Original article

# Left bundle branch area versus conventional pacing after transcatheter valve implant for aortic stenosis: the LATVIA study

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**Background** Atrioventricular block (AVB) is a frequent complication in patients undergoing transcatheter aortic valve implantation (TAVI). Right apex ventricular pacing (RVP) represents the standard treatment but may induce cardiomyopathy over the long term. Left bundle branch area pacing (LBBAP) is a promising alternative, minimizing the risk of desynchrony. However, available evidence with LBBAP after TAVI is still low.

**Objective** To assess the feasibility and safety of LBBAP for AVB post-TAVI compared with RVP.

**Methods** Consecutive patients developing AVB early after TAVI were enrolled between 1 January 2022 and 31 December 2022 at three high-volume hospitals and received LBBAP or RVP. Data on procedure and at short-term follow-up (at least 3 months) were collected.

**Results** A total of 38 patients (61% men, mean age 83 ± 6 years) were included; 20 patients (53%) received LBBAP. Procedural success was obtained in all patients according to chosen pacing strategy. Electrical pacing performance at implant and after a mean follow-up of 4.2 ± 2.8 months was clinically equivalent for both pacing modalities. In the LBBAP group, procedural time was longer (70 ± 17 versus 58 ± 15 min in the RVP group, $P = 0.02$) and paced QRS was shorter (120 ± 19 versus 155 ± 12 ms at implant, $P < 0.001$; 119 ± 18 versus 157 ± 9 ms at follow-up, $P < 0.001$). Complication rates did not differ between the two groups.

**Conclusion** In patients with AVB after TAVI, LBBAP is feasible and safe, resulting in a narrow QRS duration, either acutely and during the follow-up, compared with RVP. Further studies are needed to evaluate if LBBAP reduces pacing-induced cardiomyopathy in this clinical setting.

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Keywords: atrioventricular block, conduction system pacing, left bundle branch area pacing, pacing-induced cardiomyopathy, transcatheter aortic valve implantation

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## Introduction

Transcatheter aortic valve implantation[1,2] (TAVI) is a well established treatment for patients with aortic stenosis at moderate-to-high risk for cardiac surgery. Even if a continuous improvement is observed regarding available technology and procedural techniques, a considerable proportion of patients still experience postprocedural complications. The most frequent complication is represented by persistent, complete atrioventricular block (AVB), which occurs in 3–26% of patients undergoing TAVI and requires permanent pacing.[3] The major risk factors for developing postintervention AVB are patient-dependent or procedure-related. However, atrioventricular (AV) and intraventricular conduction may be already impaired at baseline in patients with aortic stenosis due to extensive calcification of valvular apparatus extending in the penetrating His bundle or proximal left bundle branch (LBB) and may be worsened by TAVI by pushing further calcium debris inside the conduction system of the heart.

Current European guidelines recommend pacemaker implantation for AVB post-TAVI after 1-2 days of observation. However, no specific recommendation on preferred pacing modalities or devices is provided.[3] Right ventricular myocardial pacing (RVP) represents the conventional treatment modality, but in a nonnegligible percentage of patients, it may induce ventricular dysfunction.[4–7] Cardiac resynchronization therapy (CRT) with biventricular

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pacing[8,9] and conduction system pacing (CSP)[10,11] are both accepted as pacing modalities to prevent pacing-induced cardiomyopathy (PICM).[3] Patients with valvular heart disease and TAVI are at higher risk of developing PICM,[12,13] but the adoption of CRT or CSP in TAVI patients may be limited by procedural complexity and a higher rate of complications compared with RVP. Notably, with regard to CSP procedures, permanent His bundle pacing (HBP), even if described, may have limited indication after TAVI as the site of AVB is frequently located below the His bundle.

Left bundle branch area pacing (LBBAP) is emerging as a feasible, well tolerated, and effective CSP technique,[14] granting optimal electrical performance, short procedural time, and complication rates.[15–17] However, data on LBBAP after TAVI are still sparse: Vela Martin *et al.*[18] reported a high success rate in a series of 20 patients with various postintervention conduction disturbances; Shah *et al.* performed a systematic review showing a high success rate (about 94%), making it very appealing.[19] However, available data derive from single-center series without a control group for comparison. Thus, we sought to investigate short-term feasibility and safety of LBBAP after TAVI in a prospective, multicenter, observational study with comparison versus a control group receiving RVP.

## Methods

All consecutive patients with persistent AVB needing permanent pacing after TAVI at three high-volume centers [Niguarda Hospital (A), AOU Maggiore Della Carità Novara (B), Humanitas Research Hospital (C)] were enrolled between 1 January and 31 December 2022. Standard practice in hospitals A and B was to attempt LBBAP in this setting, whereas hospital C routinely performed RVP, serving as the 'control group'. All operators had robust experience in the field of cardiac pacing, with a minimum volume of 400 pacing procedures per year (and $>$50 CSP procedures in hospitals A and B).

All patients signed an informed consent for anonymized clinical data collection. The study protocol was evaluated by the Scientific Committee of the coordinating center. Because no deviation from the local standard practice was anticipated, no additional ethical concerns were raised and no further evaluation was required.

*Feasibility* was assessed by comparing between the two groups (LBBAP versus RVP) the procedural success rate and electrical performance of the ventricular lead (capture threshold, expressed as V $\times$ 0.5 ms; pacing impedance, expressed as Ohm; sensing threshold, expressed as mV) at implant day and at a follow-up of at least 3 months. 'Acute procedural success' was defined as correct implantation of the chosen pacing system, with clinically acceptable and stable electrical measures for the pacing leads.[20] Effective LBBAP was assessed following the indication described by Huang *et al.* and subsequent studies.[21–24] Necessary criteria for correct LBBAP were the presence on 12-lead surface electrocardiogram (ECG) of: rSr' pattern in lead V1 and a left ventricular activation time (LVAT, the interval between the pacing artifact and the peak of R wave in V6 lead) less than 80 ms in the case of preimplant narrow QRS and less than 90 ms in the case of intraventricular conduction disturbance. A *Rr'* greater than 33 ms, measured as the interval between the peak R wave in V6 and peak *R'* wave in V1, although welcome for LBBAP confirmation, was not mandatory.[25] An example of LBBAP implant is depicted in Fig. 1. As all patients were enrolled and our study was completed before the last EHRA Consensus Statement on CSP was published,[26] we did not use QRS transition during threshold testing as the first-line methods for LBBAP confirmation. Nevertheless, all patients fulfilled the consensus criteria for successful LBBAP. At 3-month follow-up, the persistence of LBBAP was confirmed on 12-lead ECG by the persistence of rSr' morphology in V1 and constant LVAT compared with implantation. Unipolar-tip ventricular pacing was used in LBBAP, while bipolar pacing was preferred for RVP. Remote monitoring was guaranteed for patients in the LBBAP group.

*Safety* was assessed by comparing the complication rates at implant and during follow-up between LBBAP and conventional RVP.

Data on procedural time, fluoroscopy and QRS duration (as a measure of *efficacy* in preventing electrical activation delays of the ventricles) were also collected.

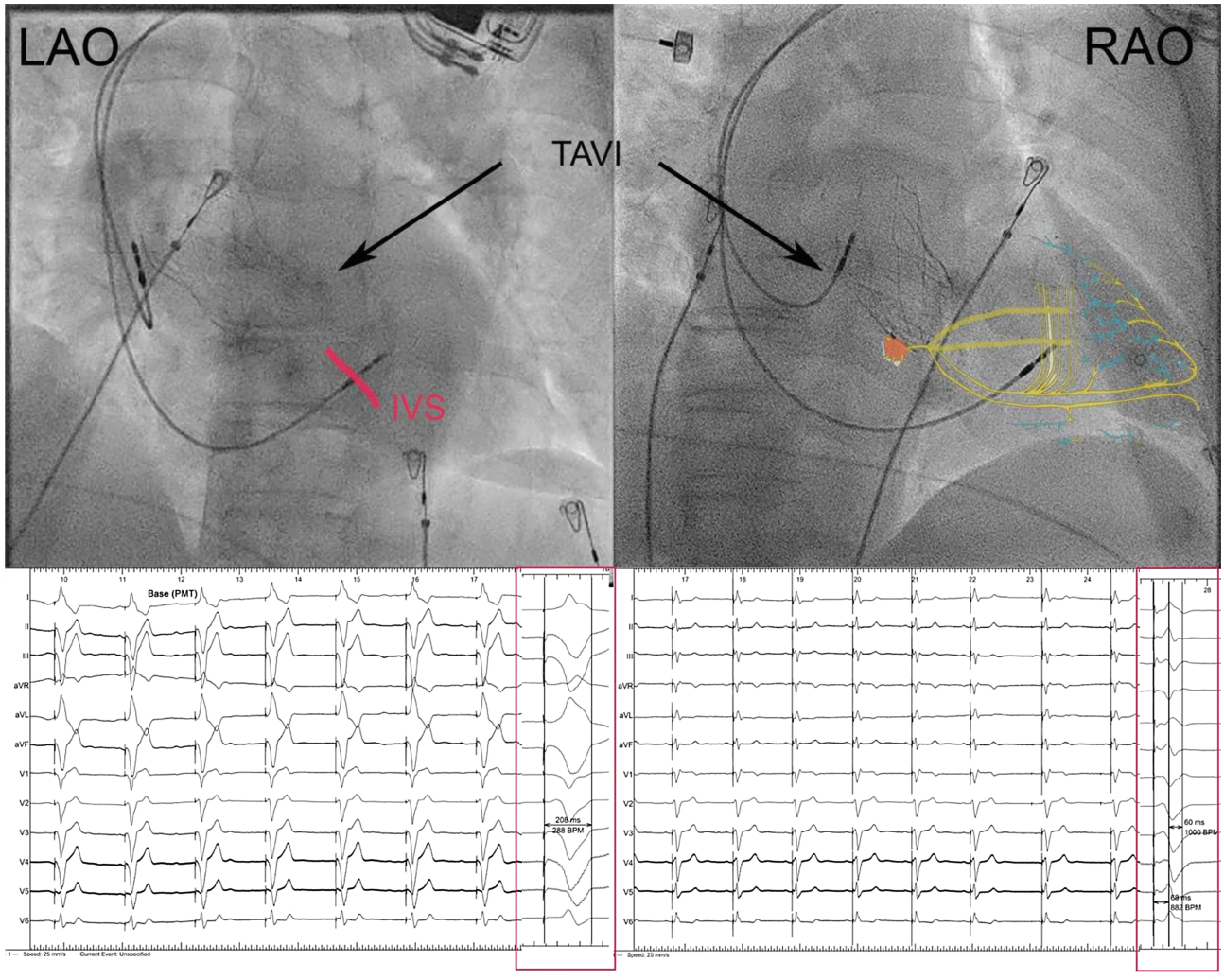
### Implant procedure

All implantations were carried out in an electrophysiology lab; continuous standard 12-lead ECG recording was always available. Venous access was chosen according to local practice, operator preference and patient's anatomy. Both stylet-driven (Solia S60, Biotronik GMBH, Berlin, Germany) and delivery-driven (3830, Medtronic, Minneapolis, USA) active-fixation catheters were employed for LBBAP, according to availability and the usual practice of the implanter. Conventional stylet-driven catheters (Medtronic) with active or passive fixation were placed at the right ventricular apex, as preferred by the implanter.

### Statistical analysis

Continuous variables with normal distribution were expressed as mean $\pm$ standard deviation (SD) and compared by two-tailed *t*-test. Nonnormally distributed variables were expressed as median (25–75% interquartile

Fig. 1




Upper panel: left anterior oblique and right anterior oblique fluoroscopy view, showing dual-chamber pacemaker with left bundle branch area lead. Lower panel: on the left, preimplant ECG during temporary pacing for complete atrioventricular block (in the red box, QRS duration of 206 ms measured at 100 mm/s velocity); on the right, final DDD pacing with LBBAP (in the red box, QRS evaluation at 100 mm/s, showing a LVAT of 68 ms and a *Rr'* of 60 ms). On LAO, IVS (interventricular septum) is marked in red, to show intramyocardial penetration of the pacing lead; on RAO, a scheme of cardiac conduction system is superimposed, showing the relationship between left bundle fascicles, His bundle and fluoroscopic anatomy. In these views, TAVI (transcatheter aortic valve implant) prosthesis serves as a landmark to help in locating His bundle area and interventricular septum. LBBAP, left bundle branch area pacing.

range) and compared by Wilcoxon–Mann–Whitney test. Normality was assessed by Kolmogorov–Smirnov test. Categorical data were expressed as percentage and compared by chi-square test or Fisher exact test. *P*-values less than 0.05 were considered statistically significant. Analyses were performed using Stata (StataCorp, California, USA).

## Results

### Population study

A total of 38 patients (61% men, mean age 83 ± 6 years) were enrolled; 20 (53%) patients received the investigational treatment (LBBAP) and 18 (47%) underwent RVP. Acute procedural success was reached in all patients, according to the chosen pacing strategy. Baseline characteristics and comparisons between the two groups are indicated in Table 1. No significant difference was observed between LBBAP and RVP patients at baseline.

Most patients (35/38, 92%) received a self-expandable transcatheter aortic valve: 15 (43%) received an Evolut Corevalve (Medtronic, Dublin, Ireland), 8 (23%) a Navitor valve, 1 (3%) a Portico valve (both Abbott Laboratories, Chicago, Illinois, USA) and 11 (31%) an Acurate Neo valve (Boston Scientific, Marlborough, Massachusetts, USA). Three patients (8%) underwent implantation of a balloon-expandable TAVI

**Table 1** Baseline characteristics

| | LBBAP ($N=20$) | RVP ($N=18$) | *P*-value |
|---|---|---|---|
| Comorbidities | | | |
| Age | 83 ± 7 | 84 ± 6 | 0.86 |
| Female gender | 6 (30%) | 9 (50%) | 0.21 |
| Systemic hypertension | 19 (95%) | 18 (100%) | 1.0 |
| Diabetes | 10 (50%) | 4 (22%) | 0.07 |
| CKD (serum creatinine >1.5 mg/dl) | 9 (45%) | 6 (33%) | 0.46 |
| COPD | 2 (10%) | 1 (5%) | 0.61 |
| Stroke/TIA | 0 (0%) | 3 (16%) | 0.10 |
| AF history | 7 (35%) | 7 (39%) | 0.82 |
| Concomitant coronary artery disease | 8 (40%) | 2 (11%) | 0.43 |
| Previous PCI | 6 (30%) | 2 (11%) | 0.15 |
| Previous cardiac surgery | 1 (5%) | 0 (0%) | 1.0 |
| Therapy at implant | | | |
| Beta blocker | 7 (35%) | 10 (55%) | 0.20 |
| ACE-i/ARB | 10 (50%) | 12 (67%) | 0.30 |
| ARNI | 2 (10%) | 0 (0%) | 0.49 |
| SGLT2 inhibitors | 1 (5%) | 0 (0%) | 1.0 |
| MRA | 4 (20%) | 5 (27%) | 0.57 |
| Diuretic agents | 14 (70%) | 11 (61%) | 0.56 |
| Antiarrhythmic drugs | 1 (5%) | 3 (16%) | 0.24 |
| Antiplatelet | 14 (70%) | 14 (78%) | 0.63 |
| OAC | 8 (40%) | 4 (22%) | 0.48 |
| Echocardiographic data | | | |
| LVEF (%) | 53 ± 11 | 58 ± 9 | 0.06 |
| TAPSE (mm) | 22 ± 4 | 22 ± 3 | 0.90 |
| PAPs (mmHg) | 35 ± 12 | 39 ± 12 | 0.79 |
| Transcatheter aortic valve data | | | |
| Self-expandable prosthesis | 17 | 18 | 0.23 |
| Balloon-expandable prosthesis | 3 | 0 | |
| Postdilatation | 5 | 6 | 0.57 |

Discrete variables are expressed as number (%); continuous variables are expressed as mean ± standard deviation. ACE-I, ACE inhibitors; AF, atrial fibrillation; ARB, angiotensin receptor blockers; ARNI, angiotensin receptor neprilysin inhibitor; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; LBBAP, left bundle branch area pacing; LVEF, left ventricular ejection fraction; MRA, mineralocorticoid receptor antagonists; OAC, oral anticoagulant; PAPs, systolic pulmonary artery pressure; PCI, percutaneous coronary intervention; RVP, right ventricular pacing; TAPSE, tricuspid annular plane systolic excursion.

(Sapien, Edwards Lifesciences, Irvine, California, USA). Valve postdilatation was done in 11 (29%) patients.

Dual-chamber pacing was used in 16 patients (80%) in the LBBAP group and in 13 (72%) of the RVP group, and single-chamber pacing was used in 4 and 5 patients, respectively ($P=0.57$ for comparison between the two groups); stylet-driven leads were used in 16 (80%) out of 20 LBBAP implants. Echocardiographic parameters were also similar: left ventricular ejection fraction (LVEF) was 53 ± 11% in the LBBAP group versus 58 ± 9% in the RVP group ($P=0.06$); longitudinal right ventricular contraction (TAPSE) was 22 ± 4 versus 22 ± 3 mmHg ($P=0.90$) and pulmonary systolic pressures (PAPs) were 35 ± 12 versus 39 ± 12 mmHg ($P=0.79$).

Mean procedural time was longer with LBBAP (70 ± 17 versus 58 ± 15 min with RVP, $P=0.02$), without difference in fluoroscopy time (5.9 ± 4.9 versus 12 ± 15 min, $P=0.12$) (Table 2). In the LBBAP group, paced QRS was shorter (120 ± 19 versus 155 ± 12 ms; $P<0.001$) and LVAT was lower (73 ± 14 versus 82 ± 4 ms, $P=0.01$). Mean follow-up duration was 4.2 ± 2.8 months. Only one patient in the RVP group did not complete 3-month follow-up because of death from refractory pulmonary oedema at 3 months, before electrical and ECG assessment were performed; no other deaths were observed.

Electrical parameters at implant and follow-up evaluation are reported in Tables 3 and 4. Sensing between the two groups was similar both at implant and at follow-up. A lower capture threshold, which was statistically significant but nonclinically relevant, was observed in favor of RVP at implant; this difference disappeared at follow-up. A numerically lower impedance was demonstrated at implant for LBBAP, becoming significant at follow-up; this is consistent with the unipolar pacing configuration required for LBBAP, instead of the bipolar configuration preferred in RVP. Paced QRS duration at follow-up remained shorter with LBBAP (119 ± 18 versus 157 ± 9 ms with RVP, $P<0.001$).

Table 2 Procedural features

| | LBBAP ($N=20$) | RVP ($N=18$) | *P*-value |
|---|---|---|---|
| Procedural time (min) | 70 ± 17 | 58 ± 15 | **0.02** |
| Fluoroscopy (min) | 5.9 ± 4.9 | 12 ± 15 | 0.12 |
| Positioning attempts | 1 (1–1.2) | 1 (1–2) | 0.5 |

Normally distributed continuous variables are expressed as mean ± standard deviation, while nonnormally distributed continuous variables are expressed as median (25–75% interquartile range). LBBAP, left bundle branch area pacing; RVP, right ventricular pacing.

Table 3 Parameters at implant

| | LBBAP ($N=20$) | RVP ($N=18$) | *P*-value |
|---|---|---|---|
| Sensing (mV) | 8.9 ± 3.9 | 11.5 ± 4.6 | 0.08 |
| Impedance (ohms) | 625 ± 240 | 736 ± 184 | 0.11 |
| Threshold ($V \times 0.5$ ms) | 0.8 ± 0.4 | 0.6 ± 0.2 | **0.01** |
| Paced QRS (ms) | 120 ± 19 | 155 ± 12 | **<0.001** |
| LVAT (ms) | 73 ± 14 | 82 ± 4 | **0.01** |
| *Rr'* (ms) | 51 ± 12 | - | |

Variables are expressed as mean ± standard deviation. LBBAP, left bundle branch area pacing; RVP, right ventricular pacing. LVAT, left ventricular activation time, measured from pacing artifact to QRS R wave peak in V6 lead at ECG; *Rr'*, interval between peak of QRS *R* wave in V6 and peak of *r'* wave in V1 leads at ECG.

From the overall population, one patient in the RVP group (3%) had a procedural complication, in particular a dislodgement of the pacing leads requiring repositioning at the end of the procedure, before exit from the operatory room. Complications at follow-up were reported in three patients (8%): in the LBBAP group, one patient had pocket hematoma after discharge, managed conservatively, whereas in the RVP group, one patient had an increase in the threshold capture of the atrial lead, without need for surgical revision, and one patient received repositioning for ventricular lead dislodgement.

## Discussion

In this multicenter, prospective, comparative, short-term observational study, we demonstrated that LBBAP in patients needing pacing for AVB after TAVI: is feasible and results in shorter QRS duration versus RVP, providing a more physiological electrical ventricular activation; presents optimal electrical parameters at implant and at short-term follow-up, clinically comparable to those observed with conventional myocardial pacing; is associated with low rates of complications, similar to what has been reported in previous articles on CSP and equivalent to RVP. These results encourage the adoption of LBBAP in the setting of patients developing AVB after TAVI, as this population usually has a high ventricular pacing rate, and therefore carries an increased risk of developing PICM.

The slight increase in procedural duration with LBBAP compared with RVP (12 min in the present cohort), without significant increase in fluoroscopy time, is counterbalanced by optimal electrical parameters observed acutely, during implantation, and maintained during follow-up. Moreover, the possibility to pace the conduction system instead of the working myocardium ensures a rapid diffusion of the action potential in the heart and, therefore, a synchronous and more physiological depolarization and contraction of the ventricles.[11,27–29] Compared with 'traditional' CSP pacing the His bundle, which is burdened by suboptimal electrical parameters, steep learning curve, moderately high rates of procedural failure (especially in case of distal AVB) and occurrence of threshold increase during follow-up, LBBAP seems to warrant synchronous ventricular contraction with optimal electrical parameters.[14–16] Of note, the unique complication observed in the LBBAP group (a conservatively managed pocket hematoma) is not specific to this technique, and it is not usually associated with unfavorable outcomes.

Table 4 Parameters at follow-up evaluation

| | LBBAP ($N=20$) | RVP ($N=17$) | *P*-value |
|---|---|---|---|
| Sensing (mV) | 9.0 ± 4.4 | 9.6 ± 5.0 | 0.74 |
| Impedance (ohms) | 528 ± 139 | 659 ± 89 | **0.003** |
| Threshold ($V \times 0.5$ ms) | 0.7 ± 0.3 | 0.7 ± 0.2 | 0.84 |
| Paced QRS (ms) | 119 ± 18 | 157 ± 9 | **<0.001** |

Variables are expressed as mean ± standard deviation. LBBAP, left bundle branch area pacing; RVP, right ventricular pacing.

The high prevalence of self-expandable TAVI in our study, even if both self-expandable and balloon-expandable devices are commonly used in the three participating centers, is not surprising, being in accordance with the higher prevalence of AV block after self-expandable prostheses described in the literature.[30] To date, however, no clear clinical superiority of one technology over the other has been documented and the choice of TAVI model should be tailored to various patient-related features, including clinical characteristics, valve anatomy and size, ascending aorta conformation, as well as to availability of the device for the implanter; therefore, ways to optimally manage unavoidable complications are welcome.

The 1-year enrollment limited the number of patients included in our study; however, this timespan was deemed sufficient to assess study endpoints, and we were not willing to postpone data analysis too much to provide some support to the ongoing clinical practice that is progressively switching to CSP instead of RVP even in the absence of strong evidence. In addition, the choice of treatment (LBBAP versus RVP) was not randomized, although the study design with 'sister hospitals' provided a reliable control group; our findings should be considered as exploratory and hypothesis-generating. Prospective registries and future larger trials on the topic have to be encouraged. Moreover, further studies on extended follow-up would clarify if the benefit in terms of QRS duration observed with LBBAP translates into a clinically relevant reduction in PICM, ventricular disfunction, development of heart failure, and consequent hospitalizations and mortality. Patients with LVEF less than 35%, for whom conventional biventricular CRT is currently preferred,[3] should also be evaluated, even if the net benefit of LBBAP over other pacing modalities will be harder to estimate in the setting of TAVI that *per se* carries a strong impact on left ventricular function and prognosis.

As a final remark, in patients who develop persistent AVB after TAVI procedures, the aortic prosthesis can even be used as a fluoroscopic landmark to guide ventricular lead implantation, maximizing the procedural success rate (Fig. 1).

Our study should be considered in light of limitations inherent to all observational, nonrandomized studies, including the risk of treatment bias and residual confounding. However, all enrolled patients were consecutive and prospectively included and followed.

## Conclusion

LBBAP appears a feasible and well tolerated pacing technique compared with RVP in patients needing pacing for AVB after TAVI. Physiological depolarization using the conduction system ensures a synchronous ventricular contraction, thus averting the potential risk of PICM, with comparable fluoroscopy time, electrical parameters, and complication rates.

## Conflicts of interest

G.D. received fees for lectures and proctorship from Biotronik. M.B. received fees for lectures and proctorship from Biotronik and Abbott Medical.

No other conflicts to disclose for the remaining authors.

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