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Vapocoolant Spray for Pain Control in Intramuscular Injection Applications: A Prospective, Randomized Controlled Trial

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Abstract

Background Many pharmacological and nonpharmacological methods have been investigated along with advances in pain treatment. One of these nonpharmacological methods is the use of vapocoolant spray.

Objective This study aimedto demonstrate the effectiveness of vapocoolant spray to reduce pain during intramuscular (IM) injection.

Patients and Methods The study included ≥18 years old patients admitted to the emergency department who were asked to undergo IM injection. Patients were randomly divided into two groups as vapocoolant spray and control group. Demographic data, injection side, and visual analog scale (VAS) of the patients were recorded.

Results Mean VAS values during IM injection were significantly lower in patients treated with vapocoolant spray compared with the control group. The severity of pain during IM injection was lower in the vapocoolant spray group as both moderate pain (VAS > 3 cm) and severe pain (VAS > 5.4 cm) compared with the control group.

Conclusion Vapocoolant spray to be applied before IM injection is effective in reducing pain caused by the injection.

Keywords
- intramuscular injection
- pain
- vapocoolant spray

Introduction

Pain is a complex phenomenon that creates unpleasant sensory and emotional experiences in the person, occurs with or without tissue damage, and is influenced by past experiences, and is the most common reason for admission to the emergency department.[1] Prevention of pain is also one of the basic requirements of human and patient rights.[2] Studies indicated that gender was a contributing factor to the differences observed in pain perception, despite the different stimuli applied. In general, the results showed an association between a higher degree of femininity and a greater perception of painful stimuli, regardless of gender.[1,2] Intramuscular (IM) injection is an invasive procedure that causes pain that can impair the patient's adherence to treatment in emergency departments.

The importance of treating and preventing pain has many benefits, from improving patient and family satisfaction to reducing patient suffering to improving patient care.[3] Recently, many pharmacological and nonpharmacological methods have been investigated along with advances in pain treatment. One of these nonpharmacological methods is the use of vapocoolant spray. Vapocoolant sprays reduce the rate of transition between nerve fibers by

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reducing the temperature of the surface they are applied to thanks to the components in their content and provide effective pain management.[4,5]

Vapocoolant spray is an agent in a volatile liquid compound that acts by lowering the temperature of the surface it is applied to, with ethyl chloride and 1,1,1,3,3pentafluoropropane/1,1,1,2-tetrafluoroethane in its content. Cooling on the surface reduces the speed of movement of stimuli between nerve fibers and a decrease in pain sensation is observed. Vapocoolant sprays is intended for local anesthesia through undercooling for temporary skin anesthesia,for example, before injection, dermatology (abscesses, removal of warts, and foreign particles), and sharp irritation of sinews (tennis elbow). It can also be applied to sports injuries of soft tissues. It can be applied by spraying continuously onto the affected area from a distance of ~10 to 20 cm until a white snow film forms. The effect is for short time, until the skin warms up again. It can be used for almost all ages. It is not recommended to be used only in angina pectoris and other cardiac dysfunctions, open wounds, arterial insufficiency, cold urticaria, and hypersensitivity reaction. Vapocoolant sprays are potentially advantageous over many anesthetics due to their cheapness, rapid effectiveness, and short application time[3–5] Some studies have reported that vapocoolant spray reduces pain during interventional procedures, whereas others have shown the opposite.[6,7] Therefore, in this study, we wanted to show the effect of vapocoolant spray on pain during IM injection.

Patients and Methods

Study Design and Setting

This prospective, randomized, controlled study was conducted on 202 patients in a tertiary hospital between January 2021 and March 2021. Our study was approved by the ethics committee and a written consent form was obtained from all patients. The patients participating in the study consisted of patients who were given IM injection decision by the physician with the diagnoses of headache, dysmenorrhea, renal colic, etc., after being examined in the emergency department. The study included ≥18 patients admitted to the emergency department who were asked to undergo IM injection (diclofenac sodium, 75 mg/3 ml) ordered by the emergency department doctor. Exclusion criteria were as follows: patients <18 years of age, patients who refused to participate in the study or did not consent, patients with a mental status disorder or who may require emergency treatment, patients with malignancy, patients with cold application-related dermatological disorders, patients with allergic reaction due to spray application, and patients who received analgesics before treatment (►**Fig. 1**).

Eligible patients were randomly assigned for eligibility screening and divided into two groups as vapocoolant spray and control group. The control group received only IM injection. The forms of application methods and the document with patient data and the forms of treatment were placed equally in a box. Patients were randomly included in the study by the randomized block method. The patient

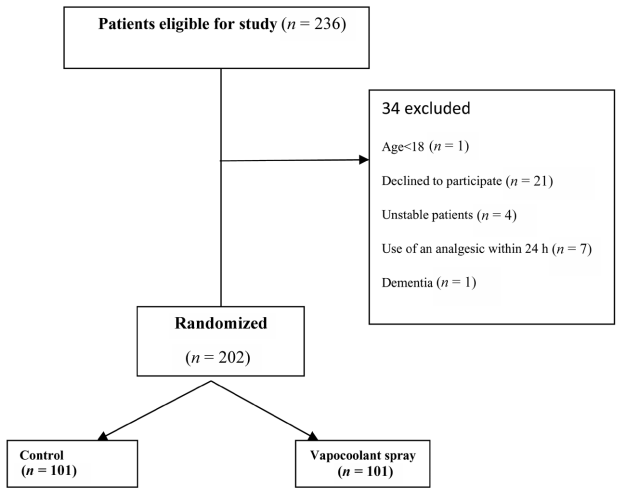

Fig. 1 Flowchart of participants.

determined the application method by taking it from a closed envelope. Only the practitioner knew about randomization when obtaining consent, and it was administered after consent. The data were recorded by the nurse administering the injection on duty 7 days/24 hours in all shifts when the patients were ready. Physicians conducting the study were not included in patient care and registration. The practitioner considered the upper outer quadrant as the application site by dividing the gluteal region into four equal parts in the standard IM injection application. The application site was located, while the patient was in the supine position and sterilization was achieved with 2% chlorhexidine solution after relaxation. All applications were standardized and performed by the nurses in charge. Diclofenac sodium was administered within 15 seconds at the rate of 1 mL/5 second. IM was performed using a standardized method in which a 21 gauge and a 5-mL syringe was used at a right angle at the injection site. Standard IM injection procedure was applied to the control group. The vapocoolant spray group was sprayed with ethyl chloride vapocoolant spray (Clordetil, Biosport Medical Ltd., Italy) at a distance of 15 cm at 90 degrees to the application surface and injection was performed after 30 seconds.

Demographic data such as gender, age, body mass index (BMI), and injection side of the patients were recorded. Patients were asked to evaluate the intensity of pain with a visual analog scale (VAS—0: no pain, 10: very severe pain) of 10 cm in length after the application. VAS > 3 cm was considered as moderate pain,while VAS > 5.4 cm was considered as severe pain in our study.[8]

The data of both groups were compared and analyzed as mean ± standard deviation in quantitative data analysis and *n* (%) in categorical data in our study. Chi-squared test, *t*-test, or Mann–Whitney U test was applied in bidirectional comparisons between the vapocoolant group and other groups. The correlation analysis for age and BMI that may affect VAS score between the groups were performed by Spearman's correlation analysis. Windows SPSS 23.0 (SPSS Inc., Chicago,

Table 1 Baseline characteristics of the groups

	Vapocoolant spray group ($n = 101$)	Control group ($n = 101$)	p-Value
Age (years) mean (±standard deviation)	37.59 ± 13.24	37.23 ± 12.49	0.981
Gender,n (%)			0.398
Male	54 (53.5)	48 (47.5)	
Female	47 (46.5)	53 (52.5)	
Marital status			0.445
Single	35 (34.7)	41 (40.6)	
Married	66 (65.3)	60 (59.4)	
Mean BMI, kg/m^2	26.58 ± 4.62	25.76 ± 4.66	0.183
Dominant hand			0.825
Right	90 (89.1)	89 (88.1)	
Left	11 (10.9)	12 (11.9)	
Application side			0.885
Right	38 (37.6)	39 (38.6)	
Left	63 (62.4)	62 (61.4)	

Abbreviation: BMI, body mass index.

Illinois, United States) was used for statistical analysis, and $p < 0.05$ was considered significant.

Results

The main characteristics of IM injected patients are summarized in ►**Table 1**. The demographic data of the patients, including age, gender, BMI, marital status, dominant hands, and injection side, were similar between the groups (►**Table 1**). Mean VAS values during IM injection were significantly lower in patients treated with vapocoolant spray compared with the control group (1.69 ± 0.16 vs. 3.87 ± 0.23; $p < 0.001$, ►**Fig. 2**). In addition, the severity of pain during IM injection was lower in the vapocoolant spray group as both moderate pain (VAS > 3 cm) and severe pain (VAS > 5.4 cm) compared with the control group (for both, $p < 0.001$).

Mean VAS values during IM injection were significantly lower in patients treated with vapocoolant spray compared with control in both men and women (for both, $p < 0.001$). In addition, the mean VAS values at the time of injection were significantly lower for both the right and left sides of the vapocoolant spray compared with the application site (►**Table 2**). No significant difference was observed between groups when VAS scores of both groups were examined according to age and BMI (►**Table 3**). No complications developed in our patients in both groups.

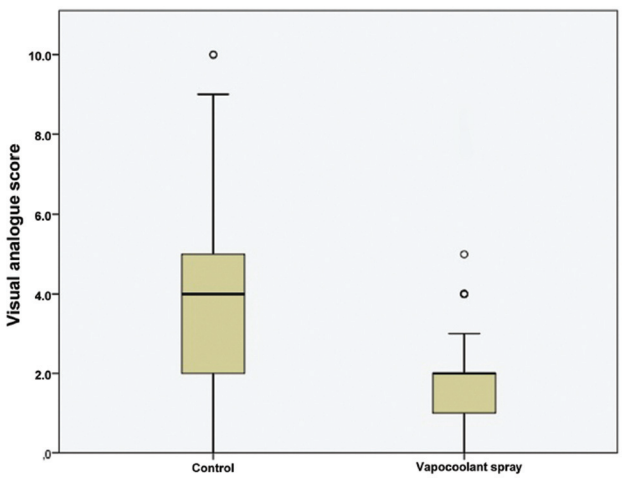

Fig. 2 Boxplot presentation of vapocoolant spray group and healthy control for visual analog scale.

Discussion

IM injection is a routine and frequent procedure performed in hospitals and clinics and is one of the medical procedures that can cause fear, stress, and anxiety in many age groups, especially pain.[9,10] This pain and anxiety can be affected by many factors such as one's emotional state, past experience, and practitioner experience. Therefore, it is recommended by international organizations to ensure optimal pain management before and in the application of procedures that may cause pain.[11] Not only pharmacological agents but also ease of use and efficacy can be used in pain management in nonpharmacological approaches and relief of anxiety that may occur afterward, as a result. Many nonpharmacological methods have been used to relieve the pain caused by IM injection, including Helfer Skin Tap, ShotBlocker, music, local ice application, and pressure application.[12,13] In addition, it has been shown to be effective in reducing pain in choosing the needle length and the area to be applied correctly. Vapocoolant sprays (such as ethyl chloride and newer halogenated compounds) are cryotherapeutic agents used for short, painful procedures.

Table 2 Group-based statistics for visual analog scale

	Vapocoolant spray group	Control group	*p*-Value
Mean VAS mm	1.69 ± 0.16	3.87 ± 0.23	<0.001
Moderete pain VAS >3 cm,*n*(%)	22 (21.8)	72 (71.3)	<0.001
Severe pain VAS > 5.4 cm,*n*(%)	3 (3.0)	25 (24.8)	<0.001
Gender			
Male	1.68 ± 0.17	3.82 ± 1.25	<0.001
Female	1.69 ± 0.26	3.92 ± 1.42	<0.001
Application side			
Right	1.56 ± 0.27	3.78 ± 2.26	<0.001
Left	1.77 ± 0.19	3.95 ± 2.38	<0.001

Abbreviation: VAS, visual analog scale.

Table 3 Correlation between age and BMI based on visual analog scale scores according to the study groups

Parameter	*n*	Correlation coefficient[a]	*p*-Value
Vapocoolant spray group			
Age	101	0.165	0.100
BMI	101	−0.22	0.827
Control group			
Age	101	−0.191	0.170
BMI	101	−0.176	0.079

Abbreviations: BMI, body mass index; *n*, frequency.
[a]Spearman's rho correlation analysis.

Previous studies have shown that they reduce pain during IM injection in pediatric cases.[14,15] This study showed that IM can be used in pain management during injection in adult patients in emergency departments.Vapocoolant sprays have been shown to provide the local anesthetic effect by evaporating from the surface in a short time and reducing the temperature on the surface.[16] It can be used reliably and effectively in both adults and children with this feature.[17] Shafii et al reported in their study on hemodialysis patients that the use of the refrigerant spray can reduce pain caused by needle insertion and can be used in routine hemodialysis patients as a nonpharmacological pain relief method.[18] Dalvandi et al found significantly lower pain after vapocoolant spray during venous intervention compared with the control group (3.22 ± 1.18 vs. 7.12 ± 1.36) in a study conducted in the pediatric age group. They also showed that vapocoolant spray is an effective alternative in patients allergic to components such as lidocaine and procaine.[14] Moon et al compared vapocoolant spray and eutectic mixture of local anesthetics cream to reduce pain during intra-articular injection of the shoulder and showed that vapocoolant spray was more effective in reducing pain.[19] Another study suggests that vapocoolant spray significantly reduces pain during intravenous cannulation in both adults and children compared with the control group and that vapocoolant spray should be used during intravenous cannulation to reduce pain.[20] We found that in our study mean VAS values during IM injection were significantly lower in patients treated with vapocoolant spray compared with the control group and there were no complications. We believe that vapocoolant spray can be used safely during IM injection based on our results.

We did not observe the effect of age on pain in our study. There are uncertainty and inconsistency according to the conditions causing pain in many studies.[21,22] Lautenbacher et al reported that aging reduced sensitivity for low severity pain and was evident for decreased sensitivity, especially heat pain and headache.[23] It was shown in another study that there is a consistent positive linear relationship between age and chronic pain experience.[24] In addition, an age-related increase in rheumatological disorders increases the prevalence of pain and physical disability, but the effect of aging on pain remains unclear in the literature.[21,25]However, further studies are required to compare the differences in pain perception by age for IM, which is a short-term invasive stimulus.

Studies have shown that the relationship between BMI and pain is unclear. Their sensitivity to thermal pain has not been shown to be the same even though obese people are more sensitive to pressure pain.[26] Another study showed that pain sensitivity in the abdomen of obese patients was lower compared with the hands.[27] Also, we did not observe the effect of BMI on pain in our study.

Studies have shown that women have higher pain sensitivity responses compared with men.[28] However, it has been reported in other studies that pain is not related to gender and may vary depending on biological, social, and cultural differences.[29] Mean VAS values were significantly lower in patients treated with vapocoolant spray compared with control in both men and women, and vapocoolant spray has been shown to reduce pain regardless of gender in our study.

The present study had some limitations. The first is that the pain that may occur in IM injection may vary depending on the depth of the needle and the application method. This may have an effect on pain since our study could not be performed by a single practitioner. Another limitation is the evaluation of the effect of anxiety, social, demographic, and cultural differences of the participants on pain. Although we state that we want the patients to evaluate their pain during the procedure, the pain conditions at the time of admission can affect the score, even if they do not have a serious pain diagnosis. Another limitation is that vapocoolant spray could not be compared with other local anesthetic agents. Multicenter studies with a larger patient population are required for the accuracy and efficacy of the data in our study.

Conclusion

Vapocoolant spray to be applied before IM injection is effective in reducing pain caused by the injection.

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None.

Conflict of Interest
None declared.

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