ARAŞTIRMA

Vapocoolant Spray For Intravenous Cannulation Pain: A Prospective, Randomized Controlled Trial

İntravenöz Kanülasyon Ağrısı İçin Vapocoolant Sprey: Prospektif, Randomize Kontrollü Bir Çalışma

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Abstract

Introduction: Peripheral intravenous (IV) cannulation are routine procedures in emergency department (ED) admissions. Vapocoolant sprays have a potential advantage over other topical agents. We aimed to see how effective vapocoolant spray was in reducing pain during intravenous cannulation versus a control group in this study.

Materials and Methods: This is a prospective, randomized control study consisting of patients who were admitted to the ED. The study included patients aged 18 and over who applied to the ED and had IV cannulation. The patients were divided into 2 groups as control and vapocoolant spray groups. Age, gender, and dominant hand status of all patient groups were recorded. Side effects were observed after the application. The Visual Analogue Scale (VAS), which is the most widely used scale to measure pain, was used.

Results: 206 individuals were randomized. The mean age of the vapocoolant spray group was 46.40 ± 16.44 years, while it was 46.75 ± 17.49 years for the control group. The vapocoolant spray group was found to have significantly lower mean VAS values during IV cannulation than the control group $(1.47\pm1.32 \text{ vs.} 3.97\pm1.97 \text{ p}<0.001)$. It was found that the vapocoolant spray-applied group had a significantly lower percentage in terms of moderate pain (VAS>3 cm) compared to the control group (7.8% vs 58.3%, p<0.001). Besides, the percentage of severe pain (VAS>5.4 cm) in the spray-applied group was found to be significantly lower than the control group (1% vs . 20.4%, p<0.001).

Conclusion: The vapocoolant spray can be used effectively to mitigate the pain associated with the pre-IV cannulation procedure and can be an alternative method for reducing pain in emergency departments.

Keywords: Intravenous cannulation, pain, vapocoolant spray

Öz

Amaç: Periferik intravenöz (IV) kanülasyon, acil servis (ED) başvurularında rutin prosedürlerdir. Vapocoolant spreylerin diğer topikal ajanlara göre potansiyel bir avantajı vardır. Bu çalışmada bir kontrol grubuna kıyasla intravenöz kanülasyon sırasında ağrıyı azaltmada vapocoolant spreyin ne kadar etkili olduğunu görmeyi amaçladık.

Materyal-Metod: Bu, acil servise kabul edilen hastalardan oluşan prospektif, randomize bir kontrol çalışmasıdır. Çalışmaya acil servise başvuran ve IV kanülasyon yapılan 18 yaş ve üzeri hastalar dahil edildi. Hastalar kontrol ve vapocoolant sprey grubu olarak 2 gruba ayrıldı. Tüm hasta gruplarının yaş, cinsiyet ve başkın el durumu kaydedildi. Uygulamadan sonra yan etkiler gözlendi. Ağrıyı ölçmek için en yaygın kullanılan ölçek olan Görsel Analog Skala (VAS) kullanıldı.

Bulgular:206 kişi randomize edildi. Vapocoolant sprey grubunun yaş ortalaması $46,40\pm16,44$ yıl, kontrol grubu içinse $46,75\pm17,49$ yıl idi. Vapocoolant sprey grubunun, IV kanülasyon sırasında kontrol grubuna göre önemli ölçüde daha düşük ortalama VAS değerlerine sahip olduğu bulundu $(1,47\pm1,32)$ ye karşı $3,97\pm1,97$ p<0,001). Vapocoolant sprey uygulanan grubun orta şiddette ağrı (VAS>3 cm) açısından kontrol grubuna göre anlamlı olarak daha düşük bir yüzdeye sahip olduğu bulundu (%7,8)e karşı %5,3, p<0,001). Ayrıca sprey uygulanan grupta şiddetli ağrı yüzdesi (VAS>5,4 cm) kontrol grubuna göre anlamlı derecede düşük bulundu (%1)e karşı %20,4, p<0,001).

Sonuç: Vapocoolant sprey, IV öncesi kanülasyon prosedürüne bağlı ağrıyı azaltmak için etkili bir şekilde kullanılabilir ve acil servislerde ağrıyı azaltmak için alternatif bir yöntem olabilir.

Anahtar kelimeler: Periferik intravenöz kanülasyon, ağrı, buhar soğutucu sprey

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Introduction

Vein piercing and peripheral intravenous (IV) cannulation are routine procedures in emergency department (ED) admissions, and many patients may feel pain during the procedure [1]. A large number of patients have a phobia of needles, which adds to the anxiety of emergency room visits, which are already stressful. This situation, in the first place, reduces patient satisfaction. Therefore, it makes pain management significant in medical care [2,3].

Despite the fact that anesthetic agents are frequently used to relieve pain during IV cannulation in ED, many physicians often provide inadequate anesthesia during this procedure, causing discomfort in the patient. Several patients may feel pain before the procedure is over. Furthermore, it is clear that it is not a practical method in highvolume ED, since topical anesthetic agents take around an hour to take effect [4-7]. Vapocoolant sprays are topical anesthetic agents that offer transient anesthesia by decreasing the temperature on the applied surface and reducing nerve fiber sensitivity with volatile liquids (6,7). Vapocoolant sprays have a potential advantage over other topical agents due to their rapid onset, low cost, and ease of use, as well as their benefits in pain relief during catheter placement, inoculation, and venipuncture [8]. While some studies suggest that vapocoolant spray helps to relieve pain during intravenous cannulation, others show the opposite [9-11]. Therefore, we wished to see how effective vapocoolant spray was in reducing pain during intravenous cannulation versus a control group in this study.

Materials and methods

This is a prospective, randomized control study consisting of patients who were admitted to the emergency department between the dates February-April 2021 and had IV cannulation. Approval was obtained from the ethics committee of our hospital for our study, and written informed consent forms were obtained from all patients. The study included patients aged 18 and over who applied to the ED and had IV cannulation. Patients ≥18 years of age who were stable and did not have mental retardation who underwent IV cannulation were included in the study. Exclusion criteria included those that did not give written consent forms, pregnant women, patients with allergic reactions to the spray ingredients or cold tolerance, as well as those with dermatological disorders that may trigger a reaction, unstable patients, patients with peripheral vascular disease, and those that underwent analgesic therapy the day before the intervention. Patients requiring more than one intervention were excluded. When one of the researchers in charge of the patients who met the inclusion criteria was in the ED, the researcher was informed and the patients were selected. Each enrolled patient was sequentially randomized to the computer study protocol independently. The protocol of the patients was determined with a note containing the treatment protocol in a closed sealed envelope. The patients did not know the treatment status until their consent was obtained. The cannulation staff of all patients and the investigators who gathered the results were blind to randomization.

The patients were divided into 2 groups as control and vapocoolant spray groups. Routine IV cannulation was applied to the control group. In the spray group, the spray was applied to all patients in the same way by the manufacturer after the venipuncture site was prepared and cleaned according to the protocol. The nurses who

will perform the emergency room cannulation procedure were given training prior to the application. The same nurse performed both the pain measurement and the procedural procedure. Routine technique of spray application; Ghiaccio (cold spray, biosport, Veggiano, Italy) spray was sprayed from the application area at a distance of 10-15cm for 5-10 seconds, after waiting for about 60 seconds and the skin was whitened, IV cannulation was applied into a peripheral vein in the antecubital fossa. This region was used in all patients. The entire IV cannulation procedure was achieved using a 18-gauge needle. Age, gender, and dominant hand status of all patient groups were recorded. Side effects were observed after the application. The Visual Analogue Scale (VAS), which is the most widely used scale to measure pain, was used. VAS scores after the application were recorded by asking to score as 0cm (no pain) and 10cm (worst). Besides, in our study, the severity of pain was divided into two groups: VAS scores above 3 cm as moderate pain, and the ones above 5.4 cm as severe pain [11].

This study was approved by Health Science University Antalya Training and Research Hospital Ethics Committee code no. 2019-340. Informed written and oral consent was obtained from each participant before the study began. The principles of confidentiality and anonymity were explained to each participant.

Statistical analysis

Data obtained were analyzed by using SPSS for Windows version 21.0. Quantitative variables mean ±standard deviation and categorical variables as the number of cases (%) expressed. In comparing the differences between groups, quantitative independent-t test for variables, chi-square for categorical variables test usedData were presented by tables. A p value<0.05 was considered as statistically significant.

Results

Of the 258 eligible participants who participated in the study, 52 were excluded from the study for various reasons. 206 individuals were randomized, and groups were analyzed, each consisting of 103 people. The flow chart of the study is given in Figure 1. The main features of the study groups are summarized in Table 1. The mean age of the vapocoolant spray group was 46.40 ± 16.44 years, while it was 46.75 ± 17.49 years for the control group. 55 (53.4%) of the spray applicants and 51 (49.5%) of the control group were women. Moreover, the percentage of the dominant hand was higher in the right hand in both the spray and control groups (76.7% vs. 78.6%, respectively). There was no significant difference in both study groups in terms of age, gender, and dominant hand characteristics.

Table 1. Baseline characteristics of the groups

	Vapocoolant spray group (n=103)	Control group (n=103)	P value
Age (years)	46.40±16.44	46.75±17.49	0.923
Gender n (%)			0.577
Male	48 (46.6)	52 (50.5)	
Female	55 (53.4)	51 (49.5)	
Dominant hand			0.738
Right	79 (76.7)	81 (78.6)	
Left	24 (23.3)	22 (21.4)	



Figure 1. CONSORT Flow Diagram of participants

The vapocoolant spray group was found to have significantly lower mean VAS values during IV cannulation than the control group (1.47±1.32 vs. 3.97±1.97 p<0.001, Figure 2). When the patients in the study groups were compared in terms of pain severity, it was found that the vapocoolant spray-applied group had a significantly lower percentage in terms of moderate pain (VAS>3 cm) compared to the control group (7.8% vs 58.3%, p<0.001). Besides, the percentage of severe pain (VAS>5.4 cm) in the spray-applied group was found to be significantly lower than the control group (1% vs. 20.4%, p<0.001). Furthermore, the values during the IV intervention were found to be significantly lower in both male $(1.22\pm1.12 \text{ vs. } 3.71\pm1.76)$ and female (1.76±1.42 vs. 4.45±1.93) in the spray group compared to the control group, regardless of gender (p<0.001). In addition, the mean VAS values during the IV intervention were found to be significantly lower in the vapocoolant spray group compared to the control group, regardless of the dominant hand condition (p<0.001). The comparison of the VAS values of the groups is given in Table 2. No complications occurred in the study groups.

Table 2. Group-based	Statistics for visual	analog scale
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	Vapocoolant spray group	Control group	P value
Mean VAS mm	1.47±1.32	3.97±1.97	<.001
Moderete pain VAS >3 cm n(%)	8 (7.8)	60 (58.3)	<.001
Severe pain Vas>5.4 cm n(%)	1 (1.0)	21 (20.4)	<.001
Gender			
Male	1.22±1.12	3.71±1.76	<.001
Female	1.76±1.42	4.45±1.93	<.001
Dominant hand			
Right	1.61±1.32	4.19±1.78	<.001
Left	1.21±0.68	3.72±2.21	<.001

VAS: visual analog scale



Figure 2. Box plot presentation of Vapocoolant spray group and healthy control for visual analog scale

Discussion

IV intervention is both a diagnostic and therapeutic process that is conducted frequently in nearly all emergency departments, and many patients suffer from pain during the intervention [6-8]. In such a painful procedure, even though many patients and their relatives request analgesia prior to the procedure, this can often be ignored in intensive emergency departments [12]. Although the topical ones come to the forefront among the anesthetic agents, local coolants such as vapocoolant spray stand out among the inexpensive, easy to apply, and fast agents due to factors such as long pre-anesthetic waiting times and cost in many topical agents [13]. Furthermore, the findings obtained in the studies highlight the fact that vapocoolant sprays neither cause permanent dermatological problems nor have microvascular side effects [14]. It also reduces edema, nerve conduction velocities, cellular metabolism and local blood flow. The effect of cryotherapy depends on the method, the duration of the ice, its temperature and the depth of the subcutaneous fat [11-14]. We demonstrated the efficacy of vapocoolant spray in mitigating pain during IV cannulation in this study.

While there are many studies that demonstrate the efficacy of vapocoolant spray in mitigating pain during IV cannulation, this issue is highly controversial as there are studies revealing the opposite. According to one study, vapocoolant spray significantly reduces pain during IV cannulation in adults while having no negative side effects [14]. Vapocoolant spray was shown to be an effective alternative for reducing procedural pain in another study with a pediatric patient population [15]. In another study, however, they found that using a vapocoolant spray before IV cannulation did not significantly reduce pain as compared to a control group [16]. Similarly, another study in a pediatric patient population found no significant difference in mean pain values during cannulation [17]. In our study, the pain during IV cannulation was found to be significantly lower in the vapocoolant spray-applied group compared to the control group, and our results showed that vapocoolant spray can be used to relieve pain during IV cannulation.

The use of the cold application to reduce pain has been known for many years. The surrounding body temperature is lowered with this method and the nerve conduction velocity of the C and A-delta fibers is reduced, thus reducing the signal that causes pain [18]. There are numerous studies showing the effectiveness of the vapocoolant spray in mitigating pain. In a study by Unal et al. [8], one of these studies, they stated that vapocoolant spray can be easily used in pain control during subcutaneous injection without causing any side effects. In another study by Moon et al. [19], vapocoolant spray during intraarticular injection was shown to be more effective in pain control than other local anesthetic agents. Topical vapocoolant spray was shown to be more efficient than lidocaine in mitigating pain during IV cannulation in a study performed by Page et al. [20], and they stressed that it could be an alternative treatment that could be used effectively in emergency department practice. In a recent study conducted by Dalvandi et al. [9], It was discovered that vapocoolant spray was effective in mitigating pain during IV cannulation in children between the ages of 6 and 12 years, compared to the control group. The vapocoolant spray group's VAS value was observed to be significantly lower than the control group in this study (3.22±1.18 vs. 7.12±1.36, p<0.001) [9]. 1410 patients were screened in 11 studies for a meta-analysis study by Zhu et al. [21], and it was found that vapocoolant spray decreases pain in IV cannulation in all age groups and can be used to relieve patients' anxiety. Biro et al. [22] found that EMLA cream decreased pain during cannulation more efficiently than vapocoolant spray, in one of the studies that contradicted the efficacy of the vapocoolant spray. In another study, Costello et al. [17] found that vapocoolant spray failed to relieve pain during IV cannulation in a measurable way. Studies show that cold spray application before cannulation in the emergency department was not effective in reducing pain caused by pre-procedure application [16,23]. We believe that the disparity between the studies is due to a variation in application technique as well as a limited sample size. We found in our study that using vapocoolant spray during IV intervention significantly reduced pain compared to the control group (1.47±1.32 vs. 3.97±1.97 p<0.001). Furthermore, in severe and moderate pain measurements, we found that the vapocoolant spray displayed a lower pain intensity than the control group.

Our study has some limitations. The first of these limitations is that, since an IV cannulation application cannot be conducted by a single practitioner, the pain can differ based on the application technique. Another limitation of ours is that it is impossible to know how much the patients' socio-cultural characteristics and comorbid conditions influence their pain perception prior to the application. The absence of the spray group that did not apply active drug as the control group is our important limitation. Besides, our most important limitation is that it cannot be compared with other local anesthetic agents and we think that studies showing the efficacy of vapocoolant spray using a multi-center study technique with a large patient population are needed.

Conclusion

The vapocoolant spray can be used effectively to mitigate the pain associated with the pre-IV cannulation procedure and can be an alternative method for reducing pain in emergency departments.

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