EARLY EXPERIENCE WITH THE VENITI VICI VENOUS STENT: UPDATE ON THE VIRTUS TRIAL

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On behalf of the Virtus Venous Clinical Trial Investigators

Disclosures
- Dr. Marston is a Principal Investigator in the VIRTUS Trial (NCT02112877), receives research funding support from the study sponsor (VENITI, Inc., St. Louis, MO USA), and is a consultant to the sponsor

Iliac vein compression syndromes
- Often result in most severe venous symptoms
- Especially if result in DVT
- Intervention with stenting rapidly growing
- Current procedures employ stents designed for use in biliary or arterial systems

Desirable characteristics for a Venous Stent
- Flexibility
- Expansile strength
- Minimal shortening on deployment for accuracy
- Resistance to hyperplastic ingrowth
- Long lengths to reduce need for multiple stents

Veniti nitinol venous stent: Design characteristics
- Nitinol self expanding
- Closed cell design
- Increased density
- No gaps between struts
- 9F delivery system
- Lengths to 120 mm
- Diameters 12 to 16 mm

In vitro testing
- High radial strength
- Maintained at stent ends
- Preserved flexibility despite closed cell design
- Limited shortening on deployment
- Placement from jugular or femoral approach
Radial strength testing

- Standard bench testing method measures crush resistance of expanded stent in Newtons

Animal Study Histology:
Luminal cross sections at 180 days

- Stainless steel stent mean intimal thickness: 1.0 ± 0.5 mm
- Novel nitinol stent mean intimal thickness: 1.2 ± 0.6 mm

Viniti VICI™ Venous Stent System: VIRTUS Trial

Objective
- Assess Efficacy and Safety in achieving patency of target venous lesions through 60 months post stent placement

Study Design
- Prospective, multicenter, single-arm nonrandomized study

Subject Population
- Up to 200 subjects ≥ 18 years old with clinically significant chronic nonmalignant obstruction of the iliofemoral venous segment

Procedure Characteristics

Target lesions (n = 54)
- Common Iliac Vein: n = 27
- External Iliac Vein: n = 18
- Common Femoral Vein: n = 9
- Length of target lesion: 118.8 ± 67.8 mm

Most involved multiple venous segments
Stenting with Veniti Vici Venous Stent

Pre-Procedure

Post-Procedure

CAUTION: Investigational device. Limited by United States law to investigational use.

Pre- and Post-Intervention Stenosis (n = 30)

- Pre-procedure lesion stenosis  81.8 ± 23.3%*
- Post-procedure lesion stenosis  8.1 ± 20.9%

* Pre-procedure target lesion stenosis for one subject was unavailable at the time of reporting

Safety and Efficacy

Composite Major Adverse Event  3.3%
- 1 device- or procedure-related DVT in non-target vessel segment

Efficacy data was not analyzed for this report and is pending core lab adjudication

Preliminary Conclusions

- Feasibility subjects are younger than population reported in literature (44.5 years vs. 60 years)  
- Most feasibility subjects are female and white (similar to literature reports)  
- Stenting with the VICI Venous Stent resulted in substantial reduction in outflow obstruction  
- Stenting with the VICI Venous Stent appears to be safe in the short-term

Principal Investigators for VIRTUS Trial for the Feasibility Cohort:
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