Mosul Journal of Nursing

Online ISSN: 2663-0311 - Print ISSN: 2311-8784
Website: https://mjn.uomosul.edu.iq

The Effectiveness of Lidocaine Spray in Reducing Pain During Intramuscular Injection: A Randomized Controlled Trial

Authors Hameed Muslim Hashem [a], Hameed Muslim Hashem [b]

Affiliation College of Nursing/University of Karbala- *Iraq.*

ARTICLEINFO

Keywords:
Intramuscular injection
lidocaine spray
pain management
Randomized controlled trial
nursing practice
local anesthesia

Abstract

Background: Intramuscular (IM) injection is a routine nursing procedure often associated with pain and discomfort for patients. Minimizing injection-related pain is a critical aspect of improving patient care and satisfaction. Lidocaine spray, a topical anesthetic, has been widely used to reduce pain in various medical procedures. This study aims to evaluate the effectiveness of lidocaine spray in alleviating pain during IM injections.

Methods: A single-blind, randomized controlled trial was conducted at Imam Al-Sadiq General Hospital in Babylon, Iraq, between December 28, 2023, and February 14, 2024. A total of 100 adult patients receiving intramuscular diclofenac sodium injections were randomly assigned to either the intervention group (lidocaine spray) or the control group (no lidocaine). Pain levels were assessed using the Visual Analog Scale (VAS). The data were analyzed using SPSS software, with a significance level set at 5% ($p < 0.05$).

Results:

The mean pain score in the intervention group was significantly lower (1.27 ± 1.340) compared to the control group (4.46 ± 2.022) ($p < 0.001$). The results indicate that lidocaine spray effectively reduces pain intensity during IM injection. Furthermore, a simple linear regression analysis identified body mass index (BMI) as a significant predictor of pain levels among participants receiving lidocaine ($\beta = 0.113$; $p = 0.028$).

Conclusion:

The findings suggest that lidocaine spray is an effective method for reducing pain during IM injections in adult patients. Its rapid onset, ease of use, and affordability make it a viable option for routine clinical practice. Further research with larger sample sizes and diverse patient populations is recommended to validate these findings.

What is already known about the topic?

- **Intramuscular (IM) injections** are one of the most commonly used routes for medication administration, often associated with significant pain and discomfort, especially in pediatric and adult patients.

*** Corresponding author.** Hameed Muslim Hashem
E-mail address: hameedmuslim333@gmail.com

DOI: 10.33899/mjn.2025.149563.1109 , Authors, 2024, College of Nursing, University of Mosul.
Date Received 05 August 2024; Received in revised form 12 October 2024; Accepted 25 November 2024, Available online 01 January 2025

Introduction

Intramuscular (IM) injection is a standard nursing procedure widely used in clinical practice for administering medications. However, improper administration can lead to various complications, including pain, muscle tightness, sterile abscess formation, tissue necrosis, granuloma, nerve injuries, intravascular injection, and hemorrhage (Aydin & Avşar, 2019). Despite the therapeutic benefits of IM injections, they are often associated with significant discomfort and pain, which can affect patient compliance and satisfaction.

Injections are among the most frequently performed medical procedures worldwide, with approximately 16 billion injections administered annually in developing and transitioning countries (Jin et al., 2015). The effective administration of IM injections requires technical proficiency and careful decision-making regarding the appropriate tools and techniques. Pain during IM injection primarily results from mechanical trauma caused by needle penetration and the rapid pressure exerted during drug administration (Sedat et al., 2019).

IM injections involve the delivery of medication deep into selected muscles, which have rich vascularization, enabling rapid absorption into systemic circulation while bypassing first-pass metabolism. These injections are commonly used for both preventive (e.g., vaccinations) and therapeutic purposes, with over 95% of IM injections administered for treatment (Gutierrez & Munakomi, 2023).

In recent years, advancements in pain management have significantly influenced nursing practice, emphasizing the importance of minimizing patient discomfort. Nurses play a crucial role in pain relief, as they are directly involved in patient care. Effective pain management depends on nurses' knowledge, competencies, and approach to painful procedures. Therefore, it is their responsibility to administer injections carefully and provide pain relief to improve patient outcomes (Aydin & Güven, 2020).

To reduce injection-related pain, both pharmacological and non-pharmacological interventions are utilized. Among the pharmacological approaches, topical anesthetics such as prilocaine, piroxicam creams, and lidocaine spray are commonly used (Kaplan et al., 2023). Lidocaine, a widely used local anesthetic, is frequently administered as a spray in clinical settings due to its moderate effectiveness in numbing the skin and mucous membranes (Marvi et al., 2023).

Lidocaine spray functions as a topical anesthetic, blocking nerve signals in the body to provide short-term pain relief. It is commonly used for medical procedures such as injections, minor surgeries, dental treatments, and insect bites. Additionally, it offers relief for conditions like sunburn and minor burns (Jamalinik et al., 2023; Hoseini et al., 2022). The 10% lidocaine spray formulation is particularly advantageous due to its rapid onset of action, painless application, easy availability, cost-effectiveness, and pleasant odor (Kulkarni et al., 2023).

The mechanism of pain alleviation with lidocaine is based on its ability to block sodium channels, thereby preventing nerve transmission and reducing pain perception. Its rapid onset and moderate efficacy make it a preferred choice for local anesthesia and pain relief in various medical applications (Marvi et al., 2023).

Aim of the Study

This study aims to evaluate the effectiveness of lidocaine spray in reducing pain levels associated with intramuscular injections. By comparing pain perception between patients receiving lidocaine spray and those in a control group, the study seeks to determine whether this intervention can serve as an effective and practical pain management strategy in clinical settings.

Materials and Methods

Study Design

This study was designed as a single-blind, randomized controlled trial to assess the effectiveness of lidocaine spray in reducing pain severity during intramuscular (IM) injections.

Blinding

A single-blind approach was employed, where the researcher was aware of the treatment allocation, but the participants were blinded to their assigned group. This blinding method ensured that participants' knowledge of treatment assignment did not influence their pain perception, thereby minimizing potential bias.

Study Setting

The study was conducted at Imam Al-Sadiq General Hospital in Babylon, Iraq, over a period spanning December 28, 2023, to February 14, 2024.

Sample and Sampling Procedure

The sample size was determined using power analysis, with a 95% confidence level and a 5% margin of error, leading to a calculated sample size of 100 participants. The study population consisted of adult patients admitted to the emergency department who required an intramuscular injection of diclofenac sodium.

Participants were randomly assigned to either the lidocaine spray group (n = 50) or the control group (n = 50) through a simple randomization process. This involved drawing a sealed envelope containing a color-coded assignment (yellow for the lidocaine spray group and green for the control group).

Eligible participants were briefed on the study objectives, and those who provided informed consent completed a baseline questionnaire before receiving the IM injection. Pain levels were evaluated using the Visual Analog Scale (VAS) one minute after the injection.

Intervention

Experimental Group (Lidocaine Spray Group)

1. The injection site was disinfected using an alcohol swab and allowed to dry (Bilgiç, 2021; Chung & Wong, 2002; Derya et al., 2015).
2. Two puffs of lidocaine spray (20 mg) were applied from a distance of 5 cm.
3. The lidocaine spray was left to act for 1 to 5 minutes, followed by a 2-minute waiting period before drug injection (Khosravi Pour et al., 2023).
4. The intramuscular injection was then administered into the ventrogluteal region at a 90-degree angle.

Control Group (No Lidocaine Spray Group)

1. The injection site was disinfected using an alcohol swab.
2. The intramuscular injection was administered without the use of lidocaine spray, specifically in the ventrogluteal region.

Data Collection Tools

1. Questionnaire Form
    - The questionnaire consisted of seven questions assessing participants' age, gender, place of residence, educational level, fear of needles, height, and weight.
    - The questionnaire was completed before the injection.

2. Visual Analog Scale (VAS)
    - The VAS is a 10 cm horizontal scale ranging from 0 ("no pain") to 10 ("severe pain") (Karabey, 2021; Aydin & Güven, 2020).
    - After the injection, participants were asked to mark their pain level on the scale.
    - Pain intensity was categorized into four levels:
        - No pain (0 points)
        - Mild pain (1–3 points)
        - Moderate pain (4–6 points)
        - Severe pain (7–10 points) (Karasu et al., 2017).

Reliability and Validity of the Scale

The Visual Analog Scale (VAS) is a widely used and validated tool for pain assessment. Previous studies confirm that VAS is reliable and valid for evaluating pain in adults aged 18 and above (Begum & Hossain, 2019; Joseph & Palappallil, 2017; Mandysová & Kadlečková, 2015).

Results

Demographic Characteristics of the Study Sample

The study included 100 participants randomly assigned to two groups: Lidocaine Spray Group (n = 50) and Control Group (n = 50). The participants' demographic and clinical characteristics are summarized in Table 1.

Table 1: Demographic and Clinical Characteristics of the Study Participants

Characteristic	Lidocaine Group (n = 50)	Control Group (n = 50)
Age (years)	18 – 53 (Mean ± SD: 31.88 ± 9.53)	18 – 54 (Mean ± SD: 32.26 ± 8.75)
Sex	Male: 29 (58.0%) Female: 21 (42.0%)	Male: 31 (62.0%) Female: 19 (38.0%)
Residence	Urban: 31 (62.0%) Rural: 19 (38.0%)	Urban: 33 (66.0%) Rural: 17 (34.0%)
Education Level	Bachelor's: 14 (28.0%) High School: 12 (24.0%)	High School: 13 (26.0%) Bachelor's: 12 (24.0%)
Fear of Needles	No Fear: 24 (48.0%) Some Fear: 16 (32.0%) Yes: 10 (20.0%)	No Fear: 24 (48.0%) Some Fear: 18 (36.0%) Yes: 8 (16.0%)
BMI Categories	Normal (18.5–24.9): 24 (48.0%) Overweight (25.0–29.9): 13	Normal (18.5–24.9): 23 (46.0%) Overweight (25.0–29.9): 20 (40.0%) Obese (≥30.0): 7 (14.0%)

	(26.0%) Obese (≥30.0): 13 (26.0%)

Pain Assessment Results

Pain levels were evaluated using the Visual Analog Scale (VAS), and the distribution of pain intensity across both groups is presented in Table 2.

Table 2: Pain Level Assessment Among Study Groups

Pain Level	Lidocaine Group (n = 50)	Control Group (n = 50)
No Pain (VAS 0)	12 (24.0%)	4 (8.0%)
Mild (VAS 1–3)	33 (66.0%)	9 (18.0%)
Moderate (VAS 4–6)	5 (10.0%)	28 (56.0%)
Severe (VAS 7–10)	0 (0.0%)	9 (18.0%)
Mean ± SD (VAS Score)	1.27 ± 1.340	4.46 ± 2.022

Interpretation:

- In the Lidocaine group, most participants (66.0%) reported mild pain, while 24.0% experienced no pain at all.
- In contrast, in the Control group, the majority (56.0%) experienced moderate pain, and 18.0% reported severe pain.
- The mean pain score was significantly lower in the Lidocaine group (1.27 ± 1.340) compared to the Control group (4.46 ± 2.022).

Comparison of Pain Levels Between Groups

A t-test was conducted to compare pain levels between the two groups (Table 3).

Table 3: Effect of Lidocaine Spray on Pain Level

Groups	Mean (M)	SD	t-value	df	η^2 (Effect Size)	p-value
Lidocaine Group (n = 50)	1.72	1.3407	7.985	98	0.39 (Large Effect)	< 0.001
Control Group (n = 50)	4.46	2.0243				

Interpretation:

- The t-value of 7.985 and p-value < 0.001 indicate a highly significant difference in pain levels between the groups.
- The effect size ($\eta^2 = 0.39$) suggests a large practical effect of lidocaine spray in reducing pain intensity.

Predictors of Pain Levels in the Lidocaine and Control Groups

A simple linear regression analysis was performed to examine predictors of pain levels in both groups.

Table 4: Predictors of Pain Levels in the Lidocaine Group

Variable	Beta (β)	t-value	p-value
Age	0.028	1.189	0.242 (NS)
Sex	0.514	1.050	0.300 (NS)
Residence	0.094	0.352	0.726 (NS)
Education Level	-0.159	-1.072	0.290 (NS)
Fear of Needles	-0.309	-1.062	0.295 (NS)
BMI	-0.113	-2.091	0.028 (Significant)

Table 5: Predictors of Pain Levels in the Control Group

Variable	Beta (β)	t-value	p-value
Age	-0.004	-0.077	0.939 (NS)
Sex	1.042	2.381	0.052 (NS)
Residence	-0.333	2.375	0.542 (NS)
Education Level	-0.118	-0.614	0.543 (NS)
Fear of Needles	0.130	0.333	0.741 (NS)
BMI	-0.374	-2.521	0.016 (Significant)

Interpretation:

- BMI was a significant predictor of pain levels in both groups.
  - In the Lidocaine group, higher BMI was associated with slightly lower pain levels (β = -0.113, p = 0.028).
  - In the Control group, higher BMI significantly increased pain levels (β = -0.374, p = 0.016).
- Other variables (age, sex, residence, education level, and fear of needles) were not significant predictors in either group.

Summary of Findings:

- Lidocaine spray significantly reduced pain compared to the control group ($p < 0.001$).
- Most participants in the Lidocaine group experienced mild or no pain, whereas the control group reported moderate to severe pain.
- BMI was a significant predictor of pain intensity, with higher BMI correlating with increased pain in the control group.
- No other demographic factors significantly influenced pain perception.

Discussion

This study aimed to assess the effectiveness of lidocaine spray in reducing pain perception during intramuscular (IM) injections and to examine the influence of socio-demographic factors on pain intensity. The findings revealed a significant reduction in pain levels among participants who received lidocaine spray compared to the control group.

A majority (66%) of participants in the lidocaine group reported mild pain (VAS: 1.27 ± 1.340), while 24% experienced no pain. Conversely, 56% of participants in the control group reported moderate pain, and 18% experienced severe pain, with a significantly higher mean pain score (VAS: 4.46 ± 2.022, $p < 0.001$).

These results align with previous studies:

- Jamalinik et al. (2023) also used the Visual Analog Scale (VAS) to evaluate the effects of lidocaine and cold spray on IM injection pain. Their findings showed a significant reduction in pain levels, with mean VAS scores of 2.63 in the intervention group versus 3.44 in the control group.
- Hoseini et al. (2022) compared lidocaine spray and acupressure for IM injections and found lower pain levels in the lidocaine spray group (VAS: 1.78) and acupressure group (VAS: 1.83) compared to the control group (VAS: 2.83).

The pain-reducing effects of lidocaine spray can be attributed to its mechanism of action as a local anesthetic. Lidocaine inhibits voltage-gated sodium channels, preventing neuronal depolarization and reducing pain transmission (Zdybski & Grodzka, 2018).

Effect of Socio-Demographic Factors on Pain Perception

1. Body Mass Index (BMI) and Pain Intensity

This study found a significant relationship between BMI and pain intensity:

- In the lidocaine group, higher BMI was associated with slightly lower pain levels ($\beta = -0.113$, $p = 0.028$).
- In the control group, higher BMI significantly increased pain intensity ($\beta = -0.374$, $p = 0.016$).

These results contrast with Bedel et al. (2022), who studied vapocoolant spray for IM injection pain relief and found no significant association between BMI and pain intensity ($p = 0.183$). This discrepancy may stem from differences in pain perception, patient experiences, emotional states, and healthcare provider techniques. Further research is needed to explore these inconsistencies.

2. Age and Sex

No significant differences in pain levels were observed based on age ($p = 0.939$) or sex ($p = 0.052$). These findings are consistent with previous research by

Jamalinik et al. (2023), Bedel et al. (2022), and Gürdap & Cengiz (2022), which reported no statistically significant influence of age or sex on pain intensity following IM injections.

3. Education Level and Pain Perception

The results showed no significant association between education level and pain intensity in both groups ($p = 0.290$ in the lidocaine group, $p = 0.543$ in the control group). This aligns with studies by Abdelkhalek (2019) and Aydin & Avşar (2019), who found that education level does not significantly impact pain perception during medical procedures.

4. Fear of Needles

Fear of injections did not significantly correlate with pain perception in either group ($p = 0.295$ in the lidocaine group, $p = 0.741$ in the control group). This is consistent with findings from Bilge et al. (2019), who examined the effectiveness of cold spray and shot-blocker in reducing IM injection pain. Their study found that fear of injections did not significantly impact pain levels ($p = 0.061$).

5. Residency (Urban vs. Rural)

The results indicated that place of residence (urban vs. rural) did not significantly affect pain perception ($p = 0.726$ in the lidocaine group, $p = 0.542$ in the control group). These findings are in line with previous studies, including Heshmatifar et al. (2022) and Karabey & Karagzolu (2021), which reported similar results.

Conclusion and Recommendations

Conclusion

This study demonstrated that lidocaine spray is an effective intervention for reducing pain during intramuscular injections. Participants who received lidocaine spray experienced significantly lower pain levels compared to the control group ($p < 0.001$).

Among socio-demographic factors, BMI was a significant predictor of pain intensity, whereas age, sex, education level, fear of needles, and place of residence had no significant impact.

Recommendations

Based on these findings, the following recommendations are proposed:

5. Routine Use of Lidocaine Spray: Healthcare providers should consider incorporating lidocaine spray as a standard practice for intramuscular injections to improve patient comfort and compliance.
6. Further Research: Future studies should investigate the long-term effects of lidocaine spray and its effectiveness in different clinical settings.
7. Larger Sample Size: Conducting studies with larger and more diverse populations will help validate these findings and explore potential differences across various patient groups.
8. Comparative Studies: Further research comparing lidocaine spray with other pain-relief techniques (e.g., vapocoolant spray, acupressure, and distraction methods) is recommended.

Limitations

This study has some limitations:

- The study focused only on patients receiving intramuscular diclofenac sodium, which may limit the generalizability of findings to other medications.
- Pain perception is subjective and influenced by individual variability, including previous experiences and emotional states.
- The study was conducted in a single hospital setting, which may not reflect broader population dynamics.

To address these limitations, future research should explore a wider range of medications, multiple hospital settings, and psychosocial factors influencing pain perception.

Ethical Considerations

The study was approved by the Committee of Scientific Research at the College of Nursing, University of Karbala (Approval Code: uok.con.23.019, Decision No: 2023.11.19, Iraq).

As part of an original randomized controlled trial, the trial protocol was registered in the Iranian Registry of Clinical Trials (IRCT) on February 21, 2024. The trial registration details are as follows:

- IRCT Registration Reference: IRCT20240127060820N1
- Trial ID: 75385
- Membership Number: 60820

All participants provided informed consent, and strict confidentiality was maintained throughout the study.

Acknowledgments

The author expresses gratitude to all participants who contributed to this study. Special appreciation is extended to:

- The College of Nursing, University of Kerbala, for academic guidance and ethical approval.
- Imam Al-Sadiq General Hospital, Babylon, Iraq, for providing the research setting and logistical support.
- The dedicated nursing staff and healthcare professionals who assisted in the implementation of this study.

References

Abdelkhalek, W. S. S. (2019). The effect of shot blocker and Z–Track techniques on reducing the needle pain and anxiety associated with intramuscular injection. *International Journal of Nursing Didactics, 9*(12), 31-38. https://doi.org/10.15520/ijnd.v9i12.2766

Aydin, E., & Avşar, G. (2019). Examining the effect of "Shotblocker" in relieving pain associated with intramuscular injection. *Complementary Therapies in Medicine, 47*, 102192. https://doi.org/10.1016/j.ctim.2019.102192

Aydin, S. T., & Güven, S. D. (2020). The effect of shot blocker application on intramuscular injection pain in adults: A randomized controlled trial. *International Journal of Nursing Didactics, 10*(03), 01-04. https://doi.org/10.15520/ijnd.v10i03.2875

Bedel, C., Selvi, F., & Akçimen, M. (2022). Vapocoolant spray for pain control in intramuscular injection applications: A prospective, randomized controlled trial. *Ibnosina Journal of Medicine and Biomedical Sciences, 14*(02), 68-73. https://doi.org/10.4103/ijmbs.ijmbs_10_22

Begum, M. R., & Hossain, M. A. (2019). Validity and reliability of visual analogue scale (VAS) for pain measurement. *Journal of Medical Case Reports and Reviews, 2*(11), 1-5. https://doi.org/10.52845/JMCRR/2019/2-11-1

Bilge, S., Aydin, A., Gun, C., Aldinc, H., Acar, Y. A., Yaylaci, S., Cinar, O., & Balci, V. (2019). Comparison of the efficacy of ShotBlocker and cold spray in reducing intramuscular injection-related pain in adults: A prospective, randomized, controlled trial. *Saudi Medical Journal, 40*(10), 996-1002. https://doi.org/10.15537/smj.2019.10.24516

Bilgiç, Ş. (2021). The comparison of the effectiveness of local ice and manual pressure application in decreasing pain related to intramuscular injection. *Clinical and Experimental Health Sciences, 11*(2), 302-307. https://doi.org/10.33808/clinexphealthsci.775278

Gürdap, Z., & Cengiz, Z. (2022). Comparison of cold spray and ShotBlocker to reduce intramuscular injection pain: A randomized controlled trial. *Journal of Clinical Pharmacy and Therapeutics, 47*(8), 1249-1256. https://doi.org/10.1111/jcpt.13663

Gutierrez, J. J. P., & Munakomi, S. (2023). Intramuscular injection. In *StatPearls*. StatPearls Publishing. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK556111/

Hafez, D. M. E., & Ali, W. G. M. (2023). ShotBlocker versus cryotherapy for reducing pain and anxiety associated with subcutaneous injection. *Frontiers of Nursing, 10*(3), 363-371. https://doi.org/10.2478/fon-2023-0036

Heshmatifar, N., Salari, M., Rad, M., Saleh, T. A., Borzoee, F., & Rastaghi, S. (2022). A new approach on the pain management of intramuscular injection: A triple-blind randomized clinical trial. *Pain Management Nursing, 23*(3), 353-358. https://doi.org/10.1016/j.pmn.2022.01.007

Hoseini, M. S., Hoseini, S. B., Mohamadzadeh Tabrizi, Z., Rastaghi, S., & Davarinia Motlagh Quchan, A. (2022). Comparison of the effect of lidocaine spray and acupressure on the severity of intramuscular injection pain. *Evidence Based Care, 11*(4), 26-32. https://doi.org/10.22038/ebcj.2022.62374.2473

Jamalinik, M., Hasheminik, M., Paivar, B., Khaleghipour, M., Khorashadizadeh, F., Bordbar, R., & Shafigh, N. (2023). Comparative study of the effect of lidocaine spray and ice spray on the pain intensity during intramuscular injection: A randomized clinical trial. *Pain Management Nursing, 24*(2), 229-234. https://doi.org/10.1016/j.pmn.2023.01.005

Jin, J. F., Zhu, L. L., Chen, M., Xu, H. M., Wang, H. F., Feng, X. Q., & Zhou, Q. (2015). The optimal choice of medication administration route regarding intravenous, intramuscular, and subcutaneous injection. *Patient Preference and Adherence, 9*, 923-942. https://doi.org/10.2147/PPA.S87271

Joseph, L. R., & Palappallil, D. S. (2017). Neck disability index, visual analog scale, and Likert scale in patients receiving pharmacotherapy for neck pain: How good do they correlate? *National Journal of Physiology, Pharmacy and Pharmacology, 7*(3), 328-332. https://doi.org/10.5455/njppp.2017.7.1233125122016

Kant, E., & Akpinar, R. B. (2017). The effect of music and the pressure applied on pain induced by intramuscular injection. *International Journal of Caring Sciences, 10*(3), 1313-1318. Retrieved from https://www.internationaljournalofcaringsciences.org/docs/36_kant_original_10_3.pdf

Kaplan, A. L. İ., Güler, S., & Avşaroğulları, Ö. L. (2023). Comparison of manual pressure and ShotBlocker on pain and satisfaction in intramuscular injection: A randomized controlled trial. *Sağlık Bilimleri Dergisi, 32*(1), 89-96. https://doi.org/10.17681/hsp.1166135

Karabey, T. (2021). The effect of manual pressure after subcutaneous injection on pain and comfort levels. *Journal of Vascular Nursing, 39*(4), 134-139. https://doi.org/10.1016/j.jvn.2021.08.003