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Psychometric Properties of the Kansas City Cardiomyopathy Questionnaire in a Surgical Population of Patients With Aortic Valve Stenosis

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The 12-item version of the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) was originally developed for patients with heart failure but has been used and tested among patients with severe aortic stenosis (AS) who underwent transcatheter aortic valve implantation. Whether the instrument is suitable for patients with AS who underwent surgical aortic valve replacement (SAVR) is currently unknown. Thus, we aimed to investigate the psychometric properties of the KCCQ-12 before and after SAVR among patients with severe AS. We conducted a prospective cohort of 184 patients with AS who completed the KCCQ-12 and the EuroQol 5 Dimension 5 Levels before and 4 weeks after surgery. Construct validity was investigated with hypothesis testing and an analysis of Spearman's correlation between the two instruments. Structural validity was investigated with explorative and confirmatory factor analyses and reliability with Cronbach's α. All analyses were conducted on data from the two time points (preoperatively and four weeks after surgery). The hypothesis testing revealed how the New York Heart Association class was significantly correlated with the preoperative KCCQ-12 total score (higher New York Heart Association class, worse score). A longer length of hospital stay and living alone were significantly associated with poorer postoperative KCCQ-12 total score. KCCQ-12 and EuroQol 5 Dimension 5 Levels were moderately correlated in most domains/the total score/Visual Analogue Scale score. Principal component analyses revealed two 3-factor structures. The confirmatory factor analyses did not support the original model at any time point. Cronbach's α ranged from 0.22 to 0.84 in three preoperative factors and from 0.39 to 0.76 in the postoperative factors. The total Cronbach's α was 0.83 for the suggested preoperative 3-factor model and 0.83 for the postoperative model. In conclusion, the Danish version of the KCCQ-12 tested in a population of patients with AS who underwent SAVR appears to have acceptable construct validity, whereas structural validity cannot be confirmed for the original four-factor model. Overall reliability is good. **(Am J Cardiol 2023;209:165−172)**

Keywords: quality of life, heart valves, cardiac surgery, psychometric testing, KCCQ

Aortic stenosis commonly develops slowly, and patients may not recognize early symptoms before experiencing limitations in their daily living.[1] Once symptomatic, physiological and hemodynamic changes might necessitate interventions, from minimally invasive procedures such as transcatheter aortic valve implantation (TAVI) to surgical aortic valve replacement (SAVR).[1] From a patient perspective, treatment goals include improvements in symptom burden and quality of life.[2] Therefore, the choice of how to measure these outcomes should be an essential perspective among healthcare professionals. As symptoms of aortic stenosis mimic those of congestive heart failure, the heart-

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See page 171 for Declaration of Competing Interest.

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failure-specific instrument, the Kansas City Cardiomyopathy Questionnaire (KCCQ), is widely used and has been suggested to be a relevant instrument for this population, although originally developed for patients with heart failure.[3,4] Still, it has been used in various studies and trials of patients who underwent TAVI and SAVR,[5–8] and it has been found to be a reliable, responsive, and valid measure for TAVI.[3] Following SAVR, we have previously demonstrated how KCCQ-12 has a wide distribution within individual scores and high ceiling effects, indicating that the instrument might not have appropriate responsiveness to detect changes before and after cardiac surgery.[6] The commonly younger age of the target population of SAVR and symptoms related to the sternotomy (e.g., changed bodily awareness and muscle pain) might also influence symptom burden and overall health status. Thus, whether the KCCQ-12 is an appropriate measure among this population is currently unknown. Therefore, the objective of the present study was to investigate the psychometric properties of KCCQ-12 before and after SAVR among patients with severe aortic stenosis.

Methods

Data derived from the Individualised Follow-up after Valve Surgery (INVOLVE) study,[9] a prospective cohort study investigating the effect of a multidisciplinary intervention consisting of early, individualized, and intensified follow-up with a historical control group.[9] Data from the prospective cohort was used in the current substudy.

Data were collected at Odense University Hospital, Denmark, from November 1, 2016, to November 15, 2017. Patients with aortic stenosis (International Classification of Diseases, Tenth Revision codes I350) who underwent SAVR were eligible for inclusion.

Consecutive patients were asked to complete a paper-based questionnaire before surgery (preoperatively, baseline status) and 4 weeks after discharge (postoperatively). The first questionnaire was completed in the hospital, and the second was completed during the clinical consultation or within 2 days at home. The patients did not receive any reminders.

Demographic and clinical data were obtained from the electronic patient records and the Western Denmark Heart Registry[10] and entered into the electronic database (Research electronic data Capture [RedCap]) hosted by the Open Patient Data Explorative Network (OPEN), Odense University Hospital.[11] Demographic data included sex, age, and cohabitant status. Clinical data contained preoperative information, including co-morbidities, body mass index, smoking and alcohol consumption, and surgical information related to the procedure, postoperative complications, and length of stay.

Patient-reported outcome measures included the KCCQ-12 and the EuroQol 5 Dimension 5 Levels Questionnaire (EQ-5D-5L). The EQ-5D-5L was included as a generic questionnaire to allow for the investigation of correlations with the KCCQ-12.

The 12-item version of the KCCQ, derived from the 23-item KCCQ, was originally developed for patients with heart failure.[12] The KCCQ-12 assesses 4 domains (physical limitation, symptom frequency, quality of life, and social limitation), which can be reported separately into the subscales or summed into an overall score. The scales range from 0 to 100, with higher scores indicating a better health status and low symptom burden.[12]

The EQ-5D-5L consists of an index score and a Visual Analogue Scale (VAS). The index score covers 5 domains of health (mobility, self-care, activity, pain/discomfort, and anxiety) rated in 5 levels and calculated into a utility score ranging from 0 (worst) to 1 (best). The VAS is a visual, graded, vertical measure from 0 to 100, with high scores indicating better health.[13,14] The EQ-5D-5L has shown high validity and has previously been tested in a small sample of patients who underwent heart valve surgery.[15]

To investigate the psychometric properties of the KCCQ-12, validity and reliability were investigated as suggested in the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist.[16,17]

The following aspects of construct validity (convergent and discriminant validity) were examined:

1. Hypothesis testing: Before conducting the analyses, 7 hypotheses were formulated based on existing research on self-reported health status and aortic stenosis. We hypothesized that female sex,[18,19] older age,[20] living alone,[21] severe aortic valve disease measured by aortic valve area, worse New York Heart Association (NYHA) functional class or ejection fraction,[22,23] reduced lung function,[24] and prosthetic valve type (biologic vs mechanical) would have an impact on the KCCQ-12 total score (worse pre- and postoperative scores). Furthermore, we hypothesized that the longer length of stay (number of days admitted)[25] would impact the KCCQ-12 total score at the postoperative measurement.
2. Correlation between scores of KCCQ-12 and EQ-5D-5L: The correlation between the 2 instruments, domains/subscales, and total scores was tested to augment current evidence about the use of disease-specific and generic PROMs and inform clinical care.

The structural validity was investigated with explorative and confirmatory factor analyses to assess the structure of the questionnaire. Structural validity refers to the degree to which the subscale scores of an instrument are an adequate reflection of the dimensions of a construct.[26]

Reliability: The internal consistency was tested with Cronbach's α coefficient as part of the explorative factor analyses. It was, therefore, calculated on each subscale in the different factor structures together with a Cronbach's α coefficient for the total instrument.

The investigation conformed with the principles outlined in the Declaration of Helsinki[27] and was approved by the Danish Data Protection Agency (18/19,152), Danish Patient Safety Authority, and registered at *ClinicalTrials.gov* (NCT03053778). In addition, all patients received written and oral information about the study and provided written informed consent.

Demographic and clinical characteristics are presented as numbers and proportions, mean and SD, or

median with 25th to 75th percentiles (interquartile range), as appropriate.

Due to the skewed distribution of both the KCCQ-12 and the EQ-5D-5L, nonparametric tests were applied. To conduct the hypothesis testing, differences in median scores of the instruments KCCQ-12 and EQ-5D-5L at the 2 time points (preoperatively and postoperatively) were tested with the Mann−Whitney *U* test, and Spearman's correlation coefficient was used to examine the correlation between the continuous data of the 2 instruments, domains/subscales and total scores.

The explorative factor analyses were conducted using principal component analyses, orthogonal rotation, including factors with an eigenvalue >1. The confirmatory factor analyses were conducted using SEM builder and estimated chi-square, root mean square error of approximation (RMSEA), comparative fit index (CFI), and Tucker-Lewis index (TLI).

The analyses were performed on complete observations, in STATA version 17 (College Station, TX: StataCorp LLC).

Results

In total, 184 patients were included, of which 129 (70%) were men, the median age was 70 years, and 44 (24%) were living alone. One patient was excluded because of language barriers. The types of surgical procedures included SAVR with a bio-prosthesis in 85% and mechanical valve prosthesis in 15%, Table 1.

Based on the hypothesis testing, NYHA class was significantly correlated with the preoperative KCCQ-12 total score (higher NYHA class, worse score). Similarly, a longer length of hospital stay and living alone were significantly associated with the postoperative KCCQ-12 total score, Table 2. The remaining hypotheses could not be confirmed.

We found several moderate correlations between domains of KCCQ-12 and domains of EQ-5D-5L on the pre- and postoperative measurements, Table 3. The highest coefficient of correlations among the preoperative scores was found among the KCCQ-12 total score and the EQ-5D-5L VAS (Spearman's ρ = 0.659). In addition, the highest coefficient of correlations in the postoperative scores was found between KCCQ-12 total and EQ-5D-5L VAS (Spearman's ρ = 0.579), Table 3.

Structural validity

The explorative factor analysis based on the principal component analyses revealed a 3-factor structure with an eigenvalue >1 (preoperative and postoperative scores). Thus, the original 4-factor structure did not fit this population. In the preoperative explorative factor analyses, factor 1 consists of 8 items from different domains in the original version of KCCQ-12 (items 1c, 3, 4, 6, 7, 8a, b, and 8c). Items 1c, 4, and 8c cross-load with the other factors. Factor 2 includes 2 items (1a and 1b) that do not represent an original domain in the KCCQ-12. The last factor, factor 3, includes Items 2 and 5 (the questions that explain the least of the total variance), Table 4.

In the postoperative explorative factor analyses, factor 1 includes 5 items (4, 6, 7, 8a, and 8b), factor 2 consists of 5 items (1a, 1b, 1c, 3, and 8c), and factor 3 consists of 2 items (2 and 5), Table 4.

The values of the confirmatory factor analysis, where the original 4-factor structure was investigated on the preoperative and postoperative scores, indicated that both models did not fit well with the population (preoperative data: chi-square = 0.001, RMSEA 0.095, CFI 0.876, TLI 0.830. Postoperative data: chi-square = 0.001, RMSEA 0.103, CFI 0.859, TLI 0.807, not shown in tables). The confirmatory factor analyses are visualized in Supplementary Figures 1 and 2.

Cronbach's α ranged from 0.22 to 0.84 in the 3 preoperatively factors, with the lowest coefficient connected to the last factor, factor 3 (0.22), Table 4. The overall Cronbach's α of 0.83 for the preoperative 3-factor model indicates good internal reliability.

Similarly, the Cronbach's α of the postoperative factors ranged from 0.39 to 0.76, with the lowest coefficient of factor 3 (0.39). The total Cronbach's α of the 3-factor model was 0.83, again indicating good internal reliability in the postoperative model, Table 4.

Table 1
Demographic and clinical characteristics

	All
N	184
Characteristics	
Sex, male, n (%)	129 (70)
Age, years, median (IQR)	70 (65-76)
Living alone, n (%)	44 (24)
Preoperative information	
Reduced pulmonary function*, n (%)	70 (38)
EuroScore II, median (IQR)	1.76 (1.08-2.9)
Aortic valve areacm^2, median (IQR)	0.8 (0.6-0.9)
Estimated glomerular filtration rate† ml/min <60, n (%)	37 (20)
Atrial fibrillation, n (%)	30 (16)
Diabetes‡, n (%)	33 (18)
Ejection fraction ≤ 50, n (%)	45 (24)
Previous PCI, n (%)	18 (10)
NYHA class ≥3, n (%)	52 (28)
BMI, median (IQR)	27 (24-30)
Current smoker, n (%)	68 (37)
Alcohol intake above national high-risk limit, n (%)	24 (13)
Surgical information, n (%)	
Type of valve procedure	
SAVR, biological valve	156 (85)
SAVR, mechanical valve	28 (15)
Concomitant CABG, n (%)	52 (28)
Post-procedure related	
Re-operation, all, n (%)	16 (9)
Length of stay, days	9 (7-12)

* Patients with forced expiratory volume,% ≤80% of predicted value, and/or a history of chronic obstructive pulmonary disease.

† Estimated glomerular filtration rate estimated by the Cockcroft-Gault equation

‡ Patients with diabetes; insulin, peroral and non-pharmacological treatment

BMI = body mass index; CABG = coronary artery bypass grafting; IQR = interquartile range, 25th to 75th quartile; NYHA = New York Heart Association Class; PCI = percutaneous coronary intervention; SAVR = surgical aortic valve replacement.

Table 2
Hypothesis testing of specific variables and KCCQ-total pre- and postoperative scores

Variable	Preoperative			Postoperative		
	KCCQ-total score, median (IQR)	Spearman's correlation ρ, p value	Mann-Whitney-U-test p value	KCCQ-12 total score, median (IQR)	Spearman's correlation ρ, p value	Mann-Whitney-U-test p value
Sex,						
Woman	66.6 (49.4-78.1)		0.723	77.0 (59.4-87.5)		0.695
Man	61.7 (52.1-76.0)			77.0 (61.4-88.5)		
Age	-	−0.005, p = 0.944			−0.148, p = 0.060	
Cohabitant status,						
Living alone	63.0 (49.0-82.8)		0.721	74.7 (54.7-83.6)		0.040
Married/living with someone	62.2 (52.1-76.0)			77.6 (64.6-89.6)		
Aortic valve area index	-	0.024, p = 0.763			−0.032, p = 0,693	
NYHA class	-	−0.212, p = 0.006			−0.120, p = 0.128	
Reduced lung function*	61.2 (48.4-76.0)		0.249	75 (59.4-82.3)		0.141
Ejection fraction	-	−0.005, p = 0.941			0.022, p = 0.782	
Ejection fraction ≤ 50%	62.0 (52.1-78.1)		0.936	77.9 (61.5-88.5)		0.817
Prosthetic valve type,						
Biological valve	63.0 (52.1-78.1)		0.228	77.1 (60.9-87.5)		0.848
Mechanical valve	60.4 (48.4-70.1)			79.7 (62.5-86.5)		
Length of stay	-	-	-		−0.296, p = 0.001	

* Patients with forced expiratory volume in one second, % ≤80% of predicted value and/or a history of chronic obstructive pulmonary disease.
IQR = interquartile range, 25th to 75th quartile; NYHA = New York Heart Association Class.

Table 3
Correlations between KCCQ-12 and EQ-5D-5L, pre- and postoperative scores

	Preoperative scores				
EQ-5D-5L domains	KCCQ-12 domains				
	Physical limitation	Symptom frequency	Quality of life	Social limitation	KCCQ-total score
Mobility	−0.477*	−0.330†	−0.158*	−0.397†	
Self-care	−0.251†	−0.184*	−0.151	−0.265†	
Usual activities	−0.465†	−0.499†	−0.441†	−0.595†	
Pain/discomfort	−0.232†	−0.367†	−0.316†	−0.372†	
Anxiety/depression	−0.165*	−0.122	−0.242†	−0.266†	
EQ-5D-5L Index					0.517†
EQ-5D-5L VAS					0.659†
	Postoperative scores				
EQ-5D-5L domains	KCCQ-12 domains				
	Physical limitation	Symptom frequency	Quality of life	Social limitation	KCCQ-total score
Mobility	−0.452†	−0.331†	−0.184*	−0.234†	
Self-care	−0.304†	−0.307†	−0.245†	−0.394†	
Usual activities	−0.318†	−0.495†	−0.476†	−0.551†	
Pain/discomfort	−0.202*	−0.164*	−0.278†	−0.283†	
Anxiety/depression	−0.354†	−0.264†	−0.378†	−0.346†	
EQ-5D-5L Index					0.558†
EQ-5D-5L VAS					0.579†

* p value <0.05.
† p value <0.01.
Sample: EQ-5D-5L pre n = 149/post n = 157. KCCQ-12 pre n = 161/post n = 167.
EQ-5D-5L = EuroQol 5 Dimension 5 Level Questionnaire; KCCQ-12 = Kansis City Cardiomyopathy Questionnaire 12-version

Table 4
Principal component analyses, preoperative- and postoperative data

Preoperative				Postoperative			
Variable	Factor 1	Factor 2	Factor 3	Variable	Factor 1	Factor 2	Factor 3
4. How many times has shortness of breath limited your ability to do what you wanted	**0.73**		0.37	**8a.** How much does your heart valve disease affect: Hobbies, recreational activities	**0.79**		
8b. How much does your heart valve disease affect: Working or doing household chores	**0.73**			**8b.** How much does your heart valve disease affect: Working or doing household chores	**0.77**		
8a. How much does your heart valve disease affect: Hobbies, recreational activities	**0.73**			**7.** If you had to spend the rest of your life with your heart valve disease, how would you feel	**0.76**		
3. How many times has fatigue limited your ability to do what you wanted?	**0.72**			**4.** How many times has shortness of breath limited your ability to do what you wanted	**0.53**		
1c. Jogging or hurrying	**0.67**		0.43	**6.** How much has your heart valve disease limited your enjoyment of life	**0.51**	0.42	
7. If you had to spend the rest of your life with your heart valve disease, how would you feel	**0.65**			**1b.** Walking 1 block on level ground		**0.85**	
6. How much has your heart valve disease limited your enjoyment of life	**0.60**			**1a.** Showering/bathing		**0.83**	
8c. How much does your heart valve disease affect: Visiting family or friends out of your home	**0.54**	0.49		**1c.** Jogging or hurrying	0.40	**0.53**	
1a. Showering/bathing		**0.89**		**8c.** How much does your heart valve disease affect: Visiting family or friends out of your home	0.48	**0.52**	
1b. Walking 1 block on level ground	0.40	**0.66**		**3.** How many times has fatigue limited your ability to do what you wanted?	0.50	**0.50**	
5. How many times have you been forced to sleep sitting up in a chair or with at least 3 pillows			**0.66**	**5.** How many times have you been forced to sleep sitting up in a chair or with at least 3 pillows			**0.76**
2. How many times did you have swelling in your feet, ankles, or legs in the morning		0.42	**0.66**	**2.** How many times did you have swelling in your feet, ankles, or legs in the morning			**0.74**
Percentage of explained variance	39	11	10	**Percentage of explained variance**	37	12	11
Eigenvalue	4.68	1.37	1.16	**Eigenvalue**	4.49	1.42	1.28
Cronbach's alpha for each factor	0.84	0.70	0.22	**Cronbach's alpha for each factor**	0.76	0.76	0.39
Total Cronbachś alpha			0.83	**Total Cronbachś alpha**			0.83

Preoperative: Barlett's test of Sphericity: p value 0.000, KMO: 0.828, n = 137. Postoperative: Barlett's test of Sphericity: p value 0.000, KMO: 0.785, n = 124.

Discussion

The present study investigated the psychometric properties of KCCQ-12 in a sample of patients with severe aortic stenosis who underwent SAVR. We found that only a few of the selected hypotheses were supported, which could be explained because of a lack of evidence, as the hypothesis testing was based on similar instruments but not KCCQ-12. One hypothesis supported by our results was how the KCCQ-12 correlated (weakly) with NYHA class, a correlation previously supported in studies of patients with heart failure.[28] As NYHA class can be a challenging measure because of large differences in how clinicians score each patient, a weak correlation seems appropriate in the present study. Also, we found a correlation between living alone and worse health-related quality of life (HRQoL). This correlation is well-known,[29] despite the differences in scores not reaching a minimal clinically important difference. When KCCQ was examined against a different instrument, the EQ-5D-5L, most correlations were moderate, with slightly better coefficients of the preoperative scores. Based on our results, investigating HRQoL and symptoms of severe aortic stenosis with a heart-failure-specific instrument is, therefore, more relevant in the preoperative period, where symptoms seem more similar. Thus, the correlation

of the 2 instruments supports how the Danish version of KCCQ-12 appears to have acceptable construct validity.

The structural validity, the degree to which the subscale scores adequately reflect the dimensions of the constructs,[26] was not confirmed in either explorative or confirmatory factor analyses performed on scores of both time points. To our knowledge, this is the first study to investigate structural validity by conducting factor analyses of the KCCQ-12 among patients with aortic stenosis who underwent SAVR, although Arnold et al[3] investigated the reliability and construct validity in a previous study. This knowledge, performance of the structural validity, is essential when KCCQ-12 is used for a new population. The lack of structural validity, as demonstrated in our study, might be explained by the apparent differences in the intended population of KCCQ-12 (patients with heart failure) and the current population (patients with aortic stenosis who underwent SAVR) —because of differences in symptom burden and other factors related to the nature of the operation. As mentioned above, some symptoms are comparable in the preoperative phase, whereas the more heart-failure-specific symptoms might be less relevant to the SAVR population. For example, in a surgical population of patients with aortic stenosis, clinical manifestations like peripheral edema (KCCQ-12 item 2) and sitting up during sleep because of dyspnea (KCCQ-12 item 5) might be less relevant, whereas symptoms of chest pain and exertional dizziness may be more prevalent in aortic stenosis. Our principal component analyses also support this argument, representing these items in the last factor, factor 3. The lack of structural validity also supports the need for a disease-specific instrument for patients with aortic stenosis who underwent SAVR and possibly for aortic stenosis in general. The Toronto Aortic Stenosis Quality of Life questionnaire[30,31] is a 16-item questionnaire assessing aortic stenosis-specific quality of life across 5 domains. The Toronto Aortic Stenosis Quality of Life questionnaire was developed after the data collection of the present study but has undergone some preliminary exploratory validation in patients with aortic stenosis who underwent TAVI.[31] The psychometric test of its performance among patients who underwent SAVR has not been performed. Thus, in general, a disease-specific instrument to support the evaluation of SAVR versus TAVI and the complexity of lifelong management of living with severe valvular heart disease is needed. Preferably, this should be supported by items covering the early postoperative period, where the symptoms are related to the surgery and the sternotomy. Although the performance and use of patient-reported outcomes are widely incorporated into cardiovascular trials and clinical practice, there is a continuous need for more development in valvular heart disease. Consequently, as measuring symptom burden and HRQoL following SAVR are of great importance for patients,[2] the psychometric properties of the chosen instruments and, thus, the clinical implications of its use should have increased focus.

The internal consistency was investigated using Cronbach's α related to the explorative factor analyses. The total Cronbach's α at both time points indicated good internal consistency and reliability, whereas the specific coefficients related to factor 3 in both models were unacceptable. Again, this supports how the 2 items, 2 and 5, might not be appropriate among a surgical population of patients with aortic stenosis.

As mentioned above, the correlations between domains of KCCQ-12 and EQ-5D-5L are slightly better at the preoperative time point, indicating how KCCQ-12 might be more relevant when measuring symptoms of aortic valve disease. However, to the best of our knowledge, an appropriate measure of symptoms directly related to the surgery does not currently exist. Therefore, an instrument developed for a surgical population is essential, as this is a vulnerable population with a high symptom burden related to the surgery and, consequently, an increased risk of readmission.[9,32] And we encourage others to develop a disease-specific instrument that covers symptoms of the underlying disease *and* symptoms related to the surgery. For example, the surgical-related symptoms might include muscle pain in the chest, bodily awareness after surgery, worries about sternal healing, and signs to detect complications such as arrhythmias, effusions, and heart failure.[33–35] In addition, to add to the clinical implications of the study, the KCCQ-12 could potentially be used as an "add-on" to current risk prediction models used before surgery, eg, the EuroScore and the Society of Thoracic Surgeons score, both commonly used to assess and predict outcomes after SAVR in terms of survival and major complications.[36–38] With the addition of KCCQ-12 to the traditional scores, it is possible to capture the patient perspective and more traditional variables. Finally, based on the above, we argue how changes in symptoms related to the underlying aortic valve disease can be measured with the KCCQ-12, whereas we cannot recommend its use in measuring outcomes directly related to the surgery.

The results should be considered and interpreted in the context of the study design and its limitations. First, the analyses were conducted on the Danish version of the KCCQ-12 delivered by the original developer of the instrument, but how the Danish version was translated is unknown. Second, the sample included 184 responses, with missing data in up to 8%. To investigate construct validity, hypotheses were tested using different clinical and demographic variables, although the specific number of variables of interest varied. However, whether the sample size is large enough to confirm the hypotheses is debatable. However, based on the COSMIN checklist, a sample size of $\geq$100 is considered "very good."[17] Also, hypotheses testing was used to investigate correlations and not statistical significance. However, in general, the relative sample size should be included in the interpretation of the results, as it has restricted the statistical power of the study. Furthermore, this might explain why some findings conflict with previous studies. We acknowledge how several factors could affect the perioperative outcomes, including surgical technique and prosthetic valve type. These factors may not be reflected in the sensitivity of the questionnaire. By performing the psychometric analyses on a relatively homogeneous group of patients with AS, not including any special types of surgical techniques, we believe that the analyses are robust enough to capture overall sensitivity but should be interpreted in that context. The reason for nonresponse is unknown but random, which is why missing data is

assumed to be "missing at random." Third, the administration of KCCQ-12 was conducted in a written format (pen and paper), but whether other modes of administration (e.g., online administration) could influence the results is unknown. Finally, the psychometric tests chosen for the present study were based on traditional methods. Newer methods for exploring internal consistency, such as McDonald's ω as an alternative to Cronbach's α, could have been chosen instead.

The use of the Danish version of the KCCQ-12 in a population of patients with aortic stenosis who underwent SAVR appears to have acceptable construct validity, whereas structural validity cannot be confirmed for the original 4-factor model. Overall reliability is good. NYHA class correlated with the preoperative KCCQ-12 total score, and a longer length of hospital stay and living alone correlated with the postoperative KCCQ-12 total score, although weakly. Used before surgery, the KCCQ-12 seems to have the potential to detect symptoms of the underlying aortic valve disease. In contrast, postoperative measurements might not capture appropriate clinical characteristics and consequences related to the surgery itself.

As the KCCQ-12 was not developed for patients with aortic stenosis, future studies are encouraged to include a disease-specific instrument when measuring symptoms before and after surgery. Preferably, the instrument should be an add-on to a survey with the KCCQ-12, allowing for a future comparison.

Declaration of Competing Interest

The authors have no competing interests to declare.

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Authors' Contributions

Britt Borregaard, Jordi Dahl, and Jacob Eifer Møller conceived the overall idea for the INVOLVE study and Britt Borregaard for the current substudy. Britt Borregaard and Sofie Moesgaard Bruvik made the statistical analyses, and Britt Borregaard wrote the first draft of the manuscript. All revised the manuscript critically. All have given their final approval of the version to be published.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2023.09.068.

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