



A PROSPECTIVE STUDY ON OFFLOADING DEVICES AND FOOTWEAR INTERVENTIONS IN PREVENTING THE RECURRENCE OF DIABETIC ULCERS IN A TERTIARY CARE TEACHING INSTITUTE

General Surgery

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ABSTRACT

Background: Diabetes can have serious side effects, such as diabetic foot ulcers (DFUs), which can cause substantial morbidity and higher medical expenses. It has been demonstrated that offloading devices and sensible footwear modifications are beneficial in halting the progression of diabetic foot ulcers (DFUs). To investigate the effectiveness of these interventions in a tertiary care teaching institute environment, more study is necessary. **Methods:** A prospective observational study on 48 patients with Diabetic Ulcer Foot who get admitted under the Department of General Surgery, to Kanyakumari Government Medical College Hospital, Nagercoil, from 1st June 2023 to 28th February, meeting the Inclusion Criteria and those who consented to participate in the study were included. The clinical characteristics and demographic data of the patients were collected. Follow-up evaluations will be carried out at one three, six and nine months. **Results:** 33 males and 15 females were included, with male preponderance 63.75%. The primary outcome measures included the incidence of recurrent foot ulcers 10%, the rate of wound healing is 85.71% and patient adherence to offloading devices and footwear interventions is 64.28%. Secondary outcome measures involved assessing patient satisfaction 57%, comfort, and the impact of these interventions on daily activities. **Conclusions:** Offloading devices and footwear interventions play a crucial role in preventing the recurrence of diabetic ulcers. This prospective study demonstrates that patients who consistently use these interventions have a lower risk of ulcer recurrence and experience improved wound healing rates.

KEYWORDS

diabetes; diabetic foot; ulcer; footwear; offloading;

INTRODUCTION

High-risk diabetic foot is prone to injury, infection and ulceration in diabetic patients. Previous studies have reported that the 1- and 5-year recurrence rates of high-risk diabetic feet 31.6%,² and approximately 70%,³ respectively. Clinical history of foot ulcers prevention and healing in patients with diabetes includes the use of castings, footwear, surgery and offloading techniques. Patients with refractory and slow healing tend to have more frequent leg amputations and higher mortality rates. In addition, patients with high risk diabetic feet have a higher risk of non-traumatic foot amputation with over 70% mortality within 5 years of foot amputation. Reducing recurrence in high risk diabetic feet can dramatically reduce the risk of foot amputation and mortality in these patients.

High-risk diabetic foot recurrence is mainly attributed to abnormal lower limb movements and changes in plantar biomechanics.⁴⁻⁷ Conventional shoes cause chronic overload and friction to your feet. Over time, this friction damages the skin on your sole or dorsal foot and worsens your gait and balance. Over time, these changes cause foot ulcers and eventually, amputation.

Even after they heal, soft tissues are vulnerable to ongoing stress, which can lead to tissue necrosis and the recurrence of high-risk diabetic foot. Nonetheless, if patients receive the right care, amputations and fatalities can be avoided.⁸⁻¹⁰ The International Working Group on the Diabetic Foot (IWGDF) states that in high-risk diabetic foot patients, the use of an offloading device can effectively prevent recurrence.¹⁰ Additionally, by shifting the body's center of gravity, this device can improve balance and lessen plantar pressure on the painful area of the foot. As a result, the gadget absorbs vibration and logically distributes pressure on the bottom of the foot to stop the recurrence of high-risk diabetic foot.¹¹⁻¹²

METHODS:

A prospective observational study on 48 patients with Diabetic Ulcer Foot who get admitted under the Department of General Surgery, to Kanyakumari Government Medical College Hospital, Nagercoil, from 1st June 2023 to 28th February 2024.

Inclusion criteria:

- Patients with diabetes mellitus and foot ulcer

- Patients who are cooperative and willing to give consent to participate in the study.
- Both men and women in the age group of 18 years and more.
- Patients who are willing to use offloading devices and adhere to prescribed footwear interventions

Exclusion criteria:

- Individuals with a documented non-diabetic cause of foot ulcers (e.g., peripheral arterial disease, vasculitis, pressure ulcers unrelated to diabetes).
- Patients with a history of lower limb amputation.
- Patients with severe foot deformities that limit the use of offloading devices or prescribed footwear interventions.
- Patients with known allergies or sensitivities to materials used in offloading devices or footwear interventions.
- Patients with severe cognitive impairment or psychiatric disorders affecting compliance.
- Patients participating in other interventional studies or clinical trials going on.

At the start of the study, the clinical characteristics and demographic data of the patients were recorded and analysed.

These included age, gender, height, BMI, duration of diabetes, Wagner classification, history of diabetic foot ulcer.

To monitor the healing of the wound, ulcer recurrence, compliance with offloading devices and footwear therapies, and wound healing progress, follow-up evaluations will be carried out at one, three, six and nine months.

Such patients were optimized which included Diabetic control, appropriate antibiotic course based on culture sensitivity report, if required and correction of other medical illness.

RESULTS:

The study was conducted at Kanyakumari medical college and Hospital, Nagercoil from the period of June 2023 to February 2024 and included 48 patients diagnosed of diabetic foot ulcer

Gender Distribution: The study comprised of total 33 males and 15

females, out of which 25 males and 9 females in control group and 11 males and 3 females in intervention group included as shown in the Figure 1

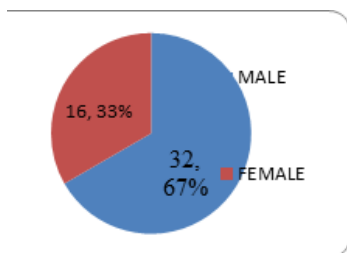


Figure 1

Age Distribution:

The mean age of the study was 57.6 years. The youngest patient was 26 years of age and oldest being 76 years of age. Maximum number of patients in the study belonged to age group of 51 to 60 years (40%). Most of the study population was between 20 and 80 years as shown in Figure 2 and 3

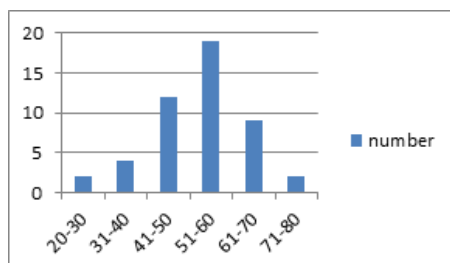


Figure 2: showing the age distribution over patients

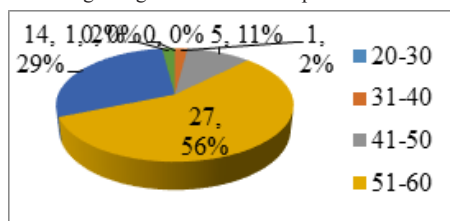


Figure 3

Body Mass Index:

Majority of the patients with diabetic foot ulcer came under normal group with BMI of 18-24.9 i.e., 32 out of 34 cases in control group and 13 out of 14 cases in intervention group. The number of cases with BMI <18 and >30 were 0 and 0 respectively. The mean BMI of patients with INCISIONAL HERNIA was 27.45. (Figure 4 and 5)

Figure 4: Table Showing Distribution Of Cases According To Bmi

S NO	BODY MASS INDEX	CONTROL	INTERVENTION
1	LESS THAN 18 (UNDER WEIGHT)	0	0
2	18-24.9(NORMAL)	32	13
3	25-29.9(OVERWEIGHT)	2	1
4	MORE THAN 30(OBESE)	0	0

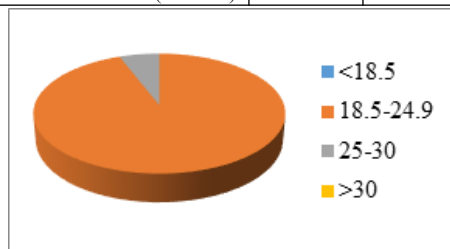


Figure 5: Showing distribution of cases according to BMI

Diabetes Duration:

Majority of the patients having diabetes between 5-10 years in control group is 24 out of 34 patients and 11 out of 14 patients in intervention

group. (Figure 6)

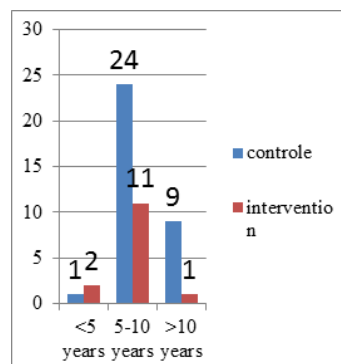


Figure 6: Table showing distribution of cases according to duration of diabetes

Wagner Classification Of Diabetic Foot Ulcer:

In our study 25 (73.52%) out of 34 patients of control group belongs to Wagner classification of diabetic foot ulcer grade 0-3 and 9 patients belongs to Wagner classification of diabetic foot ulcer grade 4-5. In spite of this 8 (57.14%) out of 14 patients of intervention group belongs to Wagner classification of diabetic foot ulcer grade 0-3 and 6 (42.85%) patients belongs to Wagner diabetic foot ulcer grade 4-5, as shown in the figure 7.

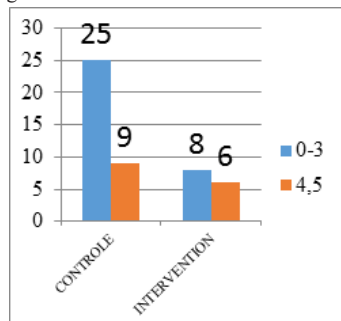


Figure 7: showing distribution of cases according to Wagner classification of diabetic ulcer

History Of Diabetic Foot Ulcer:

In our study 24 out of 34 patients in control groups were having history of diabetic foot ulcer and 11 out of 14 patients in intervention group having history of diabetic foot ulcer, as shown in the figure 8.

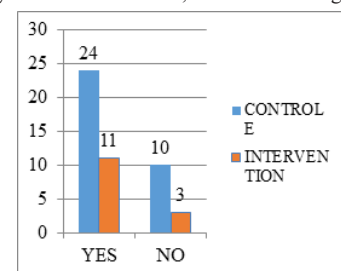


Figure 8: showing distribution of cases according to history of diabetic foot ulcer

Ulcer Recurrence:

In our study 26 out of 34 patients have ulcer recurrence in control group and 3 (10 %) out of 14 patients in intervention group has ulcer recurrence within 9 months of follow-up, as shown in figure 9.

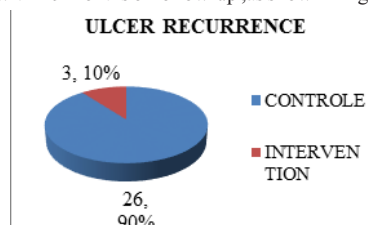


Figure 9: showing distribution of cases according to diabetic ulcer recurrence

Adherence To Prescribed Treatment Modality:

In our study 9 (64%) out of 14 patients strictly adhered to prescribed treatment modality, it includes total contact cast, Footwear includes socks, insole plugs, and shoes. Surgical offloading and Additional offloading methods include bed rest ,walkers , offloading dressings, felted foam or padding, callus debridement, gait modification, and walking exercises etc. as shown in the Figure 10.

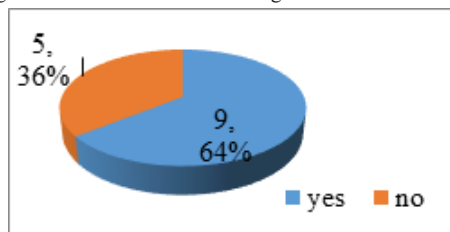


Figure 10: showing distribution of cases according to Patient adherence to prescribed treatment modality:

Patient Satisfaction For Newer Intervention:

In our study only 8 out of 14 patients were having satisfactory response for newer intervention, as shown in the figure 11.

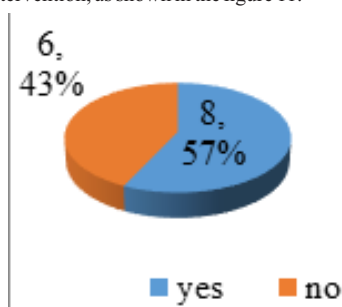


Figure 11: showing distribution of cases according to Patient satisfaction for newer intervention:

DISCUSSION:

The study was conducted at Kanyakumari medical college and Hospital, Nagercoil from the period of June 2023 to February 2023 and included 48 patients diagnosed of diabetic foot ulcer.

The study comprised of total 33 males and 15 females, out of which 25 males and 9 females in control group and 11 males and 3 females in intervention group included. The mean age of the study was 57.6years. The youngest patient was 26 years of age and oldest being 76 years of age. Maximum number of patients in the study belonged to age group of 51 to 60 years (40%). Most of the study population was between 20 and 80 years.

In our study 24 out of 34 patients in control group were having history of diabetic foot ulcer and 11 out of 14 patients in intervention group having history of diabetic foot ulcer.

In our study 25 (73.52%) out of 34 patients of control group belongs to Wagner classification of diabetic foot ulcer grade 0-3 and 9 patients belongs to Wagner classification of diabetic foot ulcer grade 4-5. In spite of this 8 (57.14%) out of 14 patients of intervention group belongs to Wagner classification of diabetic foot ulcer grade 0-3 and 6 (42.85%) patients belongs to Wagner diabetic foot ulcer grade 4-5

Patients and their families experience severe pain and financial hardship as a result of high-risk diabetic foot. In certain developed nations, diabetic foot offloading footwear—which consists of custom insoles and functional socks—has been utilized to treat the condition and is covered by medical insurance.¹³

Of the 34 patients in our study, 9 (64%) followed the recommended treatment plan to the letter, which included wearing a total contact cast, Footwear includes socks, insole plugs and shoes. Surgical offloading: osteotomy, metatarsal head resection; external fixation, Additional offloading methods include bed rest, the use of crutches, canes, or

wheelchairs, bracing, walkers that are (non-) removable, offloading dressings, felted foam or padding, callus debridement, gait modification, and walking exercises.

Nevertheless, in the majority of developing nations, medical insurance does not cover offloading devices. The effectiveness of offloading devices as a preventive measure for diabetic patients with high-risk feet is still up for debate. For instance, it was reported by Gao et al.¹⁴, Bus et al.¹⁵, and Maciejewski et al.¹⁶ that the offloading device effectively prevented diabetic foot ulcers from recurring. Additionally, the patients felt negatively about the device since it suggested that they were still recovering, which added to their psychological load. Just a small number of physicians and researchers have discussed the function of the offloading device, despite the fact that it effectively reduces mortality and amputation in patients at high risk of developing diabetic foot.

In our study 26 out of 34 patients have ulcer recurrence in control group and 3 (10 %) out of 14 patients in intervention group has ulcer recurrence within 9 months of follow-up.

Results of the present study further confirm efficacy of the offloading device as an adjuvant therapy for patients with diabetic high-risk foot. This is because wearing an offloading device significantly lowers the number of patients with high-risk diabetes feet, and subsequently reduces the socioeconomic burden, risk of infections, amputation, and death of patients associated with this condition.

This study had a few limitations. Firstly, our sample size was relatively small. Future studies should enroll more patients to establish barriers regarding continuous use of offloading footwear and help improve diabetes-related foot ulcers.

CONCLUSION:

Interventions involving offloading devices, surgical offloading and footwear are essential for halting the progression of diabetic ulcers. Patients who regularly use these therapies have better wound healing and a decreased chance of ulcer recurrence, according to this prospective study.

The results emphasise how crucial it is to incorporate footwear therapies and offloading devices into regular diabetic foot care in tertiary care teaching institutions.

In order to determine the long-term advantages and cost-effectiveness of these therapies in avoiding diabetic foot ulcers, more research is required.

Ethical Clearance taken from Ethical Committee

Source of Funding – Self

Conflict of Interest – Nil

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