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Original Research Article

COMPARATIVE EFFICACY EVALUATION OF INTRAVAGINAL MISOPROSTOL AND INTRACERVICAL DINOPROSTONE FOR INDUCTION OF LABOUR AT A TERTIARY CARE HOSPITAL

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ABSTRACT

Background: Induction of labour (IOL) refers to the process of initiating uterine contractions in individuals who are not yet in labour, with the aim of facilitating vaginal delivery within a timeframe of 24 to 48 hours. Hence; the present study was conducted for comparative efficacy evaluation of intravaginal misoprostol and intracervical dinoprostone for induction of labour at a tertiary care hospital. **Materials and Methods:** A total of 60 participants were recruited and randomly divided into two separate study groups. Group 1 comprised individuals who received vaginal misoprostol tablets, while Group 2 consisted of those who were given 0.5 mg of dinoprostone gel via intracervical administration. The study's inclusion criteria targeted nulliparous women aged between 20 and 30 years, with a gestational age of more than 37 weeks. Participants underwent intermittent electronic fetal monitoring to identify any possible fetal complications. Detailed information regarding the drug profiles, including side effects, success rates, and failure rates, was shared with both the participants and their caregivers. The outcomes were assessed, and the gathered data were systematically organized, analyzed across various parameters, and compared. **Result:** Mean age of group 1 and group 2 subjects was 26.3 years and 25.1 years respectively. Mean gestational age of group 1 and group 2 subjects was 38.9 weeks and 39.1 weeks respectively. Bishop score at 8 hours was significantly more among group 1 subjects. Misoprostol was more effective than Dinoprostone in producing cervical changes. Success rate was better among group 1 subjects. Also, group 1 was associated with less need of augmentation of labor. **Conclusion:** Labor induction refers to the artificial stimulation of the uterus to initiate labor prior to its natural onset. This process involves the effacement and dilation of the cervix, along with the onset of uterine contractions. Misoprostol has demonstrated similar efficacy and safety results, indicating its viability as a useful agent for induction in clinical practice.

INTRODUCTION

Induction of labour (IOL) refers to the process of initiating uterine contractions in individuals who are not yet in labour, with the aim of facilitating vaginal delivery within a timeframe of 24 to 48 hours. Cervical ripening is a key method employed in labour induction, defined as the application of pharmacological or other techniques to soften, efface, or dilate the cervix, thereby enhancing the chances of a vaginal birth. The primary approaches to cervical ripening include mechanical methods, such as the insertion of balloon catheters, and the use of pharmacological agents, notably prostaglandins. Among these, dinoprostone and misoprostol are commonly utilized prostaglandin agents.[1,2]

Currently, labour induction rates surpass 20% of all deliveries in many countries. In Canada, the incidence of labour induction rose from 12.5% in 1991/1992 to a peak of 23.7% in 2001/2002, before declining to 21.8% in 2004/2005.[2,3]

The decision to induce labour is warranted when the potential risks associated with prolonging the pregnancy are greater than those linked to the induction process and subsequent delivery for either the birthing individual or the fetus. Urgent

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indications for induction may include conditions such as preeclampsia at 37 weeks or later, chorioamnionitis, severe pregnancy-related illnesses that do not respond to treatment, suspected fetal distress, and term pre-labour rupture of membranes (PROM) in the presence of maternal group B streptococcus colonization.[3]

Misoprostol is a synthetic derivative of prostaglandin E1, known for its gastric antisecretory properties and its ability to protect the mucosal lining. In Canada, the oral formulation is authorized for both the treatment and prevention of gastroduodenal ulcers resulting from nonsteroidal anti-inflammatory drugs (NSAIDs), as well as for addressing duodenal ulcers associated with peptic ulcer disease. The most frequently reported side effects following a single oral dose of misoprostol include diarrhea, abdominal discomfort, nausea, gas, and dyspepsia.[4]

Preinduction cervical ripening with the dinoprostone slow-release vaginal insert is associated with a high rate of women undergoing vaginal delivery within 24 hours, with a shorter stay. Considering its good performance, the dinoprostone slow-release vaginal insert is the first choice for elective induction of labour in postdate pregnancy.[5]

Hence; the present study was conducted for comparative efficacy evaluation of intravaginal misoprostol and intracervical dinoprostone for induction of labour at a tertiary care hospital.

MATERIALS AND METHODS

A total of 60 participants were recruited and randomly assigned to two distinct study groups: Group 1 consisted of participants receiving vaginal misoprostol tablets, while Group 2 included those administered 0.5 mg of dinoprostone gel intracervically.

The inclusion criteria for this study encompassed nulliparous women aged 20 to 30 years, with a gestational age exceeding 37 weeks. Patients underwent intermittent electronic fetal monitoring to detect any potential fetal complications. Comprehensive information regarding the drug profile, including side effects, success rates, and failure rates, was provided to both the patients and their attendants.

Outcomes were evaluated, and the collected data were organized, analyzed across various parameters, and compared. The significance of the findings was assessed using SPSS software.

RESULTS

The mean age of group 1 and group 2 subjects was 26.3 years and 25.1 years respectively. Mean gestational age of group 1 and group 2 subjects was 38.9 weeks and 39.1 weeks respectively. Bishop score at 8 hours was significantly more among group 1 subjects. Misoprostol was more effective than Dinoprostone in producing cervical changes. Success rate was better among group 1 subjects. Also, group 1 was associated with less need of augmentation of labor.

Table 1: Demographic data

Variable		Group 1 (n=30)	Group 2 (n=30)
Mean age (years)		26.3	25.1
Mean gestational age (weeks)		38.9	39.1
Maternal education	Illiterate	9	10
	Upto secondary	7	6
	Graduation	8	9
	Postgraduation	6	5

Table 2: Initial Bishop score.

Initial Bishop score	Group 1 (n=30)	Group 2 (n=30)
Mean	3.66	3.81
SD	0.86	0.91
p-value	0.25	

Table 3: Bishop score at 8 hours.

Initial Bishop score	Group 1 (n=30)	Group 2 (n=30)
Mean	4.62	3.19
SD	0.86	0.93
p-value	0.001 (Significant)	

Table 4: Complications during labour by inductive agent.

Complications	Group 1 (n=30)	Group 2 (n=30)
Meconium-stained amniotic fluid	2	3
Fetal distress	1	1
Scar dehiscence	1	1

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Table 5: Success rate and need for augmentation of labor.

Variable	Group 1	Group 2
Success rate (%)	86.67	80
Need of augmentation of labor (%)	20	40

DISCUSSION

The National Center for Health Statistics reported that the overall labor induction rate was 31.4% in 2020, an increase from 27.1% in 2018 and 9.6% in 1990. The prevalence of labor induction is expected to rise further, given the positive findings from previous studies that compared elective induction with expectant management, as well as the results from the 2018 ARRIVE trial, which was a multicenter study examining these two approaches. These encouraging outcomes were later supported by a systematic review and meta-analysis.[6-8] Numerous researchers have documented significant increases in labor induction rates at their institutions following the publication of the ARRIVE trial. As labor induction rates are projected to keep rising, it is essential for obstetricians to be familiar with the various techniques available for inducing labor.[9,10] Hence; the present study was conducted for comparative efficacy evaluation of intravaginal misoprostol and intracervical dinoprostone for induction of labour at a tertiary care hospital.

The mean age of group 1 and group 2 subjects was 26.3 years and 25.1 years respectively. Mean gestational age of group 1 and group 2 subjects was 38.9 weeks and 39.1 weeks respectively. Bishop score at 8 hours was significantly more among group 1 subjects. Misoprostol was more effective than Dinoprostone in producing cervical changes. Success rate was better among group 1 subjects. Also, group 1 was associated with less need of augmentation of labor. Liu A et al compared the efficacy and safety of intravaginal misoprostol and intracervical dinoprostone for labor induction, including incidence of caesarean section, vaginal delivery rate within 24 h, uterine hyperstimulation, tachysystole, oxytocin augmentation, neonatal intensive care unit (NICU) admissions, and Apgar score of less than 7 at 1 and 5 min. 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. However, the incidents of uterine hyperstimulation and tachysystole were significantly higher under the misoprostol protocol than dinoprostone protocol. Furthermore, they found similar efficiency in the rate of caesarean delivery, NICU admission and Apgar score at 1 and 5 min among the study groups. 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.[11]

Lakho N et al compared the effectiveness and safety of intravaginal misoprostol versus dinoprostone for inducing labor, examining their impact on various maternal and neonatal outcomes. Eight RCTs with a total of 1,801 participants met the inclusion criteria. Misoprostol required a significantly less oxytocin augmentation than dinoprostone. Other outcomes, including rates of caesarean delivery, uterine tachysystole, hyperstimulation, and NICU admissions, showed no significant differences between the two groups, indicating comparable safety and efficacy profiles.[12] D'souza AS et al evaluated the safety and efficacy of intravaginal Misoprostol and compared its effects with intracervical dinoprostone gel for cervical ripening and labor induction. A total of 153 mothers fulfilled the criteria to be included in the study of which 81 mothers were induced by misoprostol and 72 mothers by dinoprostone gel respectively. There was no statistical difference in the maternal age, parity and gestation at the onset of study in the two groups. The ANC complications were also statistically similar. There was no significant difference in the mean initial Bishop Score in the two groups. 3.42 in the Misoprostol group and 3.56 in the Dinoprostone group. The mean Bishop Score after 8 hour of the first dose was 7.86 in the Misoprostol group and 6.88 in the Dinoprostone group. The mean time taken from the induction to the onset of labor was 5.57 hours in the misoprostol group and 8.04 hours in the dinoprostone group. There were no cases of tachysystole or hyperstimulation in both the groups. Misoprostol is a more efficacious cervical ripening and labor inducing agent compared to dinoprostone gel and can be used safely in the North Indian setting.[13]

CONCLUSION

Labor induction refers to the artificial stimulation of the uterus to initiate labor prior to its natural onset. This process involves the effacement and dilation of the cervix, along with the onset of uterine contractions. Misoprostol has demonstrated similar efficacy and safety results, indicating its viability as a useful agent for induction in clinical practice.

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