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ORIGINAL RESEARCH

Effect of Ultrasound-Guided Thoracolumbar Interfascial Plane Block on the Analgesic Requirements in Patients Undergoing Lumbar Spine Surgery Under General Anesthesia: A Randomized Controlled Trial

Ezzat Eltaher
Nihal Nasr
Mohamed E Abuelnaga
Yassmin Elgawish

Department of Anesthesia, Intensive Care and Pain Management, Faculty of Medicine, Suez Canal University, Ismailia, Egypt

Background: Thoracolumbar interfascial plane (TLIP) block was recently described as a regional anesthetic technique to achieve analgesia for lumbar spine surgery by blocking the dorsal rami of spinal nerves. The study aims to test the hypothesis that TLIP block can offer pain control and reduce the perioperative analgesic requirement in patients undergoing spinal surgery.

Methods: There were 60 patients scheduled for lumbar spine surgery who were randomly assigned into two equal groups, TLIP and control groups. Patients in the TLIP group received general anesthesia and TLIP block while patients in the control group received general anesthesia alone. The primary outcome was the analgesic consumption in the first postoperative 24 hours, while intraoperative additional analgesic needs, time to the first request of postoperative analgesia, and pain scores were the secondary outcomes.

Results: At 24 hours postoperatively, morphine consumption was lower in the TLIP group (5.13±1.55) versus the control group (14.33±2.58) mg. The intraoperative fentanyl consumption was lower in the TLIP group (15±35.11 mcgs) versus the control group (105±62.08 mcgs). Postoperative first request for analgesia was delayed in the TLIP group (7.30±2.69 h) compared to the control group (0.92±1.23 h). Postoperative Pain scores at rest were 2.53 ± 0.97 and 3.43 ± 0.50 at 24 hours in the TLIP group and the control group, respectively. Postoperative Pain scores at passive flexion of spine were 2.73 ±0.87 and 3.93 ±0.78 at 24 hours in the TLIP group and the control group, respectively. Patients in the TLIP group had lower perioperative hemodynamic responses to surgical stimulation in comparison to the control group.

Conclusion: Combined TLIP block with general anesthesia in patients undergoing spinal surgery reduced both postoperative and intraoperative analgesic needs, reduced intraoperative hemodynamic response to surgery, and achieved good postoperative pain control.

Keywords: TLIP block, postoperative pain, spine surgery

Correspondence: Mohamed E Abuelnaga
Department of Anesthesia, Intensive Care and Pain Management, Faculty of Medicine, Suez Canal University, The Ring Road, P.O. Box 41522, Ismailia, Egypt
Tel +2001004150671
Fax +20643208543
Email Mohamed_abuelnga@med.suez.edu.eg

Plain Language Summary

What is already known about the topic: TLIP block is a recently described regional anesthetic technique used to provide perioperative analgesia for spinal surgery. Several studies have reported that it reduced both intraoperative and postoperative analgesic needs.

What new information this study adds: Our study investigated the perioperative analgesic effects of TLIP block for different types of spinal surgery. We used intraoperative

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neuromuscular monitoring (NMT) and bispectral index monitoring to rule out the effect of awareness or inadequate muscular relaxation on hemodynamic parameters and judgment of intraoperative analgesic needs. We continued to monitor postoperative hemodynamic parameters because we believe they are indicative of postoperative pain control.

What we found in our study: TLIP block achieved good postoperative pain control with reduced consumption of both intraoperative and postoperative analgesics. Intraoperative and postoperative hemodynamic parameters were significantly lower in patients who received TLIP block, denoting favorable perioperative pain relief.

Introduction

Spinal surgeries are usually associated with marked postoperative pain that classically takes 3 days to recede.[1] Adequate perioperative pain control is significant for patients to encourage early mobilization and reduce postoperative adverse events.[1] Discectomy, laminectomy, and spinal fixation are the most frequently performed spinal surgical procedures. Extensive dissection of tissues, ligaments, and bones is often performed during spinal surgeries, resulting in a significant degree of postoperative severe pain[2]. Adequate pain management in these patients is challenging because most of them have already received ordinary analgesics and/or opioids to ameliorate preexistent chronic back pain.[3] Pain following spine surgery can result from mechanical irritation, nerve compression, or postoperative inflammatory processes. It can be generated from different structures such as vertebrae, discs, ligaments, muscles, dural sleeves, and capsules of the facet joint. Innervation of these pain generators is from the dorsal rami of spinal nerves.[4] Opioids are commonly used as effective analgesics for the management of severe pain disorders. However, their widespread use is restricted because of their side effects such as nausea, vomiting, and respiratory distress, and acquired tolerance.[5] Preemptive multimodal analgesic regimens that rely on the synergistic action of nonopioid agents given in lower doses have been used to improve postoperative pain management and reduce opioid consumption.[6] Protocols for reducing pain after lumbar surgery recommend the use of regional anesthesia techniques to reduce opioid analgesic use to the minimum.[7] Interfascial plane blocks have the potential to provide extended postoperative analgesia and to reduce opioid consumption and neuraxial-related motor block to a minimum.[8] In the transversus abdominis plane (TAP) block, the ventral rami of the thoracolumbar nerves are targets for local anesthetic drugs to provide anesthesia to the anterior abdominal wall. Similar to the TAP block but targeting the back, the TLIP block was first described by Hand et al.[9] In the TLIP block, local anesthetic agents are injected into the fascial plane lying between the multifidus and longissimus muscles at the level of the third lumbar vertebra, targeting the posterior rami of the thoracolumbar spinal nerves, thus achieving a reproducible area of anesthesia with a predictable spread. However, few studies have reported that the TLIP block can be used during lumbar spine surgery to provide good perioperative analgesia.[10–12] None of the previous studies compared the effect of TLIP block analgesia on perioperative hemodynamics. We conducted this study to assess the analgesic effect of combined general anesthesia and ultrasound-guided TLIP block versus general anesthesia alone in patients undergoing lumbar spine surgery, aiming to improve the quality of anesthesia and to reduce perioperative analgesic requirements. The primary outcome was analgesic consumption in the first postoperative 24 hours, while intraoperative additional analgesic needs, time to the first request of postoperative analgesia, and pain scores were the secondary outcomes.

Materials and Methods

This study is a randomized controlled double-blinded clinical trial, conducted for patients undergoing elective spine surgery under general anesthesia. This manuscript follows the applicable CONSORT guidelines (www.consort-statement.org). The CONSORT 2010 checklist has been uploaded as a Supplementary File 1. This study was approved by the hospital Institutional Full Board committee (Research #3433) on 18 March 2018, and written informed consent was obtained from all subjects participating in the trial. Of note, the study was registered prior to enrollment of the first patient at the Pan African Clinical Trial Registry (www.pactr.org) database (PACTR201808145298962, registration 21 August. 2018). There were 60 patients randomly allocated by an assistant anesthesiologist using a computer software program (http://www.randomizer.org) into one of two equal-sized groups. Patients in the TLIP group received a TLIP regional block with general anesthesia and the control group patients received general anesthesia alone. The allocation arrangement was hidden in opaque numbered envelopes. The anesthesia provider and participant patients were blinded with respect to the study groups. Inclusion criteria included patients of both sexes, age more than 21 years, with BMI of 18–40 kg/m^2, ASA physical status I to III, scheduled for

elective spinal surgery under general anesthesia. Exclusion criteria included pregnant women, patients who had a psychiatric disease that would interfere with pain perception and assessment, neurological or neuromuscular disease or deficit, spine deformities, previous spine surgery, allergy to local anesthetics, and refusal to participate in the study.

Preoperative Management

A preoperative patient visit was done for medical history taking, clinical examination, reassurance, and explanation of the method of anesthesia. The patient's back was examined to detect any spinal deformities and difficult regional blocks. Patients fasted for about 6 to 8 hours before surgery.

Intraoperative Management

Monitoring equipment (CARESCAPE B650^{TM} Monitor) was attached to the patients and included pulse oximetry, noninvasive blood pressure monitoring, five-lead electrocardiogram, and nasopharyngeal temperature probe. The bispectral index (BIS^{TM} Covidien) was used for monitoring the depth of anesthesia. Patients in both groups received general anesthesia after pre-oxygenation with 100% O_2 for 5 min. Induction of anesthesia was done with IV fentanyl 2 μg/kg, propofol 2 mg/kg, and atracurium 0.5 mg/kg. After oral endotracheal intubation maintenance of anesthesia was achieved with isoflurane and varying its end-tidal concentration to keep BIS in the range of 40–60 with 2 liters of 50% O_2 in air, and atracurium 0.1 mg/kg guided with the train of four neuromuscular monitoring. Inadequate analgesia in the form of increased blood pressure (BP) or heart rate (HR) of 20% from the baseline was managed by an IV 0.5 μg/kg fentanyl bolus. At the end of surgery, reversal of muscle relaxation was carried out in all patients by neostigmine 0.04 mg/kg and atropine 0.01 mg/kg. All patients received 4 mg of ondansetron and 1 g of paracetamol IV 30 min before the end of surgery. After recovery from anesthesia, patients received 1 g of paracetamol IV every 8 h for 48 h, and standardized IV patient-controlled analgesia (PCA) with morphine (0.5 mg/mL morphine concentration, no background infusion, 2-mg bolus, lock-out time 10 min, and 4 h limit of 20 mg) throughout the first 24 postoperative hours.

TLIP Block Technique

Patients were placed in a prone position; ultrasound-guided TLIP block was performed using a SonoSite M-TURBO^{TM} 2–5 MHZ Curved array (C60X) transducer. The transducer was positioned in a transverse midline position at the level of the L3 vertebra. After the identification of the spinous process and interspinous muscles, the probe was moved laterally to identify the multifidus (MF) and longissimus (LG) muscles (Figure 1). After identifying the muscles and decontamination of the skin, the TLIP block was performed under real-time ultrasound guidance using an insulated 90-mm 22G echogenic needle which was inserted in-plane lateral to the medial direction through the belly of the LG toward the MF muscle. After negative aspiration, 20-mL 0.25% bupivacaine was injected in each side bilaterally in the interface between the MF and LG muscles. The same was done for patients in the control group but with injection of 20 mL 0.9% saline on each side. The locally injected solution was prepared by an assistant anesthesiologist.

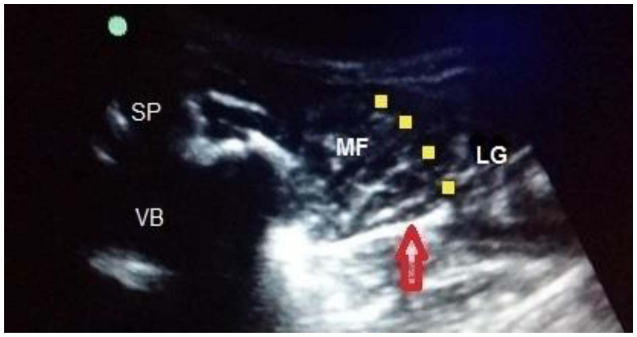

Figure 1. Sonoanatomy of paraspinal muscles (**SP**:spinous process,**VB**:Vertebral body,**MF**:Multifidus muscle,**LG**:Longissimus muscle).The red arrow shows the transverse process.The interface between MF and LG muscles is marked with yellow dots.The green colored circle :Ultrasound orientation marker showing the medial side.

Measurements

All outcomes were recorded by the anesthetist who was blinded to the allocated group. Intraoperative extra doses of fentanyl, the first postoperative request for analgesia, and total analgesic consumption during the first postoperative 24 h were recorded. Postoperative pain assessment was done at 2, 4, 6, 12, and 24 h at rest and during passive flexion of the spine using the Numerical Rating Scale score (NPR). HR and BP were recorded and analyzed at different time points: Preoperative (baseline), 10 min after the regional block, with the surgical incision, every 15 minutes until the end of the surgery, after recovery from anesthesia, and postoperatively after 1, 2, 4, 6, 12, and 24 h.

Statistical Analysis

The statistical analysis was performed using IBM SPSS Statistics® 22 for the Windows 10 operating system. The Shapiro–Wilk test and visual inspection of histograms were used for assessment of normality. For demographic and baseline comparison, the standardized difference was calculated using a web-based effect-size calculator.[13] The continuous variables (postoperative morphine consumption, hemodynamics, extra fentanyl dose) between the two studied groups were analyzed using the two-tailed *t*-test, while the categorical and dichotomous variables (number of patients requiring fentanyl use) were analyzed using the chi-square test. The time to postoperative first request for analgesia was analyzed using the Kaplan–Meier survival analysis and log-rank statistics with the evaluation of the hazard ratio by the Cox proportional hazards model. The repeated measurements of postoperative pain score at rest and passive flexion of the spine were analyzed using a linear mixed-effect model to evaluate the relationship between the NPR score over time and the intervention technique. This model included the interaction between time and treatment as fixed effects and patient indicators as a random effect. Values were expressed as mean±standard deviation (continuous variables) or as a percentage of the group from which they were derived (categorical variables). Data with variables completed were analyzed in the study. A P-value <0.05 was considered significant. Depending on our preliminary study results, a sample size of 27 patients per group was required to detect 4.52-mg differences between the means of morphine consumption during the first postoperative 24 h between the TLIP block group and the control group with a standard deviation of 5.12 mg and with 90% desired statistical power and a 5% level of significance. Considering a 10% dropout rate, the sample size required was 60 patients (30 patients per group).

Results

There were 60 patients randomly assigned into two equal groups, the TLIP group and the control group (Figure 2).

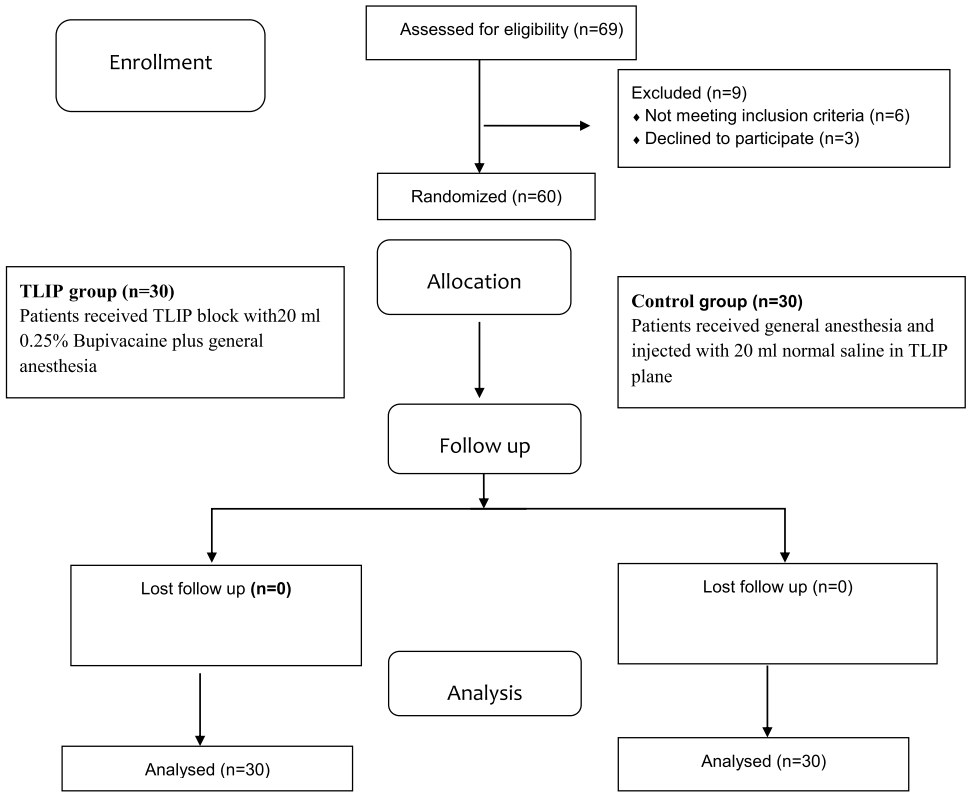

Figure 2 Flowchart of patient's participation progress throughout the study.

Table 1 Intraoperative Extra Fentanyl Consumption and Total PCA Morphine Consumption in Both Study Groups During the First 24 Postoperative Hours

	Intraoperative Excess Analgesic Consumption					
	TLIP group (n = 30)	**Control group (n = 30)**	**RR**	**d**	**95% CI**	**p-value**
Patients requiring additional fentanyl use N (%)	6 (20%)	25 (83.3%)	0.24		0.1153, 0.4997	0.0001*
Extra fentanyl dose (mcgs) mean (SD)	15 (35.11)	105 (62.08)		−1.7846	−2.383, −1.1862	0.0001*
Postoperative Analgesic Consumption						
	TLIP group (n = 30)	**Control group (n = 30)**	**RR**	**d**	**95% CI**	**p-value**
PCA IV morphine consumption (mg/24 hours) mean (SD)	5.13 (1.55)	14.33 (2.58)		−4.3228	−5.2471, −3.3985	0.0001*

Note: *Statistically significant difference (P < 0.05).
Abbreviations: d, standardized mean-difference effect size; RR, relative risk; NS, statistically non-significant difference (P > 0.05); TLIP, thoracolumbar interfacial plane block; PCA, patient-controlled analgesia.

Both groups were matched regarding demographic data; age (d: 0.1963, 95% CI: −0.311 to 0.7035, P: 0.451), sex (d: 0.0684, 95% CI: −0.4378 to 0.5746, P: 0.795), body mass index (d: −0.2826, 95% CI: −0.7911 to 0.226, P: 0.276). Surgeries performed in the TLIP group and control group, respectively, were discectomy 53.3% and 50%, laminectomy 30% and 36.7%, and spinal fixation 16.7% and 13.3% of patients with (d: 0.0014, 95% CI: −0.5047 to 0.5074, P: 0.842) and duration of surgery, Mean±SD: (123.63±54.07) and (127.63±35.78) minutes in TLIP and control group, respectively (d: −0.0872, 95% CI: −0.5935–0.4191, P: 0.737).

The total PCA morphine consumption in the first 24 postoperative hours was statistically significantly lower in the TLIP group (5.13 ±1.55) mg compared to 14.33 ±2.58 mg in the control group (d: −4.3228, 95% CI: −5.2471 to −3.3985, p: 0.0001) (Table 1).

Extra doses of fentanyl were given to six patients in the TLIP group and 25 patients in the control group, which was statistically significant (RR: 0.24%, CI: 0.1153–0.4997, P: 0.0001). Intraoperative consumption of fentanyl was significantly less in the TLIP group (15 ±35.11 mcgs) versus the control group (105±62.08 mcgs) (d: −1.7846, 95% CI: −2.383 to −1.1862, p: 0.0001) (Table 1).

Figure 3 shows the Kaplan–Meier survival curve for the time to the postoperative first request of analgesia. It was significantly delayed in the TLIP group (mean±SD, 7.30±2.69 h) compared to the control group (mean±SD, 0.92±1.23 h), P = 0.0001). The hazard ratio of requesting the first dose of postoperative analgesia in the control group patients was 18.152-times greater than in TLIP patients in a Cox proportional hazards model (hazard ratio, 18.152 [95% CI, 6.753–48.795]; P = 0.0001)

The linear mixed-effect model analysis of the NPR score showed that the interaction of intervention and time was significant (P < 0.05). The NPR at rest and passive flexion of the spine was statistically significantly lower in the TLIP group compared to the control group at all-time points during the first 24 postoperative hours (P < 0.05). Postoperative pain scores at rest were 2.47 ±1.17, 2.53 ±1.14, 2.93 ±1.08, 2.53 ±0.97 and 2.53 ± 0.97 at 2, 4, 6, 12, and 24 hours, respectively, in the TLIP group, while in the control group were 4.27 ± 0.94, 4.23 ± 0.68, 4.10 ± 0.66, 3.97 ± 0.72 and 3.43 ± 0.50 at 2, 4, 6, 12, and 24 hours, respectively. Postoperative Pain scores at passive flexion of the spine were 3.40 ±1.22, 3.67 ±1.09, 3.87 ±1.04, 3.20 ±0.96 and 2.73 ±0.87 at 2, 4, 6, 12 and 24 hours, respectively, in the TLIP group, while in the control group were 5.57 ±1.01, 5.50 ±0.94, 4.70 ±0.79, 4.40 ±0.50 and 3.93 ±0.78 at 2, 4, 6, 12 and 24 hours, respectively (Table 2).

There was a statistically significant difference between the two groups in the study regarding intraoperative hemodynamic changes at most time points during surgery (P < 0.05). Patients in the TLIP group had lower hemodynamic responses to surgical stimulation in comparison to the control group (Supplementary Figure 1. Intraoperative hemodynamic parameters in both groups of the study at different time points during surgery).

Postoperative hemodynamic parameters (HR and BP) were statistically significantly lower in the TLIP group compared to the control group at all-time points during the first 24 hours after surgery (P < 0.05) (Supplementary Figure 2. Postoperative hemodynamic

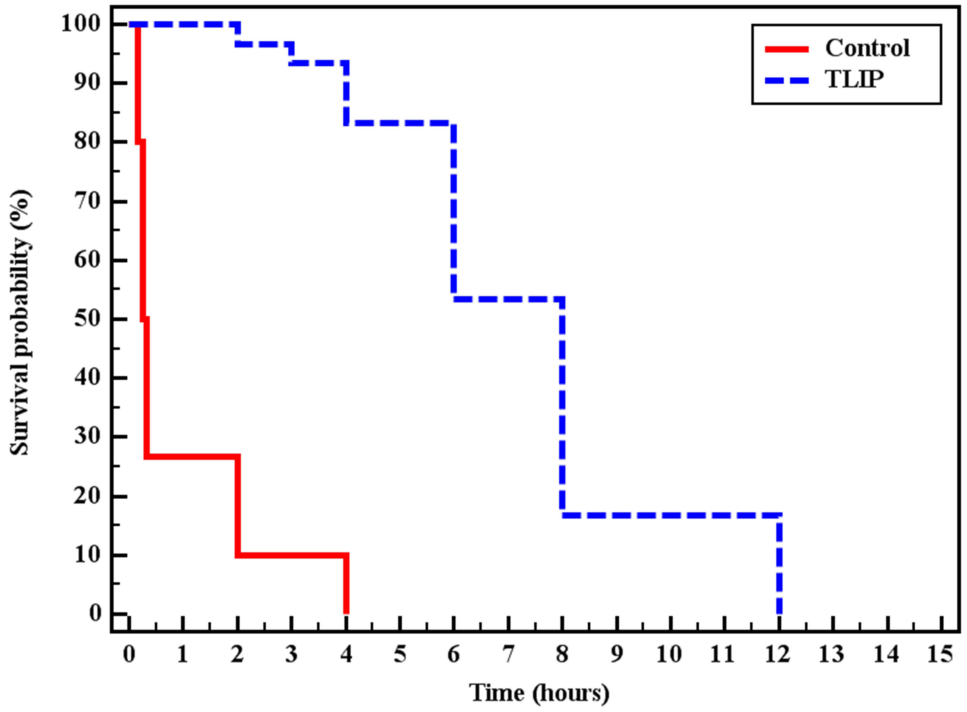

Figure 3 Kaplan-Meier survival curve for the time to the first postoperative request for analgesia (p< 0.001).

parameters in both groups of the study at different time points after surgery).

Discussion

Lumbar spine surgery usually causes marked postoperative pain. Adequate pain management accelerates patient mobility, improves satisfaction, and reduces postoperative complications.[14,15] In addition to systemic analgesics, neuro-axial regional anesthetic techniques such as subarachnoid, epidural, or paravertebral blocks can be used for postoperative pain management.[16] Ultrasound-guided TLIP block has been recently described in several studies for acute pain management after lumbar spinal surgery[17] as well as a possibility for management of chronic low back pain.[18,19] It is much safer and easily performed because it is administered more superficially.[20–22]

Table 2 Numerical Pain Rating (NPR) Score at Rest and During Passive Flexion of Spine in Both Groups of the Study During the First 24 Postoperative Hours

NPR Score at Rest		TLIP Group (n = 30)	Control Group (n = 30)	Estimated Mean Difference	95% CI	P-value
2 hours	Mean (SD)	2.47 (1.17)	4.27 (0.94)	−1.80	−2.34, −1.26	0.0001*
4 hours	Mean (SD)	2.53 (1.14)	4.23 (0.68)	−1.70	−2.18, −1.22	0.0001*
6 hours	Mean (SD)	2.93 (1.08)	4.10 (0.66)	−1.17	− 1.62, −0.71	0.0001*
12 hours	Mean (SD)	2.53 (0.97)	3.97 (0.72)	−1.43	− 1.87, −1.0	0.0001*
24 hours	Mean (SD)	2.53 (0.97)	3.43 (0.50)	−0.90	−1.29, −0.51	0.0001*
NPR score at passive flexion of spine		**TLIP group (n=30)**	**Control group (n=30)**	**Estimated mean difference**	**95% CI**	**P-value**
2 hours	Mean (SD)	3.40 (1.22)	5.57 (1.01)	−2.17	−2.73, −1.60	0.0001*
4 hours	Mean (SD)	3.67 (1.09)	5.50 (0.94)	−1.83	−2.35, −1.32	0.0001*
6 hours	Mean (SD)	3.87 (1.04)	4.70 (0.79)	−0.83	−1.30, −0.36	0.001*
12 hours	Mean (SD)	3.20 (0.96)	4.40 (0.50)	−1.20	−1.59, −0.81	0.0001*
24 hours	Mean (SD)	2.73 (0.87)	3.93 (0.78)	−1.20	−1.62, −0.78	0.0001*

Notes: *Statistically significant difference (P < 0.05); NS: Statistically non-significant difference (P > 0.05).
Abbreviations: CI, confidence interval; TLIP, thoracolumbar interfacial plane block.

The primary outcome in the current study was postoperative analgesic consumption in the first 24 h. It was found to be less in the TLIP group versus the control group.

This is consistent with Ueshima et al[23] who have studied the effect of TLIP on perioperative analgesic requirements for patients undergoing primary lumbar laminoplasty under general anesthesia (GA). They found reduced consumption of postoperative PCA fentanyl for the next 48 h following surgery in the TLIP group in comparison to the control group.

Similarly, Chen et al[24] found reduced consumption of postoperative PCA sufentanil for patients undergoing lumbar spine fusion surgery in the TLIP group versus the control group. Moreover, Ozmen et al[25] found less postoperative PCA fentanyl consumption for 24 hours following single-level lumbar disc surgery in patients who received a TLIP block versus GA alone. Ekinci et al[26] compared the analgesic effect of modified TLIP versus wound infiltration for patients undergoing endoscopic single-level lumbar discectomy and partial laminectomy. They found reduced postoperative opioid consumption in the modified TLIP group versus the wound infiltration group.

Ahiskalioglu et al[27] studied the analgesic effect of ultrasound-guided modified TLIP block for postoperative pain following spinal surgery and reported higher postoperative analgesic requirements in the control group versus the modified TLIP group, with a significant difference in the requests for supplementary analgesia that were more common in the control group compared to the modified TLIP group. In our study, intraoperative extra fentanyl consumption was found to be lower in the TLIP group versus the control group.

In contrast, Ueshima et al[28] studied the efficacy of the TLIP block for lumbar laminoplasty and reported that there was no significant difference between TLIP and GA groups in the intra-operative consumption of fentanyl. However, this study was not randomized because it was a retrospective study.

In the study done by Ke et al[24] of patients undergoing lumbar spine fusion surgery, intraoperative remifentanil consumption was found to be less in the TLIP group than in the control group.

No previous studies were found comparing the effect of TLIP block versus control on the intraoperative or postoperative hemodynamic parameters.

Several studies compared the effect of combined neuraxial anesthesia versus GA alone on intraoperative and postoperative hemodynamics in patients undergoing lumbar spine surgery. Similar to our study results, they reported that intraoperative and postoperative BP and HR were significantly higher in patients who received GA alone.[29,30]

Finally, we found significantly lower pain scores at rest and during passive flexion of the spine in the TLIP group compared to the control group at all-time points during the first 24 postoperative hours.

This is consistent with several studies that reported reduced postoperative pain scores in the groups that received TLIP or modified TLIP blocks for primary lumbar laminoplasty, lumbar spine fusion surgery, and single-level lumbar discectomy in comparison to control groups.[23,26]

In 2018, Ammar and Taeimah[31] compared combined TLIP block with GA versus GA alone for 70 patients scheduled for lumbar disc surgery. TLIP group patients were injected bilaterally with 20 mL of premixed 0.25% bupivacaine with 1% lidocaine under ultrasound guidance. Postoperative analgesia was 1 gm of IV paracetamol given every 6 hours together with IV morphine by PCA. The TLIP group showed a marked reduction of postoperative pain scores, and 24 hours postoperative morphine consumption was also significantly lower in the TLIP group than in the control group (9.7±6.38 vs 25.88±5.17 mg), together with a delayed first request for postoperative analgesia in the TLIP group versus the control group (442.7±126.47 vs 82.00±69.01 min). In comparing these results to ours, postoperative pain scores and the time to first analgesic request were comparable, but in our study, the postoperative morphine consumption was lower. This may be due to our protocol of giving intraoperative rescue analgesia as guided by hemodynamic changes.

The erector spinae plane block (ESPB) is a novel regional anesthetic technique described by Forero et al.[32] Unlike the TLIP block that targets the dorsal ramus of the spinal nerve, the ESPB targets both the ventral and dorsal rami of the spinal nerves, and it spreads over the paravertebral and epidural spaces.[33] Several studies have investigated the perioperative analgesic effect of ESPB for spinal surgery performed under GA and concluded that patients who received ESPB have lower postoperative pain scores and less postoperative opioid consumption in comparison to those who received GA alone.[34–37]

In a recent study done by Ciftci et al[38], 2020 90 patients undergoing lumbar discectomy surgery under general anesthesia were randomized to three groups, the ESPB

group, the modified TLIP block group, and the control group. Postoperative opioid consumption, postoperative passive and active pain scores, and the use of rescue analgesia were significantly lower in both the ESPB and modified TLIP groups compared to the control group. There was non-superiority between both regional techniques.

Conclusion

TLIP block can be considered a good adjuvant to GA for patients undergoing spinal surgery because it achieves adequate perioperative pain relief, reduction of perioperative analgesic consumption, and reduction of the hemodynamic response to surgical stress without causing undesirable complications.

Limitations of the Study

More large-sample and high-quality RCTs are needed in the future to demonstrate the efficacy and safety of the TLIP block compared to other regional blocks and to investigate the effect of different drug adjuvants for pain relief in patients undergoing spine surgery under GA. It would have been better to continue monitoring postoperative parameters for at least 48 h.

Abbreviations

TLIP, thoracolumbar interfacial plane; BIS, bispectral index; BP, blood pressure; HR, heart rate; PCA, patient-controlled analgesia; MF, multifidus; LG, longissimus; NPR, Numerical Rating Scale score; GA, general anesthesia; PACU, post-anesthesia care unit.

Data Sharing Statement

The individual blinded datasets that underlie the results reported during the current study will be made available. Other study documents that will be made available include the study protocol and informed consent form. Data will be accessible by directing requests to the corresponding author at Mohamed_abuelnga@med.suez.edu.eg Data will be obtainable beginning 3 months and ending 9 months after article publication.

Ethics and Consent

This study has been performed consistent with the principles of the Helsinki Declaration on Human Experimentation. This study was approved by Suez Canal University's Institutional Full Board Committee (Research #3433) on 18 March 2018 and written informed consent was obtained from all subjects participating in the trial. The study was registered before enrolment of the first patient at the Pan African Clinical Trial Registry (www.pactr.org) database (PACTR201808145298962, registered 21 August, 2018). This manuscript adheres to the applicable CONSORT guidelines.

Informed written consent was done for all patients participating in the study.

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Author Contributions

All authors made a significant contribution to the work reported, with regard to conception, study design, execution, acquisition of data, analysis and interpretation. All authors took part in drafting, critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflict of interest.

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