Negative Pressure Wound Therapy: Vacuum of Evidence, Bountiful Bias

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10/5/09
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NPWT: A Paucity of True Evidence

I: Speed of Wound Healing
   Ia: Complete Healing of Wound
   Ib: Decreasing size of Wound

II: Local wound effects: angiogenesis, bacterial load, decreased wound edema / removal of exudate

III: Cost

IV: Adverse Outcomes
NPWT: Problematic Data

- Very few RCT (15 reports, 13 trials)
- Issues:
  - Small sample size
  - No allocation concealment
  - No blinding (Patient, Practitioner, Outcome Assessor)
  - Arbitrary outcome measures with no universal endpoints
  - Use of saline gauze as only control
  - Possible influence by medical equipment manufacturer
NPWT: Complete Closure/ Coverage of Wound

- Braakenburg et al: All wound types
  - Complete healing 16 days NPWT vs. 20 days control (p = 0.32)
  - No difference in change in percent granulation tissue (1.7%/day NPWT, 1.6%/day conventional, p = 0.64)
  - Used multiple modern wound dressings (Alginate, Cutinova-Foam, CutinovaCavity, etc.)
  - Problems: KCI funded, no allocation concealment, non-blinded, n = 47

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<tr>
<th>Table 3. Wound-Healing Time</th>
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<tr>
<td>VAC</td>
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<td>(n = 32)</td>
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<td>Median time in days (95% CI) for the total group</td>
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<td>No. of diabetic/cardiovascular patients</td>
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<td>Median time in days for diabetic/cardiovascular patients (95% CI)</td>
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VAC, vacuum-assisted closure; CI, confidence interval.
*p roofs test.

NPWT: Complete Closure/ Coverage of Wound: Studies by Wound Type

- Vuerstaek et al: Chronic leg ulcers (venous, atherosclerotic, combined)
  - Complete healing: 29 days NPWT, 45 days conventional (p = 0.001)
  - Problems: KCI funded, non-blinded, use of saline gauze as control

- McCallon et al: Diabetic foot ulcers
  - Complete healing 22.8 days in NPWT vs. 42.8 in conventional
  - Problems: KCI funded, no allocation concealment, non-blinded, saline gauze only

McCallon. Ostomy Wound Manag 2000
NPWT: Complete Closure/ Coverage of Wound: Studies by Wound Type

- **Ford et al: Stage III-IV Decubitus Ulcers**
  - Complete healing: 10% of NPWT pts, vs. 13% of conservative management (Healthpoint system)
  - Problems: KCI funded, control pts older, n = 41

- **Armstrong et al: Acute Wounds (foot amputation 2/2 DM)**
  - Complete Healing NPWT 56% vs. 39% conventional (p = 0.04)
  - Problems: KCI funded, non-blinded

Armstrong. Lancet 2005
NPWT: Decrease in Wound Size:

- Braakenburg et al: All wound types
  - NPWT reduced wound size by 0.3 cm²/day vs 0.1 cm²/day conventional (p = 0.83)

- Ford et al: Diabetic Foot Ulcers
  - No significant difference (NPWT 51.8% vs. Healthpoint 42.1% reduction in wound volume, p = 0.46)

NPWT: Local Wound Effects:

- Decreased wound edema:
  - Multiple studies: decrease in wound edema, increase in angiogenesis
    - Thought to be due to decreased tissue pressure
  - Kairinos et al: Increased change in tissue pressure in tissues surrounding NPWT device
    - Dangerous implications in tissue with compromised perfusion
    - No KCI funding

- Increased tissue oxygenation:
  - Kairinos et al: Decreased partial pressure of oxygen

Kairinos. Plast Reconstr Surg 2008 (I)
NPWT: Local Wound Effects:

- Bacterial load in wound:
  - Braackenburg et al: Increased bacterial load in NPWT (85%) vs in conventional therapy (58%)
  - Moues et al: No difference in bacterial load between NPWT and conventional (saline gauze) tx groups
    - NPWT had decreased non-lactose fermenting GNR, increased Staph aureus

Braakenburg. Plast Reconstr Surg 2005
NPWT: 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 ($513) vs. conventional ($396)

Moues. J Wound Care 2005
Braakenburg. Plast Reconstr Surg 2005
NPWT: Adverse Events

- Braakenburg et al:
  - Discontinuation of NPWT 2/2 pain
  - Pressure sore associated with wound therapy hose
  - Erosion of wound edges 2/2 misplaced sponge

- Vuerstaek et al:
  - 40% of pts with NPWT vs 23% with conventional therapy developed complications
  - Increased recurrence of chronic leg ulcers in NPWT group (52%) vs. control (42%)

- Moues et al:
  - 2 pts with sepsis vs. 0 in conventional therapy

- Retained sponge leading to severe sepsis
  - Beral et al
  - Saeed et al

Braakenburg. Plast Reconstr Surg 2005
Beral. BMJ 2009
NPWT: A Conclusion:

“At present there is no worthwhile evidence to support the use of TNP [Topical Negative Pressure] in the treatment of various wounds. A far more rigorous evaluation is needed, largely in the form of RCTs. Until this has been completed, the use of TNP should not become routine or be reimbursed for local wound care.”

References