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Comparative study between Mandakini off loading and conventional gauze dressing in the management of diabetic foot plantar ulcers

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Abstract
Offloading is an essential treatment modality that is key in preventing and healing of ulcers in the foot of diabetes patients. Various different offloading modalities exist with each having their own advantage and disadvantage. What is essential in clinical practice is which one is the best that can be applied with ease and which can facilitate in healing ulcer. The basic aetiology of neuropathic diabetic foot wounds involves pressure in conjunction with cycles of repetitive stress, leading to failure of skin and soft tissue integrity. The central tenet of any treatment plan addressing neuropathic diabetic foot wounds is the appropriate debridement of nonviable tissue coupled with adequate pressure relief (off-loading).

Keywords: mandakini offloading, diabetic foot, plantar ulcers

Introduction
We all know that increased plantar foot pressure is a leading cause of ulceration in the diabetic population. Healing of these ulcers requires adequate blood supply, control of infection, excellent wound care and 'offloading' or pressure redistribution of the ulcerative area [1, 2]. Out of all these factors, 'offloading' is a unique challenge in treating chronic wounds. As diabetic foot care has evolved over the years, podiatrists have used numerous approaches including complete bed rest, cut-out felt pads, crutches, wheelchairs, zimmer frame, temporary shoes, ortho wedge shoes like rocker-bottom wedge design shoes and total contact casting to offload these wounds [3, 4, 5]. Diabetes mellitus (DM) patient spends approximately 10 % 0f his/her yearly income, DFU spends 30% of his/her yearly income and (diabetic foot lesions) DFI spends > 50 % of his/her yearly income. About 80% of the diabetic foots are having some form of Neuropathy. 15% of these suffer from DFU in their lifetime. 50% of this DFU get infected and get admitted to hospital and 50% of these patients ultimately end up with Amputation [6].
DFU is basically a patho- physiologic problem in biomechanics of foot. Due to pan neuropathy in diabetes there is altered biomechanics and insensate foot does not appreciate the pressure at planter level and ultimately land up with a diabetic planter ulcer. Plantar ulcers are the commonest neuropathic lesions in Diabetes.80% of diabetic ulcers are in plantar area. These ulcers are commonly present over the 1st MCP joint, Ball of a great toe, 5th MCP joint and heel. These ulcers are not due to medical abnormalities but it is due to altered foot biomechanics. Application of antimicrobial solutions or ointments is not the answer to heal these ulcers [7, 8, 9].

Objectives
To assess the efficacy of Mandakini offloading device in the treatment of Diabetic Foot Plantar ulcer in terms of ideal off loading features, duration of healing of ulcer and recurrence of ulcer.
To compare Mandakini off loading device with conventional gauze dressing in terms of duration of healing ulcer, infection, recurrence of ulcer and amputation rates.

Inclusion criteria
All patients with diabetic foot ulcers in plantar aspect.

Exclusion criteria
1. Diabetics foot ulcer with peripheral vascular diseases (ABPI < 0.4).
2. Diabetics foot ulcers with osteomylitis.
3. Charcot's foot.
4. Ulcers of Wagener's grade III, IV, and V.
5. Patients on radiation and immunosuppressant.

Methodology
A prospective comparative study design was conducted during the period from May 2017 to December 2017 at General surgery ward, Government Medical College, Kannauj. A total of 60patients with diabetics foot plantar ulcers were taken for this study. Out of these sixty, 30 patients were kept on Mandakini off- Loading dressing and 30 were kept on conventional dressing. These 60 patients were followed up till the complete healing of diabetics foot ulcers. This follow up was computed by the duration of length of stay in the hospital.

Statistical Analysis
The data collected at the patient admitted in General surgery ward with diabetic's foot plantar ulcers was feeded in the computer MS-Excel database. The data was presented by Mean± St.Dev for quantitative variables and for qualitative/ categorical variables frequency with their relative percentages was given. The comparison was done by Student-t test/Wilcoxon signed rank test for two groups. A p value<0.05

was considered as statistically significant.
Study Design - Comparative Study –case control study
Sampling - Simple Random Sampling Technique

Materials Used for Preparing Mandakini off- Loading Device

Used pair of gloves.
Dynaplast adhesive plaster.
Method of preparation and application.
Paired used gloves are rolled as we do for autoclaving.
It is placed on adhesive surface of dynaplast and covered circumferentially with Dynaplast.
Edges of dynaplast are approximated by sharp pressure. Now the Mandakini Offloading device is ready to place.
It acts as a soft air cushion and offloads body weight.
Fore foot lesions are attended by applying the device proximal to the lesion.
Hind foot lesions are attended by applying the device distal to the lesion.
Number of gloves will be decided according to the weight of the patient.

Comparitive Variables

1. These variables will be compared between the two group:
2. Pain scale- visual analogue scale.
3. Duration of hospital stay.
4. Total no. of dressings done during the hospital stay.
5. Morbidity rate-Rate of amputations.

Mandakini off Loading Device

Method to prepare Mandakini offloading device

Fig 1: Device is ready for off loading

Results

Table 1: Age distribution

Group Statistics				
Group		**N**	**Mean**	**Std. Deviation**
Age	Mandakini off loading Conventional dressing	30	54.9667	9.83478
		30	51.4	9.15235

Most of the patients fell within age group of 40 to 70 years. The mean +/- SD or the Mandakini dressing is (54.96+/-9.83) and conventional dressing is (51.4+/-9.15) so age distribution is statistically similar between the two groups with (p=0.151)

Table 2: Sex Distribution

			Group		**total**
			Conventional dressing	**Mandakini off loading**	
Sex	Male	count	**20**	**19**	**39**
		% within Group	66.70%	63.30%	65.00%
	Female	count	10	11	21
		% within Group	33.30%	36.70%	35.00%
Total		count	30	30	60
		% within Group	100.00%	100.00%	100.00%

The male and female sex ratio is 63.3% and 36.7 % in mandakini off loading and in conventional dressing male and female sex ratio is 66.7% and 33.3%

Table 3: Site of Ulcers

			Group		
			Conventional Dressing	**Mandakini off loading**	**Total**
Site of Ulcer	Fore Foot Ulcers	Count	18	20	38
		% within Group	60.00%	66.70%	63.30%
	Hind Foot Ulcers	count	12	10	22
		% within Group	40.00%	33.30%	36.70%
Total		count	30	30	60
		% within Group	100.00%	100.00%	100.00%

Among the patients who had undergone mandakini off loding 66.7% have fore foot ulcer ulcers and 33.3% hind foot ulcers and in conventional dressing 60% have forefoot ulcers and 40 % have hind foot ulcers. Site of the ulcer is statistically similar between the two groups with (p= 0.592)

Table 4: Chi-Square Tests Value df asymp. Sig. (2-sided)

Person Chi-Square	**0.287**	**1**	**0.592**
continuity Correction	0.072	1	0.789
Likelihood ratio	0.287		0.592
Fisher's Exact Test			
Linear-by-Linear Association	0.282	1	0.595
N of Valid Cases	60		

Among the patients who had undergone mandakini off loding 66.7% have fore foot ulcer ulcers and 33.3% hind foot ulcers and in conventional dressing 60% have forefoot ulcers and 40 % have hind foot ulcers. Site of the ulcer is statistically similar between the two groups with (p= 0.592)

Table 5: Morbidity* Group

			group		
			Conventional Dessing	**Maadakini of loading dressing**	**Total**
Morbidity	1	count	22	24	46
		% within Group	73.30%	80.00%	76.70%
	2	count	7	5	12
		% within Group	23.30%	16.70%	20.00%
	3	count	1	1	2
		% within Group	3.30%	3.30%	3.30%
Total		count	30	30	60
		% within Group	100.00%	100.00%	100.00%

Amongthe patients who had undergone Mandakini off loading 6 patients (20%) required future disarticulations /amputations to control the diseased. Where as among the conventional dressing 8 patients (26.6) % patients required future disarticulations / amputations. (p = 810)

Table 6: Chi-Square Tests

	value	**df**	**Asymp. Sig.(2-sided)**
person Chi-Square	.420	2	.810
Likelihood ratio	.422	2	.810
Linear-by-Linear	.250	1	.617
Association			
N of Valid Cases	60		

Table 7: Grade of Ulcer

			Group		**Total**
			Conventional dressing	**Mandakini off loading**	
Grade of Ulcer	1	Count	20	18	38
		% within Group	66.70%	60.00%	63.30%
	2	Count	10	12	22
		% within Group	33.30%	40.00%	36.70%
TOTAL		Count	30	30	60
		% Within Group	100.00%	100.00%	100.00%

Most of the patients had grade 1 ulcers 66.7% in conventional dressing and 60 % in Mandakini offloading (p=0.592)

Table 8: Chi-square Tests

	Value	df	Asymp. Sig.(2-sided)
Person Chi-Square	0.287	1	0.592
continuity Correction	0.072	1	0.789
Likelihood ratio	0.287		0.592
Fisher's Exact Test			
Linear-by-Linear	0.282	1	0.595
Association	60		
N of Valid Cases			

Table 9: PAIN

			Group		Total
			Conventional Dressing	Mandakini off loading	
Pain	2	count	0	7	7
		% within Group	0.00%	23.30%	11.70%
	3	Count	1	10	11
		% within Group	3.30%	33.30%	18.35
	4	count	4	5	9
		% within Group	13.30%	16.70%	15.00%
	5	count	6	4	10
		% within Group	20.05	13.30%	16.70%
	6	count	7	4	11
		% within Group	23.30%	13.30%	18.30%
	7	count	10	0	10
		% within Group	33.30%	0.00%	16.70%
	8	count	2	0	2
		% within Group	6.70%	0.00%	3.30%
Total	9	count	30	30	60
		% within Group	100.00%	100.00%	100.00%

Among the patients who have undergone offloading the 10 patients (33.3) % had pain scale 3, compare to conventional dressing maximum 10 patients (33.3) % patients had pain scale 7

Table 10: Chi-Square Tests

	value	df	Asymp. Sig.(2-sided)
Person Chi-Square	27.693	6	0.001
likelihood ratio	36.23	6	0.001
Fisher's Exact Test	29.01		
Linear-by-Linear	25.83	1	0.001
Association			
N of Valid Cases	60		

Table 11: T-Tests

Group		Number	Mean	Std. Deviation
Age	Mandakini off loading	30	54.9667	9.83478
	Conventional Dressing	30	51.4	9.15235
No of Dressing	Mandakini off loading	30	4.7333	2.22731
	Conventional Dressing	30	17.9333	6.01683
Hospital Stay	mandakini technique	30	22.0333	4.21396
	traditional technique	30	25.9333	5.61975

Table 12: Independent Samples Test

t-test for Equality of means			
		T	Sig.(2-tailed) p value
Age	Equal variances assumed	1.454	0.151
	Equal variances not assumed	1.454	0.151

Table 13: Independent Samples Test

t-test for equality of Means			
		t	Sig. (2-tailed) p value
No of Dressing	Equal variances assumed	-11.269	0.001
	Equal variances not assumed	-11.269	0.001
Hospital Stay	Equal variances assumed	-3.041	0.004
	Equal variances not assumed	-3.041	0.004

Table 14: Mandakini off Loading

S.N.	Name	IP No.	AGE	SEX	Site of Ulcer	Size of Ulcer (in cms)	No. of Dressing	Pain	Grade of Ulcer	Hospital Stay	Morbidity
1	Rekha	2507	48	2	1	7	6	3	2	22	1
2	Bhaiyalal	1987	54	1	1	8	7	6	2	27	2
3	Amit	2119	62	1	2	3	2	2	1	20	1
4	Ramkali	2098	70	2	1	5	4	3	2	16	1
5	Abdul Hasan	2108	53	1	1	4	2	2	1	26	1
6	Sabina	2748	47	2	1	6.5	3	5	2	24	3
7	Ramakant	2956	70	1	1	5	4	3	2	21	1
8	Munna	2893	65	1	2	5.5	4	3	1	19	1
9	Sumesh	2149	61	1	2	3.6	2	2	2	21	1
10	Rohanlal	2346	36	1	1	2.8	1	3	1	23	1
11	Akhtar	2198	39	1	1	7	2	5	1	18	1
12	Arti	2487	59	2	2	7	5	4	2	29	1
13	Amir	2342	49	1	1	8	9	6	1	30	2
14	Ranjana	3329	53	2	2	2	4	2	1	15	1
15	Nand Kishor	2872	57	1	1	5	2	2	1	18	1
16	Rajkishor	3407	66	2	1	5	3	6	2	22	2
17	Tej Singh	2157	65	1	1	6	2	3	1	21	1
18	varun	3126	60	1	1	3	8	4	1	20	1
19	Sanaya	2015	62	2	1	4	8	3	1	15	1
20	somesh	2212	48	1	1	3	7	2	1	18	1
21	narendra	1987	39	1	1	2	7	2	1	20	2
22	Sonal	2210	48	2	2	3	7	5	2	26	1
23	Manjula	2218	59	2	2	3	7	5	2	27	1
24	Rajnish	2132	61	1	2	5	6	3	1	26	1
25	Manoj	2099	63	1	1	2	7	4	2	24	2
26	Ramabtar	2713	39	1	2	4	4	3	1	28	1
27	Rahul	2543	65	1	2	6	4	6	2	16	1
28	shristi	2349	48	2	1	4	5	4	1	21	1
29	divya	2492	61	2	1	3	4	3	1	22	1
30	Dayanand	3252	42	1	1	5	6	4	1	26	1

Table 15: Simple Gauze Dressing

S. n.	Name	Ip no.	Age	Sex	Site of ulcer	Size of ulcer (in cms)	No. Of dressing	Pain	Grade of ulcer	Hospital stay	Morbidity
1	Abhinav	2401	48	1	1	5	22	6	1	36	1
2	Jabdulla	2480	52	1	1	6	18	7	2	32	2
3	Sima	2417	62	1	2	2	15	5	1	16	1
4	Brajesh	2445	60	2	1	3	9	7	2	18	1
5	Urmila	3397	53	2	2	7	14	8	1	28	2
6	Ramkrishn	2587	70	1	2	5	27	4	1	25	1
7	Manju	3449	41	2	2	4	10	6	2	29	1
8	Imran	1929	39	1	1	6	11	7	2	26	1
9	Shalini	1931	50	2	1	2	13	5	1	19	1
10	Faijal	2596	57	1	1	3	18	4	1	22	1
11	Akesh	2623	71	1	1	8	22	7	1	24	2
12	Kanhaiyalal	1959	42	1	2	4	7	5	2	25	1
13	Dinesh	2829	39	1	2	3	9	6	1	21	1
14	Sairabano	3455	48	2	1	6	17	6	2	17	3
15	Rajendra	2893	54	1	2	5	16	7	2	33	2
16	Kamal	2057	52	1	1	7	11	4	1	31	1

17	Neha	2727	59	2	2	4	10	6	1	23	1
18	Adesh	2640	60	1	1	3	21	7	1	37	1
19	Asha	2659	59	2	1	4	20	5	1	28	1
20	Rakesh	2312	37	1	1	2	20	7	1	32	2
21	Shyamlal	2694	53	1	2	8	28	6	2	30	1
22	Sunita	2731	47	2	1	4	20	6	1	29	1
23	Raman	2750	49	1	1	6	19	7	1	31	2
24	Nishant	2102	60	1	2	3	24	5	1	20	1
25	Ravi	3012	49	1	2	7	29	4	2	19	1
26	Mo Rafeez	2721	53	1	1	7	22	5	2	21	1
27	Anisha	2952	58	2	1	5	19	3	1	29	2
28	Urmila	2394	39	2	1	6	26	7	1	23	1
29	Umesh	3019	41	1	1	2	20	8	1	26	1
30	Om Prakash	2783	40	1	2	4	21	7	1	28	1

Discussion

This is a prospective comparative study, comparing 60 diabetic patients with plantar foot ulcers and randomly divided into 30 of whom had undergone Mandakini off loading and 30 of whom had undergone conventional dressing.

1. In the present in the present study patients who had undergone Mandakin ioff loading had significantly lesser pain scale. 10 patients (33.3) % had pain scale 3, compare to conventional dressing maximum 10 patients (33.3) % patients had pain scale 7.The results showing statistically significance with (p =0.001) Sunil V Kari in his study using 'mandakini off loading device' for off loading the diabetic foot plantar ulcers, concluded that pain experienced by the patient in off loaded group is much less, and patients were more compliant compared to not off loaded group.
2. study patients who had undergone mandakini off loading had a significantly shorter duration of hospital stay the mean duration of hospital stay for the patients who has undergoes Mandakini off loading was 22.033 days, compared to 25.933 days for conventional dressing group. The result showing statistical significance with p value 0.004. Study conducted by Gayle E. Reiber *et al*. showed that mean length of hospital stay was around 20.6 days for diabetic patients with foot ulcers.
3. In the present study patients who had undergone mandakini off loading dressing the mean score on the no of dressing was 4.733, compare to 17.933 for patients who had conventional dressing. The results showing significance with (p = 0.001). Sunil v Kari in his study concludes that, number of dressings used for off loading the diabetic plantar ulcers were significantly lesser.

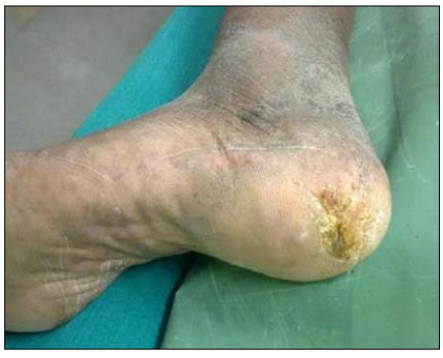

Fig 2: After 3 weeks of Off Loading

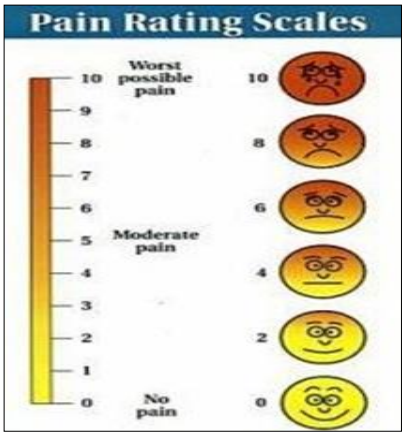

Fig 3: After 6 weeks of Off Loading

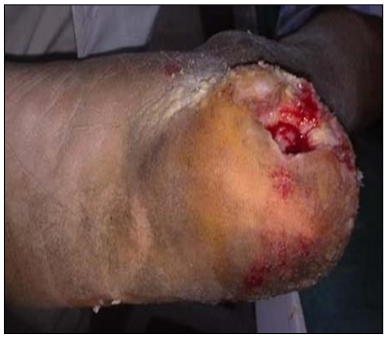

Fig 4: Example; Hind foot plantar ulcer

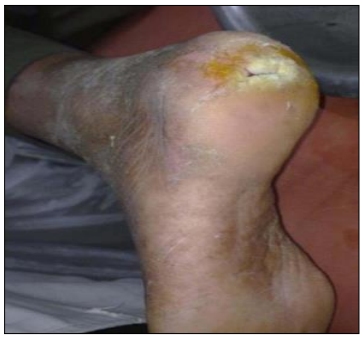

Fig 5: Pain Scales

Conclusion

This study which compares off loading technique of dressing to the conventional technique for plantar ulcers in diabetic

patients using a simple off loading device has shown that patients undergoing off loading technique had significantly lesser pain, shorter duration of hospital stay, lesser number of dressings, with a better compliance and lesser economic burden on the patient. Hence our study favours the mandakini off loading technique for plantar ulcers in diabetic patients as this technique is more tolerable, more compliant with shorter hospital stay hence lesser economic burden on the patient.

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