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COMPARATIVE AND ANALYTICAL STUDY OF EFFICACY OF TOPICAL APPLICATION OF INJ. PHENYTOIN, SUCRALFTE SYRUP AND HYDROGEL CREAM ON NON-HEALING DIABETIC FOOT ULCER IN A TERTIARY CARE CENTER

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ABSTRACT

Aim & Objectives: The primary goal of the study was to assess and compare the effectiveness of topical applications of Inj. Phenytoin, sucralfate syrup, and hydrogel cream on non-healing Diabetic Foot Ulcers; to compare the healing efficacy of phenytoin, sucralfate syrup, and hydrogel cream -Ulcer healing time; to estimate the average reduced hospital stay with each dressing; and to assess the cost of each dressing.

Methods: Over the course of 24 months, the investigation was carried out as a clinical trial at Hyderabad's Osmania Medical College/Hospital. Patients at Osmania Medical College/Hospital's Surgery Out Patient Department (OPD) who have been diagnosed with diabetic foot ulcers.

Results: The likelihood of an amputation increases with grade. At the conclusion of the first week, there was no discernible difference in the ulcer's size when using all three dressings. When phenytoin injection dressing is used instead of the Sucralfate and Hydrogel dressing, there is a discernible rate of size reduction at the end of the fourth and tenth weeks. The minimal number of days spent in the hospital for Group A patients is significantly lower than for Group B and Group C patients. When compared to Group B and Group C, patients in Group A return to work earlier and miss fewer days of work overall.

Conclusion: The current study comes to the conclusion that the management of diabetic foot ulcers with Inj phenytoin dressing has better ulcer healing and contraction rate, early recovery from the disease, and early return to work. It is also more readily accessible on the market and simpler to apply. a prolonged hospital stay will prevent cross infection. In the current study, phenytoin dressing for diabetic ulcers that are not healing caused a statistically significant effect.

Keywords: Phenytoin, sucralfate syrup, hydrogel cream, topical, diabetic foot ulcer.

INTRODUCTION

An extensive range of cutting-edge dressings have been introduced over the past two and a half decades. Numerous unconventional topical remedies, including Aloe vera, benzoyl peroxide, the protein collagen, gentian violet, 2 impregnated gauze, topical phenytoin, mercurochrome, oxygen therapy with sugar, and vinegar, have been used by people to treat wounds. Additionally, research has shown that topical sucralfate accelerates the healing of ulcers in the decubitus

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region, venous stasis ulcers, traumatic wounds, burns, and trophic ulcers, and that it is a superior method of managing diabetic ulcers. Sucralfate is an oral gastro-intestinal medicine that is primarily used to treat active duodenal ulcers, while it is also effective in treating stress ulcers and gastroesophageal reflux disease (GERD) [1]. It demonstrates potential for use in the treatment of skin injuries. Dermal fibroblasts and keratinocytes proliferate in response to sucralfate [2,3].
Additionally, it increases the release of interleukin-6 from fibroblasts that has been induced by interleukin-1 and prostaglandin E2 production in basal keratinocytes. Sucralfate increased granulation tissue thickness when daily applications were made to full-thickness wounds. Additionally, it expedites the epithelialization of second-degree burns Animal studies have demonstrated that applying sucralfate to a wound speeds up the healing process. Sucralfate has been shown in preclinical studies to promote the formation of granulation tissue, thereby promoting cutaneous ulcer healing [4,5]. Several human cellular studies have unquestionably established the fact that applied topically sucralfate is a new pharmacologically active therapy for diabetic ulcers that are resistant to conventional treatment. Numerous trials demonstrated the effectiveness of sucralfate, demonstrating full wound healing and wound size reduction. Sucralfate enhances the healing of cutaneous ulcers by stimulating granulation tissue [6–8].

Similar to phenytoin, neovascularization, enhanced granulation tissue formation, decreased collagenase activity, and reduced bacterial contamination are some of the positive effects of phenytoin on ulcer healing that have led to its widespread use by workers. Phenytoin's antibacterial properties helped to get rid of Pseudomonas, Escherichia coli, Klebsiella species, and Staphylococcus aureus. I decided to undertake a study on the local use of phenytoin on non-healing diabetic foot ulcers since some authors have claimed that the drug can be used to treat a variety of ulcers, including diabetic foot ulcers [9].

MATERIAL AND METHODS:

Over the course of 24 months, the investigation was carried out as a clinical trial at Osmania Medical College/Hospital in Hyderabad. Patients at Osmania Medical College/Hospital's Surgery Out Patient Department (OPD) who have been diagnosed with diabetic foot ulcers.

INCLUSION CRITERIA:

All the patients presenting with Diabetic Foot Ulcers

1. Between Age: 30-85 yrs of age
2. Diabetic patients (On medication)
3. Ulcer size >2 cm
4. Grade 1 and 2 foot ulcers
5. Patients who give consent

EXCLUSION CRITERIA:

1. Age less than 30 years of age or more than 85 years of age
2. Pregnant female
3. Any unexpected complications that need immediate intervention
4. Hemoglobin less than 10g/dl
5. Any color Doppler changes in both arterial and venous phase
6. Patients who do not give consent and unwilling to be a part of the study

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SAMPLING METHOD:
This study included a total of 75 patients with diabetic foot ulcers who were enrolled in the surgical outpatient department. Each alternate consenting patient who came to see us was assigned to Group A, Group B, or Group C, as appropriate.

MATERIALS & METHODS:
A diabetic foot patient who attended the Surgical OPD at OSMANIA Medical College in Hyderabad participated in this research trial. The necessary protocol was followed to get ethical committee approval. 75 diabetic foot ulcer patients are included in the study.

Out of 75, 25 will be treated in the form of standard care and with Inj. Phenytoin topical application. 25 will take treatment in the form of standard care and with topical dressing with Sucralfate syrup. 25 will be treated with standard care and dressing with hydrogel cream.
In all the groups the foot Ulcer was classified as per the Wagner's grading.

WAGNER'S GRADING:
0-Intact skin
1-Superficial ulcer of skin or subcutaneous tissue
2-Ulcers extend into tendon, bone, capsule
3-Deep ulcer with Osteomyelitis /abscess
4-Gangrene of Toes/forefoot
5-Midfoot/Hind foot gangrene

STATISTICAL ANALYSIS
The data were analysed using SPSS (Statistical Package for Social Science) software. The data collected were scored and analysed, Continuous variables were presented as means with Standard Deviation (SD) and categorical variables were presented as frequency and percentages. ANOVA test was used for testing the significance of all the mean and standard deviation in groups. Chi-square test was used to compare proportions. P value <= 0.05 was considered as statistically Significant in all statistical results.

RESULTS

TABLE 1: AGE DISTRIBUTION

AGE GROUP	STUDY GROUP					
	GROUP A		GROUP B		GROUP C	
	N	%	N	%	N	%
31 – 40 Years	4	16.00	6	24.00	2	8.00
41 – 50 Years	11	44.00	6	24.00	10	40.00
51 – 60 Years	4	16.00	8	32.00	8	32.00
61 – 70 Years	4	16.00	3	12.00	5	20.00
71 – 80 Years	2	8.00	2	8.00	0	0
Total	**25**	**100**	**25**	**100**	**35**	**100**
Mean	**49.40**		**50.80**		**52.56**	
SD	**11.62**		**10.50**		**8.52**	
ANOVA	**0.59**					
p-value	**0.56**					
Significant	**Not Significant**					

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By conventional criteria the difference between the groups were comparable since the p value is >0.05 and so it is statistically not significant. In simple words both the groups were comparable.

TABLE 2: GENDER DISTRIBUTION

Gender	STUDY GROUP					
	GROUP A		GROUP B		GROUP C	
	N	%	N	%	N	%
Male	14	56.00	15	60.00	17	68.00
Female	11	44.00	10	40.00	8	32.00
TOTAL	**25**	**100**	**25**	**100**	**25**	**100**
Chi square Value	**0.79**					
p-value	**0.68**					
Significant	**Not Significant**					

By conventional criteria the difference between the groups were comparable because the p value is >0.05 and so it is statistically not significant. Hence both the groups were comparable.

TABLE 3: DIABETIC TYPE DISTRIBUTION

TYPE	STUDY GROUP					
	GROUP A		GROUP B		GROUP C	
	N	%	N	%	N	%
TYPE I	1	4.00	2	8.00	0	0
TYPE II	24	96.00	23	92.00	25	100
TOTAL	**25**	**100**	**25**	**100**	**25**	**100**
Chi square Value	**2.08**					
p-value	**0.35**					
Significant	**Not Significant**					

By conventional criteria the difference between the groups were comparable since the p value is >0.05 and so it is statistically not significant.

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TABLE 4: SMOKING STATUS

SMOKING	STUDY GROUP					
	GROUP A		GROUP B		GROUP C	
	N	%	N	%	N	%
Yes	5	20.00	7	28.00	7	28.00
No	20	80.00	18	72.00	18	72.00
Total	**25**	**100**	**25**	**100**	**25**	**100**
Chi square Value	**0.56**					
p-value	**0.75**					
Significant	**Not Significant**					

TABLE 5: ALCOHOL STATUS

ALCOHOL	STUDY GROUP					
	GROUP A		GROUP B		GROUP C	
	N	%	N	%	N	%
YES	11	44.00	11	44.00	13	52.00
NO	14	56.00	14	56.00	12	48.00
TOTAL	**25**	**100**	**25**	**100**	**25**	**100**
Chi square Value	**2.08**					
p-value	**0.35**					
Significant	**Not Significant**					

By conventional criteria the difference between the groups were comparable since the p value is >0.05 and so it is statistically not significant. In simple words both the groups were comparable.

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TABLE 6: COMORBID CONDITION

Comorbid	STUDY GROUP					
	GROUP A		GROUP B		GROUP C	
	N	%	N	%	N	%
CAD	4	16	4	16	3	12
HTN	9	36	8	32	10	40
OTHERS	2	08	2	8	4	16
NIL	10	40	11	44	8	32
Total	**25**	**100**	**25**	**100**	**25**	**100**
Chi square Value	**1.89**					
p-value	**0.93**					
Significant	**Not Significant**					

TABLE 7: Nutrition Status

Nutrition	STUDY GROUP					
	GROUP A		GROUP B		GROUP C	
	N	%	N	%	N	%
Good	23	92	23	92	21	84
Moderate	2	8	1	4	4	16
Poor	0	0	1	4	0	0
Total	**25**	**100**	**25**	**100**	**25**	**100**
Chi square Value	**4.12**					
p-value	**0.39**					
Significant	**Not Significant**					

By conventional criteria the difference between the groups were comparable due to the p value is >0.05 and so it is statistically not significant.

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TABLE 8: Comorbid

Comorbid	STUDY GROUP					
	GROUP A		GROUP B		GROUP C	
	N	%	N	%	N	%
YES	9	36	6	24	4	16
NO	16	64	19	76	21	84
Total	**25**	**100**	**25**	**100**	**25**	**100**
Chi square Value	**2.68**					
p-value	**0.26**					
Significant	**Not Significant**					

By conventional method the difference between the groups were comparable since the p value is >0.05 and so it is statistically not significant. In simple words both the groups were comparable.

TABLE 9: WAGNER'S GRADE

WAGENERS GRADE	STUDY GROUP					
	GROUP A		GROUP B		GROUP C	
	N	%	N	%	N	%
I	2	4	6	24	4	16
II	23	96	19	76	21	84
Total	**25**	**100**	**25**	**100**	**25**	**100**
Chi square Value	**2.38**					
p-value	**0.30**					
Significant	**Not Significant**					

By conventional method the difference between the groups were comparable since the p value is >0.05 and so it is statistically not significant.

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TABLE 10: BLOOD SUGAR LEVEL

BLOOD SUGAR	STUDY GROUP		
	GROUP A (N=25)	GROUP B (N=25)	GROUP C (N=25)
Mean	216.28	200.12	214.72
SD	58.41	57.29	52.13
Anova Value	**0.63**		
p-value	**0.53**		
Significant	**Not Significant**		

By conventional criteria the difference between the groups were comparable since the p value is >0.05 and so it is statistically not significant.

TABLE 11: DURATION OF T2 DM

DURATION	STUDY GROUP		
	GROUP A (N=25)	GROUP B (N=25)	GROUP C (N=25)
Mean	7.24	6.70	6.68
sd	6.11	4.66	4.60
Anova Value	**0.09**		
p-value	**0.91**		
Significant	**Not Significant**		

By conventional criteria the difference between the groups were comparable due to the p value is >0.05 and so it is statistically not significant.

TABLE 12: GLYCEMIC CONTROL

GLYCEMIC CONTROL	STUDY GROUP					
	GROUP A		GROUP B		GROUP C	
	N	%	N	%	N	%
Irregular Control	17	68	16	64	14	56

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Regular OHA	8	32	9	36	11	44
Total	**25**	**100**	**25**	**100**	**25**	**100**
Chi square Value	**0.80**					
p-value	**0.67**					
Significant	**Not Significant**					

By conventional method the difference between the groups were comparable since the p value is >0.05 and so it is statistically not significant.

TABLE 13: TOTAL WBC COUNT

	STUDY GROUP		
	GROUP A (N=25)	**GROUP B (N=25)**	**GROUP C (N=25)**
Mean	12116.00	11890.40	10581.60
sd	4399.50	4744.86	3101.65
Anova value	**1.00**		
p-value	**0.37**		
Significant	**Not Significant**		

By conventional method the difference between the groups were comparable since the p value is >0.05 and so it is statistically not significant.

TABLE 14: WOUND C & S

WOUNDS	**STUDY GROUP**					
	GROUP A		**GROUP B**		**GROUP C**	
	N	%	N	%	N	%
Acinetobacter	3	12	0	0	2	8
E-Coli	2	8	2	8	2	8
Klebsiella	3	12	6	24	2	8
MRCONS	0	0	0	0	1	4
MRSA	3	12	2	8	1	4
MSSA	3	12	3	12	7	28
Proteus Vulgaris	0	0	2	8	1	4
Pseudomonas	6	24	6	24	3	12

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Staph Aureus	0	0	2	8	1	4
Sterile	3	12	0	0	1	4
Strep Pyogenes	2	8	2	8	4	16
TOTAL	**25**	**100**	**25**	**100**	**25**	**100**
Chi square Value	**20.33**					
p-value	**0.44**					
Significant	**Not Significant**					

By conventional criteria the difference between the groups were comparable since the p value is >0.05 and so it is statistically not significant. In simple words both the groups were comparable.

TABLE 15: Antibiotics

Antibiotics	**STUDY GROUP**					
	GROUP A		**GROUP B**		**GROUP C**	
	N	%	N	%	N	%
Amoxicillin	0	0	1	4	0	0
Cefotaxime	2	8	4	16	6	24
Cefoxitin	0	0	1	4	1	4
CFS	5	20	6	24	5	20
Ciprofloxa	2	8	1	4	1	4
Colistin	0	0	0	0	1	4
Cotrimoxaz	0	0	0	0	3	12
Imipenem	1	4	0	0	0	0
Linexolid	3	12	2	8	1	4
Meropenem	1	4	1	4	1	4
Piptaz	7	28	9	36	6	24
Vancomycin	1	4	0	0	0	0
Nil	3	12	0	0	0	0
TOTAL	**25**	**100**	**25**	**100**	**25**	**100**
Chi square Value	**25.26**					
p-value	**0.39**					
Significant	**Not Significant**					

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By conventional criteria the difference between the groups were comparable since the p value is >0.05 and so it is statistically not significant.

TABLE 16: ULCER AT ADMISSION

ULCER SIZE (Cm^2)	**STUDY GROUP**		
	GROUP A (N=25)	**GROUP B (N=25)**	**GROUP C (N=25)**
Mean	52.32	39.76	40.08
sd	32.17	29.06	23.74
ANOVA VALUE	**1.57**		
p-value	**0.21**		
Significant	**Not Significant**		

TABLE 17: ULCER AT FIRST WEEK

ULCER SIZE (Cm^2)	**STUDY GROUP**		
	GROUP A (N=25)	**GROUP B (N=25)**	**GROUP C (N=25)**
Mean	42.12	34.28	29.12
SD	31.49	23.63	16.49
ANOVA VALUE	**1.76**		
p-value	**0.18**		
Significant	**Not Significant**		

By conventional criteria the difference between the groups were comparable since the p value is >0.05 and so it is statistically not significant. In other words both the groups were comparable.

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TABLE 18: ULCER AT FOURTH WEEK

ULCER SIZE (Cm^2)	STUDY GROUP		
	GROUP A (N=24)	GROUP B (N=25)	GROUP C (N=25)
Mean	18.40	19.00	29.12
SD	13.56	12.60	23.41
ANOVA VALUE	**3.06**		
p-value	**0.03**		
Significant	**Significant**		

By conventional criteria the difference between the groups were comparable since the p value is <0.05 and so it is statistically significant.

TABLE 19: ULCER AT TENTH WEEK

ULCER SIZE (Cm^2)	STUDY GROUP		
	GROUP A (N=20)	GROUP B (N=20)	GROUP C (N=21)
Mean	13.25	13.52	23.30
SD	8.42	7.12	17.32
ANOVA VALUE	**3.28**		
p-value	**0.05**		
Significant	**Significant**		

TABLE 20: NO OF DAYS IN HOSPITAL

	STUDY GROUP		
	GROUP A (N=24)	GROUP B (N=25)	GROUP C (N=25)
Mean	9.32	11.36	15.84
sd	5.80	10.10	10.51

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ANOVA VALUE	**3.12**
p-value	**0.05**
Significant	**Significant**

TABLE 21: NO OF DAYS ABSENT FROM WORK

	STUDY GROUP		
	GROUP A (N=24)	**GROUP B (N=25)**	**GROUP C (N=25)**
Mean	32.56	36.56	41.04
sd	27.72	30.40	35.36
ANOVA VALUE	**3.49**		
p-value	**0.05**		
Significant	**Significant**		

TABLE 22: POST TREATMENT STATUS

	STUDY GROUP					
	GROUP A		**GROUP B**		**GROUP C**	
	N	%	N	%	N	%
Completely Healed	23	92	23	92	24	96
Partially Healed	2	8	2	8	1	4
TOTAL	**25**	**100**	**25**	**100**	**25**	**100**
Chi square Value	**0.43**					
p-value	**0.81**					
Significant	**Not Significant**					

DISCUSSION

Diabetic Foot Ulcers:

A foot ulceration may occur in one out of every four diabetic patients throughout the course of their lives [10]. Ischemia, neuropathy, and infection work together in a complex way to cause foot ulcers [11,12,10].

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Peripheral artery disease, which is incredibly common in people with diabetes, is blamed for ischaemia, which results in inadequate food supply to peripheral tissue [12,13]. Because neuropathy robs patients of protective sensation, trauma (such as that caused by walking on a sharp item or, more simply, from wearing shoes that are too small) may go undetected, causing more tissue damage [11,12,10].

Additionally, it causes a number of foot abnormalities that affect the plantar aspect of the foot abnormally [11,12,10]. As a result, some plantar locations experience extremely high pressures and are more prone to developing ulcers [11,12,10]. Over 50% of persistent foot ulcers eventually become infected.65 Gram-positive cocci, Gram-negative bacteria, and anaerobes typically make up an infection, which can quickly progress to necrosis [12]. Neuroischemic and neuropathic foot ulcers are divided into two types that are clinically beneficial [12,14]. In the former, ischemia and neuropathy coexist. Although peripheral neuropathy in certain people can lessen or eliminate discomfort, the ulcer is frequently on the foot's borders, has an uneven shape, and is usually unpleasant. Although it may be frigid and pulseless, the foot is not warm [12,14].

The latter is more frequently observed in high-pressure regions, particularly in locations with prominent metatarsal heads and toe apices [12,14]. It is frequently painless, heavily calloused, and may have a roughly round shape with a raised rim. Although the sensation in the foot is diminished, it is warm and has intact pulses [11,12,14].

This distinction is of vital importance, because treatment differs according to etiology [12,14].

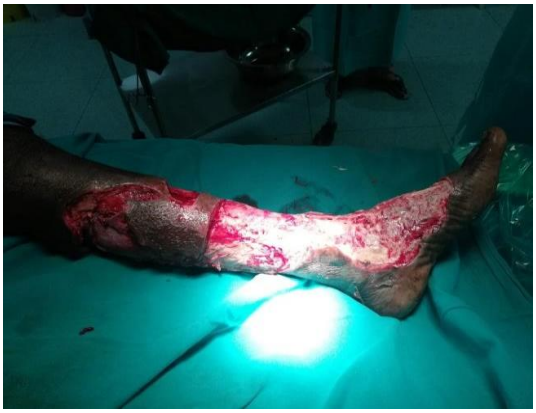

Figure 1: Non healing Ulcer with minimal Granulation and more slough

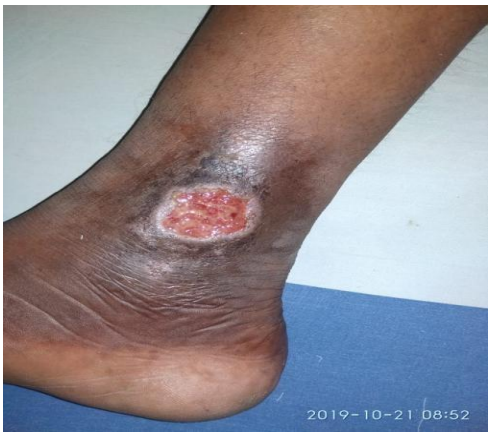

Figure 2: Healing ulcer with sloping edges

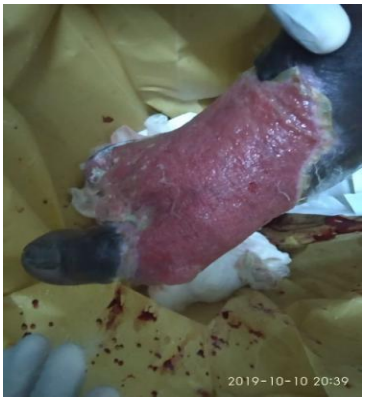

Figure 3: **Healing Ulcer with no slough, well granulation**.

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Treatment of Diabetic Foot Ulcers:

The three main causes of diabetic foot ulcers must be treated: ischemia, neuropathy, and infection.

It is crucial to recognise ischemia as soon as possible in the neuro-ischemic foot and to return the limb's blood flow to normal. According to the situation, this can be done physically (with bypass graft surgery) or intravascularly (with percutaneous transluminal angioplasty) (al, 2003).

The ulcerated area in the neuropathic foot needs to be off-loaded using casts and padding in the soles. Surgical debridement, which has been shown to encourage granulation and wound closure, is paired with off-loading. A high index of suspicion for the diagnosis of infection is required in both neuroischemic and neuropathic ulcers in order to enable prompt administration of antibiotics, initially selecting broad-spectrum drugs and later being directed by appropriate cultures. Swab cultures are typically used, while some authorities prefer deep tissue samples.

The healing rates have improved as a result of developments in various therapy techniques. However, a sizable portion of ulcers (as many as 49%) may still not heal, highlighting the need for more advancement.

PHENYTOIN AND IT'S ROLE IN DIABETIC FOOT:

Topical phenytoin sodium has wound-healing-promoting effects that are attributed to the following mechanisms: increased fibroblast proliferation, decreased bacterial contamination, decreased wound exudate formation, promoted collagen disposition, promoted collagen disposition, enhanced granulation tissue formation.

Topical phenytoin in diabetic foot ulcers was published in 1991 by Muthukumarasamy MG, Sivakumar G, and Manoharan G. Using phenytoin powder on the ulcer base, Diabetes Care conducted a prospective controlled clinical trial to examine the effects of topical phenytoin in diabetic foot ulcers. They came to the conclusion that phenytoin is a safe and efficient treatment option for diabetic ulcers.

[DaCosta ML, Regan MC, Al Sader M, Leader M, Bouchier-Hayes D. DaCosta et al. Increased collagen deposition and tensile strength in healed wounds are the outcomes of diphenylhydantoin sodium's promotion of early and significant angiogenesis. Surgery.] found that phenytoin changes the normal course of wound healing and may be helpful in clinical scenarios where improper wound collagen deposition may result in poor wound healing and subsequent morbidity and mortality. In comparison to controls, fibroblast proliferation and neovascularization were observed in the wounds treated with phenytoin at 3 days. On day 6, the treated wounds' inflammatory infiltrate had nearly entirely disappeared, although fibroblast infiltration and angiogenesis remained visibly evident. [15,16]

Shaw and others. [Shaw, J., C.M. Hughes, K.M. Lagan, and P.M. Bell. A comprehensive study of the clinical impact of topical phenytoin on wound healing. 2007; Br J Dermatol concluded that when phenytoin is administered, there are no differences between the two groups in diabetic foot ulcer closure rates or diabetic foot ulcer area over time. Tauro and co. Tauro LF, Shetty P, Dsouza NT, Mohammed S, and Sucharitha S. A comparison of the effectiveness of topical phenytoin and standard wound care for diabetic ulcers. Int J Mol Med Sci] 200 diabetic ulcer patients were observed. One hundred patients received topical phenytoin dressing, whereas the other patients received standard wound care. They came to the conclusion that topical phenytoin helps diabetic wounds heal more quickly and with greater graft take-up.

A. Vardhan et al. Using a topical phenytoin dressing lessens hospital It is superior to typical dressings with saline and povidone-iodine because it stays in place and aids in the production of granulation tissue much earlier than standard dressings.

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Pendse, Sharma, Sodani, and Hada, collectively known as Pendse et al. Phenytoin used topically for wound healing. 1993) (Int J DermatolSignificant antibacterial activities are present in phenytoin. On the seventh day of treatment, 50% of the wounds treated with phenytoin showed negative bacterial cultures, compared to 17% of the wounds in the control group.

Anstead GM, Hart LM, Sunahara JF, and Litre ME are among the group. Phenytoin in the treatment of wounds, Ann Pharmacol. 1996 A massively necrotized Grade IV decubitus ulcer that was not responding to any previous treatments was helped by phenytoin.

Jayalal JA et al. (Jayalal JA, Kumar SJ, Dhinesh, Thambithurai D, Kadar JMA. Efficiency of Topical Phenytoin on Healing in Diabetic Foot Ulcer: A Randomised Controlled Trial. Int J Sci Stud. 2015;3) demonstrated improved wound healing and feelings of wellbeing in people with diabetic foot ulcers treated with topical application of phenytoin than the other conventional wound dressing materials.

According to all of the research cited, phenytoin increases fibroblast proliferation, promotes the creation of granulation tissue, and lowers bacterial contamination. However, Shaw et al. reported that when phenytoin is taken, there are no changes between the two groups in the rates of diabetic foot ulcer closure or the extent of the diabetic foot ulcer over time. The effectiveness of phenytoin against sucralfate in the healing of diabetic foot wounds was not contrasted in any of these investigations.

IN DIABETIC FOOT HYDROGEL DRESSINGS:

Acute wounds appear to heal more quickly when their surface is maintained moist rather being allowed to dry up and scab, according to animal studies conducted more than 40 years ago (Winter 1963). According to Cardinal (2009), a moist environment offers ideal conditions for the cells participating in the healing process and permits autolytic debridement, which is considered to be a crucial step in the healing process. One of the main reasons people use wound dressings is to keep the environment around the wound wet. A very wet wound can be treated with an absorbent dressing (such as a foam dressing) to draw excess moisture away from the wound and prevent skin damage, whereas a drier wound can be treated with a more occlusive dressing to maintain a moist environment. Insoluble polymers called hydrogels hold a sizable amount of water together. To keep wounds moist, this water can then be given to them. In order to maximise the wound's moisture level, the hydrogel polymer matrix can also absorb some wound exudate because it is not completely hydrated. A hydrogel sheet dressing is created by cross-linking polymers to produce hydrogel material into a permanent structure. Hydrogel bandages for diabetic foot ulcer healing JC Dumville and others All of the available RCT evidence (five studies) on the therapeutic efficacy of hydrogel wound dressings in the treatment of diabetic foot ulcers has been identified, evaluated, and presented in their review. When data from three investigations (20, 16 and 12 weeks follow-up; n = 198) were combined, hydrogel had a statistically significant advantage over conventional wound contact dressings for ulcer healing. Due to inadequate reporting of trial methodology, the risk of bias in all trials was unclear. It is significant to note that only grade 2 ulcers were included in Jensen 1998, but D'Hemecourt 1998 included mostly grade 3 ulcers. Vandeputte 1997 did not specify the ulcer grade, however based on the inclusion criteria, it was possible for ulcers of greater severity to be included. Even though D'Hemecourt 1998 had a longer follow-up period than Jensen 1998, the varied ulcer grades may be the reason why study healing was poorer in D'Hemecourt 1998 than in Jensen 1998. There is no information available to clinicians about the clinical and/or financial effectiveness of hydrogel compared to other advanced dressings. In terms of ulcer healing, there was no evidence that

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hydrogel differed from larval treatment, platelet-derived growth factor, or different brands of hydrogel.

SUCRALFATE AND IT'S ROLE IN DIABETIC FOOT

The disaccharide sucrose octasulfate has an aluminium hydroxide salt called sucralfate. It is regarded as a cytoprotective agent and has been used in the past to prevent or cure a number of gastrointestinal conditions, including gastroesophageal reflux disease, gastritis, peptic ulcer disease, and stress ulcer. Pressure, venous, and diabetic ulcers are the key contributors to the chronic wound healing process. The use of topical sucralfate ointment to treat non-healing venous stasis ulcers in 9 patients who did not react to 8 weeks of standard therapy was initially studied by Tsakayannis et al. in a single blind fashion. In the sucralfate-treated patients, 2 of the 5 wounds had fully healed by the end of the research, while the other 3 had impressive granulation tissue, neoangiogenesis, and wound contraction. The placebo patient group's wounds, on the other hand, showed no clinical improvement. [Topical therapy of persistent venous ulcers with sucralfate: A randomised, placebo-controlled study. Tumino G et al. A double-blind, placebo-controlled, randomised research [Int J Mol Med 2008] examined the effectiveness of topical sucralfate on the healing of chronic venous leg ulcers in 50 individuals. They found that when topical sucralfate (hydrophilic gel containing precipitated sucralfate at a concentration of 25 g per 100 g gel) was applied daily for a median of 42 days to non-infected post-phlebitis/vascular ulcers, 95.6% of patients experienced full healing, as opposed to just 10.9% of those who received placebo only. Regarding local tissue inflammation, discomfort, burning, and the development of the granulation tissue, a considerable improvement was seen in the group that received sucralfate treatment.

Efficacy of Topical Sucralfate and Conventional Dressing in the Management of Diabetic Ulcer: A Clinical Study G. Nagalakshmi and others. They found that participants who received sucralfate dressing had a better area of reduction—41.97% (SD: 7.41)—than those in the control group, who only received conventional dressing (normal saline dressing), where the mean area of reduction was 18.37 (SD: 13.43). They demonstrated that sucralfate dressing is a useful modality for patients with diabetic foot ulcers to facilitate area of wound reduction and can be utilised as an adjuvant to standard mode of therapy (conventional dressings and debridement) for quicker and better healing of diabetic ulcers.

We compared the effective ulcer healing time in this trial using injectable phenytoin, sucralfate, and hydrogel cream—methods that had not been used in any prior investigations.

Patients who received phenytoin experienced a reduction in ulcer size, going from 52.32 cm2 upon admission to 13.25 cm2 at the end of the 10th week, with an average hospital stay of roughly 9.32 days.

Patients who received sucralfate saw a reduction in ulcer size from 39.76 cm2 to 13.52 cm2, and their hospital stays were roughly 11.36 days on average. Currently, 2ml of phenytoin injection costs 9–10 Rs. A 50 mg/ml phenytoin injection diluted in 10 ml will effectively cure an ulcer for 1–1.5 rupees/cm2.

In case of Sucralfate syrup. Each bottle currently cost anywhere around 100-200 rupees containing around 200 ml. Effectively treating ulcer at a rate of 1-1.5 rupees/cm2.

However, in the case of a hydrogel cream, a 50 grams of tube cost anywhere around 300-400 rupees, effectively treating ulcer at a rate of 6-8 Rupees/cm2 assuming that it is applied evenly at 1gram per cm2 of ulcer.

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Figure 4: Depicting Injection Phenytoin.

Figure 5: Sucralfate syrup

This study has been done to Evaluate efficacy of Phenytoin, hydrogel and
Sucralfate dressing in Diabetic Foot Ulcers in terms of:
1.To compare the healing efficacy of phenytoin, sucralfate syrup and hydrogel cream –Decrease in Ulcer size
2.To estimate the average reduced hospital stay with each dressing and their financial burden

Study period over 24 months by enrolling a total of 75 patients. Out of 75, 25 were treated in the form of standard care with Hydrogel dressing, 25 were treatment in the form of standard care with inj. phenytoin, 25 were treated with standard care and sucralfate syrup dressing once a day.

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MANAGEMENT:

A clinical examination and history will be recorded. There will be a thorough hemogram, fasting and postprandial blood sugar, and a renal function test. Osteomyelitis will be ruled out using an X-ray of the foot. Doppler scan for vascular disease.

Ankle reflexes, hot/cold items, and tuning forks are used in a neurological examination to detect neuropathy. Debridement, adequate infection management, and glycemic control were provided as standard treatments.

The size of the ulcer at the time of admission, the size of the ulcer at the end of the first week, the size of the ulcer at the end of the fourth week, the size of the ulcer at the end of the tenth week, the number of days spent in the hospital, the number of days missed from work, and other parameters will be evaluated and entered in a preformed protocol. Post-treatment status at study's conclusion.

These variables were placed into the prepared procedure and examined, revealing that hydrogel dressings and sucralfate syrup dressings do not have the same effect on healing times as dressings containing injectable phenytoin.

Significant differences were detected in the number of days spent in the hospital, the number of days missed at work, the size of the ulcer at the fourth and tenth weeks, as well as the cost-effectiveness of the treatment for diabetic foot patients.

At the end of the first week, there is no discernible difference between the ulcer's size change and its post-treatment state or requirement for further intervention.

AGE & GENDER DISTRIBUTION:

In age group 31-40 ,dressing with Inj phenytoin was 4(16%), dressing with Hydrogel was 6(24%) and dressing with Hydrogel was 2(8%).

Age group 41-50, dressing with Inj phenytoin was 11 (44%), dressing with Sucralfate was 6(24%) and dressing with Hydrogel was 10(40%).

Age group 51-60, dressing with Inj phenytoin was 4(16%), dressing with Sucralfate was 8(32%) and dressing with Hydrogel was 8(32%).

Age group 61-70, dressing with Inj phenytoin was 4(16%), dressing with Sucralfate was 3(12%) and dressing with Hydrogel was 5(20%).

Age group 71-80, dressing with Inj phenytoin was 1 (4%), dressing with Sucralfate was 1(4%) and dressing with Hydrogel was 0(0%).

Among the group, males who had dressing with Inj phenytoin was 14(56%), dressing with Sucralfate was 15(60%) and dressing with Hydrogel was 17(68%).

Females who had dressing with Inj phenytoin were 11(44%), dressing with Sucralfate were 10(40%) and dressing with Hydrogel were 8(32%).

Since age and gender are not statistically significant ,it means that there is no difference between the groups. Also in simple terms the groups contain subjects with the same demographic characteristics.

WAGNERS GRADING:

WAGNER GRADE 1: Patients who had dressing with Inj phenytoin were 2(4%), dressing with Sucralfate were 6(24%) and dressing with Hydrogel were 4(16%).

WAGNER GRADE 2: Patients who had dressing with Inj phenytoin were 23(96%), dressing with Sucralfate were 19(76%) and dressing with Hydrogel were 21(84%).

Since p value >0.05 it is statistically not significant.

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Since WAGNER'S GRADE are not statistically significant ,it means that there is no difference between the groups. Also in simple terms the groups contain subjects with the same demographic characteristics andare comparable.

ULCER SIZE AT END OF 1ST WEEK:

In this study, the ulcer's size was measured and documented at the end of the first week of treatment. Patients who received dressings using Inj. phenytoin had a mean dressing area of 42.12 cm2 (SD: 31.49), Sucralfate had a mean dressing area of 34.28 cm2 (SD: 23.63), and Hydrogel had a mean dressing area of 29.12 cm2 (SD: 16.49). Since the test value has a p value of 0.18 (>0.05), it is not statistically significant. Therefore, it is suggested that there is no difference in ulcer size change across the three groups at the conclusion of the first week.

ULCER SIZE AT END OF 4th WEEK:

At the conclusion of the fourth week of treatment, the ulcer's size was once more measured and noted. Inj. phenytoin dressings had a mean size of 18.40 cm2 (SD: 13.56), sucralfate dressings had a mean size of 19.00 cm2 (SD: 12.60), and hydrogel dressings had a mean size of 29.12 cm2 (SD: 23.41). The test value is statistically significant because of the low p value of 0.03 (0.05).

Therefore, it is hypothesised that by the end of the fourth week, there will be differences in ulcer size change. For example, patients who received Sucralfate and Inj Phenytoin dressings experienced faster size reduction than those who received Hydrogel dressings.

ULCER SIZE AT END OF 10th WEEK:

At the conclusion of the tenth week of treatment, the ulcer's size was once more measured and noted. Inj. phenytoin dressings had a mean size of 13.25 cm2 (SD = 8.42), sucralfate dressings had a mean size of 13.52 cm2 (SD = 7.12), and hydrogel dressings had a mean size of 23.30 cm2 (SD = 17.32). The test value is statistically significant because of the low p value of 0.05 (=0.05).

Therefore, it is hypothesised that there will be variations in ulcer size changes towards the conclusion of the tenth week. For example, patients who received Sucralfate with Inj Phenytoin dressings experienced faster size reduction than those who used Hydrogel cream.

HOSPITAL STAY (NO. OF DAYS IN HOSPITAL):

The study groups were compared and assessed based on how many days they spent in the hospital.

Patients who had dressings with injectable phenytoin wore them for an average of 9.32 days (SD=5.80), sucralfate wore them for an average of 11.36 days (SD-10.10), and hydrogel wore them for an average of 15.84 days (SD-10.51).

Here, p = 0.05 (= 0.05). Consequently, the study has statistical significance. Therefore, it is suggested that there is a difference in the number of hospital days spent. Patients who received intravenous phenytoin dressings spent fewer days in the hospital than those who received sucralfate or hydrogel, for example.

ABSTINENCE FROM WORK (NO. OF DAYS ABSENT FROM WORK):

In this study, the study groups were compared by number of days absent from work and analysed.

Patients who had dressing with Inj phenytoin had a mean 32.56 days(SD=27.72), dressing with Sucralfate had a mean 36.56 days(SD-30.40) and dressing with Hydrogel had a mean 41.04 days(SD-35.36).

Here p value is 0.05(=0.05). So the study is statistically significant. Hence it is proposed that there is difference in number of days absent from work. i.e, patients who underwent Inj

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phenytoin dressings has less number of days absent from work and early return to work when compared to Sucralfate and Hydrogel.

POST TREATMENT STATUS:

In this investigation, the study groups were compared by evaluating and analysing their post-treatment statuses. Patients who received dressings containing intravenous phenytoin, sucralfate, or hydrogel experienced complete healing in 23 (92%), 24 (96%), and 24 (96%), respectively.

Patients who received dressings containing Inj phenytoin, Sucralfate, or Hydrogel experienced partial healing in 2 (8%), 2 (8%), and 1 (4%), respectively. P value in this case is 0.81 (>0.05). The study is therefore not statistically significant. Therefore, it is suggested that at the end of the study, there will be no difference in the status of healing between the study groups.

This study's observational findings imply that Inj phenytoin dressing was superior to both Sucralfate and Hydrogel dressing, while Sucralfate dressing was superior to Hydrogel dressing in terms of change in ulcer size at the end of the fourth and tenth weeks, as well as days spent in the hospital and time spent returning to work.

The cost-effectiveness of the treatment and patients' prompt return to work for diabetic foot ulcers are highlighted in the current study.

CONCLUSION

The current study comes to the conclusion that the management of diabetic foot ulcers with Inj phenytoin dressing has better ulcer healing and contraction rate, early recovery from the disease, and early return to work. It is also more readily accessible on the market and simpler to apply. a prolonged hospital stay will prevent cross infection. In the current study, phenytoin dressing for diabetic ulcers that are not healing caused a statistically significant effect.

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Nil

CONFLICT OF INTEREST

None

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