

Oral Versus Vaginal Misoprostol for Induction of Labour

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Summary:

It is sometimes difficult to select the most effective, easy to use, safest, widely accepted and less expensive method for induction of labour and thereby spontaneous vaginal delivery. Prostaglandin E₁ analogue ie misoprostol as a successful method both in oral and vaginal form has been used for induction of labour. The present study was conducted with an aim to compare the efficacy and safety of oral and vaginal administration of misoprostol tablets for cervical ripening and induction of labour in pregnant women using similar dosing regimen in two groups of pregnant women. A prospective randomized trial was done on one hundred pregnant women for the purpose. They were between 37 and 42 weeks of gestation with singleton pregnancy, cephalic presentation and unfavourable cervix (modified Bishops score of 4 or

less) in the department of Obstetrics and Gynaecology of Dhaka Medical college Hospital during the period between February 2003 and March 2004. The mode of delivery did not vary significantly between the two groups. Mean induction delivery interval, mean doses of misoprostol, number of women delivered within 24 hours, oxytocin requirement and mean time to delivery were nearly similar in the two groups. Only nulliparous women in oral group took longer time to deliver than vaginal group though it was not statistically significant. The mode of delivery also did not differ significantly. The proportion of emergency caesarean section was high in vaginal group than oral group. Neonatal outcome was satisfactory and the results were comparable.

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Introduction:

In the everyday practice of obstetrics we need to induce labour whenever it becomes mandatory. Induction of labour is indicated wherever there is risk to mother, foetus or both, if pregnancy is further continued.

The outcome of induction depends largely on if the cervix is ripe or not. In approximately 10% of all pregnancies, women have unfavourable cervix, and when labour is induced in an unripe cervix, it is

associated with higher than normal incidence of failure of induction, prolonged labour, instrumental delivery and caesarean section.

So, induction of labour and thereby spontaneous vaginal delivery needs the most effective, easy to use, safest, widely accepted and less expensive methods to be applied.

Among the prostaglandins, prostaglandin E₁ analogue is tested for cervical ripening. Originally it is marketed for the treatment of peptic ulcer under different name such as Cytoteck, Cytomis. The first indication for its uterotonic properties came from Latin America when it was utilized to terminate pregnancy. Several studies showed intravaginal misoprostol comparing favourably with dinoprost and oxytocin³⁻⁵. Also, well-controlled studies indicated its efficacy and safety via the oral route⁶.

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The aim of present study was to compare the efficacy and safety of oral and vaginal administration of misoprostol tablets for cervical ripening and induction of labour in pregnant woman.

Materials and method:

Hundred pregnant women between 37 and 42 weeks of gestation were randomly selected and assigned to one of two equal groups. They were gravida 1-3 and para 0-2. All of the cases had a single viable pregnancy in vertex presentation with a Bishop score of 4 or less. This randomized clinical trial was performed in the department of Obstetrics and Gynaecology of Dhaka Medical College Hospital during the period between February 2003 and March 2004. There were no contraindications for labour induction by prostaglandin administration. Group I received oral misoprostol and group II received vaginal misoprostol.

An informed consent was obtained from each of the women after proper explanation of the aim and procedure of induction of labour.

Same dosing regimen of misoprostol was used both for oral as well as for vaginal groups. Hundred microgram (100 µg) of misoprostol (halving 200 µg tablet prepared by the Incepta Pharmaceutical, Bangladesh) was given to the pregnant women to ingest with 30 ml of water. The same dosing ie 100 µg of misoprostol was inserted intravaginally (in the posterior vaginal fornix).

After initial dose (100 µg), it was repeated every four hours until the occurrence of progressive labour (as evidenced by a Bishop score of 7 or more), a

contraction pattern of three every 10 minutes each lasting 40 seconds, and evidence of foetal intolerance or delivery. If an insufficient response was noted with the first application, subsequent doses to a minimum of 600 µg (3 tablets), were administered until adequate contractions were achieved. If labour was progressing, then the subsequent misoprostol was withheld and labour was observed.

Information was obtained from both groups on medical and obstetrical history, clinical examination findings and outcome of labour, and were recorded on computerized coding sheets. Induction was considered failed if established labour that is any of the following: three contractions per ten minutes and Bishop's score more than or equal to 7 did not occur after 24 hours from induction. In case of failed induction, patients were offered to do oxytocin induction or caesarean section depending on the condition of the mother and the baby. Data were analysed using SPSS package.

Results :

The two groups were closely similar to each other regarding age, gestational age and initial Bishop's scoring. (Table-I). The differences in parity (0.74+0.96 vs 0.38+0.67) and gravidity were significant between the two groups.

Indications of induction of labour in two groups were different although the difference was not statistically significant. Highest percentage of women was induced for post dated pregnancy in both groups. Preclampsia and eclampsia were the second highest cause for induction of labour (Fig.-1).

Table-I

Demographic characteristic of the patients in two groups

Characteristics	Oral group (n=50)	Vaginal group (n=50)	Significance (P value)
Age (years)	23.26 (0.418)	22.34 (3.16)	NS (0.218)
Gravidity	1.82 (0.92)	1.48 (0.74)	S-.044, t (90) = 2.043
Parity	0.74 (0.96)	0.38 (.67)	S- .033, t (98) = 2.170
Gestational age (in wks)	39.93 (1.42)	40.19 (1.38)	NS (0.355)
Initial Bishop's Score	2.1 (1.23)	1.8 (1.12)	NS (0.207)

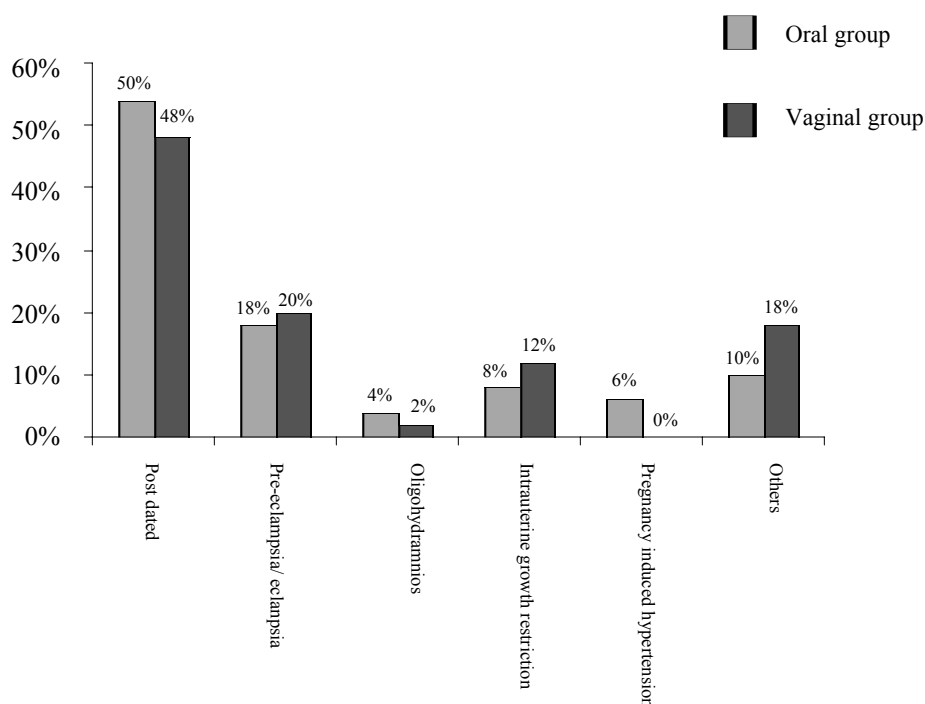


Fig.-1: Bar chart showing indication of induction of labour in two groups.

The mode of delivery did not vary significantly between the two groups (Table- II). Almost equal number of patients delivered vaginally spontaneously in both groups. There was no association between route of administration and mode of delivery. Mean induction delivery interval, mean doses of

misoprostol, number of women delivered within 24 hours, oxytocin requirement and mean time were nearly similar in the two groups. Only nulliparous women in oral group took longer time to deliver than vaginal group though the difference was not statistically significant.

Table-II

<i>Mode of delivery after induction of labour in oral and vaginal groups</i>			
Mode of Delivery	Oral Group (n=50)	Vaginal group (n=50)	Significance (P value)
Parity			
Nulliparity	27 (54%)	35 (70%)	
Multiparity	23 (46%)	15 (30%)	
Spontaneous vaginal delivery	33 (66%)	32 (64%)	NS (.789)
Forceps	0 (0)	0 (0)	
Ventouse	2 (4%)	1 (2%)	
Caesarean Section	15 (30%)	17 (34%)	

Table-III

<i>Indication of caesarean section in two groups:</i>			
Indication	Oral Group	Vaginal Group	Significance (P value)
Failed induction	3 (6%)	4 (8%)	NS .644
Foetal distress	10 (20%)	9 (18%)	
Uterine hyper tonicity	-	2 (4%)	
Nausea, Vomiting	2 (4)	1 (2%)	
Uncontrolled preeclampsia	-	1 (2%)	

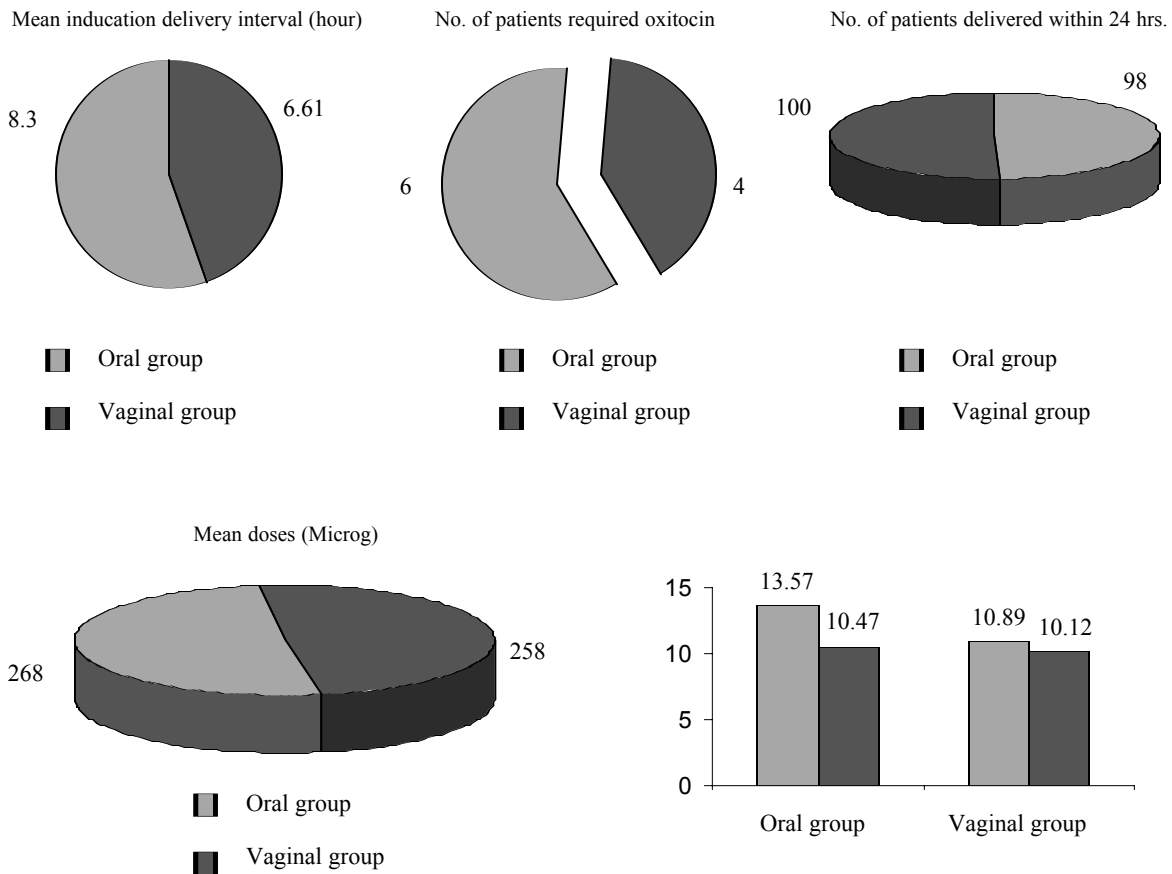


Fig.-2: Showing outcome of labour in oral and vaginal group with regard to spontaneous vaginal delivery

Neonatal outcome was very satisfactory and the results were comparable in two groups. No neonatal infection occurred. Apgar score at one minute as well as at five minutes was good in two groups. None of the babies died.

Women in the study groups developed very few complications. Nausea and vomiting were more

in oral group (4% vs 2%) and uterine hypertonicity developed in the vaginal group only (4%). They were then delivered by caesarean section. One patient in oral group developed post-partum atony that responded to injection methergin.

Table-IV

Neonatal outcome in oral and vaginal group			
Characteristics	Oral Group (n=50)	Vaginal group (n=50)	Significance (P value)
Apgar score:	8.58	8.7	
In one minute	10	9.92	NS (0.365)
In five minutes			NS (0.156)
Birth weight (kg)	2.92	2.88	NS (0.536)
	0.39	0.35	
Meconium passed	1	0	
Admission to ICU	1	2	
Neonatal infection	0	0	

Discussion:

In the present study, same dose schedule that is hundred micrograms four hourly was used for the oral as well as for the vaginal group. Induction of labour occurred in most of the cases in both groups. Spontaneous vaginal delivery occurred in 66% in oral and 64% in vaginal group. This is consistent with Hall *et al*⁸ study (70% in oral group vs 70% in vaginal group), whereas in Topozada *et al*⁷ study it was 73% vs 77%. Failed induction occurred in both the groups though nearly equal in percentage (6% in oral group and 8% in vaginal group). In others⁷⁻¹³, they increased the dose in both groups if the response was not satisfactory. Therefore, failed induction was not reported to occur in their study.

Almost equal number of patients delivered vaginally spontaneously in both groups. There was no association between the route of administration and mode of delivery. Mean induction delivery interval, mean doses of misoprostol, number of women delivered within 24 hours, oxytocin requirement and mean time for delivery were nearly similar in two groups. Only nulliparous women in oral group took longer time (13.57% hours vs 10.49%) to deliver than vaginal group though it was not statistically significant. It may be due to that nulliparous uterus is less sensitive to induction than the previously pregnant uterus in multiparous women.

The indication of labour induction did not vary between the two groups significantly and this finding

was similar to other studies⁷⁻¹³. Time interval between start of induction and to delivery was less in vaginal group than in oral group. Parity and gravidity was significantly different in the two groups ($P=0.033$ and $P=0.044$).

Mean dose requirement was similar in vaginal and oral group (268+ 136.4 µg in oral group vs 258+ 144.41 µg in vaginal). This finding is consistent with Hall *et al*⁸ study. Know *et al*¹¹ study result differs in that vaginal administrations were less in number than the oral group. The percentage of caesarean section was less in case of oral group than in vaginal group though this was not statistically significant (30% in oral group and 34% in vaginal group). This is similar other studies^{8,10,11}. In this study, vaginal group developed hypertonicity and emergency caesarean section was done. Topozada *et al*⁷ found similar result in their study. The hypertonicity was probably due to higher dose or some direct access via the vaginal route.

Conclusion:

Several researchers worked on misoprostol to find out its safety and efficacy during both vaginal and oral administration. Different regimen was used and doses were increased to achieve desired effects. From this study, it is found that the safety and efficacy of oral misoprostol is comparable to vaginal misoprostol. Yet, more studies are needed to find out the optimum oral and vaginal dose. It can be used for induction of labour under close monitoring in a facility where emergency caesarean section is possible.

The present study was carried out in a small group of patients. It is suggested that long term clinical trial with a bigger sample size should be carried out to assess the safety and efficacy of this new induction method.

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