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A Comparative Study of Topical Phenytoin Vs Conventional Wound Care in Diabetic Ulcer

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Abstract:
Aim: *To assess the efficiency of topical phenytoin compared to conventional wound care in improving the healing process in diabetic ulcers and prove that topical phenytoin can be used as relatively low cost, case of use and a better alternate in management diabetic ulcers.*
Material and methods: This is a prospective randomised comparative study where data from 100 patients with diabetic ulcer collected. Of which 50 underwent topical phenytoin dressings, remaining 50 underwent conventional wound care. The results were compared after 14 days. The variables were compared based on rate of granulation tissue formation as percentage of ulcer area covered and duration of hospital stay. The categorical variable was compared by chi square test and continuous variable by student t-test. A p value <0.05 was considered significant.
Results: *50 patients who underwent topical phenytoin, after 14 days mean rate of granulation tissue formation was 84%. Mean graft take up was 86.32% and mean hospital stay was 40.50 days. Remaining 50 patients who underwent conventional wound care mean rate of granulation formation was 58.72%. The Mean graft take up was only 74.74% of total ulcer surface area, mean hospital stay was58.52 days.*
Conclusion: *To conclude, topical phenytoin helps in faster healing of the diabetic ulcer and better graft takeup and reduces hospital stay of these patients.*
Keywords: *Topical phenytoin moist wound dressing, diabetic ulcers, rate of granulation tissue formation, graft take up.*

I. Introduction

Diabetes mellitus comprises a group of common metabolic disorder that share the phenotype of hyperglycaemia. In this millennium where mankind has succeeded in deciphering the human genetic code, the issue of chronic wound management still remains an enigmatic challenge. Chronic wounds, especially non healing types, are one of the most common surgical conditions a surgeon comes across. From time immemorial Doctors have been trying many methods to treat these types of wounds. The metabolic dysregulation associated with DM causes secondary pathophysiologic changes in multiple organ systems that imposes a tremendous burden on individual.1 The peculiarity of a chronic wound is that, whatever management you give, they refuse to heal, especially pressure ulcers or bed sores. The notion that wounds should be kept dry, although still held by a considerable number of clinicians, is steadily losing ground. We now know that wounds re-epithelial much faster or develop granulation tissue faster when treated with dressings which allow moist wound healing. We recognize that occluding wounds does not lead to infection. Even though many modalities of wound care have come up to assist a surgeon, example the use of compression bandages to treat venous ulcers, the problem of chronic wound still remains.2

A wound care revolution is currently in the making. Many techniques have been tried over the centuries to heal chronic leg ulcers. Although wound dressing have been used for at least two millennia, there exist no ideal dressing. Surgical dressing of both open and closed wound is based mainly on tradition, training and surgeons own philosophy. During the last two decades a wide variety of innovative dressings have been introduced.2 Neuropathy presents in many forms including focal neuropathy and polyneuropathy and autonomous neuropathy. Patient with distal sensory neuropathy are predisposed to develop Charcot's joint which may mimic gout or degenerative joints. Treatment involves surgical debridement and antibiotic treatment.3 Diabetic neuropathy has been defined as peripheral nerve dysfunction after exclusion of other causes which may range from hereditary, traumatic,compressive,metabolic, toxic, nutritional infectious , immune mediated neoplastic and any other secondary systemic illness. 4

Classification of diabetic neuropathy
A) Diffuse
1. Distal semetric sensory motor polyneuropathy
2. Autonomic neuropathy

A. submotor
B. cardiovascular
C. gastro intestinal
D. genitourinary
3. Symmetric proximal lower limb motor neuropathy.

B) Focal
1. Cranial neuropathy
2. Radiculopathy
3. Entrapment neuropathy
4. Asymmetric lower limb motor neuropathy.[5]

People have tried various non-conventional topical therapies in wound healing, such as aloe vera, antacids, Benzoyl peroxide, collagen, gentian violet, impregnated guaze, insulin, mercurochrome, oxygen therapy, sugar, vinegar and phenytoin.6
Studies have also shown that topical phenytoin promotes healing of Decubitus ulcers, venous stasis ulcers, traumatic wounds, burns, leprosy , trophic ulcers, and was found to be superior management of diabetic ulcers. The present study was conducted to assess the efficacy of topical phenytoin dressing as compared to conventional moist wound dressing in healing process in Diabetic ulcers and prove that Topical phenytoin can be used as much better alternative option in the management of Diabetic ulcers.6,7,8,9,10,11

Objectives Of The Study
To compare the efficacy of topical phenytoin with that of a control group using conventional wound dressings ,in healing of diabetic ulcers, in terms of:
- Number of days required for healing.
- Rate of granulations tissue formation.
- Rate of reduction in mean ulcer surface area.
- Quality of graft bed.
- Skin graft take up.
- Serial culture and sensitivity of wound swabs to assess the effect of topical phenytoin on bacterial load.

II. Materials And Methodology

This prospective randomized comparative study included 100 patients with diabetic ulcers admitted .Satisfying all the inclusion criteria mentioned below after the clearance from the ethical committee was obtained. All diabetic ulcers where conventional dressings are indicated were included in the study. The main inclusion criteria were, Patients with age between 25 - 75 years Patients with chronic ulcers with diabetic mellitus. Wound size <5% TBSA Patients giving consent for topical phenytoin therapy. The main exclusion criteria for the study included Chronic non-healing wounds of other aetiology. Diabetes mellitus with gangrenous changes. Other co-morbid condition like renal failure, generalized debility and other factors, which adversely affect wound healing. The data was collected from 100 patients who are having diabetic ulcers satisfying all the inclusion criteria mentioned above. The whole sample population was divided into two equal and comparable groups based on willingness for undergoing topical phenytoin therapy for wound. Those who were not willing were subjected to conventional wound care, forming the control group. Selection of patients was done by purposive sampling method. All patients underwent detailed clinical examination and relevant investigations and the wounds were thoroughly debrided and the ulcer dimensions as well as the surface area assessed using vernier calipers, before both types of dressings were applied. The patients were followed up on a daily basis for 14 days in both study and control groups. The control group and study group were subjected to twice-daily dressing.

Application of Dress:
Topical Phenytoin: A single IOO mg 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 TBSA.

Conventional Dressing was done with 5% w/v povidone - iodine solution. Before applying both dressing daily wound is cleaned with normal saline. At the end of 14 days the wounds in both the groups were inspected and the wounds were compared based on the following parameters.

They are, Rate of granulation tissue formation as percentage of the ulcer surface Quality of the ulcer bed Present dimensions and surface area of the ulcer Once these parameters were assessed, both the groups were subjected to split thickness skin grafting. Both groups were given the same systemic antibiotics during the postoperative period. The wounds were reassessed at the end of the fifth postoperative day and the following parameters were accounted for. They were, Skin graft take up as a percentage of ulcer surface area

Number of days of hospitalization After discharge, patients were followed up in the outpatient department. After one month to assess post skin grafting complications like contractures, itching, pain and infection. The results obtained were statistically evaluated and the main parameters, which were analysed, Rate of granulation tissue formation Graft survival and take up Duration of hospital stay

The mean rate of granulation tissue formation, graft survival and hospital stay was calculated and compared for both groups. The variables were compared using the Unpaired Student's t-test. A P value <0.05 was considered significant.

III. Observation And Result

The 100 patients admitted for the study were divided into two equal and comparable groups. Patients subjected to topical phenytion dressing were classified under Study and those who underwent conventional moist wound dressings were classified as control. The patients characteristics of the two groups were well matched in the table below

	Study	Control
No. of patients	50	50
Range of age in years	25-75	25-75
Male – Female ratio (M : F)	28:22	35:15
Range of Ulcer surface area cm^2	6-100	4-80

Age Distribution

Age in years	Study	Control
25 – 35	4	5
36 – 45	16	13
46 – 55	19	14
56 – 65	7	17
66 - 75	4	1

The age of the patients were varied from 25 to 75 years. Maximum number of cases(57%) belong to the age group of 45 to 65years.The average diabetic foot lesion in our country is 60years.
The mean age in study group was 48.96±12.49 years and in control group was 49.74±10.9 years.

Sex Wise Distribution

	Male	Female
Study	28	22
Control	35	15

In both study and control group diabetes is more common among males compared to females. Among them 67% of the patients were male and 33% were female.

Rate of granulation

Ulcer surface area	Study	Control
< 40	1	13
41 – 50	0	8
51 – 60	0	6
61 – 70	0	4
71 – 80	1	9
81 – 90	38	8
> 90	10	12

The rate of granulation tissue formation was assessed at the end of 2weeks.81 to 90% granulation was seen in study group. The patients in both the groups were subjected to split thickness skin graft as the final treatment modality. The graft take up was assessed on the fifth post operative day.

Graft take up percentage of surface area

	Study group NO of cases	Control group No of cases
Good	42	35
Average	7	12
Poor	1	3

In study group 84% cases graft take up was good and 70% in the control group.

Duration of Hospital Stay

	Mean	SD
Study	40.50	5.70
Control	58.52	9.99

The quality of life of the patients in both the groups was assessed by the assessment of total hospital stay as number of days of admission in the hospital is as above.

Percentage of Negative culture sensitivity at the end of 14 days

	Positive	Negative
Study	20	30
Control	33	17

Patient in both the groups were assessed for effect of topical agents on the bacterial load as percentage of people who are culture sensitivity negative at 14 days

The mean hospital stay in study group was 40.50±5.70(sd) days and that in control was 58.52±9.9(sd) days. In both the groups, no complications occurred during the application of dressing, skin grafting or in the post operative period. The patients were followed up after one month of discharge. The main post operative parameters were

- wound size
- contractures
- pain
- infection

All the parameters were less in study as compared to control

Grade II Ulcers

Grade III Ulcers

Grade IV

Healed Ulcer

Final Out Come

IV. Discussion

Wound dressings have evolved from the status of providing physical protection to the raw surface, absorbing exudates and controlling local infections by local medications to the level of providing adequate environment promoting wound healing. This has been achieved by modern wound dressing equines promoting granulation tissue formation. The concept of moist wound dressings which came into vogue in 1960 which revolutionized wound care .This led to further research in this direction leading to influx of many products .People have tried various non conventional topical agents in wound healing such as aleo vera, antacids , benzoyl per-oxide ,collagen ,gentian violet, impregnated guaze, insulin, mercurochrome oxygen therapy, sugar and vinegar. Each claiming a better wound healing rate than the others. As the concept of outcome based medicine evolved, the need for better wound dressing modality became more acute. Now wound dressing systems were compared not only on the basis of the rate of granulation tissue formed or the rate of wound healing but also on the cost and duration of hospital stay of the patient which was considered as a measure of the morbidity of the patient. The study is similar to the study conducted by Muthukumarswamy MG et al. The difference between the present study and the one done by Muthu was he used a thin layer of phenytoin powder over the wound. The study's sample size was 100 , fifty in each group, mean age in study group was 56.4 yrs and 58.7 yrs in control. Graft takeup was 72.4 % and 58.43 % respectively . Hospital stay 21 days in study group and 45 days in control group. In study made by me, the mean age group – in study group is 48yr and 49yrs in control group. Graft takeup was 84 % and 74 % respectively. Hospital stays 40.5 days in study group and 58 days in control group. His study was done as a prospective randomized controlled comparative study to compare the efficacy of topical phenytoin moist dressing to conventional most wound dressing in management of diabetic ulcer. The quantitative assessment of the post operative parameters like wound .contraction, pain and residual raw ulcer area was also not included in the present study, which if included, might have given a much better analysis of the efficacy of topical phenytoin moist dressings as compared to conventional moist dressings.

Future trends: The important areas where significant advances has occurred in chronic wound care are the development of wound dressing systems, which stimulate wound healing process by improved granulation tissue formation and the development of permanent composite skin replacement in the form of genetically engineered keratinocyte culture techniques and growth factors. The main problem of the latter technique is that it is still in the experimental phase and will not be available to common man in the near future.[12,13]

Extensive research is going on in the development of artificial skin substitutes by combining cultured keratinocytes with artificially formed dermal analogues, namely Integra, AlloDerm, polygalactin mesh, human allogenic dermis etc., which has immense potential. It is only a matter of time before a 'successful approach to the management of chronic wounds is devised.

V. Conclusion

In our present study it was concluded that the rate of granulation tissue formation, overall graft survival and patient compliance was better in topical phenytoin dressing group as compared to conventional dressing group. It was also seen that the overall hospital stay and post operative complications were less in the topical phenytoin dressing group. Thus, topical phenytoin moist wound dressing can be considered as a superior option in the management of diabetic ulcers . But further studies with larger population will be needed in the future before topical phenytoin dressing can be added to the wide spectrum of treatment modalities available in the management of diabetic ulcers and ulcers of other etiology.

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