Use of Non-Contact Low Frequency Ultrasound in Wound Care

BLAIRE CHANDLER
SEPTEMBER 29, 2015
VCU DPT CLASS OF 2016
Objectives

- Patient case overview
- Examine clinical evidence
  - Review intervention of interest
- Relate evidence to patient case
Patient History

- 35-year-old male
- Single MVC – unrestrained driver of car in a rollover accident:
  - TBI with right subdural hematoma (SDH) with a 1-cm midline shift, bilateral frontal lobe subarachnoid hemorrhages (SAH)
  - Right temporal bone fracture involving the TMJ, greater wing of sphenoid, and occipital bones
  - Right internal carotid artery dissection
  - C7 spinous process fracture
  - Grade 1 splenic laceration
- Glasgow Coma Scale of 3 upon admission
- Emergent right-sided craniotomy for SDH
- Of note, patient incontinent of stool and staff was practicing in and out catheterization for urinary continence
Wounds

- Multiple pressure wounds documented throughout hospital course
- Hospital day #63– First documentation of sacral wounds by wound care team

- Natal cleft wound:
  - May have originated as intertriginous dermatitis compounded by pressure
  - Wound bed: slightly bumpy, granulated appearance; 100% moist
  - Stage 3 vs. stage 2 ulcer
<table>
<thead>
<tr>
<th></th>
<th>Day #63</th>
<th>Day #70* → PT Consulted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dressing Appearance</td>
<td>Open to air</td>
<td>Intact; moist drainage</td>
</tr>
<tr>
<td>% Tissue Red</td>
<td>100%</td>
<td>60%</td>
</tr>
<tr>
<td>% Tissue Yellow</td>
<td>0%</td>
<td>40%</td>
</tr>
<tr>
<td>% Tissue Black</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Pressure Ulcer Stage</td>
<td>Stage III (difficult to determine stage II vs. stage III)</td>
<td>Unstageable</td>
</tr>
<tr>
<td>Peri-wound</td>
<td>Intact</td>
<td>Intact</td>
</tr>
<tr>
<td>Edges</td>
<td>Open</td>
<td>Open</td>
</tr>
<tr>
<td>Length x width x depth (cm)</td>
<td>3 x 0.8 x 0.1</td>
<td>5.5 x 1 x 0.3</td>
</tr>
<tr>
<td>Drainage Characteristics</td>
<td>Small amount of serosanguineous</td>
<td></td>
</tr>
<tr>
<td>Dressing Applied</td>
<td>Allevyn foam</td>
<td>Allevyn foam, Santyl</td>
</tr>
</tbody>
</table>
PT Evaluation

- Evaluated hospital day #70

**Precautions:**
- EVD
- C-Collar
- Incision/suture site – only able to be turned to left side
- PEG tube
- Tracheostomy with 40% FiO2

**Orientation and Cognition:**
- Not oriented
- Unable to follow commands

**Mobility:**
- Total assist to roll in bed
- Total assist for re-positioning in bed
Wound Evaluation & Treatment

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<td>% Tissue Black</td>
<td>0%</td>
</tr>
<tr>
<td>Pressure Ulcer Stage</td>
<td>Unstageable</td>
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<tr>
<td>Peri-wound</td>
<td>Intact; Large area of induration noted on right buttock</td>
</tr>
<tr>
<td>Edges</td>
<td>Open</td>
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<tr>
<td>Length x width x depth (cm)</td>
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Cell Mist initiated this date
PT Plan of Care

- Patient would be seen 3x/week for wound care adjunctive treatment.

- Wound would be formally re-assessed by PT on a weekly basis.

- Wound Goals:
  - Short term – Sacral wound will decrease in necrotic tissue by 25% in one week.
  - Long term – Sacral wound will be 100% healed in 30 days.
Clinical Question

Is non-contact, low-frequency ultrasound an effective treatment to manage non-stageable pressure wounds in a patient with a long term acute care stay?

- Total reduction in wound area
- Decrease in non-viable tissue
- Increase in granulation tissue
- Decrease in wound contamination
Noncontact Low-Frequency Ultrasound (NCLFU)

- AKA: cell mist, mist therapy, ultrasound mist
- Brand name: MIST Therapy ®
- “A painless, noncontact, low frequency ultrasound delivered through a saline mist to the wound bed”

**Proposed Mechanisms:**

- Removal of barriers to healing
  - Reduces a wide-range of bacteria
  - Disrupts biofilm
  - Reduces sustained inflammation

- Stimulates cells to promote healing
  - Increased blood flow through vasodilation
  - Increased angiogenesis
  - Early release of growth factors
  - Increased collagen deposition
Noncontact low-frequency ultrasound therapy in the treatment of chronic wounds: a meta-analysis

V.R. DRIVER, M. YAO, AND C.J. MILLER

WOUND REPAIR AND REGENERATION, 2011
Methods

- Studies using NCLFU on chronic wounds for a minimum of 4 weeks
- 8 studies were analyzed
  - 1 randomized, double-blind controlled trial
  - 5 retrospective analyses
  - 2 prospective, nonrandomized studies

- Primary outcomes:
  - % reduction in wound area
  - % reduction in wound volume
  - Subjective pain scores

- Data transformed to “average change in % from baseline to follow-up” to control for wound size at baseline
Study Parameters

- 444 patients receiving NCLFU
  - All wound types
  - Different control groups by study

- Treatments administered 2-3x/week in all but one study

- Treatment time determined by wound size

- Treatment duration ranged from 4-13 weeks in 6 studies
  - 21 weeks in one study
  - 2-4 weeks in one study where pain relief was primary goal

- Few of the studies reported outcomes by subgroups or wound types
Results

- Reduction in **wound area**:  
  - 4 of 8 studies reported change from baseline  
  - In a study of typical length (~7 weeks), one could expect a sample-wide average of 85.2% reduction in wound area

- Reduction in **wound volume**:  
  - 4 of 8 studies reported reduction from baseline  
  - NCLFU was associated with a 79.7% reduction in wound volume over a typical study period of ~12 weeks
Results

- **Expected healing outcomes:**
  - Average time to healing across studies was 8.2 weeks
  - 32.7% of patients were healed on average by 6 weeks and 41.7% by 12 weeks

- **Pain reduction:**
  - 3 of 8 studies reported on pain reduction
  - 78%, 79%, and 80% reductions in subjective pain scores from baseline
Conclusion

- Reductions in wound area, wound volume, and pain scores were consistently seen with treatment of noncontact, low frequency ultrasound.

- NCLFU has the “potential to outperform standard of care” but stronger studies need to be performed.
Limitations

- All but one were observational studies and nonrandomized or systematic
- Small number of studies
- “Standard of care” not defined
- Lack of true control subjects
- Multiple wound types
  - 4 studies included pressure wounds – 17 patients
A Prospective, Randomized Controlled Trial Comparing the Effects of Noncontact, Low-Frequency Ultrasound to Standard Care in Healing Venous Leg Ulcers

GARY W GIBBONS, ET AL.

OSTOMY WOUND MANAGEMENT, 2015
Introduction

- **Study Objective**: “to compare the effects of noncontact, low-frequency ultrasound (NLFU) + standard care (SC) to standard care alone on percent ulcer area reduction after 4 weeks of treatment in chronic venous leg ulcers (VLUs).”

<table>
<thead>
<tr>
<th><strong>Standard Care</strong></th>
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</thead>
<tbody>
<tr>
<td>Obtaining an appropriate history and diagnosis</td>
</tr>
<tr>
<td>Debridement of nonviable tissue</td>
</tr>
<tr>
<td>Providing/maintaining a clean, moist wound bed</td>
</tr>
<tr>
<td>Applying rigid or elastic compression therapy</td>
</tr>
</tbody>
</table>
Methods

- Prospective, randomized, controlled, parallel-group, multicenter clinical trial
  - 22 centers across the US
- April 2012 – March 2014
- Ulcer Area Measurements:
  - Weekly measurements of the non-epithelialized area of the “index ulcer”
  - Wound boundaries drawn electronically and evaluated by a blinded, outside wound expert
Inclusion & Exclusion Criteria

**ELIGIBLE PATIENTS**
- 18-90 years old
- VLU > 30 days
- VLU size between 4 – 50 cm²
- Etiology of venous stasis with reflux
- Other treatment modalities had to be completed at least 14 days prior
- ≥6 weeks post vascular/skin graft procedure

**INELIGIBLE PATIENTS**
- Etiology other than venous
- Index ulcer located within 1 cm of another ulcer
- Cellulitis, osteomyelitis, gangrene present
- Exposed tendon, muscle, or bone
- >5 ulcers on index limb
- Amputation of index limb above metatarsals
- Confounding treatments/co-morbidities

*Patient match with inclusion/exclusion criteria confirmed by blinded physician.*
Study Enrollment

- 156 patients initially enrolled → 112 met inclusion criteria
- 81 patients were randomized after the run-in phase
- Median ulcer duration: 10.3 months (1 month to 204.5 months)
- Median ulcer area: 11.0 cm² (3.7 to 41.3 cm²)
Study Design/Phases

- **Screening Phase**
  - Enrollment → Inclusion/Exclusion
  - Wound biopsies

- **2-Week Run-In Phase**
  - Standard care treatment
  - <30% wound reduction = Randomization

- **4 Week Treatment Phase**
  - SC continued with protocol
    - SC + NLFU
      - NLFU 3x/week

- **7 Week Follow-Up**
  - SC continued
Study Variables & Data Collection

- Variables measured on a weekly basis:
  - Digital ulcer measurement by a single, trained clinician
  - Ulcer bed tissue and exudate composition
  - Periwound characteristics
  - Edema level
  - Patient adherence to compression protocol

- Pain and quality of life questionnaires completed before randomization and at the end of the 4 week study
Results - Ulcer Size

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>SC</th>
<th>SC + NLFU</th>
<th>P Value Mean</th>
<th>P Value (adjusted for ulcer size and age)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Area Reduction (cm²)</td>
<td>45.0 ± 32.5</td>
<td>61.6 ± 28.9</td>
<td>0.02</td>
<td>0.01</td>
</tr>
<tr>
<td>Absolute Area Reduction (cm²)</td>
<td>4.1 ± 4.1</td>
<td>9.0 ± 9.0</td>
<td>0.003</td>
<td>0.02</td>
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Statistically significant changes in both % area reduction and absolute area reduction for the combination group including NLFU. (P <0.05)
## Results – Pain & Quality of Life

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<th>P Value Mean</th>
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<tr>
<td>Reduction in VAS Pain Score</td>
<td>0.0 ± 2.3</td>
<td>1.7 ± 3.0</td>
<td>0.01</td>
</tr>
</tbody>
</table>

**Quality of Life:** no statistically significant difference pre- and post-treatment
Conclusion

- Percent reduction in ulcer area over 4 weeks of treatment was significantly improved with the addition of NLFU added to standard care.

- Pain was significantly reduced with the addition of NLFU.

- NLFU should be considered as an adjunct therapy for the treatment of VLU.

- More research is needed.
Limitations

- Investigators and participants not blinded
- Patient-reported measures for pain and quality of life (subjective)
- Treatment groups had differing visit requirements
- Not a study done on pressure ulcers
Evidence Summary
Patient Case Summary
Patient Outcomes

Patient was seen by PT for 5 cell mist treatment sessions over 13 days.

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<th>PT Evaluation</th>
<th>Wound Care Note after Last PT Date of Service</th>
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<td>60%</td>
<td>80%</td>
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PT Wound Care Discharge

- Wound Care Team:
  - “Natal cleft wound with *decreased measurements* and *decreased presence of yellow non-viable slough tissue*”
  - “Discontinue ultrasound cellmist”
Questions?
References


4) www.misttherapy.com