Original Article

Comparative evaluation of pre-emptive analgesic efficacy of Posterior Transversus Abdominis Plane block with Fascia Transversalis Plane Block in adult patients undergoing unilateral inguinal hernia repair: A prospective, randomized, single-blind, two-arm parallel study

ABSTRACT

Introduction: Abdominal wall blocks, in conjunction with multimodal analgesia, have demonstrated efficacy in providing post-operative analgesia, reducing opioid requirements in patients undergoing inguinal hernia repair. The inguinal region is primarily innervated by the ilioinguinal nerve (IIN) and iliohypogastric nerve (IIH). Posterior transverse abdominis plane block (pTAP) and fascia transversalis plane block (TFP) have been observed to reliably block IIN and IIH. We hypothesized that posterior TAP block (pTAP) owing to its potential paravertebral spread will provide better post-operative analgesia than TFP block in patients undergoing unilateral open inguinal hernia repair.

Methods: This prospective, randomized, single-blind, two-arm parallel study was conducted over a duration of one year for which sixty patients undergoing unilateral open inguinal hernia repair under spinal anesthesia were enrolled. They were equally and randomly assigned to receive either preoperative pTAP block or TFP block. The primary aim of the study was to compare median static and dynamic NRS scores during a 24-hour period, with the secondary aim to compare the number of patients who required rescue analgesics in each group.

Results: All enrolled patients completed the study. Results showed no statistically significant difference in median static NRS scores between Group pTAP and Group TFP at the designated time of observation during the 24-hour period [1.2 (0.4-1.60 vs. 1 (0.6-1)]. Group pTAP reported a higher median dynamic NRS scores during the 24-hour period [2.6 (1.2-3) v/s 2 (1.6-2.4); $P < 0.035$], although this difference was clinically insignificant. The mean time to request for the first rescue analgesia was comparable (11.7 h v/s 12 h; $P = 0.99$). In all the patients of both groups, loss of pinprick and cold touch sensation was observed at T10, T12, and L1 dermatomal levels. However, sensory assessment at T6 and T8 levels showed variability between the two groups ($P > 0.05$).

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Conclusion: In conjunction with background analgesia and the use of dexamethasone as an adjuvant, both blocks (pTAP and TFP) were observed to be equally effective for post-operative pain relief with similar patient satisfaction scores.

Key words: Adjuvant, analgesia, inguinal hernia

Introduction

Abdominal wall blocks, in conjunction with multimodal analgesia, have demonstrated efficacy in providing post-operative analgesia, reducing opioid requirements in patients undergoing inguinal hernia repair, cesarean section, and iliac crest bone grafting.

The inguinal region is primarily innervated by the ilioinguinal nerve (IIN) and iliohypogastric nerve (IIH).[1] These two nerves exit the lumbar plexus, leaving the psoas major laterally to travel along the anterior surface of the quadratus lumborum muscle before penetrating the transversus abdominis muscle to travel in the transversalis plane. The entire course of these two nerves offers different injection sites (abdominal wall blocks) for blocking IIN and IIH, including IIN-IIH nerve block, inter-fascial plane truncal blocks like transversus abdominal plane block (TAP), quadratus lumborum block (QL), and fascia transversalis plane block (TFP).[2]

Ultrasound-guided (USG) TAP block, in the last decade, has become an integral component of multimodal opioid-sparing analgesia. It has demonstrated efficacy in providing post-operative analgesia by blocking ilioinguinal nerve (L1), iliohypogastric nerve (L1), lower intercostal nerves (T7-T11), and subcostal nerve (T12) depending on the site of injection (subcostal, anterior, lateral, or posterior TAP).[3]

The TFP block, described first by Hebbard *et al.*,[4] targets the IIN and IIH nerves when they pass between the transversus abdominis muscle fascia (thoracolumbar fascia) and the fascia transversalis, a thin aponeurotic membrane comprising part of the general layer of fascia lining the abdominal cavity.

We hypothesized that posterior TAP block (pTAP) owing to its potential paravertebral spread would provide superior post-operative analgesia than TFP block in patients undergoing unilateral open inguinal herniorrhaphy.[5] The primary aim of the study was to compare median NRS score during the first 24 hours between the two groups, and the secondary aim was to assess and compare the number of patients requiring rescue analgesics in either group.

Material Method

This randomized controlled trial was approved by the Institutional Human Ethics Committee (vide approval number 2021-249-IP-123) and registered with the Clinical Trial Registry-India (CTRI/2022/01/039778, https://www.ctri.nic.in). This prospective, randomized, single-blind, two-arm parallel study was conducted over one year at a tertiary care health facility in patients undergoing unilateral open inguinal hernia repair under spinal anesthesia according to the principles laid down in the Declaration of Helsinki 2013.

The study includes 60 patients, aged between 18 and 65 years, with American Society of Anesthesiologists (ASA) physical status scores of I and II and body mass index between 18 and 35 kg/m^2.

Exclusion criteria included known allergies to local anesthetics, infection, or redness at the injection site, anatomical anomalies (scoliosis), spondylolisthesis, spondylolysis, or coagulation disorders, renal or liver diseases, or unwillingness to participate in the study.

A biostatistician performed randomization through a computer-generated block randomization procedure. Sealed envelopes bearing the randomization assignments were opened by a single investigator 30 minutes before the scheduled case. Subsequently, patients were allocated to their respective study groups based on the revealed assignments.

During preanesthetic evaluation, all the patients were explained about the numerical rating scale (NRS). Standard monitors (SpO2, ECG, and NIBP) were attached. Intravenous injection midazolam (0.02 mg/kg) was administered. Conforming to the group allocation under complete aseptic precautions, USG-guided pTAP block or TFP block was administered using an 80 mm 20 G Stimuplex® needle (B-BRAUN, Germany) and 25 ml of 0.25 percent bupivacaine with 4 mg dexamethasone as an adjuvant was injected. Blocks were placed in either supine or lateral position using a linear or curved array transducer (depending on the patient's body habitus).

For pTAP block, USG probe (Sonosite, Inc., Bothell, WA, USA) was placed transversely along the anterolateral abdominal

wall on one side at the level of the mid-axillary line, to facilitate an identification of the external oblique, internal oblique, and transversus abdominis muscles [Figure 1a] and then moved posteriorly to reach the most posterior extent of the TAP, situated between the internal oblique and transversus abdominis muscles. The target of the procedure was the rearmost part of the TAP. The needle was then inserted in the mid-axillary line and advanced posteriorly until it reached the intended posterior end of the TAP [Figure 1b].[6] Two ml of normal saline was injected into the plane for hydro-dissection. After confirmation, the drug was injected.

For TFP block, the USG probe was placed in a transverse orientation above the iliac crest, and the external oblique, internal oblique (IO), and transverse abdominis (TA) muscles were identified and traced posteriorly until reaching the point where first the TA muscle and then the IO muscle tapered into their common aponeurosis, adjacent to the quadratus lumborum muscle. The tip of a 20-gauge 80-mm needle was positioned just deep to the TA muscle and its aponeurosis at the point where the TA tapered off [Figure 1c]. Two ml of normal saline was injected into the plane for hydro-dissection. After confirmation, the drug was injected.

Twenty minutes after block placement, the sensory assessment was done including pinprick, cold touch, bilaterally along the midclavicular line at T6 (subcostal margin), T10 (umbilicus), at T12 and L1 (inguinal ligament). Any reduction of sensation (hypoesthesia) from the non-operative side was noted. The absence of hypoesthesia at T12-L1 was considered as indicative of block failure.

The time taken for block performance was recorded, beginning with needle insertion, and concluding with the completion of drug administration. Following this, patients

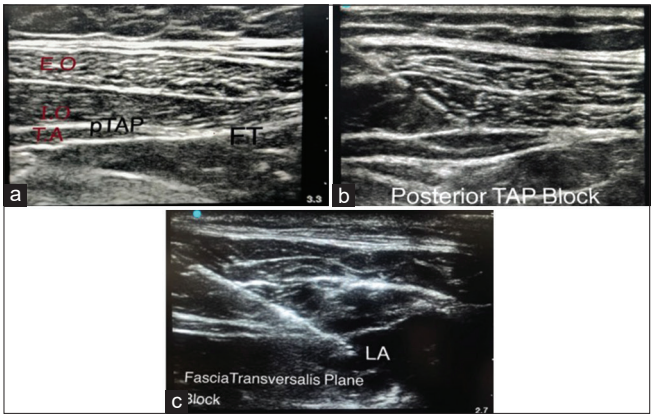

Figure 1: Ultrasound images showing Ia) the three abdominal muscles-External oblique (EO),Internal Oblique (IO), Transversus Abdominus (TA), Needle tip position and spread of local anaesthetic in Ib) Posterior TAP block (pTAP) ,1c) Fascia Transversalis Plane Block (TFP)

underwent spinal anesthesia in a seated position using a 25 G spinal needle, and 2.5 ml of 0.5% hyperbaric bupivacaine along with 15 mcg fentanyl.

Postoperatively, patients were assessed for static pain (pain at rest) and dynamic pain (pain on coughing) using an 11-point numeric rating scale with a score of zero as no pain and score of 10 as worst pain at definite time intervals (2 hrs., 6 hrs, 12 hrs, 18 hrs., and 24 hrs.). NRS score >4 was considered as the threshold for breakthrough pain.

The primary outcome of the study was the median NRS score over 24 hrs., while the secondary outcome focused on the number of patients requiring rescue analgesics during the same period. As part of multimodal analgesia, postoperatively, 1 gm of intravenous paracetamol was administered every 8 hours. Intravenous Fentanyl 25 mcg was provided as rescue analgesia for NRS>4.

The study also included the assessment of the extent of sensory blockade, incidences of breakthrough pain, patient satisfaction, the total amount of opioids used, and recording complications such as bradycardia, nausea, vomiting, and hematoma. All blocks were performed by the same anesthesiologist who had no further involvement in the case. Sensory assessment and case were conducted by different anesthesiologist. All post-operative assessment was done by a research coordinator blinded to group allocation.

Sample size

Based on previous studies (Luciano Frassanito *et al.* 2017),[6] patients in the TAP group reported significantly different pain scores (2.5 ± 1.8 vs. 5.2 ± 4.7, $P < 0.01$, Cohen d effect size of the mean difference = 0.7587) than comparative group at 24 hours assuming a similar difference in NRS scores in our study with equal to the effect size of 0.7587. At minimum two-sided 95% confidence interval and 80% power of the study, the estimated sample size in each group came out to be 29. Thus, in this study, we included 30 patients in each of the two groups. The sample size was estimated using the software G*power version 3.1.9.7.

Statistical analysis

Continuous variables followed non-normal distribution determined by the Kolmogorov–Smirnov test and presented in median (interquartile range, i.e., Q1, Q3) along with mean value within the bracket. Medians were compared between pTAP and TFP using Mann–Whitney U test. Categorical variables are presented in frequencies and percentages. Proportions were compared between two groups, using the Chi-squared test or Fisher's exact test, whichever was applicable. The error bar graph is used to present the data

in terms of their mean with a 95% confidence interval. The proportion between the two groups is presented using the bar diagram. A *p*-value <0.05 was considered statistically significant. Statistical analysis was performed using the software "Statistical Package for Social Sciences, version -23 (SPSS-23; IBM Corp, Armonk, NY, USA)."

Results

A total of 189 patients underwent eligibility assessment, with 123 not meeting the inclusion criteria, and 6 declining to participate. Ultimately, sixty patients were enrolled in the study, conducted over a period of one year. All enrolled patients were randomly allocated a treatment group as shown in Figure 2.

All patients included in the study were male. The demographic data including age, body mass index, and ASA status of patients in both groups were comparable as demonstrated in Table 1.

There was no statistically significant difference in median static NRS scores between Group pTAP and Group TFP at the specified observation times over the 24 hours [1.2 (0.4-1.60 v/s 1 (0.6-1) [Table 1, Figure 3].

Group pTAP reported a higher median dynamic NRS scores during 24-hour period [2.6 (1.2-3) v/s 2 (1.6-2.4); $P < 0.035$] although this difference was clinically insignificant [Table 1, Figure 3].

Group pTAP, in comparison with Group TFP, reported more incidence of breakthrough pain (12 v/s 2; $P = 0.005$). However, those patient in both groups reported only one such incidence during the 24-hour observation period [Table 2, Figure 4].

Mean 24-hour fentanyl consumption was significantly more in Group pTAP (20 mcg v/s 3.33 mcg; $P = 0.002$) [Table 2]. The mean time to request for first rescue analgesia was comparable (11.7 h v/s 12 h; $P = 0.99$) [Table 2, Figure 4]. Both groups showed similar patient satisfaction scores (4.7 ± 0.44 v/s 4.8 ± 0.34, $P > 0.203$) [Table 2].

The difference in block performance time was not statistically significant between the two groups (4.5 min v/s 2.5 mins; $P > 0.05$). No complications were reported in either group.

Loss of pinprick and cold touch sensation was observed in T10, T12, and L1 dermatome levels in all the patients of both

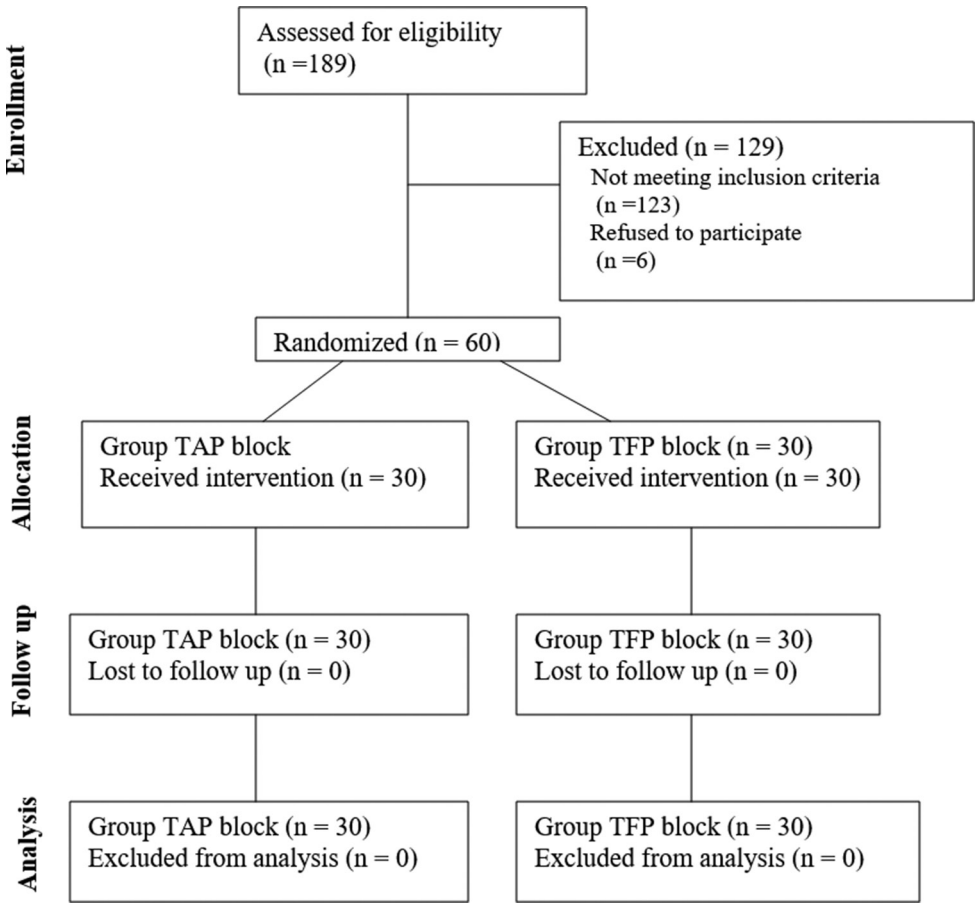

Figure 2: Consolidated Standards of Reporting Trials (CONSORT) flow diagram for patient recruitment

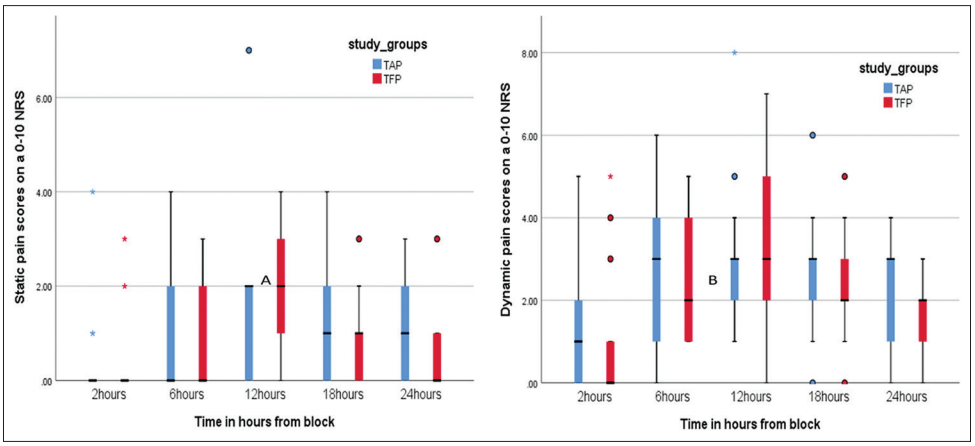

Figure 3: Box and Whisker Plot showing median (interquartile) static and dynamic pain scores on 0-10 numerical rating scale (NRS) in the two groups at different times until 24 hours, post administration of block

Table 1: Distribution of the NRS Pain score and other variables between two study groups (N=60)

Pain score	TAP (*n*=30)	FTP (*n*=30)	*P* value
Age years	44 (33,55)[43.8]	47 (30,60)[48.4]	0.314
BMI (kg/m^2)	23.8 (20,25)[23.31]	22 (20,24.6)[22.39]	0.632
NRS (Dynamic)			
2 hours	1 (0,2)[1.2]	0 (0,1)[1]	0.212
6 hours	3 (1,4)[2.73]	2 (1,4)[2.53]	0.785
12 hours	3 (2,3)[2.93]	3 (3,5)[3.73]	0.102
18 hours	3 (2,3)[2.8]	2 (2,3)[2.4]	0.092
24 hours	3 (1,3)[2.33]	2 (1,2)[1.73]	0.012
Mean	2.6 (1.2,3)[2.56]	2 (1.6, 2.4)[2.13]	0.035
NRS (Static)			
2 hours	0 (0,0)[0.4]	0 (0,0)[0.33]	0.554
6 hours	0 (0,2)[1.2]	0 (0,2)[0.8]	0.477
12 hours	2 (0,2)[1.6]	2 (1,3)[1.73	0.299
18 hours	1 (0,2)[1.27]	1 (0,1)[0.73]	0.102
24 hours	1 (0,2)[0.87]	0 (0,1)[0.53]	0.160
Mean	1.2 (0.4,1.6)[1.07]	1 (0.6,1)[0.82]	0.113
Pin prick			
T10	4 (13.3%)	0	
T8	6 (20%)	14 (46.7%)	0.022
T6	20 (66.7%)	16 (53.3%)	

Data are presented in median (IQR) [mean], compared by Mann Whitney *U* test. Number (%) compared by Chi square test/Fisher exact test. *P* value<0.05 significant.

Table 2: Distribution of the variables between two study groups (*N* = 60)

	TAP (*n*=30)	FTP (*n*=30)	*P* value
Total dose of fentanyl (microgram)	0 (0,50)[20]	0 (0,0)[3.3]	0.002
Time to give rescue (Hours) [*n* = 12, 2]	11.5 (9,15)[11.7]	12 (12,12)[12]	0.99
Rescue analgesia (Fentanyl) given			
Yes	12 (40%)	2 (6.6%)	0.002
No	18 (60%)	28 (93.4%)	
Patient satisfaction score (Mean ± SD)	4.7 ± 0.44	4.8 ± 0.34	0.203

groups. However, dermatome spread to T6 and T8 showed variation in two groups ($P > 0.05$) [Figure 5].

Discussion

To the best of our knowledge, this is the first prospective, randomized, single-blind study comparing the analgesic effect of pTAP with TFP in adult patients undergoing unilateral open inguinal hernia repair. Our results show that in the presence of multimodal analgesia and the use of dexamethasone as an adjuvant, both blocks were observed to be equally effective in ameliorating post-operative pain. Moreover, both blocks were observed to be similar in terms of time to request for first rescue analgesic dose, extent of dermatome spread, and patient satisfaction. However, the pTAP group reported more incidences of breakthrough pain and subsequently more mean fentanyl consumption.

Our results show that no statistically significant difference was observed in post-operative median static NRS scores between the two groups throughout the 24-hour period. Although patients who received the pTAP block exhibited slightly higher median dynamic NRS scores over 24 hours, this difference was clinically insignificant.

Contrary to our observations, R, Sripriya *et al*.[7] observed that in the absence of background analgesia, TAP and TFP did not decrease the rescue analgesic requirement compared to the control group in patients undergoing caesarean delivery. We observed a greater requirement for rescue analgesics in the pTAP group. A possible explanation for this observation can be attributed to the non-employment of background analgesia as TFP and pTAP are abdominal wall blocks and can provide somatic pain relief by blocking anterior and lateral cutaneous nerves

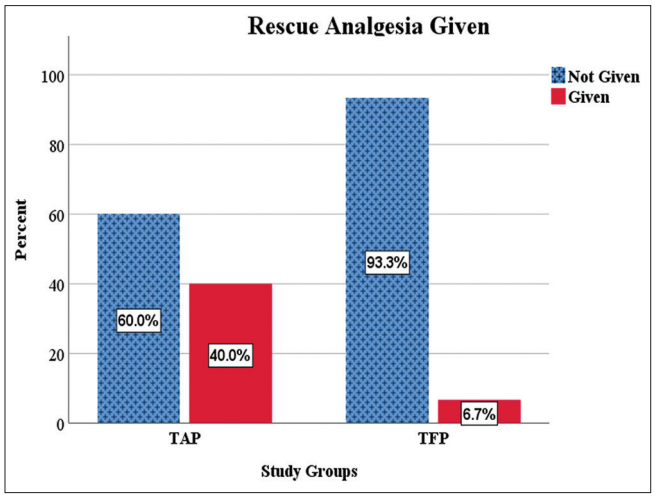

Figure 4: Percentage of the patients in the two groups who received rescue analgesics

but cannot alleviate visceral pain mediated by sympathetic chain making the deployment of multimodal analgesia imperative.

Although previous studies have demonstrated paravertebral spread achieved by pTAP,[5] we observed a higher utilization of rescue analgesics in the pTAP group.

Investigators observed that pTAP resulted in a statistically significant reduction in median static pain scores beyond 12 h when compared to the control group (0 [0-0] vs. 2 [2-2], respectively), and at 12 ($P = 0.002$) and 16 h ($P < 0.001$) when compared to Group-TFP. Contrary to this, we observed that in the presence of background analgesia (i.v paracetamol), pTAP and TFP reported similar NRS scores although mean opioid consumption was reported more in pTAP.

Furthermore, they found both interventions (TAP and TFP) to be ineffective in providing dynamic pain relief ($P > 0.008$) when compared with the control group. In our study, both blocks demonstrated comparable effectiveness in reducing median dynamic NRS scores, with TFP showing statistically better scores during the 24-hour period. Deviation from our findings may be attributed to the use of i.v paracetamol for background analgesia, the inclusion of dexamethasone as an adjuvant, variations in the extent and invasiveness of surgical procedures between the two studies, and the unpredictable nature of dermatome spread associated with fascial plane blocks.

Zanbak Mutlu ÖP *et al.*[8] reported a higher incidence of requirement of rescue analgesics (39/45,86%) in children administered pTAP for orchidopexy surgery. However, we reported an incidence of 40% in the pTAP group (12/30).

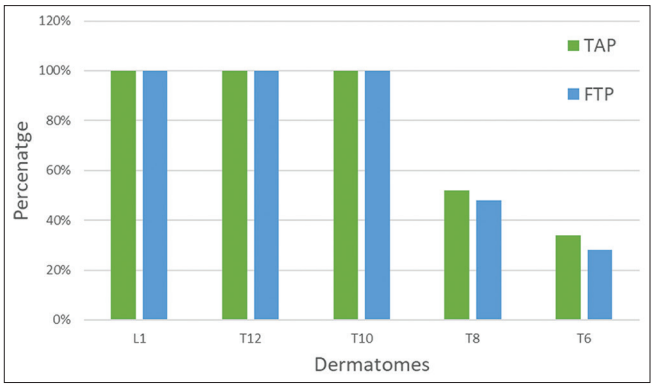

Figure 5: Dermatome assessment in the two groups

Abdelbaser *et al.*[9] reported that in children administered TFP for the inguinal hernia repair, number of children requiring rescue analgesics was 20.5% (7/34) and the time to first rescue analgesic was 7.5 h ± 2.3. Same group of investigators while evaluating TFP with QL in children undergoing hernia repair reported the incidence of the requirement of rescue analgesics in the TFP group as 15% (3/20) with the time to the requirement of rescue analgesics as 9 h, 1 h, and 4 h.[10]

In contrast, we noted a reduced incidence of breakthrough pain (2/30, 6.66%) and a longer time to the first request for rescue analgesics (11.7 h) in patients who received the TFP block. The time to the first requirement of rescue analgesic in TFP and pTAP was similar (11.7 h vs. 12 h; $P = 0.99$), and these durations were longer than those reported in previous studies. This favorable outcome may be attributed to the incorporation of background analgesia and the use of dexamethasone as an adjuvant. Furthermore, difference in observation can be attributed to pediatric patient population and use of different pain scales for pain assessment (FLACC).

López-González *et al.*[11] compared the analgesic efficacy of ultrasound-guided TFP block with anterior TAP block in patients undergoing inguinal hernia repair and observed their analgesic efficacy, requirement of additional analgesics, and cumulative dose of morphine to be similar. A higher level of sensory block was achieved in the TFP group than in the anterior TAP group, which can be explained by the relative anterior site of block placement in anterior TAP when compared with posterior TAP.

In another randomized study by Rahimzadeh *et al.*,[12] TFP and lateral TAP block demonstrated similar efficacy in providing postoperative analgesia and reducing opioid on postoperative pain in patients undergoing elective caesarean section.

Very few studies have assessed the dermatomal spread of pTAP and TFP. There is a lack of cadaveric and dye studies focusing on the dermatome spread of TFP. However, considering the proximity of site of administration of the two blocks and their relationship with thoracolumbar fascia, it well justifies the dermatome spread we observed in the two groups.[13] R Sripriya *et al*.[7] did post-operative dermatome assessment after regression of spinal anesthesia and observed that only the pTAP group demonstrated midline sensory loss at T-10 (17%), T-11 (77%), and L-1 (17%) dermatomes and none of the patients in any group had a loss of sensation in the midclavicular line in the T–10 to L–1 dermatome on either side. However, pre-operative dermatome assessment in our study observed hypoesthesia along the midclavicular line from T10 to L1 in all the patients of either group with variable spread to T6 and T8 findings, suggesting that both pTAP and TFP block anterior and lateral cutaneous branches. Our observations are congruent with cadaveric studies.[2]

Limitations of our study include absence of control group, lack of long-term follow-up for evaluating development of chronic pain. Additionally, the study did not employ patient-controlled analgesia (PCA) pump, which could have provided a more accurate depiction of the patients' post-operative pain and the necessity for pain relief.

Conclusion

As far as we are aware, this is the first study comparing the analgesic efficacy of pTAP with TFP in adult patients undergoing open inguinal hernia repair. All blocks were performed by the same anesthesiologist. We had predicted that pTAP, owing to paravertebral spread would provide better post-operative analgesia. However, we observed that, in conjunction with background analgesia and the use of dexamethasone as an adjuvant, both blocks (pTAP and TFP) were equally effective for postoperative pain relief with similar patient satisfaction scores. Furthermore, studies, including cadaveric/injectate spread study for TFP block, are warranted.

Declaration of patient consent

The authors declare that they have obtained consent from patients. Patients have given their consent for their images and other clinical information to be reported in the journal. Patients understand that their names will not be published and due efforts will be made to conceal their identity but anonymity cannot be guaranteed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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