Abstract

CLEVER: CLINICAL EVALUATION OF WEB 17 DEVICE IN INTRACRANIAL ANEURYSMS. SAFETY RESULTS FOR RUPTURED AND UNRUPTURED ANEURYSM AT 30 DAYS

1 L. Spelle*, 2 C. Cognard, 3 I. Szikora, 4 V. Costalat, 5 F. Wodarg, 6 D. Herbreteau, 7 S. Fischer, 8 M. Möhlenbruch, 9 C. Papagiannaki, 10 J. Klisch, 11 R. Rautio, 12 J. Numminen, 13 A. Berlis, 14 J. Downer, 15 M. Bester, 16 S. Velasco, 17 J. Liebig, 18 J. Byrne, 19 L. Pierot. 1-NEURI, the Brain Vascular Center, Bicêtre Hospital, Paris, France; 2-Interventional Neuroradiology, Hôpital Purpan, Toulouse, France; 3-National Institute of Neurosciences, Budapest, Hungary; 4-Guil de Chauliac, Montpellier, France; 5-Universitätsklinikum Schleswig-Holstein, Kiel, Germany; 6-CHRU Bretonneau, Tours, France; 7-Universitätsklinikum Knappschaftskrankenhaus, Bochum, Germany; 8-Universitäts Klinikum, Heidelberg, Germany; 9-CHU Rouen, Rouen, France; 10-Helios Hospital, Erfurt, Germany; 11-University Hospital, Turku, Finland; 12-Helsinki University Central Hospital, Helsinki, Finland; 13-Klinikum, Augsburg, France; 14-Western General Hospital, Edinburgh, UK; 15-University Medical Center Hamburg-Eppendorf, Hamburg, Germany; 16-CHU, Poitiers, France; 17-LMU Klinikum, Munich, Germany; 18-University of Oxford, Oxford, UK; 19-CHU Maison Blanche, Reims, France

Introduction

Intracranial flow disruption is an endovascular approach for treatment of wide-neck aneurysms and, more specifically, wide-neck bifurcation aneurysms (WNBA). The WEB device has demonstrated its efficacy and safety, for both ruptured and unruptured aneurysms. The CLEVER objective has been set up to provide safety and efficacy data on the WEB 0.017 device in treatment of bifurcation aneurysms. These results report description of the full population and safety results within 30 days post procedure. Material/Methods

CLEVER study is an observational, prospective and multicenter study conducted in 17 European sites (France, Germany, Hungary, Finland, United Kingdom) using the WEB 0.017 device, the last developed model of WEB product family with a lower profile. The data collected are 100% monitored and the primary endpoints independently evaluated. Patients’ data are collected from baseline to 12-month post-treatment with evaluation visits at discharge, 1, 6 and 12-months post-treatment. Occlusion results are assessed independently by a Corelab and adverse events are adjudicated by a Clinical Events Committee. Study design allows to analyze the study results for the full population as well as separately for ruptured and unruptured aneurysm. An intention treat analysis is performed for the safety population, and sample size calculation is based on objective performance approach for safety and efficacy rates.

Results

From March 2019 to February 2021, 163 patients (mean age, 58.1 years; 68.1% of women) with 103 unruptured aneurysms and 60 ruptured aneurysms were enrolled. The aneurysms locations were on the ACom (37.4%), the MCA bifurcation (30.1%), the PCom (10.4%), the BA (8.6%), the ICAT (3.7%), the pericallosal artery (3.7%), the ACA (0.6%) and other locations (5.5%). The aneurysms treated were ranging from 2 to 9.2 mm (mean maximum sac width = 5.0 mm). The WEB procedure was completed with success in 163 patients (100%). 147/163 (90.2%) of aneurysm were treated only with WEB implant and adjunctive implant devices were used in 16/163 (9.8%) of cases. For this report covering analysis of data up to 30 days, the primary safety endpoint was the proportion of patients with death of any nonaccidental cause or any major stroke (defined as ischemic or hemorrhagic stroke resulting in an increase of 4 points or more on the NIHSS) within the first 30 days after treatment. Two major strokes on 2/163 patients (1.2%) met the primary safety endpoint. The mortality rate at 30 days was 0%. A detailed description of events reported from per procedure up to 30 days will be provided with a specific attention to the aneurysm initial presentation (ruptured vs unruptured). The 12 months data are not yet available so will not be presented.

Conclusion

These results show good safety profile at 1 month, with low rate of neurological or neurovascular event with permanent deficit and no mortality at 30 days. These data confirm the safety of WEB use in intracranial aneurysm treatment, unruptured as well as ruptured, and are consistent with the results published up to date.

Disclosures

N. Adeeb: None.

Abstract O-003

ANEURYSM WALL ENHANCEMENT IN 3D

1 A. Raghavan*, 2 A. Galloy, 3 M. Nino, 4 S. Sanchez, 5 M. Hikerson, 6 S. Raghavan, 7 E. Samaniego. 1-Neurology, The University of Iowa Carver College of Medicine, Iowa City, IA; 2-Roy J Carver Department of Biomedical Engineering, The University of Iowa, Iowa City, IA

Introduction/Purpose

Computational fluid dynamic (CFD) and finite element (FEA) simulations can provide insight into the unique physical environment that precedes aneurysm rupture. Areas subject to decreased mechanical stresses may rupture because of inflammatory changes in the aneurysm wall. Topographic analysis of aneurysm wall enhancement (AWE), wall shear stress, and wall tension in three dimensions may identify aneurysmal compartments more susceptible to rupture.

Materials and Methods

Unruptured aneurysms were prospectively imaged with 7T MRI. Aneurysms were segmented on T1 post gadolinium contrast imaging and analyzed with CFD and FEA. AWE normalized to the corpus callosum was mapped in 3D using orthogonal probes to capture the entire aneurysm wall on 7T MRI. The mean value of all probes was defined as the 3D circumferential AWE (3D-CAWE). Aneurysms measured more enhancing than the corpus callosum (3D-CAWE≥1) were classified as 3D-CAWE+. Contour maps of time-