

Use of NeuroPhase® as an Irrigant During the Management of Diabetic Ulcers

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Abstract

Purpose: Diabetic ulcers are serious unmet medical needs effecting patient's morbidity and mortality. Topical antiseptics have a long history of use, such as sodium hypochlorite (Dakin's solution), hydrogen peroxide, acetic acid and povidone-iodine that remain in widespread use today. However used at typical concentrations, these antiseptics can actually impede wound healing. HOCI has been described as being 80-100 times more potent as a germicide than the hypochlorite anion (OCI⁻; high pH). NeuroPhase® is pure 0.01% hypochlorous acid (i.e. ~97% relative molar distribution of active chlorine species as HOCl) in a 0.9% saline solution at pH 4-5 and NovaBay has an FDA cleared 510(k) for wound care. The purpose of this study was to test the use of NeuroPhase® during the treatment of diabetic ulcers. **Methods:** We have more than 30 clinical case studies where we used NeuroPhase® with and without negative pressure wound therapy (NPWT). **Results:** Satisfactory ulcer healing was observed in patients treated with NeuroPhase® as an irrigation solution with and without NPWT. **Conclusions:** Our data show that there is a clear utility for the use of NeuroPhase® as a key agent in treatment of diabetic ulcers and to address this serious unmet medical need.

Introduction

Chronic non-healing wounds have many factors contributing to the impairment of healing such as the presence of foreign bodies, tissue maceration, ischemia, infection, and biofilms. The clinical picture can be further complicated by systemic factors such as diabetes, malnutrition, renal disease, and advanced age. Therefore, chronic non-healing wounds are a clinical problem that for some is a serious unmet medical need. HOCI (NVC-101) has been shown to be an effective topical antimicrobial and has potential application as an antimicrobial wound irrigation using a well-established chronic granulating wound rat model.¹ NeuroPhase® is a 510-k cleared self-preserved preparation of HOCl that has been shown to inactivate *P. aeruginosa*, *E. coli*, *S. aureus*, *C. albicans* and *A. niger* in solution. Using Sorbact as the wound mesh dressing in combination with NeuroPhase® as the irrigation solution showed a marked increased speed of wound healing. NeuroPhase® is not toxic to living tissue.

Materials & Methods

A combination of 0.01% NeuroPhase® as the irrigation solution and Sorbact (Abigo Medical AB, Askim, Sweden) as the wound mesh dressing was used to treat over 30 patients with chronic non-healing wounds. Before treatment, the wound area was cleansed and the wound was debrided, then the skin was dried. Then Sorbact mesh was sized and placed in the wound. A Blake drain was placed on and in the Sorbact mesh. The adhesive drape was attached and placed over the entire area including the Sorbact mesh. The area around the tubing was sealed with Stomachase. The tubing was connected to a three-way stopcock and a one-way valve was added. The VAC was then turned on and adjusted from 50 mm to 125 mm suction. The pre-determined amount of NeuroPhase® was injected through the three-way stopcock and allowed to stay in the wound for 15 minutes before it was vacuumed out. This was subsequently changed to a separate inflow tube (Blake drain) and irrigation while the VAC was kept on.

Results



Figure 1. (I)75 year old female with DM II, End-Stage renal disease presents to wound center with chronic ulcer on the right foot. (II) Wound post-debridement. (III) Wound post-debridement. (IV) Week 2 of treatment: Patient continues to heal and is now ready for biological skin equivalent to be applied.



Figure 3. (IX)This is a failed flap due to MRSA created for radical excision of a squamous cell cancer with exposed cranial bone and no granulation. (X)Treated with instill vac and Sorbact dressing with direct 0.01% NeuroPhase® irrigation at home by syringe through a Blake drain at the base.(XI) Debridement and a biological graft were also used. (XII)Healing took 5 1/2 months.



Figure 2. This is a traumatic venous ulcer in a chronic venous insufficient leg and required 3 months of therapy for healing. The topical dressing was Sorbact with irrigation of 0.01% NeuroPhase® solution. (V) before treatment; (VI& VII) during treatment; (VIII) healing.



Figure 4. (XIII, XIV, XV, XVI) This 51 y/o fell bruising left arm in a parking lot. Three days later arm flared up with streptococcal cellulitis and fasciitis with shock and ICU support. I and D one day later followed by repeat lower arm I and D with VAC and instillation of 0.01% NeuroPhase® three times a day. Repeat extension of surgery in forearm. Discharged on VAC and instillation at home 3 1/2 weeks later, now @ 5 weeks upper arm healed and lower arm @ 90% with biological graft in place. No positive cultures obtained, just gram stain streptococcus found.

Discussion

Chronic non-healing wounds have many factors contributing to the impairment of healing such as the presence of foreign bodies, tissue maceration, ischemia, infection, pressure and biofilm. The clinical picture can be further complicated by systemic factors such as diabetes, malnutrition, renal disease, and advanced age. Therefore chronic non-healing wounds impact the patient's morbidity and are a serious unmet medical need. In our studies using Sorbact as the wound mesh dressing in combination with NeuroPhase® as the self-preserved irrigation solution showed a marked increased speed of wound healing. Our 0.01% concentration of NeuroPhase® is not toxic to living tissues. Sorbact is a hydrophobic mesh that traps bacteria yet decreases maceration of the adjacent skin next to the wound. Appropriate wound care remains essential with debridement, offloading, antibiotics and appropriate follow up care in the outpatient setting. The treatment can be maximized with the use of negative pressure wound treatment (NPWT) as well by the instillation irrigation and aspiration twice daily with NeuroPhase®. In this treatment with the appropriate instillation procedure we used Sorbact mesh as the sponge which does not leave macerating fluids on the skin. Overall this simplifies the vacuum instillation procedure significantly.

Conclusions

- The results demonstrate that NeuroPhase® is an important irrigation solution in treatment of diabetic ulcers.
- Sorbact helps reduce tissue maceration.
- NeuroPhase® in combination with Sorbact as the wound mesh dressing utilizing negative pressure wound therapy enhances the speed of wound healing.
- These case studies show NeuroPhase® in combination with Sorbact® has the potential to be a very effective wound care product for use in healing wounds.

References

- ¹ Robson, M. C; Payne, W. G.; Ko, F.; Mentis, M.; Ahafii, S. M.; Culverhouse, S.; Wang, L.; Khosrovi, B.; Najafi, R.; Cooper, D.; Bassiri, M. Journal of Burns and Wounds 2007; 6: 80-90