2017 MID-ATLANTIC
CONFERENCE

7th ANNUAL CURRENT CONCEPTS IN
VASCULAR THERAPIES

Gabor Bagameri
VCU Medical Center
04/21/2017

Valvular Heart Disease: Surgery Is The Gold Standard

Is There Really Any Debate?

Disclosure

- “It is difficult to give this talk, with outcomes following TAVR improving steadily.”

Introduction

- Valvular heart disease is characterized by damage to or a defect in one of the four heart valves: the mitral, aortic, tricuspid or pulmonary.

- In valvular heart disease, the valves become too narrow and hardened (stenotic) to open fully, or are unable to close completely (incompetent).

Introduction

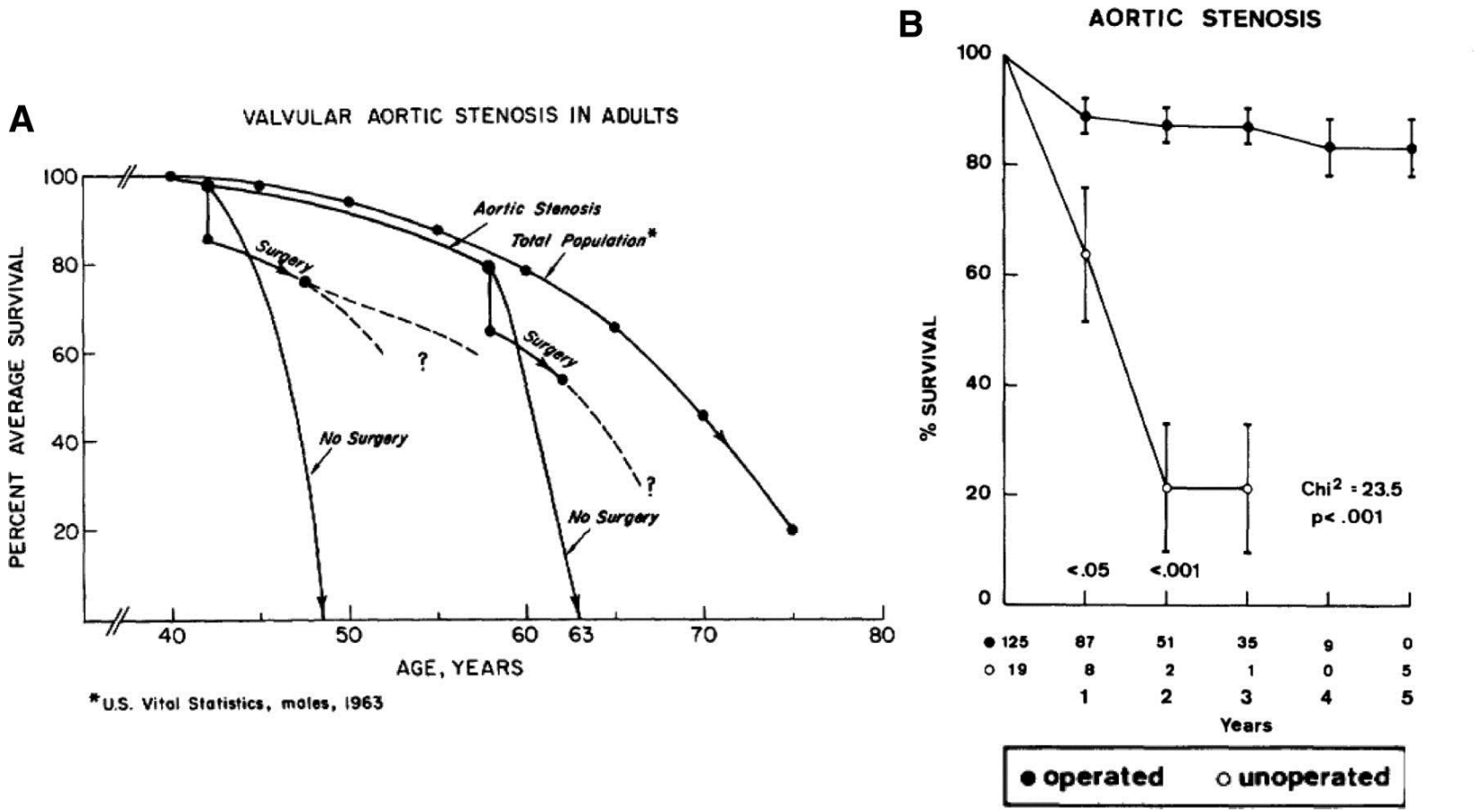
- Heart disease is the leading cause of death in the U.S., killing more than 600,000 Americans each year.
- More than five million Americans are diagnosed with heart valve disease each year.
- Diseases of the aortic and mitral valves are the most common.

Introduction

- Calcific aortic stenosis is the most common cause of aortic stenosis (AS).

- While up to 1.5 million people in the U.S. suffer from AS, approximately 500,000 within this group of patients suffer from severe AS. An estimated 300,000 patients with severe AS are symptomatic.

The dramatically favorable outcome of symptomatic aortic stenosis patients undergoing surgical valve replacement is depicted.



Prediman K. Shah Circulation. 2012;126:118-125

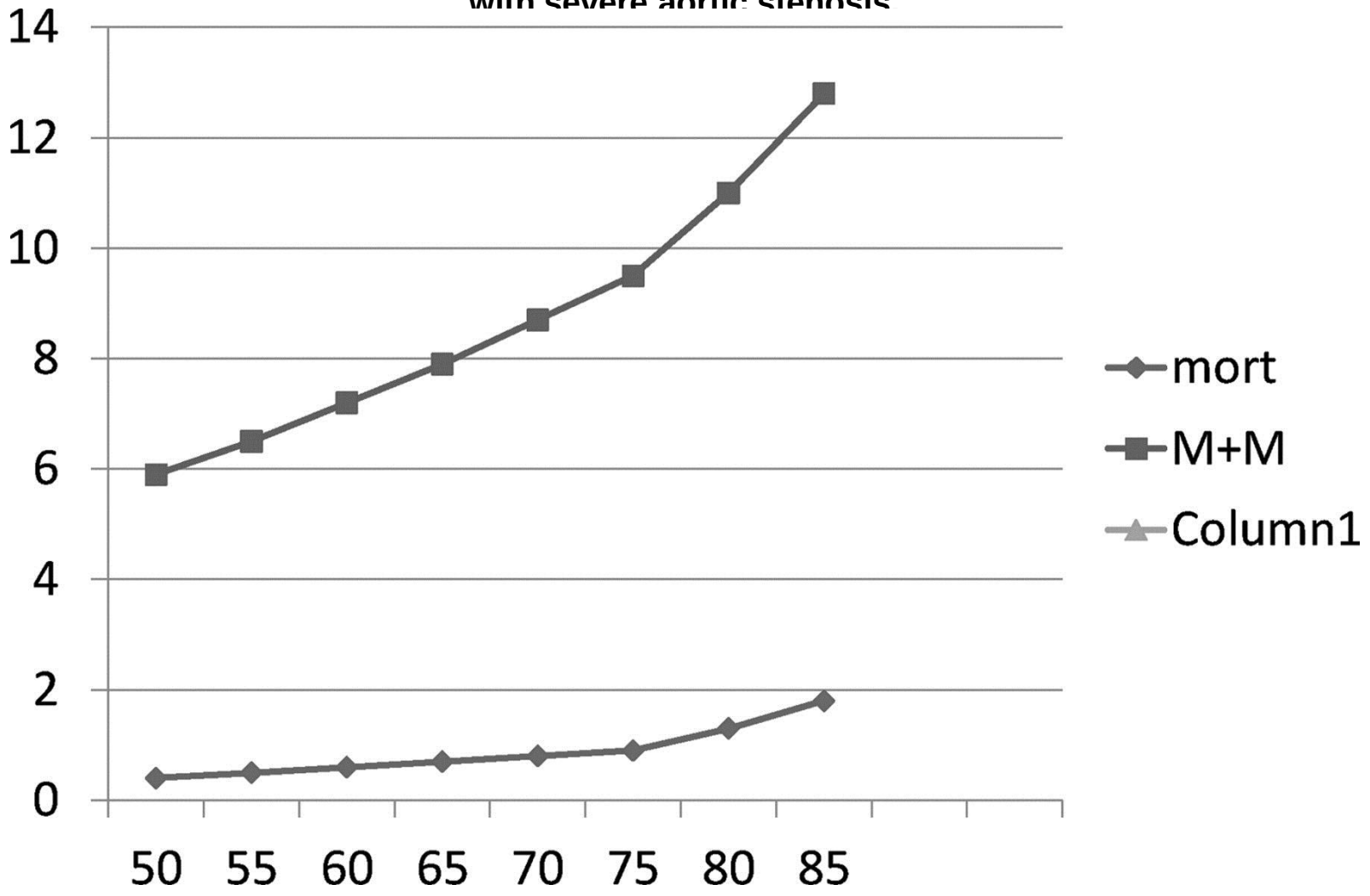
American Heart Association.

Copyright © American Heart Association, Inc. All rights reserved.

The Risk of Aortic Valve Replacement (AVR)

- For a 70-year-old man with severe AS but without coronary disease or other systemic comorbidities, the Society of Thoracic Surgeons risk calculator projects a mortality risk of just 0.8% and a combined mortality plus serious morbidity rate of 8.2%.
- This risk calculator often overestimates the risk seen in actual practice, so that actual risk is even less.

Society of Thoracic Surgeons–predicted mortality (mort, bottom line) and combined mortality and morbidity (M+M, top line) are shown by age for otherwise healthy asymptomatic patients with severe aortic stenosis

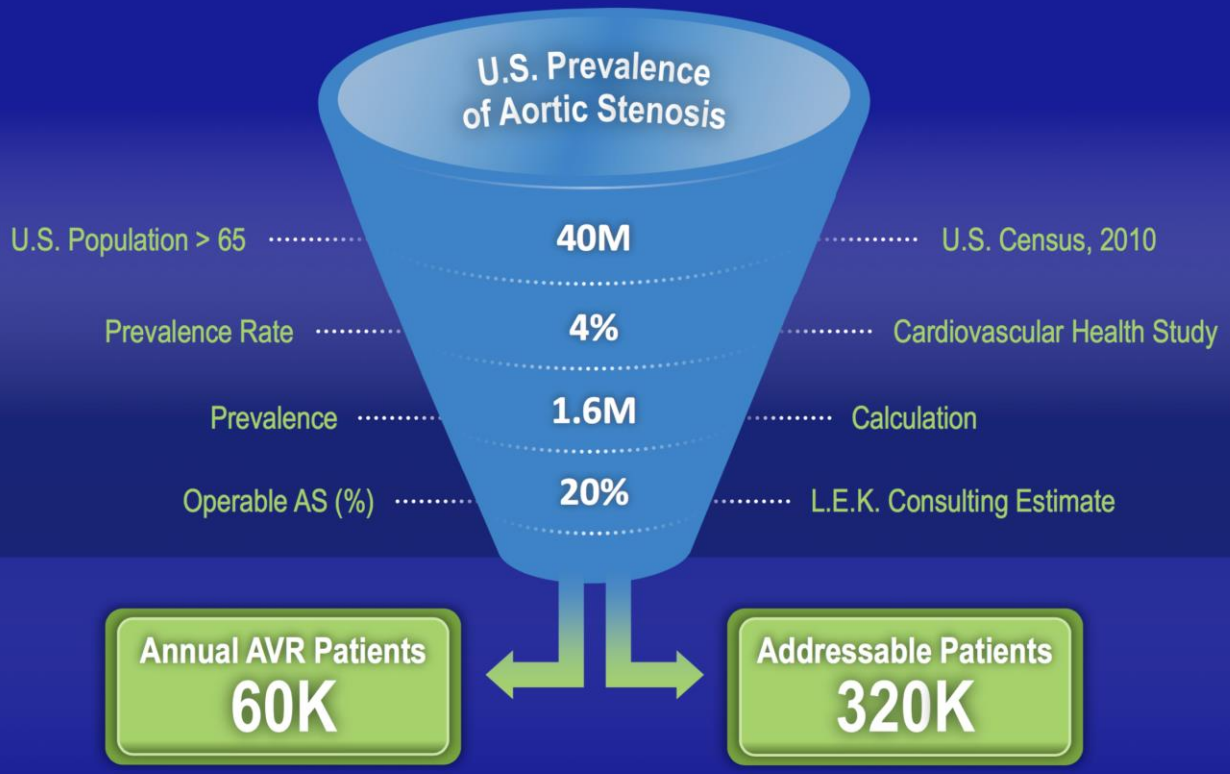


Blase A. Carabello Circulation. 2012;126:112-117

American Heart Association.

Copyright © American Heart Association, Inc. All rights reserved.

Prevalence of Aortic Stenosis in Patients Age 65 and Over



19% of those who would benefit from AVR **actually** get it.

The Placement of Aortic Transcatheter Valve (PARTNER) Trial

- TAVR with the Edwards SAPIEN valve was superior to medical therapy in the treatment of inoperable patients with aortic stenosis (cohort B)

  Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med*. 2010;363:1597–1607.

- It was not inferior to standard surgical aortic valve replacement in patients with advanced symptomatic aortic stenosis who are high risk for surgical therapy (cohort A)

  Comparison of transcatheter and surgical aortic valve replacement for aortic stenosis in patients at high-risk for operation. *N Engl J Med*. 2011;364:2187–2198.

So, what are the keys to TAVR's rapid success?

- Simply put, there was an unmet medical need: a very large pool of high-risk patients suffering from severe AS and requiring valve repair, who previously were deemed too risky to survive surgical aortic valve replacement (SAVR).

- Prior to TAVR, patients deemed unfit for surgery were left without an alternative treatment, and many such patients died as a result.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 28, 2016 VOL. 374 NO. 17

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

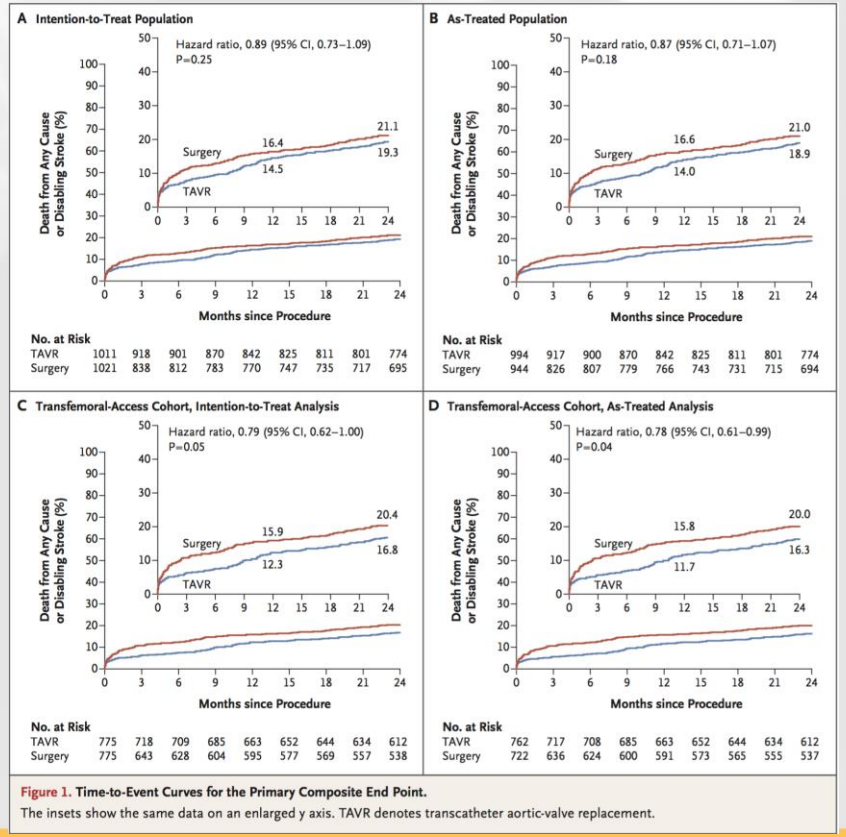


Figure 1. Time-to-Event Curves for the Primary Composite End Point.

The insets show the same data on an enlarged y axis. TAVR denotes transcatheter aortic-valve replacement.

- It’s clear that TAVR has outperformed surgery in the recent intermediate-risk studies, the patients in the trials were still up at the higher end of the risk echelon


SAVR
TAVR

The Limitations of Surgery in Low-Risk Aortic Stenosis

- Invasiveness of the procedure
- Adverse events
- Patient-prosthesis mismatch

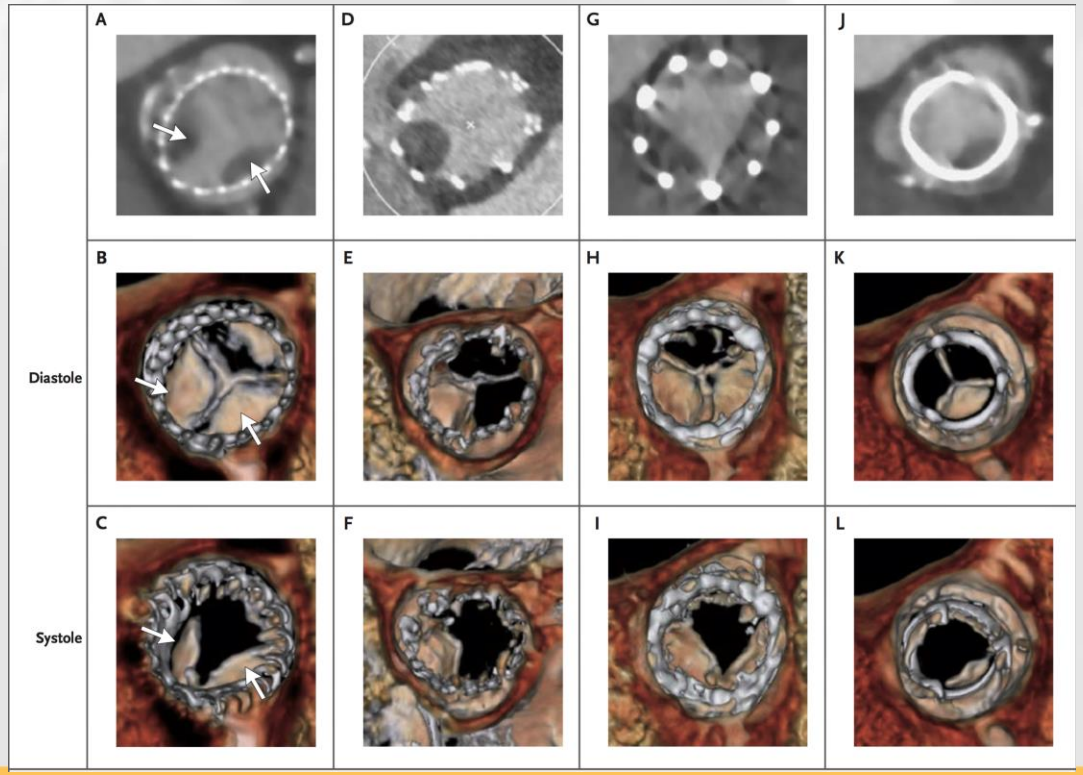
The Limitations of TAVR in Low-Risk Aortic Stenosis

- Durability remains the biggest question mark for TAVR
- Pacemaker
- Paravalvular leak
- Stroke
- Cost

ORIGINAL ARTICLE

Possible Subclinical Leaflet Thrombosis in Bioprosthetic Aortic Valves

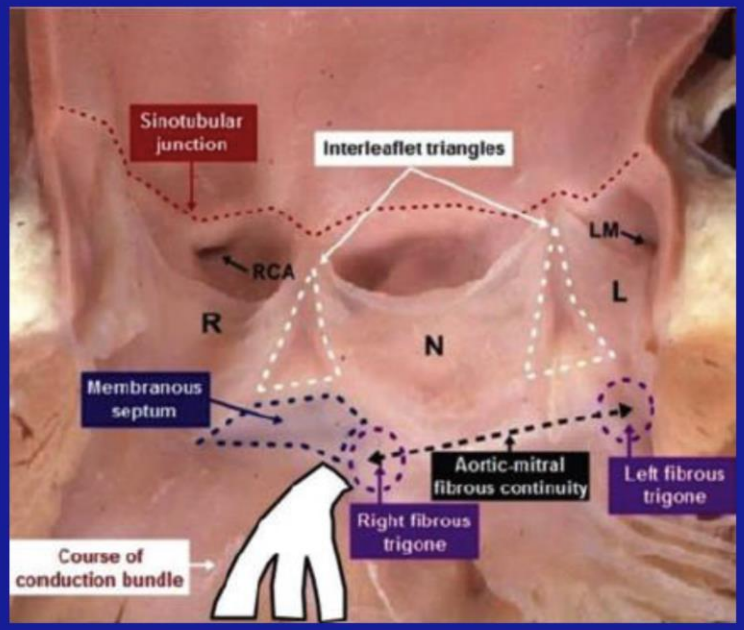
R.R. Makkar, G. Fontana, H. Jilaihawi, T. Chakravarty, K.F. Kofoed, O. De Backer,

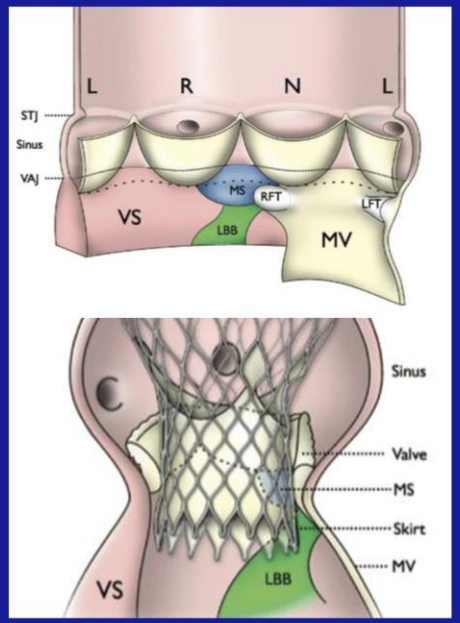


Pacemaker, Conduction Disturbances after TAVR

LBBB and PPM are Frequent Complications due to:

- High Frequency of Comorbid Conduction Disease
- Close Anatomic Proximity of Aortic Valve and Conduction System





Ferreira et al. PACE 2010;33:1364-72

Pacemaker, Conduction Disturbances after TAVR

- The need for new permanent pacemakers within 30 days after the procedure was similar in the TAVR group and the surgery group (8.5% and 6.9%, respectively; PARTNER).

- The rates among patients who received the CoreValve (25.5%) and the Evolut R valve (26.7%) were similar.

Paravalvular Regurgitation

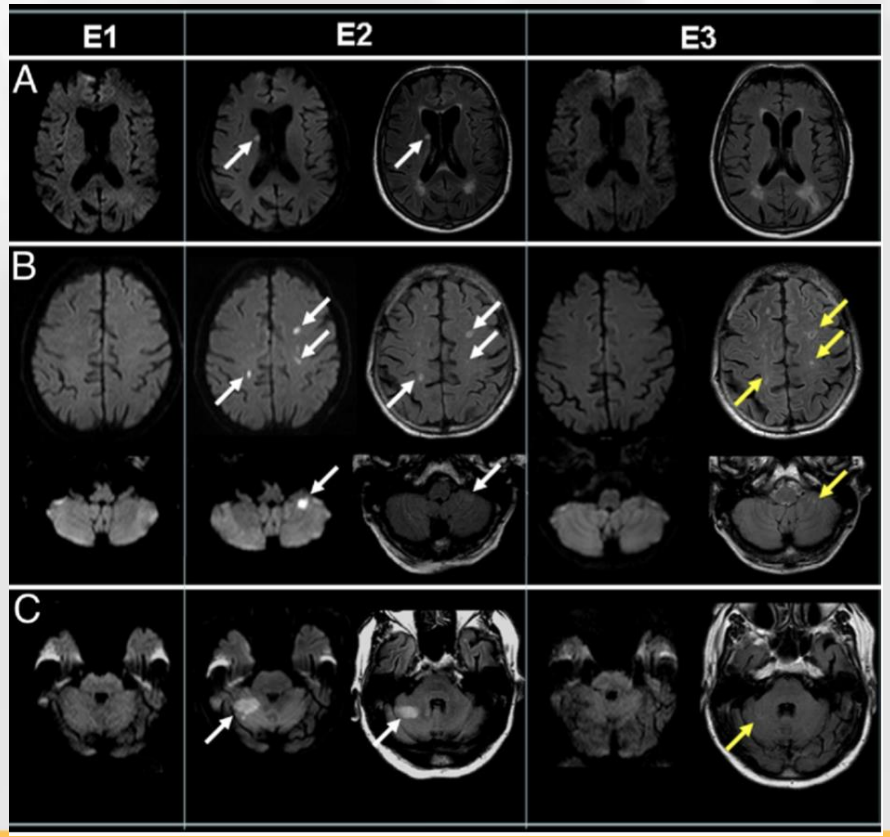
- Moderate or severe aortic regurgitation is still higher in the TAVR cohort than in the surgery cohort.

- Even mild paravalvular regurgitation might be a limitation of TAVR compared with surgery

Neurologic Complications

- The incidence of neurologic events in the PARTNER TAVR arm was twice as high as in the AVR arm (5.5% vs 2.4% at 30 days and 8.3% vs 4.3% at 1 year respectively.
- For the PARTNER high-risk as-treated patients, the rate of neurologic events in the TF stratum was 3-fold higher after than after AVR 4.6% vs 1.4% at 30 days and 6.1% vs 1.9% at 1 year

Neurologic Complications



Neurologic Complications

- TAVR is associated with a high rate of clinically silent cerebral embolism (68%-90%) and to a lesser degree after AVR in lower surgical risk patients (8%-48%) without high stroke rates

- These abnormalities have been termed ‘‘clinically silent,’’ but their potential impact on neurocognitive and higher memory function remain unclear

Cost-Effectiveness

- Procedural costs were substantially higher with TAVR than with SAVR, and that those costs were offset by savings from shortened hospital length of stay and a reduced need for post-discharge residential care.
- These offsets were not sufficient for TAVR to achieve overall cost neutrality relative to SAVR, either in the short or long term.

Conclusion

- TAVR is the treatment of choice in high-risk and inoperable patient
- TAVR should be considered as an alternative to surgery in intermediate-risk patients
- In younger, lower-risk, patients without major comorbidities surgical AVR is still the Gold Standard

Conclusion

- Functional integrated heart valve team to make sure that these complementary technologies—TAVR and surgical AVR—are used appropriately.
- Mutual respect and mutual trust
- It is very refreshing and rewarding to see cardiovascular surgeons and interventional cardiologists set aside our parochial self-interests and egos in order to work together for the patient's benefit.

Thank You !