BlueLeaf: Initial Experience with a Percutaneous Approach to Deep Vein Reflux

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Disclosure

Speaker name: Ramon L. Varcoe

☒ I have the following potential conflicts of interest to report:

☐ Receipt of grants/research support

Details:

☒ Receipt of honoraria and travel support

Details: Abbott, Medtronic, Intervene, Shockwave

☐ Employment in industry

Details:

☐ Shareholder in a healthcare company

Details:

☐ Owner of a healthcare company

Details:

☐ I do not have any potential conflicts of interest to report
Treatment Options for CVI

- **C2**: Outflow Obstruction
  - Palliative care
  - Invasive surgery (rare)

- **C3**: Superficial Reflux

- **C4**: Deep Vein Reflux

- **C5-C6**: Combination of above conditions
Surgical Precedence – Neovalve Construction

Neovalve construction in deep venous incompetence

Marzia Lugli, MD,* Sara Guerzoni, BS,* Mariano Garofalo, MD,† Gianluca Smedile, MD,‡ and Oscar Maleti, MD,* Modena and Rome, Italy

Objective: The purpose of this study is to assess the outcome of neovalve construction in two consecutive series of patients affected by postthrombotic syndrome and valve agenesis. The technique was modified in the second series so as to correct a cause of failure.

Summary Results

<table>
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<tr>
<th>Summary Results</th>
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<tbody>
<tr>
<td>Procedures (patients)</td>
<td>40 (36)</td>
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<tr>
<td>Median follow-up (range)</td>
<td>28.5 months (2-78)</td>
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<tr>
<td>Ulcer Healing</td>
<td>90% (3-19 weeks)*</td>
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<tr>
<td>DVT (%)</td>
<td>3 (7.5%)</td>
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* 3 Ulcers recurred during follow-up

Images: Maleti et al. EMC 2009, pg 43-163; Maleti et al. Eur J Vasc Endovasc Surg 2011;41:837-848
Endovenous Valve Formation (EVF)

- A **non-implantable**, non-surgical approach to DVR
- 16Fr Retrograde Common Femoral Access
- Controlled vein wall dissection
Theoretical Advantages of Endovenous Approach

- Any Valve Orientation
- Multilevel Valves
- Monocuspid or Bicuspid
CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use. To be used exclusively for clinical investigations.
Case Example

- 58-yo female
- Right leg symptoms
- C4 disease with pain in varicosities
- No history of DVT or outflow obstruction
- Axialized Deep Vein Reflux (>2s RT throughout fempop)
- Failed conservative therapy (compression)
Pre-Procedural Imaging
Procedural Imaging – Balloon Inflation
Procedural Imaging – Vein wall puncture
Valve Formation Imaging
Post-Formation Imaging

Leaflet

Lumen

Pocket

THE VERVE SYMPOSIUM
Procedural Results
Follow-up – 30 days

- **No occlusive DVT**
- **Thigh bruising at the 7 day follow-up (small AV fistula), settled by 14 days**
- 42%, 39%, and 11% decrease in RT in Prox FV, Dist FV, and Pop V, respectively
- 4 pt reduction in rVCSS (8 to 4)
- Modified Villalta and VEINS-QOL also trending toward improvement
Conclusion

• Creation of percutaneous neo-valves is technically feasible
• The INFINITE FIH trial of the Endovenous BlueLeaf device is ongoing
• Early safety and efficacy results will be available in February
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