O-013

THE SMART REGISTRY: FINAL RESULTS ON THE UTILITY OF THE PENUMBRA SMART COIL SYSTEM FOR TREATMENT OF INTRACRANIAL ANEURYSMS AND MALFORMATIONS

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Introduction The Penumbra SMART COIL® System includes a novel generation of embolic coils comprising complex and WAVE shape properties with varying levels of softness to promote dense packing and durable long-term occlusion. We present the final analysis of 997 patients at 68 U.S./Canada sites with up to 1-yr follow-up in the SMART registry to assess the utility of the SMART COIL System in the treatment of intracranial aneurysms and other malformations.

Materials and Methods The SMART registry is a prospective, multi-center registry assessing the embolization of neurovascular lesions using the Penumbra SMART COIL System. Procedures must employ $\geq 75\%$ of SMART, PC400, or POD coils to meet inclusion criteria. SMART registry endpoints included retreatment rates through 1-yr (± 6 -mo) follow-up, procedural device-related serious adverse events (SAE), and the ability to achieve adequate occlusion at immediate post-procedure.

Results This analysis of 997 patients (72.1% female; mean age 59.6 ± 13.0 yr) included cerebral aneurysms (91.0%, 907/997); arteriovenous malformations (1.1%); fistulae (4.1%); and other lesions (3.8%). Aneurysms, of which 31.8% were ruptured, were small (≤ 10 mm) in 85.3% (774/907) of patients, large (> 10 mm to 25 mm) in 14.4% (131/907), and giant (> 25 mm) in 0.2% (2/907); 63.5% (555/874) of patients had wide-neck aneurysms (dome-to-neck ratio < 2 or neck width ≥ 4 mm).

For all lesions, median coil deployment time, defined as the time from the first coil deployed until the last coil detached, was 16.0 min (IQR 8.0–32.0), and median time of fluoroscopic exposure was 37.0 min (IQR 24.0–56.0). Stent-assisted coiling was performed in 5.7% of patients, and balloon-assisted coiling was performed in 18.7% of patients. Median packing density (calculated for aneurysms only) was 29.1% [IQR 21.0–38.8].

For aneurysms, Raymond Occlusion Class (RROC) I and II was achieved in 79.7% (719/902) of cases at immediate post-procedure and in 90.1% (643/714) at 1-yr follow-up, with a recanalization rate of 12.8% (91/710) and a retreatment rate of 7.1% (52/733). In multivariate models, a large or giant aneurysm size (odds ratio [OR]=2.45, $p=0.0030$), balloon-assisted coiling (OR=1.84, $p=0.0195$), ruptured aneurysm status (OR=3.91, $p<0.0001$), and post-procedural RROC III (OR=1.91, $p=0.0180$), were predictors of incomplete

occlusion (RROC III) at 1-yr follow-up. Large or giant aneurysms (OR=2.05, $p=0.0426$), smoking (OR=0.5, $p=0.0186$), and balloon-assisted coiling (OR=2.21, $p=0.0111$) were also predictive of retreatment through 1-yr follow-up.

For non-aneurysm lesions, complete angiographic occlusion was achieved in 85.2% (23/27) of lesions post-procedure, with a recanalization rate of 6.1% (3/49) and a retreatment rate of 1.9% (1/53) at 1-yr follow-up.

Overall, procedural device-related serious adverse events (SAE) were observed in 2.6% (26/997) of subjects.

Conclusion The final results of the SMART Registry, a prospective registry with 997 subjects, demonstrate that the SMART COIL System achieves safe and adequate embolization in a wide variety of neurovascular lesions with low retreatment rates over 1 yr. Large aneurysm size and balloon-assisted coiling were predictive of incomplete occlusion at 1-yr and retreatment through 1-yr follow-up.

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O-014

INTRAVASCULAR HIGH FREQUENCY OPTICAL COHERENCE TOMOGRAPHY GUIDED WEB ANEURYSM EMBOLIZATION

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Introduction High Frequency Optical Coherence Tomography (HF-OCT)¹ is an intra-vascular imaging technique to assess device-vessel interactions and neointimal tissue growth at unprecedented spatial resolution ($\sim 10\mu\text{m}$). In this study, we tested the hypothesis that an adequately deployed (as visualized by HF-OCT) Woven EndoBridge (WEB, Microvention, Aliso Viejo, CA) will lead to a higher aneurysm occlusion rate at 12-week follow-up in an animal model of aneurysms.

Methods Elastase-induced rabbit aneurysms ($n=24$) were treated with the WEB device. HF-OCT (Vis-M; Genuity LLC, Sudbury MA) and DSA were performed after WEB deployment and repeated at 4, 8, and 12 weeks. Protrusion and malapposition were binary coded (0- present, 1- absent; 0- malapposed, 1- neck apposition $> 50\%$), respectively, on HF-OCT and DSA. A device was considered adequately deployed if it was scored as 1 on both metrics. Aneurysm healing on DSA was interpreted using the 4-point WEB occlusion score (WOS)²; with A-B considered a positive outcome. HF-OCT images acquired at 12 weeks were analyzed and neointimal coverage quantified. Scanning electron microscopy (SEM) was performed of the explanted specimens.

Results Discrepancy between HF-OCT and DSA was found: HF-OCT classified as adequately deployed a total of 5 cases, whereas 8 cases were classified as adequately deployed by DSA images. Acceptable WOS grade at 12 weeks was seen in 21% of cases ($n=5$): 80% of those cases ($n=4$) were classified as adequately deployed based by HF-OCT; whereas only 60% of those cases ($n=3$) classified adequate by DSA. A significant

Abstract O-014 Figure 1 Example of a 'not adequately deployed' device based on HF-OCT. (A-D) Baseline HF-OCT, 12 weeks final DSA, SEM, and 12 weeks HF-OCT, respectively, for a case with the presence of protrusion and absence of malapposition (white arrow, A). A large amount of uncovered device struts were found by both SEM and HF-OCT images (White arrow, D). (E-H) an example of 'adequate deployment': baseline HF-OCT, 12 weeks DSA, SEM image, and 12 weeks HF-OCT, respectively, for an animal without any protrusion or malapposition. A positive outcome

interaction between adequate deployment on HF-OCT and positive outcome was confirmed ($p=0.007$). However, there was no statistically significant relationship between good outcome and adequate deployment based on DSA images ($p=0.289$). Based on HF-OCT images, the absence of the protrusion was related with a positive outcome ($p=0.006$); however, malapposition had no significant interaction with positive outcome ($p=0.19$). The area of neointimal tissue quantified by HF-OCT showed a strong correlation with SEM assessment ($R^2=0.96$; $p<0.001$). The mean neointimal coverage on 'adequate deployment' cases was 78%, whereas a mean neointimal coverage of 31% was found for the 'not adequate deployment' cases ($p=0.001$).

Conclusion HF-OCT may be valuable prognosticate adequate aneurysm occlusion with the WEB and can be used to monitor aneurysm healing longitudinally. Absence of protrusion was associated with subsequent aneurysm occlusion; however, malapposition alone did not show an effect on the rate of aneurysm healing.

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O-015

COMFORT – COLOMBIAN MULTICENTER FLOW-DIVERTER OBSERVATIONAL RECONSTRUCTION TRIAL. LOCAL EXPERIENCE IN THE ENDOVASCULAR TREATMENT OF INTRACRANIAL ANEURYSMS WITH FRED STENT

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Purpose Flow-diverting stents, such as the Flow Re-direction Endoluminal Device (FRED; MicroVention, Tustin, California, USA), have emerged as a novel means of treating complex intracranial aneurysms. This observational analysis of the initial Colombian experience provides insight into patient selection, technical challenges, clinical and radiographic outcomes, and complication rates after the use of FRED device for intracranial aneurysms.

Materials and Methods Cases were compiled from 5 Colombian centers between March 2014 and April 2017. We performed a multicenter study evaluating patients with intracranial aneurysms treated with FRED. Technical success, morbidity and mortality were registered. Regarding safety, a well-defined variables included: spontaneous rupture of the FRED-treated aneurysm; spontaneous nonaneurysmal or distal intracranial hemorrhage (ICH); thrombo-embolic stroke; parent artery stenosis, and permanent cranial neuropathy.

Results During the defined study period, 252 patients with 268 aneurysms treated with FRED were included in this registry. Technical success stent deployment observed in all cases with exception of two cases where the operators decided to pull back the device and treated the aneurysms with other strategy. The mean aneurysm size was 12.4 ± 5 mm, and the median angiographic follow-up was 6.5 months. 81 aneurysms (30.2%) were small, 132 (49.2%) were large and 55 (20.5%) were giant. The median clinical follow-up time was 8.2 months. The neurological morbidity rate was 7.5% (19/252), and the neurological mortality rate was 2.3% (6/252). The combined neurological morbidity/mortality rate was 9.8%. The most common adverse events were ischemic stroke (5.9%, 15/252) and spontaneous ICH (1.9%, 5/252). The complete occlusion rate at the last follow-up was 87.6% (92/105).

Conclusion In the largest regional series on FRED for intracranial aneurysms to date, data suggest that treatment with the Flow Re-direction Endoluminal Device is safe and efficacious, with complication rates comparable with others FD