Effect of clinical pathway implementation and patients' characteristics on outcomes of coronary artery bypass graft surgery
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Chapter 7 | General discussion

In this final chapter the main results of the thesis are presented, followed by a general discussion concerning the main objectives of the thesis and finally, implications for practice, policy and further research are stated.

7.1 Research questions and main findings

7.1.1 Are the outcomes of CPs really evidence-based given the methodological and statistical conclusion validity?

In Chapter 2 we report the results of a systematic review where we assessed the methodological quality of 115 studies evaluating the outcomes of clinical pathways. In that review we used an evaluation tool that we had developed based on the Cochrane Library and other publications on quality assessment of studies\textsuperscript{1-4}. In relation to the main question, whether the outcomes of CPs can be denoted as evidence-based practice, we found that the majority of the publications on CP were classified as studies of low quality (67%). Regarding the internal and external validity of the studies in this larger sample of articles, most studies concerned non-randomly selected small patient populations without using a power analysis\textsuperscript{5-21}. Additionally, in half of the study sample (49.6%), the inclusion and exclusion criteria of patients were obscure and difficult to relate to the population’s characteristics. Furthermore, only 12 retrospective studies (10.4%) controlled for selection bias by matching, out of which three studies matched a random sample from a CP group with controls from the pre-pathway period group\textsuperscript{17,19,22-31}. Regarding the outcomes measured, our analysis also revealed that most studies focused on cost issues and reductions in Length of Stay (LOS), which were treated as independent outcomes although they are strongly interrelated. In relation to the use of appropriate statistical tests, more than half (59.1%) of the studies adopted parametric statistical tests without question, but 40.9% tested variables on normal distribution and, depending on the non normal distribution of the outcome, used non-parametric tests. Before–after differences in frequently measured outcomes such as LOS, costs, readmission and complications were statistically tested in few of the studies. These studies used bivariate statistical tests or multivariable techniques to decide whether differences between CP and control groups were due to sample fluctuations, while other studies reported differences without statistical tests.
7.1.2 What is the difference between the CP group and the conventional care group in relation to LOS, complications, readmission, HRQoL and psychological distress?

In Chapter 3 we focused on the difference between the CP group and the conventional care group in relation to LOS, complications, readmission, HRQoL and psychological distress. We also investigated the contribution of a CP towards an improved HRQoL six months after CABG as compared to a conventional care trajectory.

In the current study, we found that being in a pathway did not decrease LOS, which subsequently led to no decrease in hospital costs, although patients in the pathway group experienced a statistically significant reduction in hospital delay (time between admission and operation). We also found that there was no statistically significant difference between both groups in relation to the number of patients exceeding eight days of stay in the hospital. Moreover, there was no statistically significant difference between the two groups in relation to discharge destination (i.e. discharge to home or to extended care facility), attending a rehabilitation program after surgery, or readmission rate, in addition, all readmissions were to the hospital where patients had surgery. Improvement in HRQoL after CABG was realized in both groups (also for patients, who had poor health status according to our cut-off criterion). We found, however, that patients receiving conventional care improved relatively more, as compared to pathway patients, for six of the eight sub-domains of SF-36, but not for the domains of emotional role functioning and general health. Accordingly, the conventional care group improved more on both the physical and mental component summary. Regarding symptoms of depression, and anxiety, there was no difference between groups in relation to depression levels, but patients in the conventional care group decreased in anxiety relatively more when compared to the pathway-group patients.

7.1.3 Does physical and mental HRQoL differ across classes of the EuroSCORE assessed with self-reported SF-36 before and six months after CABG and is the EuroSCORE a predictor of physical and mental domains of HRQoL six after CABG?

In Chapter 4 the association between the EuroSCORE with self-reported physical and mental HRQoL before and six months after CABG is described. We posed the questions whether physical and mental HRQoL differ across classes of the EuroSCORE, assessed with self-reported SF-36 before and six months after CABG, and whether the EuroSCORE is a predictor of physical and mental domains of HRQoL six months after CABG.
Our main findings were that EuroSCORE was able to discriminate between physical HRQoL at baseline and at follow-up. It was also found that patients in a high-risk EuroSCORE class had poorer health at baseline and, despite their improvement after CABG, they still had poor physical health at follow-up, as compared to low-risk and medium-risk patients. Moreover, EuroSCORE was able to detect statistically significant and clinically important differences between low-risk and medium-risk vs. high patient-risk classes in: 1) the average number of LOS from admission to discharge, and from operation to discharge, and 2) in the number of perioperative complications.

In this study, we also found EuroSCORE predicted poor physical functioning, but not poor mental functioning. Likewise, poor physical and mental HRQoL was associated with several variables such as higher NYHA classes, readmission after six weeks of discharge, longer LOS, current smoking, history of renal insufficiency, re-exploration for bleeding and sternal re-suturing.

7.1.4 What are the predictors of deterioration in HRQoL six months following CABG and do symptoms of anxiety and depression mediate the effect of type D personality on deterioration in HRQoL?

Despite the fact that the aim of CABG is to relieve angina and improve HRQoL, some patients do not experience this improvement in multi-item domains of physical and mental HRQoL. Several studies investigated HRQoL after CABG, and most of these studies reported results which were denoted as improvement. However, very few studies investigated no changes or deterioration between baseline and follow-up. This “skewness” may be attributed to CABG being an effective treatment option for the majority of patients. A subtraction of mean baseline scores from post-intervention scores results in positive change scores, since the majority of change scores are on the improvement side of the distribution. As a consequence, the minority of observations found in the distribution of change scores, that are stable or have deteriorated, is likely to be neglected.

Accordingly, Chapter 5 focuses on the predictors of deterioration in HRQoL six months following CABG and whether anxiety and depression mediated the effect of type D on deterioration in HRQoL using structural equation modeling (SEM).

The main findings were that the majority of patients improved in their HRQoL and experienced a decrease in psychological distress between baseline (before CABG) and six-month follow-up (after CABG). Nevertheless, 20-30% of patients experienced no improvement or deteriorated in HRQoL following CABG.

The results of logistic regression showed that deterioration/no change in Physical components summary (PCS) was associated with a history of angina.
and that patients with increased levels of anxiety and depression had a higher risk of deterioration in physical and mental HRQoL. The SEM showed that increased levels of anxiety and depression mediated the relationship between Type D personality and deterioration/no change in both mental and physical HRQoL six months after CABG. Type D personality and increased anxiety and depression explained 65% of the variance in mental HRQoL change, and 25% of the variance for change in physical HRQoL.

7.1.5 What is the impact of positive affectivity on cardiac-related health complaints in CABG patients?

Our final research question is focusing on the impact of positive and negative affectivity on cardiac-related health complaints in CABG surgery patients. We examined the impact of positive affect (PA) and age on health complaints. Our main findings were that cognitive and somatic complaints (p<.001) decreased over time (the period between the point at preoperative assessment till 6 months after surgery). None of the interaction effects for time x age, time x PA, or time x age x PA were significant (p>.05). Patients with low PA reported more cognitive complaints (p<.001), and there was a trend for younger patients reporting more symptoms (p=.08). There was also a significant interaction effect for age x PA (p=.02), with younger patients with low PA scoring highest on cognitive complaints. Patients with low PA also reported significantly more somatic complaints (p<.001); neither the main effect for age (p=.17) nor the interaction effect for PA x age was significant (p=.44).

7.2 Discussion, methodological considerations, implications for practice and research

The following section discusses the results of the five research questions presented in this thesis concerning: (1) the methodological quality of CP evaluation study (2) the effect of implementing CP for CABG patients, (2) EuroSCORE as a predictor of poor HRQoL, (3) the factors contributing to deterioration in HRQoL after CABG and (4), finally, the effect of positive affectivity on cardiac related health complaints. We will also present the strengths and limitations of the studies and the implications the findings have regarding practice, and future research

7.2.1 Efficacy of clinical pathway

7.2.1.1 Discussion

The finding of our systematic review ‘Chapter 2’, showed that the main aim of designing and implementing CPs is to decrease LOS and costs, whilst at the
same time maintaining quality of care and improving patient outcomes such as HRQoL. However, the findings of our controlled longitudinal study suggest that these aims were not reached, as we found that there was no difference between both groups in relation to LOS, complications, readmission, attending a rehabilitation program and discharge destination.

As was demonstrated in many studies, improvement in HRQoL and psychological distress is mainly due to CABG, and it was expected that the implementation of the CP with all the included updated care protocols, guidelines, and interactive patient education would further improve patients’ health and satisfaction. However, in this is study our findings were not in line with these expectations.

Recently, a study by Deyirmenjian and associates\textsuperscript{45} demonstrated that patient education before CABG contributed to an increased level of anxiety, which is in line with our results, since we found that the level of anxiety decreased more in conventional care patients than in CP patients who received an interactive educational session before surgery.

To further investigate whether there were new findings supporting our results, we searched following the publication of our paper for the latest studies investigating the effect of CP implementations. It is evident that little has changed since we performed our review article\textsuperscript{46}. From 2006 to 2008, the articles investigating the effect of CP were mainly descriptive or pre-post studies in different medical and surgical fields\textsuperscript{47-64}. Only three RCT’s were found, one evaluating a CP targeted at care of patients with pneumonia in nursing homes\textsuperscript{65}, the second investigating whether implementing a pathway decreases post operative lung surgery complications\textsuperscript{54}, while the third was investigating a pathway designed for children with asthma/wheezes attending the hospital\textsuperscript{66}.

Ironically, only the study of the CP in nursing homes investigated the effect on patient related outcome, i.e. HRQoL and functional status, and found no difference between patients who followed a conventional plan or CP regarding LOS, readmissions, mortality rate, and costs also not regarding HRQoL and functional status. These findings are in line with our longitudinal study of the CABG pathways, as there was no difference between both groups regarding LOS, discharge destination, complications and readmission, although we found that patients in the conventional care plan gained more in their HRQoL. Our results are also in line with the results of other controlled studies investigating the effect of CP, which found that there was no difference between both groups in relation to LOS, discharge destination\textsuperscript{67}, and that patients in the conventional care plan had a better HRQoL\textsuperscript{68}.

More importantly, in our search we also found that in relation to cardiovascular diseases, surgery and PCI, the studies that were recently conducted were cross
sectional studies, conducted with independent samples before CP implementation and after\textsuperscript{50,53,56,58} or descriptive studies without control group\textsuperscript{59,60}, and the outcomes mainly concerned LOS, costs, readmission and patient satisfaction. It is clear that there is a lack of randomized controlled studies that evaluate intervention-related CPs longitudinally (comparing subjects after CABG with their baseline status). Therefore, it was hard to compare our results to other studies evaluating the effect of pathways, since these studies were either descriptive studies\textsuperscript{59,60,69,70} or comparative studies, that lacked a control for confounders\textsuperscript{18,71-75} or used no repeated measurement design.

### 7.2.2 The use of risk stratification model EuroSCORE

The risk stratification model EuroSCORE has been widely used\textsuperscript{76-78} to predict mortality, morbidity, LOS, costs and complications after cardiac surgery. To our knowledge, however, our study is one of the first few studies\textsuperscript{79-81} to investigate the relation between EuroSCORE and HRQoL. Our main findings were that EuroSCORE was able to discriminate between physical HRQoL at baseline and follow-up. It was also found that patients in a high-risk EuroSCORE class had poorer health at baseline and, despite their improvement after CABG; they still had poor physical health at follow-up, as compared to low-risk and medium-risk patients.

In the current study, we established that EuroSCORE was able to detect statistically significant and clinically important differences between low-risk and medium-risk vs. high patient-risk classes in average number of LOS from admission to discharge, from operation to discharge, and in number of perioperative complication. Most importantly, EuroSCORE was a predictor of poor physical functioning six months after CABG.

To our knowledge, only three studies investigated the relationship between EuroSCORE and HRQoL. In 2005 Peric and associates\textsuperscript{81} conducted a study to determine the relationship between EuroSCORE and QoL changes six months after CABG. They used the Nottingham Health Profile Questionnaire (NHP) part 1 as the model for assessing HRQoL. They found a small statistically significant correlation between EuroSCORE and the change in HRQoL only in the section of energy \((r=.27)\) which explained only 7% of the variance.

Additionally, they found, six months after CABG, that patients with a higher EuroSCORE had higher improvement scores of HRQoL in the NHP-section of energy. Finally, they concluded that EuroSCORE showed excellent results in the early mortality prediction after CABG\textsuperscript{76-78,82}, but it was obvious that EuroSCORE was not a predictor of HRQoL changes after CABG\textsuperscript{81}. Nevertheless, it is difficult to compare our findings with the findings of this
study since they used a different measure with different components to measure HRQoL.

Another study was conducted by Colak and colleagues in 2007, where they studied the differences in HRQoL of patients before and after cardiac surgery, and correlated the results with values of EuroSCORE. They used the Short Form SF-36 health survey before surgery and 1 year after discharge, to assess changes in QoL.

They found that the high-risk group of patients (EuroSCORE ≥6) were likely to have a significant improvement in a greater number of health domains following surgery than the low- and medium-risk group (EuroSCORE <6).

Finally, a study conducted by Loponen et al. in 2008 investigated whether EuroSCORE is a predictor of HRQoL at six, eighteen and thirty six months after CABG. They used the 15D, a non-disease-specific measure, to assess HRQoL. They used both logistic and additive EuroSCORE scoring methods, and found that both the additive EuroSCORE and logistic EuroSCORE correlated significantly with HRQoL at 6, 18, and 36-month, but were predictors of 15D only at 36 months follow-up. Furthermore, there was a similar clinically significant increase in the 15D score among the risk groups at 6 and 18 months, but tended to decrease towards 36 months in the medium- and the high risk group. Regarding the predictive power of the EuroSCORE, they found that EuroSCORE was associated with longer ICU stay, longer total hospitalization and more complications.

Despite the fact that it is hard to compare the findings of these studies to our study, because of different designs and tools that were used to measure HRQoL, the previous findings only confirm our findings regarding the ability of EuroSCORE to discriminate between low, medium and high risk classes regarding LOS and number complications. Yet, we also add to the knowledge that EuroSCORE is a predictor of physical functioning, but not of poor mental functioning.

### 7.2.3 Predictors of deterioration after CABG

Our findings showed that, even though the majority of patients experienced improvements in HRQoL, also referred to as health related functional status (HRFS), following CABG, 20-30% of patients experienced no benefits in HRQoL, which is in line with the findings of some other studies. Currently, it is still evident that, so far, little attention has been paid to deterioration, as after performing a search for the latest articles relating to deterioration in HRQoL in 2007-2008, we found that a small number of articles mentioned the issue of deterioration in HRQoL after CABG. The study by Merkouris and colleagues, used the MacNew Heart disease questionnaire to measure HRQoL at 4 and 12
months post CABG and they found that around 19.6% of their sample experienced deterioration. The second article by Charlson and associates evaluated patients using the SF-36 and found that functional deterioration ranged between 31.6% and 29.6% in both the study groups undergoing cardiac surgery.

Kapetanakis and associates used the SF-36 to assess HRQoL at 6 months after on pump and off pump CABG, and found that 13.8% of patients in the off pump method reported a decrease in their physical scores in comparison to 17.3% in the on-pump CABG group. Regarding postoperative change in mental scores, 10.3% in the off-pump patients reported deterioration compared to 9.3%, reporting deterioration in the on pump group.

Likewise, they found that hypertension and multivessel CAD were independent predictors of worse physical scores, whilst diabetes was associated with an improved sum physical component score after CABG regardless of the surgical approach.

In our study, patients reporting deterioration in HRQoL were more likely to have a history of angina and these patients also reported deterioration in levels of anxiety and depression post CABG. Anxiety and especially depression are well-known CAD risk factors and predictors of the course of the recovery process after MI. Both indicators of psychological distress are considered to have a negative effect on HRQoL in patients with CAD, with depressive symptoms having a greater influence compared to ejection fraction and ischemia. In CABG patients others have also found that increased symptoms of depression were predictors of no improvement in mental sum scores of the SF-36. In addition, depressive symptoms have been shown to have a negative effect on HRQoL regardless of successful medical and surgical treatment.

The results of the structural equation model highlighted the role played by the Type D personality and the effect of anxiety and depression. The model showed that the relationship between Type D and deterioration/no change in HRQoL was mediated by deterioration/no change in anxiety and depression.

We also found that Type D had a direct relationship to deterioration/no change only in mental and not physical HRQoL, but unexpectedly the results of the multivariable logistic regression analysis showed that Type D personality was not an independent predictor of deterioration/no change in HRQoL. This finding is contradictory to previous studies of CABG patients and patients treated with percutaneous coronary intervention (PCI) or an implantable cardioverter that identified Type D as an independent predictor of poor HRQoL.

However, the introduction of Type D personality to our model shed a light on the interceding effect of anxiety and depression between Type D and deterioration/no change in HRQoL. This adds to our knowledge of the role of
Type D personality and psychological distress as determinants of deterioration in HRQoL as a patient-centered outcome.

It is also worthy to mention that in this study we used standardized mean differences or effect sizes (ES) in case of statistical significance differences over time between baseline and follow-up to classify subjects as stable, improved or deteriorated and that we used widely accepted thresholds for effect size. The later subgroup of deteriorated patients was unlikely to have been identified by traditional methods, such as looking at changes in mean scores over time. Such an approach would mask intra-individual changes, whereas the approach used in the current study (i.e. the effect size statistics) is independent of measurement units and allows for comparing different outcomes. In addition, ES can be applied both to group data and to those from a single patient.

There have been other methods used to detect change, that are different from our approach, as an example in the study of Mueller and colleagues showed, where they simply tagged “negative” signs of the change scores as indicators of deterioration, while not taking into account that these negative scores may comprise trivial changes (i.e. change found by random variation).

In addition, a study by Hawkes et al., determining deterioration in CAD patients, used the suggestion of the SF-36 scoring manual, that an individual five-point change over time in the eight subscales was clinically and socially relevant. This was done despite the fact that (1) this five-point criterion was based on an American sample assessed some thirteen years ago, that (2) these five points were based on no clear definition of what constitutes a clinically meaningful change and that (3) these five points were likely to be biased by cultural and semantic differences between the original and translated SF-36.

7.2.4 Effect of positive affectivity on cardiac related health complaints after CABG

This study was conducted to examine the role of positive affectivity (PA) on health complaints in patients with CAD in general and in CABG patients in particular. The study of PA has generally been neglected in CAD with the primary focus being on negative emotions, in particular depression, and their influence on health outcomes.

As a consequence, little is known about the influence of positive affect in the case of CAD. Although earlier PA has been related to cardiovascular disease-related pathways, including inflammation and hypercortisolemia, in healthy subjects. Currently, few articles addressed this issue, for example the role of positive affectivity was presented in a recent study of patients treated.
with PCI where decreased PA was found to be an independent predictor of adverse clinical events, with increased PA exerting a strong protective effect\textsuperscript{110}. In our study, we found that low PA was associated with both increased cognitive and somatic complaints in patients undergoing CABG surgery, with particularly young patients with low PA reporting more cognitive health complaints, despite younger patients compared to older patients in general having a better clinical risk profile, as indicated by a lower EuroSCORE. These findings highlight the effect of positive affectivity and age on cardiac related health complaints in CABG patients; they show the importance of assessing positive and negative affectivity of patients before surgery.

### 7.3 General methodological considerations

Several methodological issues relating to the studies presented in this thesis merit further discussion and clarification including: the study sample, the design, the assessment point and other general considerations.

#### 7.3.1. Selection bias

Participants in this study were consecutive patients, undergoing CABG surgery (n=168; 80% males; mean (SD) age=64.49 (10.09)), between April 2005 till September 2006 at the University Medical Center Groningen (UMCG) and HAGA Hospital in The Hague, The Netherlands. The criteria for exclusion were incapacitating diseases, cognitive impairments, aged 80 and older, or insufficient proficiency of Dutch language.

Thus, we included patients from both a university hospital (UMCG) and a peripheral hospital (HAGA), which might have aroused questions regarding the differences between the two populations. We tested for differences between both groups and we found that no statistically significant differences between the two groups on e.g. age, sex, and the EuroSCORE, but regarding postoperative events, there was a higher prevalence of re-exploration for bleeding in the university hospital sample and a longer LOS following surgery (Chapter 3 and 5).

At baseline, the pathway and conventional care group differed in terms of marital status, level of education, receiving inotropic support and hours on mechanical ventilation postoperatively. According to Cohen's effect size "w" for difference in proportions, these differences were small\textsuperscript{111}. However, later we matched CP and conventional care patients on EuroSCORE, age and sex at group level.

Furthermore, (in Chapter 4) we used a regression analysis and included being in a UMCG or a peripheral hospital as an independent determinant of HRQoL, and we found that being a patient in the HAGA hospital or the UMCG was not a
predictor of HRQoL. Additionally, we found that re-exploration for bleeding and LOS were not found to predictors of HRQoL (physical component summary and mental component summary of the SF-36), yet, re-exploration for tamponade or bleeding was associated with vitality and mental health, which are two of the components of the mental scale of the SF-36.

The response rate at baseline was 77.3% (198/256), and by comparing included patients with non-responders, no differences were found between both groups except with regard to gender ($\chi^2 = 4.85$, df = 1; $p = .03$) with 33.3% vs. 21.2% females, respectively. Compared with the study baseline sample, drop-outs at follow-up did not differ systematically on gender ($\chi^2 = 1.63$, df = 1; $p = .20$) and marital status ($\chi^2 = 1.81$, df = 1; $p = .18$) nor on mean differences on age (66.1 ± 10.09 vs. 64.59 ± 9.95; df = 196; $p = .45$).

7.3.2. The study design and assessment points

We used a longitudinal, quasi-experimental pre-test/post-test design to study and compare clinical outcome, HRQoL, depression and anxiety for CP patients versus conventional-care patients six months after CABG. A conventional randomization procedure was considered inappropriate. Randomizing individual patients (or surgeons) to either a CP or conventional care within the same hospital invites contamination, because many of the same doctors, as well as care staff, are involved in treating the same population of patients, which also made blinding impossible.

Nevertheless, the assessment of patients’ outcomes was done in ignorance of the method of care they were receiving. We therefore used a pre-pathway implementation control group and applied the CONSORT criteria\cite{112-114} for the reporting of randomized controlled trials finding this the best way to obtain information from this study.

On the other hand, given that we used a prospective design, which is strongly recommended for questions regarding prognosis, or etiology and harm\cite{115}, we only included patients with complete questionnaires at both baseline and 6 months follow-up. Thus, analyses were based on 168 patients.

Evaluating outcomes at six months time interval post CABG is criticized and considered some what controversial and labeled as “early phase”\cite{116-118}, however, this criticism is mainly for detecting mortality and not HRQoL, as several studies have evaluated HRQoL at six months and three months and detected significant results\cite{40,119-125}.

Regarding the study of deterioration and assessment of change, it is vital to mention that in this study we used standardized mean differences or effect sizes (ES) between baseline and follow-up to classify subjects as stable, improved or deteriorated and that we used widely accepted thresholds for effect size, and
only statistical significant changes overtime were expressed in standardized mean differences and trivial scores of -.20 to .20 were classified as unchanged after CABG.

Other studies used different methods\textsuperscript{106}, where they simply tagged “negative” signs of the change scores as indicators of deterioration, while not taking into account that these negative scores may comprise trivial changes (i.e., change found by random variation), or just used the suggestion of the SF-36 scoring manual, that an individual five-point change over time in the eight subscales was clinically and socially relevant\textsuperscript{41}, but the limitation here was that a longer follow-up of up to one year would have provided more information on the long-term progression of psychological distress and HRQoL\textsuperscript{126,127}.

7.3.2.2. Information bias of tools and measures

With regards to the postal survey, we sent out at baseline (i.e., prior to surgery) and 6 months after CABG to 256 patients, we were able to minimize non-response rate and missing values of scales by monitoring the completeness of the questionnaires by checking that all the questions were answered at baseline as well as at follow-up. If a page was not filled in, a copy was sent with a request to please complete the questions or, if it concerned one or fewer questions, patients were interviewed by telephone. Because the completeness of the questionnaire was monitored by a computer program both at baseline and follow-up, we effectively reduced the non-response on questions and, consequently, on scales. The tools used in our study to assess different outcomes of patients have been widely used and validated in several studies. The patients in our study were classified as low, medium or high risk with the EuroSCORE (1) low (additive score of 0-2), (2) medium (scores 3-5), and (3) high risk (scores 3-5). The EuroSCORE have received some criticism about it’s validity in predicting mortality, but it has been validated as risk stratification model that predicts early\textsuperscript{76-78}, and late mortality\textsuperscript{128-131}, in addition to other related outcomes like LOS, and complications\textsuperscript{132,133}, costs\textsuperscript{134}, and, recently, HRQoL\textsuperscript{79,81,135} in cardiac surgical patients, and has been validated in different populations\textsuperscript{77,82,136,137} and several studies\textsuperscript{80,128,130,138-148}.

For evaluating QoL (also referred to as functional status), we used a generic HRQoL measure (SF-36), which is also a valid, reliable and widely used generic measure of HRQoL, that has been used in a myriad of studies investigating the impact of CABG on HRQoL\textsuperscript{40,42,72,79,84,94,95,122,124,127,149}. On the other hand, the question may arise concerning the use of other disease specific tool, like the Seattle angina questionnaire or The MacNew Heart Disease HRQoL instrument, as they are more sensitive than generic tools\textsuperscript{150}, but, unfortunately, by the time we started our research, there was no validated Dutch version of
these tools, but later the MacNew questionnaire was validated in the Dutch population\textsuperscript{151}.

As regards PD (anxiety and depression) we used the Hospital Anxiety and Depression Scale (HADS)\textsuperscript{152}. This measure of PD has been evaluated on its psychometric quality in many (international study populations). The HADS is a reliable and valid questionnaire, that performs well in screening for the separate dimensions of anxiety and depression\textsuperscript{153}, and has been used in several studies investigating outcomes of CAD and CABG\textsuperscript{127,154-157}.

Moreover, Type D Scale (DS14) was also administered prior to surgery to assess the distressed (Type D) personality\textsuperscript{158}. The DS14 is comprised of two normal and stable personality traits, negative affectivity (e.g. ‘I often feel unhappy’; 7 items) and social inhibition (e.g. ‘I am a closed kind of person’; 7 items). This measure of psychological distress has been evaluated on it’s psychometric quality in different populations including Danish and Dutch cardiac patient samples. A recent study in a large sample of MI patients showed that Type D is a stable measure over an 18-month period and is not confounded by cardiac disease severity and measures of anxiety and depression\textsuperscript{159}. Recently, the effect of Type D on outcomes of CAD, PCI and CABG has been established in a number of articles\textsuperscript{94,156,160,161}.

Furthermore, PA was measured using the positive affect subscale of the Global Mood Scale (GMS)\textsuperscript{44}, which was administered prior to surgery. The GMS has been shown to be sensitive to treatment-related changes in both negative and positive affect in cardiac patients\textsuperscript{162} and to be associated with stress, depression, fatigue and quality of life in a working population\textsuperscript{109}, although is has been neglected as a contributing factor that might be a factor associated with adverse effects related to CAD or cardiovascular invasive procedures\textsuperscript{109,110}.

Lastly, the Health Complaints Scale (HCS), which is a disease specific measure pertaining to cardiac complaints, was administered twice, namely prior to surgery and at 6 months follow-up\textsuperscript{163}. The scale is a disease-specific measure developed in cardiac patients, with the 12-item cognitive complaints subscale representing ‘health worry’ and ‘illness disruption’ (e.g. “The idea that I have a serious illness”) and the 12-item somatic complaints subscale representing ‘cardiopulmonary’, ‘fatigue’ and ‘sleep’ problems (e.g. “Tightness of the chest”)\textsuperscript{163}. The HCS has been shown to be a valid and reliable measure both in Belgian and Danish cardiac patients\textsuperscript{163,164}. The HCS is also a sensitive outcome measures for tapping treatment and cardiac rehabilitation related changes\textsuperscript{155}.
7.4. Strengths and limitations

Each presented chapter had strengths and limitations, which we summarize in this section.

In Chapter 3, the strength of this study lies in the fact that we compared outcomes of a CP with a control group under conventional care and controlled for potential confounders, namely age, gender and EuroSCORE, through matching at group level. The limitations of the study lie in the fact that (1) randomizing individual patients (or surgeons) to a CP or conventional care in the same hospital was inappropriate, as this would induce contamination bias; (2) at the start of the current study there was no controlled study that evaluated the effects of CP on HRFS, which therefore made it impossible to perform a power analysis.

In Chapter 4, where we investigated whether EuroSCORE was a predictor of HRQoL after CABG. Despite of sending reminders the non-response rate at baseline was approximately 23%, and compared to the study sample, non-responders differed for gender, since more females declined to accept the invitation to participate, which may have led to an under-representation of females. The strengths of the study lie in the fact that non-responders and excluded patients (excluded due to age over 80) did not differ from responders in their demographic and clinical baseline characteristics. Moreover, during follow-up, as compared to the study sample, dropouts did not differ for age, gender or marital status. In addition, we used the standardized SF-36 questionnaire, which is an established measure to assess HRQoL.

In Chapter 5, which addressed the predictors of deterioration in HRQoL, the strength of the study is that we used standardized mean differences (ES) between baseline and follow-up to classify subjects as stable, improved or deteriorated with widely accepted thresholds for effect size, but the limitation lies in the fact that a longer follow-up of up to one year would have provided more information on the long-term progression of psychological distress and HRQoL.

In Chapter 6 concerning the role played by positive affectivity, although no statistically significant differences between the two groups were found on demographic characteristics and the EuroSCORE, in postoperative events, there was a higher prevalence of re-exploration for bleeding in the university hospital sample and a longer LOS in hospital following surgery. Furthermore, we had no information regarding medication (both cardiac and psychotropic), nor knowledge concerning participation in cardiac rehabilitation and whether patients were being treated by a psychologist or a psychiatrist, which may serve as potential confounders on outcome. Also, clinical data were only collected prior to surgery and not during the follow-up period. Therefore, we were not able to...
examine the potential influence of changes in cardiac symptoms during the follow-up period on health complaints at 6 months. Moreover, the follow-up period was relatively short, extending to only 6 months. Hence, the results of this study should be replicated using a longer follow-up period. Yet, this study also has some strengths, including its focus on positive affect, which is new in the field of CAD, its prospective design, the use of a disease-specific outcome measure (i.e. the HCS), and the adjustment for potential confounders both of a demographic, clinical, and psychological nature.

7.5 Implications for practice and research.

The findings of this thesis have implications for both practice and research

7.5.1 Implications for clinical and nursing practice

Due to the multidisciplinary nature of CPs the results of this study have implications for policy, practice and health care personnel involved in health care planning, coordination and delivery, i.e. cardiac surgeons, case managers, critical care/cardiothoracic surgery nurses, and cardiologists. The designing and implementation of CPs is carried out by the multidisciplinary team, but nurses play a major role in implementing the pathway, delivering patient education and preparing patients for discharge. In addition, nursing case managers are responsible for coordinating the planning and designing of pathways. It is particularly of importance for nurses and health care personnel, involved in delivering care to CABG surgery patients, to recognize the factors affecting the outcomes of these patients. Therefore, we recommend that implementations of pathways should not be for the sole purpose of decreasing LOS and costs, but rather focus on improving quality of care by designing the pathways to be based on acuity of illness, i.e. different pathways for low, and high risk patients, as it was found that pathways are more successful in younger patients with lower severity of illness\textsuperscript{50,165-167}.

We previously stated that pathways were judged to be mainly addressing “the ideal patient”\textsuperscript{46,168}, who would fit perfectly into the plan and reach the designed goals without deviation. Thus, we agree with the view pointing out that pathways are more expected to be useful when implemented in areas of lower severity/complexity of illness, or patients who are not psychologically stressed, because pathways tend to be somewhat nonflexible and leaning toward patients with the expected course of care i.e. “the ideal patient”, they may not work well where care is more variable, and challenging setting as the Intensive care unit, or an emergency unit\textsuperscript{46,165,167}.

Moreover, patient-related characteristics and psychological status should be taken into consideration, which may require a health-psychologist to become a
routine member of the pathway team and incorporate protocols, that tend to manage anxiety and/or depression related to illness or pending surgery. Another issue that is worthy to mention is that the educational material and patient education program or interactive sessions should take into consideration patients level of education, socioeconomic status and anxiety level, as in our study there was over-representation of patients with elementary schooling compared to patients in the conventional care groups, which might explain why patients in the pathway group experienced higher anxiety levels than patients in the conventional care group.

**EuroSCORE and HRQoL**

The significance of our findings in Chapter 4 lie in the fact that poor physical functioning is a reflection of perceived limitation in performing all physical activities, such as having difficulties bending, stooping or lifting light objects, lifting heavy objects, climbing stairs, walking a (long) distance, bathing or dressing. Such a finding has an implication for clinical practice and for the role of health care personnel, including cardiologists, cardiac surgeons and nurse practitioners. This is because, although the development of risk models has led to the appropriate selection of patients for CABG, there are limited data available to help clinicians to predict which patients will experience an improved HRQoL after CABG. The findings of our study indicate that EuroSCORE can be used to predict health status after CABG, which will help communicate to patients what level of improvement can be expected after surgery. Risk stratification is an essential component of optimizing care in terms of recommending the most appropriate treatment strategy along with efficient patient and family counseling. It should be feasible to include the assessment of HRQoL in clinical practice, and we recommend that, in order to provide patient-centered care with effective counseling, self-reported HRQoL must be considered as part of, and integrated into, the process of diagnosis and management of the patient’s illness.

**Predictors of deterioration**

These findings have a significance to practice, as the knowledge of the predictors of deterioration/no change in patient-centered outcomes, such as HRQoL, and the role played by anxiety, depression and Type D personality is important in order to optimize care and the medical management of these patients. Poor HRQoL has also been associated with increased risk of mortality and morbidity in CAD patients. These patients should be identified at an early stage. This would enable health care professionals to provide them with more emotional and
psychological support before and after surgery, and help them cope adequately with the postoperative period and improve their HRQoL.

**Positive affectivity and health complaints**

The findings of this study have implications for practice as cardiac rehabilitation should not only target negative emotions, but also seek to increase positive affect, as poor self-reported health is a predictor of adverse prognosis and re-hospitalization in patients with CAD. If rehabilitation can enhance positive affect, this may lead to a reduction in health complaints and improvement in QoL and subsequent prolonged survival.

**7.5.2 Implications for future research**

**Clinical pathways evaluation**

In relation to future research there is a great need for more multicenter RCTs, since it is evident that the increased trend of using pathways is still disputed as very little controlled data confirmed their efficiency. Moreover, it is of importance to incorporate important outcomes as HRQoL, functional status and psychological distress as part of the pathway evaluation.

Incorporating HRQoL and psychological distress measurement, as part of a routine assessment of patient health, both pre- and postoperative, which can be easily done by cardiothoracic surgery nurse, will provide a clear view of the patient’s perception of his physical functioning and mental health, which will, in turn, have a great impact on planning care before and after surgery, which might, subsequently, improve HRQoL.

**EuroSCORE and HRQoL**

Future research is required with a larger sample and there is a need to assess the difference between a disease-specific measure, e.g. The cardiac Health Complaints Scale (HCS), and a generic measure, e.g. SF-36 or Nottingham health profile, in predicting QoL of CABG patients stratified by risk-class, in order to compare the relative validity of these measures\textsuperscript{150}.

**Deterioration after CABG**

In relation to future research, more studies with a longer follow-up are required to investigate the role played by PD and Type D personality and their effect on HRQoL of CABG patients.
Positive affectivity and health complaints

Regarding future research, clinical data should be collected prior surgery and during the follow-up period, in order to examine the potential influence of changes in cardiac symptoms during the follow-up period on health complaints and we also recommend a longer follow-up period. It is also important to adopt a PA approach in clinical research and practice, and not just study the role of negative emotions, because patients are less likely to recognize themselves in terms of negative emotions alone. Thus, including PA in psychosomatic research may increase the study compliance rate, simply because patients can identify with the questions being asked.

7.6. General conclusion

This thesis is aimed at presenting the different factors affecting HRQoL after CABG in the frame of the conceptual model based on the model of Wilson and Cleary and the modifications of Spertus and Rumsfeld. We presented the effect of an environmental factor, i.e. care in the hospital setting in Chapter 3, which was mainly concerned with the effect of implementing the CP. Then, the effect of risk factors and clinical variables were shown in Chapter 4, while the effect of personality traits and PD were presented in Chapter 5 and, finally, we investigated the effect of PA on cardiac specific health complaints Chapter 6.

Regarding the use of risk stratification models, it is clear that they can be used to predict other outcomes of patients and not just mortality, and that using risk stratifications models to predict HRQoL should become incorporated in the routine preoperative assessment of patients. Furthermore, attention should be paid to all the factors associated with deterioration in HRQoL, including factors that were not fully investigated, as anxiety, depression, personality traits Type D, positive and negative affectivity, using disease-specific measures, such as cardiac-related health complaints scale.

The main issue is that pathways were originally designed to decrease LOS in order to decrease the costs associated with hospital stay, but it was not the case here; LOS did not decrease and the causes can be attributed to patients (occurrence of complications) or can be attributed to organizational factors as the health insurance system in the Netherlands is different from the US, and the way that health insurance companies reimburse health care facilities is also somewhat different, and that might be a reason why the decrease in LOS could not be detected.

On the other hand, the CP system might be successfully implemented in Egyptian governmental, university and health insurance hospitals, where CABG is performed, as it is a very expensive procedure, as the government covers the costs of surgery and patient care. It is obvious that more controlled
studies with a larger sample is needed to detect the effect of CP on organizational and economical outcomes.

Finally, self reported HRQoL measures are strong and valuable outcome, that reflect and evaluate the effect of CABG and methods of care delivery, and we strongly recommend that it should be incorporated in the routine assessment of patients before and after surgery, as it is a reflection of patients’ perception of their own health. Such research is needed specially in the field of critical care nursing, as it is beneficial in detecting the effect of critical illness, complicated procedures and care on outcomes of critically ill patients.
7.7 Reference List


142. Keogh BE. Logistic, additive or historical: is EuroSCORE an appropriate model for comparing individual surgeons' performance? Heart 2006; 92(12):1715-1716.


