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COMPARISON OF MANUAL PRESSURE AND SHOTBLOCKER ON PAIN AND SATISFACTION IN
INTRAMUSCULAR INJECTION: A RANDOMIZED CONTROLLED TRIAL
İNTRAMÜSKÜLER ENJEKSİYONDA AĞRI VE MEMNUNİYET ÜZERİNDE MANUEL BASINÇ VE
SHOTBLOCKER'İN KARŞILAŞTIRILMASI: RANDOMİZE KONTROLLÜ BİR DENEME*

Ali KAPLAN¹, Sevil GÜLER², Ömer Levent AVŞAROĞULLARI³

¹ Kayseri University, Incesu Health Services Vocational School, Department of Medical Services and Techniques, Kayseri

²Erciyes University, Faculty of Health Sciences, Department of Nursing, Kayseri

³Erciyes University, Faculty of Medical, Department of Medicine, Kayseri

ABSTRACT

Intramuscular injection pain can create a negative experience for both patients and nurses performing the application. It has been recently become more important to reduce the pain and anxiety caused by injection in nursing care due to the prominence of the concept of quality in health services. This study was conducted to investigate the effect of manual pressure applied before injection and ShotBlocker on pain and injection satisfaction associated with intramuscular injection. This research is a randomized controlled experimental clinical trial. The sample of the study was composed of a total of 120 people over 18 years of age who applied to the emergency department of a university hospital. The participants were assigned to the ShotBlocker (40), the manual pressure (40) and the control group (40) with a randomization list generated using a computer. Visual Analog Scale and Injection Satisfaction Form were applied to the patients in the first minute after the injection. The Shot Blocker and the manual pressure groups had lower pain levels and higher injection satisfaction levels compared to the control group. Therefore, manual pressure and ShotBlocker are recommended to reduce pain associated with intramuscular injection and increase injection satisfaction.

ÖZ

İntramüsküler enjeksiyon uygulamasına bağlı yaşanan ağrı hem hastalar hem de uygulamayı yapan hemşireler için olumsuz bir deneyim oluşturabilir. Sağlık hizmetlerinde kalite kavramının öne çıkması nedeniyle hemşirelik bakımında enjeksiyonun neden olduğu ağrı ve kaygıyı azaltmak son zamanlarda daha önemli hale gelmiştir. Bu çalışma, enjeksiyon öncesi uygulanan manuel basınç ve Shot Blocker'in intramüsküler enjeksiyonla ilişkili ağrı ve enjeksiyon memnuniyeti üzerindeki etkisini araştırmak için yapılmıştır. Bu araştırma, randomize kontrollü deneysel bir klinik araştırmadır. Araştırmanın örneklemini bir üniversite hastanesinin acil servisine başvuran 18 yaş üstü toplam 120 kişi oluşturmuştur. Katılımcılar bilgisayar kullanılarak oluşturulan bir randomizasyon listesi ile ShotBlocker (40), manuel basınç (40) ve kontrol grubuna (40) atanmıştır. Hastalara enjeksiyondan sonraki ilk dakika içinde Görsel Analog Skalası ve Enjeksiyon Memnuniyet Ölçeği uygulanmıştır. Shot Blocker ve manuel basınç grupları, kontrol grubuna kıyasla daha düşük ağrı seviyelerine ve daha yüksek enjeksiyon memnuniyet seviyelerine sahip olduğu belirlenmiştir. Bu nedenle, intramüsküler enjeksiyonla ilişkili ağrıyı azaltmak ve enjeksiyon memnuniyetini artırmak için manuel basınç ve ShotBlocker önerilir.

Keywords: Pain measurement, integrative medicine, intramuscular injection, manual pressure, , shotblocker

Anahtar kelimeler: Ağrı ölçümü, bütünlleştirici tıp, intramüsküler enjeksiyon, manuel basınç, shotblocker

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Corresponding Author: Asst. Prof. Ali KAPLAN, Kayseri University, Incesu Health Services Vocational School, Department of Medical Services and Techniques, Kayseri/Türkiye, alikaplan@kayseri.edu.tr, ORCID: 0000-0001-8242-0110
Phone: +90 352 432 38 38/47522
Assoc. Prof. Sevil GÜLER, sevilbicer@erciyes.edu.tr, 0000-0002-9971-9861
Prof. Ömer Levent AVŞAROĞULLARI, lavsar@erciyes.edu.tr, 0000-0002-3359-9860

INTRODUCTION

Intramuscular (IM) injection is a fundamental skill in nursing functions and responsibilities and is one of the most common techniques among drug administration (1). In cases where the injection is not performed with the correct and appropriate methods, it can cause very serious complications (2). IM injection has many complications such as cellulitis, muscle fibrosis, tissue necrosis, hematoma and nerve injuries, and the most common complication is pain (3). In a study on pain intensity, it was founded that average pain intensity following IM injection was 7.4 out of 10 (4). Pain can cause an increase in anxiety, non-compliance with treatment, various physical symptoms such as an increase in heart rate, and the development of a lifetime fear of injections (5). The professional organization and accreditation standards applied to improve service quality given in health institutions report that pain should be reduced (6).

Today, the importance of pain control with a multidisciplinary team approach consisting of patients, nurses and physicians is accepted by everyone (7). Nurses have important roles and responsibilities in the pain management process due to their long-term interaction with patients (8). Reduced pain intensity leads to an increase in the compliance of patients to the medication treatment, in quality of patient care, in maintaining patient satisfaction and in the patient-nurse relations (9). In the literature, it is emphasized that IM injection administered based on the guidelines may be less painful and may help prevent injection-related complications (10,11). It is important that nurses have knowledge of and use proven, easy-to-use non-pharmacological methods that can minimize pain. This study was planned because it is thought that manual pressure and Shot Blocker applications will be an easy option to use in pain control due to IM injection.

Pain in IM injection develops due to trauma caused by the entry of the needle into the muscle and the sudden pressure resulting from the intramuscular administration of the drug (12). In addition, the content of the drug applied, its volume, being cold, the technique used, the position of the patient, the speed of drug administration, the injection site, the needle length and diameter, and the level of anxiety felt by the patient are among the factors that cause pain (11).

Reducing patients' pain is important for nurses. For this reason, various studies have been conducted to reduce injection pain so far (10,13). Many pharmacological and non-pharmacological methods are used to reduce the feeling of pain during IM injection (13). In the literature, applying a mixture of lidocaine and prilocaine (EMLA cream) to the injection region and application of Fluorimethane containing local cooling vapor to the injection site are included among the pharmacological methods reducing pain experienced during intramuscular injection (13). Non-pharmacological methods primarily used to manage injection-induced pain are cold application (14), manual pressure (15), internal rotation application of extremities (10), acupressure (16), vibration (17), Z track technique (11), air-lock technique (18), Buzzy and Shot Blocker (1).

Although there are many pharmacological and non-pharmacological methods to reduce pain in IM injection,

all these interventions may not be practical due to the need for preliminary preparation, the high probability of side effects, etc. For example, ice application requires pre-preparation before injection or local anesthetics cause exposure to another chemical. Therefore, simpler and more practical methods are needed to reduce pain related to IM injection (19). The use of manual pressure and Shot Blocker can be a practical intervention, as it is a quick and easy-to-use method that does not require prior material preparation, has no side effects, and is easy to use. The proposed mechanism of action of these two methods is based on the gate control theory. With manual pressure and Shot Blocker application, smaller diameter and faster nerve endings are stimulated and slower pain signals are temporarily blocked. Thus, the doors to the central nervous system are closed and the pain associated with the injection application is felt less (20).

Nurses can play an important role in reducing pain with appropriate non-pharmacological nursing interventions in painful and needle interventions and measure the effectiveness of the intervention (21). The number of such studies that will guide the nurses is very low in the literature and there is a need to implement the pain relief methods for which the nurse is primarily responsible (22). Further evidence-based studies need to be conducted on reducing pain caused by intramuscular injection with the cooperation of academicians and clinical nurses (10). Therefore, there is a need for new studies in which nurses can access concrete evidences.

This study was conducted to compare the manual pressure and the Shot Blocker on pain and satisfaction in intramuscular injection.

MATERIALS AND METHODS

Design and Participants

This study is a single-blind randomized controlled study and followed the CONSORT 2010 checklist of information to include when reporting a randomised trial.

The population of the study consists of all patients diagnosed with upper respiratory tract infection, who were in the green triage area of the emergency department of a university hospital between the data collection dates (April 2019-August 2019). In order for the participants to have similar characteristics and the results of the research to be strong, only patients who were diagnosed with upper respiratory tract infections and who were in the green triage area were included in the study.

In the sample selection of the study, minitab program power analysis method was used. The sample of our research was created by considering the study of Celik and Khorshid (1) on Shot Blocker. When the effect size was 0.10, the margin of error was 0.05, and the statistical power was 90%, it was determined that 120 people were needed, 40 in the experimental group I, 40 in the experimental group II, and 40 in the control group. A flowchart of the study design is shown in Figure I. A computer-assisted randomization program was used to assign groups. A random list was created that assigns individuals to groups. Participants who met the inclusion criteria of the study and agreed to participate in the study were numbered according to the order of arrival. These participants were assigned to the research group

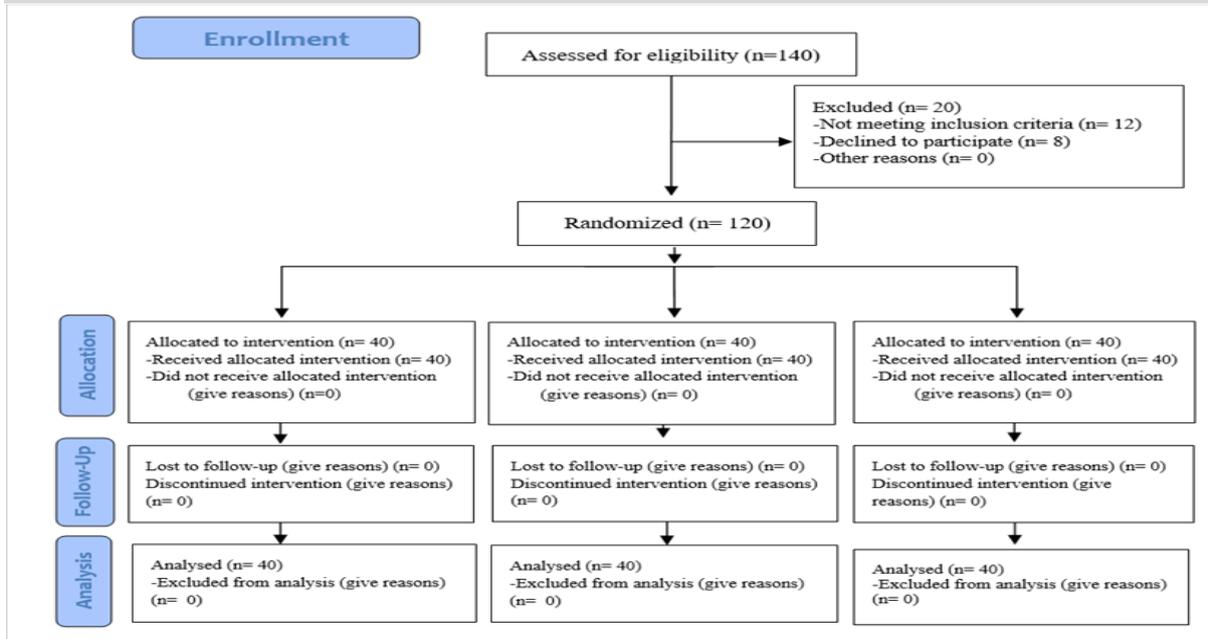


Figure 1: Flow chart of the study phases.

with their own number according to the previously created randomization list. The sample of the study consisted of 120 participants who met the inclusion criteria and agreed to participate in the study.

Participants in this research needed to meet the following inclusion criteria: (i) have not had an intramuscular injection in the last week, (ii) are over the age of 18, (iii) no complications at the intramuscular injection site, (iv) who do not have pain anywhere in their body or have a Visual analog scale score of 2 or less (out of 10), (v) is conscious and has no communication problem, (vi) not taking analgesics in the last 24 hours, (vii) without any known chronic disease and (viii) volunteering to participate in the study. The participants who did not want to participate in the study and did not meet the inclusion criteria were excluded from the study.

Data Collection Tools

Patient Information Form, Visual Analog Scale and Injection Satisfaction Form, which were created by the researchers by scanning the relevant literature, were used to collect the data of the study.

Patient Identification Form

The form prepared by the researcher by examining the relevant literature; It consists of socio-demographic characteristics of individuals such as age, gender, educational status, etc., and vital signs table (1,23). The patient introduction form was filled in by the researcher by interviewing the participants face to face and checking the patient file.

Visual Analog Scale

It is a scale used to measure pain. One end of the scale (0 mm) indicates the absence of pain, and the other end (100 mm) indicates the most severe pain that can be experienced. This scale is one of the most commonly used pain measurement tools and is more sensitive and reliable than other one-dimensional scales. In this scale, the individual indicates the severity of the pain he feels by putting a sign (24).

Injection Satisfaction Form

It is a form created to determine the satisfaction status of people after injection. Two end definitions of the injection satisfaction parameter are written on both ends of a 100 mm line and the patient is asked to indicate where this line is appropriate. "0mm" means not satisfied at all, "100mm" means very satisfied. The individual determines the degree of injection satisfaction he feels on this form.

Data Collection and Intervention

During the study, the same commercial name drug (diclofenac sodium, drug volume: 3 ml) was administered to all people included in the study to control the effects originating from the application. No fee was requested from the participants included in the study and no additional payment was made for participating in the study. Since the study is a single-blind study, pain and satisfaction assessment was conducted by single emergency nurse (graduate student) to ensure unbiasedness. The emergency nurse was informed about the use of the scales by the researcher. In order to prevent possible error due to the differences in thickness of injector needle, 21 G (needle length of 38 mm) needle tip was used for all participants. The 21 G needle tip was chosen because it is the appropriate size and diameter for IM injection application, and the most commonly used needle. Injection was made to the ventrogluteal region of all participants included in the study. In this study, by considering the reliability of the study results, a single researcher performed all intramuscular injections during this study. Side effects caused by the administered drug were taken into account. However, no side effects related to the application developed in the participants included in the study during data collection.

Participants who met the inclusion criteria of the study were informed about the purpose of the study and their written consent was obtained. Participants with written consent were numbered according to the order of admission to the study and assigned to the groups according to the previously created randomization list. Demo-

graphic data and pulse - blood pressure values of the participants assigned to the research groups were filled in by face-to-face interviews by an emergency nurse who was trained before the application. The IM injection of the participants in the Experimental I group was performed by placing a Shot Blocker on the injection site. After applying pressure to the IM injection site with the thumb of the active hand for 10 seconds, the participants in the Experimental II group were injected. Injection of the participants in the control group was performed with the normal intramuscular injection procedure without any intervention. The nurse responsible for data collection administered the Visual Analog Scale and Injection Satisfaction Form at the 1st minute after the IM injection. Pulse and blood pressure values were measured again and the data obtained were written on the data collection form.

Protocol of Experimental and Control Groups

Experimental Group I (Shot Blocker): The determined injection site was cleaned with alcohol cotton tampon by making circular movements from inside to outside with a diameter of 5 cm, and the alcohol was allowed to dry. Just prior to injection, the side of the Shot Blocker with blunt protrusions was placed on the injection site. The injector was taken as active and the cap of the needle was removed. The patient was instructed to take deep breaths. The needle was inserted through the space in the middle of the Shot Blocker at an angle of 90°.

Experimental Group II (Manual Pressure): Pressure was applied with the thumb of the active hand for 10 seconds to the determined injection site. Right after the pressure application was terminated, the determined injection area was cleaned using alcohol cotton tampon with 5-cm diameter circular movements from the inside to the outside and the alcohol was allowed to dry. The injector was taken as active and the cap of the needle was removed. The patient was instructed to take deep breaths. The needle was inserted at a 90° angle.

Control Group: Injection of the participants in the control group was performed with the normal intramuscular injection procedure without any intervention.

Statistical Analysis

The data were evaluated using IBM SPSS Statistics 23.0 (IBM Corp., Armonk, New York, USA). The normal distribution of numerical data was examined with the Shapiro Wilk test of normality. Comparisons of the categorical data between the groups were made by Fisher or Pearson chi-square analysis. Paired t test was used to compare repeated measurements. For normally distributed data, one-way analysis of variance was applied in comparisons of more than two groups. As a result of one-way analysis of variance, which was found to be significant, a post-hoc test (Tukey test) was used as a multiple comparison test. Spearman correlation coefficient was applied to statistically evaluate the relationship between the variables, the direction and severity of this relationship. $p < 0.05$ value was considered statistically significant in all comparisons.

Ethical Considerations

The study complies with the Helsinki Declaration and was approved by the Ethics Committee for Clinical Research, Faculty of Medicine (document no. 2019/255, dated April 17, 2019). All participants included in the

study participated in the study on a voluntary basis. Participants were told that they could leave the study at any time without giving any reason, and that all data obtained from the study would be kept confidential. The people included in the study were informed about the study both verbally and in writing and the written informed consent forms were signed.

RESULTS

The introductory characteristics of the participants in the research groups are presented in Table I. There was no statistical difference between the groups in terms of the descriptive characteristics of the participants ($p > 0.05$). These findings show that the study groups are similar and statistically suitable for comparison.

Table II shows the distribution of hemodynamic findings of participants before and after injection by study groups. In line with the data obtained, it was determined that there was a statistically significant difference between the mean pulse rates of the people in the Manual Pressure group before (96 ± 16.28) and after (92.02 ± 16.74) the injection ($p < 0.05$) (Table II).

Visual Analog Scale mean scores of the individuals were determined as 30.62 ± 23.04 for Shot Blocker group, 24.95 ± 19.22 for manual pressure group and 59.50 ± 22.29 for control group. Injection satisfaction level mean scores of the patient participating in the study were determined as 76.00 ± 19.58 for Shot Blocker group, 80.17 ± 19.37 for manual pressure group and 51.05 ± 22.84 for control group. When the mean scores of the Shot Blocker and manual pressure groups were compared to the control group, it was found that the mean pain scores were low and the injection satisfaction level mean scores were higher. This situation was found to be statistically significant ($p < 0.001$). In addition, there was no statistical difference between the Shot Blocker and manual pressure groups in terms of pain and injection satisfaction level (Table III).

Table IV shows the correlation analysis between Visual Analog Scale and injection satisfaction level of individuals in Experiment I, Experiment II and Control Groups. There was a negative and highly significant correlation between the post-application Pain scores of the participants in the Experimental I group included in the study and the injection satisfaction level scores ($p < 0.001$), and a very highly significant negative correlation between the participants in the Experimental II group ($p < 0.001$) and the participants in the control group had a moderately significant negative relationship ($p < 0.001$).

DISCUSSION

Nurses need to support their knowledge and practices with evidence-based studies in order to provide quality care (25). It is emphasized that evidence-based studies should be done in IM injection applications, which is one of the most applied nursing interventions in health care services (10). This study was conducted to reduce the pain experienced due to IM injection application, and the findings were discussed with the current literature. In our study, it was determined that intramuscular injection was the most painful procedure among the invasive interventions applied in the hospital and most of the participants considered intramuscular injection as a painful procedure (Table I). In studies and meta-

Table I. Descriptive characteristics of the participants (n = 120)

Characteristics	Experiment I Group (Shot Blocker) (n=40)		Experiment II Group (Manual Pressure) (n=40)		Control Group (n=40)	Test value p value
	n (%)		n (%)		n (%)	
Age						
18-28	19 (47.5)		26 (65.0)		21 (52.5)	4.472**
29-39	14 (35.0)		9 (22.5)		9 (22.5)	0.346
≥40	7 (17.5)		5 (12.5)		10 (25.0)	
Gender						
Female	24 (60.0)		26 (65.0)		23 (57.5)	0.490**
Male	16 (40.0)		14 (35.0)		17 (42.5)	0.783
Body Mass Index						
Healthy weight	18 (45.0)		19 (47.5)		21 (52.5)	0.532**
Overweight	14 (35.0)		14 (35.0)		12 (30.0)	0.970
Obesity	8 (20.0)		7 (17.5)		7 (17.5)	
Marital Status						
Married	22 (55.0)		24 (60.0)		24 (60.0)	0.274**
Single	18 (45.0)		16 (40.0)		16 (40.0)	0.872
Educational Level						
Primary education	7 (17.5)		8 (20.0)		10 (25.0)	1.261**
High school	8 (20.0)		7 (17.5)		9 (22.5)	0.868
School / Faculty	25 (62.5)		25 (62.5)		21 (52.5)	
Previous IM Injection Application Status						
Yes	39 (97.5)		37 (92.5)		37 (92.5)	1.214*
No	1 (2.5)		3 (7.5)		3 (7.5)	0.697
Is IM Injection Application a Painful Application?						
Yes	34 (85.0)		27 (67.5)		29 (72.5)	3.467**
No	6 (15.0)		13 (32.5)		11 (27.5)	0.177
Which Application Do You Think is More Painful?						
Taking Blood	6 (15.0)		7 (17.5)		6 (15.0)	1.706**
IM Injection	22 (55.0)		18 (45.0)		17 (42.5)	0.790
Intravenous Catheter	12 (30.0)		15 (37.5)		17 (42.5)	

*Fisher exact test, **Pearson Chi-square test

Table II. Comparison of the hemodynamic findings of the participants before and after injection according to the groups (n = 120)

	Experiment I Group (Shot Blocker)		Experiment II Group (Manual Pressure)		Control Group	
	X ± SD	p*	X ± SD	p*	X ± SD	p*
Pre-administration pulse	94.00±13.28		96.00±16.28		89.97±14.82	
Pulse after application	94.05±13.72	0.957	92.02±16.74	0.010	91.82±13.29	0.068
Systolic blood pressure before administration (mm / Hg)	122.27±11.45		124.02±11.81		120.97±12.12	
Systolic blood pressure after application (mm / Hg)	122.95±10.41	0.468	124.85±11.31	0.464	120.07±11.22	0.472
Diastolic blood pressure before administration (mm / Hg)	76.57±9.85		74.15±11.43		75.34±7.58	
Diastolic blood pressure after application (mm / Hg)	76.07±8.86	0.668	74.72±9.27	0.653	74.15±9.94	0.267

*Paired t test

Table III. Relationship between visual analog scale of participants by groups and injection satisfaction level (n = 120)

Characteristics	Experiment I Group (Shot Blocker) (n=40)	Experiment II Group (Manual Pressure) (n=40)	Control Group (n=40)	Test value* p value
	$\bar{x} \pm SD$	$\bar{x} \pm SD$	$\bar{x} \pm SD$	
Visual Analog Scale	30.62 ± 23.04 ^a	24.95 ± 19.22 ^a	59.50 ± 22.29 ^b	29.471 p<0.001
Injection Satisfaction Level	76.00 ± 19.58 ^a	80.17 ± 19.37 ^a	51.05 ± 22.84 ^b	23.236 p<0.001

*One way anova, ^{a/b}Tukey test

The superscripts a, b indicate a difference within a group, and the same letters indicate that there is not an in-group difference, and different letters indicate an in-group difference.

Table IV. Relationship between participants' visual analog scale and injection satisfaction level (n = 120)

		Experiment I Group (Shot Blocker) (n=40)	Experiment II Group (Manual Pressure) (n=40)	Control Group (n=40)
	Visual Analog Scale	Injection Satisfaction Level	Injection Satisfaction Level	Injection Satisfaction Level
Experiment I Group (Shot Blocker) (n=40)	Visual Analog Scale	-0.773* p<0.001		
Experiment II Group (Manual Pressure) (n=40)	Visual Analog Scale		-0.847* p<0.001	
Control Group (n=40)	Visual Analog Scale			-0.561* p<0.001

*Spearman correlation coefficient

analysis studies similar to our study, it is stated that IM injection is the most painful application among the invasive procedures applied in the hospital (10,11,26). However, in a study, it was found that the least painful procedure among invasive procedures is intramuscular injection (27). It has been reported that the pain experienced due to IM injection application develops due to tissue trauma caused by the needle entry, the content of the drug, individual factors and the injection technique (12). In addition, not using methods to reduce pain in IM injection is thought to cause IM injection to be seen as a painful application.

By stimulating the autonomic nervous system with acute pain, it can cause physiological changes (28). Acute pain alarms the organism and increases pulse and respiratory rate (29). For this reason, the physiological effects of pain were considered in our study, and the blood pressure, pulse and peripheral oxygen saturation values of all participants included in the study were measured before and after the application. In our study, it was found that the pulse rate after the application in the participants in the manual pressure group was significantly lower than the pulse rate before the application (Table II). Since the participants in the manual compression group felt less pain than the participants in the Shot Blocker and control group, it is thought that their pulse rates returned to normal. In addition, not using any tool to reduce pain during the application in the manual compression group may have caused the participants to experience less fear and anxiety. This decreased fear and anxiety may also have positively affected the pulse rates of the participants in the manual compression group.

It was found that the pain score averages of the Shot Blocker and manual pressure groups were lower than the control group, and the injection satisfaction level score averages were higher. However, it was determined that there was no statistical difference between the Shot Blocker and manual pressure groups in terms of pain and injection satisfaction level (Table III). In studies using Shot Blocker in IM injection application, it was determined that Shot Blocker reduced injection-related pain and increased patient satisfaction (22,27). However, in the study conducted by Cobb and Cohen, Shot Blocker was also used in reducing pain during vaccination in children but Shot Blocker was found to be ineffective in reducing intramuscular injection pain (30). On the other hand, there are limited studies in the

literature on manual compression. In our study, it was found that the pressure applied to the area before the injection was effective in reducing the injection pain. In a similar study, it was found that manual pressure application was effective in IM injection application (15). However, in another similarly planned study, it was determined that manual pressure application was not effective in reducing pain (23). Shot Blocker and manual pressure are assumed to reduce pain within the framework of Gate Control Theory. Smaller and faster nerve endings are stimulated by pressure on the skin. This stimulus temporarily blocks the slower pain signals during injection and reduces pain by closing the gates to the central nervous system.

The quality of pain management depends on the knowledge, behavior and abilities of the nurses conducting the painful procedure and nurses play a very important role in this process (31). Compliance of the patient in IM injection, considering the psychological characteristics, and decreasing the potential difficulties that may occur due to injection can be extremely important in terms of patient satisfaction (32). It was found that there was a strong negative correlation between the pain scores and injection satisfaction level scores of the individuals in the Shot Blocker and manual compression group included in the study (Table IV). According to this result, it is concluded that the lower the pain experienced due to IM injection, the higher the satisfaction level of the people with the injection.

Limitation

This study has some limitations. Since Shot Blocker and manual pressure were applied in the study, the participants knew which treatment was applied to them. Therefore, the fact that the participants included in the study knew to which group they were assigned prevented the study from being double-blind. In addition, these results cannot be generalized because a single drug was used in the study and a 38 mm needle was used in all participants.

CONCLUSIONS

Nurses using different nonpharmacological methods have important roles in pain relief. As a result of this study, it was determined that manual pressure and Shot Blocker decreased the pain intensity felt by intramuscular injection and increased the injection satisfaction level. Providing pain control by applying Shot Blocker and manual pressure is an inexpensive, safe and easy

method for nurses. In this respect, it can be considered as an alternative to other methods. In addition, it can be suggested that the methods used in the study should be performed in different sample groups.

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