

Toxic Inflammatory Cellulitis (Necrotizing Fasciitis) Treatment: Anti-Bacterial Versus Anti-Inflammatory Interventions

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Abstract

Necrotizing fasciitis (NF) is a descriptive term for the end stage of a disease process better termed 'toxic inflammatory cellulitis' (TIC). The four stages of wound healing are: 1) Wounding and control of bleeding; 2) Inflammatory phase; 3) Regenerative phase; and 4) Final phase of tissue remodeling. Phase 2, the destruction of defective tissue by multiple toxic products, paves the way for removal of cellular debris by monocyte ingestion. Phase 3 cannot begin until the toxic influence, along with the cellular debris, is neutralized and removed, allowing fresh cells to move into the tissue regenerative phase. Wound healing frozen in Phase 2 results in a destructive process – with an untreated mortality of over 70% – constitutes TIC. The management of TIC requires more than just antibiotics and debridement, as neutralization of the toxic mechanisms is required to change the clinical outcome. In laboratory studies, a solution of pure 0.01% hypochlorous acid* has been shown to not only inactivate pathogens but also directly neutralize bacterial toxins. In the clinical uses described here, a 41-year old female with swelling and erythema of the lower abdomen and right upper thigh; a 29-year old male with fever, pain, abscess of right hip and buttocks and soft tissue emphysema shown by X-ray; a 23-year old with an acute infection and abscess of his right finger and hand; and a 54-year old male with chills, fever, swelling and pain of scrotum and perineum, were diagnosed with necrotizing fasciitis or Fournier Gangrene after incision, drainage and debridement. NeutroPhase®, pure 0.01% hypochlorous acid (with no bleach impurity) solution with Negative Pressure Wound Therapy was successfully used as the irrigating and cleansing agent to treat these four patients, resulting in no deaths or amputations, with complete healing. Our data show that there is a clear utility for pure 0.01% hypochlorous acid* as an important part of the treatment of toxic inflammatory cellulitis.

Introduction

Necrotizing fasciitis (NF) is the common clinical name for a disease (also called flesh-eating bacteria, gas gangrene, etc.) that can be devastating when untreated. Type I necrotizing fasciitis is classified as a poly-microbial infection, whereas Type II is classified as a mono-microbial infection. Many types of bacteria can cause necrotizing fasciitis (e.g., Group A *Streptococcus* [GAS], *Streptococcus pyogenes*, Group B *Streptococcus* [GBS], *Streptococcus agalactiae*, *Staphylococcus aureus*, *Vibrio vulnificus*, *Clostridium perfringens*, and *Bacteroides fragilis*). Such infections are more likely to occur in people with compromised immune systems.¹ Normal wound healing is a highly interactive process comprising four defined phases of (I) coagulation, (II) inflammation, (III) tissue formation, and then (IV) tissue re-modeling.² NF describes a clinical situation occurring in phase II of wound healing (Inflammatory). Current standard treatment includes antibiotics, vasopressors, rehydration, incision and drainage of the destroyed tissue and counteraction of toxic shock syndrome (TSS). No therapies are available to directly inactivate bacterial toxins.

Materials & Methods

Before treatment, the wound area was cleansed, the wound was debrided and the skin dried. Then black foam (KCI) was sized and placed in the wound. A separate inflow tube (IV extension with port) was placed on and through the black foam. The adhesive drape was attached and placed over the entire area including the black foam. The area around the tubing was sealed with Stomadhese. The VAC was then turned on and adjusted from 50-125 mm Hg suction. NeutroPhase® (5 mL) was instilled via syringe through the inlet-port into the wound bed with the vacuum on (Fig. 1).

Results

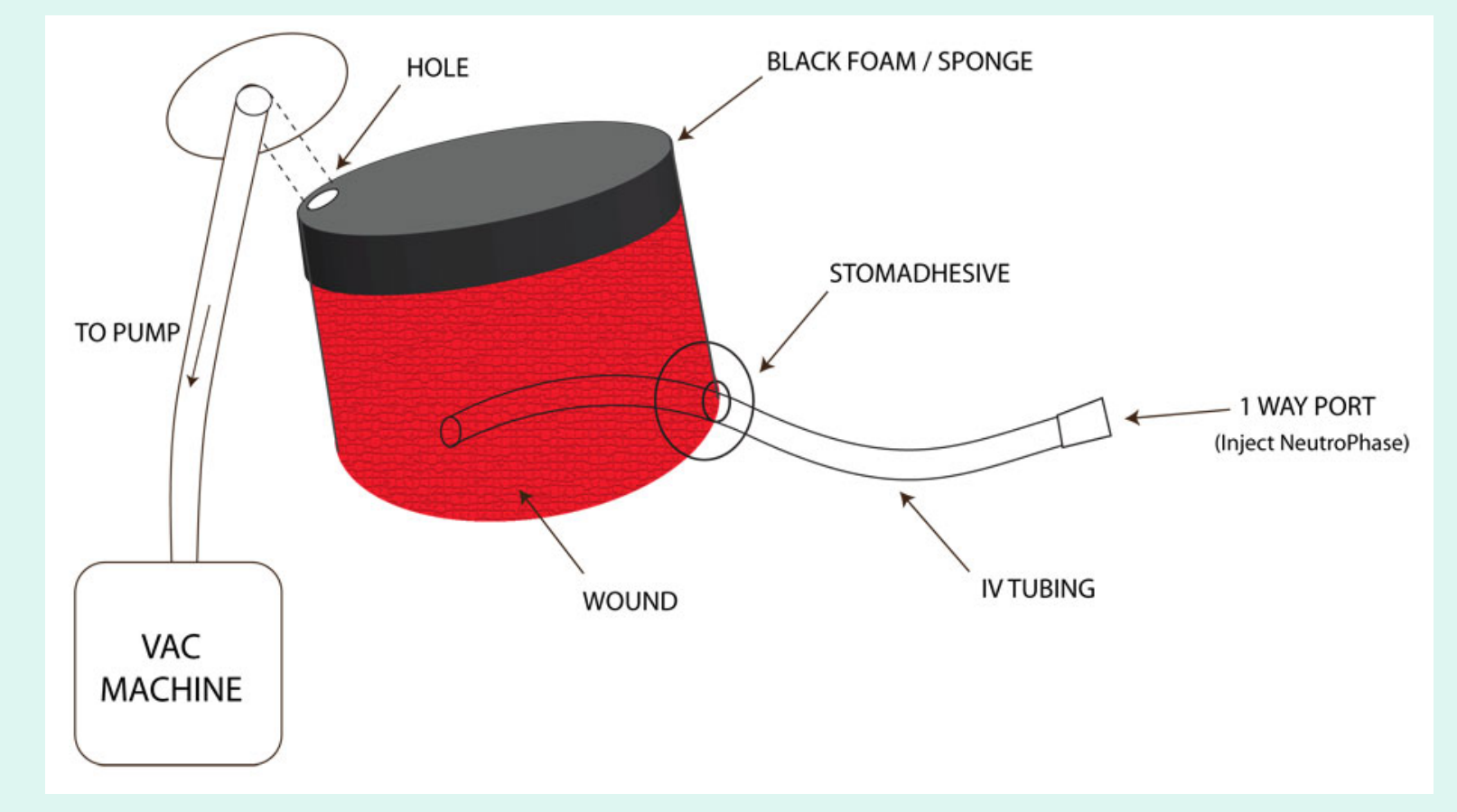


Figure 1. A line diagram of the equipment for NPWT with adjunctive NeutroPhase® irrigation



Figure 2. A: Case #3 shows a 79 year old patient with TIC in the lower leg. NeutroPhase was instilled along with limited incision and only open drainage into a sponge. B: The wound quickly changed to regenerative stage and healed.



Figure 3. A: Case #1 shows a male with abrupt onset of Fournier's gangrene. B: Immediate I and D was performed removing the necrotic skin of the scrotum and penile base followed by instill vac with NeutroPhase C: Within 2 weeks the thigh stored testicles and cord were surgically freed and eventually healed within one month with a split-thickness skin graft.



Figure 4. A: Case #2 shows a female with necrotizing fasciitis of the lower abdomen and right upper thigh. Multiple small incisions were used without removing infected fascia, just suctioning out necrotic subcutaneous tissue. B: Instill VAC irrigation was conducted through multiple ports C: The result was far less scarring with less pain and more rapid healing

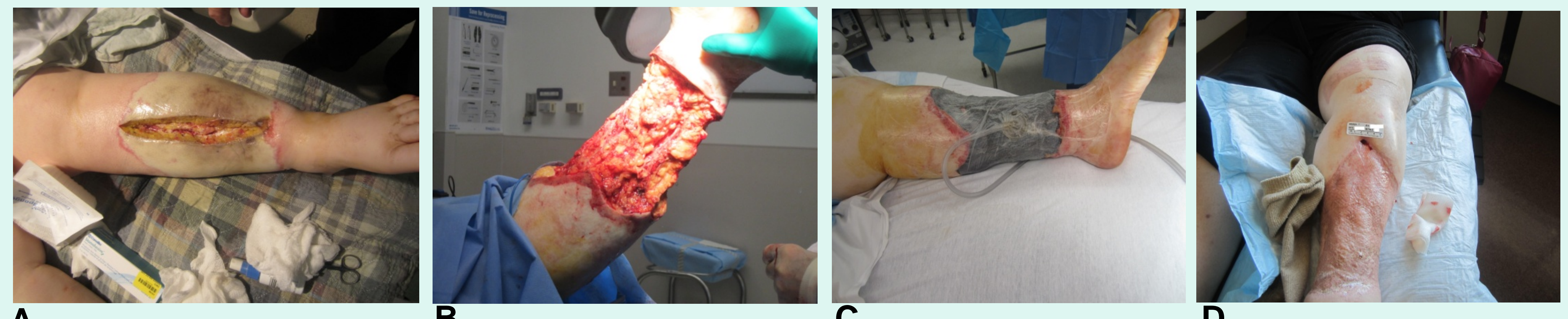


Figure 5. A: Case #4 shows a female with TIC of the lower leg. B: I and D was performed removing the necrotic tissue. C: NeutroPhase was instilled using the VAC. D. The wound quickly changed to regenerative stage and finally healed with a split-thickness skin graft.

Discussion

In addition to its anti-microbial activity in solution, hypochlorous acid has been shown in laboratory studies to disrupt biofilms, penetrate microbial cells, spore walls and amoeba cysts. It was also shown that pure hypochlorous acid rapidly inactivates *S. aureus* and *S. pyogenes* toxins³. These cases illustrate and justify its use in cleansing the wounds of patients who have necrotizing fasciitis. Over the last 4 years, at least 7 other patients were found with the diagnosis of NF in medical records at Seton Medical Center. They were treated with the standard therapy and 2 died, 1 had amputation and 3 survived. This fits with the expected outcome from the literature⁴. In comparison, 7 NF patients treated with our new therapeutic algorithm resulted in no deaths and no amputations. Two of these patients had toxic shock and both recovered, although one was intubated for 16 days in a coma before complete recovery.

Conclusions

- Necrotizing fasciitis is a serious infection of the deeper layers of skin, subcutaneous tissue, and fascia. The toxicity caused by bacterial superantigens released, combined with the cellular toxins released from the damaged cells, change the patient's situation from acute to critical, requiring surgical incision and drainage.
- The combination of pure 0.01% hypochlorous acid as a cleansing solution used for irrigation with NPWT played an important role in the recovery of our patients by rapidly killing bacteria and inactivating toxins and superantigens.
- 7 necrotizing fasciitis patients treated with our new therapeutic algorithm resulted in no deaths and no amputations, compared to 7 patients treated in the same medical center over the last 4 years with the standard therapy resulting in 2 deaths and one amputation.

*NeutroPhase®
Disclaimer: NeutroPhase® is a solution of pure 0.01% hypochlorous acid (as a preservative) in normal saline, and manufactured by NovaBay Pharmaceuticals Inc. NeutroPhase® is a 510-(k) registered product for wound cleansing only. Reductions in microbial growth in the NeutroPhase solution have not been shown to correlate with reductions in infections in patients, as clinical studies to evaluate reductions in infections have not been performed.

References

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