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# The Effectiveness of Non-Pharmacological Interventions on Reducing Intramuscular Injection-related Pain in Adult's Patients: A Randomized Control Trial

Safaa Ezzat AL-Shammary, MSc.\*; Sadeq AL-Fayyadh, Ph.D.\*\*.

\* Wasit Health Directorate, Ministry of Health, Wasit, Iraq.

Email: <a href="mailto:safaa.ezzat2102m@conursing.uobaghdad.edu.iq">safaa.ezzat2102m@conursing.uobaghdad.edu.iq</a>.

\*\* Adult Nursing Department, College of Nursing, University of Baghdad, Baghdad, Iraq **Email**: <u>s.al-fayyadh@conursing.uobaghdad.edu.iq</u>.

#### ARTICLE INFO

#### ABSTRACT

**Objective(s):** study was conducted in order to investigate the effect of **Article History** ShotBlocker on reducing intramuscular (IM) injection-related pain in adult patients. Received: 09/06/2023 Methods: A prospective, Randomized Controlled Trial, was employed Accepted: 22/08/2023 in this study. The study was conducted on 128 adult patients, who Published: 30/06/2024 received Diclofenac Sodium injections in Emergency Departments. The patients were randomized into 2 groups: ShotBlocker group (n=64) and Keywords: control group (n=64). Immediately after the injection the patients were Intramuscular Injection; asked to evaluated their level of pain. The Visual Analog Scale was used to measure pain intensity. Pain: **Results:** There are statistically significant differences in pain scores ShotBlocker; among two groups (p < .001). The ShotBlocker group had significantly lower pain scores compared to the control group (mean difference of -Non-Pharmacological 3.17188, p < .001). The control group had significantly higher pain Interventions (NPI) scores compared to the ShotBlocker group (mean difference of 3.17188, p < .001). **Conclusions:** The ShotBlocker was found to be effective in reducing pain levels when compared to the control group. Therefore, ShotBlocker is recommend as an effective NPI to reduce intramuscular injectionrelated pain. Recommendations: In-service training programs and intramuscular injection protocols should be updated to include the use of NPI, which is represented by the (ShotBlocker) as a tool for controlling pain during administering medication through intramuscular injection. © 2024 College of Nursing. Published by University of Baghdad.

\*Corresponding author: Wasit Health Directorate, Ministry of Health, Wasit, Iraq. **Email**: safaa.ezzat2102m@conursing.uobaghdad.edu.iq. (S.E. AL-Shammary). **ORCID**: https://orcid.org/0009-0005-3380-4456, https://doi.org/10.58897/d17ypv79 2024 College of Nursing. Published by University of Baghdad

# فاعلية التدخلات غير الدوائية في تقليل الألم المرتبط بالحقن العضلي عند المرضى البالغين: تجربة منضبطة معشاه

# المستخلص

| الخلفية: يتم استخدامها التدخلات غير الدوائي لتقليل الألم المرتبط بالحقن العضلي ، ويمكن تنفيذها في البيئات السريرية دون أي |
|---|
| نفقات إضافية أو ضياع الوقت. ومع ذلك ، عدد محدود من التجارب المعشاه ذات الشواهد تم استخدامها على المستوى الوطني.           |
| الهدف: أجريت هذه الدراسة من أجل التحقيق في تأثير الشوتبلوكر على تقليل الألم المرتبط بالحقن العضلي (IM) لدى المرضى         |
| البالغين.   |
| المنهجية: في هذه الدراسة تم استخدام تجربة عشوائية مستقبلية ذات شواهد. أجريت الدراسة على 128 مريضًا بالغًا ، تلقوا حقن     |
| ديكلوفيناك الصوديوم في أقسام الطوارئ وقسموا إلى مجموعتين: مجموعة الشوتبلوكر (عدد= 64) ومجموعة التحكم (عدد=                |
| 64). طُلب من المرضى تقييم مستوى الألم مباشرتا بعد الحقن. باستخدام مقياس النظير البصري لتقييم شدة الألم.                   |
| النتائج: توجد فروق ذات دلالة إحصائية في درجات الألم بين مجموعتين .(p <.001) كان لدى مجموعة الشوتبلوكر درجات ألم           |
| أقل بكثير مقارنة بمجموعة التحكم (متوسط الفرق -3.1718, p <.001 .وكان لدى المجموعة الضابطة درجات ألم أعلى بكثير             |
| مقارنة بمجموعة الشوتبلوكر متوسط الفرق 3.17188, p<.001.  |
| الاستنتاجات: وجد ان استخدام أداة مشتت الالم (الشوتبلوكر) فعال في تقليل مستويات الألم مقارنت ابالمجموعة الضابطة. لذلك ،    |
| يوصبي به أداة مشتت الالم (الشوتبلوكر) كطريقة غير دوائية فعالة لتقليل الألم المرتبط بالحقن العضلي.                         |
| ا <b>لكلمات المفتاحية:</b> الحقن العضلي؛الألم؛ شوتبلوكر. التدخلات غير الدوائية (NPI) .                                    |

#### Introduction

Intramuscular (IM) injection administration, is a typical nursing task that is often utilized in clinical practice <sup>(1)</sup>. Although IM injection are thought of as a simple and direct intervention, if they are performed incorrectly, they can result in potentially significant problems <sup>(2)</sup>. The administration of medication through the intramuscular (IM) injection route is widely used. This method offers several benefits, including a moderate absorption rate that is quicker than subcutaneous injection but slower than intravenous injection (3,4). About 90% of injection involve administering medications into muscle or skin (subcutaneous or intradermal) <sup>(5)</sup>. Despite the common use of IM injections in nursing practice, there is a lack of evidence-based protocols specifically designed to address IM injection pain<sup>(2)</sup>.

Pain is a frequent clinical condition that requires care, and there is broad agreement that pain relief should be one of the primary goals of any therapy setting <sup>(6)</sup>. This is especially important in emergency

departments (EDs), where pain is one of the most common causes for admissions. Given that each person's lived experience of pain is unique, patient reported pain levels continue to be the gold standard for determining the intensity of pain in clinical settings <sup>(7,8)</sup>.

Mechanical pain occurs as a result of needle insertion into the skin. Due to damage to the nerve endings in the skin and tissue, this causes the pain that is associated with injections <sup>(9)</sup>. Pain can also result from a drug's intramuscular administration stimulating receptors in muscle fibers <sup>(10)</sup>. A study found that 40% of patients thought intramuscular (IM) injections were extremely painful<sup>(2)</sup>.

Pain management is а crucial component of giving care, and the American Pain Association (APA) has designated it as the fifth vital sign (11). New nursing care strategies are required to assist patients feel more comfortable and calm while through unpleasant processes. It can also create a tight relationship between the patient and the nurse, resulting in increased patient satisfaction and collaboration. One of the moral and legal tasks of nurses is to use innovative IM injection techniques to provide a pleasant experience <sup>(12)</sup>.

Nursing research has placed a greater emphasis on the concept of pain in the last few years <sup>(13)</sup>. Nurses play a crucial role in managing and treating pain, setting them apart from other healthcare providers due to their close relationship with patients. Additionally, nurses are responsible for minimizing pain caused by injection and reducing overall patient pain <sup>(14)</sup>.

The nurse must ensure that it is at a safe distance from large blood vessels, nerves, and bones, when choosing a site for administering an injection. Additionally, the site should not have any tenderness, abscesses, or injury. Finally, it should be large enough to hold the volume of medication <sup>(15)</sup>. The effectiveness of pain management during a painful health care procedure is highly dependent on the skills, knowledge, and actions of the nurses who carry it out. It is also the nurses' responsibility to use effective strategies that ease the patient's anxiety and minimize injection pain. To achieve this goal, both Pharmacological and Non-Pharmacological Interventions have been employed to reduce the pain associated with intramuscular injection<sup>(16)</sup>.

Previous studies have looked at Pharmacological and Non-Pharmacological Interventions for reducing or preventing this kind of pain. The application of topical anesthetic drugs is one of the most important pharmacological approaches for minimizing IM injection-related pain. Due to the poor and gradual analgesic effects, danger of systemic toxicity, and local adverse effects, the use of anesthetics in the emergency topical department (ED) is limited <sup>(17)</sup>. To alleviate IM injection-related pain, the NPI are used. One example of such a non-pharmacological approach is the utilization of a small, flat, U-

shaped plastic device known as the Shot Blocker. The ShotBlocker (Bionix, Toledo, Ohio) is a novel tool that aims to reduce pain during intramuscular and subcutaneous injections. It is made of pliable, drug-free plastic and features multiple small, blunt contact points on the bottom, as well as a hole in the center for the injection. The device is placed directly on the skin before giving the injection, and its pressure contact points are designed to provide a stimulus that can help modify and decrease the pain sensation experienced by the patient <sup>(18)</sup>.

When the literature is evaluated, it is clear that research on this issue is largely centered on pediatric groups or during vaccination or intravenous procedures in children <sup>(19)</sup>. Because it is recognized that the pain experienced by adults differs from the pain experienced by children, there is a need for substantial research on these concerns to be undertaken with adult groups as well <sup>(20, 21,</sup> <sup>22)</sup>. However, in adults' population, the conducted studies are less and inconclusive <sup>(9,</sup> <sup>23, 24)</sup>. There is no research on the application of ShotBlocker in Iraq at the present. This is the first and only study to examine the effectiveness of using a ShotBlocker to reduce intramuscular injection-related pain. Conducting such a study is beneficial and supportive for health care providers in reducing adult people's pain and fears from using intramuscular injections. It also opened the way for researchers to carry out other similar studies. Therefore,

This randomized control trial aimed to answer the following research question: Does the ShotBlocker effect in reducing pain associated with intramuscular injection in adults, when injecting Diclofenac Sodium? **Methods:** 

# Study Design and Setting

This study was a prospective, randomized controlled trial (RCT), using single-blind technique. This study was conducted during the period of December 14<sup>th</sup>, 2022 to February 14<sup>th</sup>, 2023 on adult patients who were admitted to the emergency hospitals in Al-Azizia General Hospital and Al-Numaniyah General Hospital in Wasit, Iraq. There have been (128) patients in the sample. The sample size was calculated according to A-priori sample sizes for student t-tests, as presented in table (1). Both the intervention groups and the control group obtained an equal number of these subjects as shown in Study Protocol Algorithm Section Figure (1).

# Study Sample and Sampling

The criteria used for inclusion in the study were as follows: Adult patients aged (18-70) years old; voluntary participated in the study; did not receive analgesics/sedatives during the past 24 hours; have no problems **Figure (1). Study Protocol Algorithm**  communicating and are fully conscious; who entered the patients Emergency Department and were prescribed analgesics by the in-charge physician(s). The criteria used for exclusion in the study were as follows: Patients who refused to participate in the study; patients who have problems communicating and unconscious; those who have fibrosis, wound or infection in the injection site; patients who have had Road Traffic Accidents (RTA), stab wounds or any type of bleeding injury; patients who continue to take medication (Antibiotics, Analgesics) through a vein or muscle; pregnant women; and patients suffering from side effects of Diclofenac Sodium such as Gastric Ulcers and Asthma.



| Parameter of calculation the minimum | Selected Values |  |
|--------------------------------------|-----------------|--|
| sample size                          |                 |  |
| Anticipated effect size (Cohen's d): | 0.5             |  |
| Desired statistical power level:     | 0.8             |  |
| Probability level:                   | 0.05            |  |

 Table (1): Minimum Sample Size Determination

\*Minimum total sample size (one-tailed hypothesis): 102

\*Minimum sample size per group (one-tailed hypothesis): 51

\*Minimum total sample size (two-tailed hypothesis): 128

\*Minimum sample size per group (two-tailed hypothesis): 64

#### **Data Collection Tools**

# Demographic and Lifestyle Data of Patients

The demographic data section was designed to obtain the essential descriptive data of the participants in the study. These data included (Age, Sex, Residence, Monthly Income, Occupation, Academic Level of Education), and lifestyle data included (Fear of IM Injection).

#### Visual Analogue Scale (VAS)

This scale is used to indicate the level of subjects' pain on the 10 cm-long scale which has a left and right end for "no pain" and "severe pain," respectively (25). There are four levels of pain severity: none (0 points), mild (1-3 points), moderate (4-6 points), and points) <sup>(26)</sup>. The Visual severe (7-10 Analogue Scale (VAS) is a commonly used measurement tool both nationally and internationally. Scientific evidence has shown that VAS is a reliable and valid scale for individuals who are 18 years old and above (27, 28)

#### **Intervention**(s)

The study included adult patients who were chosen based on the aforementioned criteria. The study was carried out in the Emergency Departments with patients who had been prescribed (Diclofenac Sodium) by their physician(s). To reassure the participants, the researcher explained the study's aims, duration, and technique in terms of information confidentiality. Following that, the oral and written consents of the patients who will participate in the sample were obtained, as they were randomly divided into two groups (Total=128), tossing a coin method was chosen (i.e., heads - control, tails - intervention) to ensure randomization and non-bias: the control group (N=64), the ShotBlocker group (N=64). The injection procedure and the randomization method for selecting one of the groups are discussed with participations. The researcher introduced the patients to the Visual Analog Scale (VAS) pain intensity scale before administering the injection, placing a check in front of the number denoting the degree of the pain. For many years, healthcare providers preferred the Dorsogluteal region of the Buttocks for IM injection. Kilic et al. (2014) reported that the majority of nurses (81.5%) preferred using the DG region when administering intramuscular injection <sup>(30)</sup>. An emergency female nurse was trained to give intramuscular injection to women group, whereas the researcher deliver injection to males group. The data collection method is described in the following phases.

# **Interventional Procedure**

First, preparing an ampoule of Diclofenac Sodium before injection procedure: it comes in the form of a 75 mg/ 3 ml solution. To prepare it, researcher(s) needed a 5-cc syringe, a 70 mm (0.027 Inch) needle, 22 gage. A prone position with the toes pointed outward was ideal subject position for the IM injection. To assess the existence of fibrosis or damaged area, palpating the Dorsogluteal region with the fingertips of the hand was performed with every subject. The standard IM injection application method was used for all groups (Table 2). The following products were prepared for medication administration:

- A. Alcohol-based disinfectant
- B. Sterile cotton/ Sterile gloves
- C. Shotblocker
- D. Diclofenac Sodium Ampoule
- E. Syringe (5cc syringe and 70 mm (.027 inch) needle, 22 G)
- F. Medical waste/ sharp objective container

| container                 |
|---------------------------|
| Diclofenac Sodium75 mg/ 3 |
| Dorso-gluteal muscle      |
| 3 ml                      |
| 22 gage, 70 mm (.027 IN)  |
| 70% Ethyl Alcohol         |
| 15 seconds                |
| 90 degrees                |
|                           |

Table (2). Protocol of Intramuscular Injection

# ShotBlocker Group

It is a plastic instrument in the shape of a C with a blunt protrusion contacting the skin on one side. ShotBlocker protruding surface is maintained in place during injection by pushing against the skin; the injection is carried out through the opening <sup>(23, 29, 31)</sup>.

In addition to the IM injection standard process steps, the protruding section of the ShotBlocker was placed in contact with the skin in the group of patients after cleaning the skin. The ShotBlocker was firmly pushed against the skin, and the injection was conducted immediately with the dominant hand after the device was firmly pressed against the skin of the patient with the operator non-dominant hand, and the injection was made through the central opening. The ShotBlocker was withdrawn from the skin once the injection was completed, then it can be sterilized and used for other patients.

# **Control Group**

Standard intramuscular injection techniques were employed with this group using the same preparations expects for Shotblocker, including (22 gauge, 70 mm (.027 inch)). And a 5 mL syringe for drug administration. Stretching the skin taut while holding the syringe like a pencil or dart, place the needle at the injection site at a 90-degree angle to the skin. The medication was administered within 15 seconds.

After the injection process, all subjects were given a questionnaire to rate their pain level, using Visual Analog Scale (VAS), with (0) being no pain and (10) representing severe pain. The patients were asked to assess the pain caused by the intramuscular injection by placing a sign in front of the number indicating the pain. Patients estimate their own pain.

# Data Analysis

Descriptive statistics were used to describe the demographic data and pain levels for (Shotblocker, and control groups). Analysis of Variance (ANOVA) was used to measure the difference in the pain scores among all groups (Shotblocker, and control Fisher Exact Test. groups). as а Nonparametric test of association used to determine the relationship between pain levels and demographic variables for groups (Shotblocker, and control groups). The Statistical Package for the Social Sciences (SPSS) version 24, was used for statistical analysis of the collected data. In which descriptive and inferential statistical measures were employed.

#### **Ethical Considerations**

This research was confirmed by the Committee of Scientific Research at the College of Nursing, University of Baghdad on December,4<sup>th,</sup>2022. After obtaining the approval of the Ministry of Planning (Central Statistical Organization) on December 6<sup>th</sup> ,2022, the official approvals were taken to start work from the Wasit Health Department. And then approval of the targeted hospitals was granted on December 14<sup>th</sup> ,2022 to collect the samples. The patients were **Results**  informed that participation in the study is completely voluntary and would have no financial or legal consequences, and that the information will be kept in an absolute privacy.

# **Clinical Registry**

As an essential step of original RCT, an approval was obtained for the registration of the trial protocol in the Iranian Registry of Clinical Trials (IRCT) on January 1<sup>st</sup>, 2023. The registration reference is IRCT20220929056057N1.

| Characteristic         | ShotB | locker Group (n=64) | Contr | ol Group (n=64) |
|------------------------|-------|---------------------|-------|-----------------|
|                        | N (%) | <b>-</b> · · · ·    | N (%) |                 |
| Age Groups/Years       |       |                     |       |                 |
| 18-24                  | 22    | (34.4%)             | 26    | (40.6%)         |
| 25-31                  | 20    | (31.3%)             | 18    | (28.1%)         |
| 32 - 38                | 11    | (17.2%)             | 4     | (6.3%)          |
| 39 - 45                | 5     | (7.8%)              | 7     | (10.9%)         |
| 46 - 52                | 4     | (6.3%)              | 5     | (7.8%)          |
| ≥53 years old          | 2     | (3.1%)              | 4     | (6.3%)          |
| Sex                    |       |                     |       |                 |
| Male                   | 39    | (60.9%)             | 38    | (59.4%)         |
| Female                 | 25    | (39.1%)             | 26    | (40.6%)         |
| Occupation             |       |                     |       |                 |
| Employed               | 18    | (28.1)              | 20    | (31.3%)         |
| Earner                 | 25    | (39.1%)             | 22    | (34.4%)         |
| Housewife              | 5     | (7.8)               | 12    | (18.8%)         |
| Free Jobs              | 16    | (25.0)              | 10    | (15.6%)         |
| Levels of Education    |       |                     |       |                 |
| Does Not Read or Write | 5     | (7.8%)              | 11    | (17.2%)         |
| Read and Write         | 10    | (15.6%)             | 8     | (12.5%)         |
| Primary Education      | 13    | (20.3%)             | 7     | (10.9%)         |
| Intermediate School    | 12    | (18.8%)             | 13    | (20.3%)         |
| High School            | 5     | (7.8%)              | 13    | (20.3%)         |
| Bachelor Degree        | 18    | (28.1%)             | 10    | (15.6%)         |
| Postgraduate           | 1     | (1.6%)              | 2     | (3.1%)          |
| Fear of IM Injection   |       |                     |       |                 |
| No Fear                | 41    | (64.1%)             | 21    | (32.8)          |
| Some Fear              | 13    | (20.3)              | 31    | (48.4%)         |
| Have Fear              | 10    | (15.6)              | 12    | (18.8)          |

Table 1. Descriptive Statistics of participants` Socio Demographic and Lifestyle Data

Table1, showed some descriptive characteristics of the patients who participated in the study. In the current research regarding the age group variable, the results showed that (34.4%) of the ShotBlocker group and (40.6%) of the control group were between age (18-24) years old. Of equal importance, (60.9%) of the participants in the ShotBlocker group and (49.4%) in the control group, were males. Regarding subjects' occupational status, (39.1%) of the ShotBlocker group were

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earners and (34.4%) of the control group were earners too. Relative to educational level, more than a quarter (28.1%) in the ShotBlocker group and (20.3%) of participants have intermediate school education, Similarly, (20.3%) have intermediate school education, and (20.3%) have high school education in the control group. Finally, when subjects were asked about fear of IM injection, (64.1%) in ShotBlocker group, in contrast, almost half (48.4%) of participants have some fear of injection in the control group.

| Table 2. Descriptive Statistics of the Reported Weasured Fain Levels by Using Visual Analog Fain Search |                         |         |               |         |  |
|---|-------------------------|---------|---------------|---------|--|
| Pain Levels   | ShotBlocker Group(n=64) |         | Control Group |         |  |
| (VAS) scale   | n (%)                   |         | (n=64)        |         |  |
|   |                         |         | n             | (%)     |  |
| No Pain   | 41                      | (64.1%) | 3             | (4.7%)  |  |
| Mild Pain   |                         |         | 28            | (43.8%) |  |
| Moderate Pain   | 23                      | (35.9%) | 26            | (40.6%) |  |
| Severe Pain   |                         |         | 7             | (10.9%) |  |

Table 2. Descriptive Statistics of the Reported Measured Pain Levels by Using Visual Analog Pain Scale

In table 2, the descriptive statistics of pain levels by using visual analogue scale (VAS) showed that, in the ShotBlocker group (64.1%) reported no pain after receiving the NPI and in the control group (43.8%) reported mild pain after receiving standard injection technique.

Table 3. Statistical Relationship between Pain Levels Score and Study Variables

| Study Groups         | Fisher's Exact Test |          |  |
|----------------------|---------------------|----------|--|
|                      | Value               | P. Value |  |
|                      |                     |          |  |
| ShotBlocker Group    |                     |          |  |
| Age Groups           | 5.837               | .305     |  |
| Sex                  | 0                   | 1.000    |  |
| Fear of IM Injection | 1.120               | 0.694    |  |
| Control Group        |                     |          |  |
| Age Groups           | 23.839              | .068     |  |
| Sex                  | 9.196               | .017     |  |
| Fear of IM Injection | 13.658              | .014     |  |

The Fisher Exact Test showed that there is no statistically significant association between pain intensity and patients age group, in the ShotBlocker group ( $X^2$ =5.837, P= 0.305) and control group ( $X^2$ =23.839, P= 0.068). Concerning the patients' Sex, also, there is no statistically significant association between pain intensity and a patient's Sex in the ShotBlocker group ( $X^2$ =0, P= 1.000) and control group ( $X^2$ =23.839, P= 0.068). Lastly, there is no statistically significant association between pain intensity and fear of IM injection in the ShotBlocker group ( $X^2$ =1.120, P= 0.694) and control group ( $X^2$ =13.658, P= 0.014).

Table (4). Statistical Differences in the Pain Scores among Different Groups

| Pain Scores of Dependent Variables |                   | Mean Difference (I-J) | Std. Error | Sig. |
|------------------------------------|-------------------|-----------------------|------------|------|
| ShotBlocker Group                  | Control Group     | -3.17188              | .28356     | .000 |
| Control Group                      | ShotBlocker Group | 3.17188               | .28356     | .000 |

Table (4) shows that the ShotBlocker group had significantly lower pain scores compared to the control group (mean difference -3.17188). The control group had significantly higher pain scores compared to the ShotBlocker group (mean difference 3.17188).

# Discussion

The main aim of study was assessing the effectiveness of ShotBlocker and manual pressure applications in minimizing pain related with IM injection in adults. The descriptive statistics of pain levels using VAS found that two third of the subjects (64.1%) reported no pain after receiving IM injection using the ShotBlocker group. Additionally, in the control group, two fifth of subjects (43.8%) reported mild pain after receiving the standard IM injection (Table 2). The nonpharmacologic pain management approaches may explain that significant difference, using the pain gate control theory pillars. Bilge et al. (2019) founds that the use of certain applications, such as ShotBlocker and cold spray, can potentially reduce the sensation of pain caused by intramuscular injection <sup>(17)</sup>.

Of equal importance, the study findings showed that there is no statistically significant between pain intensity association and patients age group among the study groups. Concerning the patient's Sex there is no statistically significant association between pain intensity and a patient's Sex in the study groups (Table 3). These results were expected, because pain could be associated with social, cultural, physical, and cognitive characteristics, However, the incidence of pain resulting from intramuscular injection is directly affected by several directly related factors, including but not limited to: the method of injection, the size of the needle, the injection site, the duration of the injection <sup>(32,</sup> 33)

Regarding the fear of IM injection, findings showed that there is no statistically significant association between pain intensity and fear of IM injection among groups (Table 3). When the literature is examined, it has been concluded that many patients refuse to undergo certain treatments due to their fear of experiencing pain from intramuscular injections. Nurses have a duty to alleviate this fear by identifying methods to reduce pain and maximize comfort during any diagnostic or therapeutic procedures. The primary cause of fear for patients receiving injections is the pain from the needle, and this fear can (34) actually make the pain worse Abdelkhalek (2019) used the Beck Anxiety Inventory (BAI) between two groups at two injections, found no significant decrease in anxiety level (35). However, the difference between the current study and previous studies does not concern the researcher(s) because the variable of fear of intramuscular injection reflects the attitudes of the person himself/herself and not measured by a scale specific to fear.

In current study, the researchers found that there are a statistically differences in pain scores among groups. The ShotBlocker application were found to be effective in reducing the pain levels in patients compared to the control group. When examined the literature regarding use Shotblocker, limited studies have examined the effectiveness of ShotBlocker in reducing pain levels during intramuscular injection among adult patients. Sahan and Yildiz. (2022) <sup>(9)</sup> conducted a meta-analysis study revealed that ShotBlocker had a positive effect on reducing pain levels among adult patients receiving IM injection, and to obtain a more comprehensive and effective outcome, further high-quality research that adheres to legal research standards is necessary. In the study by Aydin & Avsar,  $(2019)^{(23)}$ , which examined the effectiveness of ShotBlocker in reducing discomfort brought on by intramuscular injection, the researchers found that the ShotBlocker was beneficial in minimizing pain related to intramuscular injection.

Another trial conducted by Karabey and Karagzolu, (2021)<sup>(4)</sup> found that the ShotBlocker was more effective than Helfer Skin Tap and traditional methods in reducing pain associated with intramuscular injections. Bilge et al. (2019) <sup>(17)</sup> aimed at evaluating the effectiveness of cold spray and ShotBlocker in reducing intramuscular (IM) injectionrelated pain in adults, found that ShotBlocker is a non-pharmacological method that is equally effective as cold spray in reducing pain associated with IM injection.

The NPI, which is represented (ShotBlocker) works based on the major pillars of Gate Control Theory. The Melzack and Wall theory, is considered a widely regarded as a revolutionary concept in pain management. This theory suggests that the presence and intensity of pain are dependent on the transmission of neurological signals and the mechanisms that control this transmission in the nervous system <sup>(36)</sup>. By using its blunt points and pressure to apply pressure on the skin and rapidly stimulating small nerve endings. This stimulation temporarily prevents or at least slows pain signals from reaching the Central Nervous System (CNS), which effectively reducing during injection. Essentially, pain the mechanism of action involves closing the gates to the CNS through the use of pressure and nerve stimulation  $^{(37)}$ .

The use NPI, presents a practical intervention that is swift, easy to use, and does not require any prior material preparation, has no known side effects, and is easy to implement. The proposed mechanism underlying these two methods is grounded in the gate control theory. By utilizing ShotBlocker, it stimulates smaller and faster nerve endings, temporarily blocking the transmission of slower pain signals. Consequently, the gates to the central nervous system close, resulting in reduced pain perception during the injection process <sup>(24)</sup>.

Nurses can play a crucial role in mitigating pain during painful procedures and needle interventions by employing appropriate non-pharmacological nursing techniques. It is important to measure the effectiveness of these interventions <sup>(23)</sup>. However, there is a limit of research studies providing guidance to nurses in this area, highlighting the necessity for implementing pain relief methods that fall under the purview of nursing responsibilities <sup>(38)</sup>. To address the pain associated with intramuscular injections, it is imperative to conduct further evidencebased studies in collaboration with academic researchers and clinical nurses. Consequently, there is a pressing need for new studies that offer concrete evidence accessible to nurses <sup>(39)</sup>.

# Conclusions

This study showed that the use of the Non-Pharmacological Interventions (NPI), which is represented by the ShotBlocker device was more effective than standard injection procedure in reducing intramuscular injections-related pain scores.

# Recommendations

training In-service programs and intramuscular injection protocols should be updated to include the use of NPI, which is represented by the (ShotBlocker) as a tool for controlling pain during administering medication through intramuscular injection. Of equal importance, nurses are advised to utilize NPI that have been validated as effective more often for alleviating pain injections. by intramuscular caused Additionally, they should remain up-to-date with advancements in this nursing specialty area and apply them in their work. Moreover, it is advisable to assess ShotBlocker effectiveness when administering other medications that could potentially cause injection-related pain.

Finally, since pain management is a crucial aspect of nursing, teaching nursing students about the non-pharmacologic techniques, and allowing them to practice these techniques in the clinical setting can be beneficial.

# Limitations

The fact that the study is new and the first in Iraq, presents many challenges, the first of which was the difficulty of obtaining the ShotBlocker inside Iraq. Therefore, the researcher imported it through electronic transaction, costing him money.

Only the Diclofenac Sodium medication was tested with the current study. Therefore, the results of this study cannot be broadly generalized to other drugs. Of equal importance, due to social traditions, it was difficult to recruit as well as dealing with female subjects, which prompted the researcher to train an emergency female nurse to conduct the injection procedure.

# **Conflict of interest**

None.

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