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Original Research Article

Conventional treatment versus vacuum therapy for diabetic foot ulcers treatment

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ABSTRACT

Background: This study compares the efficacy of vacuum therapy against conventional iodine povidone dressing with respect to area and time of ulcer.
Methods: This study is a randomized controlled trail which was conducted in Meenakshi Medical College hospital and research institute Enathur Kanchipuram. The number of patients selected were 50, which were divided into 2 groups, Group A which consisted of 25 and received vacuum therapy, Group B which consisted of 25 and received povidone-iodine solution.
Results: This study was a 16 days study, mean area of ulcer on day 0 was 11.25 cm2 in group B, 10.89 cm^2 in group A. On day 6, mean area of ulcer was 10.44 cm^2 in group B, 8.98 cm^2 in group A. Mean area of ulcer was 10.39 cm^2 in group B, 7.66 cm^2 in group A on the end of the day 16. The results show that both the groups showed decrease in the area of ulcers, but patients in group A who underwent vacuum therapy have shown greater decrease in the mean area of ulcer. The decrease in surface area of ulcer was statistically significant i.e. p=0.025. There was a greater decrease in infection in group A on 16^{th} day compared to group A on $16t^{h}$ day. On day 0, 48% and 60% growth of microorganisms was observed in patients of group B and group A respectively (p=0.428). On day 16, 28% and 8% growth of microorganisms was observed in patients of group B and group A respectively (p=0.034).
Conclusions: Vacuum therapy was more effective compared to conventional method of povidone-iodone solution dressing in rate of healing and time of healing.

Keywords: Diabetes mellitus, ECM

INTRODUCTION

Diabetic foot ulcer is a major complication of diabetes mellitus, and probably the major component of the diabetic foot. Wound healing is an innate mechanism of action that works reliably most of the time.[1] A key feature of wound healing is stepwise repair of lost extracellular matrix (ECM) that forms the largest component of the dermal skin layer. But in some cases, certain disorders or physiological insult disturbs the wound healing process. Diabetes mellitus is one such metabolic disorder that impedes the normal steps of the wound healing process. Many studies show a prolonged inflammatory phase in diabetic wounds, which causes a delay in the formation of mature granulation tissue and a parallel reduction in wound tensile strength.[2]

Treatment of diabetic foot ulcers should include: blood sugar control, removal of dead tissue from the wound, wound dressings, and removing pressure from the wound through techniques such as total contact casting. Surgery in some cases may improve outcomes. Hyperbaric

oxygen therapy may also help but is expensive. It occurs in 15% of people with diabetes, and precedes 84% of all diabetes-related lower-leg amputations.[3] Diabetic foot ulcer is a complication of diabetes. Diabetic foot ulcers are classified as either neuropathic, neuro ischaemic or ischaemic. Risk factors implicated in the development of diabetic foot ulcers are infection, older age, diabetic neuropathy, peripheral vascular disease, cigarette smoking, poor glycaemic control, previous foot ulcerations or amputations, and ischemia of small and large blood vessels. Prior history of foot disease, foot deformities that produce abnormally high forces of pressure, renal failure, oedema, impaired ability to look after personal care (e.g. visual impairment) are further risk factors for diabetic foot ulcer.[4]

People with diabetes often develop diabetic neuropathy due to several metabolic and neurovascular factors. Peripheral neuropathy causes loss of pain or feeling in the toes, feet, legs and arms due to distal nerve damage and low blood flow. Blisters and sores appear on numb areas of the feet and legs such as metatarsi-phalangeal joints, heel region and as a result pressure or injury goes unnoticed and eventually become portal of entry for bacteria and infection.[5] Assessment of diabetic foot ulcer includes identifying risk factors such as diabetic peripheral neuropathy, noting that 50 percent of people are asymptomatic, and ruling out other causes of peripheral neuropathy such as alcohol abuse and spinal injury.

The location of the ulcer, its size, shape, depth and whether the tissue is granulating or sloughy needs to be considered. Further considerations include whether three is malodour, condition of the border of the wound and palpable bone and sinus formation should be investigated. Signs of infection require to be considered such as development of grey or yellow tissue, purulent discharge, unpleasant smell, sinus, undermined edges and exposure of bone or tendon. Steps to prevent diabetic foot ulcers include frequent review by a foot specialist, good foot hygiene, diabetic socks and shoes, as well as avoiding injury. Foot-care education combined with increased surveillance can reduce the incidence of serious foot lesions and antibiotics are used only when there is evidence of infection.

Choice of antibiotics depends on common local bacterial strains known to infect ulcers. Gauze moistened with saline or other topical solutions was used conventionally, however it became difficult to uphold environment around wound which was moist.[6] Debridement, revascularization, offloading, moist wound care and antibiotic treatment of infection is required for a good clinical treatment of foot ulcer. Diabetic foot ulcer can be treated by many topical routines and devices. This study compares the efficacy of vacuum therapy against conventional iodine-povidone dressing with respect to area and time of ulcer. Vacuum therapy is also known as negative pressure wound therapy. It uses a sub atmospheric pressure ideally and it is a newer, mechanical non-invasive device. It helps in reducing edema and removes exudates from the tissues effectively. It decreases colonization of bacteria and enhances blood flow in the wounded area. Povidone-iodine solution has anti-microbial properties and decreases bacterial load. Its disadvantages are delay in healing process, high toxicity and less absorption into systemic circulation.

METHODS

This study is a randomised controlled trail which was conducted in Meenakshi Medical College hospital and research institute Enathur Kanchipuram. The number of patients selected were 50, which were divided into 2 groups, Group A which consisted of 25 and received vacuum therapy, Group B which consisted of 25 and received povidone-iodine solution. Inclusion criteria was patients who were aged more than 18 years, patients who had type I/II diabetes mellitus, patients who had Wagner grade 2-foot ulcers were included in the study. A written consent form was obtained from all the patients. Patients who were suffering from ischemic, peripheral, collagen vascular diseases, osteomyelitis, malignancy and those having immuno-compromised status were excluded from the study. This study had institutional ethical committee clearance. In group A patients, the wounds were cut in such a manner that the foam entered the wound cavity and it was cleaned and radical debridement was performed.

The drain was kept in a curl manner and the foam was covered with plastic drapes of 3-6cm around the wound tissue. The vacuum unit was connected to the drain with a standard negative pressure of 100-130mm Hg. Additional debridement was done if any slough surfaced and dressing was repeated every 48-72 hours. This treatment was performed for 16 days at a sub-atmospheric pressure. In group B patients, povidone-iodine solution was used to clean the wound and dressing was done with gauze soaked in povidone-iodine solution. Various parameters were observed after dressing the wounds such as site, size, surrounding site, shape, edge, floor, discharge, slough and area of ulcer. Wound culture was done on 0, 6 and 14 days and sensitivity were done on 0 and 16th day. During treatment, disc diffusion method was performed, and results were noted.

RESULTS

Table 1: Demographic distribution in the study.

Variable		Group A	Group B	P value
Age (mean year)		34.9	35.5	0.179
Sex	Males	10	14	0.290
	Females	15	11	

Above table shows that the mean age in years was 34.9 in group A and 35.5 in group B. Males were 10 and females were 15 in group A and in group B; males were 14 and

females were 11. The age (p=0.179, sex (p=0.290) of the patients were not statistically significant (p<0.005).

Table 2: Mean surface area of ulcer on day 0, 6 and 16.

Culture	Group B	Group A	P value
Mean area of ulcer on day 0	11.25 cm^2	10.89 cm^2	0.369
Mean area of ulcer on day 6	10.44 cm^2	8.98 cm^2	0.102
Mean area of ulcer on day 16	10.39 cm^2	7.66 cm^2	0.025

Above table shows that mean area of ulcer on day 0 was 11.25cm^2 in group B, 10.89cm^2 in group A. To check the effectiveness of the two treatments, the areas of ulcers were measured on 6th and 16th day after application of respective treatment. On day 6, mean area of ulcer was 10.44cm^2 in group B, 8.98cm^2 in group A. Mean area of ulcer was 10.39cm^2 in group B, 7.66cm^2 in group A on the end of the day 16. The results show that both the groups showed decrease in the area of ulcers, but patients in group A who underwent vacuum therapy have shown greater decrease in the mean area of ulcer. The decrease in surface area of ulcer was statistically significant i.e. p=0.025.

Table 3: Infection status of ulcer (culture) on day 0.

Culture		Group B	Group A	Total
Day 0	No growth	13 (52%)	10 (40%)	23 (46%)
	Growth present	12 (48%)	15 (60%)	27 (54%)
Total		25 (100%)	25 (100%)	50 (100%)

Table 4: Infection status of ulcer (culture) on day 16.

Culture		Group B	Group A	Total
Day 16	No growth	18 (72%)	23 (92%)	41 (82%)
	Growth present	7 (28%)	2 (8%)	9 (18%)
Total		25 (100%)	25 (100%)	50 (100%)

Above two table shows that there was a greater decrease in infection in group A on 16th day compared to group A on 16th day. On day 0, 48% and 60% growth of microorganisms was observed in patients of group B and group A respectively (p=0.428). On day 14, 28% and 8% growth of microorganisms was observed in patients of group B and group A respectively (p=0.034). Culture sensitivity was performed on day 0 and day 16. Gram Negative microorganisms such as proteas, Escherichia Coli, Klebsiella, enterococcus and pseudomonas and gram-positive microorganisms such as staphylococcus aureus were the common organisms isolated.

DISCUSSION

It is important to prevent diabetes foot ulcer (DFU) as well as stop chances of amputation. Foot is a multifaceted structure in the body, and also provides a foundation step to the body. Diabetes foot ulcer is a combination of sensation failure, due to neuropathy in which the patient's feet becomes numb and the wound is not regarded. In the present study, the mean age in years was 34.9 in group A and 35.5 in group B.

Males were 10 and females were 15 in group A and in group B; males were 14 and females were 11. The age (p=0.179), sex (p=0.290) of the patients were not statistically significant (p<0.005). Mean area of ulcer on day 0 was 11.25cm^2 in group B, 10.89cm^2 in group A. To check the effectiveness of the two treatments, the areas of ulcers were measured on 6th and 16th day after application of respective treatment. On day 6, mean area of ulcer was 10.44cm^2 in group B, 8.98 cm^2 in group A.

Mean area of ulcer was 10.39cm^2 in group B, 7.66cm^2 in group A on the end of the day 16. The results show that both the groups showed decrease in the area of ulcers, but patients in group A who underwent vacuum therapy have shown greater decrease in the mean area of ulcer. The decrease in surface area of ulcer was statistically significant i.e. p=0.025. There was a greater decrease in infection in group A on 16th day compared to group A on 16th day. On day 0, 48% and 60% growth of microorganisms was observed in patients of group B and group A respectively (p=0.428). On day 16, 28% and 8% growth of microorganisms was observed in patients of group B and group A respectively (p=0.034).[7]

Conducted a study to equate the effectiveness of vacuum-assisted closure therapy (VACT) with conventional povidone iodine dressing (CTPID) in the management of diabetic foot ulcer (DFU). It was a 14-day study in which a total of 60 patients were divided into two equal groups (n=30) using computer-generated random numbers. Group A and group B received VACT and CTPID treatment for DFU, respectively. A sub atmospheric pressure of 100-125mmHg was applied to the wound in VACT group and povidone iodine-soaked gauze was used for dressing in CTPID group. The wounds were assessed on day 0, 5 and 14 of the treatment for the mean area of ulcer.

Culture sensitivity test for bacterial growth was performed on day 0 and 14 to determine the infection status by disc diffusion method. At the end of the study (day 14), mean surface area of the ulcer treated with VACT and CTPID was reduced from 11.21cm^2 to 8.6cm^2 and 12.24cm^2 to 11.30cm^2, respectively (p = 0.029). Two patients of group A and eight patients of group B showed positive growth for gram-positive cocci such as *Staphylococcus aureus*, and gram-negative organisms such as *E. coli*, *Proteus*, *Klebsiella*, *Pseudomonas* and *Enterococcus* on day 14 of repeat culture (p=0.038). In a single-blind, randomised controlled study conducted by Akbari A et al to evaluate vacuum-compression therapy (VCT) for the healing of diabetic foot ulcers. Eighteen diabetic patients with foot ulcers were recruited through simple non- probability

sampling.[8] Subjects were randomly assigned to either an experimental or a control group. Before and after intervention, the foot ulcer surface area was estimated stereologically, based on Cavalieri's principle.

The experimental group was treated with VCT in addition to conventional therapy for 10 sessions. The control group received only conventional therapy, including debridement, blood glucose control agents, systemic antibiotics, wound cleaning with normal saline, offloading (pressure relief), and daily wound dressings. The mean foot ulcer surface area decreased from 46.88±9.28mm^2 to 35.09±4.09mm^2 in the experimental group (p=0.006) and from 46.62±10.03mm^2 to 42.89±8.1mm^2 in the control group (p=0.01).

After treatment, the experimental group significantly improved in measures of foot ulcer surface area compared with the control group (p=0.024). VCT enhances diabetic foot ulcer healing when combined with appropriate wound care. In two parallel randomized controlled trials conducted by Luca Dalla Paola et al evaluated the effectiveness of VAC Therapy in enhancing skin-graft take of diabetic foot wounds (study I) and the effectiveness in treatment of infected open minor amputations (study II).[9]

In study I, 70 patients were randomly assigned to either VAC Therapy (V1 group) or coverage of the grafts with non-adherent gauze (C1 group). In study II, 130 diabetic subjects were randomized to either surgical debridement and VAC Therapy (V2 group) or surgical debridement and semi-occlusive silver dressing (C2 group).

In study I the take rate was 80% in the V1 group versus 68% in the C1 group (p=0.05). In study II a more rapid development of granulation tissue covering the exposed bone was shown in the V2 group when compared to the C2 group (41±8 versus 59±18 days, p=0.03). Also, a better and more rapid control of the infections (10±8 days in V2 group versus 19±13 days in C2 group; p=0.05) and reduced time to complete closure of the wound was found with VAC Therapy (65±16 days in V2 group versus 98±45 days in C2 group, p=0.005). Total time required for surgical procedures was reduced in the VAC group (2.5 hours versus 6 hours in the control group, p=0.02).

In conclusion, this study demonstrates that treating diabetic wounds with VAC Therapy can result in a faster wound bed preparation, a faster closure, and in a better graft take rate when compared to standard wound care. In a study conducted by Ali M Lone et al they compared the effectiveness of vacuum-assisted closure (VAC) versus conventional dressings in the healing of diabetic foot ulcerations (DFUs) in terms of healing rate (time to prepare the wound for closure either spontaneously or by surgery), safety, and patient satisfaction.[10] This was a randomized case control study which enrolled 56 patients, divided into two groups. Group A (patients treated with VAC) and Group B (patients treated with conventional dressings), with an equal number of patients in each group. DFUs were treated until wound closure, either spontaneously, surgically, or until completion of the 8-week period.

Granulation tissue appeared in 26 (92.85%) patients by the end of Week 2 in Group A, while it appeared in 15 (53.57%) patients by that time in Group B. 100% granulation was achieved in 21 (77.78%) patients by the end of Week 5 in Group A as compared to only 10 (40%) patients by that time in Group B. Patients in Group A had fewer number of positive blood cultures, secondary amputations and were satisfied with treatment as compared to Group B. VAC appears to be more effective, safe, and patient satisfactory compared to conventional dressings for the treatment of DFUs.

CONCLUSION

From this study, vacuum therapy was more effective compared to conventional method of povidone-iodine solution dressing in rate of healing and time of healing.

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