

EDITORIAL COMMENT

Assessing Implant Depth Using Aortography in Transcatheter Aortic Valve Replacement

What You See May Not Be What You Get*

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The impact of valve implant depth on paravalvular aortic regurgitation (PAR) and permanent pacemaker implantation (PPI) after transcatheter aortic valve replacement (TAVR) has been shown repeatedly (1-6). Deep implantation has been associated with a higher incidence of significant PAR with self-expanding prostheses (e.g., CoreValve and Evolut R [Medtronic Inc., Galway, Ireland] (1) and new PPI among the balloon-expandable SAPIEN 3 valve (Edwards Lifesciences, Irvine, California) as well as self-expanding and mechanically expandable valves (2-6). Implant depth is most commonly evaluated by contrast aortography of a coaxial projection of the valve prosthesis (1-6).

SEE PAGE 119

In this issue of *JACC: Cardiovascular Interventions*, Van Gils et al. (7) reported the impact of implant depth in Lotus valve (Boston Scientific, Marlborough, Massachusetts) on PPI and PAR in the RESPOND (Re-positionable Lotus Valve System – Post Market Evaluation of Real World Clinical Outcomes) post-market study. Of 996 patients in the study, only 506 aortograms were acquired using a coaxial projection with sufficient technique, and used in the primary implant depth analysis. The authors found that depth <6.5 mm was associated with

lower PPI rate than ≥ 6.5 mm (21% vs. 41%; $p < 0.001$), and deeper implantation was an independent predictor of PPI (odds ratio per millimeter increment: 1.200; 95% confidence interval: 1.091-1.319). However, implant depth was associated with PAR by neither aortography nor transthoracic echocardiography (TTE).

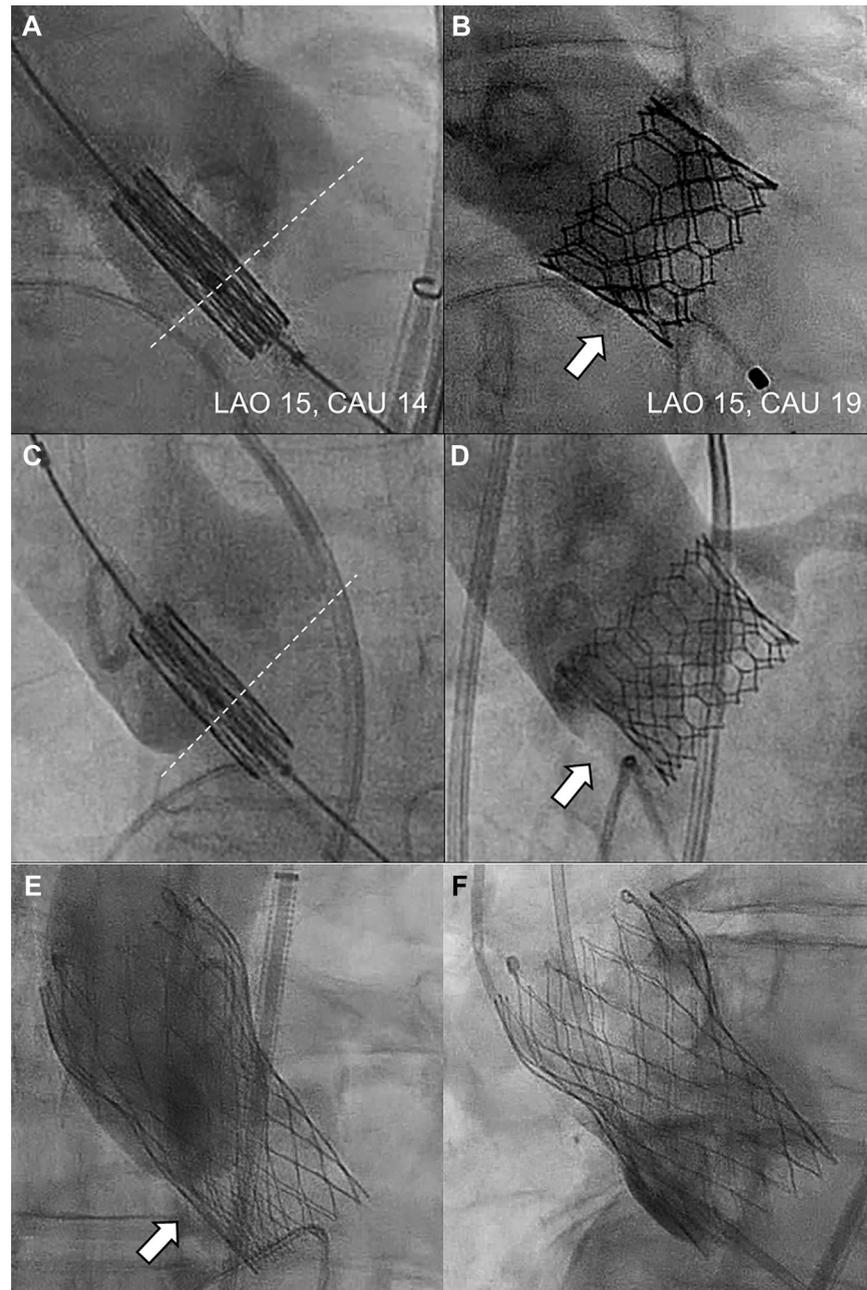
Results on implant depth and PPI in the Lotus TAVR have been mixed. Rampat et al. (8) studied 228 patients across 10 centers in the United Kingdom and did not identify implant depth as a predictor of PPI. In the REPRISE (REpositionable Percutaneous Replacement of Stenotic Aortic Valve Through Implantation of Lotus Valve System) II extended cohort study evaluating 250 patients, Dumonteil et al. (6) found a trend toward lower PPI in patients with depth ≤ 5 mm than depth > 5 mm at the left coronary sinus (23.9% vs. 36.9%; $p = 0.06$). The study by Van Gils et al. (7) was the first to report a reduced incidence of PPI with shallower implant in Lotus TAVR. The differences observed among Lotus studies stand apart from the consistent observations that deeper implantation increased PPI in both self-expanding and balloon-expandable valves (2-5). This could be due to the different mechanism of radial force applied to the conduction system by Lotus compared with the CoreValve and SAPIEN 3, regardless of its implantation depth.

The current study is notable because: 1) it was the largest study on implant depth in Lotus TAVR; 2) unlike the REPRISE II study, the RESPOND study consisted of all 3 Lotus valve sizes: 23, 25, and 27 mm; and 3) despite that higher Lotus valve implantation reduced PPI, PAR was not affected. The last finding differed from those in CoreValve and SAPIEN 3 TAVR, where studies had suggested a tradeoff with less PPI

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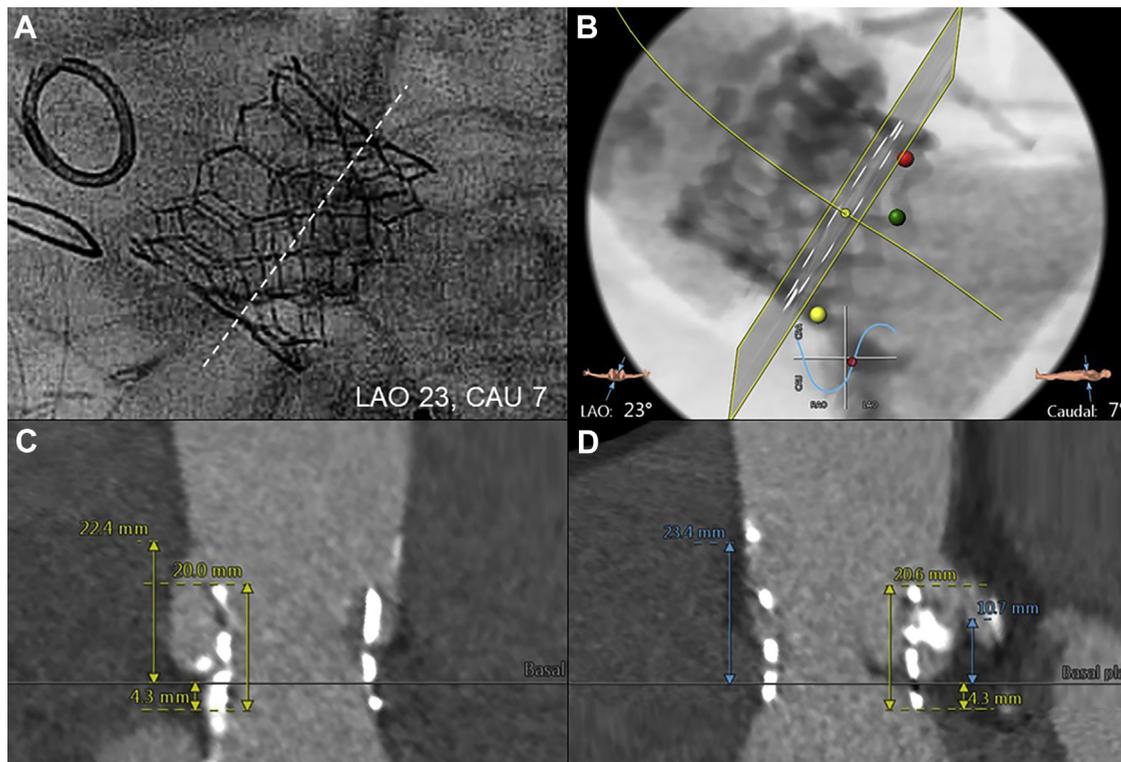
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FIGURE 1 Potential Challenges in Using Contrast Aortography in the Assessment of Prosthesis Implant Depth in Transcatheter Aortic Valve Replacement



(A, B) First, coaxial projection of the transcatheter valve may differ from fluoroscopic coplanar view during deployment. (B to E) Second, bulky leaflet calcium (solid white arrows) at the noncoronary and left coronary cusps may prevent adequate contrast filling of the base of the sinuses. C and D were obtained on the same patient. (E) Third, in a valve with supra-annular leaflets, contrast filling to the base of the sinuses may be reduced or delayed. (F) A known reliable technique to assess implant depth is to perform aortography with the pigtail catheter positioned at the base of the noncoronary sinus. Dashed lines in A and C represent the fluoroscopic coplanar view of the annulus aligning the base of 3 aortic cusps. CAU = caudal; LAO = left anterior oblique.

FIGURE 2 Differences in Implant Depth Assessment Between Contrast Aortography and Multidetector Computed Tomography



(A, B) Representative example showing that at the same fluoroscopic projection angle, (C, D) multidetector computed tomography cross-sectional analysis of the implant depth suggested a more aortic implant of the SAPIEN 3 valve (Edwards Lifesciences, Irvine, California). Dashed line represents the annular plane seen under aortography. Abbreviations as in Figure 1.

but more PAR with higher valve implantation (1-6). Unfortunately, similar to the studies using contrast aortography to evaluate implant depth, the current one had the same following limitations:

1. Coaxial projection of the valve prosthesis is a prerequisite.
2. Optimal placement of the pigtail catheter and adequate volume and speed of contrast injection are necessary to properly visualize the annular plane. The study by Van Gils et al. had 30% of their patients excluded due to the previous technical issues.
3. Definition of implant depth varied among studies. Mean implant depth was used in the current study but others have evaluated depths at both non-coronary and left coronary sinuses (1,3-7).
4. Coaxial projection of the transcatheter valve may differ from fluoroscopic coplanar view of the aortic valve (Figures 1A and 1B). This phenomenon occurs more often with self-expanding valves than with balloon-expandable valves, where the discrepancy may affect validity of the measurement of true

implant depth. Moreover, if the 2 axes are divergent, the depth assessment at the middle portion of the valve (usually right coronary cusp) becomes difficult to interpret.

5. With bulky calcium on the noncoronary or left coronary cusps, or narrow sinuses, visualizing the annular plane after valve implantation may be difficult, given the leaflet will occupy a significant portion of the sinus space (Figures 1C to 1E). This may be more problematic with a transcatheter valve with supra-annular leaflets, such as the CoreValve or Evolut R, given that contrast filling of the sinuses below the prosthetic leaflets may be reduced or delayed (Figure 1E). A known reliable method to visualize implant depth in a self-expanding prosthesis is to perform aortography with the pigtail catheter positioned at the bottom of the noncoronary sinus, as customary in CoreValve or Evolut R implantation (Figure 1F).
6. It is established that prosthesis implant depth may differ between contrast aortography and multidetector computed tomography (MDCT) (Figure 2).

In addition to implant depth, patient, procedural, and device-related factors can impact PPI rates (1-6). Recently, a combination of pre-existing right bundle branch block, implant depth, and membranous septal length measured on MDCT was found to be predictive of PPI after SAPIEN 3 TAVR (9). However, the only factor that operators can control is implant depth, and it is difficult to accurately predict the final implant depth during deployment in balloon-expandable and self-expanding valves. The SAPIEN 3 expands by inflow shortening, so even when the bottom of marker band is positioned higher than the annular plane, depending on stiff wire positioning, severity of leaflet and annular calcification, and degree of valve oversizing, asymmetric inflow shortening at the noncoronary and left coronary sinus can occur (Figures 1A and 1B). Post-dilatation may further expand the SAPIEN 3 prosthesis and shorten the inflow more, and there is no reliable and consistent mechanism to achieve a specific implant depth. The Evolut R often pivots upon release, resulting in final depth at noncoronary and left coronary sinuses different from what was seen at 80% deployment under aortography. The Evolut PRO (Medtronic Inc.) with the exterior pericardial wrap at the inflow has improved the stability of pivot upon release but there is still no reliable and consistent method to aim for a specific implant depth. The Lotus valve may offer the potential advantage of better achieving the target implant

depth upon release, but even with a higher implant, the >20% PPI rate remains a concern, especially when TAVR indications expand to lower risk and younger patients.

Van Gils et al. (7) also found no association between implant depth and PAR by contrast aortography and TTE. The authors argued that despite inherent limitations in methodology, aortography may be more sensitive than TTE in the detection of PAR. There is evidence now that multimodality evaluation of PAR, consisting of contrast aortography, intraprocedural echocardiography, and invasive hemodynamics, should be performed routinely in TAVR to optimize outcomes (10-13). We agree with the authors that aortography is a critical aspect of valve assessment, but we emphasize the importance of multimodality evaluation. This is particularly important as TAVR expands to lower-risk and younger patients, where even mild PAR may impact long-term outcomes. In this patient population, general anesthesia and transesophageal echocardiography are usually well tolerated and should be considered as one of the key imaging modalities in the assessment of PAR during TAVR.

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REFERENCES

1. Sherif MA, Abdel-Wahab M, Stocker B, et al. Anatomic and procedural predictors of paravalvular aortic regurgitation after implantation of the Medtronic CoreValve bioprosthesis. *J Am Coll Cardiol* 2010;56:1623-9.
2. Sinning J, Petronio AS, Van Mieghem N, et al. Relation between clinical best practices and 6-month outcomes after transcatheter aortic valve implantation with CoreValve (from the ADVANCE II Study). *Am J Cardiol* 2017;119:84-90.
3. Mauri V, Reimann A, Stern D, et al. Predictors of permanent pacemaker implantation after transcatheter aortic valve replacement with the SAPIEN 3. *J Am Coll Cardiol Intv* 2016;9:2200-9.
4. Husser O, Pellegrini C, Kessler T, et al. Predictors of permanent pacemaker implantations and new-onset conduction abnormalities with the SAPIEN 3 balloon-expandable transcatheter heart valve. *J Am Coll Cardiol Intv* 2016;9:244-54.
5. De Torres-Alba F, Kaleschke G, Diller GP, et al. Changes in the pacemaker rate after transition from Edwards SAPIEN XT to SAPIEN 3 transcatheter aortic valve implantation: the critical role of valve implantation height. *J Am Coll Cardiol Intv* 2016;9:805-13.
6. Dumonteil N, Meredith IT, Blackman DJ, et al. Insights into the need for permanent pacemaker following implantation of the repositionable LOTUS valve for transcatheter aortic valve replacement in 250 patients: results from the REPRIS II trial with extended cohort. *Euro-Intervention* 2017;13:796-803.
7. van Gils L, Wöhrle J, Hildick-Smith D, et al. Importance of contrast aortography with lotus transcatheter aortic valve replacement: a post hoc analysis from the RESPOND post-market study. *J Am Coll Cardiol Intv* 2018;11:119-28.
8. Rampat R, Khawaja Z, Hiling-Smith R, et al. Conduction abnormalities and permanent pacemaker implantation after transcatheter aortic valve replacement using the repositionable LOTUS device: the United Kingdom experience. *J Am Coll Cardiol Intv* 2017;10:1247-53.
9. Maeno Y, Abramowitz Y, Kawamori H, et al. A highly predictive risk model for pacemaker implantation after TAVR. *J Am Coll Cardiol Img* 2017;10:1139-47.
10. Sinning J, Hammerstingl C, Vasa-Nicotera M, et al. Aortic regurgitation index defines severity of peri-prosthetic regurgitation and predicts outcome in patients after transcatheter aortic valve implantation. *J Am Coll Cardiol* 2012;59:1134-41.
11. Hahn RT, Little SH, Monaghan MJ, et al. Recommendations for comprehensive intraprocedural echocardiographic imaging during TAVR. *J Am Coll Cardiol Img* 2015;8:261-87.
12. Sinning J, Vasa-Nicotera M, Chin D, et al. Evaluation and management of paravalvular aortic regurgitation after transcatheter aortic valve replacement. *J Am Coll Cardiol* 2013;62:11-20.
13. Kronzon I, Jelnin V, Ruiz CE, et al. Optimal imaging for guiding TAVR: transesophageal or transthoracic echocardiography or just fluoroscopy? *J Am Coll Cardiol Img* 2015;8:361-70.

KEY WORDS aortography, aortic stenosis, TAVR