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Surgery

STUDY TO COMPARE THE EFFECTIVENESS OF CONVENTIONAL NEGATIVE PRESSURE WOUND THERAPY DEVICE WITH AMBULANT NEGATIVE PRESSURE WOUND THERAPY DEVICE IN THE MANAGEMENT OF CHRONIC WOUNDS

Dr Rohit Dwivedi	Dept of Surgery, Command hospital, chandimandir, panchkula- Haryana (India)
Dr Vijay Langer*	Dept of Surgery, Command hospital, chandimandir, panchkula- Haryana (India) *Corresponding Author
Dr Subash Chawla	Dept of Surgery, Command hospital, chandimandir, panchkula- Haryana (India)
Dr Sunil Kumar	Dept of Surgery, Command hospital, chandimandir, panchkula- Haryana (India)

ABSTRACT

INTRODUCTION: In the recent few decades there have been significant advances in the management of chronic wounds. The Negative Pressure Wound Therapy (NPWT) devices are advanced dressings, which promotes wound healing with the application of negative pressure over wound surface. Currently two devices of NPWT are commercially available in Indian market, VAC™ and PICO™. Aim of the study is to compare the effectiveness of conventional VAC™ NPWT device with the ambulant PICO™ NPWT device in management of chronic wounds.

METHOD: A prospective randomised single centre study conducted with 40 patients of chronic wounds of various etiologies. Wound debridements done to prepare wounds for NPWT application. Dressings were changed on every third or fourth day. Once the wounds were adequately covered with granulation tissue, closure was done with surgical intervention.

RESULTS: Both the devices of NPWT are effective in the management of chronic wounds in terms of granulation tissue formation. Although the number of dressings and duration of dressings required by the VAC™ NPWT, were less than the PICO™ NPWT device. Complications like pain and bleeding over the wound was more with VAC™ as compared to PICO™ NPWT.

CONCLUSION: Both the NPWT devices are effective in the management of chronic wounds. The conventional VAC™ dressing is better than PICO™ NPWT in terms granulation tissue, wound size, number of dressings and number of days. Especially in treating cavitary wounds such as decubitus ulcers, ambulatory PICO™ NPWT exhibited more dressing changes and suboptimal results.

KEYWORDS :

INTRODUCTION

A chronic wound can be defined as one that has failed to proceed through an orderly and timely reparative process to produce anatomic and functional integrity within a period of 3 months[1] or that has proceeded through the repair process without establishing a sustained, anatomic and functional result [2,3]. Chronic wounds are commonly associated with chronic illnesses, with the increase in ageing population in the developed and developing countries, the incidence of these chronic wounds is expected to increase. It is estimated that 1 to 2 % of the population will experience a chronic wound during their lifetime in developed countries[4]. In one study, the prevalence of chronic wounds in the community was reported as 4.5 per 1000 population[5]. It is estimated that around 5.7 million people in USA are affected by chronic wounds annually with an estimated cost expenditure of around $ 20 billion[6].

In the recent few decades there have been significant advances in the management of chronic wounds like negative pressure wound therapy, bioengineered tissues, and hyperbaric therapy[7,8,]. In 1989, Chariker et al[9] described a wound dressing technique using gauze filler, drains, and continuous closed suction to assist wound healing and exudates management. The aim of the procedure is to use negative pressure to create suction, which drains the wound exudates and influences the shape and growth of the surface tissues in a way that helps healing.

Negative pressure wound therapy (NPWT) dressings has revolutionized the management of various acute, chronic, and high output wounds[10]. It requires fewer dressing changes than conventional practice, can be used in the outpatient setting, and became a necessary adjuvant therapy to hasten wound healing.

Image 1: VAC

Image 2:PICOCurrently, two devices commercially available in Indian market, VAC™ (KCI International, San Antonio, TX) and ambulant NPWT (PICO™ : Smith and Nephew Healthcare) are being used for negative pressure therapy. Though negative pressure wound therapy systems are effective in promoting wound healing, however the conventional devices (image 1) available in the Indian market are unwieldy, heavy and restricts the ambulation of patient. The application and maintenance of these devices is done by trained professionals which results in increased hospitalisation, loss of man hours and economic drain on the society. On the other hand, PICO™ NPWT (image 2) are compact ambulatory NPWT devices providing continuous negative pressure at wound site without compromising patient's ambulation and quality of life and is more convenient to use by the patients.

Image 1: VAC

Image 2: PICO

Aim of this study is to compare the efficacy of portable canisterless ambulatory PICO™ NPWT device with the conventional VAC™ NPWT device in the management of different chronic wounds, in terms of appearance of healthy granulation tissue, duration of treatment, Number of dressings required to achieve primary outcome and complications associated with treatment in the management of chronic wounds.

INCLUSION CRITERION:-

1. Chronic ulcers less than 20x20 cm^2
2. Chronic ulcers more than 5x5 cm^2
3. Ulcers more than 3 months duration
4. Diabetic ulcers
5. Venous ulcers
6. Pressure ulcers

7. Negative probe to bone test (to rule out osteomyelitis)

EXCLUSION CRITERION:-

1. Exposed bones and joints.
2. Exposed blood vessels or actively bleeding wound.
3. Wounds communicating with body cavities.
4. Overt evidence of infection on the ulcer like pus or abscess.
5. Positive probe to bone test (Osteomyelitis).
6. Patients who do not give consent to be a part of the study

MATERIAL AND METHODS

This single centre prospective study, conducted over a period from 01 March 2017 to 28 Feb 2018. A total of 40 patients with chronic wounds with different etiologies were enrolled in the study as per the inclusion and exclusion criterion. The patients were divided into the control group (VAC™) and study group (PICO™) by "draw of lots method". After taking detailed history of disease and the ulcer, general physical examination and local examination of wound was done and details were noted. Standard treatment for the systemic disease as per the protocol was initiated with consultation of concerned specialist.

All the patients included in the study underwent initial wound debridement to remove necrotic and non-viable tissues. Once the wound was prepared for the application of NPWT device, appropriate device was applied over the wound.

For application of VAC™, polyurethane foam was cut according to shape of the wound and secured over the wound using the transparent occlusive dressing. Suction pad was applied over the foam dressing at the centre of wound and was connected with the canister and the VAC unit. Vacuum was confirmed by starting the suction and suction pressure was kept at 100 mmHg in continuous suction mode.

For application of PICO™ dressing, appropriate sized dressing was applied over the wound surface according to the size of the wound. All the edges were secured using transparent adhesive plastic dressing. PICO™ device with fresh pair of AA batteries were applied and connected to the suction tube. Suction created and confirmed by blinking of green indicator.

In both the groups, dressings were changed after 72-96 hrs of application of previous dressing and wound were examined and details of wound size, depth, volume, granulation tissue were noted in the proforma and photographs were taken. Wound swab for culture were taken at every dressing change and antibiotics were given based on culture and sensitivity report. All wounds achieving primary outcome were covered using secondary suturing, split skin grafts or flaps.

RESULTS

(Figure 1) - Diabetic foot ulcer over left foot and lower leg with exposed extensor digitorum longus and tibialis anterior tendons with grossly necrotic tissue. The foot was at risk of being amputated

(Figure 2) - Wound condition after 2 VAC dressings for 8 days. Wound is around 90% covered with granulation tissue, which bleeds on dressing change. Tibialis anterior tendon is fully covered with granulation.

(Figure 3) - Wound continues to have good granulation, with 2 more VAC dressings for one week, the exposed tendons were covered with granulation and patient underwent final closure with split-thickness skin graft (SSG). Figure shows wound condition after 3 weeks of SSG with spotty areas of graft loss which were healed by secondary intension

(Figure 4). Deformed diabetic foot with amputated great toe at presentation. Non healing ulcer over dorsum with gangrenous 4th toe and desiccated exposed extensor digitorum longus tendons.

(Figure 5) - Wound after initial debridement and 4th toe disarticulation with exposed head of 4th metatarsal. Extensor tendons were excised due to fixed deformity of foot.

(Figure 6) - Wound being managed with PICO™ dressings

(Figure 7) - Wound condition after 3 PICO™ dressings for 10 days. Wound is around 90% covered with granulation, including the head of 4th metatarsal and partially covering the extensor tendons.

(Figure 8) – Wound underwent final closure with split-thickness skin graft (SSG). Figure shows wound condition at the time of stapler removal with almost complete coverage with the graft.

Total of 40 patients were selected with age distribution from 36-72 yrs with mean age of 56.75 ± 8.424 yrs, 20 patients each were distributed in both control (VAC) and study (PICO™) groups. Most common chronic wound studied were Diabetic Foot Ulcers (70%) followed by Decubitus Ulcer (17.5%) and Venous Ulcer (12.5%). In our study,

most of the patients developed healthy granulation tissue after the intervention, whereas, 4 patients with decubitus ulcers in the study group, developed sub-optimal results with PICO™ dressings. The percentage change in size of wound in control group was 10.61% and that of study group was 6.52% which was statistically significant with a p-value of .003 (Mann- Whitney Test). The number of dressings required to achieve the final outcome in control group was 3.20 ± .410 and that in study group was 3.75 ± .639, which was statistically significant with a p-value of .003. The number of days in the control group (9.70 ± 1.031 days) and study group (11.35 ± 2.033 days) to achieve final outcome were also statistically significant with a p-value of .003 (t-test). Two cases in the study group (5%) did not achieve final outcome and were managed with conventional dressing and flap cover. One patient lost to follow up in study group (2.5%) and one patient died (2.5%) before final outcome.

Common complications encountered with the NPWT devices were pain and bleeding from wound surface during dressing change. In the study, 30% of patients in control group perceived pain and 45% had bleeding during dressing change, whereas none of the patient in study group perceived pain or bleeding during dressing changes.

DISCUSSION

The management of chronic wounds has evolved through different phases and resulted in the availability of different treatment modalities which modifies and hasten the healing process. Application of negative pressure wound therapy over the wound surface induces the growth and healing process through improved vascularisation, cellular deformations and drainage of the exudate in a controlled and isolated wound environment. These NPWT devices require fewer dressing changes than conventional dressings and results in an enhanced wound response for a quicker wound healing.

In the study, the mean age of the patients in control group was 56.15 yrs and study group was 57.35 yrs. Most common chronic wound in the study was diabetic foot ulcer, followed by decubitus ulcer and venous ulcer. In the study, majority of patients in both the groups achieved more than 90% granulation tissue whereas in the study group 20% of the patients with decubitus ulcers achieved suboptimal results and had to go frequent dressing changes due to high soakage. In a similar study conducted by *Malin Malmsj¨o et al*[11] for the effectiveness in fluid handling by PICO™ dressings, mid week dressing changes were required in high soakage wounds. Due to suboptimal results these patients were managed with conventional dressings. In our study, it was observed that the percentage change in wound size (Chart 1) in study group was 6.52% and that in the control group was 10.61%, in a study conducted by *Malin Malmsj¨o et al*[11] for the biological effects of disposable and canisterless NPWT system observed that the wound contraction with PICO™ dressings and foam based dressings were 6% and 10% respectively, with slightly greater wound contraction with foam based NPWT.

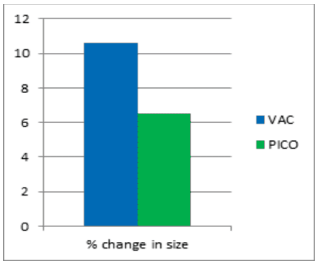

Chart 1

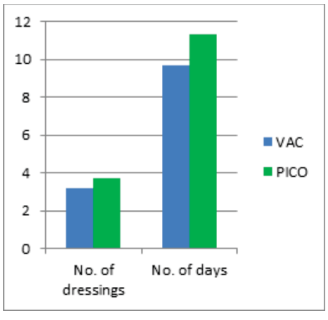

Chart 2

In our study, the mean number of dressings (Chart 2) required to achieve the primary outcome in study group was 3.75 ± 0.639 and that in the control group was 3.20 ± 0.410. In our study, the mean of number of days to achieve the primary outcome in study group was 11.35 ± 2.033 days and in the control group was 9.70 ± 1.031 days. In a study conducted by *nikunj vadia et al.*[12] the mean number of days to achieve a healthy wound for split thickness skin grafting after foam based NPWT dressing was 17.2 ± 3.55 days. The difference could be due to the initial wound debridements and preparation of wounds for NPWT device application which resulted in early outcomes.

In our study it was observed that none of the patients in study group had pain or bleeding from the wound site during the dressing changes while 30% patients in the control group perceived pain and 45% patients had oozing of blood from the granulation tissue during the dressing changes due to ingrowth of granulation into the foam dressing. In a study conducted by *Donald A Hudson et al.*[13] using the PICO™ system in the management of surgical wounds, 93% patients did not report pain during dressing change and 98% patients did not had any trauma to wound bed and surrounding skin.

In our study it was observed that the acceptance of NPWT dressings by the patients in both the groups were satisfactory. In the study group, patients were more comfortable with the use of portable size PICO™ dressings, whereas in the control group, patients remained more apprehensive and confined to bed due to the size of the VAC device.

As we can interpret from our study, that both modalities of negative pressure therapy are effective in the management of chronic wounds. The ambulant negative pressure therapy (PICO™) produce similar results as compared to foam based (VAC) dressings in terms of wound coverage with granulation, but the number of dressings and number of days required to achieve the desired results are more with PICO™ dressings than VAC dressings.

The patient's acceptance of PICO™ dressings is better over VAC dressings. However, complication in the form of pain and bleeding from wound surface was more with VAC dressing as compared to PICO dressing.

CONCLUSION

From the findings of the study we can conclude that VAC NPWT was superior to the ambulatory PICO™ NPWT in terms of changes appeared in granulation tissue, wound size and wound volume after the application of dressings. The number of days and number of dressings required to achieve the primary outcome were less with the conventional VAC dressings as compared to ambulatory PICO™ dressings, although both the negative pressure dressings were effective in achieving the primary outcome. Especially in treating cavitary wounds such as decubitus ulcers, ambulatory PICO™ NPWT exhibited more dressing changes and suboptimal results as compared to the conventional VAC dressings.

The cost of treatment and patient compliance were better in study group with PICO™ dressings than in control group with VAC dressings.

Both the groups required trained professionals for the proper application and maintenance of dressings with the advantage that patient remained more ambulant with PICO™ dressings than with VAC dressings.

The pain and oozing of blood from the wound site during the dressing changes was significantly less in study group with PICO™ dressings as compared with VAC dressings in control group.

Based on the results, we could conclude that both the modalities of negative pressure wound therapy are effective in the management of chronic wounds with advantages and disadvantages in each modality. Even though, the findings are suggestive, it is recommended that further trials, especially multicentric and randomised, to be initiated to validate the findings of the present study and to provide the definitive comparisons between both the modalities.

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