A Comparative Second-Degree Burn Treatment Trial Collagen Dressing vs. Silver Sulphadiazine Alone

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INTRODUCTION:

Burns are thermal injuries to skin caused by flame, fluids, electricity, friction, and radiation. Any serious second-degree burn needs medical assistance. These burns are painful and erythematous. Healing process of Burn injury involves initial inflammation, followed by the recruitment of tissue forming cells to the wound-site and finally the tissue remodeling activity. Silver sulpha-diazine (SS) has been the gold standard for topical burn therapy. However recent reports suggest that the slower dermal regeneration is resulted from the cytotoxic effect of SS on dermal cells. Accordingly in the act of evaluating an alternate treatment method, a type-I collagen dressing recently approved by US-FDA has been chosen for this study. The overall objective of this study is to monitor the clinical results of the patients with significant skin burn injury who have been treated with a novel type-I Collagen wound dressing (Helicoll), approved recently by US-FDA. This randomized, controlled study is designed to assess the efficacy and safety of a novel dressing containing high purity type-I collagen, Helicoll (HC) versus commonly used 1% silver sulphadiazine cream alone (SS), in the treatment of second-degree burns. The potential of this collagen dressing to reduce pain and induce normal pigmentation are also examined.

METHODS:

43 patients (aged 1 to 57 years) of either sex, with deep second-degree burn injury ranging 8% to 40% of the body surface area (evaluated by digital photo images), were randomized to receive the type-I collagen dressing (HC) or 1% silver sulpha-diazine (SS). Twenty three (23) patients were randomly allocated to HC dressing and 22 to SS. Two patients in the SS group were lost at follow-up, thus a total of 43 patients were evaluated. In each patient, after debridement and cleaning of the burn wound with appropriate antibacterial solutions, SS cream was applied topically. Wounds were then covered with sterile gauze, which was fixed with bandages. Treatments were applied once a day until the wounds healed, but for no longer than four weeks.

HC dressing was applied once only unless the dressing got relocated and removed from the site of application.

After an initial evaluation prior to the start of treatment (Day 0), clinical signs were assessed bi-weekly for the entire duration of the treatment period.

The primary efficacy endpoint was evolution of healing (% of complete/incomplete) expressed as the total time in days required for complete healing of the wound.

RESULTS:

Time for healing was analyzed by means of the incidence rate of the event, with median time. The two treatment groups were statistically compared. Pain was analyzed in a descriptive way and the change from baseline was also evaluated. Changes from baseline for itching, impairment to movement, and patient comfort were analyzed.

All of the treated burns, other than two patients in the SS group, were healed well. It was also observed the HC dressing caused a significantly more rapid re-epithelialization of burns, i.e. a shorter time for healing, than SS group. Statistical analyses showed that median time to heal was 7.2 days in the HC group versus 14.5 days in the SS group. The recorded difference 7.3 days was statistically significant ($p = 0.005$). There was a 49.7% enhanced healing with the HC group compared to the SS group. The observation also concludes shorter time to healing caused by the HC dressing is clinically relevant and further demonstrates the wound healing activity of type-I collagen. Further the itching was significantly lesser in the HC group with 90.5% of class "low to none" compared to the 71.1% of the same class of itching in the SS group.

CONCLUSION:

The type-I collagen dressing used in this study is made up of high purity Type-I collagen, which forms a substantial part of the human tissue inter cellular matrix, was aimed at overcoming the disadvantages of SS, i.e. delayed re-epithelialization of the wound. Type-I collagen has important mechanical and structural functions and also plays a key role in wound-healing processes. Besides helping the debridement, the type-I collagen may be triggering normal inflammatory response to activate neoangiogenesis in injured tissues. The reason for the favorable results of collagen dressing in terms of preventing the bacterial infection is speculated to come through its initial binding of the topically applied bacteriostatic/antibiotic agents initially used over the burn wound. It could be attached to the large high binding surface chemistry of high purity type-I collagen and the attached drug could be releasing slowly from the collagen dressing over time.