Original Article

Comparison of thoracolumbar interfascial plane block with local anaesthetic infiltration in lumbar spine surgeries – A prospective double-blinded randomised controlled trial

Address for correspondence:
Dr. Priyanka Pavithran, Department of Anaesthesiology, Aster MIMS, Govindapuram, Calicut - 673 010, India.
E-mail: priyanka.pavithran@gmail.com

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Priyanka Pavithran, Pramod K. Sudarshan[1], Salin Eliyas[2], Biju Sekhar, Kishore Kaniachallil

Departments of Anaesthesiology and [1]Spine Surgery, ASTER MIMS, Calicut, Kerala, [2]Department of Health and Family Welfare, District Medical Office, Palakkad, Kerala, India

ABSTRACT

Background and Aims: Posterior lumbar spine fusion surgeries are associated with severe postoperative pain necessitating a multimodal analgesic regime. Wound infiltration with local anaesthetic is an accepted modality for postoperative analgesia in spine surgeries. Thoracolumbar interfascial plane (TLIP) block is a novel technique being evaluated for providing analgesia in lumbar spine surgeries. This study aimed to compare the analgesic efficacy of TLIP block compared to that of wound infiltration with local anaesthetic in terms of time to request the first dose of rescue analgesic. **Methods:** Seventy-one patients scheduled for posterior lumbar spine fusion under general anaesthesia were included in this double-blinded randomised controlled trial. Preoperatively, patients were randomly allocated to receive either a TLIP block (TLIP group) or wound infiltration (LI group). The primary endpoint was the time of the first request for rescue analgesia. Secondary endpoints were the total tramadol consumption and pain and comfort scores measured at various time points in the 48-h postoperative period. The trial was terminated after second interim analysis as the analgesic benefit of TLIP was evident both clinically and statistically. **Results:** The median (interquartile range) duration of the time of the first request for rescue analgesia was 1440 (1290, 2280) min in the TLIP group and 340 (180, 360) min in the infiltration group; *P* value <.001. The mean tramadol consumption was significantly higher in the infiltration group compared to the TLIP group, with a *P* value <.001. **Conclusion:** TLIP block provided better postoperative analgesia than that provided by wound infiltration with local anaesthetic.

Key words: Fascial plane, local anaesthetics, paraspinal muscles

INTRODUCTION

Spine surgeries are associated with severe postoperative pain due to the extensive dissection and muscle retraction performed in these surgeries. Postoperative analgesia is an essential aspect of the perioperative care of these patients.[1] Adequate postoperative analgesia enables early mobilisation leading to reduced length of stay and is an essential component of the enhanced recovery pathways.[2]

The pain can arise from vertebrae, ligaments, dura, fascia and muscles. The posterior rami of the spinal nerve innervate these structures. The thoracolumbar interfascial plane (TLIP) block targets these posterior rami passing through the paraspinal muscles. Several studies have explored the analgesic efficacy of TLIP block in posterior lumbar spine surgery.[3,4] Wound

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infiltration is also a popular modality for postoperative analgesia in spine surgery. Several cocktails with various adjuvants have been explored for administration in wound infiltration in spine surgeries.[5,6] Very few studies have compared the postoperative analgesic efficacy of TLIP block with that of wound infiltration with a local anaesthetic mixture. We hypothesised that TLIP block provided better analgesia than wound infiltration in posterior lumbar spine fusion surgeries. Our primary objective was to compare the time of the first request for rescue analgesia in the TLIP group with the infiltration group. The secondary objectives were to compare the total tramadol consumption in the 48-hours postoperative period and compare the pain and comfort scores on arrival to the post-anaesthesia care unit (PACU), followed by 6, 12, 24 and 48 hours postoperatively.

METHODS

This study was conducted following the Declaration of Helsinki and reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement. We obtained Institutional Review Board (IRB) approval (IRB approval no: EC/42/2020). The trial was registered in Clinical Trials Registry, India (CTRI/2021/02/031406). Patient enrolment started on 3rd March 2021 and continued till 29th October 2021.

All patients between 20 and 70 years, belonging to the American Society of Anesthesiologists classes I–II, scheduled to undergo posterior lumbar spine fusion surgeries of up to three levels were included. Exclusion criteria were patients with allergy to local anaesthetic, patients undergoing revision surgery, patients having surgeries for infectious or malignant aetiology and patients with coagulopathy.

We obtained informed consent from all patients. Eligible patients were recruited consecutively and were randomised using a computer-generated random sequence in varying block sizes of 2, 4 and 6. The random allocation sequence was generated by the support staff of the institute who was not part of the study. The allocation sequence was used to make sequentially numbered opaque sealed envelopes (SNOSE). On inclusion of a patient, the principal investigator would open one envelope and allocate the patient to either of the arms; either to receive the TLIP block (TLIP group) or the wound infiltration with local anaesthetic (LI group). Patients and the research assistant who did the postoperative assessment were blinded to the treatment allocation.

Under standard monitoring, general anaesthesia was induced with fentanyl 2 μg/kg and propofol 2–3 mg/kg. Patients were intubated with atracurium 0.5 mg/kg with a flexo-metallic armoured endotracheal tube and positioned prone. A local anaesthetic mixture consisting of 40 ml of 0.375% ropivacaine, 10 ml of 2% lignocaine with 1:200,000 adrenaline and 4 mg dexamethasone was prepared. Patients in the TLIP group received ultrasound-guided bilateral TLIP block, which was performed by an anaesthesiologist experienced in this block. The procedure was done under sterile precautions. A high-frequency linear ultrasound probe was used for the block. The probe was placed transversely in the midline position at the level of the L_3 vertebra. The spinous process was identified. The probe was then moved laterally to identify the paraspinal muscles. A 22-G, 5-cm nerve stimulator needle was introduced from lateral to medial direction in an in-plane technique targeting the fascial plane between the multifidus and longissimus muscles. Hydrodissection using 1 ml of normal saline was used to identify the correct plane, following which 25 ml of the prepared drug was deposited, and the block was repeated on the opposite side. Patients in Group LI received an infiltration at the surgical site with the same local anaesthetic mixture. The infiltration was performed by the surgeon and all surgeries were done by the same surgeon. Both the block and the infiltration were given before the skin incision. Intraoperatively analgesia was supplemented with morphine 0.1 mg/kg and paracetamol 1 gm, which was given 5 min before the incision was placed. The heart rate and non-invasive blood pressure were noted every 10 min for half an hour after the intervention was completed, at the time of incision, and every half hour till the end of surgery. At the end of surgery, patients were extubated and shifted to the PACU and monitored for 48 h. The postoperative analgesia was managed with intravenous paracetamol 1 gm given every eighth hour. The postoperative assessment was done by the research assistant, who was blinded to the treatment allocation.

The primary outcome was the time of the first request for rescue analgesia. The secondary outcomes were the total tramadol consumption in the 48 h postoperative period and the measures of postoperative pain and comfort. Postoperative pain was assessed using the visual analogue scale (VAS) on a scale from 0 (no pain)

to 10 (worst possible pain). Postoperative comfort was evaluated using the Bruggemann Comfort Scale (BCS). BCS is scored as 0 – persistent pain, 1 – painless in resting state and severe pain either during deep breathing or coughing or both, 2 – painless in resting state and slight pain either during deep breathing or coughing or both, 3 – painless during deep breathing, and 4 – painless during coughing. Intravenous tramadol 50 mg given as rescue analgesia whenever a patient complained of pain and the VAS score was more than four. VAS and BCS scores were noted from the PACU, and then at 6, 12, 24 and 48 hours postoperatively. Occurrence of any intraoperative and postoperative complications and postoperative length of hospital stay were also noted.

Ammar *et al*.[7] compared the TLIP block combined with general anaesthesia to general anaesthesia alone; for time to first request for analgesia, a mean difference of 360.7 min was observed between the arms. The standard deviation of time to the first request for analgesia was 126.47 in the control arm. In our study, a similar increase in the pain-free interval by 5 h (300 min) was set as the margin to establish the superiority of TLIP over large volume infiltration. At an alpha error of 5% and power of 80%, the sample size was calculated as 54 in each arm using nMaster software version 2.0.

As per IRB recommendation, two interim analyses were done. We did the first interim analysis once one-third of the sample size was achieved. The second interim analysis was done once two-thirds of the sample size was achieved. In the first and the second interim analysis, we saw a significant difference in the proportion of patients requiring rescue analgesia. We considered the *P* value cut-off limits suggested by Pocock, Peto and O'Brien-Fleming methods before the decision to stop the trial based on results of interim analysis to avoid the increased chance of committing type 1 error.[8] Permission from IRB was obtained to terminate the trial after the second interim analysis and to publish the results of the same. So, the trial was terminated, and analysis conducted on the data collected from 71 patients is presented in the results.

Data were entered in Microsoft Excel Software and analysed using R software, version 4.0.1 (2020-06-06). In both groups, the continuous variables were summarised as mean and standard deviation or median with IQR depending on the distribution. Categorical independent variables were summarised as frequency and proportions. The continuous variables were compared between the groups using unpaired *t*-test or Mann–Whitney U test depending on distribution. The categorical variables were compared between the groups using Chi-square test or Fisher's exact test depending on the distribution. As the gender distribution was not similar between the groups at baseline, adjusted analysis using multivariate logistic regression and multivariate linear regression was conducted to find out adjusted effect estimate of the intervention on the need for rescue analgesia and total tramadol consumption. Survival analysis for time to rescue analgesia was done using Kaplan–Meier curves and log-rank test. Proportional Cox regression hazard ratio adjusted for gender was also calculated. A *P* value <.05 was considered to be statistically significant.

RESULTS

Eighty-eight patients were screened for eligibility, of which 72 patients were enroled in the study. In total, 72 patients received the randomised intervention. One patient in Group LI was excluded because spine instrumentation was not done due to an intraoperative change of plan. In the final analysis, 71 patients were included. The Consolidated Standards of Reporting Trials (CONSORT) flow diagram is shown in Figure 1.

The patient demographics and surgical characteristics are shown in Table 1. Patients in both groups were comparable except for the gender distribution. The time to first rescue analgesia was compared among those who needed rescue analgesia only. The median duration of time to first request for rescue analgesia in the TLIP group was 1440 min [interquartile range (IQR) 1290, 2280] and 340 min (IQR 180, 360) in the LI group with a *P* value <.001.

Table 1: Patient demographics and patient characteristics

Characteristic	LI group (*n*=35)	TLIP group (*n*=36)	*P**†
Mean age (SD) in years	51.2 (11.1)	53.2 (11.4)	0.45
Gender, *n* (%)			
Male	10 (28.6)	20 (55.6)	0.02
Female	25 (71.4)	16 (44.4)	
Mean weight (SD) in kg	70.4 (6.7)	71.6 (10.7)	0.59
Level of spine surgery, *n* (%)			
Above L_3	0 (0)	3 (8.3)	0.12
Below L_3	35 (100)	33 (95.7)	
Mean duration of surgery (SD) in minutes	147.6 (13)	152.1 (15)	0.18

**P*-value compares LI group with TLIP group. †Unpaired *t*-test to compare age, weight, duration of surgery. Chi-square test and Fisher's exact test done compare gender and level of spine surgeries, respectively. SD: Standard deviation

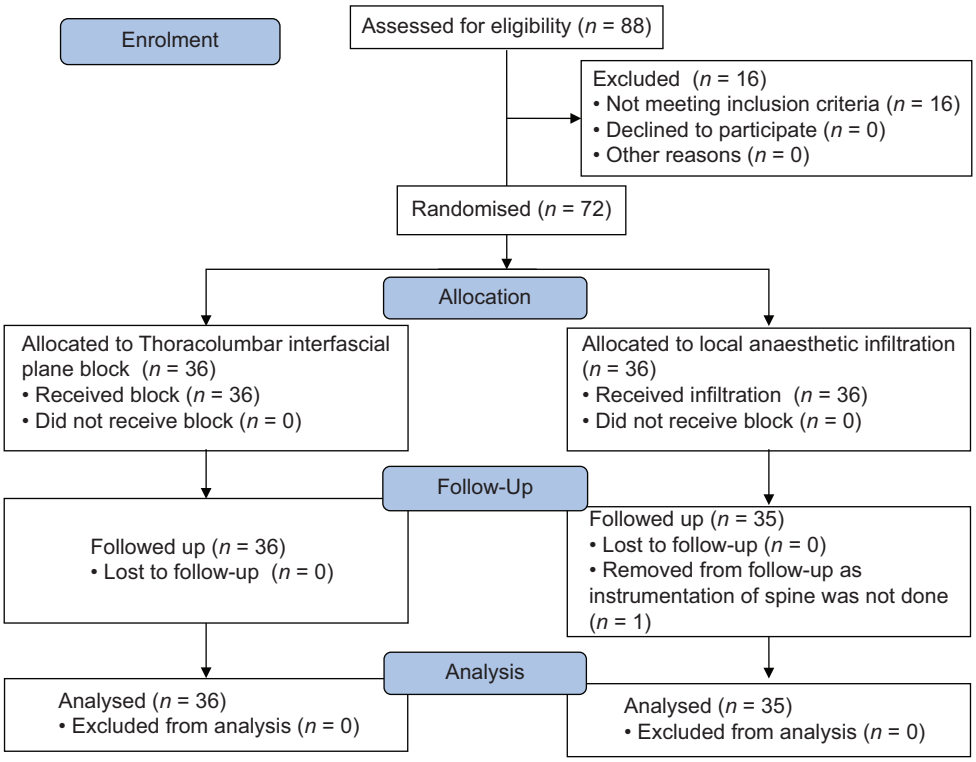

Figure 1: CONSORT (2010) diagram showing the flow of patients

The total tramadol dose was compared among those who needed rescue analgesia in both groups. The mean tramadol consumption was 220.3 ± 86.9 mg in the LI group and 100 ± 40.8 mg in the TLIP group (*P*-value <.001).

The proportion of patients who required rescue analgesia was significantly higher in the LI group compared to the TLIP group (91.4% vs. 27.8%, *P* value <.001). Table 2 shows the mean BCS scores at different observation points. The mean BCS scores were higher in the TLIP group at all time points with *P* values <.001. The median VAS scores were significantly higher in the LI group with *P* values <.001 at all time points [Table 3]. Haemodynamic profile remained stable intraoperatively and postoperatively and no other complications were noted.

Results of the multivariate logistic regression indicated that there was a significant association between intervention, gender and need of rescue analgesia (χ^2 (2) = 33.22, *P* <.001). The individual predictors were examined further and indicated that TLIP ($z = -4.5$, $P = <.001$) was a significant predictor and gender ($z = -0.5$, $P = 0.65$) was not a significant predictor in the model. After adjusting for gender, TLIP group had 96% less chance of needing a rescue analgesia compared to LI group.

Table 2: Mean (Standard deviation) Bruggemann Comfort Scale scores at different time points in both intervention arms

Time	LI group (*n*=35)	TLIP group (*n*=36)	*P*
PACU	3.1 (0.8)	4.0 (0.2)	<.001
6 h	2.6 (0.9)	3.9 (0.2)	<.001
12 h	2.4 (0.9)	3.9 (0.3)	<.001
24 h	2.0 (0.8)	3.7 (0.6)	<.001
48 h	2.0 (0.8)	3.2 (0.6)	<.001

PACU: Post-anaesthesia care unit; n: number

Table 3: Median (interquartile range) Visual Analogue Scale scores of pain at different time points in both intervention arms

Time	LI group (*n*=35)	TLIP group (*n*=36)	*P*
PACU	3 (3, 4)	0 (0, 1)	<.001
6 h	4 (4, 5)	0 (0, 2)	<.001
12 h	5 (4, 5)	2 (1, 3)	<.001
24 h	5 (5, 6)	3 (2, 4.5)	<.001
48 h	6 (4, 7)	4 (3, 5)	<.001

PACU: Post-anaesthesia care unit; n:number

Results of the multiple linear regression indicated that there was a significant collective effect between the gender, intervention type and total tramadol use (F (2, 39) = 8.6, P value <.001, R^2 =0.31). The individual predictors were examined further and indicated that TLIP ($t = -4.0$, P value <.001) was a significant predictor and gender ($t = -0.1$, P value =0.89) was not a significant predictor in the model. The TLIP

group needed a mean decreased total tramadol dose of 120 mg than the LI group adjusted with gender.

Kaplan–Meier curves for time and need for first rescue analgesia are shown in Figure 2. The log-rank test revealed significantly lower survival in infiltration group compared to TLIP group with *P* value <.001. Proportional Cox regression hazard ratio adjusted for gender was 0.1 [95% confidence interval: 0.05–0.2] in TLIP group compared to infiltration group [Figure 3].

DISCUSSION

Our trial demonstrates the superiority of the postoperative analgesia provided by the TLIP block compared to that of the wound infiltration with a local anaesthetic mixture. The patients who received TLIP block had a longer pain-free interval and longer time to request the first dose of rescue analgesia. The total dose of rescue analgesic consumed was also significantly lower among the patients in the TLIP group. Patient comfort and analgesia were also improved in participants who had received the TLIP block.

Postoperative analgesia in spine surgeries is very challenging. Regional anaesthetic techniques including epidurals, erector spinae plane (ESP) block, and local anaesthetic wound infiltration have found a place in the management of postoperative analgesia and are considered an important component of the enhanced recovery pathway in spine surgeries.[9,10]

The TLIP block was first described by Hand *et al.*,[11] in 2015, where he demonstrated this block to result in a reproducible area of anaesthesia in the lower back in a group of volunteers. In the classically described technique, the drug was deposited in the fascial plane between the multifidus and longissimus muscles. Ahiskalioglu *et al.*[12] described the modified TLIP (mTLIP) block where the drug is deposited in the fascial plane between longissimus and iliocostalis muscles.

Several trials have proven the perioperative analgesic efficacy of the TLIP and mTLIP blocks in various invasive and minimally invasive surgeries.[13,14] These blocks can help us in doing awake spine surgeries as well.[15] The TLIP block does not interfere with neurophysiological monitoring.[16] Ekinci *et al.*[17] compared wound infiltration with the mTLIP block in lumbar discectomy surgeries where they used 40 ml of 0.5% bupivacaine for the block and observed reduced postoperative opioid requirements in patients who received the block. The volume required for these blocks needs to be further studied.

Contradicting our study findings, Ince *et al.*[18] reported that TLIP block was not superior to wound infiltration in providing postoperative analgesia after single-level discectomies. This finding may have resulted due to the less-invasive nature of discectomies when compared to spine fusion surgeries. Other paraspinal blocks like the ESP have also been investigated for analgesia in spine surgeries.[19] The TLIP block targets the dorsal rami and provides more focused analgesia for spine surgeries. Similar paraspinal blocks have been investigated for utility in cervical spine surgeries.[20] The utility of dexamethasone as an adjunct in fascial plane blocks has already been proven.[21]

The competitive advantage of our study is that the novel technique was not compared to a placebo group; rather, infiltration with the same cocktail was used,

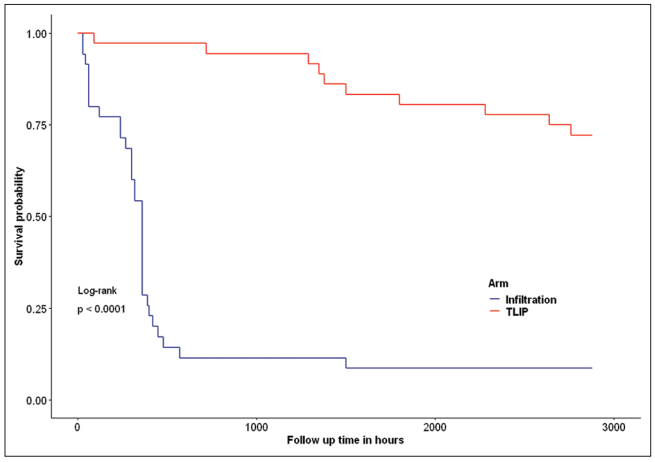

Figure 2: Kaplan–Meier survival curve of patients in each arm based on time of first rescue analgesia

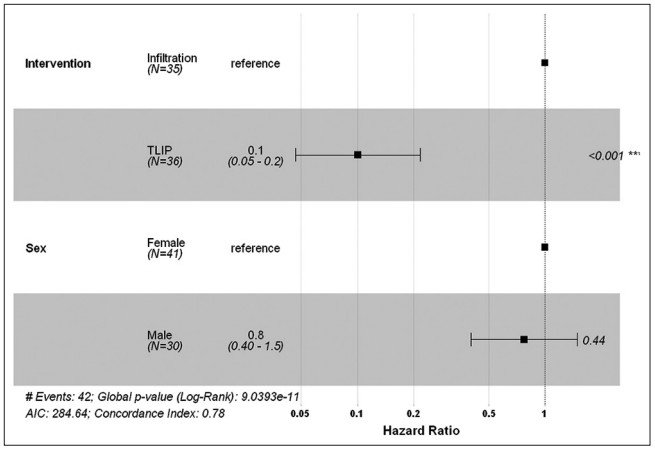

Figure 3: Forest plot of Cox proportional hazard ratio of rescue analgesia for TLIP group adjusted for gender

which would eliminate the influence of systemic effects of local anaesthetics. Our study has a few limitations. The gender distribution was not comparable between the two groups. It might have occurred as the study was terminated at the interim analysis. As the study was conducted during the COVID-19 pandemic, only essential surgeries were performed, which may have constrained the external validity of the results.

CONCLUSION

Our study demonstrated the postoperative analgesic of the TLIP block in posterior lumbar spine surgeries. The TLIP block resulted in a longer pain-free interval and improved pain and comfort scores of the patients. This block has been adopted as the new standard of care in the perioperative management of lumbar spine surgeries at our institution. Since the TLIP block does not interfere with the motor power, it can contribute to early ambulation and enhanced recovery. More research needs to be done on the exact volume and concentration of the local anaesthetic drug needed for the TLIP block. Further exploration of the analgesic efficacy and safety of the TLIP block should be done by comparing it with other paraspinal blocks.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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