Advances in Heart Valves

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Disclosures: Abbott Vascular, Medtronic, Lake Regions Medical, Boston Scientific
Key Points

Valvular Heart Disease

• Minimally invasive surgery is the standard

• Transcatheter therapy is becoming safer
  beyond high risk, and beyond aortic

• Despite advancements, valve population is at
  risk, with huge unmet needs
  a call to action is needed
62 year-old man, asymptomatic

a) Observe
b) Mitral valve replacement
c) Mitral valve repair
d) Transcatheter MitraClip
Early Surgery Is Better

Patients without Class I Indications

Survival %

Early surgery
Medical management

Follow-up, y

Log-rank $P<.001$

Suri R et al., JAMA 2013;310:609-16
Port Access for Mitral Surgery
Port Access for Mitral Surgery
A Look Back into 2011
Inoperable Aortic Stenosis

All-cause mortality (%)

NNT to save one life: 5

Leon et al., NEJM 2010
16 procedures in one visit

Complications in vulnerable patients
The Present

30-day outcomes for TF S3

- All-cause mortality: 1.6% and 1.1%
- Cardiac mortality: PVL = 3.7%

Risks like PCI
Next Generation Valves

Next-Generation Transcatheter Aortic Valve Replacement
Evolution of a Revolution

Paul Souza, MD, Wesley Peoples, MD

Transcatheter aortic valve replacement (TAVR) is a revolutionary therapy that has had a profound impact not only on the care of patients with aortic stenosis but also on the entire cardiovascular profession. To date, more than 100,000 patients worldwide have received this life-saving therapy. With continued population aging, the prevalence of candidates is expected to further increase [1]. With its demonstrated efficacy in improving survival and quality of life, TAVR is now endorsed in U.S. and European practice guidelines for the treatment of symptomatic patients with severe aortic stenosis who are either inoperable or at high surgical risk [2,3]. Now that the transformative benefits of TAVR are established, the remaining questions are focused on further improvements in the technology and its potential application in a broader population, including lower-risk patients.

Current TAVR therapy has its challenges. Even though procedural success rates for TAVR exceed 95%, the inability to retrieve and redeploy existing prostheses can lead to limbs ischemia and complications such as aortic regurgitation, coronary occlusion, and device embolization, occasionally leading to emergency surgery. With high surgical risk or inoperable status established as an indication for TAVR, emergency surgery in these patients is considerably prohibitive and may be prohibitively expensive. The irreversible nature of deployment with current TAVR prostheses therefore translates into an extraordinarily high level of training and expertise, usually facilitated by interventional cardiologists and a continued need for multiple physicians to work collaboratively to perform the procedure. Other concerns with TAVR include the need to demonstrate prosthetic durability and to further reduce the incidence of stroke, paravalvular leakage, and significant residual paravalvular regurgitation. Certainly, randomized trials and post-market registries have demonstrated that high levels of clinical efficacy can be achieved through rigorous education and the use of dedicated, specialized healthcare teams [4]. Nonetheless, these challenges remain and are relevant because complications of almost any degree in these procedures can lead to poorer survival given the high-risk aspects of these patients and their relative frailty.

The report of the REALIGN II (Repositionable Percutaneous Replacement of Biomatrix Aortic Valve Through Implantation of Lotus Valve System: Evaluation of Safety and Performance) registry by Meredith et al. [5] in this issue of the Journal highlights several innovations in TAVR therapy that help to address some of these day-by-day challenges. The Lotus valve (Boston Scientific Corp, Marlborough, Massachusetts) is a balloon-expandable, nitinol-polymerized, trileaflet aortic valve with an adaptive seal to help prevent paravalvular regurgitation, deliverable with an 18-F (7-mm valve) or 20-F (7.5-mm valve) system. The valve leaflets are fully functional early during deployment (99% of implantations), thereby allowing slow, deliberate deployment without the need for rapid ventricular pacing. The most intriguing feature of the Lotus valve is its ability to be fully repositioned after deployment and before release. The Lotus valve can thus be repositioned in the event of device misposition or an untoward complication (e.g., coronary occlusion).
Innovation in Practice

Skipping the ICU at ANW

- ICU obs
- No ICU

- Hospital LOS (d)
- Home discharge (%)
- Variable Costs ($)

Graphs showing the comparison between ICU and non-ICU observations in terms of hospital length of stay, home discharge percentage, and variable costs.
Conscious Sedation

Less is More

0.5 mg midazolam
50 mcg fentanyl

Next day
Durability

PARTNER 5-yr Follow-Up

HR [95% CI] = 1.04 [0.86, 1.24]

p (log rank) = 0.76

No. at Risk

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<th>SAVR</th>
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All-Cause Mortality vs. Months post Randomization
Tie Goes to the Runner (?)
# The Science in TAVR

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<td>Low</td>
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Transcatheter MV Repair
MitraClip

>30,000 pts worldwide
STS-PROM: 10%
Obs. mortality: 2.3%
Success: 91.8%
LOS: 3 days
First Transcatheter TMVR in U.S.

April 8, 2015
With all of these advances, how are we doing?
Population at Risk

True or False?

Survival of symptomatic AS is worse than breast cancer

AS is more malignant, yet treatable

Who are we responsible for?

Annual Patients with Severe AS

More than we thought, growing, and underserved

1,918 pts seen

426 pts treated
Who are we responsible for?

Annual patients with severe MR

More than we thought, and growing
A disease with poor prognosis that is curable

+ 

Vast majority not treated

= 

We can do a lot better
**Final Impressions:**

1. 2014 AHA/ACC guidelines for asymptomatic patients with severe mitral regurgitation recommend followup echo in 6-12 months. Symptomatic patients should be referred for cardiology evaluation.
Valve Dashboard
Population management

Patient-level, sortable data
Who are my patients?

Demographics, Diagnosis, Treatment, Costs
Population Monitoring
Survival with severe MR

 Survival Rate

Survival Rate Free of Death
Survival Rate Free of Death

1 Year: 84.8%
2 Years: 77.5%
3 Years: 70.7%
4 Years: 65.7%
5 Years: 54.2%

Survival Rate Free of Hospitalization or Death
Halo of Better Outcomes
Abbott Northwestern Hospital

No AVR
1 Year: 78.8%

AVR
92.4%
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