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A STUDY ON THE CLINICOPATHOLOGICAL COMPARISON BETWEEN VACUUM ASSISTED CLOSURE (VAC) AND CONVENTIONAL DRESSINGS IN THE MANAGEMENT OF INFECTED WOUNDS

Dr. Solanki Sandipkumar Jentilal — Former DNB Resident, Department Of General Surgery, K. J. Somaiya Medical College, Somaiya Ayurvihar, Sion, Mumbai, Maharashtra, India. Pin Code 400022.

Dr. Nilay Chakrabarti* — Professor, Department of General Surgery, K. J. Somaiya Medical College, Somaiya Ayurvihar, Sion, Mumbai, Maharashtra, India. Pin code 400022. *Corresponding author.

Dr Shalaka Indap — Associate Professor, Department Of General Surgery, K. J. Somaiya Medical College, Somaiya Ayurvihar, Sion, Mumbai, Maharashtra, India. Pin Code 400022.

ABSTRACT Microscopic Angiogenesis Grading System (MAGS) score is a scoring system used to assess the healing of the infected wounds. We conducted a clinico-pathological comparison along with MAGS score between Vacuum Assisted Closure (VAC) dressings and conventional dressings using saline + povidone iodine, in the treatment of infected wounds. A prospective, randomized, comparative study was conducted among the patients with infected wound admitted in surgical wards at a tertiary care hospital over a period of one year and nine months. A sample of 60 subjects was randomized into two groups. The patients were divided into two groups randomly Group A and Group B where Group A received VAC dressings on day 0, day 7 and day 14 i.e. three applications, and Group B received saline + povidone-iodine dressing. In Group A, dressing was opened on 7th, 14thand 21st day and dressing in Group B was done initially daily in the heavily contaminated wounds, and then on alternate days, and thereafter as per requirement. Both groups also received antibiotics and other supportive treatment. The reduction in wound size, MAGS score and bacterial culture in both groups were noted and were found significant with VAC dressings when compared to conventional dressings.

KEYWORDS :

INTRODUCTION AND BACKGROUND

Dermal wounds have been one of the commonest afflictions of mankind since centuries. In primitive societies substances derived from animals, plants and minerals were the basis of treatment.The earliest known wound care product was beer and the Mesopotamians prescribed beer for wound healing.[1] During the 19th century, the discovery of chemical preservatives and disinfectants and a better understanding of the nature of infection and inflammation allowed increased control of wound infection. In particular the use of carbolic acid by Joseph Lister in operation theatres from 1865 significantly reduced mortality rates associated with surgical procedures. Many different local agents have been used over years for wound healing like Chlorhexidine which was discovered in 1946 and introduced into clinical practice in 1954 and now widely used as an antiseptic in handwashing, and as a surgical scrub, but in wounds its application has been limited largely to irrigation.[2]. Later on many chemical agents like hydrohen peroxide, Iodine, Eusol etc were introduced and now widely used, Hydrogen peroxide has been widely used as an antiseptic and disinfectant.[3]. In wound care silver also has potent role because of its broad-spectrum antibacterial and antifungal properties.[4][5][6][7] The latest development in local wound care which accelerates the wound healing process is Vacuum Assisted Closure (VAC) . This is a relatively new procedure which works by removing blood or serous fluid from a wound or operation site and accelerating granulation tissue formation. The practice of exposing a wound to sub-atmospheric pressure for an extended period to promote debridement and healing was first described by Fleischmann W, Strecker W, Bombelli M.*et al* in 1993[8]. Once VAC has been applied to a wound its benefit lays in promoting healing of the area with decrease in wound size, decreased bacterial growth and proliferation of healthy granulation tissue. The study was made objective using the MAGS score which is a quantitative method of measuring the histologic extent of vascular and endothelial proliferation and was given by Bremm et al in 1972[9].

MATERIAL AND METHODS

A Prospective, randomized, comparative study was conducted among admitted adult patients with infected wounds in this tertiary care teaching hospital located in a metropolitan city draining a middle class/lower middle class urban population in an age group of 18-60 years. A pilot study was conducted in which 5 patients were studied in each group, i.e. VAC dressing group and conventional dressings and wound size was calculated. At 95 % confidence Levels and 80 % power, mean and standard deviations of the wound size on follow up in VAC dressing group was 13.24 +/- 8.48 and in conventional dressing it was 3.02 +/- 2.90. Based on Open EPI Software calculation, and considering non response rate of 10%, minimum sample size calculated was 57. The sample size was rounded off to 60 and divided into 2 equal arms of 30 subjects each. In present study subjects were enrolled by simple random sampling. Randomization of subjects across the group was done by using random numbers generated by computer and the study was carried out from June 2017 to March 2019. In this study all patients with superficial wounds either traumatic or surgical in nature, blood glucose of less than 200mg/dl and wound area of 1sqcm-100 sqcm were included. Patients with uncontrolled diabetes mellitus, underlying vasculitis, patients on immunosu ppr essants, malignant ulcers, deep burn wounds, tubercular ulcers and wounds with underlying bone infection were excluded. In this study, patients were divided into two groups randomly Group A and Group B where Group A received VAC dressings on day 0, day 7 and day 14 i.e. three applications, and Group B received saline + povidone-iodine dressing. In Group A, dressing was opened on the 7th, 14th and 21st day and dressing in Group B was done initially daily in the heavily contaminated wounds, and then on alternate days, and thereafter as per requirement. Both groups also received antibiotics and other supportive treatment. The outcome was measured in clinical terms as well as objectively using the Microscopic Angiogenesis Grading System (MAGS) score [8] which was calculated for each wound in both groups, and a comparison done. The end point of the comparison was a healthy, non-infected wound with a MAGS score above 80 while the end point of the study *period* was 21 days (3 weeks) from the beginning of the study. Findings were entered in the study protocol individually for each patient. Clinical wound assessment was performed at the beginning of each dressing and findings were noted considering several criteria which included wound size, exudates, odour, necrosis/ sloughing, presence or absence of pain [measured using the Visual Analogue Scale (VAS)], presence of healthy granulation tissue, and bacterial culture done along with photographic documentation of the wound. Histopathological assessment was carried out by taking a biopsy from the margin of ulcer on the first day(beginning of the study) and twenty first day(end of study). The findings were used in the assessment of angiogenesis applying the Microscopic Angiogenesis Grading System (MAGS) score. All the data was entered and compiled using EPI software version 7.2. in Microsoft Excel. Frequency, percentage, mean and standard deviation was used to summarize the

data. Bar diagrams, Pie charts were used to represent the data graphically. Unpaired "t" test, Chi Square test and Z test were used as a test of significance (At $p<0.05$).

RESULTS AND ANALYSIS

In this study 60 subjects with infected wounds were enrolled and were equally divided into two groups based on random distribution into **Group A** consisted of subjects treated with VAC dressings applied on day 0, day 7 and day 14. and **Group B** consisted of subjects treated with conventional saline and povidone-iodine dressings. Mean age of Group A(37.17 +/- 14.293) was more than Group B(35.80 +/- 14.587) however it was not statistically significant after applying Unpaired T-test. Wounds were on different sites of body in both the groups. Initial wound size in both groups were 24 sq. cms on an average and result displayed a significant average percentage reduction in wound size in Group A as compared to Group B on day 7 (20.46 & 14.80 sq. cms in Group A & Group B resp.), on day 14 (51.61 & 27.22 sq. cms resp.) and on day 21 (59.12 & 53.20 sq. cms resp.). Because of the significant reduction of wound size in Group A, Number of sessions required were 3 times in 10(33.3%), 2 times in 19(63.3%) and a single cycle in 1(3.3%) patients. When data were compared with respect to wound ready for skin graft it was significant. Reduction in pain was also significant which was done using VAS (Visual Analog Scale). In our study we found wounds contaminated with this all organism, Staphylococcus, Streptococcus, Klebsiella, E.coli, Pseudomonas and Acinetobacter from which Pseudomonas was the organism which was maximum in 1(3.3%) patients. When data were compared with respect to wound ready for skin graft it was significant. Reduction in pain was also significant which was done using VAS (Visual Analog Scale). In our study we found wounds contaminated with this all organism, Staphylococcus, Streptococcus, Klebsiella, E.coli, Pseudomonas and Acinetobacter from which Pseudomonas was the organism which was maximum in numbers. On comparison of positive bacterial culture from wounds of both groups after applying Z test, the difference on day 7 was not statistically significant but was significant on day 14 and 21 with p value of 0.0003 and 0.002 respectively. In our study we used objective criteria to assess the amount of granulation tissue i.e. MAGS score The difference was statistically not significant on day 7 but from day 14 the difference between MAGS score appeared to be statistically significant with p value of < 0.0001 on day 14 as well as on day 21. As days passed we could clearly see the MAGS score of higher value in Group A as compared to Group B which was again statistically proven.

Fig 1. VAC Application – Stepwise

Table 1. Average percentage reduction in wound size in both groups

Group	On day 7	On day 14	On day 21
Group A	20.46 +/- 6.99	51.61 +/- 16.64	59.12 +/- 8.6
Group B	14. 80+/- 4.55	27.22 +/- 9.26	52.20 +/- 13.77
P value (unpaired t-test)	0.0004	<0.0001	0.02

Fig. 2. Average percentage reduction in wound size in both groups

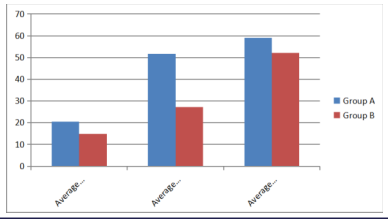


Table 2. Distribution of subjects according to bacterial growth in both group

	Group A	Group B	Total
Staphylococcus	2	5	7
Streptococcus	6	5	11
Klebsiella	5	7	12
E.coli	6	6	12
Pseudomonas	10	3	13
Acinetobacter	1	4	5
Total	30	30	60

Fig. 3. Distribution of subjects according to bacterial growth in both group

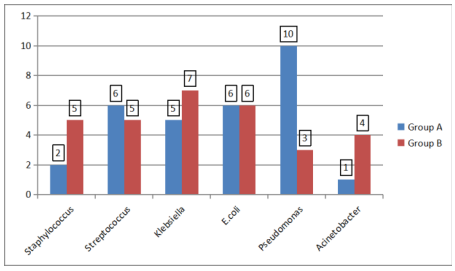


Table 3. Distribution of subjects with positive bacterial culture in both group

Group	day 0	day 7	day 14	day 21
Group A	30(100%)	18(60%)	8(26.6%)	1(3.33%)
Group B	30(100%)	24(80%)	22(73.3%)	10(33.3%)
p value (by Z test)	NA	0.09	0.0003	0.002

Fig. 4. Distribution of subjects with positive bacterial culture in both group.

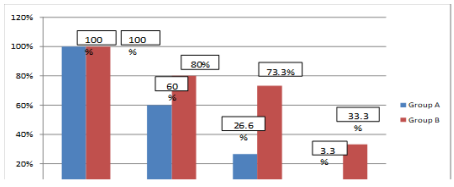
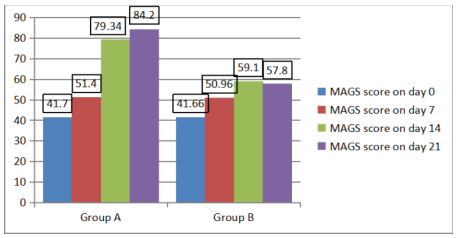


Table 4. Distribution of subjects according to average MAGS Score

Group	MAGS Score on day 0	MAGS Score on day 7	MAGS Score on day 14	MAGS Score on day 21
Group A	41.70+/-0.59	51.40+/-1.42	79.34+/-16.3	84.2+/-2.4
Group B	41.66+/-0.80	50.96+/-5.10	59.10+/-7.30	57.83+/-4.5
p value (by unpaired t-test)	0.82	0.06	< 0.0001	< 0.0001

Fig. 5. Distribution of subjects according to average MAGS Score



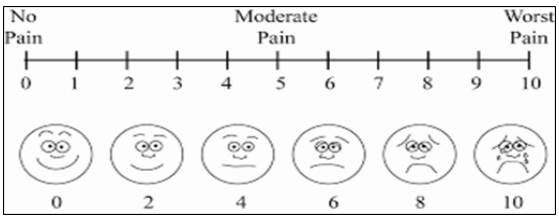
DISCUSSION

VAC also known as Negative Pressure Wound Therapy (NPWT) is a type of wound dressing system that works by applying continuous or intermittent sub-atmospheric pressure to the wound to help in healing. Applying negative pressure at the wound surface through an exclusive polyurethane reticulated foam dressing helps by tying wound edges

together, eradicates infectious fluid and stimulates the granulation tissue to hasten the wound healing. It's a latest modality of therapy which is proving to be very helpful in wound healing especially when it comes to increasing rate of wound healing. At present there are two theories considered for understanding how exactly negative pressure helps in wound healing. The first is about microstrain i.e. strain generated due to negative pressure at cellular level resulting in cellular mitogenesis, angiogenesis, and elaboration of growth factors. The second is enhancement of the microcirculation by active evacuation of excessive interstitial fluid in the form of edema. NPWT can be delivered as continuous or intermittent pressures. While some studies say that continuous pressure is more effective, some say that intermittent pressure application is better. The Vacuum machine is produced in USA by KCI (Kinetics Concept Inc.) and is widely used there as well as other parts of world including India. Various modifications in the system have been tried for example,

1. A second catheter can be installed in the foam (sponge) through which wound can be irrigated continuously/intermittently with normal saline. This helps in allowing heavily contaminated wounds to get rid of the particulate waste and bacterial matter continuously from the wound which is completely sealed
2. There are two types of sponges available, a) polyurethane black foam with a pore size of 400-600 micron and b) denser polyvinyl white foam. Most commonly used is the black foam; white foam is used where we want slow rate of granulation. There is silver coated sponge recently available which decreases the odour from the wound as well has antibacterial property.
3. Some of the devices have alarm systems which issue a warning when there is excessive fluid causing overload of the canister or when there is inadequate sealing.

It is obvious that a larger wound will take longer to heal. Size of a wound is considered the single most important parameter playing a major role in assessment of wound healing, and is also considered the most easily measurable one. On comparing both groups for average percentage decrease in size of wound the average percentage reduction on day 7, 14 and 28 all were significantly high in Group A as compared in Group B. Pain is one of the most common complaints for patients having wound. When compared to regular povidone-iodine dressing which is done by using gauze which needs contact with the wound surface and so causing pain to patient each time the dressing is changed , VAC dressing, once applied subjects the patient to continuous negative pressure which gives patient no pain. Several pain measur ement or scoring systems are available to assess the severity of pain. The simplest is the visual analogue scale (VAS) in which the severity of pain is judged by looking at the facial expression of the patient which scales from no pain to worst pain.



VISUAL ANALOG SCALE (VAS)

The results clearly indicate the superiority of VAC over conventional dressings in this aspect of the comparison. As mentioned earlier, we had chosen an objective assessment of a wound healing i.e. the MAGS score. which requires a biopsy from the wound and evaluation of angiogenesis under the microscope. On day 0 for Group A the MAGS score was 41.70+/-0.59 and in Group B it was 41.66+/-0.80. Similarly on day 7 in Group A it was 51.40+/-1.42 and in Group B it was 50.96 +/-5.10 and after applying unpaired t-test the p value obtained was 0.06(non-significant)**.** On day 14 and 21 MAGS score in Group A was 79.34+/-16.3 and 84.2+/-2.4 respectively while in Group B it was 59.10+/-7.30 and 57.83+/-4.5 which after applying unpaired t test was statistically significant. VAC appeared costly initially when compared to conventional povidone-iodine dressing as the cost of hiring VAC machine was expensive and also the dressing material used like sterile foam, opsite film, vacuum cup and tubing's were expensive, but when all other parameters where compared for example patients in Group A undergoing a skin grafting sooner and therefore were discharged from hospital earlier as compared to those in the other group with early return to work , it becomes cost effective. Research has come up with a cheaper, simpler technique based on the similar principle of NPWT where instead of expensive foam, gauze pieces are used. This is the so called GSUC (Gauze-Suction) dressing and the tubing is connected to the central vacuum machine available in the hospital. A study by Jeff et el. published as recently as in 2017 compared a cost effective alternative method of negative pressure wound therapy[10]. It was a retrospective study performed at University of Chicago medical center where data was collected from 1999 to 2014 from two patients groups , one where KCI-VAC was used and the other where GSUC was used. Results showed that a total of 35,871 days of NPWT was provided during 15 years. The average cost of KCI-VAC was $94.01/day while of GSUC was $3.61/day and after factoring in the labor cost, the cost per 1,000 days was $9,188 for GSUC versus $1,19,224 for KCI-VAC and the cost effectiveness of GSUC was conclusively proved. It is therefore evident that as VAC becomes more popular as a modality , its availability as well as the costs would fall, the ultimate beneficiary being the patient.

CONCLUSION

VAC dressing along with the routine standard of care treatment in the management of infected wounds is a better modality as compared to povidone iodine. The difference is statistically significant in favor of VAC dressing as compared to povidone iodine dressings. There is statistically significant reduction in wound size earlier as well as better histological evidence of healing in patients treated with VAC dressing as compared to conventional povidone iodine dressings. The use of VAC dressing is therefore recommended in treatment of infected wounds. Cost of treatment appears to be more in VAC dressing; however the difference in overall cost if compared long term especially in the context of decreased hospital stay, decreased overall morbidity and early suitability for skin cover, is not so significant. Therefore we concluded that there is a significant advantage of VAC dressing in early wound healing, as compared against conventional povidone iodine dressings.

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