Late-Breaking Science Oral Abstracts

Wednesday, February 22, 2017, 10:30am – 12:00 noon

LATE-BREAKING SCIENCE abstracts/studies presented at the INTERNATIONAL STROKE CONFERENCE 2017:

For late-breaking science being presented at ISC 2017, the embargo lifts when the first presentation begins in the scientific session in which the abstract is being presented: either 11:20 am CST on Wednesday, Feb. 22; 6:15 pm CST on Wednesday, Feb. 22; 11:00 am CST on Thursday, Feb. 23; 1:30 pm CST on Thursday, Feb. 23; or 11:53 am CST on Friday, Feb. 24. News media activities promoting late-breaking science are under embargo until the times noted above.

Presentation Number: LB1

Presentation Title: Head Position in Stroke Trial: An International Cluster Cross-over Randomized Trial

Author Block: Craig S Anderson, George Inst Global Health, Sydney NSW, Australia; HeadPoST Steering Committee, Investigators and Coordinators

Abstract Body: Background: Uncertainty exists over the optimal head position for patients with either acute ischemic stroke (AIS) or intracerebral hemorrhage (ICH). Potential benefits of lying flat in AIS (increased collateral blood flow) may be offset by increased risks of aspiration pneumonia and cardiac-respiratory impairment. Sitting up may reduce cerebral edema in ICH. **Aims:** The Head Position in Acute Stroke Trial (HeadPoST) aimed to determine the comparative effects of lying flat (0°) with sitting up (≥30°) head positioning in the first 24 hours of admission for patients with acute stroke on functional outcome at 90 days. **Methods:** An international, multicenter, prospective, cluster randomized, cross-over clinical trial with blinded outcome assessment, conducted across 114 hospitals in Australia, Brazil, Chile, China, Columbia, India, Sri Lanka, Taiwan, and the UK during 2014-2016. Key design features included consecutive recruitment (up to 70 patients in each phase) for implementation of the intervention as usual care policy (reduce selection bias) and central blinded outcome assessment (reduce observer bias). Power/sample size calculations were to detect ≥16% (shift) in functioning on 90-day mRS using ordinal logistic regression. Principle funding from the National Health and Medical Research Council (NHMRC) of Australia. **Results: O**ver 11,000 patients (mean age 68 yr, 60% male, 91% AIS) were included with excellent adherence to the randomized head position and follow-up. The main results are to be presented. **Conclusions:** Main results of the HeadPoST study, a large nursing intervention study, will be presented to provide randomized evidence on the most appropriate head position for patients with acute stroke. **Clinical trial registration** (ClinicalTrials.gov NCT02162017)

Author Disclosure Block: **C.S. Anderson:** None.

Presentation Number: LB2

Presentation Title: Aster Trial. Contact Aspiration versus Stent Retriever Front Line for Recanalisation in Acute Cerebral Infarction

Author Block: Bertrand Lapergue, Foch Hosp Univ Versailles Saint Quentin en Yvelines, Suresnes, France; Julien Labreuche, Dept of Biostatistics, Univ. Lille, CHU Lille, Lille, France; Michel Piotin, Dept of Diagnostic and Interventional Neuroradiology, Paris, France

Abstract Body:

Rationale

Mechanical thrombectomy (MT) with a stent retriever (SR), in association with intravenous (IV) rtPA, is now the standard of care in anterior circulation ischemic stroke caused by large vessel occlusion (LVO). Favorable outcome is strongly associated with the successful reperfusion status. New techniques for MT such as contact aspiration (CA) seem promising to increase reperfusion status and clinical outcome in retrospective studies. We aim at ascertaining whether CA is more efficient than stent retriever as a front-line endovascular procedure.

Methods and design

The ASTER trial is a prospective, randomized, multicenter, controlled, open-label with blinded outcome evaluation (PROBE) design. Patients admitted with suspected ischemic anterior circulation stroke secondary to LVO, with onset of symptoms <6 hours, were randomized 1:1 to CA or SR; stratified by center and prior IV thrombolysis. If the assigned treatment technique was not successful after three attempts, the procedure was continued with another technique at the operator's discretion. The primary outcome will be the successful recanalization (modified Thrombolysis In Cerebral Infarction [mTICI] score 2b-3) at the end of the treatment. Secondary outcome will include the successful recanalization after the assigned treatment technique, procedural times, the need for a rescue technique, complications and modified Rankin Scale (mRS) at 3-month. With a two-sided test (alpha=5%, power =90%), an anticipate rate of spontaneous recanalization and catheterization failures of 15%, the sample size estimate will be 380 patients to detect an absolute difference of 15% in primary outcome (assuming a rate of 70% in the control arm).

Result-Discussion

Patient enrollment has been completed within 12 months between October 2015 and October 2016. Data analysis is ongoing and final results will be presented at the ISC 2017. *ClinicalTrials.gov Identifier* NCT02523261.

Author Disclosure Block: **B. Lapergue:** Research Grant; Significant; Unrestricted research grant from Penumbra. **J. Labreuche:** None. **M. Piotin:** Other Research Support; Modest; Institutional grant from Stryker, Medtronic, Microvention, Balt.

Presentation Number: LB3

Presentation Title: Prospective, Multi-Center Study of Flow Diversion for Small and Medium-Sized Aneurysms: Results of the Premier Trial

Author Block: Ricardo A Hanel, Baptist Neurological Inst, Jacksonville, FL; Demetrius Lopes, Rush Univ Medical Ctr, Chicago, IL; Peter Nelson, NYU Langone Medical Ctr, New York, NY; Ajit Puri, Univ of Massachusetts Medical Ctr, Worcester, MA; Pascal Jabbour, Thomas Jefferson Univ Hosp, Philadelphia, PA; Adnan Siddiqui, Univ at Buffalo, Buffalo, NY; Geoffrey Colby, Johns Hopkins Univ Sch of Med, Baltimore, MD; Maxim Mokin, Univ of South Florida, Tampa, FL; Clemens Schirmer, Geisinger Medical Ctr, Danville, PA; Phil Taussky, Univ of Utah, Salt Lake City, UT; Frank Hellinger, Florida Hosp, Winter Park, FL; Timo Krings, Univ of Toronto, Toronto, ON; Curtis Given II, Baptist Health Lexington, Lexington, KY; Gabor Toth, Cleveland Clinic, Cleveland, OH; Justin Fraser, Univ of Kentucky, Lexington, KY; Ryan Priest, Oregon Health & Science Univ, Portland, OR; Peter Kan, Baylor Coll of Med, Houston, TX; Beverly Aagaard-Kienitz, Univ of Wisconsin Sch of Med and Public Health, Madison, WI; Orlando Diaz, Houston Methodist, Houston, TX; David Fiorella, Stony Brook Univ Sch of Med, Stony Brook, NY; Adel Malek, Tufts Medical Ctr, Boston, MA; Donald Frei, Swedish Medical Ctr, Denver, CO; Eric Sauvageau, Baptist Neurological Inst, Jacksonville, FL; David Kallmes, Mayo Clinic, Rochester, MN

Abstract Body: Background: The Pipeline Embolization Device (PED) is indicated for treatment of large/giant wide-neck IAs in the ICA from the petrous to the superior hypophyseal segments and represents an effective treatment approach for these types of IAs, with a significant majority of patients achieving sustained complete occlusion. However, its effectiveness in treating wide-neck, small/medium IAs has not been prospectively studied. The purpose of the PREMIER study was to evaluate the safety and effectiveness of the PED for treatment of unruptured, small/medium, wide-neck IAs.
Methods: PREMIER is a prospective, interventional, single-arm, multi-center, US IDE study evaluating clinical outcomes in subjects with unruptured, wide-neck IAs measuring ≤ 12 mm and located in the ICA up to the terminus or the vertebral artery segment up to and including the PICA. The primary effectiveness endpoint was complete aneurysm occlusion and absence of significant parent artery stenosis at 1 year. The primary safety endpoint was occurrence of major stroke in the territory supplied by the treated artery or neurological death at 1 year.
Results: 141 patients (mean age 54.6±11.3, 87.9% female) with 141 target aneurysms were enrolled at 22 centers from July 2014-November 2015. Mean aneurysm maximal diameter was 5.0±1.9mm (range 1.7mm-11.1mm); 84.4% (119/141) were smaller than 7mm. Technical success was achieved in 99.3% (140/141) of patients. Mean time from skin incision to closure was 87.6±110.4 minutes. The median number of PED used per procedure was 1.0, with 92.9% (131/141) of aneurysms treated with a single device. The 30-day rate of major stroke in the territory supplied by the treated artery or neurologic death was 1.4% (2/141) (95% CI: 0.17%, 5.03%).The 1-year primary effectiveness and safety endpoint results will be available for presentation at the time of the conference.
Conclusion: PREMIER is the first prospective study to assess flow diverter technology for treatment of small/medium wide-neck IAs. These preliminary results show that PED treatment is safe and can be performed with high technical success with only a single device in a significant majority of cases. The findings have the potential to alter treatment paradigms for unruptured, small/medium, wide-neck IAs.

Author Disclosure Block: **R.A.A. Hanel:** Research Grant; Significant; Medtronic, MicroVention. Ownership Interest; Significant; InNeuroCo. Consultant/Advisory Board; Significant; Medtronic. **D.**

Lopes: Honoraria; Significant; Medtronic. Consultant/Advisory Board; Modest; Medtronic. **P. Nelson:** Consultant/Advisory Board; Significant; Medtronic. **A. Puri:** Speakers' Bureau; Modest; Harvard Cerebrovascular Conference. Ownership Interest; Significant; InNeuroCo. Consultant/Advisory Board; Modest; Stryker, Codman and Medtronic. **P. Jabbour:** Research Grant; Significant; Medtronic. Honoraria; Significant; Medtronic. Consultant/Advisory Board; Significant; Medtronic. **A. Siddiqui:** Research Grant; Modest; PI/National Steering Committees: Penumbra 3D Separator, COMPASS, INVEST Trials; Covidien SWIFT PRIME and SWIFT DIRECT Trials; MicroVention FRED Trial, CONFIDENCDE Study, LARGE Trial, POSITIVE Trial. Research Grant; Significant; NINDS 1R01NS064592-01A1; NIBIB 5 R01 EB002873-07; NIH/NINDS 1R01NS091075; NIH-NICHHD R01 HD-04483101. Ownership Interest; Modest; StimSox, Valor Medical, Medina Medical Systems. Ownership Interest; Significant; Neuro Technology Investors, Cardinal, Buffalo Technology Partners Inc., International Medical Distribution Partners. Consultant/Advisory Board; Modest; Codman, GuidePoint Global Consulting, Penumbra, Stryker, MicroVention, Three Rivers Medical Inc., CereVasc LLC, Pulsar Vascular, Cerebrotech Medical Systems Inc., Rapid Medical, Neuravi, Silk Road Med. Consultant/Advisory Board; Significant; Medtronic, W.L. Gore & Associates, The Stroke Project Inc.. Other; Modest; Consultant: Rebound Medical; Board Member: Intersocietal Accreditation Committee. **G. Colby:** Research Grant; Modest; Medtronic, Stryker. Consultant/Advisory Board; Modest; MicroVention. **M. Mokin:** None. **C. Schirmer:** Research Grant; Modest; Medtronic. Honoraria; Modest; AANS, Toshiba. Ownership Interest; Modest; NTI. **P. Taussky:** Consultant/Advisory Board; Significant; Medtronic. **F. Hellinger:** Consultant/Advisory Board; Modest; Codman. **T. Krings:** Consultant/Advisory Board; Modest; Stryker, Medtronic. **C. Given:** Speakers' Bureau; Significant; Medtronic. Other; Significant; Physician Proctor: Medtronic. **G. Toth:** Research Grant; Modest; Cleveland Clinic. Other; Modest; Data Safety Management Board COMPASS Stroke Trial (Medical University of South Carolina). **J. Fraser:** Research Grant; Significant; NIH - UL1TR000117 Grant support and R21 (pending); University of Kentucky Grant NIH UL1TR000117. Ownership Interest; Significant; Fawkes Biotechnology, Stream Biomedical. **R. Priest:** Other; Modest; Physician Proctor: Medtronic. **P. Kan:** Consultant/Advisory Board; Modest; Medtronic, Stryker Neurovascular. **B. Aagaard-Kienitz:** Research Grant; Modest; Medtronic. **O. Diaz:** None. **D. Fiorella:** Research Grant; Significant; Microvention, Sequent Medical. Honoraria; Significant; Covidien, Johnson & Johnson/Codman, Stryker, Penumbra, Sequent Medical. Ownership Interest; Significant; Johnson & Johnson/Codman, Vascular Simulations. Consultant/Advisory Board; Significant; Covidien, JnJ/Codman, Stryker, Penumbra, Sequent Medical. **A. Malek:** None. **D. Frei:** None. **E. Sauvageau:** None. **D. Kallmes:** Research Grant; Modest; Medtronic, MicroVention, Sequent Medical, Codman, Neurosigma Neurogami, Shape Memory Therapeutics. Consultant/Advisory Board; Modest; Medtronic.