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LECTURE ESSENTIALS

Lecture Notes

American College of Cardiology 60th Annual Scientific Session & i2 Summit

The Transcather Versus Surgical Aortic Valve Replacement in High Risk Patients with Severe Aortic Stenosis (The PARTNER Trial)

Study Sponsor: Edward Life Sciences

Trial Registration #: NCT00530894

Background

Many patients with severe aortic stenosis (AS) and coexisting conditions are not candidates for surgical replacement of the aortic valve. Recently, transcatheter aortic-valve implantation (TAVI) has been suggested as a less invasive treatment for high-risk patients with AS.

Methods

- Multicenter
- Randomized
- n=358
- Random assignment of patients with severe AS who were considered unsuitable candidates for surgery to standard therapy (including balloon aortic valvuloplasty) or transfemoral transcatheter implantation of a balloon-expandable bovine pericardial valve

Primary Endpoint

- 1-year rate of death from any cause

Results

- At 1 year, the rate of death from any cause (Kaplan–Meier analysis) was 30.7% with TAVI compared with 50.7% with standard therapy (HR with TAVI, 0.55; 95% CI, 0.40 to 0.74; p<0.001)
- The rate of the composite end point of death from any cause or repeat hospitalization was 42.5% with TAVI compared with 71.6% with standard therapy (HR, 0.46; 95% CI, 0.35 to 0.59; p<0.001)
- Among survivors at 1 year, the rate of cardiac symptoms (NYHA class III or IV) was lower among TAVI patients than those who had received standard therapy (25.2% vs 58.0%; p<0.001)
- At 30 days, TAVI was associated with a higher incidence of major strokes (5.0% vs 1.1%; p=0.06) and major vascular complications (16.2% vs 1.1%; p<0.001) compared with standard therapy
- In the year after TAVI, there was no deterioration in the functioning of the bioprosthetic valve, as assessed by evidence of stenosis or regurgitation on an echocardiogram

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Conclusions

Compared with standard therapy in patients with severe AS who were considered unsuitable candidates for surgery, TAVI significantly reduced the rates of death from any cause, the composite endpoint of death from any cause or repeat hospitalization, and cardiac symptoms, despite the higher incidence of major strokes and major vascular events.

Further Reading

Leon MB. *N Engl J Med* 2010.