Clinical Summary:

Seven-year outcomes following aortic valve replacement with a novel tissue bioprosthesis

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Inspiring Results

Objective

The COMMENCE aortic trial is a FDA pivotal trial designed to evaluate the safety and effectiveness of a bioprosthetic valve with the novel RESILIA tissue. As the follow up time in this study advances beyond the mid-term period, direct and indirect measures of durability of valves with RESILIA tissue will be highlighted.

Key Points

- As bioprosthetic aortic valve replacement (AVR) extends to younger cohorts, tissue durability is becoming of paramount importance. Data from this trial demonstrate excellent outcomes in a study of younger patients – [66.9] years mean age
- The bioprosthetic valve with RESILIA tissue showed clinically stable gradients, high rates of freedom from mortality through 7 years, as well as high rates of freedom from reintervention and structural valve deterioration (SVD)
- Results of the COMMENCE aortic trial through 7 years indicate a favorable safety profile and strong hemodynamic performance of a bioprosthetic valve with RESILIA tissue

Methods

- A prospective, international IDE trial, now in its post-approval phase, is exploring the outcomes of AVR with a bioprosthesis utilizing a novel tissue
  - Study subjects were enrolled at 27 clinical sites in U.S. and Europe
  - At 5 years, patient re-consent was performed for extended follow-up (years 6-10) and was mandatory for the top 3 enrolling sites. If interested in extended follow-up participation, additional sites then offered all eligible patients to consent and participate
- Safety endpoints
  - All potential safety endpoints adjudicated by an independent Clinical Events Committee
  - SVD and other safety outcomes defined per "Guidelines for reporting morbidity and mortality after cardiac valve interventions" (Akins et al. 2008)
- Effectiveness endpoints
  - Hemodynamic performance evaluated by an Independent Echocardiographic Core Laboratory
  - NYHA Functional Class

Patient Demographics

- Between January 2013 and March 2016, 689 patients underwent AVR with the Edwards Pericardial Aortic Bioprosthesis with RESILIA tissue (model 11000A)
  - Mean age 66.9 ± 11.6 years
  - STS risk score 2.0 ± 1.8%
  - New York Heart Association (NYHA) Class II and III were 49.9% (344/689) and 24.4% (168/689), respectively
- A total of 512 patients completed 5-year follow up, and 190 reconsented for extended follow up

Results

- Safety endpoints, probability event-free at 7 years (shown in Table 1):
  - Kaplan-Meier analyses showed freedom from all-cause mortality was [83.9% (95% CI: 79.9, 87.9)]
  - [99.2% (95% CI: 97.9, 100.0)] freedom from SVD
  - [97.4% (95% CI: 95.5, 99.2)] freedom from reoperation
  - [98.1% (95% CI: 96.5, 99.7)] freedom from explant
  - Clinically stable hemodynamics out to 7 years:
    - Effective orifice area was [1.67 ± 0.46 cm^2 (N = 59)]
    - Mean gradient was [10.2 ± 4.7 mmHg (N = 61)]
  - [96.7%] of patients had no paravalvular regurgitation (N = 61)
  - [88.5%] had no transvalvular regurgitation (N = 61)

Conclusions

- The 7-year data from the COMMENCE aortic trial represents the longest follow-up after AVR with this novel tissue in a large IDE trial utilizing an independent clinical events committee and an echocardiography core laboratory
- With excellent outcomes through 7 years, the COMMENCE trial demonstrates encouraging results for bioprostheses with RESILIA tissue
- Ongoing follow up out to 10 years will continue to evaluate the long-term safety and effectiveness of this tissue

Edwards