

# Concomitant Electrophysiological Study with Transcatheter Aortic Valve Implantation to Predict Risk of Atrioventricular Block

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## ABSTRACT

**Introduction:** Data on the impact of left bundle-branch block after transcatheter aortic valve implantation (TAVI) are scarce, and treatment has been individualized. Based on this, the electrophysiological study (EPS) concomitant with TAVI may be a strategy for the early stratification of patients needing permanent pacemaker implantation (PPM). **Objective:** To describe the use of EPS in risk stratification of a definitive pacemaker in patients undergoing TAVI. **Materials and methods:** Data from seven patients with indications for TAVI due to critical aortic stenosis were retrospectively evaluated. The EPS was performed with a quadripolar diagnostic catheter in His bundle to measure the His-ventricle (HV) interval. Measurement of HV at 70 ms or above was used for discussion on PPM implant indication. **Results:** Four analyzed patients evolved with left bundle-branch block after TAVI. PPM implantation was indicated for one patient, and the surgery was performed uneventfully during the same hospital stay. Before TAVI, the HV interval ranged from 46 to 58 ms (mean = 53.2 ms), increasing to 52 to 84 ms (mean = 62.8 ms) immediately after valve intervention. **Conclusion:** The strategy of EPS during TAVI is viable to stratify patients early according to the risk of 2nd or 3rd-degree atrioventricular block, allowing adequate treatment.

**KEYWORDS:** Atrioventricular block; Bundle-branch block; Death, sudden; Syncope; Aortic valve.

## INTRODUCTION

Aortic stenosis (AS) is a disease that results from the narrowing of the aortic valve with a progressive increase in flow and pressure gradient between the left ventricle and the aorta, generating the classic triad of symptoms: syncope, dyspnea and angina. The etiology of this condition may be the primary involvement of the aortic valve (such as the degenerative

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ones, the leading cause in Brazil), congenital (bicuspid aortic valve) or secondary to rheumatic fever. When indicated, the treatment can be surgical or percutaneous with transcatheter aortic valve implantation (TAVI)<sup>1,2</sup>.

TAVI has become an increasingly common reality in frail patients and those with high cardiovascular risk and other risk spectrums, such as intermediate-risk and low-risk patients, the latter being approved by the Food and Drug Administration in 2019. North American data show that since 2011 the annual number of TAVI has grown progressively, with a peak in 2016, the year in which it was released for intermediate-risk patients, and the highest peak occurred in 2019 when it arrived to surpass open surgery in some new cases (72,991 versus 57,626)<sup>3-7</sup>.

The technical and scientific improvement acquired with the advancement of experience corroborated the reduction of in-hospital mortality from 5.4 to 1.3% and mortality in 30 days from 7.2 to 2.5%. The main complications reported are vascular (bleeding, arteriovenous fistulas and pseudoaneurysms), acute kidney injury secondary to the use of contrast, stroke, left bundle branch block (LBBB) and total atrioventricular block (TAVB) requiring permanent pacemaker implantation (PPM). As the technology related to the procedure was improved, vascular complications declined with a reduction in the arterial sheath and the choice of access with a lower risk of bleeding, such as the femoral route, compared to the other routes (subclavian and abdominal aorta). On the other hand, electrophysiological complications (LBBB and TAVB) remained stable, affecting an average of 27% of patients with an incidence of the need for PPM implantation after TAVI ranging from 8 to 33% (depending on the prosthesis and technique used)<sup>8-10</sup>.

The conduction system disorders arise due to the proximity between the aortic valve complex and the bundle of His, the left branch and the valve annulus. His ventricular (HV) conduction injury may occur during native valve ballooning, during or after prosthesis release, and its main risk factors are a previous disease of the conduction system, right bundle branch block, direct intraprocedural mechanical trauma or even an inflammatory process resulting from the procedure. Independent predictors of LBBB are advanced age, male gender, and increased QRS duration. The predictive factors for a pacemaker were the presence of a previous right bundle branch block (RBBB) or left anterior hemiblock, with a 1st-degree atrioventricular block (AVB). There was also a relationship with the CoreValve<sup>®</sup> prosthesis (Medtronic, Minneapolis, United States) and the use of balloon<sup>11,12</sup>.

Risk assessment for the development of TAVB can be performed by the presence of a new post-procedure LBBB or by measuring the HV interval, evidencing the delay in this conduction. The presence of syncope is a clinical manifestation secondary to low TAVB output. The measurement can be performed with a quadripolar diagnostic catheter, positioned in the bundle of His to measure the HV interval, and measurements equal to or greater than 70 ms are related to a greater risk of complete blockage of this pathway, indicating the implantation of PPM in this patients<sup>13</sup>.

To reduce the patient's exposure to unnecessary monitoring or invasive procedures, the concept of minimalist TAVI emerged, whose practice has an average duration of less than two hours, avoiding general anesthesia in favor of alternative strategies ranging from sedation to local anesthesia, using low doses contrast, with patients being monitored by transthoracic echocardiogram, angiography of the femoral and iliac arteries to assess access complications and temporary pacemaker removed in the room or within 24 hours. Thus, medical discharge occurs within 48 to 72 hours, depending on hemodynamic stability and the post-procedure electrocardiographic pattern, with or without the appearance of a new bundle branch block or the presence of TAVB. This strategy reduces the patient's immobilization time, accelerating their recovery and discharge. It is estimated that 60-70% of patients can receive the minimalist approach, and up to 72% can be discharged within three days of the procedure<sup>14</sup>.

In line with the minimalist TAVI concept, tools are needed to identify the subgroup of patients at higher risk of developing late conduction disorders. While the guidelines are pragmatic for patients with 2nd or 3rd-degree AV block, there is no consensus for patients who develop LBBB, ranging from clinical follow-up and further evaluations with electrophysiological studies (EPS) to installing implantable loopers. In this sense, the invasive assessment of atrioventricular conduction disorders with HV measurement during TAVI can predict early those patients at risk of developing TAVB, allowing an approach with PPM, not delaying discharge within the stipulated period, without significant complications being related<sup>14</sup>. That is, therefore, the objective of this study.

This series of cases was approved by the Research Ethics Committee of the Hospital de Urgências de Goiás, linked to Plataforma Brasil, under the number of the Presentation Certificate of Ethical Appreciation 55966122.3.0000.0033.

## MATERIALS AND METHODS

The study encompassed a retrospective series of seven patients with severe AS (valve area < 0.8 cm<sup>2</sup>) who underwent TAVI concomitantly with EPS with HV measurement, at Encore Hospital (Aparecida de Goiânia, Goiás), between January 2020 and December 2021. Patients whose medical records were incomplete were excluded. The criterion for indicating the procedure was the presence of anatomically severe AS, associated or not with symptoms, in patients with low, medium or high operative risk. The therapeutic decision was shared by a multidisciplinary team composed of a clinical cardiologist, an interventional cardiologist and a cardiac surgeon.

The initial assessment of patients who are candidates for TAVI required Doppler echocardiography to assess severity and anatomy; coronary angiography to rule out severe coronary artery disease requiring pre-TAVI angioplasty; CT angiography of the thoracic and abdominal aorta to anatomically evaluate the feasibility of the procedure by analyzing the aortic caliber; diameter of the valve annulus to determine the size of the prosthesis; and the height of the implant in relation to the coronary anatomy to avoid ischemic complications. After planning, the execution of the procedure was performed by a certified professional using the standardized technique for access via the right femoral artery. The prostheses used were the third generation of Sapien® and CoreValve Evolut®. A temporary pacemaker electrode was introduced at the beginning of the procedure via the left femoral artery to achieve rapid pacing during device release. In this same access (left femoral), a quadripolar catheter was inserted to quantify the conduction intervals (ms): PR, QRS, PA, AH and HV (Fig. 1).

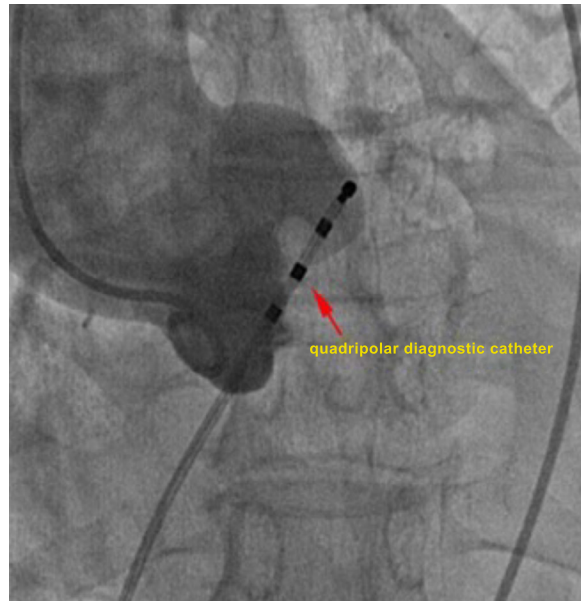


Figure 1. Fluoroscopic image of quadripolar catheter placement to quantify conduction intervals in the cardiac cycle.

Data were presented descriptively, using absolute and/or percentage variables, to describe a new approach for these patients susceptible to AVB and the main factors associated with the development of electrophysiological complications.

## RESULTS

Seven patients were evaluated: three females and four males. The mean age was 79.8 years (ranging from 72 to 90 years), and the mean body mass index (BMI) was 23.3 kg/m<sup>2</sup>. Two patients were classified as overweight, and one as underweight.

In the pre-procedure electrocardiographic evaluation, all patients were in sinus rhythm, and only one had LBBB. After TAVI, three new patients developed LBBB on the electrocardiogram, accounting for four patients with LBBB. In the invasive evaluation of myocardial impulse propagation velocities, the pre-procedure HV measurement varied between 48 and 58 ms (mean =  $53.2 \pm 4.7$  ms), and after TAVI, it varied between 52 and 84 ms (mean =  $62.8 \pm 11.7$ ms). Only one patient required PPM implantation before hospital discharge by measuring the HV interval. In this case, the pre-HV interval was 56 ms; after TAVI, it was 70 ms.

The prostheses implanted were Sapien® in five patients (size 21 to 25) and Evolut® (size 29 to 34) in the others, some requiring pre-and/or post-dilation. Due to the higher risk of LBBB, self-expanding prostheses (CoreValve®) were not used.

All EPSs were performed in the left femoral vein, the same place where the temporary pacemaker was inserted. No EPS-related complications have been described, with no significant extension in procedure duration.

There were two non-fatal complications, one with the migration of the prosthesis and the need for valve-in-valve implantation with a satisfactory resolution, and the other with the presence of paravalvular leak and resolution after placement of a plug with total occlusion of the leak. Only one in-hospital death has been described, whose etiology was due to infectious complications from the coronavirus.

Table 1 presents the primary data of the individuals included in the research.

**Table 1.** Quantitative analysis of patients.

|   | Prosthesis      | Year of TAVI | Age (years) | Gender | pre-LBBB or RBBB | post-LBBB or RBBB | pre QRS width | post QRS width | HV pre (ms) | HV post (ms) | Pre-dilation | Post-dilation | PPM | Complications during the procedure |
|---|-----------------|--------------|-------------|--------|------------------|-------------------|---------------|----------------|-------------|--------------|--------------|---------------|-----|------------------------------------|
| 1 | Sapien® 26 (-2) | 2020         | 78          | F      | No               | No                | 81            | 90             | 55          | 52           | Yes          | No            |     |                                    |
| 2 | Evolut® 34      | 2020         | 77          | M      | No               | LBBB              | 86            | 86             | 58          | 84           | No           | No            |     | Prosthesis migration VIV           |
| 3 | Evolut® 29      | 2020         | 86          | M      | No               | No                | 74            | 74             | 46          | 54           | Yes          | No            |     |                                    |
| 4 | Sapien® 23 (+1) | 2020         | 78          | M      | No               | LBBB              | 92            | 92             | 52          | 58           | No           | No            |     | Significant leak*                  |
| 5 | Sapien® 23 (-2) | 2020         | 83          | F      | LBBB             | LBBB              | 124           | 124            | 58          | 68           | No           | No            |     |                                    |
| 6 | Sapien® 26 (-1) | 2020         | 74          | M      | No               | LBBB              | 74            | 74             | 56          | 70           | No           | No            | Yes |                                    |
| 7 | Sapien® 20 (+1) | 2021         | 80          | F      | No               | No                | 70            | 70             | 48          | 54           | Yes          | Yes           |     |                                    |

TAVI: transcatheter aortic valve implantation; RBBB: right bundle branch block; LBBB: left bundle branch block; HV: His-ventricular; PPM: permanent pacemaker; F: female; M: male; VIV: *valve-in-valve*; \*periprosthetic leak closed with plug during TAVI.

## DISCUSSION

Although more than half of the patients had LBBB after the procedure, only one required PPM implantation based on the HV measure as a risk predictor for TAVB. This observation corroborates the unpredictability of the LBBB presentation, with no recommendations from scientific societies for its follow-up so far. The literature suggests some means of follow-up, such as clinical monitoring and waiting for manifestations such as a syncope episode, which can lead to serious complications<sup>15,16</sup>.

Although most conduction disturbances occur within the first week after TAVI implantation (90% of cases), they can also happen later and carry a risk of syncope and sudden death<sup>17,18</sup>. Using implantable loop recorders revealed that 20% of

patients with new-onset LBBB after TAVI had severe bradyarrhythmias, with half requiring PPM during the one-year follow-up. Therefore, it is described as a follow-up strategy for those patients who did not undergo EPS<sup>18</sup>.

The systematic implementation of PPM has been the preferred solution for many centers to avoid the aforementioned late complications. Still, it can lead to early complications (such as perioperative infections) and long-term complications, such as ventricular dysfunction, due to the impact of chronic pacing of the right ventricle. In this sense, further studies should be carried out to define the best moment for PPM implantation, either early, meeting the minimalist TAVI definitions, or a little later.

For this, EPS layering is an interesting option to document and manage a high-grade conduction disorder as early as possible. This strategy has the advantage of implanting a pacemaker only in those patients who absolutely need it<sup>17,18</sup>.

A 2011 study carried out by Rubin et al. reported the results of 18 patients undergoing EPS immediately before and immediately after CoreValve<sup>®</sup> prosthesis implantation (Medtronic, Minneapolis, MN, United States of America): the HV interval was significantly prolonged after TAVI. At follow-up, a patient who developed a new LBBB after TAVI and had a prolonged HV interval post-TAVI (76 ms) experienced recurrent syncope after discharge, demonstrably secondary to a paroxysmal AVB 10 days after TAVI, and one was implanted—all four patients undergoing PPM after TAVI had normal pre-TAVI EPS<sup>19</sup>. In the same sense, Rivard et al. reported that the HV interval after TAVI was the only predictor of AV block (heart rate – HR = 1.081 per ms, 95%CI 1.014–1.152;  $p = 0.01$ ), with sensitivity and specificity of 80 and 77.8%, respectively, for the cutoff value  $\geq 65 \text{ ms}^{20}$ .

Kostopoulou et al. reported the results of 48 patients who underwent TAVI with CoreValve<sup>®</sup> and were randomized to ECG plus EPS evaluation or ECG evaluation only. The EPS plus electrocardiogram group included 30 patients who underwent invasive assessment of the HV measurement immediately before TAVI and 48 hours after the procedure. The indication for PPM was the combination of new LBBB with infrahisian conduction delay, defined as HV interval  $> 70 \text{ ms}$ . Five of the 30 patients in the EPS group developed AV block immediately after TAVI and therefore did not undergo repeat EPS. Patients with baseline conduction abnormalities (HV interval  $> 50 \text{ ms}$ ) were at increased risk of developing post-TAVI AV block. In the two patients who developed AV block relatively late (after day 2) and underwent post-TAVI EPS, the HV interval increased significantly (to  $> 70 \text{ ms}$ ). Of the 14 patients with new complete LBBB, only one required PPM. No patients with normal post-TAVI EPS underwent PPM during long-term follow-up. The patients who underwent PPM implantation were reassessed by interrogating the pacemaker 30 days after the TAVI, 25% of them remained dependent on the PPM, while in the remaining 75%, the rhythm recovered. Two of the three patients indicated for PPM because of HV  $> 70 \text{ ms}$  remained dependent on PPM<sup>21</sup>.

On the other hand, a study by López-Aguilera et al., published in 2016, reported the results of 137 patients who underwent CoreValve<sup>®</sup> prosthesis implantation and were studied by EPS before and 30 minutes after valve implantation. Six patients needed to repeat the EPS performed between day 4 and 20 months after the TAVI. Two of these patients showed considerable deterioration in AV conduction after TAVI, which returned to normal on repeat EPS five and seven days after TAVI. Therefore, there was no correlation between HV measurement and risk prediction of TAVB<sup>22</sup>.

We know that both the CoreValve<sup>®</sup> prosthesis and the Sapien 3<sup>®</sup> prosthesis, through different mechanisms, maintain a radial force in the annular tissue, which may progressively worsen the HV conduction, justifying the results found in some studies with variable HV intervals when performed on two occasions after the TAVI<sup>19,21</sup>.

Currently, other studies are being carried out evaluating the usefulness of the EPS in patients undergoing TAVI, such as the French multicenter study by Massoulié et al., which since 2016 has aimed to perform a prognostic evaluation with invasive measurement of the HV interval in those patients who persisted for more than 24-hour LBBB after TAVI, assessing both morbidity and mortality and the validity of the HV interval in predicting the risk of syncope, TAVB or sudden cardiac death<sup>18</sup>.

Some study limitations should be highlighted, such as the low sample size. A series of seven cases may not portray the findings that would be obtained from a larger group of individuals. Still, it can raise hypotheses reinforcing the need for further studies dedicated to the subject. We were consistent with the literature, demonstrating the correlation between the presence of LBBB and the slowing down of HV conduction.

## CONCLUSION

The EPS strategy during TAVI seems feasible to stratify patients for the risk of 2nd-degree Mobitz type II AV block early on, already referring them to adequate treatment without demonstrating increased risks related to the procedure.

## FUNDING

Not applicable.

## DATA AVAILABILITY STATEMENT

All datasets were generated or analyzed in the current study.

## AUTHORS' CONTRIBUTION

**Conceptualization:** Demuner PF, Gardenghi G, Freitas DM; **Formal Analysis:** Demuner PF, Gardenghi G, Alessi SRB, Fernandes FH, Prudente ML; **Methodology:** Demuner PF, Gardenghi G, Guimaraes EG, Barbosa FP; **Writing – original draft:** Demuner PF, Gardenghi G, Guimaraes EG, Barbosa FP; **Writing – review & editing:** Demuner PF, Gardenghi G, Oliveira FL, Silva RCO.

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