

number of passes, predicts END, which suggests a casual pathway that requires further exploration.

Disclosure of Interest no.

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THE NEW GENERATION BOBBY BALLOON GUIDE CATHETER FOR MECHANICAL THROMBECTOMIES: RESULTS OF THE INTERNATIONAL PROSPECTIVE STRAIT STUDY

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Introduction The use of a Balloon Guide catheter (BGC) in mechanical thrombectomy (MT) procedures might be associated with better technical and clinical results.

Aim of Study The next generation Bobby BGC (Microvention Inc.) has been evaluated in the prospective, multicenter, single-arm observational post-market STRAIT trial.

Methods Prospective data from 171 patients enrolled in the STRAIT study were analyzed. Key inclusion criteria included acute ischemic stroke (AIS) within the anterior cerebral circulation, occlusions ranging from M1 to proximal M2, treatment initiated within 8 hours of symptom onset, NIH Stroke Scale (NIHSS) ≥ 5 , ASPECT Score ≥ 6 . Angiographic and clinical characteristics, technical proficiency, and 90-day outcomes were evaluated and analyzed, controlled by an independent core lab and the clinical event committee.

Results The population of 171 patients (49,7% female) with a median age of 73 years and a median NIHSS of 15 presented in 58.2% with M1- and in 25,3% with M2-occlusions. The primary endpoint of final successful recanalization mTICI 2b/3 was reached in 94.7% of cases. Secondary outcome results included a modified First Pass Effect (mFPE) in 63.1% of cases, and a median procedure time of 40 minutes. 61,6% (N=164) showed independent functional outcome with modified Rankin Scale (mRS) of 0-2. ENTs were observed in 4.7%, verified by independent core lab assessment. No device malfunction-related adverse events were reported.

Conclusion As one of the new generation BGCs, the Bobby demonstrated a very high effectiveness and safety profile, further underlining the positive effect of Balloon Guidance support during mechanical thrombectomies.

Disclosure of Interest yes TBB: PI of the STRAIT study, STRAIT Study is industry sponsored by MicroVention.

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ENHANCING NEUROTHROMBECTOMY PROCEDURES WITH IVASCULAR DEVICES (INEDIT, INDEEP, AND INTERCEPT): FIRST RESULTS FROM THE SEMTIC STUDY

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Introduction The iVascular neurothrombectomy devices, which include a balloon distal access catheter (iNedit), a microcatheter (iNdeep), and a stent retriever (iNtercept), have been strategically designed to incorporate the benefits of temporary proximal blood flow restriction via a balloon situated 5 cm from the catheter tip. This setup, paired with a guiding distal access catheter, facilitates clot removal through the combined action of a stent retriever and distal aspiration.

Aim of Study To assess the efficacy and safety of three devices (iNedit, iNdeep, and iNtercept) in mechanical thrombectomy for patients with acute ischemic stroke due to large vessel occlusion, presented within 24 hours from symptoms onset.

Methods SEMTIC is a prospective, single-arm, multi-center study with blinded outcomes assessment. Efficacy endpoints: successful reperfusion (eTICI \geq 2b) within three passes and mRS 0-2 at 90 days. Safety endpoints: all-cause mortality at 90 days, symptomatic intracranial hemorrhage, and embolization in a new territory.

Results A total of 115 patients participated (mean age: 73.7 \pm 10.5 years; 53.9% female). Successful reperfusion was 80% (95% CI: 72% to 86%) surpassing non-inferiority proportion reported in literature. Good functional outcomes (mRS 0-2): 56% (46%, 65%). All-cause 90-day mortality: 13.9% (95% CI: 8.2% to 21.6%). Symptomatic intracranial hemorrhage: 1.7% (95% CI: 0.5% to 6.1%). Embolization in a new territory: 5.2% (95% CI: 2.1% to 11.1%).

Conclusion The combination of three iVascular devices proved to be highly effective in mechanical thrombectomy, demonstrating non-inferiority in successful reperfusion parameters with no safety concerns.

Disclosure of Interest no.

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THE INSTROKE THROMBOASPIRATION CATHETER IN ACUTE ISCHEMIC STROKE—A SINGLE-CENTER PROSPECTIVE STUDY

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Introduction The iNStroke aspiration thrombus extraction device by iVascular is a single-lumen device (0.71') with variable stiffness from proximal to distal designed to extract emboli and thrombi from neurovascular blood vessels.

Aim of Study The aim of this study was to evaluate the efficacy and safety of the iNStroke aspiration device in mechanical thrombectomy for patients presenting with acute ischemic stroke due to large vessel occlusion within 24 hours from symptom onset.

Methods ASPIC-01 is a prospective, single-site, clinical trial. Efficacy endpoints: successful recanalization (mTICI \geq 2b) and mRS 0-2 at 90 days. Safety endpoints: combined serious adverse events (SAE) at 24 hours and all-cause mortality at 90 days. The intention-to-treat (ITT) set included all subjects meeting inclusion criteria. The device implant population included all subjects in whom only iNStroke was used. An interim analysis was performed in 48 patients.

Results Mean age: 70.3 \pm 12.3 years, 62.5% male. Baseline: NIHSS median 19.5 [13.0-25.0], ASPECTS median 9.0 [7.0-10.0]. In ITT: recanalization 68.8% (95% CI 53.8-81.3), 90-day mRS 0-2 62.5% (95% CI 47.4-76.1%). Device implant population: recanalization 100% (95% CI 87.2-100.0), 90-day

mRS 0-2 63% (95% CI 42.4-80.6%). No SAEs related to the device were reported. All-cause mortality rate at 90 days was 14.6% (95% CI 6.1-27.8%).

Conclusion The iNStroke aspiration device represents a safe and effective option for performing neurothrombectomy using primary aspiration, with a high recanalization rate observed in selected cases.

Disclosure of Interest no.

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EVALUATION OF THE CARESTO HEAL: A NOVEL FLEXIBLE CAROTID STENT WITH ANTITHROMBOGENIC COATING. SAFETY, EFFICACY, AND TECHNICAL INSIGHTS FROM INITIAL CASES OF 10 EUROPEAN CENTERS

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Introduction The CARESTO heal is a coated carotid stent aiming to stabilize atherosclerotic plaques by using a dense single-layer mesh. Due to its great flexibility, it easily navigates through tortuous anatomies. Additionally, the CARESTO features the anti-thrombogenic HEAL coating.

Aim of Study The objective of this study is to examine the technical specifics, advantages, and possible obstacles associated with the innovative stent design of the CARESTO heal.

Methods The first CARESTO implantations including data on procedural safety and efficacy have been retrospectively analyzed. Pre-treatment carotid plaque characterization was performed. For elective cases double antiplatelet medication was administered while acute cases were treated under Aspirin only.

Results Thirty-five patients from ten European neurovascular centers have been treated, including Carotid Webs and ICA dissections. The mean age was 67 years with a median degree of pre-treatment stenosis of 59%. Mean post-treatment stenosis was 10% with a technical success rate of 86% including three minor opening difficulties without compromising patient outcome. One peri-procedural retinal ischemia occurred, but no other severe complications have been observed. Already available six weeks and six months ultra sound follow up showing no recurrence of stenosis nor new neurological events.

Conclusion This initial report indicates that the CARESTO heal Stent is both safe and effective in treating carotid stenosis. Additional analysis with full follow-up data will offer thorough insights into the stent's long-term safety and efficacy. The carotid stenting technique using the CARESTO heal differs technically from other carotid stents but is particularly advantageous in challenging, tortuous vessel anatomies.

Disclosure of Interest yes FW received speakers honoraria and travel expenses from Acandis.

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RESCUE STENTING WITH CREDO® HEAL FOR RECANALISATION AFTER UNSUCCESSFUL THROMBECTOMY (RECHRUT) – INTERIM RESULTS

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Introduction Up to 30% intracranial Mechanical Thrombectomies (MT) may not result in recanalization due to an underlying stenosis, dissection or tough clot. Bail-out stenting has been reported to be a treatment option to achieve recanalization and good clinical outcome.

Aim of Study In the Rescue Stenting with CREDO® Heal for Recanalisation after Unsuccessful Thrombectomy (RECHRUT) study the efficacy and safety of the coated CREDO® heal for Bail-out stenting is evaluated.

Methods RECHRUT is a prospective, single-arm, multicentre, open-label international PMCF study. Patients treated with CREDO® heal due to acute ischemic stroke and large vessel occlusion after unsuccessful MT and suspected underlying stenosis are included. Technical success is defined as mTICI 2b-3 recanalization and good clinical outcome at 90 (±20) days as mRS 0-2.

Results Starting in March 2023, eighteen patients have been enrolled by 8 of 17 participating European sites. Mean age was 71 years and mean mRS at admission was 3.2. Treatment was successful in all cases achieving mTICI 2b-3 recanalization in 100%. Mean mRS at discharge was 2.2; mRS at 90d was available in 9 patients with 0-2 in 78%. Mean stenosis grade was 82% before and 28% after PTA and stenting. Periprocedural severe adverse events occurred in 33%. No recurrent occlusions occurred. GP IIb/IIIa antagonists were administered periprocedurally and switched two dual antiplatelet therapy during the hospital stay.

Conclusion The RECHRUT study is including patients and the early interim analysis shows technical and clinical success in line with the literature of rescue stenting.

Disclosure of Interest yes Speaker Honoraria by Acandis.

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EFFECTIVENESS OF INTRACRANIAL STENTING PROCEDURE IN IMPROVING CLINICAL OUTCOME AND REDUCING RECURRENT STROKE IN PATIENTS WITH SYMPTOMATIC INTRACRANIAL ATHEROSCLEROTIC STENOSIS (ICAS)

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Introduction Stroke is a leading cause of mortality and morbidity worldwide. ICAS accounts for 10- 15% of ischemic stroke in Western countries.