Late-Breaking Science Oral Abstracts I

Wednesday, February 17, 2016, 3:30 pm - 5:00 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: LB3

Publishing Title: ARTSS-2: Final Results of a Pilot, Phase IIb, Randomized, Multi-center Trial of Argatroban in Combination With Recombinant Tissue Plasminogen Activator for Acute Stroke

Author Block: Andrew Barreto, Univ of Texas Health Science Ctr at Houston, Houston, TX; Gary A Ford, Univ of Oxford, Oxford, United Kingdom; Loren Shen, Univ of Texas Health Science Ctr at Houston, Houston, TX; Claire Macdonald, Newcastle Univ, Newcastle, United Kingdom; Claudia Pedroza, Jon Tyson, Chunyan Cai, Mohammad H Rahbar, Univ of Texas Health Science Ctr at Houston, Houston, TX; Andrei V. Alexandrov, Univ of Tennessee Health Science Ctr, Memphis, TN; Bart Piechowski-Jozwiak, King's Coll Hosp NHS Fndn Trust, London, United Kingdom; Steven Levine, SUNY Downstate Medical Ctr, Brooklyn, NY; Christine Roffe, Royal Stoke Univ Hosp, Stoke-on-Trent, United Kingdom; Navdeep Sangha, Kaiser Permanente, Los Angeles, CA; Anand Dixit, Royal Victoria Infirmary, Newcastle upon Tyne, United Kingdom; Michael Mullen, Hosp of Univ of Pennsylvania, Philadelphia, PA; Martin James, Royal Devon & Exeter Fndn NHS Trust, Exeter, United Kingdom; James Frey, Barrow Neurological Inst, Phoenix, AZ; Usman Khan, St George's Healthcare NHS Trust, London, United Kingdom; John J Volpi, Methodist Hosp, Houston, TX; Richard Perry, Univ Coll London Hosp NHS Fndn Trust, London, United Kingdom; Jesse Dawson, Western Infirmary, Glasgow, United Kingdom; James C Grotta, Clinical Innovation and Res Inst, Houston, TX; for the ARTSS-2 Trial Investigators

Abstract Body: **Background and Objectives:**

Recombinant tissue plasminogen activator (tPA), fails to reperfuse
most large artery strokes. Concomitant thrombin-inhibition with IV-argatroban may be safe and improve recanalization. This study intended to estimate safety and benefit among tPA treated stroke patients randomized to also receive either low-dose argatroban, high-dose argatroban, or neither.

Methods:

Ischemic strokes (ages ≥18 and mRS 0 or 1) with intracranial occlusions or NIHSS ≥10 were given 0.9mg/kg IV tPA within 4.5 hours. During IV-tPA, patients were randomized 1:1:1 to receive a 100 µg/kg bolus of argatroban followed by a 48-hour infusion of 1 µg/kg/min (low-dose arm), 3 µg/kg/min (high-dose arm) or no argatroban (control arm). Infusions were adjusted to target aPTT 1.75 or 2.25 times

baseline. Endovascular therapy was excluded. Blinded personnel determined outcomes. Primary safety outcome was incidence of symptomatic intracerebral hemorrhage (sICH). Primary clinical outcome was excellent recovery (mRS 0-1) at 90-days. Unadjusted and adjusted analyses were performed using frequentist and Bayesian (neutral prior centered at RR=1.0) Poisson regression to estimate relative risk (RR).

Results:

The trial was prematurely terminated after beneficial results of embolectomy trials. Between 12/11-03/15, 90 of planned 105 patients were randomized. See table for baseline characteristics & figures for unadjusted results. Overall, 9 (10%) sICH occurred with lowest RR in the high-dose argatroban arm. Argatroban patients had higher rates of excellent recovery (31.2% combined) compared to tPA alone (20.7%). Adjusted analyses demonstrated similar direction of benefit and a 79% posterior probability that combination therapy (low+high-dose) is superior to tPA alone (RR>1).

Conclusion:

In patients treated with IV tPA, adjunctive argatroban seems safe and clinical benefit warrants further study in a definitive efficacy trial.

Variable	Control (tPA-alone) N=29	Low-Dose Argatroban + tPA N=30	High-Dose Argatroban + tPA N=31
Age, mean ± SD	68.9 ± 15.4	70.9 ± 15.1	67.1 ± 13.4
Male, n (%)	17 (58.6)	17 (56.7)	16 (51.6)
Ethnicity, n (%)			
White/Caucasian	15 (51.7)	13 (43.3)	15 (48.4)
Hispanic	2 (6.9)	4 (13.3)	4 (12.9)
Black	11 (37.9)	13 (43.3)	11 (35.5)
Asian	1 (3.5)	0 (0)	1 (3.2)
Past Medical History, n (%)			
Prior stroke	3 (10.3)	3 (10.0)	5 (16.1)
Hypertension	25 (86.2)	24 (80.0)	25 (80.7)
Diabetes mellitus	6 (21.4)	10 (33.3)	0 (29.0)
Congestive heart failure	6 (20.7)	1 (3.3)	6 (19.4)
Atrial fibrillation	5 (17.2)	7 (23.3)	11 (35.5)
Stroke onset to tPA, minutes	114.2 ± 42.8	133.7 ± 51.6	114.3 ± 46.3
Baseline NIHSS, median (IQR)	15 (11, 20)	16 (11, 21)	13 (7, 17)
Stroke Location, n (%)			
Left Anterior Hemisphere	9 (31.0)	10 (33.3)	13 (41.9)
Right Anterior Hemisphere	15 (51.7)	17 (56.7)	17 (54.8)
Posterior circulation	5 (17.2)	3 (10.0)	1 (3.2)
Glucose, median, range	123, 69-418	130, 88-309	125, 86-494
Clot location, n (%)	*N=10*	*N=18*	*N=17*
MCA (M1 or proximal M2)	8 (80.0)	14 (77.8)	15 (88.2)
Terminal ICA	2 (20.0)	2 (11.1)	2 (11.8)
Vertebrobasilar	0 (0)	2 (11.1)	0 (0)
ASPECTS score, median (IQR)	10 (8, 10)	8 (6, 10)	9 (8, 10)

No baseline characteristics differed significantly across study arms (p<0.05).

Fig. 1

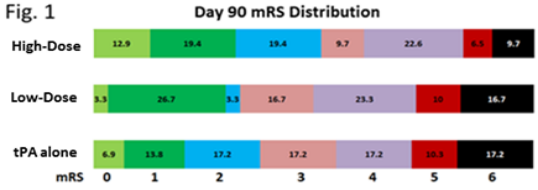
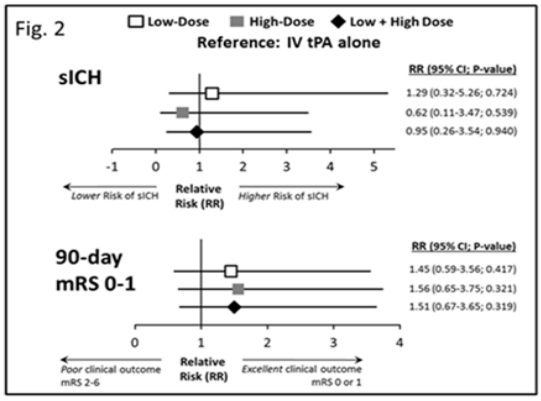


Fig. 2



Author Disclosure Block: **A. Barreto:** None. **G.A. Ford:** None. **L. Shen:** None. **C. Macdonald:** None. **C. Pedroza:** None. **J. Tyson:** None. **C. Cai:** None. **M.H. Rahbar:** None. **A.V. Alexandrov:** None. **B. Piechowski-Jozwiak:** None. **S. Levine:** None. **C. Roffe:** None. **N. Sangha:** None. **A. Dixit:** None. **M. Mullen:** None. **M. James:** None. **J. Frey:** None. **U. Khan:** None. **J.J. Volpi:** None. **R. Perry:** None. **J. Dawson:** None. **J.C. Grotta:** Research Grant; Modest; Genetech. Consultant/Advisory Board; Modest; Stryker, Frazer.

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Presentation Number: LB4

Publishing Title: ICTuS-2 Final Results

Author Block: Patrick Lyden, Cedars-Sinai Medical Ctr, Los Angeles, CA; Thomas Hemmen, Karen Rapp, Karin Ernstrom, Univ of California, San Diego, CA; Sachin Agarwal, Columbia Univ, New York, NY; Mauricio Concha, Intercoastal Medical Group, Sarasota, FL; Syed Hussain, Michigan State Univ, East Lansing, MI; Guy Dugan, Alexian Brothers Medical Ctr, Elk Grove Village, IL; Rema Raman, Univ of Southern California, Los Angeles, CA; James Grotta, Memorial Herman Health Care System, Houston, TX

Abstract Body: Background: The ICTuS 2/3 (NCT01123161) trial was a prospective, randomized, blinded endpoint, multi-center Phase 2/3 study sponsored by NINDS testing the combination of IV thrombolysis and hypothermia vs IV thrombolysis alone for acute ischemic stroke. Design: the protocol was enhanced based on excessive pneumonia during cooling in the prior ICTuS-L trial. We sought 1850 ischemic stroke patients treated with IV rt-PA, NIHSS > 7 and ≤20 (left brain) or < 24 (right brain stroke), age 22-82. Outcome: 90 day Modified Rankin score of 0 or 1. Intervention: Hypothermia with intravenous cold saline, an endovascular cooling device for 24 hours, and controlled warming for another 12 hours. Anti-shivering measures (meperidine, buspirone, skin warming) were utilized throughout the 36-hour period. Due to the publication of successful neurothrombectomy trials, we closed enrollment on 12/31/2014. Results: At closure, we had enrolled 120 patients: 16 (13%) early responders were not treated but included in the intention to treat (ITT) analysis. Four additional patients were excluded from the per protocol (PP) analysis due to disallowed procedures. The ITT primary outcome was seen in 33% of the hypothermia and 38% of the normothermia treated patients, OR (95% CL) 0.81 (0.35,1.85). Using severity adjusted outcomes based on initial NIHSS, the ITT adjusted OR was 1.37 (0.60,3.19). The PP severity adjusted outcomes OR was 0.89 (0.34,2.30), also not significant. In 33 selected patients reaching core body temperature 35°C within 6 hours of cooling onset, the 90-day mRS 0,1 was 24% compared to 38% in 47 normothermia patients, the OR was 0.52 (0.16,1.52). The incidence of serious adverse events was similar between the groups. Mortality was 8.8% in the normothermia vs. 15.9% in the hypothermia group, for an OR of 1.95 (0.56,7.79). Pneumonia was seen more often in the hypothermia group, 19% vs 10.5%, OR 1.99 (0.63,6.98), an increase similar to that seen in the ICTuS-L trial, suggesting that ICTuS 2 prevention measures did not succeed in reducing pneumonia risk. Conclusion: No statistically significant differences between the groups were noted, as expected, due to the small sample size. Future studies must address improved time to cooling and further clarify the optimal treatment duration.

Author Disclosure Block: **P. Lyden:** None. **T. Hemmen:** None. **K. Rapp:** None. **K. Ernstrom:** None. **S. Agarwal:** None. **M. Concha:** None. **S. Hussain:** None. **G. Dugan:** None. **R. Raman:** None. **J. Grotta:** None.

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Presentation Number: LB5

Publishing Title: High-dose Statin Therapy After Acute Ischemic Stroke: The Phase 2 Neuroprotection with Statin Therapy for Acute Recovery Trial (NeuSTART)

Author Block: Mitchell S Elkind, Rebeca Aragon, Harmon L. Moats, Tomoko Kitago, Columbia Univ, New York, NY; Mandip S Dhamoon, Mount Sinai Sch of Med, New York, NY; Steven K Feske, Harvard Medical Sch, Boston, MA; Michael Frankel, Emory Univ, Atlanta, GA; Michael T Mullen, Univ of Pennsylvania, Philadelphia, PA; Jose G Romano, Univ of Miami, Miami, FL; Sidney Starkman, Univ of California Los Angeles, Los Angeles, CA; Howard Andrews, Ken Cheung, Columbia Univ, New York, NY

Abstract Body: BACKGROUND: HMG-CoA reductase inhibitors, or statins, reduce neuronal injury in a dose-dependent fashion in rodent stroke models. We sought to determine whether lovastatin at doses above those currently approved can be administered safely within 24 hours after acute ischemic stroke.

METHODS: We conducted a Phase 2, multicenter, double-blind, randomized feasibility, safety, and pilot efficacy study in which ischemic stroke patients were randomly assigned within 24 hours of symptom onset to placebo (for those not already taking statins) or standard dose lovastatin (for those on statins) versus short-term high-dose lovastatin (640 mg per day for 3 days). Treatment was administered in 12 divided oral doses over 3 days. The primary outcome was musculoskeletal and hepatic toxicity, defined by clinical and laboratory criteria, within a 3 month follow-up period. Secondary outcomes included neurological (NIH Stroke Scale) and functional outcomes (Barthel Index and modified Rankin scores). Effects on inflammatory markers and lipid levels will also be assessed.

RESULTS: We enrolled 163 patients at 8 centers (78 Hispanic, 40 non-Hispanic white, 38 non-Hispanic black, 5 Asian, and 2 other); 53.4% were men. Over 90% of patients (n=148) received at least 9 treatment doses, and 68% (n=111) received all 12 doses. Three patients (<2%) developed a primary safety outcome, based on hepatic enzyme values within one week; there were no clinical liver sequelae, nor any muscle enzyme or myopathic clinical sequelae. Data safety monitoring board review identified no concerns about adverse events. Final three month follow-up visits were complete as of November 1, 2015, and all data will be available, close out visits completed, and data cleaned by December 1, 2015, after which the blind will be broken.

CONCLUSIONS: Lovastatin at doses above those currently FDA-approved is feasible for 3 days after acute ischemic stroke and associated with low risk of hepatic and muscle toxicity. Three-month outcome data will facilitate design of potential phase 3 studies of high-dose statin therapy for acute stroke

Author Disclosure Block: **M.S.V. Elkind:** Expert Witness; Modest; BMS-Sanofi. Consultant/Advisory Board; Modest; BMS-Pfizer, Boehringer-Ingelheim, Sanofi-Regeneron, BioTelemetry/Cardionet.

Research Grant; Significant; BMS-Sanofi, diaDexus. Consultant/Advisory Board; Significant; Hi-Tech. **R. Aragon:** None. **H.L. Moats:** None. **T. Kitago:** None. **M.S. Dhamoon:** None. **S.K. Feske:** None. **M. Frankel:** None. **M.T. Mullen:** None. **J.G. Romano:** Research Grant; Modest; Genentech. Consultant/Advisory Board; Modest; Vycor/Novavision, Genentech. **S. Starkman:** None. **H. Andrews:** None. **K. Cheung:** None.

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Presentation Number: LB6

Publishing Title: GAMES (Glyburide Advantage in Malignant Edema and Stroke) RP: A Phase II Study Toward Preventing Edema After Ischemia

Author Block: Kevin N Sheth, Yale Univ, New Haven, CT; Jordan J Elm, Medical Univ of South Carolina, Charleston, SC; Holly Hinson, Oregon Health Sciences, Portland, OR; Bradley Molyneaux, Univ of Pittsburgh, Pittsburgh, PA; Lauren A. Beslow, Gordon Sze, Yale Univ, New Haven, CT; Ann-Christian Ostwaldt, Massachusetts General Hosp, Boston, MA; Gregory del Zoppo, Univ of Washington, Seattle, WA; J. Marc Simard, Univ of Maryland, Baltimore, MD; W. Taylor Kimberly, Massachusetts General Hosp, Boston, MA; GAMES Investigators

Abstract Body: Objective: The primary objective is to assess the safety and preliminary efficacy of intravenous glyburide (RP-1127) compared to placebo in ischemic stroke patients who are at high risk for developing malignant edema. Here, we examine 6 month outcomes.

Background: Patients with large territory ischemic stroke are at high risk for cerebral edema and death. There is no available pharmacotherapy for the prevention of cerebral edema after stroke.

Design/Methods: GAMES-RP was a double-blind, randomized, placebo controlled phase 2 study. Patients presenting to 18 centers with baseline stroke lesion volumes between 82 and 300 cm3 on magnetic resonance imaging were randomized 1:1 to study drug or placebo. Eligible patients had a baseline lesion between 82 cm3 and 300 cm3, age 18-80 years, and time from symptom onset to drug infusion of ≤ 10 hours. Patients were treated with either RP-1127 (n=44) or placebo control (n=39) as a bolus followed by a continuous 72 hour infusion. The primary safety outcome was the frequency and severity of adverse events (SAE). The primary efficacy outcome was a composite of the modified Rankin Scale (mRS) and the incidence of decompressive craniectomy (DC), assessed at 90 days and 6 months.

Results: There was no difference in the frequency of SAE between RP-1127 and placebo (68% versus 72%, p= 0.72). There was no difference in the composite primary outcome of avoidance of DC and mRS 0-4 at 90 days (p=0.77). Patients in the RP-1127 group had 61% decreased deaths at 30 days (14% versus 36%, p=0.03) and decreased midline shift at 72-96 hours (4.4 ± 3.6 mm versus 8.8 ± 4.9 mm, p=0.0006). Six month mRS will be obtained and analyzed.

Conclusions: RP-1127 was safe but the trial did not meet the primary efficacy outcome. Among patients with large hemispheric stroke at risk for cerebral edema, RP-1127 may reduce mortality and midline shift. Further prospective study is warranted to confirm these findings.

Registry: NCT01794182

Author Disclosure Block: **K.N. Sheth:** Research Grant; Significant; Remedy. **J.J. Elm:** Research Grant; Significant; Remedy, NIH. **H. Hinson:** None. **B. Molyneaux:** None. **L.A. Beslow:** Research Grant; Significant; Remedy. **G. Sze:** Research Grant; Significant; Remedy. **A. Ostwaldt:** None. **G. del Zoppo:** None. **J.M. Simard:** Ownership Interest; Significant; Remedy. **W.T. Kimberly:** Research Grant; Significant; Remedy, NIH.

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Presentation Number: LB7

Publishing Title: Time is Brain in Endovascular Thrombectomy: Results From Individual Patient Pooled Data Analysis of Mr Clean, Escape, Extend IA, Swift Prime and Revascat

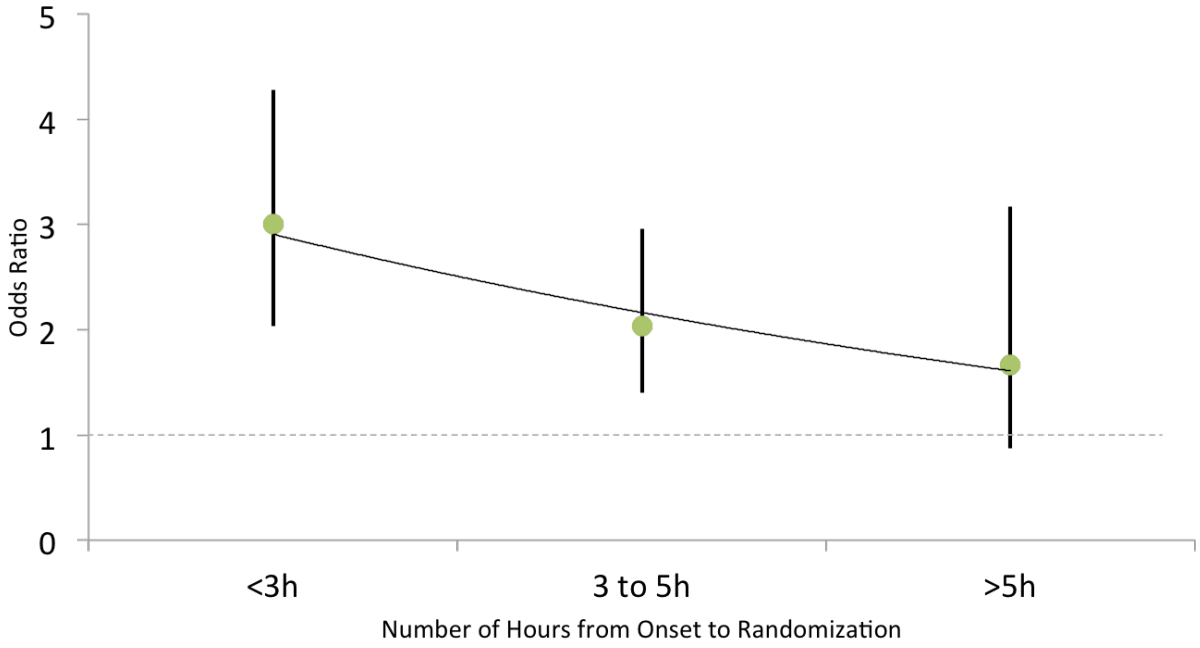
Author Block: Jeffrey L Saver, UCLA, Los Angeles, CA; Mayank Goyal, Univ of Calgary, Calgary, AB, Canada; Aad van der Lugt, Erasmus MC, Univ Medical Ctr Rotterdam, Rotterdam, Netherlands; Andrew M Demchuk, Univ of Calgary, Calgary, AB, Canada; Charles B.L.M. Majoie, Academic Medical Ctr, Amsterdam, Netherlands; Diederik W Dippel, Erasmus MC, Univ Medical Ctr Rotterdam, Rotterdam, Netherlands; Bruce C Campbell, Univ of Melbourne, Melbourne, Australia; Vitor M Pereira, Univ of Toronto, Toronto, ON, Canada; Bijoy K Menon, Univ of Calgary, Calgary, AB, Canada; Alejandro Tomasello, Hosp Vall d'Hebron, Barcelona, Spain; Pere Cardona, Hosp de Bellvitge, L'Hospet de Llobregat, Barcelona, Spain; Hans-Christoph Diener, Univ Hosp Duisburg-Essen, Essen, Germany; Donald F Frei, Swedish Medical Ctr, Englewood, CO; Elad I Levy, SUNY Buffalo, Buffalo, NY; Olvert A Berkhemer, Academic Medical Ctr, Amsterdam, Netherlands; Reza Jahan, UCLA, Los Angeles, CA; Alain Bonafe, Hop Gui-de-Chauliac, Montpellier, France; Wim H van Zwam, Maastricht Univ Medical Ctr, Maastricht, Netherlands; Stephen M Davis, Univ of Melbourne, Melbourne, Australia; Carlos Castano, Hosp Germans Trias i Pujol, Barcelona, Spain; Biggya L Sapkota, Erlanger Medical Ctr, Chattanooga, TN; Puck S Fransen, Erasmus MC, Univ Medical Ctr Rotterdam, Rotterdam, Netherlands; Carlos Molina, Hosp Vall d'Hebron, Barcelona, Spain; Robert J van Oostenbrugge, Maastricht Univ Medical Ctr, Maastricht, Netherlands; Angel Chamorro, Hosp Clinic, Barcelona, Spain; Hester Lingsma, Erasmus MC, Univ Medical Ctr Rotterdam, Rotterdam, Netherlands; Frank L Silver, Univ Health Network, Toronto, ON, Canada; Geoffrey A Donnan, Florey Inst, Melbourne, Australia; Ashfaq Shuaib, Univ of Alberta, Edmonton, AB, Canada; Bruce Stouch, Philadelphia Coll of Osteopathic Med, Philadelphia, PA; Peter J Mitchell, Univ of Melbourne, Melbourne, Australia; Antoni Davalos, Hosp Germans Trias i Pujol, Barcelona, Spain; Yvo B.W.E.M Roos, Academic Medical Ctr, Amsterdam, Netherlands; **Michael D Hill**, Univ of Calgary, Calgary, AB, Canada

Abstract Body: Background: Five recent trials showed benefit of endovascular treatment for acute anterior circulation ischemic stroke due to large vessel occlusion (LVO). All the trials used newer thrombectomy devices (stent retrievers) predominantly among patients randomized to the endovascular arm.

Methods: We performed a prespecified time analysis of the Highly Effective Reperfusion evaluated in Multiple Endovascular Stroke (HERMES) database, comprising individual patient data from MR CLEAN (permitted entry up to 6 hour post-onset), ESCAPE (up to 12 hours), EXTEND-IA (up to 6 hours), SWIFT PRIME (up to 6 hours), and REVASCAT (up to 8 hours).

Results: Among 1287 patients (intervention 634 [49.3%], control 653 [50.7%]), the two arms were well-matched with respect to age, sex, baseline NIHSS and time to randomization. More control patients received IV tPA (p=0.042). Workflow time intervals were: onset to door - 118 ± 85 mins; door to tPA - 26 ± 59 mins; door to puncture - 129 ± 159 mins; onset to randomization - 214 ± 97 mins; randomization to puncture - 66 ± 251 mins; puncture to reperfusion (TICI 2/b3) - 35 ± 22 mins; onset to reperfusion - 299 ± 127 mins. The benefit of thrombectomy showed strong time dependence (Figure). Adjusted odds ratios for functional independence (mRS 0-2) at 90d for endovascular vs control declined from 3.00 (95%CI 2.03-4.28) for time to randomization (TTR) within 3h of onset, to 2.03 (95%CI 1.40-2.96) for TTR in 3-5h, and 1.66 (0.87-3.17) for TTR in 5-7h. Effects of time delay were more marked in patients ineligible for IV tPA than in patients co-treated with IV tPA. Mortality and sICH rates also showed important time dependence.

Interpretation: The benefits of endovascular thrombectomy over medical treatment for acute ischemic stroke due to LVO decline substantially with time from onset. These findings emphasize the importance of implementing quality improvement processes to accelerate thrombectomy treatment times.



Author Disclosure Block: **J.L. Saver:** Consultant/Advisory Board; Modest; Stryker, Neuravi, Cognition Medical, Boehringer Ingelheim. Consultant/Advisory Board; Significant; Medtronic. **M. Goyal:** Research Grant; Significant; Grant to the University of Calgary from Medtronic to support the ESCAPE trial to the University of Calgary from Medtronic to support the ESCAPE trial, Consulting fee from Medtronic for design and conduct of the SWIFT-PRIME trial. Speakers' Bureau; Significant; Medtronic consulting fee. **A. van der Lugt:** None. **A.M. Demchuk:** Research Grant; Significant; Grant to the University of Calgary from Medtronic to support the ESCAPE trial to the University of Calgary from Medtronic to support the ESCAPE trial. **C.B. Majoie:** Speakers' Bureau; Modest; Stryker Lecture fee payment. **D.W.J. Dippel:** None. **B.C.V. Campbell:** Research Grant; Modest; Medtronic, Royal Melbourne Hospital Foundation, National Heart Foundation. **V.M. Pereira:** Consultant/Advisory Board; Modest; Medtronic, Stryker. **B.K. Menon:** Research Grant; Significant; Grant to the University of Calgary from Medtronic to support the ESCAPE

trial to the University of Calgary from Medtronic to support the ESCAPE trial. **A. Tomasello:** None. **P. Cardona:** None. **H. Diener:** Consultant/Advisory Board; Modest; Abbott, Allergan, AstraZeneca, Bayer Vital, BMS, Boehringer Ingelheim, CoAxia, Corimmun, Covidien AG, Daichi-SankyoS, D-Pharm. **D.F. Frei:** Consultant/Advisory Board; Significant; Penumbra. **E.I. Levy:** Honoraria; Modest; Medtronic. Ownership Interest; Modest; Intratech Medical, Blockade Medical. Ownership Interest; Significant; Medina Medical Inc. Consultant/Advisory Board; Significant; Medina Medical Inc.. Other; Modest; Abbott. **O.A. Berkhemer:** None. **R. Jahan:** Research Grant; Significant; Medtronic. Consultant/Advisory Board; Significant; Medtronic. Other; Significant; Medtronic. **A. Bonafe:** Consultant/Advisory Board; Modest; Medtronic. **W.H. van Zwam:** None. **S.M. Davis:** Honoraria; Modest; Medtronic. **C. Castano:** None. **B.L. Sapkota:** None. **P.S.S. Fransen:** None. **C. Molina:** None. **R.J. van Oostenbrugge:** None. **A. Chamorro:** None. **H. Lingsma:** None. **F.L. Silver:** None. **G.A. Donnan:** Honoraria; Modest; Boehringer Ingelheim, Sanofi, Pfizer, Bayer. Other; Modest; Astra Zeneca, Bristol Meyers Squibb, Merck Sharp & Dome. **A. Shuaib:** None. **B. Stouch:** Research Grant; Modest; Medtronic. **P.J. Mitchell:** None. **A. Davalos:** Research Grant; Significant; Grant from Medtronic for the REVASCAT trial. Consultant/Advisory Board; Modest; Medtronic. **Y.B. Roos:** None. **M.D. Hill:** Consultant/Advisory Board; Modest; Adjudication panel for Merck for a clinical trials outcomes panel.. Research Grant; Significant; Research grant to the University of Calgary from Covidien AG for the ESCAPE trial. Other Research Support; Significant; Drug in kind support for the TEMPO-1 trial from Hoffmann-La Roche Canada Ltd. Ownership Interest; Significant; Calgary Scientific Inc..

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Presentation Number: LB8

Publishing Title: Virtual Reality in Stroke Rehabilitation: Results From EVREST Multicenter Trial

Author Block: Gustavo Saposnik, Ctr for Virtual Reality Studies, St Michael's Hosp, Univ of Toronto, Toronto, ON, Canada; Robert Teasell, Parkwood Hosp, London, ON, Canada; Michelle Ploughman, L.A. Miller Ctr, Newfouland, NL, Canada; Sean Dukelow, Univ of Calgary, Calgary, AB, Canada; Peter Nord, Providence health Care, Toronto, ON, Canada; Sepideth Pooyania, Riverview health Ctr, Winnipeg, MB, Canada; Lisandro Olmos, FLENI, Buenos Aires, Argentina; Felipe De los Rios, SANNA, Lima, Peru; Yongchai Nilanont, Siriraj Hosp, Bangkok, Thailand; Ashley Cohen, St Michael's Hosp, Li Ka Shing Knowledge Inst, Toronto, ON, Canada; Donna Cheung, St Michael's Hosp, Univ of Toronto, Toronto, ON, Canada; Sandy Kandola, Judith Hall, St Michael's Hosp, Dept of Health Policy, Management and Evaluation, Univ of Toronto, Toronto, ON, Canada; Jennifer Shaw, Toronto Rehabilitation Inst, Toronto, ON, Canada; Mindy Levin, McGill Univ, Montreal, QC, Canada; Leonardo G. Cohen, NINDS, NIH, Bethesda, WA; Muhammad Mamdani, Andreas Laupacis, St Michael's Hosp, Dept of Health Policy, Management and Evaluation, Univ of Toronto, Toronto, ON, Canada; Mark Bailey, Toronto Rehabilitation Inst, Univ of Toronto, Toronto, ON, Canada; on behalf of the Stroke Outcomes Research Canada (SORCan); for the EVREST Multicenter Study Group

Abstract Body: INTRODUCTION:

Small, single center studies suggest modest benefits of virtual reality (VR) in motor recovery after stroke. Despite the limited evidence, VR is commonly used as a rehabilitation strategy. We aimed to compare the effect of VR after stroke in a multicenter trial.

HYPOTHESIS:

VR after stroke results in better motor recovery relative to recreational activities as add-on therapies to conventional rehabilitation.

METHODS:

A single-blind, RCT at 12 stroke rehabilitation units in 4 countries. Adults 3 were randomized to receive VR using the Nintendo Wii™ gaming system (VRWii) vs. recreational activities (card-playing, 'Jenga', domino) (RA). The use of an active control (RA) provides a fair time comparison to evaluate the effect of VR.

All participants received usual care consisting of conventional rehabilitation at each center. Participants received an intensive program of 10 sessions of either VR or RA, 60 minutes each, over a 2-week period.

The primary outcome was a difference in motor performance between groups using the Wolf Motor Function test (WMFT) at the end of the intervention.

RESULTS:

Between May 2012 and Oct, 2015, 141 patients received either VRWii (n=71) or RA (n=70). Mean age was 62±12 years. Mean time of conventional rehabilitation during the trial was similar between groups (VRWii: 377 min vs. RT: 400 min; p=0.70).

There was no difference in the total duration of each intervention (VRWii 528±155 min vs RA 541±142; p=0.60). No difference in stroke severity between groups.

From baseline to the end of intervention, both groups showed improvements in the WMFT performance time (decrease in mean time from 91.9 to 64.1 seconds [30.3% reduction] for VRWii vs. from 68.4 to 39.8 seconds [41.8% reduction] for RA).

Multivariable analysis revealed no significant difference between groups post-intervention (adjusted estimate 3.92, SEM 9.12; p=0.67) or in the follow up 4-weeks post-intervention (-2.68, SEM 6.67; p=0.66). There were no SAE related to the interventions. Analysis for secondary outcomes is underway.

CONCLUSIONS:

This RCT suggests no significant benefits of VR as an add-on therapy to conventional rehabilitation when compared to an active control.

ClinicalTrials.gov: NCT01406912

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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: LB9

Publishing Title: Results of the Pragmatic Ischaemic Thrombectomy Evaluation (PISTE) Trial

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Abstract Body: Background: The Pragmatic Ischaemic Thrombectomy Evaluation (PISTE) trial was a UK-based, multicentre randomised, controlled clinical trial comparing intravenous thrombolysis (IVT) alone with IVT and adjunctive intra-arterial thrombectomy (IAT) in acute ischaemic stroke patients with large artery occlusive (LAO) anterior circulation stroke (involving internal carotid artery, middle cerebral artery M1 or M2 branches) confirmed on CT angiography (CTA). Enrolment was suspended in April 2015 after presentation of other thrombectomy trial results and formally ended in July 2015. Methods: Eligible patients had IVT commenced within 4.5h of stroke symptom onset and LAO proven on CTA. Those randomised to additional IAT underwent thrombectomy using any CE-marked device, with target interval times for IVT start to arterial puncture of <90 minutes, IVT start to target vessel instrumentation of <120 minutes. All patients had repeat CT and CTA at 24h and modified Rankin Scale (mRS) at day 90. Results: Eleven UK centres enrolled 65 patients between and April 2013 and April 2015. Mean age was 64 years (range 53-89), median NIH stroke scale score 16 (IQR 13-21). Median onset to IVT start was 118 mins and to randomisation 149 mins. In the IAT arm, median interval from IVT start to arterial puncture was 82 mins and total procedure duration 60 mins. Primary and secondary outcome data will be presented. Conclusions: PISTE uniquely investigated a strategy of proceeding as fast as possible to IAT after CTA confirmation of relevant occlusion, without requiring additional tissue imaging or deferring enrolment to assess the effect of IVT. Enrolment of patients within times for IV thrombolysis initiation and IAT comparable to other international thrombectomy trials was achieved

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