

The Comparative Effects of Cryotherapy and Music Therapy on Pain and Anxiety in Vascular Access Procedures: A Randomized Clinical Trial

HADI JAFARIMANESH^{1,2}, SARA SAMIEI³, MASOUMEH ZAKERIMOGHADAM⁴,
MEHDI ZAREIE³, AMOS NAWUNIMALI SUUK^{5,6}

¹Ph.D. student, Medical Surgical Department, School of Nursing and Midwifery,
Tehran University of Medical Sciences, Tehran, Iran

²Medical Surgical Department, School of Nursing, Arak University of Medical Sciences, Arak, Iran

³Nursing Student Research Committee, Arak University of Medical Sciences, Arak, Iran

⁴Ph.D. in Nursing, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran

⁵Ph.D. student, Medical Surgical Department, School of Nursing and Midwifery,
Tehran University of Medical Sciences, Tehran, Iran

⁶Principal Health Tutor, Community Health Nurses' Training College, Tamale, Northern region, Ghana

ABSTRACT: Purpose: The fear of vascular access procedures reduces patient cooperation, often resulting in unsuccessful venipuncture attempts and prolonging the overall treatment process. Because people getting venipunctures in medical and surgical settings usually feel pain and anxiety, the goal of this study was to look at and compare how cryotherapy (CT) and music therapy (MT) affected the levels of pain and anxiety (P&A) these people felt. Method: This research utilized a randomized controlled trial methodology. The target population consisted of patients hospitalized in the medical-surgical wards of Valiasr Hospital, Arak, Iran. One hundred twenty patients were purposively selected and then randomly assigned (using block randomization) to one of four groups: MT, CT, combination therapy (COBT), or control. P&A levels were assessed using the Visual Analogue Scale (VAS) and the Visual Anxiety Intensity Scale (VAIS). Data were analyzed utilizing version 21 of the Statistical Package for the Social Sciences (SPSS) software. Descriptive statistics, including mean, standard deviation, frequency, and percentage, along with inferential statistics, such as the analysis of variance test, paired t-test, and Chi-square, were employed for analysis. Findings: The findings revealed a statistically significant disparity in pain levels among the four groups ($P < 0.001$). The mean pain score in the COBT group (1.66 ± 1.66) was lower than that of the MT group (2.03 ± 1.84) and the CT group (2.43 ± 2.16). However, the three intervention groups (MT, CT, and COBT) showed no notable difference from a statistical perspective ($P > 0.05$). Additionally, a statistically substantial distinction in anxiety levels was observed among the four groups after the study ($P < 0.05$). Both the COBT and MT therapies markedly diminished anxiety severity in comparison to the control group. Conclusion: The study results demonstrated that MT, CT, and COBT are effective in alleviating P&A in patients having venipuncture procedures. These interventions may serve as valuable complementary or alternative approaches in clinical practice.

KEYWORDS: Music therapy, cryotherapy, pain and anxiety management, vascular access, catheterization, complementary and alternative therapies.

Introduction

In hospitals, intravenous line implantation (angiocatheter) is one of the most common invasive procedures used to deliver fluids and electrolytes, transfuse blood, and administer parenteral medication. According to health statistics, 45 million people who are admitted to hospitals each year need venous implants.

Although venous line placement is a common procedure in medical centers, it is considered an unpleasant and painful experience for most patients [1].

Pain is a complex phenomenon affecting a person's physical, emotional, and mental functioning [2].

The subjectivity of pain has caused challenges in pain assessment and management. However, the patient's report is the essential criterion and standard for assessing the presence and severity of pain [3].

There are many ways to categorize pain. Often, pain is described as acute or chronic. Venipuncture causes acute pain expected to last quickly and be relieved with treatment strategies.

Procedures requiring vascular cannulation can cause pain, fear, and anxiety, which negatively affect the treatment process of patients [4].

Pain and anxiety (P&A) associated with vascular implantation reduce patient cooperation, contribute to failures in the venipuncture process, and extend the overall duration of treatment. In the United States, over 10% of adults avoid

medical care due to a fear of needles. This translates to an estimated 11.5 to 66 million individuals in the United States who are afraid of needle insertion [5].

As integral healthcare team members, nurses play a critical role in alleviating pain [6], as they spend most of their time with patients.

Additionally, nurses are responsible for assessing pain, implementing palliative interventions such as administering analgesics and evaluating the outcomes of these measures [7].

Nurses must prioritize pain management as pain diminishes the patient's quality of life, creates discomfort, and contributes to economic losses. Pain caused by needles and catheters entering blood vessels becomes particularly problematic when it is recurrent or requires constant intervention in certain conditions [8].

This type of pain can lead to irritability, an elevated basal metabolic rate, increased secretion of catecholamines, and alterations in vital signs such as hypertension and tachycardia, ultimately raising myocardial oxygen demand [9].

Complementary and alternative medicine encompasses various practices, including herbal medicine, massage therapy, acupuncture, yoga, traditional Chinese medicine, and many others, rooted primarily in different nations' indigenous and historical cultures. In recent years, complementary and alternative medicine has grown significantly and continues to gain popularity [10].

It is estimated that one in three individuals will utilize complementary medicine during their lifetime to manage common conditions such as back pain, headaches, anxiety, and depression [11].

Pain management is one area where complementary medicine methods have demonstrated notable efficacy [12].

Complementary medicine for pain control offers several benefits, including improved effectiveness, greater acceptance, reduced healthcare costs, enhanced patient autonomy, and the absence of adverse effects commonly associated with drug-based interventions.

Music intervention is one of several environmental care strategies in which nurses modify the environment to enhance their patient's health and well-being. Music therapy (MT) promotes positive changes in behavioral and physiological symptoms by lowering respiratory frequency, arterial pressure, pulse rate, muscle tension, metabolic speed, and oxygen consumption [13].

Studies have demonstrated that music alleviates physical, psychological, and cognitive issues while reducing pain in patients undergoing painful and distressing treatments [14].

Cryotherapy (CT) is one of the oldest topical treatments, effectively alleviating inflammation, soft tissue injuries, and wounds. It is among the simplest therapeutic methods, dating back to Hippocrates, used to minimize the complications of injuries. With its cooling effect on superficial and intramuscular tissues, CT induces physiological changes such as vasoconstriction, reduced metabolism, muscle relaxation, decreased inflammation, and pain relief [15].

CT alleviates pain through various mechanisms, including stimulation of peripheral nerve receptors, reduction of muscle tension, alteration of nerve conduction, slowing pain transmission to the central nervous system, and distraction of the mind. Additional mechanisms include lowering catecholamine levels and increasing endorphin levels, reducing pain. According to the Gate Control Theory of Pain (GCTP), CT effectively blocks the nerve conduction of sensory fibers, raising the pain threshold and thereby reducing pain [16].

Pain associated with vascular access and angiocatheter implantation can evoke fear and anxiety in patients. This may result in reduced patient cooperation, unsuccessful venipuncture attempts, and prolonged treatment processes.

Consequently, this study intends to investigate the effects of CT and MT on P&A induced by vascular access procedures.

Study aim

This research aims to assess the impact of CT and MT on P&A related to intravenous access procedures.

Hypothesis

This study hypothesizes that CT and MT effectively alleviate P&A related to IV access procedures.

Methods

Study design

This research was a parallel, randomized, controlled clinical trial from September 22, 2020, to May 22, 2021. The study included 120 patients admitted to the medical-surgical wards of Valiasr Hospital in Arak, Iran.

Participants were initially selected based on predefined eligibility criteria and subsequently randomized into four groups: music therapy, CT, combination therapy (COBT=CT and music therapy), or control.

Participants

According to Jafarimanesh et al. [7], using a mean and standard deviation for the intervention group (3.38 ± 2.20) and the control group (5.60 ± 2.53), with a 95% confidence interval and a five percent error margin, the necessary sample size for each group was calculated as twenty-six subjects using G*Power software. The sample size was increased to 30 participants per group to account for potential dropouts.

In this study, participants were initially selected based on predefined eligibility criteria and subsequently assigned to four groups using a randomized block allocation method: MT (A), CT (B), COBT (C), and control (D). One hundred twenty eligible patients were enrolled, with 30 participants in each group. Thirty blocks of 4 participants were created, and random allocation software was used to assign individuals to the groups.

Inclusion criteria were as follows: provision of informed consent, being conscious, patients aged 18 to 60 years, not taking analgesics before venipuncture, no history of sensory impairments or neuropathic diseases, no hearing problems, previous experience with venipuncture, and having suitable veins for angiocatheter placement. Exclusion criteria included withdrawal from the study and unsuccessful venipuncture attempts.

Data collection

In this study, data collection tools consisted of three parts:

Part 1: A basic demographic questionnaire that included age, gender, education level, length and history of hospitalization, and history of smoking and drug use.

Part 2: The Visual Analogue Scale (VAS) for measuring venipuncture pain. The value of this scale extends from 0 to 10, with 0 signifying the absence of pain and 10 representing the most severe pain. The VAS has been widely used in various studies, with its validity and reliability reported as acceptable [17].

Patients were requested to specify their pain intensity on the scale continuum.

Part 3: The Anxiety Intensity (AI), assessed using the Visual Anxiety Intensity Scale (VAIS).

Similar to the VAS, this scale ranges from 0 to 10, with 0 representing no anxiety and 10 indicating the highest level of anxiety. The VAIS has also been extensively used in research, confirming its validity and reliability as acceptable [18].

Interventions

At the start of the study, patients' P&A levels were measured using the VAS and VAIS scales.

If necessary, the area was shaved, and the surrounding skin was disinfected before angiocatheter placement. A 20-gauge angiocatheter was used for all patients. The interventions were conducted as follows:

A) Cryotherapy Group:

An ice pack, maintained at 0°C, was removed from the freezer one hour before the intervention and placed inside a cloth cover. For 20 minutes before angiocatheter placement, the ice pack was applied to the venipuncture site intermittently every 5 minutes, depending on the patient's tolerance [19].

B) Music Therapy Group:

Patients in this group listened to their preferred music using an MP3 player with headphones [20].

Music was played 5 minutes before venipuncture and continued 10 minutes after the procedure [21].

Based on Nelson's recommendations, the music was instrumental (without lyrics), selected by the patient, and played at approximately 60 decibels with a tempo of 60 to 80 beats per minute to maximize its effectiveness [22].

Patients were asked about their preferred music type before the intervention, and they listened to their selected music during the procedure [23].

C) Combined Intervention Group:

In this group, both MT (5 minutes before venipuncture and continuing for 10 minutes after) and CT (20 minutes before angiocatheter placement, applied intermittently every 5 minutes based on the patient's tolerance) were performed simultaneously [24].

D) Control Group:

No specific intervention was applied, and venipuncture was performed per routine practice.

Patients' P&A levels were reassessed 10 minutes after the intervention using the VAS and VAIS scales in all groups. Angiocatheter placement was performed by the same individual for all participants using standardized techniques.

The primary outcome was a reduction in P&A scores, measured using the VAS and VAIS scales, which indicated treatment effectiveness.

This study employed a double-anonymized design. The principal researcher and team members responsible for data collection and analysis were blinded to group assignments. The statistical specialist received anonymized questionnaires labeled as A, B, C, or D and was unaware of which represented intervention or control groups.

Data analysis

Data analysis was performed utilizing SPSS software, version 24 (SPSS Inc., Chicago, IL, USA). Descriptive statistics, encompassing mean, standard deviation, frequency, and frequency percentage, were utilized to summarize the data. Analytical statistics, including the paired t-test, chi-square test, and analysis of variance (ANOVA), were employed for inferential analysis. A p-value below 0.05 was considered meaningful.

Considerations of Ethics

The initial stages of this study involved obtaining a letter of introduction from the Vice Chancellor for Research of Arak University of Medical Sciences (AUMS), with design number 3403, ethics code IR.ARAKMU.REC.1399.143, and trial registration code IRCT20130731014229N11 from the Iranian Center for Clinical Trials.

Following approval from the AUMS, a sampling permit was acquired from the hospital where the research was conducted. Participants received detailed explanations regarding their voluntary participation in the study, the anonymity of the questionnaires, and their right to withdraw from the study at any time without consequences. Patients were guaranteed that their information would stay confidential. Informed consent was consequently obtained from all subjects in writing [25].

Findings

Follow-up

Of the 153 eligible patients, 30 failed to satisfy the inclusion requirements, and three opted not to participate. All 120 remaining patients were accepted with the study criteria and were added to the final analysis (Figure 1).

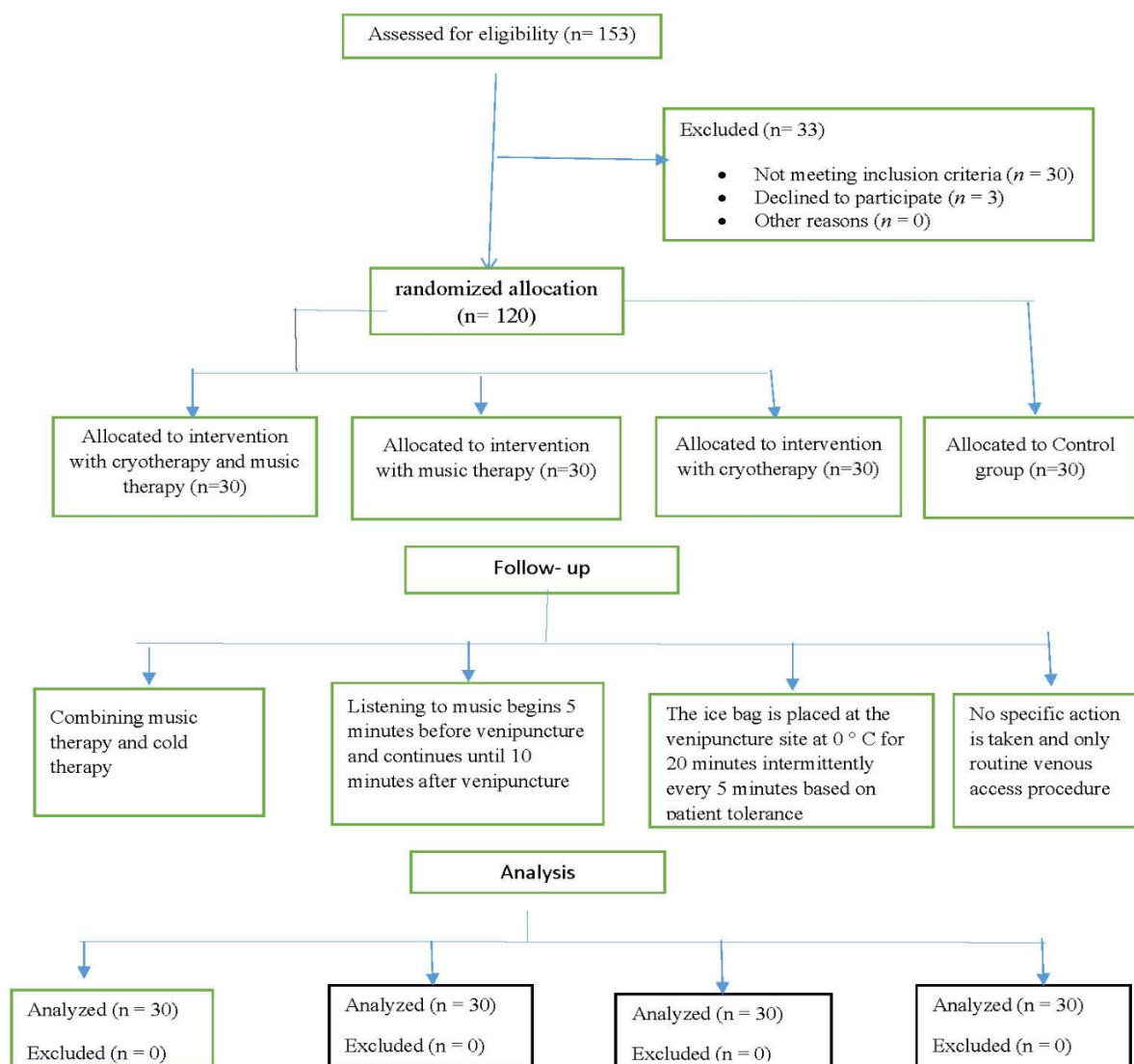


Figure 1. CONSORT Diagram of Patient Recruitment.

Baseline characteristics

The mean ages of patients in the MT, CT, COBT, and control groups were 36.30 ± 14.62 , 43.03 ± 13.89 , 42.23 ± 12.36 , and 40.46 ± 13.12

years, respectively. Additional demographic information is presented in Table 1.

No statistically notable distinctions were seen among the groups for education level, gender, age, length and history of hospitalization, or history of smoking and drug use ($P > 0.05$).

Table 1. Comparison of Demographic Characteristics Among Study Groups¹.

	Study Groups				P-value ²
	Control	music therapy	Cryotherapy	Combination therapy	
Age (y)	40.46 ± 13.12	36.30 ± 14.62	43.03 ± 13.89	42.23 ± 12.36	0.224
Duration of hospitalization (days)	5.06 ± 3.61	4.40 ± 3.39	3.66 ± 2.70	4.10 ± 3.79	0.446
Gender					0.974
Man	25 (83.3)	24 (80)	25 (83.3)	25 (83.3)	0.749
Female	5 (16.7)	6 (20)	5 (16.7)	5 (16.7)	
Level of Education					
illiterate	1 (3.3)	3 (10)	4 (13.3)	3 (10)	0.058
Elementary and middle school	9 (30)	13 (43.3)	11 (36.7)	9 (30)	
High school or diploma	16 (53.3)	9 (30)	12 (40)	12 (40)	
University	4 (13.3)	5 (16.7)	3 (10)	6 (20)	0.255
Hospitalization history					
Yes	14 (46.7)	24 (80)	20 (66.7)	18 (60)	0.582
No	16 (53.3)	6 (20)	10 (33.3)	12 (40)	
Marital status					
single	12 (40)	14 (46.7)	8 (26.7)	8 (26.7)	0.410
Marriage	18 (60)	16 (53.3)	22 (73.3)	22 (73.3)	
History of smoking					
Yes	24 (80)	23 (76.7)	20 (66.7)	24 (80)	0.410
No	6 (20)	7 (23.3)	10 (33.3)	6 (20)	
History of drug use					
Yes	28 (93.3)	28 (93.3)	30 (100)	27 (90)	0.410
No	2 (6.7)	2 (6.7)	0 (0)	3 (10)	

¹Values are expressed as mean \pm SD for continuous and frequency (percentage) for categorical variables

²Obtained by ANOVA for continuous and Chi-square for categorical variables.

The findings of this study (Table 2) demonstrate a statistically substantial disparity in pain severity among the four groups. ($P < 0.001$).

Tukey's multiple comparison tests indicated significant inequality between the control group

and the MT group ($P < 0.001$), CT ($P = 0.004$), and COBT ($P < 0.001$) groups.

In other words, all three interventions significantly reduced pain severity relative to the control group.

Table 2. Comparison of mean scores of pain scale in the study groups¹

	Study Group				P-value ²
	Control	music therapy	Cryotherapy	Combination therapy	
Pain (score)					<0.001
Before	0 \pm 0	0 \pm 0	0 \pm 0	0 \pm 0	
After	4.20 ± 2.23	2.03 ± 1.84	2.43 ± 2.16	1.90 ± 1.66	
P-value ³	-	-	-	-	
Anxiety (score)					0.299
Before	4.76 ± 1.97	5.03 ± 2.35	4.06 ± 1.63	4.56 ± 2.01	
After	4.06 ± 2.04	3.33 ± 1.09	4.16 ± 1.82	3.30 ± 1.17	
P-value ³	0.667	0.001	0.800	0.001	

¹All values are means \pm SD.

²Obtained by ANOVA.

³Obtained by paired t-test.

The mean pain score in the COBT group (1.90 ± 1.66) was lower than in the MT (2.03 ± 1.84) and CT (2.43 ± 2.16) groups.

Nonetheless, no statistically significant difference was observed among the MT, CT, and COBT groups ($P > 0.05$).

Evaluation of pain and anxiety post-intervention

Initially, there was no statistically significant disparity in anxiety levels across the four groups ($P=0.299$). By the end of the trial, a statistically significant disparity in anxiety levels had been identified among the groups ($P<0.001$).

Tukey's post hoc test indicated a statistically significant decrease in anxiety levels in the MT ($P=0.013$) and COBT ($P=0.010$) groups relative to the control group. Nonetheless, no statistically significant difference was seen between the control and CT groups ($P>0.05$).

In conclusion, both MT and COBT significantly reduced anxiety severity relative to the control group.

The mean anxiety score in the COBT group (3.30 ± 1.17) was slightly lower than in the MT group (3.33 ± 1.09); nonetheless, the difference was not statistically meaningful ($P>0.05$).

A statistically significant reduction in VAIS scores was observed before and after the intervention in the MT ($P<0.001$) and COBT ($P=0.001$) groups, indicating that anxiety was significantly reduced after these interventions.

However, no statistically significant change in anxiety severity was observed before and after the research within the CT group ($P>0.05$).

Complications associated with the interventions were carefully monitored, and no adverse effects from MT, CT, or COBT were observed in any of the study groups (Table 2).

Discussion

This study sought to compare and assess the impacts of CT and MT on P&A associated with vascular access procedures, such as venipuncture.

The results demonstrated no statistically significant differences in pain or anxiety severity among the four groups (control, MT, CT, and COBT) before the intervention. This finding indicates that the study groups were well-matched at baseline.

The present study demonstrated that after the intervention, there was a statistically significant difference in pain severity between the MT, CT, and COBT groups compared to the control group. In other words, each intervention significantly reduced pain severity compared to the control.

Although the mean pain score in the COBT group was lower than in the MT and CT groups, the differences were not statistically significant among the three intervention groups.

To determine the effect of CT on pain relief due to angiocatheter implantation, Çetin and Çevik (2019) conducted a study to assess the

impact of vibration and cold gel application on P&A in patients undergoing intravenous catheterization. They reported that the mean pain score of patients in the cold gel intervention group was significantly lower than the control group [26].

Similarly, Wonginchan et al. (2017) examined the effect of alcoholic cold compresses on the pain of preschool children receiving intravenous fluids. They found that the intervention significantly reduced pain compared to the control group [27].

Hosseinzadeh et al. (2019) compared the effects of CT and acupressure on the severity of acupuncture pain in hemodialysis patients. Their results demonstrated that the mean pain score was significantly lower after the CT intervention [28].

Farhadi and Esmailzadeh (2011) also observed that topical CT significantly reduced pain intensity during intramuscular penicillin benzathine injections compared to the control group [29].

Furthermore, Korkut et al. (2020) investigated the effects of topical heat therapy and CT on P&A levels in patients undergoing peripheral venous catheterization. Their findings revealed that pain levels in both the heat and CT groups were significantly lower than in the control group [30].

The findings of these studies align with those of the present study, emphasizing that CT is a practical, minimally invasive, and acceptable method for reducing pain during vascular access procedures in medical-surgical wards. The pain-relieving effects observed in the current study and prior studies can likely be explained by the Gate Control Theory of Pain [31].

CT may stimulate C-fibers in nerves for an extended period, thereby blocking A-delta pain signals. Additionally, CT may activate supraspinal mechanisms, increasing the body's overall pain threshold [32].

Regarding the effects of MT on pain relief during vascular access procedures, Momen Nasab et al. (2020) reported that listening to music significantly reduced pain associated with venipuncture [33].

Similarly, Caprilli et al. (2007) found that music alleviates pain and stress before, during, and after blood sampling [34].

Yarahmadi et al. (2018) demonstrated that CT and COBT (CT and MT) effectively controlled pain severity during chest tube removal [24].

The findings of these studies align with those of the present study, reinforcing that MT is a practical, minimally risky, and acceptable intervention for reducing pain during vascular

access procedures in medical-surgical wards. MT likely reduces pain by creating a distraction that limits the transmission of pain impulses. MT is well-received by patients as one of the most widely accepted non-pharmacological nursing interventions [35].

Listening to music is an affordable, accessible, and non-invasive method with no side effects, making it a safe and effective nursing intervention in hospital settings [36].

Aydin and Sahiner (2016) reported no significant differences in pain reduction during blood sampling among the MT, distraction card, combined intervention, and control groups [37].

Similarly, Aktaş and Karabulut (2019) found no differences in pain scores among the CT, MT, and lidocaine spray groups immediately and 20 minutes after chest tube removal [38].

These findings differ from those of the present study. Differences in sample populations, intervention types, and study designs may explain the discrepancies between their findings and the results of the current study.

The current investigation revealed a statistically significant disparity in anxiety levels between the MT and COBT groups relative to the control group.

Nonetheless, no statistically significant difference was observed between the CT and control groups.

In other words, both MT and COBT markedly decreased anxiety severity in comparison to the control group. Although the mean anxiety score in the COBT group was lower than in the MT group, the difference was not statistically meaningful.

A statistically significant decrease in anxiety levels was noted before and after the treatment in both the MT and COBT groups.

Anxiety levels were significantly reduced following these interventions.

However, no statistically significant change in anxiety severity was found before and after the study in the CT group.

Regarding the effects of CT and MT on reducing anxiety, Aktaş and Karabulut (2019) found that postoperative CT significantly reduced anxiety levels during chest tube removal [38].

Karbandi et al. (2020) reported a significant decrease in anxiety scores in children before and after MT intervention [39].

Similarly, Ikkaya et al. (2014) showed that patient-selected music effectively reduced surgical anxiety and enhanced patient satisfaction [40].

Lin et al. (2011) reported that MT had a more significant effect on reducing anxiety after chemotherapy compared to other interventions [41].

The findings of these studies align with those of the present study, suggesting that MT is an effective intervention for reducing anxiety during intravascular access procedures. Intravascular catheterization often causes pain and discomfort for many patients [42], and pain reduction is a critical responsibility of nurses [43].

Pain associated with venous catheterization is closely linked to anxiety, as these phenomena interact with and exacerbate one another [44].

MT, with its distraction effect, may reduce anxiety by alleviating patients' pain.

Aydin and Sahiner (2016) reported no significant difference between the MT and control groups in reducing anxiety during blood sampling [37].

These findings differ from those of the present study. The discrepancy in results may be attributed to differences in study samples, intervention types, and study designs.

The present study demonstrated that MT, CT, and COBT (MT and CT) effectively manage P&A associated with vascular access procedures. Pain management is a fundamental right of patients and a critical component of the nursing process [45].

Therefore, nurses must understand pain's psychological and physical aspects and implement effective strategies to manage it, ultimately improving patients' quality of life [46].

In conclusion, MT and CT can be effective complementary treatments for reducing P&A in patients undergoing vascular access procedures.

Limitations of the study

Certain mental states, such as fear, may influence the severity of P&A experienced during vascular access procedures.

However, these psychological factors were not measured in this study.

To mitigate their potential impact, random participants were assigned to study groups to balance such variables across groups.

Additionally, the nurse's skill in performing venipuncture can affect pain severity during the procedure.

To minimize this variability, all venipunctures were performed by the same nurse throughout the study to ensure consistency.

Conclusion

The present study demonstrated that MT, CT, and their combination significantly reduced pain severity compared to the control group.

While the mean pain score in the COBT group was lower than in the MT and CT groups, the differences among the three intervention groups were not statistically significant.

In terms of anxiety severity, the study revealed a substantial decrease in anxiety severity in the MT and COBT groups relative to the control group.

In contrast, no notable difference was identified between the CT and control groups.

These findings have critical applications in medical and nursing practice.

MT and CT are safe, effective, and non-invasive methods that can be used to manage P&A during vascular access procedures.

Incorporating these interventions into routine medical-surgical care can enhance patient outcomes by addressing physical and psychological distress.

Nurses and healthcare providers can leverage MT to create a calming environment and provide holistic care for patients experiencing anxiety.

CT, with its minimal risks, is an accessible option for reducing procedure-related pain.

Both therapies are affordable, easy to implement, and well-received by patients, making them suitable for widespread use in medical and nursing settings.

Training healthcare professionals to apply these complementary therapies can improve their effectiveness and ensure consistent patient care.

Key Practice Points

Routine painful procedures in the medical-surgical Unit have short and long-term side effects on the patient.

Cryotherapy, music therapy, and combination (cryotherapy and music therapy) have a positive effect on pain relief of venipuncture.

Music therapy and combination (cryotherapy and music therapy) have a positive effect in reducing the anxiety of patients undergoing venipuncture.

There is a need to study and establish protocols for relieving pain and anxiety in patients who need vascular access.

Funding

This research was financially supported by the Research Council of Arak University of Medical Sciences under researcher plan code 2811.

Acknowledgments

The participants are also highly appreciated for giving their precious time to participate in this study.

Conflict of interest

None to declare.

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Corresponding Author: Hadi Jafarimanesh, Ph.D. student, Medical Surgical Department, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran; e-mail: nures_science@yahoo.com, h-jafarimanesh@razi.tums.ac.ir