



## A STUDY TO ASSESS THE EFFECT OF CRYOTHERAPY ON ARTERIO-VEINUS (A.V) FISTULA PUNCTURE RELATED PAIN AMONG HEMODIALYSIS PATIENTS AT SELECTED HOSPITAL IN KOLKATA, WEST BENGAL.

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**ABSTRACT** Pain during Arterio-Venous (A.V) Fistula cannulation remains a common problem among hemodialysis patients. A non-equivalent pretest posttest control group design was adopted to assess the effect of cryotherapy on pain due to A.V Fistula in hemodialysis patients. Conceptual framework was based on 'Gate Control Theory'. A nonprobability-purposive sampling technique was used to obtain 60 patients (30 each in experimental and control groups) who were undergoing hemodialysis by using A.V.Fistula. Objective and subjective pain scoring was done on two consecutive days of hemodialysis treatment (with cryotherapy for the experimental and without cryotherapy for the control group). The tools used were a structured interview schedule examining sample characteristics, visual analogue scale for subjective pain response and an objective pain behaviour checklist for assessing objective pain behaviour. Descriptive statistics were used and deemed appropriate. Chi-square, two-sample and paired t-tests, Spearman's and Pearson's correlations were used for inferential statistics. It was found that the objective and subjective pain scores were significantly ( $p = 0.001$ ) reduced among the experimental group with the application of cryotherapy. This study highlights the need for adopting alternative therapies such as cryotherapy for effective A.V.Fistula puncture related pain management in hospital settings.

**KEYWORDS :** cryotherapy, Arterio-Venous (A.V) Fistula, pain, effect, hemodialysis

### INTRODUCTION :

Among chronic diseases, CKD is of particular significance and contributes heavily to the global CVD and end-stage renal disease (ESRD). In India, given its population more than 1 billion, the rising incidence of CKD is likely to pose major problems for both healthcare and the economy in future years. Indeed, it has been recently estimated that the age-adjusted incidence rate of ESRD in India is to be 229 per million population (pmp), and more than 100,000 new patients enter renal replacement programs annually in India(1).

Technological advances in the care of renal failure patients provide several renal replacement therapies such as hemodialysis, peritoneal dialysis, hemofiltration and transplantation (2,3). Hemodialysis (HD) is most frequently used renal replacement therapy. These patients receive chronic or maintenance dialysis therapy for the control of uremic and azotemic manifestations(4). One of the vital aspects of hemodialysis is the establishment and maintenance of adequate blood access. Without it, hemodialysis cannot be done. One of the major routes is the internal Arterio-Venous (A.V) Fistula(5,6,7). The main type of AV fistula is radio-cephalic fistula, brachio-cephalic fistula, and brachio-basilic fistula which are created in arm surgically for starting hemodialysis.

According to national kidney foundation, dialysis outcome quality initiative (DOQI), 2005 reported that AV fistula remains as a gold standard for vascular access in hemodialysis patients.

In addition to the suffering, severity of disease, patients with end-stage renal disease undergoing hemodialysis are repeatedly exposed to stress and pain from approximately 300 punctures per year to their A.V.Fistula with large bore catheter for hemodialysis (8). Considerable patient discomfort and stress can be associated with the insertion of large-gauge needles into an A.V.Fistula. Alleviation of this pain might improve their acceptance of the procedure and thus, their quality of life. (9).

Pain during A.V.Fistula cannulation (10) remains a common problem in hemodialysis patients. Local anesthesia is not frequently used due to concerns of vasoconstriction, burning sensation, scarring, and infection (11). On an average, a patient on maintenance hemodialysis undergoes ten A.V.Fistula puncture a month and would continue to do so throughout their lifetime or until a successful renal transplant. His or her comfort with the procedure is therefore of utmost importance for long term compliance with the treatment.

### Need of the study

Non-pharmacological techniques to reduce venipuncture related pain and avoid potential drug side effects are generally less costly and can be performed independently by nurses (12). A number of non-pharmacological techniques (13), such as distraction, relaxation, guided imagery, and cutaneous stimulation provide coping strategies that may help reduce pain perception, make pain more tolerable, decrease anxiety and enhance the effectiveness of analgesics (14). Among these measures, the proper use of cutaneous stimulation can reduce pain perception (Crisp and Taylor 2005) (15).

Research evidence also shows that cutaneous stimulation is an independent nursing intervention to minimize patient's pain (16,27). Gate control theory proposed by Melzack in 1965 (17,26) clearly explains the effect of cutaneous stimulation. It can be clubbed with acupressure to the large intestine energy meridian to increase its effectiveness (17,18).

An application of cold is considered to slow the ability of pain fibers to transmit pain impulses (Ball and Bindler 2003). Studies have also thrown light on the fact that cryotherapy is equally effective and important in alleviating or minimizing pain as a cutaneous stimulation technique (19,30). The researcher found it necessary to look at the effect of cryotherapy on pain due to A.V.Fistula puncture among hemodialysis patients.

Studies have also shown that there are lot of changes associated with pain which includes the blood pressure, body temperature and respiration. (20,27,29) These parameters play an important role and have to be thoroughly monitored during hemodialysis. Considering the anxiety due to painful procedures such as venipuncture, as well as the unpleasant feelings, the investigator felt that application of cryotherapy to the skin would decrease the pain-related responses associated with venipuncture. Thus, during the AV fistula puncture the researcher also felt the need to assess the pain related responses.

### Objectives:

1. To assess the A.V.Fistula puncture related pain among experimental and control group of hemodialysis patients.
2. To determine the effect of cryotherapy on A.V.Fistula puncture related pain in experimental group of hemodialysis patients.
3. To compare the A.V.Fistula puncture related pain in terms of difference in pain scores among experimental and control group.
4. To find out the association between the A.V.Fistula puncture

related pain among experimental and control group with selected demographic variables.

**Operational definition:**

**Effect:** In this study it refers to the reduction in the level of pain at the AV-Fistula site as elicited by the investigator using Visual Analogue Scale and objective pain behaviour checklist after the application of cryotherapy.

**Cryotherapy:** In this study, cold application is done with ice cubes wrapped in gloves on the web between the thumb and index finger (thenar space – Large Intestine Meridian point) of the hand not having the AV fistula (contralateral arm). The procedure is started ten minutes before venipuncture and continued throughout the puncturing procedure (approximately two minutes).

**Pain:** In this study, pain is considered as A.V.Fistula puncture related pain :

- The subjective pain which was measured by the Visual Analogue Scale and
- The objective pain which was measured by an objective pain behaviour checklist for facial expression, vocalization and biophysiological parameters such as blood pressure, pulse rate, and respiratory rate, after the AV fistula puncture.

**Hypothesis :**

**H1 :** The mean pre-intervention A.V Fistula puncture related pain score is significantly higher in the patients of experimental group who are exposed to cryotherapy than the mean post-intervention A.V.Fistula puncture related pain score as measured by Visual Analogue Scale at 0.05 level of significance.

**H2 :** The mean A.V.Fistula puncture related pain score of the patients of experimental group who are exposed to cryotherapy is significantly lower than that of the patients of the control group who are not exposed to cryotherapy as measured by Visual Analogue Scale at 0.05 level of significance.

**H3 :** The mean pre-intervention A.V Fistula puncture related pain score is significantly higher in the patients of experimental group who are exposed to cryotherapy than the mean post-intervention A.V.Fistula puncture related pain score as measured by objective pain behaviour checklist at 0.05 level of significance.

**H4 :** The mean A. V. Fistula puncture related pain score of the patients of experimental group who are exposed to cryotherapy is significantly lower than that of the patients of the control group who are not exposed to cryotherapy as measured by objective pain behaviour checklist at 0.05 level of significance.

**Research approach**

In the present study, quasi-experimental research approach is selected to accomplish the objectives of study and thought to be appropriate.

**Research design**

The research design for the study was selected as “Non-equivalent pretest posttest control group design.”

**Variables under study**

**Independent variable-** Cryotherapy

**Dependent variable-** A.V.Fistula puncture related pain

**Demographic variables-** Age, sex, occupation, Educational status, monthly family income, duration of illness, duration of hemodialysis treatment, duration of using A.V.Fistula access, Frequency of hemodialysis per week

**Population**

In the present study, population consisted of the hemodialysis patients receiving hemodialysis through A. V.Fistula access.

**Sample**

In the present study, sample consisted of the patients at Shree Jain Hospital and Research Centre receiving hemodialysis through A.V.Fistula access and who fulfilled the inclusion criteria during the data collection period.

**Sample size**

In the present study the sample size was of 60 patients. (30 patients each for both experimental and control group).

**Sampling technique**

In the present study nonprobability-purposive sampling technique was adopted for selecting the subjects.

**INCLUSION CRITERIA**

The inclusion criteria for the sample were patients:

- receiving hemodialysis for minimum of 10 cycles
- 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).

**EXCLUSION CRITERIA**

The exclusion criteria for the sample were patients:

- with neuro-vascular disorders like raynauld's syndrome, diabetic neuropathy, connective tissue disorder, peripheral vascular disease.
- requiring more than one attempt for A. V.Fistula puncture

**Data collection tools and techniques**

**Table1 Data collection tools and techniques**

Tool	Description	Variables to be measured	Technique
I	Structured interview schedule	A) Demographic data - Age, sex, occupation, Educational status, monthly family income B) Data related to illness - Duration of illness, duration of hemodialysis treatment, duration of using A.V.Fistula access, Frequency of hemodialysis per week	Interview
II	Visual analog scale	Subjective Pain Response	Assessment
III	Objective pain behavior checklist	Objective pain behavior	Observation

**Major findings of the study:**

Majority of the patients were male patients belonging to the age group of 40 – 59 years, with secondary level education, being unemployed and having monthly family income above fifteen thousand. Maximum number of patients suffered from CKD between 21 - 40 months and group had the duration of hemodialysis treatment between 11-40 cycles and also had the duration of A. V.Fistula access for 6– 10 months taking dialysis twice a week. Refer Table 2.

The frequency and percentage distribution according to A.V.Fistula puncture related pain as measured by VAS and objective pain behaviour checklist, reconfirms that both the tool measured the level of pain almost similarly and that the tool was reliable. Refer Table 3.

The AV fistula puncture pain score measured by VAS on days 1 and 2 of HD within the experimental group were found to be significantly reduced (p=0.001) from a mean of 5.07 on day 1 of HD to 2.3 on day 2 of HD. There was also a significant reduction (p=0.001) in the AV fistula puncture pain score as measured by objective pain behaviour checklist from a mean of 4.1 on day 1 of HD to 1.53 on day 2 of HD. Refer Table 4.

AV fistula puncture pain score measured by VAS on days 2 of HD within the experimental and control group showed that the pain score among the experimental group were found to be significantly reduced (p=0.001) from a mean of 2.3 among experimental group to 4.53 among control group. There was also a significant reduction (p=0.001) in the AV fistula puncture pain score as measured by objective pain behaviour checklist from a mean of 1.53 among experimental group to 3.83 among control group. Refer Table 4. It can be concluded that cryotherapy was effective in reducing A.V.Fistula puncture related pain.

There was no association between the baseline (day 1 of HD) pain

scores (objective and subjective) and the selected variables such as the gender, age and duration of illness. However, significant negative correlation was observed between pre-intervention pain perception in experimental group ( $r=-0.48$ ,  $t=3.3$ ,  $p=0.01$ ) and control group ( $r=-0.58$ ,  $t=4.63$ ,  $p=0.05$ ) with their duration of hemodialysis treatment. Hence with the increase in the duration of treatment there is a reduction of pre-intervention A.V.Fistula puncture related pain.

**DISCUSSION :**

The result of the present study revealed that the majority of patients in the experimental and control group, belonged to the age group of 40 – 59 years. This may be related to the statement stated by Abou Elsood that renal function decreases gradually with increasing age. (21).

Concerning sex, the present study showed that more than half of studied sample were male. This study was in line with Ahmed and Faheem et al. (22) and Manal E. Fareed et al (23), who found that more than half of their sample was male.

Christensen and Kockrow reported that renal failure is a serious problem that may affect the work due to loss of patients' ability and strength (24). This may explain the result of the current study which showed that more than 45% of studied sample were unemployed.

As regard to the duration of the hemodialysis treatment, it was noted from the present study that almost half of the study group belonged to 11-40 cycles. This was congruent with the study results of study done by Celik et al (9). These researchers attributes greater incidence for the smaller cycles to the short age of A.V.Fistula which may be due to failure of vascular access.

The study results was in line with Sabithia et al., who also found that the objective and subjective pain scores were significantly reduced within the experimental group with the application of cryotherapy (25). Moreover Abu Bakr et al., and Celik et al., stated that pain scoring decreased significantly in cryotherapy study group with using a superficial cooling (9,26). This result is also in line with JS Park, et al. where subjective pain score of A.V.Fistula puncture pain in experimental group was lower than the control group but the objective pain behavior score and the cardiopulmonary signs of A.V.Fistula pain were contrary to this study, where the pain score was similar in both experimental and control group. (27)

Sabithia et al., noted that female reported higher pain scores when compared to males (25). Also Jackson et al., studied gender difference in pain perception and found women typically have greater pain perception than men (28). These results were in contrast to the result of the present study that showed that no statistical difference was found between male and female regarding the pain perception. This may be due to cultural factors. But the result was congruent with Manal E. Fareed et al, Ingalls et al and Celik et al., who found that there was no significant relationship regarding pain and gender. (9,19,23)

The study, however, has a few limitations: It is a small sample-sized study, equal number of males and females in both experimental and control group were not studied which could have highlighted the difference in perception of pain in both gender, matching the duration of hemodialysis treatment (in cycles), duration of A.V.Fistula access use (in months) and frequency of hemodialysis per week in both experimental and control group were not done due to lack of time and availability of the sample.

**CONCLUSION**

On the basis of the findings of the present study, the researcher concluded that cryotherapy is effective in reducing A.V Fistula puncture related pain among hemodialysis patients. Also there were no significant relation of A.V. Fistula puncture related pain with gender, age and duration of illness while there was significant correlation with duration of treatment. The utilization of such non-pharmacological technique can reduce pain and thereby increase patient comfort and satisfaction.

**Table 2 : Demographic data and data related to illness of HD patients**

Variable	n=60 (n1=30; n2=30)	
	Experimental group	Control group
Age (% , years)	60 (40-59)	43.33 (40-59)
Male (%)	53.33	63.33
Secondary education (%)	40	43.33
Unemployed (%)	43.33	50
Monthly income (% , Rs)	26.67 (10,001-15,000)	26.67 (<5000)
Duration of illness (% , months)	36.67(10-20)	33.33(21-40)
Duration of hemodialysis (% , cycles)	36.67(11-40)	50 (11-40)
Duration of A.V.Fistula access use (% , months)	43.33(6-10)	36.67 (6-10)
Frequency of taking hemodialysis Per week (%)	twice (93.33)	twice ( 86.67 )

**Table 3: Distribution of the patients according to the pain score observed by VAS and objective pain behaviour checklist**

Day	n=60 (n1=30; n2=30)			
	Subjective pain score (% ,score)		Objective pain score (% , range)	
	Experimental	Control	Experimental	Control
Day-1 (before cryotherapy)	66.67(4-6; moderate)	60(4-6; moderate)	60(2.47-5.73; moderate)	60 (2.17-5.63, moderate)
Day-2	83.3 (1-3; mild)	60(4-6; moderate)	80(0.71-2.35; mild)	60 (2.17-5.49, moderate)

**Table 4: Comparison of the objective and subjective pain scores on Day-1 and 2 of hemodialysis among two groups**

Pain Scores	n=60 (n1=30; n2=30)			
	Subjective mean pain score		Objective mean pain score	
	Experimental	Control	Experimental	Control
Day-1 (before cryotherapy)	5.07	2.3	4.1	1.53
Day-2	2.3	4.53	1.53	3.83
P value	0.001	0.001	0.001	0.001

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