Initial Surgical Versus Conservative Strategies in Patients With Asymptomatic Severe Aortic Stenosis



Tomohiko Taniguchi, MD,* Takeshi Morimoto, MD, MPH,† Hiroki Shiomi, MD,* Kenji Ando, MD,‡ Norio Kanamori, MD,§ Koichiro Murata, MD,|| Takeshi Kitai, MD,¶ Yuichi Kawase, MD,# Chisato Izumi, MD,** Makoto Miyake, MD,** Hirokazu Mitsuoka, MD,†† Masashi Kato, MD,‡† Yutaka Hirano, MD,§§ Shintaro Matsuda, MD,* Kazuya Nagao, MD,||| Tsukasa Inada, MD,||| Tomoyuki Murakami, MD,¶¶ Yasuyo Takeuchi, MD,## Keiichiro Yamane, MD,*** Mamoru Toyofuku, MD,††† Mitsuru Ishii, MD,‡‡‡ Eri Minamino-Muta, MD,* Takao Kato, MD,* Moriaki Inoko, MD,§§§ Tomoyuki Ikeda, MD,||||| Akihiro Komasa, MD,¶¶¶ Katsuhisa Ishii, MD,¶¶¶ Kozo Hotta, MD,### Nobuya Higashitani, MD,**** Yoshihiro Kato, MD,††† Yasutaka Inuzuka, MD,‡‡‡ Chiyo Maeda, MD,§§§§ Toshikazu Jinnai, MD,**** Yuko Morikami, MD,||||||| Ryuzo Sakata, MD,¶¶¶¶ Takeshi Kimura, MD,* on behalf of the CURRENT AS Registry Investigators

ABSTRACT

BACKGROUND Current guidelines generally recommend watchful waiting until symptoms emerge for aortic valve replacement (AVR) in asymptomatic patients with severe aortic stenosis (AS).

OBJECTIVES The study sought to compare the long-term outcomes of initial AVR versus conservative strategies following the diagnosis of asymptomatic severe AS.

METHODS We used data from a large multicenter registry enrolling 3,815 consecutive patients with severe AS (peak aortic jet velocity >4.0 m/s, or mean aortic pressure gradient >40 mm Hg, or aortic valve area <1.0 cm²) between January 2003 and December 2011. Among 1,808 asymptomatic patients, the initial AVR and conservative strategies were chosen in 291 patients, and 1,517 patients, respectively. Median follow-up was 1,361 days with 90% follow-up rate at 2 years. The propensity score-matched cohort of 582 patients (n = 291 in each group) was developed as the main analysis set for the current report.

RESULTS Baseline characteristics of the propensity score-matched cohort were largely comparable, except for the slightly younger age and the greater AS severity in the initial AVR group. In the conservative group, AVR was performed in 41% of patients during follow-up. The cumulative 5-year incidences of all-cause death and heart failure hospitalization were significantly lower in the initial AVR group than in the conservative group (15.4% vs. 26.4%, p = 0.009; 3.8% vs. 19.9%, p < 0.001, respectively).

CONCLUSIONS The long-term outcome of asymptomatic patients with severe AS was dismal when managed conservatively in this real-world analysis and might be substantially improved by an initial AVR strategy. (Contemporary Outcomes After Surgery and Medical Treatment in Patients With Severe Aortic Stenosis Registry; UMINO00012140) (J Am Coll Cardiol 2015;66:2827-38) © 2015 by the American College of Cardiology Foundation.

Listen to this manuscript's audio summary by JACC Editor-in-Chief Dr. Valentin Fuster.



From the *Department of Cardiovascular Medicine, Kyoto University Graduate School of Medicine, Kyoto, Japan; †Department of Clinical Epidemiology, Hyogo College of Medicine, Nishinomiya, Japan; ‡Department of Cardiology, Kokura Memorial Hospital, Kokura, Japan; §Division of Cardiology, Shimada Municipal Hospital, Shimada, Japan; ¶Department of Cardiology, Shizuoka City Shizuoka Hospital, Shizuoka, Japan; ¶Department of Cardiovascular Medicine, Kobe City Medical Center General Hospital, Kobe, Japan; #Department of Cardiovascular Medicine, Kurashiki Central Hospital, Kurashiki, Japan; **Department of Cardiology, Tenri Hospital, Tenri, Japan; ††Division of Cardiology, Nara Hospital, Kinki University Faculty of Medicine, Ikoma, Japan; ‡‡Department of Cardiology, Mitsubishi Kyoto Hospital, Kyoto, Japan; §§Department of Cardiology, Kinki University Hospital, Osakasayama, Japan; ¶¶Department of Cardiology, Koto Memorial Hospital, Higashiomi, Japan; ##Department of Cardiology, Shizuoka General Hospital, Shizuoka, Japan; ***Department of Cardiology, Nishikobe Medical Center, Kobe, Japan; †††Department of Cardiology, Japanese Red Cross Wakayama Medical Center,

ABBREVIATIONS AND ACRONYMS

AS = aortic stenosis

AVA = aortic valve area

AVR = aortic valve replacement

HF = heart failure

IQR = interquartile range

LVEF = left ventricular ejection fraction

PG = pressure gradient

STS = Society of Thoracic Surgeons

V_{max} = peak aortic jet velocity

ortic stenosis (AS) is a slowly progressive disease and survival during the asymptomatic phase of AS is similar to that of age-matched controls with a low risk of sudden death when patients are followed prospectively and promptly report symptom onset (1-3). The potential benefits of aortic valve replacement (AVR) in asymptomatic patients with severe AS have not been thought to outweigh the operative mortality of AVR (4,5). Thus, current guidelines generally recommend a strategy of watchful waiting until symptoms emerge for AVR in asymptomatic patients with severe AS (6).

SEE PAGES 2839 AND 2842

However, the recommendation is based on previous small single-center studies that sought to evaluate symptoms and/or AVR, rather than mortality as a primary outcome measure (1-3,7). A multicenter study design seemed to be crucial for extrapolating results into real clinical practice, because the quality of echocardiographic examination, the manner of patient follow-up, and the operative mortality of AVR might vary between centers. Furthermore, there is no large-scale study comparing an initial AVR strategy with the conservative strategy in asymptomatic patients with severe AS except for 1 small single-center observational study in patients with very severe AS (8). Also, patient demographics, age, and operative mortality of AVR in contemporary clinical practice may be different from those reported in previous studies (1-3,9-13). There is an obvious clinical need to evaluate the balance between risks and benefits of AVR in asymptomatic patients with severe AS in contemporary clinical practice.

Therefore, we sought to compare an initial AVR strategy with the conservative strategy to assess long-

term outcomes of asymptomatic patients enrolled in a large Japanese multicenter registry of consecutive patients with severe AS.

METHODS

STUDY POPULATION. The CURRENT AS (Contemporary outcomes after sURgery and medical tREatmeNT in patients with severe Aortic Stenosis) registry is a retrospective, multicenter registry enrolling consecutive patients with severe AS among 27 centers (of which 20 had an on-site surgical facility) in Japan between January 2003 and December 2011. We searched the hospital database of transthoracic echocardiography, and enrolled consecutive patients who met the definition of severe AS (peak aortic jet velocity [V_{max}] >4.0 m/s, mean aortic pressure gradient [PG] >40 mm Hg, or aortic valve area [AVA] <1.0 cm²) for the first time during the study period (6). We excluded patients with a history of aortic valve repair/replacement/plasty or percutaneous aortic balloon valvuloplasty. The institutional review boards in all 27 participating centers (Online Appendix) approved the protocol. Written informed consent from each patient was waived in this retrospective study, because we used clinical information obtained in routine clinical practice, and no patients refused to participate in the study when contacted for follow-up.

Among 3,815 patients enrolled in the registry, there were 2,005 patients with and 1,808 patients without AS-related symptoms at the time of index echocardiography, excluding 2 patients whose symptomatic status was not available. In this primary report from the CURRENT AS registry, 1,808 asymptomatic patients were subdivided into the initial AVR group (n=291) and the conservative group (n=1,517) according to treatment strategy selected after the index echocardiography (Figure 1). Baseline characteristics

Wakayama, Japan; <code>###Department</code> of Cardiology, National Hospital Organization Kyoto Medical Center, Kyoto, Japan; <code>\$88\$Cardiovascular</code> Center, The Tazuke Kofukai Medical Research Institute, Kitano Hospital, Osaka, Japan; <code>###Department</code> of Cardiology, Hikone Municipal Hospital, Hikone, Japan; <code>\$98\$Pepartment</code> of Cardiology, Kansai Electric Power Hospital, Osaka, Japan; <code>###Department</code> of Cardiology, Hyogo Prefectural Amagasaki General Medical Center, Amagasaki, Japan; *****Department of Cardiology, Japanese Red Cross Otsu Hospital, Otsu, Japan; <code>###Department</code> of Cardiology, Saiseikai Noe Hospital, Osaka, Japan; <code>###Department</code> of Cardiology, Shiga Medical Center for Adults, Moriyama, Japan; <code>\$888Popartment</code> of Cardiology, Hamamatsu Rosai Hospital, Hamamatsu, Japan; <code>###Department</code> of Cardiovascular Surgery, Kyoto University Graduate School of Medicine, Kyoto, Japan. Dr. Inoko has received research support and lecture fees from Daiichi-Sankyo, Takeda Pharmaceutical, Sumitomo Dainippon Pharmaceutical Corp., Nippon Boehringer Ingelheim, MSD, Kowa Pharmaceutical Co., Mochida Pharmaceutical Co., Ltd., Bayer Yakuhin, Ltd., Pfizer Japan, Inc.; research support from Nihon Medi-Physics Co., Nippon Shinyaku Corp., Ono Pharmaceutical Co., Ltd., Edwards Lifesciences Co., Ltd., Boston Scientific Corp., Actelion Pharmaceuticals Japan Ltd., Teijin LTD., and Mebix, Inc.; and lecture fees from Astellas Pharma, Inc., Eisai Co., Ltd., and Bristol-Myers Squibb Co. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Download English Version:

https://daneshyari.com/en/article/5982199

Download Persian Version:

https://daneshyari.com/article/5982199

<u>Daneshyari.com</u>