Original Article

Study of infective rates between vacuum assisted closure and moist gauze dressings in diabetic wounds

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Abstract

Aim and Objectives: The purpose of this research was to study infective rates in VAC and MGD in diabetic wounds. **Materials and Methods:** The cases presented in this study are those patients admitted on in patient basis from general surgical wards, plastic surgery and patients with surgery reference for diabetic foot care from all other departments like Medicine, Orthopaedics in Adichunchanagiri Institute of Medical sciences, B.G. Nagar, Bellur, Mandya in the time period between January-2014 to july-2015. were assigned to the study group(VAC) based on their willingness and 30 patients to the control group (MGD). All patients were studied and clinical findings were recorded, necessary investigations ordered and appropriate treatment given. Diabetic status monitored and controlled throughout the course of treatment. **Infective rate in VAC and MGD in diabetic wounds:** All the data were analyzed using the Chisquare test and the Student's T test and the results were tabulated. A "p" value of <0.05 was considered statistically significant. **Results:** Comparatively more and mixed growth was isolated from conventional dressing patient. No growth being maximum in study/VAC group and, second being pseudomonas then coagulase negative staphylococcus aureus. In the control/MGD group along with nil growth pseudomonas. accounts for highest organism isolated, then streptococcus and klebsiella being second. highest.Other organisms isolated are Staphylococcus aureus, proteus, E.coli, enterococci, acinetobacter, citrobacter, coagulase negative staphylococcus aureus. Few cases mixed growth have been isolated. **Conclusion:** The application of VAC decreased infection rate, faster wound healing thereby improving final clinical outcome than the patients who underwent a conventional MGD dressing for their ulcers.

Keywords: Vacuum Assisted Closure (VAC); Moist Gauge Dressing (MGD);, Diabetes Mellitus; Split Skin Graft.

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INTRODUCTION

Diabetic ulcers are the most common cause of morbidity and hospitalisation among patients with diabetes. Persons suffering from diabetes have a 12% - 15% life-time risk of developing foot ulcer. Foot ulcer impacts negatively on the quality of life of persons and also costly as well (about USD 17,500 - 27,987) .Also, there may be a need for the lower limb to be amputated which may bring untold hardship to the individual.[1] The life time risk of a person with diabetes developing a foot ulcer could be as high as 25%.[2] The prevalence of diabetes in adults is about 2.4% rural and 4.0-11.6% in urban dwellers. It indicates high frequencies of impaired glucose tolerance, shown by the above studies ranging from 3.6 – 9.1% impends the potential for further rise in the prevalence of diabetes mellitus in the coming years.[3] Every 30 seconds a lower limb is lost somewhere in the world as a consequence of diabetes.[4,5] Laing, Patrick (1998): Neuropathy and ischemia, two common complications of diabetes mellitus, are the primary underlying risk factors for the development of foot ulcers and their complications.[6]

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Infective rate in VAC and MGD in diabetic wounds

Robson MC. Wound infection. (1997) : Infection in a wound, like infection elsewhere in the body, is a manifestation of a disturbed host-bacteria equilibrium favouring the bacteria. To prevent and manage wound infections requires an understanding of how each prophylactic or therapeutic maneuver works to maintain or reestablish the bacteria-host balance. Only when this equilibrium is in balance the normal process of wound healing can proceed to give a satisfactory healing.[7] Van Gils, Carl, *et al* (1999): The effect of foot ulceration on amputation is not disputed. Failure of normal wound healing after cutaneous ulceration is reported to be the best predictor of amputation risk.Amputation is estimated to occur in 6 – 43 % of diabetic out patients with foot ulceration, depending on ulcer severity.[8] Mechanism and clinical applications of Topical Negative Pressure: The use of subatmoshperic pressure dressings has been shown to be effective to accelerate wound healing. The optimal sub atmospheric pressure for wound healing appears to be around 125mmHg utilizing an alternating pressure cycle of 5 minutes on suction followed by 2 minutes off suction. The sub atmospheric pressure optimizes blood flow, decreases local tissue edema, and removes excessive fluid from the wound bed.[9]

Fig. (A): Creating an air tight seal. Fig. (B): Vacuum equipement.

Figure 1: Infective rate in VAC and MGD in diabetic wounds

AIM OF THE STUDY

The present study was conducted to assess the infectivity rate of topical negative pressure wound dressings as compared to conventional moist wound dressings in treatment diabetic foot ulcers and to prove that negative pressure dressings can be used as a much better treatment option in the management of diabetic foot ulcers.

Infective rate in VAC and MGD in diabetic wounds

OBJECTIVES OF THE STUDY

- To compare the infectivity rate in negative pressure therapy and moist gauze dressing in the treatment of diabetic wounds.
- The primary efficacy end point is the incidence of complete ulcer closure. Complete ulcer closure was defined as skin closure (100% re-epithelization).

MATERIALS AND METHODS

SOURCE OF DATA

The cases presented in this study are those patients admitted on in patient basis from general surgical wards,plastic surgery and patients with surgery reference for diabetic foot care from all other departments like medicine, orthopaedics in Adichunchanagiri Institute of Medical sciences, B.G.Nagar, Bellur, Mandya, Karnataka, India in the time period between January-2014 to July-2015.

INCLUSION CRITERIA

All cases of diabetic wounds / foot presented to the hospital during the study period.

EXCLUSION CRITERIA

- Cases of diabetic wound / foot with cancerous surrounding tissue, fistulas to the other organs or body cavities and or osteomyelitis.
- Patients with recognized active Charcot disease or ulcers resulting from electrical, chemical, or radiation burns and those with collagen vascular disease, ulcer malignancy and untreated osteomyelitis were excluded from the study.
- Concomitant medications such as corticosteroids, immunosuppressive medications, or chemotherapy; Pregnant or nursing mothers were excluded from study participation.

Infective rate in VAC and MGD in diabetic wounds

All the selected patients history,clinical presentations and physical findings were recorded according to the proforma. All patients enrolled in the study underwent the following investigations:

Blood investigations

- Haemoglobin%,total count,differential count, Erythrocyte sedimentation rate, bleeding time, clotting time, platelet count, random blood

glucose, fasting blood glucose, post prandial blood glucose, glycosylated haemoglobin in selected patients, HIV, HBsAg, blood urea and serum keratinize

- In few selected patients with other co morbidities we ordered:serum electrolytes- Na,K,cl.,Thyroid function test-T3,T4,TSH,Liver function test.
- Urine routine:albumin,sugar,microscopy.Urine culture and sensitivity in patients with urinary tract infection.
- Wound culture and sensitivity in almost all patients.

IMAGING STUDIES

- X-RAY-AP and lateral view, of the affected limb / part bearing the diabetic foot ulcer.
- Doppler ultra sound of the arterial system of the leg in patients with weak or absent peripheral pulses.

Infective rate in VAC and MGD in diabetic wounds

On admission, patients were medically treated to control their diabetic status by diet restriction, insulin (dose adjusted according to blood glucose levels later fixed doses). Wounds were debrided upon admission with an aim achieve to complete skin cover and save the limb. Regular dressings were done on a once in 2 day basis (more frequent dressing depending on wound status) for the study and control groups respectively. Moist gauze dressings applied to 30 patients (control group) and vacuum dressing for remaining 30 patients (study group). Initially study started with a vacuum suction apparatus as shown below.

Figure 2: Infective rate in VAC and MGD in diabetic wounds

The main limitation of this apparatus was high cost, low durability and non availability in our pharmacy. So from various studies and according to the affordability of the patients we found out a method which is suitable for our hospital set up. Sponge is cut in the shape of wound and sterilized. New Ryles tube is kept over the wound for each successive dressing, in some poor patients who could not afford repeated new Ryles tube the same old Ryles tube was washed with spirit, then dipped in betadine is reused maximum for 2 times.

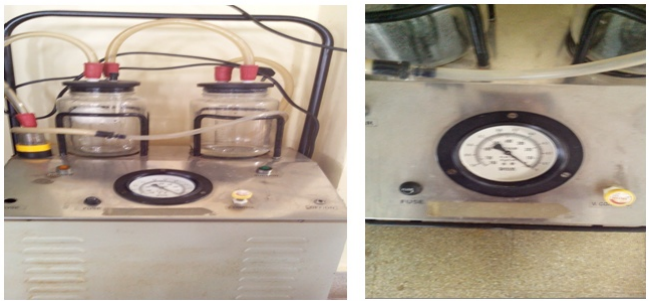

Figure 3: Mobile vacuum suction apparatus available in our wards and ICU with adjustable vacuum pressure

Figure 4: Infective rate in VAC and MGD in diabetic wounds

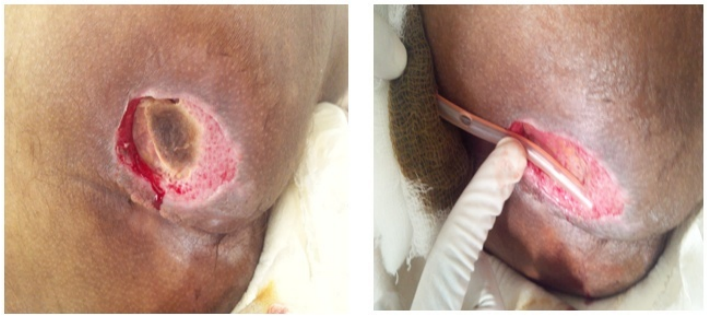

Figure 5: Fixed centralized vacuum suction apparatus, present mainly medical wards side and ICU

Bed sore of ICU patient (post road traffic accident, intracranial haemorrhage), wound debrided, surrounding area is shaved and Ryles tube placed in wound bed.

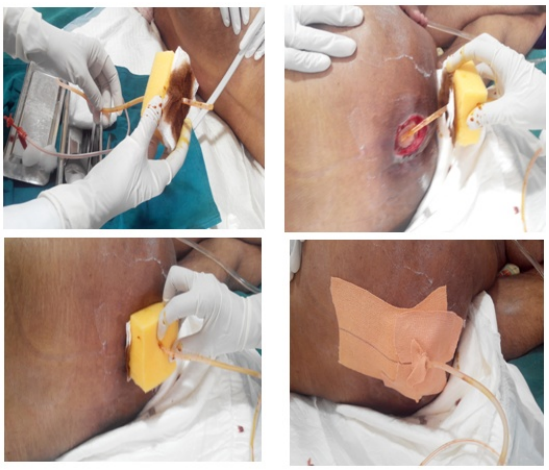

Figure 6: Infective rate in VAC and MGD in diabetic wounds

Small central hole is made in the centre of the sponge and a betadine soaked dried gauze piece over wound bed,stuck it to wound area by tegaderm first then dynaplast adhesive plaster to create tight air seal. Distal end of Ryles tube is connected to vacuum suction apparatus, intermittent every 30 minutes/1 hourly/2 hourly at pressure ranging from 150-200mmhg depending upon the stage of healing of wound.

Infective rate in VAC and MGD in diabetic wounds

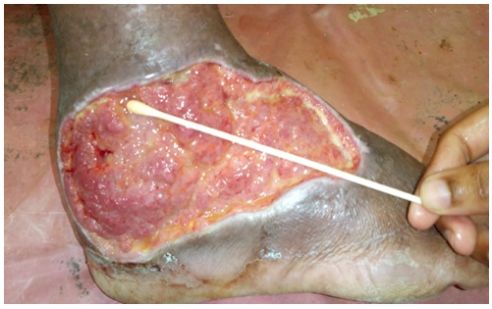

Figure 7: The maximum overall cost of this most effective above method was Rupees 200.

Figure 8: Culture sensitivity is sent from the wound bed with a swab stick for each and every case and a record of microbial growth was done in every case

Wound healing is monitored by measuring size of the wound by the paper and rate and changes in granulation tissue by photographs serially.

Infective rate in VAC and MGD in diabetic wounds

Figure 9: Moist gauze dressing done for the control group

METHOD OF STATISTICAL ANALYSIS:

The following methods of statistical analysis have been used in this study. The results for each parameter (numbers and percentages) for discrete data and averaged (mean + standard deviation) for each parameter were presented in tables and figures.

1. Proportions were compared using **Chi-square test** of significance Chi-Square (x2) test for (r x c tables)

Table 1: Infective rate in VAC and MGD in diabetic wounds

Row	Column			Total
	1	2.....	C	t_1
1	a_1	a_2	a_c	t_2
2	b_1	b_2	b_c	.
.	.	....	.	.
.	.	.....	.	
R	h_1	h_2	h_c	tr
Total	n_2	n_2	n_c	**N**

Chi square table distribution a,b…..h are the observed numbers.

N is the Grand Total

$$\chi^2 = N\left[\frac{1}{t_1}\sum_1^c \frac{a_1^2}{n_i} + \frac{1}{t_2}\sum_1^c \frac{b_1^2}{n_i} + \ldots\ldots\ldots\ldots\ldots\ldots + \frac{1}{t_r}\sum_1^c \frac{h_1^2}{n_i} - 1\right]$$

DF= Degrees of Freedom (Number of observation that are free to vary after certain Restriction have been placed on the data)

Infective rate in VAC and MGD in diabetic wounds

Student "t' test. The student't' test was used to determine whether there was a statistical difference between the groups in the parameters measured.
Student's t test is as follows:

$$t=\frac{\bar{x}_1-\bar{x}_2}{s\sqrt{\frac{1}{n_1}+\frac{1}{n_2}}} \sim\sim\sim t_{n1+n2-2} \quad \text{Where } s^2=\frac{(n_1-1)s_1^{\,2}+(n_2-1)s_2^{\,2}}{(n_1+n_2-2)}$$

In all above test P value less than 0.05 was taken to be statistically significant. The data was analyzed using SPSS package. **Infective rate in VAC and MGD in diabetic wounds**

OBSERVATION AND RESULTS

Table 2: Basic patient data

	VAC	MGD
Number of patients	30	30
Mean age in years	55.23	57.60
Male: Female ratio	1: 1.43	1: 0.43

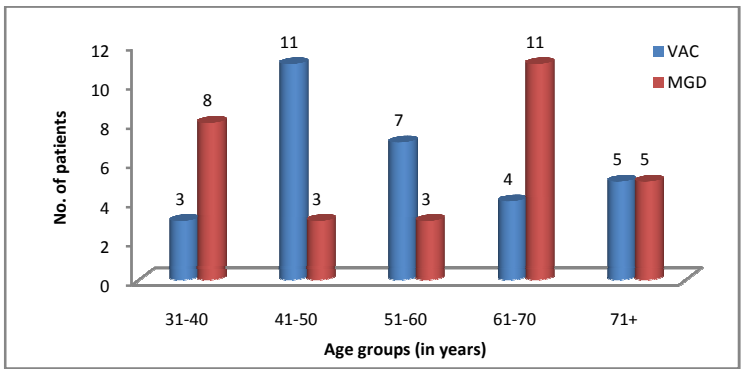

Figure 1: Infective rate in VAC and MGD in diabetic wounds

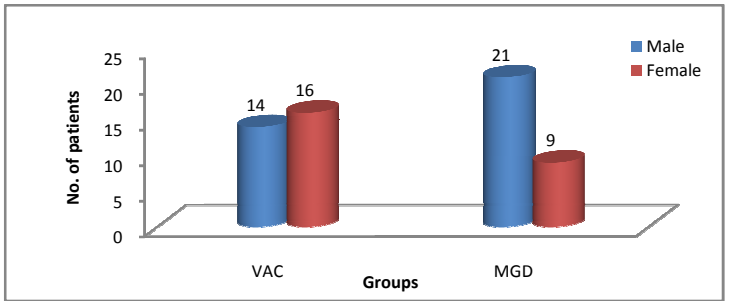

Figure 2: Organisms isolated: vac Group

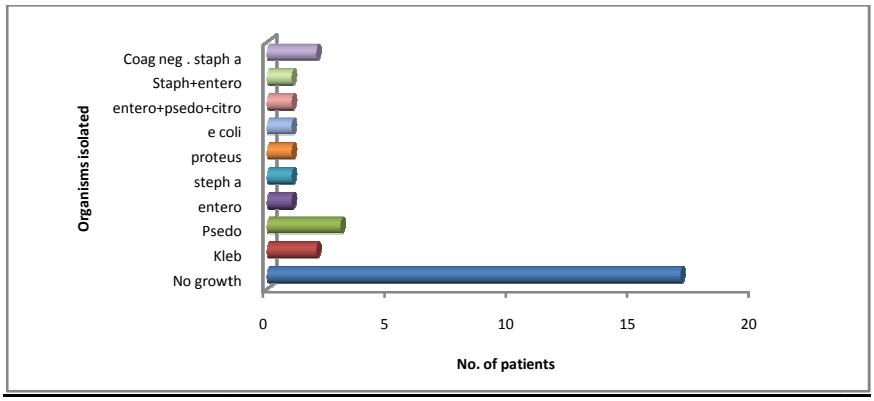

Figure 3: Infective rate in VAC and MGD in diabetic wounds

Not many organisms isolated from study i.e., VAC group, with nil culture growth being highest, second being pseudomonas then coagulase negative staphylococcus aureus.

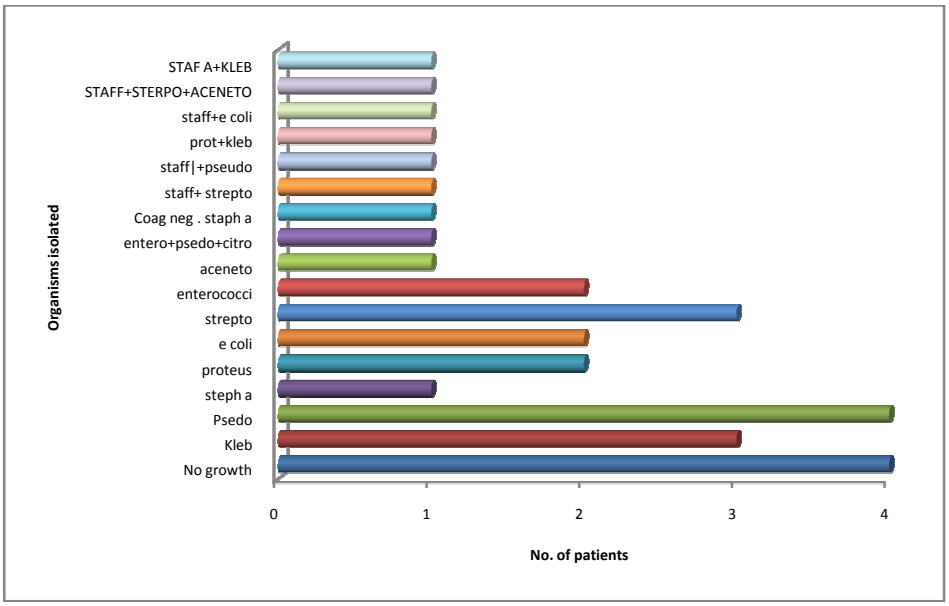

Figure 4

In the control group or MGD group along with nil growth pseudomonas accounts for highest organism isolated, then streptococcus (strepto) and Klebsiella (kleb) being second highest. Other organisms isolated are Staphylococcus aureus (steph.a/staff/stafa), proteus (prot), E.coli, enterococci, acinetobacter (aceneto), citrobacter(citro, coagulase negative staphylococcus aureus(coag neg. staph a).Few cases mixed growth have been isolated.

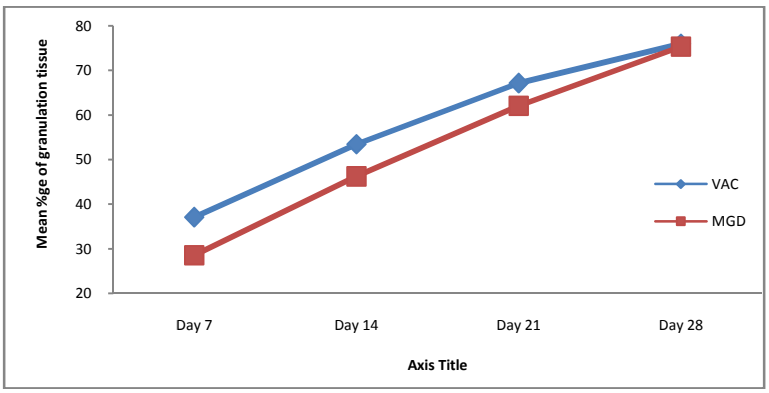

Figure 5: Percentage of ulcer floor covered with granulation tissue

Table 3: Graft uptake

Group Statistics					
	Group	N	Mean	Std. Deviation	Std. Error Mean
grapft_uptake	VAC	10	71.0000	26.64583	8.42615
	MGD	6	84.1667	3.76386	1.53659

Table 4: Final outcome

SCrosstab					
			Group		Total
			VAC	MGD	
finaloutcome	Nil	Count	1	0	1
		% within group	3.3%	0.0%	1.7%
	AKA	Count	0	1	1
		% within group	0.0%	3.3%	1.7%
	BKA	Count	1	2	3
		% within group	3.3%	6.7%	5.0%
	RE-SSG	Count	1	0	1
		% within group	3.3%	0.0%	1.7%
	SH	Count	16	12	28
		% within group	53.3%	40.0%	46.7%
	SS	Count	4	5	9
		% within group	13.3%	16.7%	15.0%
	SSG	Count	7	6	13
		% within group	23.3%	20.0%	21.7%
	SY	Count	0	2	2
		% within group	0.0%	6.7%	3.3%
	TMA	Count	0	2	2
		% within group	0.0%	6.7%	3.3%
Total		**Count**	**30**	**30**	**60**
		% within group	**100.0%**	**100.0%**	**100.0%**

Maximum number of patients were treated and healed by conservative treatment i.e., by secondary healing (SH) with a count of 16 patients (53.3%) in VAC Group and 12 patients (40%) in MGD Group achieving complete closure of the wound on discharge or on follow up. Secondary suturing (SS) was done among 4 patients (13.3%) in VAC group 5 Patients (16.7%) in MGD Group. In both the modes of treatment complete closure of the wound was achieved on discharge or on follow up. In VAC Group split skin grafting was done for 10 patients, 8 patients showed 90% graft uptake one patient had graft failure Re grafting was done, another patient wound healed by secondary intention due to graft failure. In MGD dressing group split skin grafting was done only in 6 patients among them graft uptake rate was 84%.Except the two cases all of them were well cured. In other cases where doubtful arterial supply, aetiology mainly being atherosclerosis few Necrotising fasciitis cases proceeded with amputation depending upon the level of obstruction. Datas of amputation being above knee amputation (AKA) in 1 patient accounting for 3.3% only in MGD group, below knee amputation(BKA) in 1 patient (3.3%) in VAC group and 2 (6.7%) in MGD group and Symes (SY) and transmetatarsl (TMA) amputation in 2 paients with 6.7% only in MGD group.

DISCUSSION

The concept of moist wound dressings which came into vogue in the 1960's which made revolution in wound care.[11] In the early 1990's, the concept of topical negative pressure moist wound dressing was introduced into the field of chronic wound care. This type of dressing involved a combination of hydrocolloid dressings with topical negative pressure dressings.[12] The high cost of the V.A.C. system led to the need to develop a less expensive comparably effective dressing, based on the same principles. Sterile sponge, wrapped in a layer of Jelonet is placed over the open wound. Evacuation tube is placed over the sponge, and covered with a second sponge layer. The whole area is covered with adhesive drape, creating an airtight seal.[13,14,15]

Comparison of the present study with joseph *et al.*, and peter a blume *et al*

	Peter.A,Blume *et al*[61]		Joseph *et al*[62]		Present study	
	VAC(stud Group)	MGD(cont rol group)	VAC	MGD	VAC	MGD
Sample size	169	166	18	18	30	30
Mean age(years)	58	58	52.41	53.20	55.23	57.60
Rate of granulation formation	95%	-	81.56%	54.30%	Day7-40% Day14-54%	30% 46%
Graft uptake	43.2%	28.9%	85.3%	56.43%	90%	84%
Hospital stay	63.6+/- 36.57	78.1+/- 39.29	36.24	70.4	20 days	20 days

Duration of hospital stay was very less in our study compared to other two This might be attributed to early discharge of patients in MGD group due to varied reasons and relatively longer stay of the patients in VAC group for treatment of their other co morbidities. Associated comorbidities include along with Diabetes Mellitus, Hypertension, Asthma, COPD (due to smoker patient in our trial), chronic liver diseases (due to more alcoholic patients from rural background),chronic cardiac disease and chronic CNS-post stroke(CVA),chronic epileptics, post Road traffic accident patients for observation after neurosurgical opinion for observation and on treatment. Few patients had Haemorrhoids, Hernia and Urolithiasis also. Next to Diabetes ,Hypertension was the commonest comorbidity in our patients. All medical comorbidities were treated by proper referral to physician and appropriate drugs. Most of the surgical co-morbidities were treated by operative intervention. Glycosylated hemoglobin was used as a marker to assess the severity of diabetes in bad glycemic control and poor wound healing despite of treatment. so a high level of HbA1c >8 was taken as index of severity and seen in patients who presented with gangrene and Necrotising fasciitis. Compared to the control group almost 1/3rd study group were completely cured by the end of second week and another 1/3rd by the end of third week either by conservative wound healing or by skin grafting.

Infective rate in VAC and MGD in diabetic wounds

As all the patients present here are from rural area cost constraint of the patient was taken into account and adopted a more efficient and cheaper method ,overall cost being within 200 rupees and about 95% patients were completely cured in study group and our method is best suitable for rural set up.

LIMITATIONS OF THE STUDY

- The most important limitation of the present study is its sample size. A randomized controlled comparative study with a much larger population may help to further substantiate the findings or reveal variations which were not observed in the present study.
- In our adopted method there used to be in growth of granulation tissue into the sponge, which used to disturb epithelisation, bleeding thereby wound healing on repeated dressing.
- Surrounding skin was macerated due to airtight seal. In our study last two limitations were overcome by soaking the dressing properly with normal saline for few minutes and removing the overlying gauze and sponge slowly thereby avoiding bleeding and disturbance in wound healing. Maceration of skin was prevented by leaving wound dry to air for 5-10 minutes on repeated dressing

Infective rate in VAC and MGD in diabetic wounds

Results are very good with high quality vacuum suction unit and should always be used whenever available and according to patients affordability and comfortability. Always large sample size and inclusion of all minute post operative parameters gives good and more accurate results.

CONCLUSION

In our study it was found that the application of Topical Negative Pressure increased the rate of formation of granulation tissue, **less infection rate** and had better graft uptake than the patients who underwent a conventional dressing for their ulcers. The patients in the study group had better patient compliance and had a shorter duration of hospital stay when compared to the control group. Thus, topical negative pressure moist wound dressing can be considered as a superior option in the management of diabetic foot ulcers. But further studies with larger population will be needed in the future before topical negative pressure dressing can be added to the wide spectrum of treatment modalities available in the management of diabetic foot.

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