One Year Outcomes of Peripheral Vascular Intervention in CLI Patients: Subanalysis of the LIBERTY 360 Study

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Disclosure

Speaker name: Jihad A. Mustapha

I have the following potential conflicts of interest to report:

- Consulting: Abbott Vascular, Bard Peripheral Vascular, Boston Scientific, Cagent Vascular, Cardiovascular Systems, Inc., Cook Medical, Medtronic, PQ Bypass, Spectranetics, Terumo Medical
LIBERTY 360° Study

• LIBERTY is a prospective, observational, multi-center study to evaluate procedural and long-term clinical and economic outcomes of endovascular device interventions in patients with symptomatic lower extremity PAD

• The LIBERTY study includes any FDA-approved technology to treat claudication and CLI

• 1,204 patients were enrolled at 51 sites in the U.S. and will be followed up to 5 years

• 4 core laboratories were utilized for independent analysis

• Endpoints include: Procedural and lesion success, Major Adverse Events (MAEs), Duplex ultrasound, Quality of life (QoL), Six-minute walk test (6MWT), Economic analysis

For this subanalysis, RC5 and RC6 subjects (N=404) were pooled and 1-year outcomes were assessed.
Target Lesion Location and Calcification

>76% of target lesions located below-the-knee. ~60% of target lesions were calcified, and 74% of calcified lesions were moderate to severely calcified.

Core lab reported lesions (Lesions with reported values may be less than total number of lesions treated in each arm)
23-May-2017 Data

### Predominant Plaque Morphology vs. Degree of Lesion Calcification

<table>
<thead>
<tr>
<th>Predominant Plaque Morphology</th>
<th>Focal</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degree of Lesion Calcification</td>
<td>&lt;180° and less than one-half of the total lesion length</td>
<td>&lt;180° and greater than one-half of the total lesion length</td>
<td>≥ 180° and less than one-half of the total lesion length</td>
<td>≥ 180° and greater than one-half of the total lesion length</td>
</tr>
</tbody>
</table>

N=556 lesions
Device Usage by Lesion

Balloon and/or atherectomy were the preferred devices with minimal bailout stenting (4.6%).

*N: 556 lesions

Hawk: Turbohawk, Silverhawk, Hawk One; **Bailout stent (due to angiographic complication or sub-optimal result (>50% residual stenosis)) is a subset of the Stent group

Core lab reported lesions (Lesions with reported values may be less than total number of lesions treated in each arm)

23-May-2017 Data
Procedural Success

In RC5-6 subjects, <50% residual stenosis in 83.6% of the subjects, and no angiographic complications in 90.7% of subjects. Additionally, procedural complications rarely (1.7%) resulted in post-procedural hospitalization and 89.1% of subjects were discharged to home.

Core lab reported lesions (Lesions with reported values may be less than total number of lesions treated in each arm)
23-May-2017 Data
Freedom from 12-Month Major Adverse Events

Considering the advanced disease state in RC5-6 subjects, there were high rates of 12-month amputation free survival (78.1%) and freedom from major amputation (89.6%).

Kaplan-Meier method used to obtain estimate of freedom from MAE
Greenwood’s method used to obtain the 95% confidence interval for the estimate
23-May-2017 Data
Primary Amputation should not be the First Line of Treatment

2016 AHA/ACC Guideline on the Management of Patients with PAD (Gerhard-Herman et al., 2016)

“An evaluation for revascularization options should be performed by an interdisciplinary care team before amputation in the patient with CLI. (Class I)”

CLI patients without revascularization (primary amputation treatment) vs. LIBERTY 360° RC5-6 CLI subjects (primary endovascular treatment)

Mustapha et al.
LIBERTY 360° Study Presentation at AMP 2016 Reveals Hope for Rutherford-6 CLI Patients. Cath Lab Digest. 2016;24(10).

This summary graph shows the primary amputation rates presented in the literature, but it is not a head-to-head comparison since the analyses described vary in design/method/etc.
Target Limb Wound Healing

*Significant improvement in number of wounds from baseline to 12 months in RC5-6 subjects.*

Mean Number of Wounds on Target Limb

![Graph showing the mean number of wounds over time](image)

N=404 subjects

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>30 days</th>
<th>6 Months</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects with reported wound data</td>
<td>404</td>
<td>324</td>
<td>235</td>
<td>207</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>1.5 ± 0.9</td>
<td>1.2 ± 1.0</td>
<td>0.7 ± 0.8</td>
<td>0.4 ± 0.7</td>
</tr>
<tr>
<td>Change from baseline</td>
<td>N/A</td>
<td>-0.3 ± 0.8</td>
<td>-0.9 ± 1.1</td>
<td>-1.2 ± 1.1</td>
</tr>
<tr>
<td>P-value</td>
<td>N/A</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Values presented as mean ± standard deviation. Mean number of wound differences assessed via paired t-test

23-May-2017 Data
Quality of Life: VascuQoL

Quality of life improved significantly, as measured by the total score and all subdomains of the VascuQoL, from baseline to 12 months ($p<0.001$).

N=404 subjects

Vascular Quality of Life Questionnaire; a PAD-specific health-related quality of life instrument
Higher subdomain scores indicate better rating of health
23-May-2017 Data
Conclusions

• Procedural complications rarely (1.7%) resulted in post-procedural hospitalization and 89.1% of RC5-6 subjects were discharged to home.

• Considering the advanced disease state in RC5-6 subjects, there were high rates of 12-month amputation free survival (78.1%) and freedom from major amputation (89.6%).

• Significant improvement in number of wounds from baseline to 12 months in RC5-6 subjects.

• Quality of life improved significantly, as measured by the total score and all subdomains of the VascuQoL, from baseline to 12 months.

• The findings in this novel all-comers PAD study reveals hope for Rutherford 5-6 CLI patients and suggest that “primary amputation” in RC5-6 may not be necessary—peripheral vascular intervention can be successful in this patient population.
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