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Research Article

Determination of the Effect of ShotBlocker in Reducing Intramuscular Injection Pain in Adult Patients: A Randomized Controlled Trial

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Abstract

Aim: This study aimed to evaluate the effect of the ShotBlocker device on pain intensity due to intramuscular injection in adult patients presenting to the emergency department.
Material and Method: The study was conducted as a randomized controlled trial. Data were collected from patients who presented to the emergency department of a public hospital in southern Türkiye and volunteered to participate in the study. Participants were randomly assigned to intervention and control groups using a randomization program. Data collection tools included a Personal and Medication Information Form and the Visual Analog Scale.
Results: 80 participants were equally distributed in the intervention and control groups. Gender distribution was equal across both groups. The mean age of participants was 42.20±14.60 years in the intervention group and 47.00±15.10 years in the control group. Diclofenac sodium was the most frequently administered medication in both groups (Intervention: 24, Control: 22). It was determined that the mean pain scores of the participants in the intervention group were significantly lower than those in the control group. Additionally, within the intervention group, pre- and post-injection pain scores varied according to gender, marital status, educational level, income status, and medication type.
Conclusion: The ShotBlocker appears to be a potentially effective non-pharmacological method for managing pain associated with intramuscular injections in adult patients. Its implementation in emergency care settings may contribute to improving patient comfort and enhancing pain management strategies. This study's findings are limited by its single-center design, focus solely on post-injection pain, exclusion of other outcome variables, and reliance on self-reported pain assessment.

Keywords: ShotBlocker, emergency department, pain, ıntramuscular injection, nursing

INTRODUCTION

One of the most commonly used treatment methods in injection applications is Intramuscular Injection (IMI) (1). IMI accelerates the treatment process and facilitates drug absorption by enabling systemic drugs to be administered into muscle tissue (2). Although IMI is considered a simple technique, the most common effect observed at the injection site after administration is pain (3). There are two reasons for the pain that occurs during IMI. The first is the penetration of the needle into the muscle tissue, and the second is the administration of the drug into the tissue (4). This pain can cause anxiety in patients or reduce their acceptance of the treatment. It is therefore important to reduce this pain caused by the application.

Nurses are health professionals who play a primary role in helping adults cope with negative experiences during needle-related procedures (5). Pain relief is one of the fundamental elements of nursing care, and in this context, nurses need to master effective pain control strategies (6). Nurses can take an active role in controlling pain caused by IMI using non-drug methods within the framework of their professional responsibilities. These methods are quite diverse. For this purpose, different applications such as local ice application (7), manual pressure application (8), acupuncture (9), skin-to-skin care (kangaroo care) (10) and lidocaine/prilocaine-containing creams (11) are seen in the literature. These methods are advantageous in terms of being low cost, easy to apply and having a low risk of side effects (12).

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In recent years, ShotBlocker has also gained interest in reducing IMI pain. ShotBlocker is a flexible, low-tech, cost-effective, drug-free plastic device with skin contact points and a central hole for injection (13). Since the contact points in this device are blunt, it does not damage the skin and acts according to the gate control theory. According to the gate control theory; the physical contact stimulus before the injection reaches the spinal cord before the injection pain and closes the gates against pain transmission (14). Therefore, this theory suggests that pain is not only a physiological process, but that "gating" mechanisms in the nervous system affect pain perception by regulating sensory signals. Therefore, it becomes possible to relieve pain by applying ShotBlocker before the injection. Therefore, it is possible to relieve pain by applying ShotBlocker before injection. Therefore, it is assumed that the use of ShotBlocker to reduce pain during injection is related to the gate control theory of pain. Studies have reported that no side effects were observed as a result of the use of ShotBlocker and that it was effective in patients (15-17). However, it is seen that more studies are needed in terms of its effectiveness or side effects. Since there are limited studies on the use of ShotBlocker, especially in the adult group, it is recommended that the subject be scientifically investigated more deeply in terms of the adult patient group and that non-pharmacological methods be used to increase patient comfort and improve the quality of health services in IMI frequently applied by nurses during the treatment process. In this context, it is important to investigate the effects of interventions such as ShotBlocker application before injection on pain.

This study aims to investigate the effect of ShotBlocker on injection pain during intramuscular administration of diclofenac sodium and metamizole sodium, which are frequently used in emergency department settings.

MATERIAL AND METHOD

Study Design and Protocol

This study was conducted as a randomized controlled trial to evaluate the efficacy of the ShotBlocker device in reducing pain associated with IMI, a procedure frequently performed in emergency departments. Clinical Trials were registered prior to the study (NCT06624761). Ethical approval and institutional permission for the study were obtained (*Toros* University, Date: 07.06.2024, Approval No: 6/11). Participants were informed of their right to withdraw at any time prior to the study. Participants were informed about their group allocations after the completion of the study. Additionally, ShotBlocker intervention was offered to those in the control group if they wished.

Sample and participants

Based on a significance level (α) of 0.01, an effect size of 1.583, and a statistical power of 99% in G*Power statistical software, it was determined that a minimum of 25 participants per group was required. Considering the 95% confidence interval and the possibility of participant attrition, the planned sample size was increased to 30 participants per group. A total of 80 participants were included in the study. This expanded sample size resulted in an estimated statistical power of approximately 99.7%, indicating that the observed differences were likely to be statistically significant and the results were highly reliable. Before participation, all individuals were informed about the study and their verbal and written consent was obtained. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Inclusion criteria for both groups were as follows: patients aged 18 years and over who spoke Turkish, who applied to the emergency department for prescription drug use or who would be administered diclofenac sodium or metamizole sodium as IMI upon the request of the emergency department physician, and who signed the informed consent form.

Exclusion criteria for both groups included: pregnancy, presence of a psychiatric disorder, admission to the red zone of the emergency department, presence of confusion, secondary injury or infection at the injection site, prior injection to the same site within the last 24 hours, refusal or failure to sign the informed consent form, and regular use of ShotBlocker during previous injections.

Randomization

Participants were randomly assigned to either the intervention or control groups by an independent researcher using a randomization program. The randomization process is presented in Figure 1. Group assignment was conducted using a sealed, opaque envelope method. Envelopes containing group allocations were thoroughly shuffled, and one envelope was randomly selected for each participant, resulting in Group 2 being assigned to the intervention group and Group 1 to the control group. Participants were randomized under double-blind conditions, with neither the participants nor the researchers aware of group assignments during the allocation process. All results were analyzed at baseline and immediately after treatment by an expert who was not involved in the study.

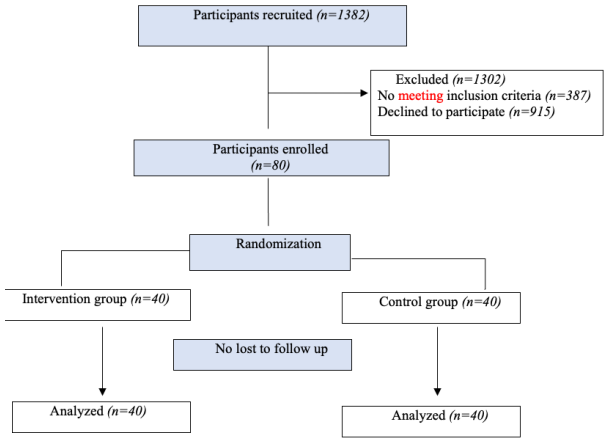

Figure 1. Consort diagram of the research

Intervention

The application steps are as follows:

Step 1: Preliminary Preparation Process

Preliminary discussions were held with nurses who were not participating in the study and who worked in the emergency department before the application began,

and detailed information was provided about the purpose, content and assessment tools to be used. The nurses were told that the ShotBlocker would be used in patients who met the research criteria and who would receive intramuscular diclofenac sodium and metamizole sodium in the ventrogluteal region, and that data would be collected from these patients. In this way, physicians were informed and prepared for the application process.

Step 2: Participant Information and Consent

The purpose of the study and the implementation procedures were explained to the participants in detail. Both verbal and written informed consent was obtained from the participants. The voluntary nature of the study and the ethical rules were taken as a basis.

Step 3: Visual Analogue Scale (VAS) Application to the Intervention Group

Pain intensity was measured using the VAS approximately two minutes after completion of the IMI in the ShotBlocker group. Since there is no direct source in the literature regarding timing, this time interval was determined by the researchers to ensure that the effect of the drug is clearly felt after the injection and to allow the patient to prepare herself before the evaluation.

Step 4: VAS Application to the Control Group

Similarly, the VAS was applied to subjects in the control group who were administered diclofenac sodium and metamizole sodium as IMI to the ventrogluteal region without using the ShotBlocker and who met the research criteria.

Measurements

Descriptive characteristics of the participants such as age, gender, income status, Body Mass Index (BMI) and type of medication used were collected using the Personal and Medication Information Form.

The pain perceived by the participants was measured with the VAS. In this scale, there is a line at one end of the ruler where there is no pain (zero) and a line at the other end where there is the most severe pain (10 cm). The person indicates their pain by marking a number from 1 to 10. On the VAS, 0-4.4 cm indicates mild pain, 4.5-7.4 cm indicates moderate pain, and 7.5-10 cm indicates severe pain (18,19).

Data Analysis

Data were analyzed using IBM SPSS Statistics for Windows, Version 23.0 (IBM Corp., Armonk, NY, USA). In descriptive statistics, frequency (n) and percentage (%) were used for categorical variables, and mean±standard deviation was used for continuous variables. Shapiro-Wilk test and Levene test were used to test the assumptions of normal distribution and homogeneity of variances, respectively. The t-test for independent samples was used for comparisons between two independent groups that fulfil these assumptions. In cases where more than two independent groups were involved, a one-factorial analysis of variance was performed. When significant differences were observed, Bonferroni post-hoc correction was applied to determine specific group differences. For all analyses, p-values ≤.05 were considered statistically significant.

RESULTS

A total of 80 people were included in the study and it was determined that the genders were equal in the intervention and control groups. The mean age of the participants in the intervention group was determined to be 42.20±14.60, and the mean age of the participants in the control group was determined to be 47.00±15.10. In addition, it was determined that the mean BMI of the participants in the intervention group was 25.30±4.00, while the mean BMI of the participants in the control group was 26.10±3.60. Table 1 shows some sociodemographic characteristics of the participants in the intervention and control groups.

The comparison of the type of medication administered and the previous administration status of the participants according to the groups is shown in Figure 2. It was determined that more than half of the participants in the intervention group and the control group received diclofenac sodium. In addition, it was determined that all of the participants in both groups had previously been administered one of these drugs.

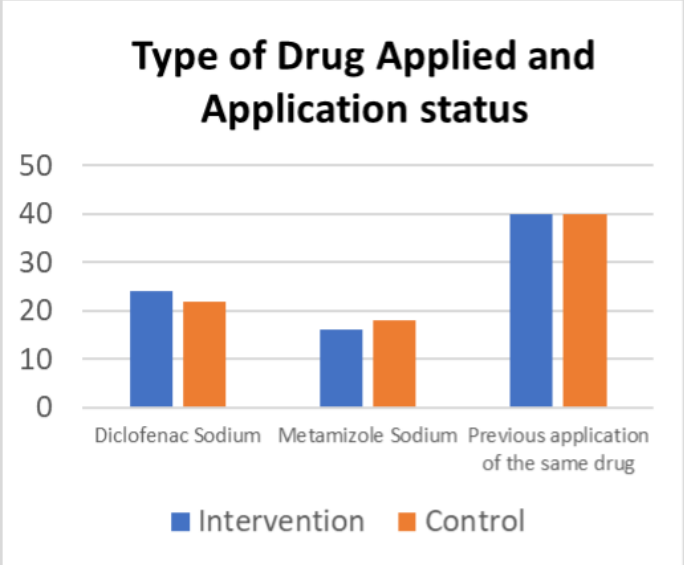

Figure 2. Comparison of the type of drug administered and previous administration status according to the groups

Table 2 presents the comparison of participants' mean VAS scores by group. The mean VAS scores of the participants before the intervention were similar in both the intervention and control groups and did not differ statistically significantly from each other. However, analysing the pain scores after the injection revealed a statistically significant difference between the groups, with the control group reporting higher mean pain scores (p<.05).

When the pre- and post-intervention mean pain scores of the intervention group were analyzed based on variables such as gender, education level, income status, and type of medication administered, the differences were found to be statistically significant (p<.05). Table 3 illustrates the comparison of participants' mean VAS scores according to selected characteristics within each group.

Table 1. Sociodemographic characteristics of participants by group (n=80)

Characteristics	Intervention group (n=40)		Control group (n=40)	
	M±SD		M±SD	
Age	42.20±14.60		47.00.±15.10	
BMI	25.30±4.00		26.10±3.60	
	n	%	n	%
Gender				
Female	20	25.0	20	25.0
Male	20	25.0	20	25.0
Level of education				
Literate	4	10.0	6	15.0
Primary school graduate	3	7.5	6	15.0
Secondary school graduate	8	20.0	6	15.0
High school graduate	16	40.0	14	35.0
University graduate	9	22.5	8	20.0
Income status				
Income less than expenditure	20	50.0	17	42.5
Income equals expenditure	20	50.0	23	57.5
Income more than expenditure	0	0	0	0

BMI: body mass index, M: mean, SD: standart deviation, n: number, %: percentage

Table 2. Comparison of participants' mean Visual Analogue Scale scores by group (n=80)

Measurement time	Intervention group (n=40)		Control group (n=40)		*p
	M±SD	Minimum-maximum	M±SD	Minimum-maximum	
VAS					
Previous pain experience	5.82±1.92	2-10	5.55±1.60	2-9	.489
Experience of pain after drug administration	3.67±1.91	1-7	4.60±2.08	1-9	.042
**p	.000		.000		

* Independent sample t test, **Dependent sample t test, M: mean, SD: standart deviation, VAS: Visual Analogue Scale, p value≤0.05

Table 3. Comparison of participants' mean Visual Analog Scale Scores by characteristics and medication type (n=80)

Measurement times	Intervention group (n=40)			Control group (n=40)		
	Previous pain experience	Pain experience after shotblocker+ drug administration		Previous pain experience	Pain experience after drug administration	
	M±SD	M±SD	*p	M±SD	M±SD	*p
Gender						
Female	6.35±1.95	3.75±1.68	.000	6.05±1.60	5.30±1.92	.028
Male	5.60±1.78	3.60±2.16	.000	5.05±1.46	3.90±2.04	.001
**p	.084	.808		.047	.032	
Level of education						
Literate[1]	5.5±1.91	3.50±2.38	.016	7.17±1.47	6.17±1.47	.203
Primary school graduate[2]	4.67±1.15	2.33±0.58	.020	6.17±1.94	6.17±2.32	1.000
Secondary school graduate[3]	6.13±2.59	3.88±2.17	.003	4.33±1.21	4.17±1.94	.741
High school graduate[4]	5.81±1.68	3.69±1.99	.000	5.43±1.02	4.43±1.40	.002
University graduate[5]	6.11±2.09	4.00±1.80	.002	5.0±1.69	2.88±2.17	.002
***p	.825	.781		.014, 1>3	.007, 1>5	
Income status						
Income less than expenditure	5.70±1.89	3.60±1.81	.000	5.29±1.35	4.58±2.06	.041
Income equals expenditure	5.95±1.98	3.75±2.04	.000	5.73±1.76	4.60±2.14	.001
**p	.686	.808		.392	.976	
Type of drug						
Diclofenac sodium	5.33±1.78	3.75±1.68	.000	5.50±1.60	5.30±1.92	.090
Metamizole sodium	6.56±1.93	3.60±2.16	.000	5.59±1.65	3.90±2.04	.020
**p	.510	.040		.860	.574	

*Independent sample t test (between groups), **Dependent sample t test (Within groups), ***One-way analysis of variance, M: mean, SD: standart deviation, VAS: Visual Analogue Scale, p value≤0.05

DISCUSSION

IMI is frequently used by nurses in clinical practice and injection pain is one of the most common problems encountered in this practice (20). Although the level of this pain varies according to the content of the drug, the rate of administration and individual factors, it may also be related to the techniques used during injection administration. In fact, the application area, needle size, injection speed and the tools used are the determining factors in injection pain (21). Therefore, in this study, it was aimed to determine the effect of ShotBlocker on IMI pain in adult patients undergoing IMI.

In our study, the intervention and control groups exhibited similar baseline pain experiences. The group using ShotBlocker during injection showed significantly lower mean pain scores compared to the control group. Similarly, previous studies have reported that ShotBlocker effectively reduces injection pain in pediatric patients (16,22). In those studies, children in the ShotBlocker group reported lower pain scores during IMI compared to both cold application and control groups, with statistically significant differences. Findings from various studies conducted across different years and age groups further support our results (23-25). The underlying mechanism of this effect can be attributed to the gate control theory, which suggests that non-painful physical stimulation—such as that provided by ShotBlocker's contact points—can inhibit the transmission of pain signals and thus reduce the perception of needle-related pain (14,26). These findings highlight the practical relevance of the theory in clinical pain management.

In our study, when the pain scores of both groups were compared according to gender, it was found that the difference between them was significant among themselves and between the groups according to the same gender. In addition, it was observed that this difference between men and women in the intervention group was not significant before and after the intervention. The results of the study conducted by Bilge et al. (2019) supported our research findings and no significant difference was observed in VAS scores according to gender between the intervention groups (27). Our results show that Shotblocker application decreased pain in both groups and gender (Table 3). This finding suggests that not only biological but also psychosocial aspects of injection pain are important. Women in particular may have higher hormonal, psychological, and sensory sensitivities, which may affect pain perception (28). It is an important and striking finding in terms of showing that pain perception before and after the application varies according to gender (Table 3). Because sex hormones affect pain responses (29). A 2002 study highlighted that women experience more pain than men and that women have a lower pain threshold in experimental pain studies (30). However, gender-based interpretations of pain should be approached holistically, taking into account not only physiological but also cognitive, emotional, and sociocultural factors.

In our study, when the pain averages of the participants in both groups were analysed according to the type of drug administered, it was found that the mean previous pain experience of the participants in the intervention and control groups were similar, while the mean pain experience of the participants taking metamizole sodium was higher. In the intervention group, it was determined that the mean pain in the metamizole sodium group decreased more than the diclofenac group after Shotblocker and the difference between them was significant according to the type of drug. This situation can be related to the fact that the pain caused by the damage left in the tissue due to the chemical structure of the drug depends on the way it is perceived by the patient.

In the control group, the decrease in the mean pain according to the type of drug and the significant difference between them may be related to the previous experience of the individuals about the application of this drug. However, this experience may not give the same result in all groups. In addition, the effects of Shotblocker on pain should not be ignored. In support of our study, Çelik and Khorshid (2015) investigated the effectiveness of Shotblocker on diclofenac and found that the average pain of the intervention group decreased compared to the control and control group (31). When the literature was examined, no study comparing the efficacy of Shotblocker in these two drug types was found. This situation reveals the originality of our study and provides a new perspective that can contribute to clinical practice.

Limitations

This study has several limitations. First, the study was conducted in the emergency department of a single state health institution on intramuscular pain. This may limit the generalizability of the findings to different institutions or different clinical settings. In addition, the study focused only on post-injection pain and other possible outcome variables (such as injection anxiety) were not assessed. In addition, pain assessment was performed only by self-report method (VAS) and no other assessment was used.

CONCLUSION

In conclusion, IMI are among the most painful procedures, regardless of the demographic characteristics of the individuals and the type of drug used. In this context, the management of pain that occurs during the injection is an important part of care. Nurses are expected to use appropriate injection technique, assess pain and use non-pharmacological methods. In this study, the use of ShotBlocker, a non-pharmacological intervention, was shown to reduce injection pain in adults. ShotBlocker's mechanism of action, based on the "gate control theory", suppresses the perception of pain that may occur during needle insertion through the painless physical stimulation it produces prior to injection. Our research shows that this effect is significant in relation to both gender and drug type. The fact that the ShotBlocker is particularly effective for painful injections such as metamizole and diclofenac speaks in favour of the applicability of the method in adults.

According to our research results; ShotBlocker is recommended to be integrated into nursing practices as a cost-effective, easy-to-use and reliable non-pharmacological method. However, in order to ensure

effective application in clinical practice, nursing staff should first be adequately informed and trained about its use. This recommendation is in line with the guidelines of the Registered Nurses' Association of Ontario (32), which emphasize the use of non-pharmacological methods—such as tactile stimulation and distraction techniques—for pain management during procedures like injections. Additionally, future studies are needed to strengthen the evidence base in different age groups, individuals with different clinical diagnoses (such as cancer pain), and with variables such as different injection sites. This will increase the generalizability and clinical applicability of the method. Additionally, future studies are needed to strengthen the evidence base in different age groups, individuals with different clinical diagnoses (such as cancer pain), and with variables such as different injection sites. This will increase the generalizability and clinical applicability of the method.

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