



ORIGINAL RESEARCH PAPER

Surgery

A PROSPECTIVE RANDOMIZED CONTROL STUDY OF NEGATIVE PRESSURE WOUND THERAPY VERSUS MOIST GAUZE DRESSING IN DIABETIC FOOT WOUNDS: AN ORIGINAL ARTICLE

KEY WORDS: Diabetic Foot Ulcers(DFU's) ; Negative Pressure Wound Therapy (NPWT) ; Moist gauze dressings

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ABSTRACT

Diabetic Foot Ulcers(DFU) are the most common cause of chronic wounds. A prospective randomized comparative study was conducted at a tertiary health care centre at Aurangabad, Maharashtra to compare the efficacy of Negative Pressure Wound Therapy (NPWT) against moist gauze dressings for treating DFU's for a period of two years. The study group comprised patients diagnosed with Diabetic foot . Sample size was 60 divided randomly into 30 patients in each group . Group A was study group i.e patient who were applied negative pressure wound therapy and Group B was control group i.e patients who were applied moist gauze dressings. Results were compared for rate of wound healing. There was statistically significant difference in appearance of granulation tissue between the two groups with granulation tissue appearing earlier in group A compared to control group. Thus our study shows that NPWT has a definitive role in healing of Diabetic foot ulcers.

INTRODUCTION

Diabetic Foot Ulcers(DFU) are the most common cause of chronic wounds. Foot complications are a major cause of hospitalization in patients with diabetes mellitus (DM), which consumes a high number of hospital days because of multiple surgical procedures and prolonged length of stay^[1] Patients with DM have up to a 25% lifetime risk of developing a foot ulcer which precedes amputation in up to 85% of cases.^{[2][3]} A mainstay of diabetic foot ulcer (DFU) therapy is debridement of all necrotic, callus, and fibrous tissue with a primary goal to obtain wound closure.^{[4][5]} The management of the DFU is largely determined by its severity (grade), vascularity of the limb and the presence of infection.^{[6][7][8]} In India, habits like walking barefooted, lack of knowledge regarding diabetic foot, hot climate leading to increased perspiration, poor hygiene, poor sanitation, diet poor in proteins, general poverty, lack of basic medical infrastructure, etc have worsened the problem. Over the years the life expectancy of diabetic patient with gangrene of foot has not changed much. Advances in treatment of diabetes have caused increase in life span of diabetic patient which has resulted in an increase in complications like vasculopathy, neuropathy and nephropathy.

The optimal topical therapy of DFU remains ill-defined. Saline moistened gauze has been the standard method. Negative Pressure Wound Therapy (NPWT) is a newer non-invasive adjunctive therapy that uses controlled negative pressure using vacuum assisted closure (VAC) device to help promote wound healing.

With this background in view the present study was conducted with the aim to compare the efficacy of NPWT against the conventional moist gauze dressings for healing of DFU's.

MATERIAL AND METHODS

A prospective randomized comparative study was conducted at a tertiary health care centre at Aurangabad, Maharashtra to compare the efficacy of NPWT against moist gauze dressings for treating DFU's for a period of two years. Ethical Committee Approval was obtained for the same. The study group comprised of both male and female patients aged 30 to 75 years diagnosed with Diabetic foot who gave informed consent were included in the study.

Sample size was 60 divided randomly into 30 patients in each group . Randomisation of patients was done by creating a blocked randomization list by online software. Ulcer area of

area > 25 cm² were included .The diagnosis of Diabetic ulcer was made by American Diabetes association criteria. Patients with septicemia , osteomyelitis, ulcers due to venous insufficiency were excluded .

Group A was study group i.e patient who were applied negative pressure wound therapy and Group B was control group i.e patients who were applied moist gauze dressings. Care was taken so that both the groups had a comparable distribution of patients with regards to the age as well as etiology of the ulcer. All the patients in group A and B underwent detailed clinical examination and relevant investigations and the wounds were thoroughly debrided and the ulcer dimensions as well as surface area assessed using vernier calipers, before both types of dressings applied.

The patients were followed up daily, moist dressings done daily once; negative pressure dressings were left undisturbed for 3 days and the wounds were compared on 4th day for next consecutive three vacuum dressings. These parameters are compared with control group. Afterwards the wounds are treated with grafting/secondary suturing/ flap/redebridement or normal dressings depending on the dimensions, and wound toilet. Patient was considered for grafting after healthy granulation for >75 % of wound, nature of discharge is serous, decrease in wound size, and overall improved general condition of patient . Once satisfactory results were obtained i.e. overall improved general condition, no systemic infection, healthy wound these patients are discharged.

These patients are followed up further in out patient department.

Materials used in VAC dressing:

- Negative pressure machine.
- Canister (container for discharge fluid).
- Foam.
- Drainage tube for drawing away exudates from wound.
- Adhesive Drape for sealing of foam

Materials use in Moist Gauze dressing:

Normal dressing was taken as a conventional Moist dressing, which is defined as Moist type.

Disinfectant used was betadine, hydrogen peroxide & normal saline and absorbent used was bactigras .

Dressing was changed on daily basis, and all parameters were checked.

RESULTS AND DISCUSSION:

COMPARISON OF THE PRESENT STUDY WITH Joseph et al., and Peter A Blume et al

| | Peter A. Blume et al | | Joseph et al | | Present study | |
|---|----------------------|---------------|--------------|---------------|---------------|----------------------|
| | Vacuum group | Control group | Vacuum group | Control group | Vacuum group | Moist Gauze dressing |
| Sample size | 169 | 166 | 18 | 18 | 30 | 30 |
| Mean age (years) | 58 | 58 | 52.41 | 53.2 | 57.27 | 58.07 |
| Sex (Male/ Female) | 83/17 | 73/27 | - | - | 67/33 | 77/23 |
| % of Patients achieving 75% ulcer closure | 62.1% | 51.2% | 81.56% | 54.3 % | 87% (D12) | 23% (D12) |
| Graft uptake | 43.2% | 28.9% | 85.3% | 56.43% | 90.43±7.674% | 79.09±9.957% |
| Undergone Amputation | 4.1% | 10.2% | 3.6% | 10.7% | 0% | 10% |
| Hospitalstay | 63.6±36.57 | 78.1±39.29 | 36.24 | 70.4 | 17.9 | 22.4 |

The above table shows a comparison of the present study to a similar study conducted by Joseph et al., and Peter A Blume et al.^{[9][10]} The mean age of appearance of diabetic foot in the present study was around (57.27-58.07) years, which is similar to those found in the other studies. The mean age in group A was 57.27 and the mean age in group B was 58. The sex ratio was around (M : F =7:3). The rate of formation of granulation tissue (though dependant on the size of the ulcer, nutrition of the patient) was faster in the group A. The ulcers were compared for rate of formation of granulation tissue on the 1st, 4th, 8th and the 12th day, the ulcers in the group A showed evidence of granulation tissue on an earlier date than the group B. On day 4, 46% in Group-A had >50% of their ulcer floors covered by granulation tissue compared to only 7% patients in group-B. On day 8, 60% in Group A had more than 75% of wound area covered with granulation as compared to only 3% of patients in Group-B. On Day 12, 87% in Group-A had already undergone some or the other surgical procedure in study group-A, whereas only 23% in Group-B had reached >75% granulation. Initially 70% of Group-A had pus discharge which progressed by serous or no discharge in 90% patients till day 8, whereas 100% patients in Group B had pus discharge on day 1, which progressed to 87% patient with serous or no discharge till Day 12.

A mean duration of hospital stay in the topical negative pressure Group-A was 22.4 ± 3.6 days as compared to 17.9 ± 5.2 days was seen in the Group-B, which was found to be statistically insignificant. Mean number of dressings required was significantly low i.e. only 6.5 dressings in Group-A compared to 27.3 dressings in Group-B which was statistically significant. Enhanced rates of wound healing, better wound conditions all favoring healing were seen in the Group-A with mean reduction in surface area 22.07cm² compared to 7.88 cm² in Group-B. Thus better healing and outcome in Group-A compared to the latter group due to enhanced vascularity, reduced wound edema, reduced bacterial growth in the former group all favor better uptake of the graft. In another similar prospective randomized study, the findings were consistent with our study.^{[11][12][13]}

CONCLUSION

Awareness among people about diabetes, diabetic foot and its complications, along with available treatment modalities should be done. Negative pressure wound therapy also known as VAC therapy is quicker and efficient method for healing of diabetic foot wounds. NPWT can be effective adjunctive for DFUS's when used appropriately. NPWT is cost effective, easy to use and patient friendly method of treating DFU's and helps in early closure of wounds and hence better outcome. More economical machines and techniques should be developed to propagate Negative pressure wound therapy as prime tool for healing.

REFERENCES

- 1] Ahmed AM. History of diabetes mellitus. Saudi Med J. 2002; 23:373-8.
- 2] Nalini S, David C, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. JAMA. 2005; 293:217-28.
- 3] Reiber GE, Vileikyte L, Boyko EJ, Del AM, Smith DG, Lavery LA, et al. Causal

- pathways for incident lower extremity ulcers in patients with diabetes from two settings. Diabetes Care. 1999; 22:157-62.
- 4] American Diabetes Association. Consensus development conference on diabetic foot wound care. Diabetes Care. 1999; 22:1354-60.
- 5] Armstrong DG, Lavery LA. Diabetic foot ulcers: prevention, diagnosis and classification. Am Fam Physician. 1998; 57:1325-32.
- 6] Frykberg RG. Diabetic foot ulcerations. In: Frykberg RG, editor. The high risk foot in diabetes mellitus. New York: Churchill Livingstone; 1991. pp. 151-95.
- 7] Frykberg RG. Diabetic foot ulcers: current concepts. J Foot Ankle Surg. 1998; 37:440-6.
- 8] Frykberg RG, Armstrong DG, Giurini J, Edwards A, Kravette M, Kravitz S, et al. Diabetic foot disorders: a clinical practice guideline.
- 9] Joseph et al. A prospective randomized trial of vacuum assisted closure versus standard therapy of chronic non-healing wounds. Wounds 2000; 12(3):60-76.
- 10] Blume PA, Walters J, Payne W et al. 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 April; 31(4): 631-6
- 11] Philbeck TE, Schroeder WJ, Whittington KT. Vacuum-assisted closure therapy for diabetic foot ulcers: clinical and cost analysis. Home Health Consult. 2001; 8:26-34.
- 12] Last's anatomy lastest... McMinn, R.M.H.: "Lower limb- sole of the foot", Chapter-3 (part 10) in Last's anatomy regional and applied, 9th Edn, Churchill Livingstone, 1994: 197-203pp. 76
- 13] Eginton MT, Brown KR, Seabrook GR et al. A prospective randomized evaluation of negative pressure wound dressings for diabetic foot wounds Ann Vasc Surg. 2003 Nov; 17(6):645-649.