IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 21, Issue 5 Ser.3 (May. 2022), PP 12-22
www.iosrjournals.org

A Clinico-Pathological Study of Diabetic Foot with Special Refference to Role of Vacuum Assisted Closure in Management of Diabetic Foot

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ABSTRACT
Diabetes foot ulcers are one of the most serious consequences of diabetes mellitus, posing a staggering 25% lifetime risk.Healing diabetic foot ulcers takes substantially longer, even with strict glycemic control and excellent infection therapy, due to the bigger raw surface that requires significant time for granulation tissue coverage.In an attempt to influence this wound healing process many kinds of treatment have been developed, for example surgical debridement, various types of dressings, topical applications, and antiseptic agents.This study aimed to compare the diabetic wound healing with vacuum assisted closure with that of the conventional dressing method.
Details of 50 cases was recorded including history and wound characteristics .They were divided into two groups, Group A with Vacuum Assisted Closure in diabetic foot healing and group B as conventional Saline and Eusol dressing on the wound.
and Follow up was done with wound bed score, appearance of granulation tissue after day 0, 3, 7, 10 and so on dressings.Better wound bed score was seen in vac dressing in comparison to traditional dressing. This study concludes that vacuum-assisted dressing is a more beneficial tool for wound healing promotion, particularly in the case of non-healing and persistent ulcers, better patient compliance and no requirement for daily dressing is add on benefit.

Date of Submission: 05-05-2022 Date of Acceptance: 19-05-2022

I. Introduction

Diabetes foot ulcers are one of the most serious consequences of diabetes mellitus, posing a staggering 25% lifetime risk.1,2 Morbidity and the prolonged requirement for hospitalization have a significant impact on the quality of life of people afflicted. The significance of these becomes much more apparent when one considers that India has the highest number of diabetics in the world.3 If infection and sepsis are not treated promptly, limb amputation may be required to prevent death.4

Diabetic foot treatment is difficult because it necessitates a multimodal approach that includes infection control with appropriate antibiotics, serial and aggressive debridement, rigorous blood sugar control, and adequate pressure off-loading. Healing diabetic foot ulcers takes substantially longer, even with strict glycemic control and excellent infection therapy, due to the bigger raw surface that requires significant time for granulation tissue coverage.

Diabetic neuropathy manifests in the nerve system's motor, autonomic, and sensory components. Damage to the innervations of the intrinsic foot muscles causes an imbalance in the affected foot's flexion and extension. This results in anatomic foot abnormalities, which create aberrant bone prominences and pressure points, causing skin breakdown and ulceration over time.5

Wound management continues to be difficult. Chronic wounds are those that do not heal or do not respond to treatment. Delayed wound healing is a major public health issue, particularly among the elderly. In addition to the agony and suffering, the wound's failure to heal imposes social and financial costs.6 Chronic Ulcers pose substantial and difficult health and economic concerns since they necessitate long-term surgical and nursing care, whether they be a Burn wound, Diabetic ulcer, Decubitus ulcer, or otherwise. Ulcers are also prone to consequences such as infection, which can lead to sepsis and limb loss. Chronic ulcers necessitate dressings several times per day. The purpose of the dressing is to protect the wound from contamination, infection, and damage, as well as to absorb ulcer drainage and immobilize the wound.

Infection in a diabetic foot is a limb-threatening condition because the implications of deep infection in a diabetic foot are more severe than elsewhere, owing to anatomical differences. The foot has multiple

compartments that communicate with one another, allowing the infection to travel from one to the next, and the lack of pain permits the patient to maintain ambulation, allowing the infection to spread even further. Soft tissues in the foot, such as plantar aponeurosis, tendons, muscle sheaths, and fascia, are also susceptible to infection. The combination of neuropathy, ischemia, and hyperglycemia exacerbates the problem by lowering the defense mechanism.7

In an attempt to influence this wound healing process many kinds of treatment have been developed, for example surgical debridement, various types of dressings, topical applications, and antiseptic agents. One of the recent developments is the application of vacuum assisted closure (VAC), a concept which emerged in the late 1980s since when several devices have been developed and marketed. Vacuum-assisted closure (VAC) therapy, which has been developed as an alternative to the standard forms of wound management, incorporates the use of negative pressure to optimize conditions for wound healing.8 It can be used to treat acute trauma in the early stages or when more traditional conservative techniques have failed. A growing number of articles have advocated for the use of VAC. The VAC technique is also known as subatmospheric pressure sealed surface wound suction, vacuum sealing, and foam suction dressing. In general, the procedure comprises inserting a dressing into the wound cavity, attaching the dressing to a vacuum pump, and closing the region with an adhesive film.

The tube is connected to a vacuum device that delivers a controlled negative (i.e., suction) pressure in the range of -50 mm Hg to -125 mm Hg. Research has shown a maximum increase in blood flow at a negative pressure of 125 mm Hg, which is therefore the advised amount of negative pressure.

Standard wound management consists of initial surgical debridement (a rapid and effective technique to remove devitalized tissue), then either wet-to moist (WM) gauze dressings or Opsite dressings, which need to be changed at least twice daily, can be used to cover the wound. These dressings are relatively inexpensive, readily available and easy to apply. However, there are some disadvantages: non-selective debridement with dressing removal, possible wound desiccation, and the need for frequent dressing changes. The Health point System (HP) involves the use of three Food and Drug Administration (FDA)-approved gel products, Accuzyme, Iodosorb and Panafil. Accuzyme, a papain-urea debridement ointment, is used initially unless the wound has been surgically debrided.

Wounds with substantial exudate are managed with Iodosorb gel, which contains hydrophilic beads that soak up bacteria and cellular debris. Clean, granulating ulcers receive Panafil, a papain urea-chlorophyllin-copper ointment. Other approaches to cleanse and prepare the wound involve the use of topical enzymes, bio-surgical therapy and topical antimicrobial agents. Vacuum-assisted closure has been suggested as an alternative that may promote faster wound healing with fewer painful dressing changes. The vacuum-assisted closure was pioneered by Dr Louis Argenta and Michael Morykwas in 1993. It is a development from the standard surgical procedure, which uses vacuum-assisted drainage to remove blood or serous fluid from an operation site to provide a drier surgical field and control blood flow.

In VAC therapy, the application of topical negative pressure (vacuum) removes blood and serous fluid and slough and controlled debridement, reduces infection rates (closed/sealed system creates a hypoxic environment and sucks out bacteria and debris therefore reduces colony count) and increases localized blood flow, thereby supplying the wound with oxygen and nutrition to promote granulation and hence accelerate the healing wound surface area.9

This study aimed to compare the diabetic wound healing with vacuum assisted closure with that of the conventional dressing method.

Diabetic foot ulcers are frequent, affecting 15% of all diabetics over the course of their lives. It is now recognized that 15 To 20% of individuals with severe foot ulcers require amputation. Diabetic foot ulcers are the cause of over 85 percent of amputations.7,10Numerous risk factors for the development of foot ulcers have been proposed, with peripheral sensory neuropathy being the most important, followed by peripheral vascular disease. In diabetics, the proportion of neuropathic, neuroischemic, and simply ischemic lesions is 54, 34, and 10%, respectively. It is estimated that nearly 40,000 legs are amputated in India each year, with 75 percent of them being neuropathic with subsequent infection, which is potentially preventable. Certain variables, such as barefoot walking, illiteracy, low socioeconomic position, late presentation by patients, primary care physician misunderstanding of diabetic foot care, and trust in alternative systems of medicine, all contribute to this high prevalence.7,10,11

Dressings: After debridement, ulcers should be kept clean and moist yet free of excess fluids. Dressings should be chosen based on ulcer features such as the amount of exudate, desiccation, or necrotic tissue. Some dressings just provide protection, whilst others enhance wound hydration or prevent excessive wetness. Wet-to-dry saline dressings are commonly employed, although they can remove both nonviable and viable tissue, resulting in a dry wound. Other dressings are impregnated with antimicrobial substances to prevent infection and promote ulcer healing. There is no high-quality evidence to demonstrate any significant differences in wound healing results when comparing various types of dressings for the therapy of diabetic foot ulcers.25,26

Negative pressure wound therapy (NPWT): NPWT, also known as vacuum-assisted closure (VAC), involves applying regulated sub-atmospheric pressure to the ulcer's surface. NPWT promotes healing by enhancing wound perfusion, decreasing edema, decreasing the local bacterial burden, and boosting granulation tissue development. The indications, contraindications, and applications of negative pressure wound therapy systems are covered in detail.

Components of NPWT system-Wound filler

Wound fillers are frequently made of polyurethane foam, polyvinyl alcohol foam, and saline soaked gauze.Traditionally, polyurethane (PU) foam (black foam) is utilized in VAC. Because PU foams are hydrophobic, they adhere to the wound bed, establishing a foam-tissue contact, resulting in quick and dense granulation formation and are thus employed in wounds with substantial defects. Polyvinyl (white) foam is hydrophilic, and because of its tensile strength and minimal adhesion, it is recommended for tunnels and shallow undermining ulcers. Saline-soaked gauzes are easy to apply to uneven wounds. These white foams are appropriate for use in wounds with exposed tendons and bone. Malmsjo et al demonstrated that wound healing rates are not affected by gauze or foams.

Negative pressure is used to seal the wound by employing an adhesive dressing, often polyurethane that is cut to the size and form of the wound. The use of idophore-alcohol adhesive dressings is also discussed, which are thought to be a better adhesive and have anti-bacterial properties that inhibit bacterial colonization. The sealed dressing is attached to the negative pressure source, which may or may not be portable, depending on whether it is powered by external power or batteries. The canisters capture the exudate pulled into the wound by the vacuum.41

Mechanism of action

NPWT stabilizes the wound environment by creating a moist (optimal for wound healing) environment that is insulated from the outside environment. It is hypothesized that NPWT stabilizes the osmotic and oncotic pressure gradients at the wound surface by draining both fluids with electrolytes and proteins.42 Oedema impedes wound healing by increasing tissue pressure, which compromises tissue perfusion and, as a result, cell death. It also reduces the proliferative response of cells by compressing them and lowering their intrinsic tension. Thus, NPWT evacuation of oedema induces a decrease in interstitial pressure, which, when it falls below capillary pressure, opens the capillaries and increases vascularity, aiding wound healing.41–43 VAC accelerates the wound healing. The normal wound healing progress through the following phases44- Hemostasis, Inflammation, Proliferation, Remodeling

Direct effects: The negative pressure system's semipermeable dressing maintains a wet and warm environment that is stable and more favourable to wound healing. The closed system creates a pressure gradient between the wound and the suction canister, promoting fluid transport from the wound bed to the interstitial space and therefore lowering wound edema. Fluid is extracted by applying pressure, similar to how compression stockings help with fluid clearance in venous stasis illness.

The actual pressure applied varies but is usually in the region of 5 to 10 mmHg. The exact pressure experienced depends on the negative pressure delivered, the nature of the wound, and its application (whether circumferential, a cavity, or a surface). Clinical judgment should therefore dictate the pressure settings applied, as certain patients' circulation may be impaired.

Indirect effects: associated with variety of indirect effect that promote the wound healing, which includes Alteration in blood flow, Diminished inflammatory response,Altered bacterial burden,Changes in wound biochemistry

Contraindication- Exposed vital structures, Presence of malignant tissue,Ischemic wound, Ongoing infection or devitalized tissue, Fragile skin, Adhesive allergy

Complications: NPWT is generally safe and well tolerated. The complications can be Bleeding, Pain, Infection, Enterocutaneous fistula

II. Review Of Literature

Kerstein MD et al (1994) worked on moist wound healing of diabetic foot where he showed; A chronic wound should prompt the health care professional to begin a search for unresolved underlying causes. Healing a chronic wound requires care that is patient centred, holistic, interdisciplinary, cost effective and evidence based. In many cases the underlying causes and factors interfering with wound healing may be mutlifactorial, an elderly patient who suffered trauma. Wounds may be classified by several methods, their aetiology, location, type of injury presenting symptoms, wound depth and tissue loss or clinical appearance of the wound Research work on acute wounds in an animal model shows that wounds heal in four phases. It is believed that chronic wounds must also go through the same basic phases. Some authors combine the first two phases. The phases of wound healing are Hemostasis, Inflammation, Proliferation or Granulation and Remodeling or Maturation, While there is still no superior substitute for reconstruction using patients own tissues and carefully thought-out reconstructive procedures; new products can help facilitate eventual healing by providing prophylaxis against

barriers to healing, augmentation of wound healing factors, assistance in temporizing and bridging time to definitive repair, and optimization of the ultimate results of wound reconstruction.45

Fleischmann W et al. worked on effectiveness of wound healing in vacuum assisted closure, where he showed; 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 burdens. Vacuum-assisted closure (VAC) therapy has been developed as an alternative to the standard forms of wound management, which incorporates the use of negative pressure to optimize conditions for wound healing and requires fewer painful dressing changes. Patients managed with VAC had increased rate of repithelialization and fewer patients required repeat split thickness skin graft to the same site. VAC was more effective at treating various chronic and complex wounds, as there was a significantly greater reduction in wound volume, depth and treatment duration.VAC results in better healing than standard methods, with few serious complications. More rigorous studies with larger sample sizes assessing the use of VAC therapy on different wound types are required.46

Müller G., et al worked on effectiveness of VAC therapy in diabetic wound care, where he showed that they used the vacuum-sealing technique in more than 300 patients. We have seen several advantages: clean and sterile wound dressing and safe wound healing. In addition, we have used the technique successfully in infected areas in combination with alloplastic material. The only problem we found is the dependency on operating theatres and a vacuum. We think the technique should be recommended for septic wounds in surgery.47

Müllner T, et al. worked on use of VAC therapy in infected soft tissue defects. Where they showed a prospective clinical trial from January 1994 to February 1996, evaluating the efficacy of a vacuum sealing technique in dealing with sacral pressure ulcers, acute traumatic soft tissue defects and infected soft tissue defects following rigid stabilization of lower extremity fractures in 45 patients. Polyvinyl foam under negative pressure generates an area of high contact forces at the wound/foam interface. This situation appears to facilitate granulation tissue production while maintaining a relatively clean wound bed. In 84% (38/45) of the patients the use of the vacuum sealing technique following irrigation and debridement decreased the dimensions of the initial wound, thus facilitating healing time and the eradication of any pre-existing infection. Wound closure by granulation, secondary closure, or split thickness skin grafting was achieved in 35 wounds. The vacuum sealing technique is an effective option in the management of infected wounds.48

Peter A. Blume, et al (2008) worked on comparison of Vacuum assisted closure with advanced moist wound therapy, where he showed Diabetic foot disease is a major health problem, which affects up to 15% of the more than 200 million patients with diabetes worldwide and is associated with an increased risk of amputation. Vacuum- Assisted Closure (V.A.C.) Therapy has been shown to be effective in the treatment of diabetic foot wounds. In two parallel randomized controlled trials they 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). 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). 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. 49

In a study by Paola LD et al., (2010) to assess the effectiveness of vacuum assisted closure therapy for treatment of diabetic foot wounds. The patients were compared with two arms, one group patients treated with the VAC and other group patients were treated with open minor amputation, which were randomly allocated. Study demonstrated 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.50

Nather A et al (2011) worked on Role of negative pressure wound therapy in treatment of diabetic foot, in which he proposed. There is a definite role for VAC therapy for diabetes foot ulcers. However, the treatment regime for diabetes wounds is different from that following trauma surgery and surgery for musculoskeletal oncology. A more intensive programme is required for diabetes wounds. The author has found VAC therapy to be particularly useful for the following: Diabetic wounds which after debridement show exposed bone, tendon, joint capsule or fascia. VAC therapy can promote the production of granulation tissue over bone, tendon, capsule or fascia. However, this takes a much longer time. Large wounds after debridement for necrotising fasciitis and Ray amputation wounds.51

Sinha K et al (2013) worked on vacuum assisted closure therapy versus standard wound therapy. Where he proposed that the study was performed to evaluate the results of vacuum assisted wound therapy in patients with open musculoskeletal injuries. The size of soft tissue defects reduced more than 5 mm to 25 mm after VAC (mean decrease of 26.66%), whereas in standard wound therapy, reduction in wound size was less than 5 mm. Vacuum assisted wound therapy was found to facilitate the rapid formation of healthy granulation tissue on open wounds in the upper limb and lower limb, thus to shorten healing time and minimize secondary so tissue defect coverage procedures.52

In a study by Ravari H et al., (2013) worked on Use of Vacuum assisted closure therapy in the treatment of diabetic foot wound, where he showed improvement of the wound in the form of reducing the diameter and depth and increasing proliferation of granulation tissue was significant in most of the patients of the VAC group after two weeks. Satisfaction of patients in the VAC group was evaluated as excellent as no amputation was done in this group. Wagner score was reduced in both the study groups, although this decrement was not significant in the moist dressing group.VAC appears to be as safe as and more efficacious than moist dressing for the treatment of diabetic foot ulcers.53

In a prospective study by Lavery LA et al., to assess the negative pressure wound therapy with low pressure and gauze dressing to treat the diabetic foot wound. After four weeks of therapy, 43 percent of trial participants had at least a 50 percent reduction in wound area. Our findings imply that using low pressure and a gauze contact could result in a high rate of wound closure.54

Ali M. Lone, Et al (2014) worked on vacuum assisted closure vs conventional dressing in the management of diabetic foot, where he proposed the purpose of this study was to evaluate the safety and clinical efficacy of negative pressure wound therapy (NPWT) compared with advanced moist wound therapy (AMWT) to treat foot ulcers in diabetic patients. This multicenter randomized controlled trial enrolled 342 patients with a mean age of 58 years; 79% were male. Complete ulcer closure was defined as skin closure (100% re-epithelization) without drainage or dressing requirements. Patients were randomly assigned to either NPWT (vacuum-assisted closure) or AMWT (predominately hydrogels and alginates) and received standard off-loading therapy as needed. The trial evaluated treatment until day 112 or ulcer closure by any means. Patients whose wounds achieved ulcer closure were followed at 3 and 9 months. Each study visit included closure assessment by wound examination and tracings. NPWT appears to be as safe as and more efficacious than AMWT for the treatment of diabetic foot ulcers. Randomized case–control study enrolling 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.VAC therapy significantly decreases the time to complete wound healing, hastens granulation tissue formation, and reduces the ulcer area compared to conventional dressing. The study did not find any significant increase in the bleeding and infection in the VAC therapy group.1

Khan A et al (2016) worked on Diabetic foot ulcer. Diabetic foot ulcer is one of the common presentations of diabetic foot. The diabetic foot may be defined as a group of syndromes in which neuropathy, ischemia and infection lead to tissue breakdown, resulting in morbidity and possible amputation (World Health Organization, 1995) According to the diabetes atlas 2013 published by the International Diabetes Federation, the number of people with diabetes in India currently is 65.1million, which is expected to rise to 142.7 million by 2035. Management of the surgical patient with diabetes should be based on knowledge of the path physiology of diabetes and on an assessment of its chronic complications.55

In a study by Amin N et al., (2016) to assess the foot at risk to the novel diabetic ulcer treatment modalities. A proper assessment of diabetic foot ulcers and care ensures a better prognosis. Revascularization operations, wound debridement, infection therapy, and ulcer offloading are used in management. The management and kind of dressing used are adapted to the type of wound and the state of the foot. The purpose of this review paper is to discuss the diabetic foot syndrome, beginning with the assessment of the foot at risk for ulceration and progressing to innovative treatment techniques.56

In a randomized controlled trial by Dsouza C et al., (2017) to assess the effectiveness of low cost hospital made VAC dressing with conventional dressing in healing of diabetic foot ulcer. In this study, it was discovered that 76.7 percent of the ulcers in the VAC dressing group developed red granulation tissue at the end of therapy, compared to 46.7 percent in the traditional group. The average wound bed preparation time in the traditional dressing group was 15.60 days and 8.50 days in the VAC therapy group. At the completion of therapy, 72.73 percent of ulcers in the VAC group had no bacteria. Vacuum Assisted Closure therapy was found to be more successful than standard dressings in the wound bed preparation of diabetic foot ulcers in this study.57

In a retrospective study by Sukur E et al., (2018) to assess the vacuum assisted closure versus the moist dressing in treatment of diabetic wound after the partial foot amputation. The average time to reach 90 percent granulation tissue in group A was much shorter (7.8 ±1.2 weeks vs. 11.1 ±1.2 weeks; $p< 0.001$). However, there was no significant difference in reamputation required between groups A and B, with 38.7 percent (12 patients) in group A and 41.2 percent (14 patients) in group B ($p = 0.839$). According to the findings of this study, the VAC therapy system appears to be an effective treatment for patients with complex DFUs who have previously undergone partial foot amputation.58

In a randomized controlled trial by Janmes SMD et al., (2019) to assess the vacuum assisted closure therapy benefits in treating the DFUs. A total of sixty patients were randomly assigned to one of two groups, with 27 in each group being studied. In the VAC group, the mean time to healing in days was substantially shorter (22.52 vs. 3.85; $P<0.0001$). The VAC group required considerably shorter time to attain 75 percent -100

percent granulation tissue cover (23.33 vs. 32.15; P<0.0001). The rate of granulation tissue formation in the VAC group was also observed to be considerably higher (2.91 cm2/day vs. 2.16 cm2/day; P = 0.0306). There was no difference between the two groups in terms of wound infection or bleeding, both of which are usually associated with VAC therapy. At week three, the VAC therapy group experienced considerably less discomfort (Visual Analog Scale score 3 vs. 4; P = 0.004). When compared to standard dressing, VAC therapy considerably lowers the time to complete wound healing, accelerates granulation tissue production, and reduces ulcer area. The VAC therapy group had no significant increase in bleeding or infection, according to the study.59

In a review study by Agarwal P et al., (2019) to assess the vacuum assisted closure or negative pressure wound therapy for treating the diabetic foot ulcers. On the third day, the VAC dressings are changed. Negative pressure therapy enhances tissue perfusion and stimulates granulation tissue and angiogenesis while stabilizing the wound environment, reducing wound edema/bacterial burden, and stimulating granulation tissue and angiogenesis. All of this increases the chance of primary wound closure and decreases the necessity for plastic operations. In terms of wound volume, depth, treatment duration, and cost, VAC therapy appears to be a simpler and more effective option than standard bandages for the management of severe wounds. 60

In a study by Vemulapalli SV et al., (2020) to compare the negative pressure dressing versus the conventional dressing in DFUs. Granulation tissue occurred in 28 patients in Group I by the end of Week 2, whereas it appeared in 11 patients in Group II by that time. By 4 weeks, the wound in Group I was more suitable for grafting than the one in Group II. The current study found that the negative pressure dressing group had a higher rate of granulation tissue formation, overall graft survival, and patient compliance than the traditional dressing group.61

In a prospective randomized controlled study by Hussein A et al., (2020) to assess the outcome of VAC versus conventional dressing in treating the diabetic foot ulcer. Wound bed healing was demonstrated by the development of granulation tissue in 11 of 15 patients (73.3 percent) in the VAC therapy group. One week after starting treatment, four patients (26.7 percent) developed granulation in conventional treatment. (P=0.01). Average granulation as a percentage of ulcer area was statistically significant, and it was considerably higher in vacuum dressing. It was 50.2 18.9 in the conventional treatment group and 77.4 19.3 in the NPWT group (p = 0.005). Furthermore, at the conclusion of the investigation, we discovered that the total mean cost in the conventional dressing group was 1993 193 EP compared to 2261 183 EP in the VAC group. Finally, there was a variation in the total cost. Despite being more expensive, VAC therapy offers a shorter hospital stay and faster healing time when compared to standard dressing. They concluded that Negative pressure wound therapy (NPWT) with vacuum-assisted closure (VAC) was more effective than standard therapy in the treatment of diabetic foot ulcers. NPWT patients were in the hospital for much less time than standard dressing patients, using fewer hospital services. This, in turn, reduces the hospital's overall budget.62

In a prospective controlled study by Ramula M et al., (2020) to assess the impact of VAC in management of non-healing ulcer. By the seventh week, 94 percent of the VAC group had no discharge, compared to only 56 percent of the standard dressing group. Granulation tissue was found in 100% of patients in the VAC group but just 63% in the standard dressing group. In our study, patients treated with VAC dressing shown comparable wound reduction capabilities, with an average wound size reduction of 58% compared to the traditional dressing group, which had an average wound size reduction of 26%. In the VAC group, the majority of lesions healed in 7 weeks. In the VAC group, patient satisfaction was significantly higher than in the standard dressing group. The use of VAC is possible, dependable, and cost-effective in the treatment of chronic non-healing ulcers.63

In a prospective randomized study by Mousa A et al., (2020) to assess the therapeutic effect of vacuum assisted closure, hyperbaric and conventional dressing for chronic diabetic ulcer of foot. There was a considerable reduction in wound size in group A, which had a mean of 70.25 percent, group B, which had a mean of 62.65 percent, and group C, which had a mean of 32.46 percent. When it came to the commencement of healthy granulation tissue production, group A had a mean of 6.5 days, group B had a mean of 7, and group C had a mean of 14 days. In group A, the frequency of debridement sessions and local wound complications were much lower than in the other two groups. In the treatment of diabetic foot infection, vacuum-assisted closure (VAC) therapy looks to be safer, more effective, and less prone to problems than the other two treatments, and it can be used in conjunction with HBOT if necessary.64

In a study by Anandi A et al., (2020) to assess the advantages of VAC over the conventional dressing in the management of chronic non-healing diabetic ulcer. In both cases and controls, the grade of the ulcer distribution was nearly comparable. The chi-square test revealed a ‘P' value greater than 0.05, indicating that the result was statistically insignificant. The chi-square test revealed that the study was not significant because the p-value was greater than 0.05. As a result, the VAC dressing had a nearly identical effect on the normal Doppler study in both the case and control groups. However, VAC dressing performed better in patients with normal Doppler studies. The chi-square test revealed a statistically significant correlation with a p-value less than 0.001. Patients who had sterile pre-VAC cultures did not become unsterile following VAC. However, after VAC, 90%

of the unsterile becomes sterile. The use of VAC dressings resulted in a shorter hospital stay. The use of VAC dressing increased the sterility of pus cultures. VAC dressing improved outcomes by reducing amputations and increasing the number of patients having skin grafts.65

In a comparative study by Kumar GP et al., (2021) to assess the microbilogical and histopathological changes in wound managed by VAC and conventional dressing method. Among the paitents Males were 76 percent of patients, while females were 24 percent. Histopathologically, group B had much less necrosis and inflammatory cell infiltrate than group A. Angiogenesis was significantly higher in group B. On microbiological grounds, Pseudomonas aeruginosa was determined to be the most frequent bacteria in both groups on days 0 and 10. However, when compared to group A, the prevalence of infection in group B was significantly lower. When compared to standard dressing, VAC therapy is a better technique for treating diabetic wounds because it increases angiogenesis while lowering necrosis, inflammatory cell infiltrate, and microbial development.66

III. Aim Of Study

The aim of study was to clinico-pathological study of diabetic foot with special reference to role of vacuum assisted closure in management of diabetic foot,

IV. Objectives Of Study:

In this prospective cohort study we intend

1. To compare and obtain reliable clinical data on role of Vacuum Assisted Closure in diabetic foot healing vs role of conventional Saline and Eusol dressing on the wound.
2. To compare the pain intensity in test and control group
3. To compare the outcome of treatment of diabetic foot ulcer among the test and control group

V. Methodology

We carried out a prospective study of the role of negative pressure wound therapy (VAC) by indigenous method for open wounds cases admitted in SUBHARTI Hospital, MEERUT (U.P.). Permission and Approval of Ethics Committee was taken before starting the study. all patients with diabetic foot presenting to the surgery opd or casualty of Subharti Hospital, referred from medical wards of Subharti Hospital or referred from outside diagnosed as case of diabetic foot between1 Oct 2019 to 30 Sep 202 . 50 patients were included in the study. Details of cases was recorded including history and wound characteristics. Follow up was done with wound bed score, appearance of granulation tissue after day 0, 3, 7, 10 and so on dressings.

Method of Patient Preparation for Dressing

The patient's wound(s) were assessed and then culture was taken from the wound site. Wound(s) were cleaned with antiseptic solution (Betadine) and hydrogen peroxide, and then moist sponge of the size of the wound was taken and placed over the wound with negative pressure tube attached (above the sponge) depending upon the type of wound. The whole wound along with the sponge and one end of the tubing is covered with a plastic adhesive dressing, thereby creating a negative sub-atmospheric environment. The other end of the tube is attached to the suction machine and a negative pressure between 125-200 mm Hg is created depending upon the type of wound.

Assessment of these wound(s) was done on a regular basis by wound bed score. Assessment of rate of granulation was done on day 3rd, day 7th and day 10th. Based on the rate of granulation, definitive surgical intervention (skin grafting, secondary closures and flap cover procedures) was done. The patient was sent home after performing the definitive surgical intervention.

Follow-up was done after 5-7 postoperative days.

Assessment of complications and secondary infections were done, recovery was also assessed.

All the data was collected in the study proforma and entered in excel sheet. The data are summarized as frequency, percentage, mean and standard deviation and presented using the tables, figures, bar diagram and pie chart. The mean difference between the independent continuous data was analysed using student t-test and for dependent paired variables using the paired t-test. The statistical difference between the categorical data was analysed using the chi-square test. All the data were analysed using the statistical software SPSS v21 operating on windows 10, considering a $p<0.05$ as statistically significant.

VI. Results

Total of 50 patients fulfilling the inclusion criteria were included in present study after obtaining the informed consent. They were divided into two groups, Group A with Vacuum Assisted Closure in diabetic foot healing and group B as conventional Saline and Eusol dressing on the wound.

Mean of the patient in Group A with Vacuum Assisted Closure in diabetic foot healing was 44.20 and group B as conventional Saline and Eusol dressing on the wound was 48.68. Number of males were 13 and number of females were12 in both Group A and Group B. 8 patients in group A and 6 in group B had diabetes

from less than 5 year . 9 patients in group A and 11 in group B had diabetes from 5-0 10 years. 8 patients in both group A and group B had diabetes from more than 10 years.Only 15 patient in group A and 16 patient in group B were taking regular treatment. Wound bed score and rate of granulation on Day 3, 7, and 10 was compared between both the groups and p value came significant which showes better wound score in Group A Vacuum Assisted Closure than in Group B Conventional Saline and Eusol dressing

Comparison of mean level of wound bed score between two groups using student's t-test					
	Vacuum Assisted Closure		Conventional Saline and Eusol dressing		p-value
	Mean	SD	Mean	SD	
Wound bed score day 1	6.40	1.35	6.56	1.69	0.713
Wound bed score day 3	9.56	1.23	8.00	1.26	0.001**
Wound bed score day 7	11.56	1.00	10.32	.69	0.001**
Wound bed score day 10	13.44	1.12	12.24	1.01	0.001**

Comparison of rate of granulation (%) between two groups using student's t-test					
	Vacuum Assisted Closure		Conventional Saline and Eusol dressing		p-value
	Mean	SD	Mean	SD	
Rate of Granulation day 3 (%)	34.68	4.52	33.20	6.87	0.373
Rate of Granulation day 7 (%)	56.08	5.14	47.96	5.25	0.001**
Rate of Granulation day 10 (%)	67.16	6.41	61.36	5.16	0.001**

Showing the change in mean level of wound bed score in group A patients using paired t-test				
		Mean	SD	p-value
Pair 1	Wound bed score day 1	6.40	1.35	0.001**
	Wound bed score day 3	9.56	1.22	
Pair 2	Wound bed score day 1	6.40	1.35	0.001**
	Wound bed score day 7	11.56	1.00	
Pair 3	Wound bed score day 1	6.40	1.35	0.001**
	Wound bed score day 10	13.44	1.12	

Showing the change in mean level of rate of granulation (%) in group A patients using paired t-test				
		Mean	SD	p-value
Pair 1	Rate of Granulation day 3 (%)	34.68	4.51	0.001**
	Rate of Granulation day 7 (%)	56.08	5.13	
Pair 2	Rate of Granulation day 3 (%)	34.68	4.51	0.001**
	Rate of Granulation day 10 (%)	67.16	6.41	

Showing the change in mean level of wound bed score in group B patients using paired t-test				
		Mean	SD	p-value
Pair 1	Wound bed score day 1	6.56	1.68	0.001**
	Wound bed score day 3	8.00	1.25	
Pair 2	Wound bed score day 1	6.56	1.68	0.001**
	Wound bed score day 7	10.32	.69	
Pair 3	Wound bed score day 1	6.56	1.68	0.001**
	Wound bed score day 10	12.24	1.01	

Showing the change in mean level of rate of granulation in group B patients using paired t-test				
		Mean	SD	p-value
Pair 1	Rate of Granulation day 3	33.20	6.87	0.001**
	Rate of Granulation day 7	47.96	5.25	
Pair 2	Rate of Granulation day 3	33.20	6.87	0.001**
	Rate of Granulation day 10	61.36	5.16	

VII. Discussion

Considerable proportion of patients with diabetes mellitus develops diabetic foot ulcers (DFU). Incidence of DFU ranges from 1% in the West to as high as 11% in African populations.68 DFU comprise the most common cause of non-traumatic amputation preceding as high as 85% of the cases.69 Mortality rate among DFU patients is almost twice than in diabetics without DFU. Five-year mortality rates after new onset DFUs have been reported between 43%-55%, and; 74% mortality has been reported in DFU patients with major amputation. Another major concern is the cost in treating DFUs. In 2007, 33% of the total cost in treating diabetes and its related complication was linked to DFUs. It was found that the cost of care in patients with DFUs was over five times higher in the first year than in diabetics without foot ulcers.70 This is mainly due to the long duration of hospital stay needed in DFU patients. The magnitude of problems is of more significance in India; owing to poor level of health education, inadequate health care system and as majority of the DFU patients belong to the lower socio-economic strata. VAC has emerged as one of the most effective methods of wound care for DFUs and has shown to enhance and fasten healing.

In present study, total of 50 patients enrolled in the present study, after obtaining the informed consent from all. The mean age of the participants was 46.02±15.6yrs of age. Among them, 25 were male and 25 were female participants. The mean age of participants in group A was 44.20±16yrs and in group B was 48.68±14.45yrs of age, this finding was not statistically different.

Duration of diabetes was found to be equally distributed between two groups. Majority of the patients had diabetes mellitus for duration of 5 to 10yrs of age in both the group. There was comparable duration of diabetes between the groups. Majority of patients in both the groups were on regular treatment for the diabetes mellitus.

The wound bed score between the two groups showed a significant difference. The wound bed score at the day 1 was comparable between the groups and was not statistically different. However, the wound bed score showed a significant difference between the groups at the follow-up days of 3, day 7 and day 10, with better scores in the group A compared to group B patients. ($p<0.001$) The rate of granulation between the two group showed a significant difference. The rate of granulation on the day 3 did not show any significant difference between the two groups, however marginal better score in the group A. the rate of granulation was found to be significantly better in the group A patients compared to group B patients on follow-up days of day 7 and day 10. ($p<0.001$) Similar to present study, Paola L et al., demonstrated 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.50 Fleischmann W et al., found that patients managed with VAC had increased rate of repithelialization and fewer patients required repeat split thickness skin graft to the same site. VAC was more effective at treating various chronic and complex wounds, as there was a significantly greater reduction in wound volume, depth and treatment duration.VAC results in better healing than standard methods, with few serious complications. More rigorous studies with larger sample sizes assessing the use of VAC therapy on different wound types are required.46

Within the group A, the wound bed score showed betterment with the follow-up days. The mean score was lowest at the day 1 and improved with the follow-up days. There was significant improvement in the mean score at follow-up day 3, day 7 and day 10 compared to the day 1 of the treatment. Similarly, the rate of granulation was better with the duration of follow-up. The rate of granulation was significantly better on day 7 and day 10 compared to day 3 of the follow-up.($p<0.001$) Mullner T et al., demonstrated that negative pressure generates an area of high contact forces at the wound/foam interface. This situation appears to facilitate granulation tissue production while maintaining a relatively clean wound bed. In 84% (38/45) of the patients the use of the vacuum sealing technique following irrigation and debridement decreased the dimensions of the initial wound, thus facilitating healing time and the eradication of any pre-existing infection. Wound closure by granulation, secondary closure, or split thickness skin grafting was achieved in 35 wounds. The vacuum sealing technique is an effective option in the management of infected wounds.48 Within the group B, the wound bed score showed betterment with the follow-up days. The mean score was lowest at the day 1 and improved with the follow-up days. There was significant improvement in the mean score at follow-up day 3, day 7 and day 10 compared to the day 1 of the treatment. Similarly, the rate of granulation was better with the duration of follow-

up. The rate of granulation was significantly better on day 7 and day 10 compared to day 3 of the follow-up. ($p<0.001$) The present study showed comparable result with various other studies, with the added benefits of the vacuum assisted closure compared to conventional dressing in patients with diabetic foot ulcer.

VIII. Conclusion

This study demonstrates that vacuum-assisted dressing is a more beneficial tool for wound healing promotion, particularly in the case of non-healing and persistent ulcers. As a result, vacuum-assisted dressing is employed as an alternative and most efficient way for ulcer and wound management. This study also demonstrates that vacuum-assisted dressing is a more beneficial tool for wound healing promotion, particularly in the case of non-healing and persistent ulcers. As a result, vacuum-assisted dressing is employed as an alternative and most efficient way for ulcer and wound management. Also adds the benefit of being convenient, pain free dressing with better patient compliance and not required for daily dressing.

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