The Effect of Distraction Method on Bone Marrow Aspiration Pain: A Randomized Clinical Trial

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ABSTRACT

Bone Marrow Aspiration (BMA) is one of the methods for diagnosis and treatment of various diseases, that now day it is widely used in regenerative medicine. Although this procedure in adults is usually performed by using local anesthesia, it is associated pain. The purpose of this study is to research into the effect of Distraction Technique (DT) on patients who have undergone BMA for appeasement of pain. This study was a parallel-randomized clinical trial. The 60 patients who underwent BMA were randomly divided into two groups. Intervention group received DT training and control group did not go through any training program. To measure the scope of severity of pain, Visual Analogue Scale (VAS) was used respectively. Comparison of pain variable in study groups revealed that the mean score of VAS average in the intervention group has been lower than that of the control group and this difference was significant (P < 0.001 respectively). Comparison of vital signs before and after BMA showed no any significant differences between groups. However, no significant change was observed in control group. DT is an effective technique to reduce pain in BMA candidate. Nurses need to be aware pain procedures during BMA.

Key words: Distraction technique, Bone marrow aspiration, Visual analog scale, Pain

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1. INTRODUCTION

Today invasive procedures are part of the treatment options that spare the lives of many patients against death threatening disease (1, 2). Bone marrow aspiration (BMA) is one of the procedures commonly used for diagnoses as well as treatments. This procedure was developed in the beginning of nineteenth century and allowed doctors to diagnose marrow disorders (3, 4). BMA has been widely used in regenerative therapeutic strategies as well (5). Although BMA has numerous diagnostic advantages, it is always associated with pain and stress. Some studies have revealed that those who underwent BMA showed some symptoms the most frequent of which is pain (3, 6, 7). For this reason, BMA is known as a painful procedure that involves the insertion of a needle into the bone and causes stress and pain. Local anesthesia is routinely applied to the skin, subcutaneous tissue and periosteum, but does not prevent the transient pain experienced during suction (7-9). Some studies have shown local anesthesia alone does not abolish the pain (7). Many studies have made stride to offer a viable approach to mitigate pain (10). These treatments encompass both pharmacological and no pharmacological approaches (11). The most commonly used pharmacological approach is to use anesthetic drugs to reduce the medical procedure-related pain (4, 7, 12). Pharmacologic treatment approaches have many complications including drowsiness, respiratory depression, prolongation of hospitalization and high medical cost (13-15). Non-pharmacological approaches often include distraction methods such as aromatherapy, acupressure, game play and deep breathing (16-18). Among which deep breathing technique (DBT) is one of distraction methods. DBT is a very easy method for the patients to learn it readily without wasting too much time and procuring expensive equipment. This technique stimulates the vagus nerve causing the reduction of pain (19, 20). Likewise, DBT is known as relaxation technique (21) which can also appease patients’ pain. Therefore, this
study aimed to investigate the effects of DT on reduction of procedural pain in Iranian patients with knee and ankle osteoarthritis and avascular necrosis undergoing bone marrow aspiration for cell therapy treatment in adult between the age's range of 35 and 60.

2. MATERIALS AND METHODS

This study was designed as a parallel-randomized clinical trial that evaluated and compared the effects of the DT intervention on pain and level of vital signs of BMA candidates. After obtaining approval from the ethics Committee (Yazd Shahid Sadoughi University of Medicine Sciences, Iran (IR.SSU.MEDICINE.REC.1394.550) the study was conducted in compliance with the Helsinki protocol. Written informed consent from the patients was achieved and 60 adult patients were examined. These patients were randomly categorized into two groups by using Random Number Tables. The targeted patients were oriented about the methods of this survey. They are allowed to quite the study at any phase if they tend to. All the relevant documents of the participants were guaranteed to remain confidential as well. The sample size of the study was determined by power analysis. On the basis of the previous research conducted with an effect size (0.80) to achieve a power of 0.80%, confidence interval 95% and \( \alpha=0.05 \) total sample size was estimated 60 subjects (each group required 30 subjects) (22). To determine sample size, we used the G-power 3.1.9.2 (Franz Faul, Kiel University, Germany) software (23). The study population consists of 35-60 year-old subjects with osteoarthritis knee, hip and avascular necrosis. The subjects underwent BMA for stem cell therapy from September 2014 and April 2015. The patients were in American Society of Anesthesiologists (ASA) physical status I and II (ability to read and write). Exclusion criteria for Patients were with: skin diseases at or around the BMA site, scars, psoriasis, active dermatitis or eczema, infection, sedative or alcohol abuse, chronic consumption of analgesics, history of peripheral neuropathy, difficulty in communication, chronic pain, prior experience of BMA, and Chronic respiratory problems. The 98 patients were evaluated for eligibility and 38 subjects were excluded from the study because 25 patients were not able to read and write, 3 with respiratory problems, 3 were addicted and 2 had chronic pain. Finally, 60 patients were selected and divided into two study groups (Figure 1).

![Figure 1. Trial Profile Details](https://example.com/figure1.png)

The measures used in this study including intensity of pain, the visual analog scale (VAS) were used with the ranges from 0 (no pain) to 10 (the worst pain imaginable). The measurement of the pain was conducted immediately after completion of BMA. Vital signs (VS) were measured by certain Pulse Oximetry set (brand of Pooyandegan Rah Saadat, Patient Monitor BPM-9500) (including systolic and diastolic blood pressure (SBP, DBP), heart rate (HR)). Intervention group was trained about DBT so that they could keep their mouth closed and inhale deeply through their nose by moving their stomach muscle to pull air in, and then exhale through Pursed lip breathing. They had to regulate inhale and exhale so that the latter take twice roughly as much the former. In the control group, no training program was conducted. All patients underwent BMA from the left the iliac crest, with Jamshidi biopsy.
needle and certain oncologist performed all processes. Localized an anesthesia was done for all patients by 10cc lidocaine 2%. The case group patients were requested do DBT during using Jamshidi biopsy needle. The control group was not subject to these instructions. The patients were asked to report the perceived pain intensity during BMA just after BMA, and the pain was assessed by using a visual analog scale (VAS). Also VS measurements were obtained just before start and after end of BMA. During the whole process BP was measured in right hand and HR was measured with left hand. All the processes from the beginning to the completion of the study were performed by a well-trained and a career nurse. Data were analyzed by using SPSS version 16 (SPSS Inc., Chicago, IL, USA) Software. To study the normality of data distribution, Kolmogorov-Smirnov test was used. For comparison of baseline data between studies group, t student and chi-square test were used and to compare VAS between groups, t student test was used and finally to compare effect DBT on SBP, DBP and HR before and after intervention, Paired t test was used. All of variables represent Mean ± Standard Deviation. Significant level was set at 0.05 for all tests.

3. RESULTS AND DISCUSSION

Given that after random allocation of subjects in intervention and control group, two patients in control group who needed analgesia during bone marrow aspiration were excluded from the study. Finally, The 28 patients in the control group and 30 patients in the intervention group were analyzed. Participant Rate was 96.6% and no side effects were observed. All the information was measured and there was no missing in this regard. All quantitative variables were normal. The mean age of the subjects was 50.63 (SD = 9.8). The 41 patients were female (70.7%) and 17 patients were male (29.3%). Data were reported mean ± SD or number (%). T student and Chi-square tests were used to comprise between study groups. Significance level was 0.05. The demographic and baseline variables of the sample are displayed in Table 1. No significant differences were observed between groups at baseline ($P > 0.05$).

<table>
<thead>
<tr>
<th>Parameter/group</th>
<th>Intervention group N=30</th>
<th>Control group N=28</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>51.8 ± 8.6</td>
<td>49.36 ± 10.86</td>
<td>0.353</td>
</tr>
<tr>
<td>Female sex, n (%)</td>
<td>23 (56.1%)</td>
<td>18 (43.9%)</td>
<td>0.301</td>
</tr>
<tr>
<td>Marig, yes (%)</td>
<td>27 (52.9%)</td>
<td>24 (47.1%)</td>
<td>0.857</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>74.22 ± 10.92</td>
<td>77.14 ± 9.89</td>
<td>3.359</td>
</tr>
<tr>
<td>ASA class</td>
<td></td>
<td></td>
<td>0.512</td>
</tr>
<tr>
<td>I (%)</td>
<td>18 (60%)</td>
<td>19 (67%)</td>
<td></td>
</tr>
<tr>
<td>II (%)</td>
<td>12 (40%)</td>
<td>9 (32%)</td>
<td></td>
</tr>
<tr>
<td>Diagnosis, n (%)</td>
<td></td>
<td></td>
<td>0.504</td>
</tr>
<tr>
<td>OA knee</td>
<td>25 (83.3)</td>
<td>21 (75)</td>
<td></td>
</tr>
<tr>
<td>OA hip</td>
<td>5 (16.7)</td>
<td>6 (21.4)</td>
<td></td>
</tr>
<tr>
<td>AVN*</td>
<td>0</td>
<td>1 (3.6)</td>
<td></td>
</tr>
</tbody>
</table>

*AVN: Avascular necrosis

Comparison of severity of pain between the two groups showed the mean score of VAS average in the intervention group was lower than that of control group and this difference was significant ($P < 0.001$). Table 2 shows the distribution of the VAS scores. In control group the pain was mild in 12 patients (42.9%), moderate in 14 (50.0%) and severe in 2 (7.1%). In intervention group the pain was mild in 26 patients (87.6%), moderate in 4 (13.3%) and severe in any patients (0.0 %) and this difference was significant ($P > 0.05$).

<table>
<thead>
<tr>
<th>Severity of pain (VAS)</th>
<th>Intervention group N=30</th>
<th>Control group N=28</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>mean ± SD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-3 (mild)</td>
<td>1.3 ± 1.5</td>
<td>3.64 ± 2.0</td>
<td>0.000**</td>
</tr>
<tr>
<td>4-6 (moderate)</td>
<td>26 (87.6)</td>
<td>12 (42.9)</td>
<td></td>
</tr>
<tr>
<td>7-10 (sever)</td>
<td>4 (13.3)</td>
<td>14 (50)</td>
<td>P&gt;0.05</td>
</tr>
<tr>
<td>total</td>
<td>30 (100)</td>
<td>28 (100)</td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as n (%) and mean ± SD. *: vas=visual analog scale. **: P<0.05

No significant differences were observed between groups at baseline of vital signs. Comparison of vital signs before and after BMA showed no any significant differences between groups ($P > 0.001$).
Pain experience during the medical procedures in clinics and hospitals may cause stress, fear and anxiety in patients (24, 25). Although type of the applied procedures may influence on pain and, there are many individual factors that may contribute to this discomfort such as emotional status, cultural background, and previous unpleasant experiences of hospitalization and individual variability of pain threshold (26). In addition to Pharmaceutical methods, non-Pharmaceutical methods could be used to reduce the pain in patients who were subjected to invasive procedures. The American Society for Pain Management Nursing (ASPMN) points out that procedures producing pain should be assessed before and during procedures (27). In spite of invasive procedures such as BMA, using general and local anesthesia is highly recommended in order to reduce the pain (28). Georges Ever, et al in one study on 132 Caucasian hematological patient shown that one hundred eleven (84.1%) reported pain during BMA. The pain was absent or minimal in 85 patients (64.4%), moderate in 26(19.7%) and severe in 21 (15.9%) (7). According to complications of pharmacological approaches, using of non-pharmacological methods such as distraction methods are widely used to reduce procedural pain (2, 29, 30) one of which is deep breathing method. Several studies have been investigated the effect of non-Pharmaceutical methods on reduction of pain in the patients with similar results in most cases. These studies have shown that the use of non-Pharmaceutical methods can be helpful in reduction of the pain. (20, 31-36). non-Pharmaceutical methods affect the nervous system, causing relaxation during the body activities as a result, reduce pain in the patients. Our study showed that using DBT - that is one of non-Pharmaceutical methods - can reduce the pain in patients who are candidate BMA, the Mean of pain anxiety score in the intervention group were less than that of control group (19). Agarwal has conducted a study and concluded some distraction method such as deep breathing decreased the Vass core significantly compared to the control group in venous cannulation pain and the application was easy and with less side effects (37). In addition, Basaranoglu has mentioned DBT stimulate Vagus nerve can cause reduction of pain and anxiety in patients who were subjected to invasive surgery (20). DBT achieved by inhalation, causes an increase in intrathoracic volume. DBT resulted in compression of the vessels within the chest and in turn leads to baroreceptor activation and consequently induces antinociception (37-39). Another justification ability of DBT to reduce pain is that it is considered as a distraction technique. In distraction technique, it is supposed that the brain has a limited capacity of focusing attention on stimulation and when attention resources are diverted to focus on a distracting task, then little focusing capacity remind for attending to painful stimulation (2, 40). Therefore, these findings need further investigation to consider between DBT and changing oxygen saturation. Likewise, the results of our study showed that in intervention group, heart rate decreased after DBT. This study focused on the pain post-operative experienced by them as a side effect of the treatment and the pain scores for the intervention group were significantly lower than that of control group. It is thought that it is important for the patients who are candidate for invasive procedures with no need for general anesthesia such as BMA to adapt themselves to relaxation methods for relieve pain. Considering the point that, the patients with different cultural, social and education of level refer to the hospital, this relaxation method must be simple, allow the patients to quickly adapt to them and need only to minimal facilities such as using deep breathing method that patients can perform it with ease anytime and anywhere.

4. CONCLUSION

DBT was found to be the most effective method for pain relief in patients’ candidate bone marrow aspiration. Nurses need to be aware of procedural pain during bone marrow aspiration.

ACKNOWLEDGMENT

Extend deep appreciation for patients endure and sobriety in implantation of this study.

FUNDING/SUPPORT

Not mentioned any funding/support by authors.
AUTHORS CONTRIBUTION
This work was carried out in collaboration among all authors.

CONFLICT OF INTEREST
The authors declared no potential conflicts of interests with respect to the authorship and/or publication of this article.

REFERENCES