Comparison between Rhythmic Breathing and Vapocoolant Spray on Pain Intensity During Needle Insertion into Arteriovenous Fistula in Hemodialysis Patients: A Randomized Controlled Trial

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Abstract

Background: Pain from needle insertion during hemodialysis is a common challenge that requires effective pain management to ensure patient comfort. This study aimed to compare the effects of rhythmic breathing and vapocoolant spray on pain intensity during needle insertion in hemodialysis patients with arteriovenous fistulas.

Method: A Randomized Controlled Trial. Conducted from 4th in December 2024, to 16th in January 2025, the study randomly assigned 85participants into three groups: control, rhythmic breathing, and vapocoolant spray. Pain intensity was measured immediately after needle insertion using the Visual Analog Scale (VAS). The rhythmic breathing group performed a structured breathing exercise before and during needle insertion, while the vapocoolant spray group received a brief spray application prior to the procedure. Data were analyzed using SPSS version 27, Mann-Whitney U test, Kruskal-Wallis H test, one-way ANOVA, Pearson correlation, and Spearman correlation.

Results: Both the rhythmic breathing and vapocoolant spray groups showed a significant decrease in pain intensity ($P < 0.001$). The vapocoolant spray group exhibited a more significant reduction in pain compared to the rhythmic breathing group ($P < 0.001$).

Conclusion: The vapocoolant spray was more effective than rhythmic breathing in reducing pain intensity during needle insertion. Rhythmic breathing, however, can be used by nurses as a non-pharmacological method with minimal complications in hemodialysis departments to alleviate pain.

Keywords: Arteriovenous Fistula, Hemodialysis, Vapocoolant Spray, Cold Spray, Pain, Rhythmic Breathing

الخلاصة

خلفية البحث: يُعد الألم الناتج عن إدخال الإبرة لإجراء الإنفاذ الدموي من التحديات الشائعة التي تتطلب تقنيات فعالة لإدارة الألم لضمان راحة المرضى. هدفت هذه الدراسة إلى مقارنة تأثيرات التنفس الإيقاعي ورذاذ التبريد على شدة الألم أثناء إدخال الإبرة في الناسور شرياني وريدي لدى مرضى الإنفاذ الدموي.

المنهجية: دراسة منضبطة معشاة. تم تنفيذ الدراسة في الفترة من 4 ديسمبر 2024 إلى 16 يناير 2025، وشارك فيها 85 مريضًا تم توزيعهم عشوائيًا إلى ثلاث مجموعات: مجموعة التحكم، مجموعة التنفس الإيقاعي، ومجموعة رذاذ التبريد. تم قياس شدة الألم مباشرة بعد إدخال الإبرة باستخدام مقياس التناظر المرئي .(VAS) قامت مجموعة التنفس الإيقاعي بأداء تمرين تنفسي منظم قبل وأثناء إدخال الإبرة، بينما تلقت مجموعة رذاذ التبريد تطبيقًا قصيرًا للرذاذ قبل الإجراء. تم تحليل البيانات باستخدام برنامج SPSS الإصدار 27، واختبارات مان–ويتنيU ، وكراسكال–واليسH ، وتحليل التباين الأحادي (ANOVA)، واختبارات بيرسون وسبيرمان.

النتائج: أظهرت النتائج انخفاضًا كبيرًا في درجات شدة الألم في كل من مجموعة التنفس الإيقاعي ومجموعة رذاذ التبريد .($P < 0.001$) علاوة على ذلك، لوحظ فرق أكثر أهمية في المجموعة التي عولجت برذاذ التبريد مقارنة بمجموعة التنفس الإيقاعي ($P < 0.001$).

الاستنتاج: أظهرت مجموعة رذاذ التبريد فرقًا أكبر في درجات شدة الألم مقارنة بمجموعة التنفس الإيقاعي. يمكن للممرضين استخدام التنفس الإيقاعي كطريقة غير دوائية ذات مضاعفات قليلة في أقسام الإنفاذ الدموي بسبب فعاليته في تخفيف الألم.

الكلمات المفتاحية: الناسور الشرياني الوريدي، الإنفاذ الدموي، رذاذ التبريد، الألم، التنفس الإيقاعي.

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1. Introduction

Chronic renal failure (CRF) is a progressive and irreversible decline in kidney function. This condition impairs the body's ability to regulate metabolic and electrolyte balance, leading to the accumulation of blood urea and nitrogen (Hosseinzadeh et al., 2019). According to the National Kidney Federation (NKF), CRF is defined as any kidney damage or a decrease in the glomerular filtration rate (GFR) to less than 60 mL/min/1.73 m^2 of body surface area for more than three months (Alipor et al., 2018). The prevalence of kidney disease is rising globally, and the number of individuals with end-stage renal disease (ESRD) in the United States is expected to reach 2,240,000 by 2030 (Shabandokht-Zarmi et al., 2017). Hemodialysis is the most common treatment for CRF and requires vascular access (Ghadimi et al., 2019).

Ensuring proper vascular access and timely dialysis is crucial for patient survival. Various methods are used in chronic hemodialysis, including arteriovenous fistula (AVF), arteriovenous graft (AVG), and different types of catheters (Rajabzadeh Malayjerdy et al., 2019). Among these, AVF is considered the best option (Golda et al., 2016; Mirtagedine et al., 2016). However, pain at the needle insertion site during dialysis is a significant concern for patients, with over one-fifth reporting it as unbearable (Mirtajadini et al., 2016; Ghafourifard et al., 2016). Since hemodialysis patients undergo needle insertions approximately 300 to 320 times per year, managing this pain effectively is crucial (Anupreethi, 2018; Arab et al., 2017). Inadequate pain control can lead to longer hospital stays, increased medical costs, dissatisfaction with treatment, and frequent medical visits (Shiasi & Yousefi, 2021). Effective pain management can enhance patient compliance with treatment and improve their quality of life (Baloochi Beydokhti, 2021). Nurses, who spend the most time with patients, play a key role in assessing, predicting, and managing pain,

making knowledge of pain relief techniques essential (Jafarimanesh et al., 2017; Alzaatreh & Abdalrahim, 2020).

Several methods have been proposed to alleviate pain, including topical anesthetics like lidocaine (Collado-Mesa et al., 2015), distraction techniques (Tran Thi et al., 2022), vibration therapy (Secil et al., 2014), pressure application (Ozturk et al., 2017), heat therapy (Abbas Ali Madadi et al., 2017), and cooling the injection site (Hogan et al., 2014; Griffith et al., 2016).

Vapocoolant sprays are a type of topical anesthetic that temporarily reduce pain by cooling the skin rapidly. These sprays work by lowering the temperature at the application site, numbing nerve endings through the quick evaporation of volatile liquid compounds (Hogan et al., 2014; Barbour et al., 2017). Vapocoolant sprays have several advantages over other anesthetic methods, including rapid action, affordability, and ease of application, making them ideal for clinical settings. They have been proven effective in reducing pain during procedures such as catheter placement, vaccinations, and venipuncture (Unal et al., 2021).

Rhythmic breathing is another effective pain management technique. It is a distraction method that helps patients shift their focus away from pain, allowing for better pain control (Borzou et al., 2013; Brown & Gerbarg, 2005). The brainstem's reticular formation can filter out pain signals when exposed to substantial sensory input, improving patient comfort during medical procedures (Hoseini et al., 2019). Research has shown that rhythmic breathing effectively reduces pain in various medical settings, reinforcing its value in pain management (Farzin Ara et al., 2018; Borzou et al., 2002; Lalegani et al., 2014; Bozorg-Nejad et al., 2018; Park et al., 2013).

2.Methods

The Study Population was male patients receiving hemodialysis who were subjected to the insertion of needles into arteriovenous fistulas.The study sample and sampling process were carefully designed to ensure the validity and reliability of the research. The minimum sample size was determined using a Sample Size Calculator, which indicated that 72 participants were required based on the accessible populationof 88 male dialysis patients using arteriovenous fistulas from six centers (four in Dhi Qar and two in Karbala), with a margin of error of 5% and a confidence level of 95%. The projected sample size for the three groups (control, rhythmic breathing, and vapocoolant spray) was set at 24 participants per group, totaling 72 participants. However, during recruitment, 134 patients initially consented to participate. After excluding 44 patients who did not meet the inclusion criteria and 5 who opted out, the final sample size was 85 participants. These participants were randomly allocated into the three groups.

A simple randomization sampling method was used to distribute participants into three groups: the control group, the rhythmic breathing group, and the vapocoolant spray group. Each participant selected a sealed envelope containing one of three colors (white, yellow, or blue), which determined their group assignment. The study was conducted as an open-label (unblinded) trial, as participants were aware of the intervention they received. The final distribution of participants across the groups was as follows: Control Group (White): 34 participants; Rhythmic Breathing Group (Yellow): 24 participants; and Vapocoolant Spray Group (Blue): 27 participants. The randomization process led to minor discrepancies in group sizes, which is inherent in random sampling.

Inclusion criteria for the study required participants to be male, undergoing regular hemodialysis treatment, alert, at least 18 years old, capable of verbal communication, and possessing a functioning arteriovenous fistula for dialysis. Exclusion criteria included individuals experiencing significant pain unrelated to needle insertion, those with an arteriovenous fistula established for over 5 years, allergies or hypersensitivity to vapocoolant spray, recent surgical interventions or trauma near the fistula, use of analgesics, diabetes for 10 years or more, cognitive impairment, mental health disorders, active infections, complications at the fistula site.

The study Conducted from 4th in December 2024, to 16th in January 2025.The study was conducted in hemodialysis facilities across Dhi Qar and Karbala Governorates in Iraq, including the Al-Hussein Center for Dialysis, Al-Shatra Dialysis Center, Souq Al-Shuyukh Dialysis Center, Al-Rifai Dialysis Center, Habib Ibn Mazahir Dialysis Center, and the Dialysis Unit at Imam Hassan Al-Mujtaba Hospital. These centers catered to a male patient population of over 100 individuals aged 18 and above, providing a comprehensive setting for the research.

Data collection involved the use of questionnaires divided into two sections: demographic and clinical characteristics(age, sex, educational level, occupation, marital status, chronic diseases, duration of hemodialysis treatment), and the Visual Analogue Scale (VAS) for pain. The VAS is a widely used tool to assess pain intensity, featuring a 10 cm line ranging from 0 (no pain) to 100 (unbearable pain). Scores were categorized as follows: 0–4 (no pain), 5–44 (mild pain), 45–74 (moderate pain), and 75–100 (severe pain). The VAS demonstrated high reliability, with a coefficient of 0.97%. Participants were seated and asked to mark their pain level on the line, which was then measured in millimeters from the "no pain" endpoint.

The study procedures were standardized to ensure consistency. Participants were positioned comfortably in a supine position two minutes before needle insertion. The fistula area was disinfected with a 70% alcohol solution by certified nursing staff. Cannulation was performed at least 5 cm from the target site, with the needle inserted at a 30–40 degree angle. Pain levels were assessed immediately after needle insertion and stabilization using the VAS scale.

For the rhythmic breathing group, participants were instructed to engage in rhythmic breathing for two minutes before needle insertion. They were asked to close their eyes, inhale deeply through their nostrils for three seconds, hold their breath for three seconds, and exhale through their mouth for three seconds. This breathing pattern continued during needle insertion, and pain was assessed immediately after needle stabilization using the VAS scale.

In the vapocoolant spray group, the spray was applied to the skin around the fistula for three to four seconds from a distance of 15–20 cm. After a 10-second wait for the spray to evaporate, the needle was inserted, and pain intensity was assessed using the VAS scale.

data were analyzed using SPSS software version 27, frequencies, Percentages, Mean of score, Standard Deviation Mann-Whitney U test, Kruskal-Wallis H , one way ANOVA , Pearson and Spearman.

3. Results

Table 1: Distribution of the Participants socio demographic data characteristics

Demographic characteristics	Subgroup	Control		Vapocoolant spray		Rhythmic breathing	
		f.	%	f.	%	f	%
Age		**Mean ± SD 54.82 ± 14.003 Min- Max 24 - 74 years**		**Mean ± SD 55.22 ± 14.219 Min- Max 18 - 80 years**		**Mean ± SD 49.50 ± 15.342 Min- Max 24 - 72 years**	
Educational level	**Not read &write**	10	29.4	11	40.7	2	8.3
	Read & write	10	29.4	6	22.2	6	25.0
	Primary school	10	29.4	5	18.5	7	29.2
	Intermediate school	1	2.9	1	3.7	5	20.8
	Secondary school	1	2.9	1	3.7	1	4.2
	Diploma graduate	2	5.9	1	3.7	1	4.2
	Bachelor graduate	0	0	1	3.7	2	8.3
	Higher education	0	0	1	3.7	0	0
	Total	34	100.0	27	100.0	24	100.0
Occupation	**Employee**	4	11.8	4	14.8	4	16.7
	Freelance	2	5.9	1	3.7	0	0
	Unemployed	21	61.8	20	74.1	12	50.0
	Retired	7	20.6	2	7.4	7	29.2
	Student	0	0	0	0	1	4.2
	Total	34	100.0	27	100.0	24	100.0
Marital Status	**Single**	2	5.9	1	3.7	3	12.5
	Married	26	76.5	20	74.1	15	62.5
	Divorced	0	0	2	7.4	4	16.7
	Widow	6	17.6	4	14.8	2	8.3
	Total	34	100.0	27	100.0	24	100.0
Chronic diseases	**Heart disease (only)**	0	0	0	0	2	8.3
	Diabetes (only)	3	8.8	0	0	2	8.3
	Both (heart disease and	1	2.9	0	0	0	0

	diabetes)						
	Hypertension (only)	10	29.4	13	48.1	7	29.2
	hypertension and Diabetes	6	17.6	4	14.8	3	12.5
	Hypertension and heart disease	1	2.9	5	18.5	5	20.8
	All three (hypertension, diabetes, and heart disease)	3	8.8	3	11.1	2	8.3
	None of the above	10	29.4	2	7.4	3	12.5
	Total	34	100.0	27	100.0	24	100.0
Duration of hemodialysis treatment	**Less than 1 year**	6	17.6	8	29.6	8	33.3
	1-5 years	25	73.5	16	59.3	13	54.2
	>5years	3	8.8	3	11.1	3	12.5
	Total	34	100.0	27	100.0	24	100.0

F= Number of frequencies, % = Percentage, M = Mean, SD = Standard Deviation In Table 1 the results showed the distribution of 85 male patients undergoing hemodialysis socio demographic data characteristics according to their groups (Control = 34, Vapocoolant spray = 27 and Rhythmic breathing = 24), mean age was 54.82 in control group, 55.22 in Vapocoolant spray group and 49.50 in Rhythmic breathing, all group most were married (76.5% in control group, 74.1% in Vapocoolant spray group and 62.5% in Rhythmic breathing) . According to the educational level, all groups most were between not read and write, read and write, and primary school (in control group 29.4% not read and write, 29.4% read and write, 29.4% primary school ,in Vapocoolant spray group 40.7% not read and write and in Rhythmic breathing 29.2% primary school). Regarding the occupation, all groups most were unemployed (61.8% in control group, 74.1% in Vapocoolant spray group and 50% in Rhythmic breathing), all groups most have Hypertension only (29.4% in control group, 48.1% in Vapocoolant spray group and 29.2% in Rhythmic breathing), all groups have a duration of hemodialysis treatment from one to five years (73.5% in control group, 59.3% in Vapocoolant spray group and 54.2% in Rhythmic breathing).

Table 2: Evaluation of the Pain Intensity During Needle Insertion into Arteriovenous Fistula in Hemodialysis Patients according to their groups (Control, Vapocoolant spray, Rhythmic breathing, Hugo point acupressure, and Rhythmic breathing integrated with Hugo point acupressure).

Group	Min	Max	Mean	SD
Control	22	86	64.79	15.847
Vapocoolant spray	20	31	25.59	3.651
Rhythmic breathing	31	47	37.79	4.293

Min= minimum, Max= maximum, M = Mean of score, S.D = Standard Deviation In Table 2 the results showed the evaluation of the pain intensity during needle insertion into arteriovenous fistula in hemodialysis patients according to their groups were high level in control group (64.79) and low level in Vapocoolant spray (25.59) and Rhythmic breathing (37.79).**Table 3. Differences between Pain Intensity Patients Groups During Needle Insertion into Arteriovenous Fistula in Hemodialysis By using the Kruskal-Wallis test and the Mann-Whitney U test.**

	Pain Intensity					
Group	**Mann-Whitney U Test**				**Kruskal-Wallis test**	
	N	**Mean Rank**	**Mann-Whitney U**	**Sig**	**Kruskal-Wallis H**	**Sig**
Control	34	43.21	44.000	.000	97.365	.000
Vapocoolant spray	27	15.63				

Control	34	39.38	72.000	.000		
Rhythmic breathing	24	15.50				
Vapocoolant spray	27	14.07	2.000	.000		
Rhythmic breathing	24	39.42				

P=probability value, NS: Non-Significant at P ≥ 0.05, S: Significant at P < 0.05, HS: Highly Significant at P < 0.001.

In Table 3, the findings elucidated through the application of the Kruskal-Wallis test demonstrated a profoundly statistically significant disparity among Rhythmic Breathing, vapocoolant spray, and Control group in relation to patients' pain intensity during the insertion of needles into arteriovenous fistulas in hemodialysis patients at $P < 0.001$.The outcomes further indicated, via the Mann-Whitney U test, that there were markedly significant statistical differences between the Control group and the vapocoolant spray group at $P < 0.001$. and between the Control group and the Rhythmic Breathing group at $P < 0.001$ regarding patients' pain intensity during needle insertion into arteriovenous fistulas in hemodialysis patients.The findings also revealed a substantial significant statistical difference between the vapocoolant spray and Rhythmic Breathing regarding patients' pain intensity during needle insertion into arteriovenous fistulas in hemodialysis patients at $P < 0.001$

4.**Discussion**

The management of pain during needle insertion in patients undergoing hemodialysis is a critical aspect of improving patient comfort and adherence to treatment protocols. The present study aimed to compare the efficacy of rhythmic breathing and vapocoolant spray as interventions for pain reduction during this procedure. The results indicated that both methods were statistically

effective in alleviating pain; however, vapocoolant spray demonstrated a superior efficacy compared to rhythmic breathing.

The findings align with previous research that emphasizes the importance of effective pain management strategies in hemodialysis patients. For instance, a study by Henneman et al. (2018) highlighted that non-pharmacological interventions, such as vapocoolant sprays, can significantly enhance patient comfort during painful procedures. This is particularly relevant in the context of hemodialysis, where patients often experience anxiety and discomfort associated with frequent needle insertions (Mason et al., 2020).

Moreover, the mechanism by which vapocoolant spray reduces pain may be attributed to its cooling effect, which can inhibit nociceptive transmission and provide immediate relief (McGowan et al., 2019). In contrast, rhythmic breathing, while beneficial, may not produce instant results and relies more on the patient's ability to control their physiological response to pain (Higgins et al., 2017). This difference in immediacy and effectiveness could explain the statistical superiority of vapocoolant spray observed in our study.

The implications of these findings are significant for clinical practice. Incorporating vapocoolant spray into routine procedures for hemodialysis patients could enhance patient satisfaction and reduce anxiety associated with needle insertions. Furthermore, this method is easy to implement and can be combined with other pain management strategies to optimize patient outcomes (Smith & Jones, 2021)..

5. Conflict of interest

There is no conflict of interest.

6. Limitations of the study

The study was conducted in few centers and the sample size was small so that cannot generalize the results.

7.Conclusion

rhythmic breathing and vapocoolant spray are effective in reducing pain during needle insertion for hemodialysis patients, with vapocoolant spray showing greater efficacy.

8.Recommendation

vapocoolant spray be considered as an effective intervention for reducing pain intensity during needle insertion in hemodialysis patients. Additionally, rhythmic breathing can be incorporated as a complementary non-pharmacological technique due to its ease of application and minimal complications. Healthcare providers, particularly nurses in hemodialysis units, should be trained in both methods to enhance patient comfort and pain management strategies.Also, future studies with big sample size are recommended.

9.Author contributor

Conceptualization, Software, Formal analysis, Investigation, Resources, Data Curation, Writing - Original Draft, Writing - Review & Editing, Visualization, Project administration, and Funding acquisition (Hassan Raysan Al-waeli). Methodology, Validation, and Supervision (Associate. Prof, Wafaa Abed Ali Hattab).

10.Ethics Statements

The study received approvals from the University of Baghdad, the IRB, the Iraqi Health Ministry, and relevant hemodialysis centers in Dhi Qar and Karbala. It was registered with the Iranian Registry of Clinical Trials (IRCT20241103063578N1) and conducted per ethical guidelines. Informed consent was obtained, ensuring participants' rights and confidentiality.

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