Decreased Pain in Sickle Cell Ulcer (SCU) Patients Following a 4-Week Therapeutic Regimen of Local Wound Care with a Polyalcohol Foam Containing Methylene Blue and Gentian Violet (HFB)*

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Abstract:
Background: Sickle cell disease (SCD) is an inherited hematological disorder that causes bone marrow to produce red blood cells with defective hemoglobin, hemoglobin S (sickled hemoglobin). The incidence of leg ulcers in SCD patients is 25%-75% and leg ulcers are the most common dermatologic manifestation of SCD. Sickled red blood cells are rigid and inflexible causing poor microvascular perfusion with consequent tissue ischemia and infarction. These ulcers are painful and have an indolent, intractable course of healing (typically healing up to 16 times slower than venous ulcers). The most common complaint of SCU patients is localized wound pain. The pain is usually severe (scoring 7-10 on a VAS scale). It is characterized as sharp, excruciating, penetrating, stinging and burning. In most patients oral or parenteral opioids are needed to achieve some pain relief. Design: This is a crossover feasibility study to evaluate the analgesic effect of HFB for the treatment of painful lower leg ulcers in patients with SCD. Methods: Eleven (11) consecutive subjects with painful SCUs were initially treated for 4 weeks with a standard of care (SOC) consisting of non-adherent siliconized foam wound dressing** plus static compression bandage. After 4 weeks (from week 4-8) the primary wound dressing was changed in all subjects to HFB but the compression therapy remained the same. In this way each patient served as their own control. Localized wound pain, wound surface area and wound characteristics were measured at baseline and weekly thereafter after each dressing change for a total of 8 weeks. Wound pain was evaluated using the Wong-Baker Faces Pain Scale and wound surface area was measured by digital photo-planimetry using PictZar CDM. Results: The mean wound pain score during the SOC phase (the initial 4 weeks of treatment) was 7.1 ± 2.9 compared to 3.1 ± 1.4 during the last 4 weeks of treatment when the primary dressing was HFB [p=0.036]. In addition there was a marked improvement in the degree of autolytic debridement during the HFB treatment phase. The relative rate of wound healing did not vary significantly between the 2 treatment phases.

Introduction:

The pathogenesis of chronic ulcers in SCD is complex, and may include the following:

- Mechanical obstruction by dense sickled red cells
- Venous incompetence
- Bacterial infections
- Abnormal autonomic control with vasoconstriction
- In situ thrombosis
- Anemia with decrease in oxygen carrying capacity
- Decreased nitric oxide bioavailability leading to impaired endothelial function

Study Design

⇒ Crossover feasibility study

⇒ Each patient serves as their own control

⇒ Primary Endpoint : Localized wound pain evaluated weekly for 8 weeks

⇒ Secondary Endpoints: Wound surface area Wound Characteristics

⇒ Anticipated & unanticipated Adverse Events

Methodology

Eleven consecutive patients with painful SCUs
- Treated for 4 weeks with SOC
- Consisting of non-adherent siliconized foam wound dressing
- Plus static short stretch 2 or 3 layer compression bandage

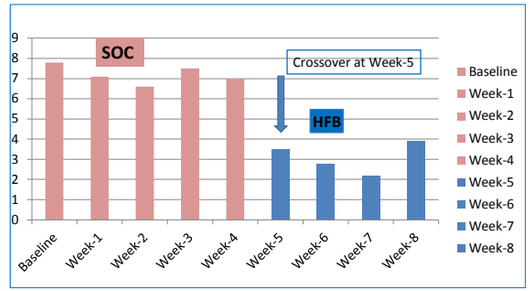
Evaluations were performed weekly for 8 consecutive weeks
- Wound pain using clinically validated Baker-Wong Faces Pain Scale
- Wound surface area using digital photo-planimetry with Pictzar CDM™
- Clinical wound characteristics (non-viable tissue, exudate, edema, erythema)

At Week-5 the primary wound dressing in all patients to HFB
- Compression therapy remained the same
- Treatment with HFB continued from Week 5-Week 8

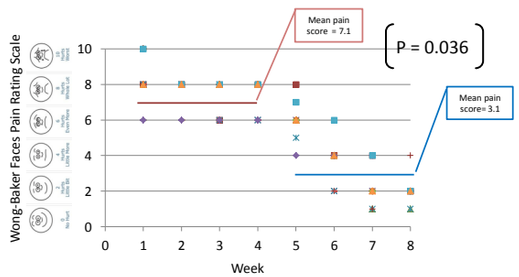
HFB is hydrated with NS and cut to fit the wound. Then covered with a foam bolster and the leg is bandaged with a 2 layer or 3 layer short stretch bandage. Wound dressings are done once weekly in the outpatient wound center.

Results

Effect of HFB on Local Wound Pain (Baker-Wong Faces Pain Scale)



Scatter Chart of Individual Patient Wound Pain Scores (N=11)



The photographs above show a SCU patient who was treated with HFB (note the effective autolytic debridement).

References:

1. 1. Van Beers E, van Tujin CFJ, MacGillvary MR et al., Sickle Cell Disease, Hematologica 2008;93(5):757-760
2. 2. Trent JT, Kirsner RS: Leg ulcers in sickle cell disease, Advances in Skin and Wound Care 2012; 17(8):410-416
3. 3. Minniti CP, Eckman J, Sebastiani P, Steinberg MH, Ballas SK: Leg ulcers in sickle cell disease, Am J Hematol 2010; 85(10):831-833

Conclusion: **The mean wound pain score during the first 4 weeks (SOC phase) was 7.1 compared to 3.1 during the last 4 weeks of treatment when the primary dressing was HFB [p=0.036]. There was also a marked improvement in autolytic debridement during the HFB treatment phase. In this feasibility study the relative rate of healing did not differ significantly between the first 4 weeks of treatment and the second 4 weeks. HFB has become our "GO TO" dressing for Sickle Ulcers. A randomized controlled trial is needed to substantiate these findings.**

***HFB is Hydrofera Blue, Hollister Wound care, Libertyville, IL**

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