3-in-1 Block with Bupivacaine VS Bupivacaine Plus Dexamethasone in Acute Pain Control for Patients Undergoing Hip Nailing Surgery: A Double Blind Randomized Controlled Trial

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Authors’ contributions

All the authors contributed significantly to the conception and design, acquisition of data, analysis and interpretation of data, drafting the article, critically revising the article and final approval of the version to be published. Anyone who participated substantially in the study has not been omitted from the article. All persons listed as authors qualify for authorship.

Article Information

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ABSTRACT

Background: Femoral 3-in-1 block is one of the most effective methods in cases of hip nailing surgery because of its ease, low cost, and fewer complications. This study aims to evaluate the effect of adding dexamethasone to peripheral nerve block solution.

Methods: Forty-four ASA (I,II & III) patients aged between 50-80 years, scheduled for elective hip-nailing surgery who met inclusion and exclusion criteria were enrolled in this double blind randomized controlled trial. Patients were allocated into two groups randomly; at the end of the surgery, femoral 3-in-1 nerve block was performed with 40 ml of bupivacaine 0.25% solution with or without 8 mg of dexamethasone. Pain score was measured for 24 hours.

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Results: We found no significant difference in pain intensity scores until hour 0.5 and the scores were below 1. Thereafter, the VAS scores increased, yet it remained below 3 in the first 12 postoperative hours. Morphine was administered during hours 12-24 in both groups, when VAS scores reached to about 4. The total amount of morphine consumption was a little lower in the case group, although the difference was not statistically significant.

Conclusion: Adding dexamethasone to bupivacaine 0.25% for 3-in-1 block has no more benefit than bupivacaine 0.25% alone for acute postoperative pain management after elective hip nailing surgery.

Keywords: Bupivacaine; dexamethasone; 3-in-1 block.

Trial registration number: IRCT NO. IRCT201201158728N1

1. INTRODUCTION

Consistent with the increase in the mean age of individuals, the prevalence of hip and intertrochanteric fractures has also increased. Most of this old patients have some underlying diseases [1,2]. High rates of morbidity and mortality such as infection, venous thrombosis, and pulmonary thromboembolism are seen in such patients. Therefore, it is necessary to perform surgery in order to rapidly restore the patients' function and avoid prolonged hospital admission, anatomical deformity, etc [3,4]. Depending on the site and case of surgery, surgical methods for such patients include hip arthroplasty and hip nailing. Of these methods, hip nailing is used by orthopedic surgeons for trochanteric region because it is more effective and less invasive.

With respect to the painfulness of hip fractures and the surgery itself, an effective method of pain control that imposes the lower risks on the patients is of utmost importance. Of the different pain control methods, the 3-in-1 femoral nerve block is one of the best methods for decrease the fracture pain or postoperative pain management in lower extremity procedures especially surgeries of the knee, femur, trochanter and hip area, because of its better effect, lesser complications, and ease. In this method, obturator and femoral nerves, as well as lateral cutaneous nerve of thigh are blocked by a single injection5% [5-7].

Marhofer and colleagues compared the effect of ropivacaine and bupivacaine with respect to the duration and the quality of analgesia on patients undergoing hip nailing surgery and found no significant difference between both drugs [8]. In another study on patients undergoing total hip arthroplasty, the amounts of pain and tramadol consumption were much lower in the group who had received blocks with bupivacaine compared with the group that had received placebo [9]. Moreover, Singelyn and co-workers found that 3-in-1 block with bupivacaine had higher analgesic effects and a faster rehabilitation rate compared with patient-controlled analgesia with intravenous morphine in patients undergoing knee replacement [10]. Ozen and colleagues found that post-procedure pain and morphine consumption were significantly lower in patients receiving the 3-in-1 block with ropivacaine compared with patients who had received morphine at the end of knee replacement surgery [11].

We aimed to study the effect of 3-in-1 block with bupivacaine 0.25% alone, and bupivacaine 0.25% plus 8 mg dexamethasone in controlling acute postoperative pain in patients undergoing hip nailing surgery to suggest the more effective method as the primary and selective treatment.

2. METHODS

This double blind randomized controlled trial, was approved in Ethics Committee of Shiraz University of Medical Sciences (Ethics Committee No. CT-P-90-1953) and Iranian Registry of Clinical Trial (IRCT NO. IRCT201201158728N1).

All patients signed the written informed consent forms. All data were kept confidential, patients’ anonymity was preserved and the patients were not charged for the study purposes.

An statement was also signed by patients under the 'Consent to publish’ heading confirming that consent to publish has been obtained from the participant (or legal parent or guardian for children) to report individual patient data.

Forty-four patients, aged between 50-80 years, American Association of Anesthesiologists’
(ASA) class I, II or III, undergoing elective hip nailing surgery at Chamran Hospital, Shiraz, Iran, were enrolled. Sample size was calculated to be 44 patients (22 in each group) with the power of 90%.

Patients who were <50 or >110 kg, unable to understand the pain grading system, or had a history of addiction, allergy to local anesthetics, peripheral neuropathy, neurological defect, coagulopathy disorder, mental retardation or dementia were excluded from this study.

Before the surgery, the pain rating system was taught to all of the patients according to the visual analog scale (VAS) (0=no pain, 10=the worst possible pain). The patients were then divided into two equal case (bupivacaine + dexamethasone [BD]) and control (bupivacaine [B]) groups using the block randomization method.

Anesthesia induction was done using midazolam (0.03 mg/kg), fentanyl (2 µg/kg), sodium thiopental (4-6 mg/kg), and atracurium (0.5-0.6 mg/kg). Anesthesia was maintained using isoflurane 1-1.5% and a mixture of 50-50 oxygen and nitrous oxide. In the case with increase in mean arterial pressure or heart beat up to 30% from baseline, remifentanil 0.1-0.2 µg/kg/min was infused.

At the end of surgery, after administering reversal of muscle relaxation and before the patient was awake, with sufficient disinfecting the site of injection, a physician who was blind to the administered drugs, injected 40 ml bupivacaine 0.25% or 40 ml bupivacaine 0.25% containing 8 mg dexamethasone, under 3-in-1 block to the control and case groups, respectively.

The block was done with the help of a nerve stimulator (B) BRAUN Germany; the contraction of the quadriceps muscle with the intensity of 0.5 mA was considered as an acceptable sign before the injection. Injection was done after negative aspiration. The Injection was carried out within a period of two minutes with distal pressure application to increase the spread of the drug to the psoas sheath. The patients were then transferred to recovery room with endotracheal tube and extubated after full awakening.

In the recovery room, the patients' blood pressure, heart rate, and arterial oxygen saturation were closely monitored. The patients were also monitored for the possible side effects such as nausea, emesis, arrhythmia, decrease level of consciousness and hematoma at the injection site. After complete awakening, a pinprick was used to evaluate the presence of sensory block in the dermatomes of the femoral, obturator and lateral femoral cutaneous nerves. In case of having sense on the territory of 2 of the mentioned nerves, the patient was excluded from the study and substituted with another patient because of an unsuccessful block.

The score of pain was evaluated at 0 (1 hour after the block), 0.5, 1, 6, 12, and 24 hours by a physician who was unaware of the study protocol. A VAS score of 1-3 was considered as acceptable analgesia. During the study, if the VAS exceeded above 3, 2 mg of intravenous morphine was administered in each bolus dose slowly every 30 minutes, if necessary, to reduce the score to <4. At hour 24, the patients' general contentment from the pain control method was evaluated using the numerical rating scale (NRS) (0=bad, 1=average, 2=good, 3=excellent).

Data analysis was done using SPSS software, version 21. P-value<0.05 was considered as significant. Demographic and clinical data were analyzed using t and Chi-Square tests. The Mann-Whitney test was also used to compare pain intensity and the amount of administered morphine as well as the patients' satisfaction of the pain control method in both groups at the studied time intervals and 24 hours after the block. To compare the experienced side effects in the groups and assess the patients who used remifentanil during surgery, Chi-Square test was used.

3. RESULTS

The demographic data of the included patients is shown in Table 1. We only found a significant difference between the pain intensity in two groups at hour 12 (P=0.048, Table 2). However, since this difference occurred when intensity scores were 2 and 3, it was considered as acceptable pain condition for the patient. As a result, this difference was ignorable.

Only one patient had received 2 mg morphine in group B during hours 6 to 12. During hours 12-24, 5 patients received 14 mg morphine in group B and 5 patients received 10 mg morphine in group BD. We found no significant difference between the two groups regarding the consumed amount of morphine (P>0.05, Table 3).
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Table 1. Mean (±SD) of some demographical and clinical variables in both groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group B</th>
<th>Group BD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (F/M)</td>
<td>13.9</td>
<td>12.10</td>
<td>0.761</td>
</tr>
<tr>
<td>Age (years)</td>
<td>66.95±7.08</td>
<td>68.55±8.35</td>
<td>0.499</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>55.15±3.16</td>
<td>55.60±1.87</td>
<td>0.577</td>
</tr>
<tr>
<td>ASA (I/II/III)</td>
<td>5/13/4</td>
<td>7/10/5</td>
<td>0.658</td>
</tr>
</tbody>
</table>

P< 0.05: significant; n: Number; F: Female, M: Male; ASA: “American Society of Anesthesiologists” Physical condition classification; Group B: Bupivacaine 0.25% (40 ml); Group BD: Bupivacaine 0.25% (38 ml)+Dexamethasone (8 mg)

Table 2. Comparison of pain scores between the two groups during 24 hours

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean ± SD</th>
<th>Mean Rank</th>
<th>Mann-Whitney U</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hour 0</td>
<td>Group B</td>
<td>0.86±0.774</td>
<td>23.27</td>
<td>255</td>
</tr>
<tr>
<td></td>
<td>Group BD</td>
<td>0.77±0.813</td>
<td>21.73</td>
<td></td>
</tr>
<tr>
<td>Hour 0.5</td>
<td>Group B</td>
<td>0.91±0.684</td>
<td>22.09</td>
<td>233</td>
</tr>
<tr>
<td></td>
<td>Group BD</td>
<td>0.95±0.653</td>
<td>22.91</td>
<td></td>
</tr>
<tr>
<td>Hour 1</td>
<td>Group B</td>
<td>1.41±0.908</td>
<td>25.55</td>
<td>175</td>
</tr>
<tr>
<td></td>
<td>Group BD</td>
<td>1.00±0.617</td>
<td>19.45</td>
<td></td>
</tr>
<tr>
<td>Hour 6</td>
<td>Group B</td>
<td>1.86±0.889</td>
<td>24.59</td>
<td>196</td>
</tr>
<tr>
<td></td>
<td>Group BD</td>
<td>1.59±0.854</td>
<td>20.41</td>
<td></td>
</tr>
<tr>
<td>Hour 12</td>
<td>Group B</td>
<td>2.55±0.596</td>
<td>25.98</td>
<td>165.5</td>
</tr>
<tr>
<td></td>
<td>Group BD</td>
<td>2.14±0.710</td>
<td>19.02</td>
<td></td>
</tr>
<tr>
<td>Hour 24</td>
<td>Group B</td>
<td>3.91±0.971</td>
<td>23.02</td>
<td>230.5</td>
</tr>
<tr>
<td></td>
<td>Group BD</td>
<td>3.02±1.140</td>
<td>21.98</td>
<td></td>
</tr>
</tbody>
</table>

P< 0.05: significant; Group B: Bupivacaine 0.25% (40 ml); Group BD: Bupivacaine 0.25% (38 ml)+Dexamethasone (8 mg); SD: Standard deviation

Table 3. Morphine consumption (mg) in the two groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group B</th>
<th>Group BD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine (mg) (Hour 0- Hour 0.5/ Hour 0.5- Hour 1/ Hour 1- Hour 6/ Hour 6- Hour 12/ Hour 12- Hour 24)</td>
<td>0/ 0/ 0/ 0/ 0/ 14</td>
<td>0/ 0/ 0/ 0/ 0/ 10</td>
<td>0.174</td>
</tr>
</tbody>
</table>

P< 0.05: significant; Group B: Bupivacaine 0.25% (40 ml); Group BD: Bupivacaine 0.25% (38 ml)+Dexamethasone (8 mg)

Table 4. Mean satisfaction scores in the two group

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group B</th>
<th>Group BD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Satisfaction (Very satisfied/ Satisfied/ Dissatisfied/ Very dissatisfied)</td>
<td>12/ 8/ 2/ 0</td>
<td>14/ 7/ 1/ 0</td>
<td>0.499</td>
</tr>
</tbody>
</table>

P< 0.05: significant; Group B: Bupivacaine 0.25% (40 ml); Group BD: Bupivacaine 0.25% (38 ml)+Dexamethasone (8 mg)

Table 5. Frequency (%) of nausea and emesis in the two groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group B</th>
<th>Group BD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>6 (27.27%)</td>
<td>5 (22.72%)</td>
<td>0.728</td>
</tr>
<tr>
<td>Emesis</td>
<td>4 (18.18%)</td>
<td>3 (13.63%)</td>
<td>0.680</td>
</tr>
</tbody>
</table>

P< 0.05: significant; Group B: Bupivacaine 0.25% (40 ml); Group BD: Bupivacaine 0.25% (38 ml)+Dexamethasone (8 mg)

Table 4 shows the patients’ satisfaction with the pain control method after completion of the pain control period during the 24 hours after the block in both groups (P>0.05, Table 4). No significant difference was found between groups B and BD with respect to nausea and emesis (P>0.05, Table 5). In the case group, 12 (54.54%) patients received remifentanil during
surgery as compared to 9 (40.9%) in the control group (P=0.365).

4. DISCUSSION

We aimed to determine whether adding 8 mg dexamethasone to the injected solution for 3-in-1 femoral block, reduces the postoperative pain as well as the need for intravenous drugs administration such as morphine for controlling pain after hip nailing surgery. We found that adding 8 mg dexamethasone to the block content (40 ml bupivacaine 0.25% containing 8 mg dexamethasone) did not have a significant effect on the postoperative pain intensity.

In a study published at 2012 by Cummings KC and coworkers, it was concluded that dexamethasone addition to bupivacaine or ropivacaine would increase the duration of interscalene block as postoperative analgesia [12]. In another study, Liu and colleagues evaluate the effect of peripheral injection of dexamethasone on the duration and intensity of the saphenous nerve block by ropivacaine. Dexamethasone had conflicting effects on the prolongation of the peripheral nerve block; there was only limited useful effect from perineural injection of dexamethasone [13]. A systemic review at 2017, has evaluate the comparison of the effect of intravenous dexamethasone injection with the perineural route to increase the time of efficacy of peripheral nerve blocks; the authors have concluded that the admixture of dexamethasone and local anesthetics would be more effective in prolongation of the neural

Fig. 1. The patients’ flow diagram
blockade if the injectate be contained epinephrine as an adjuant [14].

Our study was inconsistent with some other studies. One study was done on the patients undergoing arthroscopy of the glenohumeral joint, after ultrasound-guided brachial plexus blockade (via interscalene approach) with bupivacaine, epinephrine and clonidine showed that addition of dexamethasone to the mentioned combination would increase the sensory block duration, and reduce the opioid requirement, compared with the control group patients who received normal saline as the placebo [15]. In another study, patients with the plan of upper extremity surgery under brachial plexus block via supravacular approach were divided into two groups; One group received the block with bupivacaine + tramadol and the other group bupivacaine + dexamethasone. The researchers found that adding dexamethasone would more effectively prolong the postoperative analgesia [16]. Moreover, according to the other study findings, the axillary brachial plexus block by dexamethasone added to lidocaine, prolonged the duration of sensory and motor blockade compared with the control group (normal saline instead of dexamethasone) [17].

The inconsistent findings in our study might have several reasons; Local dexamethasone does not affect the duration and the quality of analgesia after the surgery. The sample size may be not enough to make a statistically significant difference. According to previous studies, local (not systemic) dexamethasone induces vasoconstriction [18,19]. In the studies that were inconsistent with our study, the surgical incision sites were, usually, far from the site of block injection; so, the vasoconstrictor effect of dexamethasone was more, compared with this study. Moreover, since in the present study, the surgical site was closer to the block, dexamethasone and other drugs would be washed away faster and also be absorbed systemically because of hyperemia resulting from inflammation and surgical manipulations.

Finally, the patients in both groups were similar in the field of analgesia at hour 12, which shows that the effect of nerve block still exists. Then, at hour 24, the documented pain scores had similar increase in both groups; which shows that the drugs were losing their effect, synchronously in both groups.

The considerable point in our study was that morphine administration for pain reduction was done during hours 12-24 (except for one patient) when pain scores were more than 3. The amount of administered morphine in the case group (bupivacaine + dexamethasone) was less than the control group; but no statistically significant difference was found between morphine demand in two groups. It seems feasible that this difference would be statistically meaningful if the number of the patients was more.

5. CONCLUSION

We found that adding dexamethasone to bupivacaine 0.25% for 3-in-1 block has no more benefit than bupivacaine 0.25% alone for acute postoperative pain management after elective hip nailing surgery. However, further multi-central randomized clinical trials with control groups are still needed to confirm the results and generalizability of our findings.

CONSENT

All patients signed the written informed consent forms. All data were kept confidential, patients’ anonymity was preserved and the patients were not charged for the study purposes.

ETHICAL APPROVAL

This double blind randomized controlled trial, was approved in Ethics Committee of Shiraz University of Medical Sciences (Ethics Committee No. CT-P-90-1953) and Iranian Registry of Clinical Trial (IRCT NO:IRCT201201158728N1).

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES


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