Varithena® VLU Registry: The Effects Of Polidocanol Endovenous Microfoam On Wound Healing And Recurrence

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Disclosure Statement of Financial Interest

• I, Raghu Kolluri, have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

• Consultant/ Advisor – UNCOMPENSATED
  • Bard/ BD, Boston Scientific, BTG, Inari, Intervene, Janssen, Medtronic, Philips, Vascular Insights, Vesper Medical

• Board Member – VIVA Physicians Inc, 501c

• Medical Director – Syntropic Core lab, 501c

Design

• Rationale: The purpose of this registry is to observe the effects of Varithena® on venous leg ulcer (VLU) healing in patients who have symptoms of chronic venous insufficiency. The impact of treatment on rate of healing, rate of recurrence, subject’s pain and quality of life will be observed.

Primary Endpoints

• Rate of epithelial migration – perimeter (mm/week) on photograph

• Wound closure at 12 ±1 weeks post-treatment

• Time from Varithena® treatment to wound closure

Design

• Up to 200 patients at up to 40 site in US and Canada

• VLU Treatment, imaging, and post-procedure care all performed according to standard of care

• Follow up visits – 1, 12 weeks, & 12 months

• Phone
  • 6 months post-treatment
  • 3 months post-wound closure

• Patients take photos of wound between visits using app

• 26 ulcer-free days in early intervention group

• 63% of patients received foam sclerotherapy in some form
  • Either as primary treatment or as an adjunct to other intervention

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Secondary Endpoints
- % wounds remaining closed 3 mo post-wound closure
- Recurrence at 6 months, 12 months post-treatment
- Ulcer free weeks
- Pain at ulcer location on numeric pain rating scale compared to baseline at 12 weeks, 6 months, 12 months
- EQ-SD QOL compared to baseline at 12 weeks, 12 months
- VCSS Baseline to 12 weeks, 12 months

Inclusion Criteria
- Men and women; age ≥18
- CEAP C6 with ≥ 3 months VLU - GSV and/or AASV
- Wound visualized in one plane. If circumferential, subject must be able to capture the entire wound using multiple photographs
- Reflux >500ms on duplex ultrasound
- Willing and able to collect wound photographs and data using a tablet
- Willing and able to return for follow-up and wound care visits
- Ability to comprehend informed consent form and complete questionnaires

Exclusion Criteria
- Contraindications to Varithena® 1% according to prescribing information
- Any serious concomitant disease that confounds wound healing
- Concomitant heat ablation, or heat ablation of index leg within 6 weeks prior to treatment with Varithena®
- Significant arterial disease or ankle-brachial pressure index (ABPI) ≤ 0.8
- In the opinion of Investigator, wound would close within 12 weeks without additional treatment

Demographics
- 54 ulcers in 50 patients
- Age, years (Mean ± SD) - 65.0 ± 13.67
- Gender, n (%) - Female 20 (40.0); Male 30 (60.0)
- Initial treatment
  - Volume injected above knee (mL): 4.4 ± 5.86
  - Volume injected below knee (mL): 8.7 ± 4.61
- Patients with Additional Treatment: 32%
  - Volume above knee (mL) 1.8 ± 4.97
  - Volume below knee (mL) 9.2 ± 4.12

Wound Characteristics
- Wound age in weeks: mean (min, max)
  - 27.5 (1, 142)
- Compression Rx duration, weeks: mean (min, max)
  - 23 (0, 229)
- Compression compliance: 87%
- Did not receive grafting: 96.3%
- Not hospitalized for target wound: 90.7%
- Previous Tx for index wound? 28%
- Previously healed? 20%
- Infection/bioburden: 14.8%
Reflux patterns

- GSV incompetence: 98.1%
- AASV incompetence: 14.8%
- Major perforator incompetence: 37%

Tissue Migration: median rate of change in perimeter (mm/week) by week from treatment

<table>
<thead>
<tr>
<th>Week</th>
<th>All Patients</th>
<th>Healed</th>
<th>Non-Healed</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>13.0 mm</td>
<td>13.8 mm</td>
<td>12.3 mm</td>
</tr>
<tr>
<td>3</td>
<td>9.7 mm</td>
<td>9.3 mm</td>
<td>10.2 mm</td>
</tr>
<tr>
<td>4</td>
<td>8.1 mm</td>
<td>8.5 mm</td>
<td>7.2 mm</td>
</tr>
<tr>
<td>5</td>
<td>5.2 mm</td>
<td>5.6 mm</td>
<td>4.2 mm</td>
</tr>
<tr>
<td>6</td>
<td>2.9 mm</td>
<td>3.3 mm</td>
<td>2.0 mm</td>
</tr>
<tr>
<td>7</td>
<td>2.0 mm</td>
<td>2.4 mm</td>
<td>1.7 mm</td>
</tr>
<tr>
<td>8</td>
<td>1.2 mm</td>
<td>1.5 mm</td>
<td>1.2 mm</td>
</tr>
<tr>
<td>9</td>
<td>0.8 mm</td>
<td>1.0 mm</td>
<td>0.5 mm</td>
</tr>
<tr>
<td>10</td>
<td>0.5 mm</td>
<td>0.8 mm</td>
<td>0.3 mm</td>
</tr>
<tr>
<td>11</td>
<td>0.3 mm</td>
<td>0.5 mm</td>
<td>0.1 mm</td>
</tr>
<tr>
<td>12</td>
<td>0.2 mm</td>
<td>0.4 mm</td>
<td>0.0 mm</td>
</tr>
</tbody>
</table>

Early boost in healing with a median reduction in perimeter of 12.4 mm/week for first two weeks; overall median reduction of 2.0 mm/week over 12 weeks.

On post-hoc analysis, even wounds that didn’t heal had a median size reduction of 1.8 mm/week over 12 weeks.

Interim Analysis

Wound Closure

- Healed at 12 weeks post-treatment: 46.3%
- Mean time to wound closure: 76.1 days

Wound Recurrence

- At the time of the interim analysis, 5 ulcers had a recurrence
- Mean 127 days to recurrence

VIEW-VLU Interim Analysis - Quality of Life

- EQ-5D-5L Index (0-1)
  - Baseline: 0.72 (N=54)
  - 12 Weeks: 0.80 (N=47)
  - 12 Months: 0.85 (N=10)
- Numeric Pain Rating Scale (0-10)
  - Baseline: 4.2 (N=50)
  - 12 Weeks: 2.1 (N=43)
  - 12 Months: 0 (N=11)

Conclusions

- For healed and non-healed wounds, there was an early surge in tissue migration measured by median reduction in wound perimeter, with continued improvement through 12 weeks post-treatment.
- Almost half the patients experienced complete wound closure within three months.
- This registry is an all-comers study, which did not exclude patients based on wound size or wound age. Therefore, results indicate that Varithena injectable polidocanol foam 1% shows promise in increasing the rate of wound healing and can be extrapolated to the general population.