COMPARISON OF MESH COVERED CGUARD STENT VS WALLSTENT FOR CAS: DWMRI AND CLINICAL RESULTS SHOW BENEFIT OF MESH COVERED STENT

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RISK OF CAS-RELATED EMBOLISM?

Risk of embolism

Stent deployment

Filter positioning

Proliferation

Postdilatation

Nitinol expansion

Time

PLAQUE HEALING

28 days?

IN ORDER TO CAPTURE EVERY KIND OF EMBOLISM

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PLAQUE PROLAPSE PREVENTION
CAS RANDOMIZED CONTROLLED TRIAL - 3PCAS

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.

3PCAS RESULTS

3 pts excluded for preop DWMRI lesions 58 pts randomized from January 2015 to October 2016

Cguard (29 pts) Wallstent (29 pts)

1 minor stroke (ipsilateral lesion) 8 clinically silent 72h DWMRI+
8 clinically silent 72h DWMRI+ 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 24.1%
3PCAS RESULTS
DWMRI LESIONS DIAMETER

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

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+

3PCAS RESULTS
MMSE AND MOCA

p=0.03

p=ns

3PCAS POSTOP
MMSE AND MOCA SCORES

DWI+ ≥5 lesions

p=0.007

p=0.03

CONCLUSIONS

Wallstent and Cguard stents showed not significant differences in microembolism rate 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

ADVANTAGES:

- Membrane-covered stent
- Flow-reversal embolic protection device
- Distal embolic protection device
- Stenting
- Ballooning

TO AVOID THE ARCH

REDUCTION OF PERIOPERATIVE NEUROLOGIC EMBOLIZATION

TIME

Thanks for your attention