# Assessment of Health-Related Quality of Life after Coronary Revascularization

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#### **ABSTRACT**

The use of patient-oriented outcomes, in particular health-related quality if life (HRQOL), to evaluate coronary revascularization is continuously increasing. Current data underline that patients undergoing conventional CABG show a tremendous improvement of HRQOL status as early as 3 months postoperatively. There seems to be no clear benefit concerning HRQOL for off-pump coronary surgery versus conventional CABG. The benefits of minimal invasive CABG via mini-thoracotomy are compromised by increased incidence of pain during the immediate postoperative period. Totally endoscopic approaches seem to be more effective with regard to pain reduction and resume of every day activities. Compared to catheter-based interventions there is evidence that conventional CABG offers significant advantages over PCI. The influence of drug-eluting stents and newer surgical techniques on HRQOL remains to be determined. Inclusion of HRQOL data in CABG and PCI databases can play a central role in order to identify patient groups who benefit the most from each revascularization strategy.

### INTRODUCTION

The American College of Cardiology/American Heart Association (ACC/AHA) guidelines for coronary artery bypass grafting (CABG) suggest that improvements in survival and quality of life are the principal benefits for CABG-patients and thus considered to be primary indications for surgical treatment of coronary artery disease [Eagle 2004]. Highly sophisticated technology has allowed a remarkable shift of the treatment of coronary artery disease toward the direction of invasive coronary revascularization. The outcomes after surgical or catheter-based interventions of coronary artery disease

Presented at the 2nd Annual Interdisciplinary Workshop for Interventional Cardiologists and Cardiac Surgeons, Innsbruck, Austria, February 24-25, 2005.

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have intensively been evaluated in terms of clinical effectiveness. These evaluations have invariably focused on outcome measurements such as mortality, morbidity, relief of angina and clinical functional parameters. However, in recent years there has been an increasing use of more patient-oriented outcomes, in particular health-related quality of life (HRQOL).

HRQOL measurements indicate the levels of patient's satisfaction or discomfort after revascularization, which reflect a series of parameters varying from the cosmetic aspects of the scar to the extent of functional and social limitations caused by the intervention [Hunt 1985, Jenkinson 1993, Spertus 1995, Dolan 1997]. The main problem of those measurements is the fact that the effect of subjective parameters in everyday life varies from patient to patient and depends on the patient's status before the intervention. As a result low sensitivity rate is the Achilles' heel of quality of life assessment tools [Smith 2000]. However, HRQOLscores after coronary revascularization correlate with objective clinical parameters and therefore their measurement has increasing significance in the modern medical practice [Falcoz 2002]. According to the AHA/ACC guidelines for the treatment of coronary artery disease "patient and physician together should explore the potential benefits of improved quality of life with the attendant risks of the procedure versus alternative therapy, taking into account baseline functional capacities and patient's preferences" [Eagle 2004]. Subsequently, the results of an HRQOL measurement can be a substantial part of the benefits/risks assessment of a specific treatment option and as such can be used by health planners as objective criterion of the cost-effectiveness of the treatment [Speigelhalter 1992]. Moreover, HRQOL level is an independent predictor of mortality after surgical revascularization, it reflects the quality of patient's recovery and subsequently the quality of cardiovascular care and treatment strategies [Rumsfeld 1999].

Quality of life measurements include disease-specific or generic evaluation (Appendix). Disease-specific measures focus on the complaints that are attributable to a patient population with a specific diagnosis. In contrast, generic quality of life measures are intended to be broadly applicable across different interventions, and across patients with different characteristics. Another approach to quality of life assessment is the development of the so-called "individualized" measures [Fitzpatrick 1992]. These allow patients to identify the aspects that contribute most to their overall quality of life from their own perspective.

#### HRQOL IN PATIENTS

# HRQOL in Patients Undergoing Conventional Surgical Coronary Revascularization

Surgical revascularization strategies offer an almost complete elimination of angina; however, they are associated with increased surgical trauma and longer rehabilitation period. As a result the surgical patient may benefit more in the long run but a longer phase of discomfort is required till the benefits of revascularization are reflected in his everyday activities.

Quality of life measurements after coronary revascularization like risk stratification models have been extensively investigated in CABG patients probably because the need of high standardization of the procedure is a prerequisite to achieve the best possible clinical outcome [Sjöland 1997, Yun 1999, Rumsfeld 2001, Fox 2004]. According to those studies, preoperative scores are well documented and outline a significant negative influence of angina symptoms on physical and mental aspects of HRQOL. The existence of normative data has allowed direct comparisons of the postoperative outcome with the scores achieved by healthy individuals. The potential correspondence of normative data with the subjective patient's satisfaction level has also been identified. Regarding SF-36 quality of life survey, a cut-off point of 50% in general health and 75% in all other aspects of HRQOL indicate the level of patient's satisfaction with the procedure [Falcoz 2003]. A look at the results at 6, 12, and 24 months after CABG reveals that this level is achieved in most patients particularly in the physical aspects of quality of life [Klersy 1997]. Although in most of the studies HRQOL measurements are performed 6 or even 12 months postoperatively, the positive effect of revascularization can be detected even 30 days after surgery, and at 3 months HRQOL-scores reach the levels of the age-adjusted health population [Järvinen 2003]. This fact shows that the time needed to detect the effect of surgery has been overestimated. The durability of quality of life improvement has been assessed in a study showing higher quality of life scores 10 years after CABG, despite the fact that the patients were 10 years older [Herlitz 2003]. Predictors of improved HRQOL after surgical treatment include low comorbidity rates, male gender, severe angina symptoms, and preoperative inferior quality of life scores [Järvinen 2003].

### HRQOL in Patients Undergoing Off-pump CABG

Conventional cardiopulmonary bypass (CPB) has been shown to induce a systemic inflammatory response and microembolism, which may play a role in undesirable patient outcomes. Clinically, the manifestations of CPB-associated morbidity include neurologic complications, pulmonary, and renal dysfunction [Nalysnyk 2003]. In the literature, transient cognitive impairment has been reported to occur after cardiac surgery using CPB lasting up to 3-6 months after the operation [Newman 2001]. Of interest, decline in cognitive function occurs in up to 45% of patients who undergo major noncardiac operations [Grichnik 1999]. Although several publications have documented CPB as having a role in neurocognitive impairment [Taggart 1999], there are very few comparative data on HRQOL and functional performance after on-pump and off-pump CABG.

The existing prospective non-randomized studies revealed that the improvement of HRQOL after CABG was not affected by the use of CPB, as both patients operated with and without CPB achieved equivalent levels of HRQOL improvement after surgery [Taggart 1999, Järvinen 2004]. On the other hand, off-pump coronary surgery has been associated with higher rates of incomplete revascularization and with lower anastomotic patency rates in several single-center studies [Khan 2004]. The only prospective randomized trial of surgical revascularization with and without the use of CPB performed by a single experienced surgeon demonstrated similar clinical, angiographic findings and no difference in terms of HRQOL assessed using the SF-36 and the EuroQol health surveys [Puskas 2004].

### HRQOL in Patients Undergoing Minimal Invasive or Totally Endoscopic Coronary Revascularization

During the last decade cardiac surgery with the support of evolving technology has entered an era of becoming less, or eventually minimally invasive operating through smaller incisions and obviating the need of median sternotomy. Various methods of limited access including partial sternotomy, and mini-thoracotomy have enabled the performance of multivessel revascularization with excellent postoperative results [Oliveira 2002]. Even in patients operated on pump establishment of CPB via the femoral vessels using remote port access techniques is beginning to become a routine [Schachner 2004]. Moreover, robotic technology has enabled the performance of coronary revascularization through small holes in the thorax thus preserving the integrity of the thoracic cage [Bonatti 2004, Ott 2002]. Avoidance of median sternotomy as well as minimization of the morbidity rate associated with it, improvement of the cosmetic result, reduction of pain, and shortening of the rehabilitation period have been the common aims of these approaches [Biglioli 2000].

Chronic post-sternotomy pain with prevalence rate from 28% to 56% [Eisenberg 2001] has been attributed to entrapment neuropathy [Defalque 1989] and intercostal neuralgia [Conacher 1993]. In a mini-thoracotomy setting, Walther et al describe a reduction of acute pain discomfort during the first 7 days postoperatively [Walther 1999]. Nevertheless, in this study patients having lateral mini-thoracotomy suffered more pain during the first 2 postoperative days with an improvement tendency from the third postoperative day onward. On the other hand, Grossi et al reported significantly lower pain levels, muscle soreness, shortness of breath or fatigue in a mini-thoracotomy and port access setting as compared to a historical group of sternotomy patients [Grossi 1999]. In our hands, CABG patients operated in totally endoscopic fashion had significantly lower pain levels 1 and 3 months after revascularization as compared to conventional sternotomy patients [Bonaros 2004]. In this study we proposed that totally endoscopic techniques allow minimization of intercostal nerve trauma and complete avoidance of rib cage retraction. During precise LIMA harvesting using low-energy electrocautery and up to 10-fold magnification the trauma to the harvesting site may also be reduced as compared to conventional LIMA harvesting.

In terms of quality of life no difference in the Nottingham Health Profile has been observed in patients undergoing con-

Length of Stay and Resuming of Daily Activities after Robotically Assisted Coronary Artery Bypass Grafting\*

Activity	Sternotomy	TECAB
Prim. hospitalization	8.7 ± 1.6	6.9 ± 1.6
Sec. hospitalization	$10.5 \pm 10.3$	2.9 ± 4.6†
Shower	$9.8 \pm 9.1$	3.7 ± 1.7†
Housework	31.1 ± 21.4	17.9 ± 10†
Gardening	54.2 ± 35.4	22.2 ± 13.6†
Car driving	35.5 ± 26.1	$16.4 \pm 8.1 \dagger$
Shopping	$33.4 \pm 22$	$16.3 \pm 8.4 \dagger$
Walking outdoor	15.5 ± 10.2	6.19 ± 4.3†
Public transportation	27.1 ± 16.2	14.7 ± 8.9†
Hiking	54.2 ± 33.3	37.3 ± 42.3†
Biking	67.2 ± 30.5	28.2 ± 21.5†

<sup>\*</sup>TECAB indicates totally endoscopic coronary artery bypass grafting. †One-way ANOVA between the 3 groups, *P* value <.05.

ventional sternotomy or mini-thoracotomy at 3 months after the procedure [Walther 1999]. On the other hand, Grossi et al reported significantly increased overall activity in patients after mini-thoracotomy as compared to standard sternotomy patients at 2 and 4 weeks after revascularization (58.3% versus 29.2% and 70.0% versus 45.8%, respectively) [Grossi 1999]. This discrepancy can be explained by the fact that the physical limitations caused by conventional surgery are not present at 3 months after the procedure and therefore the benefit of the minimal invasive approach is not detectable anymore. In a study performed from our group, 25 patients operated on in a totally endoscopic fashion were compared with 25 patients who underwent on-pump CABG through sternotomy. Patients operated totally endoscopically reported better scores of general health at 4 weeks and higher physical functioning levels at 3 months after the operation [Bonaros 2004]. The improvement rate of physical activity was reflected by the fact that everyday activities performed before operation were resumed between 2 and 3 weeks after totally endoscopic revascularization. On the other hand, sternotomy patients required at least 4-5 weeks in order to perform the same activities. In terms on leisure activities, conventionally operated patients required almost twice as much time as patients operated on in an endoscopic fashion (see Table). Similar results have been observed in a cohort of patients who underwent total endoscopic atrial septal defect closure. In this report robotic technology minimized the degree of invasiveness, hastened postoperative recovery, and improved quality of life, although length of hospital stay was unchanged [Morgan 2004]. This fact indicates that the implementation of robotic technology does not compromise the short and midterm postoperative HRQOL even in patients who experience technical or surgical complications. By comparison, conversions from off-pump CABG to conventional procedures using the heart lung machine lead to significant mortality and morbidity [Edgerton 2003].

# HRQOL in Patients Undergoing Percutaneous Coronary Revascularization

Numerous studies describe the efficacy of PCI for angina relief and quality of life improvement in the short and mid run after the procedure for patients with chronic stable angina, unstable angina, or non-ST-segment elevation myocardial infarction [Pocock 2000, TIME-trial, Lancet 2001]. The RITA-3 trial has directly compared the benefits of PCI with conservative strategy in the treatment of patients with unstable angina or non-ST-segment elevation myocardial infarction. At 4-month follow-up patients randomized to an early interventional strategy had a lower risk, whereas at one year both groups were comparable with respect to developing the combined endpoint of refractory angina, nonfatal myocardial infarction, or death [Fox 2002]. In this study although PCI patients reported significantly better scores at the Seattle Angina Questionnaire components, this benefit was reflected to only subtle differences of the quality of life measurements. Specifically, better scores were reported in the PCI group regarding usual activities like walking, shopping, biking, etc. (improvement 29% versus 26% and worsening 15% versus 18%), general health (59% versus 55%) and vitality at 12 months follow-up [Pocock 1996]. Interestingly, no difference was observed with regard to pain, physical functioning, and self-care ability.

In an effort to identify the patients who benefit the most in terms of quality of life after PCI, Spertus et al enrolled more than 1500 patients with stable angina and documented coronary artery disease [Spertus 2004]. According to the authors history of myocardial infarction, number of coronaries involved and the presence of other comorbidities were not associated with the HRQOL-outcome after PCI. The strongest predictors of benefit were preprocedural angina frequency and the extent of physical limitation before treatment.

# Surgical versus Percutaneous Coronary Revascularization in Terms of HRQOL

The results of randomized trials comparing health-related quality of life after PCI versus CABG surgery have been inconsistent. The Arterial Revascularization Therapy Study (ARTS Trial) and the Coronary Angioplasty versus Bypass Revascularization Investigation (CABRI) trial found equivalent one- and three-year HRQL outcomes for patients randomized to PCI versus CABG surgery [Währborg 1999, Legrand 2004]. The Bypass Angioplasty Revascularization Investigation (BARI) trial found better physical function for CABG surgery patients compared with PCI patients in the first 3 years after revascularization, but HRQL outcomes were equivalent after 3 years [BARI Investigators 1997]. Additionally, both the Randomized Intervention Treatment of Angina (RITA) study and Emory Angioplasty versus Surgery Trial (EAST) found that patients randomized to PCI had significant HRQL impairment compared with those randomized to CABG surgery [Weintraub 1995, Pocock 1996]. On the other hand, HLQR did not differ between high-risk patients with medically refractory ischemia randomly assigned to PCI or CABG, 6 months after randomization. The reasons of this discrepancy are unknown. However, although methods of HRQL assessment varied substantially for each study, the HRQL deficits for PCI patients were directly correlated to recurrent angina in all studies. It is worth to be mentioned that most of these studies do not differentiate between the use of balloon PCI and stent implantation and thus the effect of stents on the reduction of recurrent angina cannot be fully evaluated. In a meta-analysis of the studies comparing PCI and CABG in terms of recurrent angina, subsequent revascularization, and nonfatal myocardial infarction, a clear benefit of surgical versus percutaneous revascularization has been noted, despite the improved efficacy of stent-implantation [Hoffmann 2003]. Unfortunately, the authors did not elaborate on the other aspects of HRQOL. More information regarding a direct comparison of PCI with stent implantation and CABG in terms of HRQOL is provided from the Stent or Surgery trial [Zhang 2003]. According to the study patients' angina burden and physical limitation were alleviated to a greater extent after surgical revascularization during the first post-procedural year as evaluated by the Seattle Angina Questionnaire. Meanwhile, the mortality difference between the two study arms (2.5% for CABG versus 9.8% for Stent-PCI) and subsequently exclusion of dead patients from HRQOL analysis minimized the benefit of surgical revascularization. It remains to be determined whether the results would even be more in favor of surgery if all the HRQOL score of dead patients would be rated with 0. One-year HRQOL scores were found to be better in CABG patients as compared to PCIpatients with moderate and high risk of restenosis [Spertus 2005]. However, all these studies do not take into consideration the influence of drug-eluting stents, total arterial revascularization, new generation OPCAB techniques, or endoscopic procedures, which may all improve post-interventional HRQOL.

### CONCLUSIONS AND FUTURE PERSPECTIVES

Taken together, the current data show that patients undergoing conventional CABG show a tremendous improvement of HRQOL status as early as 3 month postoperatively, the durability of which is counted in years or even decades. Moreover, there is no clear evidence that off-pump coronary surgery offers benefits in terms of HRQOL over conventional CABG on the arrested heart. The benefits of minimally invasive CABG via mini-thoracotomy are compromised by increased incidence of pain during the immediate postoperative period. Totally endoscopic approaches seem to offer clear benefits and a 50% reduction of time necessary to resume every day activities. On the field of interventional cardiology, the benefits of catheter-based interventions versus conservative treatment are well documented. HRQOL improvement is especially visible in patients with severe pre-procedural angina symptoms. However, comparative studies demonstrated that conventional CABG offers significant advantages over PCI. The influence of drug-eluting stents and newer surgical techniques on HRQOL remains to be determined. For this reason prospective randomized trials including patients being offered both therapeutic strategies need to be carried out. Moreover, we consider HRQOL as a major component of clinical outcome after coronary revascularization and therefore we believe that HRQOL records are extremely important for future evaluations of revascularization strategies. Inclusion of HRQOL data in CABG and PCI databases would be an important step in order to identify patient groups who benefit the most from each revascularization strategy.

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## **APPENDIX**

### Health-related quality of life assessment tools

General health questionnaires

SF-36

Nottingham Health Profile

WHO-QoL

CODE

Euro-QoL

QOL Index

Cardiac versions of general health questionnaires

Visual Analogue Scale

Cleveland Clinic Clinical Severity Score

Ferran's & Power's QOL-Index (Cardiac Version)

Angina-specific questionnaires

Seattle Angina Questionnaire

Coronary Revascularization Outcome Questionnaire

Mc New Heart Disease HRQL

Questionnaires based on the assessment of psychological factors

Hospital anxiety and Depression Scale

**ENRICHD Social Support Instrument** 

Psychological General Well-Being Index

Post Traumatic Stress Syndrome Inventory

Mishel's Uncertainty in Illness Scale

Herth Hope Index

Beck Depression Index

Questionnaires based on the assessment of physical factors

Duke's Activity Status Index

Physical Activity Score

Karnovsky Performance Status Scale

Other questionnaires

Verbal Rating Pain Scale

Waiting List Impact Questionnaire

NYHA Class

Freedom from Angina

Canadian Cardiovascular Society Classification