

**Materials and methods** The STRATIS registry is a prospective, multicenter study of patients with large vessel occlusion (LVO) treated with the Solitaire Stentriever within 8 hours of onset. Subjects were separated by direct presentation (direct group) vs. interhospital transfer to the enrolling hospital (transfer group), and further characterized by the use of IV tPA (IVT) or mechanical thrombectomy alone (MT). Total alarm-to-revascularization time measured overall performance of the system of care. We also calculated a hypothetical 'bypass' scenario by comparing the door-to-tPA times for the two groups and adding the transfer time to the direct group for an extremely conservative estimate of additional travel time.

**Results** A total of 688 subjects were analyzed. Median times from stroke onset to revascularization for direct vs. transfer patients in the MT-alone subgroup were 238.5 and 325.0 minutes respectively, and in the IVT plus MT were 192.0 and 305.5 minutes respectively (Figure 1). Median alarm-to-revascularization times for direct vs. transfer patients in the MT subgroup were 189 and 264 minutes respectively (75 minute difference;  $p = 0.0001$ ), and in IVT were 169 and 268 respectively (99 minute difference;  $p < 0.0001$ ). These differences were accounted for by imaging-to-transfer time, which was 93 minutes for MT-alone and 87 minutes for IVT. Median door-to-tPA times were 56.5 minutes at regional hospitals and 38.0 minutes at enrolling sites ( $p < 0.0001$ ). Transfer time was 32.0 minutes, making the hypothetical bypass time-to-tPA 70.0 minutes.

**Conclusion** Time to revascularization is much slower for patients requiring interhospital transfer. The delay is accounted for by the time between imaging and departure, which is when treatment decisions and transfer arrangements are made, and should be a target for improvement.

An important consideration for many regional systems is whether certain stroke patients should bypass the nearest hospital to go directly to an endovascular center. We created a conservative model of such a scenario, which suggests that successful revascularization would be achieved 99 minutes earlier by bypass. This may have significant implications for regional stroke systems of care.

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# O-025 THE SUPERIORITY OF THROMBECTOMY OVER IV RTPA MONOTHERAPY MAY BE ASSOCIATED WITH THROMBUS LENGTH – RESULTS OF THE THERAPY TRIAL

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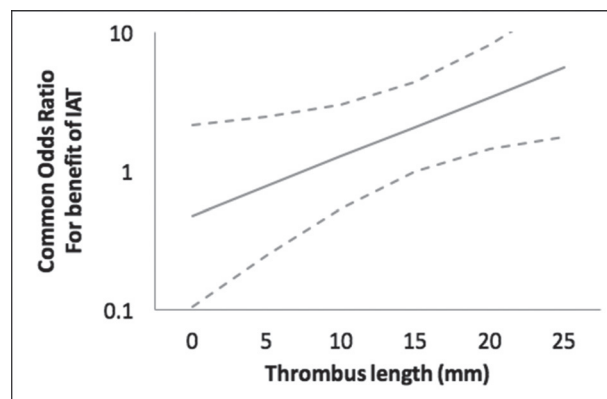
**Introduction** Limited data exist on the efficacy of intra-arterial therapy (IAT) for ischemic stroke resulting from extended thrombi. IV-rtPA has been the staple of ischemic stroke therapy, however the efficacy of IV thrombolytics is known to diminish with increasing thrombus length, subsequently reducing the potential for successful revascularization. For increasing thrombus lengths, the benefits of aspiration thrombectomy have yet to be validated in a large, randomized trial, but may offer advantages over IV rtPA; herein we present our experience of the benefits of aspiration thrombectomy on extended thrombi.

**Materials and methods** The randomized prospective THERAPY stroke trial assessed the benefits of combined aspiration thrombectomy with adjunctive IV-rtPA compared to IV-rtPA alone in patients with thrombus length  $\geq 8$  mm. The associations of thrombus length to primary and secondary endpoints were assessed by univariate and multivariate analyses, while multiplicative interaction between treatment allocation and thrombus length was assessed by multivariate ordinal regression of 90 day mRS.

**Results** In total, THERAPY enrolled 108 patients with a median thrombus length of 14.0 mm (IQR 9.7–19.5); all exhibiting large vessel occlusions in the anterior circulation, including the ICA (28%), MCA M1 (62%), and MCA M2 (10%). Analysis revealed longer thrombi to be associated with worse clinical outcomes for all dichotomized endpoints relating to presence of complication relative to median thrombus length (all  $p < 0.05$ , except mRS 0–2), and resulted in higher 90 day mRS ( $p = 0.005$ ). Additionally, longer thrombi also correlated with higher incidence of symptomatic intracranial hemorrhage ( $p = 0.03$ ), serious adverse events ( $p = 0.02$ ), and mortality ( $p = 0.01$ ). Reperfusion to mTICI 2 b-3 had no significant relationship with thrombus length, however procedural time was notably longer for patients with longer thrombi ( $\rho = 0.36$ ,  $p = 0.045$ ).

The relative benefit of IAT was apparent in patients with longer thrombi over thrombolytic monotherapy ( $p = 0.03$ ; Figure 1). Consequently, compared to patients receiving IAT, lytic therapy patients had worse 90 day mRS ( $\rho = 0.20$ ,  $p = 0.17$  for IAT vs 0.39,  $p = 0.008$  for IV-rtPA).

**Conclusion** Extensive thrombus burden presents a challenge for stroke intervention, posing greater risk of complications and poor clinical outcome. However, this effect is dampened when IAT is the interventional modality, leading to a more favorable prognosis over IV-rtPA alone. This study finding supports the use of aspiration thrombectomy in treatment of



Abstract O-025 Figure 1 Benefits of IAT increasing thrombus lengths

extended thrombi, demonstrating relative advantages over thrombolytic monotherapy, and enables better clinical outcomes.

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# 0-026 THE US WEB INTRASACULAR THERAPY STUDY (WEB-IT): 30 DAY RESULTS

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**Background** Flow Disruption with WEB is an innovative endovascular approach for wide-neck bifurcation aneurysms. Multiple prospective, multicenter good clinical practice (GCP) studies to date (WEBCAST, French Observatory, WEBCAST 2) have shown a low complication rate with good efficacy.

**Objective** To report demographic, procedural data and initial 30 day safety follow-up of the US IDE pivotal study for assessment of safety and effectiveness for the WEB treatment of wide neck bifurcation aneurysms: the WEB Intracascular Therapy Study (WEB-IT).

**Methods** WEB-IT is a prospective, multicenter, GCP (Good Clinical Practice) study dedicated to the evaluation of safety and effectiveness of WEB treatment, conducted in 25 centers in the United States, and 6 OUS centers in Canada and Europe. Inclusion criteria were ruptured and unruptured wide-neck aneurysms located in basilar artery, middle cerebral artery, anterior communicating artery, and internal carotid artery terminus. Independent study oversight and data integrity methods include: patient data monitoring, clinical event adjudication by medical monitor, core lab evaluation of the primary effectiveness endpoint, and study oversight by data monitoring committee (DMC). The study's primary effectiveness endpoint is the proportion of subjects with complete aneurysm occlusion without retreatment, recurrent subarachnoid hemorrhage, without significant parent artery stenosis (>50% stenosis) at one year after treatment. A subject will be considered an effectiveness success upon meeting all of the above criteria. The study's primary safety endpoint is the proportion of subjects with death of any nonaccidental cause or any major stroke (defined as an ischemic or hemorrhagic stroke resulting in an increase of 4 points or more on the National Institutes of Health Stroke Scale) within the first 30 days after treatment or major ipsilateral stroke or death due to neurologic cause from day 31 to the 1 year after treatment. A subject will be considered a safety failure upon meeting any of the above criteria.

**Results** The study population is 150 patients with 150 aneurysms. The demographics report will include gender distribution, aneurysm location, aneurysm size, and relevant medical history will be described. Technical success, total fluoroscopy

time, total WEB procedure time, periprocedural neurologic events, major strokes and 30 day morbidity and mortality will be reported.

**Conclusions** The WEB-IT pivotal study provides the largest prospective study of safety and effectiveness data for the WEB aneurysm occlusion system. Demographics and safety follow-up to 30 days provide initial safety information: the primary safety and effectiveness endpoints at 1 year will be reported in a subsequent abstract.

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# 0-027 THE INVEST TRIAL: A RANDOMIZED, CONTROLLED TRIAL TO INVESTIGATE THE SAFETY AND EFFICACY OF IMAGE GUIDED MINIMALLY INVASIVE ENDOSCOPIC SURGERY WITH APOLLO VS BEST MEDICAL MANAGEMENT FOR SUPRATENTORIAL INTRACEREBRAL HEMORRHAGE

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**Introduction** Spontaneous intracerebral hemorrhage (ICH) is a common subtype of hemorrhagic stroke, and has the poorest prognosis amongst all stroke subtypes. The goal of the INVEST trial, as well the parallel European EPOCH trial, is to evaluate the safety and efficacy of the minimally invasive hemorrhage evacuation with Apollo device (Penumbra Inc, Alameda, CA) compared to medical management.

**Methods** The INVEST study is a prospective multicenter US trial designed to enroll 222 patients at up to 30 centers. The parallel European EPOCH study is a 240 patient, 40 center RCT. Patients between the ages of 22–80 or <85 with baseline mRS = 0 or 1, NIHSS of at least 6, and presenting with a moderate to large volume supratentorial ICH (30–80 cc) within 24 h of onset are eligible for enrollment. Qualifying patients will be randomized (1:1) to either minimally invasive surgery (MIS) with Apollo or to the best medical management (MM). Follow up for each patient will be conducted at days 3, 7, discharge, 30, 90, 180, and 360 from enrollment. The primary endpoints are mRS ≤ 3 at 180 days and mortality at 30 days. Secondary endpoints include stroke impact scale (SIS)-mobility, SIS-ADLs and EQ-5D-5L at 180 days, and length of hospitalization. All imaging will be assessed by an independent core laboratory.

**Results** Centers are currently in the process of initiation with a potential start date of forthcoming. Updated data on trial progress will be discussed at the time of presentation.

**Conclusion** The INVEST and EPOCH studies are designed to provide an assessment of the safety and efficacy of Apollo MIS for the treatment of spontaneous supratentorial ICH. The parallel structure of the two trials presents a potential for a pooled statistical analysis provided the data are sufficiently homogenous.

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