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Comparison between Surgical Offloading and Mechanical Offloading in Treatment of Planter Diabetic Foot Ulcer

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ABSTRACT

Background: Diabetes is a systemic disease that affects all body systems and is a major cause of death. Foot problems are a source of major patient suffering and societal costs. Foot ulcers are the most prevalent problem, with a yearly incidence of around 2-4% in developed countries and likely even higher in developing countries.

Objective: This study aimed to evaluate the clinical outcome of both surgical and non-surgical methods of offloading in the treatment of neuropathic non-ischaemic plantar pressure ulcers.

Materials and methods: This prospective non-randomized comparative study was conducted on 30 patients who presented at the Outpatient Clinic of the Department of General Surgery at Zagazig University Hospital and Department of Vascular and Endovascular Surgery, National Institute of Diabetes and Endocrinology (NIDE). The study was conducted through the period from July 2019 till September 2019. All of them had an offloading method; 15 surgical, 15 non-surgical (walkers or shoes). They had followed up for six months.

Results: Successful rate for ulcers healing were 86.7% and 88% for surgical vs. non-surgical methods respectively.

Conclusion: Offloading is very important and effective in treatment of pressure unhealed plantar ulcers. Every patient should receive his tailored method of offloading. Surgical offloading is a faster way.

Keywords: Diabetes, Peripheral neuropathy, Diabetic foot, Pressure ulcer, Plantar, Offloading.

INTRODUCTION

Diabetes is a global and a systemic disease that affects all body systems and is a major cause of death. It is estimated that 415 million people were diagnosed with diabetes in 2015. It is expected to rise up to 642 million by 2040 [(1)]. DM is an increasing problem in both developed and developing nations. The majority of persons with DM have type 2 DM with only 5% to 10% of patients diagnosed with type 1 DM. About 50% of people with DM are unaware of their disease. Early DM detection and treatment can improve overall quality of life (QOL) and increase the life expectancy of persons with DM [(2)]. Diabetes mellitus is the seventh leading cause of death in the United States. Diabetes mellitus is the leading cause of kidney failure, non-traumatic lower extremity amputations, and new cases of blindness in adult Americans [(3)].

Diabetic foot ulcers (DFU) are often preventable, and treatment is frequently suboptimal. Foot problems complicating diabetes are a source of major patient suffering and societal costs. The frequency and severity of foot problems varies from region to region largely due to differences in socio-economic conditions, type of footwear, and standards of foot care. DFU is a major source of morbidity and one of the leading causes of hospitalization representing about 20% of hospital admissions among patients with DM [(4, 5)]. The incidence of diabetic foot ulcers in diabetics is 25% and 50% and 20% of them will proceed to amputations throughout their life time. 70% of these patients will have recurrent lesions within 5 years [(6, 7)]. Yearly 2% - 6.8% of diabetic patients suffer from foot ulcerations [(8)]. The most important factors underlying the development of foot ulcers are peripheral sensory neuropathy, foot deformities related to motor neuropathy, minor foot trauma, and peripheral arterial disease [(9, 10)].

This study aimed to evaluate the clinical outcome of both surgical and non-surgical methods of offloading in the treatment of neuropathic non-ischaemic plantar pressure ulcers.

PATIENTS AND METHODS

This study was conducted as a "Prospective non-randomized comparative study" that included 30 cases who presented to the Outpatient Clinic of the Department of General Surgery, Zagazig University Hospital and Department of Vascular and Endovascular Surgery, National Institute of Diabetes and Endocrinology (NIDE). It was conducted through the period from July 2019 till September 2019. All of them had an offloading method; 15 surgical, 15 non-surgical (walkers or shoes). The first case had enrolled in the study in July 2019, the last case in September 2019. They were followed up for six months. Data analysis and interpretation had done in March 2020.

Ethical approval:

Written informed consent was obtained from every participant and the study was approved by The Research Ethical Committee, Faculty of Medicine, Zagazig University. The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Inclusion criteria:

Diabetic patients with plantar ulcers (possibly pressure related) that failed to heal after 6 months with at

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least one of the foot pulses (Dorsalis pedis or Posterior tibial) was easily palpable**.**

Exclusion Criteria:

Patients with an ischaemic foot non-palpable pedal pulses or ABI less than 0.9. Patients with diabetic foot infection (IDSA grade 2, 3)**.** Sizing (cm^2) by the simple method had measured by multiplying width (cm) by length (cm) **(11)**. Planter had classified as grade 0 or 1 according to I.D.S.A classification. Osteomyelitis was diagnosed by probe-to-bone test or foot x-ray findings. A healing ulcer was defined as attempt of epithelialization of the tissue defect. A healed ulcer was defined as complete epithelialization within 6 months. The study work-up included three stages, pre-procedural, intra-procedural and post-procedural.

Pre-Procedural:

- Informed consent was taken.
- The demographic data were recorded (age and sex).
- History taking of type of diabetes, presence of co-morbidities; HTN, IHD, CKD or CVA.
- History taking with special emphasizing on duration of the ulcer, previous treatment or recurrent ulcers.
- General examination with special emphasizing on height and weight to calculate BMI.
- Lower limb and foot examinations.
- Inspection of ankle and foot [check any deformities like hallux valgus, pes planus (flatfoot), pes cavus (clawtoe), hammer toes, and rocker bottom deformity of Charcot].
- Inspection of the ulcer (site, size, shape, edge, base, floor and signs of inflammation to detect grade of infection according to IDSA classification).
- Palpation: temperature of the foot, peripheral pulsations, capillary refill and ulcer base.
- Test of peripheral sensations: deep (tuning fork) and superficial (pinprick).
- Test of osteomyelitis: probe-to-bone test.
- The wounds were photographed before intervention.
- HbA1c, CBC, INR, KFTs, LFTs and serum albumin were done for all patients.
- Foot x-rays were done for all patients.
- The modality of the offloading was determined based on: Presence of osteomyelitis, fitness for anaesthesia and patient preference.

Postoperative care:

All patients were followed up for 6 months and complications were recorded classified as granulating with ongoing healing progress, complicating in the form of infection, non-healing or recurrence.

Statistical analysis

The collected data were coded, processed and analyzed using the SPSS (Statistical Package for Social Sciences) version 24 for Windows® (IBM SPSS Inc., Chicago, IL, USA). Data were tested for normal distribution using the Shapiro Walk test. Qualitative data were represented as frequencies and relative percentages. Chi square test (χ^2) was used to calculate difference between two or more groups of qualitative variables. Quantitative data were expressed as mean ± SD (Standard deviation). Independent samples t-test was used to compare between two independent groups of normally distributed variables (parametric data). P value < 0.05 was considered significant.

RESULTS

Table (1) showed that patients were 15 males and 15 females. Ages ranged from 33-65 years in both gender. Concerning demographic data, there were no significant difference between both groups.

Table (1): Demographic data of studied cases

Data		Surgical Group (n=15)	Nonsurgical Group (n=15)	P value
Age		43±4.2	45±3.5	>0.05
Sex	**Male**	10	9	
	Female	5	6	
Smoking status	**Yes**	9	8	
	No	6	7	

Ulcer & Foot Examination:

Table (2) showed that there was no significant difference between both groupsregarding characters of ulcer.

Table (2): Characters of ulcer

Data		Surgical Group (n=15)	Nonsurgical Group (n=15)	P value
Foot deformity in ulcerated foot		12	13	>0.05
Ulcer size	**Small (<2.5cm²)**	11	10	>0.05
	Large (>2.5cm²)	4	5	
Ulcer area at entry (cm²)		1.29±1.09	1.11±0.92	>0.05

The most common plantar site of the ulcers was forefoot at the base of the metatarsal heads 62.5% (n=5), which were more in non-surgical group, only 35% at midfoot (n=14) but they were more in surgical group,and lastly only one patients has ulcer at hindfoot (2.5%) as shown in table (3).

Table (3): Plantar site of the ulcer

Plantar Site	Group A		Group B		
	No.	%	No.	%	P value
Forefoot	6	40.0	9	75.0	0.041
Midfoot	9	60.0	5	20.8	
Hindfoot	0	0.0	1	4.2	

Outcome and end result of study:

At the end of the follow up period (6 months) there was no significant different between the two groups in number of patients who had healed wounds. 13 of the 15 surgical offloading patients (86.7%) had a completely healed pressure ulcer with range of healing between 4-14 weeks. In non-surgical patients, 12 of 15 (80%) had a healed pressure ulcer with range between 3-23 weeks. There was significant difference in mean duration of healing between the two groups. Also, there was no difference between the two groups regarding reduction in ulcer area through the first 4 weeks. (tble 4).

Table (4): Clinical outcomes of studied cases

Data		Surgical Group (n=15)	Nonsurgical Group (n=15)	P-value
Dropout, in	**12 w**	7	6	0.01
	20 w	8	9	
Ulcer healing	**12 w intention totreat**	5	7	0.7
	20 w intention totreat	5	6	
	12 w , per protocol	3	1	
	20 w , per protocol	2	1	
Reduction in ulcer area in first 4weeks		77.9±26.6%	68.3±41.6%	0.6

Table (5) showed that there was significant difference between both groups regarding offloading device or Peak pressure reduction in device.

Table (5): Peak pressure (kPa) in both groups

Data	Surgical Group (n=15) (Mean±SD)	Nonsurgical Group (n=15) (Mean±SD)	P value
In offloading device	81±55	176±80	0.05
In patients own shoe	272±128	270±130	0.7
Peak pressure reduction in device	67±26%	26±34%	0.02

Table (6) showed that in surgical group, there were 2 with SAE, 3 with new ulcer, 1 with falls due to device, 3 with blister due to device, 3 with abrasiondue to device, 3 with pressure point due to device, 2 with infection, 1 case with recurrence occurred and 2 cases with no healing had been achieved. In Non-surgical group, there were 1 with SAE, 4 with new ulcer, 2 with falls due to device, 3 with blister due to device, 3 with abrasion due to device, 2 with pressure point due to device, no infection occurred in all cases, 2 cases with recurrence occurred and 3 cases with no healing has been achieved.

Table (6): Complications that occurred in the studied cases.

Complications	Surgical Group(n=15)	Nonsurgical Group(n=15)
Serious adverse event (SAE)	2	1
New ulcer/ mild infection	3	4
Falls due to device	1	2
Blister due to device	3	3
Abrasion due to device	3	3
Pressure point due todevice	3	2
Infection	2	0
Recurrence	1	2
Non healing	2	3

DISCUSSION

This study has the advantage of being prospective, which may have a positive impact on the outcome. However, we acknowledge some limitations such as limited time, small sample size, non-randomization and limited financial resources. **Finestone *et al.*** [12] showed that cure rate is likely to be about 90% in the surgical group and the non- surgical compliant group while in our study the cure rate was 86.7% for surgical group and 80% for non-surgical group. This modest difference may be attributed to the larger sample size of their study, which was 100 patients (40 in the surgical group & 60 in the non-surgical). In the same study, recurrence in the surgical group and non-surgical group was 20% and 50% respectively within a follow up period of two years, while in our study recurrence rate was 6.7% in the surgical group and 13.3% in the non-surgical group but within a follow up period of 6 months [13].

Offloading was a key treatment strategy for the management of diabetic foot ulcers and total contact casts were found to be the most effective devices to achieve ulcer healing. However, they had more complications, less compliance and affected quality of life compared to removable boots [14]. An RCT including 41 patients showed higher healing rates and shorter time to healing of forefoot plantar ulcers for a combination of surgical excision, debridement, removal of bone segments underlying the lesion, and surgical closure when compared to conservative offloading treatment (initial debridement and medication of ulcer, relief of weight-bearing and regular dressings) 95% in 47 days versus 79% in 129 days ($p<0.05$), although conservative offloading did not involve the current standard of care (TCC) [15].

A retrospective cohort study including 50 patients with recalcitrant plantar ulcers showed that fifth metatarsal head resection was as effective as offloading treatment, both 100% healing rate, but resulted in shorter time to healing (maximum 5.8 vs. 8.7 weeks). Healing time was 5.8 ± 2.9 weeks vs. 8.7 ± 4.3 weeks in the control group who received standard wound care that consisted of wound dressing changes, offloading, and weekly debridement [(16)]. While, in our study healing time was 7 ± 3 weeks in the surgical group vs. 11 ± 6 weeks in non-surgical group significantly fewer patients re-ulcerated during the 6- month follow-up after resection of the fifth metatarsal head (4.5% versus 27.8%). No significant differences were found in percentage of patients diagnosed as having an infection during follow-up (18.2% versus 22.2%; P = .8), while in our study infection was only in the surgical group (20%; p value = 0.046). Percentage of patients who underwent major amputation (4.5% versus 11.7%; P = 0.4), but in our study there was no amputations during follow up period**.** A retrospective cohort study evaluated 92 patients with multiple plantar forefoot ulcers and showed that those treated with pan metatarsal head resection healed significantly faster (mean 60.1 vs. 84.2 days, p=0.02) than those treated with conservative offloading [(17)]**.**

Results of six non-controlled studies of patients treated with single or pan metatarsal head resection after failed conservative treatment showed between 88% and 100% healing compared to removable cast walker with removable half shoe that included one trial with 50 participants. There was no statistically significant difference between removable cast walkers and temporary therapeutic shoes in the number of neuropathic and plantar foot ulcers healed (p value = 0.78). Reported time to healing, in the removable cast walker group was 6 weeks compared to 9 weeks in the temporary therapeutic shoe group with a follow up period of 12 weeks but the follow up in our study was 6 months [(18)]**.** Comparison of felted foam adhered to a temporary half-shoe that transferred eight to the heel, showed 12 cases of disease from 61 cases in a follow up period of 10 weeks or at least till healing occurred, which had higher than our results that had zero disease in non-technique [(18)].

CONCLUSION

Either surgical or non-surgical modalities could be used without significant difference between them in their outcome. We should tailor the most suitable method for every patient.

RECOMMENDATION

We recommend conducting randomized controlled reviews on a larger number of cases to reach better results.

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