

## Catheter Based Selective Hypothermia Reduces Focal Cerebral Ischemia in Adult Swine

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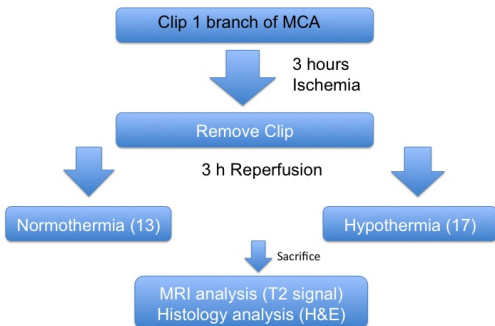
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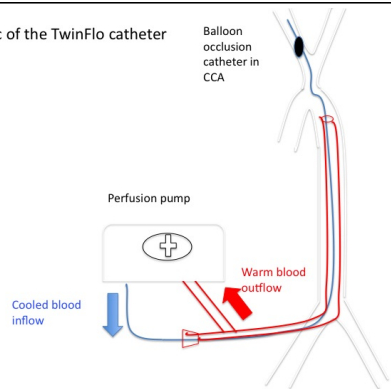
### Introduction

Background: Whole body hypothermia is an effective neuroprotectant in global cerebral ischemia.(1) Selective hypothermia applied to focal cerebral ischemia produces moderate cerebral hypothermia with only mild systemic cooling, and reduces stroke volumes.(2-4) Utilizing a swine model of focal cerebral ischemia, we previously reported that selective hypothermia reduces stroke volume.(5) An additional 5 animals have been tested using catheter based selective hypothermia, and an analysis of the entire cohort is presented.

Experimental protocol (animals alternated until last 5 all hypothermia)

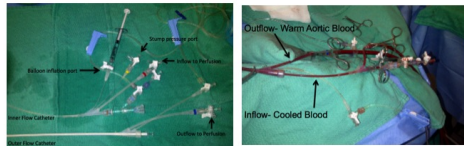


Schematic of the TwinFlo catheter



### TwinFlo (Thermopeutix, Inc)

TwinFlo is a coaxial catheter design with a 14F outer lumen (OFL) and a 9.5F inner lumen (IFL) balloon guide catheter. The IFL has a central lumen large enough for microcatheter and stent-retriever for acute stroke rescue. Blood is withdrawn from the OFL in the aorta to an extracorporeal circulation pump, where it is cooled. The cooled blood is then returned through the IFL into the carotid beyond balloon occlusion. This supplies cold blood under regulated flow and pressure to the carotid circulation for selective hypothermia.



TwinFlo set up. The Setup Time listed below includes the exchange of femoral arterial sheath for the Outer flow catheter, placement of the Inner Flow Catheter in the CCA, and purge the extracorporeal circulation.

### Data Analysis

MRI: Volume of T2 hyperintensity within the affected hemisphere to the volume of the affected hemisphere.

Pathology: Volume of ischemic damage seen on H&E staining.

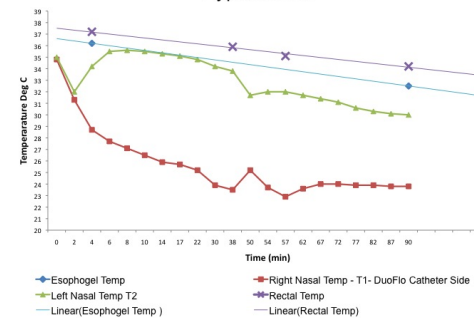
- 2 volumes were calculated, the largest contiguous stroke volume, and the total stroke volume, which would capture additional noncontiguous areas of ischemia.
- We had a new pathologist for the final 5 subjects, and they recalculated volumes for the original 25 subjects as well.

### Results

#### The Cohort

- 33 pigs, 50-55kg
  - 2 unusable, due to contusion/edema
  - 1 cardiac mortality-pulmonary stenosis on autopsy
  - 1 aortic dissection- usable but limited time of cooling
  - Since our publication, 1 animal had significant ICH.
- 30 available for analysis
  - 13 normothermia/controls;
  - 17 hypothermia

### Typical Temperature-Time Curve in Selective Hypothermia



### Hypothermia Parameters Achieved

	Median (Q1,Q3)	Min, Max
Set up Time (min)	45 (35.8, 63)	22, 144
Temp Nadir (°C)	23.7 (23.0,23.3)	20.7, 27.5
Time to <30°C (min)	15.0 (12, 34)	6, 65
Total Cooling (min)	130 (93.8,138.5)	36, 150
Total Time to <30°C (min)	74.5 (51.5, 92.5)	46, 155

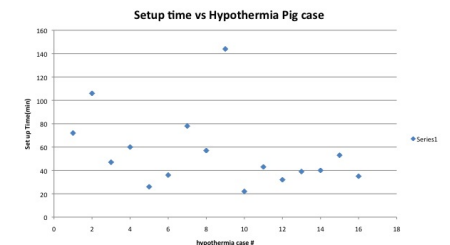
### Histology Stroke Volumes

	Normothermia (n=13)	Hypothermia (n=17)	P Value
Mean Total stroke volume (cm3) +/-SD	2.01+/-1.54	0.96+/-1.01	0.03
Mean Largest single stroke volume (cm3) +/-SD	0.95+/-0.631	0.56+/-0.59	0.09

### MRI Stroke % of Hemisphere Volume

	Normothermia (n=13)	Hypothermia (n=17)	P value
Mean+/-SD	0.050+/-0.059	0.022+/-0.039	0.06
Median	0.050	0.000	

Setup time for the TwinFlo catheter has decreased with experience



### Discussion

Endovascular selective hypothermia routinely produces rapid and profound hypothermia. Setup times have reduced over the course of the study, giving longer cooling times. Stroke volumes on MRI using T2 ratio demonstrate a reduction using selective hypothermia. Stroke volume reduction with selective hypothermia on Pathology are now statistically significant.

### Conclusions

Selective hypothermia reduces stroke volumes in an adult swine model. Additional study of catheter based selective hypothermia is warranted.

### References

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