# **Original Research Article**

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# Comparative study of negative pressure wound therapy with moist gauze dressings in the treatment of leg ulcer wounds

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## **ABSTRACT**

**Background:** Leg ulcers are one of the most commonly encountered cases in any surgical out-patient department. Causes of leg ulcers vary from traumatic, diabetic, chronic venous insufficiency, trophic, hypertensive, and so on. The purpose of this study is to evaluate the safety and clinical efficacy of negative pressure wound therapy compared with moist gauze dressings to treat foot ulcer wounds.

**Methods:** Patients presenting with leg ulcers to the department of general surgery, VMKVC hospital. 50 randomly selected patients will be assigned to the study group based on their willingness for undergoing topical negative pressure dressing and 50 patients to the moist gauze dressing, control group.

**Results:** Most of the ulcer (45.4%) got healed by secondary intention through VAC. dressing. Treating DFU with VAC therapy results in a better graft take rate (p=0.05) when compared to standard wound care. There is a statistically significant association found between interventions and the area of the ulcer on day 28.

**Conclusions:** While moist gauze dressing can be applied to any wound surfaces, vacuum dressing is limited to certain surfaces and certain wounds exposing tendon sheath, blood vessels, bones, aponeurosis cannot be treated by vacuum dressing. The frequency of dressing is lower with continuous vacuum suction dressing, while moist gauze has to be changed twice a day to obtain favorable results.

**Keywords:** Negative pressure wound dressing, Diabetic foot ulcers, Moist wound dressing, Vacuum assisted closure, wound therapy

## INTRODUCTION

Wound healing is the normal response to any injury. It is divided into acute wound healing and chronic wound healing. Acute wound healing is the normal orderly process that occurs after an uncomplicated injury and requires minimal practitioner intervention. While chronic wound healing does not follow an orderly progression of healing and often necessitates a variety of interventions to facilitate closure. A chronic wound is a wound that fails to heal in a reasonable amount of time, given the nature of the wound, etiology of the wound, location, and tissue

type.<sup>2</sup> Most chronic wounds are arrested in the inflammatory and proliferative phases of healing and have increased levels of metalloproteinases, which bind and degrade growth factors at the wound surface.<sup>3</sup> Foot wounds in people are a common and serious global health issue, which may result from various etiopathogenesis. Diabetic ulcers occupy the dominant number of cases of leg ulcers closely followed by venous stasis ulcers, arterial insufficiency ulcers, pressure ulcers, skin tears. A moist gauze dressing is changed frequently to provide adequate protection and moisture to the wound to promote the growth of healthy granulation tissue and

facilitate healing.<sup>4</sup> Moist to dry dressing provides a gentle debridement and obliteration of dead space, facilitates drainage. Negative pressure dressing provides subatmospheric pressure to a local wound through a porous foam sponge sealed over the wound with a semipermeable adhesive barrier, vacuum is applied by an external pump. They are particularly useful in covering soft tissue defects.<sup>5</sup> Hydrogel dressings, rehydrate necrotic tissue to facilitate easy debridement, adsorb the wound exudate, and maintain the moist environment for wound healing. Hydrocolloid dressings for a dry wound like venous stasis ulcer.<sup>6</sup> Alginate dressings are complex carbohydrate dressing composed of glucuronic acid and mannuronic acid derived from seaweed; these are highly absorbent and can be used for heavily exudative wounds. Hydrofibers for heavy exudates. Adhesive films for shallow wounds. Growth factors, skin substitutes, and hyperbaric oxygen therapy are other treatment options available for the treatment of chronic wounds.<sup>7</sup> Elevation of limb and compressive dressing effectively tackles edema, in cases of venous stasis, pneumatic compression devices, Unna boots can also be used.8

#### **METHODS**

This retrospective study was conducted in Vinayaka Mission's Kirupananda Variyar medical college and hospital, Salem between November 2017 and November 2019. Patients presenting with leg ulcers to the department of general surgery were included in the study. 50 randomly selected patients were assigned in the study group based on their willingness for undergoing topical negative pressure dressing and 50 patients to the moist gauze dressing, control group. Patients undergoing treatment with normothermic or hyperbaric oxygen therapy. Patients on medications such as corticosteroids, immunosuppressive medications, or chemotherapy.

## Inclusion criteria

Inclusion criteria for current study were; patients in between 18 to 75 years (adults, senior citizens), All (100) cases of either sex suffering from chronic foot ulcers presented to the hospital during the study period were included.

#### Exclusion criteria

Exclusion criteria for current study were; non-consenting patients, age <18 or >75 years, abnormal coagulation profiles; severe anemia (hemoglobin level <6 g/dl), patients with ulcers resulting from electrical, chemical, or radiation burns, patients with collagen vascular disease, ulcer malignancy, untreated osteomyelitis, or cellulitis. Active microbial growth in the wound is excluded from the study (during hospital stay patient was rendered to no growth on culture from the wound, the patient were included in the study only if willing). Patients undergoing treatment with normothermic or hyperbaric oxygen therapy were excluded from study. Patients on

medications such as corticosteroids, immunosuppressive medications, or chemotherapy were also excluded.

The sterile gauze of adequate size to give wound coverage was soaked in normal saline and squeezed to expel the excess water and packed into the wound bed, taking care to avoid exposing the peri-wound area to the moisture, as it will lead to maceration of tissues, then a sterile gamgee pad of adequate size was placed over the packed gauzes. Three layers of bandage rolls were applied to hold the gauze and pads in place. Conventionally such wound dressing was removed once the dressing dries up and replaced with saline dressing again. The principle behind this procedure was to maintain a moist environment to stimulate wound healing and to prevent dead space and provide for adequate wound drainage. In our study, the dressing for the patients in the moist gauze dressing arm was changed dressing on a twice-daily basis, and photographic comparison was done for days 0, 7, 14, 21, 28 and a review, a week post-discharge from the hospital. For negative pressure therapy, the sterile foam is cut to length to fit the size of the wound, and to provide complete coverage of the ulcer bed, a hole is made in the foam to accommodate a rubber suction catheter that will be brought out through the occlusive dressing. Then an occlusive dressing is put over the foam and stuck to the peri-wound area, taking care to maintain the suction within the wound margins only and the suction catheter is brought out through the occlusive dressing and connected to a suction pump, which is set between -75 to -150 mmHg, on continuous suction. The dressing is changed every three days and the wound is inspected and comparison photographs are taken on days 0, 7, 14, 21, 28 and a review, a week post-discharge from the hospital.

# Statistical analysis

Data entry was made in the Microsoft excel software in codes and analysis was done with an SPSS-20 computer package. Categorical variables are expressed as percentages whereas continuous variables are expressed as mean±standard deviation. Association between the categorical variable was found by the chi-square test and the relationship between the continuous variable was assessed by Student's t-test.

# **RESULTS**

There were 100 participants in current study (Table 1). The mean age of the participants was 50.4 (SD=11.1) 35% were in the age group of 51 to 60 years, 30% were in the age group of 41 to 50 years, 18% were in the age group of 61 to 70 years, 9% were in the age group of 31 to 40 years, 8% were in the age group of 21 to 30 years. Among the study participants, 67% were males and 33% were females. Among the study participants, 36% were smokers and 64% of them were non-smokers. 50% of our study participants were suffering from type 2 diabetes mellitus. Among the participants, 3% were having

TB/BA/both, while 97% of them did not have either or both. Systemic Hypertension was present in 28% of our participants, while 72% of them were normotensive. Among the study participants according to intervention 50% were treated with moist gauze, 50% were treated with VAC dressing (Table 2).

Table 1: Distribution of study participants according to age (n=100).

| Age (years) | Frequency | Percentage |
|-------------|-----------|------------|
| 21 to 30    | 8         | 8          |
| 31 to 40    | 9         | 9          |
| 41 to 50    | 30        | 30         |
| 51 to 60    | 35        | 35         |
| 61 to 70    | 18        | 18         |

Table 2: Distribution of study participants according to intervention (n=100).

| Intervention | Frequency | Percentage |
|--------------|-----------|------------|
| Moist gauze  | 50        | 50         |
| VAC dressing | 50        | 50         |

Among the study participants according to day 1 ulcer state 16% had healthy granulation tissue, 16% had necrotic granulation tissue, and 66% had their tissue with pale granulation (Table 3). Among the study participants, 51% presented with discharge on day 1 whereas 49% didn't have discharge on day 1. On day 7 of the ulcer state among the study participants, 2% got healed, 45% had healthy granulation tissue, 1% had healthy granulation, 50% had pale granulation, and 2% had to sprout granulation. On day 7 around 21% presented with discharge on the ulcer site whereas 79% don't have an ulcer (Table 5).

Table 3: Distribution of study participants according to day 1 ulcer state (n=100).

| Ulcer state          | Frequency | Percentage |
|----------------------|-----------|------------|
| Healthy granulation  | 16        | 16         |
| Necrotic granulation | 18        | 16         |
| Pale granulation     | 66        | 66         |

Table 4: Distribution of study participants according to day 7 ulcer state (N=100).

| Ulcer state           | Frequency | Percentage |
|-----------------------|-----------|------------|
| Healed                | 2         | 2          |
| Healthy granulation   | 45        | 45         |
| Necrotic debris       | 1         | 1          |
| Pale granulation      | 50        | 50         |
| Sprouting granulation | 2         | 2          |

Among the study participants on day 14 of the ulcer state 1% of them had a gangrenous ulcer, 8% got healed, 60% of them had healthy granulation tissue, and 23% had pale

granulation tissue (Table 6), 6% had to sprout granulation, Among the study participants, on day 14, 4% of them presented with discharge, whereas 96% don't have discharge.

Table 5: Distribution of study participants according to day 7 discharge (n=100).

| Discharge | Frequency | Percentage |
|-----------|-----------|------------|
| Present   | 21        | 21         |
| Absent    | 79        | 79         |

Table 6: Distribution of study participants according to day 14 ulcer state (n=100).

| Ulcer state           | Frequency | Percentage |
|-----------------------|-----------|------------|
| Gangrenous            | 1         | 1          |
| Healed                | 8         | 8          |
| Healthy granulation   | 60        | 60         |
| Not available         | 2         | 2          |
| Pale granulation      | 23        | 23         |
| Sprouting granulation | 6         | 6          |

Among the study participants on day 21, 13% of the ulcer got healed, 55% had healthy granulation tissue, 11% had pale granulation tissue, 9% had to sprout granulation, and 12% were already healed (Table 7). All the participants were not having any discharge on day 21.

Table 7: Distribution of study participants according to day 21 ulcer state (n=100).

| Ulcer state           | Frequency | Percentage |
|-----------------------|-----------|------------|
| Healed                | 13        | 13         |
| Healthy granulation   | 55        | 55         |
| Not available         | 12        | 12         |
| Pale granulation      | 11        | 11         |
| Sprouting granulation | 9         | 9          |

Table 8: Distribution of study participants according to day 28 ulcer state (n=100).

| Ulcer state           | Frequency | Percentage |
|-----------------------|-----------|------------|
| Healed                | 19        | 19         |
| Healthy granulation   | 37        | 37         |
| Not available         | 25        | 25         |
| Pale granulation      | 1         | 1          |
| Sprouting granulation | 18        | 18         |

Among the study participants on day 28 of the ulcer state, 19% of them got healed, 37% had healthy granulation tissue, 1% had pale granulation, 18% had sprouting granulation, and 25% were already healed. All the participants were not having any discharge on day 28 (Table 8).

During the follow-up period, on examining the ulcer state 28% got healed, 20% had healthy granulation, 8% had

sprouting granulation, 44% of them healed during the study (Table 9). All the participants were not having any discharge on follow-up.

Table 9: Distribution of study participants according to follow up ulcer state (n=100).

| Ulcer state           | Frequency | Percentage |
|-----------------------|-----------|------------|
| Healed                | 28        | 28         |
| Healthy granulation   | 20        | 20         |
| Not available         | 44        | 44         |
| Sprouting granulation | 8         | 8          |

At the end among the study participants, 1.3% (1) got treated by amputation, 1.3% (1) of them were treated using a collagen sheet, 38.9% (28) of the ulcer state were treated by secondary intention, 13.8% (10) were treated with secondary suturing, 44.4% (32) were treated with skin grafting (Table 10).

Table 10: Distribution of study participants according to end result (n=72).

| Ulcer state         | Frequency | Percentage |
|---------------------|-----------|------------|
| Amputation          | 1         | 1.3        |
| Collagen sheet      | 1         | 1.3        |
| Secondary intention | 28        | 38.9       |
| Secondary suturing  | 10        | 13.8       |
| Skin grafting       | 32        | 44.4       |

# **DISCUSSION**

Leg ulcers are associated with significant morbidity, high burden healthcare, an increase in the cost of domiciliary treatment, loss of productivity, and reduction in quality of life. Most of the patients who venture to a hospital setup in need of the treatment for leg ulcer wounds belong to a poor socioeconomic stratum, affordability of health care needs is often questionable with their daily income.9 While these wounds plague the individual they also spread their fair share of misery on the individual's family bringing the entire family to a standstill if the patient happens to be the sole breadwinner of the family full of dependent people.<sup>10</sup> So an effective treatment is the need of the hour for such patients, not only the individual has to spend on healthcare which is a significant burden, but the patients earning capacity during a hospital stay in most situations is also hindered, which adds to the burden even more so. Gurtner et al in their study found the Shorter duration of hospital stay was observed in the vacuum dressing group.<sup>11</sup> Sickness absenteeism is a phenomenon which explains the fact that the patient in the view of such illness is unable to contribute to the society at large, which not only stops the development of the society, it causes the patients earning capacity to fall So, his/her expenses for basic necessity are not met adequately.<sup>12</sup> This study is not aimed at the analysis of expenditure in negative pressure dressing and moist gauze dressing. Even though the cost comparison is somewhat even on the outside, there are many hidden

costs which also payout of the patients pocket and that needs to be tackled in further studies and is beyond the scope of our study, which is limited to the safety and clinical efficacy of both the treatment modalities under discussion.<sup>13</sup> Wound healing is a highly complex and virtually dynamic process that includes a sequence of cell migration causing repair and closure. This sequence begins with the removal of necrotic tissue and debris, infection, reduction of inflammation, angiogenesis, growth of granulation tissue, contraction of the wound, remodelling of the already laid down connective tissue matrix, and maturation.<sup>14</sup> When a wound fails to undergo this sequence of events in a programmed manner, chronic wound results. Saline gauze is the traditional standard method; but, it is ever so difficult to continually maintain a moist wound environment with saline dressings subsequently, various hydro fiber/hydrocolloid/alginate wound gels, growth factors, hyperbaric oxygen therapy, cultured skin substitutes, enzymatic debridement compounds, and other wound therapies have been advocated. All of these therapies are associated with the high cost and are being utilized in a few situations without much scientific evidence to favour their efficacy. 15 Negative pressure wound therapy (NPWT) is a novel non-invasive treatment modality that makes use of controlled negative pressure, using vacuum-assisted closure (VAC) device or an improvised closed suction system like used in our study to promote wound healing by removing excess fluid from wounds, to prepare the wound bed for closure, to reduce edema, and to promote formation and perfusion of granulation tissue.16 Several studies have been conducted worldwide to assess the efficacy of negative pressure wound therapy. All studies favor negative pressure wound therapy over conventional moist gauze dressing.<sup>17</sup> Our study too is in favour of results obtained by the above-mentioned studies. Campos et al reported that negative pressure wound therapy (NPWT) is a more effective method of treatment of lower limb ulcers as compared to conventional dressing with 30% faster healing rates, reduced overall complication rates, and better patient acceptance. The rate of the granulation tissue formation, the overall graft uptake and survival, and patient adherence to treatment were better in the Negative pressure wound therapy group as compared to the conventional moist gauze dressing group. 18 It is also seen that the overall hospital stay and post-op complications were significantly less in the Negative pressure wound therapy group. 19 Thus, negative pressure wound therapy can be considered a superior option in the management of chronic wounds. But further studies with a larger population will be needed in the future before negative pressure wound therapy can be added to the worldwide spectrum of treatment modalities available in the management of chronic leg ulcer wounds.<sup>20</sup>

# **CONCLUSION**

Analyzing the results of our study, we think that negative pressure wound therapy has a definitive role in the promotion of proliferation of granulation tissue, reduction in the wound size, in the rapid clearing of the wound discharge. Our data determines that negative pressure wound dressings decrease the wound size more effectively than saline gauze dressings, reduce wound discharge, promote granulation formation, bring about a much earlier definitive treatment option, and reduces hospital burden, costs, and stay. Negative pressure wound therapy has a promising cost-benefit ratio, ease of use, and is a patient friendly method of treating chronic limb ulcers helping in the early closure of wounds, preventing complications, and hence promising a better outcome. The limitations of the study controlled negative pressure applied using VAC reduces duration of hospital stay and facilitates early wound healing. The application of controlled levels of negative pressure accelerates healing in many types of wound. Diabetes and hypertension was too screened periodically.

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Institutional Ethics Committee

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