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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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
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

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

MACCE=0
5 minor strokes
2 TIAs

EuroIntervention 2018
@ 1 Year IronGuard

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
@ 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
Enrollment

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

Till August 2018, 342 Patients in 15 enrolling Centers

Target: 500 Patients
Age: 72.5 ± 7.86yy (48-97)

Male Gender: 245 (71.22%)
Tobacco Abuse: 112 (32.55%)
Diabetes: 125 (36.33%)
Hypertension: 291 (84.59%)
Dyslipidemia: 251 (72.96%)
CAD: 107 (31.10%)
50 out 342 patients (14.53%) were symptomatic

36 TIA (72%)

14 Minor Stroke (28%)
Stenosis
$84.97 \pm 6.51\%$
(50-99)
## Plaques Composition

<table>
<thead>
<tr>
<th>Feature</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperechoic</td>
<td>102</td>
<td>(29.65%)</td>
</tr>
<tr>
<td>Hypoechoic</td>
<td>77</td>
<td>(22.38%)</td>
</tr>
<tr>
<td>Isoechoic</td>
<td>45</td>
<td>(13.08%)</td>
</tr>
<tr>
<td>Disomogeneous</td>
<td>80</td>
<td>(23.25%)</td>
</tr>
<tr>
<td>Ulcerated</td>
<td>12</td>
<td>(4.09%)</td>
</tr>
<tr>
<td>Thin fibrous Cap</td>
<td>5</td>
<td>(1.45%)</td>
</tr>
<tr>
<td>Post-CEA restenosis</td>
<td>21</td>
<td>(6.10%)</td>
</tr>
</tbody>
</table>

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%)
Bovine 34 (6.10%)

All aortic arch morphologies were enrolled in the study.
**Arch Anatomies**

Thrombosis 15 (4.38%)
Calcifications 89 (26.02%)
Moderate/Severe Tortuosity 120 (35%)

1/3 of enrolled patients presented significant supra-aortic vessels tortuosity
Almost in all cases a **transfemoral approach** was chosen (98.24%), while also brachial (0.88%) and transcervical approaches (0.88%) are reported.
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

- 5 TIAs
- 1 Minor Strokes

- No AMI
- No Death
- 2 ECA occlusions
- 4 Severe Bradycardias

1.75%
@ 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%
@ 1 Month Results

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

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Thanks for your attention
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