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Shotblocker Use in Emergency Care A Randomized Clinical Trial

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ABSTRACT

This study was conducted to evaluate the effect of ShotBlocker on the intramuscular injection pain and satisfaction in emergency adult patients. This research was designed as a randomized controlled, double-blind, experimental study. The study was conducted with 74 patients who applied to the adult emergency department. Patients were randomized to ShotBlocker and control groups. Patient Assessment Form, Visual Analog Scale, and Visual Analog Patient Satisfaction Scale were used. The mean scores of postinjection pain and satisfaction level were analyzed between the groups; it was determined that while postinjection pain mean score of the experimental group was statistically significantly lower than that of the control group ($p = 0.0001$), satisfaction scores were statistically significantly higher in the experimental group than in the control group ($p = 0.004$). When the correlation between the intragroup Pain Scores (VAS) and the Satisfaction Scores (VAS) of the groups after injection was examined, a statistically significant and inverse correlation was found ($p < 0.05$). It was determined that ShotBlocker was effective in reducing intramuscular injection pain and increasing satisfaction levels. **Key words:** emergency care, pain management, satisfaction, ShotBlocker

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THE INTRAMUSCULAR INJECTION is an important intervention that nurses use as a part of their clinical practices. Although this method appears simple, it can lead patients to suffer from severe complications such as pain, abscess, necrosis, infection, and nerve damage. The majority of these complications are preventable and are caused by the use of inappropriate techniques and the lack of knowledge how to administer drugs. Intramuscular injection is a complex procedure because it requires nurses to be technically competent and to decide what tools and methods they are going to use. Despite its therapeutic properties, intramuscular injection may cause patients to suffer from pain and discomfort, even resulting in interrupted treatment (Cobb & Cohen,

2009). Intramuscular injection pain develops because of the mechanical trauma caused by insertion of the needle and the sudden pressure associated with intramuscular injection of drug (Ogston-Tuck, 2014).

Nurses play an indispensable role in pain management during intramuscular injection. What makes nurses important and thus different from other team members in pain management is that they spend long hours with patients, can use strategies to cope with pain, guide them, administer the treatment as planned, and likewise monitor the effects and outcomes of treatment (Larkin, Elgellaie, & Ashcroft, 2018). Relieving the pain of patients is important for all nurses. The quality of pain management depends on how much a nurse knows about and is skilled at how to conduct this painful procedure, and how they behave—hence, their role is pivotal during this process (Burbridge, 2007; Celik & Khorshid, 2015). Nurses are responsible for preventing and/or alleviating the patient's pain induced by the injection through the techniques they use to administer the drugs (Potter, 1999). There are studies evaluating how effective nonpharmacological methods are in reducing pain associated with intramuscular injection (Ağaç & Yapucu Güneş, 2011; Alshahwan, 2019; Ballard et al., 2019; Cobb & Cohen, 2009; Gundrum, Sherman, & Ruhlman, 2005; Sivri Bilgen & Balcı, 2019). The vast majority of these studies in the literature have been conducted on pediatric patients (Caglar, Büyükyılmaz, Cosansu, & Çaglayan, 2017; Canbulat Sahiner, Turkmen, Acikgoz, Simsek, & Kirel, 2018; Celik & Khorshid, 2015; Cobb & Cohen, 2009).

ShotBlocker (pain-away) is one of methods used to reduce pain experienced during intramuscular injection. It is a flat, horseshoe-shaped tool with short and blunt skin contact points, which are 2-mm thick, and a hole at the center of the tool that exposes the injection site (Canbulat Sahiner et al., 2018). Many studies have been conducted about the use of ShotBlocker in pediatric patients (Caglar et al., 2017; Celik & Khorshid, 2015; Cobb & Cohen, 2009; Sivri Bilgen & Balcı, 2019).

Some have concluded that the ShotBlocker is an effective means of reducing intramuscular injection pain (Bilge et al., 2019; Drago, Singh, Douglass-Bright, Yiadom, & Baumann, 2009; Sivri Bilgen & Balcı, 2019), whereas others have revealed that it is ineffective (Cobb & Cohen, 2009; Yilmaz & Alemdar, 2019). At present, there are few studies that focus on using ShotBlocker in adult patients in order to reduce pain associated with intramuscular injection.

This study was conducted to evaluate the effect of ShotBlocker on the intramuscular injection pain and satisfaction in emergency adult patients because the results of the related studies are different and there is a very limited number of studies conducted on adults.

METHODS

Study Design

This study was designed as a randomized controlled, double-blind, and experimental trial and was conducted between March 2020 and May 2020 at the adult emergency department of a training and research hospital in Istanbul, Turkey.

Sample and Participants

The sample size was calculated using G. Power Analysis. Assuming a significance level (α) of 0.05 and statistical power ($1-\beta$) of 0.80, we sought to include 35 participants in each group.

The patients who were 18 years of age or older; agreed to participate in the study; were conscious; had any communication problem; had a body mass index (BMI) of 18.5–30 kg/m²; did not receive any injection in the ventrogluteal region within the last 2 weeks; had no signs of skin pain, hematoma, necrosis, scare, incision, or infection in the ventrogluteal region; and had diclofenac sodium intramuscular injections in the treatment were included in the study.

Measurements/Instruments

The Patient Assessment Form, Visual Analog Scale (VAS), and Visual Analog Patient Satisfaction Scale were used in this study.

Patient Assessment Form: The researchers prepared the Patient Assessment Form by examining the related literature and studies. This form included five questions including some sociodemographic characteristics of the individuals (age, gender, marital status, educational background, and BMI).

Body Mass Index: A specialist nurse measured BMI values of the participants. First, they used an electronic scale to measure their height and weight and then they calculated their BMI by dividing their body weight (in kilograms) into their height (in centimeters). The devices were calibrated prior to the measurements.

Pain Level Measurement/Visual Analog Scale: Pierce et al. (1983) developed the Pain Level Measurement/Visual Analog Scale. It has been extensively used in studies to subjectively evaluate how pain level is perceived and has been found to be valid and reliable. The scale is composed of a 10-cm line that is either horizontal or vertical and includes “no pain” on one end and “worst pain” on the other. Patients should be informed in advance on how to use the VAS. The patient is asked to mark his or her pain level on an appropriate point along the line. The distance between the initial “no pain” point and the patient’s pain point is measured and recorded in centimeters. Values range between 0 and 10. The pain levels of the patients are evaluated over 10 points, with 0 indicating no pain and 10 indicating the worst pain (Price, Bush, Long, & Harkins, 1994).

Visual Analog Patient Satisfaction Scale (VAS): The Visual Analog Patient Satisfaction Scale is combined with the features of the more well-known VAS (Visual Analog Scale). It includes a 10-cm horizontal line, without numbers. On one end of the scale reads, “I am very dissatisfied,” on the other reads, “I am very satisfied.” The patients are expected to identify their satisfaction level first by syn-

thesizing together all of the components that affect them in terms of the medical care they have received and then to find the point on line that best corresponds to their condition (Fahs & Kinney, 1991).

Assessment of Intramuscular Injection Site: A specialist nurse assesses each patient’s intramuscular injection site for any signs of infection, scar tissue, ecchymosis, abscess, and incision.

Procedure

First, the researchers assigned the patients into groups according to a randomization list that they prepared before. Then, the patients were taken to the injection room. They were informed about the study and their written consent was obtained. Then, a specialist nurse took their height, weight, and BMI measurements. Since diclofenac sodium has been used in previous studies (Ağaç & Yapucu Güneş, 2011; Bilge et al., 2019; Celik & Khorshid, 2015), it is most frequently prescribed drug in the emergency department and it was used to standardize injection practice in the study. Diclofenac sodium was injected intramuscularly into the ventrogluteal region of the patients in the experimental group using a ShotBlocker and into the ventrogluteal region of the patients in the control group without a ShotBlocker. The same researcher nurse applied the same injection practice to all of the patients upon following standard procedure. Five minutes after the injection, all of the patients were given the scales so that they could assess their own pain and satisfaction levels, upon which, a separate researcher—who was blinded to the group allocation—then came around to collect the score sheets. Each procedure lasted between 10 and 15 min for each participant.

Intervention

The patient’s ventrogluteal region was determined prior to injection (see Figure 1). The needle tip was changed before the injection—after the diclofenac sodium was

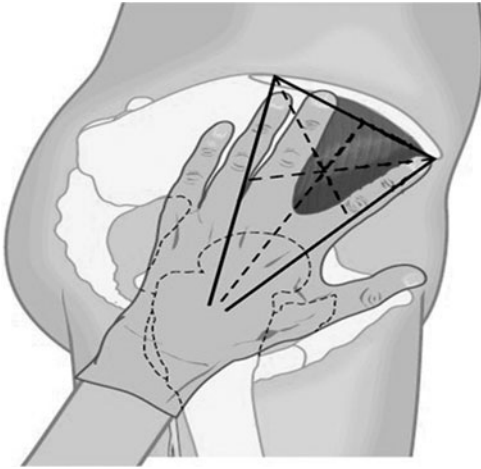


Figure 1. Examination and palpation methods were used in the evaluation of ventrogluteal region. From “Effects of Thickness of Muscle and Subcutaneous Fat on Efficacy of Gluteal Intramuscular Injection Sites,” by A. Elgellaie, E. Ashcroft, and T. A. Larkin, 2018, *British Journal of Nursing*, 27, pp. 300–305. Used with permission.

prepared. A cotton pad wetted with 70% alcohol was used to clean the injection site through circular motions from the center outwards and let to dry. The nurse then administered the injection by using his or her fingertips to lightly press the ShotBlocker over the injection site. The drug was injected slowly at constant pressure (1 ml every 10 s) using a 25 G, 0.8 × 38-mm needle at an angle of 90°. The ShotBlocker was then removed immediately after the needle was removed. Afterward, the nurse placed another cotton pad between his or her fingers and pressed down on the insertion point to swiftly remove the injector without disturbing the insertion angle. Finally, slight pressure was applied to the site with the cotton pad (Kaya, Turan, & Özdemir Aydın, 2016; Ogston-Tuck, 2014).

ShotBlocker

ShotBlocker is a patented tool that was developed by Bionix (Toledo, Ohio) to reduce both injection-induced pain and anxiety during both intramuscular and subcutaneous injections (Potter, 1999). ShotBlocker is small, flat, made of plastic, and shaped like a horseshoe.

In addition to be designed to reduce intramuscular injection pain, it is appropriate for all age groups and has no drug properties (see Figure 2).

You are supposed to use the ShotBlocker by pressing down on the surface of the skin during injection. It has no side effects (Bionix, 2020). It has short and blunt skin contact points on one side, as well as a hole that exposes the injection site at the center of the tool. The pointed surface of the tool is placed on the injection site right before the injection. When pressed firmly against the injection site, ShotBlocker provides stimulus according to the gate control theory of pain suggested by Melzack and Wall. This stimulation reduces the pain from the needle by putting pressure on large-diameter (A-beta) fibers, thus blocking pain transmission along small diameters (A-delta and C) fibers. (Aydın & Avşar, 2019; Cocoman & Murray, 2008; Cobb & Cohen, 2009; Drago et al., 2009).

Data Analysis

All of the data were analyzed using SPSS (Statistical Package for Social Sciences, Chicago, Illinois) version 24.0. In the statistical evaluation of the data, the percentages, frequencies, and mean values (minimum–maximum) were calculated. One-way analysis of variance, Pearson’s χ^2 test, Mann-Whitney *U* test, Fisher-Freeman-Halton test, and Student *t* test were also used to determine the difference between groups. Pearson’s correlation test was used to reveal the correlation between the groups. The upper limit of Type I error level for statistical significance (*p* value) was 5% ($p < 0.05$).

Ethical Considerations

To conduct the study, approval was obtained from the Istanbul Medeniyet University Clinical Research Ethics Committee (2020/0455). In addition, the study’s participants were first asked for their written informed consent. The study was conducted in accordance with the Declaration of Helsinki.

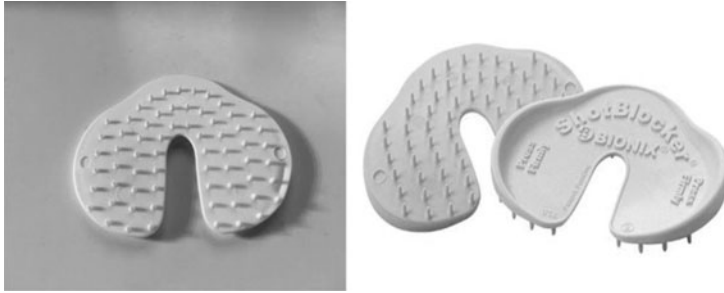


Figure 2. ShotBlocker material. From *Injection relief*, by Bionix, 2020. Retrieved from <https://bionix.com/products/pain-relief.html>. Used with permission.

RESULTS

A total of 106 patients were evaluated. The data of 74 patients were later added into the final analysis due to reasons such as the patients not wanting to continue the study or their having to take another injection (see Figure 3).

The mean age of the participants ranged between 18 and 80 years. The mean age of the experimental and control groups was

54.00 ± 11.76 and 47.57 ± 20.58 years, respectively. The majority of both groups were female (50.8% vs. 55.3%). Approximately 80.6% of the experimental group and 78.9% of the control group were married. Approximately 33.3% of the experimental group had only primary school education; 44.5% of the same group were either retired or unemployed. Likewise, 36.8% of the control group had only primary school education; 44.8% of the same group were either

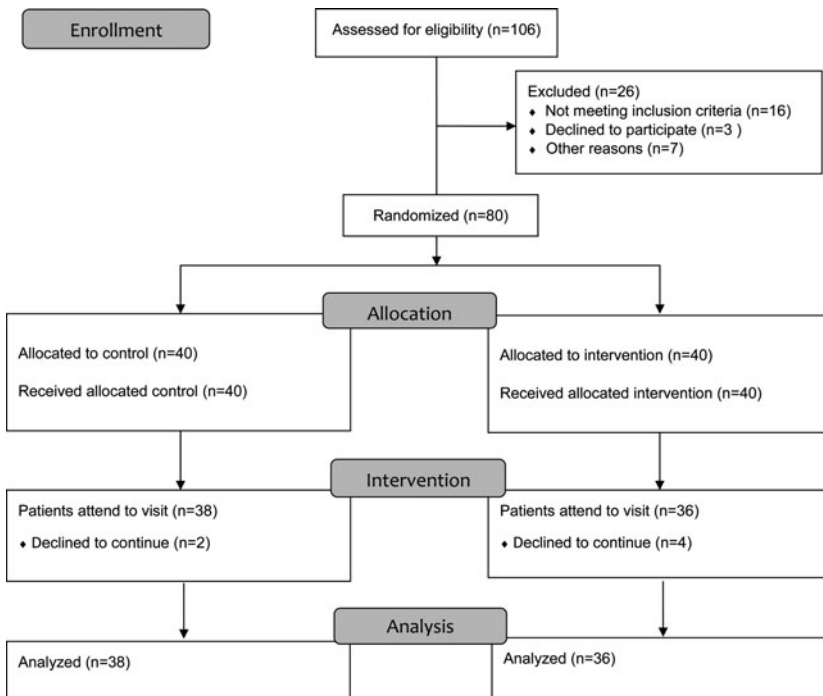


Figure 3. Consort flow diagram.

retired or unemployed. Approximately 41.7% of the experimental group and 44.7% of the control group were of normal weight. No statistical difference was found between the experimental and control groups in terms of their sociodemographic characteristics ($p > 0.05$), thus indicating that the groups were homogeneous (see Table 1).

There was no statistically significant difference between the pain mean scores of the patients in the groups and age ($p > 0.05$) and gender ($p > 0.05$). However, a statistically significant difference ($p < 0.05$) was found in the control group in terms of BMI. The results of the Bonferroni-corrected Kruskal-Wallis H test—which was performed to detect the

difference in the control group—revealed that the difference was caused by the normal weighted patients (see Table 2).

When the mean scores of postinjection pain and satisfaction level were analyzed between the groups, the postinjection pain mean score of the experimental group was found to be statistically significantly lower than that of the control group ($p = 0.0001$). The satisfaction scores of the experimental group were statistically significantly higher than those of the control group ($p = 0.004$; see Table 3).

When the correlation between the intragroup Pain Score (VAS) and Satisfaction Score (VAS) of the groups after injection was

Table 1. Sociodemographic characteristics of the participants in the groups^a

Characteristics	Groups		Test value <i>p</i>
	Experimental (<i>n</i> = 36)	Control (<i>n</i> = 38)	
Age (years)			
Mean ± SD	54.00 ± 11.76	47.57 ± 20.58	<i>F</i> : 21.81 ^b
Minimum-Maximum	20-75	18-80	0.106 ^b
	<i>n</i> (%)	<i>n</i> (%)	
Gender			
Female	18 (50.0)	21 (55.3)	χ^2 : 0.205 ^c
Male	18 (50.0)	17 (44.7)	0.605*
Marital status			
Married	29 (80.6)	30 (78.9)	χ^2 : 0.030 ^c
Single	7 (19.4)	8 (21.1)	0.863*
Educational background			
Primary school	12 (33.3)	14 (36.8)	χ^2 : 2.243 ^c
Secondary school	5 (13.90)	3 (7.9)	0.691*
High school	9 (25.0)	7 (18.4)	
University	10 (27.8)	14 (36.8)	
Occupation			
Retired-unemployed	16 (44.5)	17 (44.8)	χ^2 : 15.122 ^c
Officer worker	9 (25.0)	8 (21.1)	0.290*
Self-employment	11 (30.6)	13 (34.2)	
Body mass index			
Normal	15 (41.7)	17 (44.7)	χ^2 : 0.596 ^c
Overweight	17 (47.2)	15 (39.5)	
Obese	4 (11.1)	6 (15.8)	0.742*

^aThe data are given as mean ± SD (minimum-maximum).

^bWhitney *U* test.

^cPearson's χ^2 test.

* $p < .05$.

Table 2. Postinjection pain scores of the groups based on body mass index

Body mass index	Experimental (n = 36) Mean ± SD (minimum–maximum)	Control (n = 38) Mean ± SD (minimum–maximum)
Normal	4.66 ± 1.09 (3–8)	6.35 ± 1.11 (3–8) ^a
n	15	17
Overweight	4.70 ± 1.40 (2–8)	7.46 ± 0.63 (6–8)
n	17	15
Obese	4.00 ± 1.09 (2–8)	7.50 ± 0.54 (7–8)
n	4	6
F	0.491 ^b	7.653 ^b
p	0.5616	0.002*

^aBonferroni-corrected.

^bOne-way analysis of variance.

*p < .05. Bolded p value is statistically significant.

examined, a statistically significant and inverse correlation was found (p < 0.05). The experimental group had a strong inverse correlation (r = -0.679, p < 0.001), whereas the control group (r = -0.390, p < 0.05) had a weak inverse correlation (see Table 3).

DISCUSSION

This study was conducted to evaluate the effect of ShotBlocker on the intramuscular injection pain and satisfaction in adult pa-

tients. The findings of this study suggest that ShotBlocker has a positive effect on pain and satisfaction levels during intramuscular injections.

The ShotBlocker potentially provides more consistent stimulation than techniques such as pressing, pinching, or stretching. Theoretically, the pressing down of the nubs on the skin should stimulate A-beta signals, which inhibit the A-delta and C fiber pain transmission of the injection, consistent with the gate control theory. The presence and severity

Table 3. Comparison of injection pain scores and injection satisfaction scores of the groups

Measurements	Experimental (n = 36) Mean ± SD (minimum–maximum)	Control (n = 38) Mean ± SD (minimum–maximum)	p	Test value
Preinjection pain score	0.55 ± 0.13 (0–3)	0.45 ± 0.08 (0–3)	0.486	^a t: -0.672
Postinjection pain score	4.61 ± 1.29 (2–8) ^b	6.97 ± 1.02 (5–8) ^b	0.000*	^a t: -8.728
Postinjection satisfaction scores	6.41 ± 1.76 (1–9) ^b	5.13 ± 1.91 (2–8) ^b	0.004*	^a t: 2.995
r	-0.679 ^b	-0.390 ^b		
p	0.000*	0.042*		

^aStudent t test.

^bPearson’s correlation test.

*p < .05. Bolded p value is statistically significant.

of pain depend on the transition of neurological stimuli. Gate mechanisms in the nervous system control the transition of pain stimuli. According to the Gate Control Theory, small-diameter fibers carry pain stimuli. Large-diameter fibers close the gate to the stimuli carried by small-diameter ones. The reticular structure in the brain stem regulates sensory input. If sufficient or excessive sensory stimulation is received, the brain stem closes the gate by suppressing the passage of pain stimuli. If the gate is open, the stimulations that result in pain reach the level of consciousness. If the gate is closed, the stimulations do not reach consciousness, and thus pain does not get experienced (Aydın & Avcı, 2019; Cobb & Cohen, 2009; Drago et al., 2009). The proposed action mechanism of the ShotBlocker is that the pressure applied to the skin by the points of the tool stimulates the faster nerve endings with smaller diameters. This stimulation temporarily blocks the slower pain signals during injection and closes the gates to the central nervous system, thus reducing pain (Yılmaz & Alemdar, 2019). In one study conducted with adult patients, it was reported that the ShotBlocker not only reduced pain associated with intramuscular injection but also increased patient satisfaction (Celik & Khorshid, 2015). In another study, it was also found that the ShotBlocker also reduced pain associated with intramuscular injection (Aydın & Avcı, 2019). Similarly, in this study, the pain mean score of the experimental group after injection was lower than the pain mean score of the control group, whereas satisfaction mean score was higher. This finding is compatible with the literature.

There was no statistically significant difference between age ($p > 0.05$), gender ($p > 0.05$), and postinjection pain scores. When the postinjection pain mean scores of the patients in the experimental group were examined in terms of BMI, no significant difference was found between their BMI and pain mean scores ($p > 0.05$). However, the individuals with BMI in the normal range were observed to experience less pain than their overweight

and obese counterparts. In advanced analysis, this difference was found to be caused by normal weight individuals. In their study, Aydın and Avcı (2019) found that individuals with normal and low weight experienced more pain during intramuscular injection than their obese counterparts (Aydın & Avcı, 2019). In another study, it was reported that there was a statistically significant inverse correlation between BMI and pain severity score and patients' pain severity decreased with increasing BMI (Cocoman & Murray, 2008). The results of this study contradict with the results of these two studies. We believe that this particular finding is caused by higher number of normal weight patients in the control group compared with the number of patients in both overweight and obese groups. This study has some limitations. The sample size was small. The study was conducted using a specific drug group. Hence, further studies with larger samples and different drug groups need to be conducted and also involve different injection sites to compare the effects of different techniques.

CONCLUSION

The findings of this study suggested that ShotBlocker may be effective in reducing intramuscular injection pain and increasing patient satisfaction levels. Also, neither age nor gender affected pain or satisfaction. It can be recommended to use ShotBlocker in clinical practices more commonly as an evidence-based nonpharmacological method in reducing intramuscular injection pain and to repeat the study with large sample groups.

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