

The Effect of Cryotherapy on Arterio - Venous Fistula Puncture Related Pain among Hemodialysis Patients at Selected Hospital in City

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Abstract: *Introduction:* Pain is not just a physical sensation. It is influenced by attitude, beliefs, personality and social factors and can affect emotional and mental wellbeing of person. Pain during arterio-venous fistula (AVF) cannulation remains a common problem in haemodialysis patients. Cryotherapy is the non-pharmacological therapy which helps to reduce the pain among patients undergoing haemodialysis. *AIM:* The aim of the study was to identify the effect of cryotherapy on arterio-venous fistula puncture related pain among patients undergoing haemodialysis. *Methods:* The true experimental design was adopted in this study. A total of 70 patients undergoing haemodialysis through AVF were selected in haemodialysis unit at selected Hospital in city. Among 70 samples, 35 patients were allotted in experimental Group who were given routine care first alternated by cryotherapy on subsequent visits and other 35 patients were allotted to control Group who were not given cryotherapy in first and second visits only routine care provide. Pain assessment was done using Numerical Pain Rating scale after AVF puncture. *RESULTS:* Finding revealed that the mean score of pre-tests was 8.14 and 8.06 with standard deviation was 1.03 and 1.11 among patients in experimental Group and control Group. Whereas, the mean score of post-test pain during cryotherapy in experimental Group 3.31 with 0.15 SD and mean of routine care was 8.34 and 0.19 with standard deviation in control group. There was a significant difference in the arterio-venous fistula puncture related pain between the interventions in both Groups ($t = 20.818$, $p < 0.0001$, significant). *Conclusion:* It was concluded that cryotherapy is able to reduce intensity of pain during AV fistula puncture in hemodialysis patients. It can be used as a non- pharmacological intervention and is a simple and inexpensive therapy.

Keywords: cryotherapy, hemodialysis, a.v. fistula, non-pharmacological pain management

1. Introduction

Kidney the two bean shaped organs in the lumbar region that filter the blood, excreting the end products of body metabolism in the form of urine, and regulating the concentration of hydrogen, sodium, potassium, phosphate, and other ions in the extracellular fluid. Frequently encountered diseases of the kidney include infection (pyelonephritis), stone formation (nephrolithiasis), dilation (hydronephrosis), protein loss (nephrosis), cancer (hypernephroma), and acute or chronic renal failure.²

Chronic kidney disease involves progressive, irreversible loss of kidney function. It is defined as either the presence of kidney damage or GFR < 60 ml/min for 3 months or longer. [Normal GFR is about 125 ml/min] and is reflected by urine creatinine clearance measurements.] Kidney damage is defined as either pathologic abnormalities or markers of damage, including abnormalities in blood or urine tests or markers of damage, including abnormalities in blood or urine tests or imaging studies. Disease staging based on the decreasing the decreasing GFR.³

Chronic kidney disease is a major public health concern worldwide. There is paucity of data on the prevalence of chronic kidney disease in India, but reported prevalence ranges from $< 1\%$ to 17% with increasing incidence of diabetes among younger Indians, prevalence of Chronic Kidney Disease is expected to rise further as diabetes

accounts for 40%-60% of cases of end – stage renal disease (ESRD).

The number of hemodialysis stations in India was estimated at 12,881 in 2018. The 2016 National dialysis program envisaged setting up an eight-station dialysis facility in all 68 districts of the country to provide haemodialysis to poor patients. If patients dialyzed twice-a-week (commonly done in India), just about 50,000 new patients would be accommodated under this program, even without future growth.⁴

Much of secondary and tertiary level health – care services, dialysis in India is predominantly private sector driven, reflecting low public spending on health care. Public sector hospitals largely manage critically sick patients and those with acute kidney injury, leaving limited capacity for accommodating patients on maintenance of dialysis.⁴

Globally, 80% of chronic kidney disease (CKD) related deaths occur in developing countries. However, there is lack of kidney registries in many developing countries and it is a challenge to estimate the true prevalence of chronic kidney disease (CKD) in these countries. In developing countries, the majority of patients died because of the unaffordability of high cost treatments.²

In India, chronic kidney disease (CKD) is one of the common non-communicable disease and results in high morbidity, mortality and economic burden. In India, the

number of chronic kidney disease (CKD) related mortalities was about 5.2 million in 2008 and may rise to 7.63 million by 2020. Hot-spots of chronic kidney disease (CKD) have been reported in a few states-India, Puducherry, Andhra Pradesh, Maharashtra and Odisha. However, in India, accurate prevalence and incidence data of chronic kidney disease (CKD) is lacking as there are hardly any community-based studies.⁴

World kidney day 2019; chronic kidney disease is 6th deadliest disease worldwide, 850 million people are now estimated to have kidney diseases from various causes and chronic kidney disease causes at least 2.4 million deaths worldwide per year. And these are the numbers when the cases in India, which is home to world's 17% population, remain largely undocumented and unregistered. Haemodialysis the most common method of dialysis. More than 280,000 Americans currently receive chronic haemodialysis.⁵

In selected hospital of city in that daily 20-25 patients undergoing from hemodialysis. Monthly approximately 600-750 cycles will be completed in hemodialysis unit.

A quasi-experimental study was conducted on effectiveness of cryotherapy during of arterio-venous fistula puncturing pain in haemodialysis patients at Mangalore. They were used purposive sampling technique, 50 patients out of 25 in experimental group and 25 in control group. At the time of arterio-venous fistula puncturing cryotherapy was given with ice pack on the web between the thumb and index finger of the contra lateral hand. In the both groups the pain response checked by the numerical rating scale and observational checklist. The result of study was the significant difference between the pre-test and post-test of behavioral response scores and pain scores. So, this study was effective in reducing pain during arteriovenous fistula puncture related pain among haemodialysis.

Title of the study

Effect of cryotherapy on arterio-venous fistula puncture related pain among hemodialysis patients at selected hospital in city.

2. Problem Statement

A study to assess the effect of cryotherapy on arterio-venous fistula puncture related pain among hemodialysis patients at selected hospital in city.

3. Objectives of the Study

- 1) To assess the level of pain related to arterio-venous fistula among the haemodialysis patients in experimental and control group.
- 2) To determine the effect of cryotherapy on A.V. Fistula puncture related pain in experimental group of haemodialysis patients.
- 3) To compare the A.V. Fistula puncture related pain among experimental and control group of haemodialysis patients.
- 4) To find out the association between the A.V. Fistula puncture related pain among experimental and control

group of haemodialysis patients with selected demographic variables.

Variables

Variables are qualities, quantities, properties, or characteristics of people, things or situations that change or vary.¹⁴

The dependent variables that change as the independent variable is manipulated by the researcher; some time called criterion variables. In present study the level of arteriovenous fistula puncture related pain among patients undergoing haemodialysis is dependent variable.

Independent variables are purposely manipulated or changed by the researcher; also called manipulated variables. In present study cryotherapy is independent variable.

Demographic variables are the characteristics and attributes of the study subjects are considered demographic variables. In this study those are- Age, sex, occupation, Educational status, monthly family income, duration of illness, duration of hemodialysis treatment, duration of using A.V. Fistula access, Frequency of haemodialysis per week.

Hypothesis-

- 1) **H01**-Cryotherapy will not be effective in reducing arterio-venous fistula puncture related pain among clients undergoing hemodialysis.
- 2) **H02**- There is no significant association between levels of Arterio Venous Fistula puncture related pain among experimental and control group of hemodialysis patients with selected demographic variables.
- 3) **H1**- Cryotherapy will be effective in reducing Arterio-venous Fistula puncture related pain among clients undergoing hemodialysis.
- 4) **H2** -There is significant association between levels of Arterio Venous Fistula puncture related pain among experimental and control group of hemodialysis patients with selected demographic variables.

Research Approach

Quantitative approach was adopted for this study

Research Design

Group	Pre-test	Intervention	Post-test
Experimental	Observation 1	X	Observation 2
Control	Observation 1	-	Observation 2

Observation 1- Assessment of pain level in pre-test without intervention X- Cryotherapy procedure

Observation 2- Assessment of pain level in post-test with intervention

Samples

Samples are those who is undergoing for hemodialysis who having A.V. Fistula.

Sampling Technique

In present study simple random sampling technique was used. The random number table technique was used. The

odd serial numbers patients included in experimental group and even serial number patients included in control group.

Sample Size

Sample size of the haemodialysis patients with arteriovenous fistula was taken as 70 (Experimental 35, control 35) who fulfill the criteria

Inclusion Criteria & Exclusion Criteria

The subjects were selected based on the following inclusion and exclusion criteria.

Inclusion criteria

The patients who are:

- Receiving hemodialysis for minimum of 5 cycles in a month
- Above 18 years of age.
- Not receiving any pain reducing agent.
- Capable of giving adequate response to pain.
- Having healthy A.V. Fistula skin (no sign of inflammation, infection).
- clients who are willing to participate in the study.

Exclusion criteria

The patients who are:

- With neuro-vascular disorders like Reynaud's syndrome, diabetic neuropathy, connective tissue disorder, peripheral vascular disease, critically ill.
- Requiring more than one attempt for A.V. Fistula puncture

Methods of Developing Tool

Section A: Demographic variables.

Section B: Numerical Pain Rating scale for pain assessment.

Section A: A questionnaire was designed to collect the demographic data related to Age, sex, occupation, Educational status, monthly family income, duration of illness, duration of haemodialysis treatment, duration of using A.V. Fistula access, Frequency of haemodialysis per week.

Section B: Numerical Pain Rating scale: This scale was developed by the McCaffery and Beebe for subjective pain assessment. The scale consisted of numerical value from zero to ten. The scores were interpreted as follows:

Table 2: Numerical Pain Rating scale

Level of pain	Scores
No pain	0
Mild pain	1-3
Moderate pain	4-6
Severe pain	7-10

1) Organization of the Study Findings

The data was collected from the client undergoing hemodialysis and were organized, analyzed and presented under the following headings.

2) Section A

Demographic variables of client undergoing hemodialysis in experimental and control group

3) Section B

Assessment of A.V. Fistula puncture related pain among experimental and control group of hemodialysis patients

4) Section C

a) Assessment of effect of cryotherapy on A.V. Fistula puncture related pain among hemodialysis patients in experimental group.

b) To compare the A.V. Fistula puncture related pain among experimental and control group of hemodialysis patients.

5) Section D

a) Association between pre-test A.V. Fistula puncture related pain among experimental group of hemodialysis patients with selected demographic variable.

b) Association between pre-test A.V. Fistula puncture related pain among control group of haemodialysis patients with selected demographic variable.

Section A: Demographic variables of client undergoing hemodialysis in experimental and control group

Table 3: Distribution of client undergoing hemodialysis in experimental group and control group with their socio demographic characteristics, N=35+35=70

Sr. No	Demographic Variable	Category	Experimental group		Control group	
			Frequency	%	Frequency	%
1	Age in Years	18-28 years	6	17.14	2	5.71
		29-38 years	8	22.86	3	8.57
		39-48 years	9	25.71	15	42.86
		Above 49 years	12	34.29	15	42.86
2	Gender	Male	28	80	31	88.57
		Female	7	20	4	11.43
3	Education	Illiterate	2	5.71	1	2.86
		Primary	15	42.86	14	40
		Higher Secondary	10	28.57	14	40
		UG	7	20	5	14.29
		PG & above	1	2.86	1	2.86
4	Occupation	Farmer	13	37.14	11	31.43
		Service	6	17.14	6	17.14
		Business	6	17.14	4	11.43
		Unemployed	7	20	9	25.71
		Any other	3	8.57	5	14.29

5	Family monthly income	Below Rs. 5000	8	22.86	15	42.86
		Rs. 5001-10000	1	2.86	4	11.43
		Rs. 10001-15000	5	14.29	5	14.29
		Above Rs 15001	21	60	11	31.43
6	Duration of Disease	≤ 3 years	23	65.71	18	51.43
		3-6 Years	7	20	11	31.43
		≥ 6 Years	5	14.29	6	17.14
7	Number of hemodialysis cycle per week (Frequency)	One	4	11.43	1	2.86
		Two	19	54.29	27	77.14
		Three & Above	12	34.29	7	20
8	Duration of A V fistula (in Months)	1-6 Months	6	17.14	3	8.57
		7-12 Months	5	14.29	7	20
		13-18 Months	10	28.57	4	11.43
		19-24 & above	14	40	21	60
9	Undergoing hemodialysis since	2 years	26	74.29	13	37.14
		2-4 Years	4	11.43	11	31.43
		4-6 years	2	5.71	8	22.86
		Above 6 years	3	8.57	3	8.57
10	Associated Illness	DM	0	0	1	2.86
		Hypertension	30	85.71	21	60
		Anemia	0	0	0	0
		Any other	0	0	1	2.86
		None	5	14.29	12	34.29

Section B: Assessment of A.V. Fistula puncture related pain among experimental and control group of hemodialysis patients

Table 4: Pre-test frequency and percentage distribution of A.V. Fistula puncture related pain among experimental group and control group, N=35+35=70

Level of Pain	Score	Experimental Group		Control Group	
		Frequency	Percentage	Frequency	Percentage
No Pain	0	0	0	0	0
Mild Pain	1-3	0	0	0	0
Moderate	4-6	5	14.28	6	17.14
Severe	7-10	30	85.71	29	82.85

The table no 4 shows that, in pre-test majority 30(85.71%) in experimental group, 29(82.85%) in control group had severe pain, 5(14.28%) in experimental group, 6(17.14%) in control group had moderate pain and none of the samples in both experimental and control group had mild and moderate pain.

Table 5: Post-test frequency and percentage distribution of A.V. Fistula puncture related pain among experimental group and control group, N=35+35=70

Level of Pain	Score	Experimental Group		Control Group	
		Frequency	Percentage	Frequency	Percentage
No Pain	0	0	0	0	0
Mild Pain	1-3	18	51.42	0	0
Moderate	4-6	17	48.57	4	11.42
Severe	7-10	0	0	31	88.57

The table no 4 shows that, in post-test majority 18(51.42%) had mild pain, 17(48.57%) had moderate pain, and none of the samples had severe and no pain under experimental group. Whereas in control group 31(88.57%) had severe pain, 4(11.42%) had moderate pain and none of the samples were mild and no pain.

Section C: Assessment of effect of cryotherapy on A.V. Fistula puncture related pain in experimental group of hemodialysis patients

This section illustrates the analysis and interpretation of effect of cryotherapy on pain at A V Fistula site among hemodialysis patient.

Section C: (a) Assessment of effect of cryotherapy on A.V. Fistula puncture related pain in experimental group of hemodialysis patients.

Table 6: Assessment of effect of cryotherapy on A.V. Fistula puncture related pain in experimental group, N=35

Particular		Mean	SD	SE M	Mean difference	t-test value	p-value
		Experimental Group	Pre- test	8.14			
Post- test	3.31		0.87	0.15			

The table no.6 shows that post test mean pain score was lower 3.31 with SD±0.87 when it compared with pre test mean pain score 8.14 with SD ±1.03 in experimental group. It shows that after intervention mean pain level was reduced to 4.82. The statistical paired t test illustrates t value 23.33, p <0.0001. The difference in pain level in pre test and post test found statistically significant at 0.05% level in experimental

group. It concludes at 5% level of significance and 34 degrees of freedom that the above data gives sufficient evidence to conclude that hemodialysis patients after receiving cryotherapy effective. Hence reject null hypothesis and accept research hypothesis.

Section C: (b) Comparison of A.V. Fistula puncture related pain among experimental and control group of hemodialysis patients

Table 7: Comparison of effect of cryotherapy on A.V. Fistula puncture related pain in experimental group and control group, N=70

Particulars		Mean	SD	T value	P-value
Pre test	Experimental Group	8.14	1.03	0.334	P=0.7391* NS
	Control Group	8.06	1.11		
Post test	Experimental Group	3.31	0.15	20.818	P<0.0001* S
	Control Group	8.34	0.19		

* NS= Non significant; S= Significant

Table no 7 depicts that in pre test mean score in experimental group was 8.14 with SD 1.03, whereas in control group pre test mean score was 8.06 with SD 1.11. The calculated unpaired t value was 0.33 and p value is 0.739. By conventional criteria this difference is considered to be not statistically significant.

The table also illustrates that, in post test mean score in experimental group 3.31 with SD 0.15, whereas in control group mean score was 8.34 with SD 0.19. The calculated unpaired t value was 20.814 and $p < 0.0001$. It concludes at 5% level of significance and 68 degrees of freedom that the above data gives sufficient evidence that after receiving cryotherapy among experimental group, pain level was lower with compared to control group. Hence null hypothesis is rejected.

Section D: Association between pre-test level of A.V. Fistula puncture related pain among experimental group of hemodialysis patients with selected demographic variable

Association of pain score among hemodialysis patients in control group with their demographic variables; age, gender, education status, occupation, family monthly income, duration of disease, number of hemodialysis cycle per week, duration of A V fistula duration of hemodialysis procedure and associated illness like diabetes mellitus, hypertension, anemia. In order to compute the association between the pre test pain score and demographic variables chi-square was applied.

The data reveals that there was no significant association between pretest pain score with demographic variables.

4. Discussion

Section A - Assessment of A.V. Fistula puncture related pain among experimental and control group of hemodialysis patients

In the present study the level of pain assessed in pretest majority i.e. 30(85.71%) in experimental group, 29(82.85%) in control group had severe pain, 5(14.28%) in experimental group, 6(17.14%) in control group had moderate pain and none of the samples in both experimental and control group had mild and moderate pain.

In posttest majority 18(51.42%) had mild pain, 17(48.57%) had moderate pain, and none of the samples had severe and no pain under experimental group. Whereas in control group

31(88.57%) had severe pain, 4(11.42%) had moderate pain and none of the samples were mild and no pain.

Section B - Assessment of effect of cryotherapy on A.V. Fistula puncture related pain in experimental group of hemodialysis patients

(a) Assessment of effect of cryotherapy on A.V. Fistula puncture related pain in experimental group

In this study to assess the effectiveness the paired t-test was used. The post test mean pain score was lower 3.31 with SD ± 0.87 when it compared with pre test mean pain score 8.14 with SD ± 1.03 in experimental group. It shows that after intervention mean pain level was reduced to 4.82. The statistical paired t test illustrates t value 23.33, $p < 0.0001$. The difference in pain level in pre test and post test found statistically significant at 0.05% level in experimental group. It conclude at 5% level of significance and 34 degrees of freedom that the above data gives sufficient evidence to conclude that hemodialysis patients after receiving cryotherapy effective. Hence reject H_0 - Cryotherapy will not be effective in reducing arterio-venous fistula puncture related pain among clients undergoing hemodialysis, null hypothesis and accept H_1 -Cryotherapy will be effective in reducing Arterio-venous Fistula puncture related pain among clients undergoing haemodialysis i.e. research hypothesis.

A similar study conducted by Davtalab, Naji and Shahidi (2016) on comparing the effects of Valsalva maneuver and ice massage at Hoku. Point methods on pain intensity within the needle insertion to the arteriovenous fistula (AVF) for patients undergoing hemodialysis in the selected hospitals in Isfahan. The results of this study shows that, the averages of objective and subjective pain scores before intervention in Valsalva maneuver group and ice massage group are 2.9 ± 0.7 and 5 ± 1.6 and 3.2 ± 1.1 and 4.9 ± 1.5 respectively. And also after intervention are 2.4 ± 0.7 and 4.1 ± 1.7 in Valsalva maneuver group and 2.8 ± 1.1 and 4.2 ± 1.3 in ice massage group. The result of this study showed that the averages of objective and subjective pain scores after intervention was decreased significantly.⁴¹

Section C - Comparison of A.V. Fistula puncture related pain among experimental and control group of hemodialysis patients

The unpaired t-test was used to compare of A.V. Fistula puncture related pain among experimental and control group of hemodialysis patients. Pre test mean score in experimental group was 8.14 with SD 1.03, whereas in control group pre test mean score was 8.06 with SD 1.11. The calculated unpaired t value was 0.33 and p value is 0.739. By conventional

criteria this difference is considered to be not statistically significant.

In post test mean score in experimental group 3.31 with SD 0.15, whereas in control group mean score was 8.34 with SD 0.19. The calculated unpaired t value was 20.814 and $p < 0.0001$. It concludes at 5% level of significance and 68 degrees of freedom that the above data gives sufficient evidence that after receiving cryotherapy among experimental group, pain level was lower with compared to control group. Hence null hypothesis is rejected.

A similar study was conducted by Pachori (2017) on Comparison the level of subjective pain score between experimental and control group indicates that in control group, 13.3% of the patients were had mild pain, 36.7% had moderate pain and 50% of the patients had severe pain. In experimental group 33.3% of the patients had mild pain, 46.7% had moderate pain and 20.0% of the patients had severe pain. This difference is statistically significant ($P=0.03$). Comparison the level of pain behaviour scores between experimental and control group indicates that in control group, 13.3% of the patients had mild pain, 46.7% had moderate pain and 40% of the patients had severe pain. In experimental group 36.7% of the patients had mild pain, 46.7% had moderate pain and 16.7% of the patients had severe pain.⁴²

Section D - To find out the association between the A.V. Fistula puncture related pain among experimental and control group of haemodialysis patients with selected demographic variables.

a) Association between pre-test pain score and demographic variable of experimental group

In order to compute the association between the pre test pain score and demographic variables chi-square was applied. Association of pain score among hemodialysis patients in experimental group with their demographic variables; age, gender, education status, occupation, family monthly income, duration of disease, number of hemodialysis cycle per week, duration of A V fistula duration of hemodialysis procedure and associated illness like diabetes mellitus, hypertension, anemia. The data reveals that there was no significant association between pretest pain score with demographic variables.

b) Association between pre-test pain score and demographic variables of control group

To compute the association between the pre test pain score and demographic variables chi-square was applied. The association of pain score among hemodialysis patients in control group with their demographic variables; age, gender, education status, occupation, family monthly income, duration of disease, number of hemodialysis cycle per week, duration of A V fistula duration of hemodialysis procedure and associated illness like diabetes mellitus, hypertension, anemia. The data reveals that there was no significant association between pretest pain score with demographic variables.

Similar study of Sumyra Nazir et.al. is supporting to this study. The study was a quasi-experimental study to evaluate

the effectiveness of cryotherapy on pain during arteriovenous fistula puncturing among hemodialysis patients in dialysis unit of Safdarjung hospital, New Delhi. Demographic variables i.e. age, duration of hemodialysis and duration of AV fistula.³⁸ Another one study of Divya Pachori's supporting to this study i.e. effectiveness of cryotherapy on pain during puncture of arteriovenous fistula among the patients on hemodialysis. In that demographic variable age, duration of disease, hemodialysis started since and number of hemodialysis per week were not significant.

5. Recommendations

- The study replication could be done with larger samples to validate and generalize findings.
- The researcher has to be trained to implement effective cryotherapy during hemodialysis to reduce the level of arterio-venous fistula puncture related pain.
- Cryotherapy can be performed on undergoing hemodialysis patients.
- It can be implemented to short- or long-term centers for renal patients.

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