Endovascular Occlusion of Aneurysms Using a New Bioactive Coil
A Matched Pair Analysis With Bare Platinum Coils

Martin Bendszus, MD; Andreas J. Bartsch, MD; Laszlo Solymosi, MD

Background and Purpose—To assess safety and efficacy data of a new bioactive coil (Cerecyte) which is loaded with polyglycolic acid on the inside of the coil.

Methods—Fifty-four patients harboring 55 aneurysms were treated with Cerecyte coils. These aneurysms were matched in localization and size with aneurysms treated with bare platinum coils.

Results—Periprocedural complications and handling did not differ between both groups. Initial aneurysm occlusion was comparable in both treatment groups. At 6 months angiographic follow-up, the aneurysms occluded with Cerecyte coils had a higher chance for complete occlusion ($P=0.045$) and tended to a lower retreatment rate ($P=0.056$).

Conclusions—Cerecyte coils are as safe as bare platinum coils in the endovascular occlusion of aneurysms. This matched pair analysis indicates a higher occlusion rate of aneurysms occluded with Cerecyte coils. (Stroke. 2007;38:2855-2857.)

Key Words: aneurysm • bioactive • coil • endovascular

Recanalization after coil embolization remains a major drawback ranging between 17% and 33% of patients.1,2 Recently, a new bioactive coil (Cerecyte) has been introduced which is supposed to enhance the treatment of aneurysms by inducing a tissue response. We performed a matched-pair analysis with bare platinum coils to assess safety and efficacy of this new coil.

Methods
In a prospective study, 54 patients harboring 55 aneurysms were treated with Cerecyte coils and underwent control angiography 6 months later. Patient data of this group are shown in Table 1. Mean aneurysm size was 5.5 (SD 3.0)$\times$5.5 (SD 2.6) mm, and mean neck size was 3.3 mm (SD 0.8). Three aneurysms revealed angiographic features of a dissecting aneurysm (ie, irregular shape, partial thrombosis, vessel stenosis at the aneurysm neck).

As a control group we used a previous series of patients undergoing coil embolization of intracranial aneurysms from 2002 until November 2004. Patients were treated with bare platinum coils of the same manufacturer by the same 4 neurointerventionalists using the identical protocol. Comparison with the Cerecyte group was done concerning initial aneurysm occlusion and recanalization at 6 months. On an individual basis, every aneurysm treated with Cerecyte coils was matched with an aneurysm of this group treated with bare platinum coils. Data of these patients are shown in Table 1. Matching of the aneurysms was done exclusively according to aneurysm size and location, and blinded to the respective treatment result. In this group, mean aneurysm size was 5.4 (SD 3)$\times$5.3 (SD 2.4) mm, and mean neck size was 3.1 mm (SD 1.2). Two aneurysms revealed angiographic features of a dissecting aneurysm.

Volume calculation of the aneurysms was performed on a workstation with a 3-D software tool (Leonardo, Siemens) at a fixed window setting. Mean aneurysm volume was 198 mm$^3$ (SD 112) in the Cerecyte group and 182 mm$^3$ (SD 125) in the bare platinum group.

Coils
The Cerecyte coil consists of a regular bare platinum coil with PGA running through the lumen of Cerecyte’s primary platinum wind which also provides stretch resistance. The PGA within Cerecyte is biodegraded by hydrolysis through contact with water molecules from the blood.

Procedures
For both groups, an identical protocol was applied except of the coils used. All procedures were performed by 4 experienced interventionists. The standard approach included placement of 1 or 2 3-D coils (MicruSphere) to obtain a basket, followed by subsequent filling with standard (Helipaq) and soft (Ultipaq) coils until the aneurysm had disappeared angiographically and a preferably dense packing was achieved.

Follow-up catheter angiography was performed 6 months after initial treatment of the aneurysm including 4 standard planes and at least 2 magnified views according of the aneurysm neck. Aneurysm occlusion was determined according to published criteria.3

Statistics
For statistical analysis, the R environment for statistical computing (R version 2.3.1; R Development Core Team 2006, http://www.r-project.org/) was used. $P$ values of Fisher exact test were computed for the comparison of corpus frequency counts. For the comparison of initial treatment results between Cerecyte and bare coils, 2-sided tests were performed.
Table 1. Patient Data

<table>
<thead>
<tr>
<th></th>
<th>Bare Platinum Coils†</th>
<th>Cerecyte Coils†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female/male</td>
<td>21/34</td>
<td>18/36</td>
</tr>
<tr>
<td>Mean age, y (SD)</td>
<td>51 (10)</td>
<td>48 (11)</td>
</tr>
<tr>
<td>Hunt &amp; Hess 0</td>
<td>17</td>
<td>16</td>
</tr>
<tr>
<td>Hunt &amp; Hess I</td>
<td>15</td>
<td>21</td>
</tr>
<tr>
<td>Hunt &amp; Hess II</td>
<td>11</td>
<td>9</td>
</tr>
<tr>
<td>Hunt &amp; Hess III</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Hunt &amp; Hess IV</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Hunt &amp; Hess V</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Mean size (SD)*</td>
<td>5.4 (3)×5.3 (2.4) mm</td>
<td>5.5 (3.0)×5.5 (2.6) mm</td>
</tr>
<tr>
<td>Mean volume (SD)</td>
<td>182 (124) mm</td>
<td>198 (112) mm</td>
</tr>
<tr>
<td>Mean neck size (SD)</td>
<td>3.1 (1.2) mm</td>
<td>3.3 (0.8) mm</td>
</tr>
<tr>
<td>Anterior circulation</td>
<td>46</td>
<td>46</td>
</tr>
<tr>
<td>Posterior circulation</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Stent placement</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>No. of coils (SD)</td>
<td>7 (7)</td>
<td>6 (6)</td>
</tr>
<tr>
<td>Thrombus formation</td>
<td>n=3 (no clinical symptoms)</td>
<td>n=4 (no clinical symptoms)</td>
</tr>
<tr>
<td>Vessel occlusion</td>
<td>n=2 (1 transient hemiparesis)</td>
<td>n=3 (no clinical symptoms)</td>
</tr>
</tbody>
</table>

*Measured as largest height and width.
†No significant difference between patient and aneurysm data of both groups.

Results

In the beginning Cerecyte coils differed from bare coils in terms of increased friction and delayed coil detachment in 2 cases without clinical sequel. In December 2004, after 4 aneurysms had been treated, the design of the Cerecyte coil was modified and improved. Thereafter, handling and design of Cerecyte coils was identical to bare platinum coils. Periprocedural complications did not differ between both groups (Table 1). There was no permanent morbidity or mortality related to the procedure in both groups. The initial treatment result did not differ between bare and Cerecyte coils (Table 2, complete occlusions 39 versus 36, neck remnant 15 versus 19, residual aneurysms 1 versus 0; \( P=0.54 \), Fisher exact test). Six months control results are shown in Table 3. In the bare coil group there were 34 complete occlusions (62%), 14 neck remnants (25%), 7 residual aneurysms (13%) and 6 retreatments (11%). In patients treated with Cerecyte coils there were 43 complete occlusions (78%), 10 neck remnants (18%), 2 residual aneurysms (4%) and 1 retreatment (2%). This retreatment and 1 retreatment in the bare platinum group were necessary in a presumably dissecting aneurysm. Thus, the chance for complete aneurysm occlusion at 6 months was significantly higher in the Cerecyte group than in the bare coil group (43 versus 34), whereas the risk for a neck remnant or a residual aneurysm was significantly higher in the bare coil group (21 versus 12; \( P=0.045 \), power=0.59). Furthermore, there was a strong trend for a lower retreatment rate in the Cerecyte group (1 versus 6, \( P=0.056 \), power=0.62).

Discussion

As a principal finding of this study, Cerecyte coils were as safe and effective as bare platinum coils in the primary treatment results. The essential change in the coil design is a polyglycolic acid (PGA) suture inside of the coil which did not change the mechanical properties or handling of the coil. The amount of platinum inside of the aneurysm is unchanged compared with bare platinum coils. Previous studies on the first bioactive coil available on the market (Matrix, Boston Scientific) have demonstrated increased coil stiffness, a lower primary occlusion rate and an increased recanalization and rebleeding rate in the follow-up.\(^4\)\(^–\)\(^7\) However, in this coil the bioactive material (polyglycolic-polyactic acid polymer) is placed on the outside of the coil and changed the mechanical coil properties with increased stiffness and reduced amount of platinum.\(^4\)\(^–\)\(^6\) In some cases the bioactive material was presumably resorbed at the outside of the coil resulting in a loss of material inside of the aneurysm. By contrast, in the present study the rate of completely occluded aneurysms after 6 months was significantly higher in aneurysms treated with Cerecyte coils compared with bare platinum coils. As the most important clinical effect, the rate of retreatment was substantially lower in aneurysms treated with Cerecyte coils (1 versus 6) which owing to the small number did not reach level of significance.

Even though this was a consecutive patient series the mean aneurysm size was smaller than in previous studies which may affect the recanalization rate. Besides size and localization other factors like previous rupture or neck width have an influence on aneurysm recanalization.\(^8\)\(^–\)\(^9\) Even though there were no group differences in neck width and previous rupture, these factors were not included in the matching of the aneurysms.

We are well aware that this single-center design of a matched pair analysis is not the perfect methodological tool to prove stability in aneurysms treated with Cerecyte coils. Nevertheless, this was a comparison of 2 consecutive patient series treated by the same interventionists after the identical protocol. Our data concerning safety and efficacy provide a robust justification for a prospective randomized trial between Cerecyte and bare platinum coils.

Acknowledgments

We would like to thank Sonja Bendszus for excellent help with data collection and analysis.
Disclosures
M.B. is consultant for Cordis Neurovascular and Micrus Endovascular. M. B. has given talks with honorarium for Cordis Neurovascular and Micrus Endovascular. Micrus Endovascular had no influence on the data collection, analysis, or writing of the manuscript. M.B. holds an endowed professorship granted by Schering GmbH, Berlin to the University of Würzburg, but has no financial interest. L.S. is consultant for Micrus Endovascular but has no financial interest.

References
Endovascular Occlusion of Aneurysms Using a New Bioactive Coil: A Matched Pair Analysis With Bare Platinum Coils
Martin Bendszus, Andreas J. Bartsch and Laszlo Solymosi

Stroke. 2007;38:2855-2857; originally published online August 23, 2007;
doi: 10.1161/STROKEAHA.107.489088
Stroke is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2007 American Heart Association, Inc. All rights reserved.
Print ISSN: 0039-2499. Online ISSN: 1524-4628

The online version of this article, along with updated information and services, is located on the
World Wide Web at:
http://stroke.ahajournals.org/content/38/10/2855

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published
in Stroke can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office.
Once the online version of the published article for which permission is being requested is located, click
Request Permissions in the middle column of the Web page under Services. Further information about this
process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Stroke is online at:
http://stroke.ahajournals.org//subscriptions/