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Efficacy of Intraoperative Intravenous Lidocaine Infusion for Postoperative Quality of Recovery in Laparoscopic Gynecological Surgery: a Triple-Blind, Randomized Controlled Trial

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Abstract

Objective: To evaluate whether intraoperative continuous intravenous lidocaine infusion improves postoperative quality of recovery, pain, and opioid consumption in patients undergoing elective laparoscopic gynecological surgery.

Materials and methods: This prospective, triple-blind, randomized controlled trial enrolled patients aged 18-65 yr undergoing elective laparoscopic benign gynecologic surgery. Patients were randomized to receive either lidocaine 1.5 mg/kg intravenous bolus followed by continuous infusion at 1.5 mg/kg/h until the end of surgery, or an equivalent volume of normal saline. The primary outcome was quality of recovery assessed by the Thai QoR-35 questionnaire at 24 h postoperatively. Secondary outcomes included pain scores in the post-anesthesia care unit and at 4, 8, 12, and 24 h, incidence of severe pain, total morphine consumption within 24 h, ondansetron doses, and Ramsay sedation scores.

Results: Sixty-three patients completed the study. Baseline characteristics were comparable between groups. The mean QoR-35 score in the lidocaine group was 162.68 ± 8.43 versus 160.38 ± 7.60 in the saline group (P = 0.259). Pain scores, morphine consumption, and antiemetic requirements did not differ significantly. However, the incidence of severe pain was lower in the saline group than in the lidocaine group (16.1% vs. 43.8%; P = 0.035). No differences were observed in sedation scores

Conclusion: Perioperative intravenous lidocaine infusion did not significantly improve postoperative quality of recovery, pain scores, and opioid consumption, but was associated with a reduced incidence of severe pain.

Keywords: lidocaine infusion, laparoscopic gynecologic surgery, quality of recovery

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Introduction

Laparoscopic gynecological surgery has become a widely accepted surgical technique. Compared with open surgery, laparoscopy offers several advantages, including smaller incisions, reduced wound pain and opioid consumption, shorter hospital stays, faster recovery, and earlier return to daily activities.[1,2] Although laparoscopic surgery results in less postoperative pain than open procedures, pain is still a common issue. In addition to incisional pain from trocar and instrument placement, patients often experience abdominal and shoulder pain.[3,4]

Current postoperative analgesic strategies emphasize multimodal analgesia to minimize opioid requirements and adverse effects. Intravenous lidocaine, with both analgesic and anti-inflammatory has been shown to provide benecifial postoperative pain management. Several studies have demonstrated that intraoperative continuous intravenous infusion of lidocaine during surgery can reduce postoperative pain scores, opioid consumption, incidence of nausea and vomiting, duration of ileus and length of hospital stay in patients undergoing abdominal surgery.[5,6] Recent evidence also suggests that intravenous lidocaine infusion improves postoperative quality of recovery, particularly in laparoscopic abdominal and gynecological surgeries.[7-10] Beyond pain control, improving postoperative recovery and patient outcomes has become increasingly important. Better recovery refere to ability to resume normal daily activities and regain both physical and psychological well-being, thereby improving quality of life and patient satisfaction. Despite these potential benefits, studies specifically evaluating the use of intravenous lidocaine in laparoscopic gynecological surgery remain limited. Therefore, our study aims to investigate the efficacy of continuous intravenous lidocaine infusion during surgery on postoperative recovery quality in patients undergoing laparoscopic gynecological surgery.

Materials and methods

This prospective triple-blind, randomized controlled trial was conducted at Rajavithi Hospital from August 2024 to May 2025. The study was approved by Rajavithi Hospital Ethics Committee on June 25th, 2024 (128/2024) and approved by TCTR Committee on July 8th, 2024 (TCTR20240708004). Inclusion criteria were patients aged 18-65 years with ASA physical status I-II who underwent elective laparoscopic gynecological surgery for benign tumors at Rajavithi Hospital. All participants received information about the study and provided written informed consent. Exclusion criteria included pregnancy, body weight <40 kg or BMI >35 kg/m², history of allergy to local anesthetics, arrhythmia, liver disease, GFR <60 ml/min/1.73 m², neurological disease, allergy to NSAIDs or sulfonamides, history of gastrointestinal bleeding or peptic ulcer, chronic use of analgesics, or inability to fully understand Thai language and complete questionnaires and pain assessments. Eligible patients were randomized in a 1:1 ratio using block randomization (block size of 4) with a web-based system (http://www.randomization.com) into two groups to lidocaine group and

normal saline group. After randomization, each participant was assigned an identification number and sealed in an envelope. The envelopes were opened by a researcher not involved in anesthesia administration or outcome assessment. This researcher prepared the study syringes, labeled only with the study code, and delivered them to the anesthesia providers, who were blinded to group allocation. Both patients and outcome assessors remained blinded throughout the study.

Study protocol

All patients received standard ASA monitoring. During induction, patients in both groups received the study drug. In the lidocaine group, patients received intravenous 2% lidocaine 1.5 mg/kg as a bolus over 10 min, followed by a continuous infusion of 1.5 mg/kg/h until the end of surgery. This dosing regimen was based on the recommendations of the International Consensus Statement on the use of intravenous lidocaine for postoperative pain and recovery.[11] Patients in the normal saline group received an equal volume administered in the same manner.

General anesthesia was induced with propofol 1.5-2.5 mg/kg and/or fentanyl 1-2 mcg/kg. Neuromuscular blockade was achieved with cisatracurium 0.15-0.2 mg/kg or, in cases of suspected difficult airway, succinylcholine 1-1.5 mg/kg. The airway was secured with an appropriately sized cuffed endotracheal tube. Anesthesia was maintained with sevoflurane 1-2% in 40-60% oxygen in air, with a total flow of 2 L/min, titrated to achieve MAC 1.0-1.5. Cisatracurium was administered intermittently as required. Additional fentanyl 0.5-1.0 mcg/kg was given if mean arterial pressure exceeded 20% above baseline. All patients received intravenous parecoxib 40 mg and ondansetron 4 mg approximately 30 min before the end of surgery. During study drug infusion, suspected adverse reactions to lidocaine, including allergy or systemic toxicity (e.g., seizures, severe arrhythmia, refractory hypertension or hypotension), were managed by immediate discontinuation of the study drug, appropriate treatment, and unblinding if necessary. Reasons for withdrawal after drug administration included conversion to open surgery or serious adverse effects related to lidocaine. At the end of surgery, the study drug infusion was discontinued, and neuromuscular blockade was reversed with neostigmine and atropine.

Postoperatively, patients were observed in the post-anesthesia care unit (PACU) for 1 h with continuous vital signs monitoring and Modified Aldrete score assessment. On arrival, patients rated their pain using the numeric rating scale (NRS). If NRS ≥4, intravenous morphine 2 mg was administered. Ramsay sedation score was recorded on arrival and at 1 h (1 = agitated/restless, 2 = cooperative/oriented/tranquil, 3 = drowsy/responds to command only, 4 = brisk response to light glabellar tap or loud auditory stimulus, 5 = sluggish response to light glabellar tap or loud auditory stimulus, 6 = no response). Nausea and vomiting were treated with intravenous ondansetron 4 mg and the number of doses administered was recorded. In the ward, patients received oral paracetamol 500 mg every 6 h. Intravenous morphine 3 mg was prescribed as

rescue analgesia every 4 h as needed if NRS ≥4. Total morphine requirement over 24 h and NRS pain scores at 4, 8, 12, and 24 h postoperatively were recorded. Nausea and vomiting were treated with intravenous ondansetron 4 mg, repeated every 6 h as required, and the number of doses administered was documented. At 24 h postoperatively, all patients completed the Thai QoR-35 questionnaire, which evaluates five domains of recovery: physical comfort, pain, physical independence, psychological support, and emotional state. Scores range from 35 to 175, with higher scores indicating better recovery. The Thai QoR-35, adapted from the QoR-40 and validated by the Faculty of Medicine Siriraj Hospital, Mahidol University, demonstrated strong reliability (Cronbach's alpha coefficient 0.91) and acceptable validity (correlation coefficient 0.65).[12]

Statistical analysis

The sample size was calculated based on a previous study by Wang and colleagues.[9] In that study, the mean Quality of Recovery (QoR) score in the lidocaine group was 173 (SD = 9.8), while in the normal saline group it was 166.3 (SD = 8.2). To achieve a study power of 80% with a two-sided significance level of 0.05, 29 participants were required in each group. Considering a 10% dropout rate, the final sample size was set at 32 participants per group. Accordingly, 64 patients were recruited and randomly allocated into two study groups: lidocaine group (n = 32) and normal saline group (n = 32). Data were analyzed using IBM SPSS Statistics version 26.0. Normality was assessed using the Shapiro-Wilk test. Equality of variances between groups was evaluated using Levene's test. Continuous variables with normal distribution were analyzed using the independent t-test and presented as mean ± SD, whereas continuous variables with skewed distribution were analyzed using the Mann-Whitney U test and presented as median (IQR). Categorical variables were summarized as number (percentage) and compared using the Chi-square test or Fisher's exact test, as appropriate. Outcomes over time were analyzed using a mixed-effects model to account for random effects. Statistical significance was defined as P-value < 0.05. No missing data occurred for the study variables. Therefore, no imputation was performed.

Results

The conduct of the study is summarized in **Figure 1.** A total of 64 participants were assessed for eligibility and subsequently randomized to either the lidocaine group or the normal saline group. One patient in the lidocaine group was withdrawn due to conversion from laparoscopic to open surgery. Thus, 63 patients, 31 in the lidocaine group and 32 in the normal saline group, completed the study and were included in the final analysis. Baseline demographic and surgical characteristics showed no statistically significant differences between the two groups, as presented in **Table 1**.

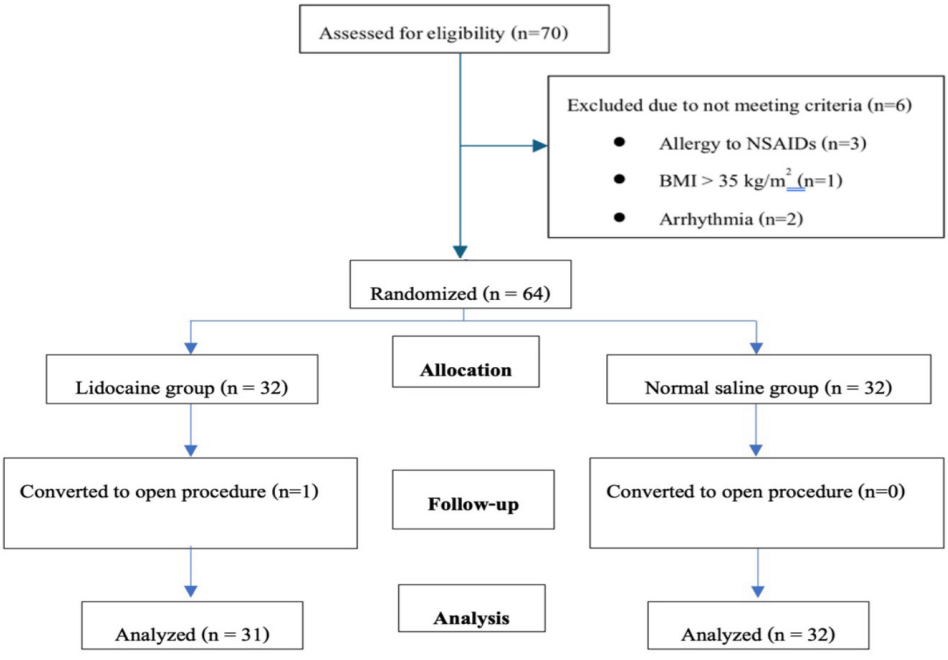


Figure 1 CONSORT diagram of study

Table 1 Baseline demographic and surgical characteristics

	Lidocaine (n=31)	Normal saline (n=32)	*P*-value
Age (yr), mean ± SD	39.4 ± 9.1	41.8 ± 8.0	0.272
Types of operation, n (%)			0.717
Hysterectomy	16 (51.6)	15 (46.9)	
Adnexal surgery	14 (45.2)	14 (43.8)	
Myomectomy	0	1 (3.1)	
Diagnostic	1 (3.2)	2 (6.3)	
Body mass index (kg/m^2), mean ± SD	23.5 ± 4.6	23.4 ± 4.3	0.881
ASA physical status, n (%)			0.714
I	23 (74.2)	25 (78.1)	
II	8 (25.8)	7 (21.9)	
Duration of surgery (min), mean ± SD	140.3 ± 47.3	159.0 ± 50.2	0.132
Duration of anesthesia (min), mean ± SD	180.3 ± 52.8	195.6 ± 52.1	0.251
Duration of drug infusion (min), mean ± SD	160.7 ± 46.8	170.9 ± 49.4	0.402
Volume of drug infusion (ml), mean ± SD	16.9 ± 4.9	17.0 ± 4.5	0.935
Total fentanyl (mcg), mean ± SD	116.9 ± 42.0	125.0 ± 38.6	0.431
Number of ports, n (%)			0.571
1	0	1 (3.1)	
2	0	0	
3	7 (22.6)	7 (21.9)	
4	24 (77.4)	24 (77.4)	

The mean QoR35 scores at 24 in lidocaine group was slightly higher compared with the normal saline group (162.68 ± 8.43 vs. 160.38 ± 7.60), although the difference was not statistically significant (*P* = 0.259). No significant differences of all subdomains of QoR35 between lidocaine and normal saline group **(Table 2)**.

Postoperative pain scores were comparable between groups at all measured time points, from the PACU to 24 h after surgery, presented in Figure 2. No significantly different between the lidocaine and normal saline groups (Table 3). However, the incidence of severe pain, defined as an NRS score ≥ 7, was significantly lower in the lidocaine group than in the normal saline group (*P* = 0.027) **(Table 2)**. The total morphine requirement during the first 24 h was lower in the lidocaine group, median (IQR) of 2 (2-5) compared with the normal saline group, median (IQR) of 5 (2.5-6), although this difference did not reach statistical significance **(Table 2)**. The number of ondansetron doses administered for postoperative nausea and vomiting has no statistical difference between the two groups **(Table 2)**. Sedation levels assessed by the Ramsay scale showed no differences between the groups either at PACU or at 1 h postoperatively showed that patients who received lidocaine infusion were not more sedated than who did not **(Table 3)**. Furthermore, our study illustrates that there are no major adverse events with the use of lidocaine infusion in our study.

Discussion

This study aimed to evaluate the effect of perioperative intravenous lidocaine infusion on the quality of recovery, postoperative pain, and opioid consumption in patients undergoing laparoscopic gynecologic surgery. Our results

Table 2 Quality of recovery score and other secondary outcomes

	Lidocaine (n=31)	Normal saline (n=32)	*P*-value
Quality of recovery score, mean ± SD	162.68 ± 8.43	160.38 ± 7.6	0.259
Physical comfort, mean ± SD	55.58 ± 3.88	55.69 ± 3.00	0.903
Physical independence, mean ± SD	19.03 ± 1.70	18.72 ± 1.67	0.463
Emotional, mean ± SD	33.58 ± 2.14	33.34 ± 1.94	0.647
Psychological support, mean ± SD	28.61 ± 2.20	27.41 ± 2.89	0.067
Pain, mean ± SD	25.87 ± 2.62	25.22 ± 3.61	0.416
Total morphine requirement (mg), median (IQR)	2.00 (2.00 - 5.00)	5.00 (2.50 - 6.00)	0.054
Number of ondansetron, mean ± SD	0.16 ± 0.37	0.19 ± 0.47	0.808
Severe pain, n (%)	5 (16.1)	14 (43.8)	0.027

Table 3 Numeric rating scores and Ramsay sedation scores

	Lidocaine (n=31)	Normal saline (n=32)	*P*-value
Numeric rating scores, mean ± SD			
PACU	3.74 ± 3.35	4.34 ± 2.96	0.452
4 h	3.10 ± 2.27	3.56 ± 2.49	0.441
8 h	2.68 ± 1.78	2.56 ± 2.38	0.829
12 h	1.87 ± 1.63	1.62 ± 1.29	0.508
24 h	1.55 ± 1.48	2.09 ± 1.75	0.187
Ramsay sedation scores, mean ± SD			
PACU	2.48 ± 0.81	2.34 ± 0.79	0.489
1 h	2.13 ± 0.43	2.13 ± 0.49	0.972

PACU = post-anesthetic care unit

P-values were calculated using a mixed-effects model to account for random effects.

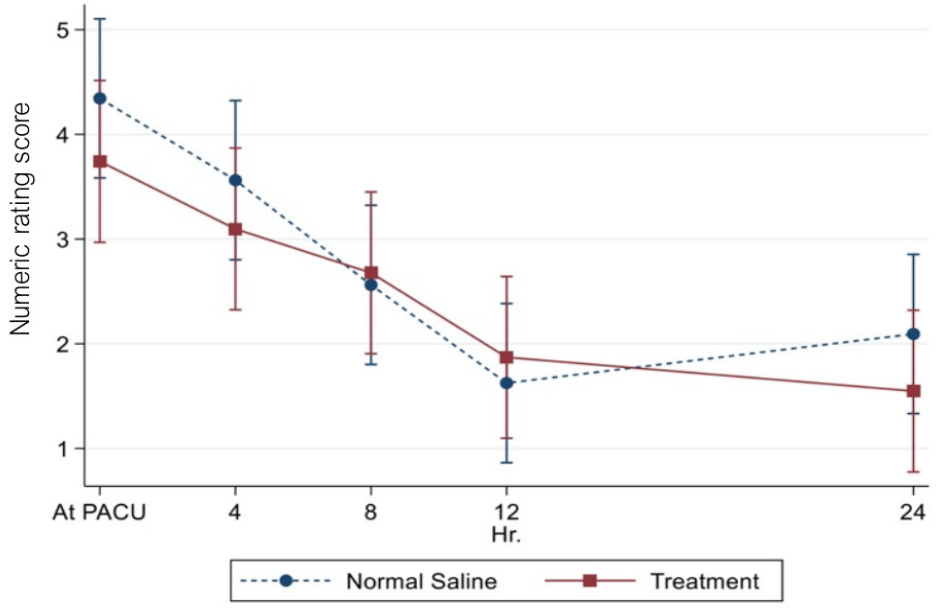


Figure 2 Mean pain scores at PACU, 4, 8, 12 and 24 h after surgery

demonstrated that lidocaine infusion at a rate of 1.5 mg/kg/h did not significantly improve the quality of recovery, as assessed by the Thai QoR-35 questionnaire, compared with the normal saline group. Furthermore, no significant differences were found between the groups in postoperative pain scores or opioid consumption within the first 24 h after surgery. However, we found that the incidence of severe pain was significantly lower in the lidocaine group than in the normal saline group.

Several limitations of our study may explain why our findings differ from several previous studies that reported beneficial

effects of perioperative systemic lidocaine on postoperative outcomes. First, previous studies have shown that intravenous lidocaine improves the quality of recovery, reduces postoperative pain, and decreases opioid requirements, particularly in patients undergoing laparoscopic abdominal surgeries.[7,13] For instance, studies on outpatient laparoscopic gynecologic procedures such as salpingo-oophorectomy and cystectomy demonstrated significant improvements in postoperative recovery and lower analgesic requirements among patients receiving lidocaine infusions.[8,10] In contrast, most cases in our study involved total hysterectomy with bilateral salpingectomy, which are more extensive and invasive operations with longer operative times. These differences in surgical invasiveness and duration could have influenced postoperative pain intensity and the course of recovery, thereby attenuating the potential benefits of lidocaine infusion.

Second, our study assessed quality of recovery score at only a single postoperative time point after surgery. Given the generally rapid recovery associated with laparoscopic gynecologic surgery, earlier assessments may have captured transient improvements in recovery that were not detectable at 24 h. In addition, baseline QoR-35 scores were not obtained preoperatively, which precluded change-from-baseline analyses. In addition, baseline QoR-35 scores were not obtained preoperatively, which precluded change-from-baseline analyses. Without baseline data, subtle postoperative improvements relative to patients' preoperative functional status may not have been fully captured. This limitation may partly explain the lower QoR scores observed in our study compared with previous reports. Regarding the assessment of quality or recovery, we utilized the Thai QoR-35 questionnaire, which has been validated and shown to be reliable in Thai patients. The version used in our study was endorsed by 25 Thai anesthesiologists with 5-20 years of clinical experience, supporting its cultural and contextual applicability. During administration, no difficulties or misunderstandings were encountered among patients, ensuring the validity of the collected responses.[12]

Third, the dosing regimen of lidocaine infusion rate used in this study may also explain the discrepancy between our results and previous reports. We administered an infusion rate of 1.5 mg/kg/h in accordance with the recommendations of the international consensus statement on the safety of intravenous lidocaine infusion to minimize the risk of local anesthetic systemic toxicity[11], and based on the study by Lv and coworkers, which demonstrated that an infusion of 1 mg/kg/h during laparoscopic radical gastrectomy improved both quality of recovery and postoperative pain.[14] In contrast, several earlier studies in laparoscopic gynecologic surgery that reported superior analgesic or recovery outcomes employed slightly higher doses, typically around 2 mg/kg/h.[8-10] This lower dosing regimen, compared with higher doses used in some previous studies, may have resulted in a smaller treatment effect.

Fourth, differences in postoperative pain management protocols may also have

contributed to the results. Due to resource limitations at our institution, rescue opioids were administered upon patient request rather than patient-controlled analgesia (PCA) for postoperative pain. This approach may underestimate actual analgesic requirements. Interestingly, our study found that significantly fewer patients in the lidocaine group experienced severe pain. This finding suggests that perioperative lidocaine infusion may still provide a beneficial effect on postoperative pain outcome.

Future studies should consider evaluating higher lidocaine infusion doses, employing earlier and repeated assessments of recovery, and standardizing postoperative analgesic management to better define the role of systemic lidocaine in enhancing postoperative recovery after laparoscopic gynecologic surgery. Importantly, our results reaffirm the safety of perioperative intravenous lidocaine infusion. No major adverse events occurred, and sedation scores were similar between groups. This favorable safety profile supports the feasibility of incorporating lidocaine infusion into multimodal analgesic regimens.

Conclusion

In patients undergoing laparoscopic gynecological surgery, perioperative continuous intravenous lidocaine infusion did not significantly improve recovery quality, reduce postoperative pain, or decrease opioid consumption among patients undergoing laparoscopic gynecologic surgery, but was associated with a reduced incidence of severe pain.

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