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Research Article

Oral Misoprostol as an Alternative Labor Induction Method: A Case Control Study

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Abstract

Background: Misoprostol is a new promising agent for cervical ripening and induction of labor. The ideal dose; route and frequency of administration of misoprostol are still under investigation.

Aims: To examine 50 µg of oral misoprostol for induction of labor for its different efficiency and safety on maternal& fetal outcomes.

Methods: This was a case control study for sample size of 300 women 152 as group and 148 as control. The participants were chosen from the labor room at Al Shifa Hospital the largest hospital in Gaza Strip & the first governmental hospital which started to use oral misoprostol for labor induction beside the routine use of prostaglandin E2. The study was conducted between September 2018, and December 2018. All the group were assigned to receive misoprostol 50 µg orally every 6 h for a maximum of 4 doses.

Results: The current study revealed that total h for the oral misoprostol induction group 20.5 h compared to 5.7 h in the control group. The Maternal complication in oral misoprostol was 12.5% versus 2.7% in the control group. Moreover, oral misoprostol group has a higher rate in birth canal injury & caesarean section 9.2%, 19.1% versus 2.0%, 0.7% respectively with control. The result revealed that, overall fetal complication was a higher rate in misoprostol group 14.5% versus 7.3% in control.

Conclusion: it was found that misoprostol induction method still has a higher maternal & fetal complication which required more investigation before being recommended as an alternative method in labor induction.

Keywords: Induction; Misoprostol; Safety; Efficacy

Introduction

Induction of labour is the process of artificial stimulation of the uterus to start & initiate labour [1]. The new approach, oral misoprostol administration was successful in minimizing the risk of cesarean section, and maternal adverse effect. The goal of labor induction is to stimulate uterine contractions by an artificial method that enhance normal vaginal delivery. As with all procedures, the risks must be weighed against the benefits to the woman and the fetus (The American College of Obstetricians and Gynecologists [2].

According to WHO reports there are increasing in the number of pregnant women who underwent induction of labor (artificially initiated labor) in developing countries with overall rates exceeding 20% of all births [3-5].

A prolonged pregnancy can lead to post-maturity of the fetus posing a great threat to its further survival in-utero that increasing postnatal morbidity & mortality. Meconium aspiration syndrome, oligohydramnios, macrosomia, fetal birth injuries, septicemia, non-reassuring fetal heart rate, fetal distress in labor are the most common neonatal complication that can exist as a result of prolong pregnancy. In other hands increased caesarean section rate, cervical tear, post-partum hemorrhage is the most maternal complication [6].

Misoprostol was manufactured and licensed to be taken orally for labor induction. However, vaginal, sublingual, buccal and

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rectal routes of administration that used in clinical practice in obstetrics and gynecology still under investigation for comparative outcomes [7].

Oral misoprostol is economy cost – effective & easy to administer as it's become a drug of choice in poor nations and countries under siege as Gaza area. The recommended dose of 50 µg intra-vaginal misoprostol has been included in the World Health Organization (WHO) complementary list as drug for IOL [8]. Low dose (<50 µg) titrated oral misoprostol solution had the lowest probability of caesarean section, whereas vaginal misoprostol (≥ 50 µg) had the highest probability of achieving a vaginal delivery within 24 h [9].

Low dose (>50 µg) titrated oral misoprostol solution had the lowest probability of caesarean section, whereas vaginal misoprostol (≥ 50 µg) had the highest probability of achieving a vaginal delivery within 24 h [10]. The aim of this study to examine 50 µ g of oral misoprostol for induction of labor for its different efficiency and safety on maternal & fetal outcomes.

Methodology

This was a case control study conducted in two groups of pregnant women who admitted to the labor room in the obstetrics department at Gaza Shifa hospital. The first group consist of pregnant women who underwent induction of labor at Al Shifa maternity hospital for the period of September 2017 till January 2018. The misoprostol group was qualified for induction due to post-date rupture of membrane (ROM) more than 24 h & other medical reason. The cases and control group were chosen from same sitting at the same duration. Matched for both group were taken into consideration for the following: gestational weeks of pregnancy & free of any medical & obstetric contraindication. The study population was consist of 152 as misoprostol group and 148 control. The medical records for women were used for obtaining data. Inclusion criteria for the misoprostol cases included all women with gestation age at 37 & more weeks, cephalic presentation, no vaginal delivery contraindications, and bishop score within normal range (3-6). The excluded criteria for the cases group with the following conditions, women who took 24 h rest after failed first trail of induction, women who went underwent more than one type of induction & any record with missed or incomplete data.

Data entry and analysis

Coding and entering data into the computer by assistance of a statistician. SPSS program version 21 was used in analyzing study results. Statistical analysis included frequencies, means and standard deviation, cross-tabulation, (t) test, and chi square test were used.

Ethical approval

Ethical approval was granted by the Institutional Review Committee of Al Shifa Maternity Hospital to conduct the study.

Results

The result for Table 1 showed that the general characteristic of study participants were statistical differences in both groups in demographic & obstetric characteristics regarding number of gravida, gestational age & bishop score with significant p value less than 0.005.

Table 1: Obstetric characteristic of study participants.

Criteria	Oral Misoprostol (group) (n=152)	Control (n=148)	p-value
Maternal Gravida	2.4 ± 1.7	3.2 ± 2.3	0.002
Gestational age	39 ± 3.9	32 ± 14	0.003
Women's bishop rang Mean	3.6 ± 2.1	6.6 ± 1.5	0.001

The result of Table 2 showed the mean total h for the oral misoprostol induction group 20.5 h while for the control group 5.7 h. The result was statistically significant with p value less than 0.005.

Table 2: Total time of labor h (t-test P-value less than 0.005).

Criteria	Oral Misoprostol group (n=152)	Control Group (n=148)	p-Value
Total time of labor	20.5 ± 14.0	5.7 ± 7.0	0.0001

Table 3 showed that the overall maternal complication in oral misoprostol was 12.5% versus 2.7% in the control group. The result was statistically significant with p value less than 0.005.

Table 3: Maternal complication.

Criteria (Maternal complication)	Oral Misoprostol (n=152)	Control Group (n=148)	p-value
Uterine rupture	2 (1.3%)	1 (0.7%)	0.51
Birth canal injury	14 (9.2%)	3 (2.0%)	0.006
Caesarean section	29 (19.1%)	1 (0.7%)	0
Postpartum hemorrhage	5 (3.3%)	1 (0.7%)	0.113

Table 4 showed that there are no significant differences in both groups for rupture uterus and postpartum haemorrhage as maternal complication. While the result showed that the oral misoprostol group have higher rate in birth canal injury & caesarean section 9.2%, 19.1% versus 2.0%, (0.7) respectively with p value less than 0.05.

Table 4: Maternal complication for two groups.

Criteria (Maternal complication)	Oral Misoprostol (n=152)	Control Group (n=148)	p-value
Uterine rupture	2 (1.3%)	1 (0.7%)	0.51
Birth canal injury	14 (9.2%)	3 (2.0%)	0.006
Caesarean section	29 (19.1%)	1 (0.7%)	0
Postpartum haemorrhage	5 (3.3%)	1 (0.7%)	0.113

Table 5 showed that the overall fetal complication was higher in group 14.5% versus 7.3% in control with significant statistical differences for neonatal admission with 11.8% in misoprostol group compared to 10.0% of control with p value 0.03.

Table 5: Fetal complication (Chi square test p-value less than 0.005).

Oral Misoprostol (n=152)	Criteria	Control Group (n=148)	p-value
22 (14.5%)	Neonatal compilation	11 (7.3%)	
18 (11.8%)	Admission to NICU	15 (10.0%)	0.038

Discussion

Misoprostol has been recently used for the induction of labor in most of developing countries including Palestine as it is more cheaper, available and could be an alternative method for PGE2 induction method. Recently the use of oral misoprostol administration showed a successful effect in minimizing the risk of caesarean section, and with a low significant difference in maternal adverse effect compared to other methods of labor induction. In the current study we try to examine the use of oral misoprostol as a method of labor induction compared with spontaneous labor efficacy and maternal-fetal outcomes. In this study we used the oral misoprostol with dose 50 µg every 6 h for 24 h if no cervical dilation with regular uterine contraction has started, the mother will have rest for 24 h and the second trail will be started again. If the second trial of oral misoprostol induction failed, CS will be recommended. However, up to now, there is still no certain conclusion or recommendation about the universal optimal dose, interval time and route of administration of oral misoprostol some institutions use oral, sublingual with different doses [11,12]. Misoprostol has been compared with other methods such as oxytocin or PGE2 induction in many studies for the induction of labor [13]. The current study revealed that total labor h for the oral misoprostol induction were 20.5 h compared to the total lobar h 5.7 h in control group. This result was similar to study conducted by Acharya [2] that showed that mean onset of labour was prolonged in misoprostol (13.6 h) compared to oxytocin (6.6 h) induction methods. Another study compared 25 mcg misoprostol with 3 mg dinoprostone administered vaginally every four h. The median induction delivery interval was longer in misoprostol 25 *vs.* 19 h (Ansar, 2914). The present study showed that the overall maternal complication in oral misoprostol was 12.5% versus 2.7% in the control group. The result was statistically significant with a p-value less than 0.005.

Conclusion

The result did show a significant difference in both groups for rupture uterus and postpartum hemorrhage as a maternal complication. However oral misoprostol group has a higher rate in birth canal injury & caesarean section 9.2%, 19.1% versus 2.0%, 0.7% respectively with control group. In addition the present study revealed that, the overall fetal complication was higher in misoprostol group 14.5% versus 7.3% in control with significant statistical differences for neonatal admission with 11.8% in misoprostol group compared to 10.0% of control with a p-value 0.03. In conclusion more research is needed to optimize the use of oral misoprostol for the induction of labor as an alternative induction method.

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