EARLY RESULTS OF A PROSPECTIVE REGISTRY OF CAROTID STENTING WITH THE NEW C-GUARD MESH-COVERED STENT IN REAL WORLD: THE IRON-GUARD REGISTRY

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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
CAS – EMBOLIZATION RISK

CAS is associated with an increased incidence of post-procedural brain DWI lesions.

This greater amount of ischemic burden may also reflect a higher rate of cerebral events after CAS.

CREST reported a greater risk of cerebral embolization and new adverse events after CAS, but...
CREST - LONG TERM DATA

Difference was in first 30-days Embolization through the stent?
PLAQUE HEALING

Plaque proplase and distal embolization through the stent struts during the first 30-day
New stents present a double-layers surface allowing the device to prevent embolization
NEW CAROTID STENT DESIGN
NEW CAROTID STENT DESIGN

SPECIAL ARTICLES

J CARDIOVASC SURG 2015;56:787-91

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

Sapienza University of Rome
University of Siena
City Hospital, Civitavecchia
Bel Colle Hospital, Viterbo
Istituto Auxologico IRCCS, Milan
Mauriziano Umberto I Hospital, Turin
Cardinal Massaia Hospital, Asti
Tor Vergata University of Rome
San Filippo Neri Hospital, Rome
Città della Salute Hospital, Turin
City Hospital, Crema
Santa Maria Hospital, Udine
C-Guard stent is an innovative monorail, self-expanding, open cell, nitinol stent covered by a polyethylene terephthalate (PET) micromesh.
AIM

To report on outcomes in a prospective series of patients submitted to protected CAS with C-Guard stent between 04-2015 and 06-2016
ENROLLMENT

Physician-initiated prospective multicenter registry
Centers performing >50 CAS per year
200 patients enrolled

Inclusion Criteria:
1) ≥ 50% symptomatic stenosis, or ≥ 70% asymptomatic stenosis;
2) target lesion located in the distal CCA, ICA, or carotid bifurcation;
3) target vessel diameter between 4mm and 9mm;
4) life expectancy > 12 months;
5) willing and able to comply with follow-up requirements.
Primary endpoints

Periop. Major Adverse Cerebrovascular Cardiac Event (MACCE)
Procedure-related brain embolism (24/72hrs DWMRI)

Secondary endpoints

technical success
procedural success
device malfunctions
instent restenosis
**DEMOGRAPHIC CHARACTERISTICS**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>72.61</td>
</tr>
<tr>
<td>ICA diameter (mm)</td>
<td>5.40</td>
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<tr>
<td>Male sex</td>
<td>66%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>87%</td>
</tr>
<tr>
<td>Smoke</td>
<td>62%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>27%</td>
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<tr>
<td>Hyperlipidemia</td>
<td>74%</td>
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<tr>
<td>CAD</td>
<td>34%</td>
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INDICATION TO CAS
Asymptomatic Stenosis ≥70% 86%
Symptomatic Stenosis ≥50% 14%

PLAQUE CHARACTERISTICS
Hyperechoic plaque 26%
Isoechoic plaque 17%
Hypoechoic plaque 17%
Disomogeneous plaque 3%
Ulcerated plaque 7%
Thin fibrous cap 1%
Post-CEA restenosis 6%
PRE-OPERATIVE CTA

Aortic Arch
Type I 49%
Type II 36%
Type III 7%
Bovine 8%

Tortuosity
None 32%
Low 26.5%
Moderate 36.5%
Severe 6%

Thrombosis/Calcification
None – Low 53%
Moderate – Severe 47%
INTRA-OPERATIVE DETAILS

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Percentage</th>
</tr>
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<tbody>
<tr>
<td>Fem access</td>
<td>97%</td>
</tr>
<tr>
<td>Radial access</td>
<td>3%</td>
</tr>
<tr>
<td>Distal filter</td>
<td>91%</td>
</tr>
<tr>
<td>Proximal occlusion</td>
<td>9%</td>
</tr>
<tr>
<td>Predilatation*</td>
<td>32%</td>
</tr>
<tr>
<td>Postdilatation*</td>
<td>86%</td>
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</tbody>
</table>

*Dilatation time ranged between 2-30 sec*
Technical Success: 100%

1/200 patients required additional stent because incomplete plaque coverage
PERIOPERATIVE RESULTS

MACCE=0

5 minor strokes
2 TIAs
@30-DAY RESULTS

No complications
No ECA occlusion
DW-MRI RESULTS

Pre and 24/72 hours postoperative

Subgroup Analysis (61 patients)

New microemboli: 12 patients (19.6%)

6 bilateral/contralateral
DW-MRI RESULTS

CARENET TRIAL (InspireMD)
New lesions in 37.0% in 30 patients
JACC Cardiovasc Interv. 2015 Aug 17;8(9):1229-34.

IRONGUARD ITALIAN REGISTRY (InspireMD)
New lesions in 19.6% in 61 patients

ROADSAVER ITALIAN REGISTRY (Terumo)
New lesions not evaluated
CONCLUSIONS

The IRON-Guard Registry shows promising results in this ad interim analysis with a low incidence of complications and the lowest reported rate of new MRDWI lesions using new generation stents.
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