Vacuum-assisted Wound Closure (VAC)

Clinical Area: Vacuum-assisted Wound Closure (VAC)
Keywords: Pressure ulcer, vacuum assisted closure

Study Type: Randomized controlled trial
Study Aim: To determine whether Vacuum-assisted Closure (VAC) is superior to the Healthpoint System (HP) for treating pressure ulcers.

Outcomes

- **Primary**: Did not specify primary outcome/s. Outcomes reported include complete healing and mean reduction in ulcer volume.

Design

- **Number of subjects**: n=28 patients (n=41 ulcers). The number of patients assigned to each group was not reported.
- **Description of study population**: Patients recruited from the plastic surgery center at Boston Medical Center. VAC group: mean age=41.7; HP group: mean age=54.4.
- **Inclusion criteria**: Between 21-80 years old; Full-thickness ulcer (stage III or IV) present for at least 4 weeks; albumin ≥ 2.0; ulcer volume after debridment=10-150 ml.
- **Exclusion criteria**: Fistula; wound malignancy; systemic sepsis; pregnant or lactating female; iodine allergy; exposure to radiation or chemicals Serious health condition (e.g. cancer, uncontrolled diabetes; chronic renal disease); cardiac pacemaker; ferromagnetic clamps or orthopedic hardware.
- **Power**: Not discussed.
- **Method of randomization**: Used table of random letters. Randomization was done by patients not wounds (i.e. for patients with multiple wounds, all wounds received the same treatment).
- **Intervention**: Individuals with osteomyelitis (proven by bone biopsy or MRI) received a 6-week course of antibiotics. If necessary, patients underwent ulcer debridement before randomization. Patients were randomly assigned to receive 6 weeks of treatment with: 1) VAC: Use of negative pressure therapy. Dressings were changed 3 times a week: or 2) HP: An FDA-approved gel treatment. Dressings were changed once or twice daily, depending on the degree of wound drainage.
- **Blinding**: Assessment was blinded.
- **Source of outcome data (e.g. patient self-report, doctor report, lab results)**: Clinic staff did wound measurements.
- **Length of follow-up**: Follow-up ranged from 3-10 months. Patients received thorough examinations at 3 and 6 weeks after initiating treatment.
- **Completeness of follow-up**: 22/28 (79%) of patients completed the study.

Validity

- **Is the study type appropriate for the questions being asked?** Yes.
- **Was the study population typical of patients with this disease?** Appears to be.
- **Were the treatment/control groups comparable at baseline?** Not known. Few demographic characteristics were presented. The HP group seems to be older than the VAC group.
- **Was the intervention compared to placebo and/or best accepted intervention?** No, alternate innovative interventions were compared.
- **Was there compliance with the intervention?** Yes.
- **Was there equal intensity of observation of study and control subjects?** Yes.
- **Was the process of observation likely to effect the outcome?** No.
- **Intention to treat analysis?** No.
Conclusions regarding validity of methods:
Although this was a randomized controlled trial, sample size was small which can lead to baseline differences between groups and unreliable outcome estimates. Differences between groups were not well described and the authors did not control for confounding. There was a 21% loss to follow-up and no intention to treat analysis which would bias results. The analysis was done by wound, rather than by patient—multiple wounds in the same patient are not independent data points.

Results

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>VAC (n=20(^1))</th>
<th>NP (n=15(^1))</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete healing, No. (%)</td>
<td>2 (10)</td>
<td>2 (13)</td>
<td>?</td>
</tr>
<tr>
<td>Mean % reduction in wound volume</td>
<td>51.8%</td>
<td>42.1%</td>
<td>0.46</td>
</tr>
<tr>
<td>Mean change in PMN, hpf</td>
<td>-37.0</td>
<td>22.7</td>
<td>0.13</td>
</tr>
<tr>
<td>Mean change in lymphocytes, hpf</td>
<td>-6.2</td>
<td>45.0</td>
<td>0.41</td>
</tr>
<tr>
<td>Mean change in capillaries, hpf</td>
<td>-5.1</td>
<td>-7.6</td>
<td>0.75</td>
</tr>
</tbody>
</table>

\(^1\)The analysis was done by the number of wounds among patients completing the study.

Authors’ Conclusions
“VAC promotes an increased rate of wound healing and favorable histological changes in soft tissue and bone compared to HP.”

Reviewer’s Conclusions
There were no significant differences in outcomes between the VAC group and the H(gel) group. The sample size may have been too small to detect clinically meaningful differences. This study was limited by possible selection bias (due to small n), lack of intention to treat analysis and analysis by number of wounds (multiple wounds in the same patients are not independent data points).