Original Research Article

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Comparison of modified vacuum dressing and wet normal saline dressing in treatment of non-healing diabetic foot ulcers

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ABSTRACT

Background: Diabetic foot a complication of diabetes can lead to significant morbidity and have financial burden. The standard of dressing diabetic foot ulcers has been saline dressings. Negative pressure vacuum devices have come and had a significant impact on treatment of diabetic ulcers. But in developing countries the cost associated with it makes it inaccessible to a large population. Our study aims to compare the use of modified vacuum dressing against saline dressing and compare healing rates, costs involved and hospital stay of patients.

Methods: Our study was prospective study of 80 patients randomised into two groups, of 40 each. Group A consisted of patients with modified vacuum dressing and group B with wet saline dressing. Simple randomisation technique was used. They were compared for healing rates, hospital stay and cost involved.

Results: There was a 43.75% decrease in area of the ulcer in group A compared to 25.15% in group B after 4 weeks. Decrease in wound depth was 55.41% and 26.94% in group A and B respectively. The mean hospital stay was 33.18 days in group A compared to 45.58 days in group B. The average cost incurred for patients in group A was rupees 14,381 compared to 19,465 rupees in group B.

Conclusions: From our study we found that modified vacuum dressing in spite of being cheap it reduces healing time, hospital stay there by the cost incurred to patients. So we recommended modified vacuum dressings as a go to method of treating diabetic foot ulcers.

Keywords: Diabetic foot, Negative pressure dressing, Modified vacuum dressing, Wound healing

INTRODUCTION

Diabetes is probably the most common disease in the world. Complications of diabetes cause huge financial burden worldwide. One of the important complications is diabetic foot. It is one which leads to increased hospital stay thereby increasing costs and decreasing productivity. Patients with diabetes have a 25% life time risk of developing foot complications. Topical therapy foot diabetic foot ulcers are ill-defined. Wet saline dressing

has been the standard method for years. However, it if difficult to maintain a moist environment with these dressings. Negative pressure wound therapy is a newer noninvasive adjunctive therapy that uses controlled negative pressure using a vacuum assisted closure device (VAC). Even though conventional are helpful in wound healing cost effectives is a major problem especially in developing countries like India. This study compares the effectiveness of modified VAC with conventional dressings in healing of diabetic foot ulcers in terms of healing rate and cost effectiveness.

METHODS

Study design: Prospective study.

Study period: November 2014 to June 2016.

Inclusion criteria

Inclusion criteria were age >40; diabetic foot ulcers with Wagner grade 2, 3; dorsal or plantar foot ulcer >2 cm² after debridement; patients in whom dorsalis pedis pulse were palpable.

Exclusion criteria

Exclusion criteria were patients who had coronary artery disease in the last 6 months; patients with chronic kidney disease on dialysis; pregnancy; lactation; ulcers resulting from electrical, chemical, collagen vascular diseases, malignancy, and inadequate perfusion; patients on corticosteroids, chemotherapy; patients using enzymatic debridement; not willing to consent.

Selection criteria

All patients who fall within the inclusion criteria were randomized into two groups based on their hospital number. Group A had VAC dressings Group B had saline dressings. Odd numbers were in Group A and even numbers in Group B.

Study procedure

Following initial surgical debridement and taking pus for culture and sensitivity all patients were started on amoxicillin and clavulanic acid empirically and then changed based on culture. In Group A patients, a sterilized gauze-based dressing was applied over the wounds under aseptic conditions. The dressing was covered with an adhesive drape (opsite) to create an airtight seal. An evacuation tube embedded in the gauze was connected to a vacuum generator machine and subatmospheric (negative) pressure of 125 mmHg on an intermittent basis (half hour VAC applied every 1 hr interval) for 72 hours was applied. The group B received once daily saline soaked gauze dressing. After every 3 days, microbial cultures were taken from the base of the ulcer to assess the bacterial flora. Ulcers were treated until the wound closed spontaneously. Patients were discharged from the hospital after wound closure. Blood glucose levels were monitored strictly and appropriate doses of insulin given. The study aimed to compare healing rates and cost effectiveness.

Ethical approval

Ethical approval was cleared by institution ethics committee.

Statistical analysis

Once data collection was over, it was entered into a Microsoft excel worksheet and analysed by SPSS statistical package. The necessary statistical tables were constructed.

RESULTS

In this study on 80 patients, we found that wound healing was much faster in cases in which modified VAC was applied.

The mean age was 51.38 in group A and 53.13 in group B. The study had 41 (51.2%) females and 39 (48.8%) males. The mean area of the ulcers in group A prior to treatment was 27.36 cm² and in group b 24.07 cm². After 2 weeks of treatment mean area of Group A was 21.82 cm² and in group b 22.52 cm². After 4 weeks mean area of group A was 16.89 cm² and group B was 19.41 cm². There was a 43.75% decrease in area of the ulcer compared to 25.15% in group B after four weeks. The patients in group A had a 55.41% decrease in wound depth compared to 26.94%. The average duration of hospital stay was 33.18 days in group A compared to 45.58 days in group B. The mean cost incurred for patients in group A was rupees 14381 compared to 19465 rupees. The cost of treatment per day was 434.45 rupees in group A compared to 429.15 in group B.

Table 1: Glycemic control – HbA1C.

		Case	Control	Total
		N (%)	N (%)	N (%)
HbA1C	7.5-8.5	15 (37.5)	9 (22.5)	24 (30)
	8.5-9.5	19 (47.5)	25 (62.5)	44 (55)
	>9.5	6 (15)	6 (15)	12 (15)
	Total	40 (100)	40 (100)	80 (100)

Table 2: Grade of ulcer among groups.

Wagner	Group A	Group B	Total
grade	N (%)	N (%)	N (%)
Grade 2	17 (42.5)	8 (20)	25 (31.3)
Grade 3	23 (57.5)	32 (80)	55 (68.8)

Table 3: Area of the ulcer.

	Group A	Control group Group B
Area prior to treatment	27.36	24.07
Week 2	21.82	22.52
Week 4	16.89	19.41

Modified VAC was effective in reducing wound area. This technique significantly improves the quality of life. There is a marked reduction in the number of inpatient days which indirectly cuts the treatment cost. The total

cost for treatment was lesser than when compared with the conventional saline group and moreover it was much lower when compared with the standard VAC therapy. Patient compliance was better with modified VAC group, as it was less painful. There was a marked reduction in wound infection particularly nosocomial and the need for therapeutic antibiotic also less in the modified VAC group.

Table 4: Reduction in depth of wound.

	Group A	Group B
Depth in mm week 1	17.98	14.3
Week 2	13.73	15.75
Week 4	8.23	11.13
% change in depth	55.41	26.94



Figure 1: Before applying modified VAC.



Figure 2: After applying modified VAC.

Our study also reveals that the non-healing diabetic foot ulcers with larger surface area and a higher Wagner score have better results with a modified VAC group. Modified VAC dressing results are complementary to the conventional VAC dressing technique in achieving complete healing in selective patients, reducing wound

surface area, depth, volume, and pain, and increasing comfort in subjects with a chronic non-healing diabetic foot ulcer. In Group A patients wound bed healed twice as fast. Neuropathy and decreased distal vascularity were identified to have a direct effect on the wound healing pattern in both the groups, as it was seen that was the effect of distal vascularity was directly proportional to the wound healing, while the presence of neuropathy dampened the healing in both the groups. There were a better patient compliance and satisfaction within the modified-VAC group.



Figure 3: Decrease in wound area.

DISCUSSION

Among topical wound management, NPWT therapy is the most discussed and described form of treatment modality. There are numerous trials done so far based on various variables all of which are aiming for a better faster healing, with an acceptable risk during treatment.⁷ The mechanisms of action that can be attributed to NPWT therapy are an increase in blood flow- perfusion (human and animal studies), Promotion of angiogenesis (animal studies only), granulation tissue formation, Reduction in the wound surface area of several types of wounds (chronic) but not all wounds (acute), A positive modulation of the inhibitory contents in the wound fluid, there is an induction of cell proliferation (in vitro and animal studies only), reduction of oedema and bacterial clearance, removal of exudates.8 In short it is a fact that VAC therapy, is a faster more effective and clinically proven wound healing. One of the major problem facing of people low socio-economic subset of the population is the cost for dressing. So we introduce a technique of topical dressing with slight modification without losing the basic concepts of negative pressure wound therapy. In our study, we consider objectives like healing rate and economic cost.⁹ In our study satisfactory healing was attained in 33.18 and 45.58 days as compared to 22.8 day

and 42.8 days in a study done by Mc Callon et al. The percentage decrease in surface area of wounds in our study were 43.75% and 25.15% in the modified vac group to control group compared to 28.4% and 9.5% by Mc callon et al. ¹⁰ The patients in group A had a 55.41% decrease in wound depth compared to 26.94% in group B vs 59% and 8% in a study by Ramanujam et al. 11 In our study, mVAC therapy group had better healing, had significantly lower 'In-Patient' days. mVAC therapy is a cost-effective and relatively safe non-invasive procedure with better outcome in terms of meeting the endpoints as incomplete closure of wounds or till skin graft ability of wound is achieved. In our study the mean duration of hospital stay in cases is 33.18 days and for the control group is 45.58 days. The mean costs of treatment for case and control groups are 14381.38 rupees and 19465 rupees respectively. Whereas the average cost for a day of treatment is 434.45 rupees and 429.15 rupees in cases and control group respectively. This is mainly because of the fact that there is a marked decrease in hospital stay, number of surgical debridement/ amputations, and decreased use of therapeutic antibiotic during treatment in cases or modified-VAC group.

CONCLUSION

Our study compared the effectiveness of Modified Vacuum dressing versus conventional wet Normal saline dressings in the healing of chronic diabetic foot ulcerations in terms of healing, economic cost, and patient stay in hospital. We found that the healing was much faster in cases in which modified VAC was applied by reducing wound surface area, depth, the volume of the ulcer. m-VAC significantly improves quality of life. There is a marked reduction in the number of "inpatient" days and there is an early achievement of endpoints which indirectly cuts the treatment cost. There is a rapid filling of granulation tissue and the disappearance of discharge from the ulcer bed. Prepare wound bed over twice as fast. Number of surgical intervention is also less and a better patient compliance. Our study also reveals that the non-healing diabetic foot ulcers with larger surface area and a higher Wagner score 3 have better results with a modified VAC group. Modified VAC dressing results are complementary to the conventional VAC dressing technique in achieving complete healing in selective patients. Our study like other previous studies has established that NPWT technique has a better outcome when compared to the conventional modalities. With adequate resource and follow up problems of chronic diabetic foot ulcer could be managed in an effective economical way.

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