

Comparative study on the outcome of negative pressure wound therapy and conventional saline dressing in chronic non-healing ulcers

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Abstract

Chronic non-healing wounds are wounds that have failed to progress through a timely sequence of repair, or one that proceeds through the wound healing process without restoring anatomic and functional results. Typically, there is physiologic impairment that slows or prevents wound healing. The wound healing society classifies chronic wounds into 4 major categories-pressure ulcers, diabetic foot ulcers, venous ulcers and arterial insufficiency ulcers.

Negative pressure wound therapy is a newer non-invasive adjunctive therapy that uses controlled negative pressure using VAC to help promote wound healing by removing fluid from open wounds through a sealed dressing and tubing which is connected to a collection container. Negative pressure wound therapy has benefits such as

Maintenance of moist, protected environment of the wound, Removal of excess interstitial fluid from the wound periphery, increased local vascularity, Decreased bacterial colonization, Quantification/qualification of wound drainage, Increased rate of granulation tissue formation, Increased rate of contraction, Increased rate of epithelialization.

Keywords: VAC, local vascularity, NPWT

Materials and methods

The study will be done on 210 patients in ESI hospital Bangalore. The patients are randomly divided into 2 groups- study group and control group. Patients are made to understand and sign the informed consent form.

Study group(A)-received NPWT (VAC KCI)

Control group(B)-received once daily dressing with saline

Source of data

The study will be conducted in Department of General Surgery, ESIMC PGIMSR, Rajajinagar, Bangalore - 10. All patients with clinical diagnosis of chronic non healing ulcer will be included in the study.

Study design

Prospective study (Case control study).

Study period

From January 2020 to June 2021.

Sample size

Based on the study conducted by Dr. Prabhdeep singhnain et.al "Role of negative pressure wound therapy in healing of diabetic foot ulcers" we hypothesized the proportion of granulated wound ready for skin grafting was 80% among study group/VAC and 60% among control group /normal saline the sample size was calculated with 80% power, 95% CI with ration of case to control 1: 1. the sample size for the study was estimated to be 105 in each group with attrition rate of 5%.

Method of collection of subjects

The prospective study (case control study) is intended to be carried out in 210 patients with chronic non-healing wounds admitted in ESIC MC BENGALURU

Inclusion criteria

1. Patients ready to give informed written consent for participation in the study.
2. Patients admitted in the department of general surgery in ESIC MC PGIMSR Bangalore diagnosed to have chronic non healing wounds.
3. Age group 18-65 years of age.
4. Ulcer area ranging between 25cm² to 100cm².

Exclusion criteria

1. Patient not willing to give informed consent.
2. Age less than 18 years old or more than 65 years old
3. Patient with osteomyelitis.

4. Malignant ulcers.

Statistical analysis: Data will be analyzed for descriptive and inferential statistics, so for descriptive statistics we calculate mean standard deviation range and proportion. For inferential statistics the continuous variable are converted to categorical variable, based on cut-off and chi-square test is applied to test the significance, A p value of <0.05 shall be considered as significant, we calculate sensitivity specificity, negative predictive value and positive predictive value.

Methodology

- Wounds of the subjects included in the study will undergo initial sharp debridement to remove slough as far as possible on the day 1. They will be then randomized (computer generated randomization) to either of the groups. Pus / Infected tissue will be sent for Culture and Sensitivity on the Day 1.
- After the debridement, VAC(KCI) is applied over the wounds of the study group under aseptic conditions. Sub atmospheric (negative) pressure was applied at - 125 mm of hg continuously. NPWT dressings will be changed every 5 days. The other control group received saline moistened gauze dressing on a daily basis.
- Broad spectrum antibiotics will be started in both the groups initially which be changed to specific Antibiotic after obtaining Culture and Sensitivity report.
- The following parameters were assessed discharge/ exudate, the Progress of Granulation Tissue, change in the size of the Wound were assessed every Fifth Day (initial wound size and final wound size were measured in mm² and wound preparedness for grafting was assessed by the end of 1 month.

- Wound culture and Sensitivity done on Day 1 will be repeated on Day 15 and Day 30 to assess the status of wound preparedness to accept skin grafting. The greater reduction in wound dimension had been attributed to the three-dimensional stress which VAC exerted across the whole area of the wound, also known as macro-strain, that drew wound edges inwards in a centripetal fashion, thus shrinking.

Observation and results

The numbers of patients studied were 210 and are divided in to two group, VAC dressing group and normal saline dressing group 105 in each group both the groups were matched in terms of

Age wise distribution

Sex distribution

Type of ulcer

Pain classification

Pus discharge

Surrounding tissue condition

Mean difference between the group

Wound healing parameters

Granulation tissue formation

Wound preparedness for grafting

Graft uptake in percentage

Number of complete cures

Estimated mean time to complete cure.

Number of complete cures in each group with each follow up.

Duration of hospital stay.

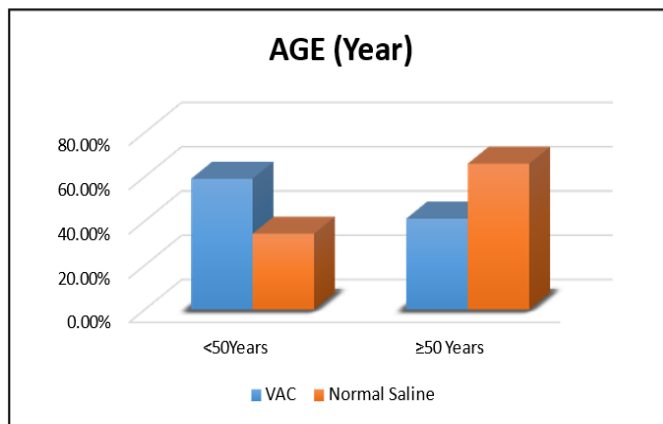
Observation and results

Table 1: Age Distribution of the study participants

	Group		Total	Chi Square	P-value
	VAC	Normal Saline			

AGE	<50Years	Count	62	36	98	14.745	0.009
CAT	% of	59.0%	34.2%	46.7%			
	Total						
≥50 Years	Count	43	69	112			
	% of	41.0%	65.8%	53.3%			
Total	Count	105	105	210			
	% of	100.0%	100.0%	100.0%			
Total	Count	105	105	210			
	% of	100.0%	100.0%	100.0%			

Figure 1: Age Distribution of the study participants

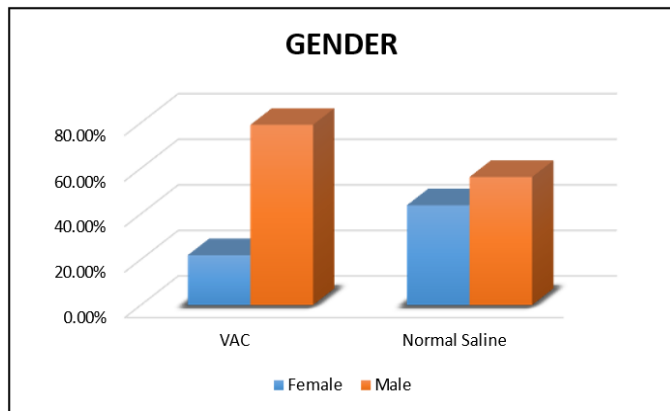


Out of 210 patients, 98 patients were aged less than 50 years, and 112 patients were aged more than 50 years. The incidence of diabetic foot ulcers is more in elderly patients, with significant p-value 0.009.

Table 2: Gender Distribution of the study participants

		Group		Chi square	P-value
		VAC	Normal Saline		
Female	Count	22	46	15.74	<0.001
	% of Total	21.9%	43.8%		
Male	Count	83	59		
	% of Total	79.1%	56.2%		
Total	Count	105	105		
	% of Total	100.0%	100.0%		

Figure 2: Gender Distribution of the study participants



Out of 210 patients, 88 were females and 142 were males. Incidence is more in males. With statistically significant p-value

Table 3 : Type of Ulcer

Type of Ulcer	VAC	Normal Saline
Diabetes ulcer	41	46
Bed sore	28	24
Ischemic ulcers	19	16
Venous ulcer	7	6
Traumatic Ulcer	10	13
Total	105	105

Figure 3: Type of Ulcer

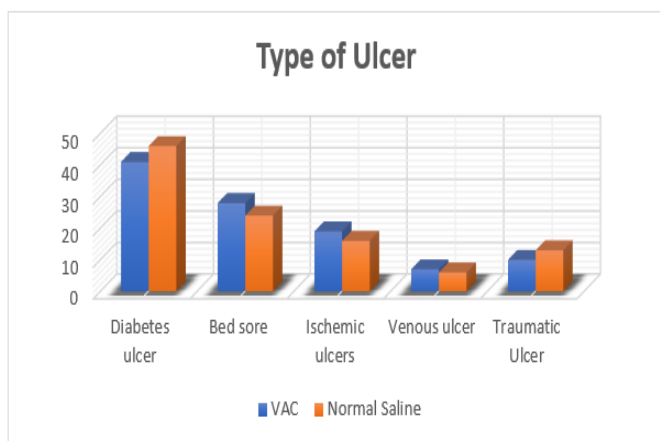
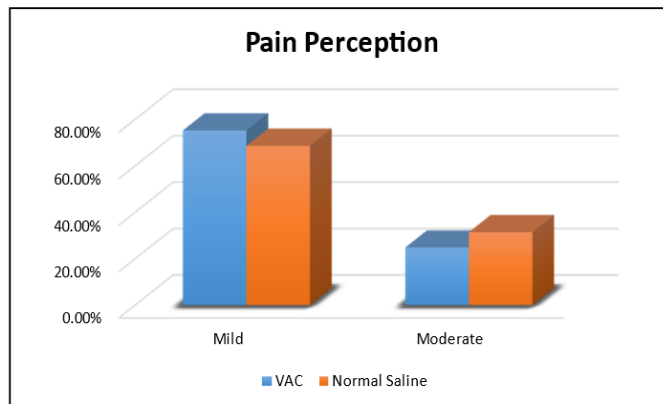


Table 4: Pain classification distribution of the study participants

	Group			Chi square	P-value
	VAC	Normal Saline	Total		

Pain Classification	Count	Group			Chi square	P-value
		VAC	Normal Saline	Total		
Mild	79	72	151	0.684	0.874	
% of Total	75.2%	68.6%	71.9%			
Moderate	26	33	59	0.684	0.874	
% of Total	24.8%	31.4%	28.1%			
Total	105	105	210			
% of Total	100.0%	100.0%	100.0%			

Figure 4: Pain classification distribution of the study participants

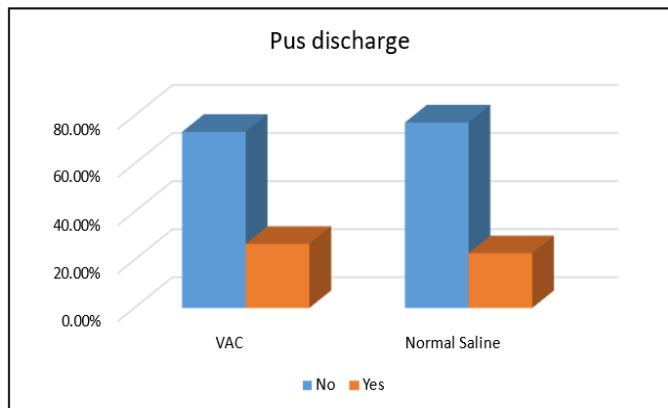


Out of 210 patients 151 patients had mild pain, 59 patients had moderate pain, with p-value 0.874. Adequate analgesia provided in both groups during the study.

Table 5: Pus discharge distribution of the study participants

	Group	Chi square	P-value			
				VAC	Normal Saline	Total
Pus Discharge	No	1.751	0.864			
	Count			77	81	158
	% of Total			73.3%	77.2%	75.3%
	Yes			Count	28	24
	% of Total	26.7%	22.8%	24.7%		
Total	Count	105	105	210		
	% of Total	50.0%	50.0%	100.0%		

Figure 5: Pus discharge distribution of the study participants

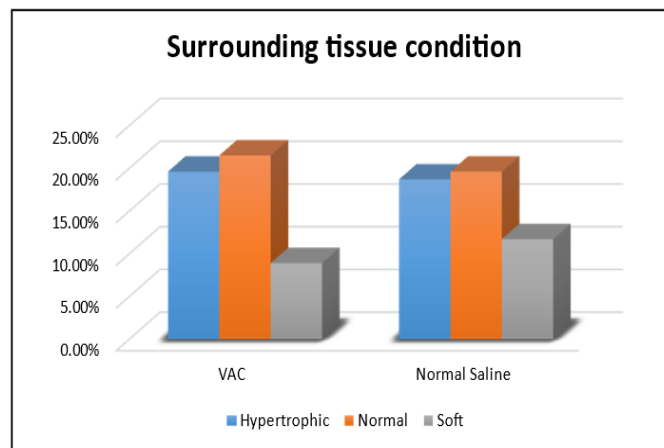


Out of 210 patients, 49 patients had pus discharge and 158 patients had no pus discharge, with no statistically significant difference i.e., p-value 0.864.

Table 6: Surrounding tissue condition

		Group			Chi square	P-value
		VAC	Normal Saline	Total		
Hypertrophic	Count	42	40	82	2.576	0.097
	% of Total	19.6%	18.7%	38.3%		
Normal	Count	46	42	88		
	% of Total	21.5%	19.6%	41.1%		
Soft	Count	17	23	40		
	% of Total	8.9%	11.7%	19.6%		
Total	Count	105	105	210		
	% of Total	100.0%	100.0%	100.0%		

Figure 6: Surrounding tissue condition



Out of 210 patients, 82 patients had hypertrophic surrounding tissue condition and 88 patients had normal surrounding tissue condition and 40 patients had soft surrounding tissue condition with no statistically significant difference. P-value 0.097.

Table 7: Mean Difference between the Groups

	Group	Mean	Std. Deviation	Std. Error Mean	T-test	P-value
AGE	VAC	55.75	10.451	1.165	1.754	0.545
	Normal Saline	53.17	9.337	1.125		
Duration of diabetes	VAC	10.92	5.477	.752	1.125	0.340
	Normal Saline	11.15	3.746	.789		
Hb1ac	VAC	8.72	2.211	.0427	1.074	0.711
	Normal Saline	8.66	.3189	.0438		
Duration of ulcer (months)	VAC	14.858	7.6989	1.0575	1.746	0.069
	Normal Saline	12.103	8.3082	1.1412		

Figure 7: Mean Difference between the Groups

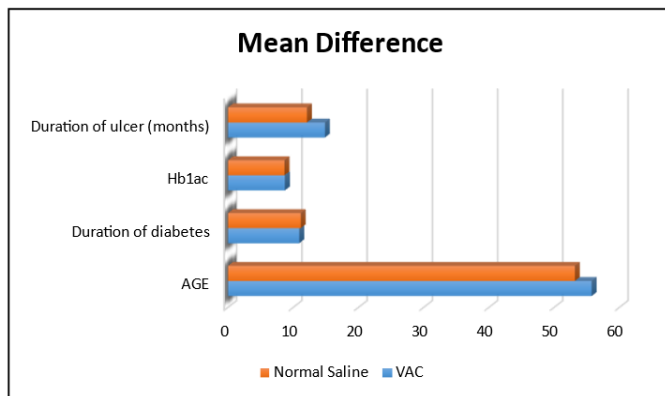


Table 8: Wound healing parameters between the study groups

	Group	Mean	Std. Deviation	Mean Percentage difference
Baseline	VAC	60.47	10.74	0.00
	Normal Saline	59.71	9.23	0.00
5th Day	VAC	49.55	8.7902	21.47
	Normal Saline	52.47	10.9828	28.16
10th Day	VAC	32.47	4.4996	48.99
	Normal Saline	45.33	3.3758	33.92
15th Day	VAC	26.45	3.9064	48.99
	Normal Saline	39.41	3.0937	41.61
20th Day	VAC	18.64	3.2297	44.02
	Normal Saline	32.44	2.9328	42.90
25th Day	VAC	10.44	2.8571	37.37
	Normal Saline	24.67	2.8521	43.61
30th Day	VAC	6.54	2.6444	52.20
	Normal Saline	15.47	2.5077	38.04

Figure 8: Wound healing parameters between the study groups

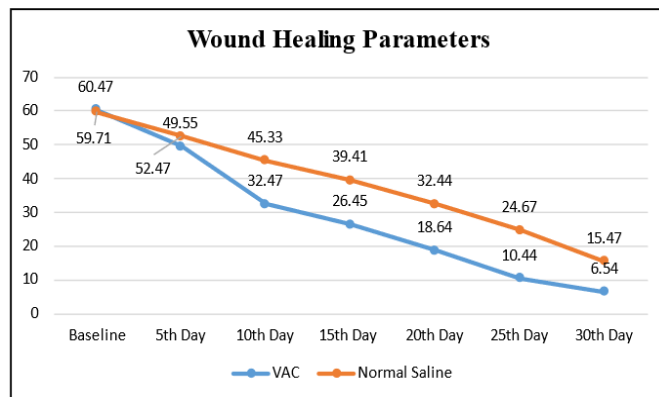
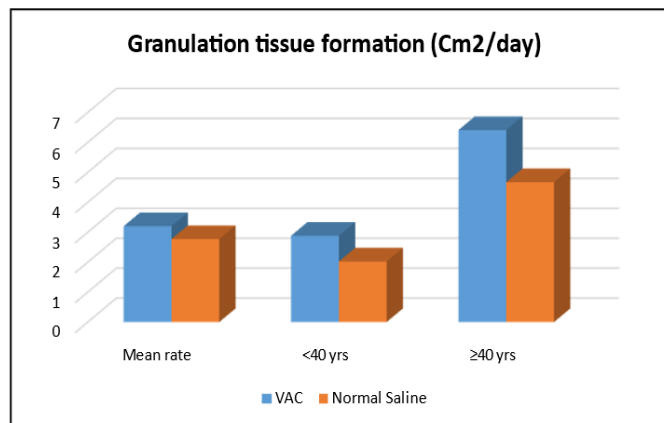


Table 9: Granulation tissue formation (cm2/day)

Granulation tissue formation (cm2/day)	VAC	Normal Saline	T test	P-value
Mean rate	3.2±5.22	2.77±4.87	14.944	0.003
<40	2.88±3.11	2.02±3.22	2.143	0.06
≥40	6.41±4.14	4.67±5.77	10.449	<0.001

Figure 9: Granulation tissue formation (cm2/day)



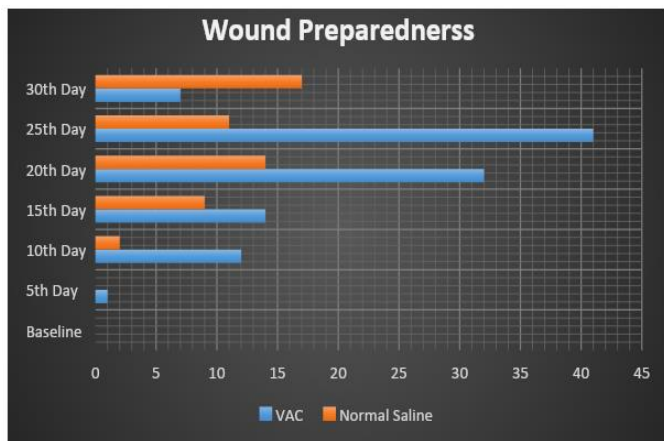
Out of 106 patients, 85 patients had granulation tissue with slough and 21 patients had slough. The p-value was 0.623, with no statistically significant difference.

Table 10: Wound Preparedness

Wound Preparedness	VAC	Normal Saline	Chi Square	P-value
Baseline	0	0	10.441	0.0021
5th Day	1	0		

10th Day	12	2		
15th Day	14	9		
20th Day	32	14		
25th Day	41	11		
30th Day	7	17		

Figure 10: Wound Preparedness

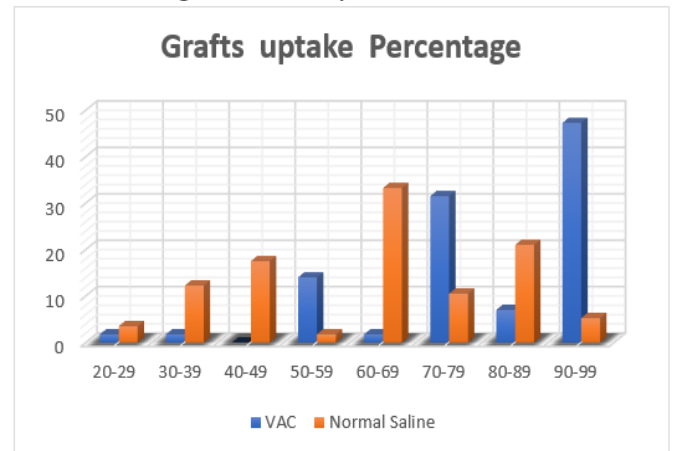


Out of 210 patients wound preparedness for skin grafting was more in VAC group as compared to normal saline group with significant P-value.

Table 11: Grafts Uptake %

Grafts Uptake %	VAC	Normal Saline
20-29	2	4
30-39	2	12
40-49	0	18
50-59	14	2
60-69	2	33
70-79	32	11
80-89	7	21
90-99	47	5

Figure 11: Grafts Uptake %



Out of 106 patients, graft uptake percentage was more in VAC group compared to normal saline group

Table 12: Number of complete cures

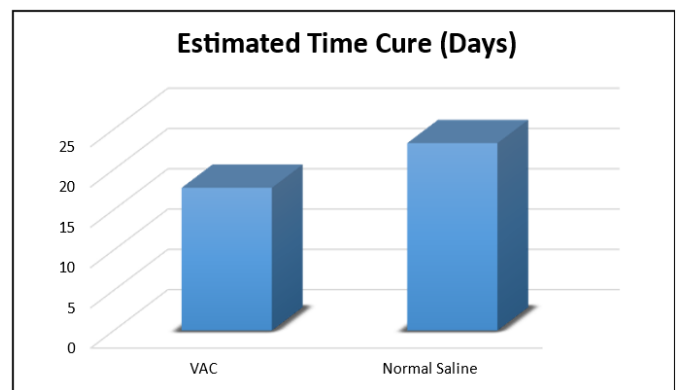


Table 13: Estimated Mean time to complete cure

Group	Estimated Mean time to complete cure			
	Estimate	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
VAC	17.706	0.145	10.423	32.990
Normal Saline	23.255	0.112	11.036	48.474

Figure 13: Estimated Mean time to complete cure

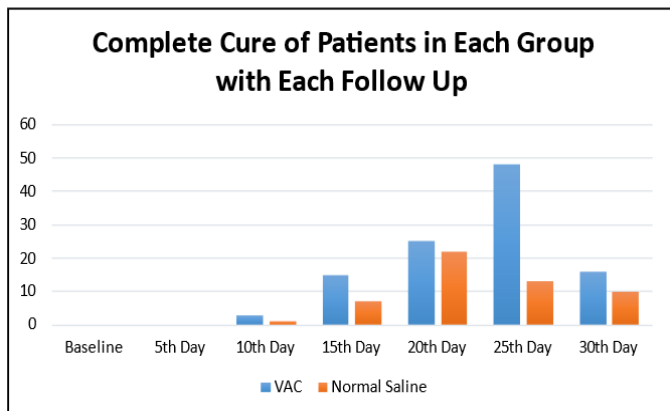


Table 14: Number of Complete Cure of Patients in Each Group with Each Follow Up

	VAC	Normal Saline
Baseline	0	0
5th Day	0	0
10th Day	3	1
15th Day	15	7
20th Day	25	22
25th Day	48	13
30th Day	16	10

Figure 14: Number of Complete Cure of Patients in Each Group with Each Follow Up

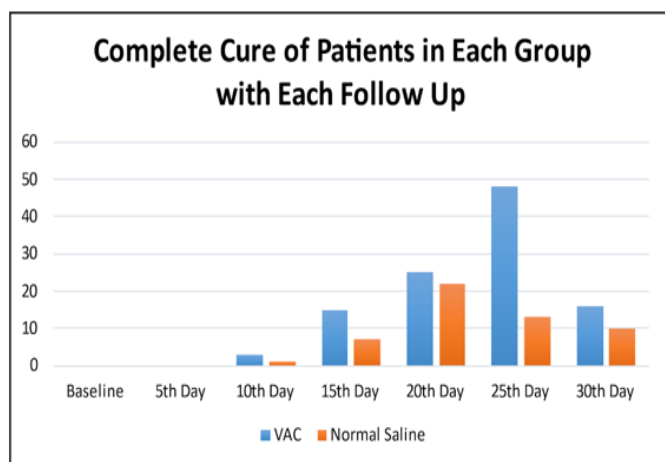


Table shows number of complete closure of ulcers in and Normal Saline VAC group with each follow up. There was no complete closure till 10th day in both the VAC and Normal Saline group. There was increased proportion of

complete closure in 15th, 20th and 25th day in VAC group as compared to the normal saline group.

Table 15: Duration of Hospital stay

Duration (days)	VAC	Normal Saline	Total	P-value
≤15	92(88.0)	85(81.0)	177(84.2)	0.015
>15	13(12.0)	20(19.0)	33 (15.7)	
Total	105(100.0)	105 (100.0)	210(100.0)	
Mean Duration Stay	21.4 ± 2.9	28.4 ± 3.6	-	0.004

Figure 15: Duration of Hospital stay

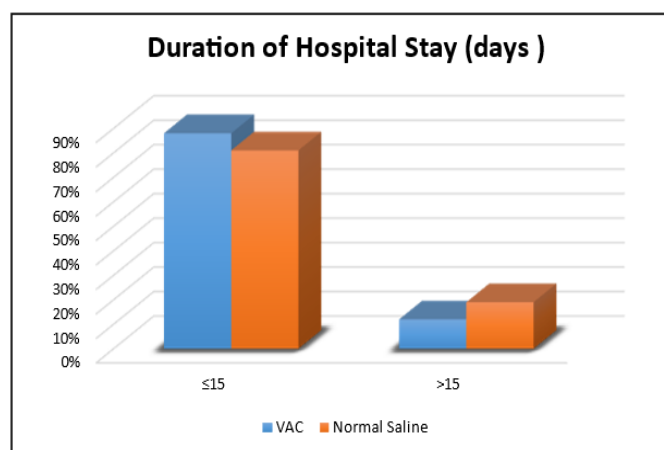


Table shows duration of hospital stay mean duration of hospital stay in both the groups are 21.4 ± 2.9 in VAC group and 28.4 ± 3.6 in normal saline group with p value is 0.004.



Day 1 of presentation chronic non healing ulcer of traumatic ulcer



After debridement



After 30th day of application of Vac



After skin grafting



After 6 months of skin grafting



Bed sore on day 1



on day 5



On day 1 of diabetic ulcer



On day 20



on day 10



After skin grafting



On day 25



On Day 1



On day 5



on day 10



On day 1

on day 5

on day 15

Discussion

The modern dressings are designed to promote and to maintain a moist wound environment in the different

phase of the wound healing. The traditional dressing has several disadvantages compared with newer dressings. The modern dressing not only provides moist environment and also reduces the contamination, minimises the trauma to delicate wound tissues and reduces the treatment cost for which the newer dressing designed to be left for several days over the wound. This study is in agreement with multiple other studies that state that VAC therapy is superior to conventional dressings for the management 6,7,8,9 of Chronic non- healing ulcers. The explanation of the success of the use of the VAC is found in the work of Argenta and Morykwas, that postulated that this new treatment technique removes excess interstitial liquid, increases angiogenesis, decreases bacterial colonization, and increases the formation of granulated tissues as a response to the stimulus of the mechanical forces created by the negative pressure transmitted through the sponge. Our study compared with the existing similar study conducted by Joseph et al., and Peter A Blume et al.

In our study the wound healing parameters was faster in VAC therapy group observed on the 5th, 10th, 15th, 20th and the 25th day, the ulcers in the study group showed evidence of granulation tissue on an earlier date than the control group.

On the 5th day the patients in the VAC study group had mean granulation tissue of about 21.47% in comparison with 28.16% of the patients in the control saline group. On day 10, the patients in the VAC study group had 48.99% mean granulation tissue on their ulcer floors when compared with 33.92% mean granulation tissues in the control saline group. A similar result was seen on day 15 with 15 patients in the study group already having some form of surgical therapy for skin closure and of the remaining patients had 48.99% mean granulation tissue

over their ulcer. The control group had 41.61% mean granulation tissues. By 25th day of the study 48 patients had already undergone treatment for their diabetic foot like split skin grafting or secondary suturing. The control group still having 38.04% mean granulation tissue on the ulcers needing further treatment. A mean duration of hospital stay in the vacuum assisted closures study group was 21.4+- 2.9 days as compared to 28.4+- 3.6 in the saline control group. Thus indicating a shorter duration of hospital stay in VAC therapy when compared to the latter group. This above study revealed that application of Vacuum Assisted Closure dressing over the ulcer surface can reduce the ulcer size and depth and promote ulcer healing to a greater extent than conventional normal saline moist wound dressings. In our study the wound preparedness for the skin grafting was observed more in no i.e 41 in VAC group on the 25th day as compared to normal saline which is 11 in with significant P- value which is 0.0021. In our study, the percentage of successful graft up take was 90-99% was observed in 47 people in the Vacuum Assisted Closure groups compared to in the control saline group 5 people . Enhanced vascularity, reduced wound edema, reduced bacterial growth in the former group all favored better uptake of the graft.

Conclusion

1. In our study it was found that the application of Vacuum assisted closure (VAC) dressing increased the rate of formation of granulation tissue.
2. The Infection rate following VAC therapy was minimal compared to Simple Saline Dressings.
3. Wounds treated with VAC therapy had better wound preparedness for skin grafting compared to saline dressings with shorter duration of time.
4. Wounds treated with VAC therapy had better graft up take than the patients who underwent a conventional

normal saline dressing for their Chronic non healing ulcers.

5. The patients in the study group had better patient compliance and had a shorter duration of hospital stay when compared to the control group. Indeed patients treated with VAC therapy were able to stay at the comfort of Home under constant Video Monitoring during the Pandemic avoiding the risk of exposure.
6. This vacuum assisted closure –wound dressing can be considered as a superior option in the management of chronic non healing ulcers , especially complex wounds like exposed bones and tendons and also reduced reconstructive surgery like flap cover to simple skin graft and the amputation rate.

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