ผลของขนาดยาลิโดเคนภายในช่องท้องต่อการบรรเทาความปวดระหว่างการทำหมันหลังคลอดด้วยการผ่าตัดเปิดช่องท้องขนาดเล็ก: การทดลองแบบสุ่มสามกลุ่มและมีกลุ่มควบคุม

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บทคัดย่อ

วัตถุประสงค์: เพื่อประเมินประสิทธิผลของลิโดเคนภายในช่องท้องขนาด 50 มิลลิกรัม และ 100 มิลลิกรัม เปรียบเทียบกับยาหลอก ในการลดความปวดระหว่างการทำหมันหลังคลอดด้วยวิธี mini-laparotomy

วิธีการศึกษา: การศึกษานี้เป็นการทดลองแบบสุ่ม ปกปิดสองฝ่าย ในสตรีหลังคลอดจำนวน 102 ราย ซึ่งได้รับการจัดสรรอย่างเท่าเทียมให้ได้รับการหยอดน้ำเกลือปกติ (ยาหลอก) ปริมาตร 20 มิลลิลิตร หรือลิโดเคน ขนาด 50 มิลลิกรัม ปริมาตร 20 มิลลิลิตร หรือ ลิโดเคนขนาด 100 มิลลิกรัม ปริมาตร 20 มิลลิลิตร ภายในช่องท้อง (ระหว่างเดือนกรกฎาคม พ.ศ. 2567 – กรกฎาคม พ.ศ. 2568) ผู้เข้าร่วมทุกคนได้รับมอร์ฟีนเข้ากล้ามขนาด 10 มิลลิกรัม ก่อนผ่าตัด 30 นาที และยาชาเฉพาะที่ลิโดเคน 1% ผสม Epinephrine ปริมาตร 15 มิลลิลิตร การประเมินความปวดในระหว่างการผ่าตัด 4 ช่วงเวลา วิเคราะห์โดยใช้แบบจำลองเชิงเส้นผสม (linear mixed-effects model) ซึ่งกำหนดตัวสกัดแบบสุ่มรายบุคคล

ผลการศึกษา: มีสตรี 96 รายที่เข้าร่วมการศึกษาครบถ้วน (กลุ่ม 100 มก. = 33 ราย, 50 มก. = 34 ราย, กลุ่มยาหลอก = 29 ราย) ลักษณะพื้นฐานของกลุ่มตัวอย่าง ได้แก่ อายุและดัชนีมวลกาย มีความใกล้เคียงกันระหว่างทั้งสามกลุ่ม ความปวดที่วัดได้ 1 นาทีหลังการหยอดยาไม่แตกต่างกัน ($p = 0.395$) เมื่อเปรียบเทียบกับยาหลอก พบค่าความแตกต่างเฉลี่ย (ยาหลอก – ลิโดเคน) ของคะแนนปวด NRS (95% CI) เท่ากับ +1.43 (0.08–2.78) และ +3.11 (1.75–4.48) ในช่วงการผูกท่อนำไข่ข้างแรก, +2.27 (0.91–3.62) และ +4.60 (3.23–5.96) ในช่วงผูกท่อน้ำไข่ข้างที่สอง, และ +1.71 (0.35–3.06) และ +3.39 (2.03–4.75) หลังการเย็บปิดแผล สำหรับลิโดเคนขนาด 50 มก. และ 100 มก. ตามลำดับ (ทุกค่า $p < 0.05$) กลุ่มที่ได้รับลิโดเคน 100 มก. มีคะแนนปวดต่ำกว่ากลุ่มที่ได้รับลิโดเคน 50 มก. อย่างมีนัยสำคัญทางสถิติ ($p \leq 0.03$) ผู้เข้าร่วม 4 ราย ร้อยละ 4.17 รายงานอาการเวียนศีรษะเล็กน้อยโดยไม่มีเหตุการณ์ไม่พึงประสงค์รุนแรง

สรุป การหยอดลิโดเคนเข้าช่องท้องขนาด 50 มก. และ 100 มก. สามารถลดความปวดระหว่างผ่าตัดได้อย่างมีนัยสำคัญเมื่อเทียบกับยาหลอก โดยขนาด 100 มก. ให้ผลบรรเทาปวดสูงสุด

คำสำคัญ: ลิโดเคน การผ่าตัดเปิดช่องท้องขนาดเล็ก การทำหมันหลังคลอด การจัดการความปวด การทดลองแบบสุ่มสามกลุ่มและมีกลุ่มควบคุม

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Effects of Different Doses of Intraperitoneal Lidocaine on Intra-operative Pain Relief During Mini-laparotomy Postpartum Tubal Ligation: A Three-group Randomized Controlled Trial

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Abstract

Objective: To determine the efficacy of 50 mg and 100 mg intraperitoneal lidocaine (IPL) compare with placebo in reducing intraoperative pain during postpartum mini-laparotomy tubal ligation.

Materials and Methods: In this randomized, double-blind trial, 102 postpartum women were allocated equally to receive 20 mL of normal saline, 50 mg lidocaine, or 100 mg lidocaine intraperitoneally (July 2024 to July 2025). All participants received 10 mg intramuscular morphine 30 minutes before surgery and local 15 ml of 1% lidocaine with epinephrine. Pain at four intra-operative points was analyzed using a linear mixed-effects model with a random intercept for each participant.

Results: Ninety-six women completed the study (100-mg group, n = 33; 50-mg group, n = 34; placebo, n = 29). Baseline characteristics, including age and body mass index, were comparable among the three groups. Pain at 1 minute after instillation did not differ among groups ($p = 0.395$). Compared with placebo, mean differences (placebo minus lidocaine) (95% CI) in NRS pain were +1.43 (0.08–2.78) and +3.11 (1.75–4.48) at first ligation, +2.27 (0.91–3.62) and +4.60 (3.23–5.96) at second ligation, and +1.71 (0.35–3.06) and +3.39 (2.03–4.75) after skin closure for 50 mg and 100 mg, respectively (all $p < 0.05$). Pain scores were significantly lower with 100 mg than with 50 mg ($p \leq 0.03$). Four participants (4.17%) reported mild dizziness without serious events.

Conclusion: Intraperitoneal lidocaine (50 and 100 mg) significantly reduced intraoperative pain compared with placebo. The 100-mg dose provided greater analgesic efficacy than the 50-mg dose.

Keywords: lidocaine, mini-laparotomy, postpartum sterilization, pain management, randomized controlled trial

Introduction

Female sterilization is one of the most widely performed surgical methods of permanent contraception. According to the United Nations World Family Planning 2022 report, in 2020, approximately 22.9% of women of reproductive age (15–49 years) who were seeking to avoid pregnancy worldwide had undergone the procedure, representing about 219 million individuals[1]. In Thailand, the rate of immediate postpartum sterilization has been reported at 17.8 %[2].

Female sterilization can be performed postpartum, during interval periods, or post-abortion. Among these, the postpartum approach offers distinct surgical advantages due to favorable anatomical changes during the puerperium[3]. Effective pain management is crucial for patient satisfaction. While general and regional anesthesia provide excellent analgesia[4], their higher costs and need for anesthesiologist support limit feasibility in low-resource settings[5-6]. Local anesthesia remains a practical alternative, with adjunctive strategies including systemic opioids[5] or intraperitoneal instillation of local anesthetics like lidocaine[6-7]

Lidocaine, an amide-type local anesthetic, exerts its effect by reversibly blocking voltage-gated sodium channels in neuronal membranes, thereby preventing sodium influx, halting depolarization, and interrupting action potential propagation, this ultimately inhibiting nociceptive transmission to the central nervous system[8]. The fallopian tubes receive sensory innervation from afferent fibers of the inferior hypogastric plexus, primarily entering at the interstitial segment[9]. Targeted administration of lidocaine at this site may therefore provide effective analgesia during mini-laparotomy postpartum tubal ligation (PPTL).

A systematic review by Werawatakul et al. demonstrated that intraperitoneal lidocaine (IPL) significantly reduced intraoperative pain compared with placebo[10]. Although the certainty of evidence was low owing to small sample sizes, risk of bias, and imprecise outcome measures. Consistent with these limitations, a recent randomized trial reported that IPL alone did not significantly reduce intraoperative pain during postpartum mini-laparotomy tubal ligation[6]. Moreover, prior studies of IPL analgesia have employed widely varying regimens, from low-dose 50 mg to as high as 400 mg, without an established consensus on the optimal dose for efficacy and safety.[10-12]

These gaps underscore the need for adequately powered randomized controlled trials of IPL in PPTL. Accordingly, this randomized, double-blind, placebo-controlled study evaluates the effectiveness of IPL by comparing intraoperative pain scores among three groups, placebo, 50 mg, and 100 mg, during postpartum mini-laparotomy tubal ligation, and explores the dose–response within the 50–100 mg range to identify a clinically meaningful effective dose for this procedure. The 50 mg and 100 mg doses were selected based on prior evidence demonstrating analgesic benefit across 50–200 mg without systemic toxicity[10-11,13]. The two lowest doses were chosen to explore whether 50 mg is sufficient to achieve effective analgesia and to define the potential ceiling effect of lidocaine within a safe clinical range. Accordingly, the objective of this study was to assess the analgesic efficacy of IPL at doses of 50 mg and 100 mg, compared with placebo, in mitigating intraoperative pain during postpartum mini-laparotomy tubal ligation.

Materials and methods

Ethic issues

Ethical approval was obtained from the Udonthani Hospital Ethical Committee in Human Subject Research (No. 127/2567), and the trial was registered with the Thai Clinical Trials Registry (TCTR20241110002).

Study design and participants

This study was designed as a randomized, double-blind, controlled trial conducted at the Department of Obstetrics and Gynecology, Udonthani Hospital, Thailand, between July 2024 and July 2025. The first participant enrollment began in November 2024. Eligible women were randomly allocated into three equal groups (n = 34 per group) using a computer-generated randomization program. Group assignments and drug preparations were concealed from both participants and investigators throughout the study.

A total of 102 postpartum women were enrolled. All participants had received standardized preoperative counseling and provided written informed consent prior to enrollment. Eligible participants were postpartum women aged between 20 and 40 years, classified as American Society of Anesthesiologists (ASA) Physical Status I, and with no contraindications to surgical procedures. Each woman elected to undergo tubal ligation via mini-laparotomy during the postpartum period, all procedures were performed by medical interns, obstetrics and gynecology residents, or attending medical staff within the department.

Participants were excluded if they had a known hypersensitivity or allergy to lidocaine or other local anesthetic agents, required additional forms of analgesia or anesthesia during the procedure, or presented with abnormal baseline vital signs, defined as heart rate greater than 120 beats per minute, blood pressure lower than 90/60 mmHg, respiratory rate exceeding 24 breaths per minute, or oxygen saturation below 94%. In addition, women with a history of renal or hepatic dysfunction, bronchial asthma, or prior lower abdominal surgery were also excluded. No changes were made to the trial methods, eligibility criteria, or outcome definitions after trial commencement.

Definitions

Lidocaine instillation: The administration of a lidocaine-containing solution directly into the peritoneal cavity.

Postpartum tubal ligation (PPTL): Surgical sterilization performed within 42 days after childbirth, usually within 48 hrs.[14]

Numerical rating scale (NRS): A validated tool for assessing pain intensity on a scale from 0 to 10, where 0 represents “no pain” and 10 denotes “the worst pain imaginable.”[15]

Randomization and blinding

Participants were randomly assigned in equal numbers (n = 34 per group) to receive 100 mg lidocaine in 20 mL normal saline (IPL 100), 50 mg lidocaine in 20 mL normal saline (IPL 50), or 20 mL normal saline (placebo) using simple randomization with a 1:1:1 allocation ratio. The random allocation sequence was generated by an independent statistician who had no role in participant recruitment, clinical care, or outcome assessment. No blocking or stratification was applied. Group assignments were concealed in sequentially numbered, sealed, opaque envelopes. Eligible participants were enrolled by attending obstetricians, and the assigned study solutions were prepared and labelled according to the concealed sequence by an in-house pharmacist who was not involved in patient care or outcome

assessment. Participants, surgeons, anesthesiologists, and outcome assessors remained blinded to treatment allocation throughout the trial. The study solutions were identical in appearance (clear, colorless, and supplied in 1 identical 20-mL ampule), ensuring maintenance of blinding across all groups.

Preoperative preparation

All participants received standardized preoperative counseling regarding the study, provided written informed consent prior to enrollment and underwent standard preoperative care for PPTL, which included at least 8 hours of fasting, abdominal skin preparation, and intramuscular administration of 10 mg morphine 30 minutes prior to surgery. Before the procedure, participants were instructed in the use of the Numerical rating scale (NRS) for pain assessment to ensure accurate reporting. Prior to the procedure, the assisting nurse drew the assigned study solution into two 10-mL sterile syringes for use during the operation.

Surgical procedure

Participants were placed in the supine position with continuous monitoring of pulse, blood pressure, and oxygen saturation. Local anesthesia was administered with 15 mL of 1% lidocaine with epinephrine (1:100,000) infiltrated into the subcutaneous tissue and rectus sheath.

A 2–3 cm transverse infraumbilical incision was made to enter the peritoneal cavity. After peritoneal entry, the allocated study solution (20 mL total; 10 mL per side) was instilled immediately at interstitial portion of both fallopian tubes. Pain was assessed with the NRS one minute after instillation.

Bilateral tubal occlusion was performed using the Modified Pomeroy technique. Pain scores were subsequently assessed at three time points using the NRS: (1) ligation of the first tube, (2) ligation of the second tube, and (3) after skin closure. Pain assessments were conducted after intramuscular morphine onset (approximately 30 minutes post-administration) to ensure steady systemic analgesia across groups. Environmental and procedural conditions, including operating room setting, surgical team composition, and absence of external stimuli (e.g., music), were standardized for all participants. If the NRS reached 4, an anesthesiologist was consulted. Additional analgesia or anesthesia was provided at their discretion.

Postoperative assessment

Oral paracetamol 500 mg was prescribed every 4–6 hours as needed for postoperative analgesia. All participants were monitored for two hours after surgery for potential lidocaine-related adverse events, including tinnitus, dizziness, or perioral numbness.

Sample size calculation

The primary outcome was to determine the analgesic efficacy of IPL (either 50 mg or 100 mg) compared with placebo. The comparison between the 50 mg and 100 mg doses was defined as a secondary outcome. The trial had three parallel arms with two primary many-to-one comparisons (50 mg vs placebo and 100 mg vs placebo); the 50 mg vs 100 mg comparison was prespecified as secondary. Based on prior data[11-12] ($\mu_{(control)}$ = 6.55, SD = 3.28; $\mu_{(lidocaine)} \approx 3.50$), we targeted a difference of 3.05 NRS points. Using n4Studies[16-17] (three-group module) with the number of primary pairwise comparisons set to $\tau = 2$—thereby controlling the family-wise two-sided $\alpha = 0.05$

across the two primary tests—with 90% power, the required sample size was approximately 29 participants per group. The comparison between the 50 mg and 100 mg groups produced an unrealistically large sample size requirement due to the minimal expected difference between these two doses; therefore, this contrast was retained only as a secondary outcome. Allowing for an anticipated 15% dropout or loss to follow-up, the adjusted sample size increased to 34 participants per group (total 102).

Statistical analysis

Statistical analyses were performed using Stata software, version 13 (StataCorp, College Station, TX, USA). Continuous variables were presented as mean ± standard deviation (SD) or median with interquartile range (IQR), as appropriate, and categorical variables were presented as frequencies and percentages.

Baseline characteristics among groups were compared using one-way analysis of variance (ANOVA) or the Kruskal–Wallis test for continuous variables. When overall group differences were observed, pairwise comparisons were performed using Bonferroni-adjusted post-hoc tests. For selected continuous variables with non-normal distributions or heteroscedasticity, linear regression models with robust standard errors were applied. Categorical variables were compared using Fisher's exact test, with pairwise comparisons conducted where appropriate. Comparisons involving pelvic inflammatory disease were not estimable because of rare events.

For the primary outcome, pain scores measured at multiple intraoperative time points were analyzed using a linear mixed-effects model with fixed effects for treatment group, time, and their interaction, and a random intercept for each participant to account for within-subject correlations. Post-hoc pairwise comparisons between groups at each time point were conducted using the margins command with Bonferroni-adjusted 95% confidence intervals (CIs). Model assumptions were assessed and deemed appropriate. The intraclass correlation coefficient (ICC = 0.62) indicated substantial within-subject correlation, supporting the use of the mixed-effects model

A per-protocol analysis was performed because participants who discontinued the assigned intervention required intravenous sedation or conversion to general anesthesia, which precluded assessment of intraoperative pain scores. All statistical tests were two-sided, and $p < 0.05$ were considered statistically significant.

All trial outcomes were prespecified in the study protocol, and no changes were made after the trial commenced. No interim analyses or formal stopping guidelines were planned.

Results

A total of 102 participants were randomized (34 per group). Of these, 96 completed postpartum mini-laparotomy tubal ligation and were included in the primary (per-protocol) analysis: 33 in IPL 100 (Group 1), 34 in IPL 50 (Group 2), and 29 in the placebo group (Group 3). Six participants required intraoperative conversion—due to inability to proceed with PPTL because of severe adhesions, conversion to general anesthesia, or conversion to monitored anesthesia care (MAC)—and were excluded from the per- protocol analysis. The participant flow is summarized in the CONSORT diagram (Figure 1). The trial was completed as planned after the target sample size had been reached; no early stopping rules were applied.

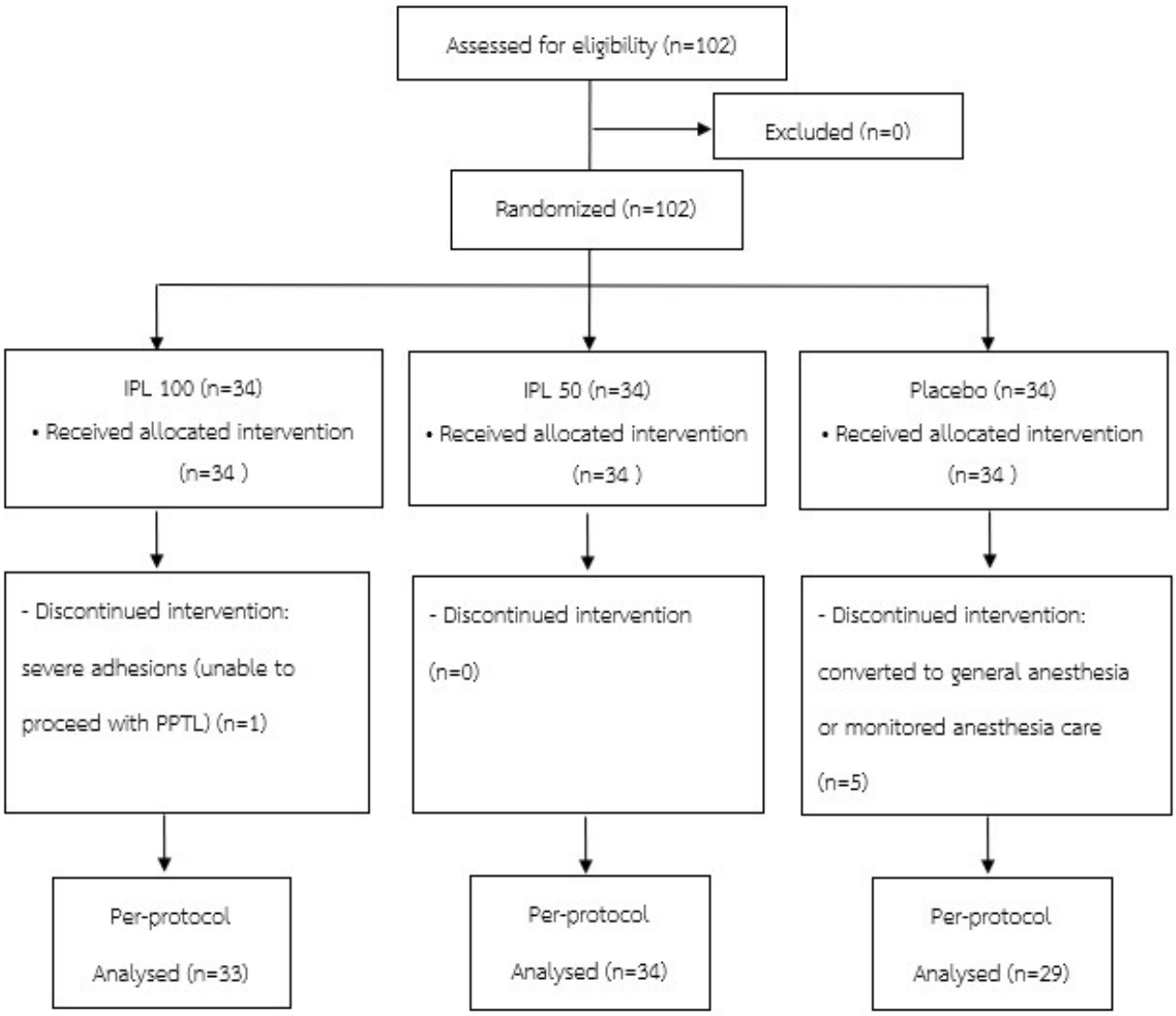


Figure 1 CONSORT flow diagram of study participants

Flow of participants through the trial, including enrollment, randomization, allocation and analysis for each treatment group

Baseline clinical characteristics were comparable among the three groups, including age, body mass index, history of pelvic inflammatory disease, and prior dilation and curettage (D&C). The interval from delivery to PPTL and operative time also did not differ significantly. Details are presented in Table 1.

Table 1. Demographic characteristics of participants among IPL 50 (n = 34), IPL 100 (n = 33) and Placebo (n = 29)

Characteristics	IPL 50	IPL 100	Placebo	p-value1	p-value2	p-value3
Age (years)*	28.5 (27-33)	31 (29-35)	31 (29-33)	0.254	1.000	0.778
Hx PID**	0	2 (6.1)	1 (3.5)	NA	NA	NA
Hx D&C**	3 (8.8)	6 (18.2)	4 (13.8)	0.305	0.694	0.738
BMI (kg/m^2)*	27.3 (23.6-32.9)	26.6 (23.4-30.5)	25.8 (24.5-30.0)	1.000	1.000	1.000
TDTL (day)*	1 (1-2)	1 (1-2)	1 (1-2)	0.278	0.428	1.000
TSTC (min)***	32.4 ± 12.2	32.6 ± 12.5	31.9 ± 12.4	1.000	1.000	1.000

*median ± interquartile range (IQR), **n (%), ***mean ± standard deviation (SD)

****in IPL 50

IPL 50: intraperitoneal lidocaine 50 mg group, IPL 100: intraperitoneal lidocaine 100 mg group, Placebo: intraperitoneal normal saline group, p-value 1: p-value between IPL 50 and IPL 100, p-value2: p-value between IPL 50 and placebo, p-value3: p-value between IPL 100 and placebo, Hx PID: history of pelvic inflammatory disease, Hx D&C: history of dilatation and uterine curettage, BMI: body mass index, TDTL: time from delivery to tubal ligation, TSTC: time from skin incision to skin closure

NA: not applicable due to rare event, precluding reliable pairwise statistical comparison

P values for continuous variables were derived from one-way ANOVA or Kruskal-Wallis test,

P values for categorical variables from Fisher's exact test.

Pain scores across operative steps were analyzed using a linear mixed-effects model with a random intercept for each participant. Model diagnostics confirmed that the assumptions of normality, homoscedasticity, and independence were adequately met. Residuals were approximately normally distributed on Q–Q plots, with no evidence of heteroscedasticity. The intraclass correlation coefficient (ICC = 0.62) demonstrated substantial within-subject correlation, supporting the use of the mixed-effects approach. There was no influential outliers. A likelihood-ratio test showed that including the group × time interaction did not significantly improve model fit (p = 0.203), indicating similar temporal pain trends across groups.

At 1 minute after intraperitoneal instillation, mean pain scores were comparable among the three groups, showing no statistically significant differences. During the first and second tubal ligations, both lidocaine regimens demonstrated significantly lower pain scores than placebo, with the 100 mg dose producing greater analgesic effects than the 50 mg dose. This dose-dependent analgesic benefit was sustained through the skin closure step, where participants receiving 100 mg lidocaine continued to report the lowest pain levels.

No participants experienced aural fullness, perioral numbness, or abnormal vital signs in any group. Dizziness occurred in four participants (4.17%): two in IPL 50 and two in IPL 100, with none in the placebo group; differences were not statistically significant (p = 0.405). Detailed pain outcomes, adverse events and mean difference are summarized in Table 2. and Table 3.

Table 2. Comparison of intraoperative pain and adverse effect among IPL 50 (n = 34), IPL 100 (n = 33) and Placebo (n = 29) after intraperitoneal lidocaine instillation

Pain score	IPL 50	IPL 100	Placebo
1 min*	2.7 ± 2.3	2.8 ± 2.3	3.7 ± 2.9
1st TR*	4.2 ± 2.4	3.4 ± 2.6	5.8 ± 2.7
2nd TR*	5.1 ± 2.5	4.7 ± 2.9	7.1 ± 2.4
Skin closure*	4.4 ± 2.2	4.2 ± 2.9	5.9 ± 2.7
Dizziness**	2 (5.9)	2 (6.1)	0

*mean ± standard deviation (SD), **n (%),

IPL 50: intraperitoneal lidocaine 50 mg group, IPL 100: intraperitoneal lidocaine 100 mg group, Placebo: intraperitoneal normal saline group, 1 min: 1 minute after solution instillation, 1st TR: pain score at first tubal ligation, 2nd TR: pain score at second tubal ligation, Skin closure: pain score after skin closure

Table 3. Mean difference of intraoperative pain scores by pairwise comparisons

Pain score	Placebo vs IPL 50	Placebo vs IPL 100	IPL 50 vs IPL 100
1 min*	1.0 (-0.6, 2.7)	0.8 (-0.8, 2.5)	-0.2 (-1.6, 1.2)
	p = 0.411	p = 0.653	p = 1.000
1st TR*	1.4 (0.1, 2.8)	3.1 (1.8, 4.5)	1.5 (0.1. 2.8)
	p = 0.038**	p < 0.001**	p = 0.030**
2nd TR*	2.3 (0.9, 3.6)	4.6 (3.2, 6.0)	2.3 (1.0, 3.6)
	p = 0.001**	p < 0.001**	p <0.001**
Skin closure*	1.7 (0.4, 3.1)	3.4 (2.0, 4.8)	1.7 (0.4, 3.0)
	p = 0.013**	p < 0.001**	p = 0.012**

*median difference (95% CI), **statistical significance

IPL 50: intraperitoneal lidocaine 50 mg group, IPL 100: intraperitoneal lidocaine 100 mg group, Placebo: intraperitoneal normal saline group, 1 min: 1 minute after solution instillation, 1st TR: pain score at first tubal ligation, 2nd TR: pain score at second tubal ligation, Skin closure: pain score after skin closure

Discussion

In this randomized controlled trial, IPL at both 50 mg and 100 mg significantly reduced intra-operative pain compared with placebo during postpartum mini-laparotomy tubal ligation under local anesthesia. The linear mixed-effects analysis further demonstrated that the 100 mg regimen consistently provided greater analgesic benefit than the 50 mg regimen across key operative steps, indicating a dose-dependent response within the lower dose range (50-100 mg). This finding suggests that incremental increases in lidocaine dosing within this range can improve intra-operative pain control.

Our findings support IPL instillation as an effective adjunct for intraoperative analgesia in postpartum mini-laparotomy tubal ligation. Mean pain scores were lower by approximately 1.5–2.4 points versus placebo at key operative steps—an effect size that is clinically meaningful on the 0–10 NRS.

These results align with Rattanalappaiboon et al.[11], who reported a reduction from 6.55 in the placebo group to 3.40–3.50 with IPL. In contrast, absolute pain scores in our trial were higher than those reported by Visalyaputra et al.[13] (NRS 0.8 with IPL plus intramuscular morphine vs 6.0 with morphine alone), likely reflecting differences in dosing/volume, and assessment protocols.

Previous studies have demonstrated the analgesic efficacy of IPL during PPTL across a wide range of doses. Rattanalappaiboon et al.[11] reported comparable pain relief between 100 mg and 200 mg IPL, while Visalyaputra et al.[13] demonstrated significant intraoperative pain reduction using intraperitoneal lidocaine in combination with intramuscular morphine. In addition, Werawatakul et al.[10], in a Cochrane systematic review, summarized that effective doses of intraperitoneal lidocaine ranged from 50 mg to 400 mg without evidence of systemic toxicity.

In contrast to these earlier studies, which primarily evaluated higher or broader dose ranges, our study focused on the lower dose window and demonstrated a significant incremental analgesic benefit between 50 mg and 100 mg IPL. These findings suggest that within the lower dosing range, increasing the dose from 50 mg to 100 mg can meaningfully improve intraoperative pain control without increasing adverse events, supporting 100 mg as a clinically practical and effective dose for routine postpartum tubal ligation.

The superior performance of 100 mg lidocaine may be explained physiologically by greater diffusion across the peritoneal and visceral surfaces, allowing a wider distribution to the pelvic viscera and uterine fundus where nociceptors are concentrated. Lidocaine blocks voltage-gated sodium channels and attenuating afferent visceral pain pathways; therefore, slightly higher local concentrations can increase receptor coverage without raising systemic levels above the safety threshold.

Our findings may inform future multimodal analgesic strategies for PPTL. While Sothornwit et al[6] reported that the addition of ibuprofen to IPL further reduced intraoperative pain, that study evaluated a combined analgesic regimen and did not examine dose responsiveness of IPL alone. In this context, our demonstration of a dose-dependent analgesic effect between 50 mg and 100 mg IPL provides foundational evidence for selecting an effective lidocaine dose when designing future multimodal, non-opioid analgesic protocols, particularly in low-resource settings where neuraxial anesthesia or intravenous sedation may not be readily available.

Although 100 mg of IPL provided superior and more consistent analgesia in this study, the principle of using the lowest effective dose remains clinically relevant. In routine practice, not all patients undergoing PPTL may require the high dose, particularly in uncomplicated procedures with minimal tissue manipulation. Accordingly, the present findings should not be interpreted as advocating a rigid fixed-dose strategy for all patients. Rather, the demonstrated dose–response relationship between 50 mg and 100 mg offers an evidence-based framework to guide flexible, individualized dose selection within a safe and effective range. From a broader perspective, although the incremental cost of increasing the lidocaine dose is modest on a per-patient basis, cumulative resource utilization at the population level warrants consideration, particularly in resource-limited settings. By defining both an effective lower boundary and the additional benefit of dose escalation, this study supports a balanced, pragmatic approach that optimizes analgesic efficacy, patient comfort, safety, and

responsible use of healthcare resources.

This study has several notable strengths. First, it is among the few randomized controlled trials conducted specifically in postpartum women undergoing mini-laparotomy tubal ligation under local anesthesia—representing a population and surgical context rarely addressed in international literature. Second, the trial design was rigorously blinded at all levels: participants, surgeons, and outcome assessors, with study medications identically prepared and coded by an independent pharmacist. Third, the pain assessment protocol was standardized and time-locked to distinct operative steps, minimizing measurement bias. Fourth, the analysis using a linear mixed-effects model enhanced statistical robustness by accounting for within-subject variability across repeated measurements, thereby strengthening the internal validity of the findings. Lastly, all procedures were performed in a real-world tertiary hospital setting, ensuring that the results are highly applicable to everyday clinical practice in low-resource obstetric units.

Some limitations merit consideration. This study was conducted in a single tertiary hospital, which may limit the generalizability of the findings to other settings with different surgical practices or patient characteristics. Although the analysis using a linear mixed-effects model strengthened the internal validity, serum lidocaine concentrations were not measured; therefore, systemic absorption and pharmacokinetic profiles could not be verified. In addition, data on participants' occupation and educational level were not collected, precluding adjustment for potential psychosocial factors that may influence pain perception and response. Future multicenter studies incorporating pharmacokinetic measurements and relevant sociodemographic variables would help confirm the external validity and optimize the clinical application of IPL in postpartum women.

Conclusion

IPL 50 mg and 100 mg significantly reduced intra-operative pain versus placebo, with 100 mg yielding the greatest effect.

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Conflict of interest

The authors report no conflict of interest.

Data availability statement

The data that support the findings of the study is available on request from the corresponding author within five years after publication. The full trial protocol is available from the corresponding author on reasonable request.

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