## Self-Efficacy as a Predictor of Patient-Reported Outcomes in Adults with Congenital Heart Disease

Corina Thomet<sup>1,2</sup>, Philip Moons<sup>2,3</sup>, Markus Schwerzmann<sup>1</sup>, Silke Apers<sup>2</sup>, Koen Luyckx<sup>4</sup>, Erwin N. Oechslin<sup>5</sup>, Adrienne H. Kovacs<sup>5,6</sup>

- <sup>1</sup> Center for Congenital Heart Disease, Department of Cardiology, Inselspital, Bern University Hospital, University of Bern, Bern, Switzerland. E-mail: <u>corina.thomet@insel.ch</u>, markus.schwerzmann@insel.ch
- <sup>2</sup> Department of Public Health and Primary Care, KU Leuven University of Leuven, Leuven, Belgium. E-mail: <u>Philip.moons@kuleuven.be</u>, silke.apers@kuleuven.be
- <sup>3</sup> Institute of Health and Care Science, University of Gothenburg, Gothenburg, Sweden
- <sup>4</sup> School Psychology and Child and Adolescent Development, KU Leuven University of Leuven, Leuven, Belgium. E-mail: koen.luyckx@kuleuven.be
- <sup>5</sup> Toronto Congenital Cardiac Centre for Adults, Peter Munk Cardiac Centre, University Health Network and University of Toronto, Toronto, Canada. E-mail: erwin.oechslin@uhn.ca
- <sup>6</sup> The Knight Cardiovascular Institute, Oregon Health & Science University, Portland, Oregon, United States. E-mail: kovacs@ohsu.edu

All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and the discussed interpretation.

Corresponding author:

Corina Thomet, MScN Center for Congenital Heart Disease Inselspital, Bern University Hospital University of Bern 3010 Bern, Switzerland Tel. +41 31 632 36 57 Fax: +41 31 632 80 50 E-Mail: corina.thomet@insel.ch

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#### Abstract

Objective: Self-efficacy is a known predictor of patient-reported outcomes (PROs) in individuals with acquired diseases. With an overall objective of better understanding PROs in adults with congenital heart disease (CHD), this study aimed to: (i) assess self-efficacy in adults with CHD, (ii) explore potential demographic and medical correlates of self-efficacy, and (iii) determine whether self-efficacy explains additional variance in PROs above and beyond known predictors.

Methods: As part of a large cross-sectional international multi-site study (APPROACH-IS), we enrolled 454 adults (median age 32 years, range: 18-81) with CHD in two tertiary care centers in Canada and Switzerland. Self-efficacy was measured using the General Self-Efficacy (GSE) scale, which produces a total score ranging from 10 to 40. Variance in the following PROs was assessed: perceived health status, psychological functioning, health behaviors, and quality of life (QOL). Hierarchical multivariable linear regression analysis was performed.

Results: Patients' mean GSE score was  $30.1 \pm 3.3$  (range: 10 - 40). Lower GSE was associated with female sex (p = 0.025), not having a job (p = 0.001), and poorer functional class (p = 0.048). GSE positively predicted health status and QOL, and negatively predicted symptoms of anxiety and depression, with an additional explained variance up to 13.6%. No associations between self-efficacy and health behaviors were found.

Conclusions: GSE adds considerably to our understanding of PROs in adults with CHD. Given that self-efficacy is a modifiable psychosocial factor, it may be an important focus for interventions targeting CHD patients' well-being.

#### Keywords: Self Efficacy; Patient-Reported Outcomes; Heart Defects, Congenital; Multicenter Study

## Introduction

In developed countries, adults with congenital heart disease (CHD) now outnumber children with CHD.<sup>1</sup> Despite significant medical and surgical improvements, CHD remains a life-long medical condition and long-term complications are common.<sup>2</sup> Living with CHD often entails physical and psychosocial adaptations to the underlying defect and its treatment and also has lifestyle implications with respect to physical activity, employment, and family planning. Thus, optimizing patients' overall well-being and quality of life (QOL) has emerged as an important goal when caring for adults with CHD.<sup>3</sup> To achieve this aim, patient-reported outcomes (PROs) are increasingly valued in addition to traditional medical parameters.<sup>4</sup> PROs are directly reported by patients, "without interpretation of the patient's response by a clinician or anyone else".<sup>5</sup> PROs thus offer unique insight into how patients sense and judge their health and well-being.

A large international study investigating PROs in CHD was performed: Assessment of Patterns of Patient-Reported Outcomes in Adults with Congenital Heart disease - International Study (APPROACH-IS).<sup>6</sup> APPROACH-IS demonstrated that PROs were independently and consistently predicted by functional status, age, and unemployment status.<sup>7</sup> The impact of self-efficacy as a potential explanatory factor above and beyond other known predictors is unknown. Self-efficacy refers to beliefs about one's ability to perform desired tasks; individuals with higher self-efficacy "approach difficult tasks as challenges to be mastered rather than as threats to be avoided". <sup>8</sup>

Self-efficacy has previously been linked with PROs. In patients with non-cardiac conditions (e.g., breast and gastro-intestinal cancer), low self-efficacy has been associated with increased symptom severity, more pain and decreased physical and emotional functioning.<sup>9</sup> Following myocardial infarction, patients who rated the perceived consequence of the disease higher also reported low general self-efficacy.<sup>10</sup> Among adolescents and adults with other chronic illnesses, such as diabetes or chronic heart failure, higher self-efficacy has been associated with better

QOL.<sup>11, 12</sup> A recent published study also found higher transition readiness in adolescent CHD patients with greater self-efficacy.<sup>13</sup> Self-efficacy has not yet been evaluated in adults with CHD, and it is unclear to what extent self-efficacy predicts PRO above and beyond known demographic and clinical correlates.

Therefore, the aims of the current study were to 1) assess self-efficacy in adults with CHD, 2) explore potential demographic and medical correlates of self-efficacy, and 3) investigate whether self-efficacy explains additional variance in PROs above and beyond known predictors.

#### Methods

The present study is a sub-study conducted within APPROACH-IS, which was a cross-sectional multicenter study of PROs in more than 4000 adults with CHD from 24 centers in 15 countries (ClinicalTrials.gov: NCT02150603).<sup>6, 14</sup> For the current sub-study, two participating centers (Toronto, Canada and Bern, Switzerland) included an additional assessment of self-efficacy within their set of questionnaires. Approval for APPROACH-IS, including this sub-study, was obtained by the corresponding local ethic committees, according to the principles outlined in the Declaration of Helsinki.

#### Study population and procedure

Inclusion criteria were consistent with the APPROACH-IS protocol: (i) CHD diagnosed before the age of 10 years, (ii) at least 18 years old at the time of study participation, (iii) physical, cognitive and language skills to complete the study questionnaires, and iv) cardiology followup at one of the two participating centers.<sup>6</sup> Exclusion criteria were: (i) prior heart transplantation and (ii) primary pulmonary hypertension. Data collection took place between January and December 2014. At the Toronto center, patients were recruited during clinic visits; survey completion (in English) occurred in the clinic setting or at home (in which case patients were given stamped, pre-addressed envelopes). At the Bern center, patients were mailed a questionnaire package with a consent form (available in either German or French) and a stamped self-addressed envelope prior to their scheduled follow-up appointment. Where no translation was already available, forward-backward procedures based on the MAPI method <sup>15</sup> to ensure that cross-cultural, conceptual and linguistic equivalence was ensured.

#### Measures

#### **Demographic and medical characteristics**

Study participants completed a demographic survey that included age, sex, marital and parenting status, education and employment status, and religiosity. Patients' functional status was assessed with the NYHA functional class I-IV self-report questionnaire, in which class I indicates no limitations and class IV indicates severe limitations with symptoms even while at rest.<sup>6</sup> Medical records were consulted to document defect complexity (categorized as mild, moderate or great),<sup>16</sup> history of cardiac surgery, history of congestive heart failure, arrhythmias, implantation of a pacemaker or implantable cardioverter defibrillator, and documented mood or anxiety disorders.

#### **General self-efficacy**

Self-efficacy was measured with the 10-item General Self-Efficacy (GSE) scale.<sup>17, 18</sup> An example of an item is "I am confident that I could deal efficiently with unexpected events." Responses are provided on a four-point scale ranging from 1 ("not at all true") to 4 ("exactly true") and summed to a total score ranging from 10 to 40. A higher total score reflects a higher level of self-efficacy. This scale has been used in various settings with internal consistency coefficients ranging from 0.75 to 0.91.<sup>19</sup> In the present study, the corresponding internal consistency coefficient was 0.90, indicating strong reliability.

#### **Patient Reported Outcomes (PROs)**

Self-report questionnaires were used to assess four PRO domains: perceived health status, health behaviors, psychological functioning and QOL.<sup>6</sup> Perceived health status was assessed with the EuroQOL-5D Visual Analog Scale <sup>20</sup> and the 12-item Short Form Health Survey. <sup>21</sup> Scores on the latter instrument produce a physical component summary (PCS) as well as a mental component summary (MCS). Health enhancing and health compromising behaviors were measured with the Health-Behavior Scale-Congenital Heart Disease. <sup>22</sup> Psychological functioning was assessed using the Hospital Anxiety and Depression Scale <sup>23</sup>, which produces an anxiety score (HADS-A) and depression score (HADS-D). Quality of life was appraised using the Linear Analog Scale (LAS-QOL) <sup>24</sup> and the Satisfaction with Life Scale (SWLS). <sup>25</sup> Online Table 1 provides an expanded definition of the domains as applied in APPROACH-IS as well as the interpretation of scores, validity and reliability of the above mentioned measurements.

#### **Statistical analysis**

For categorical variables, absolute numbers and percentages are presented. Continuous variables are presented as means and standard deviations if normally distributed, or medians with range, if not normally distributed. To investigate whether GSE differed according to demographic and medical characteristics, unpaired t-tests or ANOVA and Mann-Whitney U-test or Kruskal Wallis tests were computed as appropriate. To assess how PROs are affected by patients' self-efficacy, we conducted hierarchical, multivariable linear regression analyses. We ran separate analyses using the following dependent variables: perceived health status (Physical Component Summary (PCS), Mental Component Summary (MCS) and the EuroQol 5 Dimensions-Visual Analog Scale (EQ-VAS)), health behavior (CHD Health-Behavior scale), psychological functioning (Hospital Anxiety and Depression scale (HADS-A, HADS-D)) and QOL (LAS-QOL and SWLS). Using a hierarchical approach, in the first step we included demographic and clinical variables, namely, functional NYHA class, age and employment

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status, because these variables have been identified previously as correlates of PROs within the APPROACH-IS dataset<sup>7</sup>. Further we included sex, marital status, educational level, center (Bern vs Toronto) and disease complexity. In the second step we included general self-efficacy, which allowed us to investigate a change in explained variance. In all analyses, the null hypothesis was rejected for p-values <0.05 and two-sided tests were used. Statistical analysis was performed using IBM SPSS Statistics 21 (Armonk, NY: IBM Corp.).

#### **Results**

#### **Patient characteristics**

Of the 809 eligible patients approached by mail or in person, 454 (56%) agreed to participate and completed questionnaires. The majority of participants (80%) had CHD of moderate or great complexity. Most patients (58%) reported being in NYHA class I. A total of 365 (80%) patients had undergone cardiac repair in the past, half of them were operated in 2001 or later. Additional demographic and medical characteristics are summarized in table 1.

[Insert Table 1]

#### **General self-efficacy scores and its correlates**

The mean GSE score was  $30.1 \pm 3.3$  (range: 10 - 40). Univariate analysis showed that GSE scores were significantly lower among women (p=0.025), in patients who were unemployed, job seeking or on disability (p=0.001), or in NYHA Class III or IV (p=0.048) (Table 2). GSE scores did not differ as a function of age, marital status, children, educational background, or religiosity. There was also no association between GSE scores and the following medical characteristics: CHD complexity, history of congestive heart failure, history of arrhythmias, having a cardiac device or documented mood or anxiety disorders. When performing multivariable linear regression analysis, only gender and NYHA Class turned out to be significant correlates of GSE.

[Insert Table 2]

#### The relationship between self-efficacy and PRO

Multivariable linear regression analysis was conducted to assess whether general self-efficacy adds a significant portion of the explained variance of PROs. Results indicated that after adjusting for demographic and clinical factors, higher GSE significantly predicted better health status (PCS, MCS and EQ-VAS), less anxiety and depression (HADS-A and HADS-D), and better QOL (LAS QOL and SWLS). However, self-efficacy was not related to CHD-specific health behaviors. In Table 3, we separately present the R<sup>2</sup> variance explained by the overall model (i.e., including variables from both steps) as well as the change in R<sup>2</sup> variance after the second step in which GSE was entered. As shown in this table, the additional variance associated with the inclusion of GSE in the model was over 10% for MCS, HADS-D, and SWLS.

[Insert Table 3]

## Discussion

Although self-efficacy had been associated with QOL and other PROs in patients with other chronic conditions, its relevance for adults with CHD was previously unknown. Therefore, this study was undertaken to understand demographic and medical correlates of self-efficacy and investigate whether self-efficacy explains variance in PROs above and beyond known demographic and clinical predictors.

#### General self-efficacy in adults with CHD

The mean GSE score of adults with CHD in this study was 30.1, which is similar to the mean score of 29.5 that has been observed in the international general population.<sup>26</sup> Schwarzer & Jerusalem, the authors of the GSE scale, do not recommend categorizing in high and low self-efficacy. This suggests that, as a group, their self-efficacy is comparable to the general population. Perhaps this should not be surprising, given that most have mastered multiple health-related challenges throughout their lives.

Correlates of self-efficacy observed in the present study were consistent with findings of previous studies in diverse chronic patient populations.<sup>27-29</sup> In our patient cohort, lower self-efficacy was observed in patients who were female and not employed. We additionally found that lower self-efficacy was observed in patients with poorer functional status, but did not differ as a function of disease complexity. Although causality cannot be determined from a cross-sectional study, providers should remain aware that self-efficacy is likely more affected by the symptoms and experiences of patients rather than the original CHD diagnosis.

#### Self-efficacy as predictor of PROs

We observed that self-efficacy contributed significantly to the explained variance of PROs beyond that attributable to demographic and clinical factors. Most notably, after including GSE scores, the explained variance increased when predicting depressive symptoms (13.6%), mental health status (10.7%), satisfaction with life (10.9%), QOL (9.2%), and anxiety symptoms (5.9%). Thus, self-efficacy is a factor that warrants significant attention as clinicians and researchers strive to better understand and enhance the lives of adults with CHD. It is interesting that self-efficacy added very little (0.9%) to the model predicting physical health status. However, this might be due to the fact that the explained variance in the overall model predicting physical health status was the highest of all PROs (almost 55%) after the first step, before self-efficacy was entered into the model.

Surprisingly, we did not observe a relationship between self-efficacy and health behaviors. This was unexpected because numerous studies previously demonstrated that self-efficacy is associated with better health behaviors such as adhering with dietary or physical activity recommendations.<sup>30-32</sup> Among children and adolescents with CHD, the belief in one's self-efficacy was shown to correlate with increased physical activity, independent of disease complexity.<sup>33, 34</sup> This discrepancy with our results may be related to the fact that we used a general self-efficacy measure, instead of an exercise-related questionnaire as was administered in pediatric studies. As the GSE questionnaire was developed to measure a confidence in

managing general adverse situations, it may thus be less applicable to adherence with specific health behaviors.

Our results regarding the links between self-efficacy with mental health status, anxiety and depression are consistent with observations in healthy samples as well as patients with chronic disease. <sup>35, 36, 37</sup> A meta-analysis of 181 studies among cancer patients demonstrated large effect sizes for (i) the positive relationship between QOL and self-efficacy for coping with cancer, and (ii) the inverse relationship between distress and self-efficacy for coping with cancer. <sup>38</sup> It should be acknowledged, however, that the directionality of the relationships between self-efficacy and PROs remains unknown from our study. It is plausible that higher self-efficacy throughout the life of an adult with CHD leads to a sense of general accomplishment and thus overall well-being. <sup>8</sup> It is equally plausible that better psychological health leads one to be more optimistic that their attempts to master tasks (both related and unrelated to health) will be successful.

In summary, the recognition of the significant relationship between general self-efficacy and PROs holds important implications for interventions targeting mental health of adults with CHD. For example, a multidisciplinary self-management course based on Bandura's self-efficacy concept has shown to be effective in increasing self-efficacy for individuals with chronic conditions,<sup>39</sup> including arthritis, diabetes and heart diseases. The program included strategies on decision making, problem solving skills and social persuasion through group sessions. Participants not only showed better self-efficacy and health status (pain, depression, fatigue) after one year, but also better communication with health care providers and fewer visits to the emergency department. This example is consistent with other studies on self-management programs based on Bandura's self-efficacy concept.<sup>40</sup>

General clinical recommendations for nurses and other healthcare professionals involved in the care of adults with CHD can therefore be adapted from existing self-management guidelines: establishing a reliable and collaborative relationship, engaging in goal-setting to help patients achieve their goals (both related and unrelated to health), and asking patients about their confidence in making changes.<sup>41</sup> During regular clinical encounters in the inpatient or outpatient setting, nurses can focus on enabling patients by fully engaging them in decision-making and highlighting patient achievements. Examples warranting positive verbal reinforcement include attending clinic appointments despite logistical challenges, educating themselves about their diagnoses, and effectively explaining symptoms to providers. Some patients may also benefit from peer support groups.<sup>42</sup>

#### **Methodological considerations**

A strength of this study is that it was undertaken within a large international study with a sound research methodology based on established conceptual foundations. Further, by including patient cohorts from two centers in Canada and Switzerland, we avoided single-center bias and are thus more confident in our ability to explore the relationship between general self-efficacy and PROs. However, there are also methodological limitations to be considered when interpreting the data. The first pertains to the generalizability of study findings. We cannot conclude that our data are applicable to adults with CHD who are not followed in a major center or who are followed at our centers but chose not to take part in our study. The same refers to different ethnic groups, since the majority of our study population was Caucasian/white. Second, the cross-sectional design does not allow us to determine directionality of the relationships between self-efficacy and PROs. To investigate this, longitudinal data or an intervention targeting a change in self-efficacy would be required. Cross-lagged analyses on longitudinal data would allow us to determine if self-efficacy is influencing PROs, or vice versa. Furthermore, future studies on self-efficacy enhancing interventions are important to learn whether increasing self-efficacy yields improvements of PROs. Third, we did not measure disease-specific or behavior-specific self-efficacy, which might have contributed to the absence of a relationship between self-efficacy and health behaviors. Fourth, history of heart-failure and

arrhythmias as well as documentation of anxiety and depression was abstracted from the medical record and objective verification was not possible.

Finally, although statistically significant relationships between general self-efficacy with sex, employment status, and functional class were observed, the absolute differences were small. It would be important to define the minimal clinically important difference for the GSE scale in order to determine whether these differences are clinically meaningful.

## Conclusions

Higher self-efficacy was associated with more desirable scores in several PRO domains, notably mental health status, symptoms of depression, and QOL. Given that self-efficacy is a modifiable psychosocial variable, this holds important potential as a target for clinical intervention, both in regular clinical encounters as well as within the context of mental health intervention.

## **Implications for Practice**

- The patients' confidence in their ability to manage life challenges, was associated with several positive outcomes, particularly mental health and QOL.
- Cardiovascular nurses can play an important role in the assessment of general selfefficacy in patients with CHD.
- Promoting self-management strategies may help to enhance patients' general selfefficacy.

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The Authors declare that there is no conflict of interest.

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# **Figures and Tables**

	Participants $N = 454$
Median age in years (range)	32.0 (18-81)
Age in groups, n (%)	× ,
18-25	141 (31.1)
26-30	71 (15.6)
31-35	62 (13.7)
36-40	41(70)
41-45	32 (7.0
×45	107 (23.6)
2 TJ	107 (23.0)
Center $n(\%)$	
Toronto	176 (38 8)
Bern	278 (61 2)
bem	278 (01.2)
Male sex, n (%).	248 (54.6)
	2.10 (0.110)
Background (N = 445), n (%)	
White/Caucasian	372 (83.6)
Asian	32 (7.2)
Hispanic/Latino	18(40)
Middle-Eastern/Arabic	15 (3.4)
Black/African-American	7 (1 6)
	1(0,2)
Olici	1 (0.2)
Marital Status (N = $450$ ) n (%)	
Never married/unmarried	219 (48 7)
Married or living with a partner	207 (46.0)
Divorced or widowed	23(51)
Other	1(0,2)
Olici	1 (0.2)
Has at least one child $(N = 448)$ n (%)	154 (34 4)
Employment (N = 449) n (%)	
Full-time/Part-time	329(73 3)
Job seeking unemployed or disability	529(13.3) 64(14.2)
Homemaker or retired	28(62)
Other	28(0.2)
Ottler	28 (0.2)
Education $(N - 446)$ n (%)	
High school	206(462)
College degree	117(262)
University degree	107(24.0)
University degree	107(24.0) 16(2.6)
Less than high school	10 (3.0)
Consider self as religious or spiritual $(N - 4AA)$ n (%)	152 (34 2)
= 1000000000000000000000000000000000000	102 (01.2)

 Table 1. Demographic and medical characteristics

Complexity of the heart defect, n (%)	
Mild	91 (20.0)
Moderate	221 (48.7)
Great	142 (31.3)
History of cardiac surgery, n (%)	365 (80.4)
Congestive heart failure, n (%)	
Never	422 (93.0)
Past, not current	19 (4.2)
Current	13 (2.9)
Patient-reported functional class ( $N = 445$ ), n (%)	
NYHAI	264 (59.3)
NYHA II	137 (30.8)
NYHA III	37 (8.3)
NYHA IV	7 (1.6)
Any history of arrhythmia, n (%)	134 (29.5)
Cardiac device (N = 453), n (%)	
None	409 (90.3)
Pacemaker	35 (7.7)
Implantable Cardioverter Defibrillator	9 (2.0)
Any history of mood disorder (N = 453), n (%)	27 (6.0)
Any history of anxiety disorder, n (%)	19 (4.2)

L	Mean GSE (± Standard Deviation)	t/F-Value	р
Sex	, , ,	2.250	0.025
Male	30.6 (±4.9)		
Female	29.5 (±5.4)		
Marital Status		2.292	0.077
Never married	29.5 (±5.2)		
Married or living with a partner	30.7 (±5.0)		
Divorced or widowed	31.2 (±5.0)		
Other	34.0 (±5.2)		
Children	29.9 (±5.1)	-1.499	0.135
Yes	30.6 (±5.2)		
No			
Education		0.503	0.680
Less than high school	30.6 (±2.7)		
High school	30.1 (±5.4)		
College degree	29.6 (±5.4)		
University degree	30.4 (±4.7)		
Work		5.249	0.001
Full-time/Part-time	30.1 (±5.1)		
Homemaker or retired	31.5 (±3.8)		
Job seeking, unemployed or disability	28.5 (±5.7)		
Other	32.8 (±4.9)		
Religiosity		-1.935	0.054
Yes, I consider myself religious or spiritual	30.8 (±4.8)		
No	29.8 (±5.3)		
Patient-reported functional class		2.653	0.048
NYHA I	30.6 (±4.8)		
NYHA II	29.6 (±5.6)		
NYHA III	28.4 (±5.1)		
NYHA IV	29.0 (±2.5)		
Complexity of the heart defect		2.629	0.073
Simple	31.1 (±5.1)		
Moderate	30.1 (±4.7)		
Great	29.5 (±5.7)		

# **Table 2.** General Self-Efficacy as a function of univariate demographic and medical predictors

Congestive Heart-failure		0.047	0.954
Never	30.1 (±5.2)		
Past, not current	30.2 (±4.6)		
Current	29.7 (±6.3)		
History of arrhythmia		0.704	0.482
Yes	29.8 (±5.0)		
No	30.2 (±5.2)		
Cardiac device		2.191	0.113
None	30.2 (±5.2)		
Implantable Cardioverter Defibrillator	32.4 (±5.9)		
Pacemaker	28.7 (±4.6)		
Mood disorder		1.564	0.119
Yes	28.6 (±6.1)		
No	30.2 (±5.1)		
Anxiety disorder		1.505	0.133
Yes	28.4 (±5.5)		
No	30.2 (±5.1)		

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	PCS	MCS	EQ-VAS	HADS-A	HADS-D	Health behavior	LAS QOL	SMLS
B (Standard error)	0.4 (0.1-0.6)*	1.2 (0.8-1.4)***	0.8 (0.6-1.0) ***	-0.2 (-0.20.1) ***	-0.2 (-0.30.2) ***	-0.03 (-0.3- 0.3)	1.0 (0.8-1.3) ***	0.5 (0.4-0.6) ***
R <sup>2</sup> overall model R <sup>2</sup> change for general self-efficacy/	55.7% 0.9%	36.9% 10.7%	52.0% 5.9%	30.0% 5.9%	44.8% 13.6%	11.4% 0.0%	49.4% 9.2%	46.3% 10.9%
*=p<0.05, **=p<0.01, ***=p<0.001								

#### **Table 3.** Multivariable linear regression analysis with GSE as predictor of PROs, adjusted for patient characteristics (n=386)

# = reference category; Values in table are Estimates (95% Confidence Intervals); Color coding refers to significance of estimate; PCS=Physical Component Summary; MCS=Mental Component Summary; EQ-VAS=EuroQol 5 Dimensions-Visual Analog Scale; HADS-A=Hospital Anxiety and Depression Scale – Anxiety; HADS-D= Hospital Anxiety and Depression Scale – Depression; LAS QOL= Linear Analog Scale Quality of Life; SWLS=Satisfaction with Life Scale