

## Transcatheter Aortic Valve Replacement

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Transcatheter aortic valve replacement (TAVR) may be performed in non-surgical patients with symptomatic severe calcific aortic stenosis (AS). The United Kingdom Transcatheter Aortic Valve Implantation (TAVI) Registry followed prospectively 870 high-risk patients with a mean age of 82 years, with severe symptomatic AS undergoing 877 TAVI procedures [1]. Survival was 92.9% at 30 days, 78.6% at 1 year, and 73.7% at 2 years [1].

Of 442 persons with severe AS at increased surgical risk, mean age 82 years, 78 were treated with medical management, 107 with aortic valve replacement (AVR), and 257 with TAVI [2]. At 30-month follow-up, adjusted mortality was 49% significantly lower for AVR compared with medical treatment and 62% significantly lower for the TAVI group versus the medical treatment group. At 12 months, 92.3% of AVR patients, 93.2% of TAVI patients, and 70.8% of the medically treated group were New York Heart Association (NYHA) functional class I or II [2].

In the Placement of Aortic Transcatheter Valves (PARTNER) trial, 699 high-risk patients with severe AS with a mean age of 84 years were randomized to AVR or TAVI [3]. Mortality was 3.4% for the TAVI group versus 6.5% for the AVR group at 30 days (p not significant) and 24.2% for TAVI patients versus 26.8% for AVR patients at 1 year (p not significant). Major stroke was 3.8% for TAVI patients versus 2.1% for AVR patients at 30 days (p not significant) and 5.1% for TAVI patients versus 2.4% for AVR patients at 1 year (p not significant). Major vascular complications at 30 days were 11.0% for TAVI patients versus 3.2% for AVR patients (p<0.001). New-onset atrial fibrillation was 16.0% after AVR and 8.6% after TAVI (p=0.001). Major bleeding was 19.5% after AVR and 9.3% after TAVI (p<0.001). At 1-year, there were similar improvements in cardiac symptoms for both groups [3]. In the PARTNER trial, among inoperable patients with severe AS, compared with medical treatment, TAVI caused significant improvements in health-related quality of life maintained for at least 1 year [4].

At 2-year follow-up of 699 high-risk patients with severe AS in the PARTNER trial, all-cause mortality was 33.9% for TAVI and 35.0% for AVR (p not significant) [5]. Stroke was 7.7% for TAVI and 4.9% for AVR (p not significant). Moderate or severe paravalvular aortic regurgitation was 6.9% for TAVI and 0.9% for AVR (p<0.001) and was associated with increased late mortality [5].

At 2-year follow-up of 358 persons with a mean age of 83 years, with inoperable severe AS in the PARTNER trial randomized to TAVR or to standard therapy with balloon aortic valvuloplasty performed in 82% of this group, 43% of TAVR patients and 68% of standard therapy patients were dead (p<0.001) [6]. Incidences of cardiac death at 2 years were 31% for TAVR patients versus 62% for standard therapy patients (p<0.001) [6]. Incidences of stroke at 2 years were 14% for TAVR patients versus 6% for standard therapy patients (p=0.01) [6]. The rates of rehospitalization at 2 years were 35% for TAVR patients versus 73% for standard therapy patients (p<0.001) [6]. Echocardiographic data showed an increase in aortic valve area and a reduction in aortic valve gradient with no increase in paravalvular aortic regurgitation [6]. Their results suggest the reduction in death in patients with TAVR may be limited to patients without extensive comorbidities.

Low flow in patients with severe AS independently predicts

mortality [7]. At 2-year follow-up of 180 patients with a mean age of 84 years with low-flow inoperable severe AS in the PARTNER trial, the mortality was 76% in the medically treated patients versus 46% in the TAVR treated patients (p<0.001) [7].

At 2-year follow-up of 350 patients with a mean age of 84 years with low-flow severe AS in the PARTNER trial, death occurred in 40% in AVR treated patients versus 38% in the TAVR group (p not significant) [7]. In the inoperable group in the PARTNER trial, at 2-year follow-up, death in persons with a normal stroke volume index was 38% with TAVR versus 53% with medical management (p<0.001) [7].

One-third of 270 patients undergoing a CoreValve TAVI needed a permanent pacemaker implanted within 1 month [8]. Periprocedural atrioventricular block, balloon predilation, use of larger CoreValve prosthesis, increased interventricular septum diameter, and prolonged QRS interval were independently associated with need of implantation of a permanent pacemaker [8].

In 138 patients undergoing TAVI, mean age 79 years, without previous history of atrial fibrillation, new-onset atrial fibrillation developed in 44 patients (32%) at median time of 48 hours after TAVI [9]. At 12-month follow-up, stroke or systemic embolism occurred in 15.9% for persons with new-onset atrial fibrillation versus 3.2% for persons without atrial fibrillation (p=0.023) [9].

In 358 patients, a modified procedure of transapical TAVI with a balloon-expandable prosthesis had a low incidence of relevant prosthetic regurgitation [10]. Cumulative survival was not dependent on post-procedural regurgitation rate in this study [10].

At 42-month follow-up of 339 persons with a mean age of 81 years who had TAVI because they were inoperable or considered at very high surgical risk, 188 (56%) were dead [11]. Causes of late death in 152 persons were noncardiac comorbidities in 59%, cardiac death in 23%, and unknown in 18% [11].

At follow-up of 535 days in 198 persons who had TAVI with use of a Core Valve prosthesis, moderate/severe aortic regurgitation was the most powerful independent risk factor of all-mortality (hazard ratio=4.89, p<0.001) and of cardiovascular mortality (hazard ratio=7.90, p<0.001) [12]. Of 451 patients who had TAVR, 132 (29%) had moderate or severe mitral regurgitation after TAVR [13]. At 30-day follow-up, persons with moderate or severe mitral regurgitation had a higher incidence of death (adjusted hazard ratio=2.10, p=0.02). However, the incidences of death after 30 days were similar in those

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who had moderate or severe mitral regurgitation compared with persons who had no or mild mitral regurgitation. One year after TAVR, moderate mitral regurgitation improved in 58% of persons, and severe mitral regurgitation had improved in 49% of patients [13].

Of 900 persons with severe AS at high surgical risk evaluated for TAVI, 595 (66.1%) were treated medically [14]. In the medical arm, 345 patients had balloon aortic valvuloplasty. AVR treated persons included 146 persons (16.2%), and TAVI treated persons included 159 persons (17.6%). Persons in the medical group were followed for a median of 206 days and had an incidence of death of 46.6% (one-third noncardiac). The patients in the AVR group were followed for a median of 628 days and had an incidence of death of 26.7% (one-half noncardiac). The patients in the TAVI group were followed for a median of 399 days and had an incidence of death of 30.8% (two-thirds noncardiac) [14].

Of 353 patients who underwent transfemoral TAVI, 48 (13.6%) had a permanent pacemaker before TAVI, 98 (27.8%) had a permanent pacemaker after TAVI, and 58.6% had no permanent pacemaker after TAVI [15]. At 1-year follow-up, the incidence of death was similar in all 3 groups [15]. In 88 patients, mean age 83 years, alive 30 days after TAVI, the median survival time after TAVI was 3.4 years [16]. In 131 women and 129 men, both with a mean age of 83 years, who had TAVI, female gender had better baseline clinical characteristics and better survival at 1 year (76% versus 65%) [17].

In the United States, the Society of Thoracic Surgeons (STS)/American College of Cardiology Transcatheter Valve Therapy Registry showed that 7,710 patients underwent TAVR (20% who were inoperable and 80% who were high-risk but operable) [18]. The median age was 84 years, 49% were women, and the median STS predicted risk of death was 7%. A transfemoral approach was performed in 64% of persons, a transapical approach in 29% of patients, and other alternative approaches in 7% of patients. In-hospital mortality was 5.5% and major vascular injury was 6.4%. At 30-days' follow-up, the incidence of mortality was 7.6% (52% due to a noncardiovascular cause), of stroke was 2.8%, of dialysis-dependent renal failure was 2.8%, and of reintervention was 0.5% [18].

After TAVI, treatment with clopidogrel for 3 months in addition to aspirin is widely practiced. However, a small study of 161 patients randomized to clopidogrel for 3 months (a loading dose of 300 mg on the day prior to TAVI followed by 75 mg daily) plus aspirin 100 mg daily or aspirin 100 mg daily alone showed no significant difference in major adverse cardiac and cerebrovascular events at 30 days and at 6 months [19]. Their data need confirmation by a larger randomized study.

The 2012 American College of Cardiology Foundation/American Association for Thoracic Surgery/Society for Cardiovascular Angiography and Interventions/STS expert consensus document on transcatheter aortic valve replacement recommended TAVR in persons with severe, symptomatic, calcific stenosis of a trileaflet aortic valve with an aortic and vascular anatomy suitable for TAVR and predicted survival greater than 1 year, and with a prohibitive surgical risk as defined by an estimated 50% or higher risk of death or irreversible morbidity at 30 days or other variables such as frailty, prior radiation therapy, porcelain aorta, and severe liver or pulmonary disease [20]. These guidelines also state that TAVR is a reasonable alternative to AVR in patients at high surgical risk (PARTNER Trial Criteria: STS  $\geq$  8%). These guidelines state that major complications from TAVR are death

(3% to 5%), stroke (6% to 7%), access complications (17%), pacemaker insertion (2% to 9% for Sapien and 19% to 43% for CoreValve), bleeding, prosthetic dysfunction, paravalvular aortic regurgitation, acute kidney injury, coronary occlusion, valve embolization, and aortic rupture [20].

The European Society of Cardiology/European Association for Cardio-Thoracic Surgery guidelines recommend that TAVR is indicated in persons with severe symptomatic AS considered unsuitable for AVR assessed by a heart team and who are likely to have improved quality of life and a life expectancy of greater than 1 year after considering comorbidities (class I indication) [21]. TAVR may be performed in high-risk patients with severe symptomatic AS still suitable for AVR but in whom TAVR is favored by a heart team based on the patient's risk profile and anatomic suitability (class IIa indication) [21].

Clinical absolute contraindications to TAVR include absence of a heart team and no on site cardiac surgery, estimated life expectancy less than 1 year, improved quality of life by TAVR unlikely because of comorbidities, severe primary associated disease of other valves with major contribution to symptoms that can be treated only by surgery, anatomical contraindications (inadequate annulus size, thrombus in left ventricle, active endocarditis, increased risk of coronary ostium obstruction, plaques with mobile thrombi in the ascending aorta or arch, and inadequate vascular access) [21]. Relative contraindications include bicuspid or non-calcified valves, untreated coronary artery disease requiring revascularization, hemodynamic instability, a left ventricular ejection fraction less than 20%, and for the transapical approach severe lung disease or the left ventricular apex not accessible [21].

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