Efficacy of second-trimester termination procedure; medical, mechanic, or combine?

TUNCAY YÜCE*, DILEK YÜKSEL, ERKAN KALAFAT, ACAR KOÇ

Faculty of Medicine, Department of Obstetrics and Gynecology, Ankara University, Ankara, Turkey

*Corresponding author: Tuncay Yüce; Ankara Universitesi Tıp Fakültesi, Cebeci Hastanesi Kadın Hastahâlari ve Doğum AD, Mamak, Ankara 06590, Turkey; Phone: +90 505 594 35 21; Fax: +90 312 320 35 53; E-mail: drtuncayyuce@gmail.com

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Abstract: Objectives: During mid-trimester, it is necessary to terminate pregnancy due to some fetal anomalies and intrauterine death. Therefore, in this study, we aimed to compare abortion induction methods and combined use retrospectively. Methods: About 112 out of 223 pregnant patients were included in the study. The groups were determined as follows: Group 1 including pregnant patients who were administered misoprostol only (50 patients), Group 2 including pregnant patients who were administered single dose misoprostol (according to FIGO) and subsequently received cervical Foley catheter (30 patients), and Group 3 including pregnant patients who received Foley catheter only (32 patients). These three groups were compared in terms of effectiveness of the method, side effects, and complications as well as their characteristics. Results: In terms of characteristic of the groups, the average age of the women in the Group 1 was significantly higher than other two groups \((p < 0.001)\). In terms of effectiveness of the method, the termination period in Groups 1 and 2 was significantly lower than Group 3 \((p < 0.001)\). However, in terms of complications, it was observed that uterine rupture was developed in Group 1. Conclusions: Although medical methods may seem to be more effective in the process of termination, mechanical methods seem more reliable in terms of reliability. Especially combined methods can be used to increase effectiveness and also to reduce complications.

Keywords: second trimester, misoprostol, Foley catheter, termination, complications

Introduction

Mid-trimester is defined as the period between 14th and 28th weeks of pregnancy. During this period, screenings for fetal anomalies are intensively performed and if fetal anomalies that are incompatible with life are detected, the family is suggested that pregnancy may be terminated. In addition, in 1%—5% of pregnancies, it is necessary to terminate pregnancy because of discontinuation of fetal heart rate. Termination process begins with patients who agree to undergo the process [1]. In termination process, the most important factor is the method to be used. The methods used can be divided into two groups. The first group is surgical methods. Most commonly, dilatation curettage is used. Since surgical methods may result in morbidities, such as infection, uterine rupture, and intrauterine adhesion, less invasive medical methods, as a second method, are preferred [2].

One of the most important parameters in evacuation process is cervical bishop score. It is suggested to use methods enabling cervical ripening [3]. While mechanical methods used for cervical ripening (Foley catheter; laminaria) dilate cervix, pharmacological methods (hormonal methods; prostaglandins) provide cervical opening by softening connective tissue, providing cervical effacement, and increasing uterine activity. Foley catheter in mechanical methods and prostaglandins in pharmacological methods are the most commonly used agents in obstetrics [4]. About 94% success was obtained in the studies performed with Foley catheter [5]. Low cost, simple use, and fewer side effects are important. Beside its mechanical effect, it also increases prostaglandin release by causing separation of membranes particularly on the cervix [6]. Misoprostol use, one of the medical methods, is suggested in terms of high efficiency, low cost, and ease of use [7]. Side effects such as nausea, vomiting, intestinal cramps, and

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diarrhea can be observed in the patients, although the severity changes depending on the way of usage. High fever can be seen in 5%–10% of the patients [7].

In the meta-analysis compiling previous studies, no difference was observed between the use of Foley catheter and the use of prostaglandin in terms of risk of cesarean delivery [8].

In the declaration of ACOG in 2013, it was reported that dilatation and curettage require more advanced cervical dilation and it may take time and decompression of fetal calvaria is required in this procedure. It was reported that second-trimester pregnancy termination with medical abortion or medical induction methods can be carried out more reliably and these methods are preferred by several clinicians. As modern medical abortion methods, prostaglandin analogs, mifepristone, osmotic cervical dilators, Foley catheter, oxytocin, or a combination of these can be utilized. It is considered that use of misoprostol alone or in combination with other agents can be preferred in terms of high efficiency, low cost, and ease of use [7].

Despite all the studies already conducted, it has been still searched for a method with the least complications, side effects, and the highest efficiency. Therefore, in this study, we compared the results of pregnant patients who used Foley catheter in addition to misoprostol and patients who used only misoprostol and only Foley catheter.

Materials and Methods

Pregnant patients in 14–24 weeks whose pregnancies were terminated in our hospital between the years 2011 and 2014 were included in the study (as the rare case was terminated due to fetal anomaly between 24 and 28 weeks, patients who were at this interval were excluded from the study). During this period, a total of 223 second-trimester termination was performed. Only 112 pregnant patients whose data we could access were included in the study; among them, 50 patients were administered misoprostol only (Group 1), 30 patients were administered single dose of misoprostol and then received cervical Foley catheter (Group 2), and 32 patients received Foley catheter only (Group 3). Group 1 consisted of patients whose dosage was determined and repeated, as suggested by FIGO, according to gestational week, fetal viability, and past operations [9]. Group 2 consisted of patients who were administered single dose, as determined by FIGO, without administering a second dose and then a Foley catheter was placed [9]. Group 3, on the other hand, consisted of patients who received cervical Foley catheter only. Therefore, in this study, we compared the results of pregnant patients who used Foley catheter in addition to misoprostol with the results of patients who used misoprostol only and Foley catheter only.

All patients in three groups were compared in terms of maternal age, gestational week, past operations, gravidity, parity, maternal body mass index (BMI), termination period, fetal viability, and hemoglobin levels.

All the patients were provided ampicillin (1 g/6 h) treatment after the operation. Patients were evaluated every 4 h after the beginning of the procedure in terms of vital findings, cervical dilation, drug side effects, nausea, vomiting, fever, and infection. Symptoms such as nausea, vomiting, diarrhea, and fever that might be associated with misoprostol were recorded.

Ankara University Faculty of Medicine Ethical Committee approval was obtained for this study (Decision no: 08-348-14; Date: May 12, 2014).

Statistical analyses

Analyses of all groups were performed with analysis of variance test for parameters with normal distribution and with Kruskal–Wallis test for parameters with non-normal distribution. Categorical parameters were compared with χ² test. The groups were compared with t test for parameters with normal distribution and with Mann–Whitney U test for parameters with non-normal distribution. The p values below 0.05 were considered statistically significant.

Results

In this study, demographic characteristics of the patients were compared between the groups in terms of age, weight, height, BMI, gravidity, parity, gestational week, and number of previous cesarean section. In Group 1, age was significantly higher. No significant difference was observed in other parameters. Maximum five and minimum one single dose were used for the patients in Group 1. While no difference was observed in terms of side effects in three groups (p > 0.05), fever was observed in five patients (10%) in Group 1. In terms of serious complications, uterine rupture was observed in two patients in misoprostol group (patients with previous cesarean section of 20 and 24 weeks). When hemoglobin values were compared before and after termination, no significant differences was observed in three groups in terms of preoperative and postoperative hemoglobin values (p = 0.435). Considering termination periods, no difference was observed between Groups 1 and 2, but application period was longer than others in Group 3 (p < 0.05) (Table I). While there was no need for supplementary oxytocin need in Group 1, 18 patients (60%) in Group 2, and 13 patients (40.6%) in Group 3 were in need of oxytocin.
Table 1  Comparison of the results of three groups

|                          | Misoprostol  | Single dose misoprostol | Foley catheter | p value |
|--------------------------|--------------|-------------------------|----------------|---------|
| Age (mean ± SD)          | 32.94 ± 4.78 | 27.96 ± 7.3             | 27.6 ± 7.2     | <0.001  |
| Live fetus (%)           | 60.0         | 81.8                    | 66.7           | NS      |
| Gravity (median ± max–min)| 2 (1–4)     | 2 (1–4)                 | 2 (1–4)        | NS      |
| Parity (median ± max–min)| 0 (0–2)      | 1 (0–2)                 | 1 (0–2)        | NS      |
| Number of previous cesarean section (mean ± SD) | 0.4 ± 0.68 | 0.73 ± 0.9              | 0.42 ± 0.51    | NS      |
| Gestational age (day ± SD) | 139.3 ± 28.2 | 130.5 ± 29.9            | 149.8 ± 22.9   | 0.023   |
| BMI (mean ± SD)          | 26.75 ± 5.55 | 25.4 ± 2.83             | 25.79 ± 4.02   | NS      |
| Preoperative hemoglobin (mean ± SD) | 11.6 ± 1.44 | 12.5 ± 1.06            | 11.49 ± 1.41   | 0.005   |
| Postoperative hemoglobin (mean ± SD) | 11.2 ± 1.41 | 12.1 ± 0.91            | 11.3 ± 1.02    | 0.004   |
| Duration of termination (min) (mean ± SD) | 794.3 ± 553  | 1,184.3 ± 581            | 1,286 ± 426.8  | <0.001  |

SD: standard deviation; BMI: body mass index. *p < 0.05 is significant

Discussion

Mortality and morbidity rates of termination of second-trimester pregnancy are 3–5 times higher than the first trimester [10]. This situation is closely related to the chosen termination methods. In studies comparing techniques used in termination, it is particularly focused on the importance of cervix. However, an ideal method in cervical ripening has not yet been identified [11]. In determining a method, we will use after we make a decision for evacuation; gestational week, parity of the patient, maternal health status, previous obstetric history, maternal preference, and condition of the cervix are important. In addition, cost of the method, which is used, its easy accessibility, as well as its influence time on the cervix are important parameters. Mechanical methods have gained popularity as they are less expensive, easy to use, and do not have systemic side effects. Termination process is a painful process for the patient. For this reason, the agent used is expected to finalize termination process in a short time. Yet, mechanical methods have disadvantages in terms of termination period [12]. Similarly, termination period of mechanical applications has also been longer in this study. There are studies suggesting that mechanical applications should be combined with medical methods in order to shorten this period [13, 14]. We observed also in this study that combined method shortened this period. Absence of side effects and complications that are seen especially in the use of misoprostol is another advantage of this combined method.

When repeated dose of misoprostol use was compared to single dose of misoprostol use plus Foley catheter, it can be said that dose repetition did not provide a significant effect in terms of efficiency and time, but it may be risky in terms of complications. It is a supportive finding that another study did not report a statistically significant difference between 200 and 400 mcg misoprostol uses [15]. However, in the mentioned study, it was reported that parity of the patients and previous cesarean story might have been effective for that [15]. In this study, no difference was found in terms of these factors.

In terms of serious complications, uterine rupture developed only in 2 of 112 patients. This complication was seen in a patient with 20 and 24 weeks of multiple fetal anomalies and administered repeated dose of misoprostol (four doses and with a previous cesarean story). No serious complication was observed in the group, which was administered single dose of misoprostol plus Foley catheter and Foley catheter.

There are studies suggesting that repeated dose of misoprostol use is not reliable in termination of pregnancy, but there are also studies contrarily reporting that misoprostol use may be reliable in pregnant patients with cesarian history [16]. As a result, in our retrospective study, negative results were observed that repeated dose of misoprostol use was more risky in terms of side effects and complications, and mechanical termination where only Foley catheter was used took more time. It was revealed that the method where single dose misoprostol combination with Foley catheter was used might be a more reliable and usable method due to shorter times and non-appearance of complications.

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