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Paracervical Block for *Laminaria* Insertion Prior to Second-Trimester Abortion: A Randomized Controlled Trial

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Abstract

Objectives—To evaluate the efficacy of a paracervical block to decrease pain during osmotic dilator insertion prior to a second-trimester abortion.

Methods—In this double-blind, randomized trial 41 women undergoing *Laminaria* insertion prior to a second-trimester abortion received either a paracervical block with 18 ml 1% lidocaine and 2 ml sodium bicarbonate or a sham block. Women were between 14 and 23 6/7 weeks of gestation. The primary outcome was pain immediately after insertion of *Laminaria*. Women assessed their pain on a 100-mm visual analog scale (VAS). Secondary outcomes included assessment of pain at other times during the insertion procedure and overall satisfaction with pain control. To detect a 25 mm difference in pain immediately after *Laminaria* insertion, at an alpha of 0.05 and 80% power, we aimed to enroll 20 patients in each arm.

Results—From May 2015 to December 2015, 20 women received a paracervical block and 21 received a sham block. Groups were similar in demographics, including parity, history of surgical abortion, and number of *Laminaria* placed. The paracervical block reduced pain after *Laminaria* insertion (median scores 13 mm [interquartile range 2–39] versus 54 mm [interquartile range 27–61], $p=0.01$, 95% confidence interval [CI] –47.0–4.0). Women who received a paracervical block also reported higher satisfaction with overall pain control throughout the entire *Laminaria* insertion procedure (median scores 95 mm [interquartile range 78–100] versus 70 mm [interquartile range 44–90], $p=0.05$, 95% CI 0.0–37.0).

Conclusions—Paracervical block is effective at reducing the pain of *Laminaria* insertion. Additionally, paracervical block increases overall patient satisfaction with pain control during *Laminaria* placement.

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INTRODUCTION

Dilation and evaluation (D&E) is the most common technique used for second-trimester abortions. Because pre-operative dilation of the cervix with use of osmotic dilators, such as *Laminaria* or Dilapan-S®, decreases the risk of complications,¹ it has become standard procedure.^{2,3} Osmotic dilators are inserted several hours to days prior to a D&E procedure, and are usually inserted with no or mild sedation. As a D&E is typically performed under general or moderate sedation, the insertion of osmotic dilators is often the most painful part of the abortion experience. In studies comparing cervical preparation technique, participants typically rate the pain of osmotic dilator insertion as moderate to severe.^{4–8}

Paracervical blocks are used prior to many minor gynecologic procedures, including osmotic dilator insertion.^{3–10} Research, however, has demonstrated inconsistent efficacy in pain reduction during gynecologic procedures^{9,10} and the efficacy of a paracervical block specifically for osmotic dilator insertions has been understudied. Given that a paracervical block itself is a painful procedure and is associated with a low risk of complications, the ability of a paracervical block to reduce pain during osmotic dilator insertions should be demonstrated to justify its continued use. This study sought to assess if a paracervical block is effective at reducing the pain during placement of intracervical *Laminaria* for preoperative cervical preparation prior to second-trimester dilation and evacuation.

MATERIAL AND METHODS

We performed a double-blind, randomized controlled trial at the University of Hawaii Department of Obstetrics and Gynecology faculty practice offices in Honolulu, Hawaii, from May to December 2015. Participants were assessed for eligibility after completing informed consent for a dilation and evacuation procedure. Women were eligible for participation if they were at least 18 years old, between 14 and 23+6 weeks gestation, English-speaking, and had no contraindications to lidocaine. Women were excluded if they were incarcerated, had preterm premature rupture of membranes or evidence of intrauterine infection. Written consent for this study was obtained from all participants. This study was approved by the University of Hawaii Human Subjects Board and registered at ClinicalTrials.gov (NCT02454296).

After consenting to participate in the study, participants completed a questionnaire eliciting demographic and medical information. Participants were then randomized in a 1:1 ratio to receive either a paracervical block or a sham block prior to the *Laminaria* insertion procedure. A statistician not involved with the conduct of the study used computer-generated random allocations in permuted blocks with block sizes varying among 2, 4, and 6. The study assignments were then placed in sequentially numbered, opaque, sealed envelopes. A separate randomization scheme was created for each office location. The physician performing the *Laminaria* insertion procedure opened the study envelope and was the only research personnel aware of study assignment. Study personnel recording pain scale

responses remained blinded to study group by standing at the head of the bed facing the patient where they were unable to see the procedure.

All surgical trays were prepared with a 20 ml syringe loaded with 18 ml of 1% lidocaine and 2 ml of 8.4% sodium bicarbonate. The paracervical block and the sham control were developed based on a study by Renner et al⁹ which was the first randomized controlled trial evaluating paracervical blocks in first-trimester abortions that incorporated an appropriate control arm. Participants were asked to rate their baseline pain on a 100 mm visual analog scale (VAS), where 0=no pain and 100=worst pain in my life. The provider placed a speculum, cleansed the cervix with a povidone-iodine solution and placed a single-tooth tenaculum on the anterior lip of the cervix. Participants who were randomized to the treatment arm received the paracervical block injected over 60 seconds at the 2, 4, 8, and 10 o'clock positions at the cervicovaginal junction. Using a 25-gauge, 1-inch needle, providers advanced the needle to the hub, and injected the anesthetic while withdrawing the needle. In the control arm, the provider used the filled 20 ml syringe with a capped needle and applied pressure at the same four places at the cervicovaginal junction over the course of 60 seconds. Laminaria were then placed in the cervical canal, with the number of *Laminaria* determined by provider discretion. All procedures were supervised by one of four experienced attending physicians, and were performed by either the attending, a family planning fellow or a first year obstetrics-gynecology resident.

The primary outcome was the participant's self-reported pain on a 100-mm VAS immediately after *Laminaria* insertion. Secondary outcomes included: the participant's pain assessment after placement of the speculum, pain after the paracervical block procedure, and pain fifteen minutes post-*Laminaria*-insertion. Fifteen minutes post-*Laminaria* insertion, participants were also asked to rate their satisfaction with overall pain control and with the procedure (0=not at all satisfied and 100=very satisfied).

Based on results from the study by Renner et al.,⁹ we assumed that a paracervical block would reduce *Laminaria* insertion VAS pain scores by 25 mm with a standard deviation of 30 mm. We needed to enroll 36 patients, 18 in each group, to achieve 80% power while maintaining an alpha of 0.05. After inflating this number by 10% to account for potential dropout, we aimed to enroll a total of 40 participants (20 in each arm).

We compared the median pain reported immediately after *Laminaria* insertion in the paracervical block arm versus the sham block arm using Wilcoxon Rank-Sum test. We also used Wilcoxon Rank-Sum test to assess the secondary objectives by comparing the median difference in the pain perceived during other points in the procedure, satisfaction with the overall procedural pain and satisfaction with the *Laminaria* insertion procedure. Additionally, we assessed the trajectory of pain in each group during the insertion procedure to confirm that the primary finding was consistent with a linear mixed effects model,¹¹ which accounts for repeated measurements on the same patient. All data analyses were performed in SAS 9.3 (SAS Institute Inc., 2011). A two-tailed p-value of less than or equal to 0.05 was regarded as statistically significant.

RESULTS

During the study period, 108 D&Es were performed at 14 weeks gestation or above, and we screened 102 for eligibility. Participant flow is detailed in Figure 1. We excluded 61 patients including 19 who enrolled in another study we were concurrently conducting, and 29 who declined to participate. We enrolled 41 patients, with 20 randomized to the paracervical block arm and 21 randomized to the sham block arm. All participants received the intervention to which they were allocated and no one was lost to follow-up.

The two comparison groups were similar in demographic and peri-operative characteristics (table 1). The mean age in our study population was 27.9 ± 6.8 years. Most (56%) of the participants identified as “single, with a partner”, and 46% reported some college as their highest education level achieved. The majority (80.5%) of the participants had been pregnant before, and 39% (n=16) had had a prior surgical abortion. Our study population reflected the racial diversity of Hawaii, with 48.8% (n=20) of women identifying as Native Hawaiian or Pacific Islander, 29.3% (n=12) as Asian, and 22.0% (n=9) as Caucasian. The mean gestational age at presentation was 16.5 ± 1.9 weeks, and five of the D&Es (12.2%) were done for a fetal demise.

The median VAS pain scores for the *Laminaria* insertion procedure are shown in Figure 2. For the primary outcome, pain immediately after *Laminaria* insertion, women who received the paracervical block reported significantly lower levels of pain than women in the sham block group (median scores 13 mm [interquartile range 2–39] versus 54 mm [interquartile range 27–61], $p=0.01$, 95% confidence interval [CI] -47.0 – -4.0). The results of our linear mixed model accounting for repeated measurements confirmed the statistical significance of the difference in VAS pain scores between the paracervical block group and the sham block group for the primary outcome ($p=0.007$) (not shown). We found no difference in the pain associated with the paracervical block compared to the sham block (median scores 14 mm [interquartile range 6–31] versus 27 mm [interquartile range 6–41], $p=0.34$, 95% CI -25.0 – 6.0). Although our study was not powered for subset analyses, women in the paracervical block group who were 14–17+6 weeks gestation also reported less pain at *Laminaria* insertion (median scores 13 mm [interquartile range 1–25] versus 51 mm [interquartile range 27–73], $p=0.02$, 95% CI -50.0 – -4.0).

Table 2 shows how women rated their satisfaction for overall pain control during the laminaria insertion procedure and their satisfaction for the procedure. Women who received the paracervical block rated their satisfaction with overall pain control for the *Laminaria* insertion significantly higher than women in the sham block group (median scores 95 mm [interquartile range 78–100] versus 70 mm [interquartile range 44–90], $p=0.05$, 95% CI 0.0 – 37.0). In addition, throughout the study, there were no reported adverse events among study participants.

DISCUSSION

Our study supports the practice of using a paracervical block to reduce the pain associated with *Laminaria* insertion prior to a second-trimester dilation and evacuation. In addition to

reporting lower pain scores after *Laminaria* insertion, women who received a paracervical block reported higher satisfaction with overall procedure pain control. Because pain is subjective and pain at one point in time may be less important to a patient than pain over time, higher satisfaction with overall pain control during the *Laminaria* insertion may be the more clinically relevant outcome.

While our study was not powered to analyze subsets, there were enough participants in the lower gestational ages (14–17+6 weeks) to find a difference in *Laminaria* insertion pain scores. At these lower gestational ages, less dilation is needed, and therefore less *Laminaria* need to be placed. The pain scores reported by the women at these gestational ages suggests that even when only one or two *Laminaria* are inserted, a paracervical block may still be beneficial and clinically appropriate.

Despite widespread use of paracervical blocks for osmotic dilator insertion,^{3–8} there has been no prior evidence demonstrating its efficacy. In another study where pain after *Laminaria* insertion was the primary outcome, participants were randomized to receive either intrauterine lidocaine or intrauterine saline, in addition to a paracervical block.⁵ Investigators found no reduction in pain with the addition of intrauterine lidocaine. Furthermore, over 30% of participants reported moderate levels of pain with *Laminaria* insertion, highlighting the need to determine adequate analgesia for this procedure.

Strengths of our study include the randomized controlled study design with a sham block as a control, and that all participants completed the study in the group to which they were allocated. While using no sham block may have been a more realistic comparison, maintaining participant blinding through the use of a sham block reduced ascertainment bias. In addition, we conducted this study in a teaching facility, and 22% of participants, four in the treatment group and five in the control group, had most or all of their procedure performed by a first year obstetrics-gynecology resident. This mix of inexperienced and experienced providers increases generalizability of our results.

Several limitations are worth noting. Our study's paracervical block pain scores were lower than those in other published studies. In Renner et al,¹⁰ the mean pain associated with a paracervical block was 54 mm on a 100-mm VAS, and a paracervical block prior to intrauterine device insertion was reported as a mean pain score of 44 mm on a 100-mm VAS.¹¹ The median pain of a paracervical block in our study was 14 mm. The racial diversity of our study population, while reflective of the population in Hawaii, is unique and may affect the generalizability of our results to other communities.

Our *Laminaria* insertion pain scores were also lower than in other studies. In another published study where *Laminaria* insertion pain was the primary outcome, mean pain score was 33 mm on a 100-mm VAS for the group that received intrauterine lidocaine and a paracervical block.⁴ The median pain immediately after *Laminaria* insertion with a paracervical block in our study was 13 mm on a 100-mm VAS. Many studies have compared different cervical preparation techniques, and most of these describe use of a paracervical block prior to insertion of osmotic dilators for all participants. While the primary outcome of these studies was cervical dilation, mean pain scores after dilator insertion were 5.2 on an

11-point scale,⁵ 2 on a scale of 0–5,⁶ and 33 mm and 38 mm on a 100-mm VAS.⁹ Some of these other studies describe using 10 ml of anesthetic in the block,^{5,6} which might account for some of the difference and highlights the relative inconsistency in paracervical block technique among providers.

Over 100,000 D&Es are performed in the United States each year,¹² and a significant portion of these involve pre-operative insertion of osmotic dilators. Paracervical blocks prior to *Laminaria* insertion could be an effective technique for reducing the pain experienced by women during these procedures.

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Figure 1.
Study flow diagram.

Figure 2.

Distribution of pain scores during *Laminaria* insertion procedure and 15 minutes after insertion procedure. All comparisons analyzed using Wilcoxon rank sum test. *Colored boxes* indicate 25%–75% interquartile range, *lines* indicate nonoutliers, and *diamonds* indicate outliers.

Table 1

Demographic and perioperative characteristics

Characteristic	Sham block (n=21)	Paracervical block (n=20)
Age (years)	29.81 (6.92)	25.80 (6.12)
Race		
Caucasian	4 (19.1)	5 (25.0)
Asian	6 (28.6)	3 (15.0)
Asian multiethnic	1 (4.8)	2 (10.0)
Native Hawaiian or Pacific Islander	7 (33.3)	10 (50.0)
Native Hawaiian or Pacific Islander multiethnic	3 (14.3)	0 (0.0)
Marital Status		
Single, no partner	7 (33.3)	3 (15.0)
Single, with a partner	10 (47.6)	13 (65.0)
Married	4 (19.1)	4 (20.0)
Education		
Some high school	1 (4.8)	0 (0)
Graduated high school or high school equivalent	4 (19.1)	9 (45.0)
Some college	11 (52.4)	8 (40.0)
Graduated college	3 (14.3)	2 (10.0)
Post-college degree	2 (9.5)	1 (5.0)
Nulliparity	7 (33.3)	7 (35.0)
Previous surgical abortion	9 (42.9)	8 (40.0)
History of moderate or severe menstrual cramps	3 (14.3)	3 (15.0)
Gestational age (weeks)	17 (14–22)	16 (15–20)
BMI (kg/m ²)	26.1 (18.7–44.5)	26.5 (17.9–40.2)
Number of <i>Laminaria</i> placed	4 (1–5)	4 (2–6)
PGY-1 OB/gyn resident performed most of the procedure	5 (23.8)	4 (20.0)

Data are n(%), mean (+/– S.D.), or median (range)

BMI, body mass index; OB/gyn, obstetrics-gynecology

Table 2Overall pain control and satisfaction scores for the *Laminaria* insertion procedure on a 100-mm VAS

	Sham block (n=21) Median (IQR)	Paracervical block (n=20) Median (IQR)	P-value*
Overall pain control ("How satisfied were you with pain control for the procedure overall?")	70 (44,90)	95 (78,100)	0.05
Overall satisfaction ("How satisfied were you with the procedure?")	88 (60,98)	92 (68,100)	0.36

IQR, Interquartile range

*
Wilcoxon Rank Sum Test