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Efficiency of topical phenytoin in diabetic foot ulcer care: A randomized control trial

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Abstract

Aim: To study the efficiency of topical phenytoin on healing in diabetic foot ulcer grades 1 and 2.

Methods: Totally, 60 patients in each group with diabetic foot ulcers of more than 4 weeks duration without any co-morbid conditions and ulcers belonging to Grade 1 and 2 as per Meggitt – Wagner's diabetic foot ulcers were inducted into the study. The whole sample population was divided into two equal and comparable groups based on willingness for undergoing topical phenytoin therapy for the wound. Those who were not willing were subjected to conventional wound care, forming the control group. Antibiotics are given to both groups as per culture reports.

Results: In the study group, 13 patients had granulation tissue at 14 days of less than 75%, and 17 patients had granulation tissue at 14 days of greater than 75%. In the control group mean value of the size of the ulcer initially is 8.76cm and in 7 days is 7.12 cm and in 14 days is 5.86 cm. In the study group mean value of the size of the ulcer initially is 9.03 cm and in 7 days is 5.63 cm and in 14days is 3.3 cm.

Conclusion: Phenytoin enhances wound healing via the following mechanisms: stimulation of fibroblast proliferation, enhancement of granulation tissue development, and inhibition of collagenase activity.

Keywords: diabetic foot ulcer, granulation tissue, topical phenytoin, conventional dressings

Introduction

Management of the diabetic foot requires a multisystem approach, which includes the nervous, vascular, skeletal, immune, and integumentary systems. Phenytoin has been used by many workers because of its positive effects in ulcer healing, such as increase in the proliferation of fibroblasts and deposition of collagen, neovascularization, enhanced granulation tissue formation, decrease in the action of collagenase and bacterial contamination

Aim

To study the efficiency of topical phenytoin on healing in diabetic foot ulcer grades 1 and 2.

Materials and Methods

This randomized controlled study was done in the Department of Surgery Sri Venkateshwaraa Medical College Hospital and Research Centre Ariyur, Puducherry from January 2019 to June 2020. Inclusion criteria: Age group 25-75, both male and female, consent for inclusion in the study, patients with chronic ulcers with diabetes mellitus, wound size <5% TBSA. Exclusion criteria: Diabetic foot ulcer with Grades III, IV, V according to Meggitt's-Wagner clinical classification and diabetic ulcers with ischaemic changes, trophic ulcers caused by neuropathy, multiple sclerosis, varicose ulcers, and Marjolin's ulcers were excluded. Presence of osteomyelitis, patient on steroids, other comorbid conditions like renal failure, generalised debility which adversely affects wound healing. Patients with allergies to phenytoin.

60 patients in each group with diabetic foot ulcers of more than 4 weeks duration without any co-morbid conditions and ulcers belonging to Grade 1 and 2 as per Meggitt – Wagner's diabetic foot ulcers were inducted into the study. The whole sample population was divided into two equal and comparable groups based on willingness for undergoing topical phenytoin therapy for the wound. Those who were not willing were subjected to conventional wound care, forming the control group. Antibiotics are given to both groups as per culture reports. Daily monitoring of blood sugar was done, appropriate treatments were given. In the well cleaned and debrided wounds, the surface area of the wound is measured on days 7 and 14 using tissue paper mapping. The proper wound care and phenytoin powder application are carried out daily.

All the measurements were carried on by a single examiner for all the participants. When they were identical, the readings were recorded. If they were not, the average was recorded. Both the groups will undergo dressings twice a day. Patients in both groups followed upto 14 days. The wound is assessed in terms of Rate of granulation tissue formation, reduction in wound surface area, duration of hospital stay (at the end of 14days)

Results

In this study, 60 cases with DFU grades 1 and 2 were divided into 2 groups, case group underwent topical phenytoin and conventional wound care, forming the control group. In the control group, 18 patients and the study group, 16 patients had a duration of diabetes between 11-20 years. In the control group, 20 patients had traumatic onset, in the study group, 18 patients had a traumatic onset of diabetic foot ulcer. The mean value of fasting blood glucose in the control group is 221mg/dl and in the study group is 218 mg/dl.

The mean value of postprandial blood glucose level in the control group is 281 mg/dl and in the study group is 272 mg/dl. In the study group initially, 8 patients had ulcer size less than 5 cm, 13 patients between 6-10 cm, 9 patients between 11-20 cm. In the study group, 13 patients had granulation tissue at 14 days of less than 75%, and 17 patients had granulation tissue at 14 days of greater than 75%. In the control group mean value of the size of the ulcer initially is 8.76cm and in 7 days is 7.12 cm and

in 14 days is 5.86 cm. In the study group mean value of the size of the ulcer initially is 9.03 cm and in 7 days is 5.63 cm and in 14days is 3.3 cm. In the control group mean value of the duration of hospital stay is 24.66 days and in the study group is 17.4 days.

Table 1: Distribution of patient's characteristics

Patient characteristics	Control group	Study group	
Age group	<30	1	0
	31-40	3	4
	41-50	12	9
	51-60	10	11
	>61	4	6
Gender	Male	25	27
	Female	5	3
Duration of Diabetes	<5	2	4
	6-10	9	8
	11-20	18	16
	>20	1	1

Table 2: Distribution of Wound characteristics

Wound characteristics	Control group	Study group	
Type of Onset	Traumatic	20	18
	Spontaneous	10	12
Site of Ulcer	Plantar	20	22
	Dorsum	10	8

Table 3: Comparison of presence of granulation tissue

Presence of Granulation tissue	No granulation present	< 25% of wound filled	25-74% of wound filled	75-100% of wound filled	P-value	
Control group	Baseline	16	8	6	0	0.001
	7 days	14	4	12	0	
	14 days	7	8	8	7	
Study group	Baseline	19	6	5	0	<0.0001
	7 days	15	9	6	0	
	14 days	0	7	6	17	

Table 4: Comparison of size of ulcer

Group		Size of ulcer			P-value
		<5 cm	6-10 cm	11-20 cm	
Control group	Baseline	6	17	7	0.279
	7 days	9	14	7	
	14 days	14	11	5	
Study group	Baseline	8	13	9	0.007
	7 days	17	8	5	
	14 days	22	6	2	

Conclusion

The goal of this study was to enhance the wound/ulcers to be devoid of necrotic tissue and debris. In individuals with diabetic foot ulcers treated with topical application of phenytoin, this prospective randomised control study indicates better wound healing and sense of well-being than the other classical wound dressing products. Phenytoin promotes wound healing by following mechanisms: Stimulation of fibroblast proliferation, enhancing the formation of granulation tissue, decreasing collagenase activity.

Limitations

In the future, however, more trials with larger samples are required before topical phenytoin dressing can be applied to the broad spectrum of treatment modalities available for diabetic ulcer management.

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