Comparison of outcomes for normal saline and an antiseptic solution for negative-pressure wound therapy with instillation


Purpose
The purpose of this study was to evaluate and compare the effectiveness of normal saline and an antiseptic solution, 0.1% polyhexanide plus 0.1% betaine (PHMB), as instillation solutions with negative pressure wound therapy with instillation (NPWT; V.A.C. Ulta™ Negative Pressure Wound Therapy System with V.A.C. VeraFlo™ Instillation) for the adjunctive treatment of infected wounds.

Methods
STUDY DESIGN
• Prospective, randomized, effectiveness study

POPULATION
• Patients with infected wounds undergoing surgical debridement in the operating room were enrolled in the study and randomized before the first operation.
• Randomization: A 1:1 allocation scheme was utilized.

TREATMENT
• Patients received NPWTi-d with either normal saline (isotonic 0.9% saline) or PHMB (0.1% polyhexanide plus 0.1% betaine) instilled for 20 minutes followed by 2 hours of NPWT.

PRIMARY OUTCOMES
• Number of operative visits, length of hospital stay, time to final surgical procedure, proportion of closed or covered wounds, and proportion of wounds that remained closed or covered at the 30-day follow-up

<table>
<thead>
<tr>
<th>Patients (n)</th>
<th>Normal saline</th>
<th>PHMB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intent to treat analysis</td>
<td>49</td>
<td>51</td>
</tr>
<tr>
<td>Per protocol analysis</td>
<td>42</td>
<td>41</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time to final surgical procedure (days)</th>
<th>Normal saline</th>
<th>PHMB</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intent to treat analysis</td>
<td>5.7</td>
<td>7.7</td>
<td>0.04</td>
</tr>
<tr>
<td>Per protocol analysis</td>
<td>5.6</td>
<td>7.5</td>
<td>0.04</td>
</tr>
</tbody>
</table>

Results
• In the intention-to-treat and the per protocol analyses, patients treated with normal saline displayed a significant reduction in the time to final surgical procedure compared to the PHMB group.
• There were no significant differences between the groups in operative visits, length of hospital stay, proportion of closed or covered wounds, and proportion of wounds that remained closed or covered at the 30-day follow-up.
Discussion
- The data suggest the choice of instillation solution may not be critical to the success or failure of adjunctive treatment of infected wounds.

Conclusion
- Normal saline, when used as an instillation solution with NPWT, may be just as effective as 0.1% polyhexanide plus 0.1% betaine (PHMB) on the positive outcome of infected wounds.

Disclosure
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KCI, an Acelity company, has no independent knowledge concerning the information contained in this article, and findings and conclusions expressed are those reached by the authors.

Disclaimer
The clinical study and data results are consistent with product labeling and FDA-cleared indications for use with the possible exceptions noted below which are not endorsed or promoted by KCI.
- The text may address other published literature that report uses of instillation therapy that have not been approved by the FDA, such as references to use of instillation therapy as a treatment for periprosthetic implant infections and other types of wound infections, or as a mechanism to disrupt biofilm.
- Inferences that topical wound solutions cleared by the FDA are antimicrobials and can be used to treat infection.