ICARE Primary Results: A Phase III Stroke Rehabilitation Trial

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Abstract Body: Background: Task-oriented training is a rehabilitation intervention used to improve recovery of paretic arm function after stroke. Its effectiveness has not been established relative to content or dose. The Accelerated Skill Acquisition Program (ASAP) is a principle-based, structured, task-oriented intervention focused on skill acquisition, capacity building, and motivational enhancements.

Methods: Between 14 and 106 days after stroke, 361 adults were randomized into one of three outpatient therapy groups: ASAP, Dose-Equivalent Usual and Customary Care (DEUCC), each at 1 hour, 3x/week for 10 weeks, or Usual and Customary Care (UCC), at a dose specified by clinician prescription and/or insurance coverage. The primary aim was to compare the effect of therapy contents at equivalent doses, with secondary comparisons of dose, and both dose and contents, at 12 months post randomization on Wolf Motor Function Test (WMFT) log-transformed time score and a > 25 point increase on the Stroke Impact Scale (SIS) hand domain.

Results: The average dose by treatment group was ASAP = 28 ± 6, DEUCC = 27 ± 6, and UCC = 11 ± 9 hours. Of those randomized to ASAP or DEUCC respectively, 79% (94/119) and 74% (89/120) completed at least 90% of the prescribed 30 hours. At 12 months, the attrition rate was similar across groups, ASAP = 12.6%, DEUCC = 12.5%, and UCC = 21.3%, well below a priori projection (25%). Missed evaluations varied across groups with 19.3% of ASAP, 24.2% of DEUCC and 35.2% of UCC participants missing at least one evaluation, but the occurrence of missing all 3 evaluations was similar, ASAP = 10.1%, DEUCC = 7.5% and UCC = 12.3%. At 12 months, the overall cohort decreased WMFT from 14.9 ± 18.5 s to 6.8 ± 13.0 s; SIS hand function increased from 30.7 ± 23.4 to 67.8 ± 26.9 (max 100), and UE Fugl Meyer increased from 41.6 ± 9.4 to 52.9 ± 10.9 (max 66). There were 168 serious adverse events involving 109 participants, with 98% expected and 2% deemed related. The most common events were hospitalization (85%), and recurrent stroke (25%).

Conclusions: To maintain the embargo, results of the primary and secondary group comparisons are not included here, but will be reported in February at ISC

Author Disclosure Block S.L. Wolf: Research Grant; Significant; NIH Grant #U01NS056256, Funded by the National Institute of Neurological Disorders and Stroke and the National Center for Medical Rehabilitation Research; ICARE ClinicalTrials.gov number, NCT00871715. A.W. Dromerick: Research Grant; Significant; NIH Grant #U01NS056256, Funded by the National Institute of Neurological Disorders and Stroke and the National Center for Medical Rehabilitation Research; ICARE ClinicalTrials.gov number, NCT00871715. C.J. Lane: Research Grant; Significant; NIH Grant #U01NS056256, Funded by the National Institute of Neurological Disorders and Stroke and the National Center for Medical Rehabilitation Research; ICARE ClinicalTrials.gov number, NCT00871715. M.A. Nelsen: Research Grant; Significant; NIH Grant
R. Lewthwaite: Research Grant; Significant; NIH Grant #U01NS056256, Funded by the National Institute of Neurological Disorders and Stroke and the National Center for Medical Rehabilitation Research; ICARE ClinicalTrials.gov number, NCT00871715.

S.Y. Cen: Research Grant; Modest; NIH Grant #U01NS056256, Funded by the National Institute of Neurological Disorders and Stroke and the National Center for Medical Rehabilitation Research; ICARE ClinicalTrials.gov number, NCT00871715.

S.P. Azen: Research Grant; Modest; NIH Grant #U01NS056256, Funded by the National Institute of Neurological Disorders and Stroke and the National Center for Medical Rehabilitation Research; ICARE ClinicalTrials.gov number, NCT00871715.

C.J. Winstein: Employment; Modest; Professor Biokinesiology and Physical Therapy, University of Southern California. Research Grant; Modest; NIH HD065438 and NS056256. Other Research Support; Modest; Charles Dana Foundation.
**LATE-BREAKING SCIENCE abstracts/studies presented at the INTERNATIONAL STROKE CONFERENCE 2015:**

For late-breaking science being presented at ISC 2015, the embargo lifts when the first presentation begins in the scientific session in which the abstract is being presented: either 11 am CST on Wednesday, Feb. 11; 6:15 pm CST on Wednesday, Feb. 11; 10:55 am CST on Thursday, Feb. 12; 1:30 pm CST on Thursday, Feb. 12; or 11:30 am CST on Friday, Feb. 13). News media activities promoting late-breaking science are under embargo until the times noted above.

**Presentation Number:** LB16

**Publishing Title:** The Japan Statin Treatment Against Recurrent Stroke (J-STARS): a multicenter, randomized, open-label, parallel-group study

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**Abstract Body:**

**Background & Aims:** Although statin therapy is beneficial for preventing first strokes, the benefit for recurrent stroke and its subtypes remains to be determined in Asian population. This study examined whether treatments with low-dose pravastatin prevent recurrence in ischemic stroke patients.

**Methods:** This is a multicenter, randomized, open-label, blinded-endpoint, parallel-group study of patients with non-cardioembolic ischemic stroke (atherothrombotic infarction, lacunar infarction, infarction of undetermined etiology). All patients were diagnosed with hyperlipidemia and with a total cholesterol level between 180 and 240 mg/dL at enrollment. Patients in the pravastatin group received 10 mg/day, and those in the control group received no statin treatment. The primary endpoint was the recurrence of stroke, including transient ischemic attack. The secondary endpoints included the onset of respective stroke subtypes and functional outcomes related to stroke. (NCT00221104)

**Results:** A total of 1578 patients (491 female, age 66.2±8.5 years) were randomized to either pravastatin group (n=793) or control group (n=785). There was no significant difference in baseline characteristics between the groups. During the follow-up of 4.9±1.4 years, recurrence of stroke similarly occurred in the both groups (2.56 vs. 2.65%/years, p=0.82; respectively). Regarding respective stroke subtypes, onset of atherothrombotic infarction was suppressed in the pravastatin group (hazard ratio 0.33 [95%CI 0.15-0.74], p=0.005), whereas significant intergroup differences were not found in the onset of other stroke subtypes (lacunar infarction, p=0.31; hemorrhagic stroke, p=0.82). The reduction rate of MMSE score tended to be slower in the pravastatin group (p=0.18).

**Conclusions:** In patients with non-cardioembolic ischemic stroke, low-dose pravastatin treatment appears to reduce the incidence of atherothrombotic infarction, which is not the case for other stroke subtypes.

Modest; Lundbeck. Honoraria; Modest; Mitsubishi Tanabe Pharma Cooperation, Kyowa Hakko Kirin Pharma, Inc, Sanofi, Otsuka, Bayer, M.M., Asteras Pharma, Daiichi Sankyo, AstraZeneca, EPS, Boehringer Ingelheim, Pfizer, Stryker, Medicos Hirata, Sawai Pharma. **S. Uchiyama:** Research Grant; Modest; Otsuka, Sanofi, Boehringer Ingelheim, Daiichi Sankyo, Bayer. Honoraria; Modest; Sanofi, Boehringer Ingelheim, Daiichi Sankyo. Honoraria; Significant; Otsuka, Bayer. **Y. Shinohara:** None. **T. Yamaguchi:** None.
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Presentation Number: LB17

Publishing Title: Impact Of General Anaesthesia On Treatment Effect In The MR CLEAN Trial.

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Abstract Body: Background
In patients with acute ischemic stroke treated with intra-arterial therapy (IAT) the effect of general anaesthesia (GA) on clinical outcome is unknown. Usage of GA during IAT is often based on preferences of the interventionist. GA reduces patients’ movement during the procedure. It may decrease procedure times and procedure-related complications. However, if local anaesthetics (LA) are used (with or without use of conscious sedation) treatment initiation could be faster, there is no need for intubation, and blood pressure alterations are less severe. We assessed the impact of GA on clinical outcome and safety in MR CLEAN trial.

Methods
MR CLEAN was a randomized clinical trial of IAT versus no IAT in patients with a proximal arterial occlusion in the anterior cerebral circulation demonstrated on vessel imaging, treatable within 6 hours after symptom onset. Primary outcome was the modified Rankin Scale (mRS) at 90 days. Use of GA was prospectively collected in the online database. Patients converted to GA during IAT were scored as LA according to intention to treat principle. In this post-hoc analysis, we defined good clinical outcome as mRS≤2.

Results
Five hundred patients were included in the MR CLEAN trial, 233 were allocated to intervention. Despite being allocated to control, 1 patient received IAT and was included in this analysis. A total of 217 patients had catheter angiography of whom 82/217 (38%) were treated under general anaesthesia. Baseline characteristics balanced between groups. IAT under LA resulted in 38% good outcome (mRS≤2) compared to 23% under GA arm (P=0.026). There was no statistically significant difference in symptomatic intracranial hemorrhage or mortality during follow-up.

Conclusion
We found a negative association of GA with functional outcome after 90 days in patients treated with IAT.