



Efficacy of Vacuum Assisted Closure versus Offloading Technique in Healing Of Foot Ulcers

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Abstract

Objective -A foot ulcer is caused by trauma to the foot in combination with nerve damage and blood circulation. The study was indented to explore the efficacy of vacuum assisted closure and offloading technique in healing of foot ulcers.

Methodology - vacuum system comprising of vacuum pump, canister, tubing to connect dressing with pump ,dressing pack (foam and occlusive drapes like opsite) with the VAC therapy setting (usually 125 mm hg continuously or intermittently 30 min on/15 min off) was used. Statistical analysis was done using the SPSS version 20 software and results were generated.

Results-Out of 122 patients, 70 patients were allotted for VAC and 52 patients were allotted for offloading technique. Sloughed out wound were debrided for initial period. Then VAC and TCC were allotted to the patients. PUSH scoring was assessed at the time of admission and during the change of dressings in each method and plotted in a graph. Wound size was measured with the use of ECG paper. PUSH score was determined by wound size, exudate amount and granulation tissue. Then wound surface area and percentage of reduction in the wound surface area was calculated respectively. Also the duration of the hospital stay was also recorded.

Conclusion -Both study groups has a mean difference of age which is insignificant and the study is comparable. Also the null hypothesis is retained on the admission in both study groups.

Keywords: PUSH scoring, wound surface, offloading technique, VAC

Introduction

Foot ulcer is a major health problem that leads to morbid life style. The prevalence of foot ulcer is approximately 1 to 2 % of total world population. Delayed wound healing is a significant health problem -particularly in older people [1]. In addition, to the pain and the suffering, failure of the wound to heal also imposes a social and financial burden to the society [2]. Foot ulcers may involve the skin's surface, full thickness of the skin, tendons and even bones. It is marked by inflammation, formation of pus and sloughing of damaged tissues [3]. Delayed

wound healing is a significant health problem, particularly in older adults. In addition to the pain and suffering, failure of the wound to heal also imposes social and financial burden [4]. Causes foot ulcers include Type 1 & 2 Diabetics, peripheral neuropathy, and peripheral artery disease, Raynaud's phenomenon, Venous Insufficiency, and Injuries resulting in traumatic ulcers [5,6].

Main stay of foot ulcer treatment begins with the type of foot ulcers as per types treatments varies. Main

stay of treatment is wound debridement and dressing [7,8 and 9] . If the ulcer is due to neuropathic ulcer then the ulcer mainly the treatment depend on the pressure ulcer due to the loss of sensation due to peripheral neuropathy. If the ulcer is due to arterial disease the ulcer is accessed for vascularity by clinical examination also with the use of Doppler study and angiogram [10]. According to the vascularity treatment mode is decided. Newer method of treatments such as injection of plasma rich protein, offloading, and negative pressure wound therapy and other modalities gain more importance in recent days [11].

Vacuum-assisted closure (VAC) therapy has been developed as an alternative to the standard forms of wound management, which incorporates the use of controlled negative pressure using vacuum-assisted closure (VAC) device to optimise conditions for wound healing and requires fewer painful dressing changes. It promote wound healing by removing fluid from open wounds, preparing the wound bed for closure, reducing oedema, and promoting formation and perfusion of granulation tissue [12,13]. Total contact casting is another promising method used to treat diabetic foot ulcers by fitting a non-removable cast around the affected leg. One of the primary reasons for treating diabetic foot ulcers with total contact casting is offloading, or limiting the use of the foot with the ulcer.

In this study we are comparing the efficacy of vacuum assisted closure method also called as negative pressure wound therapy and offloading technique mainly total contact cast for healing of the foot ulcer. To know which of the two methods give promising results.

Materials and Methods

Prior ethics approval for this study was obtained from the Ethical committee of the Vinayaka mission's medical college and hospital, Karaikal. Informed and written consent taken from all the participants. A total of 122 Patients were involved in this study. They were divided into two groups. Group I (n=70) patients treated with vacuum dressing. Group II (n=52) patients treated with offloading technique. The study period is 2 years.

Calculation of PUSH score

Pressure Ulcer Scale for Healing (PUSH) score was calculated according to the standard measures. Categorization of the ulcer was done with respect to surface area, exudate, and type of wound tissue. Recorded subscore for each of these ulcer characteristics. The sub-scores were calculated into total score. A comparison of total scores measured over time provides an indication of the improvement or deterioration in pressure ulcer healing was done.

Length x Width measurement

The greatest length (head to toe) and the greatest width (side to side) were measured using a centimetre ruler. These two measurements (length x width) were multiplied to obtain an estimate of surface area in square centimetres (cm²).

Estimation of exudate

The amount of exudate (drainage) after removal of the dressing and before applying any topical agent to the ulcer was estimated. The tissue or wound type scoring was done according to the standard measures.

Statistical analysis

Descriptive Statistics were used to summarise the distribution of the demographic and clinical variables. Frequency chart and pie diagram were used to compare the variables of descriptive statistics 5.7.2 Data Analysis was carried out using Statistical Package for Social Science (SPSS Version 20.0) package.

Results

In this prospective randomised hospital based study we compared the efficacy of vacuum assisted closure and offloading technique in healing of the foot ulcers which was designed after approval of our research topic by the Ethical committee of our college. We selected a total of 122 patients with foot ulcers, satisfying the inclusion and exclusion criteria. Informed and written consent were obtained from all the patients included in the study.

Sex Distribution

In the total study population of 122 patients 76.2% are male population and 23.8% are female population. Highest number of population belongs to male sex of 76.2%.

Distribution of Comorbid Conditions

In the total study population of 122 patients 60.7 % of the study population have diabetic mellitus as comorbidity and 0.5% has hypertension as comorbidity and 20.5% have both hypertension and

diabetic mellitus as co morbidity .18% of the total study population don't have any of the co morbidity (Figure 1)

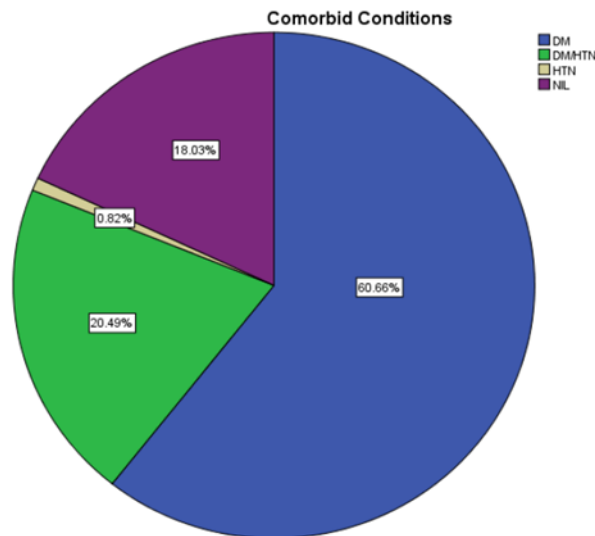


Figure 1 - Distribution of Comorbid Conditions (DM-Diabetes Mellitus; HTN-Hypertension)

Distribution of Treatment Methods

In total of 122 study population 70 patients (57.4%) were assigned to treat with vacuum assisted closure method and 52 patients (42.6%) were assigned to treat with Total Contact Cast method.

Distribution of Age

In total of 122 study population mean age distribution of the population was 53.72 in VAC group and 53.43 in TCC group .There were no significant difference in the mean age group distribution between VAC AND TCC group.

Distribution of PUSH Scores

In study population of 122 patients mean deviation of change in the PUSH score of both VAC group and TCC group is 7.17 with a standard error of 0.317. In the study population of total of 122 patients 70 patient underwent VAC treatment and 52 patients underwent TCC treatment .Mean difference between the initial treatment and after treatment with VAC is 9.39 and TCC is 4.19 with standard mean error of 0.292 and 0.316 respectively. Mean difference between two group is 5.19 and p value is 0.000 which is significant (Figure -2)

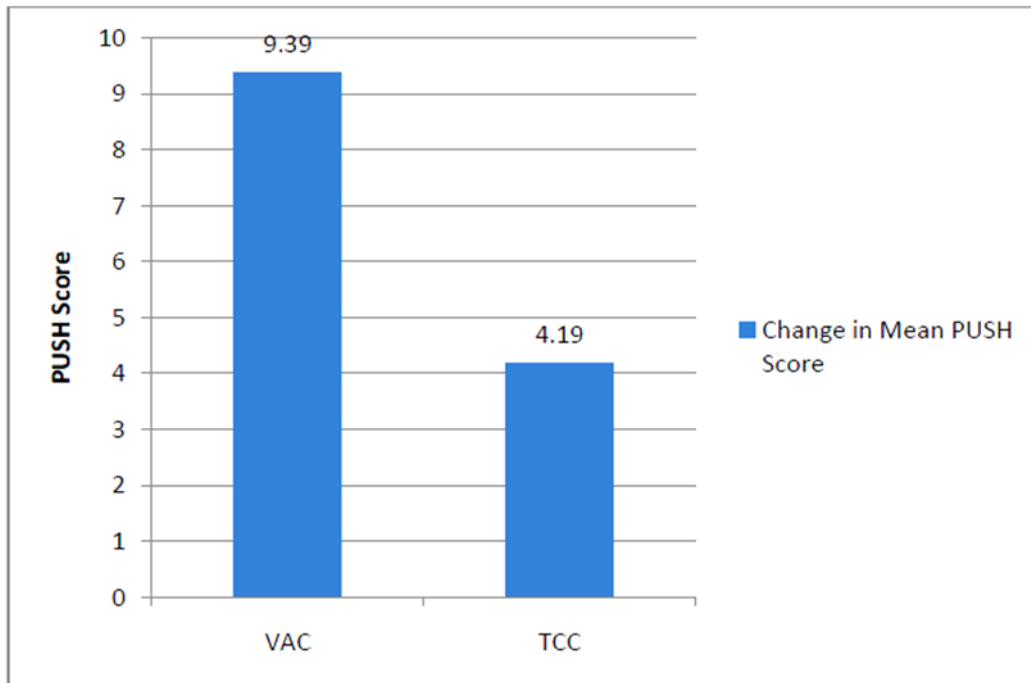


Figure 2 - Change in PUSH Scores by Treatment Methods

Descriptive Analysis of Wound Size and Hospital Stay

Mean deviation of the initial wound size is 23.55 and final wound size is 5.98 with standard mean error of 0.869 and 0.584 respectively. Mean hospital stay for including both the group is 36.15 with standard error of 1.902 (Table 1 and Figure 3). Mean wound size reduction in area is 17.20 with standard error of 0.867 and mean wound size reduction in percentage is 74.20 with standard error of 2.227.

Table 1 - Descriptive Analysis of Wound Size and Hospital Stay

	N	Minimum	Maximum	Mean	Std. Error
Wound Size-Initial	122	3	60	23.55	0.869
Wound Size-Final	122	1	30	5.98	0.584
Stay in Days	122	5	118	36.15	1.902
Size Reduction in Area	122	2	52	17.57	0.867
Size Reduction in Percentage	122	16.67	97.14	74.20	2.227

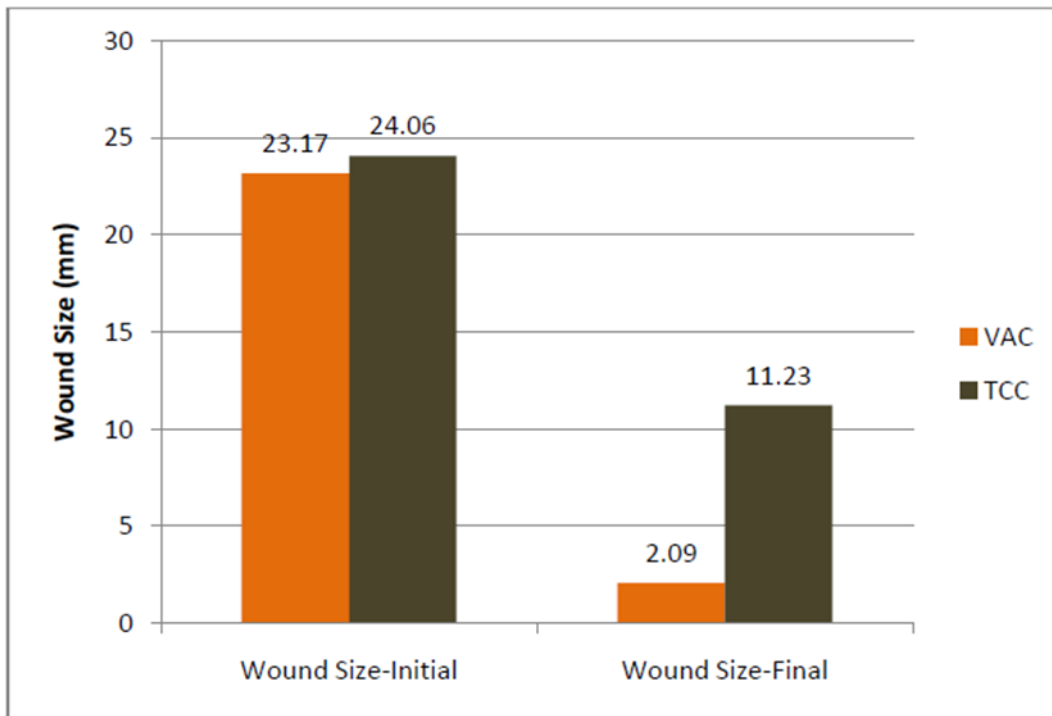


Figure -3 Descriptive Analyses of Mean Wound Size

Comparative analyses of wound size by treatment methods

In VAC group initial wound size of 70 patients and TCC patients of 52 patients with mean value of 23.17 and 24.06 respectively, with standard error in mean of 1.043 and 1.489 respectively. Mean difference between VAC and TCC IS -0.886. P value of the mean difference between VAC and TCC is 0.616. which is insignificant (Figure 4). Wound size final mean value in VAC and TCC is 2.09 and 11.23 respectively. Mean difference between VAC and TCC is -9.145 with P value of 0.000 which is significant.

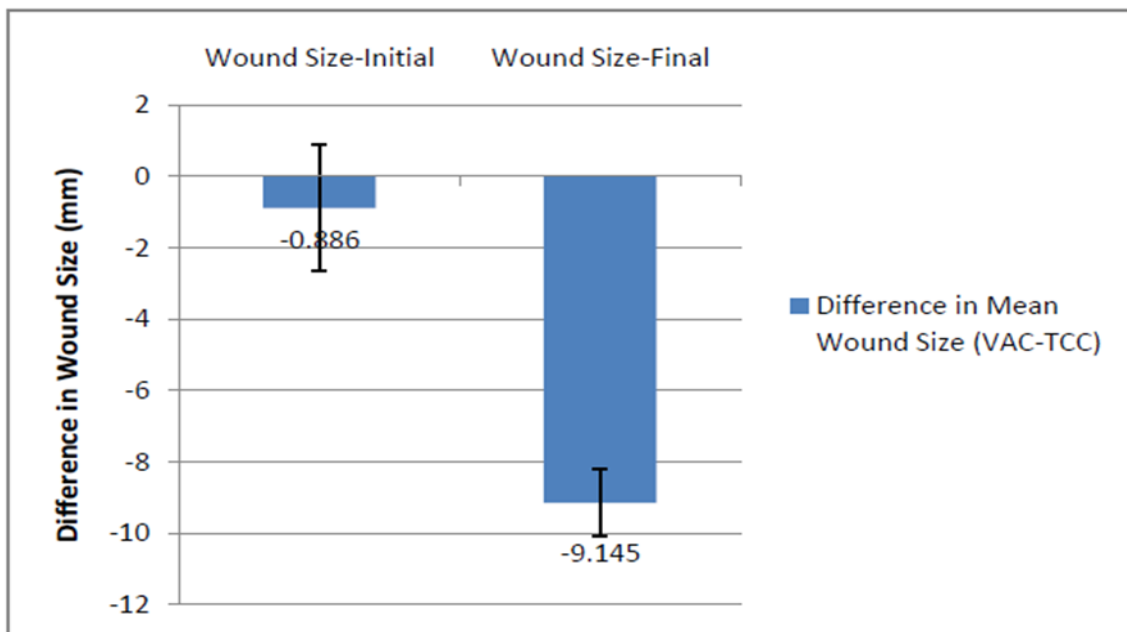


Figure 4 - Comparative analyses of wound size by treatment methods

Comparative Analyses of percentage of reduction of Wound surface area by Treatment Methods

In VAC group , mean percentage reduction of wound surface area is 90.43 with standard error of 1.098.and in TCC group mean percentage reduction in surface area in 52.36 with standard error of 3.018.Mean difference of percentage of the wound surface area reduction is 38.068. P value is 0.000 which is significant (Figure 5A and B).

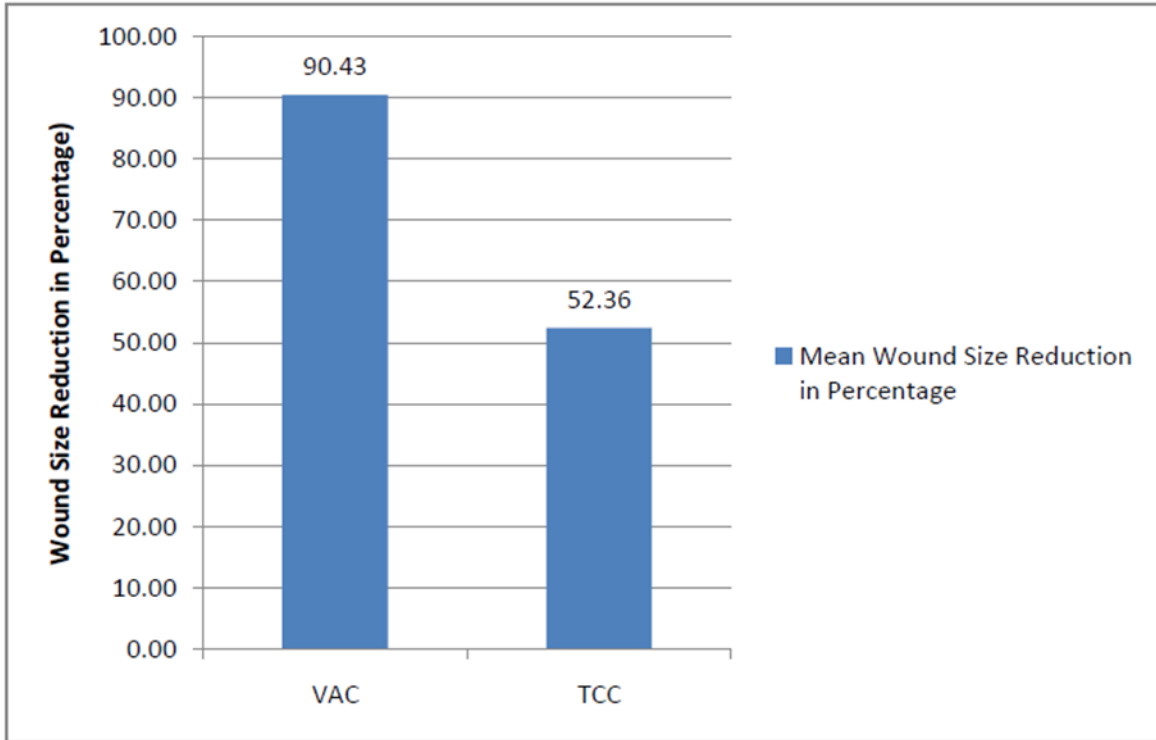


Figure 5 – Mean wound size reduction in percentage



Figure 6- Wound recovery by vaccum assisted closure

Analyses of Hospital stay by Treatment Methods

In VAC group mean hospital stay is 24.90 with standard error of 1.425 and in TCC group is 51.29 with standard error of 2.932. Mean difference between the VAC and TCC group is -26.388 with P value of 0.000 which is significant (Figure 6)

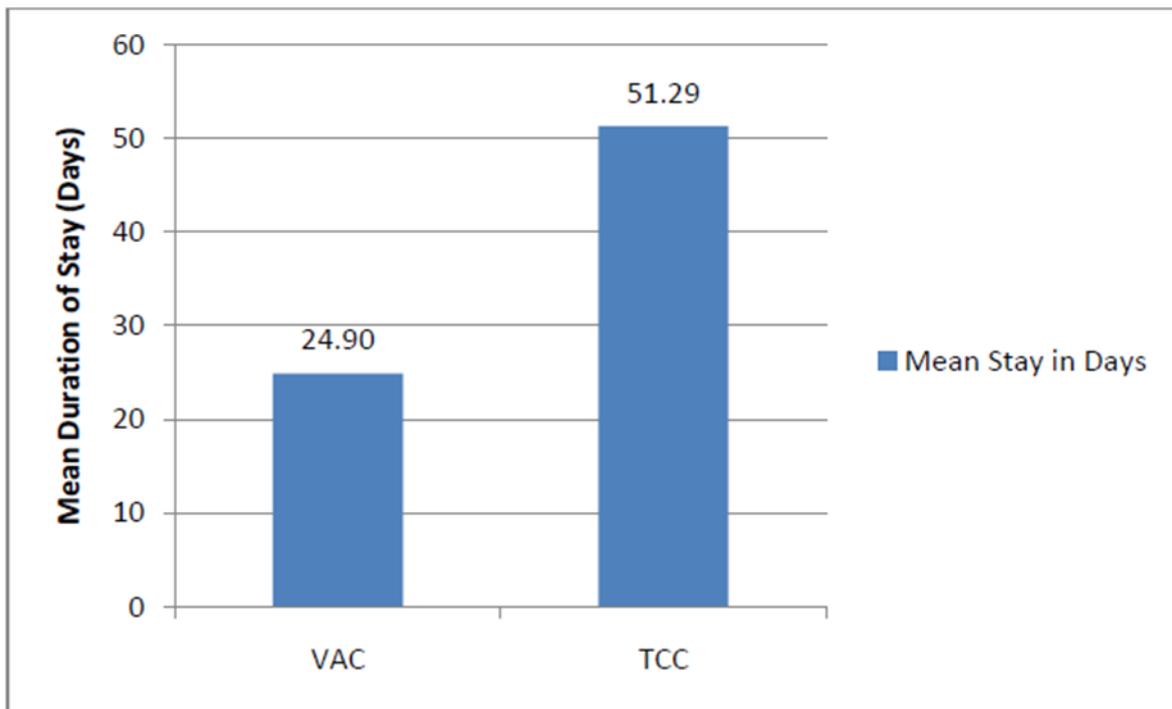


Figure 6 – Mean stay in days

Discussion

India is the top 3rd country in the world in the prevalence of diabetics 'mellitus. Diabetes cases up to 422 million worldwide; India ranks among top 3 countries with diabetic population. According to the Lancet study, China, India and USA are among the top three countries with a high number of diabetic populations [13, 14, and 15]. Negative pressure wound therapy was first described by Fleischman et al., in 1993 done in 15 patients with open fractures and reported efficient cleaning and conditioning of the wound with marked increased proliferation of granulation tissue with no bone infection or soft tissue infection [16, 17]. In this prospective randomised hospital based study we compared the efficacy of vacuum assisted closure and offloading technique in healing of the foot ulcers which was designed after approval of our research topic by the Ethical committee of our college. We selected a total of 122 patients with foot ulcers, satisfying the inclusion and exclusion criteria. Informed and written consent were obtained from all the patients included

in the study. In our study, out of 122 patients, 70 patients were allotted for VAC and 52 patients were allotted for offloading technique. Sloughed out wound were debrided for initial period. Then VAC and TCC were allotted to the patients. PUSH scoring was assessed at the time of admission and during the change of dressings in each method and plotted in a graph. Wound size was measured with the use of ECG paper. PUSH score was determined by wound size, exudate amount and granulation tissue. Then wound surface area and percentage of reduction in the wound surface area was calculated respectively. Also the duration of the hospital stay was also recorded. Statistical analysis was done using the SPSS version 20 software and results were generated. Both study groups has a mean difference of age which is insignificant and so the study is comparable. Also the null hypothesis is retained on the admission in both study groups.

Results of the study is evaluated by comparing with PUSH score, wound reduction in terms of size, percentage and surface area, and also duration of

hospital stay. And p value of all these parameters is 0.000 which shows VAC is more efficient and gives more promising result than the offloading technique. Hence we conclude our study as; vacuum assisted closure is far superior and more effective in terms of healing of the foot ulcer than Offloading technique

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