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Study examines effectiveness, safety of transcatheter aortic valve replacement in US

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Michael J. Mack, M.D., of the Baylor Health Care System, Plano, Texas, and colleagues describe the experience in the U.S. with transcatheter aortic valve replacement (TAVR), including patient selection, procedural details, and in-hospital and 30-day outcomes following TAVR, a less invasive procedure than open heart-valve surgery for replacing the aortic valve in the heart.

In November 2011, the U.S. Food and Drug Administration (FDA) approved use of a valve that could be implanted using a catheter for TAVR for the treatment of severe, symptomatic aortic stenosis in patients with inoperable status. The label for the valve was expanded in September 2012 to include patients at high-risk but operable status. Since commercial approval, this first-to-U.S.-market TAVR device has been introduced to nearly 250 U.S. clinical sites. "Although the [initial] trials demonstrated efficacy of TAVR within a select cohort of patients and hospital centers, there are no data on dissemination and utilization patterns of this technology in routine clinical practice in the United States. Additionally, concerns persist regarding the safety and effectiveness of this novel technology as it moves beyond protocolized trial care and highly experienced centers and operators," according to background information in the study.

For this study, the researchers gathered results from all eligible U.S. TAVR cases (n = 7,710) from 224 participating registry hospitals following the device commercialization (November 2011 - May 2013). Successful device implantation occurred in 7,069 patients (92 percent).

In-hospital mortality was 5.5 percent. Other major complications included stroke (2.0 percent), dialysis-dependent renal failure (1.9 percent), and major vascular injury (6.4 percent).

Median hospital stay was 6 days, with 4,613 patients (63 percent) discharged home. Among patients with available follow-up at 30 days (n = 3,133), mortality was 7.6 percent (noncardiovascular cause, 52 percent); stroke occurred in 2.8 percent, and new dialysis in 2.5 percent.

"This analysis represents the first public report from the U.S. national Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry and documents 2 major findings. First, postapproval commercial introduction of this new technology with an early-generation device has yielded success rates and complication patterns that are similar to those documented in carefully performed randomized trials. Second, the outcomes of procedures even with this early-generation approved device are similar to the global experience of TAVR, which now is based on second- and third-generation improved devices. These findings help address a lingering question of clinical outcomes with the first-generation TAVR device after controlled U.S. dissemination to a relatively narrow group of treatment centers," the authors write. "Longer-term follow-up is essential to assess continued safety and efficacy as well as patient health status."

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