

University of Groningen

## Patient-reported outcomes after cardiac surgery

Zwiers-Blokzijl, Fredrike

DOI:  
[10.33612/diss.131754816](https://doi.org/10.33612/diss.131754816)

**IMPORTANT NOTE:** You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

*Document Version*  
Publisher's PDF, also known as Version of record

*Publication date:*  
2020

[Link to publication in University of Groningen/UMCG research database](#)

*Citation for published version (APA):*  
Zwiers-Blokzijl, F. (2020). *Patient-reported outcomes after cardiac surgery: Things that really matter.* University of Groningen. <https://doi.org/10.33612/diss.131754816>

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CHAPTER

9

GENERAL DISCUSSION

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For a long time, interventions of cardiac surgery have been evaluated based on outcomes such as mortality, complications and recurrence of symptoms. Other outcomes, important from the patients' perspective, were less considered but, along with rapidly improving surgical techniques and low post surgery mortality, the focus of general healthcare and cardiac surgery as well, is now shifting towards quality of life (QoL) and other patient-reported outcomes. However, studies on postoperative patient-reported outcome measures after cardiac surgery are still low in volume, lack external validation and have been conducted in highly selected patient categories (1–3). The aim of this thesis was to evaluate the impact of cardiac surgery on patient's daily lives including patient-reported outcomes.

Data on patient-reported outcomes reflect 'patient's suffering' caused by morbidity and provide information supplementary to clinical outcomes such as mortality and complications. QoL is by far the most frequently studied patient-reported outcome in healthcare. Other patient-reported items are symptoms and satisfaction with care of which the latter is rather comprehensive (4). Satisfaction with care can be interpreted as satisfaction with care during hospitalization, but alternatively, potentially also as satisfaction with care after discharge, i.e. care in terms of cardiac rehabilitation (CR) or the follow-up at the outpatient clinic.

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## MAIN FINDINGS

### *Quality of life*

Improvement in QoL, symptom relief and survival are the main incentives to conduct cardiac surgery (5,6). Reports on QoL after cardiac surgery are contradictory and several systematic reviews emphasize the lack of well-designed sufficiently powered multicenter studies, including both pre- and postoperative QoL data and information on the patients lost to follow-up (7–9). In **chapter 3, 4, 5 and 7** QoL is thoroughly studied and discussed in patients after coronary artery bypass grafting (CABG) or aortic valve replacement.

### *Quality of life and age*

**Chapters 4 and 5** of this thesis describe a multicenter study of 2606 patients after CABG (chapter 4) and 899 patients after surgical aortic valve replacement (SAVR; chapter 5) including preoperative (baseline) and postoperative data on QoL one year after surgery. We evaluated the impact of cardiac surgery on one-year QoL and its variation with age by categorizing the patients into three age groups: younger than 65 years, between 65 and 79 years and 80 years or older. We observed that most patients experienced a beneficial effect in terms of QoL, while elderly patients are more frequently at risk for a deterioration in their physical and/or mental QoL compared to younger patients. These data correspond with the findings of our single-center study described in **chapter 3**, although baseline QoL-data was lacking. Several risk factors for a reduced QoL were observed in both our multicenter studies, such as a good QoL at baseline (CABG and SAVR), a reduced left ventricular function (CABG) and higher age (SAVR). The outcomes of

our studies suggest that people of increasing age are more at risk for deterioration in QoL after surgery and these findings are in line with other studies (10,11). Though, the cut-off values for defining elderly patients remain arbitrary and these values for elderly patients range between 70 and 80 years (12–14). In all our studies we defined elderly patients by 80 years of age or older, following the 2011 American Heart Association guidelines (12).

#### *Quality of life: definition and measurement*

Although the World Health Organization has provided a uniform definition of quality of life, there is still an ongoing debate about the meaning of QoL and what should be measured (15). In research, the terms quality of life, health-related quality of life (HRQoL) and health status are used interchangeably and confusion remains about the concepts of these terms (16,17). The World Health Organization defines QoL as: ‘an individual’s perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns’ (15). Widely validated questionnaires such as the SF-36 and EQ-5D are described as measures of QoL, HRQoL and health status. HRQoL is directly related to QoL, as reflected in the following definition: ‘quality of life is an all-inclusive concept incorporating all factors that impact upon an individual’s life. Health-related quality of life includes only those factors that are part of an individual’s health’ (18). An alternative definition of HRQoL is: ‘how well a person functions in their life and his or her perceived wellbeing in physical, mental and social domains of health’ (19). There seems to be an overlap between the definitions on QoL and HRQoL, resulting in a difficult practical question concerning QoL research: to what extent are people capable of separating their QoL from their HRQoL? We have addressed this question in chapters **3, 4, 5 and 7** where we have implicitly accepted that QoL is influenced by other factors unrelated to the cardiac surgery intervention, meaning that QoL may also be influenced by other aspects in life, hereby referring to the definition of the World Health Organization on QoL.

Similar to research, the terminology of QoL and HRQoL has also been used interchangeably in the reports of our studies. Because we have mostly used SF-36, an instrument that is also used to measure HRQoL, we cannot be certain that we have measured QoL or HRQoL until there are clearly distinct and consented constructs and definitions, as well as validated instruments that measure these constructs. Irrespective the confusions concerning the terminology, the aim of this thesis was to evaluate the patient-reported outcomes after cardiac surgery, including quality of life.

#### *Missing data*

One of the widely acknowledged difficulties in QoL-research is the large amount of missing-data referring to both missing items in scales and to missed assessments (20). Missing data can be classified as data missing at random (e.g., data missing due to a missed appointment or the patient moving abroad) and data missing not

at random, which is generally the case when data is missing e.g., due to disease progression or lack of symptom relief. The patients from whom data is missing not at random are typically elderly patients, with more comorbidities and therefore a higher preoperative risk and likely, loss to follow-up is associated with a reduced QoL (21,22). If such patients are dropping out of the study, then patients with a likely poorer quality of life are lost, possibly leading to an overestimation of QoL in the study. This also applies to the prospective study described in **chapter 7** where 6.3% of the patients were lost to follow-up due to physical or emotional problems. Loss to follow-up is also addressed in the discussions of our multicenter studies (**chapter 4 and 5**) where we compared the characteristics of the responders (completed preoperative and follow-up questionnaires) and non-responders (only completed preoperative questionnaires). The comparisons showed that in both studies the non-responding patients were older, had more comorbidities and had a higher preoperative risk for mortality. This implies that in our studies selection bias may have led to an overestimation of increase in QoL, and in addition, the numbers of patients with a decreased QoL after cardiac surgery are thought to be much higher in the total population.

#### *QoL and cost-effectiveness*

With the increasing number of elderly patients undergoing cardiac surgery and the expanding costs in healthcare, QoL is a highly relevant outcome not only for the patient, but also for cost-effectiveness evaluations. In this thesis we did not address cost-effectiveness, but an economic evaluation was planned as part of the Heart-ROCQ study (**chapter 9**). This economic evaluation will be performed to compare the costs between a preoperative and postoperative CR-program and a standard care postoperative outpatient CR-program, by estimating quality adjusted life years (QALYs) using the EQ-5D-5L (23). Utility values for the EQ-5D-5L will be calculated based on the healthcare reimbursements and the results will be reported as an Incremental Cost Effectiveness Ratio (ICER), where the difference in effect is divided by the difference in costs (24). A societal perspective was chosen for this economic evaluation, which means that not only the costs for healthcare are taken into account but also patient- and productivity-related costs and benefits.

#### *Functional status*

**Chapter 2** of this thesis is a systematic review on the benefits and harms of exercise-based CR after cardiac surgery on several outcomes which are important from the patient's perspective (i.e. mortality, serious adverse events, quality of life, functioning, return to work and in addition costs/cost-effectiveness). The results of this review did not allow us to reach any firm conclusions on exercise-based CR in patients having cardiac surgery. It is likely that exercise-based CR will improve outcome after cardiac surgery, but the results of our review highlight that patient-centered outcomes are frequently not well defined and insufficiently studied (7,25–29). In the protocol for this review, we deliberately chose not to describe the outcome 'functioning'. It turned out that most studies included in our review evaluated functioning in terms of physical capacity and/or modifiable risk factors.

For younger patients such modifiable risk factors are important, but for elderly patients (increasingly having cardiac surgery), the ability to perform daily activities and maintain independency is at least as important. Tools for assessment of this functional status could be the Karnofsky Performance Scale or the Katz Index of Independence in Activities of Daily Living (30–32). The assessment of functional status is also one of the secondary outcomes in the Heart-ROCQ study (**chapter 9**).

### ***Return to work***

Return to work after cardiac surgery was only described in four studies included in the systematic review (**chapter 2**) and is insufficiently evaluated in patients after cardiac surgery. Return to work is highly important for working age patients undergoing cardiac surgery, which is why we conducted a qualitative study on return to work after CABG by interviewing patients and their spouses approximately at six months after their surgery (**chapter 6**). The Dutch guidelines for occupational physicians (33) suggest return to work six weeks after a cardiac event, including CABG, but this appeared to be far too early for the vast majority of patients due to the impact of major invasive surgery. Patients experience many physical and mental complaints, even long after surgery and after cardiac rehabilitation. In addition, many patients reported that there was none or insufficient advice about returning to work. A case-managing professional seemed to be missing, which is also recognized by the Dutch Rehabilitation Committee (34).

### ***Cognitive function***

Cognitive function and the impact of postoperative cognitive dysfunction (POCD) on QoL was addressed in **chapter 7** of this thesis. Like functional status, this is an important outcome for young and old, but in particular for the elderly patients, since cognitive and physical impairment are reported to often co-occur in older people (35,36). The association between cognitive and physical impairment has been confirmed by several studies, including patients undergoing cardiac surgery (37–39). We observed an incidence of postoperative cognitive dysfunction of 33% at long-term follow-up (6 months), which is in line with other studies (40,41). Although we observed no association between POCD and QoL, we were able to identify several risk factors for POCD as well as risk factors for a decreased QoL. The relationship between POCD, physical impairment in terms of sarcopenia, and QoL will be studied in the near future as we have collected data on sarcopenia in addition to the cognitive tests described in **chapter 7**. Sarcopenia is defined as a syndrome characterized by progressive and generalized loss of skeletal muscle mass and strength, leading to an increased risk of adverse outcomes, including physical disability, poor quality of life and death (42).

## **SHARED DECISION MAKING**

As discussed in the introduction of this thesis, studies on patient-reported outcomes are needed to provide doctors and other allied healthcare professionals with reliable data to evaluate all benefits and harms of cardiac surgery. Patients can subsequently be adequately informed on the potential benefits and harms

of an intervention during preoperative counseling, and how these benefits and harms may apply to their personal situation. Sharing decisions, as opposed to clinicians making decisions on behalf of patients, is gradually becoming the norm across Western societies as the preferred model for making patient-centered healthcare decisions (43,44). In shared decision making (SDM) decisions are influenced by ‘what matters most’ to patients as individuals. SDM is important for several reasons, all closely related to the basic principles of ethics in healthcare:

1. Respecting autonomy: enabling individuals to make reasoned informed choices
2. Beneficence: balancing on benefits of treatment against the risks and costs
3. Non-maleficence: avoiding harm (44,45).

During the last years many SDM models have been developed, some generic and others specific to a healthcare setting. There is no consensus in the field on the best SDM-model, only on certain components (46). One proposed model on SDM in clinical practice is presented in Figure 1 (47).

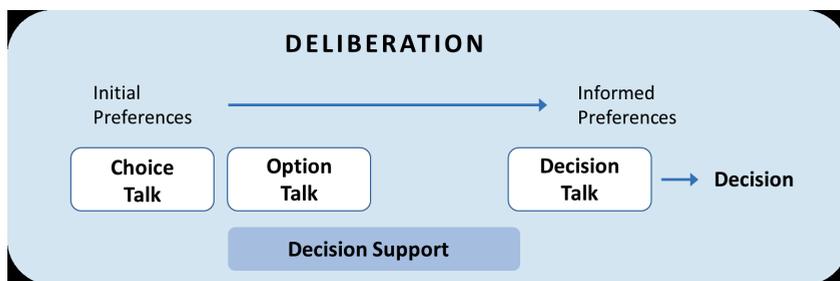


Figure 1. A shared decision making model (adapted from Elwyn et al. (2012)).

As shown in figure 1 the model is based on the deliberation process, the process where the patient becomes aware of choice, in which three key steps are important:

- Choice talk: to realize that a choice exists, can be initiated by a patient or clinician
- Option talk: patients are informed by treatment options in more detail
- Decision talk: patients are supported to explore ‘what matters most to them’ (47).

When applying this model in clinical practice, the question arises whether shared decision making is feasible within the set time for consultation at the outpatient clinic. A practical solution could be to perform the decision talk by telephone/video-call which gives the patient the opportunity to involve others, e.g., family members, in their decision. A written evidence-based patient information document, possibly with decision aids can be provided at the outpatient clinic,

as suggested in the current guidelines on myocardial revascularization (48). The integration of SDM into evidence based medicine may help clinicians to communicate about evidence and ask patients for their preference (44). The outcomes of our studies including several risk factors for impaired postoperative QoL and POCD are valuable for clinicians as well as patients in the process of SDM before cardiac surgery.

## VALUE BASED HEALTHCARE

As in shared-decision making, patients are also placed at the center of healthcare in the theory of value based healthcare. Value based healthcare (VBHC) was introduced by Porter in 2006 and the idea of this methodology is the assumption that care can be improved by concentrating on maximizing the 'value' for patients, defined as the outcomes of care and QoL in relation to the costs of care (49). VBHC is implemented in several health organizations all over the world and in the Netherlands an example is found in the Netherlands Heart Registry (NHR) formerly known as Meetbaar Beter. The NHR is a nationwide initiative of cardiac surgeons and cardiologists to improve the quality and transparency of care for patients with heart disease. All participating centres systematically collect patient-oriented and clinically relevant outcome measures such as mortality, comorbidities, quality of life and postoperative complications (50). Outcome analysis of patients with similar medical conditions can be performed based on this registry. The studies described in **chapter 4 and 5** are based on this database. Recently, a comprehensive set of patient-relevant outcome measures for coronary artery disease has been developed and implemented. The variations between the results of the hospitals using this set may further improve cardiac care in the near future (51).

## FUTURE PERSPECTIVES

### *Implications for clinical practice*

This thesis expands our knowledge on patient-reported outcomes after cardiac surgery, with particular emphasis on the outcome quality of life. Based on our findings we would like to suggest the following implications for clinical practice.

Based on the findings of our studies on QoL, a preoperative QoL assessment should be part of the general preoperative examination of all patients, as a good QoL at baseline is a risk factor for a decreased QoL after cardiac surgery and patients should be aware of what they can expect after surgery. For elderly patients we suggest an extensive preoperative screening including assessment of QoL, functional status, cognitive performance and frailty because elderly, vulnerable patients are more at risk of a deterioration in their postoperative QoL. Several hospitals in the Netherlands already provide a preoperative screening-carousel including the consultation of a geriatrician for patients  $\geq 70$  years who are candidate for cardiac surgery. Screening of patients during the preoperative phase may very well be performed by dedicated allied health professionals (i.e.

nurse practitioners or physician assistants) working in the field of cardiothoracic surgery.

Patient's preferences and expectations on postoperative recovery including QoL, and a surgeon or cardiologist's personalized risk-assessment of patient-reported outcomes should be thoroughly discussed in the preoperative phase. This may eventually lead to improved quality of care from the patient's perspective. Shared-decision making may be a valuable tool during this process.

Although identified in a small qualitative study, the process of return to work for patients after cardiac surgery should preferably start early after surgery possibly by a coordinating case-managing professional. Because little research has been done in this area, further research is required.

### ***Implications for future research***

Although current recommendations in the ESC/EACTS guidelines on myocardial revascularization are mostly based on the ability of treatments to reduce adverse events including mortality, interest in patient-reported outcome measures is growing (48). Currently, patient-reported outcomes are not routinely evaluated as key outcomes in major cardiovascular trials. However, the focus on patient-reported outcomes should be encouraged because of an increased focus on improving well-being and the increasing role of cost-effectiveness assessment.

From the patient' perspective further research is needed on the harms and benefits of elderly patients undergoing cardiac surgery. Finding the best interventions for the vulnerably elderly patients is still a challenge and needs careful evaluation. Outcomes as QoL, functional status, frailty and cognitive function should be addressed and evaluated in any randomized trial when searching for the optimal intervention, including the comparison with no intervention as a control group.

Finally, studies on patient-reported outcomes in cardiac surgery and cardiac rehabilitation in general, would benefit from a set of clearly defined outcomes as suggested by the COMET (Core Outcome Measures in Effectiveness Trials) initiative and the CONSORT PRO Extension that aim to promote the transparent reporting of patient-reported outcomes in trials (52,53). The set of patient-relevant outcome measures for coronary artery disease developed by the NHR is a good example of a clearly defined set of outcomes and hopefully more will follow in the near future.

## **CONCLUDING REMARKS**

The aim of this thesis was to contribute to the knowledge on patient-reported outcomes after cardiac surgery. Several patient-reported outcomes were addressed in this thesis to learn more about 'what really matters to patients' and to answer the three questions pointed out in the introduction.

*What is the influence of cardiac surgery on patient-reported outcomes such as quality of life and return to work?*

While most patients benefit in terms of QoL, approximately 30 - 50% do not benefit in terms of an increased QoL six to twelve months after surgery. Patients still at working age experience affective and physical complaints when returning to work and need on average more time to return to work than suggested in current guidelines. The results of our studies show that cardiac surgery is a major event in patients' lives and may have a substantial impact on patient-reported outcomes.

*Do patients undergoing cardiac surgery, benefit from cardiac rehabilitation in terms of patient-reported outcomes?*

The results of our systematic review did not allow us to reach any reliable conclusions about the effectiveness of cardiac rehabilitation following cardiac surgery on patient-reported outcomes. There was a large diversity in unclearly defined outcomes and a high risk of bias and random error.

*Are elderly patients more at risk of a decreased quality of life after surgery?*

Elderly patients are at higher risk of experiencing a deterioration in their QoL compared to younger patients. The decision to operate or not should, however, not solely be based on age but on the totality of individual preferences and expectations of the patient, as well-being and QoL are likely to be valued much more important than quantity of life by many, but especially by the elderly, vulnerable patients.

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