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EDITOR'S COMMENTARY

Advances in Transcatheter Tricuspid Valve Interventions

Implications for Health Policy

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Management of valvular heart disease in the 21st century has been transformed by the advent of transcatheter therapeutics. Propelled by the 2011 U.S. Food and Drug Administration (FDA) approval of transcatheter aortic valve replacement, the following decade has seen clinical trials of new devices in each of the 4 valves in the heart. These new therapeutic advances are a welcome development given the prevalence of valvular heart disease and the associated morbidity and mortality for affected patients. However, as is often the case for medical innovation, evolution in care paradigms must be paired with consideration for concomitant changes in health policies.

Recent advances in transcatheter treatments for tricuspid valve regurgitation provide a salient reminder of the interplay between innovation, regulation, and health policy for the practice of cardiovascular medicine. The FDA's 2024 approvals of tricuspid transcatheter edge-to edge-repair (T-TEER) and transcatheter tricuspid valve replacement (TTVR) occurred under the Breakthrough Devices Program, which offers expedited regulatory review and allows for premarket evidentiary flexibility, contingent on adequate postmarket controls. This flexibility was evident in the FDA's decision-making; the approvals of both T-TEER and TTVR were based on evidence generated from a prespecified cohort of patients representing a subset of total enrollment in the pivotal trial. The full results of the TRILUMINATE (Trial to Evaluate Cardiovascular Outcomes in Patients Treated with the Tricuspid Valve Repair System) for T-TEER,[1] and a secondary analysis of patient health status in the TRISCEND II (EVOQUE Transcatheter Tricuspid Valve Replacement: Pivotal Clinical Investigation of Safety and Clinical Efficacy Using a Novel Device) trial for TTVR,[2] were published in *JACC* to coincide with their presentations at Transcatheter Cardiovascular Therapeutics 2024, and provide information about each device's safety and effectiveness.

These approvals also offer insight into an evolving regulatory landscape for cardiovascular devices, which are the most represented specialty among approved therapeutic Breakthrough devices and were the first specialty selected for the FDA's Total Product Life Cycle Advisory Program. These programs focus on expediting device development by facilitating earlier engagement between manufacturers and regulators on issues ranging from study design questions (Breakthrough) to payer coverage policy (Total Product Life Cycle Advisory Program).

Yet even as regulators are being engaged earlier, the timing of evidence generation is being pushed later. Complete results for the pivotal trials of both tricuspid valve therapies were published months after each device's approval. The FDA is also requiring each device to complete a postapproval study using the Transcatheter Valve Therapy registry jointly coordinated by the Society of Thoracic Surgeons and American College of Cardiology, with a minimum enrollment target of 5,000 patients.

Uptake of T-TEER and TTVR is likely to evolve as patients, clinicians, and manufacturers await further clarity on payer coverage criteria. In particular,

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Medicare criteria will be critical because severe tricuspid regurgitation is most common in older adults, as demonstrated by the mean age of study participants in both TRILUMINATE (78.1 years) and TRISCEND (79.2 years). The Centers for Medicare and Medicaid Services (CMS) recently initiated national coverage determination processes for both TTVR (proposed decision expected December 2024)[3] and T-TEER (proposed decision expected April 2025).[4] The public is encouraged to submit comments to CMS to inform the agency's coverage decision. Notably, as FDA-designated Breakthrough devices, both devices have been selected to participate in a new CMS pilot called Transitional Coverage for Emerging Technologies, which provides up to 5 years of provisional Medicare coverage to allow for post-market evidence generation.[5] T-TEER and TTVR's Breakthrough status also provides for enhanced New Technology Add-on Payments beginning October 2024 to encourage adoption, a policy that has also raised criticism for encouraging higher launch prices for devices and perpetuating the access problem that these payments were initially intended to solve.

Medicare's coverage decision-making will be informed by previous experiences with transcatheter aortic valve replacement and TEER for mitral regurgitation. For example, CMS may establish its own evidence generation requirements, and may require minimum operator volumes that adjust over time as clinical experience increases. However, tricuspid valve interventions raise new challenges for evidence generation to inform coverage. The primary benefit in clinical trials to date has been for improving patient symptoms. Although use of patient-reported outcomes in medical device trials has increased, long-term follow-up has been challenging, including for the Transcatheter Valve Therapy registry jointly coordinated by the Society of Thoracic Surgeons and American College of Cardiology, indicating the need for new approaches integrating multiple data sources to durably assess quality of life changes. Although FDA and CMS policies will advance access to these therapies, the cardiovascular community must ensure that rigorous evidence is generated in a timely manner—and learn from this experience, including pivoting as necessary.

Although some have considered it the "forgotten" valve, the tricuspid valve and emergence of device-based therapies now highlight a central premise for the cardiology community—for innovation to benefit patients, evidence and policy must move forward together.

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