



Pure 0.01% Hypochlorous Acid Solution* Shows Improvement in the Infections Associated with Peritoneal Dialysis Catheters

SA-PO425

Allan G. Kavalich¹, Dmitri Debabov², Ramin (Ron) Najafi², Thomas Paulson², Russell Hoon²

¹San Bernardino Valley Home Dialysis Center, 1500 North Waterman Avenue, San Bernardino, CA 92404, ²NovaBay Pharmaceuticals, Inc., 5980 Horton Street, Suite 550, Emeryville, CA 94608

Abstract

S. aureus accounts for most exit site and tunnel infections associated with peritoneal dialysis (PD) catheters. Gram negative bacteria and fungi are less common, but difficult to eradicate and frequently lead to peritonitis if catheter removal is delayed. A solution of pure 0.01% hypochlorous acid in normal saline was used to cleanse five patients with infections associated with peritoneal catheters. A 59 year old male with exudative tunnel infection due to heavy growth of multi-resistant *E. coli* was treated with Levequin. After 10 days he was re-tested, developed resistant *E.coli* and started on pure 0.01% hypochlorous acid solution. Patient was brought into unit TID. Pure 0.01% hypochlorous acid solution was induced into tunnel via 30cc syringe and flexible IV catheter to bathe area with 5cc for 10 minutes (this was repeated four times). The pure 0.01% hypochlorous acid solution was allowed to dry, catheter was anchored, and dressing was applied. Process was repeated for 2 weeks, then at home three times per day for six weeks with complete resolution. A 55 year old male developed a *Candida albicans* peritoneal dialysis exit site infection. He was treated with IV Diflucan and Nystatin cream. Culture remained positive. Patient was cleansed with 4 sprays of pure 0.01% hypochlorous acid solution at the exit site BID for six weeks with complete resolution. Continues to use spray daily at exit site for six months with no further infections. A 64 year old male with MRSA exit site infection was cleansed solely with a spray of pure 0.01% hypochlorous acid solution TID for eight weeks with complete resolution. A 55 year old female with chronic staph epi exit site infections in the past was treated with Vanco and Rifampin. A spray of pure 0.01% hypochlorous acid solution was started. Exit site clean after six weeks. Continued spray QD without infection for six months. A 29 year old female with recurrent exit site infections was cleansed with a spray of pure 0.01% hypochlorous acid solution QID with complete resolution after four weeks. Pure 0.01% hypochlorous acid solution was the only approach showing improvement in these patients. Our data show that there is a clear utility for the use of pure 0.01% hypochlorous acid solution for the cleansing of infections associated with peritoneal dialysis catheters.

Introduction

S. aureus accounts for most exit site and tunnel infections. *Pseudomonas* is much less common, but is difficult to eradicate and frequently leads to peritonitis if catheter removal is delayed. Coagulase negative *staphylococci*, fungi and other Gram-positive organisms account for the remaining infections. In this study, we used a solution of pure 0.01% hypochlorous acid in normal saline to cleanse five patients with infections associated with peritoneal catheters.

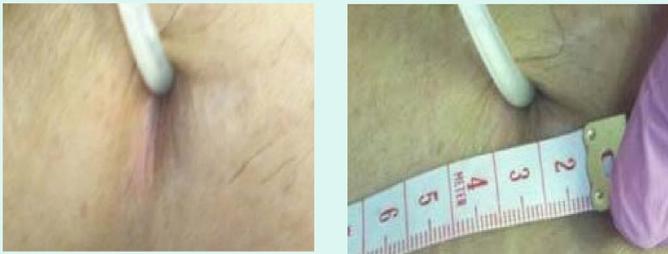
Results

59yr old male with multi-resistant *E.coli*

Treatment Day 1



Treatment Day 3



Treatment Day 5



- Heavy growth
- Treated with Levequin for 3 days
- Re-tested in 10 days with continued *E.Coli*
- Patient brought into unit
- TID pure 0.01% hypochlorous acid solution induced into tunnel via 30cc syringe & intravenous catheter to bathe area for 10 minutes 5cc at a time
- Allowed to dry, catheter anchored and dressing applied
- Process repeated continuously for 5 days
- Patient then administered via spray TID

55yr old male with *C. albicans* PD exit site infection

Treatment Day 1



Treatment Day 10



Treatment Day 18



- Developed a *Candida albicans* PD exit site infection
- Treated with IV Diflucan and Nystatin cream
- Culture remained positive
- Cleansed with 4 sprays of pure 0.01% hypochlorous acid solution to the exit site BID for 6 weeks with complete resolution
- Continues to spray daily at exit site for 6 months with no further infections

29yr old female with recurrent exit site infections

Treatment Day 1



Treatment Day 7



Treatment Day 14



- Recurrent exit site infections
- Cleansed with sprays of pure 0.01% hypochlorous acid solution QID with complete resolution after four weeks
- Pure 0.01% hypochlorous acid solution was the only approach showing improvement

* 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 510k registered product for wound cleansing only. While this study describes the effectiveness in diluted solutions, reduction in microbial growth in the NeutroPhase® solution has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infections have not been performed.

Discussion

Pure 0.01% hypochlorous acid (HOCl) in normal saline has shown in *in vitro* testing to rapidly kill bacteria and fungi on contact in less than one minute¹ and disrupt biofilm². Pure 0.01% hypochlorous acid is rapidly neutralized and evolves into normal saline. Pure 0.01% hypochlorous acid in solution has been shown to be an effective cleanser in peritoneal dialysis catheters. It did not damage the peritoneal catheter integrity. Other wound cleansers such as 0.025% sodium hypochlorite (NaOCl) are problematic since they are known to be toxic to fibroblasts³. These other cleansers can also be harmful if swallowed, come in contact with the eyes, and may degrade the peritoneal dialysis catheter.

Conclusions

- There is a clear utility for the use of pure 0.01% hypochlorous acid in solution for the cleansing of bacterial and yeast infections associated with the use of peritoneal dialysis catheters
- There appears to be no emergence of resistant organisms when cleansing with pure 0.01% hypochlorous acid in solution in these cases
- There were no side effects noted in these cases
- Pure 0.01% hypochlorous acid in solution is useful in the cleansing of multiresistant organisms and relapsing infections in these cases
- Pure 0.01% hypochlorous acid in solution has shown to be effective in these cases to cleanse bacterial peritoneal dialysis catheter tunnel infections, including dispersing biofilm on the catheter surface⁴
- Based on the positive findings from these cases, further investigation is warranted

References

1. Wang L, Bassiri M, Najafi R, Najafi K, Yang J, Khosravi B, Hwang W, Barati E, Belisle B, Celeri C and Robson MC. Hypochlorous acid as a potential wound care agent: part 1. Stabilized hypochlorous acid: a component of the inorganic armamentarium of innate immunity. *J Burns Wounds* 2007; 6: e5.
2. LeChevallier MW, Cawthon CD and Lee RG. Inactivation of biofilm bacteria. *Appl Environ Microbiol* 1988; 54: 2492-2499.
3. Wilson JR, Mills JG, Prather ID, Dimitrijevic SD. A toxicity index of skin and wound 233 cleansers used on in vitro fibroblasts and keratinocytes. *Advances In Skin & Wound Care* 234 2005; 18:373 - 378
4. Crew JR, Vanilla A, Rocas III TA, Debabov D, Wang L, Najafi A, Abdul Rani S, Najafi R, and Anderson M. 2012. NeutroPhase® in chronic non-healing wounds. *Int J Burn Trauma*; 2:126-134