DOI: 10.1111/jocs.13976

ORIGINAL ARTICLE

WILEY JOURNAL OF CARDIAC SURGERY

# Severe structural deterioration of small aortic bioprostheses treated with valve-in-valve transcatheter aortic valve implantation

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## Abstract

**Objectives:** The aim of this study was to evaluate outcomes of valve-in-valve transcatheter aortic valve implantation (VIV-TAVI) in patients with degenerated small bioprostheses.

**Methods:** Outcomes of consecutive 27 high-risk patients (logistic EuroSCORE 35.5 ± 18.5%) with a mean age of 81.0 ± 5.9 years who underwent VIV-TAVI for degenerated small bioprostheses (19 mm-11.1%; 20 mm-11.1%; 21 mm-77.8%) were analyzed. Medtronic CoreValve ($n$ = 11) or CoreValve Evolut-R prostheses ($n$ = 16) were implanted. Follow-up was 3.2 ± 2.0 years.

**Results:** Early mortality was 11.1%. One patient died intraoperatively due to left ventricle perforation, two others during the in-hospital period as a result of sudden cardiac death and pulmonary embolism. VIV-TAVI was completed in 26 cases (96.3%—success rate). Two patients required pacemaker implantation. Acute kidney injury occurred in two other patients. At discharge, mean transvalvular gradient was 19.2 ± 9.5 mmHg and in 25.9% of patients mean gradient exceeded 20 mmHg. Overall mortality was 25.9% and mortality from cardiac or unknown causes at 18.5%. Ninety percent of survivors were in New York Heart Association (NYHA) class I or II.

**Conclusions:** Transfemoral VIV-TAVI in patients with small, degenerated bioprostheses appears to be a promising alternative to surgery. Although the vast majority of patients have significant improvement in their NYHA class, the rate of persistent, residual gradients is relatively high and will need to be followed closely with serial echocardiograms.

KEYWORDS
outcomes, reintervention, structural valve deterioration, transcatheter aortic valve implantation

## 1 | INTRODUCTION

Bioprostheses have limited durability and 10-15 years following primary surgery they require replacement, predominantly due to structural valve deterioration (SVD).[1–3] One of the risk factors for the development of earlier SVD is the small size of aortic bioprostheses and freedom from reoperation is usually significantly lower in these patients.[4]

  

The valve-in-valve transcatheter aortic valve implantation (VIV-TAVI) is a less invasive therapeutic option than redo open-heart aortic valve replacement (redo-AVR). VIV-TAVI is associated with lower early and mid-term mortality and morbidity in comparison with redo-surgical aortic valve replacement, while echocardiographic parameters such as residual gradient favor redo-AVR.[5] Post-VIV-TAVI gradients were highest in small degenerated bioprostheses; thus, VIV-TAVI in these patients should be considered with caution.

The purpose of this study is to present our experience and results of VIV-TAVI in patients with degenerated small aortic bioprostheses (diameter ≤21 mm).

## 2 | MATERIALS AND METHODS

### 2.1 | Patients

After appropriate review and approval by the institutional review board, we analyzed retrospectively data of 70 patients who underwent VIV-TAVI between January 2010 and July 2018 at Sana Heart Center in Cottbus, Germany. Twenty-seven high-risk patients included in this study had VIV-TAVI performed on bioprostheses with a diameter of 21 mm or smaller. Severe prosthesis-patient mismatch (PPM) with indexed effective orifice area (iEOA) <0.65 $cm^2/m^2$ occurred in seven patients (25.9%). The mean time after primary surgery was 9.6 ± 4.2 years. In all cases a transfemoral approach was utilized (Figure 1). Preoperative demographics and selected clinical data are outlined in Table 1. Before secondary intervention, 25 patients were found to be in the New York Heart Association (NYHA) functional class III ($n$ = 16; 59.3%) or IV ($n$ = 9; 33.3%).

### 2.2 | Preoperative evaluation

Before the procedure, transesophageal echocardiography and multi-slice computed tomography (CT) were performed routinely in all patients to evaluate the aortic root dimensions, locate the coronary ostia, and choose the most appropriate size of the transcatheter prosthesis. Anatomy of the femoral artery was also assessed. The CT data set was analyzed using the dedicated OsiriX imaging software (Pixmeo, Geneva, Switzerland). A single patient requiring an emergency procedure underwent VIV-TAVI without a preoperative CT

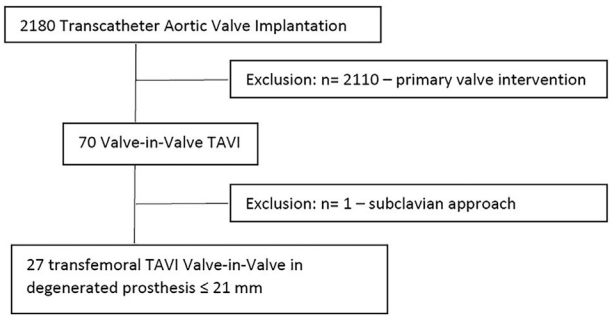


**FIGURE 1** Study population. TAVI, transcatheter aortic valve implantation

**TABLE 1** Selected demographic and preoperative clinical data

| Demographic and clinical characteristics | |
|---|---|
| Mean age ± SD, y | 81 ± 5.9 |
| Female gender (%) | 23 (85.2) |
| BMI ± SD | 27.1 ± 4.4 |
| BSA ± SD | 1.75 ± 0.2 |
| Log EuroSCORE %, ±SD | 35.5 ± 18.5 |
| STS Score %, ±SD | 16.6 ± 13.5 |
| Coronary artery disease (%) | 15 (55.6) |
| Previous PCI (%) | 4 (14.8) |
| Previous CABG (%) | 12 (44.4) |
| Previous cardiac surgery >1 (%) | 3 (11.1) |
| Previous pacemaker (%) | 5 (18.5) |
| Atrial fibrillation (%) | 10 (37.0) |
| Stroke (%) | 3 (11.1) |
| Peripheral artery disease (%) | 6 (22) |
| Carotid stenosis >50% (%) | 2 (7.4) |
| Pulmonary hypertension (%) | 6 (22.2) |
| Mild (%) | 2 (7.4) |
| Moderate (%) | 2 (7.4) |
| Severe (%) | 2 (7.4) |
| Chronic kidney disease stage ≥2 (%) | 24 (88.9) |
| CKD Stage 2, eGFR 60-89 (%) | 5 (18.5) |
| CKD Stage 3, eGFR 30-59 (%) | 16 (59.3) |
| CKD Stage 4, eGFR 16-29 (%) | 2 (7.4) |
| CKD Stage 5, eGFR<15 (%) | 1 (3.7) |
| COPD (%) | 8 (29.6) |
| Arterial hypertension % | 26 (96.3) |
| Diabetes mellitus (%) | 11 (40.7) |
| Hyperlipoproteinemia (%) | 23 (85.2) |
| Elective procedure (%) | 23 (85.2) |
| Urgent procedure (%) | 2 (7.4) |
| Emergency procedure (%) | 2 (7.4) |
| Type of degenerated bioprosthesis | |
| Type of valve | |
| Sorin Mitroflow (%) | 17 (63.0) |
| Sorin Freedom SOLO (%) | 2 (7.4) |
| Sorin Soprano (%) | 3 (11.1) |
| Medtronic Hancock (%) | 2 (7.4) |
| Carpentier-Edwards PERIMOUNT (%) | 3 (11.1) |
| Valve size | |
| 19 mm (%) | 3 (11.1) |
| 20 mm (%) | 3 (11.1) |
| 21 mm (%) | 21 (77.8) |

BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass grafting; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; eGFR, estimated glomerular filtration rate; PCI, percutaneous coronary intervention; SD, standard deviation; STS Score, The Society of Thoracic Surgery risk score. Continuous variables are presented as mean ± SD while categorical as the numbers with percentages ($n$[%]).

scan. In this case the aortic annular dimensions were calculated by means of transesophageal echocardiography.

All cases were carefully analyzed by the heart team which consisted of cardiac surgeons, cardiologists, and anesthesiologists. The indication for the reintervention was SVD in all cases. All patients had a high degree of stenosis and over half had significant insufficiency. In one patient the primary defect was isolated regurgitation. The findings of the preoperative echocardiography are summarized in Table 2.

## 2.3 | Procedure

The procedural access was transfemoral in all patients. Conscious sedation with local anesthesia was used in 26 patients. General anesthesia was necessary in two individuals due to either a critical preoperative state or procedure-related acute cardiac tamponade. All failed bioprostheses were routinely predilated (Figure 2). Post-dilatation was performed in one patient due to residual, high valve gradient caused by a technical failure to fully expand the valve. Eleven initial procedures were performed with the Medtronic CoreValve (Medtronic, Minneapolis, MN), then with the CoreValve Evolut R valves (Medtronic). To optimize positioning of the prostheses, reposition (applicable only in Evolut R valves) was performed successfully in six cases. Technical indices are listed in Table 3.

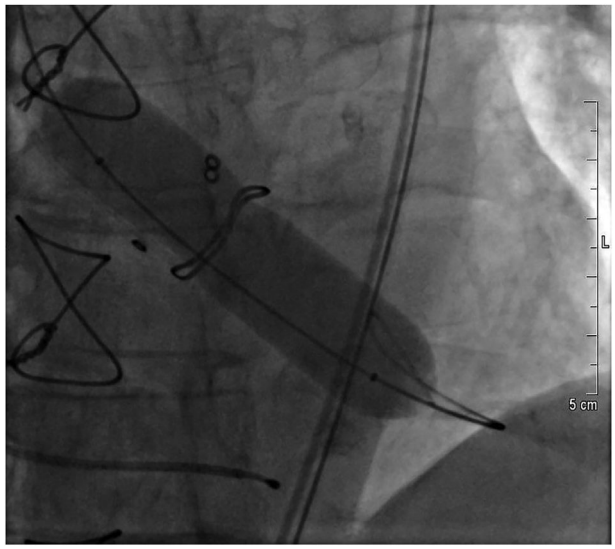


**FIGURE 2** Predilation of degenerated Hancock II bioprosthesis

**TABLE 2** Preoperative echocardiographic findings

| Echocardiographic parameters | |
|---|---|
| Aortic prosthesis stenosis (%) | 27 (100) |
| Aortic prosthesis regurgitation (%) | 15 (55.6) |
| Aortic prosthesis mixed disease (%) | 15 (55.6) |
| Leading stenosis (%) | 14 (93.3) |
| Leading regurgitation (%) | 1 (6.7) |
| Aortic prosthesis mean PG ± SD (mmHg) | 50.4 ± 20.2 |
| Aortic prosthesis peak PG ± SD (mmHg) | 84.4 ± 28.3 |
| EOA ± SD ($cm^2$) | 0.6 ± 0.2 |
| MV stenosis ≥2° (%) | 1 (3.7) |
| MV regurgitation ≥2° (%) | 9 (33.3) |
| TK regurgitation ≥2° (%) | 5 (18.5) |
| LVIDd ± SD (cm) | 4.9 ± 0.6 |
| LVIDs ± SD (cm) | 3.3 ± 0.7 |
| LA diameter ± SD (cm) | 4.2 ± 0.6 |
| LVPWd ± SD (cm) | 1.2 ± 0.3 |
| LVPWs ± SD (cm) | 1.4 ± 0.2 |
| TAPSE ± SD (mm) | 17.6 ± 4.0 |
| LVEF ± SD (%) | 56.6 ± 9.3 |
| sPAP ± SD (mmHg) | 42.5 ± 14.15 |

EOA, effective orifice area; LA, left atrium; LVEF, left ventricular ejection fraction; LVIDd, end-diastolic left ventricular internal dimension; LVIDs, end-systolic ventricular internal dimension; LVPWd, diastolic left ventricular posterior wall thickness; LVPWs, systolic left ventricular posterior wall thickness; MV, mitral valve; PG, pressure gradient; SD, standard deviation; sPAP, systolic pulmonary artery pressure; TAPSE, tricuspid annular plane systolic excursion; TK, tricuspid valve. Continuous variables are presented as mean ± SD while categorical as the numbers with percentages (*n*[%]).

## 2.4 | Assessment of outcomes

Transthoracic echocardiography was performed routinely at discharge and then 3 months later. All patients completed the follow-up period that lasted a median of (min-max) 29 months (0-71).

## 2.5 | Statistical analysis

The continuous variables were tested for normality with use of Shapiro-Wilk test. Normally distributed data are expressed as means ± standard deviations and compared with unpaired Student's *t*-test. Data are presented as median with interquartile range (min-max). Survival rate was stratified with use of Kaplan-Meier method.

**TABLE 3** Technical data of VIV-TAVI procedures

| | |
|---|---|
| Implanted valve type | |
| CoreValve, *n* (%) | 11 (40.7) |
| CoreValve Evolut R, *n* (%) | 16 (59.3) |
| Valve size | |
| 23 mm, *n* (%) | 24 (88.9) |
| 26 mm, *n* (%) | 3 (11.1) |
| Operative time ± SD, min | 59.1 ± 45.4 |
| Contrast load ± SD, mL | 172 ± 56 |
| Fluoroscopy time ± SD, min | 13 ± 4.8 |
| Implantation level | |
| <4 mm, *n* (%) | 22 (81.5) |
| >4 < 8 mm, *n* (%) | 5 (18.5) |

SD, standard deviation; VIV-TAVI, valve-in-valve transcatheter aortic valve implantation. Continuous variables are presented as mean ± SD while categorical as the numbers with percentages (*n*[%]).

Statistical significance was assumed at $P < 0.05$. Statistical analysis was computed with SPSS STATISTICS 24 (IBM Corp., Armonk, NY).

## 3 | RESULTS

### 3.1 | In-hospital outcomes

VIV-TAVI was completed in 26 patients (96.3% success rate) (Figure 3). In one case, acute tamponade occurred due to the perforation of the left ventricle by the guidewire and this patient died despite the emergency conversion to full median sternotomy. Two other patients died in the early postoperative period, one due to sudden cardiac death and another as a consequence of a pulmonary embolism.

Two patients required postoperative pacemaker implantation three days following the procedure due to postoperative complete atrioventricular (AV) block. Acute kidney injury occurred in two patients; however, none of them required dialysis. Postoperative delirium was observed in two patients. Percutaneous stentgraft implantation was necessary in one patient after catheters had caused the dissection of the external iliac artery. Mean hospital stay at the Cardiothoracic Intensive Care Unit was 1.5 ± 0.9 days. Eighteen patients were discharged home after 5.6 ± 0.9 days. Six patients required direct transfer to the Cardiac Rehabilitation Department due to high-grade functional impairment.

A significant reduction of transvalvular mean and peak gradients following the procedure and at 3 months follow-up were observed (Figure 4). Seven patients (25.9%) had postoperative mean gradients >20 mmHg; in three of them severe PPM was observed after the primary surgical intervention. All these patients got 23-mm TAVI valve size. Eight patients (29.6%) had postoperative paravalvular leaks; however, none of them had prosthetic regurgitation grade >1. No significant differences between pre- and postprocedural echocardiographic parameters, such as left ventricular ejection fraction (56.6 ± 9.3 vs 54.8 ± 9.1 %; $P$ = ns), tricuspid annular plane systolic excursion (17.6 ± 4.0 vs 16.4 ± 4.2 mm; $P$ = ns), or systolic pulmonary artery pressure (42.5 ± 14.15 vs 39.3 ± 13.5 mmHg; $P$ = ns), were noted. In most of the cases, the valve was implanted 4 mm below the neoannulus (81.5%). For implantations level <4 mm, the mean gradient was 17.65 ± 9.1 mmHg compared with 29.3 ± 5.1 mmHg for implantations level >4 < 8 mm ($P < 0.05$). Three out of seven patients with high postoperative mean gradient (>20 mmHg) had the valve implanted at 4-8 mm below the neoannulus.

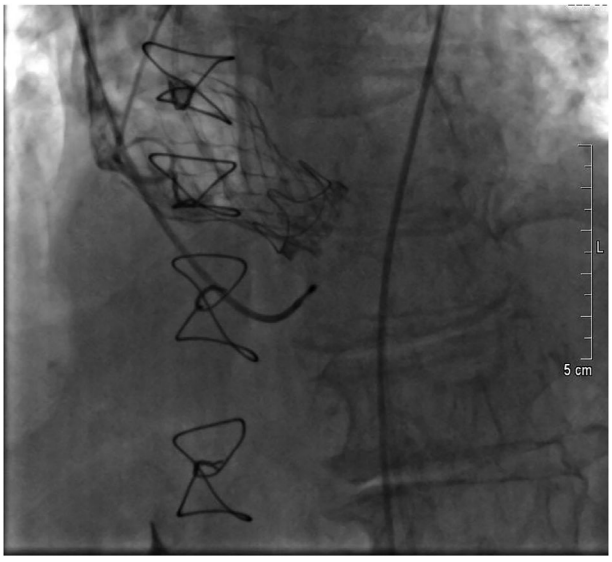


**FIGURE 3** Ideal high positioning of transcatheter valve implantation

### 3.2 | Long-term follow-up

Four patients died during the follow-up period, two of them as a result of pneumonia (after 2.8 years and 3.2 years, respectively) and two due to unknown reasons (13 months and 3.3 years following procedure). One-, two-, and three-year probability of survival was 88.9 ± 6.0%, 84.7 ± 7.1%, and 76.2 ± 10.3%, respectively (Figure 5).

Valve Academic Research Consortium-2 (VARC-2) composite endpoints are summarized in Table 4.

Three out of seven patients (42.9%) with severe PPM (mean iEOA 0.6 ± 0.04 $cm^2/m^2$) after primary valve surgery had higher mean gradients (>20 mmHg) after VIV-TAVI. One of them remained in NYHA III functional class and the rest are at NYHA I and NYHA II functional classes.

At the end of the follow-up period, functional status of the vast majority of patients improved significantly. Overall 18 out of 20 individuals (90%) who survived to the last follow-up examination were found in NYHA I or II functional classes ($P < 0.01$ vs preoperative NYHA class). Two patients remaining in the NYHA III had mean transvalvular gradients of 35 and 13 mmHg.

## 4 | DISCUSSION

Detailed previous operative reports, degenerated bioprosthesis specification (type and size), 2- and 3-dimensional transesophageal echocardiography and multislice computed tomography are necessary prior to VIV-TAVI. Our decision to use a particular valve size was based on preoperative CT measurements. Detailed preprocedural image is of paramount importance in patients with failed stentless prostheses, since the lack of fluoroscopic markers make the implantation more challenging.[6,7] Although the new VIV Aortic app (UBQO, London, UK) is very helpful to recognize the specifications of the degenerated bioprostheses, the final decision regarding the choice of optimal valve size should be always based on computed tomography and/or transesophageal echocardiography.[8]

Degenerated prostheses below 21 mm remain a considerable challenge for VIV-TAVI. Due to the technical and anatomical difficulties, the procedure can be associated with a high risk of oversizing and underexpansion of the TAVI valve. Due to a high residual gradient, patients with small, failing bioprosthesis present a higher risk of mortality during the follow-up period. Dvir et al[9] observed, in a multinational valve-in-valve registry, a 1-year survival

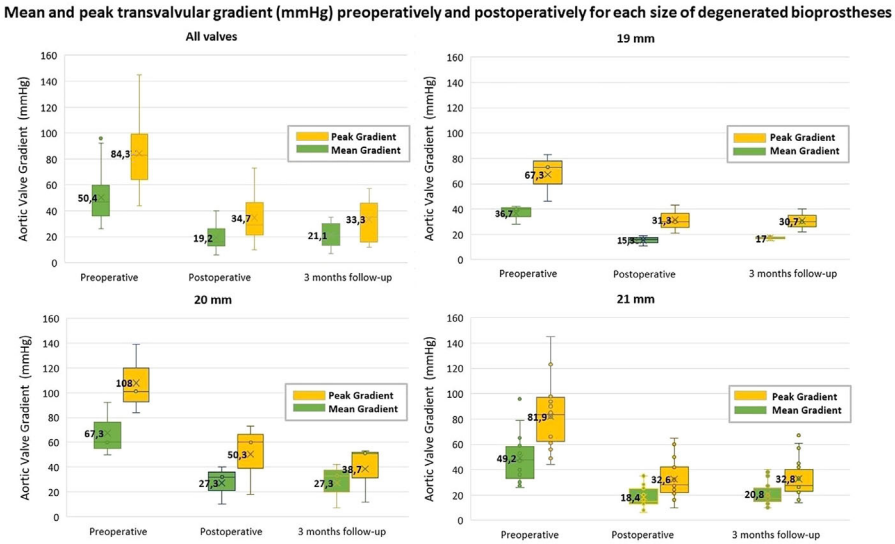


**FIGURE 4** Systolic transvalvular gradients before and after procedures

rate of 83.2%, but significantly better survival was seen in the group of patients with greater sized valves (small-sized valve 74.8%, intermediate-sized valve 81.8%, large-sized valve 93.3%, $P = 0.01$).

Identification of the current status of the aortic root is essential to ensure the optimal hemodynamic outcomes and the stable anchoring of the valve. A true level of the degenerated bioprostheses annulus can be easily identified by fluoroscopic imaging and further used for positioning of the TAVI valve. In bioprostheses without fluoroscopic marking in the frame or sewing ring, the annular position was defined with pig-tail catheter and multiple contrast injections. Our goal in these small annuli was to implant the new valve relatively high to allow for the lowest postoperative gradient.[10] Over 80% of valves were implanted <4 mm to the sewing ring of the previously implanted bioprostheses. Nonetheless, seven patients (26%) had mean transvalvular gradients of over 20 mmHg, despite the optimal valve positioning. Those patients still remain in good functional condition as shown by their NYHA class. It is of note that the higher the implantation the lower the chance of safe anchoring of the TAVI valve, which in turn is associated with an increased risk of paravalvular leak, TAVI valve migration, or coronary ostia obstruction.[11] In our opinion, the ideal implantation level was between 2 and 4 mm below the neo-annulus (see Figure 3).

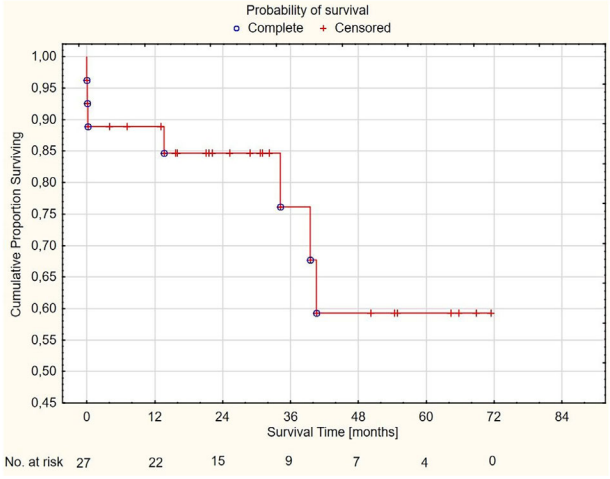


**FIGURE 5** Kaplan-Meier survival curve of patients with small degenerated aortic bioprostheses treated with valve-in-valve transcatheter aortic valve implantation

**TABLE 4** Clinical outcomes after VIV-TAVI procedures

| VARC-2 composite end points | |
|---|---|
| Device success, *n* (%) | 19 (70.4) |
| Immediate procedural mortality, *n* (%) | 1 (3.7) |
| Mean aortic valve gradient >20 mmHg, *n* (%) | 7 (25.9) |
| Moderate or severe prosthetic valve regurgitation, *n* (%) | 0 (0) |
| Early safety (at 30 days) | |
| All-cause mortality, *n* (%) | 3 (11.1) |
| Stroke, *n* (%) | 0 (0) |
| Life-threatening bleeding, *n* (%) | 1 (3.7) |
| Acute kidney injury—Stage 2 or 3, *n* (%) | 2 (7.4) |
| Coronary artery obstruction requiring intervention, *n* (%) | 0 (0) |
| Major vascular complication, *n* (%) | 1 (3.7) |
| Valve-related dysfunction requiring repeat procedure (BAV, TAVI, or SAVR), *n* (%) | 0 (0) |
| Clinical efficacy (after 30 days) | |
| Overall mortality, *n* (%) | 7 (25.9) |
| Stroke, *n* (%) | 0 (0) |
| NYHA class III or IV, *n* (%) | 3 (11.1) |
| Requiring repeat procedure (TAVI or SAVR), *n* (%) | 0 (0) |
| Prosthetic valve endocarditis, *n* (%) | 0 (0) |
| Prosthetic valve thrombosis, *n* (%) | 0 (0) |

BAV, bicuspid aortic valve; NYHA, New York Heart Association; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation; VIV-TAVI, valve-in-valve TAVI.

All our patients between 2015 and 2018 received the new Medtronic valve—Evolut R. It allows for the valve recapturing and repositioning. This option makes the optimal implantation position of the new valve much easier. We took advantage of this opportunity and repositioned the prosthesis in six patients (38% of our Evolut R implantation). Schulz et al[12] recaptured the valve in 22% prostheses, providing the delivery of the valve at the intended position 3-5 mm below the native annulus. This valve could be also beneficial for optimal positioning in patients with either small degenerated stentless bioprostheses that are not equipped with neither radiopaque components nor markers.

Another challenge for valve in valve procedure in degenerated prosthesis is a risk of coronary obstruction, which occurs in 3.5% of all cases.[13] Mortality in such cases may be as high as 50% and this complication may remain undiagnosed without autopsy.[14] This life-threatening complication is extremely high in small Mitroflow Sorin valves, due to the long leaflets mounted externally over the stent.[15–17] The leaflet height is at least 11 mm in 19 mm bioprostheses and 13 mm in 21 mm valves. The Global Valve-in-Valve Registry observed as much as a 7.7% higher incidence of coronary obstruction than in other stented valves after VIV-TAVI. Dvir et al[13] suggested that there is a greater risk of coronary obstruction in stentless valves, especially Sorin Freedom Solo valve, where the coronary obstruction occurs significantly more frequently than in the other stentless valves. Nevertheless, VIV TAVI has been successfully performed in sutureless valves.[18] Although we did not use any form of coronary ostia protection during the procedure, no coronary obstruction was observed in our series regardless of the previously implanted bioprosthesis.

The percutaneous approach allows for the procedure to be performed under local anesthesia; however, it carries a potential risk of conversion to unplanned sternotomy and general anesthesia.[19] Fröhlich et al[20] in a meta-analysis described the conversion rate from local to general anesthesia being as high as 6.3% and showed that local anesthesia was associated with significantly shorter procedure time and in-hospital stay. Ehret et al[21] suggested that local anesthesia is associated with favorable effects such as a reduced need for inotropic support and packed red blood cells transfusions. Having gained enough experience in the field of TAVI, it was possible to reduce the rate of general anesthesia to below 8%.

We analyzed only patients after transfemoral access that is considered to be the access of choice for TAVI interventions in our institution. It features not only a low invasiveness but also a greater feasibility in most of the cases.[7] In our center, only one patient with a small degenerate bioprosthesis underwent a subclavian approach due advanced stage of peripheral artery disease and was excluded from this study.

We did not observe an increased incidence of complete AV block requiring permanent pacemaker implantation in comparison with the previous reports. Five of our patients already had a pacemaker implanted before the aortic valve reintervention. The relatively low rate of new peacemaker implantations may be associated with the protective role of the failed bioprosthesis frame.[22,23] Scholtz et al[24] reported no association between degenerated bioprosthesis size and a new pacemaker implantation rate after VIV-TAVI.

## 5 | CONCLUSIONS

Transfemoral VIV-TAVI in patients with small degenerated bioprostheses appears to be a promising alternative to surgery. Although the rate of residual gradient is relatively high, late clinical improvement seems to justify VIV-TAVI in this group of patients.

### ACKNOWLEDGMENTS

We thank Jakub Marczak MD PhD for statistical support and Ivan Sazdovski MD for help in data acquisition.

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**How to cite this article:** Stankowski T, Aboul-Hassan SS, Seifi-Zinab F, et al. Severe structural deterioration of small aortic bioprostheses treated with valve-in-valve transcatheter aortic valve implantation. *J Card Surg*. 2019;34:7–13. https://doi.org/10.1111/jocs.13976