Original Research Article

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Vacuum assisted closure versus total contact casting in the healing of plantar foot ulcers: a comparative prospective study

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ABSTRACT

Background: The objective of the study was to compare the effectiveness of vacuum assisted closure (VAC) and total contact casting (TCC) in the healing of plantar foot ulcers. Chronic leg ulcers are a significant cause of morbidity in developing countries like India, leading to excessive health care expenses and loss of effective work hours, inspite of availability of various novel modalities of management. This study aims to compare the effectiveness of vacuum assisted closure and total contact casting in the healing in plantar foot ulcers, in order to standardise a procedure with maximum benefits.

Methods: This comparative prospective study was conducted on 150 individuals admitted to SVRRGG Hospital, Tirupati, with the diagnosis of plantar foot ulcers from august 2017 to march 2019. They were divided into 2 groups, Group A (75 patients treated with VAC) and Group B (75 patients treated with TCC). In this study, the outcomes assessed were reduction of wound size and length of hospital stay.

Results: In this study, mean reduction of wound surface area with VAC and TCC was 21.09 and 12.83 respectively, mean percentage of reduction of wound size with VAC is 90.43 and in TCC was 52.36. Mean hospital stay with VAC and TCC was 24.90 days and 51.29 days respectively.

Conclusions: VAC is more effective than TCC in the treatment of foot ulcers, with less duration of hospital stay and earlier returns to work.

Keywords: Plantar foot ulcers, Healing, Vacuum assisted closure, Total contact casting

INTRODUCTION

Foot ulcers are major global health care problem. It is estimated that each year around 4 million people suffer from a foot ulcer, which is caused by trauma to the foot in combination with nerve damage and decrease in blood supply to the lower limbs. 1,2 Plantar foot ulcers mainly affect the elderly population leading to decreased mobility and its consequences and if associated with poorly controlled medical problems, it may lead to loss of limb or life. In addition to pain and suffering, failure of the wound to heal also imposes social and financial

burden. In order to facilitate wound healing we are comparing the effectiveness of vacuum assisted closure and total contact casting, in the healing of plantar foot ulcers.

Diabetes is one of the main problems in health systems in the world.⁴ The world prevalence of diabetes among adults was 6.4%, and is likely to increase to 7.7% by 2030. Patients with diabetes are at greater risk of complications, the most important of them are diabetic neuropathy, and peripheral vascular disorders that lead to

diabetic foot ulcers.^{1,2} Main stay of foot ulcer treatment begins with wound debridement and dressing.

Vacuum assisted closure was useful in the management of difficult to heal wounds. The practice of exposing a wound to subatmospheric pressure was described by Fleischmann et al in the year of 1993.⁵ The first reports of the use of VAC device came from Argenta and Moryk was in the year of 1997.⁶

Vacuum assisted closure has been advocated as a novel method in the healing of foot ulcers by stimulating the chronic wound environment in such a way that it reduces bacterial burden and chronic interstitial wound fluid, increases vascularity and cytokine expression and to an extent mechanically exploiting the viscoelasticity of periwound tissues.^{6,7} Vacuum assisted closure (VAC) is generally well tolerated and, with few contraindications, is fast becoming a mainstay of current wound care.

Table 1: The University of Texas (grade and stage) wound classification system-mostly used to grade diabetic foot ulcers.³

Stage	Grade			
	0	1	2	3
A	Pre or post ulcerative leison completely epithelialized	Superficial wound not involving tendon, capsule, or bone	Wound penetrating to tendon or capsule	Wound penetrating to bone or joint
В	Infection	Infection	Infection	Infection
C	Ischemia	Ischemia	Ischemia	Ischemia
D	Infection and Ischemia	Infection and Ischemia	Infection and Ischemia	Infection and Ischemia

Vacuum assisted closure (VAC) is a newer non-invasive therapy system that uses controlled negative pressure using vacuum assisted closure device, to help promote wound healing by removing fluid from open wounds, preparing wound bed for closure, reducing edema, promoting granulation for wound healing.⁶

Total contact casting (TCC) method was widely used by Dr. Paul Brand in the mid 1960's to offload the insensitive foot in Hansen's disease⁸. It has since been identified as a 'Gold Standard' for offloading diabetic foot ulceration.⁹ He considers the pathway to diabetic foot ulceration including neuropathy, abnormal pressures and other risk factors including ethnicity but concludes that neuropathy, deformity and trauma are the most common causes of diabetic foot ulcers.

TCC, an offloading technique, is a method used to treat diabetic foot ulcers by fitting a non-removable cast around the affected leg. 10 One of the primary reasons for treating diabetic foot ulcers with TCC or offloading, is to limit the use of the area of the foot affected by ulcer. The aim of TCC is to reduce plantar pressures by increasing the weight-bearing surface of the foot (Sinacore et al).8 TCC relieves pressure on the affected foot, which enhances healing by taking pressure off the ulcer and the other areas of the foot most prone to injury. In case of prolonged casting, joint rigidity and muscular atropy have been documented. 11 In spite of availability of various novel modalities in the management, foot ulcers have become a major cause of morbidity and hence this study aims to compare the effectiveness of vacuum assisted closure and total contact casting in outcome of healing in plantar foot ulcers in order to standardize a procedure with maximum benefits.

METHODS

A hospital based comparative prospective study was conducted in the Department of General Surgery, SVRRGG Hospital, Tirupati from August 2017 to March 2019.

The eligible 150 subjects fulfilling the inclusion and exclusion criteria, were randomized into two groups, Group A, wherein the patients were treated by VAC and Group B, wherein the patients were treated by TCC.

Inclusion criteria

Inclusion criteria were plantar foot ulcers, both diabetic and non-diabetic, age between 18 to 80 yrs of both genders.

Exclusion criteria

Exclusion criteria were patients untreated osteomyelitis, malignancy, critical limb ischemia, active infection, any bleeding disorder and patients on anticoagulants.

After taking detailed history, performing clinical examination and relevant investigations, the individuals with plantar foot ulcers, were classified under university of Texas classification. Wounds of all the patients included in the study underwent sharp surgical debridement initially.

All individuals categorized under Group A, were reviewed 24 hours after the debridement and a negative suction sponge dressing was applied to the patients under aseptic conditions. The wound surroundings were inspected daily to check for any spreading cellulitis.

Sponge was changed every 4 days to check progress of healing. Negative pressure was maintained using intermittent suction with the VAC machine and with specific instructions to keep the pressure maintained in between 50 to 125 mmHg.⁷



Figure 1: Plantar foot ulcer.



Figure 2: Foot ulcer after VAC.

All the individuals categorized under Group B were reviewed after 24 hours and a soft layer of foam is placed on the ulcer, and the whole foot is wrapped in bandages prior to the application of the cast.



Figure 3: TCC lateral view.



Figure 4: TCC in plantar view.

Ulcers were treated, with repeated change of dressing for every 4 days, until the wound closes spontaneously or surgically. Blood glucose levels were monitored strictly. Treatment outcome was assessed in terms of time taken for appearance of granulation tissue and measurement of wound depth and area at subsequent follow up.

Statistical analysis

All the Quantitative data was compared using student's ttest. Qualitative data was presented as frequency and percentage and analyzed using chi-square test. All analyses were carried out by using SPSS software.

RESULTS

In the total study population of 150 patients 77.3% are male population and 22.7% are female population. Highest number of population belongs to male sex.

Table 2: Distribution of study population based on gender.

Sex	Frequency	Percentage (%)
Male	116	77.3
Female	34	22.7

Table 3: Distribution of study population based on age.

	Number	Mean age in years (%)
VAC	75	53.72
TCC	75	53.43

Mean age distribution of the population was 53.72 years in VAC group and 53.43 years in TCC group. There was no significant difference in the mean age group distribution between VAC and TCC group.

In Group A (VAC), the initial mean wound size of 75 patients was 23.17 sq.cm and the final mean wound size was 2.09 sq.cm. P value for Group A was 0.001 which was statistically significant. In Group B (TCC), the initial

mean wound size of 75 patients was 24.06 sq.cm and the Final mean wound size was 11.23 sq.cm. P value for Group B was 0.615 which was statistically insignificant.

Table 4: Comparative analysis of wound size by treatment methods.

	Initial wound size in sq.cm	Final wound size in sq.cm	P value
Group A VAC (n=75)	23.17	2.09	0.001
Group B TCC (n=75)	24.06	11.23	0.615

Table 5: Comparative analysis of wound size reduction in terms of surface area by treatment methods.

	Group A	Group B	P
	VAC (n=75)	TCC (n=75)	value
Mean reduction in surface area	21.08 (90.43%)	12.83 (52.36%)	0.001

In VAC group mean reduction in the surface area of the wound is 21.08 and TCC group mean reduction in the surface area of the wound was 12.83. P value was 0.001, which was statistically significant.

Table 6: Distribution of study population based on duration of hospital stay.

	Group A	Group B	P
	VAC (n=75)	TCC (n=75)	value
Duration of hospital stay in days	24.90	51.29	0.001

In VAC group, the mean hospital stay was 25 days and in TCC group was 52. P value was 0.001 which was statistically significant.

DISCUSSION

In our study, done on 150 patients, comparing the efficacy of VAC vs. TCC showed that the group with VAC showed effective reduction in the wound surface area with half the hospital stay, when compared to the TCC group. The mean age distribution of the study population was 53.72 years in VAC group and 53.43 years in TCC group. There were no significant difference in the mean age group distribution between VAC and TCC group. Both groups were comparable in terms of age distribution.

In our study, in VAC group mean hospital stay was 24.90 days and in TCC group was 51.29 days, with P value of 0.001 which is significant. Nather et al used vacuum

assisted closure in diabetic foot ulcers, where in the mean hospital stay was 23.3 days, comparable to our study. Sinacore et al casted thirty subjects with foot ulcers (27 diabetic and 3 control).8 The results of the study were encouraging with 81.8% of the diabetic foot ulcers healing in 43.6±51.9 days compared to the non-diabetic group healing in 129±145 days. In our study healing rate with TCC was 51.29 days, concurring with Sinacore et al. Birke et al comparing diabetic foot ulcer healing rates using alternative off-loading methods.¹³ Four treatments were compared; an accommodative dressing (including felt padding), a healing shoe, a walking splint (a simplified version of a TCC) and a TCC in one hundred and twenty subjects. Results showed that one hundred and thirteen (94%) healed within 45.5±43.4 days and there was no difference in healing time between each treatment. In our study healing rate with TCC shows 51.29 days, similar to that of Birke et al. 13

In Group A (VAC) mean initial wound size was 23.17 sq.cm and mean final wound size was 2.09 sq.cm, the P value of which was 0.001 which was statistically significant and in Group B (TCC) mean initial wound size was 24.06 sq.cm and mean final wound size was 11.23 sq.cm, the p value of which was 0.615, which was statistically not significant. In VAC group, mean percentage reduction of wound surface area is 90.43%. In a study by Lone et al using vacuum assisted dressing, where in they had studied appearance of granulation tissue growth, the granulation tissue appeared in 92.85% by the end of 2nd week, which was comparable to the results observed in our study. 14 In TCC group the mean percentage reduction in surface area is 52.36. P value is 0.001 which is significant. Armstrong et al studied that the proportion of healing in the patients treated with TCC, RCW (removable cast walker), and half-shoe was 89.5, 65.0, and 58.3%, respectively. 15 At 12 weeks, the proportion of healing was significantly higher in the TCC group than in the patients treated with the two other modalities. In our study the percentage of wound healing is 52.36% which was comparable to the study by Armstrong et al. 15

Morykwas et al also described about the importance of use of optimal pressure while doing negative pressure wound therapy and he came to the conclusion that upon use of 100-125 mm Hg pressure, he observed a 4 times increase in blood flow than with increased pressure of 400 mm Hg which showed decreased blood flow.⁶ In our study also, we had used a pressure of 125 mm Hg which showed promising results, concurring with the results of Morykwas et al, Philbeck et al suggested that intermittent/cycling application of pressure, results in rhythmic perfusion of the tissue. 16 If the wound is subjected to continuous pressure the mitosis or cell division is reduced due to its continuity. Hence he suggested that intermittent pressure given at regular cyclic interval gave more promising result than the continuous type of pressure. In our study, in the VAC group, we also had preferred intermittent pressure of 125

mm Hg with 5 min cyclic interval, which showed good results, concurring with Philbeck et al. 16

CONCLUSION

In this study we observed that the VAC group showed marked reduction in wound size and surface area with shorter hospital stay compared to the TCC group. The time duration taken for formation of healthy granulation tissue was less in VAC compared to TCC. And the granulation tissue formed was healthy and uniform in VAC than TCC. Patient's compliance is also more for VAC compared to TCC.

Hereby we conclude that the VAC method of wound dressing is more effective and superior to the offloading technique in healing of the foot ulcers.

Limitations

- In our study we used a negative pressure 50 to 125 mm Hg for vacuum assisted closure, studies using varied pressures can be carried out.
- In our study sample size was only 150, which limits the scope of research.

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