Endovascular Treatment of Cerebral Aneurysms Using the Hydrocoil Embolic System

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SUMMARY – *HydroCoils are platinum helical coils coated with a layer of hydrophilic acrylic polymer (hydrogel), which on contact with blood causes disentanglement of polymer chains and expansion. We retrospectively reviewed a series of 29 patients harboring 29 cerebral aneurysms treated with the Hydrocoil Embolic System in the period 2004-2005, discussing the results of endovascular procedures in terms of safety and efficacy. The immediate post-procedure angiographic control demonstrated complete aneurysm occlusion in 21 cases (72.4%), near-complete occlusion in seven cases (24.1%), whereas in one case (3.4%) there was a procedure failure with major perfusion of the sac. Five patients (17.2%) experienced thromboembolic complications, including an asymptomatic lacunar stroke of the head of the caudate nucleus, a thalamic infarct following hypotension secondary to pulmonary edema, temporal ischemia secondary to vasospasm and a small right occipital ischemic lesion. Only one patient (3.4%) suffered a major ischemic accident. No other procedure-related complication occurred. Three-month follow-up control with MR angiography and 12-month follow-up angiography demonstrated no recurrence of aneurysms. Overall, after a mean follow-up of 12 months, the clinical outcome was good recovery in 26 patients (89.6%), moderate disability in three patients (10.3%) and no vegetative status or death. Our HydroCoil series supports the safety and midterm durability of hydrogel-coated aneurysm coils in the treatment of cerebral aneurysms.*

Introduction

With the introduction of the Guglielmi detachable coils in the early 1990s, the employment of endovascular methods for the treatment of intracranial aneurysms has dramatically increased¹⁻⁸.

Treatment of intracranial aneurysms with bare platinum coils was shown to improve outcome in patients with ruptured cerebral aneurysms compared with surgical clipping in the ISAT multicenter study². Concern remains regarding the long-term durability because a significant proportion of coiled aneurysms can recanalize, with a subsequent rerupture rate of 2.6% at one year^{2,3}. Especially in large or gi-

ant aneurysms, clots may undergo thrombolysis with time, causing partial reperfusion of the aneurysm and thus a high risk of rebleeding⁶⁻⁸.

Stent-assisted coiling, balloon-assisted coiling and especially flow-diverter devices are now the best options for the treatment of 'uncoilable' intracranial aneurysms, i.e. wide-neck, giant and fusiform aneurysms^{9-14,21,31,33}.

A recent meta-analysis has shown unfavorable angiographic outcome rates of 20% for bare platinum coils, and 15% for the HydroCoil Embolic System¹⁹. Although the difference in unfavorable outcome rates among the various coil types was not statistically significant we were encouraged to retrospectively review a series of

Table 1 Demographic and clinical data.

Age (mean)	Sex	Number of patients	Ruptured aneurysms		Unruptured aneurysms	
20-85 (54)	15 F 14 M	29	9 (5 F; 4 M)		20	
			1	HH*1	2	Asymptomatic
			4	HH*2	6	Headache
			2	HH*3	7	Headache and nerve palsy (2 II, 2 III, 2V, 1 VI)
			2	HH*4	1	Surgical recurrence
					1	Endovascular recurrence
					3	TIA

*Hunt & Hess Clinical presentation.

Table 2 Aneurysms localization.

Aneurysm Localization		
Anterior Circulation	Anterior Communicating Artery (ACA), A1	10
	Internal Carotid Artery (ICA)	7
	Posterior Communicating Artery (PcomA)	5
	Trifurcation of the Middle Cerebral Artery (MCA)	2
Posterior Circulation	Basilar Artery (BA)	4
	Posterior Cerebral Artery (PCA)	1

29 patients harboring 29 cerebral aneurysms treated with the Hydrocoil Embolic System in the period 2004-2005.

We discuss the results of endovascular procedures in terms of safety and efficacy.

Materials and Methods

Between January 2004 and May 2005, 29 patients harboring 29 cerebral aneurysms were treated by means of the HydroCoil Embolic System (HES, MicroVention, Inc, Aliso Viejo, CA, USA). There were 14 males and 15 females with a mean age of 54 years (range 20-85 years). Among these patients, nine presented with subarachnoid hemorrhage (SAH) following aneurysm rupture, 18 with unruptured aneurysms, whereas two patients presented with recurrent aneurysm, one previously treated by surgical clipping and in the other by endovascular coiling (Table 1). Patients presenting SAH were clinically classified by Hunt and Hess scale (HH): one patient presented HH1 (asymptomatic, mild headache, slight nuchal rigidity), four HH2 (moderate/severe headache, nuchal rigidity, with-

out neurologic deficit), two HH3 (drowsiness/confusion, mild focal neurologic deficit) and two HH4 (stupor, moderate/severe hemiparesis).

Table 2 shows the anatomic location of the aneurysms is shown with the anterior communicating artery being the most frequent site, while in five cases (17%) aneurysms were located in the posterior circulation. In 19 cases (65%) the aneurysm presented a neck/dome ratio superior or equal to 2:1, with the remaining ten (35%) having a ratio less than 2:1 (Table 3).

Aneurysm volume, HES coil volume, and packing density were evaluated in all cases. Aneurysm volume was calculated by considering the aneurysm silhouette elliptical according to the following formula: aneurysm volume = $4 \pi \times (\text{height}/2 \times \text{length}/2 \times \text{width}/2)/3$. Based on the aneurysm volume measured before the procedure, the size and number of coils indicated for appropriate occlusion were determined, with aneurysm occlusion being expressed as packing density^{17,18}. Packing density was calculated according to the following formula: packing density = (coil volume/aneurysm volume) $\times$ 100%, whereas coil volume was given by: coil volume = $\pi \times (\text{radius})^2 \times \text{length}$.

Figure 1 A) Right-ICA DSA showing anterior communicating artery aneurysms. B) Control after coil deployment.

Radiologic follow-up was performed three months after treatment by magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA), and in 12 months after the procedure by means of angiography.

All patients presenting with acute SAH were treated within 72 hours of onset. In three cases, endovascular embolization was preceded by self-expanding intracranial stent implantation (Neuroform II, Boston Scientific), performed approximately three weeks before embolization.

Endovascular Technique

All procedures were undertaken via a transfemoral approach, introducing a Prowler Plus (Cordis Corp., Miami, FL, USA) microcatheter into the aneurysm. An initial detachable platinum coil (GDC 3D or Micrus SPH) was then released to form a stabilizing “basket” so as to avoid HydroCoil migration during polymerization of the device. Before application, the HydroCoils were pretreated with steam to reduce the

rigidity of the distal extremity of the device. The HydroCoil was deposited within the aneurysm using a releasing mechanism based on the density gradient with the iodinated contrast medium. Definitive placement was obtained within five minutes after initial detachment, which represents the interval in which correcting positioning maneuvers may be carried out before polymerization begins. Once a satisfying packing density was achieved, angiographic control was performed, approximately 20 minutes after the last HydroCoil placement, when maximal hydrogel expansion was completed (Figures 1 and 2). Given the HydroCoil specific composition, angiographic control focused on non-visualization of the aneurysm rather than the packing density of the HydroCoil metallic component. Thus, digital angiography without subtraction demonstrated aneurysm occlusion, even though the platinum coil material was not completely packed. Following HydroCoils deployment, additional standard soft or ultrasoft platinum coils were employed in cases of incomplete aneurysm occlusion.

Table 3 Neck/dome ratio in the population.

<i>Neck/Dome Ratio</i>	<i>Number of patients</i>
$\leq 2:1$	19
$>2:1$	10

Table 4 Percentage of aneurysm filling by HES and by all devices.

<i>Patient</i>	<i>Aneurysm volume (cc)</i>	<i>% filling with HES</i>	<i>% of aneurysm filled by all devices (Number)</i>	<i>Number of platinum coils employed</i>
1	0.067	48%	58% (1)	4
2	0.218	49%	70% (2)	5
3	0.178	36%	40% (1)	5
4	0.048	40%	58% (1)	3
5	0.176	57%	74% (2)	6
6	0.126	74%	92% (3)	3
7	0.050	37%	59% (1)	1
8	0.302	35%	77% (4)	4
9	0.183	51%	59% (2)	8
10	0.111	53%	89% (4)	1
11	0.211	51%	68% (3)	5
12	0.028	50%	78%(1)	2
13	0.235	39%	85%(5)	2
14	0.151	38%	91%(4)	1
15	0.141	77%	91%(3)	1
16	0.151	35%	69%(2)	5
17	0.302	33%	73%(4)	5
18	0.176	74%	94%(7)	1
19	0.283	68%	81%(5)	6
20	2.797	25%	50%(8)	26
21	0.019	65%	78%(1)	1
22	0.055	34%	55%(1)	4
23	0.200	71%	52%(4)	8
24	0.071	52%	70%(1)	4
25	0.308	23%	36%(1)	11
26	0.164	68%	73%(3)	5
27	0.495	57%	71%(3)	10
28	0.110	29%	34%(1)	6
29	0.320	24%	24%(1)	8

Patients' Follow-up

All patients were scheduled for three, six and 12-month follow-up with MRA with and without contrast media. The results were confirmed with

12-month digital angiography. Occlusion was classified by an interventional neuroradiologist with 20 years' experience (FB) as complete, near-complete in the presence of a neck remnant or partial when a residual body filling was observed.

Results

Table 3 summarizes aneurysm volume, number of HES coils and GDC employed and packing density for all aneurysms treated. The immediate post-procedure angiographic control demonstrated complete aneurysm occlusion in 21 cases (72.4%), near-complete occlusion in seven cases (24.1%), whereas in one case (3.4%) there was a procedure failure with major perfusion of the sac.

A mean of two to nine HES coils per aneurysm were employed (range 1-8 HES), which provided packing attenuation ranging from 23% to 77% (mean 48%) (Table 4). A minimum of one and a maximum of 26 GDC per aneurysm were used (mean 4.8 coils per aneurysm). The overall packing density ranged from 24% to 94% (mean 67%).

Five patients (17.2%) experienced thromboembolic complications among whom only one (3.4%) suffered a major ischemic accident following anterior cerebral artery occlusion during endovascular treatment of an anterior communicating artery aneurysm. The remaining complications included an asymptomatic lacunar stroke of the head of the caudate nucleus, a thalamic infarct following hypotension secondary to pulmonary edema, temporal ischemia secondary to vasospasm and a small right occipital ischemic lesion. No other procedure-related complications occurred.

Three-month follow-up control with MRA and 12-month follow-up angiography demonstrated no recurrence of aneurysms (Figure 3). Overall, after a mean follow-up of 12 months, the clinical outcome was evaluated by a Neurosurgeon (GM) and classified by the Modified Rankin Scale (mRS) as follows: no significant disability (mRS 1) in 26 patients (89.6%), moderate disability (mRS 3) in three patients (10.3%) and no vegetative status or death.

Discussion

HydroCoils are platinum helical coils coated with a layer of hydrophilic acrylic polymer (hydrogel), which, on contact with blood, causes disentanglement of polymer chains and expansion. Its use is based on the concept of filling the intra-aneurysmal space with a non-absorbable polymer and thus, rendering the aneurysmal packing independent of clot formation¹⁵⁻²¹. The HES system is a hybrid device made of platinum and hydrogel in a 30:70 ratio. The device

measures 0.009 inch in diameter and in approximately 20 minutes after implantation reaches its maximum blood-induced expansion of 0.027 inch^{17,18,37}. From a theoretical standpoint, this feature should aim to overcome the shortcomings of occlusion instability caused by the thrombolytic process as it allows for aneurysmal packing to be independent from clot formation^{10,12,13}.

Previous series of HydroCoils demonstrated a better packing density, varying from 60 to 70% compared with the packing density obtained using standard coils (25-30%)^{5-8,17,18,32}. Cloft et al. showed a statistically significant improvement of aneurysm packing using HydroCoils compared with standard platinum coils (72% versus 32%, respectively)^{17,18,32}.

Gunnarson et al. reported a retrospective analysis of periprocedural complications in a cohort of 200 intracranial aneurysms. Their retrospective analysis showed complete aneurysmal obliteration in 58.4% of small aneurysms and 42.7% of large aneurysms and morbidity and mortality in 6% of cases. At 16.3 month follow-up partial recanalization was reported in 17.7% of small aneurysms and 28.6% of large aneurysms, requiring retreatment in 6.3% and 19.0% of cases, respectively³².

HELPS was the first randomized clinical trial to compare HES with bare coils for recently ruptured and not recently ruptured/unruptured aneurysms^{37,38}. The three-month mortality rate was 3.6% in HES and 2.0% in control arms; the difference was not statistically significant. These HELPS results reinforced coiling as an effective treatment for aneurysms, with an excellent technical success rate although bare coils and HES presented an equivalent risk profile^{28,29,37,38}.

A recent meta-analysis reviewed the literature in the years 1999-2011¹⁹. Unfavorable angiographic outcomes of cerebral aneurysms treated with coil embolization as a function of coil type were analyzed. The overall unfavorable outcome rate was 19%: 20% for bare platinum coils, 23% for Matrix, 15% for HydroCoil, and 15% for Cerecyte. The difference in unfavorable outcome rates among the various coil types was not statistically significant after adjusting for baseline characteristics, including aneurysm size, rupture status, and follow-up duration.

The literature on patients with ruptured (ISAT)² intracranial aneurysms reports higher mortality or severe disability rates of 30.9% for neurosurgical clipping versus 23.5% for endovascular coiling. In unruptured cohorts of aneurysms clipping resulted in significantly

Figure 2 A) Right-vertebral artery DSA shows basilar tip aneurysms. B) Control after coil deployment.

Figure 3 A) Right-vertebral artery DSA 6 months after the procedure. B) 18-month-MRA TOF 3D MIP reconstruction, showing the stability of the occlusion (case in Figure 2).

higher disability. King et al.⁴⁰ and Raaymakers et al.⁴¹ found mortality rates of 1.0% and 2.6% and morbidity rates of 4.1% and 10.9%,

respectively; these results are worse than ours (mortality 0%; morbidity 3.4%).

Our experience with the HES device for the

endovascular embolization of cerebral aneurysms documented a relatively high percentage of aneurysm filling, with a mean value of 69% in a series of 29 aneurysms located in both anterior and posterior cerebral circulations. Such value appears promising compared with the filling percentage obtained by means of traditional platinum coils averaging approximately 25%^{4-8,22-29}. Furthermore, the packing density obtained by HES coils seems to depend on the expanding hydrogel of the coils rather than on the process of clot formation observed in cases of platinum coils^{17,18}. From a theoretical standpoint, this property should provide greater long-term occlusion stability and better resistance against blood flow. Therefore, the expected recurrence rate with this new device should be much less than that of endovascular embolization by means of traditional platinum thrombogenic coils^{14-20,22}.

Nevertheless, in some cases of our cases, follow-up MRI and MRA evaluation with the time-of-flight technique (TOF) and after contrast administration disclosed clot formation within the aneurysmal sac, likely induced by a partial interaction between blood and bio-active polymer. Moreover, in two cases angiographic control at one year after treatment showed a separation image between aneurysm and parent vessel, suggesting an initial re-epithelization process of the aneurysm neck. Such

observation was previously reported only in laboratory studies³⁵.

In another patient, 12-month follow-up angiographic control demonstrated complete internal carotid artery occlusion following endovascular treatment of an aneurysm located at the same vessel by means of a stent and subsequent embolization with HydroCoils. However, angiography also disclosed an optimal contralateral circulation compensation. The same patient reported that she had suspended antiplatelet medications by her own decision, something that could explain the clot formation within the stent. Lastly, two patients remained febrile for three and four days after treatment respectively, without further clinical consequences, and they were discharged in good health right after fever remission.

Conclusion

Our experience with HES demonstrates similar complication rates compared with historical series using pure platinum coils. Follow-up data indicate favorable recanalization rates and similar retreatment rates compared with published pure platinum coil studies. Our HydroCoil series support the safety and midterm durability of hydrogel-coated aneurysm coils in the treatment of cerebral aneurysms^{37,38}.

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