AngioDynamics Announces Publication of APEX-AV Trial Results in JSCAI

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Peer-reviewed data highlights successful clinical study with 35.5% clot burden reduction, validating the safety, efficacy, and efficiency of AlphaVac F18^{85} System in pulmonary embolism treatment.

LATHAM, N.Y.--(BUSINESS WIRE)--Jan. 13, 2025-- AngioDynamics, Inc. (NASDAQ: ANGO), a leading and transformative medical technology company focused on restoring healthy blood flow in the body's vascular system, expanding cancer treatment options and improving patient quality of life, today announced the publication of the results from the Acute Pulmonary Embolism Extraction Trial with the AlphaVac System (APEX-AV) in the Journal of the Society for Cardiovascular Angiography & Interventions (JSCAI). The article, "Novel Mechanical Aspiration Thrombectomy in Patients with Acute Pulmonary Embolism: Results from the Prospective APEX-AV Trial," was published December 27, 2024.

Pulmonary embolism (PE), a potentially life-threatening condition, affects approximately 900,000 individuals annually in the United States, with 10-30% of cases resulting in death within one month of diagnosis, according to the American Lung Association.[1]

The primary efficacy endpoint of the APEX-AV trial was the reduction in RV/LV ratio between baseline and 48 hours post-procedure. The primary safety endpoint was the rate of MAEs, including events such as major bleeding and serious device-related clinical deterioration, pulmonary vascular injury, and cardiac injury within the first 48 hours. Patients were followed for 30 days post-index procedure. The results demonstrated the device as a safe and effective treatment for acute intermediate-risk PE with a significant reduction in RV/LV ratio and clot burden with a low rate of adverse events.

The APEX-AV trial demonstrated a 35.5% reduction in clot burden (via the Modified Miller index score), comparing favorably to other mechanical aspiration devices on the market.[2] The unique design features of the device, including its funnel tip, optional wireless navigation, and blood loss mitigation, contributed to clinically significant improvements in both safety and efficacy.

"Achieving publication in a respected, peer-reviewed journal underscores the strength and importance of the APEX-AV trial findings and their potential impact on patient outcomes," said Juan Carlos Serna, AngioDynamics Senior Vice President of Scientific and Clinical Affairs. "The inclusion of the AlphaVac F18^{85} System in JSCAI validates our commitment to advancing meaningful solutions for pulmonary embolism, a life-threatening condition affecting hundreds of thousands of people each year. This milestone caps a transformative year for the AlphaVac F18^{85} System, following its FDA clearance for PE thrombectomy and its spotlight at the SCAI Scientific Sessions. We are proud to deliver innovations that equip physicians with effective tools to improve care and save lives."

The APEX-AV trial was initiated in partnership with the widely respected Pulmonary Embolism Response Team (PERT) Consortium™ and was led by co-Principal Investigators William Brent Keeling, MD, Associate Professor at the Emory School of Medicine in Atlanta, Georgia, and Mona Ranade, MD, Assistant Professor, Interventional Radiology, at the David Geffen School of Medicine at UCLA. The trial results were initially presented at The Society for Cardiovascular Angiography & Interventions (SCAI) 2024 Scientific Sessions hosted in Long Beach, California in May.

"We are incredibly excited by the results of the APEX-AV trial, which demonstrate the safety and efficacy of the AlphaVac F18 ^{85} System in treating patients with pulmonary embolism," said William Brent Keeling, MD, Associate Professor of Surgery, Department of Surgery, at the Emory University School of Medicine, and Immediate Past President, The PERT Consortium™. "These outcomes are critical for PE patients, where timely and efficient intervention can greatly improve long-term health outcomes and reduce the risk of complications."

In December 2023, AngioDynamics announced the completion of patient enrollment in its APEX-AV trial, a single-arm Investigational Device Exemption study that enrolled 122 patients with confirmed acute, intermediate-risk PE across 25 hospital-based sites in the United States to assess the AlphaVac F18^{85} System for the treatment of PE. In April 2024, the United States Food and Drug Administration (FDA) cleared the AlphaVac F18^{85} System for the treatment of PE.

"The results from the APEX-AV trial demonstrate the significant impact of the AlphaVac F18 ^{85} technology in treating pulmonary embolism," said Mona Ranade, MD, Assistant Professor, Interventional Radiology, at the David Geffen School of Medicine at UCLA. "We observed a significant reduction in clot burden pre- and post-treatment, and saw a notable improvement in pulmonary artery pressures, underscoring the efficacy of this innovative approach. The procedure was completed with remarkable efficiency, with a short procedure time, making it a promising option for patients in need of rapid and effective intervention."

The published article concluded that "Percutaneous mechanical aspiration thrombectomy with the AlphaVac system provided a safe and effective treatment for acute intermediate-risk PE with a significant reduction in RV/LV ratio and clot burden with a low rate of adverse events."

JSCAI publishes original research, comprehensive reviews, meta-analyses, study designs, society guidelines, editorials, research letters, case reports, and images. The subject matter includes all interventional subspecialities including coronary, peripheral, structural, and congenital heart disease.

To access the published material, visit: https://www.sciencedirect.com/science/article/pii/S2772930324021525.

About the AlphaVac F18^{85} System

The AlphaVac F18^{85} System is an emergent first-line device that is currently cleared for the removal of thromboemboli from the venous system and for the treatment of PE. The System includes an ergonomic handle, an 18F cannula with an 85-degree angle, an obturator and a waste bag assembly. The APEX-AV Study was designed to provide safety and efficacy data for a clearance specific to PE. For risk information, visit https://bit.ly/Angio-risk-info.

About AngioDynamics, Inc.

AngioDynamics is a leading and transformative medical technology company focused on restoring healthy blood flow in the body's vascular system,

expanding cancer treatment options and improving patient quality of life.

The Company's innovative technologies and devices are chosen by talented physicians in fast-growing healthcare markets to treat unmet patient needs. For more information, visit www.angiodynamics.com.

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[1] https://ihpi.umich.edu/news/pulmonary-embolism-deaths-disparities-high-despite-advancements-care

[2] https://www.sciencedirect.com/science/article/pii/S2772930324021525

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