age (years)	28.3	29.1	0.12
Parity	1.8	1.5	0.84
Gestation (weeks)	35.1	35.9	0.39
Infant weight during delivery (Kg)	2.790	2.840	0.61

Table 2: Comparison of induction results

Variable	Group Misoprostol		Group Dinoprostone		p-value
Need for second dose	4	8	8	16	0.001*
Need for oxytocin infusion	8	16	19	38	0.003*
Vaginal delivery	49	98	44	88	0.752

*: Significant

DISCUSSION

IOL is the artificial stimulation of cervical ripening and progressive uterine contractions to facilitate birth. Between 2007 and 2017, the percentage of people experiencing IOL increased by nearly 10%, with more than one in four (25.5%) having an IOL in 2017. More frequent use of induction techniques is driven by increasing numbers of pregnant people with medical complications during pregnancy and use of elective IOL prior to 42 completed weeks.[10, 11] In a Dutch multicenter trial, researchers compared prostaglandin E2 gel with a transcervical Foley catheter introduction for the induction of labor in women with an unfavorable cervix to see if the methods had comparable vaginal delivery rates.[12]

Misoprostol, a synthetic prostaglandin E1 analogue, was originally introduced for prevention and treatment of gastric ulcer diseases. Later, misoprostol has been found to be a useful drug with a wide range of applications in both obstetrics and gynaecology because of its effectiveness, low cost, stability in light and hot climate condition and ease of administration compared to its legalized counterpart such as dinoprostone and gemeprost.[13- 15] Prostaglandins have evolved as the most popular and frequently used pharmacologic agents for IOL, owing to their dual action of cervical ripening and uterine contraction inducing effect. Prostaglandin E2 (cerviprime gel), a registered inducing agent in many countries, is expensive and needs to be refrigerated due to its sensitivity to temperature changes. It is instilled intracervically or placed high in the posterior fornix of the vagina and may need to be re-instilled after 6 h if required.[16]

Mean age of the subjects of Misoprostol group was 28.3 years while among Dinoprostone group was 29.1 years. Need for second dose among Misoprostol group and Dinoprostone group was in 8 percent and 16 percent of the subjects respectively. Liu A et al, in a previous study, compared the efficacy and safety of intravaginal misoprostol and intracervical dinoprostone for labor induction. The use of misoprostol was significantly effective in increasing the rate of vaginal delivery within 24 h and less oxytocin augmentation when compared with dinoprostone. Intravaginal misoprostol appears to be

more efficient for labor induction than intracervical dinoprostone; however, dinoprostone has been demonstrated to be safer because of the lower incidence of uterine hyperstimulation and tachysystole.[17]

In the present study, need for oxytocin infusion among Misoprostol group and Dinoprostone group was in 16 percent and 38 percent of the subjects respectively. Vaginal delivery occurred in 98 percent of the subjects of the Misoprostol group and in 88 percent of the subjects of the Dinoprostone group. In another study conducted by Ozgür K et al, authors compared the induction of labor with intravaginal misoprostol versus intracervical dinoprostone. Sixty-five pregnant women who had the indication for labor induction were randomized in a clinical trial to receive 100 micrograms intravaginal misoprostol or intracervical gel of 0.5 mg dinoprostone. The mean time from induction to delivery for the misoprostol group was 7.6 +/- 1.9 versus 8.2 +/- 5.9 for the dinoprostone group. There were no significant differences between groups in gestational age, induced labor rates, type of delivery, fetal outcome and maternal complications. They found that intravaginal misoprostol tablet is as effective as intracervical dinoprostone for inducing second and third trimester labor.[18] The efficacy of intravaginal misoprostol and intracervical Foley catheter/intravaginal dinoprostone for cervical ripening was compared in another previous study conducted by Perry KG et al. Sixty-five patients received Foley catheter/dinoprostone gel and 62 patients received misoprostol. The mean time until cervical ripening was less in the catheter/gel group. The mean time until vaginal delivery was less in the catheter/gel group. Among vaginal deliveries, more patients in the catheter/gel group delivered within 24 hours. Intracervical Foley catheter/intravaginal dinoprostone was associated with more rapid cervical ripening, shorter induction to vaginal delivery interval, and greater number of vaginal deliveries within 24 hours.[19]

CONCLUSION

Misoprostol should be preferred to intracervical dinoprostone in induction of labor.

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