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ARAŞTIRMA / RESEARCH

Ultrasound guided rectus sheath block vs intravenous tramadol on postoperative analgesia in children undergoing inguinal hernia repair

İnguinal herni cerrahisi geçiren çocuklarda ultrason kılavuzluğunda uygulanan rektus kılıf bloğu ile intravenöz tramadol'ün postoperatif ağrı üzerindeki etkilerinin karşılaştırılması

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Abstract

Purpose: Rectus sheath block is a regional anesthesia technique for postoperative pain control. We aimed to evaluate the effects of ultrasound-guided rectus sheath block on postoperative pain relief comparing with intravenous tramadol in children undergoing open inguinal hernia repair.

Material and Methods: Forty children, aged between 2-7 years, scheduled for inguinal hernia repair were enrolled into this prospective assessor blinded randomized study. Patients were allocated into one of two groups to receive ultrasound-guided rectus sheath block with a dose of 0.2 ml/kg, levobupivacaine 0.25% (group UR, n=20) or tramadol IV of 1 mg/kg (group T, n=20) under general anesthesia. The primary endpoint was the postoperative pain degree. Postoperative pain scores, sedation levels, supplemental analgesic requirements, and side effects were recorded.

Results: Pain scores were lower in group UR compared to group T at postoperative 5 min (UR 1.90 [95% confidence interval [CI], 1.05–2.74] vs T 5.50 [95% CI, 4.31–6.68; P < 0.001]), 15 min (UR 1.00 [95% CI, 0.27–1.72] vs T 4.65 [95% CI, 3.56–5.73; P < 0.001]), 30 min (UR 0.85 [95% CI, 0.08–1.61] vs T 3.05 [95% CI, 2.14–3.95; P < 0.001]) and 60 min (UR 0.20 [95% CI, -0.12–0.52] vs T 0.95 [95% CI, 0.41–1.48; P=0.008]). Fifteen patients required supplemental analgesic in group T whereas group UR patients did not require it.

Conclusion: Ultrasound-guided rectus sheath block produces an effective postoperative pain relief in children undergoing inguinal hernia repair surgery, noticeably for the first postoperative hour, compared with tramadol.

Key words: Children, inguinal hernia, levobupivacaine, tramadol, ultrasonography.

Öz

Amaç: Rektus kılıf bloğu postoperatif ağrı kontrolünde kullanılan bir rejyonal anestezi tekniğidir. Açık inguinal herni tamiri cerrahisi geçiren çocuklarda ultrason kılavuzluğunda rektus kılıf bloğu ve intravenöz tramadol'ün postoperatif ağrı üzerindeki etkilerini karşılaştırmayı amaçladık.

Gereç ve Yöntem: Genel anestezi altında inguinal herni cerrahisi geçirecek olan 2-7 yaşları arasındaki 40 hasta prospektif randomize çalışmaya dahil edildi. Hastalar iki gruba ayrıldı. Grup UR' deki (n=20) hastalara cerrahi öncesi 0,2 mg/kg dozunda %0,25 levobupivakain ile ultrason kılavuzluğunda rektus kılıf bloğu uygulandı. Grup T' deki (n=20) hastalara ise intravenöz 1 mg/kg tramadol uygulandı. Çalışmanın birincil sonucu postoperatif ağrı derecesidir. Postoperatif ağrı skorları, sedasyon seviyesi, ek analjezik gereksinimi ve yan etkiler kaydedildi.

Bulgular: Ağrı skorları 5. dakika (UR 1.90 [95% confidence interval [CI], 1.05–2.74] ; T 5.50 [95% CI, 4.31–6.68; P < 0.001]), 15. dakika (UR 1.00 [95% CI, 0.27–1.72] ; T 4.65 [95% CI, 3.56–5.73; P < 0.001]), 30. dakika (UR 0.85 [95% CI, 0.08–1.61] vs T 3.05 [95% CI, 2.14–3.95; P < 0.001]) ve 60. dakikada (UR 0.20 [95% CI, -0.12–0.52] vs T 0.95 [95% CI, 0.41–1.48; P=0.008]) Grup T'ye göre Grup UR'de daha düşüktü. Ek analjezik ihtiyacını Grup T'de 15 hasta gösterirken Grup UR'de hiçbir göstermedi.

Sonuç: İnguinal herni tamiri geçiren çocuklarda ultrason kılavuzluğunda rektus kılıf bloğu etkili postoperatif analjezi sağlar. Bu etki tramadol ile karşılaştırıldığında özellikle postoperatif ilk 1 saat boyunca daha belirgin ortaya çıkmaktadır.

Anahtar kelimeler: Çocuk, inguinal herni, levobupivakain, tramadol, ultrason.

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INTRODUCTION

RSB was first described by Schleich in 1899 to provide a muscle relaxation on the anterior abdominal wall[1]. Rectus sheath block (RSB) is a regional anesthetic technique to reduce postoperative pain after surgeries such as pyloromyotomy and umbilical hernia repair, which are performed through midline abdominal wall incisions[2-5]. Ultrasound guidance can be more advantageous to use in the rectus sheath block than the loss of resistance technique in pediatrics because the rectus sheath is close to peritoneal structures and the abdominal wall thickness is less in pediatric patients than in adults. Ultrasound-guided regional techniques may offer advantages including real-time observation of local anesthetic spread and accurate needle advancement between the tissue layers[6]. There are no reports in literature about the effect of RSB on postoperative pain in inguinal hernia repair (IHR) surgery. We hypothesized that the RSB would provide effective postoperative analgesia in children undergoing IHR.

Our aim was to compare the effects of an ultrasound-guided rectus sheath block (USRSB) with intravenous (IV) tramadol on postoperative pain control in children undergoing IHR to test our hypothesis. Primary outcome of the study was the postoperative pain level of patients assessed by the FLACC pain score system.

MATERIAL AND METHODS

The study protocol was registered at Clinical Trials.gov (Identifier: NCT02291705) on November 7, 2014. After obtaining approval from the Institutional ethics committee of Cukurova University approval (Decision number: 13 and Date: Oct 20, 2011) and written informed parental consent, forty children scheduled for IHR, aged 2-7 years, were included in this prospective randomized study. Exclusion criteria were American Society of Anesthesiologists (ASA) physical status III or greater, a history of long-term analgesic use, analgesic medication within 24 hours before surgery, bleeding disorder, presence of infection in the intervention area, limitations to the use of the ultrasound, and hypersensitivity to local anesthetics.

No premedication was given for all patients. After patients were taken to the operating room with their parents, systolic and diastolic blood pressure (SBP and DBP), electrocardiography, heart rate (HR), and peripheral oxygen saturation were monitored by Drager Primus anesthesia monitoring device (Draeger Medical Systems, Inc., Telford, PA, 18969 USA). Anesthesia induction was obtained using 3-5 mg/kg pentothal sodium. A laryngeal mask airway was inserted after obtaining adequate muscle relaxation with 0.1 mg/kg vecuronium bromide. Randomization was performed by a computer-generated randomization list. Patients were assigned to one of two groups to receive either a USRSB (group UR, n=20) or IV tramadol (group T, n=20).

In group UR, USRSB was performed with a 22-Gauge needle using an in-plane technique (with 12-15 MHz linear ultrasound probe, MyLab Five Esaote, Maastricht, The Netherlands) at level of umbilicus. At a dose of 0.2 mL/kg, levobupivacaine 0.25% was administered to the space between the rectus abdominis muscle and its posterior sheath with real time visualization by ultrasound. Anesthesia was maintained with a 5 L/min fresh gas flow and a 50% O_2, 50% N_2O, and 1-2% sevoflurane gas mixture. The sevoflurane level was adjusted to maintain heart rate and systolic arterial pressure within 20% of precision values. In group T, patients received a tramadol IV of 1 mg/kg before the fascia closure. At the end of surgery for all patients, the neuromuscular blockade was antagonized with 0.05 mg/kg atropine and 0.015 mg/kg neostigmine. The laryngeal mask airway was removed after sufficient spontaneous ventilation. Patients were taken into postoperative care unit with their parents. All records were performed an anesthesiologist who was blinded the intervention.

The primary outcome was the pain degree assessed by the FLACC (Face, Legs, Activity, Cry, and Consolability) pain score system.[7] The secondary outcome was sedation level determined by a five-point sedation scale (awake, mild, moderate, deep sedation, and unarousable, 0-4). If sedation score was two or more, it was considered as significant sedation level. SBP, DBP, HR, FLACC pain scores, sedation levels, supplemental analgesic requirements, and side effects such as respiratory depression, hypotension, bradycardia, and allergic reactions were recorded at 5, 15, and 30 minutes and 1, 2, 4, and 6 hours, postoperatively. For supplemental analgesia, a 15 mg/kg paracetamol IV was administered to patients who had >4 in FLACC scores in postoperative care unit. After being

discharged from the hospital, 15 mg/kg of paracetamol three times per day was recommended to all patients. The information about the presence of pain and side effects in the patients was recorded every four hours for 24 hours by phone.

Statistical analysis

A sample size calculation was performed using G*Power Version 3.1.9.2 for windows program (University of Kiel, Germany). On the basis of pilot study data in two groups of eight patients, mean and standard deviation of FLACC scores were 1.0 and 1.51 in group UR and 3.37 and 3.11 in group T, respectively. The minimum number of patients needed was 18 in each group with a power of 80%, a significance level of 0.05 and an effect size of 0.96. We recruited 20 patients per group to minimize the negative impact of data loss. Statistical analysis was performed using IBM SPSS statistical software version 22.0.

Categorical measurements were expressed as numbers (n) and percentages (%), whereas continuous measurements were reported as mean and standard deviation and as median and minimum-maximum if necessary. A chi-square test was used to compare categorical variables between the groups. For comparison of continuous variables between the groups, the Student's t-test or Mann-Whitney U test was used depending on whether the statistical hypotheses were fulfilled or not. To evaluate the change in the FLACC values, the Repeated Measurements Analysis was applied. The statistical level of significance for all tests was considered to be 0.05.

RESULTS

Forty-seven patients were assessed for eligibility, 40 patients were available for the study, 7 patients were excluded for such reasons as not meeting inclusion criteria (n=3) and refusal of participation (n=4) (Fig 1). There was no difference between the groups in terms of demographic data (Table 1). There was a significant decrease in pain scores over time for both groups. Pain scores were also lower in group UR compared to group T during the first postoperative hour (Fig 2). We found a significant reduction in terms of HR in group T compared with group UR in the postoperative first two hours at each time point (Fig 3). However, postoperative SBP and DBP measurements were similar in both groups (Figures 4 and 5). Patients did not require supplemental paracetamol in group UR at any time; however, 15 patients from group T received supplemental analgesic during the postoperative first 30 minutes. None of the patients required any other analgesic drug except for the paracetamol recommended after discharge. Sedation levels were similar in both groups ($p>0.05$).

Table 1. Demographic data of the groups

	Group UR (n=20)	**Group T** (n=20)	**P value**
Age (year)[a]	5.5±2.7	4.2±2.3	0.145
Sex (F/M)[b]	14/6	14/6	1.00
Weight (kg)[a]	19.2±6.4	18.6±9.3	0.597
Surgery time (min)[a]	42.8±20.2	47.3±26.8	0.428

Values are expressed as number of patients or mean ± standard deviation. [a] Mann-Whitney U test was used. [b] Chi-Square test was used.

DISCUSSION

In the present study, our results suggest that a preoperative USRSB provides more effective postoperative pain relief, particularly during the first hour after surgery, compared with IV tramadol administration. The USRSB has not been previously performed on children undergoing IHR for postoperative pain control. This is the first study indicating that RSB has a sufficient effect on pain control after IHR. Patients treated with a USRSB did not need to use analgesic drugs during the postoperative period, whereas 15 patients from the tramadol treatment group needed to supplemental analgesic administration.

RSB can be performed in surgeries with a midline abdominal wall incision including umbilical hernia repair[2,4,8,9], pyloromyotomy[10-12], laparoscopic surgery[13-15], and major abdominal surgery[16] to provide an effective postoperative analgesia. Several studies comparing the RSB with local anesthetic infiltration proposed that RSB has some significant advantages over local anesthetic infiltration for postoperative pain reduction[3,4,17,18].

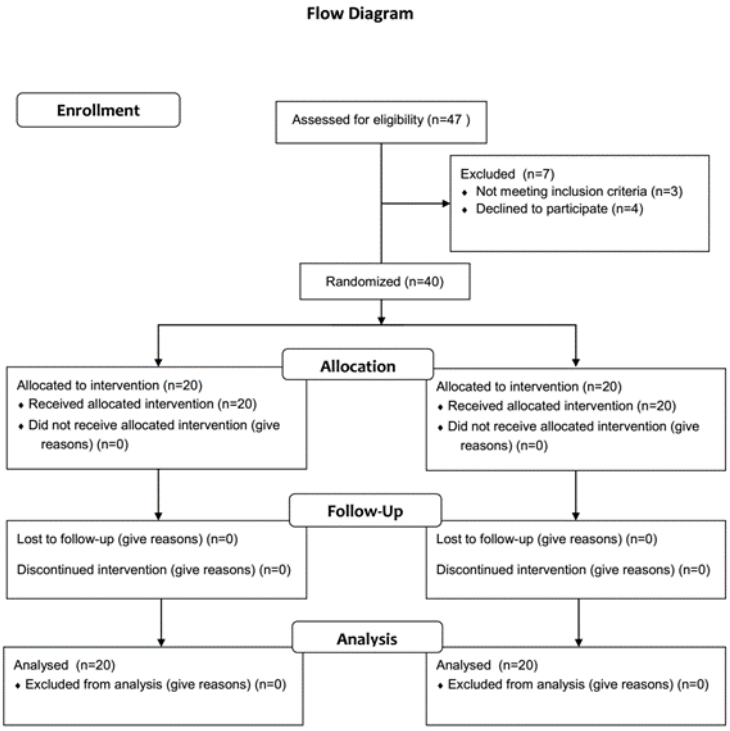

Figure 1. The flow diagram of the study.

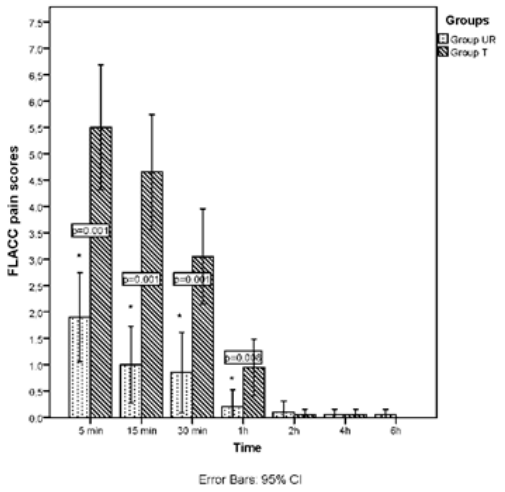

Figure 2. Postoperative FLACC pain scores

Bar graph shows mean FLACC score values (Error Bars: 95% CI). Data were compared using the Mann–Whitney U test. *p <0.05, compared with Group T. FLACC: Face, Legs, Activity, Cry, Consolability. Group UR (n=20), 0.2 ml/kg, levobupivacaine 0.25% by ultrasound guided rectus sheath block; Group T (n=20), tramadol IV of 1 mg/kg.

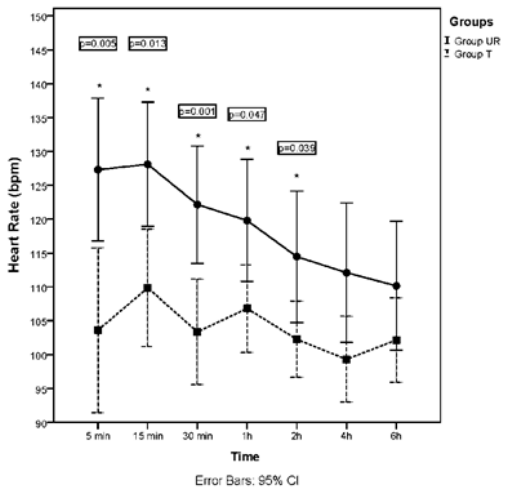

Figure 3. Mean heart rate (HR) values after surgery

(Error Bars: 95% CI).
* p <0.05, compared with group T. Mann-Whitney U test was used for statistical analysis.

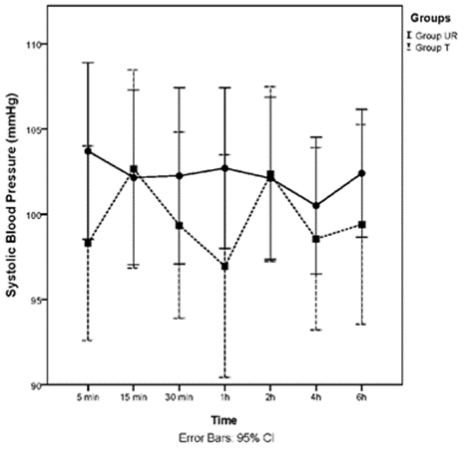

Figure 4. Mean Systolic blood pressure (SBP) values after surgery
(Error Bars: 95% CI). Mann-Whitney U test was used for statistical analysis. There was no statistically significant difference in SBP between the groups ($p > 0.05$).

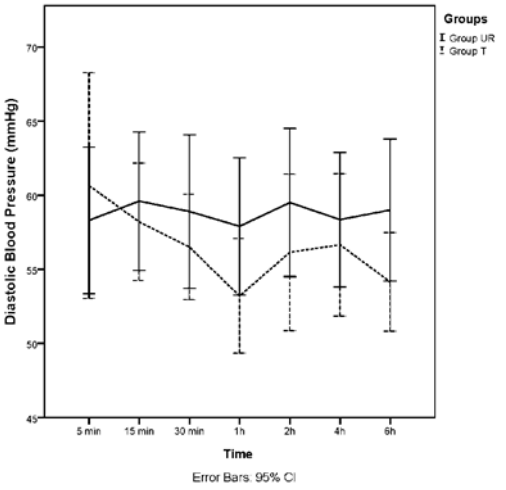

Figure 5. Mean Diastolic blood pressure (DBP) values after surgery
(Error Bars: 95% CI). Mann-Whitney U test was used for statistical analysis. There was no statistically significant difference in DBP between groups ($p > 0.05$).

However, a pilot study by Isaac et al. demonstrated that RSB has no superiority over local anesthetic wound infiltration for treatment of pain after umbilical hernia repair[19]. Similarly, Kumar et al. also found no difference between USRSB and local anesthetic infiltration in terms of postoperative pain relief in infants undergoing pyloromyotomy.10 Padmanabhan et al. stated that intermittent bupivacaine administration into the rectus sheath in midline laparotomy surgery does not decrease postoperative opioid consumption and pain scores[20].

Various local anesthetic agents have been reported for RSB in literature. Levobupivacaine is known to have less toxic effect on the central nervous and cardiovascular systems than bupivacaine[21]. A previous study used a dose of 0.1 ml/kg of levobupivacaine for bilateral USRSB in children undergoing umbilical hernia repair[3]. We did not perform a low flow anesthesia because the study included pediatric patients and we used laryngeal mask airway. Although it can be used with pediatrics and LMA, we did not consider to use low flow method in our clinical settings. For improved surgical settings during inguinal hernia repair, we administered vecuronium for muscle relaxation in the study whereas the requirement of neuromuscular blocker is generally less or absent to introduce a laryngeal mask airway device.

There are several limitations to our study. First, the rectus sheath is located at the midline of the abdominal wall, whereas the incision for inguinal hernia repair surgery projects a little outside of midline. For this reason, there is a risk that RSB may be ineffective in the inguinal region. However, our results do not support the existence of this condition. In this case, a possible muscle relaxation effect of local anesthesia on abdominal wall may be part of the pain-relieving effect[22]. Second, we did not investigate the complete distribution of local anesthetic drug over time. It would be beneficial to examine local anesthetic drug spreads using ultrasound to consider its action area. Third, patients were discharged after a six-hour follow-up period and thus our assessments were limited to the first postoperative six hours.

In conclusion, we found that USRSB reduces postoperative pain effectively in children undergoing IHR surgery, particularly in the first one hour after surgery, compared with IV tramadol administration. Further studies are needed to clarify the spread of

local anesthetic drug and its plasma concentrations for RSB.

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