**GREAT Study**
Second-Generation Hydrogel Coils for the Endovascular Treatment of Intracranial Aneurysms – A Randomized Controlled Trial

"The GREAT trial results showed significant benefits of Hydrogel technology."
Professor Christian Taschner, University of Freiburg, Germany
Principal Investigator for the GREAT Study

**AIM OF THE STUDY**
To assess the efficacy of softer, second generation hydrogel coils for the treatment of ruptured and unruptured intracranial aneurysms when compared with the use of bare platinum coils.

"GREAT Study results demonstrate that:" • Second-generation hydrogel coils contribute to the reduction of unfavorable composite (angiographic/clinical) outcomes. • Hydrogel coils appear to be as safe as platinum coils. • Hydrogel coils achieved statistically significant higher packing density with less coil length.

**CONCLUSION**
Coil embolization with second generation hydrogel coils may reduce the rate of unfavorable outcome events in patients with medium sized (4-12 mm) intracranial aneurysms.

---

**Unfavorable Composite Angiographic and Clinical Outcomes**

<table>
<thead>
<tr>
<th></th>
<th>Hydrogel Coils</th>
<th>Bare Platinum Coils</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Recurrence Rate</td>
<td>12%</td>
<td>3%</td>
</tr>
<tr>
<td>Retreatment Rate</td>
<td>18%</td>
<td>6%</td>
</tr>
</tbody>
</table>

Statistically significant reduction in the proportion of unfavorable composite primary outcome with hydrogel coils.*

45 out of 226 (19.9%) patients in the hydrogel group and 66 out of 230 (28.7%) in the control group had an unfavorable composite primary outcome. *Adjusted for rupture status.

**ANGIOGRAPHIC OUTCOMES**

**CLINICAL OUTCOMES**

<table>
<thead>
<tr>
<th></th>
<th>Hydrogel Coils</th>
<th>Bare Platinum Coils</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRS 6</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>mRS 3-5</td>
<td>1%</td>
<td></td>
</tr>
</tbody>
</table>

**HYDROGEL** | **BARE PLATINUM**
---|---
Morbidity mRS 3-5 (Prevented angiographic follow-up) | 1% | 0%
Mortality mRS 6 (Any death) | 3% | 4%

---
STUDY DESIGN\(^1,2\)

A total of 513 patients were randomly assigned to two treatment arms:

1. Coil embolization with HydroSoft\(^\circledR\)/HydroFrame\(^\circledR\) coils (≥50% of the administered coil length).

2. Coil embolization with any bare platinum coils.

PATIENT POPULATION\(^1\)

No significant difference in patient population.

<table>
<thead>
<tr>
<th></th>
<th>HYDROGEL</th>
<th>BARE PLATINUM</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Patients Analyzed</td>
<td>243</td>
<td>241</td>
</tr>
<tr>
<td>Ruptured Aneurysms</td>
<td>42%</td>
<td>44%</td>
</tr>
<tr>
<td>Mean Aneurysm Size</td>
<td>6.8 mm</td>
<td>7.1 mm</td>
</tr>
<tr>
<td>Anterior Circulation</td>
<td>74%</td>
<td>76%</td>
</tr>
</tbody>
</table>

### PRIMARY ENDPOINT\(^1-3\)

Composite outcome of major aneurysm recurrence on follow-up angiography and clinical outcome within 18 months

- Major aneurysm recurrence on follow-up at 18 month
- Retreatment for major recurrences within 18 months
- Morbidity (mRS 3 – 5) that prevented angiographic follow-up
- Any death (mRS 6)

### SECONDARY ENDPOINTS\(^1-3\)

- Clinical outcome at 6 and 18 months measured by mRS
- Total coil length deployed
- Packing density

### INCLUSION CRITERIA\(^1-3\)

- Aneurysm size 4mm to 12mm (ruptured/unruptured)
- Patients aged between 18 and 75 years old
- WFNS grade 0–3

### EXCLUSION CRITERIA\(^1-3\)

- Bioactive coils (PGA/PGLA)
- Flow diverter
- Previously treated by coiling or clipping

### PACKING DENSITY\(^1,3\)

<table>
<thead>
<tr>
<th></th>
<th>HYDROGEL</th>
<th>BARE PLATINUM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Packing Density*</td>
<td>39%</td>
<td>31%</td>
</tr>
<tr>
<td>Coil Volume</td>
<td>0.041 cm(^3)</td>
<td>0.038 cm(^3)</td>
</tr>
<tr>
<td>Coil Length</td>
<td>51.2 cm</td>
<td>61.6 cm</td>
</tr>
</tbody>
</table>

* Greater aneurysm packing density was achieved in the hydrogel group when compared to the bare platinum group. This difference was statistically significant \((p=0.001)\).

The results of the GREAT Study showed that the risk of meeting the unfavorable composite primary endpoint of major angiographic recurrence and poor clinical outcome at long term follow-up was significantly lower in patients treated with softer second-generation hydrogel coils compared to platinum coils.\(^1\)

**Study limitations are outlined in the full article, available free via Open Access:** http://stroke.ahajournals.org/content/49/3/667