GYNECOLOGY

Utility of anesthetic block for endometrial ablation pain: a randomized controlled trial

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BACKGROUND: Second-generation endometrial ablation has been demonstrated safe for abnormal uterine bleeding treatment, in premenopausal women who have completed childbearing, in short-stay surgical centers and in physicians' offices. However, no standard regarding anesthesia exists, and practice varies depending on physician or patient preference and hospital policy and setting.

OBJECTIVE: The aim of this study was to evaluate whether local anesthetic, in combination with general anesthesia, affects postoperative pain and associated narcotic use following endometrial ablation.

MATERIALS AND METHODS: This was a single-center single-blind randomized controlled trial conducted in an academic-affiliated community hospital. A total of 84 English-speaking premenopausal women, aged 30 to 55 years, who were undergoing outpatient endometrial ablation for benign disease were randomized to receive standardized paracervical injection of 20 mL 0.25% bupivacaine (treatment group) or 20 mL normal saline solution (control group) upon completion of ablation. The study was designed to test a 40% 1-hour mean visual analog scale (VAS) pain score difference with an average standard deviation of 75% of both groups' mean VAS scores, using a 2-tailed test, a type I error of 5%, and statistical power of 80%. A sample of 36 patients per study group was required. Assuming a 15% attrition rate, the study enrolled 42 patients per study arm randomized in blocks of 2 (84 total). Two-tailed cross-tabulations with Fisher exact significance values where appropriate and Student *t* tests were used to compare patient characteristics. Backward stepwise regressions were conducted to control for confounding.

RESULTS: Between April 2016 and February 2017, a total of 108 women scheduled for endometrial ablation were screened (refusals, n = 21; ineligible, n = 3) to determine whether there were meaningful differences in postoperative VAS pain scores and postoperative narcotic use. Of the 84 randomized women, 2 age-ineligible women were excluded. Intent-to-treat analyses included 1 incorrect randomization (in which the provider consciously decided to provide analgesia regardless of the protocol, after which the provider was excluded from further study participation) and 3 women having no ablation because of operative difficulties. Three were lost to second-day follow-up. Treatment group patients (n = 41) experienced 1.3 points lower 1-hour postoperative VAS pain scores than the control group (n = 41, $P = .02$). The difference diminished by 4 hours ($P = .31$) and was negligible by 8 hours ($P = .62$). Treatment group patients used 3.6 less morphine equivalents of postoperative pain medication ($P = .05$). Regression analyses controlled for confounding reduced the 1-hour postoperative treatment group pain score difference to 0.8 (confidence interval [CI], −0.6 to 0.1) but slightly increased the average postoperative morphine equivalents to 3.7 (CI, −6.8 to −0.7).

CONCLUSION: This randomized controlled trial found that local anesthetic with low risk for complications, used in conjunction with general anesthesia, decreased postoperative pain at 1 hour and significantly reduced postoperative narcotic use following endometrial ablation. Further research is needed to determine whether the study results are generalizable and whether post procedure is the best time to administer the paracervical block to decrease endometrial ablation pain.

Key words: endometrial ablation, general anesthesia, postoperative narcotic, postoperative pain

Endometrial ablation is a same-day surgical procedure for the treatment of abnormal uterine bleeding in premenopausal women who have completed childbearing.[1] These minimally invasive surgical procedures provide women the possibility of avoiding major gynecologic surgery.[2] Second-generation endometrial ablation has been demonstrated to be safely performed both in short-stay surgical centers and in physicians' offices.[3-9] No standard exists regarding anesthesia for these procedures, as techniques vary depending on physician or patient preference, practice climate, and hospital policy. Frequently, when endometrial ablation is performed as an outpatient procedure, patients are premedicated and also receive a paracervical injection of local anesthetic to control pain during the procedure.[3,5,9-11]

Anesthetic techniques may vary from nothing, to oral medication with or without a paracervical injection, to general anesthesia, all of which have been shown to be acceptable methods.[12-14] In this large academic-affiliated community hospital center, endometrial ablations are performed as outpatient procedures under general anesthesia with a variety of induction techniques and intraoperative pain management practices. According to physician preference, patients may receive an additional paracervical injection of local anesthetic before the procedure, immediately after, or not at all. To date, there are no randomized controlled trials evaluating the efficacy of local anesthetic in addition to general anesthesia for patients undergoing endometrial ablation.

Materials and Methods

After obtaining institutional review board (IRB) approval and registering the study with Clinicaltrials.gov (NCT02660918), we performed a single-blind randomized controlled trial. Patients were English-speaking premenopausal women aged 30 to 55 years

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who were scheduled to undergo outpatient endometrial ablation for benign indications.

The primary outcome assessed was a decrease in the mean 10-point visual analog scale (VAS) postoperative pain score at 1 hour after the operation. A 40% decrease was used based upon results of a separate IRB-approved retrospective chart review of the 124 most recent patients who underwent an endometrial ablation at the study institution.[15] That chart review identified 20 patients who underwent an endometrial ablation without any additional local anesthesia in the form of a paracervical block; the mean postoperative pain score at 1 hour was 2.85 ± 2.21. The 40% hypothesized reduction in pain is equivalent to approximately 1 full point on the VAS and is believed to be a clinically meaningful decrease at the lower end of the VAS that could influence policy and practice at the study site. The average standard deviation between the mean 1 hour postoperative pain scores of the 20 most recent patients who received a paracervical block and the 20 who did not was 1.78, approximately equal to 75% of the average mean pain scores for the 40 patients.

Using a 2-tailed t-test, a type I error of 5%, a statistical power of 80%, and an average standard deviation equal to 75% of the average VAS scores in both groups, the study required a sample of 36 patients per study group to test the primary outcome, the difference in mean VAS scores. The study thus enrolled 42 patients per arm assuming a 15% attrition rate (84 total participants). Secondary outcomes include the study group postoperative pain scores at 4 and 8 hours following surgery, the amount of narcotic used postoperatively prior to discharge, time to discharge, postoperative nausea/vomiting requiring medication, blood loss, and amount of oral narcotic medication used by postoperative day 1 after discharge. Over-the-counter medications taken postoperatively by participants at home were not assessed.

All eligible participants were recruited from a single academic-affiliated community hospital with an on-site same-day surgical center for all outpatient endometrial ablation procedures between April 2016 and February 2017. Women were excluded if they met any of the following criteria: endometrial ablation performed for an indication related to any gynecologic malignancy, weight less than 50 kg, known amide or dilaudid/codeine allergy, history of chronic pain or chronic opioid use, cardiac arrhythmia, inability to take pills by mouth, uterine anomaly, previous endometrial ablation, or a primary language other than English. Written informed consent was obtained from each patient on the day of their procedure. Although this may potentially influence patients' reported pain score, the randomized design would minimize the chance of between-group bias. Furthermore, the 40% hypothesized pain difference with a group average standard deviation of 75% to estimate the required sample size is applicable to any specific mean pain score, thus ruling out any potential for a systematic error to mar the true effect.

In accordance with anesthesia policy at the study institution, outpatient endometrial ablations are performed under general anesthesia. Once consented, patients were randomized by computer-generated numbers (www.randomizer.org) in blocks of 2 to either the treatment group or control group to ensure enrollment of equal numbers of patients to each group. Those randomized to the treatment group received a paracervical injection of 0.25% bupivacaine (Marcaine Bupivacaine Hydrochloride Injection, Pfizer Inc, New York, NY) at the completion of the procedure. Patients randomized to the control group received an equal-volume injection of normal saline solution with the same paracervical technique. Intraoperative pain control was at the discretion of the anesthesia provider and administration of postoperative ketorolac tromethamine (Toradol, Sagent Pharmaceuticals, Schaumburg, IL) was based on physician preference. Paracervical injection in both groups was standardized to a total dose of 20 mL divided into four 5-mL injections at the 2, 4, 8, and 10 o'clock positions on the cervix.[16]

Once general anesthesia had been induced, the circulating nurse opened the study patient's unique randomization sequence, maintained in an opaque envelope, and the appropriate study solution was drawn in the operating room. The operating room team including the surgeon, anesthesiologist, and ancillary staff were aware of the injected solution's content. The patient and postanesthesia care unit (PACU) staff were blinded to the injected solution. The patients were responsible for reporting their immediate and delayed postoperative pain, with no involvement from the operating room personnel. All staff caring for the patient postoperatively were blinded to the study solution except if necessary for any unexpected complication, in which case the principal investigator maintaining the randomization coding was able to break the code for that particular patient. As there were no unexpected complications, no incidences of code breaking occurred during the study period.

Because of the study institution's infrastructure, following their procedure, patients are taken directly from the operating room to the PACU, where their pain is assessed on arrival by trained nursing staff blinded to the patients' study group allocation. Patients are generally kept in an initial period (phase 1) of recovery for at least 30 minutes, and again for at least 30 minutes in phase 2 before discharge. At a minimum, a postoperative patient's pain is assessed every 10 minutes in phase 1, and every 15 minutes in phase 2. Patients are candidates for rescue analgesic medications if their VAS pain score is greater than 5 out of 10 on a pain VAS of 0 through 10. In phase 1, pain medication is generally given in intravenous form, whereas in phase 2, pain medication is usually given orally. Pain scores, as well as all medications administered, are routinely recorded by the nursing staff and entered into the patient's electronic health record.

Upon discharge, all patients were given 2 additional 10-point VAS forms and were instructed by nursing staff to complete them, respectively, at 4 and 8 hours after their surgery. These pain scales were labeled before discharge with the patient's study identification code,