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A COMPARATIVE STUDY OF TOPICAL PHENYTOIN VERSUS CONVENTIONAL DRESSING FOR DIABETIC FOOT ULCER

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INTRODUCTION

Diabetes mellitus leads to multiple complications when uncontrolled. One such complication of diabetes mellitus is diabetic foot ulcer. Such patients need multiple surgical procedure and prolonged hospital stay leading to consumption of high number of hospital days **[1]**. Risk of developing diabetic foot ulcer is 25% **[2]**, and if not managed properly may preceed to amputation in upto 85% of cases **[3]**. The treatment of diabetic foot ulcer includes removal of necrotic tissue, callus and fibrous tissue **[4-5]**. Size of diabetic foot ulcer, limb vascularity and presence of infection determines the management of diabetic foot ulcer **[6-8]**.

In our country, certain factors such as hot humid weather leading to poor hygiene and excessive sweating; protein malnutrition, practices such as walking barefoot, lack of basic health care facility in rural areas etc have exacerbated the problem.

Diabetes mellitus leads to complications such as neuropathy, vasculopathy and nephropathy, which itself leads to increased incidence and prevalence of diabetic foot ulcer, due to decreased sensation (neuropathy) - patient becomes more prone

to injuries going unnoticed and vasculopathy leading to decrease in blood supply.

Conservative management of diabetic foot ulcer involves dressing of the ulcer using betadine (povidine - iodine) or normal saline soaked pad. But maintain the wound in moist condition continuously is difficult.

Subsequently other therapies were put forth. These had high costs and some where without sufficient scientific evidence to prove their effectiveness **[9]**. This included various growth factors, hyperbaric oxygen treatment, hydrocolloid wound gel, etc.

In 1937, phenytoin (diphenylhydantoin) was introduced for treatment of seizures. It was observed that phenytoin caused gingival hyperplasia as side effect. Thus it was suggested that the connective wound healing in burns, diabetic foot ulcer, bedsore, trophic ulcers could be achieved the connective tissue stimulating effect of diphenylhydantoin.

AIM

Evaluation of effectiveness of topical phenytoin dressing to conventional betadine /normal saline dressing in treatment of diabetic foot ulcer is the aim of this study.

MATERIALS AND METHODS

50 patients admitted in department of surgery in Krishna Hospital, India with diabetic foot ulcer were included in the study. All diabetic foot ulcer in which conventional povidine iodine dressing is indicated have been included. A randomised controlled trial was performed.

The inclusion criteria were:

1. Chronic ulcer of diiferent etiology.
2. Gangrenous changes if present.
3. Diabetic foot ulcer with osteomyelitis
4. Severely decreased vascularity determined by arterial Doppler study.
5. Patients with comorbidities such as generalised debilitating factors, kidney failure etc.

Patients were divided into two groups – group I and group II having 25 patients each.

In all the above patients, detailed clinical examination was performed and all the routine investigations were done including blood sugar level and wound swab culture sensitivity.

Under anaesthesia, the diabetic foot ulcer debridement was done. Slough was removed, until healthy granulation tissue was visualised. In both group I and II, dressing was done once a day. On daily basis for 14 days, these patients in both study and control group were followed up. In both groups, before applying the dressing the wound was cleaned thoroughly with hydrogen peroxide and normal saline. In study group, dressing of diabetic foot ulcer was done with betadine solution. In

control group, dressing was done by placing gauze soaked in suspension of 100 mg phenytoin tablet crushed and mixed in 5ml of sterile water on the wound. The size of ulcer was checked immediately after debridement, re-examined after 7 days and 14 days in both study and control group using vernier caliper.

RESULT

Of the 50 diabetic foot ulcer patients, the majority of patients were 50-59 years of age and the next general presentation was between 60 and 69 years (**Table 1**). Of the 50 patients, 32 were male and 18 were female. In patients with diabetic foot ulcer most of them had diabetes for 5-10 years. In all these 50 patients, strict sugar control was achieved by giving human actrapid.

Most common organism found in wound swab culture and sensitivity of diabetic foot ulcer patient was Staphylococcus aureus. At the end of the 2 weeks of monitoring there were the final results; group 1 v / s group 2: unhealthy wound-03 v / s 13, healthy granulation tissue -20 v / s 12, Increased infection-Bk amputation-0, and total wound healing - 02 v / s 00. The following parameters would be considered per day 7th and 14th day.

Presence of healthy granulation tissue on Day 14: 86.95% v / s 48% (p = 0.004) (**Table 2**).

Means Reducing wound area by day 7 & 14: 41.38 & 68.17 v / s 24.56 & 47.85 (**Table 3**)

Table 1: Showing Age Incidence In Both Groups

S. No.	AGE GROUP	GROUP I %	GROUP II %
1	40-49	16	0
2	50-59	52	52
3	60-69	24	44
4	70-79	8	4

Table 2: Healthy granulation tissue- presence/ absent on Day 14 in group I and II patients

S. No.	PARAMETER	GROUP I %	GROUP II %
1	HEALTHY GRANULATION TISSUE PRESENT	86.95	48
2	HEALTHY GRANULATION TISSUE ABSENT	13.05	52

Table 3: Decrease in percentage of ulcer area in group I and II ON Day 7 and Day 14

S. No.	PARAMETER	GROUP I %	GROUP II %
1	MEAN REDUCTION ON DAY 7	41.38	24.56
2	MEAN REDUCTION ON DAY 14	68.17	47.85

DISCUSSION

Phenytoin is used as an anticonvulsant medication. One of the side effect of phenytoin are gingival hyperplasia. Phenytoin causes gingival hyperplasia due to growth of connective tissue. This

same property of phenytoin was was made use in treatment of diabetic foot ulcer, wherein it was suggested that phenytoin would cause connective tissue growth which may promote wound healing.

Phenytoin promotes proliferation of fibroblasts, reduces activity of enzyme collagenase, inhibits glucocorticoid activity, improves the formation of connective tissue. Thus helps in promoting wound healing. Phenytoin also affects inflammatory cells, growth factor beta chain in macrophages and monocytes, promotes neovascularisation, thus having indirect antibacterial activity.

The side effect of phenytoin – gingival hyperplasia was first discovered by Kimball and Horan in 1939 following which first clinical trial was conducted in 1958, which showed that there was less pain and faster healing of wounds in periodontal patient with surgical wounds who were treated with oral phenytoin compared to controls.

CONCLUSION

We conclude that phenytoin dressing for diabetic foot ulcer healing is a very good alternative to conventional betadine dressings. It is easily available, cheap, easy to use, safe, doesn't cause patient discomfort.

Topical phenytoin has the following mechanism of action.

- It increases formation of granulation tissue.
- Inhibits activity of enzyme collagenase.
- Increases proliferation of fibroblasts.
- Reduces bacterial contamination by affecting anti-inflammatory cells and promoting neovascularisation.

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