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Surgical Offloading versus Medical Conservative Methods in Management of Diabetic Foot Plantar Ulcers (Interventional Study)

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ABSTRACT
Background: As a result, peripheral neuropathy is frequently caused by diabetes (DM). Diabetic plantar foot pressure ulcers develop from the lack of protective pain sensibility as a result of recurrent shear and tear pressures. Relieving pressure on the foot's sole is necessary for the ulcers to heal.
Objective: This study aimed to test the effectiveness of surgical and non-surgical unloading procedures in healing of plantar ulcers.
Subjects and methods: 50 diabetic foot ulcer patients who visited Ain Shams University, The National Institute of DM, and the Endocrinology Outpatient Clinic participated in this interventional trial (NIDE). We employed mechanical and surgical unloading methods in this trial, and patients were monitored for 6 months to see how long it took for their injuries to recover.
Results: At the conclusion of the follow-up period, 88% of the surgical group's pressure ulcers were fully healed compared to 86.7% of the non-surgical patients (6 months). Infection, recurrence, and non-healing were complications we encountered throughout the follow-up period. Regarding the treatment of plantar diabetic foot ulcers (DFUs), offloading is crucial. Compared to using only non-surgical methods, surgical offloading may hasten the recovery time. A well-trained team is necessary to prevent the issues with improperly fitting footwear and to teach the patient how to use them on a regular basis with the non-surgical offloading technique.
Keywords: Diabetic foot, Pressure ulcer, Peripheral neuropathy.

INTRODUCTION

Patients with DM typically experience foot issues that deteriorate their health. Due to variations in socioeconomic standards, foot care practices, and foot diseases, the severity of foot problems differs by region. DFU is one of the main reasons diabetes patients are admitted to hospitals and one of the main causes of morbidity [1, 2].The primary causes of foot ulcers are peripheral neuropathy, mild trauma to the foot, peripheral arterial disease, and diabetes mellitus [3,4].

In diabetic patients, higher plantar pressure increases the risk of developing plantar ulcers, which increases the need for lower extremity amputation [5,6].The possibility of infection exists if a skin ulcer has developed. Only one-third of foot ulcers fully heal [3]. Education, blood sugar management, wound debridement, improved dressing, unloading, advanced therapies, and, in certain cases, surgery, can all help to lessen the severity of problems brought on by DFU [2].

Offloading, a pressure modulation technique, works best when pressure is reduced in an area with significant vertical or shear stress while treating diabetic foot ulcers. Bed rest, wheel chair usage, and walking with crutches are common methods of unloading the foot. However, they are impracticable due to the patient's autonomy and quality of life restrictions. Patients with diabetic foot problems can move around without limitation thanks to offloading orthotics. Whole contact casts, felted foam, therapeutic shoes, partial shoes, detachable cast walkers, and surgical offloading are a few other offloading techniques [7,8]. Off-loading is crucial for diabetic foot plantar ulcer treatment [8].This study compared surgical and nonsurgical methods of offloading in order to compare the rates of complete plantar diabetic foot ulcer healing, as well as the time until healing and the incidence of recurrence in both groups.

SUBJECTS AND METHODS

50 diabetic patients who visited the Outpatient Clinic at Ain-Shams University, National DM Institute, had diabetic foot ulcers, and the Endocrinology Department participated in this interventional trial (NIDE). They all had an unloading technique, including 25 surgical and 25 non-surgical ones. They were monitored for a minimum of six months.

Inclusion criteria: Diabetes patients with plantar non-ischemic ulcers that did not heal after six months.

Exclusion criteria: Patients with coagulopathy, those with persistent infections that have not improved after their first surgical debridement, those undergoing radiation or chemotherapy, those in poor cardiological condition (with an ejection fraction less than 35%), and those on dialysis if they had renal failure.
Cases suffering from ischemic diabetic foot ulcers were evenly divided into two groups using the closed envelope simple randomization approach, with group (A) getting group (B) receiving surgical unloading as opposed to non-surgical offloading. The research work-

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up comprises the pre-procedural, intra-procedural, and post-procedural stages.

Establishing a historical appraisal of the whole, focusing on height and weight as the main factors to determine BMI examinations of the feet and lower limbs: Look for any irregularities while inspecting the foot and ankle. By looking at the ulcer's position, size, shape, edge, base, floor, and inflammatory signs, you may determine the ulcer's infection grade using the IDSA classification. The sensation of foot warmth and radial pulsations can be felt by palpation. Testing peripheral senses of depth and surface (with a tuning fork) (pinprick). Before any therapy, pictures of the wounds were obtained.

Group (A): Mechanical modalities, patient education, patient choice of footwear, daily dressing 1 month of weekly visits, followed by 5 months of monthly visits.

Group (B) Surgical offloading group: patient preparation, appropriate anaesthesia, full aseptic technique, curetting and trimming of the edges of the hyperkeratotic ulcer, eradication of any infection, flexor tenotomy excision of exposed bone, daily dressing, weekly follow-up for one month, and monthly follow-up for five months.

Post-operative: Measurements and images of the ulcers were obtained every week for the first month, twice monthly until healing occurred, and then once a month until the end of the follow-up period to monitor their development (6 months). Each patient had a 6-month period of observation during which time any problems were identified and categorised as infections, delays in healing, or recurrences.

Measures of results: Healing of the plantar ulcers is the main result. **Additional outcome criteria** as time till healed and plantar ulcer recurrence.

Ethical approval: After receiving written informed permission from each participant, the research was authorised by the Ain Shams University Faculty of Medicine's Research Ethics Committee. The Declaration of Helsinki, the World Medical Association's guidelines of ethics for research involving human subjects, was followed in the completion of the study.Both the informed consent form and the medical photography consent form were signed by each patient.

Analytical Statistics

The data were collected, examined, coded, and entered using IBM SPSS version 20 of the Statistical Package for Social Science. The acceptable margin of error was set at 5%, and the confidence interval was set at 95%. The 0.05 p-value was therefore deemed significant.If P > 0.05 it was non-significant (NS). High statistical significance is indicated by P 0.001 (HS).

RESULTS

Table (1) revealed that there were 16 female and 34 male cases.Ages ranged from 40 to 52 years (mean 45.22 years).

Table (1): Demographic information of all patients

		All Cases
		No.= 50
Sex	Female	16 (32.0%)
	Male	34 (68.0%)
Age	Mean ± SD	45.22 ± 3.78
	Range	40 – 52

Table (2) demonstrated that there was statistically insignificant difference in age, sex, height, or smoking between group A and group B. But when it came to BMI, there was a highly statistically significant difference between group A and group B.

Table (2): Comparison between Group A and Group B (n = 25) in terms of age, sex, weight, height, BMI, and smoking

		Group A	**Group B**			
		No.= 25	**No.= 25**	***T***	**P-value**	**S**
Age	Mean ± SD	44.84 ± 3.17	45.60 ± 4.33			
	Range	40 – 50	40 – 53	-0.708•	0.482	NS
Sex	Female	8 (32.0%)	10 (40.0%)			
	Male	17 (68.0%)	15 (60.0%)	0.347*	0.556	NS
Weight	Mean ± SD	84.16 ± 19.78	100.04 ± 25.90			
	Range	55 – 127	64 – 182	-2.437•	0.019	S
Height	Mean ± SD	170.24 ± 5.40	172.40 ± 4.90			
	Range	158 – 180	164 – 182	-1.481•	0.145	NS
BMI	Mean ± SD	29.02 ± 6.71	35.01 ± 8.47			
	Range	20.96 – 44.47	21.13 – 59.43	-2.770•	0.008	HS
Smoking	No	10 (40.0%)	12 (48.0%)			
	Yes	15 (60.0%)	13 (52.0%)	0.325*	0.569	NS

Regarding the length of the wound and the duration of the DM, table (3) demonstrated that there was no statistically significant difference between Group A and Group B. (months).

Table (3): Comparison betweengroup A and group B regarding the length of DM and the duration of the wound (months)

		Group A	Group B	*T*	P-value	S
Duration of DM (years)	Mean ± SD Range	23.52±6.70 15 – 35	24.64 ± 6.42 15 – 35	0.364	0.549	NS
Wound duration(months)	Mean ± SD Range	4.62 ± 1.67 3 – 10	5.42 ± 1.32 3.5 – 7.5	-1.888	0.065	NS

Table (4): demonstrated that there was no statistically significant difference in foot deformity in ulcerated feet, ulcer size, or ulcer area at entrance (cm2) between group A and group B.

Table (4): Comparison of the foot deformity in ulcerated feet, ulcer size, and ulcer area at entrance

		Group A	Group B	*T*	P-value	S
Foot deformity in ulcerated foot	No Yes	5 (20.0%) 20 (80.0%)	3 (12.0%) 22 (88.0%)	0.595*	0.440	NS
Ulcer size	Large(>2.5cm²) Small (<2.5cm²)	7 (28.0% 18 (72.0%)	8 (32.0%) 17 (68.0%)	0.095*	0.758	NS
Ulcer area at entry (cm²)	Mean ± SD Range	1.57 ± 0.53 1 – 2.5	1.49 ± 0.47 1 – 2.34	0.589•	0.559	NS

According to Table (5), there were statistically significant difference in the plantar site between group A and group B.

Table (5): Comparison of the plantar site between group A (n = 25) and group B (n = 25)

Plantar site	GroupA		GroupB		*T*	Pvalue	S
	No.	%	No.	%			
Forefoot	10	40.0%	19	76.0%	8.793	0.012	S
Hind foot	0	0.0%	1	4.0%			
Mid foot	15	60.0%	5	20.0%			

Table (6) demonstrated that there were statistically insignificant differences in ulcer healing, dropout, ulcer area reduction, or dropout between group A and group B.

Table (6): Comparison between group A (n = 25) with group B (n = 25) regarding dropout, healing of ulcer, and reduction in ulcer area in the first four weeks

		GroupA	GroupB	*T*	Pvalue	S
Dropout, in	4 w 12 w	12 (48.0%) 13 (52.0%)	10 (40.0%) 15 (60.0%)	0.325*	0.569	NS
Ulcer healing	4w, per protocol 4w intention to treat 12w, per protocol 12w intention to treat	5 (20.0%) 8 (32.0%) 4 (16.0%) 8 (32.0%)	2 (8.0%) 11 (44.0%) 2 (8.0%) 10 (40.0%)	2.648*	0.449	NS
Reduction in ulcer area in first 4weeks	Mean ± SD Range	77.78 ± 18.21 50 – 105	68.73 ± 17.49 40 – 95	1.793•	0.079	NS

Table (7) demonstrated that there was statistically insignificant difference in complications between group A and group B.

Table (7): Comparison of the complications experienced by group A (n = 25) and group B (n = 25)

Complications	GroupA		GroupB		*T*	Pvalue	S
	No.	%	No.	%			
Serious adverse event(SAE)	3	12.0%	2	8.0%	0.222	0.637	NS
New ulcer/ mild infection	5	20.0%	7	28.0%	0.439	0.508	NS
Falls due to device	2	8.0%	3	12.0%	0.222	0.637	NS
Blister due to device	5	20.0%	5	20.0%	0.000	1.000	NS
Abrasion due to device	5	20.0%	5	20.0%	0.000	1.000	NS
Pressure point due to device	5	20.0%	3	12.0%	0.595	0.440	NS
Infection	3	12.0%	0	0.0%	3.191	0.074	NS
Recurrence	3	12.0%	2	8.0%	0.222	0.637	NS
Non healing	3	12.0%	5	20.0%	0.595	0.440	NS

DISCUSSION

Neuropathic diabetic foot ulcers are significantly impacted by peripheral neuropathy. The healing of the lesion is delayed when neuropathic foot ulcers are treated with insufficient pressure relief. The majority of studies indicate that relieving pressure is essential for curing plantar ulcers. Off-loading the foot's plantar surface while maintaining some mobility is currently advised as the best method for reducing plantar pressure [9].In contrast ***Finestone et al.***[10] stated that the cure rate is projected to be roughly 90% in the surgical group and the non-surgical compliance group, the cure rate in our study was 88% for the surgical group and 86% for the non-surgical group [10].

Our study's recurrence rates were 8% in the surgery group and 12% in the non-surgical group with a 6-month follow-up period.In contrast to the same study's 20% and 50% recurrence rates in the surgical group and non-surgical group, respectively, with a two-year follow-up time.

In contrast to cautious offloading treatment, **Piaggesi *et al.*** [11] stated that first ulcer debridement, and medication, rest from weight-bearing, and frequent dressings). Despite the fact that conservative unloading therapy is less intrusive, an RCT with 41 patients found that forefoot plantar ulcers healed faster with 95% of patients in 47 days as opposed to 79% in 129 days (p 0.05) (TCC).**Armstrong *et al***.'s retrospective cohort study [12] on 50 patients with persistent plantar ulcers revealed that unloading treatment and removal of the fifth metatarsal head both had 100% recovery rates but shorter healing times (maximum 5.8 vs. 8.7 weeks).

In our research, it took 7 weeks for the group to undergo surgery versus 11 weeks for the non-surgical group, although it took 5.8 versus 8.7 weeks for the control group receiving conventional wound care, which included weekly debridement, wound dressing changes, and offloading. Following removal of the fifth metatarsal head, considerably fewer patients (4.5% versus 27.8%) experienced re-ulceration at 6 months.

Since amputations were excluded from the analysis of the experiment, neither the percentage of patients who suffered from infection (18.2% versus 22.2%; P = 0.8) nor the number of cases who received major amputation (4.5% against 11.7%; P =.4) changed significantly.

The panmetatarsal head excision group healed much quicker than the careful unloading group.According to ***Armstrong et al.*** [13]in a retrospective cohort study on (92) cases with multiple plantar forefoot ulcers,the mean was 60.1 vs. 84.2 days (p=0.02).

Six uncontrolled investigations on patients who had single-or pan-metatarsal head excision after conventional therapy showed a recovery rate of 88% to 100% [14].

Armstrong et al. [15] compared the use of a cast walker with a detachable half shoe on 50 participants. Between short-term treatment shoes and detachable cast walkers, there was a statistically insignificant difference in the number of neuropathic plantar foot ulcers treated (p value = 0.78). The detachable cast walker group had a reported time to healing of 6 weeks and a 12-weeks follow-up period, despite the fact that the follow-up in our investigation was 6 months. The temporary treatment group reportedly needed 12 weeks to recover.

In contrast to our findings, which indicated zero infection in the non-surgical group, ***Zimny et al.***[16]in analysis of 61 patients during a follow-up period of 10 weeks or at least until healing occurred, reported 12 cases of infection. They compared the felted foam that was affixed to the foot to a temporary rehabilitation half-shoe that distributed weight to the heel.

CONCLUSION

Regarding the treatment of plantar ulcers in diabetic feet, offloading is crucial. Compared to using only non-surgical methods, surgical offloading may hasten the recovery time. A well-trained team is necessary to prevent the issues with improperly fitting footwear and to teach the patient how to use them on a regular basis with the non-surgical offloading technique**.**

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