pISSN 2320-1770 | eISSN 2320-1789

DOI: https://dx.doi.org/10.18203/2320-1770.ijrcog20223138

# **Original Research Article**

# Comparison of oral versus vaginal misoprostol for induction of labour at term

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Received: 25 October 2022 Revised: 19 November 2022 Accepted: 22 November 2022

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## **ABSTRACT**

**Background:** Preinduction cervical ripening has a great influence on induction of labor. For induction of labor various methods are used. Mechanical methods are Foleys catheter with or without extra-amniotic saline. Various pharmacological methods are misoprostol, dinoprostone, and oxytocin.

**Methods:** This was a prospective observational study conducted on 100 patients with 50 patients in each group in the department of obstetrics and gynecology, Government Medical College, Srinagar from June 2020 to March 2021 over a period of 9 months. Induction with oral misoprostol or vaginal misoprostol was done in respective groups. Various parameters noted were induction delivery interval, number of doses needed, mode of delivery, and fetomaternal outcome.

**Results:** Average number of doses of misoprostol in oral group was 3.84 and average number of doses in vaginal group was 1.90. Mean induction delivery interval in oral group was 16 hours and 10.94 hours in vaginal group. 32% patients delivered by full-term vaginal delivery (FTVD) in oral group and 18% underwent lower segment caesarean section (LSCS), while as 38% patients in vaginal group had FTVD and only 12% patients underwent LSCS.

Conclusions: Our data supported the fact that induction with vaginal misoprostol can be equally effective in either oral or vaginal route. However, induction with vaginal misoprostol leads to shorter induction delivery interval compared to induction with oral misoprostol. Our study also highlighted the fact that induction with vaginal misoprostol requires lesser doses as compared to that with oral misoprostol. However, there are no significant differences in number of caesareans between the two groups. Difference in neonatal APGAR scores and maternal complications were non-significant in both the groups.

Keywords: Labor, Misoprostol, Pre-induction cervical ripening, Apgar score

#### INTRODUCTION

Induction of labor is a common procedure in obstetrics.<sup>1</sup> Induction of labor can be defined as the artificial initiation of labor, before its spontaneous onset, for the purpose of delivery of the fetoplacental unit.<sup>2,3</sup> The status of the cervix, its form, consistency and dilatation has a significant impact on the prognosis of labour induction.<sup>4</sup> There are two categories of artificial means of cervical ripening prior to labour induction: mechanical (includes

the Foley catheter balloon with or without extra amniotic saline infusion and laminaria tents), and pharmacological (prostaglandins PGE1, PGE2, estrogen and nitric oxide donors).<sup>5</sup>

Mechanical devices dilate the cervix by exerting local pressure onto the cervix, overstretching the lower uterine segment and indirectly stimulating the secretion of prostaglandins.<sup>6</sup>

Pharmacological preparations (prostaglandins and nitric oxide donors) cause connective tissue softening, cervical effacement, and uterine activity.<sup>7,8</sup> Dinoprostone (PGE2) is available only in vaginal form. It is expensive and needs to be kept in the refrigerator.9 In comparison misoprostol (PGE1) is functional in both oral and vaginal forms. Both are widely used to induce labour for its high efficacy, considerable safety, reasonable price, easy to use, and easy to store at room temperature. 10 Also, misoprostol may influence fewer side effects such as nausea, vomiting, diarrhoea, fever and abdominal pain.<sup>11</sup> In addition, unlike other prostaglandins, misoprostol has a selective effect on the uterus and cervix and has no inconvenient effect on the bronchi and blood vessels. 12 Absorption by oral route is erratic, at the same time it is more rapid than vaginally peak administered misoprostol reaching concentrations within 30 min compared to one hour with vaginal route. Oral misoprostol is eliminated rapidly (2-3 hours) than vaginal.13

## Aims and objectives

Aims and objectives of the study were: to compare the efficacy and safety of 50 microgram oral misoprostol with 25 microgram vaginal misoprostol for pre-induction cervical ripening.

#### **METHODS**

This was a prospective observational study conducted on 100 patients with 50 in each group in the department of obstetrics and gynecology, Government Medical College, Srinagar over a period of 9 months from June 2020-March 2021. The study was planned after obtaining clearance from the institutional ethics committee.

#### Inclusion criteria

Singleton primigravida women requiring induction of labor at term pregnancy with cephalic presentation were included in the study.

# Procedure

Written informed consent was taken for participation in the study and after undergoing vaginal examination to determine the Bishop score, the patients were divided into two groups: group A induction with oral misoprostol, and group B induction with vaginal misoprostol.

Labour induction in group A was performed by 50 microgram oral misoprostol and in group B by 25 microgram misoprostol. Medications were repeated every 6 hours based on the patient's condition. Vaginal examination to determine Bishop score was done before repeating each dose. Augmentation was started with oxytocin in case that needed it because of inadequate uterine contractions. Induction delivery interval, mode of delivery and fetomaternal outcome was noted.

## Statistical analysis

Descriptive statistical analysis was carried out in the present study. Continuous variables were expressed as mean±standard deviation (SD) and categorical variables were summarized as frequencies The statistical significance of the difference between two groups were based on p value. A p value of <0.05 was considered to be statistically significant.

#### RESULTS

Table 1 shows that both the groups had comparable age and weight.

In our study, the mean gestational age in group A was 38.64 weeks and in group B it was 38.32 weeks. The p value was statistically insignificant (Figure 1).

Figure 1 shows that the mean gestational age in group A was 38.64 weeks and in group B it was 38.32 weeks. The p value was statistically insignificant.

Table 1: Demographic profile.

Variables	Group A	Group B		
Age	28.5+4	29.3+5.25; p value (0.418)		
Rural	23	21		
Urban	27	29		
Weight (kg)	68+8	69+2		
Education				
Illiterate	21	19		
Middle pass	16	17		
Graduate	13	14		

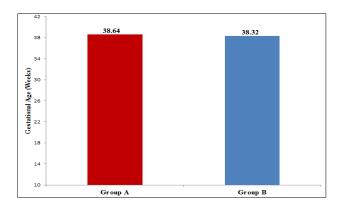


Figure 1: Gestational age of patients.

As seen from Figure 2, the mean induction delivery in group A patients was 16.04 hours and 10.96 hours in group B patient with p value less than 0.05 which is statistically significant.

As seen in Table 2, the mode of delivery in group A patients was FTVD in 32% of patients and LSCS in 18% of patients. While as in group B,38% of patients had FTVD and 12% had LSCS (p value=0.19).

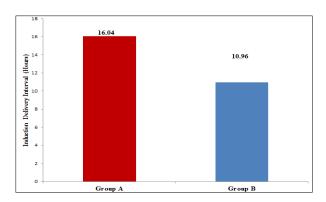


Figure 2: Induction delivery interval in two groups.

Figure 3 shows that the indication for caesarean section was acute fetal distress in 12 patients of group A and 9 patients of group B, failure of induction in 3 patients from group A and 2 patients from group B, hyperstimulation in 3 patients from group A and 1 patient from group B. However, the p value was statistically insignificant.

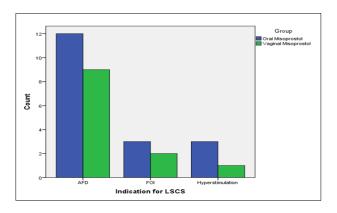


Figure 3: Indication of LSCS.

Figure 4 shows that in group A patients 2% of mothers had chorioamnionitis, 1% had endometritis and 3% had postpartum haemorrhage, while as in group B patients 1% of mothers had choriomnionits, 1% had endometritis and 3% had postpartum haemorrhage. The p value was statistically insignificant (Figure 4).

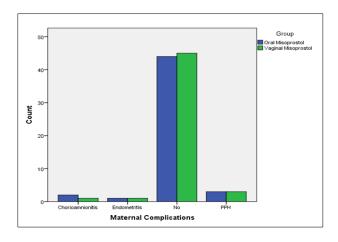


Figure 4: Maternal complications.

Table 2: Comparison based on mode of delivery in two groups.

Mode of	Group A		Group B		P value
delivery	No.	%	No.	%	
Normal	32	32	38	38	0.190
LSCS	18	18	12	12	
Total	50	50	50	50	

#### DISCUSSION

This study was done to compare the effectiveness of oral and vaginal misoproatol. In group A the mean gestational age was  $38.64 \pm 1.5$ . In Group B mean gestational age was 38.32±1.5. The mean induction delivery in group A and B patients was 16.04-4.238 and 10.94-4.789 hours respectively. The p value was less than 0.05(sig). These findings are consistent with studies of Handal-Orefice et al, Redling et al and Hokkila et al. 14-16 In group A the mean of total number of doses of misoprostol needed for cervical ripening were 3.84±1.5. In group B the mean of total number of doses of misoprostol needed were 1.90±0.8. The difference was statistically significant (p value less than 0.05). These findings were consistent with findings made by Mahajan et al.<sup>17</sup> In group A, mode of delivery was FTVD in 32% patients and LSCS in 18% patients. While as in group B mode of delivery was FTVD in 38% patients and LSCS in 12% patients. The p value was 0.190 (statistically insignificant). In group A patients, the indications for cesarean section were acute fetal distress in 40%, failure of induction in 10% and hyperstimulation in 10% patients. While as in group B patients' indication for caesarean section was acute fetal distress in 30%, failure of induction in 6.7% and hyperstimulation in 3.3% (p value=0.859). In group A, the mean Apgar score at 1 minute was 6.74±0.80 and in group B it was 6.94±1.07 with p value of 0.295. The mean APGAR score at 5 minutes in group A was  $7.32 \pm 0.71$  and in group B it was 7.08±0.634 with p value of 0.078. In group A,5 out of 50 babies had neonatal intensive care unit (NICU) admission while as in group B 11 out of 50 babies had NICU admission. The p value was 0.102. In group A patients, 2% patients had chorioamnionitis, 3% had post-partum haemorhhage and 1% had endometritis. In group B patients, 1% had chorioamnionitis, 3% had post-partum hemorrhage and 1% had endometritis (value 0.951). These results need to be verified by further research as our sample size was relatively small before drawing any final conclusion.

#### **CONCLUSION**

Our data supported the fact that induction with vaginal misoprostol can be equally effective in either oral or vaginal route. However, induction with vaginal misoprostol leads to shorter induction delivery interval compared to induction with oral misoprostol. Our study also highlighted the fact that induction with vaginal misoprostol required lesser doses as compared to that with oral misoprostol. However, there was no significant

difference in cesarean and normal vaginal delivery between the two groups. Neonatal APGAR scores were almost same in two groups. Maternal complications were same in both groups.

Funding: No funding sources Conflict of interest: None declared

Ethical approval: The study was approved by the

Institutional Ethics Committee

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Cite this article as: Fareed P, Rashid R, Wani SA. Comparison of oral versus vaginal misoprostol for induction of labour at term. Int J Reprod Contracept Obstet Gynecol 2022;11:3392-5.