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A PROSPECTIVE CASE–CONTROL STUDY- VACUUM-ASSISTED CLOSURE VERSUS SURGICAL DEBRIDEMENT IN THE MANAGEMENT OF DIABETIC FOOT ULCERS.

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ABSTRACT

India with 42 million diabetics. Foot ulceration is the most common complication affecting approximately 15% of diabetic patients during their lifetime. The objective of the study was to compare the effectiveness of vacuum-assisted closure (VAC) versus Surgical debridement in diabetic foot ulcerations (DFUs) in terms of healing rate (time to prepare the wound for closure either spontaneously or by surgery), safety, and patient satisfaction.

METHODS: The study enrolled 40 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, spontaneously, surgically, or completion of the 8-weeks.

RESULTS: Granulation tissue appeared in 14 (70%) patients by the end of Week 2 in Group A, while it appeared in 6 (30%) patients by that time in Group B. 100% granulation was achieved in all the patients by the end of Week 5 in Group A as compared to only 10 (5%) patients by that time in Group B. Patients in Group A had fewer number of positive wound cultures, secondary amputations and had better treatment compliance as compared to Group B.

CONCLUSION: VAC therapy is useful in the treatment of diabetic foot infection s, which after debridement, may present with exposed tendon, fascia or bone. These included ray amputation wounds, wounds post-debridement for necrotising fasciitis, wounds post-drainage for abscess, a heel ulcer and a sole ulcer. VAC prepared ulcers well for closure in good time. It reduced cost of therapy by hastening the reduction of wound area. VAC therapy provided a sterile, controlled resting environment to large, exudating wounds. Large diabetic foot ulcers were thus made more manageable.

BACKGROUND:

Foot ulcerations are considered to be the most common complication of diabetes mellitus in India, affecting approximately 15% of diabetics, with a 25% lifetime risk of developing foot ulceration[1]. Worldwide, chronic wounds account for about $20 billion in healthcare costs per year[2]. Foot ulceration is the precursor to approximately 85% of all diabetic amputations, with an estimated 14% to 20% of patients with foot ulcers undergoing an amputation.[3]

Various DFU treatments have been reported in the literature, including advanced moist wound therapy (AMWT) [4,5], bioengineered tissue or skin substitutes [6,7], growth factors[8,9], electric stimulation[10], and negative pressure wound therapy (NPWT) [11]. Treatment success depends on ulcer chronicity, patient compliance, appropriate off-loading of the appendage, and the mechanisms of action of the therapy.

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 [12].

NPWT is a noninvasive system that creates a localized controlled subatmospheric (negative) pressure environment. It promotes wound healing by delayed primary or secondary intention through creating a moist wound environment, preparing the wound bed for closure, reducing edema, and promoting formation and perfusion of granulation tissue[13]. Vacuum-assisted closure therapy is indicated for use in all care settings and for a variety of wound types including diabetic foot ulcers[14].

The objective of the study was to compare the effectiveness of vacuum-assisted closure (VAC) versus Surgical debridement in diabetic foot ulcerations (DFUs) in terms of healing rate (time to prepare the wound for closure either spontaneously or by surgery), safety, and patient satisfaction.

MATERIALS AND METHODS:

This study was conducted in the department of General surgery at a tertiary care hospital in India. It was a prospective randomised case-control study to compare the effectiveness of VAC with conventional dressings in the healing of diabetic foot ulcers. The study population included patients with DM aged 18-70 years, with stage 2 or 3 DFU (as defined by Wagner's classification[15]) , divided into Group A (patients treated with VAC) or Group B (patients treated with conventional dressings), with an equal number of patients in each group (n=20). Patients aged less than 18 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 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, informed consent was obtained from all patients, and then they were randomised into group A or group B.

Wounds of all the patients included in the study underwent sharp surgical debridement in the minor operation theatre, initially and during subsequent dressing change to remove necrotic tissue and slough. Debridement entailed the excision of all necrotic and infected tissue until healthy, bleeding tissue was reached[16].

After debridement in group A, a sterile, polyurethane foam dressing was placed into the wound defect after it had been trimmed to shape. Adhesive drape was used to cover the foam and an additional 3 to 5 cm of surrounding intact skin. A slit measuring 1 to 2 cm long was created in the drape acting as the diameter of the circular hole which was cut in the drape. The non-collapsible tube was placed directly over the hole in the drape and connected to the electronic vacuum pump. Finally, negative pressure was applied to the wound via the therapy unit, causing the dressing to

collapse into the wound. Sub-atmospheric (negative) pressure was applied within a range of 80-125 mmHg on a continuous basis for 72 hours. Group B received once daily saline soaked gauze dressing.

At each dressing change, the wound was carefully assessed to determine if the wound was healthy, clean and granulating. If infection or slough had surfaced in the wound, additional surgical debridement had to be performed in the operating theatre, before a new VAC dressing or saline soaked gauze dressing could be applied.

After every 3 days, cultures were taken from the base of the ulcer to assess for the bacterial flora. Broad-spectrum antibiotics were initially administered to all patients, and later changed to antibiotics 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. Once it was decided that VAC therapy or saline soaked dressing could be stopped, the patient was subjected to secondary closure or surgical intervention by split-skin grafting. A final debridement and cleansing of the wound was performed in the operating theatre before the surgical procedure.

Treatment outcome was assessed in terms of time taken for appearance of granulation tissue and the need for amputation. Treatment success was defined as appearance of granulation tissue within a period of 8 weeks and failure, as non appearance of granulation tissue within 8 weeks or the need for amputation.

Data were entered in SPSS 16 and analyzed. Categorical variables were analyzed by using the Pearson's Chi-square/Fishers exact test. Two groups were compared using Student's t-test. Results were expressed as n (%). p-Values of <0.05 were considered to be statistically significant.

RESULTS:

A total of 40 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 appearance of granulation tissue. Patients, either in VAC or conventional group, were matched for age, gender and duration of DM. The age of patients was between 39 and 69 years in Group A with a mean age of 57.56 years and between 40 and 61 years in Group B with a mean age of 53.37 years. Men constituted 85% and women around 15% in each group.

TABLE 1: Age and sex distribution

AGE GROUPS	GROUP A	GROUP B
30-40	2	1
40-50	9	10
50-60	7	8
60-70	2	1
TOTAL	20	20

By Week 2, wound discharge disappeared in six cases of Group A (30%) versus none in the control group. Wound discharge disappeared in three patients in Group A (15%) and seven (35%) in Group B in Week 8.

TABLE 2: Disappearance of wound discharge

	GROUP A	GROUP B
Week 2	6 (30%)	0
Week 4	9 (45%)	3 (15%)
Week 6	2 (10%)	5 (25%)
Week 8	3 (15%)	7 (35%)
TOTAL	20 (100%)	15 (75%)

Granulation tissue appeared in 14 (70%) patients by the end of Week 2 while it appeared in six patients (30%) in Group B. 100% granulation was achieved in all patients by the end of Week 5 in Group A as compared to only 10(50%) patients by that time in Group B, which was found to be statistically significant (p <0.05).

TABLE 3: Appearance of granulation tissue

	GROUP A	GROUP B
Week 2	14 (70%)	6 (30%)
Week 3	2 (10%)	1 (5%)
Week 4	3 (15%)	2 (10%)
Week 5	1 (5%)	1 (5%)
Week 6	0	3 (15%)
Week 7	0	2 (10%)
Week 8	0	1(5%)
Never during treatment	0	4 (20%)

Granulation tissue was defined in terms of gross appearance of ulcer (based on time to 70-100% formation in wound bed .

Wound size decreased in 18 (90%) patients in Group A as compared to 11 (55%) patients in Group B.

Four patients (20%) in group A had positive wound cultures at the end of two weeks, while nine patients (45%) in group B had positive wound cultures.

One patient required amputation in Group A as compared to three in Group B. The majority of wounds were closed by a split-thickness skin graft in both groups.

Treatment was successful in 100% of patients in Group A and 60% of patients in Group B, which was found to be statistically significant (p <0.05).

DISCUSSION:

VAC therapy has been shown by several workers to facilitate the healing of chronic DFU[17], and 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 tissues[18], besides reducing pain caused by the wound[19]. Such a sterile, occlusive environment is not given by conventional dressings.

VAC therapy has been shown to produce a greater reduction in wound dimension than conventional dressings. Eginton et al reported a 49% and 59% reduction in the wound depth and volume, respectively, of 6 VAC-treated diabetic foot ulcers. This was significantly greater than the 7.7% reduction in wound depth and 0.1% reduction in wound volume achieved when the same wounds were treated with moist gauze dressings[20].

A freshly granulating wound surface indicates good wound healing, as the formation of granulation tissue is part of the proliferative stage of wound healing. The time from VAC therapy initiation to the achievement of a continuous and fresh bed of granulation in the wound was taken as the time needed for wound bed preparation for surgical intervention. In our study, this was achieved in all 20 cases, prior to closure via split-skin grafting or secondary closure.

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. Similar observations were made in a series of animal studies using a sub-atmospheric pressure technique for wound healing[21].

Also, it was observed that the rate of disappearance of wound discharge was faster in group A as compared to group B, similar to observations made by Prabhdeep SN et al[22].

Colonization of a wound, corresponding to a level of 10^5 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. However, blood culture negativity

was documented earlier in Group A patients as compared to Group B patients.

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 number of secondary amputations in VAC treated patients as compared to those treated by gauze dressings[23]. In our study, the endpoint taken was a completely granulated wound or a wound ready for skin grafting or spontaneous healing by secondary intention.

Skin grafting was considered in the study as one of the techniques for the management of DFU after VAC therapy or saline soaked dressings. Before making the choice to use this surgical technique, it is important to evaluate the chance of success. A sufficiently vascularized and non infected wound bed is an essential factor to obtain a good outcome.

Several studies have demonstrated the effectiveness of V.A.C. in promoting the graft take rate. Improvement of the surgical outcomes might be explained by the reduction of hematomas or exudations below the mesh graft, by the reduction of dead space, by fixation of the graft to the wound surface, and by the increased perfusion induced by V.A.C. therapy. Studies also provide evidence of a reduction in repeat skin grafting in patients treated with V.A.C. compared to those treated with conventional therapy[24].

On contemplating open surgical wounds with exposure of bone structures and tendons, we must keep in mind the need for frequent repeated surgical procedures and revisions before obtaining the final result. Obviously, this determines an extension in healing time but we firmly believe that it is an acceptable condition if the final result is salvage of the limb.

In the recent past amputation was performed at a more proximal level in order to achieve closure by primary intention, thereby not salvaging limbs which otherwise might have been saved. The use of V.A.C. in this field is of fundamental importance. Before the availability of this therapy, keeping a surgical wound open and trying to close it by second intention involved a very high risk of infection.

This type of complication is now significantly reduced, as our study has demonstrated. Therefore this has allowed us to work in a way that is more conservative compared to the past.

Nonetheless, we have shown that after only several days of treatment with V.A.C., the presence of a well cleansed and granulated tissue were achieved, even in those patients that at enrollment had little to absent granulation tissue. It is the presence of granulation tissue that is critical to determining further changes in the therapeutic approach and the clinical decision to promote closure of the wound by first or second intention, skin graft etc.

CONCLUSION:

VAC therapy is useful in the treatment of diabetic foot infections, which after debridement, may present with exposed tendon, fascia or bone. These included ray amputation wounds, wounds post-debridement for necrotising fasciitis, wounds post-drainage for abscess, a heel ulcer and a sole ulcer.

VAC therapy prepares ulcers well for closure in good time, thus reducing the cost of therapy by hastening the reduction of wound area. It also provided a sterile, controlled resting environment to large, exudating wounds. Large diabetic foot ulcers were thus made more manageable.

Debridement is critically important to the initiation of healing. NPWT and other wound healing technologies work in conjunction with debridement as the foundation upon which the wound healing process can begin.

Thus, VAC appears to be more effective, safe, and patient satisfactory compared to conventional dressings for the treatment of DFUs.

COMPLIANCE WITH ETHICAL STANDARDS

1. Conflicts of interest :

The authors Dr. Rajashekara Babu G., Dr. Nikhil S. And Dr. Chandrashekar M.S. hereby declare that we have no conflict of interest.

2. Ethical approval :

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

3. Informed consent :

Informed consent was obtained from all individual participants included in the study.

REFERENCES:

1. Nalini S, David G, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. JAMA 2005; 293: 217_28.
2. Ramsey SD, Newton K, Blough D, et al. Incidence, outcomes, and cost of foot ulcers in patients with diabetes. Diab Care. 1999; 22: 382-387
3. Walters DP, Gatling W, Mullee MA et al. The distribution and severity of diabetic foot disease: a community study with comparison to non-diabetic group. Diabet Med. 1992; 9: 354-58.
4. Mulder G, Armstrong D, Seaman S: Standard, appropriate, and advanced care and medical-legal considerations: part one— diabetic foot ulcerations. Wounds 15:92–106, 2003
5. Guideline for Management of Wounds in Patients with Lower-Extremity Arterial Disease. Glenview, IL, Wound Ostomy and Continence Nurses Society, 2002
6. Martson WA, Hanft J, Norwood P, Pollak R: The efficacy and safety of Dermagraft in improving the healing of chronic diabetic foot ulcers: results of prospective randomized trial. Diabetes Care 26:1701–1705, 2003
7. Veves A, Falanga V, Armstrong DA, Sabolinski ML: Graftskin, a human skin equivalent, is effective in the management of noninfected neuropathic diabetic foot ulcers: a prospective randomized multicenter clinical trial. Diabetes Care 24: 2001–295, 2001
8. Robson MC, Payne WG, Garner WL, Biundo J, Giacalone VF, Cooper DM, Ouyang P: Integrating the results of phase IV (postmarketing) clinical trial with four previous trials reinforces the position that Regranex (becaplermin) gel 0.01% is an effective adjunct to the treatment of diabetic foot ulcers. J Appl Res 5:35– 45, 2005
9. Mannari RJ, Payne WG, Ochs DE, Walusimbi M, Blue M, Robson MC: Successful treatment of recalcitrant, diabetic heel ulcers with topical becaplermin (rh- PDGF-BB) gel. WOUNDS 14:116 –121, 2002
10. Peters EJ, Lavery LA, Armstrong DG, Fleischli JG: Electric stimulation as an adjunct to heal diabetic foot ulcers: a randomized clinical trial. Arch Phys Med Rehabil 82:721–725, 2001
11. Argenta LC, Morykwas MJ: Vacuum-assisted closure: a new method for wound control and treatment: clinical experience. Ann Plast Surg 38:563–576, 1997
12. White R, McIntosh C. Topical therapies for diabetic foot ulcers: standard treatments. J Wound Care 2008; 17: 426-32.
13. Argenta LC, Morykwas MJ. Vacuum-Assisted closure: a new method for wound control and treatment: animal studies and basic foundation. Annals of plastic surgery. 1997; 38 (6).
14. Moisidis E, Heath T, Boorer C, Ho K, Deva AK. Prospective, blinded, randomized, controlled clinical trial of topical negative pressure use in skin grafting. Plast Reconstr Surg 2004; 114: 917-22.
15. Wagner FW. The dysvascular foot: a system for diagnosis and treatment. Foot Ankle 1981; 2: 64-122.
16. Brem H, Sheehan P, Rosenberg HJ, Schneider JS, Boulton AJ. Evidence-based protocol for diabetic foot ulcers. Plast Reconstr Surg 2006;117Suppl7:S193-211
17. Eginton MT, Brown KR, Seabrook GR, Towne JB, Cambria RA. A prospective randomised evaluation of negative-pressure wound dressings for diabetic foot wounds. Ann Vasc Surg 2003;17:645-9
18. 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.
19. Banwell PE. Topical negative pressure in wound care. J Wound Care 1999;8:79-84.
20. Eginton MT, Brown KR, Seabrook GR, Towne JB, Cambria RA. A prospective randomised evaluation of negative-pressure wound dressings for diabetic foot wounds. Ann Vasc Surg 2003;17:645-9.
21. 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.
22. 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.
23. Blume PA, Walters J, PayneW, 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.
24. Scherer LA. The vacuum assisted closure device: a method of securing skin graft and improving graft survival. Arch Surg 2002. 137 (8): 930-933.