

PERSPECTIVE

Surgical Aortic Valve Replacement vs Transcatheter Aortic Valve Replacement

A Consumer's Perspective Regarding Data Education and Transparency of Hospitals

Naftali Zvi Frankel, BA
Institute for Advanced
Talmudic Studies
(affiliate of Touro
College and University
System), New York, NY.



Invited Commentary
page 496

When my grandfather had symptomatic severe aortic valve stenosis diagnosed and was evaluated as "intermediate/serious risk" for surgery, he became eligible to join a 50-50 randomized transcatheter aortic valve replacement (TAVR) trial or to choose conventional surgical aortic valve replacement (SAVR). The techniques were presented as equally acceptable options. The hospital staff physicians explained the significant advantage of not undergoing the rigors of open heart surgery.

Because my grandfather was relying on my advice, I left no stone unturned in researching which technique to use.

Initially, I located the website of a leading hospital with informational videos¹ regarding TAVR. I clicked on a link, and a video began:

"The results of the [TAVR] trial are for us, as heart surgeons and cardiologists...the same as landing a man on the moon....One of the groups who have benefited the most are the older weaker members of our community....They don't have the ability to weather the storm as younger patients might."

On the same website, I watched the moving testimony of a patient who underwent TAVR:

"No stitches, no pain, and in 3 days I was home! Unbelievable."¹

Another hospital's website included the following portrayal of TAVR:

"I had no pain' is often what we hear from our TAVR patients. While open heart surgery can be very painful with a long recovery time, TAVR patients experience very little discomfort."²

A hospital's decision as to whether a patient is a candidate for TAVR relies on a risk scoring system. Speaking at the Transcatheter Cardiovascular Therapeutics Asia Pacific 2013 Summit, Alain Cribier, a pioneer in TAVR,³ pointed out the fallacy of selecting candidates for TAVR based on a risk score index.⁴ He explained, "Today, I don't know what exactly is an intermediate-risk patient. For example, you take a patient who has a EuroSCORE (European System for Cardiac Operative Risk Evaluation) of 20%; he is a high-risk patient. If you have a EuroSCORE of 19%; he is an intermediate-risk patient. This is for me totally ridiculous."

I realized that the decision to choose SAVR or TAVR should be based not on a risk score from the Society of Thoracic Surgeons, nor on an idealized video, but on actual outcomes data.

The following are some of the significant risks that I learned are associated with TAVR and are inadequately explained to patients: increased mortality due

to aortic regurgitation⁵; increased need for pacemakers⁶; potential damage from cerebral microemboli⁷; and unknown durability of the valve.⁸ Although patients are advised of the benefits of TAVR, they are not typically informed regarding these very serious risks. However, as Aldous Huxley wrote, "Facts do not cease to exist because they are ignored (Proper Studies, 1927)."

I searched for data on the hospitals and surgeons with the best outcomes. I found national averaged outcomes statistics of SAVR and TAVR based on data gathered from dozens of superior and inferior hospitals and surgeons. However, I decided to focus on outcomes data for individual surgeons so that I could compare the performances of the treating surgeons rather than national averages.

Reviewing hospital ratings from the Society of Thoracic Surgeons (<http://www.sts.org/quality-research-patient-safety/sts-public-reporting-online>), I noticed that they did not include many high-volume hospitals, nor did they disclose outcomes for individual hospitals and surgeons.

I also reviewed the *US News and World Report* "Best Hospitals" rankings,⁹ but I wanted to clarify how they were formulated. I learned that "Best Hospitals" are ranked by specialty, not procedure. As a result, these rankings may include SAVR within the conditions analyzed, but they do not present data on outcomes for that particular procedure. Furthermore, their rankings are provided as a starting point to consider, not as a definitive guide for where to go for medical care. The Society of Thoracic Surgeons data and the "Best Hospitals" rankings were thus not of material assistance. I determined that the New York State Department of Health (NYSDOH) publishes reports with cardiac surgery outcomes from individual hospitals and surgeons in New York State.¹⁰ Having reviewed the cardiac outcomes in New York State, I proceeded to the next step: determining which hospitals and surgeons had the best outcomes specifically for isolated SAVR and TAVR.

The latest data published by the NYSDOH was from 2008 through 2010. I submitted a request to the NYSDOH for the 2012 isolated SAVR outcomes of 3 surgeons whose successful outcomes stood out in the 2008-2010 report. I also requested the outcomes of TAVR from 2 hospitals that I had determined were experienced with the procedure. I was told to request the additional data via a Freedom of Information Act request.

In response to my request, I received the 2012 outcomes data for isolated SAVR performed by the 3 surgeons requested and the 2011-2012 outcomes data for TAVR from the 2 hospitals requested.

Corresponding Author: Naftali Zvi Frankel, BA, 113 81st Ave, Kew Gardens, NY 11415 (nzfrankel9@gmail.com).

In the 2012 isolated SAVR outcomes data, the number of patients operated on per surgeon ranged from 49 to 103. The observed mortality rate (OMR) was 0% for all 3 surgeons. The observed stroke rate (OSR) ranged from 0% to 3.23%, depending on the surgeon. The same surgeon who performed the most isolated SAVR procedures in 2012 (103 patients) was the only one who had both a 0% OMR and a 0% OSR.

On the other hand, in the 2011 TAVR outcomes data from the 2 requested hospitals, the patient volumes for TAVR were 56 and 163. The OMR was 1.79% for the lower-volume and 2.45% for the higher-volume hospital, and the OSR was 0% for the higher-volume and 1.79% for the lower-volume hospital. Interestingly, the hospital with the lower OMR had the higher OSR.

In the 2012 TAVR outcomes data from the 2 hospitals, the patient volumes for TAVR procedures were 88 and 272. The OMR was 5.68% for the lower-volume and 5.51% for the higher-volume hospital, and the OSR was 2.27% for the lower-volume and 2.21% for the higher-volume hospital. Although the hospitals had had another year of experience performing TAVR, their OMRs increased by approximately

3% to 4%, and the OSR for 1 hospital increased by more than 2%. Having studied the risk of death associated with aortic regurgitation after TAVR, I sent another request for the postoperative aortic regurgitation rates from the 2 hospitals, but the records office responded that the NYSDOH does not collect data on aortic regurgitation.

In conclusion, for "inoperable" patients, TAVR is a beacon of hope and life. However, it is also an evolving procedure with risks and uncertainty. Instead of presenting an idealized vision of TAVR, hospitals and physicians should convey the benefits *and* risks of both SAVR and TAVR accurately to the public.

I observed a lack of transparency regarding outcomes statistics. Note that TAVR has been performed in the United States for more than 5 years and SAVR for more than 50 years, both without published outcomes for individual hospitals and surgeons. Patients have no way of knowing whether their surgeon has a 1% or a 50% mortality rate.

I presented my grandfather with the risks and benefits of SAVR vs TAVR and the surgeon outcomes data. On weighing the data, he chose to undergo SAVR performed by the surgeon with the best outcomes statistics in New York. His operation was successful.

Published Online: January 27, 2014.
doi:10.1001/jamainternmed.2013.12829.

Conflict of Interest Disclosures: None reported.

1. Transcatheter Aortic Valve Replacement—Dr. Mehmet C. Oz. http://www.youtube.com/watch?v=wOXm2LtPTec&feature=player_detailpage&list=PL89ED8522E84471BA#t=85s. Published June 17, 2011. Accessed June 30, 2013.

2. Transcatheter Aortic Valve Replacement (TAVR): Oklahoma Heart Institute. <http://www.oklahomaheart.com/content/transcatheter-aortic-valve-replacement-tavr>. Accessed June 30, 2013.

3. Cribier A, Eltchaninoff H, Bash A, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. *Circulation*. 2002;106(24):3006-3008.

4. TCTAP 2013 wrap-up interview: transaortic valve implantation. http://www.youtube.com/watch?feature=player_detailpage&v=pNjzm7eg-28#t=848s. Published May 15, 2013. Accessed June 30, 2013.

5. Athappan G, Patvardhan E, Tuzcu EM, et al. Incidence, predictors, and outcomes of aortic regurgitation after transcatheter aortic valve replacement: meta-analysis and systematic review of literature. *J Am Coll Cardiol*. 2013;61(15):1585-1595.

6. Bagur R, Rodés-Cabau J, Gurvitch R, et al. Need for permanent pacemaker as a complication of transcatheter aortic valve implantation and surgical aortic valve replacement in elderly patients with severe aortic stenosis and similar baseline electrocardiographic findings. *JACC Cardiovasc Interv*. 2012;5(5):540-551.

7. Kahlert P, Knipp SC, Schlamann M, et al. Silent and apparent cerebral ischemia after percutaneous

transfemoral aortic valve implantation: a diffusion-weighted magnetic resonance imaging study. *Circulation*. 2010;121(7):870-878.

8. Nainggolan L. "Favorable" five-year outcomes with early TAVI devices: Medscape. <http://www.medscape.com/viewarticle/776724>. Published December 26, 2012. Accessed November 6, 2013.

9. Top-ranked hospitals for cardiology & heart surgery. *US News Best Hospitals*. <http://health.usnews.com/best-hospitals/rankings/cardiology-and-heart-surgery>. Accessed June 30, 2013.

10. New York State Department of Health. Adult cardiac surgery in New York State 2008-2010. http://www.health.ny.gov/statistics/diseases/cardiovascular/heart_disease/docs/2008-2010_adult_cardiac_surgery.pdf. Accessed June 30, 2013.

Invited Commentary

A Consumer's Pursuit of Health Care Outcomes Daunting Even With a Guardian Angel!

Michael Mack, MD

Every patient should have a guardian angel to help navigate our health care system. Yet even with a guardian angel, the challenges encountered in deciding various treatment options can prove daunting. Frankel¹ poignantly illustrates these challenges as he describes his journey through various sources of health care information to find the best treatment for his grandfather's aortic stenosis. Among the resources he searched, with some frustration, were hospital websites, the Society of Thoracic Surgeons (STS) database, the *US News and World Report* "Best Hospitals" rankings, and reports from the New York State Department of Health.

One would think, given the huge amount of health care information available today, that by practicing proper due diligence

we should be able to make reasonable and rational informed decisions about care options. After all, shouldn't we be able to choose a heart operation with the same informed decision-making capability that we use to purchase a car, computer, or refrigerator? The consumer world is replete with resources that are purported to aid us in this quest. *US News and World Report* annually lists the best hospitals and heart programs.² *Consumer Reports* and the STS rate the best and worst heart surgery programs.^{3,4} Many websites, such as Healthgrades.com, "grade" virtually every physician in the United States.⁵ Many states, including New York, publicly report individual surgeon outcomes.⁶ In most major metropolitan areas, the "Best Doctor" issue of the local magazine draws the greatest attention in the grocery store checkout line.⁷ Even