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College of Nursing

Comparing the Effect of Using Lidocaine Spray and ShotBlocker on Pain Level during Intramuscular Injection: A Randomized Control Trial

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يُرِيدُ ٱللَّهُ أَن يُخَفِّفَ عَنكُمْ ۚ وَخُلِقَ ٱلْإِنسَٰنُ ضَعِيفًا

سورة النساء ، **الاية** (٢٨)

صدق الله العلي العظيم

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Dedication

I dedicate my effort and work to:

Who inspired me with knowledge and the ability to work ***... My God and my Lord.***

The sun that nourishes my life planet with his wisdom rays… ***My father.***

*The spring of my soul…****My mother gives me support and courage with all my love and respect.***

*The shining stars in my life…****My brother and sisters.***

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To bless them all.

Abstract

Background: Intramuscular injection is a common nursing practice in clinical settings. Although their therapeutic advantages, but can also cause pain in patients. It is necessary to reduce pain caused by intramuscular injection. The aim of this study was to comparing the effect of using lidocaine spray and shotblocker on pain level during intramuscular injection.

Methods: A randomized controlled trial was conducted in emergency department at Imam Al-Sadiq General Hospital in AL-Hilla city, during a period between December, 2023 to June, 2024. Data were collected through interviewing using the visual analog scale, scio-demographics and medical data. The researcher uses a simple random sample where patients choose a color from a sealed envelope consisting of three colors. 150 patients who receive diclofenac sodium, divided into three groups, 50 in each of the lidocaine, shotblocker and control groups. Both a descriptive statistical analysis such as (frequencies, percent, standard deviation and mean of score) and inferential statistical analysis such as (independent Sample t-test, analysis of variance, post Hoc testes and Eta Square). The significant level at p-value < 0.05.

Results: There are statistically significant differences in pain scores among ShotBlocker, lidocaine and control groups (p = .000). The ShotBlocker group compared to the lidocaine group (mean difference of -1.18, p=.000), and the control group (mean difference of -3.92, p=.000). The lidocaine group compared to the ShotBlocker group (mean difference of 1.18, p .000), and the control group (mean difference of -2.74, p = .000). The control compared to the lidocaine group (mean difference of 2.74, p =.000), and the ShotBlocker group (mean difference of 3.92, p =.000).

Conclusions: The application of ShotBlocker and lidocaine showed effectiveness pain reduction during intramuscular injection but ShotBlocker was more effective.

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List of Abbreviations, Acronyms and Symbols

Items	Meaning
ANOVA	Analysis of Variance
APS	American Pain Society
AVF	Arteriovenous Fistula
BMI	Body Max Index
CT	Computerized Tomography
DG	Dorsogluteal
EDs	Emergency Departments
EMLA	Eutectic Mixture of Local Anesthetics
GCT	Gate Control Theory
H0	Null Hypothesis
H1	Alternative Hypothesis
HCPs	Healthcare Professionals
HR	Heart Rate

ID	Identification
IM	Intramuscular
IMF	Illicitly Manufactured Fentanyl
IMI	Intramuscular Injection
IRCT	Iranian Registry of Clinical Trials
IV	Intravenous
IVC	Intravenous Cannulation
LA	Local Anesthetic
LEEP	Cervical Electrosurgical Excision
MBPS	Modified Behavioral Pain Scale
MRI	Magnetic Resonance Imaging
N_2O	Nitrous Oxide
PSA	Posterior Superior Alveolar
RCT	Randomized Controlled Trial
SC	Subcutaneous
SG	Substantia Gelatinosa
Sig	Significant
SpO2	Oxygen Saturation
SPSS	Statistical Package for Social Science
TENS	Transcutaneous Electrical Nerve Stimulation
TIVAP	Totally Implantable Venous Access Ports
US	United States
USA	United States of America
VAS	Visual Analog Scale
VDS	Verbal Descriptor Scale
VG	Ventrogluteal
VHA	Veteran's Health Administration
WHO	World Health Organization

Chapter one

Introduction

Chapter One

Introduction

1.1. Background:

Intramuscular (IM) injections are an important and essential skill that nurses must be able to administer effectively. IM injections are one of the most common injection methods, involve inserting the needle into the muscular to administer medication. In addition, intramuscular injections allow for a prolonged release of medication which may be necessary for medications such as vaccines. IM injections also allow for relatively larger volumes of medication to be administered when compared to subcutaneous injections, a patient can receive an injection and be discharged quickly (Serena et al., 2023).

Because of its rapid absorption and long-lasting effect, IM injections are commonly given in healthcare clinics. Intramuscular (IM) injections are a critical route of drug administration in emergency departments (EDs), offering a reliable and efficient method to deliver medications directly into the musclar tissue. This route is particularly valuable in emergency settings due to its rapid onset of action, suitability for patients unable to take oral medications, and the ability to administer a variety of drugs effectively (Basak et al., 2021).

The medication is given by IM injection deep into the muscular, where it is absorbed into the bloodstream quickly due to the rich blood supply in muscular tissues. This method bypasses the digestive system, allowing for faster therapeutic effects compared to oral administration. In the ED, where time is often of the essence, IM injections provide a vital option for managing acute conditions, stabilizing patients, and delivering medications when intravenous (IV) access is not feasible (Heshmatifar et al., 2022).

Some common IM injections administered in the emergency department setting include antibiotics such as ceftriaxone, vaccines such as a tetanus shot, or antipsychotics such as haloperidol (Table 1-1)

(Table 1-1) most common medication administered in the emergency department:

Medications	Example
Analgesics	Diclofenac Sodium, Ketorolac, morphine, and other opioids.
Antibiotic	Ceftriaxone.
Antipsychotics	Haloperidol, olanzapine.
Sedatives	Midazolam, lorazepam.
Vaccines	Tetanus toxoid, rabies vaccine
Antiemetics	Promethazine, metoclopramide

(Zengin, & Yayan, 2022).

Diclofenac sodium is an example of nonsteroidal anti-inflammatory drug (NSAID) commonly used for its potent analgesic and anti-inflammatory properties. When given IM injection, diclofenac sodium is very helpful for the quick treatment of severe pain and inflammation caused by a variety of diseases in the ED. Its quick onset of action and efficacy make it a go-to medication for healthcare professionals dealing with emergencies.

The most common complications of IM injection include pain and discomfort, hematoma, infection (redness, swelling, warmth, and pain), abscess formation, nerve injury (pain, numbness, or paralysis), muscle damage (damage to muscle fibers leading to pain and impaired function), allergic reactions, lipodystrophy (atrophy or hypertrophy),mechanical and chemical effects of the drug during and after injection (Ayinde et al., 2021).

One of the most common problems with IM injections is pain. Pain is a complex feeling that can be both emotional and physical, often linked

to real or possible tissue damage. It causes discomfort in both sensory and emotional ways. It can also be difficult to describe and explain because it is a unique, subjective and intimate experience (Güven & Çalbayram, 2023 and Karagözoğlu, 2020).

The level of pain experienced during an IM injection can vary depending on a number of factors. These include the type and dose of the medication, the method of administration, the patient's anxiety, the patient's body position, the speed of the injection, and the position and length of the needle (Karabey & Karagozoglu, 2021).

Mechanical trauma results from inserting the needle into the skin. Pain from the injection is caused by injury to nerve endings in the skin and tissue. Drugs administered via IM injection can cause pain by activating pain receptors in muscle fibers (Şahan & Yildiz, 2022 and Ozdemir et al., 2013).

As a nurse, relieving patients' pain should be top priority. The competence, behavior and understanding of the nurses performing this procedure are critical factors in determining the effectiveness of pain treatment (Orenius et al., 2018). Nurses are responsible for administering medication to patients or managing pain during injections using prescribed methods. In order to maintain patient satisfaction, ensure high-quality care, and promote positive nurse-patient relationships, it is necessary to reduce the physical and psychological effects of IM injection pain (Sahin & Eşer, 2018).

Innovative nursing care practices are essential to help patients feel more comfortable and calm while undergoing painful procedures. It can also promote a strong professional relationship between patient and nurse, leading to increased patient satisfaction and cooperation. One of the ethical and legal responsibilities of nurses is to provide a pleasant experience with advanced IM injection techniques (Hashmatifar et al., 2022).

Both pharmacological and non-pharmacological techniques can be used to reduce or prevent pain during IM injection (Czech et al., 2021; Erdoan and Aytekin Ozdemir, 2021).

The pharmacological techniques play a crucial role in pain management for IM injections by directly targeting pain pathways and providing more immediate relief compared to non-pharmacological methods. These techniques include the use of local anesthetics, analgesics, and other medications that can either be administered topically or injected prior to the IM injection. The pharmacological techniques include topical anesthetics such as lidocaine, prilocaine, lidocaine spray and benzocaine applied to the skin before the injection to numb the area. These agents reduce the pain by numbing the superficial layers of the skin, making the injection less painful (Kaplan et al., 2023).

Incorporating non-pharmacological techniques into clinical practice for administering IM injections can significantly reduce pain and improve patient outcomes. These methods are effective, easy to implement, and enhance the holistic care approach by addressing both physical and psychological needs. By utilizing these techniques, healthcare providers can ensure a more comfortable and positive experience for patients undergoing IM injections, fostering better compliance and overall satisfaction with medical care. The most common non-pharmacological techniques include proper injection techniques (using the right needle size and insertion angle), distraction methods (like breathing exercises and visual or auditory distractions), applying manual pressure, using cold or heat compresses, tactile stimulation (such as rubbing, tapping, or vibrating devices), and local tactile anesthesia (using devices that combine cold and vibration or pinching the skin to distract from pain, such as shotblocker) (Erdogan & Ozdemir, 2021).

One such non-drug option is to use a small, flat, U-shaped plastic device called a Shot -Blocker. This tool is just 2mm thick, with rounded

bumps meant to stimulate the skin around the injection site. ShotBlocker, which is applied to the skin, may stimulate nerve endings more quickly due to its rounded protrusions. This stimulation is thought to block the perception of pain and its transmission to the central nervous system, resulting in pain relief (Şahan & Yildiz, 2022).

Unlike traditional drug delivery devices, the ShotBlocker is a skin-contact device with thick, blunt points and a hole in the middle that is placed over the injection site. During the injection, the pointed surface is placed over the administration site, while the sharp points provide physical stimulation that may help relieve pain. ShotBlocker does not have any harmful effects and is not considered a drug (Aydin & Avşar, 2019; Susilawat et al., 2010 and Cobb & Cohen, 2009).

One of the pharmacological method to reduce pain during IM injections is Lidocaine spray. Lidocaine spray typically contains lidocaine hydrochloride, a derivative of the aminoethylamide group of local anesthetics. It is formulated as a clear, colorless liquid that can be sprayed directly onto the skin or mucous membranes. The concentration of lidocaine in these sprays can vary, but a common formulation is 10% lidocaine, providing effective analgesia with minimal systemic absorption. It is a topical anesthetic widely used in various medical settings to provide localized pain relief (Kulkarni et al., 2023).

Lidocaine spray is particularly valued for its rapid onset, ease of application, and effectiveness in numbing the skin and underlying tissues. Lidocaine, the active ingredient, is a well-established local anesthetic known for its ability to block nerve signals and provide temporary analgesia. It is used in various medical and dental procedures such as minor surgical procedures, IM injections, dental procedures, diagnostic procedures, burns and abrasions (Zhu et al., 2023).

1.2. Important of the study:

Intramuscular injection is actually a complex process that requires technical competence and effective decision-making in terms of administration tools and methods. Despite the therapeutic and healing effects of intramuscular injection, this injection may cause pain and discomfort to patients (Aydin & Avşar, 2019). According to the World Health Organization, approximately 50% of the 12 billion injections performed worldwide each year are considered unsafe (Jung Kim & Hyun Park, 2014).

The study showed that 5.3% and 22% of adult patients had a severe and moderate fear of needles, respectively. Most patients believe that intramuscular injections are an unpleasant and stressful experience and look for alternatives to relieve pain when they are prescribed the IM injection procedure (Soliman et al.,2018).

Intramuscular injection has many complications such as cellulitis, muscle fibrosis, tissue necrosis, hematoma, and nerve injuries, the most common complication being pain. Pain can cause increased anxiety, non-adherence to treatment, various physical symptoms such as increased heart rate, and the development of a lifelong fear of injections (Kaplan et al., 2023).

A study conducted by McNamara et al., (2018) pointed out that the discomfort felt during injections is more intense compared to other kinds of pain. Siu and Goubert (2015) discovered that many patients stop their treatment due to fear of injection pain. Despite injection therapy being widely used, patients still suffer considerable distress due to unresolved injection pain issues (Ozturk et al., 2017).

Pain is a frequent indication of various medical ailments and is alleviated through successful pain control. In this context, nurses play a crucial and central role. Neglecting pain management can have a significant impact on the emotional, physical, and spiritual well-being of

the patient. Healthcare professionals generally consider self-report as the most reliable method for assessing pain, as opposed to observing the patient's behavior (Ağaç & Güneş, 2011 and Serena et al., 2023). The entitlement to pain relief is among the most fundamental human rights. Over the centuries, numerous techniques have been explored to alleviate injection pain (Bilgic, 2021).

The importance of pain control with a multidisciplinary team approach consisting of patients, nurses and physicians is accepted by everyone. Nurses have important roles and responsibilities in the pain management process due to their long-term interaction with patients. 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 (Kaplan et al., 2023).

In order to manage pain properly. It is important for nurses to evaluate their patients, choose the most appropriate evidence based intervention, apply it to the patient, and observe the results. The right to ease pain is one of the most basic human rights. Many different methods have been tried throughout the centuries to ease injection pain (Oh, & Jeong, 2017).

Nurses should consider the importance of understanding the pathophysiology of pain, the psychological and physiologic effects of acute and chronic pain, and the approach used to relieve and eliminate pain. Therefore, they must know the most important methods, skills, and techniques for pain assessment and knowing the effectiveness of these interventions (Serena et al., 2023).

ShotBlocker is an innovative, simple, noninvasive, drug- free method that can be effective in reducing needle pain and anxiety during IM injection. It is a flexible plastic C-shaped device with a small bump, multiple blunt skin contact points on the back. When pressure is applied to the skin by its bump at the injection site, the sensory nerves are confused

by the pressure than the pain signal from the needle stick (EL-Mahdy et al., 2023).

The impact of the ShotBlocker on adult patients has been the subject of limited research (Fekonja et al., 2021). While one study found that the ShotBlocker is an ineffective pain management tool (Bilgic, 2021). Other studies have demonstrated that the device effectively relieves pain related to intramuscular injection (Aydin & Guven, 2020 and Ztürk et al., 2017).

Lidocaine spray is used for surface anesthesia, providing a non-invasive and convenient method. It has been utilized for various conditions like acute throat discomfort, paroxysmal pain associated with trigeminal neuralgia, and organ intubation. In these instances, lidocaine is predominantly applied to the skin surface (Oh, & Jeong, 2017).

Lidocaine spray10 % has numerous advantages, including rapid onset of action, a convenient and painless application method, easy availability, low cost, and a pleasant oder (Kulkarni et al., 2023).

1.3. Statement of the problem:

Severe pain is a common clinical problem that requires attention, and there is widespread consensus that pain relief should be the main focus of any therapeutic setting. This is especially critical in emergency departments (EDs), where pain often leads to hospitalization. Because each person's experience with pain is different, the gold standard for measuring pain intensity in clinical settings remains levels reported by patients themselves (Kapoor et al., 2016).

Pain resulting from IM injections is a common issue that can affect patient compliance and overall experience with medical treatments. This pain is typically caused by several factors, including the physical trauma of the needle piercing the skin and muscle, the volume and viscosity of the injected substance, and the pressure of the injection. Needle size and gauge also play a role, with larger needles often causing more discomfort.

Additionally, the choice of injection site can impact pain levels, as certain areas of the body are more sensitive or have more nerve endings. Muscle tension during the injection can exacerbate pain, as well as improper technique or administering the injection too quickly. Psychological factors, such as anxiety and fear of needles, can heighten the perception of pain, making the experience more uncomfortable for some patients. Understanding these factors is crucial for healthcare providers, as employing proper techniques, selecting appropriate equipment, and utilizing pain reduction methods can significantly reduce the discomfort associated with intramuscular injections, improving patient outcomes and satisfaction (Bilgic, 2021).

Globally, the administration of drugs through IM injections has a substantial history. Approximately 12 billion IM injections are conducted worldwide each year (Fekonja et al., 2021; World Health Organization, 2016). Unfortunately, a large number of patients stop their treatment due to the intense fear of pain associated with the injection. Although this method is widely used, the issue of injection pain remains unaddressed, causing great stress for patients (Ztürk et al., 2017; Sisson, 2015 and Siu & Goubert, 2015).

Some medications, such as antibiotics and vitamins, have a reputation for worsening pain. Astudy conducted by Kara and Yabuko Gunes, (2016) indicated that 40 % of patients said that IM injections were very uncomfortable. 30.6 % of people surveyed by Celik and Khorshid (2015) said they were afraid to IM injections.

Failure to treat pain greatly affects the psychological, physical and spiritual state of the patient. According to health care providers, the best way to assess pain is self-report rather than patient behavior (Aydin & Avşar, 2019).

ShotBlocker, which is among the non-pharmacological methods that nurses can use at their discretion, can be a useful tool in treating acute

injection-related pain (Caglar et al., 2017). Designed to reduce pain from IM injections, ShotBlocker is suitable for all age groups and contains no drugs. To use it, press down on the skin's surface during the injection (Yildirim & Dinçer, 2021). There have been no documented negative consequences from using the ShotBlocker tool (Abdelkhalek, 2019).

Recently, there has been increasing recognition of the importance of managing pain and discomfort associated with injections. Contemporary pain management includes non-pharmacological treatment options as well as pharmacological treatments (Czech et al., 2021).

While pharmacological techniques are effective for reducing pain from IM injections, they are not without drawbacks. Potential side effects, allergic reactions, delayed onset, short duration of action, cost, need for additional equipment and training, systemic absorption and effects, contraindications, and the pain of anesthetic injection itself are all factors that can limit their use and effectiveness. Healthcare providers must weigh these disadvantages against the benefits and consider individual patient needs and circumstances when choosing pain management strategies (Bilge et al., 2019).

The non-pharmacological techniques for reducing pain from IM injections offer many benefits. However, they also come with several disadvantages that can limit their effectiveness and applicability. Factors such as limited pain relief, the need for patient cooperation, time constraints, variability in effectiveness, and the need for specialized training can all impact the success of these methods. Understanding these limitations is crucial for healthcare providers to effectively integrate non-pharmacological techniques with other pain management strategies, ensuring comprehensive care and improved patient outcomes (Kaplan et al., 2023).

Knowledge gap in this study: Currently, no research has been conducted on the use of lidocaine spray and ShotBlocker in Iraq. This is the

first and only study to compare their effect in reducing IM injection pain on a national level. Therefore, conducting this study would be valuable in helping healthcare providers reduce pain and concerns for adult patients receiving IM injections. It also opened the way for researchers to carry out future studies, with larger sample and experimenting other commonly used medications. Additionally, both pharmacological and non-pharmacological methods have their advantages and disadvantages. Therefore, comparing them is necessary to determine which has fewer disadvantages and more advantages for reducing pain during IM injections**.**

In response to technological advances, IM injection technology has seen recent development, with evidence from scientific research influencing best practice in site selection to improve quality of care (Duarah et al., 2019).

1.4. Objectives of the Study:

1. Determine the effect of ShotBlocker on pain level during intramuscular injection in adult patients.
2. Determine the effect of lidocaine spray on pain level during intramuscular injection in adult patients.
3. Comparing the effect of using lidocaine spray and shotblocker on pain level during intramuscular injection in adult patients

1.5. Hypotheses:

Null Hypothesis: (H0)

There is no difference between the effect of using ShotBlocker and lidocaine spray in reducing pain associated with intramuscular injection.

Alternative Hypothesis: (H1)

There is a Significant difference between the effect of using ShotBlocker and lidocaine spray in reducing the pain associated with intramuscular injection.

1.6. Definition of Terms:

1.6.1. Intramuscular Injection:

1.6.1. A. Theoretical Definition:

Intramuscular (IM) injection is the parenteral administration of medication through the skin and subcutaneous tissue into large muscles of the body using the appropriate syringe and needle for prophylactic (vaccinations) and therapeutic (antibiotics, hormones) purposes (Al-Attar et al., 2022).

1.6. B. Operational Definition:

A medical procedure in which a syringe with a needle is used to administering a liquid substance (medication) directly into a muscle that can be uncomfortable and painful.

1.6.2. ShotBlocker:

1.6.2.A. Theoretical Definition:

Is flat device, horseshoe-shaped, 2 mm thick, and features sharp edges that touch the skin and a central hole that indicates the injection site (Aydin & Avşar, 2019).

1.6.2. B. Operational Definition:

It is a medical device used to reduce the pain during intramuscular injections. It consists of a small, flat, plastic disk with a central opening for the needle and multiple blunt contact points that press against the skin surrounding the injection site.

1.6.3. Pain:

1.6.3. A. Theoretical Definition:

Pain is a painful combination of sensory and emotional sensations that can result from actual or potential damage to any bodily tissue (Mahmoud & Ibrahim, 2022).

1.6.3. B. Operational Definition:

It is an uncomfortable sensation that the patient feels when a needle is inserted into the body muscle, during intramuscular injection.

1.6.4. Lidocaine Spray:

1.6.4. A. Theoretical Definition:

Is another form of topical pain relief. It is used for local anesthesia of mucous membranes and skin. The practical effect of this method and its ease of use have led to its widespread use compared to other methods (Khosravi Pour et al., 2023).

1.6.4. B. Operational Definition:

Lidocaine spray is defined as a topical anesthetic solution containing a specific concentration of lidocaine hydrochloride, usually 10 %. The spray is designed for topical application to surfaces of the skin, to induce superficial anesthesia.

Chapter Two
Review of Literature

Chapter Two

Literature Review

2.1. Intramuscular injection-induced pain:

There are several methods for administering drugs, including parenteral, oral, and topical routes. Parenteral administration encompasses IM injection, where medication is administer into large muscles. In comparison to subcutaneous injection, IM injections are more efficiently absorbed, attributed to the greater presence of blood vessels in muscles. It is crucial to determine the appropriate administration rate, syringe length, and needle depth for IM injection (YILDIZ et al., 2017).

Intramuscular (IM) injections are a vehicle to dispense medications such as antibiotics, vitamins, infertility drugs, allergy medications, and antipsychotic medications. These and other medications need to be administered IM into large gluteal muscles to allow for better absorption of high-volume medication (Ozen et al., 2019).

Approximately 90% of injections involve administering medications into muscles or the skin (subcutaneous or intradermal) (Jancy, 2019 and Kara & Yapucu Güneş, 2016).

When administering medication through IM injection, it's crucial to take into account factors like the patient's age, drug properties, and body measurements to determine the appropriate technique (Kilic et al., 2014). Typically, IM injections in the gluteal area are conducted in either the dorsoGluteal (DG) or ventroGluteal (VG) regions. The DG region, situated above an imaginary line drawn between the greater trochanter and the posterior superior Iliac Crest, is a common site for this injection. To administer the injection, the patient should assume a prone position, and the injection should be given laterally and superiorly to this imaginary line (Taylor et al., 2018 and Potter & Perry, 2005). Research indicates that the

majority (81.5%) of nurses opt for the DG region when administering IM injections (Kilic et al., 2014 and Engstrom et al., 2000).

Incorrect administration of IM injection, where it is injected into the surrounding fat rather than the intended muscle, can lead to complications. These complications include the incomplete delivery or complete loss of the medication. Additionally, adverse effects such as prolonged bleeding due to vessel damage, redness, tingling, swelling, drainage, or numbness at the injection site may occur. Research indicate that only 32% to 52% of IM injections are successful, and patients who receive the remaining successful injections may experience physical and emotional adverse effects (Micallef et al., 2020; Soliman et al., 2018 and Boyd et al., 2013).

Numerous patients fear regarding injections, expecting a painful experience. Administering a drug intramuscularly too swiftly or in an incorrect location can result in complications, including pain or damage to the Sciatic nerve. The injection-related pain may stem from nerve damage caused by needle penetration, heightened pressure due to fluid accumulation in tissues, or rapid tissue expansion resulting from fluid injection (Turul & Khorshd, 2014).

The proper location of an IM injection is determined by criteria such as the patient's age, kind and volume of drug, and health status. Carelessness, inaccuracy, and a misunderstanding of correct application can lead to major difficulties. The main problems occur when the IM injection is injected into the DG site, because this location has a thick interweaving of veins and is close to the sciatic nerve. A thinner layer of subcutaneous tissue is also present (Fekonja et al., 2021).

Nurses must possess a comprehensive understanding of the anatomical structure of the administration site and make informed decisions (Sar et al., 2017). IM injections come with various risks, including complications like abscess, necrosis, infection, tissue damage, hematoma, nerve, bone, and vein injuries, periostitis, contracture, and persistent pain

(Larkin et al., 2017). The most significant side effect is sciatic nerve damage, often resulting from injections administered to the DG site (Kaya & Palloş, 2012). The Sciatic nerve is the most commonly affected nerve, especially in children, the elderly, and underweight individuals (Jung Kim & Hyun Park, 2014).

To prevent complications and minimize patient risk, administering IM injections necessitates knowledge and experience. Nurses should have a comprehensive understanding of the pertinent anatomy and proximal anatomical structures to confidently and safely identify landmarks and site limits. Poor technique, insufficient understanding, and a lack of skill and confidence on the part of nurses may lead to avoidable complications (Sah & Maskey, 2020). To ensure the proper application of interventions in specific scenarios, nurses should rely on evidence-based practice for information. Furthermore, it is essential for nurses to prompt patients to consistently assess the effectiveness of therapy through standardized pain assessment techniques (Van et al., 2016). Effective pain management not only reduces physical discomfort but also improves the overall quality of life (Tanioka et al., 2018).

Numerous studies have been conducted to explore methods for reducing the risks associated with intramuscular injection, including applying manual pressure at the injection site (Bilgiç, 2021), utilizing the double needle method (Aaç & Güneş, 2011), introducing air bubbles or touch (Hasanpour et al., 2006 and Sparks, 2001), employing ShotBlocker (Aydin & Avşar, 2019 and Celik & Khorshid, 2015), and gradually administering the medication (Tugru & Khorshid, 2014; Ozdemir et al., 2013 and Mitchell & Whitney, 2011).

The angle of needle entry may contribute to the pain of the injection. IM injections should be given at a 90° angle to ensure the needle reaches the muscle, and to reduce pain. Tanioka et al., (2018) found that nurses did not always ensure needle entry to the skin at 90° and they speculated that

this would cause more pain for the patient, due to the needle shearing through the tissues. Hands positioned near the intended entry site results in fewer needle stick injuries and improves site accuracy. Therefore, to ensure entry at the right angle, commence the injection with the heel of your palmer sting on the thumb of the non-dominant hand, and by holding the syringe between the thumb and fore finger, a firm and accurate thrust of the needle at the correct angle can be achieved. There has been little research in the United Kingdom (UK) into the effect of different injection techniques and nurses demonstrate a variety of techniques and disparate knowledge. The traditional method of giving IM injection has been to stretch the skin over the site to reduce the sensitivity of nerve endings and to insert the needle in a dart like action at 90° to the skin (Kirk, 2018).

Injection site pain is common following IM injection. Anxiety and fear associated with pain can reduce the acceptability of treatment to patients, and for clinicians the knowledge that a procedure is painful may reduce its use. Given the frequency of IM injections and their importance as a treatment option, IM injections site pain is an important issue and a number of pharmacological, psychological, and procedural (injection technique) interventions have been proposed to reduce injection associated pain. Pharmaceutical interventions, such as injectable or topical anaesthetics can reduce pain, but are not always compatible with the medication being injected and may be associated with drug side-effects, allergies and increased cost. Physical and procedural interventions, through the use of an optimal injection technique, have the potential to reduce pain while having little effect on the length or cost of the procedure (Ayinde et al, 2021).

Nurses play a vital role in assessing patients' pain and providing appropriate pain management choices. Consequently, they possess the potential to decrease the prevalence of individuals experiencing pain and receiving insufficient pain treatment. Furthermore, they bear a substantial

responsibility for delivering outstanding healthcare to relieve a patient's pain (Liz Stokes, 2019).

The nurse should carefully select an injection site, ensuring a safe distance from major blood vessels, nerves, and bones. The chosen site should be free from tenderness, abscesses, or injury and should be adequately large to accommodate the volume of medication (Tanioka et al., 2018).

The impact of non-pharmacologic techniques on pain management can be elucidated through the pain gate control theory. This theory posits that the spinal cord has the ability to modulate the transmission of pain signals from nerves to the brain. Additionally, it suggests that activating and stimulating other receptors in the Peripheral Nervous System can diminish the transmission and perception of pain. By employing techniques like deep pressure to stimulate additional receptors in the skin and muscles, pain can be alleviated. For instance, when a needle is inserted into stretched skin, the pain is minimal due to the increased stimulation of receptors (Salari et al., 2018).

The Emergency Department (ED) is a vital component of the healthcare system, dedicated to providing immediate and comprehensive care to patients with urgent medical needs. Its multifaceted role, encompassing rapid assessment, critical interventions, and coordination of care, underscores its importance in saving lives and addressing a wide array of medical emergencies. Continuous improvements in technology, processes, and training are essential to meeting the growing demands and challenges faced by EDs worldwide (Cerit & Emen, 2020).

The role of the ED is to provide immediate care for medical emergencies and acute conditions that require prompt attention, ranging from minor injuries to life-threatening events. The ED uses a triage system to prioritize patients based on the severity of their conditions, ensuring that those with the most critical needs are attended to first. Additionally, the ED

offers initial treatment and stabilization, after which patients are either admitted to the hospital for further care, referred to specialists, or discharged with appropriate instructions (Ismailoğlu, 2021).

In the Emergency Department (ED), a diverse array of medications is used to treat a wide range of acute and urgent medical conditions. Analgesics such as morphine and fentanyl are commonly administered for severe pain relief, while non-opioid options like acetaminophen, diclofenac sodium and ibuprofen manage mild to moderate pain. Broad-spectrum antibiotics, including ceftriaxone and piperacillin-tazobactam, are essential for treating serious bacterial infections like sepsis and pneumonia. Respiratory emergencies are frequently managed with bronchodilators such as albuterol and ipratropium, and corticosteroids like methylprednisolone reduce inflammation in severe asthma attacks and COPD exacerbations. Cardiovascular emergencies often require medications like aspirin and nitroglycerin for acute coronary syndromes, and drugs like atropine and epinephrine are vital in advanced cardiac life support for cardiac arrest and severe bradycardia (Nymoen et al., 2022). For patients experiencing nausea and vomiting, antiemetics like ondansetron and metoclopramide are commonly used. Sedatives and anxiolytics, including midazolam and lorazepam, are utilized for sedation, anxiety relief, and seizure control, with propofol being a key agent for rapid induction of anesthesia in critically ill patients. Allergic reactions and anaphylaxis are treated with antihistamines such as diphenhydramine and the life-saving administration of epinephrine. Electrolyte imbalances are corrected with intravenous fluids like normal saline and lactated Ringer's, along with potassium chloride for hypokalemia. These medications are fundamental in the ED, enabling healthcare providers to address a broad spectrum of medical emergencies efficiently and effectively (Wallace et al., 2017).

Diclofenac sodium, a nonsteroidal anti-inflammatory drug (NSAID), is frequently used in the Emergency Department (ED) to manage acute pain

and inflammation. It is particularly effective for treating conditions such as musculoskeletal injuries, sprains, strains, and acute exacerbations of chronic inflammatory diseases like osteoarthritis and rheumatoid arthritis. Diclofenac works by inhibiting cyclooxygenase (COX) enzymes, which play a key role in the synthesis of prostaglandins, compounds that mediate inflammation, pain, and fever. Available in various forms including oral tablets, topical gels, and injectable solutions, diclofenac provides flexibility in administration based on the patient's specific needs and the severity of their condition (Tavano et al., 2018). In the ED, diclofenac sodium is often chosen for its efficacy in rapidly reducing pain and inflammation, making it a valuable option for patients requiring immediate symptomatic relief. However, its use is carefully monitored due to potential side effects, such as gastrointestinal irritation, renal impairment, and cardiovascular risks, particularly with prolonged use or in patients with pre-existing conditions. As with all NSAIDs, the benefits of diclofenac must be weighed against its risks, ensuring it is used appropriately to provide effective and safe relief from pain and inflammation in the emergency setting (Tavano et al., 2018 and Ulubay et al., 2018).

2.2. Historical overview of pain management:

According to historians of medicine, the practice of IM injection dates back to 500 AD, but the procedure and equipment were not improved until the late 1880s, and it was not widely adopted until later. Before the discovery of penicillin, physicians were the primary practitioners of IM drug administration. A survey conducted among nurses revealed a lack of formal instruction on IM administration techniques. Until 1957, the nursing literature had only a few articles on IM injections, focusing primarily on equipment and drug preparation (Burns & Grove, 2010 ; Beyea & Nicoll, 1995 and McTighe & Chernev 2014).

Primitive societies such as Egypt subscribed to a magical-religious understanding of pain, whereby they believed that pain not caused by

physical injury was the result of spiritual or divine influences from their deities or spirits of death. According to their belief system, these entities would enter the body through the nose or ears. In addition to employing magical or religious rituals and ceremonies, they also made use of experiential therapeutic procedures. In various parts of Egypt, papyri described the use of vomiting, coughing, and urination as methods to expel invading entities and demons. To alleviate pain, a frog was boiled in oil and then applied topically to the affected area. Furthermore, various incantations to the God Horus and other deities were believed to be helpful in reducing acute headaches (Escohotado, 2018; Göbel, 1997; Bonica, 1991 and el-Ansary, 1989).

Hippocrates, a Greek physician who lived between approximately 460 and 360 BC, suggested that pain was caused by an imbalance in the four humors: blood, mucus, yellow bile, and black bile. Addressing the patient's symptoms, effective verbal communication and interaction were critical aspects of pain management, with pain being part of the patient's overall condition. In addition to traditional remedies such as nightshade and opium, pain relief was sought through methods such as setting fire and ice, swimming, and inducing bloodshed. Juice containing salicylates obtained from poplar trees and willow bark has been used to relieve eye problems, manage childbirth pain, and lower body temperature (Medvei, 2012; Cambier et al., 1993 and Bonica, 1991).

In the Middle Ages, pain was viewed as a tangible spiritual distress that affected both the physical and spiritual aspects of an individual. However, in the Christian belief system, pain was considered a manifestation of shame and sin. Sorrow and deprivation were seen as a means of preparing for divine comfort and consolation. Basilius (approximately 330-379 A.D.) believed that God gave humanity the ability to heal, recognizing that illnesses and pain were the result of sin and

granting some alleviation of suffering (Oesterle et al., 2019 and Sabatowski et al., 2004).

Advancements in pain management during the 17th and 18th centuries were shaped by many scientific breakthroughs. Sir Joseph Priestley (1733-1804) played a role by isolating nitrous oxide (N_2O) during his observations and experiments on various gases from 1774-1777. In 1800, Sir Humphrey Davy (1778-1829) reported that inhaling N_2O relieved pain. He personally counted swallowing three doses of gas after a tooth extraction, and noticed a decrease in pain after the first breath (Rodgers, 2019). The development of pain management in the 17th and 18th century was influenced by various scientific discoveries. Nitrous Oxide (N_2O) was isolated by Sir Joseph Priestley (1733-1804) during his observations and experiments on various types of gas from 1774-1777. Sir Humphrey Davy (1778-1829) reported in 1800 that N_2O inhalation provided pain relief and described his personal experience of swallowing three doses of the gas after having a tooth extracted, with pain diminishing after the first few breaths (Rodgers, 2019).

Davy proposed the use of gas in minor surgeries, but this proposal was not adopted. Instead, nitrous oxide (N_2O) has gained popularity due to its pleasurable intoxicating effects when inhaled (Yang & Alston, 2019 and Sabatowski et al., 2004). In the early nineteenth century, advances in scientific research and experimentation led to a new understanding of the anatomy and experience of pain. A key figure in this domain was Marie Jean Pierre Flourens, a French scientist who extensively studied animal brains. In 1824, Florence asserted that gray matter served as the common physical basis of mind, memory, emotion, and perception. In addition, he noted that cerebral hemispheres were not active (Cobb, 2020 and Morgan, 1982).

Pain acts as a critical instructor, guiding us to avoid potential harm from elements such as fire, poisons, and sharp objects. Opioids initially

seemed like a promising solution to the age-old challenge of relieving pain without risking addiction However, this idea turned out to be overly optimistic. In the 17th century, many European doctors prescribed opium to relieve pain, and by the 19th century, ether and chloroform emerged as surgical anesthetics. This development raised concerns among some doctors. By the early 1900s, morphine and heroin were being used as pain relievers, marking the beginning of a division among physicians. They grappled with the desire to improve their patients' quality of life while wary of the potential for these treatments to lead to addiction (Collier, 2018).

Since the implementation of the Harrison Narcotics Act in 1914, the risk of addiction to morphine and other opioids has been a concern for both health care practitioners and patients. In response to this concern, the American Pain Society (APS) initiated a highly effective campaign called "Pain, the Fifth Vital Sign." The primary goal was to enhance health care providers' understanding and evaluation of pain management. While opioids have been presented as a potential treatment option, the campaign advocated for a significant shift in the use of opioids to treat severe pain, with a focus on improving the quality of life for individuals nearing the end of their lives (Chinchilla & Moyano, 2022).

The endorsement of pain as a fifth vital sign program by the Veterans Health Administration (VHA), the largest government-run health care system in the United States (US), in 1999, increased the campaign's legitimacy. The endorsement of pain as a fifth vital sign program by the VHA, the largest government-run health care system in the US, in 1999 further validated the legitimacy of the campaign (National Academies of Sciences, Engineering, and Medicine, 2017; Mularski et al., 2006 and Meldrum, 2003). Although pain is a widespread human experience, the systematic study of pain and the development of pain management as a medical specialty are relatively recent fields. Before the 1800s, many people viewed pain as an inherent emotion and considered it a normal

aspect of aging. However, the medicalization of pain management in the twentieth century coincided with advances in understanding the pathophysiology of pain and the emergence of a variety of pain treatment options (Anglin, 2014 and Meldrum, 2003).

In the mid-19th century, the identification of morphine as a treatment for injured Civil War soldiers marked the beginning of the introduction of analgesics in the United States. However, as the late 19th and early 20th century approached, some doctors and patients preferred non-drug treatments to anesthetics and painkillers. The landscape changed again with the return of wounded World War II soldiers, leading to the return of drug therapy as the primary treatment approach by the mid-20th century. This shift was partly influenced by the prevailing cultural and political mindset of the time (Jones et al., 2018). Before the introduction of anesthetics such as ether and chloroform in the late 1840s, cases of severe pain were documented, Burke noted. These tales continued throughout the Civil War, as soldiers and civilians alike endured great suffering. Postwar use of morphine by former soldiers presented a dilemma. Morphine and heroin, commonly used to treat chronic pain, faced restrictions in the early 1900s and 1920s, respectively (Rummans, 2018 and Jones et al., 2018).

Between 1999 and 2016, more than 630,000 people in the United States (US) lost their lives to drug overdoses, most attributable to the use of prescription opioids to treat pain. The period from 1999 to 2010 saw a gradual rise in deaths associated with opioid painkillers, representing the first phase of the opioid epidemic. Following this, subsequent waves - the second and third - affected respectively. The number of deaths increased from 52,404 in 2015 to 72,000 (provisional) in 2017 (Bernard et al., 2018).

With approximately 80 million children in the US under the age of 18, efforts to promote pain management during vaccinations may have a significant impact on the ability of the population to maintain health and use health care services as they age (Zajacova & Grol-Prokopczyk, 2022).

Public health at the national and international level may be affected by vaccination-related pain and needle phobia. For example, outbreaks of diseases previously eradicated and prevented by vaccination have resurfaced in people who refuse vaccination or as a result of weak herd immunity (Kim, 2021).

Standards developed by professional organizations and accreditation bodies to enhance service quality in health care institutions emphasize the importance of pain reduction. Nowadays, everyone understands the importance of controlling pain through a multidisciplinary team approach involving patients, nurses and doctors. Nurses, who have prolonged interactions with patients, play critical roles and bear responsibilities in the pain management process. Reducing pain intensity contributes to enhanced patient compliance with medications, improved quality of patient care, sustained patient satisfaction, and enhanced patient-nurse relationships (Kaplan & Avşaroğullari, 2023).

Recent advancements in managing pain resulting from IM injections have focused on minimizing discomfort and enhancing patient experience through various innovative approaches. Techniques such as using smaller gauge needles, ensuring proper injection techniques, and selecting optimal injection sites have proven effective in reducing pain as non-pharmacological approach. Additionally, the application of topical anesthetics and cold sprays prior to injection can significantly lessen pain perception. Incorporating distraction methods, such as verbal reassurance or engaging the patient in conversation, also helps in alleviating discomfort. Advances in pharmacology have introduced formulations with less irritating excipients and improved viscosity, further reducing injection-related pain (Sedat et al., 2019). Educating healthcare providers on best practices for IM injections, including the angle and depth of needle insertion, is crucial for pain minimization. Research into patient-specific factors, such as muscle mass and skin thickness, allows for more tailored

approaches, enhancing overall outcomes. Collectively, these strategies contribute to a more comfortable and effective pain management experience for patients undergoing IM injections (Hoseini et al., 2022).

2.3. Theoretical frameworks:

The theoretical framework is important part in every research work. The theories direct the researcher towards correct practices, as the ultimate goal of the theories is to develop knowledge and integrate it into practice, make research outputs more important, explain the relationship between theories and research variables, and motivate the production of valuable results (Lekenit et al., 2020). To provide a framework for all aspects of the research and to come up with comprehensive and practical scientific findings, two theories were chosen.

2.3.1. Gate Control Theory:

Melzack and Wall proposed the "gate control theory" (GCT) to explain pain in 1965. It has since been modified (Braz et al., 2014; Linderoth & Foreman, 2017 and Mendell, 2014).

In 1965, Ronald Melzack and Patrick Wall introduced pain GCT. This theory was groundbreaking because it proposed the idea that pain perception is not limited to a simple chain involving activation of pain pathways in the periphery and subsequent perception of pain in the brain. Instead, a "gate-like" mechanism in the dorsal horn of the spinal cord undergoes multiple modifications before pain sensation is transmitted to the central nervous system from the peripheral nervous system (Melzack and Wall, 1965 and Knotkova et al., 2021).

According to this theory, pain is a multifaceted phenomenon, which is not just a reaction to an external stimulus; Rather, it is a complex process affected by psychological, neurological, and environmental factors (Marinho, 2019). In addition, it assumes that thoughts, emotions, past experiences, and cognitive state influence the gate mechanism. This

physiologically grounded theory explains the sensory and psychological dimensions of pain perception (Campbell et al., 2020).

Melzack and Wall's theory of pain gate control claims that small neural networks scattered along the dorsal horn of the spinal cord are responsible for reducing pain in a specific area of the body when intense tactile stimulation is given there. This sensation occurs when we rub a recently injured area (Fowler, 2021).

They claim that the axons of primary afferent nociceptors and low-threshold afferent mechanoreceptors come together in the same neurons in the substantia gelatinosa (SG) in the dorsal horn of the spinal cord. In this region, inhibitory interneurons prevent nociceptive signals from reaching the brain. Mechanoreceptors, being low-threshold and having myelinated axons, generate action potentials at a high rate (Marineo, 2019).

Both nociceptive and non-nociceptive fibers, including those responsible for touch and pressure, have the potential to influence gating. The gate is opened and the transmission of pain signals is facilitated by the activation of nociceptive fibers. Conversely, activation of non-nociceptive fibers closes the gate, thus impeding the transmission of pain signals. nociceptive impulses are transmitted through unmyelinated axons, resulting in decreased density (transmission rate). Wall suggests that the Gateway Theory of Pain is a work in progress and can be improved through further discussion. The existence of gate control is no longer in doubt, but its functional role and detailed mechanism remain open to conjecture and experimentation (Pereira & Lerner, 2017 and Knotkova et al., 2021).

Controlling the transmission of pain signals, pain perception can be influenced by gate activity, which can be modulated by a variety of factors. The elements include sensory inputs (including pressure, vibration, and touch), cognitive inputs (including anticipation and attention), emotional inputs (including anxiety and dread), and descending pathways from the brain that may influence the brain in an inhibitory or facilitatory manner

(Pereira and Lerner, 2017). All axonal terminals of inhibitory neurons are inhibitory, and all axonal terminals of excitatory neurons are excitatory, according to this fact. The specialization of this neuron depends on the fact that its axons do not have a mechanism to direct inhibitory neurotransmitters to other limbs and excitatory neurotransmitters from the soma to specific limbs (Linderoth & Foreman 2017).

When the gate is open, pain impulses can freely enter the brain, enhancing the sensation of pain. In contrast, when the gate is closed or inhibited by non-nociceptive signals, pain signal transmission is limited, resulting in decreased pain perception. This idea explains why massage, acupuncture, and even distraction techniques can help relieve pain. These activities activate non-nociceptive fibers, thus closing the gate and limiting the transmission of pain signals (Fowler, 2021 and Pereira & Lerner 2017).

In addition, gate control theory emphasizes the complex interplay between mind and body in pain perception. Pain perception may be influenced by psychological variables including stress, anxiety, and emotion, which have the potential to influence the opening or closing of a gate. Gate control theory has provided a framework for understanding pain modulation and has influenced the development of various pain management techniques, including multidisciplinary approaches that incorporate physical, psychological, and pharmacological interventions to reduce pain (Braz et al., 2014 ; Goubert et al., 2021 and Melzack., 2018).

In conclusion, the GCT of pain revolutionized the understanding of how pain is perceived and managed. According to this theory, pain is not only the result of direct stimulation of pain receptors but is modulated by a "gate" mechanism in the spinal cord that either inhibits or facilitates the transmission of pain signals to the brain. This gate can be influenced by various factors, including psychological and physiological states. Non-painful stimuli, such as touch or pressure, can close the gate and thus reduce the perception of pain, while factors like anxiety and attention to the

pain can open the gate, increasing pain perception. This theory has significant implications for pain management, leading to the development of various non-pharmacological interventions such as transcutaneous electrical nerve stimulation (TENS), massage, and cognitive-behavioral therapies, which aim to modulate the gate and provide pain relief. By integrating the principles of the GCT, healthcare providers can adopt a more holistic approach to pain management that addresses both the physical and psychological components of pain (Pereira & Lerner 2017 and Melzack., 2018).

The theoretical framework that guides this research due to its distinctive theoretical principles applied in formulating the study protocol. The main reason people seek help from healthcare professionals is pain, which greatly affects their comfort. This theory emphasizes the importance of assessing changes in a patient's pain as a means of understanding their pain and ensuring the effectiveness of their care plan. By taking advantage of this theory, the researcher was able to formulate a plan to help patients reduce the pain resulting from IM injections. The theory served as a tool for analyzing the effectiveness of pharmacological and non-pharmacological interventions, and focused primarily on the design and implementation of a comprehensive nursing care plan.

2.4. Nursing responsibility in pain management:

In health care settings, nurses have a variety of responsibilities, including the safe preparation and administration of medications, educating patients and their families about the proper use of medications, and monitoring patients' reactions to medications. The primary duty of nurses is to administer medications, ensuring accurate delivery of the correct medication at the prescribed dose, by the prescribed route, and at the specified time. Furthermore, they are tasked with keeping accurate records of medication administration (Turan et al., 2019 and Kaya et al., 2016).

Pain is an inherent aspect of the human experience, with individuals typically experiencing varying degrees and durations of pain for a variety of reasons (Berger & Baria, 2022; Matthews and Malcolm, 2007 and Wood, 2002).

Nurses devote a significant portion of their time to patients, and pain often emerges as the most common reason people seek guidance from health care providers. As a result, there is widespread recognition that the nursing profession plays a crucial role in pain management. Despite nearly two decades of increased awareness regarding pain management, nurses still face challenges in providing effective care to patients with pain. Knowledge surrounding pain management and underlying beliefs that influence nurses' pain management decisions have been identified as problematic (Lui & Fong, 2008 and Samarkandi, 2018).

Inadequate pain management is a concern for hospitalized patients and is recognized as a global public health issue (Al-Shaer et al., 2011; Doody & Bailey 2017 and Wysong, 2012).

In clinical settings, nurses play a crucial role in pain assessment and management, requiring a comprehensive understanding of these processes. Undertreatment of pain may occur due to inadequate evaluation or improper administration of analgesics, especially in the case of opioids (Al-Shaer, & Anderson, 2011).

It is essential that nurses stay up to date on research findings to enhance their skills and alleviate the discomfort and problems associated with IM injections. To relieve injection-related pain, nurses must consider various factors, including pain assessment, understanding cultural and behavioral influences on pain expression, recognizing genetic and ethnic characteristics that influence pain thresholds and tolerance, and adopting current evidence-based pain management techniques (Kara & Yapucu, 2016 and Monsivais & McNeill, 2007).

Nurses play a pivotal role in preparing medications, safe injection practices, educating the patient and family about medications, and monitoring drug responses. Because nurses spend a significant amount of time administering medications, ensuring that the right medication is given to the right patient at the right dose, at the right time, and by the right route is critical. IM administration of medications, a common nursing technique, is known to cause discomfort. In one study, 40% of patients who received intramuscular injections reported it as "very painful" (Yilmaz et al., 2016).

The goal of pain management is to enhance function, enabling individuals to participate in work, go to school, or perform other daily activities. Patients and their doctors have different options for pain management, with some approaches proven more effective than others. Meditation and using visualization as a distraction can sometimes provide relief, proponents of these techniques suggest. Regardless of the treatment plan chosen, it is important to realize that pain is a controllable condition (National Institute of Neurological Disorders & National Institutes of Health, 2009).

To enhance patient comfort during painful treatments, innovative nursing care methods are essential, which promotes stronger communication between patient and nurse, resulting in increased collaboration and satisfaction for the patient (Hylton, 2019).

Pain management has been designated as the fifth vital sign by the American Pain Association, emphasizing the importance of nurses in using modern IM injection techniques to improve the patient experience (Knezevic, 2019 and Jukić and Puljak, 2018).

Various techniques, including gradual drug injection (Mohammady et al., 2017), the use of ShotBlocker (Aydin & Avsar, 2019), Z-track methods and air lock can be used (Yilmaz et al., 2016). In addition, amide-type local anesthetic (EMLA) cream (Torki et al., 2020), lodocaine spray and ice spray (Jamalinik et al., 2023) and cold compresses (Astuti et al.,

2019) are among the pharmacological and non-pharmacological methods. This research therefore seeks to support nursing's role in pharmacological and non-pharmacological pain management.

2.5. Shotblocker overview:

The ShotBlocker was developed by Bionix, a company specializing in medical devices aimed at improving patient comfort during procedures. The device was first introduced to the market in 2008, following extensive research and development focused on creating a simple, effective solution to reduce injection pain. The development of the ShotBlocker was driven by the need to address the common issue of needle fear and injection pain, which affects a significant number of patients, particularly children and those with a strong fear of needles. Since its introduction, the ShotBlocker has been widely adopted across various healthcare settings, including pediatric clinics, family practices, and hospitals, owing to its ease of use and proven effectiveness. Over the past 16 years, the ShotBlocker has become a staple in pain management during injections, praised for its non-pharmacological approach to enhancing patient comfort and reducing anxiety associated with medical injections (Merve et al., 2021).

The ShotBlocker is a small, handheld device designed to reduce the pain and anxiety associated with injections. It consists of a plastic disk with multiple blunt contact points arranged around a central opening. When pressed against the skin at the injection site, these contact points stimulate the surrounding skin, creating a sensation that distracts from the pain of the needle. This mechanism is based on the GCT of pain, which suggests that non-painful stimuli can block or diminish the perception of painful stimuli by closing neural gates in the spinal cord (Rinker et al., 2021).

The ShotBlocker is easy to use, requiring minimal training for healthcare providers, and it can be applied immediately before an injection without the need for additional preparation. Its effectiveness makes it particularly useful in pediatric care, where fear of needles is common, but it

is also beneficial for adults and those with needle phobia. The device is cost-effective, reusable after proper cleaning, and portable, making it a practical tool in various healthcare settings. However, its efficacy can vary based on individual pain thresholds and the specific injection site, and it may add a slight delay to the injection process. Overall, the ShotBlocker offers a non-pharmacological approach to pain management, enhancing patient comfort and compliance with medical procedures (Hafez & Ali 2023).

The ShotBlocker is particularly advantageous in pediatric and geriatric care, as well as for individuals with a pronounced fear of needles or low pain tolerance. It is versatile and can be used for a variety of injections, including vaccines, insulin, and other subcutaneous or IM injections. The device is disposable, ensuring hygiene and preventing cross-contamination, but it can also be cleaned and reused in non-sterile environments if needed. Healthcare providers appreciate the ShotBlocker for its ease of use and quick application. It requires no additional setup time beyond placing it on the skin before administering the injection. However, optimal results depend on correct usage, including firm pressure to ensure adequate stimulation of the surrounding skin area. This necessitates some training and practice for new users (Aydin Yilmaz et al., 2024).

Despite its many benefits, the ShotBlocker has limitations. Its efficacy can be less pronounced in areas with minimal subcutaneous tissue or in patients with very high pain sensitivity. Additionally, while cost-effective on a per-unit basis, the expense can add up for facilities administering a high volume of injections. There is also the consideration of environmental impact, as the device is designed for single-use in sterile conditions, contributing to medical waste (Cobb and Cohen, 2019).

The ShotBlocker device, works by creating a stimulator at the injection site to close the pain gate in the spinal cord, thus reducing the sensation of injection pain. In addition, the palm stimulator, developed by

the researchers to alleviate pain observed during IM injections in children, is designed in line with the principles of gate control theory. While tactile stimulation applied to the palm may have a similar expected mechanism as ShotBlocker (Zengin &Yayan 2022).

It is positioned over the injection site, with blunt contact points that come into direct contact with the skin, allowing the medication to be administered through a wide opening. During the injection, the ShotBlocker is pressed against the surface of the skin. Its purpose is to relieve pain by accelerating the stimulation of nerve endings through pressure from its round protrusions. This stimulation reduces pain by temporarily blocking the transmission of pain signals during injection and by inhibiting the central nervous system (Hafez & Ali 2023).

Although tactile stimulation physically placed in the palm can have a similar expected mechanism of action as the ShotBlocker, the Palm Stimulator relies on using a more sensitive part of the body to transmitting a stronger stimulus according to the prevailing somatosensory map and theory (Aydin et al., 2024 and Zengin & Yayan 2022). The multiple projections are designed to stimulate touch receptors in the area, thus inhibiting pain perception through a gate control mechanism. The device has been shown in previous prospective studies to be effective in reducing the pain of immunization in neonates and children, as well as IM injection in adults (Rinker et al., 2021).

2.6. Lidocaine spray overview:

Lidocaine spray has a rich history that traces back to the discovery of lidocaine itself, which was first synthesized by Swedish chemist Nils Lofgren in 1943. Recognizing its potent local anesthetic properties, lidocaine was quickly adopted into medical practice in various forms. The development of lidocaine spray came as an innovation to enhance the delivery and convenience of this anesthetic for localized pain relief (Marvi et al., 2023).

By the 1960s and 1970s, the spray formulation became increasingly popular, offering a fast-acting and easily administered method to numb specific areas of the skin and mucous membranes. This advancement was particularly beneficial in fields such as dentistry, minor surgical procedures, and emergency medicine, where quick and localized pain relief was essential. Lidocaine spray provided a practical solution for procedures like intubation, catheter insertion, and minor dermatological interventions, where it could be applied directly to the affected area to provide rapid numbing, typically within a few minutes, with effects lasting up to an hour. The ease of use and effectiveness of lidocaine spray led to its widespread adoption and integration into standard medical practice. Over the past several decades, its formulation has been refined to improve patient comfort and safety, ensuring consistent delivery and minimizing potential side effects. Regulatory approvals in various countries further solidified its place in medical toolkits worldwide (Oh, & Jeong, 2017).

Today, lidocaine spray remains a staple in pain management, valued for its versatility and rapid action. Its continued use in diverse medical settings, from emergency rooms to dental offices, highlights its enduring importance in providing effective and immediate relief from localized pain. The history of lidocaine spray is a testament to the ongoing innovation in medical anesthetics, continually improving patient care through advancements in drug delivery methods (Khosravi et al., 2023).

Lidocaine is mostly applied to the surface of the skin, a method that has been shown to be effective in several studies. It is used for superficial anesthesia, providing a comfortable and non-invasive method. It has been used for various conditions such as acute throat discomfort, paroxysmal pain associated with trigeminal neuralgia, and organ intubation (Oh, & Jeong, 2017).

Some of the pharmacological techniques are lidocaine spray, prilocaine, EMLA, and piroxicam creams. Lidocaine is one of the most

widely used biologic agents in local anesthesia. The spray form of this substance is a common formulation used clinically with its mild effect for inducing local anesthesia in the mucous membranes and skin. Anesthesia is usually created in 1-5 minutes to 10-15 minutes, depending on the site of its use. The theory of pain regression with lidocaine is based on the blocking of active and inactive sodium channels, resulting in conduction blockage and lack of stimulation, thus distributing or reducing pain. This medication is an aminoamide anesthetic, often used for local anesthesia and pain relief due to its rapid onset of action and moderate effectiveness (Marvi et al., 2023).

Lidocaine spray comes in various formulations tailored for specific medical applications, each designed to optimize pain relief and ease of use. The most common type is a 10% lidocaine spray, widely used in dental and medical procedures to numb mucous membranes before minor surgical interventions, intubation, or dental work. Another formulation includes a lower concentration, such as 4% or 5%, which is often used for dermatological applications to minimize discomfort from minor skin procedures, injections, or minor burns. Some lidocaine sprays are combined with other active ingredients, such as epinephrine, to prolong the anesthetic effect and reduce bleeding by constricting blood vessels (Zhu et al., 2023).

Lidocaine 10% spray offers several advantages, including rapid onset of action, a convenient and painless application method, easy availability, low cost, and pleasant odor (Kulkarni et al., 2023). The main component of lidocaine spray is lidocaine, which achieves the surface anesthetic effect by accumulating at the cortical pain receptors and nerve endings. Local anesthesia can be produced 1–2 min after spraying, and the duration is 15–20 min. Compared with lidocaine cream and vapocoolant spray, lidocaine spray has the advantages of quick onset, long duration of anesthesia, and convenient use. Some researchers have used lidocaine spray to relieve pain

related to venipuncture, radial artery puncture, insertion of intrauterine device, and thoracic tube removal (Zhu et al., 2023).

The discomfort arising from the injection of local anesthetics is frequently cited as a primary concern among dental patients. In the field of dentistry, topical anesthetics find widespread use, primarily aimed at managing the pain associated with needle penetration during the administration of local anesthesia (Sargolzaei et al., 2020).

In the earlier investigation, the application frequency involved three times per patient, and no impact on the extent of surface anesthesia was observed. Consequently, in this study, 10% lidocaine was sprayed consecutively three times on the venipuncture area (Oh, & Jeong, 2017).
Many local anesthetic drugs have been developed, which are applied to patients' skin, to alleviate their pain. Lidocaine, in particular, is a prominent drug for local anesthetics because of its rapid action, minimal local irritation, and long duration of action. The anesthetic effects of 8% lidocaine spray and lidocaine patch application were comparable, with spray showing a faster onset than patch application in producing local anesthesia. These results indicate that the use of a spray containing lidocaine is highly effective in mitigating a patient's pain (Oh, & Jeong, 2017 and Zhu, et al., 2023).

Also spraying lidocaine on the cervix is also a direct and effective method to control pain during various minor gynecological procedures, such as intrauterine device insertion, first-trimester surgical abortion, hysteroscopy, and cervical electrosurgical excision (LEEP) procedures. Nevertheless, there is limited research on the effectiveness of lidocaine spray specifically in the context of endometrial biopsy, and current results are inconclusive (Piyawetchakarn & Charoenkwan, 2019).

Lidocaine spray offers the advantages of quick onset, long duration of anesthesia, and convenient use. In certain investigations, venipuncture, radial artery puncture, placement of an intrauterine device, and removal of

a chest tube have all been made less painful with the application of lidocaine spray. However, conflicting results exist regarding the effectiveness of lidocaine spray in relieving pain caused by procedures such as intravenous intubation (Mirzaei et al., 2017).

The efficacy of lidocaine spray in controlling pain during non- coring needle puncture of Totally Implantable Venous Access Ports (TIVAP) is currently uncertain (Zhu et al., 2023). In additional Lidocaine spray is considered an appealing option for pain control during endometrial biopsy because of its simplicity, safety, and proven effectiveness in other minor gynecological procedures biopsy (Piyawetchakarn & Charoenkwan, 2019).

Lidocaine spray may not be sufficient to completely eliminate pain associated with venous puncture, emphasizing the potential impact of individual differences, varying lidocaine spray doses, and different puncture sites. Future investigations could explore the optimal dose of lidocaine spray to effectively manage pain during needle insertion (Zhu, et al., 2023).

2.7. Focused literature review:

Celik and Khorshid (2015) conducted a randomized, placebo-controlled experiment. To determine whether or not ShotBlocker alleviates the discomfort and anxiety that individuals experience after IM injections. This study was conducted over 20 months and included participants (aged 18 to 80 years) who were given IM injection of 75 mg/3 mL of diclofenac sodium in a hospital outpatient clinic. The researchers injected diclofenac sodium with ShotBlocker into the muscles of study participants. A visual analog scale was used to measure pain intensity after injection. When compared to the placebo and control groups, patients who took ShotBlocker reported significantly less severe pain. Based on our findings, patients reported less injection-related pain while using the ShotBlocker during IM injection, but no less anxiety overall. Therefore, adults may consider using ShotBlocker as a pain reliever during IM injection.

In a prospective randomized controlled trial (RCT) conducted by Caglar et al. (2017), examined the effectiveness of ShotBlocker in reducing injection pain associated with initial IM administration of hepatitis B vaccine in healthy full-term infants. The trial included 100 healthy newborns in Istanbul, Turkey. Pain levels before, during, and after the injection were assessed in both groups using the neonatal infant pain scale, and physiological data were collected before and after the procedure. The results revealed that ShotBlocker was successful in reducing the acute pain experienced by term infants after hepatitis B vaccination.

Mirzaei et al., (2017) conducted a study to determine the effectiveness of lidocaine spray and topical eutectic mixture of local anesthetic (EMLA) cream in relieving pain caused by arteriovenous cannulation in hemodialysis patients. This quasi-experimental study included 40 patients with arteriovenous fistula (AVF), selected through purposive sampling in 2015 in the dialysis ward of Shahid-Sadoughi Hospital. Pain intensity was assessed during AVF cannulation using EMLA analgesic cream and lidocaine spray, with a numerical scale of pain intensity. Repeated measures analysis of variance (ANOVA) was used to analyze the data using SPSS. Results indicated that the mean scores for the three pain management methods—no pain control, lidocaine spray, and EMLA analgesic cream—were 7.45±0.88, 4.22±1.33, and 2.8±0.70, respectively. Both lidocaine spray and EMLA analgesic cream demonstrated a significant reduction in pain severity compared with the conventional method ($P < 0.001$). The findings of this study indicate that EMLA analgesic cream was most effective in reducing pain associated with AVF cannulation. Therefore, it is recommended that dialysis patients apply EMLA analgesic cream themselves at the time of the procedure to mitigate the pain of cannulation.

Emel et al., (2017) Examining the effectiveness of ShotBlocker in controlling injection discomfort associated with the first IM hepatitis C

vaccine administered to healthy full-term neonates was the purpose of this prospective, RCT. In this trial, 100 newborns were randomly assigned to one of two groups: a group that received ShotBlocker (n = 50) or a control group (n = 50) at a private university hospital in Istanbul, Turkey. Neonatal Infant Pain Scale scores in the ShotBlocker and control groups were recorded before, during, and after injection. In addition, their physiological characteristics were compared before and after the procedure. Infants in the ShotBlocker group reported less discomfort during and after the injection procedure than did the control group (1.64 ± 0.80 vs. 2.96 ± 0.73 for the former and 1.42 ± 0.76 for the latter) (P = 0.000). In the non-ShotBlocker group (150.24 ± 13.36), the post-injection heart rate of the ShotBlocker group was determined to be lower (145.02 ± 13.50) (P = 0.05). When given to neonates, ShotBlocker alleviates the severe pain associated with hepatitis B immunization.

Abdelkhalek, (2019) conducted a study to evaluate the effectiveness of ShotBlocker and Z-Track techniques in mitigating anxiety and pain during IM injections in adults. The study used a quasi-experimental research design and included a representative sample of 60 adult patients aged 18–65 years. The findings indicated that the use of ShotBlocker and Z-Track techniques during the second injection significantly reduced the pain score compared to the standard approach used for the initial injection. In the second group, where the Z-Track technique was applied, patients reported a lower average anxiety score after the second injection. However, there was no significant difference in anxiety scores between the two groups before or after the injection. While the second group showed a significant difference in anxiety scores between the first and second doses, no significant difference was observed between the first and second injection in the first group. The study concluded that ShotBlocker and Z-Track techniques were effective in reducing needle pain. But only Z-Track technology has been successful in reducing anxiety.

Bilge et al., (2019) conducted a study to assess the efficacy of cold spray and ShotBlocker in alleviating pain associated with IM injections in adults. The randomized controlled study was conducted in the emergency department from January to March 2018 and included adult patients who received an IM injection of 75 mg/3 mL of diclofenac sodium. There were 40 patients in each group: the ShotBlocker group, the cold spray group, and the control group. Study results revealed no significant difference in VAS scores between the ShotBlocker and cold spray groups. However, operators reported that ShotBlocker presented more challenges compared to cold spray. In conclusion, the study suggests that ShotBlocker, as a non-pharmacological method, is as effective as cold spray in reducing pain associated with IM injections.

Piyawetchakarn & Charoenkwan, (2019) conducted a study to investigate the effectiveness of lidocaine spray in relieving pain during endometrial aspiration biopsy by comparing its effects with placebo and no intervention. Women scheduled for an endometrial aspiration biopsy between March 2017 and January 2018 were invited to participate in the study. Participants were randomly divided into three groups. In group 1 (lidocaine spray), the cervix was thoroughly sprayed with eight puffs (80 mg, 10 mg/puff, 0.8 ml) of 10% lidocaine spray, administered 3 minutes before the procedure. For group 2 (placebo spray), the cervix received 0.8 ml of normal saline spray, also 3 minutes before the procedure. Group 3 (no intervention) received no anesthesia. Participants rated their pain on a 10-cm visual analogue scale at various points, including baseline, immediately after the procedure (biopsy pain), and 10 minutes after the procedure. Patient satisfaction was also assessed on a 10-cm visual analogue scale before hospital discharge. Continuous variables were compared using the Kruskal-Wallis test, and categorical variables were evaluated by the chi-square test. Two hundred and forty patients, with 80 individuals in each group, were part of the study. Mean baseline, biopsy,

and postoperative pain scores did not show statistically significant differences between the study groups. In addition, the mean difference between biopsy and baseline pain scores was comparable between groups. Furthermore, there was no difference in satisfaction scores between groups. In conclusion, application of lidocaine spray to the cervix was found to be ineffective in reducing pain associated with endometrial aspiration biopsy. Two hundred and forty female patients participated (80 in each group). Mean baseline, biopsy, and postoperative pain scores were not significantly different between study groups. Likewise, the mean difference between biopsy and baseline pain scores was comparable between the two groups. In addition, there was no difference in satisfaction scores between groups.

Aydin and Avsar (2019) conducted a study to evaluate the effectiveness of "ShotBlocker" in reducing discomfort caused by IM injection. Each patient served as its own control group to minimize differences in individual pain perception. Data were collected using a patient information form, visual analogue scale (VAS), and ShotBlocker. Patients' pain levels were measured using VAS during the first minute after injection. In conclusion, the study demonstrated that ShotBlocker was effective in reducing pain associated with IM injection**.**

Karabey and Karagzolu (2021) conducted a single-blind, randomized controlled trial, to investigate the effect of the Helper Skin Tap technique and the ShotBlocker application on pain during IM injection. The study was conducted from October 5 to December 30, 2020 in a family health care facility in Turkey. The sample consisted of individuals who received hepatitis B vaccine, pain relief techniques were developed by the researcher, while a single nurse administered all IM injections. Study results indicated that ShotBlocker was more effective than Helper Skin Tap and traditional methods in reducing the pain associated with IM injections. Furthermore, regular practice was less successful in controlling pain than Helper Skin Tap. Furthermore, regular practice was less successful in

controlling pain than Helper Skin Tap. The study suggests that the inexpensive and easy-to-use ShotBlocker and Helper Skin Tap technology should be used to enhance pain management during IM injection.

Hoseini et al., (2022) conducted a randomized trial study to investigate effect of Acupressure and Lidocaine Spray on the Severity of IM Injection Pain. The study involved 254 participants who underwent IM injections at the Emergency Department of 22 Bahman Hospital in Neyshabur, Iran. The participants were chosen through convenience sampling and then randomly allocated to three groups—lidocaine spray, acupressure, and control—utilizing the permuted block randomization method. The collection of data involved the use of a demographic characteristics form and the visual analog scale (VAS). Following IM injections, patients commonly encounter pain. Lidocaine and acupressure are two potential methods for alleviating this pain. The study's findings indicated that there was no noteworthy distinction in the reduction of pain intensity between acupressure and lidocaine spray (P=0.400). Additionally, demographic variables did not exert an influence on the severity of pain resulting from IM injection. In practical terms, the results suggest that both acupressure and lidocaine spray did not exhibit statistically significant efficacy in reducing the severity of pain induced by IM injection. Nevertheless, a clinically meaningful reduction in mean pain intensity was observed with these methods when compared to the control group.

Kartufan, (2022) Conducted a study to assess the impact of administering lidocaine as a local anesthetic at the puncture site before cannulation on the reduction of pain during intravenous cannulation (IVC). A total of 77 patients were divided into two groups: those who received a local anesthetic before the IVC procedure (n = 40) and the control group (n = 37). Various demographic data, including age, gender, height, weight, body mass index, IV gauge, IV site, heart rate (HR), and oxygen saturation (SpO2), were collected and analyzed. Patients in both groups evaluated the

pain experienced during IVC using the VAS and the verbal descriptor scale (VDS). The study revealed no statistically significant difference between the two groups concerning demographic features. Cannula gauges and the site of IVC showed no significant differences between the groups. In the control group, there was a statistically significant increase in the mean post-IVC heart rate (HR) compared to the pre-IVC HR ($p = 0.032$). However, there was no significant difference between the mean pre- and post-procedure HR in the lidocaine group. The lidocaine group exhibited a significantly lower mean VAS score compared to the control group ($p < 0.001$). Additionally, there was a notable difference between the groups in terms of the VDS, with the lidocaine group reporting a statistically significantly higher rate of patients experiencing mild pain compared to the control subjects ($p < 0.001$). Based on the study's findings, the application of a lidocaine hydrochloride (HCL)-impregnated padded dressing before IVC resulted in a significant reduction in pain sensation during the procedure.

Sahan and Yildiz (2022) conducted a meta-analysis study with the aim of assessing the impact of ShotBlocker application on pain levels during IM injection among adult patients, aiming to promote evidence-based practice. After conducting a thorough literature review across various databases such as PubMed, Scopus, Science Direct, Ovid, and Google Scholar, the researchers concluded that the use of ShotBlocker during intramuscular injection significantly decreased pain levels among adult patients in the trial group compared to the control group. The meta-analysis revealed that ShotBlocker had a positive effect on reducing pain levels among adult patients receiving intramuscular injections. However, further high-quality research adhering to authorized research standards is necessary for a more comprehensive and effective outcome.

Gürdap and Cengiz (2022) conducted a study to investigate the impact of using cold spray and ShotBlocker to alleviate pain in adult

patients receiving IM injections in the emergency department. This randomized controlled trial included two experimental groups, two placebo groups, and a control group, totaling 195 participants who received Diclofenac Sodium injection. All five groups underwent the same injection technique, with the intervention groups receiving cold spray or ShotBlocker during the injection process, and the placebo groups receiving cold spray with distilled water or a smooth surface ShotBlocker. Pain levels resulting from the injection were measured using the VAS. The results indicated that patients in the cold spray group had significantly lower pain scores than those in the control group. However, there was no significant difference in pain scores between the ShotBlocker and cold spray groups, as well as between the control, ShotBlocker placebo, and cold spray placebo groups. The study suggests that the frequent use of cold spray, a fast-acting, cost-effective, and easy-to-use method, can enhance patient satisfaction and improve the quality of care by reducing pain during IM injections.

Jamalinik et al., (2023), in a study conducted to investigate the effect of lidocaine spray and ice spray on the intensity of pain at the IM injection site. This involved a randomized double-blind clinical trial with 90 patients attending outpatient clinics at Neyshabur hospitals. The participants were chosen through a computerized random number table, and each individual was assigned randomly to either the control group, lidocaine spray group, or ice spray group. Pain severity was assessed immediately after IM injection using a numerical pain scale. The results of the statistical tests demonstrated a notable distinction in the pain intensity of IM injection between the ice group and the control group ($p = .010$). While lidocaine spray exhibited a reduction in pain intensity, the effect was deemed statistically insignificant when compared with the control group. In conclusion, both ice and lidocaine spray show efficacy in diminishing the

intensity of IM injection pain. However, it appears that ice spray is a more effective, safe, and cost-efficient method.

Marvi et al., (2023) this study self-controlled, single-blind clinical trial was to assess and compare the impact of two interventions, lidocaine spray and rhythmic breathing, on pain intensity experienced during needle insertion into arteriovenous fistulas in hemodialysis patients. The study included 54 hemodialysis subjects with arteriovenous fistulas in Mashhad. The participants were chosen based on specific inclusion criteria and were randomly allocated to either the lidocaine spray group or the rhythmic breathing group. In both groups, pain intensity was evaluated using the VAS before the intervention. Subsequently, post-intervention pain intensity was measured during three consecutive hemodialysis sessions conducted every other day. For the lidocaine spray group, two puffs of 10% lidocaine spray (20 mg) were applied to the needle insertion site five minutes before cannulation. In the other group, participants performed a specific breathing exercise: taking a long, deep breath through the nose for three counts, holding the breath in the lungs for three counts, and then slowly exhaling through the mouth for three counts two minutes before cannulation. notable difference was identified between the pre- and post-intervention pain intensity scores in the lidocaine spray-treated group (1.16 ± 1.56) in comparison to the other group (0.508 ± 1.25). The lidocaine spray group exhibited a greater disparity in the pre- and post-intervention pain intensity scores compared to the rhythmic breathing group; however, this difference did not reach statistical significance. Rhythmic breathing can be considered by nurses as a non-pharmacological method with low complications in hemodialysis departments due to its potential to reduce pain.

2.8 Literature Synthesis:

The route of drug administration is a critical factor in determining the effectiveness, speed of action, and safety of a medication. Various routes are available, including oral, subcutaneous, intravenous,

transdermal, and intramuscular, each with its specific indications, advantages, and limitations. The choice of route depends on factors such as the nature of the drug, the desired speed of absorption, the target site, and patient-specific considerations like age, health status, and convenience. Focusing on intramuscular (IM) injection, this route is commonly used when rapid absorption is required, or when the drug cannot be administered orally due to degradation in the digestive tract. IM injections involve delivering medication directly into the muscle tissue, which has a rich blood supply, allowing the drug to be absorbed quickly into the bloodstream. This route is preferred for certain vaccines, hormonal treatments, antibiotics, and other medications that need to be administered at a controlled, steady rate.

IM injections offer several advantages, such as bypassing the digestive system, which prevents the first-pass metabolism by the liver and thus preserves the drug's potency. Additionally, they are generally easier to administer compared to intravenous injections, requiring less expertise and fewer complications. However, IM injections can cause pain and discomfort, as well as potential risks of infection, nerve damage, and muscle injury if not performed correctly.

Pain resulting from needle insertion during IM injections is a common concern and can be attributed to several factors. The primary cause of pain is the mechanical trauma caused by the needle as it penetrates the skin and underlying muscle tissue. The sensation of pain can be heightened by the size and gauge of the needle, with larger or thicker needles typically causing more pain.

Nurses have a critical responsibility in reducing pain from needle insertion during IM injections by using a combination of techniques and patient care strategies. They must select the appropriate needle size and gauge based on the patient's muscle mass and the type of medication being administered and choose the

correct injection site to minimize pain. Nurses can also employ pain mitigation devices, such as the ShotBlocker as non-pharmacological methods or lidocaine sprays (to numb the area before injection) as pharmacological methods.

ChapterThree

Methods and

Materials

Chapter Three

Methods and Materials

This chapter explains the study methods and procedures used to determine the effect of lidocaine spray and shotblocker in minimizing pain associated with IM injections in adult patients. This chapter includes the following sections: study design, ethical considerations, clinical trial registry, setting, sample of the study, study instruments (questionnaire of socio-demographics and visual analog scale). body max index, pilot study, data collection method (preparing medication administration, blinding, length measuring tape and digital weight scale, shotblocker group, lidocaine spray group and control group) statistical data analysis and study limitations.

3.1. Study Design:

This study used a randomized controlled trial (RCT). It is considered the "gold standard" in research. It is the preferred method for evaluating the effectiveness of new interventions. The researcher uses a simple randomization procedure where participants will choose a color from a sealed envelope of three colors; each color corresponds to a group (blue for the ShotBlocker group, yellow for the lidocaine spray group, and green for the control group) and participants were allocated randomly among these three groups, this method ensures that each participant has an equal chance of being assigned to any group (randomization and non-bias). The study was carried out in the Emergency Departments with patients who had been prescribed (Diclofenac Sodium) by their physicians. The study was conducted over a specific period of time, from September, 2023 to June, 2024.

3.2. Ethical Considerations and Official Agreements:

This research was approved by the scientific research committee at the College of Nursing /University of Kerbala on November 19th, 2023,

(code: uok.con.23.519) (Appendix: A1). The researcher obtained approval from the Babylon Health Directorate of the Iraqi Ministry of Health (Training and Development Division) on December 27 th, 2023 (appendix: A2), and from the Imam Al-Sadiq General Hospital (Appendix: A3). After receiving verbal approval to participate in the trial. The researcher discussed the study's procedure and aims, as well as how to administer therapy, with the use of single-blind technique and choose one of three groups recruitment procedure and answered all queries on the research procedure methods. Participants were provided with written consent form. There will be no legal or financial repercussions for patients if they choose not to participate in the study, and their information will be kept privately. In addition, patients were informed that their participation was completely voluntary (Appendix: A4).

Clinical Trial Registration, as an essential part of original RCT, the trial protocol received approval for registration in the Iranian Registry of Clinical Trials (IRCT) on February 21st, 2024. The registration reference is IRCT2024 0127060820N1 (Appendix: B).

3.3. Setting:

This study was conducted for patients who were admitted to the emergency departments in Imam Al-Sadiq General Hospital in the Hilla city. The study was performed during the period between September, 2023 to June, 2024. Imam Al-Sadiq Hospital is one of the governmental hospitals in Babil Governorate. It is located in the city center (near Al-Tahmaziyah Bridge). The hospital is affiliated with the Iraqi Ministry of Health. It is consists of 492 inpatient beds, a number of clinics and specialized centers, and 18 operating theaters. The hospital was opened in 2017. The emergency department consists of a men's ward with 20 beds and a women's ward with 20 beds, works to provide the emergency care for patients and provide them with comfort during treatment. The hospital's emergency department handles a wide range of medical cases, from minor

illnesses to life-threatening emergencies, including cardiac, respiratory, neurological, and pediatric conditions, as well as infectious diseases, gastrointestinal issues, allergic reactions and anaphylaxis, poisonings, and overdoses.

3.4. Sample of the study:

The population under study consist of adult patients who were admitted to Imam Al-Sadiq General Hospital (emergency department) and were undergoing IM administration of diclofenac sodium.

3.4.1 Sample size:

The sample size was determined to be 150 participants. These patients were equally allotted to the control group and interventions groups. The sample size was calculated according to minimum sample size determination (Appendix: C). The minimum sample size was determined by calculating the number of participants required for the survey using a free sample size calculator. The calculator helps determine how many respondents are needed to achieve statistically significant results for a specific population. Find out how many survey invitations should send to obtain the required sample size.

3.4.2. Inclusion Criteria:

1. Adult patients between the ages of 18 – 60 years old.
2. Did not receive analgesics/sedatives during the past 24 hours.
3. Voluntary participated in the study.
4. Patient did not have fibrosis, wound, infection and tenderness in the injection site.
5. Patients who entered the Emergency Department and were prescribed analgesics by the physicians.
6. Patients who have in communicating and are fully conscious.

3.4.3. Exclusion Criteria:

1. Patients who are refused to participate in the study and how are participated in the pilot study.
2. Patients with communication difficulties or unconsciousness.
3. The presence of scars, redness, fibrosis, wounds, bruising, tenderness, and infections or stiffness at the injection site.
4. Patients who have Road Traffic Accidents (RTA), stab wounds, or bleeding injuries.
5. Patients receiving medication (analgesics or sedatives) intravenously or intramuscularly**.**
6. Presence of neuropathy**.**

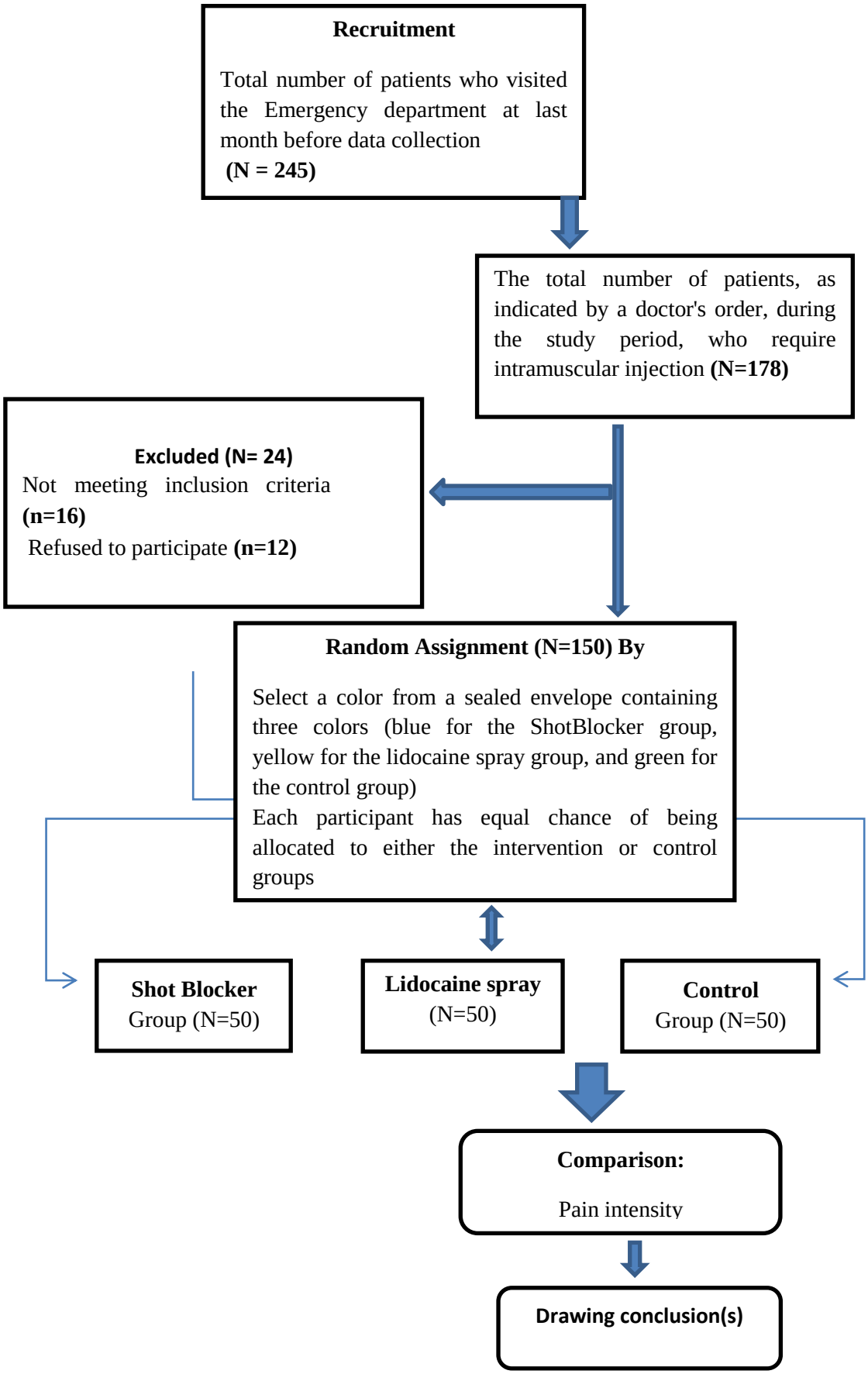

Fig. 3-1. Flowchart of Sample groups of interventional, control, and excluded patients.

3.5. Study instruments:

The study instrument consists of two parts: Part (1) includes a questionnaire for socio-demographic and medical data. Part 2: Visual Analog Scale (Appendix: D).

3.5.1. Questionnaire of socio-demographics and medical data 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, level of education, fear of needles during intramuscular injection, measurement of weight and height, alcohol drinker, smoking status). This questionnaire has not been translated into Arabic because information is collected during the interview.

3.5.2. Visual analog scale:

The visual analog scale has a long history and was initially called "graphic rating" and was first introduced in 1921, by two employees of the Scott Paper Company Hayes and Patterson, (1921) and Yeung, & Wong, (2019). The formal development and dissemination of VAS pain measurement by Huskisson, (1974). In his 1974 paper titled, “Measurement of Pain,” Huskisson described the use of a simple linear scale to measure pain intensity. This paper played a critical role in establishing VAS as a standard tool for pain assessment in research and clinical practice. Ever since, the VAS has been a common research and clinical tool in psychological medicine, especially for measuring pain.

There are four levels of pain severity: none (0 points); mild (1-3 points); moderate (4-6 points); and severe (7- 10 points). The subjects can indicate the level of their pain on the 10 cm-long scale, which has a left and right end for "no pain" and "severe pain," The scale's main benefit is that it doesn't require a language and is simple to use. It has no effect on the measurement's outcome whether the line's length or vertical or horizontal

alignment determine how the test is conducted (Huskisson, 1974; Hielm et al.,2011; Begum, 2019 and Bijur et al., 2001).

3.6. Validity and reliability of the instruments:

The Visual 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 (Begum & Hossain, 2019; Joseph & Palappallil, 2017 and Mandysová & Kadlečková, 2015).

The sixteen experts were invited to provide their thoughts and ideas about 9 items of the study questionnaire in terms of suitability, relationship to the dimensions of the study variables assigned to it, and the possibility of applying it to the environment of the study population (Appendix: E).

3.6.1. Pilot study:

The pilot study was carried out on individuals requiring IM injections prescribed by physicians in emergency departments, spanning from December 12th to December 25th, 2023. A total of 15 volunteers were included and divided into three groups: control (N=5), ShotBlocker (N=5), and lidocaine spray (N=5). Participants were chosen through a simple randomization method once they met all the criteria.

The objectives of the pilot study:

1. To assess questionnaire sections.
2. Observe participant response methods.
3. Gauge the time required for actual data collection.
4. Identify potential errors and obstacles encountered by the researcher.
5. Evaluate the effectiveness and feasibility of the recruitment approach.

The researcher using a random exploratory sample to measure the reliability of a tool, which is likely a instruments. Let's break down the process step by step:

1. **Selection of the sample**: The researcher randomly selected patients from a larger pool of potential participants. These patients were part of the study's exploratory sample.
2. **Anonymity**: The patients in the sample were not informed that they were part of a reliability study. This is to ensure that their responses are unbiased and not influenced by the knowledge of being included in the study.
3. **Initial instruments interrogation**: The researcher gave each patient a number from 1 to 15, probably to identify their responses uniquely. Then, the instrument (the tool being tested for reliability) was distributed to all patients.

3.7. Body mass index:

Body mass index (BMI) is a measurement of weight versus height. It is calculated by dividing the weight in kilograms by the square of the height in metres. It is the most widely used method of measuring obesity in adults. The World Health Organization states that the following parameters are used to classify nutritional status using the BMI:

- Underweight: BMI less than 18.5
- Normal weight: BMI 18.5–24.9
- Overweight: BMI 25–29.9
- Obesity : BMI > 30
- Obesity Class I (Moderate): BMI 30–34.9
- Obesity Class II (Severe): BMI 35–39.9
- Obesity Class III (Very Severe Obesity): BMI 40 or greater

(Regima et al., 2016 and KS, 2020).

3.8. Data collection method:

The study included adult patients who were chosen based on the study criteria. The study was carried out in the Emergency Departments with patients who had been prescribed Diclofenac Sodium by their physicians. Data collected between January 12th, Friday, 2024, and

February 26th, Monday, 2024. The researcher collects information from the participants using a questionnaire (socio-demographic and medical data), measuring the weight and height of the study participants. Follow that, the researcher uses convenience sampling and a simple randomization procedure where participants will choose a color from a sealed envelope of three colors; blue, yellow, and green. Each color corresponds to a group **(**blue for the ShotBlocker group {N=50}, yellow for the lidocaine spray group {N=50}, and green for the control group {N=50}**)**, and participants were be allocated randomly among these three groups, this method ensures that each participant has an equal chance of being assigned to any group (randomization and non-bias). The injection procedure and the randomization method for selecting one of the groups are discussed with participations. The researcher introduced the patients to the VAS pain intensity scale after 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 (DG) region of the buttocks for IM injection (Kilic et al. 2014). An emergency female nurse was trained to give IM injection to women group, whereas the researcher administers injection to males group. The data collection method is described in the following phases.

3.8.1. Preparing for medication:

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) need a 5-cc syringe, a 70 mm (.027 Inch) needle, 22 gages. 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 3 -2). The following products were **prepared for medication administration:**

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

(Table 3-2). Protocol of intramuscular injection:

Medication	Diclofenac Sodium75 mg/ 3
Injection Site	Dorso-gluteal muscle
Injection Volume	3 ml
Needle Size	22 gage, 70 mm (.027 IN)
Injection Site Cleaning	70% ethyl alcohol
Time of Injection Procedure	15 seconds
Injection Angle	90 degrees

3.8.2. Blinding:

It is recognized that implementing blinding, also referred to as "masking," is a crucial element in ensuring robust method quality, especially concerning the internal validity of randomized controlled trials (RCTs). In this experimental trial, blinding was employed as a technique to prevent performance bias and detection bias. In this experimental trial, the single-blind technique, was employed as the researcher needs to know how the subjects will be treated. Therefore, the study was done whereas the participants were unaware of the interventional group .The researcher conceals from the participants that these tools reduce pain. Instead, the researcher tells them that these are sterilization tools. With the use of this

blinding technique, the study results are well shielded from the subject knowledge of the treatment assignment.

3.8.3. Digital weight scale and hight measuring tape:

Measuring weight and height for patients in a study, a digital scale is used to measure the weight of patients. Due to their reliability, accurately and convenience, digital scales find common use in scientific investigations. Ensure that the scale is placed on a flat, stable surface. Direct the participant to step onto the scale, standing still with their feet evenly spaced and their weight evenly distributed. Ensure that they are not leaning on any surfaces or holding onto anything for support, record the weight displayed on the scale.

Study performed by Omar et al., (2014) demonstrated that scale digital weight provide digital measurements, usually displayed on an electronic display, making them accurate and easy to read (Appendix F).

Using a height measuring device (tape measure), ask the patient to stand with their back against the wall, and feet flat on the floor. After ensure that their posture is upright, with their head in a neutral position. Gently lower the measuring rod or tape until it makes firm contact with the top of the participant's head. Read the height measurement from the tape measure and record it.

Study conducted by Farahmand et al.,(2019) show tape measure is a flexible ruler made of metal or plastic, marked with units of measurement (such as inches, centimeters, or both) along its length. They usually feature a retractable mechanism that allows the band to be easily extended and retracted, making it convenient and comfortable. Portable tools for measuring lengths (Appendix: G).

3.8.4. ShotBlocker group:

ShotBlocker protruding surface is maintained in place during injection by pushing against the skin; the injection is carried out through the opening. 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, and then it can be sterilized and used for other patients.

Shotblocker is a plastic instrument in the shape of a C with a blunt protrusion contacting the skin on one side, allowing the medication to be administered through a wide opening (Hafez & Ali 2023) (Appendix: H).

3.8.5. Lidocaine spray group:

Applying lidocaine spray to the skin before IM injection. The skin is disinfected, after wiping the region with an alcohol swab and letting it dry. When applying lidocaine spray, two puffs of lidocaine (20 mg) were sprayed on the skin from a distance of approximately 5 centimeters. Because topical anesthesia caused by lidocaine spray occurs within 1 to 5 min after use, waiting 2 min for the vascular access procedure was performed. After sterilizing the region with an alcohol and lidocaine spray, the injection was conducted at the angle 90-degree.

Lidocaine Hydrochloride Spray 10% is widely used as a topical analgesic to relieve toothache or relieve injection pain (Sargolzaei et al., 2020) (Appendix: I).

3.8.6. Control Group:

Standard IM injection techniques were employed with this group using the same preparations expects for ShotBlocker and lidocaine spray. Including (22 gauges, 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, placing the needle at the injection site at a 90-degree angle to the skin. The medication was administered within 15 seconds (sec). After

the injection process, the patients were given a questionnaire to rate their pain level, using VAS, with (0) being no pain and (10) representing severe pain. Participant were a given to rate the pain resulting from the IM injection by placing a tick in front of the number indicating pain.

3.9. Statistical data analysis approach:

The researcher used SPSS-24 and Microsoft Excel (2010) to conduct a comprehensive statistical analysis of the study sample data and extract meaningful results**.** Accurate analysis of data, establishing variable correlation and applying a series of statistical tests are made possible by these programs. This method technique played a crucial role in obtaining the final results of the study, enhancing the strength and reliability of the study conclusions.

1. Descriptive approach:

Different types of mathematics and statistics descriptive statistics are used to show important features of data numerically, usually using tables and graphs. The main goal of descriptive statistics is to show and explain the data that needs to be processed, organized, summarized and put into groups. These techniques facilitate the communication of information in a straight forward and comprehensible manner, enhancing the ease with which recipients can recognize and understand the content. The analysis involves the utilization of the following methods:

A. Statistical tables, showcasing frequencies and percentages.

B. Presentation of the average score, denoted as M±.

C. Examination of Standard Deviation, represented as ±SD.

2. Inferential approach:

A. Independent Sample t-test:

The Independent Sample t-test, within the parametric framework catering to normal distributions, is used to identify dissimilarities in dependent variables associated with independent variables. It applies when

there are two categorical variables under consideration. The significance level of 0.05 aids in discerning whether statistical significance is present.

$$t = \frac{\mathbf{x\bar{}1 - x\bar{}2}}{Sp\sqrt{\mathbf{n1-1)s21 + (n2-1)s2/n1+n2-2}}}$$

B. Analysis of Variance (ANOVA):

This test is used to determine the differences in dependent variables with regards to independent variables (only with more than two class variables). At significant level (*Sig*.) 0.05 indicated the statistical differences.

C. Post Hoc Testes:

To prove the differences between three periods of measurement.

Period (I)	Period (J)	Mean Differences (I-J)	Std. Error	*Sig*.	95% Confidence Interval	
					Lower Bound	Upper Bound

D. Simple Linear Regression:

The Simple Linear Regression analysis serves the purpose of assessing which study variables hold predictive value. Here, a negative coefficient (-β) implies a negative prediction, while a positive coefficient (+β) indicates a positive prediction regarding the outcome.

$$\boldsymbol{r = mx + b}$$

E. Eta Square:

To investigate the effect size

$$\boldsymbol{\eta 2} = \frac{t2}{t2 + Df}$$

In which, the following effect size standards:

η2 < 0.1 were small effect size

η2= 0.1-0.6 were medium effect size

η2= > 0.6 were large effect size (Adams & Conway, 2021).

3.10. Limitations:

The fact that the study is new and the first in Iraq poses many challenges the first of which was the difficulty of obtaining the Shotblocker tool inside Iraq. Therefore, the researcher imported them via electronic transactions. In addition, emergency wards are designed for emergency situations, making it not feasible to conduct research experiments. The presence of morning consultation clinics also makes obtaining a sample during the morning difficult and problematic. Equally important, because of social traditions, it was difficult to recruit women as well as deal with them, which prompted the researcher to train the emergency female nurse to apply the correct method. Finally, only diclofenac sodium ampoule was tested in the present study. Therefore, the results of this study cannot be widely generalized to other drugs.

Chapter Four
Results of the Study

Chapter Four

The Results of the Study

Chapter four presents the findings of a randomized controlled trial (RCT), to compare the effect of lidocaine spray and ShotBlocker on reducing IM injection-related pain in adults. This chapter primarily focuses on presenting statistical figures and tables related to the study's main goals. The results are organized into three main sections. The first section includes tables for descriptive statistical analysis, followed by tables for statistical difference analysis in the second section. The third section explores the statistical relationship between pain level scores and patients' socio demographic data.

Section1: Descriptive Statistical Analysis:

The descriptive statistics of socio- demographic variables in lidocaine spray, shotblocker and control groups. With the present study's objectives, the findings incorporates both descriptive and inferential statistical include the following:

Table 4.1. Distribution of participants by their socio- demographic:

Characteristics	Categorize	Groups of Study					
		Lidocaine spray = 50		Shot-blocker = 50		Control = 50	
		N	%	N	%	N	%
Age/ years	18-20	4	8.0	4	8.0	3	6.0
	20-29	19	38.0	18	36.0	18	36.0
	30-39	17	34.0	18	36.0	18	36.0
	40-49	6	12.0	7	14.0	10	20.0
	50 -60	4	8.0	3	6.0	1	2.0
	Min—Mix	18—53		18—52		18—54	
	M ± SD	31.88±9.53		31.9±9.05		32.26±8.75	
Sex	Male	29	58.0	28	56.0	31	62.0
	Female	21	42.0	22	44.0	19	38.0
Residents	Urban	31	62.0	32	64.0	33	66.0
	Rural	19	38.0	18	36.0	17	34.0

Education level	Does not read and write	5	10.0	3	6.0	3	6.0
	Read and Write	4	8.0	4	8.0	4	8.0
	Primary Education	6	12.0	5	10.0	7	14.0
	Intermediate School	8	16.0	7	14.0	10	20.0
	Secondary School	12	24.0	14	28.0	13	26.0
	Bachelor Degree	14	28.0	15	30.0	12	24.0
	Postgraduate	1	2.0	2	4.0	1	2.0
Fear of needle during IM injection	Yes, I have	10	20.0	9	18.0	8	16.0
	No, Haven't	24	48.0	26	52.0	24	48.0
	I kind of have	16	32.0	15	30.0	18	36.0
	Underweight (<18.5)	0	0	0	0	0	0
BMI	Normal (18.5-24.9)	24	48.0	22	44.0	23	46.0
	Overweight (25.0-29.9)	13	26.0	14	28.0	20	40.0
	Obesity Class I (30–34.9)	13	26.0	14	28.0	7	14.0
	Obesity Class II (35–39.9)	0	0	0	0	0	0
	Obesity Class III (> 40)	0	0	0	0	0	0
Alcohol drinker	Currently	1	2.0	1	2.0	2	4.0
	Previously	4	8.0	5	10.0	6	12.0
	Never	45	90.0	44	88.0	42	84.0
Smoking	Currently	11	22.0	17	34.0	18	36.0
	Previously	5	10.0	4	8.0	4	8.0
	Never	34	68.0	29	58.0	28	56.0

N. Number; %= Percentage

Upon analysing the characteristics of the 150 patients enrolled in this study, categorized into three groups, several noteworthy distinctions

emerged. The Lidocaine spray group comprised patients aged 18 to 53, with an average age of 31.88±9.53years. Similarly, the shot-blocker group included participants within the age range of 18 to 52, with an average age of 31.9±9.05 years. The control group also had patients aged 18 to 54, with an average age of 32.26±8.75 years.

The majority of the Lidocaine spray (58.0%), shot-blocker (56.0%), and control (62.0%) groups were predominantly male. In terms of residence, urban residents were predominant in both lidocaine spray (62.0%), shot-blocker (64.0%), and control group (66.0%).

Regarding education level, patients with a Bachelor's degree constituted the highest percentage in the Lidocaine spray 28.0% and shot-blocker 30.0% groups, while secondary school graduates were more prevalent in the control group 26.0%. Fear of needle-related findings revealed that 48.0% of patients in the Lidocaine spray group demonstrated no fear, 52.0% in the shot-blocker group showed no fear, and (48.0%) in the control group exhibited no fear.

In terms of BMI, normal weight patients were predominant in both lidocaine spray, shot-blocker, and control groups, comprising 48.0%, 44.0%, and 46.0%, respectively. Findings associated with alcohol drinker indicated that the majority 90.0% in the Lidocaine spray group had never alcohol drinker, 88.0% in the shot-blocker group had never alcohol drinker and 84.0% in the control group had never alcohol drinker. Regarding smoking, 68.0% in the Lidocaine spray group had never smoked, 58.0% in the shot-blocker group had never smoked, and 56.0% in the control group had never smoked.

Table 4-2. Pain levels of intramuscular injection among study groups:

Groups	Score	No.	%	Min.	Max.	M ± SD	Eva.
Lidocaine spray	No pain	12	24.0	0	4	1.27 ± 1.340	Mild
	Mild	33	66.0				

	Moderate	5	10.0				
	Sever	0	0.00				
Shot-blocker	No pain	32	64.0	0	3	0.54 ± 0.838	No pain
	Mild	18	36.0				
	Moderate	0	0.00				
	Sever	0	0.00				
Control	No pain	4	8.0	0	7	4.46 ± 2.022	Moderate
	Mild	9	18.0				
	Moderate	28	56.0				
	Sever	9	18.0				

Min.: Minimum; Max.: Maximum, M: Mean for total score, SD=Standard Deviation for total score

Level of Pain Assessment [No pain <1; Mild= 1-3; Moderate 4-6; Sever= 7-10]

The study findings reveal varying responses among patients concerning their pain levels during intramuscular injection. A large proportion (66%) reported experiencing mild pain after receiving Lidocaine spray, with scores ranging from 0 to 4 on the assessment scale, as indicated by an average score of (*1.27 ± 1.340*). Conversely, a substantial portion (64%) of patients who received the shot-blocker expressed no pain, with scores ranging from 0 to 3 on the assessment scale and an average score of (*0.54 ± 0.838*). Moreover, 56% of patients in the control group reported a moderate level of pain, with scores ranging from 0 to 7 on the assessment scale, reflected in an average score of (*4.46 ± 2.022*).

Table 4-3. Comparison the effect of an lidocaine spray on pain level among patients during intramuscular injection:

Groups	No.	M	SD	t-value	d.f	η2	P -value
Lidocaine spray	50	1.27	1.3407	7.985	98	.39	.000

Control	50	4.46	2.0243				

. M: Mean, SD: Standard deviation, t: t-test, d.f: Degree of freedom, η^2= Eta squared; Sig: Significance level at 0.05.

The results of the independent sample t-test revealed statistically significant differences in pain levels between two groups: patients who received Lidocaine spray (mean ± SD: 1.27 ± 1.340) and those who did not receive Lidocaine spray (mean ± SD: 4.46 ± 2.022). The obtained t-value of 7.985 was associated with a p-value of 0.000, indicating positives effect of reducing pain. Additionally, the effect size, represented by $\eta^2 = 0.39$, further emphasizes the substantial impact of Lidocaine spray administration on reducing pain.

Table 4-4.Comparison the effect of an shot-blocker on pain level among patients during intramuscular injection:

Groups	No.	M	SD	t-value	d.f	η2	P -value
Shot-blocker	50	0.54	.838	12.661	98	.62	.000
Control	50	4.46	2.022				

M: Mean, SD: Standard deviation, t: t-test, d.f: Degree of freedom, η^2= Eta squared; Sig: Significance level at 0.05.

The results of the independent sample t-test revealed statistically significant differences in pain levels between two groups: patients who received shot-blocker (mean ± SD: 0.54 ± 0.838) and those who did not receive shot-blocker (mean ± SD: 4.46 ± 2.022). The obtained t-value of 12.661 was associated with a p-value of 0.000, indicating positives effect of reducing pain. Additionally, the effect size, represented by $\eta^2 = 0.62$, further emphasizes the substantial impact of shot-blocker administration on reducing pain.

Table 4-5.Comparison the effect of an lidocaine spray and Shotblocker on pain level among patients during intramuscular injection:

Groups	No.	M	SD	t-value	d.f	η2	p- value
Lidocaine spray	50	1.27	1.340	5.277	98	.22	.000
Shot-blocker	50	0.54	.838				

. M: Mean, SD: Standard deviation, t: t-test, d.f: Degree of freedom, η^2= Eta squared; Sig: Significance level at 0.05.

The results of the independent sample t-test revealed statistically significant differences in pain levels between two groups: patients who received Lidocaine spray (mean ± SD: 1.72 ± 1.340) and those who received shot-blocker (mean ± SD: 0.54 ± 0.838). The obtained t-value of 5.277 was associated with a p-value of 0.000, indicating positives effect of reducing pain. Additionally, the effect size, represented by $\eta^2 = 0.22$, this emphasizes that the shot-blocker administration are more reducing pain than the lidocaine spray.

Table 4-6. Multiple comparison of pain level between groups of lidocaine spray, shot-blocker and control groups:

(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	P -value
Lidocaine spray	Shot-blocker	1.18000*	.29643	.000
	Control	-2.74000-*	.29643	.000
Shot-blocker	Lidocaine spray	-1.18000-*	.29643	.000
	Control	-3.92000-*	.29643	.000
Control	Lidocaine spray	2.74000*	.29643	.000
	Shot-blocker	3.92000*	.29643	.000

*. The mean difference is significant at the 0.05 level

The results reveal substantial variations in pain levels experienced during intramuscular injections among patients administered Lidocaine spray, shot-blocker, and the control group (p= .000 for all). Specifically, recipients of Lidocaine spray exhibited significantly different pain levels compared to those who received shot-blocker and the control group (p= .000). Similarly, the pain experienced by patients in the shot-blocker group demonstrated statistical differences when compared to those who received Lidocaine spray (p= .000) and the control group (p= .000). Additionally, the pain levels within the control group were statistically distinct from both Lidocaine spray recipients (p= .000) and those who received shot-blocker (p= .000).

Table 4-7. Factors prediction pain level among patients received lidocaine spray:

Variables	Unstandardized Coefficients		Standardized Coefficients	T	*P - value*
	B	Std. Error	Beta		
Age	.028	.023	.196	1.189	.242
Sex	.514	.490	.191	1.050	.300
Residency	.094	.266	.057	.352	.726
Education level	-.159-	.149	-.201-	-1.072-	.290
Fear of needle during IM injection	-.309-	.291	-.166-	-1.062-	.295
BMI	-1.600-	-.003-	-.113-	-2.091-	.028
Alcohol drinker	.881	.580	.253	1.520	.137
Smoking	-.026-	.282	-.016-	-.091-	.928

Dependent Variable: Pain Level

The results of a simple linear regression test revealed that BMI emerged as a significant predictive variable for pain levels among patients administered Lidocaine spray (*β = 0.113; p = .028*). Conversely, factors including age, sex, residency, education level, fear of needle from intramuscular (IM) injection, alcohol drinker and smoking were found to be non-predictive variables for pain levels among patients receiving Lidocaine spray (p > 0.05).

Table 4-8. Factors Prediction Pain Level among Patients Received Shot-blocker:

Variables	Unstandardized Coefficients		Standardized Coefficients	T	*P – value*
	B	Std. Error	Beta		
Age	.000	.018	-.005-	-.024-	.981
Sex	-.327-	.342	-.195-	-.956-	.345
Residency	.272	.242	.157	1.123	.268
Education level	-.067-	.082	-.127-	-.816-	.420
Fear of needle during IM injection	.085	.171	.070	.498	.621
BMI	-1.602-	-.203-	-.674-	-2.966	.005
Alcohol drinker	.101	.327	.049	.308	.760
Smoking	.095	.170	.095	.556	.582

Dependent Variable: Pain Level

The results of a simple linear regression test revealed that BMI emerged as a significant predictive variable for pain levels among patients administered shot-blocker (*β = -0.674; p = .005*). Conversely, factors including age, sex, residency, education level, fear of needle during intramuscular (IM) injection, alcohol drinker and smoking were found to

be non-predictive variables for pain levels among patients receiving shot-blocker ($p > 0.05$).

Table 4-9. Factors Prediction Pain Level among Patients in Control Group:

Variables	Unstandardized Coefficients		Standardized Coefficients	T	*P - value*
	B	Std. Error	Beta		
Age	-.004-	.046	-.015	-.077-	.939
Sex	1.542	.648	.374	2.381	.052
Residency	-.333	.542	-.079	-.615-	.542
Education level	-.118	.192	-.089	-.614-	.543
Fear of needle during IM injection	.130	.391	.045	.333	.741
BMI	-1.530	-.607	-.374	-2.521	.016
Alcohol drinker	-.054	.093	-.098	-.574-	.569
Smoking	-.279	.383	-.131	-.729-	.470

Dependent Variable: Pain Level

The results of a simple linear regression test revealed that BMI ($\beta = -0.374$; $p = .016$) emerged as a significant predictive variable for pain levels among patients in the control group. Conversely, factors including age, sex, residency, education level, fear of needle during intramuscular (IM) injection, alcohol drinker and smoking were found to be non-predictive variables for pain levels among patients receiving shot-blocker ($p > 0.05$).

Chapter Five

Discussion

Chapter Five

Discussion of the Study Results

The clinical trial results are discussed and supported in this chapter along with their significance in relation to the goals of the study. The study aimed to the utilization of pharmacological and non-pharmacological approaches for pain management, specifically the effect of lidocaine spray and ShotBlocker in relieving pain produced by intramuscular injection in adult patients. This chapter seeks to answer the research question: Which ShotBlocker or Lidpcaine Spray approach is most effect in relieving pain caused by intramuscular injection?

The chapter reflects the structure of Chapter Four, which includes four main sections. The initial section provides a discussion of the socio-demographic and medical data (percentage and frequency) across all groups. Subsequently, the second section addresses statistical differences in variables related to pain response between the lidocaine spray, shot-blocker, and control groups. The third section compares the effects of lidocaine spray and shot blocker on pain levels among patients during intramuscular injection. Finally, Section fourth discusses the relationship between socio-demographic and medical data and pain scores among patients in the lidocaine, shot-blocker and control groups.

5.1. Discussion of the Socio-demographic and medical data distribution (percentage and frequency) in All Groups.

According to the data presented in (Table 4-1), Lidocaine spray group comprised patients aged 18 to 53, with an average age of 31.88±9.53 years, Similarly, the shot-blocker group included patients within the age range of 18 to 52, with an average age of 31.9±9.05 years. The control group also had patients aged 18 to 54, with an average age of 32.26±8.75 years.

The outcome of lidocaine spray group (table 4-1) is inconsistent to a previous investigation by Hoseini et al., (2022) study to evaluate the effect of lidocaine spray and acupressure on the intensity of pain induced by intramuscular (IM) injection. The mean age of participants in the lidocaine spray group was 34.14±10.15 years.

The results of shotblocker group (table 4-1) are inconsistent with study performed by Aydin & Avşar, (2019), to determine the efficacy of ShotBlocker in relieving pain caused by intramuscular injections, which found that approximately two-thirds (60%) of participants were between 18 and 28 years, with a mean age in shotblocker group of 27.64±5.14. finding differs from previous research

The results of control group (table 4-1) are conducted by Bilge et al., 2019, which study to compare the effectiveness of cold spray and ShotBlocker for relieving pain associated with intramuscular injections in adults. The mean age in control group was 38±13 years, with a range from 29 to 42, this result differs from our study.

The outcomes of this study were not surprising to the researcher, as young individuals are actively involved in community a activity, which increases their exposure to accidents and admission hospital compared to other age groups. Yousif et al., (2022), reported that young people being more involved in physical and hard work in society compared to other age groups, and thus their chances of being exposed to accidents are greater than others.

A large proportion of the lidocaine spray groups (58.0%) consisted mostly of males, a significant percentage of the shot-blocker groups (56.0%) were predominantly male and the majority of the patients of the control group (62.0%) were mostly male (Table 4-1).

This result of lidocaine spray group (table 4-1) is comparable to the previous investigation. Arab et al., (2017) conducted a study to compare the impact of hegu point ice massage and 2% lidocaine gel on fistula-

associated arteriovenous puncture-related pain in patients receiving dialysis. In the lidocaine group, there were 20 males (57.2) and 15 females (42.8).

The outcomes of ShotBlocker groups (table 4-1) contradict to the previous study undertaken by Hafez & Ali, (2023), to investigate the effectiveness of ShotBlocker against cryotherapy in minimizing anxiety and pain related with subcutaneous injection, furthermore, the research reported that women represented 55.6% in ShotBlocker groups.

Another study, performed by Yilmaz (2016), that is compatible with the current research, it found that 60.9% of the ShotBlocker sample were male and 39.1% were female.

In the control group results (table 4-1) agree with previous study carried out by Gürdap & Cengiz (2022), consistent with a randomized controlled trial in Turkey, the sex variable indicates that 59.4% of those who participated in the control group were male.

The outcomes of this investigation were anticipated by the researcher. Predominantly, males are employed in physically demanding activities that involve increased exposure to harm or disastrous events. Griffiths et al., (2019), reported that boys, but not girls, who participate in more intense physical activity are more likely to be admitted to the hospital due to an injury-related accident or to visit the emergency room than their less active counterparts. This may reflect sex differences in the type of activities undertaken and the risks associated with them.

The prevalence of urban residents in both the lidocaine spray and control groups was 62.0% and 66.0%, the number of urban residents who use shot blocks were 64.0% (Table 4-1).

The results of lidocaine spray group (table 4-1) are compatible with study by Arab et al., (2017), to investigate the impact of 2% lidocaine gel and ice Hijo point massage on pain associated with arteriovenous fistula punctures in hemodialysis patients. The study found that the lidocaine

group in the city was (62.85) and the village was (37.14), while the control group in the village was (34.28) and the city was (65.71).

The outcomes of shot blocks group (table 4-1), are comparable with study conducted by Karkhani et al., (2023), a randomized, single-blind, controlled study to assess the influence of using local pressure on the level of pain associated with needles administered via spinal anesthesia. In this research, urban resident in the study group included participants 47 (79.7), while the control group included 48 (81.4).

The researcher explains why most of the patients are in the urban residence because the place where the research is being conducted is located in the city, so most of the participants are from the city.

As for the educational level, individuals with a bachelor's degree had the highest percentage of lidocaine spray group (28.0%), and the highest percentage of a bachelor's degree (30.0%) was indicated in the shotblocker group, while secondary school graduates were more prevalent in the control group (26.0%) (Table 4-1).

The outcomes of lidocaine spray groups (Table 4-1), are consistent with study performed by Liu et al., (2021), to compare the auricular point acupressure and compound lidocaine cream to alleviate the discomfort associated with arteriovenous fistula puncture. The study show in the lidocaine group is predominant bachelor's degree 12 (40.00)

The findings in the shot-block group (Table 4-1), are compatible with the results of a Randomized Controlled Trial conducted in Turkey, wherein nearly one-fourth (23.1%) of the participants possessed a bachelor's degrees (Gürdap& Cengiz, 2022).

While in the control group (Table 4-1), results differs slightly from another study conducted by Abdelkhalek, (2019), where the highest percentage (21.4%) were of people with intermediate education.

The researcher was not surprised by the findings mentioned above. This is because individuals with higher levels of education usually possess

knowledge about managing their own health and the health of their families. These individuals are expected to have access to healthcare resources, are more likely to request emergency department visits during urgent situations, and thus can utilize essential medical services. This supported with study performed by Mahoney et al., (2018) reported that higher education levels are associated with increased emergency department visits, better handling of urgent cases, and improved access to medical services through educational and follow-up efforts.

Fear of needle-related findings revealed that 48.0% of patients in the lidocaine spray group demonstrated no fear, 52.0% in the shot-blocker group showed no fear, and 48.0% in the control group exhibited no fear table (4-1).

Results regarding fear of needles of the lidocaine spray group (table 4-1), contradicts a study performed by Abdelkhalek (2019), to examine the impact of employing ShotBlocker and Z-Track strategies on lowering needle pain and stress among adults receiving intramuscular injections, based on the study, lack of fear is prevalent in the study group (10, 33.3%).

Results regarding fear of needles of the shot blockers group (table 4-1), this result is compatible with a study performed in turkey, which aimed to investigate the influence of the Helper Skin tap technique and ShotBlocker use on pain via intramuscular injection, revealed that the largest percentage of patients (75%) do not have any fear towards intramuscular injections (Karabey & Karagözoğlu, 2021).

Results in the control group (table 4-1), are compatible to a study conducted by Bilgic, (2021) which aimed to assess the efficacy of local cold and manual pressure interventions in mitigating injection pain among patients. In that study, 68.9% of the participants reported no fear of injections, which is the most prominent finding.

The researcher's opinion to justify this result, that fear of IM injection is a variable that reflects individual attitudes and some of

participants do not acknowledge the fear of intramuscular injection because it causes embarrassment to them.

Normal weight individuals represented the largest percentage in both lidocaine spray group, (48.0%), shot-blocker group (44.0%) and in the control group (46.0%) (Table 4-1).

The results of lidocaine spray group (Table 4-1), agree with a randomized, controlled study conducted by Zhu et al., (2023), to examine the of impact lidocaine spray on reducing pain associated with non-bore needle puncture in participants with a fully implanted venous access port. The body mass index (kg/m2, x±s) for the lidocaine spray group was 21.72 ± 3.90, while the control group had 22.37 ± 3.90.

Outcomes in the shotblocker group (Table 4-1), are agreement with the study done by Emel et al., (2017), to investigate the influence of ShotBlocker on alleviation of pain for hepatitis B vaccination in the deltoid muscles in adults, normal weight in the Shotblocker group was 21.5±3.26

Results in the control group are compatible with a study performed by Merve Kolcu et al., (2021), to examine into the impact of shotblockers on anxiety, pain, and satisfaction levels in chronic spontaneous urticarial patients who received subcutaneous injections, normal weight in the control group was 13 (43.3%). In this specific area of study, the results were expected, and the association between the results and normal weight is mainly because the vast majority of participants fell within the age range (18-31), which is usually the age group most likely to be in which individuals have a normal maximum body index.

Results associated with alcohol drinker indicated that the majority (90.0%) in the Lidocaine spray group had never alcohol drinker, (88.0%) in the shot-blocker group had never alcohol drinker, and (84.0%) in the control group had never alcohol drinker (table 4-1).

The outcomes of Lidocaine spray group (table 4-1), are disagreement with a prospective, randomized controlled trial performed by

Mahawongkajit et al., (2021), to compare the effectiveness of lidocaine spray versus lidocaine ice Popsicle in patients undergoing non-sedated esophagogastroduodenoscopy. A total of 204 patients were evaluated, with 29 (28.43%) receiving lidocaine spray and 34 (33.33%) receiving lidocaine ice, with no alcohol consumption noted in either group.

Findings associated with alcohol drinker in the shot-blocker and control groups (table 4-1), these results contrast with the study conducted by Scott et al. (2018), who noted that moderate alcohol intake can lead to better health outcomes in chronic pain patients. In this study, it was noted that 659 - 34% of individuals in the control group and 157 - 32% in the study group did not consume alcohol.

The different between current and previous study is an expected, high percentage of participants who do not drink alcohol because the society and cultures are different. The majority of society is committed to the Islamic religion and considers alcohol to be forbidden and society does not encourage it. There are also legal issues, so even if he was drinking he denies it. Guo et al., (2024) reported that alcohol-related disorders are linked to specific cultural elements, such as ideas, attitudes, laws and beliefs related to drinking alcohol. It is possible for the expectations and beliefs of a culture to change. There are initial indications of a shift from previously positive and integrated drinking cultures to more negative and ambivalent beliefs in many countries, especially in Europe. This trend has the potential to contribute to an increase in alcohol-related issues.

In terms of smoking status, 68.0% of patients in the lidocaine spray group had never smoked, while 56.0% in the control group had never smoked, in the shot blocker group 58.0% of patients had never smoked.

The result of lidocaine spray group (table 4-1), is consistent with a multicenter randomized controlled trial, conducted by Liu et al., (2021), to determine auricular point acupuncture combined with lidocaine combination cream for the management of arteriovenous fistula

perforation pain, Within these investigations, the control group consisted of 14 (46.67%) smokers and 16 (53.33%) non-smokers. In the lidocaine group, 12 (40.00%) were smokers and 18 (60.00%) were non-smokers.

Results in the shot blocker group (table 4-1), is consistent with the research performed by Karkhanei et al., (2023 a single-blind, randomised, controlled clinical trial examining the impact of local pressure on the level of pain experienced during needle punctures during anaesthesia for individuals undergoing elective surgery with spinal anesthesia, this study revealed that 68.3% of the participants in the control group and 61.7% in the study group did not smoke.

The researcher's opinion to justify the results, differing demographics and medical histories of participants across groups may have contributed to differences in smoking, and furthermore. Increasing health awareness about the harms of smoking may lead to lower smoking rates among participants,

The researcher's opinion is supported with previous study conducted by Alzuhery, (2021) reported that the rising rate of smoking is a concerning sign for the health of current and future generations, and is a direct result of the lack of knowledge these people have about the negative effects of smoking.

5.2. Comparison the effect of a lidocaine spray and shot-blocker on pain level among patients undergo intramuscular injection:

The study findings reveal varying responses among patients concerning their pain levels during IM injection. A significant proportion (66%) reported experiencing mild pain after receiving Lidocaine spray, with scores ranging from 0 to 4 on the assessment scale, as indicated by an average score of (1.27 ± 1.340) (Table 4-3), while the patients who received shot-blocker (mean ± SD: 0.54 ± 0.838), the obtained t-value of 12.661 was related to p-value of 0.000, showing a significant result (positive effect on reducing pain). Additionally, the effect size, represented

by $\eta^2 = 0.62$, further emphasizes the substantial impact of shot-blocker administration on reducing pain (Table 4-4). Conversely, 56% of patients in the control group reported a moderate level of pain, with scores ranging from 0 to 7 on the assessment scale, reflected in an average score of (4.46 ± 2.022), the control group was non-significant ($p > 0.05$) (Table 4-3).

There is no previous study comparing between shotblocker and lidocaine spray, this is the first study comparing between them, the results showed that Shot Blocker had a greater effect than lidocaine spray in reducing pain during IM injection.

The results are consistent with previous studies, results showed a positive effect of lidocaine spray in reducing pain during IM injection, these results are similar to a previous investigation by Jamalinik et al., (2023) also used the VAS to assess the influence of lidocaine and cold spray on the degree of pain during IM injection. Statistical tests indicated a significant difference in pain level, the average pain score was 3.44 in the control group, while in the study group it was 2.63.

Similarly, this is compatible with results. Hoseini et al., 2022, conducted a study to evaluate the impact of lidocaine spray and acupressure on the degree of pain induced by IM injection. Both the acupressure group (1.83 on the pain level scale) and the lidocaine spray group (1.78 on the scale) reported less pain than the control group (2.83). These approaches resulted in a clinically significant decrease average degree of pain when compared to the control group.

Khosravi et al., (2023), conducted a study to examine if hemodialysis (HD) patients experienced less pain during needle insertion when treated with cooling or lidocaine sprays by using a randomized cross-over design, the results of this investigation demonstrated that lidocaine spray is useful in alleviating pain produced by HD needles.

Hoseini et al., (2022), found that the acupressure and lidocaine spray both effectively reduced IM pain, the average degree of pain scores in

the lidocaine spray group (1.78) and acupressure group (1.83) were less than the results in the control group (2.83).

Dalvandi et al., (2017) in a study using a controlled clinical trial with a crossover design aimed to compare the effectiveness of vapor cooling spray and lidocaine/procaine cream in reducing pain during intravenous cannulation. Intravenous cannulation pain was significantly reduced after application of EMLA cream and vaporizer spray compared to the control group. Jamalinik et al., (2023), indicated both cold and lidocaine spray can significantly lower the degree of IM injection discomfort, the average degree of pain was 3.44 control group, 2.63 with lidocaine spray, and 2.27 with ice spray.

To justify this results, lidocaine spray, which acts as a local anesthetic, primarily impairs the transmission of nerve messages by inhibiting voltage-dependent ion channels. This action reduces stimulus-induced depolarization and prevents the potential from reaching its threshold. Zdybski & Grodzka (2018), reported that the Lidocaine spray has the ability to alleviate various forms of pain by obstructing the transmission of pain signals from the nerves in the skin. When nerves are obstructed, it results in a perception of numbness or a brief absence of sensation.

Likewise, ShotBlocker, previous results showed good effectiveness in reducing pain during IM injection, This finding is supported by Aydin and Avşar's (2019) and also used the VAS to assess the impact of ShotBlocker for alleviating pain level during IM injection, and found that the mean pain score of the ShotBlocker group was lower than that of the control group.

Likewise, Sahan & Yildiz., (2022), in order to provide evidence-based practice, this meta-analysis study aimed to identify the effects of using ShotBlocker while injecting adults intramuscularly, which shows that

ShotBlocker was effective in decrease pain related to injections of IM in adults.

Bilge et al., (2019), indicated to ShotBlocker is a non-drug approach that effectively relieves the pain associated with IM injection and shows efficacy similar to cold spray, the scores of Shot-Blocker (11 mm) and cold spray (10 mm) on the visual analog scale were lower than those of the control group (31 mm).

Sahan, & Yildiz, (2022), performed a meta- analysis study to investigate the effect of using ShotBlocker during IM injection administration in adult patients in order to provide evidence-based practice. The study indicated that administering ShotBlocker via IM injection in adult patients reduced pain intensity.

Yildirim & Dinçer, (2021), employed a randomized, controlled, double-blind approach. This study indicates that ShotBlocker can reduce injection pain and improve patient satisfaction.

Savcıc et al., (2022), conducted a study to examine the effects of ShotBlocker and local vibration on reported pain and satisfaction during intramuscular antibiotic injections, application of local vibration and dosing was found to be most effective in reducing pain and enhancing satisfaction after intramuscular antibiotic injections compared to control groups.

Hafez & Ali, (2023) in a quasi-experimental study design was used with a purposive sample of 54 participants of both sexes. The use of cryotherapy and ShotBlocker procedures during subcutaneous injection resulted in significant reductions in pain and anxiety scores. Furthermore, the ShotBlocker group had significantly lower pain and anxiety scores than the cryotherapy group.

The researcher's opinion is to justify this result, ShotBlocker functions on the basis of the pain gate control theory. It causes pressure to the skin, which activates the nerves and distracts the brain from receiving pain signals from the injection. Bilge et al., (2019), that utilizing some

techniques, like ShotBlocker, can reduce the pain sensation caused by injections. Because these technologies work through mechanisms supported by the gate control theory, theory suggests that the spinal cord can modulate the transmission of pain signals from the nerves to the brain. By activating and stimulating peripheral receptors, the experience of pain is further mitigated.

Several studies have found that ShotBlocker reduces pain during injection, but effectiveness may vary based on individual pain tolerance and injection technique (AL-Shammiry & Sadeq 2024 and Sedat et al., 2019).

Lidocaine spray can also relieve pain during injection by numbing the skin, but its effectiveness may be affected by factors such as skin thickness, depth of injection, and individual sensitivity to the drug (Mahawongkajit et al., 2021).

5.3. Discuss how effect socio-demographic and medical data to pain levels among patients in the lidocaine spray, shot-blocker, and control groups.

The study examined the statistical difference of patient's socio-demographic characteristics for response to pain in the lidocaine spray group ($p > 0.05$).

The study result show that significant difference between body max index (BMI) and pain intensity (Table 4-7) in the lidocaine spray group ($\beta = 0.113$; $p = .028$), also the shot-blocker group (Table 4-8), show that significant difference between BMI and pain intensity $\beta = -0.674$; $p = .005$ and control group (Table 4-9), outcomes illustrate that significant difference between pain intensity and body max index (BMI) ($\beta = -0.374$; $p = .016$).

The lidocaine spray group findings are inconsistent with the outcomes of study by Bedel et al,. (2022), to illustrate vapocoolant spray effectiveness in mitigation of pain via injection of intramuscular , these

study demonstrated no significant distinction between body max index (BMI) and pain score (p-value 0.183).

The difference between previous and current study because many factor may contribute to the effect on pain intensity such as previous experience, emotional state and practitioner experience, these conflicting outcomes show that more investigation is needed.

The shot-blocker group study result was supported by Sahin & Eşer (2018), a randomized controlled experiment with single-blinding was the study's design. The purpose of the research was to examine how the Buzzy usage affected on pain level and satisfaction throughout intramuscular injections. The results showed that, based on the participants' BMI values, there was a significant variance in the study group's post-injection pain mean scores ($p < .05$).

To explain these results, the researcher believes, Individuals with a higher BMI are likely to have more adipose tissue. Adipose tissue contains fewer nerve endings than other types of tissue. Therefore, in areas with a high percentage of fatty tissue, there may be fewer nerves that transmit pain signals, resulting in decreased pain perception. Torensma et al., (2017) reported that adipose tissue has fewer nerve terminals than other types of tissues.

The results showed that age groups have no statistically significant difference in pain intensity of both groups of lidocaine spray (p-value 242) (Table 4-7), shotblocker group (p-value =.981), (Table 4-8) and control group (p-value =.939) (Table 4-9) and also there is no significant variation in severity of pain between groups of ages. These outcomes of the study (lidocaine spray group) compatible with study by Jamalinik et al., (2023) and Bedel et al., (2022), demonstrates that there is no of statistical significance variation in level of pain between age groups.

The finding of shotblocker group is consistent with other studies conducted by Bilge et al., (2019) Gürdap & Cengiz, (2022) and

Abdelkhalek, (2019), show that there is no significant variation in severity of pain between age groups.

Researcher believes in general, age-related changes in pain perception, these changes are not always consistent or significant across studies or individuals. Other elements, such as psychological factors, individual differences, pain thresholds, and anxiety levels, can have a greater impact on how painful an intramuscular injection feels. Hird et al., (2019) reported that the amount of pain experienced during an intramuscular injection can be further influenced by psychological variables, individual differences, pain thresholds, and anxiety levels.

The sex groups have no statistically significant in pain score in the lidocaine spray group (p-value .300) (table4 -7). In the shot-blocker group (Table 4-8), research findings demonstrated that sex groups have no significant variation in pain intensity (p= .345) and also in the control group not differ statistically significantly between pain intensity and sex groups (p-value .022), (tables 4-9).

The finding of lidocaine spray group is consistent with other studies conducted by Gürdap & Cengiz, (2022) and Abdelkhalek, (2019), indicates that there is no statistically significant relationship between sex groups and pain levels.

The results of the shotblocker group are similar with other research undertaken by Aydin & Avşar, (2019) and Bilge et al., (2019) appears that there is no statistically significant relationship between sex groups and pain levels.

The researcher explains that there are no differences in perception of pain between males and females due to psychological, individual coping strategies, social and cultural factors may always have a significant impact on pain perception during intramuscular injection. Aufiero et al., (2017), reported that there are many aspects that can change the way someone

experiences pain, such as coping techniques, social, cultural factors, psychological and past pain situations, can affect how you feel.

The outcomes (table 4-7) demonstrate that no significant variation between level of education and pain intensity in lidocaine spray group (p-value .290) the outcomes indicated that there was actually no significant correlation in the ShotBlocker group (p-value =.420) between educational level and pain severity (Table 4-8) and the results indicate that no significant variation between pain intensity (Table 4-9) and level of education in control group (p-value .543).

In lidocaine spray group the outcomes are consistent with past investigation performed by Abdelkhalek, (2019) and Aydin & Avşar, (2019), that appears to be no statistically significant relationship between educational level groups and pain levels.

The findings in the ShotBlocker group are consistent with previous research conducted by Gürdap & Cengiz, (2022); Abdelkhalek, (2019) and Aydin & Avşar, (2019), indicates that there is no statistically significant relationship between educational level groups and pain levels.

In the control group findings are consistent with prior investigation performed by (Bilgic, 2021; Aydin & Avsar, 2019), that appears to be no statistically significant relationship between pain levels and educational level groups.

The researcher's opinion on this finding is expected because the higher proportion of participants with higher educational levels may have resulted in increased exposure to medical procedures and increased knowledge with the sensations associated with injections. Because of their knowledge and experience, they may be able to handle stress and coping mechanisms during intramuscular injections more effectively, which may reduce their discomfort. Diotaiuti et al., (2021), reported that people who have their own knowledge and experience may be able to deal with stress and coping

mechanisms so they express less pain or discomfort during medical procedures.

Regarding fear of (IM) injection, (Table 4-7) the study result was analyzed by simple linear regression test in the lidocaine spray group. The outcomes of the study illustrate that there were no statistically significant relationship between pain score and fear of injection (p value .295) also in the shotblocker group (Table 4-8) the study result show that there was no significant difference of statistical in fear of IM injection and pain score (p-value .621) and The outcomes of the study in control group (Table 4-9), demonstrate that there is no statistically significant relationship between fear of injection and pain level (p value .741).

The study outcomes of the lidocaine spray group were supported by Gürdap & Cengiz, (2022) and Abdelkhalek, (2019), shows that there is no statistically significant correlation between fear of injection groups and pain levels.

The study result of shotblocker group was supported by Gürdap & Cengiz, (2022) Abdelkhalek, (2019) and Aydin & Avşar, (2019), indicated that there is no significant relationship between pain levels and fear of injection groups.

Researcher discuss this finding, fear of injections may lead to psychological distress or anxiety about the procedure, but this does not always translate directly into an increase in pain perception. Also the fear of intramuscular injection represents a person's attitudes. Hird et al., (2017) showed that psychological distress and pain perception are related but different constructs, and individuals may experience one without necessarily experiencing the other to the same degree.

In the lidocaine group (Table 4-7), indicated that residency had no significant effect on the patient's pain score (p=.726), in the shotblocker group (Table 4-8) The outcomes of the study illustrate that there were no statistically significant relationship between pain score and residency (p

value (0.816)) and the control group (Table 4-9), indicated that residency had no significant effect on the patient's pain score (p=.542).

The results of lidocaine group are similar to previous research performed by Heshmatifar et al., (2022) and Karabey & Karagzolu, (2021), study show that residency did not have statistical significant impact on mitigation the pain level.

The study outcomes of shotblocker group were supported by Karkhanei et al., (2023), show that residency did not have significant correlation effect on alleviating the pain level.

The researcher is not surprised by these results because many factors influence on pain perception such as individual characteristics, psychological factors, and cultural. While residence status may affect access to health care services and resources, especially in areas with limited medical facilities. Hird et al., (2019) which stated that it is important to understand that pain is a complex phenomenon affected by a variety of biological, psychological, social, and environmental factors.

Results of a simple linear regression test revealed that non-predictive variables for alcohol drinkers' pain levels (Table 4-7) were found among patients receiving lidocaine spray (p-value .137). In the shotblocker (Table 4-8), results demonstrated that alcohol use was not a predictor of pain levels among patients (p-value 760). In the control group (Table 4-9), outcomes indicated that alcohol use was not a predictor of level of pain among participants (p-value (.569)),

The results of lidocaine spray group are similar to research done by Mahawongkajit et al., (2021), this study showed not significant relationship between drinking alcohol and pain perception (p - value 0.451).

The findings of shotblocker group are similar to research performed by Karkhanei et al., (2023) these study demonstrated not significant relationship between alcohol and pain tolerance (p-value .086).

The researcher's perspective regarding the findings, ethical considerations related to alcohol drinker by participants in research studies may limit the ability to directly evaluate its effects on pain perception during intramuscular injection, because the majority of society is committed to the Islamic religion and this is socially unacceptable. Al Ansari & Conigrave, (2022), that are many countries that consider alcohol a moral, legal and social problem due to religious beliefs, especially the Islamic community

Results of a simple linear regression test revealed that non-predictive variables for smocking and pain levels (Table 4-7) were found among patients receiving lidocaine spray (p-value .928). In the shotblocker group (Table 4-8), revealed that smocking was not an indicator of pain levels among participants (p-value .582), In the control group (Table 4-9), revealed that smocking was not an significant variation of pain levels among participants (p-value .470).

The findings of lidocaine group are comparable to those of Mahawongkajit et al., (2021), these investigations indicated not significant variation between smoking and pain perception (p - value 0.483).

The outcomes of shotblocker group are similar to study carried out by Liu et al., (2021), these research investigations reported no significant association between smoking and feeling pain (p-value 0.935).

A researcher's interpretation on the findings, smoking status may affect pain perception through various physiological and psychological mechanisms, individual tolerance, and previous experiences with pain and pain thresholds play important roles in how individuals perceive and experience pain. Hird et al., (2019) which stated that it is important to understand that pain is a complex phenomenon affected by a variety of biological, psychological, social, environmental, previous experiences with pain and pain thresholds.

Conclusions and Recommendations

5.4. Conclusions:

1. The using of lidocaine spray show effective pain reduction during intramuscular injection.
2. The application of shotblocker show effective pain reduction during intramuscular injection.
3. The shotblocker demonstrated more effective than lidocaine spray in reducing pain during intramuscular injection.
4. There was no statistically significant relationship between patients' socio -characteristics and medical data (age, sex, residents, and levels of education, alcohol drinker, smoking, and fear of intramuscular injection) and pain levels in the shot blocker and lidocaine spray.
5. There is a statistically significant relationship between body mass index and pain levels in the shot blocker and lidocaine spray. When an increase in body mass index is associated with a decrease in pain perception among patients.

5.5. Recommendation:

1. In-service training programs and intramuscular injection protocols should be include the use of pharmacological (lidocaine spray) and non-pharmacological approaches (Shot Blocker) to control pain during intramuscular injection.
2. It is highly recommended to conducting further research at the national level, conducting study that use an anxiety scale to discover the best strategies for reducing and preventing pain during intramuscular injections.
3. Encourage the use of ShotBlocker to reduce patients' pain, it is essential to communicate information about its evidence-based

practice of using a non-pharmacological method in clinical nursing practice.

4. The ShotBlocker is a simple and practical way for healthy adults to manage pain caused by intramuscular injections. It is safe to use and requires no additional cost or time. It may also help to reduce pain. It can be used in conjunction with other evidence-based non-pharmacologic pain management approaches to improve patient comfort.
5. Further research will likely provide stronger evidence on the effectiveness of ShotBlocker and lidocaine spray in relieving pain during intramuscular (IM) injections by including additional pain assessment criteria. Using techniques that reduce pain during IM injections can improve patient satisfaction and overall comfort.
6. In the emergency department, it is usual to provide antibiotics that may cause severe pain, such as Amoxicillin and Ceftriaxone sodium via injection, which may result in more pain. As a result, it is recommended to evaluate the effectiveness of ShotBlocker and lidocaine spray when delivering other medications that may induce injection-related pain.

5.6. Nursing Implications:

1. Nurses should educate about the use of the ShotBlocker device and the potential benefits of reducing pain during intramuscular injections. This information may help to alleviate anxiety or concerns that patients may have about the injection process.
2. Nurses can use the ShotBlocker device to reduce pain levels during intramuscular injections. This device may be particularly effective in patients who are sensitive to pain or have a history of experiencing pain during injections. Which may increase patient satisfaction with care.

3. For patients who are afraid of injections or experience pain during injections, nurses can consider using the non-pharmacological and pharmacological techniques to reduce pain levels, and to promote patient comfort and reduce anxiety.
4. Nurses should consider assessing patients' pain levels after an intramuscular injection, Use standardized pain assessment tools, such as visual analog scales (VAS) or numerical rating scales (NRS), and addressing any pain management needs accordingly.
5. Nursing research on the use of ShotBlocker and lidocaine spray for IM injections is essential for advancing pain management practices. By conducting rigorous studies and disseminating findings, nurses can contribute to the development of effective, evidence-based strategies that enhance patient care and comfort.

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Appendices

Appendix A-1
Ethical Research Committee at the College of Nursing/University of Kerbala

Ministry of Higher Education and Scientific Research
University of Karbala / College of Nursing
Scientific Research Ethics Committee

UOK.CoN.23.019
Ethical Committee Code:
Date: ١٩ / ١١ /2023

Research Ethical Approval Form

Title of the research project	
In the English language	**In the Arabic language**
Comparing the Effect of Using Lidocaine Spray and ShotBlocker on Pain Level During Intramuscular Injection: A Randomized Control Trial	مقارنة اثر استخدام بخاخ الليدوكائين و اداة مشتت الالم في مستوى الألم أثناء الحقن العضلي : تجربة عشوائية منضبطة

Data About the Main Researcher /Student:

Full Name	Scientific Title	Mobile Number	Email
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Data About the Co-author /Supervisor:

Full Name	Scientific Title	Mobile Number	Email
Dr. Fatma Makee Mahmood	Professor	٠٧٧٠٢٩٣٤٠٣١	Fatima.makki@uokerbala.edu.iq

Study objectives

1. Determine the effect of ShotBlocker on pain level during intramuscular injection in adults.
2. Determine the effect of lidocaine spray on pain level during intramuscular injection in adults.
3. Comparing the effect of using lidocaine spray and shotblocker on pain level during intramuscular injection in adults

Time and Setting of the Study

October 2023-Aguest 2024 / Imam Al-Sadiq General Hospital in the Hilla city.

Study Design

A Randomized Control Trial

Sampling method and sample size

A Randomized sample / size of sample: ninety patients will participate in the study, the participants will be assigned into two group, sixty participants of experimental group and thirty participants of control group.

Statement of Ethical Commitment

The study will be conducted in accordance with what was mentioned in the protocol above and to commitment that all rules set by the ethical committee are followed in present research process. The researcher also makes a commitment to abide by ethical principles, moral values, law and instruction of the institutions. There is no bias will be during collecting the data, gender, regional aspects and is totally impartial and objective. The researcher will have taken an informed consent from the participants, and provide clarifications and information about the study to the sample members. The researcher deals with the data of the sample members in complete confidentiality.

Hameed Muslim H.M

Name and signature of the researcher

Recommendation of the College's Research Ethical Committee

☑ **Agreement to conduct the study** ☐ **Disagreement to conduct the study**

Instructor Dr. Sajidah Saadoon Oleiwi
Member

Ass. Prof. Dr. Zeki Sabah Musihb
Member

Ass. Prof. Dr. Ghazwan Abdalhussein
Member

Ass. Prof. Dr. Hassan Abdullah Athbi
Chairman of the Committee

Appendix A-2
Approval from the Babylon Health Directorate of the Iraqi Ministry of Health (Training and Development Division.

جمهورية العـــراق

وزارة الصحة والبيئة
دائرة صحة محافظة بابـــل
المديـــر العـــام
مركـــز التدريب والتنمية البشرية
لجنة البحوث

Ministry Of Health
Babylon Health Directorate
Email:-
Babel_Healthmoh@yahoo.com
Tel:282628 or 282621

استمارة رقم :-٠٣ /٢٠٢١

وزارة الصحة
دائرة صحة بابل
مركز التدريب والتنمية البشرية
لجنة البحوث

رقم القرار :- ٧٤
تاريخ القرار :- ١٧/ ١ /٢٠٢٤

قرار لجنة البحوث

تحية طيبة ...

درست لجنة البحوث في دائرة صحة بابل مشروع البحث ذي الرقم (٢٠٢٤/٠١٨/ بابل) المعنـــون(مقارنة اثر استخدام بخاخ الليدوكائين وأداة مشتت الألم في مستوى الألم أثناء الحقن العضلي : تجربة عشوائية منضبطة) والمقـدم من الباحث (حميد مسلم هاشم)إلى وحدة أدارة البحوث والمعرفي مركز التدريب والتنمية البشرية في دائرة صحة بابل بتاريخ ٢٠٢٤/١/١٧ وقررت :

قبول مشروع البحث أعلاه كونه مستوفيا للمعايير المعتمدة في وزارة الصحة والخاصة بتنفيذ البحوث ولا مانع من تنفيذه في مؤسسات الدائرة .

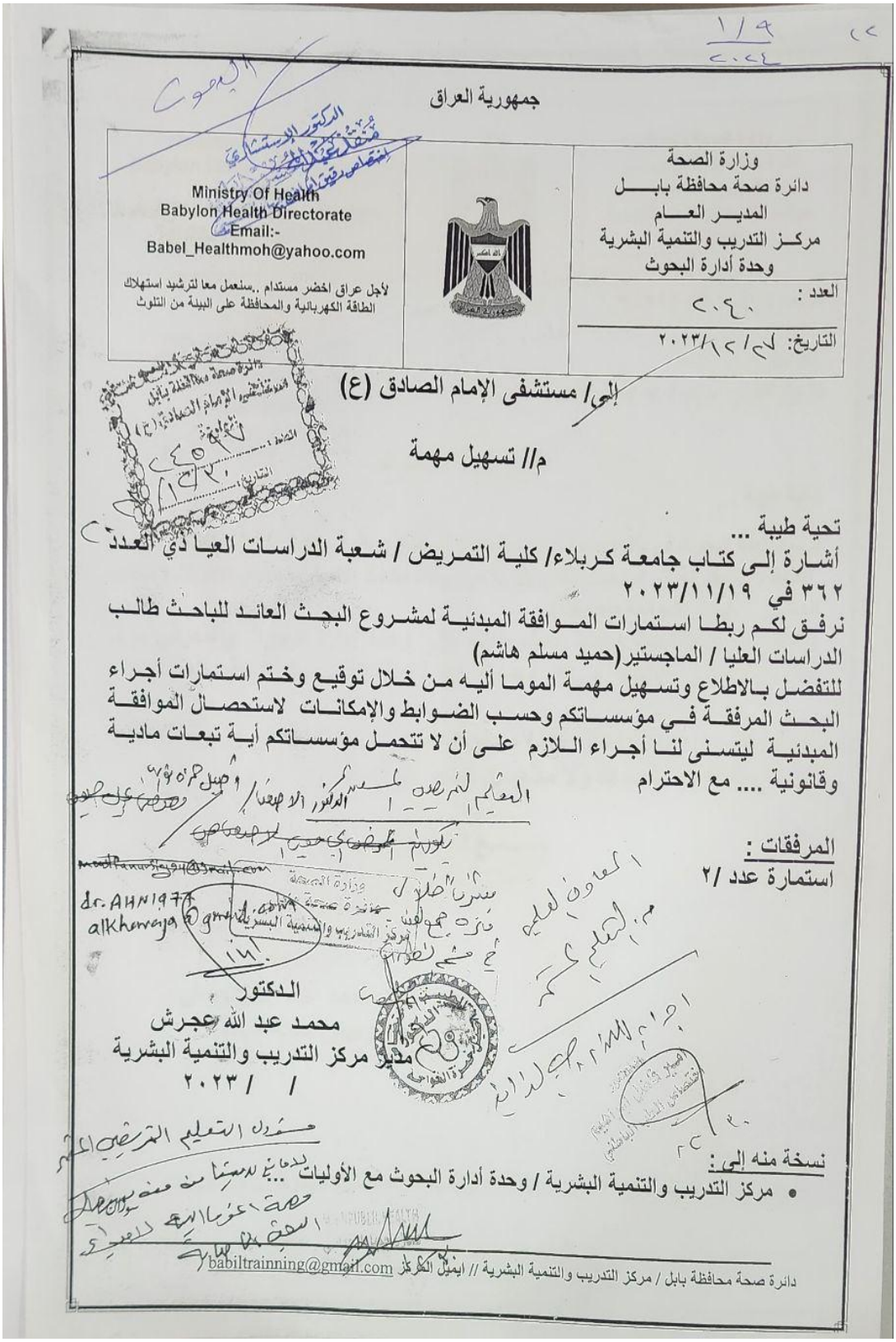
مـــــع الاحتـــــرام

الـدكتور
محمد عبد الله عجرش
رئيس لجنة البحوث
/ / ٢٠٢٤

نسخة منه إلى :
• مكتب المدير العام / مركز التدريب والتنمية البشرية / وحدة إدارة البحوث ... مع الأوليات.

دائرة صحة محافظة بابل / مركز التدريب والتنمية البشرية // ايميل المركز babiltrainning@gmail.com

Appendix A-3
Approval from the Imam Al-Sadiq General Hospital



جمهورية العراق

وزارة الصحة
دائرة صحة محافظة بابـــل
المديـــر العـــام
مركـز التدريب والتنمية البشرية
وحدة أدارة البحوث

Ministry Of Health
Babylon Health Directorate
Email:-
Babel_Healthmoh@yahoo.com

لأجل عراق اخضر مستدام ..سنعمل معا لترشيد استهلاك الطاقة الكهربائية والمحافظة على البيئة من التلوث

العدد : ٤٠٦٠
التاريخ: ٢٠٢٣/١٢/٤

إلى/ مستشفى الإمام الصادق (ع)

م// تسهيل مهمة

تحية طيبة ...
أشارة إلى كتاب جامعة كربلاء/ كلية التمريض / شعبة الدراسات العليا ذي العدد ٣٦٢ في ٢٠٢٣/١١/١٩
نرفق لكم ربطا استمارات الموافقة المبدئية لمشروع البحث العائد للباحث طالب الدراسات العليا / الماجستير(حميد مسلم هاشم)
للتفضل بالاطلاع وتسهيل مهمة الموما أليه من خلال توقيع وختم استمارات أجراء البحث المرفقة في مؤسساتكم وحسب الضوابط والإمكانات لاستحصال الموافقة المبدئية ليتسنى لنا أجراء اللازم على أن لا تتحمل مؤسساتكم أية تبعات مادية وقانونية .... مع الاحترام

المرفقات :
استمارة عدد /٢

الدكتور
محمد عبد الله عجرش
مدير مركز التدريب والتنمية البشرية
٢٠٢٣/ /

نسخة منه إلى:
- مركز التدريب والتنمية البشرية / وحدة أدارة البحوث مع الأوليات

دائرة صحة محافظة بابل / مركز التدريب والتنمية البشرية // ايميل المركز babiltrainning@gmail.com

Appendix A-4
Written Informed Consent

اخي العزيز/ اختي العزيزة...

الرجاء التوقيع في الاسفل كي تشهد بان:

بعد ان قام طالب الماجستير (حميد مسلم هاشم) بشرح و توضيح جميع ما يتعلق ببحثه الموسوم (مقارنة اثر استخدام بخاخ الليدوكائين و اداة مشتت الالم في مستوى الألم أثناء الحقن العضلي : تجربة عشوائية منضبطة)،

حيث اعلمني الباحث حول فائدة بحثه و اهميته العلمية و كذلك اطلعني ان مشاركتي هي تطوعا مني بإرادتي و باستطاعتي رفض المشاركة كما انه يمكن سحب مشاركتي بالدراسة متى شئت و لأي سبب كان. او ان لا اجيب عن اي سؤال لا ارغب بالإجابة عنه، كما و اعلمني بان مشاركتي لن تحملني اي نفقات او تعود علي بأضرار سلبية. كما اعلمني بان المعلومات سوف تعامل بسرية تامة و لن يطلع عليها اي شخص و تستعمل للأغراض العلمية فقط و لن يتم ذكر اسمي او عائلتي في هذه الدراسة.

و لهذ فاني اوقع للمشاركة في هذه الدراسة

توقيع المشارك..... التاريخ:

توقيع الباحث..... التاريخ:

Appendix - B
Approval from Iranian Registry of Clinical Trials (IRCT)

IRCT
Iranian Registry of Clinical Trials

Dear Hameed Muslim,

Registration of your trial protocol under the scientific name of

Comparing the Effect of Using Lidocaine Spray and ShotBlocker on Pain Level During Intramuscular Injection: A Randomized Control Trial

has been approved in Iranian Registry of Clinical Trials at 2024-02-21.

Your registration reference is IRCT20240127060820N1.

Best Regards

Iranian Registry of Clinical Trials (IRCT)

عزیز،

با سلام

ثبت پروتکل مطالعه کارآزمایی بالینی شما تحت عنوان

Comparing the Effect of Using Lidocaine Spray and ShotBlocker on Pain Level During Intramuscular Injection: A Randomized Control Trial

در تاریخ ۱۴۰۲/۱۲/۰۲ در مرکز ثبت کارآزمایی بالینی ایران تایید شد.

شماره کد ثبت شما IRCT20240127060820N1 است.

با تشکر

مرکز ثبت کارآزمایی بالینی ایران IRCT

Address IRCT administration team,
Central Library Building, Iran University Campus,
Hemmat freeway, next to Milad tower,
Tehran,
Iran

Tel 0098 21 8670 5503

During COVID-19 Epide 0098 936 770 7834

Fax 0098 21 8670 5503

Email admin@irct.ir

Website www.irct.ir

Appendix- C
Minimum Sample Size Determination

Confidence Level	**95 %**
Margin of Error	**5 %**
Population Proportion	**50 %**
Population Size	**245**

https://www.checkmarket.com/sample-size-calculator/#sample-size-calculator.

Appendix- D

The Study's Instrument

No …... lidocaine spray Group

ShotBlocker Group

Control Group

Part One: Socio- demographic and medical data

1-1 Age: ☐

1-2 Sex:

Male ☐

Female ☐

1-3- Residency

Urban ☐

Rural ☐

1-4 Level of Education:

Does Not Read or Write ☐

Read and Write ☐

Primary Education ☐

Intermediate School ☐

Secondary School ☐

Bachelor Degree ☐

Postgraduate ☐

1-6. Fear of needles during intramuscular injection

Yes ☐

No ☐

Appendices

1.7. Measurement

A. Weight ☐

B. Height ☐

1-8 Alcohol drinker

Current ☐

Previous ☐

Never ☐

1-9 Smoking status

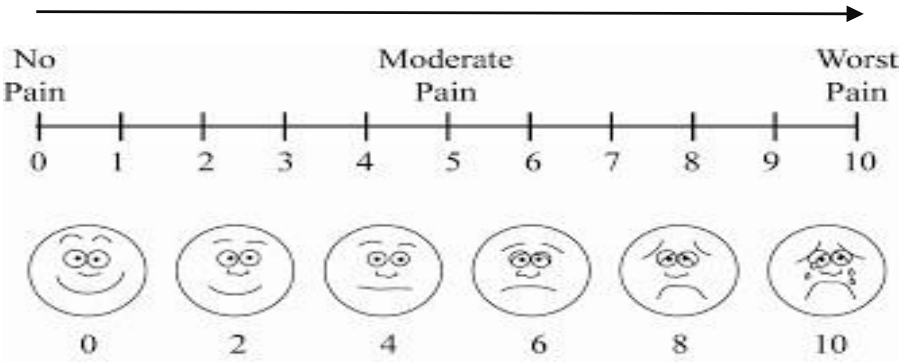
Current ☐

Previous ☐

Never ☐

Part Two: Pain Measurement (Visual analog scale)

Kindly, put a mark on the scale below to determine the level of pain you have due to the prick of the needle used to intramuscular injection. (Zero (0) means there is no pain. The closer to the number 10, mean more pain).



Appendix E

Data Collection Procedure

Appendix E

Data Collection Procedure

Appendix - F
Scale digital weight

Appendix - G
ShotBlocker Tool

Appendix - H
Lidocaine spray tool

Appendix – I
Expert's List

ت	اسم الخبير	اللقب العلمي	سنوات الخبرة	الاختصاص الدقيق	مكان العمل
1	**د.سحر ادهم علي**	**استاذ**	35	تمريض البالغين	جامعة بابل كلية التمريض
2	**د. حكيمة شاكر حسن**	**استاذ**	35	تمريض بالغين	كلية التمريض / جامعة بغداد
3	**د.علي كريم خضير**	**استاذ**	32	تمريض الصحة النفسية و العقلية	جامعة كربلاء كلية التمريض
4	**د. شذى سعدي**	**استاذ**	25	تمريض البالغين	جامعه بابل كلية التمريض
5	**د. خميس بندرعبيد**	**استاذ**	25	تمريض الاطفال	كلية التمريض/ جامعه كربلاء
6	**د. حسام داوود عباس**	**استاذ مساعد**	22	تمريض البالغين	جامعة كربلاء كلية التمريض
7	**د. حسن عبدالله عذبي**	**استاذ مساعد**	21	تمريض البالغين	جامعة كربلاء كلية التمريض
8	**د. صافي داخل نوام**	**استاذ مساعد**	20	تمريض الصحة النفسية و العقلية	كلية التمريض / جامعة كربلاء
9	**د. وفاء عبد علي حطاب**	**استاذ مساعد دكتور**	18	تمريض بالغين	جامعة بغداد كلية التمريض
10	**د.جهاد جواد كاظم**	**استاذ مساعد**	15	تمريض البالغين	جامعه الكوفة كلية التمريض
11	**د. زكي صباح مصيحب**	**استاذ مساعد**	10	تمريض الاطفال	كليه التمريض / جامعة كربلاء
12	**د. غزوان عبد الحسين عبد الواحد**	**استاذ مساعد**	9	تمريض صحة المجتمع	كليه التمريض / جامعة كربلاء
13	**د.حقي اسماعيل منصور**	**استاذ مساعد**	7	تمريض صحة المجتمع	كلية التمريض/ جامعه كربلاء
14	**د.احمد حمندي**	**دكتور**	25	طبيب اختصاص امراض دم	مستشفى المجتبى (ع)
15	**د. منقذ الجنابي**	**دكتور**	22	طبيب اختصاص باطنية /صدرية	مستشفى الامام الصادق (ع)
16	**د. اصيل حمزه ثويني**	**دكتور**	12	طبيب اختصاص طوارئ	مستشفى الامام الصادق (ع)

Appendix - J
Statistician's opinion

Republic of Iraq
Ministry of higher education & scientific research
University of Karbala
College of Nursing
Graduate studies Division

جمهورية العراق
وزارة التعليم العالي والبحث العلمي
جـــامعة كربلاء
كـلية التـمريـض
شعبة الدراسات العليا

إقرار الخبير الإحصائي

أشهد بـأن الرسالـة الموسومـة :

" مقارنة اثر استخدام بخاخ الليدوكائين واداة مشتت الالم في مستوى الألم أثناء الحقن العضلي: تجربة عشوائية منضبطة "

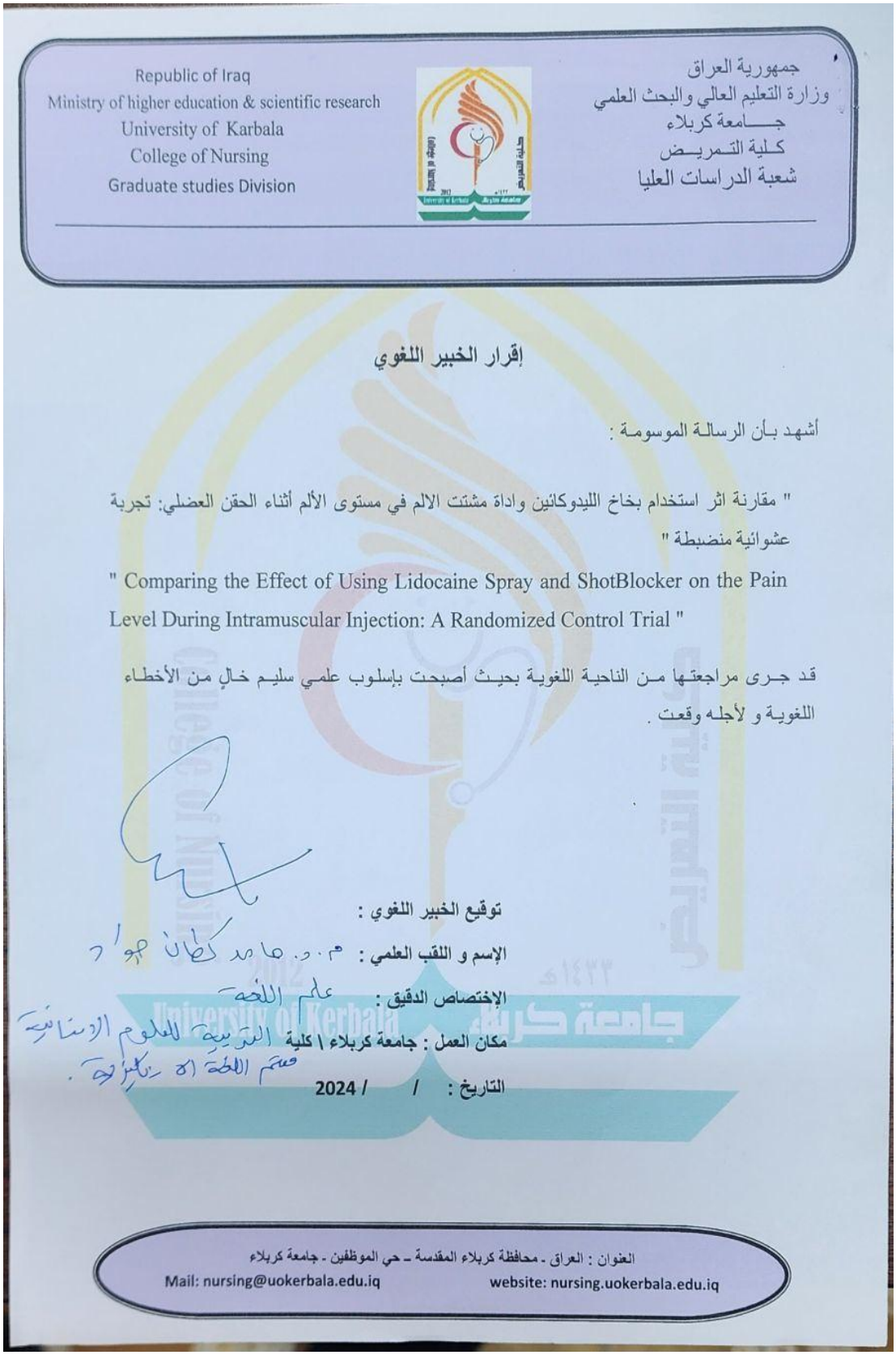
" Comparing the Effect of Using Lidocaine Spray and ShotBlocker on the Pain Level During Intramuscular Injection: A Randomized Control Trial "

قد تم الإطلاع على الإسلوب الإحصائي المتّبع في تحليل البيانات و إظهار النتائج الإحصائية وفق مضمون الدراسة و لأجله وقعت .

توقيع الخبير الإحصائي :
الإسم و اللقب العلمي :
الإختصاص الدقيق :
مكان العمل : جامعة كربلاء / كلية
التاريخ : / / 2024

العنوان : العراق - محافظة كربلاء المقدسة – حي الموظفين - جامعة كربلاء
Mail: nursing@uokerbala.edu.iq
website: nursing.uokerbala.edu.iq

Appendix-K
Linguist's opinion



Republic of Iraq
Ministry of higher education & scientific research
University of Karbala
College of Nursing
Graduate studies Division

جمهورية العراق
وزارة التعليم العالي والبحث العلمي
جـــامعة كربلاء
كـلية التـمريـض
شعبة الدراسات العليا

إقرار الخبير اللغوي

أشهد بـأن الرسالـة الموسومـة :

" مقارنة اثر استخدام بخاخ الليدوكائين واداة مشتت الالم في مستوى الألم أثناء الحقن العضلي: تجربة عشوائية منضبطة "

" Comparing the Effect of Using Lidocaine Spray and ShotBlocker on the Pain Level During Intramuscular Injection: A Randomized Control Trial "

قد جـرى مراجعتـها مـن الناحيـة اللغويـة بحيـث أصبحت بإسلـوب علمـي سليـم خـالٍ من الأخطـاء اللغويـة و لأجلـه وقعت .

توقيع الخبير اللغوي :
الإسم و اللقب العلمي : م.د. حامد كطان محمود
الإختصاص الدقيق : علم اللغة
مكان العمل : جامعة كربلاء \ كلية التربية للعلوم الإنسانية
التاريخ : / / 2024

العنوان : العراق ـ محافظة كربلاء المقدسة ـ حي الموظفين ـ جامعة كربلاء
Mail: nursing@uokerbala.edu.iq website: nursing.uokerbala.edu.iq

المستخلص

الخلفية : الحقن العضلي هو ممارسة تمريضية شائعة في الممارسات السريرية. على الرغم من مزاياها العلاجية، إلا أنها يمكن أن تسبب عدم الراحة والألم لدى المرضى. من الضروري لحد من الألم الناتج عن الحقن العضلي. تهدف هذه الدراسة الى مقارنة اثر استخدام بخاخ الليدوكائين و اداة مشتت الالم في مستوى الألم أثناء الحقن العضلي.

المنهجية البحث : تجربة عشوائية منضبطة أجريت في قسم الطوارئ في مستشفى الإمام الصادق العام في مدينة الحلة خلال الفترة ما بين أيلول 2023 إلى حزيران 2024. تم جمع البيانات من خلال المقابلات باستخدام المقياس التناظري البصري والبيانات الديموغرافية والاجتماعية ، استخدم الباحث عينة عشوائية بسيطة حيث يختار المشاركون لونا من ظرف مغلق مكون من ثلاثة ألوان. 150 مريضاً الذين يحقن لهم ديكلوفيناك الصوديوم، مقسمين إلى ثلاث مجموعات، 50 في كل من مجموعة بخاخ الليدوكائين، اداة مشتت الالم والمجموعة الضابطة. تم استخدام كلا من التحليل الإحصائي الوصفي مثل (التكرارات والنسبة المئوية والانحراف المعياري ومتوسط الدرجات) والتحليل الإحصائي الاستدلالي مثل (اختبار الفرق بين المتوسطات للعينتين مستقلتين وتحليل التباين والاختبارات البعدية ومربع إيتا). مستوى الدلالة الإحصائية عند القيمة $p < 0.05$.

النتائج : أظهرت نتائج الدراسة أن هناك فروق ذات دلالة إحصائية في درجات الألم بين المجموعات (P = .000). مجموعة اداة مشتت الالم مقارنة بمجموعة بخاخ الليدوكائين (يعني الفرق 1.18- ، p = .000)، والمجموعة الضابطة (يعني الفرق 3.92- ، p = .000). مجموعة بخاخ الليدوكائين مقارنة بمجموعة اداة مشتت الالم (يعني الفرق 1.18 ، p =.000)، والمجموعة الضابطة (يعني الفرق 2.74- ، p = .000). الضابطة مقارنة بمجموعة بخاخ الليدوكائين (يعني الفرق 2.74 ، p=.000)، ومجموعة اداة مشتت الالم (يعني الفرق 3.92، p = .000).

الاستنتاجات : خلصت الدراسة أن استخدام اداة مشتت الألم وبخاخ الليدوكائين فاعلية في تقليل الألم خلال الحقن العضلي لكن اداة مشتت الألم أكثر فاعلية في تقليل مستوى الألم من بخاخ الليدوكائين.

التوصيات : يوصى الباحث بضرورة استخدام اداة مشتت الألم كوسيلة غير دوائية فعالة لتقليل الألم خلال الحقن العضلي.

جامعة كربلاء

كلية التمريض

مقارنة اثر استخدام بخاخ الليدوكائين و اداة مشتت الالم في مستوى الألم أثناء الحقن العضلي : تجربة عشوائية منضبطة

رسالة مقدم الى

مجلس كلية التمريض / جامعة كربلاء

وهي جزء من متطلبات نيل درجة شهادة الماجستيرفي علوم التمريض

كتبتٌ بواسطة

حميد مسلم هاشم

بإشراف

أ.د فاطمة مكي محمود

حزيران / 2024 ميلادية ذو الحجة /1445 هجرية