

## Treatment of Severe Aortic Stenosis

Wilbert S Aronow\*

Department of Medicine, Division of Cardiology, Westchester Medical Center/New York Medical College, Valhalla, NY, USA

Severe valvular aortic stenosis (AS) is an aortic valve area of less than 1.0 cm<sup>2</sup>. Angina pectoris, syncope or near syncope, and congestive heart failure (CHF) are the 3 classic manifestations of severe AS. Patients with symptomatic severe valvular AS have a poor prognosis [1-4]. Ross and Braunwald found that the average survival rate was 3 years after the onset of angina pectoris in patients with severe AS [2]. Ross and Braunwald reported that the average survival rate after the onset of syncope in patients with severe AS was 3 years. Ross and Braunwald showed that the average survival rate after the onset of CHF in patients with severe AS was 1.5 to 2 years. In a prospective study, at 19-month follow-up (range 2 to 36 months), 90% of 30 patients with CHF associated with unoperated severe AS and a normal left ventricular ejection fraction (LVEF) were dead [5]. At 13-month follow-up (range 2 to 24 months), 100% of 18 patients with CHF associated with unoperated severe AS and an abnormal LVEF were dead [5]. At 20-month follow-up of 40 elderly patients with severe AS, CHF, syncope or angina, pectoris was present in 36 of 37 patients (97%) who developed new coronary events and in none of 3 patients (0%) without new coronary events [1].

Prophylactic antibiotics are not recommended to prevent bacterial endocarditis in patients with AS [6]. Patients with CHF, exertional syncope, or angina pectoris associated with severe AS should undergo aortic valve replacement (AVR) promptly. Valvular surgery is the only definitive therapy in these patients [7]. Medical therapy does not relieve the mechanical obstruction to left ventricular outflow and does not relieve symptoms or progression of the disorder.

American College of Cardiology (ACC)/American Heart Association (AHA) class I indications for AVR in patients with severe AS are 1) symptoms, 2) undergoing coronary artery bypass surgery, 3) undergoing surgery on the aorta or other heart valves, and 4) a LVEF less than 50% [7]. Although the ACC/AHA guidelines do not recommend AVR in patients with asymptomatic severe AS and normal LVEF, there are data suggesting otherwise [8-12]. Pai et al. found in their database that 99 of 338 patients (29%), mean age 71 years, with asymptomatic severe AS had AVR during 3.5-year follow-up. Survival at 1, 2, and 5 years was 67%, 56%, and 38%, respectively for nonoperated patients and 94%, 93%, and 90%, respectively for those who had AVR [8]. In the unoperated group, beta blocker use significantly reduced mortality by 48%, and statin use significantly reduced mortality by 48%.

Severe asymptomatic AS was present in 622 patients, mean age 72 years, at the Mayo Clinic [9]. Of the 622 patients, 166 (27%) developed symptoms and had AVR. Another 97 patients (16%) had AVR in the absence of symptoms. At 3-year follow-up, 52% of the 622 patients had developing symptoms, undergone AVR, or died. The most important risk factor for 10-year mortality was absence of AVR (hazard ratio=3.53, p<0.001).

Of 197 consecutive patients with asymptomatic severe AS, early AVR was performed in 102 patients (52%) [10]. The estimated actuarial 6-year all-cause mortality rates were 2% for AVR and 32% for the conventional treatment group (p<0.001). Despite being asymptomatic, patients with very severe AS have a poor prognosis [11]. Early elective AVR should be considered in these patients.

Of 73 patients with severe AS who did not undergo AVR, 15 (14%) died at 15-month follow-up [12]. Of these 73 patients, symptoms were thought to be unrelated to the AS in 31 patients. Exercise stress tests for symptoms were performed in only 4% of the 42 asymptomatic patients.

Asymptomatic patients with low-gradient severe AS and normal LVEF with reduced stroke volume index had at 46-month follow-up aortic valve events similar to those with normal stroke volume index [13]. Of 248 patients with severe AS and a normal LVEF, 94 had a low-gradient (<30 mm Hg mean gradient) (group 1), 87 had a moderate gradient (30-40 mm Hg mean gradient) (group 2), and 67 had a severe gradient (>40 mm Hg mean gradient) (group 3) [14]. Symptoms were present in 49% of group 1 patients, in 55% of group 2 patients, and in 60% of group 3 patients (p not significant). At 45-60-month follow-up, the incidence of AVR or death was 71% for group 1, 77% for group 2, and 76% for group 3 (p value not significant). Kaplan-Meier survival curves for time to death in all 3 groups were significantly better for patients with AVR versus no AVR [14]. E/E<sub>lateral</sub><sup>1</sup> was an independent predictor of time to death in patients who did not receive AVR [15].

Percutaneous heart valve implantation may be performed in non-surgical patients with end-stage calcific AS. 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 (transcatheter aortic valve replacement) TAVR [16]. All-cause mortality was 3.4% for the TAVR group versus 6.5% for the AVR group at 30 days (p value not significant) and 24.2% for the TAVR group versus 26.8% for the AVR group at 1 year (p value not significant). Major stroke was 3.8% for the TAVR group versus 2.1% for the AVR group at 30 days (p value not significant) and 5.1% for the TAVR group versus 2.4% for the AVR group at 1 year (p value not significant). Major vascular complications at 30 days were 11.0% for the TAVR group versus 3.2% for the AVR group (p<0.001). At 1-year, there were similar improvements in cardiac symptoms for both groups. In the PARTNER trial, among inoperable patients with severe AS, compared with standard care, TAVR caused significant improvements in health-related quality of life maintained for at least 1 year [17].

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.

The 2012 expert consensus document on TAVR recommends

\*Corresponding author: Wilbert S Aronow, MD, FACC, FAHA, Professor of Medicine, Cardiology Division, New York Medical College, Macy Pavilion, Room 138, Valhalla, NY 10595, USA, Tel: (914) 493-5311; Fax: (914) 235-6274; E-mail: [wsaronow@aol.com](mailto:wsaronow@aol.com)

Received December 10, 2012; Accepted December 14, 2012; Published December 17, 2012

Citation: Aronow WS (2013) Treatment of Severe Aortic Stenosis. J Cardiovasc Dis Diagn 1: e101. doi:10.4172/2329-9517.1000e101

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TAVR in patients with severe, symptomatic calcific stenosis of a trileaflet aortic valve who have aortic and vascular anatomy suitable for TAVR and a predicted survival of more than 1 year, and who have a prohibitive surgical risk with an estimated 50% or greater mortality or irreversible morbidity at 30 days or other factors such as frailty, prior radiation therapy, porcelain aorta, and severe hepatic or pulmonary disease [18]. TAVR is a reasonable alternative to surgical AVR in patients at high surgical risk (PARTNER Trial Criteria STS  $\geq$  8%) [18].

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