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A COMPARATIVE STUDY TO ASSESS THE EFFECTIVENESS OF TOPICAL APPLICATION OF PHENYTOIN AND NORMAL DRESSING ON PATIENTS SUFFERING FROM GRADE-I AND GRADE-II PRESSURE ULCERS ADMITTED IN ADESH TERTIARY CARE HOSPITAL, BATHINDA, PUNJAB

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Abstract: This study was conducted to assess the effectiveness of topical application of Phenytoin and Normal dressing on patients suffering from Grade-I and Grade-II Pressure Ulcers. A Quasi Experimental (two group pre-test post-test) design including demographical variables and Push TOOL 3.0 was used. An evaluative approach was used to conduct this study. The results of the study showed that rate of healing among patients with Grade -I and Grade – II pressure ulcer who received topical application of Phenytoin Solution was significantly higher compared to patients with Pressure Ulcer of Grade – I and Grade – II who received topical application of Betadine and Normal saline.

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I. INTRODUCTION

The skin is the largest non-solid organ in the human body. However, the skin does not receive the same kind of attention that solid organs like heart, lungs or brain receive when they display signs of compromise. Patients admitted to the critical care units are most disadvantaged when it comes to maintaining intact skin, starting from day one of their stay. Critically ill patients may be sedated, receiving mechanical ventilation, and confined to bed for long periods. Prolonged pressure on areas where bony prominences are located predisposes these patients to pressure ulcers.[1]

A pressure injury is a “localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear.” The term pressure injury is used in this study, in line with the contemporaneous position that the word injury refers to a preventable event. Skin and mucosal pressure injuries are now differentiated; mucosal pressure injuries are found on mucous membranes with a history of a medical device in use at the location of the injury both mucosal and skin pressure injuries are due to prolonged compression of tissue that causes reduction or occlusion of microcirculation to the localized area, resulting in tissue hypoxia, edema, consequent ischemia, and (when the compression is relieved) reperfusion injury.[2]

The National Pressure Ulcer Advisory Panel (NPUAP) has revised the definition and stages of pressure injury. The revision was undertaken to incorporate the current understanding of the etiology of pressure injuries and to clarify the anatomical features present or absent in each stage of injury. A NPUAP-appointed Task Force reviewed the literature and created drafts of definitions, which were then reviewed by stakeholders and the public, including clinicians, educators, and researchers around the world. Using consensus-building methodology, these revised definitions were the focus of a multidisciplinary consensus conference held

in April 2016. As a result of stakeholder and public input, along with the consensus conference, important changes were made and incorporated into the new staging definitions. The new revised staging system uses the term injury instead of ulcer.
Pressure injuries are classified and described through the use of staging systems. Staging systems describe the extent of tissue loss and the physical appearance of the injury caused by pressure and/or shear. In 1975, J. D. Shea developed a staging system for the classification of pressure injuries, and in 1988, the International Association of Enterostomal Therapy (now the Wound, Ostomy and Continence Nurses Society), created a 4-stage system based on these classifications.[3]

Suspected deep tissue injury: Purple or maroon localized area of discolored, intact skin or blood-filled blister caused by damage to underlying soft tissue from pressure or shear; the discoloration may be preceded by tissue that is painful, firm, mushy, boggy, or warmer or cooler compared with adjacent tissue
Stage-I: Intact skin with non-blanchable redness of a localized area, usually over a bony prominence; dark pigmented skin may not have visible blanching, and the affected area may differ from the surrounding area; the affected tissue may be painful, firm, soft, or warmer or cooler compared with adjacent tissue.
Stage-II: Partial-thickness loss of dermis appearing as a shallow, open ulcer with a red-pink wound bed, without slough; may also appear as an intact or open/ruptured serum-filled blister; this stage should not be used to describe skin tears, tape burns, perineal dermatitis, macerations, or excoriations.
Stage-III: Full-thickness tissue loss; subcutaneous fat may be visible, but bone, tendon, or muscle is not exposed; slough m ay be present, but does not obscure the depth of tissue loss; may include undermining and tunneling.
Stage IV: Full-thickness tissue loss with exposed bone, tendon, or muscle; slough or eschar may be present on some parts of the wound bed; often includes undermining and tunneling.
Unstageable: Full-thickness tissue loss with the base of the ulcer covered by slough (yellow, tan, gray, green, or brown) or eschar (tan, brown, or black) in the wound bed.[4]

The mainstays of pressure ulcer treatment include offloading the offending pressure source, adequate drainage of any areas of infection, debridement of devitalized tissue, and regular wound care to support the healing process.[5]

PHENYTOIN SODIUM –Phenytoin sodium is the oldest non sedative antiepileptic drug, introduced in 1938 by Merritt and Putnam following a systematic evaluation of compounds such as phenobarbital that altered electrically induced seizures in laboratory animals. Phenytoin sodium is a Diphenyl substituted Hydantoin which is most effective drug against partial seizures and generalized tonic-clonic seizures. Phenytoin Sodium has been studied in the healing of pressure ulcers, venous stasis ulcers, diabetic ulcers, traumatic wounds and burns. Topical phenytoin sodium appears to enhance healing by promoting fibroblast proliferation, facilitation of collagen deposition, glucocorticoid antagonism and antibacterial activity. Phenytoin sodium increases gene expression of Platelet derived growth factor PGDF-b chain in macrophages and monocytes hence increases the formation of granulation formation.[6]

Prevalence studies involve a snapshot of current pressure ulcers in a given unit on a given day. Typically, the hospital assesses all patient's skin to determine if each patient exhibits the physical signs of a pressure ulcer, and if so, the pressure ulcer is staged. The incidence of pressure ulcers indicates the number of patients in whom pressure ulcers develop in a given health care setting. Multiple studies show that the incidence of pressure ulcers in the ICU ranges from 10% to 41%.[7]

There is wide variation reported in the prevalence of PUs in acute care patients, ranging from 12% to 19.7%, whereas in intensive care units (ICUs) globally, PU prevalence is reported to range from 22 to 50%. This high figure may be related to increased patient acuity in the ICU and the patient's physiological responses to critical illness. Literature suggests that the development of PUs is associated with decreased quality of life, impaired physical function, an increased incidence of infection, higher healthcare costs and increased levels of care required. Tayyib *et al.* reviewed the risk factors of PU development in ICU. Their findings revealed that older age, increased ICU length of stay, prolonged immobility, history of cardiovascular disease and administration of nor-adrenaline were key risk factors for PU development. All patients admitted to an ICU should be considered at risk of PU development. Key factors have been identified that contribute to PU development – pressure, shear, friction and moisture. Immobility exposes the critically ill patients to prolonged pressure, friction and shear disrupt skin integrity through mechanical forces between the skin and interface surface. Humidity and temperature interplay and resulting moisture leads to maceration of the skin and skin breakdown.[8]

In Indian setting, the prevalence of pressure ulcers in hospitalized patients has been reported to be 4.94%. There are many studies on the incidence of pressure ulcer. In spinal cord injury patients, pressure ulcer occurs in 30-85% of patients during the first month of injury. Also, paraplegics and quadriplegics are likely to have multiple ulcers. Patients with pressure ulcers have high mortality rates. Some studies have reported 22% mortality over 6 years follow up of 23 patients with pressure ulcers while some reported 68.8% mortality amongst elderly patients with NPUAP stage 3 and 4 pressure ulcers, because of secondary systemic complications. [9]

II Population and Sample

The population comprises the aggregate of elements showing some common set of criteria. For the present study, the population comprised of patients with pressure ulcers of Grade-I and Grade-II.
The target population is the aggregate of cases about which the researcher would like to generalize. In the present study, it includes the patients who were suffering from pressure ulcers.

Accessible population: -

The accessible population is the aggregate of case that confirm to the designated criteria and that where accessible as subjects for a study. In the present study, the accessible population was patients who were having Grade-I and Grade-II pressure ulcers at Adesh Tertiary care hospital Bathinda, Punjab.

Sample

A sample is a subset of a population. Sample consists of subject of units which comprises the population selected by the investigator or researcher to participate in the research project. Samples of the present study comprised of patients admitted in Adesh Tertiary Care Hospital in different wards who met the designated criteria.

The sample size consists of 30 patients with Grade-I and Grade-II pressure ulcers to conduct the study, where n = 15 for Phenytoin and n = 15 for Normal dressing.

Sampling

Sampling is the process of selecting a portion of the population to represent the entire population. Sampling is necessary because it is more economical and efficient to work with small group of elements. Non-Probability Purposive sampling technique was employed to collect the data.

III Development and description of the tool

Data is subset of information obtained in the course of study. The most important aspects of any investigation are the collection of appropriate information which will provide necessary data to answer the question in the study.

After an extensive review of literature and discussion with the experts, the PUSH Tool 3.0 was used to assess effectiveness of topical application of phenytoin and normal dressing on patients suffering from Grade-I and Grade-II pressure ulcers.

Description of data collection tool

In this study the data collection tool was divided into two parts

PART- I

It comprised of 15 items seeking information on Demographic data such as age in years, gender, educational status, marital status, residence, occupation, type of family, income(monthly), dietary pattern, duration of stay in hospital, area of the patient‘s stay, grade of pressure ulcer, diagnosis of patient.

PART- II

A standardized tool (PUSH Tool 3.0) was used to assess the effectiveness of topical application of phenytoin and normal dressing on patients suffering from Grade-I and Grade-II pressure ulcers. It consists of 3 items:

Length x Width: Measure the greatest length (head to toe) and the greatest width (side to side) using a centimetre ruler. Multiply these two measurements (length x width) to obtain an estimate of surface area in square centimetres (cm2). Caveat: Do not guess! Always use a centimetre ruler and always use the same method each time the ulcer is measured.

Exudate Amount: Estimate the amount of exudate (drainage) present after removal of the dressing and before applying any topical agent to the ulcer. Estimate the exudate (drainage) as none, light, moderate, or heavy.

Tissue Type: This refers to the types of tissue that are present in the wound (ulcer) bed. Score as a -4 if there is any necrotic tissue present. Score as a -3 if there is any amount of slough present and necrotic tissue is absent. Score as a -2 if the wound is clean and contains granulation tissue. A superficial wound that is epithelializing is scored as a -1. When the wound is closed, score as a -0.

IV Data and Sources of Data

For this study secondary data has been collected. From the website of KSE the monthly stock prices for the sample firms are obtained from Jan 2010 to Dec 2014. And from the website of SBP the data for the macroeconomic variables are collected for the period of five years. The time series monthly data is collected on stock prices for sample firmsand relative macroeconomic variables for the period of 5 years. The data collection period is ranging from January 2010 to Dec 2014. Monthly prices of KSE -100 Index is taken from yahoo finance.

PROCEDURE FOR DATA COLLECTION

Phase: I

Formal permission was taken from the Principal, College of Nursing, Adesh University, Bathinda for conducting the study. Written permission was taken from the Medical Superintendent of Tertiary Care Hospital, Bathinda Punjab.

Phase: II

Final data collection was done from February 2020 to March 2020.

30 patients were selected randomly. The investigator established rapport, followed by self-introduction to the subjects and getting the consent form signed.

Phase: III

Total samples of the main study consisted of 30 patients having Grade-I and Grade-II pressure ulcers. Data was collected from the samples by using PUSH TOOL 3.0 after obtaining consent from participants. Each day I was searching for the pressure ulcer patients in different wards of the Hospital and after getting the required sample dressing was done with Phenytoin for Group A of patients and with Normal saline for the Group B around for 14 days each and it took a period of 8 weeks to complete the study.

Preparation of dressing

A single 100mg phenytoin sodium capsule was opened and placed in 5ml of sterile normal saline to form a suspension. Sterile gauze was soaked in the suspension and placed over the wound at 20mg/cm2 of ulcer area in Group A of patients. Conventional dressing was done with 5% w/v povidone-iodine solution. Dressings was done on daily basis for Group B of patients.

The patients were followed up on a daily basis for 14 days in both study and control groups. Wound culture/tissue culture was obtained at the start of the treatment and 14th day of treatment. Observed or spontaneously reported side effects (local and systemic) were documented. At the end of 14 days the wounds in both the groups were inspected and compared based on the following parameters.

- Rate of granulation tissue formation as percentage of ulcer surface area
- Quality of ulcer area Present dimensions and surface area of ulcer

IV RESEARCH METHODOLOGY

The methodology of research indicates the general pattern for organizing the procedure of gathering valid and reliable data for investigation. This chapter deals with description of methodology adopted for the study. It indicates research approach, research design, the setting, the population, samples, sampling technique, development and description of tools, pilot study and procedure for data collection and plan for data analysis.

Research approach:

Research approach is the most significant part of any research. The appropriate choice of the research approach depends upon the purpose of the research study which has been undertaken. A Quantitative research approach was considered the best to assess the effectiveness of topical application of Phenytoin and Normal dressing on patients suffering from Grade-I and Grade-II pressure ulcers admitted in Adesh Tertiary care hospital.

Research design:

The selection of research design is the most important step to provide the framework for the study. The research design incorporates some of the most important methodological decision that the researcher makes in conducting the study.

Keeping in view the objectives of the study, research design selected for the present study was Quasi experimental two group pre-test post-test design without control group. The design can be represented as:

Group A	O1	X1	O2
Group B	O1	X2	O2

Where; O1 = Observation before intervention, O2 = Observation after intervention

X 1= Treatment with Phenytoin solution 5mg/ml, X2= Treatment with Normal dressing.

PLAN FOR DATA ANALYSIS

Analysis is the systematic organization and synthesizing of research data and testing of research hypothesis using this data. It was decided to analyze the data using descriptive statistics on the basis of objectives and hypothesis. The collected data was carefully recorded, analyzed, summarized and tabulated through following techniques.

Descriptive Statistics

1.Frequency percentage distribution was used to describe the socio-demographic characteristics of patients such as age, gender, educational status, marital status, residence, occupation, type of family, income(monthly), dietary pattern, duration of stay in hospital, area of the patient ‘s stay, grade of pressure ulcer, diagnosis of patient.

2.Mean and standard deviation was used to assess the effectiveness of topical application of phenytoin and normal dressing on patients suffering from Grade-I and Grade-II pressure ulcers.

Inferential statistics

Chi-square test (□2), was used to find the association between sociodemographic variables and effect of topical application of Phenytoin among patients suffering from Grade-I and Grade-II pressure ulcers.

An unpaired 't' test done to see whether there is any significant difference in Mean Post Test Scores of Group A patients receiving topical application of Phenytoin Solution 5mg/ml and Group B patients receiving topical application of Betadine and Normal Saline dressing.

A paired 't’ test was conducted to see whether the observed difference between Mean Pre Test and Mean post test scores was statistically significant.

V. RESULTS

The results of the study showed that rate of healing among patients with Grade -I and Grade – II pressure ulcer who received topical application of Phenytoin Solution was significantly higher compared to patients with Pressure Ulcer of Grade – I and Grade – II who received topical application of Betadine and Normal saline.

Table No: 1 Mean, Mean difference, Standard deviation and paired „t" value of level of scores between group before and after intervention.

Mean, Mean difference, Standard deviation and unpaired „t" value of level of scores between group A and group B before and after intervention.

N=30

		PUSH SCORE				Paired T Test		
		Pre test		Post test				
Groups	N	Mean	SD	Mean	SD	df	t	Result
Group A	15	10.47	3.796	3.53	2.167	14	12.469	p value=<0.001 Significant
Group B	15	10.867	1.552	6.73	2.052	14	13.484	p value=<0.001 Significant
Unpaired T Test	df	28		df	28			
	t	0.378		T	4.153			
	Result	p value=0.708 Non-Significant		Result	p value=<0.001 Significant			

Maximum = 17 Minimum = 0

Figures

Figure-1 showing Mean, Standard deviation, Median, Range and Mean Percentages of patients having Grade -1 and Grade –II pressure ulcers before intervention.

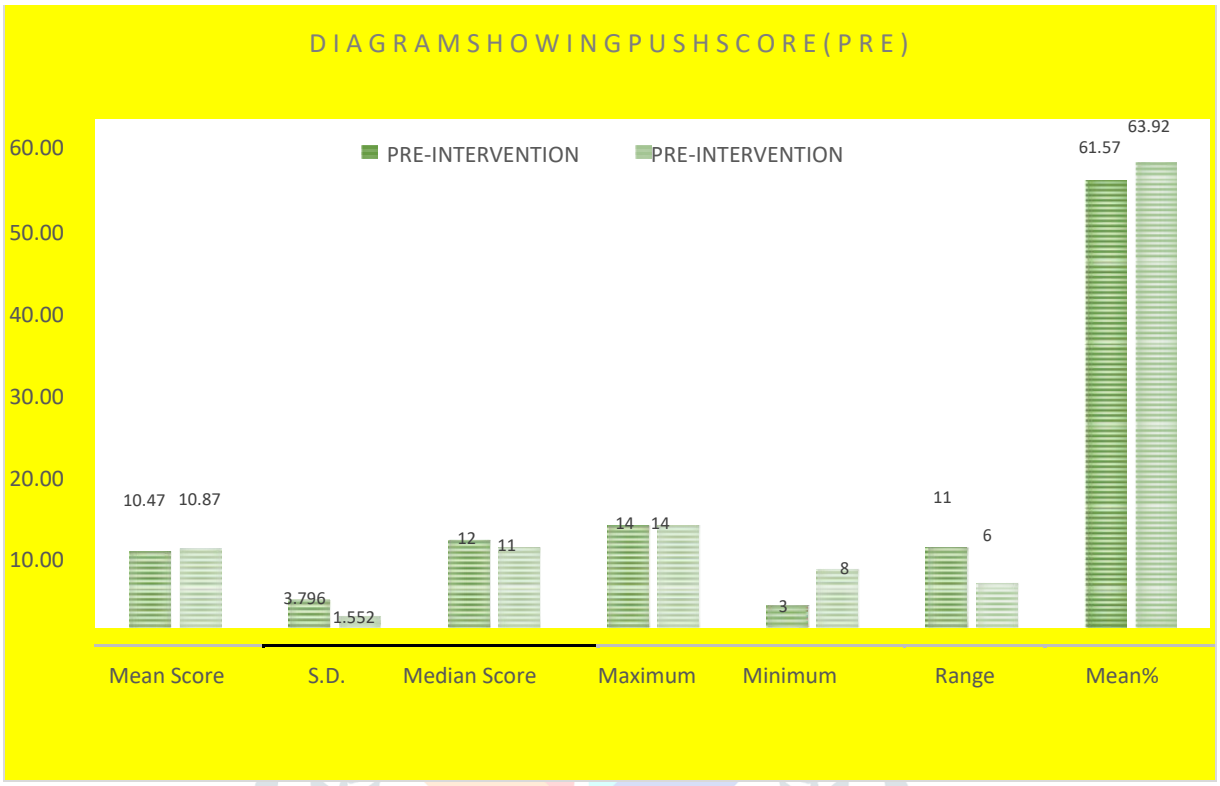

Figure-1

Figure-2 showing Mean, SD, Median score and Mean percentage of patients suffering from Grade-I and Grade-II pressure ulcers after giving intervention

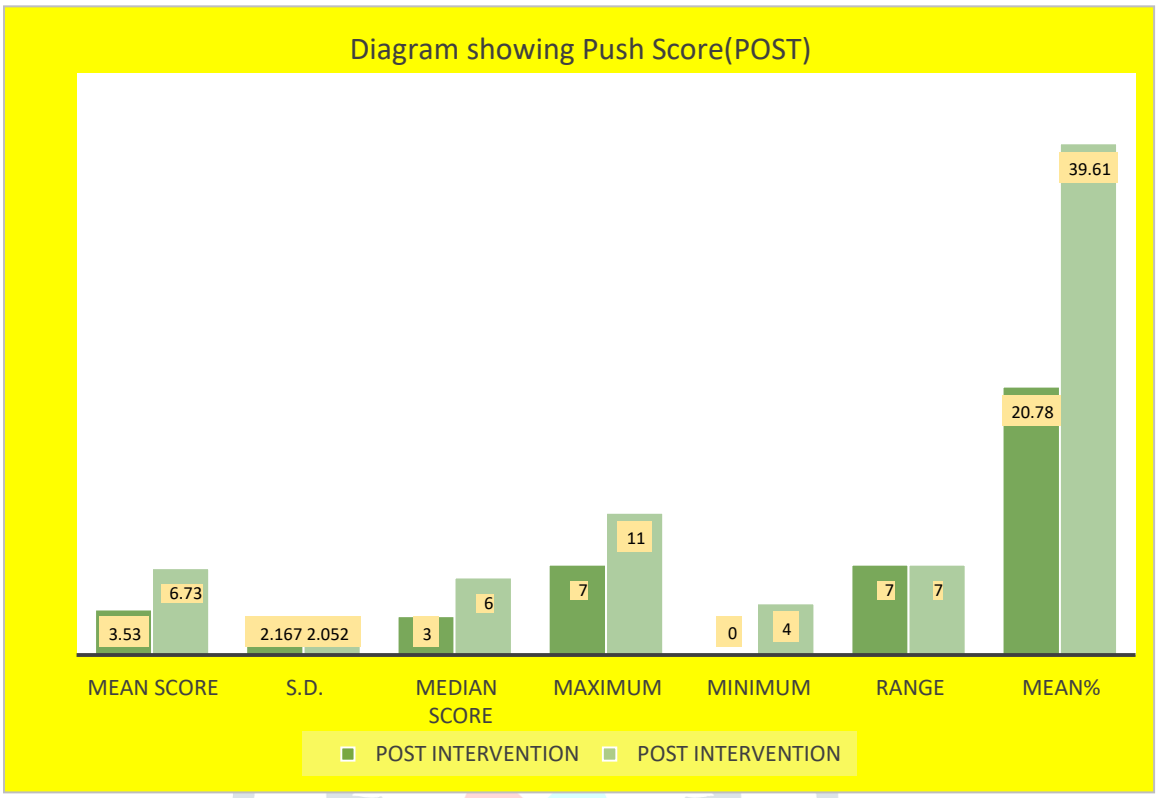

Figure-2

VI CONCLUSION

Based on the above findings, recommendations were drawn for the Nursing service, administration, education and research regarding effectiveness of topical application of Phenytoin on patients suffering from Grade-I and Grade-II pressure ulcers. The study findings revealed that there was a significant association between topical application of Phenytoin and their selected socio demographic variables like Age, Dietary pattern, Grade of Pressure ulcer and Diagnosis of Patient who were suffering from Grade- I and Grade-II pressure ulcers, other demographic variable were not significant. The investigator felt a deep sense of satisfaction for having undertaken this study. Based on the study findings, the investigator has drawn many conclusions. In this chapter the investigator also dealt with various nursing implications of the study. The expert opinion and directions from the guide and the experience of the investigator during the study helped to give suggestions and recommendations for future studies.

The investigator undertook the present study to assess the effectiveness of Topical application of Phenytoin and Normal dressing on patients suffering from Grade-I and Grade-II Pressure ulcers admitted in Adesh Tertiary Care Hospital, Bathinda Punjab.

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