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Effect of intravenous lidocaine on catheter-related bladder discomfort, postoperative pain and opioid requirement in complex fusion lumbar spinal surgery: a randomized, double blind, controlled trial

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Abstract

Background Catheter-related bladder discomfort (CRBD) and pain commonly arises postoperatively in patients who undergo intra-operative urinary catheterization. The study aims to demonstrate the effectiveness of intravenous lidocaine to prevent CRBD and postoperative pain in complex lumbar spinal surgery.

Methods Eighty male patients, aged 20–79 years, scheduled for elective fusion spine surgery at least two levels were randomly assigned to receive either intravenous lidocaine (1.5 mg/kg followed by 2 mg/kg/h) (Group L) or a parallel volume of normal saline (Group C). The primary outcome was incidence of moderate to severe CRBD in a postanesthetic care unit (PACU) between the two groups. Secondary outcomes included postoperative pain, 24-hour post operative opioid requirement, mild and moderate to severe CRBD at 1, 2, 6 and 24 h postoperatively, patient satisfaction on Global Perceived Effect Scale (GPES), and the adverse effects of lidocaine and surgical complications.

Results Group L showed a significantly lower incidence of moderate-to-severe CRBD compared to Group C in the PACU ($P=0.002$) and at 1 h postoperatively ($P=0.039$). Additionally, Group L experienced a significantly lower average pain scores compared to Group C at all time points ($P<0.001$, $P<0.001$, $P=0.001$, $P<0.001$ and $P<0.001$ at 0, 1, 2, 6 and 24 h, respectively) and demonstrated a significantly reduced postoperative morphine requirement across all time intervals ($P<0.05$). Group L also reported significantly higher satisfaction on GPES compared to group C ($P<0.001$). No adverse outcome was observed in either group.

Conclusion Intravenous lidocaine administration significantly reduced the incidence of moderate-to-severe CRBD at PACU and at 1 h postoperatively. Additionally, its use in complex spine surgery led to reductions in postoperative pain, opioid requirement, and improved patient satisfaction, without any observed side effects.

Keywords Catheter-related bladder discomfort, Lidocaine, Postoperative pain, Spine surgery

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Background

Catheter-related bladder discomfort (CRBD) is an undesirable outcome during the postoperative period, characterized by a strong urge to urinate, a burning sensation radiating from the suprapubic area to the penis, and often accompanied by discomfort or an intense need to void [1, 2]. The possible mechanism of CRBD is described by stimulus of subtype muscarinic (M3) receptors in the bladder wall adjacent to the urinary catheter [1, 3]. One related study showed that severe postoperative pain was a significant contributing factor [4].

Complex spinal surgery is defined as surgery involving at least two levels of the thoracic and/or lumbar spine [5] and is known to be an extremely painful procedure [5]. Consequently, difficulty in controlling postoperative pain, delayed ambulation, reduced functional outcomes and prolonged hospital stay are often associated with CRBD [4].

Several interventions such as peripheral nerve blocks, tolterodine, oxybutynin, tramadol, trospium, ketamine, dexmedetomidine, gabapentin and pregabalin have been proved to reduce postoperative CRBD [6–12].

Lidocaine is a widely utilized anesthetic known for its analgesic properties. Its potential mechanisms of action involve anti-inflammatory effects on histamine, prostaglandins, and kinins, along with the inhibition of C-afferent neuronal activity and a decrease in excitability of dorsal horn neurons [9, 13]. Prior study reported lidocaine diminished postoperative pain and opioid consumption in various procedures including minor and major surgeries such as transurethral resection of bladder [13], colonoscopy [14], abdominal surgery [15], and spine surgery [16–18]. However, the effect of intravenous lidocaine on CRBD in spinal surgery remains unproven. Therefore, this study hypothesizes that intravenous lidocaine could alleviate the incidence of moderate-to-severe CRBD and postoperative pain in male patients undergoing complex spine surgery.

Materials and methods

This study was a prospective, randomized, double blind, placebo-controlled trial. All patients were enrolled and signed informed consent between February 1, 2022 and January 20, 2023. The study protocol was registered with the Thai Clinical Trials Registry (TCTR20221017001) on 17/10/2022 after receiving approval from the Institutional Review Board of Medical Ethics.

Participants

Eighty male patients aged 20 to 70 years, were scheduled for complex fusion lumbar spinal surgery at least two levels under general anesthesia, with American Society of Anesthesiologists physical status I and II. Patients with a history of prior urological surgeries, bladder outflow obstruction, overactive bladder, sensory disturbances or bladder issues, spinal surgeries affecting bladder function or pelvic organs, cardiovascular disease, end-stage renal disease, or psychiatric disorders were excluded from the study.

Randomization and blinding

All participants were randomly assigned to either the lidocaine group (Group L) or the normal saline group (Group C) using blocks of four computer generated random number tables. The concealed envelopes were opened before the patient entered the operation theater, and the medication was prepared by an uninvolved first anesthesiologist. Anesthetic induction, maintenance and extubating were performed by a second anesthesiologist who was blinded to the study. A third blinded anesthesiologist recorded all outcomes and complications.

Procedures

Anesthetic premedication was not allowed all patients. Noninvasive blood pressure, electrocardiography, pulse oximetry and capnography were completed before inducing anesthesia. Intravenous anesthetic administration was performed by propofol, cisatracurium and fentanyl. Mechanical ventilation was maintained to control the end tidal carbon dioxide tension between 35 and 40 mmHg. A 50% oxygen in air mixture and sevoflurane were performed for anesthetic maintenance. After achieving an adequate depth of anesthesia, a Foley catheter ($\geq$20 Fr) was inserted; the balloon was inflated with 10 ml of sterile water and secured to the thigh with plaster. The injection of local anesthesia into the skin was not permitted either before the incision or after the surgery. The lidocaine dosage was determined based on a related study [14]. In Group L, 1.5 mg/kg of intravenous lidocaine was administered before inducing anesthesia, followed by a continuous infusion of 2 mg/kg/h during the anesthetic period. In Group C, patients received 0.9%NaCl at the same bolus volume and continuous infusion rate as Group L. All medications in both groups were discontinued, and the neuromuscular blocking agent was reversed at the end of anesthesia. Patients were extubated after fulfilling extubating criteria and were transferred to the postanesthesia care unit (PACU). Patient-controlled analgesia (PCA) morphine (1 mg/ml) was administered, with a PCA dose of 1 mg per use, a lockout interval of 10 min, no basal rate, and a maximum limit of 10 mg per hour upon arrival at the PACU. No additional rescue medication was permitted within the first 24 h. The Foley catheter was subsequently removed 24 h postoperatively.

Outcomes

The primary outcome was incidence of moderate to severe CRBD in the PACU between group comparison. The secondary outcomes included postoperative pain and opioid requirements during the first 24-hour postoperative period, mild and moderate to severe CRBD at 1, 2, 6 and 24 h postoperatively, intraoperative opioid use, patient satisfaction, adverse effects of lidocaine and surgical complications. CRBD is characterized by a strong urge to urinate, a burning sensation radiating from the suprapubic area to the penis, and often accompanied by discomfort or an intense need to void [1, 2]. The severity of CRBD was recorded as follows: none (patients did not complain of CRBD when asked); mild (reported by patients separately when questioned); moderate (reported by patients spontaneously, i.e., without being prompted and without any accompanying behavioral responses); or severe (reported by patients spontaneously, accompanied by behavioral responses such as limb waving, strong vocal responses, or attempts to pull out the catheter) [1, 7, 8]. Verbal numerical rating scale (VNRS, 0 = no pain and 10 = worst pain imaginable) was also assessed to evaluate CRBD at 0, 1, 2, 6 and 24 h postsurgery. Patient satisfaction was evaluated 6 h postoperatively using a Global Perceived Effects Scale (GPES), defined by the question: How would you estimate your satisfaction with this medication for preventing CRBD? The scale ranged from 1 (very dissatisfied) to 7 (very satisfied) [19, 20]. A subanalysis of patient satisfaction was conducted, grouping responses as follows: grades 1, 2, and 3 (dissatisfied patients); grade 4 (neither satisfied nor dissatisfied); and grades 5, 6, and 7 (satisfied patients). Sedation levels upon arrival at the PACU were assessed using the Ramsay Sedation Scale, where: 1 = anxious, agitated, or restless; 2 = cooperative, oriented, and calm; 3 = asleep but responsive to commands; 4 = brisk response to a glabellar tap or loud noise; 5 = sluggish response to a light glabellar tap or loud noise; and 6 = no response at all.

Additionally, the adverse effects of lidocaine were evaluated during the 24-hour postoperative period, and surgical complications were recorded until discharge.

Sample size calculation and statistical analysis

The sample size was determined based on the related study of Kim D et al. [13]. The probability of significantly alleviated pain in the control group was 0.667, while the probability of significantly diminished pain in the lidocaine group was 0.258. The power of study was set at 80%, and the required number of participants was at least 30 per group. All analyses were accomplished using Stata IC15 (Stata Corp, 2017, College Station, TX, USA). Continuous data were presented as mean and standard deviation (SD) for sufficiently normally distributed variables. For nominal variables, absolute and relative frequencies were presented for each group. The Chi-square test was used to assess the relationship or independence between two categorical variables, while the independent t-test was used to compare two independent groups with normally distributed continuous data. For non-normally distributed continuous or ordinal data, the Mann-Whitney U test was applied to compare two independent groups. A P-values < 0.05 were considered statistically significant.

Results

Ninety-two male patients scheduled for complex spinal surgery were initially screened for the trial. Of these, 12 were excluded: nine underwent non-instrumental procedures, two had single-level spinal fusions, and one had a psychiatric condition. This left 80 eligible patients, who were then randomized into two equal groups of 40 (Fig. 1). No clinically significant difference was detected between the groups ($P > 0.05$) in term of demographic data including age, body mass index, ASA classification, comorbidities, total surgical level, anesthetic time and intraoperative opioid use (Table 1).

Primary outcomes

Group L showed a significantly lower incidence of moderate-to-severe CRBD compared with that of Group C at PACU (15% ($n = 6$) vs. 47.5% ($n = 19$), $P = 0.002$; Fig. 2; Table 2).

Secondary outcomes

Group L experienced a significantly lower average pain score compared to Group C in all time periods. (2.8 ± 2.9 vs. 4.2 ± 2.6; $P < 0.001$, at 0 h), (2.2 ± 1.7 vs. 4.5 ± 1.8; $P < 0.001$, at 1 h), (2.7 ± 1.5 vs. 4.1 ± 1.6; $P = 0.001$, at 2 h), (2.6 ± 1.4 vs. 5.1 ± 1.5; $P < 0.001$, at 6 h) and (2.2 ± 1.5 vs. 4.9 ± 1.5; $P < 0.001$, at 24 h; Table 3).

The average intra-operative fentanyl requirement was significantly lower in Group L compared to Group C (165.2 ± 52.7 mcg vs. 227.4 ± 74.5 mcg; $P < 0.001$). Additionally, the median post-operative morphine requirement was lower in Group L at all measured time points within the first 24 h, 14 mg (IQR: 10–16) vs. 44 mg (IQR: 28–51); $P < 0.001$, as shown in Fig. 3. Group L required less morphine than Group C: 1 mg (IQR: 0.0–2.0) vs. 2 mg (IQR: 1.0–3.0); $P = 0.002$ at PACU, 2 mg (IQR: 1.0–3.0) vs. 4 mg (IQR: 1.5-6.0); $P = 0.006$ at 1 h, 3 mg (IQR: 1.0–4.0) vs. 5 mg (IQR: 3.0–6.0); $P < 0.001$ at 2 h, 3 mg (IQR: 2.0–4.0) vs. 10 mg (IQR: 6.0–12.0); $P < 0.001$ at 6 h, and 4 mg (IQR: 2.0–5.0) vs. 22 mg (IQR: 11.0–26.0); $P < 0.001$ at 24 h, as shown in Table 4.

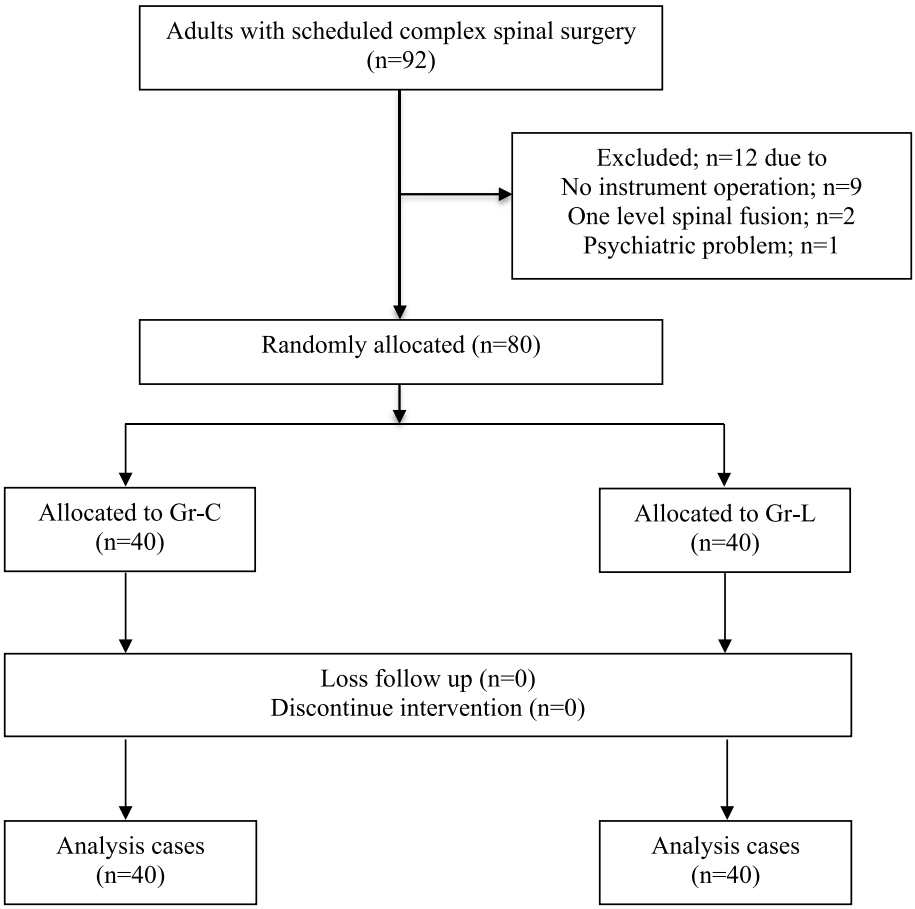

Fig. 1 Procedure flowchart. Groups are defined in method under sample size calculation and randomization

Table 1 Baseline patient characteristics

	Group C ($n=40$)	Group L ($n=40$)	*p*-value
Age(years)	58.0 (11.2)	60.2 (11.2)	0.38
Body Mass Index (kg/m^2)	26.2 (4.0)	25.4 (3.8)	0.35
ASA Classifications			0.81
1	13 (32.5%)	12 (30.0%)	
2	27 (67.5%)	28 (70.0%)	
Comorbidities			
Hypertension	23 (57.5%)	23 (57.5%)	1.00
Diabetes	8 (20.0%)	14 (35.0%)	0.13
Total surgical levels			0.38
2	23 (57.5%)	30 (75.0%)	
3	11 (27.5%)	7 (17.5%)	
4	5 (12.5%)	2 (5.0%)	
5	1 (2.5%)	1 (2.5%)	
Operative time	320.6 (86.1)	296.4 (98.7)	0.25
Intraoperative Fentanyl	225 (190–265)	175 (100–200)	< 0.001

ASA American Society of Anesthesiologists. Data are presented as mean (SD) or numbers (%) of patients. O

Group L showed significantly lower incidence of moderate-to-severe CRBD compared to Group C at 1 h (15% ($n=6$) vs. 35% ($n=14$); $P=0.039$, but not at 2 h (15% ($n=6$) vs. 22.5% ($n=9$); $P=0.39$; Fig. 2. No incidence of moderate-to-severe CRBD was noted at 6 and 24 h (Table 2). Moreover, no significant difference was found in incidence of mild CRBD between two groups at any time point ($P>0.05$; Table 2).

Group L demonstrated significantly greater satisfaction with GPES scores than Group C ($P<0.001$). In Group L, only 1 patient (2.5%) expressed being neutral (neither satisfied nor dissatisfied, grade 4), compared to 6 patients (15%) in Group C. Additionally, 39 patients (97.5%) in Group L and 34 patients (85%) in Group C reported being satisfied (grades 5, 6, or 7). No patients in either group reported dissatisfaction (grades 1, 2, or 3) according to the subgroup analysis. However, no significant difference was found between two groups regarding the Ramsay score ($P=0.17$) with most patients showing a Ramsay score of 2 (cooperative, oriented and calm). Only one patient in Group L and four patients in Group C had a Ramsay score of 3 (responds

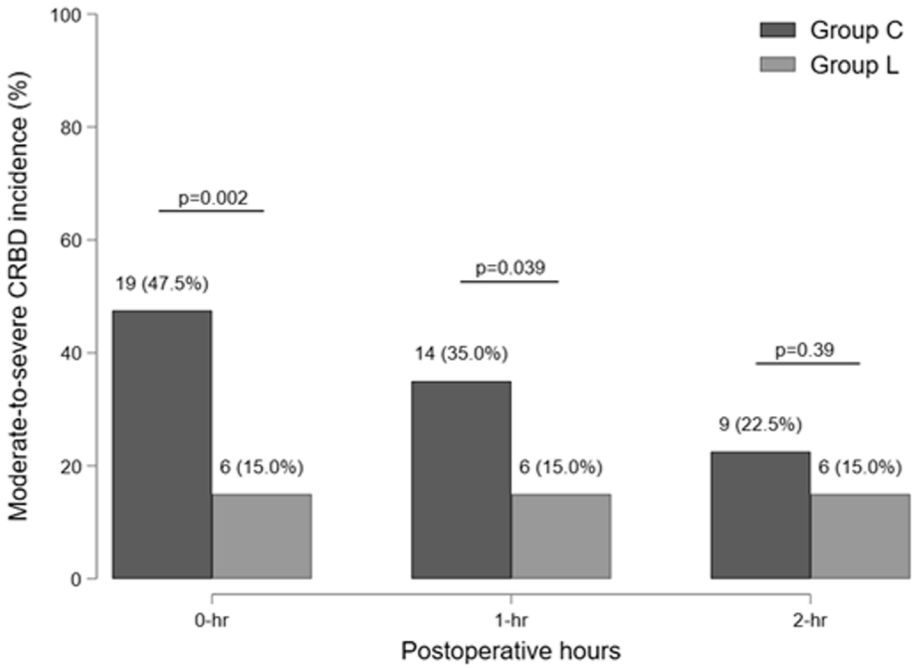

Fig. 2 Incidence of moderate to severe catheter-related bladder discomfort at 0, 1 and 2 hours in postoperative periods

Table 2 Incidence of catheter-related bladder discomfort at each postoperative period

Severity of CRBD	Postoperative time (hours)									
	0		1		2		6		24	
	Group C	Group L	Group C	Group L	Group C	Group L	Group C	Group L	Group C	Group L
None	10 (25.0%)	24 (60.0%)	14 (35.0%)	25 (62.5%)	22 (55.0%)	23 (57.5%)	25 (62.5%)	31 (77.5%)	37 (92.5%)	38 (95.0%)
Mild	11 (27.5%)	10 (25.0%)	12 (30.0%)	9 (22.5%)	9 (22.5%)	11 (27.5%)	15 (37.5%)	9 (22.5%)	3 (7.5%)	2 (5.0%)
Moderate	15 (37.5%)	6 (15.0%)	13 (32.5%)	6 (15.0%)	9 (22.5%)	6 (15.0%)				
Severe	4 (10.0%)	0 (0.0%)	1 (2.5%)	0 (0.0%)						
p-value	0.003		0.068		0.66		0.14		0.64	

CRBD Catheter-related bladder discomfort. Data are presented as numbers (%) of patients

Table 3 Average pain on the surgical site, measured using a verbal numerical rating scale, for each postoperative period

Postoperative periods (Hours)	Average VNRS		Mean difference [Group L – Group C] (95%CI)	*P*-value
	Group C (*n* = 40)	Group L (*n* = 40)		
0	4.2 (2.6)	2.8 (2.9)	-1.45 [-2.25, -0.65]	< 0.001
1	4.6 (1.8)	2.2 (1.7)	-2.32 [-3.12, -1.53]	< 0.001
2	4.1 (1.6)	2.7 (1.5)	-1.40 [-2.20, -0.60]	0.001
6	5.1 (1.5)	2.6 (1.4)	-2.53 [-3.32, -1.73]	< 0.001
24	4.9 (1.5)	2.2 (1.5)	-2.65 [-3.45, -1.85]	< 0.001

VNRS Verbal numerical rating scale; Data are presented as mean (SD) and 95% confident interval

to commands but is asleep). Ramsey sedation scores of 1, 4, 5 or 6 were not observed in either group (Table 5).

Three patients in Group L and three patients in Group C reported drowsiness during the 24-hour postoperative period ($P = 1.00$). However, no serious adverse effects, including neurological, cardiological, or surgical complications, were observed throughout the course of the study.

Discussion

Complex lumbar spinal surgery is known to be a significantly painful procedure [16] and often leads to severe postoperative pain. Related studies have described spine

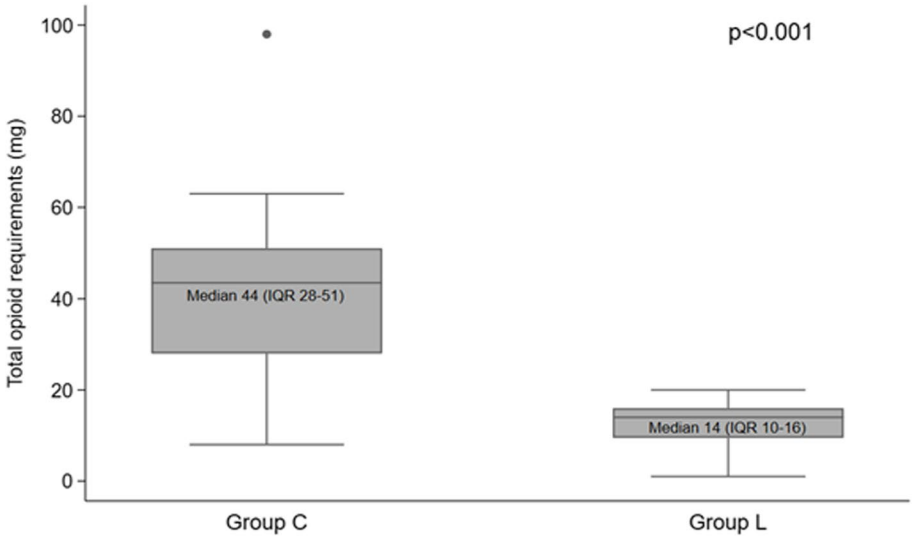

Fig. 3 Comparison of postoperative opioid requirements

Table 4 Morphine requirements at each postoperative period

Postoperative periods (Hours)	Median of morphine requirements (mg)		*p*-value
	Group C (*n* = 40)	Group L (*n* = 40)	
0	2.0 (1.0–3.0)	1.0 (0.0–2.0)	0.002
1	4.0 (1.5-6.0)	2.0 (1.0–3.0)	0.006
2	5.0 (3.0–6.0)	3.0 (1.0–4.0)	< 0.001
6	10.0 (6.0–12.0)	3.0 (2.0–4.0)	< 0.001
24	22.0 (11.0–26.0)	4.0 (2.0–5.0)	< 0.001

Data are presented as median (IQR)

Table 5 Patient satisfaction, assessed by global perceived effects on a 7-point scale (GPES) and Ramsay score between groups comparison

	Group C (*n* = 40)	Group L (*n* = 40)	*p*-value
Patient Satisfaction on GPES			< 0.001
Grade 4: neither satisfied nor dissatisfied	6 (15.0%)	1 (2.5%)	
Grade 5: slightly satisfied	5 (12.5%)	0 (0.0%)	
Grade 6: somewhat satisfied	24 (60.0%)	20 (50.0%)	
Grade 7: very satisfied	5 (12.5%)	19 (47.5%)	
Ramsay Sedation Scale			0.17
2	36 (90.0%)	39 (97.5%)	
3	4 (10.0%)	1 (2.5%)	

2 = co-operative, oriented, and tranquil, 3 = responds to commands but is asleep

surgery as activating systemic inflammatory cytokine and glia cells, which induce peripheral and central sensitization, resulting in severe postoperative pain [16, 21], which is also a common risk factor for CRBD [4].

The study identified a 47.5% incidence of moderate to severe CRBD in the PACU among male patients undergoing complex spine surgery in the control group, which is lower than the 66.7% incidence of moderate to severe CRBD which reported in related studies of male patients undergoing transurethral resection of bladder tumors (TURBT) [9]. This reduced occurrence of moderate-to-severe CRBD in our study may be attributed to the fact that complex spinal fusion surgery induces less bladder mucosal irritation and results in lower prostaglandin release compared to urological procedures. Previous studies have suggested that the severity of CRBD is influenced by the degree of muscarinic receptor activation in the bladder [10, 22] or the release of prostaglandin from bladder stimulation [23]. Additionally, TURBT necessitates the use of large-diameter urinary catheters for irrigation, as well as a rigid ureteroscope, which is associated with a higher incidence of CRBD compared to other urological and non-urological procedures [2, 24, 25]. In our study, we observed a 75% incidence of mild to severe CRBD in the PACU, a rate notably higher than the 66% reported in a previous study involving spinal surgery [8]. Our study demonstrated a 75% incidence of mild to severe CRBD in the PACU, which is markedly higher than the 66% reported in a previous study on spinal surgery [8]. This elevated incidence may be attributable to our focus on

complex lumbar fusion surgeries in male patients, procedures that are typically associated with longer operative durations. In contrast, the study by Srivastava VK et al. included both sexes, considered both cervical and lumbar spinal surgeries, and did not specifically focus on complex lumbar procedures [8]. Consequently, the type of spinal surgery and patient demographic characteristics appear to significantly influence the incidence and severity of CRBD [4].

The effective anti-inflammatory properties of intravenous lidocaine, a commonly local anesthetic, are facilitated by the inhibition of the sodium channels, reduction of cytokine release [4, 18], inhibition of the inflammatory response, suppression of the nociceptive transmission pathway, and blockage of N-methyl-d-aspartate (NMDA) receptors [2, 23]. Additionally, lidocaine significantly inhibits of M3 muscarinic acetylcholine receptors [26, 27]. As a result, the study demonstrated a significantly reduced incidence of moderate to severe CRBD.

The study revealed a significant decrease in postoperative pain and opioid requirements in the lidocaine group, aligning with the results of related studies [9, 16–18, 28]. In contrast, Dewinter G et al. reported negative effects of lidocaine infusion on postoperative opioid requirements and time to recovery in posterior spinal arthrodesis. This may have been due to the different dosages of lidocaine administered (1.5 mg/kg/hr) and the administration of 0.2 mg/kg of morphine to all patients at the end of operation [29]. However, one related study and meta-analysis revealed that the positive outcomes were significant only when lidocaine infusion dosages were greater than or equal to 2.0 ml/kg/hr [16–18]. Additionally, Ibrahim A et al. demonstrated that an intravenous lidocaine infusion 3 mg/kg/ hr significantly reduced the long-term postoperative pain for up to three months compared with placebo [30].

Thus, the analgesic properties of lidocaine depended on the total dose of infused systemic lidocaine. One related study reported 2 mcg/ml of lidocaine reduced ectopic stimulation in chronic peripheral nerve pain, 5 mg/ml inhibited central sensitization and neuronal hyperexcitability and 10 mg/ml produced general analgesic properties, which could result in systemic toxicity [31]. This suggests that a 2 mg/kg/hr lidocaine infusion is beneficial for postoperative pain in complex spinal fusion surgery.

Furthermore, no significant differences in patient satisfaction between the two groups were observed. This might be attributed to the fact that our study provided PCA morphine throughout the first 24-hour postoperative period, allowing patients to control their postoperative pain levels independently.

Limitations

Firstly, plasma lidocaine concentration was not demonstrated in the study. Therefore, it could not be documented that concentrations were maintained within the therapeutic window. However, the dosage of lidocaine used was parallel to related studies [13] which administered an initial bolus of 1 to 2 mg/kg, followed by a continuous infusion of 0.5 to 3 mg/kg/h [28], typically resulting in plasma concentrations below 5 µg/ml [28, 32] demonstrating the safety of intravenous lidocaine use. None of the patients experienced adverse effects [28, 32, 33]. Secondly, the study did not assess the impact of lidocaine on the length of hospital stay or hospital readmission. However, no adverse effects or surgical complication were observed. Thirdly, this study included a small sample size which, may not have been sufficient to detect significant differences between the groups in terms of CRBD. Larger sample sizes are recommended for further research.

Conclusion

Intravenous lidocaine was observed to significantly reduced moderate-to-severe CRBD at PACU and 1-hr postoperatively in male patients undergoing complex spine surgery. It also resulted in a reduction of postoperative pain and opioid requirement, as well as improved patient satisfaction, without any side effects.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12871-024-02789-y.

Supplementary Material 1.

Supplementary Material 2.

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Registration

Thai Clinical Trials Registry (TCTR20221017001) on 17/10/2022.

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Authors' contributions

Study concept and design: S.M; acquisition of data: E.C, N.L and S.J; analysis and interpretation of data: E.C, and S. M.; drafting of the manuscript: S. M.; critical revision of the manuscript for important intellectual content: E.C, and S. M.; statistical analysis: S.M.; administrative, technical and material support; E.C, and S.M.; Study supervision: S.M.

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The authors have no conflicts of interest to disclose.

Data availability

Data is provided within the manuscript or supplementary information files.

Declarations

Ethics approval and consent to participate
The study was approved by the Institutional Review Board of the Royal Thai Army Medical Department (Code: S058h/64), with the approval granted on 24 January 2022. Consent to participate is provided in the attached file.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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