

ORIGINAL ARTICLE**COMPARATIVE EVALUATION OF ANTIBIOTIC TREATMENT AND CONSERVATIVE SURGICAL TREATMENT FOR DIABETIC FOOT**Mohd Mubashir¹, Mohd Khalid²¹Associate Professor, Department of Surgery, Mayo Institute of Medical Sciences, ²Assistant Professor, Dept of Surgery, Mayo Institute of Medical Sciences**ABSTRACT:**

Background: One of the typical lesions occurring over the areas usually located over pressure sites is the neuropathic diabetic foot. Various treatment modalities available for the treatment of such lesions is both surgical and non-surgical. Non-surgical treatment of the uncomplicated neuropathic ulcer consists of debridement and supportive care. Surgical treatment of such lesions has been suggested by various clinicians and surgeons as an alternative way. Hence; we evaluated the efficacy of surgical and non-surgical line of treatment of patients with diabetic neuropathic foot ulcer. **Materials & Methods:** The present study was conducted in the department of general surgery of the institution and included all the patients that reported with the chief complaint of diabetic foot lesion from 2011 to 2015. Patients were randomized into two groups according to a table of randomization: group 1 received non-operative treatment, consisting of initial debridement and medication of ulcer, relief of weight-bearing regular dressings, and follow-up; group 2 underwent surgical excision of the ulcer, debridement or removal of bone segments underlying the lesion, necessary, subsequent suture of the skin, and relief of weight-bearing for 4 weeks. All the results were analyzed by SPSS software. **Results:** No. of patients in both the groups is 40 each. Mean age of the patients in group 1 and group 2 was 64.50 and 66.42 years respectively. Mean BMI index of the patients in group 1 and group 2 was 28.42 and 29.81 respectively. Non-significant results were obtained while comparing the demographic details in between the two study groups. Mean healing time for all ulcers in group 1 and 2 was 125 days and 51 days respectively. Mean healing time for healed ulcers in group 1 and 2 was 101 days and 41 days respectively. **Conclusion:** In cases of non-complicated neuropathic diabetic foot lesions, conservative surgical treatment is an effective approach.

Key words: Diabetic, Healing, Ulcer

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INTRODUCTION

One of the typical lesions occurring over the areas usually located over pressure sites is the neuropathic diabetic foot. Such lesions are painless and surrounded by hyperkeratosis, which may cover the underlying ulcer completely, with hardened walls and a base which is usually clean and sometimes covered with fibrin or degraded dermal debris.^{1, 2} Various treatment modalities available for the treatment of such lesions is both surgical and non-surgical. Non-surgical treatment of the uncomplicated neuropathic ulcer consists of debridement and elimination of hyperkeratosis, regular topical medication and relief using either total contact casts and special shoes.³ Surgical treatment of such lesions have been suggested by various clinicians and surgeons as an alternative way to treat neuropathic foot ulcers by surgery, which includes the excision of ulcer,

the debridement or removal of any involved bone and the surgical suture of the wound margins.^{4, 5} Hence; we evaluated the efficacy of surgical and non-surgical line of treatment of patients with diabetic neuropathic foot ulcer.

MATERIALS & METHODS

The present study was conducted in the department of general surgery of the institution and included all the patients that reported with the chief complaint of diabetic foot lesion from 2011 to 2015. Only those patients were included that had history of diabetic foot lesion for more than four weeks. Ethical approval was taken from the ethical committee of the institution and written consent was obtained from them. Inclusion criteria for the present study;

- Patients with history of diabetes mellitus (DM) from past 8 or more years

- Clinical finding of one or more painless foot ulcers with clinical characteristics of neuropathy
- Patients with absence of ankle reflexes,
- Patients with abnormal vibration perception threshold at malleolus and first toe.

Exclusion criteria for the present study included;

- Patients with symptomatic claudication or absence of foot pulses,
- Patients with recent ketoacidosis,
- Patients with renal failure as suggested by creatinine higher than 177 mmol,
- Presence of any other acute or chronic infection,
- Presence of any other systemic illness,
- Presence of any other known drug allergy.

After having obtained their informed consent, patients were randomized into two groups according to a table of randomization: group 1 received non-operative treatment, consisting of initial debridement and medication of ulcer, relief of weight-bearing regular dressings, and follow-up; group 2 underwent surgical excision of the ulcer, debridement or removal of bone segments underlying the lesion, necessary, subsequent suture of the skin, and relief of weight-bearing for 4 weeks. Ulcers in group 1 patients, after initial debridement of lesions and elimination of surrounding hyperkeratosis, were dressed with saline-moistened sterile gauze and patients were advised to change the dressing every 24 h, helped by a specifically trained relative if necessary. Group 2 patients were scheduled for outpatient surgery after initial assessment phase. Surgical operations were all carried out with local or regional anaesthesia; patients were observed for 3–4 hours after the intervention and then discharged home. Surgery consisted of the removal of the ulcer through conic ulcerectomy, which removes both the walls and the

bottom of the lesion; moreover, in the presence of visible bone segments under the ulcers, or in cases where bone segments might interfere with the closure of the margins of wound, their debridement or removal was performed with scalpels. The surgical wound was closed with single stitches and a drain, which was removed after 48 h. The closed wound was covered with sterile gauze and the limb was positioned in slight anti-orthostatic position for 48 h. For global level of satisfaction, patients were asked to give a score from 0 to 10, while the other areas were explored through multiple choice questions with four possible answers which ranged from 1 (= least satisfied) to 4 (= most satisfied). All the results were analyzed by SPSS software. Chi-square test was used for the assessment of level of significance.

RESULTS

Graph 1 shows the demographic details of the patients. No. of patients in both the groups is 40 each. Mean age of the patients in group 1 and group 2 was 64.50 and 66.42 years respectively. Mean BMI index of the patients in group 1 and group 2 was 28.42 and 29.81 respectively. Mean glycated Hb levels in patients in group 1 and group 2 was 10.1 and 9.1 respectively. **Table 1** shows p-value for the demographic details of the patients. Non-significant results were obtained while comparing the demographic details in between the two study groups. **Table 2** shows the difference in healing time in between in the two study groups. Mean healing time for all ulcers in group 1 and 2 was 125 days and 51 days respectively. Mean healing time for healed ulcers in group 1 and 2 was 101 days and 41 days respectively. **Table 3** highlights the p-value for the results of self reporting patient’s satisfaction.

Graph 1: Demographic details of the patients

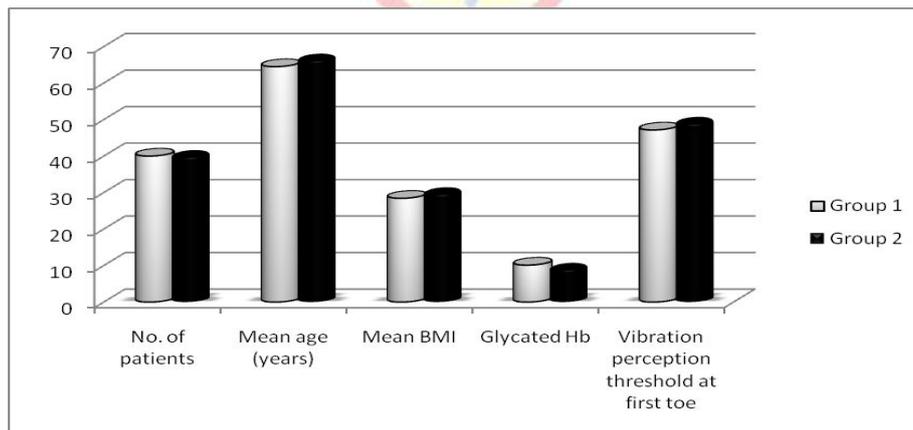


Table 1: p-value for the demographic details of the patients

Parameters	Group 1	Group 2	p-value
No. of patients	40	40	-
Mean age (years)	64.5	66.42	0.512
Mean BMI	28.42	29.81	0.145
Glycated Hb	10.1	9.1	0.845
Vibration perception threshold at first toe	47.15	49.1	0.412

Table 2: Difference in healing time in between in the two study groups

Parameter	Group 1	Group 2
All ulcers	125 days	51 days
Healed ulcers	101 days	41 days

Table 3: p-value for the results of self reporting patient's satisfaction

Parameter	Group 1	Group 2	p-value
Global satisfaction (0-10)	5.8	7.9	0.001*
Discomfort (1-4)	3.1	1.6	0.001*
Limitations (1-4)	3.7	1.5	0.001*

*: Significant

DISCUSSION

Foot ulcers affect one in ten diabetics during their lifetime. Patients with diabetes have increased risk of lower-extremity amputations and the main cause is diabetic peripheral arterial disease accelerated by the direct damage to the nerves and blood vessels by high blood glucose levels.^{6, 7} Wound healing is also impaired from affected collagen synthesis. Diabetic vascular disease has three main components: arteritis and small vessel thrombosis; neuropathy (possibly ischaemic in cause); and large vessel atherosclerosis. In combination these are almost bound to cause problems in the weight-bearing areas. The diabetic foot ulcers are often deeper and more frequently infected than other leg ulcers reflecting the severe end vessel ischaemia and opportunistic infection which is the common experience of the diabetic. Factors, such as age and the duration of the disease will increase its incidence and risk of death from uncontrolled infection.^{8- 10} Hence; we evaluated the efficacy of surgical and non-surgical line of treatment of patients with diabetic neuropathic foot ulcer.

In the present study, we observed that the general therapy of group 2 patients differed from those of group 1 in the administration of parenteral antibiotics for 5 days after surgery. However, accordingly, this was a major factor in the improved prognosis of group 2 as the therapy was only a prophylaxis against post-operative infections, and no patient showed signs of infection before the surgery. Piaggese et al tested the efficacy of the surgical treatment of non-infected neuropathic foot ulcers in comparison with conventional non-surgical management; a group of diabetic outpatients attending our diabetic foot clinic were studied. All patients who came to the clinic for the first time from January to December 1995 inclusive with an uncomplicated neuropathic ulcer were randomized into two groups. Group A received conservative treatment, consisting of relief of weight-bearing, regular dressings; group B underwent surgical excision, eventual debridement or removal of bone segments underlying the lesion and surgical closure. Healing rate, healing time, prevalence of infection, relapse during a 6-month period following intervention and subjective discomfort were assessed. Twenty-four ulcers in 21 patients were treated in group A and 22 ulcers in 21 patients in group B. Healing rate was lower in group A than in group B, and healing time was longer. Infective complications occurred significantly more often in group A patients, as did

relapses of ulcerations. There were only two minor perioperative complications in group B patients. Patients reported a higher degree of satisfaction in group B as well as lower discomfort and restrictions. Thus surgical treatment of neuropathic foot ulcers in diabetic patients proved to be an effective approach compared to conventional treatment in terms of healing time, complications, and relapses, and can be safely performed in an outpatient setting.¹¹ Ma et al compared the efficacy of topical platelet derived growth factor to placebo in treating diabetic foot ulcers. All subjects had a short leg walking cast with a window fashioned in the cast over the site of the ulcer. They randomly evaluated 46 subjects were randomized 1:1 to the test or control group and treated for up to 4 months. They observed that of the 46 subjects randomized, 38 either healed or completed 16 weeks of therapy without healing. From the results, they concluded that topical platelet derived growth factor does not appear to significantly improve healing of Wagner grade I diabetic foot ulcers that are treated by offloading with a short leg walking cast.¹² Richard assessed the effectiveness and safety of topical human recombinant basic fibroblast growth factor (bFGF) on the healing of diabetic neurotrophic foot ulcers. They analyzed 17 diabetic patients suffering from chronic neuropathic ulcer of the plantar surface of the foot and observed that in the bFGF group, three of nine ulcers healed compared with five of eight in the placebo group (NS). From the results, they concluded that topical application of bFGF has no advantage over placebo for healing chronic neuropathic diabetic ulcer of the foot.¹³

CONCLUSION

From the above results, the authors concluded that in cases of non-complicated neuropathic diabetic foot lesions, conservative surgical treatment is an effective approach, and is comparable with conventional treatment when healing in monitored.

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