

Results of a Multicenter Italian Registry of Real World CAS with the C-Guard Mesh Covered Stent: the IRONGUARD 2 Study

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Disclosure



Speaker name:

Wassim Mansour

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)

I do not have any potential conflict of interest



Starting Point



CLINICAL RESEARCH

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



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Starting Point



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

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

> > MACCE=0 5 minor strokes 2 TIAs



EuroIntervention 2018



② 1 Year Ironguard





SHORT REPORT

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



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

EuroIntervention 2018



② 1 Year Ironguard



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

No major neurological adverse event

No stent thrombosis

No ECA occlusion



EuroIntervention 2018



Enrollment



So we decide to continue our experience with a **NEW** registry:



Target: 500 Patients

Till august 2018, **342 Patients** in 15 enrolling Centers



Demographic





Age: 72.5 ± 7.86yy (48-97)

245 (71.22%)

Tobacco Abuse:	112 (32.55%)
Diabetes:	125 (36.33%)
Hypertension:	291 (84.59%)
Dyslipidemia:	251 (72.96%)
CAD:	107 (31.10%)



Symptoms



50 out 342 patients (14.53%) were symptomatic

36 TIA (72%)

14 Minor Stroke (28%)



Target Lesions



Stenosis 84.97 \pm 6.51% (50-99)







Plaques Composition



Hyperechoic	102 (29.65%)
Hypoechoic	77 (22.38%)
Isoechoic	45 (13.08%)
Disomogeneous	80 (23.25%)
Ulcerated	12 (4.09%)
Thin fibrous Cap	5 (1.45%)
Post-CEA restenosis	21 (6.10%)



97 (28.79%) presented an high-risk carotid plaque



Arch Anatomies





Type I	135 (39.47%)
Type II	161 (47.07%)
Type III	12 (3.51%)

All aortic arch morphologies were enrolled in the study





Arch Anatomies

Thrombosis15 (4.38%)Calcifications89 (26.02%)

Moderate/Severe Tortuosity 120 (35%)

1/3 of enrolled patients presented significant supraaortic vessels tortuosity





Procedural Details



Almost in all cases a transfemoral approach was chosen (98.24%), while also brachial (0.88%) and transcervical approaches (0.88%) are reported









Procedural Details





Embolic Protection Device was adopted in 99.70% of patients. Proximal occlusion device (Mo.Ma.) in 50 (14.62%), and distal filter in 291 (85.08%)



Procedural Details



Pre-dilatation 89 (26.02%)*

 Post-dilatation 286 (83.26%)

 Atropine
 216 (63.15%)

Contrast amount 61.78±37.72ml



*In IronGuard 1 predilatation was done in 64 patients (32%)



Results 24 h





No AMI No Death 2 ECA occlusions 4 Severe Bradycardias







② 1 Month Results





Data available on 255 Pts

2 neurological event (TIA, Minor Stroke)

No AMI

No Death

NO STENT THROMBOSIS

ACE patency 97.60%







Stroke rate 0.58%

(2 Minor Strokes)

TIA rate 1.72%

Cumulative neurological event rate 2.33%





@ 1 Year Results



Data available on 57 Pts

1 new MACE: IMA (fatal), no new neurological event

2 Deaths: AMI Suicide ACE patency 96.49%





Conclusions



On going analysis

We are still recruiting patients...





Thanks to all



P.I. Francesco Speziale

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ROMA CAROTIC PERIPHERAL VASCULAR TREATMENT

Symposium Chairman Francesco Speziale

Scientific Secretariat Laura Capoccia Wassim Mansour Pasqualino Sirignano

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MAY, 21st - 22ND 2019 **SAVE THE DATE**



