Dehydrated Human Amnion/Chorion Membrane Allograft as a Treatment for Stage IV Pressure Ulcers

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Abstract

Objective: Given the negative impact pressure ulcers have on health status and patient quality of life, as well as health care costs, treatments are needed that promote healing, shorten healing time, and minimize the risk of complications. Dehydrated human amnion/chorion membrane (dHACM) allografts have been shown to promote successful healing in a variety of wound types, including diabetic foot ulcers and venous leg ulcers. Our purpose was to evaluate the use of micronized, injectable, dHACM allografts as a treatment for severe, difficult to heal, Stage IV pressure ulcers.
Methods: With IRB permission, a retrospective evaluation of Stage IV pressure ulcers treated with dHACM was conducted. Chart reviews were performed for 8 patients with 12 pressure ulcers treated with dHACM. The dHACM allograft material was applied in the wound after sharp debridement, followed by standard topical dressings. The micronized powder was either sprinkled on the wound or reconstituted in 0.9% normal saline and injected into areas of tunneling. Weekly debridement as needed, dressing change and wound assessment to determine rate of closure based on complete epithelialization of prior wound bed was performed.
Results: Mean ulcer size pre dHACM treatment was 4.8 ± 6.4 cm^2, median 1.3 (0.15, 17.2). After 1 treatment with injectable dHACM, 58.3% (7/12) pressure ulcers reduced in size from baseline, while 2 ulcers increased in size and 3 did not change. For those responding to dHACM treatment, mean reduction in ulcer size after just one treatment was 33.9% ± 30.6%, median 27% (1.8, 90%).
Conclusion: These early results support the use of dHACM as a treatment for Stage IV pressure ulcers. Larger, controlled studies are needed to confirm our findings.

Background

- Stage IV pressure ulcers (PrUs) are characterized by full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures and often include undermining and tunneling.
- 95% of stage III and IV pressure ulcers do not heal within 8 weeks.[1]
- Significant complications are associated with Stage IV PrUs including pain, depression, infection, osteomyelitis, anemia, sepsis, gas gangrene, rare necrotizing fasciitis and even death. [1]
- Effective treatments which promote rapid healing create potential for improving health care outcomes and tremendous cost savings.[1]

Dehydrated Human Amnion/Chorion Membrane (dHACM)

- PURION® Processed dehydrated human amnion/chorion membrane (dHACM) has been shown to contain growth factors that help in wound healing, including PDGF-AA, PDGF-BB, bFGF, TGF-β1, EGF, VEGF, and PlGF, as well as anti-inflammatory interleukins (IL-1ra, IL-4, IL-10), and TIMP-1, TIMP-2, TIMP-4, which help regulate the matrix metalloproteinase activity. Results from *in vitro* and *in vivo* experiments established that dHACM contains factors capable of stimulating mesenchymal stem cell migration and recruitment.[2,3]
- A micronization process produces a particulate dHACM that can be sprinkled into irregular wound surfaces or reconstituted with normal saline for injection into tunneling wounds.
- In randomized controlled studies, dHACM allografts have been shown to be an effective treatment for diabetic foot ulcers and venous leg ulcers.[4,5]

dHACM = EpiFix® MiMedx Group, Inc., Marietta, GA
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Purpose

Our purpose was to evaluate the use of micronized, injectable, dHACM allografts as a treatment for severe, difficult to heal, Stage IV PrUs.

Methods

Subject Selection

- With IRB permission, a retrospective evaluation of Stage IV PrUs treated with dHACM was conducted.
- Chart reviews were performed for 8 patients with 12 PrUs treated with dHACM.
- None of the PrUs treated were hospital acquired.

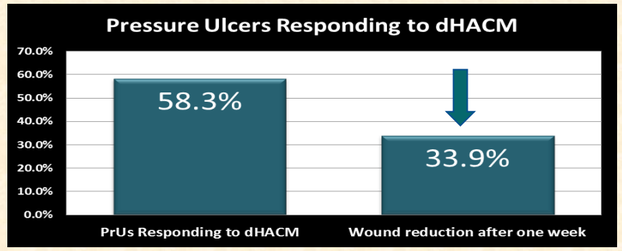
Treatment

- The dHACM allograft material was applied in the wound after sharp debridement, followed by standard topical dressings.
- The micronized powder was either sprinkled on the wound or reconstituted in 0.9% normal saline and injected into areas of tunneling.
- Wound response to one application of dHACM was assessed after 1 week.

Results

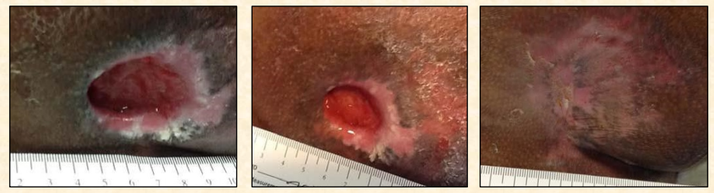
- There were 8 subjects with 12 stage IV community acquired PrUs.
- 4 males, 4 females
- Age ranged from 31-66 years (31, 33, 45, 52, 56, 57, 59, 66)
- Mean PrUs size pre dHACM treatment was 4.8 ± 6.4 cm^2, median 1.3 (0.15, 17.2).
- After 1 treatment with micronized dHACM,
  - 58.3% (7/12) PrUs reduced in size from baseline
  - 16.7% (2/12) PrUs increased in size
  - 25.0% (3/12) PrUs did not change
- For those responding to dHACM treatment, mean reduction in PrUs after just one treatment was 33.9% ± 30.6%, median 27% (1.8, 90%).

Results



Case Example

Case 7. 1st dHACM treatment. Wound measured 9.25cm^2	One week later. Wound measured 3.96 cm^2	Healed completely in 8 weeks with 4 dHACM applications.



Conclusions

- Stage IV PrUs are difficult to treat.
- These observational results support the use of dHACM as a treatment for Stage IV PrUs.
- Larger, controlled studies are warranted to assess the use of dHACM as a treatment for pressure ulcers.

References
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