ABRE IDE **Study**: Baseline Demographics

Erin murphy, MD
Sanger Heart and vascular
Atrium health
Charlotte, NC, USA

Disclosure

Speaker name: Erin Murphy, MD FACS

.....

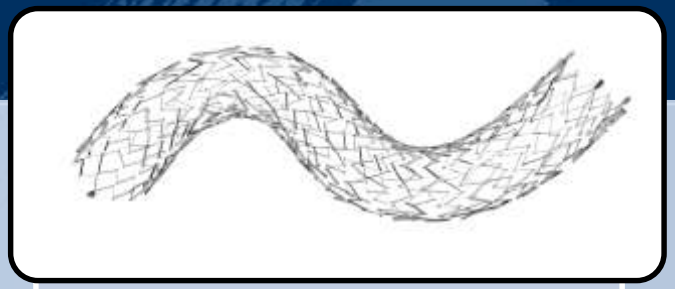
I have the following potential conflicts of interest to report:

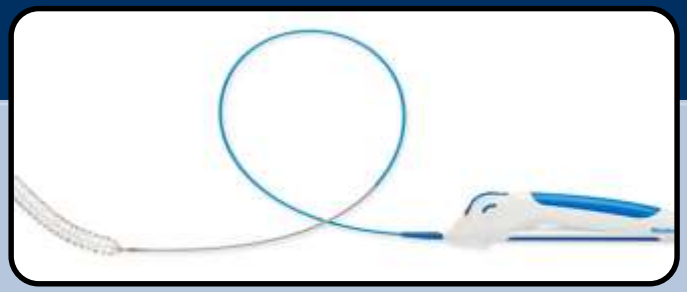
- [X] Consulting: Medtronic, Boston Scientific, Philips, Vesper, Cook
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest

PRODUCT SPECIFICATIONS:

ABRE™ Venous Self-Expanding stent \ Stent system





Stent

- Nitinol: Nickel-titanium alloy
- Self-expanding
- Open cell with three off set connection points
- 10-20 mm diameters
- 40, 60, 80, 100, 120, and 150 mm lengths

Stent Delivery System

- Over-the-wire
- 9 Fr, 0.035” guide wire compatible
- Triaxial catheter (inner shaft, retractable sheath, and an isolation sheath)
- Thumbwheel actuated deployment

Study Design

Purpose & design	Prospective, multi-center, single-arm, non-randomized study to evaluate the safety & effectiveness of the Abre venous stent system for treatment of symptomatic iliofemoral venous outflow obstruction in patients with venous occlusive disease
Principal Investigators	Erin Murphy, MD (USA), Stephen Black, MD (UK)
Sample size	**200 subjects** (US n=128, EU n=72) (first patient Dec. 2017 - last patient Nov. 2018)
Study sites	**24** Global study sites (France, Germany, Ireland, Italy, UK, and US)
Follow-up	Through **36 Months, 12 month follow-up now complete**
Patient populations	• Post-thrombotic syndrome (**PTS**) • Non-thrombotic iliac vein lesion (**NIVL**) • Acute deep vein thrombosis (**aDVT**)
Target lesion location	• Common iliac vein (**CIV**) • External iliac vein (**EIV**) • Common femoral vein (**CFV**)
Primary endpoints	• Primary effectiveness: **Primary patency at 12 months** • Primary safety: **Major adverse events at 30 days**

STUDY CENTERS:

24 TOTAL CENTERS: 8 EU, 16 US

Mr. Black
St. Thomas Hospital
London, UK

Dr. Murphy
Carolinas Med Ctr
Charlotte, NC

Dr. Bandula
University College
London, UK

Prof. Sapoval
Hop. Eur. G.Pompidou
Paris, France

Dr. Gasparis
SB Univ Hospital
Stony Brook, NY

Dr. Ross
Piedmont Atlanta Hos
Atlanta, GA

Dr. Hartung
Hôpital Nord
Marseille, France

Dr. Berland
NYU Langone MC
New York , NY

Dr. Gibson
Lake Washington Vasc
Bellevue, WA

Dr. Rundback
Holy Name Med
CtrTeaneck, NJ

Dr. Jalaie
University Hospital
Aachen, Germany

Dr. Bjarnason
Mayo Clinic
Rochester, MN

Dr. Hnath
Albany Med Center
Albany, NY

Dr. Ting
Mount Sinai Hospital
New York, NY

Dr. Lichtenberg
Klinikum Arnsberg
Arnsberg, Germany

Dr. DeFreitas
NC Heart and Vascular
Raleigh, NC

Dr. Khan
Cardiac Center Texas
McKinney, TX

Dr. Williams
UM Health System
Ann Arbor, MI

Dr. Lugli
Hesperia Hospital
Modena, Italy

Dr. Dexter
Sentara Vascular
Norfolk, VA

Dr. Kolluri
OHR Methodist Hosp
Columbus, OH

Dr. O'Sullivan
Galway Univ. Hosp
Galway, Ireland

Dr. Gagne
The Vascular Experts
Darien, CT

Dr. Razavi
Saint Joseph Hospital
Orange, CA

Key inclusion criteria

- Between ≥ 18 and ≤ 80 years of age
- At least one of the following clinical manifestations (i.e., symptoms and/or signs) of venous disease in lower extremity:
  - CEAP score ≥ 3
  - Venous Clinical Severity Score (VCSS) pain score ≥ 2
  - Suspected deep vein thrombosis (DVT)
- Obstructive lesion defined as occluded or ≥50% reduction within the CIV, EIV and/or CFV
- Acute DVT patients treated within 14 days after onset of symptoms after first undergoing successful treatment of acute thrombus (<30% residual thrombus)

KEY EXCLUSION CRITERIA

- Patient is pregnant
- Symptomatic PAD in target limb
- Known / suspected systemic infection
- Planned + intervention w/in 30D or contralateral iliofemoral lesion requiring treatment within 12M
- Requires additional venous procedures during index proc
- Active vasculitic inflammatory disorder
- Impaired renal function or on HD
- Abnormal platelet / WBC counts
- Bleeding diathesis or HIT
- Known hypersensitivity or contraindication to antiplatelets anticoagulation or nitinol, or a contrast sensitivity that cannot be adequately pre-medicated
- Severe co-morbid conditions
- Participating in another investigational drug or device study or obs competitive study
- Previously placed stent in the ipsilateral venous vasculature
- Disease that precludes safe advancement of venous stent to target lesion(s)

ABRE Study: Baseline Data

Baseline Demographics and Medical History

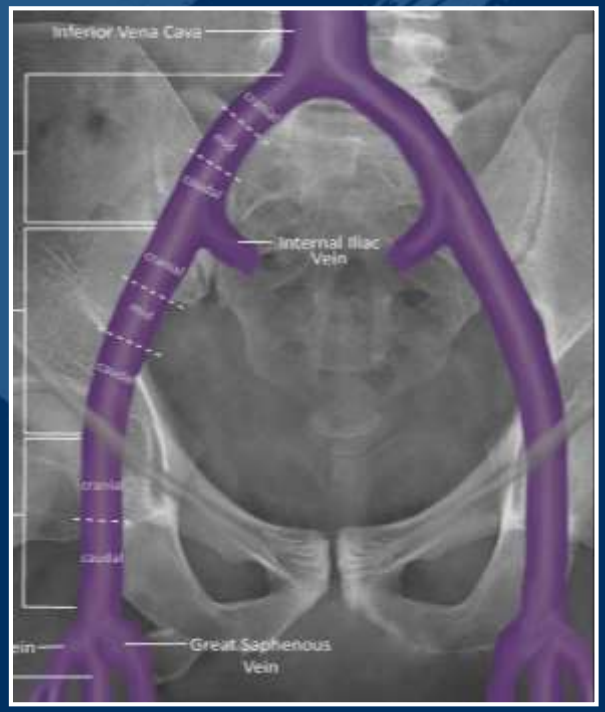
Demographics	Included Subjects (n = 200)
Age (years) (Mean ± SD)	51.5 ± 15.9
Female	66.5% (133/200)
White	78.5% (157/200)
BMI (kg/m^2) (Mean ± SD)	29.5 ± 7.1

Medical History	Included Subjects (n = 200)
Previous history of DVT	52.0% (104/200)
Target limb	96.2% (100/104)
Non-target limb	11.5% (12/104)
Venous claudication	30.0% (60/200)
Known family history of DVT	22.0% (44/200)
Pulmonary embolism	17.0% (34/200)
Thrombophilia	11.0% (22/200)
IVC filter present	5.0% (10/200)
Hypertension	31.0% (62/200)
Cancer (ongoing or remission)	11.0% (22/200)
Smoking (active)	12.0% (24/200)

Clinical Characteristics

Clinical Characteristics	Included Subjects
Primary indication	
Post-thrombotic syndrome	47.5% (95/200)
Non-thrombotic iliac vein lesion	36.0% (72/200)
Acute DVT	16.5% (33/200)
Target limb - Left limb	92.0% (184/200)
Target limb CEAP classification*	
C0 - No visible or palpable signs of venous disease	1.2% (2/166)
C1 - Telangiectasias or reticular veins	0.6% (1/166)
C2 - Varicose veins	2.4% (4/166)
C3 - Edema	61.4% (102/166)
C4a - Pigmentation or eczema	13.3% (22/166)
C4b - Lipodermatosclerosis or atrophie blanche	6.6% (11/166)
C5 - Healed venous ulcer	6.6% (11/166)
C6 - Active venous ulcer	7.8% (13/166)
Target limb VILLALTA score (Mean ± SD)	11.1 ± 5.7
Target limb VCSS score (Mean ± SD)	8.8 ± 4.7

Procedural Characteristics



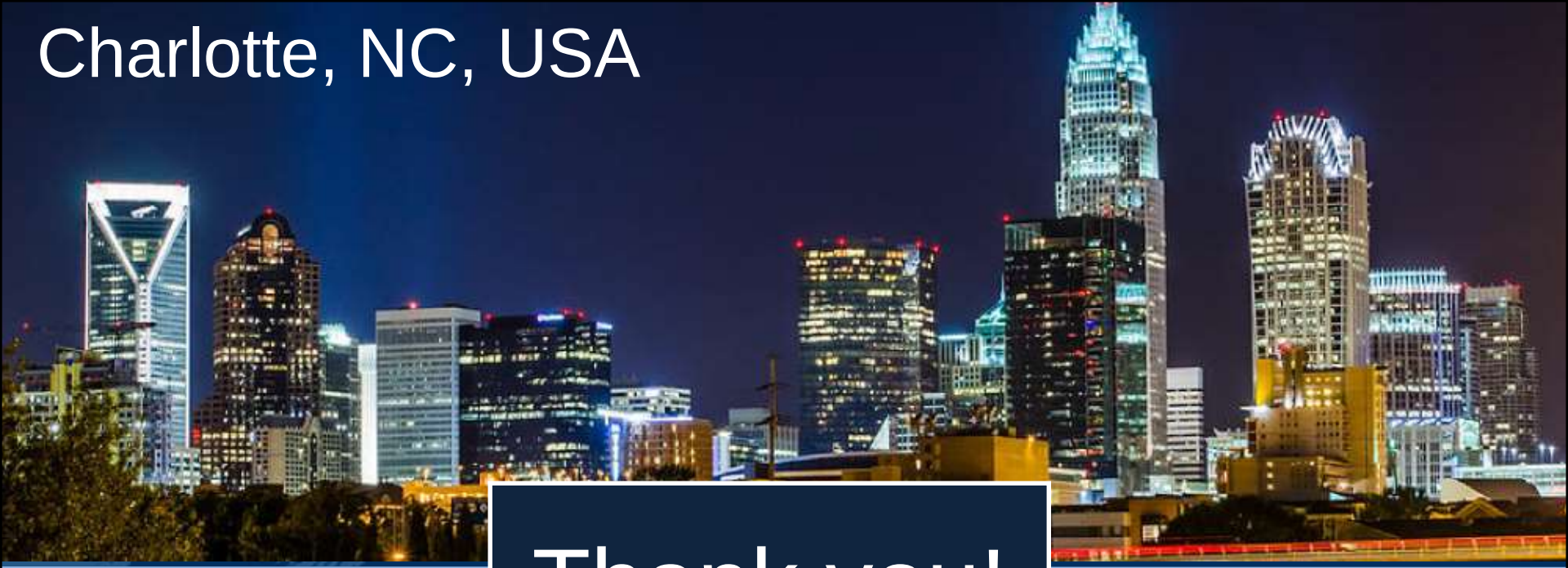
Procedural Characteristics	Included Subjects (n = 200)
Disease extent	
Common iliac vein	91.5% (183/200)
External iliac vein	66.5% (133/200)
Common femoral vein	39.5% (79/200)
Access limb	
Ipsilateral limb	94.5% (189/200)
Contralateral limb	5.5% (11/200)
Access site	
Femoral	49.0% (98/200)
Common femoral	23.5% (47/200)
Popliteal	20.0% (40/200)
Internal jugular	3.5% (7/200)
Superficial vein	2.5% (5/200)
Other	1.5% (3/200)
Procedure time (mins) (Mean ± SD)	69.0 ± 36.6
Fluoro time (mins) (Mean ± SD)	15.8 ± 14.6
Hospital stay (days) (Mean ± SD)	1.5 ± 2.2

Conclusions

- The ABRE Study is evaluating the safety and effectiveness of the Abre venous stent system for treatment of symptomatic iliofemoral venous outflow obstruction
- Enrollment was completed in <12 months, and the study includes all primary patient disease categories: PTS, NIVL, and acute DVT
- The ABRE Study baseline demographic data are as expected*
- 12-month primary endpoint follow-up is complete and data release expected at CX 2020

Age	~50 y/o
Gender	Predominantly female (~60%)
Symptoms	Pain Lower extremity edema Skin changes CEAP C3/C4
Lesion Location	Majority in left limb (~70%)

Charlotte, NC, USA



Thank you!

Carolinas HealthCare System

ABRE IDE **Study**: Baseline Demographics

Erin murphy, MD
Sanger Heart and vascular
Atrium health
Charlotte, NC, USA