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Different clinical outcomes in patients with asymptomatic severe aortic stenosis according to the stage classification: Does the aortic valve area matter?



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ABSTRACT

Background: The ACC/AHA guidelines introduced a new classification of severe aortic stenosis (AS) mainly based on maximum jet velocity (Vmax) and mean pressure gradient (mPG), but not on aortic valve area (AVA). However, prognostic value of this new classification has not yet been fully evaluated.

Methods and results: We studied 1512 patients with asymptomatic severe AS enrolled in the CURRENT AS registry in whom surgery was not initially planned. Patients were divided into 2 groups: Group 1 (N = 122) comprised patients who met the recommendation for surgery; high-gradient (HG)-AS (Vmax ≥ 4.0 m/s or mPG ≥ 40 mm Hg) with ejection fraction (EF) < 50%, or very HG-AS (Vmax ≥ 5.0 m/s or mPG ≥ 60 mm Hg), and Group 2 (N = 1390) comprised patients who did not meet this recommendation. Group 2 was further subdivided into HG-AS with preserved EF (HGpEF-AS, N = 498) and low-gradient (LG)-AS, but AVA < 1.0 cm² (N = 892). The excess risk of Group 1 relative to Group 2 for the primary outcome measure (a composite of aortic valve-related death or heart failure hospitalization) was significant (adjusted HR: 1.92, 95%CI: 1.37–2.68, P < 0.001). The excess risk of HGpEF-AS relative to LG-AS for the primary outcome measure was also significant (adjusted HR: 1.45, 95%CI: 1.11–1.89, P = 0.006). Among LG-AS patients, patients with reduced EF (<50%) (LGrEF-AS, N = 103) had extremely high cumulative 5-year incidence of all-cause death (85.5%).

Conclusion: Trans-aortic valve gradient in combination with EF was a good prognostic marker in patients with asymptomatic AS. However, patients with LGrEF-AS had extremely poor prognosis when managed conservatively.

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1. Introduction

Aortic stenosis (AS) represents a major healthcare issue because of its ever-increasing prevalence, poor prognosis, and complex pathophysiology [1]. Because the prognosis of symptomatic severe AS without

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surgical aortic valve replacement (AVR) is dismal, the general agreement is that AVR is strongly recommended for symptomatic severe AS, resulting in good long-term survival [2–6]. However, there remains controversy regarding the indications of AVR in patients with asymptomatic severe AS. Advances in technical improvement in aortic valve surgery have steadily improved the outcomes of surgery. Therefore some reports have suggested a benefit of early surgical AVR for asymptomatic very severe AS [2,6,7]. The 2014 American College of Cardiology (ACC)/ American Heart Association (AHA) guidelines introduced a new stage classification for severe AS, which were mainly based on peak

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aortic jet velocity (Vmax) and the mean-trans aortic pressure gradient (mPG), but not on the aortic valve area (AVA), especially in the asymptomatic patients [5]. According to this revision, patients with low-gradient (LG) AS (Vmax < 4.0 m/s and mPG < 40 mm Hg), but with an AVA < 1.0 cm², are excluded from the severe AS category if they are asymptomatic, and clinical follow-up is recommended for this category of patients, regardless of left ventricular ejection fraction (EF) or stroke volume. However, prognostic value of this new classification has not yet been fully evaluated. Notably, there is a paucity of data on the prognosis of patients with LG-AS, but with an AVA < 1.0 cm², as compared with patients with high-gradient (HG) AS (Vmax \geq 4.0 m/s or mPG \geq 40 mm Hg). Therefore, we aimed to evaluate the long-term clinical outcomes of conservatively managed asymptomatic AS patients according to the new stage classification.

2. Methods

2.1. Study population

The study design and primary results of the CURRENT AS (Contemporary Outcomes after Surgery and Medical Treatment in Patients with Severe Aortic Stenosis) registry have been previously reported [8]. Briefly, the CURRENT AS registry was a retrospective, multicenter registry that enrolled 3815 consecutive patients with severe AS among 27 centers in Japan between January 2003 and December 2011 (Supplementary Appendix). Severe AS was defined as Vmax > 4.0 m/s, mPG > 40 mm Hg, or AVA < 1.0 cm² [3,4]. Echocardiographic examinations were performed by experienced cardiac sonographers and/or cardiologists, and all measurements were in accordance with the criteria of the American Society of Echocardiography [9]. The protocol was independently approved by the institutional review board or ethics

committee at each participating center. Written informed consent was waived because of the retrospective nature of the study, and no patients refused to participate in the study when contacted for follow-up.

In this study, we evaluated 1517 asymptomatic patients in whom surgical AVR was not initially planned. Patients were divided into 2 groups according to the recommendation for surgical AVR based on 2014 ACC/AHA guidelines [5]. We excluded 5 patients in whom data required for the classification was missing. Group 1 consisted of 122 patients who met the recommendation for surgery; HG-AS with EF < 50%, or very HG-AS (Vmax \ge 5.0 m/s or mPG \ge 60 mm Hg). Group 2 consisted of 1390 patients who did not meet the recommendation for surgery. Group 2 was subdivided into the HG-AS with preserved EF (\ge 50%) (HGpEF-AS, N = 498) and LG-AS, but with an AVA < 1.0 cm² (N = 892) groups, and LG-AS was further subdivided according to EF: LG-AS with reduced EF (\le 50%) (LGrEF-AS, N = 103) and LG-AS with preserved EF (\ge 50%) (LGpEF-AS, N = 789) (Fig. 1).

2.2. Definitions and endpoints

The primary outcome measure for the present analysis was a composite of aortic valve-related death or hospitalization due to heart failure. Aortic valve-related death was defined as aortic procedure-related death, sudden cardiac death, or death due to heart failure considered to be related to AS. Other definitions of the clinical events were described previously [8], and clinical events were adjudicated by a clinical event committee (Supplementary Appendix).

2.3. Statistical analysis

Baseline characteristics and 5-year clinical outcomes were compared between Group 1 versus Group 2, followed by HGpEF-AS versus

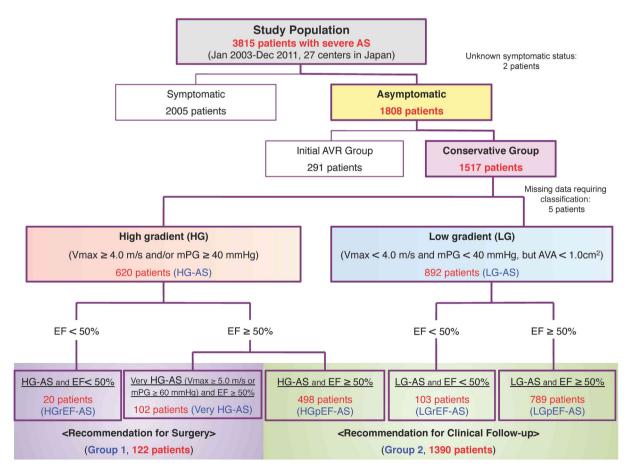


Fig. 1. Study patient flow.

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