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Effect of Contrast Bath on Level of Neuropathic Pain Among Patients with Type 2 Diabetes Mellitus

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ABSTRACT

Diabetic neuropathy is a chronic sequela of DM and contrast bath is a non-pharmacological treatment modality which can reduce neuropathic pain among them. The present study was intended to assess the effect of contrast bath on level of neuropathic pain among patients with T2DM. The main objectives of the study were to assess the level of neuropathic pain among patients with T2DM, assess the effect of contrast bath on level of neuropathic pain and to determine the association between the neuropathic pain and socio demographic and clinical variables. The research approach was quantitative and the design adopted was quasi experimental. Sample consists of 60 patients with T2DM having neuropathic pain attending OPDs of Ananthapuri hospital selected by consecutive sampling technique. The conceptual framework adopted for the study was Wiedenbach's Prescriptive theory. A structured interview schedule was used to collect socio demographic and clinical variables and Galer Neuropathy Pain Scale for assessing the neuropathic pain. Pre-test was done for both groups. After explanation and ensuring safety contrast bath was administered to experimental group for 20 minutes. Post-test was done by using the same tool for both experimental and control group. Mean, frequency, percentage were used to describe the data. Independent t test was used to assess the effect of contrast bath and association of level of neuropathic pain with socio demographic and clinical variables. The results revealed statistically significant ($p<0.01$) difference in the mean score of neuropathic pain in the experimental and control group after intervention. There was no significant association between level of neuropathic pain and socio demographic and clinical variables. The study infers that contrast bath is a simple non pharmacological home-based cost-effective intervention which can improve the daily functional abilities of patients with DM and thereby enhancing their quality of life.

Keywords: Type 2 Diabetes Mellitus; Diabetic Peripheral Neuropathy; Contrast Bath.

INTRODUCTION

Diabetes mellitus is a chronic multisystem disease related to abnormal insulin production, impaired insulin

utilization, or both.[1] Globally, the number of people with diabetes mellitus has quadrupled in the past three decades, and diabetes mellitus is the ninth major cause of death. About 1 in 11 adults worldwide now have diabetes mellitus, 90% of whom have type 2 diabetes mellitus (T2DM). Asia is a major area of the rapidly emerging T2DM global epidemic, with China and India the top two epicenters. Although genetic predisposition partly determines individual susceptibility to T2DM, an unhealthy diet and a sedentary lifestyle are important drivers of the current global epidemic; early developmental factors (such as intrauterine exposures) also have a role in susceptibility to T2DM later in life.[2]

T2DM is an expanding global health problem, closely linked to the epidemic of obesity. Individuals with T2DM are at high risk for both microvascular complications (including retinopathy, nephropathy and neuropathy) and macrovascular complications (such as cardiovascular comorbidities), owing to hyperglycemia and individual components of the insulin resistance (metabolic) syndrome. Environmental factors (for example, obesity, unhealthy diet and physical inactivity) and genetic factors contribute to the multiple pathophysiological disturbances that are responsible for impaired glucose homeostasis in T2DM. The global epidemic of prediabetes and diabetes has led to a corresponding epidemic of complications of these disorders. The most prevalent complication is neuropathy, of which distal symmetric polyneuropathy (for the purpose of this Primer, referred to as diabetic neuropathy) is very common. Diabetic neuropathy is a loss of sensory function beginning distally in the lower extremities that is also characterized by pain and substantial morbidity. Over time, at least 50% of individuals with diabetes develop diabetic neuropathy.[3] Diabetic neuropathy is a condition in which the nerves are damaged due to chronic uncontrolled blood sugar levels. The condition is thought to be as a result from a diabetic micro-vascular injury involving small blood vessels that supply nerves (vasa nervorum). The most common and debilitating microvascular complication of diabetes is Diabetic Peripheral Neuropathy (DPN), affecting 50-90% of people with diabetes.[4] Diabetic neuropathy affects all the peripheral nerves including sensory and motor nerves. Initially there is progressive loss of sensation as a result of axonopathy and demyelination of small and large fiber nerves. As the condition progresses, there is some level of motor deficits seen in the patients.[5]

Statement of the problem

A study to assess the effect of contrast bath on level of neuropathic pain among patients with type 2 diabetes mellitus in a selected Tertiary Care Hospital, Thiruvananthapuram.

Objectives of the study

1. Assess the level of neuropathic pain among patients with type 2 diabetes mellitus.
2. Assess the effect of contrast bath on level of neuropathic pain among patients with type 2 diabetes mellitus.
3. Determine the association between the neuropathic pain and socio demographic variables among patients with type 2 diabetes mellitus.
4. Determine the association between neuropathic pain and clinical variables among patients with type 2 diabetes mellitus.

Operational definitions

Effect: Effect refers to the result or outcome of a cause.[6]

In this study effect refers to the outcome of contrast bath, measured as the difference in the level of neurop-

athic pain among patients with type 2 diabetes mellitus, assessed by Galer Neuropathy Pain Scale.

Contrast Bath: Contrast bath refers to a thermal modality whereby the part of a body is alternately immersed in hot and cold water for a specified temperature, time, and duration to therapeutically decrease edema, stiffness, and pain.[7]

In this study contrast bath refers to the alternative immersion of feet of patients with type 2 diabetes mellitus in warm water (100-1050F) for 3 minutes and cold water (60-700F) for 1 minute and repeated for 5 cycles with a total duration of 20 minutes.

Neuropathic Pain: Neuropathic pain refers to the chronic pain resulting from injury to the central or peripheral nervous system.[8]

In this study neuropathic pain refers to the discomfort experienced in the feet, manifested by sharpness, dullness, itching and over all unpleasantness among patients with type 2 diabetes mellitus, assessed by Galer Neuropathy Pain Scale.

Patients with type 2 Diabetes Mellitus: Diabetes Mellitus refers to a group of metabolic diseases characterized by increased level of glucose in the blood resulting from defects in insulin secretion, insulin action, or both.[1]

In this study patients with diabetes mellitus refers to the clients medically diagnosed as type 2 diabetes mellitus for more than 5 years and having neuropathic pain in the foot.

Hypothesis

H1: There is statistically significant difference in neuropathic pain after contrast bath among patients with type 2 diabetes mellitus.

H2: There is statistically significant association between neuropathic pain and socio demographic and clinical variables among patients with type 2 diabetes mellitus.

Conceptual framework

The conceptual frame work of the present study is based on Wiedenbach's prescriptive theory (1969), which is described as a system of conceptualizations invented to serve some purpose. Theory conceptualizes both a desired situation and the prescription by which it is to be brought about. Thus, a prescriptive theory directs action toward an explicit goal.[9]

This study was based on the concept that the contrast bath helps to reduce the level of neuropathic pain among patients with type 2 diabetes mellitus. The investigator adopted the Wiedenbach's prescriptive theory as a base for developing the conceptual framework.

The prescriptive theory is made up of 3 factors or concepts

a. The Central purpose
b. Prescription
c. Realities

The Central purpose: The nurse's central purpose defines the quality of health she desires to affect or sustain in her patient and specifies what she recognizes to be her special responsibility in caring for the patient.

In this study the central purpose is to assess the effect of contrast bath on level of neuropathic pain among patients with type 2 diabetes mellitus.

The prescription: Once the nurse has identified her own philosophy and recognize that the patient has autonomy and individuality, she can work with the individuals to develop a prescription or plan for his

care.

In this study the prescription is the administration of contrast bath to type 2 diabetic patients having neuropathic pain.

The Realities: when the nurse has determined her central purpose and has developed the prescription, she must then consider the realities of the situation in which she has to provide nursing care. Realities consists of all factors such as: physical, physiological, psychological, emotional and spiritual factors.

Wiedenbach defines the 5 realities as: -

1. **Agent:** One who directs all action towards the goal and has capacities, capabilities, commitment and competence to provide care.
   In this study agent is the researcher who directs all the action towards the goal.
2. **Recipient:** One who is vulnerable and dependent and receives all attention.
   Here it was the patients with type 2 diabetes mellitus having neuropathic pain attending the Outpatient Department of Ananthapuri Hospitals and Research Institute, Thiruvananthapuram.
3. **Goals:** It refers to the desired outcome the nurse wishes to achieve. The goal is the end result to be attained.
   In this study goal refers to reduction in the level of neuropathic pain among patients with type 2 diabetes mellitus.
4. **Means:** The means comprises the activities and devices through which the practitioner is enabled to attain her goal. The means include skills, techniques, procedures, and devices that may be used to facilitate nursing practice.
   In this study means refers to the technique of administering contrast bath by using hot and cold water at desired temperature to the experimental group for reducing the neuropathic pain.
5. **The Frame work:** It consists of the human, environmental, professional, and organizational facilities that not only make up the context within which nursing is practiced but also constitute its currently existing limits.

Here the frame work refers to the Outpatient Departments of Ananthapuri Hospitals and Research Institute where patients with T2DM who seek help for their ailments and disease.

Nursing practice

The practice of nursing comprises a wide variety of services, each directed toward the attainment of one of its three components namely identification, Ministration and validation;

Identification of the patient's need for help

The study refers identification of type 2 diabetic patients having neuropathic pain using socio demographic and clinical profile and assessment of neuropathic pain using Galer neuropathy pain scale.

Ministration of the help needed

In this study ministration refers to the administration of contrast bath that is alternate immersion of feet in warm water (100-105 0F) for 3 minutes and cold water (60-70 0F) for 1 minute. The investigator does contrast bath for 5 cycles with a total duration of 20 minutes.

Validation that the help provided was indeed helpful to the patient.

It refers to a collection of evidence that shows if the client's need has been met and that his functional ability has been restored as a direct result of the nurse's action. This step involves the posttest assessment after ministering the contrast bath and the comparison/analysis to infer the outcome. This approach there

by enabled the researcher to make suitable decision and recommended action to continue, drop or modify the nursing action. The expected outcome of selected nursing intervention, contrast bath was to reduce the level of neuropathic pain by the researcher which will be designated as mild, moderate and severe pain.
Reassessment- If there was no reduction in the level of neuropathic pain after providing contrast bath the researcher recommends for reinforcement.
Enhancement- If there was reduction in the level of neuropathic pain after providing contrast bath, enhancement of the intervention was encouraged.

METHODOLOGY

Research approach: Quantitative research approach

Research design: The research design adopted for the present study was Quasi Experimental pre -test post -test design.

Variables

- **Independent variable:** Contrast bath (warm and cold bath).
- **Dependent variable:** Level of Neuropathic Pain**.**

Setting of the study

The study was conducted in the General Medicine Outpatient departments of Ananthapuri Hospitals and Research Institute, Thiruvananthapuram.

Population

The study population comprised of all patients with type 2 diabetes mellitus having neuropathic pain residing in Thiruvananthapuram district.

Sample

Patients with type 2 diabetes mellitus having neuropathic pain attending General Medicine outpatient departments of Ananthapuri hospitals and research institute, Thiruvananthapuram constituted the samples in the present study.

Sample size

Sample size was calculated using the formula

$$N = \frac{2\,(Z\alpha + Z\beta)^2\,\sigma^2}{\Delta^2}$$

Considering 10% attrition rate the sample size was upsized as 60.
Experimental group : 30
Control group : 30

Sampling Technique: Patients attending the Outpatient Departments of General medicine who met the inclusion criteria were taken consecutively in the experimental group and control group.

Inclusion Criteria

1. Clients with diabetes mellitus more than 5 years having neuropathic pain.
2. Clients who can understand Malayalam or English.

Exclusion Criteria

1. Clients who have swelling in leg, foot ulcers or gangrene.
2. Client who has intolerance to cold/warm temperature.
3. Clients with severe visual/hearing impairment.

4. Client on pain medications
5. Client with loss of sensation in the foot.
6. Seriously ill clients

Tools and technique

Tools used for data collection in the present study were

Tool 1: Interview schedule to assess socio demographic and clinical variables which consist of 2 sections.

- Section A: socio demographic variables
- Section B: Clinical variables

Tool 2: Galer Neuropathy Pain scale

Score	**Level of Neuropathic Pain**
≤ 50	Mild neuropathic pain
51-75	Moderate neuropathic pain
>75	Severe neuropathic pain

Technique: The data was collected from the study participants using interview technique and observation method.

Data collection process

The data was collected by obtaining permission from the institutional ethical committee, concerned hospital and departmental authorities of Ananthapuri Hospitals and Research Institute and written informed consent from the participants. The data was collected from 2 different General Medicine OPDs at different point of time using consecutive sampling technique. 60 participants, 30 in experimental and 30 in control group who met the inclusion criteria were selected for the study. Pre-test was done for both groups using structured interview schedule and Galer Neuropathy Pain scale. After proper explanation and convincing the importance of the procedure the investigator administered contrast bath to the experimental group in a separate room in OPD for providing privacy. The total duration of the contrast bath was 20 minutes and throughout the procedure the safety of the participants while hot and cold application was ensured. Post-test level of neuropathic pain was assessed by using the same tool among experimental group immediately after completing the procedure. Instruction was also given to them to practice the same in their home settings. Post-test from the control group was taken after completing their hospital routines before returning to their home. In order to avoid data contamination, the participants for control group and experimental group were taken from 2 different OPDs at different point of time.

DATA ANALYSIS

Data collected was analysed by using appropriate descriptive and inferential statistics using SPSS version 16. Descriptive statistics like frequency, percentage, mean and SD were used to describe the sample characteristics. Effect of contrast bath on neuropathic pain in the experimental and control group was assessed by using independent t test. Association of neuropathic pain with socio demographic and clinical variables was computed by using independent t test.

RESULT

Assessment of pre-test and post-test level of neuropathic pain among patients with type 2 diabetes mellitus.

In pretest both in experimental and control group 93.3% of participants were having moderate level of neuropathic pain and 6.7% with severe pain. After intervention 56.7% of the participants neuropathic pain were changed to mild level and 43.3% with moderate pain and none of them had severe level of neuropathic pain. In control group all the participants level of neuropathic pain remained the same.

Effect of contrast bath on level of neuropathic pain among patients with type 2 diabetes mellitus.

The mean score and SD of level of neuropathic pain in pre-test was 66.1±4.41 in the experimental group and 64.9±5 in the control group. In the post test mean score and SD of experimental group was 56.5±4.43 and in the control group it was 63.1±4.4. The post-test difference in the mean score of neuropathic pain in the experimental and control group was found to be statistically significant ($p<0.01$). Hence the alternative hypothesis H1: There is statistically significant difference in neuropathic pain after contrast bath among patients with type 2 diabetes mellitus was accepted.

Association of the neuropathic pain with socio demographic variables among patients with type 2 diabetes mellitus

There was no statistically significant association between neuropathic pain and socio demographic variables such as age, gender, place of residence, education, occupation, monthly income, type of family, dietary habits, adverse health status and family history of diabetes among patients with type 2 diabetes mellitus.

Association of neuropathic pain with clinical variables among patients with type 2 diabetes mellitus.

Statistically significant association was not found between neuropathic pain and clinical variables such as duration of diabetes mellitus, treatment of diabetes mellitus, co morbidities, duration of neuropathic pain, intake of vitamin supplements, pain on foot when injured, delay in wound healing on foot, use specialty type of footwear, regular follow up, RBS and HbA1C value among patients with type 2 diabetes mellitus. Hence the hypothesis H2: There is a statistically significant association between neuropathic pain and socio demographic and clinical variables among patients with type 2 diabetes mellitus, was rejected.

DISCUSSION

In the present study while assessing the level of neuropathic pain it was found that in both experimental and control group 93.3% of participants were having moderate level of neuropathic pain and 6.7% with severe pain and none of them had mild level of neuropathic pain. Virtually similar findings were obtained in a study conducted in Uttar Pradesh and Chennai, shows that 73.33% of the participants in experimental group were having severe neuropathic pain, 26.67% had moderate pain and none of them had mild pain. Whereas in the control group, 60% had moderate level of neuropathy pain, 40% had severe level of neuropathic pain and none of them had mild neuropathic pain.[10,11]

Findings from another study showed that in experimental group, 13.33% had severe level of neuropathic pain whereas in control group, 23.33% had severe pain. 60% in experimental group and 53.34% in control group had moderate level of neuropathic pain and 26.67% in experimental group and 23.33% in control group had mild level of neuropathic pain. [11]

The effect of contrast bath on level of neuropathic pain among patients with type 2 diabetes mellitus was assessed in the present study. The findings depicted that the mean score and SD of level of neuropathic pain in pre-test as 66.1 ± 4.41 in the experimental group and 64.9 ± 5 in the control group. The post-test

mean score and SD of experimental group was found to be 50.5± 4.43 and in the control group it was 63.1 ± 4.9. The post-test difference in the mean score of neuropathic pain after intervention in the experimental and control group was found to be statistically significant ($p<0.01$). Several studies were conducted in India to observe the effect of contrast on level of neuropathic pain among patients with T2DM and all studies reported congruent findings with the present study, which showed statistically significant difference in the post test level of neuropathic pain among clients with DM in experimental and control group ($p<0.001$). [10,11,12]

While assessing the association between level of neuropathic pain and selected socio demographic and clinical variables among patients with type 2 diabetes mellitus it was found that even though some of the variables like educational status, dietary habits, duration of DM, regular follow up for DM, RBS and HbA1C value showed clinically significant difference in neuropathic pain, statistically significant association was not observed among any of the socio demographic and clinical variables. A study conducted in Chennai also showed that no significant association between neuropathic pain and age, gender, religion, education, occupation, income, duration of diabetes mellitus and treatment of diabetes mellitus and comorbid illness.[11] In contrast with this finding a study report showed that significant association was observed between level of neuropathic pain and family income ($p=0.01$).[10]

SUMMARY

The present study was intended to assess the effect of contrast bath on level of neuropathic pain among patients with type 2 diabetes mellitus. The study adopted quantitative approach using pre-test post-test control group design (quasi experimental). The population of the present study comprised of all patients with type 2 diabetes mellitus having neuropathic pain residing in Thiruvananthapuram district and the samples were 60 patients with type 2 diabetes mellitus having neuropathic pain selected from a tertiary care hospital at Thiruvananthapuram district. The samples were collected from General Medicine Outpatient Departments of Ananthapuri Hospitals and Research Institute by consecutive sampling technique. The conceptual framework adopted for this study was based on Wiedenbach's prescriptive theory. Data was collected by using structured interview schedule and Galer Neuropathy Pain Scale.

The Pre-test was done for both groups using structured interview schedule and Galer neuropathy pain scale. After proper explanation and convincing the importance of the procedure the investigator administered contrast bath to the experimental group by providing privacy. The total duration of the contrast bath was 20 minutes and throughout the procedure the safety of the participants while hot and cold application was ensured. Post-test level of neuropathic pain was assessed by using same tool among experimental group after completing the procedure. Post-test from the control group was taken after completing their hospital routines, before returning to their home. In order to avoid the data contamination, the control group and experimental groups were taken from 2 different OPDs at different point of time.

Frequency, percentage, mean and SD were used to describe the data and independent t test was used to assess the effect of contrast bath and association of level of neuropathic pain with selected socio demographic and clinical variables. On analysis the result of the study findings revealed that, post-test difference in the mean score of neuropathic pain in the experimental and control group was found to be statistically significant ($p<0.01$). Hence the alternative hypothesis H1: There is statistically significant difference in neuropathic pain after contrast bath among patients with type 2 diabetes mellitus, was accepted. In the present study there was no significant association found between level of neuropathic pain and selected socio demographic and clinical variables among patients with type 2 diabetes mellitus. Hence

the hypothesis H2: There is statistically significant association between neuropathic pain and socio demographic and clinical variables among patients with type 2 diabetes mellitus, was rejected.

Conclusion

Diabetes is the most common cause of peripheral neuropathy and DPN is a leading cause of worldwide disability affecting the life of diabetic patients in all spheres. DPN is associated with chronic pain, high risk of falls causing functional impairment and altered activities of daily living. There is an alarming concern for quality-based cost-effective nursing care for patients with diabetic peripheral neuropathy. Life style intervention can help to improve the peripheral circulation thereby preventing the occurrence of foot ulceration leading to limb amputation. Contrast bath is a simple non pharmacological home-based intervention has a vital role in preventing pain among patients with DPN by increasing blood flow and vascular pumping to extremities. Thus, it enhances the functional ability and activities of daily living of patients with DM thereby improving their quality of life as near to normal.

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