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# Investigation of the Effectiveness of Misoprostol and Foley Catheter Use Alone or Together in Second Trimester Pregnancy Terminations

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## Abstract

**Objective:** To compare the effectiveness of misoprostol only, Foley's catheter only, and combined misoprostol plus Foley's catheter for second-trimester pregnancy terminations.

**Methods:** This retrospective study comprised 146 patients who underwent second-trimester pregnancy termination. Patients were divided into three groups: group 1 (n=62), misoprostol alone; group 2 (n=35), Foley catheter alone; and group 3 (n=49), combined group (Misoprostol plus Foley's catheter). The primary outcome in our study was determined by comparing the induction-abortion interval between methods. Secondary outcomes were termination in the first 24 h, complications including surgical removal of the placenta, and uterine rupture.

**Results:** According to the termination methods, the total termination time of the cases, the duration of hospital stays, and the termination rates in the first 24 h did not show statistically significant differences according to the procedures performed (p>0.05). The doses of misoprostol in nullipara and multiparous cases were statistically significantly higher in those who received misoprostol alone than those who received Foley + Misoprostol (respectively p=0.029; p=0.002). It was found that misoprostol dose was statistically significantly lower in those with a history of cesarean delivery (p=0.004).

**Conclusion:** Although the methods used in second trimester pregnancy terminations are not superior to each other in terms of efficiency, the combined method may be preferred in reducing the side effects associated with misoprostol, including a severe condition such as uterine rupture, in those with a history of cesarean section.

**Keywords:** Cervical ripening, foley catheter, misoprostol, pregnancy termination, second trimester

## INTRODUCTION

Second-trimester termination of pregnancy is a common obstetric procedure that constitutes 10-15% of all terminations (1). Cervical ripening is essential for the smooth termination. Various pharmacological and mechanical methods have been used for cervical ripening (2-5). Misoprostol is one of the most frequently used pharmacological methods in second trimester pregnancy termination because it is safe, effective, and easy to use (2,3,6). Although a dose of 400 mcg every 4-6 h misoprostol is effective in the second trimester pregnancy termination, it lacks safety in women with previous uterine surgery and has a risk of uterine rupture (7). The recommended dose of misoprostol in patients who have undergone uterine surgery is 100 mcg or less to reduce the risk of uterine rupture. However, this reduction in drug dose causes a prolonged induction-expulsion time (8). Foley catheter, which is one of the cervical ripening methods, is cheap, effective, and safe. In addition to its mechanical effect, it also increases prostaglandin release

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by causing separation of membranes, particularly on the cervix (9).

We designed this study to compare the effectiveness, safety, and acceptability of misoprostol only, Foley's catheter only, and combined misoprostol plus Foley's catheter in second trimester pregnancy termination.

## METHODS

In this retrospective study, second trimester pregnancy terminations at the Sakarya University Training and Research Hospital Department of Obstetrics and Gynecology between December 2016 and September 2020 were evaluated. Because the data were collected retrospectively, informed consent was not required. This study was approved by the local ethics committee according to the principles outlined in the Declaration of Helsinki (71522473/050.01.04/562). Inclusion criteria in the study: second-trimester single pregnancy between 14 and 28 weeks of gestation. Patients with a pregnancy less than 14 weeks and greater than 28 weeks, multiple pregnancies, low-lying placenta (lower located placenta) or placenta previa, patients with chorioamnionitis findings, maternal systemic diseases, coagulation disorders, misoprostol, or latex allergy were excluded from the study. One hundred and 46 patients were included in our study. The hospitalization files of these patients between the specified dates were reviewed. The official termination decisions of the cases in our study were confirmed in the registry book of our hospital, where terminations were recorded.

In our study, patients were divided into 3 groups. Group 1 (n=62); misoprostol alone with a standard regimen of moistened misoprostol (400 mcg) 4 h intravaginally was used until abortion, group 2 (n=35); Foley catheter alone, intracervical Foley catheter no. 14-16 Fr inserted, inflated with 30 mL of normal saline and strapped to the thigh and kept in place until it was expelled spontaneously. Group 3 (n=49); Combined group intracervical Foley catheter inserted with a standard regimen of moistened misoprostol (400 mcg) 4 h intravaginally was used.

In both groups, age, gestational age, body mass index (BMI), parity, previous birth history, number of previous cesarean sections, termination indications, methods applied, and results obtained depending on the method values before and after termination and indication for termination were retrieved from medical records.

The primary outcome in our study was determined as the comparison of induction - abortion time between methods. In addition, as secondary outcomes, termination in the first 24 h and complications including surgical removal of the placenta and uterine rupture were analyzed from the medical records.

### Statistical Analysis

The Number Cruncher Statistical System 2007 (Kaysville, Utah, USA) program was used for statistical analysis. Descriptive statistical methods (mean, standard deviation, median, frequency, ratio, minimum, maximum) were used while evaluating the study data. The suitability of quantitative data to normal distribution was tested by Kolmogorov-Smirnov, Shapiro-Wilk test, and graphical evaluations. Student's t-test was used for 2 group comparison of variables showing normal distribution, and Mann-Whitney U test was used for those not showing normal distribution. A one-way ANOVA test was used to compare three or more customarily distributed groups, and the Bonferroni test was used for paired comparisons. The Kruskal-Wallis test was used to compare three or more groups that did not show normal distribution. In comparing qualitative data, the Pearson chi-square test, Fisher's Exact test, and Fisher-Freeman-Halton exact test were used. Significance was assessed at least at the $p<0.05$ level.

## RESULTS

In this study, 146 cases who underwent second trimester pregnancy termination were evaluated. The ages of the patients ranged from 17 to 44 years, with a mean of 30.01±6.39 years. The distribution of demographic and obstetric characteristics of all patients is shown in Table 1. The age, parity, and BMI measurements of the patients did not significantly differ between the groups ($p>0.05$) (Table 1).

A statistically significant difference was found in terms of the gestational weeks of the cases according to the termination methods applied ($p=0.001$; $p<0.01$) (Table 1). According to the paired comparisons made, the gestational weeks of the misoprostol applied cases were significantly lower than those of the Foley and Foley + misoprostol applied cases ($p=0.001$; $p=0.001$; $p<0.01$, respectively). There was no statistically significant difference between the gestational weeks of the Foley and Foley + Misoprostol cases ($p>0.05$). As indicated in Table 1, the termination indications of the cases according to the methods did not show a statistically significant difference ($p>0.05$).

According to the termination methods, the induction to abortion interval of the cases, the duration of hospital stays, and the termination rates in the first 24 h did not show a statistically significant difference according to the procedures performed ($p>0.05$) (Table 2).

**Table 1. Demographic characteristics of the participants**

| | | Misoprostol (n=62) | Foley (n=35) | Foley + misoprostol (n=49) | p value |
|---|---|---|---|---|---|
| **Age (years)** | Min-max (median) | 20-44 (28.5) | 18-43 (30) | 17-43 (31) | [a]0.722 |
| | Mean ± SD | 30.08±6.25 | 30.63±7.01 | 29.49±6.18 | |
| **Body mass index (kg/m²)** | Min-max (median) | 18.6-31.2 (23.4) | 18.6-31.2 (23.4) | 18.6-30.5 (26) | [a]0.129 |
| | Mean ± SD | 23.87±3.89 | 24.35±4.26 | 25.35±3.41 | |
| **Parity** | Nulliparity | 22 (35.5%) | 13 (37.1%) | 12 (24.5%) | [b]0.362 |
| | Multiparity | 40 (64.5%) | 22 (62.9%) | 37 (75.5%) | |
| **Gestational age (weeks)** | Min-max (median) | 14-25 (17) | 14.4-28 (20) | 15-28 (20) | **[a]0.001**** |
| | Mean ± SD | 17.53±2.73 | 20.03±3.37 | 20.19±3.24 | |
| **Previous birth history** | Nulliparous | 22 (35.5%) | 13 (37.1%) | 12 (24.5%) | **[c]0.009**** |
| | History of vaginal delivery | 29 (46.8) | 13 (37.1%) | 13 (26.5%) | |
| | History of cesarean section | 11 (17.7%) | 9 (25.8%) | 24 (49.0%) | |
| **Number of previous cesarean sections** | 0 | 51 (82.2%) | 26 (74.3%) | 25 (51.0%) | **[c]0.004**** |
| | 1 | 7 (11.3%) | 4 (11.4%) | 15 (30.6%) | |
| | 2 | 4 (6.5%) | 2 (5.7%) | 7 (14.3%) | |
| | ≥3 | 0 | 3 (8.6%) | 2 (4.1%) | |
| **Indications for pregnancy termination** | Fetal anomalies | 34 (54.8%) | 25 (71.4%) | 30 (61.2%) | [c]0.609 |
| | Intrauterine fetal demise | 7 (11.3%) | 2 (5.7%) | 7 (14.3%) | |
| | Amnion fluid abnormalities (PPROM. anhydroamnios) | 20 (32.3%) | 7 (20.0%) | 11 (22.4%) | |
| | Others (maternal teratogen exposure) | 1 (1.6%) | 1 (2.9%) | 1 (2.0%) | |

[a]One-way ANOVA test, [b]Pearson chi-square test, [c]Fisher Freeman Halton Exact test, **p<0.01. PPROM: Preterm premature rupture of membranes, SD: Standard deviation

**Table 2. Clinical outcomes of the groups**

| | | Misoprostol (n=62) | Foley (n=35) | Foley + misoprostol (n=49) | p value |
|---|---|---|---|---|---|
| **Induction to abortion interval (hours)** | Min-max (median) | 1.5-76 (12) | 2-75 (13) | 3.5-76 (15) | [d]0.279 |
| | Mean ± standard deviation | 16.1±14.13 | 18.43±14.89 | 19.92±15.57 | |
| **Completed termination in 24 hours** | Yes | 49 (79%) | 27 (77.1%) | 34 (69.4%) | [b]0.484 |
| | No | 13 (21%) | 8 (22.9%) | 15 (30.6%) | |
| **Duration of hospital stay (hours)** | Min-max (median) | 7.5-85 (20) | 9-86 (20) | 8-82 (21.4) | [d]0.322 |
| | Mean ± standard deviation | 23.47±14.24 | 25.02±15.56 | 26.85±15.4 | |
| **Fever** | Yes | 1 (1.6%) | 0 | 4 (8.2%) | [c]0.130 |
| | No | 61 (98.4%) | 35 (100%) | 45 (91.8%) | |
| **Tachycardia** | Yes | 7 (11.3%) | 2 (5.7%) | 5 (10.2%) | [c]0.718 |
| | No | 55 (88.7%) | 33 (94.3%) | 44 (89.8%) | |
| **Bleeding** | Yes | 4 (6.5%) | 0 | 2 (4.1%) | [c]0.382 |
| | No | 58 (93.5%) | 35 (100%) | 47 (95.9%) | |
| **Surgical removal of the placenta** | Yes | 8 (12.9%) | 3 (8.6%) | 3 (6.1%) | [c]0.486 |
| | No | 54(87.1%) | 32 (91.4%) | 46 (93.9%) | |
| **Blood transfusion** | Yes | 1 (1.6%) | 0 | 2 (4.1%) | [c]0.602 |
| | No | 61 (98.4%) | 35 (100%) | 47 (95.9%) | |
| **Uterine rupture** | | 0 | 0 | 0 | |

[b]Pearson chi-square test, [c]Fisher Freeman Halton Exact test, [d]Kruskal-Wallis test

In terms of the induction to abortion interval, it was found that there was no statistically significant difference between the methods when nulliparous, multiparous, those with a history of vaginal delivery, and those with a history of cesarean section were evaluated among themselves, and these groups were compared with each other.

According to the methods, the rates of fever, tachycardia, bleeding, curettage (surgical removal of the placenta), and need for blood transfusion did not show statistically significant differences (p>0.05) (Table 2). Uterine rupture was not observed in any case (Table 2). The doses of misoprostol in nulliparous and multiparous cases were significantly higher in those who received misoprostol alone than those who received Foley + Misoprostol (respectively p=0.029; p=0.002) (Table 3). The misoprostol dose was statistically significantly lower in those with a history of cesarean delivery (p=0.004) (Table 4). The induction to abortion interval did not differ statistically significantly according to the methods in those with a cesarean delivery history (p>0.05) (Table 5).

## DISCUSSION

Misoprostol is a widely used pharmacological agent that stimulates uterine contractility and cervical ripening (10). Despite this frequent usage, there is no consensus on the administration route and interval. Uterine rupture is a life-threatening complication of misoprostol administration for second-trimester pregnancy termination, and it can occur with a scarred and unscarred uterus (11). Ho et al. (12) stated that care should be taken when using misoprostol because of the increased uterine sensitivity to prostaglandins and the risk of uterine rupture as the gestational week progresses, and it would be wise to have a lower dose of misoprostol and less frequency of administration in advanced weeks of gestation. However, no rupture was reported in a study conducted by Dickinson (13) in 720 women with one or more previous cesarean section histories in which pregnancies between 14 and 28 weeks were terminated with misoprostol. In our study, in accordance with the literature, no rupture was found in all patient groups, including nulliparous, multiparous, and those with a previous cesarean section history.

**Table 3. Evaluation of misoprostol dose according to parity and previous delivery history when used alone or in combination**

| Parity/previous delivery history | Dose of misoprostol (mcg) | Misoprostol | Foley + misoprostol | p value |
|---|---|---|---|---|
| **Nulliparous** | N | 22 | 12 | [c]**0.029*** |
| | Min-max (median) | 200-3,200 (1,000) | 200-3,200 (400) | |
| | Mean ± SD | 1236.36±834.12 | 783.33±811.10 | |
| **Multiparous** | N | 40 | 37 | [c]**0.002**** |
| | Min-max (median) | 200-2,800 (1,000) | 50-3,200 (600) | |
| | Mean ± SD | 1,115±624.10 | 744.59±679.03 | |
| **History of vaginal delivery** | N | 29 | 13 | [c]0.174 |
| | Min-max (median) | 400-2,800 (1,200) | 200-3,000 (600) | |
| | Mean ± SD | 1165.52±611.95 | 1053.85±959.70 | |
| **History of cesarean section** | N | 11 | 24 | [c]0.080 |
| | Min-max (median) | 200-2,400 (1,000) | 50-1,400 (400) | |
| | Mean ± SD | 981.82±666.06 | 577.08±397.27 | |

[c]Mann-Whitney U test, *p<0.05, **p<0,01, SD: Standard deviation

**Table 4. Comparison of misoprostol dose by parity and previous cesarean delivery history**

| Dose of misoprostol (mcg) | | | | | |
|---|---|---|---|---|---|
| | **N** | **Mean ± standard deviation** | **Min-max** | **Median** | **p value** |
| Nulliparous | 34 | 1076.47±842.82 | 200-3,200 | 800 | [c]0.563 |
| Multiparous | 77 | 937.01±673.04 | 50-3,000 | 800 | |
| Patients with no prior cesarean section | 76 | 1106.57±775.85 | 200-3,200 | 1,000 | [c]**0.004**** |
| Patients with prior cesarean section | 35 | 704.29±523.05 | 50-2,400 | 600 | |

[c]Mann-Whitney U test, **p<0.01, min: Minimum, max: Maximum

| Table 5. Comparison of methods in those with previous cesarean delivery history | | | | | |
|---|---|---|---|---|---|
| | | Misoprostol (n=11) | Foley (n=9) | Foley + Misoprostol (n=24) | p value |
| Induction to termination interval (hours) | Min-max (median) | 2-51.5 (13.4) | 2-75 (16.5) | 3.5-76 (13.7) | [d]0.878 |
| | Mean ± SD | 18.3±14.33 | 23.22±22.94 | 18.05±15.29 | |
| [d]Kruskal-Wallis test, SD: Standard deviation, min: Minimum, max: Maximum | | | | | |

Foley catheter is a mechanical method commonly used in labor induction. Few side effects, simple applicability, and cost-effectiveness are the factors that make this method attractive. Although there are studies on using Foley catheters in labor induction in third-trimester pregnancies, data on its use in second-trimester pregnancy termination are limited (14-16). Rab et al. (17) compared the Foley catheter and double-balloon catheter in patients with a previous cesarean section history of 20 weeks and whose pregnancy was planned to be terminated due to fetal death and found that the time from balloon placement to delivery was shorter in the Foley catheter group. In our study, in which only 14-28 weeks of gestation were examined, the mean induction to abortion interval was 23.22±22.94 hours in the Foley catheter group in 44 patients with a history of cesarean section during these weeks. This difference can be explained by the fact that the patient group in our study was at lower gestational weeks, and consequently, cervical maturity was lower. In a study by Demirezen et al. (18) comparing foley catheter and double-balloon catheter in 91 pregnant women scheduled for termination between 14 and 28 weeks of gestation, the time between induction and delivery was shorter in the foley catheter group. In our study, it is noteworthy that the induction to abortion interval and the duration of hospital stay were shorter from this study.

In a study investigating the effectiveness of Foley catheter traction in mid-trimester delayed abortions, termination occurred in a shorter time in the traction group than in the non-traction group (19). In this study, the mean week of gestation was lower than that in our study, and more patients were evaluated. Based on the time between induction and termination as the method's success, the termination time in this study was similar to that in our study (19).

Toptas et al. (20) involving 91 patients between 13 and 26 weeks of gestation, only misoprostol was used in one group and misoprostol and Foley were used in the other group, and they showed that the combined method did not provide an additional benefit in terms of efficacy, similar to our study. In the study conducted by Rezk et al. (21), which excluded pregnant women with a history of uterine scarring, unlike our study, the time between induction and abortion was shorter in the combined group than in the other groups.

Ercan et al. (14) stated that combining misoprostol and Foley in second-trimester pregnancy terminations resulted in shorter induction termination intervals and less need for misoprostol compared with misoprostol alone, especially in women with 2 or more cesarean sections with high rupture risk. El Sharkwy et al. (15) compared the use of low-dose misoprostol alone with misoprostol and Foley catheter in late second-trimester pregnancy terminations in patients with a previous history of multiple cesarean sections. They found that the combined method had a shorter induction-termination time and required less misoprostol (15). In our study, we found that the dose of misoprostol was lower with combined use. However, this method shortened the induction to abortion interval only in the cesarean section group compared with misoprostol alone although it was not statistically significant. The combined methods can be used in women with a history of cesarean section to reduce the risk of severe conditions such as uterine rupture and the side effects associated with misoprostol. In addition, in our study, although the combined method was not statistically significant in the group with a history of cesarean section, it was found that it was associated with less dose requirement and shorter induction to abortion interval.

### Study Limitations

The limitations of our study are that it is a retrospective study and Bishop scores were not recorded.

## CONCLUSION

Although the methods used in second trimester pregnancy terminations are not superior to each other in terms of efficiency, the combined method may be preferred in reducing the side effects associated with misoprostol, including a severe condition such as uterine rupture, in those with a history of cesarean section. Further prospective studies are required to verify these results.

### Ethics

**Ethics Committee Approval:** This study was approved by the local ethics committee according to the principles outlined in the Declaration of Helsinki (71522473/050.01.04/562).

**Peer-review:** Externally peer-reviewed.

### Authorship Contributions

Concept: Ş.K., S.Ö., Design: Ş.K., S.Ö., Data Collection or Processing: Ş.K., O.K., K.G., Analysis or Interpretation: Ş.K., O.K., K.G., Literature Search: Ş.K., O.K., K.G., M.S.B, S.Ö. Writing: Ş.K., K.G., M.S.B., S.Ö.

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