Our Experience Utilizing Advanced Wound Therapy Combined with an Evidence-Based Approach to Threatening Wounds Reduces Amputations in the Caribbean Healthcare System

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Objective

- Recent published studies suggest new guidelines that indicate a pivotal clinical decision point for using advanced therapies for a wound that fails to have at least 50% closure by 4 weeks.
- Our goal is to demonstrate that use of human amniotic tissue allograft (EpiFix®), MiMedx® Group, Inc., Kennesaw, GA along with an evidence-based approach to treating lower limb wounds may help reduce amputation rates, reduces costs for the healthcare system, and improves the quality of life for veterans.

Methods

- An evidence-based approach to treating wounds in the VA was utilized to assign patients based on risk into two categories. Basic wound care principles were applied to include debridement, off-loading, infection control, and maintenance of a moist wound environment.
- Low risk patients defined as those with a new ulcer, no infection, palpable pulse, and an ABI >0.8, received advanced therapies after 4 weeks if wounds did not decrease in size by 50%. The moderate to high risk patients defined as those with documented renal disease, previous history of ulcer or amputation, elevated HgbA1C, ulcer duration of >30 days, ABI <0.8, and no local signs of infection received advanced therapy immediately.
- Characteristics of clinic population:
  - In general, Puerto Ricans had the highest percentage of persons with diagnosed diabetes among the Hispanic population.
  - From 1997 to 2010, the age-adjusted percentage of Hispanics with diagnosed diabetes increased 29% (from 9.6% to 12.4%); among Puerto Rican males, 36% (from 7.3% to 9.9%); among Puerto Rican females, 52% (from 6.3% to 9.6%). (Figure 1)

The economic burden of amputation:

- 70-80% of all diabetes related amputations were preceded by a chronic foot ulcer
- The cost of a leg amputation = $72,775 per amputation
- Prior to 2010 the San Juan VA was above the national average for 10 years for lower limb amputations in the VA healthcare system.

Our initial experience with the PURION® Processed Human Amniotic Membrane Allograft (EpiFix®):

- 20 patients received treatment with EpiFix®
- Average number of application to closure was 2.4 applications
- Based on experience with human fibroblast-derived dermal substitute (HFDDS), the cost to treat was 42% lower with EpiFix®
- The time to closure compared to our experience with HFDDS was reduced by 50%
- All 20 patients reached full closure

Economic benefits of using advanced wound therapies and an evidence-based approach:

- Recently published data suggests the 2 year cost of an amputation in the Veterans Health Care System to be $120,000.
- From 2010 to 2012 the Caribbean Healthcare System reduced their amputation rate by 58% from 90 amputations in 2010 to 52 in 2011 and 53 in 2012. (Figure 2) This reduction occurred for the first time in 11 years despite an increase in the number of ulcer encounters. (Figure 3) The amputation rate compared to ulcer encounters also fell below 3% to 1.8% in 2011 due to the dramatic reduction in amputations and remains low in 2012.
- Based on this data we estimate that our facility has saved $9 Million dollars with the reduction of amputations over the last 2 years.

Figure 1. San Juan VA amputation rate compared to ulcer encounters .

<table>
<thead>
<tr>
<th>Year</th>
<th>Amputations</th>
<th>Ulcer Encounters</th>
<th>Amputation %</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>86</td>
<td>2,857</td>
<td>3.0%</td>
</tr>
<tr>
<td>2010</td>
<td>90</td>
<td>2,833</td>
<td>3.2%</td>
</tr>
<tr>
<td>2011</td>
<td>52</td>
<td>2,967</td>
<td>1.8%</td>
</tr>
<tr>
<td>2012</td>
<td>50</td>
<td>2,389</td>
<td>2.0%</td>
</tr>
</tbody>
</table>

Conclusions

- Utilizing advanced therapies such as the PURION® Processed Human Amniotic Membrane Allograft (EpiFix®) and an evidenced based approach to treating wounds, the clinic was able to significantly reduce costs and possibly the number of amputations, resulting in an estimated savings of $9 million.
- The PURION® Processed Human Amniotic Membrane Allograft (EpiFix®) was 42% less expensive than previously utilized advanced therapies and healed patients in less time.