

Effectiveness of Two Different Methods on the Perceived Pain and Satisfaction During Intramuscular Antibiotic Injection: ShotBlocker and Local Vibration

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Abstract

In this study aimed to examine the effectiveness of ShotBlocker and local vibration on the perceived pain and satisfaction during intramuscular antibiotic injection. The sample of the randomized controlled experimental study consisted of 100 patients (32 in vibration group, 35 in ShotBlocker group, 33 in control group) who applied to the adult emergency clinic for antibiotic (amoxicillin/cefuroxime sodium) injection between April and May 2021. The study data were collected using the Structured Information Form, VAS for Pain and VAS for Satisfaction. CONSORT statement was followed for reporting. After the intramuscular antibiotic injection, a significant difference was found between the groups in terms of the mean scores of VAS for Pain and VAS for Injection Satisfaction ($p < .001$). It was determined that local vibration application was more effective in reducing the pain and in increasing satisfaction that occurs during intramuscular antibiotic injection according to ShotBlocker and control groups.

Keywords

intramuscular injection, local vibration, nursing, pain relief methods, ShotBlocker

Introduction

The administration of intramuscular (IM) injection is one of the basic nursing skills and one of the responsibilities of the professional nurse. It is estimated that 16 billion IM injections are administered every year in the world. While vaccines constitute less than 5% of these injections, IM drug administrations applied for different purposes constitute more than 95% of them (Çelik & Khorshid, 2015; Nicoll & Hesby, 2002). IM injection may lead to complications such as vascular, tissue, and nerve injuries, and it is an application that causes pain and fear in the individual. It is known that the pain that occurs during IM injection is affected by many factors such as individual characteristics, previous injection experiences, length and thickness of the needle, injection site, technique used, amount of drug injected, and physical and chemical properties of the drug (osmolarity, pH, concentration, and auxiliary chemicals used in drug) (Çelik & Khorshid, 2012). Nurses apply some non-pharmacological methods such as distraction, application of manual pressure (acupressure), local cold application, and ShotBlocker and local vibration in order to reduce the pain caused by IM injections (Alavi, 2007; Benjamin et al., 2016; Drago et al.,

2009; Tok Aydın, 2019; Tuğrul et al., 2017; Whelan et al., 2014).

There is a limited number of studies in which ShotBlocker, that can be used quickly and easily, is inexpensive, does not require prior material preparation and is used by keeping on the skin surface during injection, was used on adult individuals (Aydın & Aşar, 2019). Romano and Cecca found that ShotBlocker application was effective in reducing the pain caused by IM injection. Furthermore, they also reported that no side effects occurred due to the application of this instrument (Romanò & Cecca, 2005; Tok Aydın, 2019). In the study of Çelik and Khorshid (2015), it was reported that the use of ShotBlocker during IM injection in adults reduced the intensity of pain.

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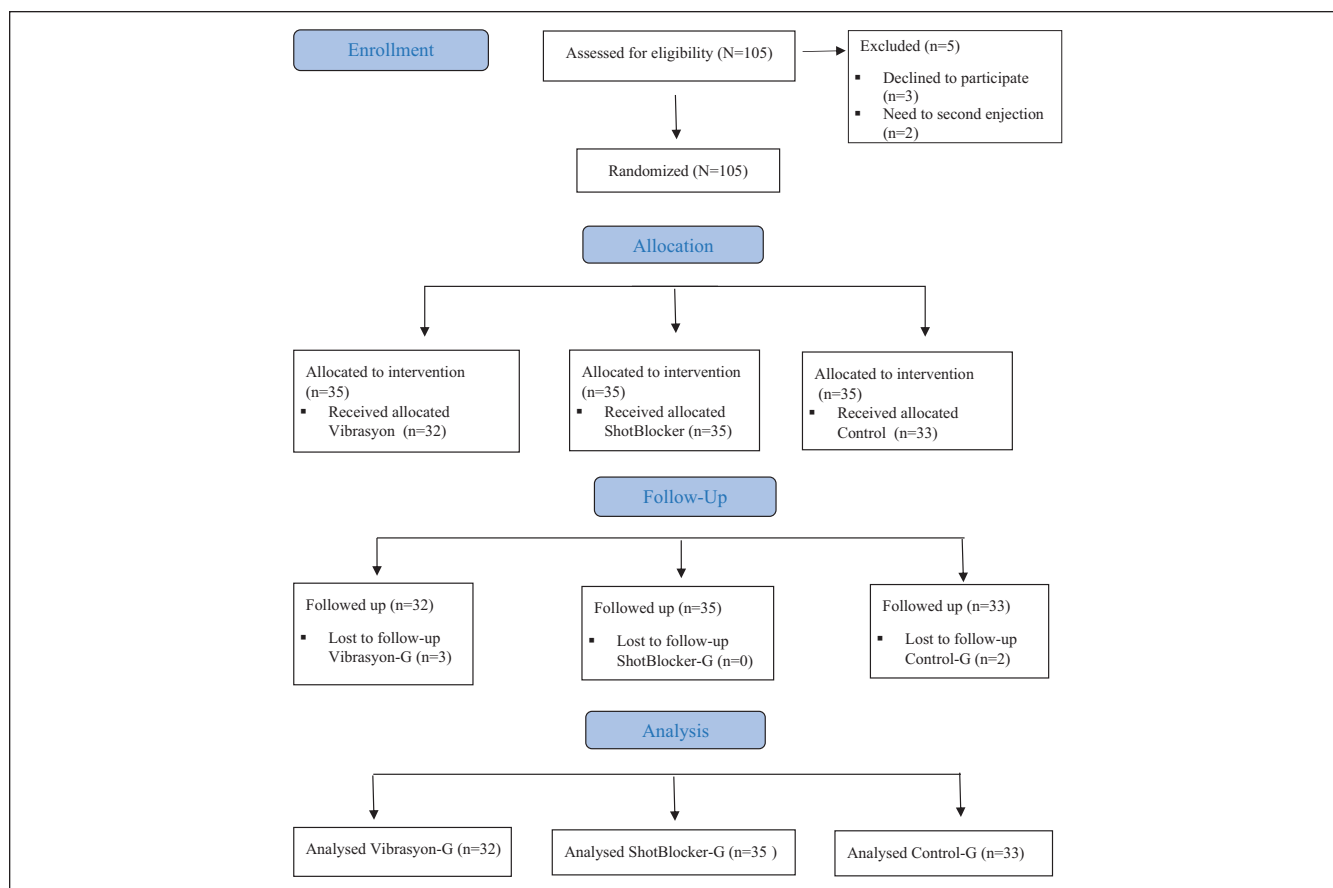


Figure 1. The flow diagram for this study (CONSORT statement).

The vibrator, which is a locally administered and vibrating instrument, can be applied in acute and chronic nonmalignant pain management such as acute and chronic muscle pain, tension-type headache, neuropathic pain, phantom pain, and rheumatoid arthritis pain (Özveren, 2011). In experimental and clinical studies investigating the effectiveness of the vibrator providing local mechanical vibration in relieving pain in pediatric and adult populations, it was observed to be an effective method for acute and chronic pain, including injection pain (Baxter et al., 2011; Benjamin et al., 2016; Thomas et al., 2018; Whelan et al., 2014).

Nurses have the responsibility to reduce the pain due to IM injection and to increase satisfaction in individuals of all age groups. When the literature was reviewed, it was determined that there was a limited number of studies in which ShotBlocker and local vibration application were used to evaluate the perceived pain and satisfaction during IM injection. Furthermore, there was no study comparing the ShotBlocker and local vibration. The aim of this study was to evaluate the effectiveness of ShotBlocker and local vibration on the perceived pain and satisfaction level during IM antibiotic injection.

Methods

Design

This randomized controlled experimental study was conducted between April and May 2021 in the adult emergency clinic of a training and research hospital located in Istanbul. The study complied with the guidelines of Consolidated Standards of Reporting Trials (CONSORT) Checklist (Figure 1).

Hypotheses of study:

H1: Using ShotBlocker during intramuscular antibiotic injection reduces the patient's injection pain.

H2: Using ShotBlocker during intramuscular antibiotic injection increases the patient's satisfaction with the injection.

H3: Using a local vibrator device during intramuscular antibiotic injection reduces the patient's injection pain.

H4: Using a local vibrator device during intramuscular antibiotic injection increases the patient's satisfaction with the injection.

Participants

Sample size was determined using power analysis (G*Power 3.1.9.2) and the results of a previous similar study as an example (Thomas et al., 2018). The minimum size for each group was 35, so the sample size was 105 with a power of 0.80, 95% confidence. A chart with three groups was created. Since the drug characteristics (active ingredients, osmolality, etc.) differed (Kizior & Hodgson, 2021; Tibet, 2020) the participants who came for amoxicillin or cefuroxime sodium and met the study criteria were assigned to groups by the study nurse to ensure an equal distribution of patients in the groups. The first patient who came for amoxicillin was assigned to the vibration group, the second was assigned to the ShotBlocker group, and the third was assigned to the control group. This procedure was also followed for patients who received cefuroxime sodium injections. The first patient who came for cefuroxime was assigned to the vibration group, the second was assigned to the ShotBlocker group, and the third was assigned to the control group. A total of 121 antibiotic injections, 26 amoxicillin and 95 cefuroxime sodium injections, were administered during the study during the work hours of the study nurse (8:00 a.m.–4:00 p.m.). As soon as the sample size for each group was reached, the process of assigning patients to the groups was ended. The study included 105 patients, 26 who received amoxicillin (9 in the vibration group, 9 in the ShotBlocker group, and 8 in the control group), and 79 who received cefuroxime sodium (26 in the vibration group, 26 in the ShotBlocker group, and 27 in the control group).

Criteria for inclusion in the study; being over the age of 18, having no communication problem such as seeing, hearing, and understanding problem, having no disease that can cause sensory loss (such as diabetic neuropathy, stroke, multiple sclerosis, etc.), not having had IM injection in the last week, having no abscess, infection, tissue necrosis, and hematoma at the injection site.

Data Collection Tools

The study data were collected using the Structured Information Form, which was prepared in line with the literature (Aydin & Avşar, 2019; Çelik & Khorshid, 2015; Thomas et al., 2018) and consisted of five questions, and VAS for Pain and VAS for Satisfaction.

Structured Information Form: Five questions about the descriptive characteristics of the participants (age, gender, body mass index [BMI], educational status, marital status) were included in the Structured Information Form. BMIs of the participants were calculated by the research specialist nurse. Before the weight measurement, the electronic weighing device was calibrated.

Visual Analog Pain Scale (VAS): The Visual Analog Scale, developed by Huskisson (1974), is accepted as a secure, valid, and applicable pain measurement tool in repetitive measurements. On a 10-cm long horizontal line, there

are definitions of “no pain” at the left end and “unbearable pain” at the right end. The patient is asked to mark the point on this line that best expresses his/her pain severity. The distance of the patient’s sign to the left end is measured. This distance, usually measured in millimeters, is interpreted as “points” (Eti Aslan, 2002; Suldur, 2001). Reliability of the pain scale for acute pain was ensured by Bijur et al. (2001). The use of the scale in acute pain has been reported to be more reliable than chronic pain (Bijur et al., 2001).

Visual Satisfaction Scale: Because satisfaction is a subjective condition such as pain, Visual Satisfaction Scale was used to evaluate satisfaction. In the visual satisfaction scale, as in the pain scale, the degree of patient satisfaction increases from left to right. The fact that the pain severity increases, while the satisfaction level decreases creates a contrary situation to one another, and hence the subsequent application of scales can be confusing for some patients. In order to prevent this situation, a vertical orientation is preferred in the satisfaction scale. There is the statement “Strongly dissatisfied” at the lower end of the line, and “Strongly satisfied” at the upper end. The measured distance is interpreted as “points” (Kılınçer & Zileli, 2006). The scale is widely used to evaluate satisfaction.

Data Collection

Initial assessment. Verbal information was given to the participants prior to the intramuscular injection, and their written consents were obtained. The “Structured Information Form” consisting of five questions was applied by face-to-face interview method. Height (kg) and weight (m) were measured, and BMI (kg/m^2) was calculated and recorded in the “Structured Information Form.”

Application. ShotBlocker was used on 35 patients and a local vibrator device was used on 32 patients during intramuscular injection.

ShotBlocker is a small, flat, and horseshoe-shaped (U-shaped) plastic tool with a thickness of 2 mm, which is used for pain control in intramuscular and subcutaneous injections, and suitable for all age groups, and which has no known side effects and does not have drug properties, and which is non-invasive (Figure 2). Since it is not an invasive tool, it is stated by the manufacturer that it can be used several times for the same patient after washing it with soap. The protruding surface of the tool is placed in the area of application just before injection. Short blunt protrusions on the surface of the tool do not pierce the skin. ShotBlocker is used to reduce pain according to the principle of gate control theory. The pressure applied by blunt protrusions to the skin stimulates nerve endings in smaller-diameter and faster, and temporarily blocks pain signals during injection, thus preventing the transmission of pain to the central nervous system (Çelik & Khorshid, 2015; Cobb & Cohen, 2009; Drago et al., 2009; Melzack, 1999).

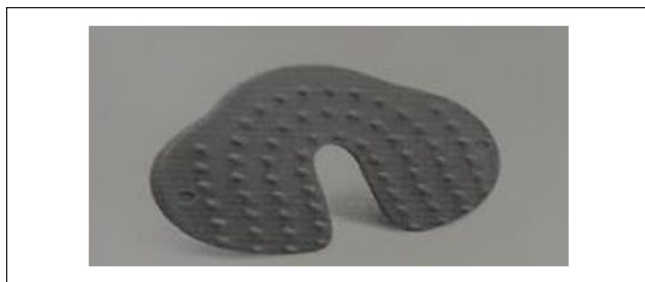


Figure 2. ShotBlocker.

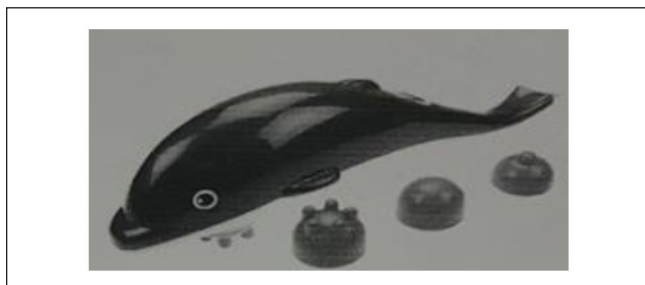


Figure 3. Local vibrator device.

Local vibrator device, one of the electric vibrator devices (dolphin massager device, 210–240 V, 50 Hz) produced by different brands was used (Figure 3). These devices with interchangeable heads have the capability to affect deep muscle groups, stimulate nerve endings, and accelerate blood circulation thanks to mechanical vibration. During application, the device is required to be in full contact with the skin (Thomas et al., 2018). Local vibration application reduces the perceived pain by stimulating nerve fibers according to Melzack and Wall's Gate Control Theory (Baba et al., 2010; Benjamin et al., 2016; Melzack, 1999; Secil et al., 2014; Thomas et al., 2018).

Intramuscular injection procedure: In the literature, it is stated that the ventrogluteal region can be used safely for application of IM injection because it does not contain large blood vessels or nerves and it is away from bone tissue (Craven et al., 2013; Kaya & Palloş, 2012; Sabuncu et al., 2008). Güneş et al. (2008) reported that the ventrogluteal region could be used safely on normal and slightly overweight individuals in IM injection applications (Güneş et al., 2008). In this study, the ventrogluteal region was used as the injection site due to the thin subcutaneous layer, the easy position to be given to the patient and the low possibility of administering the drug to the subcutaneous tissue (Craven et al., 2013; Kaya & Palloş, 2012; Sabuncu et al., 2008).

Before the drug was prepared, the physician's request was checked by the researcher. Hands were washed, the drug (amoxicillin/cefuroxime sodium) was prepared by diluting with 4 ml of water for injection, and the needle tip was changed to 21G (0.8 × 40 mm—green). The patient was

verbally informed, and his/her drug allergy was questioned. The patient was asked to lie in the prone position. The skin surface in the area where IM injection would be applied was observed for ecchymosis, scar, inflammation, or edema by the research specialist nurse. The presence of tenderness or stiffness was evaluated by palpation, paying attention to muscle integrity. For the patient group that was subject to local vibration, local vibration was applied to the region with a vibrator for 5 minutes prior to injection, following a previous study on this subject (Thomas et al., 2018). After that, 70% alcohol was used to cleanse the skin. The injection was applied with the appropriate technique, then a light pressure was applied to the area with a cotton pad for 15 to 20 seconds. For the patient group that was applied ShotBlocker, after cleansing the skin, the protruding surface of the device was placed facing the skin surface. The injection was applied with the appropriate technique, then ShotBlocker was removed and a light pressure was applied to the area with a cotton pad for 15 to 20 seconds. For the control group, IM injection into the ventrogluteal region without using any tools was performed with the appropriate technique (Aydin & Aşar, 2019; Çelik & Khorshid, 2015; Kaya & Palloş, 2012; Ogston-Tuck, 2014; Thomas et al., 2018).

During the procedure, a separate ShotBlocker was used for each patient. The vibrator head, on the other hand, was cleansed with soapy water and 70% alcohol for reuse. It was paid attention to the patient privacy and safety throughout the application. In order to eliminate interpersonal differences, all injections were administered by the same research specialist nurse.

Final assessment. VAS was applied immediately after the intramuscular injection to determine the pain and satisfaction levels of the participants.

Ethical Considerations

Approval of the ethics committee for conducting the study (Date/Number: 11.02.2021/0067) was obtained from the health institution where the study would be conducted. In accordance with the Helsinki Declaration, the patients were informed that the study data would only be used in the study, and that their privacy would be ensured. Their written consent was obtained. The study was registered in Clinical Trials with the registration number of "NCT04851158" before the first participant was recruited.

Statistical Analysis

Data were analyzed using the Statistical Package for the Social Sciences version 16.0 software (SPSS Inc.; Chicago, IL, USA). The Shapiro Wilks test was used to assess whether the data had a normal distribution (Büyüköztürk, 2009). In the statistical evaluation of the data, the averages, percentages, frequencies, and mean values (min.-max.)

Table 1. Characteristics of the Participants in the Local Vibration, ShotBlocker, and Control Groups.

Variables	Groups			Test value <i>p</i>
	Local vibration (<i>n</i> = 32)	ShotBlocker (<i>n</i> = 35)	Control (<i>n</i> = 33)	
Age (Mean $\pm$ SD)	48.68 $\pm$ 19.51 (20–75)	53.75 $\pm$ 12.21 (18–80)	48.18 $\pm$ 12.28 (18–80)	<i>F</i> :0.184 .383 ^a
Variables	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	
Gender				
Female	16 (50.8)	19 (54.2)	19 (57.57)	χ^2 :.377
Male	16 (50.2)	16 (45.7)	14 (42.42)	.828 ^b
Education status				
Primary	11 (34.32)	9 (25.71)	11 (33.33)	χ^2 :2.645
Secondary	5 (15.68)	4 (11.42)	3 (9.09)	.955 ^c
High School	7 (21.87)	10 (30.25)	7 (21.21)	
University	9 (28.12)	12 (34.28)	12 (36.36)	
Body mass index (BMI)				
Normal	12 (37.5)	16 (45.71)	12 (36.36)	χ^2 :1.262
Overweight	16 (50)	15 (42.85)	15 (45.45)	.868 ^c
Obese	4 (12.5)	4 (11.42)	6 (18.18)	
Body mass index (BMI)	Local Vibration	ShotBlocker	Control	
Mean $\pm$ SD	24.9 $\pm$ 2.35	25.0 $\pm$ 1.98	24.8 $\pm$ 1.89	

^aOne-way ANOVA.^bPearson Chi-Square Test.^cFisher Freeman, Halton Test, Bonferroni-corrected.

were calculated. One-way ANOVA, which is one of the parametric tests, and the Pearson Chi-Square Test, the Mann Whitney *U* Test, and the Fisher Freeman Halton Test, which are non-parametric test, were also used in determining the difference between the groups. Pearson's correlation coefficient was used to examine the relationship between two normally distributed quantitative variables. All results were considered significant at $p < .05$ with a confidence interval of 95%.

Results

The average age of the participants ranged from 18 to 80, the average age of the vibration group was 48.68 ± 19.51 , the mean age of the ShotBlocker group was 53.75 ± 12.21 , and the mean age of the control group was 48.18 ± 12.28 . The information of all three groups is given in Table 1, and there is no statistical difference between the groups in terms of sociodemographic characteristics ($p > .05$) (Table 1).

A significant difference was found between the groups after one-way analysis of variance (ANOVA) to determine that the pain and satisfaction scores differ between the groups ($p < .001$). As a result of the post hoc Bonferroni-corrected test performed to determine the difference, it was found that the difference for the pain score originated from the vibration group and for the satisfaction score from the control group. It was observed that the lowest pain level was perceived in patients with local vibration (3.02 ± 1.07), and the highest

pain was perceived in the control group (7.09 ± 0.94). The highest satisfaction level was measured in patients with local vibration (7.80 ± 0.90) and the lowest level of satisfaction was measured in the control group (4.93 ± 1.93). When the correlation between the pain scores (VAS) and Injection Satisfaction Scores (VAS) of the groups was examined, a statistically significant negative correlation was found in all groups ($p < .05$). A high level of correlation was found in the vibration group ($r = -.649$, $p < .001$), while a weak correlation was found in the ShotBlocker ($r = -.345$, $p < .05$) and control group ($r = -.336$, $p < .05$) (Table 2).

Discussion

Pain is one of the most common complications in IM injection application, which is one of the responsibilities and basic skills of nurses (Çelik & Khorshid, 2015; Kusumadevi et al., 2011; Tok Aydın, 2019). Nurses have an important role in pain management and control. The quality of pain management depends on the nurse's knowledge, attitude, and skill regarding painful interventions (Aydın & Avşar, 2019; Çelik & Khorshid, 2015).

In the study conducted to determine the level of pain and satisfaction during IM antibiotic injection using ShotBlocker and local vibrator, it was determined that there was no difference between the groups in terms of sociodemographic characteristics of the participants, so all three groups were considered homogeneous.

Table 2. Evaluation of VAS Pain Score and VAS Satisfaction Score after Injection.

Groups	Local vibration (n = 32) Mean $\pm$ SD	ShotBlocker (n = 35) Mean $\pm$ SD	Control (n = 33) Mean $\pm$ SD	Test value p
Visual pain scale (VAS) (cm)	3.02 $\pm$ 1.07 ^a	4.56 $\pm$ 1.34	7.09 $\pm$ 0.94	.000* F: 111.647 ^{a*}
Injection satisfaction scores (VAS) (cm)	7.80 $\pm$ 0.90	6.59 $\pm$ 1.77	4.93 $\pm$ 1.93 ^a	.000* F: 27.65 ^{a*}
r	-.649	-.345	-.336	
p	.000**	.046*	.049*	

SD = standard deviation.

^aOne-way ANOVA.^bPearson Correlation.^{*}Bonferroni-corrected.

*p < .05. **p < .001.

In the literature, some measures such as choosing the appropriate injection site, appropriateness of the drug volume, changing the needle tip, giving the appropriate position, gradual administration of the drug, using the airlock technique, and deep breathing of the patient during the procedure are recommended to reduce the pain perceived during injection (Aydin & Avşar, 2019; Güneş et al., 2008; Kara, 2013; Mitchell & Whitney, 2001). In some studies, it has been found that BMI significantly affects the severity of pain during IM injection, and individuals with light and normal weight feel more severe pain than overweight individuals (Ozdemir et al., 2013; Tuğrul et al., 2017). In this study, BMI was taken into consideration together with the above-mentioned suggestions, and the mean BMI score was found to be 24.9 $\pm$ 2.35 in vibration group, 25.0 $\pm$ 1.98 in the ShotBlocker group, and 24.8 $\pm$ 1.89 in the control group. In addition, a BMI range of 18.5 $\pm$ 29.9 is defined as safe for ventrogluteal drug injection in the literature (Kaya & Palloş, 2012). In this study, no statistically significant difference was found between the groups as a result of the BMI measurement comparisons of the three groups. The groups consist of normal weight and overweight individuals, and they are in the safe BMI range for IM drug injection into the ventrogluteal area.

This study found that local vibration reduced pain and increased satisfaction more than ShotBlocker and the control group. During IM antibiotic injections, the local vibration group had the lowest mean pain level (3.02 $\pm$ 1.07), and the control group had the highest pain level (7.09 $\pm$ 0.94). The local vibration group had the highest mean satisfaction level (7.80 $\pm$ 0.90), and the control group had the lowest satisfaction level (4.93 $\pm$ 1.93). Thomas et al. (2018) reported a significant reduction in perceived pain scores in a group that received local vibration prior to IM penicillin injections (p < .001). Park and Kim (2017) found that the severity and duration of perceived pain after injections was significantly reduced by the use of massage devices for vibration and effective pressure (p < .001). The current study found that local vibration before IM antibiotic injections reduced the patients' perceived pain scores. The local vibration group's higher satisfaction may

also have been due to relaxation and the massage effect of the vibration. No information was found in the literature concerning this effect, which future studies should investigate.

When the correlation between the pain scores (VAS) and Injection Satisfaction Scores (VAS) of the groups was examined, a statistically significant negative correlation was found in all groups. The local vibration and ShotBlocker groups had lower perceived pain scores for IM antibiotic injections in the ventrogluteal region, and their satisfaction levels increased. The control group's perceived pain scores increased, and their satisfaction scores decreased. Therefore, even though ShotBlocker is not as effective as local vibration, it, too, reduces the pain of IM antibiotic injections and increases satisfaction. Romanò and Cecca (2005) found in their study that ShotBlocker application was effective in reducing pain arising from IM injection. In the study by Çelik and Khorshid (2015), it was reported that the pain during IM injection using ShotBlocker was significantly less than the control and placebo groups. Alavi (2007) found the VAS score to be 3 $\pm$ 2 cm in the ShotBlocker-applied group and 5 $\pm$ 2 cm in the control group.

Limitations and Strengths of the Study

The low number of participants are and the use of different antibiotic limitations of the study. This study has a single-center design, therefore, the results cannot be generalized to the overall population. On the other hand, patients were randomly assigned to the groups.

Conclusion

This study found that that local vibration was reduced pain and increased satisfaction more than ShotBlocker and the control group. These results suggest that local vibration could be used as a non-pharmacological method of pain reduction for IM injections. Studies should be conducted with larger sample sizes and other drugs to compare results with other studies of non-pharmacological methods.

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Declaration of Conflicting Interests

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