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## Original Research Article

# A comparative study of twenty-five micrograms oral versus vaginal misoprostol for labour induction at term

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## ABSTRACT

**Background:** Many societies from primitive to the modern, have been interested in, the ability to induce labour. The majority of women's labours begins spontaneously and end in a normal vaginal delivery at or near term. Labour induction is often required due to medical or obstetric complications during pregnancy. This procedure has the potential to provide significant maternal and perinatal advantages.

**Methods:** Cases for this study were collected from the Narayana Medical College and Hospital Nellore between January 2021 and December 2022. Informed consent was obtained from 100 pregnant women with indications for induction of labour in the third trimester, who were divided into two groups of 50 each for the oral and vaginal routes. The study was conducted after taking approval from institute ethics committee.

**Results:** A total of 100 individuals were included in the trial, with each group of 50 receiving either oral or vaginal misoprostol 25mcg, 4th hr upto a maximum of 6 doses. In the vaginal misoprostol and oral misoprostol group, Primigravida required more doses of oxytocin compared to multigravida.

**Conclusions:** Vaginal misoprostol had lesser induction-delivery interval, lesser c-section rates than oral misoprostol. Therefore, misoprostol when administered vaginally has higher efficacy than oral route. The increased efficacy of misoprostol raises the possibility of a local cervical effect, when administered vaginally.

**Keywords:** Misoprostol, Labour, Delivery

## INTRODUCTION

Many societies from primitive to the modern, have been interested in, the ability to induce labour. The majority of women's labours begins spontaneously and end in a normal vaginal delivery at or near term.<sup>1</sup> Labour induction is often required due to medical or obstetric complications during pregnancy. This procedure has the potential to provide significant maternal and perinatal advantages. Induction of labour must achieve three goals in order to be successful. It should, first and foremost, result in labour, i.e., adequate uterine contractions and gradual cervical dilation. Second, this labour should result in a vaginal

delivery, as inducing labour solely to prepare for a caesarean section serves no purpose. Third, these goals must be met with the least amount of discomfort and danger to both mother and foetus in varied pregnancies.<sup>2</sup> A successful induction of labour results in a healthy infant being delivered vaginally in a reasonable amount of time with minimal maternal discomfort or adverse effects.<sup>3</sup> The misoprostol application to induce labour has been a hot area of research. Its great efficacy, few side effects, and cost-cutting benefits have been described by a variety of authors. The dose & timing of intravaginal use had been the subject of most studies. There are only a few clinical investigations on the use of misoprostol for labour

induction when taken orally.<sup>4</sup> In light of the foregoing, this study compares the safety and efficacy of misoprostol induction by oral and vaginal methods.

### Aims and objectives

Aim and objectives of current study were; to assess the safety and efficacy of misoprostol when taken orally versus vaginally for labour induction and to make a clinical study regarding: induction delivery interval, side-effects of the drug, maternal outcome and fetal outcome.

### METHODS

Cases for this study were collected from the Narayana medical college and hospital in Nellore between January 2020 and December 2021. The total number of deliveries in the hospital, was 1548 from January 2020 to December 2021, out of which 258 cases were induced with Misoprostol either orally or vaginally for labour induction, and 100 of these induced cases were enrolled in the current study by simple randomization. Our institute has a 1.6% incidence of labour induction. Informed consent was obtained from 100 pregnant women with indications for induction of labour in the third trimester, and it included pregnancies between 37 to 42 weeks of pregnancy. A live Singleton foetus in cephalic presentation, no history of uterine surgeries, reassuring foetal heart rate and excluded the cases with any contraindication to vaginal delivery, Epidural analgesia, cases with previous uterine incision, whose parity is greater than 5, with non-reassuring FHR pattern, significant maternal cardiac, renal or hepatic disease, hypersensitivity to misoprostol or prostaglandin analogues. who were divided into two groups of 50 each for the oral and vaginal routes. The cases were separated into two groups of 50, with each group receiving misoprostol 25 mcg (1/4 of a 100mcg pill) intravaginally or orally every four hours by simple randomization. Prior to induction, the cervical status of all patients was examined using the modified Bishop's score. The study was conducted after taking approval from institute ethics committee, Narayana medical college and hospital, Nellore. The data obtained is expressed as; qualitative data-percentage; quantitative data (mean, standard deviation, p value).

### RESULTS

A total of 100 individuals were included in the trial, with each group of 50 receiving either oral or vaginal misoprostol 25 mcg, 4th hourly upto a maximum of 6 doses. In the current study, the mean age of the study population in the VM group was  $26.46 \pm 4.57$  and in the OM group was  $26.0 \pm 4.52$ . Based on mean induction to delivery interval, in primi and multi gravida the Induction is faster in the VM group compared to OM group. This observation was statistically significant ( $p \leq 0.0001$ ). This observation is comparable with studies of Wing et al (49.6% and 52.2%), Devi et al (28% and 32.9%), Hilda et al studies.<sup>5-7</sup> Bagariya et al study reported that, vaginal

group required a smaller number of oxytocin augmentation cases, compared to oral.<sup>8</sup>

**Table 1: Age based distribution.**

Age (years)	Vaginal misoprostol (N=50)		Oral misoprostol (N=50)	
	Frequency	%	Frequency	%
<20	4	8	4	8
21-25	20	40	23	46
26-30	17	34	15	30
31-35	6	12	5	10
>36	3	6	3	6
Total	50	100	50	100
Mean	$26.46 \pm 4.57$		$26.0 \pm 4.52$	

VM Group=vaginal misoprostol group, OM Group=oral misoprostol group.

**Table 2: Mean induction delivery interval.**

Parameters (mean±SD)	Vaginal misoprostol	Oral misoprostol	P value
Primigravida	$19.05 \pm 5.22$	$19.98 \pm 6.82$	<0.001
Multigravida	$9.0 \pm 4.61$	$13.52 \pm 4.94$	<0.001
Overall mean induction delivery interval	$13.75 \pm 7.02$	$17.04 \pm 6.73$	<0.0001

There was no statistically significant association observed with relation to parity between the groups as the p value calculated to be  $>0.05$ . There was nil statistically significant difference observed between the groups with relation to gestational age as the p value calculated to be  $>0.05$ . Indications for induction of labour in the study were post-dated pregnancy, oligohydramnios, gestational diabetes mellitus, antepartum eclampsia, polyhydromnios, Severe preeclampsia, non-severe pre-eclampsia, PROM and gestational thrombocytopenia. In the VM and OM groups, in the primigravida most common indication for induction was post-dated pregnancy. In the VM group, most common indication for induction among multi was post-dated pregnancy followed by oligohydromnios. In the OM group, most common indication for induction in multi was also post-dated pregnancy. In the VM and OM group, Primigravida required more doses of oxytocin compared to multigravida. This observation was statistically significant ( $p < 0.05$ ). There was no statistically significant difference observed with relation to modified Bishop score as the p value calculated to be  $>0.05$  when compared between oral and vaginal misoprostol. In our study, 72% had underwent vaginal delivery in VM group, 68% had vaginal deliveries in OM group. In the VM group 28% and 32% in the OM group underwent LSCS. The most common indication in both was failed induction, 12% in the VM group and 12% in the OM group had fetal complications. NICU admission was needed in 8% of babies in both groups. There was a 2% incidence of neonatal death in VM group in the current study. In the current study, meconium-stained liquor was

26% in vaginal misoprostol group whereas it was 22% in oral misoprostol group.

**Table 3: Oxytocin requirement and parity.**

Oxytocin requirement	Vaginal misoprostol (N=50)		Oral misoprostol (N=50)	
	Primi	Multi	Primi	Multi
Yes	15	10	12	07
No	02	09	08	07
Total	17	19	20	14
Chi-square: 5.21, df=1, p<0.05*			Chi-square: 0.32, df=1, p=0.56	

\*statistically significant

The increased rate of meconium staining in our study was attributed to a higher number of post-dated pregnancy cases, where meconium-stained liquor is a known reality. As a result, in our study, the drug misoprostol could not be completely to blame for the meconium staining of the liquor. 50% in the VM group and 38% in the OM group were given oxytocin for augmentation of labour. More number of cases in the vaginal group required augmentation with oxytocin, as compared to oral group. In the VM and OM group, primigravida required more doses of oxytocin compared to multigravida.

## DISCUSSION

The initiation of regular uterine contractions by using medical, surgical or combined techniques for the purpose of safe vaginal delivery is known as induction of labour. Normally, pregnancies should be continued till term. Labour should start spontaneously and result in vaginal birth. If the risks continuation of pregnancy outweigh the benefits, to the foetus or maternal health, induction of labour may be indicated.<sup>9,10</sup> During labour and abortion, Keisse discovered large quantities of endogenous prostaglandins in maternal circulation and amniotic fluid in 1979.

A randomised trial in 1987 strongly proved the therapeutic potential of misoprostol as an abortifacient. Fenn and Robinson demonstrated in 1991 that misoprostol is superior than NSAIDs in preserving the stomach mucosa from injury. Danielsson et al investigated the effects of oral & vaginal misoprostol treatment on uterine contractility in 1999. When administered orally or vaginally, misoprostol is a safe and effective cervical ripening and labour inducing agent. When compared to other labour inducing medicines, it is substantially more cost effective when taken orally or vaginally (200 mcg tab. costs Rs.25/-). Modified Bishop's score and partograph are simple tools to assess the favourability of cervix, and labour progress. Induction of labour should always be conducted in a hospital for intrapartum maternal and foetal surveillance. Obstetrician, paediatrician, and anaesthetist should be available at any time. Misoprostol when administered vaginally has higher efficacy than oral route,

due to shorter induction delivery interval, less c-sections rate, and a smaller number of side-effects. Patient choice could mean that the preferred route might be oral, due to ease of administration, less chance of peripartum infections, better compliance. However, it has longer induction- delivery interval, less systemic bioavailability.

## Limitations

Limitation of current study is that the current study's conclusions must be confirmed in a larger study as the sample size is small.

## CONCLUSION

It is becoming more common to induce labour using misoprostol. This can be administered either by the vaginal or oral route. In this study women who had received misoprostol by vaginal route. Had shorter induction-delivery interval, less incidence of c-sections rate, and less side effects, when compared to oral route of administration. There was slightly increased in prevalence of meconium-stained liquor (26%) in vaginal group, compared to oral group (22%). However, vaginal misoprostol had lesser induction-delivery interval, lesser c-section rates than oral misoprostol. Therefore, misoprostol when administered vaginally has higher efficacy than oral route. The increased efficacy of misoprostol raises the possibility of a local cervical effect, when administered vaginally.

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