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REVIEW

Why should we extend transcatheter aortic valve implantation to low-risk patients? A comprehensive review

Pourquoi devrait-on étendre les indications du TAVI aux patients à bas risque? Une revue de la littérature

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Summary Within the past decade, transcatheter aortic valve implantation (TAVI) has become established as the optimal treatment option for elderly, inoperable and high-risk patients with severe aortic stenosis, and is now recommended by international guidelines. Randomized controlled trials have demonstrated the non-inferiority of TAVI to open surgery in intermediate-risk patients and, most recently, in low-risk patients. Further randomized controlled trials are underway, but existing studies have already provided reassuring data in this cohort, and TAVI is offered routinely to younger and lower-risk patients in numerous centers. Improvements in the design of devices and delivery systems, accompanied by increased operator experience, have dramatically improved the safety of the procedure, and further expansion into low-risk groups seems inevitable once concerns about valve durability and device cost have been addressed. In this article, we provide a review of the existing literature, and estimate the clinical impact of TAVI in low-risk patients. Abbreviated title: Why should we extend TAVI to low-risk patients?

Abbreviations: CI, confidence interval; HR, hazard ratio; OR, odds ratio; RR, relative risk; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; TAVI, transcatheter aortic valve implantation; THV, transcatheter heart valve.

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Résumé Durant la dernière décennie, le remplacement valvulaire aortique par cathétérisme (TAVI) est devenu le traitement optimal de la sténose aortique serrée chez les patients âgés, inopérables et à haut risque. Le TAVI est maintenant recommandé dans ces indications. Les essais randomisés contrôlés (RCT) ont démontré la non-infériorité du TAVI par rapport à la chirurgie ouverte chez les patients à risque intermédiaire et tout récemment bas risque. Pendant que de nouveaux RCT sont en cours, les données observationnelles existantes sont rassurantes dans cette sous-population et le TAVI est déjà utilisé chez les patients à bas risque dans de nombreux centres dans le monde. Les améliorations du design des systèmes implantés accompagnés de la croissance de l'expérience des opérateurs ont permis d'améliorer drastiquement la sécurité des procédures. Ainsi l'extension du TAVI aux patients à bas risque semble inévitable. Toutefois, il reste à résoudre les questions de durabilité à long terme des bioprothèses implantées par cathétérisme et du coût de la procédure. Dans cet article, nous apportons une revue de la littérature existante et évalue l'impact clinique de l'implémentation du TAVI chez les patients à bas risque chirurgical.

Background

Over the past decade, transcatheter aortic valve implantation (TAVI) has rapidly become established as the optimal treatment for high-risk patients with severe aortic stenosis. A portfolio of randomized controlled trials and observational studies has established the non-inferiority (and even superiority) of TAVI compared with surgical aortic valve replacement (SAVR) in high-risk patients [1,2]. These encouraging results, and the minimally invasive nature of the TAVI procedure, heralded extension of initial trials to patients with an intermediate surgical risk. Again, results were favorable, with overall equivalence of TAVI and SAVR in both the PARTNER 2 and SURTAVI trials, and an indication of the superiority of TAVI when performed via a transfemoral approach [3,4]. As a consequence, international guidelines have recommended the use of TAVI in inoperable and high-risk patients (Class I) and, more recently, in intermediate-risk patients (Class IIa) [5,6]. The North American PARTNER 3 and Evolut Low Risk trials were published very recently, and confirmed non-inferiority and even superiority of TAVI for some of the outcomes [7,8]. Other trials addressing the use of TAVI in younger lower-risk patients (and all-comers overall) are underway in Europe (NCT02825134, NCT03112980), and iterative device designs are attempting to address the remaining drawbacks of the procedure (such as paravalvular aortic regurgitation and the need for permanent pacemaker implantation).

We reviewed publications in PubMed, Embase and Google Scholar that were relevant to the discussion of extension of TAVI to low-risk patients.

Patient risk estimation

Routinely used risk scores (logistic EuroSCORE II and Society of Thoracic Surgeons [STS] score) predict procedural and in-hospital mortality after cardiac surgical procedures, but not TAVI [9]. Although TAVI does not require sternotomy or extracorporeal life support, the procedure has specific challenges, including the difficulties of vascular access in elderly patients with a high prevalence of severe atherosclerosis and a persistent risk of vascular complications (including stroke). The STS score and EuroSCORE II (7) have poor discrimination, and overestimate TAVI-related mortality [9,10], and attempts to develop TAVI-specific risk scores have failed so far [11]. The STS score provides better overall calibration than EuroSCORE II, and is currently the preferred risk assessment tool for TAVI [10].

An STS estimated mortality score < 4% is the most widely used definition of the low-risk patient. Guidelines recommend that patients with an STS risk score < 4% should only be considered for TAVI in the setting of a clinical trial. Although an 80-year-old patient with isolated hypertension and vascular anatomy suitable for transfemoral access may have an STS score of < 2%, many Heart Teams would consider such a patient more suitable for TAVI in view of the high likelihood of a rapid recovery and short hospital stay. So, age and frailty might also be satisfactory risk stratification factors. Accordingly, age $\geq$ 75 years and frailty have been proposed in European guidelines as arguments for TAVI compared with SAVR [5]. Furthermore, Iung et al. have developed a practical clinical risk score specifically for TAVI [12]. In practice, multidisciplinary Heart Teams, including cardiologists, surgeons, geriatricians and anaesthesiologists, aim to identify the risk/benefit ratio of TAVI versus surgery, and refine patient selection through a combination of clinical, anatomical and technical factors, data from existing literature and consideration of the preferences of each individual patient.

Mortality

TAVI has challenged standard-of-care therapy for aortic stenosis in landmark randomized controlled trials using

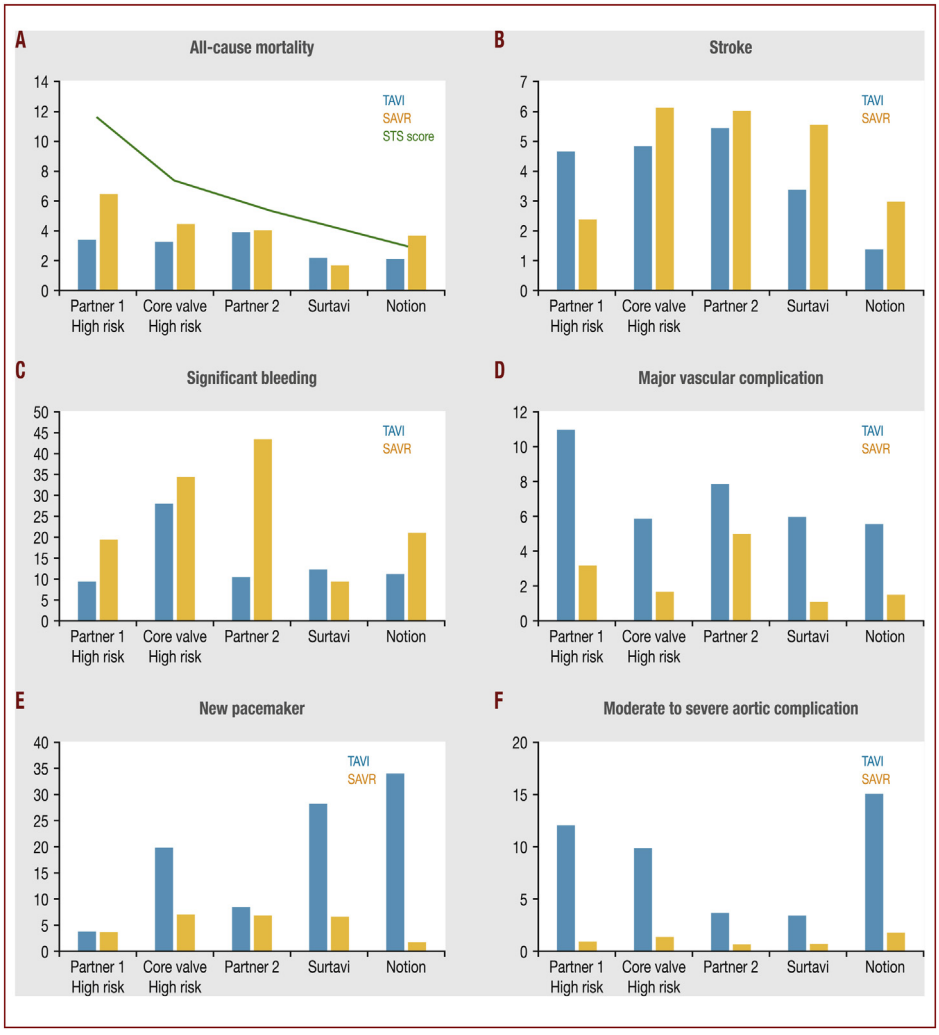

Figure 1. Thirty-day to 3-month outcomes in transcatheter aortic valve implantation (TAVI) versus surgical aortic valve replacement (SAVR) trials [1—4,16]. STS: Society of Thoracic Surgeons.

mortality as the primary outcome [1,3,4]. Although surgical risk scores overestimate actual mortality, their predictions correlate well with short-, mid- and long-term event rates (Fig. 1) in both randomized controlled trials [1,3,4] and observational studies [13,14], and for TAVI as well as SAVR [13]. Brennan et al. recently reported 1-year mortality rates of 27% in high-risk subjects (STS $\geq$ 8%), 15% in intermediate-risk/high-risk subjects (STS 5—8%) and 12% in low-risk/intermediate-risk subjects (STS 3—5%) in a large cohort of 9464 patients undergoing intervention for aortic stenosis, with no significant difference between TAVI and SAVR after propensity matching (hazard ratio [HR] for the overall cohort 0.93, 95% confidence interval [CI] 0.83—1.04) [13]. Meanwhile, observational studies have reported all-cause mortality rates after TAVI to be as low as 0—3.6% at 30 days (11.1—12.8% at 1 year), with a 30-day risk ratio favoring TAVI over SAVR in one meta-analysis (relative risk [RR] 0.67, 95% CI 0.41—1.10), although without statistical significance [15—17].

Recent observational data with a short 30-day follow-up supports the strategy of many high-volume centers that have been treating low-risk patients for several years with transfemoral TAVI instead of SAVR [17,18]. However, transthoracic TAVI (including transapical and transaortic) has been associated with worse outcomes than transfemoral TAVI [3]. For example, the STACCATO trial comparing transapical TAVI with SAVR in low-risk patients (STS score 3.1%) was stopped early as a result of excess events in the transapical TAVI group [19].

Strengths of TAVI

Atrial fibrillation

Although pre-existing atrial fibrillation is present in up to 30% of patients with severe symptomatic aortic stenosis, the risk of new-onset atrial fibrillation is 10—35% lower after TAVI [3,20] than after SAVR in clinical trials [3,4,20]. Again, the TAVI access is of importance, as non-femoral TAVI is associated with a higher incidence of new-onset atrial fibrillation (HR 2.04, 95% CI 1.47—2.81; $P = 0.001$).

Acute kidney injury

Acute kidney injury and the need for dialysis are more frequent after SAVR than after TAVI. In a meta-analysis of four studies including low-risk patients, TAVI was associated with a significant 34% reduction in the incidence of acute kidney injuries at 30-day follow-up [15]. This is notable, as chronic renal failure is frequent in the elderly, and postprocedural deterioration in renal function is related to increased long-term mortality [21].

Patient preference

Patients have a natural preference for TAVI as opposed to SAVR, because of the less invasive nature of the procedure, the potential to avoid general anaesthesia, shorter intensive care unit and overall hospital stays [3,22], the higher likelihood of direct discharge home instead of to a rehabilitation center and the reduction in delay to full recovery, particularly in elderly patients for whom quality of life is of primary importance [3,7,13,23].

Weaknesses of TAVI

Younger and lower-risk patients have greater life expectancy, and some of the usual caveats associated with TAVI have considerable impact on long-term survival and overall quality of life.

Paravalvular regurgitation

Moderate and severe aortic regurgitation are associated with higher long-term mortality and the need for rehospitalization [3,24], although newer-generation devices have significantly reduced the incidence of significant aortic regurgitation after TAVI (SAPIEN™ 3 [Edward Lifesciences, Irvine, CA, USA] 3.4%; LOTUS™ [Boston Scientific, Marlborough, MA, USA] 0.9%) [4,20,25]. To mitigate this risk, manufacturers have modified the inflow portion of the valve with either a cuff (SAPIEN™, LOTUS™) or an external sealing system (Evolut™ R; Medtronic Inc., Minneapolis, MN, USA). Partial (Evolut™ R) or complete (LOTUS™) valve repositionability assists in accurate valve deployment to further reduce the risk of pulmonary vascular resistance [26]. Even so, improved radial strength with newer-generation devices has increased the rate of new pacemaker implantation [20].

New pacemaker implantation

Rates of new pacemaker implantation vary widely with new-generation TAVI devices (2.3—36.1%) [27]. Implantation of a new pacemaker may reduce the rate of unexpected (sudden or unknown) death after TAVI (HR 0.31, 95% CI 0.11—0.85; $P = 0.023$) (27), but may also prevent improvement (or even cause deterioration) in left ventricular ejection fraction, albeit without impact on 1-year mortality (RR 1.03, 95% CI 0.92—1.16) [28]. Some of the reported predictors identified are type of device used, pre-existing right bundle branch block and depth of implantation [20,29]. Interestingly, a recent study has concluded that only one third of patients are pacemaker dependent at medium-term follow-up, suggesting a transient inflammatory cause to early conduction disturbances [30]. Further investigation with longer follow-up is warranted to address the impact of new pacemaker implantation on long-term mortality. Newer devices with lower radial force and a shorter segment inside the left ventricular outflow tract have the potential to yield lower pacemaker implantation rates, but further data are needed [31].

Stroke

Stroke is a strong predictor of 3-year mortality in low-risk patients (HR 7.4, 95% CI 3.8—14.3; $P < 0.0001$) [22], and rates of stroke may be as low as 1.2% after SAVR in younger and healthier patients [32]. The risk of stroke appears to be equivalent for up to 2 years after TAVI and SAVR in all-risk patients [1—3,8], with no influence according to the mode of access or choice of TAVI device [33]. Current early observational and randomized data demonstrate very low 30-day stroke rates (1.0—1.8%) in low-risk patients [7,22,34], although optimal antithrombotic treatment regimens to mediate intermediate and long-term stroke prevention are yet to be determined. Furthermore, procedural strategies avoiding systematic pre- and postdilatation and cerebral protection devices to reduce the risk of cerebrovascular embolic events during the procedure could improve procedure safety for low-risk patients [35]. However, these strategies require validation, and more research is warranted to identify stroke predictors during and after TAVI.

Vascular complications

Vascular complications relate to case selection, operator expertise, delivery systems and technical approaches, rather than overall risk scores. Although much progress has been achieved in reducing the caliber of TAVI delivery systems from 22F to 14F (Fig. 2), 30-day rates of major vascular complications after TAVI (6—10%) remain higher than after SAVR (< 5%) [1,3].

Room for improvement

Durability

Degeneration of surgical bioprosthetic valves relates to calcification and tearing of the valve cusps, resulting in stenosis or regurgitation. Compression of transcatheter heart valves (THVs) within the delivery system may induce structural damage to pericardial leaflets and reduce device longevity [36]. Durability is a major concern in younger, low-risk patients with prolonged life expectancy, and robust data concerning the long-term durability of TAVI are scarce. Early 5-year outcomes from the PARTNER 1 cohort are reassuring, with stable haemodynamic function as measured by mean gradient (10.6 ± 3.9 mmHg at 5 years) and aortic valve area (mean $1.5 \pm 0.3\ cm^2$ at 5 years) [37]. The stability of mean gradient and aortic surface area after TAVI with the CoreValve™ THV (Medtronic Inc., Minneapolis, MN, USA) has been also been confirmed up to 3 years by Deeb et al., by following up the CoreValve US Pivotal randomized trial high-risk cohort [38], and up to 5 years by Barbanti et al. in the

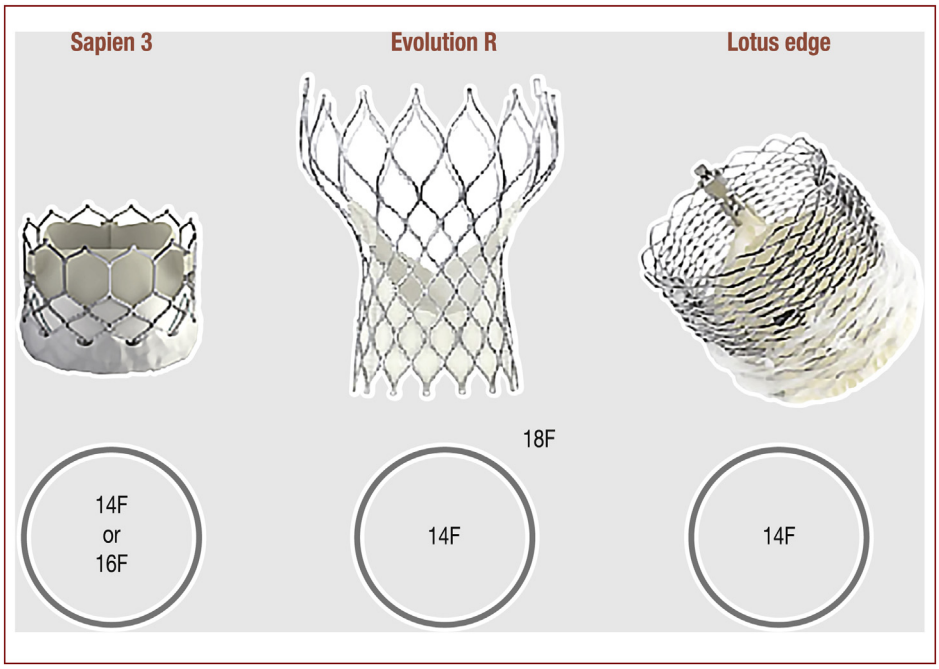

Figure 2. Contemporary transcatheter aortic valve implantation devices used in randomized controlled trials to date, and the relative size of their delivery sheaths. For the Evolut™ R transcatheter heart valve, the EnVeo™ R catheter and the integrated InLine™ sheath allowing delivery have a 14F equivalent profile corresponding to a true 18F outer diameter (Medtronic Inc., Minneapolis, MN, USA).

Italian multicentre registry data [39]. Of note, surface area and transprosthetic gradient profiles are often favourable to TAVI rather than SAVR in randomized trials [4,16].

Recently the European Association of Percutaneous Cardiovascular Interventions aimed to provide a standardized approach to THV degeneration reporting in their guidelines, and defined the notion of structural valve deterioration by an increase in mean transprosthetic gradient or aortic regurgitation [40]. A link with subclinical leaflet thrombosis has been suggested [41]. Five-year follow-up data from the FRANCE-2 registry found severe structural valve deterioration and moderate/severe structural valve deterioration rates to be 2.5% and 13.3%, respectively, without difference according to THV type (balloon-expandable or self-expandable). Severe structural valve deterioration was not associated with mortality (HR 0.71, 95% CI 0.41—1.07; $P = 0.1$), but was more frequent in smaller THVs [42]. The most recent version of the French TAVI registry (FRANCE-TAVI) also reported an association between small THVs (≤ 23 mm) and the risk of bioprosthetic valve dysfunction (increase in transprosthetic gradient ≥ 20 mmHg) after a 1-year follow-up. This report also found that anticoagulation reduced the risk of THV dysfunction (odds ratio [OR] 0.54, 95% CI 0.35—0.82; $P = 0.005$), suggesting the involvement of a thrombotic process in THV dysfunction during the first year after TAVI [43].

Ten-year and 15-year follow-up data from large international registries are keenly awaited, because they will allow a more reliable comparison of durability between TAVI and SAVR bioprostheses. Indeed, surgical bioprostheses often start to degenerate significantly after 10 years of implantation [44], and given the structural similarities of surgical bioprostheses and THVs, this might also be the case with THVs. The issue is of central importance for low-risk patients, because degeneration of the bioprosthesis exposes the patient to the need for a new replacement procedure—either valve-in-valve TAVI or redo SAVR.

Bleeding and antithrombotic treatment

Antithrombotic therapy aims to prevent thromboembolic events (mainly stroke), but is associated with an inherent risk of bleeding, which is in turn associated with higher mortality [45]. Recent clinical trials comparing TAVI and SAVR in intermediate-risk patients reported mixed results: rates of significant bleeding 30 days after TAVI were 10.4% in PARTNER 2 and 12.2% in SURTAVI, compared with 43% in PARTNER 2 and 9.3% in SURTAVI for SAVR [3,4]. The NOTION trial recruited all-comers aged ≥ 70 years, and demonstrated that TAVI was associated with a 50% reduction in the risk of major, life-threatening or disabling bleeding (TAVI 11.3% vs. SAVR 20.9%; $P = 0.03$) [16]. These findings have been confirmed in a recent meta-analysis in low-risk patients (RR of bleeding complications after TAVI compared with SAVR 0.51, 95% CI 0.40—0.67) [15].

Furthermore, the ARTE trial recently demonstrated that a simplified regimen of aspirin alone after TAVI in intermediate-risk patients was associated with a lower risk of major and life-threatening bleeding compared with dual antiplatelet therapy using aspirin and clopidogrel (3.6% vs. 10.8%; $P = 0.038$) [46]. Recently an observational study based on the FRANCE-TAVI registry demonstrated that anticoagulation after TAVI was an independent predictor of all-cause mortality (HR 1.18, 95% CI 1.04—1.35; $P = 0.013$), despite protecting against bioprosthesis valve dysfunction (OR 0.54, 95% CI 0.35—0.82; $P = 0.005$) [43]. This suspicion of excessive mortality risk for anticoagulation after TAVI was reinforced by the fact that the much-anticipated international

randomized GALILEO trial was recently stopped prematurely after including 1644 patients. Indeed, the preliminary analysis suggested harm in the rivaroxaban group versus the double antiplatelet therapy group (aspirin with clopidogrel), including higher rates of death or a first thromboembolic event (11.4% vs. 8.8%), all-cause death (6.8% vs. 3.3%) and primary bleeding (4.2% vs. 2.4%).

The optimal antithrombotic regimen remains a matter of debate, and the question will have to be resolved if TAVI is to be applied in low-risk patients to reduce the risk of bleeding while preventing THV thrombosis. Several trials are ongoing to address the question, including ATLANTIS (NCT02664649), POPular-TAVI (NCT02247128), ENVISAGE-TAVI AF (NCT02943785), AUREA (NCT01642134) and AVATAR (NCT02735902).

Valve-in-valve

Valve-in-valve TAVI procedures are feasible for most degenerating surgical bioprostheses, and were associated with similar outcomes to native valve procedures in a large multinational registry of 459 high-risk patients [47]. Thus, valve-in-valve TAVI for failing THVs may become a suitable approach for younger patients treated previously with the technique. However, valve-in-valve TAVI currently presents some noticeable setbacks compared with redo SAVR, including a higher risk of coronary obstruction, malpositioning and embolization and elevated postprocedural gradients [48,49]. Coronary access might become more difficult after a CoreValve™ type of prosthesis rather than after the shorter SAPIEN™ device, which poses the question of the timing of a required percutaneous coronary intervention regarding the TAVI procedure, which will become central as TAVI is expanded to lower-risk patients who previously would have benefited from concomitant SAVR and coronary artery bypass grafting [50]. Operators should foresee the possibility of valve-in-valve TAVI at the time of SAVR bioprosthesis selection, because valve-in-valve TAVI has been advocated to yield better results in degenerated stented rather than stentless bioprostheses [51]. However, the published non-randomized studies reported no difference in mortality between valve-in-valve TAVI and redo SAVR [52]. The major setbacks of valve-in-valve TAVI are the subject of active research, and future developments in TAVI devices and perioperative planning techniques may address the issues of valve-in-valve TAVI and establish it definitively as the most suitable treatment for degenerating surgical as well as THV bioprostheses [53,54].

Bicuspid valve

Bicuspid aortic valve morphology is frequent [55], and is associated with the onset of symptoms at a younger age [56]. As a result, the existing cohorts of patients with bicuspid aortic valve stenosis treated with TAVI included younger patients and those at intermediate surgical risk, but with a significant proportion of low-risk patients. Indeed, the mean STS score was $4.9 \pm 3.4\%$ and the mean EuroSCORE II was $4.6 \pm 3.6\%$ in the cohort published by Mylotte et al. The authors did not find differences in outcomes according to THV type (balloon-expandable versus self-expandable), but reported a high rate (17.4%) of aortic regurgitation grade ≥ 2; this is higher than the rates reported with tricuspid aortic valve [3]. However, the authors also reported a reduction in postimplantation aortic regurgitation risk after changing the sizing technique to be based on multislice computed tomography (OR 0.19, 95% CI 0.08—0.45; $P < 0.0001$) [57]. Recent improvements in valve design and sizing have further helped to reduce the incidence of significant aortic regurgitation after TAVI in intermediate-risk patients with bicuspid valves, with outcomes similar to those in patients with trileaflet valves [56]. This was also observed in the recent publication by Yoon et al., who included low-risk to intermediate-risk patients (mean age 77.2 ± 8.2 years; mean STS score $4.6 \pm 4.6\%$), and observed improvement in paravalvular leak risk (2.7 with bicuspid vs. 1.8% with tricuspid anatomy; $P = 0.53$), without difference in all-cause mortality over a 1-year follow-up (7.4% for tricuspid vs. 4.5% for bicuspid anatomy at 1 year; log-rank $P = 0.64$).

Hence, technical improvement to TAVI devices and perioperative planning were able to mitigate TAVI setbacks when applied to younger patients with bicuspid valve stenosis. Further research is warranted to confirm that patients with bicuspid morphology can nowadays expect similar results to those of patients with tricuspid morphology.

Cost-effectiveness

Aortic stenosis is the most frequently encountered manifestation of valvular heart disease in high-income countries, and 80% of the 142,000 patients treated with SAVR between 2002 and 2010 in the USA were at low risk (STS score < 4%) [32]. The potential expansion of TAVI to low-risk patients therefore has significant economic ramifications.

In a cost-effectiveness analysis of the PARTNER 1 and CoreValve US Pivotal trial cohorts [58], mean costs for the initial procedure and total costs for initial hospitalization in inoperable patients were $42,806 and $78,542, respectively. The 1-year total costs for SAVR and transfemoral TAVI in high-risk patients were similar ($97,992 vs. $96,743; $P = 0.88$), although transapical TAVI was more expensive. As a result, transfemoral TAVI was economically dominant and attractive compared with SAVR (incremental cost-effectiveness ratio < $50,000/quality-adjusted life year) [59]. A further meta-analysis including seven European and North-American cost-effectiveness studies from 2000—2012 (including PARTNER 1 analyses) concluded that TAVI was not economically preferable to SAVR in high-risk patients [60]. On the other hand, cumulative 1-year costs for TAVI using the self-expanding CoreValve™ in intermediate-risk/high-risk patients were $9207 higher per patient than for SAVR (probability of incremental cost-effectiveness ratio < $50,000/quality-adjusted life year = 40.3%). The authors concluded that incremental costs were acceptable by current standards in the USA [58]. European studies are concordant with North American data [60].

Furthermore, recent data from cost-effectiveness analyses were more favorable for TAVI with self-expandable and balloon-expandable devices in intermediate-risk patients [61,62]. Indeed, the very high price of the device, which drives the unfavorable cost-effectiveness profile of TAVI as opposed to SAVR in the perioperative context, is counterbalanced by reductions in length of hospital stay and lower follow-up costs [61,62]. Tam et al. found that

the total lifetime costs (mean ± standard deviation) in the transcatheter aortic valve replacement with the self-expandable device and SAVR arms were $44,299 ± $7,260 and $32,994 ± $13,434, respectively, and the probabilistic analysis found less than willingness-to-pay thresholds of $50,000 in 52.8% of simulations [62]. Baron et al. even found that, over a lifetime, TAVI with the balloon-expandable THV was projected to lower total costs by $8000—$10,000 as opposed to SAVR, with both SAPIEN™ XT and SAPIEN™ 3 economically dominant compared with SAVR in 84% and 97% of bootstrap replicates, respectively [61].

Hence, TAVI could be projected to yield a satisfactory cost-effectiveness profile in low-risk patients as well. Furthermore, TAVI device costs could decrease in the future, as a result of newly emerging products and competitive pricing strategies [63,64]. Dedicated cost-effectiveness studies on the upcoming low-risk randomized trials could address this question (NCT02675114, NCT02701283, NCT02825134).

Latest data

Until now, TAVI has been implemented in inoperable and high-risk patients, allowing more patients to receive appropriate treatment of aortic stenosis, with TAVI evolving in parallel with SAVR. Researcher enthusiasm and industrial dynamism have facilitated progressive improvement of TAVI devices and techniques, yielding continual improvement in the efficacy and safety of the procedure [65,66]. However approximatively 80% of patients with aortic stenosis have, in fact, a low surgical risk.

The PARTNER 3 and Evolut Low Risk trials published very recently possibly provide the most compelling arguments in favour of TAVI in low-risk patients. PARTNER 3 showed superiority of TAVI for stroke (HR 0.38, 95% CI 0.15—1.00) and the composite primary endpoint of death, stroke and rehospitalization (HR 0.54, 95% CI 0.37—0.79) at 1 year. The Evolut Low Risk trial showed non-inferiority of TAVI and SAVR regarding the composite primary endpoint of death and stroke (5.3% versus 6.7%) with a longer follow-up of 2 years, but no superiority for either morality or stroke, although the trial included more patients than PARTNER 3 [7,8]. It is interesting to note that one third of patients screened were excluded (with anatomical reasons, such as bicuspid valve, being the main reason) in PARTNER 3 compared with approximatively 15% in the Evolut Low Risk trial, which might suggest overselection in PARTNER 3.

Conclusions

TAVI is *en route* to challenge the use of SAVR in low-risk patients in clinical practice, although numerous caveats and pitfalls need to be addressed if TAVI is to emerge as the primary treatment for aortic stenosis in this cohort. Most issues (such as vascular complications or residual paravalvular aortic regurgitation after TAVI) will have technical solutions, but others (such as durability) will take longer for elucidation. Observational studies and randomized trials provide reassurance, and numerous centres with high-volume TAVI programmes have already started to treat low-risk patients. The Heart Team is destined to become the main guarantor of optimal care for individual patients, who will themselves have an increasing say in the decision-making process as healthcare processes mature.

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Disclosure of interest

The authors declare that they have no competing interest.

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