Efficacy and safety of Berberex Wound Cleanser on Post-Operative Surgical Incisions

Timothy Spencer[1], Boris Gorinshteyn[2], Timothy Ganey[3]
[1]Greater Michigan Spine & Neurological Institute, [2]Nuvision Pharmaceuticals, Roswell, GA, Atlanta Medical Center, Atlanta, GA

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INTRODUCTION: The skin is a natural barrier against infection, and despite this continuous and impermeable natural protection, if skin is injured by blister, splinter, cut or burn, bacteria can enter the body and cause an infection. Breaks in the skin that occur during a surgical procedure, synonymously incisions, present opportunities for pathogens to enter the body. A recent report notes that on any given day approximately 1 of every 25 inpatients in U.S. acute care hospitals has at least one health care–associated infection.[1] In addition to the psychosocial stress experienced by patients, antibiotic-resistant infections add costs in prolonged treatments, extended hospital stays, additional physician visits and healthcare use, and greater incidence of disability and death relative to infections. The total cost of antibiotic resistance to the U.S. economy has been estimated to vary from $20 Billion in direct healthcare costs, to $35 Billion when coupled to lost productivity.[1]

BerbereX® Wound Cleanser has been cleared by FDA for external use. *In vitro* potency has been shown against high levels of several resistant bacteria, including against MRSA, B-strep, VRE, and *E. coli*.[2] Active ingredients allantoin and benzethonium chloride have been formulated with water, ethanol, *Aloe barbadensis (Mill.), Hydrastis canadensis L., Panax quinquefolius L.*, and hydrogen peroxide. In combination the ingredients appear to have synergistic action. Based on the product's performance, a study was undertaken to evaluate 180 consecutive patients following spinal surgery.

METHODS: All subjects evaluated were treated by a single physician at the *Greater Michigan Spine & Neurological Institute* in the United States. In consultation with WIRB, the review and opinion indicated that collection of data in the medical practice pertained to patient outcomes for those undergoing spinal procedures, and thus patient medical data related to those procedures constituted quality improvement for the medical practice.

Patients varied in their ethnicities, and no subjects were excluded from the study based on recognized associated risk factor(s). Random patients received *BerbereX*® Wound Cleanser (NuVision Pharmaceuticals, Atlanta, GA) post-operatively and were asked to apply the solution twice a day for 6 months or until wound healing had occurred. Remaining patients evaluated in this retrospective analysis were asked to follow post-operative discharge instructions common to the practice that placed limitations on lifting, and that asked the patients to wash the incision wound with soap and water. All participants received written and oral information regarding the natural and potential risks of the study and gave their informed consent. The study evaluated safety, efficacy in terms of preventing infections, and surgical site healing with regard to pain at the site of incision, tissue cosmesis, and patient compliance.

RESULTS: 66 patients were treated with the *BerbereX*® Wound Cleanser; and 114 patients received the standard of care (Table 1). Within the treated group there were128 surgical levels treated, whereas 198 surgical levels were treated by the standard of care; 1.93 levels per surgical procedure for the *BerbereX*®-treated and 1.73 levels for the standard-of-care patients. Over the course of the evaluation, assuring that all infections has been treated successfully – 11 patients who followed standard-of-care protocol were treated for infection, while none of the patients who received *BerbereX*® for their post-operative care required any further treatment. Of those 11 patients who were treated for infection, 4 had serious infections and 7 had incidental infections. For the 4 serious infections, 3 received wound vac treatment, and 1 patient was readmitted for care. Of the 7 infections noted within the lumbar fusion group, 2 were multi-level, and within the 4 infections treated in the decompression population, another 2 were also multilevel. The severity of those requiring more aggressive treatment was not found to be correlated with the number of levels or the incidence of infection.

DISCUSSION: The rate of infection in the group of 144 patients receiving standard-of-care following surgery was nearly 7.6% while the incidence in those 66 patients treated with *Berberex* were zero. Taking into consideration current observations of the effects of *BerbereX*® Wound Cleanser on repair of surgical incisions that are both interventional and at the same time traumatic, this data demonstrates that incisions will heal faster with better cosmetic outcomes then under current care protocols. In this quality practice initiative, data supports clinical observation that post-operative wound dehiscence, cellulitis, seromas, low-grade infections, associated incision infections and other pathologies of the incision sites related to healing are diminished. *BerbereX*® appears to be a potent agent that positively affects cosmetic healing while protecting the wound from bacterial-affected wound infection.

SIGNIFICANCE: As an anti-microbial product, its effective wound management seems to be well paired with its economic benefits in minimizing the complications of post-operative surgical incision site care. As such, it may serve as a candidate for routine post-operative incision site care.

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	***BerbereX*® Wound Cleanser**	**Standard Care**
Patients	**66**	**114**
Number of Levels	**128**	**198**
Kyphosis	**6 (8)**	**5 (5)**
Lumbar Fusion [Inf]	**21(38)**	**50(91) [7]**
Laminectomy	**17(29)**	**13(17)**
Cervical Fusion	**20(49)**	**22(41)**
Decompression	**2(4)**	**28(44) [4]**
Infections [Inf]	**0**	**11**