The Effect of Shot Blocker Application on Intramuscular Injection Pain in Adults: A Randomized Controlled Trial

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Abstract-Introduction: Intramuscular (IM) injection is a frequently used nursing practice in clinical practice. IM injection is a complex process that requires technical competence and effective decision-making in terms of the tools and methods involved. Despite the therapeutic effect of IM injection, it may cause pain and discomfort in patients. This study was carried out to determine the effect of the ShotBlocker application on intramuscular injection-induced pain. Methods: This is a randomized controlled study. The study data were collected between November and December 2018. Data were collected using a questionnaire and Visual Analog Scale (VAS). The patients were randomized into two groups as experimental group and control groups. The study was completed with 176 patients including 88 patients in the experimental group and 88 patients in the control group. Results: The mean VAS scores of the experimental and control groups were 1.2 ± 1.3 and 1.1 ± 1.6, respectively. No significant difference was found between the mean VAS scores of the experimental and control groups (p> 0.05). Conclusion: The results of the study indicated that administration of IM injection in adults using ShotBlocker did not reduce the severity of pain.

Keywords: ShotBlocker, Intramuscular injection, Pain, Adult

INTRODUCTION

Intramuscular (IM) injection is a frequently used nursing practice in clinical practice (1,2). IM injection can cause serious complications if it is not administered with correct and proper methods. These complications include pain, cellulitis, muscle fibrosis and contracture, sterile abscesses, tissue necrosis, granuloma, intravascular injection, hematoma, and nerve injuries (3).

IM injection is a complex process that requires technical competence and effective decision-making in terms of the tools and methods involved (2). Despite the therapeutic effect of IM injection, it may cause pain and discomfort in patients (3). In particular, pain may develop due to mechanical trauma resulting from the insertion of the syringe and the sudden pressure felt when the drug is administered intramuscularly (4).

Pain treatment and pain relief studies have recently amplified and also affected nursing. The patient and the nurse are in constant contact, and the nurse plays an active role in relieving the pain (5). The quality of pain management depends on the knowledge, skills, and behavior of nurses about painful procedures (5,6). Nurses are responsible for preventing injection-related pain by carefully administering the medication and relieving patients’ pain (6).

There are many pharmacological and non-pharmacological methods to reduce the pain experienced during IM injection (6). The ShotBlocker application is one of the methods employed to minimize the pain felt during IM injection (1,4). In this method, the injection site is touched with a blunt tip plastic device with many needles when administered IM injection. The ShotBlocker is reported to relieve pain by preventing the perception of pain and its transmission to the central nervous system by applying temporary blockage to the peripheral nerve ends (7).

A limited number of studies have been carried out on the effect of the ShotBlocker on adult patients. Two studies have shown that the ShotBlocker effectively relieves pain associated with intramuscular injection (7,8), whereas another study has concluded that the ShotBlocker is an ineffective pain management tool (9).

Given the limited number of studies on adults and the contradictory findings, this study was carried out to evaluate the effectiveness of the ShotBlocker in reducing pain associated with IM injection in adult patients.

Research questions:
Is it a statistically significant difference on the level of p<0.05 in the IM injection-induced pain between the experimental and control groups?

MATERIALS AND METHODS

Design:
The study was carried out randomized controlled to determine the effect of the ShotBlocker application on IM injection-induced pain.

Sample and setting:
The study was conducted at the injection policlinic of Ankara Hospital. The study data were collected between November and December 2018. The sample size was calculated using power analysis based on 0.5 effect size and
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s, cognitive injection site, the side of the ShotBlocker with non region at a 90° angle using needle 21 with 2.5 cm length. was administered to both groups from the ventrogluteal the VAS within 1 minutes after the injection. IM injection form, and IM injections were administered by the

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Through the opening

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Visual Analog Scale (VAS):

VAS is used to evaluate pain caused by IM injection. VAS is a scale that is used for pain measurement. It consists of a 10 cm long horizontal line with the words "no pain at all" at one end and "severe pain" at the other end. Patients mark their pain on this line (11). Within 1 minutes after the injection in the study, the patients were asked to mark the severity of their pain on the scale. The number marked on the scale determined the pain score.

The ShotBlocker:

The ShotBlocker is a plastic disc with a large number of short, non-sharp skin contact points on its back with a large opening through which injections can be administered. The ShotBlocker is a novel application of the gate control theory of pain management. When administering injection with the ShotBlocker, the device is placed over the injection site, and the non-sharp skin contact points are pressed firmly against the skin at the injection site. The injection is administered through the opening (12).

Data collection procedure:

The purpose of the study was explained to the patients who met the inclusion criteria, and then they signed the consent form. After that, the patients completed the questionnaire form, and IM injections were administered by the researcher. The patients marked the severity of their pain on the VAS within 1 minutes after the injection. IM injection was administered to both groups from the ventrogluteal region at a 90° angle using needle 21 with 2.5 cm length.

The experimental group: After cleaning the skin at the injection site, the side of the ShotBlocker with non-sharp skin contacts was placed on the ventrogluteal region of the skin and pressed. The injection was administered through the opening of the ShotBlocker, and ShotBlocker was removed after the injection was completed.

The control group: After cleaning the skin at the injection site, the injection was administered in the ventrogluteal region without placing the ShotBlocker.

Data analysis:
The Statistics Package for Social Sciences for Windows Version 22 software was used to analyze the data. Frequency values, mean scores, standard deviation, chi-square, t-test, and Mann-Whitney U test were employed in the evaluation of the data. The level of statistical significance was accepted as p <0.05.

Ethical considerations:
At the outset, the ethical approval of the Nevşehir Hacı Bektaş Veli University Ethics Committee (Decision no: 2017.08.12) and the institutional permission of the state hospital where the study was conducted were obtained. Also, the consent of the participants was obtained.

RESULTS
No significant difference was found between the experimental and control groups in terms of mean gender, age, height, weight, and BMI values (p > 0.05) (Table 1).

Table 1: Descriptive Characteristics of the Experimental and Control Groups

| Characteristics | Experimental group (n=88) | Control group (n=88) | Test | p  |
|-----------------|--------------------------|----------------------|------|----|
| Age             | M±SD                     | M±SD                 | t    | p  |
|                 | 44.4±17.4                | 42.0±14.6            | 1.012*| 0.313 |
| Weight          | 73.0±16.2                | 70.6±13.9            | 1.053*| 0.294 |
| BMI             | 26.4±5.7                 | 25.7±4.3             | 0.889*| 0.375 |
| Height          | 166.0±8.5                | 165.1±9.5            | 3620,500*| 0.456 |
| n(%)            | M±SD                     | M±SD                 | Test | p  |
| Gender          | Female                   | Male                 |      |    |
| BMI             | 36(40.9)                 | 52(59.1)             | 0.023***| 0.878 |
| 37(41.5)        | 51(58.1)                 |                      |      |    |

M=Mean; SD=Standard Deviation; BMI: Body Mass Index; p: p-value
*t test; **Mann Whitney U test; *** Chi-Square test

The mean VAS scores of the experimental and control groups were found to be 1.2 ± 1.3 and 1.1 ± 1.6, respectively. There was no significant difference between the mean VAS scores of the experimental and control groups (p > 0.05) (Table 2).

Table 2: Mean VAS Score of the Experimental and Control Groups

| Groups           | VAS | Test and p |
|------------------|-----|------------|
| Experimental     | 1.2±1.3 | 3460,500* | 0.196 |
| group (n=88)     |     |            |
| Control group    | 1.1±1.6 |     |       |
| (n=88)           |     |            |

M=Mean; SD=Standard Deviation; VAS: Visual Analogue Scale; p: p-value
*Mann Whitney U test

DISCUSSION
IM As a result of the comparison of the gender, age, height, weight, and BMI measurements of the experimental and
control groups, no statistically significant difference was found between the groups. These characteristics were determined to be similar in both groups (p > 0.05) (Table 1). According to this result, both groups show homogeneous properties.

This study investigated the effect of ShotBlocker on IM injection-induced pain by comparing the experimental and control groups. In our study, the mean VAS pain score in the experimental group was 1.2 ± 1.3, while this score was 1.1 ± 1.6 in the control group; yet, the difference between the groups was not statistically significant (p > 0.05) (Table 2). The results of our study revealed that administration of IM injection in adults using the ShotBlocker did not reduce pain intensity. Tugrul, Khorshid, and Çelik (2017) investigated the effect of the ShotBlocker on the pain during the administration of hepatitis B vaccine to the deltoid muscle in individuals aged over 18. The pain score of the ShotBlocker group was 33.8 ± 26.0, while the pain score of the non-ShotBlocker group was 33.0 ± 23.8. They found that there was no significant difference between the pain severities of the two groups (9). The results of the study of Tugrul, Khorshid, and Çelik (2017) were similar to those of our study.

Besides, contrary to the results of our study, in their study with individuals aged over 18, Celik and Khorshid (2015) found that the IM injection pain score of the ShotBlocker group was 7.85 ± 7.03 and that the pain score of the control group was 26.7 ± 20.30. The difference between the pain scores of both groups was determined to be significant (8). On the other hand, in their study with individuals who were administered Diclomec on the ventrogluteal region, Aydin and Avşar (2019) found the pain score of the Shotblocker and non-ShotBlocker groups as 1.22 ± 0.62 and 2.48 ± 1.12, respectively. They found a significant difference between the pain scores of the groups (7).

According to the results of this study and the results of a limited number of studies with adults in the literature, it is clear that the use of the ShotBlocker for relieving IM injection-induced pain in adults has raised two opposing views.

**CONCLUSION**

The results of this study showed that the ShotBlocker did not have an effect on pain in IM applications. Further studies are needed to confirm the effect of the ShotBlocker on IM injection-induced pain in adults. Therefore, it may be recommended that the study be conducted with larger samples.

**LIMITATIONS**

There were some limitations of this study. First, the pain responses of the participants were evaluated by the researcher. This phase of the study was not blind. Pain assessment can be performed by a nurse who is not involved in the study. Another option may be a placebo group in which a ShotBlocker with non-sharp skin contact points is used.

The second limitation is the generalization of the results of this study to adults. There was no racial or ethnic diversity in our sample. The racial and ethnic difference may affect the effectiveness of ShotBlocker due to pain sensitivity. The study should be conducted with different racial and ethnic groups.

The third limitation is that this study was conducted with patients receiving cyanocobalamin-containing drugs. The pain after IM injection may vary depending on the content of the drug. Therefore, the study should be carried out with different drug groups.

The fourth limitation is that the patients marked the severity of pain on the VAS within 1 minutes after the injection procedure. Long-term effects of pain caused by IM injection can also be examined.

**Authors’ Contribution**

All authors contributed equally to this manuscript.

**Declaration of Competing Interests**

All of the authors declare that there are no conflicts of interest in connection with this paper.

**Ethical Statement**

Ethics committee approval was received for this study from the Ethics Committee of Nevşehir Hacı Bektaş Veli University.

**Informed Consent**

Written informed consent was obtained from the patients who participated in this study.

**Financial Disclosure**

All of the authors declare that there is no financial disclosure in connection with this paper.

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