PLAQUE PROLAPSE PREVENTION IN CAS (3PCAS)

A RCT ASSESSING SUBCLINICAL BRAIN LESIONS BY DWI AFTER CAS WITH CLOSED-CELL STENTS AND MESH-COVERED STENTS

Laura Capoccia

Vascular and Endovascular Surgery Division, Head of Division Prof. Francesco Speziale, Department of Surgery “Paride Stefanini”, Policlinico Umberto I, “Sapienza” University of Rome, ITALY
RISK OF CAS-RELATED EMBOLISM?

Risk of embolism

Stent deployment
Filter positioning
Predilatation
Postdilatation
Nitinol expansion

Time
Figure 2. Representative microscopic section of carotid artery 28 days after MER® stent implantation; ×2, VVG (A). Stent strut compressing media, internal elastic lamina layer intact (injury 0); ×20, H & E (B). Normal, mature and endothelialised neointima; ×20, H & E (C).
REDUCTION OF PERIOPERATIVE NEUROLOGIC EMBOLIZATION

Membrane-covered stent

Distal embolic protection device

Flow-reversal embolic protection device

stenting

ballooning

TIME
ARE MESH-COVERED STENTS ABLE TO CAPTURE EVERY KIND OF EMBOLISM?
EVEN THE "OFF-TABLE" ONE?
Aim: to compare the rate of off-table subclinical neurological events in two groups of patients submitted to CAS with CGUARD or WALLSTENT and distal embolic protection device (Filterwire).

Population: patients affected by asymptomatic carotid stenosis ≥70% (NASCET evaluation criteria), absence of a previous brain ischemic lesion detected at DW-MRI.

Primary outcomes measure
Rate of perioperative (intra and up to 72 hours postoperatively) neurological ischemic events detected by diffusion-weighted magnetic resonance imaging (DWMRI) in the two CAS groups.

ClinicalTrials.gov reg number: NCT02665585
3PCAS RCT

Secondary outcomes measures
Rate of perioperative (intra and up to 72 hours postoperatively)
increase ≥0.02 µg/L in **S100β** and/or
increase ≥0.3 µg/L in **NSE** serum levels,
≥5 variation in postprocedural MiniMentalStateExaminationTest - MMSE score or **MoCA** test score in the two treatment groups

**SAMPLE SIZE ESTIMATION**

Type I error α=0.05, Type II error β=0.20, power (1-β)=0.80
Assuming an event rate in the Wallstent group of 40%,
And an event rate in the C-Guard group of 10%,
sample size for each treatment group is **29**
Preoperative evaluation
DW-MRI, MMSE- MoCA test
Blood levels of NSE - S100β protein

Postoperative evaluation
Immediate postop DW-MRI
72 hours DW-MRI - MMSE - MoCA test
NSE - S100β protein at
- 5 min
- 2 h
- 12 h
- 24 h
- 48 h
3PCAS RESULTS

3 pts excluded for preop DWMRI lesions

58 pts randomized from January 2015 to October 2016

Cguard (29 pts)
- 1 minor stroke (ipsilateral lesion)
- 8 clinically silent 72h DWMRI+

Wallstent (29 pts)
- 7 clinically silent 72h DWMRI+

31%  P=0.38  24.1%

2 pts presented immediately postop DWMRI lesions
They were no more detectable at 72 hours!
3PCAS RESULTS
SIDE OF 72H DWMRI LESIONS

8 Cguard pts
• 4 ipsilateral
• 4 contra or bilateral

7 Wallstent pts
• 4 ipsilateral
• 3 contra or bilateral

17.2% vs 13.8%

P=0.38
3PCAS RESULTS
DWMRI LESIONS DIAMETER

Cguard

Mean = 3.87
SD = 1.53
95%CI 3.307 – 4.436

P = 0.49

Wallstent

Mean = 3.56
SD = 1.07
95%CI 2.871 – 4.253
3PCAS RESULTS

DWMRI LESIONS NUMBER

≥5 in 5 CGUARD pts vs. 3 WALLSTENT pts (p=0.5)

S100B X2

24 pts
12 pts with DWI+

p=0.012
3PCAS RESULTS
MMSE AND MOCA

Cguard  Wallstent

p=0.03

p=ns
3PCAS POSTOP

MMSE AND MOCA SCORES

p = 0.12

p = 0.45
3PCAS POSTOP

MMSE AND MOCA SCORES

DWI+ ≥5 lesions

p=0.007

p=0.03
Wallstent and Cguard stents showed not significant differences in microembolism rates or microemboli number at 72 postoperative hours DWMRI.

72h DWI+ 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.
BILATERAL OR CONTRALATERAL EMBOLISM?
REDUCTION OF PERIOPERATIVE NEUROLOGIC EMBOLIZATION

TO AVOID THE ARCH

Membrane-covered stent

Distal embolic protection device

Flow-reversal embolic protection device

ballooning

stenting
Thanks for your attention
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