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Original Article

Ultrasound-Guided Transverses Abdominis Plane Block versus Caudal Block for Postoperative Analgesia in Children Undergoing Inguinal Hernia Repair: A Randomized Controlled Trial

Yang Yang*, Ying Lin*, Yu-Sheng Yao, and Yan-Qing Chen

ABSTRACT

Background: This prospective double-blind, randomized controlled study compared ultrasound-guided transverses abdominis plane block (UTAP) and caudal block (CB) in pediatric patients undergoing inguinal hernia repair. We hypothesized that UTAP, compared with CB, could provide non-inferior analgesia in the first 24 hours post anesthesia.

Methods: A UTAP or CB was performed in patients as a component of multimodal analgesia. The time to use first rescue medication was estimated from intervention to 24 hours postoperatively as the primary outcome. The inferiority margin was -1 hour. If the lower limit of difference in the 95% confidence interval (CI) is greater than -1 hour, the non-inferiority is established. The secondary outcome included the number of patient not requiring rescue analgesia, the postoperative pain intensity, the incidence of emergence agitation, the residual motor block, the sedation score, and side effects.

Results: One hundred enrolled patients were randomized and assigned (1:1) into either the UTAP group or the CB group. In the first 24 hours post anesthesia, the time of first rescue medication was 6.1 hours in the UTAP group and 6.2 hours in the CB group (adjusted difference -0.5 hour; 95% CI -0.90-0.78 hour, P=0.039). Compared with the UTAP group, patients in the CB had a higher incidence of residual motor block. There were no significant statistical differences in the number of patient not requiring rescue analgesia, the postoperative pain intensity, the incidence of emergence agitation, the sedation score, and side effects between the two groups.

Conclusions: Compared with CB, the UTAP could provide non-inferior postoperative analgesia in the first 24 hours postoperatively. The UTAP is a safe and viable alternative in pediatric patients undergoing inguinal hernia repair.

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Regional anesthesia has been performed extensively for postoperative pain relief in pediatric patients (1), of which, epidural and caudal block (CB) are the most important techniques (2-4). Though CB has the advantages of simple operation, the short effective time for single CB still troubled the anesthesiologists. Comparing with peripheral blocks, local analgesics with larger amounts or concentration were performed to achieve a long-term effective analgesia, which potentially leads to a higher risk of side effect and toxicity (5).

The transversus abdominis plane (TAP) block is an alternative technique to central neuraxial block, which provides analgesic through injections between the internal oblique and transversus abdominis muscle. It was first described by Rafi in 2001 (6) and in 2007, Hebbard et al. (7) firstly conducted the ultrasound-guided TAP block (UTAP) for adults successfully. However, it was

not until 2009, the first report of UTAP for pediatric patients had been published (8). Following studies on the utility of UTAP, this technique has gradually been accepted as a cost-effective regional anesthesia technique for pediatric superficial hypogastrium surgeries, which is more effective and has lower incidence of motor block as a part of multimodal analgesia.

Though studies have demonstrated that CB and UTAP can provide sufficient analgesic after surgery (3, 9, 10), there has not been a study compared the analgesic effects of UTAP with CB under inguinal surgery. Thus we performed this prospective, randomized and double-blind study to verify the hypothesis that UTAP, compared with CB, demonstrated non-inferior analgesia in the first 24 hours post anesthesia.

METHODS

After ethical approval was obtained from the Medical Ethics Committee of Fujian Provincial Hospital, Fujian, China on 27 September 2011, this prospective, randomized, double-blinded, active controlled, and single-center trial study was conducted from October 2012 to March 2013. Our study was registered at www.clinicaltrials.gov (Ref: ACTRN12612001074886) and was in line with the principles of declaration of Helsinki and guidelines for Good Clinical Practice (GCP). One hundred and ten pediatric patients aged 2 to 5 years with American society of anesthesiologists (ASA) physical status class I-II who underwent selective unilateral inguinal hernia repair were included in our study. Exclusion criteria were coagulopathy, hypersensitivity to any local anesthetics, preexisting neurological disease, localized tissue infection and anatomical abnormalities.

Written informed consents were obtained from all guardians. Patients were randomized and assigned to either the experimental group (group UTAP) or active control groups (group CB) by a computer-generated random sequence. The allocation ratio was 1:1 for both groups. Group assignment was concealed by opaque sticking envelops which could only be opened by the anesthesiology in charge of the surgery, the patients, guardians, and investigator in the postanesthesia care unit (PACU) were blinded to group assignment.

All patients enrolled to our study received standard monitoring and general anesthesia regimen. Anesthesia was induced by sevoflurane, a laryngeal mask was placed to keep the airway unobstructed. Patients in the UTAP group were put in the supine position. After induction and sterilized, the abdominal wall was scanned by a probe moved anterolateral to lie cephalad of the iliac crest at the anterior axillary line. The block needle was introduced in an in-plane approach, and 0.4 ml/kg of 0.25% levobupivacaine was then injected. In the group CB, patients were positioned in the lateral position, with the right side uppermost and with the hip and knees flexed. A 22-gauge needle was inserted in the most proximal region of the sacral hiatus with 1 ml/kg of 0.25% levobupivacaine. Anesthesia was maintained by 2.5-3% sevoflurane, the concentration was adjusted to maintain autonomous respiration and normal end-tidal carbon dioxide tension ($ETCO_2$). After surgery, patient controlled intravenous analgesia (PCIA) with morphine was taken as postoperative analgesia from 0 to 24 hours postoperatively. According to the guardians' judgements, the patients received PCIA, which was set with no background infusion and a bolus dose of 20 μg/kg within 15 minutes lock out. During the time in PACU, patients' pain intensity, level of sedation and degree of motor blockade were assessed by a single investigator blinded to group assignment.

The primary outcome was the time to use first rescue analgesic, estimated from intervention to 24 hours postoperatively; if the children's and infants' postoperative pain scale (CHIPPS) (11) score was larger than 3, the first dose of morphine was used (first button press). The secondary outcome included the number of patient not requiring rescue analgesia, the postoperative pain intensity, the incidence of emergence agitation, the residual motor block, the sedation score, and side effects. Patients were interviewed at 0, 0.5, 1, 2, 4, 8, 24 hours to evaluate the postoperative pain intensity by CHIPPS. During the time in PACU, the level of sedation was assessed by the modified Ramsay score (12), and the incidence of emergence agitation was evaluated by the Pediatric Anesthesia Emergence Delirium Scale (PAED) (13). After regaining con-

sciousness, the degree of motor blockade was assessed by the modified Bromage scale (13) every 30 minutes for the first 2 hours, and hourly for the next 4 hours. Vital signs and side effects were assessed from intervention to postoperative 24 hours; the side effects included postoperative bradycardia, hypotension, hypoxemia, nausea and vomiting.

Our sample size was calculated based on the time to use first rescue analgesic. Allowing for a one-sided type I error of 5%, and a power of 80%, 88 patients were calculated to demonstrate non-inferiority between groups according to a margin of 1 hour and assuming a standard deviation (SD) of 2 hours (based on prior research). With a 10% loss to follow-up or drop-out, a total of 110 subjects were enrolled in this study

Statistical analysis was performed with SPSS 19.0 (SPSS Inc., Chicago, IL, USA). The normality of distribution was assessed by the Kolmogorov-Smirnov test. Parametric data were reported as means (SD) and analyzed with the independent t-test, and nonparametric data were reported as median (interquartile range [IQR]) and analyzed using the Mann-Whitney U-test. Categorical variables were analyzed by Fisher's exact test. The time to first rescue analgesia was calculated by Kaplan-Meyer plots. The differences between groups and time were measured by the repetitive measurement deviation analysis. Statistical significance was set at 0.05.

RESULTS

One hundred and ten patients were assessed to be eligible to participate in this study initially (Figure 1). Of these, eight patients did not meet the inclusion criteria, two declined to participate, and the remaining 100 patients enrolled in the study, their data were included in the analysis. Patient demographic characteristics, durations of procedures and anesthesia were with no statistically significant differences ($P>0.05$) between groups (Table 1).

Our primary outcome was presented in figure 2. Mean time to first rescue analgesic was 6.1 hours and 6.2 hours in UTAP and CB groups, respectively. The median of the adjusted difference between groups is - 0.5 hour (95% CI -0.90-0.78 hour). Considering that the lower limit is greater than -1 hour, the non-inferiority of UTAP was established.

Regarding the secondary outcomes, other

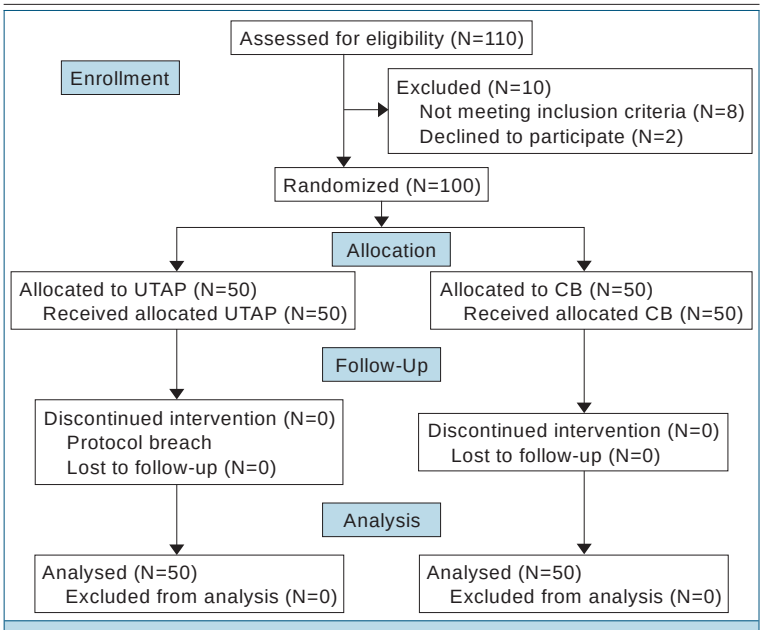

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) Flow Diagram Depicting the Progress of Subject through the Trail.

Table 1. Patient Characteristics and Operation Details.

	Group UTAP (N=50)	Group CB (N=50)	P value
Age (month)	31.3	32.9	0.063
ASA (I/II)	48/2	47/3	0.648
Height (cm)	94.6	95.4	0.326
Weight (kg)	13.7	13.9	0.409
Duration of surgery (minute)	115.0	113.0	0.487
Duration of anesthesia (minute)	132.3	131.6	0.815

Values were means (SD), median (IQR), or number (%). UTAP, ultrasound-guided transversus abdominis block.

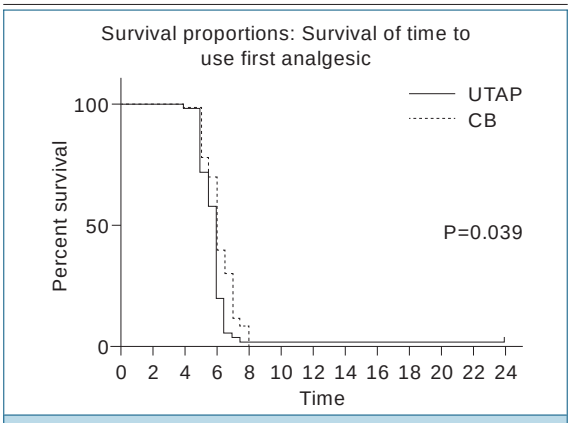

Figure 2. Survival of Time to Use First Analgesic.

Table 2. Secondary Outcomes.

	Group UTAP (N=50)	Group CB (N=50)	P value
Number of patients no need for rescue analgesic	1	0	0.317
Incidence of residual block	0/50	5/50	0.022
Sedation score	2 (2-2)	2 (2-2)	0.557
Incidence of emergence agitation	2/50	1/50	0.560
Pain intensity	3 (2-3)	2 (2-3)	0.067
Side effects			
Bradycardia	1/50	3/50	0.310
Hypotension	2/50	5/50	0.242
Hypoxemia	2/50	1/50	0.560
Nausea and vomiting	5/50	8/50	0.375

Values were means (SD), median (IQR), or number (%). UTAP, ultrasound-guided transversus abdominis block.

postoperative outcomes were presented in table 2. The number of patient not requiring rescue analgesia showed no statistical differences between groups, meanwhile the postoperative pain intensity showed no statistical significant differences between groups and time ($P>0.05$). Compared with group UTAP, the CB group had a higher incidence of residual motor block ($P=0.022$). No patient experienced deep sedation in our study and the incidence of emergence agitation were similar between groups ($P>0.05$). Additionally, side effects between groups were with no statistical significance ($P>0.05$).

DISCUSSION

This study demonstrated that UTAP is an alternative technique for pediatric inguinal surgery when compared with CB. The majority of our patients received appropriate analgesic (CHIPPS scores were less or equal to 3) in the first 24 hours post anesthesia. The UTAP exhibited non-inferiority to CB with regard to analgesic efficacy.

Different from the blind TAP block, the application of which was limited due to rough anatomical locations and uncertainty in block area, the UTAP had a more widespread utility and the safety has been improved significantly (9,14). As is shown in our study, the postoperative analgesic was proper, and no side effects have been demonstrated, which supports the notions that the more accurate positioning decreases the risk of damages to the structures in the vicinity of neurovascular tissues, and the more controllable, intuitionistic local analgesic spread potentially prompts lower volume and less toxicity (15).

Although the analgesic efficacy of UTAP has been proven, the duration of analgesia remains uncertain (16, 17). An important reason for the variability in analgesia efficacy is the unique anatomical characteristics. As the adult cadaveric studies showed, the ilioinguinal and iliohypogastric nerves were hardly located at the posterior approach level (18, 19), as with similar anatomical structures to the children, the classical approach seems not always produce anticipated analgesia for pediatric patients. To solve this problem, we place the UTAP probe cephalad of the iliac crest at the anterior axillary line in order to achieve a more extensive spread and a more sufficient analgesia, and as we expected, the non-inferiority to CB has been exhibited favorably.

Though the CB is considered to be the golden standard regional anesthesia technique for pediatric surgeries (20, 21), it has some contraindications in application, such as spinal deformities and coagulopathy. Considering these contraindications, UTAP should be a valuable alternative regional technique to CB, in view that the posture requirements for UTAP is lower and the puncture wounds are hardly affected by the coagulopathy even after cirrhosis and trauma (22, 23). Thus, we deem that UTAP is an optimal choice for ambulatory surgery and emergency operation without hematological examinations. In addition, compared with CB, UTAP is conducted with less local anesthetic. With a slower release and metabolism in blood, the risk of toxicity was reduced and a sufficient analgesia was applied for pediatric patients under inguinal hernia (24).

There are still some limitations in our study. Firstly, despite UTAP has been verified to provide non-inferior postoperative analgesia to CB in our study, whether the analgesic efficacy of UTAP is sufficient for extensive surgeries remains unknown, as the pain intensity after inguinal hernia is relatively slight. Secondly, in our study, the efficacy of TAP was exhibited confidingly to some extent, thus more experiments are needed to verify the external validity of TAP. Thirdly, the concentration of bupivacaine in our study is fixed, thus the merits and demerits between volume and concentration can't be de-

scribed clearly. Comparisons of the analgesic efficacy between the high-volume-low-concentration and the low-volume-high-concentration are required in the future.

In summary, this study verified that compared with CB, UTAP could provide non-inferior postoperative analgesia in the first 24 hours postoperatively. Further studies are required to find the optimal doses for different types of operation.

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The authors declare no other conflicts of interest.

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