The impact of surgical aortic valve replacement on quality of life—a multicenter study

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ABSTRACT

Objectives: To explore the effect of surgical aortic valve replacement on quality of life and the variance with age, particularly in patients at risk of deterioration.

Methods: In an observational, multicenter, cohort study of routinely collected health data, patients undergoing and electively operated between January 2011 and January 2015 with pre- and postoperative quality of life data were included. Patients were classified into 3 age groups: <65, 65-79, and ≥80 years. Quality of life was measured at baseline and at 1-year follow-up using the Short-Form Health Survey-12 or SF-36. We defined a >5-point difference as a minimal clinically important difference. Multivariable linear regression analysis, with adjustment for confounders, was used to evaluate the association between age and quality of life.

Results: In 899 patients, mean physical health increased from 55 to 66 and mental health from 60 to 66. A minimal clinically important decreased physical health was observed in 12% of patients aged <65 years, 16% of patients aged 65-79 years, and 22% of patients aged ≥80 years ($P = .023$). A decreased mental health was observed in 15% of patients aged <65 years, 22% of patients aged 65-79 years, and 24% aged ≥80 years ($P = .030$). Older age and a greater physical and mental score at baseline were associated with a decreased physical and mental quality of life ($P < .001$).

Conclusions: Patients surviving surgical aortic valve replacement on average improve in physical and mental quality of life; nonetheless, with increasing age patients are at higher risk of experiencing a deterioration. (J Thorac Cardiovasc Surg 2021;161:1204-10)
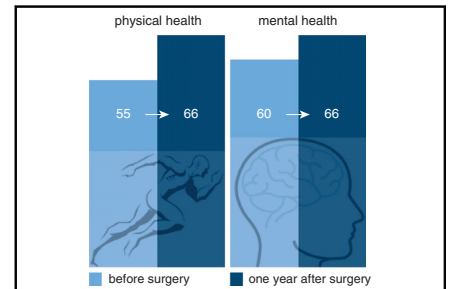
Mean quality of life scores before and 1 year after surgical aortic valve replacement.

CENTRAL MESSAGE

Quality of life should be discussed during preoperative counseling since older age is associated with a decrease in postoperative quality of life after surgical aortic valve replacement.

PERSPECTIVE

Patient-reported outcomes such as quality of life are gaining importance in cardiac surgery. Although most patients experience an improvement in postoperative quality of life, elderly patients are more at risk of deterioration. Because in vulnerable elderly patients a small decline can have important consequences, expectations on quality of life should be discussed during preoperative counseling.

In western countries, aortic valve stenosis (AS) is the most common acquired native valve disease.[1,2] The prevalence of AS increases with age due to age-related calcific degeneration. Current incidences of AS are 0.2% at age 50 to 59 years, 1.3% at age 60 to 69 years, 3.9% at age 70 to 79 years, and 9.8% at age 80 to 89 years.[3] Consequently, aortic valve replacement is increasingly performed in elderly patients.[1,2]

Abbreviations and Acronyms

AS   = aortic valve stenosis
MCID = minimal clinically important difference
MCS   = mental component summary score
PCS   = physical component summary score
QoL   = quality of life
SAVR = surgical aortic valve replacement
TAVR = transcatheter aortic valve replacement

Scanning this QR code will take you to the table of contents to access supplementary information.

With increasing severity of valve disease, patients often experience chest pain, increasing fatigue, syncope, and heart failure. These symptoms lead to decreasing quality of life (QoL) due to an inability to participate in daily activities. Patients who eventually become symptomatic face a prognosis of up to 50% mortality within 2 years, if left untreated.[4] QoL is a major important outcome after SAVR (surgical aortic valve replacement) alongside symptom relief and increased survival.[5] Two systematic reviews on QoL after SAVR revealed that methodologic differences limit interpretation, and more well-designed QoL studies are required including the use of validated QoL tools, conducted with only elective patients, and preferably set up as multicenter studies to minimize bias and increase patient numbers.[6,7] Since QoL is an important outcome after cardiac surgery, studies on QoL are valuable for both patients and surgeons because they may inform in the process of shared-decision making.[8]

In this multicenter study, we evaluated the influence of SAVR on 1-year QoL and its variation with age in a large cohort of patients. In addition, we explored whether we could identify subgroups of patients who deteriorate in QoL and hypothesized that, compared with younger patients, elderly patients would more often experience a deterioration in QoL.

METHODS

We conducted an observational, multicenter cohort study. The study was approved by the institutional review board of the Catharina Hospital Eindhoven (no. 2014-20; April 24, 2014) and conducted in agreement with the principles of the Helsinki declaration. For this study, we used methods similar to a previous cohort study on QoL after coronary artery bypass grafting.[9] The study is reported according to the REporting of studies Conducted using Observational Routinely collected health Data (RECORD) guidelines[10] (Table E1).

Eligibility Criteria

We included adult patients who had undergone elective SAVR either with or without concomitant revascularization, operated between January

1, 2011, and January 1, 2015, and for whom preoperative and 1-year follow-up QoL data were available. Patients were operated in 1 of the 3 participating centers in the Netherlands: Isala Zwolle, Catharina Hospital Eindhoven, or St Antonius Hospital Nieuwegein. Patients were classified into 3 groups: younger than 65 years, between 65 and 79 years, and 80 years or older.

Baseline Characteristics

We retrieved data from the Netherlands Heart Registry (formerly Meetbaar Beter)[11] and obtained mortality data from the regional municipal administration registration. Baseline demographic data included age, sex, body mass index, logistic European System for Cardiac Operative Risk Evaluation I, and perioperative data, including valve type and concomitant revascularization. We also collected data on previous cardiac surgery and comorbidities such as diabetes,[12] pulmonary disease,[13] arterial vascular disease,[13] renal disease,[14] and ventricular function.[15] Definitions of comorbidities are included in Appendix E1.

Outcome Measures

The primary outcome was QoL assessed using the Short Form Health Survey-36 (version 2)[16] or the Short Form Health Survey-12 (version 2). QoL data were collected at baseline (up to 2 months before surgery) and 10 to 14 months after surgery by e-mail or a written survey. Two summarized scores ranging from 0 to 100 were calculated; a Physical Component Summary (PCS) and a Mental Component Summary (MCS).[16] All data were merged into one database since both questionnaires calculate the same scores with a standard syntaxfile and the sensitivity and responsiveness to change measured by both questionnaires seem similar.[17]

Based on a minimal clinically important difference (MCID) of 5 points, we calculated for each patient an increase ($\geq$5), decrease ($\leq$–5), or no change in QoL.[18] To evaluate generalizability, we compared data between responders (patients who completed preoperative and follow-up questionnaires) and nonresponders (patients who only completed the preoperative questionnaire).

Secondary outcomes were postoperative complications including surgical re-exploration,[12] deep wound infection,[19] renal failure,[12] the implantation of a permanent pacemaker, all within 30 days after surgery,[12] and stroke within 72 hours after surgery.[20] A surgical reintervention due to valve problems or coronary reintervention in case of concomitant revascularization was measured within 1 year after surgery.[12] Definitions of complications are included in Appendix E1.

Analyses

Characteristics of patients are presented as proportions (with percentages) for categorical variables or as means (with standard deviations) for continuous variables when normally distributed. Differences in dichotomous variables were tested using χ^2 or the Fisher exact test. Analysis of variance was used with multiple comparison (Bonferroni correction) for analyses of baseline variables among age groups. Differences between the QoL scores at baseline and at 1 year were tested using a paired t test. Sensitivity analyses were conducted using a MCID of 4 points.[21] Linear regression analysis was conducted to evaluate the impact of age (independent variable) on difference in QoL (dependent variable). Bivariable analyses (since age was always included in all models) were used to identify possible deteriorating subgroups exploring the previously mentioned baseline characteristics. All variables in the bivariable analysis with $P < .1$ were included in the multivariable model and R-square was calculated. All analyses were tested 2-sided, and variables with P values $\leq.05$ were considered statistically significant. All data were analyzed using SPSS, version 23.0 (Released 2015, IBM SPSS Statistics for Windows; IBM Corp, Armonk, NY).

TABLE 1. Baseline, operative, and postoperative characteristics of patients undergoing SAVR

Characteristics	<65 y (n = 232)	65-79 y (n = 554)	≥80 y (n = 113)	P value
Baseline characteristics				
Sex (female)	70 (30)	183 (33)	63 (56)	<.001
BMI,* kg/m²				
<25	36 (21)	111 (27)	22 (27)	.49
25-30	80 (47)	195 (47)	39 (47)	
>30	54 (32)	105 (26)	22 (27)	
Log EuroSCORE I				
<10%	226 (97)	474 (86)	50 (44)	<.001
10%-20%	5 (2.2)	65 (12)	47 (42)	
>20%	1 (0.4)	15 (2.7)	16 (14)	
Diabetes mellitus	31 (13)	135 (24)	25 (22)	.003
Pulmonary disease	17 (7.3)	66 (12)	13 (12)	.16
Arterial vascular disease	13 (5.6)	72 (13)	6 (5.3)	.001
eGFR, mL/min/1.73 m²				<.001
≥60	205 (88)	402 (73)	63 (56)	
30-59	26 (11)	145 (26)	48 (43)	
<30	1 (0.4)	7 (1.3)	2 (1.8)	
LVEF†				
>50%	200 (86)	471 (85)	91 (81)	.19
30%-50%	30 (13)	64 (12)	19 (17)	
<30%	2 (0.9)	18 (3.3)	3 (2.7)	
Previous cardiac surgery‡	15 (8.7)	15 (4.9)	4 (6.5)	.26
Operative characteristics				
Bioprosthesis	122 (53)	527 (95)	110 (97)	<.001
Concomitant CABG	59 (25)	248 (45)	51 (45)	<.001
Postoperative characteristics				
Deep sternal wound infection	0 (0.0)	4 (0.7)	1 (0.9)	.41
Stroke	1 (0.4)	5 (0.9)	0 (0.0)	.72
Renal failure	2 (0.9)	2 (0.4)	0 (0.0)	.76
Surgical reintervention§	2 (0.9)	3 (0.5)	1 (0.9)	<.001
Implantation permanent pacemaker‖	1 (0.6)	6 (2.0)	3 (4.8)	<.001

All numbers are presented with percentages. *BMI*, Body mass index; *log EuroSCORE I*, logistic European System for Cardiac Operative Risk Evaluation I; *eGFR*, estimated glomerular filtration rate; *LVEF*, left ventricular ejection fraction; *CABG*, coronary artery bypass grafting. *BMI data missing for 235 patients. †LVEF data missing for 1 patient. ‡Previous cardiac surgery data missing for 358 patients. §Valve reintervention data missing for 359 patients; ‖Implantation permanent pacemaker data missing for 359 patients.

RESULTS

A total of 2958 patients underwent a SAVR with or without bypass grafting. Preoperative and postoperative QoL assessments were completed by n = 899 patients (30.4%; responders) (Figure E1).

Characteristics of the Patients

Table 1 presents baseline, perioperative, and postoperative characteristics of the study population. The proportion of women, compared with men, increased with age (P < .001) as well as the proportion of patients with renal disease (P < .001). A larger proportion of patients aged 65 to 79 years suffered from diabetes and arterial vascular disease. The incidence of implantation of a permanent pacemaker and surgical reintervention was greater in patients aged ≥80 years (P < .001). Differences between the 3 age groups concerning any of the other postoperative complications were not significant.

Quality of Life

Mean MCS and PCS scores at baseline and at 1-year follow-up are presented in bar charts per age group (Figure 1). Physical health on average increased from 55 at baseline to 66 at 1-year follow-up, and mental health on average increased from 60 to 66. All subscale scores are provided in Table E2. Differences in QoL between baseline and 1 year after surgery are presented in Figure 2, *A* and *B*. We observed a minimal clinically important decrease in physical health in 12% of patients aged younger than 65 years, in 16% aged 65 to 79 years, and in 22% aged ≥80 years (P = .023; Figure 2, *A*). We observed a minimal clinically important decrease in mental health in 15% of patients aged <65 years, in 22% aged 65 to 79 years and in 24% aged ≥80 years (P = .030; Figure 2, *B*). Sensitivity analyses (using an MCID of 4 points) revealed a smaller group of patients without change in QoL and more patients with an increased and decreased physical and mental health
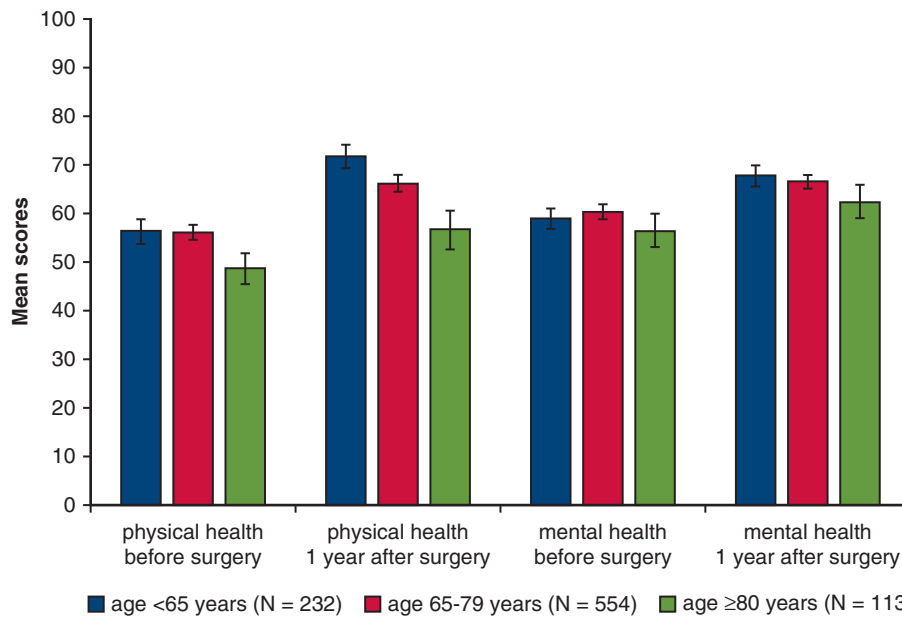
FIGURE 1. Quality of life data of patients with surgical aortic valve replacement according to age categories. Mean scores of the Physical and Mental Component Summary scores (with 95% confidence intervals) of patients with surgical aortic valve replacement before and 1 year after surgery for each age category.

(Figures E2 and E3). Subgroup analyses comparing results between patients undergoing solitary SAVR or SAVR with concomitant revascularization shows that there is no significant difference between both subgroups in difference in QoL (Table E3 and Figure E4).

Association Between Age and QoL

Table 2 shows the results of the linear regression analysis. Older age was associated with a significant decrease in QoL after 1-year follow-up (both PCS and MCS, $P < .001$). Differences in QoL between men and women were not statistically significant. Multivariable regression analysis identified older age ($P < .001$) and greater baseline PCS ($P < .001$) as independent risk factors for a decreased physical QoL. Independent risk factors for a decreased mental QoL were older age ($P < .013$) and greater baseline MCS ($P < .001$). R-squares suggest that approximately 21% and 28% of the variation in change in physical and mental

FIGURE 2. A, Difference in quality of life of patients with surgical aortic valve replacement: Physical Component Score. Differences between baseline and 1-year follow-up per age group 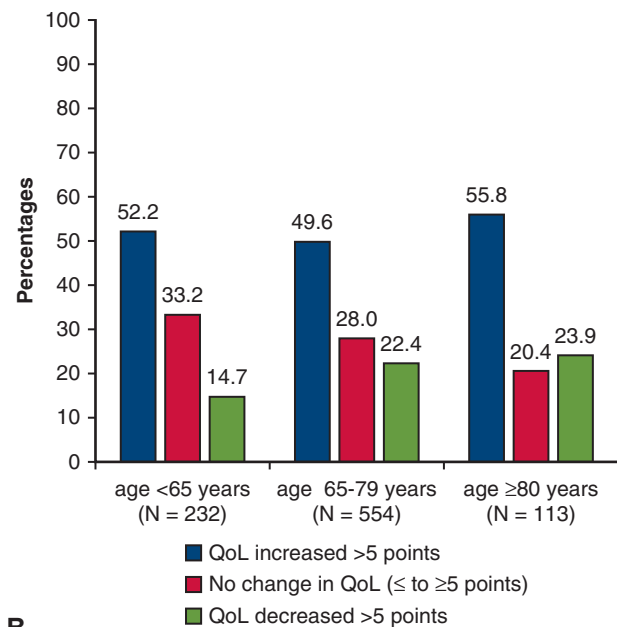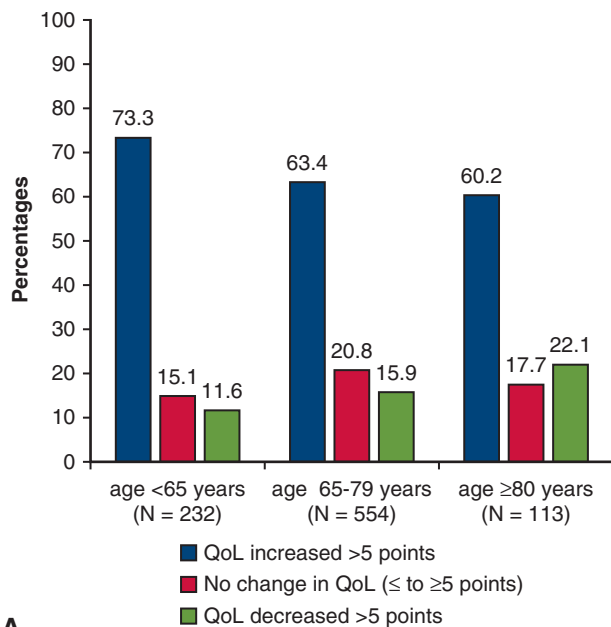in the quality of life physical component score; cut-off value 5 points. B, Difference in quality of life of patients with surgical aortic valve replacement: Mental Component Score. Differences between baseline and 1-year follow-up per age group in the quality of life mental component score; cut-off value 5 points. *QoL*, Quality of life.

TABLE 2. Association between age and difference in quality of life in 899 patients undergoing SAVR

Variables	Bivariable analysis (single component age adjusted)			Multivariable analysis (adjusted for all variables listed)		
	Beta	**95% CI**	**P value**	**Beta**	**95% CI**	**P value**
Physical Component Score						
Age	–0.33	–0.46 to –0.20	<.001	–0.42	–0.53 to –0.29	<.001
Baseline Physical Component Score	–0.41	–0.47 to –0.36	<.001	–0.41	–0.46 to –0.35	<.001
LVEF						
EF 30%-50%	2.17	–1.38 to 5.72	.23	0.07	–3.15 to 3.29	.96
EF <30%	9.73	2.26-17.19	.011	5.82	–0.94 to 12.5	.092
Mental Component Score						
Age	–0.20	–0.33 to –0.08	.001	–0.15	–0.27 to –0.32	.013
Baseline Mental Component Score	–0.49	–0.55 to –0.44	<.001	–0.49	–0.56 to –0.42	<.001
Sex	2.30	–0.09 to 4.69	.059	–0.61	–2.95 to 1.72	.61
BMI, kg/m²	0.33	0.04-0.61	.028	0.11	–0.15 to 0.37	.40
Diabetes	3.25	0.48-6.02	.022	0.07	–2.70 to 2.84	.96
LVEF						
EF 30%-50%	1.80	–1.62 to 5.22	.30	–0.77	–4.03 to 2.48	.64
EF <30%	8.89	1.71-16.08	.015	2.83	–3.63 to 9.30	.39

Adjusted bivariable- and multivariable-adjusted association between age and difference in physical or mental component score is shown. *Beta*, Unstandardized regression coefficient; *CI*, confidence interval; *LVEF*, left ventricular ejection fraction; *EF*, ejection fraction; *BMI*, body mass index.

QoL respectively, can be explained by the independent variables included in the multivariable models.

Responders and Nonresponders

Baseline characteristics, operative characteristics, and postoperative complications of the responders and nonresponders (n = 371) are listed in Table 3. Among the nonresponders, 32 patients (8.6%) died within 120 days, and 49 patients (13.2%) died within 1 year. The nonresponders were older (P < .001), had a greater European System for Cardiac Operative Risk Evaluation (P < .001), a lower baseline PCS (P < .001), and more postoperative complications.

DISCUSSION

The results of this study show that 1-year QoL after SAVR has on average increased from baseline in the majority of patients. A mean beneficial effect of SAVR on postoperative QoL was observed in all age groups; nonetheless, with increasing age, patients are at greater risk of experiencing a deterioration in QoL. QoL is often argued to be the most relevant outcome (over survival or complication rates), especially in elderly patients. For both patient and health care professionals, expected QoL benefit may be crucial for optimal patient selection and shared-decision making and for society in allocating health care resources (Figure 3).[22-24]

As the prognosis of untreated symptomatic AS is poor with an expected deterioration in QoL and a mortality rate more than 50% within 2 years, less-invasive treatments such as transcatheter aortic valve replacement (TAVR) has been proven a suitable alternative for SAVR. Both TAVR and SAVR result in important mortality reductions and symptom improvements.[4] With the PARTNER 1, 2 and 3

trials, efforts are made to optimize treatment options at various levels of surgical risk.[25-27] In future studies, it will be challenging to highlight patient-related outcomes such as QoL when deciding between TAVR and SAVR, due to variability in patients' individual values and preferences.[23]

A factor that might explain why elderly patients report a decline in QoL is that in our study, as well as in another recent study,[21] age is associated with a lower QoL after cardiac surgery. In other words, patients undergoing SAVR at an elderly age are at greater risk of experiencing a worse QoL compared with younger patients. In our multivariable model, the other independent risk factor (besides age) for a decreased QoL is a greater baseline QoL score, suggesting that patients with greater preoperative QoL scores are more likely to experience decreased QoL after surgery. We interpreted this finding as regression to the mean, which has been confirmed in other studies on QoL after cardiac surgery.[9,21,28] To correct for this finding, we included baseline QoL scores in the multivariable regression analyses. Other explanations might be residual confounding due to differences in baseline characteristics. In our study, renal disease and female sex were not associated with an impaired QoL, whereas other studies did suggest these factors as predictors for impaired QoL after SAVR.[21,29] We included patients undergoing SAVR with or without concomitant revascularization to increase groups. Subgroup analyses show that although patients with solitary SAVR on average experience a greater physical and mental QoL, change in QoL was not significantly different between both groups.

Other explanations for the decline in QoL could be side-effects of surgery (ie, new comorbidities or reduced independence) or factors not caused by or related to the intervention. Such unmeasured confounders might have been

TABLE 3. Baseline, operative, and postoperative characteristics of responders and nonresponders

Characteristics	Responders (n = 899)	Nonresponders (n = 371)	P value
Baseline characteristics			
Sex (female)	316 (35)	167 (45)	.001
Age, y, mean (SD)	69 (9.2)	73 (9.7)	<.001
BMI,* kg/m²			
<25	169 (26)	95 (29)	.23
25-30	314 (47)	138 (41)	
>30	181 (27)	99 (30)	
Log EuroSCORE I			
<10%	750 (83)	241 (65)	<.001
10%-20%	117 (13)	96 (26)	
>20%	32 (3.6)	34 (9.2)	
Diabetes mellitus	191 (21)	108 (29)	.003
Pulmonary disease	96 (11)	54 (15)	.052
Arterial vascular disease	91 (10)	50 (14)	.084
eGFR, mL/min/1.73 m²			.001
≥60%	670 (75)	242 (65)	
30%-59%	219 (24)	118 (32)	
<30%	10 (1.1)	11 (3.0)	
LVEF†			
>50%	762 (85)	288 (78)	.008
30%-50%	113 (13)	69 (19)	
<30%	23 (2.6)	14 (3.8)	
Previous cardiac surgery‡	34 (6.3)	17 (9.4)	.16
QoL score baseline: PCS, mean (SD)	55.1 (18.9)	49.8 (20.9)	<.001
QoL score baseline: MCS, mean (SD)	59.5 (18)	57.4 (20.3)	.083
Operative characteristics			
Bioprosthesis§	759 (84)	312 (84)	.025
Concomitant CABG	358 (40)	190 (51)	<.001
Postoperative characteristics			
Deep sternal wound infection	5 (0.6)	2 (0.5)	>.999
Stroke	6 (0.7)	10 (2.7)	.009
Renal failure	4 (0.4)	8 (2.2)	.008
Surgical reintervention	6 (1.1)	4 (2.4)	<.001
Implantation permanent pacemaker‖	10 (1.9)	2 (1.1)	.001

All numbers are presented as n and percentage. *SD*, Standard deviation; *BMI*, body mass index; *log EuroSCORE I*, logistic European System for Cardiac Operative Risk Evaluation I; *eGFR*, estimated glomerular filtration rate; *LVEF*, left ventricular ejection fraction; *QoL*, quality of life; *PCS*, Physical Component Score; *MCS*, Mental Component Score; *CABG*, coronary artery bypass grafting. *BMI for 274 patients unknown. †LVEF for 1 patient unknown. ‡Previous cardiac surgery for 548 patients unknown. §P value based on all valve types used. ‖Implantation permanent pacemaker for 550 patients unknown.

FIGURE 3. Visual summary of the paper on quality of life (*QoL*) after surgical aortic valve replacement.

deterioration, the numbers of patients with a decreased QoL would have been greater (Figures E2 and E3).

To interpret the generalizability of our results, we compared data from responders and nonresponders following recommendations by van Laar and colleagues.[31] Compared with the responding patients, the nonresponders had more co-morbidity, lower preoperative QoL scores, and more postoperative complications, which suggests that QoL data are not missing at random. When comparing our results with the QoL scores of the general Dutch population, the scores of our study population are greater (mean PCS 55.1 vs 50.4 and mean MCS 59.5 vs 52.5 for responders vs the general population).[32] Overall, this suggests that the responders are healthier, possibly due to selection bias, potentially leading to a positive overestimation of change in QoL for the total group, as suggested in other studies.[31,33] This implies that the numbers of patients with decreased postoperative QoL in the total population are expected to be even greater.

Our multicenter study has important limitations. First, the numbers of patients with total available QoL data are rather low (30%). Data were collected by e-mail or a written survey, which might have led to reporting bias. Second, we have a significant amount of missing data in some of the postoperative outcomes. With a more complete dataset, we might have arrived at slightly different conclusions in subsets of patients. Finally, we lack information on length of hospital stay, discharge destination, and other events influencing QoL (ie, cerebral vascular disease, marital status).

In conclusion, our study suggests that although most patients experience an improved QoL after SAVR, patients with increasing age are more at risk of deterioration in both physical and mental QoL. Well-being and QoL are likely to be valued more important than quantity of life in the elderly patients. Therefore, patients' individual preferences and expectations on postoperative QoL should be discussed prior to surgery in order to optimize shared-decision making (Video 1).

Conflict of Interest Statement

Dr Mariani has received grants from AtriCure, Inc, Edwards Lifesciences, and Abbott, Inc, and has provided training for Livanova. All other authors have nothing to disclose with regard to commercial support

present irrespective of surgery and may explain why only 21% and 28% of the variance of QoL in our regression models is associated with the included variables.

We used a MCID set at 5 points to classify the change in QoL.[18] Two recent studies[21,30] on QoL after SAVR also reported change in QoL and used lower MCID thresholds (2.5 and 3.5). The thresholds for MCID used in our study were stricter: if we had used lower MCID thresholds for
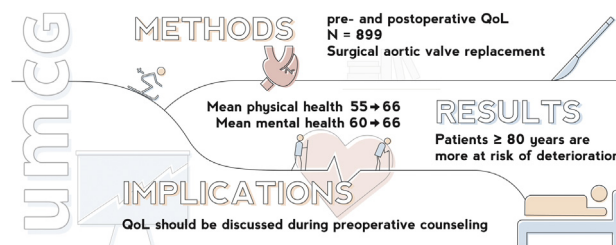
VIDEO 1. The importance and relevance of our study for patient care. Video available at: https://www.jtcvs.org/article/S0022-5223(19)32369-4/fulltext.

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APPENDIX E1. COMORBIDITIES

Diabetes: oral therapy or insulin-dependent diabetes.[12]

Pulmonary disease: prolonged use of steroids or other medication for pulmonary disease.[13]

Arterial vascular disease: peripheral or abdominal vascular pathology or operation due to arterial vascular disease.[13]

Renal disease: a reduced renal function before surgery with an estimated glomerular filtration rate <60 mL/min/1.73 m^2.[14]

Ventricular function: ejection fraction: good >50%, moderate 30%-50%, or poor <30%.[15]

POSTOPERATIVE COMPLICATIONS

Surgical re-exploration: thoracotomy due to bleeding, cardiac tamponade, graft or valve failure within 30 days after surgery.[12]

Deep wound infection (within 30 days after surgery): when deeper tissues are affected (muscle, sternum and mediastinum) and 1 or more of the following 3 criteria are met:

1. surgical drainage/refixation;
2. an organism is isolated from culture of mediastina tissue or fluid; or
3. antibiotic treatment because of a sternal wound.[19]

Renal failure (within 30 days after surgery): 1 or more of the following criteria are met:

1. renal-replacement therapy (dialysis) that was not present preoperatively; or
2. greatest postoperative creatinine level >177 μmol/L <u>and</u> a doubling of the preoperative value (the preoperative creatinine value is the value on which the EuroSCORE is calculated).[12]

Cerebral vascular accident/stroke: an acute neurological event within 72 hours after surgery with focal signs and symptoms and without evidence supporting any alternative explanation. Diagnoses of stroke requires confirmation by a neurologist.[20]

Reintervention: a percutaneous reintervention (coronary angiography or percutaneous coronary intervention) or a surgical procedure (valve repair or re-replacement of the same valve as the primary procedure) within one year after surgery.[12]

Implantation of a permanent pacemaker: implantation of a new permanent implantable cardiac defibrillator or pacemaker within 30 days after surgery.[12]
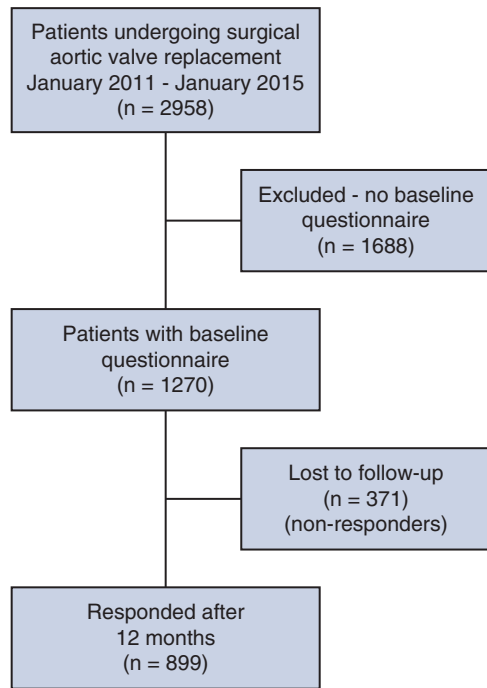
FIGURE E1. Study flowchart.

FIGURE E3. Sensitivity analysis for the Mental Component Summary score. Differences between baseline and 1-year follow-up per age group in the quality of life Mental Component Summary score; cut-off value 4 points. *QoL*, Quality of life.
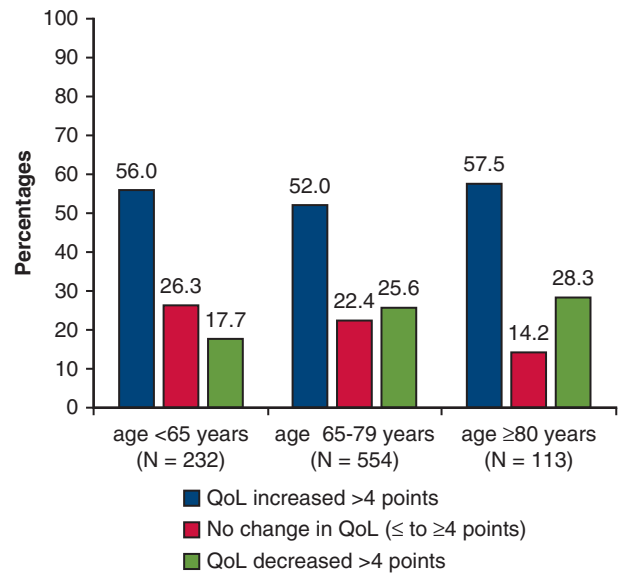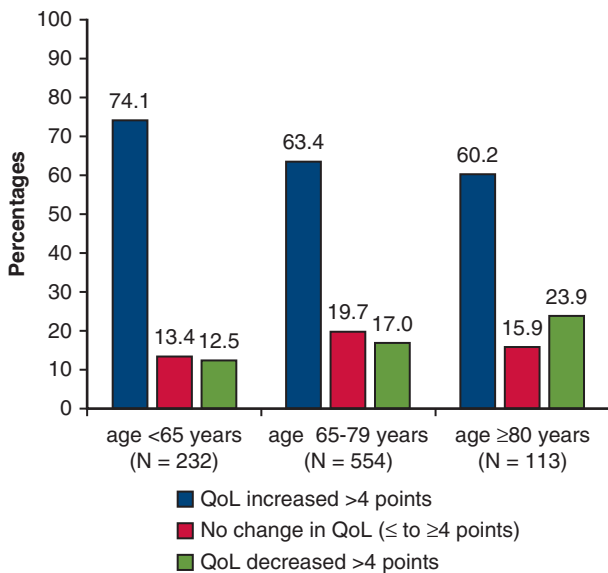

FIGURE E2. Sensitivity analysis for the Physical Component Summary score. Differences between baseline and 1-year follow-up per age group in the quality of life Physical Component Summary score; cut-off value 4 points. *QoL*, Quality of life.
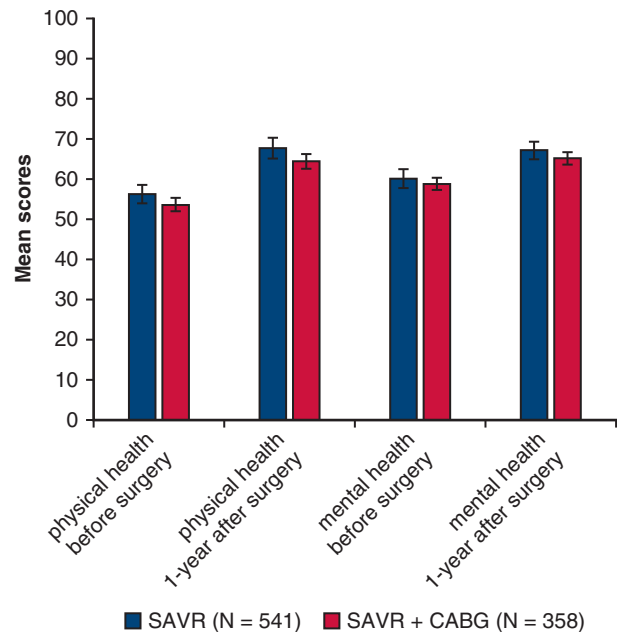

FIGURE E4. Subgroup analyses. *SAVR*, Surgical aortic valve replacement; *CABG*, coronary artery bypass grafting.

TABLE E1. Record checklist

Items	Item no.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
Title and abstract					
	1	(a) Indicate the study's design with a commonly used term in the title or the abstract. (b) Provide in the abstract an informative and balanced summary of what was done and what was found		RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included.	1
				RECORD 1.2: If applicable, the geographic region and time frame within which the study took place should be reported in the title or abstract.	2
				RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract.	n/a
Introduction					
Background rationale	2	Explain the scientific background and rationale for the investigation being reported	1-2		
Objectives	3	State specific objectives, including any prespecified hypotheses	2		
Methods					
Study design	4	Present key elements of study design early in the paper	2		
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	2		
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	2	RECORD 6.1: The methods of study population selection (such as codes or algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided.	2
		Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	n/a	RECORD 6.2: Any validation studies of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, detailed methods and results should be provided.	n/a
		Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	n/a	RECORD 6.3: If the study involved linkage of databases, consider use of a flow diagram or other graphical display to demonstrate the data	n/a
		(b) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed	n/a		

(Continued)

ADULT

TABLE E1. Continued

Items	Item no.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
				linkage process, including the number of individuals with linked data at each stage.	
		Case-control study—For matched studies, give matching criteria and the number of controls per case			
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	2	RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, an explanation should be provided.	2
Data sources/ measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	2 and Appendix E1		
Bias	9	Describe any efforts to address potential sources of bias	2		
Study size	10	Explain at how the study size was arrived	3 and Figure E1		
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	2		
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	2		
		(b) Describe any methods used to examine subgroups and interactions	2		
		(c) Explain how missing data were addressed	n/a		
		(d) Cohort study—If applicable, explain how loss to follow-up was addressed			
		Case-control study—If applicable, explain how matching of cases and controls was addressed	n/a		
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	n/a		
		(e) Describe any sensitivity analyses			
Data access and cleaning methods		…		RECORD 12.1: Authors should describe the extent to which the investigators had access to the database population used to create the study population.	2
				RECORD 12.2: Authors should provide information on the data cleaning methods used in the study.	2

(Continued)

Items	Item no.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
Linkage		…		RECORD 12.3: State whether the study included person-level, institutional-level, or other data linkage across 2 or more databases. The methods of linkage and methods of linkage quality evaluation should be provided.	2
Results					
Participants	13	(a) Report the numbers of individuals at each stage of the study (eg, numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed) (b) Give reasons for nonparticipation at each stage. I Consider use of a flow diagram		RECORD 13.1: Describe in detail the selection of the persons included in the study (ie, study population selection) including filtering based on data quality, data availability and linkage. The selection of included persons can be described in the text and/or by means of the study flow diagram.	3 and Figure E1
Descriptive data	14	(a) Give characteristics of study participants (eg, demographic, clinical, social) and information on exposures and potential confounders (b) Indicate the number of participants with missing data for each variable of interest (c) Cohort study—summarise follow-up time (eg, average and total amount)	Table 1		
Outcome data	15	Cohort study—Report numbers of outcome events or summary measures over time	3-5 and Tables 1-3		
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	n/a		
		Cross-sectional study—Report numbers of outcome events or summary measures	n/a		
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Table 2 Tables 1 and 3		
		(b) Report category boundaries when continuous variables were categorized			
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a		

(Continued)

ADULT

TABLE E1. Continued

Items	Item no.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
Other analyses	17	Report other analyses done—eg, analyses of subgroups and interactions, and sensitivity analyses	Figures E2-E4 and Table E3		
Discussion					
Key results	18	Summarize key results with reference to study objectives	3-5		
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	6	RECORD 19.1: Discuss the implications of using data that were not created or collected to answer the specific research question(s). Include discussion of misclassification bias, unmeasured confounding, missing data, and changing eligibility over time, as they pertain to the study being reported.	5-6
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	5-7		
Generalisability	21	Discuss the generalizability (external validity) of the study results	6		
Other information					
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	7		
Accessibility of protocol, raw data, and programming code	…		–	RECORD 22.1: Authors should provide information on how to access any supplemental information such as the study protocol, raw data, or programming code.	Table E1, Tables E2 and E3, Figures E1-E4, Appendix E1

The record statement: checklist of items, extended from the strobe statement, that should be reported in observational studies using routinely collected health data.[11] *n/a*, Not applicable.

TABLE E2. Subscale scores quality of life

Subscore	<65 y (n = 232) Preoperative	1-y FU	*P* value	65-79 y (n = 554) Preoperative	1-y FU	*P* value	≥80 y (n = 113) Preoperative	1-y FU	*P* value
GH	65.1 ± 22.5	73.2 ± 20.2	<.001	65.1 ± 22.9	70.9 ± 21.4	<.001	63.9 ± 22.0	69.1 ± 22.6	<.001
PF	57.6 ± 26.4	81.6 ± 23.1	<.001	54.5 ± 26.7	71.1 ± 26.8	<.001	39.9 ± 25.5	54.4 ± 30.5	<.001
RP	29.0 ± 30.6	45.0 ± 32.2	<.001	32.8 ± 29.2	42.8 ± 30.7	<.001	24.6 ± 22.6	33.7 ± 27.9	<.001
BP	75.5 ± 25.4	87.4 ± 19.4	<.001	75.4 ± 25.5	84.1 ± 22.2	<.001	69.6 ± 28.9	75.3 ± 28.5	<.001
MH	62.9 ± 19.3	73.0 ± 21.2	<.001	61.3 ± 20.1	66.6 ± 21.9	<.001	60.3 ± 18.1	62.8 ± 21.6	<.001
VT	53.5 ± 22.0	63.3 ± 18.5	<.001	55.4 ± 22.5	60.3 ± 20.6	<.001	49.3 ± 23.5	56.1 ± 20.4	.001
SF	73.0 ± 25.3	84.1 ± 22.1	<.001	72.7 ± 25.1	83.6 ± 21.7	<.001	66.8 ± 28.5	76.0 ± 26.9	<.001
RE	44.0 ± 33.2	50.5 ± 34.3	<.001	48.6 ± 31.9	51.4 ± 32.3	<.001	46.0 ± 35.5	48.9 ± 32.7	<.001

All numbers are presented as mean with standard deviation. *FU*, Follow-up; *GH*, general health; *PF*, physical functioning; *RP*, role physical; *BP*, bodily pain; *MH*, mental health; *VT*, vitality; *SF*, social functioning; *RE*, role emotional.

TABLE E3. Subgroup analyses

Scores	SAVR (n = 541)	SAVR + CABG (n = 358)	*P* value
QoL score baseline: Physical Component Score	56.2 (SD: 18.4)	53.5 (SD: 19.6)	.032
QoL score baseline: Mental Component Score	60.0 (SD: 17.6)	58.8 (SD: 18.6)	.293
QoL score 1-y follow-up: Physical Component Score	67.7 (SD: 19.6)	64.4 (SD: 20.8)	.018
QoL score 1-y follow-up: Mental Component Score	67.1 (SD: 17.2)	65.2 (SD: 17.9)	.104
Difference in QoL Physical Component Score (MCID 5 points)	11.5 (SD: 18.0)	11.0 (SD: 18.6)	.693
Difference in QoL Mental Component Score (MCID 5 points)	7.1 (SD: 16.8)	6.4 (SD: 18.2)	.581

SAVR, Surgical aortic valve replacement; *CABG*, coronary artery bypass grafting; *QoL*, quality of life; *SD*, standard deviation; *MCID*, minimal clinically important difference.