Plaque Prolapse Prevention in CAS: a randomized controlled trial 3PCAS

A.d’Adamo, L.Capoccia, P.Sirignano, W.Mansour, M.Formiconi, F.Fornelli, and F.Speziale

Vascular and Endovascular Surgery Division
Department of Surgery “Paride Stefanini” - Policlinico Umberto I
“Sapienza” University of Rome
Chief Prof F.Speziale
Plaque Prolapase Prevention after CAS: a randomized controlled trial 3PCAS

The NEW ENGLAND JOURNAL of MEDICINE

Stenting versus Endarterectomy for Treatment of Carotid-Artery Stenosis

CREST demonstrated cumulative similar outcomes and safety for both CAS and CEA.

However, patients treated with CAS had a markedly elevated 30-day periprocedural stroke or death rate.
Stenting versus Endarterectomy for Treatment of Carotid-Artery Stenosis

Risk of peri-procedural stroke/death

- CAS 4.4%
- CEA 2.3%

**P**=0.005
Plaque Prolapser Prevention after CAS: a randomized controlled trial 3PCAS

Difference was in the first 30 days
Related to embolization through the stent?
Plaque prolapse prevention after CAS: a randomized controlled trial 3PCAS

Plaque proplase and distal embolization through the stent struts during the first 30-day
Plaque Prolapse Prevention after CAS: a randomized controlled trial 3PCAS

From the Society for Vascular Surgery

Comparative study on carotid revascularization (endarterectomy vs stenting) using markers of cellular brain injury, neuropsychometric tests, and diffusion-weighted magnetic resonance imaging

Laura Capoccia, MD,
Francesco Speziale, MD,
Marianna Gazzetti, MD,
Paola Mariani, MD,
Annarita Rizzo, MD,
Wassim Mansour, MD,
Enrico Sbarigia, MD,
and Paolo Fiorani, MD,
Rome, Italy

Silent stroke and cognitive decline in asymptomatic carotid stenosis revascularization

Laura Capoccia, Enrico Sbarigia, Annarita Rizzo, Wassim Mansour and Francesco Speziale
Plaque Prolapse Prevention after CAS: a randomized controlled trial 3PCAS
Patients treated with open cells stent present an higher risk of distal embolization

**Plaque Prolapse Prevention after CAS:**
a randomized controlled trial 3PCAS

Bosiers M et al, Eur J Vasc Endovasc Surg, 2007
Plaque Prolapse Prevention after CAS: a randomized controlled trial 3PCAS

Roadsaver

Gore Carotid Stent

Cguard

New stents present a double-layers surface allowing the device to prevent embolization
Plaque Prolapse Prevention after CAS:  
a randomized controlled trial 3PCAS

Double layer micromesh design
Optimal plaque coverage
Conforms to vessel anatomy
Plaque Prolapse Prevention after CAS: a randomized controlled trial 3PCAS

ESC Guidelines underlined the crucial role of Operators’ experience and patient and material selection in determining CAS outcome.

ESC Guidelines, 2017
A Randomized Controlled Trial to compare the results of a new dual layer stent vs a conventional stent

ClinicalTrials.gov reg number: NCT02665585
To compare the rate of off-table subclinical neurological events in two groups of asymptomatic patients submitted to protected CAS.
Plaque Prolapse Prevention after CAS: a randomized controlled trial 3PCAS

METHODS

CAS patients affected by asymptomatic carotid stenosis ≥70%
Absence of a previous brain ischemic lesion detected by DW-MRI
Randomly allocated to be treated 1:1
Plaque Prolapse Prevention after CAS: a randomized controlled trial 3PCAS

METHODS

Preop | MMSE | MoCA | CAS | Postop
---|---|---|---|---
Preop | DWMRI | | |
Postop | S100β and NSE serum evaluation | 72 hours DWMRI | MMSE MoCA
5 min 2 h 6 h 12 h 24 h 48 h
Perioperative new neurological ischemic events, numbers and diameters, detected by DW-MRI

Increase in S100β and/or NSE serum levels

≥5 variation in post-procedural MMSE or MoCA
RESULTS

58/103 pts randomized from January 2015 to October 2016

Technical success 100%

Distal embolic protection device 100%

Postdilatation 86.2%

1 minor stroke
RESULTS

New DWMRI Lesions

8 (27.6%) CGuard pts 4 ipsilateral
7 (24.13%) Wallstent pts 4 ipsilateral
RESULTS

Wallstent
Mean=3.56
SD=1.07
95%CI 2.871 – 4.253

CGuard
Mean=3.87
SD=1.53
95%CI 3.307 – 4.436
**RESULTS**

**S100β** Increased in 24 pts
12 pts with DWMRI +

\[ p=0.012 \]
≥5 DWMRI lesions were significantly associated to decrease in postoperative scores in both groups.
Wallstent and Cguard stents showed not significant differences in microembolism rates or microemboli number at 72 hours DWMRI.

72h DW-MRI+ were significantly associated to increase in neurobiomarkers.

≥5 lesions were significantly associated to decrease in NPTs postoperative scores in both Wallstent and Cguard groups.

Not negligible number of bilateral or contralateral lesions were detected in both stent groups.
Plaque Prolapse Prevention after CAS: a randomized controlled trial 3PCAS

CONCLUSIONS
Plaque Prolapse Prevention after CAS: a randomized controlled trial 3PCAS

Symposium Chairman

Francesco Speziale

Scientific Secretariat

Laura Capoccia
Wassim Mansour
Pasqualino Sirignano

Vascular and Endovascular Surgery Division
Department of Surgery
“Paride Stefanini”
“Sapienza” University of Rome
Policlinico Umberto I

e-mail: caput.meeting@gmail.com