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Early Surgery or Conservative Care for Asymptomatic Aortic Stenosis

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RobotReviewer report

Risk of bias table

trial	design	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment
Kang D, 2020	RCT	+	+	?	+

Trial summaries

n	Participants	Interventions	Outcomes	punchline	finding
12	patients with nonspecific symptoms, and patients with a positive exercise test were excluded, of less than 50%, or clinically significant aortic regurgitation or mitral valve disease or if they had undergone cardiac surgery, atic patients with very severe aortic stenosis who were candidates for either early surgery or conser- vative care at four medical centers in Korea, severe aortic stenosis, 12 patients were excluded if they had ex, excluded patients who were not candidates for early surgery because of age (>80 years) or a medical condition such as cancer, screened consecutive patients who were 20 to 80 years of age and who presented with very se- vere aortic stenosis, which was assessed by means of transthoracic echocardiography, 1998 American College of Cardiology- American Heart	asymptom	ertional dyspnea, syncope, presyncope or angina, a left ventricular ejection fraction	The cumulative incidence of death from any cause was lower in the early- 117 Early Surgery for Asymptomatic Aortic Stenosis surgery group than in the conservative-care group (4% vs. 10% at 4 years and 10% vs. 32% at 8 years) (Fig. 2B).	,Üì sig decrease

Association (ACC-AHA) guide- lines and a traditional definition of severe aortic stenosis, 10,11 we defined very severe aortic steno- sis as an aortic-valve area of 0.75 cm 2 or less with either a peak aortic jet velocity of 4.5 m per second or greater or a mean transaortic gradient of 50 mm Hg or greater

Characteristics of studies

Kang D, 2020

Population	1. We also excluded patients who were not candidates for early surgery because of age (>80 years) or a medical condition such as cancer. 2. In accordance with the 1998 American College of Cardiology- American Heart Association (ACC-AHA) guide- lines and a traditional definition of severe aortic stenosis, 10,11 we defined very severe aortic steno- sis as an aortic-valve area of 0.75 cm 2 or less with either a peak aortic jet velocity of 4.5 m per second or greater or a mean transaortic gradient of 50 mm Hg or greater. 3. ertional dyspnea, syncope, presyncope or angina, a left ventricular ejection fraction of less than 50%, or clinically significant aortic regurgitation or mitral valve disease or if they had undergone cardiac surgery.
Interventio n	1. Patients assigned to the conservative-care group received treatment according to the ACC- AHA guidelines, 2,12 and they were referred for surgery if they became symptomatic during fol- low-up, if the left ventricular ejection fraction decreased to less than 50%, or if the peak aortic jet velocity increased each year by more than 0.5 m per second on follow-up echocardiography. 2. In accordance with the 1998 American College of Cardiology- American Heart Association (ACC-AHA) guide- lines and a traditional definition of severe aortic stenosis, 10,11 we defined very severe aortic steno- sis as an aortic-valve area of 0.75 cm 2 or less with either a peak aortic jet velocity of 4.5 m per second or greater or a mean transaortic gradient of 50 mm Hg or greater.
Outcomes	1. The primary end point was a composite of op- erative mortality or death from cardiovascular causes during the follow-up period (continuing until 4 years after the last patient was enrolled). 2. The cumulative incidence of the primary end point (operative mortality or death from cardiovascu- lar causes during the follow-up period), as cal- culated with the use of a Kaplan-Meier analysis, was 1% at both 4 and 8 years in the early-surgery group, as compared with 6% at 4 years and 26% at 8 years in the conservative-care group (P = 0.003) 3. Prespecified secondary end points included death from any cause, repeat aortic-valve surgery, clini- cal thromboembolic events, and hospitalization for heart failure during follow-up.

Bias	Judgement	Support for judgement
Random sequence generation	low	1. The assignment to each treatment group was computer-generated and stratified according to the participating center by means of a permuted- block sequence with variable block size. 2. Patients were randomly assigned in a 1:1 ratio to early surgery or conservative care with the use of a Web-based interactive response system. 3. We conducted this multicenter, randomized, par- allel-group, open-label trial involving asymptom- atic patients with very severe

		aortic stenosis who were candidates for either early surgery or conser- vative care at four medical centers in Korea.
Allocation concealment	low	1. The assignment to each treatment group was computer-generated and stratified according to the participating center by means of a permuted- block sequence with variable block size. 2. Patients were randomly assigned in a 1:1 ratio to early surgery or conservative care with the use of a Web-based interactive response system. 3. Medication use at baseline was also similar in the two groups.
Blinding of participants and personnel	high/ unclear	1. Third, since this trial was not blinded, the nonfatal outcomes could have been influenced by the clinician's knowledge of the treatment the patient received. 2. Patients were randomly assigned in a 1:1 ratio to early surgery or conservative care with the use of a Web-based interactive response system. 3. The assignment to each treatment group was computer-generated and stratified according to the participating center by means of a permuted- block sequence with variable block size.
Blinding of outcome assessment	low	1. Third, since this trial was not blinded, the nonfatal outcomes could have been influenced by the clinician's knowledge of the treatment the patient received. 2. An independent clinical-events committee ad- judicated all serious adverse events, and a data and safety monitoring board oversaw the safety of the trial. 3. We conducted this multicenter, randomized, par- allel-group, open-label trial involving asymptom- atic patients with very severe aortic stenosis who were candidates for either early surgery or conser- vative care at four medical centers in Korea.

References

1. Kang D et al. Early Surgery or Conservative Care for Asymptomatic Aortic Stenosis Br J Surg 2020. 2(10); 111-119 PMID: 4412607