Hysteroscopic local anesthetic intrauterine cornual block in office endometrial ablation: a randomized controlled trial

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Objective: To evaluate the efficacy of a hysteroscopic local anesthetic intrauterine cornual block (ICOB) on pain experienced during office endometrial ablation (EA) in addition to a traditional direct local anesthetic cervical block (DCB).
Design: Prospective, randomized, double-blind, placebo-controlled trial.
Setting: University teaching hospital.
Patient(s): Women with heavy menstrual bleeding scheduled for an office endometrial ablation.
Intervention(s): Before office EA, DCB plus hysteroscopic ICOB just medial to each tubal ostium using local anesthetic mixture made up of 1 mL 3% mepivacaine plus 1 mL 0.5% bupivacaine versus control group receiving DBC plus ICOB with 2 mL of placebo (saline).
Main Outcome Measure(s): Primary outcome: pain reported during procedure via visual analogue scale (VAS) from 0 to 10; secondary outcomes: postoperative pain, rescue analgesic requirement, and duration of hospital stay.
Result(s): Most characteristics were similar across groups. The mean VAS score during the procedure was statistically significantly lower by 1.44 (95% confidence interval, −2.65 to −0.21) in the active group compared with the placebo group. There were no statistically significant differences between the two groups in the postprocedural mean VAS scores, rescue analgesic requirement, or duration of hospital stay.
Conclusion(s): Used in addition to DCB, ICOB reduces the pain experienced during office EA compared with DCB alone.
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Key Words: Heavy menstrual bleeding, office endometrial ablation, pain control

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The usual intervention to control pain during an office endometrial ablation (EA) has been to use a direct cervical block (DCB) (1–3). However, it is well recognized that this method alone does not achieve satisfactory uterine anesthesia during the procedure because pain can be perceived from the upper half of the uterus, especially of the uterine fundus (4–7). The best approach to provide better pain control during the procedure has yet to be determined (5, 6).

The uterus has complex innervations (Supplemental Fig. 1, available online). Pain perception from the cervix and the corpus of the uterus is suggested to pass through two distinct neural pathways (8, 9). The cervix and lower half of the uterus is primarily innervated from the uterovaginal plexus, largely derived from the parasympathetic sacral S1–4 nerve roots, whereas the upper half of the uterus is innervated from the thoracic nerves, largely derived from the sympathetic fibers of the superior hypogastric plexus T8-T10 and L1 roots. These latter nerve fibers enter the uterus along the infundibulopelvic ligament and the path of the ovarian arteries (10). Therefore, specific targeting of the latter nerve pathway with an additional intrauterine myometrial cornual block (ICOB) may result in an

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improved anesthesia during office EA in addition to the traditional cervical block.

We initially carried out a pilot study to produce a well-designed protocol for a randomized, placebo-controlled trial by evaluating the safety, feasibility, and acceptability of a hysteroscopic intrauterine cornual block in combination with DCB during in-office Gynecare ThermaChoice (Ethicon) EA (11). The findings of the pilot study suggested that the ICOB could be successfully used to reduce women's experience of pain during office EA with a cervical block.

In this prospective, randomized, double-blind, placebo-controlled trial, we assessed the effectiveness of hysteroscopic ICOB for pain relief during office EA with the traditional DCB. Our secondary objectives were to assess whether the intervention was associated with less postprocedure pain, a reduced hospital stay, and decreased rescue analgesics requirement during the postoperative period before discharge from the hospital.

MATERIALS AND METHODS

This study was performed from February 2013 to January 2015 at Birmingham Women's Hospital, United Kingdom, a university teaching hospital. The study design and randomization protocol were approved by the National Research Ethics Service (NRES) Committee of West Midlands, South Birmingham (12/WM/0411). The intervention included administration of a hysteroscopic injection into the myometrium just medial to each tubal ostium using a local anesthetic (LA) solution consisting of a total of 2 mL of mixture made up of 1 mL of 3% mepivacaine (fast acting) and 1 mL of 0.5% bupivacaine (long acting) (AstraZeneca) or 2 mL of normal saline (placebo) before office EA.

All women between the ages of 18 and 50 years presenting to the gynecology office clinic with heavy menstrual bleeding refractory to medical treatment who had consented to an office EA under LA were offered the ICOB (focal local) in addition to DCB (direct local) during the procedure. The study protocol and procedure were explained and written information was provided so that the women could find out more about the study before deciding whether to participate.

Women with contraindications to EA such as atypical endometrial hyperplasia or endometrial cancer, undiagnosed abnormal vaginal bleeding, current lower pelvic infection or uterine abnormalities, past allergic reactions to LA agents, distorted uterine cavity, or submucosal fibroids >3 cm size were excluded from the study. Women taking antidepressants were not excluded from the study, but women who were considered vulnerable, such as those with a current mental illness, who were emotionally labile, or had learning difficulties were excluded from the study. Women who declined to be randomized or requested the additional anesthetic were also excluded.

Written informed consent for the procedure was obtained by the operating clinician (J.K.G. or V.K.) on the gynecologic ward on the day of the procedure during the preoperative ward round before randomization. All participants were advised on how to complete the visual analogue scale (VAS) chart. It was explained that one extreme of the ungraduated 10-cm horizontal line represents "no pain at all" and the other represents "worst pain as you can possibly imagine." They were asked to record their recollection of pain during childbirth (distant) and menstrual period (moderately distant) by placing an "X" mark on the line. Nulliparous patients or those with only scheduled cesarean deliveries were advised to record the menstrual pain only. These baseline VAS pain scores were collected to perform an adjusted analysis of the pain scores after the intervention (12). Patients were then asked to complete a similar VAS after the LA injection into the cervix, the cornual block, immediately after the EA procedure, at 1 hour after the procedure, and before discharge from hospital.

Afterward, the operating clinician completed a randomization form by answering questions relating to the patient's eligibility and baseline details. The randomization form was then faxed immediately to the trial coordinator at the Birmingham Clinical Trials Unit, who had not seen the patient and had not been involved in the recruitment process. The women were randomized to receive ICOB with LA or matching placebo (normal saline) using variable block randomization (13).

The trial coordinator informed an independent nurse of each woman's number and the treatment allocation group. This independent nurse, who was already provided with identical 2-mL syringes prefilled with either 2 mL of LA or 2 mL of normal saline, labeled the appropriate syringe with the study identification number only and delivered it to the operating team. The surgeon, assistant nurses in the procedure room, and the patient were all blinded to the identity of the medication in the syringe.

All women were allowed to have a normal breakfast on the ward. Women without contraindications were premedicated 1 hour before the procedure with oral analgesics (50 mg of diclofenac and two co-dydramol tablets [20 mg of dihydrocodeine and 1 g of paracetamol]) and an antiemetic (cyclizine, 50 mg orally) (4, 11). Women with contraindications to diclofenac such as hypersensitivity, peptic ulcer, severe asthma, or ischemic heart disease were given co-dydramol tablets only with an antiemetic.

The office EA was performed by two clinicians (J.K.G., V.K.) in the one-stop hysteroscopy clinic. During the procedure, every effort was made to keep the procedure room a relaxed and comfortable environment. Two dedicated registered nurses and one health-care assistant were present to support the clinician performing the procedure. The patient was positioned on the couch in a lithotomy position, and a health-care assistant stood beside her to offer psychological support (vocal local).

The clinician visualized and cleaned the cervix, and a single-tooth tenaculum was applied to stabilize the anterior lip of cervix. A DCB was administered to all women using 6.6 mL of 3% mepivacaine hydrochloride (Scandonest; Septodont), infiltrating deep to the cervical isthmus level at 12, 3, 5, 6, 7, and 9 o'clock positions using a dental needle (Solosupra) (direct local) (4, 7). After the DCB, a 3.5-mm Versascope (Gynecare, Ethicon) was passed into the uterine cavity to inspect the uterine cavity and visualize both tubal ostia.

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