Review Article

Pacemaker implantation after transcatheter aortic valve: why is this still happening?

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Abstract: During the past years, the industry and most transcatheter aortic valve operators have focused on reduction of paravalvular leaks rather than on the reduction of permanent pacemakers (PPM). However, since indication for transcatheter aortic valve implantation (TAVI) is moving toward a healthier and younger patient population, new PPMs may become more of an issue. Certain factors such as pre-existing conduction disorders or anatomical features cannot be changed. However, the amount of mechanical trauma to the conduction system and periprocedural medical management offers the potential for optimization. By optimizing our procedure, we may finally be able to achieve low, surgical-like, PPM rates.

Keywords: Aortic stenosis; atrio-ventricular block; conduction disorder; permanent pacemaker (PPM)

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Introduction

Transcatheter aortic valve implantation (TAVI) has been successfully performed in inoperable, high-risk, and intermediate risk patients with low mortality and complication rates (1,2). Trials examining the efficacy and safety of TAVI in low-risk patients are currently enrolling patients.

While newer balloon-expandable and self-expanding TAVI devices now feature sealing skirts and are repositionable and retrievable, no specific feature has been implemented to reduce the occurrence of new conduction disorders (3). Indeed, the need for a new PPM remains a matter of concern because of its high frequency, its potential negative impact on outcomes, and its association with prolonged hospital stay and costs (3,4). Long-term right ventricular pacing has been linked to electromechanical asynchrony, negative left-ventricular remodeling, increased risk for atrial fibrillation, and heart failure (5,6). In light of this evidence, we should put our efforts in reducing new PPM after TAVI, particularly in an era when the indication for TAVI may expand toward treating lower-risk patients (7).

Why is this still happening?

During the past years, the focus of both TAVI operators and the industry has been more on reduction of PVL rather than on the reduction of PPM (*Figure 1*) (18,19). For example, the reported PPM rates with the SAPIEN 3 valve (Edwards Lifesciences, Irvine, CA, USA) are more than double the rates reported with previous generation SAPIEN and SAPIEN XT valves (8,20,21). The main reason for putting the focus on PVL rather than on new PPM may have come from the literature. Even in early trials, it became clear that more than mild PVL was associated with reduced survival (22,23). On the other hand, the prognostic impact of new PPM after TAVI remained controversial (24). Indeed, implantation of a new PPM has been associated with reduced survival in some studies (25), but not all (24,26,27). A meta-analysis has even found a trend toward a protective effect from cardiac death in the first year after the

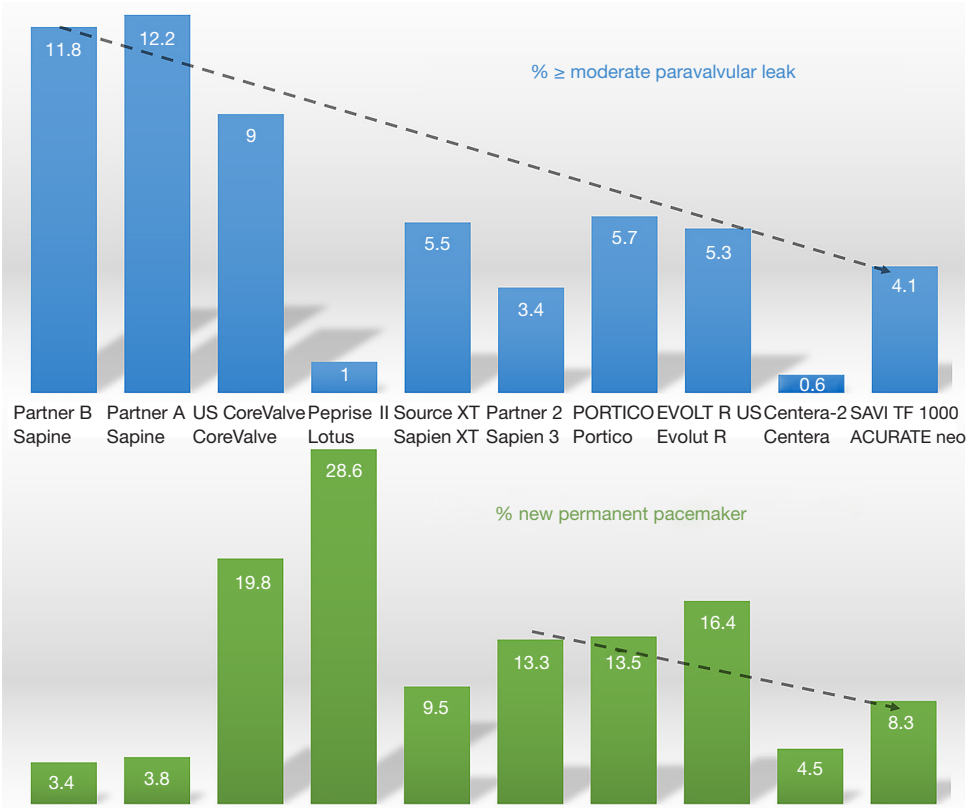

Figure 1 Evolution of paravalvular leak and need for a new permanent pacemaker after TAVI over time. Between 2011 and 2018, there was a clear trend towards reduced rates of paravalvular regurgitation. However, after the publication of PARTNER 1B and 1A, the rate of new permanent pacemakers remained high. Only some recently published registries finally yielded lower rates of new permanent pacemakers (8-17).

procedure (24). One possible explanation for this finding may be that implantation of a PPM may protect patients with conduction disorders from potential progression towards complete AVB (24,28). For instance, Auffret *et al.* recorded a pre-existing right bundle branch block (RBBB) in about 10% of TAVI recipients. Patients with an RBBB without a PPM at hospital discharge may be at especially high risk for high-degree AVB and sudden cardiac death during follow-up (29). Furthermore, evidence indicates that, similar to patients undergoing SAVR, about 50% of acquired conduction disorders after TAVI may resolve over time, and not all patients receiving a PPM may actually be paced during follow-up (30,31). However, it is clear that a low rate of conduction disorders, particularly LBBB and first degree AVB, and a low rate of new PPM facilitates in-hospital patient management, reduces the duration of in-hospital stay, costs, and might improve long-term prognosis (32).

Predictors of new conduction disorders

Several predictors for the need of a permanent pacemaker (PPM) have been identified. Some of them, such as a pre-existing RBBB, anatomical variability, the amount and distribution of calcification or LVOT stiffness, cannot be influenced by the TAVI operator (7,33). However, there are two main factors that offer the potential for optimization: the amount of trauma caused to the conduction system, and periprocedural management of medical therapy interacting with AV conduction (*Figure 2*).

Trauma to the conduction system

Parts of the conduction system, in particular the bundle of His and the left bundle branch, are located in immediate vicinity to the base of the non-coronary and right-coronary leaflets. This vicinity explains the occurrence of periprocedural conduction disorders. Electrophysiological

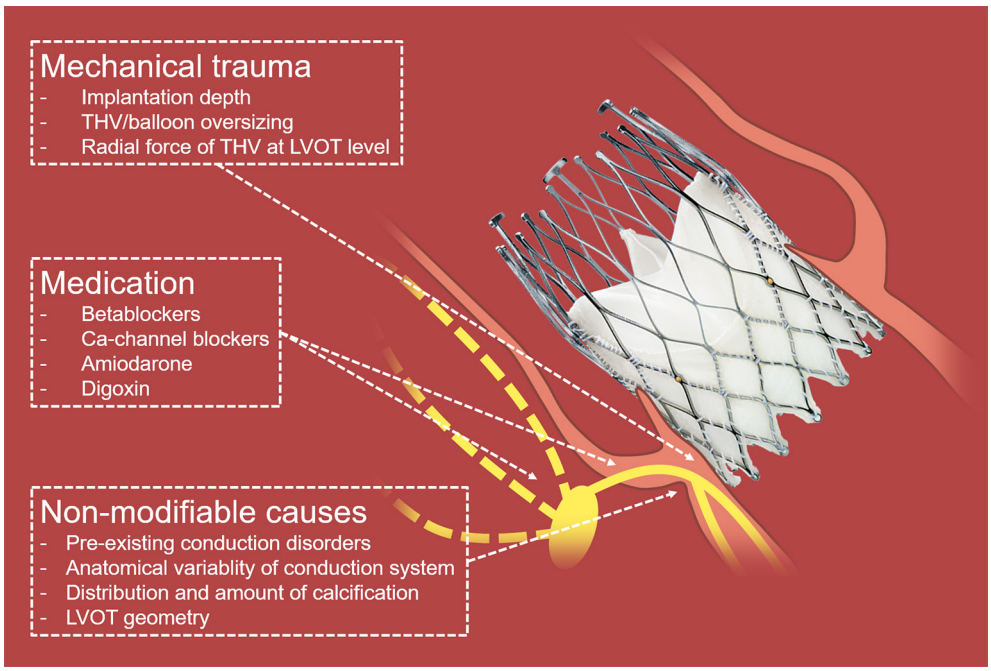

Figure 2 Modifiable and non-modifiable causes for conduction disorders after TAVI. Some causes and risk factors such as pre-existing conduction abnormalities are non-modifiable, but some can potentially be influenced by the TAVI operator, including the amount of trauma applied to the conduction system, and medical therapy potentially impairing AV conduction. In the picture, an Allegra transcatheter heart valve is shown (NVT GmbH, Hechingen, Germany).

studies performed after TAVI have shown damage to the AV node, the His, and the infra-His system (34). Of note, there is great anatomical inter-individual variability of the atrioventricular bundle. Some patients have a more right- and some a more left-sided atrioventricular bundle. Patients with a more left-sided atrioventricular bundle may be at a much higher risk for the development of high-degree AVB (7,35). As TAVI relies on oversizing to anchor the device within the native annulus and thus applies force to adjacent structures, many experts believe that PPM rates after TAVI will always be higher than the 3.6–7.1% observed after open heart surgery was carried out in potential TAVI candidates (9,10,22).

Basically, three major factors contribute to periprocedural mechanical trauma to the conduction system. These are (I) the choice of THV size and type, (II) the size of the balloon used for pre- and postdilatation, if any is used, and (III) the implantation technique (aiming to minimize trauma potentially caused to the annulus and the LVOT). One of the most consistently reported predictors for the occurrence of new conduction disorders is depth of prosthesis implantation. A higher implantation of the SAPIEN 3 or the CoreValve (Medtronic Inc., Minneapolis, MN, USA) has been associated with less PPM (36,37), but this may not be true for all THVs. Indeed, the ACURATE neo (Boston Scientific, Marlborough, MA, USA) may exhibit a lower radial force at the level of the LVOT and thus, it appears that implantation depth may not predict new PPM with this prosthesis (32). This may also explain the overall lower rate of PPM after implantation of the ACURATE neo (11,32,38,39). Furthermore, overexpansion of the LVOT by dilatation with a large balloon or implantation of an oversized prosthesis may increase the risk for conduction disorders and need for a PPM (25,40). Therefore, it is advisable to either omit predilatation or use a balloon that can be accommodated by the LVOT without overstretching the tissue.

Finally, the choice of THV plays a major role. Although there is a great amount of variability regarding the reported proportions of patients requiring implantation of a new PPM with a specific THV, it is clear that some THV such as the Lotus (Boston Scientific) have been associated with high rates of new PPM, whereas the ACURATE neo or more recently the Centera (Edwards Lifesciences) have

been associated with much lower PPM rates (12,41).

Relevance of medical therapy

There are numerous articles discussing mechanical trauma to the conduction system, but, to our knowledge, there is no evidence on how to manage medical therapy that has the potential to impair AV conduction in patients undergoing TAVI. However, we feel that this is of importance when we aim to achieve very low pacemaker rates. Negative dromotropic medication such as betablockers, non-dihydropyridine calcium channel blockers (verapamil), digoxin, or amiodarone should be stopped 1–2 days before TAVI. They should only be resumed once the ECG of the patient remains stable. In case the patient has atrial fibrillation with a fast ventricular conduction, this usually indicates preserved AV conduction. In such patients, it may be safe to restart negative dromotropic medication earlier after TAVI.

Summary

The need for a PPM remains an important and frequent problem of TAVI. There are two factors that have the potential for optimization: the amount of trauma caused to the conduction system, and periprocedural management of medical therapy affecting AV conduction. By optimizing these factors, we might finally be able to achieve a very low, surgical-like, rate of new PPM.

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Footnote

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