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LB-004 NOVEL SACCULAR ENDOVASCULAR ANEURYSM LATTICE (SEAL DEVICE) PRE-SEAL IT EARLY CLINICAL FEASIBILITY TRIAL: PROCEDURAL, 24-HOURS, AND 3-MONTH SAFETY AND EFFECTIVENESS INDEPENDENT CORE LAB ADJUDICATED OUTCOMES

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Introduction The first-in-human PRE-SEAL IT trial was designed to assess the feasibility, safety, and effectiveness of the novel Saccular Endovascular Aneurysm Lattice (SEAL^{TM}) system in patients with previously untreated ruptured and unruptured wide-neck intracranial aneurysms (IA). Here, we present the final demographic, procedural, 24-hour, and 3-month safety and effectiveness results from the 33 aneurysm that were treated in 29 patients with the SEAL^{TM} device and enrolled in the PRE-SEAL IT study.

Methods PRE-SEAL IT is a prospective, interventional, core-lab adjudicated, single-arm study performed in Medellin, Columbia and Pakistan. From January 2022 through March 2023, 29 patients with 33 IAs were enrolled into the PRE-SEAL IT trial and follow-up is ongoing. Key inclusion criteria included: 1. Age 20-80 years, 2. Saccular shape, bifurcation, or terminus IA, 3.Wide neck aneurysm with neck size ≥4mm or dome-to-neck ratio <2, and 4. IA diameter 2mm to 25mm. Consented and enrolled patients were treated with the SEAL^{TM} device. A follow-up DSA was performed at 24-hours, 6 months, and 12 months and a MRA at 3 months. Angiographic occlusion (Roy Raymond (RR) and Web Occlusion Scale (WOS)) was adjudicated by an independent interventional neuroradiologist (Oculus Imaging, TN, USA).

Results In 29 patients (twenty-two women and 7 men), 33 IAs were treated with the SEAL^{TM} device, with a mean age of 61.0± 13.5 years. Of the 33 IAs, the majority were anterior circulation (81.8%), bifurcation (75.8%), and unruptured (87.9%). Mean aneurysm width was 6.1 ± 3.0mm, with a mean neck size of 4.2±1.7mm and mean neck to dome ratio of 1.4±0.4. The SEAL Arc was used in 48.5% and SEAL Base in 51.5% of cases. No technical complications were observed in the study and technical success was achieved in 100% of cases. Immediate post-procedure complete occlusion (Grade A, B) was achieved in 4 patients (12.1%) and adequate occlusion (Grade A, B, C) in 8 (24.2.%). At 24-hour follow-up, 12 patients (36.4%) had complete occlusion, and 19 patients (57.6%) achieved adequate occlusion. At 3 months, 20/27 (74.1%) (RR I and WOS A), achieved complete occlusion, and 22/27 (81.5%) achieved adequate occlusion (RR I and II). No cases of peri-procedural stroke or new subarachnoid hemorrhage were reported up to the 3 month follow-up.

Conclusion The final procedural, 24-hour, and 3-month follow-up results of the PRE-SEAL-IT trial demonstrated promising occlusion rates at post-procedural, 24-hour, and 3 months follow-up with no safety concerns.

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LB-005 HEMERA 1 CARBOXYHEMOGLOBIN OXYGENDELIVERY FOR REVASCULARIZATION IN ACUTE STROKE: A PROSPECTIVE, RANDOMIZED PHASE 1 CLINICAL TRIAL

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Background PP-007 is a PEGylated bovine carboxyhemoglobin gas transfer molecule with pleotropic cytoprotective effects, vasodilatation, plasma expansion and optimization of oxygen delivery. Rodent middle cerebral artery occlusion models have demonstrated that PP-007 increases blood flow in the collateral circulation and reduces final infarct volumes, supporting a potential role as neuroprotective agent in acute ischemic stroke. We aim to evaluate the safety and feasibility of PP-007 as an adjunctive treatment to mechanical thrombectomy (MT) in patients with stroke secondary to large vessel occlusion (LVO).

Methods HEMERA-1 was a multicenter, prospective, randomized, controlled phase 1 clinical trial. Anterior circulation LVO patients were assigned in a 3:1 ratio to receive either PP-007 (320mg/kg: 30 minutes bolus followed by 2-hour infusion) plus MT or MT alone within 24 hours after symptom onset. Other key inclusion criteria were baseline NIHSS ≥6, baseline Alberta Stroke Program Early CT Score (ASPECTS) ≥5 and/or estimated core volumes ≤70mL with mismatch >50mL on CT perfusion, pre-morbid modified Rankin Scale <2, and ineligibility for intravenous thrombolysis. The primary endpoint comprised a comprehensive safety evaluation by a Data Monitoring Safety Board.

Results A total of 17 patients were recruited. The mean ± SD age, baseline NIHSS, and ASPECTS were 74.8±12.7 years, 17.3±4.2, and 7.9±1.8, respectively. Twelve patients were randomized PP-007 plus MT, 1 was randomized but not treated, 4 patients were randomized to MT alone. Recanalization of the occluded vessel was achieved in all patients. Seven PP-007 patients in 2 centers had temporary elevation of Partial Prothrombin Time most likely artifactual without any clinical consequences. A transient systolic blood pressure increase (20-40 mmHg) during the bolus was observed in all PP-007

patients without any clinical consequences. There were no other safety concerns.

Conclusion No significant safety concerns were identified for the adjunctive use of PP-007in patients undergoing MT (ClinicalTrials.gov NCT04677777).

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LB-006 TREATMENT OF MIDDLE CEREBRAL ARTERY BIFURCATION ANEURYSMS WITH NEW GENERATION LOW PROFILE FLOW DIVERTERS COMBINED WITH PROLONGED DUAL ANTI-PLATELET THERAPY; COVERED BRANCH ANALYSIS

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Introduction In recent years, there has been a growing interest in using flow diverters (FD) to treat MCA aneurysms.

Aim of study In this study, we investigated the safety and effectiveness of new generation low profile flow diverters to treat middle cerebral artery (MCA) bifurcation aneurysms among all patients treated for intracranial aneurysms at our center.

Methods This was a single center, single-arm retrospective study of prospectively collected data of patients treated with p48 HPC, p64 HPC, Silk Vista Baby and PED Shield Vantage at our high-volume center between March 2018–March 2023. The primary efficacy endpoint was complete occlusion as measured by a class 1 Raymond-Roy score at 1-year and 2-year follow-up. The primary safety endpoint was major morbidity and neurological mortality up to 2 years following intervention.

Results A total of 75 patients (mean age 57.1±2.7 years; 83.9% female) with 75 saccular MCA aneurysms (mean size 4.6±3.2 mm) were treated with a low-profile FD. A total of 83 devices were deployed, with 94.6% (71/75) of aneurysms requiring only one device. Intraprocedural technical complications occurred in 5.3% (4/75), 2 shortening of the device requiring an additional FD, 1 in-stent thrombosis, 1 subarachnoid hemorrhage post-procedure. Follow-up angiography was available for 73.3% (55/75) of the patients at a mean time of 12.4 months. Complete occlusion was demonstrated for 56.0% of aneurysms at 6 months, 63.2% at 12 months and 81,9% at 24 months. The overall rates of major morbidity and neurological mortality after 2 years were 2.7% (2/75) and 0% respectively. 5.3% of jailed branches presented an asymptomatic narrowing, 5.3% an asymptomatic occlusion and 1.3% presented a symptomatic occlusion. Dual antiplatelet therapy was maintained with prasugrel 10mg/day and AAS 100mg/day 1 year following FD implantation then continued with AAS 100mg/day.

Conclusion Low profile new generation flow diverters combined with prolonged DAPT therapy with prasugrel demonstrated high rates of complete long-term occlusion, as well as low rates of mortality and morbidity consistent with fewer symptomatic jailed artery occlusions.

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LB-007 SELECTIVE BRAIN COOLING IS POSSIBLE VIA CSF EXCHANGE WITH DOUBLE LUMEN EVD-PROOF OF CONCEPT IN PORCINE STROKE MODEL

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Introduction Hypothermia is seen as neuroprotective after brain insult (BI). In acute phase after BI it affects brain metabolism by decreasing oxygen and glucose consumption. Hypothermia affects apoptosis and inflammatory mediators. In the later stage of BI, enzyme activation stimulates protein and lipid breakdown, which can be slowed and decreased with hypothermia. In the latest stage of BI hypothermia has shown positive affect in angiogenesis, neurogenesis, synaptogenesis. Hypothermia also reduces vasogenic oedema and blood brain barrier dysfunction. Despite hypothermia´s neuroprotective effect randomized control trials have demonstrated its benefits only limited scenarios - mainly in global ischemia (post-cardiac infarction and ischemia of new-born). Majority of complications related to hypothermia has been due to systemic hypothermia and selective brain cooling has never been demonstrated in large mammals without changes in core temperature of subject.

Objective We hypothesized that by actively exchanging cerebrospinal fluid (CSF) to cooled NaCl and ringer acetate solution we can reduce selectively brain temperature without changes in core temperature of porcine body.

Methods We inserted double lumen external ventricular drainage (EVD) into the lateral ventricle of four porcines. We added spinal drainage to accelerate CSF exchange to cooled NaCl (one porcine)/ringer acetate (three porcine) solutions. Brain parenchymal temperature was measured from the contralateral brain hemisphere and the ipsilateral brain hemisphere. We exchanged CSF to cooled solution in 4 porcine with rates of 180ml-720ml/h. Two of porcine were induced global stroke via endovascular method by closing brains main arteries for 20 min.

Results Contralateral brain hemisphere temperature dropped by 2.2-3.1C from baseline while core temperature changed only by 0.5C. Ipsilateral temperature cooled by 4.5-7.5C from baseline to 29.9-33.8C, while core temperature was on average 37.7C. Total time needed to achieve selective cooling was highly dependent on CSF rate from 10min to 1.5h. One porcine started to have arrhythmias when brain temperature approached 30.8C, in this case CSF exchange was done with NaCl solution, other 3 porcine did not have similar adverse events with ringer acetate. In two stroke induced porcine selective brain cooling was achieved despite 140 mmHg median arterial pressure after stroke.