Impact of TCAR and the CGuard™ Micronet-Covered Embolic Prevention Stent on CAS: Do They Decrease DW-MRI Cerebral Embolic Lesions – Which Helps Most?

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DISCLOSURES

TCAR + CGuard: Study Team

Investigator-Initiated, Non-Industry Funded, Academic Study

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The Problem of Conventional Carotid Stents

Post-procedural Embolization with conventional carotid stents

DW-MRI post CAS

Mean total lesion area

Embolic Events

Procedural

Post-procedural

40-80%

Timing of neuro-embolic events after CAS

Neurological events

Procedural

Post-procedural

Baseline

24h

30 days

Stroke timing with CAS IN-CAPTURE AND CREST
Timing of neuro-embolic events after CAS

- Procedural: Plaque EPD
- Post-procedural: Stent

- 40-80% post-procedural strokes with CAS in CAPTURE and CREST

CEA excludes the plaque.

In CAS, the stent should exclude the plaque too.

Anti-Embolic Carotid Stent

CGuard™ embolic prevention system

System specifications:
- Stent type: Nitinol—self-expanding
- Micromesh aperture size: 150-180 μm
- Guides: 0.014".
- Sizes:
  - Diameter: 6-10mm
  - Length: 20-60mm
- Nitinol frame open-cell area ≈ 21 mm²
- MicroNet closed-cell area = 0.3mm²

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

Intra-procedural cerebral embolization is minimized
Post-procedural cerebral embolization is eliminated
Timing of neuro-embolic events after CAS

Embolic Protection System

Procedural
Post-procedural

Plaque
EPD
Stent

40-80%

= post-procedural strokes with CAS (CAPTURE and CREST data)

TransCarotid Artery Revascularization (TCAR)

TCAR = CLEAR ADVANTAGES
1. avoiding arch
2. avoiding access route-dependent embolization
3. DYNAMIC flow reversal => ROBUST protection

TCAR

Transcarotid Artery Revascularization (TCAR)

Blood flow is reversed from the common carotid artery

Dynamic Flow Controller & Integrated 200µ Filter

Hi / Low / Off

Blood flow is returned to femoral vein

Working channel for interventional devices

ENROUTE® Transcarotid Stent System (57cm)

TCAR = CLEAR ADVANTAGES
1. avoiding arch
2. avoiding access route-dependent embolization
3. DYNAMIC flow reversal => ROBUST protection

TCAR

Prospective evaluation of All-comer percutaneous cArotID revascularization in symptomatic and increased-stroke-risk asymptomatic carotid artery stenosis using the CGuard™ MicroNet – covered embolic prevention stent system

The PARADIGM -> EXTEND study

n=171 (16 Nov 2016)
Consecutive Patient CGuard CAS
12 High-Embolism-Risk Patients ->TCAR

MRI imaging feasible in 11

All patients subjected to DW-MRI evaluation

TCAR inclusion criteria:
- Recently (≤ 2 mo) Symptomatic
- and/or High Embolism Risk @ Lesion Level
- in addition – failed transfemoral access in 2

No exclusions (TCAR IFU)

59 – 83y (median 69), 4 women

Symptomatic – 8 (recent stroke – 4, cresc TIA – 4)

"Asymptomatic" – 3:
- Thrombus-containing
- Progressive/irregular + contralat occlusion
- Progressive, ulcerated

Ipsilateral ischemic lesions on baseline MRI in all – 100%

PARADIGM - Extend
TCAR Substudy

All patients had ipsilateral cerebral ischemic lesions on MRI prior to CAS

MRI Protocol & Analysis:
- MRI Cerebral Imaging (incl. DW-MRI with ADC)
- 3 time points: ≤24h before CAS
- ≤48h after CAS
- 90 ± 10 days after CAS
- Slice thickness 5mm
- 636 slices total, median number per patient/time-point – 19
- 2 independent radiologists, per-agreement evaluation
- Medis QBrain 1.1

100% clinical, neurologic, and MRI follow-up
No death, no stroke, no MI up to 90 days

PARADIGM - Extend
TCAR Substudy

All TCAR & CGuard CAS study patients
(ie, clinically "asymptomatic" and clinically symptomatic)

had ipsilateral cerebral ischemic lesions on MRI prior to CAS

=> HIGH CEREBRAL RISK cohort!

MRI Imaging (incl. DW-MRI with ADC)
3 time points:
- ≤24h before CAS
- ≤48h after CAS
- 90 ± 10 days after CAS

The Power of DW-MRI...
24h after RICA-CAS (TCAR + CGuard)
Complete Resolution on follow-up
TW, man 69 yo
12 Jan 2016
Critical LICA stenosis, post-stroke

First-in-Poland direct carotid access CAS (TCAR)
Under En Route (SilkRoad Medical) Flow Reversal

Surgical Team: M. Trystula, M. Kazubudzki, J. Krzywoń, A. Brzychczy, L. Pinter
Endo: P. Musialek & A. Mazurek

Lesion crossing, predil, CGuard stent implantation and postdil under En Route (SilkRoad Medical) Flow Reversal

CGuard 7.0 x 30mm full endovascular reconstruction
First-in-Poland direct carotid access CAS under En Route (SilkRoad Medical) Flow Reversal

Z E R O new lesions

24h prior to CAS
First-in-Poland direct carotid access CAS under En Route (SilkRoad Medical) Flow Reversal + CGuard MicroNet Stent

48h after CAS
TW, man 69 yo

critical LICA stenosis, post-stroke

Z E R O new lesions

First-in-Poland direct carotid access CAS under En Route (SilkRoad Medical) Flow Reversal + CGuard MicroNet Stent

WE, woman, 58 y, R haemispheric minor stroke 22 Dec and 30 Dec 2015

TCAR plus CGuard (Krakow, 12 January 2016)

lesion crossing, predil, CGuard stent implantation and postdil under En Route (SilkRoad Medical) Flow Reversal

Debris captured in the A-V shunt filter in this procedure

En Route (SilkRoad Medical) Dynamic Flow Reversal

movie

P Musialek @ VEITH 2016
WE, woman, 58 y, R haemispheric minor stroke 22 Dec and 30 Dec 2015
TCAR plus CGuard  (Krakow, 12 January 2016)

Final Result

CGuard 7.0x30 mm full endovascular reconstruction
plus NO new lesions on DW-MRI!

WE, woman, 58 y, R haemispheric minor stroke 22 Dec and 30 Dec 2015
TCAR plus CGuard  (Krakow, 12 January 2016)

Z E R O new lesions

24h prior to CAS
48h after CAS

Brain Imaging: M. Urbanczyk, RP. Banys, Dept. Radiology, JP2 Hospital, Krakow

WE, woman, 58 y, R haemispheric minor stroke 22 Dec and 30 Dec 2015
TCAR plus CGuard  (Krakow, 12 January 2016)

Z E R O new lesions

24h prior to CAS
48h after CAS

Brain Imaging: M. Urbanczyk, RP. Banys, Dept. Radiology, JP2 Hospital, Krakow

TCAR + CGuard: The ONLY Post-procedural Cerebral Lesions (n=2 pts)

Patient BK KRK-PARADIGM TCAR + CGuard #11
(S, cresc TIAs, high embolism risk)

24h prior to RICA-CAS
24h after RICA-CAS
90 days after RICA-CAS

A SINGLE lesion 0.054 mL
TOTAL resolution
NO new lesions

Patient PW (S) KRK-PARADIGM TCAR + CGuard #4

24h prior to LICA-CAS
24h after LICA-CAS
94 days after LICA-CAS

CAS-L #1
CAS-L #2
CAS-L #3

Patient PA (S) KRK-PARADIGM TCAR + CGuard #4

24h prior to LICA-CAS
24h after LICA-CAS
94 days after LICA-CAS

CAS-L #4
CAS-L #5
TCAR + CGuard For Symptomatic and High-Emboli Risk “Asymptomatic” Carotid Stenosis

- Uncomplicated procedure
- No neuro complications by discharge and 90 days
- Nearly eliminated peri-procedural embolism (MRI)
  - V. low incidence (!)
  - V. low number (!)
  - V. low volume (!)
- Totally eliminated post-procedural embolism during stent healing and by 90 days (MRI)

*High-risk plaque features plus MRI evidence of ipsilateral ischemic lesions in ALL study subjects

Uncomplicated procedure
No neuro complications by discharge and 90 days
Nearly eliminated peri-procedural embolism (MRI)
- V. low incidence (!)
- V. low number (!)
- V. low volume (!)
Totally eliminated post-procedural embolism during stent healing and by 90 days (MRI)

TCAR + CGuard™

- efficient capture & removal of intra-procedural debris
- less embolic material during CAS
- sustained anti-embolic after CAS

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The Problem of Conventional Carotid Stents

Precise 5.0x30mm (2005)
2014-2016 "increasing restenosis"

Another ( Rare but Important ) Problem of Conventional Carotid Stents: Stent Design Allows Atherosclerotic Plaque In-Growth

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Another (Rare but Important) Problem of Conventional Carotid Stents: Stent Design Allows Atherosclerotic Plaque In-Growth

Precise 5.0x30mm (2005) 2014-2016 "increasing restenosis"

Atherosclerotic Plaque Growth Into The Open-Cell Stent Lumen Treated with Neroprotected PTA Under IVUS – and CGuard™

PTA No flow (movie) Aspiration "Half-open" Vial Removal

TCAR CGuard™

In conclusion, It is NOT one "or" the other

TCAR CGuard™

In conclusion, It is NOT one "or" the other but BOTH
TCAR + CGuard™

- efficient capture & removal of *intra*-procedural debris
- less embolic material *during* CAS
- sustained anti-embolic *after* CAS

TCAR: Carotid Artery Revascularization for Stroke Prevention: A New Era

Piotr Musialek, MS, CRNA, RN, and Mike Hackleman, MS/PhD

Abstract:

Background: Carotid artery stenosis is an important cause of stroke, and various surgical and endovascular interventions are available for its treatment. However, neuroprotection and prevention of stroke during intervention remain a major challenge.

Methods: 2016 study... (abstract continues)

CGuard™ EPS

CGuard™ OCT Image - human, in situ
Courtesy Dr. Joan Rigla, MD PhD, Perceptual Imaging Lab, University of Barcelona

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