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RESEARCH ARTICLE

Epidural Gel-Foam Impregnated with Bupivacaine versus Paravertebral Intramuscular Bupivacaine for Postoperative Analgesia in Lumbar Spine Surgery: A Comparative Clinical Trial

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Abstract

Objectives: This study aimed to compare the effect of epidural gel foam impregnated with bupivacaine and intramuscular paravertebral bupivacaine on analgesia after lumbar spine surgeries.

Methods: In this single-blind clinical trial, 60 patients aged 18–65 years who underwent lumbar spine surgery under general anesthesia were randomly assigned to two groups. In the first group, a 1 × 5 cm strip of gel foam impregnated with 70 mg of 0.5% bupivacaine was placed in the epidural space. In contrast, in the second group, 70 mg of 0.5% bupivacaine was injected paravertebrally into the muscle. Pain scores based on the Visual Analogue Scale (VAS), analgesic prescriptions, time to first analgesic request, and total dosage during recovery and at 6, 12, and 24 hours postoperatively were recorded and compared between the groups.

Results: No significant difference in average pain scores at different time points (recovery, 6, and 12 hours) was observed between the two groups ($P > 0.05$). However, at 24 hours postoperatively, a significant difference was found between the groups, with the VAS score in the bupivacaine-impregnated epidural gel foam group being significantly lower than that in the paravertebral intramuscular bupivacaine group ($P = 0.04$).

Conclusion: Bupivacaine-impregnated epidural gel foam and paravertebral intramuscular bupivacaine provide similar analgesia during recovery and at 6 and 12 hours following spinal surgery. However, at 24 hours, the analgesia in the bupivacaine-impregnated epidural gel foam group is superior to that in the paravertebral intramuscular bupivacaine group.

Level of evidence: I

Keywords: Analgesia, Bupivacaine-impregnated epidural gel foam, Lumbar spine surgeries, Paravertebral intramuscular bupivacaine

Introduction

Spinal surgery is one of the most common procedures in neurosurgery, performed to alleviate pain and disability. However, it is often accompanied by severe pain both immediately after surgery and for several days postoperatively.[1-3] Spinal surgeries typically include laminectomy, discectomy, spinal fusion, scoliosis correction, and removal of spinal tumors. Conventional spine surgeries often require extensive dissection of subcutaneous tissues, bones, and ligaments, resulting in significant postoperative pain.[4] Most patients report moderate to severe pain for at least the first 3–4 days after spinal surgery.[5] Postoperative pain is a common complaint that may persist even after the recovery period, negatively affecting physical, social, and emotional well-being.[6] Inadequate pain control is generally associated with more extended hospital stays, delays in returning to normal activities, and reduced patient mobility, which increases the risk of complications such as

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deep vein thrombosis, pulmonary embolism, and pneumonia. Improved pain management not only enhances the surgical outcome but also shortens hospital stays and reduces the likelihood of postoperative pain.[3,7-9]

Nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids are commonly used as the first-line treatments for pain control following spine surgery. However, these drugs have several side effects, including confusion, drowsiness, urinary retention, ileus, respiratory depression, and even death.[10-14] In addition to opioids, some surgeons employ alternative techniques to reduce postoperative pain, such as minimizing the size of the incision, reducing pressure on the paravertebral muscles, minimizing manipulation of the nerve roots, and using sacral traction.[6] Another method involves the use of local anesthetics to alleviate postoperative pain. Long-acting local anesthetics, such as bupivacaine, have been used at the incision site for post-operative analgesia in various types of surgery, including hernia repair, gynecological procedures, and orthopedic surgery. Bupivacaine, in particular, provides analgesia for approximately twenty hours.[15]

Bupivacaine is an amino amide local anesthetic commonly used in neuro-axial and peripheral blocks. Its long duration of action and ability to provide both sensory and motor blockade contribute to its widespread use in these procedures. One of the rare side effects of bupivacaine is sudden cardiac arrest following accidental intravascular injection.[16] One of the primary side effects of both bupivacaine and other local anesthetics is nerve and cardiac toxicity, which can occur at high doses or following intravascular injection.[17] Although many studies have investigated the local use of bupivacaine in spinal surgeries, most are limited to its application at the incision site.[18,19]

Epidural catheters are used to reduce opioid side effects; however, they can lead to complications such as epidural hematoma and infection. Gel foam, composed of gelatin granules, is commonly used as an absorbable gelatin sponge. As an agent with gradual drug release, foam gel can prolong the effects of epidural drugs in some procedures compared to their direct administration in the epidural space.[1,20] A few studies have investigated the effect of using gel foam impregnated with drugs such as ropivacaine, dexamethasone, nalbuphine, and morphine in spinal surgeries.[1,20-22] Furthermore, only one study has examined the effect of epidural dexmedetomidine and bupivacaine impregnated with foam gel for postoperative analgesia following lumbar laminectomy. The results showed that patients undergoing lumbar laminectomy with epidural dexmedetomidine or bupivacaine impregnated with gel foam had a longer duration of analgesia, reduced use of painkillers, and less postoperative pain compared to the normal saline group.[23]

Spinal surgical incisions involve the skin, subcutaneous fat, thoracolumbar fascia, paraspinal muscles, bone, and peridural space, each of which can be a potential source of pain. When bupivacaine is directly applied to the dura, it can induce dermatomal anesthesia and, in some cases, dermatomal weakness, which may interfere with postoperative examination. Additionally, if bupivacaine is injected into the paravertebral muscles, the embedded drain may remove a significant amount of the anesthetic.

Based on available research, no study has compared the effects of bupivacaine-impregnated epidural gel foam and paravertebral intramuscular bupivacaine on analgesia after spine surgeries. Therefore, the present study aims to compare the analgesic effects of bupivacaine-impregnated epidural gel foam and paravertebral intramuscular bupivacaine in patients undergoing lumbar spine surgery.

Materials and Methods

Study design

Following registration on the Iranian Registry of Clinical Trials (IRCT20230520058233N1), a single-blind randomized clinical trial was conducted at Urmia Imam Khomeini Hospital on 60 patients aged 18 to 65 years with ASA (American Society of Anesthesiologists) classifications I and II, all of whom underwent lumbar laminectomy without fusion under general anesthesia. The surgical site in all cases was within the lumbar region (L3–S1). Patients were randomly allocated into two equal groups (n = 30 per group) based on a computer-generated random number table. In group A, 30 patients received bupivacaine-impregnated epidural gel foam, while in group B, 30 patients received paravertebral intramuscular bupivacaine. This clinical trial was approved by the Research and Ethics Committee of Urmia University of Medical Sciences (IR.UMSU.HIMAM.REC.1402.023).

Randomization and allocation concealment

The random sequence was generated by an independent investigator who was not involved in patient recruitment or intervention. Allocation assignments were placed in sequentially numbered, opaque, sealed envelopes. After the induction of anesthesia, an anesthesia nurse, who was not involved in outcome assessment or intervention, opened the envelope and informed the surgical team of the assigned intervention.

Blinding

Patients were blinded to group allocation. Due to the nature of the interventions, the surgeon and anesthesia team were aware of the allocation. However, postoperative outcome assessment and data analysis were performed by an independent investigator who was blinded to the allocation.

Sample size

Using the following formula, based on the average time to the first analgesic administration in the study by Prakash *et al.*[14] (11.33 ± 6.08 hours in the bupivacaine gel foam group and 6.4 ± 2.77 hours in the control group), and considering a 95% confidence interval ($Z_{1-\alpha/2} = 1.96$) and a 90% test power ($Z_{1-\beta} = 1.28$), with an additional 20% sample size increase, a minimum of 30 participants in each group was determined. The sampling method used in this study was convenient and accessible.

$$n = \frac{(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 \times (S_1^2 + S_2^2)}{(\bar{X}_1 - \bar{X}_2)^2}$$

Inclusion criteria

Patients aged 18 to 65 years with a body mass index (BMI) <30 kg/m^2 and ASA (American Society of Anesthesiologists) classifications I and II, who underwent lumbar spine surgery under general anesthesia and provided written informed consent to participate in the trial, were included.

Exclusion criteria

The study excluded individuals under 18 years of age or over 65 years, those with a body mass index (BMI) >30 kg/m^2, a history of allergy to the studied drugs, pregnancy, coagulopathy, breastfeeding, a history of seizures, severe systemic disease, mental illness, coagulation disorders, and opioid use.

Subjects and setting

All patients were kept fasting for at least 8 hours. The patients were blinded to their group allocation. In the operating room, patients were placed in the supine position and monitored using standard cardiac monitoring, pulse oximetry, partial pressure of carbon dioxide (End-Tidal Carbon Dioxide, $ETCO_2$), and a noninvasive blood pressure measurement system (NIBP). After anesthesia induction, patients were repositioned to the prone position.

Intervention design

For patients in the bupivacaine-impregnated epidural gel foam group, a 1 × 5 cm strip of gel foam impregnated with 70 mg of 0.5% bupivacaine (14 ml) was placed in the epidural space 30 minutes before wound closure, following the completion of laminectomy. In the paravertebral intramuscular bupivacaine group, 70 mg of 0.5% bupivacaine (14 ml) was injected 30 minutes before wound closure [Figure 1]. The anesthesia technique and drug doses were the same for both groups. A standard lumbar spine surgery, 8 to 10 cm in length, was performed on each side at three points 3 to 5 cm apart, using a 22-gauge needle. After the operation, the patients were placed in the supine position, muscle relaxation was reversed, and they were extubated once they were breathing adequately. Before the operation, all patients were thoroughly instructed on the visual analogue scale (VAS) for pain assessment [Figure 2],[16] where a score of 0 represented no pain and 10 represented the worst pain they had ever experienced. Pain levels were assessed and recorded using the VAS in the recovery room and on the ward at 6, 12, and 24 hours postoperatively. Both groups recorded the time of the first analgesic request (morphine), its dosage in milligrams, and the number of times it was requested at 6, 12, and 24 hours postoperatively. When the pain score was greater than or equal to 5, 5 mg of morphine was administered intramuscularly. Monitoring was conducted to record mean arterial blood pressure and heart rate during recovery and at 6, 12, and 24 hours postoperatively. Demographic characteristics (age, gender, and ASA class) were also recorded. All information was documented in a checklist, and the data were statistically analyzed between the two groups. Adverse effects, including bradycardia, hypotension, hypoxemia (SpO_2 < 90%), shivering, nausea, and vomiting, were recorded and managed.

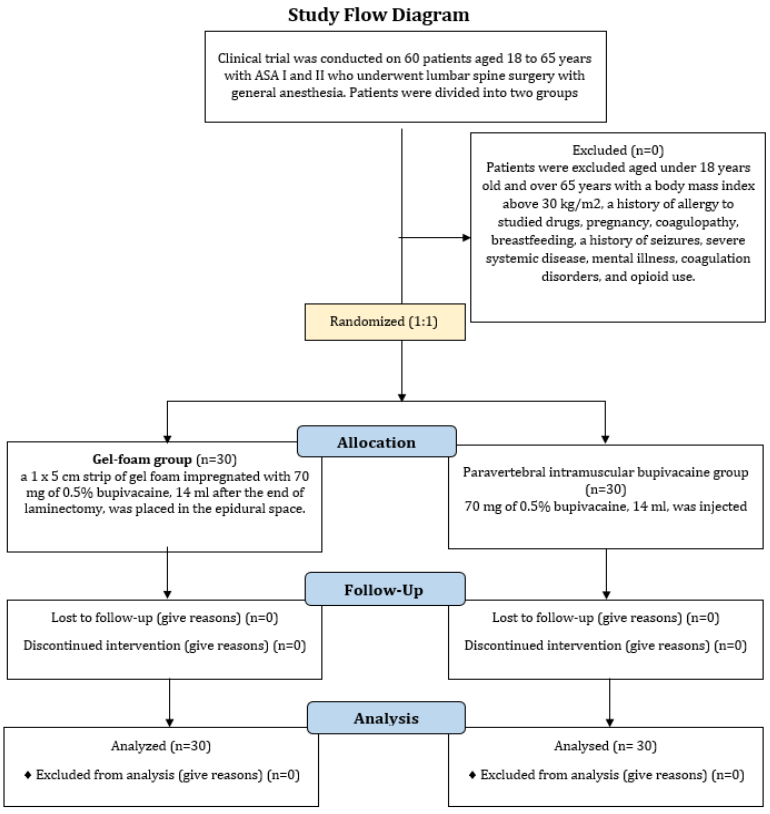

Figure 1. Study flow diagram

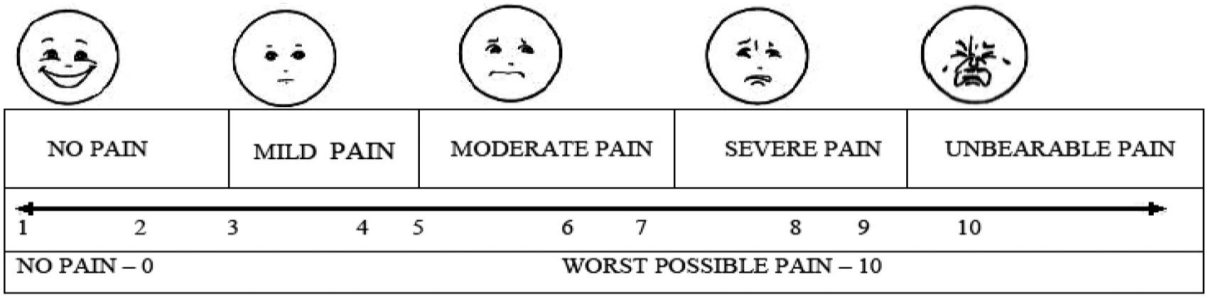

Figure 2. Visual pain scoring method based on the Visual Analogue Scale

Statistical Analysis

Quantitative variables are reported as mean ± standard deviation, while qualitative variables are reported as frequencies (percentages) in appropriate tables and graphs. The normal distribution of quantitative data was assessed using the Kolmogorov-Smirnov test. The chi-square test was used to compare qualitative variables between the two groups; an independent t-test was used for basic quantitative variables; and the repeated measures analysis was used to compare the means of quantitative data at different time points between the two groups. Data analysis was performed using SPSS version 21 software, and a significance level of less than 0.05 ($P \leq 0.05$) was considered statistically significant.

Ethical considerations

The clinical trial was conducted after receiving approval from the Ethics Committee of Urmia University of Medical Sciences (ethics code: IR.UMSU.HIMAM.REC.1402.023). To ensure full adherence to research ethics, the study objectives were thoroughly explained to each participating patient, and their informed consent was obtained before participation. Additionally, patient confidentiality was maintained, and their participation in the study incurred no costs. This clinical trial has been registered with the Iranian Clinical Trials Registration Center under the code IRCT20230520058233N1.

Results

In this study, 30 patients in the bupivacaine-impregnated epidural gel-foam group and 30 patients in the paravertebral intramuscular bupivacaine group were included in the analysis. Of these, 25 patients (41.7%) were male and 35 patients (58.3%) were female. Nineteen patients (31.7%) were classified as ASA class I, and 41 patients (68.3%) were classified as ASA class II. The mean age of all patients was 56.18 ± 13.21 years. A comparison of the demographic characteristics between the two groups revealed that the mean age, gender distribution, and ASA class were not significantly different ($P > 0.05$) [Table 1].

Table 1. Comparing the demographic characteristics of the two groups receiving bupivacaine-impregnated epidural gel-foam and the paravertebral intramuscular bupivacaine group.

Variables		Paravertebral intramuscular bupivacaine (N=30)	Bupivacaine-impregnated epidural gel-foam (N=30)	P-Value
Gender	*Male*	11 (36.7%)	14 (46.7%)	0.08¶
	Female	19 (63.3%)	16 (53.3%)	
ASA class	*I*	7 (23.3%)	12 (40%)	0.16¶
	II	23 (76.7%)	18 (60%)	
Age (Mean±SD)		57.5 ± 13.25	54.86 ± 13.16	0.45¥
BMI (kg/m2)		26.51±3.31	27.81±2.86	0.342

Values are presented as Mean ± SD or number. There were no significant differences between demographic data in the two groups (P>0.05)
¶: Chi-square test ¥: Independent t-test

The comparison of mean systolic and diastolic blood pressure at different time points (recovery, 6, 12, and 24 hours after surgery) between the two groups is shown in Table 2 [Table 2]. The results indicated that, overall, the average changes in systolic and diastolic blood pressure at different time points were not significantly different between the two groups (P-trend = 0.28 and P-trend = 0.9, respectively). In the intra-group comparison, no significant changes were observed in the average systolic and diastolic blood pressure within each group ($P > 0.05$).

Table 2. Comparison of mean systolic blood pressure at different times of measurement between two groups.

Blood Pressure	Time points of measurement	Paravertebral intramuscular bupivacaine (N=30)	within mean changes	P2¶	Bupivacaine-impregnated epidural gel-foam (N=30)	within mean changes	P1¶
		mean ± SD	*mean ± SE*		*mean ± SD*	*mean ± SE*	
Systolic Blood Pressure	*Recovery*	[a] 122.33 ± 15.01	reference	-	[a] 115.83 ± 26.01	reference	-
	6 hours	[a] 126.66 ± 14.12	4.33 ± 0.058	0.57	[a]110.67± 20.63	-5.16 ± 1.47	0.43
	12 hours	[a] 119.33 ± 15.7	-3.0 ± 1.02	0.34	[a]113.33 ± 19.88	-2.5 ± 2.07	0.24
	24 hours	[a] 120.5 ± 15.6	-1.83 ± 1.08	0.1	[a] 114.93 ± 22.5	-0.9 ± 1.77	0.61
P-trend	**0.28**						
Diastolic Blood Pressure	*Recovery*	[a] 77.0 ± 6.37	reference	-	[a] 71.00± 8.74	reference	-
	6 hours	[a] 75.83 ± 6.08	-1.17 ± 0.29	0.57	[a] 70.83 ± 8.71	-0.17 ± 0.16	0.33
	12 hours	[a] 74.67 ± 5.92	-2.33 ± 0.47	0.49	[a] 70.5 ± 8.84	-0.5 ± 0.27	0.08
	24 hours	[a] 76.0 ± 6.07	-1.0 ± 0.69	0.16	[a] 70.16± 8.95	-0.83 ± 0.48	0.11
P-trend	**0.9**						

¶: Repeated measurement

P1: intra-group comparison of each time point compared to the recovery (reference) in the gel foam epidural group impregnated with bupivacaine (In addition, in each group, the same letters indicate no significant difference in the mean at any time compared to other times)

P2: intra-group comparison of each time point compared to the recovery (reference) in the paravertebral intramuscular bupivacaine group (In addition, in each group, the same letters indicate no significant difference in the mean at any time compared to other times)

Table 3 compares the mean heart rate between the two groups at different time points (recovery, 6, 12, and 24 hours after the operation). The results demonstrated no significant difference between the two groups in the average heart rate changes at different times (P-trend = 0.17). In the intra-group comparison, no significant changes were observed in the average heart rate within each group (P > 0.05) [Table 3].

Table 3. Comparison of the mean heart rate between the two groups at different time points of measurement.

	Time points of measurement	Paravertebral intramuscular bupivacaine	within mean changes	P2¶	Bupivacaine-impregnated epidural gel-foam (N=30)	within mean changes	P1¶
		mean ± SD	*mean ± SE*		*mean ± SD*	*mean ± SE*	
Heart rate	*Recovery*	69.8 ± 9.75a	reference	-	76.53 ± 8.95 [a]	reference	-
	6 hours	76.60 ± 8.54 [a]	7.0 ± 0.38	0.08	74.70 ± 6.86 [a]	-1.83 ± 1.05	0.19
	12 hours	70.33 ± 8.52 [a]	0.53 ± 0.57	0.36	74.67 ± 6.81 [a]	-1.86 ± 1.16	0.21
	24 hours	68.3 ± 8.28 [a]	-1.5 ± 0.66	0.46	75.27 ± 6.28 [a]	-1.26 ± 1.06	0.14
P-trend	**0.17**						

¶: Repeated measurement

P1: intra-group comparison of each time point compared to the recovery (reference) in the gel foam epidural group impregnated with bupivacaine (In addition, in each group, the same letters indicate no significant difference in the mean at any time compared to other times)

P2: intra-group comparison of each time point compared to the recovery (reference) in the paravertebral intramuscular bupivacaine group (In addition, in each group, the same letters indicate no significant difference in the mean at any time compared to other times)

There was no significant difference in the average pain scores at different time points (recovery, 6 hours, and 12 hours) between the two groups: the bupivacaine-impregnated epidural gel foam group and the paravertebral intramuscular bupivacaine group [Table 4]. However, at 24 hours, a significant difference was observed between the two groups, with the VAS pain score in the bupivacaine-impregnated epidural gel foam group being significantly lower than in the paravertebral intramuscular bupivacaine group (P = 0.04).

The results of the intra-group comparison showed that in the bupivacaine-impregnated epidural gel foam group, pain intensity during recovery, at 6 hours, and 12 hours postoperatively did not change significantly. However, at 24 hours after the operation, a significant decrease in pain intensity was observed compared to the other three time points (mean change: -4.2 ± 0.29, P < 0.001).

The pain intensity during recovery did not change significantly at 6 hours compared to the other time points in the paravertebral intramuscular bupivacaine group. However, at 12 and 24 hours postoperatively, there was a significant decrease in pain intensity compared to the other two time points. The mean changes in pain scores at 12 hours and 24 hours after surgery were -2.13 ± 0.35 and -3.87 ± 0.39, respectively (P < 0.001) [Figure 3].

Table 4. Comparison of the mean pain score between the two groups at different time points of measurement.

	Time points of measurement	Paravertebral intramuscular bupivacaine (N=30)	within mean changes	P2¶	Bupivacaine-impregnated epidural gel-foam (N=30)	within mean changes	P1¶	P3
		mean ± SD	*mean ± SE*		*mean ± SD*	*mean ± SE*		
Pain Score	Recovery	8.1 ± 0.79a	reference	-	8.43 ± 0.91 a	reference	-	0.13
	6 hours	6.83 ± 0.33 a	-1.27 ± 0.24	0.29	6.64 ± 0.46 a	-1.79 ± 0.2	0.62	0.92
	12 hours	5.97 ± 1.12 b	-2.13 ± 0.35	<0.001	5.63 ± 0.51 a	-2.8 ± 0.1	0.93	0.54
	24 hours	4.23 ± 1.18 b	-3.87 ± 0.39	<0.001	3.86 ± 1.24 a	-4.2 ± 0.29	<0.001	0.04

¶: Repeated measurement

P1: intra-group comparison of each time point compared to the recovery (reference) in the bupivacaine-impregnated epidural Gelfoam group (in addition, in each group, the same letters indicate no significant difference, and different letters indicate a significant average difference in each time point relative to other times)

P2: intra-group comparison of each time point compared to the recovery (reference) in the paravertebral intramuscular bupivacaine group (in addition, in each group, the same letters indicate no significant difference and different letters indicate a significant difference in the mean at each ratio time to other times)

P3: Comparison of the mean at each measurement time between two groups of epidural gel-foam impregnated with bupivacaine and paravertebral intramuscular bupivacaine

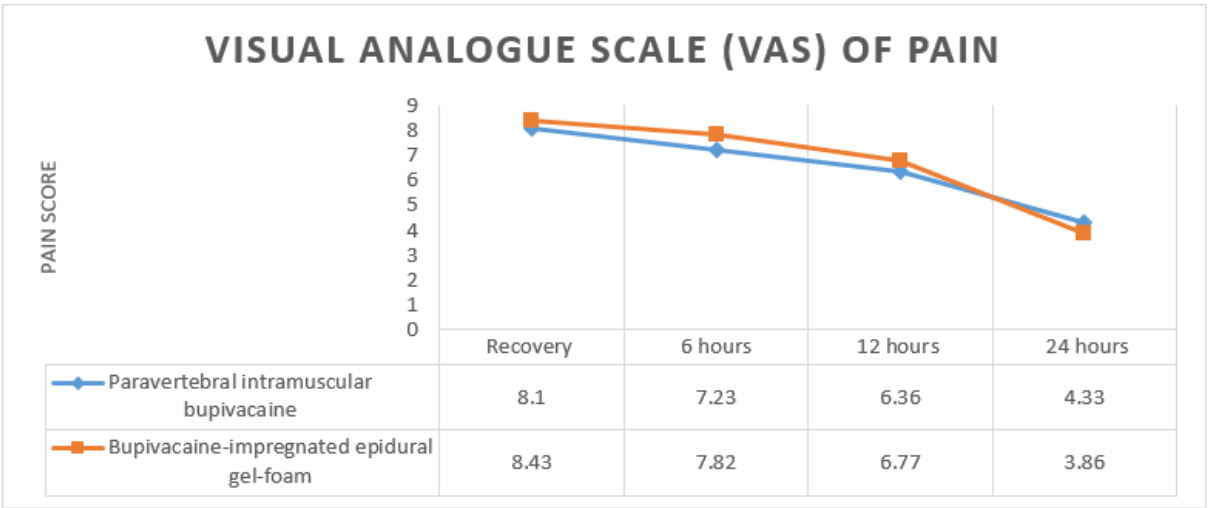

Figure 3. Changes in pain score based on VAS at different time points between the two groups

According to the independent t-test, the frequency of analgesic requests did not differ significantly between the bupivacaine-impregnated epidural gel foam group and the paravertebral intramuscular bupivacaine group (P = 0.42). No significant difference was observed between the two groups when comparing the mean time to first analgesic prescription and the corresponding dose (P = 0.64 and P = 0.27, respectively) [Table 5]. No side effects were observed in either of the two study groups.

Table 5. Comparison of the frequency of analgesic request, mean dose, and first time of morphine administration between the two groups.

Variables		Paravertebral intramuscular bupivacaine (N=30)	Bupivacaine-impregnated epidural gel-foam (N=30)	P-Value¥
Analgesic request	*First time*	13	15	0.42
	Second time	8	9	
	Third time	6	4	
First analgesic request time (minutes)		84.23±23.16	72.43±27.59	0.64
Morphine consumption (mg)		182.73±30.16	156.35±28.84	0.27

Values are presented as Mean ± SD or number. ¥: Independent t-test.

Discussion

Multimodal analgesia and effective pain control improve postoperative outcomes and patient satisfaction. This study is the first to compare the effectiveness of bupivacaine-impregnated epidural gel foam and intramuscular paravertebral bupivacaine in providing analgesia following lumbar spine surgery.

The results of the present study showed that the average pain scores at different time points (recovery, 6 hours, and 12 hours) were not significantly different between the bupivacaine-impregnated epidural gel foam group and the paravertebral intramuscular bupivacaine group. However, at 24 hours postoperatively, the VAS pain score in the bupivacaine-impregnated epidural gel foam group was significantly lower than that in the paravertebral intramuscular bupivacaine group (P = 0.04). No significant difference was found between the two groups in the frequency of analgesic requests, the mean morphine dose, or the time to first analgesic request. Additionally, pain severity at 24 hours postoperatively was significantly reduced in both groups compared to the recovery period.

A few studies have investigated the effectiveness of gel foam impregnated with drugs such as ropivacaine, dexamethasone, nalbuphine, and morphine in spine surgeries.[1,20-23] Additionally, only one study has examined the effect of epidural dexmedetomidine or bupivacaine-impregnated gel foam for postoperative analgesia following lumbar laminectomy. The results showed that patients undergoing lumbar laminectomy with epidural dexmedetomidine or bupivacaine-impregnated gel foam experienced a longer duration of analgesia, lower analgesic consumption, and reduced pain intensity postoperatively compared to the normal saline group.[14] In our study, unlike most previous studies that compared drugs based on the quality of postoperative analgesia, we compared the site of drug administration and its delivery method. The results showed that 24 hours after surgery, the level of analgesia in the bupivacaine-impregnated epidural gel foam group was significantly higher than in the paravertebral intramuscular bupivacaine group. This difference is likely due to the more gradual release of bupivacaine in the gel foam group, similar to a previous study.[15] Additionally, the duration of analgesia following intramuscular injection is typically about 10 to 15 hours, which is influenced by the drug's half-life and the high blood supply to the muscle.[20] In contrast, the slow-release drug delivery via gel foam provides a longer analgesic effect.[1] The results of this study were consistent with the findings of Ekka *et al.,* who reported that gel foam for drug delivery resulted in longer analgesia, lasting up to 36 hours.[20] However, unlike previous studies, no difference was observed in the dose of painkillers consumed or the time to first analgesic request.[21]

In a study by Ekka *et al.,* comparing 0.5% ropivacaine-impregnated gel foam and 8 mg dexamethasone-impregnated gel foam with placebo for postoperative analgesia following lumbar laminectomy, it was shown that gel foam impregnated with 0.5% ropivacaine and 2 ml epidural dexamethasone provided longer postoperative analgesia compared to placebo.[20] In another study evaluating the analgesic effect of levobupivacaine-impregnated gel foam with or without dexamethasone in the epidural space in patients undergoing lumbar laminectomy, it was found that epidural gel foam impregnated with levobupivacaine and dexamethasone prolonged the duration of analgesia, reduced postoperative analgesic consumption, and lowered VAS scores in patients undergoing lumbar laminectomy.[1] Giri *et al.* conducted a study to investigate the effect of nalbuphine-impregnated gel foam compared to ketamine on postoperative analgesia during spine surgery. The results showed that both epidural ketamine and nalbuphine-impregnated gel foam are effective methods for maintaining postoperative analgesia; however, ketamine resulted in a lower pain score, reduced painkiller consumption, and fewer side effects compared to nalbuphine.[21] In another study, Kundra *et al.* compared the effects of epidural morphine versus morphine-impregnated gel foam in lumbar laminectomy, demonstrating the effectiveness of morphine-impregnated gel foam in providing analgesia following spine surgery.[22]

The findings of the present study showed that the intensity of pain during recovery, at 6 hours, and 12 hours postoperatively did not change significantly in either group. However, at 24 hours after surgery, a significant decrease in pain intensity was observed compared to the other three time points (mean change: -4.2 ± 0.29, P < 0.001). In the paravertebral intramuscular bupivacaine group, pain

intensity during recovery did not change significantly at 6 hours compared to the other time points. However, at 12 and 24 hours postoperatively, a significant decrease in pain intensity was observed compared to the other two time points. The mean changes in pain scores at 12 and 24 hours postoperatively were -2.13 ± 0.35 and -3.57 ± 0.39, respectively ($P < 0.001$). Based on previous studies and investigations into the drug delivery properties of gel foam and direct intramuscular injection, the observed pattern of analgesic reduction can be interpreted as follows: in the intramuscular injection method, bupivacaine provides more analgesia 6 hours after the injection, whereas in the gel foam method, pain relief becomes effective after 12 hours.[20] Unlike our study, a previous study showed that intramuscular injection of bupivacaine in the paravertebral muscles did not reduce postoperative back pain, and no significant difference in pain intensity scores was observed between the groups. These findings suggest the ineffectiveness of local bupivacaine for postoperative back pain.[15] In another study, wound infiltration with ropivacaine and magnesium sulfate, compared to bupivacaine and magnesium sulfate, resulted in better postoperative analgesia and a significant reduction in opioid consumption in patients undergoing lumbar laminectomy.[16] Additionally, a study demonstrated that wound infiltration with bupivacaine and magnesium sulfate provided better pain control and effective, safe postoperative analgesia in laminectomy patients.[24,25]

The results of this study showed that no side effects were observed in either of the two groups: the bupivacaine-impregnated epidural gel foam group and the paravertebral intramuscular bupivacaine group.

Further studies are needed to explore various aspects of topical drug delivery methods, including the use of gel foam with different doses. Given the high burden of disease and the volume of lumbar fusions performed annually, even incremental improvements in postoperative outcomes discovered in future studies could have a significant impact on patient satisfaction and reduce additional costs to the healthcare system.

Limitations and Recommendations

One of the limitations of the present study was the follow-up period after patient discharge. Therefore, future studies are recommended to investigate the effects of different doses of bupivacaine-impregnated epidural gel foam on pain control following spinal surgeries and to extend the follow-up period for patients.

Conclusion

In the bupivacaine-impregnated gel foam group, pain intensity was lower 24 hours after surgery compared to the paravertebral intramuscular bupivacaine group. Additionally, pain intensity was significantly reduced in both groups compared to recovery. The frequency of pain medication requests at different time points (recovery, 6 hours, and 12 hours), as well as the mean dose and the time to first analgesic request within 24 hours postoperatively, did not differ significantly between the bupivacaine-impregnated gel foam and paravertebral intramuscular bupivacaine groups. However, bupivacaine-impregnated epidural gel foam provided greater analgesia at 24 hours postoperatively compared to paravertebral bupivacaine injection.

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