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Preemptive analgesic efficacy of ultrasound-guided transversalis fascia plane block in children undergoing inguinal herniorrhaphy: a randomized, double-blind, controlled study

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Background: Surgical repair of congenital inguinal hernia results in significant postoperative discomfort and pain. The aim of the current study was to evaluate the pre-emptive analgesic efficacy of a transversalis fascia plane (TFP) block after pediatric inguinal herniorrhaphy.

Methods: Forty-four patients aged 12 to 60 months who underwent unilateral inguinal herniorrhaphy were enrolled. Four patients were excluded, and the remaining were allocated to the control group and the TFP block group. In the TFP block group, 0.4 ml/kg bupivacaine 0.25% was instilled in the plane between the transversus abdominis and transversalis fascia, while in the control group 0.9% saline was used instead of bupivacaine. The collected data were the total dose of paracetamol consumed during the first 12 h postoperatively, the postoperative Face, Leg, Activity, Cry, Consolability (FLACC) pain score, time to first use of rescue analgesia, number of patients required additional postoperative analgesics, and parents' satisfaction.

Results: The median paracetamol consumption was significantly lower in the TFP block group than in the control group, and FLACC pain scores were significantly lower for all study times in the TFP block group with higher parental satisfaction scores than those for the control group. The number of patients who required additional analgesics was significantly lower in the TFP block group than in the control group.

Conclusions: The use of a TFP block decreases postoperative analgesic consumption and postoperative pain intensity after pediatric inguinal herniorrhaphy. Future studies with larger sample size are required to evaluate the actual complications rate of TFP block.

Keywords: Acetaminophen; Analgesia; Child; Fascia; Herniorrhaphy; Postoperative pain.

Introduction

Surgical repair of congenital inguinal hernia is a common day-case procedure during childhood that results in significant postoperative discomfort and pain [1]. Preemptive analgesia relieves pain prior to the surgical incision and during the perioperative period, and prevents the occurrence of central sensitization by interfering with the transmission of peripheral nociceptive signals to the spinal cord [2].

Ultrasound-guided transversus abdominis plane block (TAP) and ilio-inguinal/ilio-hypogastric (II/IH) nerve block are the most commonly and effectively used peripheral

nerve block techniques to alleviate postoperative pain after surgical repair of inguinal hernia in children [3].

The transversalis fascia plane (TFP) block is a peripheral ultrasound-guided nerve block in which the local anesthetic is instilled between the transversus abdominis muscle and its enclosing transversalis fascia at the level of the posterior axillary line targeting the T12 and L1 nerves that convey the nociception from the antero-lateral abdominal wall [4].

The analgesic efficacy of TFP block has been demonstrated in adult surgery, including iliac crest bone graft harvesting [5], inguinal herniorrhaphy [6], and cesarean section [7,8]. In pediatric surgery, the only report of the TFP block was provided by Ahiskalioglu et al. [9] in two children, one of them underwent unilateral open inguinal herniorrhaphy and the other was scheduled for reimplantation of the ureter into urinary bladder via pfannenstiel incision.

This prospective, controlled, randomized study was conducted to evaluate the effect of performing TFP block before skin incision in children undergoing unilateral inguinal herniorrhaphy on postoperative pain and analgesic requirements. We hypothesized that the TFP block would reduce postoperative non-opioid analgesic requirements. The primary endpoint was postoperative non-opioid analgesic consumption, and the secondary endpoints were pain score, time to first rescue analgesia use, and parental satisfaction.

Materials and Methods

This prospective, randomized, double-blinded, controlled, superiority study was conducted in our institutional university hospital from June to November 2020 after receiving approval from our Faculty of Medicine institutional research board (IRB Code Number, R.20.06.870) on 10th June 2020, and was registered at the Pan-African Clinical Trial Registry (PACTR202006532101847) prior to patient enrollment. The study was conducted in accordance with the Declaration of Helskinki and Good Clinical Practice.

After obtaining informed written consent from the patient's parents or their legal guardians, 44 consecutive eligible patients were enrolled. Children aged between 12 and 60 months with American Society of Anesthesiologists physical status I or II undergoing scheduled elective unilateral inguinal herniorrhaphy were included in the study.

Exclusion criteria included previous inguinal surgery; history of clinically significant cardiac, hepatic, renal, or neurological dysfunction; coagulopathy; known allergy to amide local anesthetics; and systemic or local infection at the puncture site.

Randomization was performed using computer-generated random numbers prior to surgery. An opaque sealed envelope was used and opened in the operative theater by an anesthesiologist who was not involved in the study and who prepared the study drugs. The anesthesiologist who was responsible for the patient and the nurse who recorded the patient data were unaware of the patient's group allocation. Patients were randomly allocated to the TFP block group or control group according to the patient randomization chart (Fig. 1).

The patient received no premedication before anesthesia induction. On arrival in the operating room, standard monitoring including pulse oximetry, non-invasive blood pressure, and three lead electrocardiography and capnography (after induction) were applied to the patient. General anesthesia was induced using 8% sevoflurane in 100% oxygen. After achieving an adequate depth of anesthesia, a 22-gauge peripheral venous catheter was inserted in the forearm, and an appropriately sized i-gel (i-gel™, Intersurgical Ltd., UK) supraglottic airway based on the child's weight was properly placed by the attending anesthesiologist. Anesthesia was maintained under controlled pressure support ventilation using 1–2% sevoflurane in a mixture of 50% oxygen/air, fentanyl 1 μg/kg, and atracurium 0.5 mg/kg. The patient received standardized fluid therapy in the form of 3–5 ml/kg/h crystalloid. The skin incision was performed 15 minutes after the block induction. Any increase in the heart rate and mean arterial blood pressure that was 20% above the preoperative value in response to skin incision was managed using fentanyl 0.5 μg/kg, repeated at 3-min intervals. At the end of surgery, the muscle relaxant was reversed, and the i-gel

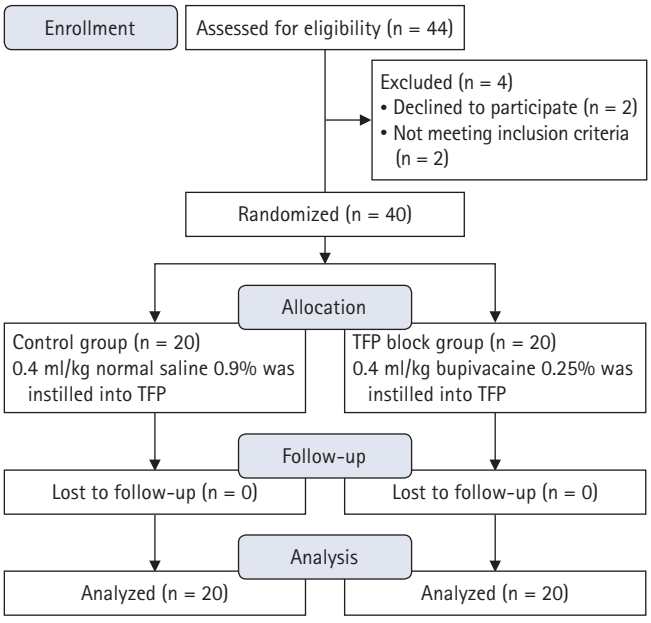

Fig. 1. CONSORT flow diagram. TFP: transversalis fascia plane.

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airway was removed after full recovery of consciousness.

Ultrasound-guided TFP block was performed immediately after induction of anesthesia by an experienced single operator under aseptic conditions. The patient was placed supine, and the skin at the site of needle puncture was sterilized with 2% chlorhexidine and isolated with sterile drapes. A high frequency (8–14 MHz), linear ultrasound pediatric probe (Mindray® 10L24EA, China) wrapped in a sterile sheath was placed over the lateral abdominal wall between the iliac crest and subcostal margin at the midaxillary line in an oblique direction with the ultrasound probe mark directed upward.

The probe was manipulated to obtain an image showing the muscles of the abdominal wall and transversalis fascia at its junction with the anterior layer of the thoraco-abdominal fascia at the lateral end of the quadratus lumborum muscle (Fig. 2A). A 22-gauge, 50-mm short bevel needle was advanced using an in-plane technique, from the anterior to the posterior wall traversing the skin, external and internal oblique muscles, and posterior tail of the transversus abdominis muscle and its enclosing fascia. Immediately after piercing the fascia of the transversus abdominis muscle, 0.4 ml/kg bupivacaine 0.25% was instilled (Fig. 2B) in TFP block group. A placebo (0.4 ml/kg 0.9% saline) was used instead of bupivacaine in the control group.

At the end of surgery, patients were transferred to a post-anesthesia care unit (PACU) where they received 1 mg/kg rectal diclofenac suppository as a part of postoperative multimodal analgesia. The patients were discharged 30 minutes after from the PACU to the ward when they were completely awake and thermodynamically stable with tolerable pain.

Postoperative pain was assessed by an experienced pediatric nurse who was blinded to the patient's group allocation using the 10-point behavioral face, leg, activity, cry, consolability (FLACC) pain scale, with a minimum score of 0 and a maximum of 10 [10]. If the FLACC score was 4 or more, 10 mg/kg paracetamol was administered intravenously as rescue analgesia, which could be repeated every 6 hours with a maximum total dose of 30 mg/kg in the first 12 h postoperatively. Fentanyl 1 μg/kg was administered if the FLACC score did not fall below 4 despite the use of paracetamol as rescue analgesia. Following standard day case surgery protocol, the patients were discharged from the hospital after 12 h.

The primary outcome measure was the total dose of paracetamol consumed during the first 12 h postoperatively. The secondary outcome measures were increase in heart rate and mean arterial pressure of more than 20% in response to skin incision,; intraoperative fentanyl consumption; postoperative FLACC pain score after 0.5 h in PACU, and 2, 4, 6, 9, and 12 h in the ward; time to first rescue analgesia use; number of patients who required additional postoperative analgesics; fentanyl consumption during the first 12 h postoperatively, and parental satisfaction evaluated using a five-point Likert scale (very satisfied: 5, satisfied: 4, neutral: 3, dissatisfied: 2, and very dissatisfied: 1) [11]. Block-related complications, including local anesthetic toxicity, lower limb motor weakness, and vascular or abdominal organ puncture, were reported.

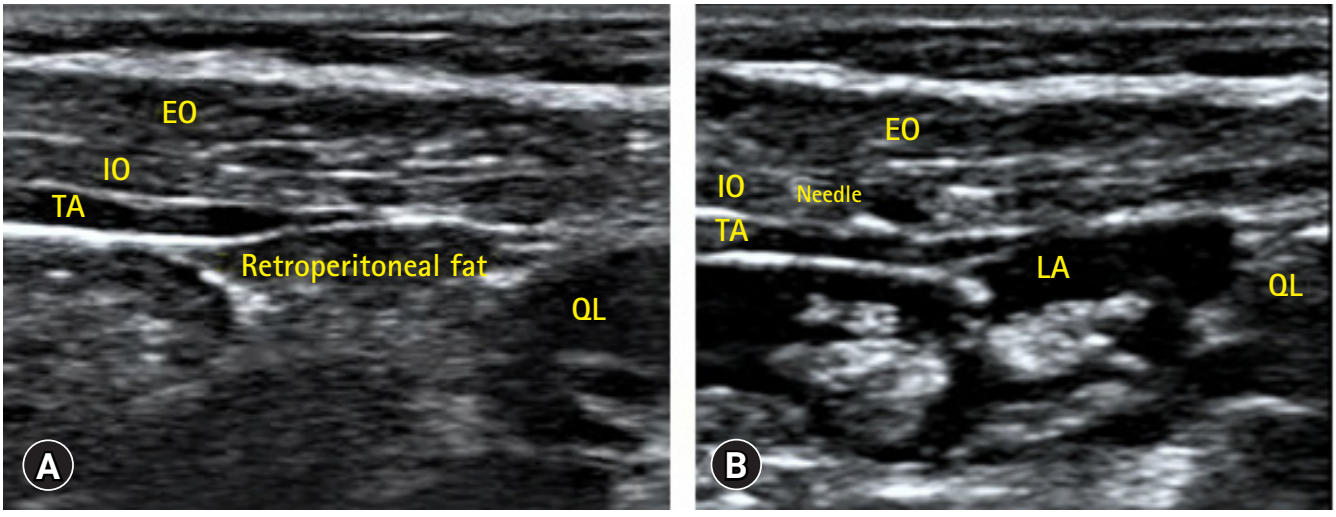

Fig. 2. (A) Ultrasound images of transversalis fascia plane before local anesthetic injection. (B) Ultrasound images of transversalis fascia plane after local anesthetic injection. EO: external oblique muscle, IO: internal oblique muscle, TA: transversus abdominis muscle, QL: quadratus lumborum muscle, LA: local anesthetic.

Sample size and statistical analyses

The sample size was calculated using G*Power software (G*Power version 3.1.9.2, Kiel University, Germany). The primary outcome was the total dose of paracetamol consumed in the first 12 h postoperatively. As there were no previous similar studies at the time of designing the study protocol, an external pilot study with five patients in each group was performed (the results were not included in the full-scale-study). From this pilot, paracetamol consumption in the first 12 h postoperatively was found to be 15.8 ± 4.7 mg/kg in the TFP block group and 20.8 ± 6.9 mg/kg in the control group. Assuming that a mean postoperative paracetamol consumption of less than 5 mg/kg would indicate a significant difference between the two study groups; a total sample of 36 patients (18 in each group) was required to achieve a power (1–β) of 80% and type I α error of 0.05. Four patients were included in each group to compensate for any dropouts. Thus, the final sample consisted of 22 patients in each group.

Statistical testing was performed using IBM SPSS Statistics for Windows, Version 21.0 (SPSS®, IBM Corp., USA). Data were tested for normality using the Shapiro-Wilk test. The distribution of data was represented as mean ± standard deviation (SD) for quantitative parametric data; frequency, number, and proportion for categorical data; and median (Q1, Q3), minimum and maximum, for non-parametric data. Data analysis was performed to display the statistically significant differences between the two groups. The Mann-Whitney *U* test was used to analyze non-parametric data. For quantitative data, the unpaired Student's t-test was used to compare the means of the two groups. Fisher's exact test was used to analyze categorical data. $P < 0.05$ was considered statistically significant.

Results

Forty-four patients were recruited for this randomized, controlled, double-blind, superiority study. Four patients were excluded because they did not meet the inclusion criteria or their legal guardians refused to consent to participation. The remaining 40 patients were allocated into two equal groups: the TFP block and control group (Fig. 1). There were no significant differences in patient characteristics (age, sex, weight, or height) or duration of surgery between the studied groups (Table 1).

The median (Q1, Q3) paracetamol consumption (mg/kg) in the first 12 h postoperatively was significantly lower ($P < 0.001$) in the TFP block group, 0 (0, 0) than in the control group, 20 (10, 30) (Table 2). The number of patients who developed an increase in heart rate and mean arterial pressure of more than 20% in response to skin incision was significantly smaller ($P < 0.001$) in the TFP block group (n = 2) than in the control group (n = 10) (Table 2). The intraoperative mean fentanyl consumption (μg/kg) was significantly lower ($P = 0.005$) in the TFP block group (1.10 ± 0.08) than in the control group (1.50 ± 0.51) (Table 2). The number of patients who required postoperative rescue analgesia was significantly greater ($P < 0.001$) in the control group (n = 20) than in the TFP block group (n = 3). The median (Q1, Q3) time to first rescue analgesia in the control group was 4.5 (1.5, 6) hours, and for the three patients who required rescue analgesia in the TFP block group was 9, 1, 6 hours respectively (Table 2). The incidence of postoperative fentanyl administration was significantly higher ($P = 0.019$) in the control group (35%), than in the TFP block group (5%). We did not experience any complications related to the block (Table 2).

The median (Q1, Q3) FLACC pain scores were significantly lower ($P < 0.001$) throughout the first 12 h postoperatively in the TFP block group than in the control group (0.5 h: 1.5 [1, 2] vs. 3 [2, 3]; 2 h: 1 [1, 2] vs. 3 [2, 3]; 4 h: 1 [1, 2] vs. 3 [3, 4]; 6 h: 1.5 [1, 2] vs. 4 [3.5, 5]; 9 h: 1.5 [0.5, 2.5] vs. 3 [2.5, 4]; and 12 h: 1.5 [0, 3] vs. 3 [3, 4], respectively) (Table 3). Parental satisfaction Likert scores were significantly higher in the TFP block group than in the control group (Fig. 3).

Discussion

This prospective, randomized, superiority, controlled study was conducted to evaluate the efficacy of the TFP block performed before skin incision in reducing postoperative pain scores and analgesic requirements in children undergoing elective unilateral inguinal herniorrhaphy. The results of the current study showed that, performing a TFP block before skin incision was associated with lower postoperative analgesic requirements (paracetamol and fentanyl), lower postoperative pain scores, lesser need for rescue analgesia, and better parental satisfaction than the control treatment. The above results demonstrate the analgesic efficacy of

Table 1. Patients Characteristics and Duration of Surgery

Variable	TFP block group (n = 20)	Control group (n = 20)	P value
Age (month)	24 (12, 54)	18.5 (12, 60)	0.198
Weight (kg)	12.5 (10, 19)	12 (8, 25)	0.199
Height (cm)	90.4 ± 12.5	86.9 ± 14.1	0.411
Sex (M/F)	18/2	18/2	1.000
Surgery duration (min)	40.9 ± 8.0	42.3 ± 6.7	0.567

Values are presented as median (Q1, Q3), mean ± SD or number of patient. TFP: transversalis fascia plane.

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Table 2. Intraoperative and Postoperative Variables

Variable	TFP block group (n = 20)	Control group (n = 20)	P value*
Number (%) of patients with 20% increase in HR and MAP after incision	2 (10)	10 (50)	< 0.001
Intraoperative fentanyl consumption (μg/kg)	1.10 ± 0.08	1.50 ± 0.51	0.005
Number (%) of patients requiring rescue analgesia	3 (15)	20 (100)	< 0.001
Time to first rescue analgesia (h)		4.5 (1.5, 6)	
First patient	9		
Second patient	1		
Third patient	6		
Postoperative paracetamol consumption (mg/kg)	0 (0, 0)	20 (10, 30)	< 0.001
Incidence of postoperative fentanyl administration (%)	5	35	0.019
Block related complications (%)	0	0	

Values are presented as number of patient (%), mean ± SD or median (Q1, Q3). TFP: transversalis fascia plane, HR: heart rate, MAP: mean arterial blood pressure. *P < 0.05, statistically significantly different from the control group.

Table 3. Postoperative FLACC Pain Score

Elapsed time after PACU admission	TFP block group (n = 20)	Control group (n = 20)	P value*
0.5 h	1.5 (1, 2)	3 (2, 3)	< 0.001
2 h	1 (1, 2)	3 (2, 3)	< 0.001
4 h	1 (1, 2)	3 (3, 4)	< 0.001
6 h	1.5 (1, 2)	4 (3.5, 5)	< 0.001
9 h	1.5 (0.5, 2.5)	3 (2.5, 4)	< 0.001
12 h	1.5 (0, 3)	3 (3, 4)	< 0.001

Values are presented as median (Q1, Q3). FLACC: face, leg, activity, cry, consolability, TFP: transversalis fascia plane. *P < 0.05, statistically significantly different from the control group.

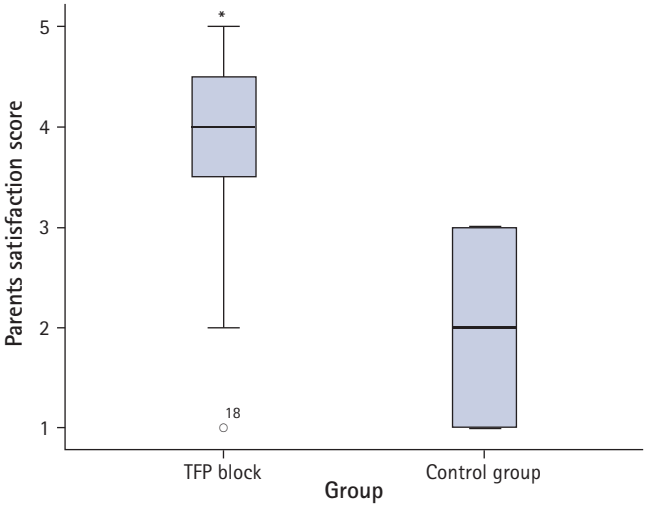

Fig. 3. Five-point Likert scale for evaluating parental satisfaction. Values are presented as median (Q1, Q3). *P < 0.05, statistically significantly different from the control group.

the TFP block for pediatric inguinal herniorrhaphy.

The inguinal region is supplied by highly variable and complex sensory neuronal innervations from the II, IH, and genitofemoral nerves (GFN). The II and IH nerves originate from the first lumbar (L1) spinal nerve root with occasional contributions from the 12th thoracic nerve root, while the GFN is formed by contributions from L1 and L2 nerve roots [12].

In pediatric surgeries, the use of ultrasound (US) guidance for fascial muscle plane blocks has been associated with increased success rate and reduced volume of local anesthetics needed for the block [13].

The most commonly used ultrasound-guided fascial muscle plane blocks to provide effective postoperative analgesia after inguinal herniorrhaphy in children are II/IH nerve block and TAP block [3]. Few studies have compared the efficacy of TAP and II/IH nerve block for providing postoperative analgesia after inguinal surgery with conflicting results [14,15]. Recently, quadratus lumborum block [16,17] and erector spinae block [18,19] have been reported to be effective in reducing postoperative pain and analgesic consumption after pediatric inguinal herniorrhaphy.

To the best of our knowledge, no prior study has been conducted to evaluate the efficacy of TFP block in reducing postoperative pain scores and analgesic consumption in children undergoing inguinal herniorrhaphy. The only case report of TFP block in

children was described by Ahiskalioglu et al. [9] who performed TFP block in two children leading to similar results to those of our study. One of the patients was a 5-year-old girl scheduled for uretero-cystostomy via Pfannenstiel incision and the other child was a 4-year-old boy scheduled for unilateral inguinal herniorrhaphy; they reported improved postoperative analgesia in both cases.

Tulgar et al. [20] performed a combination of ultrasound-guided TFP block and TAP block and reported adequate and effective intraoperative anesthesia and analgesia under propofol infusion at a sedative dose with effective postoperative analgesia in an adult patient undergoing inguinal hernia repair.

López-González et al. [6] compared the postoperative analgesic effect of both ultrasound-guided TFP block and TAP block after adult inguinal herniorrhaphy and found that both blocks provided good postoperative analgesia and a higher sensory level was associated with TFP block.

Several clinical trials have demonstrated that the TFP block is associated with good postoperative analgesia with reduced analgesic consumption after iliac crest bone graft harvesting [5] and cesarean section [7,8].

The TFP block influences the II and IH nerves in the plane between the investing fascia of the transversus abdominis and transversalis fascia. The II and IH nerves vary in their position at the level of the iliac crest as both nerves penetrate the transversus abdominis muscle at the level of the dorsal segment of the iliac crest in 61% of the population, and in 34.2% they combine to form a common trunk [12]. Therefore, more proximal blocks, e.g., TFP block, are more effective than TAP and II/IH nerve blocks.

The inguinal hernial sac is partially innervated by the genital branch of the GFN, which is not covered by II and IH nerve blocks, potentially leading to visceral pain as a result of traction on the hernial sac. Sasaoka et al. [21] found that the only benefit of performing GFN block in addition to II and IH nerve blockade was intraoperative attenuation of the hemodynamic stress response to surgical manipulation of the inguinal hernial sac without any postoperative analgesic effect.

The TFP block involves injection of local anesthetics superficial to the transversalis fascia and deep to the tapering aponeurosis of the transversus abdominis muscle, just lateral to the quadratus lumborum muscle. At this point, the transversalis fascia combines with the anterior layer of the thoracoabdominal fascia. This may explain the spread of local anesthetic to the paravertebral space blocking both the rami of the thoracic spinal nerves (dorsal and ventral) and rami communicants, which supply the sympathetic chain [22].

Two patients in the TFP block group had an increase in heart rate and mean arterial pressure of more than 20% of the preoperative value immediately after skin incision, which may be attributed to block failure.

TFP block was associated with good parental satisfaction with postoperative pain management, as their children were almost pain free with minimal need for postoperative analgesics. Pain control allows children to remain calm, sleep, and eat well, avoiding irritability and insomnia.

There were no reported complications related to the ultrasound-guided TFP block, including local anesthetic toxicity, lower limb weakness, and vascular or abdominal organ needle puncture. This indicates that the safety of TFP block with needle visualization using ultrasound is very good in children.

The current study has a few limitations. First, we could not monitor intraoperative nociception to evaluate the efficacy of TFP block in controlling painful intraoperative events, such as skin incision, as these monitors are not available in our hospital. Intraoperative nociception can be measured using the anesthesia analgesia index using a CE-certified PhysioDoloris monitor (MetroDoloris Medical Systems, France) and nociception level index measurement using a PMD-200™ (Medasense Biometrics Ltd., Israel) monitor [23]. Second, patient follow-up was limited to the first 12 h postoperatively as inguinal hernia repair is a day-case surgery and early discharge is recommended by our hospital policy. Third, we did not assess the effect of TFP block on the incidence of chronic pain after inguinal herniorrhaphy in pediatric patients as this requires several months of follow-up.

From the findings in our study, we concluded that performing a TFP block before surgical incision in children undergoing unilateral inguinal herniorrhaphy results in reduction of postoperative analgesic requirements, adequate postoperative pain control, and good parent's satisfaction. Ultrasound guidance makes the TFP block an easy and effective peripheral nerve block. Future studies with larger sample size are required to evaluate the actual complication rate of TFP block.

Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

Author Contributions

Ibrahim Abdelbaser (Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Writing – original draft; Writing – review & editing)
Nabil A. Mageed (Supervision; Writing – review & editing)

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