Pyoderma Gangrenosum Treatment *A Steroid Free Option*

Pyoderma Gangrenosum Treatment *A Steriod Free Option*

By: Patricia Conwell R.N., B.S., C.W.C.N., Lisa Mikulski R.N., B.S.N., Debra Moran R.N., Mark Tramontozzi M.D., F.A.C.S.

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™

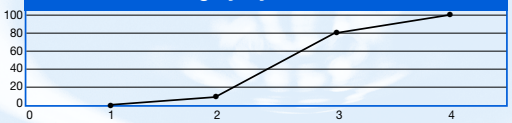

Table 4 Properties of Hydrofera Blue & how it works:

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

WOUND MANAGEMENT & PREVENTION

FEATURED DEPARTMENT

Notes on Practice: Pyoderma Gangrenosum Treatment: A Steroid-Free Option

Authors
Patricia Conwell; Lisa Mikulski; Debra Moran;
Mark Tramontozzi

Issue: Volume 50 - Issue 5 - May, 2004

Background

Pyoderma gangrenosum (PG), a rare clinical lesion, is a morpholic description of an inflammatory response presenting as a reaction pattern in the skin. The lesions usually present on the lower extremities but also may appear on the trunk, upper extremities, face, and mouth.

The papules, pustules, and plaques can evolve and resolve without passing through an ulcerative stage. Before ulceration, aspiration from these lesions 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, pain, ulcer borders that are undermined and boggy and surrounded by bluish-red areola, and a waffled wound bed appearance. The ulcers heal with a cribriform type of scar. The clinical diagnosis characteristically involves histopathology as opposed to being pathogenic, with no specific laboratory changes.[1]

Pyoderma gangrenosum is 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 also can be a cutaneous manifestation of a variety of different systemic diseases in association with myeloproliferative disorders, polyarthritis, rheumatoid arthritis, paraproteinemia (including multiple myeloma), drug reactions, and delayed altered hypersensitivity. In some cases, patients have no associated systemic disease.[2]

Until recently, determining the etiology of the lesions associated with PG was accomplished through a diagnosis of exclusion, wound biopsy, tissue culture to assess for secondary infection, and complete, detailed patient history. Treatment included control of the underlying disease process, standard local wound care, providing a clean, moist wound environment without debridement, and the use of corticosteroids, cyclosporins, and sulfones to prevent secondary infection.[3] The use of high-dose corticosteroid therapy has many untoward effects/complications, including but not limited to central nervous system affects (eg, euphoria, insomnia, seizures, cerebrovascular); alteration of prothrombin time [PT] and international normalized ratio [INR]; heart failure, arrhythmias, thromboembolism; endocrine dysfunction (eg, cushingoid state and increased blood glucose levels that could lead to the onset of diabetes); gastro-intestinal effects (eg, peptic ulceration); delayed wound healing; acute adrenal insufficiency; and infection. After prolonged use of corticosteroids, sudden withdrawal can be fatal.[4]

As part of a clinical trial, the authors began using Hydrofera Blue™ (Hydrofera, Willimantic, Conn.), a PVA sponge with methylene blue and gentian violet bound to the foam (components that have been used for more than 50 years), on Wound Care Center patients. As the clinical trial began, some remarkable, almost immediate results were noted, including the flattening of rolled wound edges, decreased inflammation, decreased pain (by 50% to 75%) within the first week of treatment, decreased (from 100% to less than 20%) fibrin covering the wound bed, and the presence of beefy red granulation tissue. The new epithelialization appeared from week to week, noted by the slightly blue hue noted in the new epithelial cells.

Within the first 2 weeks of the initial study, the authors decided to try the product on Ms. K.

Case Study 1: History/Diagnosis

Ms. K is a 65-year-old female with multiple long-standing chronic ulcers. Ms K's comorbidities include rheumatoid arthritis, multiple drug allergies, hypertension, and chronic pain. Before her treatment at the Wound Care Center, Ms. K's ulcer care had included many treatment modalities over the previous 3 years: Silvadine (Monarch, Bristol, Tenn.); hydrogel dressings, Vaseline gauze (Tyco HealthCare/Kendall, Mansfield, Mass.); wet-to-dry dressings; and antibiotic ointment. She had endured the ulcers for more than 12 months before becoming a patient of the Wound Care Center. At this time, a diagnosis of Pyoderma gangrenosum was made by biopsy (see Figure 1).

Treatment

Clinicians began treating Ms. K with the foam wound dressing on September 25, 2002. Within 24 hours of beginning treatment, epibole edges had flattened, and after 1 week of treatment, Ms. K's pain (as measured on a numeric pain scale) was reduced by 50%. By November 20, 2002, the wound had converted to two smaller wounds, with visible new epithelialization (see Figure 2). The blue hue noted is from the pigments in the dressing. By this point in the treatment, Ms. K's pain was almost gone. She was declared healed on January 22, 2003 (see Figure 3).

Prognosis/Conclusion

Because Ms. K fared so well with this product alone, the authors initiated adjunctive studies on PG patients across the country, utilizing the same wound dressing. In their initial 20-week follow-up study at the Wound Care Center, 20 patients (some with multiple wounds) completed the study; 16 experienced complete healing and four patients who healed 10 out of their 16 wounds. All of the patients reported a pain reduction of at least 50% (as measured on a numeric pain scale) within the first week and no adverse reactions were noted.

In another study conducted over 24 weeks, of the 10 initial patients with 23 wounds, eight patients (19 wounds) healed, and two patients did not heal but made great progress toward healing. All patients noted a 50% to 75% pain reduction in the first week with no adverse reactions noted during this study.

Case Study 2: History/Diagnosis

An insect bit Miss B., a healthy 3-year-old female, during a trip to the Philippines. Miss B developed large wounds on all extremities. She was admitted to the hospital and all wounds were debrided. Miss B had used a variety of products, including a number of the silver dressings. A biopsy was performed and a diagnosis of Pyoderma gangrenosum was made. Miss B was placed on steroids and saw a total of 11 specialists but the wounds continued to worsen. Miss B's father began researching Pyoderma on the Internet and found Hydrofera's website, where success using the product for Pyoderma was noted. Miss B's father contacted the company, which provided her physician with the dressings to treat Miss B. The Wound Care Center, working long-distance with photos taken by her father, lab reports that showed heavy growth of Pseudomonas, and wound documentation, assisted in Miss B's treatment.

Treatment

Miss B began using the foam wound dressings in November 2003 (see Figure 4). At the same time, Miss B also was started on antibiotic therapy to treat the *Pseudomonas* infection. In January 2004 (see Figure 5), Miss B was 70% healed, and in February 2004 Miss B was completely healed (see Figure 6).

Conclusion

From the authors' experience and observation, the wound dressing appears to have helped heal multiple cases of PG without the use of steroids and healed a variety of wounds including venous stasis, pilonidal cyst, trauma, and diabetic foot wounds, as well as heal necrotizing fasciitis. The authors now also are using the product on wounds infected with MRSA, VRE, and *Candida albicans*. Further study is encouraged and warranted.