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

¹A Spiotta*, ²M Park, ³R Bellon, ⁴B Bohnstedt, ⁵C Schirmer, ⁶R DeLeacy, ⁷D Fiorella, ⁸B Woodward, ⁹B Baxter, ¹⁰S Kale, ¹¹O Zaidat, ¹²P Sunenshine, ¹³A Yoo, ¹⁴M Kabbani, ¹⁵K Liu, ¹⁶R Starke, ¹⁷A Reeves, ¹⁸K Snyder, ¹⁹T Sivapatham, ²⁰T Dumont. ¹Dept. of Neurosurgery, Medical University of South Carolina, Charleston, SC; ²University of Virginia, Charlottesville, VA; ³Swedish Medical Center, Denver, CO; ⁴Oklahoma University Medical Center, Oklahoma City, OK; ⁵Geisinger Medical Center, Danville, PA; ⁶Mount Sinai, New York, NY; ⁷Stony Brook University Medical Center, Stony Brook, NY; ⁸Vista Radiology, Knoxville, TN; ⁹Tennessee Interventional Associates, Chattanooga, TN; ¹⁰SSM Health St. Clare Hospital, Fenton, MO; ¹¹St Vincent Mercy Health Medical Center, Toledo, OH; ¹²Banner University Medical Center, Phoenix, AZ; ¹³Texas Stroke Institute, Plano, TX; ¹⁴Gundersen Health System, La Crosse, WI; ¹⁵Penn State Milton S Hershey Medical Center, Hershey, PA; ¹⁶University of Miami Hospital, Miami, FL; ¹⁷University of Kansas, Kansas City, KS; ¹⁸University of Buffalo, Buffalo, NY; ¹⁹Christiana Care Health System, Newark, DE; ²⁰University of Arizona, Tucson, AZ

10.1136/neurintsurg-2020-SNIS.13

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.

Disclosures A. Spiotta: None. M. Park: None. R. Bellon: None. B. Bohnstedt: None. C. Schirmer: None. R. DeLeacy: None. D. Fiorella: None. B. Woodward: None. B. Baxter: None. S. Kale: None. O. Zaidat: None. P. Sunenshine: None. A. Yoo: None. M. Kabbani: None. K. Liu: None. R. Starke: None. A. Reeves: None. K. Snyder: None. T. Sivapatham: None. T. Dumont: None.

O-014

INTRAVASCULAR HIGH FREQUENCY OPTICAL COHERENCE TOMOGRAPHY GUIDED WEB ANEURYSM EMBOLIZATION

¹Z Vardar, ¹R King, ¹A Kraitem, ¹E Langan, ²L Peterson, ²B Duncan, ¹C Raskett, ¹V Anagnostakou, ¹M Gounis*, ¹A Puri, ¹G Ughi. ¹Radiology, University of Massachusetts, Worcester, MA; ²RandD, Genuity LLC, Sudbury, MA

10.1136/neurintsurg-2020-SNIS.14

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