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Effectiveness of Topical Phenytoin Versus Normal Saline Dressing in the Management of Diabetic Foot Ulcers: A Non-Randomized Interventional Study

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ABSTRACT

Diabetic foot ulcers (DFUs) are a significant complication of diabetes, often leading to chronic wounds, infections and amputations. While normal saline dressings are commonly used, topical phenytoin has emerged as a potential therapeutic option due to its anti-inflammatory and wound-healing properties. To evaluate and compare the effectiveness of topical phenytoin dressing with normal saline dressing in terms of wound healing, granulation tissue formation and reduction in bacterial contamination in patients with diabetic foot ulcers. This was a single-center, hospital-based, non-randomized interventional study conducted over 18 months at the Department of Surgery, JK Hospital, Bhopal. A total of 110 participants diagnosed with diabetic foot ulcers (Wagner grade 1 and 2) were enrolled and divided into two groups based on their dressing type: topical phenytoin (n=55) and normal saline (n=55). Baseline characteristics, including wound area, were recorded and patients were followed up weekly for six weeks. Outcome measures included wound area reduction, quality of granulation tissue and bacterial contamination rates. The phenytoin group showed significantly faster wound healing, with 61% mean reduction in wound area by week 6 compared to 33% in the saline group ($p<0.0001$). Granulation tissue formation was healthier in the phenytoin group, with 58.2% of participants showing >75% granulation tissue compared to 29.1% in the saline group ($p<0.0001$). A higher proportion of participants in the phenytoin group achieved complete wound healing (54.5% vs. 25.4%, $p=0.028$). The mean hospital stay was also shorter for the phenytoin group (18.6 days) compared to the saline group (24.3 days, $p<0.0001$). Topical phenytoin dressing is significantly more effective than normal saline in promoting faster wound healing, better granulation tissue quality and reduced hospital stay in patients with diabetic foot ulcers. Phenytoin dressings represent a promising alternative for improving outcomes in DFU management.

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Key Words

Diabetic foot ulcer, phenytoin dressing, wound healing, granulation tissue, normal saline, wound care, diabetes mellitus, interventional study

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INTRODUCTION

Diabetes mellitus, a chronic metabolic disorder characterized by elevated blood glucose levels, poses significant health, economic and social challenges for India[1]. With one of the highest numbers of diabetes cases in the world, India faces unique hurdles in managing this growing epidemic. For these reasons, India is often referred to as the diabetes capital of the world, with estimates suggesting that nearly 77 million adults were living with diabetes as of 2019[2,3]. This number is projected to rise dramatically in the coming decades due to increasing urbanization, lifestyle changes and genetic predispositions. The prevalence of diabetes not only strains the healthcare system but also exacerbates the risk of developing secondary complications such as cardiovascular diseases, renal failure and diabetic retinopathy, which further complicate management efforts[4]. The Indian healthcare system faces significant challenges in addressing diabetes due to disparities in access to care, inadequate healthcare facilities and a shortage of trained healthcare professionals[4]. Diabetic foot ulcers (DFUs) are a serious and common complication of diabetes, primarily caused by peripheral neuropathy and peripheral arterial disease, which are prevalent among individuals with long-standing diabetes[5]. These ulcers are a significant concern not only because they are difficult to treat but also because they drastically affect the patients' quality of life, potentially leading to mobility issues, chronic pain and emotional distress[6]. The development of diabetic foot ulcers is multi factorial, with neuropathy, ischemia and infection playing pivotal roles. Neuropathy reduces sensation in the feet, preventing patients from feeling injuries or irritations, which can lead to skin breakdown[6]. Risk factors for DFUs include poor glycemic control, previous foot ulcers or amputations, diabetic neuropathy, foot deformities, inappropriate footwear, and peripheral arterial disease. These factors not only increase the likelihood of ulcer formation but also complicate the healing process once an ulcer has developed[6]. Effective management of diabetic foot ulcers involves a comprehensive approach that addresses both the wounds and the underlying risk factors. Effective management of these ulcers is crucial to prevent infections, facilitate healing and reduce the incidence of amputation. Traditional treatments include a variety of topical and systemic therapies[7]. Normal saline dressings are commonly used for their simplicity and cost-effectiveness but may not adequately promote healing in more severe or chronic ulcerations. Phenytoin, known primarily as an anti consultant, has shown potential in wound care due to its pharmacological properties[8]. Topical phenytoin has emerged as a potential therapeutic option, purported to accelerate wound healing due to its anti-inflammatory, anti-microbial and wound repair -enhancing properties[8]. Therefore, the present study aimed to evaluate and compare the effectiveness of topical phenytoin and normal saline dressing on several clinical outcomes in patients with diabetic foot ulcers.

MATERIALS AND METHODS

- **Study Design:** A single centre, hospital-based, non -randomised, interventional study.
- **Study Setting:** The study was conducted at the Department of Surgery, JK Hospital, Bhopal, which is affiliated with LN Medical College, Bhopal.
- **Ethical Clearance:** After thorough scrutiny and revisions based on committee feedback, the protocol was rigorously evaluated to ensure it met all ethical requirements, including participant safety, confidentiality and informed consent procedures.
- **Study Duration:** The total duration of the present study was 18 months.
- **Follow Up:** The participants were followed up until 6 weeks.

- **Definition of the Intervention:** In the study, participants were divided into two groups based on the type of dressing applied to their diabetic foot ulcers:
- **Phenytoin Dressing Group:** This group received topical phenytoin dressings. The intervention involved applying phenytoin dissolved in normal saline directly onto the ulcer, covered by a sterile dressing, which was changed daily. This treatment aimed to assess the efficacy of phenytoin in promoting wound healing and reducing bacterial contamination.

The Dosage of Phenytoin was Determined as Follows:

- **For Ulcers with a Surface Area of 0-5 cm²:** 100 mg of phenytoin.
- **For Ulcers with a Surface Area of 5.1-9 cm²:** 150 mg of phenytoin.
- **For Ulcers with a Surface Area of 9.1-15 cm²:** 200 mg of phenytoin.
- **For Ulcers with a Surface Area Greater than 15 cm²:** 300 mg of phenytoin.

To prepare the phenytoin dressing, a single 100-mg phenytoin vial was dissolved in 5mL of sterile NaCl 0.9% to create a phenytoin-NaCl 0.9% suspension. Sterile gauze was then soaked in this suspension and applied directly over the wound.

- **Normal Saline Dressing Group:** Participants in this control group were treated with dressings soaked in normal saline. These dressings were also changed daily, providing a baseline comparison to evaluate the effects of the phenytoin dressing.

- **Study Participants:** The participants for the present study were adult patients diagnosed with diabetic foot ulcers, treated at the Department of Surgery, JK Hospital, Bhopal.

Inclusion Criteria:
- Age 18 years or older.
- Clinically diagnosed with a diabetic foot ulcer.
- Diabetic ulcer grade 1 and grade 2 according to Wagner's classification.
- Able and willing to provide informed consent for participation in the study.

Exclusion Criteria:
- Known allergy to phenytoin.
- Grade 3,4 and 5 ulcers of Wagner's classification.
- Chronic non healing wounds of other etiology (venous and arterial ulcers).
- Currently receiving other experimental treatments specifically for diabetic foot ulcers.
- Patients who are not on regular follow up.

- **Sample Size:** All eligible participants who visited the study institute during the participant recruitment period and provided written informed consent were enrolled in the present study. Following this approach, a total of 110 participants were enrolled in the study.
- **Sampling Methodology:** A non-probability convenience sampling methodology was employed to select participants.

Data Collection Procedure:
- **Obtaining Informed Consent:** Each participant was provided with a bilingual (Hindi and English) informed consent form that detailed all aspects of the study. Participants had the opportunity to ask questions and were given sufficient time to consider their participation. Upon agreeing to participate, they signed the informed consent form, which was collected and securely stored by the research team.
- **Participant Enrollment and Group Assignment:** After obtaining consent, participants were enrolled in the study. The assignment to either the phenytoin or saline dressing group was made based on mutual discussions about the available treatment options and their respective merits and demerits, respecting participant preference where feasible.
- **Baseline Data Collection:** Comprehensive baseline data were collected for each participant, including demographic details, medical history, severity and duration of diabetes, previous foot ulcer treatments and any comorbid conditions. Initial measurements of the diabetic foot ulcers were taken using digital calipers to document the size of the wound and baseline swabs were taken for bacterial culture to assess initial contamination levels.
- **Examination of Patients:** This included careful examination of the affected limb viz., physical examination of peripheral pulses and doppler examination to exclude other causes of peripheral ulcer.
- **Measurement of Wound Area:** Wound dimensions were measured using digital calipers, which provide precise measurements of length and width. This method was selected for its accuracy and repeatability, crucial for assessing changes in ulcer size over time. Frequency and Recording: Measurements were taken at each weekly visit from baseline until the conclusion of the participant's involvement in the study or until the wound healed.
- **Assessment of Discharge and Slough:** The assessment was conducted visually by attending surgeon who inspected the ulcers for signs of discharge (such as pus or fluid) and slough (dead tissue that appears white or yellowish in color). Like the wound measurements, these observations were made during each weekly visit. The findings were recorded using a standardized scale (e.g., none, mild, moderate, severe) to ensure consistency in reporting.
- **Monitoring Bacterial Contamination Rates:** Swab samples were collected from the ulcers using sterile techniques to prevent contamination. These samples were then cultured in a laboratory to identify bacterial growth. Swabs were taken at baseline and during each weekly follow-up visit. Laboratory results, including the type and quantity of bacteria identified, were recorded in the participant's file.

- **Statistical Analysis Plan:** Within Stata 17.0, the first step involved descriptive statistics to summarize the characteristics of the study population, including means, medians and standard deviations for continuous variables and frequencies and percentages for categorical variables. The next phase of analysis involved inferential statistics to test the hypotheses. Independent t-tests were used to compare continuous outcomes between the two groups, while chi-square and Fisher's exact tests were employed for categorical data, focusing on the primary and secondary outcomes.
- **Funding:** There was no external funding for this study. Additionally, participants in the study did not receive any financial compensation for their involvement.
- **Conflict of Interest:** The researchers involved in this study declare no conflict of interest in the

design, implementation and interpretation of its findings.

RESULTS AND DISCUSSIONS

(Table 1) presents the demographic and baseline characteristics of the participants. The mean age was slightly higher in the phenytoin group (51.5±7.01 years) compared to the normal saline group (47.5±5.49 years). Both groups had a similar male predominance, with approximately 85% of participants being male. The mean BMI was comparable between the groups, with 27.9±3.24 in the saline group and 28±3.45 in the phenytoin group. The average duration of diabetes was also similar, at 13.4±3.4 years in the saline group and 13.9±3.2 years in the phenytoin group. Regarding socioeconomic status, the phenytoin group had a higher proportion of participants from lower socioeconomic backgrounds compared to the saline group (45.5% vs. 27.3%, respectively). (Table 2) summarizes the baseline wound area distribution among participants in the two study groups. The wound areas were categorized into four size ranges: 5-10 cm^2, 11-15 cm^2, 16-20 cm^2 and 21-25 cm^2. Both groups showed similar distributions across these categories, with no significant difference observed (p=0.173). The majority of participants in both groups had wounds measuring between 21-25 cm^2 (43.6% in the saline group and 45.5% in the phenytoin group). The mean baseline wound area was slightly larger in the phenytoin group (17.5±6.44 cm^2) compared to the saline group (16.8±6.4 cm^2), but this difference was not statistically significant. (Table 3) outlines the healing progression of wound areas over six weeks of treatment. At baseline, both groups had no significant differences in wound area (p=1.0). By the second week, the phenytoin group demonstrated significantly greater wound healing (17%) compared to the saline group (12%), with a p-value of 0.024. This trend continued throughout the study, with the phenytoin group consistently achieving higher wound healing percentages at every time point. By week six, the phenytoin group showed a mean wound healing of 61% compared to 33% in the saline group, with a highly significant p-value (<0.0001). These findings indicate that phenytoin dressings were significantly more effective in promoting wound healing than normal saline over the course of treatment.

(Table 4) Endline Wound Area: This table compares the wound area at the end of the six-week treatment. The phenytoin group demonstrated a significantly smaller mean wound area (6.8±2.39 cm^2) compared to the saline group (10.3±3.39 cm^2), with a p-value of 0.0059. A higher proportion of participants in the phenytoin group (43.6%) achieved wound areas of 0-5 cm^2 compared to the saline group (25.5%). Conversely, larger wound areas (15-20 cm^2) were more frequent in the saline group (27.3%) compared to the phenytoin group (7.27%). These results indicate superior wound healing outcomes in the phenytoin group.

(Table 5) Difference in Wound Area: This table summarizes the changes in wound area from baseline to the end of the study. The mean wound area reduction was significantly greater in the phenytoin group (10.7±2.66 cm^2) compared to the saline group (6.5±2.37 cm^2), with a p-value of <0.0001. These findings confirm that phenytoin dressings were more effective than saline in promoting wound area reduction over the six-week treatment period.

The significance of conducting this study lies in the growing burden of diabetic foot ulcers in clinical practice, especially in regions with a high prevalence of diabetes, such as India. DFUs are known for their chronic nature, poor healing outcomes and risk of complications such as infections, gangrene and amputation. The results indicate that wound healing was significantly faster in the phenytoin group, with statistically significant differences observed as early as the second week (17% healing in the phenytoin group vs. 12% in the saline group, p=0.024). By the sixth week, the phenytoin group achieved 61% healing compared to 33% in the saline group, with p-values indicating high statistical significance throughout the study period (p<0.0001). When comparing these findings with similar studies, Nagraj *et al.* (2022) also found that phenytoin dressings significantly accelerated the formation of granulation tissue and overall wound healing compared to saline dressings[9]. Similarly, Vardhan A *et al.* (2016) reported faster granulation tissue formation and wound closure in the phenytoin group compared to conventional dressings, supporting the present study's findings of faster wound healing progression with phenytoin[10]. In their study, participants treated with phenytoin dressings had better healing outcomes by reducing wound size more effectively than saline-based treatments. Reddy SM *et al.* (2021) also observed a significant reduction in wound area with phenytoin (1856.9±724.9 mm^2) compared to saline (1066.8±565.3 mm^2), highlighting the superior healing potential of phenytoin[11]. The present study's findings reinforce this conclusion, as the phenytoin group showed a faster reduction in wound size, especially by the fourth week onward, when healing in the phenytoin group reached 38% compared to 26% in the saline group. In addition, Babu S *et al.* (2023) reported similar results, noting that phenytoin dressings led to a higher percentage of granulation tissue formation (98.09%) compared to saline (95.93%) and significantly faster healing rates[12]. Sandhu K *et al.* (2017) also observed faster healing and better granulation tissue formation in the phenytoin-treated group compared to conventional dressings, with shorter healing times[13]. The present study's data is consistent with these results, showcasing the superior efficacy of phenytoin in

Table 1: Age Distribution of Participants

	Normal Saline (n =55)		Phenytoin (n =55)	
	n	%	n	%
Mean Age±SD	47.5	5.49	51.5	7.01
Mean BMI±SD	27.9	3.24	28	3.45
Mean Duration of DM±SD	13.4	3.4	13.9	3.2
Gender				
Female	8	14.5	9	16.4
Male	47	85.5	46	83.6
Socioeconomic Status				
Lower	15	27.3	25	45.5
Upper Lower	22	40	13	23.6
Lower Middle	10	18.2	6	10.9
Upper-Middle	6	10.9	9	16.4
Upper Class	2	3.64	2	3.64

Table 2: Baseline Wound Area

	Normal Saline (n =55)		Phenytoin (n =55)	
Baseline: Wound Area (sq. cm)	n	%	n	%
5 -10	10	18.2	10	18.2
11-15	14	25.5	14	25.5
16-20	7	12.7	6	10.9
21-25	24	43.6	25	45.5
Mean, SD	16.8	6.4	17.5	6.44
	P-value=0.173			

Table 3: Healing of Wound Area During the Course of Treatment

	Normal Saline (n =55)	Phenytoin (n =55)	
Time point	**Mean**	**Mean**	**P-value**
Baseline	0%	0%	1.0
1 Week	4%	6%	0.063
2 Weeks	12%	17%	0.024*
3 Weeks	19%	24%	0.001*
4 Weeks	26%	38%	<0.0001*
5 Weeks	28%	47%	< 0.0001
6 Weeks	33%	61%	< 0.0001

Table 4: End Line Wound Area

End line: Wound Area (sq. cm)	Normal Saline (n =55)		Phenytoin (n =55)	
	n	%	n	%
0 -5	14	25.5	24	43.6
6-10	12	21.8	11	20
11-15	14	25.5	16	29.1
15-20	15	27.3	4	7.27
Mean, SD	10.3	3.39	6.8	2.39
	P-value=0.0059			

Table 5: Difference in Wound Area

	Normal Saline (n =55)		Phenytoin (n =55)		
	Mean	**SD**	**Mean**	**SD**	**P-value**
Baseline: Wound Area	16.8	6.4	17.5	6.44	0.173
End line: Wound Area	10.3	3.39	6.8	2.39	0.0059
Difference in Wound Area	6.5	2.37	10.7	2.66	< 0.0001

promoting faster wound recovery, particularly in diabetic foot ulcers, which are notoriously difficult to heal. The findings of present study show that a significantly higher proportion of participants achieved complete wound healing in the phenytoin group (54.5%) compared to the saline group (25.4%), with a p-value of 0.028, indicating a statistically significant difference between the two groups. When comparing these results with previous studies, Stephan B *et al.* (2021) also reported that topical phenytoin dressings led to more rapid and complete healing of chronic non-healing ulcers compared to conventional saline dressings. Similarly, Vardhan A *et al.* (2016) demonstrated that topical phenytoin dressings led to faster and more complete healing of diabetic foot ulcers compared to standard care, with a notable reduction in wound size and an increase in the percentage of completely healed wounds[10]. Reddy SM *et al.* (2021) also observed a significant reduction in wound area and an increased rate of complete healing in the phenytoin group compared to saline[11]. Babu S *et al.* (2023) found similar results, noting that phenytoin dressings led to faster granulation tissue formation and a higher percentage of completely healed wounds compared to saline dressings[12]. Their study, like the present one, reinforces the idea that phenytoin accelerates the healing process, leading to more patients achieving full recovery in a shorter time frame. On the other hand, Shaw J *et al.* (2011) did not find significant differences in complete healing between the phenytoin and control groups in their study on diabetic foot ulcers[14]. This contrasts with the present study, which found a statistically significant advantage for phenytoin. The differences could be due

to variations in study design, sample size, or the chronicity of the ulcers in the study populations. Nevertheless, the majority of studies, including the present one, suggest that phenytoin is superior in promoting complete wound healing. The findings show that the phenytoin group had a significantly shorter hospital stay (mean of 18.6 days) compared to the saline group (mean of 24.3 days), with a p-value of <0.0001, indicating a highly significant difference between the two groups. When comparing these findings to previous studies, Vardhan A *et al.* (2016) also reported a significant reduction in hospital stay in the phenytoin-treated group (33.4 days) compared to the group treated with conventional materials (39.7 days). Like the present study, this research highlights phenytoin's ability to accelerate the healing process, leading to shorter hospital stays and quicker recovery times. Similarly, Babu S *et al.* (2023) found that patients treated with phenytoin had a significantly reduced hospital stay (mean of 27.8±2.4 days) compared to the control group (31.3±4.2 days), which is consistent with the current study's findings of a faster healing trajectory in the phenytoin group[12]. These results confirm that phenytoin promotes more efficient healing, leading to earlier discharge and reduced healthcare costs. Sandhu K *et al.* (2017) further supports these findings, reporting a shorter duration of hospital stay in the phenytoin group (mean of 21.35±4.71 days) compared to the conventional group (27.3±6.48 days). Stephan B *et al.* (2021) also found that patients treated with topical phenytoin had shorter hospital stays due to more rapid wound healing and the formation of healthy granulation tissue. This aligns closely with the present study's outcomes, which show a significant reduction in hospital stay for patients treated with phenytoin compared to saline dressings. On the other hand, Nagaraj J *et al.* (2022), while comparing phenytoin with other treatment options like insulin and saline, found that injectable insulin led to the shortest hospital stay, but phenytoin still outperformed normal saline in terms of reducing hospitalization duration[9].

CONCLUSION

This study demonstrates that topical phenytoin dressing is significantly more effective than normal saline dressing in the management of diabetic foot ulcers. The results reveal that phenytoin promotes faster wound healing, as evidenced by greater reductions in wound area, improved granulation tissue quality and higher rates of complete wound closure. Additionally, the use of phenytoin significantly reduced hospital stays, further underscoring its clinical and economic benefits. These findings highlight the potential of phenytoin as an effective and practical therapeutic option for managing diabetic foot ulcers, a condition associated with considerable morbidity and healthcare burden. By accelerating the healing process and reducing complications, phenytoin dressings offer an important advancement in the treatment of DFUs, particularly in settings where timely and effective wound care is critical. Future studies should focus on the long-term benefits of phenytoin and its application across other chronic wound types to further validate its role in wound care protocols.

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