ORIGINAL RESEARCH

GEL THE NEC: a prospective registry evaluating the safety, ease of use, and efficacy of the HydroSoft coil as a finishing device

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ABSTRACT

Background and purpose The HydroSoft coil was developed as a finishing coil, ideally to be placed along the aneurysm neck to enhance intracranial aneurysm healing. The GEL THE NEC (Gaining Efficacy Long Term: Hydrosoft, an Emerging, New, Embolic Coil) multicenter registry was developed to assess the safety and efficacy of HydroSoft coils in treating intracranial aneurysms. We report angiographic and clinical results of this prospective registry.

Materials and methods GEL THE NEC was performed at 27 centers in five countries. Patients aged 21–90 years with a ruptured or unruptured aneurysm 3–15 mm in size were eligible for enrollment. The following variables were obtained: demographics/comorbidities, aneurysm geometry, adjunctive devices used, proportion of patients in whom HydroSoft coils were successfully placed, and long-term angiographic outcomes (graded by an independent core laboratory using the Modified Raymond Scale), and procedure-related adverse events. Predictors of good angiographic outcome were studied using χ^2 and t-tests.

Results A total of 599 patients with 599 aneurysms were included in this study. HydroSoft coils were successfully deployed in 577 (96.4%) patients. Procedure-related major morbidity and mortality were 0.5% (3/599) and 1.3% (8/599), respectively. The most common perioperative complications were iatrogenic vasospasm (30/599, 5.0%), thromboemboli (27/599, 4.5%), and aneurysm perforation (16/599, 2.7%). At last angiographic follow-up (mean 9.0±6.3 months), the complete occlusion rate was 63.2% (280/442) and near complete occlusion rate was 25.2% (107/442). The core laboratory read recanalization rate was 10.8% (46/425) and the retreatment rate was 3.4% (20/599).

Conclusions Endovascular treatment of intracranial aneurysms with HydroSoft coils resulted in complete/near complete occlusion rates of 88% and a major complication rate of 1.8%.

Trial registration number NCT01000675.

INTRODUCTION

The HydroSoft coil was developed as a finishing coil in order to allow placement of hydrogel-bearing embolic coils late in the embolization procedure, along the aneurysm neck.[1–4] Several lines of evidence suggest that stabilizing the aneurysm neck may result in better long-term angiographic outcomes.[5–7] Further, placement of hydrogel material along the aneurysm/parent vessel interface may be associated with enhanced healing of intracranial aneurysms.[3 4] GEL THE NEC (Gaining Efficacy Long Term: Hydrosoft, an Emerging, New, Embolic Coil) is a prospective multicenter registry aimed at determining the efficacy, safety, and ease of deployment of HydroSoft coils. We report angiographic outcomes and clinical results of this prospective registry.

MATERIALS AND METHODS

Patient population

GEL THE NEC is a prospective multicenter consecutive series that was conducted in 27 centers in five countries (Registry for Study of Coils in Intracranial Aneurysms Gel-the-nec, https://clinicaltrials.gov/ct2/show/NCT01000675). The predefined enrollment goal was 600 patients over a 2–3-year period. The actual enrollment phase lasted 4 years. Clinical inclusion criteria were the following: (1) patients aged between 21 and 90 years of age with ability to give informed consent and comply with follow-up; (2) patients with ruptured or unruptured aneurysms; and (3) treated aneurysm dimension 3–15 mm. Per protocol, any bare platinum coil could be used as a framing coil. For filling coils, any bare platinum coil could be used after placement of the framing coil and before the use of the finishing coil. Additionally, HydroSoft coils >3 mm were allowable for use as filling coils at the discretion of the operator but were not mandated. HydroSoft coils were to be deployed at the aneurysm neck as a finishing coil when the finishing coil was ≤3 mm. If the HydroSoft coil could not easily or satisfactorily be placed, a substitute platinum coil could be considered after removal of the HydroSoft coil.

Patient demographic and comorbidity data included in this study were age, gender, race, smoking status, and presence of hypertension. Aneurysm data included in the study were Hunt–Hess score, aneurysm rupture status, aneurysm location, aneurysm neck size, width, height, depth, and dome-to-neck ratio.

Angiographic outcomes

Immediate postoperative anatomic evaluation was obtained at the end of the endovascular treatment

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using two-dimensional digital subtraction angiography. Anatomic evaluation was performed using the three-point modified Raymond Scale which classifies the degree of aneurysm occlusion into three groups: (1) complete occlusion; (2) contrast filling the neck of the aneurysm; and (3) contrast filling the sac of the aneurysm. Immediate postoperative anatomic results were evaluated by the interventionalist performing the coiling procedure.

Long-term angiographic outcome was assessed by an independent core laboratory. We analyzed the angiographic and anatomic characteristics of aneurysms with good angiographic outcome (modified Raymond 1 and 2) and poor angiographic outcome (modified Raymond 3). Variables included were rupture status, location, neck size, maximum diameter, dome-to-neck ratio, and adjunctive device utilization. Other variables assessed by the core laboratory were, at any time point, coil herniation into the parent vessel (defined as any portion of the coil protruding into the vessel lumen, but not necessarily causing obstruction), thrombus on the coil ball, and parent artery occlusion.

Technical outcomes and adverse events

Technical outcomes studied included the following: (1) proportion of aneurysms in which HydroSoft coils were successfully deployed; (2) percent of aneurysms in which at least one HydroSoft coil had to be removed; (3) use of adjunctive devices (balloon and/or stent); (4) percent length of coil that was HydroSoft coil; and (5) packing density. Reported adverse events were the following: (1) iatrogenic vasospasm; (2) thromboembolic complications (including stroke and transient ischemic attack); (3) iatrogenic aneurysm perforation; (4) iatrogenic dissection; (5) access site infections (ie, hematoma, infection); (6) aneurysm rebleed; and (7) 'other'. In addition to reporting the adverse event, practitioners had to report whether the complication resulted in permanent neurologic deficit or mortality. Major morbidity was defined as complications resulting in permanent neurologic deficit. In order to avoid bias/incomplete reporting of adverse events, data monitors were sent to study sites to collect data on patient outcomes.

Statistical analysis

Mean and frequency comparisons were performed with the Student t-test and the χ^2 test, respectively. Differences were considered significant at $p=0.05$. Statistical analyses were performed using the SAS based statistical software package JMP V.12.0 (http://www.jmp.com).

RESULTS

Patient population and aneurysm characteristics

A total of 599 patients were included in the study. The mean patient age was 57.1±13.9 years, 442 patients (73.8%) were women, and 447 patients (74.6%) were Caucasian. The target aneurysm was ruptured in 214 cases (35.7%) and was unruptured in 385 cases (64.3%). Among the patients with ruptured aneurysms, Hunt–Hess scores were not reported in 10 patients. Of the 204 patients in whom Hunt–Hess scores were reported, 200 (98.0%) had a score of ≤3.

Of the 599 aneurysms treated, 292 (48.7%) were internal carotid artery aneurysms, 161 (26.9%) were anterior cerebral artery aneurysms, 57 (9.5%) were middle cerebral artery aneurysms, and 89 (14.9%) were vertebrobasilar aneurysms. Mean aneurysm maximum diameter was 7.3±8.3 mm, mean aneurysm neck size was 3.4±1.4 mm, and mean aneurysm dome-to-neck ratio was 1.7±0.6. These data are summarized in tables 1 and 2.

Technical and angiographic outcomes

HydroSoft coils were successfully deployed in 577 patients (96.4%). At least one HydroSoft coil had to be removed in 87 patients (14.5%). No adjunctive devices were used in 264 patients (44.0%), stent assisted coiling was performed in 89 patients (14.8%), balloon assisted coiling was performed in 230 patients (38.3%), and both stents and balloons were used in 17 patients (2.8%). The mean percent length of HydroSoft coil in treated aneurysms was 42.8±25.1%. These data are summarized in table 3.

Of the 577 aneurysms in which a HydroSoft coil was successfully deployed, immediate angiographic outcome data were available in 558. Of these, 262 aneurysms (47.0%) had a modified Raymond score of 1, 270 aneurysms (48.4%) had a

Table 1 Patient characteristics

Patient characteristics	
N	599
Mean age (SD)	57.1 (13.9)
N (%) female	442 (73.8)
Race	
Caucasian	447 (74.6)
Black	57 (9.5)
Hispanic	35 (5.7)
Asian	52 (8.7)
Other	8 (1.3)
Smoking status	
Prior smoker	243 (40.5)
Current smoker	200 (33.3)
Hypertension	323 (53.8)

Table 2 Aneurysm characteristics

Variable	N (%)
N (%) unruptured	385 (64.3)
N (%) ruptured	214 (35.7)
Hunt–Hess score	
I	81 (37.7)
II	67 (31.1)
III	52 (24.2)
IV	3 (1.4)
V	1 (0.5)
NA	11 (5.1)
Aneurysm location	
Internal carotid artery	292 (48.7)
Anterior cerebral artery	161 (26.9)
Middle cerebral artery	57 (9.5)
Vertebrobasilar	89 (14.9)
Aneurysm geometry	
Mean (SD) maximum diameter	7.3 (8.3)
Mean (SD) neck size	3.4 (1.4)
Mean (SD) width	5.3 (2.2)
Mean (SD) height	6.1 (2.5)
Mean (SD) depth	5.9 (8.4)
Mean (SD) dome-to-neck ratio	1.7 (0.6)

modified Raymond score of 2, and 26 aneurysms (4.7%) had a modified Raymond score of 3.

Follow-up core laboratory angiographic outcomes were available for 442 patients (73.7%) who had HydroSoft coils successfully deployed. The mean length of follow-up was 9.0 ±6.3 months. The complete occlusion rate was 63.2% (280/442) and near complete occlusion rate was 25.3% (107/442). The incomplete occlusion rate was 12.4% (55/442). The core laboratory read recanalization rate was 10.8% (46/425). Progressive occlusion was seen in 13.4% of cases (57/425) and retreatment was reported in 3.4% of cases (20/599).

Table 3 Technical and angiographic outcomes

Technical outcome	N (%)
HydroSoft successfully deployed	577 (96.4)
At least one HydroSoft had to be removed	87 (14.5)
Adjunctive device	
None	264 (44.0)
Stent	89 (14.8)
Balloon	230 (38.3)
Balloon and stent	17 (2.8)
Immediate angiographic outcome	
Complete occlusion	262 (47.0)
Near complete occlusion	270 (48.4)
Incomplete occlusion	26 (4.7)
Coil herniation	179 (42.1)
Thrombus on coil ball	28 (6.6)
Parent artery occlusion	4 (0.9)
Long-term angiographic outcome	
Complete occlusion	280 (63.2)
Near complete occlusion	107 (25.2)
Incomplete occlusion	55 (12.4)
Recanalization	46 (10.8)
Progressive occlusion	57 (13.4)
No change	321 (75.5)
Retreatment	20 (3.4)

Variables associated with good angiographic outcomes (ie, complete or near complete occlusion) included smaller aneurysm size ($p<0.0001$), higher packing density ($p<0.0001$), smaller neck size ($p=0.0002$), and lack of necessity for an adjunctive device ($p=0.02$). These data are summarized in table 4.

Adverse events

The overall mortality for patients in the GEL THE NEC registry was 3.8% (23/599). Procedure-related mortality was 0.5% (3/599) and subarachnoid hemorrhage-related mortality was 2.2% (13/599). In the unruptured group the mortality rate was 2.1% (8/385); mortality was related to the procedure in 0.8% (3/385) of cases. In the ruptured group the mortality rate was 7.0% (15/214); mortality was related to the procedure in none of these cases.

Overall major morbidity for the GEL THE NEC registry was 5.0% (30/599). Major morbidity was procedure related in 1.3% of cases (8/599). Among patients in the unruptured group, 4.7% (18/385) suffered major morbidity, which was related to the procedure in 1.3% (5/385) of cases. In the ruptured group, 5.6% (12/214) of patients suffered major morbidity which was related to the procedure in 1.4% (3/214) of cases.

The most common procedure-related complications were iatrogenic vasospasm (30 patients, 5.0%) and thromboemboli (27 patients, 4.5%). Iatrogenic aneurysm perforation occurred in 2.7% (16/599) of cases and there was one case of post-coiling aneurysm rupture (0.2%). There were two cases of hydrocephalus in the unruptured aneurysm group following coiling (0.5%). These data are summarized in table 5.

DISCUSSION

This study provides robust evidence regarding the safety and efficacy of the use of HydroSoft as finishing coils in aneurysm embolization. Nearly 90% of patients had complete or near complete occlusion of their aneurysm at follow-up. Only 1.3% of patients suffered a permanent neurologic deficit resulting from a procedure-related complication and the mortality rate was less than 1%. Furthermore, in the vast majority of patients, HydroSoft coils were successfully placed into aneurysm cavities.

Table 4 Predictors of good angiographic outcome

	Good angiographic outcome	Poor angiographic outcome	p Value
Aneurysm rupture status, N (%)			
Ruptured	118 (31.4)	20 (41.7)	0.16
Unruptured	258 (68.6)	28 (58.3)	
Aneurysm location, N (%)			
Internal carotid artery	198 (52.7)	23 (47.9)	0.54
Anterior cerebral artery	97 (25.8)	17 (35.4)	
Middle cerebral artery	34 (9.0)	3 (6.3)	
Vertebrobasilar artery	47 (12.5)	5 (10.4)	
Mean (SD) neck size	3.3 (1.2)	4.1 (1.8)	0.0002
Mean (SD) maximum diameter	5.9 (2.6)	8.0 (2.9)	<0.0001
Mean (SD) dome to neck ratio	1.7 (0.6)	1.6 (0.5)	0.27
Mean (SD) percent Hydrocoil	42.3 (23.8)	37.1 (20.6)	0.11
Mean (SD) packing density	41.6 (32.6)	26.6 (15.2)	<0.0001
Adjunctive device, N (%)			
No adjunctive device	171 (46.3)	14 (29.8)	0.02
Balloon	136 (36.9)	28 (59.6)	
Stent	56 (15.2)	5 (10.6)	
Other	6 (1.6)	0 (0.0)	

Table 5 Procedure-related adverse events

	Unruptured	Ruptured	Total
No of patients	385	214	599
Overall mortality	8 (2.1)	15 (7.0)	23 (3.8)
Procedure-related	3 (0.8)	0 (0.0)	3 (0.5)
Subarachnoid hemorrhage-related	0 (0.0)	13 (6.1)	13 (2.2)
Non-neurologic mortality	5 (1.3)	0 (0.0)	5 (0.8)
Overall morbidity	18 (4.7)	12 (5.6)	30 (5.0)
Procedure-related	5 (1.3)	3 (1.4)	8 (1.3)
Subarachnoid hemorrhage-related	0 (0.0)	9 (4.2)	9 (1.5)
Other neurologic morbidity	12 (3.1)	0 (0.0)	12 (2.0)
Non-neurologic morbidity	1 (0.2)	0 (0.0)	1 (0.2)
No of device or procedure-related complications	67 (1.7)	30 (1.4)	97 (16.2)
Type of complication			
Iatrogenic vasospasm	20 (5.2)	10 (4.7)	30 (5.0)
Thromboembolic	20 (5.2)	7 (3.3)	27 (4.5)
Iatrogenic perforation	6 (1.6)	10 (4.7)	16 (2.7)
Iatrogenic dissection	2 (0.5)	2 (0.9)	4 (0.7)
Access site complications	6 (1.6)	1 (0.5)	7 (1.2)
Postoperative aneurysm rupture	1 (0.2)	0 (0.0)	1 (0.2)
Other	12 (3.1)	1 (0.5)	13 (2.2)

Data shown are n (%).

This current data suggest that treatment of the aneurysm neck with HydroSoft coils is safe and effective, with high rates of aneurysm occlusion and low rates of treatment-associated complications.

Hydrogel coils are designed with an expansile hydrogel that fills more of the aneurysm lumen than standard platinum coils and also may serve as a substrate for aneurysm healing.[8] In general, studies advocate using standard coils to form a basket or framework for subsequent deposition of hydrogel coils.[4] Some comparative studies of hydrogel-coated coils and inert coils have demonstrated that hydrogel coils achieve greater packing density with decreased coil length and may have lower aneurysm recurrence rates.[9 10] Recently published post hoc subgroup analyses of the HydroCoil Endovascular Aneurysm Occlusion and Packing Study (HELPS) demonstrated that, compared with bare platinum coils, the use of HydroCoils is independently associated with significantly lower rates of major recurrence for treatment of ruptured aneurysms <10 mm in size (20% vs 48%) as well as for aneurysms with irregular shapes and wide necks.[1 2] However, a recently published meta-analysis showed no statistically significant difference in aneurysm recanalization rates when modified coils such as the HydroCoil were compared with bare platinum coils.[11]

More recently, a number of studies have reported technical and clinical outcomes of HydroSoft coils, a second generation hydrogel-coated coil. In a recently published randomized controlled trial comparing HydroSoft coils with bare platinum coils, Taschner *et al*[12] found that pre-specified complication rates were approximately 12% in both groups, with similar rates of neurologic morbidity and mortality. Packing density was significantly higher in the HydroSoft group than in the bare platinum group. However, because long-term angiographic results from this trial have yet to be published, the effect that improved packing density will have on recanalization rates is still unclear.[12 13] In a single-center study comparing HydroSoft coils with bare platinum coils, Lee *et al* found that the use of HydroSoft coils was associated with improved packing densities (36% vs 32%) and significantly lower retreatment rates (2% vs 9%). In a study comparing stent-assisted coiling with bare platinum and HydroSoft coils, Jiang *et al* found significantly higher rates of complete occlusion at follow-up in the HydroSoft group compared with the bare platinum group (89% vs 71%). Multiple non-comparative studies have also reported complete occlusion rates of the order of 85–90% at 1 year with low rates of perioperative morbidity and mortality (<3%).[14 15] Findings from these previously published studies corroborate those of our own study, which demonstrated high rates of angiographic complete or near-complete occlusion (88.4%) as determined by an independent core laboratory with low rates of procedure-related morbidity (1.3%) and mortality (0.8%).

Limitations

This study has a number of limitations. First, immediate angiographic outcomes were not assessed by a core laboratory. Prior studies have noted marked interobserver variability in the assessment of angiographic outcomes.[16] Furthermore, in a study comparing angiographic outcomes as measured by core laboratories versus operators, core laboratories were twice as likely to report negative angiographic outcomes.[11] Thus, it is possible that the rate of immediate complete/near complete occlusion in this study may be lower. We had incomplete evaluation of angiographic outcomes as follow-up imaging was available from the core laboratory in only 74% of cases. Theoretically, each of the missing cases could have had a major recurrence. Another limitation stems from the fact that clinical outcomes from complications were not graded using a scale such as the modified Rankin score. The use of a pre- and post-treatment modified Rankin score would allow for a more objective and definitive assessment of clinical outcome following coiling. Complications were physician reported which could introduce bias. There was no control group in this study. Selection bias is another limitation of this study as there was no mechanism to avoid selectively including patients who may benefit from HydroSoft coil therapy.

CONCLUSIONS

The results of the GEL THE NEC registry demonstrate that HydroSoft coils are associated with complete and near-complete occlusion rates of nearly 90% at last angiographic follow-up and procedure-related morbidity and mortality rates of 1.3% and 0.5%, respectively. Further clinical trials are needed to determine if HydroSoft coils result in improved angiographic and clinical outcomes compared with bare platinum coils.

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