ORIGINAL RESEARCH

Initial experience with an extremely soft bare platinum coil, ED coil-10 Extra Soft, for endovascular treatment of cerebral aneurysms

Kei Harada,¹ Jun Morioka²

ABSTRACT

Background and purpose  The ED coil-10 Extra Soft (EDC-10 ES) is an extremely soft coil with excellent operability for embolization of cerebral aneurysms and is frequently used as a ‘finishing coil’. The aim of this study was to evaluate the efficacy and safety of this coil.

Methods  Clinical data were analyzed retrospectively for 92 consecutive aneurysms for which at least one EDC-10 ES was used. Follow-up angiography at 6 months was available for 69 aneurysms. Initial and follow-up outcomes were evaluated using three-category occlusion grading. Factors that affect the packing density were also investigated.

Results  Of the 92 aneurysms, 63 (68.5%) were classified as complete occlusion, 11 (12.0%) as having a neck remnant and 18 (19.6%) with dome filling immediately after the embolization procedure. The mean±SD packing density was 29.5±10.6%. Periprocedural complications were observed in three cases (3.3%). At 6 months the rate of completely occluded cases increased to 78.3% (54/69) and those for neck remnant and dome filling decreased to 11.8% (8/69) and 10.1% (7/69), respectively. Recanalization occurred in six aneurysms and one aneurysm was retreated during the follow-up period, giving an overall recurrence rate of 10.0% (7/70). Linear regression analysis showed a significant association of packing density with the percentage EDC-10 ES volume (p<0.001) and with the maximum aneurysm size (p<0.001).

Conclusions  Use of the EDC-10 ES permits safe and effective embolization of a cerebral aneurysm and contributes to a reduction in the rate of recanalization.

INTRODUCTION

Two decades have passed since endovascular treatment of cerebral aneurysms with platinum coil embolization was introduced into clinical practice.¹ ² This treatment has become accepted worldwide as an effective and less invasive alternative to surgical clipping to occlude ruptured and unruptured cerebral aneurysms. The most representative large-scale clinical study, the International Subarachnoid Aneurysm Trial, revealed a significantly lower rate of immediate morbidity and mortality in endovascular coiling than in surgical clipping.³ However, medium- and long-term follow-up of patients treated with coil embolization has shown that some cases undergo compaction of the coil ball and recanalization or regrowth of the treated aneurysm.⁴⁻⁷ Various types of coils have been developed to circumvent these disadvantages of coil embolization, including bioactive coils and hydrogel-coated coils. These innovative coil technologies have contributed to a reduction in the recanalization rate, but the problems associated with recanalization have not been completely resolved.⁸⁻⁹

Improvement in the mechanical properties of coils has been achieved by approaches that reduce the stiffness of the platinum element wire and soften the coils to improve handling properties. The ED coil-10 Extra Soft (EDC-10 ES; Kaneka Medix Corporation, Osaka, Japan) is an extremely soft coil manufactured with an unprecedentedly small diameter of the element coil wire (0.0014 inches). Although the coil is a bare platinum coil, it allows higher packing and contributes to a better outcome through its excellent handling properties due to the extreme softness of the coil. The EDC-10 ES is now commonly used for coil embolization, but the clinical performance of the coil has not been examined in detail. The purpose of this study was to examine the clinical efficacy and safety of the EDC-10 ES for treatment of aneurysms as a representative extremely soft bare coil.

MATERIALS AND METHODS

Patient background and aneurysm characterization

From April 2008 to December 2010 the EDC-10 ES coil was used in endovascular coil embolization of 92 consecutive cerebral aneurysms in 89 patients in our hospital. These cases were judged to be suitable for embolization after evaluation by neurosurgeons and neurointerventionalists or because the patient refused clipping. The clinical records of these cases were retrospectively analyzed to evaluate the clinical efficacy and safety of the coil. The background of the patients and aneurysm characterization are summarized in Table 1.
The mean±SD dome size and neck size were 5.8±2.4 mm (median 5.3 mm; range 2.0–12.9 mm) and 3.3±1.4 mm (median 3.0 mm; range 0.9–9.5 mm), respectively. The mean±SD dome to neck ratio of each aneurysm was 1.86±0.73 (median 1.61; range 1.0–4.50). Of the 92 aneurysms, 70 (76.1%) were in the anterior circulation and 22 (23.9%) in the posterior circulation.

Endovascular treatment

Coil embolization of aneurysms was performed by a single consultant neurosurgeon (KH). Of the 92 embolizations, 41 (44.6%) were performed with a simple technique and 51 with an adjunctive technique, including the balloon-assist technique for 42 (45.7%) and the double catheter technique for 9 (9.8%). Hyperform (ev3, Irvine, California, USA) or Hyperglide (ev3) were used in the balloon-assist technique. In most cases, GDC-18 360, GDC-10 360 (Boston Scientific, Fremont, California, USA), Compass-18, Compass-10 (Terumo, Tokyo, Japan) or Trufill Orbit (Cordis, Miami Lakes, Florida, USA) three-dimensional coils were used as framing coils at initiation of embolization. The EDC-10 ES was mainly used in the middle and later stages of the procedure, and most frequently as a finishing coil in the final stage in all aneurysms.

Angiographic evaluation

A three-dimensional angiogram was recorded immediately after treatment and at follow-up using a biplane system (BRANSIST Safire, Shimadzu, Kyoto, Japan). The size of aneurysms in three planes (height, length and width) was measured on the three-dimensional angiograms with reference markers included in the view. The maximum aneurysm size was defined as the longest dimension. The aneurysm sac volume was calculated using the following equation:

\[
\text{Aneurysm sac volume} = \frac{4}{3} \times \pi \times \left( \frac{\text{length}}{2} \right) \times \left( \frac{\text{width}}{2} \right) \times \left( \frac{\text{height}}{2} \right).
\]

The volume of the inserted coil was calculated as follows:

\[
\text{Coil volume} = \pi \times \left( \frac{\text{diameter of coil}}{2} \right)^2 \times \left( \text{length of coil} \right).
\]

Packaging density (%) was calculated by dividing the volume of the inserted EDC-10 ES by the total volume of inserted coils×100.

Statistical analysis

Linear regression analysis was performed to evaluate the relationships of packing density with dome to neck ratio, maximum aneurysm size, percentage EDC-10 ES volume and aneurysm volume. Statistical analysis was performed using SPSS software V16.0 (SPSS, Chicago, Illinois, USA).

RESULTS

Initial and follow-up angiographic outcomes

Quantitative and angiographic results are summarized in table 2. The mean±SD packing density was 29.5±10.6% (range 15.8–68.4%).

Statistical analysis

Procedural complications

<table>
<thead>
<tr>
<th>Total number</th>
<th>92</th>
</tr>
</thead>
<tbody>
<tr>
<td>RS1</td>
<td>63 (68.5%)</td>
</tr>
<tr>
<td>RS2</td>
<td>11 (12.0%)</td>
</tr>
<tr>
<td>RS3</td>
<td>18 (19.6%)</td>
</tr>
</tbody>
</table>

6-month follow-up angiographic occlusion

<table>
<thead>
<tr>
<th>Total number</th>
<th>69</th>
</tr>
</thead>
<tbody>
<tr>
<td>RS1</td>
<td>54 (78.3%)</td>
</tr>
<tr>
<td>RS2</td>
<td>8 (11.6%)</td>
</tr>
<tr>
<td>RS3</td>
<td>7 (10.1%)</td>
</tr>
</tbody>
</table>

Improved

| Total number | 10 (14.5%) |

Stable

| Total number | 56 (81.2%) |

Worsened

| Total number | 6 (8.7%) |

6-month recanalization rate

<table>
<thead>
<tr>
<th>Total number</th>
<th>70</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recanalization (worsened+retreatment)</td>
<td>7 (10.0%)</td>
</tr>
</tbody>
</table>
68.4%) and the mean±SD percentage EDC-10 ES volume was 40.5±25.1% (range 4.9–100.0%). Initial angiographic results showed that the sac and neck were completely occluded in 63 (68.5%) of the 92 aneurysms, which were evaluated as RS1. Complete occlusion was not achieved in the other 29 aneurysms, which were classified as RS2 in 11 cases (12.0%) and RS3 in 18 (19.6%).

Of the 63 aneurysms initially graded as RS1, 47 were stable and evaluated as RS1, 1 had degraded to RS2 and the other 15 had been lost to follow-up at 6 months after treatment. Of the 11 aneurysms initially graded as RS2, 2 had improved to RS1, 5 were stable, 2 had degraded to RS3 and 2 had been lost to follow-up at 6 months. Of the 18 aneurysms initially graded as RS3, 7 had improved to RS1 or RS2, 2 were stable, 3 had worsened within the RS3 grade, 1 had been retreated and 5 had been lost to follow-up at 6 months.

In total, one ruptured aneurysm was retreated due to recanalization and 22 were lost to follow-up during the 6-month follow-up period, included 19 ruptured and 3 unruptured aneurysms. Therefore, 69 aneurysms (38 ruptured and 31 unruptured) were subjected to angiographic evaluation at 6 months after treatment. Compared with the initial results, the angiographic outcome improved in 7 (10.1%) cases, worsened in 6 (8.7%) and remained at the same grade in 56 (81.2%). Thus, 54 (78.3%) of the 69 aneurysms were graded as RS1, 8 (11.6%) as RS2 and 7 (10.1%) as RS3 at 6 months after treatment. Of these 69 aneurysms, the 6 degraded aneurysms were considered to be recanalized. With addition of the one early recanalized aneurysm during the follow-up period, the overall recanalization rate was 7/70 (10.0%).

**Clinical and technical complications**

Clinical complications were observed in three of the 92 patients (3.3%), including one aneurysmal perforation with no symptoms and two ischemic complications, including one that caused a permanent deficit in the visual field and one transient deficit. There was no technical complication including unraveling of coils during the embolization procedure.

**Factors affecting the packing density**

Linear regression analysis was conducted to examine parameters with a possible effect on packing density. There was no significant correlation between the dome to neck ratio and packing density (figure 1A; R=0.12; 95% CI –4.74 to 1.29; p=0.258). Aneurysm volume had a weak but significant correlation with packing density (figure 1B; R=0.38; 95% CI –0.04 to –0.01; p<0.001) whereas, interestingly, percentage EDC-10 ES volume had a stronger significant correlation (figure 1C; R=0.55; 95% CI 0.16 to 0.30; p<0.001).

**DISCUSSION**

Coil embolization is widely accepted as a safe and effective treatment option for cerebral aneurysms but the high rate of recanalization is a remaining problem. The rate of recanalization of aneurysms embolized with bare platinum coils can be as high as 20–40%.

Second-generation aneurysm embolization coils, including surface-modified coils, have been developed to reduce this high recanalization rate. The matrix coil was the first surface-modified coil, with the wire strand coated with biodegradable polymer to induce mild inflammation and accelerate intra-aneurysmal clot formation, thus preventing inflow of circulating blood from the parent artery to the aneurysmal sac. However, the initial results with the matrix coil were not satisfactory in terms of reduction of the recanalization rate, which still remained at well over 10%. These disappointing results were attributed to inadequate packing of the aneurysm due to handling difficulties of the coil caused by friction produced by the uneven surface design of the coated polymer.

Cerecyte coils after a 6-month follow-up period. Linfante et al obtained better results with only five cases of recanalization in 45 cases (11.1%) at 12-month follow-up angiography. These results suggest that improved handling properties contribute to reducing recanalization.

The HydroCoil is an innovative surface-modified coil coated with a swelling hydrogel to increase the embolization volume. While the coil acquires higher packing density than the same volume of platinum coils by expanding the coil volume after deployment, handling is not optimal mainly because of the stiffness and friction of the coil caused by the hydrogel overlaying the coil surface. Thus, improvement of the recanalization rate with the HydroCoil has not been as good as expected. Gunnarsson et al found average recanalization rates of 17.7% for small aneurysms (<10 mm) and 28.6% for large aneurysms (10–25 mm) at a mean follow-up of 16.3 months while Deshaies et al found...
Regression analysis between packing density and the percentage EDC-10 ES volume also provides a rough indication of the EDC-10 ES volume required for preventing recanalization. Assuming that a 25% packing density is an index for stable embolization, a 17.6% EDC-10 ES volume is required based on the regression equation deduced from the analysis shown in figure 1C. In fact, we used EDC-10 ES coils as 40.5% of the total volume and obtained a packing density of 29.5%. Thus, using more EDC-10 ES coils is likely to contribute to increasing the packing density. Achievement of adequate packing then reduces the recanalization rate.

In this study we examined the clinical records of 92 aneurysms treated with coil embolization in which at least one EDC-10 ES coil was used, with the goal of evaluating the efficacy and safety of this coil. Although the EDC-10 ES is an extremely soft bare platinum coil, the overall results were comparable to those for most studies using second-generation coils. Throughout our treatment series only three (3.3%) periprocedural complications occurred (table 2) and none were due to the properties of the coil. This result shows the safety of the EDC-10 ES. The rate of complete occlusion (RS1) was 68.5% (63/92) at the point of initial treatment which improved to 78.3% (54/69) at 6 months later. Recanalization occurred in only seven of 70 aneurysms (10.0%) in our treatment series, indicating a similar or better recanalization rate than most reported series.

The main limitation of this study is that data were examined from a small number of cases based on a short-term follow-up period. Another limitation is the study design of retrospective observation. Therefore, the results require validation in a multicenter prospective cohort study with a larger number of cases and a longer follow-up period. Within these limitations, we found that the EDC-10 ES coil has excellent handling properties due to the softness of the coil filament and that these beneficial properties led to adequate embolization and a higher packing density. This contributed to a reduced recanalization rate comparable to that of second-generation coils.

CONCLUSION

Embolization of cerebral aneurysms with an extremely soft bare platinum coil (EDC-10 ES) resulted in a favorable packing density and recanalization rate. These results show that improvement of the mechanical properties of embolization coils produces desirable effects on handling properties and contributes to a better outcome.

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Contributors KH was a main operator of the endovascular treatment, designed the research and drafted the manuscript. JM was a main assistant of the endovascular treatment and reviewed the manuscript.

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REFERENCES


