ORIGINAL ARTICLE

Titrated Oral Misoprostol Solution Versus Intravenous Oxytocin for Augmentation of Labour

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ABSTRACT:

Objective: To compare the efficacy of titrated oral mis oprostol solution with intravenous oxytocin for augmentation of labour in term primigravidae in active phase of labour with inadequate uterine contractions.

Methodology: This randomized control trial was conducted in the department of Gynaecology and Obstetrics, Pakistan Institute of Medical Sciences, Islamabad, over a period of six months from 14-April to 13-October, 2014. A total of 760 (two groups of 380 each) primigravidae, between age 20-39 years, who had completed 37-42 gestational weeks by dates, or by ultrasound scan, with regular contractions and an effaced cervix dilated between 3-4 cm, and who later developed inadequate uterine contractions during the first stage of labour were included in the study. Group A received titrated oral misoprostol solution 200µg tablet dissolved in 200ml tap water and 20ml (20µg/hour) and group-B was given Intravenous oxytocin (10 units in 1000cc Hartman's solution at 8 drops/minute, doubling every 30 minutes up to a maximum of 64 drops/min for 2 hours).

Results: Mean (±SD) age of the patients was 26.4±4.4 and 26.6±4.6 years in group-A and B respectively. In group-A, 322 patients (84.7%) and in group-B 326 patients (85.8%) were delivered vaginally. Mean (±SD) augmentation to delivery interval was 293.82±99.36 and 311.65±106.73 minutes in group-A and B respectively. Mean (±SD) gestational age in group-A was 38.82±1.32 and in group-B 38.83±1.09 week. Caesarean section was performed in rest of the patients in both groups. There was no significant association between mode of delivery in both groups (P-value= 0.682).

Conclusion: Labour augmentation with titrated oral misoprostol or intravenous oxytocin resulted in about similar rates of vaginal delivery.

Keywords: Augmentation of labour, Titrated oral Misoprostol, Intravenous oxytocin.

INTRODUCTION:

The problems of prolonged labour, both for mother and foetus have been perceived for long time. The mother is presented to high risk of infections, ketosis and labour dystocia while embryo confronts the threat of infections, asphyxia and unnecessary cranial embellishment. The idea of dynamic management of labour has affected the obstetricians to change their standpoint with respect to the administration of first phase of labour.[1] Significant relationship has been stated between active management of labour, low occurrence of prolonged labour and low caesarean section rates.[2] Although, strategies for increasing uterine contractility, for instance amniotomy and oxytocin have been shown to accelerate cervical dilatation, yet these methods are not without complications.[3]

Spasmolytic and spasmoanaelgesic mixtures are administered to facilitate dilatation of cervix and to shorten the first stage of labour.[4-8] A perfect antispasmodic for increasing speed of cervical dilatation ought to have a brief and enduring activity, no adverse effects on uterine contractility and be free from uterine inertia with minimal adverse effects on mother and foetus.[9] Phloroglucinol is one of spasmolytic, principally used for gastrointestinal colic.[10] The medication was widely used during 1970s and early 1980s for augmentation of labour.[4] Other spasmolytics, such as misoprostol are also being used, which is easy to administer, with fewer side effects, such as nausea, vomiting, diarrhea and fever.[3,4]

The use of spasmolytic is increasing day by day in all clinics and hospitals indiscriminately, and there is no definite study to show the exact dose required, when to be given, and its effects on the mode of delivery. Hence this study was conducted to evaluate the effect of misoprostol in labour so that its use can be promoted further and guidelines can be provided for the safe use of drug.

METHODOLOGY:

This was a randomized control trial conducted in the Department of Gynaecology and Obstetrics, Unit II, Maternal and Child Health Centre, Pakistan Institute of Medical Sciences, Islamabad. Study was done over a period of six months from 14-April-2014 to 13-October-2014.

A total of 760 (380 in each group) pregnant women of age 20 to 39 years, who had completed 37-42

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gestation weeks by dates or by ultrasound scan,with regular contractions (3 in 10 min); primigravidae with an effaced cervix, dilated between 3-4 cm, and who later developed inadequate uterine contractions (two or less compressions every 10 minutes) in the course of the first stage of labour were enrolled in the study. Adequate uterine contractions were defined as occurring every 2-3 minutes and lasting 60-90 seconds. All the pregnant women with previous history of any uterine surgery, for example, myomectomy, previous history of allergy to misoprostol and any contraindication of augmentation of labour such as foetal distress, cephalopelvic disproportion (CPD) and mal-presentation were excluded from the study. Data was collected on a pre-designed proforma by fourth year post graduate. Written consent was taken from eligible women. Consent was taken from the hospital ethical committee. All the eligible patients were randomly assigned into two groups by lottery method. Group A received titrated oral misoprostol solution (200µg tablet dissolved in 200ml tap water and 20ml (20µg/hour) until passable uterine contraction was accomplished). If contraction did not occur even after four hours (4 doses), the dose was boosted to 40µg and was repeated every hour until uterine contractions occurred. Once uterine activity was adequate over 1 hour, no further misoprostol was administered. If contractions subsequently became inadequate, hourly doses of misoprostol solution were started at 10µg/hour, which were increased to 20µg/hour as much as 40µg/hour based on uterine responsiveness. The maximum dose of misoprostol was 1600µg. Group B was given intravenous oxytocin (10 units in 1000cc Hartman's solution at 8 drops/minute doubling every 30 minutes up to a maximum of 64 drops/min for 2 hours).

Once labour augmentation had begun, partogram was maintained to observe the progress of labour and to keep a record of the maternal vital signs, foetal heart rate, color of liquor (if meconium stained) and the dose of the uterotonic administered. All data was entered and analyzed using SPSS version 18. Mean ± SD was computed for all the quantitative variables. Chi Square test was applied to assess significant association of maternal age and mode of delivery in the two groups. P-value<0.05 was considered statistically significant.

RESULTS:

Mean age of the patients was 26.4±4.4 and 26.6±4.6 years in group A and B respectively. Mean augmentation to delivery interval was 293.82±99.36 and 311.65± 106.73 minutes in group A and B respectively. Mean gestational age in group A was 38.82± 1.32 and in group B was 38.83± 1.09 weeks (Table-1). Majority of the patients in both groups were between 20-30 years of age. In group A, 322 (84.7%) patients and in group B 326 (85.8%) patients delivered vaginally. Caesarean section was performed in rest of the patients of both group, however there was no noteworthy association of maternal age and mode of delivery (P-value=0.579 and 0.682 respectively, Table-2).

Table: 1
Characteristics of study participants

Variables	Group A Mean ±SD	Group B Mean± SD
Maternal age (years)	26.4± 4.4	26.6 ± 4.6
Augmentation to delivery interval (min)	293.82± (99.36)	311.65 ± (106.73)
Gestational age (weeks)	38.82± 1.32	38.83± 1.09

Table: 2
Distribution of maternal age and mode of delivery between both the groups

	Group-A Titrated oral Misoprostol		Group-B Intravenous Oxytocin		P-value
	n	%	n	%	
Maternal age (years)					
20-30	311	81.8	305	80.3	0.579
31-39	69	18.2	75	19.7	
Mode of delivery					
Vaginal delivery	322	84.7	326	85.8	0.682
Caesarean section	58	15.3	54	14.2	

DISCUSSION:

In extended labour, high infection hazards, ketosis and labour dystocia are the problems faced by mothers whereas; foetus confronts the hazard of infection, asphyxia and un-due cranial molding.[1] It has been reported that in numerous developed countries, caesarean section birth rates are above 20%.[11] Data was collected from 150 countries over 24 years (1990-2014) and reported overall birth rate by C-section to be 15%, fluctuating from 6% in the least developed region to 27.2% in the utmost established county.[12] The elementary finding adding to the high rate of caesarean section in nulliparous ladies is dystocia or delayed labour. An approach of early amniotomy with administration of oxytocin to evade postponement in labour advancement is related to an inconspicuous diminishment in the rate of caesarean sections.[13] No significant difference has been reported in caesarean delivery rate, neonatal outcome, and maternal outcome between the low and high doses of oxytocin on labour extension with the exception of amplification of labour interval.[14] However, intravenous infusion of oxytocin should be controlled through an intravenous pump machine and it might be too demanding in specific settings. Various trials have revealed that misoprostol is a successful operator for cervical maturing and labour advancement. A study done to assess the effect of orally administered misoprostol versus titrated intravenous oxytocin for labour initiation in females

with good cervical condition (Bishop Score of =6) demonstrated no benefit with higher likelihood of uterine hyper stimulation.[15]

Therefore, orally administered misoprostol of fixed dosage without individualization is not an ideal choice. In patients with unfavorable cervical status, the idea that titrated oral misoprostol administration is related to lower frequencies of uterine hyper stimulation and caesarean births than vaginal misoprostol for labor impelling is settled.[16]

Since titrated oral misoprostol solution is less demanding to administer than titrated intravenous oxytocin, we deliberated that it was worth directing this randomized controlled trial to look at the ideal treatment regimen for labour augmentation. Vaginal delivery within 12 or 24 hours is the most vital clinical factor. We found that there was no statistically significant difference in percentages of vaginal deliveries between both the groups. Therefore, titrated oral misoprostol solution can be considered as an effective alternative method for labour augmentation.

In another study, complete vaginal delivery occurred within 12 hours for 92 (78.0%) and 97 (85.8%) women in the misoprostol and oxytocin group respectively (P=0.121). However, for vaginal deliveries within 24 hours, no significant differences were observed between the two groups.[2] Sadaf et al reported no significant difference in side effects and neonatal outcome between both the groups, therefore concluded that oral misoprostol might be used as an alternative for escalation of labour.[17]

Another study reported higher failure of induction, lesser induction to delivery duration in oxytocin group than misoprostol group, whereas maternal and foetal complications were similar in both the groups.[18] Less failure to induction in misoprostol group was observed as compared to oxytocin group, with comparable maternal and foetal complications in both groups, but shorter induction-to-delivery time was reported in misoprostol group than oxytocin group.[19]

Several studies reported shorter admission to drug interval in misoprostol group, approximately equal time between induction of augmentation and delivery; and alike maternal and neonatal outcomes in both misoprostol and oxytocin groups.[20,21] Another study reported shorter induction-to-delivery time in misoprostol group but equal proportions of neonatal outcomes, as well as vaginal and caesarean delivery in both misoprostol and oxytocin group.[22] In contrast to our study, another study has demonstrated lower caesarean rate and, induction to delivery period in misoprostol group.[23,24] The findings of our study were similar to Shaheen et al, who reported nearly comparable complications and same ratio of vaginal and caesarean delivery in both the groups. The most common reason of caesarean delivery was dystocia in oxytocin group and foetal distress in misoprostol group (P-value<0.01).[25]

CONCLUSION:

Winding up the topic, labour augmentation with titrated oral misoprostol and intravenous oxytocin resulted in about analogous rates of vaginal delivery. In addition, misoprostol leads over oxytocin in different aspects like longer shelf life, stability at room temperature, and in ease of administration.

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