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Abstract Number - 5: Interim Results of PRE-SEAL IT Saccular Endovascular Aneurysm Lattice System First in Human Interventional Trial

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Abstract

Introduction

Preliminary in vivo animal intracranial aneurysm (IA) studies have demonstrated promising immediate and follow-up aneurysm occlusion rates using the novel Saccular Endovascular Aneurysm Lattice (SEAL) system. The PRE-SEALTM IT trial was designed to assess the feasibility, safety, and effectiveness of the SEAL system in patients with previously untreated ruptured and unruptured wide-neck IA.

Methods

PRE-SEAL IT is an on-going, prospective, interventional, core-lab adjudicated, single-arm study performed in Medellin, Columbia. Key inclusion criteria included: 1. Age 20–80 years, 2. Saccular shape, bifurcation, or terminus IA, 3. Wide neck aneurysm with neck size ≥4 mm or dome-to-neck ratio <2, and 4. IA diameter 2mm to 25mm. Consented and enrolled patients were treated with the SEALTM device. A follow-up DSA was performed at 24-hours, 6 months, and 12 months and a MRA at 3 months. Final clinical follow-up was at 24-months. Primary efficacy outcome was achieving complete occlusion (WOS grade A or B) at 6 months angiographic follow up. Primary safety outcome was any stroke with an increase in NIHSS of 4 up to discharge.

Results

From December 2021 through June 2022, 15 patients have been enrolled into the PRE-SEAL IT trial. Ten women and 5 men were treated with the SEAL device, with a mean age of 56.8±9.5 years. Of the 15 IA, 12 were anterior circulation (ICA-T (1), MCA (7), AcomA (3), A2-A3 (1)) and 3 posterior circulations (Basilar, VBJ-fenestration, SCA), and 14 were unruptured (93.3%). Mean aneurysm width was 6.1±2.5mm. Immediate post-procedure complete occlusion (Grade A, B) was achieved in 9 patients (60%) and adequate occlusion (Grade A, B, C) in 13 (86.6%). At 24-hours follow-up, 12 patients (80%) had complete occlusion and 15 (100%) achieved adequate occlusion. Six-month complete occlusion rate (Grade A and B) was 100% (8/8). Interim results were site adjudicated. No cases of intraoperative rupture, or bleeding or re-bleeding, or clinical stroke were observed.

Conclusions

The interim results of the PRE SEAL-IT trial demonstrated promising complete occlusion rates at 24-hour and 6 month follow-up with no safety concerns. Trial enrollment will be completed in October, and final 24-hour results will be presented at the 2022 SVIN Annual Meeting.

Footnotes

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