Negative Pressure Wound Therapy (NPWT): Preliminary Observations of a Multicenter V.A.C.® Therapy Trial on Pressure Ulcer Treatment

Jeffrey A. Niezgoda, MD, FACHM, FACEP, Aurora St. Luke's Medical Center; Milwaukee, Wisconsin and the V.A.C. Pressure Ulcer Study Group – Research sponsored by KCI, San Antonio, Texas

Abstract

Purpose: Comparison of wound-healing trajectories of Stage III and IV pressure ulcers on trunk or trochanter regions between Negative Pressure Wound Therapy* (NPWT) and moist ulcer therapy (MUT), in a randomized controlled trial (RCT).

Methods: Study group patients received NPWT, while control group patients received MUT following WOCN guidelines. Wound area measurements were obtained repeatedly during the 84-day study period and compared to pre-treatment baseline. Wound-healing trajectories compared number of treatment days until >50% and >75% closure were initially observed. Preliminary analysis on 147 patients (79 NPWT, 68 MUT) was stratified on baseline wound area.

Preliminary Observations: Wound closure event rates were based on Kaplan-Meier estimates. In larger pressure ulcers, >75th percentile (29.68 cm²) at baseline, 28.7% NPWT patients achieved >75% closure within 42 days, compared to 8.3% MUT patients (p=0.028). Greater than 50% closure was observed in 70.8% NPWT patients, compared to 30.7% MUT patients. For the intent-to-treat population, time to 50%, 75%, and 100% wound closure was clearly trending in favor of NPWT, although not significant. In smaller wounds, there was less discrimination; however, comparison was favorable for NPWT. For large pressure ulcers, NPWT patients were 3 times more likely to achieve >75% closure, compared to MUT patients.

Study Description

- Ongoing multicenter, randomized, controlled trial (15 active sites)
- Two-arm study of 12-month duration:
  - Negative pressure wound therapy (NPWT) (V.A.C.® Therapy, KCI USA, Inc., San Antonio, Texas)
  - Moist ulcer therapy (MUT), following WOCN guidelines
- Study period:
  - Ulcer closure or 84 days
  - Two long-term follow-up visits: the first is 12 weeks after wound closure and the second is 26 weeks after the first follow-up visit.

Study Aims

- Primary
  - Incidence of complete wound closure
  - Accelerated ulcer closure or facilitation of surgical closure
  - Reduction in ulcer area and volume over time
- Primary Secondary
  - Reduction in complications
  - Pain reduction
  - Reduction in average total cost of care

Eligibility Criteria

- Inclusion
  - Stage III or IV pressure ulcer on trunk or trochanter region.
  - Age >18 years
- Exclusion:
  - Conditions contraindicated for use of V.A.C.® Therapy or underlying disease conditions that may impede wound healing (e.g., sickle-cell disease)
  - Growth factors, dermal substitutes, HBO, normothermic, or other confounding therapies within 60 days of study participation
  - V.A.C.® Therapy within 60 days of study participation

Sample Size

- Study sample: 214 intent-to-treat (ITT) patients
- September 2004 preliminary sample: 147 ITTpatients
  - V.A.C.® Therapy = 79 pts
  - MUT = 68 pts

Methods

- Patients randomized to V.A.C.® Therapy (V.A.C.) or moist ulcer therapy (MUT), following WOCN guidelines
- Patients placed on Group II/III bed surface; wheelchair pressure relief surface as needed
- Wound area measurements recorded at 7 predetermined intervals during active treatment phase of 84 days
- Patients treated until ulcer closure or until Day 84, whichever occurs first
- Wound healing trajectories between V.A.C.® Therapy and MUT were derived from Kaplan-Meier estimates.
  - This time-to event analysis used number of days until >50% and >75% reduction in wound area were initially observed.
  - Heterogeneity among pressure ulcers (based on wound area at baseline) was factored into analysis.

Demographic Data: Preliminary Sample (N=147)

Category	V.A.C.® Therapy (n=79)	Control (n=68)
Mean patient age (years)	57.4±18.7	60.5±18.6
Smokers, Past (%)	26 (33)	17 (25)
Smokers, Current (%)	20 (25)	13 (19)
Diabetic patients (%)	19 (24)	19 (28)

- Groups well-matched for age and risk factors – no significant differences

Demographic Data: Patients with Larger Wounds (N=37)

Category	V.A.C.® Therapy (n=21)	Control (n=16)
Mean patient age (years)	61.8±16.6	54.6±20.0
Smokers, Past (%)	5 (24)	6 (38)
Smokers, Current (%)	5 (24)	3 (19)
Diabetic patients (%)	9 (38)	6 (38)

- Subset of ITT patients with wounds ≥75th percentile (>29 cm²)

Baseline Wound Characteristics: Preliminary Sample (N=147)

Day 0	V.A.C.® Therapy (n=79)	Control (n=68)
Mean area (cm²)	22.4±24.6	21.3±23.5
Mean volume (cm³)	30.8±53.1	40.1±80.4

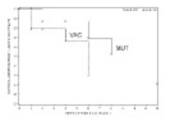
- No significant differences between groups

Baseline Wound Characteristics: Patients with Larger Wounds (N=37)

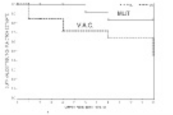
Day 0	V.A.C.® Therapy (n=21)	Control (n=16)
Mean area (cm²)	54.7±27.6	56.8±21.8
Mean volume (cm³)	80.5±72.7	132.6±127.4

- Subset of ITT patients with wounds ≥75th percentile (>29 cm²)
- No significant differences between groups

Preliminary Observations for Patients with Larger Wounds: ≥50% reduction in wound area



Preliminary Observations for Patients with Larger Wounds: ≥75% reduction in wound area



Preliminary Observations for Patients with Larger Wounds: >50% reduction in wound area

- Subset of ITT patients with wounds >75th percentile (>29 cm²):
  - V.A.C.® Therapy = 21 pts (27%)
  - MUT = 16 pts (24%)
- Percent of patients achieving >50% reduction in wound area at 42 days: 70.8% V.A.C.® Therapy vs 30.7% MUT
- Difference not significant (P=0.388)

Preliminary Observations for Patients with Larger Wounds: >75% reduction in wound area

- Subset of ITT patients with wounds >75th percentile (>29 cm²):
  - V.A.C.® Therapy = 21 pts (27%)
  - MUT = 16 pts (24%)
- Percent of patients achieving >75% reduction in wound area at 42 days: 28.7% V.A.C.® Therapy vs 8.3% MUT
- Significant difference (p=0.028)
- Percent of patients achieving >75% reduction in wound area at 84 days: 54.2% V.A.C.® Therapy vs 16.7% MUT
- The >75% reduction in wound area observed in the V.A.C.® Therapy group at 42 days (28.7%) was not achieved in the MUT group at 84 days of treatment (16.7%)

Preliminary Safety Observations

No device-related SAEs for any wounds in the preliminary sample

Summary

First large multicenter RCT of V.A.C.® Therapy in the treatment of Stage III and Stage IV pressure ulcers: enrollment is ongoing.

September 2004 preliminary sample: 147 ITT patients

In the subset of 37 patients with larger wounds, V.A.C.® Therapy appears be positive with respect to >75% reduction in wound area.

References

1. [illegible]
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7. Philbeck TE, Whittington KT, Millsap MH, Briones RB, Wight DG, Schroeder WJ. The clinical and cost effectiveness of externally applied negative pressure wound therapy in the treatment of wounds in home healthcare Medicare patients. Ostomy/Wound Management, 1999; 45(11):

41-50.Product Notation: "Vacuum Assisted Closure®; Kinetic Concepts, Inc., San Antonio, TX

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