ABSTRACT

Objective To evaluate the analgesic effectiveness of two novel regional nerve blocks in paediatric patients with developmental dysplasia of the hip (DDH) after open reduction surgeries.

Design Prospective, double-blinded, randomised controlled trial.

Setting 2 tertiary teaching hospitals in China between August 2017 and July 2018.

Participants 110 paediatric patients aged 2–10 years with DDH undergoing open reduction surgeries were recruited, 95 were randomised and 90 were included in the final analysis.

Interventions Random assignment to quadratus lumborum block III (QLB III) group, transversalis fascia plane block (TFPB) group and the control (no region nerve block) group.

Primary and secondary outcome measures The primary outcome was the Face, Legs, Activity, Cry and Consolability (FLACC) Scale Scores. Secondary outcomes included perioperative opioid consumption, the time until first press of nurse-controlled analgesia/patient-controlled analgesia (NCA/PCA) pump and the total counts number of pressing, length of postanaesthesia care unit (PACU) stay, length of hospital stay, parental satisfaction with pain management and adverse events.

Results Mean FLACC Scores were significantly lower in QLB III group and TFPB group while in the PACU and for 48 hours postoperatively, compared with control group (p<0.0001, p<0.0001, respectively). No differences were found for FLACC Scores between QLB III group and TFPB group, neither at rest (p=0.0402) nor while posture changing (p=0.0306). TFPB prolonged the first-time request for NCA/PCA analgesia and decreased the total counts number of pressing.

Conclusions We suggested that both ultrasound-guided QLB III and TFPB should be considered as an option for perioperative analgesia in children with DDH undergoing open reduction surgeries. TFPB was superior to the QLB III because it prolonged the first-time request for NCA/PCA analgesia and decreased the total counts number of pressing.

Trial registration number NCT03189966/2017.

INTRODUCTION

Open hip surgery for developmental dysplasia of the hip (DDH) in paediatric patients led to extensive injuries and severe pain. Multi-modal analgesia was required to deal with postoperative pain and to prevent undesirable side effects such as sedation, nausea, vomiting and constipation.

Postoperative analgesic effects of the quadratus lumborum block III and transversalis fascia plane block in paediatric patients with developmental dysplasia of the hip undergoing open reduction surgeries: a double-blinded randomised controlled trial

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Strengths and limitations of this study

► The first time to evaluate the analgesic effectiveness of two novel regional nerve blocks for hip arthroplasty in paediatric patients with developmental dysplasia of the hip.
► Patients were randomised, allocation was concealed and the assessor was blinded in two centers of China.
► Investigated the different characteristics of quadratus lumborum block III and transversalis fascia plane block which were two similar but different techniques.
► Wider implementation of these techniques is recommended to confirm results in a broader population.
► Lack of visualised evidence of local anesthetic diffusion.
Caudal extradural anaesthesia (CEA)\textsuperscript{2–4} and lumbar plexus block (LPB)\textsuperscript{1,3,5} were still the most common regional anaesthesia techniques for perioperative analgesia in children undergoing open hip surgeries. Sometimes paediatric anaesthesiologists hesitated to choose CEA and LPB because of potential complications such as intravascular and intrathecal injection, urine retention, convulsions, retroperitoneal haemorrhage or renal puncture.\textsuperscript{4,6,7}

Some novel techniques of regional anaesthesia were explored. The quadratus lumborum block (QLB) uses the quadratus lumborum muscle (QLM) as its principal sonographic landmark. There were three approaches of QLB,\textsuperscript{8} namely QLB I, QLB II and QLB III. The classification was based on the direction of needle insertion and the spread of LA (anterior, lateral or posterior to the QLM). Various approaches of QLB have been used to alleviate pain after hip surgery.\textsuperscript{8–11} The transversalis fascia plane block (TFPB) was first described by Hebbard,\textsuperscript{12} in which the endpoint of injection was deep to the muscular tip of transversus abdominis muscle rather than the aponeurosis of transversus abdominis muscle/internal oblique muscle. TFPB targeted nerves anatomically between the LPB and the transversus abdominis plane (TAP) block. Previous studies of TFPB demonstrated that it provided effective analgesia for anterior iliac crest bone graft harvesting\textsuperscript{13} and improved the coverage of the proximal surgical incisions used for hip surgery.\textsuperscript{14,15}

Choice of approach may affect success of QLB, despite accurate needle placement. The aim of this study was to investigate the efficacy and safety of ultrasound-guided (US-guided) QLB III and TFPB for perioperative analgesia in children with DDH during the first 48 hours of undergoing open hip surgeries.

METHODS

The study was a prospective, randomised, double-blinded controlled trial. We applied the Consolidated Standards of Reporting Trials guidelines. Written informed consents were obtained from all patients’ guardians.
Participants
This study was conducted at Beijing Jishuitan Hospital and the Second Affiliated Hospital of Wenzhou Medical University between August 2017 and July 2018. Enrolled patients aged 2–10 years with American Society of Anesthesiologists physical status I or II who underwent a salter acetabular osteotomy combined with proximal femoral rotation osteotomy. Patients allergic to local anaesthetics or who had a mental disability that precluded the administration of the Face, Legs, Activity, Cry and Consolability (FLACC) Scale, peripheral neuropathy, coagulopathy disorders, localised infection in the area or any reason/cause of reoperation were excluded from the study.

Sample size
To estimate the group size, a pilot study was conducted for measuring the FLACC Pain Score at 12 hours after surgery (seven patients in each group). We hypothesised that either QLB III or TFPB could provide adequate pain relief when compared with the control and expected the capability to show a difference of 2 in the FLACC Pain Score at 12 hours after surgery between any intervention group and the control group. The sample size calculation was based on superiority test for two means with 90% power and 5% level of significance, 25 patients per group were needed. Considering a compliance rate of 80%, we asked 90 patients to participate in this study (online supplemental file 1).

Randomisation and blinding
The enrolled patients were randomly divided into three groups using computer-generated randomised numbers which were enclosed in a sealed opaque envelope and kept by a research coordinator. The designed member prepared local anaesthetic (LA) labelled ‘trial drug’ in accordance with the allocation sequence and participated in the trial only at this stage. All of the procedures were performed by a single operator who was not blinded to the type of regional block. Anaesthesiologists were blinded to the study groups. Each patient was assessed by a blinded postanaesthesia care unit (PACU) nurse observer and a blinded ward nurse observer, both trained to evaluate the outcomes.

Interventions
While in the operation room, all patients were monitored with heart rate (HR), mean blood pressure (MBP),
nasopharyngeal temperature and peripheral oxygen saturation (SpO₂). General anaesthesia (GA) was induced by intravenously administering propofol 3 mg/kg, fentanyl 2 μg/kg and cis-atracurium 0.2 mg/kg. GA was maintained with remifentanil at 0.15–0.2 μg/kg/min and 2%–3% sevoflurane. All the blocks were performed after intubation before onset of surgery under ultrasound guidance (FUJIFILM SonoSite, Bothell, Washington, USA). The patients in the control group only received GA without any nerve block.

The QLB III was performed with the patient in a lateral position. A curvilinear low-frequency, 5–2 MHz, 30 cm linear array ultrasound probe (C60xp; FUJIFILM SonoSite) was placed transversely at the posterior axillary line between the iliac crest and the costal margin. After QLM, psoas major (PM) muscle, erector spinae (ES) and L3 transverse process were identified by the ‘Shamrock view’ method,16 17 a 22-gauge, 100 mm needle penetrated the QLM with an in-plane approach from the posterior side of the ultrasound probe. The target endpoint was the interfascial plane between the quadratus lumborum and PM muscle just deep to the transversalis fascia (figure 1-1).

After ensuring negative aspiration of blood, 0.3% ropivacaine at 0.8 mL/kg was administered.

### Table 1 Demographic characteristics and basic surgical data (mean (95% CI))

|                     | Control (n=30) | QLB III (n=30) | TFPB (n=30) | P value |
|---------------------|---------------|----------------|-------------|---------|
| Age (year)          | 5.3 (4.5 to 6.2) | 5.1 (4.0 to 6.3) | 5.5 (4.5 to 6.5) | 0.7369  |
| BMI (kg/cm²)        | 16.5 (15.5 to 17.7) | 16.9 (16.0 to 17.8) | 16.9 (15.7 to 18.1) | 0.8882  |
| Gender              |               |                |             | 0.0126  |
| Male                | 14 (46.67%)   | 4 (13.33%)     | 7 (23.33%)  |         |
| Female              | 16 (53.33%)   | 26 (86.67%)    | 23 (76.67%) |         |
| ASA                 |               |                |             | 0.484   |
| I                   | 26 (86.7%)    | 25 (83.3%)     | 28 (93.3%)  |         |
| II                  | 4 (13.3%)     | 5 (16.7%)      | 2 (6.7%)    |         |
| Time between nerve block and incision (min) | NA | 20.3 (18.5–22.1) | 19.0 (16.9–21.1) | 0.2269  |
| Operation time (min) | 182 (159 to 205) | 188 (169 to 208) | 184 (160 to 207) | 0.6403  |

ASA, American Statistical Association Score; BMI, body mass index; QLB III, quadratus lumborum block III; TFPB, transversalis fascia plane block.

### Table 2 Pain intensity at rest and at movement by using FLACC in preselected time points (mean (95% CI))

| FLACC | QLB III (n=30) | TFPB (n=30) | Control (n=30) | Type III GEE analysis |
|-------|----------------|-------------|----------------|-----------------------|
|       | Source         | χ²          | P value        |
| Rest  | Group          | 32.47       | <0.0001*       |
|       | Time           | 0.36        | <0.0001*       |
|       | Group×Time     | 47.56       | <0.0001*       |
|       | Gender         | 0.36        | 0.5460         |
|       | QLB III versus TFPB | 4.21   | 0.0402         |
|       | QLB III versus control | 28.59 | <0.0001*       |
|       | TFPB versus control | 34.83 | <0.0001*       |
| Movement | Group          | 34.31       | <0.0001*       |
|       | Time           | 63.19       | <0.0001*       |
|       | Group×Time     | 39.91       | <0.0001*       |
|       | Gender         | 1.33        | 0.2488         |
|       | QLB III versus TFPB | 4.68   | 0.0306         |
|       | QLB III versus control | 29.83 | <0.0001*       |
|       | TFPB versus control | 36.38 | <0.0001*       |

Data are showed as mean (95% CI).

*Statistically significant.

FLACC, Scores of Face, Legs, Activity, Cry and Consolability; GEE, generalised estimation equation; PACU, postanaesthesia care unit; QLB III, quadratus lumborum block III; TFPB, transversalis fascia plane block.
| Variables                                              | QLB III          | TFPB             | Control          | Statistics and p value | Post hoc test | Statistics and p value |
|--------------------------------------------------------|------------------|------------------|------------------|------------------------|---------------|------------------------|
| Intraoperative opioid (μg/kg)                           | 46.6 (40.8 to 52.5) | 48.9 (43.5 to 54.3) | 49.2 (44.3 to 54.1) | H=0.9525 p=0.6211      | QLB III versus TFPB Z=-0.4657 p=0.6414 |
|                                                         |                  |                  |                  |                        | QLB III versus control Z=-1.0719 p=0.2838 |
|                                                         |                  |                  |                  |                        | TFP versus control Z=-0.2587 p=0.7958 |
| Fentanyl consumption in PACU (μg/kg)                    | 0.23 (0.10 to 0.37) | 0.36 (0.19 to 0.53) | 0.72 (0.60 to 0.85) | H=16.4930 p=0.0003*   | QLB III versus TFPB Z=-0.9671 p=0.3335 |
|                                                         |                  |                  |                  |                        | QLB III versus control Z=-4.0223 p<0.0001* |
|                                                         |                  |                  |                  |                        | TFP versus control Z=-2.5647 p=0.0103* |
| Fentanyl rate in PACU                                  |                  |                  |                  | χ²=17.7239 p=0.0001*   | QLB III versus TFPB Z=0.2871 p=0.5921 |
| No                                                     | 20 (66.67%)      | 18 (60.00%)      | 5 (16.67%)        | χ²=15.4286 p<0.0001*   | QLB III versus control Z=11.9154 p=0.0006* |
| Yes                                                    | 10 (33.33%)      | 12 (40.00%)      | 25 (83.33%)       | χ²=11.9154 p=0.0006*   | TFP versus control Z=11.9154 p=0.0006* |
| Morphine as rescue analgesia in ward (mg/kg, 48 hours) | 0.01 (0.00 to 0.03) | 0.01 (−0.00 to 0.02) | 0.09 (0.06 to 0.12) | H=34.2590 p<0.0001*   | QLB III versus TFPB Z=−0.2382 p=0.8117 |
|                                                         |                  |                  |                  |                        | QLB III versus control Z=−4.6822 p<0.0001* |
|                                                         |                  |                  |                  |                        | TFP versus control Z=−4.7552 p<0.0001* |
| The time until first press NCA/PCA pump (hours)        | 11.7 (6.6 to 16.8) | 22.5 (16.2 to 28.7) | 2.9 (1.8 to 4.0)  | H=42.7590 p<0.0001*   | QLB III versus TFPB Z=−3.3093 p=0.0009* |
|                                                         |                  |                  |                  |                        | QLB III versus control Z=−3.8914 p=0.0001* |
|                                                         |                  |                  |                  |                        | TFP versus control Z=6.1636 p=0.0001* |
| The total counts number of pressing NCA/PCA pump        | 3.8 (2.8 to 4.8)  | 2.4 (1.3 to 3.6)  | 11.7 (5.5 to 17.9) | H=35.2526 p<0.0001*   | QLB III versus TFPB Z=2.5393 p=0.0111* |
|                                                         |                  |                  |                  |                        | QLB III versus control Z=4.3733 p<0.0001* |
|                                                         |                  |                  |                  |                        | TFP versus control Z=5.2705 p<0.0001* |
| PACU stay (min)                                         | 26.6 (24.0 to 29.2) | 37.4 (32.0 to 42.8) | 58.0 (51.6 to 64.4) | H=47.0495 p<0.0001*   | QLB III versus TFPB Z=−3.1385 p=0.0017* |
|                                                         |                  |                  |                  |                        | QLB III versus control Z=−6.4762 p<0.0001* |
|                                                         |                  |                  |                  |                        | TFP versus control Z=−4.2932 p<0.0001* |

Continued
The TFPB was performed at the supine position. A high-frequency, 15–6 MHz, 6 cm, linear array probe (HFL50xp; FUJIFILM SonoSite) was placed transversely over the lateral abdomen between the iliac crest and the costal margin. After the external oblique, internal oblique, transversus abdominis muscle and QLM were identified. A 22-gauge, 100 mm needle was advanced from the anterior using an in-plane technique and passed through the posterior ‘tail’ of the transversus muscle.12 18 19 After passing through the deep surface of transversus abdominis muscle, local anaesthetic was injected to separate the transversalis fascia from the transversus muscle (figure 1-2). After ensuring negative aspiration of blood, 0.3% of ropivacaine at 0.8 mL/kg was injected.

Postoperative pain control was provided by a nurse-controlled analgesia (NCA)/patient-controlled analgesia (PCA) infusions of sufentanil (2 μg/kg) for 48 hours. Paracetamol (po, 15 mg/kg) was routinely administered postoperatively every 6 hours for 48 hours. The pain was measured by the assessors with the FLACC Scale.11 If a Pain Score was >3, the patient in the PACU would receive fentanyl (intravenous, 1 μg/kg), while in the surgical ward morphine (intravenous, 0.05 mg/kg) was administered. Satisfaction from all patients’ guardians were surveyed with regard to the postoperative analgesia of their children at the time of the NCA/PCA pump removal.

### Outcomes

Primary outcome was the FLACC Scores of patients in the PACU and at 2 hours, 4 hours, 8 hours, 12 hours, 24 hours and 48 hours postoperatively. Secondary outcomes included intraoperative MBP and HR at the endpoints of Salter acetabular osteotomy (T1), femoral rotation osteotomy (T2) and anterior superior iliac spine osteotomy (T3) during the surgery; intraoperative opioid consumption (remifentanil was converted into fentanyl equivalents); duration of the surgery; postoperative fentanyl consumption in the PACU, postoperative morphine consumption in the ward; the length of PACU stay; the time until first press of NCA/PCA pump and the total counts number of pressing the pump; length of hospital stay and complications (eg, immediate complications such as vessel puncture and possible undesirable effects such as hypotension, bradycardia, epidural local anaesthetic spread or postoperative nausea and vomiting).

### Statistical analysis

Data were presented as mean with 95% CI for continuous variables and counts with percentages for categorical variables. For the normally distributed variables, one-way analysis of variance was used for comparisons in three groups. For the non-normally distributed data, Kruskal-Wallis test was adopted for analysing the differences in three groups. Intergroup comparisons were adjusted using the Bonferroni test and p value below 0.0167 to denote statistical significance. Generalised Estimation Equation analysis for the FLACC Scores among three groups due to the pain intensity was a dynamic response value in the whole procedure. A p value less than 0.05 was considered statistically significant. Statistical analyses were performed using SPSS Statistics for Windows V.11 (SPSS; 2001).

### Patient and public involvement

Participants were not involved in the setting of the research question and designing and conducting or
counts number of pressing the NCA/PCA pump in TFPB group was significantly less than in QLB III group (p=0.011) and control group (p<0.0001) (table 3).

The FLACC Scores in control group were significantly higher than those in the other groups (p<0.05), while no significant difference was observed between QLB III group and TFPB group (table 2). Compared with control group, the consumption for postoperative analgesics (both fentanyl consumption in PACU and morphine as rescue analgesia in ward) significantly decreased and Parental Satisfaction Scores significantly increased in the other groups (p<0.05), while no significant difference was observed between QLB III group and TFPB group (table 3).

The length of PACU stay in QLB III group was significantly shorter than in TFPB group (p=0.0017) and control group (p=0.0001), while the length of hospital stay in TFPB group was significantly shorter than in control group (p=0.0001) (table 3). No adverse events were observed among three groups.

**DISCUSSION**

To the best of our knowledge, it was the first study to assess the analgesic effects of QLB III and TFPB in paediatric patients with DDH. In this study, we found that QLB III and TFPB similarly relieved the pain, decreased the consumption of additional analgesics, shortened the PACU stay and improved the parental satisfaction.

The efficacy of the QLB in hip surgery is supported by case reports and RCTs (randomized controlled trials). QLB III is a modified approach which was described by Børglum et al., in which the needle was advanced in a posterior-to-anterior direction to reach the anterior (ventral) surface of QLM. The primary mechanism of action proposed for the QLB was local anaesthetic spread to the paravertebral space spread. Carline et al demonstrated the stained regions after QLB III spread consistently to L1 and L3 nerve roots, subcostal nerves and within PM and QLM, including ilioinguinal (II), iliohypogastric (IH), lateral femoral cutaneous (LFC) and genitofemoral and obturator nerves. Other recent cadaveric studies of the US-guided QLB III showed that the dye solution spread to subcostal, IH, LFC and obturator nerves consistently or in a varying degree.

Most surgical incisions for hip surgery are located in the proximity of the greater trochanter of the femur. The cutaneous innervation of the area includes at a minimum the lateral cutaneous branch (LCB) and the anterior cutaneous branch (ACB). The needle (N-TFPB) passing through anterolateral abdominal wall to posterior abdominal wall can be showed clear and pointed to lumbar vertebrae (L3) closely above the peritoneum (P). The location of the local anaesthetic (LA-TFPB) across the anterior surface of the quadratus lumborum (QL) and behind the transversalis fascia (TF) is shown. The needle (N-QLB III) penetrated the QL from back. The target point (LA-QLB III) is the interfascial plane between the QL and the psoas major (PM) muscle just deep to the TF, lumbar plexus (LP), erector spinae (ES), transversus abdominis (TA), internal oblique (IO) and external oblique (EO). QLB III, quadratus lumborum block III; TFPB, transversalis fascia plane block.

**RESULTS**

Overall, 110 patients were approached to participate, with 95 agreed and were eligible, and 90 were included in the final analysis. A flow diagram of this study was shown in figure 2. Demographic data were shown in table 1.

**Intraoperative period**

There were no statistically significant differences among three groups with regard to HR, MBP and SpO₂ before skin incision (p>0.05). The MBP and HR were significantly higher in the control group than in the other groups at T1, T2 and T3 (all p<0.05). There were no significant differences in fentanyl and remifentanil requirements among three groups during intraoperative periods (p=0.6211) (table 2).

**Postoperative period**

The time asking for first NCA/PCA analgesia in TFPB group was significantly longer than in QLB III group (p<0.0001) and control group (p<0.0001). There were no statistically significant differences among three groups with regard to HR, MBP and SpO₂ before skin incision (p>0.05). The MBP and HR were significantly higher in the control group than in the other groups at T1, T2 and T3 (all p<0.05). There were no significant differences in fentanyl and remifentanil requirements among three groups during intraoperative periods (p=0.6211) (table 2).

No adverse events were observed among three groups.

Figure 3 Transverse diagram of TFPB and QLB III. The course of the subcostal nerve (SCN) is indicated, including the lateral cutaneous branch (LCB) and the anterior cutaneous branch (ACB). The needle (N-TFPB) passing through anterolateral abdominal wall to posterior abdominal wall can be showed clear and pointed to lumbar vertebrae (L3) closely above the peritoneum (P). The location of the local anaesthetic (LA-TFPB) across the anterior surface of the quadratus lumborum (QL) and behind the transversalis fascia (TF) is shown. The needle (N-QLB III) penetrated the QL from back. The target point (LA-QLB III) is the interfascial plane between the QL and the psoas major (PM) muscle just deep to the TF, lumbar plexus (LP), erector spinae (ES), transversus abdominis (TA), internal oblique (IO) and external oblique (EO). QLB III, quadratus lumborum block III; TFPB, transversalis fascia plane block.

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It was interesting to note that TFPB provided a more effective block than QLB III, indicated by a longer time asking for the first press of NCA/PCA pump analgesic and less total counts number of pressing the pump. The diffusion of the local anaesthetic solution with different puncture approaches may explain these results (figure 3). The endpoint of TFPB results in more localised spread, specifically targeting the LCB from II, IH and subcostal nerves where they run deep to transversus abdominis muscle before ascending into the TAP and potentially longer lasting of analgesia. The other reason was the transversalis fascia is continuous to the tissue plane deep to the fascia iliacus, which incidentally houses the femoral nerve. However, two cadaveric studies of the QLB III claimed that no dye was seen to surround femoral nerve. Therefore, the higher successful rate of femoral nerve blockade in TFPB than QLB III was another potential mechanism. Further cadaveric study about TFPB will hopefully provide some clarity. Moreover, it was easier for TFPB to get satisfactory quality of ultrasonographic visualisation than QLB III in the clinical setting.

There were still some limitations. First, the number of female paediatric patients was significantly greater than that of the male in the QLB III and TFPB groups, while not in the control group. The statistical results had been corrected by gender. Second, we did not perform pinprick or cold tests to determine sensorial block distribution, because it was not allowed for paediatric patient. Third, the study lacked visualised evidence of local anaesthetic diffusion.

CONCLUSION
In conclusion, US-guided QLB III and TFPB provided similarly adequate postoperative analgesia in children with DDH undergoing open reduction surgeries. We recommended TFPB technique which resulted in a longer-lasting analgesic effect postoperatively and was much more beneficial to recovery in paediatric patients as compared with QLB III.

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Contributors CH contributed to design the study, conduct the study, analyse the data and write the manuscript. XZ and CH were the designed anaesthesiologists to perform the quadratus lumborum block and transversalis fascia plane block. CD and CL contributed to evaluate the Face, Legs, Activity, Cry and Consolability Scores and collect the data. JL contributed to analyse the data and revise the manuscript. LY contributed to design the study, conduct the study, analyse the data and revise the manuscript. All authors contributed to conceptualise ideas and interpret findings and reviewed drafts of the manuscript.

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Competing interests None declared.

Patient consent for publication Parental/guardian consent obtained.

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Data availability statement All data relevant to the study are included in the article or uploaded as supplemental information.

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