International Journal of Gynecology and Obstetrics 135 (2016) 154–157

Contents lists available at ScienceDirect

International Journal of Gynecology and Obstetrics

journal homepage: www.elsevier.com/locate/ijgo

CLINICAL ARTICLE

Physical symptoms and emotional responses among women undergoing induced abortion protocols during the second trimester

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ARTICLE INFO

Article history:
Received 13 February 2016
Received in revised form 15 May 2016
Accepted 25 July 2016

Keywords:
Emotions
Induced abortion
Mifepristone
Misoprostol
Oxytocin
Second trimester

ABSTRACT

Objective: To compare the physical and emotional effects of two medical protocols for induced abortion during the second trimester. *Methods:* The present study was part of a prospective randomized controlled trial comparing mifepristone followed by oxytocin or misoprostol that was conducted at the Hadassah Hebrew University Medical Center, Jerusalem, Israel, from January 10, 2009, to February 22, 2012. Inclusion criteria were pregnancy (14–24 weeks), epidural analgesia, and medical induction of abortion (either elective or following missed abortion). A structured questionnaire was used to assess the participants' physical symptoms and emotional responses. The primary outcome for the present analysis was the degree of physical symptoms reported. *Results:* Overall, 68 women in the oxytocin group and 67 in the misoprostol group received epidural analgesia and completed the questionnaire. As assessed using a five-point Likert scale, women in the misoprostol group were more likely than those in the oxytocin group to experience diarrhea (1.34 ± 0.84 vs 1.10 ± 0.55; $P = 0.05$) and shivers (3.03 ± 1.75 vs 1.75 ± 1.21; $P < 0.001$). No other between-group differences were detected for the physical or emotional variables evaluated. *Conclusion:* Differences in physical symptoms experienced by the two treatment groups did not influence the participants' subsequent emotional response.
ClinicalTrials.gov: NCT00784797

1. Introduction

Medically induced abortion during the second trimester of pregnancy (14–24 weeks) promotes expulsion of the fetus [1]. The main indications for this procedure are late missed abortion and elective abortions owing to fetal conditions such as chromosomal and structural abnormalities. Other indications include concerns about the mother's physical and emotional well-being [2,3]. Late missed abortions affect approximately 0.3%–5.0% of all pregnancies [4]. Furthermore, approximately 42 million elective abortions are performed worldwide each year [5].

Induced abortion can trigger a mix of physical and psychological distress [6–8]. At the time of the procedure, women might experience physical symptoms, including discomfort, pain, treatment-related adverse effects, and bleeding [8,9]. Emotional distress reflects the negative feelings of grief and sadness associated with fetal loss; however, most women tend to overcome these feelings and do not experience any long-term mental health problems [6].

One way to help women to overcome the emotional difficulties associated with induced abortion is to provide women with positive emotional support throughout the procedure. This approach has proven to boost self-efficacy and improve emotional state [3,10]. From a physical standpoint, highly stressful medical interventions can potentially cause poor long-term emotional health outcomes [11,12]. Nevertheless, whether minimizing the physical effects of the medical regimens can enhance emotional coping strategies and help to improve mental outcomes remains unclear.

Over the past 30 years, various drugs have been introduced to both improve the efficacy of induced abortion during the second trimester and decrease treatment-related complication rates. The most widely used medical regimen comprises mifepristone followed by a prostaglandin [1,13]. When administered alone, prostaglandins (e.g. misoprostol, a synthetic prostaglandin E_1) cause cervical ripening and stimulation of uterine contractions [1], but their efficacy for abortion is increased when they are given after treatment with the progesterone antagonist mifepristone [14]. However, approximately 30% of patients given prostaglandins experience adverse effects—including shivers, fever, nausea, vomiting, and diarrhea [15]. Consequently, an alternative method

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http://dx.doi.org/10.1016/j.ijgo.2016.05.008
0020-7292/

to induce second-trimester abortion was devised that comprised mifepristone followed by a high dose of intravenous oxytocin [16]. This combination has fewer adverse effects than does mifepristone plus misoprostol—a prostaglandin regimen that is considered to be most widely used—but requires a longer duration of treatment [17].

Several studies have investigated the combination of mifepristone with oxytocin or misoprostol. Some data collected as part of these studies could be used to assess physical and emotional symptoms associated with second-trimester induced abortion. Therefore, the aim of the present study was to use data from a randomized controlled trial [17] to evaluate women's physical symptoms during second-trimester abortion and their subsequent emotional responses. The hypothesis was that women who experienced fewer negative physical symptoms during the abortion would also report less emotional distress and have more positive feelings toward the treatment method.

2. Materials and methods

The present study was part of a prospective randomized controlled trial conducted in the Obstetrics and Gynecology ward of Hadassah-Hebrew University Ein Kerem Medical Center, Jerusalem, Israel, from January 10, 2009, to February 22, 2012. Full methods of the trial have been reported elsewhere [17]. Briefly, healthy women aged 18–50 years undergoing induced abortion at 14–24 weeks of pregnancy were eligible for inclusion. The procedure could be either elective or necessary owing to missed abortion. Exclusion criteria were spontaneous abortion before randomization, more than one previous cesarean delivery, preterm premature rupture of membranes, and contraindications to study drugs. All procedures were approved by the local Legal Abortion Committee. The trial was approved by the local ethics committee of the Hadassah Medical Organization and registered at www.ClinicalTrials.gov (NCT00784797). All women who agreed to participate signed an informed consent form.

Eligible participants were recruited by medical staff and received detailed oral patient education from a qualified medical professional regarding the treatment protocols. Each participant then chose a sealed envelope from a shuffled pile for randomization into one of the two treatment groups (oxytocin or misoprostol). The envelopes were pre-prepared, and the staff members who offered the envelopes to the participants to choose were unaware of their contents. Participants, investigators, and data analysts were not masked to assignment after the selected envelopes had been opened.

All participants received 200 mg oral mifepristone followed by uterine uterotonic medication administered 36–48 hours later. Before the uterotonic drug was given to the patient, a constant flow of epidural analgesia was established using a patient-controlled analgesia pump. Patients could also press a button attached to the patient-controlled analgesia device to receive additional doses. Women assigned to the oxytocin group received a high concentration of oxytocin administered intravenously via a drip: patients received 50 mIU/min for 20 minutes, 100 mIU/min for the next 20 minutes, and then 150 mIU/min from 40 minutes to a maximum of 36 hours. Those in the misoprostol group received 800 μg vaginal misoprostol followed by 400 μg oral misoprostol every 3 hours for a maximum of four doses, as previously described [17]. Reasons for discontinuing treatment were no response to the treatment protocol within 36 hours of using the uterotonic agent or severe adverse effects. All women underwent the procedure in a private room and were accompanied by a family member or their partner.

Demographic data, reason for abortion, vital signs, and duration of the procedure were recorded by the medical staff. Hemoglobin levels (as a surrogate for blood loss) were assessed on the basis of a complete blood count performed within 24 hours of the procedure. If women recovered quickly and were discharged early, they did not undergo a complete blood count. Rates of successful abortion and time to fetal expulsion were recorded as endpoints of the overall trial.

The present analysis used data obtained via a questionnaire completed within 24 hours of the abortion. This questionnaire collected information on physical symptoms, emotional responses, and feelings about the procedure and the method used. The questionnaire was tested on 15 women before use. The reliability of the questionnaire was validated using the Cronbach α test ($\alpha = 0.85$). The questions were designed to obtain information about the levels of adverse effects, abdominal pain, back pain, and other physical symptoms experienced during the procedure, as well as any negative emotional responses experienced during the procedure, the highest level of pain experienced during the procedure, and the degree of satisfaction with the medication and treatment duration.

The women were asked to rate their physical symptoms and emotional responses on a five-point Likert scale, which ranged from 1 (none) to 5 (extreme). Feelings regarding fulfillment of expectations about the length of treatment were also presented on a scale ranging from 1 (much shorter than expected) to 5 (much longer than expected). Satisfaction with the medical treatment was scored from 1 (much easier than expected) to 5 (much harder than expected). Pain was measured using a 10-point visual analogue scale, which ranged from 0 (no pain) to 10 (unbearable pain).

The primary outcome for the present analysis was the degree of physical symptoms, including adverse effects, pain, bleeding, and physical discomfort. Secondary outcomes included emotional responses such as mental stress and expectations about the duration of treatment and the level of satisfaction with the procedure.

The data were analyzed per protocol using SPSS/PC + version 19 (IBM, Armonk, NY, USA). Women who did not receive epidural analgesia before proceeding to the uterotonic medications, either by choice or because of contraindications, and those who did not complete the questionnaire were excluded from analyses. Descriptive data were described as mean and standard deviation. The association between two categorical variables was described by the χ^2 test. An independent two-sample t test was used to compare quantitative variables. $P < 0.05$ was considered statistically significant.

3. Results

Overall, 68 women in the oxytocin group and 67 in the misoprostol group completed the questionnaire and were included in the analysis (Fig. 1). Demographic characteristics are presented in Table 1.

Table 2 outlines the physical symptoms experienced during induced abortion. Results indicated moderate levels of pain, irrespective of the treatment group ($P = 0.16$). Levels of other negative physical symptoms (back pain, abdominal pain, and physical discomfort) were rated as high in both groups. By contrast, women in the misoprostol group were more likely than those in the oxytocin group to experience diarrhea ($P = 0.05$) and shivers ($P < 0.001$).

No between-group differences were found for objective and subjective amounts of vaginal bleeding. A total blood count test was performed among 66 women in the oxytocin group and 63 in the misoprostol group. Most women who underwent a total blood count test experienced decreases in their hemoglobin levels of 0–20 g/L; one woman in each treatment group required a blood transfusion (Table 3). No statistically different between-group differences were detected regarding the participants' subjective feelings about the intensity of bleeding during the procedure.

Emotional responses to the procedure are shown in Table 4. No differences were found between the two treatment groups for either emotional feelings or satisfaction with the procedure.

4. Discussion

The present study found that women who were treated with misoprostol reported experiencing diarrhea and shivers more frequently than did women treated with oxytocin. Although the duration of