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Original Article

J Shaheed Suhrawardy Med Coll, December 2014, Vol.6, No.2 ISSN 2226-5368

Clinical Outcome Following Induction of Labour with Misoprostol

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Abstract

Background: Induction of labour in the third trimester of pregnancy may be considered beneficial in many clinical circumstances. **Objective:** The aim of this study was to find the effectiveness and safety of a novel dosing regimen of oral misoprostol in a Bangladeshi sample. **Methods:** A cross sectional study was conducted in the Department of Obstetrics and Gynecology, Sir Salimullah Medical College & Mitford Hospital, Dhaka from October 2008 to September 2009 based on the guideline of American College of Obstetricians and Gynecologists. Fifty nine cases were enrolled according to inclusion criteria by clinical pelvimetry and bishop scoring. Contracted pelvis, evidence of cephalopelvic disproportion, placenta previa, unexplained vaginal bleeding, grand multipara, fetal malpresentation, previous uterine scar and fetal distress cases were excluded. Misoprostol was administered per orally. Maternal outcome was assessed by normal vaginal delivery, caesarean section, maternal distress, perineal tear, cervical tear, uterine hyper-stimulation and fetal outcome was assessed in the form of fetal distress, meconium stained amnions, neonatal admission, perinatal death and no complication. Statistical analysis was done using SPSS v 13. Probability value was set at $P<0.05$ for statistical significance. **Results:** Mean age was 25.69(5.04) years and mean age of gestation was 38.23(4.3) weeks and 59% were in regular antenatal checkup. Misoprostol was administered orally, 15% single, 37% double, 34% three and 14% were more than three doses. Following induction, 85% had normal vaginal delivery, 10% caesarean section and 5% had forceps delivery. For induction, 56% were due to preeclampsia, eclampsia & other pregnancy induced hypertension, 10% postdated pregnancy, 9% were unfavorable cervix, 7% IUD, 14% elective cases due to medical disorder, 2% had premature rupture of membrane, other causes were 3%. By bishop score assessment 54% had unfavorable and 46% had favorable cervix. In neonate's outcome, 34% had no complications, 19% meconium stained, 19% neonatal admission, 9% fetal distress and 20% had perinatal death including IUD. In maternal outcome, 69% no complications, 10% perineal tear, 10% caesarean section, 3% maternal distress, 3% cervical tear, 2% uterine hyper-stimulation, 2% episiotomy. There were no significant differences. **Conclusions:** Stepwise oral misoprostol was well tolerated with no increase in maternal side effects. There was also a trend towards more fetal safety in the oral misoprostol. Perhaps the most significant finding of our study is the lower cesarean section rate in the women who received the oral regimen. [J Shaheed Suhrawardy Med Coll, December 2014;6(2):49-52]

Keywords: Clinical outcome; labour; misoprostol

Received: December 2013; **Reviewed:** 19 February 2014; **Accepted:** June 2014

Introduction

Artificial initiation of uterine contractions prior to spontaneous onset resulting in progressive cervical dilatation and effacement with subsequent delivery is called as labor induction[1]. It may be required in a variety of maternal and fetal indications and 3 to 25% of all live births are reported to be pharmacologically or mechanically induced[2-3]. Induction of labor in the third trimester of pregnancy may be considered beneficial in many clinical circumstances[4]. The main problems associated with induction of labor are ineffective labor and excessive uterine activity, which may cause fetal distress. Both problems may lead to an increased risk of cesarean section[5-6]. Inducing labor may involve the use of the hormone oxytocin which causes the uterus to contract[7].

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Funding agency: None
Conflict of Interest: None
Contributions by authors: All authors contributed from protocol preparation upto manuscript writing

When labor is induced with oxytocin early in pregnancy, this has been associated with long and painful labors, as the uterus is less sensitive to oxytocin before term[8]. Prostaglandins have been used as an alternative to oxytocin and are particularly useful where a woman's cervix is unfavorable or not ready to commence labor[9]. Prostaglandins have been administered orally[10], vaginally[11], into the cervix (intracervical), outside the amniotic sac (extra-amniotically)[12], or intravenously[13]. There are also mechanical devices which have been developed to dilate or open the cervix[14].

Misoprostol is a synthetic prostaglandin that is structurally related to prostaglandin E1 (PGE1). Misoprostol is licensed for use as an anti-ulcer medication in the treatment of gastric ulcer disease and does not have a product license for use in pregnancy anywhere in the world. Despite this, the use of misoprostol in obstetric and gynecological practice has increased, being used widely in the management of first and second trimester abortion[15] and for termination in the third trimester of pregnancy following intrauterine fetal death[16]. More recently, misoprostol has been used in the induction of labor at term in the presence of a viable fetus, with both vaginal[17] and oral[18] routes of administration being used. Misoprostol has been investigated for use in the third stage of labor to prevent post-partum haemorrhage[19]. Misoprostol which is first described as a gastric cytoprotective agent is cheap, available as tablet, can be broken and administered orally, vaginally or sublingually[20-21]. It further requires no refrigeration and does not restrict patient mobility in early labor. The ideal dose and regimen still remain to be determined. On the other hand, uterotonic activity may result in potentially excessive and irreversible adverse effects such as uterine rupture, intrapartum fetal death, meconium passage, neonatal academia and increased cesarean section rates due to fetal distress which require further randomized con-trolled studies[18]. The purpose of this study was to evaluate fetomaternal outcome of administered misoprostol with pregnant women undergoing labour induction.

Methodology

This cross sectional study was conducted in the Department of Obstetrics and Gynecology, Sir Salimullah Medical College & Mitford Hospital, a tertiary teaching and referral center in Dhaka, Bangladesh, from October 2008 to September 2009 based on the guideline of American College of Obstetricians and Gynecologists. The Institute Ethics Committee approved the protocol and written informed consent from all participants was taken prior to data collection. Fifty nine cases were enrolled according to inclusion criteria (postdated & post termpregnancy, diabetes, hypertensive disorder, preeclampsia, eclampsia, IUD, singleton gestation, gestational age 34 weeks and above) by clinical pelvimetry and bishop scoring. Contracted pelvis, evidence of cephalopelvic disproportion, placenta previa, unexplained vaginal bleeding, grand multipara, fetal malpresentation, previous uterine scar and fetal distress were excluded. Misoprostol was administered per orally as recurred. Maternal outcome was assessed by normal vaginal delivery, caesarean section, maternal distress, perineal tear, cervical tear, uterine hyper-stimulation and fetal outcome was assessed in the form of fetal distress, meconium stained amnions, neonatal admission, perinatal death and no complication. Pre-designed questionnaire was used to collect socio-demographic and other clinical information. Statistical analysis was done using SPSS v 13. Probability value was set at $P<0.05$ for statistical significance.

Results

Among participants mean age was 25.69(5.04) years and mean age of gestation was 38.23(4.3) week. Maximum 59% were in regular antenatal checkup followed by 37.3% were in irregular checkup and 3.4% were having no antenatal checkup. Misoprostol was administered orally, 15% were single, 37% double, 34% three and 14% were more than three doses. Following induction, 85% had normal vaginal delivery, 10% were undergone caesarean section and 5% had forceps delivery. Among vaginal delivery, 58% cases induction delivery interval were 24 hours, 20% were 18 hours and 22% were 12 hours respectively. For induction, 56% were due to preeclampsia, eclampsia & other pregnancy induced hypertension, 10% postdated pregnancy, 9% were unfavorable cervix, 7% IUD, 14% elective cases due to medical disorder, 2% had premature rupture of membrane, other causes were 3%. By bishop score assessment 54% had unfavorable and rest had favorable cervix. Among the neonates, 34% had no complications, 19% were meconium stained, 19% cases needed neonatal admission, 9% fetal distress and 20% had perinatal death. Regarding maternal outcome, 69% had no complications, 10% perineal tear, 10% caesarean section, 3% maternal distress, 3% cervical tear, 2% uterine hyperstimulation, 2% had episiotomy. There were no significant differences ($p=0.096$).

Discussion

Bangladesh is a tropical developing country and it has a The purpose of study was to find out the effectiveness and safety of a novel dosing regimen of oral misoprostol (25 µgm). Mean age of the patients was 25.69±5.04 and p value was 0.093. Mean age of gestation was 38.23±4.3 and p value was 0.008 which was significant. Nasreen et al[22], determined the efficacy and safety of stepwise oral misoprostol with vaginal misoprostol for cervical ripening for induction of labour, mean maternal age 28.1±6.7 and gestational age 38.8±1.9 in case of oral misoprostol. On the other hand mean maternal age 27.2±6.4 and mean gestational age 39.1±1.8 in case of vaginal misoprostol. Among all of the participants 37.3% were comes from middle class family and maximum 62.7% were from lower class family. There was none from upper class. Most of the participants (47.5%) were live in suburban followed by 32.2% were in urban and 20.3% were in rural. Among the participants 10.2% were illiterate, 45.8% were primary, 35.6% were secondary and 8.5% were higher secondary and above.

Shetty at el[23]. compared the efficacy and patient acceptability of 50 microg of sublingual misoprostol with 100 microg of oral misoprostol in the induction of labour at term. Fifty micrograms of sublingual misoprostol or 100 microg of oral misoprostol was administered every four hours after random allocation, to a maximum of five doses. Number of patients delivering vaginally within 24 hours of the induction, mode of delivery, neonatal outcomes and patient acceptability was evaluated. There was no significant difference in the number of women delivering vaginally within 24 hours of the induction in the sublingual group as compared with the oral group (62.8% vs 59%, RR 1.1, 95% CI 0.6-2.1), or in the mean induction to delivery time (21.8 vs 24.1 h, mean difference 2.3 h 95% CI -2.2 to +6.7). There was no difference in the uterine hyperstimulation rates (1.6% in both groups), operative delivery rates or neonatal outcomes. In the sublingual group, 92.6% found the induction acceptable with 15.8% finding the tablets with an unpleasant taste, while in the oral group it was 96.9% and 4%, respectively. More patients in the oral group thought that they would consider the same method of induction again as compared with the sublingual group (58.6% vs 40%, RR 1.4, 95% CI 1.04-1.91). Doddet al[24] compared oral misoprostol solution with vaginal prostaglandin gel (dinoprostone) for induction of labour at term to determine whether misoprostol is superior. 741 women were randomised, 365 to the misoprostol group and 376 to the vaginal dinoprostone group. There were no significant differences between the two treatment groups in the primary outcomes, vaginal birth not achieved in 24 hours (misoprostol 168/365 (46.0%) vs dinoprostone 155/376 (41.2%); relative risk 1.12, (95% confidence interval 0.95 to 1.32; P = 0.134), caesarean section 83/365 (22.7%) vs 100/376 (26.6%); 0.82, 0.64 to 1.06; P = 0.127), caesarean section for fetal distress 32/365 (8.8%) vs 35/376 (9.3%); RR=0.91, (95% CI 0.57 to 1.44; P = 0.679), or uterine hyperstimulation with changes in fetal heart rate (3/365 (0.8%) vs 6/376 (1.6%); RR=0.55, (95 % CI 0.14 to 2.21; P = 0.401). Although there were differences in the process of labour induction, there were no significant differences in adverse maternal or neonatal outcomes.

In our participants with assessment of labour by bishop score maximum (54.2%) was undergone to be unfavorable condition and 45.8% were in favorable condition. Out of all respondents maximum 49.1% were vaginal delivery within 24 hours after use of misoprostol followed by 10.2% were caesarean section, 18.9% were vaginal delivery within 12 hours, 16.9% were vaginal within 18 hours, 5.1% were forceps delivery.

Among the all neonates 33.9% had no complication, both meconium stained amnios and neonatal admission had 18.6%, foetal distress had 8.5%, perinatal death had 2. Out of all participants 69.4% had no complication, 10.0% had perineal tear, 10.2% had caesarean section, 3.4% had maternal distress, 3.4% had cervical tear, 1.7% had uterine hyperstimulation, 1.7% had episiotomy. There were no significant differences.

Among all the participants by indication of induction of labor maximum 55.9% were belongs to pre-eclampsia, eclampsia and APH followed by 13.6% were elective, 10.2% were prolonged pregnancy, 8.5% were unfavorable cervix, 6.8% were IUD, 3.4% were other, 1.7% premature rupture of membrane. Nasreenet al.22 determined most common indications were postdates and hypertension. Misoprostol was administered orally. 15.3% were single dose, 37.3% were double dose, 33.9% were three dose and more than three dose were 13.6%.

Conclusion

Majority of FCPD were female coming from rural areas Oral misoprostol was well tolerated with no increase in maternal side effects. There was also a trend towards more fetal safety and lower cesarean section rate in the women who received the oral regimen misoprostol.

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