

Immediate and one-month results from a prospective real-world multicentre clinical practice of **CAS** using the **CGuard** embolic prevention system: the **IRONGUARD 2** study

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I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

X I do not have any potential conflict of interest

CLINICAL RESEARCH INTERVENTIONS FOR HYPERTENSION AND STROKE

Thirty-day results from prospective multi-specialty evaluation of carotid artery stenting using the CGuard MicroNet-covered Embolic Prevention System in real-world multicentre clinical practice: the IRON-Guard study



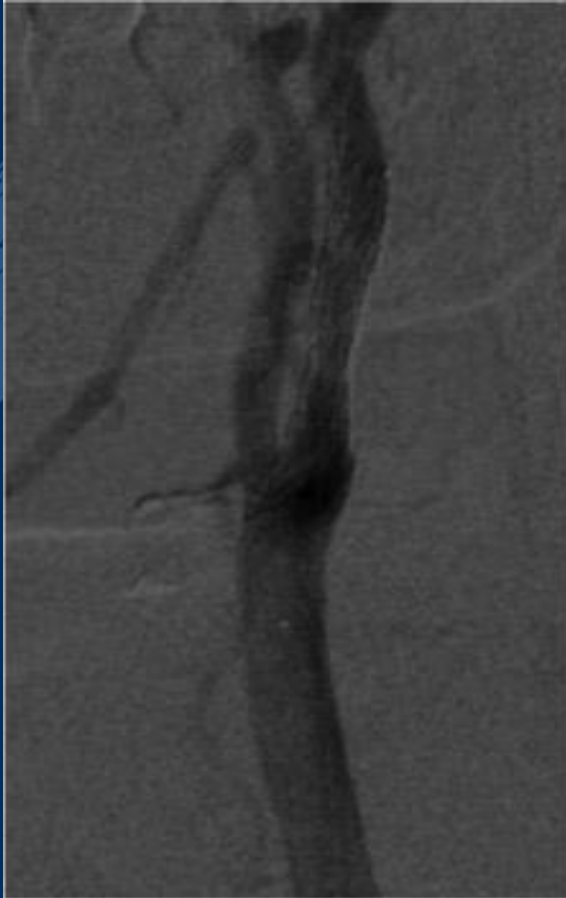
Francesco Speziale¹, MD; Laura Capoccia^{1*}, MD; Pasqualino Sirignano¹, MD; Wassim Mansour¹, MD; Chiara Pranteda¹, MD; Renato Casana², MD; Carlo Setacci³, MD; Federico Accrocca⁴, MD; Domenico Alberti⁵, MD; Gianmarco de Donato³, MD; Michelangelo Ferri⁶, MD; Andrea Gaggiano⁷, MD; Giuseppe Galzerano³, MD; Arnaldo Ippoliti⁸, MD; Nicola Mangialardi⁹, MD; Giovanni Pratesi⁸, MD; Sonia Ronchey⁹, MD; Maria Antonella Ruffino¹⁰, MD; Andrea Siani⁴, MD; Angelo Spinazzola¹¹, MD; Massimo Sponza¹², MD



CGUARD™
Carotid Embolic Prevention System

InspireMD

Starting Point



April 2015 – June 2016
200 enrolled patients
Technical Success: 100%

MACCE=0
5 minor strokes
2 TIAs

EuroIntervention. 2018





CGUARD™
Carotid Embolic Prevention System

InspireMD

SHORT REPORT

PERIPHERAL INTERVENTIONS

Twelve-month results of the Italian registry on protected CAS with the mesh-covered CGuard stent: the IRON-Guard study



Laura Capoccia*, MD; Pasqualino Sirignano, MD; Wassim Mansour, MD; Enrico Sbarigia, MD; Francesco Speciale, MD

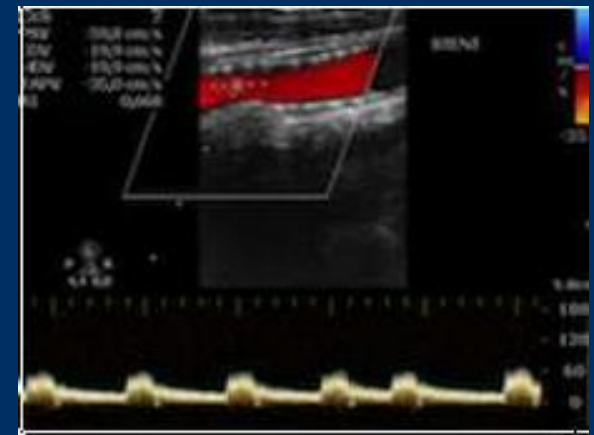
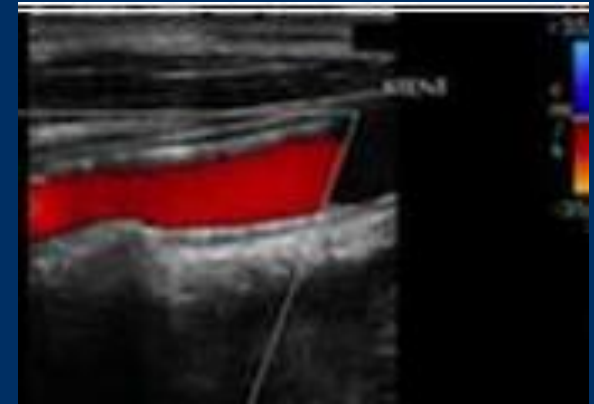
Vascular and Endovascular Surgery Division, Department of Surgery "Paride Stefanini", "Sapienza" University of Rome, Rome, Italy

This paper also includes supplementary data published online at: http://www.pcronline.com/eurointervention/143rd_issue/206

No major neurological event

No stent thrombosis

No ECA occlusion



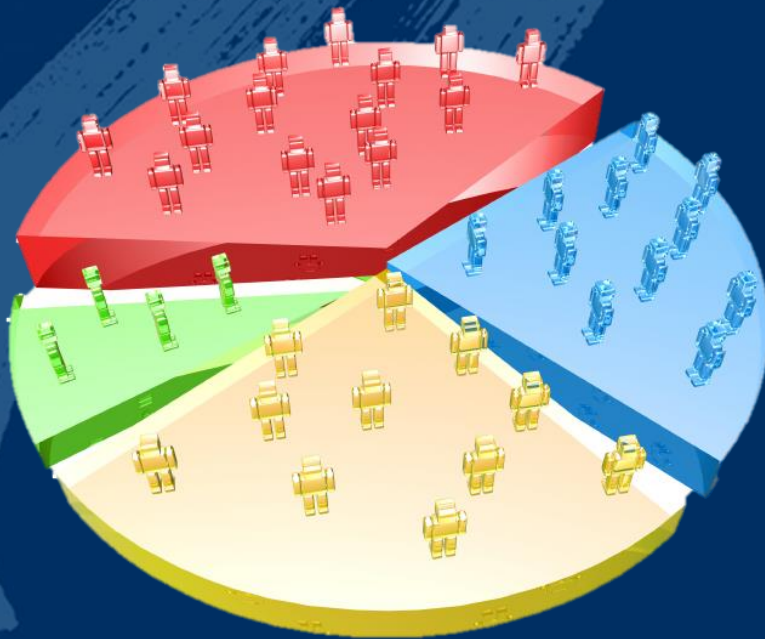
NEW registry:

733 Patients

in 20 enrolling Italian Centers



Demographic



Age: 73.03 ± 7.84yy (48-97)

Male Gender: 516 (70.39%)

Tobacco Abuse:	439 (58.52%)
Diabetes:	264 (36.01%)
Hypertension:	622 (84.85%)
Dyslipidemia:	429 (58.52%)
CAD:	278 (37.92%)

Unpublished Data

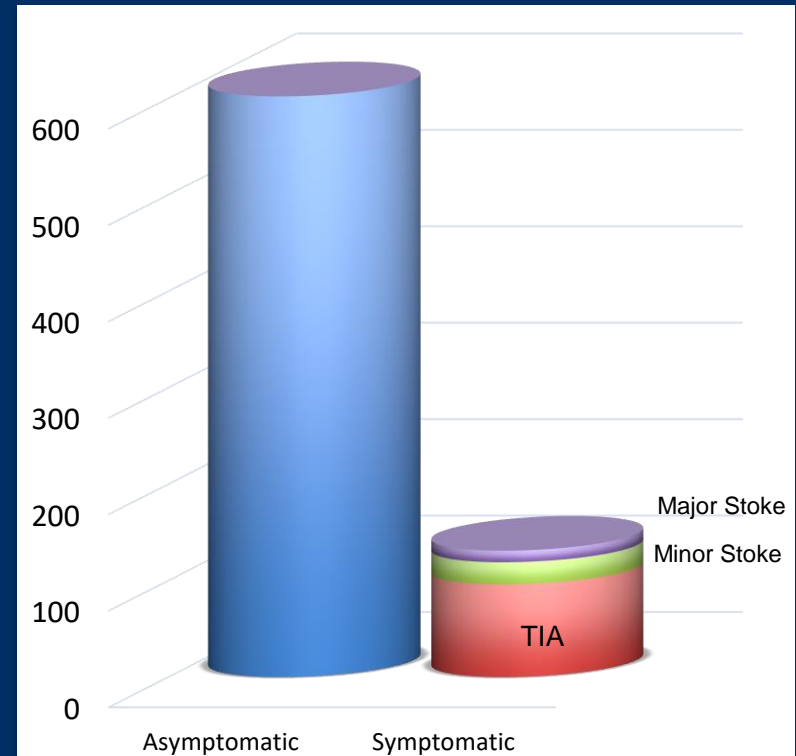
Symptoms

131/733 patients (17.87%)
were symptomatic

96 TIA (73.28%)

23 Minor Stroke (17.55%)

12 Major Stroke (9.17%)

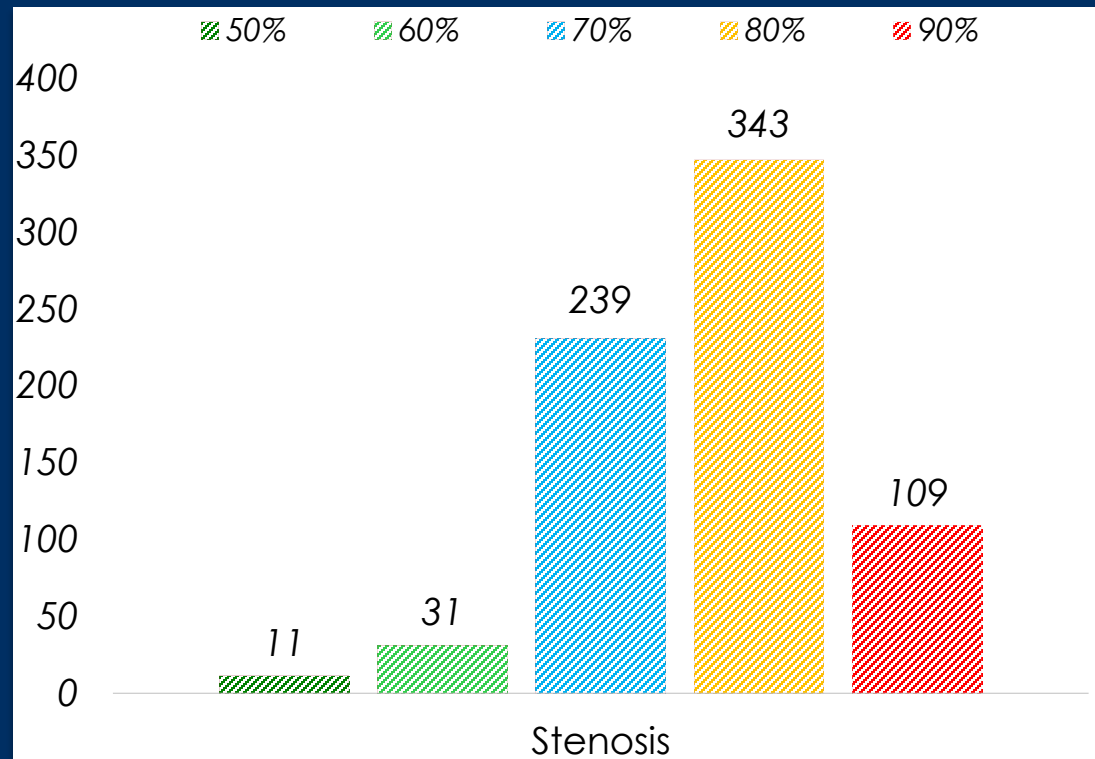
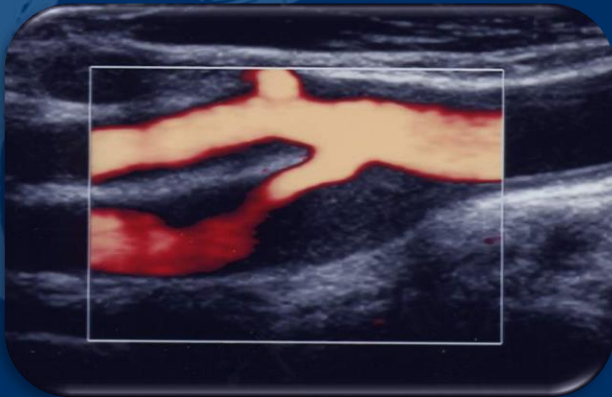


Unpublished Data

Target Lesions

Stenosis

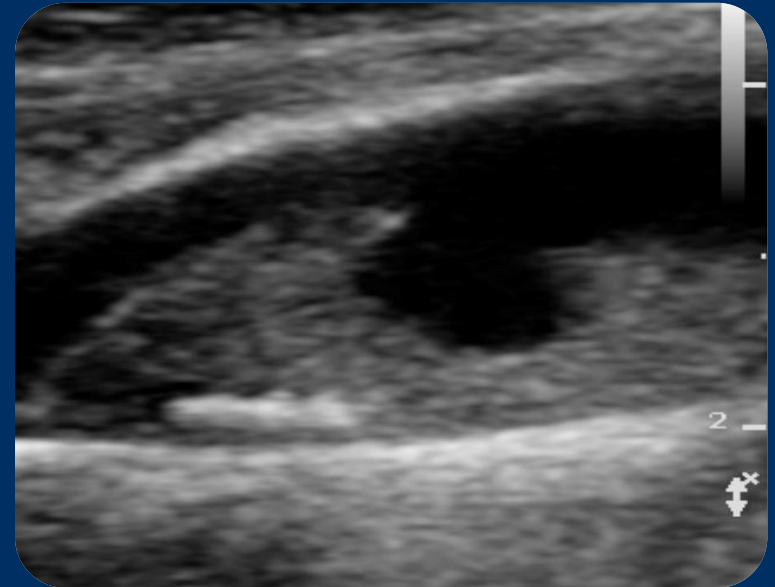
$84.97 \pm 6.51\%$
(50-99)



Unpublished Data

Plaques Composition

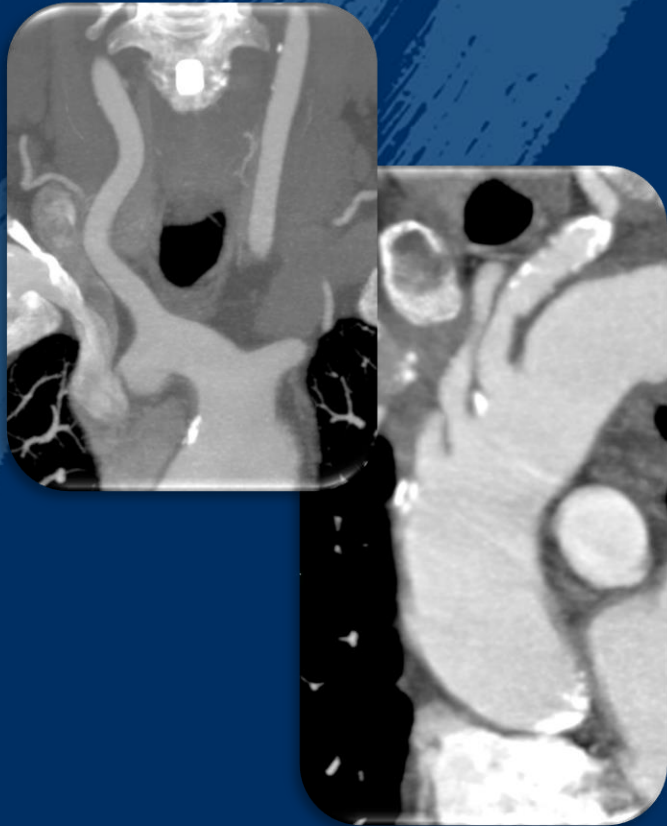
Hyperechoic	163 (22.2%)
Hypoechoic	181 (24.7%)
Isoechoic	107 (14.6%)
Disomogeneous	172 (23.4%)
Ulcerated	40 (5.5%)
Thin fibrous Cap	29 (4%)
Post-CEA restenosis	41 (5.6%)



**>50% presented an
high-risk carotid plaque**

Unpublished Data

Arch Anatomies



Type I 369 (50.3%)

Type II 268 (36.6%)

Type III 39 (5.3%)

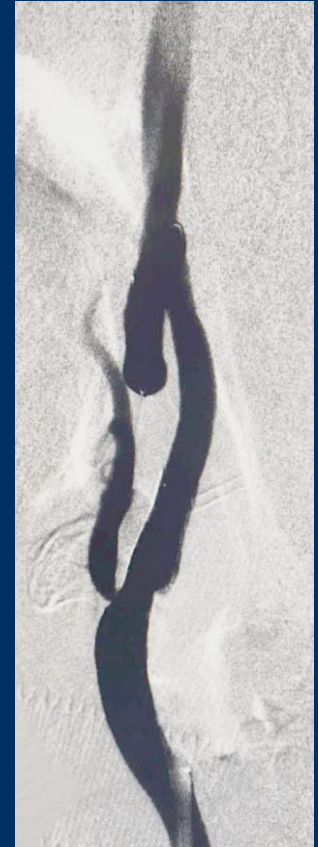
Bovine 57 (7.8%)

**All aortic arch morphologies
were enrolled in the study**

Unpublished Data

Thrombosis	20%
Calcifications	27.1%
Moderate/Severe Tortuosity	34.6%

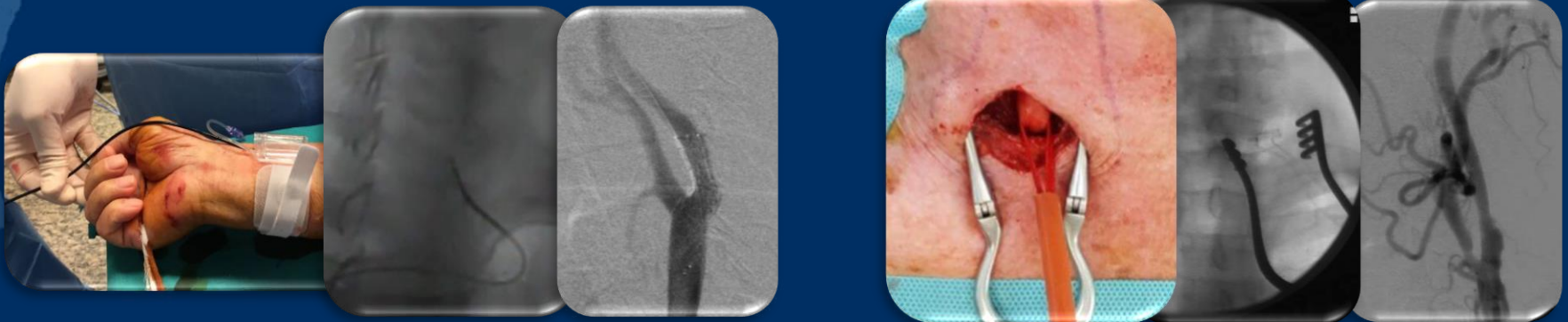
**1/3 of enrolled patients
presented significant supra-
aortic vessels tortuosity**



Unpublished Data

Procedural Details

Almost in all cases a **transfemoral approach** was chosen (**97.27%**), while also brachial (1.63%) and transcervical approaches (1.11%) are reported



Unpublished Data



Embolic Protection Device was adopted in **99.72%** of patients:
proximal occlusion device (Mo.Ma.) in 14.62%, and distal filter
in 80.9%

Unpublished Data

Procedural Details

Procedural success 100%

Technical success was obtained in all but one patient (99.86%) due to the impossibility to advance the CGuard EPS system: patient was consequently treated by Carotid WallStent



Unpublished Data

1 fatal haemorrhagic stroke

(*urgent Patient treated for cTIA*)

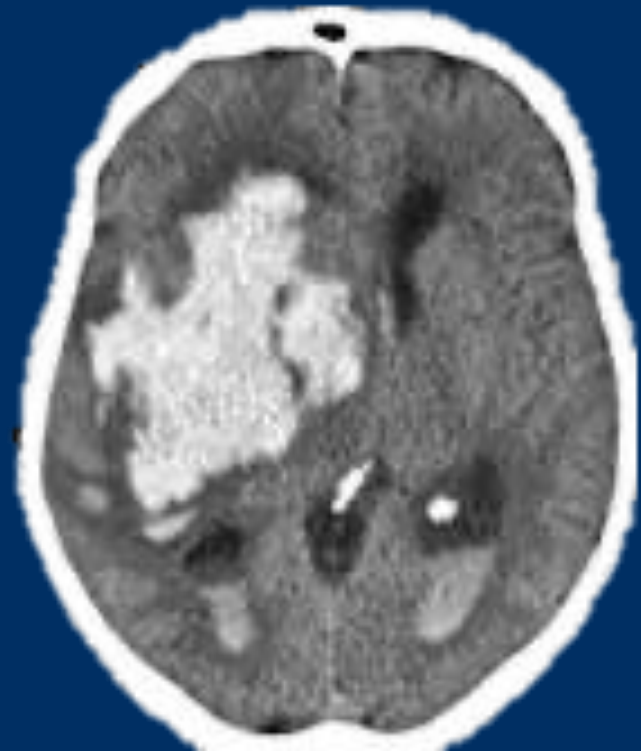
2 Minor Strokes

6 TIAs

1 AMI

No Death

8 ECA occlusions (1.09%)



Unpublished Data

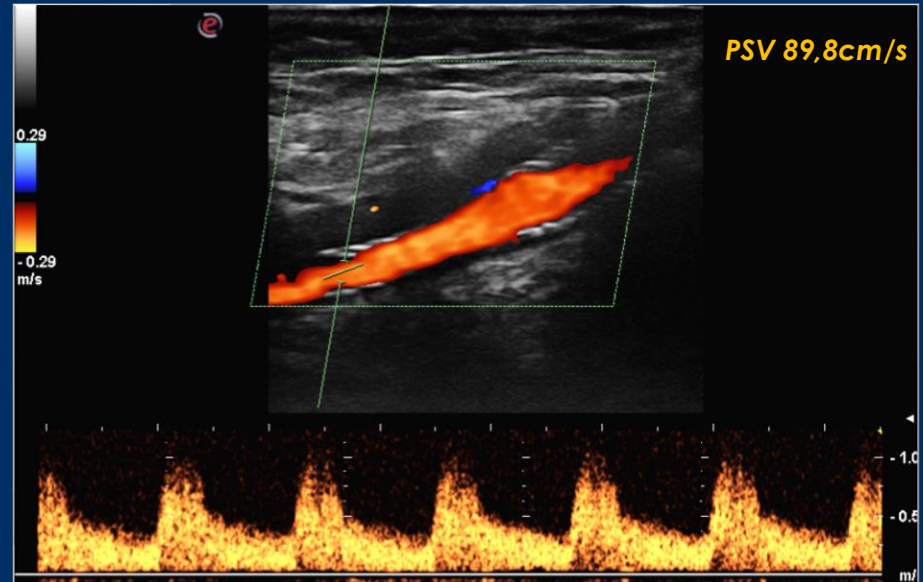
1 Minor Stroke

2 TIAs

3 AMI

No Death

No stent thrombosis/occlusions



Unpublished Data

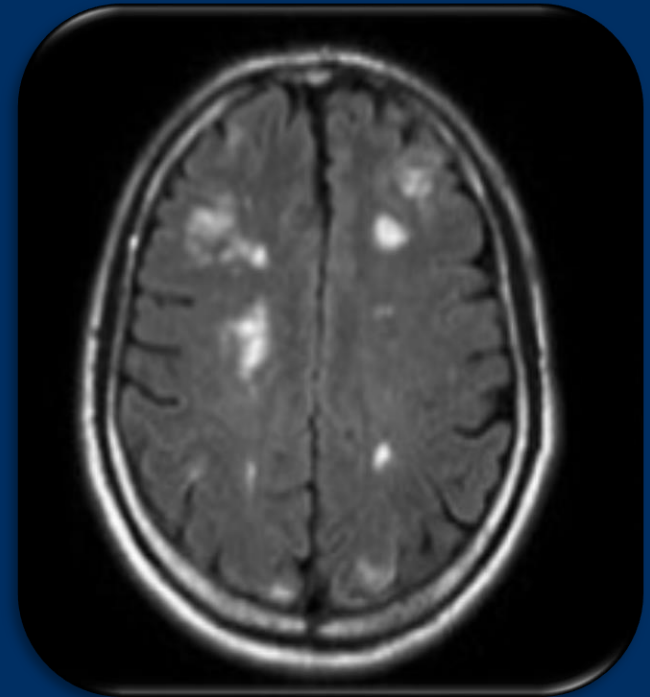
@ 1 Month Results

Stroke rate 0.54%

(3 Minor Strokes, 1 haemorrhagic)

TIA rate 1.09%

Cumulative neurological event rate 1.63%



Unpublished Data

Data available on 253 Pts

2 new MACE: 2 IMAs (fatal), no new neurological event

7 Deaths: 2 AMI, 4 neoplasms

1 Suicide

ACE patency 95.65%



Unpublished Data

On going analysis!!!



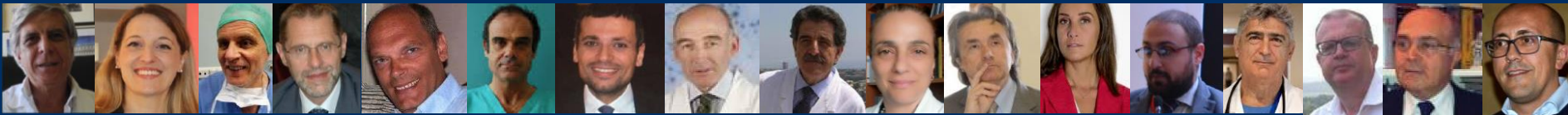
Thanks to everyone!



P.I. Francesco Speziale

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Symposium Chairman

Francesco Speziale

Symposium Co-Chairman

Enrico Sbarigia

Scientific Secretariat

Wassim Mansour

Pasqualino Sirignano



ROMA CAPVT MUNDI

Carotid Aortic Peripheral Vascular Treatment

MAY, 12th - 13th 2020

NH Vittorio Veneto, Corso d'Italia, 1 - Rome

Save the date



Vascular and Endovascular Surgery Division - "Sapienza" University of Rome

