Late-Breaking Science Oral Abstracts

Thursday, January 25, 2018, 10:30am – 12:00 noon

LATE-BREAKING SCIENCE abstracts/studies presented at the INTERNATIONAL STROKE CONFERENCE 2018:

For late-breaking science being presented at ISC 2018, the embargo lifts when the first presentation begins in the scientific session in which the abstract is being presented: either 11:20 am PST on Wednesday, Jan. 24; 6:30 pm PST on Wednesday, Jan. 24; 11:00 am PST on Thursday, Jan. 25; 3:33 pm PST on Thursday, Jan. 25; or 11:53 am PST on Friday, Jan. 26. News media activities promoting late-breaking science are under embargo until the times noted above.

Presentation Number: LB4

Presentation Title: A Comparison of Direct Aspiration vs. Stent Retriever as a First Approach ("COMPASS"): A Randomized Trial

Author Block: **J Mocco**, Mount Sinai Hosp, New York, NY; Adnan Siddiqui, Univ at Buffalo, Buffalo, NY; Aquilla Turk, III, Medical Univ of South Carolina, Charleston, SC

Abstract Body:

Background and Objective

Stent retriever thrombectomy of large vessel occlusion results in better outcomes than medical therapy alone. A recent European study designed to evaluate superior angiographic outcomes with an aspiration first pass approach failed to show superiority but suggested similar clinical outcomes. COMPASS is designed to evaluate whether patients treated with a direct aspiration first pass (ADAPT) approach have non-inferior functional outcomes to those treated with a stent retriever as first-line (SRFL) approach.

Materials and Methods

270 patients were enrolled into this prospective randomized open label, blinded outcome assessment and core lab adjudicated trial. Randomization was 1:1 to treatment with either ADAPT or SRFL thrombectomy. Primary outcome is non-inferiority of clinical outcome at 90d as measured by the percentage of patients achieving mRS of 0-2. Secondary outcomes include angiographic outcome, procedural time, mortality and cost analyses.

Results

COMPASS completed enrollment on July 5th, 2017. Final Data Lock is anticipated by October 31st, 2017; upon all follow-up completion and data verification. Preliminary demographic and presentation-imaging analyses show excellent balance between cohorts (Table 1). COMPASS has achieved successful collection of 96% of 90d mRS for enrolled patients and 100% of imaging data. Final results will be made available for presentation at ISC 2018.

Conclusions

COMPASS is the first prospective randomized open label, blinded outcome assessment and core lab adjudicated trial of patients treated with either ADAPT or SRFL approaches specifically designed to determine non-inferiority in functional outcome. Current indicators demonstrate COMPASS has achieved an extremely low loss-to-follow-up rate. These data will provide substantial insight into the appropriateness of aspiration thrombectomy

Table 1: Demographic and Clinical Characteristics of the Patients

Characteristics	ADAPT (N=134)	SR (N=136)	p-value
Age	71.83±2.26	71.09±2.22	0.64
Male sex-No./total(%)	57/134(42.5)	68/136(50)	0.27
Race-No./total(%)			
Asian/Pacific Islander	5/134(3.7)	5/136(3.7)	1.00
African American	14/134(10.4)	29/136(21.3)	0.02
Caucasian	99/134(73.9)	93/136(68.4)	0.39
Hispanic	11/134(8.2)	4/136(2.9)	0.10
Other	0/134(0)	1/136(0.7)	1.00
Medical History			
Ischemic Stroke History	12/134(9)	23/136(16.9)	0.08
Hemorrhagic Stroke History	3/134(2.2)	1/136(0.7)	0.60
Transient Ischemic Attack History	7/134(5.2)	8/136(5.9)	1.00
Current or Past Tobacco Use	52/127(40.9)	67/134(50)	0.11
Myocardial Infarction	10/134(7.5)	14/136(10.3)	0.55
Diabetes	36/134(26.9)	40/136(29.4)	0.74
Hypertension	92/134(68.7)	102/136(75)	0.31
Hyperlipidemia/Hypercholesterolemia	65/134(48.5)	63/136(46.3)	0.81
Atrial Fibrillation	65/134(48.5)	56/136(41.2)	0.27
Peripheral Artery Disease	2/134(1.5)	4/136(2.9)	0.70
Current stroke event			
Systolilc Blood Pressure	154(137-176)	156(142-181)	0.22
NIHSS Score,Median(Quartile)	6(1-16)	7(1-16)	0.62
Prestroke mRS No./total(%)			
0-1	131/134(97.8)	133/136(97.8)	1.00
Site of Occlusion,No./total(%)			
ICA	26/134(19.4)	21/136(15.4)	0.49
MCA	124/134(92.5)	123/136(90.4)	0.69
Basilar	0/134(0)	1/136(0.7)	1.00
Other	2/134(1.5)	1/136(0.7)	0.99
Transferred from other sites,No./total(%)	59/134(44)	59/136(43.4)	1.00
Onset to puncture time,Median(Quartile)			
Onset to imaging	133(80-212)	141(74-219)	
Imaging to puncture	52(27-89)	53(29-77)	

Author Disclosure Block: **J. Mocco:** Ownership Interest; Significant; Blockade Medical, Cardinal, Endostream, Rebound Medical, Apama, Viseon, 3Rivers Medical, Serenity, Synchron, Cerebrotech. Consultant/Advisory Board; Modest; Cerebrotech, The Stroke Project, Endostream, Rebound Medical, Viseon, 3Rivers Medical, Synchron. Other; Modest; COMPASS is an investigator initiated and run trial. Penumbra played no role in the trials execution, data collection, or analysis. However, Penumbra did provide grants that funded COMPASS. **A. Siddiqui:** Ownership Interest; Significant; Apama Medical, Buffalo Technology Partners, Inc., Cardinal, Endostream Medical, Ltd., International Medical Distribution Partners, Medina Medical Systems, NeuroTechnology Investors, StimMed, Valor Medical. Consultant/Advisory Board; Modest; Amnis Therapeutics, Ltd., Cerebrotech Medical Systems, Inc., CereVasc, LLC, Claret Medical, Inc., Codman, Corindus, Inc., GuidePoint Global Consulting, Medtronic (Formerly Covidien), MicroVention, Neuravi, Penumbra, Pulsar Vascular, Rapid Medical, Rebound Therapeutics Corporation, Silk Road Medical, Stryker, The Stroke Project, Inc., Three Rivers Medical, Inc., Toshiba America Medical Systems, Inc., W.L. Gore & Associates. Other; Modest; COMPASS is an investigator initiated and run trial. Penumbra played no role in the trials execution, data collection, or analysis. However, Penumbra did provide grants that funded COMPASS. **A. Turk, III:** Ownership Interest; Significant; The Stroke Project, Cardinal Consulting, Cerebrotech, Synchron, Serenity, NeuroTechnology Investors. Consultant/Advisory Board; Modest; Styker, Microvention, Cardinal Consulting, Vastrax, Endostream, Three Rivers Medical, Cerebrotech, Shape Memory. Consultant/Advisory Board; Significant; Medtronic, Penumbra, The Stroke Project. Other; Modest; COMPASS is an investigator initiated and run trial. Penumbra played no role in the trials execution, data collection, or analysis. However, Penumbra did provide grants that funded COMPASS..

Presentation Number: LB5

Presentation Title: ARISE II Trial Result

Author Block: Osama Zaidat, Mercy Health St Vs Hosp, Toledo, OH; Hormozd Bozorgchami, OHSU Stroke Ctr, Portland, OR; On Behalf of the ARISE II Investigators

Abstract Body:

Background

EmboTrap® is a novel stent-retriever designed to achieve substantial reperfusion in acute ischemic stroke (AIS) patients by addressing varying compositions of the clot causing large vessel occlusions (LVO). We evaluated EmboTrap's safety and efficacy compared to US-approved predicate devices.

Methods

ARISE II was a prospective, multicenter study, comparing Embotrap® device to a performance goal derived using a Bayesian meta-analysis from SWIFT and TREVO2 trials. We enrolled patients from 19 sites (11 in the USA and 8 in Europe). Patients were eligible for inclusion if they had AIS with moderate to severe NIHSS and LVO within 8 hrs of symptom onset. The primary efficacy endpoint was modified thrombolysis in cerebral infarction (mTICI) scores≥2b reperfusion. Primary safety endpoint was the occurrence of Symptomatic Intracerebral hemorrhage (sICH) within 24 hours (-8/+12 hrs) post-procedure with any other Serious Adverse Device Effects. Secondary outcomes were modified Rankin's Scale 0-2 at 90 days, and rate of first pass effect. ClinicalTrials.gov:NCT02190552

Results

Between Oct 2016 and Feb 2017, a total of 227 patients were enrolled in the study. The mean age was 68.1 (13) years; 46.1% were male. Median baseline NIHSS was 16 and 65.8% received IV-tPA.
Results for the primary efficacy endpoint and primary safety endpoint will be reported in the treated and per-protocol populations. Additional revascularization data including rate of first pass effect will be described. The rate of modified Rankin Scale of 0-2 at 90 days will be presented.

Conclusion

The ARISE II trial will provide important revascularization, safety and clinical outcome data after EmboTrap mechanical thrombectomy in AIS.

Funding

Neuravi

Author Disclosure Block: **O. Zaidat:** None. **H. Bozorgchami:** None.

Presentation Number: LB6

Presentation Title: Subgroup Analyses of the DEFUSE 3 Study

Author Block: **Maarten G Lansberg**, STANFORD UNIVERSITY, Stanford, CA; DEFUSE 3 Investigators

Abstract Body:
Background: DEFUSE 3 is a phase 3 randomized controlled trial of endovascular plus medical therapy versus medical therapy alone in the 6-16 hour time-window for stroke patients with a large vessel occlusion in the anterior circulation and evidence of salvageable brain tissue on baseline MR or CT imaging. The aim of this abstract is to report the effect of endovascular therapy on functional outcome as a function of potentially important effect modifiers.
Methods: Co-variates that were a priori believed to be potentially important effect modifiers included time-to-treatment, baseline infarct volume, age, CT vs MRI patient selection, and baseline ASPECT score. The interactions between endovascular therapy and these co-variates on clinical and radiological outcomes were assessed with multivariable regression analyses. The primary clinical outcome was the modified Rankin Scale score at day 90 and the primary radiological outcome was early lesion growth defined as the change in infarct volume between baseline and 24-hour follow-up MRI.
Results: Of the 182 patients enrolled in the DEFUSE 3 study, 72.6% were selected using multimodal CT imaging and 26.8% using MR. Median age was 70.5 (IQR 59 - 80), median NIHSS 16 (IQR 11-21), median ASPECTS score was 8 (IQR 7-9), baseline ischemic core lesion volumes ranged from 0 ml to 70 ml, and median time from stroke to randomization was 10h 48m (IQR 8h 43m - 12h 42m; range 6h 5m - 15h 54m). The results of the analyses that assess whether the effect of endovascular treatment is modified by these baseline variables are under embargo and will be presented at the International Stroke Conference.
Discussion: The selection criteria utilized in the DEFUSE 3 trial resulted in a patient population that varies widely in terms of age, baseline clinical and radiological severity, and time from symptom onset to randomization. This heterogeneity allows us to compare the effect of endovascular treatment across a wide range of patient subgroups.

Author Disclosure Block: **M.G. Lansberg:** None.

Presentation Number: LB7

Presentation Title: The Effect of Rivaroxaban with Aspirin on Stroke Outcomes in the Cardiovascular Outcomes for People Using Anticoagulation Strategies (COMPASS) Trial

Author Block: **Mukul Sharma**, John W Eikelboom, Stuart J Connolly, Jackie Bosch, Olga Shestakovska, Kelvin K Ng, Luciana Catanese, Population Health Res Inst, McMaster Univ, Hamilton, ON, Canada; Katalin Keltai, Semmelweis Univ, Budapest, Hungary; Victor Aboyans, Dupuytren Univ Hosp, Limoges, France; Astrid Schut, Amphia Ziekenhuis and WCN, Utrecht, Netherlands; Jong-Won Ha, Yonsei Univ Coll of Med, Seoul, Korea, Republic of; John D Varigos, Monash Univ, Melbourne, Australia; Deepak L Bhatt, Brigham and Women's Hosp Heart and Vascular Ctr, Harvard Medical Sch, Boston, MA; Keith A Fox, Ctr for Cardiovascular Science, Univ of Edinburgh, Edinburgh, United Kingdom; Aldo P Maggioni, ANMCO Res Ctr, Florence, Italy; Scott D Berkowitz, Bayer US LLC, Parsippany, NJ; Salim Yusuf, Robert G Hart, Population Health Res Inst, McMaster Univ, Hamilton, ON, Canada

Abstract Body:
Background: COMPASS compared the effects of rivaroxaban alone or combined with aspirin in patients with atherosclerosis in 27,395 participants. Significant reductions in stroke were noted in individuals assigned rivaroxaban 2.5mg BID plus ASA 100 mg OD compared with ASA alone. We examined the effects of treatment on stroke disability and determined the predictors of stroke in the COMPASS cohort and the absolute reductions in stroke in those at high risk.
Methods: COMPASS randomized patients with stable coronary artery disease (91%), peripheral artery disease, including carotid stenosis or revascularization (27%) or both (18%). Major exclusion criteria included stroke within 1 month, symptomatic lacunar stroke or intracerebral hemorrhage. Stroke was adjudicated by blinded adjudicators and classified as ischemic, hemorrhagic and uncertain. Modified Rankin scores were obtained at 7 days in those with stroke. Proportional hazards regression models were constructed to identify independent determinants of stroke and characterize participants by risk status.
Results: Participants with incident stroke (342, 1.2%) were older (70 vs 68) and more likely to be Asian, have hypertension, diabetes, or heart failure. Compared with ASA, the risk of ischemic stroke was significantly reduced by the combination of rivaroxaban and ASA and with no significant difference in hemorrhagic stroke or hemorrhagic transformation of ischemic stroke (Table). The risk of disabling stroke was decreased by the combination compared with aspirin. In those at highest risk, combination therapy reduced the risk of stroke from 1.5% to 0.8% per year (HR 0.54, 95 CI 0.34-78).
Conclusion: Rivaroxaban with ASA is associated with fewer ischemic strokes and a higher likelihood of disability-free status at 7 days without a significant increase in hemorrhagic strokes. The risk of ischemic stroke in high-risk patients was nearly halved by rivaroxaban plus aspirin vs. aspirin.

Outcome	R + A (%/yr)	A (%/yr)	R+A vs A HR (95% CI)
Stroke	0.5	0.8	0.58 (0.44-0.76)
Ischemic	0.4	0.7	0.51 (0.38-0.69)
Hemorrhagic Transformation	<0.1	<0.1	0.35 (0.13-0.99)
Hemorrhagic	<0.1	<0.1	1.49 (0.67-3.31)
Death within 30 days of stroke	<0.1	<0.1	0.84 (0.38-1.88)
mRS 0-2 mRS 3-6	0.3 0.2	0.5 0.3	0.56 (0.40-0.79) 0.58 (0.37-0.89)

Author Disclosure Block: **M. Sharma:** Research Grant; Significant; COMPASS was funded by Bayer. Consultant/Advisory Board; Modest; Bayer, BMS, BI, Daiichi Sankyo. **J.W. Eikelboom:** Honoraria; Modest; Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Daiichi, Janssen, Pfizer. **S.J. Connolly:** None. **J. Bosch:** None. **O. Shestakovska:** None. **K.K.H. Ng:** None. **L. Catanese:** None. **K. Keltai:** None. **V. Aboyans:** Honoraria; Modest; Bayer, Bristol-Myers Squibb, Pfizer, Novartis. **A. Schut:** None. **J. Ha:** None. **J.D. Varigos:** None. **D.L. Bhatt:** Research Grant; Modest; Amarin, Amgen, AstraZeneca, Bristol-Myers Squibb, Chiesi, Eisai, Ethicon, Forest Laboratories, Ironwood, Ischemix, Lilly, Medtronic, Pfizer, Roche, Sanofi Aventis, The Medicines Company. Consultant/Advisory Board; Modest; Cardax Advisory Board, Elsevier Practice Update Cardiology Advisory Board, Medscape Cardiology Advisory Board, Regado Biosciences Advisory Board. Other; Modest; Board of Directors Boston VA Research Institute, Board of Directors Society of Cardiovascular Patient Care. **K.A.A. Fox:** Honoraria; Modest; Bayer, Janssen, Astra Zeneca. **A.P. Maggioni:** Honoraria; Modest; Bayer, Novartis, Cardiorentis, Frenesius. **S.D. Berkowitz:** Employment; Significant; Bayer. **S. Yusuf:** Research Grant; Significant; Bayer. Honoraria; Modest; Bayer. **R.G. Hart:** Research Grant; Significant; Bayer. Honoraria; Modest; Bayer.