Pyoderma Gangrenosum Treatment *A Steroid Free Option*

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Finally we have a way to treat Chronic Ulcers with an etiology of Pyoderma gangrenosum (PG) without the use of corticosteroid therapy.

Pyoderma gangrenosum (PG), a rare clinical lesion, is a morpholic description of an inflammatory response presenting as a reaction pattern in the skin. The distinctive features of PG are listed in *table 1*.

Pyoderma gangrenosum was associated with patients with Ulcerative Colitis, but recent findings have expanded the association to other systemic diseases. Only about 50% of patients with PG have ulcerative colitis. PG has been associated with other bowel diseases such as Crohn's disease, active chronic hepatitis, and diverticulitis. It can also be a cutaneous manifestation of a variety of different systemic diseases in association with myeloproliferative disorders, polyarthritis, and rheumatoid arthritis, paraproteinemia (including multiple myeloma), drug reactions, and delayed altered hypersensitivity. In some cases the patients have no associated systemic disease.

Current treatment for PG prior to the use of Hydrofera Blue™, is a treatment of the symptoms. *See table 2*. This treatment has included the use of high dose corticosteroid therapy, which as you know, have many untoward effects/ complications including but not limited to: CNS: euphoria, insomnia, seizures, CV: Alters PT and INR, heart failure, arrhythmias, thromboembolism, Endocrine; cushingoid state, increased blood glucose levels which could lead to the onset of diabetes, GI: peptic ulceration, SKIN: delayed wound healing, OTHER: acute adrenal insufficiency, infection, after prolonged use sudden withdrawal can be fatal, death.

We began using Hydrofera Blue™ in a clinical trial utilizing this dressing on Wound Care Center patients. As the clinical trial began we noted some remarkable, almost immediate results including: rolled wound edges flattened, inflammation decreased, pain decreased by 50 to 75% within the first week of treatment, fibrin covering the wound bed decreased from 100% to less than 20% with the wound bed presenting with beefy red granulation tissue. You can actually watch the new epithelialization form week to week by the slightly blue hue noted in the new epithelial cells.

Within the first two weeks of the initial study we decided to try the Hydrofera Blue™ on a long-term patient of ours at the Wound Care Center. This patient had multiple long-standing chronic ulcers. This patient had tried many treatment modalities over the past three years including: Silvadine, Hydrogel, Vaseline gauze, wet to dry dressings, and Antibiotic ointment. Once this patient became a patient of the Wound Care Center the diagnosis of Pyoderma gangrenosum was made. *See case study #1*

What is Hydrofera Blue™? *See table 3.*

How Does Hydrofera Blue™ work? The three components of the dressing noted above each play an important role in how and why this product works so well. *See table 4.*

Hydrofera LLC produces this new product, Hydrofera Blue™, in Willimantic, Connecticut.

As this first PG case did so well with Hydrofera Blue™ alone we decided to begin an adjunctive study on PG patients across the country.

The results of both studies are as follows: Initial Wound Care Center study. *See table 5*, Pyoderma gangrenosum study. See *table 6*, Overall Clinical observations. *See table 7.*

We are now using Hydrofera Blue™ on: Radiation Burns, Folliculitis, Psoriasis, Eczema, Cellulitis, All types of chronic non-healing ulcers, necrotizing fasciitis, Pyoderma gangrenosum, infected wounds including MRSA, VRE, and Candida Albicans. To date there have been no untoward reactions to the Hydrofera Blue Dressing.

In conclusion Hydrofera Blue™ has been effective on all types of wounds: infected wounds, venous wounds, trauma wounds, pilonydal cysts, and even Pyoderma gangenosum. It is administered at a fraction of the cost of other dressings with similar properties. Hydrofera Blue is safe and simple to use. We have successfully treated multiple PG cases with Hydrofera Blue alone, not with the usual high dose steroids. I would recommend the use of Hydrofera Blue on any PG wound with or without the use of steroids. I would certainly use Hydrofera Blue as an initial first line dressing on any wound in the Wound Care Center.

Table 1 Pyoderma Gangrenosum (PG)

- The lesions usually present on the lower extremities; may also appear on trunk, upper extremities, face and mouth
- Lesions include papules, pustules, and plaques that can evolve and resolve without passing through an ulcerative stage
- Aspiration from lesions of PG before ulceration shows no bacterial growth. The role of bacteria cultured from ulcerated lesions is that of secondary invaders or colonizers.
- Salient clinical features of PG are the rapid development of a necrotizing ulceration.
- Phagedenic ulcerations are characteristic: painful, the boarders are undetermined and boggy and surrounded by bluish-red areola. Waffled wound bed appearance. Ulcers heal with cribiform type of scar.
- Diagnosis clinical: histopathology is characteristic but not pathognomonic; no specific laboratory changes.

Table 2 Treatment of PG prior to Hydrofera Blue™

- Often a diagnosis of exclusion
- Wound Biopsy
- Tissue culture to assess for secondary infection
- Complete detailed patient history
- Control of Underlying Disease Process is Imperative
- Standard local wound care
- Clean, moist wound environment without debridement
- Corticosteroids, cyclosporins, sulfones
- Prevention of secondary infection

Table 3 Hydrofera Blue™

Hydrofera Blue™

{ PVA sponge } + { Methylene Blue and Gentian Violet }

A Simple, Safe, and Effective Moist Wound Dressing, to take on the most Difficult Wounds

Endotoxin Binding by Hydrofera Blue™

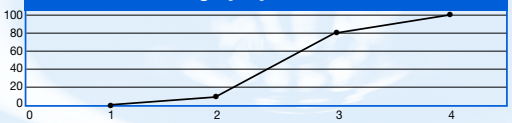

Table 4 Properties of Hydrofera Blue & how it works:

Hydrofera PVA Sponge
- Naturally Hydrophillic
- Extremely Soft "wet"
- Natural Vacuum
- Biocompatible
- Extremely Strong
- Micro Pore Structure
- Capture Affinity
- Used in treatment for >30 years

Methylene Blue
- Used Safely in treatment for >50 years

Currently used in:
- Iv Methemoglobinemia
- Blood Sterilization
- OP Site Markers
- Kills Gram Negative Organisms
- Preferentially Bonds to PVA

Gentian Violet
- Used Safely in treatment for >50 years
- Kills Gram Positive Organisms
- Preferentially Bonds to PVA

Currently used in:
- IV Treatment of Chagas Disease
- Treatment of Candida Albicans
- Topical Antiseptic

Table 5 Clinical Program

- 24 Initial Patients in the study with a total of 46 wounds
- 20 Week Study
- 4 Patients with a total of 7 wounds were discontinued from the study (1 for osteomyelitis, 3 for noncompliance with visits to the center)
- By week 20 16 patients are completely healed, the other four patients (18 wounds) have healed 10 of the 16 wounds
- All patients stated at least a 50% reduction in pain within the first week
- No adverse reactions noted

Table 6 Pyoderma Gangrenosum Study

- 10 initial patients, with 23 wounds
- 24 week study
- 8 patients healed, with 19 wounds
- 2 patients did not heal but have made great progress towards healing
- All patients stated a 50 to 75% pain reduction in the first week
- No adverse reactions noted

Table 7 Overall Clinical Observations with Hydrofera Blue™:

- Appears to Draw bacteria to the wound surface and kill it
- Nothing resistant to date including; MRSA & VRE
- Does not Macerate Surrounding Skin
- Helps to Decrease and/or Eliminate Pain
- Dramatically decreases Rolled Wound Edges and Soothes Surrounding Inflamed tissue within 48 hours
- Dramatically Reduces Inflammation
- Provides Optimal Moist Wound Healing Environment
- Healed a 4 year old pyoderma case
- Gentle on Newly Formed Granulation Tissue
- Healed Pyoderma with out the use of steroids
- Healed Venous Stasis wounds
- Healed Pilonidal Cyst wounds
- Healed severe yeast infections
- Healed Poison Ivy
- Healed Folliculitis
- Healed trauma wounds
- Healed diabetic foot wounds
- Healed Necrotizing Faciitis

Case Study 1

65 Year-old female with Rheumatoid Arthritis for 20 years developed open wounds on bilateral lower extremities. She was treated by her primary care physician for over a year with multiple dressing including wet to dry and Silvadine. The patient presented to the wound care center, a biopsy was done and a diagnosis of Pyoderma Gangrenosum was made. The patient began using Hydrofera Blue™ dressings as part of a study group on 9/25/02. The wound duration prior to this treatment was 12 months.

The patient noted a 75% pain reduction within the first week of treatment and the wound edges flattened without debridement, as debridement is contraindicated in Pyoderma. On 11/2/02 the wounds converted to two smaller wounds and on 1/22/03 the wounds were healed.

9/25/02
Hydrofera Blue™ Treatment Began

11/20/02
Converted to two wounds

1/22/03
Healed

Sponsored by: Hydrofera®

Pioneering Advancements in PVA Technology

Case Study 2

3 year old female took a trip to the Philippines and was bitten by an insect. She developed large wounds on all extremities. She was admitted to the hospital and all wounds were debrided. She had used a variety of products including a number of the silver dressings. A biopsy was done and a diagnosis of Pyoderma Gangrenosum was made. She was placed on steroids and had seen a total of 11 specialists and the wounds continued to get worse. Her father was researching Pyoderma on the Internet and found Hydrofera's website, stating the dressing had successfully treated Pyoderma. He contacted Hydrofera and Hydrofera provided her physician with the dressings to treat her. We worked with her, long distance, with pictures her father was taking, lab reports (showing heavy growth of pseudamonas) and wound documentation. Today both lower extremities are healed and the upper extremities are well on the way to being healed.

11/03
Left Leg Pseudamonas infection began ABT and Hydrofera Treatment

1/04

2/04

11/03
Right Leg

1/04

2/04