International Surgery Journal
Sanjeev S et al. Int Surg J. 2019 Oct;6(10):3754-3761
http://www.ijsurgery.com
pISSN 2349-3305 | eISSN 2349-2902

DOI: http://dx.doi.org/10.18203/2349-2902.isj20194437

Original Research Article

Pressure off-loading Mandakini dressing versus conventional wet gauze dressing in the treatment of neuropathic plantar ulcers: a randomized controlled trial

Sreenivasan Sanjeev, Thirugnanasambandam Nelson, Sathasivam Sureshkumar*, Sadasivan Jagdish, Chinnakali Palanivel

Department of Surgery, Jawaharlal Institute of Postgraduate Medical Education and Research, Pondicherry, India

Received: 22 August 2019
Revised: 20 September 2019
Accepted: 21 September 2019

***Correspondence:**
Dr. Sathasivam Sureshkumar,
E-mail: drsureshkumar08@yahoo.com

ABSTRACT

Background: Plantar ulcers are one of the significant causes of morbidity in diabetic and non- diabetic neuropathic foot and remain a major initiating event for amputation. This randomized controlled trial was carried out to establish the benefits of the 'Mandakini' dressing in comparison with conventional wet gauze dressings, in patients with neuropathic plantar ulcers.
Methods: The treatment group received 'Mandakini' dressing which was changed every week. Control group received conventional wet gauze dressings. Size of the ulcer, grade of the ulcer and wound surface area was assessed at the end of every week up to 6 weeks in both groups. The percentage of wound covered with granulation tissue, the percentage of wound covered with non-viable tissue and the time taken for healing of the ulcer were compared between the two groups.
Results: A total of 60 patients were randomized into treatment and control group with 30 patients in each. The 'Mandakini' dressing group had a significant reduction in the wound size at 6 weeks compared to the control group (1.29 vs. 2.31 cm^2; $p \leq 0.0001$). Time taken for healing of the ulcer was significantly less in 'Mandakini' dressing group (4.83 vs. 5.4 weeks; p=0.013).
Conclusions: Mandakini dressing significantly reduces the wound size and time taken for the healing of plantar ulcer compared to conventional wet gauze dressing. Patient acceptability, patient satisfaction, quality of life and cost of the total treatment were better in Mandakini dressing group.

Keywords: Mandakini dressing, Off-loading pressure techniques, Neuropathic foot, Plantar ulcers

INTRODUCTION

With increasing diabetic population, the burden of treating neuropathic foot ulcer is expected to become more challenging. Most of the interventions focus on the aspects of foot care, elimination of infection and diabetic control.[1] Among the off-loading pressure techniques, total contact cast is said to be the gold standard device but still has its disadvantages of difficulty in making, cumbersome application, the need for immobilisation and high cost involved.[2-4]

In a developing country like India, where the number of diabetic patients is dangerously increasing and the magnitude of neuropathic foot posing a significant threat for limb loss; too high to be ignored, we require a simple pressure off-loading device. This device should also allow the patients to be ambulant to meet their social responsibilities and at the same time reduce the financial

burden in terms of making and applying the device and the number of hospital visits.[5,6] This study intended to measure the effect of the novel Mandakini pressure off-loading device, in treating neuropathic plantar ulcers, and compare it with the conventional wet gauze dressing.

METHODS

This study was a randomized controlled trial carried out in Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry from January 2015 to December 2017. This trial included all patients with neuropathic plantar ulcers fit for daily dressing. Patients with ulcers of Wagner's grades III, IV and V, ulcers with features of gangrene, Charcot's foot, ischemic foot (ankle brachial pressure index <0.4), patients with single limb using crutches and those who cannot come for regular follow up are excluded. Institute Human Ethics Committee approval was obtained for the study. The nature, methodology and risks involved in the study were explained to the patient and informed consent was obtained. All the information collected was kept confidential and patient was given full freedom to withdraw at any point during the study. All provisions of the declaration of Helsinki were followed in this study (Figure 1).

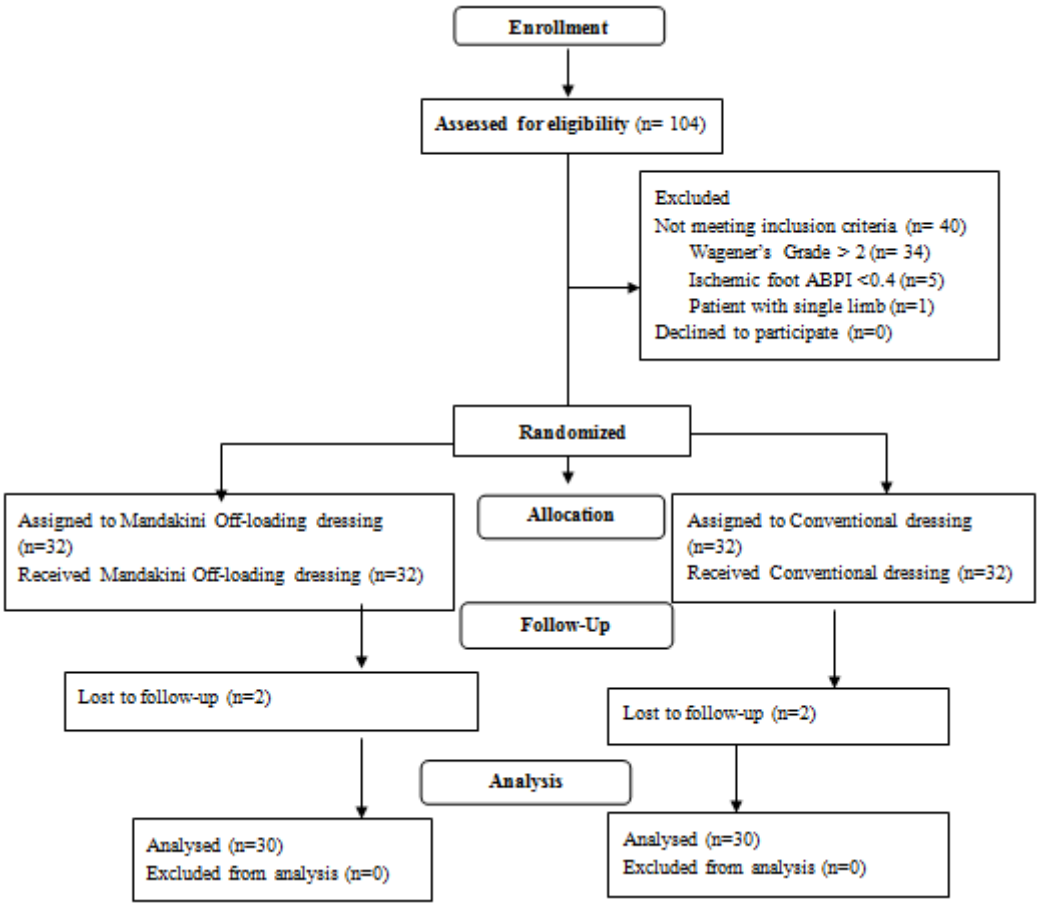

Figure 1: CONSORT schematic representation of study.

Patients included in the study were optimized for a period of two weeks and which included screening for HbA1C control, appropriate antibiotic course based on culture sensitivity report of the wound, surgical debridement of the ulcer if required and correction of other medical illness. Following the optimization, the test group received Mandakini pressure off-load device dressing, which was changed every week. Mandakini dressing was prepared by rolling paired gloves as done for autoclaving. It is placed on adhesive surface of adhesive plaster (Dynaplast) and covered circumferentially with it.[7, 8] The edges of Dynaplast are approximated by applying sharp pressure (Figures 2A and 2B).

It acts like a soft air-cushion and off-loads body weight. The forefoot and hind foot lésions were attended by applying the device proximal and distal to the lesions respectively. The number of gloves used was decided based on the weight of patient to provide a soft cushion. The control group received conventional wet gauze dressing. The dressing was changed every day by patient or the treating physician. The primary outcome parameters like reduction in the wound size (in cm) and grade of the ulcer were assessed at the end of every week up to 6 weeks. The status of the above parameters at the end of six weeks was taken as the end point. The longest diameter of the ulcer was taken as a size of the wound.

Grade of the ulcer was assessed using the Wagner's grades.

Figure 2 (A and B): Edges of dynaplast are approximated by applying sharp pressure.

The effective duration of dressing for complete wound healing was measured in weeks in both the groups. The percentage of wound covered with granulation tissue and the percentage of wound covered with slough or non-viable tissue were measured using a visual score at first visit and henceforth at every subsequent dressing change which happened every week up to six weeks. The percentage of wound covered with granulation tissue was assessed and given a score that ranged from 1 to 4 (1= nil; 2= ≤25%; 3= 25-74% and 4= 75-100% of wound covered by granulation tissue). The wounds were given a visual score of 1 to 6 based on percentage of wound covered with slough, nonviable necrotic tissue (1= 76-100%, 2= 51-75%, 3= 26-50%, 4= 11-25%, 5= 0-10% wound covered with nonviable tissue and 6= no necrotic tissue). Dressing was discontinued before 6 weeks if the ulcer is considered healed (complete re-epithelization of the ulcerated area) to the satisfaction of the treating surgeon.

Secondary outcome parameters such as number of debridement required in each group, patient satisfaction towards the treatment and the healing of the ulcer, requirement of major/ minor amputation and cost of the total treatment were also studied. The patient satisfaction was measured using a Likert scale for three individual parameters- pain relief, comfort of the device and ulcer healing.

Statistical analysis

The sample size was calculated to assess the reduction in the size of the wound at six weeks. Taking the reduction in wound size of 2 cm as clinically significant difference, considering the alpha error of 5%, power of 80%, and expected dropout rate of 10%, the sample size was calculated to be 32 in each group. P value <0.05 was considered significant.

All categorical data between both groups were compared using Chi-square test or Fischer's exact test. The data related to continuous variables were compared using Independent Student t-test. All non-Gaussian variables were compared with Mann-Whitney U test. One-way repeated measures of ANOVA were used to compare changes in continuous variables over time in both groups and two-way repeated measures of ANOVA were used to compare changes in continuous variables over time between groups. Correlation analysis was carried out to assess the association of continuous variables. Regression analysis was used to identify the factors associated with the outcome. All statistical analysis was carried out for two-tailed significance and p-value <0.05 was considered significant.

RESULTS

Demographic parameters

After the initial screening period, 64 eligible patients were randomized to receive either Mandakini pressure off-loading device dressing or the conventional wet gauze dressing, with 32 patients in each group, based on a computer generated random number table. Allocation concealment was carried with sequentially numbered, opaque sealed envelopes (SNOSE) technique.

Table 1: Comparison of demographic profile between Mandakini dressing and conventional dressing group.

Demographic parameter	Mandakini dressing group (n=30)	Conventional dressing group (n=30)	P value
Age (years)	54.03	51.67	0.699
BMI (kg/m^2)	26.04	25.84	0.751
Haemoglobin (g/dl)	11.42	11.14	0.339
HbA1c	6.7	6.7	0.979
Diabetes mellitus	24 (80%)	21 (70%)	0.375
Oral hypoglycemic agents	9 (37.5%)	15 (78.9%)	0.061
Insulin	18 (75%)	15 (62.5%)	0.621
Hypertension	8 (26.6%)	12 (40%)	0.275
Fore foot ulcer	7 (23.33%)	10 (33.33%)	0.394
Hind foot ulcer	23 (76.67%)	20 (66.67%)	0.394

Table 2: Comparison of size of the ulcer between Mandakini dressing and conventional dressing group at the end of week 0 and week 6.

Week interval	Size the ulcer (cm)		P value
	Mandakini dressing group (n=30)	Conventional dressing group (n=30)	
Week 0	4.65±1.10	5.12±0.84	0.072
Week 6	1.29±0.85	2.31±1.23	0.0001

The envelope was opened after enrolment and initial stabilization of wound and patient optimization and before the start of treatment. Two patients in each group did not come for regular follow up, hence were excluded from analysis. The cases and controls were found to be comparable for demographic parameters. Neuropathic ulcers were situated in the forefoot in 7 (23.3%) cases and in 10 controls (33.3%). The hind foot ulcers were present in 23 (76.7%) cases and 20 (66.7%) controls. The location of ulcer in both the groups were comparable (p value= 0.394) (Table 1). The wound parameters such as wound size, grade, necrotic tissue and granulation tissue score were comparable between the two groups at week 0 before the start of the intervention.

Wound size

The size of the ulcers at week 0 was 4.65 cm (±1.10) and 5.12 cm (±0.84) among cases and controls respectively (p=0.072). This reduced to 1.29 cm (± 0.85) and 2.31cm (±1.23) for cases and controls respectively at six weeks. The difference in size at six weeks between the groups was found to be statistically significant (p≤0.0001) (Table 2).

Table 3: Comparison of Grade of ulcer between Mandakini dressing and conventional dressing group at the end of week 0 and week 6.

Wagner's grading of ulcer	Week 0 (n=30)			Week 6 (n=30)		
	Mandakini dressing group (%)	Conventional dressing group (%)	P value	Mandakini dressing group (%)	Conventional dressing group (%)	P value
Grade 1	04 (13.3)	01 (3.3)	0.148	29 (96.7)	22 (73.3)	0.042
Grade 2	26 (86.7)	29 (96.7)		01 (3.3)	07 (23.3)	
Grade 3	0	0		0	01 (3.3)	

Grade of the ulcer

The grades of ulcers between study and control group, according to Wagner's grading at week 0 were comparable (p=0.148). The frequency variation of the ulcer grading showed 96.7% of the ulcers in the study group and 73.3% of the ulcers in the control group improved to grade I after six weeks. At week 6 only one patient had grade II ulcer in the Mandakini group, whereas seven patients reminded in grade II in control group and the difference was found significant (p=0.042). One patient had developed grade III ulcer in the control group during the course of treatment (Table 3).

Necrotic tissue score and granulation tissue score

As given by a visual score the percentage of non-viable/ slough tissue covering the surface of the wound was analyzed between the two groups at the beginning and at the end of 6 weeks. Majority of the patients in both the groups has the score of 2 and 3 and the difference was not significant between study and control group. At the end of 6 weeks, significant number of study group patients improved to score 6 compared to the control group (86.6% vs.26.7%, p=0.0001) (Table 4).

Table 4: Comparison of percentage necrotic tissue over the ulcer surface between Mandakini dressing and conventional dressing group at the end of week 0 and week 6.

Necrotic tissue score	Week 0 (n=30)			Week 6 (n=30)		
	Mandakini dressing group (%)	Conventional dressing group (%)	P value	Mandakini dressing group (%)	Conventional dressing group (%)	P value
1	2 (6.7)		0.4	-	-	0.0001
2	11 (36.7)	12 (40)		-	1 (3.3)	
3	15 (50)	18 (60)		-	-	
4	2 (6.7)	-		2 (6.7)	13 (43.3)	
5	-	-		2 (6.7)	8 (26.7)	
6	-	-		26 (86.6)	8 (26.7)	

Table 5: Comparison of percentage granulation tissue over the ulcer surface between Mandakini dressing and conventional dressing group at the end of week 0 and week 6.

Granulation tissue score	Week 0 (n=30)			Week 6 (n=30)		
	Mandakini dressing group (%)	Conventional dressing group (%)	P value	Mandakini dressing group (%)	Conventional dressing group (%)	P value
1	19 (63.3)	22 (73.3)	0.09	-	-	0.0001
2	11 (36.7)	7 (23.3)		1 (3.3)	1 (3.3)	
3	-	1 (3.3)		2 (6.7)	23 (76.7)	
4	-	-		27 (90)	6 (20)	

Granulation tissue score was similar at week 0 between the two groups with almost all the patients in both the groups had <25% of their wound covered with granulation tissue. Similar to necrotic tissue score, at the end of six week significant number of study group patients had their wound completely covered with granulation tissue compared to the control group (90% vs. 20%, p=0.0001) (Table 5).

Duration of dressing

The effective duration of dressing for complete wound healing was found to be 4.83 (±2.2) weeks among cases and 8.4 (±1.24) weeks among controls. The Mandakini dressing group had significantly reduced duration of dressing (p=0.0001) and hence reduced follow up period.

Requirement of debridement and amputation

Majority of the patients in Mandakini dressing group required debridement once or twice. Only 3% of the patient in the Mandakini dressing group required third debridement compared to 40% patients in the conventional dressing group who required four sessions of debridement in the course of treatment which was statistically significant (p=0.0006) (Table 6).

No minor or major amputations were reported in the study group. One patient in the conventional dressing group underwent a minor amputation of the great toe for underlying soft tissue infection and osteomyelitis.

Table 6: Number of debridement's required.

No. of debridement required	No. of debridement required (%)		P value
	Mandakini dressing group (n=30)	Conventional dressing group (n=30)	
0	13 (43.3%)	4 (13.33%)	0.0006
1	9 (30%)	6 (20%)	
2	7 (23.3%)	8 (26.67%)	
3	1 (3.3%)	12 (40%)	

Table 7: Patient satisfaction scores for pain relief, healing of ulcer, comfort of dressing.

Patient satisfaction scores (Likert's scale)	Patient satisfaction scores (mean)		P value
	Mandakini dressing group (n=30)	Conventional dressing group (n=30)	
Pain relief	3.37	2.73	0.0001
Healing of ulcer	2.63	1.87	0.0001
Comfort of dressing	2.93	2.03	0.003

Patient satisfaction

The patient satisfaction was measured using a Likert's scale for three individual parameters- pain relief, ulcer healing and comfort of the device. All three parameters, pain relief (cases– 3.37, controls– 2.73), ulcer healing (cases– 2.63, controls– 1.87) and comfort of the dressing (cases- 2.93, controls– 2.03) were significantly higher in the study group as compared to the control group (Table 7).

The distribution of organisms grown in culture in the study group and control group were similar. The most common organism grown in both groups was found to be *Streptococcus* species. Both groups demonstrated a reduction in the bacterial burden of the ulcer with the progress of the study. Thirteen of the Mandakini dressing

group and sixteen of the conventional dressing group patients received one course of antibiotics.

DISCUSSION

Neuropathic ulcers or trophic ulcer are formed due to loss of protective touch sensation in the weight-bearing areas secondary to underlying neurological condition like diabetes, Hansen's, subacute combined degeneration, etc. Sensory loss is the hallmark of neuropathy and occurrence of an ulcer over a pressure point is the characteristic clinicopathological feature. The typical location of a neuropathic ulcer is on the weight-bearing surfaces including plantar surface of the foot, metatarsal heads, and heels, which are common sites of painless and minor repetitive trauma.[3-6,9] Neuro-ischemic ulcers have a component of neuropathy, added to which ischemia of the tissues significantly escalates the risk of infection.[3-6, 9-10]

The average size of ulcers at first visit was 4.65 cm among the study group and 5.12 cm in the control group. At the end of six weeks, the ulcer size was reduced to 1.29 cm in the study group which was significantly better than the conventional dressing group. The better granulation cover in addition to lesser necrotic tissue cover of the wound in the Mandakini dressing group could have contributed for the better wound healing in terms of significant reduction in the wound size. Agarwal et al also noted a considerable reduction in the wound size and wound surface area in patients treated with Mandakini dressing as compared to the conventional dressing group.[8]

The simple and most effective technique for wound management in foot ulcers is adequate wound debridement and effective off-loading of the pressure. Debridement removes necrotic tissue, helps adequate drainage of the wound and prevents abnormal pressure on the foot. Off-loading a neuropathic foot is an important practice to redistribute pressure evenly over the areas at high risk for ulcerations. Inadequate off-loading predisposes the foot to tissue damage and ulceration. The need of the hour for the treatment of neuropathic plantar ulcers is a two-pronged approach encompassing both debridement and pressure off-loading. The latter takes centre stage since the basic pathogenesis of a trophic ulcer starts from abnormal foot biomechanics causing pressure imbalance at different regions of the plantar aspect of the foot.[9-11]

The primary objectives of this study was to assess the effect of Mandakini pressure off-loading device on the healing of neuropathic plantar ulcers by assessing the changes in wound parameters due to the device. In the basic demographic evaluation between the two groups, the mean age, body mass index, haemoglobin, HbA1c, the average gender distribution and the distribution of co-morbidities were found to be equally randomized among both the groups thus eliminating confounding factors between the two groups.

The distribution of ulcer was found to be more on the hind foot in the study population. Traditionally total contact casts have been favoured in off-loading forefoot ulcers rather than hind foot ulcers, the reason being described by Frykberg et al and later by Armstrong et al. that a large proportion of the pressure reduction realized in the forefoot with the total contact cast is transmitted along the cast wall and to the rear foot.[10,12] Off-loading device helps in wound healing in both forefoot and hind foot ulcers significantly in this study which included a majority of hind foot ulcers.

The baseline Wagner's ulcer grading showed majority of patients in both groups having grade II ulcers, with very few patients in both groups having grade I ulcers. The ulcer grade at 6 weeks showed 96.7% of cases and 73.3% of controls to be grade I. There was only one patient among the study group who had a grade II ulcer, but in the control group 6 patients had grade II ulcers and 1 patient advanced to grade III ulcer. This was similar to the results produced by Mandakini off-loading device in the study by Agarwal et al.[8]

Certain parameters which can help to assess healing of wound includes scores for quantitative assessment of necrotic tissue and granulation tissue in an ulcer. These subjective scores are based on visual assessment and have been found valid in assessing the healing of diabetic foot ulcers by Kari et al and Agarwal et al in their trials.[7,8] At every dressing change an independent observer assesses the wound and allots a particular granulation tissue score and necrotic tissue score to the patient. The pattern of rise or fall in these scores can act as a guide for assessing the wound healing.

During the study period, weekly analysis of percentage of necrotic tissue has been seen to be progressively decreasing in the study group more than the control group. By the end of 6 weeks, only 2 cases (6.7%) had necrotic tissue of 11-25%, and majority (86.6) had no necrotic tissue in the wound. The patients in the control group also showed a fall in percentage of necrotic tissue, however at the end of six weeks, significant number of patients still had their wound covered with 25% of necrotic tissue. The difference in the score was found to be statistically significant between cases and controls. Similar results were found in the study by Agarwal et al, which showed the number of patients with zero necrotic tissue in the study group to be significantly higher as compared to the control group.[8] Population studies revealed that off-loading along with surgical bedside debridement had a synergistic action in terms of enhancement of granulation tissue, faster wound bed preparation and reduction of necrotic tissue.[13,14]

Both in study group and control group, a majority of patients had no granulation or <25% granulation at first

visit. At six weeks, 90% of patients in study group had their wound completely covered by granulation tissue compared to the control group where only 20% of the patients had near complete granulation cover of the wound. The difference was statistically significant (p=0.001). Agarwal et al observed that the number of patients whose wounds filled up with granulation to be significantly higher among their study group.[8] The number of debridement required was also significantly high in the conventional group explains that the higher necrotic score requiring more number of debridement and lesser granulation cover in the conventional dressing group.

The basic principle of wound healing in trophic ulcers is off-loading. The two major factors which determine the use of an offloading device are device cost and patient compliance. This study shows that the basic expenditure towards each dressing for patients in both study groups are the same with getting a Mandakini offloading device costing 1.06 U.S Dollar($) and conventional dressing costing 1.01$. This is significantly lower when compared to using removable cast walkers (150-200) or total contact cast (75$ to 100$ for every dressing) or accommodative shoes (25-50).[8,13]

The effective duration of dressing required for complete healing of the ulcer was found to be 4.83 weeks in the study group as compared to 8.4 weeks in the control group. This difference was found to be statistically significant (p = 0.0001), which indicates that when a Mandakini offloading device is used, the wound heals faster, requires lesser duration and lesser number of dressings, which in turn translates to better patient compliance.[7-9]

The overall patient satisfaction was more in the study group and each parameter for measuring patient satisfaction i.e. pain relief (p=0.0001), comfort of dressing (p=0.0001) and ulcer healing (p=0.003) was found to be statistically significant. This translates to better and higher patient compliance for the Mandakini offloading device.

The gold standard for off-loading a neuropathic foot is the total contact cast (TCC).[10] Although it ensures compliance to a form of off-loading, it is cumbersome, heavy and is not easy to remove. In addition to the high cost, the other disadvantages of TCC include skin irritation if it is directly applied on dry skin, new ulceration if it is applied inappropriately, interference with activities of daily living like bathing,walking and many patients may not tolerate it in warm climates. Some studies have also shown that the TCC can reduce healing by at least six weeks, in patients with a unilateral uncomplicated plantar ulcer since the daily inspection of the wound becomes difficult and signs of spreading infection may go unnoticed.[10,16] TCCs should be avoided in patients with ischaemia because of the risk of inducing new footulcers.[10,16] Removable devices such as removable cast walkers, healing sandals and crutches, walkers and wheelchairs also has limitations with respect to patient compliance due to high cost and inappropriate method of usage.

The Mandakini Off-loading device was first described by Kari et al from Mandakini Hospital in India, consists of gloves rolled up inside elastic adhesive bandage to make a cushion device.[7] The device is comfortable to wear and causes much less patient discomfort in comparison to the bulky contact casts. This also aids patient ambulation and weight bearing. Hence, it is less likely to hinder the activities of daily living of patients. Considering the low cost, efficacy and ease of application, the device is likely to produce greater compliance. Few studies have shown that the Mandakini off-loading device when compared with conventional wet gauze dressing, demonstrates faster wound healing and lesser recurrence rates.[7,8] In a working class population, with people who cannot afford to get admitted or who cannot afford daily visits to the practitioner, the presence of neuropathic ulcer demands a form of off-loading which is not cumbersome, does not hinder in day-to-day ambulation and also is cost-effective. Several studies have shown that total contact casts although effective in healing forefoot ulcers were difficult to manage and were restrictive in terms of activities of daily living. The present study has shown that Mandakini off-loading device is a simple, cost-effective, easy to apply and remove, effective form of off-loading for non-ischemic neuropathic ulcers.

Strength of the study is that being a prospective randomized controlled trial, follow up had been recorded meticulously and data compilation had been prospective. The population included in the study was randomized adequately to remove confounding factors. As it was carried out on Indian population in a tertiary care hospital, the above results can be extrapolated to the Indian population. Limitation of the study was that full impact of Mandakini off-Loading device on diabetic wound healing has not been adequately assessed since this study included non-diabetic cases also. Future studies focusing on comparing the Mandakini off-loading device with other off-loading devices and including selective patients of diabetic neuropathic ulcers or non-diabetic foot ulcers and higher grades (Wagner's grade III, IV and V) of trophic ulcers may bring out better understanding on the application of this cost-effective device for wide recommendations.

CONCLUSION

Mandakini off-loading dressing has shown significantly better wound healing with respect to reduction in the grade of ulcer, reduced necrotic tissue in the ulcer, improved granulation cover and significant reduction in the size of the wound compared to the conventional dressing for the neuropathic plantar ulcer. It has also shown to significantly reduce the number of debridement required and significant reduction in the duration of

treatment for neuropathic plantar ulcer. The Mandakini off-loading dressing significantly improved the patient satisfaction with respect to pain relief; comfort of dressing and ulcer healing compared to the conventional dressing and the cost of both Mandakini off-loading dressing and conventional dressing is principally the same (1$).

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Ramsey SD, Newton K, Blough D, McCulloch DK, Sandhu N, Reiber GE, et al. Incidence, outcomes, and cost of foot ulcers in patients with diabetes. Diabetes Care. 1999;22:382-7.
2. American Diabetes Association. Consensus development conference on diabetic foot wound care. Diabetes Care. 1999;22:1354–60.
3. Pinzur MS, Dart HC. Pedorthic management of the diabetic foot. Foot Ankle Clin. 2001;6:205–14.
4. Armstrong DG, Liswood PL, Todd WF. Potential risks of accommodative padding in the treatment of neuropathic ulcerations. Ostomy Wound Management. 1995;41:44–9.
5. Boulton AJ, Armstrong DG, Albert SF, Frykberg RG, Hellman R, Hellman MS, et al. Comprehensive foot examination and risk assessment. Diabetes Care. 2008;31:1679-85.
6. Scott G. The diabetic foot examination: A positive step in the prevention of diabetic foot ulcers and amputation. Osteopathic Family Physician. 2013;5:73–8.
7. Kari SV. The economical way to off-load diabetic foot ulcers [Mandakini off-loading device]. Indian J Surg. 2010;72:133–4.
8. Agrawal VP, Sreeramulu PN. Most Easy on the Pocket Offloading Device Costing<1$ for Rural Diabetic Foot Ulcers. Surgery Curr Res. 2012;2:124.
9. Sussman C, Barbara BJ. Wound Care: a collaborative practice manual for health professionals. Lippincott Williams & Wilkins. 3rd ed. Wolters Kluwer; 2006: 21–47.
10. Armstrong DG, Lavery LA, Nixon BP, Boulton AJ. It's not what you put on, but what you take off: techniques for debriding and off-loading the diabetic foot wound. Clin Infect Dis. 2004;39(2):92-9.
11. Decarlo AA, Whitelock J, Ellis AL. Wound and Cutaneous Injury Healing with a Nucleic Acid Encoding a Proteoglycan Polypeptide. Available at: https://patents.google.com/patent/WO2008143863A1/en. Accessed on 10 May 2018.
12. FrykbergRG. Diabetic foot ulcers: pathogenesis and management. Am Fam Physician. 2002;66:1655-62.
13. Steed DL, Donohoe D, Webster MW, Lindsley L. Effect of extensive debridement and treatment on healing of diabetic foot ulcers. Diabetic Ulcer Study Group. J Am Coll Surg. 1996;183:61-4.
14. Edwards J, Stapley S. Debridement of diabetic foot ulcers. Cochrane Database Syst Rev. 2010;1:23-34.
15. National Institute for Health and Care Excellence. NHS Evidence. Diabetic foot problems: evidence update. Available at: http:// www. evidence.nhs.uk. Accessed on 10 March 2013.
16. Bakker K, Apelqvist J, Schaper NC; International Working Group on the Diabetic Foot Editorial Board. Practical guidelines on the management and prevention of the diabetic foot 2011. Diabetes Metab Res Rev 2012;28(1):225-31.

Cite this article as: Sanjeev S, Nelson T, Sureshkumar S, Jagdish S, Palanivel C. Pressure off-loading Mandakini dressing versus conventional wet gauze dressing in the treatment of neuropathic plantar ulcers: a randomized controlled trial. Int Surg J 2019;6:3754-61.