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Patient-reported outcomes after aortic and mitral valve surgery – results from the DenHeart Study

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Abstract

Background: Clinical course, co-morbidity and age often differs between patients undergoing aortic and mitral valve surgery and this might affect patient-reported outcomes.

Aims: The purpose of this study was to describe differences in patient-reported physical and mental health and health-related quality of life after aortic valve or mitral valve surgery, and to identify demographic and clinical characteristics associated with worse patient-reported physical and mental health, and health-related quality of life.

Methods: Patient-reported outcomes were measured at discharge as a part of a national, cross-sectional study (DenHeart). Patient-reported outcome measures included: Short-Form-12, Hospital Anxiety and Depression Scale, EuroQol-5D-5L, HeartQol and Edmonton Symptom Assessment System. Demographic and clinical information was obtained from national registers.

Results: Of 354 patients (65% men, mean age: 68 years), 79% underwent aortic valve surgery. Patients who had undergone aortic valve surgery had more symptoms of anxiety compared with patients who had undergone mitral valve surgery (34% vs 17%, p=0.003, Hospital Anxiety and Depression Scale anxiety cut-off score of eight). Being female was associated with worse patient-reported outcomes on all measures, whereas being unmarried was associated with worse physical health (Physical Component Score Short-Form-12) and symptom burden (Edmonton Symptom Assessment System). Length of stay was associated with worse symptoms on EuroQol-5D-5L Visual Analogue Scale. Age and comorbidity were not associated with patient-reported outcomes.

Conclusion: Patients who had undergone aortic valve and mitral valve surgery did not significantly differ in patient-reported health at discharge, except for symptoms of anxiety. Being female was the only characteristic associated with overall worse patient-reported outcomes at discharge.

Keywords

Patient-reported outcomes, quality of life, registries, heart valves

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Introduction

Worldwide, 42 million people suffer from heart valve diseases,[1] and the number is expected to increase in the future due to ageing populations.[2] Typically, patients suffer from diseases on the aortic valves (stenosis or regurgitation) or the mitral valves (stenosis or regurgitation).[3] Clinical symptoms of aortic stenosis include angina, syncope, dyspnoea, heart failure and sudden cardiac death. Mitral regurgitation often progresses slowly over time, with symptoms appearing only when the disease is very severe.[3]

After heart valve surgery, patients are at risk of complications, such as atrial fibrillation, pneumonia, pleural or pericardial effusion and heart failure.[4] These complications, as well as surgery itself, affect patients both physically and mentally.[4–6] Likewise, high postoperative anxiety and depression scores are associated with morbidity and risk of readmission.[4]

Several studies have shown that the physical and mental condition of the patient worsens immediately after heart valve surgery, compared with age-matched general populations.[4,7] Therefore knowledge regarding patients' experiences and outcomes after surgery is important when optimising the clinical pathway.[2] Knowledge from the patients can help reduce disease burden, improve overall wellbeing and prolong life, and is thus a way of optimising the pathway.[2,8] This knowledge can be captured with the use of patient-reported outcomes (PROs).[9] PROs are defined as a 'measurement of any aspect of a patient's health status that comes directly from the patient (i.e. without the interpretation of the patient's responses)' (p.2).[10] Previous studies have compared PROs in patients undergoing different procedures on different valves. Increased physical capacity has been reported after aortic repair compared with mechanical replacement, while similar outcomes have been reported after transcatheter aortic valve implantation (TAVI) compared with surgical aortic valve replacement.[11,12] Patients with aortic valve disease have a very different clinical course, age profile and co-morbidity compared with patients with mitral valve disease,[3] and they might also have different PROs. It is uncertain, however, whether these differences are related solely to the differences in age, sex and co-morbidity between groups, or whether the underlying pathophysiology of the valve disease also affects PROs.

The hypothesis in this study was that PROs after heart valve surgery differ between patients who undergo aortic valve and mitral valve surgery, respectively.

The objectives of this study were to: (a) describe differences in patient-reported physical and mental health, and health-related quality of life (QoL) after aortic valve or mitral valve surgery, and (b) identify demographic and clinical characteristics associated with worse patient-reported physical and mental health, and health-related QoL.

Methods

The DenHeart study is a national, cross-sectional study investigating PROs across cardiac diagnoses. The design of the study has been described previously in detail.[13] The current study reports solely on the subset of patients from the DenHeart study who underwent aortic or mitral valve surgery.

Participants

Data were collected at three Danish surgical heart centres from 15 April 2013–15 April 2014. Prior to discharge or transfer from one of these centres, eligible patients who had undergone aortic or mitral valve surgery were invited to complete a paper-based questionnaire with overall 62 items conducted from six validated instruments and some ancillary questions. The patients were asked to fill it in on the day of discharge, or, if not possible, at home within three days, and in the final analysis all questionnaires returned within four weeks after discharge were included. Patients who were transferred (to a cardiology ward) were asked to fill in the questionnaire at discharge as well. This time during the pathway of the patient was chosen in other to try to capture similar outcomes for all patients, at discharge. Patients under the age of 18 years and patients without a Danish civil registration number were excluded.[13]

The population was coded using surgical codes obtained from the Danish National Patient Registry. Patients who had undergone an aortic valve procedure were coded: KFCA60, KFCA70, KFMD00, KFMD10, KFMD96, KFMW96 and patients who had undergone a mitral valve procedure were coded: KFKB10, KFKC00, KFKC30, KFKC50, KFKC60, KFKC96, KFKD00, KFKD10 (see Supplementary Material, Appendix 1).

Patients undergoing surgery on the tricuspid and pulmonary valves were not included in this study, as only 3% of all heart valve surgical patients undergo these procedures in Denmark.[14]

Data

Patient characteristics. Demographic and clinical information was obtained from: The Danish Civil Registration System,[15] The Danish National Patient Register (DNPR),[16] The Danish Education Register[17] and The Danish Register on personal income. Data on lifestyle factors were obtained from the survey and therefore only available for responders. Information on co-morbidity for the previous 10 years and length of stay was obtained from the Danish National Patient Register (excluding the index admission). Comorbidity was calculated based on the TU index score, which is the number of cardiac-related co-morbidities based on primary and secondary diagnoses.[18]

Variables. PROs were obtained from the following instruments: Short-Form 12 (SF-12),[19] Hospital Anxiety and Depression Scale (HADS),[20] EuroQol (EQ-5D-5L),[21] HeartQoL[22] and Edmonton Symptom Assessment Scale (ESAS).[23] The questionnaire was tested for feasibility (understanding, layout and duration of completing the questionnaire) in a small sample (n=12) before inclusion in the study.[13]

PRO instruments

The SF-12 is a self-reported health assessment instrument. The results are expressed in terms of two summary scores: the Physical Component Summary (PCS) and the Mental Component Summary (MCS) with higher scores indicating better outcomes.[19]

To assess anxiety and depression, the HADS was used.[20] This instrument is composed of 14 items, seven for anxiety (HADS-A) and seven for depression (HADS-D). The HADS-scale is reported with the use of subscales from zero (minimum symptom level) to 21 (maximum symptom level). The scale is used with the cut-off score≥8, suggesting the presence of anxiety and depression (for screening purposes, not as a diagnostic tool).[20]

The EQ-5D-5L is a generic questionnaire consisting of a classification system (EQ-5D Profile) and a Visual Analogue Scale (EQ-VAS). The EQ-5D Profile covers five domains of health (mobility, self-care, usual activities, pain/discomfort and anxiety/depression).[24] The EQ-VAS is a graded, vertical thermometer type of measure anchored at zero (worst imaginable health state) and 100 (best imaginable health state).[21]

The HeartQoL is a 14-item, disease-specific questionnaire for cardiac patients that measures QoL. The instrument consists of a global score and two subscales. Higher scores on the physical and emotional scales indicates a better QoL status.[22]

Symptom distress was assessed with the ESAS, which is composed of 10-point VASs to assess different symptoms: pain, tiredness, nausea, depression, anxiety, drowsiness, appetite, well-being, shortness of breath and distress. Scores range from zero (best possible) to 10 (worst possible).[23]

Validity and values of Cronbach Alphas has previous been described for the chosen measurements.[13]

Ethics

The investigation conforms with the principles outlined in the Declaration of Helsinki.[25] The study was approved by the Danish Data Protection Agency no: 2007-58-0015/30-0937 and registered at ClinicalTrials.gov (NCT01926145). Each participant signed an informed consent form.

Statistical methods

In the descriptive analysis, categorical variables are reported as proportions, while continuous outcome variables are reported as means and standard deviations. Differences in demographic variables for responders and non-responders were tested by F-tests for means and Pearson χ^2-test for frequencies. Fisher's exact test was used when the expected values in the groups were less than five.

Differences in PROs for patients who underwent aortic or mitral valve surgery were tested by F-tests for means and Pearson χ^2-test for frequencies.

To identify demographic characteristics associated with worse PROs at discharge, multiple logistic regression analysis was applied. Poor health status identified by the SF-12 (both PCS and MCS), EQ-5D crosswalk/-VAS, HeartQol Global and/or ESAS were recorded as the worst quartile of the observed PRO scores. For the HADS-A and HADS-D scores, ≥8 were used to indicate poor health state. All regression models were adjusted for sex, age, marital status, length of hospital stay, comorbidity index-score (TU), BMI and education. Significance level, p, was set to 0.05.

Statistical analyses were conducted in SPSS (IBM Statistics 21).

Results

Across the DenHeart population, 1084 patients who had undergone aortic or mitral valve surgery were potentially eligible, Figure 1. Of the 354 (33%) who completed the questionnaire, the majority (79%) had undergone aortic valve surgery. Baseline characteristics and differences between the responders and non-responders are presented in Table 1.

The sociodemographic characteristics were similar for participants who had undergone aortic and mitral valve surgery, though participants who had undergone mitral valve surgery were significantly younger (68 (12) vs 64 (12) years, p=0.019). Moreover, there were significant differences between groups in educational level, several co-morbidities and body mass index (BMI) (Table 1).

Participants who had undergone aortic valve surgery reported significantly worse anxiety symptoms than participants who had undergone mitral valve surgery on HADS-A (mean scores 6.1±4.0 vs 5.1±3.7, p=0.049, and HADS-A≥8: 34% vs 17%, p=0.003). After adjusting for sex and age, similar results were found (Table 2).

On the SF-12 PCS, HADS-D scores, EQ-5D, HeartQol and ESAS, no significant differences were found between the two groups in either raw or adjusted analyses (Table 2). Also, on analysing the individual dimensions of the EQ-5D and symptoms of the ESAS (Table 3), no significant differences between the two groups were found, apart from the symptom nausea, where participants who had undergone mitral valve surgery reported worse symptoms.

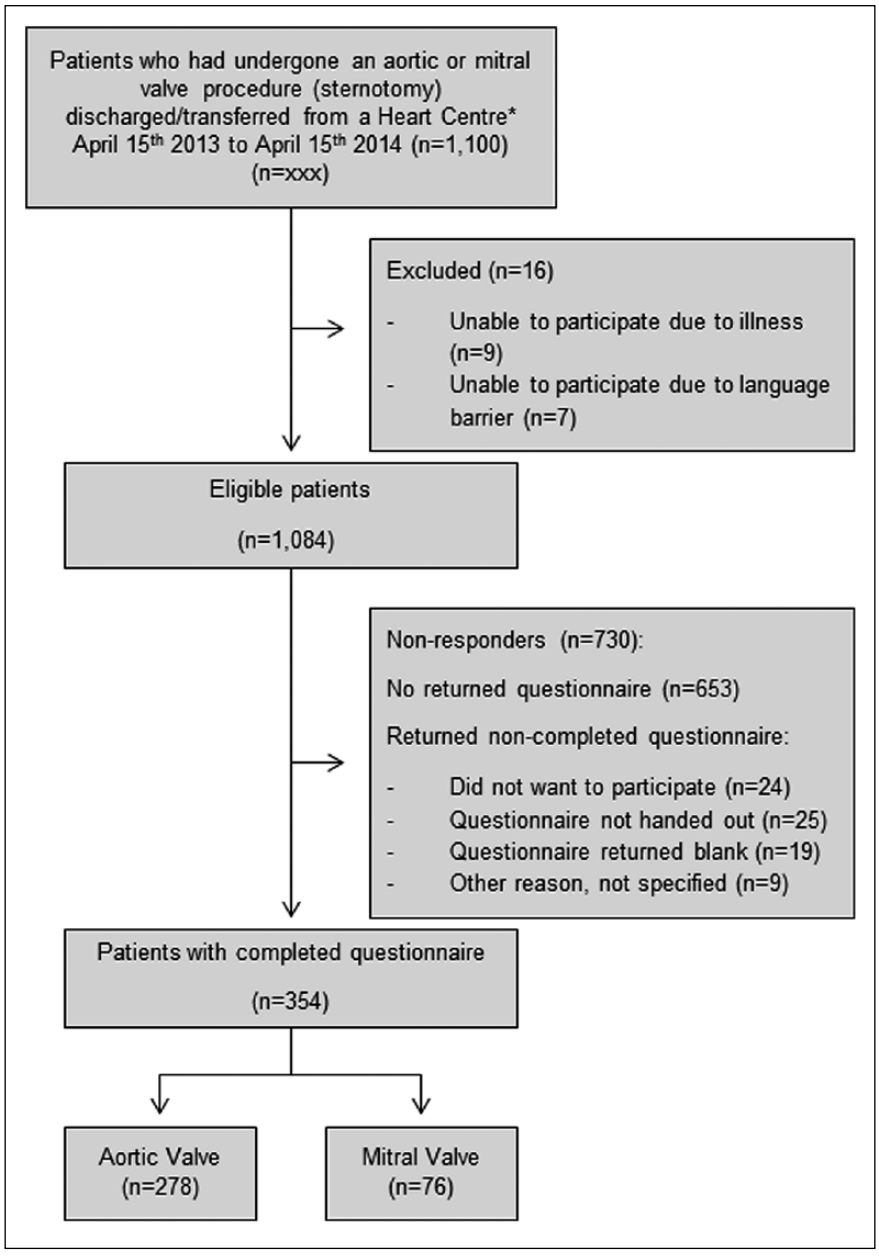

Figure 1. Flowchart of eligibility of patients.

A few demographic characteristics were associated with worse PROs at discharge (Figure 2). Analysis adjusted for valve-type, sex, age, marital status, length of hospital stay, comorbidity index-score (TU), BMI and education indicated that female sex was significantly associated with worse PROs on SF-12 PCS (odds ratio (OR) 2.7, 95% confidence interval (CI) 1.4–5.2, p=0.003), HADS (HADS-A OR 2.9, 95% CI 1.6–5.2, p=0.000, HADS-D OR 2.7, 95% CI 1.5–4.9, p=0.002), EQ-5D (Crosswalk OR 2.4, 95% CI 1.3–4.2, p=0.003, VAS OR 2.9, 95% CI 1.6–5.2, p=0.000), HeartQol Global (OR 2.7, 95% CI 1.5–4.9, p=0.001) and ESAS (OR 2.3, 95% CI 1.2–4.2, p=0.008).

Mitral valve surgery was significantly associated with better PROs on HADS-A (OR 0.4, 95% CI 0.2–0.8, p=0.008); being married was associated with better outcomes on SF-12 PCS (OR 2.0, 95% CI 1.0–3.9, p=0.048); longer length of stay with better outcomes on EQ-5D VAS (OR 1.1, 95% CI 1.0–1.2, p=0.040) and BMI with better outcomes on SF-12 PCS (OR 1.1, 95% CI 1.0–1.1, p=0.043).

Discussion

In this cross-sectional study differences in patient-reported physical and mental health and health-related quality of life at discharge after aortic and mitral valve surgery were

Table 1. Demographic and clinical characteristics.

	Aortic valve surgery			Mitral valve surgery			$p^{a,b}$
	Responders	Non-responders	p^a	Responders	Non-responders	p^a	
Characteristics							
n (%)	278 (32)	544 (68)	–	76 (32)	149 (68)	–	0.486
Sex (male, *n* (%))	195 (70)	376 (69)	0.413	53 (70)	84 (56)	0.035	0.006
Age (mean (SD))	69 (10)	70 (11)	0.390	66 (11)	62 (13)	0.045	<0.001
Married (*n* (%))	177 (64)	331 (61)	0.238	49 (65)	98 (66)	0.480	0.179
Length of stay (mean (SD))	8.8 (3.4)	9.5 (5.3)	0.087	9.1 (3.7)	11.7 (9.8)	0.033	<0.001
Educational level, *n* (%), income mean (SD)							
Basic school	102 (37)	197 (38)	0.625	22 (30)	39 (28)	0.896	0.036
Upper secondary or vocational school	114 (42)	199 (38)		32 (44)	59 (43)		
Higher education	59 (22)	124 (24)		19 (26)	40 (29)		
Income in DKK, before tax (100,000), mean (SD)	275 (384)	240 (170)	0.075	276 (146)	335 (568)	0.391	0.009
Comorbidity, previous 10 years, *n* (%)							
Prior PCI	18 (7)	52 (10)	0.084	5 (7)	7 (5)	0.379	0.072
Prior CABG	1 (1)	19 (4)	0.003	0 (0)	2 (1)	0.438	0.117
Hypertension	104 (38)	245 (45)	0.037	19 (25)	36 (24)	0.507	<0.001
Arrhythmia	52 (19)	149 (27)	0.006	24 (32)	59 (40)	0.151	<0.001
Myocardial infarction	20 (7)	54 (10)	0.121	2 (3)	4 (3)	0.673	<0.001
Renal disease	3 (1)	23 (4)	0.009	2 (3)	6 (4)	0.455	0.523
Heart failure	25 (9)	88 (16)	0.005	7 (9)	34 (23)	0.008[a]	0.065
Diabetes with complications	19 (7)	60 (11)	0.033	3 (4)	11 (7)	0.242	0.107
Diabetes without complications	36 (13)	74 (14)	0.443	1 (1)	6 (4)	0.251	<0.001
Chronic obstructive pulmonary disease	14 (5)	47 (9)	0.039	8 (11)	13 (9)	0.414	0.225
TU co-morbidity score, *n* (%)							
0	156 (56)	224 (41)	<0.001	42 (55)	55 (36)	0.109	0.147
1	84 (30)	181 (33)		19 (25)	59 (40)		
2	21 (8)	96 (18)		10 (13)	16 (11)		
3+	17 (6)	43 (8)		5 (7)	19 (13)		
BMI≥25[c]	174 (68)			27 (38)			0.000
BMI≥30[c]	60 (23)			9 (13)			0.030
Ever smoked	164 (62)			38 (51)			0.050
Smokes daily	12 (5)			2 (3)			0.367
Alcohol intake above high risk limit[d]	21 (9)			1 (1)			0.023

BMI: body mass index; CABG: coronary artery bypass grafting; PCI: percutaneous coronary intervention; SD: standard deviation.
[a]Significance level *p* set at $p<0.05$.
[b]Differences between responders in the two groups, aorta/mitral.
[c]Information about BMI, smoking and alcohol intake is part of the DenHeart questionnaire and therefore only presented for the responders.
[d]The Danish National Board of Health defines the high risk limit for alcohol consumption as a weekly intake of 21 units for men and 14 units for women.

examined. We found that patients who had undergone aortic valve surgery report significantly worse symptoms of anxiety (HADS-A) compared with patients who had undergone mitral valve surgery. No significant differences were found on physical symptoms or health-related QoL. We also found, that female sex is associated with worse PROs on all measures.

The hypothesis tested was that PROs after heart valve surgery differ between patients who had undergone aortic valve and mitral valve surgery. Surprisingly, apart from differences on anxiety scores, we did not find other differences. Overall, the anxiety and depression scores in the present study were worse than those reported by others.[4,11] In a recent study, Sibilitz et al. report that physical and

Table 2. Patient-reported outcomes at hospital discharge.

	Aortic valve *n*=278	Mitral valve *n*=76	*p*[a]	Adjusted *p*[a]
SF-12, mean (SD)				
PCS	38.2 (9.6)	39.0 (9.5)	0.529	0.672
MCS	46.3 (12.0)	49.7 (10.4)	0.064	0.068
HADS				
HADS-A, mean (SD)	6.1 (4.0)	5.1 (3.7)	0.049	0.032
HADS-A≥8, *n* (%)	88 (34)	12 (17)	0.003	0.005
HADS-D, mean (SD)	5.3 (3.7)	4.5 (3.7)	0.118	0.133
HADS-D≥8, *n* (%)	71 (27)	12 (17)	0.051	0.085
EQ-5D, mean (SD)				
EQ-5D 5L crosswalk	0.7 (0.1)	0.7 (0.2)	0.881	0.883
EQ-5D VAS	66.4 (18.7)	66.9 (22.7)	0.840	0.941
HeartQol, mean (SD)				
HeartQol global	1.5 (0.7)	1.5 (0.8)	0.686	0.843
HeartQol physical	1.3 (0.8)	1.3 (0.9)	0.621	0.839
HeartQol emotional	2.0 (0.8)	2.0 (0.9)	0.918	0.995
ESAS, mean (SD)				
ESAS, overall score	25.3 (15.5)	24.6 (16.9)	0.745	0.773

EQ-5D: EuroQol; ESAS: Edmonton Symptom Assessment Scale; HADS: Hospital Anxiety and Depression Scale; HADS-A: HADS for Anxiety; HADS-D: HADS for Depression; MCS: Mental Component Summary; PCS: Physical Component Summary; SF-12: Short-Form 12; VAS: Visual Analogue Scale. Differences in means between the groups were tested using the *F*-test (unadjusted and adjusted p-values from linear regression models adjusted for sex and age). Differences in proportions between all diagnostic groups were tested by the Pearson χ^2-test (un-adjusted and adjusted *p*-values from logistic regression models adjusted for sex and age).
[a]Significance level, $p<0.05$.

Table 3. Sub-scale differences in patient-reported outcomes at hospital discharge.

	Aortic valve *n*=278	Mitral valve *n*=76	*p*[a]
EQ-5D 5L, mean (SD)			
Mobility	1.97 (0.94)	2.00 (0.97)	0.809
Self-care	1.51 (0.82)	1.50 (0.66)	0.897
Usual activities	2.83 (1.30)	2.84 (1.23)	0.943
Pain/discomfort	2.03 (0.79)	2.24 (0.93)	0.055
Anxiety/depression	1.57 (0.78)	1.48 (0.72)	0.376
ESAS, mean (SD)			
Pain	2.62 (2.19)	2.85 (2.32)	0.433
Tiredness	4.80 (2.73)	4.55 (2.78)	0.489
Nausea	1.31 (2.26)	2.05 (2.89)	0.020
Drowsiness	3.26 (2.50)	2.95 (2.51)	0.337
Appetite	3.32 (2.75)	3.11 (2.94)	0.557
Shortness of breath	3.78 (2.80)	3.60 (2.90)	0.633
Depression	2.09 (2.40)	1.79 (2.12)	0.335
Anxiety	1.85 (2.41)	1.42 (1.94)	0.168
Distress	1.76 (2.36)	1.82 (2.28)	0.833
Well-being	2.15 (2.18)	2.33 (2.29)	0.523

EQ-5D: EuroQol; ESAS: Edmonton Symptom Assessment Scale; SD: standard deviation.
Differences in means between the groups were tested using the *F*-test.
[a]Significance level, $p<0.05$.

mental health and health-related QoL after heart valve surgery are worse compared with a sex and age-matched reference population. Time lapse from surgery to PRO response varied from 6–12 months, and worse PRO scores were found close to surgery.[4]

Anxiety and depressive symptoms after heart valve surgery have also been reported in a qualitative study, showing that patients with anxiety have more difficulties managing their life after surgery.[6] To optimise the beneficial effects of a heart valve procedure, an ability to resume daily activities and independence are important goals,[6] which is why an effort should be made to minimise anxiety and depression symptoms in the future.

The difference in anxiety symptoms was statistically significant, but less than what is considered a minimal clinical important difference. These differences represent the smallest level of benefits that the patient can both recognise and value.[26] The minimally clinical important difference for HADS is reported to be 1.5 points or 20%, meaning that a minimal important difference has to been larger than this to be present.[26] In this study the difference is less than this, indicating that the difference between the two groups is not clinically important, but anxiety remains a problem for both group.

In general, previous studies have compared PROs between conventional aortic valve procedures and modified treatment methods (TAVI or mini-sternotomy), instead of comparing with patient undergoing mitral valve surgery.[11,12] This makes the present study unique, but also difficult to compare with other studies. Although the evidence indicates that the disease profiles are very different

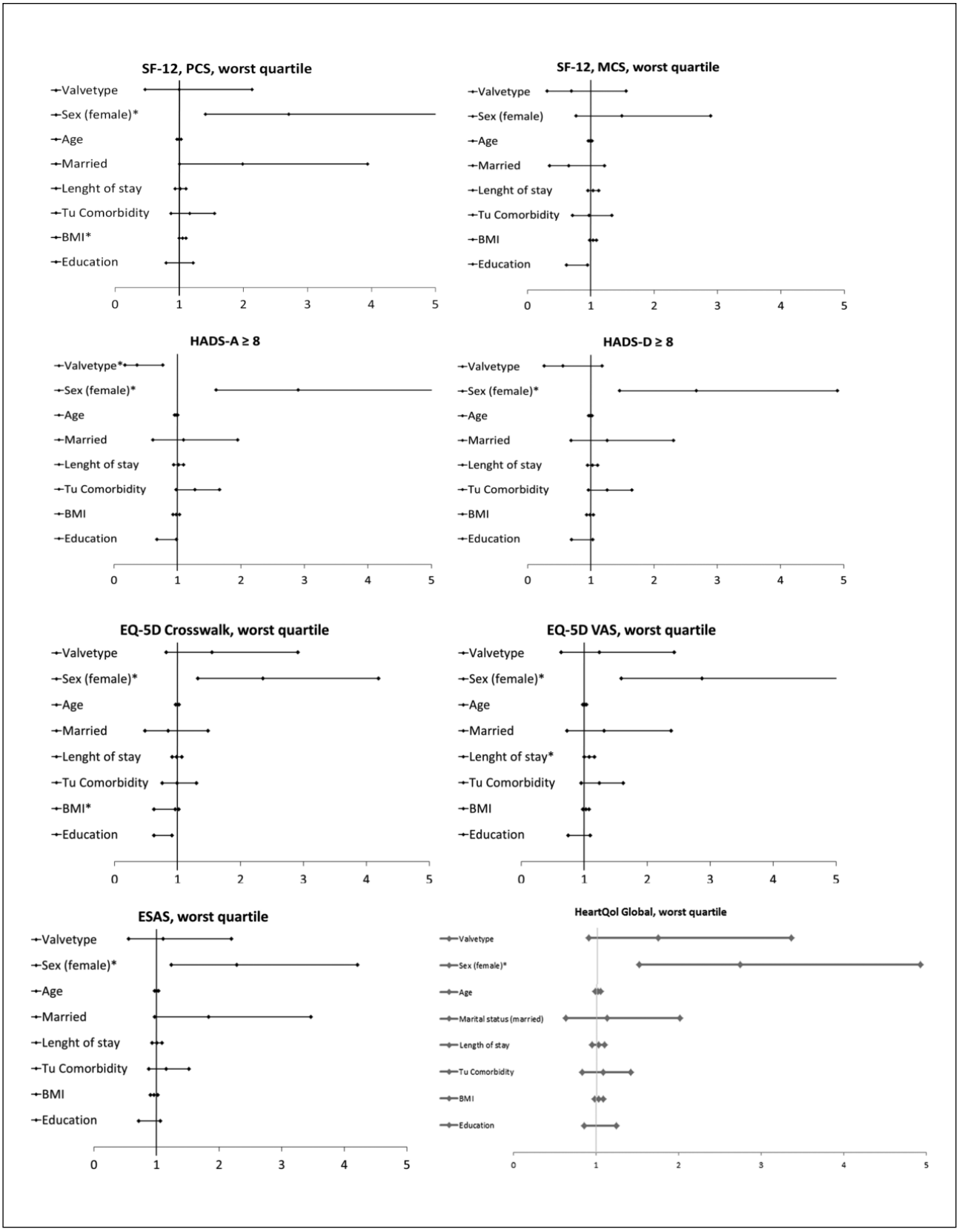

Figure 2. Associations with worse patient-reported outcomes at discharge.
BMI: body mass index; HADS-A: Hospital Anxiety and Depression Scale for Anxiety; HADS-D: Hospital Anxiety and Depression Scale for Depression; MCS: Mental Component Summary; PCS: Physical Component Summary; SF-12: Short-Form 12.

for patients undergoing aortic valve and mitral valve surgery,[2,3] the present analysis showed significant differences only on anxiety scores between the two groups. Despite the fact that patients who had undergone mitral valve surgery are younger, have higher educational levels and different co-morbidity, these are not associated with different PROs at discharge.

The findings concur with previously findings that females report worse PROs after heart valve surgery.[27] A recent study by Mokhles et al. describes that women tend to have more advanced valve disease at time of surgery, which could be a possible explanation.[28] As seen above, it has previously been reported that women have worse physical outcomes and more complications after heart valve surgery, but more evidence and awareness on the topic is needed.

Living alone has been shown to be an independent predictor of psychological and mental symptoms, such as anxiety and depression in a number of studies.[29] This is comparable with the general findings in our study, where being unmarried was associated with worse mental health and symptom burden – although it is seen in our study that being married is significantly associated with worse outcomes on SF-12 and PCS. This is discussed further in the study limitations.

As expected, in general, both length of stay and TU co-morbidity score were found to be associated with worse PROs on some of the instruments, indicating that PROs reflect the severity of the disease of the patients. Although length of stay is significantly associated with worse outcomes on EQ-5D, the overall tendency, with no association with worse PROs, is in line with a review by Prina et al., where it was found that depression was associated with a longer hospitalisation and risk of readmission.[30]

Strengths and limitations

The response-rate in the study is low (33%), and although this is not uncommon in surveys, it could cause concern for selection bias and generalisability, meaning that with low response rates there is a risk, that only a selected group answers (e.g. 'better' patients) and that the results therefore cannot be generalised to the whole population.[8] By nature, self-reported information is subjective and may be biased. In general, non-responders had more co-morbidity and would presumably have represented worse outcomes. This could indicate that the poor PROs in our study are underestimated.

Missing data was between 3–9% for most outcomes, but up to 26% for the SF-12 PCS and MCS. This might be a possible explanation for the different results on SF-12 on length of stay, where it is seen that the result is significantly different than for the other PRO measures.

A complete dataset based on register data for both responders and non-responders was available, and knowing more about the illness burden of the patients, such as functional level by New York Heart Association (NYHA) class or EuroScore would have been a strength in this study. However, knowledge on the non-responders from the registers shows, that there are only a few differences between responders and non-responders, indicating that the responders are representative of the total population. As part of the analyses, all data were examined and the number of surgical patients were comparable to clinical databases.

A strength of the study is the prospective design, and that a wide range of validated instruments for PRO assessment were used, showing different views of the perspective of the patients. Nevertheless, the wide range of different instruments in the total questionnaire might have caused the low response-rate, due to overburden for the patients.

Not all of the chosen PRO measures have been validated among heart valve surgical patients, and further studies should validate the used PRO measures for the population.

To our knowledge, the study is the first to compare PROs at discharge after aortic and mitral valve surgery.

As a conclusion in this study, patients who underwent aortic valve and mitral valve surgery did not significantly differ in patient-reported physical health at discharge, except for symptoms of possible anxiety; however, the difference was not found to reach clinical importance. Being female was the only characteristic associated with overall poorer PROs at discharge.

Implications for practice

- Increased awareness of the high rate of anxiety symptoms after heart valve surgery.
- Knowledge on patient-reported outcomes (PROs) at discharge can be used to form the clinical pathway and plans for follow-up after hospital admission.
- As females report poorer PROs, this knowledge should be incorporated into clinical care when follow-ups are planned, but also the severity and extent of comorbidities are important to consider.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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