A comparison study of outcome of induction of labor with vaginal misoprostol versus oxytocin: a randomized clinical trial

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Abstract: Background: Shorter length of hospitalization of mothers will be helpful in economical, social terms. Since last few decades oxytocin infusion has been used for induction of labor, but due to its complications, new drugs need to be evaluated. The efficacy of misoprostol for induction of labor is controversy. Therefore, the effects of vaginal misoprostol on labor time and latent phase were investigated. Materials and Methods: This randomized clinical trial was conducted on 180 pregnant women in 2009 in Mobini Hospital, Sabzevar, Iran. Oxytocin infusion was used in one group and vaginal misoprostol (50mcg) was used in the other one. Total duration of labor and latent phase period in both groups were analyzed by T-student test. All tests were assumed two-sided. Findings: Total duration of labor for misoprostol was 10 hours and for oxytocin was 17 hours (p=0.01). Also latent period phase in misoprostol method was lower than that of oxytocin (6 hours Vs. 13 hours, respectively) (p=0.01). Cesarean section rate was reported 11% for vaginal misoprostol and 35% for oxytocin (p=0.01). Conclusion: using misoprostol compared with oxytocin, significantly reduces both the latent phase and the total labor time. Also CS rate is lower in the use of misoprostol compared oxytocin

Keywords: Misoprostol; oxytocin; Induction of labor; cervical ripening; randomized controlled trial; latent Period

Introduction
Childbirth is one of the most human physiological processes. Short and good enough delivery will have positive physical and psychological effects on the health of both mother and baby. Moreover, a shorter length of hospitalization of mothers will be helpful in economical, social, and personal terms (1). Induction of labor is necessary in cases such as post-term pregnancy, pre-eclampsia, severe chronic maternal diseases (kidney, heart diseases), premature rupture of membranes (PROM), and intrauterine fetal death (IUFD) (2). There are several methods for cervical ripening and consequently induction of labor, which are classified into mechanical and pharmacological groups. Oxytocin infusion can be noted as the main pharmacological methods (3). Since last few decades (1955) oxytocin infusion has been used for induction of labor (4). Infusion pump should be used in this method, overdosing may be associated with hypertonic uterine contractions, fetal arrhythmia, and also uterine rupture. Unfortunately, response to oxytocin takes place very slowly in patients who don’t have ripe cervix, and even sometimes this problem results in distocia and CS (5). Therefore new drugs have been investigated in last years. Misoprostol pills (PGE1 or Cytotec) which first were introduced in 1990s to prevent peptic ulcers, used by American obstetricians in 2000 to induce labor (6).

Materials and Methods
The study was conducted on pregnant women admitted to Shahid Mobini Maternal Hospital, Sabzevar, Iran, in 2009 according to inclusion and exclusion criteria. Inclusion criteria were patients who admitted in maternity hospital and needed their pregnancy get terminate or symptoms of delivery. Only primigravida or secondparous were included. Subjects with history of maternal diseases (kidney, heart diseases), premature rupture of membranes (PROM), and intrauterine fetal death (IUFD) were excluded from the study. The effect of this drug to induce labor has been shown in various studies (7, 8). However, their effectiveness and safety are controversial (9).

Obtaining informed consent from participants, the two groups were randomly assigned with the use of the random numbers table. Women in the control group received oxytocin infusion, while the intervention group received 50mcg of misoprostol (a quarter of the 200-mcg Cytotec pill) which was used vaginally in posterior Cul-de-sac of those who were undergoing induction of labor. After induction of
labor with oxytocin and misoprostol in pregnant women, the desired outcome was evaluated in both groups. A midwife who was blind to the research protocol controlled and evaluated data from latent phase (the outcome) and the total labor period. Both groups underwent careful monitoring on uterine contractions and fetal heart rate (FHR) which was conducted by an obstetrician. There were no differences between the two groups in descriptive data. To examine random assignment process, control variables in both groups were evaluated. The average latent and the total labor period for two independent groups were performed by T-student test. The analyses in this study were performed by SPSS software. All tests were two-sided and significance level was considered 0.05.

Results
The average duration of labor in oxytocin group was 17 hours and in misoprostol group was 10 hours (table 1). The average duration of latent phase in pregnant women who received oxytocin and misoprostol was 13 hours and 6 hours, respectively (table 1). Also the average Induction-Delivery phase (I.D) in both misoprostol and oxytocin groups showed a significant difference (P-Value = 0.01). Notably, the CS ratings in two groups who received vaginal misoprostol and oxytocin were 11% and 35%, respectively.

Table 1: Outcome of labor induction (Oxytocin VS Vaginal Misoprostol) in 180 pregnant women in a randomized clinical trial, Sabzevar, Iran

<table>
<thead>
<tr>
<th></th>
<th>Oxytocin</th>
<th>Misoprostol</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of latent phase (hour)</td>
<td>13</td>
<td>6</td>
<td>0.01</td>
</tr>
<tr>
<td>Induction-Delivery phase (hour)</td>
<td>17</td>
<td>10</td>
<td>0.01</td>
</tr>
</tbody>
</table>

*Independent sample T-test

Discussions
This study showed that using misoprostol compared with oxytocin, significantly reduces both the latent phase and the total labor time. Also CS rate is lower in the use of misoprostol compared with oxytocin. Similar studies were conducted to evaluate the efficacy of oxytocin and misoprostol in Iran, but they have used different forms (sublingual, oral) of these drugs.

Eftekhari et al, (2000) in a study during a clinical trial in Iran that was conducted with a sample size of 60 subjects showed that in terms of the duration of the labor, there is no significant statistical difference between the two groups and CS rate is also similar in both groups (12). These findings, which are different from ours, can be due to the small number of samples in each group. However, in a 2012 study in Tehran the findings were similar to ours so that both I.D. Period and CS rate were lower in those who had received misoprostol (13). A systematic review of previous studies has shown that vaginal misoprostol for induction of labor is much more effective than oral misoprostol (14, 15). The findings of a study in 2011 on 200 pregnant women in India also showed that in misoprostol method I.D.Period and CS rate are lower than oxytocin (16). In this study, similar to the present study, misoprostol was used for intervention group. Also in a number of randomized trials in some studies labor time for both groups have been reported as equal (17, 8). Finally, this study is consistent with results of meta-analyses (18-20). It appears if there is a good monitoring in vaginal misoprostol method; it will be a useful technique in terms of economical, maternal and fetal health and also reduction of CS rate. Although in this study fetal Apgar score between two groups didn't show any significant difference, the study team suggests further comprehensive trials by further studies on delivery and neonatal outcomes, examine the impact and effectiveness of these methods to report.

Acknowledgments
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References
1. Little, W.J., On the influence of abnormal parturition, difficult labours, premature birth, and asphyxia neonatorum, on the mental and physical condition of the child, especially in relation to deformities. Trans Obstet Soc Lond, 1862. 3(293): p. 1861-1862