JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 10, NO. 12, 2017

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER
http://dx.doi.org/10.1016/j.jcin.2017.05.012

EDITORIAL COMMENT

LOTUS Valve

Increasing the Pace of Device Iterations*

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In this issue of *JACC: Cardiovascular Interventions*, Rampat et al. (1) report on early (in-hospital) conduction anomalies and need for permanent pacemaker (PPM) associated with implantation of the LOTUS transcatheter heart valve (THV) (Boston Scientific, Marlborough, Massachusetts). Derived from what appears to be a group of experienced and high-volume THV implanters with what could be qualified as the most "optimal" LOTUS depth implantation published so far (~6 mm), the main findings of this report are as follows: 1) among patients with no prior PPMs at baseline, the need for a new PPM was 32%, and the occurrence of new left bundle branch block (LBBB) (excluding patients requiring PPMs) was 55%, resulting in approximately 80% of the cohort experiencing major conduction disturbances after LOTUS implantation; and 2) among patients requiring PPMs, the vast majority (64%) had no baseline conduction disturbances, and most of the PPMs (72%) were implanted for complete atrioventricular block.

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Since 2002, transcatheter aortic valve replacement (TAVR) has gone through several phases of development and improvement. Initially, vascular complications and bleeding were seen as the main issues; these problems were easily and rapidly solved with the emergence of lower profile devices. Then came the problem of paravalvular leak (PVL); even mild PVL was considered detrimental (2). This issue was clearly seen as the potential Achilles' heel of TAVR compared with surgical aortic valve replacement (3). Innovative new devices and iterations subsequently followed (LOTUS system [sealing cuff] and SAPIEN 3 [sealing skirt], Edwards Lifesciences, Irvine, California; and now Evolut PRO [outer wrap] Medtronic, Minneapolis, Minnesota), with the LOTUS system probably offering the most effective solution for this specific problem. Currently, PVL could be seen as "under control," with most patients undergoing TAVR today experiencing mild or less PVL if appropriate sizing and favorable anatomy are present.

The promises of the LOTUS included safe, controlled, and predictable deployment, with the capacity to reposition the THV to achieve optimal results in terms of PVL and coronary occlusion, and the capacity (luxury) to completely retrieve the THV if a satisfactory result was not achieved. Clearly, the LOTUS system succeeded at lowering the rate of PVL and providing a safe and controlled procedure, negating any concerns about root rupture and procedural coronary coverage, especially in challenging aortic root and annular anatomy (4,5). That said, the first-generation LOTUS devices consistently demonstrated a relatively high rate of PPM implantation (~30%) and new conduction disturbances (4). This is rather surprising, as one would think that the repositionability feature would allow optimal placement to limit conduction disturbances.

From the present report, many questions arise. What is the acceptable PPM rate among patients undergoing contemporary TAVR? Although there is no ready answer, it may be reasonable to accept no more than the baseline PPM rates of the studied cohort, which in this case was 12%. Consistently, from large randomized trials, prior PPM rates among patients

*Editorials published in *JACC: Cardiovascular Interventions* reflect the views of the authors and do not necessarily represent the views of *JACC: Cardiovascular Interventions* or the American College of Cardiology.

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TABLE 1 Rates of New Permanent Pacemaker Implantation 30 Days After Transcatheter Aortic Valve Replacement From the Most Recent Available Data Using Contemporary Transcatheter Heart Valve Prostheses

	SAPIEN 3 (11)	Evolut PRO*	LOTUS Safe Guard†
Patients	1,077	60	50
Patient risk (STS score)	5.2%	6.4%	4.4%
New permanent pacemaker implantation	10.2%	10%	17.8%

*John K. Forrest, American College of Cardiology 2017, Chicago, IL. †Nicolas Van Mieghen; CRT 2017; Washington, DC.

STS = Society of Thoracic Surgeons.

with severe symptomatic aortic stenosis were about 9% to 12% (6,7). Any post-procedural rate above this could be seen as unacceptable and clearly "procedure related." From this report, 32% is clearly unacceptable. Whether this high rate of PPM is device, operator, or patient related, or a combination of these, remains unknown.

Can we predict and identify patients who will require PPMs after TAVR? From the present report, the most concerning finding is that the vast majority (approximately two-thirds) of the patients requiring PPMs had no rhythm disturbances at baseline. The unpredictability of these new conduction disturbances after LOTUS implantation is worrisome. One can ask if the repositioning feature in the current form of the device was used appropriately. In contrast, one can argue that among a less sick patient population (lower risk), the need for PPM implantation will be lower. But how much lower, and are we sure about that? When treating a lower risk patient, the bar will be high. We will have to be almost perfect in every aspect of the procedure. If replicated in a low-risk population, these results would not be acceptable, especially compared with surgical aortic valve replacement.

Can LOTUS implantation be optimized to reduce PPM rate and conduction disturbances? With almost 80% of patients experiencing new conduction disturbances (either new PPM implantation or new LBBB), we can easily agree that there is room for improvement. To this extent, recent data emerging from a very experienced center demonstrate a lower rate of new PPM placement with the LOTUS system, about 15% at 30 days, especially with higher (more aortic, less ventricular) implantation (N. Van Mieghen, personal communication, May 2017). As previously noted with other prostheses, a ventricular implantation depth of about 1 to 3 mm might result in more acceptable outcomes (8).

Finally, for those arguing and hiding behind the concept that new PPM placement and new LBBB are not associated with mortality or adverse events, I firmly oppose those erroneous and insensitive excuses. Indeed, the detrimental impact of PPM placement and LBBB has been well demonstrated in many circumstances (increased rehospitalization, increased composite of death and rehospitalization, need for future PPM, and lack of improvement in left ventricular ejection fraction) (9,10), and this type of reasoning should be banished from any discussion focusing on innovation, scientific advancement, and long-term improvement in patient care.

TAVR has evolved and matured as a predictable, scalable procedure. Multiple innovations and device iterations have made this less invasive procedure beneficial to many patients. Today, vascular, bleeding, and PVL complications have been marginalized. With this procedure potentially expanding to the low-risk population, conduction disorders, coronary access, and THV durability seem to be the remaining issues. Whether upcoming LOTUS iterations (LOTUS Edge, LOTUS Depth Guard) and implantation optimization techniques will keep the LOTUS valve in the race of contemporary THV devices remains to be seen (**Table 1**).

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REFERENCES

1. Rampat R, Khawaja MZ, Hilling-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.

2. Kodali S, Pibarot P, Douglas PS, et al. Paravalvular regurgitation after transcatheter aortic valve replacement with the Edwards SAPIEN valve in the PARTNER trial: characterizing patients and impact on outcomes. Eur Heart J 2015;36:449–56.

3. Genereux P, Head SJ, Hahn R, et al. Paravalvular leak after transcatheter aortic valve replacement: the new Achilles' heel? A comprehensive review of the literature. J Am Coll Cardiol 2013;61:1125–36.

4. Meredith Am IT, Walters DL, Dumonteil N, et al. Transcatheter aortic valve replacement for severe symptomatic aortic stenosis using a repositionable valve system: 30-day primary endpoint results from the REPRISE II study. J Am Coll Cardiol 2014; 64:1339–48.

5. Soliman OI, El Faquir N, Ren B, et al. Comparison of valve performance of the mechanically expanding Lotus and the balloon-expanded SAPIEN3 transcatheter heart valves: an observational study with independent core laboratory analysis. Eur Heart J Cardiovasc Imaging 2017 Jan 6 [E-pub ahead of print].

6. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. N Engl J Med 2016; 374:1609–20.

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JUNE 26, 2017:1254–6

7. Reardon MJ, Van Mieghem NM, Popma JJ, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. N Engl J Med 2017; 376:1321–31.

8. Krackhardt F, Kherad B, Krisper M, Pieske B, Laule M, Tschope C. Low permanent pacemaker rates following LOTUS device implantation for transcatheter aortic valve replacement due to modified implantation protocol. Cardiol J 2017 Mar 1 [E-pub ahead of print].

9. Nazif TM, Dizon JM, Hahn RT, et al. Predictors and clinical outcomes of permanent pacemaker implantation after transcatheter aortic valve replacement: the PARTNER (Placement of Aortic Transcatheter Valves) trial and registry. J Am Coll Cardiol Intv 2015;8:60–9.

10. Nazif TM, Williams MR, Hahn RT, et al. Clinical implications of new-onset left bundle branch block after transcatheter aortic valve replacement: analysis of the PARTNER experience. Eur Heart J 2014;35:1599–607.

11. Thourani VH, Kodali S, Makkar RR, et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. Lancet 2016;387:2218–25.

KEY WORDS aortic stenosis, left bundle branch block, LOTUS, pacemaker, transcatheter aortic valve