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Effectiveness of Negative Pressure Dressing In Chronic Non Healing Wound

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Abstract: *Management of chronic non healing wound is always a challenging problem to the treating surgeon. So many newer modalities are now available and all are under trial .Here we are comparing the effectiveness of vacuum assisted wound closure in management of chronic non healing wound. We found out its more effective in granulation tissue formation and to reduce the bacterial overload and also it considerably reduced the incidence of amputation rate also.*

Key Words: *granulation tissue , non healing chronic ulcer , negative pressure dressing , tissue cover ,Vacuum assisted closure.*

I. Introduction

In past few centuries medicine is so much advanced in spite of that management of chronic wounds remains a tough challenge. To solve this lot of modalities of dressings and local applicants have been developed and lot of studies are still going on. Wounds which are showing characters of delayed healing or non healing is a problem which given rise to various complications in addition to financial and psychological burden. There are reports of employing wounds to sub atmospheric pressure in addition to regular debridement may help in acceleration of wound healing and granulation tissue formation following which procedures like grafting or flap surgeries may be done.

The application of controlled levels of negative pressure has been shown to accelerate healing in many different types of wounds. The optimum levels of negative pressure appears to be 125mm Hg And there is evidence that it is most effective if it applies in cyclical fashion.

It is believed that negative pressure assist removal of interstitial fluid, decreasing localized edema & increased blood flow. This in turn decreases tissue bacterial loads. Additionally mechanical deformation of cells thought to result in protein & matrix molecule synthesis which increases the rate of cell proliferation. Even though significant costs involved the technique is said to be comparable favorably in financial terms with conventional treatment in management of difficult non healing wounds.

Numerous studies described in using negative pressure wound therapy for intensive degloving injuries. infected sternotomy wounds, various tissue injuries prior to surgical closure, Grafting or reconstructive surgeries.

II. Aims And Objectives

To compare the efficacy of healing process of chronic or acute lower limb Ulcers treated by vacuum assisted closure with conventional methods of dressing.

It found relevant this technique could give better and early healing for chronic non healing ulcers.

Variables which are studied include duration of negative pressure application. appearance of granulation tissue, wound size, bacterial flora study, antibiotic usage, and duration of hospital stay.

III. Materials And Methods

This prospective randomized comparative study included 120 patients with lower limb ulcers of varying etiology, admitted to the surgery ward MES medical college, perinthalmanna, during October 2011 to march 2013 who satisfied the inclusion criteria as mentioned below. This study was done because lower limb ulcers are major burden in the society due to their chronic course and non healing nature. The clearance from ethical committee obtained. Consent had taken from the study population.

The data was collected prospectively from inpatients of surgery ward MES medical college, with lower limb ulcers of size greater than $2cm^2$.

3.1 INCLUSIONCRITERIA

1. Ulcer size > $2cm^2$.
2. Patients with age above18years
3. All types of lower limb ulcers irrespective of the etiology.
4. Patients giving consent for topical negative pressure.

Exclusion criteria include active Charcot disease, ulcers resulting from chemical or radiation burns and malignant ulcers untreated osteomyelitis and cellulites, dry gangrene.

The whole sample was divided into two equal and comparable groups of 60 patients each, based on the willingness for vacuum assisted wound dressings and those who are not willing are subjected to conventional moist wound dressings and included in the control group. Selection of patients was done by purposive sampling method. 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 1 and 2 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, conventional dressings done daily once, negative pressure dressings left undisturbed for 10 days and the wounds were compared 10^{th} day. Cultures were taken from the wound bed.

3.2 Materials used:

The negative pressure used in the vacuum assisted closure of the wounds is delivered by normal suction apparatus used in the wards. This is cheaper and use full variant of expensive VAC unit.

1. Suction apparatus
2. Opsite film
3. Sterilized sponge of 0.28 mm pore size 2-3 inches thickness with drains

3.3 Technique of application:

The vacuum assisted wound dressings comprises of air tight dressing with intermittent negative pressure. This includes five steps.

1. After thorough debridement and cleaning of wound sponge with perforated drains is kept covering entire surface of the wound.
2. Then the sponge with drains and surrounding normal skin are covered with thin adhesive film (opsite) to achieve an airtight dressing of the wound.
3. The other end of the drain tube is now connected to suction device which delivers a negative pressure 100-200 mmhg. The suction was applied intermittently at rate of hourly once for 10 minutes.
4. These whole dressings were covered with cotton bandages to protect the film of opsite.
5. The dressings were kept intact for 10days wounds examined on the 10^{th} day.

The fluid from the wound is absorbed by foam and is removed by the suction. This dressing is kept for 10days at the end of 10 days wounds are examined for amount of granulation tissue as percentage of ulcer surface area, dimensions of the ulcer, swab taken for culture and sensitivity.

These parameters are compared with control group. Afterwards the wounds are treated with grafting or normal dressings depending on the dimensions, and wound toilet. Once satisfactory result obtained these patients are discharged. These patients are followed up further out patient, in patient or telephonic interviews depending on the requirement.

The mean rate of granulation tissue formation, duration of the hospital stay, bacterial loads calculated and compared for both groups

The values are compared using un paired student- t test. A p value of < 0.05 is considered as significant

IV. Observation And Results

The 120 patients admitted in our hospital selected for study are divided into two equal and comparable groups. Those patients who were subjected vacuum pressure dressing were considered as group1, and who underwent conventional moist dressings were included in group2.

Table 1

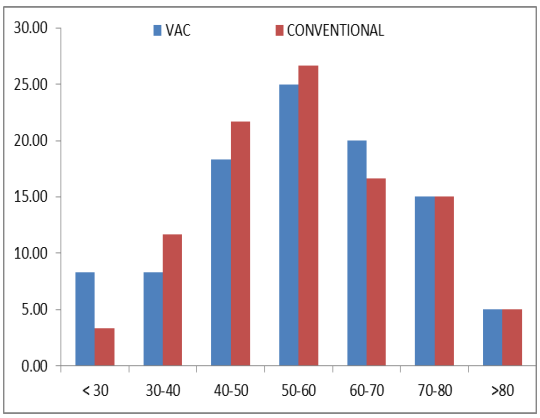
The patients' characteristics were well matched as shown in the table

Si no:	Group 1	Group2
Number of patients	60	60
Range of age	21-95	25-95
Male –female ratio	32:28	28:32
Range of ulcer surface area	8-220	6-180

Age wise distribution of the patients included in this study: group1 people with mean age of 56.13 and group 2 people with mean age of 55.73. And most of the people are middle aged ranging between 40-60 years of age.

Table 2
Age wise distribution of the patients

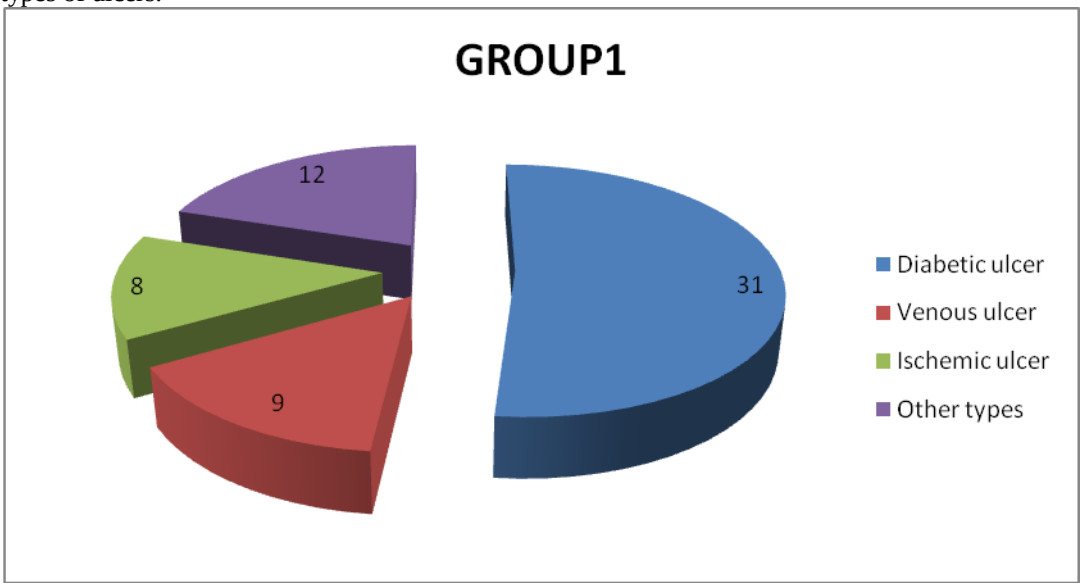
AGE	Type of dressing			
	VAC		CONVENTIONAL	
	#	%	#	%
< 30	5	8.33	2	3.33
30-40	5	8.33	7	11.67
40-50	11	18.33	13	21.67
50-60	15	25.00	16	26.67
60-70	12	20.00	10	16.67
70-80	9	15.00	9	15.00
> 80	3	5.00	3	5.00

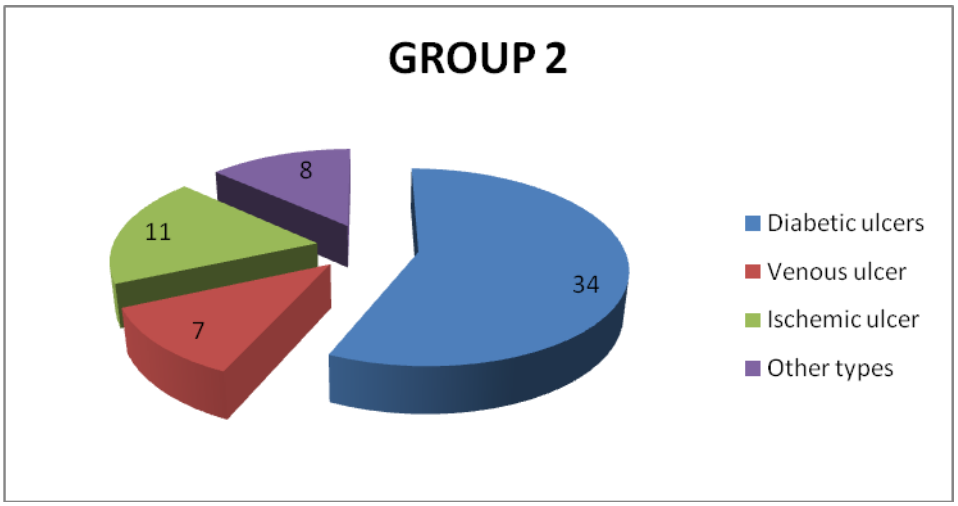


Graph.1 Age wise distribution of the patients.

Etiology wise distribution of patients :

All the patients who were included in the study were suffering from chronic or acute ulcers of varying etiology; the etiology of the ulcers was comparable in both the groups. Leading cause of lower limb ulcers was diabetes followed by ischemic and venous ulcers. Traumatic, pressure, and infectious ulcers included in the other types of ulcers.

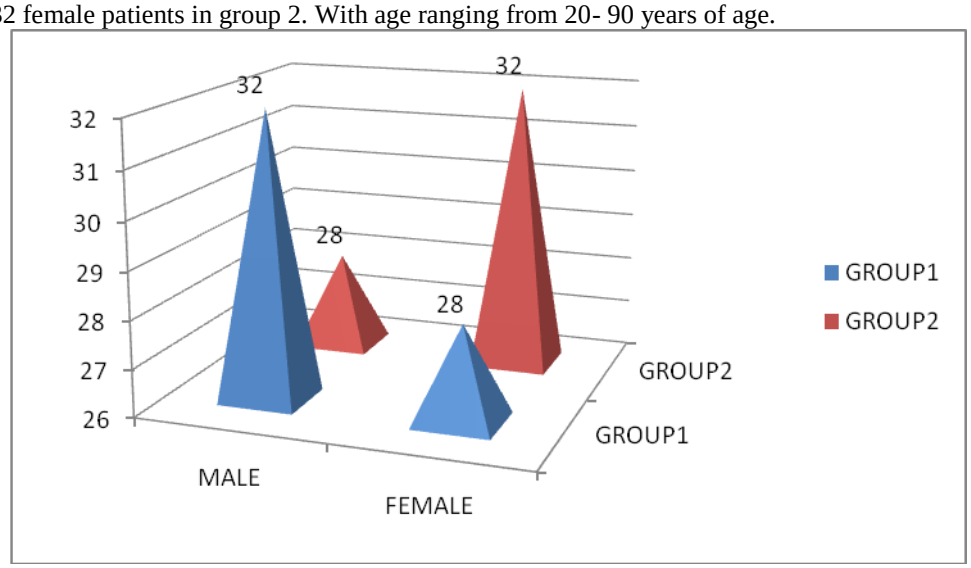




Graph 2 etiology wise distributions in both the groups.

SEX WISE DISTRIBUTION OF THE TWO GROUPS IS AS FOLLOWS

Total 120 members are included in the study out of them 32 are male and 28 female in group. And 28 male and 32 female patients in group 2. With age ranging from 20- 90 years of age.

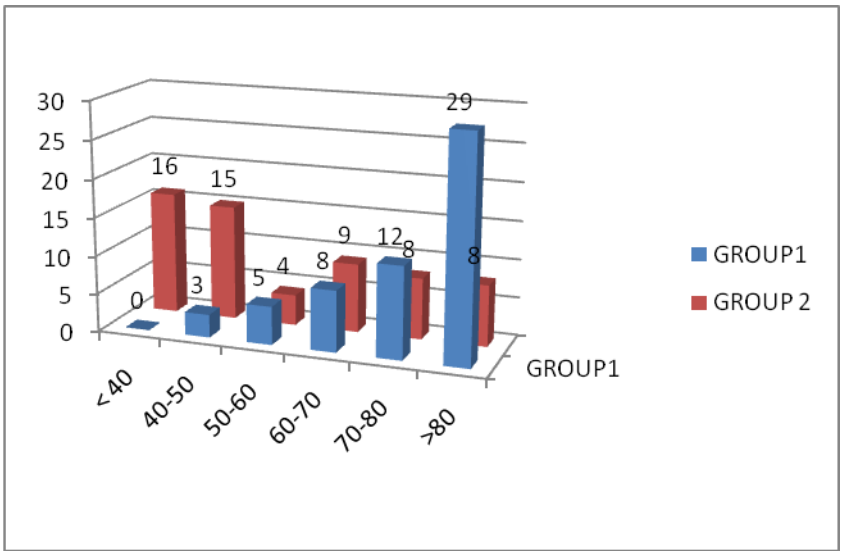


Graph .3 Sex wise distribution of the patients in both the groups

DISTRIBUTION OF PATIENTS ON RATE OF GRANULATION TISSUE FORMATION

The efficacy of the dressings was assessed as the percentage of healthy granulation tissue after 10 days. The mean rate ofgranulation tissue formation is 79.40± 15.20 in group 1 patients and 55.38± 19.43 in group2 patient.

%GT	Type of dressing			
	VAC		CONVENTIONAL	
	#	%	#	%
< 40	0	0.00	16	26.67
40-50	3	5.26	15	25.00
50-60	5	8.77	4	6.67
60-70	8	14.04	9	15.00
70-80	12	21.05	8	13.33
>80	29	50.88	8	13.33

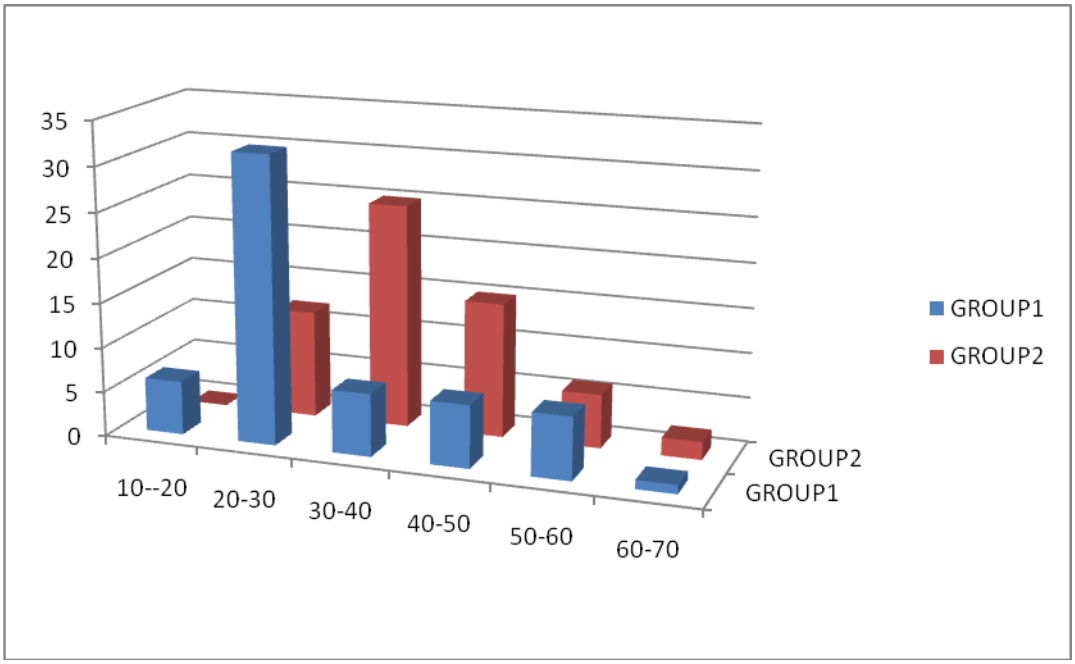


Graph .4 Rate of granulation tissue formation

DISTRIBUTION OF PATIENTS ON DURATION OF HOSPITAL STAY:

The mean duration of hospital stay is less in group1 patients those are treated by negative pressure dressings. The mean duration of hospital stay in VAC treated patients is 32.22± 11.68 which is significantly less when compared to group 2 which is 39.07± 9.07 .

DURATION	Type of dressing			
	VAC		CONVENTIONAL	
	#	%	#	%
10-20	6	10.00	0	0.00
20-30	32	53.33	12	20.00
30-40	7	11.67	25	41.67
40-50	7	11.67	15	25.00
50-60	7	11.67	6	10.00
60-70	1	1.67	2	3.33



Graph .5 Distribution of patients on Duration of hospital stay

In both groups few patients are subjected to grafting as per the need. The graft take up is better in group1 patients compared to group 2 patients.

Bacterial loads identified by cultures are less in vacuum dressing patient population compared to conventional group. Overall results by all the above parameters are better in vacuum dressing people compared to conventional dressings.

ANALYSIS OF THE DATA

Both groups participated in the study comparable age sex and type of ulcers though of diverse etiology. In all types of ulcers at any age group vacuum dressing have shown a definite advantage over conventional dressings.

The mean percentage of granulation tissue formation in group1 79.40 with standard deviation of 15.20 and the mean percentage of granulation formation ingroup2 is 55.38 with standard deviation of 19.43. these results are analyzed in unpaired student t- test which showed significant granulation formation in group 1 with $p<0.0001$.

The mean duration of hospital stay for vacuum group is 32.22 with standard deviation of 11,98is less compared to the control group with mean duration of stay as 39.07 with standard deviation of 9.07.analysis of data with unpaired student t-test revealed significant $p<0.001$.

Bacterial load in wound bed less in group1 compared to group 2 and graft uptake is also better in group 1 patients. Comparing the cost of dressing and complication rates there is not much difference between the two groups. There is definite advantage of decreased manual effort for cleaning and dressing daily which was taken care by suction.

V. Discussion

The life time risk of an adult to develop leg ulcer is 2.6% but may be as high as 20% in the tropics with significant economic consequences for individual and society. Chronic ulcers have a low frequency of spontaneous healing with long duration of healing. [(1)]

Negative pressure wound therapy was first described by Fleischman et al in 1993 done in 15 patients with open fractures and reported efficient cleaning and conditioning of the wound. Marked proliferation of granulation tissue. No bone infections in any patient and one have soft tissue infection and got treated.[(3)]In 1998 kovacs et al described how vacuum sealing could be used for the treatment of chronic radiation ulcers. [(3)]Morykwas et al 1997 addressed there issues in a series of animal studies deep circular defects of 2.5cm produced on back of pigs dressed with open cell polyurethane-ether foam pore size ranging from 400-600nm [(4)]

In first series a laser Doppler technique used to measure blood flow in subcutaneous tissue and muscle surrounding the wounds as exposed to increased negative pressure applied continuously and intermittently observed 4 times increase in blood flow with 125 mmHg and blood flow inhibited with pressure of 400mm Hg and above hence negative pressure value of 125 mm Hg selected for further studies.[(4)]

Rate of granulation tissue production is determined by measuring reduction in wound volume over time which is compared with control wounds. (Moist saline dressing wounds), Observed increased rates of granulation tissue with both continuous (63.3% +/_ 26.1%mmHg) and intermittent (103%+/_ 35.3%) negative pressure therapies.Thus intermittent or cycled treatment appears more effective than Continuous therapy. 2 possible explanations were advanced by philbeck et al[(5)].Suggested that intermittent cycling results in rhythmic perfusion of the tissue which is maintained capillary auto regulation is not activated and the cells which are undergoing mitosis must go through a cycle of rest for cellular component production and division. The same author suggested that this may follow a 48 hours period of continuous vacuum which can be applied to exert rapid initial cleaning effect.

Microbiological studies done by culturing the punch biopsy specimen from the wound. Tissue bacterial counts of vacuum treated wounds decreased significantly after 4 days. [(6)]

In a final part of same study by Morykwas et al observed effect of vacuum therapy was found increase flap survival by 21 % compared with control values[(8)]

Following their investigation Morykwas& colleagues suggested the removal of interstitial fluid decreases localized edema and increases blood flow, which in turn decreases tissue bacterial levels and proposed that mechanical tissue deformation or stress within the tissue resulting in protein and matrix molecule synthesis and enhanced angiogenesis.[(8)]

Vacuum Assisted Closure(VAC): Argenta and Morykwas determined that intermittent negative pressure at 125mmHg promoted wound healing by improving blood flow, granulation tissue growth rates and nutrient flow while reducing bacterial levels.

Based on these findings, Kinetic Concepts(San Antonio, Texas) developed the VAC system. The VAC consists of a wound dressing(a charcoal-impregnated sponge-like material) connected by tubing to a wound canister, with a pump that creates negative pressure. A transparent drape or film over the dressing establishes the

seal needed to create a vacuum. The pump can be adjusted for various levels of intermittent or continuous pressure. Exudates is collected in the canister. The VAC also is said to reduce the eAlthough extensive research is going on in the field of wound debridement, the treatment modalities available for chronic ulcers are limited. Most of the above mentioned techniques have their own limitations when chronic wound management is concerned. The concept of applying a sub atmospheric environment on wounds to accelerate the healing process came into practice in 1993 and was first described by Fleischmann et al. the science behind topical negative pressure dressings is to apply a sub atmospheric pressure over wound bed and maintain the negative pressure environment by means of a semi permeable occlusive coverage. Since the wound is occluded from the surrounding environment, it is also called "Limited Access Dressing(LAD)".[9.10]

5.1PRINCIPLES AND MECHANISM OF ACTION

The fundamental principle behind topical negative pressure dressing is the application of sub atmospheric pressures ranging from -25 to -200 mm Hg at the wound bed. A number of factors are found to be involved in delayed wound healing in chronic wounds, when conventional methods of wound dressings are used. These factors mainly include: [11]

1) Peripheral edema and circulatory compromise at wound bed
2) Bacterial colonization
3) Retarded granulation tissue formation

Peripheral edema and circulatory compromise

When negative pressure is applied over the wound bed, the edema fluid is evacuated along with all growth inhibiting factors. This relieves the back pressure effect on the healing tissues leading to improvement in local perfusion, local immunity, cellular waste disposal and tissue nutrition and oxygenation.

Laser Doppler studies have shown there is a fourfold increase in the local perfusion at the wound site when the topical negative pressure is applied. Studies have shown that pressures below -400 mm of hg inhibit local blood flow. The most optimum negative pressure range is -25 to -200 mm of Hg.

5.2BACTERIAL COLONIZATION

Topical negative pressure application is believed to achieve this by removal of accumulated interstitial fluid, improved local circulation and oxygenation and improved local immunity.

5.3Retarded granulation tissue formation

Topical negative pressure application has been proved to be effective in improving granulation tissue formation and maturation. Studies conducted by Morykwas and colleagues have shown that the mechanical stress that is applied on tissues by topical negative pressure has a stimulatory action on granulation tissue. This is by multiple mechanisms like,

a) Stimulation of mitosis
b) Enhanced angiogenesis
c) Increased protein and matrix synthesis
d) Improved epithelialisation[12,1,14,15,16]

Patient selection is very important prior to application of topical negative pressure therapy. The conditions mentioned as contraindications are those conditions where this mode of wound management either fails or is dangerous.

In wounds where devitalized tissue is present, especially in case of osteomyelitis, all the dead tissue including dead bone must be removed and any underlying infection must be treated prior to application of topical negative pressure. This is believed to be due to the fact that presence of devitalized tissue acts as a medium for bacterial growth and thus impedes healing.

In cases where fistulas are associated with the wound, topical negative pressure application may prove more dangerous. The suction device may not have sufficient capacity to accommodate the discharge removed by suction especially in case of high output fistulas. The negative pressure may also cause more fluid leakage through the fistulous tract leading to delayed healing of fistula.

In case of malignancies associated with ulcers, topical negative pressure application is a dangerous alternative as this mode of treatment has a potential for inducing and accelerating self proliferation. Since a moist environment is being maintained at the wound site, topical negative pressure therapy is not to be used in dry gangrene as there is a high chance for the gangrene to become wet.

Wound dressings were evolved from the status of covering the raw surface to absorb the exudates, and local applicants which promote healing and prevent infection. This has been achieved by promoting formation of granulation tissue by modern dressings.

The concept of moist wound dressings came into existence during 1960's which revolutionized wound care. This led to further research in this direction leading to influx of many products like semi permeable plastic

film dressings, hydrocolloids, hydro gels collagen dressings into the wound care scenario. In the early 1990s the concept of topical negative pressure moist wound dressings were introduced into the field of chronic wound care.

Advantages:

This technique is relatively new one with a further scope of development in management of chronic non healing ulcers and to enhance healing in acute wounds.

1. Increased percentage of granulation tissue
2. Decreased hospital stay
3. Decreased bacterial loads
4. Decreased Wound size
5. Increased graft take up (revascularization)
6. Decreased antibiotic usage
7. Cost effective
8. Decreased manual labor and thus decreasing wound contamination.

5.5 Limitations of the study:

The most important limitation is not quantifying all the above mentioned variables. Another important limitation is its sample size, though it is sufficient for statistical analysis, a randomized controlled comparative study with a much larger population helps to substantiate the findings or reveal variations which were not observed in the present study. The other variables like complications, pain, residual raw area, were not compared which would have given much better analysis of the effectiveness of negative pressure wound therapy.

5.6 FUTURE TRENDS

The significant advances in the chronic wound care are development of wound dressing systems, which not only prevent infections but also promote wound healing process by improved granulation tissue formation. The development of permanent composite skin replacement in the form of genetically engineered keratinocyte culture techniques and growth factors is one of the examples but the main problem of the later technique is that it is still in the experimental phase.

Lot of research is going on in the development of artificial skin substitutes by combining cultured keratinocytes with artificially formed dermal analogues, like Integra, Alloderm, polygalactin mesh, human allogenic dermis etc., which has immense potential.

VI. Conclusion

In our present study in treating lower limb ulcers, the topical negative pressure dressing has a definite advantage over conventional dressings. The granulation tissue formation, patient compliance wound healing is better with the negative pressure dressing group. It is also noted that duration of hospital stay and post operative complications are less with topical negative pressure dressing group. The graft survival and decline in bacterial loads are better with negative pressure dressings.

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