3048

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

P. Musialek[1], A. Mazurek[1], M. Trystula[2], A. Borratynska[3], T. Tomaszewski[3], A. Lesniak-Sobelga[1], M. Brozda[1], U. Gancarczyk[1], N. Dluzniewska[1], M. Urbanczyk[4], R.P. Banys[4], P. Judzialo[5], T. Drazkiewicz[2], L. Partyka[5], P. Podolec[1]

[1]Jagiellonian University, John Paul II Hospital, Dept of Cardiac & Vascular Diseases, Krakow, Poland; [2]John Paul II Hospital Dept. Vascular Surgery, Krakow, Poland; [3]John Paul II Hospital, Dept. Neurology, Krakow, Poland; [4]John Paul II Hospital, Dept. of Radiology, Krakow, Poland; [5]KCRI, CoreLab, Krakow, Poland

On behalf of PARADIGM-Extend Investigators

Funding Acknowledgement: K/ZDS/007819 Jagiellonian University Medical College

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 core-lab, 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.