PROCEDURAL SEDATION AND PAIN MANAGEMENT

ПРОЦЕДУРНАЯ СЕДАЦИЯ И ЛЕЧЕНИЕ БОЛИ

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The perioperative analgesic effects of thoracolumbar interfacial block and erector spinae plane block for open lumbar fusion: a randomized controlled trial

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Abstract

OBJECTIVE: The purpose of this study is to compare the pain reduction effectiveness of thoracolumbar interfascial plane (TLIP) block with erector spinae plane (ESP) block for open lumbar fusion. **MATERIALS AND METHODS:** From October 2021 to October 2022, 100 patients participated in a randomized prospective intervention study at Hanoi Medical University Hospital. The patients were randomly assigned to three groups: the control group (group C, $n = 33$), the TLIP group (group T, $n = 34$), and the ESP group (group E, $n = 33$). The pain status of the patients in three groups was assessed using the intraoperative mean Analgesia Nociception Index (ANIm), postoperative the Numerical Rating Scale (NRS) at rest and on movement at 1, 2, 4, 8, 12, 24 hour safter surgery. The intraoperative fentanyl and morphine consumption at 12 and 24 hour postoperatively were recorded. **RESULTS:** the ANIm of group C was the lowest at most of the time points studied during surgery ($p < 0.05$). Group E consumed the least fentanyl intraoperatively ($p < 0.001$). The postoperative NRS at rest and on movement was lowest in group E and highest in group C ($p < 0.05$). At 12 hours and 24 hours following surgery, group E›s morphine consumption was lowest ($p < 0.001$). The postoperative initial mobilization and hospital stay were lowest in group E and highest in group C ($p < 0.001$ and $p = 0.039$, respectively). **CONCLUSIONS:** both ESP and TLIP block provide good pain relief during and after open lumbar fusion. However, ESP block is more successful than TLIP block in relieving perioperative pain.

Периоперационные анальгетические эффекты грудопоясничной межфасциальной блокады и блокады мышцы, выпрямляющей позвоночник, при открытом поясничном спондилодезе: рандомизированное контролируемое исследование

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Реферат

ЦЕЛЬ ИССЛЕДОВАНИЯ: Сравнение эффективности снижения боли грудопоясничной межфасциальной блокадой (TLIP) с блокадой мышцы, выпрямляющей позвоночник (ESP), при открытом поясничном спондилодезе. **МАТЕРИАЛЫ И МЕТОДЫ:** С октября 2021 г. по октябрь 2022 г. 100 пациентов приняли участие в рандомизированном проспективном исследовании в больнице Ханойского медицинского университета. Пациенты были случайным образом распределены на три группы: контрольная группа (группа C, $n = 33$), группа TLIP (группа T, $n = 34$) и группа ESP (группа E, $n = 33$). Оценка выраженности боли у пациентов в трех группах оценивалась с использованием среднего индекса анальгезии и ноцицепции (ANIm) интраоперационно, послеоперационно — числовой рейтинговой шкалы (NRS) в покое и при движении через 1, 2, 4, 8, 12, 24 ч после операции. Регистрировалось интраоперационное потребление фентанила и морфина через 12 и 24 ч после операции. **РЕЗУЛЬТАТЫ:** ANIm в группе C был самым низким в большинстве временных точек, исследованных во время операции ($p < 0,05$). Группа E потребляла наименьшее количество фентанила во время операции ($p < 0,001$). Послеоперационный NRS в покое и при движении был самым низким в группе E и самым высоким в группе C ($p < 0,05$). Через 12 и 24 ч после операции потребление морфина в группе E было самым низким ($p < 0,001$). Послеоперационная начальная мобилизация и пребывание в больнице были самыми низкими в группе E и самыми высокими в группе C ($p < 0,001$ и $p = 0,039$

соответственно). **ВЫВОДЫ:** Как блок ESP, так и блок TLIP обеспечивают хорошее обезболивание во время и после открытого поясничного спондилодеза. Однако блок ESP более эффективен по сравнению с TLIP при послеоперационном обезболивании.

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KEYWORDS: patient-controlled analgesia, spinal fusion, ultrasonography, local anesthesia, postoperative pain

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Objective

Modern open lumbar fusions, particularly those involving the implantation of spinal orthopedic devices, are becoming more and more common. Frequently, these procedures result in intense, protracted pain following the procedure. Having effective pain management during and after spine surgery speeds up the healing process. Nowadays, there are numerous ways to relieve pain following spinal surgery, including spinal morphine, oral and intravenous analgesic, and epidural anesthesia. However, these methods come with a number of side effects, including respiratory depression, nausea, vomiting, itching, urinary retention, and inhibition of intestinal motility. Numerous studies on ultrasound-guided regional anesthetic techniques have been conducted recently, demonstrating their potential to effectively relieve pain, ease of use, and low risk of problems. Introduced in 2015, the thoracolumbar interfascial plane block (TLIP block) is a novel procedure that distributes local anesthetic between the multifidus muscles and longissimus muscles, thereby targeting the dorsal branches of spinal nerves [1]. The goal of the erector spinae plane block (ESP block), which was initially described in 2016, is to inject an anesthetic into the space between the transverse vertebral process and the erector spinae muscle in the hopes that it will diffuse to the nerve [2]. Studies showing the pain-relieving benefits of TLIP block and ESP block for patients undergoing lumbar spine surgery have been conducted recently [3, 4]. There are, nevertheless, a small number of academic studies comparing the analgesic effects of ESP and TLIP blocks for open lumbar fusion [5, 6] . There hasn't been any comparable research conducted in Vietnam yet. Thus, we conducted a study in order to compare the pain reduction effects during and after surgery of the (ESP block) with the thoracolumbar (TLIP block) in open lumbar fusion patients [7].

Materials and methods

We conducted this study in compliance with the principles of the Declaration of Helsinki. The study's protocol was reviewed and approved by the Hanoi Medical University (number 208/QD-DHYHN) and registered on ClinicalTrials.gov (registration number: NCT06082245). Written informed consents were obtained.

A randomized controlled study was conducted at Hanoi Medical University Hospital from October 2021 to October 2022 with patients who had a diagnosis of lumbar spinal stenosis, spondylolisthesis or lumbar disc herniation, scheduled for open lumbar fusion (transforaminal lumbar interbody fusion, TLIF or posterior lumbar interbody fusion, PLIF), age 18 to 80 and American Society of Anesthesiologists (ASA) physical status I–II. Patients were excluded from the study if: the patient did not agree to participate in the study; patients with severe underlying diseases: liver failure, kidney failure, heart failure, arrhythmia, neuromuscular disease; history of mental disorders, communication difficulties; pre-existing chronic pain; patients with acute lumbar spine injury or a history of lumbar spine surgery, lumbar abscesses or infections.

A total of 110 patients had their eligibility evaluated between October 2021 and October 2022. Ten individuals were not included in the study (5 patients declined to take part, 3 patients did not comply with doctor orders, and 2 patients had prior lumbar spine surgery). Therefore, 100 patients in all took part in the study. After signing consent forms, each patient was randomly assigned to one of three groups: control (group C), ESP block (group E), or TLIP block (group T) (fig. 1). The allocation ratio was set at 1 : 1 : 1, and a computer-generated random number was used to determine the grouping

Before the administration of general anesthesia, the ESP block and TLIP block were performed. The TLIP block was carried out in accordance with Hand et al [1]. A low-frequency curvilinear array probe (4C; LOGIQ P7, GE Ultrasound, Korea) was positioned in the middle utilising the third lumbar vertebra (L3). Next, 20 ml of 0.25 % ropivacaine was injected into the interfascial plane between the patient's longissimus muscle and multifidus muscle on each side (fig. 2) through a 100mm-22G-block needle (Stimuplex A, B. Braun, Melsungen, Germany). The ESP block was carried out roughly in accordance with Diwan et al. [8]. The patient was placed in the lateral position for the lumbar ESP block. A low-frequency curvilinear array probe (4C; LOGIQ P7, GE Ultrasound, Korea) was utilized. In the parasagittal plane, the 12th rib was located. The L3 transverse process (TP) was then located by shifting the probe caudad and medially. After locating the needle point between the L2 and L3, a 100 mm-22G-block needle (Stimuplex A, B. Braun, Melsungen, Germany) was inserted in-plane until it approached the transverse process. 20 mL of 0.25 % ropivacaine were administered into the ESP (fig. 3).

Patients in the control group were administered with 20 ml of 1 % lidocaine on each side of the planned incision after general anesthesia.

An Analgesia Nociception Index were continuously measured intraoperative with ANI monitor V2, Mdoloris medical system, software version 2.2.3.0, France. This parameter based on Heart Rate Variability analysis, which allows measuring the parasympathetic tone of the patient [9]. This technique enables practitioners to personalize analgesic drug administration, preventing both underdosing and overdose. Clinical studies have shown that keeping the mean ANI (ANIm) in the range of

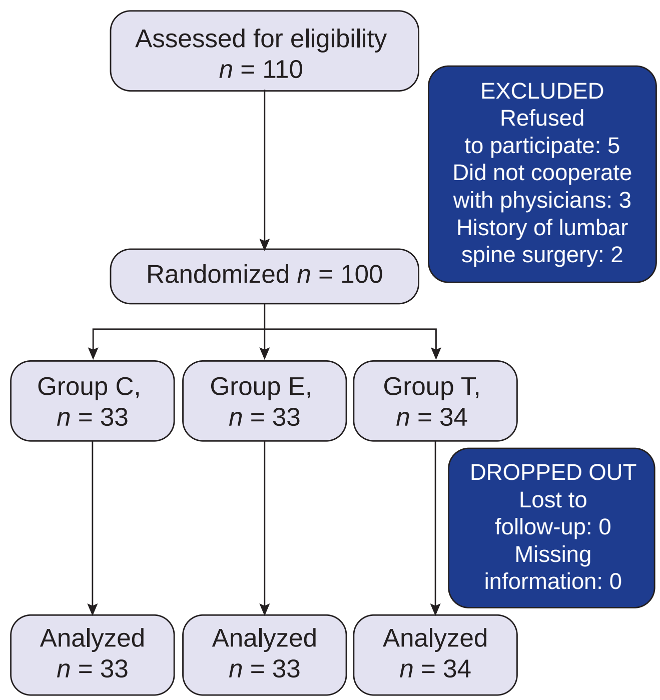

Fig. 1. Flow diagram of study participants

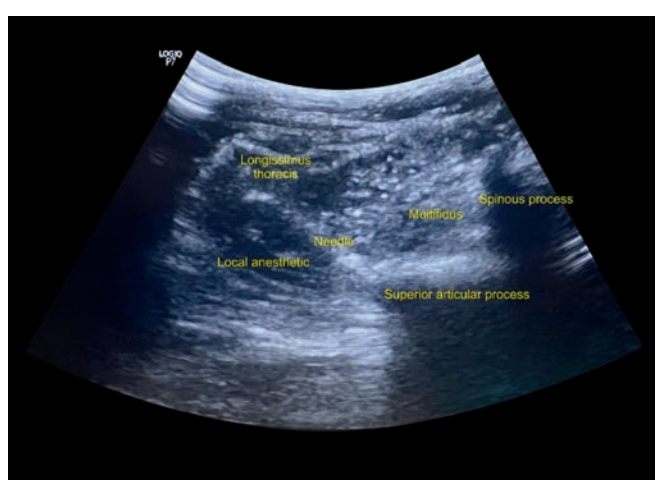

Fig. 2. Ultrasound image of thoracolumbar interfascial plane block (TLIP block)

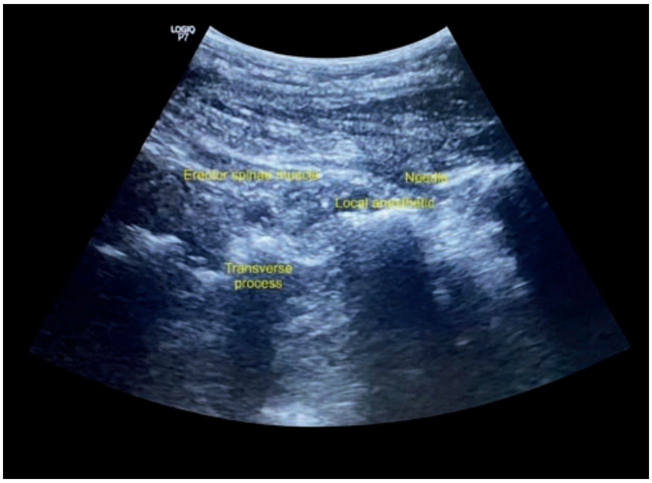

Fig. 3. Ultrasound image of erector spinae plane block (ESP block)

50–70 can help patients avoid unintentional hemodynamic events such as hypertension, hypotension, tachycardia, and bradycardia [10, 11].

Anesthesia and monitoring procedure: all patients were induced with intravenous injection of fentanyl 2 mcg/kg, propofol 2–3 mg/kg, rocuronium 0.6 mg/kg. During maintenance of general anesthesia, 0.8–1 Minimum Alveolar Concentration (MAC) sevoflurane and rocuronium 100 μg/kg/hour were used. Intraoperative fentanyl was used based on ANIm continuously: when ANIm index is below 50 : 50 mcg fentanyl bolus, after 5 minutes can be repeated until ANIm ≥ 50. When ANI is above 70: no need to repeat opioid during surgery, consider reducing the dose. Recorded the amount of fentanyl used during surgery and the ANIm index at the time of the study: when skin incision (T0) and every 10 minutes until the end of surgery.

After surgery, all patients were transferred to the postoperative recovery room, extubated and received intravenous paracetamol 1 g, ketorolac 30 mg. The Numerical Rating Scale (NRS), which ranges from 0 to 10 (0 = no pain, 10 = greatest imagined pain), was used to evaluate the patients' pain. An additional 1mg of morphine was tiltrated every 10 minutes if the NRS score in the recovery room was 4 or above, until the NRS score decreased to under 4. After that, all patients were given patient-controlled analgesia, PCA (CADD-Legacy PCA model 6300, USA): morphine 1 mg/ml, background dose 0 ml/h, self-demand dose 1mg, lockout period 10 minutes. Within the first twenty-four hours, the number of PCA-administered bolus doses was documented. Patients were given 1 g intravenous paracetamol every 8 hours during the ward follow-up.

Demographics and surgical data, such as age, height, weight, gender, ASA status, surgical levels, anesthetic and duration of operations, were evaluated for each group. The primary outcomes of the research were the intraoperative fentanyl consumption, the NRS scores at movement and static state at 1, 2, 4, 8, 12, 24 hours postoperation, and the total morphine consumption during the postoperative period of 12 and 24 hours. The secondary outcome of our research comprised opioid side effects (nausea and vomiting, pruritus, respiratory depression), the initial mobilization following surgery and length of postoperative hospital stay.

Statistical analysis was performed using SPSS 22.0 software (SPSS Inc., USA). The sample size was calculated using G* power software (version 3.1.9.7, Heinrich Heine University, Düsseldorf, Germany) based on data from our prior pilot study. Our previous pilot study showed that the average 24-hour postoperative morphine consumption of patients in the control, TLIP block and ESP block groups was 21.3, 19.5 and 20.8 (mg), respectively. The effect size was calculated using the one and found to be 0.759. To ensure adequate sampling, it was planned to include at least 30 patients in each group, with a power of 90 %, a 5 % margin of error (two-tailed), and a 10 % rate of patient attrition. We recruited 100 patients in the study and randomly divided them into 3 groups.

The Student *t*-test was used for analyzing parametric data, whereas the chi-square test was used for nonparametric data. A one-way analysis of variance (ANOVA) was utilized to investigate repeated measurements within and across groups. Data with a normal distribution were provided as the mean and standard deviation, but non-normal data were reported as the median, while categorical were presented as percentages. A probability less than 0.05 indicated significant differences between groups.

Results

A total of 100 patients were randomly divided into three groups: 33 were allocated to group C, 33 to group E, and 34 to group T.

In table 1, it was concluded that no statistically significant differences between the groups in terms of gender, age, weight, height and body mass index (BMI), ASA physical status classification. Similarly, no statistically significant differences were identified among three groups for surgical procedure levels, percentage of lumbar interbody fusion techniques and operation length ($p > 0.05$). The average time for first mobilization post-surgery was highest in group C (20.03 ± 1.83 hours), lowest in group E (14.05 ± 1.79 hours), the difference was statistically significant ($p < 0.001$). The postoperative hospital-stay gradually decreased from group C (4.36 ± 0.92 days) to group T (4.15 ± 0.94 days) and was lowest in group E (3.76 ± 1.02 days), this difference was statistically significant ($p = 0.039$).

Data from fig. 4 showed that, at the time of the investigation (H10, H20, H40, H50, H80, H90, H110, H120, H130, H150, H160, H170), group C had lower ANIm values than group T and the highest in group E, with statistically

Table 1. Patient demographic characteristics

Parameter		Group E ($n = 33$)	Group T ($n = 34$)	Group C ($n = 33$)	p
Age (years)	$\bar{X}$ ± SD	55.1 ± 10.5	56.7 ± 11.6	54.3 ± 13.1	0.692
	Min–Max	31–72	30–75	21–72	
Height (cm)	$\bar{X}$ ± SD	156.4 ± 5.5	159.0 ± 6.8	158.8 ± 7.1	0.187
	Min–Max	149–172	148–173	146–175	
Weight (kg)	$\bar{X}$ ± SD	56.7 ± 8.0	58.7 ± 9.4	56.3 ± 8.9	0.487
	Min–Max	42–74	46–85	45–75	
BMI (kg/m^2)	$\bar{X}$ ± SD	23.1 ± 2.6	23.2 ± 2.9	22.2 ± 2.2	0.655
	Min–Max	17.97–27.47	17.26–31.62	18.37–27.51	
Operation duration (minute)	$\bar{X}$ ± SD	159.7 ± 21.1	147.1 ± 33.9	136.2 ± 35.1	0.253
	Min–Max	105–180	55–185	70–180	
Gender	Male (*n*, %)	18 (54.5 %)	19 (55.9 %)	19 (57.6 %)	0.970
	Female (*n*, %)	15 (45.5 %)	15 (44.1 %)	14 (42.4 %)	
ASA classification	I (*n*, %)	20 (60.6 %)	19 (55.9 %)	17 (51.5 %)	0.758
	II (*n*, %)	13 (39.4 %)	15 (44.1 %)	16 (48.5 %)	
Method of spondylodesis	TLIF (*n*, %)	27 (81.8 %)	30 (88.2 %)	30 (90.9 %)	0.529
	PLIF (*n*, %)	6 (18.2 %)	4 (11.8 %)	3 (9.1 %)	
Surgical procedure level	1 (*n*, %)	19 (57.6 %)	19 (55.9 %)	20 (60.6 %)	0.930
	2 (*n*, %)	12 (36.4 %)	11 (32.4 %)	10 (30.3 %)	
	3 (*n*, %)	2 (6 %)	4 (11.7 %)	3 (9.1 %)	
First postoperative mobilization (hour)	$\bar{X}$ ± SD	14.06 ± 1.79	16.97 ± 1.92	20.03 ± 1.83	**< 0.001**
	Min–Max	10–18	14–22	17–24	
Postoperative hospital stay (days)	$\bar{X}$ ± SD	3.76 ± 1.02	4.15 ± 0.94	4.36 ± 0.92	**0.039**
	Min–Max	2–6	2–6	3–7	

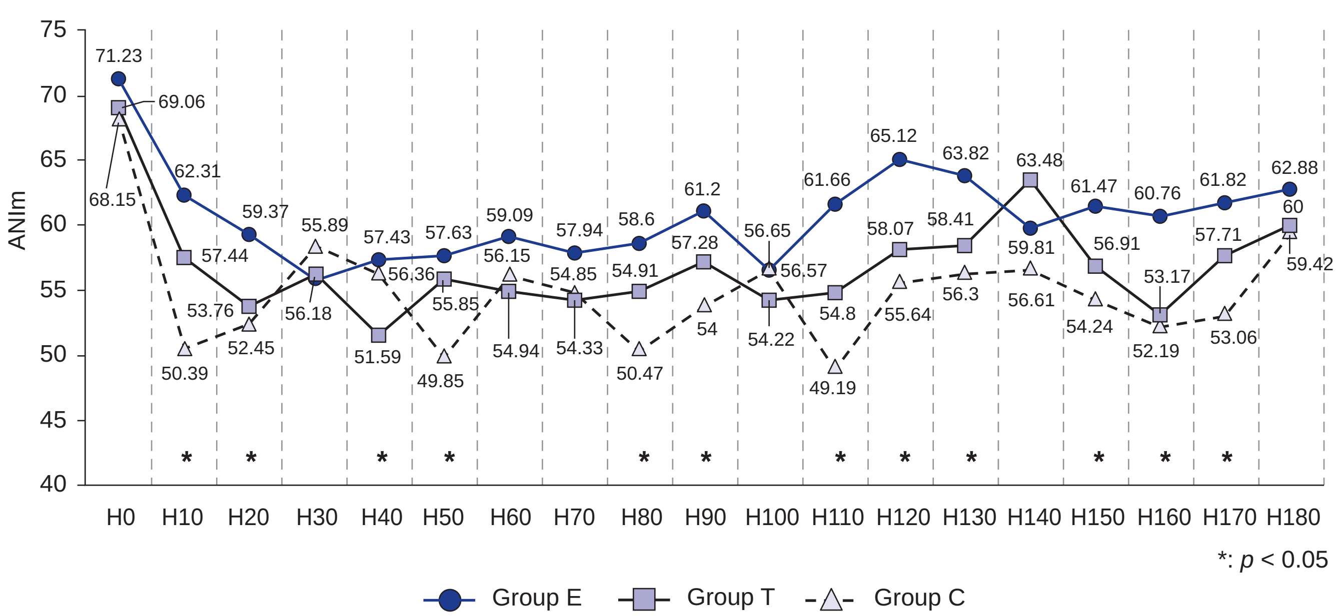

Fig. 4. Intraoperative ANIm of three groups

significant difference ($p < 0.05$). A comparison of groups E and T revealed that ANIm did not differ at any time point during the trial ($p > 0.05$).

Results from fig. 5 demonstrated that NRS scores of group E were lower than those of group C and group T at rest and during movement; this difference was statistically significant ($p < 0.001$). At all study times postoperative, in both static and dynamic states, NRS score of group E was less than 4, much lower than that of the group T ($p < 0.05$).

Results from table 2 showed that group E and group T had significantly decreased intraoperative fentanyl consumption, 12-hour postoperative and 24-hour postoperative morphine consumption, compared to group C ($p < 0.001$). Based on these criteria, a comparison between groups E and T revealed that group E consumed less opioid during perioperative time, this difference was statistically significant ($p < 0.001$).

From data of table 3, there were no difference among three groups about the incidence of opioid side effects (respiratory depression, pruritus, nausea, vomitting) within 1-day postoperatively ($p > 0.05$).

Discussion

Severe postoperative pain from lumbar spinal fusion surgery hinders a speedy recovery from the procedure [12]. Despite the rise in spinal procedures in recent years, there are still few choices available for managing pain during surgery. When used with a multimodal analgesic technique, plane blocks can easily offer adequate, consistent, and appropriate analgesia in the context of improved recovery after surgery [13].

The results of our research showed that group E had considerably shorter hospital stays and postoperative mobilization periods than group T and group C ($p = 0.039$ and $p < 0.001$, respectively). There was no statistically significant difference among the three groups about the surgical location and technique, so it did not affect the results of the study›s assessment of pain relief during and after surgery. Regarding the effectiveness of pain relief during surgery, it is reflected in the ANIm index: at the time points H10, H20, H40, H50, H80, H90, H110, H120, H130, H150, H160, H170, the ANIm of group C was lower than that of group T and group E ($p < 0.05$). The trend toward higher

Table 2. Consumption of intraoperative fentanyl and postoperative morphine

Parameter		Group E ($n = 33$)	Group T ($n = 34$)	Group C ($n = 33$)	p
Intraoperative fentanyl (mcg)	$\bar{X}$ ± SD	222.86 ± 42.60	298.53 ± 35.86	365.15 ± 55.18	< 0.001
	Min–Max	150–300	250–350	250–450	
					$p_{group\ E–T} < 0.001$
Morphine consumption in 12 hours post-surgery (mg)	$\bar{X}$ ± SD	4.69 ± 1.43	11.03 ± 2.05	18.12 ± 4.46	< 0.001
	Min–Max	3–6	8–15	14–27	
					$p_{group\ E–T} < 0.001$
Morphine consumption in 24 hours post-surgery (mg)	$\bar{X}$ ± SD	6.06 ± 2.45	12.79 ± 3.65	20.45 ± 5.83	< 0.001
	Min–Max	5–9	11–19	19–33	
					$p_{group\ E–T} < 0.001$

Table 3. Incidence of opioid side effects in the groups in the first 24 hours postoperatively

Parameter	Group E ($n = 33$)	Group T ($n = 34$)	Group C ($n = 33$)	p
Respiratory depression (n, %)	0	0	0	1
Itchy skin (n, %)	2 (6.1 %)	2 (5.9 %)	3 (9.1 %)	0.847
Nausea (n, %)	1 (3.0 %)	1 (2.9 %)	4 (12.1 %)	0.195
Vomitting (n, %)	1 (3.0 %)	2 (5.8 %)	3 (9.1 %)	0.584

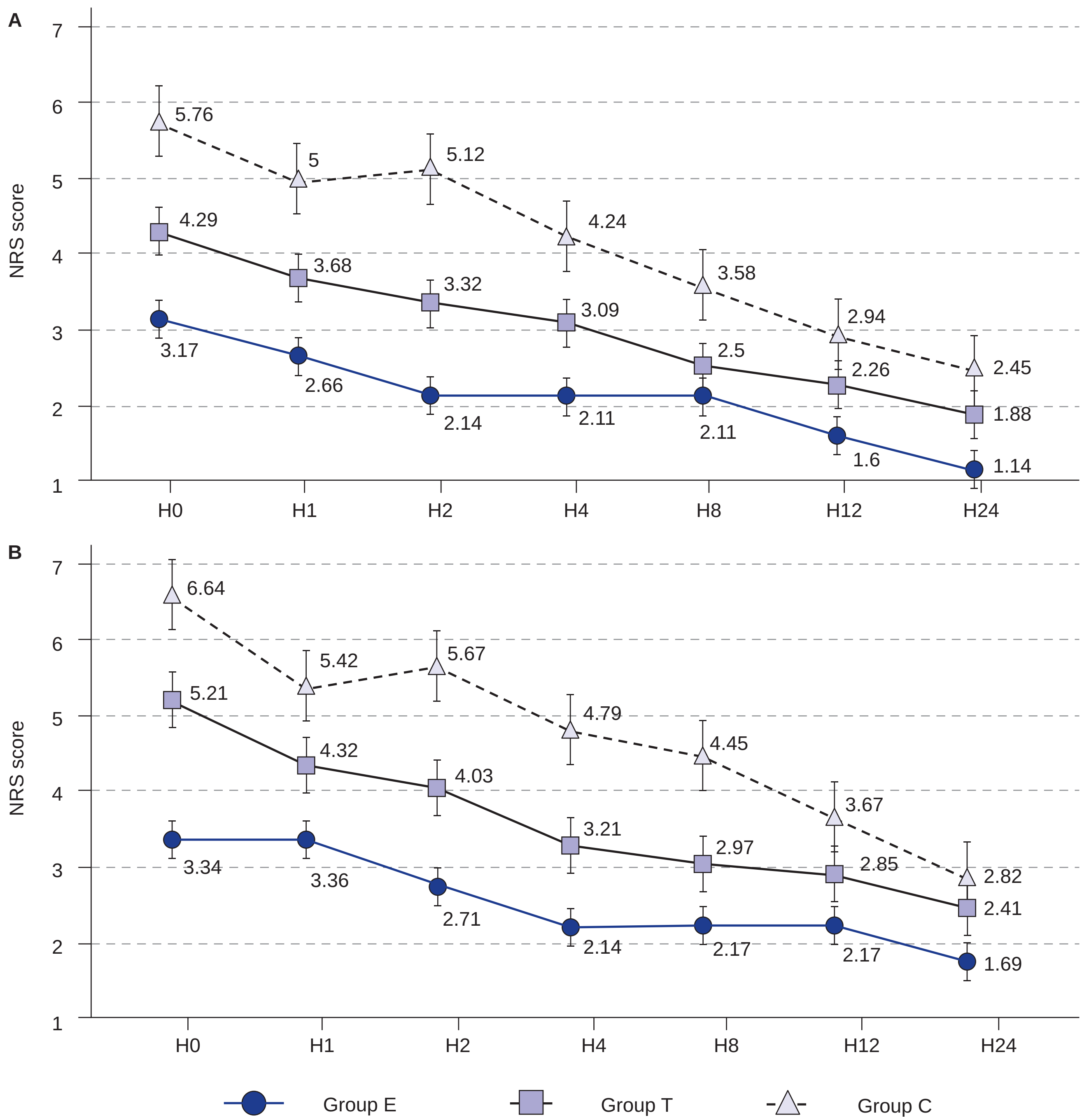

Fig. 5. Postoperative NRS score at rest (A) and on movement (B) of three groups

ANIm in the group E showed that the level of intraoperative pain in this group was lower than that in the group T, but the difference was not statistically significant. The amount of intraoperative fentanyl in the group C was much higher than the two groups that received ultrasound blockade, with a significant difference ($p < 0.001$). The group E also consumed a lower mean amount of intraoperative fentanyl than the group T ($p < 0.001$). Research on postoperative opioid consumption also showed that the amount of morphine in the group E was the lowest and the group C was the highest, the difference was statistically significant ($p < 0.01$). This result is also consistent with those noted in the studies of Wang L.et al, Kumar A. et al when it was found that ESP block has the ability to reduce pain after lumbar spine surgery better than TLIP block, when comparison of opioid intake after surgery [5, 14]. The results of morphine consumption in the 24 hours after surgery also show that lumbar spine surgery is a surgery that causes a lot of pain, mainly in the first 12 hours after surgery and gradually decreasing thereafter. This trend is also consistent with the publication of authors such as Ye Y. et al [4], Hu Z et al [15]. The average NRS score in the first 24 hours after surgery of group E was much lower than that of group T, while group C always had the highest NRS score, this difference was statistically significant ($p < 0.05$). Thus, it can be seen that both methods of plane anesthesia under ultrasound in our study are effective in reducing postoperative pain, in which ESP block is more effective than TLIP block. This result was similar to the research of Dilsiz P. et al [16], Wang L. et al [5], Ciftci B. et al [17]. The trend clearly indicates that ESP block is more successful than TLIP block for lumbar spine surgery, even though these studies differ from ours in terms of the type of lumbar spine surgery, the type of anesthetic, as well as its volume and concentration. This tendency can be explained by the directional mechanism of anesthetic spread. In terms of mechanism, the effects and spread of anesthetics in TLIP block are still not fully and clearly understood. But most believe that in TLIP block only affects one branch of the dorsal branch, which only governs skin sensation and movement of the erector spinae muscle, while the source of pain after spinal surgery can come from damage to other structures such as ligaments, discs, dura mater, and joint capsules. With ESP block, anesthetic is injected into the position between the erector spinae muscle and the transverse vertebral process and can spread to the paravertebral space, blocking both the dorsal and ventral branches of the spinal nerves, thus providing better pain relief.

There are many constraints on our research. Firstly, the study's sample size was insufficiently enormous. Secondly, the duration of the postoperative pain monitoring period is still brief, and the research has not been extended to include other local anesthetic volumes and concentrations. Finally, our research subjects are limited to open lumbar fusion; we have not included alternative lumbar spine surgery modalities, such as minimally invasive or endoscopic lumbar spine surgery, in the study.

Key points

- Open lumbar fusion surgery is associated with a high degree of pain, particularly in the 12 to 24 hour postoperative period.
- Both the thoracolumbar interfascial plane block and the erector spinae plane block are useful in minimizing pain during and following open lumbar fusion surgery.
- Multimodal analgesia helps patients recover from surgery more quickly, spend a shorter period in the hospital following surgery, and enhancing rehabilitation effectiveness.

Conclusions

Both the ESP and TLIP blocks provide effective pain management during and after open lumbar fusion. However, ESP block is more effective than TLIP block in reducing perioperative pain.

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