REPORT

24(103), May - June, 2020

ISSN
2321–7359
EISSN
2321–7367

Medical Science

Efficacy of VAC (Vacuum assisted closure) therapy versus handcrafted vacuum assisted devices in healing of chronic wounds

Anuja Vivek Pande, Darshana Tote

Department of General Surgery, JNMC Sawangi, Wardha, Maharashtra, India

Article History
Received: 22 December 2019
Reviewed: 24/December/2019 *to* 11/February/2020
Accepted: 12 February 2020
E-publication: 18 February 2020
P-Publication: May - June 2020

Citation
Anuja Vivek Pande, Darshana Tote. Efficacy of VAC (Vacuum assisted closure) therapy versus handcrafted vacuum assisted devices in healing of chronic wounds. *Medical Science*, 2020, 24(103), 1111-1121

ABSTRACT

A chronic wound is any disruption in the continuity of the body's surface that requires a sustained time to heal, does not heal, or recurs. In other words, chronic wound is defined as wound that is not able to progress through usual phases of wound healing, in terms of sequence and periodicity. We at our tertiary care rural hospital tried a low cost NPWT using the suction machine available in the wards with some minor pressure modifications and using materials like gauze, pads and Ryle's tube. This type of vacuum assisted closure has the potential to be used on a daily basis in hospitals with budget constraints. It was a prospective observational study conducted in AVBRH Sawangi rural hospital on 50 patients where 25 patients each were subjected to low cost handcrafted VAC and high cost VAC and wounds were assessed at the end of 5 days. On comparison there was statistically similar amount of reduction in area and volume in both techniques. Statistically similar number of ulcers were converted to healthy granulation tissue ($p<0.05$). Both handcrafted & VAC dressing effectively reduced area &volume of the wounds thereby reducing the duration of

healing in chronic wounds. The total cost of handcrafted dressings was lower than VAC dressing thus making handcrafted dressing more cost-effective.

Keywords: chronic wound, handcrafted, VAC dressing, wound healing

1. INTRODUCTION

A chronic wound is any disruption in the continuity of the body's surface that requires a sustained time to heal, does not heal, or recurs. In other words, chronic wound is defined as wound that is not able to progress through usual phases of wound healing, in terms of sequence and periodicity (Venlar and bailey et al., 2009). Few Indian studies on the epidemiology of chronic wounds have taken place, one such study assessed the prevalence at 4.5/1000 population (Shukla and Ansari et al., 2005). Chronic wound care is a common medical problem that poses a significant financial burden to our healthcare system. Wound care management accounts for almost 4% of that total health system cost from current estimates, with total global wound management market projected to be worth over $18.5 billion by 2021 (Kim JJ and Franczyk M et al., 2017).

The major idea behind wound dressing is to kill the bacteria and reduce the bacterial load, removal of non-viable tissue, obtain moist wound bed. Normal saline is one of the routinely employed dressings in case of chronic wound (Dabiri G and Damstetter E et al., 2016). In the early 1990s Argenta and Moryk was developed a system that uses suction to help draw wound edges together; commercialized in 1995, negative pressure wound therapy (NPWT;V.A.C.®Therapy) creates a closed, moist wound environment while applying sub atmospheric pressure that removes exudate (Téot L and Guillot-Masanovic M et al., 2014). There are four primary NPWT mechanism of action: macro deformation, micro deformation, fluid removal and environmental control of the wound. Negative pressure wound therapy combines suction with a foam dressing and a semi-occlusive drape to keep the wound moist, facilitate fluid removal and stimulate healing at both macrocellular and microcellular levels (Téot L and Guillot-Masanovic M et al., 2014).

In developing countries like India, it may not be possible to make VAC therapy units available in all government hospitals due to the high cost of unit and disposables required. Negative pressure wound therapy (NPWT) also known as Vacuum assisted wound closure (V.A.C) has emerged to be a promising technology over the years. First described by Fleischman et al. (Fleischmann W and Strecker W et al., 1993) in 1993 done in 15 patients with open fractures, negative pressure therapy or vacuum assisted closure proved to be effective in cleaning and conditioning of the wound. One of the greatest drawbacks of this commercially available V.A.C apparatus was the high cost, limiting its use on a daily basis in the financially backward regions. But, as rightly said, necessity is the mother of inventions, we at our tertiary care rural hospital, tried a low cost NPWT using the suction machine available in the wards with some minor pressure modifications and using materials like gauze, pads and Ryle's tube. This type of vacuum assisted closure has the potential to be used on a daily basis in hospitals with budget constraints. In our setup understanding the etio-pathogenesis factors leading to chronic wounds and efficacy of our indigenous hand-crafted vacuum assisted devices versus VAC machine therapy in healing of this chronic wound is of utmost need.

Aim and objectives

Aim

To study the efficacy of VAC therapy and hand-crafted vacuum assisted device in healing of chronic wound.

Objectives

To study the various etiological factors leading to chronic wounds

To study the efficacy of hand-crafted vacuum assisted devices and VAC machine therapy in healing of chronic wounds in terms of-

Change in area of wound

Change in volume of wound

Change in granulation tissue of wound

To study cost-effectiveness of handcrafted against high cost VAC.

2. MATERIALS AND METHODS

This prospective observational study was conducted at AVBRH in Wardha, Mahrashtra, India over a period of 2 years. The study group comprised of 50 patients of chronic wound admitted in department of surgery. They were categorized into two groups. One of the groups was subjected to vacuum assisted closure therapy, and the other group to handcrafted vacuum assisted devices of low cost.

This study design was prospective observational study. Study populations were the patients coming with chronic non healing wound. Duration of study was from August 2017 to August 2019. Patients were included in the study after a written, valid and informed consent and were approved by the Institutional Ethical Committee (IEC) DMIMS (DU)/IEC/2017-18/6638.

After explanation of the diagnosis and treatment options, the patients were informed about this protocol, including the objectives, implications, possible outcomes and complications. The patients were made to understand the possible risks and consequences, and if they accepted to be included, an informed consent was signed. The patients' demographic details such as age and sex were collected. Also, etiologies and associated co morbidities were noted for each patient. Patients in each of the two groups, on admission underwent a detailed clinical examination. All the basic routine clinical investigations like complete blood counts, random blood sugar levels, renal function tests like serum creatinine and blood urea nitrogen and liver function tests were performed for all the admitted patients. All the enrolled patients were categorized into two groups as follows-

Group A

A group chronic non healing wound subjected to negative suction wound therapy by hand crafted vacuum assisted devices. Sample size - 25 patients

Group B

A group of chronic non healing wound patients subjected to Negative suction wound therapy via vacuum assisted closure device available commercially. Sample size - 25 patients

Inclusion criteria

Chronic wounds of size ranging from 5-10cm
Both genders male and female
Age-18-80 years of age

Exclusion criteria

Malignant ulcers
Patients with coagulopathies
Wounds having exposed blood vessels

Methodology

All patients admitted with chronic non healing wounds were evaluated for participation in the study on the basis of inclusion and exclusion criteria given above. Written informed consent was taken from the patient prior to enrollment. Study & procedure requirements were Gauze, Ryle's tube no. 14, Suction machine, Air tight dressing like IO ban dressing material, Vacuum assisted closure machine, VAC dressing set.

Methods

Group 1 - Handcrafted Vacuum Assisted Dressing

Step 1 Wound preparation (Figure 1 and Figure 2)
The necrotic and devitalized tissue is debrided.

Figure 1 & 2 Wound preparation

Step 2 Suction system placement (Figure 3 and Figure 4)
Sterile gauzes are placed totally covering the ulcer and within 5–12 mm besides ulcer margins. Ryle's tube no. 14 is fenestrated in the last 5 cm and the tip placed in the ulcer's center.

Figure 3 & 4 Suction system placement

Step 3 Hermetic closure (Figure 5)
A sterile adhesive plate is placed over the gauzes and 2 cm surrounding wound border

Figure 5 Hermetic closure

Step 4 Vacuum-assisted system activation (Figure 6)
A sterile tube is connected to the Nelaton catheter and both of them connected to a suction system to obtain intermittent pressures between 100 mmHg and 125 mmHg. The suction is switched on and off intermittently for one hour.

Figure 6 Vacuum-assisted system activation

Step 5 Assessment
This unit is kept for 5 days and wound parameters measured.

Group 2 - VAC Dressing
Step 1 (Figure 7 and Figure 8)

The foam dressing is cut to the approximate size of the wound with scissors and placed gently into position.

Figure 7 & 8 Foam dressing

Step 2 (Figure 9)
The perforated drain tube is then located on top of the foam and a second piece of foam placed over the top.

Figure 9 perforated drain tube is then located on top of the foam

Step 3 (Figure 10)
The foam, together with the first few inches of the drainage tube and the surrounding area of healthy skin, is then covered with the adhesive transparent membrane supplied.

Step 4 (Figure 10)
The distal end of the drain is connected to the VAC unit (Kinetic Concepts, Inc, San Antonio, TX), which is programmed to produce the required level of pressure.

Figure 10 distal end of the drain is connected to the VAC unit

Step 5 (Figure 10)
Once the vacuum is switched on, the air is sucked out of the foam causing it to collapse inwards drawing the edges of the wound in with it.

Step 6 (Figure 10)
Fluid within the wound is taken up by the foam and transported into the disposable container within the main vacuum unit.
This unit is kept for 5 days and wound parameters measured.

At the end of the study, all the patients of both the groups will be assessed for following criteria

Assessment
Percentage of decrease in wound
Type of granulation tissue
Duration of wound healing
Percentage of decrease in wound was calculated on the basis of decrease in area and volume of wound.

For the purpose of explanation, we have divided wounds on the basis of area into three categories-
Small- Wounds having total surface area of1-10cm^2
Medium-Wounds having total surface area of11-20cm^2
Large-Wounds having total surface area of21-30cm^2

On a similar note wounds were also classified on the basis of total volume into 4 categories-
Type I - <50 cm^3
Type II-51-100 cm^3
Type III- 101-150 cm^3
Type IV - >151 cm^3

Wounds were also classified on the basis of amount of exudates (percentage of dressing soaked in 24 hours)
Small – Discharge involves less than 25% of dressing.
Moderate-Drainage involves 25% to 75% of dressing.
Copious- Drainage involves more than 75% of dressing.

Statistical calculation
Database was created, and the statistical program graph pad prism version 8 was used to perform statistical data analysis. Complications, evolution and general characteristics were registered and compared between the groups using Pearson's Chi square/Fisher's exact test, mean and average, with p\0.05 considering to be statistically significant. Two groups were compared using Student's t test. Results were expressed as n (%).

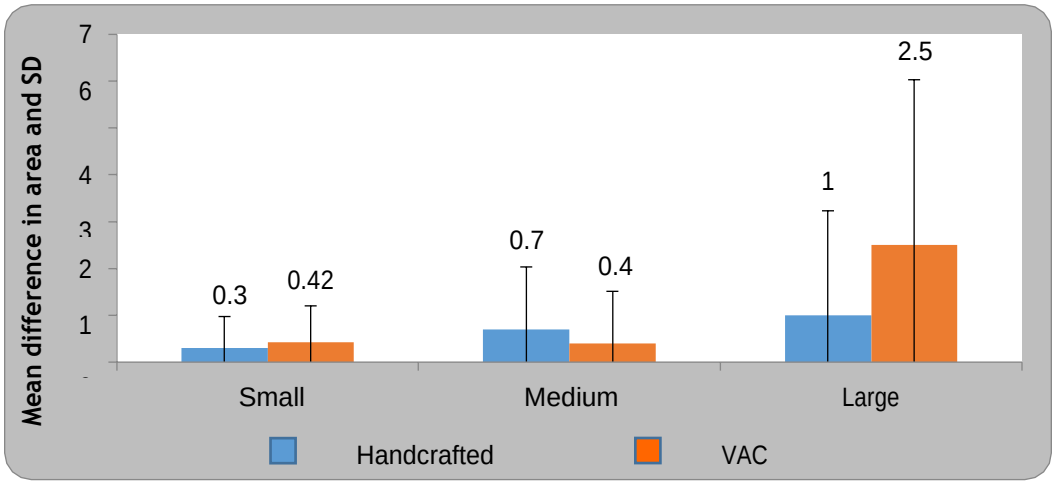
3. OBSERVATION AND RESULTS

Area

Table 1 Mean reduction in area of wound with handcrafted and VAC dressings

	Handcrafted	VAC	Mean Difference	p-value
Small	0.30±0.67	0.42±0.78	0.12 ± 0.25	0.36 p=0.72, NS
Medium	0.70±1.33	0.40±1.11	0.29 ± 0.48	0.60 p=0.55, NS
Large	1±2.23	2.50±3.53	1.50 ± 2.13	0.70 p=0.51, NS

The mean difference between handcrafted and VAC for small size wound was0.12± 0.25 cm^2, which was not found to be significant. The mean difference between handcrafted and VAC for medium size wounds was 0.29 ± 0.48 cm^2 which was not significant. The mean difference between handcrafted and VAC for large size wounds was 1.50 ± 2.13 cm^2 which was not significant. Thus, it can be inferred that both modalities are equivocal for reduction in area of wound (table 1 & graph 1).



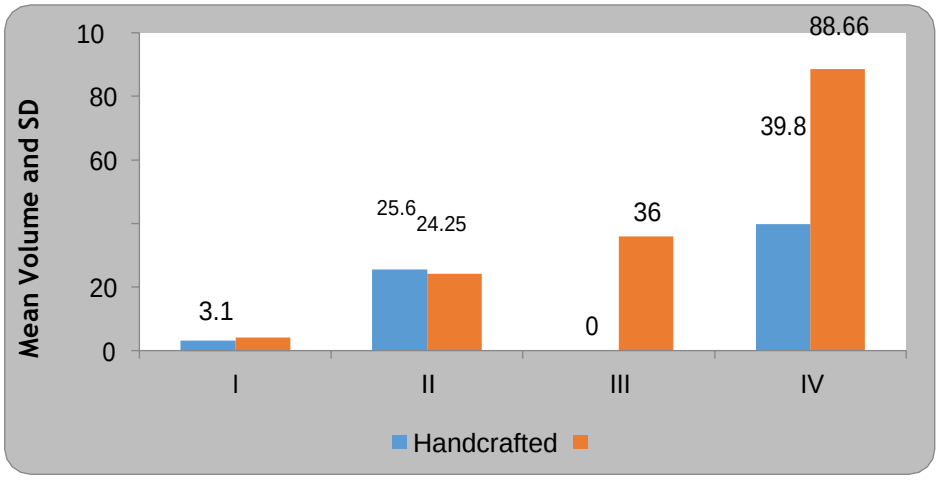
Graph 1 Mean reduction in area of wound of handcrafted and VAC dressing

Volume

Table 2 Mean reduction in volume of wound of Handcrafted and VAC dressing

	Handcrafted	VAC	% reduction	p-value
I	3.10±10.07	4.03±7.43	0.93 ± 3.56	0.26 p=0.79, NS
II	25.60±22.62	24.25±15.92	1.35±12.51	0.10 p=0.91, NS
III	0±0	36±0	-	-
IV	39.80±41.77	88.66±81.99	48.86±38.33	1.20 p=0.26, NS

The mean difference between handcrafted and VAC for Type I was 0.93 ± 3.56 cm^3 which was of no significance. The mean difference between handcrafted and VAC for Type II was1.35±12.51cm^3 which was considered not significant. The mean difference between handcrafted and VAC for Type IV was 48.86 ± 38.33 cm^3 which was considered insignificant. No comment can be made on type III wounds as no patient of this category underwent handcrafted dressing (table 2 & graph 2). Thus, it can be inferred that handcrafted and VAC dressing gives comparable reduction in volume.



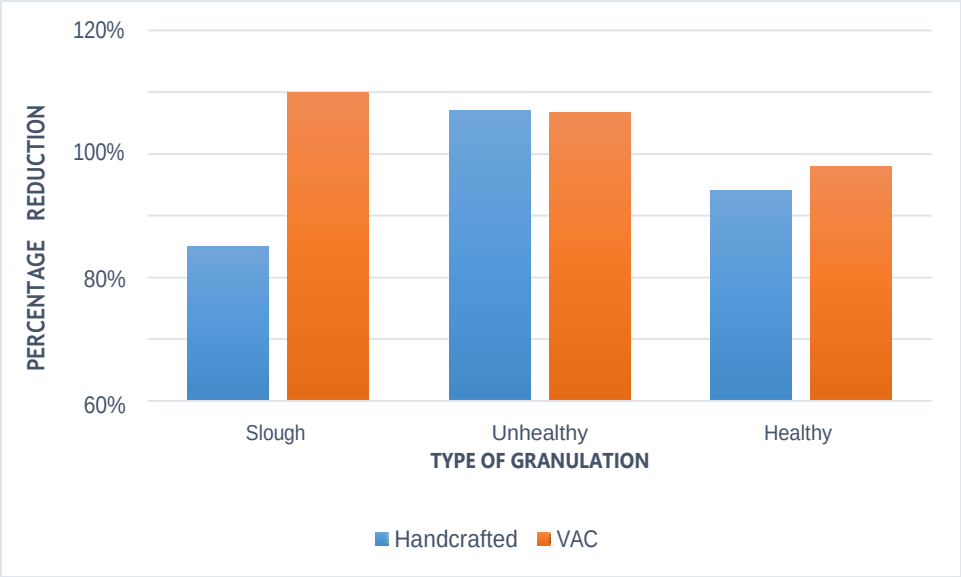
Graph 2 Mean reduction in volume of wound of Handcrafted and VAC dressing

Change in granulation tissue

Table 3 Change in the type of granulation tissue in handcrafted and VAC dressing

Granulation Tissue	Handcrafted	VAC	p-value
Slough	50%	100%	0.04, S
Unhealthy	94%	93.5%	0.66, NS
Healthy	68%	76%	0.27, NS

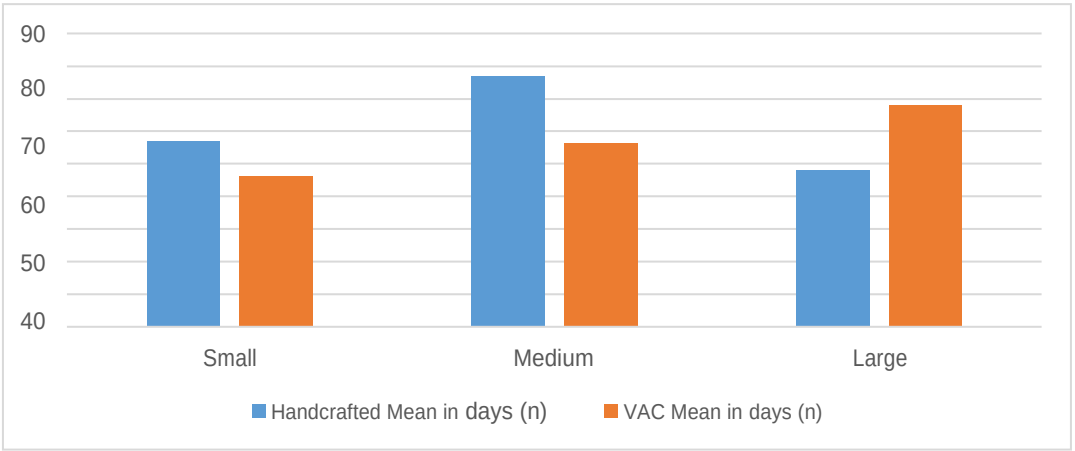
The table 3 & graph 3 signifies that on comparing handcrafted and VAC dressing, VAC significantly reduces the slough by 100%, while handcrafted reduces the slough by 50%. Handcrafted dressing has reduced the number of subjects having unhealthy granulation by 94% which is comparable to VAC which has reduced unhealthy granulation by 93.5%. Both the groups have reported an increase in subjects of 68% and 76% in healthy granulation in handcrafted and VAC dressing respectively.



Graph 3 Change in the type of granulation tissue in handcrafted and VAC dressing

Comparison of duration of healing of wound by handcrafted and VAC dressings

The table 4 & graph 4 shows patients of small size who underwent handcrafted dressing took 56.9±23.14 days to heal completely while patients who underwent VAC dressing took 46.1±17.34 days to heal. These were statistically insignificant. Patients of medium size who underwent handcrafted dressing took 77±34. 4days to heal while patient who underwent VAC dressing took 56.375±14.5 days to heal which was statistically significant in favour of VAC dressing. Patients of large size who underwent handcrafted dressing took 48±11.6 days to heal while patients who underwent VAC dressing took 68±22 days to heal which was statistically insignificant.



Graph 4 Duration of healing in handcrafted and VAC dressing

Table 4 Mean duration of healing in handcrafted and VAC dressings.

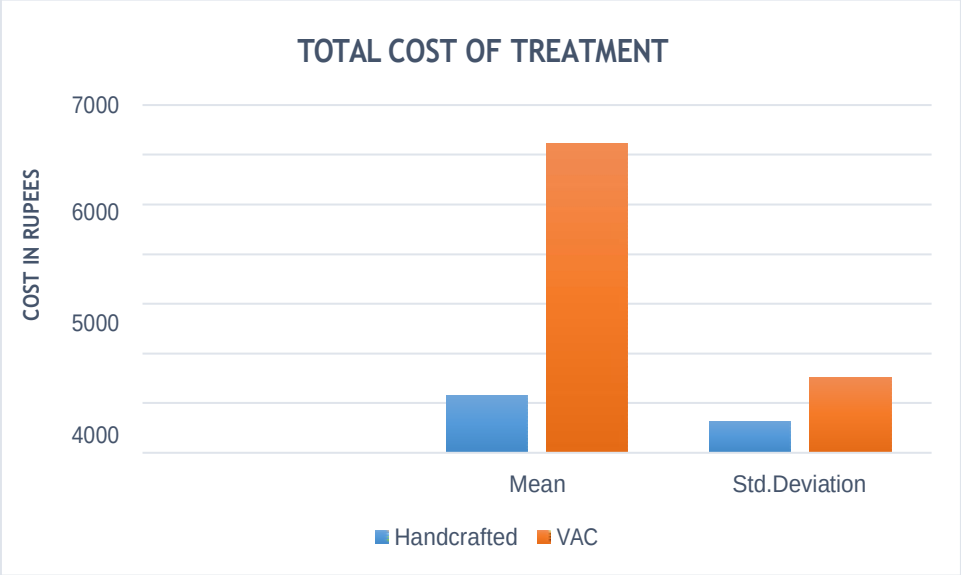
Area of wound	Handcrafted Mean in days (n)	VAC Mean in days (n)	p value
Small	56.9±23.14 (10)	46.1±17.34 (7)	0.4630
Medium	77±34.4 (10)	56.375±14.5 (16)	0.043
Large	48±11.6 (5)	68±22 (2)	0.15
Total no. of patients	25	25	

Comparison of cost between VAC and handcrafted dressing

Table 5 Comparison between cost of handcrafted and VAC dressing

Type of dressing	N	Mean	Std. Deviation	p-value
Handcrafted	25	1160.00	624.4998	P<0.0001 S
VAC	25	6232	1504.083	

The total cost of hospital-stay for patients who underwent handcrafted was Rs 1160 ± 624.4998 while for the patients who underwent VAC dressing the cost was Rs 6232 ± 1504.083 which was highly significant (table 5 & graph 5).



Graph 5 Comparison between cost of handcrafted and VAC dressing

4. DISCUSSION

Chronic ulcers are a significant public health problem, which substantially affect the social and psychological life of young and the elderly. The financial burden which is borne by the patients and their families warrants the need of a cheaper and economical treatment modality which can provide good results in a shorter period of time. Hence, an alternative to traditional wound treatment was developed in which controlled negative suction was used on wounds. Thus, came the existence of VAC (Vacuum assisted closure). Many literature studies are available which compare VAC with conventional dressing materials. But there is a paucity of studies where accurate comparison is made between high cost VAC (Vacuum assisted closure) and cost-effective handcrafted dressing. Our study has been conducted keeping in mind the above-mentioned deficit. It was conducted in Acharya Vinoba Bhave Rural Hospital, Sawangi Meghe, Wardha which is a perfect setup for the assessment of a low-cost handcrafted versus a high cost VAC dressing.

Percentage reduction in area

In present study, area was reduced by 4.05%, 4.02% and 3.57% in small medium and large size chronic wounds of handcrafted dressing which was statistically insignificant when compared to 5.37%, 2.67% and 10.41% of VAC. Another study was conducted by Dorafshar et al., 2012 which recorded reduction in wound surface area of 4.5%/day for GSUC (wall suction applied to a sealed gauze

dressing) and 4.9%/day for VAC (Dorafshar AH and Franczyk M et al., 2012). A notable study by Kamamoto et al., 2017 compared low cost handcrafted vs high cost VAC and found a statistically insignificant change in surface area of both the group (Kamamoto F and Lima AL et al., 2017).

Percentage reduction in volume

In current study, percentage reduction in volume in Type I, type II and type IV were 14.41%, 31.44% and 20.55% respectively in handcrafted dressing, whereas in VAC dressing they were 14.48%, 33.79% and 26.85% respectively which were not found to be significant. Dorafshar et al., 2012 also documented reduction in volume of 8.4%/day in GSUC (wall suction applied to a sealed gauze dressing) and 9.8%/day in VAC group (Dorafshar AH and Franczyk M et al., 2012).

There were episodes of three air leaks in high cost VAC dressing in current study, which was taken care of. No such incidents were observed in group of handcrafted dressings which can be credited to the use of IO-Ban which creates mesentery around the drain giving proper airtight control. While the study done by Kumar et al., 2016 shared another alternative to IO-ban. After covering the wound with gauze piece and roller, urosac was used to cover the ulcerated wound and Ryle's tube connected to negative suction. Final covering was given by dynaplast /plaster thus making the whole dressing airtight (Kumar NA and Nihar SS, 2016).

Change in granulation tissue

There was increase in patients having healthy granulation to 68% in handcrafted which were comparable to 76% of VAC which had no statistical significance. The similar percentages show that both the dressings are analogous in promoting formation of granulation tissue and can be used interchangeably. While, Kamamoto et al., 2017 reported the rate of change of granulation tissue to be 53.01% for handcrafted and 44.18% for VAC (Kamamoto F and Lima AL et al., 2017). Subjects having slough were reduced by 100 % by conventional VAC and by 50% by handcrafted dressing (which was of statistical significance) indicating that slough is better removed by conventional high cost VAC dressing.

The commercially available 'vacuum-assisted closure' device makes use of a polyurethane-ester sponge, which has a reticulated open-air cell structure that allows the transmission of a uniform suction pressure across the sponge. This allows direct negative pressure applied to the sponge to reach the wound surface. In contrast, the gauze and pads, used in our cases, has smaller and thicker-walled closed air cells, which transmit negative pressure less effectively which explains significantly more reduction of slough by VAC (Fenn CH and Butler PE, 2001).

Cost

The cost of dressing with VAC system is Rs. 1,100/dressing and cost of equipment is approximately 5 lacs. When this instrument is used on rental basis it costs Rs. 5,000/day. Due to budgetary constraints, widespread use of this equipment is not feasible at our institute. So, we have developed a modified system to deliver NPWT using materials available in general wards which costs approximately Rs. 1000/dressing.

Mean duration of healing

Small size wounds took a mean duration of 56.9 days for healing by handcrafted dressings while they took 46.1 days by VAC dressing which was statistically insignificant. Medium size wounds in our study took 77 days by handcrafted dressings and 56.375 days by VAC dressing which was statistically in favor of VAC. Large size wounds took 48 days to heal by handcrafted dressing and 68 days to heal by VAC dressing which was statistically insignificant. A study conducted in Chile by Gustavo Sepúlveda et al., 2009 compared conventional dressing with handcrafted dressing in a sample size of 11 patients where healthy granulation (90%) was obtained in a mean time of 18 days (p=0.007). Hence, our study depicts that handcrafted dressing is just as efficacious as VAC dressing in terms of reduction in size and volume of wound. It also promotes formation of healthy granulation tissue which exponentially increases the rate of wound healing (Sepúlveda G and Espíndola M et al., 2009).

Limitations

Following are the limitations of the study: i) Due to limited economical & other resources, the study was conducted with only one sitting of the dressing therapies. ii) Due to rural set-up of our study, high cost VAC was not affordable by many patients.

5. CONCLUSION

From our study we conclude that Infective, traumatic, arterial or venous diseases were the major etiological factors leading to chronic wounds. Both Handcrafted and VAC dressings show equivocal results in view of Reduction in wound area. Reduction in

wound volume. Improvement in type of granulation tissue. Both handcrafted & VAC dressing effectively reduced area & volume of the wounds thereby reducing the duration of healing in chronic wounds. The total cost of handcrafted dressings was lower than VAC dressing thus making handcrafted dressing more cost-effective.

Conflict of interest

The authors declare no conflict of interest related to present manuscript

Acknowledgment

The present research was carried out with the support of Datta Meghe Institute of Medical Sciences University.

Funding: This research received no external funding.

REFERENCE

1. Dabiri G, Damstetter E, Phillips T. Choosing a wound dressing based on common wound characteristics. Advances in wound care. 2016 Jan 1;5(1):32-41.
2. Dorafshar AH, Franczyk M, Gottlieb LJ, Wroblewski KE, Lohman RF A prospective randomized trial comparing sub-atmospheric wound therapy with a sealed gauze dressing and the standard vacuum-assisted closure device. Ann Plast Surg. 2012 Jul; 69(1):79-84.
3. Fenn CH, Butler PE. Abdominoplasty wound-healing complications: assisted closure using foam suction dressing. British journal of plastic surgery. 2001 Jun 1;54(4):348-51.
4. Fleischmann W, Strecker W, Bombelli M KL. vacuum sealing as treatment of soft tissue damage in open fractures. Unfallchirurg. 1993;96(9):488–92.
5. Kamamoto F, Lima AL, Rezende MR, Mattar-Junior R, Leonhardt MD, Kojima KE, Santos CC. A new low-cost negative-pressure wound therapy versus a commercially available therapy device widely used to treat complex traumatic injuries: a prospective, randomized, non-inferiority trial. Clinics. 2017 Dec;72(12):737-42.
6. Kim JJ, Franczyk M, Gottlieb LJ, Song DH. Cost-effective alternative for negative-pressure wound therapy. Plastic and Reconstructive Surgery Global Open. 2017 Feb;5(2)
7. Kumar NA, Nihar SS, Chetan K. Low Cost Negative Pressure Wound Therapy for Treatment of Diabetic Foot Ulcers. International journal of scientific study. 2016 Jul 1;4(4):220-4
8. Mansoor J, Ellahi I, Junaid Z, Habib A, Ilyas U. Clinical evaluation of improvised gauze-based negative pressure wound therapy in military wounds. International wound journal. 2015 Oct;12(5):559-63
9. Sepúlveda G, Espíndola M, Maureira M, Sepúlveda E, Fernández JI, Oliva C, Sanhueza A, Vial M, Manterola C. Healing assisted by negative pressure compared to conventional treatment of diabetic foot amputation. Random clinical trial. Spanish surgery. 2009 Sep 1;86(3):171-7.
10. Shukla VK, Ansari MA, Gupta SK. Wound healing research: A perspective from India. Int J Low Extrem Wounds 2005;4:7-8.
11. Téot L, Guillot-Masanovic M, Miquel P, Truchetet F, Meaume S, Dompmartin A, Charles Kerihuel J, Trial C, Faure C. Clinical impact of negative-pressure wound therapy: A 1,126-patient observational prospective study. Wound Repair and Regeneration. 2014 May;22(3):341-50.
12. Velnar T, Bailey T, Smrkolj V. The wound healing process: an overview of the cellular and molecular mechanisms. Journal of International Medical Research. 2009 Oct;37(5):1528-42.