Pain Management Nursing 24 (2023) 229–234

Contents lists available at ScienceDirect

Pain Management Nursing

journal homepage: www.painmanagementnursing.org

Original Article

Comparative Study of the Effect of Lidocaine Spray and Ice Spray on the Pain Intensity During Intramuscular Injection: A Randomized Clinical Trial

Mehdi Jamalinik[*], Morteza Hasheminik[†], Bahareh Paivar[‡], Mostafa Khaleghipour[§], Fatemeh Khorashadizadeh[‖], Reza Bordbar[¶], Rasool Lakziyan[#], Mohammad Siavoshi[**,1], Navid Shafigh[††]

[*] Vasei Hospital, Sabzevar University of Medical Sciences, Sabzevar, Iran
[†] Department of Nursing, Sabzevar Branch, Islamic Azad University, Sabzevar, Iran
[‡] Quchan School of nursing, Mashhad University of Medical Sciences, Mashhad, Iran
[§] Department of Anesthesiology, 22 Bahman Hospital, Neyshabur University of Medical Sciences, Neyshabur, Iran
[‖] Department of Epidemiology and biostatistics, Neyshabur University of Medical Sciences, Neyshabur, Iran
[¶] 22 Bahman Hospital, Neyshabur University of Medical Sciences, Neyshabur, Iran
[#] Kashmar Center of Higher Health Education, Mashhad University of Medical Sciences, Mashhad, Iran
[**] Department of Nursing, Neyshabur University of Medical Sciences, Neyshabur, Iran
[††] Department of Anesthesiology and Critical Care Medicine, School of Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran

ARTICLE INFO

Article history:
Received 21 February 2021
Received in revised form 12 July 2022
Accepted 30 July 2022

ABSTRACT

Background: Intramuscular injection is one of the most common, invasive, and painful ways to deliver medicine to the body.
Aim: Since one of the nurse's duties is to employ different methods to reduce pain caused by treatment procedures, this study was conducted to determine the effect of lidocaine spray and ice spray on pain intensity at the muscle injection site.
Method: A clinical trial was performed on 90 patients presenting to outpatient clinics of Neyshabur hospitals. The samples were selected using a computerized table of random numbers, and each participant was randomly assigned to one of the control, lidocaine spray, and ice spray groups. Pain severity was measured immediately after intramuscular injection using a numerical pain scale. Descriptive statistics along with statistical tests (chi-square, Fisher, etc.) were used to analyze the data in the R environment version 3.6.2. Ordinal logistic regression was used to compare pain intensity in the three groups by adjusting the effect of age variables and sensory disorders.
Results: The mean pain intensity was 3.44 without intervention, 2.63 with lidocaine spray, and 2.27 with ice spray. Statistical tests indicated a significant difference in pain intensity of intramuscular injection between the ice group and the control group ($p = .010$). Although lidocaine spray reduced the pain intensity, its effect was insignificant compared with the control group.
Conclusions: Both ice and lidocaine spray can be effectively used to reduce the intensity of intramuscular injection pain; however, it seems that ice spray is a more effective, safe, and affordable method.

It is estimated that 12 billion intramuscular injections (IM) are annually done in the world (Serena, 2010). According to the reports, 96% of IM injections are used to administer antibiotics, vitamins, and painkillers. The average number of injections per individual per year was estimated to be between 0.9 and 8.5, and it is estimated that each person in developing countries receives 1.5 injections per year on average. (Lala & Lala, 2003; Raddadi et al., 2017; Simonsen et al., 1999). Patients often find IM injections uncomfortable and stressful. Studies have shown that 5.3% of the adult patients have severe fear and 22% have a moderate fear of needles (Celik & Khorshid, 2015). Pain at the injection site causes anxiety and discomfort, reduces the patient's confidence in the nurse's ability, and makes the patient avoid subsequent injections (Şahiner et al., 2015). Researchers have tried to introduce different

[1] Address correspondence to: Neyshabur University of Medical Sciences, Janbazan Blv, Neyshabur, Iran.
E-mail address: siavoshi_mohammad@yahoo.com (M. Siavoshi).

https://doi.org/10.1016/j.pmn.2022.07.009
1524-9042/

methods of pain reduction during injections. Using local anesthetics is one of the methods to reduce the pain caused by injections (Taddio et al., 1992).

Ice and lidocaine spray are two topical anesthetics that are easy to use (Mohiuddin et al., 2015). Synthesized lidocaine, the most commonly used group of topical anesthetics, was first made in 1943 by the accomplished chemist Nils Lofgren. This chemical reversibly inhibits the conduction of impulses along axons and other irritating membranes that use sodium channels to generate an action potential. This effect is used in clinical practice to control pain sensation in certain body parts. There are different forms of lidocaine (Hawley et al., 2020). Choosing the best type of analgesic depends on the method of administration, duration, and extent of its required effect. In addition, the drug should have fewer side effects, be affordable and easy to use, and should not interfere with care and treatment procedure (Fiorelli et al., 2019). Topical lidocaine spray is one of the most common forms of lidocaine for local anesthesia of mucous membranes and skin with a moderate duration of action. Depending on the location, anesthesia is usually induced within 1 to 5 minutes and lasts for 10 to 15 minutes (Açmaz et al., 2015).

Comparing the benefits and drawbacks of various forms of lidocaine in pain relief reveals that intradermal injection of lidocaine is more effective in reducing pain than other forms of injection, has a faster onset of action, and causes less fear in patients because of the needle's shortness and thinness (Hawley et al., 2020). However, because of its quick onset of action and convenience of application, lidocaine spray is more widely employed in clinical settings (Açmaz et al., 2015).

Another way to relieve pain is to stimulate the skin. Skin stimulation can reduce pain perception. It is carried out in a variety of ways, including using an electric vibrator, massaging, or applying local heat and cold to the injection site. Among various methods of skin stimulation, the use of topical cold, such as ice spray, is preferred over other methods because of its low cost, availability, and ease of use (Arab et al., 2017). Topical cold therapy reduces the ability of nerve fibers to transmit pain (Yilmaz & Kiyak, 2017). Given that pain management is a moral and spiritual commitment for caregivers, using easier interventions to prevent or reduce the pain caused by injections is necessary (Zore & Dias, 2014).

While the effects of lidocaine and ice spray on relieving injection pain have been investigated separately, very few studies have compared the effect of these methods (Seyedfatemi et al., 2014). Therefore, it is necessary to further study the effects of these two methods by controlling the confounding variables. Hence, a double-blind randomized trial was conducted to compare the effects of lidocaine and ice spray on pain during intramuscular injection.

Methods

A randomized double-blind clinical trial was conducted to compare the effects of two novel methods of reducing the pain of intramuscular injection. The protocol of the study was approved by Neyshabur University of Medical Sciences, and the study was registered in the Iranian Registry of Clinical Trials at www.irct.ir (IRCT20171219037967N3).

Subjects and Sampling Method

The participants were patients presenting to the outpatient clinics of 22 Hospitals in Neyshabur for IM injection. They were categorized into three groups, including: (1) the control group (injection using the routine method and without lidocaine or ice spray); (2) lidocaine spray; and (3) ice spray. All the patients received the injection based on the Z-track method, in which the leakage of medicine into the subcutaneous tissue is prevented by lifting the skin of obese participants and pulling the skin of the thinner ones. The participants were assigned to one of the study groups using a computerized table of random digits. Because of cultural and religious customs in Iran, as an Islamic country, male patients were given the injection by male nurses, and female nurses administered the injection to the female patients. After injection, all patients were asked to complete a self-report demographic questionnaire containing questions on their age, marital status, income, history of sensory disorders, and type of drug injected.

Selection of Subjects

All subjects presenting to the outpatient clinics of the hospitals during the study period were invited to join the study. The inclusion criteria were: the ability to write and read to complete the informed consent form; consciousness; not taking painkillers or sedatives 6 hours before the injection; lack of severe and sensible pain; aged greater than 20 years; lack of skin problems or anesthesia at the injection site; and not having a negative history of allergy to lidocaine and ice spray. The exclusion criteria were: lack of consent to continue at any stage of the study; having mental health issues; giving incomplete information; or having an incomplete questionnaire. Patients whose IM injection was inherently painful, including those with ceftriaxone and penicillin injections, were also excluded.

For covering the ethical considerations, the informed consent form was reviewed by the Neyshabur University of Medical Sciences Ethics Committee before using in the study.

Study Protocol and Measurement of Outcomes

A numerical scale was used to measure the pain intensity, which was numbered between 0 and 10, with 0 indicating no pain and 10 representing the most intense pain possible. Before the injection, the scale was explained to all participants, but the participants were not aware of their group. In all three groups, pain intensity was measured 1 minute after the injection and recorded by trained nurses who were unaware of the group to which each patient belonged. Prior to IM injection, the participants were asked about their sensory disorders, such as diabetes and discopathy, and the results were recorded. In the control group, all patients had their injections based on routine practice without any local or oral painkillers.

In the lidocaine spray group, after cleaning and disinfecting the skin of the injection site with an alcohol cotton ball, two puffs of (equivalent to 20 mg) lidocaine 10% (Iran Daroo Co.) were sprayed on the skin surface—where the needle was to be inserted—at a distance of 5 cm by a trained nurse. Then, the IM injection was done in the dorsogluteal area using a 5-cc syringe with a black G22 needle (Soha Helal Iran Co). Because local anesthesia occurs 1 to 5 minutes after applying the lidocaine spray, the injection was given 5 minutes after administering the lidocaine spray.

In the ice spray group, similar to the lidocaine spray group, after cleaning the skin area using alcohol, two puffs of ice spray (Dispotech, Italy) were sprayed on the skin surface at a distance of 25 cm. The intramuscular injection was performed 3 to 5 seconds after using the ice spray.

At the end of the injection procedure, every patient received a coded questionnaire. Blinding steps were taken for data collection and analysis, and the data were collected in separate rooms by a data collector who was blind to the groups.

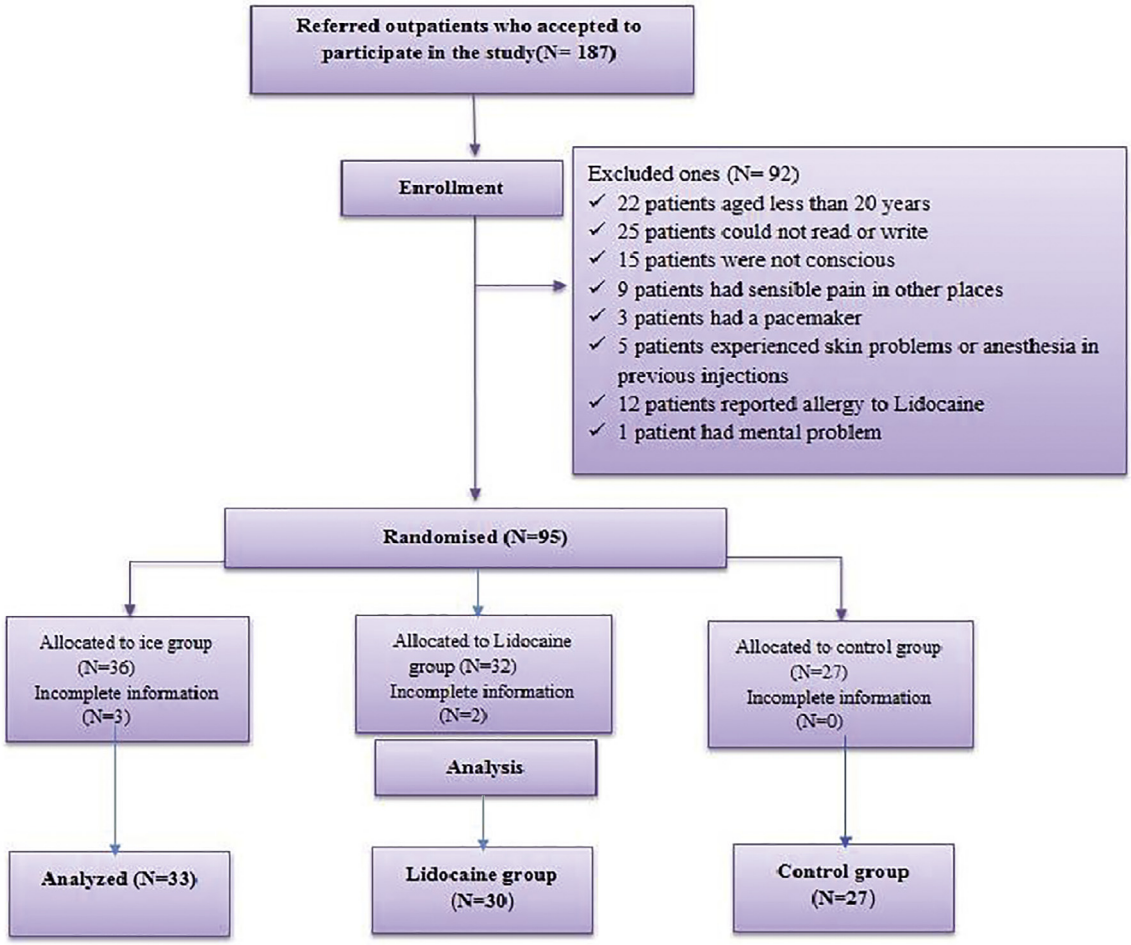

Figure 1. Consolidated standards of reporting trials (CONSORT).

Statistical Analysis

Statistical analysis was performed separately for the control, lidocaine, and ice spray groups, and categorical variables were presented as frequency and percentage. Age was expressed as median (interquartile range [IQR]) because of its asymmetric nature. The differences in the characteristics of the three groups were tested using the chi-square and Fisher's exact tests for categorical variables. Ordinal logistic regression was applied to compare the pain intensity between the study groups after adjusting the effect of some covariates (age, sensory disorders). All statistical analyses were performed using the R software version 3.6.2 for Windows. The two-sided p value $<.05$ was considered statistically significant.

Results

Of 187 patients presenting to the injection rooms of 22 Bahman Hospital during the sampling period, 95 patients accepted to participate in the study, of whom 5 did not complete the questionnaires completely. Finally, the data of 90 individuals were evaluated, including 39 women and 51 men. Twenty-seven people were randomly assigned to the control group, 30 to the lidocaine group, and 33 to the ice group (Fig. 1). The categorical baseline characteristics of the subjects according to the group are shown in Table 1. The majority of the patients were married. The participants were mostly homemakers (33%) and self-employed (29%). Most of the patients in the study had low incomes and lived in the city. The median age was 32 years (IQR = 26-40 years) in the control group, 40 years (IQR = 32.75-48.50 years) in the lidocaine group, and 31 years (IQR = 23-42 years) in the ice group.

No significant difference was found in demographic and clinical characteristics between the groups except for age and sensory disorders. The Kruskal-Wallis test showed a significant difference in age between the three groups ($p = .020$).

Figure 2 presents the difference in scores reported by all participants in the three groups. The median pain score was 3 in the control group and 2 in the other two groups (Fig. 2). In control, lidocaine, and ice groups, the mean pain score was 3.44, 2.63, and 2.27, respectively (Fig. 3).

The ordinal logistic regression showed a significant difference in pain intensity between the control and ice groups based on the numerical pain scale (AOR= 0.28, 95% CI: 0.11-0.74, $p = .010$) after adjustment for age and sensory disorders. However, there was no significant difference between lidocaine and control groups regarding pain intensity.

Discussion

The aim of this study was to compare the effects of lidocaine and ice sprays on the pain intensity during IM injection. A numer-

Table 1
Socio-demographic and clinical profile of the participants for categorical variables

Variables	Control group	Lidocaine group	Ice group	Total	*p*
Sex					
Male	16 (59.26)	17 (56.67)	18 (54.55)	51 (56.67)	.935
Female	11 (40.74)	13 (43.33)	15 (45.45)	39 (43.33)	
Marital status					
Married	20 (74.07)	27 (90.00)	23 (69.70)	70 (77.78)	.126
Single	6 (22.22)	3 (10.00)	10 (30.30)	19 (21.11)	
Widowed	0 (0)	0 (0)	0 (0)	0 (0)	
Divorced	1 (3.70)	0 (0)	0 (0)	1 (1.11)	
Employment status					
Worker	4 (14.81)	1 (3.33)	4 (12.12)	9 (10.00)	.508
Employee	1 (3.70)	4 (13.33)	3 (9.09)	8 (8.89)	
Self-employed	10 (37.04)	12 (40.00)	7 (21.21)	29 (32.22)	
Homemaker	7 (25.93)	11 (36.67)	12 (36.36)	30 (33.33)	
Retired	0 (0)	0 (0)	1 (3.03)	1 (1.11)	
Unemployed	2 (7.41)	0 (0)	3 (9.09)	5 (5.56)	
Other	3 (11.11)	2 (6.67)	3 (9.09)	8 (8.89)	
Income level (million Rials)					
<2	24 (88.89)	24 (80.00)	25 (75.76)	73 (81.11)	.426
2-4	3 (11.11)	6 (20.00)	8 (24.24)	17 (18.89)	
>4	0 (0)	0 (0)	0 (0)	0 (0)	
Residence					
City	20 (74.07)	21 (70.00)	24 (72.73)	65 (72.22)	.940
Village	7 (25.93)	9 (30.00)	9 (27.27)	25 (27.78)	
Injection					
Penicillin	3 (11.11)	8 (26.67)	7(21.21)	18 (20.00)	.318
Dexamethasone	2 (7.41)	3 (10.00)	6 (18.18)	11 (12.22)	
Ketorolac	8 (29.63)	5 (16.67)	4 (12.12)	17 (18.89)	
Methocarbamol	0 (0)	2 (6.67)	3 (9.09)	5 (5.56)	
Vitamins	4 (14.81)	4 (13.33)	3 (9.09)	11 (12.22)	
Ranitidine	0 (0)	3 (10.00)	1 (3.03)	4 (4.44)	
Ondansetron	1 (3.70)	1 (3.33)	0 (0)	2 (2.22)	
Others	9 (33.33)	4 (13.33)	9 (27.27)	22 (24.44)	
Sensory disorders					
Yes	6 (22.22)	5 (17.24)	0 (0)	11 (12.64)	.012
No	21 (77.78)	24 (82.76)	31 (100)	76 (87.36)	

ical pain scale was used to measure the pain intensity in the two intervention groups (lidocaine and ice spray before injection) and the control group (no intervention).

Lidocaine spray is a well-known method to reduce pain of IM injections. Based on the results of this study, by application of lidocaine spray the intensity of pain decreased, however, in comparison with the control group, pain reduction was not statistically significant. Several studies have evaluated the efficiency of lidocaine in reducing injection pain. A study by Asgari et al. (2013) found that lidocaine spray reduced the severity of the pain caused by inserting vascular needles. The analysis was performed on 30 hemodialysis patients, and the results showed a significant difference in the mean pain intensity between the lidocaine and placebo spray groups ($p = .001$). Valdovinos et al. (2009) investigated the effect of lidocaine ointment on the severity of pain during intravenous catheter insertion in 43 adults and found a significantly lower pain score in the intervention group compared with the control group. The fixation of neuronal membranes by limiting ion flow is the mechanism of action of lidocaine for pain relief. Therefore, applying lidocaine to the injection site restricts or stops the generation and transmission of nerve impulses (Karasu et al., 2017).

Another safe, non-pharmacologic method used to reduce pain during needle insertion and intramuscular injection is the application of topical cold therapy to the site immediately before injection. In this study, the pain intensity of IM injection following the use of ice spray was evaluated, and the results showed a mean pain intensity score of 2.27. Compared with the control group, the pain intensity was significantly reduced in the ice group ($p = .010$). These findings are in line with previous studies. For example, in a meta-analysis, the effect of cold therapy on the pain and bruising of subcutaneous injection of low-molecular-weight heparin was reviewed. The results showed that the use of local cold reduced the pain intensity and bruising up to 72 hours after the injection (Wang et al., 2020). Moreover, the results of a study by Mutlu & Yılmaz (2020) showed that cold treatment for more than 20 minutes reduced the pain in patients with soft tissue injuries. Cold therapy reduces the pain associated with different clinical procedures by changing the condition of the pain stimulus, reducing the metabolism of different cells, and slowing tissue hypoxia (Yağiz On, 2006). Interestingly, cold therapy was effective in reducing anxiety after chest tube removal in cardiac patients (Aktaş & Karabulut, 2019). Therefore, cold therapy can be considered an effective and easy-to-perform non-pharmacologic method for pain reduction (Yarahmadi et al., 2018).

Limitations

The main limitation of the study was the small sample size due to the COVID-19 pandemic, which ultimately led to a decrease in the test power. Therefore, it is necessary to conduct studies with larger sample sizes to confirm the results. Since data collection was carried out during the COVID-19 pandemic, patients were rarely admitted to hospitals for outpatient services, resulting in a marked decrease in the available samples.

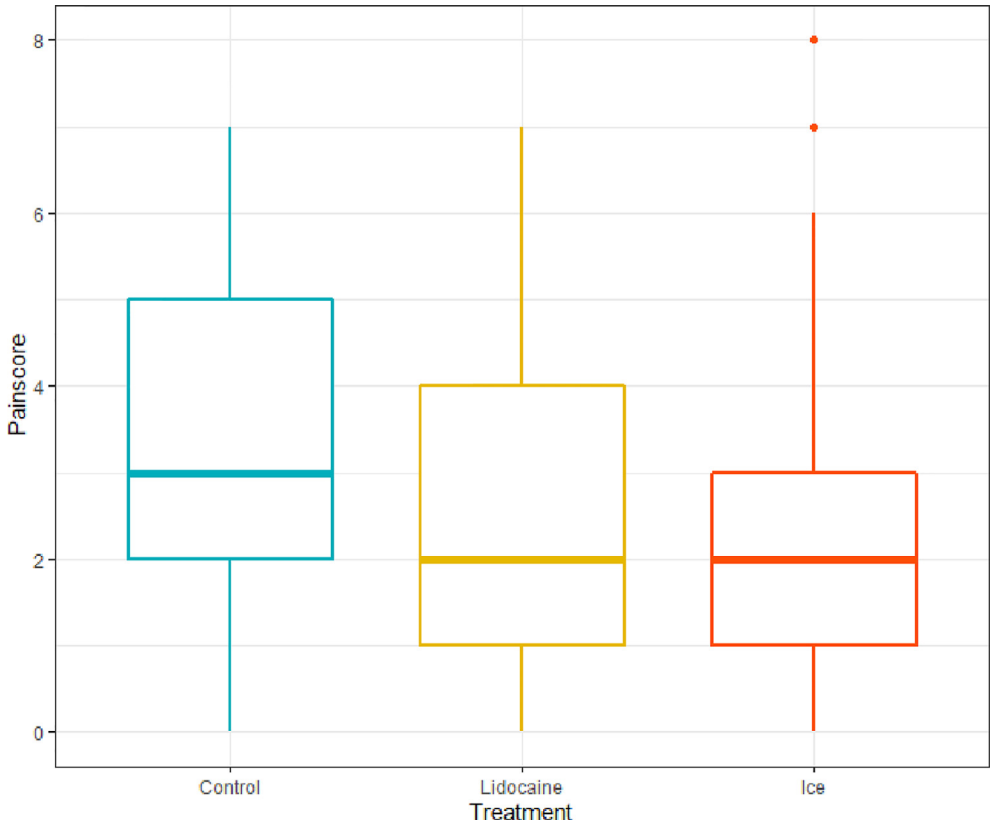

Figure 2. Boxplots of the 3 groups with median and interquartile range (IQR) values.

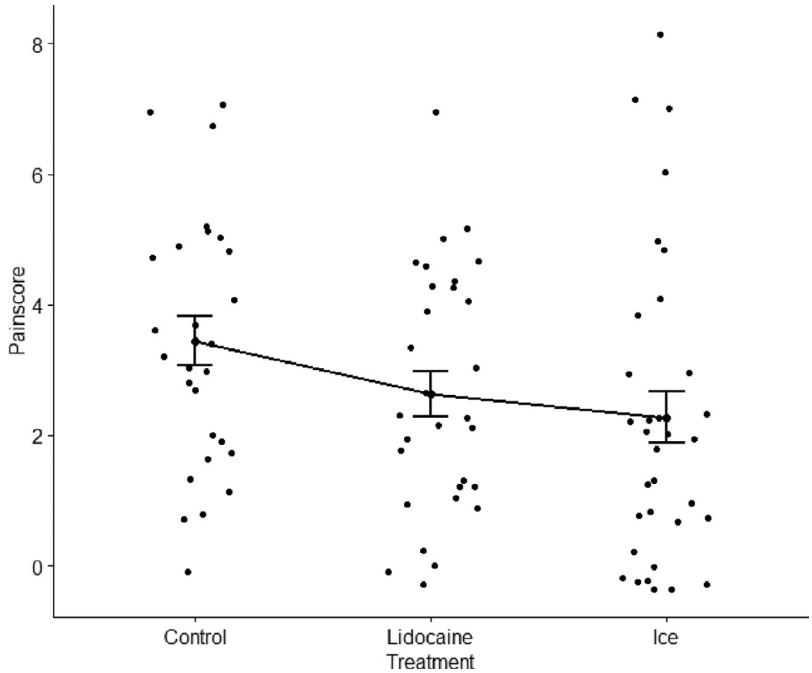

Figure 3. Mean plots and error bars for three groups.

Conclusions

A lower pain score was reported by patients who used ice and lidocaine spray before the IM injection. Accordingly, it can be concluded that both pharmacologic (lidocaine spray) and non-pharmacologic (ice spray) methods were effective in relieving the pain severity reported by patients during IM injection. However, because of its lower cost and reduced side effects, ice spray may be more efficient than other methods. Therefore, by giving proper training to nurses and patients on the use of non-pharmacologic therapies alone or in combination with pharmacologic approaches for pain reduction, patients will experience less pain during IM in-

jection. Moreover, with the development of new practical methods of pain reduction before injection such as cold therapy, patients have a range of options to use. It could be also informative to assess possible side effects of this method in future studies.

Declaration of Competing Interest

None.

Acknowledgments

The authors wish to thank Neyshabur University of Medical Sciences for funding this study (grant number IRNUMS.REC.1398.029).

References

Açmaz, G., Bayraktar, E., Aksoy, H., Başer, M., Yilmaz, M. O., & Müderris, I. I. (2015). Effect of paracetamol, dexketoprofen trometamol, lidocaine spray, pethidine & diclofenac sodium application for pain relief during fractional curettage: A randomized controlled trial. *Indian Journal of Medical Research, 142*(4), 399–404.

Aktaş, Y. Y., & Karabulut, N. (2019). The use of cold therapy, music therapy and lidocaine spray for reducing pain and anxiety following chest tube removal. *Complementary Therapies in Clinical Practice, 34*, 179–184.

Arab, V., Bagheri-Nesami, M., Mousavinasab, S. N., Espahbodi, F., & Pouresmail, Z. (2017). Comparison of the effects of hegu point ice massage and 2% lidocaine gel on arteriovenous fistula puncture-related pain in hemodialysis patients: A randomized controlled trial. *Journal of Caring Sciences, 6*(2), 141–151.

Asgari, M. R., Motlagh, N. H., Soleimani, M., & Ghorbani, R. (2013). Effect of lidocaine spray on the pain intensity during insertion of vascular needles in hemodialysis patients. *Koomesh, 14*(3), 271–279.

Celik, N., & Khorshid, L. (2015). The use of ShotBlocker for reducing the pain and anxiety associated with intramuscular injection. *Holistic Nursing Practice, 29*(5), 261–271.

Fiorelli, A., Pace, C., Cascone, R., Carlucci, A., De Ruberto, E., Izzo, Passavanti, B., Chiodini, P., Pota, V., Aurilio, C., & Santini, M (2019). Preventive skin analgesia with lidocaine patch for management of post-thoracotomy pain: Results of a randomized, double blind, placebo controlled study. *Thoracic Cancer, 10*(4), 631–641.

Hawley, P., Fyles, G., & Jefferys, S. G. (2020). Subcutaneous Lidocaine for cancer-related pain. *Journal of Palliative Medicine, 23*(10), 1357–1364.

Karasu, Y., Cömert, D. K., Karadağ, B., & Ergün, Y. (2017). Lidocaine for pain control during intrauterine device insertion. *Journal of Obstetrics and Gynaecology Research, 43*(6), 1061–1066.

Lala, K. R., & Lala, M. K. (2003). Intramuscular injection: review and guidelines. *Indian pediatrics, 40*(9), 835–845.

Mohiuddin, I., Setty, J. V., Srinivasan, I., & Desai, J. A. (2015). Topical application of local anaesthetic gel vs ice in pediatric patients for infiltration anaesthesia. *Journal of Evolution of Medical and Dental Sciences, 4*(74), 12934–12940.

Mutlu, S., & Yılmaz, E. (2020). The effect of soft tissue injury cold application duration on symptoms, edema, joint mobility, and patient satisfaction: A randomized controlled trial. *Journal of Emergency Nursing, 46*(4), 449–459.

Raddadi, Y., Adib-Hajbaghery, M., Ghadirzadeh, Z., & Kheirkhah, D. (2017). Comparing the effects of acupressure at LI4 and BL32 points on intramuscular injection pain. *European Journal of Integrative Medicine, 11*, 63–68.

Şahiner, N. C., İnal, S., & Akbay, A. S. (2015). The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety levels in children. *Journal of Perianesthesia Nursing, 30*(3), 228–235.

Serena, S. (2010). Rhythmic skin tapping: an effective measure to reduce procedural pain during IM injection. *Nursing Journal of India, 101*(8), 178–180.

Seyedfatemi, N., Borimnejad, L., Hamooleh, M. M., & Tahmasebi, M. (2014). Iranian nurses' perceptions of palliative care for patients with cancer pain. *International Journal of Palliative Nursing, 20*(2), 69–74.

Simonsen, L., Kane, A., Lloyd, J., Zaffran, M., & Kane, M. (1999). Unsafe injections in the developing world and transmission of bloodborne pathogens: A review. *Bulletin of the World Health Organization, 77*(10), 789–800.

Taddio, A., Nulman, I., Reid, E., Shaw, J., & Koren, G. (1992). Effect of lidocaine-prilocaine cream (EMLA®) on pain of intramuscular Fluzone® injection. *Canadian Journal of Hospital Pharmacy, 45*(6), 227–230.

Valdovinos, N. C., Reddin, C., Bernard, C., Shafer, B., & Tanabe, P. (2009). The use of topical anesthesia during intravenous catheter insertion in adults: A comparison of pain scores using LMX-4 versus placebo. *Journal of Emergency Nursing, 35*(4), 299–304.

Wang, H., Guan, J., Zhang, X., Wang, X., Ji, T., Hou, D., Wang, G., & Sun, J. (2020). Effect of cold application on pain and bruising in patients with subcutaneous injection of low-molecular-weight heparin: A meta-analysis. *Clinical and Applied Thrombosis/Hemostasis, 26*(3), 1–10.

Yağiz On, A. (2006). Cold applications for the treatment of pain. *The Journal of the Turkish Society of Algology, 18*(2), 5–14.

Yarahmadi, S., Mohammadi, N., Ardalan, A., Najafizadeh, H., & Gholami, M. (2018). The combined effects of cold therapy and music therapy on pain following chest tube removal among patients with cardiac bypass surgery. *Complementary Therapies in Clinical Practice, 31*, 71–75.

Yilmaz, N., & Kiyak, E. (2017). The effects of local cold application on fibromyalgia pain. *International Journal of Rheumatic Diseases, 20*(8), 929–934.

Zore, G., & Dias, R. (2014). Effectiveness of nursing interventions on pain associated with intramuscular injection. *International Journal of Science and Research, 3*(6), 1995–2000.