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Original research article

Intrauterine lidocaine for pain control during laminaria insertion: a randomized controlled trial☆,☆☆,★

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Abstract

Objective: To determine if intrauterine administration of 5 cc of 2% lidocaine in addition to paracervical block reduces pain during laminaria insertion, when compared with paracervical block and saline placebo.
Study Design: This was a randomized, double blind placebo-controlled trial. Women presenting for abortion by dilation and evacuation (D&E) at 14–24 weeks gestational age were randomized to receive an intrauterine instillation of either 5 mL of 2% lidocaine or 5 mL of normal saline, in addition to standard paracervical block with 20 cc of 0.25% bupivacaine. Our primary outcome was self-reported pain scores on a 100 mm Visual Analogue Scale (VAS) immediately following laminaria insertion. Secondary outcome was self-reported VAS pain score indicating the maximum level of pain experienced during the 24–48-h interval between laminaria insertion and D&E procedure.
Results: Seventy-two women were enrolled, and data for 67 women were analyzed, only two of whom were more than 21 weeks on gestation. The range of pain scores at both time points was large (1–90 mm at laminaria insertion; 0–100 mm in laminaria–D&E interval). Mean pain scores were not different between treatment groups at laminaria insertion, (33 vs. 32, p=.8) or in the laminaria – D&E interval (43 vs. 44, p=.9).
Conclusion: Intrauterine administration of 5 cc of 2% lidocaine in addition to paracervical block did not reduce pain with laminaria insertion when compared to paracervical block with saline placebo.
Implications: Intrauterine lidocaine combined with paracervical block does not improve pain control at laminaria insertion when compared with paracervical block and saline placebo. Wide variation in pain scores and persistent pain after laminaria insertion suggests patient would benefit from more effective methods of pain control at laminaria insertion and during the post-laminaria interval.

Keywords: Abortion; Dilation and evacuation; Cervical preparation; Anesthesia

1. Introduction

Second trimester abortion by dilation and evacuation (D&E) requires greater cervical dilation than first trimester procedures; to improve safety the dilation is commonly done by placement of osmotic dilators such as laminaria one or two days before the D&E procedure [1–3]. Many women find laminaria placement painful if no anesthesia is used [4,5]; several studies have reported that the procedure may be associated with moderate to severe pain even when cervical or paracervical block is performed [6–8]. While multiple studies have evaluated various methods for controlling pain in abortion procedures [9], no studies to date have specifically evaluated different methods of pain control for laminaria insertion.

Innervation of the uterus is complex. Pain from the cervix and lower uterine segment is largely conducted via the utero-vaginal plexus to the inferior hypogastric plexus. However, some of the pain fibers from the uterine body may enter the hypogastric plexus at a level superior to the utero-vaginal junction [10,11]; additional afferent pain fibers from the

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uterine body may be carried along with the autonomic nerves which travel with the ovarian plexus[11]. While paracervical block can effectively control pain as conducted by the utero-vaginal plexus, additional procedure-related pain may be mediated by these other pathways which are unaffected by paracervical block. Pain control during gynecologic procedures may be improved by incorporating adjunctive techniques such as intrauterine instillation of local anesthetic agents which could provide anesthesia at these sites [12–14].

Several studies have shown that instillation of 5–10 mL of 1%, 2% or 4% lidocaine into the cervical canal and uterine cavity may produce clinically and statistically significant reductions in pain scores in endometrial biopsy [15–17], fractional curettage [18,19] hysteroscopy [20], saline infusion sonograms [21] and first trimester abortion [22]. In these studies, authors have shown reduction in pain during both uterine cavity instrumentation and cervical dilation and manipulation [19,22]. Much of the pain of laminaria insertion is related to cervical manipulation, and is predominantly mediated by the lower plexus. That moderate to severe pain is frequently reported with laminaria insertion even when paracervical block is used suggests that these other innervation pathways may also be involved in procedure-related pain. Given the effectiveness of intrauterine anesthetic in other procedures, we hypothesized that it could be effective in controlling pain associated with laminaria insertion as well. We performed a randomized clinical trial to evaluate the effectiveness of intrauterine anesthesia plus paracervical block in improving pain scores during laminaria insertion when compared with saline placebo and paracervical block.

2. Materials and methods

This study was performed in the Family Planning clinic of the University of North Carolina at Chapel Hill from April 2012 to November 2013. Study participation was offered to patients with singleton or multiple pregnancies between 14 and 24 weeks of gestation presenting to the clinic for elective outpatient abortion by D&E. Women were eligible for enrollment if they were over 18 years of age, English speaking, weighed over 45 kg, had no contraindications to receiving lidocaine, and were expected to have D&E completed within 48 h after laminaria insertion. Women undergoing D&E for rupture of membranes or infection were not eligible for this study. Standard practice at our clinic is to perform D&E 48 h after laminaria insertion, though occasionally D&E procedures are scheduled to be completed earlier, typically 24 h after laminaria insertion, if a patient's individual circumstances require expedited care. The study was approved by the institutional review board (IRB) of the University of North Carolina at Chapel Hill and registered at ClinicalTrials.gov (NCT01541293).

Patients were approached by research staff regarding the study after standard surgical consent for D&E was completed. After study enrollment and informed consent, participants were randomized in a 1:1 ratio to receive an intrauterine instillation of either 5 mL of 2% lidocaine or 5 mL of normal saline as placebo. Both participants and providers were blinded to treatment. Randomization was accomplished with a computer generated block randomization scheme using randomly permutated blocks of four, six and eight. The randomization sequence document was generated prior to study initiation by a member of the research team not involved in participant enrollment or care. The randomization document indicated treatment arm "placebo" or "lidocaine" for each sequential participant number. The randomization document was held by the institutional Investigational Drug Services (IDS) pharmacy. Research staff involved in patient care did not have access to the randomization sequence at any time during the study. After participant enrollment, the IDS pharmacist would note the treatment arm assignment for that sequential participant number; the IDS pharmacist then prepared the appropriate study medication. The medication was dispensed to a research staff member in a syringe labeled only with the study ID number. The syringes containing either lidocaine or placebo which were handled by the study staff were visually identical.

All participants underwent laminaria insertion using standard clinical practices. After speculum insertion, the cervix was cleaned with betadine solution. One cc of 0.25% bupivicaine was injected into the anterior lip of the cervix. The anterior lip of the cervix was grasped with a single tooth tenaculum. Paracervical block using 19 cc of 0.25% bupivicaine was then placed by injection at the 8-o'clock and 4-o'clock positions at a depth of approximately 1 cm. The study medication was then instilled into the cervical canal using a Uterine Explora catheter (Cooper Surgical MX 130 Model 2 – uterine biopsy pipelle with a luer lock for syringe attachment). The catheter was inserted to the internal os of the cervix and the medication was administered with a slow push over 30 s, instilling the medication into the uterus just above the internal os. The catheter was held in place for 60 s after completed push to prevent backflow from the cervical os. The catheter was removed and the laminaria insertion was completed. All laminaria were placed by an attending physician, family planning fellow, or senior resident. Three attending physicians, three fellows and seven residents were involved in the clinical care in the study. The total number of laminaria inserted was determined by the gestational age and clinical judgment. The goal for all participants was placement of the maximum number of laminaria and serial insertion continued until the supervising attending concurred that no further laminaria could be safely placed. Participants were instructed to take 600 mg ibuprofen as needed for pain at home following the insertion.

Our primary outcome was participant self-report of pain score on a 100 mm visual analogue scale (VAS) immediately following the procedure (0=no pain; 100=worst pain imaginable). All pain scores were recorded within 2 min of