Clinical outcomes of endovascular treatment of ambulatory PAD for 4 French and 6 French femoral access strategies – full cohort analysis of the BIO4AMB multicenter, controlled trial

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On behalf of the BIO4AMB Investigators

Disclosure - I have the following potential conflicts of interest to report

- **X** **Research grant Consulting**
- ○ **Employment in industry**
- ○ **Stockholder of a healthcare company**
- ○ **Owner of a healthcare company**
- ○ **Other(s)**
- ○ **I do not have any potential conflict of interest**

Ambulatory Treatment Today

Just getting started in Europe

From the Society for Clinical Vascular Surgery

Office-based endovascular suite is safe for most procedures

Krishna Jain, MD, John Munn, MD, Mark C. Rummel, MD, Dan Johnston, MD, and Chris Longton, RN,
Kalamazoo, Mich

Ann Vasc Surg 2014; 28: 137–143

Clinical and Economic Evaluation of Ambulatory Endovascular Treatment of Peripheral Arterial Occlusive Lesions

Bénédicte Albert,[1] Jean-Michel Davaine,[1,2] Marie-Pierre Chaillet,[3] Gaël Grimandi,[4] Béatrice Guyomarch,[5] Laure Azéma,[1,6] Alain Costargent,[1] Philippe Chaillou,[1] Philippe Patra,[1,6] and Yann Gouëffic,[1,6] Nantes, France

33rd Annual Meeting of the French Society for Vascular and Endovascular Surgery

Ambulatory Versus Conventional Hospitalization for the Treatment of Peripheral Arterial Disease with Endovascular Techniques (AMBUVASC): Perioperative Clinical Results

Lucie Salomon Du Mont, Jean-Luc Pin, Jean Sabatier, Yves Alimi, Eric Steinmetz, Pierre-Edouard Magnan, Simon Rinckenbach, Olivier Marret, Alain Cardon, Jean-Pierre Favre, Bénjamin Kretz, Beatrice Delasalle, Yann Gouëffic

French Guidelines for the Management of Ambulatory Endovascular Procedures for Lower Extremity Peripheral Artery Disease

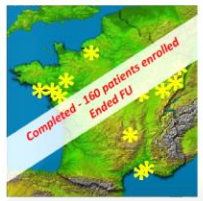
Yves Alimi,[1,2] Alexandra Hauguel,[3] Laurent Casbas,[4] Pierre-Edouard Magnan,[5] Jean-Luc Pin,[6] Jean Sabatier,[7] Olivier Régnard,[8] and Yann Gouëffic,[3,9,10] On behalf of the French Society of Vascular and Endovascular Surgery (SCVE), Marseille, Nantes, Toulouse, Dijon, Rouen, and Trelaze, France

Annals of Vascular Surgery
Volume 59, August 2019, Pages 248-258

AMBUVASC trial

ClinicalTrials.gov identifier: NCT02581150

French multicenter randomized and controlled medico-economic trial to evaluate the efficiency of outpatient endovascular PAD intervention



Investigator initiated study

PI: Prof. Yann Gouëffic

Sponsor: Nantes univeristy hospital

13 centers : CHU de Nantes, CHU de Rennes, CH de La Roche sur Yon, CHU de Dijon, CH de Colmar, Clinique de l'Europe, Rouen Clinique Océane, Vannes Clinique de la porte de l'Orient, Lorient CHU de Besançon, CHU de Strasbourg, Hôpital Nord AP-HM La Timone AP-HM, CHU de Saint Etienne.

Funding source: PRME 2014

Take home message

- **Ambulatory hospitalization for PAD endovascular treatment is safe**:
  - Similar perioperative results in term of clinical outcomes
  - No re-hospitalization within the first 24h in the ambulatory groups
- **Ambulatory is less expensive and more efficient (Qualys) from the societal and CPAM prospectives**

Presented by Prof. Yann Gouëffic (Nantes, France)

Medizinische Universität Graz

Ambulatory Treatment Today

Well established in the US

In 2008, Medicare modified reimbursement rates to encourage more efficient outpatient use of PVI in the United States.

A total of 39,339 Medicare beneficiaries underwent revascularization for PAD between 2006 and 2011. The rate of PVI declined in inpatient settings from 209.7 to 151.6 per 100,000 Medicare beneficiaries ($p < 0.001$), whereas the rate expanded in outpatient hospitals (184.7 to 228.5; $p = 0.01$).

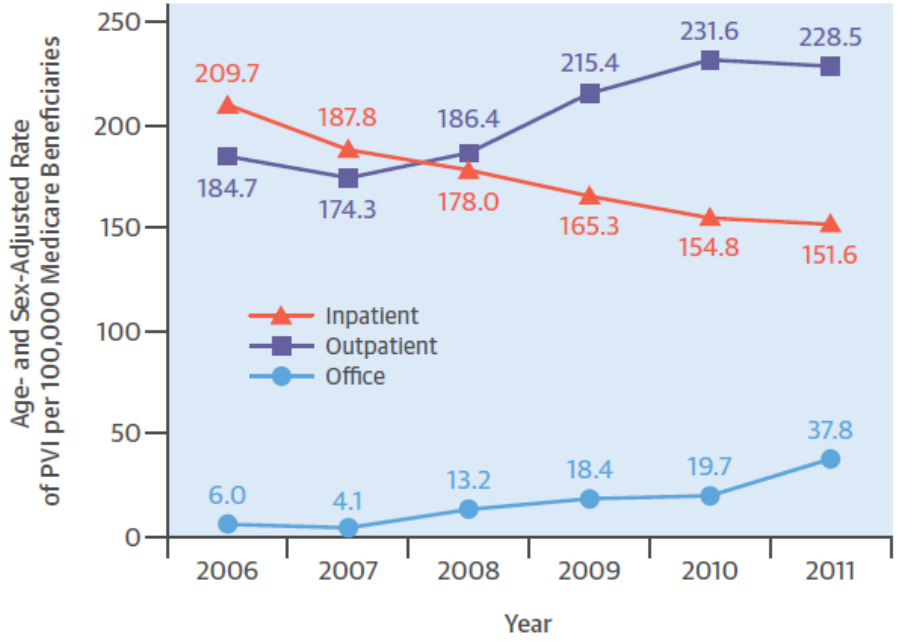


TABLE 4 Total Costs of Peripheral Vascular Intervention by Procedure, Setting, and Year*

Setting	2006	2007	2008	2009	2010	2011
Atherectomy						
Inpatient	11,342 ± 4,295	11,688 ± 4,094	12,583 ± 4,568	13,122 ± 5,511	12,945 ± 6,896	11,446 ± 6,383
Outpatient	2,763 ± 1,920	3,226 ± 2,291	5,720 ± 3,732	6,790 ± 3,909	7,204 ± 4,142	8,680 ± 4,970
Office	–†	–†	–†	–†	–†	13,478 ± 4,768
Stent						
Inpatient	11,589 ± 4,179	11,960 ± 4,796	11,994 ± 3,825	12,550 ± 4,634	12,901 ± 6,351	12,466 ± 7,077
Outpatient	4,367 ± 2,541	4,562 ± 2,756	6,012 ± 3,329	6,858 ± 3,356	7,341 ± 3,693	5,982 ± 3,639
Office	1,678 ± 1,724	1,432 ± 1,502	5,402 ± 2,643	5,543 ± 2,292	5,542 ± 1,914	6,379 ± 2,986
Angioplasty						
Inpatient	11,044 ± 3,736	11,554 ± 3,904	11,796 ± 3,739	11,820 ± 4,674	11,623 ± 3,590	13,197 ± 4,711
Outpatient	2,374 ± 1,441	2,361 ± 1,568	2,734 ± 1,670	3,164 ± 1,738	3,437 ± 1,902	3,742 ± 2,014
Office	3,789 ± 1,520	3,511 ± 1,478	3,781 ± 1,566	3,472 ± 1,400	3,546 ± 1,551	4,800 ± 2,028

Values are in U.S. dollars and are presented as mean ± SD. *Costs include professional and facility costs and patient deductibles and coinsurance. †The Centers for Medicare & Medicaid Services cell size suppression policy stipulates that no cell containing data for fewer than 11 observations may be displayed.

Jones et al. JACC VOL . 65 , NO. 9, 2015, Trends in PVI Among Medicare Beneficiaries

BIO4AMB Study Design

BIO4AMB

DESIGN:

Controlled, multicenter, non-inferiority trial to compare the rate of access site complications (ASC) in 4 French (4F) vs. 6 French (6F) femoral access endovascular interventions of lower extremity peripheral artery disease in an outpatient setting

STUDY GOALS:

To evaluate ambulatory PAD treatment and the occurrence of ASC using 4F or 6F femoral access devices

PRIMARY ENDPOINTS:

- Peri- and post-procedural access site complications [1]

SECONDARY ENDPOINTS:

- Ambulatory failure[2]
- MAE

[1] Access site complications are defined as a composite of:1- Groin hematoma (larger than 5 cm in diameter, visible by sonography, and haemoglobin decrease <3 g/dL) 2-Pseudoaneurysm 3-Groin as well as retroperitoneal bleeding (defined as requiring acute intervention for haemostasis, need for blood transfusions, or haemoglobin decrease > 3 g/dL) 4-AV fistula (visible by shunting in colour coded sonography between the common femoral artery and vein) 4-Arterial dissections at access site (visible with fluoroscopy or sonography as a membrane causing stenosis in the vessel lumen) 5-Thrombosis 6- VCD related ASCs

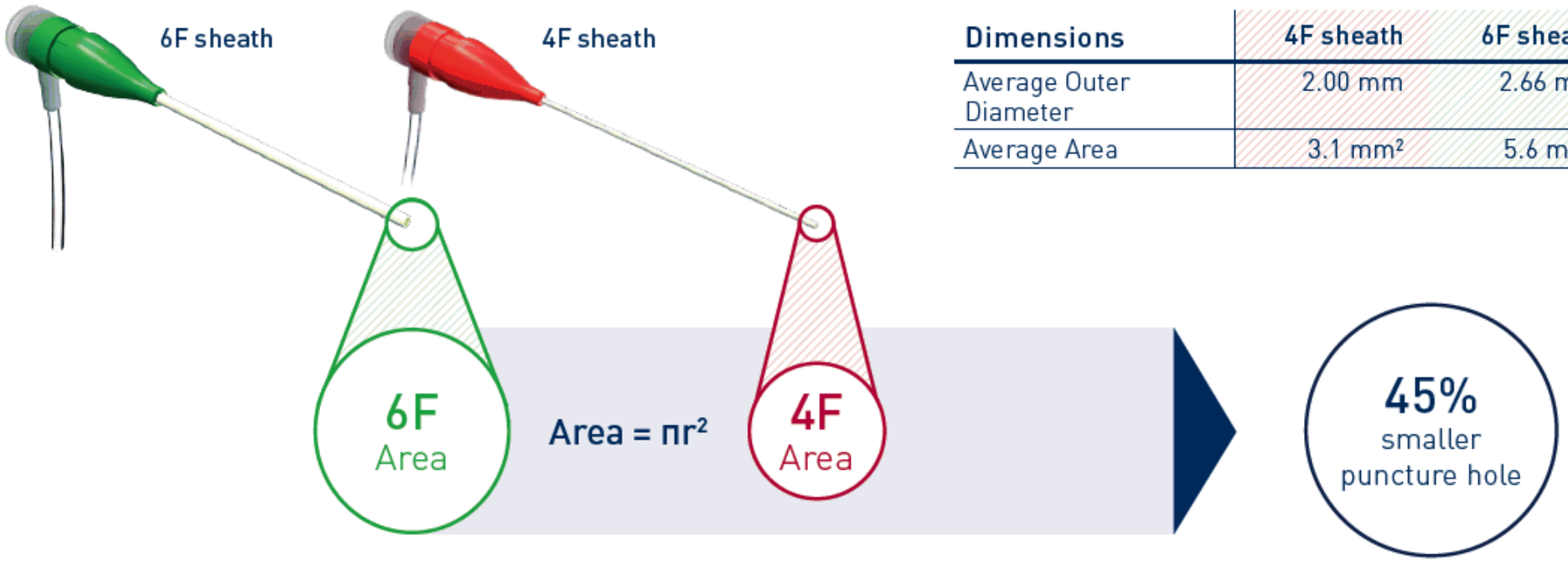
[2] Ambulatory failure is described as unplanned overnight hospitalization

*Single Monitoring Visits missing due to COVID-19. Therefor small changes possible for final report

Subjects with major protocol violations where excluded from all presented evaluations

4 French vs 6 French

Comparison of Puncture Size



Dimensions	4F sheath	6F sheath
Average Outer Diameter	2.00 mm	2.66 mm
Average Area	3.1 mm²	5.6 mm²

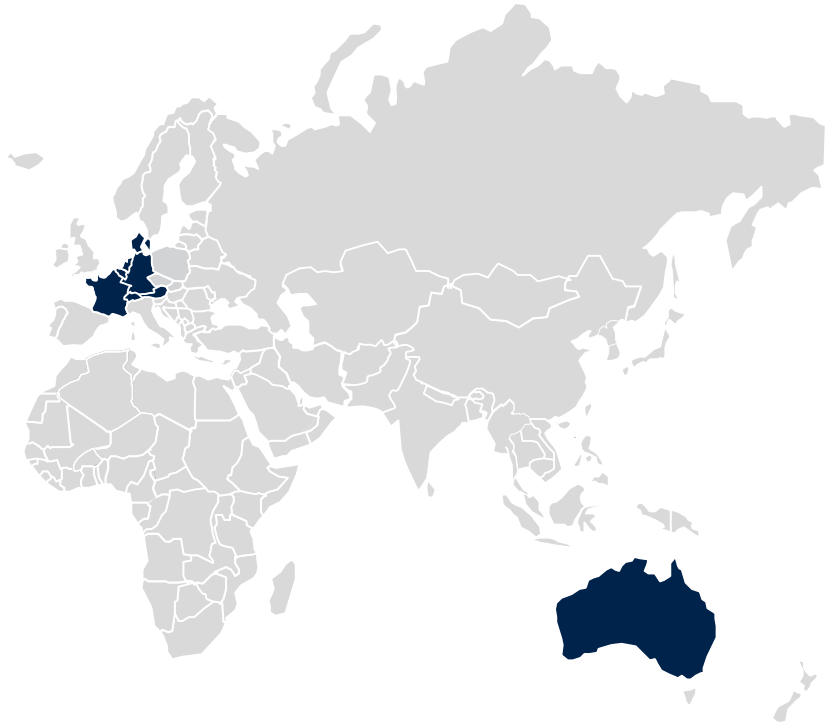
Smaller puncture hole may…

- reduce need for Vascular Closure Devices
- lower rate of access site complications

➢ **have potential for ambulatory treatment**

BIO4AMB Study Sites

Austria	**Prof. Marianne Brodmann (CCI)**	**University Clinic Graz**
Switzerland	**Prof van den Berg (CCI)**	**Ospedale Regionale di Lugano**
Belgium	**Dr. Koen Deloose (SCM)**	**AZ Sint Blasius Hospital**
France	**Pr Steinmetz (SCM)**	**CHU de Dijon - Hôpital Le Bocage**
Australia	Dr Manfred Spanger	Box Hill Hospital, Melbourne
Australia	Dr Shirley Jansen	Sir Charles Gairdner Hospital Perth
Australia	Dr Carsten Ritter	Fiona Stanley Hospital, Perth
Australia	Dr Vikram Puttaswamy	Royal North Shore Hospital
Australia	Pr Bibombe Patrice Mwipatayi	Hollywood Private Hospital
Australia	Dr. Mark Jackson	Gold Coast Private Hospital, Gold Coast Public Hospital
Austria	Prof. Klaus Hausegger	LKH Klagenfurt
Belgium	Dr. Jean-francois De Wispelaere	Cliniques Universitaires de Mont Godinne
Belgium	Dr. Jos Vandekerhof	Jessa Ziekenhuis
Belgium	Dr. Lieven Maene	OLVZ Aalst
Belgium	Dr. Jürgen Torsten Verbist	Imelda Hospital
Belgium	Dr David Lambrechts	AZ Heilige Familie
Denmark	Dr Flemming Randsbaek	Regionshospitalet Viborg
France	Pr Steinmetz	CHU de Dijon - Hôpital Le Bocage
France	Pr Eric Ducasse	CHU de Bordeaux - Hôpital Pellegrin
France	Dr Raphael Coscas	Hôpital Ambroise Paré
France	Pr Pascal Desgranges	Hôpital Henri Mondor
France	Pr Ludovic Berger	CHU de Caen
France	Dr Jonathan Sobocinski	CHU de Lille
France	Dr Gilles Miltgen	Clinique Axium
France	Dr Bahaa Nasr	CHU de Brest
France	Dr Fabrice Schneider	CHU de Poitiers - Hôpital Jean Bernard
France	Dr Pierre Jules Delannoy	Clinique du Tonkin
France	Dr Olivier Regnard	Clinique Saint Joseph
France	Dr Armand Bourriez	Clinique de l'Europe
France	Dr Sébastien Veron	Hôpital Privé de la Loire
France	Pr Simon Rinkenbach	CHU de Besancon
France	Dr Adrien Kaladji	CHU de Rennes
France	Dr Didier Paneau	Hôpital Albert Schweitzer
France	Dr Laurent Casbas	Clinique Rive Gauche
Germany	Prof. Dr. Johannes Dahm	Herz- und Gefäßzentrum Göttingen



Demographics

Baseline Patient Information

Total Subjects	4F N=361*	6F N=405*	P-value
Male (n, %)	260 (72.0%)	310(76.5%)	0.152
Age	69.93 ± 10.67	69.03 ± 10.55	0.242
Smoking (n, %)	273 (75.6%)	311 (76.8%)	0.705
BMI[1]	26.81 ± 4.39	27.01 ± 4.52	0.558
Diabetes (n, %)	106 29.4%)	135 (33.3%)	0.238
Hypertension (n, %)	289 (80.1%)	326 (80.5%)	0. 879
Renal disease (insufficiency)(n, %)	82 (22.7%)	65 (16.0%)	0.019
History of PAOD	206 (57.1%)	244 (60.2%)	0.372
Hyperlipidemia (n, %)	214 (59.3%)	286 (70.6%)	0.001
Previous peripheral intervention/surgeries	168 (46.5%)	197 (48.6%)	0.561

[1] N here does not include the patients with missing values
*Single Monitoring Visits missing due to COVID-19. Therefor small changes possible for final report
Subjects with major protocol violations where excluded from all presented evaluations

Lesion Location and Characteristics

Baseline Lesion Information

Total Lesions	4F N=516	6F N=608	P-value
Common femoral (n, %)	23 (4.5%)	31 (5.1%)	0.616
SFA (n, %)	293 (56.8%)	346 (56.9%)	0.966
Popliteal artery (n, %)	73 (14.1%)	107 (17.6%)	0.116
BTK (n, %)	98 (19.0%)	80 (13.2%)	0.008
Other (n, %)	29 (5.6%)	44 (7.2%)	0.273
Total Lesions	**N=516**	**N=608**	
Calcification[1](moderate/heavy) (n, %)	101/104 (19.8%/20.4%)	178/106 (29.4%/17.5%)	0.002
TASC Classification[1](C/D) (n, %)	127/83 (24.8%/16.2%)	129/90 (21.3%/14.9%)	0.335
Thrombus present (n, %)	70 (13.6%)	73 (12.0%)	0.434

[1] N here does not include patients with missing values
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Safety and Efficacy

Primary Endpoints ITT and Propensity Score Matched

Total Subjects (subject based)	**4F**	**6F**	**P-value**
• **ITT**	**N=356**	**N=402**	
• **Propensity Score Matched**	**N=304**	**N=305**	
Freedom from Access Site Complications[1] (subject based, %)			
• ITT	346 (97.2%)	389 (96.8%)	0.734
• Propensity Score Matched	294 (96.7%)	294 (96.4%)	0.830
ASCs (event based) **ITT / Propensity Score Matched**			
Groin hematoma (>5cm)	4 / 4	4 / 4	
Pseudo-aneurysm	5 /5	6 / 5	0.851
Groin as well as retroperitoneal bleeding	1 / 1	2 / 1	0.985
Arterial dissections	0 / 0	1 / 1	
Thrombosis	1 / 1	0 / 0	

The primary endpoint was tested for potential confounding effects by propensity score matching.

Neither in the ITT nor in the Propensity Score Matched analysis was any significant difference seen.

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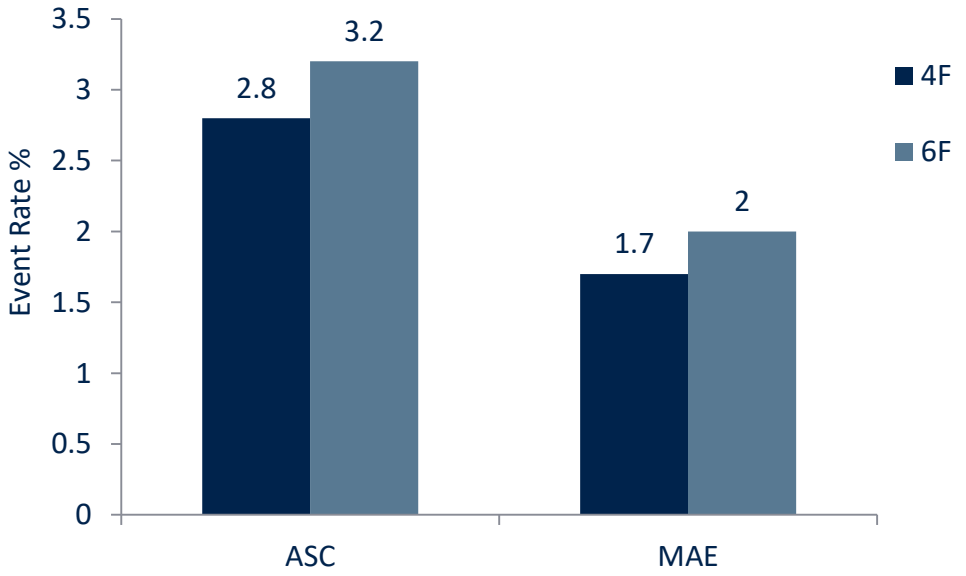
Safety and Efficacy

Primary and Secondary Endpoints ITT Population

Total Subjects	**N=356**	**N=403**	**P-value**
Major Adverse Events (subject based, %)	6 (1.7%)	8 (2.0%)	0.794
MAE (event based)			
Clinically driven TLR	6	6	>0.999
Major target limb amputation	1	0	0.470
Procedure or device related death	0	2	0.501



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Safety and Efficacy for selected Subgroups

Primary and Secondary Endpoints Subgroups

Subgroup	Endpoint	4F	6F	P-value
ITT Full Cohort	➢ Freedom from ASC (subject based, %)	346 (97.2%)	389 (96.8%)	0.734
	➢ MAE (subject based, %)	6 (1.7%)	8 (2.0%)	0.794
	➢ Discharge same day	343 (95.0%)	383 (94.6%)	0.782
CFA & SFA	➢ Freedom from ASC (subject based, %)	194 (96.5%)	216 (96.9%)	0.843
	➢ MAE (subject based, %)	3 (1.5%)	3 (1.3%)	>0.999
	➢ Discharge same day	194 (95.1%)	213 (95.5%)	0.838
BTK	➢ Freedom from ASC (subject based, %)	36 (100%)	17 (100%)	N/A
	➢ MAE (subject based, %)	1 (2.8%)	0 (0%)	>0.999
	➢ Discharge same day	34 (91.9%)	17 (100%)	0.227
Popliteal	➢ Freedom from ASC (subject based, %)	29 (93.5%)	32 (94.1%)	0.924
	➢ MAE (subject based, %)	0(0%)	0 (0%)	N/A
	➢ Discharge same day	28 (90.3%)	31 (91.2%)	0.905

• Single Monitoring Visits missing due to COVID-19. Therefor small changes possible for final report
Subjects with major protocol violations where excluded from all presented evaluations

Safety and Efficacy for selected Subgroups

Primary and Secondary Endpoints

Subgroup	Endpoint	4F	6F	P-value
Age >65	➢ Freedom from ASC (subject based, %)	235 (96.7)	249 (96.5)	0.904
	➢ MAE (subject based, %)	4 (1.6)	4 (1.5)	>0.999
	➢ Discharge same day	231 (94.3)	247 (94.6)	0.863
Diabetics	➢ Freedom from ASC (subject based, %)	101 (98.1)	131 (97.0)	0.619
	➢ MAE (subject based, %)	1 (1.0)	2 (1.5)	>0.999
	➢ Discharge same day	100 (94.3)	129 (95.6)	0.667
Female	➢ Freedom from ASC (subject based, %)	95 (94.1)	90 (94.7)	0.837
	➢ MAE (subject based, %)	3 (3.0)	2 (2.1)	>0.999
	➢ Discharge same day	93 (92.1)	91 (95.8)	0.279
Antegrade Access	➢ Freedom from ASC (subject based, %)	249 (98.0)	237 (97.1)	0. 513
	➢ MAE (subject based, %)	4(1.6)	4 (1.6)	>0.999
	➢ Discharge same day	242 (94.5)	232 (93.9)	0.771

* Single Monitoring Visits missing due to COVID-19. Therefor small changes possible for final report

Summary & Conclusion

- Within the range of this study, ambulatory treatment is a valid and safe option for endovascular treatment of lower extremity peripheral artery disease

- 4 French compatible products show similar results when compared to the already well-established 6 French devices and are a valid alternative based on patient need and physician preference, while avoiding the additional need of a VCD.

➢ Further studies and a deeper look into the health economic aspects of outpatient treatment for PAD are needed to better define the appropriate patient population that profit most from ambulatory procedures and a minimized hospital stay.