

Transcatheter aortic valve-in-valve implantation in degenerative rapid deployment bioprostheses



Uri Landes^{1,2}, MD; Danny Dvir³, MD; Wolfgang Schoels⁴, MD; Christophe Tron⁵, MD; Stephan Ensminger⁶, MD; Matheus Simonato³, MD; Ulrich Schäfer⁷, MD; Matjaz Bunc⁸, MD; Gabriel Aldea⁹, MD; Alfredo Cerillo¹⁰, MD; Stephan Windecker¹¹, MD; Antonio Marzocchi¹², MD; Martin Andreas¹³, MD; Nicolas Amabile¹⁴, MD; John Webb³, MD; Ran Kornowski^{1,2*}, MD

1. Rabin Medical Center, Petah Tikva, Israel; 2. Sackler School of Medicine, Tel Aviv University, Ramat Aviv, Israel; 3. St. Paul's Hospital, Vancouver, BC, Canada; 4. Klinikum Duisburg, Duisburg, Germany; 5. Charles-Nicolle Hospital, Rouen, France; 6. Diabeteszentrum Bad Oeynhausen, Bad Oeynhausen, Germany; 7. Structural Heart Disease Program, Hamburg, Germany; 8. University Medical Centre Ljubljana, Ljubljana, Slovenia; 9. University of Washington Medical Center, Seattle, WA, USA; 10. G. Pasquinucci Hospital, Massa, Italy; 11. Bern University Hospital, Bern, Switzerland; 12. Policlinico S. Orsola Malpighi, Bologna, Italy; 13. Medical University of Vienna, Vienna, Austria; 14. Institut Mutualiste Montsouris, Paris, France

This paper also includes supplementary data published online at: http://www.pcronline.com/eurointervention/152nd_issue/8

KEYWORDS

- degenerative valve
- TAVI
- valve in valve

Abstract

Aims: The aim of this study was to evaluate transcatheter aortic valve-in-valve (ViV) implantation performance in rapid deployment (ViVr) vs. conventional (ViVc) surgical heart valves.

Methods and results: A multicentre registry was developed as part of the VIVID international registry. A total of 30 ViVr patients (Perceval, n=24, ATS 3f Enable™, n=5, and the INTUITY, n=1) were evaluated and compared with 2,288 ViVc patients. Propensity score (PS) matching was performed to adjust further for bias. Compared with ViVc, ViVr patients presented twice as early after surgical heart valve (SHV) implantation (55.2±36.1 vs. 118.4±57.7 months, p<0.001), were more commonly female (82.8% vs. 41.3%, p<0.001), and had shorter body stature and reduced body weight (p<0.05 for both) prior to PS. Implantation was successful in all ViVr cases and, compared with ViVc, was associated with equally favourable haemodynamic outcomes (mean gradient: 14.6±8.3 vs. 16.2±8.9 mmHg, p=0.356; regurgitation ≥mild: 3.7% vs. 5.2%, p=0.793). Periprocedural complication rates were similar and low in both groups. There was no coronary obstruction event in any ViVr case; one patient (3.6%) died during one year of follow-up.

Conclusions: ViVr appears effective, safe and associated with favourable haemodynamic outcome.

*Corresponding author: Rabin Medical Center, Derech Ze'ev Jabotinski 39, Petah Tikva, 4941492, Israel.

E-mail: ran.kornowski@gmail.com

Abbreviations

SHV	surgical heart valve(s)
SHVc	conventional surgical heart valve
SHVr	rapid deployment surgical heart valve
ViV	valve-in-valve implantation

Introduction

Bioprosthetic surgical heart valves (SHV) are less thrombogenic than mechanical SHV and do not require lifelong anticoagulation therapy. Nevertheless, bioprostheses eventually tend to degenerate and to require subsequent treatment¹⁻⁴. Although still the benchmark, valve reoperation carries substantial risks⁵⁻¹⁰. Therefore, transcatheter heart valve (THV) implantation into a degenerated bioprosthetic aortic SHV (valve-in-valve [ViV] procedure) has evolved as a viable, less invasive strategy in suitable cases of SHV failure. Rapid deployment SHV (SHVr) are a relatively novel subcategory of aortic bioprostheses. Similar to conventional SHV (SHVc) surgery, SHVr surgery requires native aortic valve excision and annular decalcification but it avoids the need for permanent sutures at the decalcified annulus. SHVr may be particularly beneficial in reducing surgical procedure time and are also easier to implant, with smaller non-sternotomy incisions. Moreover, rapid deployment valves (RDVs) are designed to allow larger residual effective orifice area in patients with small aortic annuli, as avoiding a sewing ring typically enables upsizing the implanted device by one or two sizes. Thus, the rationale for their use lies in their potential to facilitate minimally invasive surgical approaches, reduce operation time, and allow implantation in severely calcified and particularly narrowed aortic roots¹¹. Consequently, SHVr are increasingly being used, mainly offered to older patients at higher surgical risk and in more complex surgeries¹²⁻¹⁴. The absence of sutures could, on the other hand, have potential disadvantages that include paravalvular leakages, valve dislocation, and stent infolding. All may cause valve failure and require reintervention^{15,16}. Because of their potential benefits, SHVr prostheses are often implanted in patients already at relatively high risk, and therefore re-operating these patients is a high-risk procedure. Hence, ViV intervention may potentially play a major role in suitable patients, if and when SHVr failure should occur. Currently, ViV in degenerative SHVr (ViVr) experience is very minimal, with only a few cases reported in the literature¹⁵⁻¹⁷. The purpose of this study was to evaluate the ViVr procedure and outcomes and to compare them against ViV in conventional SHV (ViVc).

Methods

STUDY POPULATION AND DESIGN

Centres were solicited to participate through the Valve-in-Valve International Database (VIVID) registry as described in detail previously¹⁸. Briefly, the VIVID registry is a global data collection of ViV procedures in the aortic, mitral and tricuspid positions. Since 2010, the registry has been prospectively collecting data from centres in Europe, North America, South America, Africa,

Oceania, and the Middle East using a dedicated case report form. Centres were requested to submit consecutive data for successful and unsuccessful procedures, as well as for patients who underwent catheterisation planned for ViV but in whom no implantation was attempted. The institutional review board or ethics committee at each participating centre approved the submission of data. In the following analysis, all cases of ViV in the aortic position were included, and ViVr patients were compared against ViVc patients.

STUDY MEASURES AND ENDPOINTS

Data collected included basic demographic, historical and diagnostic information, procedural details and follow-up information related to THV function, reintervention, adverse events and clinical status. Major clinical endpoints were assessed according to the Valve Academic Research Consortium-2 consensus document¹⁹. Post-implantation haemodynamic data were obtained from either intraprocedural or first post-procedural echocardiography, with additional echocardiography performed during follow-up. The primary outcome was defined as 30-day mortality. Secondary outcomes were defined as stroke, need for a second valve, >mild residual aortic regurgitation and residual mean aortic valve gradient (mmHg) higher than 20 at 30 days, as well as mortality at one year. Other VARC-2-defined 30-day outcomes were also measured and reported.

STATISTICAL ANALYSIS

Categorical variables are reported as n (%) and continuous variables as mean (\pm standard deviation) or median (interquartile range [IQR]), depending on variable distribution. Group comparisons were analysed using the Student's t-test or Wilcoxon rank-sum test. The χ^2 and Fisher's exact tests were used to compare categorical variables. The time-to-event curve was calculated using the Kaplan-Meier method. The Student's t-test was used to compare normally distributed continuous variables and the Wilcoxon rank-sum test was used for variables not normally distributed. The χ^2 and Fisher's exact tests were used to compare categorical variables. To account for missing data, we used multiple imputation, and pooled the results across imputations. A two-sided $p < 0.05$ was considered statistically significant. A propensity score matching based on patients' calculated propensity (0.0-1.0) of having had a ViVr procedure was also conducted. The propensity score was estimated using a "saturated" logistic regression adjusting for preprocedural factors including five continuous terms (age, body surface area [Mosteller formula], body mass index, left ventricular ejection fraction, and mean aortic valve gradient), four binary or categorical terms (patient gender, mechanism of failure, whether the patient had renal failure, and whether the patient had diabetes), all two-way interactions of the covariates (continuous-continuous, continuous-categorical, and categorical-categorical), and all squared and cubed terms of the continuous variables. Nearest neighbour propensity score matching with replacement was performed using the `teffects psmatch` command in Stata 14.2 (StataCorp, College Station, TX, USA).

Results

Between April 2007 and January 2018, there were 30 ViVr implantations performed at 17 out of 135 sites participating in the VIVID registry, using: 24 Perceval (Sorin Biomedica, Saluggia, Italy), five ATS 3f Enable (Medtronic, Minneapolis, MN, USA) and one INTUITY (Edwards Lifesciences, Irvine, CA, USA) valves. No ViVr was performed between 2007 and 2011, nine were performed between 2012 and 2014, and 18 were performed between 2015 and 2017. During these years, 2,288 ViVc implantations were performed at the 135 centres participating, and these were included for comparative purposes.

BASELINE CHARACTERISTICS AND CLINICAL PRESENTATION

The mean age of ViVr patients was 80.1 ± 7.6 years and their mean STS score was $9.5 \pm 7.0\%$. Compared with the ViVc group of patients, ViVr patients were more commonly female (82.8% vs. 41.3%, $p < 0.001$) with shorter body stature (159.9 ± 7 vs. 167.5 ± 9 cm, $p < 0.001$) and reduced body weight (69.0 ± 13 vs. 75.9 ± 17.2 kg, $p = 0.035$). The surgical risk as assessed by the EuroSCORE II and STS score was similar between the groups ($14.7 \pm 6.6\%$ vs. $14.3 \pm 9.4\%$, $p = 0.660$ and $9.5 \pm 7.0\%$ vs. $8.8 \pm 8.1\%$, $p = 0.855$, for ViVr and ViVc, respectively), as were other baseline characteristics, all presented in **Table 1**.

Compared with ViVc patients, ViVr patients presented more commonly with a combined (stenosis and regurgitation) mechanism of

SHV failure (60% vs. 31%, $p = 0.003$) and at shorter surgical AVR to ViV time interval (55.2 ± 36.1 vs. 118.4 ± 57.7 months, $p < 0.001$). The SHV label size (23.0 ± 1.5 vs. 23.3 ± 2.2 mm, $p = 0.338$), baseline aortic valve area (0.84 ± 0.36 vs. 0.79 ± 0.56 cm², $p = 0.610$) and mean transvalvular gradients (36 ± 15 vs. 36 ± 17 mmHg, $p = 0.856$) were similar between ViVr and ViVc patients, respectively (**Supplementary Table 1**).

TECHNICAL PROCEDURAL CHARACTERISTICS AND HAEMODYNAMIC OUTCOME

Figure 1 shows each SHVr type along with ViV procedural illustrations. In both groups, the majority of procedures were performed using the transfemoral access (72.4% ViVc vs. 77.8% ViVr, $p = 0.579$). Compared with ViVc, ViVr procedures were more frequently carried out utilising a balloon-expandable THV (70% vs. 42.2%, $p = 0.022$), with a trend towards using a smaller THV diameter size (23.9 ± 2.1 vs. 24.6 ± 2.2 mm, $p = 0.078$).

Implantation was successful in all ViVr patients. Compared with ViVc, aortic valve area after ViVr was numerically, but not statistically, larger (1.28 ± 0.69 vs. 1.02 ± 0.78 cm², $p = 0.124$) and accompanied by lower maximal (21.2 ± 10.7 vs. 28.9 ± 14.8 mmHg, $p = 0.013$) and similar mean (14.6 ± 8.3 vs. 16.2 ± 8.9 mmHg, $p = 0.356$) residual transvalvular gradients. Residual aortic regurgitation was \geq mild in one (3.7%) ViVr and in 107 (5.2%) ViVc patients, $p = 0.793$.

Table 1. Patient baseline characteristics according to surgical heart valve (SHV) type.

	Rapid deployment SHV n=30	Conventional SHV n=2,288	p-value
Age, years	80.1 ± 7.6	77.5 ± 10.0	0.160
Male sex	17.2%	58.7%	<0.001
Height, cm	159.9 ± 7	167.5 ± 9	<0.001
Weight, kg	69.0 ± 13	75.9 ± 17.2	0.035
BSA, m ²	1.72 ± 0.10	1.85 ± 0.12	–
BMI, kg/m ²	27.1 ± 5.1	27.0 ± 5.8	0.946
STS score	9.5 ± 7.0	8.8 ± 8.1	0.855
EuroSCORE II	14.7 ± 6.6	14.3 ± 9.4	0.664
Diabetes mellitus type 2	25.1%	23.3%	0.821
Peripheral artery disease	13.8%	20.5%	0.370
Renal failure	37.9%	49.8%	0.206
Previous stroke/TIA	30.8%	16.0%	0.147
Chronic lung disease	20.7%	21.2%	0.948
NYHA functional Class III–IV	85.7%	86.5%	0.756
Peak aortic valve gradient, mmHg	62 ± 23	60 ± 27	0.803
Mean aortic valve gradient, mmHg	36 ± 15	36 ± 17	0.856
Aortic valve area, cm ²	0.84 ± 0.36	0.79 ± 0.56	0.610
Left ventricular ejection fraction, %	56 ± 8	52 ± 13	0.035

BMI: body mass index; BSA: body surface area; STS: Society of Thoracic Surgeons; TIA: transient ischaemic attack

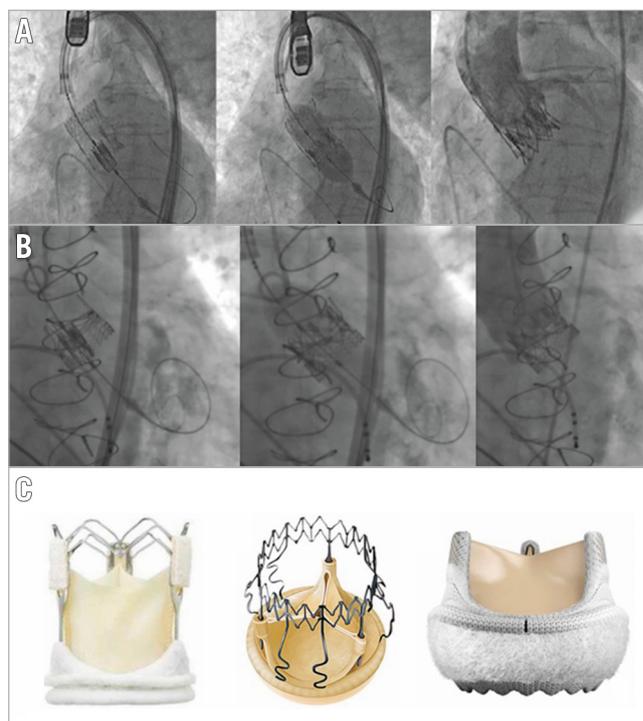


Figure 1. Transcatheter aortic valve implantation into (A) Perceval and (B) INTUITY sutureless surgical heart valves. (C) Left: ATS 3f Enable (Medtronic); middle: Perceval (Sorin Biomedica); right: INTUITY (Edwards Lifesciences).

EFFICACY AND SAFETY OUTCOMES

VARC-2-defined periprocedural complication rates (i.e., stroke, kidney injury, vascular complications, etc.) were similar in patients who underwent ViVr vs. ViVc, and low in both groups (**Table 2**). In the ViVr patient group, at 30 days there was one (3.6%) case of a second THV implantation, three (11%) cases of permanent pacemaker implantation, and no case of coronary artery obstruction. One patient (3.6%) died during 30-day follow-up, and there were no additional deaths during one-year follow-up. The Kaplan-Meier survival curve in respect of SHV type is presented in **Figure 2**.

Symptomatic improvement (vs. baseline) assessed by NYHA functional class de-escalation was evidenced in 95.5% of the patients at 30 days ($p<0.001$) and remained steady at one year, with no difference in ViVr vs. ViVc patients.

Using propensity score matching across imputation, 56 patients (28 pairs) were found eligible for 1:1 ViVr to ViVc matching. Baseline covariates and procedural characteristics were evenly distributed across the groups, including patients' sex, body stature and body weight, yet excluding surgical AVR to ViV time interval (65.3 ± 30.9 months ViVr vs. 126.4 ± 69.9 months ViVc, $p=0.001$) (**Supplementary Table 2**). Thirty days after the procedure, aortic valve area was 1.28 ± 0.70 vs. 0.91 ± 0.61 cm² ($p=0.228$), maximal residual transvalvular gradient was 20.9 ± 10.9 vs. 31.5 ± 18.0 mmHg ($p=0.061$) and mean residual gradient was 14.7 ± 8.6 vs. 17.2 ± 8.8 mmHg ($p=0.306$) in ViVr vs. ViVc,

Table 2. Valve-in-valve outcome according to surgical heart valve (SHV) type.

	Rapid deployment SHV n=30	Conventional SHV n=2,288	p-value
30-day mortality	4.3%	4.4%	1
1-year mortality	9.5%	13.3%	0.94
Stroke (major)	0.0%	1.4%	1
Acute kidney injury (any)	6.7%	5.5%	0.678
Vascular complications	Major	2.9%	0.825
	Minor	7.2%	
Bleeding (major/life-threatening)	3.3%	4.9%	1
Valve malposition	0.0%	8.0%	0.164
Need for a second valve	3.6%	3.9%	1
Residual regurgitation	None	66.5%	0.793
	Mild	28.3%	
	Moderate	4.2%	
	Moderate-severe	6.0%	
	Severe	4.0%	
Aortic valve area, mm ²	1.28 ± 0.69	1.02 ± 0.78	0.124
Residual gradient, max (mmHg)	21.2 ± 10.7	28.9 ± 14.8	0.013
Residual gradient, mean (mmHg)	14.6 ± 8.3	16.2 ± 8.9	0.356
Need for permanent pacemaker	11.0%	6.7%	0.252
Coronary artery obstruction	0.0%	2.4%	1
Hospital stay, days	12.0 ± 14.7	9.5 ± 9.0	0.146

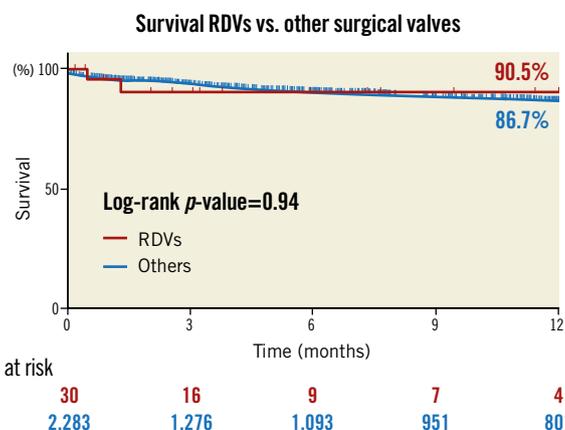


Figure 2. Kaplan-Meier survival curve after transcatheter aortic valve implantation into a failed surgical heart valve bioprosthesis (valve-in-valve) in respect of SHV type. RDVs: rapid deployment valves

respectively. No significant difference was observed between the groups in terms of clinical outcomes, including 30-day mortality, cerebrovascular events, vascular complications, acute kidney injury or need for permanent pacemaker (**Table 3**).

Table 3. Propensity score-matched patients' outcome.

	Rapid deployment SHV n=28	Conventional SHV n=28	p-value	Standardised difference
30-day mortality	4.5%	4.5%	1.000	0.03
Stroke (major)	0	0	1.000	0.00
Acute kidney injury (any)	0	7.1%	0.150	0.39
Vascular complications				
Major	10.7%	10.7%	1.000	0.00
Minor	0	3.6%	0.313	0.27
Bleeding (major/life-threatening)	10.7%	3.6%	0.299	-0.28
Valve malposition	3.7%	0	0.313	-0.27
Need for a second valve	3.8%	3.8%	1.000	0.01
Residual regurgitation				
None	68.0%	76.0%	0.529	0.20
Mild	28.0%	20.0%	0.508	-0.30
Moderate	0	4.0%	0.312	0.28
Moderate-severe	0	0	1.000	0.00
Severe	0	0	1.000	0.00
Aortic valve area, mm ²	0.91 ± 0.61	1.28 ± 0.70	0.228	0.40
Residual gradient, max (mmHg)	31.5 ± 18.0	20.9 ± 10.9	0.061	-0.71*
Residual gradient, mean (mmHg)	17.2 ± 8.8	14.7 ± 8.6	0.306	-0.26
Need for permanent pacemaker	4.0%	12.0%	0.297	0.28
Coronary artery obstruction	0	0	1.000	-0.27
Hospital stay, days	8.7 ± 8.7	12.6 ± 15.1	0.275	0.32

* – standardised difference is larger than might occur simply by chance. AKI: acute kidney injury; SHV: surgical heart valve

Discussion

The first ViV inside SHVr cases were only recently described and the overall ViVr experience is so far limited¹⁵⁻¹⁷. Incidence of SHVr deterioration at one year is reported to be 0.4%¹⁴, yet no strict follow-up criteria have been applied and there are no data yet regarding the long-term deterioration rate. If we expect SHVr to have durability/longevity comparable to SHVc, then we are likely to witness an increase in the incidence of patients presenting with SHVr failure over the next few years. This assumption motivated us to look into the largest global ViV registry so far and to solicit ViVr cases, in order to learn about this important patient cohort.

Our report suggests that ViVr is feasible and safe in selected cases of degenerated SHVr, with results similar to those seen in conventional ViV patients. In this analysis, several observations are important and deserve additional consideration.

As SHVr are frequently utilised to augment surgical AVR in patients with a small left ventricular outflow tract, it is not surprising that overall ViVr patients were more commonly female and had shorter body stature and reduced body weight. Albeit that they were 2.5 years older (not statistically significant), ViVr patients' baseline characteristics were similar to ViVc characteristics excluding the above aspects. However, the clinical presentation differed significantly between the two groups, with twice as short a time lapse between the surgical AVR and the ViV procedure in patients with SHVr compared to SHVc, and with SHVr patients presenting more often with SHV failure due to regurgitation compared to SHVc, which more commonly presented with predominant stenosis. Even after PS-matched analysis ensuring evenly distributed baseline parameters across the two groups, surgical AVR to ViV time remained shorter in SHVr patients. Although our study is unable to identify factors explaining the degeneration process systematically, this point is mandatory and hypothesis-generating, as traditional SHVc function usually deteriorates due to leaflet failure secondary to leaflet calcification, pannus, tears, etc., while SHVr may be more susceptible to frame failure and develop paravalvular leak due to partial collapse of the non-sutured valve frame^{15,16}, which may also lead to valvular stenosis and/or regurgitation due to leaflet deformity, as demonstrated in **Figure 3**.

ViVr patients showed a numerically more favourable residual valve area and lower residual gradients. These haemodynamic results were obtained even though SHV area and transvalvular gradients were similar between the groups at baseline, the THV size utilised was similar (with a trend for being smaller in ViVr), and despite the fact that ViVr used a higher proportion of balloon-expandable to self-expanding THVs (self-expanding THVs are associated with a more supra-annular position, in which the frame is less constrained by the SHV ring/frame, thereby enabling a larger residual effective orifice area and reduced residual gradients after ViV implantation)²⁰. These favourable ViVr haemodynamic results were also maintained after propensity analysis, hence are less likely to be related to group dissimilarities in sex,

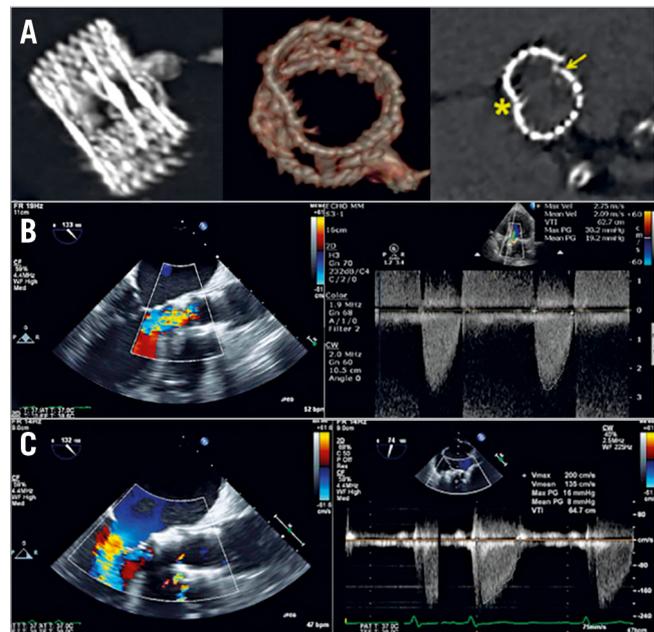


Figure 3. Bioprosthetic degeneration of a Perceval sutureless valve in one of the patients in the study. *A) Computed tomography demonstrating stent disfigurement with the valve in-folding at the right and non-coronary sinuses. B) Echocardiography demonstrating severe valve regurgitation (left: colour Doppler showing a mosaic pattern of diastolic flow; right: continuous wave Doppler showing transvalvular gradients and the regurgitation flows). C) After valve-in-valve: no residual leakage (left) and normal pressure gradients (right).*

body stature, or weight. Alternatively, several other explanations may be more applicable. To begin with, the failure mechanism of SHVr less commonly involved pure stenosis, which is associated with lower residual valve area and higher residual gradients compared with SHV regurgitation or stenosis-regurgitation combination¹³. Additionally, differences between SHV structure and mechanics may hypothetically contribute to more advantageous haemodynamics after ViVr compared to ViVc. As opposed to SHVc, SHVr frames lack the restrictive sewing ring (a recent target for fracturing by some operators)²¹ and therefore may be more elastic and extendable by the THV, allowing the ViV to restore a more favourable frame geometry. In this regard, ViVr is similar to THV in stentless SHV and THV-in-THV implantation (redo transcatheter aortic valve replacement), which are also associated with favourable haemodynamic outcomes²².

The clinical outcome of ViVc is generally good, and comparison with benchmark transcatheter native valve aortic valve replacement (AVR) shows ViV to be both safe and effective overall²³. Although the number of ViVr cases in the current study is still too small, this analysis supports the safety and efficacy of this procedure, as it demonstrates ViVr to be associated with outcomes comparable to ViVc, a low mortality rate, low complication rate and symptomatic benefit. It is worth pointing out that there

were no coronary artery occlusion events within this series of ViVr patients. Interestingly, the Perceval (which constituted 80% of ViVr cases) and the Freedom Solo™ SHV (Sorin Biomedica) actually use the same leaflets, which are very long and thought potentially to jeopardise the coronary ostia and thus at least in part be responsible for the high coronary obstruction risk associated with ViV within the last²⁴. We do not yet know if the zero rate of coronary obstruction events in our series is a consequence of patient selection (i.e., low coronary obstruction risk anatomy with wide aortic root sinuses, high coronary ostia, etc.) or whether the frame design of these devices somehow protects from this devastating complication.

Limitations

Our findings should be interpreted with caution and should be considered as hypothesis-generating, since our registry has inherent selection bias as it has collected a miscellany of patients chosen for ViV by the local teams of experts. Also, results can be subject to differences in mode of practice and documentation patterns at participating institutions. Importantly, the ATS 3f Enable and the INTUITY were under-represented, the overall number of ViVr patients is still low despite being the largest so far, and imbalance in size and baseline characteristics exists between the study groups. We tried to overcome these differences by supplementary analysis of propensity-matched cohorts, but other confounders may still have influenced the results.

Conclusions

ViV in selected patients with degenerated rapid deployment SHV is feasible, safe and associated with clinical and haemodynamic outcomes which are comparable to ViV in conventional SHV. Further evaluation is needed in larger cohorts of patients and with longer follow-up.

Impact on daily practice

Transcatheter valve-in-valve implantation (ViV) is used to treat failed surgical aortic valve bioprostheses but was only anecdotally described in rapid deployment surgical valves (SHVr), which are increasingly being used. Compared to conventional ViV (ViVc), ViVr patients presented twice as early after surgery, and more commonly with aortic regurgitation. Implantation was successful in all ViVr cases and associated with favourable haemodynamic outcome, low periprocedural complications (including coronary obstruction) and a low one-year mortality rate. Although further evaluation with longer follow-up and larger cohorts is needed to assess ViVr fully, ViV might be a valid treatment option in selected patients with failed SHVr.

Acknowledgements

The authors wish to acknowledge Alex Woerschling, MS, for his statistical analysis contribution in this study.

Conflict of interest statement

M. Andreas reports being a proctor for Edwards Lifesciences and receiving scientific grants from Edwards, Abbott and Medtronic. J. Webb is a consultant for Edwards Lifesciences. R. Kornowski reports institutional research grants from Medtronic. The other authors have no conflicts of interest to declare.

References

1. McClure RS, Narayanasamy N, Wiegierinck E, Lipsitz S, Maloney A, Byrne JG, Aranki SF, Couper GS, Cohn LH. Late outcomes for aortic valve replacement with the Carpentier-Edwards pericardial bioprosthesis: up to 17-year follow-up in 1,000 patients. *Ann Thorac Surg.* 2010;89:1410-6.
2. Hammermeister K, Sethi GK, Henderson WG, Grover FL, Oprian C, Rahimtoola SH. Outcomes 15 years after valve replacement with a mechanical versus a bioprosthetic valve: final report of the Veterans Affairs randomized trial. *J Am Coll Cardiol.* 2000;36:1152-8.
3. Brennan JM, Edwards FH, Zhao Y, O'Brien S, Booth ME, Dokholyan RS, Douglas PS, Peterson ED; DEClIDE AVR (Developing Evidence to Inform Decisions about Effectiveness—Aortic Valve Replacement) Research Team. Long-term safety and effectiveness of mechanical versus biologic aortic valve prostheses in older patients: results from the Society of Thoracic Surgeons Adult Cardiac Surgery National Database. *Circulation.* 2013;127:1647-55.
4. Vahanian A, Alfieri O, Andreotti F, Antunes MJ, Barón-Esquivias G, Baumgartner H, Borger MA, Carrel TP, De Bonis M, Evangelista A, Falk V, Lung B, Lancellotti P, Pierard L, Price S, Schäfers HJ, Schuler G, Stepinska J, Swedberg K, Takkenberg J, Von Oppell UO, Windecker S, Zamorano JL, Zembala M; ESC Committee for Practice Guidelines (CPG); Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC); European Association for Cardio-Thoracic Surgery (EACTS). Guidelines on the management of valvular heart disease (version 2012): the Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur J Cardiothorac Surg.* 2012;42:S1-44.
5. Kaneko T, Vassileva CM, Englum B, Kim S, Yammine M, Brennan M, Suri RM, Thourani VH, Jacobs JP, Aranki S. Contemporary Outcomes of Repeat Aortic Valve Replacement: A Benchmark for Transcatheter Valve-in-Valve Procedures. *Ann Thorac Surg.* 2015;100:1298-304.
6. Maganti M, Rao V, Armstrong S, Feindel CM, Scully HE, David TE. Redo valvular surgery in elderly patients. *Ann Thorac Surg.* 2009;87:521-5.
7. Akay TH, Gultekin B, Ozkan S, Aslim E, Uguz E, Sezgin A, Aslamaci S. Mitral valve replacements in redo patients with previous mitral valve procedures: mid-term results and risk factors for survival. *J Card Surg.* 2008;23:415-21.
8. Filsoufi F, Anyanwu AC, Salzberg SP, Frankel T, Cohn LH, Adams DH. Long-term outcomes of tricuspid valve replacement in the current era. *Ann Thorac Surg.* 2005;80:845-50.

9. Van Nooten GJ, Caes F, Taeymans Y, Van Belleghem Y, François K, De Bacquer D, Deuvaert FE, Wellens F, Primo G. Tricuspid valve replacement: postoperative and long-term results. *J Thorac Cardiovasc Surg.* 1995;110:672-9.
10. Vassileva CM, Shabosky J, Boley T, Markwell S, Hazelrigg S. Tricuspid valve surgery: the past 10 years from the Nationwide Inpatient Sample (NIS) database. *J Thorac Cardiovasc Surg.* 2012;143:1043-9.
11. Fischlein T, Meuris B, Hakim-Meibodi K, Misfeld M, Carrel T, Zembala M, Gaggianesi S, Madonna F, Laborde F, Asch F, Haverich A; CAVALIER Trial Investigators. The sutureless aortic valve at 1 year: a large multicenter cohort study. *J Thorac Cardiovasc Surg.* 2016;151:1617-26.
12. Shrestha M, Fischlein T, Meuris B, Flameng W, Carrel T, Madonna F, Misfeld M, Folliguet T, Haverich A, Laborde F. European multicentre experience with the sutureless Perceval valve: clinical and hemodynamic outcomes up to 5 years in over 700 patients. *Eur J Cardiothoracic Surg.* 2016;49:234-41.
13. D'Onofrio A, Messina A, Lorusso R, Alfieri OR, Fusari M, Rubino P, Rinaldi M, Di Bartolomeo R, Glauber M, Troise G, Gerosa G. Sutureless aortic valve replacement as an alternative treatment for patients belonging to the "gray zone" between transcatheter aortic valve implantation and conventional surgery: a propensity-matched, multicenter analysis. *J Thorac Cardiovasc Surg.* 2012;144:1010-6.
14. Phan K, Tsai YC, Niranjana N, Bouchard D, Carrel TP, Dapunt OE, Eichstaedt HC, Fischlein T, Gersak B, Glauber M, Haverich A, Misfeld M, Oberwalder PJ, Santarpino G, Shrestha ML, Solinas M, Vola M, Yan TD, Di Eusanio M. Sutureless aortic valve replacement: a systematic review and meta-analysis. *Ann Cardiothorac Surg.* 2015;4:100-11.
15. Di Eusanio M, Saia F, Pellicciari G, Phan K, Ferlito M, Dall'Ara G, Di Bartolomeo R, Marzocchi A. In the era of the valve-in-valve: is transcatheter aortic valve implantation (TAVI) in sutureless valves feasible? *Ann Cardiothorac Surg.* 2015;4:214-7.
16. Landes U, Sagie A, Kornowski R. Transcatheter aortic valve implantation in degenerative sutureless percutaneous aortic bioprosthesis. *Catheter Cardiovasc Interv.* 2018;91:1000-4.
17. Amabile N, Zannis K, Veugeois A, Caussin C. Early outcome of degenerated self-expandable sutureless aortic prostheses treated with transcatheter valve implantation: A pilot series. *J Thorac Cardiovasc Surg.* 2016;152:1635-7.
18. Dvir D, Webb JG, Bleiziffer S, Pasic M, Waksman R, Kodali S, Barbanti M, Latib A, Schaefer U, Rodés-Cabau J, Treede H, Piazza N, Hildick-Smith D, Himbert D, Walther T, Hengstenberg C, Nissen H, Bekeredjian R, Presbitero P, Ferrari E, Segev A, de Weger A, Windecker S, Moat NE, Napodano M, Wilbring M, Cerillo AG, Brecker S, Tchetché D, Lefèvre T, De Marco F, Fiorina C, Petronio AS, Teles RC, Testa L, Laborde JC, Leon MB, Kornowski R; Valve-in-Valve International Data Registry Investigators. Transcatheter aortic valve implantation in failed bioprosthetic surgical valves. *JAMA.* 2014;312:162-70.
19. Kappetein AP, Head SJ, Généreux P, Piazza N, van Mieghem NM, Blackstone EH, Brott TG, Cohen DJ, Cutlip DE, van Es GA, Hahn RT, Kirtane AJ, Krucoff MW, Kodali S, Mack MJ, Mehran R, Rodés-Cabau J, Vranckx P, Webb JG, Windecker S, Serruys PW, Leon MB; Valve Academic Research Consortium-2. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. *J Thorac Cardiovasc Surg.* 2013;145:6-23.
20. Landes U, Kornowski R. Transcatheter valve implantation in degenerated bioprosthetic surgical valves (ViV) in aortic, mitral, and tricuspid positions: a review. *Structural Heart.* 2017;1:225-35.
21. Nielsen-Kudsk JE, Christiansen EH, Terkelsen CJ, Nørgaard BL, Jensen KT, Krusell LR, Tang M, Terp K, Klaaborg KE, Andersen HR. Fracturing the Ring of Small Mitroflow Bioprostheses by High-Pressure Balloon Predilatation in Transcatheter Aortic Valve-in-Valve Implantation. *Circ Cardiovasc Interv.* 2015;8:e002667.
22. Barbanti M, Webb JG, Tamburino C, Van Mieghem NM, Makkar RR, Piazza N, Latib A, Sinning JM, Won-Keun K, Bleiziffer S, Bedogni F, Kapadia S, Tchetché D, Rodés-Cabau J, Fiorina C, Nombela-Franco L, De Marco F, de Jaegere PP, Chakravarty T, Vaquerizo B, Colombo A, Svensson L, Lange R, Nickenig G, Möllmann H, Walther T, Della Rosa F, Elhmidi Y, Dvir D, Brambilla N, Immè S, Sgroi C, Gulino S, Todaro D, Pilato G, Petronio AS, Tamburino C. Outcomes of Redo Transcatheter Aortic Valve Replacement for the Treatment of Postprocedural and Late Occurrence of Paravalvular Regurgitation and Transcatheter Valve Failure. *Circ Cardiovasc Interv.* 2016;9:e003930.
23. Tuzcu EM, Kapadia SR, Vemulapalli S, Carroll JD, Holmes DR Jr, Mack MJ, Thourani VH, Grover FL, Brennan JM, Suri RM, Dai D, Svensson LG. Transcatheter Aortic Valve Replacement of Failed Surgically Implanted Bioprostheses: The STS/ACC Registry. *J Am Coll Cardiol.* 2018;72:370-82.
24. Cockburn J, Dooley M, Parker J, Hill A, Hutchinson N, de Belder A, Trivedi U, Hildick-Smith D. Transcatheter aortic valve-in-valve treatment of degenerative stentless supra-annular Freedom Solo valves: A single centre experience. *Catheter Cardiovasc Interv.* 2017;89:438-44.

Supplementary data

Supplementary Table 1. Valve-in-valve procedural characteristics according to surgical heart valve (SHV) type.

Supplementary Table 2. Propensity score-matched patients' baseline characteristics.

The supplementary data are published online at:
http://www.pconline.com/eurointervention/152nd_issue/8



Supplementary data

Supplementary Table 1. Valve-in-valve procedural characteristics according to surgical heart valve (SHV) type.

	Rapid deployment SHV n=30	Conventional SHV n=2,288	<i>p</i> -value
Surgical AVR to ViV interval, months	55.2±36.1	118.4±57.7	<0.001
Surgical valve type			<0.001
Stented		83%	
Stentless		17%	
Perceval	80%		
ATS 3f	17%		
INTUITY	3%		
Surgical valve label size, mm	23.0±1.5	23.3±2.2	0.338
≤21	23.3%	28.1%	
21–25	36.7%	34%	
25≤	23.3%	33.4%	
Unknown	16.7%	4.7%	
Mechanism of surgical valve failure			0.003
Stenosis	23.3%	38.9%	
Regurgitation	16.7%	29.9%	
Combined	60%	31.2%	
Transcatheter valve type			
Self-expanding	30%	57.8%	0.022
Balloon-expandable	70%	42.2%	
Transcatheter valve diameter, mm, external	23.9±2.1	24.6±2.2	0.078
Procedural access			
Transfemoral	72.4%	77.8%	0.579
Non-transfemoral	27.6%	21.2%	
Anaesthesia			
General	46.7%	61.6%	0.129

Light sedation or local	53.3%	38.4%	
Transoesophageal echocardiography	48.3%	55.2%	0.460
Balloon pre-inflation	23.3%	19.9%	0.646
Balloon post-inflation	24.1%	13.5%	0.102

Rapid deployment SHV include the Perceval (Sorin Biomedica), ATS 3f Enable (Medtronic), INTUITY (Edwards Lifesciences). Conventional: “sutured”, both stented and stentless. The (label) size of the Perceval was converted from S / M / L to [mm] according to Perceval user instructions. AVR: aortic valve replacement; ViV: transcatheter valve-in-valve implantation

Supplementary Table 2. Propensity score-matched patients' baseline characteristics.

	Rapid deployment SHV (n=28)	Conventional SHV (n=28)	<i>p</i> -value	Standardised difference
Age, years	80.5±4.3	81.3±5.1	0.514	0.18
Male sex	17.9%	17.9%	1.000	0.00
Height, cm	160.5±7.4	159.9±7.5	0.743	-0.09
Weight, kg	71.8±12.2	69.0±12.7	0.352	-0.22
BSA, m ²	1.78±0.17	1.74±0.18	0.350	-0.22
BMI, kg/m ²	27.9±4.7	27.1±5.1	0.495	-0.17
STS score	7.5±5.4	9.7±7.0	0.218	0.36
EuroSCORE II	15.0±8.7	14.7±6.6	0.935	0.05
Diabetes mellitus type 2	28.6%	25.0%	0.763	-0.08
Peripheral artery disease	18.5%	14.8%	0.715	-0.08
Renal failure	14.3%	39.3%	0.035	0.58*
Previous stroke/TIA	7.7%	30.8%	0.135	0.42
Chronic lung disease	25.9%	22.2%	0.750	-0.13
NYHA functional Class III–IV	96.3%	85.2%	0.159	-0.39
Peak aortic valve gradient, mmHg	53.7±25.9	61.7±23.7	0.304	0.42
Mean aortic valve gradient, mmHg	32.3±16.3	35.9±15.3	0.349	0.23
Aortic valve area, cm ²	1.01±0.51	0.84±0.37	0.159	-0.44
Left ventricular ejection fraction, %	56.1±6.9	56.8±7.6	0.720	0.09
SAVR to ViV, months	126.4±69.9	65.3±30.9	0.001	-0.97*
Mechanism of surgical valve failure				
Stenosis	21.4%	25.0%	0.752	0.04
Regurgitation	32.1%	17.9%	0.217	-0.38
Combined	39.3%	57.1%	0.181	0.29

* - standardised difference is larger than might occur simply by chance. BMI: body mass index; BSA: body surface area; NYHA: New York Heart Association; SAVR: surgical aortic valve replacement; STS: Society of Thoracic Surgeons; TIA: transient ischaemic attack; ViV: transcatheter aortic valve-in-valve implantation