IRONGUARD 2

LINC

12 months results from a prospective real-world multicenter clinical practice of CAS using the CGuard EPS: the IRONGUARD 2 study

Pasqualino Sirignano, MD

Vascular and Endovascular Surgery Division
Department of Surgery "Paride Stefanini"
Policlinico Umberto I
"Sapienza" University of Rome

Chief Prof Francesco Speziale

SISTEMA SANITARIO REGIONALE
AZIENDA OSPEDALIERO-UNIVERSITARIA POLICLINICO UMBERTO I

SAPIENZA UNIVERSITÀ DI ROMA

ROMA CAPVT MUNDI

SOCIETÀ POLISPECIALISTICA ITALIANA DEI GIOVANI CHIRURGHI

Disclosure

Speaker name:

.....Pasqualino Sirignano.....

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)..... Travel Grant by InspireMD

☐ I do not have any potential conflict of interest

A story started in 2015…

Protocol Vers_ 1.03

Iron Guard

Physician-initiated prospective Italian Registry of carotid stenting with the C-Guard mesh-stent.

Confidential

SPECIAL ARTICLES

J CARDIOVASC SURG 2015;56:787-97

Physician-initiated prospective Italian Registry of carotid stenting with the C-Guard mesh-stent: the IRON-Guard registry. Rationale and design

C. SETACCI [1], F. SPEZIALE [2], G. DE DONATO [1], P. SIRIGNANO [2], F. SETACCI [1], L. CAPOCCIA [2], G. GALZERANO [1], W. MANSOUR [2]
On behalf of IRON-Guard Study Group.

[1]Vascular and Endovascular Surgery Unit, Policlinico "Santa Maria alle Scotte", University of Siena, Siena, Italy
[2]Vascular and Endovascular Surgery Unit, Policlinico "Umberto I", "Sapienza" University of Rome, Rome, Italy

According to the World Health Organization, every year, 5 million peoples die for stroke and another 5 million are permanently disabled. Although there are many causes of acute stroke, a common treatable cause of acute stroke is atheromatous narrowing at the carotid bifurcation. Carotid endarterectomy is still the standard of car, even if carotid artery stenting (CAS) has become an effective, less invasive alterantive. Unfortunately, CAS procedure is not yet perfect; regardless the use of an embolic protection device (EPD), percutaneous treatment has been correlated with a risk of cerebral ischemic events related to distal embolization. The objective of the IRON-Guard Registry is to evaluate the clinical outcome of treatment by means of stenting with the C-Guard (InspireMD, Boston, MA, USA) in subjects requiring CAS due to significant extracranial carotid artery stenosis with a physician-initiated, Italian, prospective, multicenter, single-arm study. A total of 200 enrolled subjects divided over different centers are planned to be enrolled. CAS will performed by implanting of C-Guard stent. Procedure will be performed according to the physician's standard of care. Standard procedures will be followed based on the Instructions for Use, for the C-Guard device of Inspire. The primary endpoint of this study is the 30-day rate of major adverse events (MAE), defined as the cumulative incidence of any periprocedural (≤30 days postprocedure) death, stroke or myocardial infarction. Secondary endpoints are rate of late ipsilateral stroke (31 through 365 days), system technical success, device malfunctions, major adverse events (MAEs), serious device-related and procedure-related adverse events, target lesion revascularization, and in-stent restenosis rates.

KEY WORDS: Stroke – Stents – Embolization, therapeutic.

Correspondence: Author: C. Setacci, Vascular and Endovascular Surgery Unit, Department of Medicine, Surgery and Neuroscience, University of Siena, Viale Bracci 1, 53100 Siena, Italy. E-mail: setacci@unisi.it

According to the World Health Organization, every year, 5 million peoples die for stroke and another 5 million are permanently disabled. For those, stroke is the third-leading cause of death in the United States and the leading cause of serious long-term disability[1].

Although there are many causes of acute stroke including emboli from the heart, blood vessel dissection, and small perforator vessel occlusion, a common treatable cause of acute stroke is atheromatous narrowing at the carotid bifurcation. It is generally believed that in this situation ischemic stroke most commonly occurs from local thrombus formation that develops as a consequence of both ulceration and laminar flow disturbances in and around the stenotic lesion. Less frequently, ischemic stroke may be due to low flow from a critical stenosis resulting in a hemodynamic insufficiency to a region of the brain[2]. In case of significant carotid stenosis, surgical removal of atheromatous material from inside the artery by carotid endarterectomy (CEA) represents the standard of care. With the advent of new technologies and with the more frequent requests of minimally invasive techniques, carotid artery stenting (CAS) has become an alternative to open surgical procedures, especially for subjects with surgical risk factors for CEA[3-5].

The SAPPHIRE Trial [6] has proved the non-inferi-

CLINICAL RESEARCH
INTERVENTIONS FOR HYPERTENSION AND STROKE

EuroIntervention 2018;13:1714-1720 published online jaa May 2017

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 Speziale[1], MD; Laura Capoccia[1]*, MD; Pasqualino Sirignano[1], MD; Wassim Mansour[1], MD; Chiara Pranteda[1], MD; Renato Casana[1], MD; Carlo Setacci[1], MD; Federico Accrocca[1], MD; Domenico Alberti[1], MD; Gianmarco de Donato[1], MD; Michelangelo Ferri[1], MD; Andrea Gargiano[1], MD; Giuseppe Galzerano[1], MD; Arnaldo Ippoliti[1], MD; Nicola Mangialardi[1], MD; Giovanni Pratesi[1], MD; Sonia Ronchey[1], MD; Maria Antonella Ruffino[1], MD; Andrea Siani[1], MD; Angelo Spinazzola[1], MD; Massimo Spezia[1], MD

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 Speziale, 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/13thd_issue/209

The Registry

IRONGUARD 2

733 Patients

in 20 enrolling Italian Centers

The aim of the present study was to evaluate periprocedural (**24h**), post-procedural (up to **30-day**), and **12-month outcomes** in a large, prospective, multicenter series of patients submitted for protected CAS with CGuard EPS dual layer stent.

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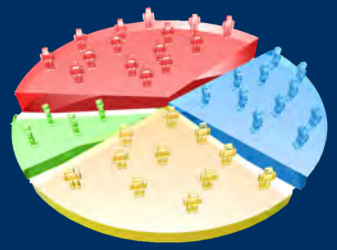
Demographic & Clinical Presentation



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%)

131/733 patients (17.87%) were symptomatic

96 TIA (73.28%)

23 Minor Stroke (17.55%)

12 Major Stroke (9.17%)

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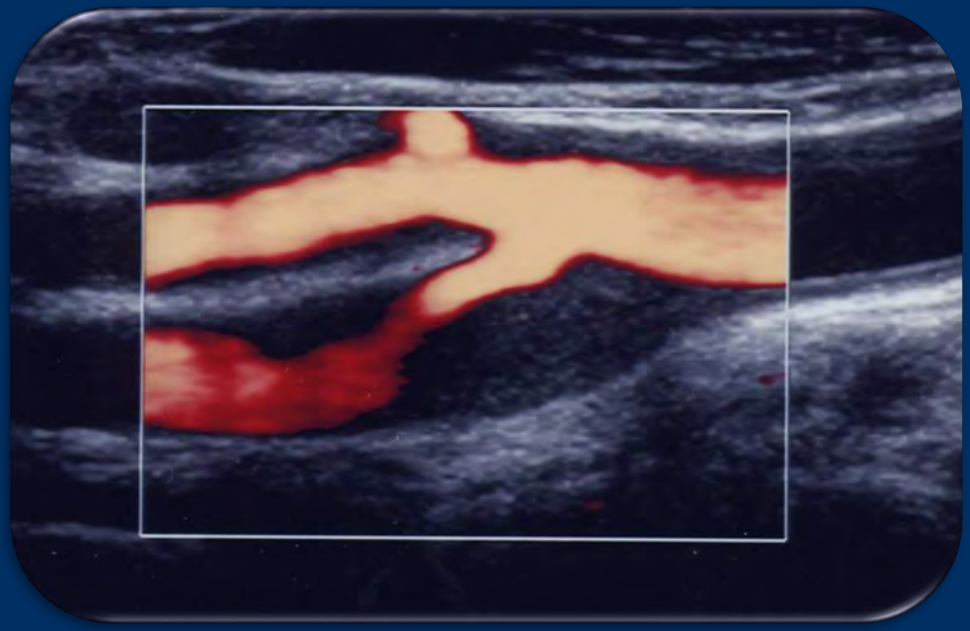
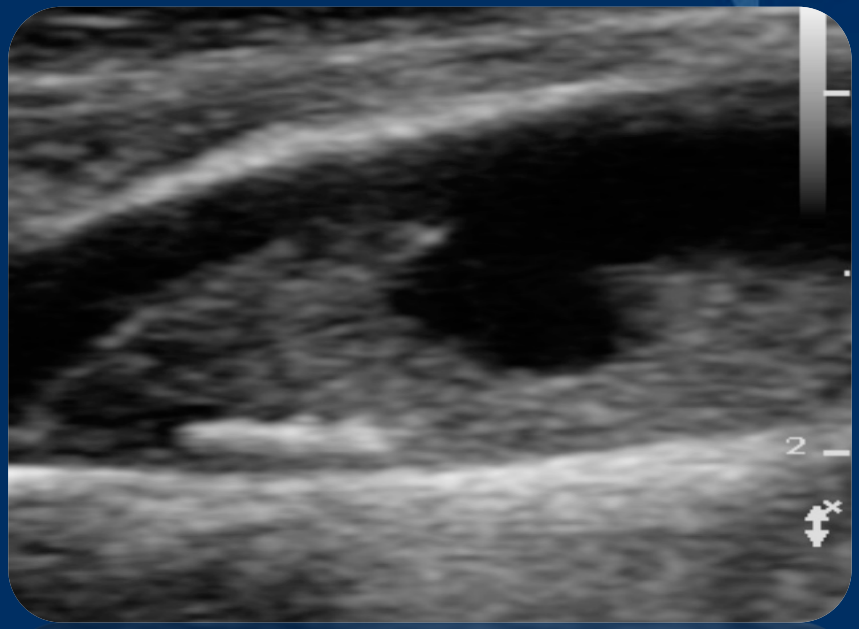
Lesions Characteristics

Stenosis

84.97±6.51%

(50-99)





>50% presented an high-risk carotid plaque

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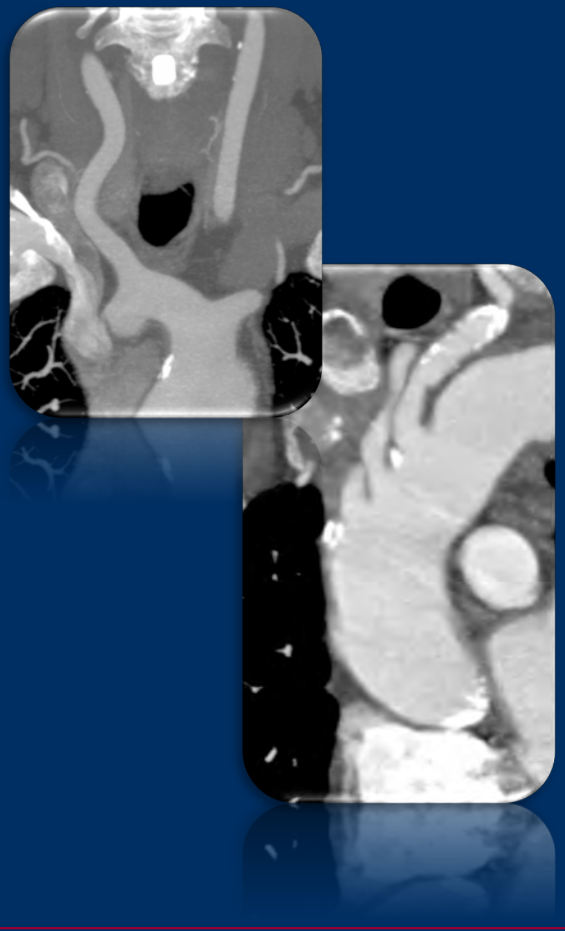
Arch Anatomies



Type I 369 (50.3%)

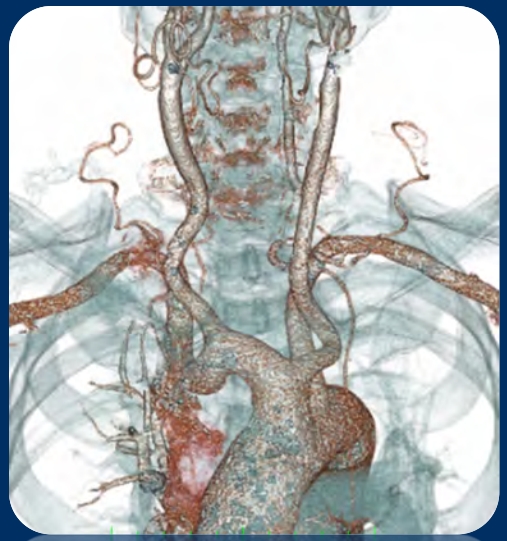
Type II 268 (36.6%)

Type III 39 (5.3%)

Bovine 57 (7.8%)

All aortic arch morphologies were enrolled in the study

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



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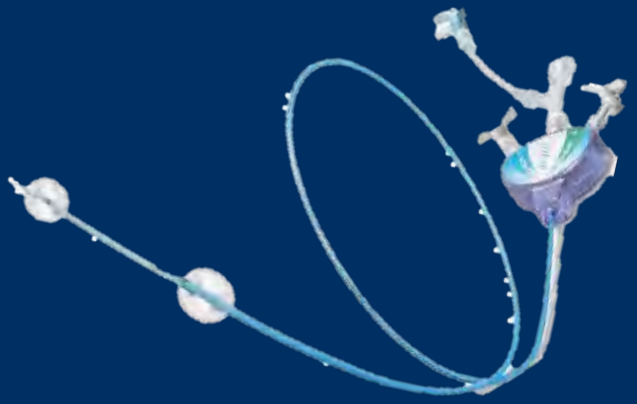
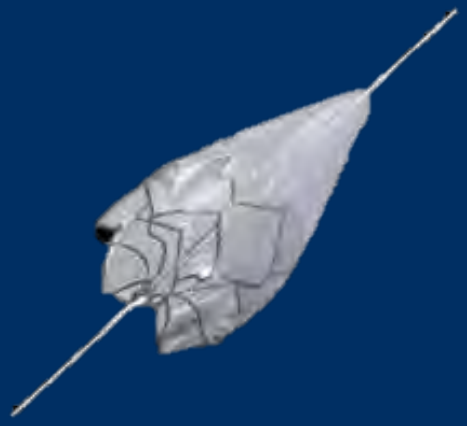
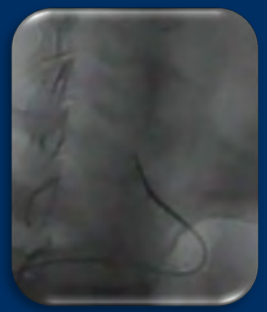
Procedural Details

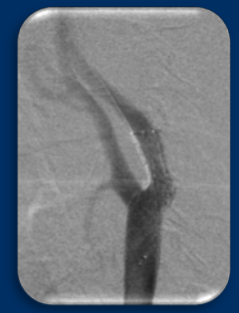
Transfemoral approach was chosen in 97.27% of cases, brachial (1.63%) and transcervical approaches (1.11%) are also reported

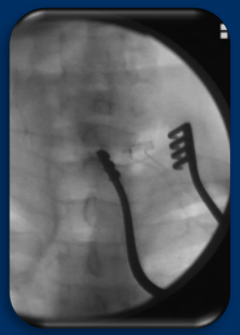
Embolic Protection Device was adopted in 99.72% of patients (Mo.Ma. in 14.62%)











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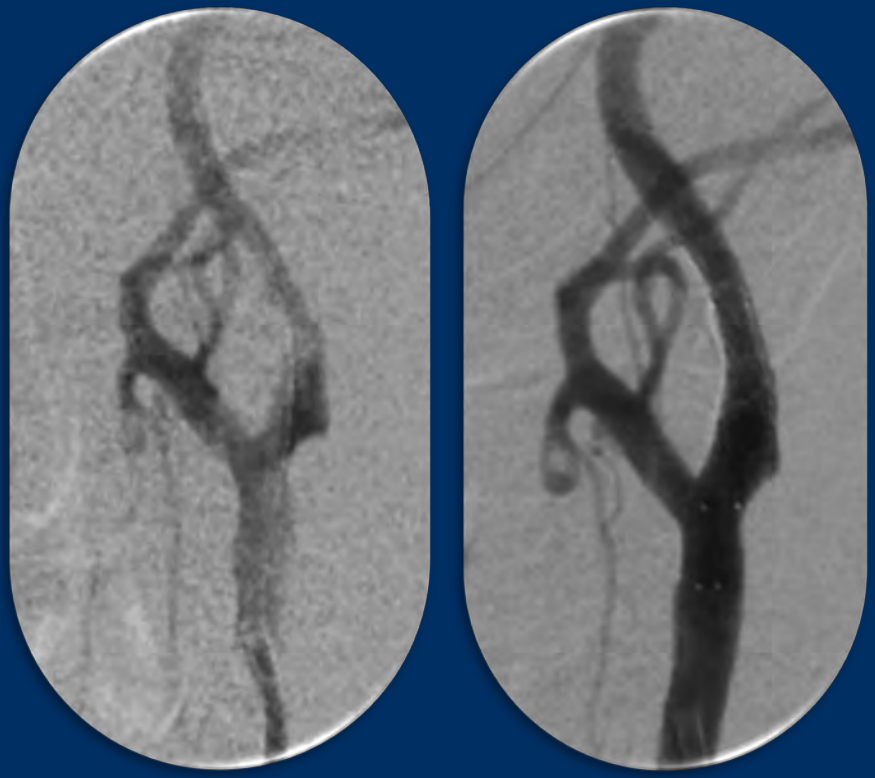
Procedural Results



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

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@24 hours Results

1 fatal haemorrhagic stroke

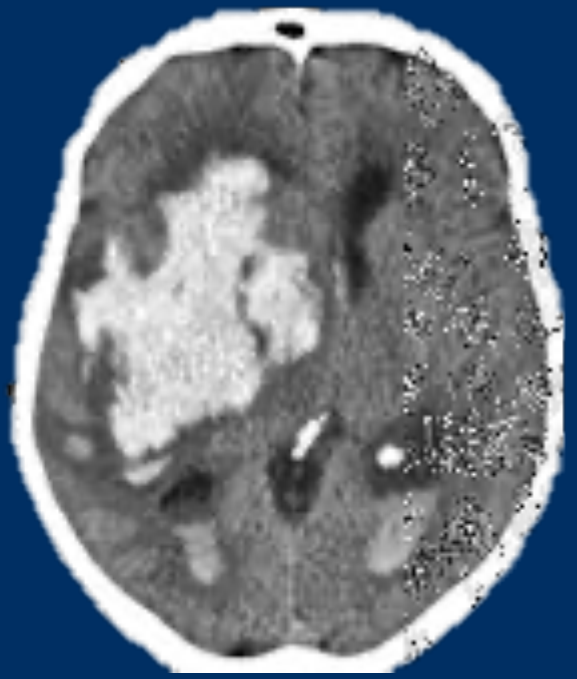
(*urgent Patient treated for cTIA*)

2 Minor Strokes

6 TIAs

1 AMI

No Death



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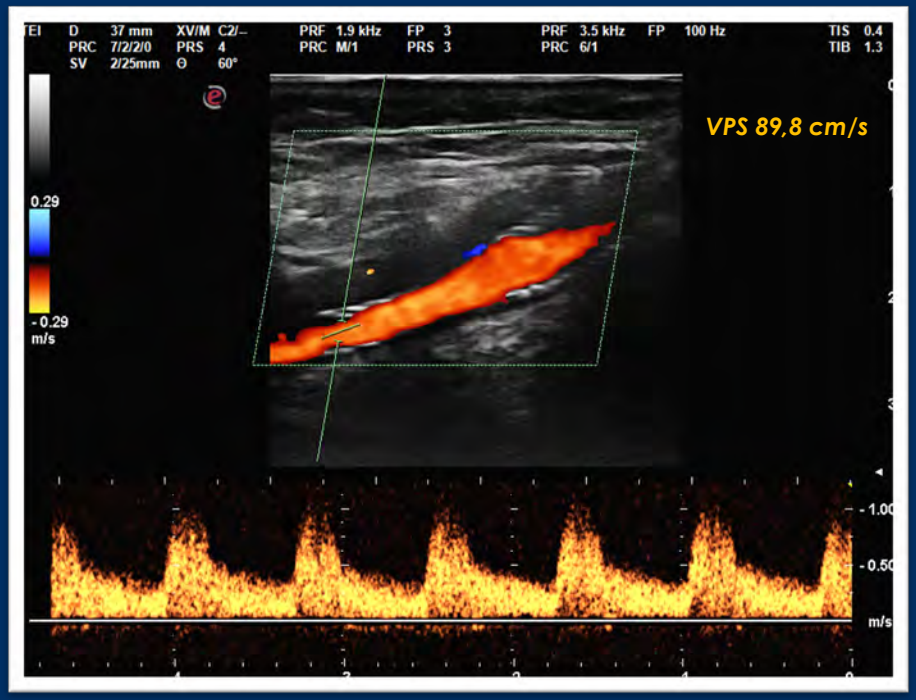
@30 days Results



1 Minor Stroke

2 TIAs

3 AMIs

No Death

No stent thrombosis/occlusions

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@1 year Results

Data available on **726/733** treated patients

1 Minor Strokes

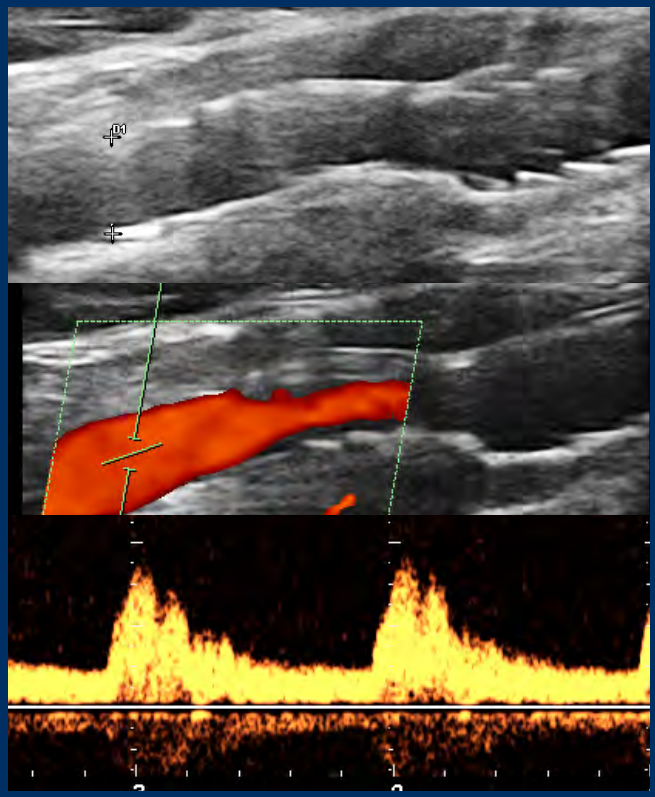
4 TIAs

2 IMAs (fatal)

6 stent restenosis (2 stent-in-stent)

8 deaths

(4 malignancies, 1 suicide, 1 undefined complication in Guillain-Barré Syndrome, and 2 AMIs)



Unpublished data

Cumulative @1 year Results

	Incidence without the variable N (%)	Incidence with the variable N (%)	P (OR; 95% CI)
Hypertension	0 (0)	5 (0.80)	0.34 (NA)
Diabetes	2 (0.42)	3 (1.13)	0.26 (2.68; 0.44-16.16)
Dyslipidaemia	1 (0.55)	4 (0.72)	0.80 (1.31; 0.14-11.83)
Smoking History	3 (0.98)	2 (0.46)	0.41 (0.48; 0.08-2.91)
Coronary Artery Disease	3 (0.65)	2 (0.71)	0.92 (1.09; 0.18-6.57)
Octogenarians	3 (0.51)	2 (1.41)	0.23 (2.82; 0.46-17.06)
High clinical risk	2 (0.59)	2 (0.50)	0.49 (0.53; 0.08-3.25)
Symptomatic Stenosis	3 (0.49)	2 (1.52)	0.19 (3.09; 0.51-18.71)

*At **univariate analysis**, none of the clinical, anatomical, or procedural characteristic was found to be statistically related to new stroke occurrence during the entire study period*

Plaque	Hyperechoic	4 (0.70)	1 (0.61)	1.00 (NA)
	Isoechoic	3 (0.47)	2 (1.89)	
	Hypo-anechoic	4 (0.72)	1 (0.55)	
	Disomogeneous	5 (0.89)	0 (0)	
	Ulcerated	4 (0.57)	1 (2.5)	
	Thin fibrous cap	5 (0.71)	0 (0)	
	Post-CEA restenosis	5 (0.72)	0 (0)	
	Unstable	4 (0.60)	1 (1.44)	0.41 (2.42; 0.26-22.01)
Aortic Arch	Type I	2 (0.54)	3 (0.81)	1.00 (NA)
	Type II	3 (0.64)	2 (0.74)	
	Type III	5 (0.72)	0 (0)	
	Bovine	5 (0.73)	0 (0)	
Tortuosity	None	4 (0.74)	1 (0.51)	1.00 (NA)
	Low	2 (0.45)	3 (1.03)	
	Moderate	4 (0.73)	1 (0.52)	
	Severe	5 (0.74)	0 (0)	
	Significant	4 (0.82)	1 (0.40)	0.50 (0.48; 0.05-4.32)
Severe Calcification		3 (0.56)	2 (1.00)	0.51 (1.79; 0.29 -10.83)
Severe Thrombosis		3 (0.51)	1 (0.68)	0.99 (0.99; 0.11-8.98)
Distal Protection		1 (0.71)	4 (0.67)	0.76 (0.70; 0.07-6.84)
Predilatation		4 (0.70)	1 (0.59)	0.80 (0.83; 0.09-7.50)
Postdilatation		1 (0.80)	4 (0.65)	0.86 (1.20; 013-10.88)

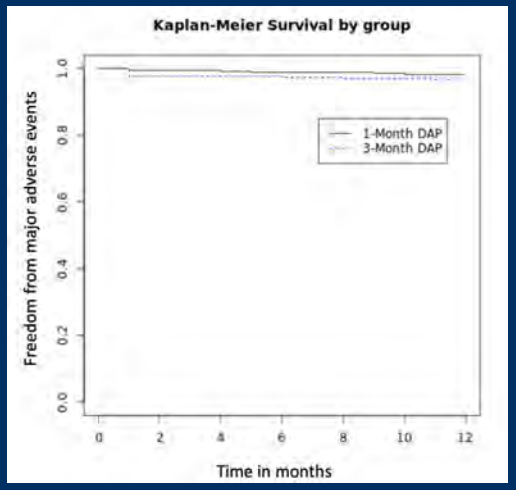
Unpublished data

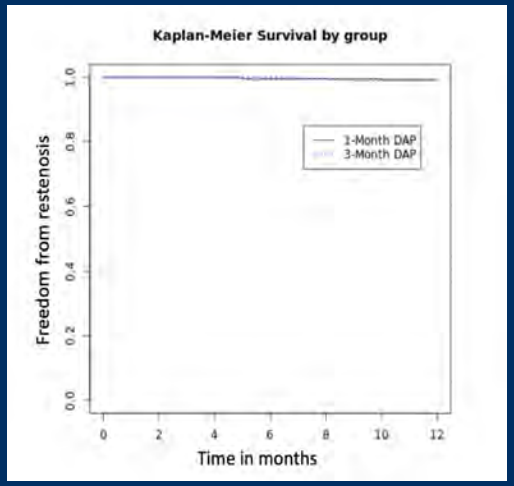
Cumulative @1 year Results

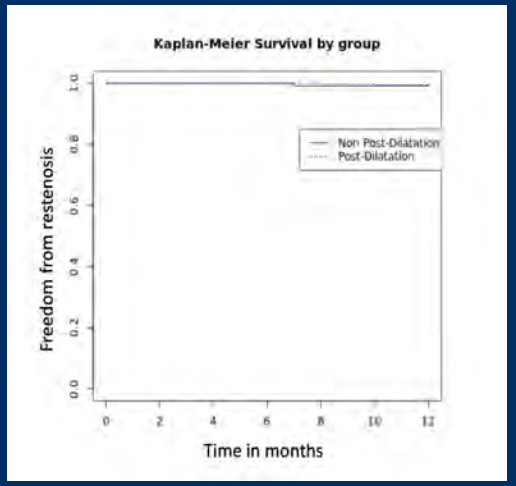
	24 hours	30 days	1-year
Stroke	3; 0.41%	4; 0.54%	5; (0.68%)
Death	1; 0.13%	1; 0.13%	9; (1.22%)
Stroke & Death	4; 0.54%	5; 0.68%	14; (1.90%)
AMI	1; 0.13%	4; 0.54%	6 ;(0.81%)

Stroke rate 0.68%

(4 Minor Strokes, 1 haemorrhagic)







Unpublished data

Conclusions

In a real-world evaluation of CAS with DLS can be safely used for treatment of extracranial carotid artery stenosis, allowing a **low rate of of post procedural adverse events** by 12 months

Duration of DAP after DLS implantation could be **safely limited up to 30th postoperative day**, because no difference in terms of major adverse events neither of restenosis rates were found between patients submitted to a 30-day or a 90-day DAP protocol

One-year **restenosis rate was not affected by the performance of intraprocedural post-dilatation** after DLS implantation, and, consequently, stent post-dilatation should not be considered a mandatory phase of a CAS procedure using this new-generation device

Thanks to everyone!!!

IRONGUARD 2 Study Collaborator:

Francesco Speziale (PI), Pasqualino Sirignano, Eugenio Stabile, Wassim Mansour, Laura Capoccia, Federico Faccenna, Francesco Intrieri, Michelangelo Ferri, Salvatore Saccà, Massimo Sponza, Paolo Mortola, Sonia Ronchey, Barbara Praquin, Placido Grillo, Roberto Chiappa, Sergio Losa, Francesco Setacci, Stefano Pirrelli, Maurizio Taurino, Maria Antonella Ruffino, Marco Udini, Domenico Palombo, Arnaldo Ippoliti, Nunzio Montelione, Carlo Setacci, Gianmarco de Donato, Massimo Ruggeri