Trends in Surgical Aortic Valve Replacement in More Than 3,000 Consecutive Cases in the Era of Transcatheter Aortic Valve Implantations

Miriam Silaschi[1,*]   Lenard Conradi[1,*]   Hendrik Treede[1]   Beate Reiter[1]   Ulrich Schaefer[2]
Stefan Blankenberg[2]   Hermann Reichenspurner[1]

[1] Department of Cardiovascular Surgery, University Heart Center Hamburg, Hamburg, Germany
[2] Department of Cardiology, University Heart Center Hamburg, Hamburg, Germany

Address for correspondence Miriam Silaschi, MD, Department of Cardiovascular Surgery, University Heart Center Hamburg, Martinistraße 52, Hamburg 20246, Germany (e-mail: m.silaschi@uke.de).

Abstract

Objectives Biological prostheses for surgical aortic valve replacement (sAVR) are increasingly being considered in patients < 60 years of age. Likely, preserving the option of performing a transcatheter valve-in-valve (ViV) procedure in cases of structural valve deterioration has contributed to this development. We assessed the use pattern in sAVR over an 11-year period.

Methods   From 2002 through 2012, a total of 3,172 patients underwent sAVR at our center.

Results   Mean age was 70.4 ± 10.6 years and mortality was 1.9%. From 2002 to 2012, mean manufacturer given valve size increased from 22.8 ± 1.7 to 23.9 ± 2.0 mm ($p < 0.001$). Mean true internal diameter and effective orifice area increased from 19.6 to 20.3 mm ($p = 0.027$) and 1.41 to 1.56 cm^2 ($p < 0.001$), respectively. Use of mechanical valves decreased from 10.9 to 1.8% ($p < 0.001$), and patients were younger in 2012 than in 2002 (52.8 ± 16.5 vs. 41.0 ± 14.3 years; $p = 0.028$).

Conclusion   Profound change of use pattern in sAVR was observed as indication for biological prostheses became more liberal. Larger prostheses were implanted during the observational period. Especially in younger patients, optimal sizing is essential to preserve the option for subsequent ViV procedures.

Keywords

► aortic valve
► aortic root
► cardiac surgery
► heart valve
► transcatheter aortic valve implantation

Introduction

Surgical aortic valve replacement (sAVR) is the gold standard for the treatment of aortic stenosis.[1] It can be performed safely and is associated with low perioperative morbidity and mortality. According to national German statistics, mortality was 2.9% in 2013 for isolated aortic valve replacement. A substantial increase in use of biological prostheses was seen during the last years with a share of 62.5% of prostheses used in 2004 and 86.9% in 2013.[2]

According to international guidelines (AHA and ESC/EACTS), use of biological prostheses in the aortic position is generally recommended in patients >60 years.[3] However, there seems to be a trend toward use in younger patients even though structural valve deterioration (SVD) and graft failure remain problematic as they are known to occur earlier in younger patients.[4] Likely, preserving the option of performing a subsequent transcatheter valve-in-valve (ViV)

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* Both the authors contributed equally to this work.

procedure in cases of SVD has contributed to this development. Reoperation has formerly been the only treatment option for degenerated biological prostheses and it is associated with an increased perioperative risk of mortality of 5.1% in the overall population and up to 20% in high-risk patients.[5,6] Besides the increasing implementation of ViV procedure, improved durability of biological valves and avoidance of permanent anticoagulation favor the use of biological prostheses.

Recently, transcatheter ViV procedures have been established as a less invasive alternative for treatment of degenerated biological prostheses. These can be performed safely with acceptable outcome in recent series of high-risk patients.[7–9]

According to the global ViV registry, mortality was 7.6% from 2007 to 2013.[9] Current literature recommends that ViV procedure should only be performed at experienced centers due to the complexity of the procedure. Potential disadvantages of ViV procedure may be elevated residual pressure gradients. Other clinical concerns include coronary ostia obstruction and malpositioning of the transcatheter heart valve (THV).[10] Internal dimensions of the surgical prosthesis are of crucial relevance for successful ViV procedures as the size of the initially implanted prosthesis correlates with the postoperative gradient[9] and the gradient in turn correlates directly with midterm patient survival.[9,11] Therefore, optimal sizing during the initial sAVR is essential to preserve the option of subsequent ViV therapy when deterioration of the implanted biological prosthesis has occurred.

The objective of the present study was to investigate trends in our sAVR program. We aimed to review age development, valve types and sizes used, and the impact on use frequency of mechanical prostheses, and to assess possible impact of the introduction of transcatheter aortic valve implantation (TAVI) in 2007 on the use pattern of sAVR.

Methods

Study Population and Data Collection

From 2002 to 2012, 3,172 consecutive patients underwent sAVR at our center. All combined or isolated procedures (e.g., additional coronary artery bypass graft [CABG] or valve procedures), as well as reoperative procedures for degenerated biological prostheses, were included. Reoperative procedures for acute prosthesis endocarditis were excluded from our analysis.

Data were collected retrospectively and entered into a dedicated database. In addition to baseline characteristics, information about valve types and manufacturer given sizes, true internal diameter (true ID), and standard effective orifice area (EOA) of the implanted prostheses as reported in the literature[12] was gathered and patient–prosthesis mismatch (PPM) calculated. True ID was defined as the ID of the inflow of the biological prosthesis as measured by Hegar dilators.[13]

PPM was graded according to the definition by Blais and colleagues,[14] where it was quantified by relating EOA to body surface area (BSA) (indexed EOA, iEOA). Based on iEOA, three categories of PPM are defined: not relevant ($>0.85 \ cm^2/m^2$), moderate ($0.65–0.85 \ cm^2/m^2$), and severe ($<0.65 \ cm^2/m^2$). BSA was derived using the Du Bois equation.[15]

Statistical Analysis

Data are presented as absolute numbers and percentages for categorical variables and mean values and standard deviations for continuous variables. Dichotomous variables are compared using Fisher exact test and continuous variables by t-tests. Linear regression was applied to examine the association between valve size (manufacturer size, true ID, EOA) and the year of treatment. The regression coefficient was applied to estimate the change in valve size per year. p-Values are reported without correction for multiple testing. Level of significance is set to a two-tailed $p < 0.05$. All statistical analysis was performed using SPSS 19.0.

Results

Development of sAVR in the TAVI Era

During the study period from 2002 to 2012, 3,172 patients underwent sAVR at our center. Additionally, 750 patients underwent TAVI from 2007 to 2012.

Combined surgical procedures were performed in 1,342 patients. Number of procedures performed in a single year increased from 139 patients in 2002 to 322 patients in 2012 (+131%). A total of 85 patients underwent reoperative sAVR for degenerated bioprostheses.

Until the introduction of TAVI at our center in 2007, annual numbers of sAVR increased by 43% ($n = 226$ in 2006 to $n = 324$ in 2007; ►**Fig. 1**), but slightly declined from 2007 to 2012 ($n = 324$ in 2007 vs. $n = 322$ in 2012). Mean 30-day mortality was 1.9% for sAVR during the study period and did not change significantly in between single years ($p = 0.245$; see ►**Fig. 1**). In 2012, 30-day mortality was 0% after isolated sAVR. Mean age of sAVR patients was 70.4 ± 10.6 years through the study period and did not differ significantly between the years ($p = 0.235$). Regarding biological prostheses, the proportion of patients aged 50 to 60 years increased significantly from 6.9% in 2002 to 12.4% in 2012 ($p = 0.015$). Proportion of patients <50 years was 4.6% in 2002 and 2.3% in 2012 and did not change significantly in between years ($p = 0.180$). The same was true for the proportion of patients >60 years with 88.5% 2002 and 85.3% in 2012. Proportion of patients 70 to 80 years increased from 42.4% in 2002 to 49.1% in 2012 ($p = 0.222$).

Patient Characteristics

Comparison of patients undergoing biological sAVR in 2002 and 2012 yielded no significant differences regarding typical baseline variables (►**Table 1**). The proportion of patients undergoing biological sAVR after any kind of previous cardiac surgery decreased significantly from 14.4% in 2002 to 5.0% in 2012 ($p < 0.001$). Reoperations for degenerated biological prostheses were performed in a total of 85 cases throughout the study period; here, mean proportion did not change significantly (6.5% in 2002 vs. 3.4% in 2012; $p = 0.178$; ►**Fig. 2**). Time to reoperation for SVD was
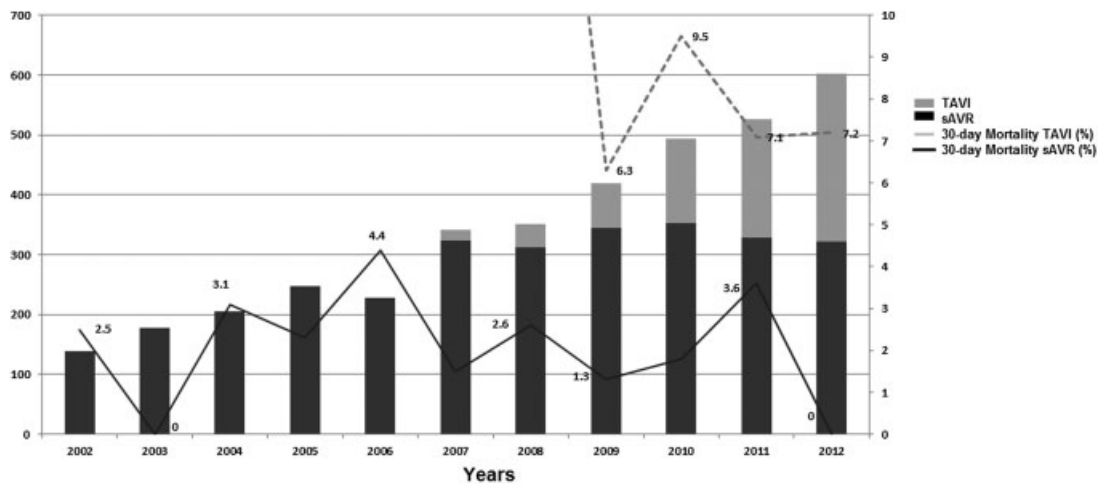
Fig. 1 Total number of sAVR and TAVI procedures at UHC Hamburg. Total caseload of sAVR constantly increased at our center; the addition of TAVI to this calculation produces a threefold increase in surgical activity. Since the introduction of TAVI, total numbers of sAVR slightly declined. Thirty-day mortality of isolated sAVR decreased from 4.4% before the introduction of TAVI in 2006 to 0% in 2012 ($p = 0.029$).

11.8 ± 5.6 years in 2002 and 10.1 ± 6.3 years in 2012 ($p = 0.540$; ►**Fig. 2**). Mode of degeneration was leaflet tear with consecutive regurgitation in the majority of patients (46/85, 54.2%). Leaflet thickening with resultant prosthesis stenosis was observed in 29.4% of patients (25/85) and mixed steno-insufficiency was seen in 15.4% of patients (13/85). In one case, mode of degeneration was not described. Combined procedures (e.g., additional valve or CABG) were performed in 49.6% ($n = 64$) in 2002 and 51.6% ($n = 161$) in 2012 ($p = 0.630$).

Valve Details

Of all patients, 94.9% ($n = 3{,}010$) received biological prostheses. In the majority of cases, pericardial valves were used (61.1%). Proportion of porcine valves decreased from 48.5% in 2002 to 33.4% in 2012 ($p < 0.001$). The three most commonly used brands were Edwards Perimount (27.5%; Edwards Lifesciences Inc., Irvine, California, United States), Medtronic Hancock (II or Ultra) (32.2%; Medtronic Inc., Minneapolis,

Minnesota, United States), and Sorin Mitroflow (28.7%; Sorin Group, Milano, Italy) (►**Table 2**).

The proportion of mechanical valves decreased from 10.9% in 2002 to 1.8% in 2012 at our center ($p < 0.001$). Mean age of patients receiving a mechanical valve decreased significantly from 2002 to 2012 (52.8 ± 16.5 vs. 41.0 ± 14.3 years; $p = 0.028$).

Valve Size

From 2002 to 2012, mean valve size as specified by the manufacturer increased from 22.8 ± 1.7 to 23.9 ± 2.0 mm ($p < 0.001$); the regression coefficient indicated a mean increase of 0.11 ± 0.01 mm per year. The most commonly used valve size was 23 mm throughout the study period, although its overall proportion decreased from 54.6% in 2002 to 33.6% in 2012 ($p < 0.001$). The proportion of small valve sizes (≤ 21 mm) decreased significantly from 27.7% to 19.0%, while use of larger sizes (≥ 25 mm) increased significantly from 17.7% to 47.4% (both $p < 0.001$).

Table 1 Baseline variables of patients undergoing sAVR and TAVI

Variable	sAVR 2002 ($n = 139$)	sAVR 2012 ($n = 322$)	p-Value	TAVI 2009 ($n = 75$)	TAVI 2012 ($n = 281$)	p-Value
Age (y)	69.7 ± 12.1	70.2 ± 9.4	0.673	79.6 ± 6.9	79.9 ± 7.3	0.725
Body surface area (m^2)	1.9 ± 0.2	2.0 ± 0.2	0.233	n.a.	n.a.	–
Female gender (%)	33.3	31.5	0.823	52.0	49.5	0.850
Logistic EuroSCORE I (%)	8.8 ± 8.4	9.1 ± 9.5	0.815	26.8 ± 12.8	19.5 ± 12.2	<0.001
Arterial hypertension (%)	50.0	74.5	<0.001	76.0	78.3	0.613
Diabetes (%)	13.8	17.7	0.399	24.0	25.6	0.910
Dialysis (%)	1.5	1.9	1.000	5.3	1.1	0.038
Reoperation[a] (%)	14.4	5.0	<0.001	21.3	19.2	0.743
Combined procedures (%)	49.6	51.4	0.630	n.a.	n.a.	–

Abbreviation: TAVI, transcatheter aortic valve implantation.
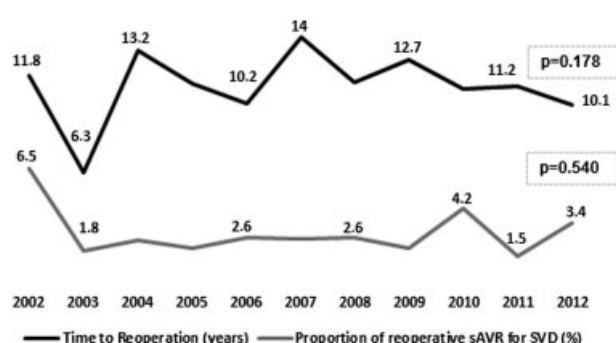[a]Including all kinds of previous cardiac surgeries.

Fig. 2 Development of reoperative sAVR for degenerated biological SHV. Both proportion of reoperative sAVR for SVD and mean time to reoperation did not change significantly during the study period.

Correspondingly, true ID and EOA of biological prostheses increased from 19.6 ± 1.7 to 20.3 ± 2.1 mm ($p < 0.001$) and 1.4 ± 0.2 to 1.6 ± 0.2 cm^2 ($p < 0.001$), respectively. Mean increase by each year in regression analysis was 0.10 ± 0.01 mm and 0.02 ± 0.01 cm^2 for true ID and EOA, respectively. Results are summarized in ►Fig. 3.

Severe PPM, defined as an iEOA ≤ 0.65 cm^2/m^2, tended to be less frequent, although this did not reach statistical significance (24.4% in 2002 vs. 10.7% in 2012; $p = 0.092$; ►Fig. 4). Mean iEOA increased significantly from 2002 to 2012 (0.75 ± 0.1 vs. 0.80 ± 0.1 cm^2/m^2; $p = 0.020$).

Age and Valve Size
Throughout the study period, younger patients (≤ 60 years) received significantly larger prostheses compared with patients ≥ 60 years (23.8 ± 1.7 vs. 22.6 ± 1.6 mm in 2002 and 24.7 ± 2.3 vs. 23.7 ± 2.0 mm in 2012; both $p < 0.001$). Mean difference in valve size between patients ≤ 60 years and patients ≥ 60 years was 1.0 ± 0.1 mm. Although in both patient groups an increase in valve sizes was seen regarding manufacturer given size, differences between age groups remained unchanged. iEOA was significantly larger in

patients ≤ 60 in 2002 (0.83 ± 0.12 vs. 0.73 ± 0.10 cm^2/m^2; $p = 0.045$) and tended to be larger in 2012, although this was not statistically significant (0.81 ± 0.20 vs. 0.79 ± 0.11 cm^2/m^2; $p = 0.360$).

Discussion

Development of sAVR in the TAVI Era
Total number of sAVR increased significantly from 2002 to 2012. The addition of TAVI procedures to this calculation resulted in a threefold increase in surgical activity at our center (►Fig. 1). However, in the most recent 5 years a slight decline of sAVR was observed. This is in contrast to the national background where total numbers of sAVR remained stable after the introduction of TAVI.[2] The decline in sAVR numbers after introduction of TAVI at our center may be explained by a substantial amount of patients eligible for both types of procedures and the consequence that in a center with a large interventional program this leads to a reduction of those patients treated surgically. As 30-day mortality of isolated sAVR decreased to 0% in 2012, we assume that the introduction of TAVI may have had an influence on mortality rate of sAVR by decreasing the amount of unsuitable surgical candidates, leading to a more individual decision-making process. There has been a tendency toward a slightly more liberal indication for TAVI at our center; however, it is still restricted to high-risk patients. Moreover, as we report data obtained in a surgical center, the real number of TAVI performed may be underestimated as there are nonsurgical centers performing TAVI as well. The introduction of TAVI did lead to an increased overall caseload of procedures performed on the aortic valve, suggesting an on-top recruitment phenomenon.

Age Development
During the study period, an increasing trend toward implantation of biological prostheses in patients ≤ 60 years was observed. Several factors may have contributed to this liberal

Table 2 List of SHV brands used at UHC Hamburg

Brand %	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Edwards Perimount	50.8	18.3	48,7	51.8	56.4	24.5	26.7	14	21.6	14.5	12.2
Medtronic Hancock[a]	38.9	53.6	48.6	42.6	29.4	38.6	34.8	21.1	19	25.3	32.5
Sorin Mitroflow	0	0	0	0	3.9	35.8	35.4	57.4	45.6	49.1	30.2
Sorin Freedom Solo	0	0	0	0	2.9	0	0.7	1.8	9.2	5.4	1.3
Medtronic Freestyle	0	0	0	0	0	0	2.1	3.1	0.3	0.9	0.9
Edwards Magna	0	0	0	0	0	0	0	0	0.8	3.6	3.2
St. Jude Trifecta	0	0	0	0	0	0	0	0	0.3	0	17.4
St. Jude Biocor/Epic	7.9	10.2	0.5	0	0	0	0	0	0	0	0
Edwards SAV	0	0	0	2.8	4.9	0	0	0	0	0	0
Sorin Perceval S	0	0	0	0	0	0	0	0	2	0.3	0
Shellhigh	2.4	1.4	1.1	2.3	2.5	0.9	0	0	0	0	0

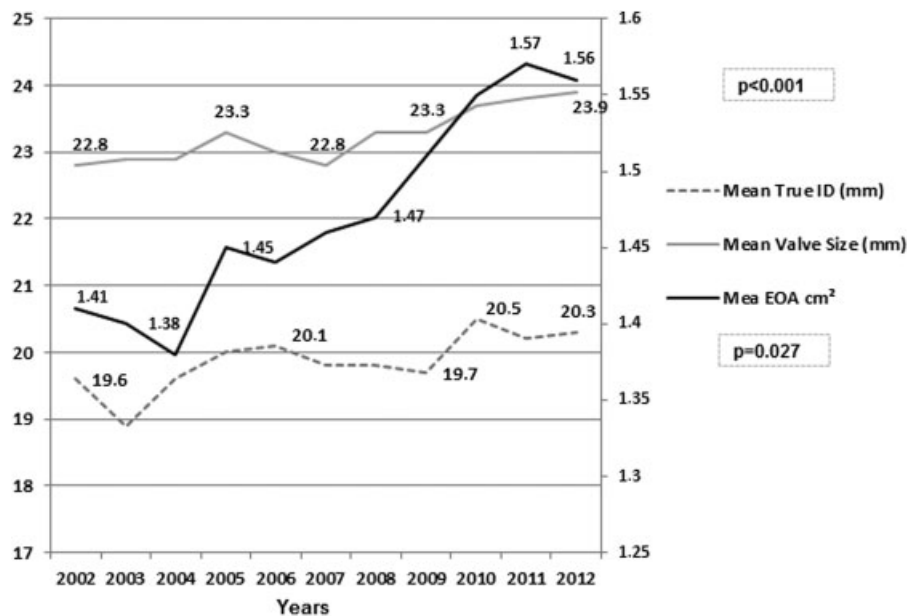[a]Hancock includes Hancock, Hancock II, and Hancock II Ultra.

Fig. 3 Development of mean valve size and mean true ID from 2002 to 2012. Mean valve size as specified by the manufacturer increased by 1.1 mm from 2002 to 2012 ($p < 0.001$). Correspondingly, mean true ID increased by 0.7 mm during the study period ($p = 0.027$) and EOA increased by 0.14 cm^2 ($p < 0.001$).

indication. For one, improved durability of biological prostheses has been suggested, but not proven.[16] In our experience, mean time to reoperation from 2002 to 2012 did not increase (►**Fig. 2**); therefore, this hypothesis remains subject of further investigation. On the other hand, avoidance of permanent anticoagulation is among the most important reasons for patients' choice of a biological prosthesis. Our observation regarding lower age limits for biological sAVR corresponds to data reported in the literature.[16,17] The factor age for the choice of a valve is still important in considerably young patients but not a major selection criterion in patients ≥60 years.[18] It is well known with extensive documentation

in the literature that probability of SVD dramatically increases in a younger patient population.[18] This has to be taken into consideration when choosing the type of prosthetic heart valve: the common treatment of SVD used to be reoperative sAVR with either a biological or mechanical prosthesis.

More recently, the option of subsequent ViV avoiding complex reoperation may influence decision making. ViV has proven to be technically safe and feasible in most biological prostheses with a clearly defined landing zone easily identifiable by the radio-opaque valve sewing ring. This may be more challenging in certain types of stented biological prostheses or in stentless prostheses. It is possible
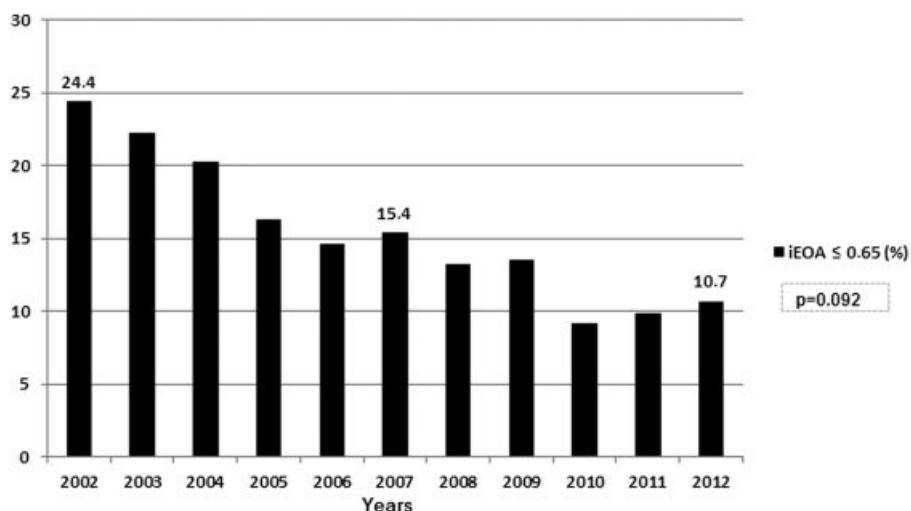

Fig. 4 Proportion (%) of iEOA ≤ 0.65 cm^2/m^2 among sAVR patients. Severe PPM (iEOA ≤ 0.65 cm^2/m^2) decreased constantly from 24.4% in 2002 to 10.7% in 2012, although this was not significant ($p = 0.092$).

to perform it via transapical or transarterial access, and major complications seen after conventional TAVI, such as conduction disturbances and paravalvular leakage, are expected to occur less frequently in ViV. The recently reported rate of paravalvular leakage is ~5% in ViV compared with 17.2% in conventional TAVI.[19] Pacemaker implantation rate is significantly lower after ViV compared with TAVI in native aortic stenosis (17% in TAVI vs. 8.3% in ViV).[9,20]

As a consequence, it seems possible to reach advantages of a biological prosthesis in a younger person (< 60 years) without the dilemma of a future reoperation. As performing a ViV will not complicate possible subsequent open reoperative AVR, it may be justified even in younger patients aged between 50 and 60 years who are more likely to experience structural deterioration of the THV used for ViV. Thus, surgical options are preserved. However, to date no clinical evidence exists that the implantation of a biological prosthesis into a young patient (< 60 years) with subsequent ViV therapy ensures more quality of life and less complications in comparison to other treatment strategies using mechanical devices. Until scientific evidence proves superiority of the above-described concept, international guidelines should be followed and biological prostheses should only be implanted in patients ≤ 60 years if indicated either by patients' choice or by contraindication to life-long anticoagulation.

Mean age of patients undergoing sAVR did not change significantly at our center. This observation may be explained when considering that there has also been a substantial increase in elderly patients as well. Especially the introduction of TAVI led to a broadened referral pattern, since elderly and high-risk patients were historically often denied surgical treatment and are now increasingly referred to our center as a consequence of supplementary treatment options. Likely, this caused a crossover of patients in between interventional and surgical treatment options.

Patient Characteristics

Typical baseline patient characteristics did not change significantly throughout the study period (see ►Table 1), although sAVR was less frequently a reoperative procedure after any kind of previous cardiac surgery (14.1 vs. 5.0%; $p < 0.001$). It seems possible that patients with severe aortic stenosis and a history of previous cardiac surgery are more likely to receive TAVI in 2012 than to undergo sAVR.

On the other hand, rate of reoperative sAVR for degenerated surgical heart valve (SHV) at our center remained stable, being 2.6% before the implementation of ViV in 2008 and 3.4% in 2012. Evidently, the introduction of ViV did not lead to a reduction of reoperative sAVR for degenerated SHV. We state that some patients still have to undergo reoperative sAVR in times of ViV despite elevated operative risk when considering that there are different types of biological prostheses, some of them not suitable for a ViV procedure as they might lead to elevated postinterventional pressure gradients. ViV is an effective treatment option for degenerated biological prostheses but indication in some cases is limited due to an adverse aortic root anatomy with low-coronary takeoff and shallow aortic

sinuses, or the presence of paraprosthetic leakage and endocarditis. Furthermore, conventional reoperative SAVR is a proven therapeutic option with predictable long-term performance which is—and still should be—recommended to patients at low surgical risk. Therefore, we state that both procedures serve as complementary approaches toward an increasing population of patients with degenerated SHV.

Valve Details

The use of porcine valves decreased significantly from 2002 to 2012 at our center. This reflects an observed national tendency toward pericardial valves, for which there may be some indication of superior durability beyond 10 years after implantation.[21]

Generally, we expect the suitability of a biological prosthesis for later ViV to be of growing importance as the awareness of ViV procedures will increase. This will lead to an influence on the surgeons' decision on which biological prostheses to implant. Biological prostheses not suitable for ViV may be avoided if future need for ViV due to SVD is probable. However, the suitability of different biological prostheses for ViV is scarcely described and should be further analyzed in future to adapt surgical strategies accordingly.

A substantial reduction in the rate of mechanical valves implanted was seen, from 10.9 to 1.8% ($p < 0.001$), at our center. This effect was more pronounced compared with the national background ($p < 0.001$) where a decrease from 44.8 to 14.1% was observed. In each year during the study period, the rate of mechanical AVR was lower as compared with corresponding years of the national background.[2] Possibly, this is due to a higher awareness for ViV in a center with a large TAVI program. Patients receiving mechanical valves at our center were significantly younger in 2012 compared with 2002.

One could argue that the use of a mechanical prosthesis is limited to considerably young patients and if the patient clearly requests it. Furthermore, according to international guidelines,[3] mechanical sAVR is still recommended in patients with increased risk of SVD, in patients already on anticoagulation as a result of having a mechanical prostheses in another valve position, or in patients with reasonable life expectancy for whom future reoperative valve surgery would be a high-risk procedure. The latter argument appears to become less relevant when considering possible future ViV procedure as a bailout strategy in high-risk cases. In addition, even in young patients, the use of anticoagulation for a mechanical prosthesis may restrict quality of life substantially and tremendous complications can occur, a circumstance that physicians and patients are increasingly becoming aware of, and consequently biological prostheses are chosen over mechanical prostheses.

To date, several studies regarding survival after biological versus mechanical sAVR exist and are contradictory; thus, no clinical evidence exists that one treatment option is superior to the other in patients <60 years.[17,18] It has been demonstrated that the risk of major bleeding after mechanical sAVR equals the risk of reoperation after biological sAVR in patients aged 60 years at surgery.[18]

In a large historical trial, a survival advantage for mechanical prostheses was present at 12 years; however, the actuarial survival curves between the groups converged at 20 years of follow-up.[22] Further studies comparing two strategies—biological sAVR at an age of 50 to 60 years using subsequent ViV versus mechanical sAVR—are needed to determine advantages of either strategy and to evaluate long-term outcomes.

Valve Size

There are two predictors of SVD: patient age at the time of sAVR and severe PPM defined as iEOA $\leq$0.65 cm².[23] Growing awareness that PPM independently increases the risk of SVD and decreases survival[23] may have led to a strategy avoiding implantation of valves sized $\leq$21 mm. The proportion of valves $\geq$23 mm increased significantly, as well as mean true ID and EOA without a significant change of BSA. Therefore, during the past years, truly larger valves were implanted at our center. However, this may also in part be explained by an improved valve design of biological prostheses with a positive impact on hemodynamic performance. The changes in use of prostheses are documented in ►Table 2. However, the use of valve sizes <25 mm has decreased significantly, indicating a change in surgeon's practice. We expect that this leads to better hemodynamic performance and fewer cases of SVD in the later course.

Age and Valve Size

Throughout the study period, patients <60 years received significantly larger valves, while there was a significant increase in mean valve size both in patients aged <60 and >60 years. In 2013, Price and colleagues reported that PPM adversely affects survival only in patients <70 years.[24] As mean valve size was larger in patients <60 years, it appears likely that at our center we tended to avoid surgical maneuvers to increase EOA in elderly patients to limit both procedural times and surgical risk. Similarly, Price and colleagues recommend that root enlargement techniques should be reserved for patients <70 years.[24] In their cohort, the incidence of severe PPM in patients 70 years old or older was 16.5% (46/279), compared with 4.5% (20/428) in patients less than 70 years old ($p < 0.001$). This corresponds to our observation that iEOA is larger in patients $\leq$60 years (0.83 ± 0.12 vs. 0.73 ± 0.10 cm²/m², $p = 0.045$ in 2002, and 0.81 ± 0.20 vs. 0.79 ± 0.11 cm²/m², $p = 0.360$ in 2012). As ViV performed inside smaller biological prostheses ($\leq$23 mm) can lead to elevated postoperative pressure gradients, the strategy to implant larger valves into younger patients seems reasonable. Small-sized stented valves in small aortic roots may by nature not provide sufficient EOA. To avoid PPM and preserve later ViV options, in these cases root enlargement may help to increase the achievable iEOA. Additionally, valves suitable for later ViV should be implanted.[25]

Conclusion

Profound change of use pattern in sAVR was observed at our center as indication for biological prostheses became more liberal. Furthermore, significantly larger prostheses were implanted considering manufacturer size, true ID, and orifice area leading to increased iEOA. Less reoperative sAVR and implantations of mechanical prostheses were performed after the introduction of TAVI at our center. In younger patients with high risk of later SVD, it is essential to implant biological prostheses of suitable size and type for ViV. Optimal sizing is of crucial relevance to preserve the option for subsequent ViV procedures.

Limitations

This is an observational, retrospective single-center study and as in any retrospective analysis may contain hidden bias. Therefore, conclusions drawn from results of our analyses have to be interpreted with caution. In particular, a causal relationship between trends in sAVR and availability of TAVI is unproven and purely hypothetical at present.

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Editor's Commentary

Markus K. Heinemann

Address for correspondence Markus K. Heinemann, MD, PhD, Department of Cardiac, Thoracic and Vascular Surgery, Universitaetsmedizin Mainz, Langenbeckst. 1, # 505, D 55131 Mainz, Germany (e-mail: heinemann@uni-mainz.de).

Experience with new techniques sometimes spurs even newer ideas. The article by Silaschi et al is a perfect example. In the era of fast-developing transcatheter aortic valve implantation (TAVI) technology, valid data from large centers are of high interest for the scientific community. Although the Editor was somewhat surprised by the conclusions the authors drew and the policy they advocate, he still thought the article valuable. To stimulate discussion, one of our Editorial Board members, who had also reviewed the manuscript, was invited to write a commentary. Any Letters-to-the-Editor to continue this debate are very welcome.

As for the Editor himself suffice it to cite the sentence so often (wrongly) attributed to Voltaire: "I may disapprove of what you say, but I will defend to the death your right to say it"—because this is an adamant editorial principle.

Biological versus Mechanical Heart Valve Prostheses. Has the Paradigm Shifted Definitively?

Manuel J. Antunes[1]

[1] Center of Cardiothoracic Surgery, University Hospital and Faculty of Medicine, Coimbra, Portugal

Address for correspondence Manuel J. Antunes, MD, PhD, DSc, Center of Cardiothoracic Surgery, Coimbra, Portugal (e-mail: antunes.cct.chuc@sapo.pt).

In this article of the *Thoracic and Cardiovascular Surgeon*, Silaschi et al analyze the trends in surgical aortic valve replacement (sAVR) over the last decade in their institution, which is a high-volume center in both surgical and percutaneous intervention on the aortic valve.[1] In the background of this study is the fact that they are increasingly considering biological prostheses for sAVR in patients ≤60 years of age, based on the premise that this practice will preserve the option of performing a transcatheter valve-in-valve (ViV) procedure in case of structural valve deterioration.

During an 11-year period, from 2002 to 2012, over 3,000 patients with a mean age of ∼70 years underwent sAVR at their center. Use of mechanical valves decreased from 10.9 to 1.8% and the mean age of the patients decreased from ∼53 to 41 years in the same time period. According to the authors, the "indication for biological prostheses became more liberal" as a result of the perspective option for subsequent ViV procedures.

There are two aspects of this work that deserve careful reflection. First, this "liberal" use of bioprostheses, reaching patients in their 40s, is well out of the recommendations of current guidelines from both sides of the Atlantic, which clearly recommend the use of mechanical prostheses in the aortic position in patients below 60 years of age, unless contraindicated.[2,3] Use of bioprostheses is recommended above 65 years by the ESC/EACTS and above 70 years by the AHA/ACC. Either a bioprosthetic or mechanical valve is reasonable in patients between 60 and 70 years of age (Class IIa indication).

Guidelines are based on best current scientific evidence, and since their recent publication, there has been no new evidence that could lead to substantial modification of these recommendations. Naturally, guidelines are not commandments and need not be rigorously followed, but the advice coming from them should seriously be considered. Conversely, significant deviation cannot be condoned.[4]

Second, the authors' main argument for preference of bioprostheses is that, in the near future, ViV will become common practice; hence, degeneration of surgically implanted bioprostheses will be less of a problem. Although this trend is followed by many other teams, in my view the current series has gone to an extreme, perhaps a dangerous

one. Let us see. Assuming a mean durability of 15 years, and we are not sure if all bioprostheses will last that long, a 40-year-old patient with a life expectancy of 85 years would have to undergo at least three ViV procedures, assuming a similar durability of 15 years, which is even less probable. In any case, this is technically impossible, as, with an initial 23-mm bioprosthesis, the valve would become unacceptably stenotic. Besides, as the authors also point out, current mortality of ViV is 7%, far in excess of that of repeat surgery for young, low-risk patients, in whom the mortality of reoperation should not exceed 3%, and there are reports with even lower mortality.

Hence, in my opinion, this paper gives the wrong message to the surgical community, especially to young surgeons. The future may prove them right, but it is far too soon to enter it.

During the process of revision of this manuscript, which resulted in some substantial modifications of the original text, the authors admitted that "there is no evidence of a survival advantage for the practice of implanting biological valves into very young patients when structural valve deterioration has to be expected" and emphasized "the need for evidence as in current practice the 'borderline' group of patients aged between 50 and 60 years is significantly increasing." But these statements are clearly not in tune with their real practice, as described. Not even the claim that "patients with heart valve diseases have a reduced life expectancy compared to the average population, therefore making it unlikely that these patients experience SVD of three generations of biological prostheses" can be considered an attenuating factor.

The authors suggest that "as performing a ViV will not complicate possible subsequent open reoperative AVR, it may be justified even in younger patients aged between 50 and 60 years who are more likely to experience structural deterioration of the transcatheter heart valve used for ViV." But it then means pushing a second surgery to a much older age, which, naturally, is not desirable. On the contrary, I see it more appropriate to start by reoperation and leave the eventual ViV procedure for later.

Evidently, I agree with the authors' statement that "until scientific evidence proves superiority of the above-described concept, international guidelines should be followed and

biological prostheses should only be implanted in patients ≤60 years if indicated either by patients' choice or by contraindication to life-long anticoagulation." I can only suggest that they follow their own advice.

To solve this difficult equation, they propose that "further studies comparing two strategies—biological sAVR at an age of 50–60 years using subsequent ViV versus mechanical sAVR—are needed to determine advantages of either strategy and to evaluate long-term outcomes." However, although improved durability of biological prostheses has often been suggested, it has not been proven. In fact, in the experience of Chan et al, the median interval to reoperation of contemporary, stented aortic bioprostheses was 7.74 years in patients less than 40 years and 12.93 years in patients between 40 and 60 years of age.[5] The authors confirm that in their experience the mean time to reoperation did not increase from 2002 to 2012.

On the other hand, and in opposition to what the authors state, newer generation of mechanical valves have shown remarkable performance with regard to freedom from serious complications, including thromboembolism, so much so that lowering the dosage of anticoagulation, and hence of INR levels, has been recommended.[6]

The question of the patients' choice also deserves some discussion. This concept has become fashionable. Indeed, the ESC/EACTS guidelines include, as class I indication, "the desire of the informed patient." Naturally, the patient has to be included in the decision process, but what is an "informed patient" if we, the "experts" in the matter, most often fail to reach consensus? Should we peacefully accept a young patient's choice of a bioprosthesis just because he does not "feel like" taking anticoagulants? I do not think so! Fortunately, in my country, and I suppose in most others, the patients most often follow our advice.

There is, however, one important message to be learnt from this paper: surgeons must do everything in their power to increase the size of prostheses implanted, not just to avoid patient–prosthesis mismatch, but to prepare for the future, if and when bioprostheses degenerate and ViV may be indicated. This can also be done by adequate choice of more hemodynamically efficient prostheses. From this point of view, the authors' experience has been positive, as the use of valve sizes < 25 mm decreased significantly and the mean size of the prostheses implanted has increased by ~1 mm during the study period. This may require a wider use of annular enlargement procedures, which are simple to perform and efficacious.

In the authors' institution, there has been a decline in sAVR numbers after introduction of transcatheter aortic valve implantation (TAVI), which they say "may be explained by a substantial amount of patients eligible for both types of procedures and the consequence that in a center with a large interventional program this leads to a reduction of those patients treated surgically." Although this appears to be a trend in Germany, where more than 40% of the isolated aortic valves are now treated percutaneously (although with stable sAVR numbers),[7] it is by no means a universal experience, most reports showing exactly the inverse, that is, an increase in surgical numbers, probably resulting from a much greater referral of patients with aortic stenosis for evaluation of the heart teams, the majority still ending in surgery.

The authors state that because theirs is a "center with a large interventional program" there is a more liberal switch to TAVI, although the indication for it remains "high-risk" patients. One cannot avoid feeling that "difficult" patients are increasingly included in that classification. Naturally, a better selection has resulted in improved outcomes, as happened in their experience where the 30-day mortality of isolated sAVR was 0% in 2012, which is certainly a goal but remains elusive for most surgical groups.

Concluding, the new technologies in valve substitution are certainly poised to take an increased, perhaps preponderant, role in the future, but the progress in this regard must take into account lessons learned in the past with surgical procedures. And surgeons need not necessarily take "steps longer than their legs." Rather, we should be aware that our surgical results can still be significantly improved and keep working toward that goal.

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