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Effects of Adding Dexmedetomidine to Local Infiltration of Bupivacaine on Postoperative Pain in Pediatric Herniorrhaphy; A Randomized Clinical Trial

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Running title: Post op pain in pediatric herniorrhaphy

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Effects of adding dexmedetomidine to local infiltration of bupivacaine on postoperative pain in pediatric herniorrhaphy: a randomized clinical trial

Running title: Post op pain in pediatric herniorrhaphy
Abstract

Background: We aimed to compare addition of dexmedetomidine to local infiltration of bupivacaine to promote the post-operative pain relief in children undergoing inguinal herniorrhaphy.

Methods: This double-blind randomized clinical trial included 60 children aged 6-72 months undergoing unilateral herniorrhaphy at selected hospitals, Shiraz, Iran, who were randomly allocated into two groups. One group received 1 µg/kg dexmedetomidine plus local infiltration of 0.2 mL/kg bupivacaine 0.5% (BD) at the site of operation before the surgery, and the other group received bupivacaine and normal saline (BO). Postoperative pain and sedation score were assessed until 4 hours after the operation. Analgesic requirements, emergence time, and nausea/vomiting were recorded. Heart rate (HR), systolic blood pressure (SBP), and arterial oxygen saturation (SaO2) were recorded at baseline, 10, and 20 minutes after injection.

Results: 60 patients were recruited in the study, 30 in each group. In the both groups, 24 patients (80%) were boys and 6 (20%) were girls. Mean age was 22.75±18.63 months. There was no difference between the groups regarding SaO2 and SBP, while HR was significantly lower in BD group after 10 and 20 minutes (P<0.05). In BD group, pain score was significantly less than BO group in the first and second hours after the operation (P<0.001). Sedation score was significantly higher in BD group at the first three time intervals and the emergence time was significantly longer (all P<0.001).

Conclusions: Addition of dexmedetomidine to local infiltration of bupivacaine in children undergoing herniorrhaphy can significantly reduce postoperative pain and increase their sedation.

Keywords: Bupivacaine; Dexmedetomidine; Herniorrhaphy; Pain, Postoperative; Child; Vital signs.
Introduction

Indirect inguinal hernia, caused by a patent processus vaginalis, is a common pathology in the first year of life, especially in low-birth weight male neonates [1]. Surgery (inguinal herniorrhaphy) is considered as the main treatment, for which various techniques, such as open and laparoscopic procedures have been proposed [2]; nevertheless, despite the variety of techniques proposed for its correction, it is associated with severe adverse effects, such as recurrence, and persisting postoperative pain [3, 4].

Among the postoperative adverse effects, pain has a significant importance, especially in children, as uncontrolled acute pain may lead to chronic pain that can increase the patients’ stress and deteriorate the health-related quality of life. It can also increase the duration of hospital stay and total health costs [5]. Thus, researchers have investigated the efficacy of various analgesics including bupivacaine, levobupivacaine, clonidine, and naloxone, on post-herniorrhaphy pain in children administered at different times through various routes [6, 7], such as caudal analgesia, inguinal nerve block, or local infiltration combined with a general anesthetic [8]. However, review studies have determined no significant difference between various strategies [9].

Dexmedetomidine (DEX) (Precedex®) is a highly selective α2-adrenergic agonist with a receptor affinity greater than clonidine, which acts through various mechanism, like increased hyperpolarization of action potential, causing hypnotic and analgesic effects [10]. Adding dexmedetomidine as an adjuvant to bupivacaine has been proven to be effective in post-operative pain relief in various procedures, such as cesarean section [11], abdominal hysterectomy [12], and knee replacement therapy [13]. Even a combination of DEX with bupivacaine is proposed to be superior to bupivacaine alone or with tramadol in cholecystectomy procedures [14]. In children undergoing lower abdominal procedures, adding dexmedetomidine to caudal bupivacaine increased the analgesia without side-effects [15, 16]. Recently,
researchers have postulated the extended duration of postoperative pain relief and reduced response to hernial sac traction by 1 µg/kg DEX, combined with bupivacaine, in children undergoing hernia repair [17, 18]. Higher doses of DEX has also been proposed as a feasible anesthetic in pediatric inguinal hernia repair [19]. Furthermore, premedication with sublingual DEX is established to be more effective than sublingual midazolam in children aged <12 years undergoing inguinal hernia repair [20].

Local infiltration of drugs into the surgical wounds is considered as an effective measure in reducing postoperative pain and is considered as a safe method because it does not have the hemodynamic effects of the drug when administered intravenously [21]. A combination of DEX with a local anesthetic, such as bupivacaine or ropivacaine, has been suggested as an appropriate method for postoperative pain relief in adult patients undergoing abdominal hysterectomy [22] and lower segment cesarean section [23]. However, the effect of combination of DEX with bupivacaine has not been reported in pediatric population. Thus, in the present study we aimed to assess the combined effect of dexmedetomidine and local infiltration of bupivacaine to improve post-operative pain relief in children undergoing inguinal herniorrhaphy.
Materials and Methods

2.1. Study design

This randomized clinical trial (RCT) was conducted on 60 children undergoing unilateral herniorrhaphy in Nemazee and Ghadir Hospitals, affiliated to Shiraz University of Medical Sciences, Shiraz, Iran. The protocol of the study was approved by the Research Ethics Committee of Shiraz University of Medical Sciences (Approval number: IR.SUMS.REC.1394.5.945) and was registered in the Iranian Registry of Clinical Trials (IRCT2016060314372N8). Before the recruitment of participants, the objectives of the study were explained to the parents of children and written informed consent was obtained from them. The study was conducted under the principles outlined in the Declaration of Helsinki.

Based on the calculated sample size, 60 children aged 6-72 months with unilateral inguinal hernia and ASA class I were included in the study. Children with developmental problems, mental retardation, history of seizures, coagulopathies, sensitivity to dexmedetomidine and bupivacaine, congenital heart disease, history of bleeding disorders, upper respiratory tract infection, liver or kidney failure, and neurological diseases were not recruited into the study. The flow diagram of patients’ recruitment is shown in figure 1.

The included patients were randomly divided into two groups based on a computer-generated list: one group received 1 µg/kg dexmedetomidine plus local infiltration of 0.2 mL/kg bupivacaine 0.5% (BD), and the other group received local infiltration of 0.2 mL/kg bupivacaine 0.5% with 1 mL normal saline (BO), which were prepared before surgery in similar syringes. The prepared drugs were injected at incision site just before the incision.

The patients were kept in “nothing by mouth” (NPO) state the night before surgery but could drink liquids until 3 hours before the procedure. About 20 to 30 minutes before entering the operating
In BD group, 1 μg/kg dexmedetomidine + 0.2 mL/kg bupivacaine 0.5% and in BO group 0.2 mL/kg bupivacaine 0.5% were injected at the site of incision before starting the surgery. The drugs (BD and BO) that were prepared before surgery in similar syringes, were provided to the surgeon, who was blind to the groups’ allocation. The drugs in this study were prepared by an investigator who was not involved in the other parts of the study. The anesthesiologist, the surgeon, and the nurses were not aware of the content of the syringes. The monitoring during surgery included electrocardiography (ECG), pulse oximetry, and non-invasive blood pressure (NIBP) measurement. At the end of the procedure, the patients were transferred to the post-anesthesia care unit (PACU), where their vital signs were monitored every 15 minutes by a nurse.

The sedation level and severity of pain (based on the “children’s and infant’s postoperative pain scale” [CHIPPS]) were assessed by an expert nurse 1, 2, 3, and 4 hour(s) after surgery. In the case of CHIPPS≥3, 15 mg/kg Apotel (acetaminophen) was infused and in case of nausea/vomiting, 0.15 mg/kg ondansetron was administered. Also, analgesic requirements, time of emergence, and nausea/vomiting were recorded for all participants by the same nurse. Sedation score was considered as 0 when the patient was awake and alert; 1, mild sedation, easy to rouse; 2, asleep, easy to rouse; 3, moderate sedation,
inability to remain awake; and 4 when there was difficulty to rouse [18]. The emergence time was calculated from the end of surgery until eye opening following calling the child’s name.

The primary endpoint of this study was postoperative analgesia and the secondary endpoint included postoperative sedation, hemodynamic change, and emergence time.

2.2. Statistical analysis

The minimum sample size required for this study was calculated 23 in each group using the sample size estimation formula to compare mean values considering confidence level of 95%, power of 80%, standard deviation (SD) of 0.90 and 0.85 and difference of means between the groups at 0.75 (these data were gathered from the study by Xiang and colleagues [18]). To address the possibility of drop out, 30 patients were included in each group, resulting in a total of 60 patients. The data were presented as mean and SD for parametric, and median with range for non-parametric variables. We used independent samples t-test to compare normally distributed variables and Mann-Whitney U test for pain and sedation score, emergence time, and duration of surgery between the groups. SPSS software version 21.0 for windows (SPSS Inc., Chicago, IL) was used for statistical analysis. P values<0.05 were considered as statistically significant.
Results

A total of 60 patients were recruited in the study, 30 in each group. In both groups, 24 patients (80%) were boys and 6 (20%) were girls. The mean age of the participants was 22.75±18.63 months (27.97±20.78 in BD group vs. 17.53±14.77 in BO group). The age distribution of the participants in the two groups is demonstrated in table 1, which shows the most frequency was in the age category of <12 months in both groups.

The results of comparing the vital signs between the groups, in the three time points, are shown in table 2. As demonstrated, there was no difference between the groups regarding SaO₂ and SBP (P>0.05), while HR was significantly lower in the BD group after 10 and 20 minutes (P<0.004 and< 0.008, respectively). The trend of changes in vital signs in the two study groups is shown in figure 2. There was a significant time effect on HR (P<0.001), and group × time interaction (P<0.008). Also, time had a significant effect on SaO₂, but the trend of changes during time was not different between the groups (P=0.5). Time did not have a significant effect on SBP (P=0.08), and there was no difference between the groups in the trend of changes in SBP during the study (P=0.3).

In BD group, the median pain score was significantly lower than BO group in the first and second hours after the operation (P<0.001), but there was no significant difference in median pain scores between the groups in the third and fourth hours after the operation (Table 3). The effect of time was significant in both groups (P<0.001 and P<0.003, respectively).

The sedation score was significantly higher in the BD group at the first three time points (1, 2, and 3 hours after surgery) (P<0.001). The effect of time was significant in the BD group (P<0.001), but not in the BO group (P=0.8, table 3).
Emergence time (time from the end of the operation until eye opening on calling the children’s name) was significantly longer in BD group [20min(10-25)], compared with BO group [5min(3-20)] (P<0.001), duration of surgery was not different between the two groups (P=1.0). No episode of nausea or vomiting was recorded.
Discussion

The results of the present study indicated lower postoperative pain in the BD group in the first and second hours, as well as significantly higher sedation scores in this group in the first, second, and third hours after the operation compared with BO group. Besides, the emergence time was longer in the BD group and there was no case of nausea/vomiting in both groups. There were no statistically significant differences in arterial O₂ saturation (SaO₂) and systolic blood pressure in the two groups. Heart rate in the BD group was significantly slower compared with BO group 10 and 20 minutes after the infiltration of the drugs, but there was no statistically significant change of HR in each group. Several studies have demonstrated the greater analgesic effect of dexmedetomidine plus bupivacaine in caudal analgesia compared with bupivacaine alone in children undergoing lower abdominal procedures under sevoflurane anesthesia, without significant side effects and have proposed similar adjuvant efficacy for DEX and clonidine [15, 16]. They are in line with the results of the present study, indicating the high analgesic and sedative effect of DEX when added to other anesthetics, although the type of anesthetic and administration method was different. In accordance with our study, Saadawy and colleagues have also confirmed significantly longer sedative and analgesic effects in the BD group than BO group in 60 children aged 1-6 years with ASA class I undergoing inguinal hernia repair [17]. They concluded similar pain scores in the first 4 hours between BD and BO group, which is inconsistent with our results, as we observed lower pain scores in the BD group, 1 and 2 hours after the surgery. This difference could be attributed to the different pain scale [objective pain scale (OPS)] used in their study [17]. Xiang and colleagues have demonstrated that supplementation of 1 µg/kg DEX to caudal bupivacaine could extend the duration of post-operative pain relief and reduce the need for rescue analgesia [18]. This is consistent with the results obtained in the present study as in our study, at the first hour postoperatively, 22 patients
in the BD group (73.3%) had CHIPPS 0 while 24 (80%) in the BO group had CHIPPS 3 (P<0.001). In the 2nd postoperative hour, 21 patients (70%) in the BD group and 11 (36.6%) in the BO group had CHIPPS 0 (P<0.006). However, they have demonstrated no statistical difference in CHIPPS pain scores between the two groups until 4 hours [18]. In their study, during the first four hours, analgesia was adequate in all subjects of both groups. As a result of the study by Xiang and colleagues [18] showed, adding dexmedetomidine to caudal bupivacaine prolonged the duration of postoperative analgesia.

The results of our study on the analgesic effect of DEX administered as surgical site infiltration in adjunction to bupivacaine are in line with the results of previous studies about adding DEX to other local anesthetics. Several studies have investigated the effect of adding DEX to ropivacaine, administered as incisional infiltration, in different procedures, such as inguinal hernia [24], laparoscopic cholecystectomy [25], and lower segment cesarean section [23]. The results of these studies showed significantly lower visual analogue scale (VAS) scores until 24 hours after surgery in the DEX+ropivacaine group than ropivacaine alone, while nausea/vomiting or other complications were not different between the groups. Although the general results of these studies confirm the efficacy of adding DEX to local anesthetic, there were several differences between them and our study. First, the type of local anesthetic used was different (ropivacaine vs. bupivacaine); second, the study populations were different, as they investigated the adult population, while we evaluated pediatrics. In addition, in the current study, we used CHIPPS for assessment of postoperative pain, similar to the study by Xiang and co-workers [18], while other studies have alternatively used other scales, such as Face, Legs, Activity, Cry, Consolability (FLACC) Pain Scale [15], objective pain scale (OPS) [17], and VAS scale [23-25]. Nevertheless, they have all concluded similar results regarding the efficacy of adding DEX to bupivacaine and other local anesthetics in adults and children. Other studies have also indicated the efficacy of incisional infiltration of DEX on post-operative pain relief, supplemented with other
anesthetics, such as levobupivacaine [26], lignocaine with adrenaline [27], suggesting that co-infiltration of local anesthetics can prolong their anesthetic and analgesic effect by peripheral action [28].

Another important finding in our study was significant higher sedation scores in BD group at the first three time points (1, 2, and 3 hours after surgery) as well as longer emergence time in this group, which indicate deeper sedation in BD group, which is similar to the result of Xiang and others. In the study by Abdelnaim and colleagues, the researchers reported significantly higher Ramsay sedation scores in the BD group compared with BO and DEX+magnesium groups [29], which confirms the results of our study. It has been previously indicated that intravenous administration and infiltration of DEX causes greater sedation compared with normal saline [30]. The sedative effects of dexmedetomidine are mainly the result of the stimulation of α₂ adrenoreceptors in the locus coeruleus [18]. Evaluation of the postoperative sedation scale in our study reveals more satisfactory sedation in the BD group, compared with the BO group in the first three hours.

The strengths of the present study include assessing adjuvant efficacy of local infiltration of DEX in children undergoing inguinal hernia repair in a double-blind RCT. Nevertheless, the present study had some limitations. The main limitation is the age difference between the two groups, despite the random allocation of participants and sufficient sample size, which could affect the results of the study. Also, we have only evaluated patients until 4 hours after surgery, while longer follow-up periods may provide a wider spectrum for the best drug choice for researchers and physicians.

Local infiltration of DEX as supplementation to bupivacaine can significantly reduce the post-operative pain of children undergoing herniorrhaphy, especially in the first post-operative hour and can induce higher sedation after the surgery without significant side effects on the hemodynamic status of the pediatric patients. Thus, it is suggested that local infiltration of DEX be used as adjuvant therapy with
bupivacaine after pediatric herniorrhaphy. Future studies with longer follow-up periods on a larger population can indicate the best anesthetic for children undergoing inguinal hernia repair.
References


10. Brummett CM, Hong EK, Janda AM, Amodeo FS, Lydic R. Perineural dexmedetomidine added to ropivacaine for sciatic nerve block in rats prolongs the duration of analgesia by blocking the hyperpolarization-activated cation current. Anesthesiology 2011;115:836-43.


Table 1: Age distribution of participants in BD group and BO group

<table>
<thead>
<tr>
<th>Age groups</th>
<th>BD group</th>
<th>BO group</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>Percent</td>
<td>Frequency</td>
</tr>
<tr>
<td>&lt;1 yr</td>
<td>11</td>
<td>33.66</td>
<td>18</td>
</tr>
<tr>
<td>1-2 yrs</td>
<td>7</td>
<td>23.33</td>
<td>6</td>
</tr>
<tr>
<td>2-3 yrs</td>
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<td>13.33</td>
<td>2</td>
</tr>
<tr>
<td>3-4 yrs</td>
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<tr>
<td>4-5 yrs</td>
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<tr>
<td>5-6 yrs</td>
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<tr>
<td>Total</td>
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<td>100</td>
<td>30</td>
</tr>
</tbody>
</table>

*The results of Chi-square test, considered significant at values <0.05

BD group: dexmedetomidine plus local infiltration of 0.2 mL/kg bupivacaine 0.5% BD,

BO group: bupivacaine and normal saline
Table 2: Comparison of heart rate, oxygen saturation, and systolic blood pressure in three different time points

<table>
<thead>
<tr>
<th></th>
<th>BD group</th>
<th>BO group</th>
<th>P value*</th>
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</thead>
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<tr>
<td>Heart rate (beat/min), mean±SD</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>baseline</td>
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<tr>
<td>10 minutes post-injection</td>
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</tr>
<tr>
<td>20 minutes post-injection</td>
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<td>128.3±12.0</td>
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<td>Oxygen saturation (%), mean±SD</td>
<td></td>
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<td></td>
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<tr>
<td>baseline</td>
<td>97.1±2.8</td>
<td>97.2±2.6</td>
<td>0.8</td>
</tr>
<tr>
<td>10 minutes post-injection</td>
<td>99.3±0.6</td>
<td>99.1±0.9</td>
<td>0.4</td>
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<tr>
<td>20 minutes post-injection</td>
<td>99.3±0.6</td>
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<tr>
<td>Systolic blood pressure (mmHg), mean±SD</td>
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<td></td>
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</tr>
</tbody>
</table>

*The results of independent samples t test

BD group: dexmedetomidine plus local infiltration of 0.2 mL/kg bupivacaine 0.5%

BO group: bupivacaine and normal saline
Table 3: Comparison of pain and sedation scores in the two groups

<table>
<thead>
<tr>
<th></th>
<th>First hour</th>
<th>Second hour</th>
<th>Third hour</th>
<th>Fourth hour</th>
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<td><strong>Pain score</strong></td>
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<td></td>
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</tr>
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<td></td>
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<td>3.0</td>
<td>1.0</td>
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</tr>
<tr>
<td></td>
<td>Minimum</td>
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<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Maximum</td>
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<td>1.0</td>
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<tr>
<td>BO group</td>
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<td>Range</td>
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<tr>
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<td>Minimum</td>
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<tr>
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<tr>
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<td>Minimum</td>
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<tr>
<td>BO group</td>
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<tr>
<td>P value*</td>
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*The results of Mann-Whitney U test, †The results of Friedman test, all tests were considered as significant at value <0.05

BD group: dexmedetomidine plus local infiltration of 0.2 mL/kg bupivacaine 0.5%

BO group: bupivacaine and normal saline

Pain score was assessed by CHIPPS: children and infants postoperative pain scale
Figure Legends

Figure 1: Flow diagram for study enrollment

Assessed for eligibility

Enrollment

Excluded (n=0)
Not meeting inclusion criteria (n=0)
Declined to participate (n=0)

Randomized (n=60)

Allocation

Group BD (n=30)
1 μg/kg dexmedetomidine plus local infiltration of 0.2 mL/kg bupivacaine 0.5%

Group BO (n=30)
Local infiltration of 0.2 mL/kg bupivacaine 0.5% with normal saline

Follow-Up

Evaluation of vital signs, severity of pain (CHIPPS), analgesic requirements, and restlessness level, time of emergency, and nausea/vomiting

Evaluation of vital signs, severity of pain (CHIPPS), analgesic requirements, and restlessness level, time of emergency, and nausea/vomiting

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Figure 2: The trend of changes in vital signs (heart rate [HR]), systolic blood pressure, and arterial oxygen saturation [SaO2]) of BD (receiving dexmedetomidine plus local infiltration of 0.2 mL/kg bupivacaine 0.5%) and BO groups (receiving bupivacaine and normal saline)