MicroVention® TERUMO

HELPS Trial Results

Hydrogel-coated coils versus bare platinum coils for the endovascular treatment of intracranial aneurysms (HELPS): a randomized controlled trial

White PM, Lewis SC, Gholkar A, Sellar RJ, Nasher H, Cognard C, Forrester L, Wardlaw JM for the HELPS trial collaborators
The Lancet, Vol 377, 1655-1662, May 14, 2011

KEY POINTS:

- ▷ Angiographic outcomes statistically significant
- ▷ 24% relative risk reduction of angiographic remnant/ recurrence with HydroCoil Embolic System
- ▷ Primary composite outcome has strong trend favoring HydroCoil Embolic System
- ▷ 84% medium to large size aneurysm in study (25% were large) and 50% deemed complex
- ▷ Ruptured aneurysm composite outcomes favors the HydroCoil Embolic System arm
- ▷ When target usage of HydroCoil implants was met, a good outcome was significantly more likely than with bare platinum
- ▷ 20% relative risk reduction in HydroCoil implant length used but with greater packing attenuation
- ▷ Unexplained hydrocephalus risk, concentrated in basilar tip aneurysms >12mm, was not significantly increased with HydroCoil implants

HELPS Trial

- Dr. Phil White, Edinburgh, Scotland – Primary Investigator
- Dr. Jean Raymond, Montreal, Canada – Core Lab / CHUM
- Prospective, randomized controlled trial, with a blinded independent core lab review, compared the results from the HydroCoil® Embolic System to results from bare platinum coils from September 2004 – February 2007. This multi-center, multi-national trial was the first comparative adjudicated study completed since the International Subarachnoid Aneurysm Trial (ISAT) was presented in 2002
- Enrollment in 24 centers and in 7 countries
- 499 patients enrolled since 2004
- 18 month follow-up
  - ▷ Mean follow-up of 17.4 months
- Stents and balloons allowed and any manufacturer's bare platinum coils to reflect current standard of care
- WFNS Grade 0-3
- Age range 18-75

SUMMARY OF RESULTS

- 249 HydroCoil Embolic System, 250 bare platinum patients randomized
  - ▷ 91% follow-up (228 HydroCoil Embolic System and 239 bare platinum)
- Aneurysm size 2mm – 25mm
  - ▷ 84% of aneurysms in HELPS were medium to large aneurysms (25% were large) and 50% of all aneurysms in the trial were deemed complex
- HydroCoil implants had more stable angiographic results with a statistically significant decrease in major remnant/ recurrence rates *(See Chart 1)*
  - ▷ 8.6% absolute difference in improvement
- The primary composite endpoint is neutral with a strong trend in favor of the HydroCoil Embolic System. *(See Chart 2)*
  - ▷ Composite adverse outcome is defined as: Presence of angiographic major aneurysm recurrence at 18 months and adverse clinical outcomes or no angiographic follow-up

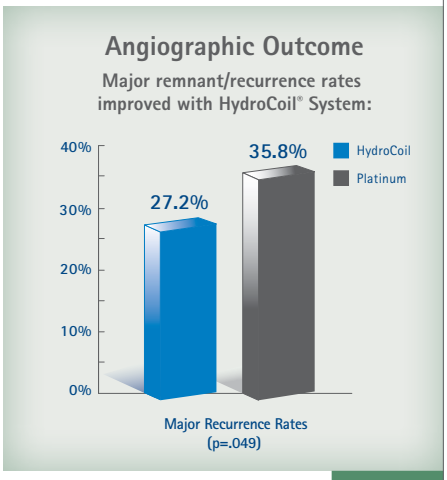

Chart 1

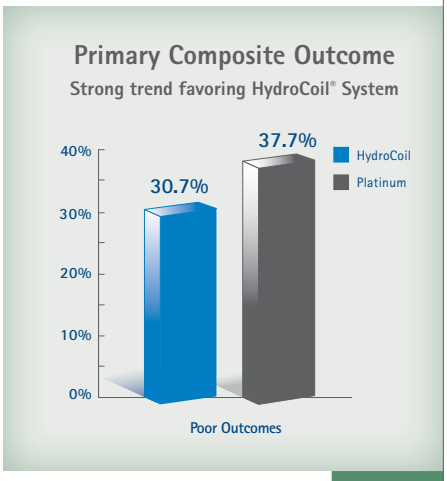

Chart 2

SUMMARY OF RESULTS *cont.*

- There was a very low overall retreatment rate
  – Retreatment rates: 3.0% (7/236) HES – 4.0% (9/253) bare platinum
- Ruptured aneurysm composite outcomes favors the HydroCoil Embolic System over bare platinum:
  – HydroCoil 68% vs bare platinum 50% *(See Chart 3)*
- When the target HES usage was met, good outcomes were significantly more likely than bare platinum[1] *(See Chart 4)*
- HydroCoil implants have lower thromboembolic complications: 5.6% HydroCoil vs 10% bare platinum[2] *(See Chart 5)*
- A 20% relative reduction in HydroCoil implant length was realized[2] with a difference in packing density of 63.9% for HydroCoil implants and 23.2% for platinum implants. *(See Chart 6)*

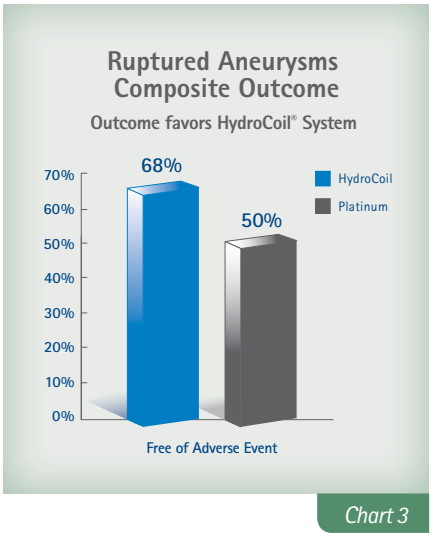

Chart 3

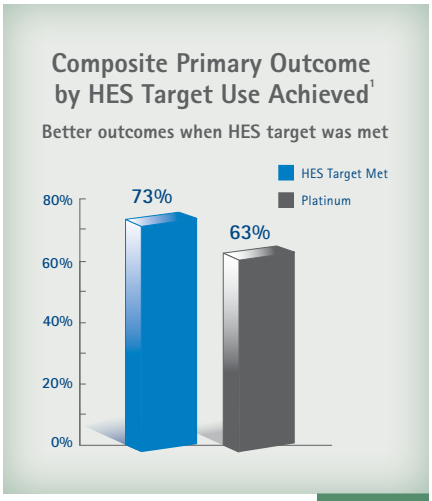

Chart 4

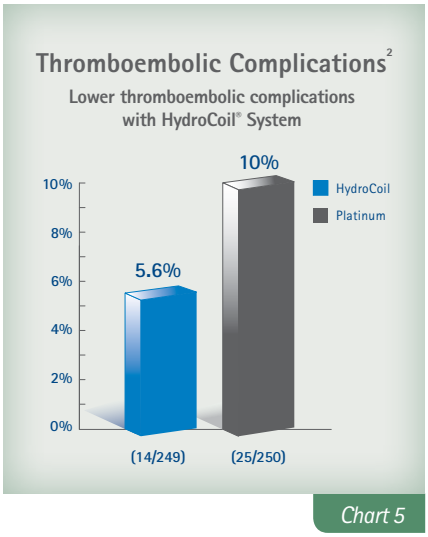

Chart 5

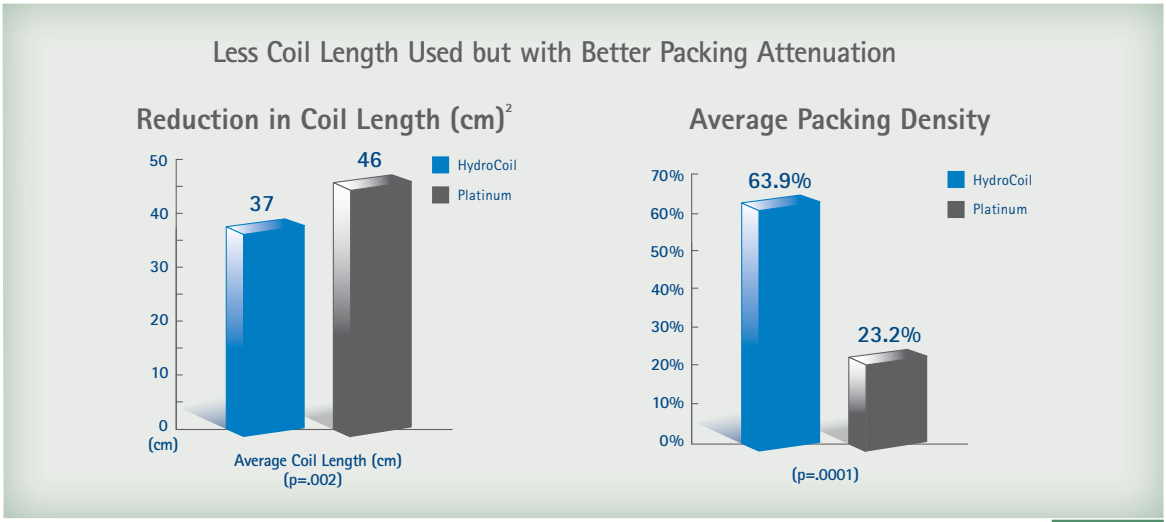

Chart 6

1. Target Guideline: *Aneurysms 2-9.9mm:* at least 50% of total coil length deployed should constitute HES, *Aneurysms ≥10mm:* at least 66.6% total length of coil deployed should constitute HES
2. HydroCoil Endovascular Aneurysm Occlusion and Packing Study (HELPS Trial): Procedural Safety and Operator-Assessed Efficacy Results, P.M. White, et. al., AJNR; 29: 217-223, February 2008

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Note: MicroVention does not have access to the HELPS raw data