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Comparative study of Vac dressing with moist gauze dressing in the treatment of diabetic foot ulcer in tertiary care center

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Abstract--Background: Diabetic foot 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. Objectives: 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. 40 randomly selected patients will be assigned to the study group based on their willingness for undergoing topical negative pressure dressing and 40 patients to the moist gauze dressing, control group. Results: Most of the ulcer (46%) 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 21. Among the study participants according to day 1 ulcer state 16% had healthy granulation tissue, 14% had necrotic granulation tissue, and 50% had their tissue with pale granulation. On day 7 of the ulcer state among the study participants, 2% got healed, 45% had healthy granulation tissue, and 50% had pale granulation. 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, 6%

had to sprout granulation. 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. Conclusions: 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.

Keywords---negative pressure, wound dressing, diabetic foot ulcers, moist wound dressing, vacuum assisted closure, wound toileting.

Introduction

Ulcers of the lower extremities, particularly in individuals older than 65 years, are a common cause for visits to the podiatrist, wound care specialist.[1] The incidence of ulceration is rising as a result of the ageing population and increased risk factors for atherosclerotic occlusion such as smoking, obesity, and diabetes. Leg ulcers are reported to have impact on virtually every aspect of daily life: pain is common, sleep is often impaired, mobility and work capacity tend to be restricted, and personal finances are often adversely affected. It is also known that social activities are restricted due to fear of injury and negative body image. Leg ulcers are usually associated with significant morbidity, high cost of healthcare, loss of productivity, and reduced quality of life.[2]

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.[3] 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.[4] 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.[5]. Diabetic ulcers occupy the dominant number of cases of leg ulcers closely followed by venous stasis ulcers, arterial insufficiency ulcers, pressure ulcers, skin tears.

Saline-moistened gauze has been the standard method; however, it has been difficult to continuously maintain a moist wound environment with these dressings. Subsequently, various hydrocolloid wound gels, growth factors, enzymatic debridement compounds, hyperbaric oxygen therapy, cultured skin substitutes, and other wound therapies have been advocated. All of these therapies are associated with significant expense and are being utilized in some situations without sufficient scientific evidence in favor of their efficacy.[6] Negative pressure wound therapy (NPWT) is a newer non-invasive adjunctive therapy system that uses controlled negative pressure, using vacuum-assisted closure (VAC) device, to help promote wound healing by removing fluid from open wounds, preparing the wound bed for closure, reducing edema, and promoting formation and perfusion of granulation tissue. The rationale behind the study was

to evaluate the safety and clinical efficacy of negative pressure wound therapy compared with moist gauze dressings to treat foot ulcer wounds.

Materials and Methods

It was retrospective study was conducted in Vinayaka Mission's KirupanandaVariyar medical college and hospital, Salem between November 2019 and November 2021. Patients presenting with leg ulcers to the department of general surgery were included in the study. 40 randomly selected patients were assigned in the study group based on their willingness for undergoing topical negative pressure dressing and 40 patients to the moist gauze dressing, control group.

Inclusion criteria

patients above 18 years, All (80) cases of either sex suffering from chronic foot ulcers presented to the hospital during the study period were included. An informed written consent was obtained from the patient

Exclusion criteria

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.

Methodology

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 gauze 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

The statistical software namely statistical package for social sciences (SPSS) 22.0 was used for the analysis of the data. Categorical data represented in frequencies and proportions. Chi-square test has been used to find the significant association of findings of preoperative score with post-operative outcome. $P < 0.05$ is considered as statistically significant value.

Results

Table 1
Distribution of Study participants as per Age and Discharge

Age(years)	Frequency	Percentage
21 to30	8	10
31 to40	9	12
41 to50	20	25
51 to60	25	30
61 to70	18	23
Discharge		
Present	15	20
Absent	65	80

As per table 1 the most common age group was found to 51 to 60 years (30%), followed by 41 to 50 years (25%). Around 20% of patients have discharge after 7 days.

Table 2
Distribution of Study participants according to ulcer state

Ulcer state	Day 1	Day 7	Day 14	Day 21	Day 28
Gangrenous	0	0	1	0	0
Healed	0	2	8	13	21
Healthygranulation	16	34	60	40	29
Necrotic granulation	14	4	2	12	2
Palegranulation	50	40	23	11	7
Sproutinggranulation	0	0	6	4	21

As per table 2 different ulcer states at different days are seen. Among the study participants according to day 1 ulcer state 16% had healthy granulation tissue, 14% had necrotic granulation tissue, and 50% had their tissue with pale

granulation. On day 7 of the ulcer state among the study participants, 2% got healed, 45% had healthy granulation tissue, and 50% had pale granulation. 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, 6% had to sprout granulation. 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 and it was statistically significant ($p < 0.05$). Among the study participants on day 28 of the ulcer state, 24% of them got healed, 37% had healthy granulation tissue, 1% had pale granulation, and 18% had sprouting granulation. All the participants were not having any discharge on day 28. 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. All the participants were not having any discharge on follow-up.

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.[7] 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.[8] 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.[9]

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, tackling infection, reduction of inflammation, angiogenesis, growth of granulation tissue, contraction of the wound, remodelling of the already laid down connective tissue matrix, and maturation.[10]. Aslam R et al in a randomized control trial comparing vacuum assisted closure versus conventional dressings in diabetic foot ulcers, in terms of mean number of days of wound healing found mean age of patients in group A (N=60) (vacuum assisted closure therapy) was found to be 55.45 with a SD of ± 6.279 and mean age of patients in group B (N=60) (conventional dressing for wound closure) was found to be 55.23 with a standard deviation of ± 6.220 , which was statistically not significant.[11] 63.3% were males and 36.7 % were females. Blume PA et al study on comparison of negative pressure wound therapy using vacuum assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers found 342 patients with a mean age of 58 years; 79% were male.[12] Singh B et al in a prospective time bound comparative study found

average mean age was 54.4 years (37-74-year-old). Twenty-two patients (73.3%) were male.[13]

Priyatham K et al in a prospective study assessing the efficacy of vacuum assisted closure as compared to conventional moist wound dressings in improving the healing process in chronic wounds reported better graft take up was observed in vacuum dressing group as compared to the conventional dressing group.[14]. 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.[15] It is also seen that the overall hospital stay and post-op complications were significantly less in the Negative pressure wound therapy group.[16] Thus, negative pressure wound therapy can be considered a superior option in the management of chronic wounds.

Conclusion

Analyzing the results of our study, 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. The 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.

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Conflict of Interest- None declared

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