

SUMMARY OF OPEN LABEL IN-HOUSE MULTICENTER TRIAL

William D. Lucky, M.D., Ph.D. WCC, CWS, FACOG

September 26, 2013

I was introduced to BerbereX wound cleanser - an antimicrobial product in May of this year. It was at that time I agreed to give a trial usage of this product at three of my nursing home where I am a wound care consultant.

Below is an account of three patients with three different kinds of wounds. Overall, my wound care nurses are pleased with the products (BerbereX), and it should be noted that none work for me; they are employees of the respective nursing homes where they work. I should also point out at this time that I have no financial stake in this company what so ever, nor do I hold any stock options. I am not a paid consultant; I only agreed to request that the wound nurses substitute this product (BerbereX) in place of the wound cleanser they were previously using. The results so far are amazing. Below are selected examples achieved with BerbereX on a surgical wound, a chronic wound and a pressure ulcer.

Patient 1, ID is an 83-year-old male that I have been following for a diabetic heel since August 10, 2011. For the past two years all manner of conventional wound products were used - including Tallymed, negative pressure therapy, Santyl, MediHoney, collagen, and anti-infective. All had some positive influences for a short period of time, but all failed to jump-start the healing cascade.

I began using this product on May 28, 2013 at that time the wounds measurements were 3cm X 2cm x 0.2cm for a surface area of 7.5 cm². By June 25 this chronic ulcers measurements were 2.4cm X 1.4cm X 0.1cm with a surface area of 3.92 cm², for a decrease in size of 45%. There was a two week period when the supply of BerbereX was disrupted and we had to resort to the previous wound cleaner, this chronic ulcer increase in surface area to 3.92 cm², a 25% increase in size in just two weeks.

Once our supply of the BerbereX was restored; on July 9, 2013 the surface area had fallen to 2.0 cm², a 51% reduction in size and an overall reduction in size of 73% from the time we began using this product. I am happy to report that this chronic wound was declared healed on August 10, 2013.

Patient 2, DJ 56-year-old paraplegic who has had a suprapubic for years and it was discontinued and a Foley catheter inserted. This catheter tract had been open for years, prior to treatment its measurements were 0.5 cm X 0.5 cm X 0.5 cm for an area of 0.25 cm. This fistulas-like area was declared closed on August 6, 2013. Even his urologist was surprise at the speed of its closure. DJ also had a stage III left gluteus ulcer, 7.5 cm X 3.5 cm X 0.2cm, area of 26.25 cm², and stage III sacral ulcer, 1cm X 1.5cm X 0.1cm, area 1.5 cm². As of the last time I saw him, August 27, 2013, his stage III sacral ulcer was declared healed and his left gluteus ulcer measured 3cm X 2cm X 0.1cm, for an area of 6.0 cm². This was a reduction in size in three weeks of 77%.

Patient 3, TD 97-year-old with a stage III left gluteus ulcer that as of July 8, 2013 measured 1.8cm X 2.7 cm X 0.1cm, for a surface area of 4.86 cm², she was last seen by me on August 20, 2013 where the surface area measurements were 1.0 cm², for a reduction of 80%.

This I believe to be a fair representation of BerbereX use and the type of results one can expect. It has been used on more than a 120 patients and there have been no reported side effects. I have encouraged each facility to recommend to their corporate higher ups to consider placing it on their formulary.

Sincerely,

Dr. William D. Lucky