

## Late-Breaking Science Oral Abstracts

Wednesday, February 11, 2015, 10:30 am - 12:00 noon

*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:** LB1

**Publishing Title:** Endovascular treatment for **Small Core** and **Anterior circulation Proximal** occlusion with Emphasis on minimizing CT to recanalization times (ESCAPE)

**Author Block:** **Michael D Hill**, Univ of Calgary, Calgary, AB, Canada

**Abstract Body: Background:** There is conflicting randomized trial evidence that modern endovascular therapy is better than routine care, including routine intravenous thrombolysis, for acute ischemic stroke. There is nevertheless, strong evidence that endovascular therapy can result in faster, more complete recanalization (high recanalization rates of about 80%) and that this should result in better stroke outcomes.

**Methods:** The ESCAPE trial was a Phase 3, randomized controlled, open-label with blinded outcome evaluation (PROBE) design. The primary objectives were to show that rapid endovascular revascularization (in addition to guideline based medical care) amongst radiologically selected (small core/proximal anterior circulation occlusion/good collaterals) patients with ischemic stroke results in improved outcome compared to patients treated in clinical routine (guideline based standard of care including IV-tPA as appropriate in a 4.5h window). The secondary objectives of this study were to demonstrate the safety and feasibility of achieving rapid endovascular revascularization in this population of patients (<90 min CT-recanalization). Primary efficacy outcome is the shift (common OR) on the mRS scale at 90 days.

**Results:** The study involved 22 sites in Canada, US, UK, Europe and South Korea. A total of 316 patients were randomized. The study was halted at the recommendation of the DSMB on 6nov2014 after an interim analysis revealed that the study had crossed a pre-planned overwhelming efficacy boundary. Follow-up continues on the remaining 72 patients in the trial. Final results will be presented at the ISC.

**Conclusion:** The pillars of the ESCAPE trial are: (1) careful patient selection using CT, CTA; (2) very fast treatment; (3) high quality reperfusion rates using modern devices. Endovascular therapy with careful imaging selection, very fast treatment and high reperfusion rates is associated with an overwhelming clinical benefit.

**Author Disclosure Block:** **M.D. Hill:** Research Grant; Significant; Covidien. Grant for clinical trial. Ownership Interest; Significant; Calgary Scientific Incorporated. Imaging company.. Consultant/Advisory Board; Modest; Merck. Adjudicator for clinical trial.

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**Presentation Number:** LB2

**Publishing Title:** EXTEND-IA - Endovascular Therapy After Intravenous t-PA Versus t-PA Alone For Ischemic Stroke Using CT Perfusion Imaging Selection

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### **Abstract Body: Background**

Trials of endovascular therapy versus IV tPA for ischemic stroke have had mixed results. We conducted the EXTEND-IA investigator-initiated trial to test whether more advanced imaging selection, superior devices and earlier intervention improve outcomes.

### **Methods**

Ischemic stroke patients receiving 0.9mg/kg tPA <4.5h after onset with dual target of arterial (internal carotid or middle cerebral) occlusion and salvageable tissue on CT perfusion (ischemic core <70ml), were randomized to either tPA + clot retrieval <6h with the Solitaire FR device (IV-IA group), or tPA only. The pre-specified co-primary outcomes were i) the proportion of the perfusion lesion reperfused at 24h on CT or MR perfusion imaging, and ii) the proportion of patients with early neurological improvement, defined as  $\geq 8$  point reduction in NIHSS, or reaching 0-1, by day 3. Secondary outcome was ordinal analysis of mRS at 90 days. The trial was stopped early 4 Nov 14 (70 of the planned 100 patient sample) by the data safety and monitoring committee for overwhelming efficacy on the co-primary outcome (Haybittle-Peto stopping boundary with Bonferroni-Holm step-down  $p < 0.0005$  for first and  $p < 0.001$  for second co-primary outcome, intention to treat analysis) in a review prompted by the release of positive MR-CLEAN trial results.

### **Results**

There were 35 patients in the IV-IA group (mean age 68.6, sd 12.3, median NIHSS 17, IQR 13-20, median onset-recanalization 259min) and 35 who received tPA alone (mean age 70.2, sd 11.8, median NIHSS 13, IQR 9-19). The IV-IA group had greater median %reperfusion (100% vs 42%  $p < 0.00001$ , adjusted for site of arterial occlusion) at 24h (>90% reperfusion in 89% vs 37%,  $p < 0.0001$ ) and early neurological improvement (80% vs 37%  $p = 0.001$ , adjusted for age, baseline NIHSS, site of arterial occlusion) at 3 days than the tPA group. Symptomatic intracerebral hemorrhage (SITS) occurred in 0/35 IV-IA and 2/35 (5.7%) tPA patients. Complications in the IV-IA group were 1 wire perforation and 1 groin hematoma. Day 90 mRS will be presented.

### **Conclusions**

Early endovascular thrombectomy with Solitaire FR after tPA resulted in greater reperfusion and early neurologic recovery than tPA alone in a population with major arterial occlusion and salvageable tissue on CT perfusion imaging.

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