Introduction

Given the mixed results of recent clinical trials, the role of bridging therapy with intravenous thrombolysis (IVT) in patients undergoing mechanical thrombectomy (MT) remains contested. These results highlight the need to identify subgroup specific strategies to optimize patient selection. Patients undergoing MT for intracranial atherosclerotic disease (ICAD) are more likely to require rescue intracranial stenting and an attendant load of dual antiplatelet drugs. Whether bridging thrombolysis increases hemorrhagic complications in patients requiring rescue intracranial stenting is unclear and may affect frontline thrombolysis decisions in patients with suspected ICAD related large vessel occlusions (LVOs). Here we determine whether bridging therapy modifies procedural and clinical outcomes in patients requiring rescue intracranial stenting after a failed MT.

Methods

We performed a retrospective cohort study of the Stroke and Aneurysm Registry (STAR) from January 2015 to December 2021 and identified 8,988 patients who underwent MT, 108 (1.2%) of whom underwent rescue intracranial stenting after failed MT for anterior circulation LVOs. Prospectively defined baseline characteristics and clinical outcomes were compared.

Results

108 patients underwent rescue stenting, 32 (29.6%) of whom received IVT and 76 (70.4%) did not. Patients receiving IVT presented significantly earlier (700 [312–1178] vs 242 [179–333] min, p<0.001), but were otherwise comparable in baseline demographics. A similar number of mechanical thrombectomy passes were employed in both cohorts (3 [2–5] vs 3 [2–5], not significant) with comparable procedural times. Any post-procedural hemorrhage within the first 36 hours was similarly common between both groups (24.6% vs. 31.3%). Symptomatic hemorrhage or type-2 parenchymal hematomas were rare in both groups, with a non-significant trend towards increased events with IVT (2 vs. 4 events, 2.9% vs 12.5%, p=0.078). Good functional outcomes, defined as a modified Rankin score of 0–2 measured 90 days post discharge, were comparable between groups (23.7% vs 37.0%, p=0.209). IVT use did not associate with hemorrhagic complications or good functional outcomes at 90 days in multivariable binary logistic regression analyses.

Conclusions

In this international, retrospective cohort study of likely highly-selected patients, IVT exposure did not modify hemorrhagic complications or outcomes in patients requiring intracranial rescue stenting after failed MT. These results are consistent with several randomized clinical trials which did not demonstrate increased hemorrhagic complications in unselected patients undergoing bridging thrombolysis. These data suggest that acute intracranial stenting (with attendant dual antiplatelet loading) may be safe in selected patients exposed to IVT and argue against withholding IVT for patients at higher risk of needing rescue stenting.

Initial Clinical Experience with a Novel Mechanical Thrombectomy Device—The ThrombX Retriever

O-019

D. Behme, M. Wiesmann, O. Nikoubashman, H. Ridwan, D. Hassan, T. Liebig, C. Trumm, M. Hofmannspötter, M. Marks, I. Szikora, Otto-von-Guericke University Clinic, Magdeburg, Germany; University Hospital RWTH Aachen, Aachen, Germany; Ludwig Maximilian University Hospital, Munich, Germany; Radiology, Paracelsus Medical University, Nuremberg, Germany; Radiology, Stanford University Medical Center, Palo Alto, CA; National Institute of Mental Health, Neurology and Neurosurgery, Budapest, Hungary

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 ≤ 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≤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. Hofmannspötter: 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

1D Fiorella*, R Gupta, R Chapat, J Saver. SUNY SB, Stony Brook, NY; 2Webstar, Marietta, GA; 3Alfried-Krupp Krankenhaus, Essen, Germany; 4UCLA, Los Angeles, CA

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 ± 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 TIGERTRIEVER 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.

Disclosures: D. Fiorella: 1; C; Rapid Medical. R. Gupta: None. R. Chapat: None. J. Saver: None.

O-021

Validation of the Delayed Functional Improvement after Neurothrombectomy (DEFIANT) Score in the Tiger Study

1S Desa*, R Jha, M Caplan, R Gupta, J Saver, E Levy, O Zaidat, D Yavagal, A Ladaiu, HonorHealth Research Institute, Scottsdale, AZ; 2Barrow Neurological Institute, Phoenix, AZ; Neuroscience, Wellstar Medical Group, Atlanta, GA; 3Neurology, University of California Los Angeles, Los Angeles, CA; 4State University of New York at Buffalo, Buffalo, NY; 5Departments of Endovascular Neurosurgery and Stroke, St. Vincent Mercy Medical Center, Toledo, OH; 6University of Miami School of Medicine, Miami, FL

Objectives: The DEFIA NT study is designed to confirm the previously reported association between the DEFIANT score and length of functional improvement after mechanical thrombectomy for large-artery occlusion of the intracranial Middle Cerebral Artery, M1 segment. A secondary objective is to examine the association between DEFIANT score and functional improvement after mechanical thrombectomy for large-artery occlusion of the intracranial Middle Cerebral Artery, M1 segment.

Methods: The DEFIANT study is a single-center observational study. The study population consists of patients who underwent mechanical thrombectomy for large-artery occlusion of the intracranial Middle Cerebral Artery, M1 segment. The primary outcome measure is the DEFIANT score, which is a validated score that predicts functional improvement after mechanical thrombectomy. The secondary outcome measure is the mRS score at 90 days.

Results: A total of 100 patients were enrolled in the study. The mean age of the patients was 65 years. The majority of patients (70%) were males. The mean NIHSS score at baseline was 24. The mean DEFIANT score was 1.5. The median mRS score at 90 days was 1. The correlation coefficient between DEFIANT score and mRS score at 90 days was 0.7. The p-value was 0.001.

Conclusion: The DEFIANT score is a valid predictor of functional improvement after mechanical thrombectomy for large-artery occlusion of the intracranial Middle Cerebral Artery, M1 segment.