

Eliciting Patient Risk Willingness in Clinical Consultations as a Means of Improving Decision-Making of Aortic Valve Replacement

Amjad I. Hussain, MD; Andrew M. Garratt, PhD; Cathrine Brunborg, MSc; Svend Aakhus, MD, PhD; Lars Gullestad, MD, PhD; Kjell I. Pettersen, MD, PhD

Background—Treatment decisions for aortic valve replacement (AVR) should be sensitive to patient preferences. However, we lack knowledge of patient preferences and how to obtain them.

Methods and Results—We assessed the mortality risk patients were willing to accept when undergoing AVR by using the Standard Gamble method and aimed to show how this risk willingness was affected by level of disease burden. We report findings from 439 patients, aged >18 years with severe aortic stenosis who were referred for evaluation of AVR to our institution. The vast majority of patients accepted a mortality risk regarded as high or prohibitive according to current guidelines. Of the 439 patients, 51% patients were willing to forego surgery with high mortality risk (8–50%) and 19% were willing accept a prohibitive mortality risk (>50%) as defined in current guidelines. However, the risk willingness varied considerably. Acceptance of prohibitive risk willingness (>50%) was associated with reporting of 3 to 5 different restricting symptoms, with an odds ratio of 4.07 (95% Cl 1.56–10.59) opposed by increasing score on EuroQol–Visual Analog Scale, with an odds ratio of 0.99 (95% Cl 0.97–1.00). The poor ability to predict risk willingness based on available clinical variables and health status suggests that other factors may be important advocating the need for tools for soliciting patient's preferences individually.

Conclusion—When undergoing AVR, patients were willing to accept considerably higher perioperative risk than what is considered acceptable in current guidelines and practice. Patient preferences varied considerably, and they should be directly assessed and taken into account in decision-making and guidelines.

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Key Words: aortic stenosis • cardiovascular diseases • patients • shared decision-making • surgery • valves

T reatment decisions for aortic valve replacement (AVR) are based on symptoms, valve severity, cardiac findings, comorbidity, and individual characteristics. Risk calculations, including the Society of Thoracic Surgeons (STS) Predictor Risk of Mortality (PROM), are used to guide decision-making and to identify high surgical risk or inoperable patient

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conditions, when selecting appropriate operative techniques and medical treatments. $^{1} \end{tabular}$

Recent developments in the decision-making process include a shift toward increased patient involvement including the consideration of patient preferences. Referral and treatment decisions are often based on the physician's perception of prognosis, tradeoffs between potential benefits and burdens of different treatment options, and the patient's values and needs. However, patients might appraise the benefits and burdens differently. Guidelines state that surgery should only be performed in informed and motivated patients,¹ but it is not clear how this information should be obtained and weighted compared with the risk associated with the planned intervention. To the best of our knowledge, no published studies have considered patient preferences and risk willingness in determining treatments for severe aortic stenosis (AS).

For assessing patient preferences in circumstances involving risk, the preferred instrument is the Standard Gamble (SG).² It obtains preferences directly from the

From the Department of Cardiology, Oslo University Hospital, Rikshospitalet, Oslo, Norway (A.I.H., S.A., L.G., K.I.P.); Knowledge Center for the Health Services, Norwegian Institute for Public Health, Oslo, Norway (A.M.G.); Oslo Centre for Biostatistics and Epidemiology, Research Support Services, Oslo University Hospital, Oslo, Norway (C.B.); Faculty of Medicine, University of Trondheim, Norway (S.A.).

Correspondence to: Amjad I. Hussain, MD, Department of Cardiology, Oslo University Hospital, Post Box 4950 Nydalen, 0424 Oslo, Norway. E-mail: amjad.i.hussain@gmail.no

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patients and is the most theoretically valid method of eliciting preferences, 3,4 and the inclusion of risk makes it relevant in this context.

In this study, we assessed the sudden mortality risk patients were willing to accept associated with aortic valve replacement (AVR) by using the SG in the setting of a preoperative examination. We assessed differences in characteristics among patients willing to accept low-intermediate, high, or prohibitive risk, as defined by guidelines of the American Heart Association and the American College of Cardiology in 2014.¹ Finally, we intended to identify important determinates for accepting operative risk of death of >50%, defined as prohibitive by guidelines.

Materials and Methods

The Study Population

The Severe Aortic Stenosis (SAS) study is a prospective cohort study undertaken between May 2010 and May 2015 at Oslo University Hospital, Rikshospitalet, Norway. Consecutive patients referred from May 2010 to April 2014 were invited to participate. Of 573 eligible patients aged >18 years with severe AS who were referred for surgery, 68 patients declined and 56 were excluded. Of the excluded patients, 24 had possible cognitive impairment (Mini Mental Status Exam [MMSE] score <24), 9 had missing MMSE scores, 18 were diagnosed with moderate AS, and 5 were diagnosed with other conditions. The 449 eligible patients underwent routine preoperative assessments. The MMSE and SG were performed by an experienced clinical research nurse, trained by a senior researcher (K.I.P.). The SG interview followed the MMSE status and blood sampling, which gave the research nurse sufficient time to establish a relation with the patients and discuss confidentiality and that the interview was not linked to clinical decision-making and the actual mortality risk.

The SG interview took up to 10 minutes and was supplemented with a visual aid that showed bars representing the risk of death. The bars started off at a level of 95% risk of sudden death and the concurrent survival probability. The death risk was then reduced in 5% intervals. The interview began with patients being asked about symptoms of concern and to consider their physical and mental health, activity limitations, medications and treatments being taken, and any worries or concerns about their health caused by AS-related symptoms. They were informed that the outcome of AVR and "full health" would relieve AS-related symptoms and concerns and that their life expectancy after AVR would be equal to that of an individual of similar age and sex without giving the number of years. Before attending the hospital, patients completed questionnaires to assess patient-reported outcomes, number of different weekly restricting symptoms, and sociodemographic characteristics.

Health Status and Clinical Measures

The SG is a method for revealing preferences in situations of uncertainty and risk.^{2,3} Patients choose between the option of certainty of continued life in their present health state or undergoing an intervention that restores full health with the risk of sudden death. The probability p defines the probability of sudden death during the intervention, and (1 - p) defines the rate of success. To determine the patient preference, p is varied to the point of indifference between taking the risk and remaining in the present health state. At that point, p defines the risk the patient is willing to take, and (1 - p) defines their preference value.

The Short Form 36-Item Health Survey Version 2 is a selfadministered, 36-item, generic instrument assessing healthrelated quality of life (HRQL) across 8 scales and 2 summary scales of physical and mental health.⁵ The Short Form 36-Item includes a single item of health transition assessing patients' perception of change in health compared with 1 year earlier, rated on a 5-point scale. The instrument has evidence for validity and reliability in patients undergoing cardiac surgery.⁶

EuroQol 5 Dimension of health, each with three levels of problems (EQ-5D 3L) is a generic HRQL instrument with 5 items (eg, mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and 3 levels (no problems, some problems, and extreme problems). Each EQ-5D health state has a preference weight attached derived from the UK general population with scores ranging from -0.59 to 1.00, where 1.00 is the best possible health.⁷ The EuroQol Visual Analogue Scale (EQ-VAS) is an interval scale in the form of a thermometer ranging from 0 to 100, where 100 is the best possible health state.⁸

The Hospital Anxiety and Depression Scale is a 14-item instrument for assessing anxiety and depression in patients admitted to nonpsychiatric clinics with evidence for validity and reliability.⁹ Item responses are summed to give 2 scores ranging from 0 to 21. Scores in the range of 7 to 10 are suggestive of and scores \geq 11 represent a high likelihood of a mood disorder.

Self-reported symptom frequency was assessed by using a locally derived questionnaire about the occurrence of limiting symptoms during the past 2 to 4 weeks. The questionnaire was based on the Kansas City Cardiomyopathy Questionnaire¹⁰ and the Seattle Angina Questionnaire¹¹ and was adapted for severe AS based on clinical experience. Fatigue, dyspnea, and dizziness were reported on a 7-point ordinal scale from "persistent" to "not at all" in the past 2 weeks. Chest pain (angina) was reported on 6-point scale from "≥4

times a day" or "multiple times daily" to "not at all" the past 4 weeks. Syncope was reported on a 4-point scale from " \geq 3 times a month" or "multiple times a month" to "not at all" the past 3 months.

Clinical assessment was performed to classify dyspnea based on the New York Heart Association functional classification.¹² Comprehensive resting standard echocardiography was performed with a Vivid 7 or E9 (GE Ving Med Ultrasound) according to guideline standards.^{13,14} The perioperative risk scores were calculated with use of the STS v2.73 calculator (http://riskcalc.sts.org/).

Statistical Analysis

The cohort was divided into 3 groups of patients according to risk willingness with mortality risk classified as lowintermediate (\leq 8%), high (>8–50%), or prohibitive (>50%), as defined by American Heart Association/American College of Cardiology 2014 guidelines.¹ One-way ANOVA was used to compare risk willingness groups with least significant difference correction for multiple comparisons or the Kruskal–Wallis test where appropriate. The χ^2 test was used to detect associations between categorical independent variables.

The association was assessed between risk willingness of >50% and health status, disease burden, clinical variables, and sociodemographic characteristics. The low-intermediate— and high-risk groups were merged and compared with prohibitive risk willingness to form a binary variable in logistic regression analysis. Disease burden was represented by the number of different restricting symptoms occurring weekly (range 0–5 symptoms), perceived change in health compared with 1 year earlier (health transition), EQ-VAS scores, and the New York Heart Association functional classification.

Univariate analysis for risk willingness >50% or not was performed for all the variables, and any variable with P<0.25 was considered for the multiple logistic regression analysis. When Spearman correlation coefficients (r) between 2 independent variables were >0.70, only 1 of the variables was included in the multivariate model to circumvent problems with multicollinearity. Manual backward stepwise elimination was used, and the effect between potential risk factors and prohibitive risk willingness (>50%) was quantified by odds ratio (OR) with 95% Cls. Evaluation of the accuracy of the models was assessed by calibration and discrimination. Calibration was evaluated with use of the Hosmer-Lemeshow goodness-of-fit test, with nonsignificance indicating model adequacy. Discrimination was evaluated by analysis of the area under the ROC curve with acceptable discriminatory ability defined as >0.7. The significance level was set to 5%, based on 2-sided tests.

IBM SPSS Statistics (IBM SPSS Inc), version 21 was used for the analyses.

Ethics

The study was approved both by our institutional review committee and the Regional Committee for Medical Research Ethics. All patients signed an informed consent form.

Results

The SG was completed by 439 (98%) patients. Compared with those with complete data for the SG and MMSE, those with missing data did not differ significantly for age, gender, clinical or echocardiographic measures. There was considerable variation in risk willingness across the population. The overall median risk willingness was 25% (inter-quartile range 25–50%). The distribution showed that 104 (24%) patients were not willing to risk death at all (risk willingness=0); 44 (10%) patients were willing to take a 25% risk of death, 92 (21%) patients were willing to take a 50% risk of death, and 17 (4%) patients were willing to take a mortality risk of 95% to 100% reflecting their perception of current health state close to or worse than dead (Figure 1).

Baseline characteristics are shown in Tables 1 and 2. The mean age was 75 years and 56% were men. There were no significant differences in calculated STSPROM scores, age,

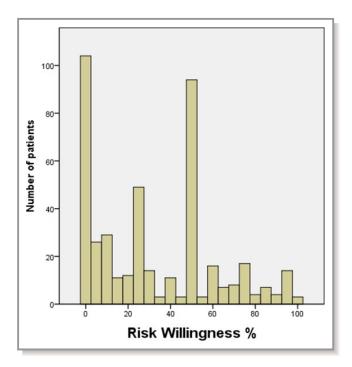


Figure 1. Distribution of risk willingness (N=439). The overall median risk willingness was 25% (range 25–50%). The distribution had 1 peak at 0 reported by 104 patients, the next peak median value of 25% was reported by 44 patients, and the third peak at 50% risk willingness was reported by 92 patients.

 Table 1. Characteristics and Clinical Findings According to the Amount of Risk Patients Were Willing to Take With Cutoff Levels

 Defined by AHA/ACC 2014 Guidelines for Assessing the 30-Day Mortality Risk in Patients Undergoing Surgical AVR (STS PROM)

Characteristics	Risk Willingness Group					
	Low-Intermediate ^A (≤8%)	High Risk ^B (>8–50%)	Prohibitive Risk ^C (>50%)	Overall P Value		
N=439, n (%)	130 (30)	224 (51)	85 (19)			
Age, y	75 (11)	74 (10)	76 (11)	0.711		
Sex (male), %	50	59	58	0.251		
Education, y (range 7-20)	12 (3)	12 (3)	11 (3)	0.207		
Medical history, %			·			
Hypertension	47	42	51	0.396		
Heart failure	5	9	9	0.315		
Atrial fibrillation	22	25	20	0.577		
Diabetes	12	13	11	0.794		
Pulmonary disease	12	23	15	0.019*		
Kidney failure	5	9	5	0.363		
Perioperative STS PROM risk		·		· ·		
Median (range)	9.85 (2.40-32.20)	12.0 (2.20–54.90)	13.10 (2.20–53.20)	0.141		
Echocardiographic valve character	istics	·	'	·		
Peak jet flow, m/s	4.6 (0.7)	4.4 (0.6)	4.4 (0.7)	0.014 [†]		
Mean gradient, mm Hg	56 (16)	52 (16)	52 (17)	0.049 [‡]		
Estimated valve area, cm ²	0.7 (0.2)	0.7 (0.2)	0.7 (0.2)	0.100		
Cardiac index, L/min	2.7 (0.6)	2.7 (0.6)	2.7 (0.5)	0.934		
Left ventricular ejection fraction, 9	6			· · ·		
Normal (>50%)	92	81	89	0.010		
NYHA functional classification, %				<0.001§		
I	20	9	5			
II	46	44	34			
III/IV	17	42	61			

Values are presented as mean (SD) unless otherwise indicated. One-way ANOVA adjusted for multiple comparison by least significant difference or Kruskal–Wallis test was performed to compare risk willingness groups. The χ^2 test was applied to detect associations between categorical independent variables. NYHA classes III and IV were merged because there were few patients in NYHA class IV. AHA indicates American Heart Association; ACC, American College of Cardiology, AVR, aortic valve replacement; STS, Society of Thoracic Surgeons; PROM, Predicted Risk of Mortality; NYHA, New York Heart Association.

*Higher proportion of high-risk willingness patients had pulmonary disease.

[†]A vs B (*P*=0.001) and A vs C (*P*=0.02).

[‡]A vs B (*P*=0.02).

[§]A higher proportion of the patients in prohibitive risk willingness group were in NYHA class III/IV.

gender, education level or comorbidities for the different risk-willingness groups, with the exception that more patients in the high risk group had a history of pulmonary disease (P=0.02).

Patients with low-intermediate risk willingness had higher aortic peak flow velocity (P=0.02) and higher mean aortic gradient (P=0.05) compared with the high risk willingness group. All 3 groups had a similar proportion of estimated valve area, cardiac output but those with low-intermediate risk willingness had a higher proportion of preserved EF compared with the high risk willingness group (Table 1). Tables 1 and 2 along with Figure 2 show assessment of NYHA class, number of reported symptoms, HRQL and health transition. Compared with patients in the low-intermediate risk willingness group, those in the high and prohibitive risk willingness groups were characterized by worse NYHA class, lower scales of physical and mental health, reduced HRQL as assessed by EQ-5D and EQ-VAS and poorer health transition scores. The Hospital Anxiety and Depression Scale depression and anxiety scores were similar. Patient risk willingness varied widely within the patient groups defined by the different disease markers (Figure 2). Table 2.Patient Measures According to the Amount of Risk Patients Were Willing to Take With Cutoff Levels Defined by AHA/ACC2014 Guidelines for Assessing the 30-Day Mortality Risk in Patients Undergoing Surgical AVR (STS PROM)

	Risk Willingness Group	Risk Willingness Group				
	Low-Intermediate ^A (≤8%)	High Risk ^B (>8–50%)	Prohibitive Risk ^C (>50%)	Overall P Value		
No. of different weekly restricting symptoms reported *, %				<0.001*		
0	39	20	8			
1–2	44	39	32			
3–5	17	42	61			
Patient-reported outcomes						
SF-36						
PCS	42 (10)	38 (10)	34 (10)	<0.001 [†]		
MCS	52 (10)	49 (10)	46 (10)	<0.010 [‡]		
Health transition, %	n transition, %			<0.001 [§]		
Better/unchanged	50	30	14			
Somewhat/worse	41	46	53			
Much worse	9	24	33			
EQ-5D	0.76 (0.21)	0.72 (0.21)	0.65 (0.23)	0.001		
EQ-VAS	69 (17)	56 (21)	50 (22)	<0.001 [¶]		
HADS						
Anxiety	4.7 (4.0)	4.7 (3.8)	4.8 (3.9)	0.820		
Depression	3.7 (3.1)	4.1 (3.0)	4.4 (3.7)	0.645		

Values are expressed as mean (SD) unless otherwise indicated. AHA indicates American Heart Association; ACC, American College of Cardiology, AVR, aortic valve replacement; STS, Society of Thoracic Surgeons; PROM, Predicted Risk of Mortality; SF-36, Short Form 36-Item Health Survey; PCS, physical component summary measure; MCS, mental component summary measure; health transition, SF-36 item 2 "change in health compared with 1 year ago"; EQ-5D 3L, EuroQol 5-dimensional health-related quality of life questionnaire; EQ-VAS, EQ-5D 3L visual analog scale; HADS, Hospital Anxiety Depression Scale.

*Number of different restricting weekly symptoms reported were dyspnea, angina, fatigue, dizziness, and syncope. One-way ANOVA adjusted for multiple comparison by least significant difference or Kruskal–Wallis test was performed to compare risk willingness groups. The χ^2 test was applied to detect associations between categorical independent variables. *A vs B and A vs C (*P*<0.001).

[‡]Higher MCS scores were reported by A vs C (*P*<0.01).

[§]Patients in the prohibitive risk willingness group reported more symptoms and worsening health compared with the other groups.

^{II}A vs C and B vs C.

[¶]A vs B and by A vs C (*P*<0.01).

From the univariable analysis age, perioperative STS PROM risk score, scales of physical and mental health, health transition, NYHA classification, EQ-5D 3L and depression were identified as candidates for the multiple regression analysis. The final multiple logistic regression model showed that only reported number of different weekly restricting symptoms and EQ-VAS were the strongest independent risk factors of risk willingness >50% (Table 3). Reporting 3 to 5 different weekly symptoms was associated (OR 4.07, 95% CI: 1.56-10.59, P=0.004) with prohibitive risk willingness as compared with not experiencing any limiting symptoms. Risk willingness >50% was associated with decreasing EQ-VAS scores (OR 0.99, 95% CI: 0.97-1.00, P=0.047). The Hosmer and Lemeshow test indicated satisfactory model fit $(\chi^2 = 9.091, df = 8, P = 0.34)$. The area under the receiver operating characteristic curve was 0.68 (95% Cl: 0.61-0.75) indicating a limited discriminative ability between patients with risk willingness of >50% or not.

Discussion

The vast majority of the patients with severe AS referred for surgery were willing to take a mortality risk regarded as high or prohibitive, according to current guidelines. High-risk willingness was associated with high frequency of symptoms restricting physical capacity, perceived worsening of health, and low HRQL experienced by the patients. However, there was a poor ability to predict risk willingness based on available clinical variables and health status measures, suggesting that other factors may be important.

To the best of our knowledge, this study is the first to assess risk willingness in patients with severe AS. Risk willingness in our patients was comparable to that for patients with pulmonary arterial hypertension¹⁵ and for patients awaiting lung transplantation.¹⁶ Consistent with findings from other studies,^{16,17} we observed a broad variation in risk willingness and an increase in risk willingness with more

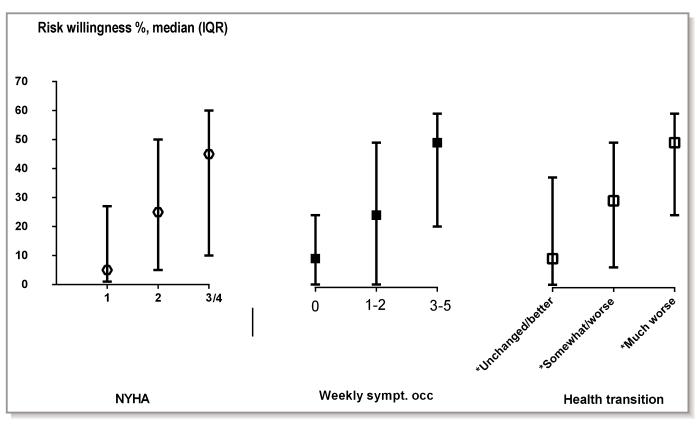


Figure 2. Association between risk willingness, New York Heart Association Functional classification, reported number of weekly symptoms, and health transition (median and IQR). Symbols represent the median risk willingness (whiskers=IQR) that patients in each category were willing to take. All median values were significantly different (P<0.001), based on the Mann–Whitney *U* test with Bonferroni adjustments for multiple testing. Weekly symptoms reported were angina or chest pain, dizziness, dyspnea, fatigue, and syncope. The health transition (item 2 on the Short Form 36-Item) reflects the patient's perceptions of health change compared with 1 year earlier.

severe disease. The high variability of SG results combined with poor ability of health measures and clinical variables to explain it suggests that risk willingness should be assessed directly at the individual patient level.

Table 3.Independent Risk Factors of Risk Willingness >50%Identified Using Multiple Logistic Regression

Variable	Odds Ratio	95% CI	P Value			
No. of weekly restricting symptoms (dyspnea, angina, fatigue, dizziness, and syncope)						
0	1.0					
1–2	2.02	0.77–5.31	0.2			
3–5	4.07	1.56–10.59	0.004			
EQ-VAS	0.986	0.97–1.00	0.04			

Age, perioperative Society of Thoracic Surgeons Predicted Risk of Mortality risk score, physical component summary measure, mental component summary measure, health transition (Short Form 36-Item item 2 "change in health compared with 1 year ago"), New York Heart Association functional classification, EuroQol 5-dimensional health-related quality of life questionnaire, and depression were identified as candidates for the multiple regression analysis; however, only EQ-VAS and number of different restricting symptoms remained significant using manual backward stepwise elimination method in the final multiple regression analysis; explaining 6.7% (Cox and Snell R^2) and 10.4% (Nagelkerke R^2). EQ-VAS indicates EQ-5D 3L visual analogue scale.

The high variation in risk willingness within heart function classes (New York Heart Association) and other groups defined by disease markers is supported by the considerable variability in myocardial remodeling observed leading to development of left ventricular dysfunction with progression to pulmonary hypertension and overt heart failure despite similar valvular narrowing.^{18,19} Further, patients often adjust their activities and ascribe their symptoms to the normal aging process, which may mask their symptoms. This biological and individual variability supports the observed variability in risk willingness. This weakens the contribution of clinical variables and measures of HRQL as predictors of patient preferences for use in making treatment decisions. Hence, measuring patient preferences with methods such as the SG is likely to be informative, especially in patients facing high-risk interventions or in situations with uncertainty about patient preferences.

Self-assessed measures of health status do not take into account the uncertainty of the intervention and do not include preferences.²⁰ The variation in SG ratings that was not explained by these other measures may reflect important differences in risk preferences. Willingness to accept risk is somewhat more than the sum of health status and symptom

burden and may include other individual characteristics, including risk aversion,²¹ knowledge, the way information is presented and comprehended,²² emotions, and previous health care experiences. The SG is something of a gold standard in the assessment of preferences taking into account the risk associated with surgery. We previously found that the SG has evidence for acceptability, feasibility, and validity as a method for assessing patient utilities,²³ and the current study represents an important first step in assessing the preferences of patients with severe AS in a scientifically rigorous manner.

Guidelines use the terminology "motivated" for AVR, which is a complex concept that is not easily assessed.²⁴ Sufficient risk willingness is likely to make an important contribution and is a prerequisite for motivation of AVR. A high proportion of our patients were willing to accept considerably higher mortality risk than that considered acceptable or borderline acceptable risk (13–50%) by most physicians and guidelines. Beyond a general agreement that dementia and advanced or untreatable cancer make AVR inappropriate, it is uncertain to what extent the presence of other illness should influence the AVR decision and there is no clear definition of unacceptable high risk. However, an unacceptable high operative risk is commonly cited as a reason against AVR in patients aged >80 years, and there is a tendency of physicians to subjectively overestimate the risk.^{25–27}

The surgeons' AVR decision-making may also be based on considerations of disabling stroke, loss of function, long-term ventilator dependencies, and other factors such as frailty including categories of patients most likely to have poor outcomes other than death. However, decision-making is prone to bias due to differences in local practice, experience, and specialty of the clinician.²⁵ A tendency to select patients with intermediate risk at the expense of higher risk groups may arise as increasing evidence of satisfactory safety and efficacy outcomes of transcatheter AVR compared with surgical AVR emerges in intermediate risk groups.^{28,29} This raises the question of whether the physicians' conservative interpretation of "do not harm" and their sense of responsibility might restrict them from providing patients with objective information and advice regarding AVR. A considerable proportion of motivated patients might remain unoperated due to physician caution in risk interpretation, which may not reflect patients' preferences.³⁰ In many instances, the final decision is made by a heart team without the presence of the patients. The extent to which patient preference is discussed in such technically focused heart team meetings is unclear and should be explored. Research comparing patient preferences before consultation with cardiologists/surgeons' perceptions of patient eligibility and motivation is recommended. Research relating to how patients can be best informed about treatment risk and how their needs and values can be elicited together with evidencebased decision tools is also recommended.

Catheter-based and minimally invasive procedures have increased eligibility of older and more comorbid patients for cardiac interventions. Shared knowledge and evidence-based decision-making are cornerstones in the selection of treatment and recommendation of new interventions.³¹ Patient risk willingness should play a central role in physician consultations within the context of shared decision-making. Assessments of patient motivation and risk willingness must be systematic, objective, and evidence based.

Limitations

There are several study limitations that should be addressed before the SG can be more widely applied in the assessment of patients with AS undergoing AVR.

The SG has face validity and reflects the substantial risk of death during surgery that AVR patients face. However, there are important methodological issues with the framing of the SG. The widely applied SG option of remaining in the current health state^{16,17} does not reflect the natural course of the disease, including the rapid progressive deterioration of health with a mortality rate of 60% to 80% over 5 years if left unoperated.³² This may have led to an underestimation of risk willingness. The starting point of the SG can also lead to framing effects, or what is referred to as anchor bias.²¹ We started with a 95% mortality risk, but other starting points and risk reductions may have given different estimates, which should be explored in future studies.

The SG was not designed to cover attitudes toward other adverse events related to surgery and recovery. Patients with similar risk willingness may differ in their perceptions of risk probabilities related to organ complications, cognitive impairments, and loss of function caused by surgery.

The SG was interview administered due to the cognitively demanding nature of the task. Interviewing may be more acceptable and appropriate in our elderly patient population but is more costly than self-administration. Future research should further consider patients' ability to understand the task including the tradeoffs with which they are presented. The only statistically significant difference between completers and noncompleters of the SG was lower scores on the Short Form 36-Item domains of role-emotional and mental health for noncompleters. The low numbers mean that this should be interpreted with caution, but it could indicate that patients with poorer mental health find that the SG less acceptable in this setting.

The setting of a tertiary center may have resulted in more highly motivated patients than those not referred. Therefore, the results may not be generalizable to all patients with severe AS. We did not consider the health care received before referral, and no attempt was made to assess patient understanding and knowledge of their disease and treatment options.

Conclusion

The majority of patients with severe AS were willing to accept substantial high mortality risk defined by current guidelines, which challenges current risk levels in decision-making in the choice of treatment. However, risk willingness varied considerably among patients and was poorly associated by clinical and HRQL variables, suggesting that risk willingness should be assessed directly and individually in patients facing high-risk interventions.

The decision of whether to operate is often based on the physician's judgment without patient involvement in consideration of the pros and cons. Our study suggests that assessment of risk willingness should play a greater role in shared decision-making and accommodated in clinical guidelines. The increase in high-risk procedures being offered to an increasingly older and comorbid population creates the need for a systematic approach to revealing patient preferences and risk willingness.

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Disclosures

None.

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