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Original Article

Surgery Section

Comparison of Offloading Dressing with Conventional Dressing in Healing of Plantar Diabetic Foot Ulcers: A Randomised Clinical Trial

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ABSTRACT

Introduction: The first ever description of Diabetic Foot Ulcers (DFUs), made in the literature was in the mid 19th century. The management principles for it were laid by late 19th century and are still being followed. For a chronic DFU to heal, offloading of pressure, surgical debridement, correction of hyperglycaemia, the use of antibiotics are the corner stone of management. Offloading is an essential modality of prevention and treatment of recurrent plantar DFU.

Aim: To compare offloading dressing to conventional dressing in promoting healing of diabetic plantar foot ulcers.

Materials and Methods: This randomised clinical trial was conducted at Mahatma Gandhi Medical College and Research Institute, Pondicherry, India, between January 2019 to June 2020 among the patients with DFU coming to the Department of General Surgery. A total of 44 patients were included in the study, 22 of these patients underwent offloading dressing and 22 underwent conventional dressing and these patients were followed-up for a duration of 6 weeks and compared on 2nd, 4th and 6th weeks. The patients were compared according to age, gender, duration of diabetes, glycaemic control, risk factors, previous surgery such as wound debridement or previous toe amputation, vascular assessment and site of ulcer, reduction in size of ulcer. The ulcers in both the groups were classified according to the Wagener's grading of ulcer classification. All data collected was entered into Microsoft Excel 2016 and analysed using Statistical Package for the Social Sciences (SPSS) version 16.0 (IBM SPSS, US) software. A p-value less than 0.05 was considered as statistically significant.

Results: Among 44 patients, there was equal number of males and females in both the groups, with the total mean age 53.97±10.10 years. The majority of the study population belonged to the 5th decade (51-60 years), where the youngest patient was of 29 years and oldest was of 72 years. There were 22 patients in offloading group and 24 patients in conventional dressing group as one patient had bilateral plantar ulcers and one patient had two separate ulcers on the plantar aspect of the foot. Total of 45.45% in conventional group and 31.82% of the study population in offloading group had diabetes for 5-10 years of duration. Bad glycaemic control was seen in 40.90% of offloading group and 50% in conventional group. The size reduction percentage of ulcers on comparing both the groups was found to be significant for 2nd week review (p-value=0.03) and was nearly significant for the 6th week review (p-value=0.05).

Conclusion: Summarising the above conducted study, offloading dressing was found to be a more efficacious alternative to the conventional dressing as there was greater difference observed in the reduction of the size of ulcer and the patients in the conventional group needed more number of dressings and the duration of healing in the two groups.

Keywords: Peripheral arterial disease, Shoe model cast, Total contact cast

INTRODUCTION

Until 19th century, Diabetic Foot Ulcers (DFUs) were treated with prolonged bed rest, however the wounds returned once the patient started mobilising [1]. Until the end of 19th century, Fredrick Treves had laid the three most important principles for treatment of ulceration of foot: sharp debridement, offloading pressure and education about foot care which have continued to be followed-up until now [1].

India is considered as the diabetes capital of world with an increase in the population from 26 million (1990) to 65 million (2016), with a fair chance of reaching the alarming mark of 69.9 million by 2025 and 80 million by 2030 [2]. The pathophysiology behind a DFU is multifactorial and can be attributed to many causes, leading cause being increased plantar foot pressure, mechanical changes occurring in conformation of the bony architecture of the foot, peripheral neuropathy and atherosclerotic peripheral arterial disease, all of these factors occur with higher frequency and intensity in the diabetic population [3].

Offloading is an essential modality of prevention and treatment of plantar diabetic foot ulcers. Various offloading modalities such as Total Contact Cast (TCC), Removable Contact Cast (RCC), Customised therapeutic footwear, Shoe Model Cast (SMC) exist, but all these have their own advantages and disadvantages [4]. Majorly being lack of availability for the rural diabetic population even if available, are not affordable for common man.

In this day-to-day advances happening in medical science from application of 3D bioprinting for diabetic foot ulcers to use of economical ways such as mandakini dressing for offloading DFU [5,6]. Each method has its own application process but it all lies down on same ideology of redistributing the pressure in the foot and offloading the ulcer, some methods have tedious process of usage therefore lack of comprehension from the patient side is noted.

Therefore, the aim of the present study was to compare an offloading dressing with a conventional dressing based on its efficacy in reduction in size of the ulcer and cost-effectiveness which can be put to use by all the classes of patients irrespective of their socio-economical background.

MATERIALS AND METHODS

This randomised clinical trial was conducted in the Department of Surgery at a tertiary care institute (Mahatma Gandhi Medical College and Research Institute), Pondicherry, India, between

January 2019 to June 2020. The study population included all the patients with plantar DFUs visiting the Department of General Surgery at MGMCRI during the study period. The study protocol was approved by the Institutional Human Ethics Committee (IHEC). PG DISSERTATION/02/2019/42 dated 26/02/2019.

Inclusion and Exclusion criteria: Patients with plantar DFU Wagner's grade I, II and III above 18 years of age were included in the study [7,8]. Ulcers of Wagner's grade IV and V were excluded as they involve deeper underlying tissue with extensive destruction sometimes extending into tendon, ligament or bone. Patients on corticosteroids, receiving radiation therapy and immunosuppressant and DFU with peripheral vascular diseases (ABPI <0.4) were also excluded.

Peripheral arterial disease in DFUs is associated with the most severe adverse outcomes, including lower probability of healing, longer healing times, higher probability of ulcer recurrence, greater risk of toe as well as major amputations, and potentially higher mortality [9]. A total of 60 patients with plantar DFUs reporting to the Department of Surgery were recruited for the study.

Sample size estimation: However, due to the global pandemic and its effects on healthcare system, the sample size of study had to be reduced to 22 patients in each group after a formal approval by the Ethical Committee. Therefore, 44 patients were a part of the final clinical study.

Procedure

Patients who fulfilled inclusion criteria were included in the study after duly obtaining an informed written consent, a detailed history of all the patients were noted including demographic data, symptomatology, duration of diabetes. A total of 44 patients with plantar DFUs reporting to the Department of Surgery were recruited. The study participants were divided with a computer generated block randomisation method into two groups with block size of 4.

- Offloading dressing group=22 and
- Conventional dressing group=22.

The patients were subjected to clinical examination, vascular assessment {(clinical palpation of peripheral pulses Posterior Tibial Artery (PTA) and Dorsalis Pedis Artery (DPA) as well as hand held doppler assessment)}, and neuropathic assessment of the lower extremity [10,11]. A thorough clinical examination of the patient was conducted to determine the site, size, shape, extent and depth of the ulcer and peripheral pulses.

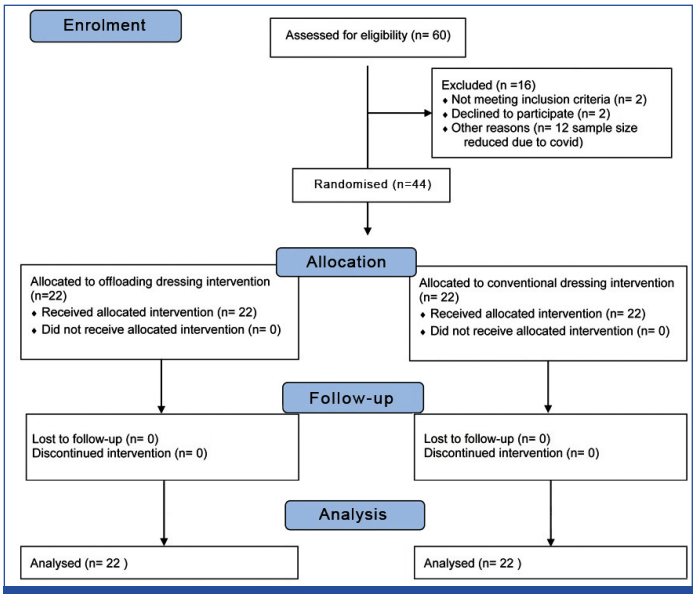
Patients underwent routine investigations such as Complete blood count, Renal function test with serum electrolytes, urine routine and microscopy, chest X-ray, Electrocardiogram (ECG), and specific investigations such as Fasting Blood Sugar (FBS), Postprandial Blood Sugar (PPBS), Haemoglobin A1c (HbA1c), urine ketones (if blood glucose levels>250 mg/dL) X-ray foot, hand held arterial doppler and pus culture were done, if required.

In this study "Prozole Adhesive Felt Pad" was used as offloading device, (Dynamic Techno Medicals, Aluva, Kerala) after creating a window in accordance with size of the ulcer in the adhesive felt pad according to the size of the ulcer. The ulcer accommodates within the window and is surrounded by the pad which provides it a cushion-like effect and offloads it from the body weight [Table/Fig-1]. This offloading device is a low priced and an economic cost saving method. The estimated average cost of each dressing using the offloading device, used for this study was approximately Rs. 58/- per dressing and the average expenditure incurred by a patient for conventional dressing was Rs. 50/- per dressing.

The patients were compared according to age, gender, duration of diabetes, glycaemic control, risk factors (smoking and alcohol consumption), history of previous surgery (wound debridement or previous toe amputations) [11-13], site of ulcer, Wagner's grading system [7,8], vascular assessment, reduction in size of ulcer and number of dressings.

Vascular assessment of the patients were done [9] i.e, if clinically palpable peripheral pulse present or not; as well as, hand held doppler assessment, site of ulcer (forefoot, mid-foot, hind-foot) and reduction in size of ulcer was recorded. The reduction in size of the ulcer was evaluated at 2nd, 4th and 6th week. Flow chart to summarise the sequence is presented in [Table/Fig-2].

[Table/Fig-1]: Shows an image of Offloading device with a window created in a patient with grade 1 ulcer in mid foot.



[Table/Fig-2]: CONSORT Flow diagram.

STATISTICAL ANALYSIS

All data collected was entered into entered into MS Excel 2016. The statistical analysis was carried out using SPSS version 16.0 (IBM SPSS, US) software. The findings in both the groups were compared and calculated in form of percentage of reduction. The normally distributed continuous variables were expressed as mean±SD and compared using Independent t-test and the non normally distributed variables were presented as median±Interquartile Range (IQR) and compared using the Mann-Whitney U test to assess the p-value. A p-value less than 0.05 was considered as statistically significant.

RESULTS

Among 44 patients, there were equal number of males and females in both the groups, with the total mean age 53.97±10.10 years. The mean age in the offloading group was 55.68±10.92 years and 52.41±7.07 years in the conventional group. The majority of the study population belonged to the 5th decade (51-60 years), where the youngest patient was of 29 years and oldest was of 72 years [Table/Fig-3]. Patient had bilateral plantar ulcers and one patient had two separate ulcers on the plantar aspect of the foot. Hence, 24 ulcers in the conventional group and 22 ulcers in the offloading group were assessed. The peak incidence was noted between 41-60 years.

Age (years)	Offloading group		Conventional group	
	Male n (%)	Female n (%)	Male n (%)	Female n (%)
18-30	0	1 (4.54)	0	0
31-40	0	1 (4.54)	1 (4.54)	2 (9.09)
41-50	2 (9.09)	2 (9.09)	2 (9.09)	3 (13.64)
51-60	4 (18.18)	6 (27.27)	7 (31.81)	3 (13.64)
61-70	2 (9.09)	1 (4.54)	1 (4.54)	2 (9.09)
> 70	3 (13.64)	0	0	1 (4.54)
Total	11 (50%)	11 (50%)	11 (50%)	11 (50%)

[Table/Fig-3]: Age and gender distribution.

In the studied population, one patient was recently diagnosed with Type 2 Diabetes Mellitus (T2DM) in the offloading group, while there was no recently diagnosed patient in the conventional group. Most of the patients had diabetes for a duration of 5-10 years both in offloading and conventional group which was 31.82% and 45.45% respectively. In offloading group 22.73% and 13.64% in conventional group had duration of diabetes between 11-15 years. One (4.54%) patient in the offloading group had history of recent diagnosis of diabetes and presented with a plantar ulcer of 2 months duration [Table/Fig-4].

Duration of diabetes (years)	Offloading group n (%)	Conventional group n (%)
Recently diagnosed	1 (4.54)	0
<5	4 (18.18)	3 (13.64)
5-10	7 (31.82)	10 (45.45)
11-15	5 (22.73)	3 (13.64)
16-20	2 (9.09)	4 (18.18)
>20	3 (13.64)	2 (9.09)
Total	22 (100)	22 (100)

[Table/Fig-4]: Duration of diabetes.

In the study population, the glycaemic control was found to be under bad control category in majority of the population. In offloading group, 40.91% and 50% of the conventional population had their HbA1c more than 10. The rest of the 36.36% in offloading group and 31.82% in conventional group had a poor glycaemic control (7.5-10). However, 22.73% of offloading and 18.18% of the conventional population had a good control of the HbA1c (5.7-7) [Table/Fig-5].

Glycaemic control	Offloading group n (%)	Conventional group n (%)
Good control	5 (22.73)	4 (18.18)
Poor control	8 (36.36)	7 (31.82)
Bad control	9 (40.91)	11 (50)
Total	22 (100)	22 (100)

[Table/Fig-5]: Glycaemic control.
According to ADA guideline 2019, Good control HbA1c value- 5.7 -7, Poor 7.5- 10, Bad >10 [12].

In the offloading group, 27.3% of the population were smokers and 31.8% were alcoholics while in the conventional group 31.8% each were smokers and alcoholics. However, there was no significant difference between the two groups regarding the risk factors, smoking and alcohol (p-values were 0.74 and 0.627, respectively) [Table/Fig-6].

Risk factors	Offloading group		Conventional group		p-value
	Yes n (%)	No n (%)	Yes n (%)	No n (%)	
Smoking	6 (27.3)	16 (72.7)	7 (31.8)	15 (68.2)	0.74
Alcohol	7 (31.8)	15 (68.2)	7 (31.8)	15 (68.2)	0.627

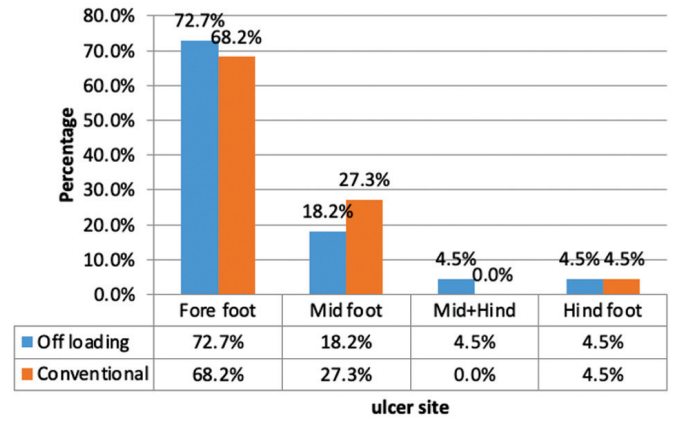
[Table/Fig-6]: Risk factors.
Chi-square test

In our study, the number of patients with significant history of previous surgery in the foot such as toe amputations, Incision and Drainage (I and D) and wound debridement included 36.4% of the offloading group and 27.3% of conventional group. The rest of the 63.6% in the offloading group and 72.7% in the conventional group had no previous history of surgeries in the foot [Table/Fig-7].

History of previous surgery	Offloading group n (%)	Conventional group n (%)	p-value
Present	8 (36.4)	6 (27.3)	0.517
Absent	14 (63.6)	16 (72.7)	
Total	22 (100)	22 (100)	

[Table/Fig-7]: History of previous surgery.
Chi-square test

One patient in the offloading group underwent open reduction and internal fixation of the transmetatarsal joint in view of long standing Charcot's foot with a non healing forefoot ulcer on the plantar aspect. Authors observed that forefoot was the most common site involved in both offloading and conventional group. The most common site of plantar DFU is the heads of 2nd -5th metatarsals followed by the mid-foot. In our study, 4 (18.2%) of offloading group and 6 (27.3%) of conventional group had mid-foot lesions [Table/Fig-8].



[Table/Fig-8]: Site of ulcer.

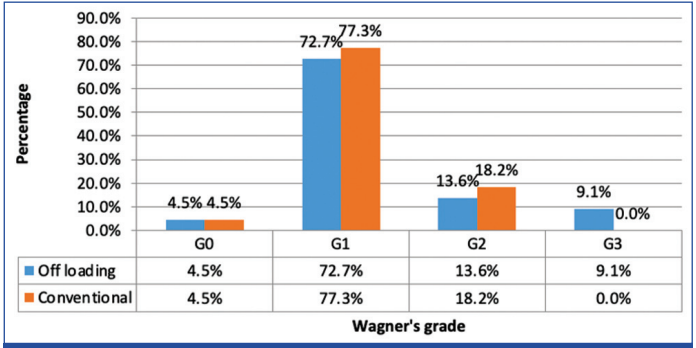
One patient in the offloading group had an ulcer occupying both the mid foot and hind foot approximately 12 cm² in size and 4.5% of population had hind foot lesions in both cases and controls.

In the conventional group, one patient was included who had bilateral plantar foot ulcers and one patient had two ulcers in the plantar aspect hence, the sample size was statistically considered as 24 considering these as two separate entities.

While comparing both the groups Wagner's grading system was applied to assess the ulcer depth, presence of osteomyelitis or gangrene [7,8]. It is the most widely accepted classification system and it was observed that grade 1 ulcers (superficial ulcers) were common in offloading and conventional groups, 72.7% in the former and 77.3% in the latter. Grade 2 ulcers were 13.6% (deep ulcer not involving tendon, capsule or bone with cellulitis without abscess or

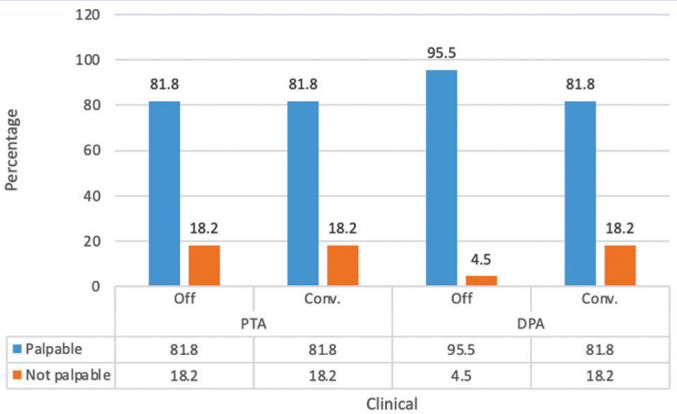
osteomyelitis) in the offloading group and 18.2% in the conventional group.

There were two patients with grade 3 ulcers (deep ulcer involving tendon, capsule or bone/abscess formation) in the offloading group, both being diabetic foot abscess. These patients were managed with incision and drainage/debridement under antibiotic coverage for one week and were continued with offloading dressing after the abscess was drained. One patient each in the offloading and conventional group had a grade 0 ulcers (no open lesion) [Table/Fig-9].



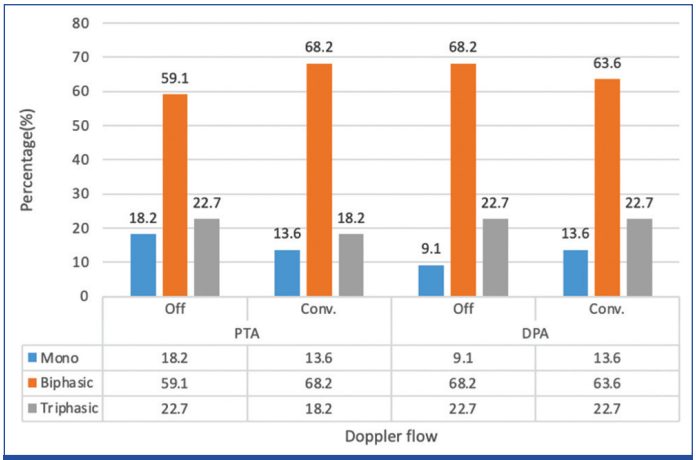
[Table/Fig-9]: Wagner's grading system [7,8].

The 44 patients who were subjected to clinical examination, vascular assessment (clinical as well as doppler), noted that, in vascular assessment Posterior Tibial Artery (PTA) was not clinically palpable in 4 (18.2%) patients in both offloading and conventional group (N=23 as one patient presented with bilateral plantar DFU) while Dorsalis Pedis Artery (DPA) was not clinically palpable in 1 (4.5%) patient in the offloading group and 4 (18.2%) in the conventional group which matched with the monophasic flow in hand held doppler study [Table/Fig-10]. While the rest of the patients had biphasic and triphasic flow. Maximum number of patient showed biphasic flow on doppler study and in the offloading group PTA was absent in 4 (18.2%) and DPA was absent in 1 (4.5%) while in the conventional group 4 (18.2%) patients had absent DPA and PTA [Table/Fig-11]. The p-value for clinical assessment and hand held doppler for PTA in both the groups was 1 and 0.820 respectively. For DPA, p-value was 0.154 and 0.741 in the former and latter assessment which was not found to be significant [Table/Fig-10,11].



[Table/Fig-10]: Clinical assessment of PTA and DPA.

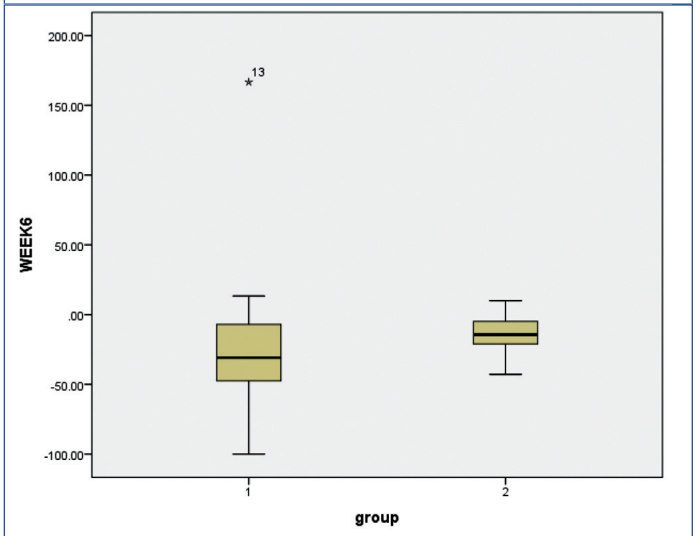
Reduction in size of the ulcer at 2nd, 4th and 6 weeks was calculated using mean for 2nd and 4th week and using median±IQR (Interquartile Range) for the 6th week. The p-value was expressed using Independent t-test for the 2nd week and 4th week. However, Mann-Whitney U test was used for the 6th week as it included data with non normal distribution. The size reduction percentage of ulcers on comparing both the groups was found to be significant for 2nd week review (p-value=0.03) and was nearly significant for the 6th week review (p-value=0.05) [Table/Fig-12,13].



[Table/Fig-11]: Doppler study of PTA and DPA vessels.

Time of assessment during the follow-up	Mean (reduction in size) (in cm^2)	Median (in cm^2)	Mean difference (size reduction of Ulcer) (in cm^2)	IQR (25^{th}-75^{th})	p-value (Mann-Whitney U test/Independent t-test)
2nd week					
Offloading (22)	-14.0964	-8.12	17.13853	-20.55 to 0	0.03
Conventional (24)	-3.7054	-3.23	4.67028	-4.7 to 0	
4th week					
Offloading (22)	-27.3304	-22.11	21.76595	-34.63 to -12.77	0.54
Conventional (24)	-23.7198	-20.09	21.92673	-31.03 to -10.97	
6th week					
Offloading (22)	-24.1322	-30.9	51.98026	-48.12 to -5.25	0.05
Conventional (24)	-13.7256	-14.37	13.52662	-21.18 to -4.22	

(-) in the above table indicates percentage of reduction in size of ulcer



[Table/Fig-12]: Reduction in size of ulcer at 2nd, 4th and 6th weeks and box plot (6th week IQR).

Total of 13.6% of the patients in offloading group required upto 10 dressings and 86.4% of them required 10-20 dressings. In the conventional group, 9.1% of the population required upto 10 dressings, 63.6% of the population required 11-20 dressings and 27.3% patients required more than 20 dressings in the period of 6 weeks [Table/Fig-14].

On comparing the number of dressings applied for both the groups and its cost effectiveness, the offloading dressing was found to be more cost-effective as the number of dressing required by the offloading group was overall less on comparison with the conventional

group. During the follow-up period, one patient in the offloading group and one in the conventional group missed the 6th week review.

[Table/Fig-13]: (a, b and c) shows offloading forefoot plantar ulcer of a patient at 2nd week, 4th and 6th week respectively.

Number of dressings	Offloading group n (%)	Conventional group n (%)	p-value
0-10	3 (13.6)	2 (9.1)	0.03
11-20	19 (86.4)	14 (63.6)	
>20	0	6 (27.3)	
Total	22 (100)	22 (100)	

[Table/Fig-14]: Number of dressings.
Chi-square test; p-value <0.05 considered significant

Secondary infection of the ulcer was noted in one of the patients in the offloading group and three patients in the conventional group and were managed with antibiotics (inj. augmentin 1.2 g for 5 days duration) and wound debridement and regular dressings. Complete epithelialisation of the ulcer was noted in three patients of the offloading group in the 4th and 6th week. Similarly, in the conventional group one patient showed signs of complete healing of the ulcer with a callosity and two other patients underwent split skin grafting for closure of the raw area due to chronicity of the ulcer. There was no evidence of oedema, skin changes and maceration noted with the offloading device.

DISCUSSION

This randomised controlled trial aimed at comparing the offloading with conventional dressing in healing of diabetic plantar foot ulcers. Both groups were comparable as there was no statistical difference in the parameters studied. Age and gender assessment, vascular assessment, previous foot surgeries and risk factors were not statistically significant in both the groups while the other variables such as reduction in size of ulcer at 2nd week and number of dressings applied was found to be significant. Majority of the study population belonged to the 5th decade (51-60 years) and 10 out of 22 were in this age group. The youngest patient was 29 years of age and oldest 72 years of age. The peak incidence was noted between 41-60 years. The mean age in our study was 53.97±10.10 years. Sinharay K et al., in their study stated that DFU were present in 4.54% of newly diagnosed diabetes mellitus patients [13].

Ragnarson TG and Apelqvist J, in their study concluded that diabetic patients are at high risk of developing foot ulcers and subsequent amputations [14]. Frykberg RG et al., in their study stated that in diabetes related amputations, toe amputations are the most common [15]. Lane KL et al., in their study aimed at evaluating the association between glycaemic control and the outcomes of wound healing and Lower Extremity Amputation (LEA) in patients with DFUs, they concluded that HbA1c levels more than or equal to 8 and fasting blood glucose more than or equal to 126 mg/dL are associated with increased likelihood of LEA in patients with DFUs [16]. Strandness DE et al., concluded in their study that hypercholesterolemia and smoking are the strong risk factors for atherosclerosis mainly seen in the proximal vessels of the lower limb [17]. In a meta-analysis conducted by Fu XL et al., showed that smoking had an overall negative effect on the wound healing of diabetic foot individuals [18]. Faglia E et al,. concluded osteomyelitis can affect any bone but most frequently the forefoot (90%), followed by the mid-foot (5%) and the hind-foot (5%) [19]. Sutkowska E et al., in their study interpreted that the forefoot is the most frequent region of the foot which bears highest pressure on the sole especially in patients with diabetes it is the central part of the forefoot the 2nd and 3rd metatarsal heads. They also stated that females with higher basal metabolic index are more prone to it [20].

In a similar prospective comparative study conducted by Ganesh P and Kannan R over 110 patients with plantar DFU, divided into test (offloaded) and control group (not offloaded), majority of the patients had grade 1 and 2 ulcers. Grade 1 ulcers were seen in 25% and 30% of test and control group population respectively and grade 2 ulcers were noted in 23% of the test group and 32% of control group which is comparable with our study [21]. The reduction in size of ulcers on comparing both the groups was found to be significant for 2nd week review (p-value=0.03) and was nearly significant for the 6th week review (p-value=0.05). Ganesh P and Kannan R in their study of over 110 patients with plantar diabetic foot ulcers, divided into test (offloaded) and control group (not offloaded) assessed at 3rd, 4th ,5th and 6th week also found that the mean size of ulcer was 4.5 cm and the mean±SD of test group was (4.36±2.19) cm and in control group is (4.36±2.18) cm. Grade 1 and 2 ulcers were prevalent in both test and control groups and the reduction in wound surface area was significantly higher in test group at 3rd week follow-up (p-value=0.025) at 4th week (p-value=0.015), at 5th week (p-value<0.001) and at 6th week (p-value<0.001) when compared to control group [21].

This offloading device is a low priced and economic method of cost saving. The estimated average cost of each dressing using the offloading device, used for this study was approximately Rs. 58/- per dressing and the average expenditure incurred by a patient for conventional dressing was Rs. 50/- per dressing. However, on comparing the number of dressings applied for both the groups and its cost-effectiveness, the offloading dressing was found to be more cost-effective as the number of dressing required by the offloading group was overall less on comparison with the conventional group and the p-value was found to be significant (p-value=0.03).

Ranade SS et al., conducted a similar study in which they compared variables like number of dressings, cost effectiveness, duration of hospital stay, patient compliance and many other variables and their observations were similar to the present study [22].

Kari SV, in his observational study concluded that, number of dressings used for offloading the diabetic plantar ulcers were significantly lesser. Total 68% patients who undergone offloading dressings required upto 1-5 dressings and 58% patients required more than 10 dressings showing statistical significance between conventional dressing and dressing with offloading technique [6].

Limitation(s)

Limitations experienced in the study was the reduction in sample size due to the coronavirus disease-2019 pandemic affecting the patient care activities which was impacted worldwide.

CONCLUSION(S)

The policy makers and the clinicians should build strategies aimed at preventing foot ulcers which are cost-effective to be the primary choice for treatment of DFUs. These strategies could be more beneficial if emphasis is laid on strengthening of patient

education and awareness of foot care regime. Summarising the above conducted study authors recommend a keen surveillance on patients with recognised risk factors and co-morbidities for the development of foot problems. Regular visit to the foot clinic once a trimester and adequately offloading the foot, we would like to recommend use of offloading dressing upto two weeks or more depending on the size, depth and extent of ulcer followed by use of conventional dressing with customised footwear/ insoles which carry a high value in preventing ulcer recurrence.

Acknowlegement

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