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
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...
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.
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%)

Sirignano P, et al. JACC Cardiovasc Int . 2020
Lesions Characteristics

Stenosis

84.97 ± 6.51%

(50-99)

>50% presented an high-risk carotid plaque

Sirignano P, et al. JACC Cardiovasc Int. 2020
Type I 369 (50.3%)
Type II 268 (36.6%)
Type III 39 (5.3%)
Bovine 57 (7.8%)

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

All aortic arch morphologies were enrolled in the study

Sirignano P, et al. JACC Cardiovasc Int. 2020
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%)
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.
@24 hours Results

1 fatal haemorrhagic stroke

(urgent Patient treated for cTIA)

2 Minor Strokes

6 TIAs

1 AMI

No Death
@30 days Results

1 Minor Stroke
2 TIAs
3 AMIs
No Death

No stent thrombosis/occlusions

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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)
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.
Cumulative @1 year Results

Stroke rate 0.68%

(4 Minor Strokes, 1 haemorrhagic)
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 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!!!

IRONGLAURD 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