Current Status And Future Prospects For TAVI: An Interventional Cardiologist’s Perspective

Ted Feldman, M.D., MSCAI FACC FESC
Evanston Hospital

Vascular and Endovascular Issues, Techniques, Horizons
42nd Annual Symposium
November 17-21, 2015
New York City

Newly Approved in the US

Medtronic CoreValve
Edwards Lifesciences

Evolut R
S3

Partners I and II Trials
Overall and TF Patients

All-Cause Mortality at 30 Days.
Edwards SAPIEN Valves (As Treated Patients)

SAPIEN S3
SAPIEN S3 HR
SAPIEN S3 i

Mortality
All Stroke

Ted Feldman MD, MSCAI FACC FESC

Disclosure Information

The following relationships exist:

Grant support: Abbott, BSC, Cardiokinetik, Edwards, WL Gore
Consultant: Abbott, BSC, Caferes, Edwards, JenaValve, Mitroline, Dicachi Sankyo-Lilly, WL Gore

Off label use of products and investigational devices will be discussed in this presentation.
All Strokes at 30 Days
Edwards SAPIEN Valves

PARTNER I and II Trials

Neurologist evaluations (pre- and post)

Possible Subclinical Leaflet Thrombosis in Bioprosthetic Aortic Valves

STS Risk Distribution

PARTNER II Trial
Study Design

An All-comers Randomized Clinical Trial
Comparing Transcatheter with Surgical AVR
NOTION Randomized Trial

Mean age 79 years
Mean STS 3%
**1 Year in As-Treated Population**

**Next Gen TAVR US Trials**

- **LOTUS**
  - Fully retrievable, no PVL, early function
  - CE Study n=250, CE approved 10/2013
  - EU post market n=1000
  - Enrollment nearing completion

- **Direct Flow**
  - Fully retrievable, no PVL, early function
  - CE Study n=100, CE approved 1/2013
  - US Feasibility n=30, US IDE n=912
  - Enrollment beginning

- **Portico**
  - Fully retrievable, early function
  - CE Study n=102, CE approved 9/2015
  - EU Study n=220
  - Enrollment beginning

**A person who never made a mistake never tried anything new.**