

Vashe® Wound Therapy versus Sulfamylon® in the management of grafted burns: results of a pilot study

KN Foster, VL Tanner, KJ Richey, MA Pressman, JS Champagne, MD Peck, DM Caruso

Message:

A clinical trial was set up to determine whether Vashe Wound Therapy is an effective alternative for Sulfamylon 5%, used as an irrigant over excised and grafted burns, where tangential excision and meshed grafting had taken place at the same session. The hypotheses of the study was that Vashe Wound Therapy would be equivalent to Sulfamylon as an irrigant in controlling microbial infection, that wounds treated with both materials would have similar healing results, that the graft take and rate of reepithelialization would be similar among both groups, that the Vashe Wound Therapy patients would show a reduction in the use of analgesics or a reduction in pain per se, that Vashe Wound Therapy would be more cost effective as an irrigant than Sulfamylon, and that it would be non-inferior in terms of safety outcomes.

Methods:

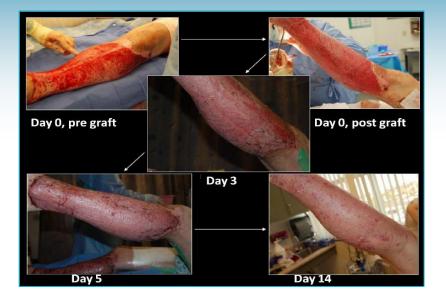
To test these hypotheses, graft take, reepithelialization, incidence of infection, pain, cost of materials used, and adverse experiences in patients who underwent tangential excision and same session autografting were evaluated. Prior to the surgical procedure, patients were randomized to Vashe Wound Therapy, or (Sulfamylon) mafenide acetate 5% solution. The grafted areas were dressed with one layer of fine mesh gauze, which was then covered with an 8-ply burn dressing. The dressing was moistened every 6-8 hours for 5 days.

Results:

Average graft take on post grafting day 14 was 97.4% and 96% respectively (p=0.92) and length of stay 21.6 and 15.6 days respectively (p=0.01). The median pain level during the study was 4.9 for both Vashe Wound Therapy and control. For wound irrigation, a total of 68.58 liters of Vashe was used, versus a total of 33.10 liters for Sulfamylon. This breaks down to approximately \$250 for the hospital per patient for Vashe and nearly \$400 for Sulfamylon. The average costs for the patient were \$1,559 and \$1,965 respectively. The safety profile for both treatment groups was equivalent.

Conclusions:

In this pilot study, <u>Vashe Wound Therapy was shown to be safe and equivalent to 5% Sulfamylon solution with regard to graft take, healing percentage and healing speed, and infection rate.</u> <u>Costs of care with Vashe</u> Wound Therapy were substantially lower and pain control was shown to be somewhat better.



Graft take and reepithelialization over the course of 14 days



Graft take and reepithelialization over the course of 14 days (same timeline as above)



Author's Reference:

Arizona Burn Center, Maricopa Integrated Health Systems, Phoenix, AZ

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