УНИВЕРЗИТЕТ У НОВОМ САДУ
UNIVERSITY OF NOVI SAD

TOP ACHIEVEMENTS 2022

FACULTY OF MEDICINE

Published work in journal category M21a, 2/143, IF 39.922 (title of work: Aortic valve replacement versus conservative treatment in asymptomatic severe aortic stenosis: AVATAR Trial)

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Prof. Dr. Lazar Velicki, associate professor

Surgical aortic valve replacement (SAVR) represents a class I indication in symptomatic patients with severe aortic stenosis (AS). However, indications for early SAVR in asymptomatic patients with severe AS and normal left ventricular function remain debated. The AVATAR trial (Aortic Valve Replacement Versus Conservative Treatment in Asymptomatic Severe Aortic Stenosis) is an investigator-initiated international prospective randomized controlled trial that evaluated the safety and efficacy of early SAVR in the treatment of asymptomatic patients with severe AS, according to common criteria (valve area ≤1 cm2 with aortic jet velocity >4 m/s or a mean transaortic gradient ≥40 mm Hg), and with normal left ventricular function. Negative exercise testing was mandatory for inclusion. The primary hypothesis was that early SAVR would reduce the primary composite end point of all-cause death, acute myocardial infarction, stroke, or unplanned hospitalization for heart failure compared with a conservative strategy according to guidelines. The trial was designed as event-driven to reach a minimum of 35 prespecified events. The study was performed in 9 centers in 7 European countries. Between June 2015 and September 2020, 157 patients (mean age, 67 years; 57% men) were randomly allocated to early surgery (n=78) or conservative treatment (n=79). Follow-up was completed in May 2021. Overall median follow-up was 32 months: 28 months in the early surgery group and 35 months in the conservative treatment group. There was a total of 39 events, 13 in early surgery and 26 in the conservative treatment group. In the early surgery group, 72 patients (92.3%) underwent SAVR with operative mortality of 1.4%. In an intention-to-treat analysis, patients randomized to early surgery had a significantly lower incidence of primary composite end point than those in the conservative arm (hazard ratio, 0.46 [95% CI, 0.23–0.90]; P=0.02). There was no statistical difference in secondary end points, including all-cause mortality, first heart failure hospitalizations, major bleeding, or thromboembolic complications, but trends were consistent with the primary outcome. In asymptomatic patients with severe AS, early surgery reduced a primary composite of all-cause death, acute myocardial infarction, stroke, or unplanned hospitalization

for heart failure compared with conservative treatment. This randomized trial provides preliminary support for early SAVR once AS becomes severe, regardless of symptoms.