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Indran GP Nair
Post Graduate, Department of General Surgery, Sree Mookambika Institute of Medical Sciences, Kulasekharam, Kanyakumari, Tamil Nadu, India

Gopika GP Nair
Medical Officer, KMJ Hospital, Perumbavoor, Ernakulam, Kerala, India

Jayakrishnan Shaji
Medical Officer, Santhwana Hospital, Perumbavoor, Ernakulam, Kerala, India

Corresponding Author:
Indran GP Nair
Post Graduate, Department of General Surgery, Sree Mookambika Institute of Medical Sciences, Kulasekharam, Kanyakumari, Tamil Nadu, India

A prospective study design for a randomised controlled trial evaluated the best non-surgical treatment for diabetic foot ulcers with surgical offloading methods

Indran GP Nair, Gopika GP Nair and Jayakrishnan Shaji

Abstract
Background: High pressure beneath a bony prominence is frequently linked to diabetic foot ulcers. Conservative treatment includes offloading with orthopaedic shoes and custom made orthotics or plaster casts. While primary foot ulcer healing with plaster casting is typically successful, recurrence rates are significant. This protocol compares non-surgical treatment for individuals with diabetic foot ulcers to offloading surgery (percutaneous flexor tenotomy, mini-invasive floating metatarsal osteotomy, or Keller arthroplasty) in a semi-crossover planned RCT.
Materials and Methods: The best non-surgical option or a surgical offloading operation will be offered to 60 patients with foot ulcers caused by diabetic neuropathy, including ulcers under the hallux interphalangeal joint, under the metatarsal heads, and at the tips of the toes. Patients will be given orthopaedic shoes and specially constructed orthotics after a successful offloading procedure (ulcer closure with complete epithelization). Patients will be given the option of surgical offloading if unloading via cast for at least 6 weeks is unsuccessful or the ulcer returns. Following randomization, there will be follow-up for a period of two years.
Results: The mean duration of ulcer in Group A was 144.7±29.73 days and in Group B were 147.63±28.16 days. There was significant decrease in necrotic tissue, significant increase in granulation tissue, and considerable increase in surface area in Group A more than Group B.
Conclusion: We found that surgical offloading treatments were superior in treating diabetic foot ulcers.

Keywords: Diabetic foot ulcers, offloading surgery, non-surgical treatment

1. Introduction
A prominent global cause of amputation, hospitalisation, and impairment is diabetic foot ulcers (DFUs). An estimated 130 million people are at risk of developing diabetic peripheral neuropathy, and about 26 million people globally have DFU each year. Patients with peripheral neuropathy frequently experience pressure ulcers as a consequence. Nowadays, diabetic mellitus (DM) is the most common cause of peripheral neuropathy, which affects up to 67% of people with type 2 DM. The frequency of diabetic foot ulcers worldwide is as high as 6.3%, and ulcers have been linked to up to 84% of diabetic foot amputations. The annual incidence of ulcers in patients with DM is around 2%.
An ulcer can form in a foot with normal architecture as a result of an acute injury in the context of sensory neuropathy and a loss of protective feeling. The foot's anatomical deformity, which typically results from a long-lasting muscular imbalance linked to the neuropathy itself, causes inappropriate pressure to develop more frequently. The treatment of diabetic foot ulcers (DFU) is frequently ineffective and frequently preventive. Diabetes-related foot issues cause significant patient suffering and high societal expenses. Since socioeconomic situations, footwear preferences, and standards of foot care vary greatly from place to region, so do the prevalence and severity of foot issues. DFU accounts for 20% of hospital admissions among DM patients and is a significant cause of morbidity and hospitalisation [4, 5]. Diabetes patients have a 25% to 50% chance of developing diabetic foot ulcers, and 20% will eventually need to have their feet amputated. Within 5 years, 70% of these individuals would experience recurrent lesions [6, 7].

Diabetes patients experience foot ulcerations 2%-6.8% of the time [8]. Peripheral sensory neuropathy, motor neuropathy-related foot deformities, minor foot trauma, and peripheral arterial disease are the main causes of foot ulcers [9, 10]. Offloading is essential for both treating and avoiding ulcers. You can achieve this with footwear, orthotics, and contact casts [11-14]. Although they are generally successful in the short term, ulcers frequently return over time for a variety of reasons, including patients' noncompliance. Surgical treatment of foot abnormalities is a more effective means of unloading [15, 16]. The natural history of recurring or persistent ulcers is so grim that a more aggressive and surgical treatment may be justified, even though any surgery in these individuals is a significant undertaking. Newer, less invasive surgical methods could reduce the significant complication rates that were once dissuasive.

2. Materials and Methods

This was a prospective interventional cohort study of 60 patients within the period of two years conducted in Department of Surgery, Sree Mookambika Institute of Medical Sciences. After obtaining Ethical committee Approval, informed written consent from the patients, they are categorised randomly into two groups. Group A - Surgical Offloading, patients will be operated within 1 week and Group B - Non-surgical treatment (best available). Randomized patients in Group A that decline surgery (post randomization) will be excluded from per-protocol analysis. Group B1 - include all patients randomized to cast offloading that completed at least 6 weeks of treatment or had complete ulcer healing. Group B_2 - include patients randomized to cast offloading that failed to complete 6 weeks of cast offloading due to complications or lack of compliance.

A patient included in this study was between 18 to 80 years of age, both sexes with Diabetes mellitus and Diabetic Foot Ulcer. Patients with a Texas stage A, grade 1 or 2 diabetic-neuropathic ulcer in the tip of a toe, under metatarsal head or under the big toe, ulcer attributable to an anatomical deformity, Tip of toe ulcer related to hammer or claw toe, Ulcer under metatarsal head related to low-riding metatarsal head, Ulcer under the interphalangeal joint, related to "functional hallux limitus" with high pressure under the hallux were included, and ABI > = 0.9 with palpable pulses or a duplex scan that demonstrates bi/triphasic pulses to vessels at the level of the ankle were included. Patients with peripheral vascular disease, Patients with grade IV and V ulcers by Wagner's classification, patients having Infection, Ischaemia of the limb and patients having more than one ulcer in the assigned foot (with the exception of tip of lesser toe ulcers with no other ulcers) were excluded in this study.

Non-surgical treatment will be continued until the ulcer heals or up to 12 weeks. Primary assessment will be at 6 weeks. If the ulcer is improving, further cast treatment will be recommended, up to 12 weeks. If the ulcer is not healing with non-surgical treatment, or has not healed completely at 12 weeks, the patient will be offered surgery. Crossover to surgery will not be permitted before 6 weeks of nonsurgical treatment. When the ulcer heals (complete epithelization) the cast will be replaced by orthopaedic shoes and custom made offloading insoles. At weeks 1, 2, 4 and 6 after surgical offloading done Weekly during non-surgical treatment up to complete wound closure or up to 12 weeks. Follow-up will be at 3, 6-, 12-, 18- & 24-months following treatment. Failure is defined as, "a composite of lack of complete closure at 12 weeks or recurrence within 2 years from surgery". Primary (intention to treat) analysis of treatment success will be between 3 groups (A versus B_1 & B_2). Recurrence will be compared between all patients whose ulcer healed (group A versus groups B_1 & B_2). Total 2-year success rate is calculated as the percentage of patients without ulcer and without recurrence (any recurrence of an ulcer at any time during the 2 years will count as recurrence).

3. Statistical Analysis

Statistical analyses of the data are conducted using the software IBM SPSS 21.0 version standard deviations are derived for all parametrical variables. P value of <0.05 was considered statistically significant and all the tests were two tailed.

4. Results

This study conducted in 60 patients, in that Mean Age in Group A was 55.23±13.28 years and in Group B were 55.1±9.52 years.

In this study, 25 patients were male in Group A, in Group B 18 were male patients. 5 patients were females in Group A and 12 in Group B. In our study patients had co morbidities like diabetes, hypertension and smoking. In Group A 17 patients were Diabetic, 8 were hypertensive and 5 were smokers. In Group B 18 patients were Diabetic, 9 were hypertensive and 3 were smokers.

The mean duration of ulcer in Group A was 144.7±29.73 days and in Group B was 147.63±28.16 days, P value was 0.349 (> 0.05) which was statistically insignificant.

In Group A, the mean hemoglobin was 13.92±17.62 gm/l, in Group B was 13.81±17.64 gm/l. Mean RBS was more in both group that was > 200mg/dl. Mean RBS in Group A was 206.4±84.99 mg/dl and in Group B was 212.66±89.07 mg/dl, this was statistically insignificant (P Value=0.3907).

Table 1: Mean value of parameters between groups

Parameters	Group A	Group B	P Value
Mean Age(years)	55.23±13.28	55.1±9.52	0.482
Gender Distribution			
Male	25	18	0.157
Female	5	12	
Comorbidity			
Diabetes	17	18	0.745
Hypertension	8	9	
Smoking	5	3	
Duration of ulcer (days)	144.7± 29.73	147.63±28.16	0.349
Hemoglobin (gm/L)	13.92±17.62	13.81±17.64	0.49
RBS (mg/dl)	206.4±84.99	212.66±89.07	0.3907

In Grading of necrotic tissue, baseline grading was comparable in both groups. There was significant decrease in necrotic tissue on follow-up in Group A compared with Group B, these were statistically significant.

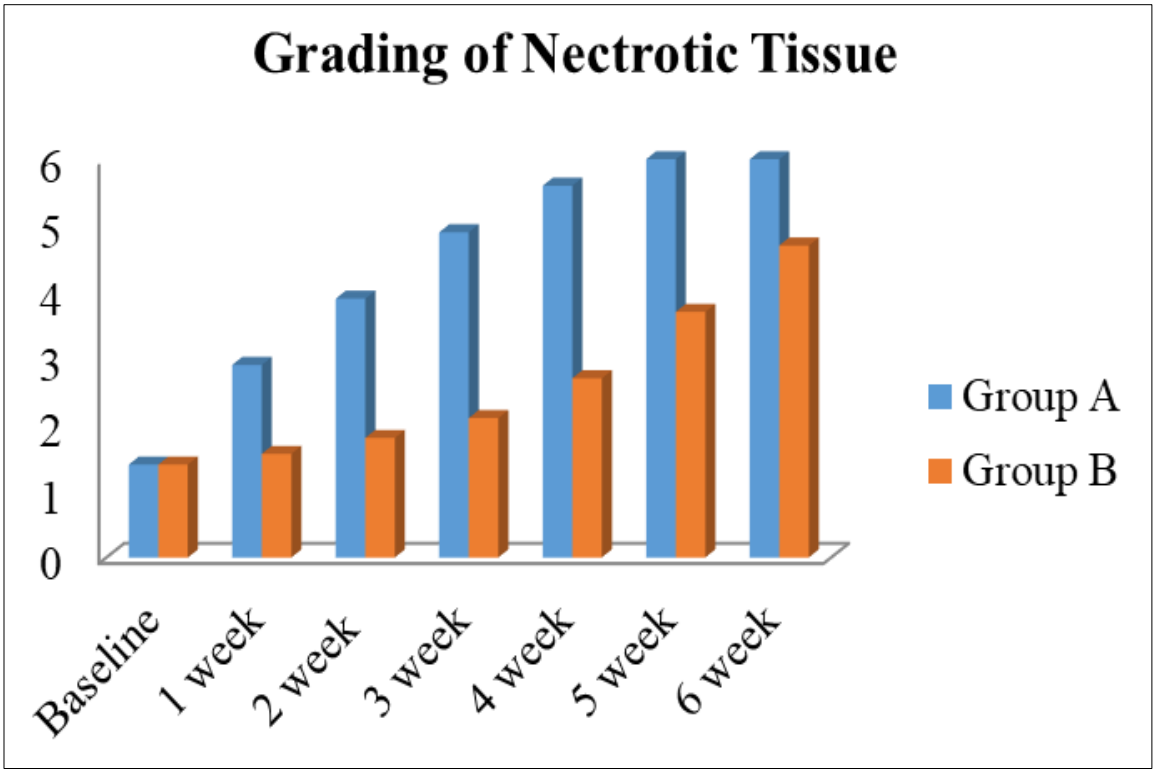

Fig 1: Graphical representation of the necrotic tissue of the patients among the group

In Grading of granulation tissue, baseline grading was comparable in both group A and Group B. There was significant increase in granulation tissue on comparison up to 6 weeks in Group A compared with Group B, these were statistically significant.

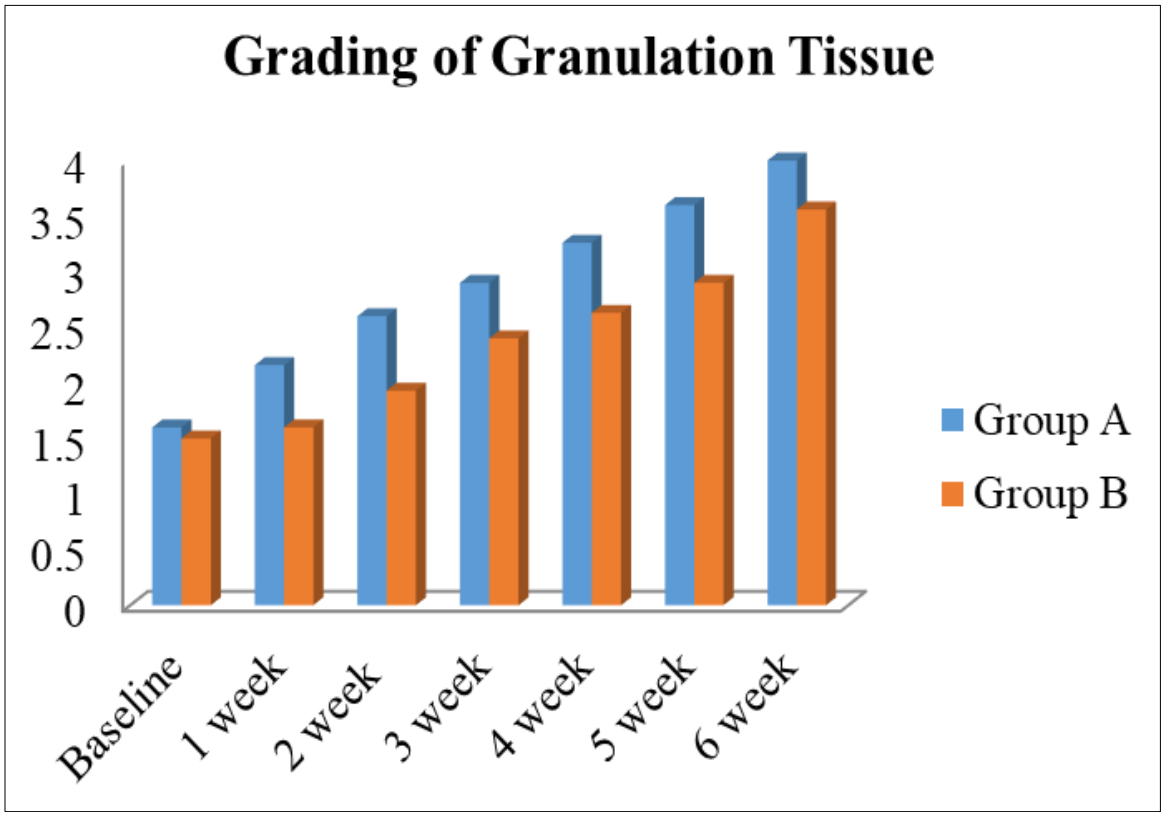

Fig 2: Graphical representation of the granulation tissue of the patients among the groups

In this study the surface area of the ulcer in both groups were comparable in baseline and in 1week follow-up. Then there was a considerable increase in surface area till 6 weeks follow-up in Group A more than Group B. these values were statistically significant (P Value < 0.05).

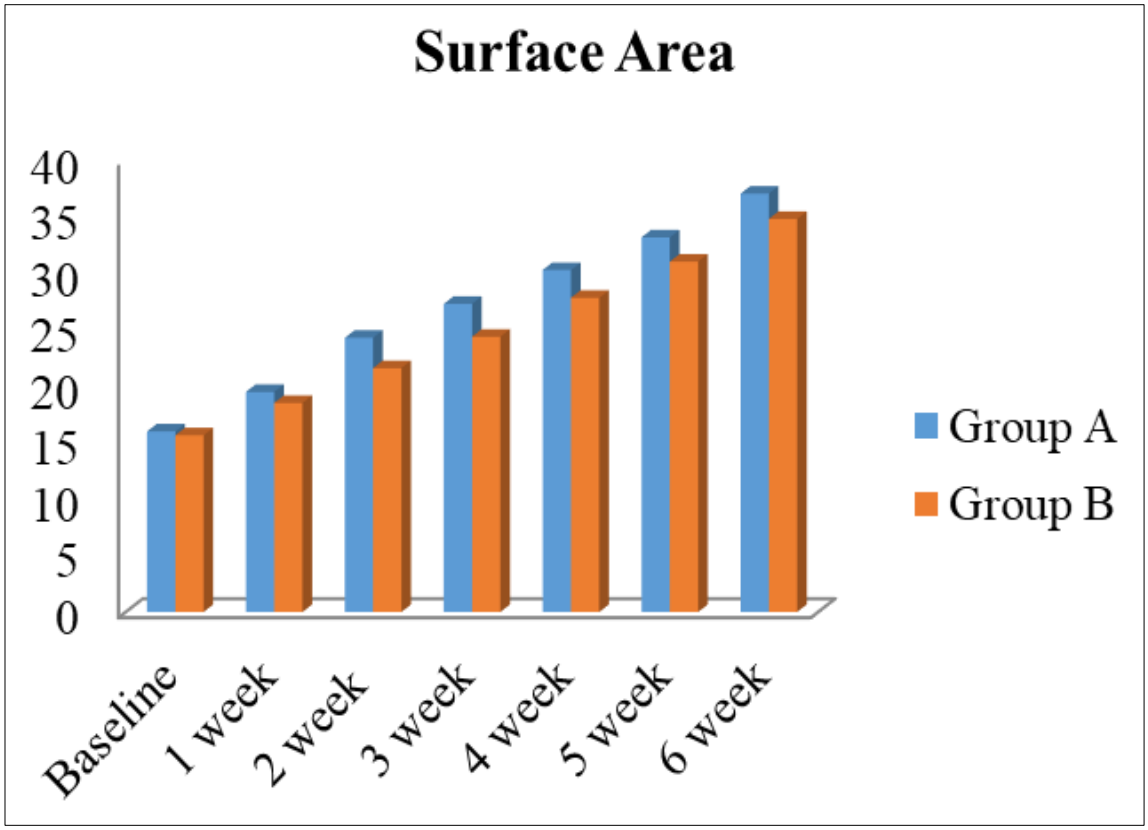

Fig 3: Graphical representation of the surface area of the patients among the groups

5. Discussion

One of the most serious and debilitating complications of diabetes is known as diabetic foot, which is defined as a foot affected by an ulceration that is linked to neuropathy and/or peripheral artery disease of the lower limb in a diabetic patient. In the diabetic community, diabetic foot ulceration occurs 4-0% of the time elderly diabetic patients are more likely to experience the problem. Approximately 5% of diabetic patients are thought to currently have a history of foot ulceration, despite the 15% lifetime risk that diabetic patients may experience this problem.

60 to 80 percent of foot ulcers will heal, but 15 to 20 percent will persist and, within six to eighteen months of the initial evaluation, 5 to 24 percent will necessitate amputation of a limb. While neuroischemic ulcers take longer to heal and frequently result in limb amputation, neuropathic wounds are more likely to do so over the course of 20 weeks. It has been found that people with diabetes account for 40–70% of all nontraumatic lower limb amputations. In addition, numerous studies have revealed that foot ulcers occur in around 85% of all diabetic patients who need to have their legs amputated.

Debridement of the wound, treatment of any infections, revascularization techniques when necessary, and off-loading of the ulcer make up the well-known diabetic foot ulcer treatments.

Patients in Group A of this trial had surgical offloading operations, while patients in Group B received non-surgical care for diabetic foot ulcers.

Group A's mean age was 55.23 13.28 years, whereas Group B's was 55.1 9.52 years. In the study by Wesam *et al*., the mean age of the surgery group was 43.424.2 and that of the nonsurgical group was 453.5 years.

Male patients made up 25 of the study's patients in Group A and 18 of the study's patients in Group B. 12 patients in Group B and 5 individuals in Group A were female.

Patients had co-morbid conditions such diabetes, hypertension, and smoking in our study. 17 patients in Group A had diabetes, 8 had hypertension, and 5 smoked. 18 of the patients in Group B had diabetes, 9 had hypertension, and 3 smoked.

The mean number of days an ulcer persisted in Group A was 144.729.73 and Group B was 147.6328.16. The average haemoglobin in Group A was 13.92–17.62 g/l, while it was 13.81–17.64 g/l in Group B. This group's P value was 0.49, which was statistically insignificant (greater than 0.05). Both groups had a mean RBS that was higher than 200mg/dl. Mean RBS was more in both group that was > 200mg/dl. Mean RBS in Group A was 206.4±84.99 mg/dl and in Group B was 212.66±89.07 mg/dl

Baseline grading for assessing necrotic tissue was similar between the two groups. On follow-up, there was a statistically significant decrease in necrotic tissue in Group A compared to Group B.

Baseline grading in the grading of granulation tissue was comparable between groups A and B. On comparison up to 6 weeks, there was a statistically significant increase in granulation tissue in Group A compared to Group B. In this investigation, the baseline and 1-week follow-up ulcer surface areas in the two groups were comparable. Then, Group A had a greater increase in surface area than Group B up to the 6-week follow-up.

6. Conclusion

We found that surgical offloading treatments were superior in expanding granulation tissue, surface area, and reducing necrotic tissue in diabetic foot ulcers when comparing them

to non-surgical treatment for patients with tropical foot ulcers.

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