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EDITORIAL
Valvular heart disease

Transcatheter aortic valve implantation in patients with severe aortic stenosis and cardiogenic shock: an important step forward

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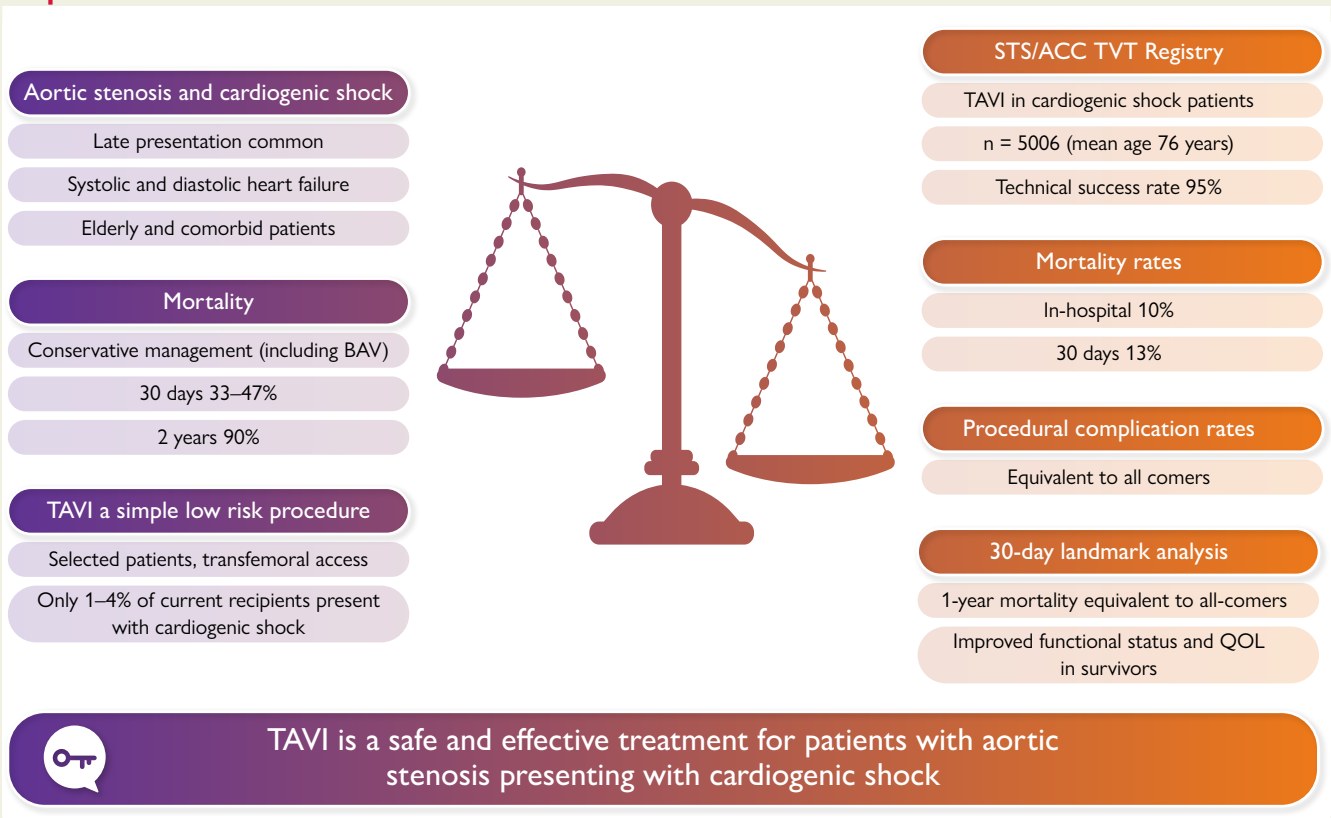
This editorial refers to 'Outcomes of transcatheter aortic valve replacement in patients with cardiogenic shock', by K. Goel *et al.*, https://doi.org/10.1093/eurheartj/ehad387.

Graphical Abstract



Within 20 years of its inception, transfemoral transcatheter aortic valve implantation (TAVI) has become an established treatment option for patients with symptomatic severe aortic stenosis (AS) that is supported by class IA recommendations in current European and US guidelines on the management of valvular heart disease.[1,2] Technological innovations and procedural refinements have made TAVI a safe and streamlined intervention, while accumulating long-term follow-up data suggest that durability will be comparable with surgical aortic bioprostheses.

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As a consequence, extended recommendations to younger and lower risk patients seem inevitable, while newer indications for intervention in asymptomatic patients, those with pure aortic regurgitation, or those with moderate AS and heart failure are being investigated in ongoing randomized trials (NCT 03094143, NCT 03042104, NCT 02661451, and NCT 04415047).

Cardiac damage with resulting acute and/or chronic heart failure is the final common pathway for all patients with valve disease.[3] Aortic stenosis, in particular, has a bi-modal natural history characterized by a long asymptomatic pre-clinical phase followed by dramatic late deterioration as initially adaptive left ventricular hypertrophy and fibrosis transition to systolic and diastolic heart failure.[4] Late presentation is therefore common, and this trend is exaggerated by insidious symptom progression, a lack of awareness amongst medical practitioners of the prognostic implications of valve disease, and the reluctance of patients (many of whom are elderly with multiple comorbidities) to report symptoms. Thus, valve disease was the primary cause of acute heart failure in the ESC-HF-LT registry (affecting 11.8% of patients) and severe AS was an independent predictor of all cause mortality at 1 year.[5] These observations have translated into everyday clinical practice where decompensated AS is frequently encountered—either in patients whose diagnosis of AS was overlooked during the COVID pandemic or in those with diagnosed AS awaiting a TAVI procedure.

Cardiogenic shock is the ultimate presentation of heart failure and has a perilous prognosis in patients with severe AS, characterized by a vicious cycle of subendocardial ischaemia and deleterious changes in preload and afterload, resulting in acute decompensation and high risk of mortality.[6] Previous studies evaluating the role of balloon aortic valvuloplasty in this setting reported mortality rates of 33%–47% and 90% at 30 days and 2 years, respectively.[7–9] In the modern era, surgical aortic valve replacement is seldom contemplated in patients with cardiogenic shock owing to the high risk of peri-operative morbidity and mortality, and TAVI is a potentially attractive treatment option given its swift and less invasive characteristics. However, only 1%–4% of patients who currently undergo TAVI have presented with cardiogenic shock, and outcome data beyond 30 days are limited.[10]

In this issue of the *European Heart Journal*, Goel *et al.* use the resources of the the Society of Thoracic Surgeons (STS)/American College of Cardiology Transcatheter Valve Therapy (TVT) Registry to investigate the safety and efficacy of TAVI using contemporary balloon-expandable valves in the setting of cardiogenic shock over a 7-year study period between June 2015 and September 2022.[11] Amongst >300 000 patients undergoing TAVI with a balloon-expandable valve during this time frame, 5006 (1.6%) presented with cardiogenic shock (defined according to registry coding data, pre-procedural use of inotropic or mechanical circulatory support, and/or cardiac arrest within 24 h prior to the procedure). Valve implantation (undertaken at a mean of 7 days from the date of hospital admission) was successful in 98% of patients, with a technical success rate of 95% according to VARC-3 criteria.[12] Propensity-matched analysis demonstrated that TAVI performed in the context of cardiogenic shock was associated with higher in-hospital (9.9% vs. 2.7%), 30-day (12.9% vs. 4.9%), and 1-year (29.7% vs. 22.6%) mortality (and equivalent procedural complication rates) compared with the control cohort (all other patients undergoing TAVI in the same time period). Importantly, however, these survival statistics compared favourably with the historical outcomes of conservative management (including balloon aortic valvuloplasty).[13] Furthermore, in a landmark analysis at 30 days, risks of 1-year mortality were similar in the two groups whilst survivors noted significant improvements in quality of life and functional status.

This observational real-world study incorporating >5000 patients in the active intervention arm is the largest series to date and demonstrates that TAVI is a safe and effective treatment for the small (but increasing) proportion of patients with AS who present with cardiogenic shock. Despite the high mortality generally observed in this setting, >90% of patients survived initial hospitalization, and the majority of these were alive at 1 year with significant improvement in quality of life and functional status. TAVI should therefore be considered as a definitive treatment for most patients with severe AS presenting with cardiogenic shock, provided that they are anatomically suitable for a transfemoral procedure and do not have prohibitive co-morbidities that will curtail long-term survival. Although the present analysis was restricted to patients undergoing TAVI using contemporary balloon-expandable valves (for reasons relating to restriction of data sharing), there is no reason to expect different findings after TAVI with alternative (mainly self-expanding) devices.

The observational study design infers a possibility of selection bias and it is highly likely that TAVI was not undertaken in the sickest patients. Patient selection is clearly essential to avoid potentially futile procedures and, although haemodynamic data and lactate levels were unavailable within the TVT registry dataset, it is important to note the findings of multivariate analysis demonstrating that older age, lower mean gradient, lower albumin, end-stage renal failure, immunocompromised state, peripheral arterial disease, and the pre-existing presence of an implantable defibrillator were independent predictors of higher 1-year mortality. Similarly, the impact of concomitant percutaneous coronary intervention (PCI)—undertaken in 30% of the cardiogenic shock cohort—was not formally evaluated. Nevertheless, the fact that 30-day landmark analysis showed no difference in mortality between the propensity-matched study groups suggests a good long-term prognosis if patients survive beyond the initial TAVI procedure and its recovery phase.

Until now, patients with severe AS presenting with cardiogenic shock have generally been managed conservatively, with frequent use of balloon aortic valvuloplasty as a 'bridge to TAVI' in those who survive. Refinement of the TAVI procedure and adoption of streamlined techniques mean that the additional steps involved in transcatheter valve implantation are minimal, particularly if pre-procedural evaluation indicates that a straightforward transfemoral procedure is feasible. Indeed, the data provided by Goel *et al.* support the view of many experienced TAVI operators who have been suggesting for some time that 'primary TAVI' is a more appropriate approach in this setting.

There was a time (not so long ago) when PCI was only performed as a scheduled elective procedure for patients with stable angina, whereas it is now used predominantly in the urgent and emergency treatment of those with unstable manifestations of coronary artery disease. The present data suggest that a similar approach to the use of TAVI in patients with severe AS presenting with cardiogenic shock is not only appropriate, but life saving.

Declaration

Disclosure of Interest

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