



## COMPARING THE IMPACT OF LIDOCAINE SPRAY AND ICE SPRAY ON PAIN INTENSITY DURING THE CATHETERIZATION OF HEMODIALYSIS PATIENTS: A TRIPLE-BLIND CLINICAL TRIAL

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*The most common pain among hemodialysis patients is caused by the cannulation of arteriovenous fistula due to the diameter and length of these needles. This study aimed to compare the impact of lidocaine spray and ice spray on the intensity of pain during the IV insertion in hemodialysis patients and examine the amount of pain relief during this intervention. This is a triple-blind clinical trial that was conducted on 50 patients between 18 to 65 years of age who needed the insertion hemodialysis catheters. Each patient received a total of three sprays, one type of spray per session. The insertion pain was measured using the VAS scale. It took 10 minutes from applying the lidocaine spray to disinfection and injection. However, the process of disinfection and insertion started immediately after applying ice spray and control spray (70% alcohol). Wilcoxon and Friedman tests (non-parametric) were carried out to examine the results of the research, and SPSS V16 was used to analyze the data. According to the mean values, there is a significant difference in the pain scores of ice spray, lidocaine spray, and control spray (alcohol), indicating that lidocaine spray is more effective than ice and alcohol sprays in reducing the intensity of the pain caused by dialysis needles. ( $P=0.010$ ). Compared with ice spray, lidocaine spray results in a greater reduction in the pain caused by hemodialysis cannulation. Therefore, this method can be used as a proper, inexpensive, accessible, and easy approach to reducing the pain of inserting hemodialysis vascular needles.*

**Keywords:** lidocaine spray, ice spray, hemodialysis catheterization, arteriovenous fistula pain, hemodialysis, cannulation

### INTRODUCTION

Currently, the prevalence of chronic kidney failure is increasing worldwide. In the year 2000, the global number of chronic kidney failure patients under treatment was around 1,100,000. At the end of 2009, this number

reached 2,654,000. In Iran, the growth rate of this disease is about 12% per year, higher than the global average<sup>1</sup>. Hemodialysis is the most important and the most common alternative treatment for kidney patients<sup>2</sup>. In Iran, with more than 13,000 dialysis patients, approximately 150,000 dialysis sessions are

performed per month<sup>3</sup>. Vascular access is essential for successful hemodialysis<sup>4</sup>. Venous arterial fistula is the best standard for vascular access in hemodialysis patients<sup>5</sup>. In the clinical situation, various diagnostic and therapeutic procedures lead to pain, the most common of which is the pain caused by venous catheterization for therapeutic purposes in the hospital<sup>6</sup>. In hemodialysis patients, the most common cause of pain caused by inserting needles in the arteriovenous fistula due to the large diameter and length of the needles<sup>7</sup>. On average, hemodialysis patients undergo dialysis 3 times a week, each time for 3-4 hours, and they experience the pain of fistula needle, 300 to 320 times annually. This pain continues lifetime or until a successful kidney transplant is done<sup>8</sup>. Studies showed that 47% of hemodialysis patients were afraid of needles and regarded the catheterization as the most stressful part of the treatment and their biggest concern during hemodialysis<sup>9</sup>. Therefore, the fear of catheter leads to transfer patient's reduced or lack of patient's cooperation, the lack of success in the injection process, pain, contraction, and the increased overall time of the treatment procedure<sup>10</sup>. The repeating pain caused by the insertion of hemodialysis needles can cause depression, decreased quality of life, discomfort, and stress in these patients, while having control over this pain can improve the acceptance of hemodialysis and the quality of life<sup>11</sup>. Considering the importance of pain, pain relief should be included as part of the treatment of these patients<sup>7</sup>. The American Pain Society has considered pain as the fifth vital sign, due to its importance<sup>12</sup>. Currently, there is no single and appropriate approach to pain relief among the patients undergoing hemodialysis during arteriovenous fistula catheterization<sup>13</sup>. Medical and traditional methods, or pharmacological and non-pharmacological methods, can be used to relieve the pain caused by hemodialysis needles. Pharmacological and non-pharmacological pain relief methods are used more frequently than medical and traditional treatments. Applying lidocaine spray, prilocaine cream, EMLA cream, and piroxicam ointment is among medicinal methods; skin stimulation, cryotherapy, inhaling lavender, rhythmic breathing, hot foot bath, skin electrical stimulation, and deliberate mind

wandering are some of the non-pharmacological methods of relieving this pain<sup>14</sup>. Today, lidocaine is the most common substance used for local anesthesia<sup>15</sup>. The standard method of skin pain relief includes the injection of lidocaine and prilocaine using a thin needle, into the subcutaneous tissue<sup>16</sup>. The injection of anesthetic is painful and there is a risk of injury by the needle, which causes discomfort, fear, and anxiety. As a result, using it for the insertion of hemodialysis needles does not seem helpful<sup>17</sup>. Therefore, it seems logical to choose a fast-acting anesthetic with less complications. Lidocaine anesthetic spray can address these issues. The results of the study by Javadi et al (2018) showed that lidocaine spray was effective in reducing the intensity of pain during hemodialysis catheterization. Thus, based on the results of their study, its application can be recommended before the insertion of arterial needles, in order to reduce pain in hemodialysis patients<sup>18</sup>. Cryotherapy (cold therapy) can also be used as a safe and secure method to reduce pain in hemodialysis patients<sup>19</sup>. Reduced edema, inflammation, blood flow, and nerve conduction, slowed metabolism, and decreased muscle temperature are other known effects of cold. On the other hand, cold reduces the speed of neural conduction (both motor and sensory messages) and alters synaptic activities, ultimately, leading to nerves' inability to conduct neural messages. In another study, Gottlieb (2016) concluded that cold spray can reduce pain on the IV injection site<sup>18</sup>. The present study aims to compare the impact of lidocaine spray and ice spray on the intensity of pain during cannulation in hemodialysis patients admitted to the dialysis ward of Sabzevar Vasei Hospital.

## MATERIALS AND METHODS

This study is a triple-blind clinical trial, on the 18 to 65-year-old patients which was conducted visiting Sabz-e-Mehr Clinic and the Dialysis Ward of Vasei Hospital, in Sabzevar, June to December 2023. The sample size was determined to be 50 people. Sampling was done according to the inclusion and the exclusion criteria. Then, subject allocation was carried out randomly according to a random number table and the patients were placed into

an intervention group (using a crossover design), where each sample is considered as its own control group. Each sample received all three interventions in a total of three different sessions (one type of spray per session). Therefore, the confounding factors that could have a negative effect on the results of the study were minimized. The inclusion criteria consisted of being 18-65 years old, having the ability to read and write, requiring hospitalization and the insertion of a dialysis line using vascular needles, the possibility of catheterization, having no other conditions (such as verbal, mental and visual disabilities), not having diabetes for over 10 years, no allergy to anesthetic drugs, being conscious and aware of time and space, and not being addicted to narcotics or narcotic analgesics. The exclusion criteria consisted of the patient's absence at the next dialysis session for any reason, changing the dialysis method in the next sessions, and the patient's lack of consent to continue the research. The tools used in this research included the personal information form and the pain assessment tool. The tool used to assess pain was the Visual Analog Scale (VAS), which measures pain from 0 to 10. Number 0 indicates *no pain* and 10, the maximum level of pain. The content validity of VAS has been examined and confirmed in different studies; it has also been approved by the study of Hjermstad et al<sup>20</sup>. The reliability of VAS is also globally approved, and it has been used in scientific papers and books<sup>21</sup>. In this study, alcohol spray (70% ethanol) was used as a placebo for all the patients before catheterization along with cotton sprayed. The patients did not know the name of the drug and the nature of the effect of each spray. The sprays were covered in paper and then applied on the desired site for each patient. To this end, first, the desired site for the insertion of IV needles was chosen, and then two puffs of 10% lidocaine spray, two puffs of alcohol spray (70% ethanol) as the control spray, and two puffs of ice spray were applied at the fistula, from proper and similar distances (one type of spray per session). It took at least 10 minutes for the lidocaine spray to reach the peak of its effect. Then, after inserting the needle, the VAS visual scale was provided to the patients and the intensity of pain was marked by them. Both the examiner (the nurse) and the patient

were unaware of the content of the sprays and their effects, and both had covered their faces with masks. The sprays could be distinguished with the letters A, B and C. During the research, all the injections were done by a nurse. The data were analyzed using descriptive statistics (frequency distribution tables for qualitative variables) and correlational data analysis to fulfill the crossover design. Data analysis was carried out using SPSS V16. This study has been approved by the Iranian Registry of Clinical Trials (IRCT), under the code IRCT20201017049054N1 and by the Ethics Committee of Sabzevar University of Medical Sciences, under the code IR.MEDSAB.REC.1399.123.

## RESULTS AND DISCUSSION

### Results

The subjects were between 18 and 65 years of age. The mean age was 48.82 years. Eighteen subjects (36%) were women and 32 (64%) were men. Twenty-three (46.0%) were unemployed, 13 (26.0%) were self-employed, and 14 (28%), employees. One subject held a master's degree (2.0%), 7 of them bachelor's (14.0%), 3 had associate's degree (6.0%), 14 (28%) had a high-school diploma, and 25 (50%) had elementary school education who were able to read and write. The highest BMI was 36.0 and the lowest, 14.70. The mean and the standard deviation of BMI were 23.75 and 4.61, respectively.

Nine patients (18%) had hypertension, 7 patients (14%) had diabetes, 12 (24%) had both hypertension and diabetes, and 22 (44%) had no underlying disease. All these 50 patients had chronic kidney disease (CRF). Twenty-two subjects (44.0%) attended the morning shift, 17 subjects (34.0%), the evening shift and 11 of them (22.0%), the night shift.

There was no significant relationship between gender and the score of pain, according to the Mann-Whitney test for none of the sprays ( $P$ -value  $> 0.05$ ). Moreover, the score of pain had no significant relationship between other variables including occupation, level of education and underlying disease, for none of the sprays.

The relationship between the catheterization duration and the score of pain according to Kruskal-Wallis test (**Table 1**).

Given the non-normality of the data, in order to compare the amount of pain reduction caused by each of the three sprays (lidocaine, ice, alcohol), Friedman's test was applied. According to the test, a significant difference in the score of pain intensity was observed among the three applied sprays, where lidocaine spray had the highest impact in reducing the

catheterization pain in hemodialysis patients, followed by the ice spray and alcohol, respectively (**Table2**).

Wilcoxon test was also used to compare lidocaine and ice sprays. According to the mean values, there was a significant difference in the scores of pain between the two sprays, indicating that lidocaine spray is more effective in reducing the intensity of the pain caused by catheter insertion ( $P = 0.010$ ) (**Table 3**).

**Table 1:** Variable correlation of vascular needle placement time and interventions.

Intervention	Time of vascular needle placement	Average rank	Kruskal-Wallis test P-value
Lidocaine	Morning	28.11	0.423
	Noon	22.18	
	the night	25.41	
Ice	Morning	26.14	0.849
	Noon	23.91	
	the night	26.68	
Control	Morning	28.34	0.187
	Noon	20.35	
	the night	27.77	

**Table 2:** Comparing the effect of lidocaine spray and ice spray and control.

Spray	Number of patients	Average rank	P-value
Lidocaine	50	1.77	0.036 Friedman test
Ice	50	2.01	
Control	50	2.22	

**Table3:** Comparing the effects of lidocaine spray and ice spray.

Spray	Ranks	Average rank	P-value Wilcoxon test
Lidocaine - ice	Negative ratings	12.32	0.010
	Positive ratings	22.43	

## Discussion

The aim of this study is to compare the effect of lidocaine spray and ice spray on the intensity of the pain caused by catheterization in hemodialysis patients.

In China, Zhu et al (2018) conducted a meta-analysis of a randomized controlled trial on 1410 patients, comparing the impact of ice spray and placebo spray on reducing pain during intravenous cannulation. The results of the Meta-analysis showed that ice spray reduces the pain of IV cannulation in adults and children more significantly than the placebo spray does or compared to when no intervention is involved. In addition, the ice spray significantly increased patients' satisfaction. This meta-analysis shows that ice spray significantly reduces pain during IV cannulation compared to placebo spray or the lack of treatment in both adults and children<sup>8</sup>.

Xiaohui Liu et al (2018) conducted a randomized controlled trial study in the Traditional Chinese Medicine Hospital of Henan Province (Zhengzhou) on 120 dialysis patients with the aim of assessing the impact of different forms of lidocaine for pain management in the site of arteriovenous fistula cannulation in hemodialysis patients. The patients were randomly divided into 4 groups consisting of *cream group* (group A), *spray group* (group B), *wet compression dressing group* (group C), and *control group* (group D). The score of Visual Analog Scale (VAS), puncture success rate, analgesic onset time, patient satisfaction rate and adverse reactions were compared in these 4 groups. The findings showed that the score of VAS group A was lower pain than groups B and C, and the values obtained in all three groups were lower than group D. A significant difference in the score of pain was observed among the 4 groups ( $P < 0.001$ ). The results were better in group A compared to the other three groups. This study showed that the three applied forms of lidocaine can be effectively used to manage the pain of AVF puncture site. More precisely, it can be said that the application of cream has a slower onset of effect, but a better analgesic impact, while the spray has much faster onset of effect. These results are consistent with the results of the present study and show the importance of using an effective analgesic such

as lidocaine which, in the form of a spray, can yield faster effects<sup>22</sup>.

Mahawongkajit et al (2021) conducted a prospective single-center randomized controlled trial in Thailand comparing lidocaine spray and lidocaine ice popsicle in the patients undergoing unsedated esophagogastroduodenoscopy (EGD). They developed the lidocaine formulation in the form of ice popsicles and compared its effectiveness and tolerability with lidocaine spray in the patients undergoing EGD without sedation. The unsedated EGD patients were randomly assigned to lidocaine spray group (group A) or lidocaine ice popsicles (group B). A total of 204 unsedated EGD patients were evaluated. Compared to the spray, the lidocaine ice popsicle group showed better effectiveness scores based on the endoscopist's satisfaction. Both spray and ice popsicle formulations of lidocaine were effective and safe options for diagnosing EGD, with ice popsicle being more promising. They suggested ice popsicle formulation for topical pharyngeal anesthesia in the patients undergoing unsedated diagnostic EGD, especially during the COVID-19 pandemic. In fact, lidocaine spray reduces the intensity of pain where sensory nerves are inhibited as sodium ions are blocked along the neural membrane, preventing the transmission of neural messages, which can be seen in both studies. The inhibited perception of pain in cryotherapy using ice popsicles occurs through changes in the speed of neural signal conduction (both sensory and motor messages), peripheral nerve synaptic activity and, ultimately, the neural inability to transmit neural messages. Although the results of the aforementioned study are not consistent with those of the present study, it can be clearly seen that if two analgesic substances are combined, a better result can be obtained. Here, the combination of cryogenics and anesthetic substances is used, which results in a synergic impact and yields better results<sup>23</sup>. Khosravi Pour et al (2023) compare the effects of cooling and lidocaine sprays on needle insertion pain in hemodialysis patients. In this randomized cross-over clinical trial study, the hemodialysis patients were selected through convenience sampling according to inclusion criteria and randomly assigned to three intervention groups using the block

randomization method .Each patient received three interventions in a cross-over design: Cooling spray or 10% lidocaine spray or placebo spray. There was a 2 week wash-out time between each intervention. The pain score was measured four times for each patient by the Numerical Rating Scale. Results Forty-one hemodialysis patients were included. The results showed a significant interaction between time and group, so only observations of time 1 with adjustment for baseline values were used to evaluate the effect of the intervention. Patients receiving cooling spray reported less pain score on average compared to .Also, patients receiving cooling spray reported a lower pain score than those receiving lidocaine spray, but this difference was not statistically significant). The cooling spray was effective in reducing the needle insertion pain<sup>24</sup>.

### Conclusion

Since pain management is one of the duties of nurses, it is important for them to acquire the necessary knowledge on the implementation of such methods, which will lead to patient satisfaction as the most important goal of the medical staff.

### Clinical Implications

Based on the results of this study, this type of pain reducing spray can be used during the insertion of IV catheters and other cases of venipuncture. Nurses can use this easy, accessible and inexpensive method in medical centers for various types of catheterization.

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## نشرة العلوم الصيدلانية جامعة أسيوط



### مقارنة تأثير رذاذ الليدوكائين ورذاذ الثلج على شدة الألم أثناء قسطرة مرضى غسيل الكلى: تجربة سريرية ثلاثية التعمية

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ينتج الألم الأكثر شيوعاً بين مرضى غسيل الكلى عن إدخال الفينة في الناسور الشرياني الوريدي بسبب قطر وطول هذه الإبر. هدفت هذه الدراسة إلى مقارنة تأثير رذاذ الليدوكائين ورذاذ الثلج على شدة الألم أثناء إدخال القسطرة الوريدية لدى مرضى غسيل الكلى وفحص مقدار تخفيف الألم أثناء هذا التدخل، وهي تجربة سريرية ثلاثية التعمية أجريت على ٥٠ مريضاً تتراوح أعمارهم بين ١٨ و ٦٥ عاماً ممن يحتاجون إلى إدخال قسطرة غسيل الكلى. تلقى كل مريض ما مجموعه ثلاثة بخاخات، نوع واحد من البخاخات في كل جلسة. تم قياس ألم الإدخال باستخدام مقياس VAS استغرق الأمر ١٠ دقائق من وضع رذاذ الليدوكائين إلى التطهير والحقن، ومع ذلك، بدأت عملية التطهير والإدخال مباشرة بعد وضع رذاذ الثلج ورذاذ التحكم (٧٠% كحول). تم إجراء اختبارات ويلكوكسون وفريدمان (غير البارامترية) لفحص نتائج البحث، واستخدم برنامج SPSS V16 لتحليل البيانات.

فقا لمتوسط القيم، يوجد فرق كبير في درجات الألم في رذاذ الثلج ورذاذ الليدوكائين ورذاذ التحكم (الكحول)، مما يشير إلى أن رذاذ الليدوكائين أكثر فعالية من رذاذ الثلج والكحول في تقليل شدة الألم الناجم عن إبر غسيل الكلى ( $P=0.010$ )، وبالمقارنة مع رذاذ الثلج، يؤدي رذاذ الليدوكائين إلى تقليل الألم الناجم عن إدخال إبر غسيل الكلى بشكل أكبر. ولذلك، يمكن استخدام هذه الطريقة كطريقة مناسبة وغير مكلفة وسهلة المنال وسهلة الاستخدام لتقليل الألم الناجم عن إدخال إبر غسيل الكلى الوعائي.