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Comparison of the effect of guided visualization technique and cryotherapy on pain intensity during needle insertion into arterial–venous vessels of hemodialysis undergoing patients: A cross-over clinical trial

Zahra Ghazanfari, Saeed H. Teshnizi[1], Pooneh Yousefi[2], Aref Faghih[2]

Department of Nursing, Student Research Committee, Hormozgan University of Medical Sciences, Bandar Abbas, Iran, [1]Mother and Child Welfare Research Center, Hormozgan University of Medical Sciences, Bandar Abbas, Iran, [2]Department of Nursing, School of Nursing and Midwifery, Hormozgan University of Medical Sciences, Bandar Abbas, Iran

Address for correspondence:
Prof. Aref Faghih, Department of Nursing, Faculty of Nursing and Midwifery, Hormozgan University of Medical Sciences, Bandar Abbas, Iran.
E-mail: aref_faghih@yahoo.com

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Abstract:

BACKGROUND: End-stage renal disease patients experience pain during needle insertion each time they undergo vascular access. This pain is the most severe aspect of hemodialysis-related stress. Based on this, this study was conducted with the aim of the effect of guided visualization technique and cryotherapy on the intensity of pain when the needle enters the arterialvenous vessels in patients undergoing hemodialysis.

MATERIALS AND METHODS: This cross-over clinical trial was conducted on 60 patients undergoing hemodialysis from September to December 2023. Patients were randomly assigned to three independent groups ($n = 20$ people per group). This study was conducted in three stages, during which each group received guided visualization, cryotherapy, and routine care (control) separately. Pain intensity was measured individually using the numerical rating scale at the end of each interventions. Data analysis was performed using data statistics (Stata) version 14 and Statistical Package for the Social Science version 26.

RESULTS: The results showed that guided visualization significantly outperformed cryotherapy across all three groups and stages. Additionally, both guided visualization and cryotherapy significantly outperformed the control group in reducing pain following needle insertion in patients undergoing hemodialysis.

CONCLUSION: Guided visualization can be used as a safe and secure method to reduce pain when the needle enters the arteriovenous fistula in patients undergoing hemodialysis.

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Keywords:

Arteriovenous fistula, cryotherapy, guided imagery, hemodialysis, pain

Introduction

Hemodialysis is the most common treatment for end-stage renal disease, both in Iran and worldwide.[1] Nearly two million patients rely on dialysis globally,[2] and it is predicted that the number of hemodialysis patients will reach 3.5 million.[3] Vascular access is necessary for hemodialysis in patients with kidney failure. Arteriovenous fistula (AVF) is the standard method of vascular access in these patients.[4] Although dialysis has prolonged the lives of patients, it is extremely stressful and results in many physical and psychological

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complications.[5] The most common complications of dialysis include muscle pain, headache, chest pain, back pain, fatigue,[6] stress, and pain caused by needle insertion.[7] These patients usually undergo hemodialysis three times a week for 3–4 h each time, in approximately 90% of cases, and experience needle insertion pain in the AVF approximately 320 times a year.[8] The results of studies show that hemodialysis patients experience pain in more than 50% of cases, and 47% of them are afraid of needles, considering the placement of vascular catheters the most stressful part of treatment and their biggest concern during hemodialysis.[9] Hemodialysis patients who experience pain are more likely to suffer from depression, anxiety, an inability to cope with stress, and increased mortality. Studies show a significant correlation between mortality, pain severity, and pain recurrence in these patients.[2] Many advances have now been made in the treatment of pain, and many pharmacological and nonpharmacological methods have been introduced to relieve pain.[10,11] Due to the complications of drugs, such as skin rashes, allergic reactions after long-term use of a medication, economic burden, and adverse effects of chemical drugs, there is an increasing trend in the use of nonpharmacological methods and complementary medicine for pain relief.[12,13] Complementary medicine can be incorporated into nursing care.[14] Today, nonpharmacological interventions such as cognitive-behavioral methods, mind distraction, muscle relaxation, aromatherapy, skin stimulation, cold therapy, and guided imagery are used for pain relief in hemodialysis patients.[15] Guided visualization is a psychological and relaxation technique that creates and recreates vivid mental images in the brain by consciously using the power of imagination. With this technique, people can imagine their favorite and relaxing places, such as the seashore, mountains, forests, sounds, and natural smells, in their minds.[16] This technique is noninvasive and affordable, requires no special or expensive equipment, is easily accepted by the patient, and increases the self-confidence and self-efficiency of patients.[17,18] Various studies have shown that guided imagery has been effective in reducing symptoms in patients undergoing chemotherapy,[19] reducing pain and anxiety in women with breast cancer,[20] improving the quality of life of patients undergoing coronary artery bypass surgery,[17] reducing stress in pregnant women, and reducing anxiety, pain, and depression in hemodialysis patients.[21] However, the results of the study by Jong *et al*.[22] in 2012, which aimed to investigate the effect of guided imagery on preoperative anxiety and control postoperative pain control in patients who underwent cele cystectomy, showed that guided imagery did not have a significant effect on pain control and patients' anxiety.

Cryotherapy is a pain reduction mechanism explained by Melzack gate control theory.[23,24] Cold therapy is a common treatment for injuries, bleeding, and trauma and is widely used to relieve pain. It works by causing vasoconstriction and stimulating thermal pain receptors by lowering the skin temperature. It exerts its analgesic effect by reducing nerve conduction velocity.[25] The colon pressure point, also known as Hugo's point, is located on the back of the hand between the thumb and index finger. Hugo point is the most important pain-relief points in the body, and its stimulation can help reduce pain in various areas.[26] Several studies have demonstrated the positive effects of cryotherapy in reducing pain intensity following needle insertion into the arterial and venous vessels of hemodialysis patients.[27-29] However, Dehghan *et al*.[30] (2023) found that acupressure was more effective than cryotherapy in reducing pain caused by needle insertion in dialysis patients. Conducting research is imperative to advance scientific understanding, establish evidence-based treatment alternatives, enrich patient-centered care, explore alternative therapies, and potentially improve preventive care strategies. So, this study aimed to conduct a comparative analysis of guided imagery and cryotherapy on pain intensity following needle insertion in the arterial–venous vessels of hemodialysis patients.

Materials and Methods

Study design and setting

This research was a crossover clinical trial without blinding, conducted between September and December 2023 in Shahid Shariati Hospital in Fasa.

Study participants and sampling

The study population included 60 hemodialysis patients, who were selected using a convenience sampling method. None of the patients were excluded from the study. According to previous studies, and considering $\alpha = 0.05$ and $\beta = 0.2$, and given that there were three independent study groups, the sample size for each group was set at approximately 20. The participants were assigned to three groups ($n = 20$ people per group) based on a table of random numbers. To allocate participants to the three study groups, a random sequence was generated using the Randomization Main table random sequence with six blocks of ten. Then, to allocate each intervention to a participant, a nursing expert who was not part of the study allocated the groups in the order in which patients entered the study.

$$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 (\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2} = 14$$

$$n' = \sqrt[2]{k-1} \times n = \sqrt{3-1} \times 14 = 20$$

The inclusion and exclusion criteria

Inclusion criteria included individuals over 18 years of age; awareness of time, place, and person; absence of eczema and wounds at the massage site; absence of diabetes and hypertension or if present, a controlled condition; having a fistula; and at least six weeks of dialysis history. Exclusion criteria included having a mental illness or peripheral vascular disease, a history of using painkillers or similar compounds within 8 h before dialysis, and lack of consent to participate in the research. This study was conducted in three stages: In the first session, guided visualization intervention was performed for the first group, cryotherapy intervention was given to the second group, and the third group received the routine action. The fistula site was well disinfected in the last 30 seconds of the intervention, when the patient was still undergoing the intervention. Also, the needle was inserted into the fistula by the researcher, and the pain level was immediately measured and recorded. To avoid transferring treatment effects from the first stage to the second stage, a three-day washout period or cleansing period was implemented.

In the second session, for the group that had received guided visualization intervention in the first session, cryotherapy intervention was administered, the group that had received cryotherapy intervention in the first session, routine actions was used in this session. Furthermore, in the group that had been in the control group in the first session, guided visualization intervention was conducted at this stage. The fistula site was well disinfected in the last 30 seconds of the intervention, when the patient was still undergoing the intervention. Also, the needle was inserted into the fistula by the researcher, and the pain level was immediately measured and recorded. To avoid transferring treatment effects from the second stage to the third stage, a three-day washout period or cleansing period was implemented.

In the third session, the group that had received cryotherapy intervention in the second session, this session was replaced with without intervention, routine procedures. For the group that had received routine actions in the second session, guided visualization intervention was performed in this session. For the group that had received guided visualization intervention in the second session, cryotherapy intervention was performed in this session. The fistula site was well disinfected in the last 30 seconds of the intervention, when the patient was still undergoing the intervention. Also, the needle was inserted into the fistula by the researcher, and the pain level was immediately measured and recorded.

In this way, each patient received different treatments at different time periods (first, second, and third stages) [Figure 1].

Guided imagery method

In the guided imagery method, a private space was first provided for the patient. The patient was then asked to lie down on the bed, take a few deep breaths in a relaxed position to release mental and physical tension, close their eyes. Afterward, a guided imagery CD was played through headphones for 18 min, which included imagined scenes of a forest, the sea, beautiful landscapes, and positive affirmations emphasizing improved health and pain reduction.[31]

Cryotherapy method

In the cryotherapy method, a 2 × 2 cube-shaped ice piece was first wrapped in gauze and then placed in a plastic bag. It was then placed between the patient's thumb and index finger (Hugo point) on the fistula-free hand, and the patient was asked to hold it for 10 min (with 2 min of massaging and 15 s of rest) before needle insertion.[30]

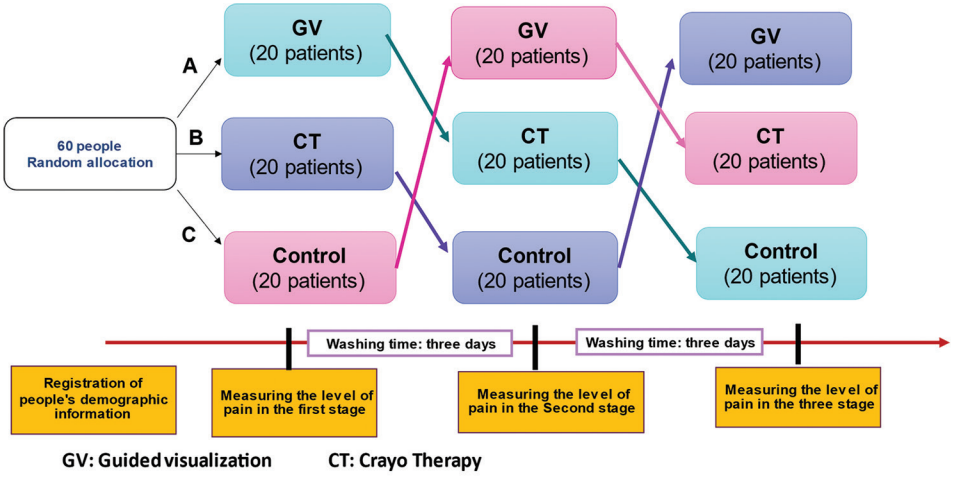

Figure 1: Steps of conducting the study in three groups

In the control group, routine measures were performed, and the spatial and environmental conditions were kept constant at all stages of the research. All tests were carried out in accordance with the relevant guidelines and regulations.

Data collection procedures

The data was collected using a questionnaire. The study tool consisted of two parts: 1. Demographic characteristics, including: age, sex, occupation, level of education, duration of dialysis, duration of fistula use, diabetes, and hypertension. 2. NRS, which is numbered between 0 and 10. Numbers 0, 1–3, 4–6, 7–10 indicate the absence of pain, mild pain, moderate pain, and severe pain, respectively, as reported by the patient.[32,33] The validity and reliability of the NRS have been investigated in many studies. Reliability was assessed using Cronbach's alpha method ($\alpha = 0.95$), and its test power was 0.90.[34]

Data analysis

Data analysis was carried out using Stata Ver. 14 and Statistical Package for the Social Science Ver. 26 statistical software. Descriptive statistical tests included the mean and standard deviation in the three studied groups. Additionally, repeated measures analysis of covariance, Bonferroni's *post hoc* test, one-way Analysis of variance (ANOVA), and Dunnet's test were used. A *P* value of <0.05 was considered statistically significant.

Ethical consideration

All participants provided written informed consent to participate in the study. The present study was conducted in accordance with the principles of the revised Declaration of Helsinki, a statement of ethical principles that guides physicians and other participants in medical research involving human subjects. Participants were assured of the anonymity and confidentiality of their information. Moreover, this study was registered with the Ethics Committee of Hormozgan Faculty of Medical Sciences under the code IR.HUMS.REC.1401.206 and in Iranian Registry of Clinical Trials under the code IRCT202308080590.

Results

In Table 1, the frequency distribution of demographic characteristics across the three studied groups is presented.

The results of the crossover analysis test are reported in Table 2. It can be stated that the mean pain intensity score in each therapeutic intervention was not affected by the effect of sequence, carryover, or period effects.

The three therapeutic interventions, three periods, and mean pain intensity after the intervention are shown in Table 3.

Overall, guided visualization significantly outperformed cryotherapy in all three periods, and both interventions significantly outperformed the control condition [Figure 2].

Discussion

The results showed a significantly more reduction in pain during needle insertion in the guided imagery group than in the cryotherapy and control groups, which indicates a clear promise for the use of nonpharmacological treatment and nursing care to reduce pain in hemodialysis patients. A literature review showed that there is no study that has directly compared the effects of guided imagery and cryotherapy on the intensity of pain caused by the insertion of needles into the AVF of hemodialysis patients. In the study titled "The effectiveness of progressive muscle relaxation and interactive guided imagery as a pain-reducing intervention in advanced cancer patients", De Paolis *et al*.[31] (2019) concluded that guided imagery is a nursing intervention that can be considered an effective adjuvant in alleviating pain-related distress in terminal cancer patients. Similarly, in a randomized controlled trial titled "Effectiveness of Guided visualization on Symptoms, Sleep quality, Anxiety, and Satisfaction with Postoperative Nursing Care," Acar *et al*.[32] (2019) concluded that guided visualization is effective in reducing the intensity of pain and anxiety and improves the level of satisfaction and sleep quality of patients. Dos Santos Felix *et al*.[33] (2019), in their review of eight articles, found that guided visualization as a relaxation therapy is effective in managing and reducing postoperative pain and suggested that nurses use this technique to reduce and manage patients' pain. In another study on the effect of guided imagery interventions on preoperative anxiety and postoperative pain, Álvarez-García and

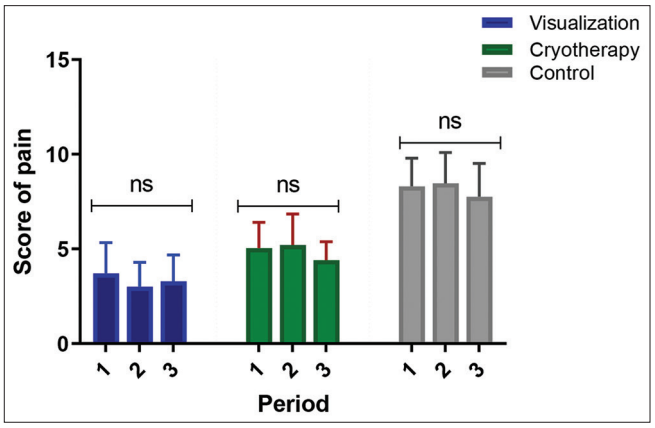

Figure 2: Comparison of average pain in three periods (1, 2, 3) by guided visualization, cryotherapy, and control groups. ns = lack of statistical significance

Table 1: Frequency distribution of demographic characteristics

Variable	Levels	Study groups			*P*
		Group A (*n*=20) *n* (%)	Group B (*n*=20) *n* (%)	Group C (*n*=20) *n* (%)	
Gender	Male	13 (65/0)	11 (55/0)	13 (65/0)	0/754
	Female	7 (35/7)	9 (45/7)	7 (35/7)	
Marital status	Single	5 (25/0)	2 (30/0)	4 (15/0)	
	Married	13 (65/0)	16 (80/0)	14 (70/54)	0/809
	Widowed/divorced	2 (10/0)	2 (10/0)	2 (10/0)	
Education level	illiterate	5 (25/0)	6 (30/0)	3 (15/0)	0/747
	elementary	5 (25/0)	6 (30/0)	3 (15/0)	
	guidance	4 (20/0)	4 (20/0)	7 (35/0)	
	diploma	5 (25/0)	2 (10/0)	5 (25/0)	
	university degree	2 (10/0)	2 (10/0)	1 (5/0)	
Dialysis time	Less than 3 months	0 (0/0)	0 (0/0)	1 (5/0)	0/70
	Three months to a year	4 (20/0)	5 (25/0)	4 (20/0)	
	More than a year	18 (80/0)	15 (75/0)	15 (75/0)	
Fistula age	Less than a year	6 (30/0)	5 (25/0)	8 (40/0)	0/787
	1–3 Year	4 (20/0)	3 (15/0)	4 (20/0)	
	More than 3 years	10 (50/0)	12 (60/0)	8 (40/0)	
Age (standard deviation±mean)		53/10±15/89	58/10±13/38	55/30±15/88	0/759

Table 2: The results of analysis of variance for cross-over data analysis

Source of changes	Sum of squares	Degrees of freedom	Sum of squares	*F*	*P*
Inside people					
Sequence	4/55	2	2/27	63	0/535
Error	205/3	57	3/60	2/41	-
Between people					
Treatment	156/26	2	78/13	52/43	<0/001
Carryover	4/4	2	2/2	1/36	0/262
Period	4/52	2	2/26	1/52	0/224
Error	169/87	114	1/49	-	-

Omnibus measure of separability of treatment and carryover=47.2954%

Table 3: Comparison of the mean pain intensity following the needle insertion among the studied groups in three periods

First period	Second period	Third period	The results of the analysis of variance with repeated measures			
			Sequence	Makhli test, *P*	*F*	*P*
Guided visualization (*n*=20)	Guided visualization	Guided visualization	Cr->Co->V	0/937	70/06	<0/001
3/70±1/63	3/00±1/33	3/30±1/38				
Cryotherapy (*n*=20)	Cryotherapy	Cryotherapy	Co->V->Cr	0/77	96/4	<0/001
5/05±1/36	5/20±1/64	4/75±1/64				
Control (*n*=20)	Control	Control	V->Cr->Co	0/637	75/32	<0/001
8/30±1/49	8/30±1/62	7/75±1/77				

Yaban[34] (2020) found that guided imagery reduced postoperative pain in children and preoperative state anxiety in adults. Consistent with this finding, in a study titled "Effectiveness of Progressive Muscle Relaxation, Deep Breathing, and Guided Imagery in Promoting Psychological and Physiological States of Relaxation," Toussaint *et al*.[35] (2021) found that the simultaneous use of progressive muscle relaxation, guided visualization, and deep diaphragmatic breathing all increased the state of relaxation for participants. Consistent with this finding, in a study titled "Effects of Progressive Muscle Relaxation, Guided visualization, and Deep Diaphragmatic Breathing on the Quality of Life in the Elderly with Breast or Prostate Cancer," Shahriari *et al*.[36] (2017) found that the simultaneous use of progressive muscle relaxation, guided imagery, and deep diaphragmatic breathing improved the quality of life of these individuals. In another study on the effect of guided imagery on pain, anxiety, and certain hemodynamic factors in patients undergoing coronary angiography, Foji *et al*.[37] (2015) found that guided imagery plus relaxation significantly reduced the anxiety score of patients in the intervention group compared to the control group Moreover, the mean pain scores, as measured by the pain scale, showed that the

control group had a slower level of pain. In this regard, Nader Aghakhani *et al*.[38] (2021), in a study titled "The effect of guided imagery on the quality and severity of pain and pain-related anxiety associated with dressing changes in 70 burn patients," concluded that guided imagery reduced the quality and severity of pain and pain-related anxiety. However, the difference is that the McGill Pain Questionnaire and Visual Analog Scale (VAS) were used to measure pain in this study. According to the results of the above studies, guided visualization had an evident positive effect in reducing pain, improving anxiety, depression, sleep sufficiency, and quality of life, improving vital signs, psychological symptoms, and increasing mental peace in patients. To explain the use of guided visualization, it can be concluded that guided imagery, as a mind-body therapy, is based on the fact that the mind and body are interrelated and can interact to treat illness and improve health status. By highlighting the power of thought, the guided imagery method can deeply affect how patients perceive themselves and their sense of efficiency. In this technique, a person—either with the help of another person or alone—creates or imagines a mental image that leads to the recall or perceptual simulation of a sense of vision, hearing, taste, smell, movement, or an image related to the sense of touch, such as feeling different surfaces and textures, heat, cold, and pressure. Additionally, the person may experience mental or imaginative that can evoke intense emotions, relaxation, and pain reduction. In fact, this method helps patients control and reduce their pain by using positive and energizing images.

Limitations

- Inability to implement blinding due to the nature of the interventions and method of pain assessment
- Individual differences in pain perception and intensity.

Conclusion

Given the type of disease, the condition of hemodialysis patients, and their living conditions, most patients do not accept medication. Additionally, the fewer drugs hemodialysis patients use, the more ideal their conditions will be. Therefore, the present study showed that patient prefer and more easily accepts guided imagery, a nonpharmacological treatment in complementary medicine; for this reason, it has a positive effect on reducing pain intensity during needle insertion. While guided imagery is a useful, low-cost, comfortable, and safe method with no side effects, it is a new technique to relieve pain during needle insertion in hemodialysis patients.

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Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to the necessity to ensure participant confidentiality policies and laws of the country but are available from the corresponding author at a reasonable request.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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