



Psychological approaches to a patient-centered cardiology

*Somatic symptom burden, illness perceptions and supportive care needs
in patients with cardiac diseases*

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Abstract

Patient-centered care is a new treatment approach for chronic conditions. Based on patients' personal experience with a condition it aims at empowering patients to become active partners in health care. The positive effect of patient-centered care on health outcomes is well-established for several chronic diseases. In 2012 the American College of Cardiology highlighted the role of patient-centered care and strongly emphasized the clinical implementation of a patient-centered cardiology. Although psychological approaches could enhance the outcomes of a patient-centered cardiology they have not been considered yet. Psychological approaches could capture patients' perception of symptoms, cardiac diseases and treatment needs, and thus, provide a basis for an effective patient-centered cardiology. The present dissertation is based on three studies that investigated the perspective of patients with cardiac diseases on symptom, disease, and treatment level.

The first study addresses patients' perceived symptom level and investigates subjective somatic symptom burden in patients with coronary heart disease. Results indicate that somatic symptoms are frequent and burdensome with a wide spectrum. Rather than cardiac symptoms, pain and energy loss are most frequent. Over and above cardiac markers, psychological factors (i.e. depression and anxiety) predict somatic symptom burden. Moreover, as the overall somatic symptom severity largely contributes to a decreased quality of life, the wide spectrum of somatic symptoms (i.e. energy loss) needs to be targeted in clinical routine.

The second study focuses patient's perceived disease level and examines whether patients at risk for decline in health status can be identified before heart valve replacement surgery by profiling their illness perceptions. Results show that patients can be grouped according to the nature and value of illness perception profiles (stable vs. changing; negative vs. positive). Moreover, pre-operative illness perception profiles predict cardiac health status and quality of life one year after heart valve replacement surgery. As follows, patients at risk for decline in health status could be detected before surgery by assessing their illness perception profiles.

The third study targets patients' perceived treatment level. To date, it is the first investigation of supportive care needs in patients with cardiovascular disorders.

Results indicate that needs concerning health information and psychological support are frequent unmet supportive care needs. Rather than the cardiac risk profile, patients' experience with the treatment (i.e. emergency referral, surgery, medication), mood state (i.e. depression and anxiety), and quality of life are associated with supportive care needs. Interestingly, patients who have been in psychotherapy report fewer unmet health needs. An effective treatment of cardiovascular disorders should not only be based on patients' cardiac risk profile but should also incorporate the subjective need for help on health information and psychological issues.

Based on the results of three studies, the present dissertation highlights the importance of incorporating psychological approaches into a patient-centered cardiology. In terms of clinical applications, assessing patients' perspective on symptom, disease and treatment level with psychological questionnaires could enhance a patient-centered cardiology. Patient-centered cardiology is defined as an evidence-based model of practice. As follows, further research is needed to validate the implementation of the investigated psychological approaches in clinical practice.

Zusammenfassung

Patientenzentrierte Versorgung ist ein neuer Ansatz bei der Behandlung chronischer Erkrankungen. Basierend auf der persönlichen Erfahrung mit seiner Erkrankung soll der Patient als aktiver Partner in die Behandlung mit einbezogen werden. Die Effektivität patientenzentrierter Behandlung hinsichtlich eines verbesserten Gesundheitszustandes konnte für verschiedene chronische Erkrankungen gezeigt werden. Im Jahr 2012 hat das American College of Cardiology die Bedeutung von patientenzentrierter Versorgung hervorgehoben. Die klinische Anwendung einer patientenzentrierten Kardiologie wird ausdrücklich empfohlen. Psychologische Ansätze könnten eine patientenzentrierte Versorgung verbessern, wurden aber bislang nicht mitberücksichtigt. Mit der Erfassung der wahrgenommenen Symptome, des individuellen Krankheitskonzeptes und der subjektiven Behandlungsbedürfnisse könnten psychologische Ansätze die Basis für eine patientenzentrierte Kardiologie bilden. Die vorliegende kumulative Dissertation basiert auf drei Studien, die die Symptom-, Krankheits- und Behandlungsebene aus Sicht von Patienten mit kardialen Erkrankungen untersucht haben.

Die erste Studie fokussiert die Symptomebene aus der Patientenperspektive und untersucht die wahrgenommene Belastung durch körperliche Beschwerden bei Patienten mit koronarer Herzerkrankung. Die Ergebnisse zeigen, dass körperliche Beschwerden häufig und belastend sind sowie eine große Bandbreite von Symptomen beinhalten. Im Vordergrund stehen jedoch weniger kardiale Symptome sondern vielmehr Schmerzen und Energielosigkeit. Das Ausmaß an Belastung durch körperliche Symptome wird über alle Variablen hinweg (inklusive kardialer Marker) am besten durch psychologische Faktoren (d.h. Depression und Angst) vorher gesagt. Die Belastung durch körperliche Beschwerden ist wiederum stark mit einer reduzierten Lebensqualität assoziiert. Folglich sollte das gesamte Spektrum an somatischen Beschwerden in der klinischen Routine erfasst werden.

Die zweite Studie erfasst die Krankheitsebene aus Sicht des Patienten und untersucht das subjektive Krankheitskonzept von Patienten mit Herzklappen-erkrankungen mit der Fragestellung, ob Risikopatienten aufgrund ihres Krankheitswahrnehmungsprofils bereits vor Herzklappenoperation erkannt werden

können. Die Ergebnisse zeigen, dass Patienten entsprechend der Valenz und des zeitlichen Verlaufs ihrer Krankheitswahrnehmung nach Profilen gruppiert werden können (negativ vs. positiv; stabil vs. sich verändernd). Präoperativ erfasste Krankheitswahrnehmungsprofile sagen sowohl den kardialen Gesundheitsstatus als auch die Lebensqualität ein Jahr nach Herzklappenoperation vorher. Durch die Erfassung von Krankheitswahrnehmungsprofilen könnten Patienten mit dem Risiko einer Gesundheitsverschlechterung bereits vor Herzklappenoperation identifiziert werden.

Die dritte Studie zielt auf die vom Patienten wahrgenommene Behandlungsebene ab und ist bis zum jetzigen Zeitpunkt die erste Untersuchung, die den Unterstützungsbedarf von Patienten mit kardiovaskulären Erkrankungen erfasst. Die Ergebnisse zeigen, dass der höchste Bedarf hinsichtlich mehr Gesundheitsinformationen aber auch psychologischer Unterstützung besteht. Das Ausmaß an nicht erfülltem Unterstützungsbedarf ist weniger mit dem kardialen Risikoprofil assoziiert. Vielmehr bestehen Zusammenhänge zwischen Unterstützungsbedarf und der persönlichen Erfahrung des Patienten mit der kardialen Behandlung (d.h. Notaufnahme, Operation, Medikation), aber auch seiner Stimmung (d.h. Angst und Depression) sowie der Lebensqualität. Interessanterweise berichteten Patienten, die bereits in Psychotherapie waren, weniger Unterstützungsbedarf in allen Bereichen. Eine effektive Behandlung kardiovaskulärer Erkrankungen sollte folglich nicht nur auf dem kardialen Risikoprofil des Patienten basieren, sondern auch den subjektiven Bedarf hinsichtlich mehr Gesundheitsinformationen und psychologischer Unterstützung mit einbeziehen.

Aufbauend auf diesen Ergebnissen unterstreicht die vorliegende Dissertation die enorme Bedeutung psychologischer Ansätze für eine patientenzentrierte Kardiologie. Die Erfassung der Symptom-, Krankheits- und Behandlungsebene aus Sicht von Patienten mittels psychologischer Fragebögen könnte eine patientenzentrierte kardiologische Behandlung deutlich verbessern. Patientenzentrierte Kardiologie ist als evidenzbasiertes Praxismodell definiert. Insofern sollte zukünftige Forschung die Implementierung der hier untersuchten psychologischen Ansätze in der klinischen Praxis überprüfen.

1. Introduction

The introduction presents the theoretical background of the present dissertation. First, the term patient-centered cardiology is clarified. Then, the theoretical concepts of somatic symptom burden, illness perceptions and supportive care needs are described and possible applications to cardiology are summarized.

1.1 Patient-centered cardiology

Patient-centered care is a broad concept that is widely used in medicine. It has been described as “the experience (to the extent the informed, individual patient desires it) of transparency, individualization, recognition, respect, dignity, and choice in all matters, without exception, related to one’s person, circumstances, and relationships in health care” (Berwick, 2009, p. 560). The American Institute of Medicine (2001) defines care as patient-centered if it is “respectful of and responsive to individual patient preferences, needs, and values and ensures that patient values guide all clinical decisions”. Based on an evidenced-based model of practice, patient-centered care aims at empowering patients to become active participants in their own health care.

The term “patient-centered” was probably first introduced by Balint (1969) as a mini-psychotherapy for patients with mainly psychosomatic disorders. Balint’s concept of “patient-centered” contrasted with “illness-oriented care”. This understanding of medical treatment was in line with other critiques of “modern” medicine’s emphasis on pathophysiology to the exclusion of other means of knowing and treating the patient. Since then, the term has been refined through other concepts such as Engel’s (1977) biopsychosocial model of medicine, Cassel’s (1985) transcriptions of clinical encounters or Kleinman’s (1989) definition of “disease” and “illness” as contrasting the doctor’s understanding of disordered biomechanics with the patient’s subjective experience of feeling sick. Over the last 10 years, patient-centered care has received attention when designing health interventions for chronic diseases (Bergeson & Dean, 2006; Dwamena et al., 2012; Hudon et al., 2012). Taken together, findings suggest that a patient-centered approach results in effective disease management

programs for several chronic diseases, such as cancer, Alzheimer's disease, diabetes, and human immunodeficiency virus (Dijkstra, Niessen, Braspenning, Adang, & Grol, 2005; Edvardsson, Winblad, & Sandman, 2008; Knowlton et al., 2010; Ouwens et al., 2010).

Cardiovascular disorders are one of the leading causes of death worldwide (Go et al., 2013; Sidney, Rosamond, Howard, & Luepker, 2013). In Germany, for instance, 40% of all deaths are caused by cardiovascular disorders (Statistisches Bundesamt Deutschland, 2011). Effective disease management of cardiovascular disorders, however, is still a major challenge (Banegas et al., 2011; Dallongeville et al., 2012). Several studies conclude that there is large room for improvement in terms of referral to, enrolment in and completion rates of secondary prevention for cardiac diseases (Balady et al., 2011; Bittner, 2012; Mosca et al., 2005). In terms of primary prevention, a European multicenter study showed that of 7641 patients treated for cardiovascular risk factors only 39% had sufficient blood pressure control, 41% had their cholesterol controlled and only 37% reached their insulin control target (Banegas et al., 2011). One of the greatest obstacles to successful cardiovascular treatment is not considered to be inefficient medical treatment (i.e. medication or surgical procedures) but rather, poor interaction between patients and clinicians. Mounting evidence underpins that a large proportion of patients with cardiac diseases do not receive either proven medical and behavioral interventions or adequate information and support for self-management (Gazmararian et al., 2006; Ho, Bryson, & Rumsfeld, 2009; McGlynn et al., 2003). By definition, patient-centered care should focus on barriers between patients and clinicians.

The American College of Cardiology Foundation, therefore, published a health policy statement with practical recommendations to implement patient-centered care in cardiology (Walsh et al., 2012). According to the committee, patient-centered care should incorporate the following elements: enhanced patient-clinician communication, health literacy, clinician-directed patient education, assessment of patient-reported outcomes, shared decision making, collaborative care planning and goal setting, patient empowerment and self-management. In sum, these elements mainly target the medical need to efficiently reach treatment goals in cardiovascular medicine. Whereas economic reasons are stated as the main barriers to a patient-centered cardiology,

patient factors (such as motivation, depression, or anxiety) are rarely considered as limits to an effective treatment. Moreover, the basis of a patient-centered cardiology, namely, the patients’ perspective of symptoms, cardiac diseases, and their treatment, is poorly conceptualized. Still, a press release by the American College of Cardiology states that “beyond knowing the technical aspects of the disease, we need to do a better job of understanding patients’ perception of their disease, their goals and life experience so we can together chart a course for how we are going to manage the disease” (Abraham, 2012, p.1). Therefore, the health statement policy recommends systematically assessing patients’ experience with symptoms, their perception of the cardiac illness, and unmet needs to cope with the cardiac disease. Ideally, a comprehensive approach should link the clinician’s and the patient’s perspective in a process model capturing the symptom level, the disease level and the treatment level. Yet, it remains unclear how the patient’s perspective of symptoms, the cardiac disorder and treatment needs should be assessed. Psychological approaches could provide valuable insight into patient’s perception of symptoms, the cardiac disorder and associated health needs. For a better understanding, a working model for a patient-centered cardiology that incorporates psychological approaches is introduced (see Figure 1).

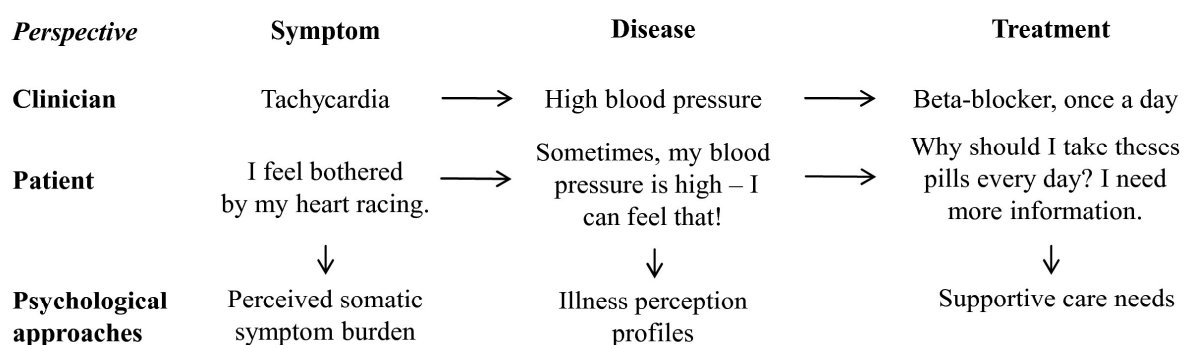


Figure 1. Working model for a patient-centred cardiology

In the following three paragraphs, the concepts of subjective somatic symptom burden, illness perceptions and supportive care needs are introduced and possible applications to a patient-centered cardiology are described.

1.2 Somatic symptom burden

Somatic symptom reports in the general population are common (Creed et al., 2012). In a population-based-study, Hiller, Rief, and Brähler (2006) report that within a week four of five persons indicate at least one current physical complaint that is associated with at least mild distress. In primary care settings, prevalence of somatic symptoms is increased and patients report a very broad spectrum (Barsky, Orav, & Bates, 2005; Interian, Allen, Gara, Escobar, & Díaz-Martínez, 2006; Kroenke, Spitzer, & Williams, 2002). Most frequently, symptoms of pain are reported (e.g. back pain, joint pain, pain in extremities). A 2-year prevalence is estimated by 30% (Rief, Hessel, & Braehler, 2001). In terms of cardiac-related symptoms, the estimated prevalence of palpitations, breathlessness, and chest pain ranges around 10%, 6%, and 5%, respectively (Rief et al., 2001). Taken together, at least one-third of these symptoms remain medically unexplained even after several medical consultations. This results in patient and doctor frustration but also increased doctor visits and health care costs (Barsky et al., 2005). Furthermore, patients with frequent somatic symptoms show increased functional impairment, disability, decreased quality of life and are more likely to suffer from affective disorders (Creed et al., 2012; Escobar et al., 2010; Löwe et al., 2008; Mewes et al., 2009). In brief, reports of somatic symptoms are frequent in the general population, in primary care and in other non-cardiac populations. The negative impact of the overall somatic symptom severity on health is well-established (Kroenke et al., 2010). Whereas the overall somatic symptom burden is well studied in the general population, in primary care, and in other non-cardiac patients, research on somatic symptom severity of patients with cardiac diseases is scarce.

Ideally, core symptoms of a cardiac disease (e.g. angina pectoris) should be an indicator of a diagnosis (e.g. coronary heart disease). However, extensive research showing that cardiac chest pain is a poor predictor of a cardiac disease underpin the assumption that somatic symptoms are less dependent on the cardiac primary diagnosis (Glombiewski et al., 2010; Swap & Nagurney, 2005). Moreover, patients without a specific disease indicate disease-specific symptoms just as frequently as patients with somatic diagnoses (Katon, Lin, & Kroenke, 2007; Löwe et al., 2008; Sha et al., 2005). Disease severity, phase, and type also seem to be unrelated to the amount

of somatic symptoms (Kroenke et al., 2010). In contrast, numerous studies suggest that psychological factors (e.g. anxiety and depression) predict the indication of cardiac symptoms rather than cardiac biomarkers (e.g. left-ventricular ejection fraction) (Katon et al., 2007; Krantz & McCeney, 2002; Martens et al., 2010; Ruo et al., 2003; Whooley et al., 2008). Indeed, the perception of somatic symptoms is based not only on somatic markers but also on psychological factors (Barsky, Goodson, Lane, & Cleary, 1988; Rief, Mewes, Martin, Glaesmer, & Braehler, 2010).

Despite these findings, somatic symptoms in patients with cardiac disorders have been investigated either as part of the underlying cardiac disorder or as part of a mental disorder (e.g. depressive disorder) (Carney & Freedland, 2012; Nabi et al., 2010; Smolderen et al., 2009). Research on chest pain underpins this assumption. On the one hand, numerous studies focused on misinterpretation of cardiac chest pain, which is associated with delay in help-seeking and, finally, mortality. On the other hand, a body of literature examined the over-amplification of chest pain (so called non-specific chest pain) and concluded that this type of chest pain is related to ineffective treatment, functional disability, psychological disorders (such as somatization), and finally, increased health care costs (Glombiewski et al., 2010; Schroeder et al., 2012; Sekhri, Feder, Junghans, Hemingway, & Timmis, 2007). In contrast to research on cardiac-related symptoms, non-cardiac-related symptoms, so called affect-related symptom (such as energy loss) have been a major focus of psychiatric research. Epidemiological studies estimated increased prevalence rates of affective disorders. For instance, rates of major depression have been reported up to 40% depending on the severity of the underlying cardiac disease (e.g. more prevalent in chronic heart failure than in coronary heart disease) (Freedland et al., 2003; Lichtman et al., 2008; Mills, Greenberg, Linke, Reis, & Rutledge, 2006; Nicholson, Kuper, & Hemingway, 2006). In brief, much research has been done to investigate whether somatic symptoms can be attributed to an affective disorder or to the underlying cardiac disease. However, instead of focusing a dichotomous approach (either somatic or psychological disorder) recent research argues for a bi-directional continuous process to understand the relationships between somatic symptoms, affect and cardiac diseases (de Jonge & Roest, 2012; Ormel & de Jonge, 2011).

Not only from a scientific perspective but also from a clinical one it is vital to account for somatic symptoms in cardiac diseases. To implement a patient-centered care in cardiology, the American College of Cardiology highlights that assessing patients' health status entails explicitly inquiring about patients' symptoms (Walsh et al., 2012). The Canadian Cardiovascular Society classification system for angina and the New York Heart Association classification for chronic heart failure are traditional measures that are based on the physicians' interpretation of patients' health status (Campeau, 2002; The Criteria Committee of the New York Heart Association, 2012). Still, the inter-rater reliability of these techniques has been shown to be poor (Bennett, Riegel, Bittner, & Nichols, 2002). Therefore, it is recommended to incorporate health status measures that assess patients' symptoms. Nevertheless, research focuses solely on cardiac-related symptoms and the enhancement of medical treatment goals. So far, the spectrum of patients' perceived somatic symptom and research on the associated health burden have not been taken into account.

Taken together, despite of the well-established negative impact of somatic symptoms on health for non-cardiac populations, research on the prevalence of somatic symptoms and its burden on health in patients with cardiac diseases is rare and rather historical (Friedman, Ury, Klatsky, & Siegelau, 1974; Malley, Jones, Feuerstein, & Taylor, 2000). Previous research highlighted the role of psychological factors as predictor for somatic symptom severity. Still, a dichotomous approach to understand the burden of somatic symptoms (either the psychiatric or the cardiac disease) has been applied. Whereas the American College of Cardiology (2012) acknowledges the importance of patients' perceived symptoms, it remains unclear how to assess them. As follows, it is more than vital for an effective patient-centered cardiology, to account for the patient's perspective of symptoms. Accordingly, the first article of this dissertation has three major aims: First, the investigation of the prevalence and the spectrum of perceived somatic symptoms, second, the identification of predictors of high somatic symptom severity, and third, the examination of the impact of somatic symptoms on health-related quality of life.

Starting with the symptom level, the next section describes an approach to understand the patient's perspective of the disease level. The concept of illness perceptions and its application to patients with cardiac diseases will be introduced.

1.3 Illness perceptions

The concept of illness perceptions is based on Leventhal's Common Sense Model which emerged from studies designed to define the nature of health threat representation (Leventhal, Meyer, & Nerenz, 1980). According to this self-regulation model, the individual is conceptualized as a problem solver dealing with two phenomena: the perceived reality of the health threat and emotional reactions to it. Based on cognitive and emotional appraisal, patients make sense of their symptoms by forming causal attributions about the illness, how long they think it will last, if it can be controlled or cured, and what consequences symptoms will have. These illness perceptions serve as working model for the patient and, in turn, are supposed to guide behavior directed at managing the condition (Petrie & Weinman, 2012).

In terms of cardiac diseases, various studies in the past two decades have shown that cardiac patients develop a wide range of illness perceptions (Astin & Jones, 2006; Devcich, Ellis, Gamble, & Petrie, 2008; Weinman, Petrie, Moss-Morris, & Horne, 1996) and that these perceptions are associated with disease-related disability (Byrne, Walsh, & Murphy, 2005; Juergens, Seekatz, Moosdorf, Petrie, & Rief, 2010), non-adherence to medication (Molloy et al., 2009; van der Wal, MHL et al., 2006), and recovery (French, Cooper, & Weinman, 2006; Stafford, Berk, & Jackson, 2009). Rimington, Weinman, and Chambers (2010) investigated health outcomes in 225 patients after heart valve replacement. Results showed that measures of functional disability (e.g. walking distance) were related to patients' perceptions of control over their condition rather than preoperative cardiac functions (i.e. left ventricular systolic and diastolic function). In terms of coronary heart disease, Dickens et al. (2008) assessed illness perceptions in 269 patients with first-time myocardial infarction and examined their levels of depression. Patients who developed depression over the following year were more likely to believe at baseline that the heart condition would last a long time and was unlikely to be cured. Given the numerous studies that report

associations between illness perceptions and health outcomes, small, cost-effective interventions have been developed and have shown that targeting patients' illness beliefs can enhance recovery. In terms of myocardial infarction, two randomized controlled trials have shown that patients receiving an illness perception intervention had a quicker return to work and reported less chest pain six months after discharge from hospital (Broadbent, Ellis, Thomas, Gamble, & Petrie, 2009; Petrie, Cameron, Ellis, Buick, & Weinman, 2002). Taken together, illness perceptions provide a valuable approach to capture patients' perspective of the cardiac disease.

Illness perceptions are highly individualized and, therefore, may not be in accordance with medical facts. As follows, one of the most obvious applications of examining illness perceptions is the identification of patients who are at risk of coping poorly with the demands of their illness. In light of an effective patient-centered cardiology, it is crucial to detect patients with poor health literacy, poor self-management, and non-adherence. Furthermore, a systematic assessment of illness perceptions can identify subjective treatment beliefs (e.g. "I take my medication when I feel that my blood pressure is high") that interfere with medical treatment goals (e.g. "Daily regular in-take of beta-blocker"). In accordance, the American College of Cardiology (2012) already recommended that systemically capturing patients' perspective of the cardiac disease should be part of clinical routine (Walsh et al., 2012). As follows, assessment of illness perceptions in patients with cardiac diseases could fill in this unsolved clinical gap.

However, one fact might hinder the application of illness perceptions to identify patients at risk. It is very likely that patients' illness perceptions change during the course of the cardiac diseases as cardiac diseases are associated with frequent diagnostics (e.g. electrocardiography), changing treatment regimens (e.g. medication or surgery), and spontaneous emergency visits (e.g. in terms of heart arrhythmias). Systematic screening for at-risk patients requires well-defined and clinically meaningful stable risk factors.

Yet, there is very little research examining the stability and change in illness perceptions in cardiac patients and none which has examined longitudinal changes following a surgical intervention, such as valve replacement surgery. Since this type of surgery is often planned, it is therefore possible to assess illness perceptions

pre-operatively and then again after a period of recovery. In this way it becomes possible to assess the extent to which patients' perception change as the result of a surgical treatment and whether any such changes are related to important health outcomes. In this way, risk factors for poor outcome could be detected prior to surgery. While it is possible to conduct this type of analysis with separate illness perceptions, such as perceived consequences or control, there is growing evidence that examining the overall profile of a patient's illness perceptions may provide a more powerful and parsimonious approach to this type of research (Hobro, Weinman, & Hankins, 2004; Skinner et al., 2003). Profiles of illness perceptions would seem to provide a more complete picture of illness schemata which may reflect stable dispositions towards an illness and therefore, may pose a stable risk factor.

In light of the well-established impact of illness perceptions on health outcomes and open research questions in patients with cardiac disorders, the second article of the current dissertation had three objectives. First, investigating profiles of illness perceptions before and after heart valve surgery, second, determining how much change in profiles is related to pre- and post-operative health outcomes, and, third, testing whether illness perceptions profiles are predictive of functional health status one year after surgery.

Within the previous two paragraphs, the theoretical background to understand patients' perspective on symptom and disease level has been described. The last paragraph introduces the concept of supportive care needs which is an approach to capture the patients' perception of the treatment level.

1.4 Supportive care needs

Supportive care need is a new approach widely used in psycho-oncology. It tries to capture the subjective burden of an illness "by directly measuring patients' own perceptions of their need for help on given issues as well as the magnitude of their desire for help in dealing with those needs" (Boyes, Girgis, & Lecathelinais, 2009, p. 602). According to Bonevski et al. (2000) needs assessments have three major advantages over other patient-reported-outcomes: First, direct indication of needed

resources, second, quantifying unmet needs, and respectively allocating health resources, and, third, identification of patients and subgroups with levels of need and consequently, need-targeted prevention and early intervention.

Research on supportive care needs in patients suffering from cancer has identified important, but also unresolved health-issues concerning emotional distress (e.g. fear of progression), health information (e.g. health self-management), physical and daily living (e.g. pain), patient care (e.g. treatment choices), and sexuality (e.g. changes in sexual feelings). Moreover, various studies have shown associations between these need-domains with psycho-social morbidity (Lehmann, Koch, & Mehnert, 2012), satisfaction with health-care, symptom complaints (Armes et al., 2009; Molassiotis, Wilson, Blair, Howe, & Cavet, 2011) and quality of life (Catt, Chalmers, & Fallowfield, 2008; McDowell, Occhipinti, Ferguson, Dunn, & Chambers, 2010; Snyder et al., 2008). In light of these results, the National Institute for Clinical Excellence (2004) as well as the American Institute of Medicine (Adler & Page, 2008) highlighted improving supportive care needs based care for patients with cancer. Taken together, results from oncology underpin the assumption that a supportive care needs approach could also enhance a patient-centered care in cardiology.

In clinical settings, it has been shown that patients often do not express their needs. Symptoms that are associated with stigmatization (e.g. erectile dysfunction) and not supposed to be relevant for treatment are not mentioned in clinical consultation. Jones and colleagues (2011) investigated whether a patient-centered process of supportive care can improve patient-clinician communication. Results indicated that this approach helps patients to reflect, to initiate a discussion and to get validation on their unmet needs. Patients felt encouraged to seek help and support and could focus clinicians' attention towards unmet needs. In brief, a supportive care needs approach can enhance a patient-centered care as health care resources can be allocated to the issues patients themselves have identified as the most important.

Supportive care needs have been a subject in various non-cardiac patient populations (such as HIV, renal disease, Chorea Huntington). Only a few small studies investigated needs in cardiac patients (Cortis & Williams, 2007; Davidson, Cockburn, Daly, & Fisher, 2004). The use of disease-specific instruments (such as the Heart Failure Needs Assessment Questionnaire) but also the focus on very specific patient-

groups (e.g. patients with chronic heart failure and comorbid depression) make it difficult to compare results with other cardiac patient groups. In terms of the concept of supportive care needs neither their amount nor their content has been investigated in patients with cardiovascular disorders. In clinical practice, a comparison of perceived unmet needs with favorable medical treatment advice could establish a treatment consensus. Ultimately, increased treatment adherence can reduce the health and economic burden of cardiovascular disorders. This assumption is reflected by the American College of Cardiology (2012) that highlights that a patient-centered care should take account for patients' treatment needs.

Therefore, the third article addressed two major research issues. First, characterizing the quantity and the content of unmet supportive care needs in hospitalized patients with cardiovascular disorders, and, second, investigating associations between supportive care needs with patients' characteristics, primary cardiac disorder, quality of life, psychological and cardiac risk factors.

The present dissertation is based on three studies that investigate somatic symptom burden, illness perceptions and supportive care needs in patients with cardiac disease. In the following paragraphs, background, methods and results of the papers are presented and, finally, their relevance for a patient-centered cardiology is discussed.

2. Studies

2.1 Paper 1: Somatic symptom burden in patients with coronary heart disease

Citation: Kohlmann S., Gierk B., Hümmelgen M., Blankenberg S., & Löwe B. (submitted). Somatic symptoms in patients with coronary heart disease: prevalence, risk factors, and quality of life.

Background

Somatic symptom reports are common in the general population and half of the encounters in primary care are due to non-specific symptoms (such as nausea). Increased prevalence of somatic symptoms has been reported for patients with chronic conditions (e.g. cancer) and patients with affective disorders (e.g. depression). Despite the well-established negative impact of somatic symptoms on health (such as functional disability, psychopathology, and decreased quality of life), research in patients with cardiac diseases is scarce. The purpose of the present study was to investigate the prevalence, predictors, and associated health burden of somatic symptoms in patients with coronary heart disease.

Method

Prevalence of somatic symptoms was assessed in 408 consecutive patients with coronary heart disease using the Patient Health Questionnaire-15. To identify predictors and to determine the impact of somatic symptoms on quality of life (EuroQol-5D), multivariate logistic regression analyses were performed. Models were adjusted for socio-demographic data, anxiety (General Anxiety Disorder-7), depression (Patient Health Questionnaire-9), cardiac risk factors (including hypertension, family history, diabetes, dyslipidemia, obesity, smoking), and New York Heart Association classification.

Results

Somatic symptoms were frequent, with 50% of patients reporting at least five bothersome somatic symptoms. Whereas energy loss and sleep disturbance were

reported by more than 70% of patients, chest pain was reported by less than 50% of patients. Of those patients who had chest pain less than 20% indicated that this symptom was very bothersome. Hypertension was the only cardiac risk factor associated with increased somatic symptom severity (Odds Ratio [OR], 1.85; 95% Confidence Interval [CI], 1.06-3.21; $P < 0.05$). Patients with even mild anxious or depressive symptoms were more than twice as likely to report high somatic symptom severity (OR, 2.38; 95%CI, 1.44-.3.94; $P < .001$, and OR, 2.13; 95%CI, 1.15-.3.93; $P < .001$, respectively). Over and beyond all other factors, high somatic symptom severity predicted decreased health-related quality of life (OR, 0.40; 95%CI, .29-0.55; $P < 0.001$).

Discussion

To our knowledge, this is the first study to demonstrate that somatic symptoms in patients with coronary heart disease are frequent and burdensome with a wide spectrum. Estimated prevalence of somatic symptoms is comparable with patients suffering from chronic diseases and comorbid affective disorders. Rather than cardiac markers, psychological factors such as depression and anxiety are predictors of somatic symptoms. More longitudinal research is necessary (1) to investigate the impact of overall somatic symptom severity on cardiac progression, (2) to clarify the underlying mechanisms between somatic symptoms, affective disorders, and coronary heart disease, and (3) to examine why patients with coronary heart disease report such a high prevalence of somatic symptoms. Nevertheless, somatic symptom severity itself poses a major health burden as it substantially contributes to a decreased health-related quality of life. Therefore, it is vital that patient-centered care in patients with coronary heart disease targets the whole spectrum of somatic symptoms.

2.2 Paper 2: Profiling illness perceptions in patients with heart valve replacement

Citation: Kohlmann S., Rimington H., & Weinman J. (2012). Profiling illness perceptions to identify patients at-risk for decline in health status after heart valve replacement. *Journal of Psychosomatic Research*, 72(6):427-433.

Background

Valve replacement surgery has become a safe procedure to enhance cardiac function and decrease mortality. Patients' post-operative health status, however, is best reflected by functional measures (such as quality of life and the New York Heart Association classification). Illness perceptions provide a valuable approach to the challenging identification of patients at risk for poor health status after surgery. Therefore, the aim of the present study was to identify risk factors for decline in subjective health status by profiling illness perceptions before and one year after heart valve replacement surgery.

Method

Prospective data from 225 consecutive first time valve replacement patients was assessed before and one year after surgery. Patients were asked about their illness perceptions (Illness Perception Questionnaire-Revised) and mood state (Hospital Anxiety Depression Scale). Health status was defined by quality of life (Short-Form 36) and New York Heart Association (NYHA) class. Hierarchical cluster analyses were conducted to identify illness perception profiles over time. Predictors of health status after surgery were analyzed with multivariate methods including socio-demographic data, cardiac risk factors, mood state, and illness perception profiles.

Results

For pre- and post-surgical data, two-cluster solutions were independently indicated. Patients were grouped according to the stability and nature of their illness perception profile (stable vs. changing and positive vs. negative). One year after surgery, patients holding a negative illness perception profile showed a lower physical quality of life and were diagnosed in a higher NYHA class ($F=16.99$, $P<.001$ and

$F=7.8$, $P<.001$) than patients changing to positive and patients with stable positive illness perceptions. Over and above cardiac factors, pre-surgery illness perception profiles ($\beta=.35$, $T=3.93$, $P<.001$ and $\beta=-.27$, $T=-2.5$, $P=.02$) predicted post-surgery physical quality of life and NYHA class ($R^2=.52$, $F=17.12$, $P<.001$ and $R^2=.39$, $F=7.8$, $P<.001$).

Discussion

To our knowledge, this is the first study which has examined the course of illness perceptions before and after heart valve replacement surgery and related the findings to clinical and functional outcomes. Results suggest that patients with valve disease can be categorized into one of two stable illness perception profiles that predict health status one year after heart valve replacement surgery. In terms of a patient-centered cardiology, patients could benefit from early screening as negative illness perceptions are modifiable risk factors. Based on the present findings, future research should investigate (1) whether assessment of illness perceptions could be used as a diagnostic tool in clinical routine, (2) what health behavior is linked to positive illness perceptions, and, finally (3), which factors determine change in illness perceptions. Consequently, these determinants should be targeted in patient-centered illness perception interventions.

2.3 Paper 3: Supportive care needs in patients with cardiovascular disorders

Citation: Kohlmann S., Kilbert M., Ziegler K., & Schulz K.-H. (accepted 04th January 2012). Supportive care needs in patients with cardiovascular disorders. *Patient Education and Counseling*.

Objectives

Unmet medical needs are a major focus in cardiovascular disorder (CVD) research. Rather than focusing unmet medical needs, however, studies from oncology suggest that targeting patients' subjective needs can lead to an effective patient-centered treatment. Despite the clinical importance of supportive care needs, few studies have investigated patients' perceived needs. To our knowledge, this is the first study that examines supportive care needs and their relations to health characteristics in patients with CVD.

Method

Unmet needs on five dimensions (psychological, health information, physical and daily living, patient care, and sexuality) were assessed in 260 consecutive in-hospital patients with CVD using the Supportive Care Needs Survey. First, frequency and content of unmet needs were examined. Second, the frequency of unmet needs was compared between CVD-diagnoses and correlation analyses were conducted between supportive care needs and risk factors (including hypertension, dyslipidemia, diabetes, obesity, smoking, and alcohol consumption), treatment characteristics (including way of referral, surgical procedures, medication, length of stay, and contact to psychotherapy), mood state (Hospital Anxiety Depression Scale) and quality of life (Short Form-12).

Results

Unmet supportive care needs were indicated by 21% of all patients: health information (37%) and psychological needs (23%) were the most frequent. Needs concerning daily living (14%), patient care (11%), and sexuality (18%) were less frequently indicated. Patients with chronic heart failure were more likely to indicate

daily living needs (Odds Ratio, 2.95; 95% Confidence Interval, 1.39-6.25; $p < 0.005$). No differences in the number of unmet needs between other CVD-diagnoses were shown. Unmet needs were not related to cardiac risk factors. Among all treatment characteristics variables, contact with psychotherapy showed highest the associations with decreased unmet needs on all dimensions ($r = .17-.30$, all $p < .01$). In terms of health outcomes, unmet needs were associated with increased anxiety and depression level ($r = .44-.71$, $p < .01$, respectively $r = .38-.63$, $p < .01$), as well as decreased physical and mental quality of life ($r = .21-.47$, $p < .01$, respectively $r = .29-.65$, $p < .01$).

Discussion

Supportive care needs are common in patients with CVD. Similar prevalence rates of unmet needs have been reported for in-hospital patients with cancer. Rather than on cardiac factors, supportive care needs are based on patients' treatment characteristics, mood state and subjective well-being. Patients with cardiovascular disorders and increased unmet needs could benefit from psychological interventions. Still, more longitudinal research is needed to investigate (1) the determinants of unmet needs, (2) associations with health care resources and, finally, (3) cardiac treatment outcomes. In clinical practice, systematic needs assessments could easily detect unmet needs in patients with CVD. As follows, supportive care needs provide a valuable approach to implement a patient-centered cardiology that effectively links medical treatment goals with patients' perceived needs.

3. Discussion

Based on three studies, the present dissertation investigates how psychological approaches could contribute to a patient-centered cardiology. Taken together, results provide valuable insights into patients' perspective of symptoms (somatic symptom burden), disease (illness perception profiles) and treatment (supportive care needs). In the following paragraphs, research and clinical implications of each paper are discussed. Then, overall shortcomings are noted. The last paragraph summarizes overall clinical applications of psychological approaches to a patient-centered cardiology and outlines perspectives for future research.

3.1 Somatic symptom burden in patients with coronary heart disease

Despite the well-established negative impact of somatic symptoms on health, research in patients with coronary heart disease is scarce. Therefore, the first article of this dissertation had three major objectives: estimating the prevalence, identifying the predictors, and examining the health burden of somatic symptoms in patients with coronary heart disease.

In brief, results demonstrate that the prevalence of somatic symptoms is high with a broad spectrum that is associated with substantial health burden. Interestingly, rather than cardiac markers, psychological factors seem to predict somatic symptom severity. The main result shows that somatic symptom severity largely contributes to a decreased quality of life and, therefore, poses a health burden itself. Regardless of cardiac function, thus, the broad spectrum of somatic symptoms in patients with coronary heart disease needs to be targeted.

Based on these findings, three major research implications can be derived. First of all, longitudinal research is needed to investigate the impact of overall somatic symptom severity on cardiac progression. Given the numerous studies showing that the somatic-affective component of depression (e.g. energy loss) is predictive of worse cardiac outcomes, it is likely that somatic symptom severity itself could pose a risk factor for morbidity and mortality in patients with coronary heart disease (Carney &

Freedland, 2012; Ormel & de Jonge, 2011; Prescott et al., 2003; Vroege, Zuidersma, & de Jonge, 2012).

Second, it is necessary to clarify the underlying mechanisms between somatic symptoms, affective disorders, and coronary heart disease. Whereas previous studies focused a dichotomous approach (either the somatic or psychological disorder) the present study suggests a bi-directional continuous analysis: Affect might influence the indication of somatic symptoms and, in turn, somatic symptoms might act as a trigger for the development of affective disorders which are also highly prevalent in patients with coronary heart disease (de Jonge & Roest, 2012; Ormel & de Jonge, 2011).

Finally, and most importantly, replication studies are necessary to examine why patients with coronary heart disease report such a high prevalence of somatic symptoms. Biological factors such as high inflammation contribute to the etiology of somatic symptoms (Euteneuer et al., 2012). In line with previous research on somatization disorder, findings from this study suggest that psychological processes rather determine who is presenting with somatic complaints in medical consultation (Arnold et al., 2009; Howren & Suls, 2011; Rief et al., 2010). However, further research is clearly needed to clarify whether a diagnosis such as the proposed *Somatic Symptom Disorder* (American Psychiatric Association, 2011) is appropriate and could enhance treatment benefits for patients with coronary heart disease and increased somatic symptom severity (Rief, Mewes, Martin, Glaesmer, & Brähler, 2011).

In the introduction of the present dissertation, a press release from the American College of Cardiology was cited (Abraham, 2012). It stresses the necessity to account for patients' perspective of symptoms. In terms of clinical implications, results of the first article demonstrate that not only cardiac symptoms, but also the whole spectrum of somatic symptoms in patients with coronary heart disease needs clinical investigation. As recommended by the American College of Cardiology, results underpin the statement that a systematic assessment of patients' perceived symptoms should be the basis for an effective patient-centered care (Walsh et al., 2012). Traditional measures of cardiac symptom severity (such as the New York Heart Association classification) are already part of clinical routine. Based on present and previous findings, it is time to implement patient-rated instruments (such as the Patient-Health Questionnaire-15) to assess the overall somatic symptom severity of

patients with coronary heart disease. In terms of future perspectives, the influence of patients' personal background (e.g. health literacy), health characteristics (e.g. other comorbidities) but foremost psychological factors (e.g. emotional state) should be considered when evaluating somatic symptoms in clinical consultation. To understand how cardiac patients cope with somatic symptoms, the course of somatic symptoms in relation with significant treatment events (e.g. medication changes, emergencies, side-effects), risk factors (e.g. smoking), symptom monitoring (e.g. testing blood pressure), and self-management (e.g. regular doctor visits) could provide crucial insights for further patient-centered interventions.

In sum, to provide an effective patient-centered treatment, somatic symptoms need to be focused as they determine the interplay between mental and physical health in patients with coronary heart disease.

3.2 Illness perceptions in patients with heart valve diseases

Concerning the disease level, results of the second article suggest that patients with heart valve disease can be grouped into stable illness perception profiles. A pre-operative stable negative illness perception profile predicts worse quality of life and New York Heart Association classification one year after valve replacement surgery. Therefore, a stable negative illness perception profile constitutes a risk factor for decline in functional health status in patients undergoing valve replacement surgery.

Based on these findings four major research implications can be derived. So far, theoretical papers have highlighted the importance of overall illness perception pattern which could reflect stable dispositions towards an illness and therefore, pose a stable risk factor (Clatworthy, Hankins, Buick, Weinman, & Horne, 2007; Hagger & Orbell, 2003; Petrie & Weinman, 2012). Despite their relevance for clinical practice, only few studies have investigated the overall illness perception patterns in patients with chronic diseases (Graham, Rose, Hankins, Chalder, & Weinman, in press; Hobro et al., 2004). First of all, more empirical work is needed to determine whether there are stable illness perceptions profiles across different cardiac diseases.

Second, results from the second article suggest that a negative illness perception profile is a risk factor for decline in health status after heart valve replacement surgery.

To make illness perception profiles applicable to clinical practice, future research should establish clinical meaningful cut-offs for negative illness perception profiles. In turn, these cut-offs should be validated in clinical routine.

Third, more research is necessary to determine the development of illness perceptions and illness perception profiles over time (Petrie & Weinman, 2012). For cardiac patients it has been shown that even diagnostic tests influence single illness perception domains (Devcich et al., 2008). However, results from the second study suggest that profiles of illness perceptions provide a rather time stable concept. More studies are needed to track illness perceptions over the course of a cardiac disease and significant treatment events (such as first-time diagnosis, surgery, new medication, rehabilitation, etc.). Even more, further research is necessary to examine how stable profiles of illness perceptions are formed.

Fourth, and finally, to design effective interventions for cardiac patients, it is more than necessary to focus on the development of illness perceptions before and after surgery, and to investigate what negative illness perceptions lead to illness risk behavior (such as non-adherence to anticoagulation therapy). Identifying these core illness beliefs is vital to implement psychological interventions that, ultimately, improve the effectiveness of a patient-centered cardiology.

Addressing a patient-centered cardiology, the second article of the present dissertation highlights the application of illness perception screening in patients going for heart valve replacement. Cardiac surgeries (e.g. bypass) and minimal invasive procedures (e.g. coronary stent implantation) are standard treatments in cardiology. The clinical validity of illness perception screening and its benefits for patients undergoing cardiac surgeries should be investigated. The Brief-Illness Perception Questionnaire is a nine-item measure, easy to administer and to analyze, and might be an effective tool for detecting surgery at-risk patients (Broadbent, Petrie, Main, & Weinman, 2006). Using this instrument in clinical practices, cardiologists and surgeons could easily get an insight of patients' perspective of the cardiac disease. In addition, to effectively implement interventions based on illness perceptions into a patient-centered cardiology, it would be vital to investigate whether there are common shared core illness perceptions that contrast with medical treatment goals. Modifying stable negative illness perceptions but also adapting medical treatment goals to the

patients' perspective of the cardiac disease will be a major challenge for a patient-centered cardiology.

3.3 Supportive care needs in patients with cardiovascular disorders

By definition a patient-centered cardiology should focus on patients' unmet needs, including needs concerning the cardiac disease, medical treatment, but also coping with the cardiac condition. As research in this field is scarce, the third article of this dissertation is the first study that investigated the quality and quantity of supportive care needs in patients with cardiovascular disorder and related findings to important health outcomes.

In brief, results show that supportive care needs are frequent in hospitalized patients with cardiovascular disorders. Similar high rates of unmet needs have been reported for in-patients with a cancer (Lehmann et al., 2012). Rather than cardiac health status, certain patient characteristics (such as emergency referral), emotional distress (i.e. increased depression level), and decreased quality of life were associated with unmet needs. Surprisingly, patients who have been in psychotherapy, report less unmet needs across all supportive care dimensions. Taken together, these results suggest that unmet supportive care needs are based on patients' subjective illness experience rather than on cardiac health status.

As the third study of the present dissertation is the first to investigate supportive care needs in cardiovascular disorders, it provides several research implications: First of all, there is need for replication studies and validation in other clinical settings. For instance, out-patients might differ in their unmet need profile, as they may rather focus on unmet needs concerning their day-to-day ability to cope with cardiovascular disorders.

Second, the study highlights the importance to address patients' health information needs. However, in hospital settings with fast changing treatment regimens (medication, surgery, emergency) and varying clinical staff an effective information management is challenging. In light of the numerous studies that show non-adherence to treatment guidelines in cardiology, it is more than crucial not only to focus the patient but also the health care providers (Cabana et al., 1999; Mosca et al.,

2005). It would be worth designing minimal trainings for clinicians in cardiac settings to sufficiently deliver health information based on patients unmet needs.

Third, and surprisingly, unmet needs for psychological help were second most frequent. This finding is well-established for patients with cancer and has provided clinical applications of psycho-oncology (Adler & Page, 2008; Mehnert, Petersen, & Koch, 2003; National Institute for Clinical Excellence, 2004). However, this finding is novel for patients with cardiac diseases and calls for the clinical application of psychocardiology. Still, to effectively target psychological needs, more research is needed to clarify what are common shared psychological issues in patients with cardiac disorders (e.g. fear of progression of the cardiac disease).

Fourth, studies that directly compare need profiles between patients with cardiovascular disorders and other patient populations are lacking. To tailor patient and disease-specific secondary prevention programs, it is vital to examine whether patients with chronic conditions differ in their perceived supportive care needs.

Fifth, in light of the economic pressures on health care systems more longitudinal research is necessary to investigate possible links between supportive care needs with allocation of health resources and health care cost.

Finally, it would be worth investigating whether patients benefit from a psychological treatment approach based on their need profile. So far, psychopathology has been targeted in patients with cardiovascular disorder with minor success (Ormel & de Jonge, 2011). It would be a promising approach to base psychological interventions on treatment issues that patients have identified as most important.

Based on the results, several clinical implications to improve a patient-centered cardiology can be derived. As supportive care needs are frequent and associated with less favorable health outcomes, they should be targeted in patients with cardiovascular disorders. By applying a supportive care needs assessment, clinicians could easily detect unmet needs and patients could get validation for their subjective need for help. In turn, treatment goals could be established in accordance with the patient. Thus, unmet medical treatment as well as patient perceived needs could be effectively linked and sufficiently targeted. In light of the numerous studies estimating that about one third of patients with cardiac risk factors remain still at high risk for developing a cardiovascular disorder, a needs-based intervention is a promising approach (Banegas

et al., 2011; Spertus, 2008). In addition, needs assessment in cardiology has also the means to detect specific patient groups that need more health resources. Consequently, the effectiveness of need-based health resource allocation in cardiac practice should be tested. To sum it up, as patient-centered care defines the patient as the key-player in managing the disease, a systematic assessment of patients' unmet needs should be part of clinical routine in cardiology.

3.4 Shortcomings

Although the findings of the studies are based on large samples with well-categorized, consecutive patients from diverse clinical settings, there are some shortcomings. First of all, results of all articles in the present dissertation are only applicable to patients with certain cardiac diseases (i.e. heart valve disease and coronary heart disease) and to specific treatment settings (i.e. outpatients or inpatients).

Second, the first article ("*Somatic symptoms in patients with in coronary heart disease*") and the third article ("*Supportive care needs in patients with cardiovascular disorders*") are based on a cross-sectional study design which does not allow causal inferring concerning patient characteristics and health outcomes. Still, conceptually and in line with previous findings, it makes sense that at least part of the directionality is psychological factors (e.g. somatic symptom burden) influencing health outcomes (e.g. quality of life) rather than the converse.

Third, although drop-out rates were not high and comparable to other studies from cardiology, they have to be critically discussed. It might be that patients with more severe health conditions were more likely to early end participation. However, it must be noted that patients who were not included into the analyses did not differ on cardiac health status from patients who were.

Fourth, results were adjusted for cardiac factors but were not controlled for other somatic comorbidities. Still, in line with previous findings and based on multivariate models, the results from the present dissertation strongly suggest that, rather than somatic markers of a disease, psychological factors influence subjective health outcomes.

Even though it might be common sense, fifth, and lastly, it must be noted that psychological factors were assessed purely by patient-report. Yet, all measures used in the studies were validated and showed reasonable psychometric properties in patients with chronic diseases.

3.5 Perspective

The present dissertation examined three psychological approaches that could enhance patient-centered cardiology on symptom, disease and treatment level. As patient-centered cardiology should be based on an evidenced-based model of practice, possible applications in clinical practice and open research questions are outlined in this paragraph.

In brief, results of the three articles suggest that patients with cardiac diseases (1) frequently report a broad spectrum of somatic symptoms, (2) can be grouped according to illness perception profiles, and (3) frequently have unmet needs concerning more health information and psychological support. Taken together, these three psychological approaches have in common that they are related to quality of life. Based on the results of the present dissertation, it would be vital to directly address issues that patients perceive as most bothersome (such as somatic symptoms) and fulfill unmet psychological and health information needs by modifying negative illness perception profiles. Future research should evaluate interactions of these promising approaches in a timeline process model (from symptoms over cardiac disease to treatment).

Based on the results of the present dissertation three main clinical applications for a patient-centered cardiology can be derived. The first article addressed patients' perceived symptom level. Results suggest that a systematic assessment of patients' perceived somatic symptoms' could be a cost-effective minimal intervention to identify patients with increased health burden. The second article focused patients' perceived disease level and results suggest that screening for illness perception profiles could detect at-risk patients before cardiac surgeries. The third article targeted patients' perceived treatment level. Results suggest that a needs assessment could make out unspoken but also unmet supportive care needs that hinder effective

treatment. As patient-centered care is defined as an evidenced based model of practice, the impact of assessing these psychological approaches on cardiac treatment should be evaluated in clinical routine.

Taken together, the results of the present dissertation could stimulate future research. First of all, there is need to compare the investigated psychological approaches with other concepts that could effectively capture the patient's perspective, such as beliefs about medicines or treatment expectations (Horne, Weinman, & Hankins, 1999; Laferton, Shedden Mora, Auer, Moosdorf, & Rief, 2012; van der Wal, M.H.L. et al., 2006). Moreover, this brings us to the point to look at active ingredients for psychological interventions in patients with cardiac diseases. In sum, results from the present dissertation show that the investigated psychological approaches were linked with emotional states (i.e. anxiety and depression). Is it useful to design interventions to modify negative emotional states in order to improve health outcomes in patients with cardiac disorders? A number of well-planned, multicenter randomized-controlled trials that targeted affective disorders have found only minimal effect on emotional well-being and none concerning cardiac health outcomes (Berkman et al., 2003; van Melle et al., 2007). Even more, an expert committee from the American College of Cardiology doubts the usefulness of depression screening for patients with coronary heart disease (Thombs et al., 2008; Ziegelstein, Thombs, Coyne, & de Jonge, 2009). Based on the results of the present dissertation, it is promising to test interventions that directly address issues patients have perceived as most interfering with their health (e.g. increased somatic symptom burden).

To develop and design patient-centered interventions that include psychological approaches, first, it is necessary to determine what psychological constructs are relevant process variables (e.g. illness perception profiles). Second, meaningful health outcomes (e.g. somatic symptoms) must be tested. From a health provider perspective, there is much effort to define health outcomes for patient-centered care (Appleby, 2012; Xie et al., 2008). But, what are meaningful outcomes from a patient's perspective? The present dissertation highlights that more research is necessary to define outcomes that are significant to patients. Establishing health outcomes from a patient's point of view can foster patient's motivation to reach unmet medical treatment goals in cardiac diseases.

Even more, a comprehensive patient-centered care should bridge barriers between patients and physicians bi-directionally. In light of numerous studies that show non-adherence to treatment guidelines in cardiology, it is more than vital to also focus on the physicians' perspectives (Cabana et al., 1999; Mosca et al., 2005). As follows psychological approaches could also be useful to get an insight into cardiologists' perception of cardiac diseases, their perceived barriers to treatment, and foremost, how they perceive their patients.

To summarize, results of the present dissertation contrast with traditionally organ-oriented cardiology but strongly emphasize the importance of targeting the subjective somatic symptom burden by incorporating patients' illness perceptions and acknowledging patients' perceived supportive care needs. Therefore, the current work suggests that a patient-centered care should not focus "cardiac patients" but ultimately needs to understand "patients with cardiac disorders" as individuals dealing with health demands ("The doctor told me to take these pills every day.") that compete with subjective concepts of well-being ("Taking pills every day means I am really sick – I just have high blood pressure, so, I rather take 'em every second day."). Applying psychological approaches to a patient-centered cardiology has the means to identify patients' motives, therefore, to foster responsibility for one's health and, finally, to engage patients as active partners in health care. The greatest challenge, however, will be to motivate patients to stay an active partner in managing the health burden of cardiac diseases.

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5. Appendix

Appendix A: Paper 1

Title:

Somatic Symptoms in Patients With Coronary Heart Disease:
Prevalence, Risk Factors, and Quality of Life

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Abstract

Background

Despite the well-established negative impact of somatic symptoms on health, research in patients with coronary heart disease is scarce. The purpose of the present study was to investigate the prevalence, predictors, and associated health burden of somatic symptoms.

Methods

Using a cross-sectional study design, prevalence of somatic symptoms was assessed with the Patient Health Questionnaire-15 in 408 consecutive-patients with coronary heart disease. To identify predictors and determine the impact of somatic symptoms on quality of life, multivariate analyses were performed. Models were adjusted for socio-demographic data, anxiety, depression, cardiac risk factors, and the New York Heart Association classification.

Results

Somatic symptoms were frequent, with 50% of patients reporting at least five bothersome somatic symptoms. Whereas energy loss and sleep disturbance were reported by more than 70% of patients, chest pain was reported by less than 50%. Hypertension (Odds Ratio [OR], 1.85; 95% Confidence Interval [CI], 1.06-3.21; $P<0.05$) was associated with increased somatic symptom severity. Patients with even mild anxious (OR, 2.38; 95%CI, 1.44-.3.94; $P<0.001$) or depressive symptoms (OR, 2.13; 95%CI, 1.15-.3.93; $P<0.001$) were more than twice as likely to report high somatic symptom severity. Over and beyond all other factors, high somatic symptom severity predicted decreased health-related quality of life (OR, 0.40; 95%CI, 0.29-0.55; $P<0.001$).

Discussion

This is the first study to demonstrate that somatic symptoms in patients with coronary heart disease are burdensome with a wide spectrum. Rather than cardiac markers, psychological factors such as depression and anxiety are associated with somatic symptoms. As somatic symptom severity substantially contributes to a decreased health-related quality of life, it is vital that effective patient-centered care targets the whole spectrum of somatic symptoms of patients with coronary heart disease.

Introduction

Patients in primary care report a broad spectrum of somatic symptoms and more than half of medical visits are due to non-specific somatic symptoms (e.g., nausea, headache, dizziness).^{1,2} Furthermore, patients with frequent somatic symptoms, show increased functional impairment, disability, and a decreased quality of life.^{3,4} Although, patients with coronary heart disease (CHD) might also present with more than only cardiac symptoms (such as angina pectoris), research on the prevalence of somatic symptoms and its burden on health is rare and rather historical.⁵⁻⁷

Ideally, core symptoms of a disease (e.g. angina pectoris) should be an indicator of a diagnosis (e.g. CHD). However, extensive research showing that cardiac chest pain is a poor predictor of a cardiac disease underpin the assumption that somatic symptoms are less dependent on the cardiac primary diagnosis.^{8,9} Moreover, patients without a specific disease indicate disease-specific symptoms just as frequently as patients with somatic diagnoses.¹⁰⁻¹² Disease severity, phase, and type also seem to be unrelated to the amount of somatic symptoms.¹³

Numerous studies suggest that psychological factors (e.g. anxiety and depression) predict the indication of cardiac symptoms rather than cardiac biomarkers (e.g. left-ventricular ejection fraction).^{11,14-17} Indeed, the perception of somatic symptoms is based not solely on somatic markers but also on psychological factors.^{18,19} Despite these findings, somatic symptoms in patients with CHD have been investigated either as part of a mental disorder (e.g. depressive disorder) or as part of the underlying cardiac disorder.²⁰⁻²² As follows, studies that consider both psychological and cardiac factors are crucial to understand the interaction between affective disorders, somatic symptoms, and CHD.²³

In light of the well-established negative impact of somatic symptoms on health for non-cardiac populations, it is more than vital to investigate prevalence, spectrum, and health burden also in patients with CHD. Even more, identifying characteristics of patients with increased somatic symptom severity is inevitable to provide an effective patient-centered care for CHD. First, this study investigates the prevalence and the spectrum of perceived somatic symptoms in patients with CHD. Second, predictors of high somatic symptom severity are examined. Third, the impact of somatic symptoms on health-related quality of life is tested.

Methods

Setting and Sample

The present study is based on cross-sectional data from the DEPSCREEN-INFO trial, which is described in detail elsewhere (German Clinical Trials Register: Identifier: DRKS00003277).²⁴ Between September 15, 2011 and May 31, 2012 patients presenting in five cardiac out-patient clinics were consecutively approached. Patients were invited to participate if they had a clinically confirmed CHD, were aged above 18 years and had sufficient language skills (German). Patients were excluded if they met one of the following exclusion criteria: (1) life threatening health status, (2) severe somatic or psychiatric disorder that needs urgent treatment, (3) severe cognitive, motor or visual difficulties, or (4) no written informed consent, as directed by the local Ethics Committee (No. PV3845/ Ethics' approval date: September 1st 2011).

Procedure & Measures

While waiting for medical consultation patients filled in questionnaires assessing socio-demographic data, somatic symptom severity, depression, anxiety and health-related quality of life. In addition, smoking, heredity, and obesity were asked. Socio-demographic data included age, gender, first language, education, living situation, and employment status. Cardiac risk factors including hypertension, diabetes, dyslipidemia, and New York Heart Association (NYHA) classification were obtained from medical records.

Patient Health Questionnaire-15

Somatic symptoms were assessed with the Patient Health Questionnaire-15 (PHQ-15).¹ It assesses the frequency and the severity of the 15 most frequent somatic symptoms in outpatient settings. Retrospectively, patients rate as to how much they were bothered by somatic symptoms over the last four weeks (“not bothered at all”, “bothered a little”, “bothered a lot”). Score ranges from 0 to 30 and higher scores reflect greater somatic symptom severity. A cut-off score over 9 points reflects high somatic symptom severity. The PHQ-15 has been validated in various patient populations.^{12,25}

Patient Health Questionnaire-9

Depression was assessed with the Patient Health Questionnaire-9 (PHQ-9).²⁶ Patients can respond as to how often they experienced 9 depressive symptoms over the last 2 weeks (“not at all”, “several days”, “more than half the days”, “nearly every day”). The score range is 0 to 27 points. Cut-off scores are 5, 10, and 15 points and reflect a mild, moderate or, severe depressive disorder. Psychometrics properties have been shown to be good in several validation studies.^{27,28}

General Anxiety Disorder-7

The 7-item General Anxiety Disorder (GAD-7) scale is a validated scale to assess severity of anxiety.²⁹ Patients are asked how much they were bothered by seven symptoms of anxiety (“not at all”, “several days”, “more than half the days”, “nearly every day”). Score ranges between 0 to 21 points. Cut-off scores are 5, 10, and 15 points and reflect a mild, moderate, or severe level of anxiety. Psychometric properties were investigated in several studies and have been shown to be good.³⁰

EuroQol-5D

Health-related quality of life was measured with the EuroQol-5D (EQ-5D) which is a simple generic measure that summarizes health-related quality of life into a single index.³¹ Current health state in 5 dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) is assessed on a 3-point scale (“no problems”, “moderate problems”, “extreme problems”). A population based index (EQ-5Dindex) is calculated to reflect the current health state. Score ranges from -0.205 to 0.999. In hospitalized patients with CHD an average score range between 0.76 and 0.82 has been reported.³²⁻³⁴

Statistical Analysis

First, base rates to estimate prevalence and to describe the spectrum of somatic symptoms were analyzed. Second, to identify possible predictors of somatic symptom severity, bivariate associations between somatic symptom severity and socio-demographic data, cardiac and psychological characteristics were calculated. As

recommended by Aiken & West, variables that correlated significantly on a P-value $\alpha < .10$ with somatic symptom severity were used for multivariate analyses.³⁵ Third, analyses of variance (ANOVA) were conducted to test for differences in somatic symptom severity between the number of cardiac risk factors and NYHA classifications. Fourth, multivariate logistic regressions were performed to identify predictors of somatic symptom severity and to test the impact of somatic symptom severity on health-related quality of life. Models were adjusted for socio-demographic, cardiac, and psychological factors. Sample size estimation was based on a power-analysis to detect small to medium sized effects (Cohen's $f^2 = 0.05$) using a maximum of 15 predictors in a multivariate model to predict somatic symptom severity ($\beta = 0.80$; $\alpha = 0.05$).³⁶ Based on these estimations and suggesting a conservative attrition rate of 15% we determined sample size of N=440 patients as appropriate. According to statistical recommendations, single missing values were imputed using the expectation maximization algorithm.³⁷ All analyses were performed using SPSS Version 18.0 (Chicago Inc).

Results

Study Sample

In total, 832 out-patients were consecutively screened. Of these, 441 patients had a CHD and were eligible. Finally, 408 patients gave written informed consent and were recruited for the study (participation rate: 92%). The mean age was 68 years (Standard Deviation[SD]=10.3 years; range: 32-91 years). Most patients were male (71.1%), spoke German as a first language (91.4%) and most were not living alone (72.1%). On average they spent 13.7 years (SD=2.6 years; range: 7-19 years) in full time academic education. The most frequently indicated employment status was retired (57.4%), followed by unable to work (20.8%), employed (16.9%), and unemployed (4.9%).

In terms of cardiac health, most patients were rated as being in NYHA classification I (75.2%), followed by NYHA classification II (17.9%), and NYHA classification III (6.9%). More than half of the patients were diagnosed with hypertension (63%), and dyslipidemia (57.1%). Nearly one-third had obesity (29.4%).

Almost half of patients (47.5%) had a family history of heart diseases and 13.5% of patients indicated that they smoke.

The mean PHQ-15 somatic symptom severity score was 8.02 (SD=4.98; range: 0-22). A moderate to severe level of symptom severity (PHQ-15-score>9) was indicated by 34.7% of patients.

Concerning mental health, the mean PHQ-9 depression sum score was 5.54 (SD=4.70; range: 0-22). Of all patients, 9.8% had moderate and 5.9% severe depressive symptoms. The mean GAD-7 anxiety sum score was 3.87 (SD=4.18; range: 0-21). Moderate and severe levels of anxiety were measured in 7.4% and 2.9% of patients.

On average, participants rated their health-related quality of life (EQ-5Dindex) being 0.82 (SD=0.22; range: 0.06-1.00). A quality of life under the median (<0.88 points) was present in 37.0% of all patients.

Frequency of Somatic Symptoms

Frequencies and spectrum of the 15 somatic symptoms are presented in table 1. Of these 15 somatic symptoms, 11 were rated as being present by at least 30% of patients. At least five somatic symptoms were present in 50% of patients. The five most common symptoms were trouble sleeping (76.7%), feeling tired or having low energy (70.8%), pain in arms, legs or joints (62.0%), back pain (61.2%), and shortness of breath (59.4%). Chest pain as a core symptom of CHD was reported by less than every second patient (45.2%). Racing heart (45.7%) and dizziness (45.0%) were also indicated by less than half of the patients. Of those patients who reported somatic symptoms, the five most bothersome symptoms were: Back pain (36.3%), pain during sexual intercourse (38.2%), shortness of breath (40.4%), having low energy (42.3%), and pain in arms, legs or joints (43.4%). Chest pain (21.1%) was reported as one of the five least bothersome somatic symptoms by patients who reported symptoms. Headaches (16.9%), fainting spells (21.1%), stomach pain (21.2%), and dizziness (21.3%) were also indicated as less bothersome.

Table 1. Prevalence of somatic symptoms in 387 patients with coronary heart disease

Somatic symptoms	All symptoms reported		Bothered a little ^b		Bothered a lot ^b	
	No. (%)	95% CI	No. (%)	95% CI	No. (%)	95% CI
Trouble sleeping	297 (76.7)	72.5-81.0	193 (49.9)	44.9-54.9	104 (26.9)	22.5-31.3
Feeling tired or having low energy	274 (70.8)	66.3-75.3	158 (40.8)	35.9-45.7	116 (30.0)	25.4-34.5
Pain in arms, legs or joints	244 (63.0)	58.2-67.9	138 (35.7)	30.9-40.4	106 (27.4)	22.9-31.8
Back pain	237 (61.2)	56.4-66.1	151 (39.0)	34.2-43.9	86 (22.2)	18.1-26.4
Shortness of breath	230 (59.4)	54.5-64.3	137 (35.4)	30.6-40.2	93 (24.0)	19.8-28.3
Feeling your heart pound or race	177 (45.7)	40.8-50.7	138 (35.7)	30.9-40.4	39 (10.1)	7.1-13.1
Chest pain	175 (45.2)	40.3-50.2	138 (35.7)	30.9-40.4	37 (9.6)	6.6-12.5
Dizziness	174 (45.0)	40.0-49.9	137 (35.4)	30.6-40.2	37 (9.6)	6.6-12.5
Nausea, gas, indigestion	140 (36.2)	31.4-41.0	110 (28.4)	23.9-32.9	30 (7.8)	5.1-10.4
Constipation, diarrhea, loose bowels	129 (33.3)	28.6-38.0	98 (25.3)	21.0-29.7	31 (8.0)	5.3-10.7
Headaches	118 (30.5)	25.9-35.1	98 (25.3)	21.0-29.7	20 (5.2)	3.0-7.4
Pain during sexual intercourse	76 (19.6)	15.7-23.6	47 (12.1)	8.9-15.4	29 (7.5)	4.9-10.1
Stomach pain	66 (17.1)	13.3-20.8	52 (13.4)	10.0-16.8	14 (3.6)	1.8-5.5
Menstrual problems or cramps ^a	7 (6.3)	3.8-8.7	5 (4.5)	2.4-6.5	2 (1.8)	0.5-3.1
Fainting spells	19 (4.9)	2.8-7.1	15 (3.9)	2.0-5.8	4 (1.0)	0.0-2.0

Abbreviations: No, Number; CI, Confidence Interval.

^a Menstrual symptoms were asked only in n=112 women.

^b Patients could respond from “not bothered at all” to “bothered a little” to “bothered a lot”.

Correlates of Somatic Symptom Severity

Somatic symptom severity (Means±SD) according to patient characteristics is presented in table 2. Higher somatic symptom severity was related to female gender ($P<0.001$) and living alone ($P=0.022$). In terms of cardiac risk factors, patients with hypertension ($P=0.004$), family history ($P<0.001$), dyslipidemia ($P=0.030$), and those who were obese ($P<0.001$) reported higher somatic symptom severity. Concerning mental health, patients with higher scores on the depression ($P<0.001$) and anxiety ($P<0.001$) scales indicated increased somatic symptom severity. Patients with a lower quality of life indicated higher somatic symptom severity ($P<0.001$).

Cardiac risk factors, NYHA Classification and Somatic Symptom Severity

Somatic symptom severity (Means±SD) according to NYHA classification and the number of cardiac risk factors are presented in table 3. The number of risk factors and NYHA classification were associated with somatic symptom severity ($F=11.81$; $P<0.001$, respectively $F=51.22$; $P<0.001$). Bonferroni-corrected post-hoc tests revealed that patients with two or less cardiac risk factors reported less symptom severity compared to patients with more than 2 risk factors ($P<0.01$). Patients with 3 or 4 risk factors did not differ in their symptom severity from patients with 5 or more risk factors ($P=0.25$). Similarly, patients with NYHA I showed less symptom severity compared to patients with NYHA II or III ($P<0.001$). Patients with NYHA classification II reported less symptom severity compared to patients with NYHA-classification III ($P=0.045$).

Table 2. Patient characteristics and PHQ-15 somatic symptom severity

Characteristics	No. of patients	Mean±SD	p-value	
Gender			<.001	
Male	274	7.42±4.73		
Female	112	9.48±5.28		
Native language			.757	
German	355	8.00±4.93		
Other	31	8.28±5.60		
Living situation			.022	
Not alone	280	7.66±4.84		
Alone	106	8.96±5.24		
Years of full time education			.375	
<13 years	233	8.23±4.94		
13-16 years	87	8.03±5.07		
>16 years	66	7.26±5.00		
Employment status			.136	
Working	67	7.39±5.09		
Retired	219	8.00±4.57		
Unemployed	19	10.41±5.34		
On sick leave	81	8.14±5.73		
NYHA classification			<.001	
I	293	6.77±4.33		
II	68	11.26±4.67		
III	25	13.83±4.99		
Cardiac risk factors				
Hypertension	Yes	245	8.38±4.97	.013
	No	122	7.10±4.72	
Family history	Yes	183	8.89±5.00	<.001
	No	146	6.60±4.70	
Diabetes	Yes	114	8.47±4.70	.535
	No	241	7.83±5.17	
Dyslipidemia	Yes	221	8.27±5.07	.119
	No	127	7.41±4.91	
Obesity	Yes	113	9.60±5.46	<.001
	No	273	7.36±4.62	
Smoking	Yes	52	7.86±4.88	.817
	No	329	8.03±4.99	
Quality of Life (EQ-5D _{index})			<.001	
Lower Percentile (<25%)	138	11.09±4.79		
Middle Percentile (25-75%)	135	7.95±3.93		
Upper Percentile (>75%)	109	4.32±3.72		
Depression (PHQ-9)			<.001	
Minimal (0-4)	180	4.94±3.59		
Mild (5-9)	123	9.07±3.36		
Moderate (10-14)	39	12.66±4.08		
Severe (≥ 15)	22	16.52±3.40		
Anxiety (GAD-7)			<.001	
Minimal (0-4)	255	6.38±4.26		
Mild (5-9)	76	9.93±4.49		
Moderate (10-14)	30	13.15±4.29		
Severe (≥ 15)	11	17.09±2.72		

Abbreviations: No, Number; SD, Standard Deviation; NYHA, New York Heart Association; EQ-5D_{index}, EuroQol-5D index; PHQ-15, Patient Health Questionnaire-15; PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalized Anxiety Disorder-7.

Table 3. NYHA classification, cardiac risk factors, and means and standard deviations of PHQ-15 somatic symptom severity

No. risk factors	NYHA classification			
	I	II	III	All classes
0 to 2	5.78±4.29 (n=109)	8.96±5.08 (n=17)	11.48±4.51 (n=7)	6.49±4.65 (n=133)
3 to 4	7.15±4.01 (n=127)	11.58±4.72 (n=33)	14.26±5.14 (n=12)	8.50±4.82 (n=172)
5 or more	8.20±4.66 (n=45)	12.42±3.36 (n=16)	14.45±4.31 (n=5)	9.69±4.86 (n=66)

Abbreviations: No, Number; NYHA, New York Heart Association; PHQ-15, Patient Health Questionnaire-15.

Predictors of Somatic Symptom Severity

The results of the multiple logistic regression model to determine the impact of patient characteristics on high versus low somatic symptom severity (PHQ-15<10 vs. PHQ-15≥10) are presented in table 4. Patients with hypertension were 1.85 times more likely to have high somatic symptom severity (OR=1.85; 95% CI, 1.06-3.21). With every unit increase in NYHA classification the likelihood of high somatic symptom severity also increased by 3.68 times (OR=3.68; 95% CI, 2.27-5.97). Psychological factors were also associated with increased risk for high somatic symptom severity. For every cut-off (5 unit increase) on the depression scale the likelihood of high somatic symptom severity increased by 2.13 times (OR=2.13; 95% CI, 1.15-3.93). Similarly, the likelihood to have high somatic symptom severity increased by 2.38 times for every cut-off (5 unit increase) on the anxiety scale (OR=2.38; 95% CI, 1.44-3.94).

Table 4. Multivariable predictors of symptom severity^a

Variable	Odds Ratio (95% CI)
<i>Step: Socio-demographic factors</i>	
Age (per 10 years)	1.72 (0.95-3.12)
Gender (female vs. male)	1.02 (0.77-1.35)
Living situation (not alone vs. alone)	1.27 (0.69-2.33)
Years of full time academic education (<13 years vs. 13-16 years vs. >16 years)	0.99 (0.68-1.42)
<i>Step: Cardiac risk factors</i>	
Hypertension (absent vs. present)	1.85 (1.06-3.21) ^b
Heredity (absent vs. present)	1.16 (0.78-1.74)
Dyslipidemia (absent vs. present)	1.36 (0.86-2.16)
Obesity (absent vs. present)	1.69 (0.93-3.04)
<i>Step: Cardiac health rating</i>	
NYHA-class (I vs. II vs. III)	3.68 (2.27-5.97) ^d
<i>Step: Psychological factors</i>	
Depression (PHQ-9 score per 5 U on 0-27 scale)	2.13 (1.15-3.93) ^c
Anxiety (GAD-7 score per 5 U on 0-21 scale)	2.38 (1.44-3.94) ^d

Abbreviations: CI, Confidence Interval; U, Unit; PHQ-15, Patient Health Questionnaire-15, NYHA, New York Heart Association, PHQ-9, Patient Health Questionnaire-9, GAD-7, Generalized Anxiety Disorder-7.

^a Multiple logistic regression for high versus low PHQ-15 sum score (low=PHQ-15<10, high=PHQ-15≥10), $\chi^2=45.61$, $P<0.001$, $R^2=0.43$.

^b Significant on $P<0.05$.

^c Significant on $P<0.01$.

^d Significant on $P<0.001$.

Somatic Symptom Severity and Quality of Life

Results of the multiple logistic regression analysis to predict high versus low scores on health-related quality of life (EQ-5Dindex<0.88 vs. EQ-5Dindex≥0.88) are shown in table 5. Increase in age (OR=0.76; 95%CI, 0.59-0.98), living alone (OR=0.50; 95%CI, 0.29-0.87), and lower level of academic education (OR=1.61; 95%CI, 1.12-2.32) were associated with a greater likelihood of a low quality of life. Over and above all other socio-demographic, cardiac or psychological factors, every 5 unit increase in the level of somatic symptom severity (OR=0.40; 95%CI, 0.29-0.55)

was associated with a 2.52 times greater likelihood of a low health-related quality of life.

Table 5. Multivariable predictors of quality of life ^a

Variable	Odds Ratio (95% CI)
<i>Step: Socio-demographic factors</i>	
Age (per 10 years)	0.76 (0.59-0.98) ^b
Gender (female vs. male)	1.02 (0.58-1.80)
Living situation (not alone vs. alone)	0.50 (0.29-0.87) ^b
Years of full time academic education (<13 years vs. 13-16 years vs. >16 years)	1.61 (1.12-2.32) ^b
<i>Step: Cardiac risk factors</i>	
Obesity (absent vs. present)	0.81 (0.47-1.41)
<i>Step cardiac health rating</i>	
NYHA-class (I vs. II vs. III)	0.75 (0.48-1.16)
<i>Step: Psychological factors</i>	
Depression (PHQ-9 score per 5 U on 0-27 scale)	0.72 (0.41-1.27)
Anxiety (GAD-7 score per 5 U on 0-21 scale)	1.02 (0.65-1.59)
<i>Step: Somatic symptom severity</i>	
Somatic symptom severity (PHQ-15 score per 5 U on 0-30 scale)	0.40 (0.29-0.55) ^c

Abbreviations: CI, Confidence Interval; U, Unit; EQ-5D_{index}, EuroQol-5D index; PHQ-15, Patient Health Questionnaire-15; NYHA, New York Heart Association; PHQ-9, Patient Health Questionnaire-9; GAD-7; Generalized Anxiety Disorder-7.

^a Multiple logistic regression for below versus above the mean of the EQ-5D_{index} (low= EQ-5D_{index}<0.88, high= EQ-5D_{index} ≥.88), $\chi^2=32.96$, $P<0.001$, $R^2=0.33$.

^b Significant on $P<0.05$.

^c Significant on $P<0.001$.

Comment

The main findings of present study show that somatic symptoms in patients with CHD are broad, numerous and burdensome. Interestingly, rather than cardiac risk factors, psychological factors (such as anxiety and depression) strongly influenced the indication of somatic symptoms. Over and above any other socio-demographic or bio-

medical factor, health-related quality of life was strongest predicted by somatic symptom severity.

The prevalence of somatic symptom was high in this study sample compared to data from the general population but also compared primary care.^{1,12,25,38,39} Even more, results suggest that somatic symptom severity in patients with CHD is almost as high as in chronically ill patients with comorbid pain or affective disorders.¹³ Every second patient reported being bothered by at least five somatic symptoms. Results also demonstrate that patients with CHD do not only present with cardiac-related symptoms. Indeed, a broad spectrum of somatic symptoms was indicated. In the general population the point prevalence of energy loss is estimated by 17.5%.³⁹ In contrast, low energy was reported by more than two-third of the current study sample. In congruence with primary care research, pain-related symptoms were indicated frequently and were perceived as being the most bothersome.^{8,39} Angina pectoris, however, was not among the most frequent pain symptoms. Moreover, only every fifth patient who had angina pectoris indicated that this symptom was bothersome.

The identification of patients at high risk of developing burdensome somatic symptoms is crucial.^{40,41} In terms of cardiac risk factors, patients with hypertension were more likely to indicate somatic symptoms. Nevertheless, over and above socio-demographic markers, cardiac risk factors, or NYHA classification, psychological factors strongest predicted somatic symptom severity. Patients with even mild anxiety-related or depressive symptoms were twice as likely to report high somatic symptom severity compared to patients with no affective symptoms. This finding underpins the hypothesis that the presentation of somatic symptoms is strongly linked to affective states.^{18,19,42}

Nonetheless, the current study highlights that the indication of high somatic symptom severity constitutes a health burden above and beyond cardiac and psychological factors. Somatic symptoms had the strongest impact on health-related quality of life. Although, age and living situation influenced quality of life, no cardiac risk factors, or psychological factors were associated with decreased quality of life when accounting for somatic symptom severity. As follows, patient-centered cardiac treatment that targets the overall somatic symptom severity could enhance quality of life for patients with CHD. Previous findings already showed that the strongest

predictor of benefit from percutaneous coronary revascularization is the severity of patients' angina.^{43,44} However, results from the present study highlight that the whole spectrum of somatic symptoms needs clinical investigation.

Three major research implications can be derived. First, the impact of the overall somatic symptom burden on cardiac progression needs longitudinal investigation: Given the numerous studies showing that the somatic-affective component of depression is predictive of worse cardiac outcomes, it is likely that somatic symptom severity itself could pose a risk factor for morbidity and mortality in patients with CHD.^{20,45-47} Second, instead of a dichotomous approach (either the somatic or psychological disorder) results suggest that a bi-directional continuous analysis is needed to clarify the underlying mechanisms between somatic symptoms, affective disorders and CHD. Affect might influence the indication of somatic symptoms and, in turn, somatic symptoms might act as a trigger for the development of affective disorders.^{23,45} Third, and most importantly, it remains unclear why patients with CHD report such a high prevalence of somatic symptoms. Biological factors such as high inflammation contribute to the etiology of somatic symptoms, but findings from this study suggest that psychological processes rather determine who is presenting with somatic complaints in medical consultation.^{19,42,48,49}

In terms of clinical implications, the present study highlights that the frequent, burdensome, and wide spectrum of somatic symptoms in patients with CHD needs to be targeted. The American Heart Association also highlighted that the systematic assessment of patients' perceived symptoms should be the basis for an effective patient-centered care.⁴¹ The current study contributes that focusing psychological factors (such as depression and anxiety) could also lower somatic symptom severity in patients with CHD.

Although the findings of the present study are based on a large well-categorized, consecutive sample of patients from five out-patients clinics there are some shortcomings. First, the cross-sectional design does not allow causal interpretation. In line with previous findings, results of the present study suggest that psychological factors are predictors of somatic symptoms and that increased somatic symptom burden is a predictor of low quality of life. Second, assessment of the somatic symptoms was purely by patient-report. However, the primary aim was to

investigate subjective somatic symptom burden. Moreover, compared to interview-based diagnoses, self-report measures are not prone to interview-related bias and patients may, furthermore, be more likely to report stigmatized symptoms such as pain during sexual intercourse than in an interview. Third, results were not controlled for other somatic comorbidities. In line with previous findings, the present results which are based on the multivariate models strongly suggest that, rather than somatic markers of a disease, psychological factors are predictors of somatic symptoms.

To our knowledge, this is the first study that investigates the burden of somatic symptoms in patients with CHD. The main results show that somatic symptoms are frequent, broad and largely cardiac-unrelated. Psychological factors such as depression and anxiety, however, are strong predictors of somatic symptom severity. Even more, the present study demonstrates that above and beyond socio-demographic, cardiac, or psychological factors, somatic symptom severity has the greatest impact on health-related quality of life. To provide an effective patient-centered treatment, somatic symptoms need to be focused as they determine the interplay between mental and physical health in patients with CHD.

Declaration of conflicting interests

The authors declare that there is no conflict of interest.

Contributors

Sebastian Kohlmann, Benjamin Gierk and Bernd Löwe had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analyses.

Study concept and design: Kohlmann, Gierk and Löwe.

Acquisition of data: Kohlmann, Gierk, Hümmelgen and Blankenberg

Analysis and interpretation of data: Kohlmann, Gierk and Löwe.

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Study supervision: Löwe and Blankenberg.

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Appendix B: Paper 2

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Profiling illness perceptions to identify patients at-risk for decline in health status after heart valve replacement

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ABSTRACT

Objective: Identification of risk factors for decline in health status by profiling illness perceptions before and one year after heart valve replacement surgery.

Methods: Prospective data from N=225 consecutively admitted first time valve replacement patients was assessed before and one year after surgery. Patients were asked about their illness perceptions (Illness Perception Questionnaire-Revised) and mood state (Hospital Anxiety and Depression Scale). Health status was defined by quality of life (Short-Form 36) and New York Heart Association (NYHA) class. Cluster analyses were conducted to identify illness perception profiles over time. Predictors of health status after surgery were analyzed with multivariate methods.

Results: Patients were grouped according to the stability and nature (positive, negative) of their illness perception profile over one year. One year after surgery patients holding a negative illness perception profile showed a lower physical quality of life and were diagnosed in a higher New York Heart Association class than patients changing to positive and patients with stable positive illness perceptions ($P<.001$). Over and above biological determinants, post-surgery physical quality of life and NYHA class were both predicted by pre-surgery illness perception profiles ($P<.05$).

Conclusion: Patients going for heart valve replacement surgery can be easily categorized into illness perception profiles that predict health status one year after surgery. These patients could benefit from early screening as negative illness perceptions are modifiable risk factors.

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Introduction

Valve replacement surgery has become a safe procedure to decrease mortality in patients with heart valve disease [1]. Recent studies have shown that patients also benefit from an enhanced functional health status after surgery [2–5]. Cardiac factors such as the preoperative etiology or a reduction in the heart's function as a pump, as measured by the left ventricular ejection fraction, predict mortality [6]. However, patient's post operative health status is better reflected by functional measures, such as walking distance, quality of life and the New York Heart Association functional classification [7,8]. Ideally, patients should receive an accurate prognosis about their likely functional health status after surgery. Moreover, patients being at-risk for a poor functional outcome after surgery should be identified and offered treatment [9]. Therefore, exploring risk factors for decline in functional health status after valve replacement surgery is crucial.

Illness perceptions in cardiac diseases

As the physical, psychological and social characteristics of cardiac patients vary widely, the investigation of risk factors across all patients is challenging [10]. A valuable approach that can be applied to all patients focuses on the perceptions and beliefs, which patients develop about their cardiac disease [11]. According to the Common-Sense Model of illness representation [12] patients make sense of their symptoms by forming causal attributions about the illness, how long they think it will last, if it can be controlled or cured, and what consequences symptoms will have. Various studies in the past two decades have shown that cardiac patients develop a wide range of illness perceptions [13–15] and that these perceptions are associated with disease-related disability [16,17], adherence to medication [18] and recovery [19,20].

In terms of heart valve disease, Rimington and colleagues [7] found that, one year after valve replacement surgery, patients showed an improved walking distance but still reported a reduced physical quality of life. Whereas walking distance was only weakly correlated with preoperative cardiac functions (i.e. left ventricular systolic and diastolic function), it was independently associated with patients' perceptions of control over their condition. Furthermore, correlations

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between pre-operative illness representations and post-operative quality of life were also found. These authors propose that functional health status after valve replacement surgery could be optimized by early intervention to modify negative illness perceptions. Indeed, randomized controlled trials on illness perception interventions in patients with myocardial infarction have shown that recovery can be optimized by treating negative illness perceptions [21,22]. However patients' illness perceptions may change during the course of an illness, especially after a cardiac surgery.

Yet, there is very little research examining the stability or change in illness perceptions in patients with cardiac problems [23]. Moreover, no study has examined longitudinal changes following successful surgical treatment, such as valve replacement. Since this type of surgery is usually planned in advance, it is possible to assess illness perceptions prior to surgery and again after a period of recovery. In this way, it should be possible not only to assess the extent to which patients' perceptions change as the result of surgery but also whether any such changes are related to important health outcomes, and whether pre-operative risk factors can be identified.

Profiling illness perceptions

To date, research has focussed on individual components of illness perceptions rather than their overall pattern [24]. However, profiles of illness perceptions would seem to provide a more complete picture of illness schemata which may reflect stable dispositions towards an illness and therefore, may pose a stable risk factor. In an attempt to do this, Hobro and colleagues [25] were able to categorize patients who shared similar illness perceptions about their pain-disorder. Using cluster analysis, they were able to identify two groups of pain patients, whom they referred to as illness 'adapters' and 'non-adapters'. They then used this to comment on the likely needs of these patients as a basis for identifying factors for possible pain management interventions. In a longitudinal design, cluster analysis could be used to investigate the stability of illness perception patterns and define illness perception profiles. If there are stable illness perceptions profiles, risk profiles of negative illness perceptions could be determined to detect these patients at an early stage in order to communicate associated risk and, in turn, offer tailored treatment based on patients' illness perception profile. In terms of heart valve disease, patients at-risk for decline in functional health status after surgery may be early identified before surgery.

Objectives

The purpose of this longitudinal study is to a) investigate profiles of illness perceptions before and after heart valve surgery, b) determine how much change in profiles is related to pre- and post-operative health outcomes and c) test if illness perception profiles are predictive of functional health status one year after surgery.

Methods

Sample

To estimate the sample size a power-analysis was carried out: expecting a medium effect size between two illness perception clusters (Cohen's $d=0.5$) a sample of 180 patients was estimated to detect a significant effect ($\alpha=0.05$) with 80% power. Using multiple regression analysis to detect predictors of quality of life a sample size of 180 would allow 15 predictor variables to be used [26]. Allowing for a conservative attrition rate of 20% led to a recruitment target of 225.

351 patients were approached and invited to participate in the study. Of the 232 patients that consented, one died at home prior to admission and six did not have their valve replaced at surgery because

of medical decisions. A total sample of 225 patients having their first time valve replacement at St. Thomas' Hospital between January 2003 and June 2005 were enrolled prospectively. The mean age was 67.1 (range 26 to 89) years and 155 (69%) were male. Of these, 202 patients (90%) had an aortic valve replacement and 99 (44%) had concomitant coronary artery bypass grafting. Most ($n=146$, 65%) received a biological and 79 patients (35%) a mechanical valve. All patients gave written informed consent as directed by St Thomas' Hospital Research Ethics Committee. All patients enrolled were studied in a consecutive manner preoperatively during their admission for surgery; 204 patients were assessed again one year after surgery as outpatients (15 died, 4 withdrew consent and 2 were lost to follow up).

Demographic and clinical variables

Relevant socio-demographic variables age, gender, years of education, working status, and social support were assessed. To determine health status New York Heart Association (NYHA) class, comorbidities, number of drugs taken, left ventricular ejection fraction and type of valve prosthesis were assessed. A six-minute-walking test (Measuremeter, Trumeter, UK) was performed to test exercise tolerance. Patients were advised that the aim was to "measure what represents a normal amount of exercise for you at the moment" and that they could change speed or pause as required; distance walked in 6 min was recorded regardless of pauses or early termination of the test. Damage to the heart was measured with transthoracic echocardiogram (ATL HDI 5000, Seattle, Washington, US or GE VingMed System Five, Horten, Norway); the left ventricular ejection fraction (LVEF) was estimated semi-quantitatively [27].

Questionnaires

Short-Form 36 (SF-36) [28]

The SF-36 is a reliable and well-validated tool to measure quality of life in multiple groups of patients and several recent studies have proven its validity in cardiovascular research. Its 36 items assess both physical and mental health, which are represented by the physical component summary score (PCS) and the mental component summary score (MCS).

Illness Perception Questionnaire – Revised (IPQ-R) [29]

The IPQ-R was developed according to the Common-Sense Model of illness representations [30]. In numerous studies with cardiac patients it has shown good psychometric properties. Patient's perceptions of illness are assessed on 8 sub-scales: *identity* (the symptoms the patient ascribes to their illness), *timeline* (perceived illness duration), *consequences* (the effects on their life), *personal control* (how much influence they feel they have), *treatment control* (how well they rate their treatment efficacy), *coherence* (how well they understand their illness), *timeline cyclical* (the extent to which their illness is perceived as cyclical or permanent) and *emotional representations* (the emotional impact of the illness). Scores on each subscale are derived by summing the responses for each item. No cut-off scores are used but low scores on control subscales and high scores on identity, timeline, consequences, timeline cyclical, coherence, and emotional representations represent negative illness perceptions. These scores are then combined into illness perception profiles using cluster analysis (see *Statistical analysis*).

Hospital Anxiety and Depression Scale (HADS) [31]

The HADS is a 14-item self-report measure and was developed to screen for emotional distress in medical outpatients. It has proven to be a reliable and well-validated scale in various studies [32,33]. Total scores range from 0 to 21, where a score between 0 and 7 is in the 'normal' range, a score of 11 or more indicates the presence of a moderate or severe mood disorder and a score between 8 and 10 is suggestive of a mild mood disorder.

Statistical analysis

Hierarchical cluster analyses were performed to identify patterns of illness perceptions. Clatworthy and colleagues [34] also highlight this method to group like-minded individuals. Cluster method and final cluster solution was chosen according to recommendations [35,36]. To examine the stability of patterns over time and to define illness perception profiles, independent cluster analyses with illness perceptions assessed before and one year after surgery were calculated. According to the stability of illness perception profiles over one year patients were categorized into one of four groups (stable negative; stable positive; change from positive to negative; change from negative to positive).

Independent t-tests and chi-square tests were calculated for any differences in demographics, health status and emotional distress at baseline. ANOVAs were conducted to detect differences in NYHA class and quality of life one year after surgery between illness perception profiles; post-hoc tests were calculated using Bonferroni corrections. To determine the influence of stable illness perception profiles on health outcomes, multiple regressions with backward method were analyzed. All variables correlating on a bi-variate level P -value 0.1 were included and models with the highest adjusted R-square are reported. All analyses were performed using SPSS for windows version 15.0 (SPSS Inc, Chicago).

Results

Out of the 225 patients recruited for the study, illness perceptions (IPs) from 204 pre-operative patients and 145 post-operative patients were entered into cluster analysis. As only complete datasets can be analyzed with hierarchical cluster methods, only 136 patients could be identified before and again after surgery. For pre- and post-surgical data, two-cluster solutions were independently indicated by agglomeration schedules and confirmed through dendrogram-chart examinations. Before surgery, a cluster of patients ($n=84$) with negative IPs compared to a second subgroup ($n=120$) with positive IPs was indicated, i.e. these patients reported less health worries, feared fewer consequences, had higher control beliefs, associated fewer symptoms with their illness and perceived the course of their illness as predictable (Table 1). Similar clusters were found after surgery showing a subgroup ($n=61$) with negative IPs compared to a second subgroup ($n=84$) with positive IPs (Table 1). But a number of patients were identified whose profiles had changed across the course of the study. Thus, according to their IP pattern over one year patients were grouped in the following IP profiles: a) stable positive IPs, b) stable negative IPs, c) changing from positive to negative IPs, and d) changing from negative to positive IPs (Fig. 1).

Demographic and clinical characteristics of illness perception profiles before surgery

Patients with a stable positive IP profile were older ($T=2.53$, $P<.01$) and more likely to be male patients had a positive IP profile ($\chi^2=4.44$, $P=.04$). In terms of health status, patients with a stable negative IP profile had a higher NYHA class ($T=-3.3$, $P<.01$), had more comorbidities ($T=2.53$, $P<.01$) and a shorter walking distance ($T=2.53$, $P<.01$). No differences between stable IP profiles were indicated for etiology, type of valve replacement, left ventricular ejection fraction, number of drugs taken and rehab attendance after surgery. Patients having a stable positive IP profile reported a higher physical ($T=5.09$, $P<.01$) and mental quality of life ($T=4.85$, $P<.01$) before surgery. Higher levels of anxiety ($T=2.53$, $P<.01$) and depression ($T=2.53$, $P<.01$) were indicated by patients with a stable negative IP profile (Table 2).

No differences for any demographic and health variables were indicated between patients that changed their IP profile. However, a trend was shown that patients developing

negative IPs reported a higher mental quality of life ($T=1.83$, $P=.07$) before surgery. In contrast, no difference was indicated for physical quality of life. Patients developing positive IPs reported higher levels of anxiety ($T=-3.18$, $P<.01$). They also tended to report higher levels of depression ($T=-1.7$, $P=.1$) (Table 2).

Functional health status one year after surgery

ANOVAs indicated the four IP profile groups significantly differed on physical quality of life ($F=16.99$, $P<.001$), mental quality of life ($F=7.14$, $P<.001$) and NYHA class ($F=7.8$, $P<.001$) after surgery. For all three health variables, post-hoc tests and pairwise comparisons indicated the same significance pattern: patients with a stable positive IP profile differed from patients with a stable negative ($P<.001$) and patients developing positive IPs differed from patients with a stable negative IP profile ($P<.01$). One year after surgery patients with a stable positive IP profile and those who developed a positive profile reported a higher physical quality of life and were categorized in lower NYHA-class than patients with a stable negative profile (Table 3).

Predictors of functional health status one year after surgery

The regression model for NYHA class one year after surgery accounted for 39% variance ($F=7.8$, $P<.001$). NYHA class was independently predicted by IP profile ($\beta=-.27$, $T=-2.5$, $P=.02$), walking distance ($\beta=-.25$, $T=-2.0$, $P=.05$), and depression ($\beta=-.25$, $T=-2.16$, $P=.03$). There was a trend that pre-surgery assessed NYHA class could account for a unique variance as well ($\beta=.19$, $T=1.7$, $P=.09$).

The regression model for physical quality of life one year after surgery accounted for 59% variance ($F=17.12$, $P<.001$). Physical quality of life after surgery was independently predicted by IP profile ($\beta=.35$, $T=3.93$, $P<.001$) and years of full time education ($\beta=.22$, $T=2.77$, $P<.01$). There was a trend that walking distance ($\beta=.17$, $T=1.72$, $P=.09$) and physical quality of life ($\beta=.19$, $T=1.75$, $P=.08$) assessed before surgery also could account for a unique variance in physical quality of life after one year.

The model for mental quality of life one year after surgery explained 50% variance ($F=12$, $P<.001$). It was independently predicted by left ventricular ejection fraction ($\beta=-.20$, $T=-2.39$, $P<.05$) and depression ($\beta=-.34$, $T=-2.26$, $P<.05$). A trend was also indicated that age ($\beta=.18$, $T=1.87$, $P=.07$) and walking distance ($\beta=.20$, $T=1.87$, $P=.07$) could also predict mental quality of life (Table 4).

Discussion

As far as we know, this first study which has examined the course of illness perceptions before and after heart valve replacement surgery and related the findings to clinical and functional outcomes. Overall, our results show that patients with valve disease can be categorized into one of two stable illness perception profiles. Patients who hold or develop a stable negative illness perception profile during the course of their valve disease show a worse quality of life and are categorized in a more severe NYHA class before and after surgery. Moreover, since a stable negative illness perception profile assessed before surgery predicts physical quality of life and NYHA class one year after valve replacement surgery, it could constitute a possible risk factor for decline in functional health status in patients undergoing valve replacement surgery.

Before surgery two clusters of illness perceptions were indicated, accounting for all patients entered into cluster analysis. The majority of patients (59%) had positive perceptions of their heart valve disease compared to a subgroup with negative illness perceptions; the latter patient group associated more symptoms and reported less medical and self-control over their valve disease; these patients feared more consequences, were more emotionally involved, perceived their valve

Table 1
IPQ-R subscales per cluster before and after surgery

IPQ-R subscale	Pre-OP-cluster 1 negative IP (n=84)	Pre-OP-cluster 2 positive IP (n=120)	Post-OP-cluster 1 negative IP (n=61)	Post-OP-cluster 2 positive IP (n=84)
Identity* (Mean±SD)	4.90±2.51	3.44±2.52	4.39±2.70	1.15±1.40
Timeline*	18.76±5.47	14.51±4.45	22.49±3.75	18.35±5.32
Consequence*	21.81±3.95	17.37±3.65	20.61±4.42	13.99±3.92
Personal control*	18.68±3.77	21.60±3.56	19.31±4.46	22.07±3.26
Treatment control*	18.96±2.89	20.48±2.48	18.13±3.44	21.70±2.65
Coherence*	12.46±3.98	10.65±3.98	12.17±4.25	10.34±3.57
Timeline cyclical*	11.25±3.27	8.08±2.39	9.79±3.36	7.71±2.67
Emotional representations*	21.40±3.50	15.89±4.81	20.18±5.62	14.25±4.21

* Significant at $P<.01$.

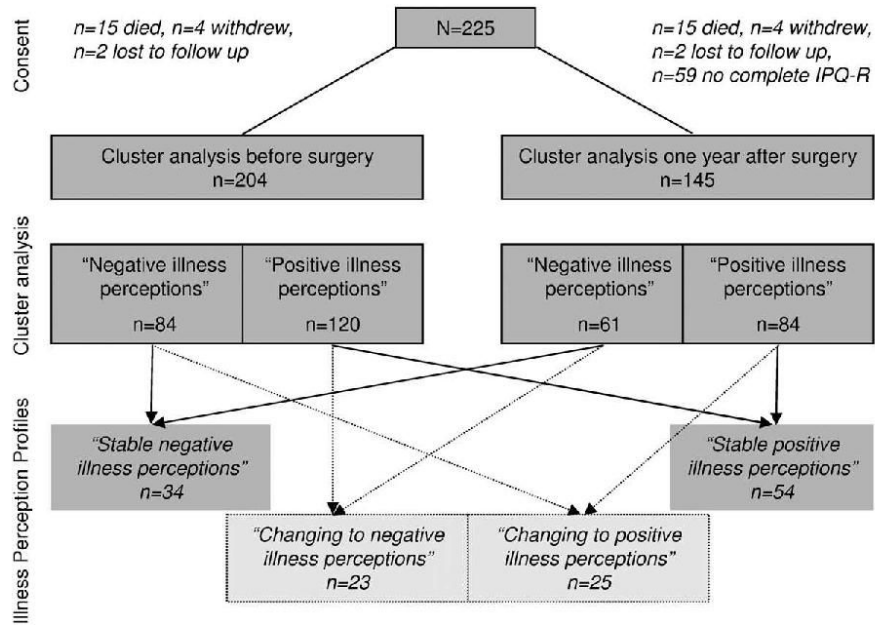


Fig. 1. Consort flowchart.

disease as cyclical, and had a less coherent understanding of their illness. To our surprise, similar illness perception patterns were shown one year after surgery. Subsequently, four profiles of illness perceptions could be derived and patients were grouped into their profile over time

in 'stable negative', 'stable positive', 'changing to negative', and 'changing to positive'. Compared to results from Devcich and colleagues [13] who showed that cardiac patients change their illness perception shortly after coronary angiography, our findings indicate that one year after

Table 2 Demographics, health status, quality of life and mood state before surgery

Variable	Illness perception profile			
	Stable negative (n=34)	Changing to negative (n=23)	Changing to positive (n=25)	Stable positive (n=54)
	Mean±SD or number (%)			
Demographics				
Age	60.21±13.35	67.74±13.38	63.28±13.39	66.81±9.19
Gender	14 (41.1%) female	3 (13%) female	9 (36%) female	11 (20%) female
Years of education	10.29±3.62	11.65±2.89	11.28±2.17	11.48±2.84
Retired	25 (73.5%)	4 (17%)	9 (36%)	42 (77.7%)
Hours spent working	9.74±17.33	10.46±17.84	9.92±22.88	9.49±13.59
Hours spent for hobbies	5.82±6.76	5.39±6.53	5.56±5.70	8.23±7.08
Caring spouse	20 (58.8%)	11 (47.8%)	17 (68%)	37 (68.5%)
Health status				
Biological graft	15 (44.1%)	15 (65.2%)	16 (64%)	31 (57.4%)
Mechanical graft	19 (55.9%)	8 (34.8%)	9 (36%)	23 (42.6%)
Aortic valve replacement	28 (82.3%)	23 (100%)	19 (76%)	52 (96.3%)
Mitral valve replacement	2 (5.8%)	0	2 (24%)	2 (3.7%)
LVEF	64.71±13.76	58.70±16.53	60.00±14.58	59.72±14.29
NYHA class	2.44±0.66	2.00±0.67	2.12±0.67	2.02±0.53
Walking distance (meter)	249.06±146.32	296.86±158.57	297.77±155.67	358.66±113.05
Number of drugs	3.32±1.95	3.78±2.33	3.29±3.37	2.93±2.09
Comorbidities	2.21±1.30	1.43±1.16	1.88±1.30	1.61±1.23
Rehab attendance (n=85) after surgery	22 (64.7%)	12 (52.2%)	15 (60%)	36 (66.7%)
Quality of life				
PCS	22.97±11.52	29.82±14.05	28.80±14.08	37.07±12.92
MCS	40.46±13.00	51.94±9.42	46.59±10.74	52.86±10.33
Mood State				
Anxiety	9.35±5.16	5.04±2.85	8.24±3.97	5.70±3.67
Depression	7.79±4.98	4.43±2.79	6.24±4.32	3.67±3.29

Table 3
New York Heart Association class, physical and mental quality of life one year after surgery

Variable	Illness perception profile				P-value
	Stable positive (n=54)	Changing to positive (n=25)	Changing to negative (n=23)	Stable negative (n=34)	
	Mean±SD				
NYHA	1.38±0.49	1.46±0.59	1.65±0.65	1.94±0.56	<.001
PCS	45.56±10.28	39.96±13.06	33.54±12.51	28.57±10.93	<.001
MCS	55.32±7.99	51.43±8.42	51.82±11.54	43.20±14.07	<.001

valve replacement surgery there is a fairly large group of patients with a stable perception of their heart valve disease their illness and a smaller group whose perceptions change after surgery. This leads to the assumption that some patients change their perceptions from negative to positive even without receiving specific illness perception interventions. Rehab attendance might influence illness perceptions (e.g. improve illness control belief) [37,38]. However, our results indicated that illness perception profiles were not related with rehab attendance, suggesting that a change in the overall illness perception pattern is not directly influenced by interventions aiming at cardiac rehabilitation.

Results from cluster analysis also indicate that patients with heart valve disease can be categorized into illness perception profiles despite the heterogeneity of health characteristics. This finding is of special interest in terms of identifying a specific risk factor all patients share. Moreover, it can be assumed that cardiac patients can be screened for negative illness perception profiles. Unfortunately, comparable longitudinal studies categorizing patients according to their illness perceptions are missing. Based on our results and future studies, objective cut-off points defining risk profiles could be derived and used as a basis for developing interventions to facilitate recovery (see below).

Before surgery, illness perception profiles were associated with clear differences in health status: patients with a stable negative profile were categorized in a higher NYHA class, were diagnosed with more

comorbidities, had a shorter walking distance and reported a worse quality of life and higher emotional distress. In accordance with other cross-sectional findings these results show that negative illness perceptions correspond with a worse objective health status [39,40]. Consequently, illness perceptions assessed before surgery give diagnostic information about patients' health status and may help to identify patients at-risk before surgery. In our sample nearly half of the patients (40%) had a negative perception of their valve disease before and even one year after surgery. This finding again highlights the need to screen for surgery patients at-risk because of negative illness perceptions.

Counterintuitively, patients who developed positive illness perceptions reported higher anxiety scores before surgery. Anxious but not depressed patients are more concerned about their health and are motivated to follow doctor's advice [41,42]. Thus, these patients may gather health-relevant information, form an accurate view of their valve disease and develop positive illness perceptions. Female patients were more likely to hold negative illness perceptions over one year. Corresponding results show that female patients also tend to report a worse physical and mental quality of life [2,10,43]. Unexpectedly, younger patients were categorized with a stable negative illness perception profile. This contrasts with previous studies on risk factors after valve surgery, in which 'young age' has been found to be a protective factor [6]. Therefore, there is a clinical need to investigate why young patients have particularly negative perceptions of their valve disease. In sum, characteristics of patients with changing illness perception profiles should be focussed with in-depth interviews and multi-assessment strategies. Moreover, future studies should test determinants for changing illness perceptions and then target these determinants in illness perception interventions.

One year after surgery, patients with a stable negative illness perception profile were diagnosed in a higher NYHA class and showed a worse physical and mental quality of life compared to patients having or developing positive illness perceptions. Though patients with stable illness perception profiles already differed in health status before surgery, results show that patients developing a positive perception of their valve disease showed a better health status one year after surgery. Hence, it can be argued that developing positive illness perceptions is associated with better health outcomes. Results from regression analyses underline this assumption: physical quality of life after surgery was firstly predicted by illness perception profile assessed before surgery and secondly by years of education. Well-known predictors like walking distance, number of comorbidities, left ventricular ejection fraction [43] and even pre-surgery assessed physical quality of life lost their predictive value, when illness perception profile was entered into the regression model. Although somatic health markers improve, physical quality of life has been found to be reduced one year after valve replacement surgery [7]. Our results indicate that the illness perception profile is a unique determinant for physical quality of life one year after valve replacement surgery. Similar results from multiple regression analysis were indicated for NYHA class that was over and above any other health marker strongest predicted by illness perception profile. Whereas previous studies on illness perceptions in cardiac patients have focussed on self-ratings and psycho-social factors as health outcomes, this study shows that an external cardiac rating is predicted by a subjective perception of an illness. So far, only depression has been found to be associated with NYHA class [44,45]. Results from this study replicate these findings but in addition they indicate that illness perception profiles can significantly improve the model to predict cardiac health status.

Taken together, these findings indicate the potential for clinical application of illness perceptions in patients undergoing valve replacement surgery: illness perceptions are formed by personal experiences during the development of a heart valve disease and they are less influenced by medical changes [11]. Thus, the influence of illness perception profiles on health outcomes should be independent from the course of surgery [16]. As preoperative illness perception profiles predict health

Table 4
Hierarchical multiple regression analysis predicting New York Heart Association class, physical and mental quality of life one year after surgery

Variables	B	SE B	Beta	F-value-adjusted R ²
NYHA class				7.8–.39**
PCS pre-surgery	-.01	.01	-.23	
NYHA pre-surgery	.18	.11	.19	
Walking distance	-.001	.00	-.25*	
Depression	-.03	.02	-.25*	
Years of education	-.02	.02	-.1	
Hours spent for working	-.004	.00	-.01	
Illness perception profile	-.16	.07	-.27*	
Quality of life – PCS				17.12–.59**
PCS pre-surgery	.18	.1	.19	
Walking distance	.02	.01	.17	
Comorbidities	-1.25	.89	-.12	
Number of drugs	-.82	.54	-.12	
Years of education	.94	.31	.22*	
Hours spent for working	.09	.07	.10	
Illness perception profile	4.74	1.21	.35**	
Quality of life – MCS				12.0–.50**
PCS pre-surgery	-.1	.10	-.11	
MCS pre-surgery	.15	.12	.16	
LVEF	-.17	.07	-.20*	
Walking distance	.02	.01	.20	
Depression	-.91	.40	-.34*	
Age	.18	.01	.18	
Illness perception profile ^a	1.59	1.22	.13	

* Significant at P<.05.

** Significant at P<.01.

^a Positive illness perception profile=1; negative illness perception profile = -1.

outcomes after surgery, they should be used as a diagnostic tool. Ekman and colleagues [46] highlight that the recognition of symptoms and appreciation of their importance justifies the use of a structured assessment in order to provide optimal medical care. The 'Brief-Illness Perception Questionnaire' is a nine-item measurement, easy to administer and analyze, and an effective tool for detecting surgery patients at-risk [47]. Based on our results, clinical cut-off points defining negative and positive illness perception profiles could be established and tested in future studies.

So far, it is neither known why some patients develop positive illness perceptions, nor why these patients benefit from a better health status. In other surgical disciplines there might be patients that have favorable medical outcomes, but report negative illness perception before surgery. Thus, future studies should focus on the development of illness perceptions within the first year post-surgery and on what health behavior is linked to positive illness perceptions. In terms of valve disease, stable inaccurate perceptions of one's valve disease may lead to non-adherence to medication, i.e. anticoagulation therapy, and as Butchart [48] comments (p. 723), 'probably the single most important thing that we can do for our patients is to ensure that they have good-quality anticoagulation control'. Exploring these behavioral mechanisms could provide a basis for new illness perception interventions in patients undergoing valve replacement surgery. Promising results from two randomized controlled trials showing that a short in-hospital illness perception-intervention leads to a faster recovery after myocardial infarction underline this argument [21,22].

The limitations of this study in terms of sample representativeness must be noted: First, our results are only applicable to aortic valve replacement patients as these comprised 90% of the sample. Second, patients were only recruited from one hospital and multi-centre studies are now needed. Third, one year dropout rate due to incomplete datasets on illness perceptions must be mentioned. Patients who did not finish participation in the study might suffer from problematic health conditions that prevented them from further participation. However, it should be noted that patients who were not included into the cluster analysis did not differ in health status from patients who were. In comparable longitudinal study designs, similar dropout rates have been reported [49–51]. In short, replications of our results are needed to confirm representativeness for heart valve patients and to extend them to other cardiac surgery patients.

In sum, findings from this study show that patients undergoing valve replacement surgery can be categorized according to their illness perception profiles: whereas some patients hold a stable negative or positive illness perception, there is a group that changes their profile to positive or negative. Moreover, findings indicate that illness perception profiles not only correspond with functional health status but also predict quality of life and NYHA class one year after valve replacement surgery. Future studies on patients with heart valve disease should take account of negative illness perception profiles, their development, and association with treatment adherence. As negative illness perceptions are modifiable risk factors, these patients could benefit from an early illness perception screening.

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Contributors

HR and JW designed the study. HR studied the patients. SK managed the literature searches and analyses, undertook the statistical analysis and wrote the first draft of the manuscript. All authors contributed to and have approved the final manuscript.

Declaration of interest

All authors declare that they have no conflicts of interest.

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Appendix C: Paper 3:

Supportive care needs in patients with cardiovascular disorders

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Keywords

Cardiology; cardiovascular disorder; needs assessment; patient communication; supportive care.

Abstract

Objectives

Unmet medical needs are a focus in cardiovascular disorder (CVD) research. However, few studies have investigated patients' perceived needs. The present study examined supportive care needs in patients with CVD and their relation to health characteristics.

Methods

In total 260 in-patients with CVD were consecutively assessed with the Supportive care Needs Survey. Primarily, frequency and content of unmet needs were examined. Secondly, CVD-diagnoses were compared and correlations with risk factors, treatment characteristics, mood-state and quality of life were analyzed.

Results

Supportive care needs were indicated by 21% of all patients: unmet health information (37%) and psychological (23%) needs were most frequent. The number of unmet needs did not differ between most CVD-diagnoses. Unmet needs were not related to cardiac risk factors. However, treatment characteristics ($r=.17-.23$, $p<.01$), anxiety ($r=.44-.71$, $p<.01$), depression ($r=.38-.63$, $p<.01$), physical ($r=.21-.47$, $p<.01$) and mental ($r=.29-.65$, $p<.01$) quality of life were associated with unmet needs.

Conclusions

Supportive care needs are common in patients with CVD. They are based on patients' treatment characteristics, emotions and subjective well-being rather than on cardiac factors.

Practice implications

Needs assessments in patients with CVD could detect unmet needs, enhance patient education and communication and, therefore, effectively target patients' perceived needs and medical needs.

1. Introduction

Recent epidemiological studies show declining mortality rates of cardiovascular disorders in western countries [1]. Despite major medical advances, however, the absolute number of treated patients increases due an ageing population [2]. This fact makes cardiovascular disorders a health and economic burden which is associated with loss of quality-adjusted life years and increasing health care costs [3]. There is, therefore, considerable need for cost-effective and patient-tailored disease management programs on the one hand and risk-population based prevention programs on the other.

However, effective disease management programs are difficult to implement [4-7]. A major challenge for secondary prevention programs could be the discrepancy between medical treatment advice (as well as favorable treatment goals) and patients' perceived illness related disability and their associated need for help. Supportive care needs is a new approach widely used in psycho-oncology which tries to capture this subjective burden of an illness "by directly measuring patients' own perceptions of their need for help on given issues as well as the magnitude of their desire for help in dealing with those needs" [p. 602, 8]. According to Bonevski and colleagues [9] needs assessments have three major advantages over other patient-reported-outcomes: (1) direct indication of needed resources, (2) quantifying unmet needs, and respectively allocating health resources, (3) identification of patients and subgroups with levels of need and consequently, need-targeted prevention and early intervention.

Research on supportive care needs in patients suffering from cancer has identified important, but also unresolved health-issues concerning emotional distress (e.g. fear of progression), health information (e.g. health self-management), physical and daily living (e.g. pain), patient care (e.g. treatment choices), and sexuality (e.g. changes in sexual feelings). Moreover, various studies have shown associations between these need-domains with psycho-social morbidity [10], satisfaction with health-care, symptom complaints [11-12] and quality of life [13-15].

Jones and colleagues [16] investigated whether a patient-centered process of supportive care can improve patient-clinician communication. Results indicated that this approach helps patients to reflect, to initiate a discussion and to get validation on their unmet needs. Patients felt encouraged to seek help and support and could focus

clinicians' attention towards unmet needs. By enhancing patient-clinician communication, health care resources can be allocated to the issues patients themselves have identified as the most important. Moreover, in clinical practice, a comparison of perceived unmet needs with favorable medical treatment advice has the means to establish a treatment consensus. Ultimately, increased treatment adherence can reduce the health and economic burden of cardiovascular disorders.

To our knowledge this is the first study to examine supportive care needs in patients with cardiovascular disorders. The primary aim was to characterize the quantity and content of unmet needs. As secondary aims, we compared the amount of needs across different cardiovascular disorders and examined associations between supportive care needs with risk factors, treatment characteristics, mood state and quality of life.

2. Method

2.1. Study group

Inpatients with any known cardiovascular disorder were screened for eligibility between the 15th September and 15th December 2010 on all wards except for the intensive care unit. Inclusion criteria were sufficient language skills, age greater than 18 years, and written informed consent as directed by the local Ethics Committee. Exclusion criteria were kept at a minimum to assess a representative sample of inpatients with cardiovascular disorders. Patients who were discharged early, those with cognitive or motor deficits, or symptomatic transitory psychotic syndrome were excluded.

2.2. Assessment

Patients were screened for eligibility if they were diagnosed with any cardiovascular disorder by an experienced cardiologist from the university heart center. Additionally, medical records were checked if the cardiovascular disorder was the primary diagnosis for current inpatient treatment. On average, on the 5th day ($SD \pm 8$) of stay, patients filled out a questionnaire assessing their levels of unmet needs. In addition, patients answered questions on socio-demographic data, mood state, quality of life, and the following risk factors: smoking, alcohol consumption, and

obesity. The following risk factors were assessed through medical records: Hypertension, hyperlipidemia, diabetes, obesity, nicotine, and alcohol abuse. To define treatment characteristics the way of referral, surgical procedures, medication, and length of stay were also assessed. Additionally, we asked patients if they had ever been in psychotherapy.

2.3. Questionnaires

2.3.1. Supportive Care Needs Survey (SCNS-SF34) [8]

The SCNS-SF34 is a validated 34-item instrument which measures patients' perceived needs across a range of five domains: psychological (emotions and coping), health system and information (treatment center and information about the disease), physical and daily living (coping with physical symptoms, side effects, performing usual physical tasks), patient care (health care providers showing sensitivity to physical and emotional needs, privacy and choice) and sexuality needs (sexual relationships). Across various studies in patients with cancer the SCNS-SF34 has shown high internal consistency (Cronbach's α : 0.86 to 0.96) and demonstrated convergent validity with other measures of psychosocial well-being. The questionnaire was adapted to cardiovascular disorder by replacing the term cancer with cardiovascular disorder and rephrasing single items (e.g. "fear of cancer spreading" into "fear of cardiovascular disorder progressing"). To quantify supportive care needs, patients are asked to answer on a five-point likert scale ('no need', 'need, but satisfied', 'low need', 'moderate need', 'high need'); to identify patients with unmet needs answers are dichotomized in "no need" ('no need', 'need, but satisfied') versus "unmet need" ('low need', 'moderate need', 'high need'). Additionally, to assess overall need sum scales can be calculated ranging from 0-100.

2.3.2. Short-Form 12 (SF-12) [17-18]

The SF-12 is a reliable and well-validated tool to measure quality of life in multiple groups of patients and several recent studies have demonstrated its validity in cardiovascular research [19-20]. The 12 items assess both physical and mental health which are represented by the physical component summary score (PCS) and the

mental component summary score (MCS). These scores were calculated according to the German manual (for detailed information see [21]).

2.3.3. Hospital Anxiety and Depression Scale (HADS) [22]

The HADS is a 14-item self-report measure and was developed to screen for emotional distress in medical patients [23-24]. It has been shown to be a reliable and well-validated scale in various studies in patients with cardiovascular disorders [25-26]. Two sum scores are calculated for anxiety and depressive symptoms. Total scores range from 0 to 21, where a score between 0 and 7 is in the 'normal' range, a score between 8 and 10 is suggestive of a mild mood disorder and a score of 11 or more indicates the presence of a moderate or severe mood disorder.

2.4. Statistical analysis

Primarily, in analogous fashion to previous research on supportive care needs, descriptive analyses were conducted examining the quantity, distribution, frequency and contents of unmet needs. As secondary analyses we examined associations between supportive care needs domains and important health markers. First, odds-ratios were calculated to compare levels of supportive care needs between primary cardiovascular diagnoses. Second, bivariate correlational analyses testing associations between supportive care needs with risk factors, treatment characteristics, mood state, and quality of life were calculated. Sample size estimation was based on other studies examining the frequency and content of supportive care needs [8]. For secondary explorative analyses, a power analysis was carried out to detect small to medium effects (Pearson's $r=.15$) while calculating bivariate correlation analyses ($\beta=.80$ and $\alpha=.05$). Based on these estimations and incorporating a conservative attrition rate of 15% we determined that a sample size of $N=300$ patients would be appropriate. Single missing values were estimated and completed using multiple-imputation analysis according to recommendations [27]. All analyses were performed using SPSS for windows version 18.0 (SPSS Inc, Chicago, USA).

3. Results

3.1. Sample

A total of 333 patients with any cardiovascular disorder were screened for eligibility (see Figure 1). Of these, 260 patients gave written informed consent as directed by the local Ethics Committee and were included into analyses. Table 1 summarizes the patients' characteristics. Most patients were male (70%), on average 63 years old, not living alone (76%) and still working (63%). On average they spent seven days in hospital with nearly half of them (47%) received invasive procedures. Most came electively (70%). Still, more than half of the sample (52%) reported a physical quality of life below average. Almost every fourth patient (23%) reported a mental quality of life below average with 38% experiencing anxious and 26% having depressive symptoms. Nearly every fifth patient (18%) reported having received psychotherapy. In terms of risk factors, patients' self-reports differed from physicians' ratings: 23% were diagnosed with nicotine abuse, but 73% of the patients indicated themselves as being a current or past smoker. In contrast, 2% were diagnosed with alcohol abuse, 12% reported drinking alcohol on daily occasion. Finally, 12% were also diagnosed as obese, however, nearly twice as many reported a Body-Mass Index above 30.

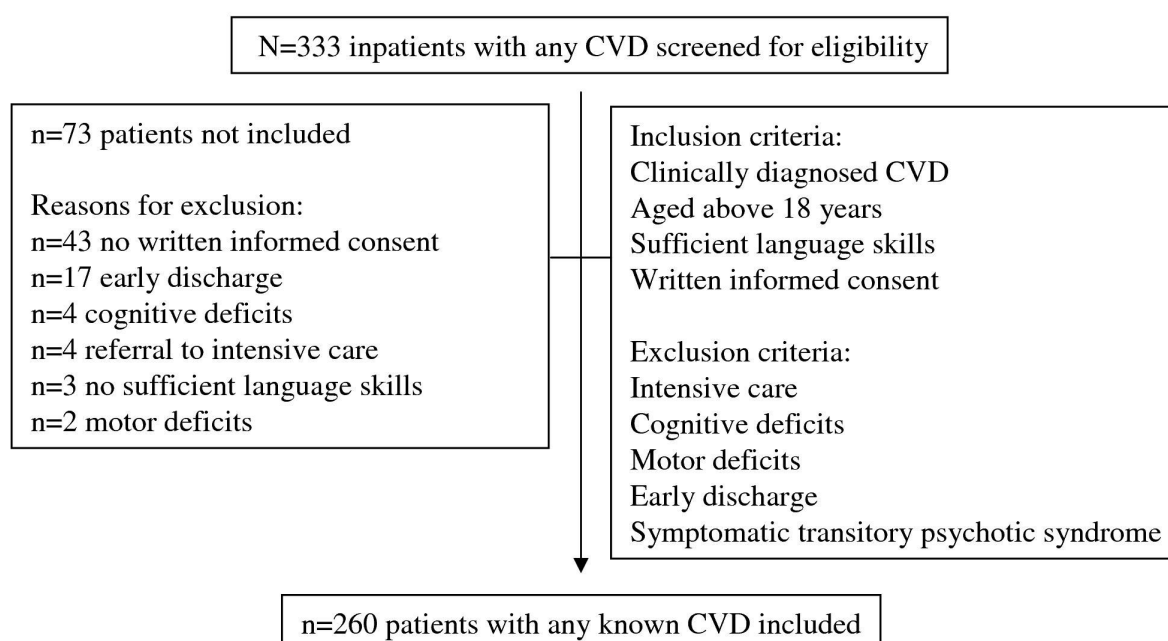


Figure 1. Patient flow chart

Table 1. Characteristics of the study sample

Variable	Mean±SD / Percentage (Nr)
<i>Demographics</i>	
Age	62.6±12
Male gender	70% (184)
Years of education	14.5±2.8
Living alone	24% (62)
Not working	37% (96)
<i>Primary diagnosis</i>	
Coronary heart disease	18% (47)
Chronic heart failure	12% (33)
Heart valve disease	10% (27)
Heart arrhythmia	39% (100)
Peripheral arterial disease	4% (9)
Other CVD diagnosis	10% (27)
Other non CVD diagnosis	6% (15)
<i>Risk factors – physician-rated</i>	
Hyperlipidemia	30% (77)
Diabetes	13% (31)
Hypertension	60% (155)
Adiposity	12% (31)
Alcohol abuse	2% (6)
Nicotine abuse	23% (60)
Nr. of comorbid CVD	1.2±1.4
<i>Risk factors – self-rated</i>	
Smoker	
Yes	15% (38)
Yes, in the past	58% (151)
No, never	26% (68)
Daily alcohol use	12% (31)
Body-Mass Index >30	22% (57)
<i>Treatment characteristics</i>	
Referral	
Elective	70% (182)
Emergency	20% (53)
From other hospital unit	10% (25)
Invasive procedures	47% (124)
Nr. of drugs	6.7±3.2
Length of stay	7.3±10.9
Ever in psychotherapy	18% (47)
<i>Quality of Life</i>	
Physical Component Summary	
Below average	52% (135)
In average	48% (124)
Above average	<1% (1)
Mental Component Summary	
Below average	23% (60)
In average	70% (182)
Above average	7% (18)
<i>Mood State</i>	
Anxiety	
Moderate	25% (65)
Severe	13% (35)
Depression	
Moderate	18% (47)
Severe	8% (22)

3.2. Supportive Care Needs Survey – Psychometric properties

For all sum scales internal consistency (Cronbach's α) was indicated as substantial, as follows: psychological $\alpha=.94$, health information $\alpha=.96$, daily living $\alpha=.97$, patient care $\alpha=.88$ and sexuality $\alpha=.80$. Intercorrelations between subscales were moderate and ranged from $r=.49$ to $r=.73$ (for all: $p<.001$).

3.3. Supportive Care Needs Survey – Descriptive analysis

Frequency analysis indicated that on average 21% of all patients indicated unmet supportive care needs. Concerning the need domains, 37% of all patients reported unmet health-information needs, 23% psychological needs, 14% needs concerning daily living, 11% patient care needs and 18% needs concerning sexuality. Means and standard deviation errors of need domains are shown in table 2.

Item content analysis showed that there were five supportive care needs indicated by over half of the patients. These needs mainly comprised of health information needs concerning contact to hospital staff, coping with disease, diagnostic information, treatment benefits and side-effects. However, more than 50%

of patients also indicated unmet psychological needs to deal with the fear of disease progression (see table 3).

Table 2. Patients reporting low, moderate or high supportive care needs

<i>Domain</i>	<i>Means ±SDe</i>	<i>Low need</i>	<i>Moderate need</i>	<i>High need</i>
Health information	36.8±1.9	23% (60)	9% (23)	5% (14)
Psychological	30.7±1.6	15% (40)	7% (18)	<1% (1)
Daily living	23.6±1.4	10% (27)	3% (7)	<1% (1)
Patient care	20.6±1.5	6% (15)	3% (9)	2% (5)
Sexuality	21.6±1.5	12% (30)	5% (13)	1% (3)

3.4. Supportive Care Needs Survey – Differences in primary diagnosis

Figure 2 displays odds-ratios (OD) with confidence intervals (CI) to compare need domains in patients with different primary cardiovascular disorders including chronic heart failure, coronary heart disease, heart valve diseases and heart arrhythmias. Patients with chronic heart failure reported 2.95 times greater needs concerning daily living (OD=2.95, CI=1.39-6.25, $p=.005$) and tended to indicate 1.62 times greater psychological needs (OD=1.62, CI=.77-3.41 $p=.20$). In contrast patients with heart arrhythmias showed 2.32 times lower needs in daily living compared to patients with other primary cardiovascular disorders (OD=2.32, CI=1.23-4.36, $p=.009$). Most ODs of the comparisons between patients with different primary cardiovascular disorders ranged around one indicating that there were no significant differences in supportive care needs between these groups of patients.

Table 3. Supportive care needs indicated by at least 50% of the study population

<i>Item</i>	<i>Domain</i>
Having one member of hospital staff with whom you can talk to about all aspects of your condition, treatment and follow-up.	Health information
Being informed about things you can do to help yourself to get well.	Health information
Being adequately informed about the benefits and side-effects of treatments before you choose to have them.	Health information
Being given explanations of those tests for which you would like explanations.	Health information
Fears about the progression of the disease.	Psychological

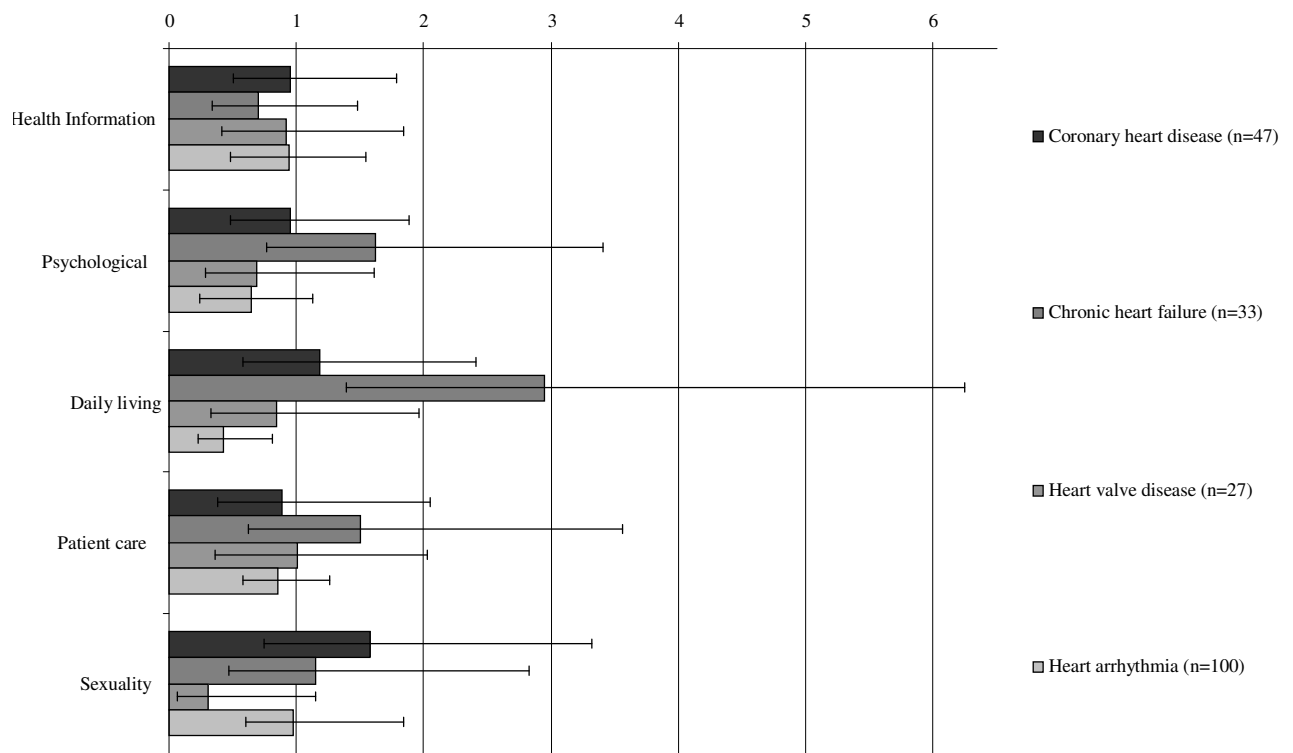


Figure. 2. Primary diagnosis and supportive care needs (odds-ratios and confidence intervals)

3.5. Supportive Care Needs Survey – Correlational analysis

No correlations between socio-demographic data and supportive care needs were evident, except a low correlation with years of education ($r=-.14$, $p<.05$) suggesting that higher education was related to lower daily needs. In terms of cardiovascular risk factors, associations with need-domains were relatively low: non-smokers tended to report lower psychological ($r=.12$, $p<.05$) and sexual needs ($r=.12$, $p<.05$); patients with diabetes reported higher needs concerning daily living ($r=.16$, $p<.05$) and patient-care support ($r=.12$, $p<.05$); the more diagnoses the more daily living needs ($r=.15$, $p<.05$) and sexuality needs ($r=.12$, $p<.05$) were reported. Patients with daily alcohol consumption indicated fewer needs concerning daily living ($r=.13$, $p<.05$) and patient-care support ($r=.12$, $p<.05$). Several correlations with variables defining treatment characteristics were indicated (see table 4), showing significant associations to needs concerning daily living ($r=.17-.23$, all $p<.01$) but also psychological needs ($r=.14-.30$, all $p<.01$). Results indicated strong associations between unmet needs and contact to psychotherapy: patients who had been in

psychotherapy reported less unmet needs across all supportive care need domains ($r=.17-.30$, all $p<.01$).

Table 4. Correlations between supportive care needs and treatment characteristics

Variable	Supportive Care Need Domains				
	Psychological	Health information	Daily living	Patient care	Sexuality
Emergency referral	.11	.03	.17**	.08	.03
Invasive procedure	.06	-.04	.17**	.03	-.01
Nr. of drugs	.17**	.09	-.26**	.14*	.19**
Length of stay	.14*	.04	.28**	.08	.07
Ever in psychotherapy	-.30**	-.17**	-.23**	-.26**	-.21**

*=significant at $p<.05$; **=significant at $p<.01$

Strong associations between supportive care needs mood state and quality of life were shown (see table 5): higher scores across all need-domains related with higher level of depression ($r=.38 - .63$, all $p<.01$) and anxiety ($r=.44 - .71$, all $p<.01$), but lower scores on physical ($r=-.21 - -.47$, all $p<.01$) and mental ($r=.29 - .65$, all $p<.01$) quality of life. In other words, patients reporting unmet needs were more likely to report a lower quality of life and worse mood state.

Table 5. Correlations between supportive care needs, mood state and quality of life

Variable	Supportive Care Need Domains				
	Psychological	Health information	Daily living	Patient care	Sexuality
Quality of life					
Physical component	-.27**	-.21**	-.47**	-.29**	-.27**
Mental component	-.65**	-.29**	-.60**	-.42**	-.46**
Mood state					
Depression	.60**	.38**	.63**	.47**	.41**
Anxiety	.71**	.44**	.58**	.51**	.46**

*=significant at $p<.05$; **=significant at $p<.01$

4. Discussion

The treatment of cardiovascular disorders mainly aims to reduce and control medical risk factors. Integrating patients' perceptions of need for help into patient-consultation could enhance achievement of these treatment goals. To our knowledge, this is the first study in patients with cardiovascular disorders that has examined perceived supportive care needs and quantified, detected and characterized unmet needs. Moreover, associations between unmet needs with risk factors, treatment characteristics, mood state and quality of life were shown. Based on these findings, future research and clinical implications can be derived.

On average every fifth patient treated for a cardiovascular disorder reported unmet supportive care needs. Similar rates have been shown for inpatients suffering from cancer [10, 28]. Patients with cardiovascular disorders showed a broad spectrum of supportive care needs. Needs concerning health information and psychological support were the most frequent. Less frequently patients reported unmet needs concerning daily living, patient care and sexuality. It is possible, however, that the need profile of this patient population was influenced by the current inpatient treatment. Routinely, patients receive their health information at discharge and, therefore, unmet health information needs might decrease after discharge. In the current sample 38% of patients indicated anxious and 26% showed depressive symptoms these negative emotional states can influence information processing [29]. As follows, this could influence perceived unmet health information needs. Increased rates of depression and anxiety might be the reason why the second most frequent perceived needs were psychological needs. Negative emotional states might decrease after discharge and so psychological needs might also decrease. Patients who had ever been in psychotherapy reported lower unmet needs. As follows, it would be worth investigating whether patients benefit from a psychological treatment approach based on their psychological need profile. However, future studies should firstly investigate whether this need profile can be replicated. Even more importantly, the supportive care need profile of outpatients should be examined, as these patients may rather focus on unmet needs concerning their day-to-day ability to cope with the cardiovascular disorders.

So far, studies directly comparing the amount of unmet needs between different diseases are lacking. Interestingly, results from this study showed, that unmet needs did not differ between most primary diagnoses. Similar results have been reported for patients with different tumor diagnoses [30]. Still, it must be noted that patients with chronic heart failure reported higher needs concerning daily living compared to patients with other cardiovascular disorders. This might be due to greater symptom distress associated with chronic heart failure (e.g. dyspnoea oedemas, fatigue). In contrast, patients with heart arrhythmias were less likely to indicate that they had unmet needs concerning daily living. Heart arrhythmias occur spontaneously and the

associated symptoms might not interfere with daily living. Thus, these patients might report less need for help with their daily routine.

Interestingly, unmet needs were not related to objective health status (e.g. diagnosis, comorbidities) and associations with established risk factors (e.g. smoking, hypertension, diabetes) were marginal. Patients reporting unmet needs, however, showed specific treatment characteristics: they were more likely to be referred by emergency, stay longer in hospital, have more medications, and receive surgical procedures. Furthermore, these patients with unmet needs indicated a worse quality of life, as well as higher depression and anxiety scores. The latter result is a consistent finding in patients with cancer [12, 31-32].

Taken together, these results suggest that unmet supportive care needs are based on patients' subjective experience with their cardiovascular disorder rather than on medical health status or cardiac risk factors. Strong associations between unmet needs with decreased quality of life and increased emotional distress underpin this assumption. Future studies should longitudinally investigate whether perceived health burden is influenced by unmet needs. Recent interventional trials targeting supportive care needs in patients with cancer did not find an effect on quality of life and emotional well-being [33-34]. Results from this study suggest that treatment characteristics are related to supportive care needs. Focusing unmet needs could help to meet patients' specific treatment characteristics. Even more, integrating a need-assessment into patient-consultation could have the means to allocate health resources to those patients most needing them, thus, reducing health burden and health-care costs. But before testing these hypotheses, future studies should longitudinally investigate associations between supportive care needs with treatment characteristics, allocation of health resources and health care cost.

As Jones and colleagues [16] have shown, a supportive care needs approach can enhance patient-clinician communication. Patients whose unmet needs are not considered in medical treatment may focus on alternative therapies and might be less motivated to focus on medical risk factors (e.g. hypertension). By applying a supportive care needs assessment, clinicians could easily detect unmet needs and patients could get validation for their subjective need for help. In turn, treatment goals could be established in accordance with the patient. Banegas and colleagues [4]

conclude that about one third of patients that are treated for a cardiac risk factor remain at high risk for developing a cardiovascular disorder. In a multicenter study they showed that of 7641 patients treated for cardiovascular risk factors only 39% had sufficient blood pressure control, 41% had their cholesterol controlled and only 37% reached their insulin control target. Moreover, referral, enrollment, and completion rates of secondary prevention programs could be optimized [5-6]. In clinical routine, a supportive care needs approach could enhance patient-tailored disease management programs to reduce under-controlled risk factors. It would be worth investigating whether such a treatment approach could increase treatment adherence in patients with cardiovascular disorders.

Few shortcomings of the current study must be mentioned: Our sample consisted of consecutively assessed patients treated for any cardiovascular disorder in a university medical center. As unmet supportive care needs were not related to diagnoses and risk factors, we would not expect community-hospital patients to differ in supportive care needs from our sample. Still, it must be noted that results only apply for inpatients and may not necessarily apply to outpatients with cardiovascular disorders. We cannot rule out that results might be influenced by other variables (such as gender, education, or income). That is why replications of this study with larger sample sizes are needed to estimate the prevalence of unmet needs and compare our findings with other patient groups suffering from cardiovascular disorders. In terms of psychometric properties, the Supportive Care Needs Survey yielded good internal consistencies across all subscales and moderate inter-correlations indicated divergent internal validity between subscales. Thus, this survey is a reliable instrument to assess perceived supportive care needs in patients with cardiovascular disorders. Still, it must be noted that this is the first study evaluating this survey in this patient group and further validation is clearly needed.

4.1. Practical Implications

Despite the fact that patients treated in hospital have direct contact to health care providers five unmet needs were indicated by more than half of the patients: (1) hospital staff member with who they can discuss all aspects of their illness, treatment and follow-up, (2) information about illness self-management, (3) information about treatment benefits and side-effects, (4) diagnostic information about medical

procedures, and (5) psychological help to deal with the fear of disease progression. These five supportive care needs could be directly addressed when consulting patients with cardiovascular disorders.

4.2 Conclusion

Firstly, this study demonstrated that patients with cardiovascular disorders report unmet supportive care needs. These needs mainly comprised health information and psychological needs. Unmet needs for help were related to subjective well-being and treatment characteristics, but not to health status or medical risk factors. A supportive care needs assessment could be a valuable approach to improve patient-clinician communication, especially as cost-effective and patient-tailored disease management programs are needed to sufficiently target treatment goals in patients with cardiovascular disorders.

Declaration of conflicting interests

The authors declare that there is no conflict of interest.

Contributors

SK, KZ and KHS designed the study. MSK and SK collected data and studied the patients. SK conducted the literature searches and analyses, undertook the statistical analysis and wrote the first draft of the manuscript. All authors contributed to and have approved the final manuscript.

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Appendix D: Curriculum vitae

Persönliche Daten

Name: Sebastian Kohlmann
 Geburtsdaten: 25. Dezember 1982 in Hünfeld
 Nationalität: Deutsch
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Schul- und Bildungslaufbahn

Seit 10/2010	Weiterbildungsstudiengang Psychologische Psychotherapie (Verhaltenstherapie), Deutsche Gesellschaft für Verhaltenstherapie
10/2009 – 10/2010	Weiterbildungsstudiengang Psychologische Psychotherapie (Verhaltenstherapie), Universität Würzburg
Seit 09/2009	Promotion: „ <i>Psychological approaches to a patient-centered cardiology</i> “, Prof. Dr. Rief, Philipps-Universität Marburg
04/2009	Diplom in Psychologie, Philipps-Universität Marburg
02/2007 – 07/2007	Postgraduate Program in Health Psychology, University of Auckland, New Zealand
2004 – 2006	Student der Psychologie, Philipps-Universität Marburg
2003 – 2004	Student der Mathematik, Philipps-Universität Marburg
06/2002	Abitur, “Wigbert – Gymnasium” in Hünfeld

Wissenschaftliche & berufliche Tätigkeit

Seit 05/2011	Wissenschaftlicher Mitarbeiter (25%), Institut für Psychosomatische Medizin, Universitätsklinikum, Hamburg-Eppendorf (Prof. Dr. Löwe)
Seit 10/2010	Psychologischer Liaisondienst (50%), Universitäres Herzzentrum, Universitätsklinikum, Hamburg-Eppendorf (Prof. Dr. Dr. Schulz)
07/2009 – 09/2010	Psychotherapeut in Ausbildung, Klinik für Psychiatrie, Psychosomatik & Psychotherapie, Universitätsklinikum Würzburg (Prof. Dr. Deckert)
05/2009 – 09/2010	Wissenschaftlicher Mitarbeiter, BMBF Projekt: „Effekte einer selektiven Serotonin-Wiederaufnahmehemmung auf Morbidität, Mortalität und Stimmungslage bei Patienten mit Herzinsuffizienz und Depression (MOOD-HF)“, Universitätsklinikum Würzburg (Prof. Dr. Angermann)
10/2008 – 12/2008	Forschungspraktikum, Institute of Psychiatry, Clinical Health Psychology, King’s College London (Prof. Dr. Weinman,)
01/2008 – 10/2008	Studentische Hilfskraft, Institut für Medizinische Psychologie, Universitätsklinikum Hamburg-Eppendorf (Prof. Dr. Dr. Schulz)
07/2007– 09/2007:	Forschungspraktikum, Department of Psychology, Health Psychology, University of Auckland (Prof. Dr. Cameron)
04/2005 – 02/2007	Studentische Hilfskraft, Institut für Psychologie, Kognitive Psychophysiologie, Philipps-Universität Marburg (Prof. Dr. Rösler)

Wissenschaftliche Mitgliedschaften

Seit 10/2010	Deutsche Gesellschaft für Verhaltenstherapie
Seit 10/2009	Deutsche Gesellschaft für Verhaltensmedizin & Verhaltensmodifikation
Seit 06/2009	European Health Psychology Society

Lehre am Universitätsklinikum Hamburg Eppendorf

Seit 2011	Mitbetreuung von Cand. Dr. med. K. Prahl
Seit 2011	Lehre im medizinischen Wahlblock Psychosomatische Medizin
Seit 2010	Seminar mit klinischem Bezug: Psychokardiologie
Seit 2010	Mitbetreuung von Cand. Dr. med. M. Kilbert

Preise & Förderungen

07/2012	Posterpreis der European Association of Psychosomatic Research
07/2012	Reisekostenstipendium, Stiftungsmittel Universität Hamburg
10/2011	Reisekostenstipendium, Deutsche Gesellschaft für Verhaltensmedizin & Verhaltensmodifikation
08/2011	Reisekostenstipendium, Stiftungsmittel Universität Hamburg
07/2010	Reisekostenstipendium, Deutscher Akademischer Austausch Dienst
09/2008-12/2008	Auslandsstipendium, Leonardo Da Vinci Programm, EU
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Klinische Praktika

07/2006 – 10/2006	Medizinisch-Psychosomatische Klinik, Bad Bramstedt
02/2006 – 04/2006	Kinder- und Jugendpsychiatrie, St. Joseph Krankenhaus, Berlin
03/2004 – 04/2004	Klinik im Kurpark, Klinik für Psychosomatik, Bad Hersfeld

Hamburg, 23. January 2013

Sebastian Kohlmann

Appendix E: Publications

Peer reviewed articles

Kohlmann, S., Gierk, B., Hümmelgen, M., Blankenberg, S., & Löwe, B. (2012). Somatic symptoms in patients with coronary heart disease: prevalence, risk factors, and quality of life. *Submitted*.

Gierk, B., Murray, A., Kohlmann, S., & Löwe, B. Measuring the perceived stigma of mental illness with Stig-9: A re-conceptualisation of the Perceived-Devaluation-Discrimination-Scale. *Submitted*.

Kohlmann, S., Kilbert, M., Ziegler, K., & Schulz, K.-H. (2012). Supportive care needs in patients with cardiovascular disorders. *Patient Education and Counseling, accepted for publication*.

Kohlmann, S., Rimington, H., & Weinman, J. (2012). Profiling illness perceptions to identify patients at-risk for decline in health status after heart valve replacement. *Journal of Psychosomatic Research, 72(6)*, 427-433.

Peer reviewed abstracts

Kohlmann, S., Kilbert, M., Ziegler, K., & Schulz, K. H. (2012). Psychological needs in patients with cardiovascular disorders. *Journal of Psychosomatic Research, 72(6)*, 489.

Kohlmann S., Weinman J. & Rimington H. (2011). Krankheitswahrnehmungsprofile: Ein cluster-analytischer Ansatz zur Identifikation von Risikopatienten nach Herzklappenoperation. *Verhaltenstherapie, 21(S1)*, 11.

Kohlmann, S., Brenner, S., Hamann, B., Rief, W., & Stoerk, S. (2010). The role of executive function on adherence in patients with heart failure. *International Journal of Behavioral Medicine, 17(S1)*, 153.

Kohlmann S., Störk S., Hamann B., Faller H., Deckert J. & Angermann C. A. (2010). Profil-Analyse depressiver Symptome bei Patienten mit Herzinsuffizienz. *Zeitschrift für Klinische Psychologie und Psychotherapie*, 39(S1), 57.

Kohlmann S., Weinman J. & Rimington H. (2009). Clustering illness beliefs to identify patients at-risk after heart valve replacement. *Psychology&Health*, 24(S1), 41.

Kohlmann S., Cameron L.D. & Rief W. (2009). Einfluss einer 3D Herzsimulation auf Emotionen, Risikowahrnehmung und Gesundheitsverhalten: Evaluation eines computergestützten Präventionsprogramms für kardiovaskuläre Erkrankungen. *Verhaltenstherapie*, 19 (S1), 33.

Oral presentations

Kohlmann, S., Kaller, T., Langguth, N., Ganschow, R., Nashan, B., & Schulz, K.-H. (2012). *Development of children after liver transplantation: The Live!®-Study*. Paper presented at the European Conference on Psychosomatic Research, Aarhus, Denmark.

Gierk, B., Kohlmann, S., Raczka, K. A., Wahl, I., Rose, M., & Löwe, B. (2012). *Erwartete Abwertung und Diskriminierung psychisch erkrankter Menschen – Entwicklung und Validierung eines deutschsprachigen Stigma-Fragebogens*. Oral presentation at the 63. Arbeitstagung des Deutschen Kollegiums für Psychosomatische Medizin, München.

Kohlmann, S., Rimington, H., & Weinman, J. (2011). *Krankheitswahrnehmungsprofile: Ein cluster-analytischer Ansatz zur Identifikation von Risikopatienten nach Herzklappenoperation*. Oral presentation at the 13. Kongress der Deutschen Gesellschaft für Verhaltensmedizin und Verhaltensmodifikation, Luxemburg.

Kohlmann, S., Kilbert, M., Ziegler, K., & Schulz, K. H. (2011). *Psychological needs in patients with cardiovascular disorders*. Oral presentation at the 41st European Association of Behavioural and Cognitive Therapies Congress, Reykjavik, Island.

Kohlmann, S., Brenner, S., Hamann, B., Rief, W., & Stoerk, S. (2010). *The role of executive function on adherence in patients with heart failure*. Oral presentation at the 11th International Congress of Behavioral Medicine, Washington D.C, USA.

Kohlmann, S., Rimington, H., & Weinman, J. (2009). *Clustering illness beliefs to identify patients at-risk after heart valve replacement*. Oral presentation at the European Health Psychology Society Conference, Pisa, Italy.

Poster presentations

Kohlmann, S., Kilbert, M., Ziegler, K., & Schulz, K. H. (2012). *Psychological needs in patients with cardiovascular disorders*. Poster presentation at the European Conference on Psychosomatic Research Aarhus, Denmark.

Kohlmann, S., Westermann, S., Hamann, B., Schulz, K. H., & Rief, W. (2011). *Emotionregulation und Essverhalten bei Menschen mit Adipositas*. Poster presentation at the 7. Workshopkongress der Fachgruppe Klinische Psychologie, Berlin, Germany.

Kohlmann, S., Störk, S., Hamann, B., Faller, H., Deckert, J., & Angermann, C. E. (2010). *Characteristics of depressive Symptomatology in Heart Failure – A Cluster Analysis*. Poster presentation at the Cardiovascular Healing Symposium Würzburg, Germany.

Kohlmann, S., Störk, S., Hamann, B., Faller, H., Deckert, J., & Angermann, C. E. (2010). *Profil-Analyse depressiver Symptome bei Patienten mit Herzinsuffizienz*. Poster presentation at the 28. Symposium der Fachgruppe Klinische Psychologie und Psychotherapie, Mainz, Germany.

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6. Affirmation

Ich versichere, dass ich meine Dissertation

„Psychological approaches to a patient-centered cardiology
Somatic symptom burden, illness perceptions and supportive care needs
in patients with cardiac diseases”

selbstständig ohne unerlaubte Hilfe angefertigt und mich dabei keiner anderen als der von mir ausdrücklich bezeichneten Quellen und Hilfen bedient habe.

Die Dissertation wurde in der jetzigen oder einer ähnlichen Form noch bei keiner anderen Hochschule eingereicht und hat noch keinen sonstigen Prüfungszwecken gedient.

Hamburg, Januar 2013

Sebastian Kohlmann