

Buccal Misoprostol Compared With Synthetic Osmotic Cervical Dilator Before Surgical Abortion

A Randomized Controlled Trial

Deborah Bartz, MD, MPH, Rie Maurer, MA, Rebecca H. Allen, MD, MPH, Jennifer Fortin, MPH, Bernice Kuang, BA, and Alisa B. Goldberg, MD, MPH

OBJECTIVE: To compare the efficacy and acceptability of buccal misoprostol or a synthetic osmotic cervical dilator for cervical preparation before same-day late first-trimester and early second-trimester surgical abortion.

METHODS: In this randomized, double-blind trial, we compared 400 micrograms of buccal misoprostol with one synthetic osmotic cervical dilator administered 3–4 hours before surgical abortion among women at 12–15 weeks of gestation. The primary outcome was mean cervical circumferential dilation at the time of surgery. Randomization was stratified by parity and sample size calculated to detect a 3-French difference between groups with 90% power with a two-sided α of .05. Secondary outcomes included ease of further mechanical dilation, procedure time, complications, ripening and procedural pain, and participants' satisfaction.

RESULTS: One hundred twenty-five women were randomized with a mean gestational age of 13 3/7 weeks. Treatment with the synthetic osmotic dilator and buccal misoprostol resulted in similar preoperative dilation (mean French 33.9 compared with 32.1, $P=.065$). Procedure time, procedural pain, number of complications, and participants' satisfaction and preferences did not differ between treatment groups. Misoprostol participants experienced more pain during ripening ($P=.008$). All but six participants, three in each arm, required mechanical dilation at the time of the procedure. This manual dilation was subjectively easier in participants who received the synthetic osmotic cervical dilator ($P=.015$). All participants were able to have their procedure in 1 day without further cervical preparation.

CONCLUSION: Either buccal misoprostol or a synthetic osmotic cervical dilator provides adequate dilation for same-day late first-trimester and early second-trimester abortion. Despite more pain with misoprostol, patient satisfaction with misoprostol and the synthetic dilator is similar.

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Cervical ripening before pregnancy termination by dilation and suction curettage (D&C) improves procedure safety.^{1,2} Although not frequently used before first-trimester D&C, where the risk of injury is low, it is usually used before late first-trimester and second-trimester procedures.^{3–5} In second-trimester dilation and evacuation, laminaria tents are the most common method of cervical ripening.⁵ However, the full dilatory effect of laminaria is achieved only after prolonged exposure, which often requires that

From the Department of Obstetrics, Gynecology, and Reproductive Biology and the Center for Clinical Investigation, Brigham and Women's Hospital, Harvard Medical School, and Planned Parenthood League of Massachusetts, Boston, Massachusetts; and the Department of Obstetrics and Gynecology, Women and Infant's Hospital, Providence, Rhode Island.

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Corresponding author: Deborah Bartz, MD, MPH, Department of Obstetrics, Gynecology, and Reproductive Biology, 75 Frances Street, Boston, MA 02115; e-mail: dbartz@partners.org.

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abortions be completed over 2 days.⁶ Given restricted access to abortion services⁷ and patient preferences for expedited care, physicians commonly provide 1-day procedures using more rapidly acting methods of cervical ripening for women in the late first trimester and early second trimester.⁴

Misoprostol is the most commonly used medicine for cervical ripening.⁸ Buccal administration is convenient while producing the same effect on uterine tone as vaginal dosing but with less interpatient variability.⁹ The peak dilatory effect is achieved between 3 hours and 4 hours of use.¹⁰ A large body of literature demonstrates that misoprostol is effective before first-trimester D&C.¹¹ In second-trimester surgical abortion, the efficacy of misoprostol is less clear. Compared with overnight laminaria, misoprostol administered several hours preoperatively does not achieve the same degree of cervical dilation.^{12,13} However, differences in safety and ability to complete the procedure have not been found.^{12–14}

Dilapan-S, a synthetic osmotic cervical dilator, exerts mechanical force and chemical cervical dilation through the endogenous release of prostaglandins as the cervix is stretched.¹⁵ Its appearance, insertion technique, and mechanism of action are similar to that of laminaria. However, this synthetic osmotic cervical dilator exerts a more rapid clinical effect on the cervix with one 4-mm rod resulting in 10–12.5 mm of dilation after 4 hours.^{15,16} One report describes the success of same-day cervical ripening with this synthetic osmotic cervical dilator with one 4-mm dilator allowing for completion of the abortion at 16–18 weeks of gestation.¹⁷

The purpose of this study was to compare the dilatory effect of buccally administered misoprostol with a synthetic osmotic cervical dilator before surgical abortion performed between 12 0/7 weeks and 15 0/7 weeks of gestation.

MATERIALS AND METHODS

For this double-blind, randomized trial, we recruited English-speaking or Spanish-speaking women who were in good health, aged at least 18 years old, and between 12 0/7 weeks and 15 0/7 weeks of gestation by ultrasonographic examination seeking outpatient pregnancy termination at Planned Parenthood League of Massachusetts. Patients were recruited on the day of their procedures. Enrollment took place between January 2009 and December 2011. Women were included if they had multiple gestations or fetal demise but excluded if they had a known allergy to misoprostol, inflammatory bowel disease, a prior cervical procedure that could possibly affect the ripening process, including loop electrosurgical exci-

sion procedure or cone biopsy, or if a cervical or uterine abnormality was noted on examination that the examining clinician thought would require dilation with laminaria, such as large fibroids. The study was approved by the Partners Human Research Committee of Partners Research Management.

Participant enrollment and randomization were stratified by parity into two cohorts, nulliparous and multiparous women, with multiparous indicating any prior delivery, either vaginal or cesarean. Blocked randomization schemes, using blocks of four and six, were created for each cohort using computer-generated random number tables by research staff not responsible for recruitment or study conduct. Randomization assignments were masked by placing them into sequentially numbered, individual, opaque envelopes, which were then sealed. Patients were approached for study recruitment after ultrasonographic evaluation, medical eligibility determination, and after they had provided informed consent for abortion. Written informed consent for study participation was obtained by the physician who would perform the D&C blinded to treatment arm. All women then received 600–800 mg ibuprofen unless contraindicated. The patient then underwent a bimanual examination by a second, non-blinded study clinician and, if eligible by examination, was enrolled. A research associate opened the next sequentially numbered envelope within the participant's stratum and notified the nonblinded clinician of the assigned treatment. Neither the patient nor the operating physician who would later assess cervical dilation and perform the D&C was informed of the treatment group assignment.

All cervical ripening procedures were performed by the nonblinded clinician. Participants randomized to the synthetic osmotic cervical dilator group underwent a speculum examination followed by a three-point paracervical block with 20 mL of 1% buffered lidocaine and placement of a tenaculum on the anterior cervical lip. Initial mechanical predilation was not performed. One 4-mm synthetic osmotic cervical dilator rod was inserted into the cervix and the tenaculum was removed. **No sponge was left in the vagina.** On completion of the synthetic osmotic cervical dilator placement, the participants randomized to this treatment group were given two placebo tablets to place buccally, which they were then instructed to swallow 30 minutes after buccal administration. Participants randomized to misoprostol started their cervical ripening process with a speculum examination and a one-point block of the anterior cervical lip at 12 o'clock using 2–5 mL of 1% buffered lidocaine. A tenaculum was placed on the anterior lip.



After a moment, the tenaculum was then removed. On removal of the speculum, the participant was given two 200 microgram misoprostol tablets buccally, which she was instructed to swallow after 30 minutes. After the cervical ripening procedures, all participants were escorted to the recovery room where they were administered a questionnaire to assess pain during the synthetic osmotic cervical dilator or sham placement and to establish a baseline of wellness with questions regarding nausea, fever, chills, and cramping over the past week. The participants waited 3–4 hours under nurse supervision in the recovery room until the D&C.

At the close of the 3-hour to 4-hour ripening period, participants were given a second questionnaire regarding comfort during and side effects of the cervical ripening experience and were then escorted back to the procedure room for the D&C. Abortion procedures were performed either with moderate sedation using fentanyl and midazolam or local anesthesia using paracervical block alone per patient preference. The nonblinded clinician who performed the cervical preparation earlier that day removed the synthetic osmotic cervical dilator if necessary, placed the speculum, administered a three-point paracervical block with 20 mL of 1% buffered lidocaine with 5 units vasopressin, and placed a tenaculum on the anterior cervical lip. The operating physician blinded to treatment arm then entered the procedure room and the nonblinded clinician left.

Before beginning the procedure, the operating physician measured mean cervical circumferential dilation using serially smaller Pratt dilators beginning at 49 French and decreasing in size sequentially. If any resistance was felt, to prevent inadvertent dilation during measurement, that dilator was removed and measurement with the next smaller dilator was attempted. Once measurement was complete, a stopwatch was used to begin timing the procedure, which began either with mechanical dilation, when required, or with the introduction of the suction cannula. Additional dilation, if needed, was achieved using Pratt dilators, and the pregnancy was removed by a combination of suction curettage using the appropriate-sized cannula and forceps, if necessary, according to routine clinic protocol. The timer was stopped when the last instrument was removed from the uterus. All procedures were done in their entirety under ultrasonographic guidance, which conforms to standard clinical practice at this clinic. No intrauterine devices were inserted postprocedurally. At D&C completion, the operating physician was asked to rate the difficulty of mechanical dilation (0=none needed, 1=very easy, 2=somewhat easy, 3=moderate,

4=somewhat difficult, and 5=very difficult) and to estimate blood loss. The operating physician and the participants were asked to guess the treatment arm to evaluate the adequacy of blinding. Participants completed a final questionnaire at the time of discharge to gauge discomfort during the procedure, patient satisfaction, and future preferences. For all three questionnaires administered to each participant, pain was assessed by using a 5-point Likert scale and experiences of other side effects were measured on either a 0–3 scale or in a binary fashion.

The sample size determination was based on the primary outcome of mean cervical circumferential dilation after ripening with the synthetic osmotic cervical dilator or misoprostol as measured with Pratt dilators. From clinical experience, we expected the synthetic osmotic cervical dilator to achieve greater preoperative dilation. For the sample size calculation, we estimated that one synthetic osmotic cervical dilator would provide an initial cervical circumferential dilation of 36.4 French (standard deviation 3.8) or 11.6 mm in diameter based on two prior studies.^{18,19} We estimated that women treated with misoprostol would have an initial cervical circumferential dilation of 33.0 French (standard deviation 7.2) or 10.5 mm in diameter based on a separate study of misoprostol for cervical ripening.¹² Using these estimates, to have 90% power at the .05 significance level, we required enrollment of 120 participants total to detect a 3-French or 1-mm difference, evenly split among the intervention groups. Because the dilation data used from prior studies included a mix of both nulliparous and multiparous participants and because parity may affect cervical response to dilation method, we evenly recruited nulliparous and multiparous participants into each arm.

Categorical variables were compared using either χ^2 or Fisher's exact tests. Numerical variables were compared using either *t* tests or Wilcoxon two-sample tests. The primary outcome of cervical dilation was compared using the *t* test and two-way analysis of variance test. Prior cesarean delivery was also included as a covariate to adjust for a baseline difference noted between treatment arms. A three-way analysis of variance test including treatment, parity, and prior cesarean delivery was performed to control for this covariate. An assessment of our blinding procedures was performed using a χ^2 test. In the case of missing data, participants were excluded from the analysis of the missing variable. All statistical analysis was performed using SAS 9.2.

RESULTS

Over the course of the study, 276 patients met eligibility requirements and were approached to



participate. No patients were excluded based on the results of their initial examination. A total of 125 women enrolled in the study, with 61 randomized to receive the synthetic osmotic cervical dilator and 64 randomized to receive buccal misoprostol. Three participants (2.4%) were excluded after randomization: one nulliparous participant randomized to misoprostol, but who had not yet received it, decided to reschedule her procedure for another day; one multiparous participant randomized to misoprostol, but who had not yet received it, could not tolerate the speculum examination without general anesthesia; and one multiparous participant randomized to the synthetic osmotic cervical dilator, and who did receive it, had to have her D&C performed by the same doctor who did the cervical ripening procedures as a result of an unexpected schedule change in the clinic over the course of the day. Analysis is presented for the remaining 122 participants. Five participants (4%) were randomized within the wrong strata with four nulliparous participants and one multiparous participant being misclassified before randomization. The data from these participants are included in the intention-to-treat analysis subsequently.

The mean participant age was 24 years, the mean gestational age was 13 3/7 weeks, and the mean body mass index (calculated as weight (kg)/[height (m)]²) was 25.4 for all participants. The demographic and reproductive histories were not significantly different between the two groups, except that participants

who received the synthetic osmotic cervical dilator had significantly more cesarean deliveries, with 24.6% of the participants in the synthetic osmotic cervical dilator arm having had a prior cesarean delivery compared with 9.4% in the misoprostol arm ($P=.022$) (Table 1).

Treatment with the synthetic osmotic dilator and buccal misoprostol resulted in similar preoperative dilation ($P=.065$) (Table 2). When this analysis was controlled for the inequity of cesarean deliveries between the two arms, treatment with the synthetic osmotic cervical dilator demonstrated statistically improved dilation over misoprostol ($P=.049$). When the five participants who were misclassified according to strata were removed in a per-protocol analysis, the improved dilation seen with the synthetic osmotic cervical dilator was statistically significant between the remaining 117 participants ($P=.047$) (Table 2).

All procedures were able to be completed on the first attempt after the single, assigned ripening method. To complete the procedure, 57 (95%) participants who received the synthetic osmotic cervical dilator and 59 (95%) participants who received misoprostol needed further dilation ($P=1.0$). Procedures did not differ by treatment group in procedure time, estimated blood loss, the need for forceps, postprocedural recovery time, or in the number of acute complications. The ease of further mechanical dilation was subjectively noted to be easier in participants who received the synthetic osmotic cervical dilator ($P=.015$) (Table 2). A χ^2 test

Table 1. Participant Characteristics by Treatment Group (N=125)

Characteristic	Synthetic Cervical Dilator (n=61)	Misoprostol (n=64)	P
Age (y)	24.0±5.0	24.1±5.5	.921
Gestational age (d)	93.9±4.9	93.8±5.6	.911
BMI (kg/m ²)	25.2±6.1	25.7±5.4	.612
Insurance*			
Medicaid	18/59 (30.5)	16/62 (25.8)	.729
Private insurance	29/59 (49.2)	30/62 (48.4)	
Self-pay	12/59 (20.3)	16/62 (25.8)	
Race and ethnicity*			
White, non-Hispanic	25/52 (48.1)	27/56 (48.2)	.700
Black, non-Hispanic	13/52 (25.0)	15/56 (26.8)	
Latina, Hispanic	8/52 (15.4)	9/56 (16.1)	
Other	6/52 (11.5)	5/56 (8.9)	
Parity			
Nulliparous	29 (47.5)	33 (51.6)	.653
Multiparous	32 (52.5)	31 (48.4)	
Reproductive history			
Prior cesarean delivery	15 (24.6)	6 (9.4)	.022
Prior induced abortion	36 (59.0)	39 (60.9)	.827

BMI, body mass index.

Data are n (%) or mean±standard deviation unless otherwise specified.

* P values were generated by excluding missing data.



Table 2. Procedural Outcome Measures by Treatment Group (n=122)

Outcome Measure	Synthetic Cervical Dilator (n=60)	Misoprostol (n=62)	P
Preprocedural circumference for all participants in French (diameter in mm)	33.9±4.7 (10.8±1.5)	32.1±6.0 (10.2±1.9)	.065
Nulliparous participants (n=61)	32.0±4.8 (10.2±1.5)	30.3±6.0 (9.6±1.9)	.224
Multiparous participants (n=61)	35.7±3.8 (11.4±1.2)	34.0±5.6 (10.8±1.8)	.167
Preprocedural circumference in French (diameter in mm), adjusting for parity and prior cesarean delivery*	33.5 (10.7)	31.7 (10.1)	.049
Preprocedural circumference in French (diameter in mm), adjusting for parity excluding participants misclassified by parity (n=117)*†‡	34.0 (10.8)	32.1 (10.2)	.047
Mechanical dilation at time of D&C needed	57 (95)	59 (95)	1.0
Ease of further dilation			
None needed (score of 0)	3 (5)	3 (5)	.015
Very-somewhat easy (score of 1-2)	27 (45)	29 (47)	
Moderate (score of 3)	24 (40)	12 (19)	
Somewhat-very difficult (score of 4-5)	6 (10)	18 (29)	
Procedure time (min)†	3.0 [2.2, 3.9]	2.8 [2.0, 3.8]	.525
Estimated blood loss (mL)			
Less than 10 (score of 1)	11 (18.3)	20 (32.3)	.191
10-50 (score of 2)	43 (71.7)	39 (62.9)	
51-100 (score of 3)	5 (8.3)	3 (4.8)	
More than 100 (score of 4)	1 (1.7)	0 (0.0)	
Forceps needed	1 (1.7)	4 (6.5)	.365
Acute complications			
None	57 (95.0)	59 (95.2)	1.0
Same day reaspiration	2 (3.3)	2 (3.2)	
Other	1 (1.7)	1 (1.6)	
Recovery time (min)	53.9±19.8	52.4±22.3	.706

D&C, dilation and curettage.

Data are mean±standard deviation, n (%), or median [quartile 1, quartile 3] unless otherwise specified.

* Data presented as least square means.

† P values were generated by excluding missing data.

‡ n=56 treated with the synthetic osmotic cervical dilator, n=61 treated with misoprostol.

to assess the success of blinding demonstrated no association between physician's guess and actual treatment assignment.

Six participants (4.8%) experienced an acute complication on the day of their procedure with three complications occurring in each of the two study arms ($P=1.0$) (Table 2). Two women in each treatment arm needed a reaspiration of the uterus on the day of their procedure either immediately after initial procedure completion for concern of incomplete evacuation on inspection of the tissue or as a result of participants' symptoms of cramping or bleeding while in the recovery room. The two participants in the misoprostol arm who needed reevacuation were at 12 3/7 weeks and 14 1/7 weeks of gestation. The two participants in the synthetic osmotic cervical dilator arm needing reevacuation were at 12 5/7 weeks and at 13 3/7 weeks with the former also having received a dose of intramuscular Methergine. Two other study participants experienced complications that did not require reevacuation. One participant who received the synthetic osmotic

cervical dilator at 13 3/7 weeks of gestation had an estimated blood loss of 300 mL that was successfully treated with Methergine, misoprostol, and oxytocin at the time of the procedure. One patient who received misoprostol at 13 3/7 weeks of gestation had a minor cervical laceration that was treated with cervical pressure.

In the week before their procedure, participants in the two treatment arms reported the same amount of nausea, vomiting, diarrhea, and vaginal bleeding. Over the course of the 3- to 4-hour ripening period, participants who received misoprostol experienced more cramping pain than those who received the synthetic osmotic cervical dilator ($P=.008$). However, there was no difference in bleeding, nausea, vomiting, or diarrhea during ripening between the two treatment arms. There was no overall difference in patient satisfaction with the ripening period between the two treatment arms. There was no difference in the use of local anesthesia compared with moderate sedation during the procedure between the two treatment arms with the majority of the participants choosing



Table 3. Women's Assessment of Pain, Adverse Effects, and Acceptability by Treatment Group (n=122)

	Synthetic Cervical Dilator (n=60)	Misoprostol (n=62)	P
Symptoms with ripening agent			
Pain with administration (0=no pain, 1–2=mild pain, 3–4=moderate pain, 5=severe pain)	1 [0, 2]	1 [1, 3]	.008
Bleeding (0=no bleeding, 1=spotting, 2=moderate bleeding, 3=heavy bleeding)	1 [0, 1]	1 [0, 1]	.813
Nausea (0=no nausea, 1=mild nausea, 2=moderate nausea, 3=severe nausea)	0 [0, 0.5]	0 [0, 1]	.148
Chills			
No	0 [0, 0]	0 [0, 0]	.606
Yes			
Do not remember			
Overall satisfaction with ripening (1=very dissatisfied, 2=dissatisfied, 3=neutral, 4=satisfied, 5=very satisfied)	4 [4, 5]	4 [3, 5]	.130
Patient anesthesia choice			
Intravenous	53 (88.3)	57 (91.9)	.556
Local anesthesia	7 (11.7)	5 (8.1)	
Procedural pain (0=no pain, 1–2=mild pain, 3–4=moderate pain, 5=severe pain)	3 [1, 4]	3 [1, 4]	.430
Overall satisfaction with entire experience (1=very dissatisfied, 2=dissatisfied, 3=neutral, 4=satisfied, 5=very satisfied)	4.5 [4, 5]	4 [4, 5]	.993

Data are median [quartile 1, quartile 3] or n (%) unless otherwise specified. P values were generated by excluding missing data.

moderate sedation. There was no difference in the level of pain experienced during the procedure. Overall satisfaction with the entire procedure was the same between the two treatment arms (Table 3).

DISCUSSION

Limited access to abortion care and patient preference have led health care providers to seek methods of cervical preparation that do not require overnight treatment. Both misoprostol and the synthetic osmotic cervical dilator ripen the cervix quickly.^{11,15} We found that misoprostol and the synthetic dilator provided the same degree of preoperative dilation when used 3–4 hours before late first-trimester and early second-trimester pregnancy termination. There was a slight, albeit significant, improvement in circumferential cervical dilation in participants treated with the synthetic osmotic cervical dilator, whether by intention-to-treat analysis or by per-protocol analysis, after adjustment for parity and cesarean delivery. Further mechanical dilation was significantly easier after treatment with the synthetic osmotic cervical dilator, and women treated with the synthetic osmotic cervical dilator had less cramping than those treated with misoprostol. Both methods are effective and allowed for all participants to have their procedure done in 1 day. Our randomization failed in that significantly more women with a history of cesarean delivery were assigned to the synthetic osmotic cervical dilator group, which may

have diminished the difference of effect between the two treatment arms.

Within our study, we had 14 physicians who perform second-trimester abortions contributing to data collection, representing a wide range of clinical practice that represents good generalizability of our results. The blinded nature of our study resulted in minimized bias and the efficacy of the two methods could truly be compared. This study was powered to detect a small difference of effect between the two treatment arms, 1 mm of difference in cervical diameter, or one incremental increase in suction cannula size. Ultimately, cervical dilation and procedure time, a primary outcome also frequently used in cervical ripening studies, serve as proxies for complications. Although the complication rate is the most clinically useful outcome to compare between cervical ripening methods, complications are rare, making them difficult to study in a randomized fashion as a result of the large sample size that would be needed to see a difference between groups.

We chose a regimen of 400 µg of buccal misoprostol administered 3–4 hours before the procedure for multiple reasons. In prior research, this misoprostol regimen is concluded to have the greatest amount of efficacy on uterine tone¹¹ while also balancing clinic convenience and patient acceptability. Within the few studies of misoprostol before second-trimester surgical abortion, this misoprostol dose and treatment



interval has been the most frequently reported and studied.^{12,13} There is less published literature on regimens of the synthetic osmotic cervical dilator before second-trimester surgical abortion. According to the prescribing information, one 4-mm synthetic osmotic cervical dilator rod should reach 10–12.5 mm of dilation within 4 hours and use should be limited to one rod in the setting of same-day use.¹⁵ Many clinics use misoprostol or the synthetic osmotic cervical dilator for shorter preoperative intervals, which may be associated with less cramping but also affect effectiveness.

Another recognized limitation of this study stems from the blinding procedures and their effect on patient experience and satisfaction and on clinic flow. Within this study protocol, all participants underwent pelvic and speculum examinations as part of the cervical ripening procedure to administer or simulate the administration of the cervical osmotic dilator. In clinical practice, administering buccal misoprostol without a pelvic examination could reasonably be expected to affect the patient's experience and expedite clinic flow. Because the full paracervical block was performed only in those participants who received the synthetic osmotic cervical dilator, this may in part explain why participants who received misoprostol had more cramping during cervical ripening. However, in practice, the paracervical block is often used before synthetic osmotic cervical dilator placement and often not used before buccal misoprostol. Thus, our methodology reflects actual practice and the differences in pain that would be expected clinically.

This randomized double-blind study compared the efficacy of 3–4 hours of preprocedure treatment with either 400 micrograms of buccal misoprostol or synthetic osmotic dilation. There was no difference in consequent cervical dilation, need for further mechanical dilation, or patient satisfaction. Close to 90% of U.S. counties do not have an abortion provider.²⁰ Globally, the lack of access to abortion services is even more pronounced.²¹ Therefore, using efficacious same-day cervical ripening has the potential to improve access to abortion care.

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