

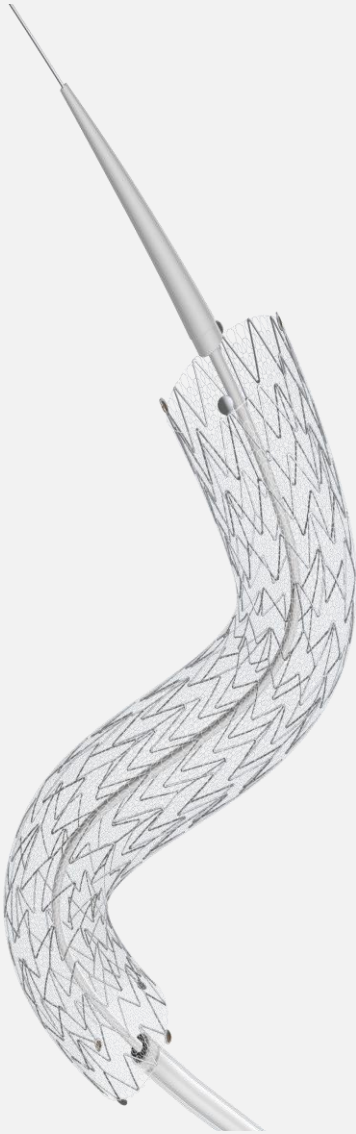


C-Guard MicroNet Carotid Stent in Symptomatic Lesions

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Coimbatore



Disclosure statement of financial interest

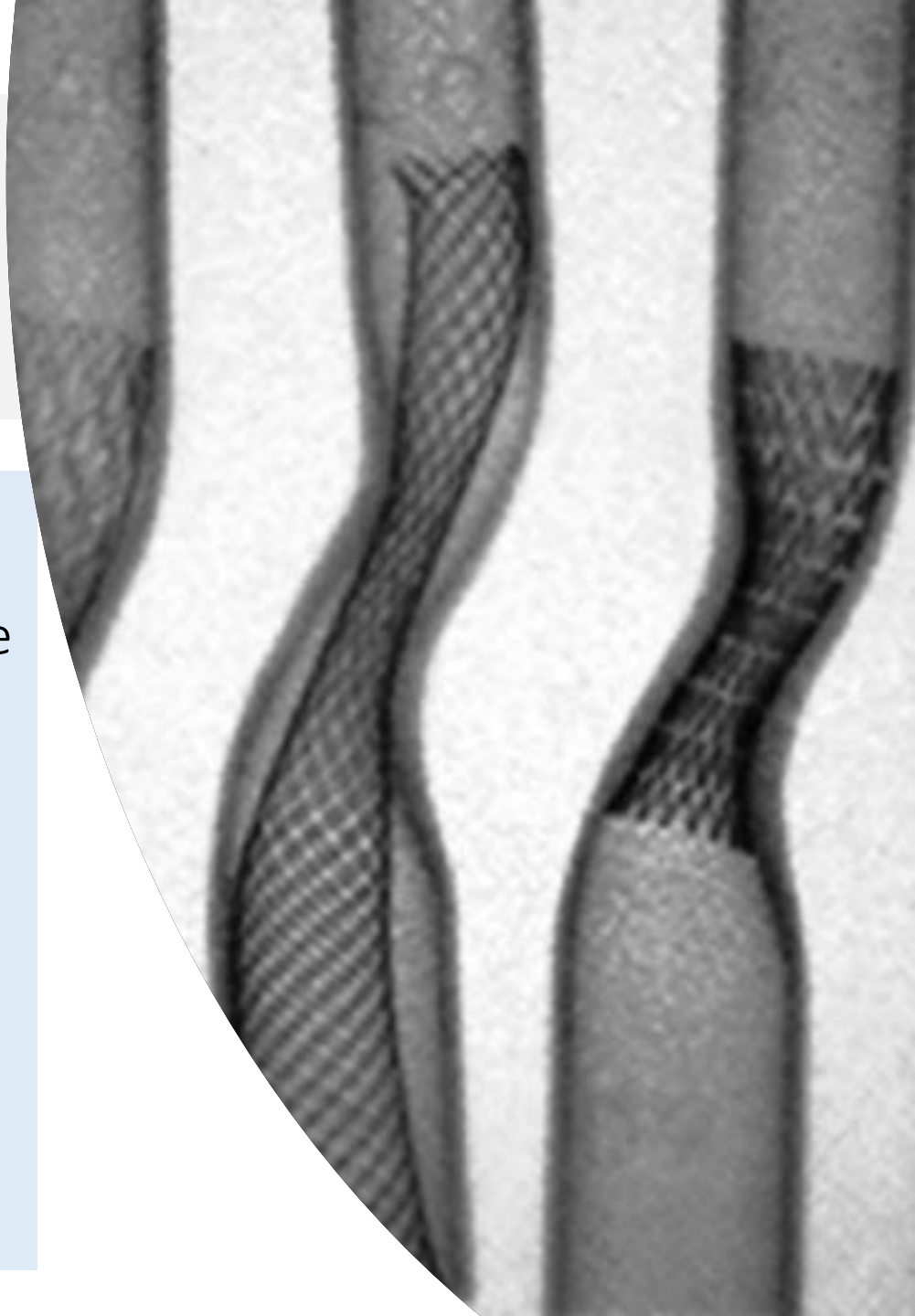
Within the past 12 months, I or my spouse/partner have had no financial interest/arrangement or affiliation with any organization(s) .

Disclosure statement of financial interest

I, Dr. Mathew Cherian DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Stent apposition

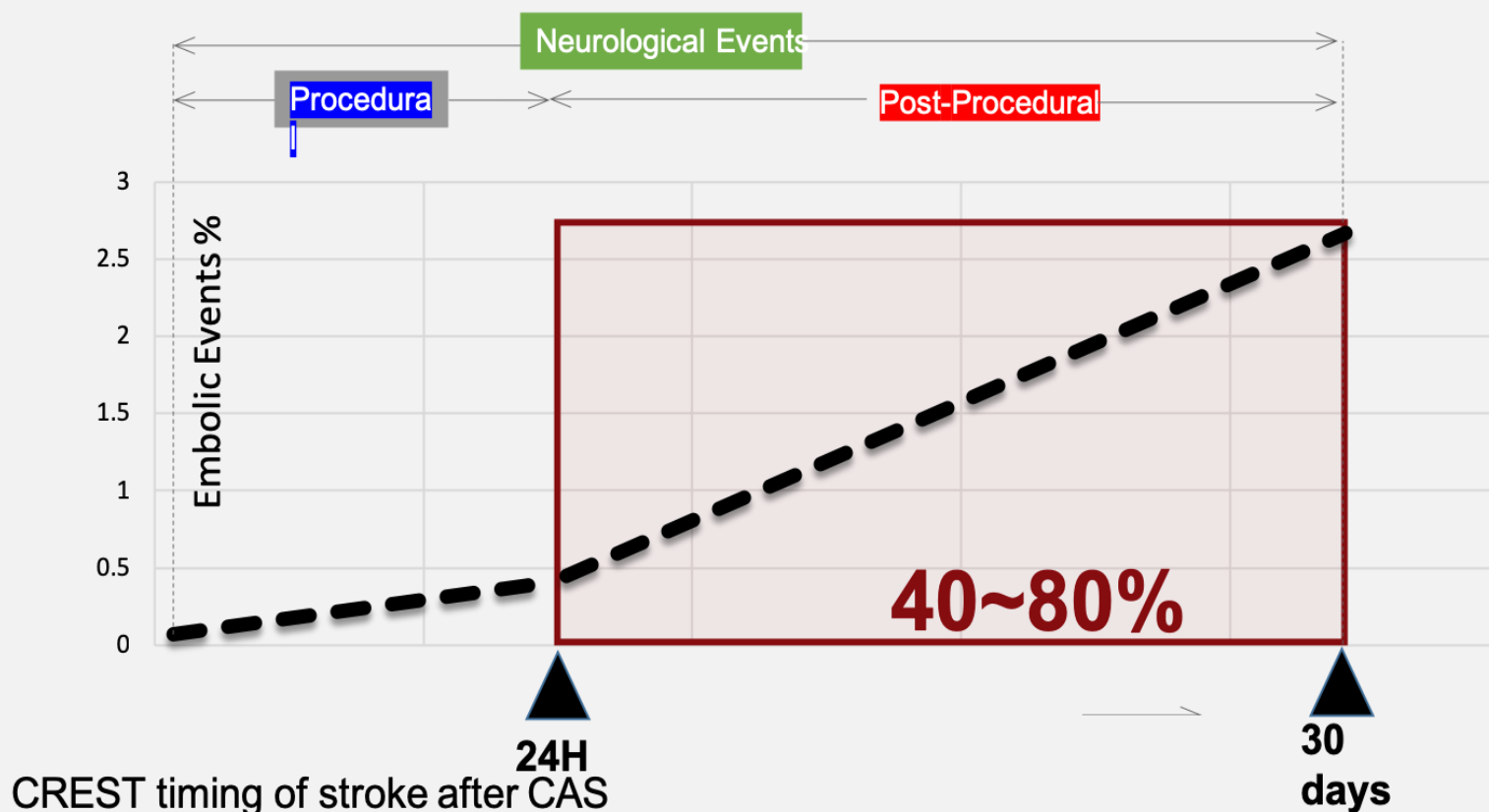
- Open Cell Stents are conformable within a vessel, but associated plaque prolapse
- Closed Cell Stents limit plaque prolapse but associated with straightening/kinking of arteries



Problems with
conventional
carotid artery
stenting

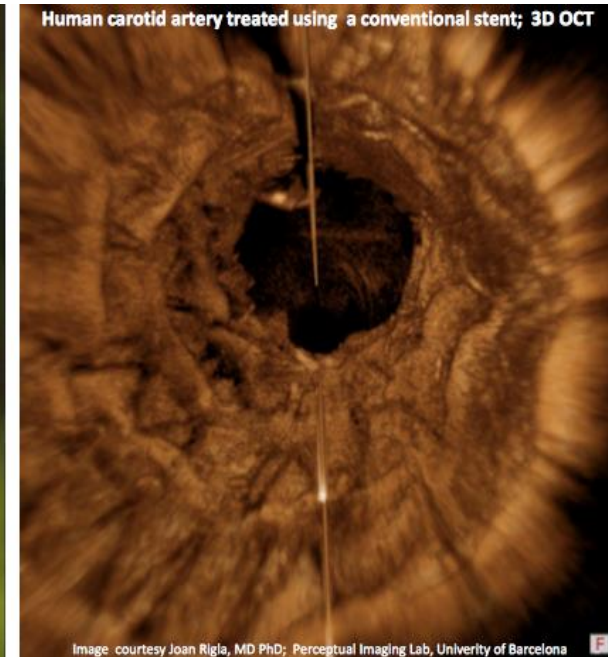


40~80% of embolic events are post-procedural

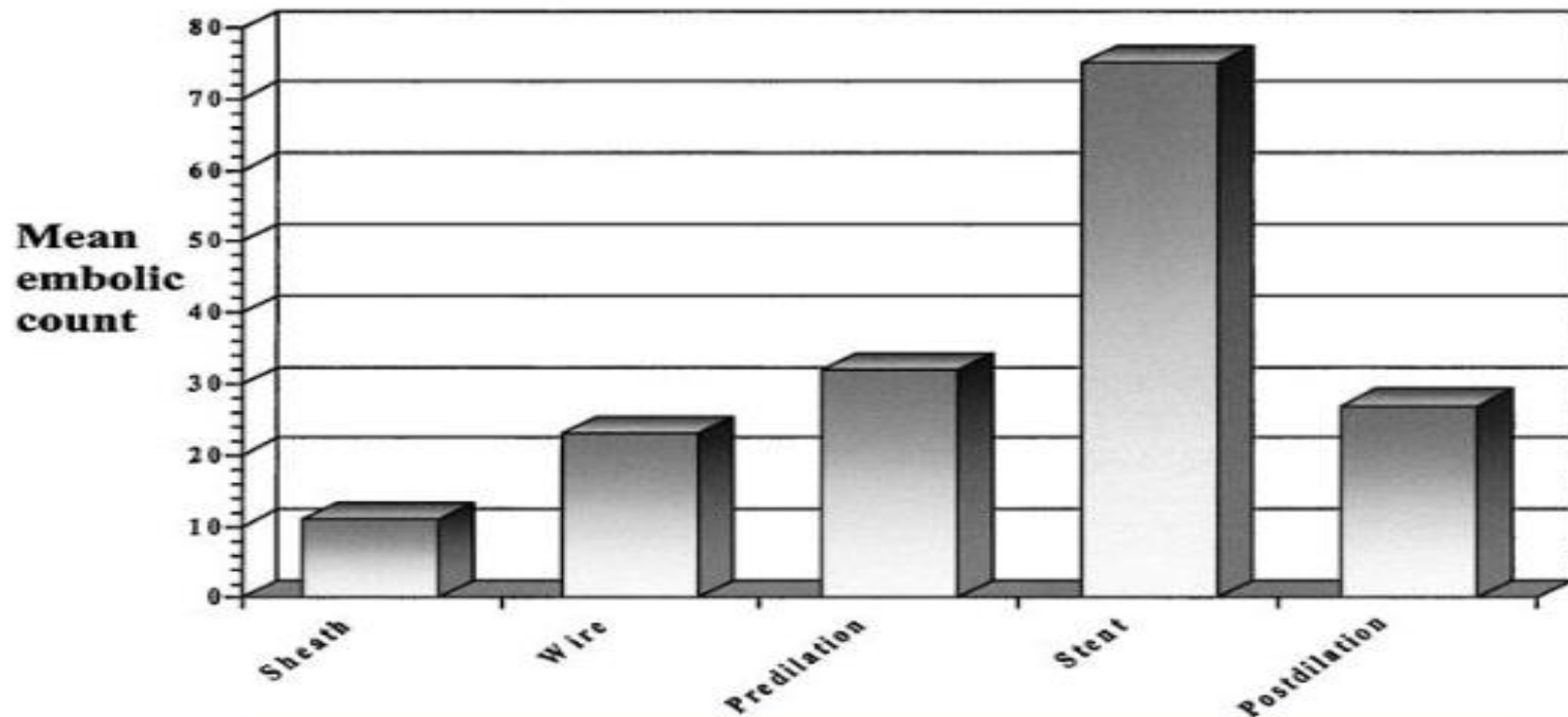


Problems with conventional carotid stent

- Protrusion of plaque within stent.
- Plaque protrusion may lead to early and late distal emboli.



CAS will remain an emboli generating procedure



- Carotid endarterectomy removes the plaque.
- In CAS, ideally the stent should exclude the plaque and prevent further distal embolization.



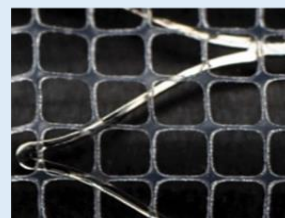
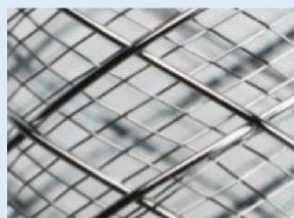
K	M
C	H



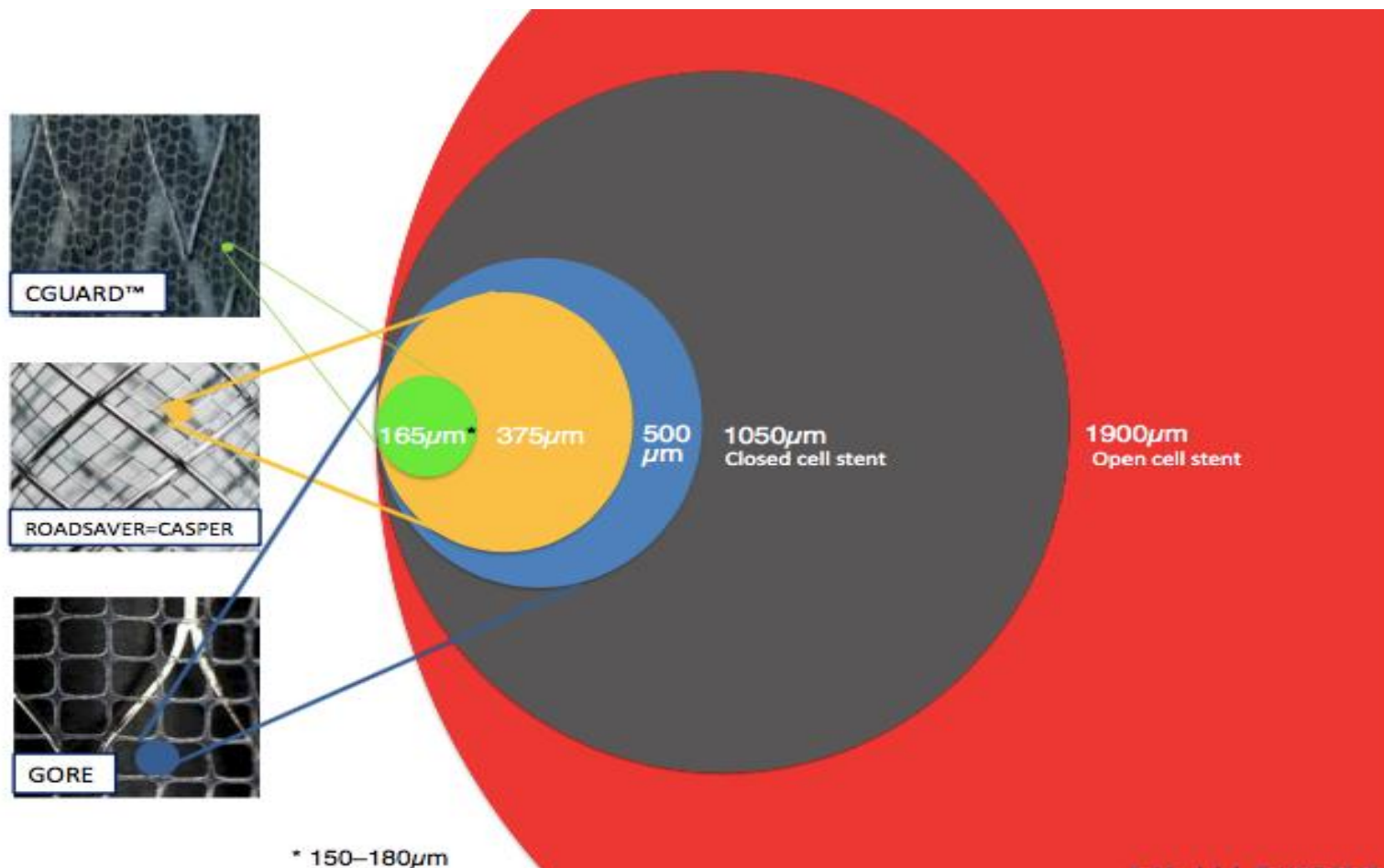
Making things
better to prevent
post-procedural
embolization



Available 'dual layer' stents



Name	Terumo RoadSaver / Casper	Gore Scaffold	CGuard™ Embolic Prevention System
Type & Material	close-cell/ Nitinol	open-cell/ Nitinol	open-cell/ Nitinol
Mesh Location	Inner mesh	Outer mesh	Outer mesh
Mesh material	Nitinol	PTFE	PET
Mesh structure	braided	inter-woven	single-fiber knitted
Pore size	375-500 µm	500 µm	150 - 180 µm



Roadsaver/Casper design

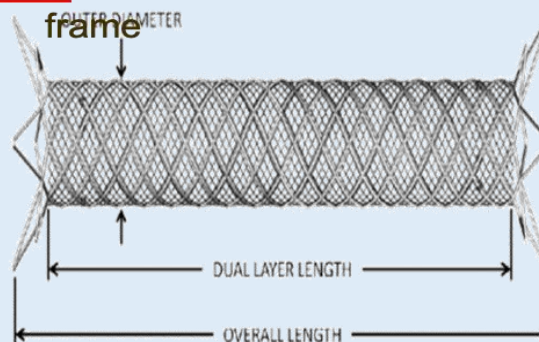
Closed cell,
Braided Stent



Large pore size
and uncovered
flared ends

Unpredictable
stent length upon
deployment

nitinol mesh **INSIDE** the nitinol

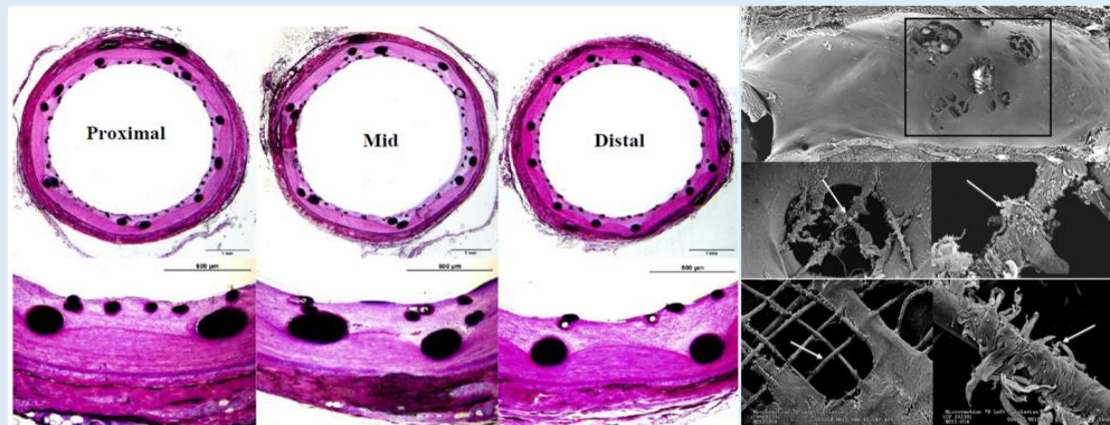


5F sheath,
Double layered
nitinol stent

Road saver - endothelialization

HISTOLOGICAL and REM DATA

AFTER 6 MONTHS FOLLOW-UP THE STENT IS NOT ENDOTHELIALIZED

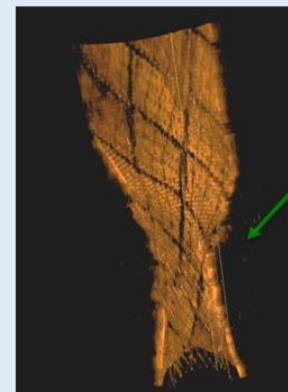
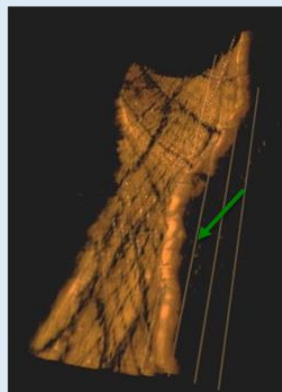
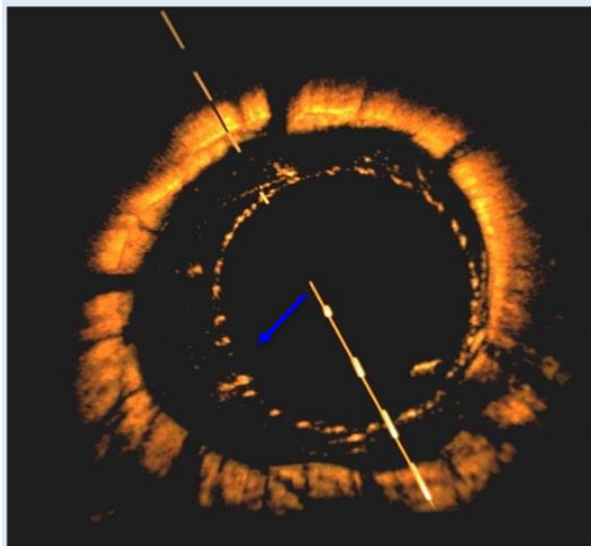


This is consequence of the stent design:

- Poor expansion radial force
- Poor conformability with frequent incomplete apposition
- The mesh is inside the stent
- The stent struts and mesh struts have two crossing points which requires twice the endothelialization.

Poor apposition - Roadsaver

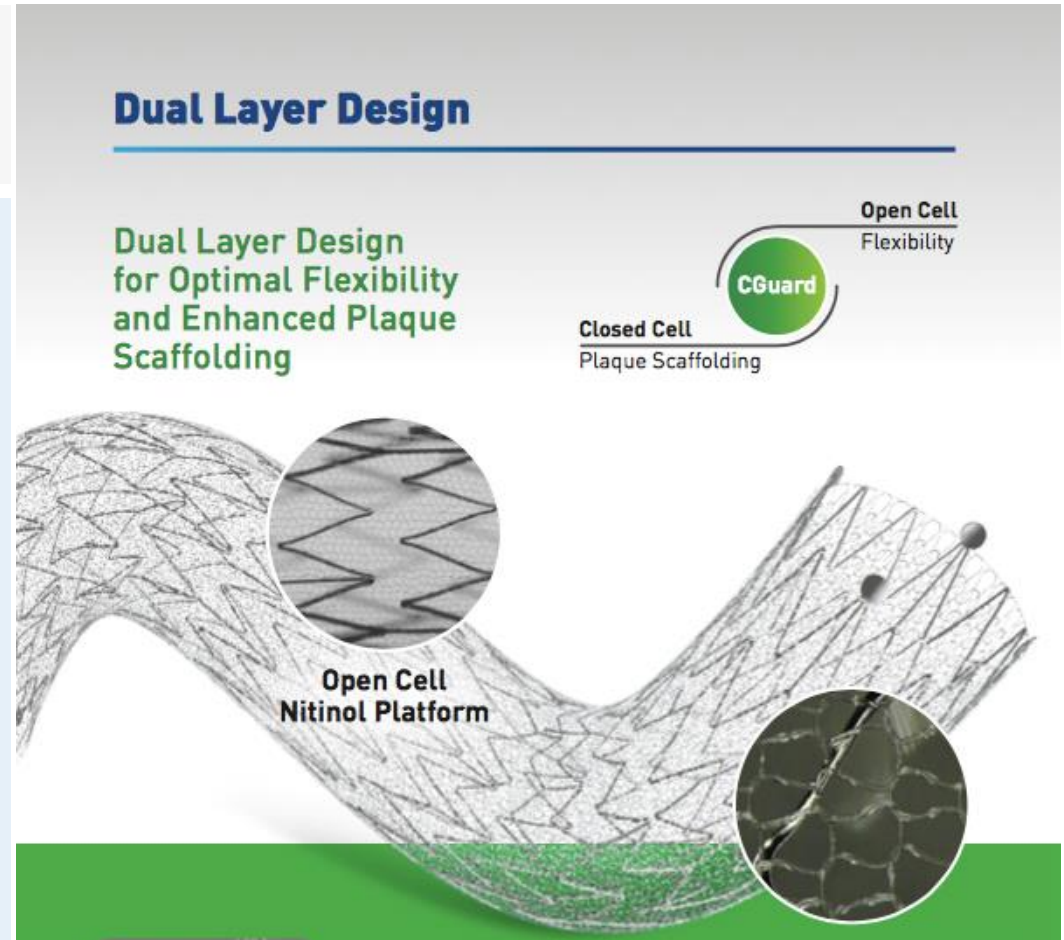
POST IMPLANTATION IMAGES



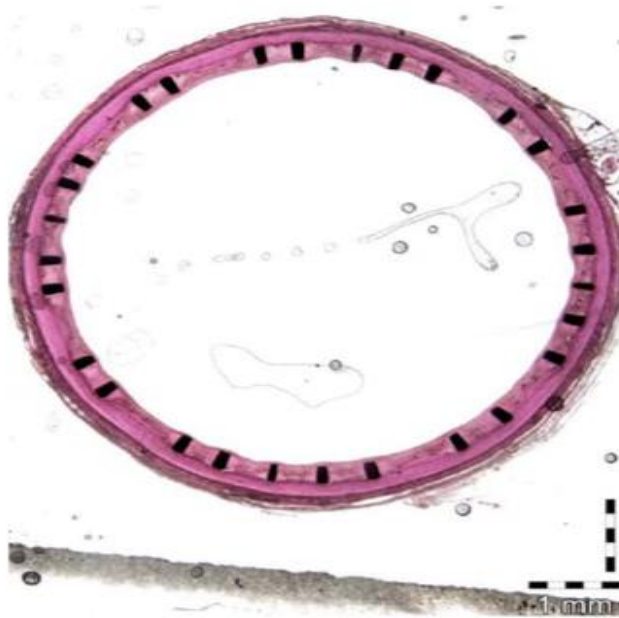
After implantation **under-expansion** and **incomplete-apposition** is frequent in the cases analyzed
 Courtesy Dr Setacci, Run 9; Pt #Roadsaver1

C-guard Design

- It has dual layer design.
- Stent: Nitinol (Nickel-titanium alloy), open cell design.
- Mesh: Micro-Net material-Polyethylene terephthalate, PET, closed cell design provide plaque scaffolding.



C-guard endothelialization : 90 days/pig

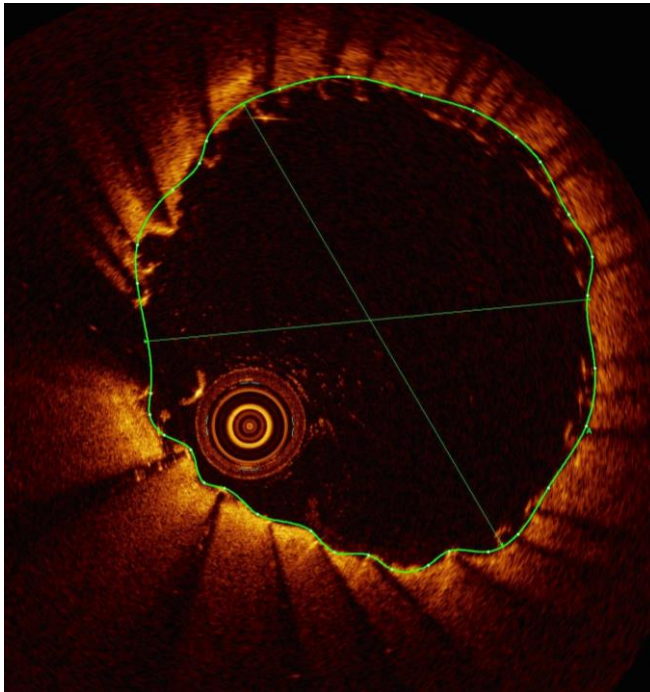


InspireMD data / by permission



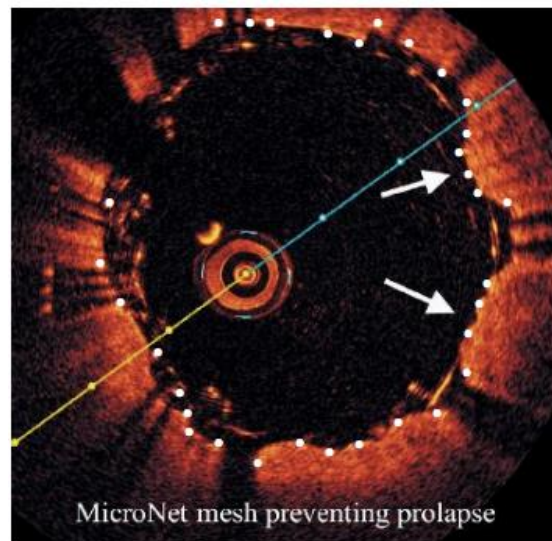
P Musialek @ ePCR 2018

Perfect apposition : C-guard



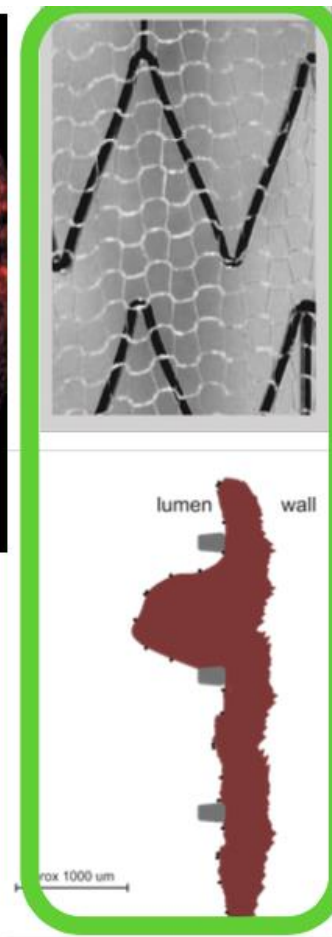
C-guard

Micronet mesh preventing prolapse of thrombus in Optical Coherence Tomography.



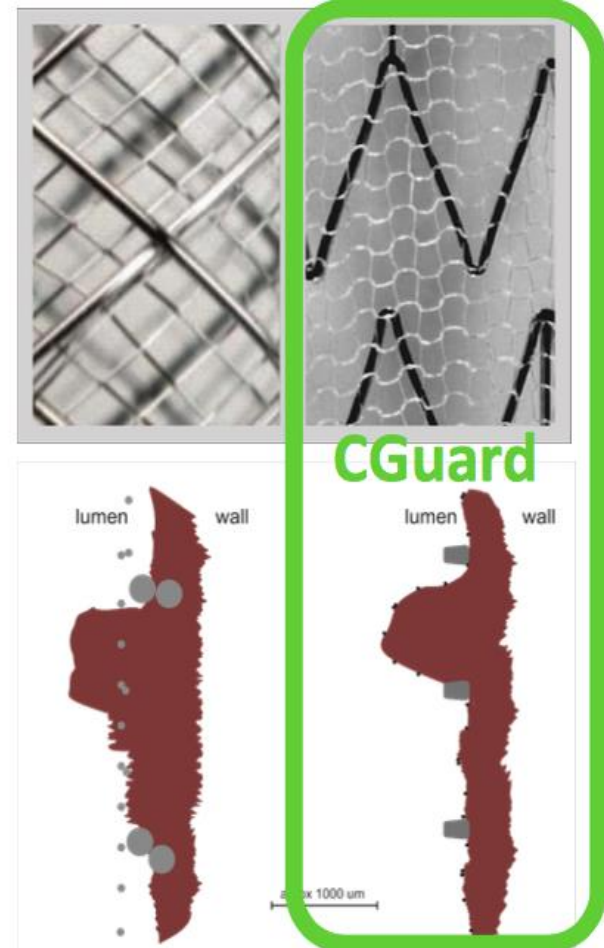
MicroNet mesh preventing prolapse

Tomyuki Umemoto et al.
EuroIntervention 2017





Roadsaver vs C-guard



Musialek & Stabile
EuroIntervention 2017

A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent



The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet)

Joachim Schofer, MD,* Piotr Musiałek, MD, DPHIL,† Klaudija Bijuklic, MD,* Ralf Kolvenbach, MD,‡
Mariusz Trystula, MD,† Zbigniew Siudak, MD,†§ Horst Sievert, MD||

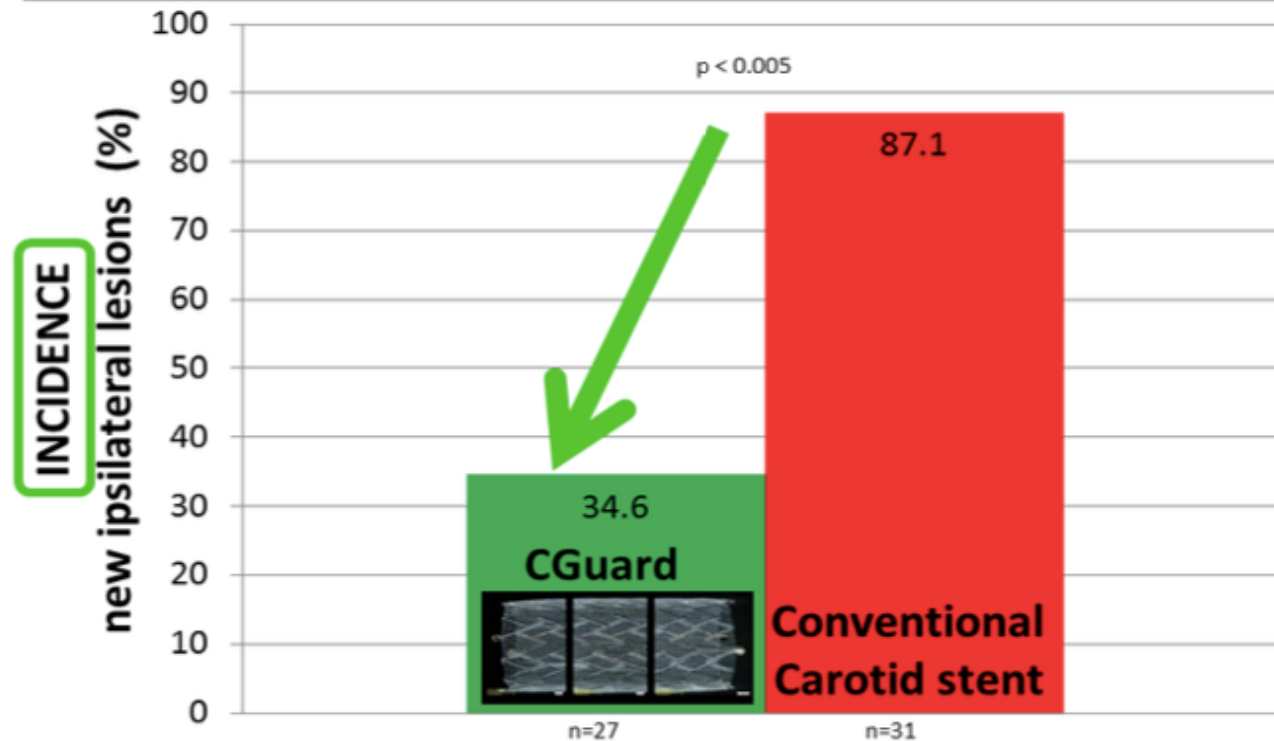
RESULTS The primary combined endpoint was the procedure success of the CGuard system and the number and volume of new lesions on the ipsilateral side assessed by diffusion-weighted magnetic resonance imaging at 48 h post-procedure and at 30 days. The secondary endpoint was 30-day major adverse cardiac or cerebrovascular events (death, stroke, or myocardial infarction). Protection devices were used in all procedures. Procedure success was 100%, with 0% procedural complications. The 30-day major adverse cardiac or cerebrovascular events rate was 0%. New ipsilateral ischemic lesions at 48 h occurred in 37.0% of patients and the average lesion volume was $0.039 \pm 0.08 \text{ cm}^3$. The 30-day diffusion-weighted magnetic resonance imaging showed complete resolution of all but 1 periprocedural lesion and only 1 new minor (0.116 cm^3) lesion in relation to the 48-h scan.

CONCLUSIONS The use of the CGuard system in patients undergoing carotid artery stenting is feasible. In addition, the benefit of using CGuard may extend throughout the stent healing period. (J Am Coll Cardiol Interv 2015;8:1229-34)



Filter-protected CAS procedures **CARENET** vs **PROFI**: DW-MRI analysis

DW-MRI analysis @ 48 hours



* see patient fluxogram
Bijuklic et al. *JACC*, 2012;59

J. Schofer, P. Musialek et al. *JACC Interv* 2015;8:1229-34
Bijuklic et al. (manuscript in preparation)

CARENET DW-MRI analysis^{*}

All but one peri-procedural ipsilateral lesions

RESOLVED

DW-MRI analysis @ 30 days^{*}

Incidence of new ipsilateral lesions	1
Average lesion volume (cm ³)	0.08 ± 0.00
Permanent lesions at 30 days	1

^{*} External Core Lab analysis (US)

J. Schofer, P. Musialek et al. *JACC Intv* 2015;8:1229-34

C-guard 'Carnet trial'

- Intra-procedural cerebral embolization is minimized.
- Post-procedural procedural cerebral embolization is eliminated.

K	M
C	H



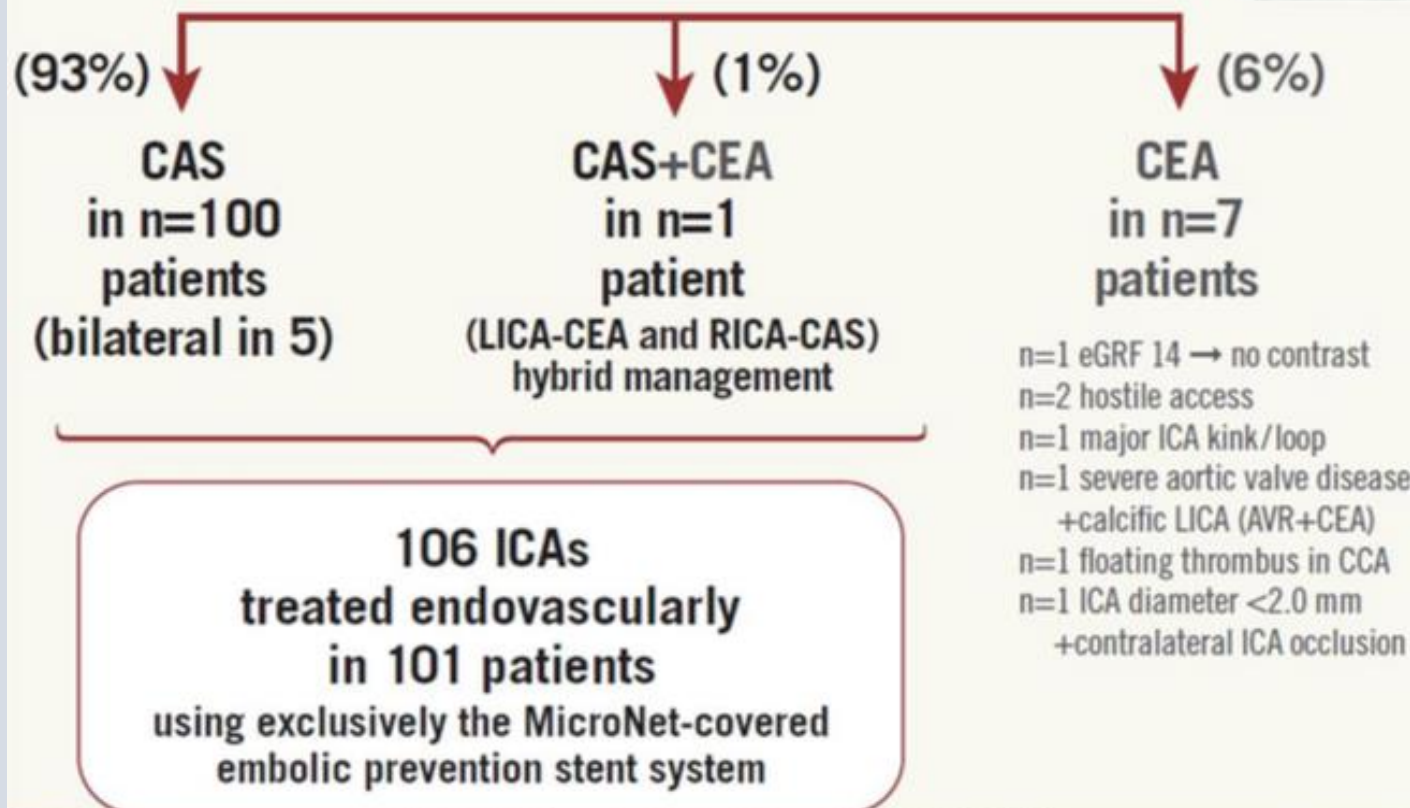
Prospective evaluation of
All-comer percutaneous
carotid revascularization
in symptomatic and
Increased-risk
asymptomatic carotid
artery stenosis using the
C-Guard Micronet covered
embolic prevention stent
system





PARADIGM study: revascularisation flow chart

108 patients for carotid revascularisation



P. Musialek, A. Mazurek et al. *EuroIntervention* 2016;12:e658-70



Table 1. Clinical characteristics of the study patients (n=101).

Age, mean±SD (min-max)	69±7 (51-86)
Male, % (n)	70% (71)
Symptomatic, % (n)	55% (55)
Symptomatic ≤14 days, % (n)	22%* (12)
Acutely symptomatic (emergent CAS), % (n)	14%* (9)
Index lesion (CAS), % (n)	
RICA	51% (52)
LICA	49% (49)
RICA+LICA	5% (5)
CAD, % (n)	63% (64)
h/o MI, % (n)	32% (32)
CABG or PCI in the past, % (n)	40% (40)
PCI as bridge to CAS, % (n)	18% (18**)
AFib (h/o or chronic), % (n)	9% (9)
Diabetes, % (n)	41% (41)
h/o neck or chest radiotherapy, % (n)	6% (6)
*proportion of symptomatic patients; **simultaneous (one-stage) PCI+CAS in 4 patients; h/o: history of	



K	M
C	H



Carotid endarterectomy like effect with
C-guard stent

Clinical results peri-procedural

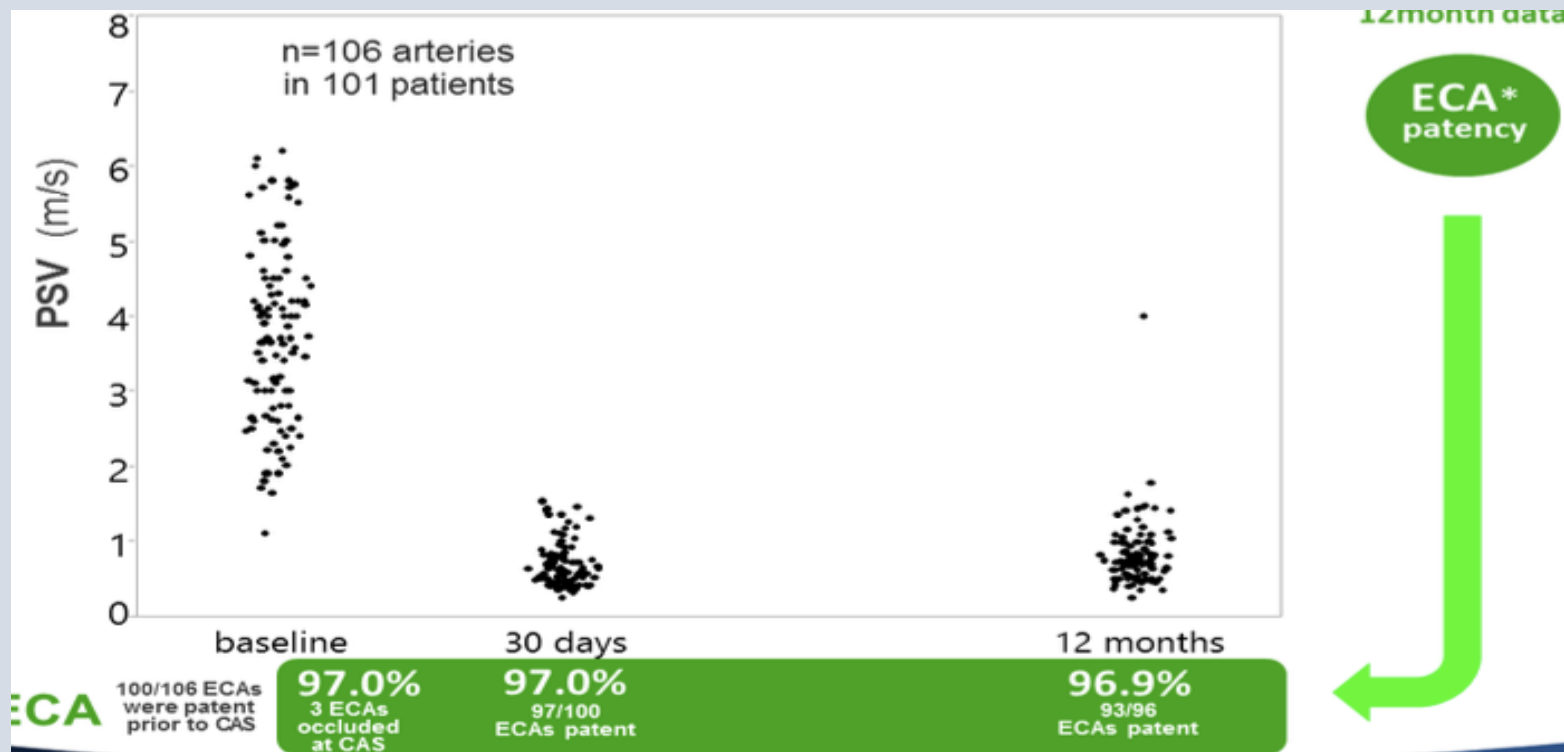
- 0 Peri-procedural death/major stroke/MI - 0 %
- 1 Peri-procedural minor stroke - 0.9 %
- 0 New clinical events by 30 days - 0 %

Clinical results between 30 days to 12 months

- Stroke - 0 %
- TIA - 0.9 %
- MI - 0 %



C-guard paradigm study 12 months USG data for 'ECA patency'



K	M
C	H



Paradigm study' continued as
'Paradigm extend study'

C-guard paradigm extend 2018 update (2 years data)

- 251 patients/263 arteries
- Peri-procedural outcome:
 1. 0 death / major stroke – 0%
 2. 1 minor stroke - 0.4 %
 3. 1 MI (type 2) – 0.4 %

C-guard paradigm-extend 2018 update (2 years data)

- 30 days outcome:
 - I. Hemorrhagic transformation of prior ischemic cerebral infarct,
leading to death – 0.4%.
 - I. Major stroke/Minor stroke/Death/MI – 1.2 %

C-guard paradigm-extend 2018 update (2 years data)

- Clinical outcome 1 -12 months:
0 stroke/stroke related death- 0%

C-guard paradigm- extend May 2018 update (2 years data)

- Clinical outcome 12-24 months:
 - I. 0 carotid stroke/stroke related death- 0%
 - II. 1 clinically silent stent occlusion in a patient who initiated neck radiotherapy course 2 months after CAS due to cancer relapse



CGUARD™
Carotid Embolic Prevention System



24-month data

PARADIGM

@ 24 months

Favourable Clinical Outcome

- NO device-related adverse events
- NO procedure-related events

sustained stroke prevention

2018 euro
PCR

K	M
C	H



Can this be the future of carotid artery
Revascularization ?

Is there really a need
of filter/distal
embolic protection
device ??

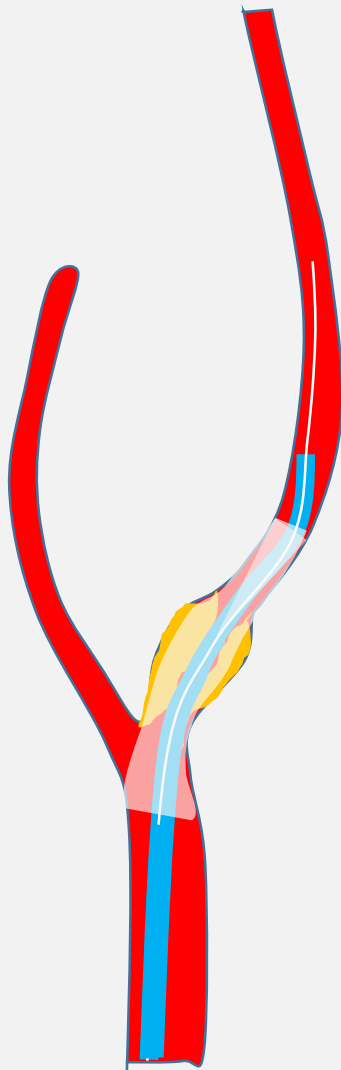


- Most of the peri-procedural distal emboli take place during deployment of stent.
- If we start deploying the stent 1 cm above the lesion, stent mesh will completely cover upper edge of carotid plaque and will behave as embolus capture device.



K	M
C	H

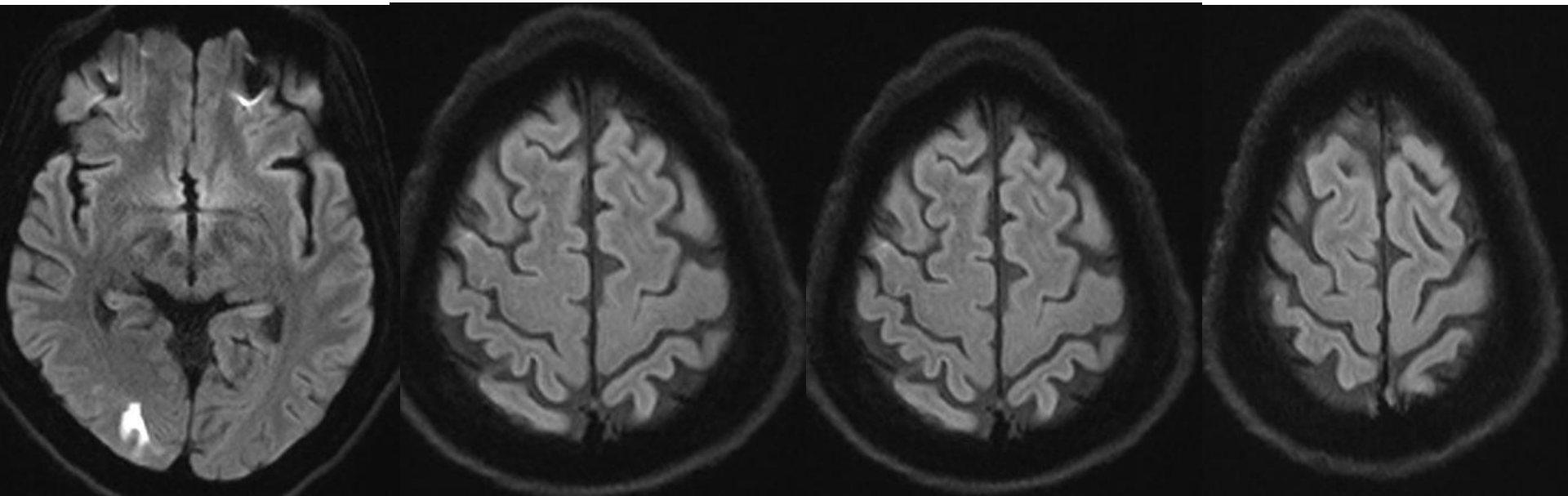
ICCA STROKE 2019



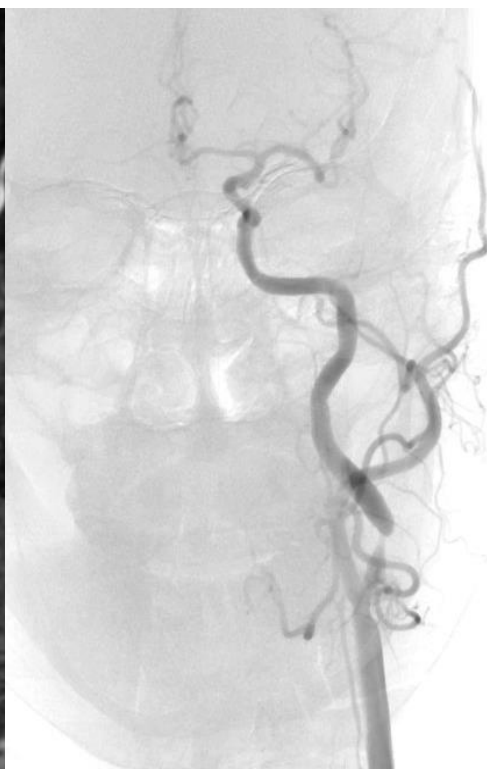
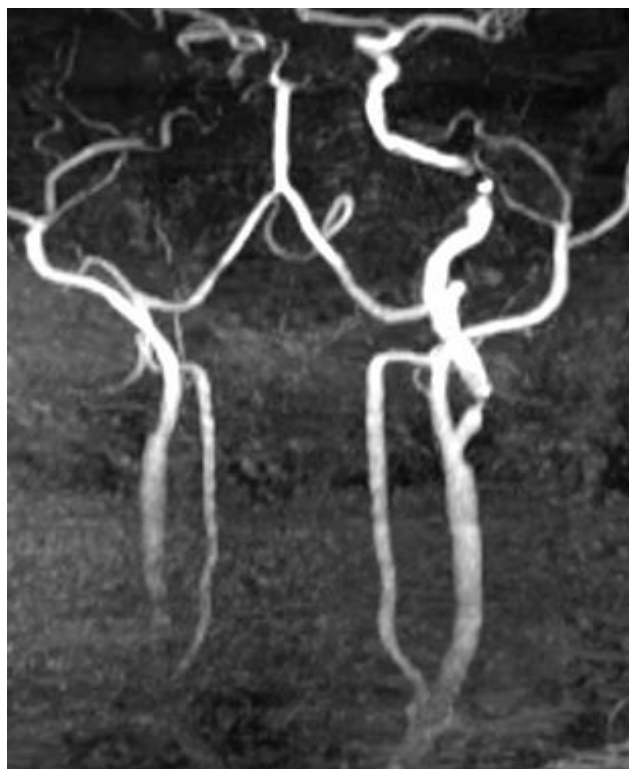
Case 1: Left ICA – 80% stenosis, Right ICA-chronic occlusion

- 54 year old male,
- Left side hemiparesis one month back
- Power- 4/5
- HT- on Angiotensin II receptor blocker
- DM, CAD – on medical management

Pre-procedure MRI-Lt . Stenosis

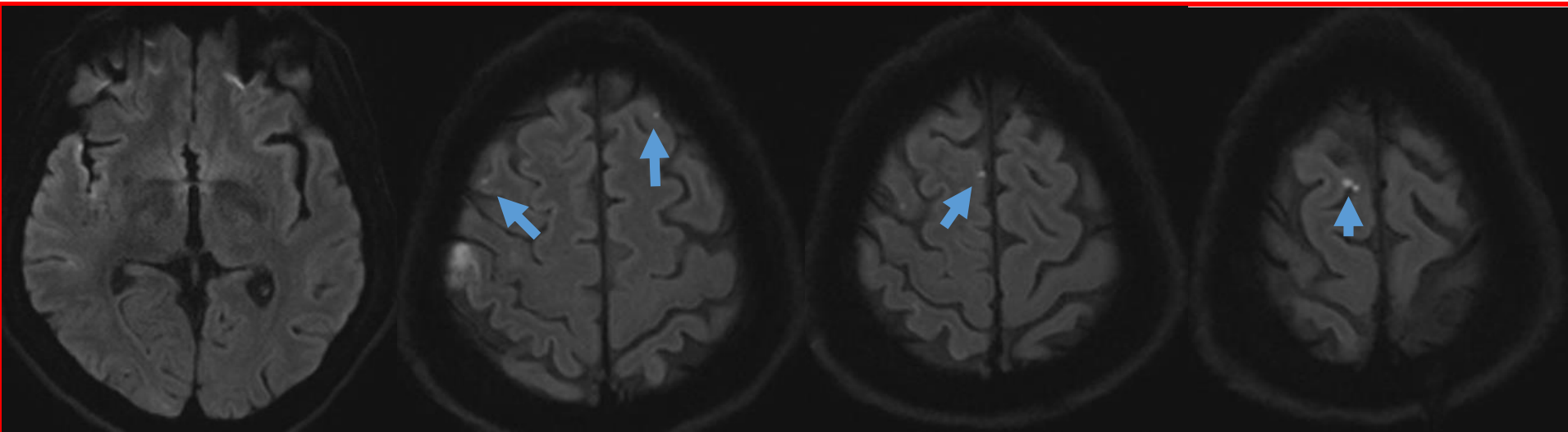


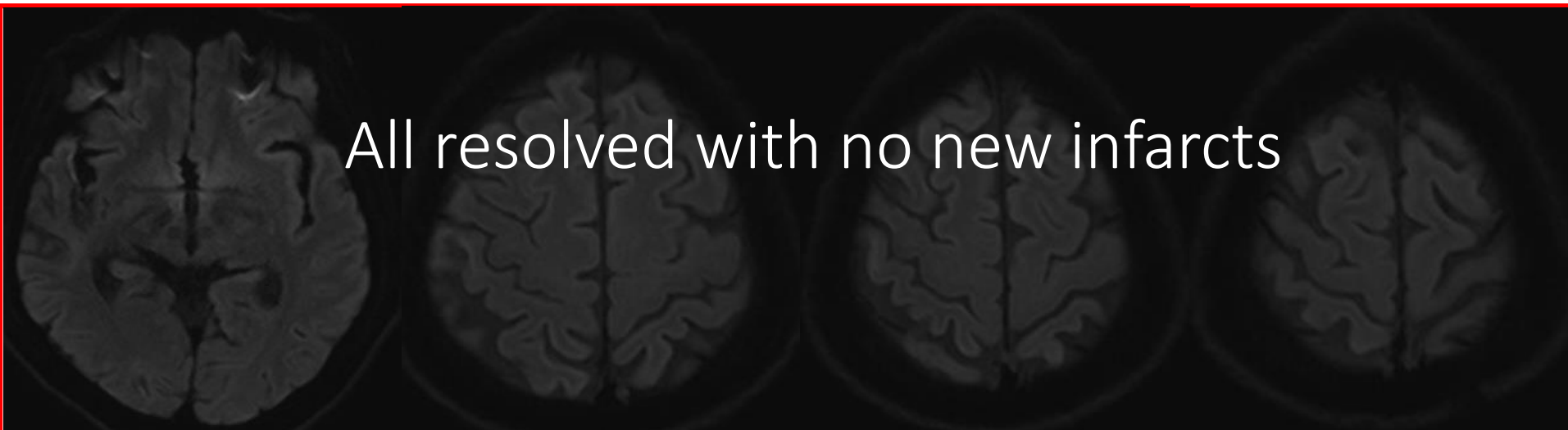
Left ICA stenting



K	M
C	H

Left ICA – 80% stenosis, Right ICA- chronic occlusion

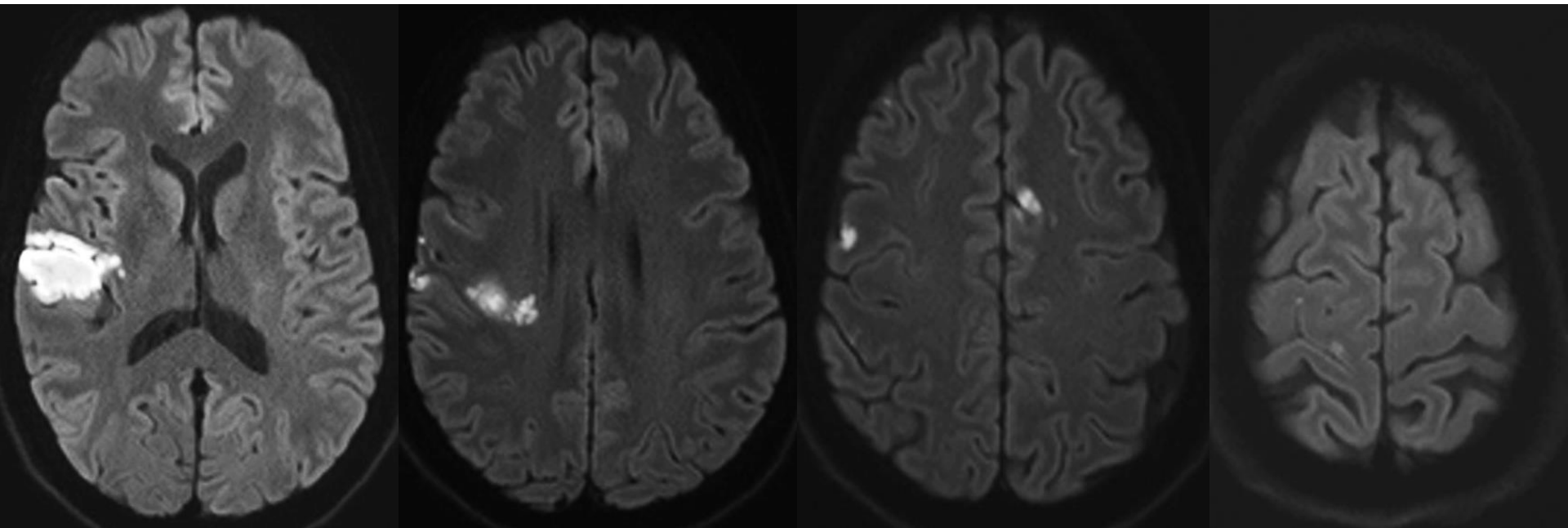




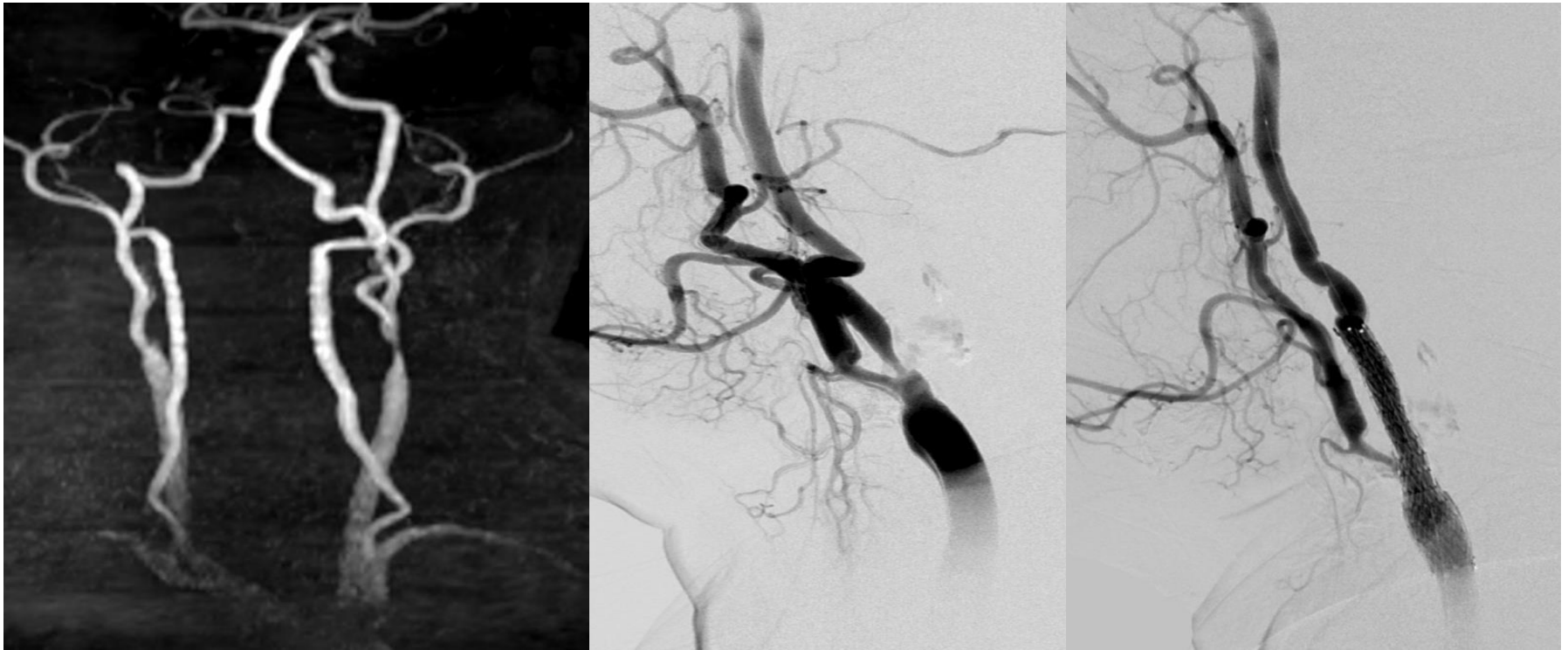
Case-2 : Right ICA chronic occlusion, left ICA - 95 % stenosis

- 49 year female,
- B/l MCA territory minor stroke 4 months back
- Right UL/LL-4/5
- Known DM
- No history of HT/CAD/CKD

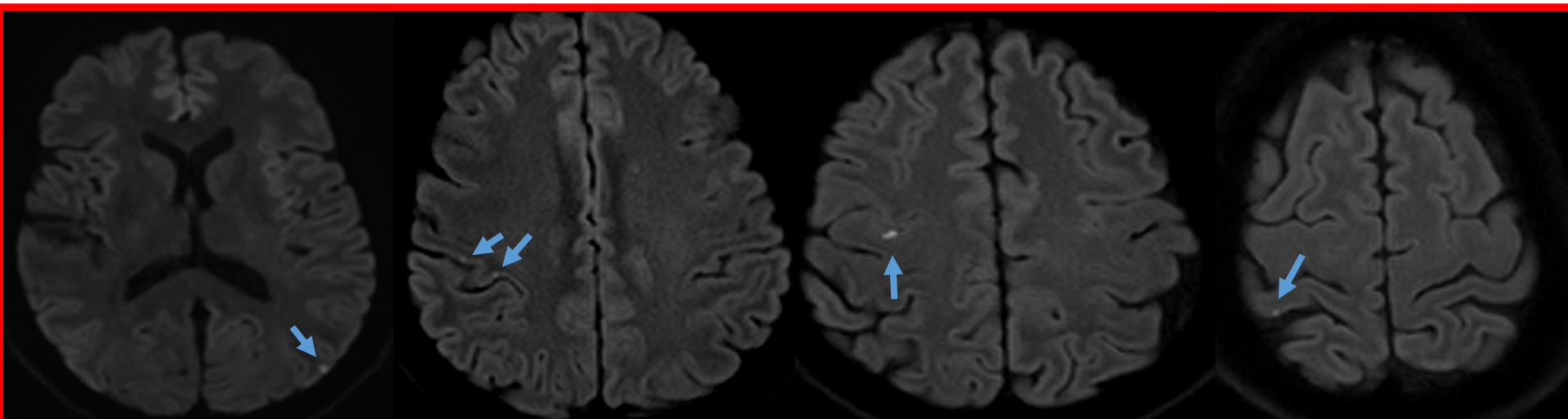
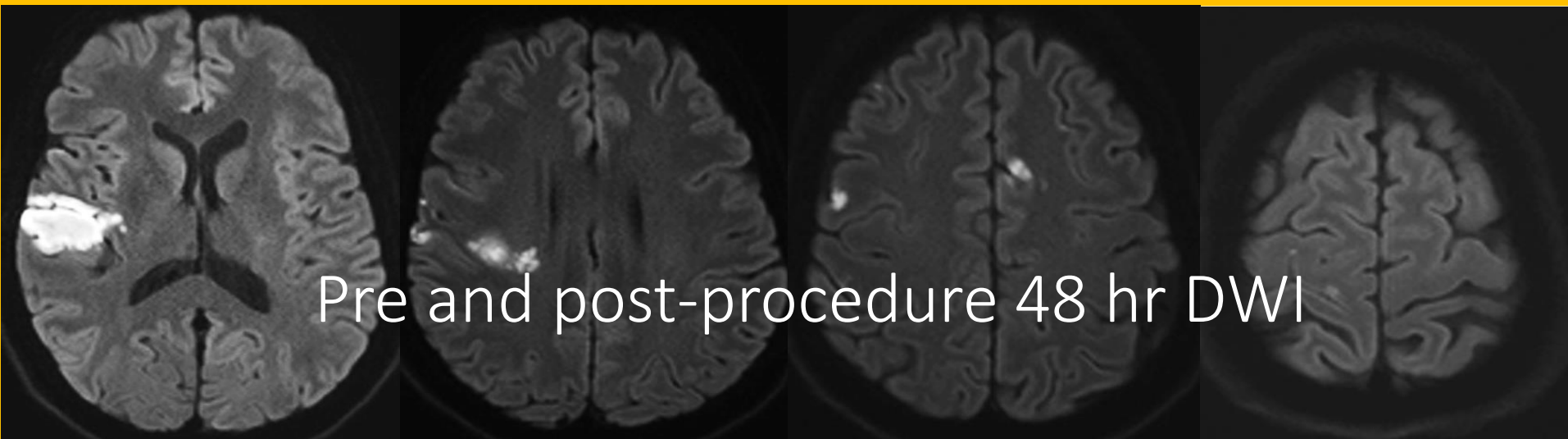
Pre-procedure MRI -LEFT ICA - 95 % STENOSIS



Left ICA stenting



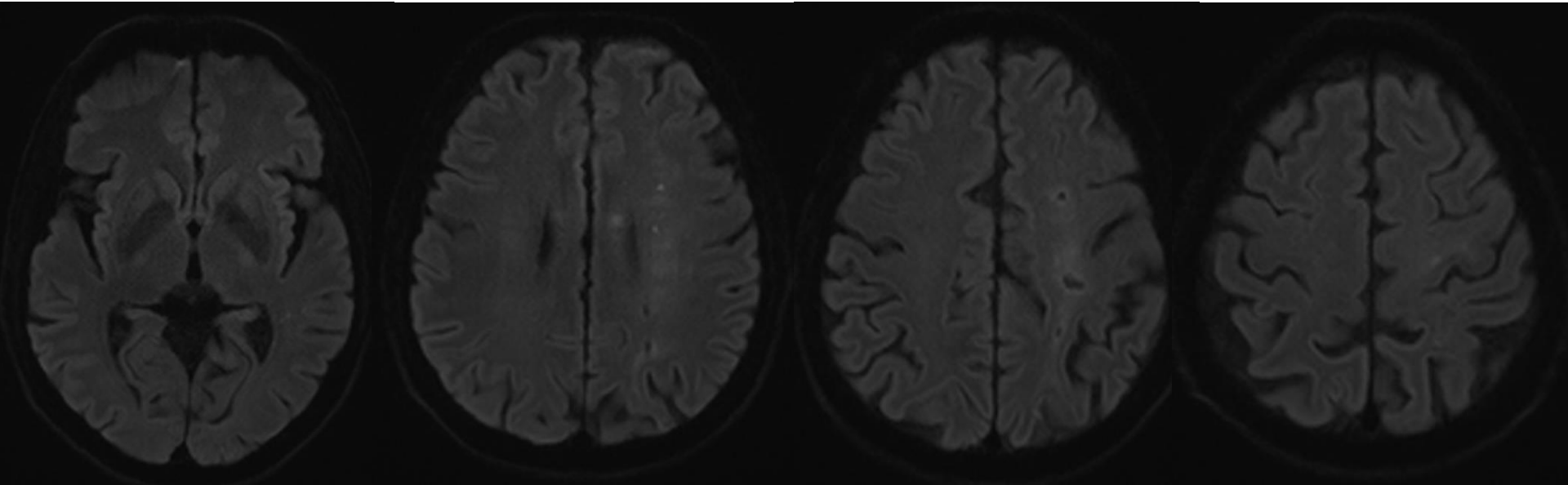
Pre and post-procedure 48 hr DWI



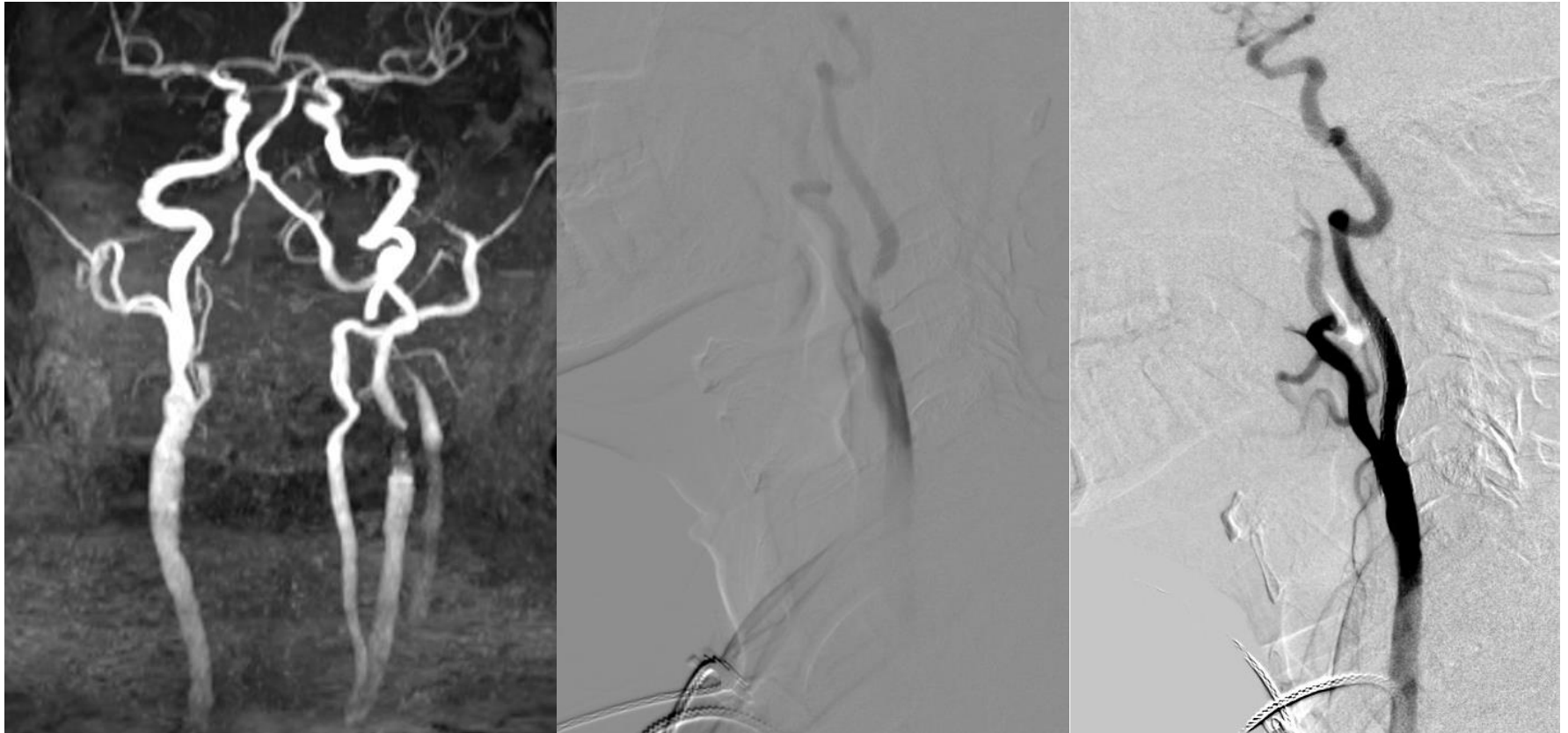
Case 3: Left ICA – 99% stenosis

- 65 year old male,
- Right side hemiparesis and slurring of speech one week back
- Power- 4/5
- HT- on ACE inhibitor

Pre-procedure MRI-Left ICA – 99% stenosis



Left ICA stenting





Pre and post-procedure 6 hr DWI

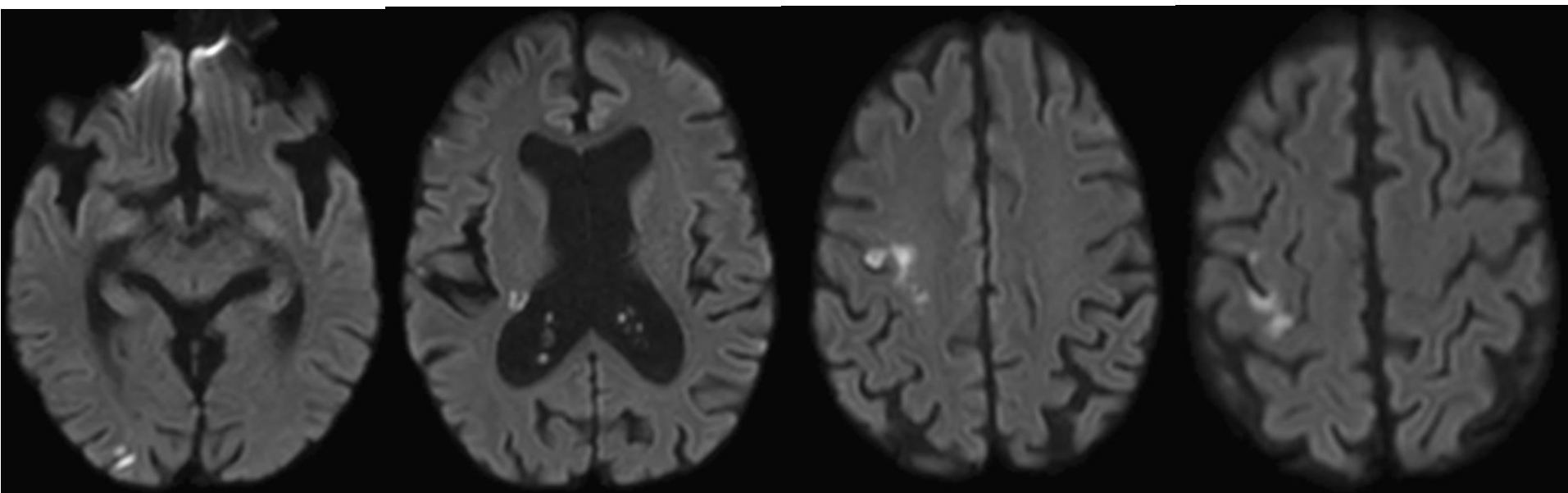


No new infarcts on DWI

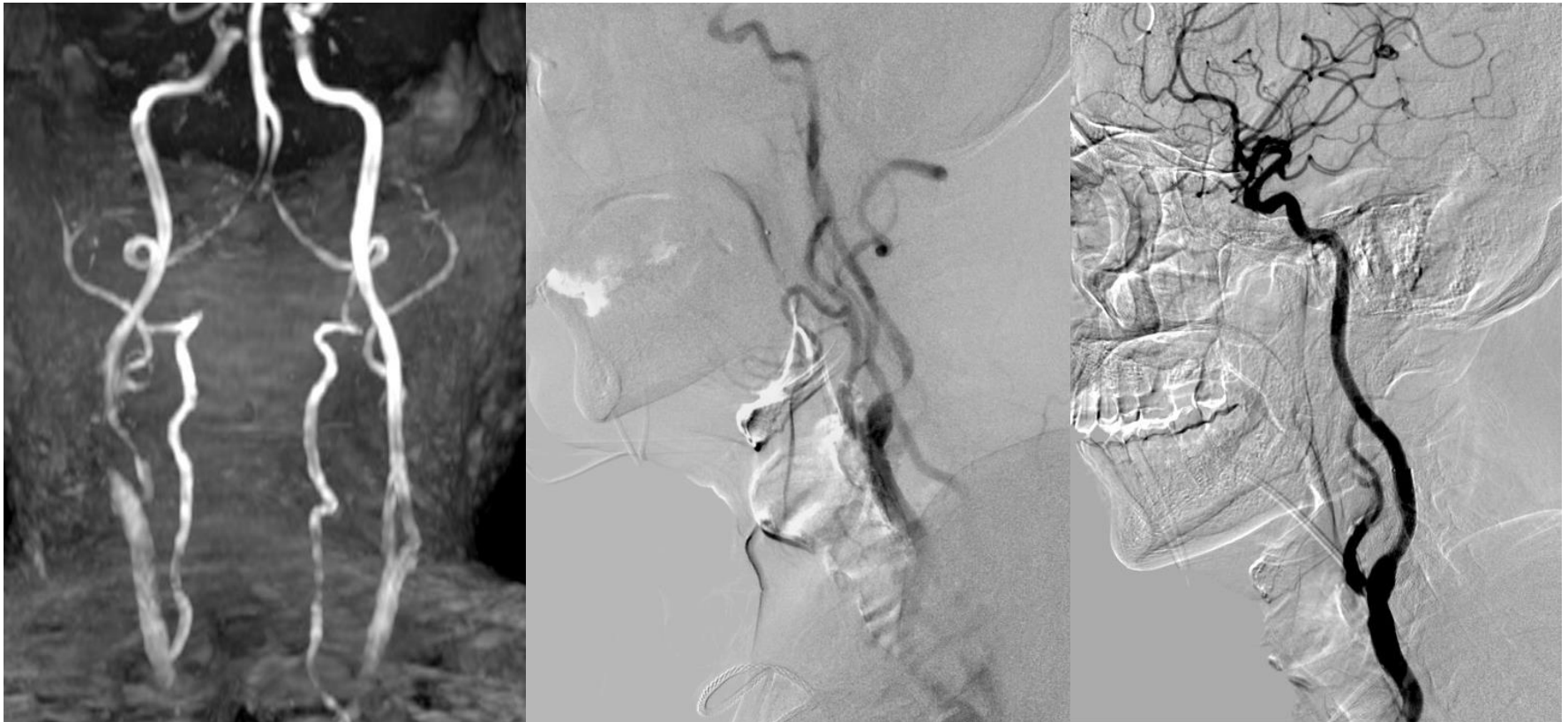
Case 4: Right ICA- 95-99 % stenosis

- 78 year old male,
- Acute stroke in right MCA water shed area -1 week back
- Left UL/LL Power-4/5
- HT – on ACE inhibitor

Pre-procedure MRI-Right ICA- 95-99 % stenosis



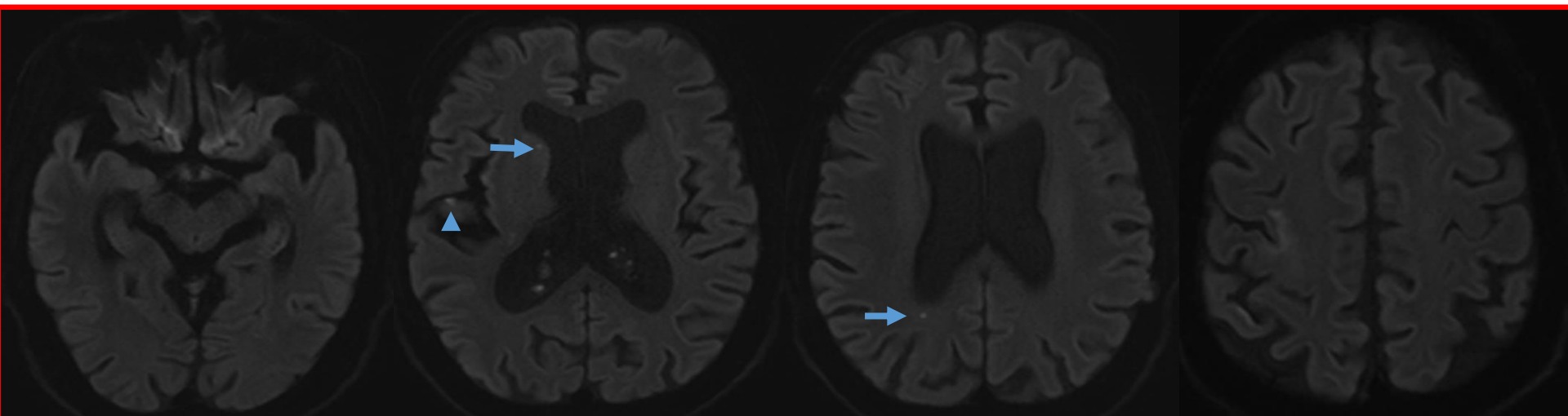
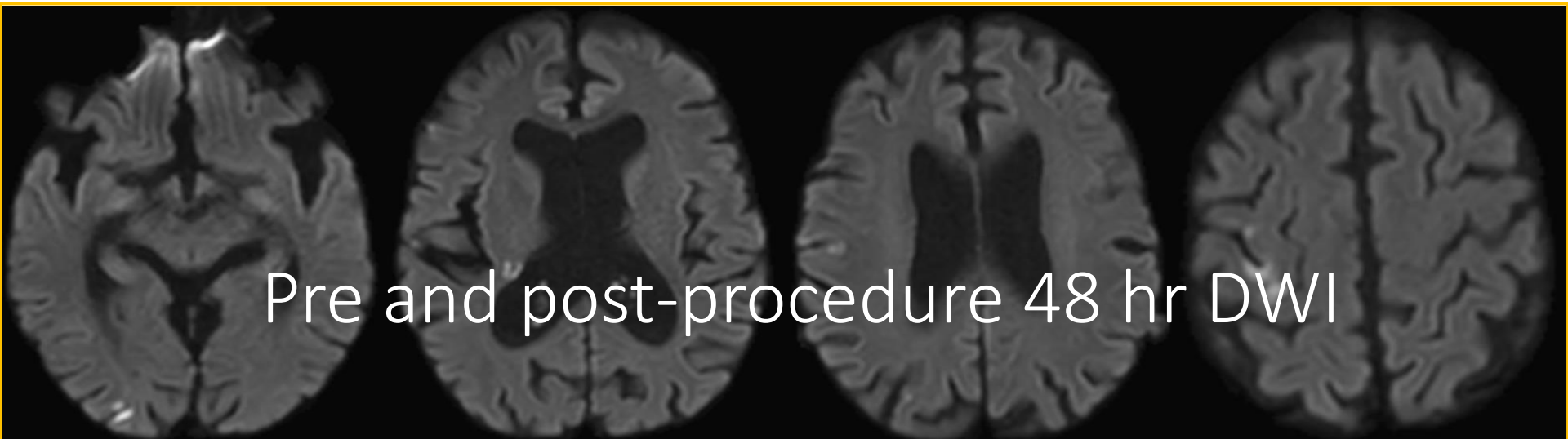
Right ICA stenting



Right ICA- 95-99 % stenosis



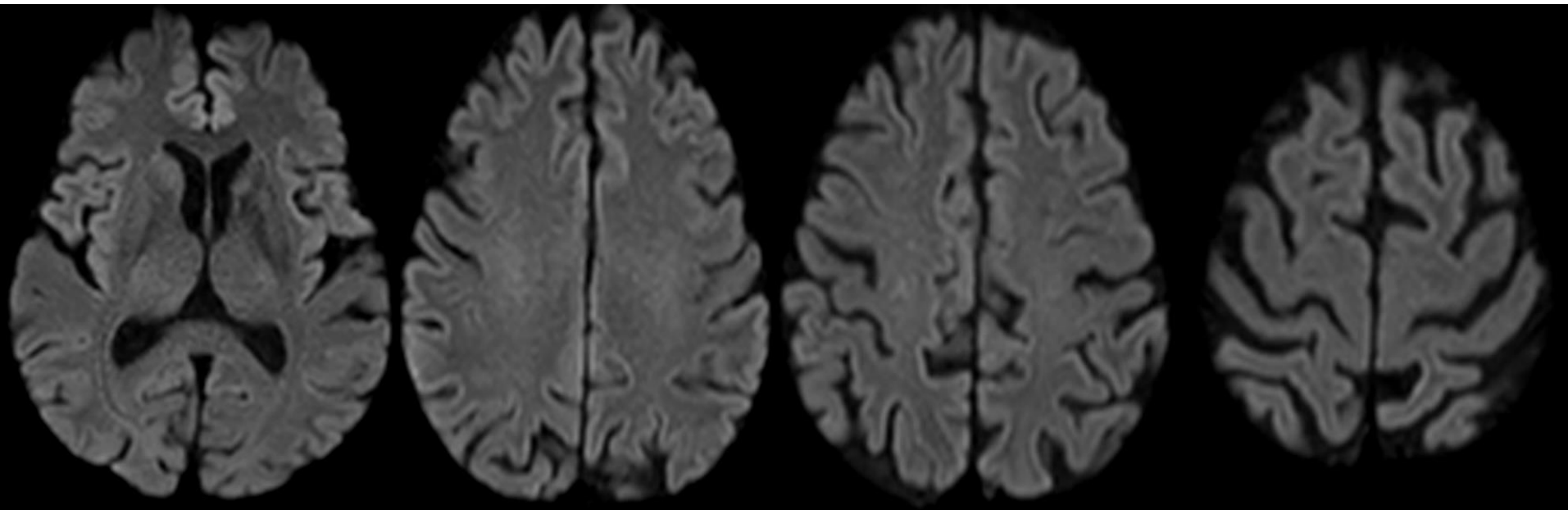
Pre and post-procedure 48 hr DWI



Case 5: Right ICA stenosis

- 64 year old Male,
- TIA – weakness in left UL, recovered
- Hypothyroidism- on medical management
- No HT

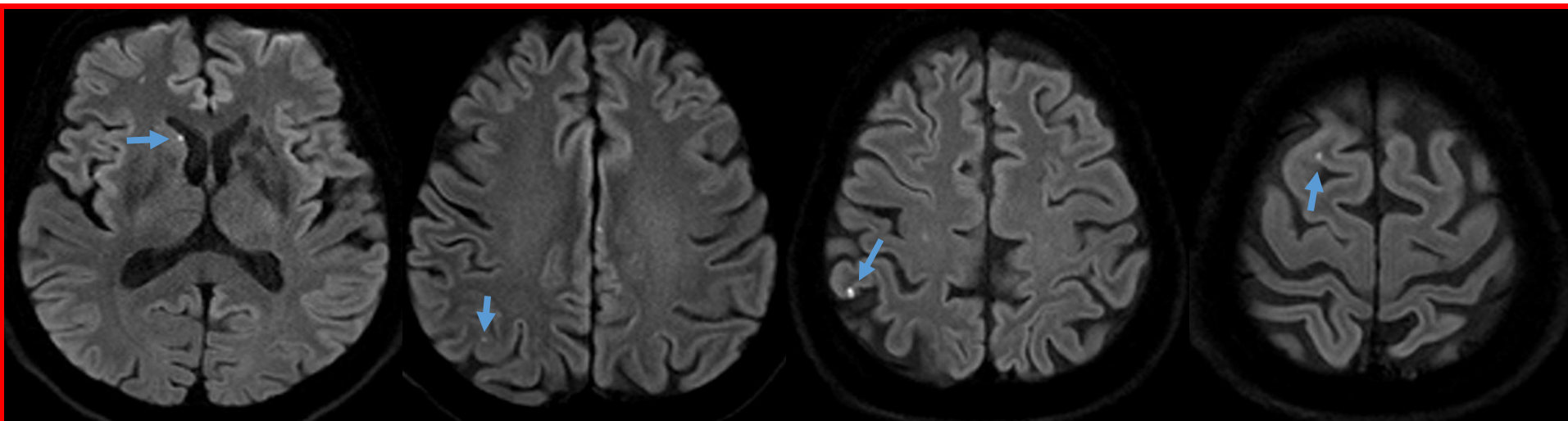
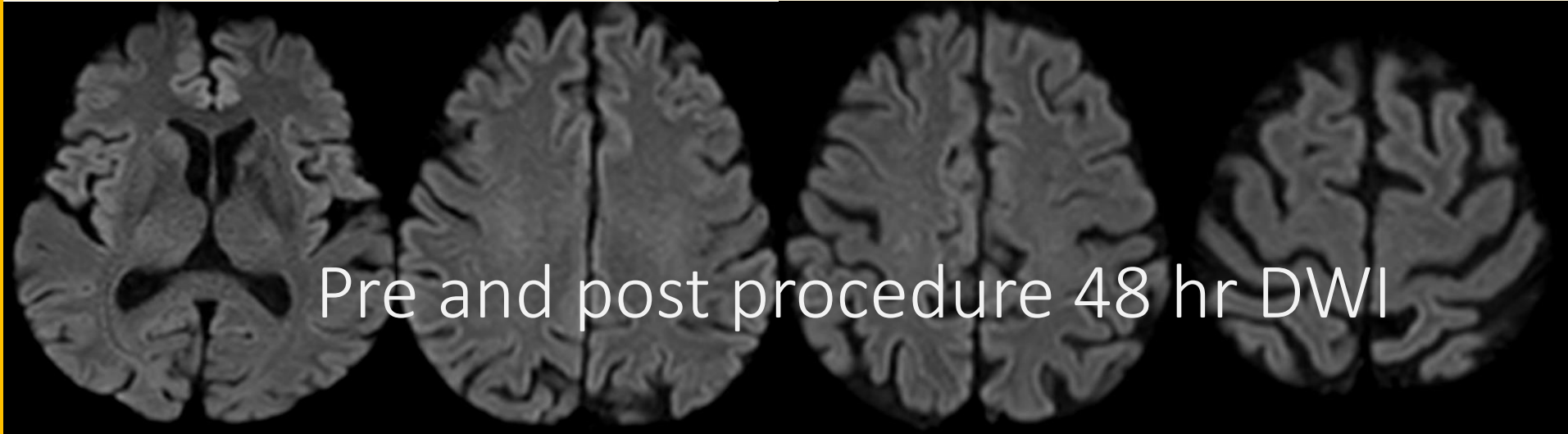
Pre-procedure DWI



Right ICA stenting



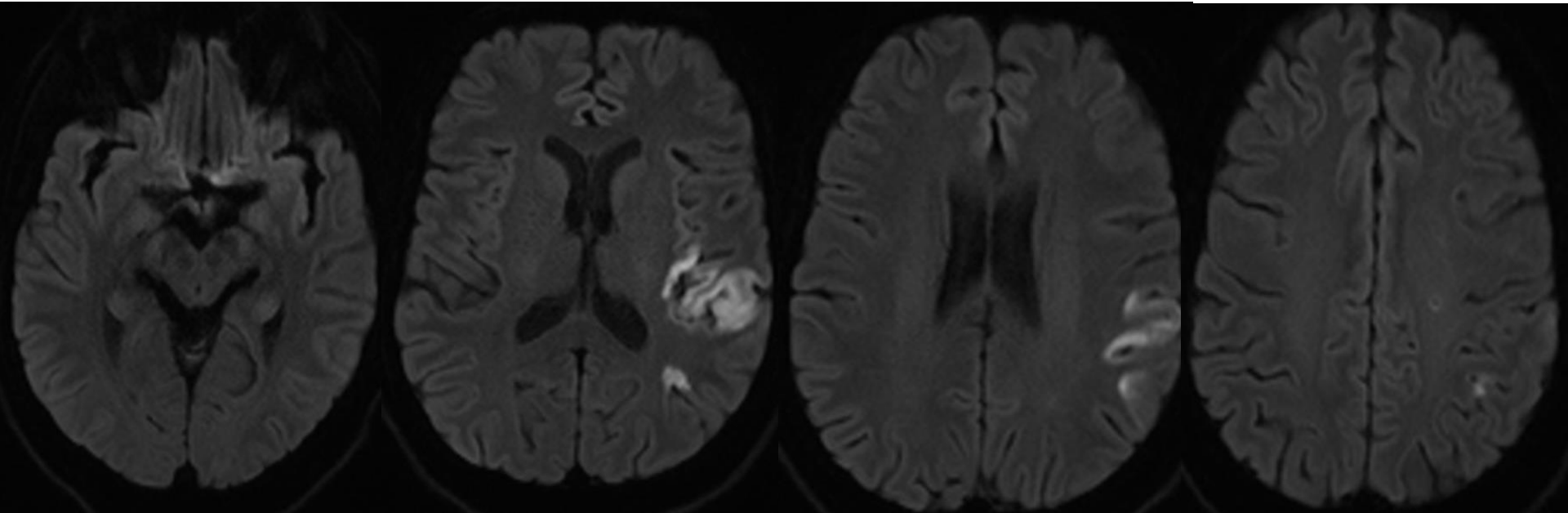
Pre and post procedure 48 hr DWI



Case 6: Left ICA – 99% stenosis

- 60 year Male,
- Broca's aphasia
- No motor weakness

Pre-procedure DWI -Left ICA – 99% stenosis

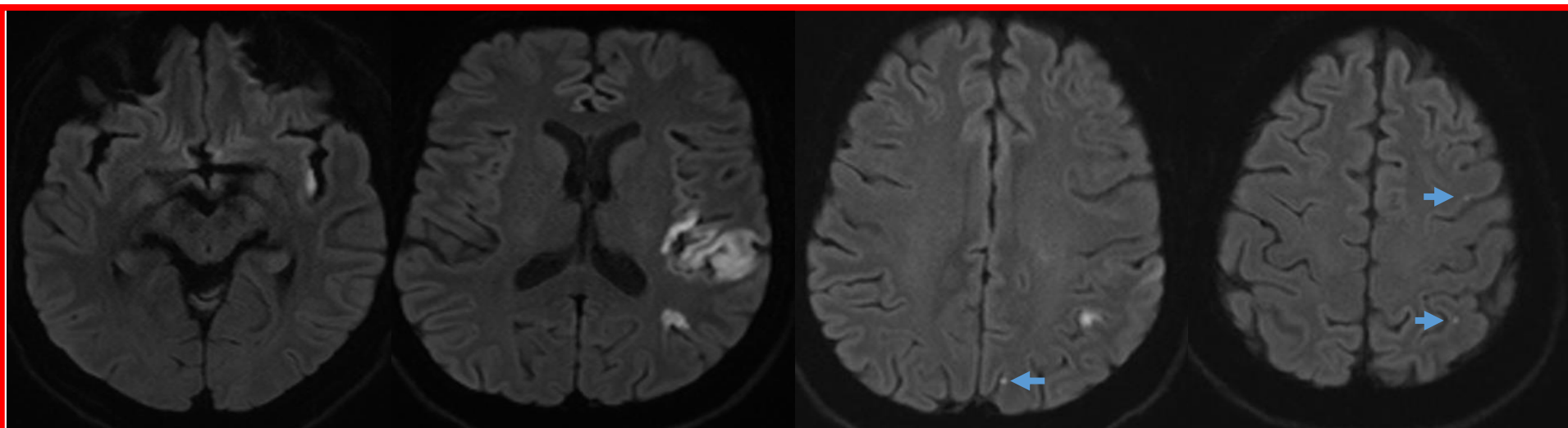


Left ICA stenting



Left ICA – 99% stenosis

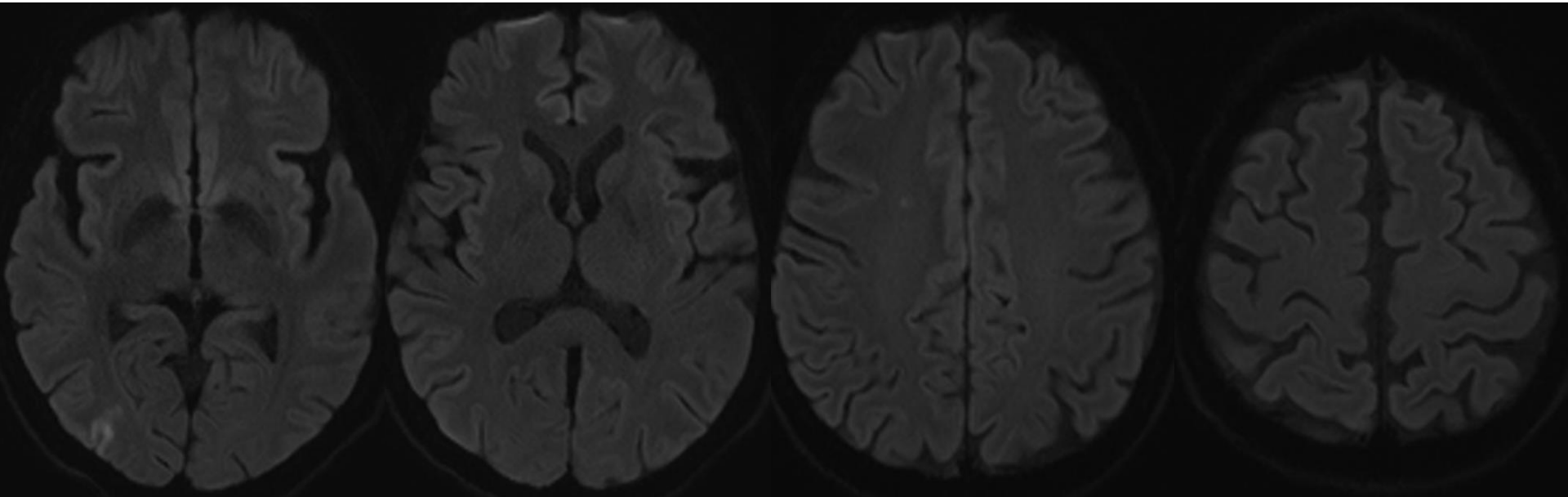
Pre and post-procedure 48 hr DWI



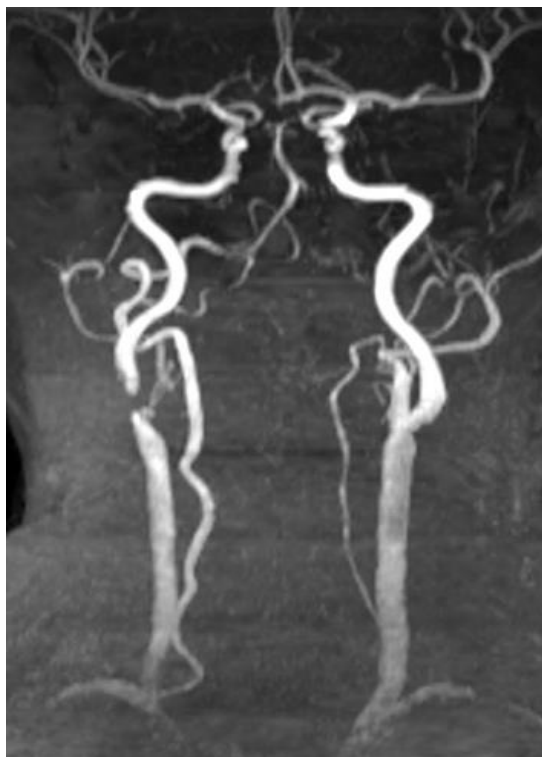
Case 7: Right ICA stenosis

- 65 year old female,
- Complain of double vision, giddiness, blurred vision
- Perimetry - peripheral field constriction
- Power - 5/5 in all four limbs
- No HT

Pre-procedure DWI- Right ICA stenosis

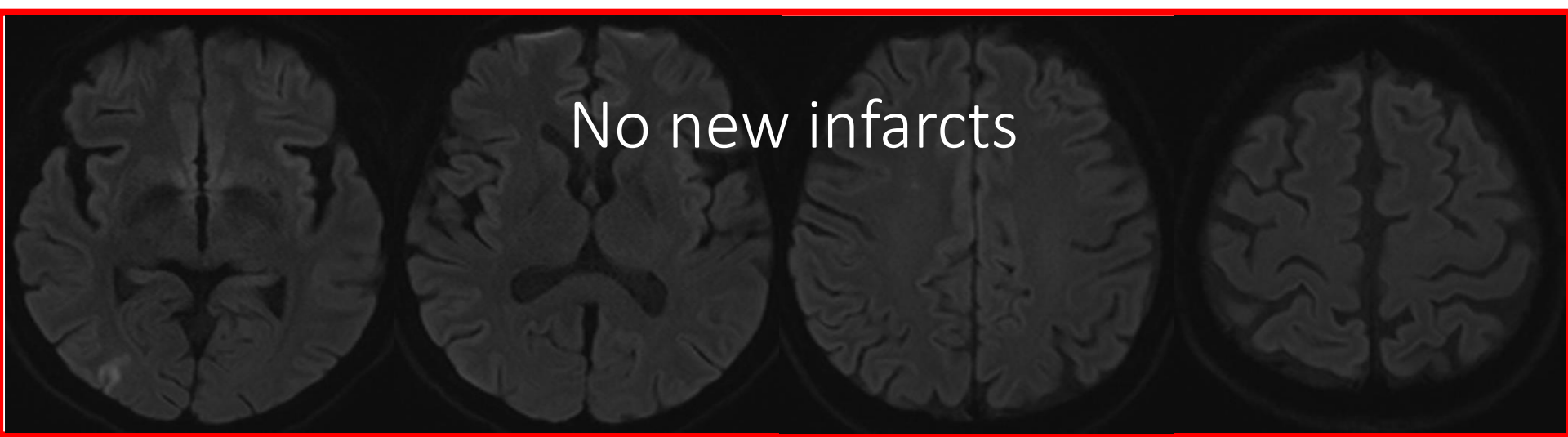


Right ICA stenting





Pre and post-procedure 48 hr DWI

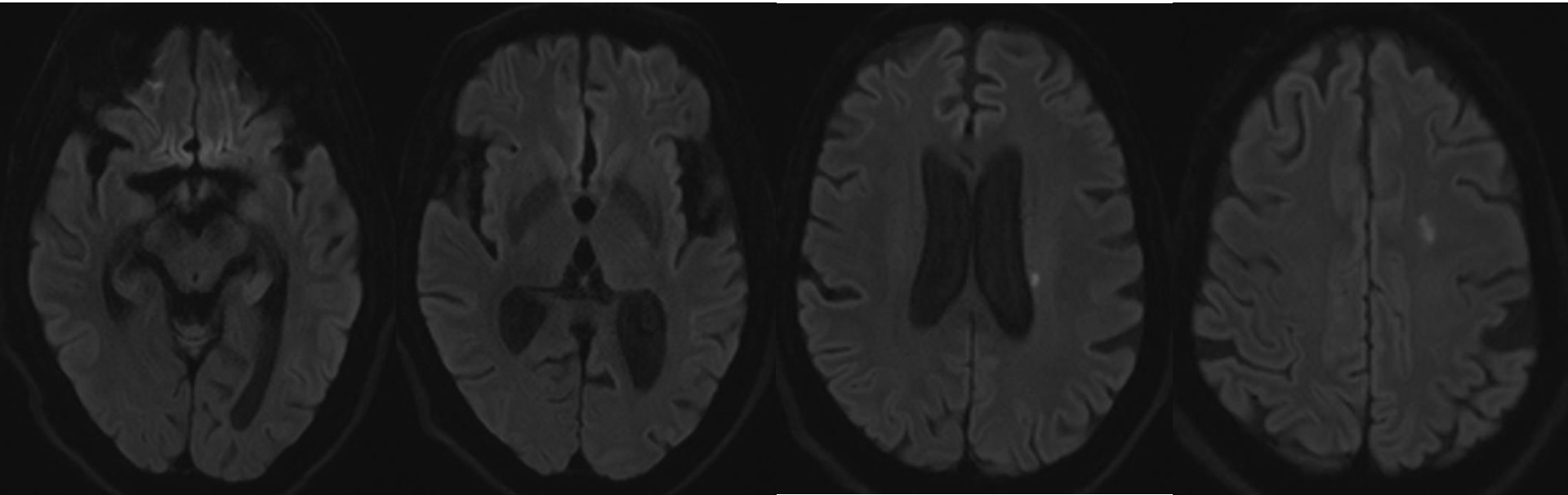


No new infarcts

Case 8: Left ICA stenosis- 90 % stenosis

- 68 year old male,
- Right side recurrent TIA
- HT- On Arkamine and Ca channel blocker.

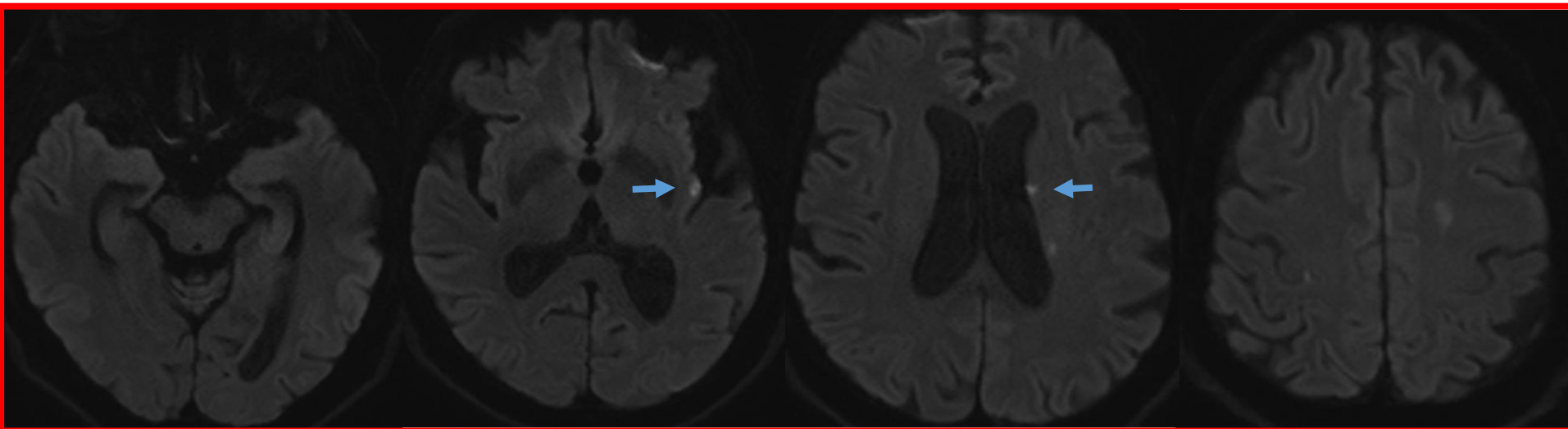
Pre-procedure DWI- Left ICA stenosis- 90 %



Left carotid stenting



Pre and post procedure 48hr DWI



K	M
C	H

ICCA STROKE 2019



Total 15 cases
From June 2018 to February 2019

Demographics of 15 patients

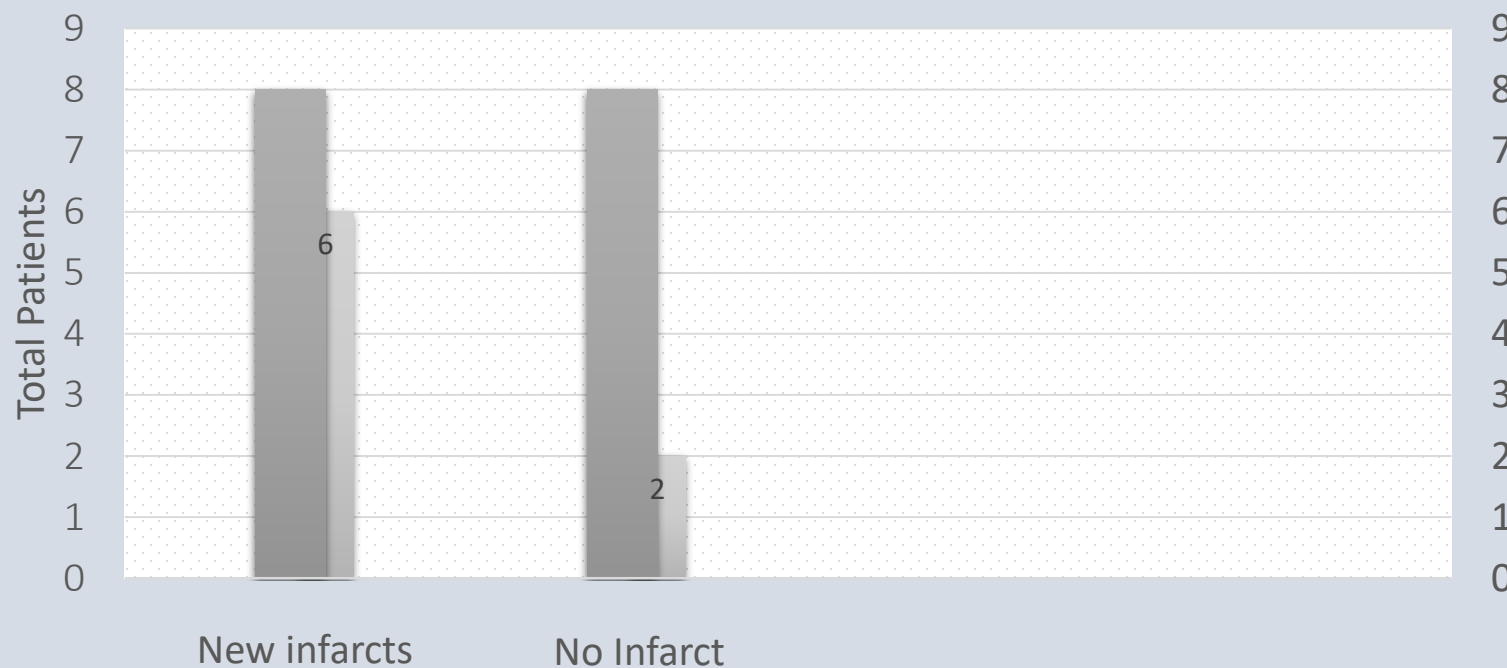
Characteristics	Variable
Age, mean	65
Sex	
Female	3 (20%)
Male	12 (80%)
Index Lesion	
Right ICA	5 (33.3%)
Left ICA	10 (66.6%)
Asymptomatic	0 (0%)
Symptomatic	15 (100%)
DM	12 (80%)
HT	8 (53.3%)
CAD	6 (40%)

Outcome- Immediate 48 hours

- Out of 15 patients, we have performed post-procedure MRI in 8 patients.

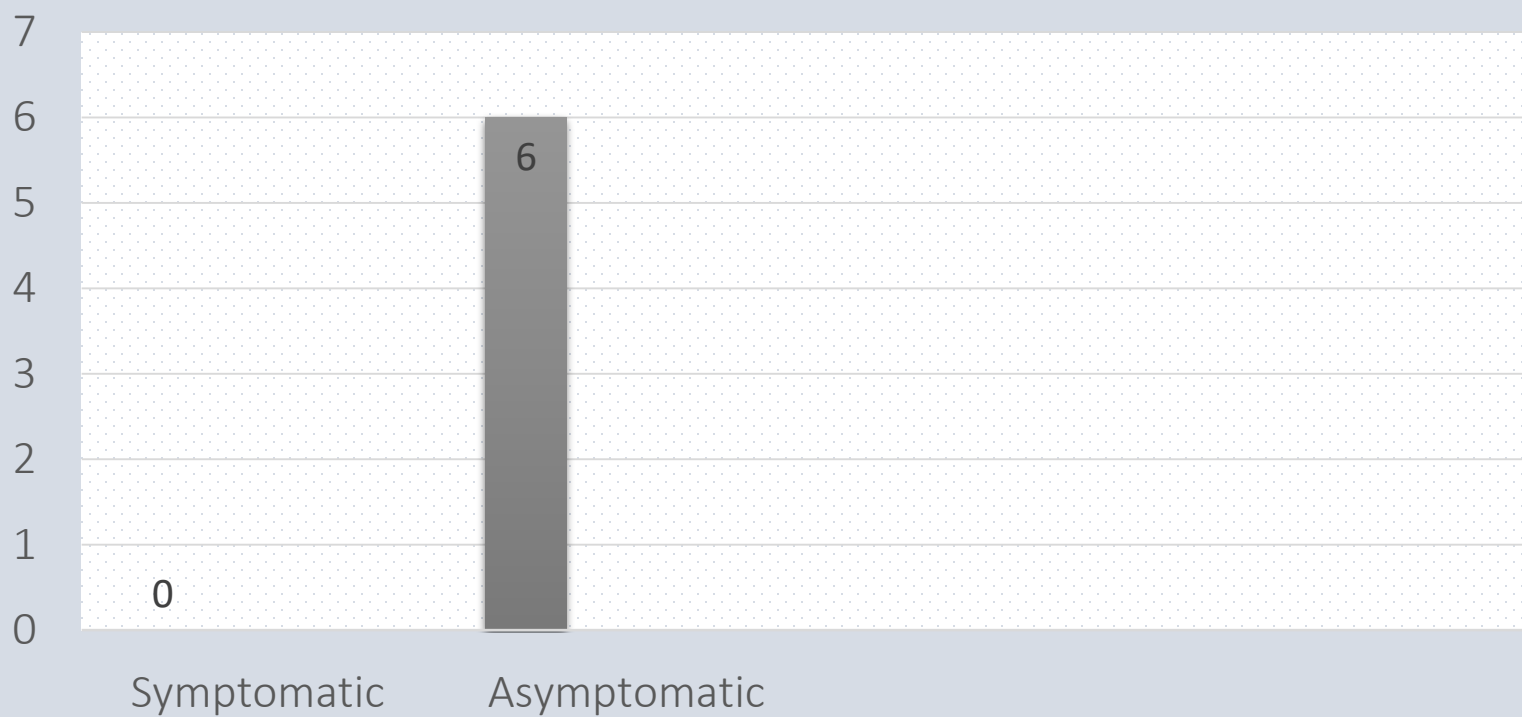


New infarcts on DWI- 48 hours



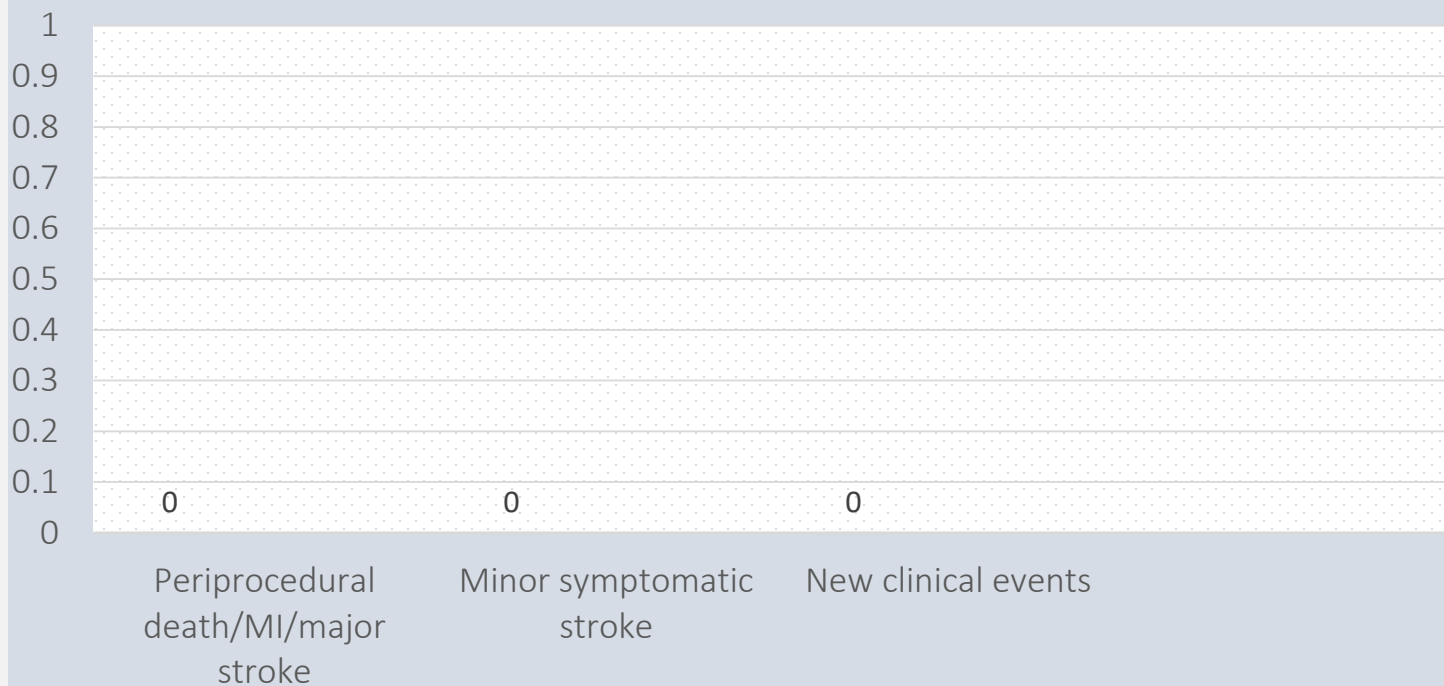


DWI infarct/Clinical symptoms



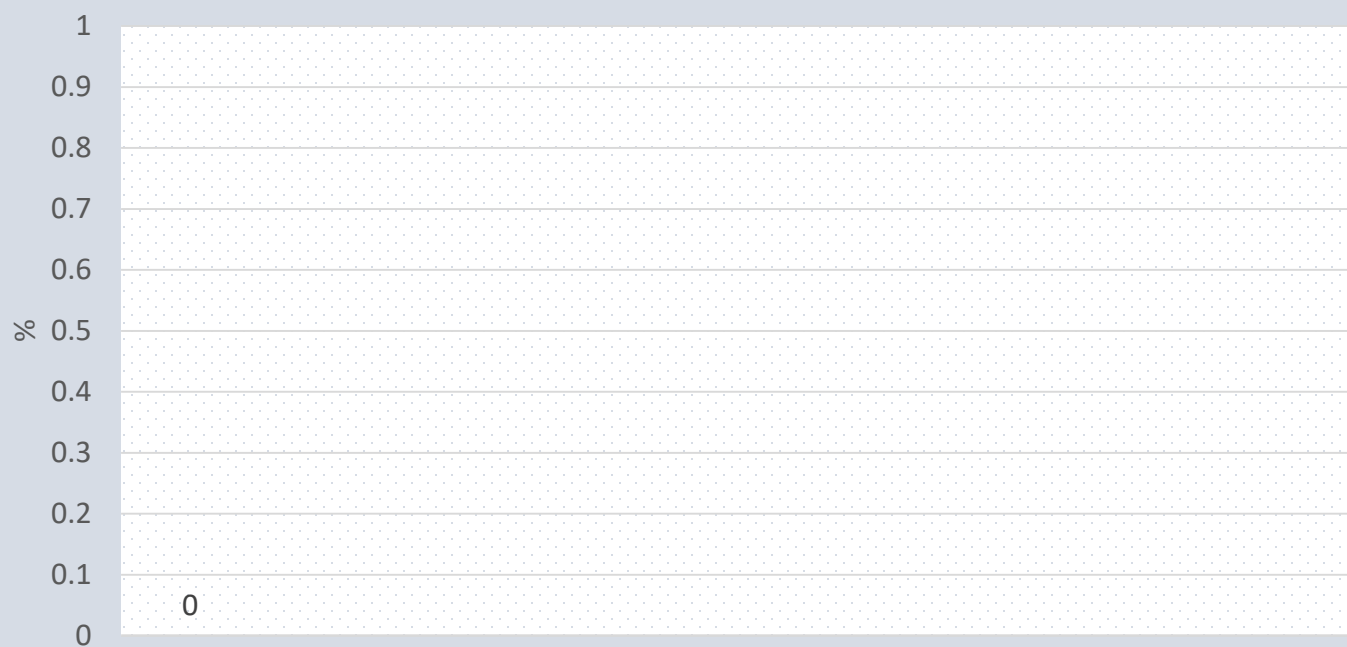


Peri-procedural complication





In-stent stenosis/occlusion-upto 9 months



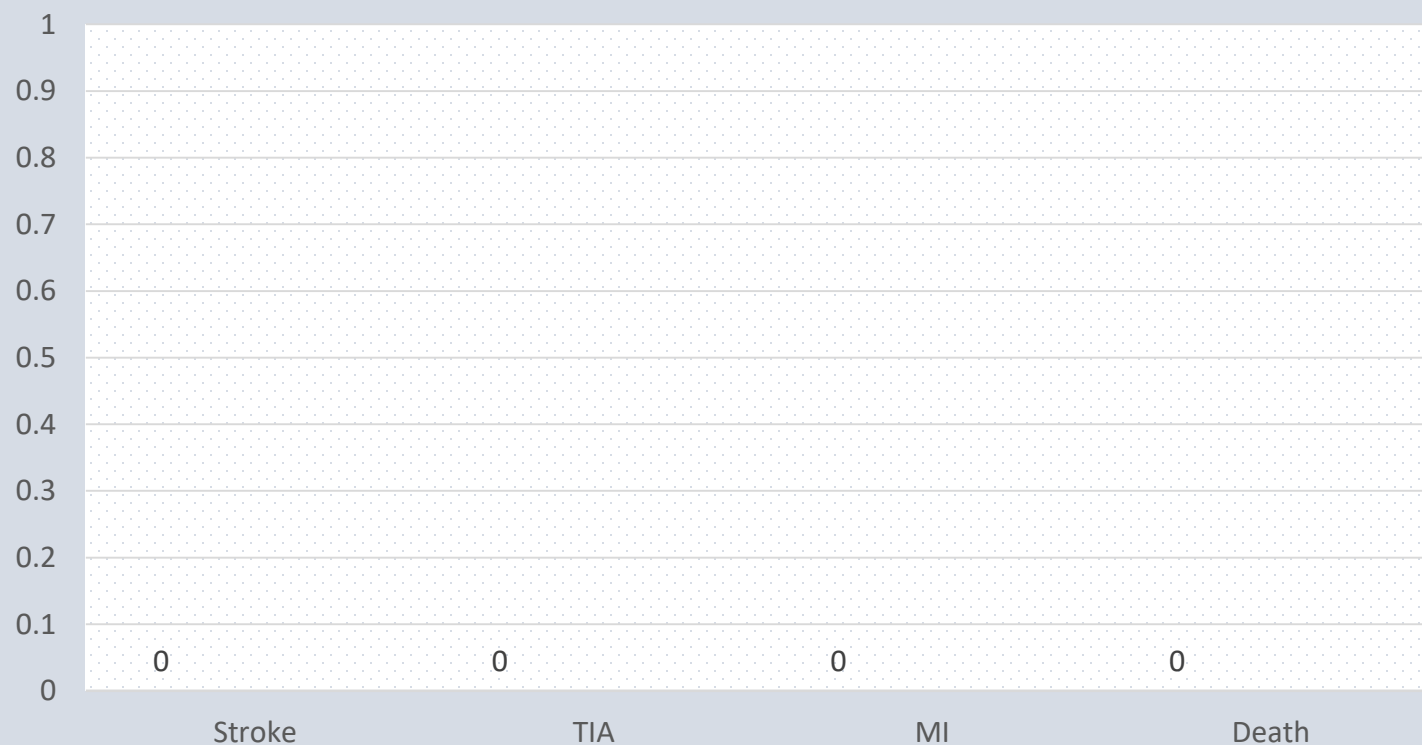
In-stent stenosis/occlusion

K	M
C	H

ICCA STROKE 2019



Follow up upto 9 months



Blood pressure

- No evidence of drop in BP/postural hypotension following carotid stenting with C-Guard.

