ORIGINAL ARTICLE

Vacuum-assisted Closures Versus Conventional Dressings in the Management of Diabetic Foot Ulcers: A Comparative Study

Mohammad Noor A Alam[1], Sharmin Abbasi[2], Md. Moshiur Rahman[3], Md. Shamim Hossain[4]

Abstract :

Foot complications are major cause of morbidity and mortality in patients with diabetes mellitus. Vacuum-assisted closure (VAC) therapy is a popular treatment for the management of both acute and chronic wounds in diabetic foot complications. The study compared between VAC therapy versus conventional dressings in the management of diabetic foot ulcers. To compare the effectiveness and safety between Vacuum-assisted closure versus conventional dressings in the management of diabetic foot ulcers this prospective comparative study was conducted among 68 diabetic patients in BIRDEM General hospital and Shaheed Khaleq Ibrahim general Hospital in Dhaka in 2 years. Changes in wound dimension, disappearance of wound discharge, presence of wound granulation ,infection status, amputation rate, skin graft, successfully healed andpatientssatisfactionwere compared between 2 groups. By VAC therapy healing was achieved rapidly and effectively.23wounds was closed by split-skin grafting and 7 wounds by secondary closure and wound of 3 patients healed spontaneously. The average length of treatment with VAC therapy was 23.3 days. Wounds of 33 patients were satisfactorily granulated and cleared of bacterial infection at the end of VAC therapy.In conventional group 2patients had spontaneous closure and 20 patients need split skin graft.VAC therapy group one patient need amputation but in conventional group 7 patients ended up with amputation. VAC appears to be more safe and effective compared to conventional dressings in the treatment of diabetic foot ulcer.

Introduction :

Diabetic foot disease is a debilitating complication of diabetes mellitus, ultimately affecting up to 50% of patients with both type 1 and type 2 diabetes. Currently, this complication leads to significant loss of quality and years of life of the affected patient[1]. Furthermore, it represents at least 12-15% of the overall cost associated with diabetes.Foot ulcers arecommon cause of Hospital stays for people with diabetes. It may take weeks or even several months for foot ulcers to heal. DFU mainly treated by debridement of all necrotic, dead and devitalized tissue with the target to obtain wound healing. The conventional methods are saline, povidone iodine solution and eusol soaked gauze dressing . On the other handNegative Pressure Wound Therapy (NPWT), also called vacuum-assisted wound closure, refers to wound dressing systems that continuously or intermittently apply sub atmospheric pressure to the surface of a wound[2]. In essence the technique is very simple.

1. Associate professor and unit head, Department of Surgery ,BIRDEM and Ibrahim Medical College
2. Assistant professor, Department of Obstetrics and gynecology, Anwer Khan Modern Medical College Hospital
3. Assistant Professor, Neurosurgery, Holy Family Red Crescent Medical College Hospital, Dhaka
4. Assistant Professor, Department of Surgery, Holy Family Red Crescent Medical College Hospital, Dhaka

A piece of foam with an open-cell structure is introduced into the wound and a wound drain with lateral perforations is laid on top of it. The entire area is then covered with a transparent adhesive membrane, which is firmly secured to the healthy skin around the wound margin. When the exposed end of the drain tube is connected to a vacuum source, fluid is drawn from the wound through the foam into a reservoir for subsequent disposal[3].VAC helps to 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[4]. NPWT has become a popular treatment modality for the management of many acute and chronic wounds in diabetic patients[5]. We conducted a study to compare the effectiveness of VAC with conventional dressings in the management of diabetic foot ulcer.

Materials and Method :

This study was conducted in the departments of surgery over 2 years period from january 2015-January 2017 in BIRDEM General Hospital and Shaheed Khaleq Ibrahim General Hospital ,Dhaka . It was a prospective comparative study to compare the effectiveness and safety of VAC with conventional dressings in the healing of DFU. The study population included patients with DM .They were divided in to Group A (n=34; who treated with VAC) and Group B (n=34; who treated with conventional dressings).Exclusion criteria were-patients with foot ulcers other than diabetes, osteomyelitis of the underlying bone, peripheral vascular disease, patients with history of taking corticosteroids,immunosuppressive agents or chemotherapy. Informed consent was taken and after that history, clinical examination and relevant investigations were performed in all patients.

In both groups initially sharp surgical debridement of wound was done and after that subsequent dressing was needed to remove necrotic tissue and slough. After debridement , a foam-based dressing was applied over the wounds in group A 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 75-125 mmHg on a continuous basis for 72 hours. In Group B once daily povidin,eusol and or vinegar soaked gauze dressing was done. Before starting of treatment and 10 days after regular dressing ,cultures were taken from the base of the ulcer to assess for the bacteriological status.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 6weeks period, whichever was earlier. Blood glucose levels were monitored strictly during treatment and controlled by appropriate doses of insulin or anti diabetic drugs. Patients who were discharged from the hospital after wound closure were followed weekly, then twice weekly after that according to patients need.

Treatment outcome and patient satisfaction were 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 6 weeks and failure, as inability of wound closure within 6 weeks. Patient satisfaction was also

considered according to time of wound closure,need of antibiotic,and need of amputation.

Data was analyzed with SPSS version 17. Continuous variables were analyzed as means ± SD. P value <.05 is significant.

Result :

A total of 68 patients with DM with foot ulcer were included . The age of patients were between 25 and 65 years with a mean age of 48+_6.8years in group A and 46.32+_7.1 years in group B. Male constituted 64.7% and women around35.3% in group A and male 78.8% and female 21.2% in Group B. Most of the patients needed insulin for control of their DM and some needs additional anti diabetic drugs.

Regarding Wound discharge disappearence data were significantly difference between 2 groups. Wound discharge disappeared in 29 patients (85.3%) in VAC group versus no patients in conventional dressing group at the end of 4 weeks. Wound discharge disappeared in rest 5 (14.7%) patients in Group A and 19 (55.9%) patients in Group B by Week 6. Granulation tissue appeared in 28(82.3%) patients by the end of Week 4 in Group A in contrast to 14 (42.4%) patients by that time in Group B and it was statisticaly significant. 100% granulation was achieved in 33 (97.1%) patients by the end of Week 6 in Group A as compared to 28(84.8%) patients by that time in Group B.

Table-I : Disappearance of wound discharge

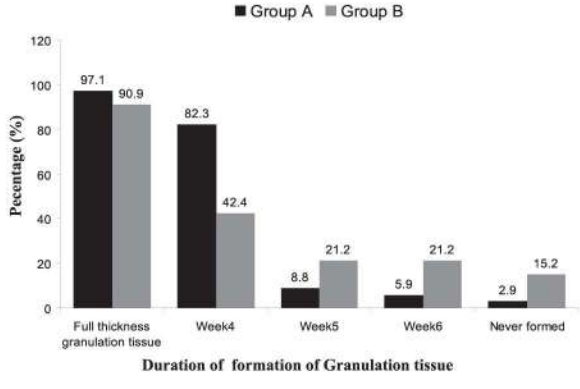
Parameter	Group A (n=34)	Group B (n=34)	P value
Week2	4 (11.8%)	0	0.042^{s}
Week3	8 (23.5%)	0	0.003^{s}
Week4	17(50.0%)	0	$<0.001^{s}$
Week5	4(11.8%)	11(32.4%)	0.034^{s}
Week 6	1(2.9%)	8(23.5%)	0.011^{s}

Data were analyzed by Chi-square test, ns= not significant, s=significant

Table-II : Duration of formation of Granulation tissue

Parameter	Group A (n=34)	Group B (n=34)	P value
Full thickness granulation tissue	33(97.1%)	29(90.9%)	0.288^{ns}
Week4	28(82.3%)	15(42.4%)	0.001^{s}
Week5	3(8.8%)	7(21.2%)	0.154^{ns}
Week6	2(5.9%)	7(21.2%)	0.066^{ns}

Data were analyzed by Chi-square test, ns= not significant, s=significant



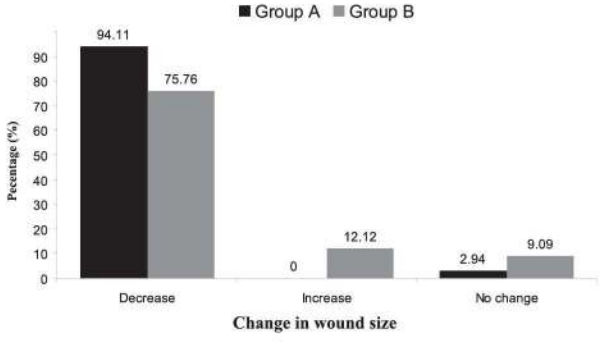


Table-III: Change in wound size

Parameter	Group A(34)	Group B (34)	P value
Decrease	33 (94.11%)	25(75.76%)	0.035 s
Increase	0(0%)	4(12.12%)	0.036 s
No change	1(2.94%)	5(9.09%)	0.288 ns

Data were analyzed by Chi-square test, ns= not significant, s=significant

Table-IV : Outcome of the patients:

Parameter	Group A (n=34)	Group B (n=34)	P value
Spontaneous wound closure	3(11.8%)	2(9.1%)	0.721 ns
Secondary closure	7(20.6%)	5(24.2%)	0.719 ns
Full thickness skin graft	23(67.6%)	20(66.7%)	0.931 ns
Need for amputation	1(2.94%)	7(21.21%)	0.004 s
Endpoint reached	33(97.05%)	27(84.84%)	0.080 ns
Hospital stay	20±5 days	30±5 days	<0.001 s

Qualitative data were analyzed by Chi-square test and quantitative data analyzed by Unpaired t-test, ns= not significant, s=significant

Initial wound area ranged from 7.3 to 105.0 cm2, the average area being 56.26 cm2. After VAC therapy, wound area size decreased from 2.1 to 103.1cm2.Wound size decreased in 32(94.11%) patients in Group A as compared to 25 (75.76%) patients in Group B. The majority of wounds in Group A 32 (94.11%) got closed in 5 weeks as compared to only 21 (63.63%) in Group B in 8 weeks. One patient required amputation in Group A as compared to seven in Group B. The majority of wounds were closed by a split-thickness skin graft in both groups. Treatment was successful in 97.05% of patients in Group A and 84.84% of patients in Group B. Patient satisfaction was excellent in the majority of patients in Group A compared to those in Group B.VAC group needed less hospital stay than conventional group.

Discussion:

VAC therapy has the ability to provide an occlusive environment in which wound healing could take place under moist, clean and sterile conditions[6]. This environment increased the rate of granulation tissue formation 33 (97.05%) patients in our study. Occlusive environment does not existin conventional dressings. Thus, VAC therapy was particularly useful for the treatment of large diabetic foot ulcers. Wounds in our study had an average surface area of 56.26 cm2 This was 2 to 3 times larger than the average wound area of 20.7 cm^2 in the study by Armstrong and Lavery8. Two patients in our study with necrotising fasciitis in the lower limb presented with especially large wounds after radical debridement, with areas of 124 and 116 cm^2. Use of VAC therapy in large wounds obviated the need for a daily change of dressing, hence removing the trouble of a daily change of dressing, which was painful, difficult to perform and could lead to increased fluid loss. 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[7].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[8]. However, when the wound area before and after VAC therapy was compared .Eginton et al found no significant reduction in the area[9].The greater reduction in wound dimension had been attributed to the three-dimensional stress which VAC exerted across the whole area of the wound, also known as macro-strain, that drew wound edges inwards in a centripetal fashion, thus shrinking the

wound[10]. Reduction in wound area was observed in 32 (94.11%) in wounds of VAC therapy group. This decrease in size was statistically significant. Besides reducing wound size, VAC therapy encouraged wound healing by stimulating the formation of granulation tissue. Morykwas et al demonstrated that wounds treated with negative pressure achieved more granulation using either continuous or intermittent pressure than those treated using conventional dressing[11]. 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 cases, prior to closure via split-skin grafting or secondary closure. In this study, the length of time taken to complete VAC therapy ranged from 20 to 25 days, with an average of 23.3 days. This was much shorter than the average time taken by conventional group. Armstrong et al of 32.9 days and Clare et al of 57.4 day[12]needed for conventional group.For inpatients, the cost of hospitalisation adds on to the cost of VAC therapy. In order to make VAC therapy more affordable for patients, surgical treatment was performed once the wound had been adequately prepared with sufficient formation of granulation tissue and wound culture shown to be negative for bacteria, instead of waiting for further reduction in wound area through prolonged application of VAC therapy[13].

NPWT 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 fluid16, increases vascularity and cytokine expression[14] and to an extent mechanically exploiting the viscoelasticity of periwound tissues[15]. VAC is generally well tolerated and, with few contraindications or complications, is fast becoming a main stay of current wound care.

Patient satisfaction in terms of time taken for wound closure, number of antibiotics used, treatment related complications and outcome was better in Group A compared to Group B and overall resource utilization was more in Group B. Apelqvist J et al. also found a beneficial effect in terms of direct economic cost and resource utilization in patients treated with VAC compared to standard moist wound therapy[16].

Conclusion :

VAC therapy is useful in the treatment of diabetic foot ulcers.VAC therapy effectively reduces wound size,achieves early bacteriological clearance and enhances granulation tissueappearance and therefore promotes early healing as compared to conventional dressing.So, VAC appears to be more safe and effective compared to conventional dressings in the treatment of diabetic foot ulcers .

References :

01. Li XY, Li WZ, Li YJ , et al. The influence of vacuum-assisted drainage on the growth of capillaries in the wound produced by explosion in pig. Zhonghua Shao Shang ZaZhi. 2007;23(4):292-5.

02. Johnston DH, Fairclough JA. Rate of bacterial recolonisation of the skin after preparation: four methods compared. Br J Surg. 1987;74(1):64.

03. Morykwas MHL. Vacuum-assisted closure: a new method for wound control and treatment: animal studies and basic foundation. Ann Plast Surg. 1997;38(6):553-62.

04. Herscovici D JR, Sanders RW, et al. Vacuum-assisted closure (VAC therapy) for the management of patients with high-energy soft tissue injuries. J Orthop Trauma. 2003;17(10):683-8.

05. Mous CM, Vos MC, et al. Bacterial load in relation to vacuum assisted closure wound therapy: a prospective randomized trial. Wound Repair Regen. 2004;12(1):11-7.

06. Singh S, Mackey S, Soldin M. VAC it - Some techniques on the application of VAC dressings. Ann R Coll Surg Engl. 2008; 90:161-2.

07. Birke-Sorensen H, Malmsjo M, Rome P , et al. Evidence-based recommendations for negative pressure wound therapy: treatment variables (pressure levels, wound filler and contract layer) - steps towards an international consensus. J PlastReconstrAesthet Surg. 2001;64 (Suppl):S1-16.

08. Chariker ME, Jeter KF, Tintle TE, Bottsford JE. Effective management of incisional and cutaneous fistulae with closed suction wound drainage. Contemp Surg. 1989;34:59-63.

09. Fleischmann W, Strecker W, Bombelli M, Kinzl L. Vacuum sealing as treatment of soft tissue damage in open fractures. Der Unfallchirurg. 1993;96(9):488-92.

10. Argenta LC, Morykwas MJ. Vacuum-assisted closure: a new method for wound control and treatment: clinical experience. Ann Plast Surg. 1997;38:563.

11. Singer AJ, Clark RA, Rodriguez PG, Felix FN, Woodley DT, Shim EK. The role of oxygen in wound healing: a review of the literature, Cutaneous wound healing. N Engl J Med. 1999;341:738-46.

12. Otgill DP, Manders EK, SumpioBE , et al. The mechanisms of action of vacuum assisted closureL More to learn. Surgery. 2009;146(1):40-51. [PubMed]

13. Scherer SS, Pietramaggiori G, Mathew JC, Prsa MJ, Huang S, Orgill DP. The mechanisms of action of the vacuum assisted closure device. PlastReconstr Surg. 2008;122(3):786-97.

14. Webb LX, Dedmond B, SchlattererD , et al. The contaminated high- energy open fracture: a protocol to prevent and treat inflammatory mediator storm-induced soft-tissue compartment syndrome (IMSICS). J Am AcadOrthop Surg. 2006;14(Suppl):S82-6.

15. Saxena V, Hwang CW, Huang S , et al. Vacuum-assisted closure: microdeformations of wounds and cell proliferation. PlastReconstr Surg. 2004;114:1086-96.

16. Kiessling AH, Lehmann A, Isgro F, Moritz A. Tremendous bleeding complication after vacuum-assisted sternal closure. J Cardiothoracic Surg. 2011;6:45-47.