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**Early Surgery or Conservative  
Care for Asymptomatic Aortic  
Stenosis**

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# Abstract

## Background:

The timing and indications for surgical intervention in asymptomatic patients with severe aortic stenosis remain controversial.

## Methods:

In a multicenter trial, we randomly assigned 145 asymptomatic patients with very severe aortic stenosis (defined as an aortic-valve area of  $\leq 0.75$  cm<sup>2</sup> with either an aortic jet velocity of  $\geq 4.5$  m per second or a mean transaortic gradient of  $\geq 50$  mm Hg) to early surgery or to conservative care according to the recommendations of current guidelines. The primary end point was a composite of death during or within 30 days after surgery (often called operative mortality) or death from cardiovascular causes during the entire follow-up period. The major secondary end point was death from any cause during follow-up.

## Results:

In the early-surgery group, 69 of 73 patients (95%) underwent surgery within 2 months after randomization, and there was no operative mortality. In an intention-to-treat analysis, a primary end-point event occurred in 1 patient in the early-surgery group (1%) and in 11 of 72

patients in the conservative-care group (15%) (Hazard ratio, 0.09; 95% confidence interval [CI], 0.01 to 0.67; P = 0.003). Death from any cause occurred in 5 patients in the early-surgery group (7%) and in 15 patients in the conservative-care group (21%) (Hazard ratio, 0.33; 95% CI, 0.12 to 0.90). In the conservative-care group, the cumulative incidence of sudden death was 4% at 4 years and 14% at 8 years.

## Conclusions:

Among asymptomatic patients with very severe aortic stenosis, the incidence of the composite of operative mortality or death from cardiovascular causes during the follow-up period was significantly lower among those who underwent early aortic-valve replacement surgery than among those who received conservative care.

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*Randomized Controlled Trial*

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