Late-Breaking Science Oral Abstracts II

Thursday, February 18, 2016, 1:30 pm - 3:00 pm

LATE-BREAKING SCIENCE abstracts/studies presented at the INTERNATIONAL STROKE CONFERENCE 2016:

For late-breaking science being presented at ISC 2016, 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, Feb. 17; 3:30 pm PST on Wednesday, Feb. 17; 6:15 pm PST on Wednesday, Feb. 17; 11:00 am PST on Thursday, Feb. 18; 1:30 pm PST on Thursday, Feb. 18; or 11:53 am PST on Friday, Feb. 19. News media activities promoting late-breaking science are under embargo until the times noted above.

Presentation Number: LB15

Publishing Title: Predictors of Intracranial Hemorrhage and Clinical Outcome After Stentriever Thrombectomy: Pooled Analysis From Swift Prime, Swift and Star Trials

Author Block: Radoslav Raychev, Jeffrey Saver, UCLA Stroke Ctr, Los angeles, CA; Reza Jahan, Div of Interventional Neuroradiology, UCLA, Los angeles, CA; Raul Nogueira, Marcus Stroke and Neuroscience Ctr, Grady Memorial Hosp, Dept of Neurology, Emory Univ Sch of Med, Atalanta, GA; Mayank Goyal, Depts of Radiology and Clinical Neurosciences, Univ of Calgary,, Calgary, AB, Canada; Vitor Pereira, Div of Neuroradiology and Div of Neurosurgery, Dept of Medical Imaging and Dept of Surgery, Toronto Western Hosp, Univ Health Network, Univ of Toronto, Toronto, ON, Canada; Elad Levy, Dept of Neurosurgery, SUNY at Buffalo, Buffalo, NY; Cristoph Cognard, Dept of Diagnostic and Therapeutic Neuroradiology, Univ Hosp of Toulouse, Toulouse, France; Dileep Yavagal, Univ of Miami/Jackson Memorial Hosp, Miami, FL; Jan Gralla, Inselspital, Univ of Bern, Bern, Switzerland; David Liebeskind, Neurovascular Imaging Res Core, Dept of Neurology, UCLA, Los Angeles, California, USA, Los angeles, CA

Abstract Body: Introduction

Despite the proven benefit of Solitaire for treatment of acute ischemic stroke, symptomatic intracranial hemorrhage (ICH) remains the most feared procedural complication. The aim of this analysis was to identify the factors determining ICH after neurothrombectomy with Solitaire stentriever.

Methods

All patients (N = 389) treated with Solitaire in SWIFT, SWIFT PRIME, and STAR trials were analyzed for incidence of 5 different ICH subtypes. Each ICH subtype was correlated with baseline clinical, imaging and procedural characteristic (age, NIHSS, hypertension,, diabetes, atrial fibrillation, hyperglycemia, INR, platelet count, ASPECTS, general anesthesia, collateral grade, number of devices passes, final TICI, rescue therapy). Multivariate stepwise logistic regression model was used to identify the predictors of individual ICH subtypes.

Results

ICH was observed in 21.6% (N=84) of which sICH was 1.0% (N=4), reperfusion hemorrhage (defined as HI and PH) 19.3% (N=75), PH 5.4% (N=21), and SAH 2.3% (N=9). The most significant predictors of any ICH and RH are included in table 1. No specific predictors of SAH; PH, and sICH were identified. Patients who achieved functional independence at 90 days (mRS 0-2) had significantly lower incidence of any ICH, RH, PH, and no SICH (table 2).

Conclusions

Higher baseline ASPECTS, better collaterals and general anesthesia are associated with lower incidence of ICH after neurothrombectomy with Solitaire stentriever. Reperfusion hemorrhage is distinctly associated with prolonged onset to groin puncture. Of all ICH subtypes, sICH has the strongest impact on functional independence at 90 days

Any ICH (HI, PH, SAH, IVH, RIH)				
Predictor	**Odds ratio**	**Lower CI**	**Upper CI**	**p-value**
ASPECTS	0.80	0.66	0.98	0.032
General anesthesia	0.36	0.18	0.71	0.003
Collateral grade	0.71	0.50	1.01	0.057
Reperfusion hemorrhage (HI and PH)				
ASPECTS	0.78	0.68	0.91	0.001
General anesthesia	0.54	0.31	0.92	0.023
Onset to groin puncture (per 15 min)	1.08	1.03	1.12	0.001

Table 1. Predictors of ICH. Abbreviations: HI – hemorrhagic infarction; PH – parenchymal hematoma; SAH – subarachnoid hemorrhage; IVH – intraventricular hemorrhage; RIH – remote intracranial hemorrhage

ICH subtype	**Functional independence with ICH**	**Functional independence without ICH**	**p-value**
Any ICH (HI, PH, SAH, IVH, RIH)	32.1% (27/84)	61.4% (183/298)	<0.001
Reperfusion hemorrhage (HI + PH)	30.7% (23/75)	60.9% (187/307)	<0.001
SAH	44.4% (4/9)	55.2% (206/373)	0.74
PH	19.0% (4/21)	57.1% (206/361)	0.001
SICH	0.0% (0/4)	55.6% (210/378)	0.040

Table 2. Clinical outcome

Author Disclosure Block: **R. Raychev:** None. **J. Saver:** Consultant/Advisory Board; Modest; Medtronic, Stryker, Neuravia, Cognition Medical, Boehringer Ingelheim (prevention only). **R. Jahan:** Consultant/Advisory Board; Modest; Medtronic. **R. Nogueira:** Consultant/Advisory Board; Modest; Medtronic Neurovascular, Stryker Neurovascular, Penumbra, Rapid Medical. **M. Goyal:** Consultant/Advisory Board; Modest; Medtronic. **V. Pereira:** Consultant/Advisory Board; Modest; Medtronic. **E. Levy:** Honoraria; Modest; Medtronic Neurovascular. Expert Witness; Modest; Renders Medical/Legal Opinions. Ownership Interest; Modest; Intratech Medical, Ltd Blockade Medical LLC, Medina Medical Inc. Consultant/Advisory Board; Modest; Medtronic, Pulsar, Blockade Medical LLC, Medina Medical Inc. **C. Cognard:** Consultant/Advisory Board; Modest; Medtronic Neurovascular, Stryker, Microvention, Sequent, Codman. **D. Yavagal:** Consultant/Advisory Board; Modest; Medtronic. **J. Gralla:** Consultant/Advisory Board; Modest; Medtronic. **D. Liebeskind:** Consultant/Advisory Board; Modest; Medtronic, Stryker.

LATE-BREAKING SCIENCE abstracts/studies presented at the INTERNATIONAL STROKE CONFERENCE 2016:

For late-breaking science being presented at ISC 2016, 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, Feb. 17; 3:30 pm PST on Wednesday, Feb. 17; 6:15 pm PST on Wednesday, Feb. 17; 11:00 am PST on Thursday, Feb. 18; 1:30 pm PST on Thursday, Feb. 18; or 11:53 am PST on Friday, Feb. 19. News media activities promoting late-breaking science are under embargo until the times noted above.

Presentation Number: LB16

Publishing Title: Randomized Trial of Revascularization with Solitaire FR® dDevice versus Best Medical Therapy in the Treatment of Acute Stroke due to Anterior Circulation Large Vessel Occlusion Presenting Within Eight Hours of Symptom Onset) REVASCAT Trial- Final Results at 12 Months

Author Block: Antoni Davalos, Hosp Germans Trias y Pujol, Barcelona, Spain; Erik Cobo, Univ Politecnica de Catalunya, Barcelona, Spain; Angel Chamorro, Hosp Clinic, Barelona, Spain; Carlos Molina, Hosp Vall d'Hebron, Barcelona, Spain; Maria Angeles De Miquel, Hosp de Bellvitge, Barcelona, Spain; Luis San Roman, Hosp Clinic, Barcelona, Spain; Alex Rovira, Hosp Vall d'Hebron, Barcelona, Spain; Joaquin Serena, Hosp Josep Trueta, Girona, Spain; Millan Monica, Hosp Germans Trias y Pujol, Barcelona, Spain; Marc Ribo, Hosp Vall d'Hebron, Barcelona, Spain; Lucia Aja, Pere Cardona, Hosp de Bellvitge, Barcelona, Spain; Xavier Urra, Hosp Clinic, Barcelona, Spain; Elena Lopez-Cancio, Hosp Germans Trias y Pujol, Barcelona, Spain; Alejandro Tomasello, Hosp Vall d"Hebron, Barcelona, Spain; Carlos Castano, Hosp Germans Trias y Pujol, Barcelona, Spain; Jordi Blasco, Hosp Clinic, Barcelona, Spain; Tudor G Jovin, UPMC Stroke Inst, Pittsburgh, PA

Abstract Body: Background and significance: recently published randomized trials comparing best medical therapy to endovascular therapy in stroke have demonstrated benefit of endovascular therapy at three months post randomization. Whether this benefit is sustained in the long term is unknown. A unique feature of REVASCAT is that a pre-planned 6 month and 12 month outcome assessment was included in the study protocol. Here we report the results of a pre-specified secondary analysis assessing the difference between the endovascular group and the best medical therapy group with respect to the primary endpoint (modified Rankin Scale - mRS) and to the overall health status (EQ-5D) at 12 months.

Methods: Patients with acute ischemic stroke treatable within 8 hours of symptom onset with confirmed proximal anterior circulation occlusion were randomized to medical therapy (including iv t-PA when eligible) and endovascular treatment with Solitaire stent retriever versus medical therapy alone. Primary outcome measure was global disability at 90 days expressed as mRS. Effect size measure was a cumulative logistic regression odds ratio (shift analysis). Main analysis adjusted both for minimization factors and iv t-PA use. A pre-specified secondary outcome was the primary outcome at one year as well as the difference in health status expressed as difference in median EQ-5D at 6 and 12 months. At 6 months the mRS was obtained via structured phone interview by a blinded investigator. At 12 months it was obtained both locally, in person via structured interview by a blinded investigator and centrally by a blinded adjudicator through video review of the filmed interview. The central, video based assessment will be used for the main 12 months endpoint analysis.

Results: A total of 206 patients were randomized, 103 in each group. At 90 days, the primary endpoint analysis showed a common odds ratio of improvement in the distribution of the modified Rankin scale score of 1.7 (95% CI, 1.05 to 2.8) favoring thrombectomy. No missing outcomes were recorded at 3 months or at 6 months. There are 15 patients with pending 12 months outcomes to date. The last patient will be evaluated by the end of November 2015. Final results will be available for presentation in February 2016.

Author Disclosure Block: **A. Davalos:** Consultant/Advisory Board; Modest; Covidien (STAR Steering Committee. **E. Cobo:** None. **A. Chamorro:** None. **C. Molina:** None. **M. De Miquel:** None. **L. San Roman:** None. **A. Rovira:** None. **J. Serena:** None. **M. Monica:** None. **M. Ribo:** None. **L. Aja:** None. **P. Cardona:** None. **X. Urra:** None. **E. Lopez-Cancio:** None. **A. Tomasello:** None. **C. Castano:** None. **J. Blasco:** None. **T.G. Jovin:** Consultant/Advisory Board; Modest; Silk Road Inc., Neuravi, Codman, Medtronic (unpaid), Stryker (unpaid).

LATE-BREAKING SCIENCE abstracts/studies presented at the INTERNATIONAL STROKE CONFERENCE 2016:

For late-breaking science being presented at ISC 2016, 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, Feb. 17; 3:30 pm PST on Wednesday, Feb. 17; 6:15 pm PST on Wednesday, Feb. 17; 11:00 am PST on Thursday, Feb. 18; 1:30 pm PST on Thursday, Feb. 18; or 11:53 am PST on Friday, Feb. 19. News media activities promoting late-breaking science are under embargo until the times noted above.

Presentation Number: LB17

Publishing Title: Expanding Opportunities for Intravenous Alteplase Treatment of Patients With Unwitnessed Acute Stroke Using MRI-based Patient Selection: Imaging Results of the MR WITNESS Multicenter Trial (NCT01282242)

Author Block: Ona Wu, Massachusetts General Hosp, Boston, MA; Shlee S Song, Cedar Sinai Hosp, Los Angeles, CA; William A Copen, Massachusetts General Hosp, Boston, MA; Albert J Yoo, Texas Stroke Inst, Plano, TX; Andria L Ford, Washington Univ at St Louis, St Louis, MO; Amie Hsia, NINDS Intramural Stroke Program, Bethesda, MD; Alona Muzikansky, Rebecca Betensky, Gregoire Boulouis, Arne Lauer, Michael H Lev, Pedro T Cougo-Pinto, Gordon J Harris, Massachusetts General Hosp, Boston, MA; Steven Warach, Univ of Texas, Austin, Austin, TX; Lee H Schwamm, Massachusetts General Hosp, Boston, MA; Lawrence L Latour, NINDS Intramural Stroke Program, Bethesda, MD; for the MR WITNESS Investigators

Abstract Body: Background: Combining qualitative FLAIR-negative MRI (FLAIR-) with quantitative FLAIR lesion signal intensity ratio (SIR) analysis may increase sensitivity for identifying acute ischemic stroke (AIS) patients in the early stages of stroke without affecting specificity. We compared this combined approach vs FLAIR- by visual inspection alone criteria for selecting patients in MR WITNESS, a multicenter, open-label Phase IIa clinical trial investigating the safety of giving IV tPA to stroke patients with unclear onset times.

Methods: Patients with unwitnessed strokes who would otherwise qualify clinically per AHA guidelines for IV tPA up to 4.5 hr were screened by MRI. Patients were treated if they had either no FLAIR signs of ischemia (FLAIR-) or a FLAIR lesion (FLAIR+) with signal intensity ratio (SIR) <1.15. Good outcome was defined as modified Rankin Scale 0 or 1 at 90 days. Intracranial hemorrhages (ICH) were classified using ECASS definitions. Outcomes of FLAIR- and FLAIR+ subjects were compared using 2-sided Fisher's exact test for categorical variables and Wilcoxon test for continuous variables.

Results: Eighty subjects were enrolled and treated with tPA. Only 40 (50%) of these patients were considered FLAIR- by the sites. There was no significant difference in terms of safety or outcome between FLAIR- compared to FLAIR+ patients (see Table). Both groups exhibited similar characteristics except in SIR ($P<0.001$).

Discussion: Without adversely affecting safety, combining qualitative FLAIR- criteria with quantitative SIR analysis doubled the number of patients who were treated with tPA compared to patients who would have been treated using FLAIR- criterion alone. Many of our FLAIR+ patients that would have been excluded by FLAIR- criterion had good outcome at 90 days (39%) and comparable ICH rates, suggesting FLAIR- alone is too strict.

Conclusion: Treating unwitnessed AIS patients with IV tPA based on combined FLAIR-negative MRI with SIR criteria is safe.

TABLE: Patient characteristics and clinical outcomes among patients with unwitnessed stroke onset receiving extended window IV tPA, comparing those who presented with FLAIR-negative MRI findings by visual inspection (FLAIR-) and those who did not (FLAIR+). *P<0.05, FLAIR- vs FLAIR+ group.

	All Patients (N=80)	FLAIR– (N=40)	FLAIR+ (N=40)	P-value
Age, mean year (S.D.)	67.5 (13.5)	68.8 (13.3)	66.2 (13.6)	0.27
Male Sex, N (%)	45 (56.3)	22 (55.0)	23 (57.5)	1.00
NIHSS (N=78), median (IQR)	7.5 (4-14)	7 (5-13)	8 (4-15)	0.93
TPA TREATMENT:				
Time since last known well, median (IQR) hour	11.45 (9.4-13.8)	11.40 (9.4-15.0)	11.50 (9.1-13.7)	0.87
Time since discovery, median (IQR) hour	3.5 (2.9-4.0)	3.6 (2.6-4.0)	3.4 (3.0-4.0)	0.42
IMAGING FINDINGS:				
FLAIR SIR, median (IQR)	1.08 (1.02-1.12)	1.03 (1.00-1.10)	1.09 (1.06-1.13)	<0.001*
Symptomatic ICH at 24 hour CT scan, % [95% CI]	1.25 [0.03-6.8]	0 [0.00-8.8]	2.5 [0.06-13.2]	1.00
Any ICH at 24 hour CT scan, % [95% CI]	25 [16-36]	25 [13-41]	25 [13-41]	1.00
Type of Asymptomatic ICH at 24 hour CT				0.78
-HI 1 or HI 2, N	13	6	7	
-PH 1 or PH 2, N	4	3	1	
-SAH, N	2	1	1	
CLINICAL OUTCOMES:				
mRS Score at 90 days (N=72), median (IQR)	2 (1-3.75)	2 (1-4)	2 (1-3)	0.41
mRS (0-1) at 90 days (N=72), % [95% CI]	34.7 [24-47]	31 [16-48]	39 [23-57]	0.62
Mortality (N=72), % [95% CI]	9.7 [4-19]	14 [4.7-29]	5.6 [0.7-18.7]	0.43

Preliminary results only: Final data will be available by end of January 2016. NIHSS, NIH stroke scale; SIR, signal intensity ratio; ICH, intracranial hemorrhage; HI, hemorrhagic infarction; PH parenchymal hematoma; SAH, subarachnoid hemorrhage; CI, 95% exact confidence intervals; mRS, modified Rankin Scale.

Author Disclosure Block: **O. Wu:** Research Grant; Significant; PI of MR WITNESS NINDS P50NS051343, NINDS R01NS082285, NINDS R01NS086905. Other Research Support; Significant; Genentech provides additional site supplemental payments for MR WITNESS and support for a parallel expanded selection arm of the trial. **S.S. Song:** Research Grant; Modest; Genentech- PRISMS Site PI, MRWITNESS Site PI, California Community Foundation Grant, POSITIVE Site PI.. **W.A. Copen:** None. **A.J. Yoo:** Research Grant; Modest; Neuravi Inc.. Research Grant; Significant; Penumbra Inc, Stryker Inc. **A.L. Ford:** Research Grant; Significant; NIHK23NS069807, NIHR01HL129241, Institute of Clinical and Translational Sciences at Washington University UL1 TR000448, AHA 15GRNT25830020 Grant-in-Aid. **A. Hsia:** None. **A. Muzikansky:** Research Grant; Significant; NINDS P50 NS051343. **R. Betensky:** Research Grant; Significant; NINDS P50 NS051343. **G. Boulouis:** Research Grant; Modest; J. William Fulbright 2014-2015 Research Scholar Grant, Monahan Foundation 2014-2015 Biomedical Research Grant. **A. Lauer:** None. **M.H. Lev:** Research Grant; Significant; NINDS P50 NS051343. Other Research Support; Significant; GE Healthcare. Consultant/Advisory Board; Modest; GE Healthcare, Millenium Pharm. **P.T. Cougo-Pinto:** None. **G.J. Harris:** Research Grant; Significant; NINDS P50 NS051343. **S. Warach:** None. **L.H. Schwamm:** Research Grant; Significant; PI of MR WITNESS NINDS P50 NS051343 with alteplase provided free of charge plus supplemental site payments by Genentech. Consultant/Advisory Board; Significant; DSMB Penumbra Separator 3D trial, Intl Steering Committee DIAS 3&4, Lundbeck.. **L.L. Latour:** None

LATE-BREAKING SCIENCE abstracts/studies presented at the INTERNATIONAL STROKE CONFERENCE 2016:

For late-breaking science being presented at ISC 2016, 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, Feb. 17; 3:30 pm PST on Wednesday, Feb. 17; 6:15 pm PST on Wednesday, Feb. 17; 11:00 am PST on Thursday, Feb. 18; 1:30 pm PST on Thursday, Feb. 18; or 11:53 am PST on Friday, Feb. 19. News media activities promoting late-breaking science are under embargo until the times noted above.

Presentation Number: LB18

Publishing Title: Endovascular Treatment in Acute Ischemic Stroke: A Meta-analysis of Individual Patient Data From Mr Clean, Escape, Extend IA, Swift Prime and Revascat

Author Block: Mayank Goyal, Univ of Calgary, Calgary, AB, Canada; Wim H van Zwam, Univ of Maastricht Medical Ctr, Maastricht, Netherlands; Bijoy Menon, Univ of Calgary, Calgary, AB, Canada; Diedrik W.J. Dippel, Erasmus Univ Medikcal Ctr, Rotterdam, Netherlands; Peter J Mitchell, Royal Melbourne Hosp, Univ of Melbourne, Melbourne, Australia; Andrew Demchuk, Univ of Calgary, Hotchkiss Brain Inst, Calgary, AB, Canada; Antoni Davalos, Hosp Germans Trias y Pujol, Barcelona, Spain; Charles B Majoie, Academic Medical Ctr, Amsterdam, Netherlands; Aad V. Lugt, Erasmus Univ Medical Ctr, Erasmus, Netherlands; Maria Angeles De Miquel, Hosp de Bellvitge, Barcelona, Spain; Geoffrey Donnan, Univ of Melbourne, Melbourne, Australia; Yvo Bw Roos, Academic Medical Ctr, Amsterdam, Netherlands; Alain Bonafe, Hosp Guy de Chaulliac, Montpellier, France; Reza Jahan, UCLA Medical Ctr, Los Angeles, CA; Hans-Christoph Diener, Univ Duisburg Essen, Medical Ctr, Essen, Germany; LUcie A van den Berg, Academic medical Ctr, Amsterdam, Netherlands; Elad I Levy, State Univ of New York, Buffallo, Buffallo, NY; Olvert A Berkhemer, Academic Medical Ctr, Amsterdam, Netherlands; Vitor Pereira, Univ of Toronto, Toronto, ON, Canada; Jeremy Rempel, Univ of Edmonton, Edmonton, AB, Canada; Monica Millan, Hosp Germans Trials y Pujol, Barcelona, Spain; Stephen Davis, Royal Melbourne Hosp, UNiversity of Melbourne, Melbourne, Australia; Daniel Roy, CHUM Hop Notre Dame, Montreal, QC, Canada; John Thornton, Beaumont Hosp, Dublin, Ireland; Luis San Roman, Hosp Clinic, Barcelona, Spain; Marc Ribo, Hosp Vall d"Hebron, Barcelona, Spain; Debbie Beumer, Maastricht Univ Medical Ctr, Maastricht, Netherlands; Bruce Stouch, Philadelphia Coll of Osteopathic Med, Philadelphia, PA; Bruce C Campbell, Royal Melbourne Hosp, Univ of Melbourne, Melbourne, Australia; Robert J van Oosterbrugge, Maastricht Univ Medical Ctr, Maastricht, Netherlands; Jeffrey Saver, David Geffen Sch of Med, Univ of Los Angeles, Los Angeles, CA; Michael Hill, Univ of Calgary, Calgary, AB, Canada; **Tudor G Jovin**, UPMC Stroke Inst, Pittsburgh, PA

Abstract Body: Background: Five recent trials have shown benefit of endovascular treatment for acute anterior circulation ischemic stroke due to large vessel occlusion. All the trials used newer thrombectomy devices (primarily stent retrievers).

Methods: We did a pre-specified patient-level meta-analysis (Highly Effective Reperfusion evaluated in the Multiple Endovascular Stroke Trials - HERMES Collaboration) of the MR CLEAN (500 patients), ESCAPE (315 patients), EXTEND IA (70 patients), SWIFT PRIME (195 patients) and REVASCAT (207 patients) trials. Primary analysis was a shift in the modified Rankin Score (mRS). Secondary outcomes included mRS 0-2, and mortality.

Results: A total of 1,287 patients were included (intervention arm 634 [49.3%], control arm 653 [50.7%]). The two arms were matched with respect to age, sex, baseline NIHSS and time to randomization (52.9% male; median age: 68.0 (IQR 19.0); 85.1% received IV tPA, median baseline NIHSS 17 (1QR 8). More control arm patients received IV tPA (p: 0.0417). Adjusted odds ratio for mRS 0-2 at 90 days for treatment (device vs. control): 2.70 (95%CI 2.09 to 3.48). There was no difference in mortality (p=0.1024 [OR for mortality 0.78, 95%CI 0.58 to 1.04). Figure 1 shows results of the major sub-groups. Figure 2 shows correlation between age and final mRS (a) and baseline NIHSS and final mRS (b).

Interpretation: Endovascular treatment of acute stroke using modern devices (primarily stent retrievers) shows substantial benefit compared to standard of care irrespective of age, sex, baseline NIHSS score, and co-treatment with IV tPA. Increasing age and NIHSS are strong prognostic factors for poorer outcome.

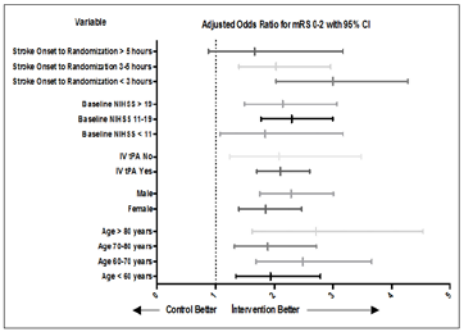

Figure 1: Forest plot showing the results of the major sub-groups.

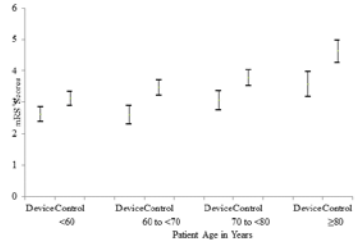

Figure 2a: Mean mRS Scores at 90 Days with 95% Confidence Limit s for the Device and Control Groups by Age Categories

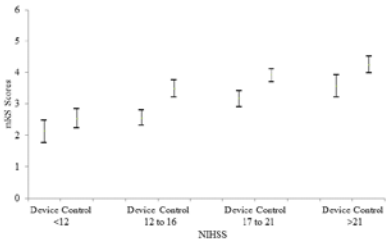

Figure 2b: Mean mRS Scores at 90 Days with 95% Confidence Limits for the Device and Control Groups by NIHSS Categories

Author Disclosure Block: **M. Goyal:** Other Research Support; Modest; Medtronic Neurovascular. Consultant/Advisory Board; Modest; Medtronic Neurovascular. **W.H. van Zwam:** Honoraria; Modest; Stryker (paid to Institution). **B. Menon:** None. **D. Dippel:** None. **P.J. Mitchell:** None. **A. Demchuk:** Research Grant; Significant; partially funded by means of unrestricted grant for ESCAPE from Medtronic Neurovascular. **A. Davalos:** Consultant/Advisory Board; Modest; Medtronic Neurovascular (Steering Committee STAR). **C.B.L. Majoie:** Speakers' Bureau; Modest; Stryker (paid to institution). **A.V.D. Lugt:** None. **M. De Miquel:** None. **G. Donnan:** Research Grant; Modest; Australian National Health, Medical Research Council.. Other; Modest; Boehringer, Sanofi, Pfizer, Bayer. Astra Zeneca, Bristol Meyers-

Squibb, Merck Sharp & Dohme.. **Y.B. Roos:** None. **A. Bonafe:** Consultant/Advisory Board; Modest; Medtronic Neurovascular. **R. Jahan:** Research Grant; Modest; Medtronic Neurovascular. Consultant/Advisory Board; Modest; Medtronic Neurovascular. **H. Diener:** Research Grant; Modest; German Research Council (DFG), German Ministry of Education and Research (BMBF), European Union, NIH, Bertelsmann Foundation, Heinz-Nixdorf Foundation. Other Research Support; Modest; Modest; AstraZeneca, GSK, Boehringer Ingelheim, Lundbeck, Novartis, Janssen-Cilag, Sanofi-Aventis, Syngis, Talecris.. Consultant/Advisory Board; Modest; Abbott, Allergan, AstraZeneca, Bayer Vital, BMS, Boehringer Ingelheim, CoAxia, Corimmun, Covidien, Daiichi-Sankyo, D-Pharm, Fresenius, GlaxoSmithKline, Janssen-Cilag, Johnson & Johnson, Knoll, Lilly,. **L.A. van den Berg:** None. **E.I. Levy:** Honoraria; Modest; Medtronic Neurovascular. Expert Witness; Significant; renders medico-legal opinions. Ownership Interest; Modest; Intratech Medical, Ltd, Blockade Medical LLC.. Ownership Interest; Significant; Medina Medical. Consultant/Advisory Board; Modest; Pulsar, Blockade Medical. Consultant/Advisory Board; Significant; Medina Medical. Other; Modest; Abott. **O.A. Berkhemer:** None. **V. Pereira:** Consultant/Advisory Board; Modest; Medtronic Neurovascular, Stryker. **J. Rempel:** None. **M. Millan:** None. **S. Davis:** Honoraria; Modest; personal feees from Medtronic during the conducty of EXTEND-IA. **D. Roy:** None. **J. Thornton:** None. **L. San Roman:** None. **M. Ribo:** None. **D. Beumer:** None. **B. Stouch:** None. **B.C.V. Campbell:** Research Grant; Modest; National Health and Medical Research Council of Australia, National Heart Foundation of Australia, Royal Australasian College of Physicians, Royal Melbourne Hospital Foundation, Medtronic.. **R.J. van Oosterbrugge:** None. **J. Saver:** Consultant/Advisory Board; Modest; Stryker, Neuravia, Cognition Medical, Boehringer Ingelheim (prevention only). Consultant/Advisory Board; Significant; Medtronic. **M. Hill:** Research Grant; Significant; Partial funding for ESCAPE through unrestricted grant from Medtronic. **T.G. Jovin:** Ownership Interest; Modest; Silk Road. Consultant/Advisory Board; Modest; Neuravi, Codman, Stryker (unpaid), Medtronic (unpaid).

LATE-BREAKING SCIENCE abstracts/studies presented at the INTERNATIONAL STROKE CONFERENCE 2016:

For late-breaking science being presented at ISC 2016, 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, Feb. 17; 3:30 pm PST on Wednesday, Feb. 17; 6:15 pm PST on Wednesday, Feb. 17; 11:00 am PST on Thursday, Feb. 18; 1:30 pm PST on Thursday, Feb. 18; or 11:53 am PST on Friday, Feb. 19. News media activities promoting late-breaking science are under embargo until the times noted above.

Presentation Number: LB19

Publishing Title: MultiStem® Treatment Reduces Length of Hospitalization When Administered Within 36 Hours After Onset of Ischemic Stroke: Implications on Lowering Stroke Related Health Care Costs

Author Block: Lawrence R. Wechsler, Univ of Pittsburgh Medical Ctr, Pittsburgh, PA; Susana M. Bowling, Summa Health, Akron, OH; L. Dana DeWitt, Univ of Utah, Salt Lake City, UT; Wayne M. Clark, Oregon Health and Science Univ, Portland, OR; David Chiu, Houston Methodist, Houston, TX; David C. Hess, Georgia Regents Univ, Augusta, GA; B01-02 Investigators; Robert W. Mays, ATHERSYS INC, Cleveland, OH

Abstract Body: INTRODUCTION: MultiStem administration within 36 hours of the onset of stroke confers improved functional benefit through multiple mechanisms, including down-regulation of the peripheral immune response. We sought to determine whether this translated to improved clinical benefit as a function of patient time in the hospital and ICU, and the implication for this therapy in decreasing the burden of stroke on the health care system.

METHODS: B01-02 was a double-blind, placebo-controlled study of ischemic stroke patients (NIHSS 8-20, inclusive) treated within 24-48 hours of symptoms at 33 sites in the U.S. and U.K. Patients were randomized 1:1 and received infusion of 1.2 billion cells or placebo. Patients were followed for the first 90 days after treatment, and length of time hospitalized and in the intensive care unit were compared between treatment groups (Satterwaite t-test).

RESULTS: 126 patients formed the ITT population, 65 receiving MultiStem, 61 placebo. The mean age of the cell treatment group was 61.8, median NIHSS score=13.0; for placebo, mean age was 62.6, median NIHSS=13.0. Post-hoc analyses indicate that, compared to placebo (n=52), patients who received cell treatment earlier in the treatment window (≤36 hrs, n=27) experienced reduced hospitalization of 3.6 days (6.7d vs. 10.3 d, $p<0.01$), as well as approximately 2 fewer days in the ICU (3.0 days for cell treatment, 4.8 days for placebo, p=.09). MultiStem treatment was also associated with lower rates of infections, and a reduction in life threatening adverse events and death. With published averages of neuro-ICU days at around $6,000 per day in the US, and the average cost of a hospital day around $2,000, substantial cost savings per patient time in the hospital is realized when comparing cell to placebo treatment in the B01-02 trial.

CONCLUSIONS: Administration of MultiStem to ischemic stroke patients within the first 36 hours of onset reduces hospitalization time and ICU time when compared to placebo treated patients in the B01-02 study, demonstrating a significant potential health-economic benefit for this therapy. These benefits would be expected to increase further over time

Author Disclosure Block: L.R. Wechsler: Consultant/Advisory Board; Modest; Athersys, Inc.. **S.M. Bowling:** None. **L.D. DeWitt:** None. **W.M. Clark:** None. **D. Chiu:** None. **D.C. Hess:** Other Research Support; Modest; Athersys, Inc.. Consultant/Advisory Board; Modest; Athersys, Inc. **R.W. Mays:** Employment; Significant; Athersys, Inc.. Ownership Interest; Significant; Athersys, Inc..

LATE-BREAKING SCIENCE abstracts/studies presented at the INTERNATIONAL STROKE CONFERENCE 2016:

For late-breaking science being presented at ISC 2016, 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, Feb. 17; 3:30 pm PST on Wednesday, Feb. 17; 6:15 pm PST on Wednesday, Feb. 17; 11:00 am PST on Thursday, Feb. 18; 1:30 pm PST on Thursday, Feb. 18; or 11:53 am PST on Friday, Feb. 19. News media activities promoting late-breaking science are under embargo until the times noted above.

Presentation Number: LB20

Publishing Title: Validation of a Simplified Eight-item NIHSS to Identify Acute Ischemic Stroke Patients With Large Vessel Occlusion

Author Block: Jelle Demeestere, John Hunter Hosp, Newcastle, Australia; Longting Lin, Hunter Medical Res Inst, Newcastle, Australia; Nicolas R Smoll, Sch of Med and Public Health, Univ of Newcastle, Newcastle, Australia; Timothy E. Ang, John Hunter Hosp, Newcastle, Australia; Andrew Bivard, Hunter Medical Res Inst, Newcastle, Australia; Mark Parsons, Christopher Levi, John Hunter Hosp; Univ of Newcastle, Newcastle, Australia

Abstract Body: Introduction:

The effect of endovascular stroke treatment is time-dependent. Patients more likely to have an intracranial large vessel occlusion (LVO) therefore ideally are identified before hospital arrival and transferred to a centre offering endovascular treatment. We assessed if a simplified 8-item version (NIHSS-8) of the NIHSS scale can be used for identification of acute stroke patients with LVO.

Methods:

We used expert consensus to select 8 items of the NIHSS maximally covering the acute stroke clinical spectrum (Table 1). Following a training period, we assessed interrater reliability for the NIHSS-8 scale between Ambulance officers and the John Hunter Stroke Team (JHHST), using Cohen's Kappa statistics. We retrospectively calculated NIHSS-8 scores for stroke patients admitted within 4.5 hours from stroke onset between 12/2012 and 08/2015. LVO was defined as an occlusion of the common carotid artery, internal carotid artery, carotid-T, M1-middle cerebral artery, basilar artery or P1-posterior cerebral artery. An experienced vascular neurologist reviewed the presence of a causal LVO. We calculated sensitivity (SE), specificity (SP), positive predictive value (PPV) and negative predictive value (NPV) for each NIHSS-8 cut-off point using standard 2 x 2 contingency table methodology.

Results:

Ambulance officers and JHHST reached substantial agreement (Agreement 86%, Kappa = 0.61, p <0.0001) on simultaneous blinded scoring of 50 acute stroke patients. We scored 235 acute stroke patients admitted within 4.5 hours from stroke onset using the NIHSS-8 scale (51% female; median age 74 (average 71, range 27-96)). Optimal SE of 0.74 and SP of 0.84 were achieved using a cut-off score of 8, with a PPV of 0.82, NPV of 0.77 and accuracy of 0.79.

Conclusion: A short 8 item version of the NIHSS can be reliably performed by ambulance personnel in the field and can be used to identify acute stroke patients with LVO that might benefit from endovascular stroke treatment.

NIHSS-8 Item	Scoring Definition	Score
1. LOC	0-alert (A) 1-rousable to minor stimulation (V) 2-rousable only to painful stimulation (P) 3-reflex response or un-rousable (U)	
2. LOC Questions – Ask patient's age and current month (Must be exact)	0-Both correct 1-one correct or dysarthria, foreign language 2-Neither correct	
3. Commands – opens/close eyes, grip and release non paretic hand Other 1 step commands or mimic ok)	0-Both correct (Ok if impaired by weakness) 1-One correct 2-Neither correct	
4. Best Gaze – Test horizontal eye movements tracking object/face	0-Normal 1-partial gaze, abnormal gaze in 1 or both eyes 2- Forced eye deviation or total paresis which cannot be overcome	
5. Facial Palsy – Show teeth, close eyes tight, raise eyebrows. If stuporous, check symmetry of grimace to pain	0-Normal 1-Minor paralysis, flat NLF, asymmetrical smile 2-Partial paralysis (lower face) 3-Complete paralysis (upper & lower face)	
6. Motor Arm - arms outstretched 90deg (sitting or 45 deg (supine) for 10secs. Encourage best effort. Score for Left and then Right arm.	0-No drift for 10 secs 1-drift but does not hit bed 2-Some antigravity effort but can't sustain 3-Unable to overcome gravity, minimal proximal movement present 4-No movement at all X-Unable to assess due to amputation, fusion,fx etc	Left: Right:
7. Dysarthria – read or repeat list of words (see reverse of page)	0-Normal 1-mild-mod slurred speech but intelligible 2- Unintelligible or mute X-intubation or mechanical barrier	
8. Extinction / Neglect – simultaneously touch patient on both hands or legs with their eyes closed, show fingers in both visual fields.	0-Normal none detected 1-neglect or extinction to double simultaneous stimulation in any modality (sensory, visual) OR visual/sensory loss on one side 2-profound neglect in both visual and sensory modalities	
Total Score		

Table 1. Eight items of the NIHSS-8 scale.

Author Disclosure Block: **J. Demeestere:** None. **L. Lin:** None. **N.R. Smoll:** None. **T.E. Ang:** None. **A. Bivard:** None. **M. Parsons:** None. **C. Levi:** None.

LATE-BREAKING SCIENCE abstracts/studies presented at the INTERNATIONAL STROKE CONFERENCE 2016:

For late-breaking science being presented at ISC 2016, 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, Feb. 17; 3:30 pm PST on Wednesday, Feb. 17; 6:15 pm PST on Wednesday, Feb. 17; 11:00 am PST on Thursday, Feb. 18; 1:30 pm PST on Thursday, Feb. 18; or 11:53 am PST on Friday, Feb. 19. News media activities promoting late-breaking science are under embargo until the times noted above.

Presentation Number: LB21

Publishing Title: Cost-effectiveness of Solitaire + IV-tPA for Acute Ischemic Stroke: Results From the Swift-Prime Trial

Author Block: Theresa I Shireman, Brown Univ, Providence, RI; Kaijun Wang, Saint Luke's Mid America Heart Inst, Kansas City, MO; Jeffrey L Saver, Univ of California Los Angeles, Los Angeles, CA; Mayank Goyal, Univ of Calgary, Calgary, AB, Canada; Alain Bonafe, Hôpital Gui-de-Chauliac, Montpellier, France; Hans-Christoph Diener, Univ Hosp of Univ Duisburg-Essen, Essen, Germany; Elad I Levy, Univ at Buffalo, Buffalo, NY; Vitor M Pereira, Toronto Western Hosp, Toronto, ON, Canada; Greg W. Albers, Stanford Univ, Stanford, CA; Christophe Cognard, Univ Hosp of Toulouse, Toulouse, France; Werner Hacke, Univ of Heidelberg, Heidelberg, Germany; Olav Jansen, Christian-Albrechts-Univ Kiel, Kiel, Germany; Tudor G. Jovin, Univ of Pittsburgh Medical Ctr, Pittsburgh, PA; Heinrich P Mattle, Univ of Bern Inselspital, Bern, Switzerland; Raul G. Nogueira, Grady Memorial Hosp, Atlanta, GA; Adnan H Siddiqui, Univ at Buffalo, Buffalo, NY; Dileep R. Yavagal, Univ of Miami/Jackson Memorial Hosp, Miami, FL; Thomas G. Devlin, Erlanger Hosp at Univ of Tennessee, Chattanooga, TN; Demetrius K. Lopes, Rush Univ Medical Ctr, Chicago, IL; Vivek K. Reddy, Brown UnivUniv of Pittsburgh Medical Ctr, Pittsburgh, PA; Richard du Mesnil de Rochemont, Klinikum der Goethe-Univ, Frankfurt, Germany; Reza Jahan, Univ of California Los Angeles, Los Angeles, CA; Katherine A Vilain, John House, Saint Luke's Mid America Heart Inst, Kansas City, MO; Jin-Moo Lee, Washington Univ, Saint Louis, MO; David J Cohen, Saint Luke's Mid America Heart Inst, Kansas City, MO

Abstract Body: Background Recently, the SWIFT-PRIME trial demonstrated that among patients receiving IV-tPA for acute ischemic stroke, use of thrombectomy with Solitaire led to improved functional outcomes at 90 days. We examined the cost-effectiveness of this approach.

Methods We performed a prospective economic substudy alongside the SWIFT-PRIME trial. In-trial costs were assessed for all pts using a combination of resource-based accounting (for the thrombectomy procedure), hospital billing data (for ancillary costs), and detailed medical resource utilization. Utility weights were assessed for all pts at 30 and 90 days using the EQ-5D. Post-trial costs and life expectancy were estimated for each surviving pt using inputs derived from a cohort of ischemic stroke survivors (n= 958) whose records were linked with Medicare claims and the National Death Index.

Results From 12/2012 to 11/2014, 196 pts were randomized to Solitaire + tPA (S-T group, n=98) or tPA only (T group, n=98). Mean index hospitalization cost was $17,183/pt higher in the S-T than the T group ($45,761 vs. $28,578, p<0.001), driven mainly by initial procedure cost. Between discharge and 90 days, costs were $4904/pt lower in the S-T group ($11,270 vs. $16,174, p=0.014), due to reductions in both re-hospitalization and rehabilitation-related costs; nonetheless, total 90-day costs remained higher for the

S-T group ($57,031 vs. $44,752, p<0.001). Utility values were higher for the S-T group at both 30 and 90 days, leading to higher in-trial quality-adjusted life years [QALYs] (0.131 vs. 0.105, p=0.005). In life-time projections, S-T was projected to lead to substantial gains in QALYs (6.79 vs.5.05) and overall savings of $23,203/pt. S-T was economically dominant in 90% of bootstrap replicates and cost-effective at a threshold of $50,000/QALY in 100%—results that were robust across a range of sensitivity and subgroup analyses.

Conclusions Among pts with acute ischemic stroke enrolled in SWIFT-PRIME, thrombectomy with Solitaire was associated with higher initial treatment costs, but was projected to improve outcomes and reduce overall health care costs over a lifetime horizon compared with IV-tPA alone.

Author Disclosure Block: **T.I. Shireman:** None. **K. Wang:** None. **J.L. Saver:** Consultant/Advisory Board; Modest; Stryker, Neuravia, Cognition Medical, Boehringer Ingelheim (prevention only). Consultant/Advisory Board; Significant; Medtronic. **M. Goyal:** Research Grant; Significant; Medtronic Neurovascular. Consultant/Advisory Board; Significant; Medtronic Neurovascular. **A. Bonafe:** Consultant/Advisory Board; Modest; Medtronic Neurovascular. **H. Diener:** Research Grant; Modest; German Research Council, German Ministry of Education and Research, European Union, NIH, Bertelsmann Foundation. Other Research Support; Modest; AstraZeneca, GSK, Boehringer Ingelheim, Lundbeck, Novartis, Janssen-Cilag, Sanofi-Aventis, Syngis, Talecris. Consultant/Advisory Board; Modest; Abbott, Allergan, AstraZeneca, Bayer Vital, BMS, Boehringer Ingelheim, CoAxia, Corimmun, Covidien, Daiichi-Sankyo, D-Pharm, Fresenius, GlaxoSmithKline, Janssen-Cilag, Johnson & Johnson, Knoll, Lilly, MSD, Medtronic, Mindframe, Neurobiological Technologies, Novartis, Novo-Nordisk, Paion, Parke-Davis, Pfizer, Sanofi-Aventis, Schering-Plough, Servier, Solvay, Syngis, Talecris, Thrombogenics, WebMD Global, Wyeth, Yamanouchi. **E.I. Levy:** Honoraria; Modest; Medtronic Neurovascular. Expert Witness; Significant; Renders Medical/Legal Opinions. Ownership Interest; Modest; Intratech Medical, Ltd, Blockade Medical LLC. Ownership Interest; Significant; Medina Medical Inc. Consultant/Advisory Board; Modest; Pulsar, Blockade Medical LLC. Consultant/Advisory Board; Significant; Medina Medical Inc. Other; Modest; Abbott. **V.M. Pereira:** Consultant/Advisory Board; Modest; Medtronic Neurovascular, Stryker. **G.W. Albers:** Research Grant; Significant; NIH. Ownership Interest; Significant; iSchemaView. Consultant/Advisory Board; Significant; iSchemaView. **C. Cognard:** Consultant/Advisory Board; Modest; Medtronic Neurovascular, Stryker, Microvention, Sequent, Codman. **W. Hacke:** Research Grant; Significant; Boehringer Ingelheim. Speakers' Bureau; Modest; Boehringer Ingelheim, Bayer, Daichi Sankyo. Consultant/Advisory Board; Modest; Boehringer Ingelheim, Daichi Sankyo, Medtronic Neurovascular. **O. Jansen:** Consultant/Advisory Board; Modest; Medtronic Neurovascular. **T.G. Jovin:** Research Grant; Significant; Fundacio Ictus Malaltia Vascular (recipient of unrestricted grant by Medtronic Neurovascular). Ownership Interest; Modest; Silk Road Medical. Consultant/Advisory Board; Modest; Medtronic Neurovascular, Silk Road Medical, Stryker, Air Liquide. **H.P. Mattle:** Speakers' Bureau; Modest; Bayer, Biogen, Medtronic Neurovascular, Daiichi Sankyo, Novartis, Sanofi/Genzyme, Serono, Teva. Consultant/Advisory Board; Modest; AstraZeneca, Bayer, Biogen, Boehringer Ingelheim, Daiichi Sankyo, Genzyme, Merck-Serono, Medtronic, Neuravi, Novartis, Pfizer, Sanofi/Genzyme, Servier. **R.G. Nogueira:** Consultant/Advisory Board; Modest; Medtronic Neurovascular, Stryker Neurovascular, Penumbra, Rapid Medical. **A.H. Siddiqui:** Research Grant; Significant; NIH. Speakers' Bureau; Modest; Codman & Shurtleff, Inc.. Honoraria; Modest; Penumbra. Ownership Interest; Modest; StimSox, Blockade Medical LLC, Lazarus Effect, Pulsar Vascular, Medina Medical. Ownership Interest; Significant; Hotspur, Intratech Medical, Valor Medical. Consultant/Advisory Board; Modest; Codman & Shurtleff,

Inc., GuidePoint Global Consulting, Penumbra, Stryker, Pulsar Vascular, Lazarus Effect, Blockade Medical, Reverse Medical, ICAVL, Medina Medical. Consultant/Advisory Board; Significant; Medtronic Neurovascular, Microvention, WL Gore & Associates. **D.R. Yavagal:** Consultant/Advisory Board; Modest; Medtronic Neurovascular. Other; Modest; ESCAPE trial - DSCMB member. **T.G. Devlin:** None. **D.K. Lopes:** Honoraria; Significant; Medtronic Neurovascular. Consultant/Advisory Board; Significant; Medtronic Neurovascular. **V.K. Reddy:** None. **R. du Mesnil de Rochemont:** None. **R. Jahan:** Research Grant; Significant; Medtronic Neurovascular. Consultant/Advisory Board; Significant; Medtronic Neurovascular. **K.A. Vilain:** None. **J. House:** None. **J. Lee:** None. **D.J. Cohen:** Research Grant; Significant; Medtronic Neurovascular. Consultant/Advisory Board; Modest; Medtronic Neurovascular.