Presented at SNIS 2018 – Late Breaking Abstract Session, Wednesday July 25

HEAT Trial

Randomized, controlled, postmarket study of new generation hydrogel coils in the treatment of intracranial aneurysms across 46 centers in the United States and Canada.

Study Purpose

To compare the clinical and angiographic outcomes in patients treated with **hydrogel coils** versus patients treated with **bare platinum coils**.

Primary endpoint

Aneurysm recurrence at any point during follow-up (through 24 months) defined as any progression on the Raymond-Roy Occlusion Classification.

Study Results Demonstrated:

Greater efficacy[1]

Hydrogel coils significantly reduced recurrence for aneurysms 3 to 14 mm in size. (p <.001)

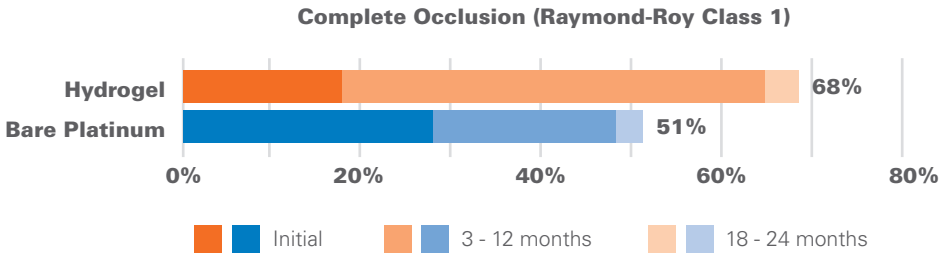
Primary Endpoint

Hydrogel
4.4%
ANEURYSM RECURRENCE

Bare Platinum
15.4%
ANEURYSM RECURRENCE

More progressive occlusion[1,2]

In the HEAT Trial, hydrogel coils achieved more progressive occlusion at 18-24-month follow-up than bare platinum coils.



Higher efficiency[1]

Hydrogel coils were shown to provide a higher average packing density with fewer coils used.

	Average Packing Density	Average Number of Coils	Average Length of Coils Used
Hydrogel	33.0%	5.3	51.1 cm
Platinum	24.8%	6.0	56.2 cm

Comparable safety[1]

Hydrogel coils showed no significant difference in adverse events compared to bare platinum. (p = .498)

Study Design

600 patients randomized to receive either[1]:

1. Coil embolization with hydrogel coils (≥ 90% hydrogel by length)
2. Coil embolization with any bare platinum coils

Inclusion criteria	Exclusion criteria
• Untreated, ruptured, or unruptured aneurysms • 18–75 years of age • Aneurysms 3–14 mm in size	• Hunt and Hess 4 and 5 • Concurrent intracranial pathology • Acute or uncontrolled comorbidities

Hydrogel coils in the trial[1]

- HydroFrame® Coils
- HydroFill® Coils
- HydroSoft® Coils

Patient Population

	Hydrogel Coils	Bare Platinum Coils
Number of patients analyzed	297	303
Average patient age	56.5	56.9
Mean aneurysm size	7.3 mm	7.5 mm

PI.: Bernard Bendok
Sponsor: Northwestern
Funded: MicroVention

References:

1. Bendok BR. New Generation Hydrogel Endovascular Aneurysm Treatment Trial. The HEAT study. Presented at: 15th Annual Society of NeuroInterventional Surgery Meeting; July 23–26, 2018; San Francisco, CA.
2. Dabus G. New Generation Hydrogel Endovascular Aneurysm Treatment Trial. The HEAT Study. Presented at: 10th Congress of the European Society of Minimally Invasive Neurological Therapy; September 6-8, 2018; Nice, France.

INDICATIONS FOR USE: The HydroCoil® Embolic System (HES) is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature. The device should only be used by physicians who have undergone pre-clinical training in all aspects of HES procedures as prescribed by MicroVention.
RX Only: Federal (USA) law restricts this device to sale by or on the order of a physician. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopy equipment. The HydroCoil® Embolic System should only be used by physicians who have received appropriate training for the device.
RX Only: Federal (USA) law restricts this device to sale by or on the order of a physician.

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