Contraception 91 (2015) 406–411

Contraception

Original research article

Laminaria vs. vaginal misoprostol for cervical preparation before second-trimester surgical abortion: a randomized clinical trial☆,☆☆

Ron Sagiv*, Yossi Mizrachi*, Hagit Glickman, Ram Kerner, Ran Keidar, Jacob Bar, Abraham Golan

Department of Obstetrics and Gynecology, E. Wolfson Medical Center, Holon, Israel
Sackler Faculty of Medicine, Tel-Aviv University, Tel-Aviv, Israel

Received 7 October 2014; revised 27 January 2015; accepted 27 January 2015

Abstract

Objective: To compare the efficacy and tolerability of vaginal misoprostol and laminaria for cervical preparation before second-trimester surgical abortion.
Study design: We performed a prospective, randomized trial comparing midnight administration of misoprostol 600 mcg vaginally to midnight placement of laminaria, before surgical abortions among women at 13–20 weeks of gestation. The primary outcome was preoperative cervical dilation. Secondary outcomes were the need for further dilation, procedure duration and difficulty, immediate complications and side effects.
Results: Eighty-four women were randomized, with a median gestational age of 16.5 weeks. The mean time interval between misoprostol and laminaria placement and dilatation and evacuation initiation was 11.0±2.9 and 11.2±2.0 h, respectively (p=.17). Cervical dilation was not greater in the laminaria group as compared to the misoprostol group (12.8 vs. 12.4 mm, respectively; p=.32). No difference was demonstrated regarding the need for additional dilation or the difficulty of the procedure. Procedures performed after laminaria insertion were 1 min longer (median 11 vs. 10 min, p=.04). Participants found laminaria placement more uncomfortable than vaginal misoprostol placement. Other than pain, additional side effects occurred only in the misoprostol group, primarily nausea and vomiting. One participant in the misoprostol group experienced fetal expulsion during the night before the intended procedure.
Conclusion: Either vaginal misoprostol or laminaria provides adequate dilation for second-trimester surgical abortion. Laminaria causes more pain at insertion and misoprostol causes more side effects.
Implications statement: We found that cervical preparation in an inpatient setting for approximately 11 h with misoprostol 600 mcg vaginally is comparable to 11 h of laminaria. However, given the potential for spontaneous expulsion and more side effects with misoprostol, laminaria is likely a better general option in such a setting.

Keywords: Cervical preparation; Misoprostol; Laminaria; Surgical abortion

1. Introduction

Dilatation and evacuation (D&E) is the most common mode of second-trimester elective abortion in the United States [1]. Cervical preparation before D&E is essential to minimize complications such as cervical trauma, uterine perforation and excessive bleeding [2–6]. The cervix may be prepared with pharmacological agents such as misoprostol, or with mechanical agents such as laminaria. Vaginal, oral or buccal administration of misoprostol has proven successful for cervical preparation in first- and second-trimester surgical abortion. Overall, vaginal administration results in more consistent absorption and better cervical dilation than oral administration [7–12].

Several studies compared the efficacy of misoprostol and osmotic dilators for cervical preparation prior to second-trimester D&E. A previous randomized trial [13] compared the administration of same-day 400 mcg vaginal misoprostol to overnight laminaria before early second-trimester surgical

☆ Financial disclosure: No potential conflicts of interest for any of the authors.
☆☆ Clinical trial registration: http://clinicaltrials.gov/show/NCT01678703.
* Corresponding authors. Department of Gynecology & Obstetrics, E. Wolfson Medical Center, 62 Halochamim Street, Holon 58100, Israel. Tel.: +972 3 502 8329; fax: +972 3 502 8503.
E-mail address: sagivr@wolfson.health.gov.il (R. Sagiv).

http://dx.doi.org/10.1016/j.contraception.2015.01.018
0010-7824/

abortion. Participants who underwent preparation with laminaria were found to have greater dilatation at the time of the procedure. Moreover, procedures took longer and were technically more challenging after cervical preparation with same-day misoprostol. A second randomized trial [14] compared the efficacy of same-day 400 mcg buccal misoprostol to laminaria inserted the day before D&E among women at 13–19 weeks of gestation. Both regimens were found to have similar low rates of adverse effects. Misoprostol participants were more likely to require additional mechanical dilation.

A Chocrane Database Systemic Review [15] assessed all available randomized trials of cervical preparation prior to second trimester D&E. Cervical preparation with osmotic dilators and/or misoprostol was found to be safe and effective. Osmotic dilators appeared to provide superior cervical dilation; however, this difference in cervical dilation did not appear to result in differences in procedure time or complication rates.

The Society of Family Planning (SFP) [16] states that the use of misoprostol as an alternative to osmotic tents increases the risk of inadequate cervical dilation. It recommends that only experienced providers capable of managing difficult cervical dilation should use protocols omitting osmotic tent placement prior to D&E. However, the SFP examined only studies that used a short same-day regimen of misoprostol.

Our objective was to compare extended administration of 600 mcg vaginal misoprostol with placement of laminaria for cervical preparation before second-trimester surgical abortion.

2. Materials and methods

We performed a prospective, unblinded, randomized (1:1) study in 84 patients who underwent D&E for termination of pregnancy at 13–20 weeks of gestation. The study was performed from January 2008 to January 2011 at the Edith Wolfson Hospital in Holon, Israel. The study protocol was approved by the institutional review board.

Patients were referred to have surgical termination of pregnancy, and these were performed according to Israeli law after approval from a pregnancy termination committee. Eligible participants were all at least 15 years old and in good general health. Gestational age was confirmed by first-trimester ultrasound examination. Exclusion criteria were allergy to misoprostol, fetal demise, bleeding disorder, current anticoagulation therapy, previous loop electrosurgical excision procedure or conization procedure, multiple gestation and breast-feeding. Patients with previous cesarean scar were not excluded.

All participants were hospitalized the day before the procedure. Subjects were randomly assigned to cervical preparation with either misoprostol or laminaria. Randomization was performed using a computer-generated list of random numbers by a researcher not involved in subject recruitment or care. Treatment allocation was concealed by placing assignments in sequentially numbered opaque envelopes. After providing a written informed consent, a research assistant opened the envelope and notified the physician performing the subject's preoperative evaluation of treatment assignment.

Participants randomized for laminaria had them placed at midnight before the procedure. The vagina was cleansed with aqueous Betadine® solution. The direction of the cervix was noted, and one to six laminaria tents were placed within the cervical canal using a tenaculum applied to the cervix. The number of laminaria tents was determined by the clinician. Paracervical anesthesia was not performed. Participants assigned for misoprostol had three 200-mcg tablets (a 600-mcg dose) administered vaginally to the posterior fornix at midnight. Subjects who had vaginal bleeding or expulsion of the fetus during the night before the intended procedure were evaluated and, when indicated, transferred immediately to the operating room to complete the evacuation.

For the procedure, all subjects received general endotracheal anesthesia. Procedures were performed by four physicians, all of whom had more than 10 years of experience performing D&Es. The operating physicians were not blinded to the treatment arm. The operating physician placed a speculum and then assessed initial cervical dilation by gradual insertion of Hegar dilators, noting the largest dilator that fit through the cervix without resistance. Timing of the procedure was started with the onset of either additional rigid dilation, when required, or introduction of a forceps or suction cannula. Ring forceps were used for the procedures. Procedure time was ended when the last instrument was removed from the uterus. Procedures were performed under ultrasound guidance. Subjects were discharged when medically stable 6–8 h after the procedure.

Upon completion of the procedure, the operating physician was asked to rate the difficulty of the procedure on a 5-point Likert scale, defined as: 0=no difficulty, 1=mild difficulty, 2=mild to moderate difficulty, 3=moderate difficulty, 4=moderate to marked difficulty and 5=marked difficulty. Adverse effects were assessed with a series of questionnaires.

Pain was assessed using the VAS score (ranging from 1=no pain to 10=the worst possible pain), ranked by the participants at various time periods: immediately after laminaria or misoprostol placement, 3 to 4 h after laminaria or misoprostol placement, and upon discharge from the department. Pain control management was similar in both groups. Upon request, participants were given 1 g dipyrone (Optalgin®) orally. Participants requesting additional analgesia received 75 mg diclofenac (Voltaren®) intramuscularly. If needed, additional dose of dipyrone was given after 6 h, and additional dose of diclofenac was given after 8 h. Other adverse effects were reported by the participants 3 to 4 h after laminaria or misoprostol placement using a yes or no questionnaires. Subjects' demographics, reproductive history and complications were abstracted from the medical record.