CLINICAL STUDY

Intraarterial Lidocaine for Pain Control in Uterine Artery Embolization: A Prospective, Randomized Study

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ABSTRACT

Purpose: To assess efficacy of two different techniques of lidocaine injection in the uterine arteries to reduce pain following uterine artery embolization (UAE) for leiomyomas.

Materials and Methods: This prospective randomized single-blinded study was performed with 60 patients enrolled between November 2014 and December 2015 equally randomized to 3 arms. Group A received 10 mL lidocaine 1% (100 mg) mixed with polyvinyl alcohol particles (355–500 μm). Group B received the same dose of lidocaine injected after embolization. Group C was a control group. Pain was assessed on a 100-point visual analog scale at 4, 7, and 24 hours after the procedure. Narcotic agent dose to 24 hours was recorded. Outcomes were examined by analysis of variance and pairwise comparison. Leiomyoma infarction was assessed with magnetic resonance imaging 3 months after the procedure.

Results: Technical success rate of UAE was 100%. Mean pain score at 4 hours was significantly lower in the lidocaine groups (group A, 28.6; group B, 35.8) compared with the control group (59.4; $P = .001$). Pain scores at 7 and 24 hours were not statistically different among the 3 arms. The mean in-hospital narcotic agent dose was significantly lower in both lidocaine groups than in the control group (group A, 8.5 mg [$P = .002$]; group B, 11.1 mg [$P = .03$]; group C, 17.4 mg). There were no adverse events related to the use of lidocaine. The number of patients with complete infarction of leiomyomas at 3 months was significantly lower in group A at 38.9% (group B, 77.8%; group C, 75%; $P = .0451$).

Conclusions: Lidocaine injected in the uterine arteries reduced postprocedural pain and narcotic agent dose after UAE. There were more cases of incomplete necrosis when lidocaine was mixed with the particles.

ABBREVIATIONS

PVA = polyvinyl alcohol, SD = standard deviation, UAE = uterine artery embolization, VAS = visual analog scale

Uterine artery embolization (UAE) is a validated minimally invasive treatment for women with symptomatic uterine leiomyomas (ie, fibroid tumors). It has been shown that UAE is safe and effective in improving patients' symptoms (1–8). The greatest challenge in the management of patients undergoing UAE is postprocedural pain. To some extent, all patients experience cramping pain after a UAE procedure. In a study evaluating 290 patients (9), 35% of women undergoing UAE experienced pain equal or worse than that of labor despite antiinflammatory drugs and patient-controlled analgesia (9). The exact cause of the pain is not known, but it is generally believed to be secondary to uterine ischemia (10). High narcotic agent doses are often needed to control the pain, with side effects such as

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From the SIR 2016 Annual Meeting.

K.T.T. receives personal fees from Cook (Bloomington, Indiana) and grants from Cook, Biotronik, Medtronic (Dublin, Ireland), Boston Scientific (Marlborough, Massachusetts), and W.L. Gore & Associates (Flagstaff, Arizona). None of the other authors have identified a conflict of interest.

J Vasc Interv Radiol ▮▮▮▮; ▮:▮▮▮–▮▮▮

http://dx.doi.org/10.1016/j.jvir.2016.10.001

nausea, drowsiness, and constipation. Lidocaine is a widely used intermediate-acting local anesthetic agent of the amide type. It has been used intraarterially to reduce pain in hepatic chemoembolization (11) and for analgesia in peripheral arteriography (12–16). The aim of the present study was to assess the efficacy of two methods of administration of lidocaine in the uterine arteries in reducing pain and narcotic agent dose after UAE.

MATERIALS AND METHODS

This study was approved by the hospital's research ethics board. Participation was voluntary, and informed consent was obtained in all patients before enrollment and randomization.

Study Design

This study was a prospective, randomized clinical trial. Patients were randomized to one of three groups: lidocaine injected during embolization (group A), lidocaine injected after embolization (group B), and control (group C). Randomization was done by using permuted blocks of size two and four. There were no stratification factors considered. Sealed envelopes were used to identify the strata of assignment. This study was single-blinded with patients unaware in which group they were randomized, but the operators and the study team were informed of the randomization assignment considering the differences in the lidocaine injection for the two test groups. Primary outcome was defined as the pain level evaluated 4 hours after the procedure. Secondary outcomes included pain scores at 7 hours and 24 hours, narcotic agent dose in the first 24 hours, time to discharge, and degree of leiomyoma infarction at 3 months.

Inclusion and Exclusion Criteria

For the embolization procedure, inclusion criteria were (*i*) uterine leiomyomas documented by a recent pelvic magnetic resonance (MR) imaging scan (less than 6 mo earlier); (*ii*) one or more symptoms such as heavy menstrual bleeding, dysmenorrhea, pelvic pressure, or urinary frequency; (*iii*) preference for UAE versus surgical options such as myomectomy; and (*iv*) no acute or chronic pelvic infection or uterine or ovarian malignancy. Exclusion criteria were (*i*) a previous UAE procedure, (*ii*) documented history of allergy or intolerance to lidocaine or other anesthetic agents of the amide type, and (*iii*) documented history of second- or third-degree atrioventricular heart block.

Patients

Between November 2014 and December 2015, 70 patients were screened. Three patients were excluded (previous UAE in two patients and atrioventricular node dysfunction for one). Seven patients refused to participate in the study. A total of 60 patients were consented and randomized equally into three groups of 20 patients. Patients provided consented to the study and were enrolled by a study coordinator. Mean age was 46.7 years ± 5.7 (standard deviation [SD]). Patient characteristics are presented in Table 1. There were no significant differences in age, race, parity status, presenting symptom, or uterine or leiomyoma size among groups.

Embolization Procedure

Procedures were performed by four interventional radiologists with 17, 17, 17, and 14 years of experience in performing UAE, respectively. As standard of care, before intervention, a Foley catheter was inserted in the bladder and a peripheral intravenous access was obtained. One hour before the procedure, patients received acetaminophen 1,000 mg, ibuprofen 400 mg, and controlled-release oxycodone 10 mg orally, and ondansetron 4 mg and dexamethasone 6 mg intravenously over 30 minutes (Sandoz; Boucherville, Quebec, Canada).

The procedures were performed under mild conscious sedation with fentanyl and midazolam (Sandoz) with electrocardiographic and oxygen saturation monitoring and nurse surveillance. The randomization envelope was opened by a study coordinator as the procedure was started. The right common femoral artery was used for access in all patients. A 5-F Roberts catheter (Cook, Bloomington, Indiana) was used for uterine artery catheterization and for embolization. Microcatheters were used only when there was marked tortuosity of the arteries or catheter-induced spasm. The left uterine artery was embolized first, with the catheter in the horizontal portion of the uterine artery. All patients received 355–500-μm nonspherical polyvinyl alcohol (PVA) particles (Contour; Boston Scientific, Marlborough, Massachusetts). The embolization endpoint was stasis of flow in the horizontal portion of the uterine artery for five cardiac beats.

Lidocaine Injection

For patients randomized to test group A (lidocaine during embolization), the first vial of PVA was mixed with 10 mL of contrast agent (iodixanol 320 mgI/mL; Visipaque; GE Healthcare, Little Chalfont, United Kingdom) and 10 mL (100 mg) of lidocaine 1% (Xylocaine; Alveda, Toronto, Ontario, Canada).The mixed particles and lidocaine were injected under fluoroscopic visualization. If more particles were needed, subsequent vials were mixed with 10 mL of contrast agent and 10 mL of saline solution. For patients randomized to test group B (lidocaine after embolization) and test group C (control group), each vial of particles was mixed with 10 mL of contrast agent and 10 mL of saline solution. For patients in test group B,