Clinical Factors and Cost Effectiveness Associated with Healing of Venous Leg Ulcers with Dehydrated Human Amnion/Chorion Membrane Allografts

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Abstract

Purpose: Venous leg ulcers (VLU) are the most common wounds of the lower extremities and are associated with significant medical costs due to their protracted healing periods. Adjunct-related treatment costs are directly related to the time to wound closure. We sought to identify clinical factors associated with healing of venous leg ulcers.

Methods: Secondary analysis of data collected in a multicenter randomized controlled trial (RCT) examining venous ulcer healing rates over a four-week period with advanced dehydrated human amnion/chorion membrane (dHACM) allograft in addition to standard multilayer compression therapy. Logistic regression analysis was performed to identify clinical factors associated with reduction in wound size of at least 40% over the four-week study period. Percent reduction in wound size with adjunctive dHACM therapy was recorded and number-needed-to-treat (NNT) calculated.

Results: In the RCT 63% (39) of patients receiving dHACM and 32% (10) of patients receiving only multilayer compression achieved ≥ 40% wound closure at week 4. Estimated healing rates at 24 weeks and NNT calculations are presented in Table 2 below. Estimated costs of dHACM and T-ESS treatment for VLUs are presented in Table 3. Despite larger VLU size at treatment initiation, costs per patient were estimated to be more than 60% less for dHACM vs. T-ESS. At least 97% of each T-ESS graft was wasted compared with 6% wastage of dHACM.

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Effect | Odds Ratio | 95% Wald Confidence Limits | p-value
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Gender (M/F) | 1.376 | 0.517 | 3.663 | 0.5277
Obese (Y/N) | 0.704 | 0.222 | 2.229 | 0.5509
dHACM (Y/N) | 1.609 | 1.361 | 9.570 | 0.0099
ES or Older (Y/N) | 1.182 | 0.405 | 3.444 | 0.7597
Wound Duration <1yr (Y/N) | 2.853 | 0.944 | 8.624 | 0.0632
Wound ≤10 cm² (Y/N) | 3.968 | 1.069 | 14.720 | 0.0394

Results

- We performed a secondary analysis of data collected during an IRB approved multicenter RCT that examined rates of VLU healing during a 4 week study period with dHACM in addition to multilayer compression vs. multilayer compression alone (n=93).
- The RCT study population consisted of patients receiving care from physicians specializing in wound care and podiatric specialists at eight out-patient wound care centers in the United States (Pennsylvania, Massachusetts, Florida, Oklahoma, Indiana, and Texas).
- A long term follow-up study conducted to evaluate if the 4 week study outcome correctly correlated with rates of complete healing within 24 weeks, showing that 80% of patients with ≥ 40% healing at 4 weeks were completely healed within 24 weeks.

Conclusion

- VLU treated with only 1 or 2 dHACM allografts were almost 4 times likely to heal 40% or more in 4 weeks than VLU treated with compression alone.
- Advanced treatments such as dHACM can accelerate VLU closure and are cost effective compared with other T-ESS.
- With an NNT of 5, these data suggest that dHACM is an effective treatment for VLU.