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## GYNAECOLOGY

# Lidocaine Infiltration in Mesosalpinx for Reducing Operative Time in Postpartum Tubal Sterilization: A randomized, controlled trial

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## ABSTRACT

**Objectives:** To evaluate the efficacy and dosage of lidocaine infiltration in mesosalpinx for reducing operative time in postpartum tubal sterilization.

**Materials and Methods:** A randomized, double-blinded, placebo-controlled trial was conducted in 105 women at Khon Kaen Hospital between April and July 2020. The participants were randomly assigned into three groups 4 ml of 2% lidocaine, 1% lidocaine, and normal saline solution (NSS) infiltrated in the mesosalpinx. Systemic sedative drugs were administered before the procedure in all groups. Operative time from skin incision to closure was recorded. Intra-operative, immediately and 1 hour post-operative pain score were evaluated.

**Results:** Age and body mass index were not statistically different between 2% lidocaine, 1% lidocaine, NSS groups (29.00 ± 4.54, 30.37 ± 5.92, 31.03 ± 5.08 yrs. and 25.08 ± 3.14, 25.88 ± 2.82, 26.08 ± 2.60 kg/m$^2$, respectively). Other baseline characteristics including postpartum duration before sterilization, parity, gestational age, and level of surgeon experience were similar across groups. Mean operative time for 2% lidocaine, 1% lidocaine, and NSS group was 17.9 ± 6.19, 21.6 ± 9.72, and 23.1 ± 12.04 min. The operative time of 2% lidocaine was significantly shorter than NSS ($p = 0.027$), and pain scores in 2% lidocaine were significantly lower than for NSS for all periods. The operative time of 1% lidocaine was not significantly different compared to NSS whereas 1% lidocaine had a significantly lower pain score only immediately and 1 hour post-operation. There were no serious adverse events found.

**Conclusion:** Two percent lidocaine infiltration in the mesosalpinx significantly shortened operative time and could reduce pain throughout postpartum tubal sterilization.

**Keywords:** lidocaine, mesosalpinx, postpartum, tubal sterilization, operative time, pain score.

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# *การฉีดลิโดเคน (lidocaine) เข้าเนื้อเยื่อใต้ท่อนำไข่เพื่อลดระยะเวลาการผ่าตัดในการทำหมันหลังคลอด: การทดลองแบบสุ่ม*

***วิชชุณี นิธิวัฒนศักดิ์, เจษฎา วุฒิธรรมสุข***

## *บทคัดย่อ*

***วัตถุประสงค์:*** *เพื่อศึกษาประสิทธิผลและขนาดของยาลิโดเคนในการฉีดเข้าเนื้อเยื่อใต้ท่อนำไข่เพื่อลดระยะเวลาการผ่าตัดในผู้ป่วยทำหมันหลังคลอด*

***วัสดุและวิธีการ:*** *งานวิจัยนี้เป็นการศึกษาแบบสุ่ม ปกปิดทั้งสองฝ่าย ทำการศึกษาในหญิงหลังคลอด 105 คน ที่โรงพยาบาลขอนแก่น ระหว่างเดือนเมษายน ถึง กรกฎาคม พ.ศ.2563 โดยทำการสุ่มหญิงหลังคลอดแบ่งเป็น 3 กลุ่ม ได้แก่ กลุ่มที่ได้รับ 2% ลิโดเคน, กลุ่มที่ได้รับ 1% ลิโดเคน และกลุ่มที่ได้รับสารละลายน้ำเกลือ ปริมาณ 4 มิลลิลิตร โดยฉีดเข้าเนื้อเยื่อใต้ท่อนำไข่ โดยทุกกลุ่มได้รับยาระงับประสาททางหลอดเลือดดำก่อนทำหัตถการ บันทึกระยะเวลาการผ่าตัดตั้งแต่ลงแผลผ่าตัดจนเย็บปิดแผล บันทึกคะแนนความปวดในขณะผ่าตัด หลังเสร็จสิ้นการผ่าตัดทันที และหลังการผ่าตัด 1 ชั่วโมง*

***ผลการศึกษา:*** *อายุและดัชนีมวลกายในกลุ่มที่ได้รับ 2% ลิโดเคน, กลุ่มที่ได้รับ 1% ลิโดเคน,กลุ่มที่ได้รับสารละลายน้ำเกลือไม่แตกต่างกันทางสถิติ (29.00 ± 4.54, 30.37 ± 5.92, 31.03 ± 5.08 ปี และ 25.08 ± 3.14, 25.88 ± 2.82, 26.08 ± 2.60 กก./ม$^2$ ตามลำดับ) ลักษณะพื้นฐานประชากรอื่นๆ ประกอบด้วย จำนวนการคลอด, อายุครรภ์, ระยะเวลาหลังคลอดก่อนการทำหมัน และระดับความชำนาญของแพทย์ผู้ผ่าตัด คล้ายคลึงกันในทุกกลุ่ม โดยระยะเวลาผ่าตัดเฉลี่ยของกลุ่ม 2% ลิโดเคน, 1% ลิโดเคน และ สารละลายน้ำเกลือ เท่ากับ 17.9 ± 6.19, 21.6 ± 9.72 และ 23.1 ± 12.04 นาที ตามลำดับ ซึ่งระยะเวลาในการผ่าตัดของกลุ่มที่ได้รับ 2% ลิโดเคน น้อยกว่ากลุ่มสารละลายน้ำเกลืออย่างมีนัยสำคัญทางสถิติ (p = 0.027) และคะแนนความเจ็บปวดในกลุ่มที่ได้รับ 2% ลิโดเคน น้อยกว่ากลุ่มที่ได้รับสารละลายน้ำเกลืออย่างมีนัยสำคัญทางสถิติในทุกช่วงเวลา ส่วนระยะเวลาการผ่าตัดเปรียบเทียบระหว่างกลุ่มที่ได้รับ 1% ลิโดเคน และกลุ่มที่ได้รับสารละลายน้ำเกลือไม่มีความแตกต่างกัน ในขณะที่กลุ่มที่ได้รับ 1% ลิโดเคน มีคะแนนความเจ็บปวดน้อยกว่ากลุ่มที่ได้รับสารละลายน้ำเกลืออย่างมีนัยสำคัญทางสถิติเฉพาะในช่วงหลังผ่าตัดทันทีและ 1 ชั่วโมงหลังการผ่าตัด ไม่พบเหตุการณ์ไม่พึงประสงค์ที่รุนแรง*

***สรุป:*** *การฉีด 2% ลิโดเคน เข้าเนื้อเยื่อใต้ท่อนำไข่สามารถลดระยะเวลาการผ่าตัดได้อย่างมีนัยสำคัญทางสถิติและสามารถช่วยลดความเจ็บปวดตลอดการทำหมันหลังคลอด*

***คำสำคัญ:*** *ลิโดเคน, เนื้อเยื่อใต้ท่อนำไข่, หลังคลอด, การทำหมันหญิง, ระยะเวลาการผ่าตัด, คะแนนความปวด์*

## Introduction

Bilateral tubal sterilization is the most popular and effective permanent contraception method with a low rate of side effects[1]. Mini-laparotomy uses a small incision of about 2-3 cm placed either in relation to the uterine fundus or the infraumbilical site for postpartum sterilization[2], and requires only basic surgical instruments. This operation is appropriate for low-resource settings where specialized surgical equipment is not available[2]. Postoperative pain originates from three sources: the infraumbilical skin incision, the transection site, and the ligation site on the fallopian tubes[3]. This pain causes sensory and emotional discomfort and may also cause fear and anxiety perioperatively[4]. The inferior hypogastric nerves innervate the cervix, the body of the uterus, and the medial portion of each fallopian tube. The nerve plexus that runs along each ovarian artery innervates each ovary and the lateral portion of each fallopian tube. The suture ligation of a 2 cm segment of the fallopian tube may be transected or crush nerve endings from both medial and lateral nerve fibers. To reduce pain, the latter would require local anesthetic infiltration to both the medial and lateral transection sites on each fallopian tube to block afferent nociception[5].

Local anesthesia has proven to be the most appropriate anesthesia for mini-laparotomy. The aim of anesthesia is to reduce pain, anxiety, and to allow performance of a surgical procedure[6].

Lidocaine has fewer side effects, is inexpensive, potent, and readily available[1]. It blocks initiation and transmission of nerve impulses at the site of application by stabilizing the neuronal membrane[7]. Lidocaine is a moderately long-acting, local anesthetic, duration for 1-3 hours, onset within 1-5 min following mucosal application, infiltration, and spinal or dental nerve block[7]. The maximum dose of lidocaine for local infiltration is up to 400 mg[7].

In a previous study, lidocaine 40 mg was injected into the fallopian tubes compared with placebo to reduce pain. The result showed that the pain score was not significantly different between groups and might extend the operative time[8]. Long operative time may be due to patient intra-operative pain, so adequate pain control could reduce operative time. There is neither sufficient evidence nor any systematic reviews evaluating local anesthesia for operative time and pain reduction during tubal sterilization.

The current study was thus conducted to compare the efficacy of 80 mg vs. 40 mg of lidocaine, 80 mg lidocaine vs. normal saline (NSS), and 40 mg lidocaine vs. NSS infiltration in the mesosalpinx for reducing operative time during postpartum tubal sterilization. The secondary outcomes were pain score, adverse events, surgical complications, and patient satisfaction.

## Materials and methods

This was a single center, double-blinded, randomized controlled trial. The subjects were postpartum women scheduled for tubal sterilization at Khon Kaen Hospital between April and July, 2020. Inclusion criteria were as follows: completed childbearing, no contraindication for surgery, had an American Society of Anesthesiologists (ASA) physical I and II[9], delivered within 72 hours before tubal sterilization, understood Thai language (speak, read, and write). Exclusion criteria were body mass index (BMI) ≥ 30 kg/m$^2$, lidocaine allergy, history of pelvic infection, and prior pelvic surgery. The study was reviewed and approved by the Khon Kaen Hospital Institute Review Board in Human Research (KEF62018). After obtaining written informed consent, all participants were randomized into three groups using a computer-generated program: the 2% lidocaine group, the 1% lidocaine group, and the normal saline group. The randomization lists were kept in sealed opaque envelopes.

All postpartum patients needed to fast for 6-8 hours prior to the tubal sterilization. Before the operation, numerical rating score (NRS) from

0-10[10] was used to evaluate the participant's understanding. The study was masked to the participants, surgeons, and nurses involved in the study. The sealed opaque envelopes were opened by a nurse who not involved in the study at the operative room and prepared the solutions for each group. The solutions were delivered with a 5 ml syringe containing 4 ml of 2% lidocaine, 4 ml of 1% lidocaine, and 4 ml of normal saline for each group, respectively. All solutions were transparent, and apparently identical without label.

The postpartum tubal sterilization was performed by all levels of residents or staff. Before the operation was started, all participants received a systemic sedative drug (morphine 0.1 mg/kg and diazepam 5 mg intravenously) and 20 ml of 1% lidocaine with adrenaline (1:100,000) infiltrated to the abdominal layer at the infra-umbilical site. A 2-cm transverse infra-umbilical incision was made. After approaching the intra-peritoneum, the fallopian tube was identified and held with Babcock forceps. As per the respective group assignment, 2 ml of solution was infiltrated into the avascular area of the mesosalpinx. After one minute of infiltration, tubal sterilization was performed using the Modified Pomeroy technique. The same procedure was performed on the other side so that a total of 4 ml of solution was given to each participant. The NRS was recorded thrice (a) immediately after resecting both sides of the fallopian tubes, (b) immediately after skin closure, and (c) 1 hour after surgery by a nurse not apprised of the study outcome measures.

Vital signs and pulse oximetry were monitored before, during, and after the operation to monitor for any local anesthetic, cardiovascular, respiratory emergencies. If any emergency events or intraoperative complications occurred, standard care and treatment were immediately administered.

We recorded operative time from skin incision to skin closure using standardized watch, which were recorded by a nurse not apprised of the study outcome measures. Adverse events, complications of surgery, and patient satisfaction (Likert scales) were recorded at 1 hour post-operation.

Statistical analyses were done using STATA version 13 software. The sample size calculation was based on the data of operative time from a pilot study of 10 participants in each group with an alpha of 0.05 and a beta of 0.2. Mean operative time for 2% lidocaine, 1% lidocaine, and NSS was 18.57 ± 7.25, 19.00 ± 3.82, and 24.57 ± 10.18 min. The total sample size was 35 participants per group. The operative time and pain score were presented as means ± standard deviation (SD) to compare between 2% lidocaine vs. 1% lidocaine, 2% lidocaine vs. NSS, and 1% lidocaine vs. NSS. Differences in continuous variables were analyzed using a one-way Analysis of Variance (ANOVA). Categorical variables were analyzed using chi-squared and Fisher's exact test as appropriate. Continuous variables were analyzed using the independent t-test presented as mean differences and 95% confidence intervals (CI). A p value $< 0.05$ was considered statistically significant.

## Results

One hundred and nineteen postpartum women were assessed for eligibility. Fourteen women were excluded: 12 had a BMI $\geq 30$ kg/m$^2$, and 2 declined to participate. One hundred and five women were randomized into 3 groups: the 2% lidocaine group, the 1% lidocaine group, and the normal saline group: 35 per group (Fig. 1). Data recorded included age, BMI, postpartum duration before sterilization, gestational age (GA), parity, levels of surgeon experience, operative time, pain score, side effects, patient satisfaction, and complications of surgery.

Baseline characteristics of the participants were presented in Table 1. There were no statistically significant differences between the three groups with respect to age, BMI, postpartum duration before sterilization, GA, parity, and levels of surgeon experience ($p > 0.05$).

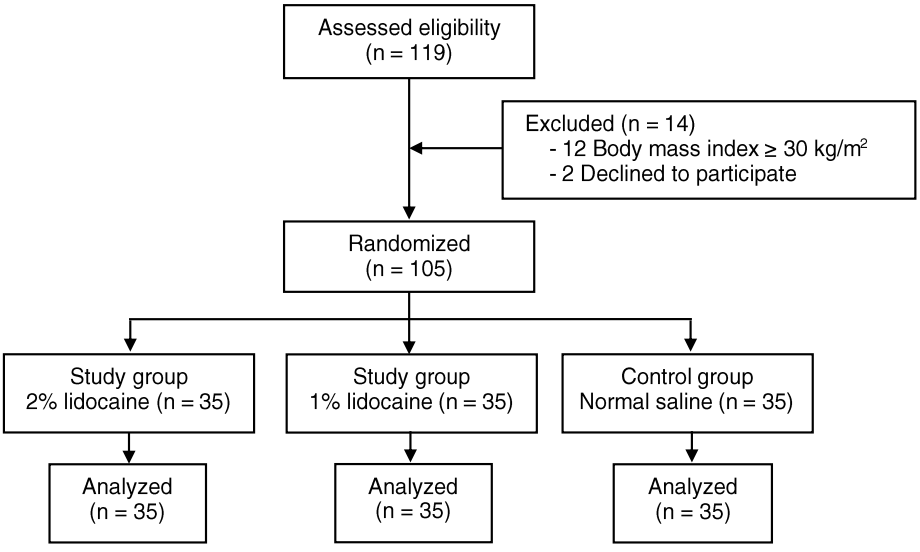


**Fig. 1.** Study flow diagram.

**Table 1.** Baseline characteristics.

| | 1% Lidocaine (n = 35) | 2% Lidocaine (n = 35) | Normal saline (n = 35) | p value |
|---|---|---|---|---|
| Age (years), mean ± SD | 29.00 ± 4.54 | 30.37 ± 5.92 | 31.03 ± 5.08 | 0.26[a] |
| BMI (kg/m$^2$), mean ± SD | 25.08 ± 3.14 | 25.88 ± 2.82 | 26.08 ± 2.60 | 0.31[a] |
| Postpartum (hours), mean ± SD | 42.11 ± 19.22 | 36.57 ± 18.46 | 34.86 ± 16.24 | 0.22[a] |
| GA (days), mean ± SD | 268.89 ± 12.02 | 271.37 ± 8.50 | 267.89 ± 7.60 | 0.30[a] |
| No. of gravida | | | | |
| Parity, n (%) | | | | 0.93[b] |
| 2 | 23 (65.7) | 22 (62.9) | 26 (74.2) | |
| 3 | 10 (28.5) | 10 (28.5) | 8 (22.9) | |
| 4 | 1 (2.9) | 2 (5.7) | 1 (2.9) | |
| 5 | 1 (2.9) | 1 (2.9) | 0 (0.0) | |
| Surgeon, n (%) | | | | 0.72[b] |
| Resident 1 | 15 (42.9) | 16 (45.7) | 16 (45.7) | |
| Resident 2 | 11 (31.4) | 12 (34.3) | 8 (22.9) | |
| Resident 3 | 0 (0.0) | 0 (0.0) | 2 (5.7) | |
| Staff | 9 (25.7) | 7 (20.0) | 9 (25.7) | |

[a] One way ANOVA, [b] Fisher's exact test

SD: standard deviation, BMI: body mass index, GA: gestational age

The respective mean operative time for the 2% lidocaine, 1% lidocaine, and NSS group was 17.9 ± 6.19, 21.6 ± 9.72, and 23.1 ± 12.04 min (Fig. 2). Operative time for the 2% lidocaine group was significantly less than that for the NSS group (mean difference = -5.17 min, 95%CI -9.74 to -0.61, p =

0.027). There were no significant differences between the 1% lidocaine group and the NSS group (mean difference = -1.43 min, 95%CI -6.65 to 3.79, p = 0.587) and the 2% lidocaine and the 1% lidocaine group (mean difference = -3.74 min, 95%CI -7.63 to 0.14, p = 0.059) (Fig. 2).

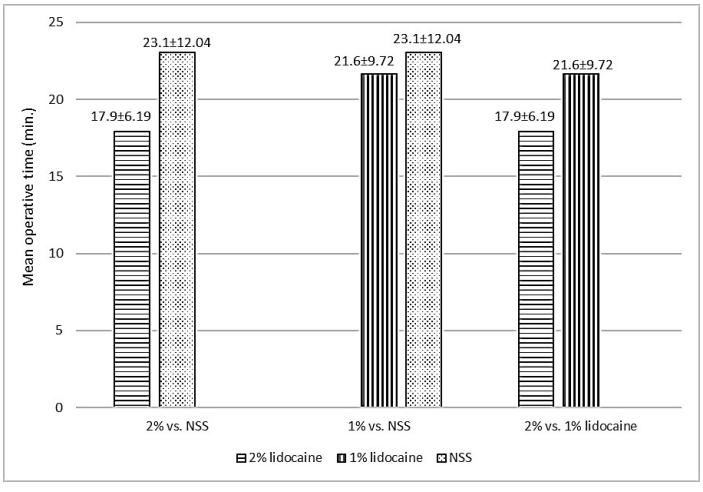


**Fig. 2.** Mean operative time.

Pain scores in the 2% lidocaine group were significantly lower than those of the NSS group for all periods (i.e., the respective intra-operative; immediate post-operative; and, 1 hour post-operative mean difference was -2.29, 95%CI -3.45 to -1.12, p < 0.001; -2.94, 95%CI -4.12 to -1.77, p < 0.001; and -2.74, 95%CI -3.87 to -1.62, p < 0.001) (Fig. 3). By comparison, the 1% lidocaine group had a significantly lower pain score than that of the NSS group (i.e., the respective immediate post-operative and 1 hour post-operative mean difference was -1.43 (95%CI -2.54 to -0.32, p = 0.012) and -1.94 (95%CI -3.09 to -0.79, p = 0.001) (Fig. 3). The 2% lidocaine group had a lower pain score than that of the 1% lidocaine group (i.e., the respective intra-operative and the immediate post-operative mean difference was -1.34 (95%CI -2.50 to -0.18, p = 0.024) and -1.52 (95%CI -2.75 to -0.28, p = 0.017) (Fig. 3). The mean pain score showed that increasing the concentration of lidocaine could reduce the pain score (Fig. 3).

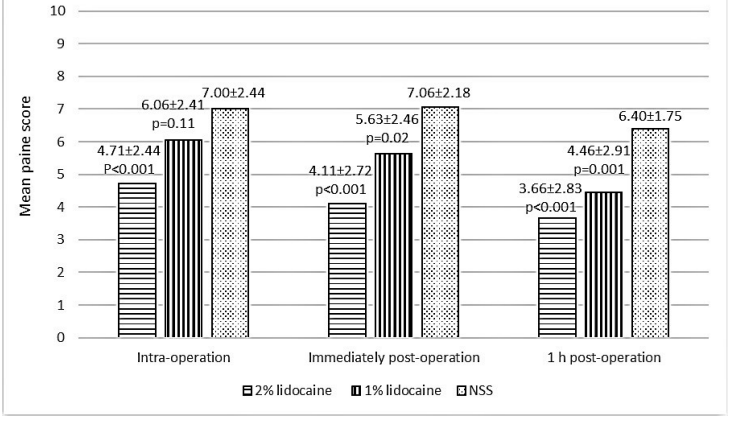


**Fig. 3.** Mean pain score.

There were no statistically significant differences between the three groups with respect to side effects, patient satisfaction without complications of surgery ($p > 0.05$) (e.g., bleeding, hematoma, and tear mesosalpinx) (Table 2).

**Table 2.** Side effects and patient satisfaction.

| | 1% Lidocaine (n = 35) | 2% Lidocaine (n = 35) | Normal saline (n = 35) | p value |
|---|---|---|---|---|
| Side effects, n (%) | | | | |
| Nausea and vomiting | 0 (0.0) | 1 (2.9) | 1 (2.9) | 0.61[b] |
| Headache | 2 (5.7) | 2 (5.7) | 0 (0.0) | 0.55[b] |
| Tremor | 1 (2.9) | 0 (0.0) | 0 (0.0) | 0.37[b] |
| Dizziness | 2 (5.7) | 0 (0.0) | 1 (2.9) | 0.78[b] |
| Numbness and tingling | 0 (0.0) | 0 (0.0) | 0 (0.0) | N/A |
| Patient satisfaction, n (%) | | | | 0.07[b] |
| Poor | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Fair | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Good | 1 (2.9) | 2 (5.7) | 1 (2.9) | |
| Very good | 13 (37.1) | 10 (28.6) | 21 (60.0) | |
| Excellent | 21 (60.0) | 23 (65.7) | 13 (37.1) | |

[b] Fisher's exact test
N/A: non applicable

## Discussion

The current randomized, double-blinded, placebo-controlled trial evaluated the effectiveness of lidocaine infiltration in the mesosalpinx for reducing operative time in postpartum tubal sterilization. We found that 2% lidocaine reduced operative time in postpartum sterilization, but 1% lidocaine yielded no greater effectiveness compared to placebo. The operative time may reflect the surrogate outcome of pain control during operation proxied by more patient cooperation and resulting in a shorter operative time. Generally, during the search for each fallopian tube, the patient is asked to pull in the stomach so as (a) to pull down the abdominal wall close to the uterus and (b) the bowels not obscure the view. In cases where the patient suffers from pain during tubal ligation and transection of the first side, the patient may push out the abdomen causing the bowels to come down which can interfere with the operative field. In such cases, there is a need for deep force (i.e., abdominal traction or bowel packing) to expose the surgical field which can increase the operative time. There are other factors that can affect operative time such as intra-abdominal tissue traction due to thickness of the abdominal wall, fundal height, parity, and surgeon experience. Participant BMI, postpartum duration before sterilization, parity, and level of surgeon skill were not statistically significant differences in the current study.

The current study showed that 2% lidocaine was able to significantly reduce pain to a mild to moderate pain score throughout postpartum tubal sterilization until 1 hour post-operation whereas 1% lidocaine only reduced pain to a moderate pain score immediately and 1 hour post-operation compared to NSS. The result confirmed that intravenous sedative drug and local abdominal infiltration with lidocaine during tubal

sterilization did not adequately control pain. Our findings were comparable to those of Songserm et al[8], who reported that 1% infiltrated lidocaine provided no better intra-operative pain relief than normal saline infiltrated into mesosalpinx of the fallopian tubes. In the current study, participants received low doses of systemic sedative drug during tubal sterilization so that all participants remained consciousness and able to assess their pain score.

To our knowledge, there has been no previous study comparing operative time as a primary outcome. Several studies have evaluated the effectiveness of lidocaine for reducing intra-operative pain as a primary outcome; however, pain measurement is subjective and there are many idiosyncratic factors that can affect the level of pain (e.g., individual pain threshold and experience of pain).

The strength of our study was that it was a double-blinded, randomized, controlled trial. The limitation of the study was that the duration of operative time might be affected by abdominal wall thickness, fundal height, and the level of surgeon experience.

## Conclusion

Two percent lidocaine infiltration in the mesosalpinx significantly shortened operative time and reduced operative pain in postpartum tubal sterilization without any serious adverse events.

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## Potential conflicts of interest

The authors declare no conflict of interest.

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