Abbott

CLINICAL INSIGHTS

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 that patients with severe AS at high/extreme risk should go TAVI, patients at intermediate risk can go 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.[2,3]

When post-TAVI permanent pacemaker implantation (PPI) is needed, it is associated with longer hospitalizations, more repeat hospitalizations, and adverse results such as higher mortality rates.[4-7,16]

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

UNDERLYING CONDUCTION SYSTEM DISEASE

Studies show that the strongest electrocardiographic (ECG) predictors of post-TAVI PPI are:[4-16]

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

Clinicians should also consider several factors:[8]

- Anatomic structure, the likelihood of implanting deeper than the membranous septum is higher when the membranous septum is shorter, which is predictive of high-degree AV block[9]
- Implant depth, since there's an increase in PPI with valve implantation depth[10-13,17]

Post-TAVI PPI can be predicted by certain baseline conduction abnormalities.[14-16]

Because there is intervariability in post-TAVI PPI rates among centers, as well as clinical studies, a JACC Scientific Expert Panel published guidelines for a more uniform strategy:[13]

- Assess pre-procedure ECGs since conduction issues are often present pre-TAVI.
- Position Transcatheter Heart Valves (THVs) higher in the native valve since this is associated with fewer conduction disturbances post-TAVI; for Abbott TAVI valves maintain an implant depth of 3 mm.[17]
- Know the most recent THV PPI rates since some newer devices have lower PPI rates.
- Avoid valve oversizing.

Importantly, many TAVI studies report the incidence of new PPI as a proportion of the entire study population, which includes patients with preexisting PPI.[7] This reduces the true rate of new PPI following TAVI since patients with preexisting PPI would be ineligible to receive a new pacemaker.

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 following a straightforward implant technique.[1,10,11,18,19]

PPI RATES AND IMPLANT TECHNIQUE RELATED TO RAO & LAO VIEWS[1]

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, 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. And when using guideline-directed PPI indications, the PPI rate was lower: 8.2% PPI with RAO vs 15.3% PPI with LAO.

12.6% RAO
PPI at 30 Days
(N=183)

18% LAO
PPI at 30 Days
(N=183)

All PPI

8.2% RAO
PPI at 30 Days
(N=183)

15.3% LAO
PPI at 30 Days
(N=183)

Guideline directed PPI*

NAVITOR US IDE REGULATORY APPROVAL STUDY: TARGET IMPLANT DEPTH FOR LOWER RISK OF PPI[18]

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

Study Type: Prospective, global, multi-center study with 260 patients at high or extreme surgical risk.

30-Day Findings: PPI rates are influenced by implant depth (target depth is 3 mm) and preexisting AV conduction abnormalities (noted in 34% of subjects). Implantation depth less than MS length reduces risk of new PPI.

14.1%
PPI at 30 Days
Overall for Implant Depth
2-4 mm
(N=85)

~50% reduction in PPI in subjects at optimal depth without AV block or RBBB

7.5%
PPI at 30 Days
Subjects without 1st degree AV block and/or RBBB for Implant Depth
2-4 mm
(N=66)

50.0%
PPI at 30 Days
Overall for Implant Depth
>7 mm
(N=24)

Deep implant drives high PPI rate despite no presence of conduction abnormalities known to be associated with new PPI

47.6%
PPI at 30 Days
Subjects without 1st degree AV block and/or RBBB for Implant Depth
>7 mm
(N=21)

CONFIDENCE REGISTRY[10]

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.

12.6%
PPI at 30 Days
For 2-4 mm Implant Depth
(N=261)

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

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**.
Always check the regulatory status of the device in your region.

OPTECH RESULTS: OPTIMAL IMPLANT DEPTH[11]

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

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

30-Day Findings: PPI at optimal implant depth as follows:

6.3%
PPI
for 3-5 mm Implant Depth
(N=49)

MULTI-CENTER AUSTRALIAN OBSERVATIONAL STUDY: FIRST-GENERATION ABBOTT TAVI VALVE[19]

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).

30-Day Findings: PPI data on 265 patients.

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)

EXPERIENCE WITH THE "NOVEL NAVITOR™ [VALVE][20]

Evaluating: The Navitor Valve

Study Type: Prospective observational study (data from the ongoing RISPEVA registry) from 39 consecutive patients.

2.9%
PPI at 30 Days
(N=39)

CONCLUSION

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

Technique: Since data show the following:

- Lower PPI rates are associated with shallower implant depth[10,11,18]
- When implanting a Navitor™ valve, an RAO view—vs the LAO view—results in a guideline directed PPI rate in the single digits[1]

Anatomic Structure: The likelihood of implanting deeper than the membranous septum is higher when the membranous septum is shorter, which is predictive of high-degree AV block[9]

Choice of THV: Since different THVs are associated with differing rates of PPI

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.

† Includes patients with pacemakers at baseline

REFERENCES

1. Wang X, Wong I, Bajoras V, et al. Impact of implantation technique on conduction disturbances for TAVR with the self-expanding Portico/Navitor valve. Catheter Cardiovasc Interv. 2022;1-11.
2. Otto CM, Nishimura RA, Bonow RO, et al. . 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2021 Feb 2;143(5):e35-e71.
3. Vahanian A, Beyersdorf F, Praz F, et al. ESC/EACTS Scientific Document Group. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. 2022 Feb 12;43(7):561-632.
4. 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 TraNscathertER Valves) trial and registry. JACC Cardiovasc Interv. 2015;8:60-69.
5. Dizon JM, Nazif TM, Hess PL, et al. Chronic pacing and adverse outcomes after transcatheter aortic valve implantation. Heart. 2015;101(20):1665-1671.
6. Mohananey D, Jobanputra Y, Kumar A, et al. Clinical and echocardiographic outcomes following permanent pacemaker implantation after transcatheter aortic valve replacement: meta-analysis and meta-regression. Circ Cardiovasc Interv. 2017;10(7):e005046.
7. Chen S, Chau KH, Nazif TM. The incidence and impact of cardiac conduction disturbances after transcatheter aortic valve replacement. Ann Cardiothorac Surg. 2020;9(6):452-467.
8. Sharma R, Sharma RP. Permanent pacemaker implantation after TAVR. Card Interv Today. 2019;13(2):79-83.
9. Hamdan A, Guetta V, Klempfner R, et al. Inverse relationship between membranous septal length and the risk of atrioventricular block in patients undergoing transcatheter aortic valve implantation. JACC Cardiovasc Interv. 2015;8(9):1218-1228.
10. Möllmann H. CONFIDENCE Registry: Valve hemodynamics and 1-year survival following implantation of the PorticoTM Valve. Presented at: TCT; September 16-19, 2022; Boston, MA.
11. Taramasso M. , Maisano F, Worthley S, et al. Optimal sizing and implant depth of the Portico™ Valve: OpTech results, a substudy of the Portico I trial. Presented at: PCR London Valves Conference; November 22-24, 2020; London, England.
12. Sammour Y, Banerjee K, Kumar A, et al. Systematic Approach to High Implantation of SAPIEN-3 Valve Achieves a Lower Rate of Conduction Abnormalities Including Pacemaker Implantation. Circ Cardiovasc Interv. 2021 Jan;14(1):e009407.
13. Rodés-Cabau J, Ellenbogen KA, Krahn AD, et al. Management of conduction disturbances associated with transcatheter aortic valve replacement: JACC Scientific Expert Panel. J Am Coll Cardiol. 2019;74(8):1086-1106.
14. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med. 2010;363(17):1597-1607.
15. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. 2011;364:2187-2198.
16. Adams DH, Popma JJ, Reardon MJ, et al. Transcatheter aortic valve replacement with a self-expanding prosthesis. N Engl J Med. 2014;370:1790-1798.
17. Navitor™ TAVI System IFU.
18. Sultan I., Predictors and trends of new permanent pacemaker implantation in the Navitor IDE study. Presented at: TVT 2023, June 7-10, 2023, Phoenix, AZ.
19. Camuglia AC, Cole CM, Boyne N, et al. 30-day outcomes with the Portico transcatheter heart valve: insights from a multi-centre Australian observational study. Heart Lung Circ. 2022:S1443-9506(22)01124-6.
20. Corcione N, Berni A, Ferraro P, et al. Transcatheter aortic valve implantation with the novel-generation Navitor device: procedural and early outcomes. Catheter Cardiovasc Interv. 2022;100(1):114-119.

Abbott

3200 Lakeside Dr., Santa Clara, CA. 95054 USA

www.structuralheart.abbott

Abbott