ORIGINAL ARTICLE

The Effect of Oral Misoprostol in Prelabour Rupture of Membranes at Term

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ABSTRACT

OBJECTIVE: The effect of oral Misoprostol for induction of labour in Primigravidas with prelabour rupture of membranes at term.

STUDY DESIGN: This is Quasi-experimental study.

PLACE AND DURATION OF STUDY: This study was conducted at the Department of Obstetrics and Gynecology Unit-II Fatima Jinnah Medical College/ Sir Ganga Ram Hospital, Lahore, during the period of one year (1-1-2008 to 31-12-2008).

SUBJECTS AND METHODS: This study included sixty singleton primigravidas with cephalic presentation who had prelabour rupture of membranes (PROM) at term with no contraindication for induction of labour or for Misoprostol usage.100 microgram (µg) of Misoprostol was given orally at 4 hours interval for the maximum of two doses with or without Oxytocin augmentation. The outcome measures included induction to delivery time, oxytocin augmentation, mode of delivery, fetal outcome and maternal complications.

RESULTS: Majority of subjects (58.34%) required two doses of Misoprostol. In these women, the induction to delivery time was longer (9.6 hrs) as compared to subjects who had single dose (8.2 hrs).about mode of delivery, 50 women (83.30%) delivered vaginally with episiotomy, 9 (25%) had emergency lower segment Caesarean section (LSCS) due to fetal distress and 1 (1.6%) had instrumental delivery. About 80% of women who had vaginal delivery also required augmentation with Oxytocin. The maternal complications were nausea/vomiting in 4 (6.6%) and fever in 2 patients (3.3%). All newborns had good Apgar score at 1 & 5 minutes.

CONCLUSION: Oral Misoprostol is a safe and effective agent for induction of labour in primigravidas with PROM at term in a set up with adequate feto-maternal monitoring facilities.

KEYWORDS: Induction, Labour, Misoprostol, PROM, Oxytocin augmentation.

INTRODUCTION

Prelabour rupture of membranes is defined as rupture of membranes at term with a latent period before the onset of spontaneous uterine activity. In these cases, active management with induction of labour is preferred over expectant therapy because of lower risks of maternal and neonatal infections and increased level of maternal satisfaction[1,2].

Primary agents for induction of labour are Oxytocin, Prostaglandins and a combination of both. Misoprostol is a recent addition to the list. It is a synthetic analogue of prostaglandins E_1 which is widely used for the treatment of peptic ulcer. However, drug is being used by various groups by vaginal or oral routes for later indication [3,4]. In the present era of evidence base medicine, a drug can be prescribed for an off label indication only on the basis of sound scientific evidence[5,6,7].

Misoprostol has uterotonic actions and is also useful for cervical ripening. It is a stable and inexpensive agent which can be stored at room temperature for many years and has only a few systemic effects[8]. On the other hand, the traditional Prostaglandins used for induction of labour are very expensive and need refrigeration for their storage. Therefore, in a poor resource setting like in our country with limited health facilities, misoprostol can be a good alternative agent for induction of labour. This concept was the main stimulus for the present study with the objective to asses the efficacy of oral misoprostol for induction of labour in primigravidas with PROM at term in our women.

PATIENTS AND METHODS

This Quasi-experimental study was carried out in the Department of Obstetrics and Gynecology, unit II at Sir Ganga Ram Hospital / Fatima Jinnah Medical College Lahore during a period of one

year that is from 1st January 2008 to 31st December 2008.

A total of 60 singleton primigravidas at term with cephalic presentation who were diagnosed to have prelabour rupture of membranes were recruited in this study after informed consent. These women had no contraindication for induction of labour or vaginal delivery or prostaglandin usage. In each case, detail evaluation was carried out by complete history and general physical and systemic examination. Sterile speculum examination was performed to visualize amniotic fluid drainage through cervical os to confirm diagnosis of PROM. Vaginal examination was carried out under sterile condition to asses Bishop Score by a senior resident. Fetal well being was assessed by a cardiotocography (CTG) in each case.

Each woman was given 100µg of misoprostol orally to a maximum of two doses 4 hours apart. Second dose was only given if Bishop Score remained unfavorable and uterine contraction did not start or were mild. Partogram was maintained in each case. If the progress of labour was slow in active phase, Oxytocin infusion (5units/ 1L of normal saline), was given for augmentation at a starting rate of 10 drops/ minute and increased after every half an hour by 10 drops/minute depending upon uterine contractions.

Outcome measures of the study were induction to delivery time, augmentation with oxytocin, uterine hyperstimulation, tachysystole, nausea, vomiting, pyrexia, mode of delivery, post partum haemorrhage and fetal outcome in terms of Apgar score at one and fine minutes of birth and admission to neonatal intensive care unit (NICU). These variables were assessed by an experienced doctor and were also recorded on a specially designed Proforma. The data was analyzed by SPSS software version 10 to calculate the frequencies and percentages of all variables.

RESULTS

A total of sixty primigravidas having prelabour rupture of membranes at term were induced either with a single oral dose of 100 µg or with a maximum of two doses (4 hours apart) of 100 µg of Misoprostol. The mean

Bishop Score of these women was 3.25. 35 women (58.34%) required two doses (Fig. 1). The induction to delivery time was 9.6 hours among subjects requiring two doses and 8.2 hours for women who had established labour with single dose (Fig.II).

Majority of subjects had normal vaginal delivery (83.3%), nine (15%) had emergency caesarean section (C/S) and outlet forceps was applied to one women due to failure to push (Table 1). Indications for C/S were fetal distress, diagnosed on the basis of meconium staining of the liquor and abnormal CTG patterns.

About 80% of the women who had vaginal delivery also required augmentation with Oxytocin. No maternal complications in the form of hyperstimulation, tachysystole, failed induction and post partum haemorrhage(PPH) were noted. Only side effects were nausea and vomiting in 4 (6.6%) and fever in two cases (3.3%).

Neonatal outcome was good. Mean Apgar score was 7.5 & 8.5 at one and five minutes (Table II) and average weight of newborns was 3.2kg. There was no admission to intensive care unit or septicaemia or neonatal death in study group. However, antibiotic cover was given to all newborns in the nursery.

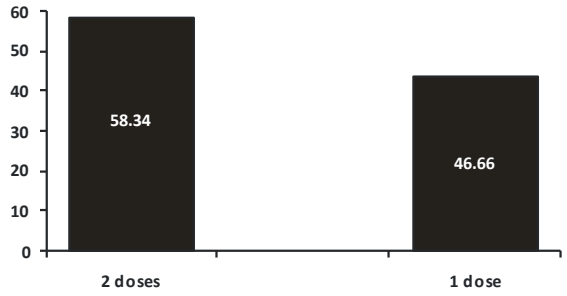

Figure 1: Dose of Misoprostol used for induction of labour (100µg/ dose)

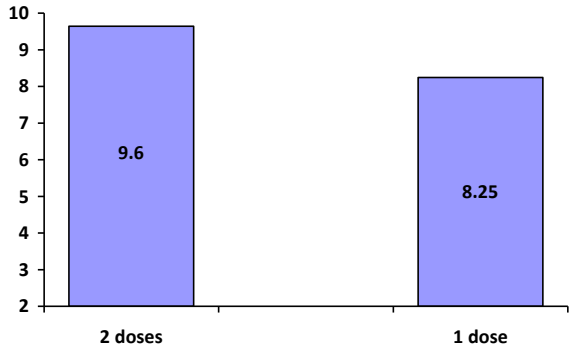

Figure 2: The Induction- Delivery time (in hours) in the study group

Table 1: Mode of Delivery in the study population

Normal vaginal delivery	50 (83.3%)
Outlet forceps delivery	1 (1.6%)
LSCS	9 (15%)

Table 2: Fetal Outcome and Maternal complications

Fetal Outcome	
Fetal Distress (Meconium passage)	9 (15%)
Mean Apgar score at 1 minute	7.5
Mean Apgar score at 5 minutes	8.5
Maternal Complications	
Nausea/ vomiting	4 (6.6%)
Fever	2 (3.3%)

DISCUSSION

The present study demonstrated the safety and efficacy of oral Misoprostol for induction of labour with Prelabour rupture of membranes at term. There were no major maternal or fetal complications seen in study population. Monitoring during labour is important when using Misoprostol for labour induction, to detect uterine hyperstimulation and fetal distress. Early intervention is necessary, if any such condition arise in order to achieve a good maternal and fetal outcome.

About 100µg of Misoprostol was effective by oral route to induce labour in this study which is similar to dose used by Lo et al [9] and Mozurkewich et al[10] as 50µg may lengthen induction delivery interval[11] which is not desired in case of PROM. Majority (80%) of our subjects required augmentation of labour with oxytocin, while 47.5% had augmentation after misoprostol induction as quoted by Mozurkewich et al[10] although the dose given in this study was similar but at 6 hourly interval.

Regarding induction to delivery time all subjects in present study delivered at less than 12 hours interval and there was no failed induction while another local study revealed 14.3% primigravidas delivered within 12 hours but the reason could be use of 50µg dose at 6 hourly interval in that study[12]. Study of Mozurkewich et al[10] revealed mean induction delivery interval 11.9 hours.

In the present study 83% of women delivered vaginally while Cheung PC[13] quoted 97% vaginal delivery, reason of which could be difference of maximum limit of dose up to 6 while we gave only two doses.

Caesarean section rate was 15% in our subjects while it was 11.53% in study of Crane et[14]. The dose used in that study was 75 µg instead of 100 µg in present study.

The most significant maternal side effect recorded with oral Misoprostol were nausea, vomiting and fever in about 10% of cases while 65.3% of the subjects experienced nausea and vomiting in study of Ara J[12]. There was not a single case of uterine tachysystole, hypertonus, or hyperstimulation syndrome or uterine rupture seen in present study while 6% had uterine hyperactivity with fetal heart decelerations in study of Lo et al [9] but sample in these studies is not enough to conclude about these issues. A meta-analysis by Lin et el[15] revealed safety of Misoprostol for labour induction in PROM. All newborns were delivered with good Apgar score at 1 & 5 minutes after birth. There was no case of septicemia or admission to the neonatal intensive care unit or neonatal death while 9.6% of newborns were admitted in intensive care unit and 1.9% neonatal deaths due to sepsis reported by Ara J[12].

In short, the present study suggests that oral Misoprostol can be a safe option for the induction of labour in women with PROM at term in a set up with adequate feto-maternal monitoring facilities.

The traditional prostaglandins are expensive and beyond the reach of many patients in our society. Oxytocin is ineffective when cervix is unfavorable. Misoprostol is an effective, stable, cheap and safe agent for induction of labour with less fetal or maternal complications. However, large multi-centers randomized clinical trials are needed urgently to give further evidence about the safety and efficacy of Misoprostol as a labour inducing agent.

CONCLUSION

Oral Misoprostol is effective and safe option for induction of labour in primigravida with PROM at term in a set up with adequate feto-maternal monitoring facilities.

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