



ORIGINAL ARTICLE

The comparison of ultrasound-guided ilioinguinal/iliohypogastric nerve block and pre-incision wound infiltration for pediatric inguinal hernia repair: A prospective randomized clinical study

Pediatric inguinal herni onarımında ultrasonografi eşliğinde iliyoinguinal/iliyohipogastrik sinir bloku ile preinsizyonel yara yeri infiltrasyonunun karşılaştırılması: Prospektif randomize klinik çalışma

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Summary

Objectives: Inguinal hernia repair is one of the most common daily surgeries performed in pediatrics. This prospective randomized clinical trial aims to compare ultrasound (USG)-guided ilioinguinal/iliohypogastric (IL/IH) nerve block and pre-incisional wound infiltration (PWI) in terms of post-operative analgesia on pediatric unilateral inguinal hernia repair.

Methods: After receiving ethics committee approval, 65 children aged 1–6 years who had unilateral inguinal hernia repair were allocated to USG-guided IL/IH nerve block (group IL/IH, n=32) and (group PWI, n=33). In both groups, 0.5 mg/kg 0.25% bupivacaine+2% prilocaine mixture was used by calculating the volume as 0.5 mL/kg for the block and infiltration. The primary outcome was to compare both groups' post-operative Face, Legs, Activity, Cry and Consolability (FLACC) scores. The secondary outcomes included the time to first analgesic request and the total acetaminophen consumption.

Results: The FLACC pain scores at the 1st, 3rd, 6th, and 12th h were statistically significantly lower in group IL/IH than in group PWI (p=0.013, p<0.001, p<0.001, and p=0.037, respectively) (p<0.001). There was no difference between the groups at the 10th and 30th min and at 24 h (p=0.472, p=0.586, and p=0.419, respectively) (p>0.05).

Conclusion: USG-guided IL/IH nerve block in pediatric patients with inguinal hernia repair was found to be superior to PWI in terms of lower pain scores, less additional analgesia requirement, and longer first analgesia requirement.

Keywords: Ilioinguinal/Iliohypogastric; inguinal hernia; post-operative analgesia; ultrasonography; wound infiltration.

Özet

Amaç: İnguinal herni onarımı, pediatrikte en sık yapılan günlük ameliyatlardan biridir. Bu prospektif randomize klinik çalışma, pediatrik tek taraflı kasık fıtığı onarımında ultrasonografi eşliğinde iliyoinguinal/iliyohipogastrik (IL/IH) sinir bloku ve insizyon öncesi yara infiltrasyonunu (PWI) postoperatif analjezi açısından karşılaştırmayı amaçlamaktadır.

Gereç ve Yöntem: Tek taraflı inguinal herni onarımı yapılan 1–6 yaş arası 65 çocuğa ultrasonografi eşliğinde IL/IH sinir bloku (grup IL/IH, n=32) ve insizyon öncesi yara infiltrasyonu (grup PWI, n=33) uygulandı. Her iki grupta da blok ve infiltrasyon için hacim 0,5 mL/kg olarak hesaplanarak 0,5 mg/kg %0,25 bupivakain+%2 prilokain karışımı kullanıldı. Birincil sonuç, her iki grubun operasyon sonrası "Face Legs Activity Cry Consolability (FLACC)" skorlarını karşılaştırmaktı. İkincil sonuçlar, ilk analjezik isteğine kadar geçen süreyi ve toplam asetaminofen tüketimini içeriyordu.

Bulgular: Birinci, üçüncü, altıncı ve 12. saatlerde FLACC ağrı skorları grup PWI'ya göre istatistiksel olarak anlamlı derecede düşüktü (sırasıyla p=0,013, p<0,001, p<0,001 ve p=0,037) (p<0,001). Gruplar arasında 10. ve 30. dakika ile 24. saatte fark yoktu (sırasıyla p=0,472, p=0,586 ve p=0,419) (p>0,05).

Sonuç: İnguinal herni onarımı olan pediatrik hastalarda ultrasonografi eşliğinde IL/IH sinir bloku, daha düşük ağrı skorları, daha az ek analjezi gereksinimi ve daha uzun ilk analjezi gereksinimi açısından PWI'ya göre daha üstün bulundu.

Anahtar sözcükler: Iliyoinguinal/iliyohipogastrik; inguinal herni; postoperatif analjezi; ultrasonografi; yara yeri infiltrasyonu.

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Submitted (Başvuru) 08.12.2020

Revised (Revizyon) 21.03.2022

Accepted (Kabul) 08.04.2022

Available online (Online yayımlanma) 05.04.2023

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Introduction

Inguinal hernia repair is the most common surgical procedure in early childhood. Post-operative pain is an important problem in these children. Analgesics or local anesthetics given before surgical stimulation can prevent or reduce post-operative pain by reducing the excitability of the central nervous system.^[1,2] Oral or intravenous analgesics, surgical wound infiltration, caudal and lumbar epidural blocks, and peripheral nerve blocks are successfully used among the perioperative pain management options available today. Infiltration itself is widely used by pediatric surgeons, surgeons, and emergency physicians for skin laceration repair or minor superficial surgery. In addition, wound infiltration can provide reliable analgesia for superficial skin surgery.^[3] In recent years, ultrasound (USG) technology has been adopted as a gold standard for nerve localization in clinical anesthesia and is widely used in peripheral nerve block.^[4] USG-guided ilioinguinal/iliohypogastric (IL/IH) nerve block is successfully applied with general anesthesia for post-operative analgesia.^[5,6] There are very few studies in the literature comparing USG-guided IL/IH nerve block and local wound infiltration methods in children.^[7] Therefore, this prospective randomized clinical study was planned to compare the effects of pre-operative USG-guided IL/IH nerve block and pre-incisional wound infiltration (PWI) on pain management after pediatric hernia repair surgery. The primary outcome was to compare the post-operative pain levels of both groups. Secondary outcomes included the time to first analgesic request and the total acetaminophen consumption.

Material and Methods

Patient Eligibility

After receiving ethical committee approval (Ref no: 2020/14), the prospective, randomized clinical study was completed in the pediatric operating room of Selcuk University, School of Medicine, Anesthesiology and Reanimation Department. This study followed the ethics rules in the 1964 Declaration of Helsinki, which was amended in 2013, and informed consent was obtained from every participant. After obtaining the participants' parents' written informed consent, 70 patients aged 1–6 years whose American Society of Anesthesiologists' physical status (ASA PS) was I–II, who had been scheduled to undergo unilat-

eral inguinal herniotomy, were enrolled in the study. Exclusion criteria included patients with known allergy to study drugs, coagulopathy, local infection at injection sites, cardiac, neurologic, hepatic, and renal failure, previous inguinal surgery, and those whose pain scores could not be evaluated. Furthermore, the body mass index was $>30 \text{ kg/m}^2$.

Study Protocol

All patients were pre-medicated with 0.5 mg/kg of PO midazolam (Dormicum® 5 mg, İstanbul, Türkiye) approximately 30 min before induction of anesthesia. General anesthesia was induced with 6–8% sevoflurane in 50% nitrous oxide and 50% oxygen by a facemask. After establishing intravenous cannula access, propofol (Propofol-PF® 1%, Polifarma İlaç San, Tekirdağ, Türkiye) 2,5 mg/kg, fentanyl (Talinat® 0.1 mg, Vem İlaç San, İstanbul, Türkiye) $1 \mu\text{g/kg}^{-1}$ was given. An i-gel was placed after the patient was noted to be in an adequate depth of anesthesia. Anesthesia was maintained with at least 1.2 minimum alveolar concentration of sevoflurane and mixed 50% oxygen+air. Intraoperative monitoring included electrocardiography, heart rate, pulse oximetry, non-invasive blood pressure, and end-tidal carbon dioxide concentration. The skin incision was performed 15 min after the block was achieved. Failed block was defined as an increase in heart rate to more than 20% of baseline, movement at the time of skin incision, or pain (Face, Legs, Activity, Cry and Consolability=FLACC ≥ 4) on admission to the post-anesthesia care unit (PACU).

Randomization

The patients were randomly divided into two groups, the IL/IH nerve block (group IL/IH) and the group PWI according to the random list created using a computer randomization program (<http://www.randomization.com>). IL/IH nerve block was performed by the same experienced anesthesiologist who is experienced in USG-guided nerve blocks. Pre-incisional wound infiltration was also performed by the same experienced pediatric surgeon.

IL/IH Group

The abdominal anterior wall muscles were visualized in real-time using USG (Esaote MyLab 30 US, Florence, Italy) to reveal the targeted nerves (IL/IH nerves). Following aseptic preparation of the skin and linear probe, the probe was placed between the

anterior superior iliac spot and the umbilicus. Using a sonovisible 22-G 50-mm needle (Stimuplex® Ultra 360, B Braun Melsungen, Germany) with the 6–13 MHz in-plane method, a 0.5–1-mL 0.9% NaCl test dose was given first between the internal oblique and transversus abdominis muscles, and the needle location was confirmed. Then, a 50–50% local anesthetic mixture of 0.25% bupivacaine and 2% prilocaine was calculated from 0.5 ml/kg volume and injected between the internal oblique and transversus abdominis muscles after negative aspiration. A successful block was defined as confirmation of the correct position of the needle tip and the diffusion of local anesthetic around the IL/IH nerves under USG guidance or no incision site retraction to the skin incision and leg movements.

Pre-Incisional Wound Infiltration Group

In group PWI, before the beginning of the surgery, the infiltrations were performed subcutaneously 1.5 cm above the midpoint of the inguinal ligaments with 0.5 mg/kg 0.25% bupivacaine (Buvicaine® 0.5% Polifarma İlaç San, Tekirdağ, Türkiye)+2% prilocaine (Pricain® 2% Polifarma İlaç San, Tekirdağ, Türkiye) with 0.5 mL/kg volume by a pediatric surgeon.

Intraoperative Management

The skin incision was permitted 10 min after block/wound infiltration procedures in both groups. Increases in heart rate or mean arterial pressure to more than 20% of baseline or patient movement owing to the skin incision or during the intraoperative period, were considered signs of a failed block/wound infiltration or inadequate analgesia. In such a case, additional opioids were given intravenously, but the post-operative data of those patients were excluded from the statistical analysis.

Post-Operative Management and Data Collection

The patients were monitored in the PACU postoperatively. Demographic properties of the patients (age, weight, and sex), ASA status, duration and side of surgery, and duration of anesthesia were recorded. The parents were admitted to the PACU to decrease post-operative anxiety that the children might feel because they were in an unfamiliar environment. At the end of the surgery, the follow-up was taken over by an anesthesiologist who did not know the study groups. The patients were trans-

ferred to the PACU postoperatively and pain assessments were made at the 10th and 30th min, and then after 1, 3, 6, 12, and 24 h until discharge. Face, Legs, Activity, Cry and Consolability (FLACC) pain scores were used as pain assessment scores. The FLACC scale is used to assess pain for children aged 2 months to 7 years or individuals that are unable to communicate their pain. The scale is scored in a range of 0–10 with 0 representing no pain.^[8]

For rescue analgesia, an acetaminophen (Paranox-S® 120 mg, Biofarma İlaç Sanayi, İstanbul, Türkiye) suppository (15 mg/kg) was administered to the patients. Following rescue analgesic administration, pain scores of the patients with the rescue analgesia were recorded every 5 min to assess pain relief or the requirement for further rescue analgesic medications.

The first analgesic request time and the total amount of analgesia of patients who needed post-operative rescue analgesics were recorded. If present, local anesthetic toxicity, allergy, methemoglobinemia, bradycardia, hematoma or tissue edema, and post-operative vomiting and nausea were recorded as post-operative complications.

The anesthesiologist who performed the block and the surgeon who administered the infiltration were not present during the pain evaluation and data collection. The parents were not informed about the group in which they were included in the study.

Statistical Analysis

Statistical analyses were performed using the SPSS for Windows version 21.0 package program. Numerical variables were summarized with mean and standard deviation. The normality of numerical variable distribution was examined using the Shapiro–Wilk test. Student's t-test was used in independent groups to compare variables with normal distribution. The Mann–Whitney U-test was used for variables that did not provide normality. Comparisons between groups for continuous variables were evaluated using variance analysis. Related values were tested between groups using the Mann–Whitney U-test, and intragroup comparisons were realized using the Friedman test. $p < 0.05$ was considered statistically significant.

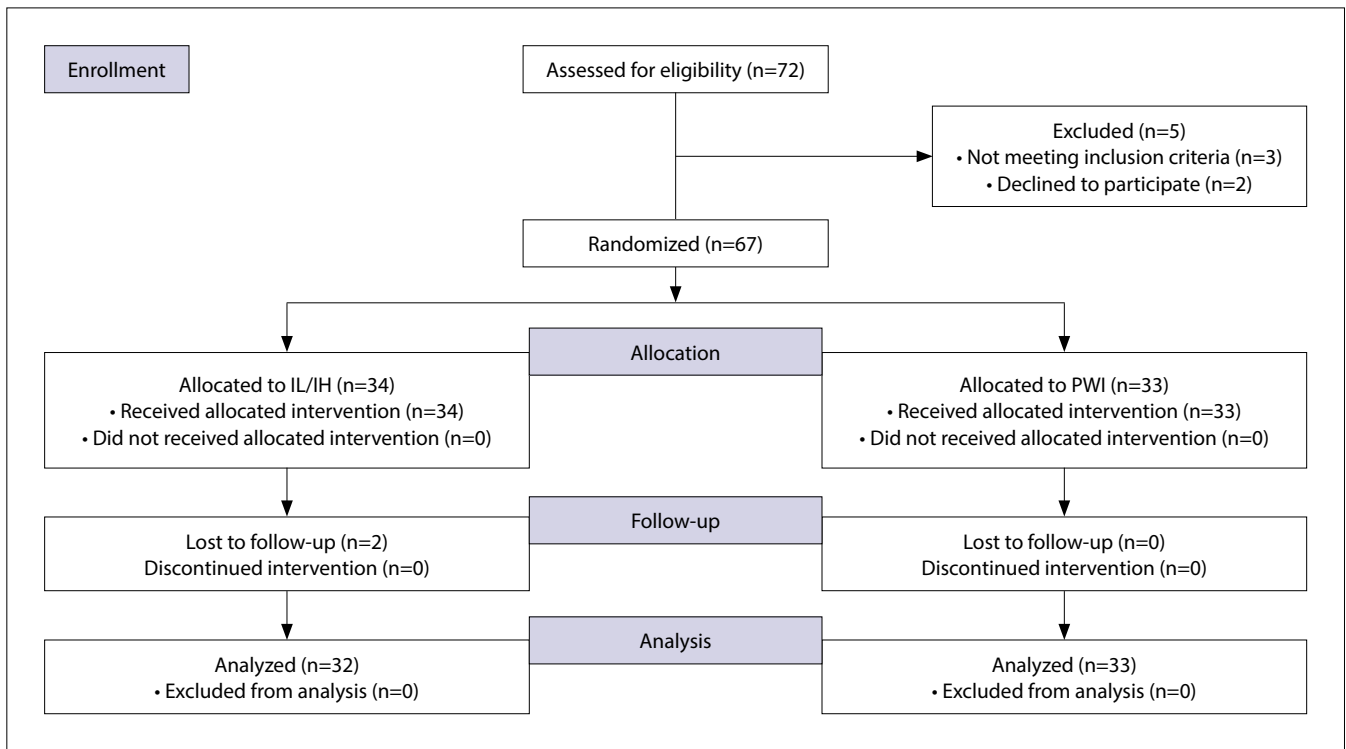


Figure 1. This randomization flow diagram displays the progress of all subjects throughout the study. IL/IH: Ilioinguinal/iliohypogastric nerve block; PWI: Pre-incisional wound infiltration.

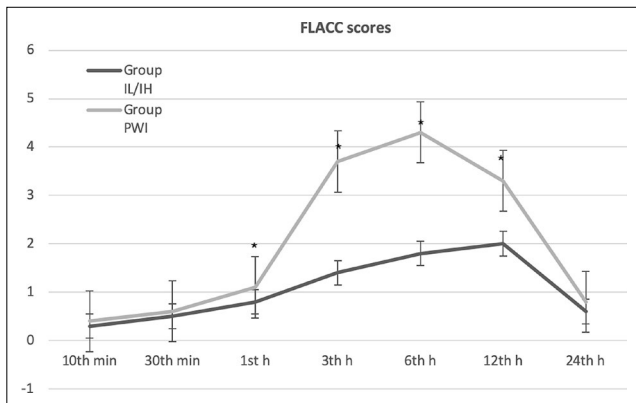


Figure 2. Comparison of post-operative FLACC scores at the time of both groups.

There was a statistical difference in FLACC scores between the groups according to the 1st, 3rd, 6th, and 12th h (p=0.013, p<0.001, p<0.001, and p=0.037, respectively).

Sample Size

Our study was designed to have a 95% power at the 5% significance level to detect a 25% decrease in the FLACC values at post-operative 24th h as reported by El-Emam et al.^[9] Based on the previous study evaluating FLACC values at post-operative 24 h in patients who had undergone pediatric inguinal herniotomy, we calculated that 33 patients for each group and a total of 66 patients were required considering possible dropouts. Allowing for a 10% dropout rate throughout the study period, a total of 72 patients were enrolled, 36 patients in each group.

Table 1. Sociodemographic and clinical data of patients

	Group IL/IH n=32	Group PWI n=33
Gender (F/M)	12/20	8/25
Age (year)	3.5±2.3	3.8±2.7
Weight (kg)	15.4±5.7	16.2±6.3
BMI (kg/m ²)	15.6±1.3	15.4±1.2
ASA I/II	29/3	30/3
Duration of anesthesia (min)	20.4±4.5	20.8±4.2
Duration of surgery (min)	15.9±3.4	16.2±2.9
Side of surgery (R/L)	17/15	20/13

Values are presented as means±standard deviation or number of patients. BMI: Body mass index; F: Female; M: Male; IL/IH: Ilioinguinal/iliohypogastric nerve block; PWI: Pre-incisional wound infiltration; ASA: American Society of Anesthesiologists. There was no statistical difference between the groups (p>0.05).

Results

Seventy-two patients were included in the study; seven patients were not eligible, and they were excluded from the study. In total, 65 patients were recruited in the study (CONSORT flow diagram is presented in Fig. 1). No significant difference was observed between the groups in terms of sex, age, weight, ASA status, duration of anesthesia/surgery, and side of surgery; both groups were similar (p>0.05) (Table 1).

Table 2. The first analgesic requirement time and the total amount of morphine consumed over the first 24 h after surgery

	Group IL/IH n=32	Group PWI n=33	p
The first analgesic requirement time (hour)	12.6±1.8	3.9±1.7	0.003
Total amount of acetaminophen consumption (mg)	235.0±55.5	737.1±135.3	<0.001

Values are presented as means±standard deviation. IL/IH: Ilioinguinal/Iliohypogastric nerve block; PWI: Pre-incisional wound infiltration. There was a statistical difference between the groups ($p>0.05$).

Post-operative pain was evaluated using the FLACC pain scale in the first 24 h. The FLACC scores are shown in Figure 2. Accordingly, although the FLACC pain scores at the 1st, 3rd, 6th, and 12th h were statistically significantly lower in group IL/IH than in the group PWI ($p=0.013$, $p<0.001$, $p<0.001$, and $p=0.037$, respectively) ($p<0.001$), there was no difference between the groups at the 10th and 30th min and the 24th h ($p=0.472$, $p=0.586$, and $p=0.419$, respectively) ($p>0.05$).

The times of the first requirement for analgesia in the IL/IH and PWI groups were 12.6±1.8 and 3.9±1.7 h, respectively. The difference between the groups was significant ($p=0.003$) (Table 2).

The total acetaminophen consumption was significantly lower in the IL/IH group than in the PWI group at 24 h postoperatively (235.0±55.5 vs. 737.1±135.3 mg; $p<0.001$) (Table 2).

There was no statistically significant difference between the groups in terms of post-operative complications ($p>0.05$).

Discussion

In this study, we found that USG-guided IL/IH nerve block delivered better analgesia in the post-operative period in inguinal hernia surgery compared with pre-incision wound infiltration until the post-operative 12th h.

Inguinal hernia repair is one of the most common daily surgeries performed in pediatrics. Adequate post-operative analgesia is essential for rapid mobilization and early discharge of the patient.^[10] Various methods have been adopted to reduce this pain, including parenteral opioids, non-steroidal anti-inflammatory drugs (NSAIDs), central neuraxial analgesia, caudal block, transverse plane (TAP) block, IL/IH nerve blocks, and wound infiltration with varying outcomes.^[11–14] In recent years, the introduction of USG into pediatric regional anesthesia has resulted in a breakthrough in

this field due to the superficiality of most nerves, especially in young children.^[15] In pediatric inguinal hernia repair, the success rate of IL/IH nerve block with USG guidance varies between 74 and 94.8%.^[16,17] Çanakçı et al.^[18] showed mean VAS values of post-operative pain as approximately 1.0 at various time intervals in an IL/IH block group, which was the control group in adult inguinal hernia surgeries, in the first 12 h post-operatively. Darcin et al.^[19] found VAS values between 1.2 and 1.86 in the bupivacaine group in IL/IH nerve block performed with two types of local anesthetic. 20. Abdellatif et al.^[20] reported that ilioinguinal block was an effective method for post-operative analgesia when compared with a caudal block in a clinical study in children. However, in a very recent study, it was shown that post-operative analgesia findings were similar between IL/IH nerve block and caudal block.^[21] Furthermore, they were shown analgesia time as 253±102.6 minutes. Sardar et al.^[22] reported that the first analgesic requirement was at 2.83±2.01 h in the IL/IH nerve block group, which was the control group. In that study, post-operative VAS values were higher in the IL/IH block compared with the other two groups. In our study, the FLACC values in the IL/IH nerve block group at 1, 3, 6, and 12 h with a statistical difference were 0.8±0.25, 1.4±0.19, 1.8±0.25, and 2.0±0.18, respectively. We believe that USG-guided IL/IH nerve block increases the success rate and provides better analgesia quality. In addition, the block also reduced the anesthetic volume and toxicity, as well as the risk of undesirable adverse effects.

The rigorous direct application of local anesthetics to each identifiable layer during the surgical procedure is very attractive for both the surgeon and the anesthesiologist, as it is a simple, effective, and inexpensive way to provide good analgesia.^[23] This procedure can be performed before (at the beginning of the surgery) or after (at the end of the procedure) the skin incision.^[24] It is stated that the application of pre-incisional local anesthetic as pre-emptive analgesia suppresses the hyperexcitability state re-

sponsible for post-operative pain by preventing nociceptive stimuli from reaching the central nervous system.^[25] A wound infiltration should include at least the skin and subcutaneous tissue but can be performed up to the parietal peritoneum.^[26] In our study, the infiltration of the local anesthetic solution was administered at the beginning of the surgery along all abdominal incision layers.

In previous studies, the effects of PWI application on post-operative analgesia were examined, and it was stated to be beneficial.^[27,28] In a previous study comparing caudal block with local wound infiltration, the two groups were similar in terms of the requirement for additional post-operative analgesia and the incidence of adverse effects.^[29] A meta-analysis showed that selected pre-emptive analgesia such as epidural analgesia, local wound infiltration, and systemic NSAID administration generally had a beneficial effect from traditional analgesic regimens.^[30] In a recent pediatric inguinal hernia repair study, Ahiskalioglu et al.^[31] showed an average of 5.9 ± 3.0 for pain scores in the PWI group up to the first 24 h postoperatively. In a recent study comparing wound infiltration and TAP block, the authors reported the mean pain scores in the PWI group mean mCHEOPS score=7.0, the time of the first analgesic requirement as 4.7 ± 1.6 h, and total acetaminophen consumption as 53.0 ± 6.4 mg/kg.^[32] In our study, FLACC values in the PWI group, the initial analgesia requirement time, and total acetaminophen consumption were similar to those of Sahin et al.^[32] The height of the FLACC values in the PWI group, the height in the total analgesic requirement, and the shortening of the time of the first analgesia may be due to insufficient analgesia owing to the blind injection to the non-target region such as the subcutaneous layer or muscle plane.

The use of opioid drugs in the treatment of post-operative pain has serious adverse effects such as sedation, nausea, and vomiting, which prolong hospital stay.^[33] In our study, nausea and vomiting were observed in one patient in the IL/IH group and two in the PWI group. None of the complications mentioned in the literature were observed in any other patients.

Our study has some limitations. First, because the effectiveness of peripheral nerve blocks under USG guidance depends on the operator's skills, the two main researchers supervised all regional blocks and

provided a homogeneous technique of each block in this study. However, these researchers were not blinded to the randomization. Nevertheless, the surgeons and pre-operative and post-operative evaluators were unaware of group allocation. Second, IL/IH nerve block and PWI-related sensory block levels have not been tested in all cases under general anesthesia. Instead of a direct sensory block evaluation, the success of all regional blocks was confirmed by stable hemodynamic parameters following a skin incision. Third, although the criteria for a successful block in our study were confirmation of needle tip position, local anesthetic diffusion on USG, absence of skin retraction at the incision site, and absence of leg movements, no unsuccessful blocks occurred in any patients in the PWI group. However, these visual criteria may not guarantee 100% success. In group IL/IH, a block did not occur in two patients. Our IL/IH nerve block success rate was 94.1%. Finally, the sample size of the study was not sufficient in terms of the complications of the study.

Conclusion

The findings demonstrated that USG-guided IL/IH nerve block in pediatric patients undergoing inguinal hernia repair compared with pre-incision wound infiltration has lower pain scores, less additional analgesia requirement, and longer times till the first requirement for analgesia.

Ethics Committee Approval: The Selçuk University Clinical Research Ethics Committee granted approval for this study (date: 30.04.2020, number: 2020/14).

Conflict-of-interest issues regarding the authorship or article: None declared.

Peer-review: Externally peer-reviewed.

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