SPECIAL ARTICLE

The Year in Cardiothoracic and Vascular Anesthesia: Selected Highlights from 2016

Harish Ramakrishna, MD, FASE, FACC,* Jacob T. Gutsche, MD,† Prakash A. Patel, MD,† Adam S. Evans, MD,‡ Menachem Weiner, MD,§ Steven T. Morozowich, DO, FASE,* Emily K. Gordon, MD, MSEd,† Hynek Riha, MD, DEAA, FCCP,‖ Joseph Bracker, DO,† Kamrouz Ghadimi, MD,¶ Sunberri Murphy, DO,† Warren Spitz, MD,† Emily MacKay, DO,† Theodore J. Cios, MD, MPH,# Anita K. Malhotra, MD,# Elvera Baron, MD,§ Shahzad Shaefi, MD,** Jens Fassl, MD,†† Stuart J. Weiss, MD, PhD,† George Silvay, MD, PhD,§ and John G.T. Augoustides, MD, FASE, FAHA†

THIS SPECIAL ARTICLE is the 9th in an annual series for the *Journal of Cardiothoracic and Vascular Anesthesia*.[1] The authors thank the editor-in-chief, Dr. Kaplan, and the editorial board for the opportunity to continue this series, namely the research highlights of the year that pertain to the specialty of cardiothoracic and vascular anesthesia. The major themes selected for 2016 are outlined in this introduction, and each highlight is reviewed in detail in the main body of the article. The literature highlights in the specialty for 2016 begin with the rapidly evolving developments in minimally invasive cardiac procedures, including transcatheter aortic valve replacement (TAVR). Given this rapid progress, it is likely that the indications for this disruptive technology will expand beyond high- and intermediate-risk patients to include low-risk patients with severe aortic stenosis (AS). The second major theme in the specialty for 2016 was the set of major trials that recently explored the role of surgical therapy in ischemic heart disease with respect to interventions such as surgical ventricular restoration, coronary artery bypass grafting (CABG), and mitral valve repair. The third major theme for the specialty in 2016 was the progress in platelet blockade and coronary stents that prompted recent guidelines for dual-antiplatelet therapy (DAPT) in ischemic heart disease. The fourth major theme for the specialty in 2016 was the role of steroids in cardiac surgery with cardiopulmonary bypass (CPB), given the publication of recent landmark randomized trials. The themes selected for this 9th special article are only a sample of the advances in the specialty during 2016. These highlights likely will further improve important perioperative outcomes for patients with cardiovascular disease.

TRANSCATHETER AORTIC VALVE REPLACEMENT

The past decade has been the dawn of the era of minimally invasive and catheter-based procedures in cardiac surgery.[1,2] Across the entire spectrum of cardiac surgery, a striking surge in minimally invasive cardiac interventions performed worldwide has occurred, including TAVR.[3,4] In part, this growth reflects a shift toward an aging population with more prevalent cardiac disease, comorbidities, and frailty that together render the risks of traditional open surgery unacceptably high.[2–4] Although these techniques may offer both clinical and economic benefits, additional trials still are required to delineate more clearly the extent of their benefits. The highlight in 2016 in the field of TAVR has been the publication of high-quality trials that have extended the indications for this therapy for AS from high-risk to intermediate-risk patients.[5–7]

*From the *Cardiac Anesthesia, Anesthesiology, Mayo Clinic, Scottsdale, AZ; †Cardiovascular and Thoracic Section, Department of Anesthesiology and Critical Care, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA; ‡Department of Anesthesiology, Cleveland Clinic Florida, Weston, FL; §Anesthesiology and Critical Care, Icahn School of Medicine, Mount Sinai Hospital, New York, NY; ‖Cardiothoracic Anesthesiology and Intensive Care, Department of Anesthesiology and Intensive Care Medicine, Institute for Clinical and Experimental Medicine, Prague, Czech Republic; ¶Cardiothoracic Anesthesiology, Department of Anesthesiology and Critical Care, Duke University, Durham, NC; Anesthesiology, Penn State University, Hershey, PA; **Cardiothoracic Anesthesiology and Critical Care, Department of Anesthesiology, Harvard Medical School, Boston, MA; and ††Cardiovascular and Thoracic Section, Department of Anesthesia and Intensive Care Medicine, University of Basel, Basel, Switzerland.*

Address reprint requests to John G. T. Augoustides, MD, FASE, FAHA, Cardiothoracic Section, Anesthesiology and Critical Care, Dulles 680, HUP, 3400 Spruce Street, Philadelphia, PA 19104-4283. E-mail: yiandoc@hotmail.com

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Trends in Aortic Valve Replacement for Aortic Stenosis

Calcific AS is the most common cardiac valvular disease in developed countries, with an estimated incidence of moderate-to-severe AS greater than 4% in those older than 65 years.[8] The high incidence of AS increases even further with advanced age, rendering many patients candidates for aortic valve replacement.[8,9] As outlined in recent clinical guidelines, surgical aortic valve replacement (SAVR) has been the traditional gold standard of care for patients with symptomatic severe AS, leading to substantial outcome benefit.[10] Despite this gold standard, SAVR for AS may not be feasible in the setting of multiple comorbidities.[2,3,9–11] In the past, these patients were deemed inoperable and subsequently were eligible for palliation with medical therapy and/or balloon valvuloplasty.[12]

After the clinical introduction of TAVR in 2002, rapid developments took place. The technology in TAVR quickly matured with rapid growth, large degree of success, and marked innovation as experience increased.[13] Recent data from a large clinical registry in the United States have demonstrated a steady growth in TAVR volume, with great success and acceptable morbidity in high-risk patient cohorts.[14,15] Within just a few years, TAVR rapidly became first-line therapy for patients with inoperable severe AS and a less-invasive alternative, with widespread acceptance of SAVR in operable high-risk patients.[16,17] The rapid success and acceptance of this new technology have resulted in a steady increase in TAVR procedures around the world such that it is now a routine therapy for high-risk patients with severe AS.[18,19] The number of TAVR procedures has more than doubled in most European countries within the last 5 years.[18–20] Since the commercial approval of TAVR in the United States in late 2011, the number of centers performing TAVR across the 50 states has more than doubled.[14,21] This global trend toward more TAVR procedures seems likely to continue, especially as the technology and techniques advance even further and the approved indications continue to expand.[7,21,22]

Although multiple hardware options for TAVR are commercially approved in Europe, currently there are 2 principal TAVR systems commercially available in the United States—the Edwards SAPIEN balloon-expandable valve system (Edwards Life Sciences, Irvine, CA) and the self-expanding bioprosthetic CoreValve system (Medtronic Inc, Minneapolis, MN).[7,21] Each of these TAVR platforms has unique characteristics and associated complications that have been reviewed previously.[23–25] The TAVR access options in the contemporary era include transfemoral, transsubclavian, transapical, and transaortic approaches.[26] The access route for the individual patient should be planned carefully by the heart valve team, taking into account multiple factors such as comorbidities, vascular anatomy, and valve options.[26]

The current guidelines from the American College of Cardiology (ACC) and American Heart Association (AHA) have recommended SAVR in patients with severe AS who have low or intermediate surgical risk (class-I recommendation).[10] In these same guidelines, TAVR has been recommended in patients with severe AS who have either prohibitive (class-I recommendation) or high (class-IIa recommendation) surgical risk.[10]

The First Paradigm Shift: From Prohibitive-Risk to High-Risk Patients

In 2010, Leon et al [27] reported the results from the landmark multicenter Placement of Aortic Transcatheter Valves (PARTNER 1) trial in patients with both severe AS and prohibitive surgical risk. In this clinical trial, patients were assigned randomly to either standard therapy, including balloon aortic valvuloplasty, or transfemoral TAVR with a balloon-expandable bovine pericardial valve (Edwards Lifesciences). At 1 year, the rate of all-cause death was 30.7% with TAVR compared with 50.7% with standard therapy (hazard ratio [HR] 0.55; 95% confidence interval [CI] 0.40-0.74; $p < 0.001$).[27] Furthermore, all-cause death at 2 years was reported to be lower with TAVR (43.3%) compared with standard medical therapy (43.3% *v* 68%; HR 0.58; 95% CI 0.36-0.92; $p = 0.02$).[28] There also was a reduction in repeat hospitalizations (55% *v* 72.5%; $p < 0.001$) and marked improvements in functional status ($p < 0.001$) associated with TAVR.[28] The risk of stroke, however, was significantly higher with TAVR at 2 years (13.8% *v* 5.5%; $p = 0.01$) due to a higher risk of ischemic events in the first 30 days (6.7% *v* 1.7%; $p = 0.02$) and thereafter due to a higher risk of hemorrhagic events (2.2% *v* 0.6%; $p = 0.16$).[28] The overall superior clinical outcomes of TAVR still were apparent in this cohort after 5 years.[29]

These landmark results in prohibitive risk cohorts from 2010 were followed up in 2011 with the published PARTNER 1 outcomes in high-risk patients with severe AS who were randomly assigned to either SAVR or TAVR.[30] At 1 year, the rates of death from any cause were 24.2% in the TAVR group and 26.8% in the surgical group ($p = 0.44$), although there was a trend for a higher stroke risk in the TAVR cohort (5.1% *v* 2.4%; $p = 0.07$).[30] These overall equivalent clinical outcomes persisted at 2 and 5 years.[31,32] The 5-year outcomes from PARTNER 1 demonstrated similar mortality, functional outcomes, and improvements in valve function in patients who underwent TAVR or SAVR.[32] The risk of death at 5 years was reportedly 67.8% with TAVR compared with 62.4% with SAVR (HR 1.04; 95% CI 0.86–1.24; $p = 0.76$).[32] Although valve durability appeared equivalent in both cohorts, the risk of hemodynamically significant aortic regurgitation was significantly higher in the TAVR cohort (14.0% *v* 1.0%; $p < 0.0001$).[32] This degree of aortic regurgitation was important because it was associated with a higher mortality risk at 5 years (72.4% *v* 56.6%; $p = 0.003$). The findings have challenged whether SAVR still is the gold standard for patients with severe AS at high surgical risk.[32] These trials also have highlighted the importance of interventions to minimize paravalvular leak after TAVR and have reported on the innovation drives in hardware and imaging that already have been discussed in detail elsewhere in this *Journal*.[3,4,7,12,24,25,33]

Concurrent with these trials, the CoreValve clinical investigators found the CoreValve to be safe and effective in an extreme-risk patient cohort with severe AS.[34] Furthermore, CoreValve also was found to be superior to SAVR in high-risk patients with severe AS.[35] In that multicenter study, 795 extreme-risk patients were assigned randomly to TAVR or SAVR with the primary endpoint being death from any cause at 1 year. The investigators reported a significant decrease in all-