The VAC and New-Fangled Strategies for Wound Management: Overrated

John James
3/14/11
General Surgery Grand Rounds
Overview

- Wound healing
- Barriers to wound healing
- Idea behind negative pressure wound therapy
- Why it is not better
- “New-Fangled Strategies”
Wound Healing

- **Hemostasis**
- **Inflammation**
- **Proliferation**
- **Remodeling**
Barriers to Wound Healing

- **Infection**
  - Remains in the inflammatory phase

- **Edema**
  - Extra fluid in extracellular matrix impedes blood flow and increases diffusion distances for oxygen and nutrients

- **Dryness**
  - Scab forms to keep moisture in wound: reduces cell proliferation, leukocyte activity, wound contraction, revascularization and epithelialization

- **Poor blood flow**
  - Needs oxygen and nutrients
Idea Behind Wound Vac

- Contraction of wound
- Stabilization of wound
- Removal of extracellular fluid
- **Increase blood flow**
- **Increase granulation tissue**
- Increased compliance (fewer dressing changes)
Proponents of NPWT cite the supposed increase in blood flow and angiogenesis

- Laser doppler measures red cell velocity (not flow)
- A decrease in vessel diameter can increase fluid velocity even though the overall flow is decreased
- Wackenfors (2004) measured “flow” (laser doppler) around porcine wounds treated with VAC: hypoperfusion within about 1.5 cm from the edge. While tissue peak flow increased when the vacuum was turned off, it actually decreased during the “on” periods.
- Kairinos (2009) measured tissue perfusion in healthy subjects with a radiotracer technique and showed a decrease in perfusion correlating to increased suction
- Negative-pressure wound therapy should be used with caution on tissues with compromised vascularity,
Granulation

- Braakenburg (2006) showed no significant difference in overall granulation.
Wound Surface Area

- Braakenburg showed no difference in overall change in surface area
Potential Complications

- Since 2007 the FDA has received reports of **12 deaths and 174 injuries** associated with negative-pressure wound therapy (www.FDA.gov)

- **Bleeding**
  - 4 of 69 (5.8%) with deep sternal infections treated with NPWT (Petzina 2010)

- **Infection (mixed results)**
  - Braackenburg: bacterial growth in 84% of the wounds treated with vacuum-assisted closure and in 58% treated conventionally
  - Moues: 54 pts (½ assigned to VAC, ½ assigned to dressing changes with NaCl) Pts with nonfermentative, gram-negative bacilli had decreased bacterial loads over time, whereas patients with *staph aureus* had increased bacterial levels over time

- **Retained foam dressing pieces**

- **Adherent foam**
Exposed vasculature

Nerves

Anastamotic sites

Organs

The polyvinyl alcohol foam is a white, nonadherent foam that is used by some clinicians over and to reduce pain with dressing changes; there are no Level I or II studies using this type of foam.
Cost

- Moues et al:
  - Significantly higher material cost in NPWT vs. conventional therapy ($601 vs $21, p < 0.0001)
  - No significant difference in total cost ($3249 vs. $3728)
  - Study funded by KCI

- Vuerstaek et al:
  - Conventional dressing total cost significantly more expensive than NPWT ($5452 vs. $3881, p = 0.001)
  - Study funded by KCI

- Braakenburg et al:
  - Total greater for NPWT (E353) vs. conventional (E273)
Problems with the research

- Mostly retrospective clinical studies and case series
- Subjective endpoints
- Heterogeneity of the wounds
- Difficulty blinding
- Device company supported trials
### Table 1  Quality assessment of included studies

<table>
<thead>
<tr>
<th>Reference</th>
<th>Randomization</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
<th>16</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>Sealed envelopes</td>
<td>Yes</td>
<td>P</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>?</td>
<td>Yes</td>
<td>KCI</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Block randomization</td>
<td>Yes</td>
<td>P</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>?</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>KCI</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>with envelopes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Random number generator</td>
<td>Yes</td>
<td>P</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>16</td>
<td>Odd/even patient numbers</td>
<td>No</td>
<td>P</td>
<td>Yes</td>
<td>Yes</td>
<td>?</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>17</td>
<td>Random letters</td>
<td>?</td>
<td>P</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Some</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>KCI</td>
<td>(among others)</td>
</tr>
<tr>
<td>18</td>
<td></td>
<td>?</td>
<td>P</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>?</td>
</tr>
<tr>
<td>19</td>
<td>Labelled files</td>
<td>No</td>
<td>W</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>?</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>?</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Partly by KCI</td>
</tr>
<tr>
<td>20</td>
<td>Computer generated</td>
<td>Yes</td>
<td>P</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>21</td>
<td>Flip of coin</td>
<td>No</td>
<td>P</td>
<td>?</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>22</td>
<td></td>
<td>?</td>
<td>W</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>23–25</td>
<td>Patients picked envelope</td>
<td>Yes</td>
<td>P</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Some</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>KCI and Esser foundation</td>
</tr>
<tr>
<td>26</td>
<td>Computer randomization in</td>
<td>Yes</td>
<td>P</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>KCI</td>
</tr>
<tr>
<td></td>
<td>three strata</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27</td>
<td></td>
<td>No</td>
<td>P</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Total (%)</td>
<td></td>
<td>46</td>
<td>62</td>
<td>69</td>
<td>46</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>31</td>
<td>69</td>
<td>77</td>
<td>62</td>
<td>92</td>
<td>85</td>
<td>53</td>
<td>38</td>
<td></td>
</tr>
</tbody>
</table>

Variables: 1, allocation concealment; 2, unit of allocation (P, patient; W, wound); 3, group comparable at baseline; 4, withdrawals described; 5, intention to treat; 6, evidence differential loss to follow-up; 7, patient blinded; 8, healthcare workers blinded; 9, outcome assessors blinded; 10, proportion of patients that completed follow-up over 80 per cent; 11, similar treatment apart from intervention; 12, reliability of outcome measures; 13, informed consent; 14, approved by medical ethics committee; 15, financial support and, if so, by whom; 16, sample size calculation performed.
## Older Conclusions

### Table. Health technology assessment summary

<table>
<thead>
<tr>
<th>Health Technology Assessment</th>
<th>Conclusions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ontario Health Technology Advisory Committee, 2004&lt;sup&gt;14&lt;/sup&gt;</td>
<td>VAC therapy may be useful for healing various types of wounds but effectiveness could not be empirically quantified</td>
<td>- Small sample size and patient populations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Poor study design</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Outcome measures could not be compared</td>
</tr>
<tr>
<td>AHRQ/BlueCross/BlueShield, 2004&lt;sup&gt;15&lt;/sup&gt;</td>
<td>Body of evidence insufficient to support conclusions about effectiveness</td>
<td>- Small number of studies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Inadequate randomization in most studies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Study groups not comparable</td>
</tr>
<tr>
<td>Cochrane Review, UK, 2003&lt;sup&gt;16&lt;/sup&gt;</td>
<td>Weak evidence of effectiveness</td>
<td>- 3 articles met inclusion criteria</td>
</tr>
<tr>
<td>Centre for Clinical Excellence, Australia, 2003&lt;sup&gt;17&lt;/sup&gt;</td>
<td>VAC may have advantages over other forms of wound dressings studied but too few reports to say</td>
<td>- No Level I or II were identified</td>
</tr>
<tr>
<td>NHS Quality Improvement Scotland, 2003&lt;sup&gt;18&lt;/sup&gt;</td>
<td>Limited evidence for effectiveness and adverse events</td>
<td>- Saline gauze is not standard treatment of wounds in Scotland</td>
</tr>
<tr>
<td>Cochrane Review, UK, 2001&lt;sup&gt;19&lt;/sup&gt;</td>
<td>Weak evidence that TNP is superior to gauze dressings</td>
<td>- Need for more RCTs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Small sample sizes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Methodological limitations</td>
</tr>
</tbody>
</table>

VAC, Vacuum-assisted closure; AHRQ, Agency for Healthcare Research and Quality; RCT, randomized clinical trial; TNP, topical negative pressure.
Conclusions

- Gregor 2008: “Although there is some indication that NPWT may improve wound healing, the body of evidence available is insufficient to clearly prove an additional clinical benefit of NPWT. The large number of prematurely terminated and unpublished trials is reason for concern.”

- Ubbink 2008: “There is little evidence to support the use of TNP in the treatment of wounds.”
Decision Time

- No strong evidence to support NPWT use
- Proven risks
New Fangled

- Topically applied growth factors

- Alginates, absorbent, promote and the breakdown of necrotic tissues while decreasing pain

- Silver coated foam

- Instillation VAC
References

- Leininger B.E., Rasmussen T.E.: Experience with wound V.A.C. and delayed primary closure of contaminated soft tissue injuries in Iraq. J Trauma 63. (1): 248-249.2007; Citation