Comparison of 3 different regional block techniques in pediatric patients

A prospective randomized single–blinded study

Levent Sahin, MD, Assoc. Prof., Mahmut H. Soydinc, MD, Elzem Sen, MD, Assist. Prof., Omer Cavus, MD, Mehrican Sahin, MD.

ABSTRACT

الأهداف : مقارنة فعالية مسكنات الاحصار العجزي والموجات الصوتية الموجّهة وكتل TAP وII/IH اجريت جميعها لتوفير تسكين بعد العملية الجراحية في الأطفال المرضى الذين يخضعون لعملية جراحة من جانب واحد أسفل البطن .

الطريقة : اجريت هذة الدراسة الاستطلاعية العشوائية مفردة التعمية في قسم طب الطوارىء، في كلية الطب، جامعة غازي عنتاب، غازي عنتاب، تركيا من يوليو 2013 إلى 2015. وكانت الجرعات المستخدمة على النحو التالي 0.5 ml/kg(المجموعة T) وفي(المجموعة I 0.3 ml/kg) وفي المجموعة C 0.7 ml/kg و 0.25% محلول ليفوبوبيفاكين مع 1/200,000 من الأدرينالين لكلا من TAP و II/IH كان الهدف الأساسي مقارنة استهلاك مسكن مابعد العملية الجراحية في غضون الاربع وعشرين ساعة الأولى بعد الجراحة .وكان الهدف الثانوي مقارنة نتيجة mCHEOPS والوقت اللازم للتسكين الأولي والعلامات الحيوية والآثار غير المرغوب فيها مثل الغثيان والقيء، والتي سجلت في جناح الجراحة في 1 و 4 و 8 و 16 و 24 ساعة بعد الجراحة .

النتائج : تم اختيار تسعين مريضاً بشكل عشوائي إلى ثلاث مجموعات بحسب نظام تصنيف الحالة البدنية التابع للجمعية الأمريكية لأطباء التخدير (المجموعة I, T, C). كان استهلاك المسكن في المجموعةI اعلى بكثير من المجموعتين الأخرين (0.003=p) وكانت درجات الألم خلال 1 و 4 و 8 ساعات أعلى بكثير في المجموعة الأولى مقارنة مع المجموعتين الأخرين ومع ذلك كانت درجات الألم في المجموعة الأولى خلال 16 ساعة أعلى بكثير بالمقارنة مع المجموعة C p<0.05

الخاتمة : كتل الاحصار العجزي و TAP اكثر فعالية من كتل II/IH العصبيه في وقت مبكر بعد الجراحة .

Objectives: To compare the analgesic efficiencies of caudal blocks, ultrasound (US)-guided transversus abdominis plane (TAP) blocks, and ilio-inguinal/ilio-hypogastric (II/IH) blocks performed to provide postoperative analgesia in pediatric patients undergoing unilateral lower abdominal surgery.

Methods: This prospective, randomized, single-blinded study was conducted in the Department of Pediatric Surgery, Faculty of Medicine, Gaziantep University, Gaziantep, Turkey from July 2013 to January 2015. The doses used were as follows: 0.5 ml/kg (group T), 0.3 ml/kg (group I), and 0.7 ml/kg (group C) of a 0.25% levobupivacaine solution with 1/200,000 adrenalin for the TAP block, II/IH block, and caudal block. The primary aim was to compare postoperative analgesic consumption within the first 24 hours after surgery. The secondary aim were to compare the mCHEOPS score, first analgesic requirement time, vital signs, and undesirable effects such as nausea and vomiting, which were recorded in the surgical ward at 1, 4, 8, 16, and 24 hours after surgery.

Results: Ninety patients with American Society of Anesthesiology physical status class I-II were randomized into 3 groups (group I, group T, and group C). The total amount of analgesic consumption was significantly higher in Group I compared with Groups T and C ($p=0.003$). Pain scores at 1, 4, and 8 hours were significantly higher in Group I compared with the other 2 groups; however, pain scores in Group I at 16 hours were significantly higher only compared with Group C ($p<0.05$).

Conclusion: Caudal and TAP blocks are more effective than II/IH nerve blocks in the early postoperative period.

Address correspondence and reprint request to: Dr. Omer Cavus, Department of Anesthesiology, The Ohio State University, Wexner Medical Center, Columbus, Ohio, United States of America. E-mail: omrcvds@gmail.com ORCID: http://orcid.org/0000-0002-2930-3975

Effective postoperative analgesia is as important in pediatric patients as it is in adults, due to of the potential benefits of reduced complications, early ambulation, and a shorter hospital stay. Different regional anesthesia techniques have been used to provide postoperative analgesia in infants and children. Caudal epidural block is currently the most common used method in pediatric patients; however, peripheral nerve blocks have gained popularity in recent years due to a lower incidence of side-effects compared with neuraxial techniques. With the introduction of ultrasound (US) into the practice of anesthesiology in the last decade, regional block techniques such as the transversus abdominis plane (TAP) and ilio-inguinal/ilio-hypogastric (II/IH) nerve blocks that are performed based on anatomical landmarks and not preferred earlier by the anesthesiologists have recently gained popularity. The TAP and II/IH nerve blocks are alternative methods to neuraxial blocks.[1] Although there are many studies on these techniques in the literature. The aim of the present study was to compare the analgesic efficiencies of caudal blocks, US-guided TAP blocks, and II/IH blocks performed to provide postoperative analgesia in pediatric patients undergoing unilateral lower abdominal surgery.

Methods. The present prospective, randomized, single-blinded study was conducted in the Department of Pediatric Surgery, Faculty of Medicine, Gaziantep University, Gaziantep, Turkey from July 1 2013 and January 13 2015, after obtaining approval from the Ethics Committee of Gaziantep University Faculty of Medicine (22.10.2013/357). The study included pediatric patients between 1-7 years of age with American Society of Anesthesiology (ASA) physical status of I-II, scheduled for elective unilateral lower abdominal surgery in the Department of Pediatric Surgery at Gaziantep University, for whom the parents provided a written informed consent. The study also adhered to the principles of the Declaration of Helsinki. Patients for whom the parents did not provide consent for the block method, those with an infection at the site of insertion, those with ages not within the specified age range, those using anticoagulants, those with coagulation disorders, and those who were allergic to local anesthetic agents or NSAIDs were excluded. The parents of pediatric patients, who were scheduled for unilateral lower abdominal surgery under elective conditions, were provided information regarding the study 45 minutes before the operation and their signed informed consent was obtained. The patients who were scheduled to undergo the operation were randomly divided into 3 groups. The recovery room nurse and data collector assigned to each patient were blinded to the group allocation. After routine assessment (monitoring of electrocardiogram, heart rate, non-invasive arterial blood pressure, and peripheral oxygen saturation) upon entrance to the operating room, peripheral venous access was established using a proper size intravenous catheter in patients who were able to cooperate with the operator.

After installing the venous access device, the patients were administered 2 mg/kg of propofol 1% (Propofollipuro 1% B. Braun, Melsungen, Germany). In uncooperative patients, anesthesia was induced with inhalation of a mixture of sevoflurane 8% (Sevorane®, Likid 100%, Queenborough, UK.), 50% air, and 50% oxygen and peripheral vascular access was established after induction. All patients received 0.5 mg/kg of atracurium (Neucurium vials 25 mg/2.5ml, VEM Pharmaceuticals, Istanbul, Turkey) to facilitate endotracheal intubation, which was performed using a proper-size intubation tube. The anesthesia was maintained using 60/40% air/oxygen mixture with 2-3% sevoflurane. Maintenance of intravenous fluid therapy was provided by 0.45% NaCl added to 5% dextrose solution (Izodex; Eczacıbası/Baxter, Istanbul Turkey) at an infusion rate of 10 mL/kg/hour. Before proceeding to surgery, arrangements were made to provide postoperative regional analgesia. All groups received 0.25% levobupivacaine (Chirocaine®, Abbott, Norway) added to 1/200,000 adrenaline at a dose of 0.5 ml/kg for the TAP block (Group T), 0.3 ml/kg for the II/IH block (Group I), and 0.7 ml/kg for the caudal block (Group C). All blocks were applied by LS (6 years of experience with regional block), ES (5 years regional block experience), or HS (3 years regional block experience). The patients who were to receive a TAP block were placed in the supine position and the lateral abdominal wall was prepared with povidone-iodine solution. In all patients, the operator remained at the side of the operation site and 10-18 MHz linear US (Esaote Mylab30; Esaote, Florence, Italy) probe covered with a sterile sheath was placed transversely on the hemi-abdominal wall between the costal margin and

iliac crest. The initial view was optimized by moving the probe in the cephalo-caudal or anterior-posterior direction, or changing the angle of the probe in order to acquire clear images of the 3 lateral abdominal wall muscles (the external oblique, the internal oblique, and the transversus abdominis). A 20-gauge, 50-mm needle was introduced and advanced anterior to the tip of the probe using the in-plane technique. After confirming the placement of the needle tip in the TAP with 0.5-ml local anesthetic injection, levobupivacaine 0.25% added to 1/200,000 adrenalin was injected at a dose of 0.5 mg/kg. The needle was removed after observing dispersion of the local anesthetic in the TAP, before proceeding with surgery.

For the II/IH block, the patients were placed in the supine position, and after skin preparation, 10-18 MHz linear US probe covered with a sterile sheath was placed obliquely on the hemi-abdominal wall between the anterior superior iliac spine (ASIS) and the umbilicus. The external oblique, internal oblique, and transversus abdominis muscles, and the peritoneum were visualized. The II/IH nerves were observed as 2 small, hypoechoic structures between the internal oblique and transversus abdominis muscle layers, approximately 6.7 mm away from the ASIS. A 20-gauge, 50-mm needle was advanced using the in-plane technique. After confirming the placement of the needle tip with a 0.5-ml local anesthetic injection, levobupivacaine 0.25% was injected at a dose of 0.3 ml/kg. The needle was removed after observing dispersion of the local anesthetic around the nerve, before proceeding with surgery. The patients undergoing a caudal block were placed in the left lateral decubitus position by pulling the knees toward the abdomen and forming a 90-degree angle. After skin preparation, the sacral horns and sacral hiatus were palpated. A 22-24-gauge sterile needle was introduced at an angle of 60 degrees to the skin in vertical axis, and advanced through the skin and subcutaneous fat tissue, and a typical pop was felt as the sacrococcygeal membrane was punctured. Then, the needle's angle was dropped to 30 degrees and it was advanced 3-5 mm into the epidural space. Aspiration was performed to check for the presence of blood or cerebrospinal fluid using a serum physiologic-filled syringe after which 0.25% levobupivacaine solution was injected into the epidural space at a dose of 0.7 ml/kg. The patient was then placed in the supine position to proceed with surgery. After completion of the surgical procedure, administration of anesthetic gases was discontinued and the patients were ventilated with 100% oxygen; neostigmine methylsulfate (Neostigmine

vials 0.5 mg/ml, Adeka, Turkey) at a dose of 0.05 mg/kg, and atropine sulfate (Atropin vials 0.5 mg, Biofarma, Turkey) at a dose of 0.015 mg/kg were administered intravenously to antagonize the neuromuscular block. The patients were extubated if respiration was deemed sufficient after restoration of spontaneous respiration with 97% oxygen saturation with room air. Type of surgery, total duration of surgery, and total duration of anesthesia were recorded.

Patients with an mCHEOPS score above 5 (range 1 to 10) were considered to require analgesics, and time from the beginning of the postoperative period to the first administration of analgesics was recorded as the time to first analgesic requirement. The patients requiring analgesics were administered paracetamol 15 mg/kg via the oral or rectal route. In case any of the patients had a pain score above 5, 30 minutes after paracetamol administration, they were administered IV morphine sulfate at a dose of 0.05 mg/kg. The patients experiencing nausea and/or vomiting were administered metoclopramide at a dose of 0.15 mg/kg. The primary outcome was the postoperative analgesic consumption after surgery within 24 hours. The secondary outcomes were the mCHEOPS score, first analgesic requirement time, vital signs, and undesirable effects such as nausea and vomiting; these were recorded in the surgical ward at 1, 4, 8, 16, and 24 hours after surgery.

Statistical methods. Based on our retrospective data, the minimum number of cases was calculated to be 24 cases per group at α = 0.05 level and power (1-β) of 0.80 in order to be able to find a statistically significant difference between Group T and Group C in terms of total amount of analgesic consumption. The Kolmogorov-Smirnov test was used to check whether continuous variables were normally distributed. The relationship between categorical variables was evaluated using the chi-square test and the relationship between numeric variables was tested using Spearman's rank correlation analysis. Descriptive statistics included frequency, percentage, mean±standard deviation, and median [25%-75%] values. Statistical Package of Social Sciences version 22 (IBM Corp., Armonk, NY, USA). was used in the statistical analysis and a *p*-value less than 0.05 was considered statistically significant.

Results. Of 90 patients evaluated, all were included in the study. Demographic data were not significantly different between the 3 groups (**Table 1**). Vital parameters (heart rate, systolic and diastolic blood pressure, respiratory rate per minute) were also not significantly different between the groups. There were no significant

differences between the 3 groups in terms of type of operation or duration of surgery (**Table 2**). There was no significant difference between Group T and Group C in terms of total amount of analgesic consumption (paracetamol) within 24 hours (primary outcome) (*p*=1.00), whereas the consumption was significantly higher in Group I compared with the other 2 groups (*p*=0.005) (**Table 3**). None of the patients included in the 3 groups needed morphine. There was no significant

difference between the groups in terms of time to first analgesic requirement (*p*=0.6) (**Table 4**). There was no significant difference between Group T and Group C when the mCHEOPS scores were compared at certain time points. Pain scores at 1, 4, and 8 hours were significantly higher in Group I compared with the other 2 groups; however, pain scores in Group I at 16 hours were significantly higher only compared with Group C (*p*<0.05) (**Figure 1**). There was no significant difference

Table 1 - Demographic data of the 3 groups (n=90).

Characteristics	Group T (n: 30)	Group I (n: 30) Mean± SD	Group C (n: 30)	*P*-value
Age (month)	42.50± 23.08	36.40 ± 23.98	32.60 ± 24.98	0.279
Weight (kg)	16.40 ± 7.94	14.83 ± 6.88	13.46 ± 6.95	0.299
ASA I	73.3 % (n: 22)	66.7 % (n: 20)	70 % (n: 21)	
				0.853
ASA II	26.7 % (n: 8)	33.3 % (n: 10)	30 % (n: 9)	

Group T: The Group of Transversus Abdominis Plane Block, Group I: The Group of Ilio-inguinal/Ilio-hypogastric Blocks, Group C: The Group of Caudal Block, SD - Standard Deviation, ASA - American Society of Anesthesiology, n - Number of Patients

Table 2 - Distribution of the groups according to operation type and duration of surgery.

Duration of and type of Surgery	Group T (n:30)	Group I (n:30)	Group C (n:30)	*P*- value
Duration of Surgery	63.83 ± 23.21	72.00±28.60	60.50±31.90	0.271
Operation Type				
Herniorrhaphy	12	12	9	0.426
Orchiopexy	10	6	8	0.162
Hydrocelectomy	5	7	6	0.344
Testicular detorsion	3	5	7	0.198

Table 3 - Total amount of analgesic consumption of the groups (mg).

Group T (n: 30) Mean ± SD	Group I (n: 30) Mean ± SD	Group C (n: 30) Mean ± SD	*P*-value
33.33 ± 91.28	99 ± 104.33 *	6.66 ± 36.51	0.003
* *p* <0.05 for group C and group T , Mean±SD - mean standard deviation			

Table 4 - Time to first analgesic requirement in the study groups (hour).

Group T (n:30) Mean ± SD	Group I (n:30) Mean ± SD	Group C (n:30) Mean ± SD	*P*-value
8.25 ± 10.59	9.15 ± 6.89	8 ± 0.00	0.0662
Mean±SD - mean standard deviation			

between the groups in terms of the occurrence rate of adverse events ($p > 0.05$) (**Table 5**).

Discussion. The present prospective, randomized, single-blinded study showed that II/IH nerve blocks produce higher pain scores and analgesic consumption in the early postoperative period compared to caudal and TAP blocks in pediatric patients undergoing elective lower abdominal surgery. Caudal anesthesia is the most common used regional anesthesia technique in children. It is a simple, safe, and effective technique in alleviating postoperative pain after infraumbilical procedures that can reduce the need for intraoperative anesthesia.[2,3] Furthermore, US-guided II/IH nerve
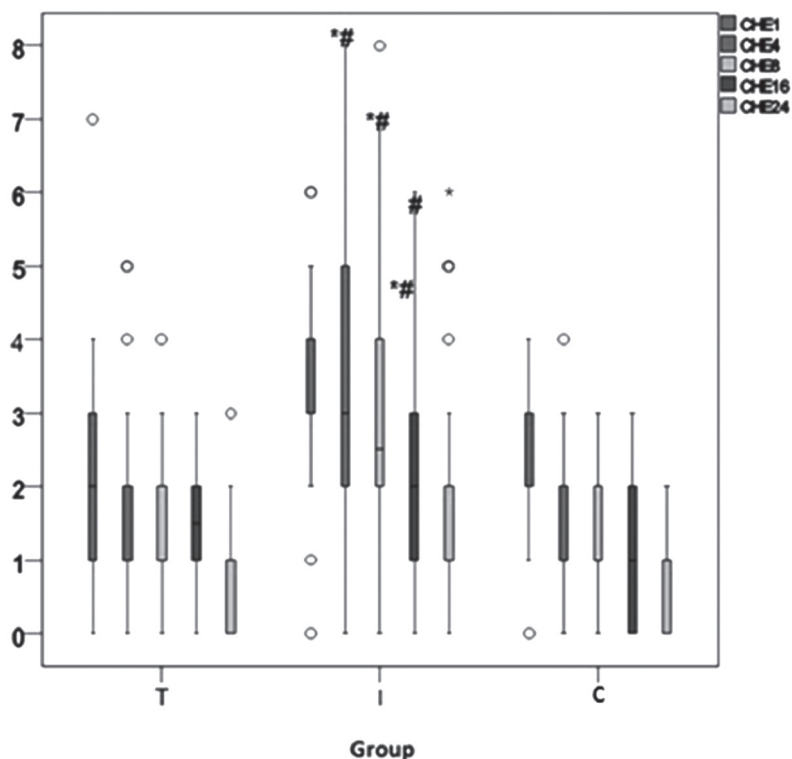

Figure 1 - Comparison of mCHEOPS scores in certain time frames between the groups, *Statistically significant difference between group I and group T, #Statistically significant difference between group I and group C.

Table 5 - Comparison of nausea-vomiting data between the groups.

Nausea-Vomiting	group T (n=30)	group I (n=30)	group C (n=30)	*P*-values
		(n) %		
1. hour	0 (n: 0)	6.7 (2)	0 (0)	0.129
4. hours	3.3 (1)	0 (0)	3.3 (1)	0.600
8. hours	3.3 (1)	6.7 (2)	0 (0)	0.355
16. hours	0 (0)	0 (0)	0 (0)	NA
24. hours	0 (0)	0 (0)	0 (0)	NA

block in addition to caudal block reduces the severity of postoperative pain in children undergoing inguinal surgery.[4]

A few studies have reported that caudal blocks and II/IH nerve blocks performed after general anesthesia are effective in postoperative pain control in children undergoing orchiopexy or herniorrhaphy, and no significant difference has been reported between these 2 techniques.[5,6] However, the doses used in those studies were different; they used 0.25% bupivacaine at a dose of 2.5 ml/kg in the caudal block group and 4-6 ml in the II/IH group. In these studies, a higher dose than suggested for II/IH blocks was used and lower doses were used for caudal blocks. It is possible that as different volumes were used in the present study, this study yielded different results.[5] Findlow et al[7] evaluated caudal block versus II/IH nerve block in children undergoing orchiopexy. They reported a considerably higher amount of analgesic requirement in the postoperative period in the II/IH block group. Although the volume of local anesthetic used was different from our study, concentrations of the anesthetics were similar and their results support our findings.

In another study, US-guided II/IH nerve blocks using low volume of local anesthetic were found to be as effective as caudal blocks in providing postoperative analgesia in children undergoing unilateral surgery in the inguinal region.[8] No significant difference was observed when time to first analgesic requirement was compared between the groups in the present study; however, group I required analgesia at an earlier point in the postoperative period compared with group C and the total amount of analgesic consumption was significantly lower in group C compared to Group I. The difference between the above-mentioned study and the present study is that a lower dose of local anesthetic (0.1 ml/kg) was used in the former, and all anesthesia procedures were conducted by the same anesthesiologist. In the present study, anesthesia procedures were conducted by 3 anesthesiologists and the difference between the anesthesiologists in terms of skill level or experience might have reduced success rates of the blocks. As II/IH nerve block is not a block of an area as is a TAP or caudal block, the II/IH block depends on the experience of the operator even if it is performed under the guidance of US.

There are many studies reporting effective analgesia with TAP blocks in infants, children, and adolescents undergoing any type of lower abdominal surgery.[9-11] Our findings suggest that a TAP block provides analgesia equivalent to that provided by a caudal block and there is no significant difference between these 2 methods in terms of analgesic consumption; TAP blocks could be used an alternative to caudal blocks in patients undergoing lower abdominal surgery for reducing both pain scores and 24-hour morphine consumption.[12,13] There are case series reporting the efficacy and safety of this analgesia technique not only in patients undergoing inguinal hernia surgery, but also in patients undergoing appendectomy.[14,15] In addition, many case reports about TAP blocks performed in unilateral[16] and bilateral[17] procedures and those performed in patients with VACTERL syndrome[18] and regarding TAP block catheters[19] provide sufficient evidence of effective postoperative analgesia in neonates.

Sahin et al[20] used bupivacaine 0.25% added to 1/200,000 adrenalin at a dose of 0.5 ml/kg under US guidance and evaluated TAP block versus infiltration anesthesia. They found that TAP blocks provided prolonged postoperative analgesia and reduced the amount of analgesic requirement in children undergoing unilateral inguinal hernia surgery, similar to the findings of our study. Avelin et al[21] evaluated TAP block versus II/IH nerve block in patients undergoing repair of inguinal hernia. Pain scores at 4, 12, and 24 hours, and postoperative morphine consumption were lower in patients who underwent a TAP block. Similarly, in the present study, the postoperative analgesic consumption was significantly higher in Group I compared with Group T. When the mCHEOPS scores of the groups were compared, there was no significant difference between group C and group T; however, the scores were significantly different at 1, 4, and 8 hours in group I compared with the other 2 groups. The scores were significantly different at 16 hours post operation only in group C. Frederickson et al[22] compared the analgesic efficiencies of US-guided II/IH blocks and US-guided TAP blocks in infants and children undergoing elective repair of inguinal hernia. In contrast to our study, pain scores and ibuprofen consumption were higher in the TAP block group and they reported that an ilioinguinal block provided superior analgesia compared to a TAP block. In the present study, time to first analgesic requirement was shorter in group I compared with group T, although the difference was not statistically significant. Total amount of analgesic consumption was significantly higher in group I compared with group T. Frederickson et al[22] used a local anesthetic volume of 0.3 ml/kg both in the II/IH block and TAP block. However, it is known that TAP block is a block of an area and the volume of the local anesthetic is the most important factor affecting success in regional blocks. We consider a local anesthetic volume of 0.3 ml/kg insufficient for a TAP block and this could explain

the unsuccessful outcomes observed in some studies; a volume of 0.5 ml/kg used in the present study would be more effective.

In a recently published study, the TAP block and caudal block were compared in children undergoing lower abdominal surgery. Although there was no significant difference in the rescue analgesia requirements, the number of children not requiring any rescue analgesia in the first 24 hours postoperatively was significantly higher in the TAP group. Caudal blocks provided a significantly prolonged duration of postoperative analgesia when compared with TAP blocks.[23] This report is similar to our report about level of effectiveness for TAP and caudal blocks.

When the literature on these 3 blocks is compared, the results obtained show a wide range of opinion. A few of the reasons for the variations in results are as follows: experience of the practitioners, type of surgery, differences in local anesthetics, difference in anesthetic doses and volumes, use of different pain scores, and the type of intraoperative opioids and their doses. In the present study, the use of 3 different local anesthetic volumes in the 3 techniques might be criticized. However, these 3 techniques produce nerve blocks in different locations and, therefore, require different local anesthetic volumes. We have selected the optimal local anesthetic volume for each technique in light of the current literature. Taylor et al[24] reported that use of levobupivacaine 0.25% in caudal anesthesia was effective and safe during the repair of inguinal hernia in patients less than 2 years of age. Many studies in the literature have used this drug concentration and the volume is determined according to the level of surgical incision. In the present study, we also provided effective postoperative analgesia using levobupivacaine 0.25%. We did not encounter serious complications in any of the 3 groups. There was no significant difference between the groups in terms of undesirable effects such as nausea and vomiting. The occurrence of nausea and vomiting was attributed to the use of inhalational anesthesia rather than to the technique of regional anesthesia. Authors have emphasized US-guided abdominal wall block as an effective regional anesthesia technique in providing successful postoperative analgesia in children undergoing abdominal surgery.[25,26] In the present study, we also used US guidance while performing the TAP block or II/IH block to reduce the risk of complications and increase the success rate of the procedure.

Pain assessment is more difficult in pediatric patients compared to adults. This is due to the inability to use some of the available methods of pain assessment in children, and this in turn becomes a challenge for providing effective pain control. The method must be selected based on the general condition of the child, age, and pain perception level. In addition, monitoring of the findings using standard parameters would increase the success rate of the diagnosis and pain treatment.[27] The mCHEOPS is a pain assessment table that has been shown to allow easy assessment of pain by doctors and nurses. The assessment of pain using the same method is important for the planning of therapy. In the present study, we preferred the mCHEOPS scoring as it allows easy, simple, and understandable assessment of the results. There are some limitations to this study. Our sample size is not large. There are likely to be different results in larger series. Additionally, the blocks were performed by 3 anesthesiologists with different experience levels, which could potentially have affected the duration of the blocks.

In conclusion, caudal blocks, II/IH nerve blocks, and TAP blocks provided effective postoperative analgesia; however, the caudal block was equivalent to the TAP block and superior to the II/IH block when compared by pain scores and total amount of analgesic consumed.

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Ethical Consent

All manuscripts reporting the results of experimental investigations involving human subjects should include a statement confirming that informed consent was obtained from each subject or subject's guardian, after receiving approval of the experimental protocol by a local human ethics committee, or institutional review board. When reporting experiments on animals, authors should indicate whether the institutional and national guide for the care and use of laboratory animals was followed.