Clinical Insights

ABBOTT TAVI VALVE

ACHIEVING LOW PERMANENT PACEMAKER IMPLANTATION (PPI) WITH THE ABBOTT TAVI VALVE

PERFORMANCE OF THE ABBOTT TAVI PLATFORM

Current ACC (American) and ESC (European) guidelines propose: Patients with severe aortic stenosis at high/extreme surgical risk should be treated with TAVI, patients at intermediate risk can be treated with either SAVR or TAVI depending on patient suitability and choice, and patients at low risk are still recommended to pursue SAVR given long-term durability data (>5 years) for TAVI is limited.[1,2]

Post-TAVI permanent pacemaker implantation (PPI) has been reported to be associated with longer index hospitalizations, more repeat hospitalizations, impaired LVEF recovery post-TAVI and lower LVEF at longer term, and possibly higher mortality rates.[3-6]

This Clinical Insights will present PPI rates for Abbott Transcatheter Heart Valves, as well as examine factors that can reduce the need for PPI post-TAVI.

MITIGATING THE RISK OF POST-TAVI PPI

Studies show that the strongest electrocardiographic (ECG) predictors of post-TAVI PPI are:[3,6-8]

- Preexisting right bundle branch block (RBBB)
- Preexisting first degree atrioventricular (AV) block

Clinicians should also consider several factors:[7]

- Anatomic structure: The bundle of His is located just below the membranous septum (MS). When the valve is implanted deep and interacts with the bundle of His this may disrupt the electrical conduction system in the heart. Therefore, patients with a short MS have a higher likelihood of the valve causing post-TAVI AV block leading to the need for PPI.[9]
- Implant depth: Deeper valve implantation is more likely to impact the heart's conduction system, leading to an increased likelihood of post-TAVI PPI.[8,10-13]

A Journal of the American College of Cardiology Scientific Expert Panel published an expert consensus proposing a more uniform approach to mitigate the risk of post-TAVI PPI:[8]

- Assess pre-procedure ECGs, since conduction issues are often present pre-TAVI and may be associated with increased of post-TAVI PPI.
- Position THVs higher in the native valve since this is associated with fewer conduction disturbances post-TAVI; for Abbott TAVI valves, an implant depth of 3 mm is recommended.[14]
- Avoid valve oversizing.

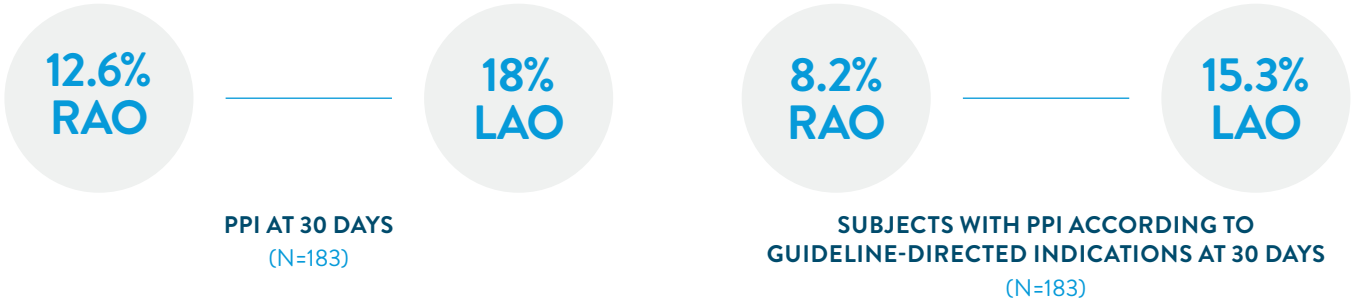
Clinical studies suggest that a single-digit rate of new PPI with Abbott TAVI valves is achievable when implanting at a target depth of 3 mm.[11,13,15-17]

COPENHAGEN OBSERVATIONAL STUDY[15]
PPI RATES AND IMPLANT TECHNIQUE RELATED TO RAO & LAO VIEWS

Evaluating: PPI rates when using right anterior oblique (RAO)/caudal and left anterior oblique (LAO) views with the Abbott TAVI valve.

Study Type: Retrospective study of consecutive TAVI patients without preprocedural pacemaker, with 183 patients prospensity matched in each group—RAO view and LAO view.

30-Day Findings: When using the right–left (R–L) cusp overlap (RAO) view vs the conventional LAO view, there was a clear trend toward a lower PPI rate: 12.6% PPI with RAO vs 18.0% PPI with LAO. Also, the proportion of subjects with PPI according to guideline-directed indications* was lower: 8.2% with RAO vs 15.3% with LAO.



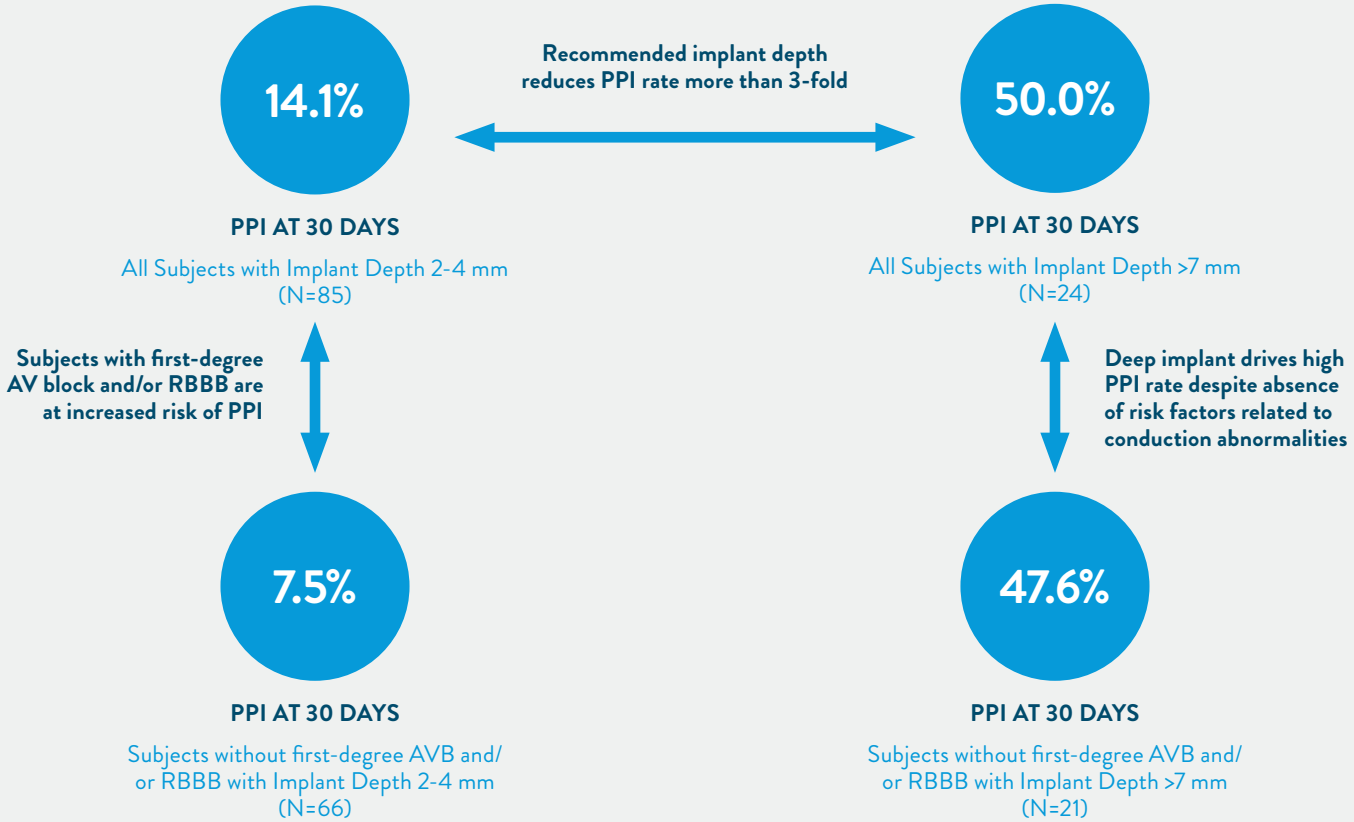
* Guideline-directed PPMI indication was defined as third degree AVB, second-degree AVB type 2, and severe bradycardia/junctional rhythm.

NAVITOR VALVE™ IDE STUDY[13]
TARGET IMPLANT DEPTH FOR LOWER RISK OF PPI

Evaluating: PPI rates with the Navitor valve in the Navitor IDE Study.

Study Type: Navitor valve US IDE regulatory approval study. Prospective, global, multi-center study with 260 patients at high or extreme surgical risk.

30-Day Findings: PPI rates are influenced by preexisting AV conduction† abnormalities (noted in 34% of subjects) and implant depth relative to MS length. Implantation depth less than MS length reduces risk of new PPI.



† Preexisiting AV conduction abnormalities include AV block (1st, 2nd, and 3rd), left anterior fascicular block, left bundle branch block, and right bundle branch block.

CONFIDENCE REGISTRY[10]
OPTIMAL IMPLANT DEPTH

12.6%

PPI AT 30 DAYS
For 2-4 mm Implant Depth
(N=261)

Evaluating: The first-generation Abbott TAVI valve with the first-generation Delivery System (DS) vs the second generation FlexNav™ DS.

Study Type: Prospective, multi-center, nonrandomized, real-world study at 28 centers; of the 1,001 patients, half were implanted using the second-generation FlexNav DS.

30-Day Findings: Data on the first-generation Abbott TAVI valve, with the second-generation FlexNav DS, reveal that an implant depth of 2-4 mm produced the lowest PPI rates, and PPI increased with greater implant depth.

OPTECH STUDY[11]
OPTIMAL IMPLANT DEPTH

6.3%

PPI AT 30 DAYS
for 3-5 mm Implant Depth
(N=49)

Evaluating: Valve sizing and implant depth of the first-generation Abbott TAVI valve.

Study Type: A substudy of a first-generation Abbott TAVI valve registry with 277 patients.

30-Day Findings: PPI at optimal implant depth was 6.3%.

MULTI-CENTER AUSTRALIAN OBSERVATIONAL STUDY[16]
FIRST-GENERATION ABBOTT TAVI VALVE

Evaluating: The safety and efficacy of the first-generation Abbott TAVI valve at 30 days; comparative data for Abbott's first-generation DS and second-generation FlexNav DS.

Study Type: Retrospective, real-world cohort of 269 all comer patients (mean age 82.1 years).

30-Day Findings: Data on first-generation Abbott TAVI valve, with 2nd generation FlexNav DS, demonstrated a PPI rate of 9.2% compared to data on the first generation Abbott TAVI valve with first-generation DS PPI rate of 10.2%

9.2%†

PPI FOR FIRST-GENERATION ABBOTT TAVI VALVE WITH 2ND GENERATION FLEXNAV DS
(N=65)

10.5%†

PPI FOR FIRST-GENERATION ABBOTT TAVI VALVE WITH 1ST GENERATION DS
(N= 200)

RISPEVA REGISTRY[17]
EXPERIENCE WITH THE NEXT-GENERATION NAVITOR™ DEVICE

2.9%

PPI AT 30 DAYS
(N=35)

Evaluating: Procedural and early clinical outcomes of patients undergoing TAVI with the next-generation Navitor device

Study Type: Prospective observational study (data from the ongoing RISPEVA registry) from 39 consecutive patients of whom 35 had no preprocedural pacemaker.

30-Day Findings: Only one (2.9%) patient required permanent pacemaker implantation.

† Includes patients with pacemakers at baseline

CONCLUSION

Clinicians can often minimize the need for post-TAVI PPI by evaluating factors such as the following.

Technique:

- Lower PPI rates are associated with shallower implant depth[10,11,13] (Navitor recommended implant depth: 3 mm).
- When implanting a Navitor™ valve, the use of an RAO view —vs the LAO view—reduces the risk of post-TAVI PPI.[15]
- Single-digit PPI rates are achievable with the Navitor valve[11,13,15,16,17], particularly when complying with the recommended implant depth and using RAO view.

Anatomic Structure: A shorter MS increases the risk of interference of the valve with the conduction system.[9]

As TAVI continues to expand into younger and lower risk patient populations, it is important to examine ways to reduce PPI, and to be cognizant of the PPI rates of currently used THVs.

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