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

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Abstract

Introduction: Chronic kidney disease (CKD) is one of the most devastating medical, social and economic problems for patients and their families in our country. Patients undergoing hemodialysis are repeatedly exposed to pain from approximately 300 punctures per year. Therefore, pain assessment and management are considered as the nursing priority and one of the important aspects of clinical nursing and one of the therapies to reduce pain is cryotherapy. A quasi-experimental study was conducted to evaluate the effectiveness of cryotherapy on pain during arteriovenous fistula puncturing among hemodialysis patients in the dialysis unit of Safdarjung Hospital, New Delhi.

Methods: The research approach adopted was experimental research approach using quasi-experimental research design. The independent variable of the study was cryotherapy and the dependent variable was pain during AV fistula puncture. The present study was conducted in the dialysis unit of Safdarjung Hospital, New Delhi. The sample consisted of patients with CKD receiving hemodialysis through AV fistula on their arm. The selection of the sample was done by non-probability purposive sampling technique followed by random assignment of 60 subjects to experimental and control groups. Three tools were utilized to collect the data.

Results: Results revealed that the mean pain score in experimental and control groups were 7.7 and 7.8 respectively, but in experimental group the mean pain score continued to decrease, which shows reduction of pain in experimental group as evident from mean pain scores of 7.7 and 2.5 on 1st and 7th day respectively. The mean pain score in control group does not show any major changes in score, indicating no significant decrease in pain score.

Conclusion: It was concluded that cryotherapy was able to reduce the intensity of pain due to AV fistula puncture in hemodialysis patients. It can be used as a non-pharmacological intervention and is a simple and inexpensive therapy.

Keywords: Effect, AV fistula puncture related pain, Cryotherapy
Introduction

Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. Chronically kidney disease (CKD) is a progressive irreversible deterioration in renal function in which body’s ability to maintain metabolic, fluid and electrolyte balance fails. It is now emerging as a public health problem globally. In India, the projected number of deaths due to chronic disease was around 5.21 million in 2008 and is expected to rise to 7.63 million in 2020 (66.7% of all deaths). According to National Kidney Foundation Dialysis Outcome Quality Initiative (DOQI) 2005, AV fistula remains as a gold standard for vascular access in hemodialysis patients.

Pain during arteriovenous fistula cannulation remains a common problem in hemodialysis patients. Therefore, pain assessment and management is considered as the nursing priority and one of the important aspects of clinical nursing. Investigator in dialysis unit observed that patients undergoing hemodialysis through arteriovenous fistula reported severe pain during arteriovenous fistula puncture. So the investigator felt the dire need to study the effect of cryotherapy on arteriovenous fistula puncture-related pain which will be helpful.

Studies have also thrown light on the fact that cold therapy (cryotherapy) is one of the effective cutaneous stimulation techniques in alleviating pain. Cryotherapy is defined as the use of a substance that is applied to the body to decrease tissue temperature. The effect of cutaneous stimulation is best explained through gate control theory proposed by Melzac in 1965.

A study was conducted to evaluate the effectiveness of hoku point ice massage versus local anesthetic ointment during arteriovenous fistula puncturing among hemodialysis patients in terms of pain and anxiety in Safdarjung Hospital, New Delhi. It was concluded that both hoku point ice massage and local anesthetic ointment were able to reduce pain and anxiety due to AV fistula puncture in hemodialysis patients but hoku point ice massage was found to be more effective in reducing pain than local anesthetic ointment. Thus it was recommended as a non-pharmacological intervention for pain relief during AV fistula puncture in hemodialysis patients.

Objectives

- To assess the pre-interventional pain score during arteriovenous fistula puncturing among hemodialysis patients in experimental and control group.
- To assess the impact of cryotherapy on pain score during arteriovenous fistula puncturing among hemodialysis patients by comparing pre- and post-interventional pain scores in experimental group.
- To determine the impact of cryotherapy on pain score during arteriovenous fistula puncturing among hemodialysis patients by comparing the findings of experimental and control group.
- To identify the association between the post-interventional pain scores during arteriovenous fistula puncturing among hemodialysis patients and selected demographic variables like age, gender, duration of AV fistula, and duration of hemodialysis.

Materials and Methods

The research approach adopted was experimental research approach, using quasi-experimental research design. The independent variable of the study was cryotherapy and the dependent variable was pain during AV fistula puncture. The final study was conducted in the dialysis unit of Safdarjung Hospital, New Delhi. The population in the present study comprised patients with chronic kidney disease undergoing maintenance hemodialysis in Safdarjung Hospital, New Delhi. In the present study, the sample comprised patients with CKD undergoing maintenance hemodialysis through AV fistula in Safdarjung Hospital, New Delhi, during the data collection period. In the present study, non-probability purposive sampling was the sampling technique. The selection of samples was purposive but assignment of samples to the experimental and control group was random through lottery method. The final study was conducted on 60 patients undergoing hemodialysis through AV fistula (30 in the experimental group, 30 in the control group). Three tools were utilized to collect data – an interviewing questionnaire to assess sociodemographic and medical data, Abbey Pain Scale to assess objective pain behavior and 0–10 Numeric Pain Scale to assess subjective pain.

In order to measure the content validity, the tool was given to nine experts. To check the reliability for numerical pain rating scale and Abbey pain assessment scale inter-observer reliability was computed. The reliability coefficient was calculated using coefficient of correlation ‘r’ by Rank order formula, which was found to be 0.86 and 0.81 respectively. The tools were found to be reliable.

Administrative approval was obtained from the Ethical Committee and Administrative head of Safdarjung Hospital, New Delhi, for the try out, pilot study and final study. Written informed consent was obtained from the patients after explaining the purpose of the study. Confidentiality and anonymity was assured and maintained throughout the study. Formal administrative permission was obtained from the head of department of Nephrology, Safdarjung Hospital, New Delhi. Data collection started from 16th December, 2017 to 7th January, 2018, from hemodialysis patients.

All patients who met the criteria were selected by purposive sampling and assigned to experimental and control groups. In the first visit, the researcher initiated data collection by...
assessing sociodemographic data and medical data through interviewing each participant individually using tool 1. A technician of the unit performed the puncture of AV fistula according to the unit schedule and the researcher assessed objective pain behavior during the AV fistula puncture to determine the objective pain scoring using tool 2. Patients were asked after the AV fistula puncture to tick on the numerical pain rating scale to indicate how strong their pain was during AVF puncture using tool 3. On second visit, cryotherapy intervention was applied in the dialysis unit to the experimental group while no intervention was given to the control group. This cold application was done with ice cubes wrapped in gloves on the web between the thumb and index finger of the hand not having AV fistula (contra lateral arm). This procedure was started two minutes before the puncture and continued throughout the puncture procedure (approximately two minutes). The researcher herself performed the ice massage while the technician performed the AVF puncture. During AVF puncture, the researcher assessed objective pain behavior for each participant by using tool 2 and after AVF puncture, the researcher assessed subjective pain for each participant by using tool 3. These assessments were done during the third and fourth visits to the patients, and then a comparison between both objective and subjective pain scores at AV fistula puncture site before and after cryotherapy was done by the researcher.

Results

The results of the present study are divided into the following sections:

Section I: Description of Sample Characteristics

Table 1. Frequency and Percentage Distribution of Demographic Characteristics of Samples by Age, Gender, Religion, Duration of Hemodialysis, Duration of AV Fistula, Duration of Disease and Chronic Disease

| S. No. | Sociodemographic Data                | Experimental Group | Control Group | Combined |
|-------|--------------------------------------|--------------------|---------------|----------|
|       |                                      | F                | %            | F        | %        | F    | %        |
| 1.    | Age (Years)                          |                   |               |          |          |
|       | 20–30                                | 4                 | 13.34         | 5        | 16.67    | 9    | 15       |
|       | 31–40                                | 6                 | 20            | 7        | 23.3     | 13   | 21.67    |
|       | 41–50                                | 11                | 36.67         | 12       | 40       | 23   | 38.33    |
|       | 51–60                                | 9                 | 30            | 6        | 20       | 15   | 25       |
| 2.    | Gender                               |                   |               |          |          |
|       | Male                                 | 19                | 63.34         | 22       | 73.34    | 41   | 68.33    |
|       | Female                               | 11                | 36.6          | 8        | 26.6     | 19   | 31.6     |
| 3.    | Religion                             |                   |               |          |          |
|       | Hindu                                | 17                | 56.6          | 15       | 50       | 32   | 53.3     |
|       | Muslim                               | 9                 | 30            | 10       | 33.3     | 19   | 31.67    |
|       | Sikh                                 | 4                 | 13.3          | 3        | 10       | 7    | 11.67    |
|       | Christian                            | 0                 | 0             | 2        | 6.66     | 2    | 3.32     |
| 4.    | Duration of disease (Years)          |                   |               |          |          |
|       | 5 years and less                     | 28                | 93.34         | 25       | 83.34    | 53   | 88.34    |
|       | More than 5 years                    | 2                 | 6.66          | 5        | 16.66    | 7    | 11.66    |
| 5.    | Duration of hemodialysis             |                   |               |          |          |
|       | Once a week                          | 5                 | 16.66         | 4        | 13.33    | 9    | 15       |
|       | Twice a week                         | 14                | 46.66         | 16       | 53.34    | 30   | 50       |
|       | Thrice a week                        | 11                | 36.67         | 10       | 33.33    | 21   | 35       |
| 6.    | Duration of AV Fistula (Years)       |                   |               |          |          |
|       | 0–2                                  | 18                | 60            | 16       | 53.33    | 34   | 56.67    |
|       | 3–5                                  | 10                | 33.33         | 9        | 30       | 19   | 31.66    |
|       | 6–8                                  | 2                 | 6.66          | 5        | 16.67    | 7    | 11.66    |
| 7.    | Chronic diseases                     |                   |               |          |          |
|       | Hypertension                         | 12                | 40            | 8        | 26.67    | 20   | 33.34    |
|       | Hepatitis C                          | 0                 | 0             | 1        | 3.33     | 1    | 1.66     |
|       | Diabetes                             | 10                | 33.34         | 9        | 30       | 19   | 31.66    |
|       | COPD                                 | 8                 | 26.67         | 12       | 40       | 20   | 33.33    |
Section II: Computing “t” Value to Find out Significant Difference between Pre-Test and Post-Test Pain Scores of Experimental Group

Table 2. Comparison of Pain Score after Cryotherapy in Experimental Group by Numerical Pain Rating Scale

| Group          | Observation         | Mean | Mean Difference | Standard Deviation Difference | Standard Error of Mean Difference | t-value |
|----------------|---------------------|------|-----------------|-------------------------------|-----------------------------------|---------|
| Experimental   | First visit         | 7.7  | 1.8             | 0.06                          | 0.163                             | 11.04*  |
| group          | (Pre-intervention)  | 5.9  |                 |                               |                                   |         |
|                | Second visit        | 7.7  | 3.4             | 0.14                          | 0.162                             | 22.67*  |
|                | (post-intervention) | 4.3  |                 |                               |                                   |         |

Data in Table 2 shows that the mean pain score in experimental and control group is 7.7 and 7.8 respectively, but in experimental group the mean pain score continues to decrease, which shows reduction in pain in experimental group as evident from pain scores of 7.7 and 2.5 on 1st and 7th day respectively.

The mean pain score in control group does not show any major changes in score indicating no significant decrease in pain score.

Table 2a. Comparison of Pain Score after Cryotherapy in Experimental group by Abbay Pain Assessment Scale

| Group          | Observation         | Mean | Mean Difference | Standard Deviation Difference | Standard Error of Mean Difference | t-value |
|----------------|---------------------|------|-----------------|-------------------------------|-----------------------------------|---------|
| Experimental   | First visit         | 11.1 | 2.8             | 0.48                          | 0.23                              | 12.17   |
| group          | Second visit        | 8.3  |                 |                               |                                   |         |
|                | First visit         | 11.1 | 4.2             | 0.84                          | 0.29                              | 14.49   |
|                | Third visit         | 6.9  |                 |                               |                                   |         |
|                | First visit         | 11.1 | 5.2             | 0.68                          | 0.22                              | 23.64   |
|                | Fourth visit        | 5.9  |                 |                               |                                   |         |

Data given in Table 2a indicates a significant decrease in pain scores after cryotherapy in experimental group.

Section II B: Computing “t” Value to Find out the Significance of Mean Difference between Post-Test Pain Scores in Experimental and Control Group by Numerical Pain Rating Scale

Table 3

| Group          | Observation         | Mean | Mean Difference | Standard Deviation Difference | Standard Error of Mean Difference | t-value |
|----------------|---------------------|------|-----------------|-------------------------------|-----------------------------------|---------|
| Experimental   | Second visit        | 5.9  | 1.5             | 0.10                          | 0.197                             | 7.6*    |
| Control group  | Second visit        | 7.4  |                 |                               |                                   |         |
| Experimental   | Third visit         | 4.3  | 3.2             | 0.14                          | 0.152                             | 21.05*  |
| Control group  | Third visit         | 7.5  |                 |                               |                                   |         |
| Experimental   | Forth visit         | 2.5  | 5.3             | 0.25                          | 0.168                             | 31.5*   |
| Control group  | Fouth visit         | 7.8  |                 |                               |                                   |         |

Data represented in Table 3 shows mean pain score in experimental and control group on day 3 as 5.9 and 7.4 respectively. For day 5, mean pain score in experimental and control group is 4.3 and 7.5 respectively and for day 7 mean pain score in experimental and control group is 2.5 and 7.8 respectively. It means that cryotherapy decreases the pain level in patients during AV fistula puncture.
Computing “t” Value to Find out the Significance of Mean Difference between Post Test Pain Scores in Experimental and Control Group by Abbay Pain Assessment Scale

Table 3a. Comparison of Pain in Experimental and Control group by Abbay Pain Assessment Scale

| Group | Observation | Mean | Mean Difference | Standard Deviation Difference | Standard Error of Mean Difference | t-value |
|-------|-------------|------|-----------------|-------------------------------|-----------------------------------|---------|
|       | Experimental group |        |                 |                               |                                   |         |
|       | Second visit | 8.3  | 1.91            | 0.30                          | 0.21                              | 9.05    |
|       | Second visit | 10.2 |                  |                               |                                   |         |
|       | Third visit | 6.9  | 3.9             | 0.06                          | 0.152                             | 25.6    |
|       | Third visit | 10.8 |                  |                               |                                   |         |
|       | Fourth visit | 5.9  | 5.6             | 0.03                          | 0.18                              | 31.1    |
|       | Fourth visit | 11.5 |                  |                               |                                   |         |

*t value* df (58) level=2, *=significant at 0.05 level

Data represented in Table 3a also shows that cryotherapy decreases the pain level in patients during AV fistula puncture.

SECTION III: Findings related to Association of Pain after Cryotherapy with Selected Factors Age, Sex, Duration of AV Fistula and Duration of Disease

Table 4. Chi-Square Values Showing Association between Post-Intervention Pain Scores and Selected Factors in Experimental Group

| S. No. | Sample Characteristics | Pain Scores df | Obtained Chi-Square Value ($X^2$) | Table Value of Chi-Square |
|--------|------------------------|----------------|----------------------------------|---------------------------|
| 1      | Age (in Years)         |                |                                  |                           |
|        | 20–30                  | 1              | 3                                | 0.642<sup>**NS**</sup>   | 7.815                     |
|        | 31–40                  | 2              | 4                                |                           | 3.841                     |
|        | 41–50                  | 6              | 5                                |                           |                           |
|        | 51–60                  | 6              | 3                                |                           |                           |
| 2      | Gender                 |                |                                  |                           |
|        | Male                   | 10             | 9                                | 4.08<sup>**</sup>        | 3.841                     |
|        | Female                 | 2              | 9                                |                           |                           |
| 3      | Duration of hemodialysis |              |                                  |                           |
|        | Once a week            | 2              | 3                                | 0.112<sup>**NS**</sup>   | 5.991                     |
|        | Twice a week           | 6              | 8                                |                           |                           |
|        | Thrice a week          | 4              | 7                                |                           |                           |
| 4      | Duration of AV fistula |                |                                  |                           |
|        | 0–2                    | 7              | 11                               | 1.77<sup>**NS**</sup>    | 5.991                     |
|        | 3–5                    | 5              | 5                                |                           |                           |
|        | 6–8                    | 0              | 2                                |                           |                           |

N=30

Data presented in Table 6 shows that only in gender Chi-square is significant at 0.05 level of significance. The computed Chi-square values of other selected variables, i.e., age, duration of hemodialysis, and duration of AV fistula are not significant at 0.05 level of significance.

Discussion

The aim of the study was to assess the effectiveness of cryotherapy on pain related to arteriovenous fistula puncture among patients on hemodialysis in experimental and control groups. The result of the present study revealed that the mean age of studied sample was 41 to 50 years. This is near to the result of El-Gahsh who reported that the studied samples’ mean age was 41.5±10.7years for experimental group and 46.6±10.6years for control group. This may be related to the statement by Abou Elsood that renal function decrease gradually with increasing age.

 Concerning sex, the present study showed that more than half of the studied samples were male. This study was in line with Ahmed and Faheem et al., who found that more than half of their sample was male. Related to the duration of the AV fistula, it was noted from the present study that the majority of the sample had fistula for 0–2 years. In a similar study done by Hassan, the mean duration was...
3.26 years.\textsuperscript{11} Also Celik et al. found that the mean age of AVF was 4.0±3.3 years.\textsuperscript{12} These researchers attribute the short age of AVF may be due to failure of vascular access.\textsuperscript{12}

Regarding the presence of other chronic diseases, it was found that 1.66\% of studied sample had hepatitis C. This result is inconsistent with the result of Sabitha et al. who stated that minority of studied subjects had positive hepatitis C.\textsuperscript{13} Also less than half of the current sample had hypertension. This is in line with Elham et al., who reported that hypertension is one of the most common complications of hemodialysis.\textsuperscript{14} Sabitha et al. noted that females reported higher pain scores when compared to males.\textsuperscript{13} These results are in accordance to the result of the present study that showed that females reported higher pain scores when compared to males.

The author, therefore, concludes that cryotherapy is effective in reducing AV fistula puncture pain of hemodialysis patients.

\textbf{Conclusion}

It was concluded that cryotherapy was able to reduce the intensity of pain due to AV fistula puncture in hemodialysis patients. It can be used as a non-pharmacological intervention and is recommended as a pain-relief technique during AV fistula puncture in hemodialysis patients, irrespective of age and sex, and is a simple and inexpensive therapy.

\textbf{Conflict of Interest:} None

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