Efficacy of Intra operative Combined Epidural and Intramuscular (back muscle) Bupivacaine Injection for Post-Operative Pain Assessment in Lumbar Spine Surgery

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Abstract:

Background: Spine surgery patients often experience severe postoperative pain from nociceptive, neuropathic, and inflammatory mechanisms. Local anesthetics like lidocaine and bupivacaine reduce pain, opioid use, and costs by blocking nerve signals but may increase resource expenses.

Objectives: to evaluate the efficacy of intra-operative combined epidural and intramuscular bupivacaine injection for post-operative pain management after lumbar spine surgery

Patients and methods: This randomized, double-blind study enrolled 60 spine surgery patients into two groups: a combined injection group and control group receiving a placebo. Standard monitoring and general anesthesia were done. The treatment group received 7 ml of bupivacaine epidurally and 7 ml intramuscularly before wound closure. Pain was assessed at intervals up to 24 hours**.**

Results: Demographic data showed non-significant differences between the 2 groups. Postoperative pain scores were significantly lower in the combined injection group at 2 hours (1.87±0.88 vs. 2.7±1.49, P=0.0391), 6 hours (2.23±1.58 vs. 4±1.79, P < 0.0001), 18 hours (1.77±1.67 vs. 2.9±1.51, P=0.0019), and 24 hours (0.83±0.9 vs. 2.03±1.22, P=0.0002). The first request for analgesia was delayed in the combined group (5.2±3.82 vs. 3.8±5.25, P=0.0373), and a higher proportion required only one dose (63.33% vs. 30%, P=0.0091). Anxiety was absent in the combined group but present in 30% of the control group (P=0.0019).

Conclusion: Combined intraoperative epidural and intramuscular bupivacaine significantly improves postoperative pain management in lumbar spine surgery patients and is associated with higher satisfaction with pain relief and mobility, along with fewer instances of anxiety and shorter hospital stay.

Keywords: Epidural and Intramuscular block; Pain; Lumbar spine surgery; Analgesia.
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Introduction

Most spine surgery patients report moderate to severe postoperative pain. The pain mechanism is nociceptive, neuropathic, and inflammatory. Poor pain treatment can cause immobilization, persistent pain, thromboembolism, opioid abuse, and an extended hospital stay **(Mahmoud et al., 2023).**

Lidocaine and bupivacaine are analgesic, anti-hyperalgesic, and anti-inflammatory local anesthetics. Lumbar spine surgery often uses local anesthetics for wound closure. Infusion of local anesthetics extends pain alleviation but increases resource expenses. Intravenous lidocaine, intrawound bupivacaine, and epidural bupivacaine reduce postoperative opioid usage **(Tsai et al., 2021).**

Local anesthetics impede nerve signals by blocking Na pumps. Local pain anesthetics lower the cost of anti-inflammatory medications, opioids, and infusion pumps **(Kayalha et al., 2020).**

This study aims to evaluate the efficacy of intra-operative combined epidural and intramuscular bupivacaine injection for post-operative pain management in patients undergoing lumbar spine surgery.

Patients and methods

Study Design

This prospective double-blind randomized controlled trial aimed to evaluate the combined efficiency of intramuscular and epidural bupivacaine injections in reducing post-operative pain among patients undergoing lumbar spine surgery. The trial was conducted at the Neurosurgery Department of Qena University Hospital, South Valley University.

Study Population

The participants included adults aged 18 years and above who were scheduled for elective lumbar spine surgery. Eligible patients were required to understand and complete the Visual Analogue Scale (VAS) for pain assessment and have no contraindications to bupivacaine, such as allergies. They also had to be willing to comply with the study procedures and provide informed consent. The exclusion criteria ruled out patients with chronic pain, drug abuse, bleeding disorders, significant psychiatric conditions, adverse reactions to local anesthetics, cognitive impairments, or intra-operative complications like dural tears.

Participant allocation

A total of 60 patients were enrolled and randomly divided into two groups: the combined injection group and the control group. Randomization was performed using computer-generated assignments. Both the participants and the medical staff were blinded to the group allocations to ensure unbiased assessment throughout the study.

Interventions

- **Combined Injection Group:** Participants received both intramuscular and epidural bupivacaine injections at a dosage of 1 mg per kg of body weight, which typically amounts to about 14 ml for an average adult.
- **Control Group:** Participants received a placebo injection that was visually identical to the active treatment to maintain blinding.

The hospital pharmacist prepared and delivered the study medications to the operating room.

Sample Size Calculation

The sample size was determined using the following formula aiming for a 95% confidence level. Given a 24% expected proportion based on previous studies and a precision of 0.05, the calculated sample size was 60 patients, which was deemed sufficient for the trial.

$$n = \frac{Z^2 p(1-p)}{d^2}$$

Methods

Preoperative Phase: Before the surgery, all patients enrolled in the study underwent interviews to discuss the study purpose and endpoints. The block procedure was thoroughly explained, and informed consent was obtained. A detailed physical examination was conducted, emphasizing the assessment of vital signs and exclusion of any contraindications. Laboratory investigations included a complete blood count, liver and kidney function tests, and a coagulation profile. To prepare for surgery, patients fasted for at least six hours from solid food and two hours from clear fluids. The Visual Analogue Scale (VAS) for pain (ranging from 0 for no pain to 10 for the worst pain) was introduced and explained during the preoperative visit **(Shafshak and Elnemr, 2020).** Intravenous access was established with an 18-gauge cannula, and patients received intravenous fluids and supplemental oxygen (6–8 L/min) via a face mask. Sedation was provided as needed using midazolam (0.03–0.04 mg/kg).

Intraoperative Phase: Upon arrival at the operating room, standard monitoring (non-invasive blood pressure, electrocardiogram, and pulse oximetry) was set up for all patients. Both groups received general anesthesia following a standardized protocol. Heart rate, mean arterial pressure, and oxygen saturation (SpO_2) were continuously monitored throughout the procedure.

Intervention and Techniques: The study drugs included bupivacaine 0.5% for the treatment group and a placebo for the control group.

Combined Injection Group (Mowafy, 2022): Patients received both epidural and intramuscular bupivacaine. In the prone position, at the end of the surgery before wound closure, 7 ml of bupivacaine was applied over the exposed epidural area. Subsequently, another 7 ml was infiltrated into the paraspinal muscles with retractors still in place. The total dosage of bupivacaine administered was 1 mg/kg, amounting to a volume of 14 ml (0.5 ml per injection of the 5% solution).

Control Group: Patients in the control group received a placebo injection with the same appearance and timing as the active treatment to maintain blinding.

At the conclusion of the surgery, inhalational anesthesia was stopped. Patients were administered neostigmine (0.05 mg/kg) and atropine sulfate (0.01 mg/kg) for reversal of muscle relaxation. Airway suction and extubation were performed before transferring the patients to the Post Anesthesia Care Unit (PACU).

Postoperative Pain Management: In the postoperative phase, all patients were given paracetamol intravenously as standard analgesia, dosed at 15 mg/kg for 24 hours, with a maximum dose up to 4 grams. Pain levels were monitored using the Visual Analogue Scale (VAS), which ranged from 0 (no pain) to 10 (severe pain) **(Shafshak and Elnemr, 2020)**. Assessments were conducted at intervals of 2, 6, 12, 18, and 24 hours after surgery. If a patient pain score reached 3 or higher, pethidine (20 mg) was administered slowly via intravenous injection as rescue analgesia. The time until the first request for additional pain relief (rescue analgesia) was recorded, and the total consumption of analgesics within the first 24 hours was documented.

Study tools and data collection

The primary tool for pain assessment was the VAS, which helped evaluate the efficacy of the combined epidural and intramuscular bupivacaine injection in controlling pain post-surgery.

A comprehensive data collection form was used to record patient demographics, surgical details, and information on the administration of medications. This form captured variables

such as age, gender, weight, type and duration of lumbar spine surgery, the dosage of bupivacaine, and any additional analgesics given. Additionally, a medication administration record documented the specifics of pain medication, including the name, route, dosage, frequency, and timing of administration.

Considerations for drain management

To minimize the potential impact of surgical drains on the study pain outcomes, a standardized approach was employed. In lumbar surgery following bupivacaine injection, the use of drains could affect pain perception, so the surgical team carefully controlled this factor. Drain management was standardized for all participants, including consistent protocols for placement, maintenance, and removal. The timing of drain removal was uniform across patients, occurring before the assessment of pain relief outcomes. Specifically, the drain was left closed for one hour after skin closure to ensure the absorption and action of the local anesthetic before being opened. This strategy helped reduce variability and ensured a more accurate evaluation of the analgesic effects of bupivacaine.

Ethical approval code: SVU-MED-NES014-1-23-11-757.

Statistical analysis

Data were analyzed using SPSS version 23. Qualitative data were presented as numbers and percentages, while quantitative data were expressed as mean ± standard deviation (SD). Statistical tests included the Student t-test for comparing means between two groups, the Mann-Whitney test for non-normal distributions, ANOVA for comparing more than two groups, and the Chi-square or Fisher exact test for assessing associations. Significance was set at a p-value < 0.05. Univariate and multivariate analyses were also conducted to identify significant correlations.

Results

The control group average age was 38.57 ± 9.56 years, while the combined injection group was 40.5 ± 8 years, showing no significant difference (P=0.38). Gender distribution was similar, with 60% males in the control group and 70% males in the combined group (P=0.43). BMI averaged 29.78 ± 1.46 kg/m² in the control group and 30.28 ± 1.45 kg/m² in the combined group (P=0.18). ASA classification was also comparable, with 53% ASA 1 and 47% ASA 2 in the control group versus 60% ASA 1 and 40% ASA 2 in the combined group (P=0.60). (**Table.1).**

Table 1. Demographic characteristics of the studied groups

Variables	Control group (n = 30)	Combined Injection Group (n = 30)	P. Value
Age	38.57 ± 9.56	40.5 ± 8	0.3837 [MWU]
Gender			
• **Male**	18 (60%)	21 (70%)	0.4254 [X]
• **Female**	12 (40%)	9 (30%)	
BMI (Kg/m2)	29.78 ± 1.46	30.28 ± 1.45	0.1827 [MWU]
ASA class			
• **1**	16 (53.33%)	18 (60%)	0.6023 [X]
• **2**	14 (46.67%)	12 (40%)	

BMI: Body mass index, ASA class: American Society of Anesthesiologists class. MWU: Mann Whitney test, X: chi square test. *: Significant difference.

There were no significant differences in operative data between the Control (n = 30) and Combined Injection (n = 30) groups. Discectomy with laminectomy occurred in 40% of the Control group and 30% of the Combined group (P=0.43), while laminectomy without discectomy was more common in the Combined group (53.33% vs. 30%, P=0.07). Fenestration and spinal decompression showed no significant differences (P > 0.05). Surgery duration was similar: 115.93 ± 5.47 minutes in the Control group and 116.13 ± 5.12 minutes in the Combined group (P=0.89). (**Table,2, Fig.1).**

Table 2. Operative data of the studied groups:

Variables	Control group (n = 30)	Combined Injection Group (n = 30)	P. Value
Type of surgery			
• **Discectomy with laminectomy**	12 (40%)	9 (30%)	0.4254 [X]
• **Laminectomy without discectomy**	9 (30%)	16 (53.33%)	0.0687 [X]
• **Spinal decompression and fixation**	7 (23.33%)	5 (16.67%)	0.5267 [X]
• **Fenestration**	2 (6.67%)	0 (0%)	0.1555 [X]
Duration of surgery (min)	115.93 ± 5.47	116.13 ± 5.12	0.8862[t]

X: chi square test, t: student t-test.

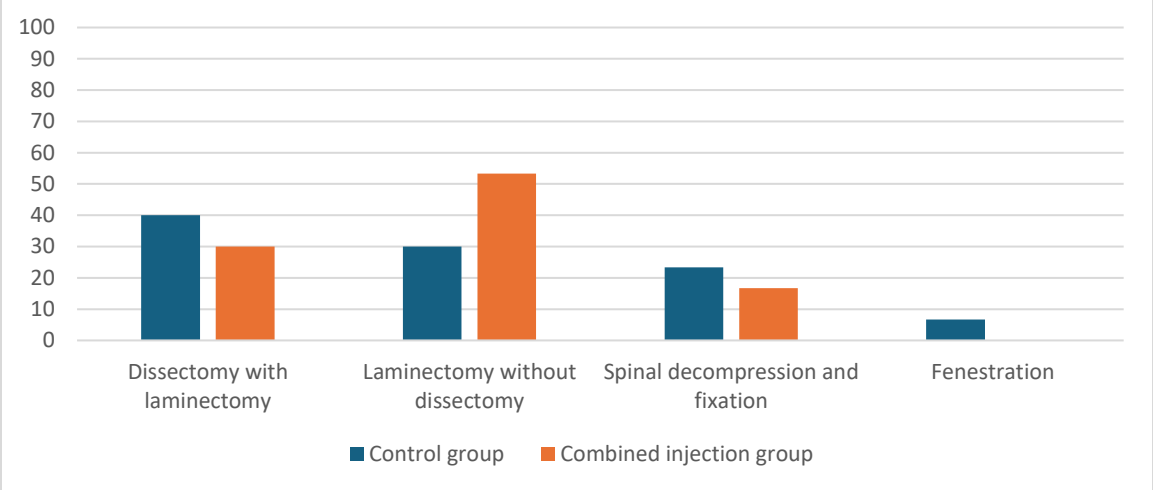

Fig.1. Type of surgery among the studied groups.

Preoperatively, the Control group had a VAS score of 6.97 ± 0.8, and the Combined Injection group had a score of 7 ± 0.77 (P=0.88). Postoperatively, significant differences were observed at several time points. At 2 hours, the Control group scored 2.7 ± 1.49, while the Combined Injection group scored 1.87 ± 0.88 (P=0.0391). At 6 hours, the Control group scored 4 ± 1.79, and the Combined Injection group scored 2.23 ± 1.58 (P < 0.0001). At 12 hours, there was no significant difference (P=0.129). At 18 hours, the Control group scored 2.9 ± 1.51, and the Combined Injection group

scored 1.77 ± 1.67 (P=0.0019). At 24 hours, the Control group scored 2.03 ± 1.22, and the Combined Injection group had a lower score of 0.83 ± 0.9 (P=0.0002). **(Table.3), Fig.2).**

Table 3. Comparison between the studied groups regarding pain severity using VAS score

VAS	Control group (n = 30)	Combined Injection Group (n = 30)	P. Value
Preoperative	6.97 ± 0.8	7 ± 0.77	0.8751 [t]
Postoperative			
• **2 h**	2.7 ± 1.49	1.87 ± 0.88	0.0391* [t]
• **6 h**	4 ± 1.79	2.23 ± 1.58	<0.0001* [t]
• **12 h**	2.1 ± 0.83	2.03 ± 1.45	0.129 [t]
• **18 h**	2.9 ± 1.51	1.77 ± 1.67	0.0019* [t]
• **24 h**	2.03 ± 1.22	0.83 ± 0.9	0.0002* [t]

VAS: visual analogue scale. t: student t-test. *: Significant difference.

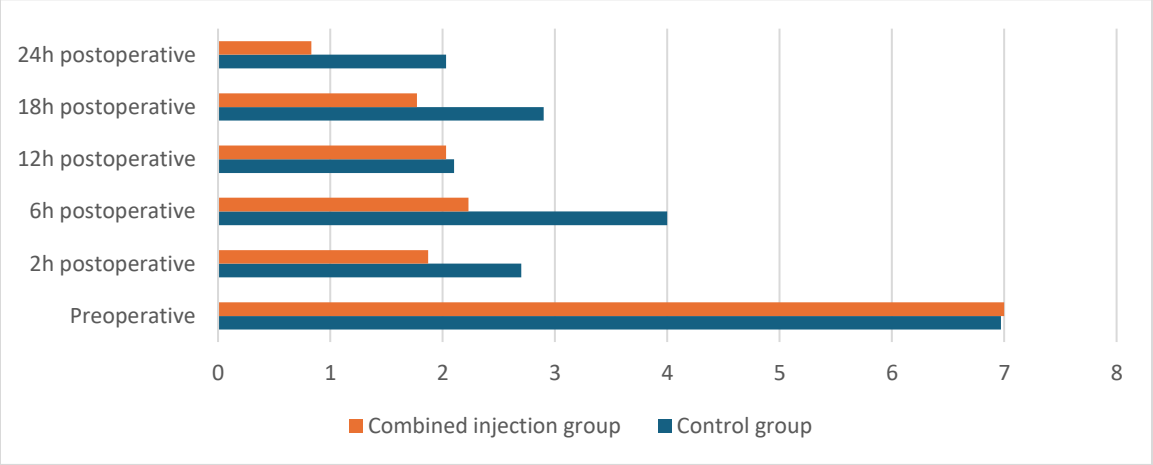

Fig.2. Comparison between the studied group regarding the mean VAS score

The control group received their first analgesia dose at 3.8 ± 5.25 hours, while the combined injection group received it at 5.2 ± 3.82 hours (P=0.0373). A lower proportion in the control group (30%) required only one dose compared to the combined injection group (63.33%), which required two doses (P=0.0091). Headache was reported by 26.67% of the control group and 13.33% of the combined injection group (P=0.197). Anxiety was observed in 30% of the control group but absent in the combined injection group (P=0.0019). The duration of hospital stay was significantly shorter in the combined injection group compared to the controls (3 ± 0.77 vs 4.5 ± 1.2; P < 0.0001), **(Table .4, Fig.3).**

Table 4. Comparison between the studied groups regarding postoperative analgesia

Postoperative analgesia	Control group (n = 30)	Combined Injection Group (n = 30)	P. Value
Time of 1st dose	3.8 ± 5.25	5.2 ± 3.82	0.0373* [t]
Frequency			
• **1**	9 (30%)	19 (63.33%)	0.0091* [X]
• **2**	21 (70%)	11 (36.67%)	

Side effects			
Anxiety	9 (30%)	0 (0%)	0.0019* [f]
Duration of Hospital stay (days)	4.5 ± 1.2	3 ± 0.77	0.0001* [MWU]

X: chi square test, t: student t-test, f: Fisher exact test, MWU: Mann Whittney U test, *: Significant difference.

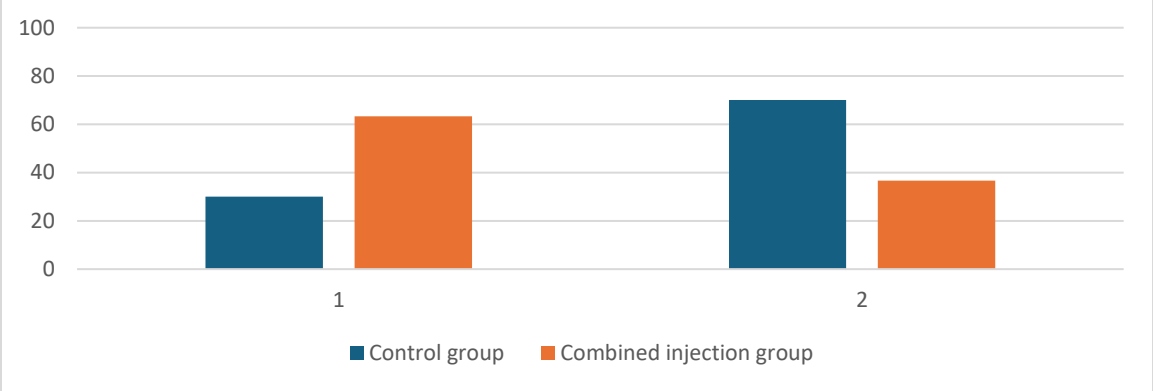

Fig.3. Comparison between the studied group regarding frequency of analgesic requirement.

Discussion

The control and combined injection groups had similar age, gender, BMI, and ASA classifications in our study. **Cine and Uysal (2023)** revealed no demographic variations in three groups receiving different caudal epidural analgesia treatments, supporting our findings. In Groups 2 and 3, participants had mean ages of 49 ± 12 and 50 ± 10 and received Bupivacaine (50 mg) + 2 ml methylprednisolone (40 mg) + 8 ml NS, 10 ml Bupivacaine + 10 ml NS, and 20 ml NS. These groups had 28 (70%) ASA-I patients in Group 2 and 19 (47.5%) in Group 3, with no statistically significant differences ($P > 0.05$).

We found no significant differences between the control and combined injection groups in surgery kinds, duration, or preoperative pain levels. However, the combination injection group had considerably greater postoperative pain alleviation at 2, 6, 18, and 24 hours. Bupivacaine's epidurally and intramuscularly improved analgesic effects may have explained our much lower VAS scores than the control group. The dual dose of bupivacaine helped block pain better, resulting in reduced pain scores at the designated time points postoperatively. Preoperative VAS values were similar. Our study found that this combination strategy enhanced and sustained pain alleviation, making it a more effective alternative to current treatments, according to **Ottoboni et al. (2020) and Pergolizzi et al. (2020).**

The effects of subdermal and intramuscular bupivacaine injections on postoperative pain following lumbar decompression surgery were similar to **Kayalha et al. (2020).** The bupivacaine group had significantly lower pain severity than the control group at 3, 12, and 24 hours postoperatively ($P < 0.05$). Using a repeated measures design, there was no significant difference in mean pain intensity between the two groups ($P > 0.05$). However, the bupivacaine group showed substantial decrease in pain severity over 24 hours ($P < 0.05$).

A meta-analysis by **Hermans et al. (2021)** reviewed intraoperative epidural analgesia trials in lumbar decompressive surgery and supported our findings. This study includes eight research, seven of which reported substantial VAS pain score reductions and six significant analgesic use reductions.

Bajwa and Haldar (2015) agreed that spinal operations cause considerable

postoperative pain and that pain management improves functional outcomes. Combination therapy or multimodal analgesia was indicated for post-spinal surgery pain.

Our findings contradict **Rahmanian et al. (2016),** who examined bupivacaine's impact on postoperative back pain after lumbar laminectomy. In the control group, paravertebral muscles received 30 ml of 0.25% bupivacaine and 30 ml of normal saline. There were no significant variations in pain severity between groups. Rahmanian et al. found no improvement in postoperative back pain, with patients having higher VAS values at 6 and 12 hours, especially at 6 hours. Their study may disagree since the higher mean age of their patients and lower sample size of 60 may have affected their results.

Our investigation found that the combination injection group needed fewer analgesic doses and started later than the control group. **Deer et al. (2012) and Chane et al. (2024)** found that epidural and intramuscular bupivacaine directly addressed nociceptive and neuropathic pain at pain transmission locations, which may have extended and focused analgesia. Bringing bupivacaine closer to the nerves, reducing local inflammation, and maintaining steady pain relief may have improved pain control, explaining the longer time until the first dose and the reduced analgesic needs in the combined injection group **(Gadalla et al., 2021).**

Our findings are validated by **Perera et al. (2017),** who included 438 patients (212 control and 226 intervention). Intramuscular local anesthetic injection led to a longer time to initial analgesic demand (mean difference: 65.88 minutes, P=0.002) and significantly reduced postoperative opioid demand (MD: -9.71 mg, P=0.0004). There was a little decrease in postoperative VAS at 1 hour (MD −0.87, P=0.01), but not at 12 or 24 hours (P=0.93 and P=0.85). Our study's epidural and intramuscular methods may have offered more prolonged pain management than **Perera et al.'s.** Our epidural bupivacaine directly targeted spinal nerves, producing longer and stronger pain-blocking effects than **Perera et al.,** whose technique was intramuscular injection only.

Additionally, **Cleary et al. (2023)** examined the pain alleviation of intraoperative bupivacaine wound infiltration after noninstrumented posterior spine surgery. Bupivacaine infusion reduced postoperative opioid usage for 72 hours and pain ratings, improving heart rate regulation. This low-cost strategy improved patient outcomes with few hazards and no increase in surgery time or hospital stay, validating localized analgesic approaches.

Our findings match **Donadi et al. (2014),** who included 60 lumbar laminectomy patients (30 per group). The time to initial analgesic consumption was substantially longer in the bupivacaine with magnesium group (7.78 ± 1.35 hours) compared to the bupivacaine group (4.62 ± 0.997 hours, $P < 0.0001$). Additionally, the bupivacaine group drank more tramadol (202.5 ± 76.9 mg) than the magnesium group (117.5 ± 63.4 mg, $P < 0.0001$), with the magnesium group having greater pain management satisfaction (2.77 ± 0.626 vs 2.0 ± 0.587, $P < 0.001$). Our study found that better pain management, whether with magnesium or mixed delivery routes, can delay analgesia and reduce opioid use.

In our study, the combination injection and control groups had identical headache rates, while the control group had much higher anxiety. The intraoperative combined bupivacaine method lowered pain and stress, reducing anxiety in the combined injection group. However, headache rates did not change considerably, suggesting that patient responses or surgical stress may affect side effects rather than the analgesic

approach. Combined bupivacaine injections alleviated anxiety but did not reduce headaches **(Lovich-Sapola et al., 2015; Tan et al., 2015).**

Strøm et al. (2018) found that five factors—pain, lack of information, disability, return to work, and mental health—significantly affected anxiety and depression symptoms before and after spinal surgery, supporting our study's findings on pain management's psychological benefits.

We agree with **Razak et al. (2024)** that multimodal postoperative analgesia strategies improve recovery and outcomes for spine pathology patients, who have greater rates of chronic pain and opiate usage.

Almost all the studies focused on the effect of combined injection pain while few studies evaluated the cost of the medications used. IV strong patient-controlled analgesia (PCA), when compared with epidural and intramuscular injections with bupivacaine had the lowest absolute cost. The cost of IV PCA includes that of the medication used, the equipment leased, as well as possible expenses incurred from adverse events. Intramuscular injections with bupivacaine had a small increase in cost when compared to IV PCA while maintaining a similar effect on analgesia. The cost of TAP infiltration includes that of the medication used as well as possible expenses incurred from a failed infiltration or adverse events. Epidural seemed to carry the highest cost with an increment of around $4000 from the least costly intervention (IV PCA). The cost includes that of the medication used, the device leased, the procedure of inserting an epidural catheter, staff fees for the procedure, as well as possible expenses incurred from a failed insertion or prolonged hospitalization **(Babazade et al., 2019).**

In our study, significantly shorter hospital stay was associated with the cobined injection technique ($P< 0.0001$).

Studies have controversial results regarding the effect of combined injections on the length of hospital stay (LOS). Some studies determined that the combined epidural and intramuscular injections decreased LOS by reducing pain scores and duration of ileus **(Tilleul et al., 2012),** while others reported prolonged LOS by causing urinary retention and hypotension **(Marret et al., 2007).**

Conclusion

Our study shows that combined intraoperative epidural and intramuscular bupivacaine significantly improves postoperative pain management in lumbar spine surgery patients. This approach led to lower pain scores at multiple postoperative time points, delayed the first analgesic dose, and reduced total analgesic consumption. Additionally, the combined injection group reported higher satisfaction with pain relief and mobility, as well as fewer instances of anxiety. These findings suggest that this combined method enhances postoperative comfort and recovery outcomes.

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