Comparative study of low pressure VAC versus high pressure VAC in the management of pressure sore

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Abstract
A pressure ulcer is defined as any lesion caused by unrelieved pressure, resulting in damage to underlying tissue, and is acknowledged to be a clinical challenge for both the clinician and the patient.[1] Negative Pressure Wound Therapy (NPWT) uses negative pressure to assist wound healing. It not only drains fluid from the wound, thus removing the substrate for growth of microorganism but also accelerates granulation tissue formation and angiogenesis. The mechanical stimulation of cells by tensile forces also plays a role by increasing cellular proliferation and protein synthesis and promotes the formation of granulation tissue. Various studies have found NPWT more beneficial in wound healing in bedsores as compared to conventional wound therapy. But to the best of our knowledge, there is no study in the literature yet comparing low versus high pressure VAC therapy in management of pressure sore. This study was done to compare the efficacy of low NPWT versus high NPWT in the management of pressure ulcers and to observe wound disinfection, decrease in wound size, appearance of granulation tissue and duration of hospital stay in both groups. We also intend to compare the impact of the device on daily living and satisfaction quotient to device therapy. 50 patients having chronic pressure sore were studied. 25 cases were randomly chosen for study with low negative pressure WT and 25 cases were subjected to high NPWT.

Keywords: Negative Pressure Wound Therapy (NPWT), Bed sore, Chronic wounds, Suction device.

Introduction
Pressure sores are areas of tissue damage that occur in people who cannot reposition themselves, the acutely ill, the older person, and the malnourished. It is detrimental to the quality of life and impose a significant financial burden on healthcare systems.[2] Wound healing is a complex cellular and biochemical cascade that leads to restitution of integrity and function.[3] The unpredictable nature of healing response of a pressure sore of an individual patient is influenced by many factors (local and systemic): bacterial load and infection; oedema; pressure; moisture; chronic medical conditions or comorbidities such as anaemia, diabetes mellitus, and renal or hepatic dysfunction; tissue oxygenation; and nutritional status.

Recent studies have revealed sacrum (28.3%) is the most common site for pressure ulcerations followed by heel (23.6%) and buttocks (17.2%).[4] Non-reactive hyperemia sites, Stage I, were responsible for most reported ulcers, at 46.95%, while Stage II ulcers comprised 32.66%.[5]

In the past few years there have been significant advances in complex acute and chronic wound management. There are different treatment methods for pressure ulcers, like advanced moist wound dressing,[6] bioengineered tissue or skin substitutes,[7] growth factors,[8] low-potential laser therapy and negative pressure wound therapy (NPWT).

VAC is a non invasive system that functions by localised negative sub atmospheric pressure. The mechanism of this therapy is delivery of continuous sub atmospheric pressure, through a specified pump, which is connected to the resilient, foam-surfaced dressing that collects the wound exudates.[9,10] Negative pressure is usually maintained between -50 to -125 mm Hg. Clinical benefits of negative pressure therapy have been demonstrated in randomized control trails and case control studies. It produces a closed wound healing, reduces oedema, promotes perfusion, and removes infectious materials and chronic inflammatory cells from the wound environment by applying topical negative pressure.[11] It also stimulates blood flow to the wound bed,[12] resulting in delivery of fresh leukocytes and plasma that counteract the toxic chronic wound environment reducing the frequency of dressing change and maintains anatomically challenging wounds clean. The uniform, sustained negative pressure leads to tissue deformation and cell stretching, leading to metabolic activity, fibroblast migration, and cell proliferation. VAC therapy has been widely accepted over the years for the treatment of chronic non healing ulcers and pressure sores. However, high pressure VAC has its own drawbacks. Pain, tissue damage, noncompliance are the major drawbacks of high pressure VAC. Low pressure VAC overcomes these flaws and proves to be the superior alternative with lesser complications and more patient compliance.

Fig.1: Showing grade 3 ischial pressure sore after being subjected to low NPWT for 12 days and planned for elective flap repair

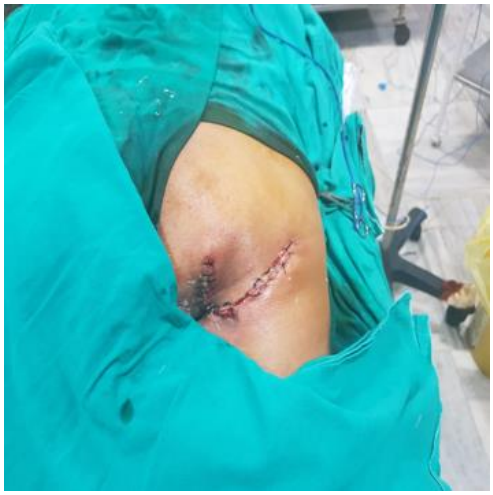


Fig. 2: V to Y closure based on inferior gluteal artery in the patient shown in Fig 1

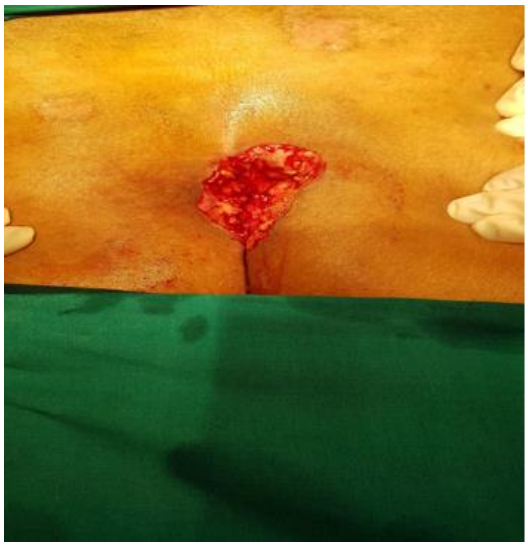


Fig. 3: Showing a grade 3 sacral pressure sore after being subjected to 14 days of low NPWT.

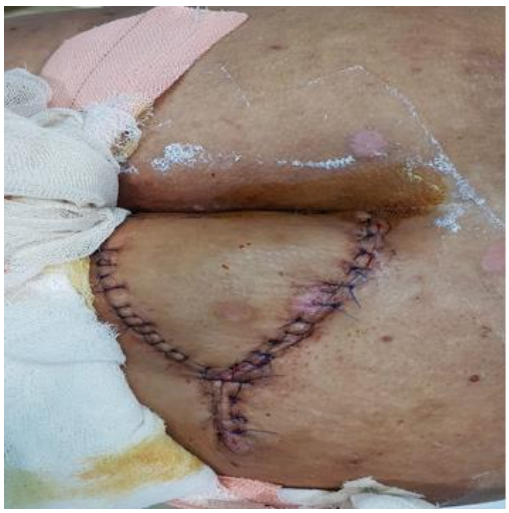


Fig. 4: Showing operated sacral pressure sore by flap repair.

Materials and Methods

Sample Size-50

Study period

The study was performed over a period of 18 months (July 2019 to December 2020)

Study place

The study was performed in the Department of Burns and plastic surgery, Jawaharlal Nehru (JLN) Hospital and Research Center, a Tertiary Care Teaching Hospital located in Bhilai, Chhattisgarh.

Study design

This was a single centre, cross-sectional, and comparative study.

Study population

All the patients presenting to the OPD with pressure sore (other than stage 1), or admitted to wards of Department of Burns and Plastic Surgery, J.L.N HRC, Bhilai.

Inclusion criteria

All the patient admitted with pressure sore to department of burn and plastic surgery fulfilling the following criterias:

1. Age ≥ 18 years, male or female.
2. Provide informed consent.
3. Target ulcer involving a full thickness skin loss.
4. Acceptable state of health and nutrition with serum albumin level ≥ 2g/dl.
5. Hb1Ac levels ≤ 12%.
6. Arterial supply adequacy (ABI ≥ 0.70 and ≤ 1.20 with normal triphasic waveform pattern at ankle).
7. Total surface area of target ulcer ≥ $2cm^2$ and ≤ $112cm^2$.
8. Target ulcer duration ≥ 2 days and ≤ 104 weeks.
9. If the subject has multiple pressure ulcers, then the ulcer with the largest dimension would be selected as target ulcer (separation between the ucers must be more than 5 cm).
10. Stage 2,3,4 pressure sores excluding stage 1.

Exclusion criteria

1. Subjects with known allergies to product component like silicone adhesives, acrylic adhesives, polyurethane films, polyethelyne fabrics and super absorvent dressing powder.
2. Therapy with another agent for more than 30 days prior to screening.
3. Ulcers which are highly exudating as per investigators dissertion.
4. Current diagnosis of osteomyelitis and not yet started on therapy (old treated and patient on medication without any acute exacerbation can be included).
5. Malignancy in the target ulcer.
6. Current diagnosis of vasculitis.
7. Current systemic therapy with any cytotoxic drugs.
8. Previous treatment with NPWT device or hyperbaric oxygen within 7 days of screening.

9. Stage 1 pressure sores.

Study procedure

A total of 58 consecutive patients with pressure sore were initially screened for the study and were explained the study procedure through the patient information leaflet in their native language. Of these 58 patients, 2 of them succumbed even before the initiation of therapy, 2 had malignant ulcers, and 4 patients did not give consent. Excluding these 8 patients, those who were willing to participate and signed the informed consent document were enrolled in the study.

The patients were prospectively randomized by the help of nursing staffs (who were completely unaware of the study) into one of the two treatment groups receiving either the high NPWT or low NPWT. Files were marked with red (high pressure vacuum assisted closure therapy) or yellow (low pressure vacuum assisted closure) labels on the inside panel and were randomly organized. A file was randomly picked for each patient with the treatment determined by the label colour. Patients with file marked red will be subjected to pressure in the range of negative of 100-150 mm hg while those with yellow markings were subjected to negative pressure in the range of -50 to -99 mm hg.

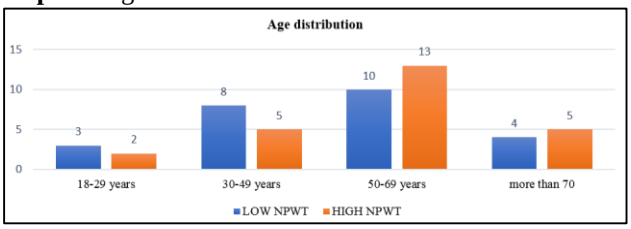
Method of Use of NPWT Dressing

Step 1: The sterile hydrocolloid sheet of approximate size of the wound is placed gently into position.
Step 2: The perforated drain tube is then placed on top of sheet and a second hydrocolloid sheet placed over the top.
Step 3: The wound, 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. At this stage it is important to ensure that the membrane forms a good seal both with the skin and the drainage tube.
Step 4: The distal end of the drain is connected to the suction device which provide sub atmospheric pressure ranges from 50 mmHg to 99 mmHg in the yellow tagged patients and 100 to 150 mm hg in the red ones. This was achieved by ROMOVAC Suction device; suction was applied continuously or intermittently based on the amount of wound discharge.

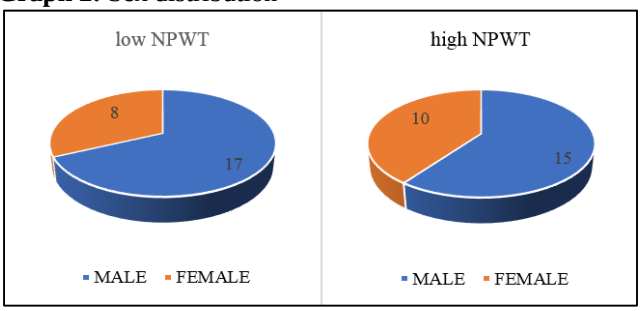
Results

The efficacy of low Negative Pressure Wound Therapy versus high NPWT in treating pressure ulcers was studied. There were no toxicity or hypersensitivity reactions to either therapies reported in our study. The following observations have been made in the study.

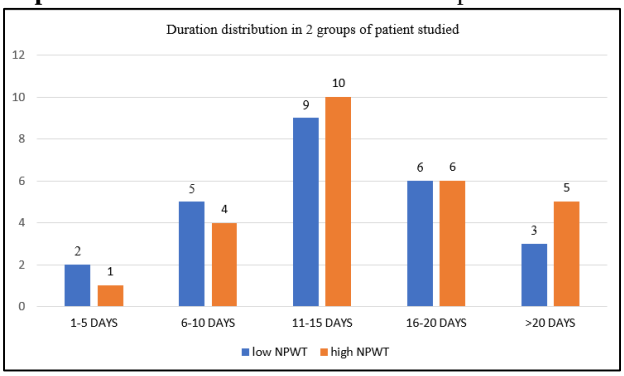
Graph 1: Age distribution



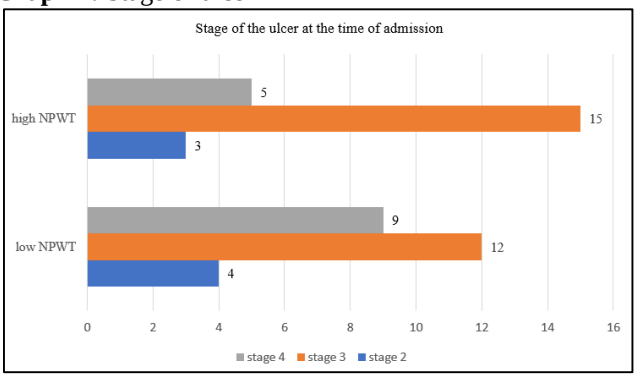
Graph 2: Sex distribution



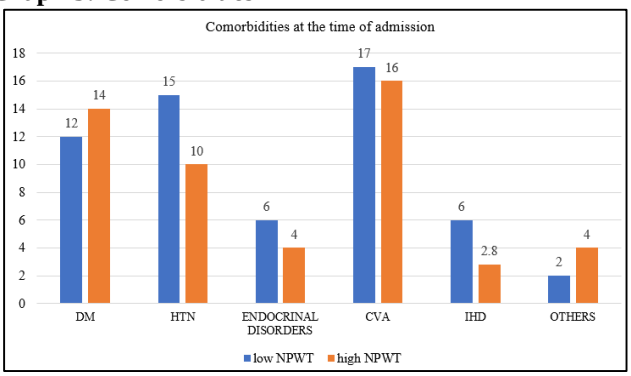
Graph 3: Duration of wound at the time of presentation



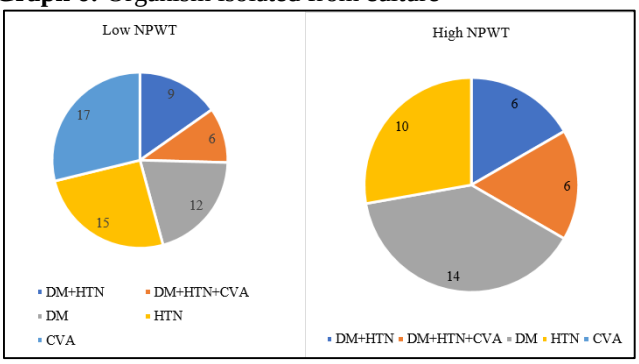
Graph 4: Stage of ulcer



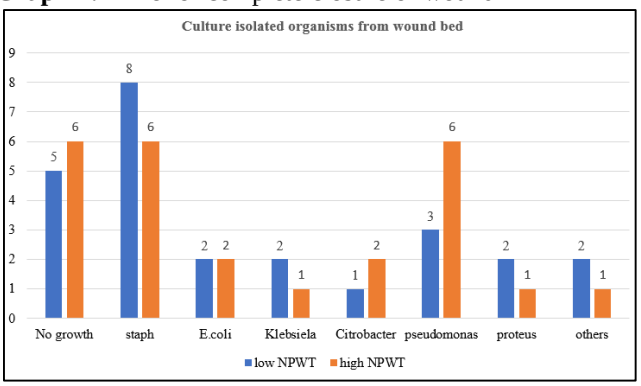
Graph 5: Comorbidities



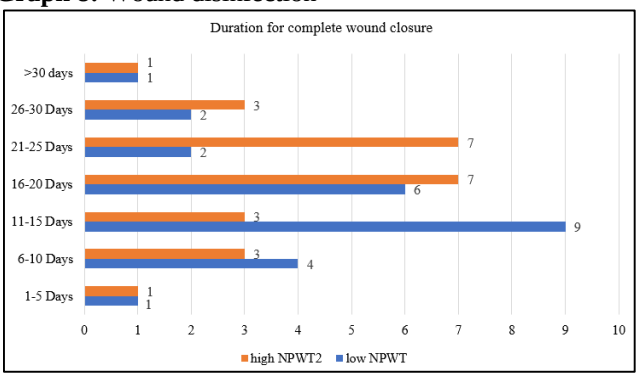
Graph 6: Organism isolated from culture



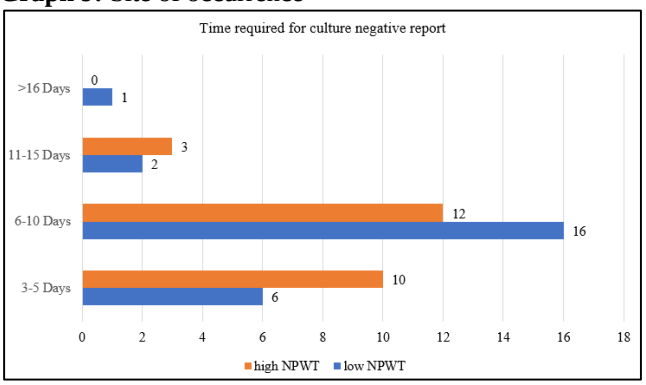
Graph 7: Time for complete closure of wound



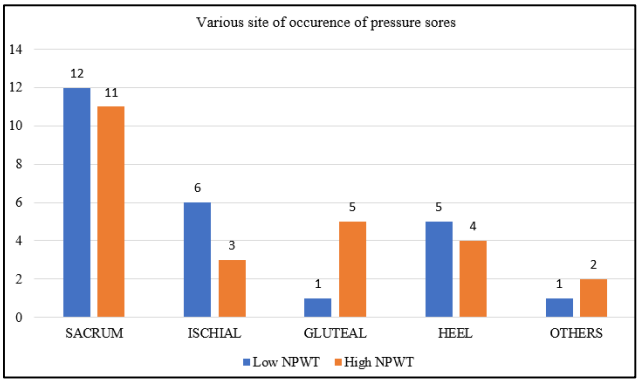
Graph 8: Wound disinfection



Graph 9: Site of occurrence

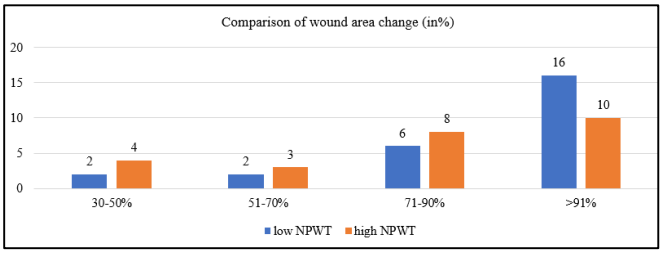


Graph 10: Change in the target ulcer area after end of the treatment



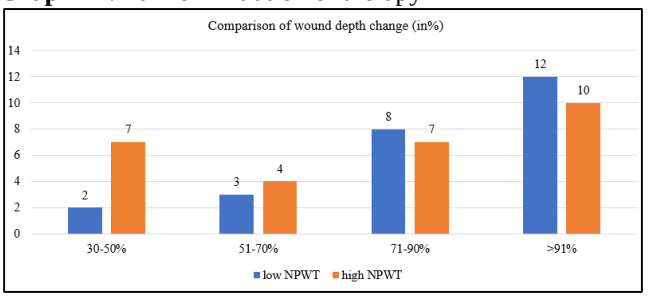
Wound size was measured at baseline Day 1 for all patients by serial photographs. The change in the wound size (% change) was calculated from baseline (Day 1) and final day (either the day of complete closure or the day of any surgical intervention).

Graph 11: Change in the target ulcer depth at the end of treatment



Ulcer area was analysed for depth measurement (in mm), then the percentage change from the baseline measurement (day 1) till the day of complete closure or the day of surgical intervention was calculated.

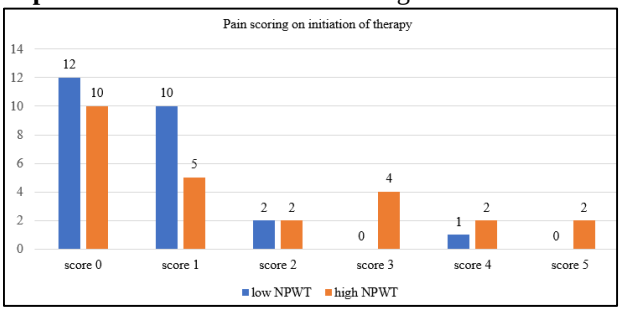
Graph 12: Pain on initiation of therapy



Subject will be queried regarding the pain levels on initiation of NPWT and will have to score the levels of pain on a scale of 0-5,0 meaning no pain or discomfort and 5 meaning severe pain.

Score	Interpretation
0	No pain
1	Mild discomfort
2	Mild pain
3	Moderate pain subsiding with analgesics
4	Severe pain subsiding with analgesics
5	Severe pain not responding to analgesics

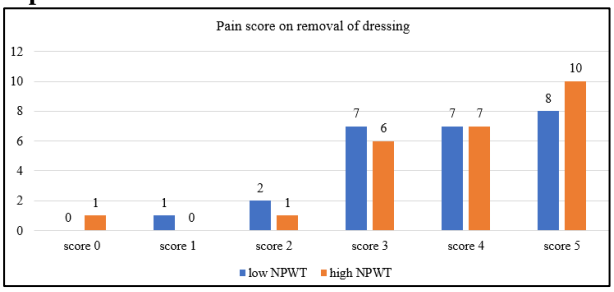
Graph 13: Pain on removal of dressing



Subject will be queried regarding the pain levels on removal of dressing and will have to score the levels of pain on a scale of 0-5,0 meaning no pain or discomfort and 5 meaning severe pain.

Score	**Interpretation**
0	No pain
1	Mild discomfort
2	Mild pain
3	Moderate pain subsiding with analgesics
4	Severe pain subsiding with analgesics
5	Severe pain not responding to analgesics

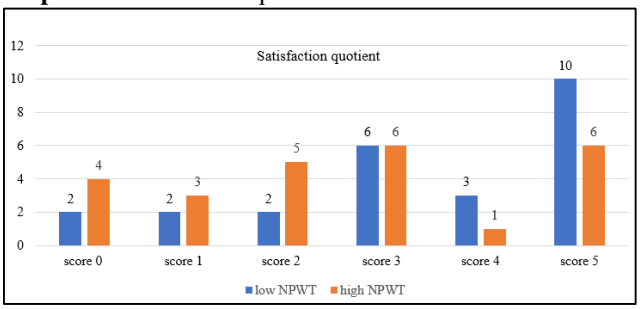
Graph 14: Patient satisfaction level



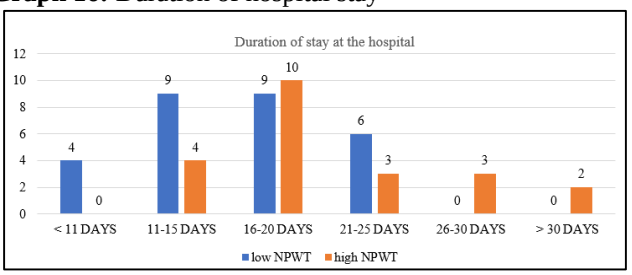
Subjects will be interviewed regarding the comfort and satisfaction levels and will have to score on a scale of 0-5, 0 meaning very poor experience and 5 meaning extremely satisfied.

Score	**Interpretation**
0	Very poor experience
1	Poor experience
2	Bad experience but acceptable
3	Pleasant but sometimes uncomfortable
4	Pleasant
5	Very pleasant

Graph 15: Satisfaction quotient



Graph 16: Duration of hospital stay



Discussion

In the present study, the effect of low NPWT versus high NPWT in the management of pressure ulcers in a group of 25 patients each was studied. The mean age of the patients in the study was 53.62 SD 13.46 years, 64% of patients were male.

54% of patients were admitted with stage 3 pressure ulcers while 86% of all patients were admitted with stage 3 or more. The mean duration of wound at presentation was 13.42 SD 5.34 and 76% of all the subjects were admitted after 10 days of ulcer presentation.

66% of all the patients were having any form of CVA while 52% and 50% had DM and HTN respectively. 24% of all the subjects had DM, HTN along with CVA.

Staphylococcus is the most common organism isolated from the culture with 28% followed by absence of any growth of organism in 22% of the subjects. Pseudomonas accounted for 18% of the subjects.

The mean duration of closure of the wound was 17.92 SD 7.49 days. When treated by low NPWT, 36% of them attained full wound closure within 15 days while 56% of all subjects exposed to high NPWT had their wound closure within 20 days of initiation of therapy.

64% of all patients treated with low NPWT became culture negative within 10 days of NPWT therapy as compared to 48% receiving high NPWT.

Total 46% of all the subjects had sacral pressure sore followed by ischial (18%) and pressure sore over heel (18%).

The mean duration of hospital stay was 15.24 SD 4.05 days among those receiving low NPWT therapy as compared to 20.92 SD 5.11 days with the ones on high NPWT therapy.

Variables used to asses Wound healing outcome eg; decrease in size, culture negativity etc were compared between two groups. In this study the mean wound size at initial presentation in low NPWT group was 43.16 SD 12.89 while 43.28 SD 13.56 was the mean for high NPWT group

which was almost similar but there was significant reduction in wound size, in the low NPWT as compare to the high NPWT group. The average reduction in wound size from day 1 to day 21 was statistically significant, with the low NPWT group showing more rapid reduction in wound size compared to group treated with high NPWT. There was a 35% average reduction in wound size in Group A (low NPWT) as compared to 17% in Group B (high NPWT) at Day 21(P value <0.001).

64% of subjects with low NPWT regimen had more than 90% change in the surface area as compared to only 40% of those on high NPWT regimen at the end of the treatment.

In our study the patient compliance was found to be more among the patients with low NPWT as it causes less pain and irritation which was revealed by the pain scoring and quality of life subjective scoring. The satisfaction quotient was pretty high among those subjected to low pressure VAC.

Conclusion

This study confirms that Low Negative Pressure Wound Therapy is safe, has faster response in wound healing and gives better efficacy with better compliance as compared to high Negative Pressure Wound Therapy in management of pressure ulcers.

Conflict of Interest

The authors declare that there are no conflicts of interest in this paper.

Source of Funding

None.

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