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## State-of-the-art - Cardiac general

# Quality of life after cardiac surgery: underresearched research

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### Abstract

Improved quality of life is a major goal for cardiac surgery. This review concerns 29 articles published between January 2004 and December 2010. Only nine studies present preoperative and postoperative registered quality of life data. These studies have a short follow-up and a limited number of patients included. Most other studies starts at a certain point in the follow-up and compare different patient groups or techniques, but do not evaluate postoperative vs. preoperative quality of life. In an era of evidence-based medicine, there is a lack of major and well-organized clinical studies dealing with quality of life after cardiac surgery. Based on this review, five requirements for 'good' studies on this subject can be formulated: information about the total number of patients that could be included; the number of patients actually included; information about preoperative quality of life; information on what was done about patients with missing data; and at least minimum information about demographics, co-morbidity and the cardiac risk of patients who were not included or who dropped out. These points seem to us to be essential for validation of the results presented.

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### 1. Introduction

Although improved quality of life (QoL) is a major objective of cardiac surgery [1, 2], there are few reports concerning QoL after cardiac surgery. QoL relates to more than just the presence of symptoms of disease or the side effects of a treatment or surgery; it is based on how patients perceive and experience these manifestations in their daily life. QoL covers a broad range of experiences related to overall well-being. This means that QoL is based on subjective functioning in relation to personal expectations and is defined by subjective experiences and perceptions.

During the past five years, our group has published several studies concerning QoL after cardiac surgery [3–6]. However, when elaborating the discussions of these studies, we were confronted by several curious observations concerning the number of patients, the follow-up time and the availability of preoperative QoL data. Those who reviewed our studies have also, and rightly so, been critical of these aspects.

This review focuses on these three points, because they are of fundamental value for the conclusions of studies concerning QoL after cardiac surgery. It must be clear that we will not discuss the different QoL questionnaires or the methodology of analyses, because other papers deal with these subjects [7–9].

### 2. Methods

Using PubMed, we performed a search for articles concerning QoL before and after cardiac surgery, restricting the search to publications between January 2004 and December 2010. The search command is presented in Table 1.

### 3. Results

Thirty-three papers were found using the PubMed search [3–6, 10–38]. For this review, we excluded the four studies generated by our own group [3–6]. The other 29 studies were screened for the three respective study points [10–38]. Table 2 summarizes our results. Beside the study authors, the effective number of patients with QoL information, the follow-up period, the mean, median or range, the knowledge of preoperative QoL information (yes or no) and the primary intention of the study are presented.

Only nine out of 29 (31%) studies present preoperative QoL data and compare these with the postoperative data [16, 19, 22, 24, 29–31, 36, 38]. The other 20 studies start with a number of patients that were identified only postoperatively. The follow-up period in these studies varies between a couple of months and several years. However, the term 'follow-up' is rather misleading because it was only after identifying the surviving patients at that point of follow-up that the patients were invited to fill out a QoL questionnaire. Afterwards, the resulting data were primarily used for a comparison between different techniques – off-pump vs. on-pump [13, 22, 24], mechanical vs. biological

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Table 1. PubMed search command

#1	Quality of life [MESH]
#2	SF 36/Short form 36 [Title/Abstract]
#3	EuroQol/EQ-5D [Title/Abstract]
#4	Thoracic surgery [MESH] AND #1 OR #2 OR #3
#5	Cardiac surgery [Title/Abstract] AND #1 OR #2 OR #3
#6	Heart surgery [Title/Abstract] AND #1 OR #2 OR #3
#7	Coronary artery bypass [MESH] AND #1 OR #2 OR #3
#8	Aortic valve replacement [Title/Abstract] AND #1 OR #2 OR #3
#9	Mitral valve replacement [Title/Abstract] AND #1 OR #2 OR #3
#10	Tricuspid valve replacement [Title/Abstract] AND #1 OR #2 OR #3
#11	Aortic root replacement [Title/Abstract] AND #1 OR #2 OR #3
#12	Ascending aortic replacement [Title/Abstract] AND #1 OR #2 OR #3

Limits: Published in the last five years, English.

valve implantation [10, 26, 34] – or different patients groups – male vs. female, older than 70 years vs. younger patients, as indicated in Table 2. Here, only patients who survived the ‘follow-up period’ and whose registered QoL data were complete were included in the analysis.

As already mentioned, only nine studies present pre- and postoperative QoL data. These studies have a slightly shorter follow-up time, from three months to one year, than the previously described group. Six of these nine studies only give information about the number of patients included in the study [16, 24, 31, 36, 38]. They give no information on the total number of patients that could have been included in the study, nor do they provide reasons for their exclusion.

Table 2. Quality of life (QoL) and cardiac surgery

Study (reference)	Number of patients	Follow-up period	Preoperative QoL	Study intent
Aboud et al. [10]	136	2 years	No	Mechanical vs. biological valve replacement and in different age groups
Accola et al. [11]	529	9 months–18 years	No	Valve replacement, male vs. female in patients aged ≥65 years
Akhyari et al. [12]	38	3.2 and 4.2 years	No	Bentall vs. Ross procedure
Ascione et al. [13]	328	3 years	No	Off-pump vs. on-pump
Barry et al. [14]	1072	6 months	No	QoL predischARGE vs. six months postoperatively in CABG patients
Bjessmo and Sartip [15]	210	10 years	No	Elective vs. acute CABG
Bonaros et al. [16]	120	6 months	Yes	Robotically assisted vs. standard CABG
Bradshaw et al. [17]	2051	10 years	No	Survivors postCABG with or without angina
Dunning et al. [18]	621	10 years	No	Relation between preoperative data, operative data and QoL 10 years postoperatively
El Baz et al. [19]	168	6 months	Yes	Difference in QoL related to the use or otherwise of a clinical pathway
Fukuoka et al. [20]	206	1 year	No	Identify elderly ≥65 years after PCI/CABG at risk for poor QoL
Gjeilo et al. [21]	203	3 years	No	<70 years vs. ≥70 years and female vs. male in CABG patients
Jensen et al. [22]	99	3 months	Yes	On-pump vs. off-pump
Jideus et al. [23]	126	20 months	No	CABG patients with vs. without SWI
Kapetanakis et al. [24]	191	6 months	Yes	On-pump vs. off-pump
Kurlansky et al. [25]	597	4.7 years	No	Isolated valve replacement vs. valve replacement+CABG
Kurlansky et al. [26]	634	5.33 years	No	Mechanical vs. biological valve replacement
Kurlansky et al. [27]	390	5.33 and 4.3 years	No	Aortic valve replacement vs. combined aortic valve+CABG in elderly patients (>65 years)
Lee [28]	109	5 years	No	Identification of determinants of QoL after CABG
Lie et al. [29]	185	6 months	Yes	Impact of a home-based intervention program on QoL
Nogueira et al. [30]	202	1 year	Yes	On-pump vs. off-pump, <65 years vs. ≥65 years
Rimington et al. [31]	204	1 year	Yes	Outcome after valve replacement
Sedrakyan et al. [32]	72	18 months	No	Mitral valve repair vs. replacement
Stalder et al. [33]	172	26.6 months	No	Ascending aortic disease with or without disease of the aortic valve
Vicchio et al. [34]	121	3.4 years	No	Tissue vs. mechanical valve replacement in octogenarians
Vigano et al. [35]	56	5 years	No	QoL after tricuspid valve surgery
Zhao et al. [36]	171	1 year	Yes	Mitral valve repair vs. replacement
Folkman et al. [37]	126	1 year	No	Aortic valve replacement with or without CABG in octogenarians
Taillefer et al. [38]	82	3 months	Yes	Mechanical vs. biological valve replacement and male vs. female

CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention; SWI, sternal wound infection.

Only three studies start with a description of the initial group of patients, although none of these studies provides information about the operative risk and/or preoperative QoL of the patients who were not included [19, 22, 29]. The three studies do show that the group of patients that was actually studied is only a small part of the number of patients who could have been included in the study [19]: 168/256 (65%), six months’ follow-up; [22]: 120/206 (58%), three months’ follow-up; [29]: 185/422 (44%), six months’ follow-up).

#### 4. Discussion

This review shows that information about QoL after cardiac surgery is limited, not only because the number of studies is small, but also because the set-up of the studies differs widely. One reason is that QoL seems to be only a ‘soft’ end point in comparison with survival. Soft end points are difficult to evaluate and highly individual. QoL covers several domains, each affecting the others. Furthermore, the point of departure is different for each patient, as are their expectations of the operation. Yet, in contrast to survival studies, which start with a number of living patients and compare that to the number of patients still alive at a certain moment postoperatively, most QoL studies do not start with preoperative QoL data. Instead, QoL is used (or misused) to compare the effect of, for example, different techniques on the QoL of the patients.

The results, however, are very questionable. For one thing, there is no information about preoperative QoL. Second, patients are selected at a certain moment postoperatively, and only those patients that meet the study criteria – complete QoL information – are eventually included in the evaluation. If we compare this with a simple survival analysis, this means that, at a certain moment postoperatively, a number of surviving patients would be identified and a conclusion about survival made based on only the patients meeting the study criterion – survival. This should mean 100% survival. Another point is that several of these studies pretend to have a long follow-up period. These studies are, however, also misleading. The patients included have a certain follow-up period, but QoL information is provided only at one moment: the studies do not provide information on how QoL has changed during the follow-up period.

The few studies that start with preoperative QoL assessment and go on to compare this to a postoperative QoL registration have a problem of a different kind, since they can only include patients with complete pre- and postoperative registration of the QoL data in their final analysis. In these studies, it is important for the preoperative QoL data of the studied group to be compared to the preoperative QoL data of the excluded group before the conclusion based on the studied data can be generalized to the total population. A striking aspect of these studies is the high drop-out of patients, even at a relatively short follow-up time. In contrast to survival studies, where the only criterion is survival – yes or no – these QoL studies make use of QoL questionnaires based on several domains. Therefore, it is important not only that patients reply to the questionnaire, but also that they provide a clear and complete reply. This often proves to be a problem and is an important reason for the high drop-out rate. It is no coincidence that studies with both pre- and postoperative data have only a limited follow-up.

In our personal experience, we also see a progressive drop-out of patients participating in our yearly organized follow-up after two or three years' follow-up [39]. This drop-out is not the same as 'lost to follow-up'. Patients reply to the questionnaire, however, with incomplete data for evaluation of their QoL. Usually, complete case analysis is performed, so all subjects with missing values are excluded. It is a shame that all patients with missing data have to be excluded from a study, and this also decreases the validity of the study. It is possible to input missing data, but this needs a good knowledge of the imputation models and, if used, has to be clearly described [40].

Another point, which is not the focus of our review but something to be aware of nonetheless, is that when the follow-up is long, it is questionable whether the QoL questionnaire used gives good information at that specific moment. For example, QoL might be studied after 10 years in a patient population operated on at age of 70 years or older. At the moment of follow-up, the patients will be over 80 years old, an age to which frailty questionnaires will probably give more information about QoL than the SF-36 or EuroQoL questionnaire that was used preoperatively.

In an era when evidence-based medicine is of such great importance, the lack of QoL information after cardiac surgery seems incomprehensible. However, the problem is

not the absence of good prospective studies, but more the absence of QoL information studies. The reality is that, in cardiac surgery, prospective studies constitute the minority of our outcome research. Methodologically, it would be also very difficult to obtain good QoL data that would answer clinical questions. For example, if one wanted to study the impact of arterial grafting on QoL, one would need to follow-up a few thousand patients for up to 10 years. Another important, but insoluble, question is of course to what degree the difficulties described and the lack of QoL information affect our surgical practice and knowledge. The lack of major and well-organized clinical studies dealing with QoL after cardiac surgery is understandable, but it is a pity that many of the existing studies do not provide real information about the impact of cardiac surgery on patients' QoL.

In spite of these objections, but based on our findings from our review, we formulate five minimal basic requirements to increase the value of studies concerning QoL after cardiac surgery. Information should be given on the following:

- The number of patients that could be included in the study. This means defining not only the patient population, instances of isolated coronary artery bypass grafting, isolated aortic valve surgery, etc., but also the inclusion and/or exclusion criteria.
- The number of patients with preoperative and postoperative QoL information and, because QoL information is compound, the number of patients with complete QoL information.
- Whether the study has been performed only on patients with complete data and whether imputation methods have been used to handle the missing data.
- The reason for the missing preoperative QoL data and a comparison of demographics, co-morbidity, cardiac data and risk stratification of the groups with and without preoperative QoL data.
- The reason for the missing postoperative QoL data, and a comparison of demographics, co-morbidity, cardiac data, risk stratification and even preoperative QoL of the groups with and without postoperative QoL data.

These five points seem to us to be important for interpreting a study's results. Information about the percentage of patients included, risk stratification of patients included vs. not included and information about patients who have dropped out is essential for validation of the results.

## 5. Conclusions

We conclude that there is a need for good clinical trials concerning QoL after cardiac surgery. As Koch et al. have stated in their review concerning the analytic approach of QoL data, medical doctors need information on the impact of interventions and cardiac operations and on the resulting QoL, not only to justify their decision to operate, but also to be able to inform their patients about the pro and cons of any cardiac operation [9]. From the patient's point of view, however, it is equally striking that there is no greater call for information about postcardiac surgery QoL.

Based on our review, we suggest that studies present at least preoperative and postoperative registered QoL data

and also information about demographics, co-morbidity and cardiac risk of the patients who were excluded and who dropped out before generalization of their results.

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**eComment: Quality of life after cardiac surgery: underresearched research**

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In their review article (study period 2004 to 2010) regarding the assessment of quality of life after cardiac surgery, Noyez and colleagues found only nine studies presenting the proper preoperative and postoperative data [1].

We would like to add to their data our prospective randomised trial related to outcome of patients after mitral valve surgery plus biatrial modified radiofrequency Maze procedure using the Medtronic Cardioblate System, vs. mitral valve surgery plus intensive rhythm control strategy for persistent or permanent AF [2]. All patients completed the SF-36 Health Survey preoperatively and 3 months and 1 year after surgery.

Grady et al. in their study compared health-related quality of life among cardiac surgical patient groups before and after cardiac operations for isolated procedures and found that health-related quality of life improves early

after cardiac operations and remains relatively constant long-term, independent of procedure type [3].

In conclusion, we agree with Noyez et al. that well-designed prospective randomised trials should present preoperative and postoperative registered quality of life as well [1].

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