

# Comparison of Oral Versus Vaginal Misoprostol for Induction of Labour at Term

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## Abstract

**Background:** To compare the efficacy and safety of oral versus vaginal administration of Misoprostol for induction of labour at term.

**Methods:** In this interventional study primigravida were assigned in two groups; A and B, using non-probability convenient sampling technique. Group-A (n=50) had Misoprostol orally, while group-B (n=50) received the drug by vaginal route. Dosage was 100 µg four hours apart in group-A and six hours apart in group-B. Maximum of four doses were given. Main outcome measures of study were labour-induction interval, labour-delivery interval, mode of delivery, neonatal outcome and feto-maternal complications.

**Results:** The mean dosage requirement for induction of labour in groups A and B was  $2.1 \pm 1.1$  and  $2.4 \pm 1.8$  (p-0.23) respectively. Mean labour-induction interval in group A and B were  $7.5 \pm 4.2$  and  $7.3 \pm 4.1$  (p-0.87) hours respectively, which is not significant statistically. Mean labour delivery interval was shorter in vaginal group ( $4.9 \pm 2.7$  hours) versus oral group( $6.0 \pm 2.2$ ) hours (p-0.04). Need for Oxytocin augmentation was less in vaginal group (21%) versus oral group (68%) (p-0.009). There was no statistical difference between the groups with respect to mode of delivery and neonatal outcome. The incidence of hyper-stimulation was similar in both groups.

**Conclusion:** Misoprostol is a cost effective alternate for induction of labour. Misoprostol through vaginal route results in successful cervical ripening, less need for oxytocin and shorter time to delivery with acceptable safety profile.

**Key words:** Induction labour, Misoprostol, primigravida, maternal complication, fetal complication.

## Introduction

Induction of labour is an important and common clinical procedure in obstetrics. Labour induction is indicated when the benefits of delivery to the mother or fetus outweigh the potential risk of continuing the pregnancy. The widespread availability

of cervical ripening agents has contributed to this rising trend but the search for an ideal agent, timing and dosage interval to convert an unfavourable cervix to one receptive to delivery is an ongoing process. PGE2 has been used extensively and effectively for ripening cervix and labour initiation. PGE1 (Misoprostol) is a recently introduced drug for the same purpose.<sup>1,2</sup> In these days of financial constrains, Misoprostol is an economical and effective drug for labour induction.

Misoprostol is well absorbed by oral route, with peak plasma concentration achieved earlier and higher than vaginal administration, although the plasma concentration is detectable for long period by vaginal route.<sup>3,4</sup>. When used in low doses Misoprostol is as effective as vaginal Dinoprostone, with no increase in hyper-stimulation.

## Patients and Methods

This study was performed in department of Gynaecology and Obstetrics, Ittefaq Hospital Trust, Lahore, from June 2008 to May 2009. One hundred patients, with indications for induction of labour, at term (37- 42 weeks) were included . After history and clinical examination patients were selected using non-probability convenient sampling technique. 100 µg of Misoprostol was administered through oral and vaginal routes, (50 in each group). A preliminary admission CTG was done to assess fetal condition.

Inclusion criteria were women with primigravida, singleton pregnancy, vertex presentation and gestational age 37- 42 weeks, Bishop score less than 5 and a reactive fetal cardiac trace. Women with fetal abnormality, intrauterine death, were also included in the study. Exclusion criteria were multiple gestations, scarred uterus, and malpresentation.

Initially 100 µg of Misoprostol was given orally and vaginally. Further doses were repeated four hourly in group-A, six hourly in group-B and to a

maximum of four doses were given.

Patients were monitored for uterine contraction, fetal heart rate, hyper-stimulation, nausea, vomiting, diarrhoea, fever, vaginal bleeding and other untoward side effects. Partograph was maintained. CTG was done before induction and after each insertion of Misoprostol and then intermittently during labour. Requirement for augmentation of labour with Oxytocin in either group was also recorded.

## Results

A total of one hundred patients were included in this study. Two groups were made with equal number of cases in each group. There was no significant difference in terms of maternal and gestational ages (Table - I).

The mean dosage for induction of labour in group A and B was  $2.1 \pm 1.1$  and  $2.4 \pm 1.8$  ( $p=0.23$ ) respectively. Mean labour-induction interval in group A and B was  $7.5 \pm 4.2$  and  $7.3 \pm 7.4.1$  ( $p=0.87$ ) hours respectively which was not significant statistically. Mean labour-delivery interval was shorter in vaginal group  $4.9 \pm 2.7$  hours versus oral group  $6.0 \pm 2.2$  hours ( $p=0.04$ ).

**Table 1: Demographic data of the study subjects**

Characteristics	Group-A Oral (n=50)		Group-B Vaginal (n=50)	
	Mean	Standard deviation	Mean	Standard deviation
Age (years)	24.8	2.4	25.3	3.1
Gestational age (weeks)	38.1	1.4	39.7	1.3

Need for Oxytocin augmentation was less in vaginal group 21% versus oral group 68 %  $p=0.009$  (Table - 2). Main indication for intervention was non-progress of labour and fetal distress. Apgar score at 5 minutes in group-A and group-B were  $8.2 \pm 0.83$  and  $7.9 \pm 0.94$  ( $p=0.119$ ). The incidence of hyper-stimulation was similar in both groups.

There was no difference between the groups with respect to mode of delivery and neonatal outcome. Caesarean delivery rate was similar in both groups  $p=0.685$  (Table - 3).

Postpartum haemorrhage was not observed in any case. No case of uterine rupture or severe birth asphyxia was reported. No case of nausea, diarrhoea, headache, dizziness and shivering was noticed.

**Table 2: Main outcome measures**

Outcome	Group-A (n=50)		Group-B (n=50)		p-value
	Mean	Standard deviation	Mean	Standard deviation	
Induction-labour interval (hours)	7.51	4.29	7.31	7.59	0.87
Labour-delivery interval (hours)	6.00	2.26	4.97	2.75	0.04
Need of Oxytocin augmentation	34	68%	21	42%	0.009
Apgar score at 5 minutes	8.20	0.83	7.92	0.94	0.11
Uterine hyperstimulation	1	2%	1	2%	
Uterine tachysystole	1	2%	7	14%	0.065

**Table 3: Mode of delivery**

Mode of delivery	Group		
	Group-A	Group-B	p-value
SVD with Episiotomy	28	56	25
LSCS	20	40	22
Outlet Forceps delivery	2	4	2
Vacuum delivery	0	0	1
Total	50	100	50
			100

## Discussion

All methods of labour induction not only need a careful appraisal of risks and benefits of labour outcome, but also require critical assessment of possible benefits and morbidity of the fetus.

Misoprostol has been extensively studied for induction of labour through various routes and it has proved to be more efficient in stimulating labour compared to Oxytocin and Dinoprostil but its dosage is not yet licensed because of risk of uterine hyperstimulation and its consequences.<sup>5</sup> Several studies have been performed in which Misoprostol has been used in repeated small doses of 50 µg four to six hourly through oral and vaginal routes and has been

found safe in induction of labour.<sup>6,7,8</sup> Intracervical Misoprostol 50 µg has resulted in 90% success rates in other studies regardless of Bishop Score and now induction is being tried with greater dosage.<sup>9,10</sup>

This study compares effectiveness and safety of 100 µg of Misoprostol through oral and vaginal routes. Results show that both the routes are safe and effective for induction of labour and can be alternatively used. However Misoprostol 100 µg through the vaginal route resulted in short induction delivery interval and less need of Oxytocin for labour augmentation. Same results have been proved by Castaneda in his study that 100 µg of vaginal Misoprostol resulted in successful cervical ripening and short induction delivery interval with acceptable safety profile.<sup>10</sup>

In present study there was no significant difference between two groups with regard to the caesarean section rate, uterine hyperstimulation, maternal complications like post partum haemorrhage and neonatal outcome. Few cases of tachysystole were observed with vaginal route but without any neonatal compromise. Similarly Memon in her study used 100 µg of Misoprostol through the vaginal route for induction of labour and proved it to be a safe and effective labour inducing agent.<sup>11</sup>

Several studies have proved that initial 50 µg of oral Misoprostol is less effective and associated with longer induction delivery interval because of first pass effect and greater efficiency of vaginal route because of greater bioavailability of vaginal Misoprostol.<sup>12-15</sup>

## Conclusion

Optimum , oral and vaginal dose of Misoprostol , for induction of labour at term, needs standardization .

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