

# Tubal surface lidocaine mediates pre-emptive analgesia in awake laparoscopic sterilization: A prospective, randomized clinical trial

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**OBJECTIVE:** The purpose of this study was to determine whether lidocaine that is instilled onto the Fallopian tubes reduces pain scores in awake patients who undergo laparoscopic sterilization with Filshie clips.

**STUDY DESIGN:** This was a prospective, randomized, placebo-controlled, double-blinded, clinical trial study that was approved by our institutional review board.

**RESULTS:** Pain scores (visual analogue scales) were lower in the lidocaine group (n = 12 patients) than in the placebo group (n = 12 patients) at clip application (6 vs 71 mm;  $P < .0001$ ) and after 15 minutes after operation (15.5 vs 44.5 mm;  $P < .005$ ). No significant differences occurred at 1-hour after operation or discharge, but more rescue analgesia was required in the placebo group ( $P < .05$ ), with more side effects ( $P < .05$ ). In a separate group of 20 women, serum lidocaine levels were measured (maximum level, 16.0  $\mu\text{mol/L}$ ). Holter monitoring of these patients revealed no significant arrhythmias.

**CONCLUSION:** One percent lidocaine that is instilled onto the Fallopian tubes reduces pain scores in awake patients who undergo laparoscopic sterilization with Filshie clips. (Am J Obstet Gynecol 2002;186:383-8.)

**Key words:** Laparoscopic sterilization, Filshie clip, outpatient, local anesthesia, analgesia, lidocaine

Laparoscopic sterilization is a common gynecologic procedure, usually performed in an outpatient setting. Although categorized as minor surgery, it can be associated with significant postoperative pain<sup>1</sup> and result in a prolonged recovery period and even hospital admission.<sup>1-3</sup>

The specific form of tubal interruption can influence the extent of postoperative pain. Electrocautery appears to be associated with the least postoperative pain<sup>4-6</sup>; but the attendant complications, particularly with unipolar diathermy, are potentially more serious.<sup>7</sup> Tubal rings produce the most pain during and after occlusion,<sup>8</sup> and fallopian clips cause intermediate levels of pain.<sup>8</sup>

Several analgesic strategies have been introduced to reduce perioperative pain. In addition to the use of the more traditional narcotic and nonnarcotic analgesics, several treatment modalities that use local anesthetics have been developed. Local anesthetics have been applied topically as solutions to the fallopian tubes,<sup>2,6</sup> in gel form to the clip/ring before application,<sup>9,10</sup> injected into the mesosalpinx,<sup>11</sup> or instilled per cervix into the fallop-

ian tubes.<sup>12</sup> Local anesthetics have also been instilled in relatively large volumes into the peritoneal cavity to reduce subdiaphragmatic and shoulder pain caused by residual pneumoperitoneum.<sup>13</sup>

Since the 1970s there has been some enthusiasm in the gynecologic literature for the use of local anesthetic solutions that are applied topically to the fallopian tubes at the time of occlusion. Large series of patients were thus successfully sterilized while receiving local anesthesia with minimal postoperative pain or other associated morbidity.<sup>14</sup> As a technique, it is easy to learn, is not likely to be associated with risks of mesosalpinx injection (bleeding, intravascular or visceral injection), and does not require cervical manipulation (which is itself painful, vagotonic, and emetogenic) or the large volumes of local anesthetic needed for intraperitoneal instillation.<sup>13</sup> However, most of these early reports are limited by poor design. Many were not placebo controlled<sup>2,6,15</sup> and lacked randomization,<sup>6,15</sup> blinding,<sup>2,15</sup> or the use of a valid and reliable method of pain measurement.<sup>16,17</sup> Some ingenious studies anesthetized 1 fallopian tube and rated the pain of each side separately<sup>16,17</sup> without demonstrating whether patients can reliably locate the source of pelvic pain under these circumstances. Furthermore, some patients underwent second procedures<sup>17</sup> for which they had been given an additional paracervical block.

Noxious stimuli, once initiated, may produce prolonged changes in central neural processing that contribute to postoperative pain and associated pain behavior

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0002-9378/2002 \$35.00 + 0 6/1/121079  
doi:10.1067/mob.2002.121079

long after central afferent input has ceased.<sup>18</sup> This phenomenon of neuroplasticity has resulted in the practice of preventative or pre-emptive analgesia.<sup>19</sup> The technique of laparoscopic sterilization with the use of local anesthesia with minimal sedation provides a unique opportunity to clinically test whether the application of local anesthesia to the fallopian tubes, before occlusion, minimizes the immediate noxious stimulus and continues to have an effect into the recovery period and beyond.

The present study was therefore designed to determine the analgesic effect of the topical application of a solution of local anesthetic to the fallopian tubes in awake patients who undergo Filshie clip tubal occlusion.

### Material and methods

This study was approved by the Institutional Review Board and was a prospective, randomized, double-blinded, and placebo-controlled clinical trial. To achieve a power of 0.9 and an alpha of .05, it was determined that 11 patients were required per group to detect a difference in visual analogue scale (VAS) pain scoring of at least 30 mm. Therefore, 24 women who were rated as American Society of Anesthesiologists Physical Status 1 (healthy) and 2 (mild systemic disease, no functional limitations) were enrolled, after giving informed consent.

The patients were randomized by computer-generated random number allocation to receive either 1% lidocaine or normal saline solution instilled onto each fallopian tube (5 mL of solution per fallopian tube) before tubal occlusion, which resulted in 2 groups: the active treatment "lidocaine group" and the control "placebo group," respectively.

After consent and before premedication, the pain scales were explained to the patients. A 100-mm VAS (where zero represented "no pain at all" and 100 represented "the worst pain imaginable") and a categoric word score (CWS; where 1 = none, 2 = mild, 3 = moderate, 4 = severe pain) were used for pain scoring.

Premedication was with 2 tablets of Aspav (500 mg aspirin and 10 mg papaveretum per tablet). Papaveretum is a mixed opium alkaloid drug and contains the equivalent of anhydrous morphine 47.5% to 52.5%, anhydrous codeine 2.5% to 5%, noscapine 16% to 22%, and papaverine 2.5% to 7%. Papaveretum (10 mg) is approximately equal to morphine (6.25 mg). The Aspav was taken orally 1 hour before the operation. After intravenous access was secured, the surgeon marked the proposed point of instrument entry in the subumbilical and suprapubic regions and demonstrated the expected angle of entry of each instrument. The patient was then sedated with 25 mg of meperidine and 2.5 mg of midazolam, which was given intravenously in divided doses until she felt ready to proceed.

Forty milliliters of 1% lidocaine with 1:200,000 epinephrine was infiltrated intra- and subdermally, which ensured that most of the solution was applied to the parietal peri-

toneum. Care was taken to follow the expected angle of instrument entry previously demonstrated by the surgeon. The patient was allowed to rest for a few minutes then walked with assistance from the procedure room into the operating room. The surgical procedure was performed as previously described,<sup>20</sup> with insufflation of 1 to 1.5 L of nitrous oxide rather than the more irritant carbon dioxide.

The study solution (lidocaine 1% with 1:200,000 epinephrine or placebo) was dripped onto each fallopian tube under direct vision before clip application. During the entire procedure (anesthetic and surgical), the patient was aided by relaxing small talk from a midwife, who was present mainly for this purpose. Patients were thus quite awake throughout the procedure (duration, 10-15 minutes after anesthesia became effective); some of the patients watched through the teaching aid of the laparoscope.

Immediately after each clip application, the patient was asked to mark a pain score on the VAS. A categoric word score was obtained at the same time. The pain scores were repeated at 15 minutes and 1 hour after the operation and again at discharge. Supplementary analgesia was offered to the patient after each set of pain scores was taken (25 mg meperidine intravenously after clip application and at any time after the operation when the word score was given as severe; 500 mg mefenamic acid orally for moderate postoperative pain; and 1000 mg acetaminophen for mild postoperative pain). Analgesic doses could be repeated, and each dose was counted as a single treatment intervention. The site and nature of the pain was also noted during the pain scoring, along with any other signs or symptoms. Postoperative nausea and vomiting were treated with 10 mg metoclopramide intravenously.

At discharge from the unit, all women received a questionnaire that was to be completed on postoperative day 5 and returned to the investigators.

The primary outcome measures for the study were the VAS scores: categoric word scores, requirement for additional analgesia, side effects, and patient satisfaction were secondary outcome variables.

Because of the large volumes of lidocaine required for the technique, in a preliminary study, a separate group of 20 women were tested for lidocaine levels at intervals throughout the procedure (the lidocaine level group). To test for local anesthetic-associated arrhythmias, an electrocardiogram was continuously recorded by Holter monitor in each of these 20 patients. This was recorded continuously from the time the patient entered the procedure room for placement of the abdominal wall block until discharge (average duration, 3 hours). All 20 women in this group received the active solution (1% lidocaine with 1:200,000 epinephrine, 5 mL per fallopian tube) in a nonblinded fashion. This group did not participate in pain scoring.

Demographic data were compared with the use of 1-way analysis of variance and the Tukey-Kramer multiple com-

**Table I.** Comparison of the characteristics that were evaluated among the 3 groups

Characteristic	Group			P value
	Lidocaine levels	Lidocaine	Placebo	
N	20	12	12	
Age (y)	36.5 ± 6.3	37.5 ± 5.7	35.5 ± 4.4	.6926
Height (inch)	64.9 ± 2.7	64.9 ± 2.7	64.9 ± 2.7	.6016
Weight (kg)	64.9 ± 2.7	64.9 ± 4.1	63.7 ± 2.3	.4427
Parity (n)	2.2 ± 1.2	2.2 ± 1.0	2.0 ± 1.1	.8995
Lidocaine dose (mg/kg)	7.93 ± 1.28*†	8.36 ± 0.66‡	6.63 ± 0.77	.0006§
History of abdominal or pelvic operation	—	3	2	1.0
Medical history of pelvic inflammatory disease	—	0	0	1.0
Retroverted uterus (lithotomy position)	—	3	2	1.0
Adhesion	—	1	1	1.0
Fibroid	—	1	0	1.0

Data are expressed as mean ± SD; *P* < .05, significant.

\**P* > .05, lidocaine levels group versus lidocaine group, based on Tukey-Kramer multiple comparison test.

†*P* < .01, lidocaine levels group versus placebo group, based on Tukey-Kramer multiple comparison test.

‡*P* < .001, lidocaine group versus placebo group, based on Tukey-Kramer multiple comparison test.

§Analysis of variance.

parison test. Pain scores were not all normally distributed and therefore were analyzed with the use of the Mann-Whitney test (2-tailed) and the Kruskal-Wallis test. The Fisher exact test was used to compare analgesic requirements and occurrence of side effects. Normally distributed data are expressed as mean ± SD; data that are not normally distributed are expressed as the median value (lower 95th percentile confidence interval-upper 95th percentile CI). A probability value of <.05 was considered significant. All analyses were performed with the use of the statistical package InStat (GraphPad Software, Inc, San Diego, Calif).

### Results

All patients successfully completed the study, and there were no unexpected or untoward side effects or complications. All patients were discharged within 4 hours of arrival at the clinic. There were no significant demographic differences among the 3 groups of patients (Table I). In particular, there were no differences among the groups with respect to the incidence of factors that may affect pain scores, such as previous abdominal or pelvic surgical procedures, pelvic inflammatory disease, retroverted uterus, or adhesions noted at operation.

**Study of lidocaine levels.** There was no difference in the total lidocaine dose or the dose of lidocaine (milliliters per kilogram) used in the lidocaine level group compared with the lidocaine group. Because the placebo group received 10 mL of saline solution for topical application to the fallopian tubes, these patients received a lower dose of lidocaine than either the lidocaine level group or the lidocaine group (Table I). The lidocaine level group received an average of 6.3 ± 1.1 mL/kg lidocaine plus 1:200,000 epinephrine for the abdominal wall block and a further 10 mL 1% lidocaine with 1:200,000 epinephrine for the direct surface anesthesia of the fallopian tubes (Table I). The mean plasma concentrations

at the different time intervals ranged from 6.7 ± 4.0 μmol/L to 7.9 ± 2.6 μmol/L, with a maximum individual concentration of 16 μmol/L, which was measured 15 minutes after clip application (Table II). These values are within the safe treatment range reported by the reference laboratory for patients who were given lidocaine intravenously for arrhythmia control (6-21 μmol/L).

**Holter studies.** There were no episodes of arrhythmia noted by Holter monitoring, other than 3 patients with a sinus tachycardia that was associated temporally with walking to the operating room. These episodes of sinus tachycardia were not associated with any signs or symptoms in the patients.

### Pain scores and analgesic requirements

**Abdominal wall block.** All 24 patients received 40 mL of 1% lidocaine plus 1:200,000 epinephrine for the abdominal wall block. The sedation requirement before the block was placed was the same for all the women (25 mg meperidine and 2.5 mg midazolam), except for 1 patient in the placebo group who required an extra 15 mg meperidine before proceeding with the block.

**Incision.** All patients tolerated surgical incision and insertion of laparoscopic instruments satisfactorily. There were no requirements for additional analgesia for incision.

**Filshie clip application.** Patients in the lidocaine group gave significantly lower median VAS scores than the placebo group at the time of clip application (6.0 mm [range, 6.74-29.34 mm] vs 71.0 mm [range, 49.33-75.09 mm]; *P* < .0001; Fig 1) along with lower CWS (0.0 [range, 0.32-1.01] vs 2.5 [range, 1.79-2.62]; *P* < .0001; Fig 2). No patient in the lidocaine group required additional intraoperative analgesia, whereas 7 patients were treated with intravenous meperidine in the placebo group during clip application (*P* < .0046).

**Recovery period.** Fifteen minutes after the end of the operation, VASs remained significantly lower in the lido-

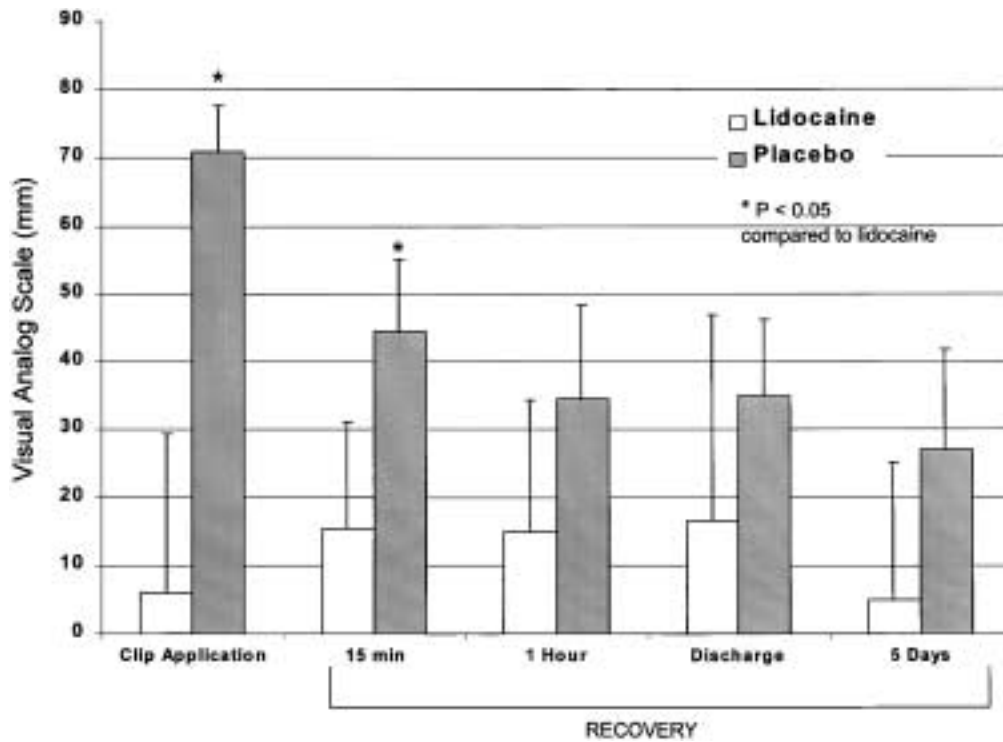


Fig 1. VASs at the time of clip application, 15 minutes after the operation, 1 hour after the operation, at discharge, and 5 days after the operation. Values are expressed as median score plus upper 95% CI.

caine group (15.5 mm [range, 5.29-31.10 mm] vs 44.5 mm [range, 32.06-55.11 mm];  $P = .0034$ ; Fig 1), in spite of significantly more intraoperative "rescue" analgesia given to the placebo group. CWS given at the same time tended to be lower in the lidocaine group (1.0 [range, 0.42-1.58] vs 2.0 [range, 1.16-2.01];  $P = .1072$ ). Significantly more patients in the placebo group also requested analgesic treatment at this time. Seven of the 12 patients in the placebo group required additional postoperative analgesia; some of the patients demanded repeated doses, so 10 treatment interventions were given, (3 intravenous and 7 oral treatments), compared with a single oral dose in the lidocaine group ( $P = .0272$ ).

VAS scores continued to be lower in the lidocaine group than in the placebo group at 1 hour after the operation (15.0 mm [range, 9.01-34.32 mm] vs 34.5 mm [range, 22.03-48.31 mm];  $P = .1260$ ) and at discharge (16.5 mm [range, 12.17-47.0 mm] vs 35.0 mm [range, 18.32-46.20 mm];  $P = .8395$ ). CWS were 1.0 (range, 0.77-1.73) versus 1.0 (range, 0.92-1.75) with a probability value of .6385 and 1.0 (range, 0.77-1.90) versus 1.5 (range, 0.84-1.83) with a probability value of .9269. At 1 hour, 8 patients were given oral analgesia (9 doses) in the placebo group, compared with only 2 patients in the lidocaine group (4 doses;  $P = .0361$ ). One patient in each group was given oral analgesia at the time of discharge.

*Pain scores in the lidocaine group over time.* There was no significant trend with time in either the VAS score ( $P =$

.3834) or the CWS score ( $P = .0864$ ) in the lidocaine group.

*Pain scores in the placebo group over time.* The pain scores in the placebo group displayed a significant trend with time ( $P = .0017$  for the VAS and  $P = .0043$  for CWS). At 1 hour after the operation, there was a significant reduction in both the VAS (71.0 mm-34.5 mm;  $P < .05$ ) and CWS (2.5-2.0;  $P < .05$ ) from the time of clipping. The pain scores remained lower at discharge than at the time of clipping ( $P < .05$  for both VASs and CWSs). The scores were no different from each other at 15 minutes and 1 hour after operation and at discharge.

*Pain location.* Nine of 12 women in the placebo group reported abdominal or pelvic pain after the operation compared with none in the lidocaine group ( $P = .0003$ ). Three women in the placebo group and 5 women in the lidocaine group reported subdiaphragmatic and/or shoulder tip pain,  $P = .6668$ .

*Side effects.* More women in the placebo group required treatment for nausea or vomiting (4 women vs 1 woman;  $P = .3168$ ). Three women in the placebo group were drowsy during the recovery period, 1 of whom was treated with supplemental oxygen. One woman in the placebo group reported feeling faint and was treated with a fluid bolus and recovery in the Trendelenburg position. All of these women had received additional intravenous meperidine at the time of clip application. Only 1 woman in the lidocaine group reported feeling dizzy. The total

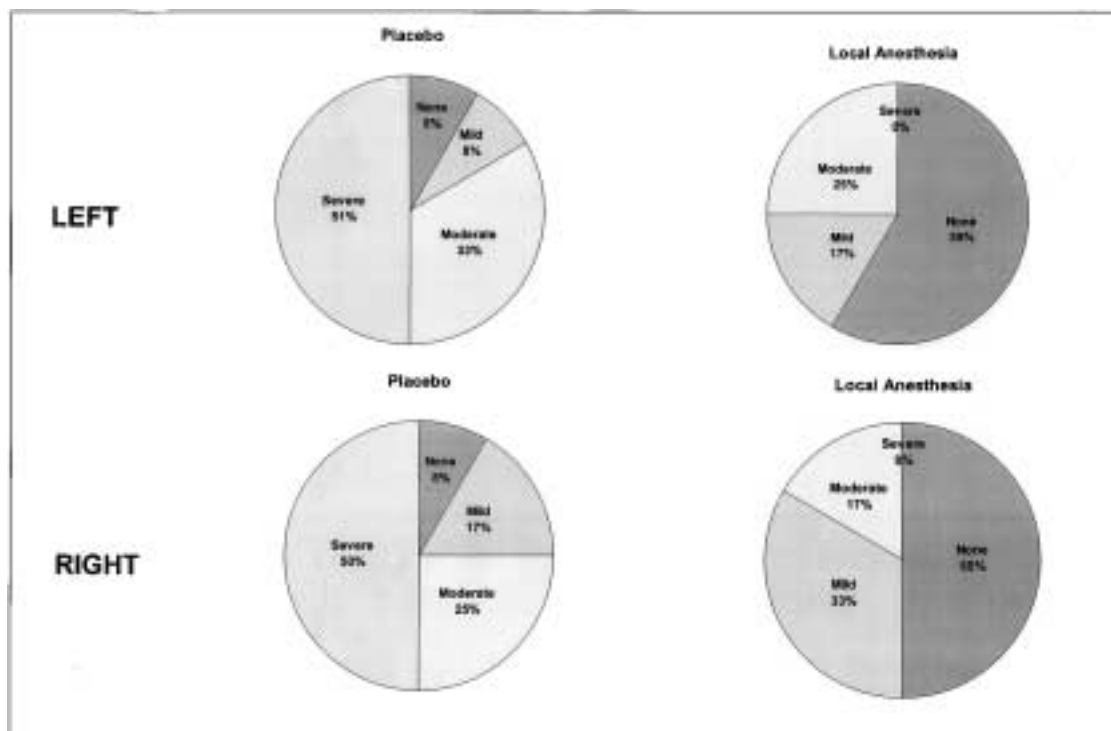


Fig 2. Percentage of patients who gave the categorical word scores of “none,” “mild,” “moderate,” or “severe” at the time of clip application to left and right Fallopian tubes.

Table II. Serum lidocaine levels (micromoles per liter) in 20 women who underwent laparoscopic sterilization after the administration of local anesthesia with lidocaine instilled onto the fallopian tubes\*

	Mean ± SD
Weight (kg)	64.9 ± 2.7
Total volume of 1% lidocaine (mL)	49.2 ± 4.1
Total dose of lidocaine (mg/kg)	7.9 ± 1.3
Serum lidocaine levels after abdominal infiltration (μmol/L)	6.72 ± 4.01
Serum lidocaine levels before application of lidocaine to the Fallopian tubes (μmol/L)	7.66 ± 3.62
Serum lidocaine levels after 15 minutes of recovery (μmol/L)	7.26 ± 2.84
Serum lidocaine levels at discharge (μmol/L)	7.87 ± 2.64

\*Reported therapeutic levels for the reference laboratory (patients receiving lidocaine infusions) are 6 to 21 μmol/L.

number of adverse side effects were 8 in the placebo group versus 2 in the lidocaine group ( $P = .0361$ ).

**Rehabilitative period.** Thirteen women returned the 5-day VASs (54% of the total subjects), 8 from the lidocaine group and 5 from the placebo group. Median scores were lower in the lidocaine group than in the placebo group: 5.0 mm (range, -2.57-25.07 mm) versus 27.0 mm (range, -2.94-41.77 mm);  $P = .8329$ . Twenty questionnaires were returned (83%; 10 from each group). Nine women in each group responded to the question, “Was the operation worse than or better than you expected?” All 9 women in the lidocaine group thought that it was better, whereas 4 women in the placebo group thought it was worse ( $P = .0824$ ). Of the 10 women in each group

who replied to the question, “Would you have preferred the operation under general anesthetic?,” 1 woman in the lidocaine group and 2 women in the placebo group said that they would have preferred a general anesthetic ( $P = 1.00$ ). Women in the lidocaine group felt that they had returned to full recovery in  $5.0 \pm 3.7$  days, compared with  $6.7 \pm 4.7$  days in the placebo group ( $P = .2326$ ).

#### Comment

Topically applied local anesthetic significantly reduced intraoperative and postoperative discomfort in patients who underwent laparoscopic sterilization. This study is consistent with the notion of pre-emptive analgesia, because the pain at the time of occlusion was significantly

reduced; this effect lasted into the recovery period, allowing for patient comfort with the reduced use of postoperative analgesia and subsequent side effects. None of the women in the lidocaine group, who complained of any postoperative pain, reported it to be either abdominal or pelvic. They complained of shoulder tip pain, most likely associated with residual gas under the diaphragm. In contrast, two thirds of the complaints of postoperative pain in the placebo group were reported as being abdominal or pelvic. These observations are consistent with preemptive analgesia at the site of tissue damage.

Visceral pain, particularly of genitourinary origin, is frequently associated with nausea and vomiting. It is speculated that fewer women in the lidocaine group experienced postoperative nausea and vomiting not only because of the reduction in opiate use but also because afferent input to the central nervous system was blocked by the previous application of lidocaine. The treatment of postoperative nausea and vomiting with metoclopramide may be synergistic because it is itself highly effective in reducing the cramping sensation typical of gynecologic pain<sup>21</sup>; yet, in spite of this action, there continued to be a greater demand for analgesia in the placebo group.

There is great interest in the phenomenon of neural blockade and the prolonged reduction of postoperative pain beyond the pharmacologic activity of a local anesthetic or analgesic. Recent evidence suggests that the prompt reduction of noxious afferent input may reduce prolonged or chronic pain,<sup>19</sup> perhaps by reducing the spinal cord hyperexcitability and receptor field changes that may be initiated by tissue injury. We sought to explore the phenomenon of neuroplasticity (ie, pain modulation beyond the pharmacologic effect of the local anesthetic). However, this study was powered on the basis of VASs, which required 11 scores in each group to detect a difference; we failed to receive adequate numbers of pain scores for postoperative day 5 to examine this question. It would be difficult to conduct a larger study to examine the effect of lidocaine into the rehabilitative period now that the usefulness of intraoperative instillation of lidocaine onto the fallopian tubes has been demonstrated.

In conclusion, the present study confirms the findings of clinic reports and other studies,<sup>2,3,11,14,16,17</sup> namely that local anesthetic application before occlusion reduces the pain that is associated with tubal occlusion. Simple direct instillation of the anesthetic solution onto the tubes is sufficient, significantly reducing pain at the time of occlusion and avoiding the addition of a transcervical procedure or the relative invasiveness of mesosalpingeal injections. The technique is associated with a reduced re-

quirement for supplemental analgesia and consequently fewer narcotic side effects in the perioperative period.

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