Ultrasound-Guided Lumbar Plexus Block Reduces Emergence Agitation in Children Undergoing Hip Surgery: A Prospective Randomized Controlled Trial

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Research Article

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Abstract

Background

Emergence agitation (EA) is a common and challenging postoperative problem in children emerging from general anesthesia. It is associated with self-injury, increases stress on healthcare team members and postoperative maladaptive behavioral changes. However, no completely effective prevention has been found for EA. Pain is considered to be an important contributor to EA. Ultrasound-guided lumbar plexus block is a safe and effective anesthetic technique that can provide satisfactory pain relief in pediatric hip surgery. We aim to investigate the effect of ultrasound-guided lumbar plexus block on emergence agitation in children undergoing hip surgery.

Methods

This prospective, randomized, controlled study was conducted in children aged 1-6 yr undergoing elective hip surgery. Subjects were randomly assigned to receive either ultrasound-guided lumbar plexus block combined with general anesthesia (Group Block, n=60) or routine general anesthesia (Group Control, n=60). The primary outcome was the incidence of EA at 30 min after emergence from general anesthesia, assessed using the Pediatric Anesthesia Emergence Delirium (PAED) scale. The secondary outcomes included the incidence of severe EA, postoperative pain evaluated by the Children's Hospital of eastern Ontario Pain Scale (CHEOPS) and the incidence of postoperative adverse complications. PAED, CHEOPS were measured at 0, 5, 10, 20, and 30 min after emergence from anesthesia.

Results

The incidence of EA was significantly lower in Group Block than in Group Control [13.3% vs. 43.3%, odds ratio (OR) 0.201, 95% confidence interval (CI) 0.082 to 0.496, p<0.001]. Group Block had a lower incidence of severe EA than Group Control [3.3% vs. 18.3%, odds ratio (OR) 0.154, 95% confidence interval (CI) 0.032 to 0.727, p=0.019]. CHEOPS was lower in Group Block than in Group Control [mean (95%CI), 4.5(4.4-4.6) vs. 4.9 (4.8-5.0), p<0.001].

Conclusion

Ultrasound-guided lumbar plexus block could decrease the incidence and severity of emergence agitation in children undergoing hip surgery effectively.

Trial registration:

Chinese Clinical Trial Registry: ChiCTR-INR-17011525 (30/05/2017)
Background

Emergence agitation (EA) in young children, especially preschool-aged children, is a common and challenging problem in the early postoperative period, characterized by a series of presentations including non-purposeful movement, inconsolability, restlessness, thrashing and agitation[1]. The incidence varies from 10 to 80%[2]. Although EA is self-limiting and lasts for a short time about 30 min, EA causes self-injury of children, increases stress on healthcare team members [3, 4] and even leads to postoperative maladaptive behavioral changes[1, 5, 6], such as sleep disturbances, attention seeking and temper tantrums. The detailed mechanism remains unknown under this phenomenon. Consequently, it is recommended that EA should be considered as a ‘vital sign’ and has become heightened interest [1].

Various strategies have been proposed for the prevention of EA, including some pharmacological intervention and non-pharmacological strategies[1]. The most favorable prevention method is not currently available [7]. Many studies have found that different anesthetic techniques may influence the incidence and severity of EA[1, 8–10]. Nerve block has been shown to be beneficial in emergence agitation risk reduction[11]. Ultrasound-guided nerve block has become increasingly popular in pediatric orthopedic surgery in recent years, since it increases the safety and provides effective analgesia[12, 13]. Moreover, pain is considered as an important factor in EA[1]. Taken together, it is expected that ultrasound-guided nerve block has benefit on EA. To date, none of studies has assessed the effect of ultrasound-guided lumbar plexus block on EA.

Therefore, in this prospective, randomized and controlled study, we aimed to evaluate whether ultrasound-guided lumbar plexus block combined with general anesthesia would reduce the incidence of EA in children undergoing elective hip surgery.

Methods

Ethics approved and registration

This prospective, single-center, randomized, controlled trial was approved by the Ethics Committee of Shanghai Sixth People's Hospital affiliated to Shanghai Jiao Tong University and written informed consent was obtained from parents or guardians. The protocol was registered at the Chinese Clinical Trial Registry (http://www.chictr.org.cn/, Principal investigator: Hui Zhang, Registration number: ChiCTR-INR-17011525, Date of registration: 30/05/2017) and published [14]. The study complied with the Declaration of Helsinki and was monitored by the Good Clinical Practice (GCP) Unit at Shanghai Sixth People's Hospital affiliated to Shanghai Jiao Tong University. The study was conducted from May 2017 to February 2020 in Shanghai Sixth People's Hospital affiliated to Shanghai Jiao Tong University.

Inclusion and exclusion criteria

We screened a total of 126 children, aged 1 to 6 yr with the ASA physical status I or II scheduled for osteotomy for developmental dislocation of the hip. Exclusion criteria included contraindication for
lumbar plexus block, developmental delays, neurological or psychiatric disease, local infection at the needle entry point, coagulopathy, nerve injury, allergy to anesthetics and study medications, and lack of parental consent for the child's participation in the study.

**Randomization and blinding**

Randomization was based on computer-generated allocation and a randomization number was concealed in an opaque envelope. All participants were randomly assigned to either ultrasound-guided lumbar plexus block group (Group Block) or control group (Group Control) at a 1:1 allocation ratio after induction of general anesthesia. Anesthesiologist who performed intraoperative anesthetic care knew the assignment. Patients, parents, surgeons, assessment investigators, the medical staff who provided postoperative care in the post-anesthesia care unit (PACU), data collectors, and statisticians were all blinded to the group allocation. The nerve block details were recorded, kept in a sealed envelope and opened when medically necessary and at the beginning of statistical analysis.

**Conduct of the study**

Standard monitoring including electrocardiograph (ECG), non-invasive blood pressure (NIBP), pulse oximetry (SpO₂), end tidal carbon dioxide (ETCO₂), and temperature were applied after all participants entered the operating room. Anesthesia induction was carried out using midazolam (0.1mg·kg⁻¹), fentanyl (2μg·kg⁻¹), propofol (3mg·kg⁻¹) and vecuronium (0.1mg·kg⁻¹) administered intravenously. Patients were intubated endotracheally after the induction, and ETCO₂ was aimed at 35 to 40mmHg.

Patients in Group Control received a bolus injection of fentanyl 1μg·kg⁻¹ intravenously before skin incision.

Patients in Group Block received ultrasound-guided lumbar plexus block before skin incision. Ultrasound scans of lumbar plexus were carried out using the S-Nerve™ Ultrasound System (Sonosite Inc., Bothell, WA, USA) in patients assigned to Group Block. A linear array (6~13MHz) transducer was used to perform lumbar plexus block with the longitudinal approach. All nerve blocks in this study were performed by the same experienced anesthesiologist, who was qualified for ultrasound-guided lumbar plexus block. After induction, every patient assigned to Group Block was placed in the lateral decubitus position with the operative side upwards and the hips and knees flexed in order to enlarge interspinous spaces and provide better image of lumbar plexus. When transducer was placed 1.5~2 cm lateral to the midline of the patient's back and parallel to the long axis of the spine at the level L3-4, the lumbar transverse processes produced a ‘trident sign’[15]. Because the psoas major muscle is anterior to the transverse processes, the lumbar plexus was distinguished within the major psoas muscle. With ultrasound guidance, the block needle was advanced cautiously perpendicular to the skin until the needle tip was located 1-1.5 cm below the space between the transverse processes. All patients received 0.2% ropivacaine 1ml·kg⁻¹ (Naropin 10mg·ml⁻¹, Astrazeneca, Wilmington, DE, UAS)[16]. The maximum dose of ropivacaine was limited to 20 ml[16].
The success of lumbar plexus block was defined as follows: (i) visualization of the needle tip in the right position, the spread of local anesthetic around the lumbar plexus nerve; (ii) an increase of no more than 15% in heart rate, blood pressure in response to the skin incision; (iii) an increase of no more than 25% in heart rate, blood pressure during the operation[17]. Patients in Group Block were considered as failed blocks once one of the above criteria could not be met. The surgery was performed at least 15 min after the nerve block.

Anesthesia was maintained with 60% nitrous oxide, 40% oxygen and 2% end-tidal sevoflurane. The concentration of sevoflurane was added by 0.5% if the values of heart rate, blood pressure increased more than 15% from the baseline values during the operation. Conversely, the concentration of sevoflurane was reduced by 0.5% if the values of heart rate, blood pressure decreased more than 15% from the baseline values. If the increase was more than 25% from the baseline values, additional bolus of fentanyl 1μg·kg⁻¹ was administered. Patients recorded as a failure or a inadequate lumbar plexus block were followed up. Intention-to-treat analysis was used to analyze data including failed block.

**Intraoperative anesthetic management and postoperative assessments**

During the operation, if the heart rate reduced to less than 50 beats per min, atropine 10μg·kg⁻¹ was used. Ephedrine 0.1mg·kg⁻¹ was used to treat hypotension when blood pressure decreased more than 25% from the baseline value. At the end of the operation, sevoflurane and nitrous oxide were discontinued and oxygen flow was increased to 6l·min⁻¹. Patients were transferred to PACU and monitored until the end of the study.

Intraoperative data collection included heart rate, blood pressure, respiratory rate, concentration of sevoflurane, and fentanyl dose. The average value of end-tidal sevoflurane concentration (EtSev%) was calculated from all values recorded every 5 min throughout the operation.

After extubation and emergence, a blinded well-trained observer performed all assessments. EA was assessed by PAED scale[18] at 0, 5, 10, 20, and 30 min after emergence. We defined EA as PAED score≥10[18, 19]. Severe EA was defined as PAED score≥13[18] and treated with a bolus of fentanyl 0.5μg·kg⁻¹ [8,18]. The primary outcome was the incidence of EA 30 min after emergence from anesthesia. Postoperative pain at 0, 5, 10, 20, and 30 min after emergence was evaluated by the CHEOPS scale[20]. Patient with CHEOPS>7 was treated with a bolus of fentanyl 0.5μg·kg⁻¹ [8,18].

Emergence time (from discontinuation of sevoflurane to the first response to a simple verbal command), extubation time (from the end of anesthesia to extubation), intraoperative collective fentanyl rescue dose, adverse effects and complications were recorded.

At the end of study, that is, 30 min after emergence, the patients were given nurse controlled analgesia (NCA) with morphine. Bolus dose is 10 μg·kg⁻¹, lockout interval 30 min and background infusion is 10 μg·kg⁻¹·h⁻¹.
**Statistical Analysis**

The incidence of EA for pediatric hip surgery was approximately 42% in our pilot study. Therefore, a minimum sample size of 60 patients in each group would have 90% power to detect an absolute reduction of 15% in the incidence of EA in the intervention group at a significance level of 0.05, considering a possible dropout rate of 10%.

Categorical variables such as the incidence of EA and severe EA were expressed as frequencies (percentage) and analyzed with Chi-square test or Fisher's exact test. One-way Repeated-measures ANOVA or Generalized estimated equation (GEE) was applied to analyze data for PAED and CHEOPS according to the test for normality and homogeneity of variance. Continuous variables with a normal distribution were summarized with mean (standard deviation, SD) and were analyzed with an independent-sample *t* test.

The level of significance for each test was set at $\alpha=0.05$, 2 tailed. All data were subjected to the Kolmogorov-Smirnov test for normality. All data were analyzed with SPSS 23.0 (IBM SPSS Statistics for Windows, Version 23.0; IBM Corp., Armonk, NY). Intention-to-treat strategy was performed in every case.

**Results**

A total of 120 subjects were randomly assigned to two groups (n=60 per group) and completed the study (Fig. 1). All children in Group Block received an effective lumbar-plexus block, as evidenced by the fact that all criteria for a successful block were met in each case. Table 1 shows patients baseline demographics and clinical characteristics. There were no significant differences between groups.

| Table 1 | Patients baseline demographics and clinical characteristics |
|---------|-------------------------------------------------------------|
|         | **Group Block** (n=60) | **Group Control** (n=60) | **P-value** |
| Age(years) | 4.1(0.94) | 4.0(0.91) | 0.92 |
| Weight(kg) | 16.5(1.9) | 16.7(1.7) | 0.66 |
| Sex (male/female) | 27/33 | 30/30 | 0.58 |
| ASA classification (I/II) | 60/0 | 60/0 | NA |
| mYPAS | 8.2(1.6) | 7.9(1.2) | 0.17 |
| Duration of surgery (min) | 115.3(6.9) | 116.1(5.9) | 0.51 |
| Duration of anesthesia (min) | 142.6(5.1) | 143.4(4.8) | 0.43 |

Data are presented as mean (standard deviation) or number of patients. mYPAS, modified Yale Preoperative Anxiety Scale; ASA, American Society of Anesthesiologists.
For the primary outcome, there was a significant difference between the two groups in the incidence of EA 30 min after emergence from anesthesia, with a lower incidence in Group Block than in Group Control [13.3% (8/60) vs. 43.3% (26/60), odds ratio (OR) 0.201, 95% confidence interval (CI) 0.082 to 0.496, p<0.001, Fig. 2]. Similarly, the percentage of patients with severe EA was significantly lower in Group Block than in Group Control [3.3% (2/60) vs. 18.3% (11/60), odds ratio (OR) 0.154, 95% confidence interval (CI) 0.032 to 0.727, p=0.019, Fig. 2].

A generalized estimated equation was applied to analyze data for PAED, showing that lumbar-plexus block was associated with a decrease in PAED scores (Wald $X^2=19.7$, p<0.001, Table 2). Subjects in both groups had the highest PAED scores at emergence and trended down to below 5 at 10 min after emergence. CHEOPS was analyzed by a generalized estimated equation, showing a significant difference between groups (Wald $X^2=50.3$, p<0.001, Table 2).

| Variable                        | Group Block (n=60) | Group Control (n=60) | P-value |
|---------------------------------|-------------------|----------------------|---------|
| Mean PAED (mean, 95% CI)        | 5.7 (5.3-6.1)     | 6.9 (6.6-7.3)        | <0.001  |
| Mean CHEOPS (mean, 95% CI)      | 4.5 (4.4-4.6)     | 4.9 (4.8-5.0)        | <0.001  |
| Post-anesthesia complications   |                   |                      |         |
| PONV (n)                        | 1                 | 2                    | 0.559   |
| Desaturation (n)                | 1                 | 3                    | 0.309   |
| Laryngospasm (n)                | 0                 | 0                    | NA      |
| Emergence time (min) (mean, SD) | 11.7 (2.0)        | 18.3 (2.5)           | <0.001  |
| Extubation time (min) (mean, SD)| 16.8 (2.4)        | 23.8 (2.4)           | <0.001  |
| NA, not applicable; PONV, Postoperative nausea or vomiting. |

The average value of end-tidal sevoflurane (EtSev%) in Group Block was significantly less than in Group Control [2.10 (0.15) vs. 2.9 (0.34), p<0.001, Fig. 3]. In summarize, total fentanyl dose ($\mu$g·kg$^{-1}$) was significantly less in Group Block than in Group Control [2.1 (0.15) vs. 5.2 (0.62), p<0.001, Figure 3]. Significantly fewer patients in Group Block need fentanyl rescue in PACU compared to Group Control [12% vs. 30%, odds ratio (OR) 5.2, 95% confidence interval (CI) 1.9 to 14.1, p=0.001].

There was no case treated with atropine or ephedrine. In Group Control, two cases of blood pressure decreased more than 15% and less than 25% from the baseline values. The concentration of sevoflurane was reduced by 0.5%. No significant difference was observed in the incidence of postoperative adverse events between the two groups (Table 2). There was no case of local anesthetic intoxication and nerve
damage in Group Block. Emergence time and extubation time were significantly shorter in Group Block than in Group Control (Table 2).

**Discussion**

This prospective, randomized and controlled study revealed that ultrasound-guided lumbar plexus block could decrease the incidence and severity of EA effectively and offer better analgesia in children aged 1-6 yr undergoing elective hip surgery. Furthermore, ultrasound-guided lumbar plexus block reduced the use of fentanyl and sevoflurane.

The exact etiology of EA remains unclear [1]. Amongst numerous factors associated with EA, pain plays an important role in EA. Adequate analgesia can contribute to a decrease of EA. According to several reports, nerve block can provide satisfactory analgesia [12, 13, 15, 21]. The effect of nerve block on EA remains uncertain since previous studies have not been consistent [1]. Some previous studies have reported nerve block can reduce the incidence of EA [8, 9]. The primary reasoning behind its benefit was providing satisfactory postoperative analgesia and the evident reduction in sevoflurane [8]. In contrast, Ohashi et al. [17] found ilioinguinal/iliohypogastric block does not affect the incidence of EA. Ohashi et al. [17] attributed such result to the fact that the type of operation was minimally invasive and they thought ilioinguinal/iliohypogastric block would be more useful for invasive surgery. In this study, we chose osteotomy in children with developmental dislocation of the hip which is not only a common pediatric procedure but also associated with intense pain. Most previous studies about the effect of nerve block on EA were limited in short-term procedures with minimal to moderate postoperative pain and several superficial nerve [8, 9, 17]. Our study aims to assess the effect of lumbar plexus block, a relatively deep procedure, on EA after long-term surgery. Ultrasound technology has revolutionized pediatric anesthesia, and ultrasound-guided nerve block has increased in popularity in pediatrics because of its efficacy [16, 22]. The results demonstrated when ultrasound-guided lumbar plexus block was applied, the incidence and severity of EA in children undergoing hip surgery were indeed reduced. Meanwhile, Group Block had lower pain scores and less total fentanyl consumption than did Group Control. According to previous reports, nerve block decreased the incidence of EA by providing effective analgesic properties [8, 9]. Our results and above literature are consistent. Patients need fentanyl rescue were significantly fewer in Group Block compared to Group Control. We assumed that better analgesic effect of ultrasound-guided lumbar plexus block might be a major factor reducing the incidence of EA. Emergence time and extubation time in Group Block were shorter than in Group Control. The reason may be lumbar-plexus block reduces the use of fentanyl.

Distinguishing between pain and emergence agitation is challenging [1]. Pain may remain a confounder in studies of EA in patients who are likely to experience postoperative pain. We use PAED which is currently the standard to diagnose EA in children [11]. Considering fentanyl is considered as a first-line agent with respect to PAED [11], we use fentanyl as rescue medication for agitation [8, 18]. To minimize the confounding effect of pain on EA, we used sufficient fentanyl to ensure adequate analgesia in both groups. Patients with a CHEOPS score of >6 were considered to have pain [23]. Our results showed mean
CHEOPS scores were lower than 6 in both groups, indicating that patients received effective pain relief and patients of EA were experiencing EA instead of pain.

The PAED score was validated to reflect the presence of EA. Generalized estimated equation analysis for PAED showed the lumbar plexus block was associated with a decrease in PAED score. Our study showed a downward trend of PAED after emergence, which is in agreement with the study of Frederick et al [24]. PAED scores peaked at emergence and declined to below 5 at 30 min after emergence in both groups, this result confirmed that EA is self-limited and lasts for a short time about 30 min.

The use of sevoflurane has been associated with a high incidence of EA [11]. Data from clinical studies suggest that intrinsic effect of sevoflurane is associated with EA [25–27] and dose reduction of sevoflurane might be a major contributor for reducing the incidence of EA [19]. As a consequence, reducing the use of sevoflurane is strongly considered in children with a high risk of EA [11]. The average value of end-tidal sevoflurane concentration in Group Block was significantly lower than in Group Control in our study. Ultrasound-guided lumbar plexus block reduced the amount of sevoflurane. Thus, the decreased amount of sevoflurane could be another mechanism by which lumbar plexus block reduces the incidence of EA. Recent studies [28, 29] have reported that nerve blockage might attenuate postoperative inflammation to improve postoperative cognitive impairment. This could also be a potential mechanism of effect of lumbar plexus block on EA in our study, which needs to be defined in further studies.

Whatever the mechanism of lumbar plexus block on EA, lumbar plexus block provides better control of pain and reduction of sevoflurane use and hence ameliorates EA.

Although benefits of ultrasound-guided lumbar plexus block on EA were achieved by this prospective, randomized study, there are several limitations in our study. Our study was limited to 30 minutes after emergence because EA lasts for a short time about 30 minutes mostly. Further study is required to elucidate if lumbar plexus block could improve long-term effect especially maladaptive behavior [1]. The second limitation is that the target lumbar plexus would be more precise if ultrasound guidance was combined with nerve stimulation. However, this limitation may be offset somewhat because the ultrasound landmarks of lumbar plexus in children are more easily identified when compared with adults. To this end, we drew up a standard procedure of nerve block and could ensure satisfactory regional block in our study.

**Conclusion**

In conclusion, our findings indicate that the incidence and severity of EA in children undergoing hip surgery were decreased when applying ultrasound-guided lumbar plexus block. Lumbar plexus block is a potential practicable technique for the prevention of EA in pediatrics after general anesthesia.

**Abbreviations**
Declarations

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Authors’ contributions

HZ, JFZ, TX, QF, AZW contributed to the study’s conception and design. QF and AZW performed coordination of the study. XFW and TX conceived the study. Data collection was performed by HY and YZC. Data analysis was performed by YGY and HY. The first draft of the manuscript was written by HZ and all authors commented on previous versions of the manuscript.

All authors read and approved the final manuscript to be submitted.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Ethics approval and consent to participate

This single-center, prospective, parallel-groups clinical trial was approved by the Ethics Committee of Shanghai Sixth People's Hospital affiliated to Shanghai Jiao Tong University and registered at the Chinese Clinical Trial Registry website (http://www.chictr.org.cn/index.aspx, ChiCTR-INR-17011525, 30/05/2017). Written informed consent was obtained from parents or legal guardians of each child before the trial began.

Consent for publication

All parents or legal guardians of the patients enrolled in this study consented to their data being published.

Competing interests

The authors declare that there are no conflicts of interest.

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Figures
Figure 1

CONSORT flowchart.

Assessed for eligibility (n=126)

3 declined to participate

Consented for participation (n=123)

3 rescheduling operation

Randomised (n=120)

Group B (n=60)
Received general anesthesia combined with ultrasound-guided lumbar plexus block

Lost to follow-up (n=0)

Analysed (n=60)
Excluded from analysis (n=0)

Group C (n=60)
Received routine general anesthesia

Lost to follow-up (n=0)

Analysed (n=60)
Excluded from analysis (n=0)
Figure 2

Incidence of emergence agitation (EA).

*P<0.01 vs. Group Control. #P<0.05 vs. Group S.

EASevere
Figure 3

Total fentanyl dose and average value of end-tidal sevoflurane (EtSev%). *P<0.01 vs. Group Control.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- CONSORT2010Checklist.doc