

A Quasi-Experimental Study Performed in a Particular Coimbatore Hospital to Assess the Effect of Sodium Phenytoin Dressing on the Healing of Diabetic Foot Ulcer Patients' Wounds

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Abstract

Diabetic foot ulcers are a common and serious complication experienced by individuals with both type I and type II diabetes. Sodium phenytoin dressings have shown significant potential in accelerating tissue regeneration in such cases. Phenytoin aids wound healing through several physiological mechanisms, including stimulating fibroblast activity, enhancing collagen production, minimizing glucocorticoid-related delays in healing, and providing mild antimicrobial action.

This study aimed to determine the effectiveness of sodium phenytoin dressings in improving wound healing among patients with diabetic foot ulcers in a selected medical facility in Coimbatore. Using purposive non-probability sampling, 30 patients were selected, with 15 placed in the experimental group and 15 in the control group. Demographic and clinical data were collected through an interview schedule, and baseline wound conditions were assessed using the Modified Bates-Jensen Wound Assessment Scale. The experimental group received finely powdered sodium phenytoin once daily for 15 days, while the control group received standard saline dressings during the same period. Wound-healing status was reassessed on day 15, and data were analyzed using descriptive and inferential statistical methods.

The results showed a significant improvement in wound-healing scores among patients treated with sodium phenytoin. The experimental group recorded a mean post-treatment score of 41.8, compared to 33.5 in the control group, yielding a mean difference of 8.3. The standard deviations were 5.25 and 5.83, respectively. The calculated t-value of 6.014 exceeded the table value of 2.048 at the 0.05 significance level, confirming a statistically significant difference.

Keywords: *Diabetic ulcer, sodium phenytoin, fibroblast activity, collagen formation, glucocorticoid antagonism, antimicrobial effect.*

1.Introduction

China alone accounts for 115 million cases, followed by the US with 30 million and India with 73 million. In numerous developed countries, diabetes ranks as the fourth or fifth leading cause of mortality, while its prevalence continues to increase across developing and transitional economies (Callaghan et al., 2020).

Diabetes mellitus is a metabolic disease marked by a continuous rise in blood sugar levels resulting from inadequate insulin secretion, impaired insulin action, or both. Thus, diabetes occurs when the body fails to utilize glucose effectively(1).

Globally, an estimated 463 million adults are affected by diabetes. India alone has around 77 million diabetic individuals, second only to China. Diabetes represents a major burden on healthcare systems. Research suggests that approximately one-quarter of diabetic patients will develop foot ulcers during their lifetime, and such ulcers account for nearly 30% of diabetes-related hospital admissions(2). Treatment expenditures are high, with diabetic foot complications consuming nearly 20% of total diabetes-related healthcare costs often exceeding the expenses associated with other complications.

About 85% of lower-limb amputations are linked to foot ulcers. Of these, which are largely preventable. Neuropathy accounts for 80% of diabetic foot problems in India, while neuro-ischemic disease accounts for about 20%. The likelihood of amputation increases markedly with age: approximately 3.2% of diabetic patients under age 50 experience amputation, compared to 33% among those aged 80. India records an estimated 100,000 amputations annually, and this number continues to rise (Ashok Das, 2020).

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One of the most serious, expensive, and crippling side effects of diabetes is diabetic foot. People with diabetes are 10–20 times more likely than people without the condition to have an amputation(3). Every 30 seconds, diabetes causes the loss of a lower limb or a portion of a leg worldwide. Diabetic foot complications including chronic ulcers and amputations affect an estimated 40–60 million diabetic individuals worldwide, severely diminishing quality of life and increasing infection risk (International Diabetes Federation, 2020).

Diabetic Foot Ulcer (DFU) is among the most frequent and high-risk outcomes of long-standing diabetes. Well-recognized risk factors include peripheral sensory loss, vascular insufficiency, and impaired pain sensation. Poorly managed DFU may lead to amputation or mortality. Despite advancements in diabetic foot care, amputation rates remain high, and disparities in healthcare access persist. Early identification and prevention guided by structured clinical protocols are crucial to reducing the burden of DFU (American Diabetes Association; Katherine McDermott, 2023).

Several categories of wound dressings are used for diabetic ulcers, such as conventional gauze bandages, cotton-based dressings of various shapes and sizes, soft polyurethane foam dressings, hydrocolloid membranes, and hydrogel-based products(4). Among emerging therapeutic options, phenytoin has shown promise due to its ability to accelerate tissue repair. The medication increases collagen synthesis and fibroblast activity to aid in wound healing, acting as a glucocorticoid antagonist, and providing antimicrobial effects.

Phenytoin is one of the oldest non-sedative anticonvulsant medications, introduced in 1938 by Merritt and Putnam after extensive studies of compounds influencing electrically induced seizures in laboratory animals. In addition to its established role in managing tonic-clonic and other epileptic seizures, phenytoin has been evaluated for its benefits in treating burns. Phenytoin used topically appears to accelerate healing by enhancing fibroblast proliferation, stimulating collagen synthesis, exerting glucocorticoid-blocking effects, and reducing microbial load(5). It may also increase the expression of the PDGF- β chain gene in macrophages and monocytes, thereby promoting granulation tissue formation (Ramalingam, 2017).

2.Requirement for the Research

An estimated 463 million persons between the ages of 20 and 79 will have diabetes by 2045; this number is expected to increase to about 700 million. Diabetes is increasing across most nations, and approximately 79% of affected adults reside in low- and middle-income countries. Among older adults, one in five individuals over the age of 65 has diabetes, while half of all adults with the disease about 232 million remain undiagnosed. Diabetes is responsible for 4.2 million deaths annually, and Over 1.1 million children and teenagers worldwide suffer with type 1 diabetes. (Stanton et al., 2019)(6).

Globally, roughly 20 million people struggle with diabetes daily, and projections indicate that by 2050 it may become the leading cause of mortality. Of the more than one million limb amputations performed worldwide each year(WHO, 2017).

In India, diabetic foot ulcers occur in approximately diagnosed type 2 diabetes cases. With 50.8 million individuals affected, India holds one of the highest national burdens of diabetes surpassing According to the International Diabetes Federation (2017).

Diabetic complications develop in about 15% of patients at some moment in their lives. The recommendations of the National Institute for Health and Clinical Excellence (NICE), timely and appropriate management of diabetic foot ulcers (DFUs) can significantly reduce complications and improve quality of life. Proper glycemic control, wound debridement, and appropriate dressings play an essential role in DFU care. Sodium phenytoin dressings have been shown to enhance wound healing by accelerating tissue regeneration (Global Research and Clinical Practice, 2020)(7).

Although diabetic foot ulcers can cause substantial morbidity, they can be successfully managed when treated promptly and appropriately. Considering its proven ability to support wound repair as well as its affordability, accessibility, ease of application, and good safety profile phenytoin is strongly recommended as a beneficial therapeutic option for diabetic ulcers. Larger prospective studies are nevertheless required to confirm these results. Participants were divided into two groups at random: one receiving conventional saline dressings and the other receiving phenytoin therapy. Outcomes were evaluated through changes in discharge, slough, wound size reduction, and hospital stay duration. Notably, wound discharge and slough decreased significantly by day 14 in the phenytoin group, but required up to 21 days in the control group. Hospitalization averaged 20 days for patients treated with phenytoin and 26 days.

3. Description of the problem

At a particular hospital in Coimbatore, a quasi-experiment was carried out to evaluate the efficacy of sodium phenytoin dressing in accelerating the healing phase of wounds in individuals who have diabetic foot ulcers(8).

Objectives

- To ascertain whether sodium phenytoin dressings improve wound-healing results among people who have diabetic foot ulcers.
- To identify the relationship between wound-healing progress and selected sociodemographic and clinical variables among patients with diabetic foot ulcers(9).

Hypotheses

H1: The experimental group's wound-healing status will improve statistically significantly both before and after the sodium phenytoin dressing is applied.

H2: Patients in the experimental group receiving sodium phenytoin dressing will have wound-healing outcomes that differ statistically significantly from those in the control group(10).

H3: There will be a strong correlation between wound-healing outcomes and certain clinical and sociodemographic characteristics in patients with diabetic foot ulcers.

4. Conceptual Structure

Conceptualization is the process of developing and structuring ideas that form the foundation of a study's conceptual framework. It gives the researcher the logical and abstract foundation for connecting the study's findings to the broader field of nursing knowledge.

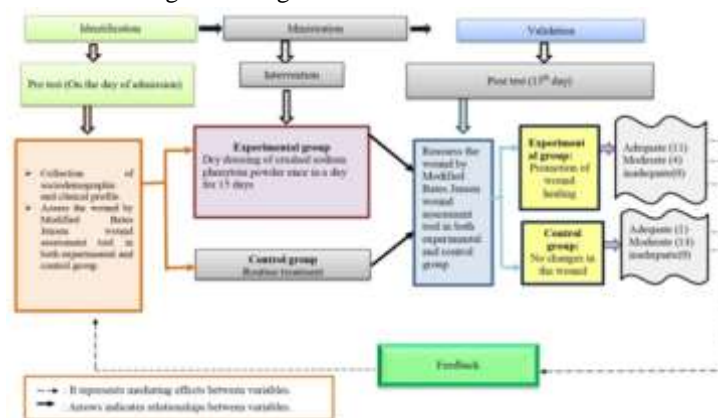


FIGURE 1 Conceptual Structure for Expanded Bach's Clinical Nursing Theory

A conceptual framework offers a coherent and meaningful structure that supports the planning, execution, and interpretation of research. Effective nursing practice, according to Wiedenbach, comprises identifying a patient's need for assistance, providing the necessary care, and confirming that the care successfully satisfies the patient's needs(11).

5. Methodology

Research Methodology:

For this study, a quantitative research methodology was used

Design of Research:

The investigation utilized a quasi-experimental design featuring a pretest–posttest structure with a control group.

Setting:

The research was conducted in both general and specialty wards at Bhagirathi Medical Centre, Coimbatore, among hospitalized patients diagnosed with type II diabetic foot ulcers.

Population:

People with diabetic foot ulcers made up the target demographic. Patients admitted to Bhagirathi Medical Centre and Hospital in Coimbatore who had foot ulcers were among the accessible population.

Sample Size:

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A non-probability purposive sampling technique was used to choose 30 patients with diabetic foot ulcers.

Sampling Technique:

Non-probability purposive sampling technique was employed for selecting study participants(12).

Instruments and tools for data collection

Section A: Sociodemographic and Clinical Profile

A structured questionnaire was developed to gather sociodemographic and clinical information from the participants. The tool included variables such as age, gender, educational level, occupation, monthly income, personal habits, dietary pattern, blood glucose level, duration of diabetes, duration of the ulcer, and duration of the current treatment.

Section B: Assessment Tool Modified

There were initially 13 parameters in the Wound Assessment Tool, each scored from 1 to 5, where a score of 1 denotes healthy tissue healing and a score of 5 indicates wound deterioration. For this study, a modified version of the tool was utilized, consisting of 10 selected items(13). Each item included five response options based on specific wound characteristics, scored from 1 to 5. Higher scores reflected better wound status. The maximum obtainable score on the modified scale was 50.

TABLE 1 Maximum score for the rating

Percentage	Scoring	Assessment of wound healing
76 – 100%	39 – 50	Sufficient recovery
51 – 75%	26 – 38	Moderate recovery
<50%	< 25	Insufficient

Validity of the Instrument

In this study, the tool underwent validation by subject experts and the medical guide. They were asked to evaluate each item for relevance, clarity, accuracy, and overall appropriateness. Based on their feedback, necessary modifications were incorporated. The expert review confirmed that the tool possessed strong content validity(14).

Reliability of the Tool

The study's Modified Assessment Tool was found to be statistically reliable. The instrument demonstrated a reliability coefficient of $r = 0.82$, indicating a high level of internal consistency and dependability.

Ethical Considerations

Ethical approval for this study was secured from the Institutional Ethical Committee of PPG Group of Institutions, Coimbatore. Written permission was obtained to conduct the research.

6. Methods for Interpreting and Analyzing Data

The information obtained from diabetic foot patients ulcers were systematically arranged, examined, and explained in the sections that follow:

Section I:

Sociodemographic and clinical profiles of patient diagnosed with diabetic foot ulcers.

Section II:

Evaluation of the condition of wounds in people with foot ulcers.

Section III:

Evaluation of the impact of sodium phenytoin dressing on wound healing rate in both the experimental and control groups.

Section IV:

Examination of the relationship between wound-healing outcomes and selected sociodemographic and clinical factors among patients treated with sodium phenytoin dressing(15).

TABLE 2 Effects of sodium phenytoin dressing on diabetic foot ulcer patients' wound healing

S.No	Collaboration	Mean	SD	Mean difference	Calculated 't' value
1	Pre test	28.4	5.38	13.4	10.81*
2	Post test	41.8	5.25		

(P < 0.05*)

A paired "t" test was used to compare the patients' wound-healing results with diabetic foot ulcers in the control group before and after the test. The mean wound-healing score increased from 28.4 in the pre-test to 41.8 in the post-test, with a 13.4 total difference (16). The Both test standard deviations were 5.38 and 5.25, respectively. At the 0.05 level of significance, the projected t value of 10.81 is more than the crucial table value of 2.042. Thus, the research hypothesis H. The experimental group's wound-healing scores before and after the sodium phenytoin dressing was applied showed a notable difference.

TABLE 3 Examination of the degree of wound healing in diabetic foot ulcer patients in the control group undergoing routine treatment

S.No	Control Group	Mean	SD	Mean difference	Calculated 't' value
1	Pre test	27.3	6.01	6.2	4.92
2	Post test	33.5	5.83		

(P < 0.05*)

A paired t-test was used to compare the wound-healing scores of the control group before and after the test. The research revealed a mean difference of 6.2, with the mean wound-healing score rising from 27.3 in the pre-test to 33.5 in the post-test. The pre-test and post-test had standard deviations of 6.01 and 5.83, respectively. Even among patients who got conventional saline dressings, as evidenced by the computed t value of 4.92 exceeding the crucial table value of 2.042 at the 0.05 significance level (17).

TABLE 4 Comparing the post-intervention wound-healing results of individuals with diabetic foot ulcers in the study group treated with sodium phenytoin dressing with the control group treated with conventional saline dressing

S.No	Study group	Mean	SD	Mean difference	Calculated 't' value
1	Experimental group	41.8	5.25	8.3	6.014*
2	Control group	33.5	5.83		

(P < 0.05*)

The results were compared using an independent post-test wound-healing scores of patients in the experimental group treated with sodium phenytoin dressing and those in the control group treated with standard saline dressing. The Results revealed that the experiment group achieved a mean wound score of 41.8, whereas the control group recorded a mean score of 33.5, resulting in a mean difference of 8.3. The standard deviations were 5.25 for the control group and 5.83 for the experimental group (18). The computed t value of 6.014 exceeded the critical table value of 2.048 at the 0.05 level of significance, indicating a statistically significant difference in wound-healing outcomes between the two groups.

TABLE 5 Association between wound-healing outcomes and selected sociodemographic and clinical variables among patients treated with sodium phenytoin dressing

SL. No	Variables	Moderate healing		Adequate healing		χ^2	P
		F	%	F	%		Value
1	Age:					111.2*	5.991
	35-55	1	7%	5	33%		
	56-75	2	13%	6	40%		
	Above 75	1	7%	0	-		

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2	Gender						
	Male	3	20%	7	47%	0.2	3.841
	Female	1	7%	4	26%		
3	Education						
	Absence of formal schooling	1	7%	1	7%	11.0*	9.488
	Primary schooling	2	13%	2	13%		
	Secondary schooling	0	-	2	13%		
	Higher education	0	-	3	20%		
	Graduate	1	-	3	20%		
			7%				
4	Occupation						
	Coolie	2	13%	3	20%	22.7*	5.991
	Private employee	2	13%	6	40%		
	Govt employee	0	-	2	13%		
5	Income						
	Up to 30000	2	13%	3	20%	37.2*	5.991
	3000-60000	1	7%	6	40%		
	Above 60000	1	7%	2	13%		
6	Habit						
	None Smoking	2	13%	5	33%	24.4*	7.815
	Alcoholism	0	-	4	27%		
	Tobacco chewing	1	7%	2	13%		
		1	7%	-	-		
7	Dietary pattern						
	Vegetarian Non vegetarian	0	- 26%	1	7%	0.1	3.841
		4		10	67%		
8	Blood glucose levels: 80–120 mg/dl, 121–160 mg/dl, and higher than 160 mg/dl						
		0	-	4	26%	8.5*	5.991
		1	7%	4	26%		
		3	20%	3	20%		

9	Duration of illness Below 1yr 1-3yr Above 3yr	0 1 3	- 7 %	4 2 5	26% 13% 34%	9.8*	5.991
10	Duration of ulcer Under a week 1-3 weeks. Over 3 weeks	0 2 2	- 13 %	4 4 3	27% 27% 20%	8.9*	5.991

(P < 0.05*)

This shows that for a number of sociodemographic and clinical factors, such as gender, education, occupation, personal habits, length of illness, and duration of ulcer, the computed values of post-test wound-healing scores exceeded the corresponding critical table values. At the $p < 0.05$ level, this shows statistical significance(19). Therefore, it can be concluded that certain sociodemographic and clinical characteristics, such as gender, educational background, occupation, lifestyle habits.

7.Findings regarding the extent of wound healing in individuals with diabetic foot ulcers

Pre-test Diabetic Foot Ulcer Patients' Wound-Healing Status

During the pre-test assessment, 12 patients (80%) in the experimental group demonstrated a moderate level of wound healing, while 3 patients (20%) exhibited an inadequate degree of recovery. Six patients (40%) and nine patients (60%) in the control group had insufficient healing and moderate healing, respectively(20).

Diabetic Foot Ulcer Patients' Post-test Wound-Healing Status

Following the intervention, the post-test findings revealed that in the experimental group, 11 patients (73%) achieved an adequate level of wound healing, and the remaining 4 patients (27%) demonstrated a moderate level of healing. In contrast, in the control group, 14 patients (93%) showed a moderate level of wound healing, while only 1 patient (7%) reached an adequate healing level.

Sodium Phenytoin Dressing's Impact on Wound Healing

The average wound-healing score for the experimental group was 41.8, while the control group's was 33.5, with an 8.3 mean difference(21). The experimental group's standard deviation was 5.25, while the control group's was 5.83. The difference was statistically significant since the computed t value of 6.014 was greater than the table value of 2.048 at the 0.05 significance level. As a result, hypothesis H which claims that using sodium phenytoin dressing significantly improves wound-healing outcomes when compared to routine care was accepted.

Supporting Evidence From Previous Research

These findings are consistent with a research conducted by Abdulhussein Marzooq et al. (2019) that examined the effects of betadine and sodium phenytoin dressings on 100 type II diabetes patients in Lublin who had foot ulcers(22). The study reported a significant difference in outcomes, with Group A showing superior analgesic efficacy ($p = 0.012$) compared to Group B, indicating notable improvements in wound-healing progression. This supports the present study's conclusion that sodium phenytoin dressing facilitates significant enhancement in diabetic wound healing.

Association Between Wound-Healing Levels and Selected Sociodemographic and Clinical Variables

The relationship between wound-healing levels and selected Clinical and sociodemographic traits of diabetic foot patients ulcers was examined using the chi-square test(23).

The findings revealed that gender ($\chi^2 = 0.218$) and dietary pattern ($\chi^2 = 0.166$) showed no significant association with wound-healing outcomes. However, several other variables demonstrated a statistically significant association at the $p < 0.05$ level. These included age ($\chi^2 = 111.22$), education ($\chi^2 = 11.092$), occupation ($\chi^2 = 22.79$), income ($\chi^2 = 37.29$), habit ($\chi^2 = 24.42$), duration of illness ($\chi^2 = 9.87$), and duration of ulcer ($\chi^2 = 8.90$).

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Based on these results, it was concluded that wound-healing levels following sodium phenytoin dressing are significantly associated with selected sociodemographic and clinical factors such as age, educational status, occupation, lifestyle habits, blood glucose level during fasting, length of illness, and length of ulcer(24).

Recommendations

- Sodium phenytoin dressing is suitable and advantageous for individuals who have had diabetic foot ulcers for fewer than three years.
- It is an effective intervention for use in both clinical and community healthcare settings(25).
- Sodium phenytoin dressing can be safely administered to patients presenting with diabetic foot ulcers.

Suggestions for Future Studies

The efficacy of sodium phenytoin dressings for people with type I and type II diabetes who have diabetic foot ulcers may be compared.

The results would be more broadly applicable if the study were repeated with a bigger sample size.

7.1 Nursing Implications

Nursing Education

The findings of this study highlight that sodium phenytoin dressing can significantly enhance wound healing in patients foot ulcers. Nurse educators should incorporate updated knowledge about sodium phenytoin into training programs and emphasize its value as an evidence-based, cost-effective, and practical wound-care intervention. Integrating this method into nursing curricula would strengthen clinical competency and wound-management skills(26).

Nursing Administration

Nurse administrators play a crucial role in promoting effective wound-care practices. They should encourage the integration of sodium phenytoin dressing into routine care within diabetic care units. Supporting staff training and ensuring the availability of materials can further enhance patient outcomes.

Nursing Practice

Sodium phenytoin dressing is an effective nursing intervention that supports wound healing and prevents complications related to diabetic foot ulcers. Nurses must develop strong clinical skills, knowledge, and critical thinking to apply this method effectively within standard wound-care protocols(27).

Nursing Research

This study contributes evidence supporting sodium phenytoin dressing's efficacy in promoting wound healing.

8. Conclusion

Diabetic foot ulcers commonly develop as a complication in individuals with diabetes. These ulcers are typically managed through glycemic control and other therapeutic interventions. Sodium phenytoin dressing serves as a simple and effective pharmacological approach for treating such wounds. It has been demonstrated that this approach helps diabetic individuals heal, lessen the severity of their ulcers, and achieve favorable results. Individuals who received this intervention reported greater comfort and indicated their willingness to continue using it in both clinical and community healthcare settings.

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Conflicts of interest

The authors have no conflicts of interest to declare

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