

Same-Day Synthetic Osmotic Dilators Compared With Overnight *Laminaria* Before Abortion at 14–18 Weeks of Gestation

A Randomized Controlled Trial

Sara J. Newmann, MD, MPH, Abby Sokoloff, MPH, Mithu Tharyil, MD, Tushani Illangasekare, MD, Jody E. Steinauer, MD, MSc, and Eleanor A. Drey, MD, EdM

OBJECTIVE: To increase access to early second-trimester surgical abortion by determining noninferiority of same-day synthetic osmotic dilators compared with overnight *Laminaria* for cervical preparation before early second-trimester dilation and evacuation.

METHODS: We enrolled women between 14 and 18 weeks of gestation and randomized them to same-day synthetic osmotic dilators or overnight *Laminaria*. Study participants and clinicians were blinded to group assignment. The primary outcome was procedure duration. The trial was powered to assess noninferiority of synthetic osmotic dilators to exclude a mean difference of 5 minutes or longer.

RESULTS: We enrolled 72 patients: 36 were randomized to same-day synthetic osmotic dilators and 36 to overnight *Laminaria*. Mean procedure duration was 8.1 and 5.9 minutes, respectively, with a mean difference of 2.1 minutes (97.5% confidence interval –0.3 to 4.5).

From the Bixby Center for Global Reproductive Health, Department of Obstetrics, Gynecology, and Reproductive Sciences, and the Department of Family and Community Medicine, University of California, San Francisco, San Francisco, California.

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Corresponding author: Sara J. Newmann, MD, MPH, San Francisco General Hospital, 1001 Potrero Avenue, San Francisco, CA 94110; e-mail: newmanns@obgyn.ucsf.edu.

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Same-day synthetic osmotic dilators resulted in less initial cervical dilation than overnight *Laminaria* (mean circumference 48 compared with 60 mm Pratt, $P<.001$) and required more mechanical dilation (69% compared with 27%, $P=.001$). There was no difference in complications, all of which were minor, or in the median procedural difficulty score rated by physicians. Most patients in both groups would choose a same-day procedure if necessary in the future.

CONCLUSION: Despite less initial cervical dilation and a greater need for mechanical dilation, same-day synthetic osmotic dilators are not inferior to overnight *Laminaria* with respect to procedure duration. Same-day osmotic dilation is preferred by patients and may be a reasonable alternative to overnight *Laminaria* for cervical preparation before early second-trimester dilation and evacuation.

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LEVEL OF EVIDENCE: I

Many women in the United States have limited access to second-trimester surgical abortions. A small percentage of abortion providers offers second-trimester services, and women often have to travel long distances for care.¹ Surgical abortion between 14 and 18 weeks of gestation generally is offered as a 2-day procedure in which patients undergo cervical preparation with *Laminaria* for 24 hours before the abortion.² This multiday procedure creates further barriers to abortion access because women often have to travel, take several days off work, arrange for child care, or a combination of these to have the abortion completed.

Another option for dilation is same-day use of **Dilapan-S**, a synthetic osmotic cervical dilator that dilates



the cervix more rapidly than *Laminaria*. It reaches its maximum diameter in 4–6 hours, whereas *Laminaria* reach their maximum diameter in 18–24 hours.^{3,4} Multiple studies have been conducted investigating same-day methods for cervical preparation for second-trimester abortion, especially in the first half of the second trimester.^{5–11} However, no randomized or prospective studies have been performed comparing same-day synthetic osmotic dilators with overnight *Laminaria* before early second-trimester surgical abortion.

We conducted a double-blind, randomized trial comparing same-day synthetic osmotic dilators with overnight *Laminaria* before early second-trimester surgical abortion between 14 and 18 weeks of gestation. We used a noninferiority design to determine whether same-day dilation with synthetic osmotic dilators is inferior to the widely used cervical preparation method of overnight *Laminaria* with respect to procedure duration.

MATERIALS AND METHODS

Women were recruited at the Women's Options Center at San Francisco General Hospital between October 2008 and February 2010. Two research assistants recruited and enrolled English- and Spanish-speaking women who were at least 18 years old and between 13 6/7 and 17 6/7 weeks of gestation by ultrasound dating the day before their abortions. We excluded women if they were incarcerated, did not understand Spanish or English, or had a known allergy to synthetic osmotic dilators or *Laminaria*. Our study was approved by the Committee on Human Research, the institutional review board of the University of California, San Francisco, and registered with ClinicalTrials.gov (NCT00775983). An Investigational Device Exemption was obtained from the U.S. Food and Drug Administration to study off-label use of the synthetic osmotic cervical dilator for research.

Women who consented to participate were randomized to receive either synthetic osmotic dilators on the day of the abortion or overnight *Laminaria*. Randomization was completed using a computer-generated, random number-producing algorithm with permuted block randomization in blocks of four and six. Study allocation was concealed in sequentially numbered, opaque, sealed envelopes prepared by a research assistant not involved in the study.

To maintain subject blinding, all study participants underwent a speculum examination on the day before the abortion. Women randomized to same-day dilators underwent a sham examination, including placement of a sterile gauze, and women randomized

to overnight *Laminaria* received a paracervical block and insertion of medium *Laminaria* (mean diameter 4 mm) followed by placement of a sterile gauze. Medium-sized *Laminaria* were placed using the following guideline: number of weeks of gestation minus 10. The health care provider performing the examination was a resident physician, attending physician, or certified nurse midwife, all of whom had experience with dilator insertion and were not going to do the dilation and evacuation.

All women heard the same script from health care providers performing the “sham” or actual dilator placement. Health care providers were instructed to say sentences such as “This may be a little uncomfortable,” “You’re going to feel some pressure,” or both while performing the speculum examination and “sham” or actual dilator placement. After the examination, patients were discharged from the clinic.

On day 2 of the study, all participants returned to the clinic in the morning and completed a questionnaire about their symptoms overnight. Participants then underwent a second speculum examination. Patients randomized to synthetic osmotic dilators had the gauze removed, a paracervical block placed, synthetic osmotic dilators inserted, and a sterile gauze placed. For patients between 14 0/7 and 15 6/7 weeks of gestation on the day of the abortion, two to three synthetic osmotic dilators were inserted. For patients between 16 0/7 and 18 0/7 weeks of gestation, two to five synthetic osmotic dilators were inserted. One medium *Laminaria* also was placed to facilitate the removal of the synthetic osmotic dilators before the abortion.¹² Patients randomized to *Laminaria* had a sham examination: the gauze was removed and replaced. Patients then waited 4–6 hours for their abortions.

Immediately before the abortion, patients completed a second questionnaire and reported any symptoms experienced during that day's waiting period. In the procedure room, a study staff member who was unblinded to group allocation removed the dilators and disposed of them out of sight of the dilation and evacuation provider—either an attending physician or family planning fellow who was blinded to the study arm. The health care provider then entered the procedure room, inserted a speculum, cleansed the cervix with povidone–iodine, and placed a paracervical block that included 5 units of vasopressin. We measured cervical dilation by using sequentially smaller dilators with initial dilation being that of the first dilator that passed without resistance.

A research assistant, blinded to group assignment, used a stopwatch to time the abortion, which either began with mechanical dilation of the cervix using



Pratt dilators if needed or insertion of a cannula to begin suction. Using ultrasonographic guidance, surgeons emptied the uterus by a combination of forceps and suction curettage with a 14-mm cannula. Procedure duration ended when the last instrument was removed from the uterus. The abortion provider completed a questionnaire after the abortion to assess difficulty of the procedure. Before discharge, patients filled out a final study questionnaire, which asked questions about symptoms and satisfaction with their clinic experience.

Our primary outcome was procedure duration with secondary outcomes including cervical dilation, difficulty of additional dilation, blood loss, major complications, and patient satisfaction. Procedure duration was chosen as the primary outcome because it is a marker for procedural difficulty and thus a proxy for potential procedural difficulty and complications. Additionally, we thought clinicians would be interested in the effect on procedure duration when considering protocol changes related to same-day cervical preparation. We chose a noninferiority margin of 5 minutes; thus, if the mean difference in procedure duration between the two study arms was within 5 minutes, synthetic osmotic dilators would be determined as being noninferior to overnight *Laminaria*. We felt that

up to a 5-minute difference in procedure duration would be acceptable in terms of adopting a same-day dilation protocol for early second-trimester surgical abortion. However, we thought that more than a 5-minute difference could potentially disrupt clinic flow in a way that would not be acceptable for most busy abortion clinics.

Mean difference in procedure duration between the two groups and the 97.5% confidence interval (CI) were calculated to compare procedure durations between the two groups. Linear regression was completed to adjust for baseline covariates that were different between the two arms at a *P* level of $\leq .05$. Interaction terms were created, and assessed using linear regression, among patient age, parity, gestational duration, health care provider type, and anesthesia received during the dilation and evacuation because these covariates could plausibly interact with the relationship between study arm and procedure duration. Additional continuous outcomes were compared using the Student's *t* test or the Wilcoxon rank-sum test. We compared dichotomous outcomes using the Pearson χ^2 test or Fisher's exact test when any cell size included data from fewer than five study participants.

To power the study for our noninferiority hypothesis, we assumed a standard deviation of 5 minutes

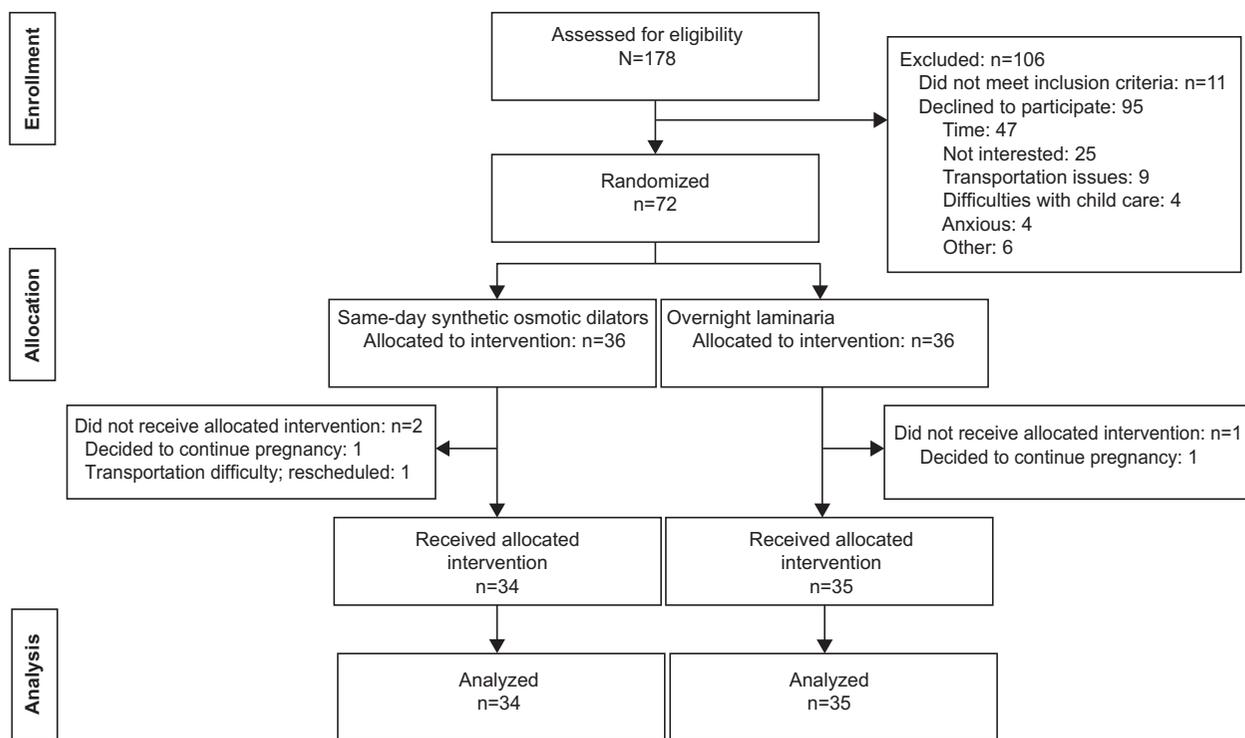


Fig. 1. Randomization table.

Newmann. *Same-Day Synthetic Osmotic Dilators vs. Overnight Laminaria*. *Obstet Gynecol* 2014.

based on historical data at The Women's Options Center for mean surgical abortion procedure duration performed between 14 and 18 weeks of gestation, an α of 0.025, and a noninferiority margin of 5 minutes as discussed previously. We calculated we would need 30 participants in each study arm to give 95% power assuming a 10% attrition rate to conclude noninferiority of same-day synthetic osmotic dilators compared with overnight *Laminaria*. Thus, if we found that same-day synthetic osmotic dilators are not inferior to overnight *Laminaria* with respect to dilation and evacuation duration, the upper bound of the 97.5% CI around the point estimate for mean difference in overall procedure duration would be 5 minutes or longer.

RESULTS

We enrolled 78 women into the study. Thirty-six participants were randomized to each study arm and three dropped out of the study: two from the same-day osmotic dilator arm and one from the overnight *Laminaria* arm (Fig. 1). Two women who had received the allocated overnight *Laminaria* decided on the

morning of the abortion that they did not want to wait 4 hours to have the procedure. Their abortions were completed that morning and their clinical data were included in the intent-to-treat analysis; however, their corresponding subjective data were not available for analysis.

Baseline characteristics of the randomized groups differed in terms of insurance status, age, and gestational duration (Table 1). There was no difference between the two groups in the number of women who had multiple gestations or fetal anomalies.

The mean difference in overall procedure duration between the two groups was 2.1 minutes (97.5% CI -0.3 to 4.5 ; Table 2). Noninferiority was determined because the upper bound of the 97.5% CI around the mean difference in procedure duration was less than 5 minutes. The median procedure durations and interquartile duration ranges for the same-day synthetic osmotic dilators and overnight *Laminaria* groups were 6.4 (3.9–11.7) and 5.5 (3.5–9.8) minutes, respectively ($P=.08$). We also completed a sensitivity analysis excluding one procedure that took 32 minutes (same-day dilator arm). One nulliparous patient in

Table 1. Demographic and Clinical Characteristics of Women Randomized to Same-Day Synthetic Osmotic Dilators or Overnight *Laminaria* Before Early Second-Trimester Abortion

Characteristic	Same-Day Dilators (n=34)	Overnight <i>Laminaria</i> (n=35)	P*
Demographic characteristics			
Age (y)	26.5 (22.0–32.0)	21.0 (19.0–26.0)	.03
Race			.55
White	8 (24.2)	4 (11.8)	
Black	15 (45.5)	16 (47.1)	
Latina	8 (24.2)	10 (29.4)	
Asian or Pacific Islander	2 (6.1)	4 (11.8)	
Public insurance	26 (76.5)	34 (97.1)	.01
Clinical characteristics			
Gestational duration (wk)	16.6 \pm 1.1	16.2 \pm 1.1	.03 [†]
14–15 6/7	7 (20.6)	16 (45.7)	
16–18	27 (79.4)	19 (54.3)	
Body mass index (kg/m ²)	27.1 (23.4–31.4)	27.5 (23.6–32.6)	.81
Nulliparous	9 (26.5)	12 (34.3)	.48
Prior vaginal delivery	14 (41.2)	15 (42.9)	1.00
Prior cesarean delivery	11 (32.4)	9 (25.7)	.60
Prior induced abortion	22 (64.7)	22 (62.9)	.87
Prior pregnancies	4.0 (2.0–6.0)	3.0 (2.0–5.0)	.30
Sedation provider [‡]			.96
Nurse	29 (85.3)	30 (85.7)	
Anesthesiologist	5 (14.7)	5 (14.3)	
Clinician type			.48
Attending	25 (73.5)	23 (65.7)	
Fellow	9 (26.5)	12 (34.3)	

Data are median (interquartile range), n (%), or mean \pm standard deviation unless otherwise specified.

* Wilcoxon rank-sum, Pearson χ^2 , or Fisher's exact test (if cell size is less than five).

[†] $P=.12$ for comparison of gestational duration as continuous variable with t test.

[‡] Anesthesia administered by nurses included fentanyl and midazolam. Anesthesia administered by anesthesiologists included propofol, fentanyl, and midazolam.



Table 2. Differences in Procedure Duration and Interactions Between Clinically Significant Covariates Among Women Randomized to Same-Day Synthetic Osmotic Dilators or Overnight *Laminaria* Before Early Second-Trimester Abortion

Clinical Characteristics	Same-Day Dilators (n=34)	Overnight <i>Laminaria</i> (n=35)	Mean Difference (97.5% CI)	P for Interaction
Overall	8.1±5.5	5.9±2.9	2.1 (−0.3 to 4.5)	
Patient age (y)				.60
24 or younger (13, 22)*	9.8±7.3	6.5±3.2	3.23 (−0.9 to 7.4)	
Older than 24 (21, 13)	7.0±3.8	4.8±1.8	2.13 (−0.4 to 4.8)	
Parity				
Nulliparous (9, 12)	11.4±8.2	6.4±2.4	5.0 (−0.2 to 10.2)	.09
Prior vaginal delivery (14, 15)	7.3±4.5	5.7±2.7	1.7 (−1.1 to 4.5)	.72
Gestational duration on day of abortion (wk)				.17
14–15 6/7 (7, 16)	4.1±1.1	4.9±2.5	0.8 (−1.3 to 2.9)	
16–18 (27, 19)	9.1±5.7	6.8±2.9	2.3 (−0.99 to 5.6)	
Provider type				.95
Attending (25, 23)	7.9±5.9	5.8±2.7	2.1 (−0.6 to 4.8)	
Fellow (9, 12)	8.5±4.3	6.2±3.3	2.3 (−1.2 to 5.7)	
Sedation provider [†]				.38
Nurse (29, 30)	8.4±5.8	5.9±2.9	2.5 (0.1–4.9)	
Anesthesiologist (5, 5)	6.2±1.4	6.3±3.0	0.1 (−3.3 to 3.5)	

CI, confidence interval.

Data are mean procedure duration±standard deviation (minutes) unless otherwise specified.

* Parentheses next to variable strata include the number of patients in that stratum per treatment arm (n same-day dilators, n overnight *Laminaria*).

[†] Anesthesia administered by nurses included fentanyl and midazolam. Anesthesia administered by anesthesiologists included propofol, fentanyl, and midazolam.

the same-day synthetic osmotic dilator group whose abortion took 32 minutes was given 400 micrograms buccal misoprostol for 2 hours after several health care providers were unable to remove the dilators despite multiple attempts. After the misoprostol, the dilators

were removed without difficulty. The mean time difference between the two groups when excluding this outlier was 1.2 minutes (97.5% CI −0.6 to 3.0). We applied the resampling method of bootstrapping to account for distortions within our study sample and

Table 3. Additional Clinical Outcomes Among Women Randomized to Same-Day Synthetic Osmotic Dilators or Overnight *Laminaria* Before Early Second-Trimester Abortion

Clinical Outcome	Same-Day Dilators (n=34)	Overnight <i>Laminaria</i> (n=35)	P*
Dilation			
Initial dilation (circumference, mm)	48.0±11.3	59.7±10.0	<.001
Mechanical dilation required	22 (68.8)	8 (26.7)	.001
Complications			
Bleeding requiring uterotonics	7 (20.6)	10 (28.6)	.58
Respiration	3 (8.8)	2 (5.7)	.67
Cervical laceration	0	1 (2.9)	1.00
Blood loss			
Estimated blood loss (mL)	61.0±27.1	64.9±46.6	.68
Difference in preprocedure and postprocedure hemoglobin	−0.3±1.0	−0.6±1.6	.28
Analgesic use			
Preprocedure opiate use [†]	27 (79.4)	7 (20.0)	<.001
Intraoperative analgesia, standardized dose [‡]	17.2±5.8	18.7±7.0	.33
Postprocedure opiate use [†]	4 (11.6)	17 (48.6)	.001

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

* *t* test, Pearson χ^2 , or Fisher's exact test (if cell size less than five).

[†] Opiate use included hydrocodone or acetaminophen, morphine, or hydromorphone hydrochloride.

[‡] Intraoperative analgesics included propofol, midazolam, fentanyl, or all. Quantities of each were standardized to a mean of 10, standard deviation of 2. Standardized doses for each were then added to obtain the total.



to increase the accuracy of our estimate of the 97.5% CIs around the overall mean procedure duration. The result was a procedure time difference of 2.1 minutes (97.5% CI 0.3–4.6) with the upper bound 97.5% CI value less than 5. When adjusting for patient age, gestational duration, and insurance type—the three covariates found to be significantly different between the two study arms (Table 1)—the mean procedure time was 1.5 minutes (97.5% CI 1.0–4.0). Additionally, neither patient age, parity, gestational duration, provider type, or anesthesia received interacted significantly with the relationship between study arm and procedure time (Table 2).

Preoperative dilation was less with same-day synthetic osmotic dilators compared with overnight *Laminaria* (mean initial dilation circumference 48 mm compared with 60 mm, $P<.001$; Table 3). Fewer dilators were placed in the women in the same-day synthetic osmotic dilator arm compared with the women in the overnight *Laminaria* arm (mean number of dilators 4.5 compared with 5.4, $P<.01$, respectively). Fifteen patients in the *Laminaria* arm had one fewer *Laminaria* placed than recommended by study guidelines. One patient in the synthetic osmotic dilators arm at 17 6/7 weeks of gestation had only one synthetic osmotic dilator placed instead of two to five as recommended in the study protocol. More women in the same-day synthetic osmotic dilators group needed additional mechanical dilation compared with the overnight *Laminaria* group (68.8% compared with 26.7%, $P=.001$).

A greater proportion of women in the synthetic osmotic dilator group required opiates for pain before the abortion (79.4% compared with 20.0%, $P<.001$), whereas a greater proportion of women in the *Laminaria* group required opiates for pain postoperatively (48.6% compared with 11.6%, $P=.001$). There was no difference between study arms in the amount of pain

medication administered during the dilation and evacuation and no difference in complications.

A greater proportion of physicians in the same-day synthetic osmotic dilators group reported the initial cervical dilation to be inadequate (59.4% compared with 23.3%, $P<.01$; Table 4). Surgeons reported no difference between the two groups regarding level of difficulty of mechanical dilation when needed or the difficulty of the abortion itself. A greater proportion of the physicians in the same-day synthetic osmotic dilators group was able to correctly identify to which study arm their patient had been randomized (56.3% compared with 40.0%, $P<.01$).

The majority of women in both groups reported being satisfied with their abortions and overall clinic experience (Table 5). One woman in the *Laminaria* group reported preferring overnight cervical preparation. In the same-day synthetic osmotic dilator group, 87.5% said they preferred same-day cervical preparation compared with 69.0% in the *Laminaria* group ($P=.15$).

Overnight, significantly more women in the *Laminaria* group reported being “a great deal” or “a very great deal” bothered by a variety of symptoms (Table 5). Immediately before the abortion, significantly more women in the same-day synthetic osmotic dilator group reported being bothered by a variety of symptoms. In the recovery room, women in the same-day dilator group reported having significantly less pain and required less pain medication than women in the *Laminaria* group with the majority already having received opiate analgesics while waiting for the dilation and evacuation. A greater proportion of women in the same-day dilator group accurately guessed what kind of dilators they had (75.8% compared with 55.2%, $P<.001$; Table 5). More women in the *Laminaria* group were unsure as to what kind of dilators had been placed.

Table 4. Physician Assessments of Procedural Difficulty and Dilator Type by Study Arm

Assessment	Same-Day Dilators (n=32)	Overnight <i>Laminaria</i> (n=30)	P*
Procedural difficulty			
Inadequate dilation	19 (59.4)	7 (23.3)	<.01
Difficulty of additional dilation [†]	0 (0–1)	0 (0–1)	.57
Difficulty of procedure [†]	0 (0–1)	0 (0–1)	.17
Ascertainment of dilator type			<.01
Correct	18 (56.3)	12 (40.0)	
Incorrect	3 (9.4)	6 (20.0)	
Do not know	11 (34.4)	12 (40.0)	

Data are n (%) or median (interquartile range) unless otherwise specified. Proportion percentages may vary slightly by variable as a result of occasional missing data.

* *t* test, Pearson χ^2 , Fisher’s exact test (if cell size less than five), or Wilcoxon rank-sum test.

[†] Difficulty scale: not difficult (0), mildly difficult (1), moderately difficult (2), very difficult (3), extremely difficult (4).



Table 5. Patients' Satisfaction, Side Effects, and Ascertainment of Dilator Type

Outcome	Same-Day Dilators (n=34)	Overnight <i>Laminaria</i> (n=33)	P*
Satisfaction and patient preference [†]			
Satisfaction with abortion	26 (81.3)	24 (80.0)	1.0
Satisfaction with overall clinic experience	25 (89.3)	22 (84.6)	.70
Patient preference			.15
1-d procedure	28 (87.5)	20 (69.0)	
2-d procedure	0	1 (3.5)	
Do not know	4 (12.5)	8 (27.6)	
Side effects [‡]			
Overnight			
Abdominal pain or cramping	2 (6.1)	23 (71.9)	<.001
Vaginal bleeding	0	4 (12.5)	.05
Nausea	2 (5.8)	12 (37.5)	<.01
Vomiting	3 (8.8)	13 (41.99)	<.01
Diarrhea	1 (2.9)	1 (3.1)	1.00
Bothered by any symptoms	2 (5.9)	12 (34.3)	<.01
Immediately before abortion			
Abdominal pain or cramping	25 (73.5)	7 (23.3)	<.001
Vaginal bleeding	2 (6.1)	2 (6.9)	1.00
Nausea	6 (18.2)	6 (20.0)	1.00
Vomiting	5 (15.6)	5 (16.6)	1.00
Bothered by any symptoms	17 (50.0)	2 (5.7)	<.001
In recovery room			
Abdominal pain or cramping	8 (24.2)	16 (53.3)	.02
Vaginal bleeding	22 (66.7)	22 (73.3)	.60
Nausea	2 (6.1)	3 (10.0)	.66
Vomiting	3 (9.1)	3 (10.3)	1.00
Ascertainment of dilator type			<.001
Correct	25 (75.8)	16 (55.2)	
Incorrect	1 (3.0)	2 (6.9)	
Do not know	7 (21.2)	11 (37.9)	

Data are n (%) unless otherwise specified. Proportion percentages may vary slightly by variable as a result of occasional missing data.

* Pearson χ^2 or Fisher's exact test (if cell size less than five).

[†] Women who answered 4 or 5 (somewhat or very satisfied) on the satisfaction scale were considered satisfied with their abortions or overall clinic experience.

[‡] Data are shown for patients who reported: moderate, severe or unbearable abdominal pain or cramping, nausea, or diarrhea; light, moderate, or heavy bleeding; one or more episodes of emesis during the time interval; or feeling bothered a great deal or a very great deal by their symptoms during the specific time interval shown.

DISCUSSION

Our findings show that same-day dilation with synthetic osmotic dilators is a reasonable alternative to overnight *Laminaria* when used before dilation and evacuations between 14 and 18 weeks of gestation. Same-day abortions could increase access for women in need of early second-trimester abortions and decrease the myriad logistical barriers frequently faced by women presenting for abortion later in pregnancy.¹³

Mean gestational duration was slightly higher in the synthetic dilator group, which likely increased the mean procedure duration in that study arm. Had randomization of women between 16 and 18 weeks of gestation been equal, we likely would have found a smaller difference in procedure durations and shown noninferiority of same-day synthetic osmotic dilators with greater precision.

Mechanical dilation was required in two-thirds of the patients who received same-day synthetic osmotic dilators and in only one-fourth of those with overnight *Laminaria*. Although we do not know the long-term consequences of mechanical dilation in the context of an osmotically prepared cervix, the theoretical concern remains that mechanical dilation could decrease cervical integrity and increase future risk of miscarriage or preterm births. However, this has not been documented in the literature.¹⁴⁻¹⁶ Our results suggest the need for caution when using same-day synthetic osmotic dilators among nulliparous women in the early second trimester because their procedures took longer, although all abortions among nulliparous patients were completed without any significant difference in complications. It is also notable that one procedure in the synthetic osmotic dilator arm was significantly longer than the others as



a result of extreme difficulty removing the dilators. Health care providers who adopt a same-day protocol using synthetic osmotic dilators sometimes may experience difficult dilator removal as a result of their being wedged within a potentially noncompliant cervix.

Although our study was completed as a randomized trial, it has several limitations. Our study had inadequate power to compare complications directly between groups; thus, procedure duration was chosen as a proxy for procedural difficulty and potential complications. A much larger study is needed to assess whether immediate or long-term complications differ as a result of increased mechanical dilation, which was necessary with same-day osmotic dilators. None of the patients in our study actually had a 1-day experience; thus, our data regarding patient preference of a same-day procedure are based on patient supposition. It is always possible that blinding was not uniformly successful; however, given that a substantial proportion of health care providers and patients were unsure of dilator type or guessed incorrectly, blinding appeared somewhat effective.

Additionally, the trial was conducted as a non-inferiority study with the primary outcome of procedure duration; some might prefer a superiority design or other outcomes to be considered primary. Finally, we conducted our study at a busy, urban, hospital-based clinic with high second-trimester abortion volume and multiple health care providers who are skilled in second-trimester abortion. Our study findings may not be generalizable to smaller clinics with fewer staff, different patient demographics, and less second-trimester abortion volume.

Same-day cervical preparation with synthetic osmotic dilators before early second-trimester abortion may be beneficial not only to increase women's access to abortion during this gestational duration, but also may benefit clinics by increasing the number of early second-trimester patients they can serve and by decreasing expenses associated with multiple clinic visits. The barriers to same-day protocols lie mainly with clinic flow. Health care practitioners and clinics who are considering instituting a same-day cervical preparation method for women who present for abortion within the early second trimester will need to consider the ways in which such a protocol would influence patient flow within the clinic with respect to ultrasound dating, dilator placement, waiting space and time, and medication and pain management. Medicine is transitioning to more patient-centered models,¹⁷ and the majority of patients in this and previous studies^{5,11} preferred a shorter procedure. Despite a greater need for mechanical dilation, same-day dilation with synthetic osmotic dilators is a reasonable alternative to overnight

Laminaria for a cervical preparation before early second-trimester abortion among clinics that are able to accommodate the required changes in patient flow.

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