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To cite this article: Roberto Scarsini, Rafail A. Kotronias, Giovanni Luigi De Maria, Skanda Rajasundaram, Thomas J. Cahill, Robin Brown, James D. Newton, Adrian P. Banning & Rajesh K. Kharbanda (2019): Routine Left Ventricular Pacing for Patients Undergoing Transcatheter Aortic Valve Replacement, Structural Heart, DOI: [10.1080/24748706.2019.1649771](https://doi.org/10.1080/24748706.2019.1649771)

To link to this article: <https://doi.org/10.1080/24748706.2019.1649771>



Accepted author version posted online: 29 Jul 2019.
Published online: 23 Aug 2019.



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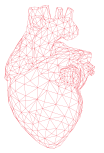
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ORIGINAL RESEARCH



Routine Left Ventricular Pacing for Patients Undergoing Transcatheter Aortic Valve Replacement

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ABSTRACT

Background: Rapid ventricular pacing is often required during transcatheter aortic valve replacement (TAVR) procedures. Pacing via the retrograde left ventricular guidewire (LV-GW) is an alternative strategy to conventional pacing using a right ventricular temporary pacing wire (RV-TPW). We report our single center experience with this strategy.

Methods: Two-hundred twenty-six patients who underwent transfemoral TAVR using pacing via LV-GW were included in this retrospective observational study.

Results: LV-GW pacing was successful in 224 (99%) of the cases. In two (1%) patients, a RV-TPW was inserted after attempted LV-GW pacing because of stimulation failure (n = 1) or instability (n = 1). Procedural TAVR success was obtained in 94.7% of the cases. Procedural complication rate was low and included 2.7% vascular complications, 0.9% unsuccessful valve deployment and 3.1% in-hospital death. Pericardial effusion requiring intervention occurred in three (1.3%) cases and was related to LV perforation (0.9%) and annular rupture (0.4%). As expected, no case of RV perforation was observed.

Conclusions: Pacing using LV-GW is a valuable alternative to RV-TPW for TAVR procedures. This avoids the need for an RV-TPW placement and reduces the risk of cardiac tamponade from RV perforation.

ARTICLE HISTORY Received 24 November 2018; Revised 30 June 2019; Accepted 24 July 2019

KEYWORDS Transcatheter aortic valve implantation; structural heart interventions; complications

Introduction

Transcatheter aortic valve replacement (TAVR) has become the standard of care for patients with aortic stenosis (AS) at high surgical risk and for a significant proportion of AS patients at intermediate surgical risk.¹ As the indications for TAVR expand into younger patients and those at lower surgical risk, further reduction in procedural complications becomes even more important. Furthermore, there has been a continuous effort to standardize the TAVR procedure with a transition to transfemoral access, local anesthesia, and conscious sedation to facilitate early post-procedural discharge.^{2,3}

Rapid ventricular pacing may be required for both balloon aortic valvuloplasty (BAV) and valve deployment. Moreover, back-up ventricular pacing may be required during TAVR in case of severe conduction abnormalities during or immediately after the valve deployment. Conventionally, ventricular pacing during TAVR is performed using a temporary pacing wire (TPW) placed in the right ventricle (RV) via femoral vein access. Although this technique can be performed safely in the majority of the cases, it is not free

from complications.⁴ Cardiac tamponade (caused by RV perforation) occurs in approximately 2% of the cases and may lead to irreversible hemodynamic collapse.^{4,5} Other potential complications such as vascular access site complication and infections have also been described.^{6,7}

Recently, the feasibility of performing rapid pacing in TAVR using the retrograde left ventricular (LV) guidewire (GW) has been demonstrated in relatively small series.^{4,5} This technique has the potential to offer reliable temporary pacing without RV-TPW placement.

The aim of the present analysis was to describe the feasibility of LV-pacing during modern transfemoral TAVR practice in a larger series of patients and to report on the procedural complications related to this technique.

Materials and methods

All patients undergoing TAVR at the Oxford Heart Centre were prospectively included in a registry. The Oxford TAVR registry (OxTAVI) was used to identify patients who underwent rapid pacing LV-GW during transfemoral TAVR



between March 2017 and September 2018. Procedural outcomes were obtained through hospital records review.

Rapid pacing using retrograde left ventricular guidewire

Rapid ventricular pacing via the LV support guidewire (Safari wire, Boston Scientific) was used for balloon valvuloplasty or valve deployment. The cathode of an external pacemaker was placed on the external end of the wire using an alligator clamp and a standard connector. A standard wire was introduced into the inferior vena cava (IVC) from the femoral vein. The anode of the pacemaker was placed on the IVC wire using an alligator clamp (**Figure 1**). Rapid pacing capability was tested at 12 V, without threshold testing, and we assessed consistent and reliable capture.

In case of post-TAVR major conduction abnormalities and need for RV-TPW, the same femoral vein access was used for advancing the TPW after disconnecting the pacemaker anode from the IVC wire. RV-TPW was then performed in a standard fashion.

Study endpoints

The primary endpoint was rapid pacing failure defined as the failure of delivering consistent and reliable capture for rapid pacing and consequent bailout RV-TPW placement. Secondary endpoints were: (a) the occurrence of pericardial effusion (PE) requiring percutaneous or surgical treatment. (b) TAVR device success defined according to the VARC2 definition. In particular, TAVR malpositioning was defined as valve migration or embolization according to VARC2 criteria.⁸

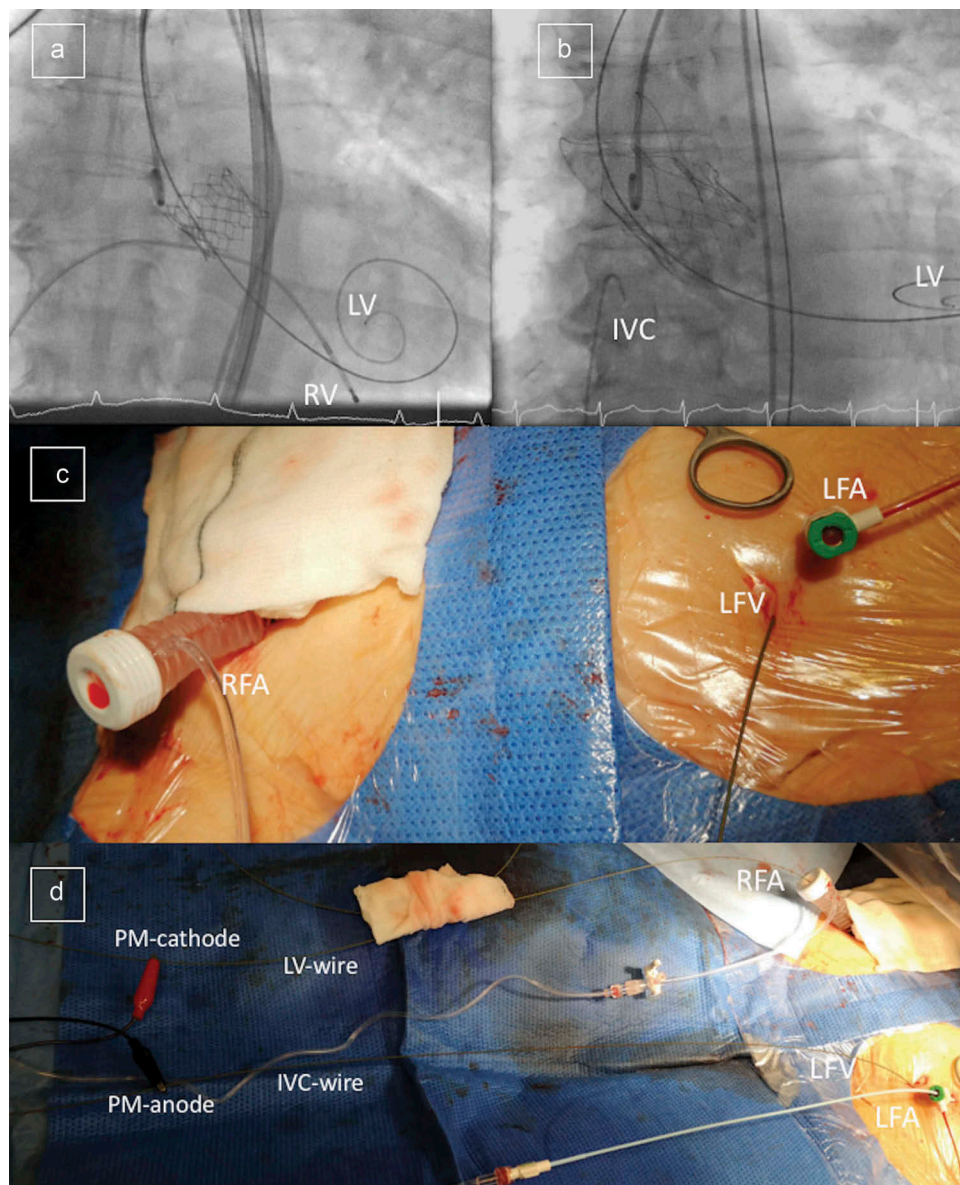


Figure 1. Procedural setting for LV pacing during TAVR. Fluoroscopy showing conventional TPW in the RV (a). LV-GW pacing strategy. A standard angiographic wire is placed in the IVC. LV pacing is performed via Safari (Boston Scientific) wire (b). Vascular access setting in detail (c). The cathode of an external pacemaker is placed on the external end of the wire using an alligator clamp (red). The anode of the pacemaker was placed on the IVC wire using an alligator clamp (black) (d). IVC, inferior vena cava; RFA, right femoral artery; LFR, left femoral artery; LFV, left femoral vein.

Statistical analysis

Categorical data are presented as percentages. Continuous data are presented as means with standard deviations for normally distributed variables and as medians with interquartile range for variables that were not normally distributed. All the statistical analysis was performed with the use of SPSS 25.0 software (SPSS Inc., Chicago, Illinois, USA).

Results

A total of 263 patients underwent transfemoral TAVR at Oxford Heart Centre during the study period. Thirty-seven patients underwent pacing via RV-TPW and were excluded from the report. An initial strategy of LV-GW pacing was used in 226 cases.

Demographics

The baseline characteristics of the study population are shown in **Table 1**. The vast majority of TAVR procedures were performed under local anesthesia and conscious sedation (221[97.8%]). Notably, more than 20% of the cases were ‘urgent’ procedures (50/226 = 22.1%) in decompensated AS patients.

Retrograde left ventricular guidewire pacing

LV-GW pacing strategy was successful in 224 out of 226 (99.1%) of the cases. In two (0.9%) cases an RV-TPW was required because of failure to capture. In 17 out of 224 (7.6%)

cases of successful LV-GW rapid pacing, the patient developed major conduction disturbances after TAVR. In these cases pacing via LV-GW was effective in supporting patient’s hemodynamic but an RV-TPW was required, in order to remove the LV wire and allow continuous temporary pacing. Overall, a permanent pacemaker was implanted in 30 (14%) patients who underwent LV-GW pacing during TAVR.

Procedural outcomes

PE requiring intervention occurred in only 3 out of 226 (1.3%) patients. These cases were related to LV perforation (2/226 = 0.9%) and annular rupture (1/226 = 0.4%). No significant difference was observed between elective vs urgent TAVR procedures in the occurrence of PE (2/176 [1.4%] vs 1/50 [2%], $p = .53$) or need for bailout RV-TPW (2/176 [1.4%] vs 0/50 [0%], $p = .61$). Vascular access complications occurred in six (2.7%) patients. Unsuccessful valve deployment was observed in only two cases (0.9%) and valve malposition in four (1.7%) cases. Overall, in-hospital death was observed in seven (3.1%) patients.

Discussion

Our analysis confirmed the feasibility and safety of rapid pacing via retrograde LV-GW during TAVR procedures as a routine strategy. Our data show a low procedural complication rate, with no PE related to RV perforation.

Growing experience in TAVR has led to a significant reduction in procedural mortality and major complication rates.^{9–13} The PARTNER 2A and SURTAVI trials found no significant difference in the primary endpoint of death and disabling stroke between TAVR and surgical aortic valve replacement (SAVR) at 2 years of follow up.^{14,15} Moreover, transfemoral TAVR was superior to SAVR in terms of lower rate of death and major stroke compared to SAVR.¹⁶ Recently, two large-randomized trials demonstrated the non-inferiority of TAVR compared to surgery in patients with low surgical risk (STS <4%).^{17,18} Therefore, a continuous effort to further reduce procedural complications is important.

Rapid pacing is often required in TAVR procedures to lower the LV cardiac output during balloon aortic valvuloplasty or valve deployment. In many centers rapid pacing is not routinely performed during TAVR especially when a self-expandable valve is deployed. Currently, in our institution rapid pacing is performed only during balloon-expandable valve deployment and for pre- or post-dilatation. Moreover, we recently introduced the TRUE® Flow Valvuloplasty Perfusion Catheter (Bard, Franklin Lakes, NJ, USA) in cases where we are concerned about the risk of rapid pacing, such as in patients with severely impaired LV systolic function. Nonetheless, considering a ventricular pacing back-up option is important to prevent the risk of hemodynamic instability in the case of high-grade conduction disturbances occurrence. Our current institutional practice is to use LV-GW pacing by default and to consider RV-TWP in cases at greater risk of developing high-grade AV block after TAVR (e.g., right bundle branch block and AV block I).

Table 1. Clinical and procedural characteristics of the study cohort.

| Variable | |
|--|------------------|
| Number of patients | 226 |
| Age, years | 83 (79, 86) |
| Female sex, % | 111 (49.1) |
| Urgent, % | 50 (22.1) |
| Diabetes, % | 57 (25.2) |
| Creatinine, mmol/L | 89 (71, 111) |
| Coronary artery disease, % | 90 (40.4) |
| NYHA III-IV, % | 220 (97.3) |
| Echocardiographic data | |
| Pre-TAVR AVA, cm ² | 0.7 (0.6, 0.8) |
| Pre-TAVR mean gradient, mmHg | 44 (38, 50) |
| LVEF <50%, % | 56 (25.0) |
| Post-TAVR mean gradient, mmHg | 6 (5, 9) |
| Post-TAVR aortic regurgitation (moderate/severe) | 7 (3.1) |
| Procedural data | |
| Local anesthesia, % | 221 (97.8) |
| Valve type | |
| CoreValve | 62 (27.4) |
| Sapien | 37 (16.4) |
| Lotus | 0 (0) |
| Accurate Neo | 127 (56.2) |
| BAV pre-TAVR, % | 121 (53.5) |
| BAV post-TAVR, % | 34 (15.0) |
| Procedural time, min | 65 (60, 80) |
| Fluoroscopy time, min | 8.2 (6.6, 11.4) |
| X-rays exposure (G/cm ²) | 1115 (600, 1911) |

**Table 2.** Previously published data on LV-GW pacing in TAVR.

| Study | Sample size | Successful LV-pacing (avoidance of RV-TPW) | Pericardial effusion | Intra-procedure conduction abnormalities requiring RV-TPW | Valve malposition | LV pacing technique |
|----------------------|-------------|--|-----------------------|---|-------------------|--|
| Faurie et al. | 113 | 101 (89.4%) | 1 (0.9%) ^b | 12 (10.6%) | 1 (1.1%) | Cathode of an external pacemaker placed on the external end of the 0.035" LV-GW. Anode placed on a subcutaneous needle. |
| Hildick-Smith et al. | 132 | 120 (90.9%) ^a | 0 (0%) | 6 (4.5%) | na | Cathode of an external pacemaker placed on the external end of the 0.035" LV-GW. Anode attached to the skin or placed on a subcutaneous needle. |
| Scarsini et al. | 226 | 207 (91.6%) | 3 (1.3%) ^c | 17 (7.6%) | 4 (1.7%) | Cathode of an external pacemaker placed on the external end of the 0.035" LV-GW. Anode placed on the external end of 0.035" guidewire placed in the IVC. |

^aSix patients require late (>24 h) TPW as bridge to PPM.

^bIn this series the etiology of cardiac tamponade was not available.

^cTwo cases of LV perforation and 1 case of annular rupture.

Table 3. Procedural variations of LV-GW pacing technique in TAVR.

| LV pacing technique | Pacemaker cathode | Pacemaker anode | Advantage | Disadvantage |
|---------------------|--|--|--|---|
| Variant 1 | Attached to the external end of the 0.035" LV-GW using alligator clamp | Attached to the skin using alligator clamp | <ul style="list-style-type: none"> Reduced risk of vascular complications Uninterrupted LV-pacing support in case of venous access for RV-TPW required | <ul style="list-style-type: none"> Possible anode dislocation during the procedure. Need for central vein access if bailout RV-TPW needed |
| Variant 2 | Attached to the external end of the 0.035" LV-GW using alligator clamp | Attached to a subcutaneous needle using alligator clamp | <ul style="list-style-type: none"> Reduced risk of vascular complications Uninterrupted LV-pacing support in case of venous access for RV-TPW required | <ul style="list-style-type: none"> Possible anode dislocation during the procedure. Need for central vein access if bailout RV-TPW needed |
| Variant 3 | Attached to the external end of the 0.035" LV-GW using alligator clamp | Attached to the external end of the 0.035" guidewire placed in the IVC using alligator clamp | <ul style="list-style-type: none"> Ready available central venous access for bail-out RV-TPW placement | <ul style="list-style-type: none"> Increased risk of venous vascular complication Risk of temporary instability during switch for RV-TPW |

In our experience, adequate rapid pacing was possible via the LV guidewire in the vast majority of the patients (99%). In only two (0.9%) cases, an RV-TPW was required to complete the procedure.

Additionally, in a further 7.6% of the cases, an RV-TPW was required after the valve implantation after the occurrence of major conductance disturbances as a bridge to PPM implantation. In these cases, pacing via LV-GW was useful as back-up ventricular pacing to support patient hemodynamic during the critical phases of valve deployment. However, RV-TPW was required when the LV-GW has to be removed to conclude the case. Therefore, in case of severe conduction abnormalities after the valve deployment, it may be sensible to place an RV-TPW while the LV-GW is still in place and able to provide pacing back-up

A new PPM is required in a significant proportion of patients undergoing TAVR. Predictors of PPM implantation after TAVR have been identified by previous studies and included pre-existing conduction disturbances, especially right bundle branch block, older age, male sex, small outflow tract and calcification of the valve annulus.¹⁹ Procedural variables, including valve design, height of implantation and balloon post-dilatation, also contribute to the risk of conduction disturbances after TAVR.²

Thus, even though the LV guidewire pacing technique showed an optimal procedural success rate in a large spectrum of TAVR patients, those at high-risk of developing peri-procedural complete

heart block, may be considered for RV-TPW placing or elective PPM implantation.

Our study has confirmed the observations made by other investigators in a much larger series.^{4,5} In fact, in agreement to the previously published data, the LV-GW pacing during TAVR was able to reduce the need for an RV-TPW in the majority of the patients and was associated with a small complication rate (Table 2).

We modified the LV-GW technique by placing a guidewire into the femoral vein and advancing the wire into the IVC, whereas in previous reports the pacemaker anode was connected to the skin or to a subcutaneous needle and no systematic femoral vein puncture was performed.^{4,5} Our approach has the advantage of allowing prompt RV-TPW placement in case of significant heart block requiring PPM implantation at the end of the TAVR procedure, or as a bailout strategy in case of LV-GW pacing failure (Table 3). These events occurred rarely in our experience (7.6% and 0.9%, respectively).

Our approach may carry an additional risk of vascular damage. However, emergency femoral vein access can be occasionally challenging, especially in the setting of hemodynamic instability, and we systematically use ultrasound-guided vascular puncture for both femoral vein and artery in order to reduce the risk of vascular complication. Furthermore, our procedural setting helps to avoid the risk of muscular leg spasm that is observed occasionally with the subcutaneous needle technique.



Limitations

Our study has the recognized limitations of a single center analysis of practice, and an observational study design. However, procedural and outcome data were systematically and prospectively registered in the OxTAVI registry.

Conclusion

Ventricular pacing via the retrograde LV guidewire is feasible and safe during TAVR. LV guidewire pacing is a further simplification of the TAVI procedure and potentially reduces the procedural complication tamponade rate compared with standard RV TPW. Further prospective research is warranted to confirm our results and define the best strategy for rapid pacing during TAVR.

Acknowledgment

We would like to thank Mr David Gee for the IT support of the project.

Disclosure statement

Dr Scarsini received an educational and training grant from the European Association of Percutaneous Cardiovascular Interventions (EAPCI). Professor Kharbanda and Professor Banning are partially funded by the Oxford National Institute for Health Research (NIHR).

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