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

Disclosures R. von Kummer: 2; C; Penumbra, Inc. **J. Mocco:** 1; C; Penumbra, Inc. **O. Zaidat:** 6; C; Penumbra, Inc. **P. Khatri:** 1; C; Penumbra, Inc. **R. Gupta:** 6; C; Penumbra, Inc. **D. Frei:** 6; C; Penumbra, Inc. **D. Lopes:** 6; C; Penumbra, Inc.. **H. Shownkeen:** None. **O. Berkhemer:** None. **D. Meyer:** 5; C; Penumbra, Inc.. **M. Chauke:** None. **S. Hak:**5; C; Penumbra, Inc. **S. Kuo:** 5; C; Penumbra, Inc. **H. Buell:** 5; C; Penumbra, Inc. **A. Bose:** 4; C; Penumbra, Inc.. 5; C; Penumbra, Inc. **S. Sit:** 4; C; Penumbra, Inc.. 5; C; Penumbra, Inc. **A. Yoo:** 1; C; Penumbra, Inc., National Institute of Health, Remedy Pharmaceuticals.

O-026 THE US WEB INTRASACCULAR 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 Intrasaccular 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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O-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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