TAVI in 2022: Remaining issues and future direction

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Citation *Archives of Cardiovascular Disease. 2022;115(4) 235-242*

Objectives

- Present an overview of current challenges when considering transcatheter aortic valve implantation (TAVI) in populations at lower surgical risk
- Summarise the different approaches that have been developed to address these concerns

Study design

Review paper

Materials and methods

The results of the following papers were analysed:

- PARTNER TRIAL - Smith CR, Leon MB, Mack MJ et al. PARTNER Trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med.* 2011; 364(23):2187-98
- PARTNER II TRIAL - Leon MB, Smith CR, Mack MJ et al. PARTNER II Investigators. Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. *N Engl J Med.* 2016; 374(17):1609-20
- PARTNER 3 TRIAL - Mack MJ, Leon MB, Thourani VH et al. PARTNER 3 Investigators. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med.* 2019; 380(18):1695-705
- SURTAVI TRIAL - Reardon MJ, Van Mieghem NM, Popma JJ et al. SURTAVI Investigators. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. *N Engl J Med.* 2017; 376(14):1321-31
- EVOLUT LOW RISK TRIAL – Popma JJ, Deeb GM, Yakubov SJ et al. EVOLUT Low Risk Trial Investigators. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med.* 2019; 380(18):1706—15
- NOTION TRIAL – Sondergaard L, Ihlemann N, Capodanno D et al. Durability of transcatheter and surgical bioprosthetic aortic valves in patients at lower surgical risk. *J Am Coll Cardiol.* 2019; 73(5):546—53

Key results

Evidence in lower risk populations

- The PARTNER and PARTNER II trials provided evidence for TAVI in patients at prohibitive, high, and intermediate surgical risk using the balloon expandable SAPIEN valve, SAPIEN XT valve and SAPIEN 3 valve
- In the PARTNER 3 trial, TAVI using SAPIEN 3 valve met criteria for non-inferiority and superiority compared with SAVR for primary endpoint of all-cause mortality, stroke, or rehospitalisation at 1 year follow up in patients at low surgical risk
- In the SURTAVI trial, TAVI was non inferior to SAVR in low-risk patients using self-expandable CoreValve and Evolut R valves
- In the NOTION trial – there was no significant difference between self-expandable TAVI versus SAVR in low-risk patients for composite endpoint of death, stroke, or myocardial infarction at 1 year follow up.
- EVOLUT trial – compared TAVI with SAVR using self-expandable CoreValve Evolut R and Evolut PRO THVs in low-risk patients. Death and disabling stroke similar at 1 year follow up, TAVI non inferior to SAVR for mortality or disabling stroke at 2 years follow up.
- The increase in rates of TAVI procedures in the low-risk population resulted in a shift towards younger patients (from >80 to 73-74 years)

Transcatheter heart valve (THV) durability

- In both balloon-expandable and self-expandable transcatheter heart valves (THVs), low incidences of valve degeneration were reported with medium term use at 5 years follow up.
- Caution should be taken regarding durability when considering TAVI in younger patients as younger age is a well-known risk factor for surgical bioprosthetic valve failure

Repeatability of TAVI procedure: Redo TAVI

Redo TAVI is a safe and feasible treatment option which is being performed increasingly

Future coronary access

- Future coronary access may be challenging in the right and left coronary arteries for both balloon-expandable and self-expandable THV platforms
- Coronary access may be even more challenging when considering valve in valve (ViV) or redo TAVI

Conduction disorders

- Conduction disorders and pacemaker implantation are a concern for patients undergoing TAVI with incidence of pacemaker implantation at 1 month follow up varying according to THV platforms and techniques.
- Pre-existing atrioventricular and intraventricular conduction disorders are a main risk factor for pacemaker implantation
- The type of THV platform, diameter, and depth of the THV should be considered
- Recent implantation techniques that reduce the depth of the THV implantation reduce the need for new pacemakers

Paravalvular leak (PVL)

- Despite a decrease in PVL over recent years, mild PVL remains high in patients undergoing TAVI and occurs more frequently after TAVI than SAVR
- Risk factors for PVL after TAVI include bulky and asymmetric calcification, degree of THV oversizing and device malpositioning, and unfavourable anatomical features especially in younger populations

Lifetime management

Both TAVI and SAVR should be integrated into a combined strategy should there be a need for future interventions

Future directions

- The risks of new conduction disorders, pacemakers, PVL, annular injury, compromised coronary access or coronary occlusion should be taken into consideration when determining the optimal intervention and optimal THV platform
- Ideally TAVI should be repeatable without risk of coronary obstruction, occlusion, or sinus sequestration in patients with the potential for longevity
- THV durability may impact future redo TAVI (THV in THV procedures).

Conclusions

- TAVI is becoming the standard of care for many patients with aortic stenosis
- Indication of TAVI has been extended to patients at lower risk, who are typically younger
- Outcomes can be optimised with a tailored approach by an experienced Heart Team, rigorous patient selection, and integrating aortic stenosis management strategies throughout the lifetime of the patient
- Caution should be taken regarding THV durability when considering TAVI in younger patients
- New studies are being conducted to address the potential issue of future coronary access, with techniques to improve THV commissural alignment showing some success, and newer THV systems being developed to facilitate this.

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