Randomized Controlled Trial of a First-Generation Carotid Stent versus MicroNet-Covered Stent: 12-month outcomes

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Disclosure

Speaker name:

Bugurov Savr

I have the following potential conflicts of interest to report:

☐ Consulting

☐ Employment in industry

☐ Stockholder of a healthcare company

☐ Owner of a healthcare company

☐ Other(s)

☒ I do not have any potential conflict of interest

Objectives

The key objective of this randomized study was to compare the number of new periprocedural DW-MRI lesions after CAS with the novel CGuard™ mesh-covered stent compared with the Acculink™ reference stent.

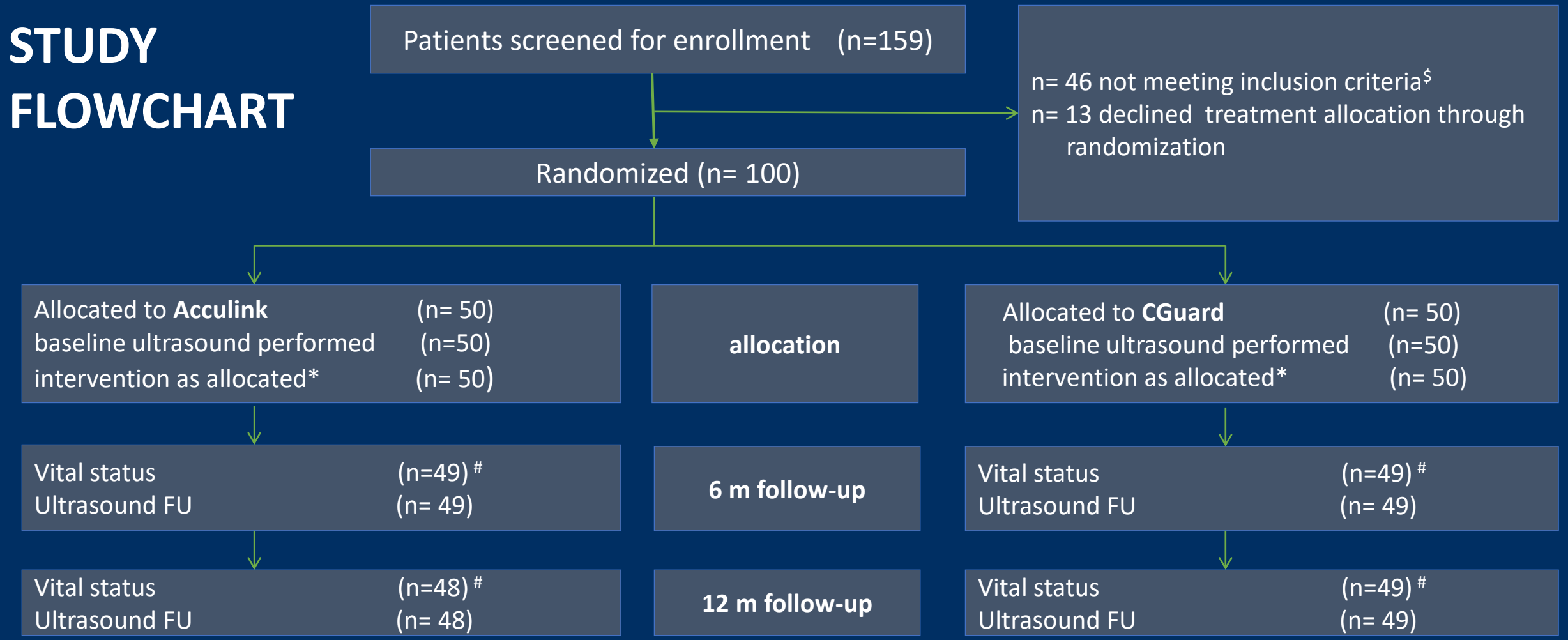
Results of MRI analysis were presented and published before (J Am Coll Cardiol Intv. 2021 Nov, 14 (21) 2377–2387)

- Current analysis evaluates major adverse cardiac and neurologic (death, stroke, myocardial infarction (MACNE) and restenosis rate in the 2 study groups in the 12-month follow-up.

Study design

- This randomized control trial is an independent, single-centre, open-label, comparison of two interventional arms – CGuard vs. Acculink*.
- The study was externally monitored and imaging data were evaluated by an independent core laboratory
- 100 consecutive patients were enrolled with 1y clinical FU
- Ultrasound of the ICA scan at baseline, 24-48 hours after the procedure and after 30, 180 and 365 days of follow-up.
- *The study used in both arms (100% of patients) the anti-embolic device **Emboshield NAV**, the pore diameter of the device is similar to the diameter of the cells of the CGuard stent (pore size 165 µm)

STUDY FLOWCHART



* - all CAS with EmboShield NAV6 as per the Centre routine

$ - atrial fibrillation (n=14)
- severe renal failure (n=12)
- restenotic lesion (n=9)
- MRI contraindication (n=11)

\# 3 patients withdrew from the study.

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CLINICAL AND LESION CHARACTERISTICS

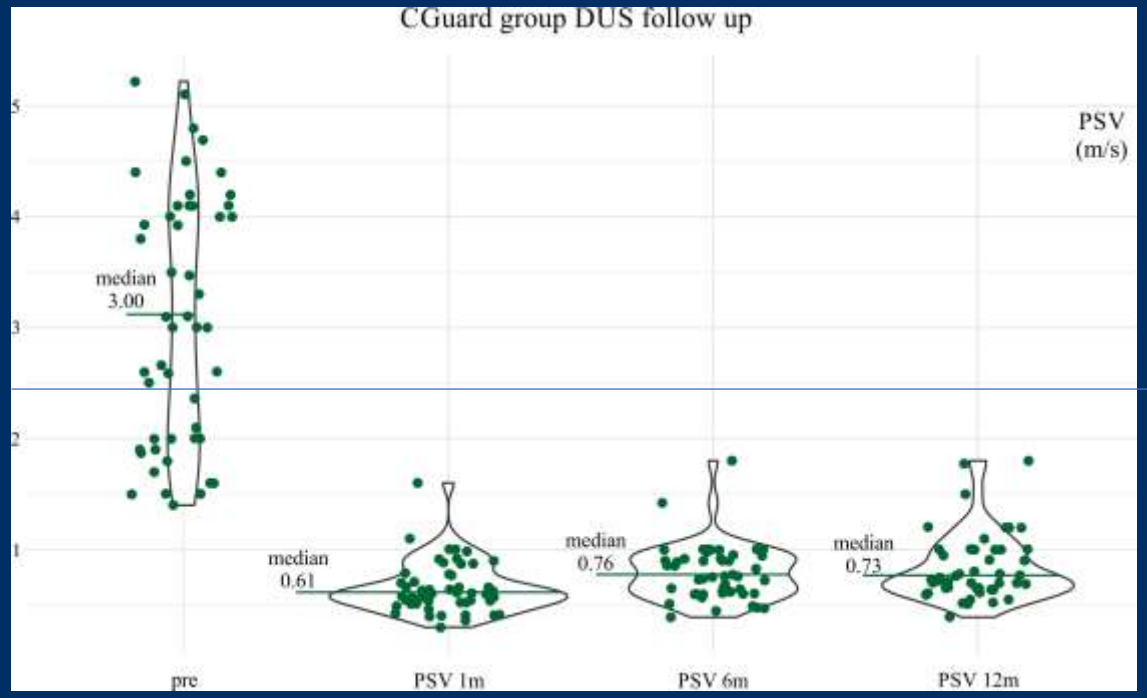
	ACCULINK n=50	CGUARD n=50	P
Age, years [range]	67 [62;72]	65 [61;69]	0.27
Gender, (male) n (%)	35 (70 %)	38 (76%)	0.65
Coronary heart disease, n (%)	42 (88 %)	39 (78 %)	0.61
Previous coronary revascularization (CABG or PCI), n (%)	25 (50 %)	22 (32 %)	0.69
Chronic heart failure, n (%)	44 (88 %)	45 (90 %)	1
Diabetes mellitus treatment, n (%)	8 (16 %)	10 (20 %)	0.79
Arterial hypertension, n (%)	49 (98 %)	48 (96 %)	1
Current smoking, n (%)	20 (40 %)	17 (34%)	0.67
Peripheral arterial disease, n (%)	17 (34%)	15 (30%)	0.83
Ipsilateral stroke ≤ 6m, n (%)	6 (12%)	11 (22%)	0.18
Ipsilateral TIA ≤ 6m, n (%)	3 (6.0 %)	5 (10 %)	0.46
Contralateral carotid artery stenosis ≥50%; n (%)	9 (18%)	18 (36%)	0.75
Contralateral carotid artery occlusion; n (%)	3 (6.0%)	8 (16%)	0.11
Degree of stenosis (QCA, % [range])	76 [67;88]	75 [72;89]	0.72
Affected side right, n (%)	27 (54 %)	30 (60%)	0.77

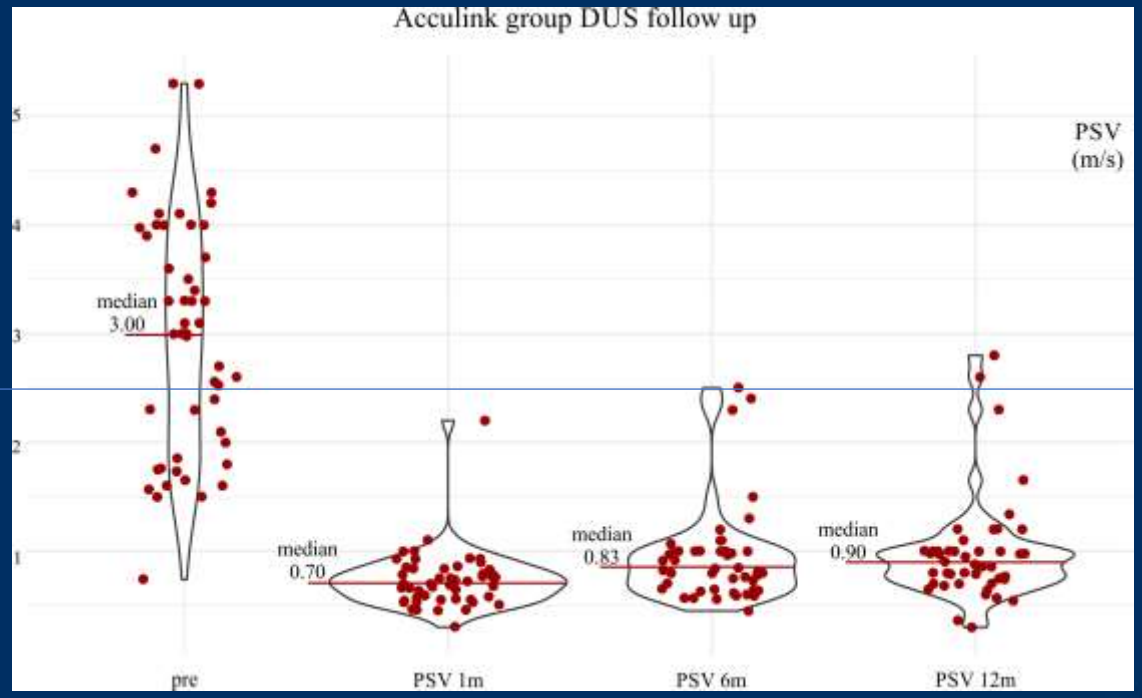
CURRENTLY REPORTED SECONDARY ENDPOINTS

- The frequency of restenosis and reocclusion according to the ICA ultrasound, within 6 and 12 months.

- 6-month and 12-month adverse events (MACE)

Violin graph for Peak Systolic Velocity of stented ICA segments during 30, 180 and 365 days.





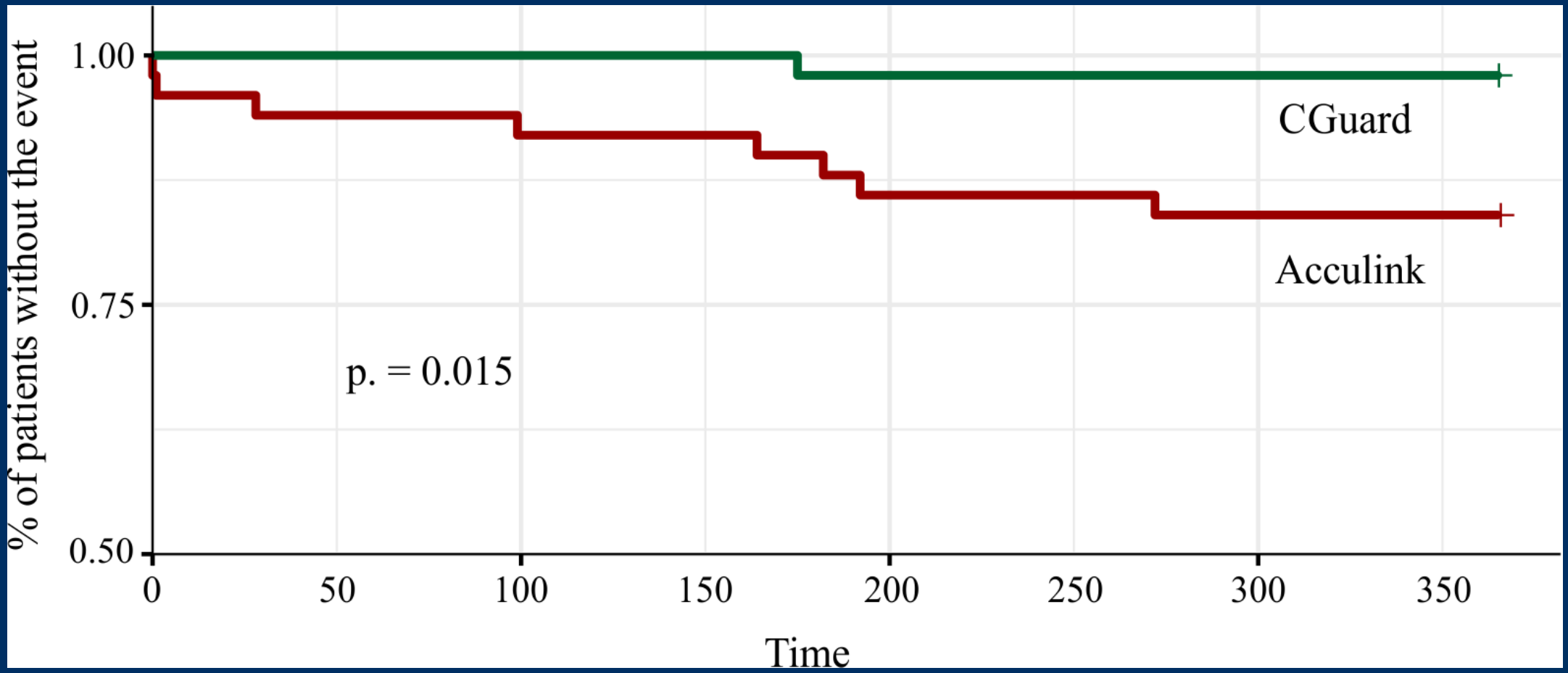
Incidence of restenosis and reocclusion between study arms at 365 days.

	ACCULINK n=50	CGUARD n=50	P
Restenosis	3 (6%)	0 (0%)	0.24
Vessel occlusion	1 (2%)	0 (0%)	1
Restenosis + Vessel occlusion	4 (8%)	0 (0%)	0.12

Incidence of MI,stroke, death between study arms at 365 days.

	ACCULINK n=50	CGUARD n=50	P
MI	1 (2%)	0 (0%)	1
Stroke	2 (4%)	0 (0%)	0.49
Deaths	2 (4%)	1 (2%)	1
TOTAL MACE	5 (10%)	1 (2%)	0.20

Combined MACNE and/or in-stent restenosis/occlusion rate



Kaplan-Meier Plot,

CONCLUSION

In a randomized controlled study powered for peri-procedural and 30-day cerebral embolism by magnetic resonance imaging …..

- **12-month outcomes demonstrated a significantly higher prevalence of the combined endpoint of MACNE and in-stent restenosis/occlusion rate in first-generation (single-layer) carotid stent CAS vs. MicroNet-covered stent CAS.**

(NCT03488199)

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