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Safety, Immediate and Mid-Term Results of Newer Generation Hydrogel Coils in the Treatment of Ruptured Aneurysms: a Multicenter Study

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HydroCoil EMBOLIC SYSTEM

KEY TAKEAWAYS:

- *"The treatment of acutely ruptured aneurysms using newer generation Hydrogel coils is safe and effective, with only a small number of procedural complications and high immediate occlusion rates."* [1]

Immediate Results:

- *Complete or near complete aneurysm occlusion:* **90.0%**
- *Residual aneurysm (Raymond III):* **10.0%**

Mid-Term Follow-Up (Mean 6.8 Months):

- *Complete or near complete aneurysm occlusion:* **98.1%**
- *Residual aneurysm (Raymond III):* **1.9%**
- *No cases of aneurysm re-hemorrhage*
- *No thromboembolic events*

Hydrogel Expanded

OBJECTIVE

To assess the real-world performance of the newer generation HydroCoil® Embolic System (HydroSoft®, HydroFrame®, and HydroFill® coils) in ruptured aneurysms.

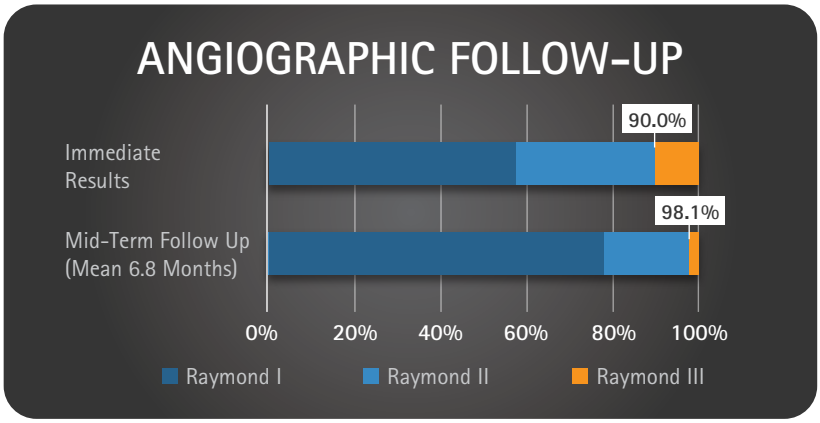
BACKGROUND

Multi-center retrospective study to analyze angiographic and clinical outcomes of consecutive patients with ruptured aneurysms treated with at least 70% of newer generation Hydrogel coils.

- 80 patients (54 female and 26 male)
- Age: 22-86 years old (mean 55.1 years)
- Aneurysm size: 2-16mm (mean 5.8mm)
  - 52.5% of aneurysms were ≤5mm; 10% were ≥10mm
- Packing density: 9.3%-92.6% (mean 48.5%)
- 55% of patients were presented in good clinical grade (mRS 1 and 2)

SUMMARY OF RESULTS

Clinical follow-up available in 73 patients showed a good outcome (mRS 0-2) in 76.3%.



Conclusion: *"Our data show that the use of the newer-generation Hydrogel coils in the treatment of ruptured aneurysms is feasible, safe and effective with high immediate and mid-term occlusion rates and low morbidity."* [1]

[1] Dabus G, et al. J NeuroIntervent Surg 2016;0:1–7. doi:10.1136/neurintsurg-2016-012780

ADDITIONAL STUDY INFORMATION

Q: Which Hydrogel coils were included in the study?

A: All of MicroVention's second generation Hydrogel coil products were included in the study. (HydroSoft®, HydroFill®, and HydroFrame® coils)

Q: Who participated in this study?

A: Six high volume (>100 aneurysms treated per year) sites across North America participated in this study.[1,2,3,4,5,6]

Q: What was the technical success rate of the study?

A: There was a 100% technical success rate (80/80 patients) during this study, meaning that all aneurysms were successfully filled with coils.[7]

Q: What was the aneurysm location distribution?

A: Of aneurysms treated: 40% were located on the ACom, 31.3% were located on the PCom, and 28.7% were classified as 'others'.

Q: How were the aneurysms treated?

A: Of aneurysms treated: 56.7% were unassisted coil embolization; 39.6% were balloon-assisted coil embolization; 3.7% were stent-assisted coil embolization.

Q: What was the procedural complication rate?

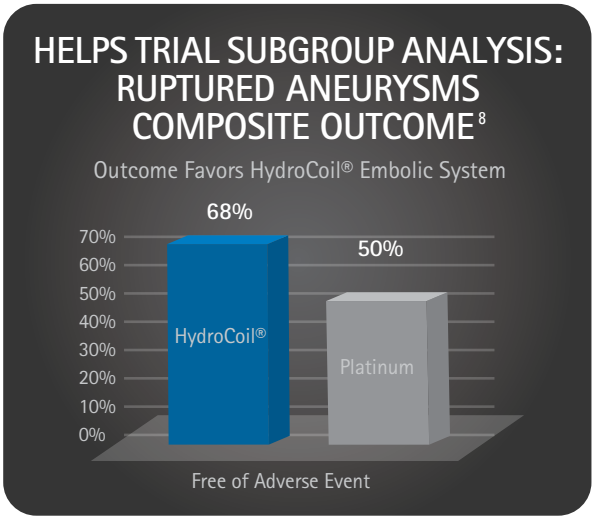
A: Clinically significant procedure complications occurred in three cases (3.75%). All three cases were intraoperative perforations that were not related to the devices. All aneurysms were treated during the acute phase. There were no reported cases of aneurysm re-hemorrhage, no observed clinically relevant thromboembolic complications, and no procedure related morbidity or mortality.

Q: Was this study sponsored or funded by MicroVention, Inc.?

A: No. This was a retrospective investigator-initiated study that was neither sponsored nor funded by MicroVention, Inc.[7]

Q: How do the results of this study compare to the ruptured aneurysm outcomes from other studies?

A: The results of this study similarly reflect the outcome from the ruptured aneurysm sub-analysis in the *HELP Trial = Medium Sized Aneurysms Sub-analysis:*



HELPS Trial Subgroup Analysis: Angiographic and Clinical Results of Patients with Recently Ruptured Medium-Sized Aneurysms at 15-18 Months.[9]

Patients with Ruptured Aneurysms	HydroCoil Group n=59 (%)	Platinum Group n=59 (%)	P-value
Any recurrence	22 (37.3%)	38 (64.4%)	0.006
Major recurrence	12 (20.3%)	28 (47.5)%	0.003

Reference
1. Miami Cardiac & Vascular Institute and Baptist Neuroscience Center, Miami, Florida, USA 2. Sutter Health, Sacramento, California, USA 3. Radiology of Huntsville, Huntsville, Alabama, USA 4. St John Neuroscience Institute, Tulsa, Oklahoma, USA 5. Mount Sinai Hospital, New York, New York, USA 6. Medical University of South Carolina, Charleston, South Carolina, USA
7. Personal conversation with Guilherme Dabus on 10/28/2016 8. Table 3: Angiographic and clinical results of patients with recently ruptured medium-sized aneurysms at 15-18 months. W. Brinjikji, P.M. White, H. Nahser, et al. -- Am J Neuroradial 2015; 36:1136-1141
9. 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

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.

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