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O-019 INITIAL CLINICAL EXPERIENCE WITH A NOVEL MECHANICAL THROMBECTOMY DEVICE-THE THROMBX RETRIEVER

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Background and Purpose The ThrombX Retriever is a novel mechanical thrombectomy device that adjusts the distance between two mesh segments to axially hold thrombus. A post-market study assessed safety and performance in acute ischemic stroke patients with large artery occlusion.

Methods A single-arm prospective multi-center study enrolled patients at 5 European Centers. Patients had a symptomatic large-artery occlusion of the intracranial Internal Carotid or the Middle Cerebral Artery, M1 segment. The primary outcome measure was the modified treatment in cerebral infarction (mTICI) score, on the immediate post-procedure angiogram after up to three device passes. Key secondary outcome measures were the mTICI score after a single pass and functional independence, defined as an mRS score $\leq$ 2 at 90 days.

Results Thirty patients (16 Females, mean age 72 years), with NIHSS 4–25 (mean 15.5) were treated. Twenty-nine (97%) achieved mTICI 2b-3 within 3 passes, and 24 (80%) were with the first pass (FP). FP mTICI 2c-3 reperfusion was achieved in 19 (63%) cases. Seventeen of 24 (71%) patients treated with a balloon guide and the ThrombX Retriever had a FP mTICI 2c-3 reperfusion. After all interventions, mTICI 2b-3 was seen in 30 (100%) patients. Twenty-one of the 29 (73%) patients with 90-day follow-up were functionally independent (mRS$\leq$2). No device-related serious adverse events were observed.

Conclusion This preliminary study suggests the ThrombX Retriever is safe and has a high rate of substantial reperfusion. A larger prospective trial to assess the device effectiveness is planned.

Disclosures D. Behme: 2; C; Thromb X Medical, Phenox, Penumbra, Balt, Vesalio, Acandis. **M. Wiesmann:** 1; C; Stryker Neurovascular. 2; C; Stryker Neurovascular. 6; C; AB Medica, Acandis, Cerenovus, Kaneka Pharmaceuticals, Medtronic, Mentice AB, Phenox, Philips Healthcare, Stryker Neurovascular. **O. Nikoubashman:** 1; C; Stryker Neurovascular. 6; C; Phenox, Stryker Neurovascular. **H. Ridwan:** 2; C; ThrombX Medical. **D. Hassan:** None. **T. Liebig:** None. **C. Trumm:** None. **M. Holtmannspötter:** 2; C; Microvention, Phenox, Medtronic. 6; C; Cerenovus, Rapid Medical, Microvention, Stryker. **M. Marks:** 4; C; ThrombX Medical. 5; C; ThrombX Medical. **I. Szikora:** 1; C; Stryker Neurovascular, Medtronic, Cerenovus. 2; C; Stryker Neurovascular, Medtronic, Cerenovus.

O-020 THE TIGERTRIEVER 13 DISTALS STUDY: DISTAL ISCHEMIC STROKE TREATMENT WITH ADJUSTABLE LOW-PROFILE STENTRIEVER

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Objectives This is the first FDA approved IDE study for mechanical thrombectomy to treat distal occlusions. DISTALS is a randomized study planned to evaluate the safety and effectiveness of the TIGERTRIEVER 13 Revascularization Device in restoring blood flow in the neurovasculature by removing thrombus in subjects presenting within 24 hours of onset with an ischemic stroke with disabling neurological deficits due to a primary distal vessel occlusion (DVO), as compared to medical management.

Methods 118 patients of age 18–85 will be randomized in 1:1 ratio in USA and outside USA clinical centers. The primary endpoint will be successful reperfusion at 24 $\pm$ 6 hours post randomization, measured either by CTP or MR PWI. The secondary endpoints will include 90 days mRS shift, delta NIHSS at discharge compared to baseline, Quality of life measured by EQ-5D and cognitive assessment measured by MoCA at 90 days. Safety endpoints will include symptomatic and asymptomatic intracranial hemorrhages. Key inclusion criteria will be disabling presenting deficits that localize to the territory of the distal vessel occlusion; NIHSS 4–24, or NIHSS 2–24 for patients with aphasia and/or hemianopia, CTP or MR PWI confirmed lesions non-dominant or co-dominant M2, M3, PCA or ACA; 24 hours since last known well. Patients with excessive tortuosity, treated with IV thrombolysis therapy, intracranial hemorrhage, bilateral stroke or stroke in multiple territories will be excluded. CT, MRI and Radiographic Images will be analyzed by an independent core lab (UCLA).

Results Technical aspects of the TIGERTIEVER 13 device, will be presented as well as summary of the European experience with the device. More study details and the study status will be discussed.

Conclusion The TIGERTRIEVER 13 device with operator controllability and high fluoroscopy visibility and its small size can potentially provide a safe and effective clot removal in patients with distal vessels occlusion.

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O-021 VALIDATION OF THE DELAYED FUNCTIONAL IMPROVEMENT AFTER NEUROTHROMBECTOMY (DEFIANT) SCORE IN THE TIGER STUDY

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