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Please cite this article as https://doi.org/10.4097/kja.20601
Title

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

Author information

Ibrahim Abdelbaser* (MD), Nabil A. Mageed (MD), El- Sayed M El-Emam (MD), Mahmoud M ALseoudy (MD), Mohamed M. Elmorsy (MD)

Department of Anesthesia and Surgical Intensive Care, Faculty of Medicine, Mansoura University, Mansoura, Egypt.

Running title

TFP block in pediatric patients

Corresponding Author

Ibrahim I. Abd Elbaser, MD, Department of Anesthesia and Surgical Intensive Care, Faculty of Medicine, Mansoura University, 2 El-Gomhouria Street, Mansoura 35516, Egypt.

Tel: +20 100 497 6825

e-mail: ibrahimbaser2010@yahoo.com

Previous presentation in conferences

Not applicable
Conflict of interest

Not applicable

Funding

Not applicable

Acknowledgments

Not applicable

IRB number

Institutional Review Board (IRB): Approval from the Institutional Research Board, Faculty of Medicine, Mansoura University given a code number (IRB Code Number, R.20.06.870).

Clinical trial registration number

Clinical Trial Registry: Pan African clinical trial registry (PACTR202006532101847).
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Running title: TFP block in pediatric patients
Abstract

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

Methods: In this randomized, double-blinded, controlled, superiority study, 44 patients aged 12 to 60 months, undergoing unilateral inguinal herniorrhaphy were enrolled. Four patients were excluded and the remaining were allocated into the control group and TFP block group. In TFP block group 0.4 mL/kg bupivacaine 0.25% was instilled in the plane between transversus abdominis and transversalis fascia, while in control group 0.9 saline was used instead of bupivacaine. The primary outcome measure was the total dose of paracetamol consumed during the first postoperative 12 hours (h). The secondary outcome measures were the postoperative Face, Leg, Activity, Cry, Consolability (FLACC) pain score, time to first rescue analgesia, number of children required additional postoperative analgesics and parents' satisfaction Likert scale.

Results: During the first postoperative 12 h, the median paracetamol consumption was significantly lower in TFP than the control group and FLACC pain scores were significantly lower all over the study time in TFP block group with higher parents' satisfaction score than the control group. The time to first rescue analgesia was significantly longer and the number of patients who required additional analgesics were significantly lower in TFP block group than the control group.

Conclusions: The use of TFP block decreases postoperative analgesic consumption and postoperative pain intensity after pediatric inguinal herniorrhaphy.

Keywords: Child; Herniorrhaphy; Analgesia; Postoperative pain; Transversalis fascia; Acetaminophen.
Introduction

Surgical repair of congenital inguinal hernia is a common day-case procedure during childhood that results in a significant postoperative discomfort and pain [1]. Preemptive analgesia relieves pain prior to 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 post-operative pain after surgical repair of inguinal hernia in children [3].

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

The analgesic efficacy of TFP block have been demonstrated in adults' surgeries, including iliac crest bone graft harvesting [5], inguinal herniorrhaphy [6] and caesarean section [7,8]. In pediatric surgery, the only report of TFP block was described by Ahiskalioglu et al. [9] in two children.

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 TFP block would reduce the postoperative non-opioid analgesic requirements. The primary endpoint was the postoperative non-opioid analgesic consumption and the secondary endpoints were pain score, time to first rescue analgesia time and parents' satisfaction.
Material and Methods

This prospective, randomized, double-blinded, controlled, superiority study was conducted in our institutional university children hospital from June to November 2020 after receiving the approval letter from our faculty of medicine institutional research board (IRB Code Number, R.20.06.870) at 10 June 2020 and registered at pan African clinical trial registry (PACTR202006532101847) prior to patients enrollment.

After obtaining an informed written consent from the patient's parents or their legal guardians, 44 consecutive eligible patients were enrolled. Children aged between 12 to 60 months with American Society of Anesthesiologists physical status I or II undergoing scheduled elective unilateral inguinal hernia repair 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 simple using computer-generated random numbers of the studied patients prior to surgery. Opaque sealed envelope was used and opened in the operative theatre by an anesthesiologist who was not involved in the study and who prepared the study drugs. The anesthesiologist who was responsible of the patient and the nurse who recorded the patient data were unaware of patient’s group allocation. Patients were randomly allocated to the TFP block group or the control placebo group according to patient randomization chart (Fig. 1).

The patient received no premedication before induction of anesthesia. On arrival in the operating room, standard monitoring including pulse oximetry, non-invasive blood pressure, 3 leads electrocardiography and capnography (after induction) were applied to the patient. General anesthesia was induced by 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., Wokingham, Berkshire, UK) supraglottic airway based on the child weight was properly placed by the attending anesthesiologist. Anesthesia was maintained under controlled pressure support ventilation by 1-2% sevoflurane in a mixture of 50% oxygen/air, fentanyl 1µg/kg and atracurium 0.5 mg/kg. The patient received a standardized fluid therapy in the form of 3-5 mL/kg/h crystalloid. Skin incision was allowed 15 minutes after the block. Any increase in the heart rate and mean arterial blood pressure by 20% above the preoperative value in response to skin incision was managed by fentanyl 0.5 µg/kg, repeated at 3 minutes intervals. At the end of surgery, the muscle relaxant was reversed and I-Gel airway was removed after full recovery.

Ultrasound-guided transversalis fascia plane block was performed immediately after induction of anesthesia by an experienced single operator under complete aseptic precautions. The patient was placed supine with sterilization of the skin at the site of needle puncture with 2% chlorhexidine with its isolation with sterile drapes. A high frequency (8-to 14-MHz), linear ultrasound pediatric probe (Mindray® 10L24EA, Shenzhen, China) wrapped in a sterile sheath was placed over the lateral abdominal wall between 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 muscles of 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. 2 A). A 22-gauge, 50 mm short bevel needle was advanced in an in-plane technique, from the anterior to the posterior wall traversing skin, external and internal oblique muscles and posterior tail of transversus abdominis muscle and its enclosing fascia. Immediately, after piercing the fascia of transversus abdominis muscle, 0.4 mL/kg bupivacaine 0.25% was instilled (Fig. 2B). A placebo (0.4 mL/kg 0.9% saline) was used instead of bupivacaine in the control group.
By the end of surgery, patients were recovered and transferred to a post anesthesia care unit (PACU), where they received 1mg/kg rectal diclofenac suppository as a part of postoperative multimodal analgesia. The patients were discharged after 30 minutes from 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 blind of patient's group allocation using behavioral FLACC (Face, Leg, Activity, Cry, Consolability) pain 10-point scale, the minimum score is 0 and the maximum is 10 [10]. If FLACC score was 4 or more, 10 mg/kg paracetamol was administered intravenously as a rescue analgesia, that could be repeated every 6 hours with the maximum total dose of 30 mg/kg in the first postoperative 12 hours. Fentanyl 1 μg/kg was administered if FLACC score didn’t decrease below 4 despite of the use of paracetamol as rescue analgesia. On the basis of day case surgery, the patients were discharged from hospital after 12 hours.

The primary outcome measure was the total dose of paracetamol consumed during the first postoperative 12 hours. The secondary outcome measures were the increase of heart rate and mean arterial pressure more than 20% in response to skin incision, intraoperative fentanyl consumption, postoperative FLACC pain score at 30 minutes in PACU and at 2, 4, 6, 9, 12 hours in ward, time to first rescue analgesia, number of children required additional postoperative analgesics, fentanyl consumption during the first 12 postoperative hours and parent satisfaction that was evaluated using a five points Likert scale (very satisfied: 5, satisfied: 4, neutral: 3, dis-satisfied: 2, and very dissatisfied: 1) [11]. The block related complications including local anesthetic toxicity, lower limb motor weakness and vascular or abdominal organ puncture were reported.

Sample size and statistical analyses
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 consumption in the first postoperative 12 hours. As there were no previous similar studies at the time of designing the study protocol, an external pilot study on 5 patients in each group was done (its results were not included in the full-scale-study). From this pilot, paracetamol consumption in the first postoperative 12 h was found to be 15.8±4.7 mg/kg in TFP block group and 20.8±6.9 mg/kg in the control placebo group. Assuming that, the 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) were required to achieve a power (1–β) of 80%, and type I α error of 0.05. Four patients were added to each group to compensate for any drop out. Thus, the final sample was 22 patients in each group.

The statistical testing of data was achieved by using IBM SPSS Statistics for Windows, Version 21.0 (SPSS®, Armonk, IBM Corp, USA). Data were tested for normality using Shapiro-Wilk test. The distribution of data was done by mean ± standard deviation (SD) for quantitative parametric data, frequency, number & proportion for categorical data and median, minimum, maximum and interquartile range (IQR) for non-parametric data. The data analysis was done to display the statistically significant differences between the two studied groups. Mann-Whitney U test was used to analyze the non-parametric data. For quantitative data unpaired student t-test was used to compare between the means of two groups. Fisher's exact test was used for the analysis of categorical data. P value <0.05 at confidence interval 95% was considered statistically significant.
Results

Forty-four patients were recruited for this randomized, controlled, double-blind, superiority study. Four patients were excluded as they were not meeting the inclusion criteria or their legal guardians refused to participate. The remaining 40 patients were allocated into 2 equal groups; TFP block and control group (Fig. 1). There were no significant differences regarding patients characteristics (age, gender, weight and height) and duration of surgery between the studied groups as shown in Table 1.

The median paracetamol consumption (mg/kg) in the first postoperative 12 h was significantly lower (P< 0.001) in TFP block group, 0 (0-0) than the control group, 20 (10-30) (Table 2). The number of patients who developed an increase in HR and MAP by more than 20 % in response to skin incision was significantly smaller (P <0.001) in TFP block group (n=2) than the control group (n=10) (Table 2). Intraoperative mean fentanyl consumption (μg/kg) was significantly lower (P=0.005) in the TFP block group (1.1±0.08) than the control group (1.5±0.513) (Table 2). The number of patients who required postoperative rescue analgesia was significantly greater (P<0.001) in control group (n=20) than TFP block group (n=3) and the time to first rescue analgesia (hours) was significantly shorter (P <0.001) in the control group, 4.5(1.5-6) than TFP block group, 0(0-0) (Table2). The median postoperative fentanyl consumption (μg/kg) was significantly higher (P =0.019) in the control group, 0(0-1) than TFP block group (0, range =0-0) (Table 2). We didn’t report any complications related to the block (Table 2).

The median FLACC pain scores were significantly lower (P <0.001) all over the first postoperative 12 h in TFP block group than the control group at 30 min:1.5(1-2) vs 3(2-3); at 2 h: 1(1-2) vs 3(2-3); at 4 h: 1(1-2) vs 3(3-4); at 6 h:1.5(1-2) vs 4(3.5-5); at 9 h: 1.5(0.5-2.5) and at 12 h: 1.5(0-3) vs 3(3-4) respectively (Table 3). The parent's satisfaction Likert score was significantly higher in TFP block group than the control group as seen in Figure 3.
Discussion

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

The inguinal region is supplied by a highly variable and complex sensory neuronal innervations from ilio-inguinal (II), ilio-hypogastric (IH) and genitofemoral nerves (GFN). Ilio-inguinal and IH nerves originate from the first lumbar (L1) spinal nerve roots with occasional contributions from 12th thoracic nerve roots, while genitofemoral nerve 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 have been associated with increased the 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 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, there is no prior study has been conducted to evaluate the efficacy of TFP block on reducing the postoperative pain scores and analgesics 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 with similar results to that of our study, one of them was 5 years old girl scheduled for uretero-cystostomy via Pfannenstiel incision and the other child was 4 years boy scheduled for unilateral inguinal herniorrhaphy and they reported improved postoperative analgesia in both cases.

Tulgar S et al. [20] performed a combination of ultrasound-guided TFP block and TAP block and they 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 JM et al. [6] compared the postoperative analgesic effect of both ultrasound-guided TFP block and TAP block after adult inguinal herniorrhaphy and they found that, both blocks provided good postoperative analgesia and a higher sensory level was associated with TFP block.

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

Transversalis fascia plane block targets II and IH nerves in the plane between the investing fascia of transversus abdominis and transversalis fascia. Ilio-inguinal and IH nerves varies in their position at the level of iliac crest, as both nerves penetrate transversus abdominis muscle at the level of dorsal segment of iliac crest in 61% of population and in 34.2% combine to form a common trunk [12]. Therefore, the more proximal blocks as in case of TFP block are more effective than TAP and II/IH nerve blocks.
The inguinal hernial sac is partially innervated by genital branch of GFN which is not covered by II and IH nerve block, that may cause visceral pain during traction on hernial sac. Sasaoka N et al. [21] found that, the only benefit of addition of GFN block to IIN and IHN blockade was intraoperative attenuation of the hemodynamic stress response to surgical manipulation of inguinal hernial sac without any postoperative analgesic effect.

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

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

TFP block was associated with good parents' satisfaction about postoperative pain management as their children were almost pain free with minimal needs for postoperative analgesics. Pain control makes the children calm without any irritability, sleep without insomnia and eat well.

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 the safety of TFP block as the needle visualization by ultrasound is very good in children.

The current study has few limitations. Firstly, we couldn’t 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. The intraoperative nociception can be measured using the anesthesia analgesia index by CE-certified PhysioDoloris monitor (MetroDoloris Medical...
Systems, Lille, France) and nociception level index measurement using PMD-200™ (Medasense Biometrics Ltd, RamatYishai, Israel) monitor [23]. Secondly, patient follow up was limited to the first postoperative 12 hour, as inguinal hernia repair is a day-case surgery and early discharge is recommended by our hospital policy. Thirdly, we didn’t assess the effect of TFP block on the incidence of chronic pain after inguinal herniorrhaphy in pediatrics, as this requires patient follow up for several months.

From the findings of our study, we concluded that, performing TFP block before surgical incision in children undergoing unilateral inguinal herniorrhaphy results in reduction of postoperative analgesics requirements, adequate postoperative pain control and good parent’s satisfaction. Ultrasound guidance makes TFP block an easy and effective peripheral nerve block.
References


Table 1. Patients characteristics and duration of surgery

<table>
<thead>
<tr>
<th>Variable</th>
<th>TFP block group (n=20)</th>
<th>Control group (n=20)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (month)</td>
<td>24 (12-54)</td>
<td>18.5 (12-60)</td>
<td>0.198</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>12.5 (10-19)</td>
<td>12 (8-25)</td>
<td>0.199</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>90.35±12.48</td>
<td>86.85±14.08</td>
<td>0.411</td>
</tr>
<tr>
<td>Gender (male/female)</td>
<td>18/2</td>
<td>18/2</td>
<td>1.000</td>
</tr>
<tr>
<td>Surgery duration (min)</td>
<td>40.9±7.99</td>
<td>42.25±6.74</td>
<td>0.567</td>
</tr>
</tbody>
</table>

Data are presented as median (minimum, maximum), mean ± SD (standard deviation), number (n). TFP; transversalis fascia plane.
Table 2. Intraoperative and postoperative variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>TFP block group (n=20)</th>
<th>Control group (n=20)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number &amp;% of patients with 20% increase in HR and MAP after incision</td>
<td></td>
<td></td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Intraoperative fentanyl consumption (μg/kg)</td>
<td>1.1±0.08</td>
<td>1.5±0.513</td>
<td>0.005*</td>
</tr>
<tr>
<td>Patients requiring rescue analgesia (n&amp;%)</td>
<td>3 (15%)</td>
<td>20 (100%)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Time to first rescue analgesia (h)</td>
<td>0 [0-0]</td>
<td>4.5 [1.5-6]</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Postoperative paracetamol consumption (mg/kg)</td>
<td>0 [0-0]</td>
<td>20 [10-30]</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Postoperative fentanyl consumption (μg/kg)</td>
<td>0 [0-0]</td>
<td>0 [0-1]</td>
<td>0.019*</td>
</tr>
<tr>
<td>Block related complications (n&amp;%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as mean ± SD (standard deviation), number (n) and percentage (%), median and interquartile range. TFP: Transversalis fascia plane; HR: Heart; MAP: Mean arterial blood pressure. * P <0.05 is statistically significant when compared with the control group.
<table>
<thead>
<tr>
<th>FLACC score</th>
<th>TFP block group (n=20)</th>
<th>Control group (n=20)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>At 30 min</td>
<td>1.5 [1-2]</td>
<td>3 [2-3]</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>At 2 h</td>
<td>1 [1-2]</td>
<td>3 [2-3]</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>At 4 h</td>
<td>1 [1-2]</td>
<td>3 [3-4]</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>At 6 h</td>
<td>1.5 [1-2]</td>
<td>4 [3.5-5]</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>At 9 h</td>
<td>1.5 [0.5-2.5]</td>
<td>3 [2.5-4]</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>At 12 h</td>
<td>1.5 [0-3]</td>
<td>3 [3-4]</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

Data are presented as median and interquartile range. TFP: Transversalis fascia plane. * P < 0.05 is statistically significant when compared with the control group.
Fig. 1. CONSORT (Consolidated Standards of Reporting Trials) flow chart outlining patients' enrollment, exclusion, randomization, group allocation, follow up and analysis. TFP: Transversalis Fascia Plane.
**Fig. 2A.** Ultrasound images of transversalis fascia plane before local anesthetic injection. EO: External Oblique Muscle; IO: Internal Oblique Muscle; TA: Transversus Abdominis Muscle; QL: Quadratus Lumborum Muscle; LA: Local Anesthetic.

**Fig. 2B.** 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.
Fig. 3. Five points Likert scale for evaluating parents' satisfaction. Data are presented as median and interquartile range. * P <0.05 is statistically significant when compared with the control group.