Simultaneous Single-Stage Endovascular Carotid Revascularization and Urgent Cardiac Surgery Under Open-Chest Cardiopulmonary Bypass in Extreme High-Risk, Unstable Patients

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Disclosure of Relevant Financial Relationships

I, Karolina Dzierwa DO NOT have any relevant financial relationships to disclose.

Faculty disclosure information can be found on the app

Background

- In patients with **increased stroke-risk carotid stenosis** and **severe, unstable cardiac disease** requiring **urgent cardiac surgery**, any intervention limited to treating just one of the two conditions may significantly increase the risk of complications arising from the “other”, untreated pathology

- In this challenging group of **extreme-risk patients**, we evaluated safety and feasibility of **true hybrid** carotid artery stenting (**CAS**) under open-chest extracorporeal circulation (**ECC-standby**) **combined with cardiac surgery**. (***SIM-GUARD**** *study)*

**SIMultaneous urgent cardiac surgery and micronet-covered CGUARD stent carotid revascularization in extreme-risk patients (NCT04973579)*

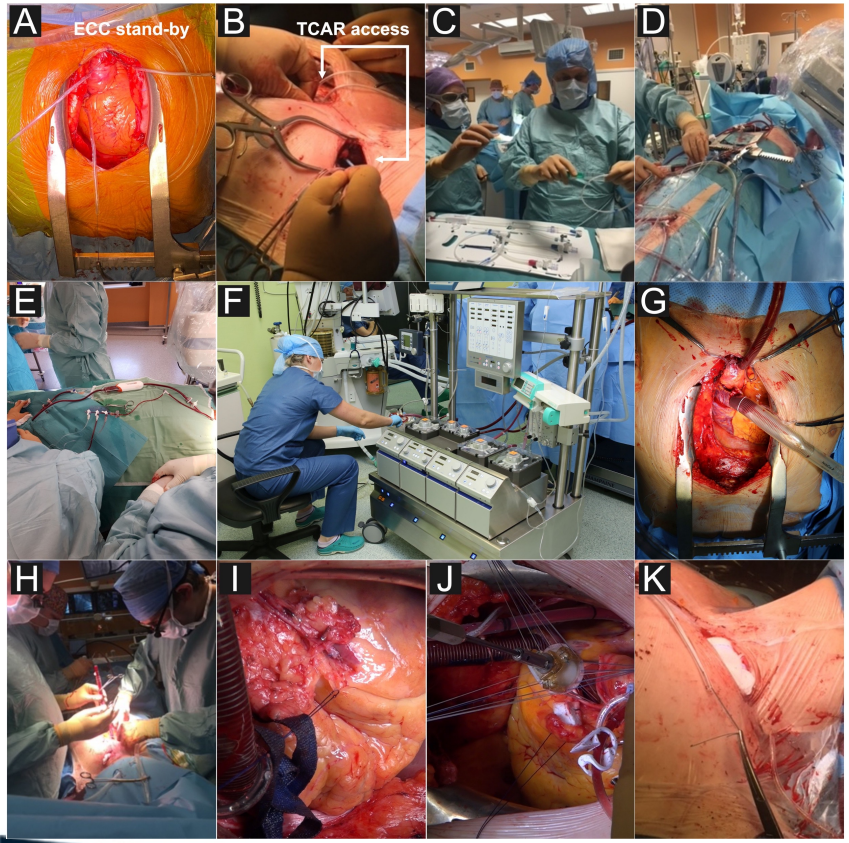
Methods

- **extreme risk patients** defined as the **need of urgent/emergent cardiac surgery** + severe/symptomatic **increased-stroke risk carotid stenosis → cumulation of risks**
- consecutive, all-comer patients with acute myocardial infarction (AMI)/unstable angina (UA) or NYHA III/IV heart failure **requiring urgent/emergent cardiac surgery**

coexisting with

- **the need of carotid revascularization-** severe internal carotid artery stenosis with increased-stroke risk lesion characteristics and neurologic symptoms and/or radiologic signs of cerebral injury ipsilateral to carotid lesion

Methods – hybrid room



- both procedures **CAS + cardiac surgery** performed in a hybrid room **simultaneously in one stage**
- after general anesthesia induction and chest opening, **ECC** was connected in **stand-by** and started immediately in case of hemodynamic instability
- CAS with implantation of micronet-covered stent was performed via femoral/radial or direct carotid access with a **mandatory** use of **neuroprotection device**
- cardiac surgery followed immediately - surgical team and endovascular team overlap, **no-delay strategy**
- CAS+ cardiac surgery performed on **ASA and UFH**, **clopidogrel** (300 mg) was given **postoperatively** ≥6 hours post-surgery (after extubation or via nasogastric tube)

SIM-GUARD study patients

CEA+cardiac surgery, n=98

One-day, *sequential* CAS+cardiac surgery, n= 149

cardiac surgery with carotid revascularization WITHIN 24 hours before/after cardiac surgery
(78 months)
n=307

extreme risk urgent/emergent patients
SIM-GUARD STUDY ITT
n=60, (age 70.7±6.9, 85% male)

Per-protocol (PP)
n= 45, (75%)

- ***33 CAS+CABG***
- ***7 CAS+AVR***
- ***4 CAS+AVR+CABG***
- ***1 CAS+PCI+AVR***

Not per-protocol (NPP)
n= 15, (25%)

cardiac + carotid treated (within one session), n=9

Surgery declined by anesthesia (severe COPD, poor mobility, severe obesity):
- 4 CAS + multivessel PCI
- 1 CAS +TAVI

Hybrid room not immediately available:
- 4 sequential CAS in angio suite + cardiac surgery

cardiac treated, carotid untreated, n=6

Strict ESC/ESVS/ESO **2017 guideline adherence**[1] (**initial 28 months**: in 3 patients ICA stenosis (did not meet guideline listed increased sroke risk criteria[1])
- 1 fatal ipsilateral stroke on 1st post-CABG day
- 1 ipsilateral stroke on 3rd post-AVR+CABG day
- 1 ipsilateral stroke 6 days post TAVI (patient rejected from AVR)

→ **Care to maximize to asymptomatic lesion revascularization if published evidence increased risk criteria present or not[2]; months 29-78**
- 1 cardiac arrest in transportation,
- 1 consent withdrawal ipsilateral stroke on day 18
- 1 ICA stenosis severity not confirmed on angiography- cardiac surgery performed, no carotid intervention

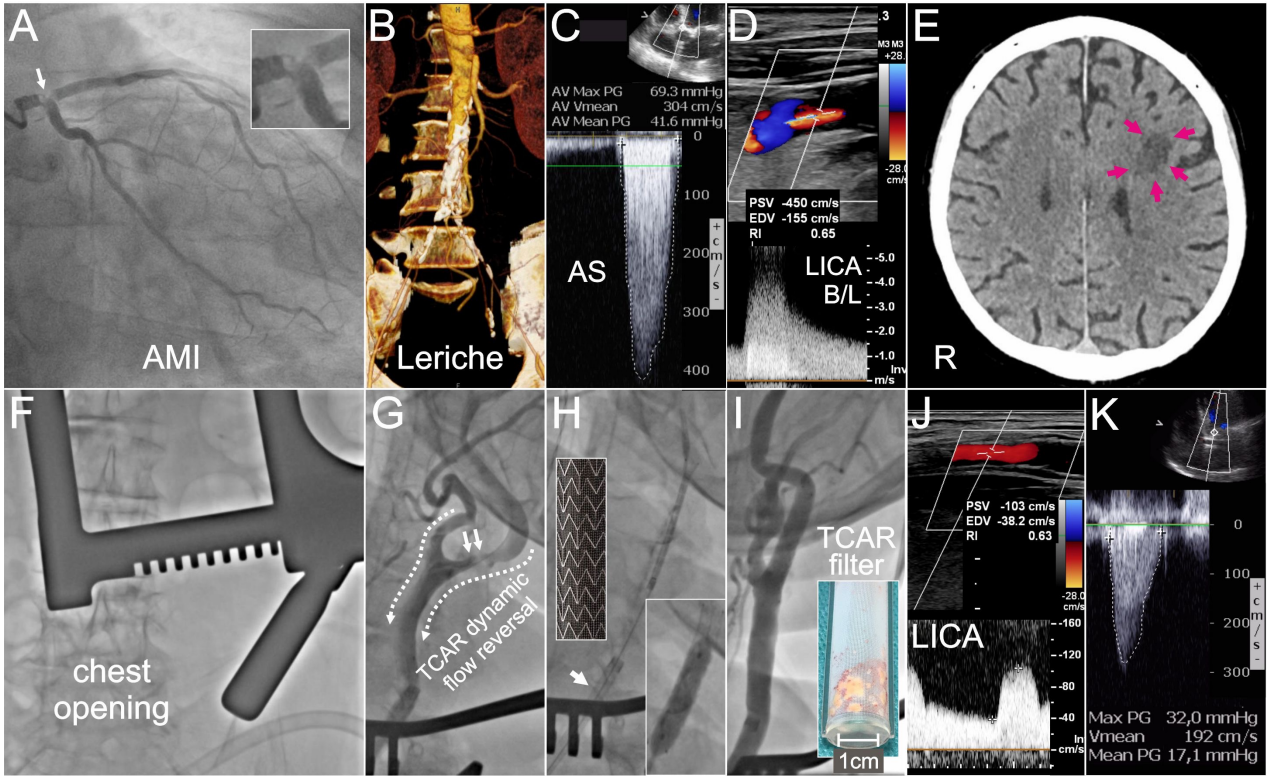
1. Aboyans et al, Eur Heart J. 2018; 39:763-816; 2. Musialek et al. Cardiovasc Res. 2023; 25: cvad135 (epub ahead of print)

Results

	ITT n = 60	PP n = 45	NPP n = 15	*P* Value
ipsilateral stroke/TIA	19 (31.7%)	12 (26.7%)	7 (46.7%)	0.2
AMI	13 (21.6%)	8 (17.8%)	5 (33.3%)	0.28
UA	36 (60%)	31 (68.9%)	5 (33.3%)	0.03
AMI/UA+ neurological symptoms	15 (25%)	13 (28.9%)	2 (13.3%)	0.3
ICA stenosis ≥90%	28 (46.7)%	21 (46.7)%	7 (46.7)%	0.83
high risk plaque	38 (63.3%)	29 (64.4%)	9 (60%)	1.0
LMCA stenosis	26 (43.3%)	19 (42.2%)	7 (46.7%)	0.76
euroSCORE II median, Q1-Q3	4.2 (3.05–7.89)	3.75 (2.96–6.06)	8.67 (3.37– 10.52)	0.02
femoral/radial access	52 (86.7%)	42 (93.3%)	10 (100%)*	1.0
direct carotid access	3 (5%)	3 (6.7%)	-	1.0
proximal NPD	37 (61.6%)	30 (66.7%)	7 (77.8%)*	0.7
switch to ECC	5 (8.3%)	5 (11%)	-	-
drainage (ml) median Q1-Q3	450 (332-715)	440 (325-675)	700 (380-820)	0.2

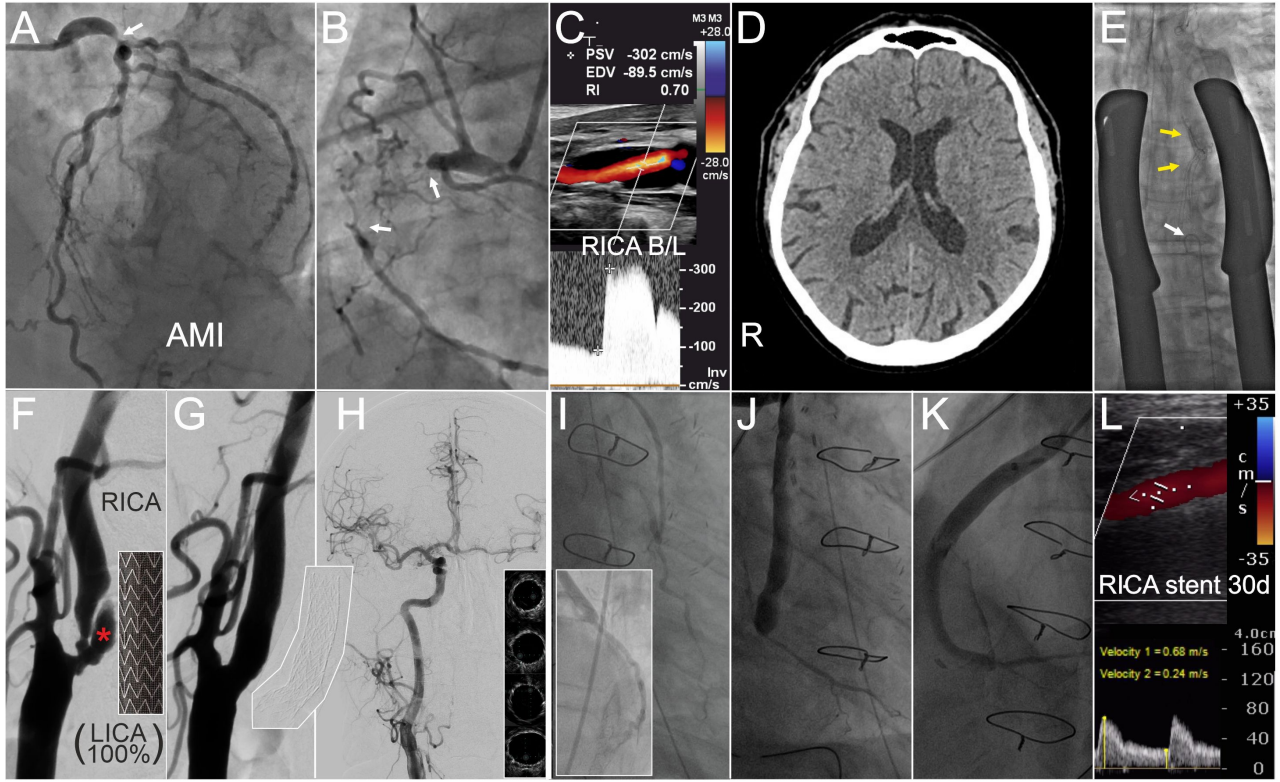
**9 patients in NPP group underwent carotid revascularization - CAS*

True hybrid CAS + cardiac surgery



True simultaneous micronet-covered stent (CGuard 8x30 mm) TCAR+AVR+CABG

True hybrid CAS + cardiac surgery



True simultaneous micronet-covered stent (CGuard 10x40 mm) CAS+CABG (femoral access)

30-day results

	ITT n=60	PP n = 45	NPP n = 15	*P* Value
Freedom from death	56 (93.3%)	44 (97.8%)	12 (80%)	0.045
Freedom from ipsilateral stroke	55 (91.6%)	45 (100%)	10 (66.7%)	<0.001
Freedom from any stroke	53 (88.3%)	43 (95.5%)	10 (66.7%)	0.008
Freedom from death/ ipsilateral stroke	52 (86.7%)	44 (97.8%)	8 (53.3%)	<0.001
Freedom from death/any stroke	50 (83.3%)	42 (93.3%)	8 (53.3%)	0.001
Freedom from death/ipsilateral stroke/MI	51 (85%)	43 (95.5%)	8 (53.3%)	<0.001
MCS patency	54 (100%)	45 (100%)	9 (100%)*	

NPP management was identified as a predictor of:

- **death, OR 11.0 (1.1 – 115.5), p=0.009**
- **death/ipsilateral stroke/, OR 38.5 (4.2 – 156.8), p=0.001**
- **death/ipsilateral stroke/MI, OR 18.8 (3.29 – 107.5), p=0.001**

**9 patients in NPP group underwent carotid revascularization - CAS*

Conclusion

- In cardiac unstable patients requiring cardiac surgery at increased carotid-related stroke risk, hybrid room, **true simultaneous CAS** with **micronet-covered** stent use **combined with cardiac surgery** is **feasible** and **safe** with 95.5% freedom from death/ipsilateral stroke/MI at 30-days

- This novel strategy appears effective in **minimizing perioperative ipsilateral stroke risk**