

# Stent-Assisted Coil Embolization for the Treatment of Ruptured Aneurysms at the Anterior Circulation: Comparison Between HydroSoft Coils and Bare Platinum Coils

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Received: 28 April 2013 / Accepted: 1 September 2013 / Published online: 12 November 2013

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## Abstract

**Purpose** To evaluate the perioperative safety and mid-term prognosis ( $\leq 12$  months) of HydroSoft coils in treating ruptured aneurysms at the anterior circulation compared with bare platinum coils.

**Materials and Methods** Patients with aneurysmal subarachnoid hemorrhages admitted to our hospital between January 2009 and March 2012 were retrospectively analyzed. According to strict inclusion and exclusion criteria, cases were selected and classified into two groups: In group A, HydroSoft coils were used as the primary filling coils ( $\geq 40\%$  of total coil length); in group B, only bare platinum coils were used. Cases in both groups were all treated with stent-assistance. A comparison between the two groups was performed for periprocedural complications as well as immediate and mid-term outcomes. The stents used included Enterprise, Neuroform, and Solitaire.

**Results** Fifty-six aneurysms were in group A patients, and 68 aneurysms were in group B patients. Compared with group B, group A did not have increased incidence of complications but had greater packing attenuation ( $44.5 \pm 8.8$ – $29.8 \pm 9.1\%$ ,  $t = 2.577$ ,  $P = 0.014$ ) and increased initial complete occlusion rates ( $63$ – $44\%$ ,  $\chi^2 = 4.161$ ,  $P = 0.041$ ). Radiologic follow-up were performed in 46 patients from group A and 51 patients from group B. Complete occlusion rates at follow-up were significantly greater in group A than in group B ( $89.1$ – $70.6\%$ ,  $\chi^2 = 5.08$ ,  $P = 0.043$ ); the difference in recanalization rates were statistically insignificant between the groups ( $6.5$ – $5.9\%$ ,  $P = 1.000$ ).

**Conclusion** HydroSoft coils proved safe during the periprocedural period and provided greater initial complete occlusion rates, greater packing density, and better follow-up results compared with bare platinum coils.

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## Introduction

Endovascular embolization has become an effective modality for the treatment of intracranial aneurysms; however, relatively greater recurrence rate remains one of the major handicaps of this technique [1]. Low packing density is among the various factors potentially affecting aneurysm recurrence [2–4]. To improve packing density, various modified coils have been used [5–7]. HydroCoils, which are hydrogel-coated coils, have shown the encouraging results of decreasing recurrence rates [8]. However, these coils are stiffer than the bare coils, which limits their use. To overcome the shortages of the HydroCoil, the HydroSoft coil was developed. It is constructed as a platinum coil with an inner core of hydrogel and a stretch resistant filament, thus providing relatively low stiffness. A

multicenter study has shown that compared with pure platinum or other coated coils, embolization using HydroSoft improves initial occlusion rates and durability [5].

Thus, the present work was aimed at assessing the perioperative safety as well as initial and mid-term outcomes of stent-assisted HydroSoft coil embolization for the treatment of ruptured aneurysms at the anterior circulation compared with bare platinum coils.

## Materials and Methods

### Patient Selection

Consecutive patients with aneurysmal subarachnoid hemorrhages (aSAHs) admitted to our hospital between January 2009 and March 2012 were retrospectively analyzed. The inclusion criteria were as follows: (1) ruptured intracranial aneurysms situated in the anterior circulation; (2) stent-assisted coil embolization performed; (3) Hunt and Hess (H–H) grades of I to approximately III. The exclusion criteria were as follows: (1) embolization with modified coils other than HydroSoft; (2) HydroSoft coils used but not as the primary filling coil (<40 % of total coil length); (3) multiple aneurysms in which it was difficult to determine the “culprit one” that caused SAH; (4) staged embolization; (5) repeat embolization for recanalized or recurrent aneurysm; and (6) fusiform, infectious, traumatic, or dissecting aneurysms.

Cases were then classified into two groups: Group A, in which HydroSoft coils were used as the primary filling coils ( $\geq 40$  % of the total coil length); and group B, in which only bare platinum coils were used. Forty percent of HydroSoft coil percentage length was set as the cut-off value because we regarded to be sufficient to cause a packing difference compared with bare coil according to our experience. The study was reviewed and approved by the Ethical Committee of our institute.

### Embolization Procedure

All endovascular treatments were performed with the patients under general anesthesia. After systemic heparinization, a guiding catheter (Envoy; Cordis, Miami Lakes, FL) was placed in the internal carotid artery to obtain a stable position. A microguidewire was introduced distally to the aneurysm with the help of a suitable microcatheter. The stent was then placed, after which the aneurysm was catheterized by way of stent mesh and subsequently coiled in the same session; or, before deploying the stent, the embolization microcatheter was navigated into the aneurysm and the stent fully deployed after the completion of coil embolization or a coil basket covering the entire

perimeter of the aneurysm was achieved. The goal for stent placement was to ensure the stent extended at least 5 mm past each side of the aneurysm neck. The appropriate size and length of the stent were chosen, and Enterprise stents (Codman Neurovascular, Raynham, MA), Neuroform stents (Boston Scientific, Natick, MA), and Solitaire stents (ev3, Irvine, CA) were used. Y-configuration deployment was excluded because our previous experience suggested a greater thromboembolic event rate with such; overlapping or stent-in-stent configuration was excluded because stents played a role as a flow diverter in this situation.

Regarding coil embolization, a series of coils of appropriate dimensions were selected. HydroSoft (Microvention Terumo, Aliso Viejo, CA), GDC (Boston Scientific, Fremont, CA), and Microplex (Microvention, Aliso Viejo, CA) were used. In the HydroSoft coils group, three-dimensional platinum coils were generally used to establish the initial framework in the aneurysm lumen and form a multiplanar structure for subsequent HydroSoft coil deposition; however, HydroSoft coils could be used as framing, filling, or finishing coils. In the bare platinum coils group, no modified coils were used. In each case, the objective of the procedure was angiographic occlusion of the aneurysm.

### Anticoagulation and Antiplatelet Regimens

A loading dose of clopidogrel and aspirin (300 mg each) was administered orally or rectally at 2 h before stenting. From January 2009 to June 2010, all patients were maintained on aspirin (300 mg daily) and clopidogrel (75 mg daily) for 6 weeks followed by aspirin alone (100 mg daily), which was continued indefinitely. After June 2010, the initial 300-mg daily aspirin dose was decreased to 100 mg daily [9].

### Initial Outcome Assessment and Follow-Up

Digital subtraction angiography (DSA) results before and immediately after endovascular treatment were obtained. Immediate aneurysmal occlusion was defined by the modified Raymond-Roy classification as complete, residual neck, or residual sac [10].

The standard angiographic follow-up protocol consisted of a first angiography performed 1–6 months after the procedure and follow-up angiography at 6 or 12 months afterward. In patients with angiographic total occlusion, the follow-up was continued by magnetic resonance angiography on a yearly basis. For patients with angiographic recurrence, we continued follow-up by annual DSA. Follow-up data over 12 months were collected.

Follow-up results were further classified as stationary (contrast media filling increased <10 % or decreased <10 %), improved (contrast media filling decreased  $\geq 10$  %), or worsened (contrast media filling increased

**Table 1** Baseline patient characteristics

Characteristics	Group A	Group B	Statistics	<i>P</i>
No. of patients	56	68		
Sex (M:F)	17:39	25:43	$\chi^2 = 0.563$	0.453
Age (year)	56.3 ± 13.1	54.2 ± 11.8	$t = 0.283$	0.756
Aneurysm location (%)				
PCoMA	22 (39.3)	31 (45.6)		
AchoAOphthalmic	3 (5.4), 6 (10.8)	2 (2.9), 9 (13.2)		
ICA	3 (5.4)	5 (7.4)	$F = 4.115$	0.693
ACoMA	19 (33.9)	16 (23.5)		
ACA	2 (3.6)	1 (1.5)		
MCA	1 (1.8)	4 (5.9)		
Aneurysm size in mm (%) <sup>a</sup>				
<4	23 (41.1)	21 (33.9)		
4–10	28 (50.0)	39 (53.2)	$\chi^2 = 1.441$	0.526
>10 Neck size in mm (%)				
≤4	25	22	$\chi^2 = 1.971$	0.160
>4	31	46		
Ruptured status <3 days (%)	49 (87.5)	53 (72.6)	$\chi^2 = 1.923$	0.238
>3-d HH score II to III (%)	7 (12.5) 26, 22, 8	15 (27.4) 31, 30, 7	$\chi^2 = 0.580$	0.766

<sup>a</sup> Although tiny aneurysms were commonly regarded as measuring  $\leq 3$  mm, many aneurysms 3–4 mm in size were treated with a single coil in our institution. Thus, 4 mm was set as the cut-off size

$\geq 10$  %). A worsened result was regarded as recanalization. A blinded reviewer determined the occlusion status of each aneurysm on angiography. The packing density was defined as the ratio between the volume of coils inserted into the aneurysm and the aneurysm volume as has been described by previous studies [11]. Modified rankin scale (mRS) score was used to evaluate the clinical outcomes when patients were discharged and followed-up by rehospitalization, clinical visits, or phone calls.

#### Complications

Any periprocedural and postprocedural complications that were potential results of endovascular treatment was documented along with their clinical consequences, including the presence or absence of permanent disability.

#### Statistical Analysis

Continuous variables were described by means and SDs. Categorical variables were described by counts and percentages. *P* values for continuous variables were calculated using unpaired Student *t* test; *P* values for categorical variables were calculated using Fisher's exact test or Pearson Chi square test. Statistical Package for the Social Sciences (version 18.0 for Windows; SPSS, Chicago, IL) was used to analyze the data. A *P* value of  $<0.05$  was considered significant.

## Results

### Patients and Aneurysms

A total of 336 ruptured aneurysms were treated by stent-assisted coil embolization in our hospital from January 2009 to March 2012, among which 124 aneurysms were eligible for the study. These cases include the following: 56 ruptured aneurysms in 56 patients treated using HydroSoft coils (group A) and 68 ruptured aneurysms in 68 patients treated using only bare platinum coils (group B). Stents were typically used for wide-neck aneurysms (neck  $>4$  mm and/or a dome-to-neck ratio  $<2$ ) and for aneurysms that involved significant circumferential portions of the parent vessel. All cases were wide-necked aneurysms. Enterprise stents were used in 111 aneurysms, Neuroform stents in 8 aneurysms, and Solitaire stents in 5 aneurysms. Aneurysms included were located in a wide variety of locations in the anterior circulation. Patient demographics, aneurysm characteristics, and treatment information for these groups are listed in Table 1.

### Complications

In group A, one MCA aneurysm ruptured during the intraprocedural period and caused SAH. The aneurysm ruptured after the first bare platinum coil placement; two HydroSoft coils were placed to obliterate the aneurysm,

**Table 2** Procedural and postprocedural complications

Complications	No.	Morbidity	Mortality
Thromboembolism	3 (2) <sup>a</sup>	0 (1)	0 (0)
Intraprocedural hemorrhage	1 (0)	0 (0)	0 (0)
Postprocedural hemorrhage	1 (1)	1 (0)	0 (1) <sup>b</sup>
Vasospasm	0 (1)	0 (0)	0 (0)
Total	5 (4)	1 (1)	0 (1)

<sup>a</sup> Numbers in parentheses are for the bare platinum coil group

<sup>b</sup> This male patient had SAH 3 days after embolization without definite lesion, and although he was treated actively, he eventually died from the bleeding

**Table 3** Degree of aneurysmal occlusion at immediately after surgery and aneurysm progression at last follow-up

Angiographic results	Follow-up			
	Immediate (%)	Stationary (%)	Improved (%)	Worsened (%)
Group A	56	27 (59)	16 (35)	3 (7)
Complete	35 (63)	26 (96)	0 (0)	1 (4)
Residual neck	6 (11)	NA	5 (83)	1 (17)
Residual sac	15 (27)	1 (8)	11 (85)	1 (8) <sup>a</sup>
Group B	68	31 (61)	17 (33)	3 (6)
Complete	30 (44)	23 (92)	NA	2 (8)
Residual neck	16 (24)	2 (25)	6 (75)	NA
Residual sac	22 (32)	6 (33)	11 (61)	1 (6)

<sup>a</sup> A male patient died 3 months after initial embolization due to aneurysmal rerupture and a lack of money for treatment

and decompressive craniectomy was then performed. The patient fully recovered without any neurologic deficit. Thromboembolism occurred in three cases; intravenous injection of tirofiban was given, which resulted in the disappearance of thrombi as seen on DSA. Postprocedural events included the following: one AchoAOPphthalmic aneurysm rebleeding, which occurred 4 h after procedure and was treated by occlusion of the parent artery with Hydrogel-coated coils (Table 2).

In group B, two cases of thromboembolism occurred during surgery; one case of vasospasm occurred 8 days after surgery, and balloon dilation was performed. One 83-year-old female patient of pcom aneurysm aneurysm underwent SAH 3 days after the procedure and eventually died (Table 2). Nine patients underwent ventriculostomy or ventriculoperitoneal shunt placement (six in group A and three in group B), and there was no symptomatic catheter-related hemorrhage or radiographic hemorrhage was found. Compared with the bare platinum coil group, the use of HydroSoft coils did not increase complications, and no complications were definitively attributed to the use of HydroSoft coils.

**Table 4** Angiographic results immediately and at follow-up

Angiographic results	Immediate		Follow-up		$P_1^a$	$P_2^b$
	Group A	Group B	Group A	Group B		
Complete	35	30	41	36	0.041	0.043
Residual neck	6	16	2	8	0.063	0.096
Residual sac	15	22	3	7	0.500	0.324

<sup>a</sup>  $P_1$  represents the comparison between the two groups on immediate angiography

<sup>b</sup>  $P_2$  represents the comparison between the two groups on a follow-up angiography

## Radiological Results

Initial complete occlusion rates between groups A and B was significantly different (63–44 %,  $\chi^2 = 4.161$ ,  $P = 0.041$ ) (Tables 3, 4). The HydroSoft coil provided a packing attenuation of  $44.5 \pm 8.8$  % compared with  $29.8 \pm 9.1$  % using bare platinum coils, and the difference is significant ( $t = 2.577$ ,  $P = 0.014$ ).

In the HydroSoft coils group, radiologic follow-up data were available for 46 (82 %) aneurysms after coiling (mean interval 9.3 months). One patient in this group had aneurysmal rerupture and rebled 3 months after treatment; due to a lack of money, he did not receive any treatment and eventually died. Fifty-one (75 %) of the bare platinum coil-treated patients underwent follow-up angiography (mean interval 10.1 months). Detailed results are listed in Table 3.

Complete occlusion rates at follow-up were significantly greater in group A than in group B (89.1–70.6 %,  $\chi^2 = 5.08$ ,  $P = 0.043$ ) (Table 4); three cases in group A and another three in group B showed worsened/recurring result at follow-up, and the difference in recanalization rates were statistically insignificant between the groups (6.5–5.9 %,  $P = 1.000$ ).

In the respect of progressive occlusion of the initially incompletely occluded aneurysms, the difference between group A and B was insignificant (16/19–17/26,  $P = 0.191$ ). In the neck remnant cases, 5/6 of group A and 6/8 of group B achieved improvement ( $P = 1.000$ ); in the sac remnant cases, 11/13 in group A and 11/18 in group B achieved improvement ( $P = 0.238$ ). Detailed data are listed in Table 3.

## Clinical Results

In group A, mid-term follow-up was available for 53 of 56 patients with a mean of 11.2-month follow-up. One patient died at 3 months (Table 3). There were no or mild disability (mRS  $\leq 2$  [favorable outcome]) in 92.5 % (49 of

53) of patients. Three patients had moderately severe disability (mRS score 3 or 4).

In group B, long-term follow-up was available for 61 of 62 patients with a mean of 10.5-month follow-up. There were no or mild disability (mRS  $\leq 2$  [favorable outcome]) in 95.1 % (58 of 61) of patients. Two patients had moderately severe disability (mRS score 3 or 4).

## Discussion

Despite the proven efficacy of endovascular coil embolization for the treatment of ruptured intracranial aneurysm reported in International Subarachnoid Aneurysm Trial [12], long-term durability still remains a major handicap of this treatment technique. Among the many factors leading to recurrence, initial low packing density and subtotal obliteration are regarded as prominent impacting factors. Greater packing density has been correlated with decreased coil compaction and theoretically decreases recurrence rates [13], but in clinical studies there have been conflicting results [2, 3, 14, 15].

Intracranial stents have a multifactorial favorable role in aneurysm embolization: It may enable dense coil mass packing [16, 17], change vascular morphology, induce intraaneurysmal flow modifications [18–22], and provide a structural basis for endothelialization [23, 24]. However, the use of stent-assisted coil embolization more commonly has been reserved for unruptured aneurysms in order to determine the difference between thromboembolic events and hemorrhagic events when treating acutely ruptured aneurysms compared with unruptured ones. Bodily et al. [25] reviewed 339 patients with acutely ruptured aneurysms treated by stent-assisted coiling, all of whom received dual-antiplatelet therapy during or immediately after surgery. They found an 8 % incidence of hemorrhagic complications and a 6 % incidence of thromboembolic events. In our study, rates of both kinds of complications were lower; this may due to three reasons. First, for patients who need a craniotomy for drainage of hematoma, the stent-assisted technique was generally avoided, and only a few external ventricular drainages were performed in our series, which increased the number of hemorrhagic complications [26]. Second, there were patients in our series who were admitted into our hospital >3 days after the onset of SAH. Last, only patients with H–H grade I to III were included in our series.

Hydrogel-coated coils were developed to increase packing density and promote endothelialization. They are platinum coils coated with polymeric gel composed of cross-linked acrylamide/sodium acrylate that absorbs water by diffusion in an optimal acid–base environment of blood, resulting in swelling to improve the volumetric occlusion

of aneurysms [27]. Hydrogel-coated coils target dead space, which is present even in angiographically completely occluded aneurysm.

The precedent HydroCoils are generally used as filling coils rather than framing or finishing coils due to its stiffness. In a randomized controlled trial, HydroCoil Endovascular Aneurysm Occlusion and Packing Study, White et al. [8, 28] proved that HydroCoils can lower recurrent rates while not increasing periprocedural complications. Similar results were showed by Cloft et al. [29, 30].

The new design, HydroSoft, comprises a platinum coil with hydrogel inside. The new coil possesses lower stiffness while the coil-expansion decreases compared with the HydroCoil (0.013 vs. 0.022 inches). In addition, the HydroSoft coil does not require prehydration for softening, and there is virtually no time limitation for deployment after it is exposed to blood. HydroSoft is extremely gentle in treating smaller aneurysm or deployed as final coils near the neck of an aneurysm [31–34] and can complement the HydroCoil system for challenges, such as resistance or microcatheter instability.

We used HydroSoft coils both as framing, filling, and finishing coils in selected cases. A combined deployment of platinum coils and HydroSoft coils was performed in group A to maximize the benefits of each coil type to achieve better occlusion of aneurysms.

By using HydroSoft in embolization, Guo et al. [33] reported packing attenuation of 47 %, and Park et al. [5] reported packing attenuation of 42 %. Our study conforms to their results. Significantly greater aneurysm packing density was achieved with HydroSoft than bare coils, although the volumetric packing density calculation assumes full hydrogel expansion, which might not occur in vivo. Packing densities achieved in our study were lower than previously reported in studies using HydroCoils (45–85 %) [30, 33, 35, 36] and greater than what has been achieved with stent-assisted bare coils (36.59 %) [16].

Previous studies showed initial complete occlusion rates from 27–73 % [37–40] in treating aneurysms by stent-assisted coiling; compared with these studies, our results appeared moderate (63 % in group A and 44 % in group B). The cases included in the present series were all wide-necked and ruptured aneurysms, thus posing a challenge to angiographic occlusion. Although our neurointerventionists were experienced, angiographic occlusion was difficult to achieve in some aneurysms. For the HydroSoft-treated cases, due to the slow hydrogel expansion, greater packing density and initial complete occlusion rate were more easily achieved. Animal experiments have reported similar results [41].

In animal model studies, it is suggested that hydrogel increased neointima formation and thrombus organization

and promote a healing reaction compared with bare platinum coils, suggesting a greater progressive occlusion rate [42, 43]. However, in our series, progressive occlusion rates (34 and 33 % of HydroSoft and bare coil, respectively) were lower than previous studies [44–46] and showed no significant difference among the two groups. The different results may be due to anticoagulation therapies after embolization and different judgment criteria.

In our series, three patients had rebleeding. Although one of them recovered well after endovascular therapy; one remained with mild neurological deficit; and one eventually died from SAH without definite lesion. The one death may have been due to the patient's advanced age and hypocoagulable status. This suggests that postprocedural rebleeding is highly dangerous and that dual-antiplatelet therapy should be carefully used for older patients, although it was safe for most patients.

Complete occlusion rates at follow-up were significantly greater in group A than in group B; however, the recurrence rates were not significantly different between the two groups. This suggests that although HydroSoft improved complete occlusion rate, the bare coil was also effective at 12-month follow-up. It is possible that HydroSoft would result in lower recurrence rates if the follow-up period lasted longer.

## Conclusion

This is the first study that has focused on stent-assisted HydroSoft coils in treating ruptured aneurysms in the anterior circulation. In this study, the use of HydroSoft coils proved to be safe periprocedurally, provided greater packing density, and resulted in better initial and follow-up aneurysm obliteration compared with bare platinum coils.

**Conflict of interest** The authors declare that they have no conflict of interests.

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