Abre Study: 12-month data update

Erin H. Murphy, MD FACS

Sanger Heart and Vascular, Atrium Health

Charlotte, NC

Disclosure

Speaker name: Erin H. Murphy, MD FACS

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I have the following potential conflicts of interest to report:

- [x] Consulting: Medtronic, Philips, Boston Scientific, Gore, Cordis
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

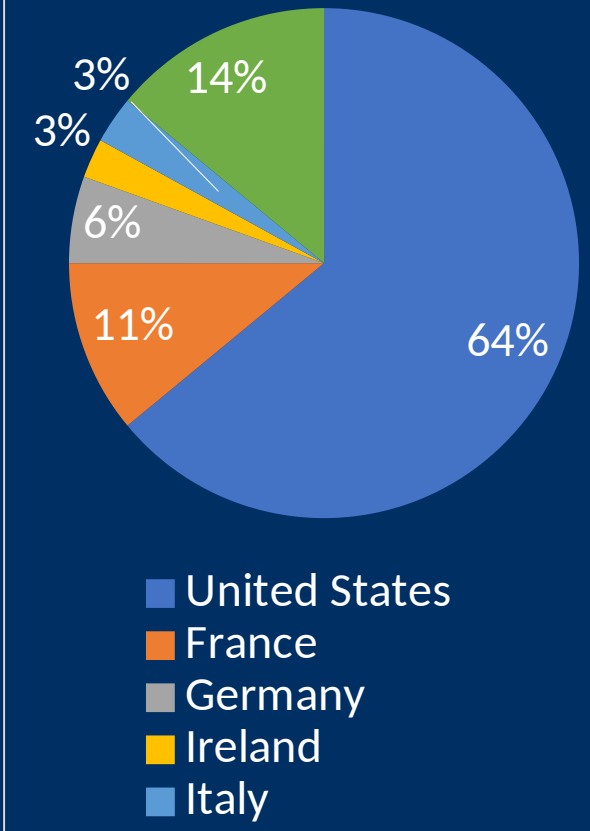
- [ ] I do not have any potential conflict of interest

ABRE Study Design (Pivotal IDE)

Purpose	Evaluate the safety and effectiveness of the Abre™ venous self-expanding stent system for treatment of symptomatic iliofemoral venous outflow obstruction
Design	Prospective, multi-center, non-randomized, single-arm ▪ 200 subjects ▪ 24 global sites - 16 US sites and 8 EU sites (France, Germany, UK, Ireland, Italy) ▪ 1-, 6-, 12-, 24-, & 36-months follow-up
Global Principal Investigators	Stephen Black, MD St. Thomas' Hospital, London Erin Murphy, MD Carolinas Medical Center, North Carolina USA
Initial Clinical Presentation[1]	Post-thrombotic syndrome (PTS) Non-thrombotic iliac vein lesion (NIVL) Acute DVT (aDVT)
Primary Endpoints	(1) Safety: Major adverse events (MAEs) at 30 days, including all-cause death, clinically significant pulmonary embolism, major procedural bleeding complication, stent thrombosis, and stent migration (2) Effectiveness: Primary Patency at 12 months, defined as freedom from occlusion and ≥50% restenosis of the stented segment of the target lesion and freedom from clinically driven target lesion revascularization
Secondary Endpoints	▪ Acute success (device success, lesion success, procedure success) ▪ Primary assisted patency and secondary patency ▪ Target lesion revascularization ▪ Major adverse events and major bleeding complications ▪ Stent fracture and delayed stent migration ▪ VEINES-QOL/Sym, EQ-5D, Villalta, and VCSS assessments
Independent Analysis	▪ Duplex Ultrasound (DUS) analysis: VasCore ▪ Venography, X-ray, and Intravascular Ultrasound (IVUS) analysis: Syntactx Core Laboratory ▪ Clinical Events Committee (CEC): Adjudicated select AEs and Clinical Endpoints ▪ Data Safety Monitoring Board (DSMB): Ensured continued safety of study and well-being of subjects

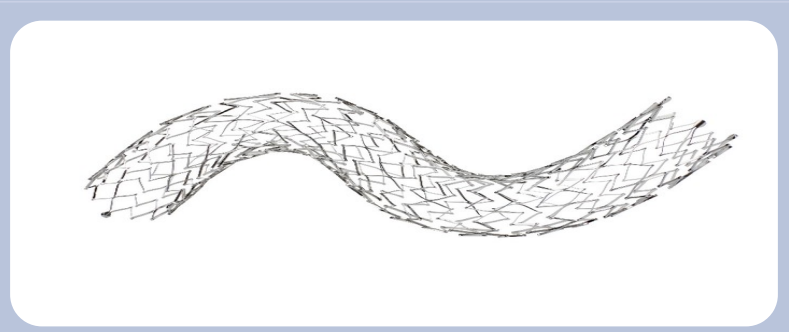
[1]Assigned by clinician based on their evaluation.

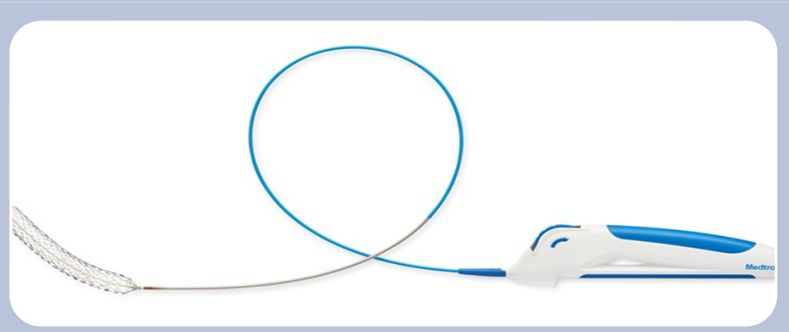
Enrollment by Country



Abre Venous Self-Expanding Stent System

Product Specifications





Stent

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

Delivery System

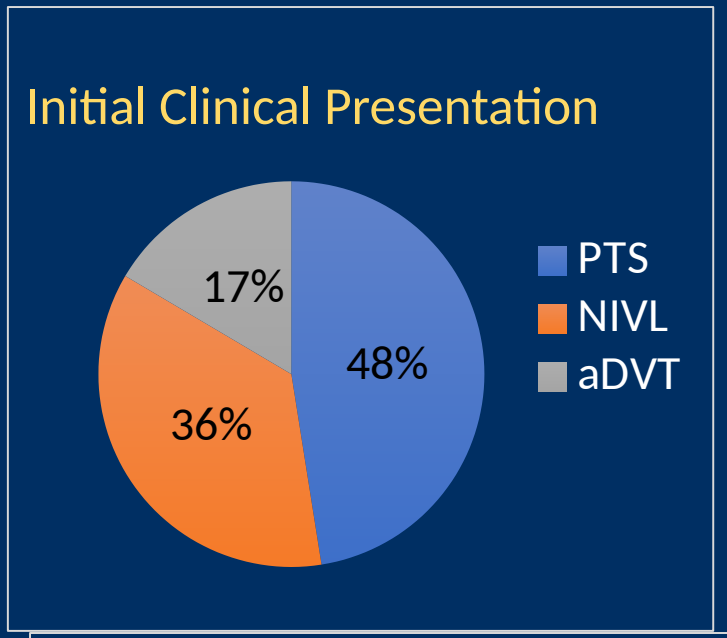
- Over-the-wire
- 9 Fr, 0.035” guide wire compatible
- Triaxial catheter (inner shaft, retractable sheath, and an isolation sheath)
- Thumbwheel actuated deployment

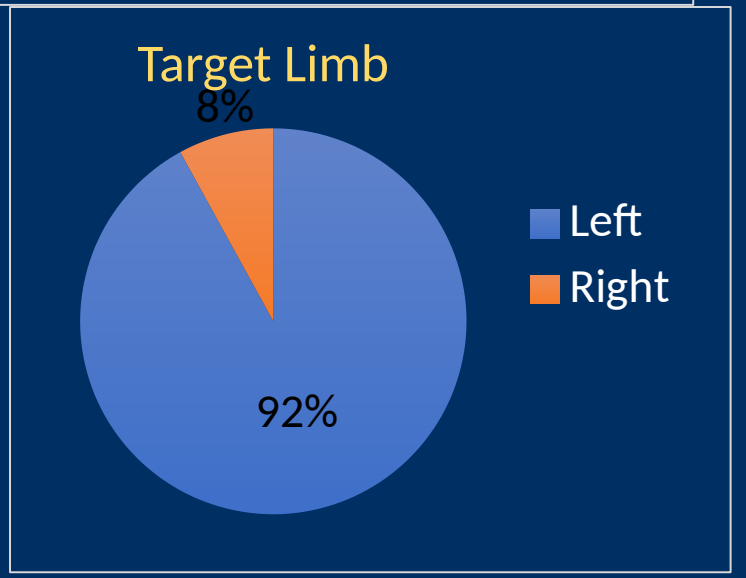
Baseline Patient Characteristics

Demographics	
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	
Previous history of VTE	52.0% (104/200)
Hypertension	31.0% (62/200)
Venous claudication	30.0% (60/200)
Known family history of DVT	22.0% (44/200)
Pulmonary embolism	17.0% (34/200)
Smoking (active)	12.0% (24/200)
Thrombophilia	11.5% (23/200)
Cancer (ongoing or remission)	11.0% (22/200)
IVC filter present	5.0% (10/200)

VTE=Venous thromboembolism





Baseline Patient Characteristics

Thrombotic Patients

Medical History – Previous History of VTE		
	PTS	aDVT
	87.4% (83/95)	33.0% (11/33)
Target Limb	100% (83/83)	72.7% (8/11)
Deep Vein	100% (83/83)	100% (8/8)
Iliofemoral	62.7% (52/83)	62.5% (5/8)
Femoral	43.4% (36/83)	37.5% (3/8)
Popliteal	28.9% (24/83)	0.0% (0/8)
Other	13.3% (11/83)	12.5% (1/8)

Medical History – Known Family History of DVT	
PTS	aDVT
28.4% (27/95)	21.2% (7/33)

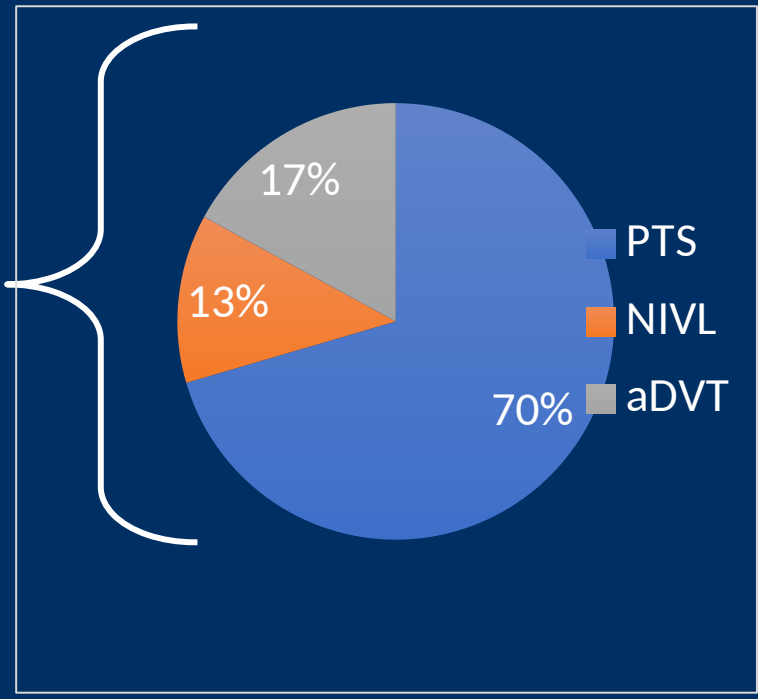
Medical History – History of Pulmonary Embolism	
PTS	aDVT
26.3% (25/95)	15.2% (5/33)

Procedural Data

Assessment	
Reference vessel diameter (mm) (Mean ± SD)	15.0 ± 2.7
% Area stenosis (Mean ± SD)*	74.9 ± 16.8
% Diameter stenosis (Mean ± SD)	62.8 ± 28.7
Lesion length (mm) (Mean ± SD)	112.4 ± 66.1
Total stented length (mm) (Mean ± SD)	134.3 ± 58.0
Number of Abre stents implanted per subject	1.5 ± 0.6
Stented vein location†	
Common iliac vein	96.0% (192/200)
External iliac vein	80.5% (161/200)
Common femoral vein	44.0% (88/200)

Of those subjects presenting with PTS, 35.5% (33/93) had complete occlusion confirmed by core lab.

CFV Stented (n=88)



Challenging population treated in the ABRE Study:
stents in 88 subjects (44%) extended below the inguinal ligament.

Data from IVUS
†Site data was used when core laboratory data was not available, stent extended across the locations

Primary Safety and Effectiveness Endpoints

Primary Safety Endpoint	Results	Performance Goal	p-value
Rate of MAEs within 30 days[1]	2.0% (4/200)	12.5%	<0.0001

Primary Effectiveness Endpoint	Results	Performance Goal	p-value
Primary Patency at 12 Months[2]	88.0% (162/184)	75.0%	<0.0001

Primary safety and effectiveness endpoints were met.

[1]Major adverse events (MAEs) include all-cause death occurring post-procedure, clinically significant PE, procedural major bleeding, stent thrombosis confirmed by imaging as assessed by core lab & stent migration confirmed by imaging as assessed by core lab

[2]Primary patency defined as freedom from occlusion of the stented segment of the target lesion, restenosis ≥50% of the stented segment of the target lesion, and clinically-driven target lesion revascularization

Note: 95.5% (191/200) subjects completed the 12-moth follow-up visit

Major Adverse Events Within 30 Days

Primary Safety Endpoint Components	
MAEs within 30-Days	2.0% (4/200)
All-cause death occurring post-procedure	0.0% (0/200)
Clinically significant pulmonary embolism	0.5% (1/200)
Major bleeding complication (procedural)	0.0% (0/200)
Stent thrombosis	1.5% (3/200)
Stent migration	0.0% (0/200)

All-cause death, clinically significant pulmonary embolism and bleeding complications were CEC adjudicated; stent thrombosis and stent migration were reported by the imaging core laboratory.

All 30-day MAEs occurred in PTS subjects.

Primary Patency at 12 Months

Primary patency at 12 months (%, n)			
All Subjects	PTS	NIVL	aDVT
88.0% (162/184)	79.8% (67/84)	98.6% (68/69)	87.1% (27/31)

Primary patency at 12 months for subjects where stent extended into CFV (%, n)			
All Subjects	PTS	NIVL	aDVT
78.0% (64/82)	71.9% (41/57)	100.0% (11/11)	85.7% (12/14)

Secondary Endpoints

Acute Success Results

Acute Success	
Device Success[1]	100.0% (302/302)
Lesion Success[2]	100.0% (200/200)
Procedure Success[3]	99.0% (198/200)

Two PTS subjects had confirmed stent thrombosis MAEs prior to hospital discharge within 30 days.

[1]Device success: Successful delivery and deployment of the Abre stent in the target lesion with successful removal of the delivery system.

[2]Lesion Success: Venographic evidence of <50% final residual stenosis of the stented segment of the target lesion after post-dilation, when applicable, and as assessed by core laboratory. If core laboratory is unable to assess the venographic evidence, site reported procedure form "post-stenting" data will be used.

[3]Procedure Success: Lesion success without procedure-related MAEs prior to hospital discharge within 30 days.

Secondary Endpoints

Primary Assisted Patency, Secondary Patency, and MAEs

Secondary Endpoints at 12 Months	
Primary Assisted Patency[1]	91.8% (169/184)
Secondary Patency[2]	92.9% (171/184)
MAEs	6.1% (12/197)
All-cause death occurring post-procedure	1.0% (2/197)
Clinically significant pulmonary embolism	0.5% (1/195)
Major bleeding complication (post-procedural)	0.5% (1/195)
Stent thrombosis	4.1% (8/195)
Stent migration	0.0% (0/195)

[2]Secondary patency: patency of the stented segment of the target lesion after subsequent intervention for an occlusion

The majority of the MAEs reported at 12 months occurred in PTS subjects (91.7%).

One stent thrombosis occurred in a NIVL subject (8.3%).

Secondary Endpoints

Stent Fractures & Delayed Stent Migration

Secondary Endpoint at 12 Months	
Number of stents with fracture	0.0% (0/270)

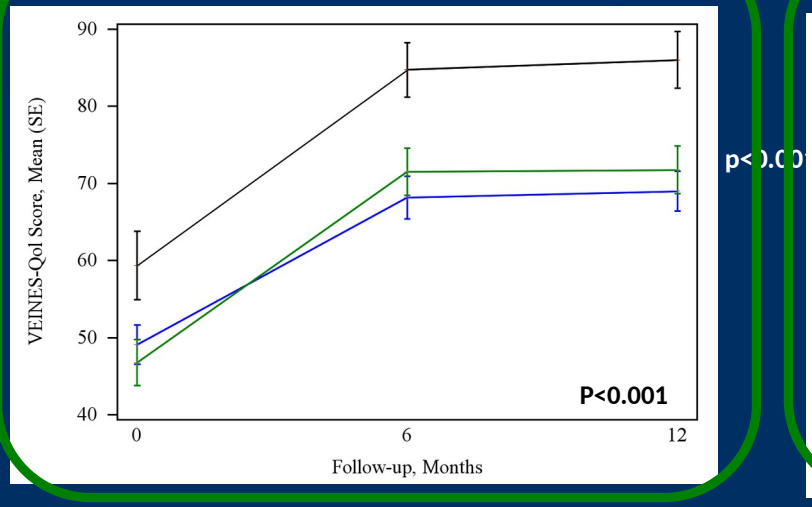
Secondary Endpoint at 12 Months	
Delayed stent migration[1]	0.0% (0/271)

[1]Position change of a venous stent observed with an imaging modality >1 cm from its original location at the conclusion of the index procedure, as determined with regard to a reference anatomic structure.

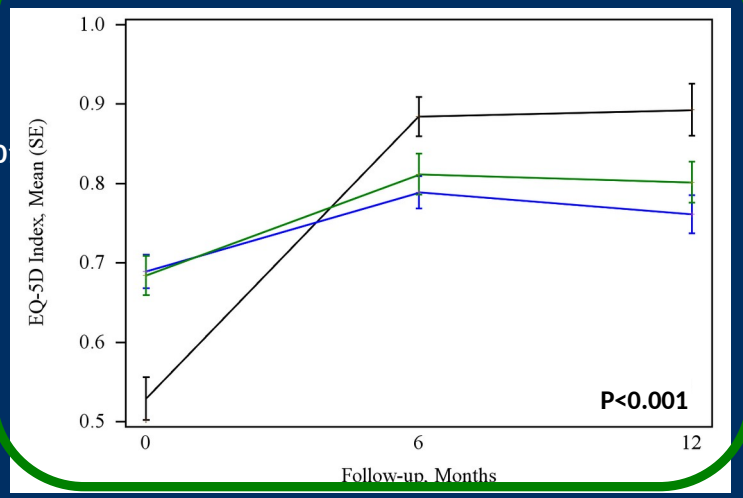
No stent **fractures** or delayed stent **migration** reported through 12 months.

Secondary Endpoints

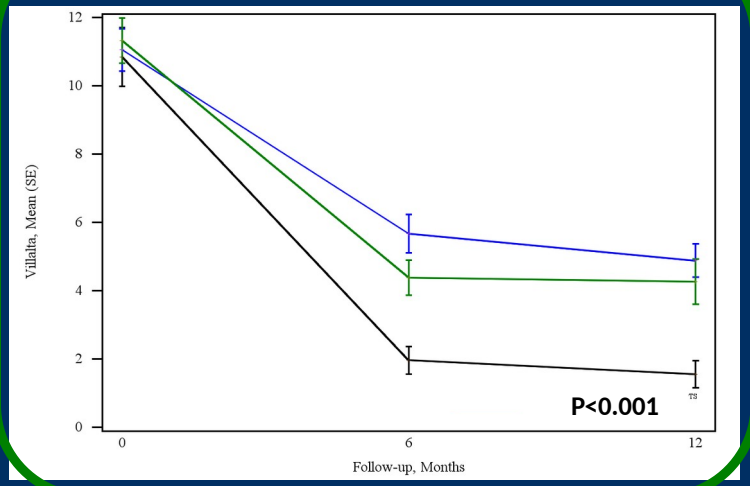
VEINES-QOL Results



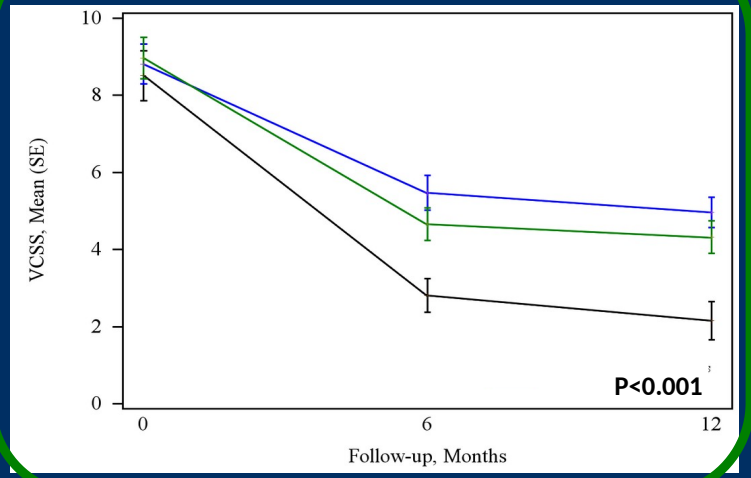
EQ-5D Index QOL Results



Villalta Results



VCSS Results



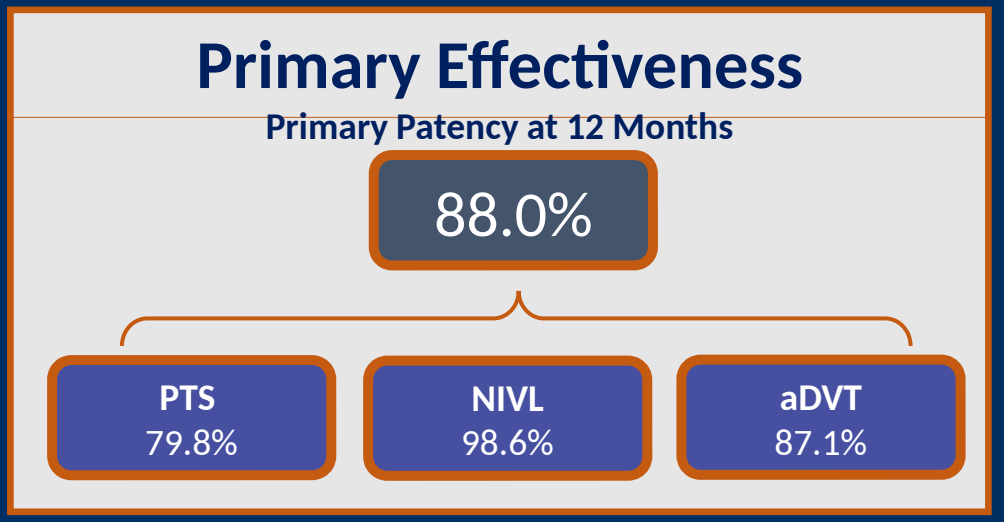
Demonstrated **clinically meaningful** & **sustained** improvements in QOL measures and venous functional assessment scores at 12 months compared to baseline.

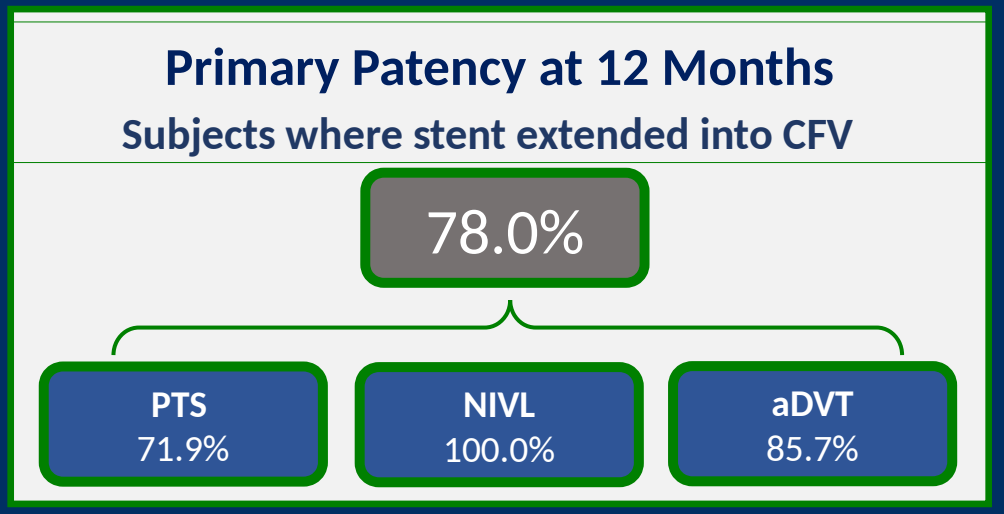
Key:

- PTS
- NIVL
- aDVT

Conclusions

- ABRE trial enrolled a real-world population with all patient disease states causing iliofemoral venous obstruction, including PTS, NIVL and DVT, which were represented in proportion to reported prevalence rates in the general population.
- Primary safety and primary effectiveness endpoints were met.
- 100% device success was achieved.
- A challenging population was enrolled with:
  - → Nearly half (95) of the patients categorized as having post-thrombotic disease.
  - → 88 subjects having a stent extending *below* the inguinal ligament, of which 62 were post-thrombotic subjects.
- No stent fractures and no delayed stent migrations were observed.
- All patient groups demonstrated sustained and clinically meaningful improvements in QoL measures and venous functional assessment scores at 12 months compared to baseline.
- Follow-up continues through 3 years.





Thank you