Article published online: 2024-05-02

Original Article

Analgesic Efficacy of Thoracolumbar Interfascial Plane Block versus Standard Care in Patients Undergoing Lumbar Spinal Surgeries—A Randomized Controlled Trial

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J Neuroanaesthesiol Crit Care

Abstract

Background Patients who undergo spine surgery often experience severe pain postoperatively. Multimodal analgesia inclusive of a regional block provides optimal pain relief. Thoracolumbar interfascial plane (TLIP) block may provide promising analgesia in these patients.

Materials Fifty consenting adults aged between 18 and 60 years undergoing elective lumbar spinal surgeries under balanced general anesthesia were divided into two equal groups (group T: received bilateral TLIP block, and group C**:** received conventional opioid analgesia). All the patients were taken care of by an independent anesthesiologist unaware of the study protocol in the postanesthesia care unit. The postoperative pain was assessed by visual analog scale (VAS). Time to first rescue analgesia, total morphine consumption, complications, and patient satisfaction were also recorded.

Results Postoperative mean VAS scores till 12 hours were significantly higher in the control group. The mean time to the first analgesic requirement among group T and group C patients was 404.4 ± 25.1 and 150.2 ± 12.4 minutes, respectively ($p < 0.001$). Morphine consumptions in 24 hours were also significantly higher in group C (3.36 ± 1.04 vs. 7.84 ± 1.43; $p < 0.001$). Mean intraoperative fentanyl consumption was significantly more in group C (122.4 ± 16.4 µg and 140.4 ± 21.7 µg; $p = 0.001$). Complications were similar in both groups. However, patient satisfaction was significantly higher in group T ($p < 0.001$).

Conclusion TLIP block provided superior analgesia, decreased opioid consumption, and improved patient satisfaction as compared with patients receiving standard general anesthesia with opioid analgesics. Hence, TLIP block could be a component of multimodal analgesia in patients undergoing lumbar spine surgeries.

CTRI No.: CTRI/2021/03/031682

Keywords
- analgesia
- TLIP block
- postoperative
- spinal fusion
- regional anesthesia

DOI https://doi.org/10.1055/s-0044-1782506.
ISSN 2348-0548.

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Thieme Medical and Scientific Publishers Pvt. Ltd., A-12, 2nd Floor, Sector 2, Noida-201301 UP, India

Introduction

Patients frequently report severe and persisting postoperative pain after spine surgery. Therefore, pain management is a prime concern as inadequately managed pain can reduce patient satisfaction, delay recovery, and have the potential to cause negative effects on patient outcomes.[1,2]

Multimodal analgesia using systemic opioids, nonsteroidal anti-inflammatory drugs, and regional anesthesia is recommended as the best strategy for controlling postoperative pain in spinal surgeries.[2,3] Regional anesthesia is recommended by enhanced recovery after surgery (ERAS) protocol as well as it helps supplement the multimodal approach and improve the quality and duration of postoperative analgesia.[4]

The cornerstone of multimodal analgesia is regional anesthesia. Lumbar epidural, caudal epidural, and subarachnoid block have been used for analgesia after spinal surgery, but these blocks are more invasive than peripheral nerve block and can cause hemodynamic instability and motor block.[2,4] Wound infiltration of the local anesthetics has been used very commonly in spine surgery; however, the efficacy of local infiltration analgesia has not been well established due to its limited spread.[3] Parenteral analgesics may be effective but can have potentially serious adverse effects and can delay postoperative recovery and rehabilitation.[5] Therefore, there has always been a need to devise the optimal strategy for pain management following spine surgeries.

There are only a few regional anesthesia options that are utilized in spine surgery despite the severe postoperative pain. Though epidural anesthesia has been favored for spine surgery, neuraxial techniques are technically difficult and have various associated complications. In recent years, erector spinae plane block (ESPB) at the lumbar level has been described as a safe and effective regional anesthesia technique with the main advantage of an easily identified landmark of transverse process on ultrasonography. Since the target site is away from important vessels and nerves, the technique is generally considered safe. In a recent systematic review and meta-analysis, the authors found that the ESPB decreased postoperative pain scores and opioid consumption in patients undergoing spine surgeries as compared with controls.[6] However, the authors highlighted that the current evidence is relatively insufficient and further clinical trials are required to support its widespread use for lumbar spine surgery. Furthermore, though the incidence of reported complications such as vascular puncture, nerve injury, or neuraxial blockade is very low, the studies done till now are not powered adequately to detect these complications. Hence, the regional analgesia modalities further away from the neuroaxis would be considered desirable.

The thoracolumbar interfascial plane (TLIP) block is a new regional analgesia technique described for lumbar spine surgeries and has its effect due to action on spinal nerves dorsal rami.[7] TLIP block at the third lumbar vertebrae was found to provide a predictable effect from L1- S1 dermatomes covering the back from the left to the right posterior axillary line.[7] The TLIP block is still not widely practiced and there are only a handful of randomized controlled trials that have been conducted on the classical medial approach that has been investigated in this study. In the few studies conducted on medial TLIP block to date, it has been observed to significantly reduce opioid requirements in multimodal analgesia regimens after lumbar spine procedures, thereby facilitating recovery.[8,9] However, the methodologies were heterogeneous and the results of all the studies are not in concurrence. A recent meta-analysis conducted on the block concluded that though it is worth being applied in lumbar spine surgery extensively in future, evidence is still low and further studies are warranted on this subject for stronger evidence to establish its efficacy in spine surgeries.[10]

Hence, in light of this background, we planned this study to evaluate the efficacy of the TLIP block to examine the hypothesis that ultrasound-guided TLIP block will provide more effective postoperative pain control than standard care in patients undergoing lumbar spinal surgeries.

The primary outcome was to compare the postoperative analgesia at the time "0" in the two groups. The secondary objectives were analgesic duration, visual analog scale (VAS) scores for the first postoperative day, total morphine consumption over 24 hour, and patient satisfaction.

Materials and Methods

This prospective randomized interventional parallel-group trial was performed in a tertiary care center after institutional ethics committee approval and prospective registration of this trial with the clinical trial registry of India from March 2021 to December 2021.

Fifty consenting adult (18–60 years) patients of either gender belonging to American Society of Anesthesiologists (ASA) grade I/II and posted for single or two-level elective lumbar spinal fusion surgeries were recruited for the study. Patients with any history of allergy to local anesthetics, coagulopathies, those on anticoagulants, local infection at the block site, or history of previous lumbar spine surgery, those with body mass index more than 30 kg/m2, inability to understand VAS, inability to operate the patient-controlled analgesia (PCA) pump, cardiopulmonary, renal or hepatic disease were excluded from the study.

After written informed consent, patients were randomly divided into two groups of 25 patients. Block randomization was used for the randomization process, wherein five blocks of ten each randomly generated treatment allocations assigned patients into two groups and the allocated codes were kept within sealed opaque envelopes. Once an eligible patient consented, general anesthesia was administered following which an envelope was opened, and the patient was allotted to the assigned group. Hence, the patient was blinded to the group allocation. The person administering the blocks was not involved in the study any further and the person recording the postoperative study outcomes was blinded to the group allocation, thereby minimizing the possibility of any bias.

Group T (TLIP group) received a bilateral TLIP block (20 ml of 0.25% bupivacaine with 1:200000 adrenaline on both sides) after the balanced general anesthetic and PCA morphine postoperatively.
Group C (control group) received balanced general anesthesia and conventional intravenous (IV) opioid analgesia intra and postoperatively.

All patients underwent a detailed preanesthetic checkup and were instructed to fast overnight before surgery. The advantages and disadvantages of TLIP block were described, and the patients were familiarized with the use of the VAS Scale and PCA pump. All the patients received tablets of alprazolam 0.25 mg and ranitidine 150 mg orally the night before the surgery.

In the operating theater, ASA standard monitors including the electrocardiogram, noninvasive blood pressure, arterial oxygen saturation (SpO2), temperature, and end-tidal carbon dioxide were applied. Baseline heart rate (HR), mean arterial pressure (MAP), and SpO2 were noted. An IV access was secured, and anesthesia was induced using propofol (1–2 mg/kg) and fentanyl (2 µg/kg). The trachea was intubated after achieving muscle relaxation using vecuronium (0.1 mg/kg). Isoflurane (0.5–1%) in a mixture of oxygen and nitrous oxide was used for anesthesia maintenance to achieve a minimum anesthetic concentration of 1. Positioning was carefully done to ensure that the abdomen was free from any compression. Normovolemia was maintained and any episode of hypotension was treated with inj. ephedrine 6 mg boluses. Despite the good anesthetic depth and adequate muscle relaxation if MAP or HR increased more than20% above baseline value, then 1 µg/kg fentanyl was administered IV. After shifting the patient to the prone position, a ultrasonography-guided TLIP block was given to group T (►**Fig. 1**). All the patients received inj. paracetamol 1 gm IV after induction.

A high-frequency (8–13MHz) linear transducer (Sonosite S-Nerve; SonoSite, Bothell, Washington, United States) was positioned transversely at the level of the third lumbar vertebra (L3) in the midline and the corresponding spinous and transverse processes were identified. Thereafter, the probe was moved laterally to identify the multifidus and the longissimus muscles (►**Fig. 1A**). A 10 cm 21G Stimuplex needle (Braun Medical Inc, Bethlehem, Pennsylvania, United States) was inserted in-plane through the belly of the longissimus toward the longissimus–multifidus interface in a lateral to medial orientation. After confirming needle tip placement between the two muscles by saline hydro-dissection, a 20mL local anesthetic mixture of 0.25% bupivacaine with 1 in 2,00,000 adrenaline was injected in small aliquots with frequent aspiration (►**Fig. 1B**). The block technique was repeated on the opposite side with the same local anesthetic mixture and volume.

Postoperative nausea and vomiting (PONV) prophylaxis was provided by IV ondansetron (0.1 mg/kg) to all patients. After completion of the surgery, the patients were turned supine, neuromuscular blockade was reversed using IV neostigmine 0.05mg/kg and IV glycopyrrolate (0.01mg/kg), and following the return of adequate spontaneous respiration, the trachea was extubated. Thereafter, all the patients were shifted to the postanesthetic care unit (PACU), for postoperative care. Oxygen was administered at a flow rate of 6L/min and an IV PCA pump (Caesarea Medical Electronics) was attached to all the patients. The initial settings of the PCA pump were a bolus dose of morphine 1 mg, lockout time of 15min with no background infusion, and the maximum dose allowed was 4mg/h. The total amount of drug used by the patient in the first 24 hours by the PCA pump was noted, and the pain was assessed by the patients themselves using self-rating VAS scores ranging from "0" (no pain) to "10" (worst pain) at 0, 2, 4, 6, and 24 hours after completion of surgery. The time of shifting the patient to PACU was defined as time "0." The time to the first analgesic dose was the time from block administration till the first dose of analgesic was self-administered by the patient using PCA. The parameters recorded intraoperatively included HR, MAP, and intraoperative fentanyl requirement. Postoperatively, the VAS scores (0, 2, 4, 6, 12, and 24 hour), time to the first rescue analgesia, and total morphine consumed at the end of 24 hour were assessed. Adverse effects like sedation [using Richmond Agitation sedation scale (RASS)], PONV using the nausea vomiting scale,[11] respiratory depression, and itching were also recorded. Patient satisfaction in terms of the

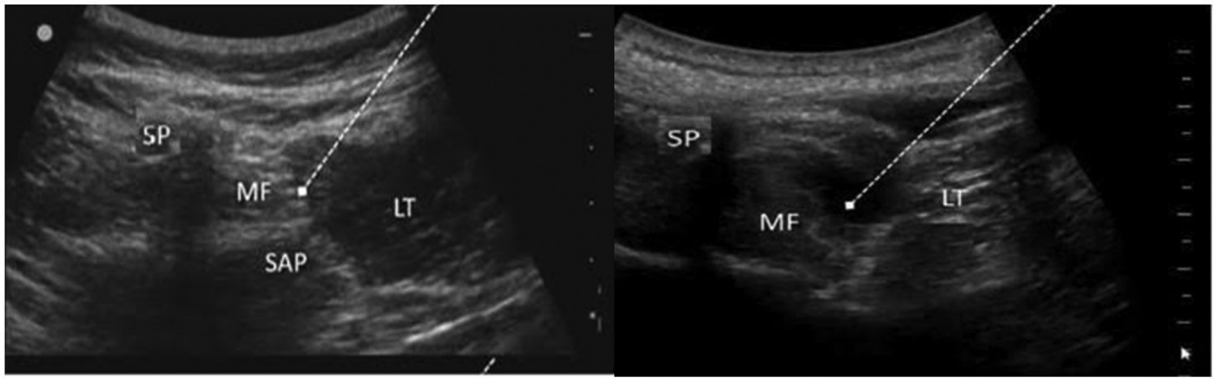

Fig. 1 Transforaminal lumbar interbody fusion (TLIF) block: (**A**) Relevant anatomy (LT, longissimus thoracis muscle; MF, multifidus; SAP, superior articular process; SP, spinous process; white arrow-needle track); (**B**) After local anesthetic injection (white arrow-local anesthetic deposited).

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quality of pain relief was also noted at the end of 24 hour postoperatively using the Likert scale.[12]

Sample Size Calculation

The study of Ammar and Taeimah[9] observed that the median and interquartile range of VAS at "0" hour was 4 (4–5) in the control group and 2 (1–2) in the TLIP group. For the calculation of sample size, the standard deviation (SD) was calculated as the interquartile range/1.35, that is, 0.74.[13] If we take 1 unit in VAS score as a clinically important difference and round off the SD to 1 unit from 0.74 then with 80% power and 5% levels of significance, we needed 18 subjects per group. Since we planned to apply the nonparametric test in the study, so we inflated the sample size by 15% and required 22 subjects per group for which, we enrolled 25 subjects per group for this study.

Statistical Analysis

Data were analyzed using the software Statistical Package for Social Sciences (SPSS) version-21 (IBM, Armonk, New York, United States). Continuous variables were presented as mean ± SD and categorical variables were presented in number and percentage (%). The data were tested for normality using the Kolmogorov–Smirnov test. Quantitative variables were compared using the unpaired *t*-test or Mann–Whitney U test (for non-normal distributed datasets). Qualitative variables were evaluated using the chi-squared test or Fisher's exact test. A *p*-value of less than 0.05 was considered statistically significant.

Results

Sixty-two adult patients were posted for elective lumbar spinal fusion surgeries (single level or two level) under general anesthesia and were assessed for eligibility for inclusion in this prospective randomized study. However, 50 patients were randomized to either the interventional or control group. (►**Fig. 2**) The morphometric parameters, ASA grading, type of spine surgery (one or two level), and duration of surgery were similar in the two groups (►**Table 1**).

Mean VAS scores at rest (0 hour), 2 hours, 4 hours, 6 hours, and 12 hours were significantly higher in group C (►**Table 2** and ►**Fig. 3**). The mean time for the first analgesia requirement (min) was significantly longer in group T (404.4 ± 25.1

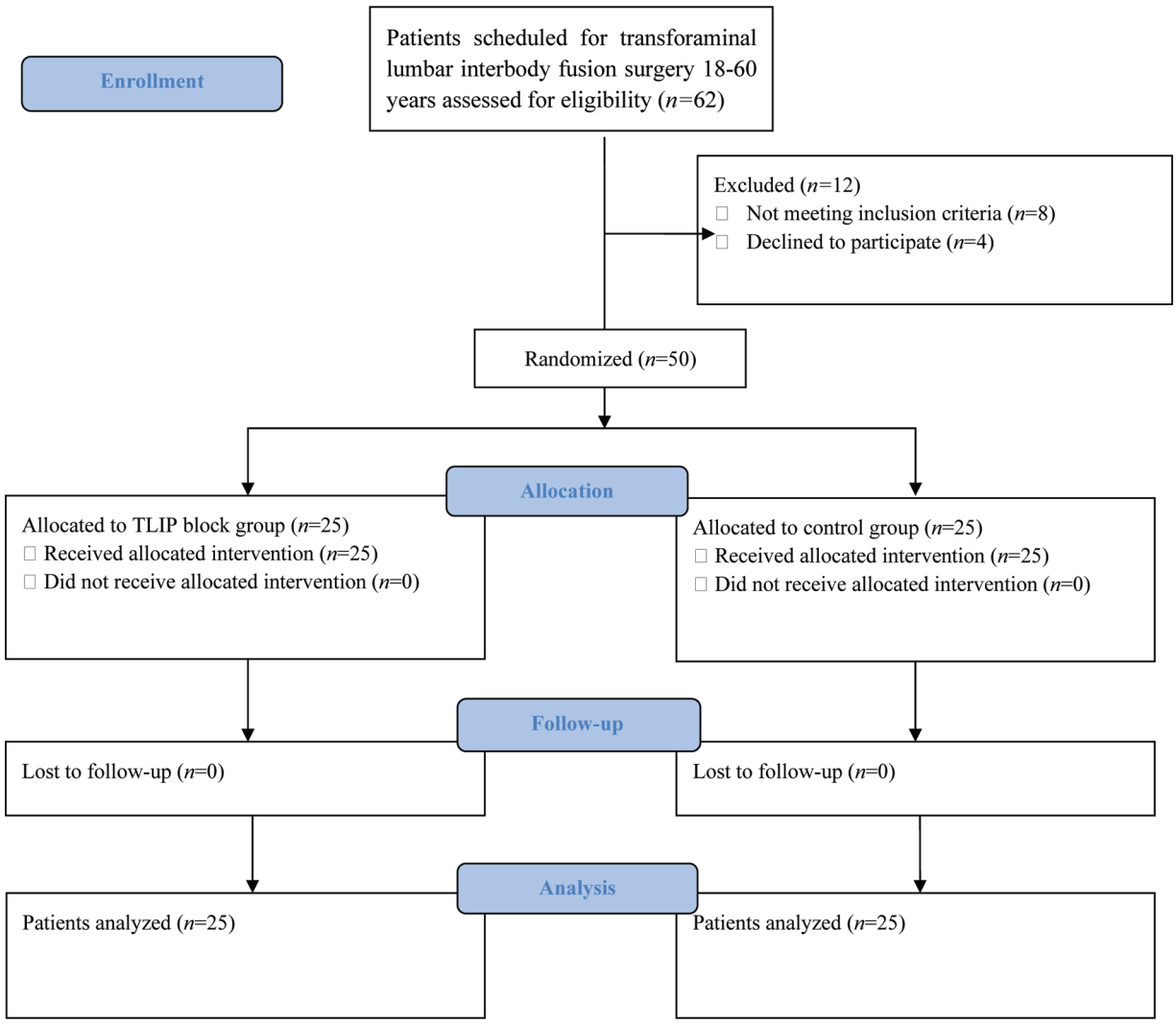

Fig. 2 Consort diagram. TLIP, thoracolumbar interfascial plane.

Table 1 Demographic and clinical characteristics

	Group T	Group C	*p*-Value
Age	44.6 ± 10.24	46.1 ± 9.3	0.18
Gender (M/F)	15/10	13/12	0.74
ASA (I/II)	14/11	15/10	0.39
Weight (kg)	67.6 (6.66)	69.2(7.1)	0.17
Height (cm)	1.70(0.10)	1.75(0.11)	0.32
BMI (kg/m^2)	23.2(1.9)	22.6(2.9)	0.87
Single-level/two-level TLIF	18/7	20/5	0.74
Duration of surgery (min)	127.1 (15.78)	131.3(8.67)	0.67
Intraoperative fentanyl consumption (μg)	122.4(16.4)	140.4(21.7)	0.001

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; TLIF, transforaminal lumbar interbody fusion.

Table 2 Postoperative analgesia outcomes

Parameter	Group T	Group C	*p*-Value
Postoperative morphine consumption (mean [SD] mg)			
PACU (0 hour)	0.52(0.58)	1.44(0.51)	0.03
2 hours	0.76(0.59)	1.36(0.7)	<0.001
4 hours	0.56(0.58)	1.24(0.72)	<0.001
6 hours	0.60(0.64)	1.56(0.58)	0.01
12 hours	0.48(0.58)	1.32(0.74)	<0.001
24 hours	0.4(0.5)	1.00(0.91)	0.02
Postoperative VAS scores (mean [SD])			
PACU	2.2(0.4)	4.1(1.6)	0.01
2 hours	2.4 (0.5)	3.7(1.6)	<0.001
4 hours	2.3(0.8)	4.1(1.7)	0.01
6 hours	2.5(0.9)	3.7(1.1)	0.02
12 hours	3.1(1.1)	4.2(1.8)	0.03
24 hours	2.3(0.4)	2.8(0.8)	0.13
Total morphine consumption in 24 hours	3.36(1.04)	7.84(1.43)	<0.001
Time to first analgesic requirement (minutes)	404.4(25.1)	150.4(12.4)	<0.001
Patient satisfaction (*n*) (very unsatisfied/unsatisfied/neutral/satisfied/very satisfied)	0/2/3/9/11	1/4/6/10/4	<0.001
Richmond Agitation Sedation scale (mean [SD])	0.08(0.57)	-1(0.82)	<0.0001
Postoperative complications			
Nausea/vomiting	3	5	0.44
Respiratory depression	0	1	0.33

Abbreviations: PACU, postanesthetic care unit; SD, standard deviation; VAS, visual analog scale;

minutes vs. 150.2 ± 12.4; $p < 0.001$; (►**Table 2**, ►**Fig. 4**). The mean morphine consumption at various assessment times (1.44, 1.36, 1.24, 1.56, 1.32, and 1 vs. 0.52, 0.77, 0.56, 0.6, 0.48, and 0.4 mg, respectively, at time 0, 2, 4, 6, 12, and 24 hours; ►**Table 2**) and total morphine consumed at 24 hour was significantly higher in group C (3.36 ± 1.04 mg vs. 7.84 ± 1.43 mg; $p < 0.001$; ►**Fig. 5**).

Mean intraoperative total fentanyl consumption among the patients of group T and group C was 122.4 ± 16.4 and 140.4 ± 21.7 μg, respectively; $p = 0.001$; ►**Table 2**).

After 24 hours, 44% of the patients in group T were highly satisfied, while 36% patients were satisfied, and 8% were unsatisfied. In group C, 16% of the patients were highly satisfied, while 40% of the patients were satisfied. Sixteen percent of the patients were unsatisfied while 4% of the patients were very unsatisfied with the analgesia.

PONV was lower in the patients in group T (12 vs. 20%). The mean value of the PONV scale was comparable among the two groups (0.88 ± 2.06 and 1.2 ± 2.9; $p = 0.68$). Respiratory depression (respiratory rate <8/min or SpO2 <90%) was

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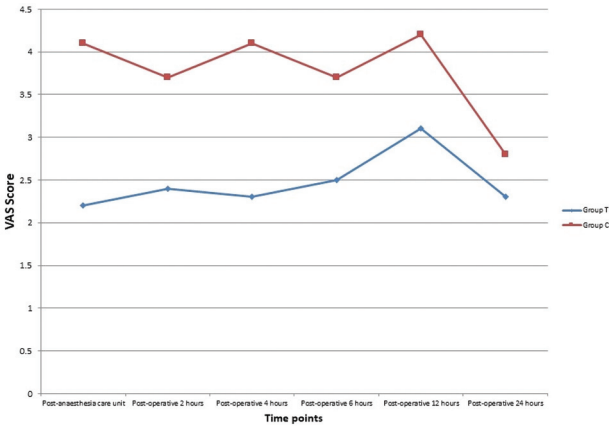

Fig. 3 Comparison of visual analog scale (VAS) scores in the two groups.

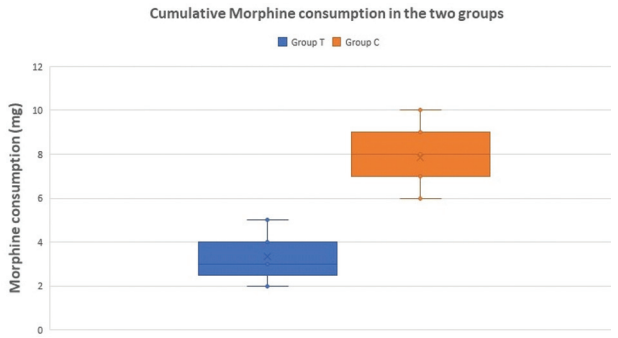

Fig. 5 Box-and-whisker plots illustrating 24 hours of morphine consumption (in mg) with group T and group C. The inner horizontal line within the box represents the median, and the outer horizontal lines of the box represent the 25th and 75th quartiles. The horizontal lines of the whiskers represent the 95% confidence intervals.

seen in 4% of patients in group C and none in group T. It was managed by assisted respiration using bag-mask ventilation and a single bolus dose of naloxone 0.4 mg.

The mean value of the RASS among the patients of the group T and group C were 0.08 ± 0.57 and -1 ± 0.82, respectively ($p < 0.0001$).

Discussion

The results of this study revealed that the patients receiving TLIP block had significantly higher analgesic duration, lesser mean VAS scores, consumed lesser opioids in the perioperative period, and had higher satisfaction levels after lumbar spine surgeries as compared with the control group.

Spine surgeries are known to be traumatic in nature and patients undergoing spine surgeries are known to endure severe and diffuse perioperative pain. In a review analyzing 179 surgical procedures, spine surgeries were rated among the top six procedures causing maximum postsurgical pain.[1] Inadequate postoperative pain relief worsens patient satisfaction, undermines rehabilitation, prolongs hospital stay, and increases the possibility of chronic postsurgical pain. One of the main goals of the ERAS program is to use perioperative opioid-sparing regimes and reduce postoperative pain.[2] Enumerable nonopioid pharmacological pain management options like gabapentinoids, nonsteroidal anti-inflammatory drugs, and ketamine are available for multimodal analgesia in spine surgery, but regional analgesia is undoubtedly the cornerstone of opioid-sparing analgesia.[3] Interfascial plane blocks are gaining popularity as they provide prolonged analgesia, reduce opioid consumption, and decrease the associated motor blockade. ESPB has been utilized for analgesia following lumbar spine surgery, but the evidence is insufficient to support its widespread use for this

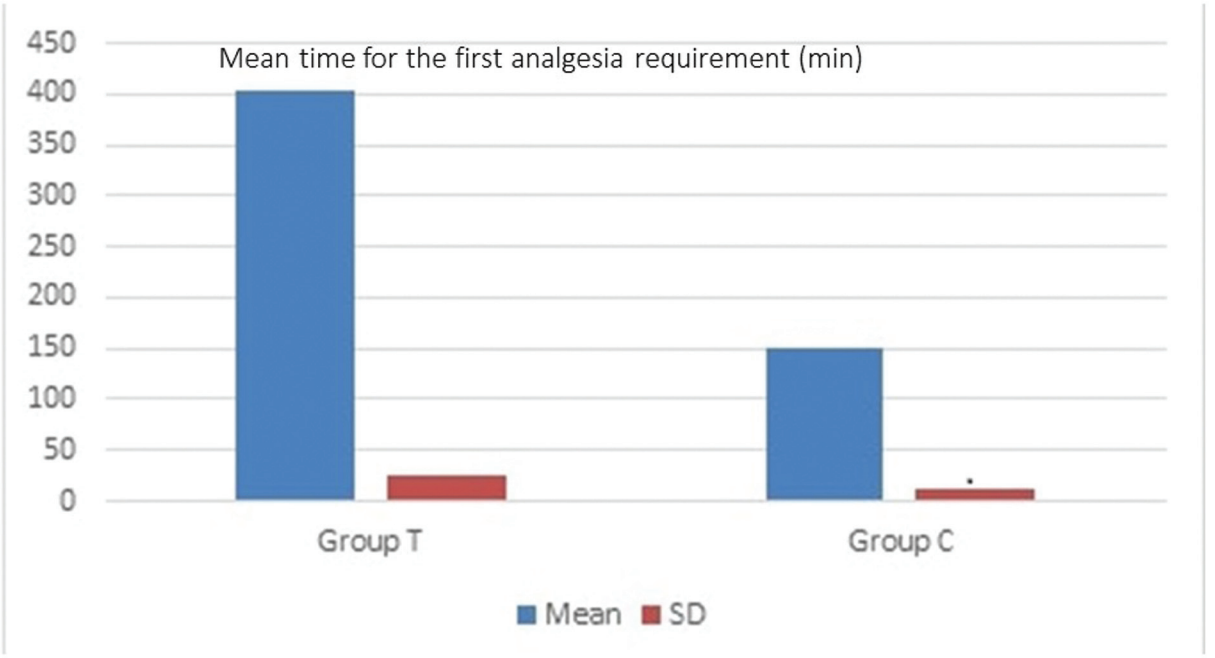

Fig. 4 Comparison of time to first analgesic requirement. SD, standard deviation.

purpose.[13] Moreover, ESP being a deep block is technically demanding and may lead to complications.

TLIP block is a new interfascial plane block that targets the dorsal rami of lumbar spinal nerves.[6] It has been reported to effectively prevent the occurrence of severe pain and reduce opioid consumption in those with lumbosacral spine surgery.[7–9] Recently, some studies have reported favorable findings with TLIP in comparison to conventional management or other regional blocks (ESPB) in spine surgery.[7,14] However, the role of TLIP block has still not been firmly established as a regional analgesia modality in spine surgery.

In this study, the mean time to first rescue analgesia was significantly higher among the patients of group T and is similar to the results of Ammar and Taeimah.[9] Furthermore, this study revealed that the mean VAS scores were significantly higher in group C at various postoperative time points. Ozmen et al similarly reported lower mean pain scores with a superior quality of recovery in the TLIP group.[14] Similar to our study, a previous study had also reported significantly higher VAS scores in the standard care group compared with the TLIP group.[8]

In our study, the patients who received TLIP block consumed a significantly lower quantity of morphine at different time intervals of comparison along with reduced total morphine consumption at 24 hours. Our results were in concordance with those of other previous authors[7,8,15,16] who had also reported a similar decrease in morphine consumption. Ozmen et al[14] similarly reported a significantly higher mean dose of rescue fentanyl consumed in their control group (total fentanyl dose; 446 vs. 742.5 µg).

The results of our study revealed that a significantly greater number of patients were highly satisfied in group T in comparison to the control group. Furthermore, none of the group T patients were "very unsatisfied" with the postoperative analgesia as compared with 4% of the patients in group C. Our results were in concordance with those obtained by Ozmen et al.[14] In their study, complete patient satisfaction was seen in 70% of the control group patients and 90% of those in the TLIP group (p-value < 0.05). This was probably due to excellent pain relief provided by the regional analgesia that maintained lower VAS scores resulting in lower morphine consumption and more alert patients who could participate more in their postoperative care and thereby had a better overall experience.

We found that PONV and sedation were seen in a higher proportion of patients in group C and respiratory depression was seen only in group C. The higher average morphine consumption presumably led to increased PONV, sedation, and respiratory depression in the control group. Our results were similar to the results obtained by Ozmen et al and Chen et al who had also reported similar findings in their study.[8,14]

The findings of this study are clinically important as multimodal analgesia inclusive of regional technique was found to provide multiple benefits to patient outcomes. The postoperative pain following spine surgery is usually severe and difficult to control. An uncontrolled acute postoperative pain could lead to chronic persistent pain and affect the quality of life.[17,18] In addition in the absence of regional blocks, higher consumption of opioids may lead to adverse effects. TLIP block attenuates the acute pain after surgery, reduces opioid consumption, and may reduce chronic persistent pain.[14] We need further studies with longer follow-up periods to ascertain the perceived long-term benefits of TLIP.

Further studies are needed to define the optimal dose (volume and concentration) of local anesthetic for optimal analgesia with TLIP blocks.

Limitations

Our study has certain limitations. It was a single center and further large multicentric trials would be desirable to firmly establish the routine use of TLIP block. The group standardization regarding single or two-level transforaminal lumbar interbody fusion (TLIF) could not be done. However, most surgeries were single-level TLIFs (►**Table 1**) and the numbers were comparable, so it should not affect the results. Furthermore, only patient blinding was done and assessor blinding could not be done as the block was administered only in group T and a sham block was not administered to the control group. In addition, the outcome assessment was limited to 24-hour after surgery.

Conclusion

Patients receiving TLIP block had lesser mean VAS scores, lower morphine consumption, prolonged time to rescue analgesic requirement, and higher patient satisfaction as compared with the standard opioid analgesia-based regime. Hence, TLIP block is a safe, and effective regional technique that could be used as a part of the anesthetic regimen in patients undergoing lumbar spine surgeries.

Conflict of Interest
None declared.

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