COMMENTARY

Alternative Approval Mechanisms

BY RODNEY WHITE, MD

Thoracic aortic endografts have been shown in preliminary investigations to treat indications beyond thoracic aortic aneurysms and have demonstrated a significant reduction in procedural morbidity and mortality, including paraplegia. Of particular interest is the role of these devices in redefining the treatment of aortic dissections and traumatic transections. Because of the apparent benefit in these critical indications, the Food and Drug Administration (FDA) has wisely agreed to the development of alternative study designs, avoiding the need for the collection of concurrent control data, to expedite broader-labeled indications for appropriately designed devices.

In response to the suggestion that the FDA would consider alternative approval mechanisms, the Society for Vascular Surgery (SVS) Outcomes Committee in collaboration with the Society for Vascular and Interventional Radiology (SIR), the Society for Thoracic Surgery (STS), and the American Association for Thoracic Society (AATS) have established a database that collects data using standardized definitions from studies that were performed using FDA-approved Investigational Device Exemption (IDE) protocols utilizing thoracic endografts to treat aortic dissections and traumatic transections. The data collection was funded solely by the academic societies. Extensive analysis of data from 5 institutions (Arizona Heart Institute, Cleveland Clinic Foundation, Harbor-UCLA Medical Center, Stanford University, and Union Memorial Hospital) that have FDA-approved single-center IDE protocols to evaluate the utility of thoracic endografts for these indications has been completed. The data collection and analysis was performed by the SVS administration and the New England Research Institutes, Inc. to create Master Access Files available through the SVS that has been submitted to the FDA and can be used to define a performance goal by manufacturers performing studies that broaden the indications for thoracic endografts.

The first Master Access File has been completed and includes approximately 100 patients who had acute thoracic aortic dissection with malperfusion syndromes, and a second file of approximately 60 patients with acute aortic transections is anticipated to be completed by the end of August.

Using this mechanism, the results of contemporary data using thoracic endografts for acute aortic dissections and traumatic transections from an IDE-level dataset can be complimented by other sources of available data regarding this therapy and potentially provide comparative information that can be used to expedite studies and provide approval for devices in a cost-effective and responsible manner in the current "off-label" environment. ■

For information regarding the Master Access Files, contact Sarah Murphy, Assistant Director, Socioeconomics and Professional Affairs, Society for Vascular Surgery, 633 North Saint Clair Street, 24th Floor, Chicago, Illinois 60611. Ms. Murphy may be reached at (312) 334-2305; smurphy@vascularsociety.org.

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