Valve-in-valve treatment of dysfunctional aortic bioprostheses – single-centre experience

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Introduction

Modern valvular bioprostheses show good durability, but there are several mechanisms that adversely affect their functionality. Besides dysfunction due to endocarditis (1–6%) or prosthetic valve thrombosis (up to 1%), structural valve degeneration (SVD) is the major concern [1]. Structural valve degeneration is defined as deterioration of the valve's leaflets/structures resulting in thickening, calcification, tearing, or disruption of the prosthetic valve materials with or without hemodynamic dysfunction [2]. It may occur early after implantation, but typically starts approximately 8 years after valve replacement, and its prevalence rates rapidly increase 10 years after the procedure [3, 4]. The frequency of SVD is notably time-dependant: it ranges from 5–10% after 10 years, up to 36–51% after 20 years [5]. The growing number of patients requiring re-intervention due to bioprosthetic valve dysfunction and high periprocedural mortality associated with reoperation justifies the need for less invasive procedures [6]. Thus, transcatheter aortic valve-in-valve implantation (ViV-TAVI) is emerging as a promising treatment option [7, 8]. The transcatheter approach has been successfully attempted also in dysfunctional mitral bioprostheses, but the lack of dedicated mitral devices still limits its application mainly to patients with failed aortic bioprostheses [9]. In current guidelines, ViV-TAVI is considered as a therapeutic option for severely symptomatic patients with aortic bioprosthesis dysfunction and assessed by the Heart Team to be at high or prohibitive risk of reoperation, in whom improvement in hemodynamic is anticipated (Class IIa, LOF: B) [10].

Aim

This paper presents our single-center experience in ViV-TAVI for treatment of patients with dysfunctional bioprostheses after surgical aortic valve replacement (SAVR).

Material and methods

From a total of 311 transcatheter aortic valve implantations (TAVI) at our institution, we selected 8 cases treated due to SVD of a surgically implanted aortic bioprosthesis (either stented type or homograft). The baseline clinical characteristics of the ViV-TAVI group are shown in Table I. All patients were referred for ViV-TAVI by the local Heart Team due to high risk of reoperation.

Sizing of transcatheter heart valves (THV) was based on surgical valve label information, transoesophageal echocardiography (TEE) and/or computed tomography (CT) imaging supported with the Valve in Valve app (version 2.0, UBQO limited).

ViV-TAVI procedures were performed under general anaesthesia through transfemoral (n = 7) or carotid (n = 1) access. All valves were implanted without predilatation. Only patient 1, who was treated for pure aortic regurgitation in homograft, required post-dilatation following implantation of the second Medtronic CoreValve due to incorrect positioning of the first THV.

No post-dilatation was used in the remaining cases, where proper device positioning was achieved and no significant paravalvular leaks were observed. Post-dilatation with a non-compliant balloon may be used for bioprosthetic valve fracturing to facilitate ViV-TAVI, but there was no such case in out practice (see Discussion).

All echocardiographic data were acquired with Philips iE33/Epiq7C systems with s5-1/x5-1/x7-2t/x8-2t probes and stored on Philips Xcelera PACS. The clinical and echocardiographic data were collected at three time points: initial evaluation (baseline) before ViV-TAVI, 30-day follow-up and up to 2-year follow-up (long-term follow-up). The detailed echocardiographic evaluations were made in all cases with calculation of left ventricle ejection fraction (LVEF; Simpson method),

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Table I. Baseline clinical characteristics of patients treated by transcatheter valve-in-valve procedure due to dysfunctional bioprosthesis after SAVR

Parameter	Patient							
	1	2	3	4	5	6	7	8
Age [years]	64	74	79	64	62	61	79	67
Sex (M/F)	F	F	F	F	M	M	M	M
EuroSCORE [%]	10	9	10	7	7	7	9	8
LogEuroSCORE [%]	19.46	13.61	18.02	7.48	7.18	6.75	13.64	9.74
STS score	3.04	3.81	7.15	3.93	2.24	2.22	2.45	2.17
Diabetes mellitus	–	–	+	–	–	+	+	–
Hypertension	–	+	+	+	–	–	+	+
COPD	–	–	–	–	–	–	–	–
AF	+	–	+	–	+	–	+	–
OAC	+	+	+	–	+	–	+	+
MI	–	–	–	–	–	+	–	+
Previous stroke/TIA	–	–	–	–	–	+	–	–
CABG	+	+	–	–	–	+	–	+
PCI	–	–	+	–	–	+	–	+
GFR [ml/min/m^2]	57	43	87	41	53	60	56	38
HGB [g/dl]	13.7	10.3	11.8	11.7	14.65	15.35	11.41	14.93
> 1 previous SAVR	+	–	–	–	–	–	–	+
SAVR valve type	Homograft	Medtronic Hancock II	Medtronic Mosaic	SJM Trifecta	Homograft	SJM Epic	Medtronic Hancock II	SJM Trifecta
Labeled SAVR valve size [mm]	n/a	21	21	23	n/a	21	21	25
Dysfunction type	AR	AS	AS	AS	AR	AS	AS	AR/AS
SAVR-ViV time [months]	164	36	84	24	180	12	60	60
ViV-TAVI valve type	Medtronic CoreValve	Medtronic Evolut R	Medtronic Evolut R	Medtronic Evolut R	Medtronic Evolut R	Medtronic Evolut R	Medtronic Evolut R	Medtronic Evolut R
ViV-TAVI size [mm]	29	23	23	23	29	23	23	26
LT-FU [months]	64	43	40	36	26	21	1	7
NYHA/baseline	3	3	3	3	3	2	1	3
NYHA/last-FU	2	1	1	1	1	1	1	1
LVEF (%) baseline	18	60	55	65	49	35	69	38
LVEF (%) last-FU	26	64	61	49	50	45	68	45

aortic valve area (AVA) and indexed AVA (iAVA) before the procedure. After ViV-TAVI aortic effective orifice area (AEOA) and indexed aortic effective orifice area (iAEOA) were calculated. All area calculations were based on continuity equitation.

Local bioethical committee gave permission for the procedures.

Results

The ViV-TAVI population is characterized by a lower mean age than the classical aortic stenosis TAVI (AS-TAVI) cohort (68.7 ±7.5 years, 95% CI: 62.5–75 vs. 78.5 ±7.2, 95% CI: 77.5–79.3, $p < 0.05$). Mean follow-up time was 30.7 ±18.9 (7.3–64) months. Due to availability and personal experience of the implanters only self-expandable aortic bioprostheses were used.

In AS-TAVI compared to VIV-TAVI, both AEOA and iAEOA differed significantly at the 30-day follow-up in all valve sizes: for 23 mm (AVA vs. AEOA 0.8 ±0.12 vs. 1.76 ±0.07; $p < 0.001$; iAVA vs. iAEOA 0.45 ±0.05 vs. 1.02 ±0.06; $p < 0.001$); for 26 mm (AVA vs. AEOA 1.32 vs. 1.76; iAVA vs. iAEOA 0.62 vs. 1.05); for 29 mm – only homograft patients – (AVA vs. AEOA 1.15 ±0.21 vs. 1.88 ±0.38; $p < 0.013$; iAVA vs. iAEOA 0.66 ±0.9 vs. 1.03 ±0.09; $p < 0.04$) (Figure 1).

In all cases, except for patient 2, AVA successfully increased above expected minimal values (AEOA > 1.2 cm^2) at 30 days [11]. The location of the bioprosthesis frame (Medtronic Hancock II) in this case was atypical, positioned at 45° from the medial aortic line, which resulted in suboptimal THV deployment. ViV-TAVI in this case was complicated by the early patient-prosthesis mismatch

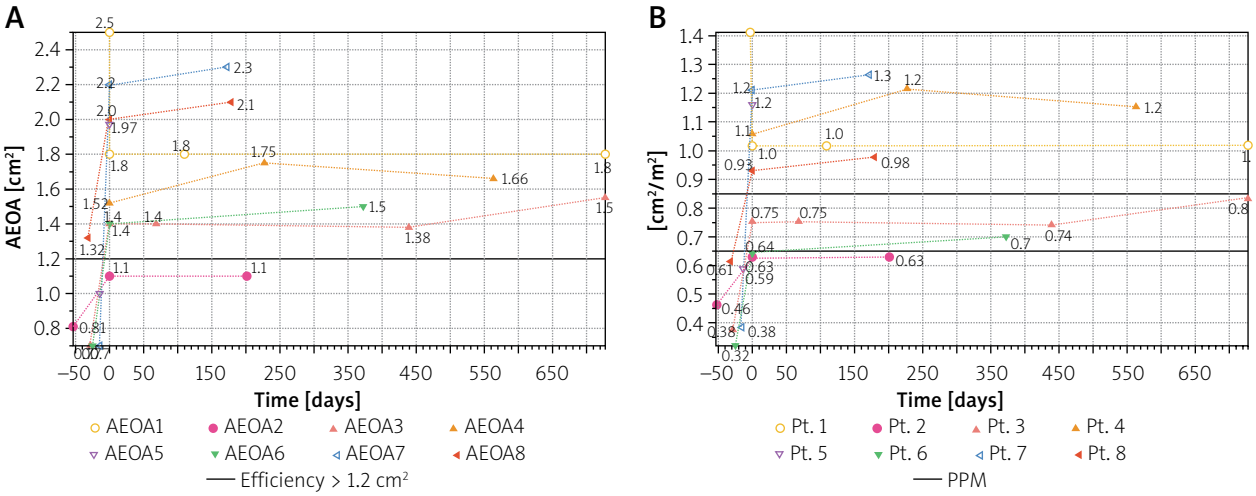

Figure 1. A – Changes of aortic effective orifice area (AEOA) after procedure, **B** – changes of aortic indexed effective orifice area after procedure

(PPM), but patient 2 already had a history of two redo-SAVRs and aortic annuloplasty.

PPM (iAEOA ≤ 0.85 cm²/m²) at 30 days after ViV-TAVI was also observed in patient 3 ($iAEOA_{pt2}$ = 0.75 cm²/m²). High body surface area (BSA) was the major causative factor in this patient, despite the relatively large AEOA.

Similarly, high values of BSA and body mass index (BMI) in patient 6 resulted in low iAEOA ($iAEOA_{pt6}$ = 0.64 cm²/m²), suggesting occurrence of severe PPM (iAEOA ≤ 0.65 cm²/m²). However, AEOA was acceptable ($AEOA_{pt6}$ = 1.4 cm²) and further body weight reduction allowed the patient's iAEOA to be increased in the long-term follow-up.

Overall, no decrease of AEOA and iAEOA were observed in long-term follow-up. Moreover, no paravalvular leaks or intra-valvular aortic regurgitations were observed at either 30-day or later follow-up. A tendency of increasing LVEF and reduction of NYHA functional class were observed after the procedure.

According to the VARC-2 composite endpoints (let alone PPM in device success definition), all procedures can be classified as successful, efficient and safe both at 30 days and 90 days [12].

In patient 1, after 64 months, severe intra-valvular regurgitation of THV (leaflet rupture) was observed. Because of end-stage chronic renal failure, co-morbid diseases and general fragility, conservative treatment was chosen. The patient died due to multi-organ failure. Patient 8 died due to small cell carcinoma 9 months after ViV-TAVI. Remaining patients achieved time-related valve safety according to the VARC-2 criteria.

Discussion

The present study shows that ViV-TAVI is a safe and effective mode of treatment in high-risk patients with failed surgical bioprostheses – including in long-term observation [10].

The early results of ViV-TAVI procedures are highly dependent on the prosthesis positioning. Device malposition may lead to dysfunction of the new prosthesis or coronary ostia obstruction. The procedure is less demanding in failed stented bioprostheses due to visible frame struts or radiological markers, which facilitate precise and safe implantation. In contrast, the stentless surgical valves or homografts have no radiological reference points and identification of the landing zone might be troublesome. However, in relation to the hemodynamic effects, stentless design of surgical bioprostheses allows for better expansion of THV within the surgical valve. It translates into higher values of effective orifice area and lower risk of PPM compared to stented bioprostheses – especially when dealing with small failed valves.

The supra-annular attachment of leaflets in the self-expandable aortic bioprostheses we used during ViV-TAVI might potentially increase long-term durability of THV and provide better iAEOA with lower incidence of PPM. Additionally, the second generation of self-expanding THV can be recaptured and repositioned in case of malpositioning. It significantly improves the ViV-TAVI procedure and limits the necessity for the second THV in comparison to the first generation (patient 1).

The ViV-TAVI procedure for failed stented surgical valves raises other challenges, particularly concerning the optimization of final AEOA. Large registries reported incidence of intra-procedural failures up to 6.9%, but there were none in our material [13].

The results of our work suggest that ViV-TAVI is a safe procedure – no major adverse cardiovascular events occurred in 30-day follow-up. Long-term outcomes are similar to those observed in other studies [9, 14]. After the procedure, aortic valvular function improved in relation to AEOA. No paravalvular leaks larger than mild and no intra-valvular regurgitations were observed up to 2 years of follow-up [14]. In comparison to the larger studies the

frequency of PPM in our cohort is lower [9]. It must be noted that fracturing of the failed surgical bioprostheses with a non-compliant balloon catheter should be currently considered as an option to avoid PPM in some small stented bioprostheses [15].

Conclusions

The ViV-TAVI procedure seems to be a safe and effective treatment option for patients with SVD of surgically implanted bioprostheses.

Conflict of interest

Zenon Huczek – proctoring and consulting fees from Medtronic. Others authors declare no conflict of interest.

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