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Acute Stroke of CArotid Artery BiFurcation Origin Treated With Use of the MicronEt-covered CGUARD Stent: SAFEGUARD-STROKE

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for SAFEGUARD-STROKE Investigators

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Disclosure

Speaker name: **Lukasz Tekieli**

I do not have any potential conflict of interest

SAFEGUARD-STROKE: Multi-centric, multi-specialty study

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Background

Acute ischaemic stroke of carotid artery bifurcation origin (AIS-CA):

A **REAL challenge!**

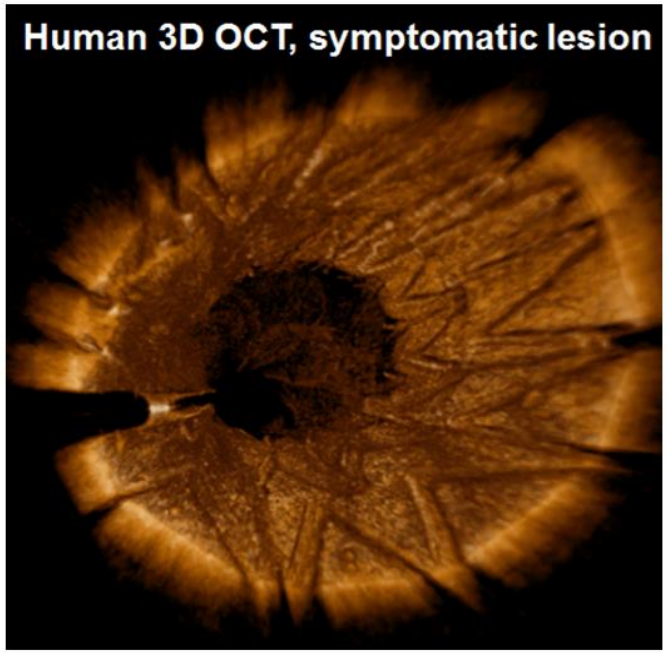
- large volume of affected brain tissue
- large thrombus load with poor efficacy of thrombolytic therapy
- inability of surgery to address the intracranial occlusion in tandem lesions, mixed data on emergent CAS
- **single-layer carotid stents have significant limitations (inability to insulate the lesion; optimization vs emboli risk)**

Background

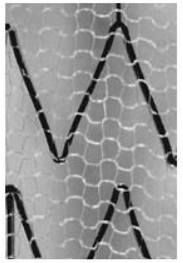
A novel **MicroNET-covered stent system** (CGuard) has level-1 evidence* to **profoundly reduce procedural cerebral embolism** in elective CAS, but has not yet been systematically evaluated in carotid artery bifurcation origin stroke.

The CREST Study stent

MicroNet-Covered Stent



OCT Images
P Musialek, G deDonato. Carotid Artery Revascularization Using the Endovascular Route In: Peripheral Arterial Interventions – A Practical Guide 2023 (in press)



*Karpenko et al. Randomized Controlled Trial of Conventional Versus MicroNet-Covered Stent in Carotid Artery Revascularization JACC Cardiovasc Interv. 2021;14:2377-2387.

Aim

To evaluate **clinical and imaging outcomes** using the Micronet-covered stent in **consecutive** patients with carotid artery bifurcation origin **stroke eligible for emergency recanalization**

Methods

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DESIGN

- Multi-centric
- Multi-specialty
- Consecutive patients
- Micro-NET-covered stent; other management as per centre routine

OUTCOMES

- Device and procedure success (technical, clinical)
- Discharge stent patency, patency at 3 months
- Clinical (mRS) and DUS outcomes at 3 months

Clinical characteristics, n=75

Age, years; range	**67** [61-74]; 40 - 89
Gender, woman	21 (28.0)
ASPECTS on admission; range	**9** [9-10]; 6 - 10
NIHSS on admission	**14** [12-19]
mRS before admission	0 [0-1]
Time from symptom onset to presentation in Stroke Centre, h	3 [2-6]
Type of stroke (mechanism) Hemodynamic+Embolic* Hemodynamic# Embolic**	 20 (26.7) 37 (49.3) 18 (24.0)
Type of stroke (clinical) Hyperacute Crescendo TIA/stroke-in-evolution Stuttering/aggravating	 65 (86.7) 6 (8.0) 4 (5.3)
Side, right	38 (50.7)
ICA lesion type Atherothrombus Dissection Atherothrombus + dissection	 69 (92.0) 5 (6.7) 1 (1.3)

Values are given as median[Q1,Q3] or n (%) as applicable

*flow limiting

#evidence of cerebral vessel occlusion on CTA or cQA (embolic carotid-related stroke mechanism was considered applicable in case of a non-flow limiting carotid lesion)

Clinical characteristics, cont'd

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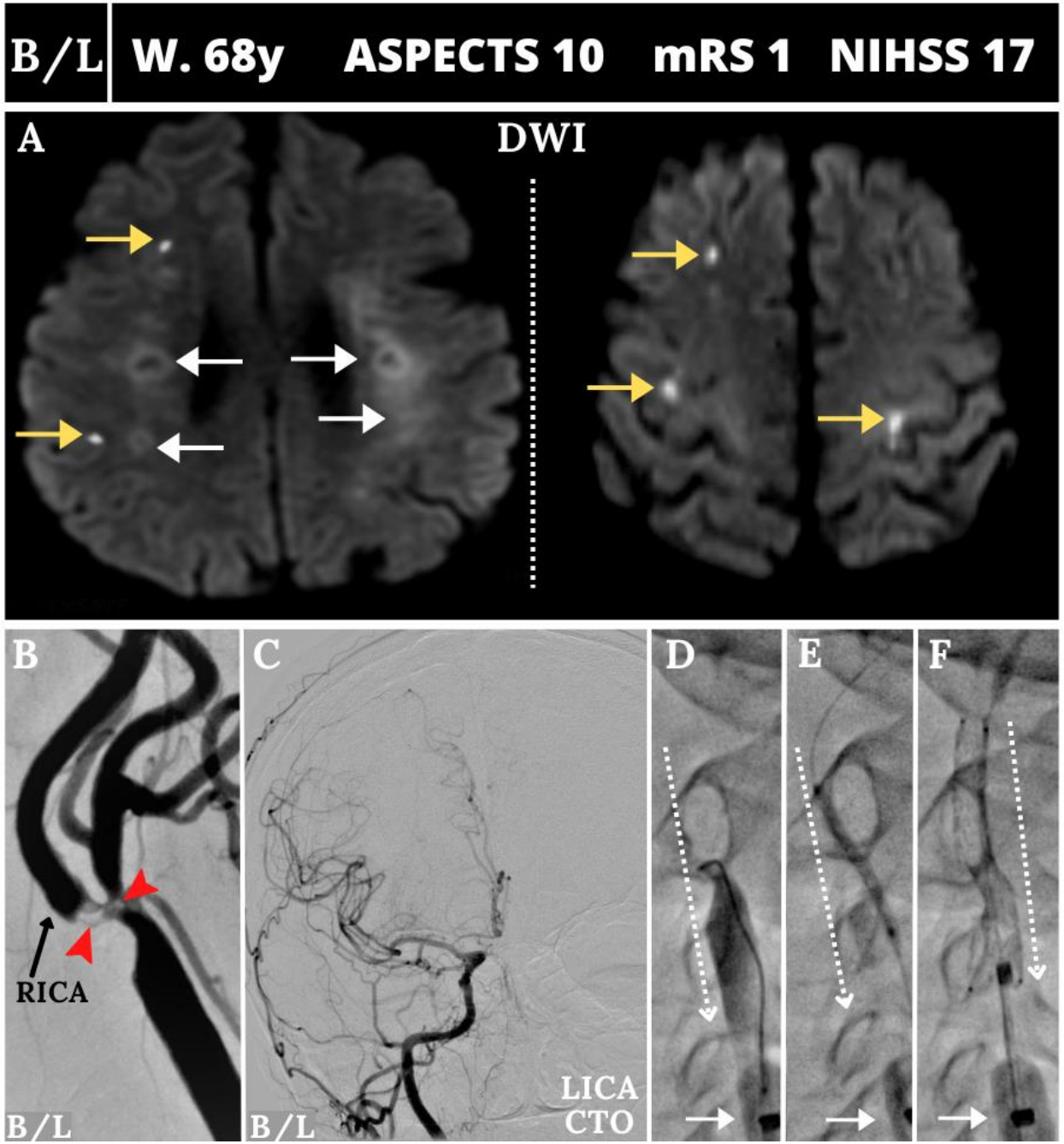
ICA thrombus†	42 (**56.0**)
ICA heavy calcifications‡	24 (**32.0**)
Tandem lesion	38 (**50.1**)
Smoking history No Current Ex-smoker	 33 (44.0) 26 (34.7) 16 (21.3)
Diabetes	25 (33.3)
Hypertension	67 (89.3)
Hypercholesterolemia or hypolipidemic therapy prior to stroke	62 (82.7)
Stroke in history TIA in history	7 (9.3) 17 (22.7)
Coronary artery disease	26 (34.4)
Atrial fibrillation	10 (13.3)
Symptomatic PAD	8 (10.7)
History of neck/chest radiotherapy	3 (4.0)

Values are given as median[Q1,Q3] or n (%) as applicable
†angiographic thrombus presence
‡ angiographic evidence of heavy calcifications

Case example #1

Thrombotic, non-tandem



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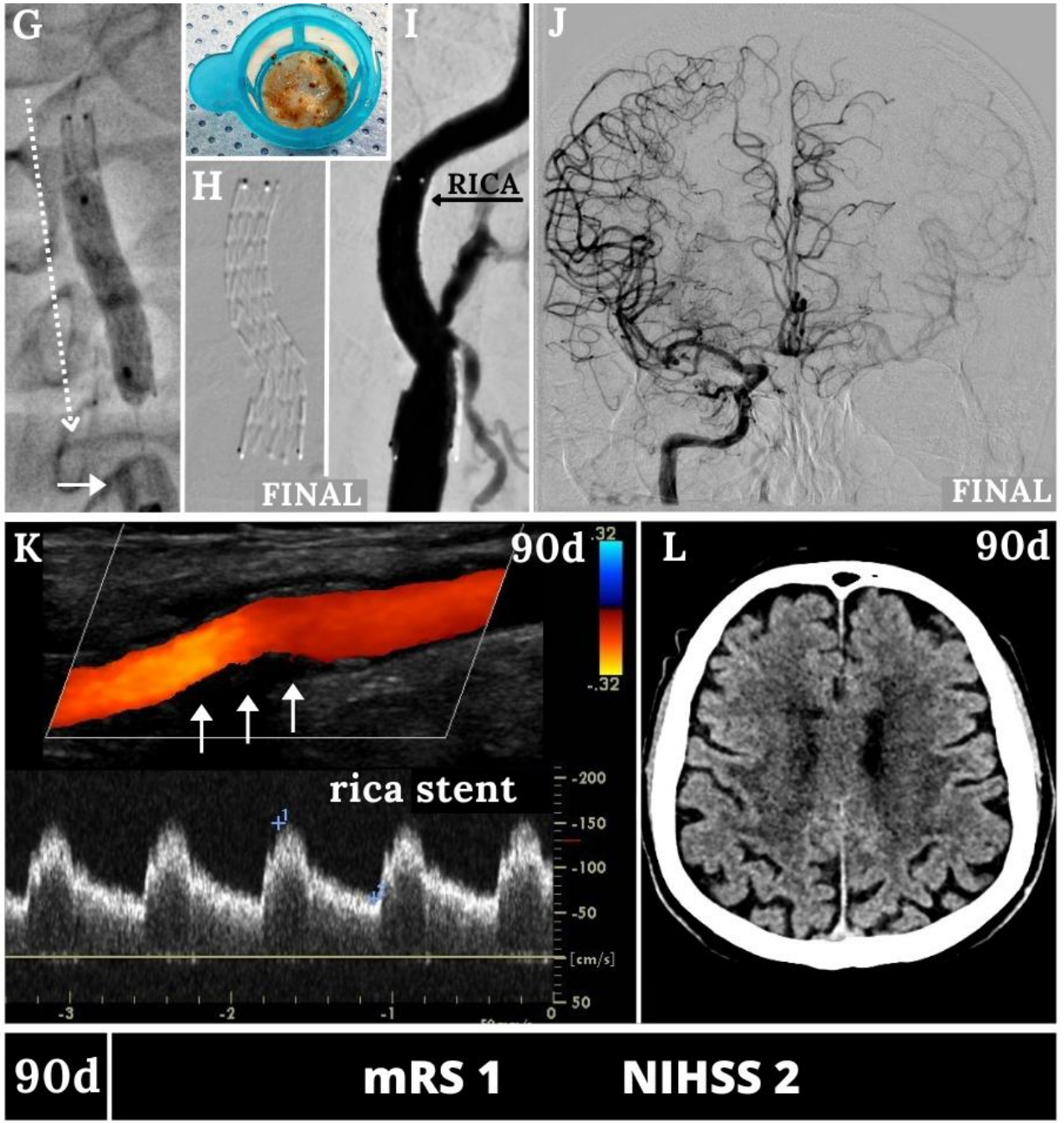
Case example #1 (cont'd)



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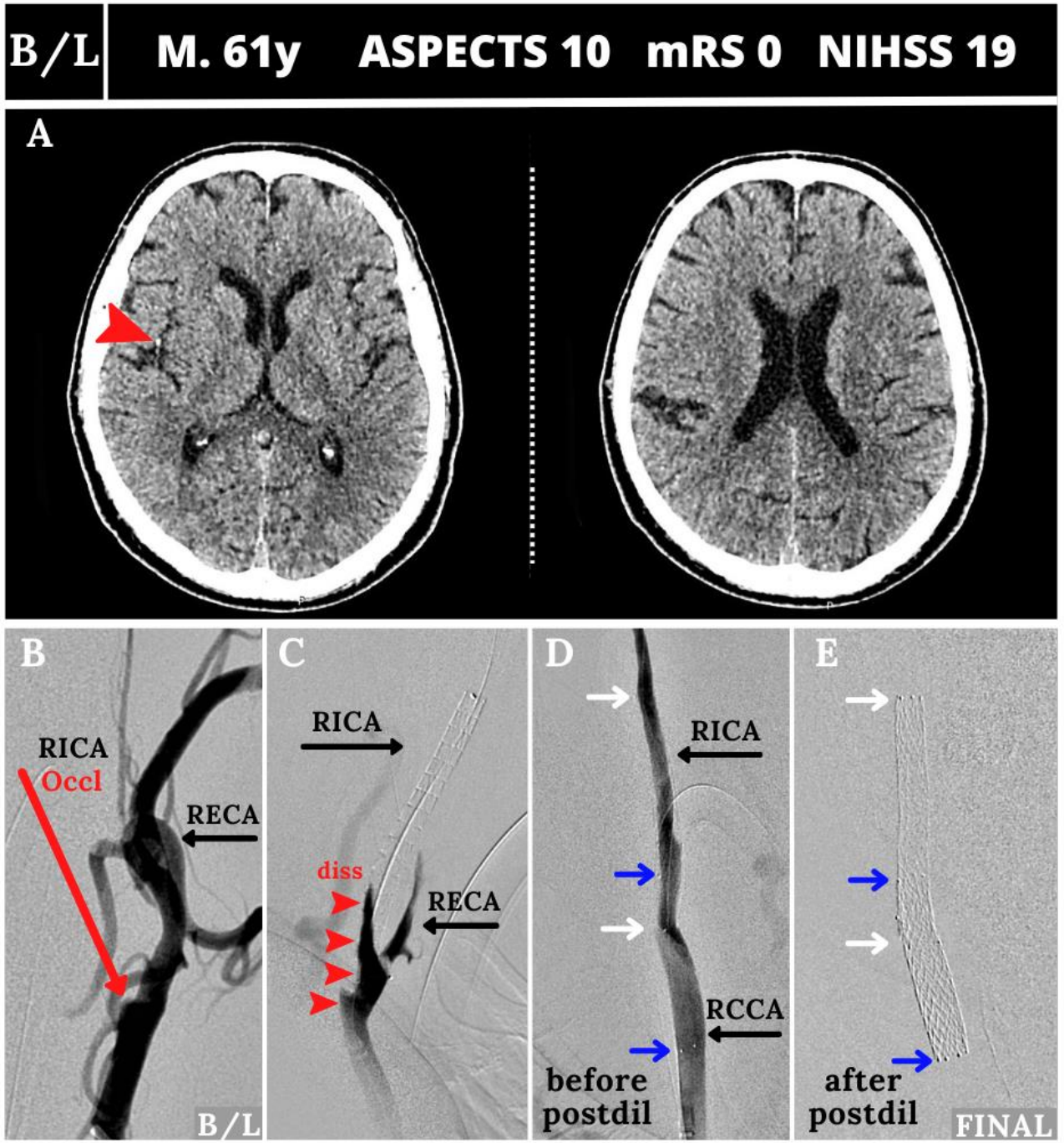
Case example #2

Dissection/occlusion, tandem

Antegrade strategy



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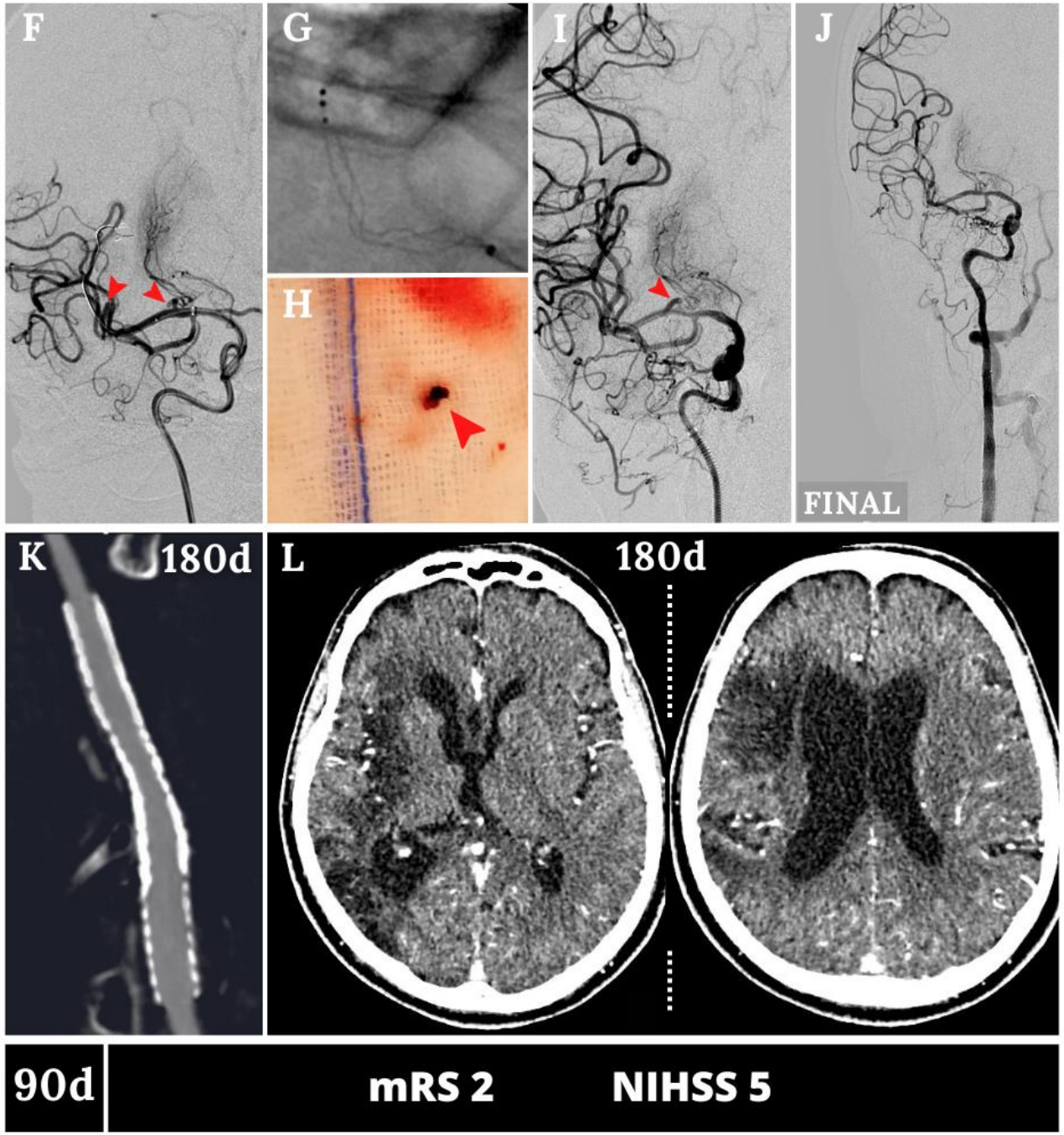
Case example #**2** (cont'd)



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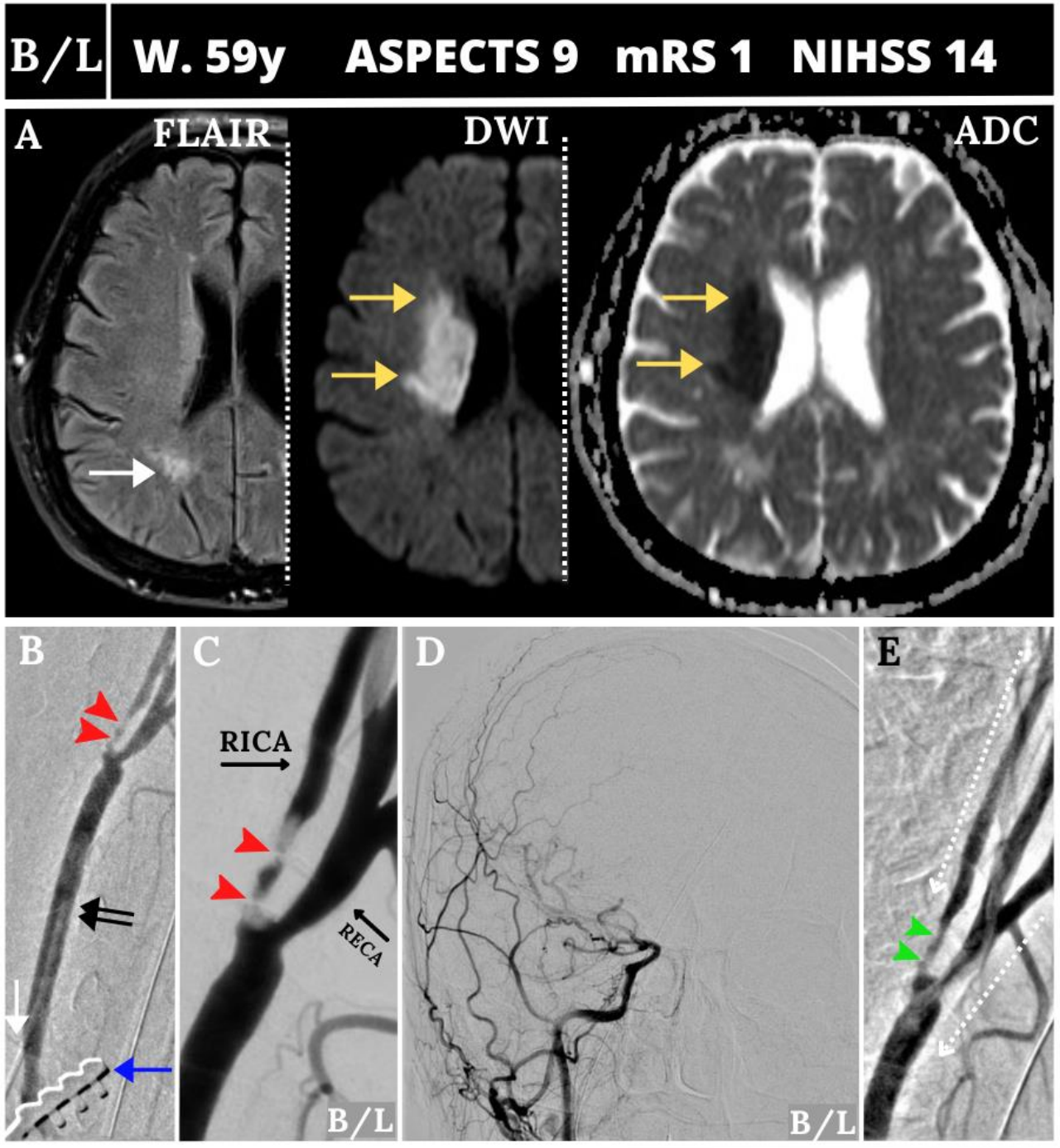
Case example #3

Thrombotic sub-occlusion,
No iliac/radial access
=> TCAR



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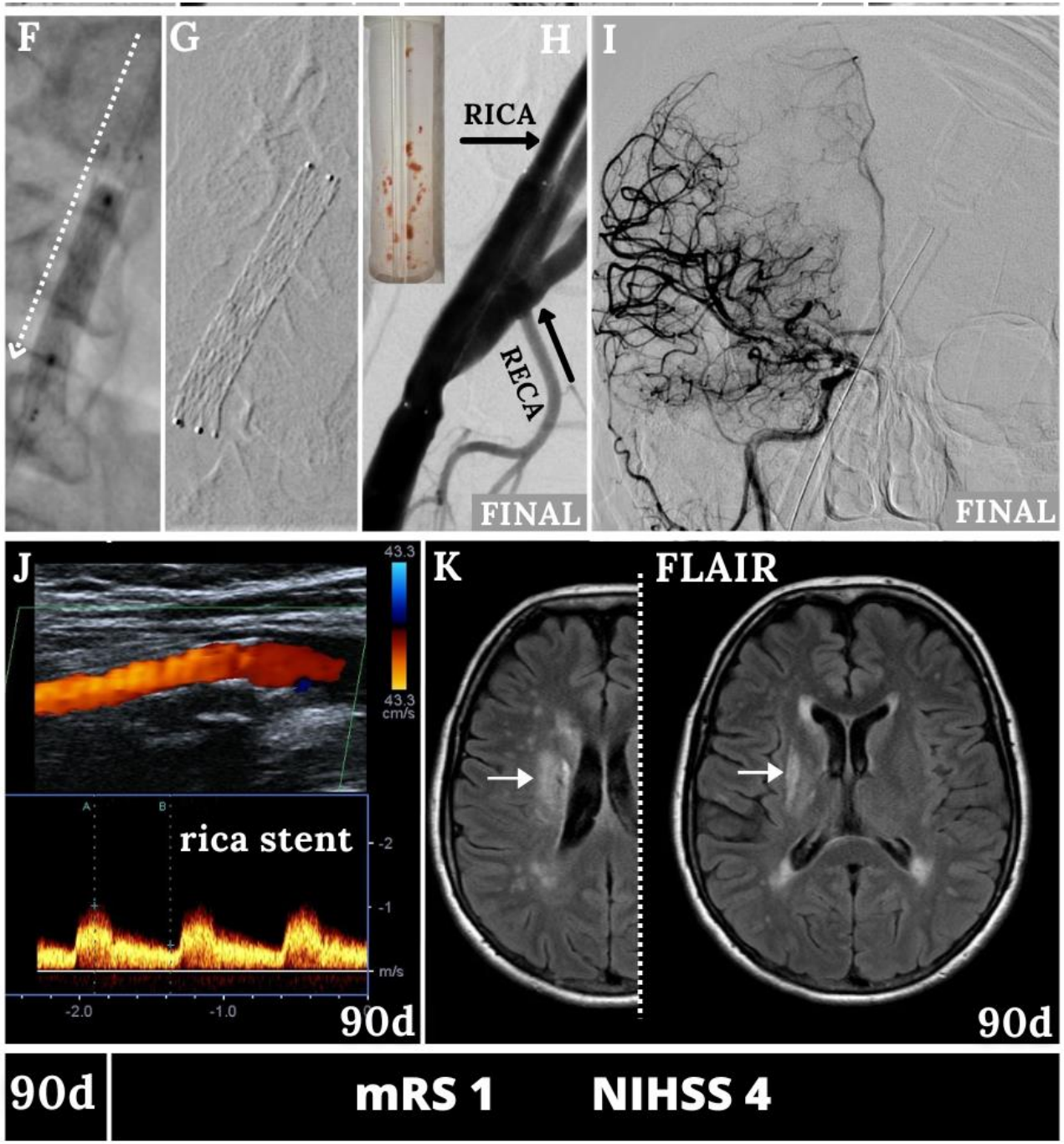
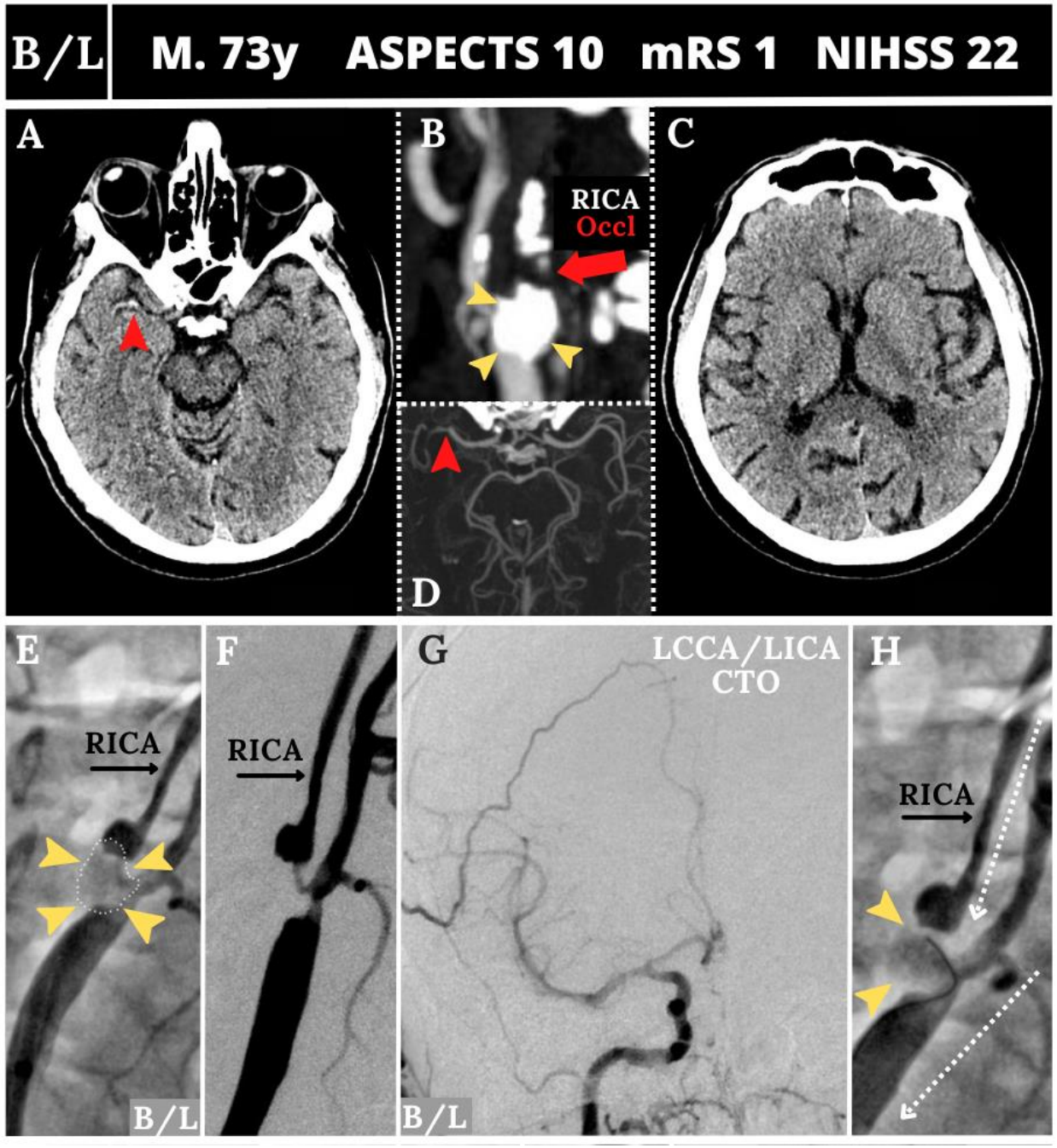
Case example #**3** (cont'd)



Case example #4

Massive calcium, tandem
rt-PA background



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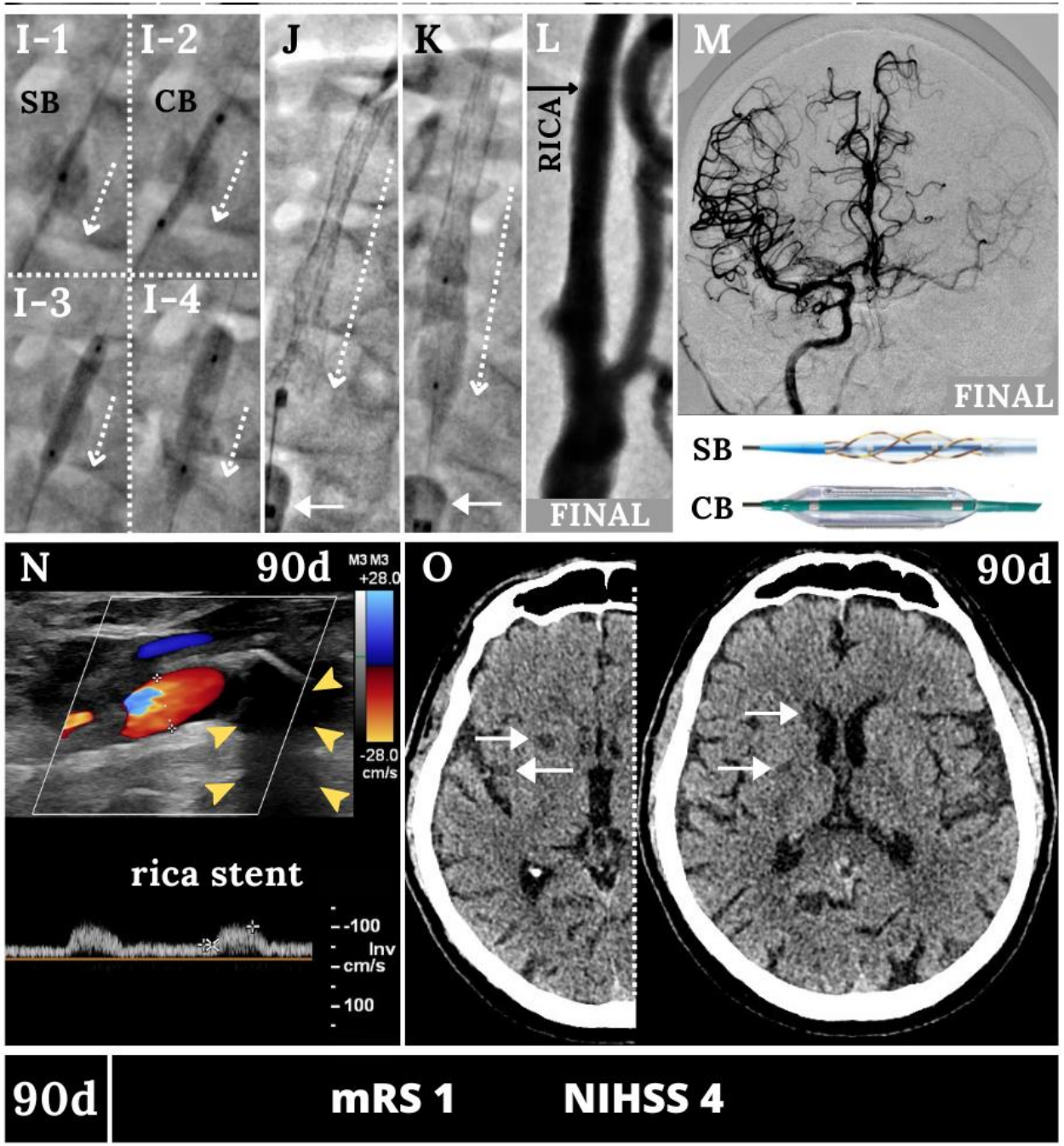
Case example #**4** (cont'd)



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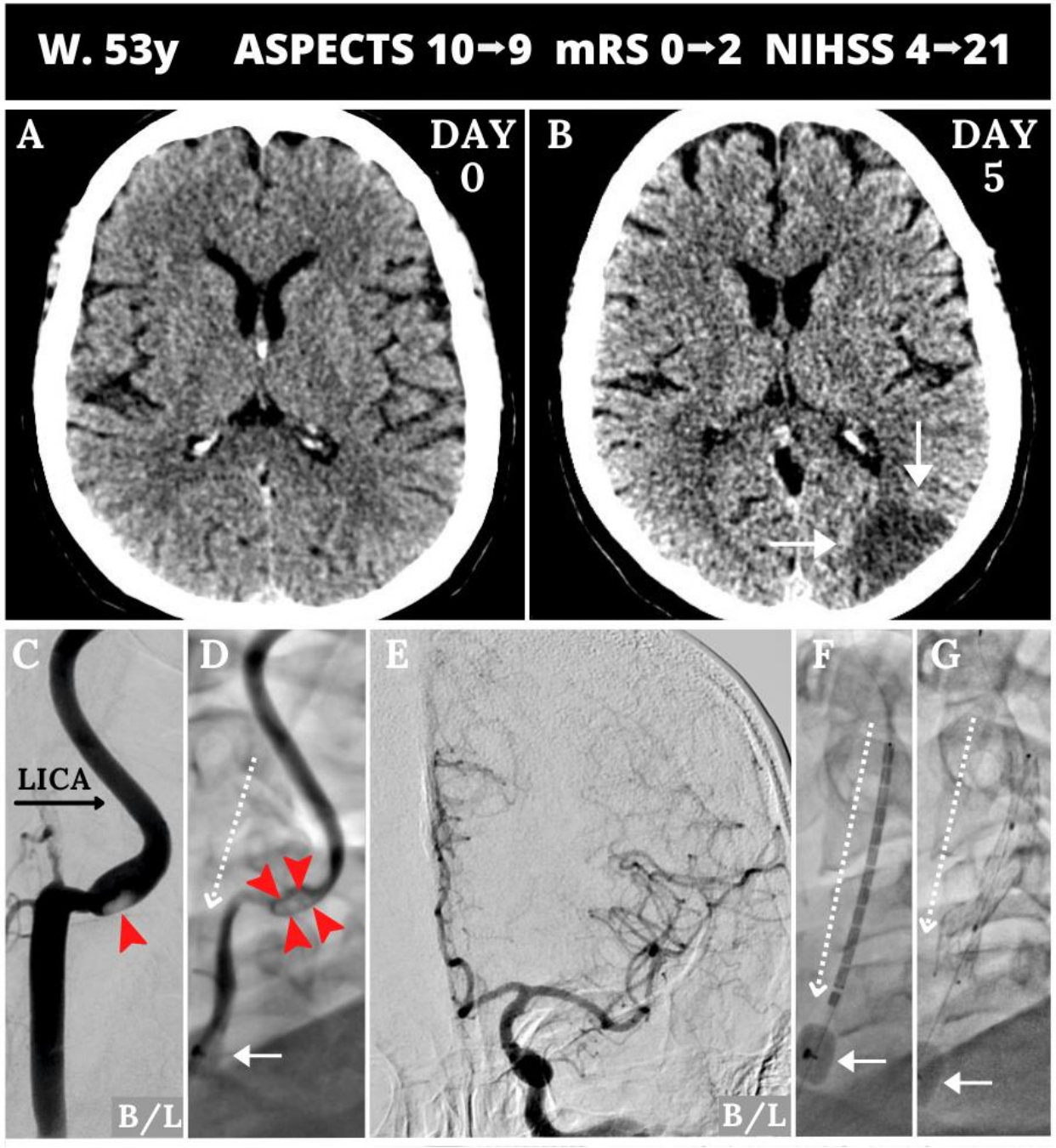
Case example #5

Thrombotic, stuttering,
non-tandem (initial tandem?)



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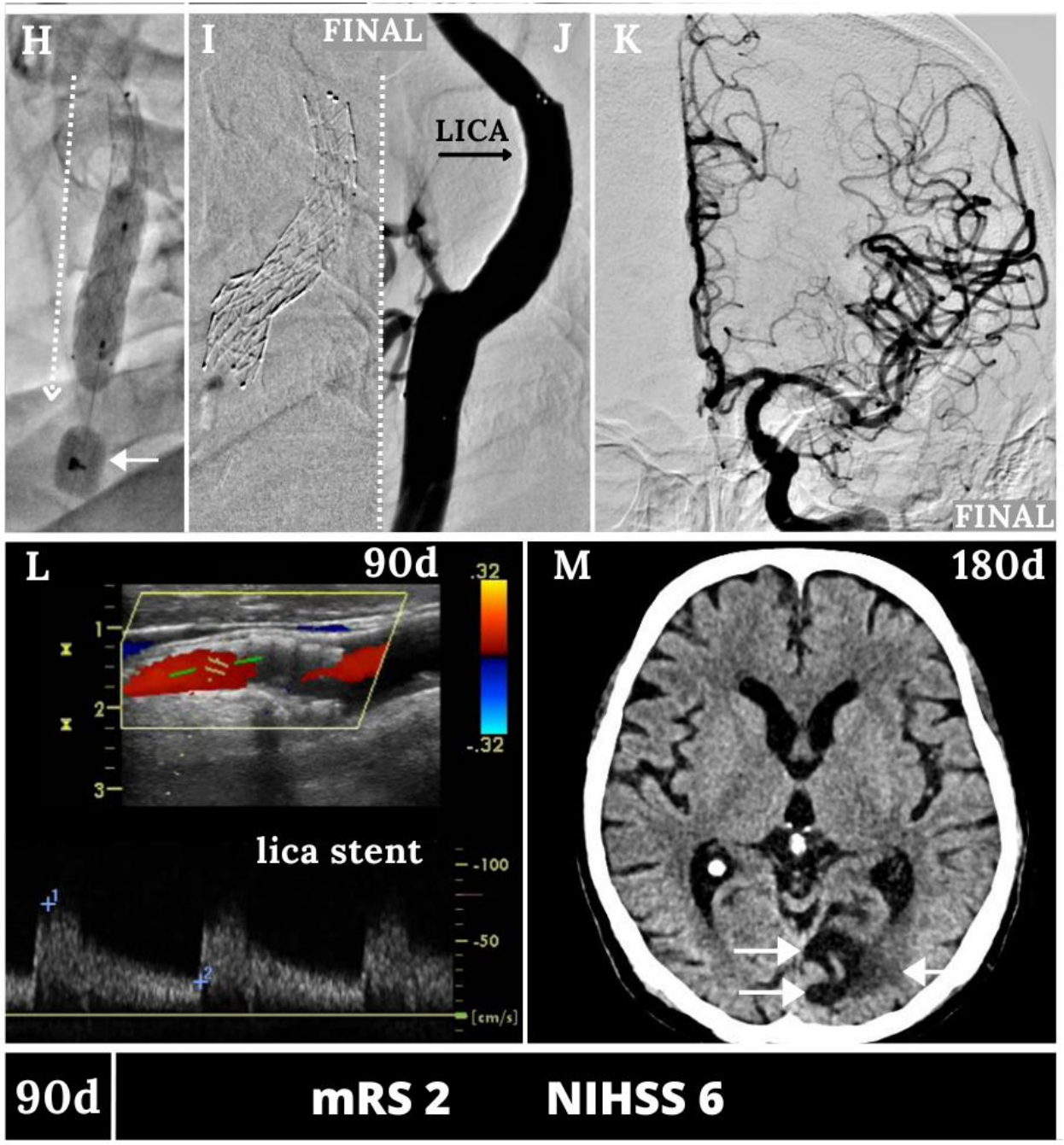
Case example #**5** (cont'd)



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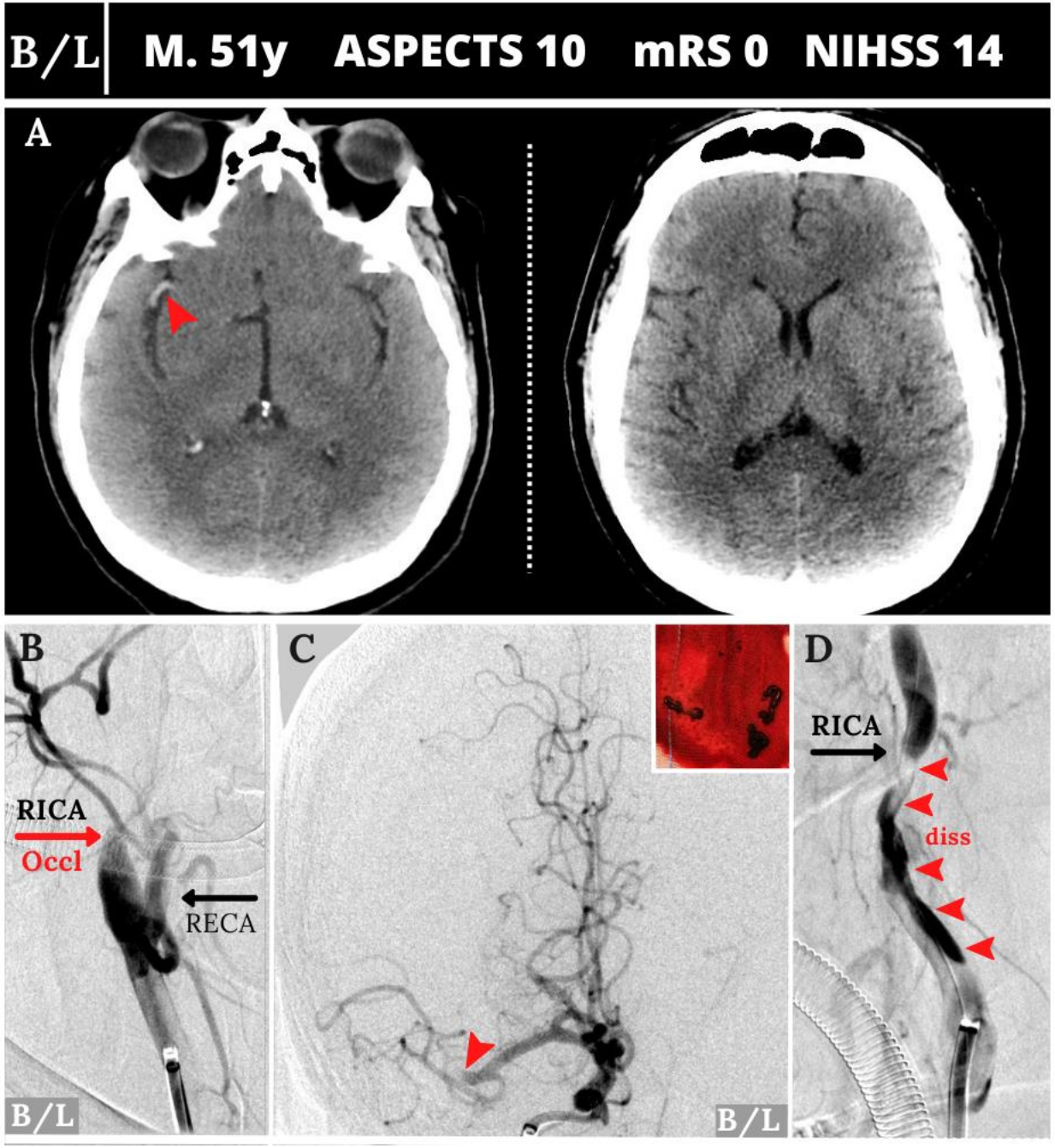
Case example #6

Dissection, tandem,
Retrograde strategy



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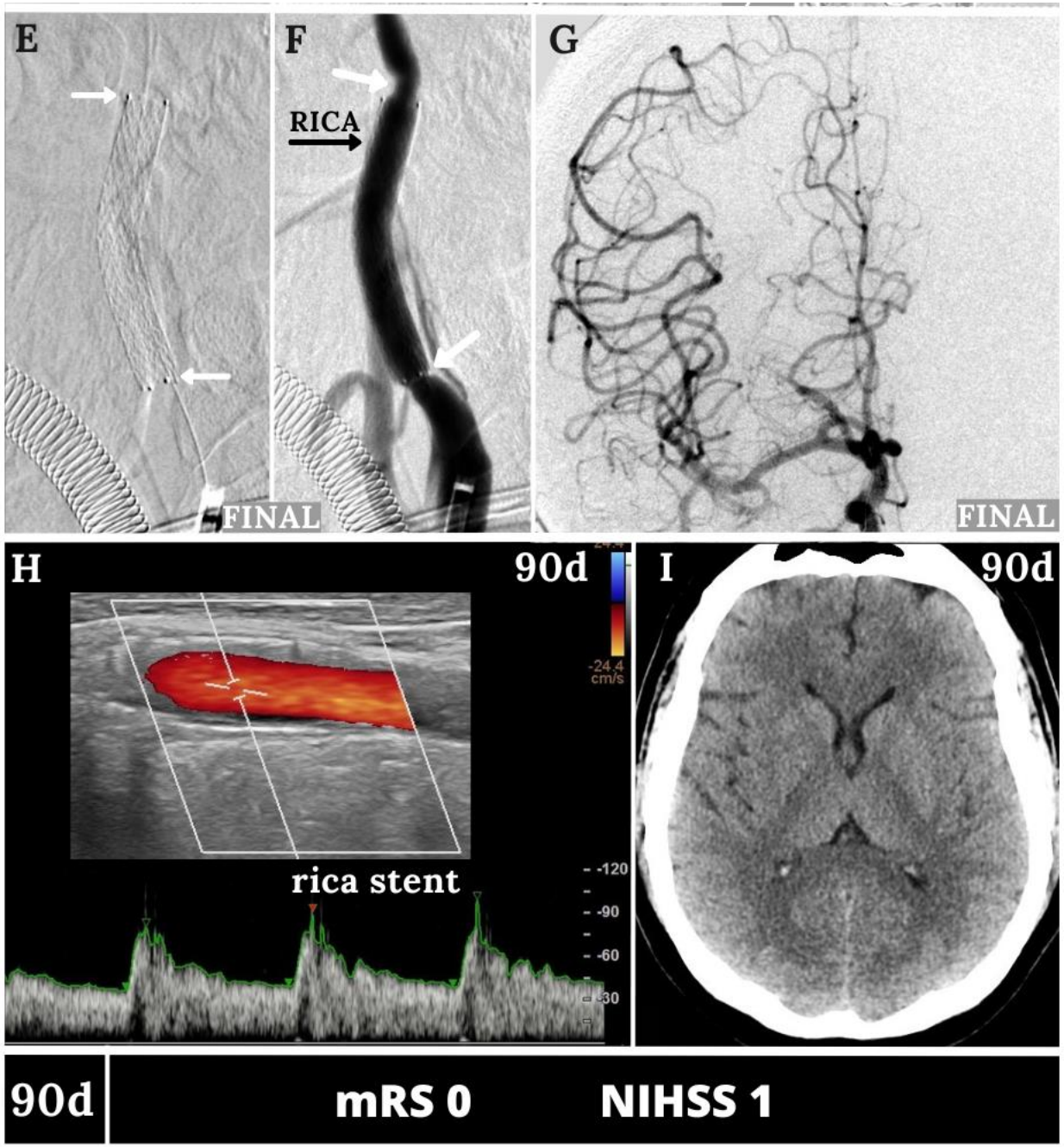
Case example #**6** (cont'd)



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Procedural data (1)

Vascular access (n=75)	
Femoral	67 (89.3)
Radial	5 (6.7)
Transcarotid	3 (4.0)
Extra/intracranial thrombectomy* (n=75)	
● Extracranial	23 (30.7)
Aspiration	20 (26.7)
Large-bore ST	3 (4)
● Intracranial	36 (48)
Aspiration	21 (28)
Aspiration plus ST	12 (16)
ST	3 (4)

Values are given as n (%)
*other than flow reversal

Procedural data (2)

Intracranial Mechanical Thrombectomy (n=36, in n=5 > 1 level)	
ICA	8 (22.2)
M1	21 (58.3)
M2	12 (33.3)
Number of passages during intracranial MT	2 [1-4]
range	1-9
Extracranial lesion strategy	
Predilation	46 (61.3)
'Direct' stenting	29 (38.7)
Carotid stent strategy in tandem lesions	
Antegrade	11 (28.9)
Retrograde	27 (71.1)

x

Procedural data (3)

Predilation balloon diameter, mm	3.5 [3.0-3.5]
Range	1.0-5.0
Stent size, mm x mm	
6 x 40	2 (2.7)
7 x 30	5 (6.7)
7 x 40	6 (8.0)
8 x 30	10 (13.3)
8 x 40	7 (9.3)
9 x 30	12 (16.0)
9 x 40	17 (22.7)
10 x 30	4 (5.3)
10 x 40	8 (10.7)
10 x 60	4 (5.3)

>1 stent implantation required, n (%)	3 (4.0)
Second stent reason	
dissection	0
thrombus	0
lesion length	3 (4.0)
Final postdilation balloon diameter	5 [5.0-5.5]
Range	4-8
Final postdilation balloon pressure, mmHg	18 [12-20]
Range	10-24

Values are given as median[Q1,Q3] or n (%) as applicable

Procedural data (4)

Final mTICI	
0/1	3 (4.0)
2a	5 (6.7)
2b/c	17 (22.7)
3	50 (66.7)
Procedure time	70 [49-90]
Range	33-170
Intraprocedural heparin use	75 (100)
Intraprocedural heparin regimen	
Limited to catheter(s) flush drip	6 (8.0)
Additional heparin dose	69 (92.0)
<3000 IU	11 (14.7)
3000-5000 IU	21 (28.0)
ACT-adjusted dosing (≥ 250 sec)	37 (49.3)

x

Procedural data (5)

Periprocedural antiplatelet administered	75 (100.0)
iv. ASA	7 (9.3)
oral/nasogastric tube ASA	68 (90.7)
IIb/IIIa inhibitor use (ia/iv)	16 (21.3)
ia. bolus only	4 (5.3)
ia. bolus + iv infusion	12 (16.0)
Postprocedural antiplatelets	
One drug	4 (5.3)
Two drugs	71 (94.7)
Timing of second antiplatelet agent administration (n=71)	
≤24h	38 (53.5)
>24h	33 (46.5)
If delayed - when given, hours	28 [26-31]
range	24-48
Recommended DAPT (SAPT) duration, months	3 [3-3]
range	1-12

x

Key in-hospital outocomes

In-hospital (by discharge) outcomes	
Any intracranial hemorrhage	12 (16)
asICH	8 (10.7)
sICH	4 (5.3)
In-hospital death	7 (9.3)
NIHSS on discharge	4 [2-8]
range	0-23
mRS at discharge	1 [1-3]
range	0-6
Stent patent[#] by discharge	66 (94.3)

90-day deaths are provided per enrolled subjects (n=75)
[#]in alive patients unless DUS performed within 24 hours prior to death (n=70)

Key 90-day outcomes

90-day outcomes†	n=66
New stroke by 90-days, any ipsilateral contralateral posterior circulation	2 (3) 1 (1.5) 0 1 (1.5)
90-day death (total*)	9 (12.0)
NIHSS at 90 days	3 [2-5]
mRS‡ at 90 days	1 [1-2]
Stent patent¥ by 90 days	59 (92.2)
DUS PSV/EDV (cm/s) [Q1-Q3]	64/24 [55-84]/[21-30]

†in patients alive at 90 days, unless specified otherwise
*8 deaths as stroke consequence (one COVID-19 infection-related death),
‡including deaths
¥in patients alive by 90 days, unless occlusion (0) diagnosed prior to death between discharge and 90 days; (n=64 eligible at 90 days, total 5 occlusions)

Predictors of sICH

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Univariate	**Mulitvariate**
IIb/IIIa inhibitor full dose* OR 6.4 (1.8-24.5), p<0.001	IIb/IIIa inhibitor full dose* OR 16.9 (4.8-34.3), p<0.001
T-occlusion OR 3.9 (1.9-15.1), p<0.001	
Tandem lesion OR 3.4 (1.3-35.9), p=0.010	
IVT OR 1.9 (1.1-11.2), p<0.001	
Additional dose of heparin# OR 1.4 (1.1-20.6), p=0.020	

95% CIs are provided in paretheses

*(ia. bolus + iv. infusion) #other than in flush

Predictors of bad clinical outcome (mRS >2) at 90 days

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Univariate	**Mulitvariate**
IIb/IIIa inhibitor full dose* OR **23.8** (5.3-94.5), p<0.001	NIHSS > 20 OR **14.7** (2.1-78.2), p=0.006
ASPECT < 8 OR **11.2** (3.2-38.9), p<0.001	IIb/IIIa inhibitor full dose* OR **13.9** (5.1-84.5), p<0.001
NIHSS > 20 OR **8.3** (2.4-32.6), p<0.001	ASPECT < 8 OR **12.8** (2.0-81.6), p=0.007
Tandem lesion OR **6.1** (1.8-20.8), p=0.004	
Postdilatation balloon < 5mm OR **4.6** (1.2-17.6), p=0.020	
Immediate DAPT OR **0.77** (0.41-0.92), p=0.006	
Occlusion balloon catheter OR **0.68** (0.21-0.89), p=0.003	

95% CIs are provided in paretheses
*(ia. bolus + iv. infusion)

Predictors of stent patency loss by 90 days

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Univariate	Mulitvariate
Heparin limited to flush OR **14.3** (1.5-33.1), p=0.007	**Postdilatation balloon < 5mm** OR **15.2** (5.7-42.3), p<0.001
mTICI < 2b OR **12.7** (4.9-97.9), p=0.001	mTICI < 2b OR **6.3** (0.98-45.2), p=0.080
Tandem lesion OR **9.2** (1.1-18.4), p=0.030	
Postdilatation balloon < 5mm OR **7.1** (5.4-57.9), p=0.002	
ASPECT < 8 OR **6.2** (1.3-14.1), p=0.024	

Conclusions

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This **first systematic evaluation** of using **MicroNET-covered** stent **routinely** in carotid-related stroke patients (eligible for emergency recanalization) indicates:

- safety and efficacy of strategy to seal the atherosclerotic/thrombotic ”culprit” material with anatomical reconstruction of the lumen
- feasibility of both antergrade and retrograde stent implantation in tandem lesions
- high rate of acute angiographic success and in-hospital stent-patency
- favorable 90-day clinical outcomes in this complex patient cohort
- high 90-day stent-patency rate (when postdilation done with balloon ≥5mm)

This opens up expanding the MicroNET-covered stent indications to acute carotid syndrome