Remittances Review
May, 2023
Volume: 8, No: 4, pp. 1809-1821
ISSN: 2059-6588 (Print) | ISSN 2059-6596 (Online)
remittancesreview.com

Received: 11 November 2022 Accepted: 28 March, 2023
DOI: https://doi.org/10.33182/rr.v8i4.125

Efficacy of Cryotherapy in Reducing Pain Related to Arteriovenous Fistula Puncture in Hemodialysis Patients: A Randomized Controlled Trial

Rafal Dyaa Neamah[1], Diaah K. Abd Ali[2]

Abstract

Background: *Pain is a major dilemma for patients undergoing hemodialysis due to the arteriovenous fistula puncture procedure. Pain associated with this procedure can have a significant impact on a patient's quality of life, both physical and mental. It is important to understand the philosophy of pain understand, the underlying causes of pain related to fistula puncture, and to find appropriate solutions for managing pain.* ***Study Objective:*** *Determination of the efficacy of cryotherapy in relieving pain related to arteriovenous fistula puncture using the Rating Analogues and comparison groups participants.* ***Methods and Results:*** *This paper presents the findings of a randomized controlled trial examining the efficacy of cryotherapy in reducing pain related to arteriovenous fistula puncture in hemodialysis patients. Non-probability (homogenous purposive sample) of 80 participants was split into two groups of 40; the experimental group was treated with cryotherapy, while the comparison group was not. The effectiveness of cryotherapy was measured using the RAS pain intensity scale and the results were compared to the comparison group. The results confirmed that cryotherapy was successful in reducing pain from severe and moderate intensity to mild pain, with a statistically significant p-value of 0.0001.* ***Conclusion and Recommendations:*** *These findings suggest that cryotherapy could be a viable option for reducing the pain of arteriovenous fistula puncture for hemodialysis patients and should be further explored. This research has implications for the clinical application of cryotherapy in pain management and the development of evidence-based nursing practice..*

Keywords: *Attitudes , Adult community , COVID-19 Vaccination.*

Introduction

Chronic kidney disease (CKD) is a progressive condition that affects the kidneys over time, leading to a gradual loss of renal function 1 It is characterized by a decrease in the glomerular filtration rate (GFR), or the rate at which the kidneys filter blood. As CKD progresses, the kidneys are unable to filter waste and excess fluid from the body, resulting in a variety of symptoms including fatigue, swelling, and changes in urination. Over time, CKD can lead to end-stage renal disease (ESRD), which requires dialysis or kidney transplantation , 75% of patients with kidney failure prefer dialysis over kidney transplantation even though it is the best choice for treatment rather than dialysis due

[1] MSc, College of Nursing, University of Kufa, Najaf, Iraq, e-mail: rafaldheyaa290@gmail.com
[2] Assist. Prof, University of Al-Ameed, college of Nursing, Karbala, Iraq; University of Kufa, college of Nursing, Najaf, Iraq

to several reasons: absence of a kidney donor, inappropriateness of kidney transplantation, or unexpected diagnosis of kidney failure Risk factors for CKD include diabetes, hypertension 2 and genetic diseases. Early detection and treatment of CKD can help to reduce its progression and delay the onset of ESRD 3, 4 , 5.

There are two options of dialysis , hemodialysis and peritoneal dialysis 5 Hemodialysis is the most common type of dialysis used for people with ESRD. In hemodialysis, blood is removed from the body, filtered through a dialyzer 6 and then returned to the body. The dialyzer contains semi-permeable membranes that allow for the removal of waste products and excess fluid. Hemodialysis is typically performed s times per week, and can be done in a hospital or at an outpatient center. The process typically takes two to four hours and is performed using a special machine called a hemodialyzer.

During the procedure, blood is removed from the body, circulated through the dialyzer, and then returned to the body. The dialyzer removes waste and excess fluid, which is then discarded. Hemodialysis helps to replace kidney function, reduce symptoms, and improve quality of life for people with ESRD 7 , 8 .

Unfortunately, Venipuncture is considered one of the most painful procedure for a hemodialysis patients , which he exposed frequently weekly throughout life as long undergoing hemodialysis treatment 9. Puncture by needle is the most frequent cause of pain for 47 % of hemodialysis patients, Because of the length and diameter which approximately 15 – 16 gauge of the fistula's needle tip10 , 11 , 12

Pain associated to arteriovenous fistula puncture is a clinical issue that has long caused controversy over its treatment in many clinical settings and unaddressed 13, 14 which in turn will affect the nature of patients' acceptance to dialysis and thus the continuation of treatment, so controlling pain during the dialysis process is very important and a great priority in order to keep the dialysis level and the patient in high comfort and reduce complications of hemodialysis 15 Effective drugs are used to reduce pain, such as the use of lidocaine in several types as a (pharmacological way)

whether it is a topical cream, a spray, or even an injection of 2% intradermal, but such drugs are costing , Moreover, it is difficult to apply such interventions for a long time to the patient's skin due to the number of negative side effects on it 11, 14

Cryotherapy is a form of medical treatment (non-pharmacological techniques) that involves exposing the body to extremely cold temperatures in order to reduce inflammation and pain , The theory behind cryotherapy in reducing pain is that cold temperatures can reduce the activity of the nerve fibers responsible for sending pain signals. The theory is that by reducing inflammation and the transmission of pain signals, cryotherapy can provide relief from pain 16, 17

This study aims to try a new technique in the field of pain reduction for hemodialysis patients with AVF puncture , describe as cryotherapy, and to know whether this technique is useful for such

patients or not, knowing that this study is the first of its kind in the application of cryotherapy in Iraq to reduce pain for many patients who suffer from it. This study can fill a scientific gap in nursing research in Iraq and be of importance in its field.

Research Question:

Are the patients who are undergoing hemodialysis who attend cryotherapy treatment exhibit low pain intensity related AVF puncture compare with those patients who are not attend ?

Research Hypothesis H1 :

The patients who are attend cryotherapy treatment exhibit low pain intensity compare with those patients who are not attend

Methods and Materials

- **Design of the Study:** a Randomised Control Trail (RCT) is used to investigate the efficacy of cryotherapy in reducing pain related to arteriovenous fistula puncture in patients undergoing hemodialysis .
- **Ethical consideration:** Prior to conducting the research, the National Research Ethics Committee's standards were observed and approval was obtained from the relevant government entity to ensure ethical considerations. Patients were initially hesitant to sign any forms, but after the researcher clarified the purpose of the study, informed the patients of their right to voluntarily participate and gave them the option to withdraw at any time, written informed consent was obtained.
- **The Setting of the Study:** The study is performed in Al-Najaf Al-Ashraf Government , Al-Najaf Al-Ashraf Health Directorate , Al-Sadder Medical City, The specialized Center for Kidney Diseases and Transplantation in hemodialysis Unit .
- **Study Sample and sampling technique:** The study included a non probability (homogenous purposive sample) selection of patients diagnosed with end stage kidney disease under hemodialysis who had AVF puncture, they were randomly assigned into two groups, experimental group and comparison group.

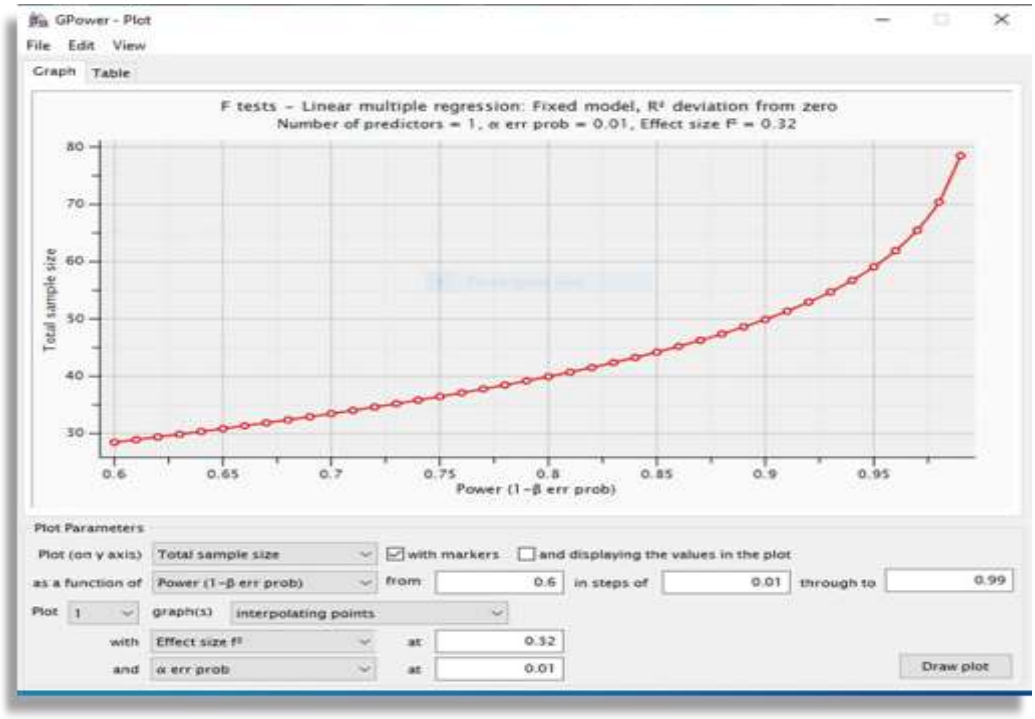
I. Inclusion criteria of study sample:

1. All adult patients males and females who agreed to participate in the study .
2. Patients aged 18 years old and above .
3. Patient's diagnosed with end stage kidney disease undergo hemodialysis with AVF puncture .
4. Conscious patients to availability of communicate and determine the score of pain precisely.

II. Exclusion criteria of study sample :

1. Patients with arteriovenous graft and central venous catheter.
2. Patients with emergency hemodialysis because there is not enough time to apply cryotherapy .
3. Paediatric patients and children.
4. Patients with psychiatric disorders.

- **Sample Size and Power Analysis:** Power is the probability of detecting an effect when it exists; level of significance is the probability of rejecting the null hypothesis when it is true (α=0.05); effect size is a measure of the magnitude of a relationship/difference (Grove et al., 2013). Power analysis was conducted to determine sample size using G*Power (power=95%, significance level=0.05, size effect=0.32, resulting in 60 participants). Increasing power to 99% and significance level to 0.01 increased sample size to 80 participants. As shown in photo below:



- **Groups Assignment (Randomization) :**

The sample contains 80 participants who were randomly divided into two groups, an experimental group (40 participants) and a comparison group (40 participants). The researcher used the random block method (lottery method) to divide the participants into those two groups. Then the

researcher pulled out a scrap and put it in the experimental group, and then another in the comparison group, until the scraps ran out of the container got 40 randomly selected participants in each group without the researcher and the respondent knowing which participants were in the experimental group and which were in the comparison group.

- **Study tool :**

An assessment tool used to assess the pain intensity among patients undergoing hemodialysis , the tool included 3 parts :

Part I:Patient's Socio-Demographic Characteristics :

It is measured subjectively and includes five variables age, gender, level of education, residence, and BMI contained 2 item hight and weight.

Part II: Clinical Data:

It is measured subjectively and include 6 items, the duration of hemodialysis treatment, the number of hemodialysis sessions, the duration of each session, the time of feeling pain, the associated comorbidities and the use of sedatives before the time of hemodialysis

Part III : Pain Intensity :

It consists 2 items , Rating Analogue Scale (RAS) and Vital Signs .

panel experts (10 experts) within the specialty of Nursing and Medicine were consulted in order to assess the validity of the tool , and they agreed to the questionnaire, and some suggested some amendments and additions, all of which were taken into consideration.

Since the pain scale intensity is a global scale , and there is no modification suggested by the experts.

Therefore , the reliability of the scale is not estimated .

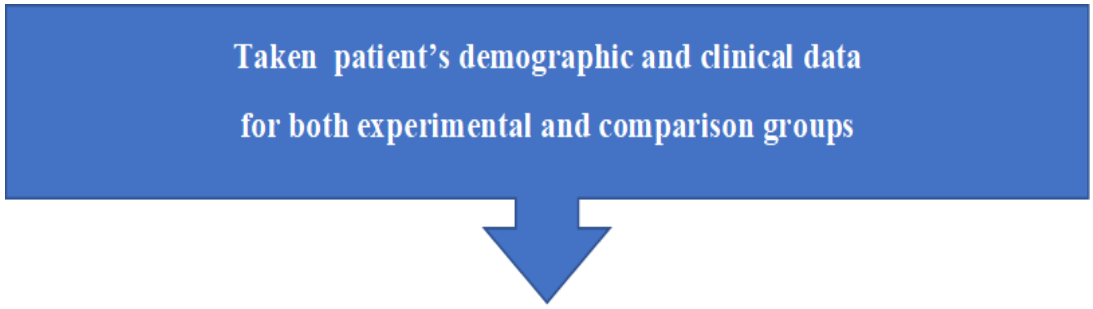
- **Data Collection :**

80 patients were chosen purposively and randomly assigned into two groups (comparison and experimental) to be interviewed face-to-face, their demographic and clinical data taken, and pain intensity measured.

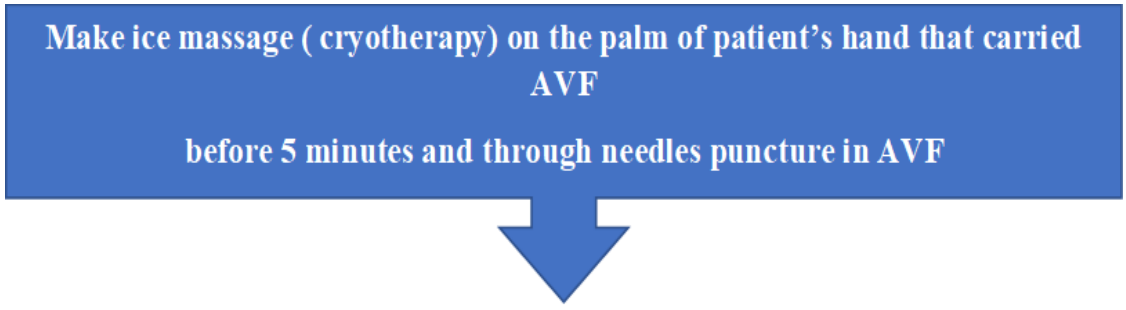
The experimental group received ice massage 5 minutes before needle insertion and during the insertion, with pain intensity and vital signs recorded afterwards. While no intervention was made in the comparison group.

- **Implementation of the program :**

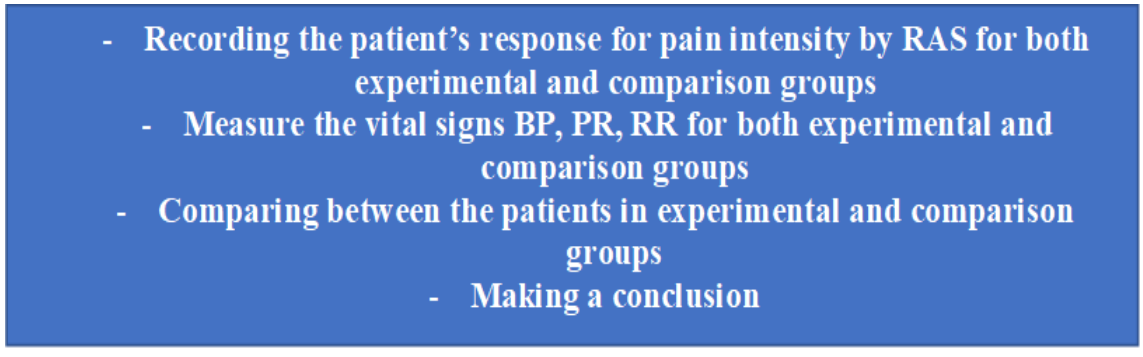
1. **Assessment Phase**



2. **Implementation Phase**



3. **Evaluation Phase**



- **Statistical Analysis:** After the data are prepared for statical analysis, the descriptive and inferential statistics employ for data analysis using the Statical Package of the Social Sciences (SPSS), version (IBM 22) as follows:

1. **Descriptive statistics:**

- Frequency and percentage tables.
- Mean and standard deviation.

2. Inferential statistics

Independent sample t-test, to test the difference between two independent groups(experimental and comparison groups) .

Study results

Table (4.1) Study Sample Demographic Characteristics

Demographic Characteristics	Rating And Intervals	Statistics	Groups	
			Experimental	Comparison
Age / years	20-29	Freq.	6	8
		Percentage	15.0%	20.0%
	30 – 39	Freq.	3	11
		Percentage	7.5%	27.5%
	40 – 49	Freq.	14	7
		Percentage	35.0%	17.5%
	50 – 59	Freq.	5	8
		Percentage	12.5%	20.0%
	60 and more	Freq.	12	6
		Percentage	30.0%	15.0%
Mean (Std. dev.)			48.4 (14.7)	46.6 (15.3)
Total		Freq.	40	40
		Percentage	100.0%	100.0%
Gender	Male	Freq.	24	21
		Percentage	60.0%	52.5%
	Female	Freq.	16	19
		Percentage	40.0%	47.5%
Total		Freq.	40	40
		Percentage	100.0%	100.0%
Educational level	Doesn't read and write	Freq.	11	8
		Percentage	27.5%	20.0%
	Primary school	Freq.	18	23
		Percentage	45.0%	57.5%
	Secondary school	Freq.	8	8
		Percentage	20.0%	20.0%
	Diploma	Freq.	2	0
		Percentage	5.0%	0.0%
	Bachelor	Freq.	1	1
		Percentage	2.5%	2.5%
Total		Freq.	40	40
		Percentage	100.0%	100.0%
Residence	Urban	Freq.	25	27
		Percentage	62.5%	67.5%
	Rural	Freq.	15	13
		Percentage	37.5%	32.5%
Total		Freq.	40	40
		Percentage	100.0%	100.0%

Table 4.1 showed that the largest age group in the experimental group was 40-49 (35%) and in the comparison group was 30-39 (27.5%). Males had the highest percentage in both groups (60% experimental and 52.2% comparison)and primary school had the highest educational level (45% experimental and 57.5% comparison). Urban residence was the highest in both groups (62.5% experimental and 67.5% comparison).

Table (4.2) Distribution of the Study Sample according to their Body Mass Index

Body Mass Index Levels	**Statistics**	**Groups**	
		Experimental	Comparison
Thin	Freq.	2	2
	Percentage	5.0%	5.0%
Normal	Freq.	22	28
	Percentage	55.0%	70.0%
Obese	Freq.	9	2
	Percentage	22.5%	5.0%
Overweight	Freq.	7	8
	Percentage	17.5%	20.0%
Overall Mean		24.8	23.3
Total	Freq.	40	40
	Percentage	100.0%	100.0%

Table (4.2) shows that the highest percentage of BMI is the normal limit for both groups, at 55% for the experimental group and 70% for the comparison group.

Table (4.3) Study Sample Clinical Characteristics

Clinical Characteristics	**Rating and Intervals**	**Statistics**	**Groups**	
			Experimental	Comparison
Duration of Dialysis Treatment / years	Less Than One Year	Freq.	8	6
		Percentage	20.0%	15.0%
	1-2	Freq.	10	8
		Percentage	25.0%	20.0%
	3-4	Freq.	5	2
		Percentage	12.5%	5.0%
	5-6	Freq.	5	3
		Percentage	12.5%	7.5%
	7 and more	Freq.	12	21
		Percentage	30.0%	52.5%
Total		Freq.	40	40
		Percentage	100.0%	100.0%
Number of Dialysis Sessions / week	1	Freq.	1	0
		Percentage	2.5%	0.0%
	2	Freq.	33	34
		Percentage	82.5%	85.0%
	3	Freq.	6	6
		Percentage	15.0%	15.0%
Total		Freq.	40	40

		Percentage	100.0%	100.0%
How long is the Hemodialysis session? / Hours	3	Freq.	2	7
		Percentage	5.0%	17.5%
	4	Freq.	38	33
		Percentage	95.0%	82.5%
Total		Freq.	40	40
		Percentage	100.0%	100.0%
When do you feel pain related AVF puncture ?	Through AVF	Freq.	40	40
		Percentage	100.0%	100.0%
Total		Freq.	40	40
		Percentage	100.0%	100.0%
Associated Comorbidities	None	Freq.	8	11
		Percentage	20.0%	27.5%
	Diabetes mellitus	Freq.	2	1
		Percentage	5.0%	2.5%
	Diabetes mellitus +Hypertension	Freq.	8	5
		Percentage	20.0%	12.5%
	Systemic Lupus Erythematous + Hypertension	Freq.	1	1
		Percentage	2.5%	2.5%
	Hypertension	Freq.	21	22
		Percentage	52.5%	55.0%
Total		Freq.	40	40
		Percentage	100.0%	100.0%
Sedation drugs taken at time of dialysis	Yes	Freq.	1	6
		Percentage	2.5%	15.0%
	No	Freq.	39	34
		Percentage	97.5%	85.0%
Total		Freq.	40	40
		Percentage	100.0%	100.0%

Table 4.3 shows the clinical features of the two groups, with the highest percentages for 7 years or more duration of dialysis, 3 sessions/week, 4 hours duration of dialysis session, 100% of pain through AVF, hypertension as the highest Comorbidity , and 97.5% in the experimental group and 85% in the comparison group not using sedatives.

Table (4.4) Assessment of Pain Intensity among the Study Sample

Pain intensity levels	**Statistics**	**Groups**	
		Experimental	Comparison
None	Freq.	6	0
	Percentage	15.0%	0.0%
Mild	Freq.	32	0
	Percentage	80.0%	0.0%
Moderate	Freq.	2	33
	Percentage	5.0%	82.5%
Sever	Freq.	0	7

	Percentage	0.0%	17.5%
Overall Mean		2.2	6.0
Total	Freq.	40	40
	Percentage	100.0%	100.0%

Table (4.4) shows that there is 80 % of experimental group with mild pain while 82.5 % of comparison group present with moderate pain (i.e. the study results indicate that there is an improvement in the pain intensity among the patient in experimental group comparing with those in the comparison group) .

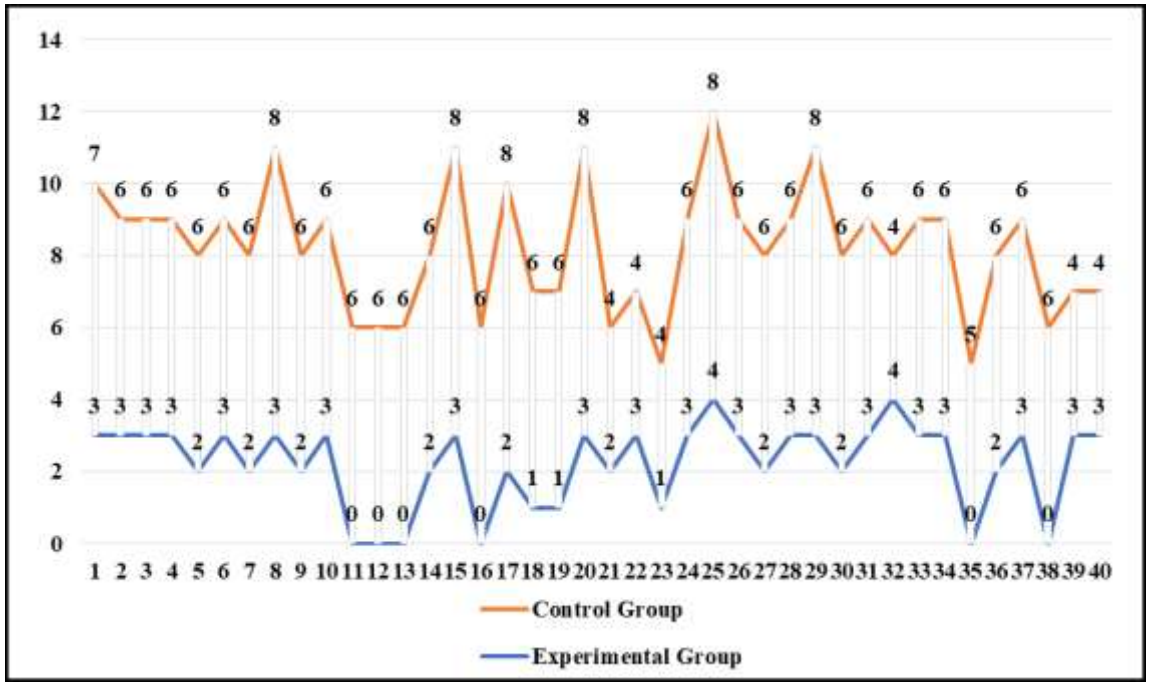


Figure (4.1) Distribution of the Study Sample according to their Pain Intensity

Table (4.5) Summery Statistics of the Pain Intensity with Comparison Differences

Main Studied Domain	Groups	Mean	Std. Deviation	Std. Error Mean
Pain Intensity	Experimental	2.23	1.165	.184
	Comparison	6.00	1.132	.179
t-value (14.69)	d.f. (78), p-value (0.0001) S			

Table (4.5) The study result indicate that there is a significant difference between experimental and comparison group , based it on means there is an improvement in pain intensity for experimental group compare with comparison group.

Discussion

The pain intensity is one of the most important variable assessed in the present study to use the cryotherapy as a non pharmacological technique to relieved .The study result indicate that after the application of the cryotherapy the pain intensity is mild at the experimental group and moderate at the comparison group. Additionally the study result show that there is a significant difference in pain intensity between the experimental group and comparison group . Cryotherapy is a form of therapy that involves exposing the body to extremely cold temperatures for a short period of time. It is used to treat a variety of medical conditions, including muscle pain, inflammation, and skin conditions.

Applying cold to the body helps reduce pain by decreasing inflammation and numbing the area. Cold temperatures cause the blood vessels to constrict, which reduces swelling and inflammation. The cold also numbs the area, which can help reduce pain. there are several theories that support cryotherapy techniques. There are several theory that discuss the philosophy of decreasing pain through cooling technique (cryotherapy):

Gate Theory suggests that cooling can reduce pain by temporarily blocking pain signals from being sent to the brain 17. Endorphin Theory: This theory suggests that cryotherapy may trigger the release of endorphins, the body's natural painkillers, reducing pain levels 18, 15 , 14 Founded that cryotherapy was effective for reducing pain

Conclusion and Recommendations

Cryotherapy is an effective, non-invasive and low-cost treatment for arterial fistula puncture pain relief in hemodialysis patients. Studies show an 80% success rate, with quick treatment and no additional medications. This makes cryotherapy a safe and successful alternative to other treatments.

Recommendation

1. The Ministry of Health should provide adequate resources to support the implementation of cryotherapy as a pain management technique in hemodialysis patients. This should include training and guidance for healthcare providers to ensure proper use of cryotherapy, access to the necessary equipment, and availability of medications that may be used in conjunction with cryotherapy.

2. The Ministry of Education should work to create awareness about the use of cryotherapy for pain management in hemodialysis patients. This should include education on the proper use of cryotherapy and the potential benefits of its use in pain management.

References

1. Al-Mudheffer ZAA, Al-daraji RAM. Effect of Hemodialysis on Spirometric Measurement in Patients with Chronic Kidney Disease. Kufa Journal for Nursing Sciences [Internet]. 2016 Aug 25 [cited 2023 Jun 21];6(2):170–7. Available from:

https://journal.uokufa.edu.iq/index.php/kjns/article/view/2652
2. Fatma Makee Mahmood, Ani A. Assessment of Hemodialysis Patient's Compliance to the Treatment and Follow up in Baghdad Teaching Hospitals. Kufa Journal for Nursing Scie. 2014 Aug 25;4(2):128–37.
3. Surveillance report 2017 – Chronic kidney disease (stage 4 or 5): management of hyperphosphataemia (2013) NICE guideline CG157, Chronic kidney disease in adults: assessment and management (2014) NICE guideline CG182 and Chronic kidney disease: managing anaemia (2015) NICE guideline NG8 [Internet]. PubMed. London: National Institute for Health and Care Excellence (NICE); 2017 [cited 2023 Jun 21]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK551826/
4. Benjamin O, Lappin SL. End-Stage Renal Disease [Internet]. Nih.gov. StatPearls Publishing; 2019. Available from: https://www.ncbi.nlm.nih.gov/books/NBK499861/
5. Ammirati AL. Chronic Kidney Disease. Revista da Associação Médica Brasileira. 2020;66(suppl 1):s03–9.
6. Mussa YM. Awareness of Nurses Concerning the Procedure of Hemodialysis and Related Complications. Kufa Journal for Nursing Sciences [Internet]. 2013 Apr 25 [cited 2023 Jun 21];3(1):93–9. Available from: https://journal.uokufa.edu.iq/index.php/kjns/article/view/2425
7. Ibrahim R, Naim M, Premtim R. Evaluation of the pain scale during arteriovenous fistula puncture with and without lidocaine gel 2% in patients undergoing haemodialysis in Kosovo. Annals of Medicine and Surgery. 2022 Jul;79:103913.
8. Chavda A, Singh S. Intradialytic stretching exercises: A conservative way to reduce muscle cramps [Internet]. Google.com. International Journal of Nursing and Medical Investigation; 2023 [cited 2023 Jun 21]. Available from: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjo-cGfldX_AhXqVfEDHZWCDOYQFnoECAgQAQ&url=https%3A%2F%2Fmedicopublication.com%2Findex.php%2Fijfmt%2Farticle%2Fdownload%2F16249%2F14546%2F31774&usg=AOvVaw0iSYaepPLyove-HRj8SR_N&opi=89978449
9. Alhani F, Shad H, Anoosheh M, Hajizadeh E. The Effect of Programmed Distraction on the Pain Caused by Venipuncture among Adolescents on Hemodialysis. Pain Management Nursing. 2010 Jun;11(2):85–91.
10. Figueiredo AE, Viegas A, Monteiro M, Poli-de-Figueiredo CE. RESEARCH INTO PAIN PERCEPTION WITH ARTERIOVENOUS FISTULA (AVF) CANNULATION. Journal of Renal Care. 2008 Dec;34(4):169–72.
11. Back Y, Lee Y. Optimal Time of Thermotherapy for Reducing Pain, Anxiety, and Side Effects in Arteriovenous Fistula Puncture Patients: A Randomized Controlled Trial. International Journal of Environmental Research and Public Health. 2020 Sep 29;17(19):7147.
12. Mahajan S, Gupta S, Agarwal M, Yadav S, Sabitha P, Khakha D. Effect of cryotherapy on arteriovenous fistula puncture-related pain in hemodialysis patients. Indian Journal of Nephrology. 2008;18(4):155.
13. Gonella S, Clari M, Conti A, Simionato L, Tassone C, Berchialla P, et al. Interventions to reduce arterial puncture-related pain: A systematic review and meta-analysis. International Journal of Nursing Studies. 2022 Feb;126:104131.
14. Kortobi L, Belymam H, Chkairi N, Zamd M, Medkouri G, Gharbi M, et al. Management of

pain at arteriovenous fistula puncture: Cryotherapy versus lidocaine/prilocaine. Saudi Journal of Kidney Diseases and Transplantation. 2020;31(3):597.

15. jafari-koulaee A, Moosazadeh M, Bagheri Nesami M, Goudarzian AH. Effect of cryotherapy on arteriovenous fistula puncture-related pain in hemodialysis patients: A systematic review and meta-analysis. Complementary Therapies in Medicine. 2020 Mar;49:102326.
16. Attia AAM, Hassan AM. Effect of cryotherapy on pain management at the puncture site of arteriovenous fistula among children undergoing hemodialysis. International Journal of Nursing Sciences. 2017 Jan;4(1):46–51.
17. Melzack R, Wall PD. Pain Mechanisms: A New Theory. Science [Internet]. 1965 Nov 19;150(3699):971–8. Available from: https://www.science.org/doi/abs/10.1126/science.150.3699.971
18. Barłowska-Trybulec M, Zawojska K, Szklarczyk J, Góralska M. Effect of whole body cryotherapy on low back pain and release of endorphins and stress hormones in patients with lumbar spine osteoarthritis. Reumatologia/Rheumatology. 2022;60(4):247–51.