One-Year Outcomes from the STS/ACC Transcatheter Valve Therapy (TVT) Registry

**History:** Transcatheter Aortic Valve Replacement (TAVR) has recently been approved by the FDA for patients who have symptomatic aortic stenosis and are determined to be inoperable, or high-risk but operable, for standard valve replacement surgery. The TVT Registry was created to monitor the safety and efficacy of TVT devices for the treatment of aortic stenosis.

**Question to answer:** What is the safety and efficacy of TAVR in broad clinical use?

**Trial Design**
- Prospective, observational, multicenter clinical registry program at 224 participating hospitals
- **Participants:** All eligible US TAVR patients after Nov. 2011 FDA approval of TAVR device; N=5,980
- **F/U:** Outcomes at 30 days and one year; outcomes after first year collected via CMS* database

**Primary Endpoint**
- Major adverse cardiac and cerebrovascular events

**Trial Results**
- **In-hospital**
  - Death rate: 5.3%
  - Stroke rate: 1.7%
- **1 year**
  - Death rate: 26.2%
  - Stroke rate: 3.6%

**Take Away:** Based on one-year outcomes data, real-world outcomes with TAVR are comparable to those observed in clinical trials.

*CMS=Centers for Medicare & Medicaid Services

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