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

Pasqualino Sirignano

Vascular and Endovascular Surgery Division
Department of Surgery “Paride Stefanini”
Policlinico Umberto I
“Sapienza” University of Rome
Chief Prof Francesco Speziale
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)

X I do not have any potential conflict of interest
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, MD; Laura Capoccia*, MD; Pasqualino Sirignano, MD; Wassim Mansour, MD; Chiara Pranteda, MD; Renato Casana, MD; Carlo Setacci, MD; Federico Accrocca, MD; Domenico Alberti, MD; Gianmarco de Donato, MD; Michelangelo Ferri, MD; Andrea Gaggiano, MD; Giuseppe Galzerano, MD; Arnaldo Ippoliti, MD; Nicola Mangialardi, MD; Giovanni Pratesi, MD; Sonia Ronchey, MD; Maria Antonella Ruffino, MD; Andrea Siani, MD; Angelo Spinazzola, MD; Massimo Sponza, MD
Starting Point

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

MACCE=0
5 minor strokes
2 TIAs
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/eurontervention/143nd_issue/206
@ 1-y IRONGUARD

No major neurological event

No stent thrombosis

No ECA occlusion
NEW registry:

733 Patients

in 20 enrolling Italian Centers
Demographic

Age: 73.03 ± 7.84 yy (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Unpublished Data
131/733 patients (17.87%) were symptomatic

96 TIA (73.28%)

23 Minor Stroke (17.55%)

12 Major Stroke (9.17%)
Stenosis $84.97 \pm 6.51\%$ (50-99)
<table>
<thead>
<tr>
<th>Plaques Composition</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperechoic</td>
<td>163</td>
<td>22.2%</td>
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<tr>
<td>Hypoechoic</td>
<td>181</td>
<td>24.7%</td>
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<tr>
<td>Isoechoic</td>
<td>107</td>
<td>14.6%</td>
</tr>
<tr>
<td>Disomogeneous</td>
<td>172</td>
<td>23.4%</td>
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<tr>
<td>Ulcerated</td>
<td>40</td>
<td>5.5%</td>
</tr>
<tr>
<td>Thin fibrous Cap</td>
<td>29</td>
<td>4%</td>
</tr>
<tr>
<td>Post-CEA restenosis</td>
<td>41</td>
<td>5.6%</td>
</tr>
</tbody>
</table>

>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
Arch Anatomies

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

1/3 of enrolled patients presented significant supra-aortic vessels tortuosity
Almost in all cases a **transfemoral approach** was chosen (97.27%), while also brachial (1.63%) and transcervical approaches (1.11%) are reported.
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
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.
1 fatal haemorrhagic stroke

(urgent Patient treated for cTIA)

2 Minor Strokes

6 TIAs

1 AMI

No Death

8 ECA occlusions (1.09%)
@ 30-day Results

1 Minor Stroke
2 TIAs
3 AMI
No Death

No stent thrombosis/occlusions
@ 1 Month Results

Stroke rate 0.54%
(3 Minor Strokes, 1 haemorrhagic)
TIA rate 1.09%
Cumulative neurological event rate 1.63%
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%
Conclusions

On going analysis !!!
Thanks to everyone!

P.I. Francesco Speziale
Laura Capoccia
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Domenico Palombo
Sonia Ronchey
Massimo Ruggeri
Maria Antonella Ruffino
Pasqualino Sirignano
Francesco Spinelli
Eugenio Stabile
Massimo Sponza
Maurizio Taurino

Vascular and Endovascular Surgery Division - “Sapienza” University of Rome
Symposium Chairman

Francesco Speziale

Symposium Co-Chairman
Enrico Sbarigia

Scientific Secretariat
Wassim Mansour
Pasqualino Sirignano

Save the date

MAY, 12th - 13th 2020
NH Vittorio Veneto, Corso d’Italia, 1 - Rome
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