

Percutaneous Transcatheter Aortic Valve Replacement

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Percutaneous heart valve implantation may be performed in non-surgical patients with end-stage calcific aortic stenosis (AS). Eighteen high-risk patients, mean age 76 years, with severe AS and moderate coronary artery disease amenable to percutaneous coronary intervention had combined percutaneous coronary intervention followed by minimally invasive aortic valve replacement (AVR) [1]. One of 18 patients (6%) died postoperatively with no late mortality after a mean follow-up of 19 months. This hybrid strategy is a new therapeutic approach for elderly high-risk patients with combined severe AS and coronary artery disease.

The United Kingdom Transcatheter Aortic Valve Implantation (TAVI) Registry followed prospectively 870 high-risk patients, mean age 82 years, with severe AS undergoing 877 TAVI procedures [2]. Survival was 92.9% at 30 days, 78.6% at 1 year, and 73.7% at 2 years [2].

Of 442 patients with severe AS at increased surgical risk, mean age 82 years, 78 were treated with medical management, 107 with AVR, and 257 with TAVI [3]. At 30-month follow-up, the adjusted mortality was 49% significantly lower for AVR compared with medical treatment and 62% significantly lower for TAVI compared with medical treatment. At 1-year, 92.3% of AVR patients, 93.2% of TAVI patients, and 70.8% of medically treated patients were NYHA functional class I or II [3].

In the Placement of Aortic Transcatheter Valves (PARTNER) trial, 699 high-risk patients with severe AS, mean age 84 years, were randomized to AVR or TAVI [4]. All-cause 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 the TAVI group versus 26.8% for the AVR group at 1 year (*p* not significant). Major stroke was 3.8% for the TAVI group versus 2.1% for the AVR group at 30 days (*p* not significant) and 5.1% for the TAVI group versus 2.4% for the AVR group at 1 year (*p* not significant). Major vascular complications at 30 days were 11.0% for the TAVI group versus 3.2% for the AVR group (*p*<0.001). Major bleeding was 19.5% after AVR and 9.3% after TAVI (*p*<0.001). New-onset atrial fibrillation was 16.0% after AVR and 8.6% after TAVI (*P*, 0.001). At 1-year, there were similar improvements in cardiac symptoms for both groups [4]. In the PARTNER trial, among inoperable patients with severe AS, compared with standard care, TAVI caused significant improvements in health-related quality of life maintained for at least 1 year [5].

One-third of 270 patients undergoing a CoreValve TAVI needed a permanent pacemaker implanted within 30 days [6]. Peri-procedural atrioventricular block, balloon predilation, use of the larger CoreValve prosthesis, increased interventricular septum diameter, and prolonged QRS duration were independently associated with the need for permanent pacemaker implantation [6].

In 138 patients undergoing TAVI, mean age 79 years, with no prior history of atrial fibrillation, new-onset atrial fibrillation developed in 44 patients (32%) at a median time of 48 hours after TAVI [7]. At a median follow-up of 12 months, the incidence of stroke or systemic embolism was 15.9% for patients who developed new-onset atrial fibrillation versus 3.2% for patients who did not develop new-onset atrial fibrillation (*p*=0.023) [7].

In 358 patients, a modified procedure of transapical TAVI with a balloon-expandable prosthesis was associated with a low incidence of relevant prosthetic regurgitation [8]. Cumulative survival was not dependent on post-procedural regurgitation rate in this study.

At 2-year follow-up of 358 patients, mean age 83 years, with inoperable severe AS in the PARTNER trial randomized to transcatheter aortic valve replacement (TAVR) or to standard therapy with balloon aortic valvuloplasty performed in 82% of this group, 43% of the TAVR patients and 68% of the standard therapy patients were dead (*p*<0.001) [9]. The rates of cardiac death at 2 years were 31% for the TAVR group versus 62% for the standard therapy group (*p*<0.001) [9]. The rates of stroke at 2 years were 14% for the TAVR group versus 6% for the standard therapy group (*p*=0.01) [9]. The rates of rehospitalization at 2 years were 35% for the TAVR group versus 73% for the standard therapy group (*p*<0.001) [9]. Echocardiographic data showed a sustained increase in aortic valve area and a reduction in aortic valve gradient with no worsening of paravalvular aortic regurgitation [9]. Their data suggest that the mortality benefit in patients with TAVR may be limited to those who do not have extensive comorbidities.

Low flow in patients with severe AS independently predicts mortality [10]. At 2-year follow-up of 180 patients, mean age 84 years, with low flow inoperable severe AS in the PARTNER trial, the mortality was 76% in the standard therapy group versus 46% in the TAVR group (*p*<0.001) [10]. At 2-year follow-up of 350 patients, mean age 84 years, with low flow severe AS in the PARTNER trial, the mortality was 40% in the AVR group versus 38% in the TAVR group (not significant) [10].

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

On the basis of the available data, AVR should be performed in operable patients with severe AS. However, TAVR should be performed in non-operable patients with symptomatic severe AS to improve survival and quality of life compared with medical management.

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 before TAVI followed by 75 mg daily) plus aspirin 100 mg daily or aspirin 100 mg daily alone showed no significant difference in major

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Received August 28, 2013; Accepted August 30, 2013; Published September 02, 2013

Citation: Aronow WS (2013) Percutaneous Transcatheter Aortic Valve Replacement. J Clin Exp Cardiol 4: e129. doi:10.4172/2155-9880.1000e129

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adverse cardiac and cerebrovascular events at 30 days and at 6 months [12]. These data need confirmation by a larger randomized study.

The European Society of Cardiology/European Association for Cardio-Thoracic Surgery guidelines recommend TAVR in patients with severe symptomatic AS who are considered unsuitable for surgical AVR because of severe comorbidities [13]. Clinical absolute contraindications to TAVR include estimated life expectancy less than 1 year, improvement of 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, and anatomical contraindications [13].

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