Conventional Dressings versus Vacuum-Assisted Closure and Hydrojel Dressing in the Management of Diabetic Foot Ulcers: A Prospective Case–Control Study

Ravi satasia*, Krunal solanki, Sanket katara*****

Assistant Professor, Surgery Dept. AMC MET Medical College Ahmadabad

Abstract: Comparison between conventional dressings, vacuum assisted dressing and hydrojel dressing in the healing of diabetic foot ulcerations in terms of healing duration. Method: Randomized case–control study enrolling 60 patients, divided into three groups. Group A [patients treated with VAC] and Group B [patients treated with conventional dressings] and Group C [hydrojel dressing] with an equal number of patients in each group. Diabetic foot ulcers were treated until wound closure, either spontaneously, surgically, or until completion of the 8-week period. [Ravi S NJIRM 2017; 8(3):130-134]

Key Words: diabetic foot ulcer, infections, conventional dressings, VAC (vacuum-assisted closure), wound closure, hydrojel

Author for correspondence: Ravi Satasia, 8-Shrinath Bunglows, B/H Girivar Bunglows, Ramvadi-Isanpur, Ahmedabad-382443 E-Mail: r_satasia@yahoo.com M: 9898261222

Introduction: The increasing prevalence of diabetes has resulted in concomitant illness[1]. The critical effects of hyperglycemia include micro-vascular complications (nephropathy, neuropathy and retinopathy) and macro-vascular complications (coronary artery disease, stroke and peripheral arterial disease). Diabetes is a leading cause of non-traumatic lower extremity amputation, which is often preceded by a non-healing ulcer. The lifetime risk of foot ulceration in people with diabetes is 15%-20%[2]. More than 15% of foot ulcers result in amputation of the foot or limb[3]. Several other population-based studies indicate a 0.5%-3% annual collective incidence of diabetic foot ulcers. The prevalence of foot ulcers reported varies from 2% to 10%[4]. Approximately 45%-60% of all diabetic foot ulcerations are purely neuropathic, whereas 45% have both neuropathic and ischemic components[5]. It has been estimated that around 15%-27% patients with diabetes require lower limb amputations predominantly (50%) due to infection[6].

What we do know is that wounds are more susceptible to healing in a moist, clean, and warm environment.[7] A moist wound bed will allow growth factors and numerous cell types including epithelial cells to migrate, facilitating wound edge contraction.[8] To create and maintain this environment, appropriate dressings come into play. There are four basic principles involved in choosing an optimal dressing.[9] If a wound proves to be dry or desiccated, it will need hydration. If a wound produces excessive exudates, the fluid needs to be absorbed. If a wound has necrotic tissue or evident debris, it will need debridement. Lastly, if a wound is infected, it needs to be treated with the appropriate antibacterial agent. 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. NPWT can be used to treat Charcot neuroarthropathy wounds produced as a result of neuropathy and deformity, following debridement of infection or amputation, and in reconstructive soft tissue and osseous procedures[10]. The use of sub-atmospheric pressure devices, available commercially as VAC devices, has been shown to be an effective way to accelerate healing of various wounds.

Hydrogels are complex hydrophilic organic cross-linked polymers, consisting of an 80%–90% water base. These gels are available in a free-flowing amorphous or fixed flexible sheet form. They can absorb a minimum amount of fluid by swelling, but they also can donate moisture to a dry wound, thereby facilitating autolytic debridement and maintaining a moist wound environment that is thermally insulated. They have also been shown to promote granulation and epithelialization and reduce the temperature of a wound bed by up to 5°C.35,36 They are permeable to gas and water and have proven to be a less effective bacterial barrier than occlusive dressings. The main application of these dressings is hydrating dry wound beds and softening and loosening slough and necrotic wound debris. They are unable to absorb heavy drainage due to their high water concentration; they absorb very slowly and therefore are not useful on bleeding wounds, and they generally require a secondary dressing. They can be used on a variety of wounds including pressure ulcers,

partial and full-thickness wounds, and vascular ulcers. Maceration can be of concern, as periwound skin areas need to be protected from excess hydration. Among its benefits, hydrogels can be used in conjunction with topical medications or antibacterial agents. The fixed form of hydrogels should not be used in infected wounds. Hydrogels need to be covered with secondary dressings while remaining in place for up to 3 day.

Methods: This study was conducted in the departments of general surgery at L.g hospital in ahmedabad . It was a randomized case–control study to compare the effectiveness of VAC with conventional dressings and hydrojel dressing in the healing of DFU. The study population included patients with DM aged 40–70 years, with stage 2 or 3 DFU (as defined by Wagner's classification[10], randomized either to Group A [patients treated with VAC] or Group B [patients treated with conventional dressings],and Group C[patient treated with hydrojel dressing] with an equal number of patients in each group (n=20). Patients aged <40 or >70 years, pregnant or nursing mothers, patients with foot ulcers other than diabetes, osteomyelitis of the underlying bone, peripheral vascular disease, comorbidities involving respiratory, cardiovascular or other systems of the body, were not included. Similarly, people on medications, such as corticosteroids, immunosuppressive agents or chemotherapy, were also not included. A detailed history, clinical examination and relevant investigations were performed in all patients. An institutional ethical committee approved the study.

Before starting the treatment, patients were made to understand in their local language and informed consent was obtained before randomizing into the three groups. Group A and C composed of patients with an even hospital medical record number and Group B composed of patients with an odd hospital number. Wounds of all the patients included in the study underwent sharp surgical debridement initially and during subsequent dressing change to remove necrotic tissue and slough. After debridement in the emergency operation theatre, a foam-based dressing was applied over the wounds of the study group patients under all aseptic conditions. The dressing was covered with an adhesive drape to create an airtight seal. An evacuation tube embedded in the foam was connected to a vacuum and sub-atmospheric (negative) pressure was applied within a range of 80–125 mmHg on a continuous basis for 72 hours. The B group received once daily saline or betadin soaked gauze dressing. Analgesics were administered to all groups of the patients at the time of changing the dressing. After every 3 days, cultures were taken from the base of the ulcer to assess for the bacterial flora. Blood cultures were also taken regularly from all groups. Standard antibiotic regimens were administered to all patients, which consisted of broad-spectrum antibiotics initially and later guided by the culture sensitivity reports. Ulcers were treated until the wound was closed spontaneously, surgically or until completion of the 8-week period, whichever was earlier. Blood glucose levels were monitored strictly during treatment and controlled by appropriate doses of insulin. After wound closure, patients were followed on a regular basis. Patients who were discharged from the hospital after wound closure were followed weekly, then bi-weekly, followed by monthly and then every 2 months.

Treatment outcome and patient satisfaction was assessed in terms of time taken for wound closure, the number of antibiotics used and the need for amputation. Treatment success was defined as wound closure within a period of 8 weeks and failure, as inability of wound closure within 8 weeks. Patient satisfaction was considered to be excellent, if wound closure occurred before 8 weeks and needed only one antibiotic during treatment; very good, if the wound closed before 8 weeks and needed two antibiotics; good, if the wound closed during Week 8 with multiple antibiotics; and; unsatisfactory, if the wound did not close within the treatment period or if the patient had either one or two digits or foot amputation.

Data were entered in SPSS 14 and analyzed. Categorical variables were analyzed by using the Pearson's Chi-square/Fishers exact test. Three groups were compared using Student's t-test. Results were expressed as n (%). p-Values of <0.05 were considered to be statistically significant.

Result: A total of 60 patients with DM and grade 2–3 DFU were randomly assigned to either VAC or conventional dressing as per the pre-defined protocol with the end points of healing rate and patient satisfaction. Patients, either in VAC, hydrojel dressing or conventional group, were matched for age, gender

and duration of DM. The age of patients was between 47 and 64 years in Group A with a mean age of 53.79 years and between 48 and 62 years in Group B with a mean age of 54.57 years, and between 45 to 62 years in Group C with mean age of 53.79 Men constituted 35.71% and women around 64.28% in each group. All of the patients needed insulin for control of their DM and were initially managed with multiple subcutaneous insulin injections and followed by two doses of premixed insulin (30/70), once their glycemic control was achieved.

By Week 4, wound discharge disappeared in 35% of group a versus none in the l group band 15% in group c. Wound discharge 25% patients in Group A and seven (20%) in Group Band Group C in Week 8. Granulation tissue appeared in 14 (70%) patients by the end of Week 4 in Group A in contrast to 6 (30%) patients by that time in Group B and 8(40%) in Group C. 100% granulation was achieved in 16(80%) patients by the end of Week 5 in Group A as compared to only 8 (40%) patients by that time in Group B and 10(50%) in Group C. Granulation tissue was defined in terms of gross appearance of ulcer (based on time to 76–100% formation in wound bed (Table 1).

Table 1: Safety and efficacy of VAC over conventional dressings in the treatment of diabetic foot ulcers

Patient characteristics	Group a	Group b	Group c
Age (mean±SD years)	53.79	54.57	53.79
100% granulation (*N*)	20	20	20
Week 4 (%)	14 (70%)	6(30%)	8(40%)
Week 5	2(10%)	2(10%)	2(10%)
Week 6	1(5%)	2(10%)	2(10%)
Week 7	0	1(5%)	1(5%)
Week 8	0	1(5%)	1(5%)
Never during treatment	3(15%)	8(40%)	6(30%)
Disappearance of wound discharge			
Week 2	1(5%)	0	0
Week 3	2(10%)	0	0
Week 4	7(35%)	0	3(15%)
Week 5	2(10%)	3(15%)	4(20%)
Week 6	1(5%)	6(30%)	5(25%)
Week 7	2(10%)	7(35%)	4(20%)
Week 8	5(25%)	4(20%)	4(20%)
Blood culture positivity	8(40%)	10(50%)	7(35%)
Change in wound size			
Decrease	14(70%)	10(50%)	12(60%)
No change	3(15%)	7(35%)	5(25%)
Increase	1(5%)	2(10%)	3(15%)
Need for amputation	1(5%)	2(10%)	0
Spontaneous wound closure	2(10%)	1(5%)	1(5%)
Endpoint reached			
Yes	18(90%)	12(60%)	13(65%)
No	2(10%)	8(40%)	7(35%)

Wound size decreased in 14(70%) patients in Group A as compared to 10 (50%) patients in Group B and 12(60%) patient in Group D . One patient required amputation in Group A as compared to two in Group B. The majority of wounds were closed by a split-thickness skin graft in all groups. Treatment was successful in 90% of patients in Group A and 60% of patients in Group B and 65% of patient in Group C.

Discussion: VAC has been advocated as a novel method in the healing of DFU by stimulating the chronic wound environment in such a way that it reduces bacterial burden and chronic interstitial wound fluid, increases vascularity and cytokine expression and to an extent mechanically exploiting the viscoelasticity of periwound tissues10. VAC is generally well tolerated and, with few contraindications or complications, is fast becoming a mainstay of current wound care. Hence, we planned to use VAC for the treatment and fast healing of DFU. Our study composed of 60 patients who were randomly divided into three groups. The demographic profile was statistically studied and found comparable with no significant difference between the all groups. The mean age was comparable to the previous multicenter randomized controlled trial, enrolling 342 patients, who had a mean age of 58 years[11].

Application of negative pressure over the wound bed allows the arterioles to dilate, increasing the effectiveness of local circulation, promoting angiogenesis, which assists in the proliferation of granulation tissue[12]. We observed that the patients on VAC therapy had the early appearance of granulation

tissue as compared to the patients treated by moist saline gauze dressings. Complete (100%) granulation was achieved earlier and in a higher proportion of patients in Group A as compared to Group B,however granulation in Group C was better than Group B. Similar observations were made in a series of animal studies using a sub-atmospheric pressure technique for wound healing. Armstrong and Lavery observed that the use of negative pressure therapy resulted in an increased rate of granulation tissue formation and a higher proportion of healed wounds compared to saline gauze dressings. We observed that the rate of disappearance of wound discharge was faster in Group A as compared to Group B and Group C which was statistically significant , similar to observations made previously[13]. The patients who underwent amputation were excluded from this analysis.

Colonization of a wound, corresponding to a level of >105 colonies of bacteria per gram of tissue, has been recognized as a detrimental factor in the process of wound healing. VAC therapy enhances bacterial clearance, which may account for the wound healing effects. Blood culture positivity was less with patients in Group A compared to Group B and Group C. However, blood culture negativity was documented earlier in Group A patients as compared to Group B and Group C patients. The majority of wounds in the VAC group decreased in size as compared to that in the conventional group and hydrojel group). McCallon et al. observed an average decrease of 28.4% (±24.3) in wound size in the VAC group as compared to 9.5% (±16.9) average increase in wound size in the control group (treated by saline-moistened gauze dressings) [14]. Mark et al. had also observed that the wound volume and depth decreased significantly in VAC dressings as compared to moist gauze dressings[15]. We observed the safety of VAC over saline-moistened gauze dressings, in terms of fewer numbers of secondary amputations in Group A as compared to Group B. While assessing the safety of VAC, Blume et al. also reported fewer numbers of secondary amputations in VAC treated patients as compared to those treated by gauze dressings[16]. In our study, the endpoint taken was a completely granulated wound or a wound ready for skin grafting or spontaneous healing by secondary intention.

All of the groups received similar treatment for the closure of the wound, the most common mode of wound closure being a split-thickness skin graft. In 80% of patients, wounds were closed by a split-thickness skin graft in Group A as compared to 90% of patients in Group B and 88% in Grouo C. The rest of the patient's wounds were closed spontaneously. Our observations are consistent with those of Prabhdeep et al. who also reported a split-thickness skin graft as the most common mode of wound closure[17]. In Group A patients, overall lower doses of insulin were required to control hyperglycemia compared to Group B and Group C. Success rate in terms of complete granulation and readiness for closure by split-thickness skin grafting or secondary intention was more in Group A compared to other Group and the need for amputation was more in Group B. Armstrong et al. observed that NPWT delivered by VAC .device was safe and effective treatment for complex diabetic foot wounds and could lead to a higher proportion of healed wounds, faster healing rates and potentially fewer re-amputations than standard care

Conclusion: VAC appears to be more effective, safe and patient-satisfactory compared to conventional dressings and hydrojel dressing in the treatment of foot ulcers in people with DM

References:

1. IDF Diabetes. Chapter 2: The global burden. 2013. pp. 29–49. Available from: http://www.idf.org/sites/default/ files/EN_6E_Ch2_the_Global_Burden.pdf.
2. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. JAMA. 2005;293:217–228.
3. Reiber GE. Epidemiology and health care costs of diabetic foot problems. In: Veves A, Giurini JM, LoGerfo FW, editor(s) , editors. The Diabetic Foot. New Jersey: Humana Press; 2002. pp. 35–58.
4. Frykberg RG, Zgonis T, Armstrong DG, Driver VR, Giurini JM, Kravitz SR, Landsman AS, Lavery LA, Moore JC, Schuberth JM, et al. Diabetic foot disorders. A clinical practice guideline (2006 revision) J Foot Ankle Surg. 2006;45:S1–66.
5. Reiber GE, Vileikyte L, Boyko EJ, del Aguila M, Smith DG, Lavery LA, Boulton AJ. Causal pathways for incident lower-extremity ulcers in patients with diabetes from two settings. Diabetes Care. 1999;22:157–162.
6. Richard JL, Sotto A, Lavigne JP. New insights in diabetic foot infection. World J Diabetes. 2011;2:24–32. [PMC free article] [PubMe

7. Okan D., Woo K., and Ayello EA.: The role of moisture balance in wound healing. Adv Skin Wound Care 2007; 20:39.
8. Attinger CE., Janis JE., Steinberg J., Schwartz J., Al-Attar A., and Couch K.: Clinical approach to wounds: debridement and wound bed preparation including the use of dressings and wound healing adjuvants. Plast Reconstr Surg 2006; 117(7S):72
9. Morin RJ. and Tomaselli NL.: Interactive dressings and topical agents. Clin Plast Surg 2007; 34:643.
10. Wagner FW. The dysvascular foot: a system for diagnosis and treatment. Foot Ankle. 1981;2:64–122.
11. Armstrong DG, Lavery LA, Diabetic Foot Study Consortium Negative pressure wound therapy after partial diabetic foot amputation: a multicenter randomized controlled trial. Lancet. 2005;366:1704–10.
12. Blume PA, Walters J, Payne W, Ayala J, Lantis J. Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers: a multicenter randomized controlled trial. Diabetes Care. 2008;31:631–6.
13. Morykwas MJ, Argenta LC, Shelton B, McGuirt W. Vacuum-assisted closure: a new method for wound control and treatment: animal studies and basic foundation. Ann Plast Surg. 1997;38:553–62.
14. Prabhdeep SN, Sanjeev KU, Ramneesh G, Kuljyot B, Shirin G. Role of negative pressure wound therapy in healing of diabetic foot ulcers. J Surg Tech Case Rep. 2011;3:17–22.
15. McCallon SK, Knight CA, Valiulus JP, Cunningham MW, McCulloch JM, Farinas LP. Vacuum-assisted closure versus saline-moistened gauze in the healing of postoperative diabetic foot wounds. Ostomy Wound Manage. 2000;46:28–32.

Conflict of interest: None
Funding: None
Cite this Article as: Ravi s, Krunal s, Sanket k. Conventional Dressings versus Vacuum-Assisted Closure and Hydrojel Dressing. Natl J Integr Res Med 2017; 8(3):130-134