Enhancing Pulmonary Embolism Treatment: Insights From the APEX-AV Study on the AlphaVac F18[85] Catheter

A summary of the study's findings and their implications on managing patients with acute intermediate-risk PE.

By Brent Keeling, MD; Mona Ranade, MD; and Seth Sokol, MD

Pulmonary embolism (PE) poses significant challenges in clinical management, necessitating innovative approaches for effective treatment. Endovascular interventions have emerged as promising strategies for selected patients, and the AlphaVac multipurpose mechanical aspiration (MMA) F18[85] system (AngioDynamics, Inc.) represents a novel addition to this armamentarium. The APEX-AV study was pivotal in evaluating the safety and efficacy of the AlphaVac MMA F18[85] catheter system in patients with acute intermediate-risk PE, shedding light on its potential role in improving patient outcomes.

STUDY DESIGN AND OBJECTIVES

The APEX-AV study (NCT05318092), a single-arm, prospective, multicenter investigational device exemption trial, aimed to assess the safety and effectiveness of the AlphaVac MMA F18[85] system in patients with acute intermediate-risk PE. The primary effectiveness endpoint focused on the reduction in right ventricular/left ventricular (RV/LV) ratio within 48 hours postprocedure compared to a predefined performance goal based on literature data. Safety endpoints included major adverse events (MAEs) within 48 hours, with comparisons to established benchmarks. Secondary endpoints encompassed various clinical parameters and outcomes related to safety and effectiveness, providing a comprehensive assessment of the device's performance.

RESULTS

The APEX-AV study enrolled 122 patients across 25 United States clinical sites, meeting inclusion criteria consistent with acute intermediate-risk PE. A significant reduction of 0.45 in RV/LV ratio (the primary effectiveness endpoint) was demonstrated, surpassing the predefined performance goal ($P < .001$). Additionally, the mean intensive care unit and overall hospital stays were 1.4 and 5.2 days, respectively, indicative of favorable postprocedural recovery. Furthermore, there was a notable 35.5% reduction in clot burden, as measured by the modified Miller Index, within 48 hours postprocedure. Notably, the study revealed a statistically significant decrease in mean pulmonary artery pressure pre- to postprocedure ($P < .001$), particularly notable in patients with pulmonary hypertension.[1]

In terms of safety, the analysis of the primary endpoint demonstrated a MAE rate of 4.1% within 48 hours, significantly lower than the predefined performance goal ($P < .001$). MAEs observed were consistent with expectations for the patient population, with no reported deaths during the study period. Noteworthy MAEs included five major bleeding events, one instance of clinical deterioration, and one pulmonary vascular injury.[1] These findings underscored the extremely favorable safety profile of the AlphaVac MMA F18[85] system in treating acute intermediate-risk PE.

CONCLUSION

The APEX-AV study substantiated the safety and efficacy of the AlphaVac MMA F18[85] system in patients with acute intermediate-risk PE. By achieving significant reductions in RV/LV ratio and clot burden while demonstrating a favorable safety profile, this endovascular approach presents a minimally invasive alternative for PE management. The volume of clot removed may be superior to competing thrombectomy devices. The study outcomes support the integration of the AlphaVac F18[85] catheter into clinical practice, offering potential benefits in improving patient outcomes and enhancing the therapeutic armamentarium for PE treatment. ■

1. Keeling B. Evaluating the safety and efficacy of the AlphaVac F1885 system in acute intermediate-risk PE patients: APEX-AV trial. Presented at the Society for Cardiovascular Angiography & Interventions (SCAI) 2024 scientific sessions; May 2-4, 2024; Long Beach, California.

Brent Keeling, MD
Associate Professor of Surgery
Division of Cardiothoracic Surgery,
Department of Surgery
Emory University School of Medicine
Atlanta, Georgia
brent.keeling@emory.edu
Disclosures: Consultant to AngioDynamics and Viz.ai; steeing committee, STRIKE-PE (Penumbra, Inc.).

Mona Ranade, MD
Assistant Professor
Interventional Radiology
David Geffen School of Medicine at UCLA
Los Angeles, California
mranade@mednet.ucla.edu
Disclosures: Consultant to AngioDynamics, Medtronic, Asahi Intecc, and Boston Scientific.

Seth Sokol, MD
Professor, Department of Medicine
Albert Einstein College of Medicine
Chief, Division of Cardiology
NYC Health and Hospitals/Jacobi
Bronx, New York
seth.sokol@nychhc.org
Disclosures: None.