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CLINICAL INSIGHTS

NAVITOR™ TAVI SYSTEM

Minimizing PPI Risks

SUMMARY AND CONCLUSIONS

1. The need for implantation of a permanent pacemaker after TAVI is determined by multiple factors. Aspects increasing the risk for PPI include
   - The presence of a first-degree AV block or a RBBB.
   - An implant depth greater than the MS length.
   - And an implant depth greater than the recommended 3 mm target depth.[1]
2. An optimal fluoroscopic view of the valve orientation and implant depth can be obtained in the R-L cusp overlap view. This view provides a (nearly) parallax-free view of the aortic annulus plane and the delivery system, thereby facilitating optimal device placement and reducing the risk of post-TAVI PPI.[2]
3. Operators may need to go through a learning curve to achieve a low PPI rate.[3]
4. Using best implant practices, operators may achieve PPI rates of 10% or lower.[3] In particular, using the most optimal implantation view (R-L cusp overlap view) to achieve the 3 mm target implant depth appears to be a critical aspect of mitigating the risk of PPI.[2]

INTRODUCTION

A new onset conduction abnormality is a known complication of transcatheter aortic valve implantation (TAVI). Studies have reported multiple factors that may influence the need for post-procedural permanent pacemaker implantation (PPI), including aspects related to the patient, the device and the procedure. This paper discusses recently reported results obtained with the Navitor™ TAVI system in relation to PPI.

REASONS FOR PPI AFTER TAVI ARE MULTI-FACTORIAL

Analysis of the outcomes of the Navitor IDE Study showed that there are multiple causal factors contributing to the risk of post-TAVI conduction disturbances and PPI.[1,4]

This study is a prospective, single-arm multi-center study to evaluate the clinical safety and performance of the Navitor TAVI system.

From 26 sites across the U.S., Europe and Australia, the study included 260 patients with severe symptomatic aortic stenosis and high or extreme surgical risk. Outcomes were evaluated by an independent clinical events committee and an echocardiographic core laboratory.

Of the 232 pacemaker naïve patients, 44 patients (19.0%) had undergone PPI at 30 days after TAVI. Further analyses of these 30-day outcomes identified several factors that were correlated with PPI in the subgroup of pacemaker naïve patients.

Patients with a pre-existing first-degree AV block or right bundle branch block were approximately three times more likely to receive a new pacemaker after TAVI, compared to those without these conditions. Differences were statistically significant ($p < 0.0001$). In contrast, a left bundle branch block at baseline did not increase the risk for PPI (Figure 1).

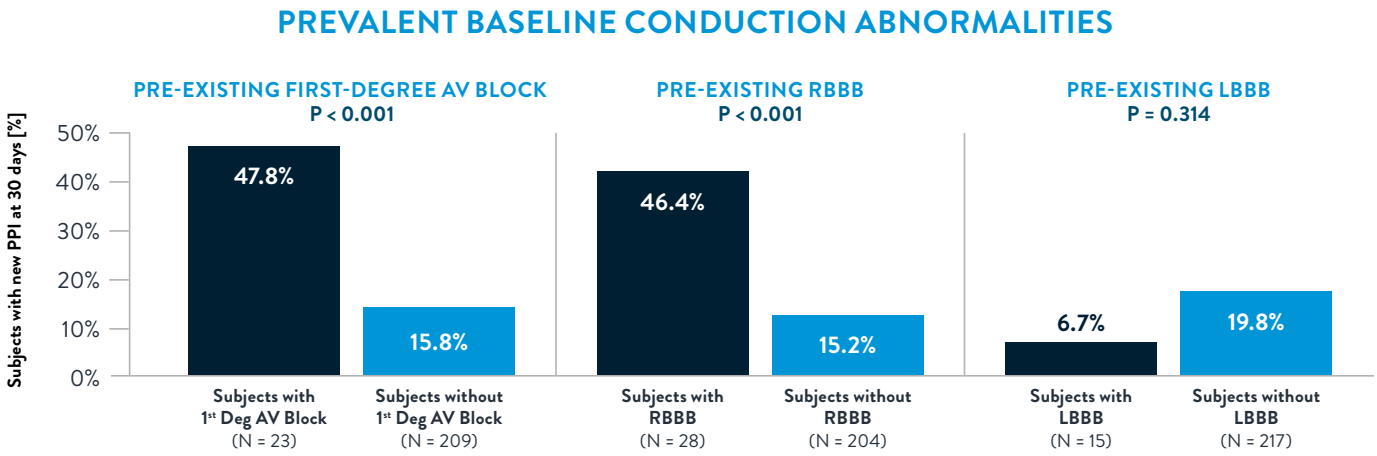

Figure 1: The need for PPI after TAVI in relation to pre-existing conduction disorders in the Navitor IDE Study. Analysis of 30-day outcomes in pacemaker naïve patients. The incidence of post-TAVI PPI was approximately three times higher in patients with 1st degree AV Block (AVB) or right bundle branch block (RBBB) than in those without. Left bundle branch block (LBBB) does not increase the incidence of PPI.

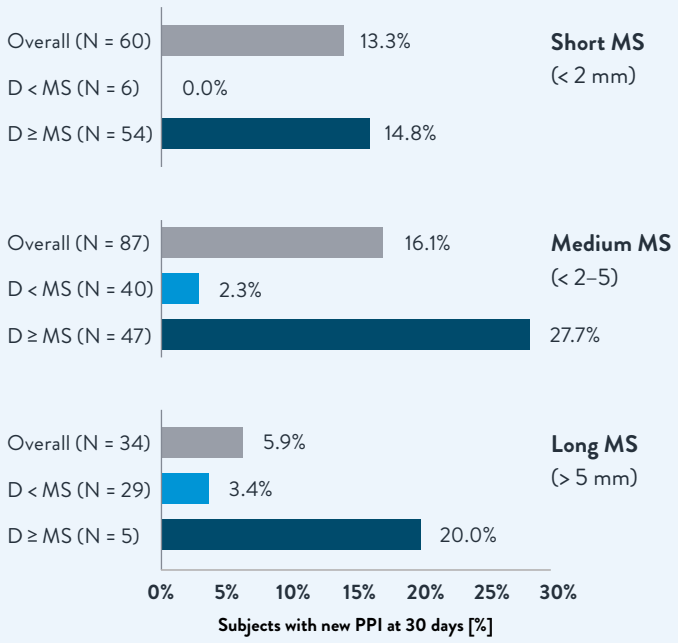

Figure 2: The need for PPI after TAVI in relation to the length of the membranous septum (MS) and implant depth (D) in the Navitor IDE Study, stratified per actual MS length. Analysis of 30-day outcomes in pacemaker naïve patients, excluding patients with pre-existing first-degree AV block or RBBB.

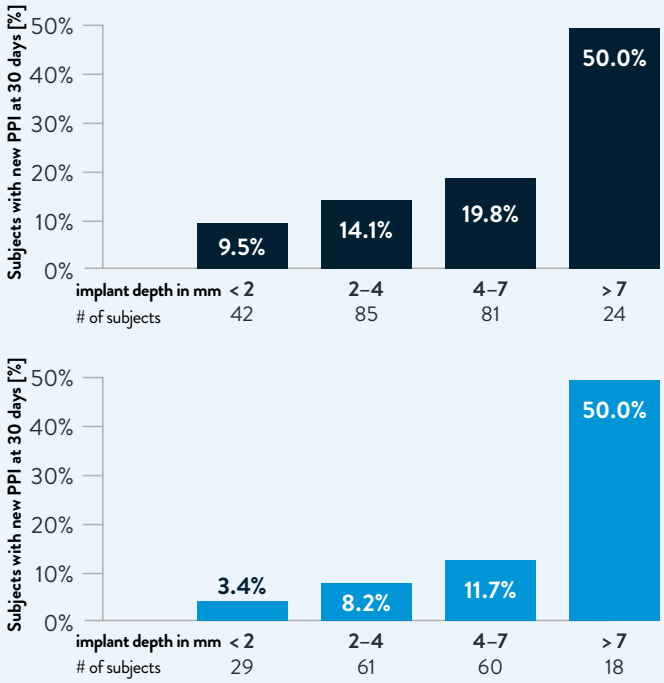

Figure 3: The need for PPI after TAVI in relation to achieved implant depth versus recommended target depth in the Navitor IDE Study. Analysis of 30-day outcomes in pacemaker naïve patients.

An anatomical aspect that is commonly recognized as a factor influencing the need for PPI after TAVI is the length of the membranous septum (MS) which separates the aortic annulus and the conduction system. An implanted valve that extends beyond the lower boundary of the MS may interfere with the conductive tissue and thus increase the risk of PPI. The critical relationship between MS length and implant depth was demonstrated by results of the Navitor IDE Study. Results showed that an implant depth equal to or greater than the MS length is a significant independent predictor of PPI (Figure 2). For this analysis, MS length was measured by CT and the implant depth was determined at the non-coronary cusp. Patients with a short or medium MS length (< 5 mm) have an increased risk for PPI compared to patients with relatively long MS length. Overall, an implant depth exceeding the MS length increases the risk of PPI. To avoid confounding effects of pre-existing first degree AV block and RBBB, patients with these conduction disorders were excluded from this analysis.

For the Navitor™ valve, a target implant depth of 3 mm is recommended. Results of the Navitor IDE Study were analyzed with respect to the achieved implant depth in relation to this target implant depth (Figure 3). For all pacemaker naïve patients (including those with and without pre-existing conduction disorders) the incidence of post-TAVI PPI increases with increasing implant depth. An implant depth less than or close to the 3 mm target depth is associated with PPI rates between 9.5% and 14.1%.

Similar observations are made in patients without pre-existing AV conduction disorders. In these patients an implant depth < 4 mm is associated with single digit PPI rates. These results underline the importance of achieving an implant depth as close as possible to the target depth, independent from patient-related aspects such as pre-existing conduction disorders or actual MS length.

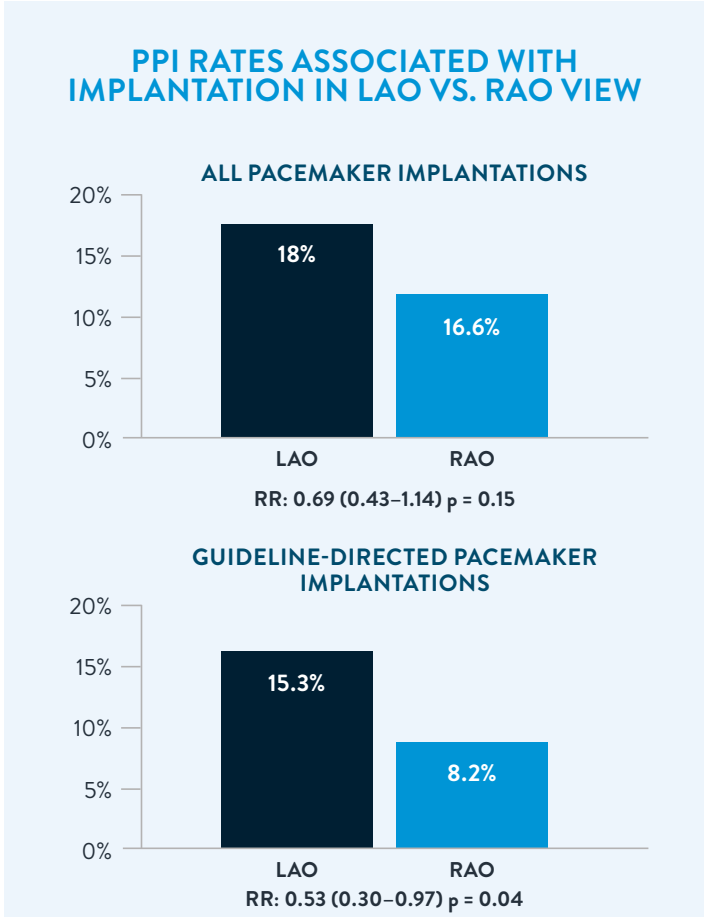

Figure 4: PPI rate at 30 days after TAVI, using an LAO or RAO implantation view. Propensity score matched groups. RR, relative risk with 95% confidence intervals.

LEFT/RIGHT CUSP OVERLAP VIEW PROVIDES OPTIMAL FLUOROSCOPY VIEW AND REDUCES THE RISK OF POST-TAVI PPI

Procedural approaches should be optimized to mitigate the risk of post-TAVI PPI. Among these aspects, fluoroscopic views utilized during valve implantation are reported to impact the PPI rate. A recent Danish study provided further insights regarding the effects of fluoroscopic views used for implantation of the Portico and Navitor valves.[2] The study included 544 consecutive pacemaker naïve patients with severe aortic stenosis undergoing TAVI using either an LAO view or a RAO view (corresponding to left/right cusp overlap view) during valve implantation. Analyses were performed on data from propensity score matched groups (LAO view versus RAO view) of 183 patients each. Matching accounted for age, sex, STS score, and the presence of pre-procedural RBBB, LVOT calcification and a bicuspid aortic valve.

The majority of implantation views in the LAO group were obtained in an LAO-caudal (CAU) projection, while implantation views in the RAO group were mostly obtained in an RAO-CAU projection. With an LAO implantation view, the aortic annulus plane was significantly more tilted than with an RAO implantation view (median: 23° vs 0°, p < 0.001). In the R-L cusp overlap view the left and right coronary cusps overlap and a parallax-free in-plane view of the aortic annulus is obtained. This view also provided a parallax-free view of the delivery system in nearly 60% of the cases in the RAO group.

The RAO group showed a trend towards a lower PPI rate at 30 days after TAVI, compared to the LAO group (12.6% vs. 18.0%, relative risk: 0.69, 95% CI: 0.43–1.14, p = 0.15, Figure 4). The 30-day rate of guideline-directed PPI was significantly lower in the RAO group compared to the LAO group (8.2% vs. 15.3%, relative risk: 0.53, 95% CI: 0.30–0.97, p = 0.04).

The authors provided further discussion as to how an RAO view, and more specifically the R-L cusp overlap view, may help reducing the risk of PPI. Ideally, the implantation view should provide a parallax-free view of the aortic annulus plane as well as the delivery system. This provides the best conditions to evaluate the implant orientation and depth. While this is typically achieved in an RAO-CAU projection, there is only a single combination of RAO and CAU angles providing a parallax-free view of both the annulus plane and the delivery system. The R-L cusp overlap view coincides with, or is close to this unique RAO-CAU projection and may be achieved by using the coronary cusps as anatomical landmarks.

OCEAN-TAVI REGISTRY: MORE EXPERIENCE RESULTS IN LOWER PPI RATES

The OCEAN-TAVI Registry is an ongoing Japanese multicenter registry. Data collected in this registry was analyzed with respect to several outcomes, including PPI.[3] The study included 463 patients implanted with the Navitor™ TAVI valve. At enrollment, 30 patients (6.4%) had a permanent pacemaker, and 32 patients (6.9%) had a pre-existing RBBB.

A new permanent pacemaker was implanted in 45 patients (10.4% of 433 pacemaker naïve patients). In their early experience (first 50% of all cases per institution) operators achieved a PPI rate of 13.0%, while after gaining more experience (second 50% of all cases per institution) a PPI rate of 8.0% was achieved (Figure 5). These results suggest that experience with the Navitor valve and proctoring with regard to device-specific implantation techniques may help to reduce the PPI rate.

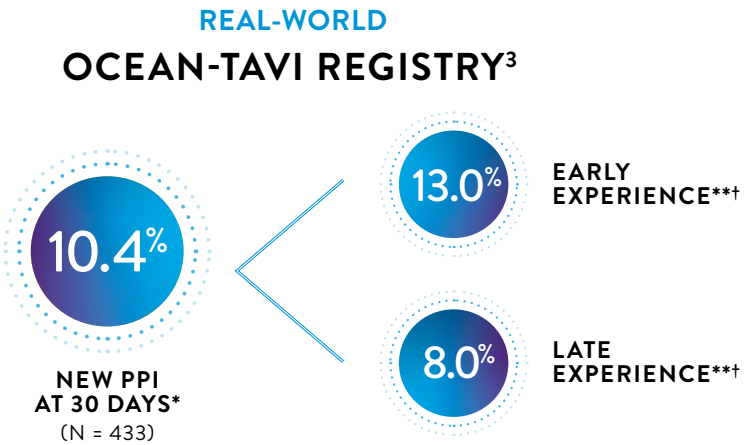

Figure 5: PPI rate at 30 days after TAVI in the OCEAN-TAVI Registry.
*Excludes patients with a pacemaker at baseline.
**Early experience defined as first half of cases, late experience as last half of cases in each institution.
†In pacemaker naïve patients.

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Important Safety Information

NAVITOR™ TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM

INDICATIONS

The Navitor™ Transcatheter Aortic Valve Implantation System is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).

CONTRAINDICATIONS

The valve is contraindicated for patients with inability to tolerate antiplatelet/anticoagulant therapy or nitinol alloy (nickel and titanium), or who have active infections, including endocarditis.

POTENTIAL ADVERSE EVENTS

Adverse events potentially associated with the use of transcatheter bioprosthetic heart valves include but are not limited to: access site complications (e.g., pain, bleeding, infection, hematoma, pseudoaneurysm, etc.); acute coronary obstruction; acute myocardial infarction; allergic reaction to antiplatelet agents, contrast medium, or valve components; aortic rupture; ascending aorta trauma; atrio-ventricular node block; cardiac arrhythmias; conduction system injury; conversion to open surgical procedure; death; dissection; embolism; emergent balloon valvuloplasty; emergent percutaneous coronary intervention (PCI); emergent surgery (i.e., coronary artery bypass, heart valve replacement); endocarditis; explantation; heart failure; hemodynamic compromise; hemolysis; hemolytic anemia; hemorrhage; hypotension or hypertension; infection; myocardial ischemia; mitral valve insufficiency; multi-organ failure; non-structural dysfunction (i.e., entrapment by pannus, paravalvular leak, inappropriate sizing or positioning); pannus; pericardial effusion; perforation of the myocardium, ventricle, or a blood vessel; permanent disability; permanent pacemaker; regurgitation; renal insufficiency or renal failure; reoperation; respiratory failure; sepsis; stroke; structural deterioration (i.e., calcification, leaflet tear); thrombosis; tamponade; transfusion; valve embolization or migration; vessel dissection or spasm.

REFERENCES

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4. Reardon M et al. 30-Day Clinical Outcomes of a Self-Expanding Transcatheter Aortic Valve: The International PORTICO NG Study. J Am Coll Cardiol Intv 2023;16(6):681-689.

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