



## Effect of Using Lidocaine Spray on Level of Pain during Intramuscular Injection: A Randomized Control Trial

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### ABSTRACT

**Background:** Intramuscular injection is a typical nursing procedure in clinical settings. Injections into the muscle can cause pain and suffering in patients, even with their therapeutic benefits, because of the emphasis on quality in health care, it is becoming increasingly important to reduce injection-related pain in nursing care.

**Objectives:** The aim of this study was to determine how utilizing lidocaine spray changed the level of pain caused by intramuscular injections.

**Methodology:** This is a randomized controlled experiment, the data was gathered using a socio-demographic questionnaire and the visual analog scale between December 28th, 2023 and February 14th, 2024. The study included 100 participants, with 50 assigned to the study group and the other 50 to the control group. The statistical tests were conducted utilizing the SPSS software for Microsoft Windows, specifically version, with a level of significance of 5% ( $p$  value < 0.05).

**Results:** The average pain scores for the control group ( $4.46 \pm 2.022$ ) and the experimental group ( $1.27 \pm 1.340$ ) and there was a statistically significant variation between them ( $P < 0.001$ ). The obtained t-value of 7.985 was associated with a p-value of 0.000, indicating positives effect of reducing pain. The lidocaine group compared to the control group (mean difference of -2.74000,  $p < .000$ ).

**Conclusion:** The study found that using lidocaine spray during intramuscular injections in adults reduced the severity of pain. A simple linear regression test indicated that body max index (BMI) significantly predicted pain levels among the study group ( $\beta = 0.113$ ;  $p = .028$ ).

**Keywords:** intramuscular injection, lidocaine spray, pain.

### INTRODUCTION

Intramuscular (IM) injection administration is a standard nursing procedure in clinical settings. However, inadequate administration may lead to a variety of complications, encompassing pain, tightness, sterilized abscess, necrosis of the tissue, granuloma, nerve injuries intravascular injection and hemorrhage (Aydin & Avşar, 2019).

Injections are one of the most common medical procedures worldwide. At least 16 billion are produced annually in developing and transition countries (Jin et al., 2015). Administering an IM injection demands technical proficiency and effective decision-making regarding the tools and techniques employed. While IM injections offer therapeutic benefits, they can lead to patient discomfort and pain.

Specifically, pain may arise from mechanical trauma caused by syringe insertion and the abrupt pressure experienced during intramuscular drug administration (Sedat et al., 2019).

Intramuscular (IM) injection involves injecting medication deep into specifically selected muscles. Massive muscles are characterized by good vascularization, as a result of which the injected drug quickly enters the systemic circulation and thus into the specific area of action, bypassing first-pass metabolism. Drugs can be administered intramuscularly for preventive purposes (about 5% of vaccinations) and therapeutic purposes (over 95% of intramuscular injections) (Gutierrez & Munakomi 2023).

Recent advances in pain management and palliation have greatly influenced nursing practice. Nurses play a crucial role in relieving patients' pain as they are constantly engaged with patients. The effectiveness of pain management depends largely on nurses' knowledge, competencies and approach to painful procedures. It is the responsibility of nurses to carefully administer the medication and provide relief to patients from pain associated with the injection (Aydin & Güven, 2020).

Reducing patient pain is a major concern for nurses, leading to many studies aimed at alleviating injection pain. Both pharmacological and non-pharmacological methods are used for this purpose (Kaplan et al., 2023).

Several pharmacological approaches are used, including prilocaine, piroxicam creams, and lidocaine spray. Lidocaine is an essential substance that is widely used in the field of local anesthesia. This drug is often given as a spray in clinical settings. Due to its moderate impact in producing local anesthetic in the skin and mucous membranes (Marvi et al., 2023).

A topical anesthetic, lidocaine spray is a medication commonly used to numb the surface of the skin or mucous membranes.

It works by blocking nerve signals in the body. The spray is also applied to the skin or mucous

membranes to relieve from pain or discomfort during medical procedures such as injections, minor surgeries, dental treatment, and insect bites. It can also be used to relieve pain associated with conditions such as sunburn and minor burns. (Jamalinik et al., 2023; Hoseini et al., 2022). 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 theory of alleviating pain with lidocaine depend on blocking active and inactive channels of sodium, leading to transmission blockage and a lack of stimulation, and thus distributing or decreasing pain. This drug is a lidocaine spray, which is frequently used for local anesthesia and pain treatment because of its rapid onset of effects and moderate efficacy (Marvi et al., 2023).

## AIMS OF THE STUDY

The aim of this study was to determine how utilizing lidocaine spray changed the level of pain caused by intramuscular injections.

## METHODOLOGY

### The Study Design:

This study is a single-blind, and randomized controlled trial. It was used to assess the influence of applying lidocaine spray on the severity of pain via intramuscular (IM) injection.

### Blinded:

The single-blind technique, was employed as the researcher needs to know how the subjects will be treated. Therefore, the study was conducted the participants were unaware of the interventional group. Using of this blinding technique, the study results are well shielded from the subject knowledge of the treatment assignment.

### Setting:

The study was conducted at Imam Al-Sadiq General Hospital in Babylon city, Iraq. The study was

conducted during the period from December 28th, 2023 to February 14th, 2024.

### Sample and sampling procedure

The sample size was determined by power analysis, calculator computes the minimum samples size, considering a 0.05 error margin, Confidence Level 95%, Population Proportion 50% and Population size 134, Consequently, The sample size was calculated as 100 participants for both study and control groups, (Table A). The total number of monthly visitors to the hospital is approximately 134 patients (adult) who were admitted to the emergency department while receiving an intramuscular injection of diclofenac sodium.

(Table A), Minimum Sample Size Determination

<b>Confidence Level</b>	<b>95 %</b>
<b>Margin of Error</b>	<b>5 %</b>
<b>Population Proportion</b>	<b>50 %</b>
<b>Population Size</b>	<b>134</b>

The process will involve a simple randomization procedure wherein participants will select a color from a sealed envelope containing two colors. Each color corresponds to a group (yellow or the lidocaine spray group, 50 patients and green for the control group, 50 patients) and participants will be allocated randomly among these groups.

Patients who met the inclusion criteria were briefed about the study's objectives and. Following that, participants completed a questionnaire form, and the investigator delivered intramuscular injections. Within 1 minute post-injection, Participants evaluated the severity of their pain on the Visual Analogue Scale.

### Experimental Group:

The skin is disinfected, wiping the region with an alcohol swab and left it dry (Bilgic, 2021; Chung & Wong, 2002; Derya et al., 2015).

After that, two puffs of lidocaine spray (20 mg) were applied to the skin from a distance of around 5 cm. The blood vessel access method requires 1 to 5 minutes of local anesthetic, then a 2-minute wait

period before the drug is injected (Khosravi Pour et al., 2023).

After sterilizing the ventrogluteal region with an alcohol and lidocaine spray, the injection was performed at the angle 90-degree.

### Control group

After skin sterilization at the injection site, injections were administered without lidocaine spray, specifically in the ventrogluteal region.

### Data collection tools:

The data collection process included the use of, visual analogue scale, and questionnaire.

#### 1. Questionnaire form:

The questionnaire included seven questions to determine age, gender, place of residence, educational level, fear of needles during intramuscular injection, and weight and height measurements. Before administering the injection, participants completed the questionnaire.

#### 2. Visual analog scale:

The visual analogue scale is one of the scales used to evaluate pain, It consists of a horizontal line that is 10 cm long and has the phrase (no pain) at one of the ends and (severe pain) at the opposite end, participants marked score of the pain, on this line (Karabey, 2021; Aydin & Güven, 2020).

Following intramuscular injection, participants were asked to mark a scale to determine their pain level. There are four levels of pain severity: (mild 1-3 points, moderate 4-6 points, severe 7-10 points, and none at all 0 point) (Karasu et al., 2017).

#### 2.1 Reliability and Validity of the scale

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; Mandysová & Kadlečková, 2015).

### Ethical considerations

The Committee of Scientific Research confirmed this research at the College of Nursing / University of Karbala, (code: uok.con.23.019, Decision no: 2023.11.19) Iraq. As an essential part of original randomized controlled trial, the trial protocol

received approval for registration in the Iranian Registry of Clinical Trials (IRCT) on February 21st, 2024. The registration reference (IRCT20240127060820N1: Trial Id 75385, Membership number 60820).

### RESULTS

**Table (1):** Distribution of Study Sample by their Characteristics (socio-demographic and medical data)

Characteristics	Characteristics	Lidocaine= 50		Control = 50	
		N	%	N	%
Age/ years	<20	4	8.0	3	6.0
	20-29	19	38.0	18	36.0
	30-39	17	34.0	18	36.0
	40-49	6	12.0	10	20.0
	50 and older	4	8.0	1	2.0
	Mix—Min	18—53		18—54	
	M ± SD	31.88±9.53		32.26±8.75	
Sex	Male	29	58.0	31	62.0
	Female	21	42.0	19	38.0
Residents	Urban	31	62.0	33	66.0
	Rural	19	38.0	17	34.0
Education level	Illiterate	5	10.0	3	6.0
	Read and Write	4	8.0	4	8.0
	Primary Education	6	12.0	7	14.0
	Intermediate School	8	16.0	10	20.0
	High School	12	24.0	13	26.0
	Bachelor Degree	14	28.0	12	24.0
	Postgraduate	1	2.0	1	2.0
Fear of needle during IM injection	Yes, I have	10	20.0	8	16.0
	No, I Haven't	24	48.0	24	48.0
	I kind of have	16	32.0	18	36.0
BMI	Normal (18.5-24.9)	24	48.0	23	46.0
	Overweight (25.0-29.9)	13	26.0	20	40.0
	Obesity (≥30.0)	13	26.0	7	14.0

N. Number; %= Percentage

The Lidocaine group comprised participants aged 18 to 53, with an average age of 31.88±9.53 years and the control group also had participants aged 18 to 54, with an average age of 32.26±8.75 years. A significant majority of the Lidocaine (58.0%) and control (62.0%) groups were predominantly male. Regarding of residence, urban residents were predominant in both the Lidocaine (62.0%) and control group (66.0%). Regarding education level, individuals with a Bachelor's degree constituted the highest percentage in the Lidocaine (28.0%) and while high school graduates were more prevalent in the control group (26.0%). Fear of needle-related findings revealed that (48.0%) of participants in the Lidocaine group demonstrated no fear and (48.0%) in the control group exhibited no fear. In terms of BMI, normal weight individuals were predominant in both the Lidocaine and control groups, comprising (48.0% and 46.0%), respectively.

**Table (2):** Assessment of the Pain Level of Intramuscular Injection among Study Groups

Groups	Score	No.	%	Min.	Max.	M ± SD	Eva.
Lidocaine	No pain	12	24.0	0	4	1.27 ± 1.340	Mild
	Mild	33	66.0				
	Moderate	5	10.0				
	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 concerning pain levels during intramuscular injection. A significant proportion (66%) reported experiencing mild pain after receiving Lidocaine, with scores ranging from 0 to 4 on the assessment scale, as indicated by an average score of (1.27 ± 1.340). Conversely, (56%) of participants 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 (3):** Comparison of the Effect of Lidocaine on Pain Levels among Patients undergo Intramuscular Injection

Groups	No.	M	SD	t-value	d.f	η <sup>2</sup>	Sig.
Lidocaine	50	1.72	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<sup>2</sup>= Eta squared; Sig: Significance level at 0.05.

The obtained t-value of 7.985 was associated with a p-value of 0.000, indicating a highly significant result. Additionally, the effect size, represented by η<sup>2</sup> = 0.39, further emphasizes the substantial impact of Lidocaine administration on reducing pain.

**Table (4):** Factors Prediction Pain Level among Patients Received Lidocaine spray

Variables	Unstandardized Coefficients		Standardized Coefficients	T	Sig.
	B	Std. Error	Beta		
Age	.028	.023	.196	1.189	.242
Sex	.514	.490	.191	1.050	.300
Residents	.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

Dependent Variable: Pain Level

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

**Table (5):** Factors Prediction Pain Level among Patients in Control Group

Variables	Unstandardized Coefficients		Standardized Coefficients	T	Sig.
	B	Std. Error	Beta		
Age	-.004	.046	-.015	-.077	.939
Sex	1.042	.548	.374	2.381	.052
Residents	-.333	.542	.387	2.375	.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	<b>.016</b>

The simple linear regression test results 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, residence, education level and fear of needle during intramuscular (IM) injection, were found to be non-predictive variables for pain levels among patients not receiving lidocaine spray ( $p > 0.05$ ).

## DISCUSSION:

### The findings would benefit from additional reinforcement from previous research.

The current research seeks to examine the impact of lidocaine spray and socio-demographic data on the perception of pain levels during intramuscular injection. The study findings reveal varying patient responses concerning their pain levels during intramuscular injection. A significant proportion (66%) reported experiencing mild pain after receiving Lidocaine, with scores ranging from 0 to 4 on the assessment scale, as indicated by an average score of  $(1.27 \pm 1.340)$ . Conversely, (56%) of participants in the group of control reported a moderate level of pain, with scores ranging from 0 to 7 on the assessment scale, reflected in an average score of  $(4.46 \pm 2.022)$ . While the control group was non-significant ( $p > 0.05$ ).

These results are similar to a previous investigation by Jamalinik et al. (2023), who also used the VAS to assess the influence of lidocaine and cold spray on the degree of pain during intramuscular 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 our results. Hoseini et al., 2022, study research 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 in the average degree of pain when compared to the control group.

To justify this finding, lidocaine, 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).

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

The study results show that significant difference between body mass index (BMI) and pain intensity in the group of lidocaine ( $\beta = 0.113$ ;  $p = .028$ ). These findings are inconsistent with the outcomes of a study by Bedel et al. (2022), study conducted to illustrate vapocoolant spray effectiveness in the mitigation of pain via injection of intramuscular, these study demonstrated no

significant distinction between body mass index (BMI) and pain score (p-value (0.183)).

The difference between previous and current studies is that many factors 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.

In the group of control, (Table 5) The outcomes illustrate that significant difference between pain intensity and body mass index (BMI) ( $\beta = -0.374$ ;  $p = .016$ ) These results are consistent with the outcomes of study by Hoseini, et al.,(2022) ,this study used a visual analogue scale, aims to Comparison of the effectiveness of acupressure and lidocaine spray on pain perception via intramuscular (IM) injection.

The results (Table 4), showed that age groups have no statistically significant difference in pain intensity in the group of study ( $p = .939$ ). These outcomes of the study are compatible with the study by (Jamalinik et al., 2023); Bedel et al., 2022), Similarly, sex groups have no statistically significant in pain score(p-value (.052)). This finding is consistent with other studies conducted by (Gürdap & Cengiz, 2022; Abdelkhalek, 2019).

In the control group (table 5), Sex groups have no significant difference in pain level (p-value (.052)). Similarly, indicated that age groups have no significant variation in pain intensity (p-value (.939)). These results are consistent with the study for both (Gürdap & Cengiz, 2022; Aydin & Avşar, 2019; Kant & Akpinar, 2017).

The outcomes (table 5) demonstrate that there was no significant variation between level of education and pain intensity in the study group (p-value (.290)). These outcomes are consistent with past investigations performed by (Abdelkhalek, 2019; Aydin & Avşar, 2019).

The results (Table 5) indicate that no significant variation between pain intensity and level of education in the control group (p-value (.543)).

These findings are consistent with prior investigations performed by (Bilgic, 2021; Aydin & Avsar, 2019).

Regarding fear of intramuscular (IM) injection, (Table 4) the study result was analyzed by simple linear regression test in the lidocaine spray group. The outcomes of the study illustrate that there was no statistically significant relationship between pain score and fear of injection (p value (.295)). The study outcomes were supported by (Gürdap & Cengiz, 2022; Abdelkhalek, 2019).

The outcomes of the study in the control group (Table 5), demonstrate that there is no statistically significant relationship between fear of injection and pain level (p value (.741)). These results of the study are compatible with the previous investigation conducted by Bilge et al. (2019), their purpose of the study to evaluate of cold spray and shot-blocker in mitigating pain through injection of intramuscular (IM) in adults The finding of the study show that fear of intramuscular injection did not have statistical significant impact on mitigation the pain level in the control group ( $p = 0.061$ ).

In the study group (Table 4), indicated that residency had no significant effect on the patient's pain score ( $p = .726$ ). These results are similar to previous research performed by (Heshmatifar et al., 2022; Karabey & Karagzolu, 2021).

In the control group (Table 5), it was indicated that residency had no significant effect on the patient's pain score ( $p = .542$ ). These outcomes are similar to previous research conducted by (Bilgiç, 2021; Aydin & Avşar, 2019).

## CONCLUSIONS:

Research results showed that using lidocaine spray reduces pain during intramuscular injections. More research is needed to confirm the impact of applying lidocaine spray on degree of pain caused by intramuscular injections in adults.

**RECOMMENDATIONS:**

As a result, it is recommended that the study be conducted with larger sample sizes.

**Limitation:**

The limitation of this study is that it focuses on patients receiving diclofenac sodium drugs because pain levels following IM injection can differ depending on the drug's composition. Therefore, the results of this study cannot be broadly generalized to other drugs.

**Acknowledgments:**

The author would like to express his gratitude to all the patients who participated in the study, as well as the college of Nursing at University of Kerbala and Imam Al-Sadiq General Hospital in Babylon, Iraq.

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