PRELIMINARY SAFETY AND CLOSURE PERFORMANCE FROM REDUCE - A RANDOMIZED PFO CLOSURE TRIAL

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OBJECTIVE/PURPOSE

The REDUCE trial aims to establish superiority of PFO closure in conjunction with antiplatelet therapy over antiplatelet therapy alone in reducing the risk of recurrent clinical ischemic stroke or new brain infarct in patients with cryptogenic stroke. This analysis sought to characterize procedure- and device-related safety and device closure performance.

METHODS

This controlled, open-label trial randomized 664 subjects with cryptogenic stroke at 63 multinational sites in a 2:1 ratio to either antiplatelet therapy plus PFO closure (with GORE® HELEX® Septal Occluder or GORE® CARDIOFORM Septal Occluder) or antiplatelet therapy alone. Adverse events are collected during prospective follow-up with both neurologists and cardiologists for up to five years. Device subjects have core lab review of echocardiography with bubble study at 1, 12, and 24 months. Data from this ongoing study were exported on 11/14/2016 for this analysis.

RESULTS

Enrolled subjects had a mean age of 45.4 years and were 59.2% male. Compared to the RESPECT trial (ref), PFO closure with Gore Occluders in the REDUCE study was associated with a low rate of serious adverse events related to the device or procedure (Table 1). The rate of any atrial fibrillation in the device group appears to be higher than in the control group. However, the overall rate of serious atrial fibrillation is low and comparable to the AMPLATZER™ PFO Occluder studied in the RESPECT trial. The rate of any deep vein thrombosis or pulmonary embolism is low and does not appear to have clinically meaningful differences between the treatment groups.

Table 1. Summary of safety outcomes for the Gore REDUCE study and the RESPECT trial test arm.

	REDUCE Control Arm	**REDUCE Test Arm**	**RESPECT Test Arm**
Device-related SAE	--	0.9%	2.0%[1]
Procedure-related SAE	--	2.3%	2.4%[1]
Any atrial fibrillation	0%	4.3%	3.6%[2]
Serious atrial fibrillation	0%	1.6%	1.0%[1]
Any DVT or PE	0.9%	0.5%	3.6%[2]

Death	0.2%	0%	1.2%[2]

Technical implant success defined as the successful delivery and release of any Gore occluder when attempted was achieved in 98.8% of device subjects. Moderate or smaller residual shunt status (0-25 bubbles) was observed by the core lab for 94% of device subjects at the 12-month echocardiography assessment.

CONCLUSIONS

These REDUCE safety data indicate that Gore Occluders demonstrate an expected, acceptable safety profile when used to close PFOs for prevention of recurrent cryptogenic stroke. The technical success and closure performance results reflect positively on the ability of Gore Occluders to completely or substantially close a patient's PFO.

REFERENCE

AMPLATZER™ PFO Occluder for the Prevention of Recurrent Ischemic Stroke Sponsor's Executive Summary, Circulatory System Devices Panel, Meeting Date: May 24, 2016. Available from: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM502195.pdf