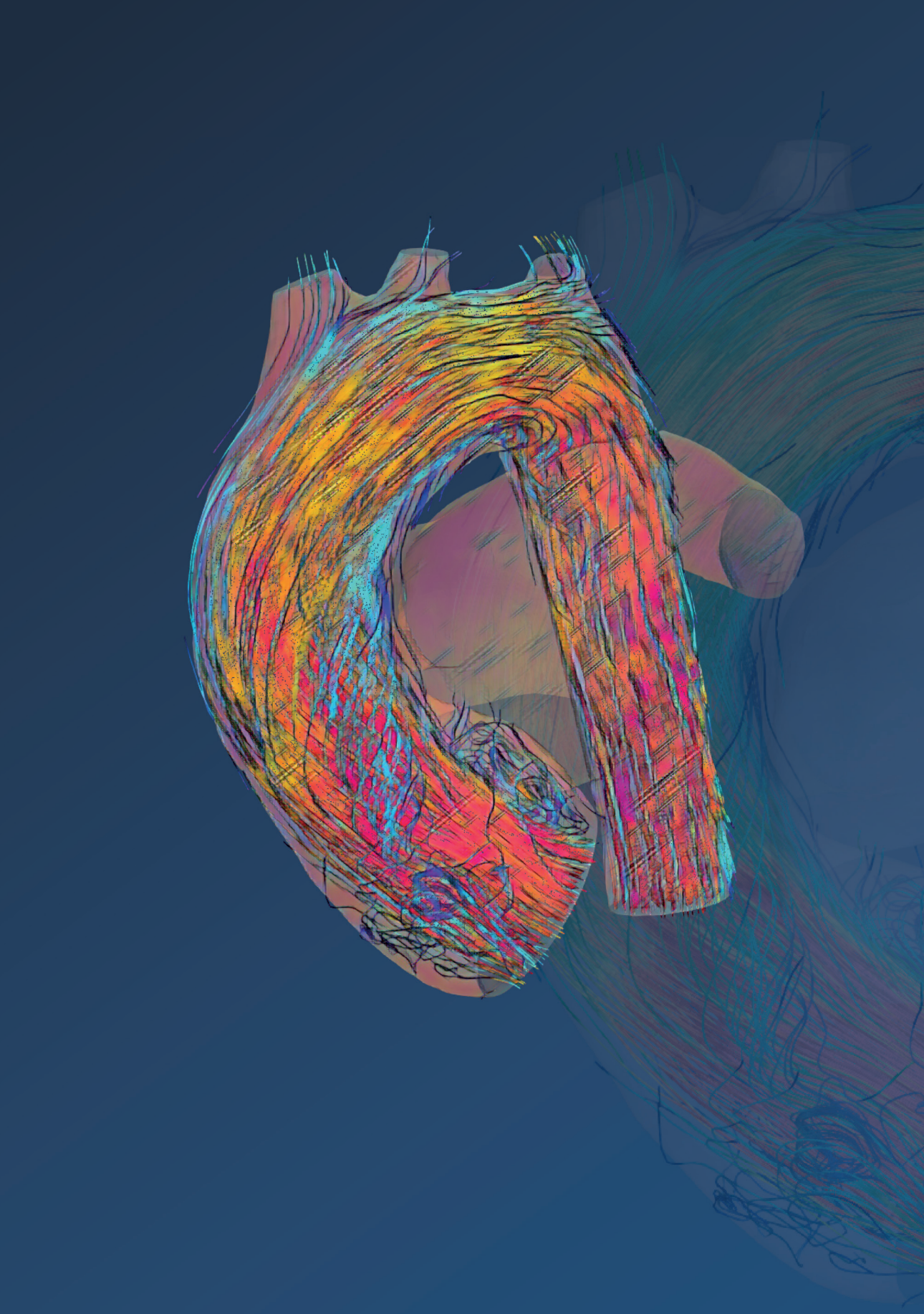
Surgical solutions for complex aortic root pathology

Schneider, A.W.



REINTERVENTIONS AFTER FREESTYLE STENTLESS AORTIC VALVE REPLACEMENT:

An assessment of procedural risks

Adriaan W. Schneider, Mark G. Hazekamp, Michel I.M. Versteegh,
Arend de Weger, Eduard R. Holman, Robert J.M. Klautz,
Eline F. Bruggemans, Jerry Braun

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CHAPTER 8

ABSTRACT

OBJECTIVES

Repeat aortic valve interventions after previous stentless aortic valve replacement (AVR) are considered technically challenging with an increased perioperative risk, especially after full-root replacement. We analysed our experience with reinterventions after stentless AVR.

METHODS

A total of 75 patients with previous AVR using a Freestyle stentless bioprosthesis (31 subcoronary, 15 root-inclusion and 29 full-root replacement) underwent reintervention in our centre from 1993 until December 2018. Periprocedural data were retrospectively collected from the department database and follow-up data were prospectively collected.

RESULTS

Median age was 62 years (interquartile range 47–72 years). Indications for reintervention were structural valve deterioration (SVD) in 47, non-SVD in 13 and endocarditis in 15 patients. Urgent surgery was required in 24 (32%) patients. Reinterventions were surgical AVR in 16 (21%), root replacement in 51 (68%) and transcatheter AVR in 8 (11%) patients. Early mortality was 9.3% ($n = 7$), but decreased to zero in the past decade in 28 patients undergoing elective reoperation. Per indication, early mortality was 9% for SVD, 8% for non-SVD and 13% for endocarditis. Aortic root replacement had the lowest early mortality rate (6%), followed by surgical AVR (13%) and transcatheter AVR (25%, 2 patients with coronary artery obstruction). Pacemaker implantation rate was 7%. Overall survival rate at 10 years was 69% (95% confidence interval 53–81%).

CONCLUSIONS

Repeat aortic valve interventions after stentless AVR carry an increased, but acceptable, early mortality risk. Transcatheter valve-in-valve procedures after stentless AVR require careful consideration of prosthesis leaflet position to prevent obstruction of the coronary arteries.

INTRODUCTION

The Freestyle stentless bioprosthesis (Medtronic Inc., Minneapolis, MN, USA) offers excellent haemodynamics in patients who require an aortic valve replacement (AVR) [1, 2]. However, as with all biological prostheses, structural valve deterioration (SVD) limits its durability, eventually necessitating reintervention. The growing use of bioprostheses for AVR in younger patients over the past decades, together with the increasing life expectancy, will result in an increased number of reinterventions in patients with bioprostheses [3]. The periprocedural risks associated with reinterventions may vary between different types of prostheses and could, therefore, influence the prosthesis choice during primary AVR.

Reinterventions after implantation of a stentless aortic bioprosthesis are potentially technically more demanding compared with reinterventions after implantation of a stented bioprosthesis or mechanical valve and, therefore, carry a supposedly higher perioperative complication risk. After stentless full-root (FR) implantation, reoperations may be more difficult because of dense adhesions around the aortic root, and care should be taken during re-excision of the coronary buttons. Resection of a calcified stentless prosthesis after subcoronary (SC) implantation may lead to laceration of the aortic annulus and thus require root replacement instead of valve replacement alone. Experience with transcatheter reintervention in this specific setting is limited [4].

Regarding the actual periprocedural risks associated with reinterventions after AVR with stentless bioprostheses, limited data are available. From 1993 until December 2018, the Freestyle stentless bioprosthesis has been used for AVR or root replacement in 818 patients at our institution. In this study, we describe our experience with different types of reinterventions after stentless AVR to quantify the risks accompanying these procedures, examining the different primary implantation techniques, the different aetiologies determining the indication for reintervention and the different reintervention techniques.

METHODS

All patients with a Freestyle stentless bioprosthesis in the aortic position who underwent a reintervention in our institution from 1993 until December 2018 were included in this study. Patients' preoperative and operative data regarding the reintervention were retrospectively collected from the department database.

Postoperative events were assessed according to current guidelines [5]. Early mortality was defined as death within 30 days after surgery or during index hospital admission. Patients' vital status was last checked on 12 December 2018 and was 100% complete. The local ethics committee approved the study design and waived the need for patient informed consent.

Decision on type of reintervention

The Freestyle prosthesis was implanted during primary AVR using one of the techniques previously described [6]. Patients with prosthesis dysfunction were discussed in the local heart team to decide on the indication for and type of reintervention. Redo-AVR or root replacement was the preferred reintervention. In selected high-risk patients, percutaneous valve-in-valve (ViV) techniques were deemed appropriate from 2008 onwards. Patients were categorized as high risk by the local heart team after considering patient-related factors (e.g. frailty, comorbidities) and procedural factors (e.g. porcelain aorta, position of coronary arteries). Final valve prosthesis selection (biological versus mechanical) was the result of a shared decision-making process involving patient and surgeon. Homografts were not routinely used for aortic valve or root replacement in our institution.

Statistical analysis

Continuous data are expressed as mean ± standard deviation when normally distributed or as median [interquartile range (IQR)] when non-normally distributed. Categorical data are expressed as *n* (%). Comparisons between subgroups were performed using the Mann–Whitney *U*-test or Kruskal–Wallis test for continuous data and Fisher's exact test for categorical data. Survival was estimated using the Kaplan–Meier method. Analyses were performed using IBM SPSS Statistics 23 for Windows (IBM Corp., Armonk, NY, USA).

RESULTS

A total of 75 patients underwent reintervention after previous stentless AVR or root replacement (Table 1). Median age at reintervention was 62.0 years (IQR 47.1–71.8 years) and 23 (31%) patients had undergone 2 or more previous surgeries. Median EuroSCORE II was 8.3 (IQR 5.3–14.6). During the initial stentless AVR, 31 (41%) prostheses were implanted using the SC technique, 15 (20%) using the root-

inclusion (RI) technique and 29 (39%) prostheses were used for FR replacement. Over time, there was an increased use of FR replacement, while the RI technique was abandoned in 1998.

Table 1: Patient characteristics per reintervention type

Characteristics	SAVR	SARR	TAVR	Total
Number of patients	16 (21.3)	51 (68.0)	8 (10.7)	75 (100)
Male gender	14 (87.5)	33 (64.7)	5 (62.5)	52 (69.3)
Age at reintervention (years), median (IQR)	61.5 (51.9–76.3)	55.0 (45.4–67.2)	82.2 (79.7–84.3)	62.0 (47.1–71.8)
Preoperative NYHA functional class				
I	4 (25.0)	10 (19.6)		14 (18.7)
II	3 (18.8)	22 (43.1)	4 (50.0)	29 (38.7)
III	4 (25.0)	13 (25.5)	1 (12.5)	18 (24.0)
IV	5 (31.3)	6 (11.8)	3 (37.5)	14 (18.7)
Preoperative atrial fibrillation	1 (6.3)	4 (7.8)	1 (12.5)	6 (8.0)
Number of previous surgeries				
1	12 (75.0)	34 (66.7)	6 (75.0)	52 (69.3)
2	1 (6.3)	12 (23.5)	1 (12.5)	14 (18.7)
3	3 (18.8)	3 (5.9)	1 (12.5)	7 (9.3)
4		1 (2.0)		1 (1.3)
5		1 (2.0)		1 (1.3)
Previous cerebrovascular accident		7 (13.7)	1 (12.5)	8 (10.7)
Previous myocardial infarction			2 (25.0)	2 (2.6)
Insulin-dependent diabetes mellitus	1 (6.3)			1 (1.3)
Hypertension	6 (37.5)	16 (31.4)	3 (37.5)	25 (33.3)
Chronic obstructive pulmonary disease		3 (6.0)		3 (3.9)
Renal dialysis		1 (2.0)	1 (12.5)	2 (2.7)
Implantation technique during primary AVR				
Subcoronary	9 (56.3)	15 (29.4)	7 (87.5)	31 (41.3)
Root-inclusion	6 (37.5)	8 (15.7)	1 (12.5)	15 (20.0)
Full-root replacement	1 (6.3)	28 (54.9)		29 (38.7)
EuroSCORE II, median (IQR)	5.2 (2.6–11.6)	8.9 (6.4–14.7)	10.6 (8.4–14.7)	8.3 (5.3–14.6)
Preoperative echocardiography				
AR ≥ grade 3	13 (81.3)	31 (60.8)		52 (69.3)
MR ≥ grade 3	3 (7.0)	4 (7.8)	2 (25.0)	6 (8.0)
LVEF ≤ 30%	1 (6.3)	2 (3.9)	2 (25.0)	5 (6.7)
Pulmonary hypertension (echocardiographic) (mmHg)				
30–55	3 (18.8)	10 (19.6)	2 (25.0)	15 (20.0)
>55	1 (6.3)	2 (3.9)		3 (4.1)

Data are presented as counts (%) unless stated otherwise.

AR: aortic regurgitation; AVR: aortic valve replacement; eGFR: estimated glomerular filtration rate; IQR: interquartile range; LVEF: left ventricular ejection fraction; MR: mitral regurgitation; NYHA: New York Heart Association; SARR: surgical aortic root replacement; SAVR: surgical AVR; TAVR: transcatheter aortic valve replacement.

Modes of failure of the stentless valve

In 47 (63%) patients, SVD was the failure mode of the stentless prosthesis. These patients typically presented with (sub-)acute dyspnoea due to sudden increase of aortic regurgitation caused by leaflet tear or perforation. Non-SVD was the failure mode in 13 (17%) patients and prosthesis endocarditis in 15 (20%). Median interval from implantation to reintervention was 7.8 years (IQR 3.5–12.6 years), with a significant difference between indications for reintervention (SVD versus non-SVD versus endocarditis 11.2 vs 3.5 vs 2.7 years; $P < 0.001$).

Operative details

Reinterventions were surgical AVR in 16 (21%; 8 mechanical, 7 biological, 1 sutureless), aortic root replacement in 51 (68%; 34 biological, 15 mechanical, 2 pulmonary autograft) and ViV transcatheter AVR (ViV-TAVR) in 8 (11%; 6 balloon expandable, 2 self-expanding) patients. Urgent surgery was required in 24 (32%) patients, mainly because of haemodynamic compromise or endocarditis. In patients undergoing surgical reintervention, 43 (64%) underwent a total of 50 concomitant procedures, mostly replacement of the ascending aorta (Table 2). Aortic root replacement with or without replacement of the ascending aorta was performed in case of dilatation of the root and ascending aorta, prosthesis endocarditis with perivalvular extension, and extensive calcification of the native aortic root (mostly at the suture lines of the stentless prosthesis) or a calcified prosthetic root.

Table 2: Procedural details and complications per reintervention type

	SAVR	SARR	TAVR	Total
Number of patients	16 (21.3)	51 (68.0)	8 (10.7)	75 (100)
Time between implantation and reintervention (years), median (IQR)	3.2 (0.9–6.4)	8.2 (4.6–12.8)	15.2 (11.4–18.1)	7.8 (3.5–12.6)
Timing				
Elective	11 (68.8)	34 (66.7)	6 (75.0)	51 (68.0)
Urgent	5 (31.3)	17 (33.3)	2 (25.0)	24 (32.0)
Indication				
SVD	6 (37.5)	33 (64.7)	8 (100)	47 (62.7)
NSVD	9 (56.3)	4 (7.8)		13 (17.3)
Endocarditis	1 (6.3)	14 (27.5)		15 (20.0)
Patients with concomitant surgery	4 (25.0)	39 (76.5)		43 (64.2)
Ascending aorta replacement	1 (6.3)	29 (56.9)		30 (44.8)
Mitral valve repair	1 (6.3)	8 (15.7)		9 (13.4)
Mitral valve replacement	1 (6.3)	2 (3.9)		3 (4.5)
Tricuspid valve repair		2 (3.9)		2 (2.9)
Coronary artery bypass grafting	1 (6.3)	5 (9.8)		6 (8.9)
Cross-clamping time (min), median (IQR)	123 (85–152)	171 (141–211)		168 (134–209)
Complications				
Left ventricular failure	2 (12.5)		2 (25.0)	4 (5.3)
Right ventricular failure		3 (5.9)	1 (12.5)	4 (5.3)
Postoperative intra-aortic balloon pump	1 (6.3)	2 (3.9)	1 (12.5)	4 (5.3)
Postoperative extracorporeal membrane oxygenation		2 (3.9)		2 (2.7)
New onset atrial fibrillation at discharge	1 (6.3)	2 (3.9)		3 (4.0)
Permanent pacemaker implantation		4 (7.8)	1 (12.5)	5 (6.7)
Postoperative myocardial infarction			2 (25.0)	2 (2.7)
Re-exploration for bleeding	2 (12.5)	5 (9.8)		7 (9.3)
Early mortality	2 (12.5)	3 (5.9)	2 (25.0)	7 (9.3)

Data are presented as counts (%) unless stated otherwise.

IQR: interquartile range; SARR: surgical aortic root replacement; SAVR: surgical AVR; TAVR: transcatheter aortic valve replacement.

Median cross-clamping time was 168 min (IQR 134–209 min) and was significantly longer in patients after primary FR implantation (FR versus other: 190 vs 151 min; $P = 0.002$).

Postoperative course and late survival

In total, there were 7 (9.3%) early deaths (Table 3). In 28 consecutive patients reoperated on for SVD since the last mortality in 2007, early mortality rate was zero. Early mortality was not significantly different in patients after primary FR implantation [FR versus other: 10% (3/29) vs 9% (4/46), *P* = 1.0]. Early mortality per indication was 8.5% (4/47) for SVD, 7.7% (1/13) for non-SVD and 13.3% (2/15) for endocarditis. Per reintervention type, early mortality was 12.5% (2/16) for surgical AVR, 5.9% (3/51) for aortic root replacement and 25% (2/8) for ViV-TAVR.

Table 3: Causes of early mortality

Patient	Age at reintervention (years)	Number of previous surgeries	Year of reoperation	Primary implantation technique of stentless valve	Reoperative procedure	Indication for reintervention	Cause of death
1	78	1	1996	Root-inclusion	Stentless bioprosthesis (subcoronary)	NSVD	Multi organ failure
2	54	1	1996	Subcoronary	Mechanical valve	SVD	Preoperative critical state (inotropics). Postoperative cardiac failure
3	20	4	2007	Full root	Annular extension (Konno incision), mechanical valve implantation, pulmonary valve replacement and CABG	SVD	Cardiac failure

Patient	Age at reinter-vention (years)	Number of previous surgeries	Year of reoper-ation	Primary implantation technique of stentless valve	Reoperative procedure	Indication for reinter-vention	Cause of death
4	81	1	2009	Subcoronary	ViV-TAVR	SVD	MI due to obstruc-tion of left coronary artery
5	75	1	2012	Full root	Stentless bio-prosthesis (full root), ascending aorta replace-ment and CABG	Endocar-ditis	RV failure due to obstruc-tion of the RCA despite emergen-cy con-comitant CABG
6	64	3	2012	Full root	Reconstruction of aortic-mitral continuity and left atrium, stentless bioprosthesis (full root) and ascending aorta replacement	Endocar-ditis	Multi organ failure
7	83	1	2013	Subcoronary	ViV-TAVR	SVD	MI due to obstruc-tion of left coronary artery

CABG: coronary artery bypass grafting; MI: myocardial infarction; NSVD: non-structural valve deterioration; RCA: right coronary artery; RV: right ventricle; SVD: structural valve deterioration; ViV-TAVR: valve-in-valve transcatheter aortic valve replacement.

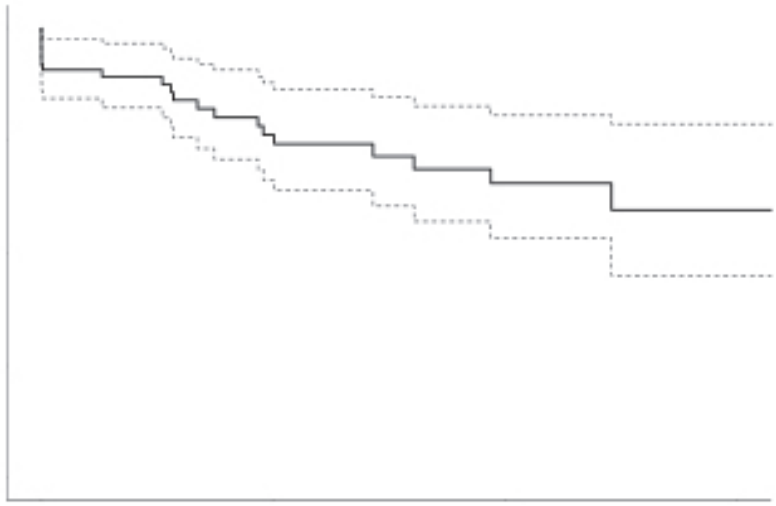
In both ViV-TAVR patients who died, a SAPIEN balloon-expandable valve (Edwards Lifesciences, Irvine, CA, USA) was used, and in both patients, obstruction of the left coronary artery (LCA) resulted in periprocedural death. Although a wire was placed in the LCA prior to valve deployment to facilitate possible emergency intervention

in one of these patients, LCA obstruction occurred and emergency stenting could not prevent fatal myocardial infarction.

Five patients (6.7%) required postoperative circulatory support for cardiac failure with an intra-aortic balloon pump (*n* = 3), extracorporeal membrane oxygenation (*n* = 1) or both (*n* = 1). The latter 2 patients survived. Five patients required permanent pacemaker implantation due to a new conduction block, 4 after redo root replacement and 1 after ViV-TAVR.

Median follow-up time was 5.0 years (IQR 1.4–10.2 years). Overall survival rates at 1, 5 and 10 years were 90.7% [95% confidence interval (CI) 84.3–97.5%], 76.2% (95% CI 66.2–87.8%) and 69.2% (95% CI 53.2–80.5%), respectively (Fig. 1). Late death (*n* = 13) was valve-related in 2 (1 endocarditis, 1 prosthesis dehiscence), sudden unexplained in 2 and non-cardiac related in 7 patients. For 2 patients, no data on the cause of death could be retrieved.

Figure 1:



Kaplan–Meier curve of overall survival with 95% confidence interval.

DISCUSSION

The decision on valve prosthesis is complex, especially in younger patients, but essentially comes down to a bioprosthesis versus a mechanical prosthesis. However, within bioprostheses, there still are several options. Stented valves with or without vascular graft, stentless valves or stentless roots, homografts and the Ross procedure all offer a biological, but still very different, solution to treat aortic valve and root disease. This makes the choice between a biological and mechanical prosthesis not as straightforward as it would seem.

Our centre was one of the first to use the currently discussed Freestyle prosthesis. Based on our experience over the past 25 years, the haemodynamic and structural advantages of this prosthesis have led to its use in younger patients. This study describes the perioperative risks of the main disadvantage of this prosthesis: reinterventions.

All bioprostheses have the disadvantage of limited durability, especially in younger patients. Patients aged 50 years who undergo a stentless bioprosthetic aortic root replacement have ~23% probability of requiring reintervention at 15 years [7], compared to ~8% after mechanical-valved prostheses [8]. The longer durability of mechanical prostheses, however, comes at the cost of a higher life-time risk of thromboembolism and bleeding events (33% for mechanical prostheses vs 17% for bioprostheses) [8, 9]. Whether the benefits of mechanical prostheses outweigh those of bioprostheses therefore largely depends on the risks of reintervention after bioprosthetic AVR. If these can be performed with minimal mortality and morbidity, the use of bioprostheses in younger patients may be justified. Earlier series on reoperations after stentless AVR report high mortality rates of 10–20%, thus perhaps not justifying stentless AVR in young patients [4, 10, 11]. However, the more recent experience in this series with zero mortality in the latest 28 consecutive patients reoperated on for SVD may change this perspective. Another recent paper by Yang *et al.* [12] in 143 consecutive patients reported an reoperative early mortality rate of 2% after primary Freestyle AVR. It seems that in valve centres with a vast experience in reoperative aortic root replacement, these procedures can be performed safely. Therefore, young patients with a strong preference for a bioprosthesis should not be declined this option. It has been suggested by a previous studies that the higher risk of reintervention compared

with primary surgery may not be related to the procedure itself, but rather to patient characteristics [13, 14]. In our series, 2 of 7 early deaths were reoperated on for prosthetic valve endocarditis and 2 patients were among the first to undergo ViV-TAVR. Another patient died after a fifth operation with double valve replacement and coronary artery bypass surgery.

Although not mentioned in the most recent European guidelines on valvular interventions [15], the Ross procedure offers a good alternative for patients who want a biological solution for their aortic valve disease, with long event-free survival [16]. However, this procedure is restricted to experienced centres and, therefore, not available to a large population of patients.

Considerations in surgical reinterventions

FR replacement is often required in redo-AVR after previous Freestyle implantation, even in patients with SC implanted prostheses. As SC and RI implanted prostheses have grown into the native aortic root wall and annulus at the time of reintervention, complete resection of the prosthesis without damaging the native wall or annulus is often impossible. This results in either a lacerated annulus or an inadequate remaining diameter at the level of the annulus, necessitating root replacement. However, in these patients, root replacement often is straightforward as adhesions around the native root are generally mild. True redo root replacements (i.e. after previous root replacement), on the other hand, are more challenging. The prosthetic stentless root is almost always calcified. Calcifications around the coronary artery buttons can be problematic, as the remaining rim of supple tissue can be very small after excision from the calcified prosthetic wall. Therefore, during primary root replacement with a Freestyle prosthesis, a sufficiently large rim of native aortic wall should be left on the coronary artery buttons to facilitate re-excision and reimplantation during redo surgery. This is especially important in younger patients, as they have a higher lifetime probability of requiring redo surgery.

An alternative for reintervention after root replacement is a sutureless valve-in-root procedure, provided that an adequately large annulus remains after resection of the prosthetic valve leaflets. This procedure reduces cross-clamping times considerably. In this series, only 1 patient underwent a sutureless valve-in-root procedure in a calcified RI implanted Freestyle prosthesis.

All but 2 patients who were reoperated on for endocarditis received a stentless bioprosthesis in this series. Surgical considerations in this group of patients have been reported previously [17].

Considerations in valve-in-valve transcatheter aortic valve replacement

The mode of failure in degenerated Freestyle prostheses is predominantly leaflet tear, especially in FR implanted prostheses [7]. Although the prosthetic root is often calcified, providing an anchoring point for TAVR prostheses, they often lose their sinus shape and become a straight tube, increasing the chance of coronary obstruction by prosthetic valve leaflets during ViV-TAVR. Partly because of this, we have refrained from ViV-TAVR in the Freestyle prosthesis after FR replacement. In SC implanted Freestyle prostheses, the prosthetic leaflets calcify more often and provide anchoring points for TAVR prostheses. However, coronary obstruction may still occur due to the position of the implanted Freestyle prosthesis (which might be closer to the coronary ostia than the native leaflets) and the absence of prosthesis struts that limit lateral displacement of the prosthetic leaflets [18]. The absence of radio-opaque markers in the Freestyle prosthesis makes it especially difficult to determine the correct position of the transcatheter valve. In our practice, we inject contrast dye into the aortic root during rapid pacing in order to identify the location of the prosthesis leaflets to guide valve deployment on fluoroscopy, adding 3-dimensional transoesophageal echocardiographic imaging.

Coronary obstruction, a severe complication often associated with a fatal outcome, occurred in 2 of 8 patients who underwent ViV-TAVR, both after primary SC implantation. The European Society of Cardiology/European Association of Cardiovascular Surgery guidelines state that a low coronary height favours surgical AVR over TAVR [15]. Although no minimum height is defined, a minimal distance of 10–14 mm has been suggested for TAVR in native valves [19, 20]. Conzelmann *et al*. [21] reported on TAVR in patients with a low coronary height of <7 mm. Out of the 10 patients after ViV-TAVR in their study, 2 had coronary obstruction, and the early mortality rate was 30%. Sang *et al*. [22] reported their experience with ViV-TAVR in 22 degenerated Freestyle prostheses, with no early mortality. One patient required stenting of the LCA because of obstruction. In our series, both cases of coronary obstruction occurred with a balloon-expandable valve. The

resulting high early mortality rate after ViV-TAVR in this series, however, should be interpreted in relation to the low number of ViV procedures in this particular patient population and the limited early experience at that time. Periprocedural management has been adapted to decrease the risk of coronary obstruction. Preprocedural computed tomography scanning is performed to assess the height of the coronary ostia relative to the aortic prosthesis annulus, the height of the stentless valve leaflets and the sinus wall shape. In patients considered at increased risk for coronary obstruction, a valvuloplasty balloon is inflated prior to valve implantation to detect possible coronary obstruction. In that case, the ViV procedure is aborted and the patient is scheduled for conventional reoperation if eligible. Periprocedural extracorporeal membrane oxygenation support during ViV-TAVR is not routinely used in our institution. The risk of coronary obstruction may also be decreased by using transcatheter prostheses that anchor the prosthetic valve leaflets to the transcatheter valve [23].

Limitations

Different primary implantation techniques of the stentless valve and different indications for reoperation make this a heterogeneous series. The low number of patients and events limit the possibility for risk factor analysis.

CONCLUSION

The incidence of repeat aortic valve interventions, both surgical and transcatheter in nature, after stentless AVR will increase because of the growing use of bioprostheses to replace the aortic valve or root in younger patients together with an increase in life expectancy in general. Although reinterventions have an increased early mortality rate, especially in more severe pathology, this study shows that elective redo surgery after primary stentless AVR can be performed with acceptable risks and complication rates. While aortic root replacement is often required, also in patients who did not undergo initial root replacement, this more extensive surgery did not lead to an increased mortality rate compared to surgical and transcatheter AVR. Transcatheter ViV procedures after stentless AVR require careful consideration of prosthesis leaflet position relative to coronary ostia position to prevent obstruction of coronary arteries. Although bioprostheses are not optimal in young patients due to the higher lifetime probability of

reinterventions, the risks of these reinterventions do not preclude their use in young patients with a strong preference for a biological solution to treat their aortic valve disease.

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