Endovascular Selective Cerebral Hypothermia

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Disclosure

Speaker name: Ronald J. Solar

I have the following potential conflicts of interest to report:

- Consulting ✔
- Employment in industry
- Stockholder of a healthcare company ✔
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Introduction

Major limitations in acute ischemic stroke (AIS) therapies

- Time limitation for lytics excludes most patients
- Mech revascularization limited by small number of trained physicians
- Recanalization limited by reperfusion injury* — need neuroprotection

Therapeutic hypothermia (TH) — the most potent neuroprotectant in the laboratory

- Influences a variety of cell death mechanisms — “combinational protective strategy”

BUT, a failed therapy in AIS — Failures due to cooling techniques employed

Stroke literature shows efficacy of TH is critically dependent on the duration and depth of hypothermia, and that there may be an efficacy threshold of \( \leq 31 \, ^\circ\text{C} \)\(^*\).

Current TH devices and techniques provide systemic cooling, which is slow, limited to \( \geq 32 \, ^\circ\text{C} \), and unpredictable in cooling the brain.

TwinFlo™ provides very rapid, deep and selective brain cooling with faster cooling rates, and temperatures much lower than what can be achieved by any other hypothermia device and technique.

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H Van der Worp, et al. Brain 2007; 130:3063-3074
Rapid, Selective Cerebral Hypothermia

- Proprietary perfusion catheter
  - Isolates, selectively perfuses CA
  - Single femoral insertion
- Used with std. extracorporeal circuit
  - Simplified set up since no membrane oxygenation is required
Percutaneous selective cerebral hypothermia

2. Warm blood removed, cooled blood returned

3. Carotid artery perfusion

1. Central aorta
Counter-current flow provides insulation.
TwinFlo™ Catheter — Novel endovascular selective cerebral hypothermia device and technique

In addition to providing hypothermia, the design allows selective delivery of drugs (e.g., lytics, Mg) and other devices (e.g., stentreivers and microcatheters), as well as control of perfusion pressure; recanalization be done in a cooled, protected brain to avoid reperfusion injury.
In Vivo Pig Studies

- Demonstrated cerebral cooling rates up to 2°C/min
- Brain temperatures as low 15°C
- Minimal systemic cooling
- No adverse events
- Normal heart rhythm, systemic arterial blood pressure, arterial blood values
- No rebound *hyper*thermia with passive rewarming
Porcine stroke model*

- 3 hours of ischemia followed by 3 hours of reperfusion
  - Pigs randomized to selective cooling or normothermia during reperfusion period. Analysis blinded.

- Blood pressure, heart rate, hemoglobin, glucose, and oxygenation levels did not differ between normothermic and hypothermic cohorts

- Statistically significant reduction in stroke volume by selective cooling with TwinFlo™ to mean 28°C for 1-3 hrs.

Initial Human Experience

- Neurosurgical repair of giant aneurysm of MCA in a 59 yom; 2 hr. occlusion time
  - TwinFlo™ selectively cooled brain at 26°C with systemic normothermia. Full, rapid recovery with no neurological deficit
- Cardiac arrest, PEA in a 30 yom; no response after 22 min CPR and 6 hours of 33°C ECMO
  - TwinFlo™ selectively cooled brain at 18-22°C for 12 hours. Full, rapid recovery with no neurological deficit
Conclusion

This new endovascular system and technique may offer an improved method for neuroprotection in cardiac arrest, acute stroke and other conditions producing cerebral ischemia.
Endovascular Selective Cerebral Hypothermia

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