Update On The CGuard™ MicroNet Covered Stent For CAS: Longer-Term Results: Advantages And Are There Late Downsides Like ISR Or Late Thrombosis?

Piotr Musialek, MD DPhil
Jagiellonian University Dept. of Cardiac & Vascular Diseases
John Paul II Hospital, Krakow, Poland

Conventional Carotid Stents Do Have A Problem

CEA excludes the plaque

• CEA excludes the plaque
• In CAS, the stent should exclude the plaque too
The CGuard™ MicroNet-Covered Embolic Prevention Stent System is effective in reducing peri- and post-procedural cerebral embolism. Routine DW-MRI data in CARENET; results reproduced by 2+ other studies.
Intra-procedural cerebral embolization is minimized

Post-procedural cerebral embolization is eliminated


Tomyuki Umemoto et al. EuroIntervention 2017

Per-Protocol DW-MRI cerebral imaging at B/L, 24-48h after CAS, and at 30 days

No stroke(s)/TIA(s)

No ISR

The PARADIGM Study

Prospective evaluation of All-comer percutaneous carotid revascularization in symptomatic and Increased-risk asymptomatic carotid artery stenosis using the CGuard™ Micronet-covered embolic prevention stent system
Objective

- to evaluate feasibility and outcome of routine anti-embolic stent system use in unselected, consecutive patients referred for carotid revascularization ('all-comer' study)

PARADIGM

Methods (cont’d):

- ASYMPTOMATIC patients treated interventionally only if at stroke risk
- established lesion-level increased-risk criteria used:
  - thrombus-containing
  - documented progressive
  - irregular and/or ulcerated
  - contralateral ICA occlusion/stroke
  - asymptomatic ipsilateral brain infarct

Stabile et al. 2019 (at review)

Patient-level meta-analysis of 4 clinical trials @12mo (RoadSaver-250; CGuard-306)

Fathered Pat at: American College of Cardiology @2019
chronic ischemic lesions in both hemispheres

"fresh" ischemia surrounding old lesions
chronic ischemic lesion in R hemisphere

Flow reversal time 7min 10sec
Intolerance in the last 80sec
(active aspiration still (!) performed)
Patient A/S, discharged home, unremarkable follow-up

Normal stent image

Normal velocities

ECA patent

Appropriate Procedural Heparinization & DAPT, and Optimal Device Implantation: The fundaments for normal healing and optimal long-term result

PARADIGM – Extend continues as an ALL-Comer Multi-Centre Study

- 402 patients / 436 arteries
- NeuroVascular Team decision-making on endovascular revascularization
- Age 48-87 years, 56.4% symptomatic
- Crossed the trial first follow-up window (30d)
- 100% CGuardEPS use, Proximal/distal EPD ≈ 50% : 50%
- Angiographic diameter stenosis was reduced from 84±8% to only 6.9±5% (p<0.001, ‘CEA-like’ effect of CAS)

PARADIGM – Extend continues as an ALL-Comer Multi-Centre Study

- Total
- 30-day death/MI/any stroke – 0.995 % (4/402)
- no post-proc. ischaemic stroke by 30 days – 0.0 % (0/402)
- then clinical (inc. Neurology exam) and Duplex follow-up every 12 months
Aortic stenosis progression to severe AS

Optimal endovascular reconstruction

78 yo man, symptomatic LICA

PGuard 9.0x40mm
Post-dil 5.0/24atm

46 yo man, asymptomatic RICA
(progressive plus increased-stroke-risk morphology)

PGuard 8.0x30mm
Post-dil 5.0/20atm

54 yo woman, symptomatic RICA

PGuard: Long-Term Angiography

54 yo woman, symptomatic RICA

26 months

Endovascular Solution for All-Comers

Endovascular Reconstruction of the Carotid Bifurcation
Prevention of embolism, High radial force, Conformability

Normal healing
No Stent Thrombosis
No abnormal ISR signal
**Acknowledgements**

R. Paweł Banyś
Anna Borratyńska
Mateusz Brózda
Andrzej Brzychczy
Władysław Dąbrowski
Natalia Dłużniewska
Tomasz Dąbrowski
Urszula Gancarczyk
Paulina Judziało
Marek Kazibudzki
Artur Klecha
Klaudia Knap
Artur Kozanecki
Agata Leśniak-Sobelga
Adam Mazurek
Jarosław Miszczyk
Marcin Misztal
Zbigniew Moczulski
Piotr Paluszek
Łukasz Partyka
Piotr Pieniążek
Piotr Podolec
Grażyna Stankiewicz
Tomasz Tomaszewski
Mariusz Trystuła
Małgorzata Urbańczyk
Piotr Wilkołek
Agnieszka Zwolińska

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**PARADIGM-EXT.**

@ 48 months
Favourable Cerebral Outcome

• NO device-related adverse events
• NO procedure-related events
sustained stroke prevention

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**Ostial CCA lesions**

(note adequate radial force and placement precision)

OPTIMAL angiographic + clinical + duplex result @ 12mo (and LECA patent)

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**Double-Layer Carotid Stents: From the Clinical Need, through a Stent-in-Stent Strategy, to Effective Plaque Isolation... the Journey Toward Safe Carotid Revascularization Using the Endovascular Route**

**TCT 2016 Featured Research**

**CGuard™ OCT**