Abstract: 3048

PARADIGM-Extend prospective academic trial: Accumulating long-term evidence for MicroNet-covered stent safety and stroke prevention efficacy

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Aims
To provide long-term clinical (incl neurologic) and duplex ultrasound (DUS) evaluation of the CGuard MicroNet-covered embolic prevention stent system (EPS) routine use to perform CAS in all-comer (no exclusion criteria) patients with symptomatic or increased-stroke-risk asymptomatic carotid stenosis recommended for revascularization by the NeuroVascular Team.

Methods and results: PARADIGM-Extend is a non-industry-funded, prospective academic study in all-referrals-tracked symptomatic and asymptomatic carotid stenosis. In asymptomatic lesions, intervention is mandated only in case of increased-stroke-risk features. There is first-line consideration to use the study device, with EPD choice according to tailored-CAS algorithm. Independent neurologist evaluation and DUS are performed before CAS, at 48h, 30 days, and then every 12 months. There is external source data verification, external angiographic corelab, and external statistical analysis. Currently 325 patients (48-87 years, 54.2% symptomatic) crossed the 1st follow-up window. There has been 100% CGuardEPS use. Angiographic DS was reduced from 84±8% to only 6.9±5% (p<0.001, ‘CEA-like’ effect of CAS).

Peri-procedural death or major stroke rate was 0%. One event was CEC-adjudicated as minor stroke (0.3%), and there was one (type2) MI (0.3%). By 30 days there was one haemorrhagic transformation leading to death (0.3 %) and one bleeding-related death (0.3%). Thus total death/major stroke/minor stroke rate at 30 days was 0.9%, and total death/major stroke/minor stroke/MI rate at 30 days was 1.2%. At 1- 12 months were no strokes or stroke-related deaths (0%). At 12-24 months there was one cerebellar stroke in an AFib patient that was confirmed on MRI imaging but no carotid-territory stroke or stroke deaths (0%). By 24 and 36 months there was one posterior circulation (cerebellal) infarct but no cerebral infarctions. Post-procedural in-stent velocities were normal and remained normal throughout the 36-month follow-up period (peak-systolic/end-diastolic velocity 0.69±0.29/0.18±0.09 m/s at 30 days, 0.82±0.47/0.22±0.13m/s at 12 months, 0.73±0.31/0.19±0.09m/s at 24months and 0.80±0.31/0.21±0.11 at 24months), indicating normal device healing.

Conclusions: PARADIGM-Extend accumulating 36-month clinical and DUS evidence is consistent with unprecedented, sustained safety and cerebral embolism prevention efficacy of the CGuard™ MicroNET-covered embolic prevention stent system used routinely for stroke prevention in symptomatic and increased-stroke-risk asymptomatic subjects with carotid stenosis.