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Response of Arteriovenous Fistula Puncture-Related Pain to Different Cryotherapy Applications in Hemodialysis Patients: a Randomized Controlled Study

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ABSTRACT

INTRODUCTION. Patients receiving continuous hemodialysis commonly experience pain associated with arteriovenous fistula puncture. Relieving the pain may increase their appreciation of the procedure and hence their quality of life.

AIM. To find out how different ways of applying cryotherapy changed the pain of arteriovenous fistula punctures in hemodialysis patients.

MATERIALS AND METHODS. During the seven weeks of this randomized controlled study, ninety hemodialysis patients of both sexes with end-stage renal disease who had received medical treatment were allocated to one of three groups at random: ipsilateral (received cryotherapy at the site of needle insertion), contralateral (received cryotherapy at the site opposite to the needle insertion), or control (followed medical treatment without cryotherapy application). Cryotherapy was applied for five to ten minutes, three times a week. Prior to and following the seven-week intervention period, assessments of upper limb function (by Arm Motor Ability Test), pain severity (by Visual Analogue Scale), beside anxiety and depression (by Hospital Anxiety and Depression Scale) were carried out.

RESULTS AND DISCUSSION. The final results showed that all evaluated outcomes improved after the intervention, with no statistically significant difference between the ipsilateral and contralateral groups ($p \geq 0.05$). Yet, when comparing the contralateral or ipsilateral groups to the control group, all parameters had statistically significant differences ($p < 0.05$).

CONCLUSION. For hemodialysis patients, cryotherapy is one of the best ways to manage pain from arteriovenous fistula punctures, upper limb dysfunction, depression, and anxiety.

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KEYWORDS: anxiety, arteriovenous fistula, cryotherapy, pain measurement, renal dialysis

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Реакция боли, связанной с пункцией артериовенозной фистулы, на различные методы криотерапии у пациентов, находящихся на гемодиализе: рандомизированное контролируемое исследование

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РЕЗЮМЕ

ВВЕДЕНИЕ. Пациенты, получающие непрерывный гемодиализ, часто испытывают боль, связанную с пункцией артериовенозной фистулы. Облегчение боли может повысить их восприятие процедуры и, следовательно, качество жизни.

ЦЕЛЬ. Выяснить, как различные способы применения криотерапии изменяют боль при пункции артериовенозной фистулы у пациентов, находящихся на гемодиализе.

МАТЕРИАЛЫ И МЕТОДЫ. В течение 7 недель этого рандомизированного контролируемого исследования 90 гемодиализных пациентов обоих полов с болезнью почек в конечной стадии, получавших медикаментозное лечение, были случайным образом распределены в одну из 3 групп: ипсилатеральную (получали криотерапию в месте введения иглы), контралатеральную (получали криотерапию в месте, противоположном месту введения иглы) или контрольную (проходили медикаментозное лечение без применения криотерапии). Криотерапия проводилась в течение 5–10 минут 3 раза в неделю. До и после семинедельного периода вмешательства проводилась оценка функции верхней конечности (по тесту двигательной способности руки), выраженности боли (по визуально-аналоговой шкале), а также тревоги и депрессии (по госпитальной шкале тревоги и депрессии).

РЕЗУЛЬТАТЫ И ОБСУЖДЕНИЕ. Окончательные результаты показали, что все оцениваемые показатели улучшились после вмешательства, при этом статистически значимой разницы между ипсилатеральной и контралатеральной группами не было ($p \geq 0,05$). Однако при сравнении контралатеральной и ипсилатеральной групп с контрольной группой все параметры имели статистически значимые различия ($p < 0,05$).

ЗАКЛЮЧЕНИЕ. Для пациентов, находящихся на гемодиализе, криотерапия является одним из лучших способов купирования боли при проколах артериовенозных фистул, дисфункции верхних конечностей, депрессии и тревожности.

РЕГИСТРАЦИЯ: Идентификатор Clinicaltrials.gov № NCT06520631, зарегистрировано 04.08.2024.

КЛЮЧЕВЫЕ СЛОВА: тревога, артериовенозная фистула, криотерапия, измерение боли, почечный диализ

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INTRODUCTION

End-stage renal disease (ESRD), which is defined by an irreversible decrease of renal function, is a growing global public health concern [1]. Regular hemodialysis (HD) is necessary for about 90 % of ESRD patients to maintain their survival as renal replacement treatment [2].

For many HD patients, inserting needles into a major blood vessel is a painful and mandatory procedure. Because of the frequent punctures, HD patients are anxious before the needle is inserted, and more than 90 % of them suffer from acute pain [3]. Patients experience needle-related tension and distress about 320 times a year, considering that hemodialysis typically occurs three times a week and lasts three to four hours each time [4].

Therefore, one of the most crucial elements of patient management is to mitigate this pain and suffering properly. Desensitization treatment and other psychologist-delivered interventions are necessary for needle phobia, which is marked by extreme physiological reactions, including withdrawal reactions and vasovagal syncope. Additionally, it causes anxiety, lowers patients' quality of life and psychological burdens such as depression, and makes managing dialysis more difficult [5].

The arms and hands must function properly to perform tasks essential for daily activities. Patients with chronic renal failure (CRF) receiving HD may experience significant loss of upper extremity function, which impairs their independence and quality of life [6].

Since cryotherapy slows down the rate at which nerves conduct electricity, it is among the approaches used in many studies to relieve pain and raising the pain threshold [7]. With fewer constraints and greater efficiency, cryotherapy may be suggested as a solution for arteriovenous fistula (AVF) puncture pain [8].

Many studies have demonstrated the beneficial effects of ice packs in relieve AVF associated pain in HD patients; however, studies' findings varied in terms of pain intensity [9]. Furthermore, no prior research has compared

the impact of applying cryotherapy at the same and opposite sites of AVF insertion on the patients' arm mobility and psychological state along with their capacity to lessen the discomfort brought on by the puncture.

AIM

To ascertain the effects of different cryotherapy application procedures (ipsilateral or contralateral to the insertion site) on hemodialysis patients' anxiety and depression, arm function, and AVF puncture pain.

To find out how different ways of applying cryotherapy changed the pain of arteriovenous fistula punctures in hemodialysis patients.

MATERIALS AND METHODS

Study design

The study was registered at ClinicalTrials.gov (NCT 06520631) and authorized by the institutional Physical Therapy Faculty ethics committee (P.T.REC/012/005168). It was carried out using a prospective randomized trial design between 04.05.2024, and 24.08.2024, and each participant provided written consent that complied with the Declaration of Helsinki. The computations were performed using G* Power version 3.1.9.2 (Franz Faul, Uni Kiel, Germany). The repeated measure F-test (MANOVA) between factors with a power of 80 % and a type I error of 5 % was used to get the sample size. G* Power 3.1.9.2 was employed to determine the effect size (0.26) from the primary outcome (VAS) based on data from the pilot study, five patients within each group. The minimum sample size was 75, and to take into consideration for dropouts, the number was raised by 20 %.

Participants

To be eligible for the study, patients had to be aged between 30 and 50, have end-stage kidney failure, be able to report pain adequately, have received regular haemodialysis (HD) for at least three months, undergo treatment at least twice a week and have had an arteriovenous fistula in use for at least 12 months. Patients with any of the following conditions were excluded: advanced age, severe diabetes, heart failure, cold allergies, Raynaud's phenomenon, fractures, heart failure, nerve and tissue damage, unwillingness to cooperate, diabetic neuropathy, and cognitive impairment that might interfere with an accurate assessment of pain.

Randomization

Randomization was used to allocate participants evenly between the experimental or control groups. The participants and research team members (except for the physiotherapists who participated in the intervention) were unaware of the assignment in a masked centrally randomized technique with allocation concealment, which was carried out by a statistician who was not a member of the research team. The randomization sequence was built using R Software (version 2.11) and separated into groups based on body mass index (BMI), age (30–50 years), and gender. Block sizes were set at random from four to eight to ensure a fair number of participants in each group.

Outcome variables and measurements

To compare between groups, measurements were made both before and after the 7-week intervention. To minimize experimental biases, an independent evaluator who was blind to the patient's assignment conducted the measurements. At baseline, information was collected on age, gender, height, weight, BMI, and years of HD.

Visual analog scale

The severity of the pain was measured with the Visual Analog Scale (VAS), a numerical rating system for evaluating pain and health conditions. The VAS administration process was easy to comprehend, time-efficient, and less expensive. It is a straight line, with the worst suffering conceivable at one end and no pain at the other. The following terms were used to categorize VAS (0–10): no pain (0), mild pain (1–3), moderate pain (4–6), severe pain (7–9), or worse pain (10). The patient indicates the level of pain by marking a point on the line [10].

Arm Motor Ability Test

The functional limitation of the upper extremities (UE) was measured using the Arm Motor Ability Test (AMAT). The patients completed 13 conventional unilateral and bilateral tasks, each of the tasks being timed and scored using two 6-point ordinal scales: the Quality of Movement scale, which measures how the task is executed, and the Functional Capacity scale, which measures the capacity to accomplish the activity. The patient is permitted to do the subtasks continuously and fluidly even if they are timed separately [11]. Typically, each task has a time constraint of one to two minutes. Each component is scored on a 6-point Likert scale from 0 (no hand use) to 5 (normal hand use). The Functional Ability: 0 — no use, 1 — very slight use, 2 — slight use, 3 — moderate use, 4 — almost normal use, 5 — normal use, and the Quality of Movement: 0 — no use, 1 — very poor, 2 — poor, 3 — fair, 4 — almost normal, 5 — normal. Activity limits decrease with a lower score and increase with a higher score [12].

Hospital Anxiety and Depression Scale

It is a valid, reliable, and intuitive practical tool for detecting and measuring anxiety and depression is the Hospital Anxiety and Depression Scale (HADS). With a 4-point Likert scale (range 0–3), it has 14 items. With seven items for each subscale, it is intended to assess depression and anxiety. The sum of the 14 items determines the overall score, and the sum of the seven items for each subscale (which range from 0 to 21) determines the score for each subscale [13]. Scores ≥ 7 indicate "no depression or anxiety," 8–10 indicate slight depression or anxiety, 11–15 indicate moderate depression or anxiety, and ≥ 16 indicate severe depression or anxiety [14].

Intervention

Prior to the needle puncture used to start the dialysis, ice packs were applied to both the ipsilateral (received ice application at the site of needle insertion) and contralateral (received ice application at the site opposite to the needle insertion) groups. For seven weeks, ice was applied for five to ten minutes, three times a week.

For the ipsilateral group, the application was carried out as follows: the patients were either high supine or long sitting, and they were told to expose their arms at the AVF puncture site. Disposable plastic sheets were then placed directly on the puncture site. Following the ice

application, alcohol and Sterillium were used to disinfect the ice packs. The contralateral group's arm opposite the puncture site was covered with disposable plastic sheets. Ice packs were placed on the area opposite from the puncture site to provide a cold application [15]. As shown in Figure 1 (A, B).

Statistical analysis

The normality of the data and the group homogeneity were confirmed using Shapiro — Wilk and Levene's tests for variance homogeneity. The data were normally distributed, with homogeneous variance. When matching groups using all available demographic information, one-way ANOVAs were utilized. The effects of therapy on VAS, HADS, and AMAT were studied with mixed MANOVA. When the MANOVA yielded significant findings, more univariate ANOVAs were run. For multiple comparisons, post-hoc testing with the Bonferroni correction was employed. The significance level for all statistical tests was set at $p = 0.05$. SPSS 23 was used.

RESULTS AND DISCUSSION

Ninety patients of both sexes with end-stage renal disease receiving routine HD participated in this study. The patients were chosen from Al-Kasr Al-Ainy's HD unit. They were divided into three groups at random: a contralateral group (who received cryotherapy at a location opposite the needle insertion site); and an ipsilateral group (who received cryotherapy at the needle insertion site) (Fig. 2).

Demographic Characteristics

The patients' characteristics for the three groups are displayed in Table 1. Regarding the general characteristics of the patients, there were no statistically significant differences between the two groups ($p \geq 0.05$).

Table 1. Demographic characteristics of participants ($n = 90$)*

	Ipsilateral group	Contralateral group	Control group	*p*
	± SD	± SD	± SD	
Age (years)	41.83 ± 7.41	42.77 ± 6.16	43.1 ± 6.83	0.76
Weight (kg)	73.8 ± 8.9	73.13 ± 7.6	71 ± 10.3	0.81
Height (cm)	162.4 ± 14.6	164.83 ± 9.11	164.07 ± 11.7	0.73
BMI (kg/m^2)	28.31 ± 5.73	26.84 ± 4.96	25.9 ± 6.12	0.25
HD (years)	2.3 ± 0.69	2.3 ± 0.69	2.67 ± 0.88	0.19
Gender, n (%)				
Male	17 (56.67 %)	16 (53.33 %)	18(60 %)	0.87
Female	13 (43.33 %)	14 (46.67 %)	12(40 %)	$X^2 = 0.27$

Note: *BMI — body mass index; X^2 — Chi Square; MD — mean difference; HD — hemodialysis duration. Data are mean ± SD for all demographics except gender (%); $p < 0.05$ indicate statistical significance.*

A B

Fig. 1. A — ipsilateral application of cryotherapy, B — contralateral application of cryotherapy

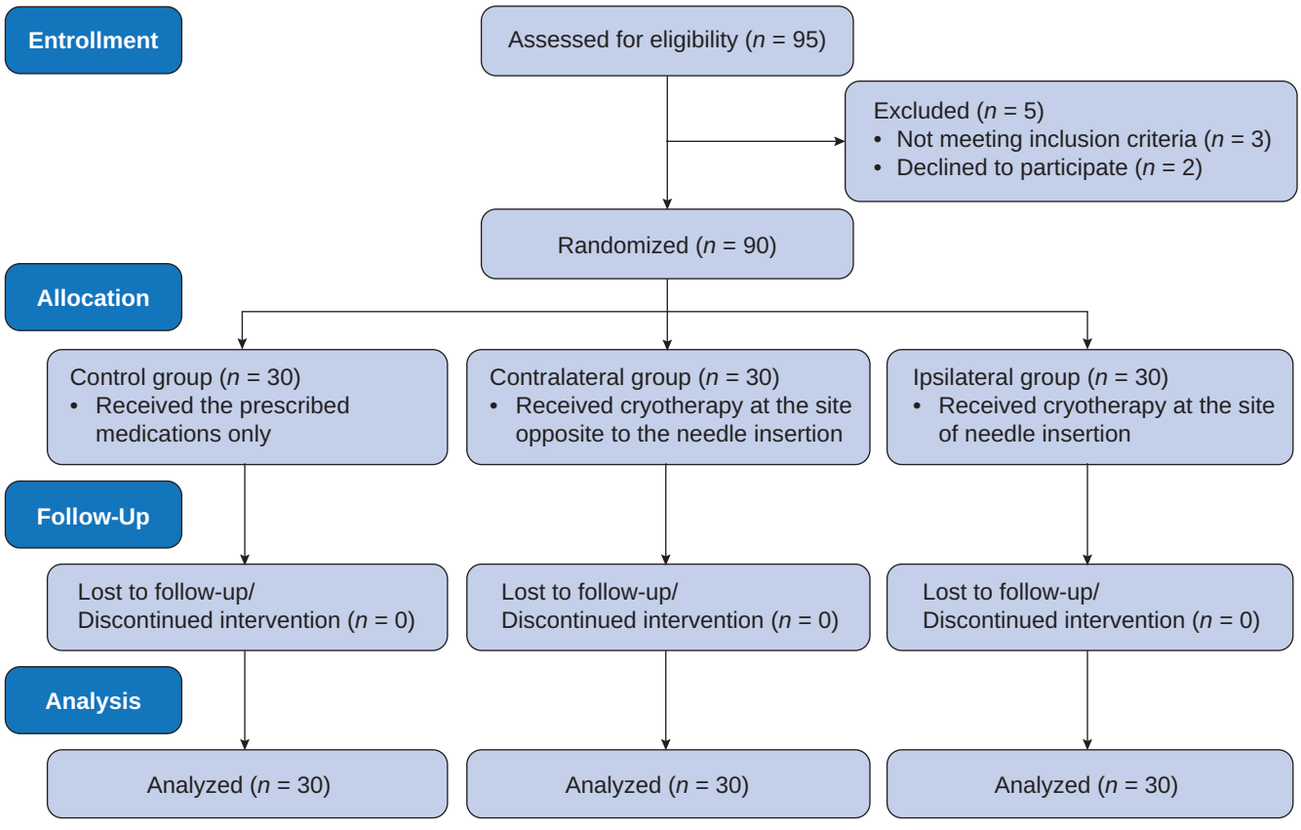

Fig. 2. Study flowchart

Between-groups comparison: Baseline and after twenty sessions of intervention

A mixed design multivariate analysis was used to determine the effect of therapy on the measured variables. Wilk's A = 0.2, F (8, 168) = 25.77, $p < 0.001$, Partial Eta Squared (η^2) = 0.55 indicated a statistically significant difference between groups. Also, there was a statistically significant effect on time (pre-post treatment) as Wilk's A = 0.05, F (4, 84) = 436.62, $p < 0.001$, $\eta^2 = 0.95$, and for the interaction between groups and time, Wilk's A = 0.1, F (8, 168) = 46.76, $p < 0.001$, $\eta^2 = 0.69$.

Table 2 shows that there were no significant differences between the three groups in all assessed variables at baseline ($p \geq 0.05$). After 20 sessions of intervention, there were no statistically significant differences between the ipsilateral and contralateral groups. However, there were statistically significant differences between the ipsilateral and control groups, as well as between the contralateral and control groups ($p < 0.05$), as shown in Tables 2–3.

Within-groups comparison

Comparing the pre- and post-intervention results in ipsilateral and contralateral groups revealed statistically significant differences in all outcome measures ($p < 0.05$), but there was no statistically significant difference in the control group, as shown in Table 2.

Pain management is crucial for hemodialysis patients because of the detrimental consequences that arteriovenous fistula puncture-related pain has on their physical and emotional well-being [16]. In this context, researchers have employed non-pharmacological techniques like acupuncture, lavender aromatherapy, EMLA anesthetic cream, and self-selected calming music to lessen the pain associated with arteriovenous fistula punctures. The findings of their studies demonstrated the beneficial effects of the aforementioned techniques on lowering the degree of pain. In addition, cryotherapy, either ipsilateral or contralateral, has been utilized in multiple trials to alleviate discomfort associated with fistula punctures [7]. Several studies found that cryotherapy had a favorable impact on lowering fistula puncture-related pain. The changes in pain intensity between the experimental and control groups after cryotherapy were varied in the studies [7]. So, the current study compares the effect of cryotherapy ipsilateral against contralateral and determines which is more effective and produces the best outcomes.

Following 20 sessions of ipsilateral and contralateral cryotherapy, the study demonstrated a statistically significant decrease in pain intensity as measured by VAS ($p < 0.001$), with no statistically significant changes between the two groups. This is in line with the findings of Sabitha P.B. et al., who found that AV fistula puncture pain levels decreased from an average of 3.8 on day 1 (when the patient received standard care) to 0.7 on day 2 (when contralateral cryotherapy was administered). This was a significant decrease ($p = 0.001$) [17]. Yan L.J. et al. also discovered that patients treated with ipsilateral cryotherapy needed less analgesia (26.19 % vs. 48.84 %, $p < 0.05$) and had a lower VAS pain score from 30 to 48 hours after surgery ($p < 0.05$) [18].

The gate control research given by Melzack R. best explains the mechanics involved in pain reduction by cryotherapy [19]. Evidence suggests that cold signals are conveyed to the spinal cord solely via A-delta fibers rather than C fibers, which might give a mechanism for distinguishing between the many feedback systems that underlie analgesia [20]. Cryotherapy decreases nerve sensitivity to alleviate pain by decreasing the conduction velocity of the nerve impulse transmission [21].

Table 2. Within and between group analysis for VAS, HADS and AMAT (*n* = 90)

η^2	*p* (between groups)	Control group	Contralateral group	Ipsilateral group	Variables
VAS (cm)					
	0.28	3.57 ± 0.96	3.9 ± 0.61	3.83 ± 0.75	**Pre-treatment**
0.72	0.001	3.37 ± 0.67	1.47 ± 0.51	1.5 ± 0.51	**Post-treatment**
		0.17	< 0.001	< 0.001	***p* (within-group)**
HADS (depression domain) (score)					
	0.55	12.87 ± 1.85	12.27 ± 2.5	12.37 ± 2.43	**Pre-treatment**
0.77	0.001	12.67 ± 1.86	6.73 ± 1.14	6.2 ± 1.85	**Post-treatment**
		0.62	< 0.001	< 0.001	***p* (within-group)**
HADS (anxiety domain) (score)					
	0.08	14.47 ± 3.55	13.07 ± 1.62	13.8 ± 1.16	**Pre-treatment**
0.73	0.001	14.1 ± 3.8	5.57 ± 0.73	6.87 ± 1.28	**Post-treatment**
		0.21	< 0.001	< 0.001	***p* (within-group)**
AMAT (score)					
	0.17	33.73 ± 2.96	35.7 ± 4.96	34.73 ± 3.88	**Pre-treatment**
0.6	0.001	33.93 ± 2.88	52.53 ± 7.85	51.8 ± 6.68	**Post-treatment**
		0.89	< 0.001	< 0.001	***p* (within-group)**

Note: *n — number; MD — mean difference; CI — confidence interval; p — probability value; Data are mean ± SD; p ≤ 0.05 indicate statistical significance difference; VAS — visual analogue scale; cm — centimeter; HADS — hospital anxiety and depression scale; AMAT — arm mobility ability test.*

Table 3. Between group analysis of all outcome variables (*n* = 90)

Outcome	Ipsilateral group versus contralateral group		Ipsilateral group versus control group		Contralateral group versus control group	
	MD (95% CI)	*p*	MD (95% CI),	*p*	MD (95% CI)	*p*
VAS (cm)						
	0.03 (–0.32, 0.39)	0.99	–1.87 (–2.22, –1.5)	< 0.001	–1.9 (–2.26–1.54)	< 0.001
HADS (depression domain) (score)						
	–0.53 (–1.57,0.51)	0.64	–6.47 (–7.51, -5.43)	< 0.001	–5.93 (–6.97, -4.89)	< 0.001
HADS (anxiety domain) (score)						
	1.3 (–0.18, 2.78)	0.1	–7.23 (–8.71, –5.75)	< 0.001	–8.53 (–10.01, –7.05)	< 0.001
AMAT (score)						
	–0.73 (–5.27, 3.81)	0.98	17.87 (13.28, 22.41)	< 0.001	18.6 (14.06, 23.14)	< 0.001

Note: *n — number; MD — mean difference; CI — confidence interval; p — probability value; VAS — visual analogue scale; cm — centimeter; HADS — hospital anxiety and depression scale; AMAT — arm mobility ability test. Data are mean ± SD; p ≤ 0.05 indicate statistical significance difference.*

Furthermore, the signal for cold travels quicker than the signal for pain in nerve fibers, so the cold is felt more intensely than the pain, indirectly raising the pain threshold [20]. Cold treatment may relieve pain through a variety of processes, including nociceptor suppression, muscular spasm reduction, and/or decreased metabolic enzyme activity levels [22]. Furthermore, it slows blood flow and cellular metabolism in the damaged region, minimizes inflammation, improves muscular relaxation, and enhances the pain threshold [18].

The study found that both cryotherapy procedures significantly reduced anxiety and depression, as measured

by HADS ($p < 0.001$). This conclusion aligns with the findings of Abdrabouh M.A. et al. [23], who discovered a substantial change in overall mean anxiety score among older patients before and after cryotherapy ($p < 0.001$). Before the intervention, the overall mean anxiety score was 35.78 + 6.32, which fell to 23.78 + 5.06 during the post-intervention period. Also, Lu H.Y. et al. discovered that cold treatment administered for both periods (less than 15 minutes and up to 20 minutes) effectively reduced post-chest tube removal anxiety and pain [24].

In contrast, Sajedi-Monfared's Z. study discovered that breathing relaxation techniques and cold treatment were ineffective in reducing the pain and anxiety associated with chest tube removal [25]. The variation in the sample population and length of intervention might explain the disparity with the previously reported study.

Pain can trigger feelings of depression and anxiety, which might worsen the patient's vulnerability to the pain. So it appears that lowering pain reduces negative psychological feelings [25]. Pain, sadness, and anxiety are all tightly related and have a role in the development of long-term disorders; therefore, physicians should address them as soon as feasible. Furthermore, these symptoms should be evaluated and treated during treatment to maximize outcomes [26]. Because of the limited results of pharmaceutical therapy Cryotherapy could be a useful tool for treating pain and depression [27]. Benefits of cold therapy for mental health include improved emotions of well-being and life satisfaction as well as a reduction in anxiety and depression symptoms [28].

Our study found that ipsilateral and contralateral cryotherapy had a significant positive effect on arm mobility as measured by AMAT ($p < 0.001$). This is consistent with Feys P. et al. findings that whole arm cooling for 15 minutes using multiple cold packs for tremors in MS patients resulted in a clinically noticeable effect on tremor severity and improved functional performance [29]. Cryotherapy has been utilized and analyzed to help athletes restore functional qualities, including strength, elasticity, and neuromuscular control [30]. Furthermore, Durairaj S. et al. discovered that using cryotherapy (ice massage) in conjunction with task-oriented training for three sessions per week for two months reduced spasticity and improved tactile registration function, resulting in upper limb function improvement in hemiplegic cerebral palsy children [31]. Following cryotherapy, the mechanoreceptor, muscle spindle, and Golgi tendon organ received sufficient input to the higher center neural system, resulting in a sufficient muscle response during motor action in healthy subjects. Additionally, the motor neuron pool was facilitated to achieve controlled muscle action, which may account for the improvement in upper limb function [32].

Limitations

Our research, however, has certain drawbacks: 1) It is a limited sample size research, and the findings should be validated by larger, multicenter investigations. 2) Furthermore, although individuals with diabetic neuropathy were excluded from the research, subjective measurements such as degree of pain and level of satisfaction are susceptible to possible bias.

Strength of study

This is the first randomized trial to illustrate the efficacy of cryotherapy via two distinct applications, both of which had a similar substantial effect on HD patients. It also demonstrated the psychological and functional effects of the intervention.

Future recommendations

Management of arteriovenous fistula puncture-related pain alleviates stress, increases satisfaction, and reduces negative psychological effects [33]. As a result, adverse effects from medications are more likely to occur. As a consequence, it is critical to develop suitable treatment strategies to increase patients' comfort and reduce pain through non-pharmacological means. Cryotherapy was investigated and shown to be useful in pain reduction. In recent years, the type and technique of cryotherapy have not been standardized among clinical institutions. It would be useful to promote the study protocols as a standard protocol for the practical application of cryotherapy. Further future research focusing on non-pharmacologic pain alleviation strategies should be pushed to encourage such intervention, which will be extremely beneficial to patients with renal failure. Cryotherapy should be used in standard hemodialysis patient treatment to manage needle puncture discomfort.

CONCLUSION

Given the good effect of cryotherapy on lowering fistula puncture-related pain, cryotherapy as a low-risk and simple approach appears to be helpful and useful in reducing pain and hence the unpleasant psychological and physical repercussions of pain. Consequently, it can be concluded that cryotherapy is a superior option due to its lower cost, convenience, and fewer adverse effects.

ADDITIONAL INFORMATION

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editing; Hamed N. — data curation, writing — original draft, visualization, investigation; El-Khashab S.O. — formal analysis; El-Moatasem A.M. — conceptualization, methodology, software, validation, formal analysis, investigation, resources, data curation, writing — original draft, writing — review & editing.

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