# Pressure ulcer management in paraplegic patients with a novel negative pressure device: a randomised controlled trial


• **Objective:** A randomised controlled trial to compare negative pressure wound therapy (NPWT) using our innovative negative pressure device (NPD) and the standard pressure ulcer (PU) wound dressing of in traumatic paraplegia patients.
• **Method:** This study was conducted in the Department of Orthopaedic Surgery at King George's Medical University, Lucknow, India. Traumatic paraplegia patients with sacral pressure ulcers of stage 3 and 4 were randomised into two groups, receiving either standard wound dressings or NPWT with NPD. The outcomes monitored were length, width (surface area), depth of PU, exudates, discharge, tissue type (necrotic, slough and red granulating tissue), and cost-effectiveness during 0 to 9 weeks follow-up.
• **Results:** Length and width were significantly ($p<0.01$) decreased in NPWT group as compared with standard care group at week 9. At weeks 1, 2 and 3, depth was significantly ($p<0.05$) higher in NPWT group, whereas at week 9 a significant reduction ($p=0.01$) was observed. Exudates were significantly ($p=0.001$) lower in NPWT group at weeks 4 and 9. Conversion of slough into red granulation tissue was significantly higher in NPWT group ($p=0.001$). Discharge became significantly ($p=0.001$) lower in NPWT at week 2 and no discharge was observed after week 6. In all parameters, decrease was larger in NPWT group compared with standard care, which was significant for exudates type ($p=0.03$) and tissue type ($p=0.004$).
• **Conclusion:** Our NPD is better than standard wound care procedures and cost-effective for management of PU.
• **Declaration of interest:** The authors have no conflict of interest to declare.


pressure ulcer; negative pressure wound therapy; negative pressure device

Pressure ulcers (PU) are visible evidence of pathological changes in the blood supply to dermal tissues.[1] Factors contributing to PUs in traumatic paraplegic patients are immobility, constant pressure, moisture, and irritation to the skin.[2] Standard methods of daily dressings and serial debridement require prolonged hospitalisation, and may lead to additional comorbidities and increased socioeconomic burden.[1,2] Alternative methods, such as hyperbaric oxygen therapy, electrical stimulation, silver and hydrocolloid dressing, are cumbersome, expensive and not readily available.[2]

Management of PUs is an ongoing clinical challenge,[3] and these represent a serious health-care problem, particularly in traumatic paraplegia patients in developing countries where socio-economic conditions often dictate treatment modalities.[3,4] Traumatic paraplegia patients are at an increased risk of PUs because of anaesthetic skin and prolonged bedrest.[5]

Negative pressure wound therapy (NPWT) is a vacuum-assisted method for wound care that imparts a negative pressure of −60 to −125mmHg on the wound bed.[6] The mechanism by which NPWT promotes wound healing is unclear. It is believed that the negative pressure aids removal of interstitial fluid, decreasing oedema, increasing blood flow and formation of new blood vessels thereby supplying wound with oxygen and nutrition and decreasing tissue bacterial levels.[7,8]

In 2012 the estimated the cost of treatment of PU in UK varied from £1214 to £14,108.[9] However, there is a lack of high-quality research estimating cost-efficiency to support the use of NPWT.[10,11] Negative pressure devices (NPDs) are costly and hard to afford in developing countries. Considering this limitation, a non randomised control trial (RCT) with an innovative locally constructed NPD was conducted at our centre with encouraging results.[2] A pilot RCT of NPWT for grade III and IV PUs was published in 2012[12] indicating large trials were required. This study was planned as a full RCT comparing our NPD to standard wound dressings.


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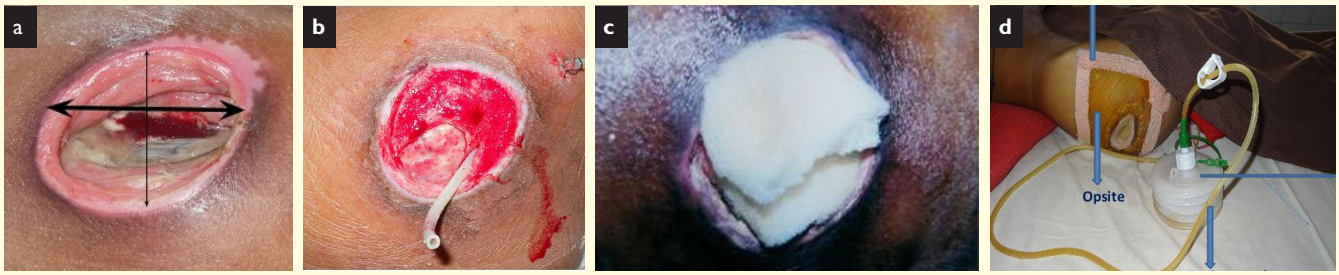
Continued page 202

**Fig 1. Step 1 mark the length and width of the ulcer (a). Step 2 one end of drainage tube of Romovac is placed on ulcer bed (b). Step 3 sterilised foam placed on top of wound (c). Step 4 Opsite covers the ulcer with an airtight seal and other end of drainage tube is connected to Romovac (d)**




## Methods

This RCT was registered (CTRI/2014/09/0050) and conducted in the spinal cord injury (SCI) unit of the Department of Orthopaedic Surgery in collaboration with the Department of Physical Medicine and Rehabilitation at King George's Medical University (KGMU) and Department of Plastic Surgery, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow. The study was conducted according to guidelines set out in the Declaration of Helsinki and approved by the Institutional Ethics Committee (IEC) of the University (KGMU) (IEC-2265/R-Cell/8-12-2010). The study protocol was explained to patients in their local language and informed consent was obtained.

The inclusion criteria were:

- Traumatic paraplegia
- Age 16–60 years
- Either gender
- Stage III-IV PU as defined by the European Pressure Ulcer Advisory Panel (EPUAP)[13]
- Subjects able to give informed consent.

The exclusion criteria were:

- Necrotic tissue unlikely to tolerate debridement
- Chronic osteomyelitis not treatable by antibiotics alone
- Exposed blood vessels and nerves
- Comorbidities such as diabetes mellitus, rheumatoid disease, vasculitis, neuropathy, chemotherapy, radiation therapy
- Poor nutritional status as determined by a Braden scale nutritional assessment score of 2 or 1
- Serum albumin <2.5g/L, haemoglobin<9.0g/L.

Sample size was calculated for a 0.5% significance level with 80% power (% chance of detecting).

**Table1. Basic characteristics of the patients:**

| | | Standard care group (n=23) | NPWT group (n=21) | p-value |
|---|---|---|---|---|
| Age in years | | 32.52 ± 11.41 | 38.38 ± 7.65 | 0.05* |
| Gender | Male | 19 (82.6) | 18 (85.7) | 0.77† |
| | Female | 4 (17.4) | 3 (14.3) | |
| Stage | III | 13 (56.5%) | 4 (19.0%) | 0.01 † |
| | IV | 10 (43.5%) | 17 (81.0%) | |

Values are given as mean ± standard deviation (SD) or frequency (%) as appropriate.
*Unpaired t-test, †Chi-square test; NPWT–negative pressure wound therapy

### Baseline assessment

At enrolment, one PU was graded as stage III or IV, this would be followed up and monitored throughout the study period.[13] Information regarding patient demographics, PU history and comorbidities was obtained from patients and/or their carers. The grade and location of the reference ulcer was determined by visual inspection. Each PU was given an identification code (ID), and the shape and location of the ulcer drawn on a diagram similar to the body shape.

### Randomisation

A computer-generated random table was obtained and used to allocate participants to one of the two treatment groups: either NPWT or standard care (SC). Treatment was allocated on an individually named patient basis and participants commenced their allocated treatment immediately following randomisation. Participants were assigned an identification number, which was used to identify them throughout the trial. Allocation of participants was done by one of the co-authors. Initial debridement for slough and necrotic tissue was done for all patients at the time of enrolment and before randomisation.

### Standard care

The PU was cleaned with normal saline and packed with sterilised gauze to cover the wound. The dressing was changed once or twice daily depending on the absorbancey of the dressing.[2]

### Negative pressure wound therapy

Our NPD was applied exclusively as a bedside procedure. The a low-cost device, comprises of a low-power continuous-suction apparatus consisting of a bellow unit of 800ml capacity, a connecting tube with clamp, a 'Y' connector, a curved needle with

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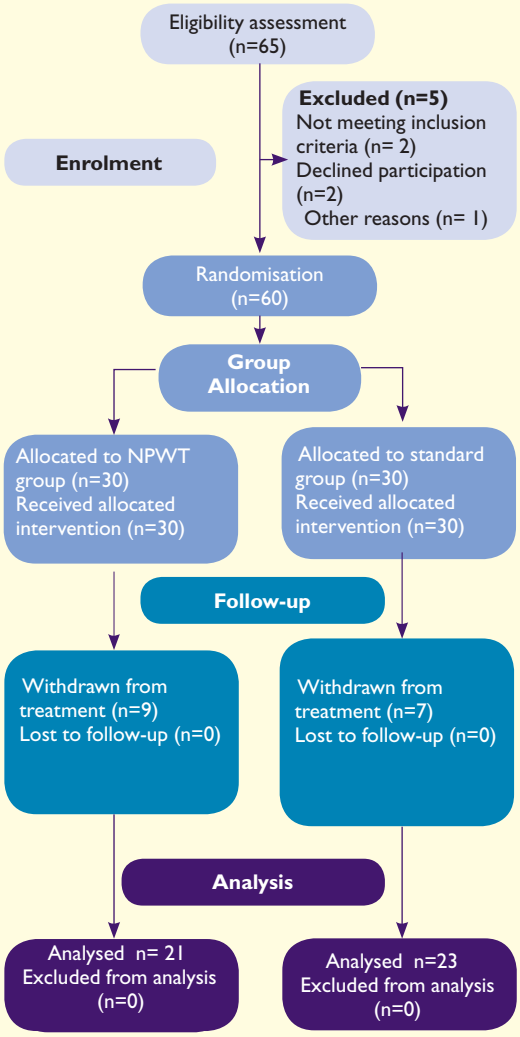
**Fig 2. Consort flow chart**




matching catheter and spare perforated catheter (ROMOVAC SETGS-5002 SIZE-10; Romsons Scientific and Surgical Industries Pvt. Ltd. Agra, U.P., India), a sterilised piece of foam and a transparent polyurethane adhesive dressing (Opsite; G. Surgiwear Ltd., Shahjahanpur, U.P., India).[2] The components of the device are readily available and used for other surgical procedures in the country.[2] NPD was changed every week or earlier if required. The dressing was changed by resident staff with the help of research staff. All participants were admitted to the SCI unit of Department of Orthopaedic Surgery would the end of follow-up period. PUs were evaluated and documented by clinical photography and were treated until the wound was closed spontaneously or until completion of the 9-week study.

### Application of the negative pressure device

The perforated end of the drainage tube of the Romovac was placed on wound surface and its other end exits through the skin 10cm away from the wound margin (Fig 1a) and connected to Romovac bellow. Sterilised foam was trimmed according to the size and geometry of the wound and placed on top as a cover (Fig 1b). Opsite finally covered the wound and the adjoining healthy skin with an airtight seal (Fig1c). The bellow of Romovac is charged to attain appropriate cyclical/intermittent negative pressure (Fig 1d). The pressure was measured by a pressure monitoring device (Romsons Scientific and Surgical Industries Pvt. Ltd). Patients and caregivers were tauht how to charge the Romovac and advised to charge it after every 5–6 hours.[2]

The outcome measures were length, width (surface area) and depth of PU, exudates, discharge, tissue type (necrotic tissue, slough and red granulating tissue) and cost-effectiveness from 0–9 weeks follow up. Data were recorded every seven days.

PUs in both the groups were measured at each time point (weekly) using the same procedure. The ulcer was measured for its greatest length and greatest width with a centimetre ruler. Surface area was estimated from these values. PU depth was measured with a sterilised cotton-tipped applicator, which was inserted into the ulcer and marked at the deepest level. The amount of exudate was categorised as none (0), light (1), moderate (2), or heavy (3) after the dressing was removed in both NPWT and SC group with the help of the Pressure Ulcer Scale for Healing (PUSH) Tool Version 3.0 (NPUAP, 2003).[14] Necrotic tissue, slough and formation of red granulation tissue were assessed by visual inspection at the time of dressing change. Weekly assessment of PUs for every outcome measures and clinical photography was carried out by the same co-author throughout the trial. The actual cost of all consumables required for NPWT by our NPD and for SC were calculated for two representative PUs of similar size in each group.

### Cost analysis

Costs were obtained from the record of hospital's central supply department but did not include things common to both groups (such as sterilisation of materials, dressing forceps, scissors). All dressing materials were considered as single use. The total costs for one NPWT group and one SC group were collated and total the daily cost calculated based on once or twice-daily dressing change of the SC group and a change every 7 days for NPD group. The total NPWT and SC cost of one representative PU was determined by multiplying the daily cost by the number of days required to achieve wound granulation.

**Table 2. Comparison of surface area and depth**

| Time period | Surface area ($cm^2$) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Length (cm) | | | Width (cm) | | | Depth (cm) | | |
| | Standard care group | NPWT | p-value† | Standard care group | NPWT | p-value† | Standard care group | NPWT | p-value† |
| At admission | 7.16±2.27 | 7.46±2.02 | 0.64 | 6.31±2.17 | 6.53±1.65 | 0.71 | 5.31±0.75 | 5.71±1.38 | 0.06 |
| Week 1 | 7.09±2.29 | 7.27±2.05 | 0.78 | 6.16±1.98 | 6.53±1.92 | 0.53 | 4.21±0.75 | 5.49±1.39 | 0.001* |
| Week 2 | 6.79±2.36 | 6.72±2.03 | 0.91 | 5.91±2.09 | 5.58±1.60 | 0.56 | 3.94±0.77 | 4.90±1.24 | 0.003* |
| Week 3 | 6.38±2.20 | 6.05±2.01 | 0.60 | 5.41±1.79 | 5.03±1.45 | 0.44 | 3.60±0.75 | 4.35±1.30 | 0.02* |
| Week 4 | 5.94±2.02 | 5.30±1.92 | 0.29 | 4.98±1.79 | 4.48±1.43 | 0.31 | 3.16±0.66 | 3.62±1.22 | 0.13 |
| Week 5 | 5.32±1.73 | 4.55±1.90 | 0.16 | 4.63±1.93 | 3.63±1.29 | 0.06 | 2.75±0.51 | 3.24±1.38 | 0.12 |
| Week 6 | 4.79±1.72 | 3.80±1.83 | 0.07 | 4.07±1.93 | 2.79±1.16 | 0.01* | 2.36±0.58 | 2.58±1.27 | 0.46 |
| Week 7 | 4.23±1.87 | 3.05±1.99 | 0.04* | 3.51±1.67 | 2.57±2.12 | 0.10 | 1.95±0.56 | 1.84±1.15 | 0.68 |
| Week 8 | 3.76±1.66 | 2.21±1.81 | 0.005* | 3.04±1.69 | 1.81±1.86 | 0.02* | 1.55±0.55 | 1.30±1.12 | 0.36 |
| Week 9 | 3.24±1.65 | 1.51±1.66 | 0.001* | 2.55±1.72 | 1.19±1.33 | 0.006* | 1.16±0.50 | 0.60±0.84 | 0.01* |

Values are represented as mean ± standard deviation (SD) *Significant; †Unpaired t-test; NPWT–negative pressure wound therapy;

### Analysis

Statistical analysis was carried out using SPSS version 16.0 (Chicago, Inc., USA). The results were presented in mean ± standard deviation (SD) and % as appropriate. An unpaired t-test was used to compare the continuous parameters at baseline and follow-up. The $\chi^2$ test was used to compare the difference in gender and stage. The mixed linear model was used to find the changes from baseline to week 9. The diagonal repeated covariance was used. Fixed and random effects model was used. A $p<0.05$ was considered significant.

## Results

With continuity correction, 65 patients with sacral PUs undergoing treatment in the SCI unit were enrolled in the study (Fig 1). Of these 60 patients fulfilled the inclusion criteria and were randomised into two groups; 30 patients in group A who received standard dressing (SC) and 30 patients in group B who received NPWT. There were nine patients withdrawn from the NPWT group and seven from the standard group. Data from 44 patients were analysed.

The age and gender distribution between the

**Table 3. Comparison of exudate amount and tissue type (slough to granulation tissue)**

| | Exudate (graded using PUSH tool)[14] | | | Tissue type (graded by visual inspection)- | | |
|---|---|---|---|---|---|---|
| | Standard care group | NPWT | p-value[1] | Standard care group | NPWT | p-value† |
| At admission | 3.04±0.20 | 3.10±0.30 | 0.50 | 3.26±0.44 | 3.10±0.30 | 0.16 |
| Week 1 | 3.04±0.20 | 3.10±0.30 | 0.50 | 3.09±0.28 | 2.95±0.21 | 0.09 |
| Week 2 | 3.00±0.00 | 3.00±0.00 | NA | 3.00±0.00 | 2.95±0.21 | NA |
| Week 3 | 2.96±0.21 | 2.62±0.49 | 0.001* | 3.00±0.00 | 2.86±0.35 | NA |
| Week 4 | 2.78±0.42 | 2.10±0.53 | 0.001* | 2.87±0.34 | 2.24±0.43 | 0.001* |
| Week 5 | 2.65±0.48 | 1.71±0.56 | 0.001* | 2.74±0.44 | 2.05±0.21 | 0.001* |
| Week 6 | 2.17±0.49 | 1.52±0.68 | 0.001* | 2.52±0.51 | 2.00±0.31 | 0.001* |
| Week 7 | 1.91±0.59 | 0.67±0.73 | 0.001* | 2.13±0.34 | 1.62±0.59 | 0.001* |
| Week 8 | 1.78±0.51 | 0.33±0.57 | 0.001* | 2.13±0.34 | 1.00±0.31 | 0.001* |
| Week 9 | 1.35±0.75 | 0.14±0.35 | 0.001* | 2.04±0.36 | 1.00±0.31 | 0.001* |

Values are represented as mean± standard deviation (SD) *Significant ($p<0.05$) †Unpaired t-test; NPWT–negative pressure wound therapy

**Table 4. Comparison of wound discharge (ml)**

| | Standard care group | NPWT group | p-value† |
|---|---|---|---|
| At admission | 3.26±0.44 | 3.09±0.30 | 0.16 |
| Week 1 | 3.08±0.28 | 2.95±0.21 | 0.30 |
| Week 2 | 3.00±0.11 | 2.95±0.21 | 0.001* |
| Week 3 | 2.91±0.41 | 1.90±0.94 | 0.001* |
| Week 4 | 2.86±0.34 | 1.09±0.43 | 0.001* |
| Week 5 | 2.73±0.44 | 0.61±0.49 | 0.001* |
| Week 6 | 2.52±0.51 | 0.09±0.30 | 0.001* |
| Week 7 | 2.13±0.34 | 0.00±0.00 | NA |
| Week 8 | 2.13±0.34 | 0.00±0.00 | NA |
| Week 9 | 2.04±0.36 | 0.00±0.00 | NA |

Values are represented as mean ± standard deviation (SD); NPWT–negative pressure wound therapy; NA–not available; *Significant ($p<0.05$); †Unpaired t-test

groups were similar. The % of stage III was higher in standard groups than NPWT (Table 1).

The majority of PUs were acute and while most wounds were large, they ranged widely in size (SC range: 12.9–168.0 $cm^2$, NPWT range: 20.2–96.0 $cm^2$) (Table 2). The length, width and depth were similar in both the groups at the time of admission. There was no significant difference in the length and width between the groups until week 5 (Table 2). However, the depth was significantly ($p<0.05$) higher in NPWT group than SC at weeks 1, 2 and 3 and became significantly ($p=0.01$) lower at week 9 (Table 2). The length and width were also significantly decreased ($p<0.01$) at week 9 in the NPWT group compared with SC (Table 2).

Exudates were similar ($p>0.05$) at the time of admission between the groups (Table 3). Exudate levels became significantly ($p=0.001$) lower in NPWT group compared with standard care from week 4 (2.78±0.42 versus 2.10±0.53, SC and NWPT respectively). Through to week 9 (1.35±0.75 versus 0.14±0.35, SC and NWPT respectively). Conversion of slough into red granulation tissue was significantly higher in NPWT group after week 4 ($p=0.001$) (Table 3).

Discharge was significantly ($p=0.001$) lower in the NPWT than SC group at week 2 (3.00±0.11 versus 2.95±0.21, SC and NWPT respectively) and remained until week 6. There was no discharge in NPWT after week 6 (Table 4). In all the parameters, the decrease was higher in NPWT group compared with SC which was significant for exudates type ($p=0.03$) and tissue type ($p=0.004$) (Table 5). The decrease was higher in males than females in all the study parameters. The effect of age was negligible (Table 5).

The quality of healed scar with NPD was satisfactory. Matured scars were pliable with less vascularity. There was no scar breakdown at the end of follow-up and the scar colour matched with normal skin.

The total cost of a 9-week treatment of one PU in NPWT group was approximately 47% less than the costs of conventionally treated comparable PU (Table 6).

## Discussion

Patients with PUs have longer stays when admitted to hospital, which increases costs,[9] as PU management incurs high expenditure and use of human resources.[2,9,12,15]

Traumatic paraplegia patients often seek hospital care late and present with PUs moderate to large in size.[2] We found that treatment of PUs with our NPD led to accelerated healing in the majority of cases in terms of reduction of length, width and depth. As the NPWT group had a greater number of grade IV than grade III PUs (17 versus 4 respectively), the data support NPD as a manageable method for treatment of chronic stage IV PU. This does not limit use of NPD for grade III PUs; however further validation is required.

Prospective non-RCTs on PUs have shown positive results using NPWT to aid healing.[2,16,17] A non-RCT trial of 48 patients showed a statistically significant improvement in PU healing in terms of slough removal, granulation tissue formation, discharge and culture positives to negative using NPWT.[2] Furthermore, there was a significant reduction in size and depth using NPWT compared with SC at week 9 of follow-up.[2]

NPWT has become a popular wound-closure option in the management of PUs in despite the paucity of well-designed large scale RCTs.[2,12,18] None of the RCTs to date, have a revealed significant increase in formation of granulation tissue.[18–20] However, a significant reduction in wound surface area was found in one study in which patients with PUs were part of the total random sample.[19] In our study, granulation tissue formation was faster in the NPWT group compared with the standard group.

A study conducted by Wanner et al.[20] in 2003 showed PUs of the pelvic region healed faster with vacuum-assisted closure, compared with traditional wet-to-dry/wet-to-wet gauze soaked in Ringer's solution.[20] Another RCT compared a locally constructed topical NPD with wet-to-dry gauze dressings on various wound aetiologies, including diabetic foot ulcers, PUs, cellulitis/fasciitis and other types of ulcer.[18] The authors saw, no statistically significant differences in the time to closure between the two treatment groups with the exception of those with PUs, where there was a significant difference in time to closure between the

**Table 5. Results of mixed linear model**

| | Beta coefficient | SE | p-value[1] |
|---|---|---|---|
| **Length** | | | |
| NPWT group | -0.91 | 0.90 | 0.31 |
| Standard care group | Ref. | | |
| Male | -0.28 | 1.22 | 0.82 |
| Female | Ref. | | |
| Age | 0.03 | 0.04 | 0.44 |
| **Width** | | | |
| NPWT group | -0.68 | 0.79 | 0.40 |
| Standard care group | Ref. | | |
| Male | -0.40 | 1.08 | 0.71 |
| Female | Ref. | | |
| Age | 0.02 | 0.04 | 0.65 |
| **Depth** | | | |
| NPWT group | 0.26 | 0.65 | 0.69 |
| Standard care group | Ref. | | |
| Male | -0.64 | 0.85 | 0.46 |
| Female | Ref. | | |
| Age | 0.02 | 0.03 | 0.49 |
| **Exudates** | | | |
| NPWT group | -0.62 | 0.28 | 0.03* |
| Standard care group | Ref. | | |
| Male | -0.10 | 0.38 | 0.80 |
| Female | Ref. | | |
| Age | 0.02 | 0.01 | 0.83 |
| **Tissue type** | | | |
| NPWT group | -0.60 | 0.19 | 0.004* |
| Standard care group | Ref. | | |
| Male | -0.09 | 0.26 | 0.74 |
| Female | Ref. | | |
| Age | 0.03 | 0.01 | 0.78 |

NPWT–negative pressure wound therapy; Ref.–reference category; SE–standard error; *p<0.05

**Table 6. Comparison of cost at 9 weeks**

| Consumables | NPWT group (n=21) | Standard care group (n=23) |
|---|---|---|
| Components of negative pressure device (NPD) Romovac, opsite, dynaplast, foam | 105 | 0 |
| Dressing materials; $H_2O_2$, chlorine water, normal saline, betadine lotion, sterilised gauze piece | 0 | 200 |
| **Total cost US$ (GBP)** | $105 (£73) | $200 (£139) |

NPWT–negative pressure wound therapy

treatment and control group.[18] In our study, wound closure in NPWT group was faster than those in the standard care group, matching the findings of both of these studies.

The direct costs to aiding healing were also lower in the NPWT compared with the SC.[18] The cost-effectiveness of NPWT obtained by Mody et al. was in agreement to this RCT and our previously reported non-RCT trial.[2]

Morykwas and Argenta[16] in 1997 compared the commercial V.A.C. device with standard wound dressing on acute wounds in animal models advocating intermittent negative pressure and reported that negative pressure (−125mmHg) improved wound blood flow, particularly after intermittent cessation of pressure.[16] Our NPD provides intermittent/cyclical negative pressure of an average −80mmHg pressure (−60 to −120 mmHg) when fully charged. With time, the negative pressure is gradually lost, after about 5–6 hours of use, requiring the device to be recharged. Our device gave similar results as commercial electricity-driven devices. These results supports current recommendations for commercial NPD settings, although data comparing healing rates on different regimens are lacking

The results of this study suggest that wound healing outcomes using NPD made from indigenous available resources are similar to those reported using commercially available NPWT dressings.[2,18,21,22]

The time and costs associated with wound care are a considerable problem in India, especially for SCI patients. Evidence relevant to wound care in Southern India has been published, but not specifically on PUs.[18] Apelqvist et al.[23] in 2008 found a beneficial effect in terms of direct economic cost and resource use in patients treated with NPWT compared to standard moist wound therapy. One UK primary care trust estimated that 33% of its NPWT-associated costs may be incurred for the treatment of severe PUs.[12] Our study gave sufficient evidence of cost-effectiveness of NPWT for management of PUs using innovative NPD in India where resources are limited.

A retrospective review sought to determine if PUs and other chronic wounds treated at home with NPWT close faster and result in reduced treatment costs compared with standard therapies (for example, low-airloss surface and saline-soaked gauze). In 1999 Philbeck et al. claimed that NPWT speeds wound closure, reduces infection rates and cuts labour costs.[24] NPWT has also been shown to rapidly reduce wound surface area and volume[2,16,25] and may be especially useful with deep wounds like PUs and diabetic foot ulcers. The sub-atmospheric pressure removes wound exudate as well as microbial flora, thereby decreasing oedema,

cytokines, and matrix metalloproteinases.[16,22,26] Weed et al.[27] have shown decreased wound closure time for a variety of wounds using NPWT. This is consistent with the findings of our study on the treatment of PUs in traumatic paraplegia patients.

The patient concordance was good to excellent as the device was patient friendly and the air tight seal was socially acceptable as it minimised the foul odour of discharge. The procedure was well tolerated by the patients as home care, and is safe with minimal side effects so could be promoted as an outpatient procedure with weekly follow ups for dressing change, reducing hospital stay.

## Limitations

This NPD is ineffective in low sacral ulcers close to the natal cleft because the Opsite cannot be properly applied to get an airtight seal.[2] The sterile foam used in the NPD has a tendency to disintegrate and make the secretions viscous, sometimes clogging the drain. These limitations will be addressed in future studies with new innovation. Finally the lack of grade III PUs in the NPWT group limited the conclusions we could make regarding treatment for this grade of PU.

## Conclusions

NPWT by our innovative NPD is a bedside procedure, easy to apply and cost effective in managing PUs in traumatic paraplegia patients. Our device is financially viable in settings where resources are limited and effective in providing cyclical/intermittent negative pressure at the wound site. It provides better wound care and minimal discharge, and soiling of clothes and bed sheets because of the air tight seal. ■

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