LIBERTY 360 Study: Procedural and 30-day Outcomes of Endovascular Interventions in Patients with Symptomatic Lower Extremity Peripheral Arterial Disease

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On behalf of the LIBERTY Investigators
Consultant to:

- Abbott Vascular
- Bard Peripheral Vascular
- Boston Scientific
- Cardiovascular Systems, Inc.
- Cook Medical
- Medtronic
- Spectranetics
- Terumo
>200 million people have PAD worldwide\(^1\)

- 27 million persons suffer from CLI in North America and Europe\(^2\)
- CLI is highly prevalent in older patients with DM and/or ESRD\(^3\), and is associated with high risk of amputation and mortality\(^4\)
- Primary amputation continues to be first-line therapy in up to 67% of CLI patients\(^4-8\)
  - 73%\(^6\) had no diagnostic angiogram and 54%\(^9\) received no vascular procedure prior to the amputation
- The results following the primary amputation can be devastating
  - 27% of the patients will have one or more re-amputation(s) within 1 year\(^10\)
  - 35% will have a higher level of limb loss\(^11\)
  - 55% will get the other limb amputated within 2-3 years\(^12\)
- The mortality rates after primary amputation are very high
  - 1-year mortality rates ranging from 9% to 33%\(^10,11,13,14\)
  - 5-year mortality rates ranging from 26% to 82%\(^10,13,15\)

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 technologies to treat claudication and CLI.

- 4 core laboratories were utilized for independent analysis.

- 1,204 subjects were enrolled at 51 sites and will be followed up to 5 years.

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

LIBERTY Enrollment and 30-day Follow-up

1,204 Subjects Enrolled at 51 sites
All Comers / All Treatments

Rutherford 2-3
500 Subjects*
595 Lesions
Rutherford 2-3
474 Subjects
3.0% withdrawal/lost to follow-up
2.4% missed 30-day visit

Rutherford 4-5
589 Subjects*
744 Lesions
Rutherford 4-5
535 Subjects
5.5% withdrawal/lost to follow-up
5.8% missed 30-day visit

Rutherford 6
100 Subjects
146 Lesions
Rutherford 6
83 Subjects
7.0% withdrawal/lost to follow-up
10.0% missed 30-day visit

*Due to site closure and lack of PI signature, baseline & procedure data from 15 subjects were excluded.
Rutherford 2, N=97; Rutherford 3, N=403; Rutherford 4, N=285; Rutherford 5, N=304
Core Lab reported lesions.
LIBERTY Device Usage by Lesion

Balloon and/or atherectomy were preferred devices.

- Rutherford 2-3 (N=595)
- Rutherford 4-5 (N=744)
- Rutherford 6 (N=146)

Comparison between Rutherford categories significant (p<0.05)

*Bailout stent group is a subset of Stent group

Core Lab reported lesions.
Lesions with reported values may be less than total number of lesions treated in each arm.
LIBERTY Target Lesion Percent Stenosis

High mean pre-procedure stenosis across all Rutherford Classes and approximately 30% final percent stenosis post-PVI across all groups.

Comparison between Rutherford categories significant (p<0.05)

Core Lab reported lesions.
Lesions with reported values may be less than total number of lesions treated in each arm.
LIBERTY Runoff Vessels

*Number of runoff vessels increased post-PVI with significant improvement seen in RC4-5 and RC6 compared to RC2-3, showing the utility of PVI for even the most difficult patients.*

Comparison between Rutherford categories significant (p<0.05)
In RC6 group, <50% residual stenosis in 77.7% of the subjects, and no angiographic complications in 86.7% of subjects.

Procedural Success Endpoint

Core Lab reported lesions.
Severe angiographic complications include: Perforation, Dissection C-F, Distal Embolization, and Acute Vessel Closure
P-Values from Fisher's Exact Test.

Comparison between Rutherford categories significant (p<0.05)
Duplex Ultrasound (DUS): 30-days

High patency rate in RC2-3 subjects

- Core Lab Analyzed (VasCore)
- Collected only for Rutherford 2-3 Subjects

95.5% (n=336/352) of the RC2-3 subjects had a Target Lesion Peak Systolic Velocity Ratio (PSVR) ≤ 2.4
High freedom from TVR was reported across all Rutherford Classes (99.4% in R2-3, 96.9% in R4-5, and 97.9% in R6). More than 95% of the RC6 subjects were free from death and major amputation at 30-days, respectively. PVI may be considered as the primary option for RC6 patients, not primary amputation.

Kaplan-Meier method used to obtain estimate of freedom from MAE. Greenwood’s method used to obtain the 95% confidence interval for the estimate.
Procedural complications rarely (0.8%-2.0%) resulted in post-procedural hospitalization in all Rutherford Classes and 78% of RC6 subjects were discharged to home.
Quality of Life: VascuQoL

Quality of life improved from baseline at 30-days across all Rutherford Classes

Vascular Quality of Life Questionnaire; a PAD-specific health-related quality of life instrument

Higher subdomain scores indicate better rating of health.

Activity subdomain: Significance noted (p<0.05) in change from baseline in 2-3 vs. 4-5.

Pain subdomain: Significance noted (p<0.05) in change from baseline in 2-3 vs. 6.
Primary Amputation as a First Line of Treatment

CLI Patients without Endovascular Treatment vs. LIBERTY 360° R6 CLI Patients

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.

Conclusions

• High freedom from 30-Day Major Adverse Events (MAE: TVR, death, and major amputation) seen across all Rutherford Classes.

• Procedural complications rarely (0.8%-2.0%) resulted in post-procedural hospitalization in all Rutherford Classes and 78% of RC6 subjects were discharged to home.

• The LIBERTY 360 clinical data through 30 days demonstrated that on average PAD patients (Rutherford Class 2-6) post-PVI had favorable outcomes and improved quality of life.

• The early findings in this novel all-comers PAD study suggest that “watchful waiting” in RC2-3 and “primary amputation” in RC6 may not be necessary—PVI can be successful in this patient population as well.
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