Randomized Controlled Trial of a First-Generation Carotid Stent versus MicroNet-Covered Stent: 3- Year outcomes

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Disclosure

Speaker name:

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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

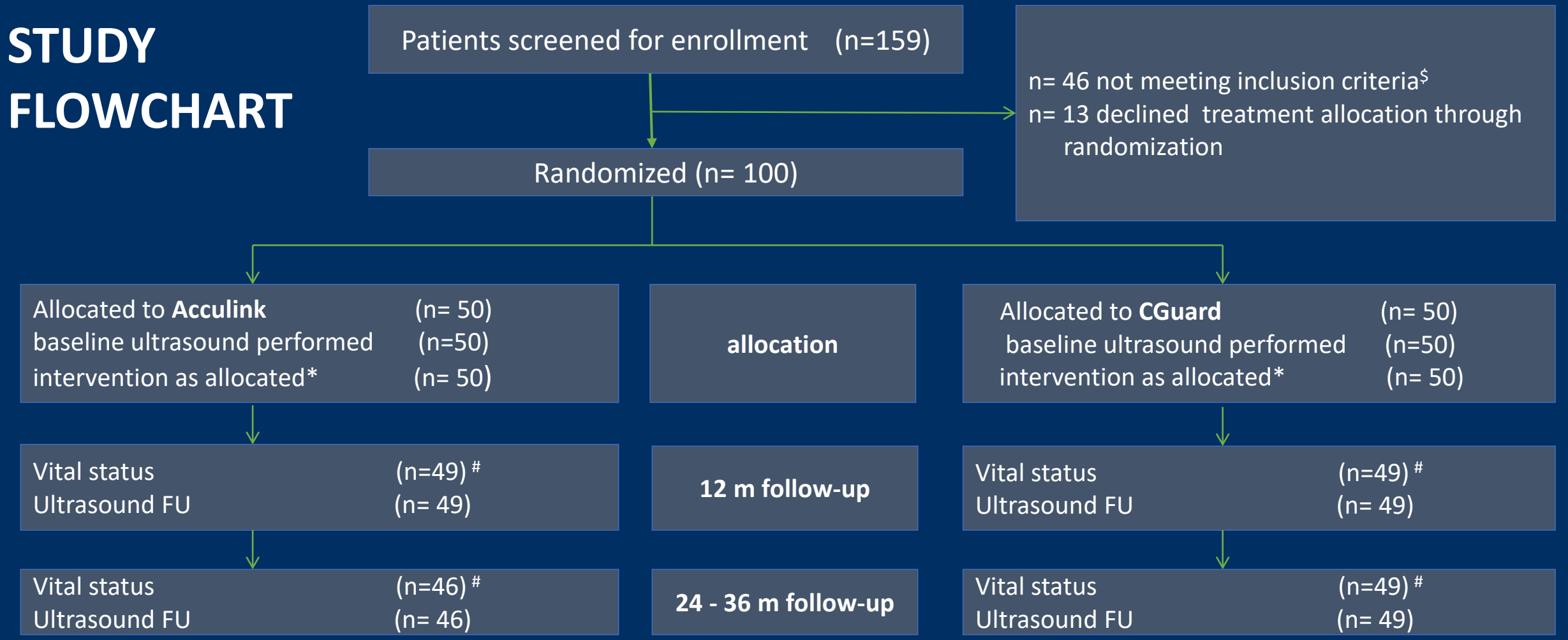
Objectives

- The primary objective of the randomized trial was to compare the number of new periprocedural acute cerebral ischemic lesions observed on diffusion-weighted magnetic resonance imaging (DW-MRI).
- The results at 30 days were published in the JACC Cardiovasc Interv. on November 8, 2021; volume 14, issue 21, pages 2377-2387. PMID: 34736737.
- The current presentation reports the clinical outcomes at 36-month follow-up.

Study design

- Investigator-initiated, single-centre, open-label, randomised control trial comparing CGuard versus Acculink*
- Per protocol, ultrasound of the ICA was performed at baseline, 24–48 hours after ICA stenting, and at 12, 24, and 36 months.
- The study was monitored externally and the imaging data were assessed by an independent core laboratory
- *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)

\# 5 patients withdrew from the study.

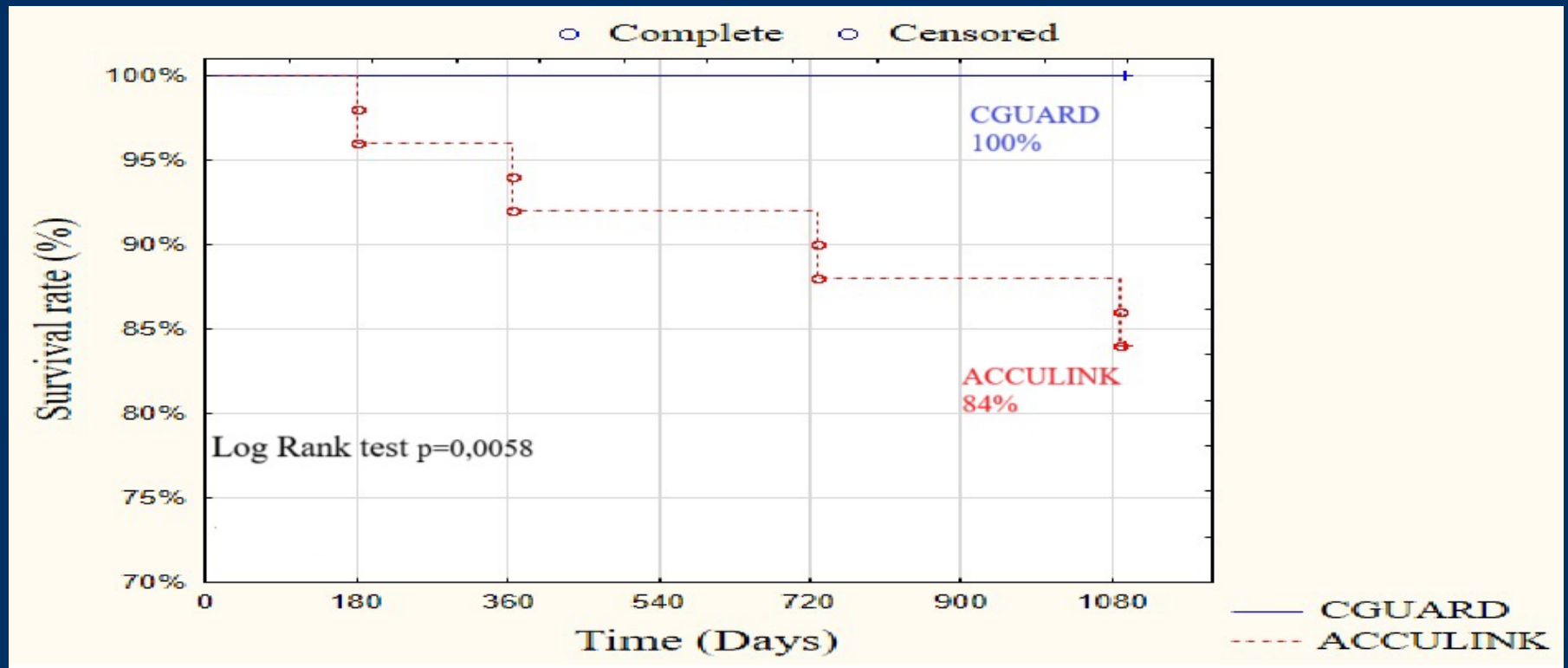
CLINICAL AND LESION CHARACTERISTICS

	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]	0.71
Affected side right, n (%)	27 (54 %)	30 (60%)	0.77

36 months - **Year clinical Outcomes**

	ACCULINK n=50	CGUARD n=50	P
Restenosis	7 (14%)	0 (0%)	0.0125
Vessel occlusion	1 (2%)	0 (0%)	1
Restenosis + Vessel occlusion	8 (16%)	0 (0%)	0.0058

Frequency of freedom from restenosis and stent occlusion in both groups over 36 months



TIME (DAYS)	0	180	360	540	720	900	1080
CGUARD	50	50	50	50	50	50	50
ACCULINK	50	50	48	46	46	44	44

36 months - **Year clinical Outcomes**

	ACCULINK n=50	CGUARD n=50	P
MI	2 (4%)	1 (2%)	1
Stroke	3 (6%)	0 (0%)	0.24
Deaths	4 (8%)	1 (2%)	0.36
TOTAL MACE	9 (18%)	2 (4%)	0.05

CONCLUSION

While the Randomized Control Trial was not powered for clinical endpoint subanalysis,

The 3 year follow-up indicates that :

- Significant benefit for CGuard when compared with Acculink in the accumulated restenosis and reocclusion
- Higher occurrence of MI, stroke, or death with Acculink in the when compared with CGuard.