Effect of clinical pathway implementation and patients’ characteristics on outcomes of coronary artery bypass graft surgery

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CHAPTER 1 | INTRODUCTION
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General introduction, aims and outline

Coronary artery bypass graft (CABG) surgery is one of the most frequently performed cardiac surgical procedures with unquestionable benefits, aimed at relieving anginal symptoms and improving health related quality of life (HRQoL). In the past decades, there has been a great development in the methods of delivering care to CABG patients, one of which was the introduction of a clinical pathway. A clinical pathway (CP) is a method of delivering care that was developed in the 1980’s in the United States and since then it has been widely used in other parts of the world. Recently, the use of CP as a method of delivering care was initiated and introduced at the University Medical Center Groningen (UMCG) in the Netherlands, where the Thoracic Surgery department, UMCG, implemented a clinical pathway for patients undergoing CABG.

This study was undertaken to investigate the effect of CABG pathway on the patients’ outcomes. The outcomes investigated were length of stay (LOS), readmission and complications and outcomes that were rarely examined when evaluating the effects of CABG pathways, such as health-related quality of life (HRQoL) and psychological distress (PD), i.e. anxiety and depression. Existing studies evaluating the effect of clinical pathways on outcomes of patients were mainly of poor methodological quality. These studies also concentrated on evaluating organization related outcomes, e.g. LOS and costs, and few articles investigated the effect of CPs on patients' related outcomes, like complications, HRQoL, and psychological distress. Therefore, the aim of our study was to investigate the effect of implementing the CABG pathway plan on patient related outcomes compared to patients in a conventional care plan. The significance of the current study lies in the fact that it is a controlled study and we investigated patients’ outcomes that were mainly rarely addressed by studies evaluating the effect of pathways, e.g. HRQoL and psychological distress. Furthermore, this study also reports on the role played by the EuroSCORE on predicting outcomes other than mortality, e.g. functional status, LOS, and postoperative complications. Moreover, we are presenting the effect of other patients’ characteristics that can affect the desired outcomes of CABG surgery as Type-D personality, and psychological distress (anxiety and depression), and lastly the effect of positive affectivity on cardiac related health complaints after CABG.

In this chapter, we also present an overview of the epidemiology and pathophysiology of coronary artery disease (CAD) in order to present an outline of the disease process and the development of anginal symptoms which in turn
affect patients’ functional abilities. In addition, this introductory chapter presents the significance of HRQoL measurements in patients undergoing critical procedures, i.e. CABG, and reviews the process of development and evaluation of clinical pathways. Finally, at the end of this introductory chapter we present a conceptual model that we developed based on the conceptual model of Wilson and Cleary in 1995, which provided the basis for the research questions and the aims formulated.

1.1 Coronary artery disease

1.1.1 Epidemiological data
Coronary artery disease (CAD) is a leading cause of mortality and morbidity in the developed world. It involves the narrowing or total occlusion of the arteries that provide oxygenated blood and nutrients to the cells of the heart as a result of plaque forming on the lining of the arteries by the atherosclerotic process. In the Netherlands, according to the Dutch Heart Foundation, the incidence of cardiac infarction in 2004 in men was 32,000 and in women 36,000. Furthermore, it was found that the prevalence of ischemic heart diseases in both men and women ≥ 55 years was 277,300 in 2004, while mortality due to ischemic heart disease constituted 32,5% among the other diseases causing mortality in 2003.

The concept of ‘burden of disease’ combines mortality and morbidity into a single indicator denoted as the Disability Adjusted Life Years (DALYs). According to the Atlas of heart disease and stroke, the disability-adjusted life years lost, can be thought of as healthy years lost to a disease, and they indicate the total burden of disease as opposed to simply the resulting deaths. By comparing the data from the Netherlands with Egypt regarding DALYs, we may conclude that the burden of CAD in Egypt is three times higher compared to the Netherlands.

1.1.2 Pathophysiology
CAD is a chronic process that begins early in life, particularly during adolescence, and slowly progresses throughout life. The main cause of CAD is the development of atherosclerosis. The word Atherosclerosis originates from the Greek words athera meaning gruel or paste or porridge and sclerosis meaning hardness. Risk factors of CAD include: older age, male gender, family history of premature coronary artery diseases, cigarette smoking, diabetes mellitus, hypertension, hyperlipidemia, inactive lifestyle, obesity and as well as stressed personality behavior. These risk factors accelerate a complex and chronic inflammatory process that manifests as fibrous atherosclerotic plaque. Recently, psychological distress presented in depression and anxiety were
also proven to be risk factors for the development of CAD, and poor prognosis\textsuperscript{12,13}.

1.2 Types of CAD
Coronary artery diseases can be classified into angina pectoris, myocardial infarction (MI) and acute coronary syndrome (ACS).

1.2.1 Angina pectoris
The word angina comes from the Latin word meaning ‘to choke’\textsuperscript{14}. Angina pectoris, however, is the term used to describe chest pain or discomfort that results from CAD. The patient may describe the sensation as pressure, fullness, squeezing, heaviness or pain\textsuperscript{15}.

Angina can be classified into\textsuperscript{16}:
1. Angina pectoris: which is an uncomfortable sensation in the chest and neighboring anatomic structures produced by myocardial ischemia. Angina pectoris is caused by temporary, reversible myocardial ischemia induced by an imbalance between myocardial oxygen demand and myocardial oxygen supply, which occurs as a result of atherosclerotic narrowing, arterial inflammation, and obstruction resulting from intense focal spasm of the coronary arteries. Other causes of unstable angina are fever, tachycardia and thyrotoxicosis leading to increased oxygen demand.
2. Stable angina which is a chronic pattern of transient angina pectoris, precipitated by physical activity or emotional upset, relieved by rest within a few minutes. Episodes are associated with temporary depression of ST segment, but it does not result in permanent myocardial damage.
3. Variant angina or angina inversa is a typical angina discomfort, usually at rest, that occurs in cycles and develops because of coronary artery spasm rather than an increase of myocardial oxygen demands. It is usually associated with ST segment elevation.
4. Unstable angina is a pattern of increased frequency and duration of angina episodes produced by less exertion or at rest, there is also a high risk of progression to myocardial infarction if untreated\textsuperscript{16}.

The severity of anginal symptoms can be classified either by New York Heart Association Functional Classification\textsuperscript{17} or Canadian Cardiovascular Society Functional Classification\textsuperscript{18}. The New York Heart Association (NYHA) Functional Classification places patients in one of four categories based on how much they are limited during physical activity; the limitations/symptoms are in regards to normal breathing
and varying degrees in shortness of breath and or angina pain. NYHA Class Symptoms are classified into: Class (I) No symptoms and no limitation in ordinary physical activity; Class (II) Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity; Class (III) Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g. walking short distances (20-100 m), and comfortable only at rest; Class (IV) Severe limitations: experiences symptoms even while at rest; mostly bedbound patients.

Furthermore, the Canadian Cardiovascular Society Angina Grading Scale is also commonly used for the classification of severity of angina and it is classified as follows: Class (I) – Angina only during strenuous or prolonged physical activity; Class (II) – Slight limitation, with angina only during vigorous physical activity; Class (III) – Symptoms with everyday living activities, i.e. moderate limitation; and Class (IV) – Inability to perform any activity without angina or angina at rest, i.e. severe limitation.

1.2.2 Myocardial infarction
Myocardial infarction (MI) is the rapid development of myocardial necrosis caused by a critical imbalance between oxygen supply and demand of the myocardium. This usually results from plaque rupture with thrombus formation in a coronary vessel, resulting in an acute reduction of blood supply to a portion of the myocardium.

The size of the infarction is determined by factors such as extent, severity and duration of ischemia, the size of the vessel affected and amount of collateral circulation, the status of intrinsic fibrinolytic system, vascular tone, and metabolic demands of the myocardium at time of event.

MI mostly results in damage of the left ventricle, leading to compromise of left ventricular function. MI can also occur in the right ventricle or both ventricles. When all the tissues of the layers of the myocardium are necrotic it is called transmural infarction. As a result the pumping effect of the heart is affected which compromises cardiac output.

Signs and symptoms of MI: the onset of symptoms in MI is usually gradual, lasting several minutes, and rarely instantaneous. Chest pain is the most common symptom of acute myocardial infarction and is often described as a sensation of tightness, pressure, or squeezing. Pain radiates most often to the left arm, but may also radiate to the lower jaw, neck, right arm, back, and epigastrium, where it may mimic heartburn. Levine’s sign, in which the patient localizes his chest pain by clenching his fist over the sternum, has classically been thought to be predictive of cardiac chest pain, although a prospective observational study showed that it had a poor positive predictive value.
Shortness of breath (dyspnea) occurs when the damage to the heart limits the output of the left ventricle, causing left ventricular failure and consequent pulmonary edema. Other symptoms include diaphoresis (an excessive form of sweating), weakness, light-headedness, nausea, vomiting, and palpitations. These symptoms are likely induced by a massive surge of catecholamine from the sympathetic nervous system which occurs in response to pain and the hemodynamic abnormalities that result from cardiac dysfunction. Loss of consciousness (due to inadequate cerebral perfusion and cardiogenic shock) and even sudden death (frequently due to the development of ventricular fibrillation) can occur in myocardial infarctions. Complications that may arise include: recurrent MI, cardiogenic shock, ventricular septal wall rupture, left ventricular wall rupture, pericarditis, thromboembolism, dysrhythmias, and conduction disturbances caused by affection of sinoatrial (SA) and atrioventricular (AV) nodes.

1.2.3 Acute coronary syndrome

The terminology acute coronary syndrome (Figure 1.) is used to describe clinical symptoms compatible with acute myocardial ischemia and includes unstable angina and acute MI. Unstable angina refers to unexpected chest pain or discomfort that occurs at rest. Patients with MI are either those with ST segment elevation MI or non-ST segment elevation MI.?²²

![Acute coronary syndromes diagram]

**Figure 1. Clinical classification of acute coronary syndromes**

N QMI = non-Q wave myocardial infarction; NSTEMI = non-ST elevation myocardial infarction; Q wave MI = Q wave myocardial infarction; ST = ST segment of ECG tracing
1.3 Treatment of CAD

The aim of therapy in patients with angina is to restore the balance between oxygen supply and oxygen demand. This can be achieved by modification of risk factors, pharmaceutical therapy or invasive therapy.

*Pharmacological therapy* includes nitroglycerin, morphine, beta blockers, calcium antagonists and anti-platelet therapy. In case of MI, the medical therapy includes: thrombolytic therapy, oxygen therapy, nitroglycerine and morphine sulfate. *Invasive treatment* includes percutaneous coronary intervention (PCI) or (CABG).

*Cardiac rehabilitation*: one of the important aspects of treating MI is cardiac rehabilitation. The rehabilitation program begins by preparing patients for discharge following the initial treatment through education about the program which includes exercise, smoking cessation, lipid management, weight control, psychological intervention, blood pressure control and return to work. Family members are also included in the program, so they can learn about heart diseases and help achieve the goals of the program.

1.3.1 Non invasive treatment

Non invasive treatment of CAD is aimed at controlling symptoms and slowing or stopping the progression of disease. The method of treatment is based on many factors determined by symptoms, a physical exam and diagnostic testing. In many cases, if the blockage is less than 70 percent, medications may be the first line of treatment. Treatment includes modification of risk factors and medication. Risk factors of CAD are either modifiable e.g. smoking, stress, obesity, high blood cholesterol, high blood pressure, physical inactivity, diabetes mellitus, alcohol and high fat diet or non modifiable, e.g. increased age, male sex and heredity factors (including race). The medications used to treat CAD include: anticoagulants, which help in decreasing the clotting (coagulating) ability of the blood, help to prevent harmful clots from forming in the blood vessels and may prevent the clots from becoming larger and causing more serious problems. Antiplatelet agents most commonly prescribed is Aspirin which keeps blood clots from forming by preventing blood platelets from sticking together in patients who have had a heart attack, unstable angina, ischemic strokes, or transient ischemic attacks. Angiotensin II Receptor Blockers (or Inhibitors) prevent this angiotensin from having any effects on the heart and blood vessels, and prevent rise in blood pressure. Moreover, Beta Blockers which act to decrease the heart rate and cardiac output, subsequently lowering the blood pressure and making the heart beat at a slower rate and with reduced force, Calcium Channel Blockers interrupt the movement of calcium into the cells of the heart and blood vessels, which
decreases the heart’s pumping strength and relaxes blood vessels, thus lowering
the blood pressure and chest pain related to reduced blood supply. Diuretics help
the body to rid itself of excess fluids and sodium through urination, which
relieves the heart's workload, decrease blood pressure and edema. Vasodilators
relax blood vessels and increase the supply of blood and oxygen to the heart,
while reducing its workload leading to relief of chest pain. Digitalis increases
the force of the heart's contractions, which can be beneficial in case of heart
failure and for irregular heart beats. Finally, statins are also prescribed to
lower blood cholesterol level\textsuperscript{15,19,25}.

1.3.2 Invasive treatment of CAD

1.3.2.1 Types of Invasive treatment
Treatment generally aims to reduce cardiac workload, improve coronary artery
blood flow, and, over the long term, slow down and reverse the atherosclerotic
process. Coronary blood flow can be improved by PCI or CABG, our main
concern in this study is CABG surgery.

Coronary artery bypass graft surgery
The indications of CABG are listed in Table 1. according to the guidelines
established by the 2004 American College of Cardiology (ACC) and American
Heart Association (AHA).
In CABG, native vessels or conduits are ‘harvested’ during the initial phase of
surgery to reroute or bypass blood flow past diseases areas of coronary arteries.
The first saphenous vein aortocoronary bypass graft was performed in 1964.
Since then, the use of CABG has become an acceptable treatment for CAD.
Selection of the graft or conduit depends on the diameter similar to coronary
arteries, absence of disease or wall abnormalities, and adequate length. The
commonly used grafts are saphenous vein grafts, internal mammary artery
grafts, radial artery, and right gastroepiploic artery. After one year, about 85%
of the venous bypass grafts are patent, but after ten years, as many as 97% of
the internal mammary artery grafts are patent. Arteries show hypertrophy to
accommodate the increased blood flow, where veins do not.
CABG has proved to be effective in relieving angina and improving exercise
tolerance, and it prolongs life in patients with left main CAD and three vessels
disease with poor left ventricular function. To decrease mortality associated
with bypass surgery, it is necessary to consider several factors: urgency of
operation, age, previous heart surgery, sex, left ventricular ejection fraction,
percentage of stenosis of the left main coronary artery, and the number of major
<table>
<thead>
<tr>
<th>Class I (procedure is useful and effective)</th>
<th>Class IIa (opinion is in favor of usefulness/efficacy)</th>
<th>Class IIb (usefulness/efficacy is less well established)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST-elevation MI (STEMI)</td>
<td>- Persistent or recurrent ischemia</td>
<td>- Non candidates for PCI or fibrinolysis within 6-12 hours of evolving STEMI</td>
</tr>
<tr>
<td></td>
<td>- Hemodynamic instability if PCI fails</td>
<td>- Cardiogenic shock as noted in Class I but age &gt; 75</td>
</tr>
<tr>
<td></td>
<td>- Patient is not a candidate for PCI</td>
<td>- None</td>
</tr>
<tr>
<td></td>
<td>- Cardiogenic shock developing within 36 hours of STEMI if CABG is possible within 18 hours of developing shock (age &lt; 75)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Life threatening ventricular arrhythmias with left main ≥ 50% or 3 vessel disease (VD)</td>
<td></td>
</tr>
<tr>
<td>Unstable angina/ Non-ST-elevation MI</td>
<td>- Left main coronary artery stenosis ≥ 50%</td>
<td>- Proximal LAD with 1.2 Vessel Disease (VD)</td>
</tr>
<tr>
<td></td>
<td>- Left main equivalent ≥ 70% in proximal left anterior descending artery (LAD) and circumflex artery</td>
<td>- 1.2 VD not involving LAD</td>
</tr>
<tr>
<td></td>
<td>- Refractory ischemia on maximal medical therapy</td>
<td></td>
</tr>
<tr>
<td>Stable angina</td>
<td>- Left main ≥ 50%</td>
<td>- Proximal LAD with 1 VD</td>
</tr>
<tr>
<td></td>
<td>- Left main equivalent</td>
<td>- 1.2 VD without proximal LAD with moderate area of ischemic myocardium</td>
</tr>
<tr>
<td></td>
<td>- 3 VD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 2 VD with &gt; 70% proximal LAD and EF &lt; 50% or + exercise tolerance test (ETT)</td>
<td>- None</td>
</tr>
<tr>
<td></td>
<td>- 1.2 VD without proximal LAD but large area of ischemic myocardium</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Refractory angina with - ETT</td>
<td></td>
</tr>
<tr>
<td>Condition</td>
<td>Description</td>
<td>Diagnosis</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>------------------------------------------------</td>
</tr>
<tr>
<td>Asymptomatic/Mild angina</td>
<td>Left main ≥ 50%</td>
<td>Proximal LAD with 1-2 VD</td>
</tr>
<tr>
<td></td>
<td>Left main equivalent</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 VD</td>
<td></td>
</tr>
<tr>
<td>Poor left ventricular function</td>
<td>Left main ≥ 50%</td>
<td>Significant viable, dysfunctional myocardium</td>
</tr>
<tr>
<td></td>
<td>Left main equivalent</td>
<td>with CAD other than noted at left</td>
</tr>
<tr>
<td></td>
<td>Proximal LAD 2-3 VD</td>
<td></td>
</tr>
<tr>
<td>Ventricular arrhythmias</td>
<td>Left main ≥ 50%</td>
<td>Emissary 1-2 VD</td>
</tr>
<tr>
<td></td>
<td>3 VD</td>
<td>Proximal LAD with 1-2 VD</td>
</tr>
<tr>
<td>Failed PCI</td>
<td>Ongoing ischemia or threatened occlusion</td>
<td>Foreign body in crucial position</td>
</tr>
<tr>
<td></td>
<td>Hemodynamic compromise</td>
<td>Hemodynamic compromise with coagulopathy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>if no previous streptothomy</td>
</tr>
<tr>
<td>Re-operation</td>
<td>Disabling angina on maximal medical therapy</td>
<td>Emissary arteries with large area of ischemia</td>
</tr>
<tr>
<td></td>
<td>No patent graft but Class I indications for surgery for native vessel disease</td>
<td>Atherosclerotic vein graft to left anterior</td>
</tr>
<tr>
<td></td>
<td>(Left main, left main equivalent, 3 vessel diseases)</td>
<td>descending artery or a large area of myocardium</td>
</tr>
</tbody>
</table>

LAD: left anterior descending artery, VD: vessel disease, NonSTEMI: non-ST segment elevations myocardial infarction, MI: myocardial infarction, EF: ejection fraction, ETT: exercise tolerance test, LV: left ventricular, CAD: coronary artery disease, PCI: percutaneous coronary intervention, ITA: internal thoracic artery, Left main equivalent disease: greater than or equal to 10% stenosis in both the proximal left anterior descending (LAD) and proximal left circumflex arteries, left main coronary artery stenosis: greater than 50% reduction in lumen diameter.
coronary arteries with greater than 70% stenosis.

Complications of CABG
CABG is typically performed during cardiopulmonary bypass with the heart stopped; a heart lung machine pumps the blood, removes carbon dioxide (CO\textsubscript{2}) and oxygenates the blood. The main risks of the procedure include stroke and MI. For patients with a normal-sized heart, no history of MI, good ventricular function, and no additional risk factors, risk is < 5% for peri-operative MI, 2 to 3% for stroke, and ≤ 1% for mortality; risk increases with age and presence of underlying disease. Operative mortality rate is 3 to 5 times higher for a second bypass than for the first; thus, timing of the first bypass should be optimal. After cardiopulmonary bypass, about 25 to 30% of patients develop cognitive dysfunction, possibly caused by micro-emboli originating in the bypass machine. Dysfunction ranges from mild to severe and may persist for weeks to years. To minimize this risk, some centers use a beating heart technique (i.e., no cardiopulmonary bypass), in which a device mechanically stabilizes the part of the heart upon which the surgeon is working.

Prognosis of CABG
CAD may progress despite bypass surgery. Postoperatively, the rate of proximal obstruction of bypassed vessels increases. Vein grafts become obstructed early if thrombi form and later (several years) if atherosclerosis causes slow degeneration of the intima and media. Aspirin prolongs vein graft patency. Continued smoking has a profound adverse effect on patency.

1.4 The role of nursing care in CABG surgery
The nursing care of patients is not limited to the postoperative period, but nurses are responsible for patients' care during preoperative and postoperative phases. The main focus during preoperative phase involves: history recording, physical examination, diagnostic procedures, preoperative teaching, including operative procedure, intensive care unit (ICU), invasive lines and recovery period. Postoperative care mainly includes transporting the patients to ICU, where they will recover from anesthesia and may remain for up to 24 hours after surgery.

This phase involves monitoring of vital signs, cardiac output, connection to mechanical ventilator, measuring end-tidal CO\textsubscript{2}, SpO\textsubscript{2}, peripheral pulses and perfusion signs, output of chest tubes and body temperature to prevent hypothermia. Once the patient is hemodynamically stable, urine output is measured and assessed, clinical data are obtained, chest radiograph, 12 lead ECG, routine blood work, assessment of neurological status and pacemaker
function. Furthermore, the patient is closely monitored for systematic inflammatory responses, severity and control of pain and prevention of complications.

The achievement of optimum patient outcomes following CABG surgery is the aim of health care providers involved in patient care, especially critical care nurses. In the past decades there has been a great focus on the use of managed care, due to increased costs and demand for high quality care. This presented a unique challenge for critical care nurses to integrate theoretical knowledge, assessment skills, and problem solving ability to provide optimal, high quality nursing care \textsuperscript{15,27}.

1.5 Outcomes of coronary artery bypass graft surgery

CABG is an established treatment procedure with clear benefits, including symptom relief, prolonged survival and improved health related quality of life. Studies evaluating the effect of CABG primarily concentrated on mortality rates, occurrence of complications and length of stay in the health care facility.

In the past decades there has been a great interest in the effect of both CABG the factors affecting HRQoL before and after the operation. Several studies were conducted to examine whether patient related factors \textsuperscript{28-36}, such as: (i) age, (ii) sex, (iii) educational level, (iv) type of work, (v) marital status and (vi) social support, or clinical variables such as: (vii) severity of illness, (viii) left ventricular ejection fraction (LVEF), (ix) multiple vessels diseases \textsuperscript{28,30,33,35,37} and recently the role of (x) psychological distress (anxiety and depression) \textsuperscript{31}, and (xi) type of personality \textsuperscript{38-40} affect the HRQoL of patients after CABG.

1.5.1 HRQoL in relation to critical illness

Over the last decades quality of life (QoL) has become an increasingly important concept in evaluating healthcare outcomes in several fields of critical care, including open heart surgery, which is considered a major surgery and the first few months after surgery are considered a critical and crucial period. Nevertheless, some clinicians disregard HRQoL measures as they perceive them as “soft” or “not as scientific” as physiological measures \textsuperscript{41}. However, health care personnel working in any critical or intensive care setting recognizes that a patient’s physical status at discharge is only a preliminary measure of success of therapeutic outcomes. Short term outcomes include changes in clinical status and improvement or relief of symptoms, while long term outcomes take into consideration the impact of hospitalization, undergoing a critical procedure (e.g. open heart surgery), and the nature of care the patient receives following surgery in ICU or intermediate care units on his HRQoL after discharge.
There is a need for longer period of assessment to evaluate the meaningful effects of the treatment received. In order to assure that clinical protocols have resulted in the required outcomes, symptoms relief and return to normal functioning. More importantly, a patient’s perception of his health is unique and the main factor in explaining and predicting outcomes. Thus, HRQoL measures should be advocated in critical care research. Currently, there has been a great interest in the effect of critical care and treatment on HRQoL. Several studies have attempted to address this issue and came up with the conclusion that HRQoL measurement is an important aspect of patient care, evaluation and follow-up.

1.5.2 CABG, HRQoL and related factors
Several studies investigated the effect of CABG surgery on HRQoL and also factors affecting HRQoL after CABG. Their findings were mainly that CABG improved HRQoL in the majority of patients and there were several factors that affected this outcome. These factors can be classified into patients related characteristics, e.g. age, female gender, marital status, type of work, personality trait, smoking habits, high alcohol intake and high socioeconomic deprivation, and biological and medical factors, such as diabetes mellitus, a body mass index of >35kg/m², chronic obstructive pulmonary disease, peripheral vascular disease, NYHA class at baseline, gastrointestinal problems, congestive heart failure, decreased forced expiratory pressure, LVEF, elevated serum creatinine, and health status at baseline, sleep problems, hypertension, infection, history of psychiatric diseases, postoperative events, like hospital readmission, and not following a rehabilitation program after CABG. Furthermore, mood disturbances and psychological aspects, like depression and anxiety, were also found to play a major role in affecting patients HRQoL undergoing CABG. It was reported that a higher score of depression at baseline has been shown to predict deterioration in mental HRQoL.

Risk stratification models for cardiac surgery, like the Parsonnet score and Cleveland Clinic score, were developed over the last few decades mainly to predict operative mortality. Currently, the European System of Cardiac-Operative Risk Evaluation score (EuroSCORE) is a widely used operative risk-prediction tool, that has been shown to be a valuable measure for prediction of operative mortality related to adult cardiac surgery. Higher levels of EuroSCORE were associated with increased in-hospital and thirty-day mortality, longer stay in the ICU and more frequent readmission. However, very few studies attempted to investigate whether risk stratification models, specifically EuroSCORE, can predict postoperative HRQoL.
1.6 The clinical pathway experience
The following section presents the history of CPs development and the use of CP in the UMCG, in addition to the process of designing, implementing and evaluating a CPs.

1.6.1 Early phases of CP development
In the early 1980’s critical pathways were developed in The New England Medical center in Boston, Massachusetts in the United States of America. CPs are also referred to as clinical pathway, integrated care pathway, care map, and multidisciplinary action plan. CPs have been developed in health care as multidisciplinary care plans that outline the sequence and timing of actions, necessary for achieving expected patient outcomes and organizational goals, regarding quality, costs, patient satisfaction and efficiency.
The concept of CPs refers to specific guidelines for care that describe patient treatment goals and define a sequence and timing of intervention for meeting those goals efficiently. They can also be defined as care plans that detail essential steps in patient care with a view to describing the expected progress of the patient\textsuperscript{69}. The use of CPs has become very popular in the past decades in a lot of diseases and surgical procedures. CABG pathway as designed contained the following components: assessment, consultations, rehabilitation, tests, treatments, activities, diet and nutrition, elimination, medications, education and counseling of patients and their families, and preparation for discharge.
The efficacy of CPs designed for patients undergoing CABG were mainly described in studies without randomized clinical trial design or did not use (matched) control groups\textsuperscript{70,71}. Studies that compared CP with standard care only evaluated the success of the pathway on decreasing length of stay and costs\textsuperscript{72,73}, but recently studies have shifted to evaluate the effects of CPs on other outcomes like readmission, complications, patients’ satisfaction, and quality of life\textsuperscript{74-76}. In a recent review article we recommended that more (randomized) controlled studies should be conducted in which patients are randomly assigned to the condition of either a pathway or conventional care, and that standardized tools should be used to measure important outcomes, like HRQoL, cardiac related complaints, anxiety and depression.

1.6.2 Clinical pathways in the UMCG
The department of Thoracic Surgery in the UMCG decided in the spring of 2004 to implement a CP for patients undergoing CABG surgery. Collaboration was started between the former Care Sciences Department at the Medical Faculty and the department of Thoracic Surgery to evaluate the effect of the clinical pathway on patient outcomes, including: physical and mental functioning
(overall HRQoL), quality of care, LOS, hospital waiting time till surgery, psychological stress, use of health services, patient expectation of care and staff job satisfaction. The process of developing, implementing and evaluating the clinical pathway is presented in Figure 2.

The Steering Committee
The formulation of the CP was overseen by a Steering Committee (stuurgroep) that planned the designing, and implementation of the CP. The Steering Committee consisted of: the head of the Thoracic Surgery Department, the nursing care manager of the Thoracic Center, the head of Anesthesiology and the coordinator of Thoracic Anesthesia.

The Committee provided support to determine what is needed to initiate the pathway, determine the needed resources, and direct all disciplines involved in the pathway. The Committee conducted a review of literature to evaluate existing LOS in the UMCG and also determined the best practice available. Next, the committee facilitated the setting of the actual team that developed the pathway and assisted the team in overcoming any difficulties. The project team included the head nurse of Thoracic Surgery, acute care nurse practitioner, staff nurse, physiotherapist, social worker and dietician. The Committee also determined that 8 days-CP was suitable for the patient population at the UMCG.

Furthermore, the latest patient care evidence based guidelines were revised. All the current protocols were also revised and updated, and new protocols regarding sternal wound infection control, nutrition and pain control were added.

Development of the pathway
The pathway team, which included all disciplines involved in patient care, determines the type and sequence of care that will be provided to the patient, in addition to the daily goals that must be achieved in order to reach the clinical outcomes expected by the time of discharge. The pathway comprised of 8 days template and comprised of the following elements: general assessment, circulation, respiration, intake and output balance, pain relief, neurological, nutrition/metabolism, physiotherapy, activity/movement, and patient information/education.

Education of the staff
The development and implementation of CP require changes and modifications in clinical practice, and patient care in the Thoracic Surgery unit. Thus, the staff
members of different disciplines involved in patient care received educational sessions about the components of the pathway before the implementation.

**Patient interactive educational sessions**
During the pre-operative period, patients who were visiting the out-patient clinic were invited to join interactive education sessions. Patients were also informed about what to expect during the immediate preoperative, postoperative periods till discharge (in the pathway), and were invited to express their feelings of anxiety and their concerns about surgery and recovery. Furthermore, patients were provided with booklets with information regarding surgery and expected outcomes.

**Tracking of variances (Appendix II.)**
Variances occur when the patient does not follow the plan and sequence outlined in the CP. Variances can be classified into patient or family, care provider or clinician, hospital or system, or community. Patient variances occur when a patient develops a complication or is unable to reach a goal set in the pathway plan. Care provider variance is when a staff member or clinician does not carry out the task that is crucial for a patient to be discharged on the preset time. Hospital or system variance is due to inefficiencies such as not scheduling a test on time. Finally, community variances occur when discharge is postponed, because the patient needs further care that can not be arranged after discharge.

Tracking and analyzing variances facilitates the patient’s progress along the CP. When the CP fails to meet 70% of the patients needs, the pathway should be reevaluated. Variance data are collected every few months and analyzed for repeating trends or patterns. It is recommended that the pathway be evaluated every six months. Tracking of variances was performed by a nursing director at the UMCG and a full variance analyses report was presented to the Thoracic Surgery Department.

**Outcome evaluation**
The efficacy of the pathway is determined by measuring patient outcomes. Outcomes measured include: LOS (meeting discharge date), readmission rate, morbidity, mortality and patient satisfaction. In this study we also measure HRQoL, health complaints, anxiety and depression.
Figure 2. The process of designing, implementing and evaluating the clinical pathway

1.7 The conceptual model
The central concepts of this study are introduced in a conceptual model (Figure 3.) based on a model developed by Wilson and Cleary, 1995\textsuperscript{77}, and the modifications of Spertus \textit{et al.}, 2002\textsuperscript{78}, and Rumsfeld, 2002\textsuperscript{24}. The Wilson and Cleary model has been used in several publications investigating the factors affecting HRQoL\textsuperscript{33,79-83}. Wilson and Cleary proposed a valuable framework for classifying predictors of HRQoL. They distinguished physiological/biological factors, symptoms (including emotional and cognitive variables), individual patient characteristics, such as gender or age\textsuperscript{51,54} and environmental characteristics, such as provision of services, e.g. cardiac rehabilitation\textsuperscript{84}.

The biological/physiological or medical characteristics that have been constantly related to poor HRQoL outcomes after CABG include the New York Heart Association (NYHA) classification of dyspnoea, current smoking, poor left ventricular ejection fraction, presence of a chronic disease, such as diabetes, or pulmonary disease as chronic obstructive pulmonary disease (COPD), operative related variables, such as complications arising from the surgery that may well also affect HRQoL after surgery\textsuperscript{28,30,50,51,54,85,86}. In our model we also added the EuroSCORE as variable affecting HRQoL. Recently, there has been an interest in whether there is an association between the EuroSCORE and HRQoL\textsuperscript{66,68,87,88} (Figure 3).
Furthermore, the model includes symptoms of depression and anxiety that have an effect on mental HRQoL and worse outcomes after CABG. It is of note that in patients scheduled for CABG the prevalence of depressive symptoms is high\textsuperscript{89}. Preoperative anxiety and depression has been known to predict the incidence of adverse symptoms or psychopathology following surgery\textsuperscript{13,90-94}. A study by Höfer and colleagues\textsuperscript{31} found that depression has the main indirect effect on HRQoL in CAD patients. Thus, we included in our model psychological factors (anxiety and depression) in addition to positive and negative affectivity\textsuperscript{95-99}.

Moreover, We included patients’ characteristics that have been linked to poor HRQoL outcomes after coronary procedure, such as age and gender. Younger patients\textsuperscript{30,100} have reported more physical improvement in HRQoL compared to older patients\textsuperscript{30,50}. The findings regarding the influence of gender, reported that women benefit less from CABG in relation to HRQoL\textsuperscript{30,80,101,102}. Other socioeconomic data, such as marital status or having a partner\textsuperscript{85,103} working or not\textsuperscript{33}, have been associated with poor HRQoL. We also took into account the type of personality (Type-D personality), which has been found to affect HRQoL after cardiac related intervention\textsuperscript{39,104-106}.

In relation to environmental influence on HRQoL outcomes used cardiac rehabilitation (CR) program attendance is one of the factors affecting HRQoL\textsuperscript{84,107}. In our model, we further added the effect of method of care provided, i.e. care in a CP plan to determine it’s effect on HRQoL and psychological distress. Other outcomes we included were the effects of these variables on cardiac related complaints after CABG, which we measured using the health complaints scales (HCS)\textsuperscript{108}. Thus, it is theorized here that physiological, psychological, and environmental variables influence symptom status, which in turn affects functional health and general health perceptions, which influences overall HRQoL. Furthermore, we are addressing the issue of the discrepancy between the expected effect of surgery, which is an improvement in cardiac function and which is the main focus of clinicians, versus patient focus, which is mainly concerned with the interpretation of this improvement into a meaningful change in his functional status and HRQoL. In light of this proposed model we formulated our research questions.
1.8 Research questions

Finally, we present the research questions of this thesis, which were developed based on the presented conceptual model.

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

2. What is the difference between the CP group and the conventional care group in relation to LOS, complications, readmission, HRQoL and psychological distress? Does a CP contribute towards an improved HRQoL six months after CABG as compared to a conventional care trajectory?

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

4. What are the predictors of deterioration HRQoL six months following CABG? Do anxiety and depression mediate the effect of type D personality on deterioration in HRQoL using structural equation modeling?

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

1.9 Outline of the thesis

Following this introductory chapter, Chapter 2 is a systematic review addressing the question whether the outcomes of CPs are evidence-based and provides a critical appraisal of the evaluation studies that examined the effects of clinical pathways. Chapter 3 presents the effect of implementing a CABG pathway on patients’ outcomes in comparison with conventional care. It addresses short term outcomes like: LOS, hospital delay, readmission and complications, and long term outcomes, like HRQoL and psychological distress. The focus is mainly the question regarding whether pathway patients gained more in their HRQoL compared to patients who received conventional care. Chapter 4 reports on the use of EuroSCORE as a predictor of health related physical functioning six months after CABG and highlights the association between EuroSCORE and physical functioning before and after CABG, in addition to the association between EuroSCORE and LOS, and number of complications.
Chapter 5 is addressing the important topic of factors associated with deterioration in health after CABG. In this chapter we present the results of a regression model and a structural equation model that highlights the role played by PD, i.e. anxiety and depression and Type D personality in deterioration of patients HRQoL six months after CABG. Whilst Chapter 6 is mainly presenting the results of investigating the impact of positive affectivity and age on cardiac related health complaints measured by health complaints scales in CABG surgery. Chapter 7 summarizes the main results of the thesis, general conclusion concerning the main objectives of the thesis are formulated and discussed, and finally, implications for future research and clinical practice discussed and formulated.
1.10 Reference List


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