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ORIGINAL RESEARCH

A Comparative Study of Topical Phenytoin with Conventional Dressing versus only Conventional (5% Povidone Iodine) Dressing in the Management of Diabetic Ulcer

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ABSTRACT

Aim/Introduction: This study is being done to see if Topical Phenytoin with Conventional (5% Povidone Iodine) Dressing acts as a better dressing modality in the treatment of Diabetic Ulcer and helps patient recover better than the Conventional (5 % Povidone Iodine) Dressing**. Patients and Methods:** A Randomized Control Trial Study was conducted for a period of 18 Months. Total 60 patients with Diabetic Foot Ulcers were included in the study. The wounds were thoroughly debrided - surgically under anesthesia and ulcer dimensions (measuring maximum length and breadth using a sterile scale) were assessed immediately after debridement and were then reassessed after 7 days and 14 days in either type of dressings and compared**. Results:** Mean age of the study group was 56.53+12.02 and 76.7% patients had BMI>25 and mean BMI was 28.60 SD 3.95. 81.7 % of the patients had HbA1c > 7.5 and Mean HbA1c level was 9.20 SD 1.82. 45% of the patients had no comorbidities other than Type 2 Diabetes Mellitus whereas 31.7% of the patients had single comorbidity amongst which Hypertension was the most prevalent of all i.e. 41.7%. Mean Percentage of Granulation Tissue formed in 14 days in the Conventional Povidone Dressing Group was 50.83 SD 10.54 % whereas in the Topical Phenytoin with conventional dressing group is 69 SD 9.51 % which is significantly higher than the Conventional Povidone Iodine Dressing Group. (p value- <0.001). In Dressing done with Povidone Iodine, ulcers show 24.57 SD 4.91 % reduction in dimensions, whereas in Dressing done with Topical Phenytoin with Conventional dressing, ulcer show 37.07 SD 4.85% reduction in dimensions which is significantly higher (p value <0.001) than the Povidone iodine group. **Conclusion:** Topical Phenytoin with Conventional (5% Povidone Iodine) dressing, when used as a dressing agent for diabetic ulcers, performed better than conventional 5% Povidone Iodine Dressing in terms of Granulation tissue formation and reducing the ulcer dimensions.

Keywords: diabetic ulcer, topical phenytoin, povidone-iodine, wound healing, diabetic foot, randomized control trial.

INTRODUCTION

Diabetes mellitus, while common, poses a significant medical threat that has been on the rise in recent decades, presenting a significant public health challenge in the twenty-first century [1].

In the year 1980 there were approximately 108 Million Diabetics which increased to approx. 422 million in 2014. Additionally, the global incidence of diabetes among adults over 18 years old has surged from 4.7% in 1980 to 8.5% in 2014[2].

Early diagnosis of diabetes is crucial as untreated diabetes can lead to severe complications. There are four common types of diabetes mellitus (DM). Type 1 DM (T1DM), also known as insulin-dependent diabetes mellitus (IDDM), results from the autoimmune destruction of pancreatic β-cells, leading to no insulin production[3].

15% of all diabetics will experience DFU at some point in their lives. While precise prevalence rates are challenging to determine, DFU affects between 4%

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and 27% of patients [4,5]. This complication significantly contributes to the burden of Non Communicable Diseases.

The economic burden is substantial, as the disease leads to a loss of productive working hours for the patient and increased healthcare costs for the country [6,7].

Phenytoin was initially introduced as a treatment for convulsive disorders. Phenytoin promotes the proliferation of fibroblasts, increases collagen deposition, stimulates neovascularization, enhances granulation tissue formation, and reduces the activity of collagenase and bacterial contamination. Its antibacterial properties help eliminate Staphylococcus aureus, Escherichia coli, Klebsiella species, and Pseudomonas, thereby improving the quality of the graft bed and enhancing graft uptake. These effects make phenytoin an effective agent for better wound management in patients [8,9,10,11]

The conventional dressing agent 5% PVP-I (polyvinylpyrrolidone-iodine) is a water-soluble iodophor that combines iodine with a solubilizing polymer carrier, polyvinylpyrrolidone. PVP-I penetrates microorganisms, oxidizing essential proteins, nucleotides, and fatty acids, resulting in cell death. PVP-I dressings and solutions are also relatively inexpensive compared to other antimicrobial therapies .[12]

Hence among the various modalities available, topical phenytoin and conventional povidone iodine dressing have emerged as promising options for wound management. However, there is a lack of high-quality evidence comparing the efficacy of these treatments in managing diabetic foot ulcers (DFUs).

AIM

This study is being done to see if Topical Phenytoin with Conventional (5% Povidone Iodine) Dressing acts as a better dressing modality in the treatment of Diabetic Ulcer and helps patient recover better than the Conventional (5 % Povidone Iodine) Dressing

OBJECTIVES

- To evaluate the effectiveness of Topical Phenytoin with Conventional Dressing as methods of dressing in management of Diabetic Foot Ulcer
- To compare the outcomes of Topical Phenytoin with Conventional Dressing v/s Only Conventional Dressing using Povidone - Iodine - 5% w/v

PATIENTS AND METHODS

A Randomized Control Trial Study was conducted in the Department of General Surgery, Shri Mahant Indiresh Hospital, Dehradun for a period of 18 Months. Total 60 patients with Diabetic Ulcers who were admitted in the Surgery Department were included in the study. All Diabetic Ulcers where conventional dressings were indicated were included in the study .

Inclusion Criteria

1. Patients with Diabetic Ulcers with Type - 2 Diabetes Mellitus
2. Grade - I and Grade - II Ulcers according to Meggit-Wagner Classification of Diabetic Foot Ulcer.

Exclusion Criteria

1. Chronic Non-Healing Wounds of other Etiology
2. Diabetes mellitus with Gangrenous Changes
3. Wounds with Osteomyelitis.
4. Wounds with Poor Vascularity determined by Arterial Doppler Study
5. Other Comorbid Conditions like Renal Failure, Generalised Debility, and other factors, which adversely affect wound healing.

All eligible patients were properly counseled and were explained about the nature and purpose of study. All 60 patients were randomly divided into two groups of 30 each using a Simple Chit system. All patients underwent detailed clinical examination and relevant investigations.

Regular Sugar Monitoring was done and Adequate Sugar Control was done.

The wounds were thoroughly debrided – surgically under anesthesia and ulcer dimensions (measuring maximum length and breadth using a sterile scale) were assessed immediately after debridement and were then reassessed after 7 days and 14 days in either type of dressings .

Pus culture and sensitivity swabs were sent from the ulcer site and antibiotics were then started accordingly.

After signing informed written consent, patients were recruited into the study. Patients were studied as per the working proforma attached. Valid and appropriate statistical tests were applied in the data collected to obtain the results.

PREPARATION FOR DRESSING

Topical Phenytoin with Conventional Povidone Iodine Dressing

A single 100 mg capsule was opened and placed in 5 ml of sterile normal saline to form a suspension. Sterile gauze piece was soaked in suspension and 5% Povidone Iodine Solution and was placed over the wound.

Conventional Dressing

Conventional dressing was done with 5% Povidone-Iodine Solution.

All data was then analyzed using Software SPSS. .

RESULTS

The following observations were made during the study:

Mean Age of Study Group

Mean age of the study group was 56.53 SD 12.02.

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Mean BMI of the Study Group

76.7% of patients had BMI>25 and mean BMI was 28.60 SD 3.95.

Mean HbA1c of the Study Group

81.7 % of the patients had HbA1c > 7.5 and Mean HbA1c level was 9.20 SD 1.82.

Mean Percentage of Granulation Tissue Formation in 7 Days and 14 Days

Mean Percentage of Granulation Tissue formed in 7 days in the Conventional Povidone Dressing Group was 20.83 % SD 6.71% whereas in the Topical Phenytoin with Conventional dressing group it was 32.67 % SD 8.78 % which is significantly higher (p-value <0.001).

Mean Percentage of Granulation Tissue formed in 14 days in the Conventional.

Povidone Dressing Group was 50.83 SD 10.54% whereas in the Topical Phenytoin with conventional dressing group is 69 SD 9.51 % which is significantly higher than the Conventional Povidone Iodine Dressing Group. (p value- <0.001)

Reduction in Dimensions of Ulcer after 14 Days

In Dressing done with Povidone Iodine, ulcers show 24.57 SD 4.91 % reduction in dimensions, whereas in Dressing done with Topical Phenytoin with Conventional dressing, ulcer show 37.07 SD 4.85% reduction in dimensions which is significantly higher (p value <0.001) than the Povidone iodine group.

Gender had no role in the outcome in both the dressing groups.

Percentage Reduction in dimensions of Ulcer after 14 days according to Diabetes Status among Treatment Groups

In conventional 5 % Povidone Iodine group, Patients with diabetes with HbA1c <7.5 showed 25.61 SD 4.96 % reduction in dimensions of ulcer after 14 days , whereas in Topical Phenytoin with conventional (5 % Povidone Iodine) Group, it was reduced by 38.00 SD 2.45%, which is not significantly higher (p value 0.09). In patients with diabetes with HbA1c > 7.5 who had conventional 5% povidone iodine dressing showed 21.14 SD 2.91 % reduction in dimensions of ulcer after 14 days , whereas in Topical Phenytoin with conventional 5 % Povidone Iodine group, dimensions of ulcers showed 36.92 SD 5.14 % reduction.

Pus Culture and Sensitivity Swab Results

In patients in Povidone Iodine Group, Pus Culture swab taken at the time of presentation showed growth on culture in 96.7% of patients whereas in patients in Topical Phenytoin with conventional Dressing group, pus culture swab taken at the time of presentation showed growth on culture in 76.7% of patients.

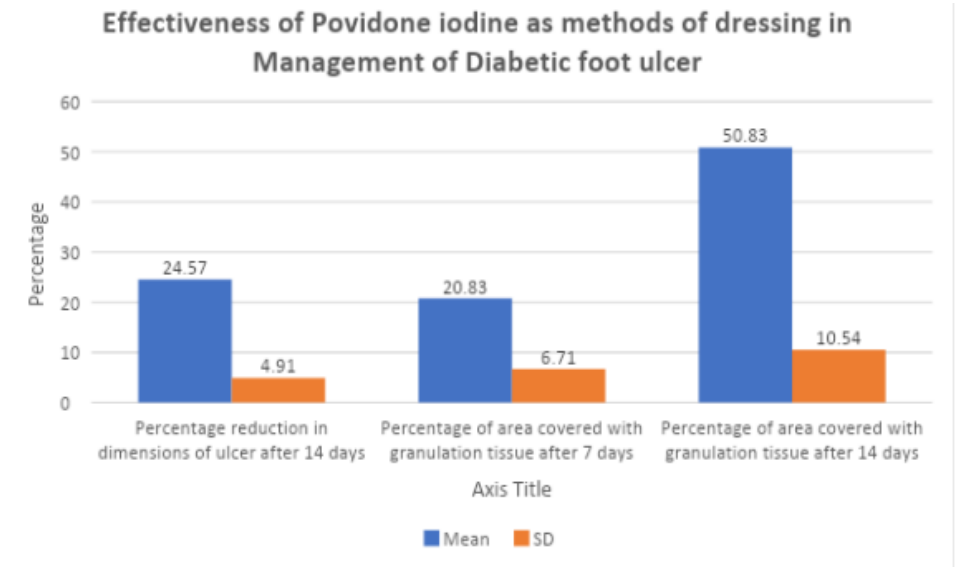
The most common organism found in both the groups was Staphylococcus aureus i.e 30 % in Povidone-Iodine group and 26.7 % in Topical Phenytoin with Conventional (5 % Povidone Iodine) Dressing Group.

Comparison of Adverse Effects Observed in Both the Study Groups

Incidence of adverse effects like Skin irritation and itching was observed only in 1 case (3.3%) in the Conventional Povidone Iodine dressing. Adverse effects such as burning sensation and erythema were noted among 2 cases (6.7%) with Topical Phenytoin with Conventional (5 % Povidone Iodine) Dressing group.

Comparison of Biochemical Parameters among Treatment Groups

Conventional Povidone Iodine Group showed mean RBS 289 SD 66.76 whereas in Topical Phenytoin with conventional (5 % Povidone Iodine) group the mean RBS was 293 SD 44.75. Mean FBS was 147 SD 32.44 and 159.62 SD 30.58 and mean HbA1c was 9.22 SD 2.02 and 9.17 SD 1.62 in the respective groups.



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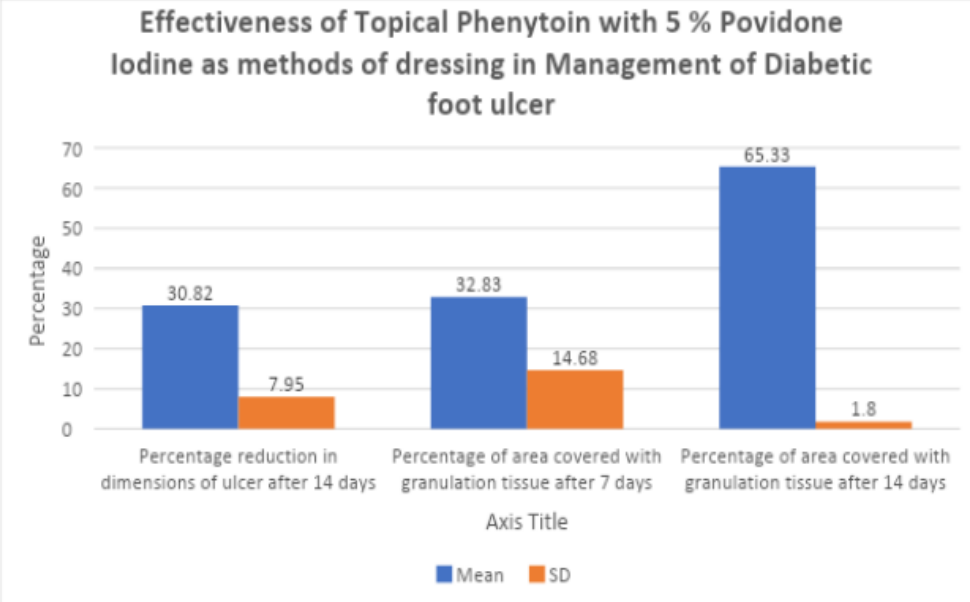

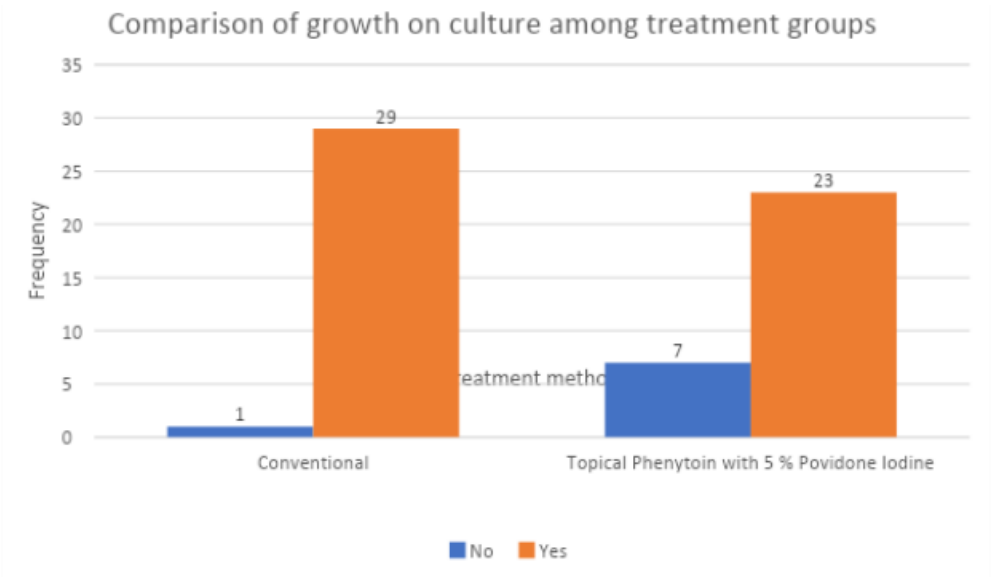

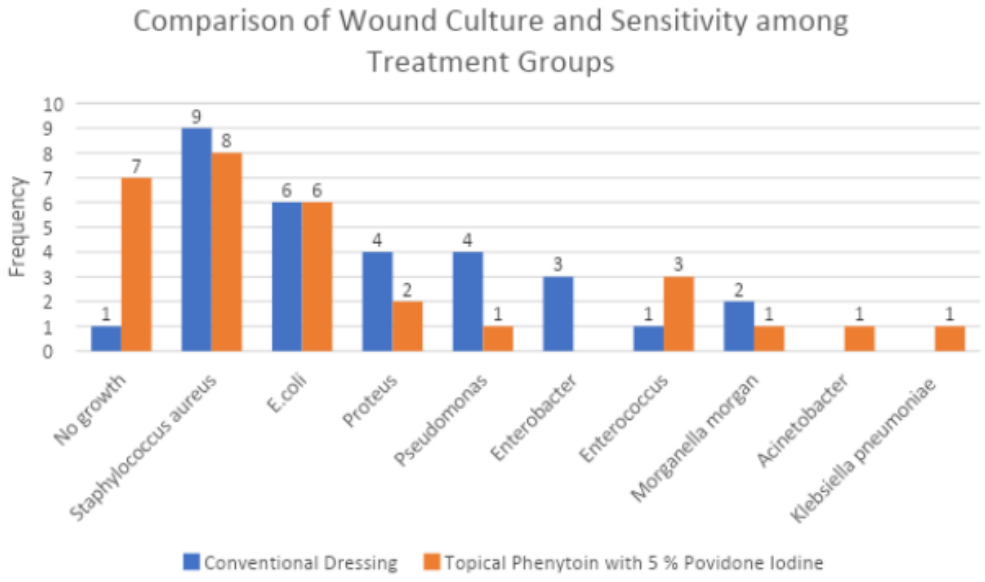

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DISCUSSION

Diabetic ulcer is a common and disabling condition which may eventually lead to amputation of the leg.[14] Furthermore, due to mobility limitations, impaired ability to perform daily life activities, fear of amputation, chronic pain, and frustration, diabetic ulcer has an adverse impact on patients' mental health also [15],[16],[17]

Wound debridement, reducing ulcer load, treatment via drugs, wound dressing, and prevention of infection by keeping the ulcer clean are the gold standards for treating Diabetic ulcer,[18] amongst which Dressing plays a major role in healing of wounds along with debridement . [19]

Amongst the various agents used for dressing, Phenytoin is cheap, easy to use and readily available for medical practice.[20] It promotes wound healing by various mechanisms: Fibroblast Proliferation, quick formation of granulation tissue, reducing collagenase activity, antagonizing glucocorticoid activity, antibacterial activity by affecting inflammatory cells, neovascularization and phenytoin increases gene expression of the platelet derived growth factor β chain in macrophage and monocytes . [21.22]

In the present study, we aimed to compare effectiveness of Topical Phenytoin with Conventional Dressing versus only Conventional - 5% Povidone Iodine Dressing in the management of Diabetic Ulcer in terms of granulation tissue formation and reduction in area of ulcer. We also tried to correlate it with factors like age, sex, height, weight, BMI, Fasting Blood Sugar, Random Blood Sugar, HbA1c, Controlled or Uncontrolled Diabetes status and adverse reactions associated with the use of both agents .

Study included a total of 60 cases of Diabetic Ulcer. They were divided into 2 groups (30 each): one receiving Conventional Povidone Iodine dressing and the other receiving Topical Phenytoin with Conventional - 5 % Povidone Iodine dressing . The results were compared after 14 days.

Out of the 60 patients, the mean age of the study group is 56.53 SD 12.02. Vardhan A[23] et al. also had most cases in 51-60 yr which were 50% cases. Yadwadkar S et al[24] also had most cases in 51-60 yrs which were 44% of cases .

According to a study conducted in Belgium in 2023, men presented with more severe Diabetic foot ulcer than women[25] In both the groups of our study , the majority of the patients are Male ie. 80% in Conventional Povidone Iodine Group and 83.3% in Topical Phenytoin with Conventional-5% Povidone Iodine dressing group. Similar to our study, in a study conducted by Sudhir S, Ganashree MH, Naik D, Dilip DK. in 2020 , male predominance was found amongst the study groups i.e. 65% in Phenytoin group and67% in conventional dressing group . [26]

In our study, mean BMI was 28.60 SD 3.95. In a study conducted by Tabana C and others,[27] the mean BMI for both cohorts was constant at 27.5 (with a deviation of 1.8 in the phenytoin group and 1.7 in the conventional group), showing that both groups were moderately overweight .

The HbA1c is now recommended as a standard of care (SOC) for testing and monitoring diabetes [28]

In our study, the majority of patients had HbA1c levels > 7.5 i.e 81.7 % whereas 18.3% had HbA1c levels <7.5 as shown in table 3. These results were comparable to a study conducted by Swathika Rajendran and others in 2021, in which 23% patients had HbA1c levels of 6.5-7.5(mmol/l), 44% patients had 7.6-8.5(mmol/l) and 33% patients had 8.6-9(mmol/l) [29]

Mean FBS was 153.32 SD 31.89, mean RBS was 291.45 SD 56.40 and mean HbA1c was 9.20 SD 1.82.

In our study, the majority of patients i.e. 40% in Conventional Povidone Iodine Dressing group and 50% in Topical Phenytoin with conventional dressing group had no comorbidities other than Type - 2 Diabetes Mellitus. 36.7% and 46.7% were hypertensives whereas 23.3% and 3.3% had other comorbidities in the respective groups. 36.7% and 26.7% had a single comorbidity in the Povidone iodine group and Topical Phenytoin with conventional dressing group respectively.

Percentage reduction in dimensions of ulcer after 14 days according to comorbidities was calculated but was statistically insignificant (p value 0.180). Similar results were found in a study conducted by Dr. K. Sreehita and Dr M. Anurag [30] , Hypertension was the most common comorbidity followed by Coronary Artery Disease (CAD)

In our study, most common organism isolated from the wound was Staphylococcus aureus similar to the study done by Bharadva PB et al [31], the most common organism isolated was Staphylococcus aureus as was in the study by Ayesha Nageen in 2016.[32], Adel Abdulrazak and others[33]. In a study, conducted by Brandon K. Hawkins [34] Klebsiella pneumoniae (20%) was the most common pathogen.

Most common side effects associated with use of systemic use of phenytoin are Gingival Hyperplasia, coarsening of the facies, enlargement of the lips, and thickening of the scalp and face, hirsutism amongst the others. These side effects were not observed in our study as we used phenytoin as a topical agent.

In our study, the majority of the patients i.e. 96.7 % in the conventional dressing group and 93.3% in Topical Phenytoin with conventional dressing group had no adverse effects.

In the conventional Povidone dressing group, 3.3% of the patients had adverse effects such as Skin irritation and itching whereas in the Topical Phenytoin with conventional dressing group, 6.7% of the patients had Adverse effects such as Burning sensation and mild Erythema which is statistically not significant (p-value- 0.5).

In our study, Mean Percentage of Granulation Tissue formed in 7 days in the Conventional Povidone Iodine Group is 20.83 SD 6.71 whereas in the Topical

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Phenytoin with conventional dressing group is 32.67 SD 8.78 which is significantly higher (p-value <0.001).

Mean Percentage of granulation tissue formed in 14 days in the conventional povidone iodine group is 50.83 SD 10.54 whereas in Topical Phenytoin with conventional dressing group is 69 SD 9.51 which is significantly higher than the former group. (p value-<0.001) Our results are comparable with the study conducted by Prasad S et al, the mean rate of granulation tissue is 42.50%, and in the control group mean rate of granulation tissue formation is 36.68% [35] and TauroL.F et mean rate of granulation tissue formation at the end of 14 days in the Phenytoin group was 87.94% and in control group was 74.64%.[36] The results of study conducted by M.K.M.G.et al were also similar to our study which shows rate of granulation tissue as 46% in phenytoin when compared to 20% in Betadine group

In our study, patients in povidone iodine group in diabetes with HbA1c<7.5 showed 25.61 SD 4.96 % reduction in dimensions of ulcer after 14 days, whereas in Topical Phenytoin with conventional dressing group, it was reduced by 38.00 SD 2.45%, which is not significantly higher (p value 0.09). In diabetic patients with (HbA1c>7.5) who had Povidone Iodine dressing showed 21.14 SD 2.91% reduction in dimensions of ulcer after 14 days , whereas in Topical Phenytoin with conventional dressing group, it was 36.92 SD 5.14% reduced which is statistically not significant (p-value - 0.306).

Similar results were observed in study conducted by Dr. Sudhir S, Dr. Ganashree MH, Dr. Deepak Naik, and Dr. Dilip DKin 2019 which concluded that Topical Phenytoin significantly hastens the wound healing by formation of granulation tissue and reducing the wound size but their result was statistically significant p value 0.0001 [37]

In a study conducted by Vijaya Patil, Rashmi Patil; Phenytoin was found useful in promoting wound healing and control of infection in diabetic ulcers, study was conducted on 100 patients and results were-significant reduction [p-value<0.005] of discharge and slough in wound by 14 days in phenytoin group and 21 days in control group

In our study we found that in patients who underwent Topical Phenytoin with conventional dressing showed 37.07 SD 4.85% reduction in dimensions of ulcer. In a study by Dr. Sudhir S, Dr. Ganashree MH, Dr. Deepak Naik, and Dr. Dilip DK, patients who underwent phenytoin dressing showed 59.22+10.43% reduction in the dimensions of ulcers.[26]

CONCLUSION

In our study we concluded that Topical Phenytoin with Conventional (5% Povidone Iodine) dressing, when used as a dressing agent for diabetic ulcers, performed better than conventional 5% Povidone Iodine Dressing in terms of Granulation tissue formation and reducing the ulcer dimensions.

LIMITATIONS

The most important limitation of the present study is its sample size. A sample size of 30 patients per treatment group may not be enough to justify the beneficial effects of Topical phenytoin with Povidone Iodine Dressing to the population of Diabetic patients with Ulcer.

The study lacks a longer follow up period for the patient, which might be very crucial and important to study the long term effects and safety of the Topical Phenytoin with Povidone Iodine when compared to its counterpart ie. The Povidone - Iodine Dressing in the Management of Diabetic Ulcers.

This study design does not account for a very important confounder ie. the patient adherence to intake of OHA and proper sugar control which is a very important aspect for the healing and management of Diabetic Ulcer.

Our study does not take into account the cost effectiveness of Topical Phenytoin with Conventional 5 % Povidone Iodine Dressing when compared to Only Conventional 5% Povidone Iodine, which is a very important factor in Clinical Practice.

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