Section: General Surgery

Original Research Article

# AN OBSERVATIONAL STUDY TO CHECK THE EFFECTIVENESS OF NEGATIVE PRESSURE WOUND THERAPY FOR CLOSURE OF DIFFERENT TYPES OF WOUNDS

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## ABSTRACT

**Background:** An observational study to check the effectiveness of negative pressure wound therapy (NPWT) for wound closure for different types of wounds. Also to assess percentage reduction in wound size, rate of formation of healthy granulation tissue and to assess reduction in hospital stay. **Materials and Methods:** Enrolment of patient with Ulcer or wound (age above 18 years) admitted in General surgery ward of tertiary care center done according to inclusion and exclusion criteria. Written informed consent taken. Patients were assessed for all the objective and subjective parameters by chief investigator. All the patients in study group were the subjects who have been advised or opted for NPWT as standard of care for wound management by the treating Doctor and the parameters have been recorded as per objectives. Patients were observed for detailed clinical examination and relevant investigations according to case proforma. Wound assessment done on day-0(Before application of NPWT),7,14,21, and 24 days. Each time diameter, surface area and other clinical parameters described below were noted. Wound swab was taken on every 7th day until microbial negativity and then weekly thereafter. Wound photograph was taken each time we assessed the wound for comparison. End point of study was taken as complete healing of the wound. **Result:** The mean duration of stay in hospital was 23.2+/-13.8 days (9-69). None of the subjects participated in the study had undergone revision surgery. The mean duration of wound closure was 44.1+/-17.9 days. **Conclusion:** This study supports efficacy of NPWT and provides clinical evidence to support use of NPWT for wound management. NPWT helps in reduction in hospital stay, requirement of re-debridement or revision surgery and amputations and has role in significant reduction of morbidity. There is significant reduction in time taken for wound closure and NPWT is a safe method for wound management.

## INTRODUCTION

In past few centuries the field of medicine is so much advanced despite that management of wounds remains a tough challenge. To solve this lot of modalities of dressings and local applicants have been developed and still studies are going on. Wounds which are showing characters of delayed healing or non-healing is a problem which given rise to various complications in addition to financial and psychological burden. There are evidences in favour of employing wounds to sub atmospheric pressure in addition to regular debridement may help in acceleration of wound healing and granulation tissue formation following which wound closure is accelerated.

The application of controlled levels of negative pressure has been shown to accelerate healing in many different types of wounds. The optimum levels of negative pressure appear to be about -100mmHg and there is evidence that it is most effective if it applies in cyclical fashion.

It is believed that negative pressure assists removal of interstitial fluid, decreasing localized oedema & increasing blood flow. This in turn decreases tissue bacterial loads. Additionally mechanical deformation of cells thought to result in protein & matrix molecule synthesis which increases the rate of cell proliferation. Even though significant costs involved


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the technique is said to be comparable favourably in financial terms with conventional treatment in management of difficult non-healing wounds. Numerous studies described in using negative pressure wound therapy for intensive degloving injuries, infected sternotomy wounds, various tissue injuries prior to surgical closure, abdominal wounds, Grafting or reconstructive surgeries.

NPWT is being used since past many years as a standard of care for wound management. There have been various studies or literature which have shown that NPWT has been beneficial, and an effective therapy for wound closure for different types of wounds. Our study will be about NPWT at a tertiary care center.

## MATERIALS AND METHODS

**Study design:** Prospective Observational study.
**Place of study:** A Tertiary care Hospital.
**Duration of study:** 11 months
**Inclusion Criteria**

- AGE – 18 years or above
- Wounds without any fistula
- Ulcer size > 2cm2.
- All types of wounds except Abdominal wounds irrespective of the etiology.
- Patients giving consent for topical negative pressure.

**Exclusion Criteria**

AGE – younger than 18 years

- Abdominal wounds
- Ischemic wounds with monophasic flow on arterial doppler.
- Pregnant and lactating females.
- Wounds with active Hemorrhage or enteric fistula
- Ongoing infection
- Devitalized tissue — Inadequate debridement with the presence of devitalized soft tissue or bone increases the risk for infection.
- Malignant tissue.
- Fragile skin
- Adhesive allergy

Withdrawal criteria Any patient who is not willing for the study anytime during the study was considered for withdrawal.

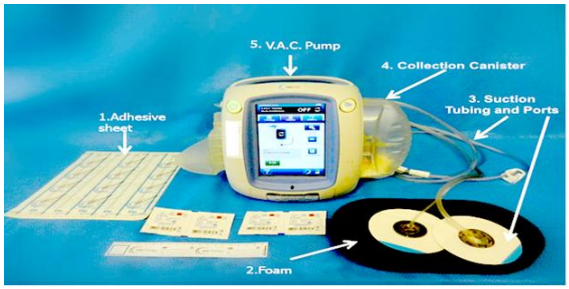

**Figure 1: Materials Used for NPWT application**

INDICATIONS -Negative pressure wound therapy (NPWT, also called vacuum-assisted wound closure) has been applied to a wide range of clinical situations, including the open abdomen, following surgical debridement of acute or chronic wounds (e.g., orthopedic, necrotizing infection, pressure ulcer), diabetic foot ulcers, and reconstructive surgery (e.g., burns, skin graft, muscle flap).

Advantages — Compared to traditional wound care modalities, NPWT offers several clinical advantages compared to usual care.

- Traditional therapy consists of moist saline dressings that are changed up to three times daily. If too much time elapses between dressing changes, the gauze may become painfully adherent, and its removal may debride desirable granulation tissue as well as devitalized tissue. Much of the pain associated with wound care occurs during dressing changes. In contrast, NPWT dressings are changed once every 3 to 10 days, and anticipated pain can be managed as per need.
- Compared with other forms of wound dressing, NPWT is easier to tailor and maintain in position. Almost every configuration of wound, including circumferential extremity wounds (i.e., degloving injuries) and wounds located in proximity to orthopedic fixation frames, can be managed with relative ease [41-42,45]. As a result, NPWT may allow fewer complex modes of reconstructive surgery. Complex wounds that required a pedicle flap may, after NPWT, be converted to a wound requiring a rotation flap or skin graft [38].
- Accelerated wound healing with NPWT significantly reduces the time to wound closure in diabetic patients, returning these patients to baseline more quickly and improving quality of life.
- Reduced complexity of subsequent reconstructive procedures.

Disadvantages —

- From the patient's perspective, the main disadvantage of NPWT is the need to carry the portable pump.
- NPWT systems are more expensive than traditional wound dressings. However, the overall cost of wound care depends upon the frequency of dressing changes, need for skilled nursing care, and duration of treatment. Significant clinical reductions in time to wound closure would be needed to offset the increased cost of the device and special supplies for NPWT to be cost effective, but data are limited.

**Methodology** Enrolment of patient with Ulcer or wound (age above 18 years) admitted in General surgery ward of tertiary care center done according to inclusion and exclusion criteria. Written informed consent taken. Patients assessed for all the objective and subjective parameters by chief investigator. All the patients in study group are be the subjects who have been advised or opted for NPWT as standard of


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care for wound management by the treating Doctor and the parameters will be observed as per objectives. Patients are observed for detailed clinical examination and relevant investigations according to case proforma. Wound assessment done on day-0(Before application of NPWT),7,14,21 and 24 days. Each time diameter, surface area and other clinical parameters described below were noted. Wound swab was taken on every 7th day until microbial negativity and then weekly thereafter. Wound photograph was taken each time we assessed the wound for comparison. End point of study: complete healing of the wound.

**Clinical assessment of wound:**

**1. Wound size:**

A. The wound size assessed by sequential measurement on day-0,7, 14,21 and 24 by using sterile polyethene dressing kept over the wound already covered by a sterile gauze piece with edges left exposed, the wound size marked on a transparent acetate sheet with grid tracing of squares each of size 1cm2 and smallest square of 1mm2, using different colour markers for each sequential reading, as shown in the photographs below.

a. Tracing a wound for measurement and measuring a wound. (Figure)

**Figure 2: ?**

B. In cases of difficulties with irregular wounds, surface area was measured by taking diameters at eight different points nearly 22.5 degree apart or at irregular wound margins and connected all the points to form an irregularly shaped outline of wound surface.

C. In irregularly shaped wounds the area was measured by adding up the number of small squares contained within the margin of outline drawn over it.

D. In wounds that are approximately circular multiply the longest diameter in one plane by the longest diameter in the plane at right angles to it.

**2. Character of exudate:** It can be serous detected by just soakage of dressing, serosanguinous detected by blood-stained dressing, semi-purulent or purulent detected by just pressing the wound or its surrounding area or seen in canister.

- Grade 1: - Serous
- Grade 2: - Serosanguinous
- Grade 3: - Semi-purulent
- Grade 4: - Purulent.

**3. Granulation tissue:** It is new connective tissue and microscopic blood vessels that form on the surface of wound during healing process. Characteristics of granulation tissue are it's light red or dark pink in color, moist, soft to the touch, bleeds on touch due to newly formed capillary loops, no slough, no discharge and painless.

It can be assessed as, Granulation tissue consisting of

- <25% of area of the wound
- 25-50% of area of the wound
- 50-75% of area of wound
- >75% of area of wound.
- Edges of the wound: - Sloping edges suggest healing wound.
- Inflammatory changes in surrounding area: -

There are 4 signs of inflammation, that are redness, warmth, swelling and tenderness. Each sign will be assigned with 1 point.

Patients were followed up during hospital stay then on OPD basis and telephonic contact know whether he/she required revision surgery within 30 days and outcome of the patient till the end point of study.

**Laboratory and radiological investigations:**

- Investigations done as a routine standard of care will be recorded on a case record form and no additional investigations will be done for the purpose of study.
- We collected information regarding the duration of diabetes mellitus, ulcer duration, presence of claudication pain, hemoglobin levels, leucocyte count, serum creatinine, admission plasma glucose, HbA1c, lipid profile, presence of PAD (peripheral arterial disease) or neuropathy, empirical antibiotics given, and organisms grown in tissue/pus culture, X-ray findings and Doppler studies.
- The diagnosis of diabetes mellitus was measured at the initial admission.

## RESULTS

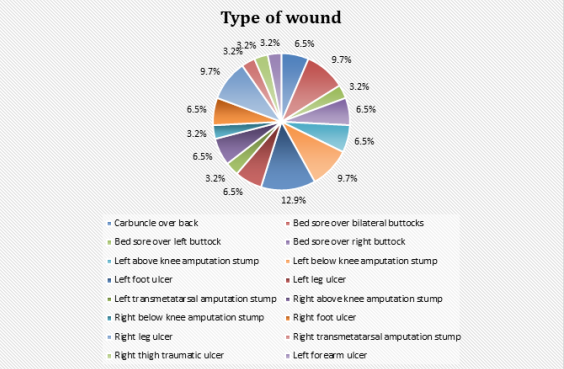


**Figure 3: type of wound**

**Table 1: Duration of diabetes mellitus**

| Duration of diabetes mellitus | Frequency | Percentage |
|---|---|---|
| None | 8 | 25.8 |
| Recently | 4 | 12.9 |


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|---|---|---|
| 1-5 years | 10 | 32.2 |
| 6-10 years | 4 | 12.9 |
| > 10 years | 5 | 16.1 |
| Total | 31 | 100 |

**Table 2: presence of comorbidities**

| Presence of comorbidities | Frequency* | Percentage* |
|---|---|---|
| None | 16 | 51.6 |
| CVA | 1 | 3.2 |
| Hypertension | 10 | 32.2 |
| Ischemic heart disease | 7 | 22.6 |

**Table 4: wound size**

| Day of/after application of VAC | Day 0 (n=31) | Day 7 (n=31) | Day 14 (n=3) | Day 21 (n=3) |
|---|---|---|---|---|
| Wound size in area cm2 | 71.5+/-36.6 | 41.2+/-21.7 | 55+/-19.1 | 25.5+/-14.1 |
| Percentage reduction compared to Day 1 readings | - | 41.3+/-14.3% | 53.6+/-15.8% | 79.3+/-9.3% |

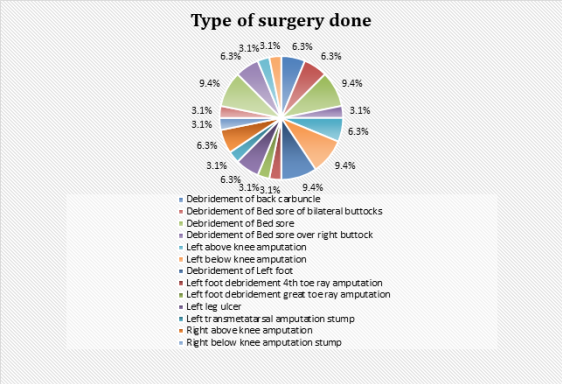


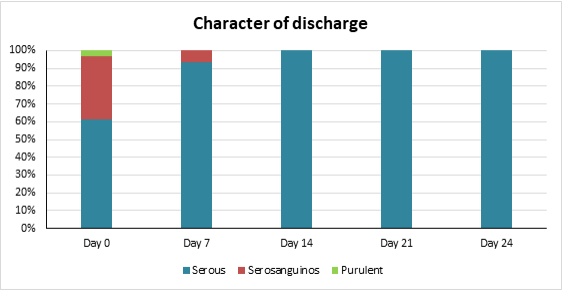


**Table 5: character of discharge**

| Character of discharge | Day 0 | Day 7 | Day 14 | Day 21 | Day 24 |
|---|---|---|---|---|---|
| Serous | 19 (61.3%) | 29 (93.5%) | 31 (100%) | 31 (100%) | 31 (100%) |
| Serosanguinous | 11 (35.5%) | 2 (6.5%) | - | - | - |
| Purulent | 1 (3.2%) | - | - | - | - |

**Table 6: healing of granulation tissue**

| Healing of granulation tissue | Day 0 | Day 7 | Day 14 | Day 21 | Day 24 |
|---|---|---|---|---|---|
| <25% of area of the wound | 31 (100%) | 29 (93.5%) | 6 (19.4%) | - | - |
| 25-50% of area of the wound | - | 2 (6.5%) | 23 (74.2%) | 15 (48.4%) | 3 (9.7%) |
| 50-75% of area of wound | - | - | 2 (6.5%) | 16 (51.6%) | 28 (90.3%) |



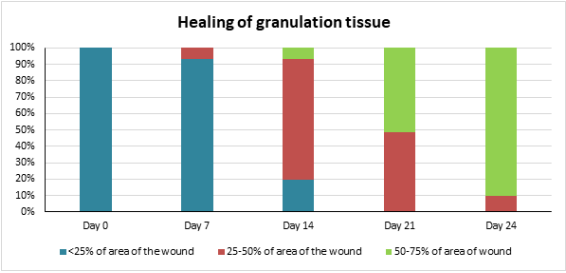




**Table 7: healing of wound edges**

| Healing of wound edges | Day 0 | Day 7 | Day 14 | Day 21 | Day 24 |
|---|---|---|---|---|---|
| <25% | 31 (100%) | 23 (74.2%) | 4 (12.9%) | - | - |
| 25-50% | - | 8 (25.8%) | 24 (77.4%) | 16 (51.6%) | 9 (29%) |
| 50-75% | - | - | 3 (9.7%) | 15 (48.4%) | 21 (67.7%) |
| >75% | - | - | - | - | 1 (3.2%) |

**Table 8: inflammatory changes in surrounding area of skin**

| Inflammatory changes in surrounding area of skin | Day 0 | Day 7 | Day 14 | Day 21 | Day 24 |
|---|---|---|---|---|---|
| 0 | 16 (51.6%) | 26 (83.9%) | 28 (90.3%) | 31 (100%) | 30 (96.8%) |
| 1 | 10 (32.3%) | 3 (9.7%) | 3 (9.7%) | - | - |
| 2 | 3 (9.7%) | 1 (3.2%) | - | - | 1 (3.2%) |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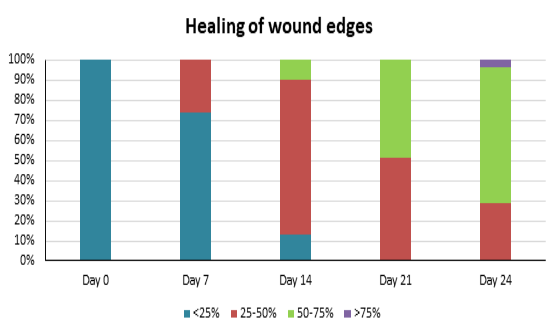
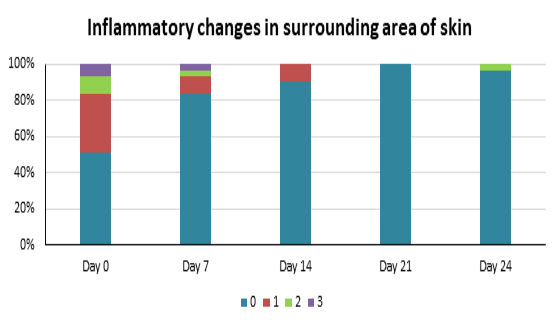
|---|---|---|---|---|---|
| 3 | 2 (6.5%) | 1 (3.2%) | - | - | - |




In our study we have assessed ulcer surface area and maximum ulcer diameter parameters to assess the rate of wound healing. The mean duration of wound closure was 44.1+17.9 days. Different wound parameters were studied during the study.

A. Rate of formation of healing granulation tissue:

About 90% of patients develop granulation tissue in 50-75% wound area by 24 days from application of negative pressure wound therapy. This shows the NPWT is an effective method if applied in a meticulously selected wound.

B. Rate of formation of healing wound edges:

- Like healing granulation tissue, healing wound edges along with disappearance of signs of inflammation in surrounding skin area indicate early recovery of the ulcer.
- Majority of patients developed healing/sloping edges by day 7 of application of NPWT.

C. The character of Discharge from the wound:

It changes from purulent to seropurulent after debridement and as ulcer heals it converts to serosanguinous then finally to serous. This change is faster in with application of negative pressure wound therapy. Hence character of ulcer exudate is one of the good assessment parameters for healing of ulcers. Few representative images are shown here.

**Image 1: Case of Right leg ulcer (Before, with and after NPWT)**

**Image 2: Case of above knee amputation before and after NPWT**

**Image 3: Case of Bedsore over Sacral region and bilateral buttocks Before, with and after NPWT**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D. Reduction in hospital stay: The mean duration of stay in hospital was 23.2+/-13.8 days (9-69) which itself shows the contribution of NPWT in significantly reducing the morbidity.
E. Requirement of Revision surgery: None of the subjects participated in the study had undergone revision surgery.

Outcome: All patients were discharged from the hospital and examined on follow up.

Duration of wound closure: The mean duration of wound closure was 44.1+17.9 days.

**Statistical analysis:**

- With the Ethics Committee approval, we collected the information in a preformed case record form from patient's case record sheets regarding patient's demographics, co-morbidities, clinical features, laboratory values, empirical antibiotics given and outcome of the patient. Appropriate statistical analysis was applied to obtain statistically significant results.
- Data from the case record forms will be entered into a Microsoft excel sheet and analyzed using SPSS version 21 software.
- Descriptive statistics have been assessed and represented as Means+/-SD, frequency and percentages.
- Normality of quantitative data have been assessed using Shapiro Wilk test.
- Pre and post quantitative data within the group have been compared using paired t test for normally distributed data or Wilcoxon signed rank test for data which is not normally distributed.
- Pre and post qualitative data have been compared using Chi square test.
- Level of significance in the study will be less than 0.05.

## DISCUSSION

Managing the Ulcers and wounds remains a challenge for the medical professionals in terms of amount of expenditure, significant morbidities in terms of multiple debridement surgeries finally ending up into amputation of limb and sometimes mortality because of complications such as infections. Invention Negative pressure wound therapy has been proven to be an effective method for the management of wounds. With Multiple Mechanisms. NPWT fastens the rate of wound healing and reduces the significant morbidity for the patient.

Negative pressure wound therapy (NPWT) has shown great advantages in the management of a wide range of clinical problems such as wound or chronic wound healing; open wounds with exposed bone, nerve, or tendon; and orthopedic implants and related infection in the orthopedics field. Even though it has shown positive efficacy in treating infection (wound infection or orthopedic implant infection), its molecular mechanisms of action remain unclear and require further exploration. Since NPWT is widely used in the clinical setting, a comprehensive understanding of its biological effect will assist in appropriate clinical application.[1]

Burhan A et al did a systematic review and meta-analysis on effectiveness of negative pressure wound therapy on chronic wound healing. A total of 15 articles were included, with 3,599 patients with chronic wounds. The RE model showed a significant positive effect of the NPWT on chronic wound healing. The observed effects include decreased rate of surgical site infection, controlled inflammation, oedema, and exudate, as well as increased tissue with varying forest plot size, as demonstrated by the small effect size. The analysis results show that the standard low pressure of 80-125 mmHg could improve microcirculation and accelerate the healing process of chronic wounds.[2]

Xie X et al did a systematic review to estimate the efficacy of negative pressure wound therapy (NPWT), based on a systematic review of reported randomised controlled trials (RCTs). They identified 17 RCTs, of which five had not been included in previous reviews or health technology assessments. For diabetic foot ulcers (seven RCTs), there was consistent evidence of the benefit of NPWT compared with control treatments. For pressure ulcers (three RCTs), results were conflicting. In trials involving mixed wounds (five RCTs), evidence was encouraging but of inadequate quality. Significant complications were not increased. It was concluded that NPWT is safe, and accelerates healing, to justify its use in the treatment of diabetes-associated chronic leg wounds. Review by Nie B et al summarizes the biological effect of NPWT on bacteria and cell growth as well as the possible mechanisms associated with NPWT applied in wound healing. Authors also highlighted novel antibacterial dressings for NPWT. PubMed, and Web of Science database searches were conducted. Several search terms were used including negative pressure wound therapy, bacterial growth, growth factor, wound healing, dressing.[3]

Zhang N et al showcased the effect of negative pressure wound therapy on the outcome of diabetic foot ulcers. It has been shown to be superior to conventional techniques in randomized controlled trials (RCTs). A systematic review of RCTs and observations was carried out to evaluate the effectiveness and security of negative pressure wound therapy (NPWT) treatment for diabetes foot ulcers. The results showed that NPWT was associated with a reduction in amputations. In a subgroup of RCT trials, nine RCT trials showed a reduction in amputations. In both RCT trials, NPWT also showed a reduction in amputations. NPWT can help to heal the wound and lower the risk of amputations in people with diabetes. The subgroup analysis showed similar results for the RCT and non-RCT trials. NPWT can be used to treat diabetes foot ulcers caused by diabetes.[4]


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Apelqvist J et al studied negative pressure wound therapy: overview, challenges, and perspectives. Since its introduction in clinical practice in the early 1990's negative pressure wounds therapy (NPWT) has become widely used in the management of complex wounds in both inpatient and outpatient care. NPWT has been described as an effective treatment for wounds of many different etiologies and suggested as a gold standard for treatment of wounds such as open abdominal wounds, dehisced sternal wounds following cardiac surgery and as a valuable agent in complex non-healing wounds. Increasingly, NPWT is being applied in the primary and home-care setting, where it is described as having the potential to improve the efficacy of wound management and help reduce the reliance on hospital-based care.[5]

NPWT has become an integral part of modern wound care, and is used routinely in hospitals throughout the world. It is estimated that 300 million acute wounds are treated globally each year NPWT has successfully been used for the treatment of acute, chronic, and complex wounds. There is a substantial body of clinical and economic evidence supporting the efficacy of NPWT in wound management, including early discharge and faster healing, fewer readmissions, and better patient quality of life. NPWT cannot replace surgical procedures, but may allow a wound to progress to the point at which a less invasive procedure is possible. It is being increasingly recognized that NPWT can be used to achieve a variety of treatment goals, which vary according to the patient and the characteristics of the wound.

## CONCLUSION

- This study supports efficacy of NPWT and provides clinical evidence to support use of NPWT for wound management.
- This study also supports NPWT helps in reduction in hospital stay, requirement of re-debridement or revision surgery and amputations and has role in significant reduction of morbidity.
- This study also confirms that there is significant reduction in time taken for wound closure.
- This study Supports that NPWT helps in achieving microbial negativity in the wound.
- This study also supports that NPWT is a safe method for wound management.

**Limitations of this study**

- Our study was not a randomized study.
- Population was heterogeneous with having different inherent wound healing capacity due to different age, gender and co-morbid conditions leading to multiple confounding factors.
- Limitation of sample size as it depends on the availability of resources at the study place.

**Strengths of this study**

- Our study is prospective study.
- Accurate measurement of ulcer surface area and maximum diameter (with tracing paper with minimum surface area of 1 mm2).
- Since study population is heterogeneous, results are applicable to wider range of population.
- Various new parameters of ulcer have been studied which have not studied previously i.e. character of exudate, presence of ulcer odor, rate of formation of healing granulation tissue and rate of formation of healing wound edges after application of NPWT.

**Lacunae in present studies:**

- There are no clear-cut guidelines regarding precise pressure to be applied, and number of sessions of NPWT required.
- No long term proven adverse effects of NPWT have been discovered yet.

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