

## 1-Year Results From the NOTION Randomized Clinical Trial



### No News Is Good News?

The NOTION (Nordic Aortic Valve Intervention) trial compared transcatheter aortic valve replacement (TAVR) versus surgical aortic valve replacement (SAVR) in predominantly low-risk patients (1). Available evidence is consistent in suggesting that TAVR is associated with a better immediate outcome, given the less invasive nature of the procedure. However, the less favorable immediate outcome reported with SAVR is offset by improved survival, which is the primary therapeutic goal for patients at low- and intermediate-risk.

As partly recognized by Thyregod et al. (1), there are several study limitations to acknowledge:

- Patients with significant concomitant coronary disease were not recruited, so that nearly 90% of patients were excluded at enrollment. In other words, it is not for “all-comers,” as the title says.
- Hospital costs are higher for TAVR than SAVR procedures, and the hypothesis tested in the study would result in an unsustainable healthcare expenditure.
- The “modern TAVR” is compared with the “ancient SAVR.” However, it should be taken into consideration that, at present, SAVR can be performed using different approaches (e.g., minimally invasive surgery, sutureless bioprostheses) that may compete well with current interventional techniques.
- The rate of post-operative cardiogenic shock and major/life-threatening bleeding in this low-risk SAVR population seem unusually high (10.6% and >20%).
- The high rate of post-operative pacemaker implantation in the TAVR group (34.1%) seems to be correlated with the prosthetic device used rather than with TAVR *per se*. This complication deserves further discussion, given the well-known association between pacemaker stimulation and ventricular deterioration.
- At 1-year follow-up, TAVR patients had more dyspnea compared with SAVR patients, likely due to paraprosthetic regurgitation. This has been frequently described as a complication occurring with current-generation TAVR devices and has been associated with increased mortality. However, the mortality rate after TAVR in the NOTION trial is 1 of the lowest ever reported, and the short follow-up period can account for this positive finding.

\*Giuseppe Santarpino, MD  
Theodor Fischlein, MD  
Steffen Pfeiffer, MD

\*Department of Cardiac Surgery  
Paracelsus Medical University  
Breslauer Strasse 201  
Nuremberg 90471  
Germany

E-mail: [g.santarpino@libero.it](mailto:g.santarpino@libero.it)

<http://dx.doi.org/10.1016/j.jacc.2015.05.075>

Please note: Dr. Fischlein has served as a consultant for Sorin Company. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

### REFERENCE

1. Thyregod HG, Steinbrüchel DA, Ihlemann N, et al. Transcatheter versus surgical aortic valve replacement in patients with severe aortic valve stenosis: one-year results from the All-comers Nordic Aortic Valve Intervention (NOTION) randomized clinical trial. *J Am Coll Cardiol* 2015;65:2184-94.

## Less Dyspnea Is Better Than More Dyspnea



### More or Less?

With interest we read the paper by Thyregod et al. (1) on transcatheter aortic valve replacement (TAVR) versus surgical aortic valve replacement (SAVR) in patients with severe aortic valve stenosis. TAVR has been considered an acceptable treatment option for patients with inoperable severe aortic valve stenosis or at high risk for surgery (2). The NOTION (Nordic Aortic Valve Intervention Trial) study was the first randomized trial comparing TAVR with SAVR in an all-comers patient population with severe symptomatic aortic valve stenosis regardless of their predicted mortality score. It was a multicenter, randomized, nonblinded, superiority trial.

No significant differences were found regarding death from any cause, stroke, or myocardial infarction; cardiovascular mortality; or prosthesis re-intervention after 1 year. Power calculations in the trial were far too weak to detect a small ( $\approx 3\%$ ) absolute difference in primary outcome between groups. Need for permanent pacemaker implantation (38.0% vs. 2.4%;  $p < 0.001$ ), New York Heart Association functional class II at 1 year (29.5% vs. 15.0%;  $p = 0.01$ ), and moderate-to-severe regurgitation at 1 year (15.7% vs. 0.9%;  $p < 0.001$ ) were all better in the SAVR group. Bleeding, acute kidney injury, cardiogenic shock, new-onset atrial fibrillation, and duration of indexed hospitalization were better in the TAVR group, although they did not corroborate to a worse overall 1-year outcome or a difference in the