Paravertebral Block vs. Caudal Block Using Dexmedetomidine Plus Local Anesthetics for Inguinal Hernia Repair in Pediatrics: A Randomized Prospective Trial

Naglaa Khalil and Hesham M Marouf
Faculty of Medicine, Tanta University, Egypt

*Corresponding author: Hesham M Marouf, Faculty of Medicine, Tanta University, Egypt, Tel: +00201274366808; E-mail: heshammarouf@hotmail.com

Received date: July 14, 2017; Accepted date: August 07, 2017; Published date: August 10, 2017

Abstract

Aim: We aimed to compare the effects of caudal block (CB) and paravertebral block (PVB) using dexmedetomidine plus local anesthetics on postoperative pain and analgesia requirements in pediatrics after inguinal hernia surgery.

Methods: This randomized prospective study was carried out on 80 pediatric patients underwent inguinal hernia repair. Two groups (each 40 patients) were included in the study: group CB and group PVB. After a standardized general anaesthesia, caudal or lumbar paravertebral block was performed using bupivacaine (0.25%) and dexemetomidine 1 μg/kg . We recorded FLACC score, number of patients needed rescue analgesia, the total number of doses of rescue analgesia, the duration of postoperative analgesia, parents satisfaction and adverse events.

Results: FLACC score was higher in group (CB) compared with group (PVB) at 12 h and 16 h postoperative. The total number of patients need postoperative analgesia and the total number of doses of postoperative analgesia were higher in group (CB) compared with group (PVB). The duration of postoperative analgesia was significantly longer in group (PVB) than group (CB) (16.25 ± 1.66 vs. 10.69 ± 1.34). Parent satisfaction was higher in group (PVB) than group (CB). No major complications were detected in both groups.

Conclusion: paravertebral block (using dexmedetomidine+local anaesthetics) was associated with better postoperative analgesia and higher parents satisfaction compared to caudal block (using dexmedetomidine+local anaesthetics) for inguinal hernia repair in children.

Keywords: Paravertebral; Caudal; Dexmedetomidine; Hernia; Pediatric

Introduction

One of the most common surgical procedures in pediatrics is inguinal hernia repair. This surgery lead to different degree of pain postoperative [1].

Regional anesthetic procedures can reduce intra-operative anesthetic requirement, allow rapid recovery, and decrease postoperative pain and opioids use [2].

Caudal block is the most popular regional anaesthesia technique used to relieve pain in children after surgery of the lumbosacral to midthoracic dermatomal level. Caudal block using single shot technique is associated with short duration of analgesia [3].

Paravertebral block (PVB) is a regional anaesthesia technique where local anesthetic is injected close to the site where the nerves come out from the intervertebral foramina. Paravertebral block affords a good analgesia after thoracotomy and abdomen surgery [4,5].

Both caudal and paravertebral blocks were used successfully in pediatrics to improve postoperative analgesia [6,7].

Dexmedetomidine is an Alpha (α)-2-adrenergic receptor agonist which has sedative, sympatholytic, and analgesic effects. Adding dexmedetomidine to local anesthetics during peripheral nerve blockade and regional anesthesia procedures is proved to be effective for the surgical patient [8].

The aim of the present study was to compare the effects of caudal block and paravertebral block using dexmedetomidine plus local anesthetics on postoperative pain and analgesia requirements in pediatric patients after unilateral inguinal hernia surgery

Pan African Clinical Trials Registry (PACTR) registration number : PACTR201611001695146.

Methods

After approval by local ethical committee, this randomized prospective study was performed in Tanta University Hospital for 6 months from 1/4/2016 to 1/10/2016 on 80 pediatric patients (ASA I-II) scheduled for elective unilateral inguinal hernia surgery. A written and informed consent was obtained from the parent of each patient.

Patients were randomly allocated into 2 equal groups (each 40 patients)

- Caudal group (group CB) (40 patients)
• Paravertebral block (group PVB) (40 patients)

Randomization was performed using computer generated block randomization to create a list of numbers, each number referred to one of the 2 groups. Then each number was sealed in opaque envelope. Each parent asked to choose one of the envelopes and was given it to the anesthesiologist who compared the number with computer generated list and accordingly assigned the patient to one of the 2 groups.

Inclusion criteria

Patients were involved in the study if they were aged 3-7 years, had ASA I-II, and scheduled for elective unilateral inguinal hernia surgery.

Exclusion criteria

Patients were omitted from the study if they had contraindication to regional anesthesia, such as congenital abnormalities of spine and meninges, coagulopathy or anticoagulation therapy, infection at the site of injection, mental retardation or history of developmental delay or allergy to local anaesthetics drugs.

Procedure

On arrival of the patients to the operative theatre, and after placement of the standard monitoring (including ECG, noninvasive blood pressure, and pulse oximetry, capnograph), general inhalational anesthesia was induced by face mask with sevoflurane (Kahira pharmaceuticals and chemical industries company, Egypt under license of Abbvie UK) (4-8%) in 100% oxygen, IV canula was secured then intravenous Propofol [9] (Astra Zeneca UK) 1-2 mg/kg was injected. No muscle relaxant or intraoperative opioids were given. All children were allowed to breathe spontaneously via a laryngeal mask airway. Anesthesia was maintained with isoflurane (Kahira pharmaceuticals and chemical industries company, Egypt under license of Abbvie UK 0.5-2%) in oxygen-air mixture. Paracetamol [10] (Pharco B international, Egypt) 15 mg/kg was given intravenously.

Caudal or lumbar paravertebral block was performed prior to surgery with patients in the lateral decubitus position.

In group (CB) patients were placed in a lateral position and povidone iodine solution was used to clean the skin over the sacrum, then under complete aseptic precautions 25 G needle was used to perform single dose caudal block. To confirm the correct position of the needle tip the patient should be noticed during penetration of the sacro-coccygeal ligament, which was followed by the whoosh test [11] using 0.5 ml of air. After needle insertion and negative aspiration of blood or cerebrospinal fluid, bupivacaine (Aldebelky pharma Egypt) (0.25%) 1 ml/kg and dexmetomidine [10] (Pfizer, USA) 1 mic/kg were injected.

In group (PVB) PVB was performed as previously described by Hadzic and Vloka [12]. Graduated epidural needle was inserted perpendicularly to the skin (1 to 2 cm lateral to the spinal process at the level of second lumbar vertebra) and when the needle reached the transverse process it was withdrawn to the subcutaneous tissue and redirected to walk off the caudal edge of the transverse process. When the needle reached the paravertebral space (which was identified by loss of resistance to air) and after negative aspiration to be sure it is not intravascular a bolus of 0.5 ml/kg of bupivacaine (0.25%) [13] and dexmetomidine 1 mic/kg [14] were injected.

We used blind technique for both PVB and CB as the ultrasound machine was not working well during our study (due to maintenance problem). Fifteen min after performing PVB or CB, surgery was initiated. Cardioacceleration changes (increasing noninvasive mean arterial pressure and heart rate >15% in response to painful surgical stimulation) and/or patient movement of his limbs were interpreted as insufficient analgesia. In such instances, PVB or CB was considered failed, then 1-2 µg/kg IV fentanyl were administered, and the patient was excluded from the study.

Postoperatively the patients were given regular paracetamol (E.I.P.L.CO. Egypt) 15 mg/kg [10] every 6 h intravenous.

FLACC score and other data were collected by anesthesiologist who is blind to the group of the patients.

Postoperative pain was assessed in both groups by FLACC [15] score to evaluate the effectiveness of the block (face, legs, activity, cry and consolability) at 15 min, 1 h, 4, 8, 12, 16, 20, and 24 h postoperative.

If a FLACC score was more than 3, the child was managed nonpharmacologically (position changing, tactile stimulation, etc) if no effect after 5 min, intravenous fentanyl [16] (Sunny pharmaceutical, Egypt under license of Hameln pharmaceutical, Germany) as rescue analgesia was given in a dose 0.5 mic/kg if FLACC score still more than 3 after 10 min another 0.5 mic/kg of fentanyl was given.

Primary outcome

Primary outcome included number of patients needed rescue analgesia.

Secondary outcome

Secondary outcome included FLACC score, the total number of doses of rescue analgesia, the duration of postoperative analgesia (time from recovery to first dose of fentanyl) and parents satisfaction (Parents were asked to rate their degree of satisfaction on scale from 1 to 10 where 1=completely dissatisfied and 10=completely satisfied). Any postoperative adverse events were documented as bradycardia (heart rate less than 65 beat/min) hypotension (blood pressure less than 20% of base line reading), and respiratory depression (SpO2 less than 95%).

The minimally required sample size to detect 30% difference in the number of children needed rescue analgesia between the PVB and CB groups was 34 patients in each study group assuming power of 80% and an alpha error of 0.05. We aimed to include 40 patients in each group.

Statistical analysis

Statistical analysis was done using SPSS programme version 20 (IBM, Armonk, NY, United States of America). Quantitative data were expressed as mean ± standard deviation (SD) and analyzed using Independent-samples t-test. Qualitative data were expressed as frequency and percentage and analyzed using Chi-square (X^2) test.

Results

Our result showed that one patient in PVB group had failure of paravertebral block because it was difficult to detect the paravertebral space, another patient in CB group had vascular puncture during the
procedure. Both patients were excluded from the study and the study was done on 39 patients in each group. Table 1 shows that no significant differences were detected among the two groups in terms of demographic data including age, sex; body weight and duration of the surgery (P > 0.05) (Table 1).

Table 1: Patients’ characteristic.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group (CB)</th>
<th>Group (PVB)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>4.69 ± 1.32</td>
<td>4.74 ± 1.37</td>
<td>0.86</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>16.58 ± 2.77</td>
<td>17.48 ± 2.96</td>
<td>0.17</td>
</tr>
<tr>
<td>Sex M/F</td>
<td>23/16</td>
<td>24/15</td>
<td>0.82</td>
</tr>
<tr>
<td>Duration of surgery</td>
<td>70.2 ± 6.7</td>
<td>71.4 ± 7.03</td>
<td>0.44</td>
</tr>
</tbody>
</table>

Data are presented as mean ± SD or ratio. (* ) significant p value<0.05.

Table 2: FLACC scores.

<table>
<thead>
<tr>
<th>FLACC scores</th>
<th>(CB) group</th>
<th>(PVB) group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>At 15 min</td>
<td>1.41 ± 0.49 (1.24-1.57)</td>
<td>1.23 ± 0.42 (1.09-1.36)</td>
<td>0.09</td>
</tr>
<tr>
<td>At 1 h</td>
<td>1.07 ± 0.48 (0.92-1.23)</td>
<td>1.2 ± 0.46 (1.05-1.35)</td>
<td>0.24</td>
</tr>
<tr>
<td>At 4 h</td>
<td>1.79 ± 0.65 (1.58-2)</td>
<td>1.74 ± 0.67 (1.52-1.96)</td>
<td>0.73</td>
</tr>
<tr>
<td>At 8 h</td>
<td>1.89 ± 0.63 (1.68-2.1)</td>
<td>1.74 ± 0.64 (1.53-1.95)</td>
<td>0.29</td>
</tr>
<tr>
<td>At 12 h</td>
<td>2.87 ± 0.97 (2.57-3.17)</td>
<td>1.69 ± 0.69 (1.46-1.91)</td>
<td>0.00*</td>
</tr>
<tr>
<td>At 16 h</td>
<td>3.1 ± 0.91 (2.8-3.39)</td>
<td>2.10 ± 1.03 (1.79-2.46)</td>
<td>0.00*</td>
</tr>
<tr>
<td>At 20 h</td>
<td>2.71 ± 0.75 (2.43-2.89)</td>
<td>2.61 ± 0.98 (2.24-2.77)</td>
<td>0.61</td>
</tr>
<tr>
<td>At 24 h</td>
<td>1.79 ± 0.69 (1.56-2.02)</td>
<td>1.41 ± 0.49 (1.24-1.57)</td>
<td>0.006</td>
</tr>
</tbody>
</table>

Data are presented as mean ± SD (95% confidence interval). (*) significant p value<0.05.

Table 3: Postoperative data.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group (CB)</th>
<th>Group (PVB)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of patients needed rescue analgesia</td>
<td>21/39 (53.8%)</td>
<td>7/39 (17.9%)</td>
<td>0.001*</td>
</tr>
<tr>
<td>Number of patients needed single dose of rescue analgesia</td>
<td>15/39 (38.5%)</td>
<td>6/39 (15.4%)</td>
<td>0.022*</td>
</tr>
<tr>
<td>Number of patients needed two doses of rescue analgesia (h)</td>
<td>6/39 (15.4%)</td>
<td>1/39 (2.6%)</td>
<td>0.048*</td>
</tr>
<tr>
<td>Duration of postoperative analgesia (h)</td>
<td>10.69 ± 1.34 (10.12-11.25)</td>
<td>16.25 ± 1.66 (15.71-16.79)</td>
<td>0.001*</td>
</tr>
<tr>
<td>Parents satisfaction</td>
<td>6.07 ± 1.43</td>
<td>7.23 ± 2.52</td>
<td>0.00*</td>
</tr>
</tbody>
</table>

Data are presented as mean ± SD, mean ± SD (95% confidence interval ) or number and percentage. (*) significant p value<0.05.

Discussion

Our study showed that group (PVB) (using dexmedetomidine+local anaesthetics) was associated with lower FLACC score (at 12 h and 16 h postoperative), fewer number of patients who needed rescue analgesia, longer duration of postoperative analgesia, less postoperative rescue analgesia requirements and higher parents satisfaction as compared to group (CB) (using dexmedetomidine+local anaesthetics). In the present study we gave paracetamol as base line analgesia and we measured number of patients who needed rescue analgesia (fentanyl) and duration postoperative analgesia which was defined as time from recovery to first dose of fentanyl.

The relative avascularity of the paravertebral space and hence the slow uptake of local anaesthetic explained the prolonged duration of analgesia in PVB than CB [17].

Our result was supported by the study done by Tug R et al. [18] who found that the number of patients who did not need postoperative analgesia was higher in (PVB) group compared to (CB) group, and the duration of analgesia was longer in (PVB) group than (CB) group. But regarding FLACC score Tug R et al. [18] reported that no difference was recorded between both groups while in our study FLACC score was lower in (PVB) group compared to (CB) group. Also our result was in line with the study done by Akçaboy et al. [19] who reported that PVB had effective and prolonged analgesia compared with spinal block in adult patients. Our results agreed with the study done by Lonnqvist and Olsson [6] who compared lumbar epidural blocks with somatic paravertebral block in children and reported that the number of patients who required no morphine was lower in paravertebral group than the epidural group.

Berta et al. [7] studied the effect of PVB on postoperative pain in children undergoing renal surgeries under general anaesthesia and reported that the median duration of postoperative analgesia was 600 min (range 180-720 min) and 10 patients (41.7%) did not need analgesia while 14 patients (58.3%) needed analgesia during the first 12 postoperative hours, but in our study the duration of postoperative analgesia was 16.25 ± 1.66 h (mean ± sd) and 7 patients (17.9%) needed analgesia during the first 24 postoperative hours. The differences between our results and Berta’s results may be due to different type of surgeries in both studies also in our study we used

local anaesthetic drug pluse dexametomidine which is known to potentiate the effect of local anaesthetics as reported by Esmaoqlu A et al. [20].

In contrast to our results Davies et al. [21] reported (in their systemic review and meta-analysis) that analgesia was similar in epidural group and paravertebral group but paravertebral group was associated with less complications. The differences between our results and Davies’ s results may be due to differences in the techniques (thoracic epidural and caudal block) or differences in type of surgery.

No major complications were recorded in both groups in the present study, similar results have been reported in other studies [18,22].

Our study showed that parent satisfaction was significantly higher in PVB group compared to CB group. This result was supported by the studies done by Tug R et al. [18] and Naja ZM at al. [23].

**Conclusion**

In conclusion, paravertebral block (using dexametomidine+local anaesthetics) in combination with general anaesthesia resulted in improved and prolonged postoperative analgesia, higher parents satisfaction compared to caudal block (using dexametomidine+local anaesthetics) for inguinal hernia repair in children.

**Limitations**

Limitations from our point of view there are 2 limitations to the study. The first is absence of control group. The second is that blindness to the group was impossible for the anaesthesiologist during study. But we think that these limitations did not affect the strength of the study.

**References**