

Late-Breaking Science Oral Abstracts

Thursday, February 23, 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: LB4

Presentation Title: Intensive Versus Guideline Antiplatelet Therapy For Preventing Recurrence In Patients With Acute Ischaemic Stroke Or TIA: Main Results From The Triple Antiplatelets For Reducing Dependency In Ischaemic Stroke (TARDIS) Trial

Author Block: Philip M Bath, Lisa J Woodhouse, Katie Flaherty, Diane Havard, Timothy J England, Nikola Sprigg, Univ of Nottingham, Nottingham, United Kingdom

Abstract Body: Background: The risk of recurrence following ischaemic stroke (IS) or transient ischaemic attack (TIA) is high, especially immediately after the event. One antiplatelet agent is more effective than none, and two are superior to one, so more intensive treatment might be even more effective in preventing recurrence. **Methods:** TARDIS was an international prospective randomised open-label blinded-endpoint controlled trial. Patients with acute (<48 hours) non-cardioembolic IS or TIA were randomised to intensive antiplatelet therapy (combined aspirin, clopidogrel and dipyridamole) or guideline antiplatelets (clopidogrel alone, or combined aspirin and dipyridamole) given for one month. The primary outcome was stroke and TIA recurrence, and their severity (modified Rankin Scale), at 3 months. Patients (relatives) gave written informed (proxy) consent and all sites had research ethics approval. Funding was from the British Heart Foundation and NIHR Health Technology Assessment programme. **Results:** The Independent Data Monitoring Committee recommended stopping the trial in March 2016 since a definitive result had been reached. 3,096 (of a planned 4,100) patients were enrolled from 106 sites in 4 countries between April 2009 and March 2016 (with 71% patients recruited from October 2012). At baseline: mean age 69; male 63%; recruitment from UK 95%; prior stroke 11%; diabetes 19%; index event IS 70%, TIA 30%; severity of IS (National Institutes of Health Stroke Scale) 4.0; ABCD2 in TIA 5.5; onset to randomisation <12 hours 10%, <24 hours 31%. **Summary:** The main results will be available for presentation in quarter 4 2016. TARDIS is large enough to influence clinical practice.

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Presentation Number: LB5

Presentation Title: Cilostazol Versus Aspirin in Ischemic Stroke Patients With Intracerebral Hemorrhage or Multiple Microbleeds

Author Block: Sun U. Kwon Sr., Asan Medical Ctr, Seoul, Korea, Republic of; Bum Joon Kim, Kyung Hee Univ Hosp, Seoul, Korea, Republic of; Keun-Sik Hong, Ilsan Paik Hosp, Inje Univ, Ilsan, Korea, Republic of; Jong-Ho Park, Seonam Univ Myongji Hosp, Goyang, Korea, Republic of; Yong-Jae Kim, Ewha Womans Univ Sch of Med, Seoul, Korea, Republic of; Ji Sung Lee, Asan Medical Ctr, Seoul, Korea, Republic of; June-Young Lee, Korea Univ, Seoul, Korea, Republic of; Sung Hyuk Heo, Kyung Hee Univ Hosp, Seoul, Korea, Republic of; Ka Sing Wong, Prince of Wales Hosp, The Chinese Univ of Hong Kong, Hong Kong, China; Jose C Navarro, Univ of Santo Tomas Hosp, Manila, Philippines; Dong-Wha Kang, Asan Medical Ctr, Seoul, Korea, Republic of; PICASSO Investigators

Abstract Body: Background: We aimed to investigate the safety and efficacy of cilostazol in ischemic stroke patients prone for cerebral hemorrhage. **Methods:** We conducted an international, multicenter controlled trial of ischemic stroke patients with high-risk cerebral hemorrhage; patients with a history or an imaging finding of intracerebral hemorrhage or multiple microbleeds. The participants were randomly assigned to receive cilostazol (200mg/day) or aspirin (100mg/day). The co-primary endpoints of safety and efficacy which were time to event of hemorrhagic stroke and composites of stroke, myocardial infarction and vascular death were analyzed. The non-inferiority test for efficacy and superiority test for safety was performed. **Results:** Among 1512 participants, 755 received cilostazol and 757 patients received aspirin. After a mean follow-up of 2.0 years, 63 events (4.27/100 person-year) of composite vascular events occurred in the cilostazol group versus 80 events (5.33/100 person-year) in the aspirin group, and satisfied the non-inferiority of cilostazol to aspirin ($p=0.0038$). For the safety outcome, 8 events (1.1%, 0.61/100 person-year) occurred in the cilostazol group versus 16 events (2.1%, 1.20/person-year) in the aspirin group ($p=0.0916$). Stroke occurred less in the cilostazol group (48 events, 3.25/100 person-year) than in the aspirin group (73 events, 4.86/100 person-year; $p=0.0273$). However, myocardial infarction occurred more in the cilostazol group (9 events, 0.61/100 person-year) than in the aspirin group (2 events, 0.13/100 person-year; $p=0.0319$). **Conclusion:** Cilostazol can be used for secondary stroke prevention in ischemic stroke patients prone to cerebral hemorrhage as it decreased stroke in comparison to aspirin, but may need consideration for myocardial infarction risk.

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Presentation Number: LB6

Presentation Title: Resumption of Oral Anticoagulation After Intracerebral Hemorrhage is Associated With Decreased Mortality and Favorable Functional Outcome

Author Block: **Alessandro Biffi**, Massachusetts General Hosp, Boston, MA; Joji Kuramatsu, Univ of Erlangen-Nuremberg, Erlangen, Germany; Audrey Leasure, Yale Univ Sch of Med, New Haven, CT; Hooman Kamel, Weill Cornell Coll of Med, New York, NY; Christina Kourkoulis, Kristin Schwab, Alison M Ayres, M. Edip Gurol, Steven M Greenberg, Anand Viswanathan, Christopher D Anderson, Massachusetts General Hosp, Boston, MA; Stefan Schwab, Univ of Erlangen-Nuremberg, Erlangen, Germany; Jonathan Rosand, Massachusetts General Hosp, Boston, MA; Daniel Woo, Univ of Cincinnati, Cincinnati, OH; Hagen B Huttner, Univ of Erlangen-Nuremberg, Erlangen, Germany; Kevin N Sheth, Yale Univ Sch of Med, New Haven, CT

Abstract Body: Objective: To determine whether Oral Anticoagulation Treatment (OAT) resumption after primary intracerebral hemorrhage (ICH) is associated with long-term outcome.

Background: OAT resumption is a therapeutic dilemma in post-ICH care, particularly for lobar hemorrhages related to Cerebral Amyloid Angiopathy. However, the impact of ICH location on functional outcome after OAT resumption has not been explored.

Design/Methods: We meta-analyzed individual patient data from: 1) a multi-center OAT-ICH study conducted in Germany (n=542); 2) a longitudinal primary ICH study conducted in Boston, US (n=268); 3) the multi-center Ethnic/Racial Variations of Intracerebral Hemorrhage (ERICH) study (n=217). We determined whether, at one year from index ICH, OAT resumption was associated with: 1) mortality and 2) favorable functional outcome (modified Rankin Scale [mRS] 0-3). We separately analyzed non-lobar and lobar ICH cases using multivariable (Cox regression) models, adjusting for ICH volume, discharge mRS, CHADS2 and HAS-BLED scores.

Results: We included 641 non-lobar OAT-ICH and 386 lobar OAT-ICH survivors. Among non-lobar ICH survivors 179/641 (28%) resumed OAT, while 88/386 (23%) lobar ICH survivors did. ICH volume, CHADS2 and HAS-BLED scores were not associated with OAT resumption in either lobar or non-lobar ICH (all $p > 0.20$). Discharge mRS was associated with OAT resumption in lobar ICH only (OAT: median 3.5, Inter-Quartile Range [IQR] 3-5; no OAT: median 4.0, IQR 3-5; $p = 0.011$). In multivariable analyses OAT resumption after non-lobar ICH was associated with decreased mortality (Hazard Ratio [HR]=0.22, 95% Confidence Interval [CI]=0.16-0.30, $p < 0.0001$) and improved functional outcome (HR=5.12, 95% CI=3.86-6.80, $p < 0.0001$) at one year. OAT resumption after lobar ICH was associated with decreased mortality (HR=0.25, 95% CI=0.17-0.38, $p < 0.0001$) and favorable functional outcome (HR=4.89, 95% CI=3.25-7.36, $p < 0.0001$).

Conclusions: OAT resumption was associated with decreased mortality and favorable outcome after both non-lobar and lobar ICH. These findings support conducting randomized clinical trials to explore risks and benefits of OAT resumption after ICH.

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Presentation Number: LB7

Presentation Title: Efficacy and Safety of Nimodipine in Vascular Mild Cognitive Impairment:A Randomized Placebo Controlled Trial

Author Block: **Huaguang Zheng**, Tao Feng, Penglian Wang, Anxin Wang, Xingquan Zhao, Xianwei Wang, Yuesong Pan, Liping Liu, Kehui Dong, Yilong Wang, Yongjun Wang, Capital Medical Univ, Beijing Tiantan Hosp, Beijing, China

Abstract Body: Background: The efficacy and safety of the calcium antagonist nimodipine in vascular cognitive impairment without dementia(VCIND)is insufficient. We aimed to assess whether Nimodipine prevents cognition function decline in acute stroke patients with mild cognitive impairment.

Methods: We did a randomised, double-blind, placebo-controlled trial at 23 sites in the China. Eligible patients were randomly allocated (1:1) to receive 30 mg nimodipine three times a day or placebo . The primary endpoint was the change of cognition function on Mini-Mental State Examination (MMSE, change from baseline to 6 month ≤ -3) or vascular AD assessment scale cognitive subscale (V-ADAS-cog, change from baseline to 6 month ≥ 4) . Secondary endpoints included the scores change from baseline to 6 month on the Montreal cognitive assessment score (MoCA) and frontal assessment battery (FAB) . This trial is registered with ClinicalTrials.gov, number NCT00103948.

Results: 329 participants were randomly assigned to receive nimodipine and 325 to receive placebo. 476 patients fulfilled the 6-month follow up and were involved into the final analyse. Baseline was well balanced between the two groups. The primary effective outcome were similar between the two groups (For MMSE, 4.18% vs 7.22%, $R=0.56(95\% \text{ CI } 0.271-1.163)$, $p=0.15$ and for V-ADAS-cog, 8.36% vs 8.93%, $OR=0.93(0.52-1.66)$, $p=0.88$). The secondary effective outcome did not differ between the nimodipine group and the placebo group (MoCA 1.89 ± 2.98 vs 1.66 ± 3.20 , $P=0.35$, FAB 0.85 ± 2.05 vs 0.67 ± 2.27 , $P=0.32$). For separated Cognitive domains evaluated , abstraction by MoCA scale (1.37 ± 0.76 Vs 1.23 ± 0.78 , $P < 0.05$) and orientation by V-ADAS-cog (0.20 ± 0.56 Vs 0.32 ± 0.64 , $P < 0.05$) were better in nimodipine group than in placebo group. Subgroup analysis did not show cognition function was better in the nimodipine group than in placebo group.

Conclusions: Nimodipine did not prevent the cognitive function decline in acute stroke patients with mild cognitive impairment. Nimodipine might have an effect on some specific cognitive domain.

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Presentation Number: LB8

Presentation Title: Second Generation Hydrogel-coated Coils for the Endovascular Treatment of Intracranial Aneurysms: Final Results of a Randomized Controlled Trial

Author Block: **Christian Taschner**, Univ Hosp Freiburg, Freiburg, Germany; René Chapot, Alfried-Krupp Krankenhaus, Essen, Germany; Vincent Costalat, Paolo Machi, CHU Montpellier, Montpellier, France; Patrick Courthéoux, CHU Caen, Caen, France; Xavier Barreau, Jérôme Berge, CHU Bordeaux, Bordeaux, France; Laurent Pierot, Krysztof Kadziolka, CHU Reims, Reims, France; Betty Jean, CHU Clermont-Ferrand, Clermont-Ferrand, France; Raphaël Blanc, Fondation Rothschild Hosp, Paris, France; Alessandra Biondi, CHU Besançon, Besançon, France; Hervé Brunel, CHU Marseille, Marseille, France; Sophie Gallas, Hôpital Henri-Mondor, Créteil, France; Ansgar Berlis, Augsburg Hosp, Augsburg, Germany; Denis Herbreteau, CHU Tours, Tours, France; Joachim Berkefeld, Univ Hosp Frankfurt, Frankfurt, Germany; Horst Urbach, Samer Elsheikh, Univ Hosp Freiburg, Freiburg, Germany; Jens Fiehler, Univ Hosp Hamburg, Hamburg, Germany; Hubert Desal, CHU Nantes, Nantes, France; Erika Graf, Univ of Freiburg, Freiburg, Germany; Alain Bonafé, CHU Montpellier, Montpellier, France

Abstract Body: Background The use of hydrogel-coated coils (HydroCoil) lowers major recurrence for endovascular aneurysm treatment. Technical limitations of HydroCoils (coil stiffness, time restriction for placement) have prevented their wider clinical use. Softer hydrogel-coated coils have been brought to clinical practice. This trial aims to assess efficacy of second generation hydrogel-coated coils. **Methods** Adult patients (≥ 18 years) with intracranial aneurysms (ruptured or unruptured) were enrolled into this trial at 22 clinical sites in France and Germany. Patients were randomized (by web-based system, in a 1:1 ratio, stratified by rupture status) to aneurysm coiling with either second generation hydrogel-coated coils (HydroSoft, HydroFrame; MicroVention Inc., Tustin, CA) or bare platinum coils. Assist devices could be used as clinically required. Independent imaging core laboratory was masked to allocation. Primary endpoint is a composite outcome including angiographic and clinical outcomes at 18 months. Analysis was by modified intention to treat. **Findings** Randomization was started on October 15, 2009, and was stopped on January 24, 2014, after randomization of 513 patients (hydrogel $n=256$, bare platinum $n=257$). Twenty patients were excluded for missing informed consent and nine patients for treatment related criteria. Four hundred eighty-four patients were analyzed as randomized (hydrogel $n=243$, bare platinum $n=241$), 208 were treated for ruptured aneurysms (43 %). The analysis for the main study outcomes is expected to be completed in late 2016. **Conclusion** The final results will be available for presentation in February, 2017. **Funding** MicroVention Inc

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