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A CAUSAL MODEL OF HEALTH-RELATED QUALITY OF LIFE IN THAI HEART FAILURE PATIENTS

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พวงผกา กรีทอง : โมเดลเชิงสาเหตุของคุณภาพชีวิตผู้ป่วยที่มีภาวะหัวใจวาย (A CAUSAL MODEL OF HEALTH-RELATED QUALITY OF LIFE IN THAI HEART FAILURE PATIENTS) : อ. ที่ปรึกษา : ศ. ดร. วิฬา จีระแพทย์, อ.ที่ปรึกษาร่วม : ผศ. ดร.ชนกพร จิตปัญญา, ASSOC. PROF. REBECCA S. SLOAN, 210 หน้า.

การวิจัยครั้งนี้มีวัตถุประสงค์เพื่อทดสอบความสัมพันธ์เชิงสาเหตุระหว่างปัจจัยด้านความสามารถในการทำหน้าที่ของหัวใจ การสนับสนุนทางสังคม อาการของภาวะหัวใจวาย ข้อจำกัดในการปฏิบัติกิจกรรม การรับรู้ภาวะสุขภาพโดยรวม และคุณภาพชีวิต โดยใช้กรอบแนวคิดคุณภาพชีวิตของวิลสันและแคริเป็นแนวทางในการศึกษา กลุ่มตัวอย่างคือผู้ป่วยภาวะหัวใจวายจำนวน 422 คน ที่มารับการตรวจที่คลินิกผู้ป่วยนอกโรคหัวใจ ของโรงพยาบาล 9 แห่งจาก 4 ภาคของประเทศไทยและกรุงเทพมหานคร เก็บรวบรวมข้อมูลโดยใช้แบบบันทึกข้อมูลส่วนบุคคลและแบบบันทึกข้อมูลด้านสุขภาพ แบบสอบถามการสนับสนุนทางสังคม แบบสอบถามข้อมูลเกี่ยวกับข้อจำกัดในการปฏิบัติกิจกรรม แบบวัดระดับการรับรู้ภาวะสุขภาพโดยรวม และแบบสอบถามข้อมูลเกี่ยวกับคุณภาพชีวิตของผู้ป่วยภาวะหัวใจวาย วิเคราะห์ข้อมูลด้วยโปรแกรมสำเร็จรูป SPSS และ AMOS

ผลการทดสอบโมเดล พบว่าโมเดลมีความกลมกลืนกับข้อมูลเชิงประจักษ์ (χ^2=19.87, df = 13, χ^2/df (1.53), p = 0.10, GFI = 0.99, AGFI = 0.97, RMSEA = 0.04) โดยปัจจัยด้านความสามารถในการทำหน้าที่ของหัวใจ การสนับสนุนทางสังคม อาการของภาวะหัวใจวาย ข้อจำกัดในการปฏิบัติกิจกรรม และการรับรู้ภาวะสุขภาพโดยรวม สามารถร่วมกันอธิบายความผันแปรของคุณภาพชีวิตของผู้ป่วยภาวะหัวใจวายได้ร้อยละ 58 ทั้งนี้ปัจจัยที่มีอิทธิพลต่อคุณภาพชีวิตของผู้ป่วยภาวะหัวใจวายมากที่สุดคือ อาการและอาการแสดงของภาวะหัวใจวายโดยมีอิทธิพลทางลบ ทั้งโดยตรงและโดยอ้อมผ่านข้อจำกัดในการปฏิบัติกิจกรรมและการรับรู้ภาวะสุขภาพโดยรวม (β = -0.69, p <.0001) ในขณะที่ข้อจำกัดในการปฏิบัติกิจกรรมมีอิทธิพลทางลบ ทั้งโดยตรงต่อคุณภาพชีวิตและโดยอ้อมผ่านการรับรู้ภาวะสุขภาพโดยรวม (β = -0.32, p <.05) ส่วนการรับรู้ภาวะสุขภาพโดยรวมมีอิทธิพลโดยตรงทางบวกต่อคุณภาพชีวิต(β = 0.24, p <.0001) นอกจากนี้ความสามารถในการทำหน้าที่ของหัวใจมีอิทธิพลโดยอ้อมทางบวกต่อคุณภาพชีวิตผ่านข้อจำกัดในการปฏิบัติกิจกรรมและการรับรู้ภาวะสุขภาพโดยรวม (β = 0.16, p <.0001) ส่วนปัจจัยที่มีอิทธิพลต่อคุณภาพชีวิตของผู้ป่วยภาวะหัวใจวายน้อยที่สุดคือ การสนับสนุนทางสังคม (β = 0.04, p <.05) โดยมีอิทธิพลโดยตรงทางลบต่อคุณภาพชีวิต และมีอิทธิพลโดยอ้อมทางบวกต่อคุณภาพชีวิตผ่านอาการและอาการแสดงและการรับรู้ภาวะสุขภาพโดยรวม

ผลการศึกษาบ่งชี้ว่า การพัฒนาการปฏิบัติการพยาบาลเพื่อส่งเสริมหรือคงไว้ซึ่งคุณภาพชีวิตที่ดีของผู้ป่วยภาวะหัวใจวาย องค์ประกอบหลักที่สำคัญของการปฏิบัติการพยาบาลต้องมุ่งเน้นกิจกรรมพยาบาล เพื่อควบคุมและจัดการอาการเพื่อลดความถี่และความรุนแรงของการเกิดอาการของภาวะหัวใจวาย ซึ่งเมื่อควบคุมอาการของภาวะหัวใจวายได้ จะช่วยเพิ่มความสามารถในการปฏิบัติกิจกรรมเพื่อการดำเนินชีวิตประจำวันและความสามารถในการดูแลตนเอง เพื่อคงไว้ซึ่งคุณภาพชีวิตที่ดี ทั้งนี้กิจกรรมดังกล่าวต้องคำนึงถึงปัจจัยด้านความสามารถในการทำหน้าที่ของหัวใจ ข้อจำกัดในการปฏิบัติกิจกรรม การสนับสนุนทางสังคม การรับรู้ภาวะสุขภาพโดยรวม และปัจจัยร่วม เช่น เพศ อายุ ที่มีอิทธิพลต่อคุณภาพชีวิต

สาขาวิชา พยาบาลศาสตร์ ลายมือชื่อนิสิต.....

ปีการศึกษา 2550 ลายมือชื่ออาจารย์ที่ปรึกษา.....

ลายมือชื่ออาจารย์ที่ปรึกษาร่วม.....

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KEY WORDS: HEART FAILURE/ HEALTH-RELATED QUALITY OF LIFE/ SYMPTOM STATUS/ FUNCTIONAL STATUS/ GENERAL HEALTH PERCEPTION

PHUANGPHAKA KRETHONG: A CASUAL MODEL OF HEALTH-RELATED QUALITY OF LIFE IN THAI HEART FAILURE PATIENTS. THESIS ADVISOR: PROF. VEENA JIRAPAET, RN, DNSc, THESIS COADVISOR : ASSIST. PROF. CHANOKPORN JITPANYA, RN, PhD, ASSOC. PROF. REBECCA S. SLOAN, RNC, PhD, 210 pp.

The purpose of this study was to examine the causal relationship among bio-physiological status (LVEF), social support, symptom status, functional status (NYHA), general health perception, and health-related quality of life (HRQOL) in Thai heart failure patients. The hypothesized causal model of HRQOL in Thai heart failure patients was based on Wilson and Cleary's Health-Related Quality of Life Conceptual Model. Stratified four stage random sampling was employed to obtain the sample of 422 heart failure patients aged 18 years and above who visited nine hospitals from four regions of Thailand and metropolitan Bangkok. Research instruments consisted of Personal Information Questionnaire, the personal LVEF medical record sheet, the ENRICHD Social Support Instrument (ESSI), the Cardiac Symptom Survey (CSS), the subjective NYHA functional classification, a General Health Perception, and the Minnesota Living with Heart Failure Questionnaire (MLHFQ). Data were analyzed using SPSS and AMOS computer programs.

Goodness of fit indices indicated that the model fitted well with the empirical data (χ^2 =19.87, df = 13, χ^2 /df =1.53, p = 0.10, GFI = 0.99, AGFI = 0.97, and RMSEA = 0.04). The overall model explained approximately 58% of the variance in overall health-related quality of life in Thai heart failure patients. Symptom status of heart failure was the most influential factor affecting HRQOL by having both negative direct and indirect effects through functional status and general health perception (β = -0.69, p <.0001). In addition, functional status (NYHA) had negative direct and indirect effects on HRQOL through general health perception (β = -0.32, p <.05). General health perception had only a positive direct effect on HRQOL (β = 0.24, p < .0001). Bio-physiological status (LVEF) had a positive indirect effect on HRQOL through functional status and general health perception (β = 0.16, p< .0001). However, social support was the least influential factor affecting HRQOL (β = 0.04, p < .05). It had a negative direct effect on HRQOL, but a positive indirect effect on HRQOL through symptom status and general health perception.

The findings indicated the prominent components of nursing intervention focusing on maintaining or enhancing HRQOL in Thai heart failure patients The intervention components should consist of symptom controlling and symptom management to decrease symptom frequency and symptom severity. This will help heart failure patients to maintain or improve their functional ability to perform their normal daily activities, and their self-care ability. Nurses should consider about bio-logical status, social support, and general health perception and some mediator factors such as age, gender, affecting HRQOL in planning the intervention.

Field of study NURSING SCIENCE Student's signature.....

Academic year 2007 Advisor's signature.....

Co-advisor's signature.....

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CHAPTER I

INTRODUCTION

Background and significance of the study

The terms heart failure, cardiac failure, congestive heart failure, chronic heart failure or advanced heart failure are used interchangeably to describe a complex chronic progressive health problem. Heart failure is caused by a variety of functional or structural disorders of the heart that weakens its pump performance (Cowie & Zaphiriou, 2002; Grady et al., 2000). Heart failure is frequently a symptom of another cardiac disease (Resnick, 2004). Heart failure is an increasing health problem with high incidence, prevalence, morbidity and mortality. The international incidence and prevalence of heart failure are expected to increase over the coming years. Close to 5 million Americans suffer from heart failure, with a startling estimated 550,000 new cases anticipated each year (Artinian, 2003, American Heart Association: AHA, 2006). Stewart et al. (2003) projected the future burden of heart failure from contemporary epidemiology data as 5.1 million in Scotland's population in 2000-2020. Moreover, the Ministry of Public Health in Thailand (2006) reported that cardiovascular problems are the first in 10 non-communicable diseases in Thailand. The increasing numbers of patients with heart failure are due to better treatment and "salvage" of patients with acute myocardial infarctions earlier in life (AHA, 2006; MacMahon & Lip, 2002).

Heart failure is the most costly cardiovascular disease (McMurray et al., 1998; Fonarow, 1997). The cost of heart failure has increased by two- to three-fold in the past decade in most countries (Stewart, 2005).Two thirds of heart failure costs were on average attributable to hospitalization and approximately half of those costs to routine and critical care services (Lee et al., 2005). In the USA, indirect and direct costs have been estimated at

$27.9 billion for the year 2005, while approximately $2.9 billion annually is spent on drugs for the treatment of heart failure (AHA, 2006).

Despite recent advances in the medical technology and pharmacological management of heart failure, this disease is still characterized by frequent hospitalizations and high mortality rates (Grady, 1999). About 78% of patients with heart failure have at least two admissions per year for heart failure exacerbation and 16% had three admissions per year (Stromberg, 2004). In addition, The Medical Department of Bangkok Metropolitan Administration in Thailand (2005) reported about 40% of heart failure patients had to be readmitted more than once per year and 18% came back in less than one month after being discharged. Furthermore, Michalsen, Koning and Thimme (1998) found that approximately 29-59% of patients with heart failure require hospitalization within 6 months after discharge. In addition, the 1-year mortality rate associated with heart failure still remains high (MacMahon & Lip, 2002). The 6 year mortality rates have been reported as high as 84% for men and 77% for women (O'Connell, 2000 cited in Clark & Lan, 2004).

As in other countries, heart failure is one of the chronic health problems in Thailand which lead to many physical changes and psychological problems (Thongyim, 2000). Previous studies indicated that heart failure symptoms affect HRQOL. Maneesils (1999) and Sammranbua (2001) illustrated that dyspnea is commonly reported in patients with cardiac disease and especially when individuals have developed heart failure. Many studies also explored what factors affected HRQOL in cardiac patients who developed heart failure. For example, Boonyapatkul (2000) found that when symptoms were occurring, the patients were usually aware of the functional, emotional and financial effects of their current condition. Furthermore, Sirirat (1999) illustrated how heart failure associated

fatigue impacted patients' lives and health by decreasing quality of life, decreasing activity, and effecting role transitions.

Patients with heart failure live with a chronic illness characterized by periods of acute cardiovascular decompensation alternating with periods of relative stability (Leventhal, Riegel, Carlson et al., 2005). Heart failure may be experienced as a crisis event requiring multiple drugs and invasive procedures especially in the acute phase (Stull, Starling, Haas & Young, 1999). In addition, people who survived heart failure usually report that their lives were confused and disrupted as well as fraught with physical, emotional and social turbulence (Zambroski, 2005). Their life satisfaction also decreased due to their health condition. Furthermore, lifelong and complex treatment with a multitude of medications taken twice or more daily (Stromberg et al., 1999), medication side effects and behavior changes also reduced their health related quality of life.

Health-related quality of life (HRQOL) is a widely accepted and frequently used outcome measure in clinical trials and health services research (Butler, 1992; Faden & German, 1994; Andresen et al., 1997; and Mozes et al., 1999 cited in King & Hint, 2003). Health related quality of life (HRQOL) in heart failure patients is decreased when compared with individuals with other chronic health problems and the population in general (Johansson, Agnebrink, Dahlstrom, & Brostrom, 2004; Hobbs et al., 2002; Yamsakul, 1999). Approximately 50% of people with heart failure are symptomatic and as a result have a reduced HRQOL (Lainscak & Keber, 2003). Health related quality of life measures in heart failure patients indicate significant impairment in all dimensions (Calvert et al., 2005; Hobbs et al, 2002; Thongin, 1999). It is decreased by functional status limitations, multiple hospitalizations, and high mortality from multiple physical and psychological symptoms (American Heart Association: AHA 2006; Chin & Goldman, 2003).

The limitation of activities also directly influenced physical, psychological, and socioeconomic aspects of cardiac patients who developed heart failure resulting from valvular heart disease (Samranbua, 2001; Maneesilpa, 2000) and coronary artery disease (Jubjal, 1997; Sriton, 2003; Methajarn, 2001; Sriprasong, 2001; Thongin, 1999; and Nathongkham, 2000). Leingkobkij (1999) illustrated that the severity of coronary artery disease affected physical and social function aspects of HRQOL. Tongsai (2005) compared cardiac patients' quality of life before and after open heart operations. They found that quality of life before was poorer than after open heart operations due to heart failure symptoms.

Individual and environmental characteristics of cardiac patients also have effect on HRQOL. Chaiaree (1999) illustrated that social support; educational level and monthly income were related to HRQOL of patients with heart failure. In additional, Tongin (1999) found that the socio-economic status of patients with coronary artery disease is significantly affected. These patients have to reduce their activities and even stop working. They cannot maintain their family status and responsibilities. As their socio-economic status cannot be maintained, these patients have to depend on other people while having to face more financial difficulties from being out of work. This causes them anxiety and depression which also decreases their HRQOL.

Although the relationships among factors that effect HRQOL are complicated, most previous studies indicated only direct relationships. Thus some factors such as age, sex and marriage status alone were not reported as significant or directly related to HRQOL (Chaiaree, 1999). Furthermore, many studies explored some parts of HRQOL but did not explain the whole picture of HRQOL in heart failure patients. In additional, current assessment of outcome in heart failure still relies primarily on a model that targets

biological parameters and mortality, yet fails to include more recently developed bio-psychosocial concepts. To enhance understanding of the causal and complex relationships of variables and their effect on HRQOL, Wilson and Cleary's health-related quality of life conceptual model (WCM) was used as a conceptual model of this study. WCM is a combination of both biological approaches and sociological approaches which more fully explained the causal relationship of HRQOL.

Important to the profession of nursing, the virtual explosion of new research in HRQOL in recent years has advanced the credibility of HRQOL in nursing. Nurses are key players in ensuring quality of life outcomes. HRQOL refers to "that which makes life worth living and connotes the caring aspects of nursing, because nursing is concerned not only with survival and decreased morbidity, but with the whole patient" (Padilla & Grant cited in King& Hint, 2003:pp. 45). In providing care to patients with heart failure, nurses help patients to manage the side effects of therapy and assist the patient with adjustment to changes in symptom, role function, and to living with a chronic health problem. This holistic viewpoint of nursing care delivery can help the patient to maintain or improve the length and the quality of their life. The nurse can help the patient to make the changes needed in order to adjust to a life with heart failure. It is essential that nursing care build on the content presented by a causal model of HRQOL. It will lead in further developing and testing cost-effective interventions to control physical and psychological symptoms, promote independence, help maintain or recover function, and enhance HRQOL in heart failure patients. Furthermore, in both research and clinical practice, nurses have collaborated with those in other disciplines to expand knowledge regarding the impact of heart failure symptoms and heart failure treatment on HRQOL.

Existing knowledge contributed to understanding health related quality of life in heart failure patients. Most earlier studies focused on the level of the HRQOL, and factors with correlated and predicted quality of life. Most previous research studies in HRQOL in heart failure were conducted to explain the relationship in some part of each concept; such as demographic variables, biology/physiology of heart failure, symptoms status, and general health perception. But, no study has been conducted to systematically explain the comprehensive relationship of all these concepts in Thai heart failure. In addition, previous studies in Thailand conducted in patients diagnosed with cardiovascular diseases who developed symptoms of heart failure did not cover all these factors that may impact HRQOL in Thai heart failure patients. In additional, as the interest in HRQOL issues continues to increase, nurses will continue to be actively involved locally, regionally, nationally, and internationally. Furthermore, HRQOL is a subjective perception of patients and may be culturally affected. Thus, most of the studies about HRQOL in heart failure done in the West may be not be include appropriate socio-economic and cultural factors in Thailand.

There was need to examine the causal model of HRQOL in Thai heart failure patients because of (1) an increased incidence of cardiovascular disease which will develop into heart failure in Thailand; (2) HRQOL is significantly decreased in patients diagnosed with heart failure and with others cardiac disease which develop into heart failure, and (3) as therapeutic efforts and nursing intervention focus more on improving patient function and well being, the need to understand the causal relationships of health related quality of life in heart failure will facilitate the design of optimally effective nursing interventions. Furthermore, study of the causal model of HRQOL provides more understanding of both direct and indirect causal relationships among factors effecting HRQOL in Thai heart

failure patients. As a result of this study, development of a more complete causal model of variables influencing HRQOL provide important information for clinical nurses and researchers attempting to develop effective interventions to enhance HRQOL in Thai heart failure patients.

Research Questions

1. Do biological/physical status (LVEF), social support predicts health-related quality of life directly and/or indirectly through symptom status, functional status, and general health perception?

2. Do symptom status, functional status predicts health-related quality of life directly and/or indirectly through general health perception?

3. Does general health perception predict health-related quality of life directly?

4. Does the hypothesized model of HRQOL in Thai heart failure patients adequately fit the sample data collected from Thai heart failure patients?

Purpose of the study

1. To develop the causal model of health related quality of life derived from Wilson and Cleary's Health-Related Quality of Life Conceptual Model in Thai heart failure patients.

2. To examine the causal relationships among bio-physiological status (LVEF), social support, symptom status, functional status, general health perception, and health-related quality of life (HRQOL) in Thai heart failure patients.

Research Hypotheses and Rationales

This study was guided by Wilson and Cleary's Health-Related Quality of Life Conceptual Model (WCM) (more detail in chapter II), and was supported by selected variables derived from the empirical literature. The research hypotheses were set in 5 statements as follow:

1. Biological and physiological status which was quantified by left ventricle ejection fraction (LVEF) would have a negative direct effect on symptom status and functional status (NYHA). Further, it would have a positive indirect effect on HRQOL through symptoms status, functional status, and general health perception.

Rationale: The biological and physiological variable referred to the status of cells, organs, and organ systems. It was an objective physical heart function measurement which was indicated by the left ventricular ejection fraction (LVEF). The blood flow to meet the requirement of body organs is decreased when LVEF is decreased. When the LVEF is less than 40 %, patients will have symptoms of heart failure (AHA, 2006). Decreasing LVEF is associated with increasing severity of heart failure. In contrast, a higher LVEF will be found in patients with less or no symptom of heart failure. In addition, LVEF is related to functional status, for example LVEF in NYHA functional class III and class IV are usually less than class I and class II. Thus, reduced LVEF indicates symptom distress and limited functional status, causing heart failure patients to rate their general health perception as poor and also reduces their HRQOL.

2. Characteristics of the environment (social support) would have a negative direct effect on symptom status and functional status (NYHA), but would have a positive direct effect on general health perception and HRQOL. And it also would have a positive indirect effect on HRQOL through symptom status, functional status and general health perception.

Rationale: Characteristics of the environment are defined by Wilson and Cleary as support provided by family, friends, and others. Thus, social support would be indicated as an environmental characteristic of heart failure, because of its reported large effect on HRQOL in heart failure patients. Social support would be positively correlated with physical functioning (Rayond et al., 1997). Support from the family would help patients to perform activities of daily living which would also make their HRQOL increased. Support would provide less symptom distress which would also increase functional status and health perception. Furthermore, social support has been reported as a predictor of health-related quality of life in heart failure patients (Bennett et al., 2001).

3. Symptom status would have a positive direct effect on functional status (NYHA), but would also have a negative direct effect on HRQOL. And, it would have a negative indirect effect on HRQOL through functional status and general health perception.

Rationale: Symptom status refers to patients' subjective perceptions of presence and severity of abnormal physical, mental, and cognitive conditions. Increasing heart failure symptoms will decrease functional status of heart failure patients. For example, dyspnea and fatigue in heart failure patients may be restricted in performance of normal every activity (van der Berg-Emons, Bussmann, Balk, Keijzer-Oster, & Stam, 2001). Function status will also decrease when there is an increase of psychological symptom such as depression (Murberg et al., 1998) or anxiety (Januzzi, Stern, Paternak & DeSanctis, 2000). Patients who are depressed will not try to do anything. For instance, they do not want to meet anyone, to go to hospital, or take medication (Elatre et al., 2003). In addition, heart failure patients cannot perform their social activities because of their anxiety. General health perception will also decrease concurrent with increased symptom distress and functional limitation, which in turn reduce HRQOL in heart failure patients.

4. Functional status (NYHA) would have a negative direct effect on general health perception. And, it would have a negative indirect effect on HRQOL through general health perception.

Rationale: Functional status refers to patients' ability to perform several aspects of tasks or functions, such as physical, social, emotional, role, and cognitive functions. Many studies in heart failure define functional status as patients' ability to perform their daily activity living limited by heart failure. NYHA functional classification is commonly used to indicate functional status in cardiac patients. Functional status limitations will make heart failure patients unable to perform their normal activities, they will then rate their general health perception as poor (Stewart et al., 2004).

5. General health perception would have a positive direct effect on HRQOL.

Rationale: General health perception is defined as patients' global perceptions of their health. General health perception in heart failure patients was a significant factor associated with HRQOL (Lu et al., 2005; Beckie & Hayduk, 2003). Heart failure patients who assess their general health as well will also perceive their HRQOL as increased.

Scope of the Study

This study examined the causal relationships of HRQOL in heart failure patients who were 18 years of age and over. The settings were outpatient cardiac clinics of tertiary hospitals in Thailand. The independent variables were LVEF, social support, symptom status, functional status and general health perception, while HRQOL served as dependent variable of the study.

Definitions of terms

1. Heart failure patients were patients who had been medically diagnosed with heart failure and patients diagnosed with cardiovascular diseases who also developed symptoms of heart failure. They had to have signs and symptoms from heart pumping failure such as dyspnea, fatigue, edema, and/or chest pain.

2. Health related quality of life was defined as a patient's subjective perception of the impact of heart failure on physical, psychological and social function aspects of his or her daily life (Wilson & Cleary, 1995). Physical function was defined as a physical dimension of HRQOL in heart failure patients which was influenced by the condition of heart failure. In addition, psychological function was defined as a psychological dimension of HRQOL in heart failure. Finally, social function was a measure of how social activity and economic status was affected by heart failure, and was also defined as socio-economic dimension of HRQOL in heart failure patients. HRQOL was operationalized by the specific HRQOL instrument, The Minnesota Living with Heart Failure Questionnaire.

3. LVEF served as a bio-physiological measure of heart status. It is a measurement of heart function and is decreased when the physiology of the heart itself is compromised or pathology from other health problems related to heart failure occurs.

4. Characteristics of the individual included personal states such as age, gender, income, duration of disease. For this study, age of heart failure patients was 18 years of age and above. Both male and female heart failure patients were enrolled. Income was determined by the family monthly income of each heart failure patient. Duration of disease was used to identify the month or year since the individual had been diagnosed or had experienced symptoms of heart failure.

5. Characteristics of the environment included the social support that heart failure patients received from family, friends and others (Wilson & Cleary, 1995). Social support was measured using the modified ENRICHD Social Support Instrument (ESSI) Thai version (Lortajakul, 2006).

6. Symptom status was defined as a patient's subjective perception of the presence and severity of abnormal physical, mental, and cognitive conditions (Wilson & Cleary, 1995). Symptom status is conceptualized as a personal perception of the frequency and severity of common physical and psychological symptoms of heart failure. Physical symptoms were chest pain, dyspnea or breathlessness, fatigue, swelling of feet, ankles or legs edema, and heart palpitation. Psychological symptoms were depression, anxiety, sleep disturbance and poor appetite. Symptom status was operationalized by one dimension, symptom evaluation of the modified Cardiac Symptom Survey (CSS) Thai version (Lortajakul, 2006).

7. Functional status was defined as a patient's subjective perception of his or her ability to perform their activities of daily living, such as the patients' ability to perform several aspects of tasks or functions, such as physical, social, emotional, role, and cognitive functions (Wilson & Cleary, 1995). Functional status of patients with heart failure was quantified by the subjective New York Heart Association (NYHA) functional classification, the most commonly used to measure functional status in heart failure patients (AHA, 2006).

8. General health perception was defined as a patient's global self-assessed health. It was operationalized with a 100-mm horizontal visual analogue scale indicating the range of general health perception.

Expected usefulness of the study

1. This study provides a basic knowledge base to explain and predict the phenomena of HRQOL in Thai heart failure patients.

2. The research contributes to the body of knowledge concerning the WCM. The findings supported the validity of the WCM, and explained the causal relationship of the relevant aspects of the theory in the phenomena of HRQOL in Thai heart failure patients.

3. This study proposed a middle range theory of HRQOL in Thai heart failure patients. It provides a data base about the causal relationships among the selected variables. It is crucial to help nurse and health care providers to understand both the direct and indirect effects of predictive factors on HRQOL in Thai heart failure patients.

4. The findings provide a scientifically-based guideline for health care providers, multidisciplinary teams and policy makers to provide suitable support and guidance to enhance HRQOL in Thai heart failure patients.

5. Nurses will be able to use the findings of this study to develop research and nursing interventions to help heart failure patients to improve their HRQOL.

CHAPTER II

LITERATURE REVIEW

This chapter presents an integrative review of theoretical and empirical literature describing interesting concepts and interrelationship among factors affecting Health related quality of life (HRQOL) in heart failure patients. The review covers the following topics:

2.1 Heart failure

2.2 Quality of life and Health-Related Quality of Life (HRQOL)

2.3 Health-Related Quality of Life in heart failure patients

2.4 Wilson and Cleary's Health-Related Quality of Life Conceptual Model

2.5 Factors related to HRQOL in heart failure patients

2.6 The hypothesized causal model of HRQOL in Thai heart failure patients

2.7 Statistic for causal model analysis

2.1 Heart Failure

2.1.1 Definition

Heart failure is a symptom from an impaired pumping action of the heart that is caused by an underlying disease (The American Heritage Stedman's Medical Dictionary, 2004). Heart failure refers to a grouping of clinical findings rather than a specific diagnosis or a single disease. It can be considered as a chronic health problem that requires ongoing management over a period of years or decades (WHO, 2002). It is also a complex clinical syndrome that can result from any structural or functional cardiac disorder (Hunt, Baker, Chin, Cinquegrani, Feldman, & Francis et al., 2005). Such a rise in the importance of cardiovascular disease is likely to translate into an increased incidence and prevalence of

heart failure (Mendez, & Cowie, 2001; AHA, 2006). Left ventricular dysfunction is an important functional disability of the heart, while cardiomyopathy is as a structural disability of the heart resulting in heart failure. But the majority of patients with heart failure have symptoms due to impairment of left ventricular function (AHA, 2006).

2.1.2 Causes of heart failure

Heart failure is frequently a symptom of another cardiovascular problem that causes either systolic or diastolic dysfunction with reduced ventricular filling and reduced myocardial contractility (Resnick, 2004). The most common cause of heart failure is coronary artery disease (Bennett, Cordes, Westmoreland, Castro, & Donnelly, 2000; Moser, Macho, & Worster, 2000). Coronary artery disease is the cause of heart failure in about two thirds of patients with left ventricular systolic dysfunction (Gheorghiade & Bonow, 1998). The other causes are non-ischemic cardiomyopathy, which may have an identifiable cause (e.g., hypertension, thyroid disease, valvular disease, or myocarditis) or may have an unknown cause (e.g., idiopthic dilated cardiomyopathy) (Hunt et al., 2005.). Furthermore, about 30% of patients with dilated cardiomyopathy may have a genetic cause (Francis & Pierpont, 1988 cited in Hunt et al., 2005). In addition, Sritama et al. (2004) found that most of the younger patients developed heart failure from congenital heart diseases and rheumatic heart disease, while the older patients developed it from disease of cardiac muscle such as myocardial infarction and hypertension. In fact, nearly any form of heart disease may ultimately lead to the heart failure syndrome (AHA, 2006).

Mendez and Cowie (2001) reported that rheumatic heart disease continues to be a major health problem in developing countries (especially Africa and Asia) where it is still an important cause of heart failure, often in the younger patients. They also indicated that in all countries undergoing epidemiological transition, coronary artery disease is an

increasingly important cause of heart failure. Joshi, Mohanan, Sengupta, and Salkar (1999) illustrated that rheumatic heart disease was the most common etiology (52%) of heart failure, followed by ischaemic and/or hypertensive heart disease (27%) in India. In addition, the 1992 National Household survey on Health of Indonesia indicated that cardiovascular disease had become the leading cause of death accounting for 16% of all mortality (Boedhi-Darmojo, 1993). In the last two decades rheumatic heart disease has been replaced by ischemic heart disease as the main etiology of patients admitted with heart disease in the most developed countries. In Europe and North America coronary artery disease accounts for the majority of cases of heart failure (Mendez, & Cowie, 2001). Hypertension is the main etiology of heart failure especially in the African and African–American population, in almost half of all cases of heart failure (Ofili et al.,1999; Dries et al., 1999) and also in Indonesia (Boedhi-Darmojo, 1993).

2.1.3 Diagnosis of Heart failure

The American College of Cardiology and the American Heart Association: ACC/AHA (2005) Guideline Update for the Diagnosis and management of heart failure in the adult identified the development of the heart failure syndrome into four stages: A, B, C, and D). Stages A and B patients are best defined as those with risk factors that clearly predispose toward the development of heart failure. For example, patients with coronary artery disease, hypertension, or diabetes mellitus who do not yet demonstrate impaired left ventricular function, hypertrophy, or geometric chamber distortion would be considered Stage A, whereas patients who are asymptomatic but demonstrate left ventricle hypertrophy (LVH) and/or impaired left ventricle function would be designated as Stage B. Stage C describes patients with current or past symptoms of heart failure associated with underlying structural heart disease (the bulk of patients with heart failure). Stage D designates patients

with truly refractory heart failure who might be eligible for specialized, advanced treatment strategies, such as mechanical circulatory support, procedures to facilitate fluid removal, continuous inotropic infusions, cardiac transplantation or other innovative or experimental surgical procedures, or for end-of-life care, such as hospice (Hunt et al., 2005).

The other indicator to point out related to left ventricular dysfunction is the left ventricular ejection fraction (LVEF). LVEF is the primary functional information gained from the echocardiogram. It is the most useful diagnostic test in the evaluation of patients with heart failure (Francis & Tang, 2004). Echocardiography is often performed in patients with heart failure to measure the ejection fraction and determine if systolic function is reduced or preserved, or if diastolic heart failure is present (Redfield et al., 2003). LVEF is the volume of blood flow from the left ventricle. An ejection fraction of 50% to 75% is considered normal and, in general, a low percentage is considered an indication of failure. Patients with a left ventricular ejection fraction less than 40% are generally considered to have systolic dysfunction (Bonow et al., 2005). The ejection fraction in left-side heart failure typically falls below 40%. In severe failure it may drop as low as 5% (Nidus Information Services, 2001).

In addition, measurement of left ventricular ejection fraction with echocardiography, radionuclide imaging, or ventriculography provides the quantification necessary to document the severity of systolic dysfunction (Cohn, 1996). Moreover, the echocardiogram allows for the quantitative assessment of the dimensions, geometry, thickness, and regional motion of the right and left ventricles and qualitative evaluation of the atria, pericardium, valves, and vascular structures. Such a comprehensive evaluation is important, since it is not uncommon for patients to have more than one cardiac abnormality that can cause or contribute to the development of heart failure.

2.1.4 Management of heart failure

As heart failure is a permanent or ongoing condition, it requires long periods of observation and complex management regimens. The goals of treatment are to slow the progression of the disease, prevent complications, maintain function, and sustain the HRQOL (AHA, 2006). Pharmacological treatment of heart failure includes the use of diuretics, angiotensinconverting enzyme (ACE) inhibitors, beta blockers, spironolactone (in moderate to severely symptomatic patients), and digoxin (in selected cases) (Hunt et al., 1996; Canadian Cardiovascular Society Consensus Guideline, 2001). ACE inhibitors are a mainstay of therapy of heart failure, reducing mortality and hospitalizations (Tsuyuki, 2004). These medications may have side effects such as coughing and dizziness. Diuretics remove excess salt and fluid from the circulation, and their most common side effects are extensive diuresis, dry mouth, and dizziness (Konstam et al., 1994 cited in Stromberg et al., 1999).

Nonphamacological treatments are also useful and include modified behavior changes such as eating a low salt diet, restricting water intake, and self-monitoring had been used to prevent and reduce symptom severity (AHA, 2006; Artinian et al., 2002; Bentley, 2006; Bushnell, 1992 cited in Stromberg et al., 1999; Rockwell & Riegel, 2000). Recommendations are to reduce daily dietary sodium intake to 2000 mg or less and daily fluid intake to 2000 ml. or less (Koelling et al., 2005). Sodium restriction (2-3 gram/day) is considered essential in the management of symptomatic heart failure (Dracup et al., 1992 and Krauss et al., 2000 cited in Neily et al., 2002). Thus, non pharmacological treatments such as behavioral changes that prevent or minimize signs and symptoms and disease progression are just as important as the medications prescribed to treat heart failure (Paul & Sneed, 2004).

2.2 Quality of Life (QOL) and Health-Related Quality of Life (HRQOL)

2.2.1 Definition

Many terms are used synonymously with quality of life (QOL) in the literature, such as well-being, happiness, condition of living and life satisfaction. QOL is a broad concept that encompasses varying dimensions across the spectrum of living (Rapley, 2003). The World Health Organization defined QOL as “an individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation of their goals, expectations, standards and concerns” (Calvert, Freemantle & Cleland, 2005, p 243). QOL is a multidimensional concept referring to a person's total well-being including his or her functional capacity, psychological status, social functioning, physical health and health perceptions (Moser et al., 2000; Calvert et al., 2005). It is often measured as physical, psychological and social well-being (Arnold et al., 2004). From a health perspective, the term health-related quality of life (HRQOL) has become more usual (Calvert et al., 2005) than QOL.

Health-related quality of life originates from the WHO definition of health: “Health is a state of physical, mental, social well-being and not merely the absence of disease or infirmity” but offers a more narrow scope than the definitions of quality of life (Farquhar, 1995). The development of HRQOL was guided by the need to have subjective outcomes in clinical studies and measures intended to assess physical, social and emotional domains (Cella et al., 1993; Aaronson et al., 1993; Priestman et al., 1993; Ware, 1995 cited in Atein, 2001). HRQOL is usually used to refer to quality of life specifically related to health (Testa & Nackley cited in Rapley, 2003). HRQOL can be defined as “the functional effect of an illness and its consequent therapy upon a patient, as perceived by the patient”

(Guyatt, 1993 cited in Coelho et al., 2005: 3). It has seemed logical to distinguish sharply between diseases which explain illness behavior, and other states of health which do not have an explanatory element but might be seen as a consequence of having one or more illnesses (Beck, 1990 cited in Coelho et al., 2005) So, health-related quality of life measures the illness experience as opposed to the disease, it defines the patient's reality, and his or her point of view in perception of their life (Siegristy & Junge, 1990 cited in Coelho et al., 2005). Some studies proposed this concept as one part of the whole of quality of life (Westlake et al. 2002). Some used the term "health status" as HRQOL (De Jong et al., 2004). Thus, to reduce the confusion in this study we used the term of HRQOL.

Health-related quality of life is a multidimensional concept. The dimensions of HRQOL may vary from study to study (Fayer & Machin 2000). For example, Johansson, Agnebrink, Dahlstrom, and Brostrom (2005) defined HRQOL as a multi-dimensional construct that can be assessed on the basis of four principal components: physical condition, psychological well-being, social activities and everyday activities, which include both subjective and objective components. In addition, Wilson and Cleary (1995) illustrated that HRQOL should included at least physical, symptoms, emotional, and social status.

2.2.2 Measurement of Quality of life and HRQOL

Although, QOL and HRQOL is a broad construct which varies from study to study, the measurement of QOL and HRQOL in patients with heart failure usually follows one of two approaches: general and specific instruments (Berlin & Schatz, 2005; Coelho et al, 2005).

1) Generic instruments to measure quality of life.

Some well- known generic instruments are the Sickness Impact Profile (SIP) by Bergner et al (1981); the Nottingham Health Profile (NHP) by Hunt and McEwen

(1980) and the Rand SF-36 Health Status Profile by Ware and Sherbourne (1992). All of these instruments attempt to provide a summary of quality of life and they can be standardized and applied widely to those with different types of illness to enable comparisons. However, they lack the range, sensitivity and flexibility to account for the special problems of particular illnesses. The advantage of this approach is that instruments that are also used in non-heart failure populations are used, therefore allowing broad comparisons between heart patients and patients with other diseases. The most commonly used generic instrument is the SF- 36.

The SF-36: The best-known general health questionnaire is the SF-36, which grew out of work at the Rand Corporation in the late 1970's and 1980's. It searched for a means to determine patient outcomes from disease and treatment, as well as a means to monitor a specific disease. The SF-36 gives a general assessment of an individual's health status. The SF-36 could be used to measure changes in health status over time. This instrument is used widely to evaluate HRQOL across various populations. The SF-36 is a multi-purpose, short-form health survey with only 36 questions which cover 8 domains. The domains are physical functioning; role limitations due to physical health problems; bodily pain; social functioning; general mental health; role limitations due to emotional problems, vitality, energy or fatigue; general health perceptions. The questionnaire items selected also represent multiple operational indicators of health, including: behavioral function and dysfunction, distress and well-being, objective reports and subjective ratings, and both favorable and unfavorable self-evaluations of general health status (Ware et al., 1993). It yields an 8-scale profile of functional health and well-being scores as well as psychometrically-based physical and mental health summary measures and a preference-based health utility index. Variable scaling for different questions includes: Excellent, very

good, good , fair, poor; Limited a lot, limited a little, not limited at all; Yes/No; Not at all, slightly, moderately, quite a bit, extremely; None, very mild, mild, moderate, severe, very severe; All of the time, most of the time, a good bit of the time, some of the time, a little of the time, none of the time; and others. The SF-36 has proven useful in surveys of general and specific populations, comparing the relative burden of diseases. It has been translated in more than 50 countries as part of the International Quality of Life Assessment (IQOLA) Project, nearly 4,000 publications. The SF-36 was constructed to satisfy minimum psychometric standards necessary for group comparisons. Those chosen represent the most frequently measured concepts in widely-used health surveys and those most affected by disease and treatment.

2) Specific instruments for measuring HRQOL.

The second approach uses quality of life instruments specific to heart failure patients. Some of these include the Chronic Heart Failure Questionnaire, Quality of Life Questionnaire in Severe Heart Failure, SOLVD Quality of Life Questionnaire, Daily Dyspnea Questionnair, Fatigue Scale, Quality of Life Scores, Breathlessness Visual Analog Scale, Heart Condition Assessment, Visual Analogue Scale for Activities, Four-domain "Symptom Complex" Index and the Profile of Mood States. The advantage of this approach is that the level of measurement can be very specific to the symptoms and functional problems experienced by persons with heart failure. The most commonly used is the Minnesota Living with Heart Failure Questionnaire (MLHFQ) (Riegel, Moser, Glaser, Carlson & Deaton, 2002).

The Minnesota Living with Heart Failure Questionnaire (MLHFQ) was developed by Rector et al in 1987 for evaluating the quality of life of patients with heart failure. Several studies have validated it as a means of measuring responses to medical

treatment, and its usefulness has been tested in several geographical settings and in different languages. It has been used in many clinical trials that have included HRQOL as a primary or secondary endpoint. The content of MLHFQ was selected to be representative of the ways heart failure and treatments can affect the key physical, emotional, social and mental dimensions of HRQOL. Physical effects of heart failure are measured including the impact of frequent physical symptoms like shortness of breath, fatigue, peripheral edema, and difficulty sleeping. Psychological symptoms like anxiety and depression may also be an outcome of heart failure. In addition, the effects of heart failure on physical/social functions including walking, climbing stairs, household work, need to rest, working to earn a living, going places away from home, doing things with family or friends, recreational activities, sexual activities, eating and mental and emotional functions of concentration, memory, loss of self control, and being a burden to others are incorporated into the measure. A more recent version of the questionnaire increases items which ask about side effects of 'treatments' rather than 'medications' to reflect the growing use of non-pharmaceutical treatments for heart failure.

The Minnesota Living with Heart Failure questionnaire is a 21-item specific questionnaire with 6-point response scales of 0 to 5. On the MLHFQ, patients rate the extent to which physical and emotional symptoms of HF have prevented them from living as desired in the past month (Rector, Francis, & Cohn, 1987; Rector, Kubo, & Cohn, 1987). A total MLHFQ score is computed by summing the responses to the 21 items, with higher scores indicating poorer HRQOL. The MLHFQ has a physical and an emotional subscale (eight and five items, respectively), with eight additional items that are part of the total MLHFQ score but not part of a subscale score. The validity, reliability, and sensitivity of the MLHFQ have been documented. Responsiveness of the MLHFQ refers to its ability to

detect changes in HRQOL that clinicians and patients discern and believe to be important. An instrument's ability to detect change depends, in part, on the amount of noise or measurement error inherent in repeated assessments.

Bennett et al. (2003) conducted a study to empirically compare psychometric properties of the Chronic Heart Failure Questionnaire (CHQ), the Minnesota Living with Heart Failure Questionnaire (MLHFQ), and the General Health Survey Short-form-12 (SF-12). A total of 165 heart failure patients completed the entire 26-week study. They found that reliability of the three instruments were satisfactory. Responsiveness to changing conditions, as evaluated by analysis of variance, receiver operating curve characteristics, and the minimal clinically important difference method, indicated that the CHQ and MLHFQ were more responsive to changing conditions than the SF-12. The MLHFQ and SF-12 were easier and took less time to administer than the CHQ. They indicated that while all three instruments were reliable and valid, the CHQ and MLHFQ were more sensitive than the SF-12 in detecting clinically important changes over time.

According to the benefits of each type of instrument, it is often recommended that both generic and specific instruments should be used. Furthermore, instruments used in measuring HRQOL must be (1) valid (it is really measuring what is supposed to measure), (2) reliable (it gives the same measurement after repeated administration in stable patients), (3) sensitive (it is able to reflect clinically meaningful differences in HRQOL across the broad spectrum of the clinical conditions), and (4) responsive (it detects changes when the patients' conditions change). Wiebe, Guyatt, Weaver, Matijevic, and Sidwell (2003) illustrated that specific instruments tend to be more responsive than generic instruments, but generic instruments still provide very useful information beyond that provided by specific instruments. Because they are designed to

capture all aspects of HRQOL, generic instruments provide a broader context in which to interpret the information about changes in HRQOL.

Because heart failure patients are living with chronic health problems, health related quality of life is influenced from their illness, thus disease specific instrument should be used for evaluating their HRQOL (Al-Kaade & Hauptman, 2001). The specific instruments clarify how HRQOL is effect by disease and illness than generic instruments. Thus, the MLVHF was used in this study.

HRQOL is as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation of their goals, expectations, standards and concerns (Calvert, Freemantle & Cleland, 2005: 243). Lip et al. (2004) used a cross sectional survey to investigate if differing ethnic groups will have different levels of knowledge and perceptions of heart failure and treatments for this condition. They found that Indo-Asians believe God/fate is control of one's health, while the majority of white patients believe that the greatest factor influencing their health was the doctor. White patients were aware of their primary diagnosis of heart failure, whereas the majority of Indo-Asians were not. Although white patients perceived their illness was severe, the majority of Indo-Asians felt it was not severe. White patients' perceived that they were taking pharmacological treatment to relieve their symptoms, while Indo-Asian took drugs because their doctor told them to. This finding is similar to many studies in heart failure patients from multiethnic populations in the UK and North America by (Artinian et al., 2003; Vaccarino, Gahbauer, & Kasl et al., 2001). In additional, Johansson et al. (2004) illustrated that different of human values exist regarding what constitutes a good HRQOL. They also found that nursing care is based on the individual heart failure patient's perspective, so the maintenance of the patients' autonomy and independence is maintained.

2.3 Health-Related Quality of Life in Heart Failure Patients

HRQOL in heart failure patients decreased due to multiple physical and psychological symptoms, functional status decline, multiple hospitalization, and high mortality (AHA, 2006; Lavenson et al., 2003; Chin & Goldman, 2003; Masoudi et al., 2004; Lainscak & Keber, 2003; Calvert et al., 2005; Thongyim, 2000). In addition, patients with heart failure suffer through experiences from their disease and changing patterns of their life style.

Many previous studies conducted in cardiac disease which developed into heart failure reported that patients with cardiac disorder have many stressful symptoms, physical and role function limitations and decreased HRQOL when compared with normal populations (Johansson, Agnebrink, Dahlstrom, & Brostrom, 2004; Hobbs et al., 2002). HRQOL of Thai coronary artery disease patients was poor in overall and poor in the 3 dimensions: physical, psychosocial, and independent (Masnaragorn, 2001). In addition, Hobbs et al. (2002) studied the impact of heart failure and left ventricular systolic dysfunction on HRQOL in 6162 people who were not hospitalized. They found that patients with heart failure have statistically significant impairment of all aspects of HRQOL, not simply physical functioning.

2.4 Wilson and Cleary's Health-Related Quality of Life Conceptual Model

There are many conceptual models of HRQOL, but the development of several of these models was prompted by the observation that commonly used measures of functional status frequently include conceptually distinct constructs of disease, functional limitations, and self-rated health (Bergner, 1985; Nagi, 1965; Read & Quinn, Hoefer, 1987, Patrick & Bergner, 1990; Verbrugge, 1991; and Johnson & Wolinsky, 1993 cited in Wilson & Cleary, 1995). However, none of these models included the full range of variables that now

typically are included in HRQOL assessments. Further, most do not specify the links between biological and other types of measures. Although some modeling work has been done, the principal goal of the field should be to validly and comprehensively describe health status (Wilson & Cleary, 1995).

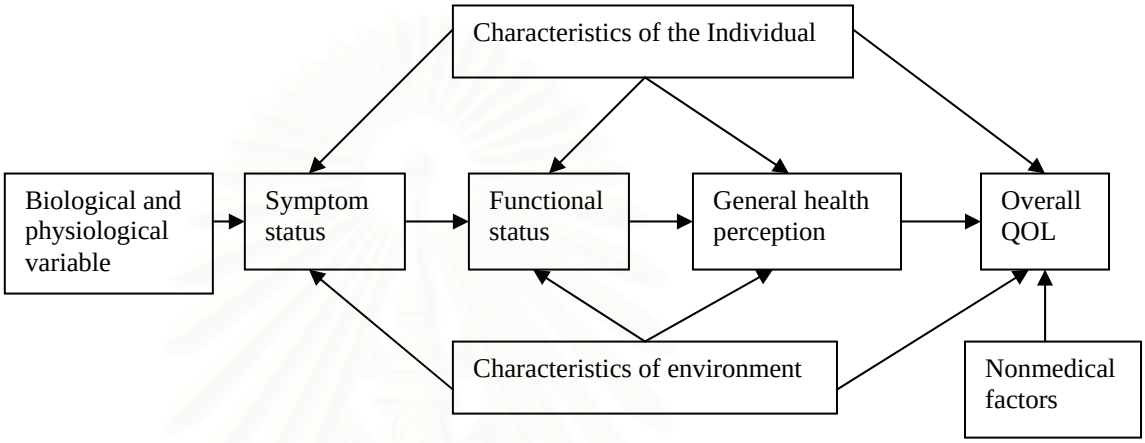

Fig. 1 Wilson and Cleary's Health-Related Quality of Life Conceptual Model. This model is used with the permission of Dr. Wilson, Dr. Cleary, and JAMA. *(*Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes: JAMA 1995; 273: 59–65). Copyright American Medical Association 1995.

Because HRQOL is a bio-psycho-social perception, Wilson and Cleary's Health-Related Quality of Life Conceptual Model (WCM) was selected as the conceptual framework of this study. Wilson and Cleary (1995) provided a conceptual model of HRQOL that moved beyond observation of health status toward assessment of causal relationships among components of HRQOL. Wilson and Cleary proposed their model based on theory, clinical practice, and others' research findings. Their goal was to help clinicians or researchers begin to consider and test potential causal relationships to provide more effective interventions to improve patients' HRQOL (Wilson & Cleary 1995). The WCM is a heuristic, theoretical model that identifies demographic and patho-physiologic antecedents to HRQOL. The

model also specifies causal indirect pathways via individual characteristics, such as beliefs and perceptions about health, and environmental factors, such as social support. This model provides an approach for explaining and predicting HRQOL.

There are seven categorical variables proposed to be directly or indirectly related to HRQOL in the WCM. These are biological/physiologic status, symptom status, functional status, general health perception, individual characteristics, and environmental characteristics and non-medical factor. In the model as illustrated by Wilson and Cleary, the terms QOL and HRQOL are used interchangeably.

Biological and physiologic (bio-physiological) status refers to the status of cells, organs, and organ systems. Symptom status refers to patients' subjective perceptions of abnormal physical, mental, and cognitive conditions. Functional status refers to patients' ability to perform several aspects of tasks or functions, such as physical, social, emotional, role, and cognitive functions. General health perception is defined as patients' global perceptions of their health. Although, individual characteristics and non-medical were not defined by Wilson and Cleary (Wilson & Cleary, 1995), it was used as age gender income, ethnicity, family history, and genetics factors. Environmental characteristics are defined as support provided by family, friends, and others.

Wilson and Cleary's HRQOL Conceptual model have been cited in more than 300 published papers (Hofer et al., 2005). Parts of this HRQOL conceptual model have been widely applied to different populations, including patients with cancer, Parkinson's disease, heart disease, HIV/AIDS and normal populations (Cosby, Holzemer, Henry, & Portillo, 2000; & Jang et al., 2001). Studies in cardiac patients also used the WCM as a conceptual framework. Sullivan et al. (2000) found that the relationship between biological variables and general health perceptions was mediated by symptoms and physical functioning in

patient with coronary heart disease. Sullivan also reported direct relationships between biological variables and physical functioning, between symptoms and general health perceptions, and between biological variables and general health perceptions (Sullivan et al., 2000). In addition, Heo et al. (2005) used a secondary analysis to test the WCM in 293 patients with heart failure during hospitalizations for heart failure exacerbations at community hospitals in Southern California and Central Ohio. They found that general health perception, symptom status, and age predicted the total quality of life. The emotional scale, general health perception, symptom status, and New York Heart Association classification can also predict the physical scale. General health perception was a mediator of the effect of symptom status on HRQOL. They also suggested that the most influential variables associated with HRQOL were the subjective variables, general health perception and symptom status. Although, WCM had been found to be valid in studies of HRQOL in cardiac patients by these two studies, only the first was structural equation modeling analysis approach in patients with coronary heart disease. Because of socio-economic and cultural sensitivities in the perception of HRQOL, it may not generate those results when applied to the situation of HRQOL in Thai heart failure patients.

HRQOL in heart failure patients requires a clinical and psychosocial approach. Patients living with hearth failure face a complex mix of biomedical and psychosocial issues, all of which affect patients' HRQOL (Bosworth et al., 2004). Thus, Wilson and Cleary's HRQOL Conceptual Model was used to organize both biological and psychosocial variables in a causal model of HRQOL in Thai heart failure. We adapted Wilson and Cleary's model in order to incorporate the direct and indirect causal relationships between selected variables. We investigated whether empirical data support the hypothesized causal model of HRQOL in Thai heart failure patients. According, to the previous studies, some

directions, which not propose in WCM were applied in the hypothesized causal model of health related quality of life, such as the direction from symptom status to HRQOL, symptom status to general health perception, and functional status to HRQOL.

2.5 Factors effecting HRQOL in heart failure patients.

Health-related quality of life has been considered a multi-dimensional construct, which includes at least physical, symptom, emotional, and social status (Wilson & Cleary, 1995). Many factors were examined for their direct and indirect effect on HRQOL.

2.5.1 Characteristics of the individual and non medical factors.

This concept was not defined by Wilson and Cleary, but it refers to patients' demographic status such as age, gender, income, and educational level. It has been reported to have both direct effects on HRQOL and indirect effects on HRQOL through symptom status, functional status and general health perception. Age, gender, income, and education are explored for their effect on HRQOL in heart failure patients. Many studies in the West illustrated that age and gender are related to health perception (Clark et al., 2003, Evangelista et al., 2001) and to HRQOL (Calvert et al., 2005; Hou et al., 2004; Clark et al., 2003). The largest impact of heart failure on HRQOL occurred in the younger age group (Calvert et al., 2005; Masoudi et al., 2004; Hou et al., 2004; Gottlieb et al., 2004). Studies in Thailand illustrated that, not only age and gender, but also occupation, education, and income are also related to HRQOL in cardiac disease which usually develops into heart failure (Phonphet, 2001; Yamsakul, 1999). Age also had been reported to be related to physical function (Sriprasong, 2000). Gender had been reported in many studies to effect symptoms status and functional status (Chin & Goldman, 1998; Calvert

et al., 2005, Gottlieb et al., 2004, Mallki et al., 2005; Friedman, 2001). When matched for age and ejection fraction, women had significantly worse general life satisfaction, physical function, and social and general health scores than men (Riedinger et al., 2001).

According to the WCM, non-medical factors such as age gender, education, and income can influence HRQOL through other concepts not directly related through symptom status, functional status and general health perception. Factors such as income, education or gender cannot be manipulated by the researcher. Thus, these non-modifiable variables were not proposed in hypothesized causal model of heart failure (Figure 1), but were accounted for in the descriptive of sample characteristics.

2.5.2. Biological and physiological variable

Biological and physiological variable refers to the status of cells, organs, and organ systems. Left ventricular ejection fraction (LVEF) was used to determine the level of biological/ physiological function in heart failure. LVEF affected symptom status of heart failure patients. Left ventricular dysfunction with an ejection fraction of less than 35% was associated with a 30 percent risk of symptomatic heart failure in three years (The SOLVD Investigators, 1992 cited in Cohn, 1996). In addition, some studies indicated that having an LVEF less than 40 % will make patients have symptoms of heart failure (Bonow et al., 2005). Having a decreased LVEF frequently impacts mental health with signs of depression (Bhaskaran et al., 2004; Lu et al., 2005; .Elatre, Aria, Cayasoo, Huiskes, Beckwith &Heywood, 2003). Having a decreased LVEF also affects functional status, where individuals with a NYHA functional class III and class IV are usually less than class I and class II. Although having a decreased LVEF is shown to have a significant direct effect on symptom and functional status of heart failure, it had been reported in many studies to have a weak or no significant direct effect on HRQOL (Clark et al., 2003; Juenger et al., 2002; Riegel et al.,

2002; De Jong et al., 2004). Furthermore, Carel (2004) and Mitani et al (2003) found no association between LVEF and any of the HRQOL subscales.

2.5.3 Characteristics of environment

Characteristics of environment are defined by Wilson and Cleary as support provided by family, friends, and others. Thus, social support was indicated as the environmental characteristics of heart failure, because of its' reported large effect on HRQOL in heart failure patients (Bennett et al., 2001).

Because of the effect of social support on symptom status, Taylor (2005) indicated that social support can reduce psychological distress such as anxiety. Social support may also increase the ability to cope with stressors through receiving informational and emotional support, and improved coping may result in fewer physiological and psychological symptoms of illness (Hogan, Linden, & Najarian, 2002). Bennett (1998) illustrated that social support was significantly, though not strongly, correlated with the impact of physical symptoms. Social support was also positively correlated with physical functioning (Rayond et al., 1997). Sriprasong (2000) illustrated that social support was associated with functional status. In contrast, a study conducted by Buarapha (2004) indicated that social support was significantly negative as related to physical activity of Thai heart failure. In addition, Riedinger et al. (2002) illustrated that the correlation between social and general life satisfaction was moderate (0.63). Furthermore, social support was reported as a predictor of health-related quality of life in heart failure patients (Bennett et al., 2001). Furthermore, Samranbua (2001) revealed that social support shows significant positive correlation with holistic health in valvular heart patients.

2.5.4 Symptom status

Symptoms of heart failure can be conceptualized as multidimensional in

nature and include components of frequency, severity and distress (Lenz et al., 1997 cited in Zambroski et al., 2005). Absolute freedom from all symptoms may not be a realistic outcome in patients with heart failure. Heart failure symptoms consist of shortness of breath, pitting edema, enlarged tender liver, engorged neck veins, and pulmonary rales (The American Heritage Stedman's Medical, 2004). The most common physical symptoms of heart failure reported by patients in previous studies have been fatigue and dyspnea resulting from exertion (Friedman et al., 1997; Wilson et al., 1995). Many research studies illustrated that physical symptoms and psychological symptoms are associated with functional decline, mortality and reduced HRQOL scores (Gottlieb et al., 2004; Lainscak & Keber, 2003; Sullivan et al., 2004; Vaccarino et al., 200; AHA, 2006; Lavenson et al., 2003; Chin & Goldman, 2003; Moser & Worster, 2000).

Dyspnea, breathlessness, and shortness of breath are interchangeable terms used by health care providers to describe reports by patients of breathing discomfort (Caroci & Lareau, 2004). Dyspnea is the most common symptom reported by patients with heart failure (Parshall, 1999; Friedman, 1997; Welsh et al., 2002). Dyspnea can be present also during the night, especially in the advanced stage of the condition. One can experience either orthopnea or paroxysmal nocturnal dyspnea, causing sleep disturbances, lack of refreshing sleep and daily sleepiness. All further reduce one’s HRQOL (Lainscak & Keber, 2003).

Fatigue was the other frequently occurring physical symptom at both measurement times, and it significantly increased with time (Friedman & King, 1995). Chiraporn (1999) found that fatigue was usually found in Thai heart failure patients. Further more, Ekman and Ehrenberg (2002) indicated that fatigue occurs in younger ages with women than men, and there are few differences between gender at older ages. Fatigue

in older women with heart failure is related more to other physical symptoms than psychological factors (Friedman & King, 1995).

According to psychological symptoms, anxiety and depression are highly correlated in heart failure patients (Jiang et al., 2004), the level of anxiety and depression are rated as moderate to severe (Januzzi, Stern, Paternak & DeSanctis, 2000). Psychological symptoms are related to increased morbidity, a reduction in life quality, and increased impairment in physical functioning. Results from qualitative studies suggested that individuals with heart failure often experience impairment in psychological functioning such as a disturbance in mood, anxiety, insecurity, powerlessness, worthlessness, a sense of disruption and incoherence, feelings of being a burden to others, and feeling imprisoned by the illness (Mahoney 2001; Martensson, Karlsson, & Fridlund, 1998).

The severity of depression was significantly related to a worse prognosis of heart failure (Jiang et al., 2004). Depression had a greater impact on the overall health and HRQOL in heart failure patients (Nabb et al., 2006). Depression is often overlooked in heart failure patients due to overlapping signs and symptoms such as apathy or fatigue. Depression in individuals with heart failure was strongly associated with the perception of physical limitations (Murberg et al., 1998).

Anxiety is typically defined as a future-oriented, negative affective state with a component of fear, resulting from a perception of threat and typified by a perceived inability to predict, control, or obtain desired results in upcoming situations (Kawachi et al., 1994 & Beekman et al., 2002 cited in Jiang et al., 2004). Anxiety or emotional distress prior to hospitalization was twice as common in patients with heart failure when compared to other patients (Lainscak & Keber, 2003). Anxiety also related to physical symptoms

(specifically dyspnea) and poor prognosis of heart failure (Artinian, 2003; MacMahon & Lip, 2002).

Anxiety and depression are significantly related to functional limitation (Elatre et al., 2003; Mayou et al., 2002, and Friedman, 2001). For example, NYHA functional class was impacted with signs of depression (Bhaskaran et al., 2004; Lu et al., 2005; Murberg et al., 1998) and anxiety (Januzzi, Stern, Paternak & DeSanctis, 2000). Patients who are depressed will not try to do anything, such as they do not want to meet anyone, to go to the hospital, or take medication (Elatre et al., 2003). In addition, heart failure patients cannot perform their social activities because of their anxiety. Lu et al. (2005) found that psychological distress, poor functional status and negative health perception were significant predictors of reduced health related quality of life in heart failure patients. Moreover, physiological symptoms and psychological symptoms also related to each other. Ramasamy et al. (2006) confirmed that dyspnea is a multi-factorial construct which links psychological distress and overall health perception in heart failure patients.

2.5.5 Functional status

Functional status can be viewed from various perspectives. According to Wilson and Cleary (1995), functional status refers to patients' ability to perform several aspects of tasks or functions, such as physical, social, emotional, role, and cognitive functions. Here patients indicated their functional status from the perspective of disability or disablement, focused on the loss of function and its effects on daily life (Stineman et al., 2005). In addition, many previous studies in heart failure defined functional status as patients' ability to perform their daily living activities limited by heart failure.

Heart failure patients report physical and social limitations, including a

limited capacity to perform activities of daily living, not being able to take care of family responsibilities as they were used to, reduced sexual activity, decreased mobility and inability to travel which disrupted social interactions with family and friends (Scott, 2004; Grady et al., 1995; Jaarsma et al., 1999; Albanese et al., 1999 cited in Johansson et al., 2005). In addition, Lainscak and Keber (2003) illustrated that health impaired patients' were unable to work, and not able to perform normal daily activities, hobbies or sport and social activities. In a sample of approximately 700 women with heart failure, fewer than half reported that they were healthy enough to perform everyday activities (Riedinger, Dracup, & Brecht, 2002). Patients felt loneliness or loss of control over the life. Furthermore, heart failure patients equated HRQOL with the ability to perform physical functions in the same way they did before developing heart failure, grieved for their former abilities and expressed lower self-esteem due to loss of independence from physical limitations (Paul & Sneed, 2002).

Functional status varied not only because of physical disabilities caused by cardiac disease which developed into heart failure, but also because of individual perceptions of symptoms, barriers in the environment, the availability of assistance and social support, and psychological factors such as depression (Belardinelli, 2005; Murberg et al., 1998, Sean, 2000; Friedman & Griffin, 2001; Vaccarino et al., 2001). For example, the negative impact of depressive symptoms on functional status appears to be stronger for women than for men with heart disease (Mallki et al., 2005). Murberg et al. (1998) illustrated that there were strong associations between subjective indicators of physical limitations and symptoms of depression among the males, but this relation was not significant among the females. Although, the subjective NYHA functional class was associated with all HRQOL scales (Juenger, Schellberg & Kraemer et al., 2002; Lu et al.,

2005), a study conducted by Carels (2004) suggested that functional impairment had a much weaker direct association with HRQOL.

2.5.6 General health perception

General health perception had been defined as a patient's global self assessed health. General health perception in heart failure patients was a significant factor associated with HRQOL (Lu et al., 2005; Beckie & Hayduk, 2003). Hoe et al. (2005) found that general health perception was a mediator of the effect of symptom status on HRQOL in heart failure patients. In addition, De Jong et al. (2004) illustrated that general health perception strongly related to symptom status and was moderately related to activity level. In additional, Rayond, Rosen, Contrada, Gorkin and Kostis (1997) illustrated that high levels of perceived health were associated with low levels of emotional distress and high levels of physical functioning.

2.6 The hypothesized causal model of HRQOL in Thai heart failure patients.

The hypothesized causal model of HRQOL in Thai heart failure was derived from Wilson and Cleary's Health-Related Quality of Life Conceptual Model. Variables and the relationships among variables have been modified from this conceptual framework and its supporting literature. Because Wilson and Cleary's Health-Related Quality of Life Conceptual Model presented only linear causal relationships among concepts proposed in the model, some additional direction between concepts was added in the hypothesized causal model of HRQOL in Thai patients with heart failure. The new directions were established with support of the most significant factors affecting HRQOL in heart failure patients. The causal relationship is shown as figure 2.

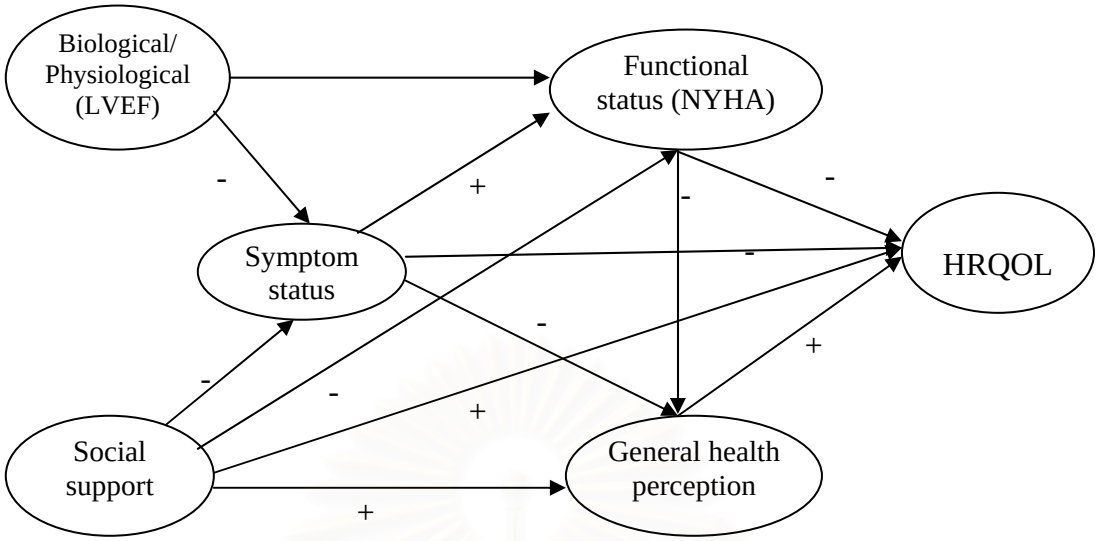

Figure 2 A hypothesized causal model of HRQOL in Thai heart failure patients

According to Wilson and Cleary's health-related quality of life model, the terms overall QOL, QOL and HRQOL are used interchangeably. Thus for reducing the confusion, the term HRQOL was used in this study for determining patient's subjective perception of the impact from heart failure on various aspects of his or her daily life. In addition, characteristics of individual and non-medical factors were not presented in the hypothesized causal model of HRQOL in heart failure. Although, Wilson and Cleary does not mention indirect relationships exist in WCM, the selected variables proposed in the hypothesized model (figure 2) presented both direct and indirect effect on HRQOL in heart failure patients. The causal relationships between concepts were explained as follow.

2.6.1. Biological and physiological variable (left ventricle ejection fraction) would have a negative direct effect on symptom status and functional status. It also would have a negative indirect effect on HRQOL through symptom status, functional status, and general health perception in heart failure patients.

Biological and physiological variable refers to the status of cells, organs, and organ systems. It was an objective measurement of physical heart function as indicated by the left ventricular ejection fraction (LVEF). Decreased LVEF would have a negative direct effect on symptom status and functional status. The blood flow to meet the requirement of body organs is also decreased together when LVEF is decreased. Having an LVEF less than 40 % indicates that patients will have symptoms of heart failure (Bonow et al., 2005). Decreasing LVEF is associated with increased severity of heart failure. In contrast, a higher LVEF is associated with less or no symptom of heart failure. LVEF related to functional status, such as LVEF in NYHA functional class III and class IV are usually less than class I and class II. Furthermore, physical and psychological symptoms are causes of function limitations which in turn reduce general health perception and HRQOL.

2.6.2 Characteristics of environment had a negative direct effect on symptom status and functional status. It had a positive direct effect on general health perception. It also had a positive indirect effect on HRQOL through symptom status, functional status and general health perception.

Social support was indicated as the environmental characteristic of heart failure, because of its' reported much effect to HRQOL in heart failure patients (Bennett, et al., 2001). Social support had a negative direct effect on symptom status, but it had a positive direct effect on functional status, general health perception and HRQOL. Riedinger et al. (2002) indicated that the correlation between social and general life satisfaction was moderate ($r = 0.63$). Social support was positively correlated with physical functioning (Rayond et al., 1997). Social support will provide less symptom distress which also increases functional status and health perception. Furthermore, social support was reported as a predictor of health-related quality of life in heart failure patients (Bennett et al., 2001).

2.6.3 Symptom status had a positive direct effect on functional status as defined by NYHA. It had a negative direct effect on general health perception and HRQOL. And, it also had a negative indirect effect on HRQOL through functional status and general health perception.

Symptoms of heart failure were reported as having a large effect on HRQOL in heart failure patients (Gottlieb et al., 2004; Lainscak & Keber, 2003; Vaccarino et al., 2001). Dyspnea and fatigue were the most common physical symptoms of patients with heart failure and had both a direct and an indirect effect on patients' HRQOL (Friedman, 2001; Chatvichai, 2003; Maneeslip, 1999; Yamsakul, 1999). Function status of heart failure patients is limited by symptoms and the stage of heart failure (Konstam et al., 1996; Maneesilp, 2000; Baskaran et al., 2004; Lu et al., 2005). Patients in NYHA class III and IV had more frequent problems in daily life than patients in NYHA classes I and II (Majani et al., 1999). Friedman & Griffin (2001) found that physical symptoms and physical functioning of heart failure patients were moderately correlated (r = -0.32). Symptom of heart failure was reported to reduce health perception of heart failure patients (Sullivan et al., 2004). Therefore, symptoms were a cause of function limitation which in turn reduced general health perception and HRQOL.

2.6.4 Functional status had a negative direct effect on HRQOL and had a negative indirect effect on HRQOL through general health perception.

According to functional status, it was quantified as the NYHA functional classification. The higher NHYA functional classification, the lower functional status, for example, heart failure patients with NYHA functional class III and IV had more limited functional status than NYHA I and II. In addition, patients with NYHA class III and IV had more frequent problems in daily life than patients in NYHA classes I and II (Majani et al.,

1999). Functional status limitations will make heart failure patients unable to perform their normal activities, causing them to rate their general health perception as poor (Stewart et al, 2004), and also HRQOL. The subjective NYHA functional class was reported in studies conducted in Thailand and were related to Western reports of HRQOL (Juenger et al., 2002; Parajon et al., 2004; Samranbua, 2001; Maneeslip, 1999). Lu et al. (2005) indicated that the greatest effect on HRQOL in heart failure patients were NYHA functional class where higher NYHA functional class was significantly associated with the poorer HRQOL

2.6.5 General health perception had a positive direct effect on HRQOL.

General health perception was defined as patients' global perceptions of their health. General health perception in heart failure patients was a significant factor associated with HRQOL (Lu et al., 2005; Beckie & Hayduk, 2004). Heart failure patients who assess their general health as well will also perceive their HRQOL as increased.

2.7 Statistic for causal model analysis

Structural equation modeling (SEM) is also known as analysis of covariance structures, or causal modeling (Byrne, 2001). This approach has a more powerful way which takes into account the modeling of interactions, nonlinearities, correlated independents, measurement error, correlated error terms, multiple latent independents each measured by multiple indicators, and one or more latent dependents also each with multiple indicators (Hoyle, 995; Byrne, 2001). Structural equation modeling (SEM) was used to test the theoretical model against the observed dataset. SEM is a more theory-driven approach, and the resulting prediction equations are a more accurate representation of the true causes of variation in the dependent variable than standard regression method (Pedhazur, 1997; Byrne, 2001).

There are several steps in structural equation modeling (Kline, 2005; Hoyle, 1995): 1) developing a model based on theory; 2) identification of unique values that can be used for the parameters to be estimated in the theoretical model; 3) application of various estimation techniques, for example, maximum likelihood; and 4) testing the fit of the model against the data. According to the results, the researcher might 5) modify the measurement model based on theoretical justifications; revise the model by adding, deleting, or modifying relationships between latent variables; or use measures indicating lack of fit for specific parts of the model when theoretically justified.

Structural equation modeling encompasses two major components: 1) measurement models and 2) structural path components. Although SEM is capable of testing the measurement model and structural model simultaneously, the recommendation is that the measurement model should be tested separately to detect any inadequate fits prior to testing the full model (Hoyle, 1995; Byrne, 2001; Kline, 2005). This allows the researcher to pinpoint where the model is misspecified (whether the measurement portion or the structural portion). As described by Kline (2005), there are two approaches that can be used: (1) two-step modeling as proposed by Anderson and Gerbing (1988) and (2) four-step modeling as recommended by Mulaik and Millsap (2000). The two-step approach has the advantage of simplicity and does not require at least four indicators per factor (Kline, 2005). Therefore, the two-step modeling approach was implemented for the analysis.

This study used both measurement models and structural path components to build a full latent variable model, or hybrid model. Before the full latent variable model was tested, each measurement model (e.g., social support, symptom status, and HRQOL) included in the full model was tested separately to ensure its fit, by using the two-step approach. This process involved an evaluation of the hypothesis that the indicated measured items or scales

reflect the latent constructs. Models for each construct were defined by permitting each of the relevant test items or scale scores to load on a single factor representing the latent construct that it was hypothesized to measure.

Goodness of fit indices was used as an indicator of model fit. Chi-square tests were used as an index of the significance of the discrepancy between the original (sample) correlation matrix and the (population) correlation matrix estimated from the model. RMSEA values help to answer the question of how well the model would fit the population covariance matrix if it were available. The lower the discrepancy measured by the RMSEA the better, with an RMSEA of 0.0 indicating a perfect fit (Byrne, 2001). Acceptable values of RMSEA is less than .08. For the comparison of models, we used the chi-square statistic. The other criteria for results interpretation was explained in chapter 3.

LISREL, AMOS, and EQS are three popular statistical packages for doing SEM. The first two are distributed by SPSS. LISREL popularized SEM in sociology and the social sciences and is still the package of reference in most articles about structural equation modeling. AMOS (Analysis of MOment Structures) is a more recent package which, because of its user-friendly graphical interface, has become popular as an easier way of specifying structural models (Hoyle & Rick, 1995; Byrne, 2001). Although these three programs provide different analysis technique, AMOS is a reliable available program for SEM like LISREL and EQS. However, AMOS performs state-of-the-art estimation by full information maximum likelihood instead of relying on ad-hoc methods like listwise or pairwise deletion, or mean imputation. The program can analyze data from several populations at once. It can also estimate means for exogenous variables and intercepts in regression equations. The program also reports several statistics appropriate for comparing such models. It provides a test of univariate normality for each observed variable as well as

a test of multivariate normality and attempts to detect outliers. AMOS provides Bollen-Stine bootstrap or Satorra-Bentler scaled chi-square, which infers the exact structural fit for non-normality. AMOS Bollen-Stine bootstrapping method adjusts the critical value of the chi-square test instead of the obtained chi-square test statistic.

Summary

There are many significant factors related to health related quality of life in heart failure patients. Individual characteristics, characteristics of environment, symptom status, functional status, and general heath perception were also reported to affect HRQOL. Various evidences have indicated that social support, functional status, and general health perception has a positive direct effect on HRQOL. Symptom status has a negative direct effect on HRQOL. Left ventricular ejection fraction has been used as an indicator to quantifying biological and physiological status of heart failure, but studies reported less or no direct effect on HRQOL. There have been mixed findings concerning the association among factors affecting HRQOL in heart failure patients. NYHA functional classification has been used to determine functional status in heart failure patients but is inconsistent in its effect on HRQOL. Social support was reported as having a negative direct effect on HRQOL in Thai heart failure patients in one study, while another study reported in the opposite way. Moreover, many previous studies conducted to examine the relation ship between only one or two selected factors on HRQOL. Particularly, they emphasized only on direct effects on HRQOL. There are few studies providing an understanding of indirect effects of factors on HRQOL, and also the interrelationship among factors related to HRQOL. Furthermore, most of them provide information of the selected factors affect on only one dimension of HRQOL.

Therefore, the results from previous studies could only partially explain factors influencing HRQOL in heart failure. The causal relationship among many significant factors effect on HRQOL is still not established. There are problematic conclusions about the relationships and the interrelationships between significant factors and HRQOL in heart failure. Because of the inconsistency of the results, it could be a problem of using different research methodologies, or conducting studies in different settings and populations. Therefore, it might be in appropriate to generalize the existing knowledge into a Thai context. Furthermore, most studies conducted in Thailand reported small sample sizes and examined only direct relationships of some factors related to some dimensions of HRQOL. Thus, basic knowledge relevant to HRQOL in Thai heart failure patients is still not clear. In order to develop effective nursing interventions for maintaining and improving HRQOL in Thai heart failure patients, basic knowledge is still required.

Considering the holistic approach of nursing to human being in the real world, we can not leave out some parts of human being. For example, we can not stop with the social environment and explore only direct effects of functional status on HRQOL. The current causal model of health-related quality of life in heart failure patients was developed to examine the direct and indirect effects of biological/physiological status (LVEF), social support, symptom status, functional status, and general health perception on health-related quality of life in Thai heart failure patients. This current study has been conducted to obtain the information in order to gain a better understanding of the relationships and interrelationships between factors and HRQOL in heart failure patients. The findings would lead to a greater understanding of the nursing implications in this chronic condition. The findings would play a major role in the development of interventions to enhance HRQOL or develop further research in HRQOL in heart failure patients.

CHAPTER III

METHODOLOGY

This chapter describes the research design and methods that were used to conduct the present study. The research design, population, sampling technique and sample selection, instrumentation, protection of human subject, data collection and data analysis procedures are included.

3.1 Research design

A descriptive correlation, cross-sectional research design was used to test a causal relationship of HRQOL in Thai heart failure patients. Drawing related variables from biological/physiological status (LVEF), individual environment (social support), symptom status, functional status, and general health perception.

According to Polit and Hungler (1995), a descriptive cross-sectional research design is limited in its ability to explain the causal relationship between variables due to a lack of manipulation or control of independent variables. However, it has many advantages. First of all, it can explore the relationships among variables in natural occurring situations without any artificial manipulation. Next, it is appropriate when experimental design is not feasible. Finally, it allows the investigator to collect a large amount of data in an economic way.

Following this information, this study used this research design because of its advantages. Firstly, this study had to explore the phenomena of HRQOL and the effect of various factors on HRQOL in the natural perception of heart failure patients. Secondly, the variety of situations of HRQOL in heart failure patients are broad and sensitive not only to

biological factors, but also socio-economical factors, thus a large sample size was required. Finally, Wilson and Cleary's health related quality of life conceptual model (WCM) was selected for this present study of causal relationships among biological, clinical, and sociological variables that might affect HRQOL in Thai heart failure patients.

3.2 Population and sample

The population of interest in this study was Thai heart failure patients who attended out patient cardiac clinics of tertiary government hospitals in Thailand.

3.2.1 Sample size

The sample size was determined by two criteria. First, the variance of the dependent variable (HRQOL) was taken into account in the formula of:

$$n = \frac{Z^2_{\alpha/2}\,\sigma^2}{d^2}$$ (Daniel, 1991)

Where, n = Sample size

$Z_{\alpha/2}$ = the standard estimate under normal curve at α. = .05, α/2 = .025, Z = 1.96

σ^2 = Variance of quality of life from the study of Lortajakul (2006) = 66.98^2.

d^2 = Error allowed for estimating quality of life = 0.1 x σ, = 0.1 x 66.98 = 6.698^2

By calculation the following formula:

$$n = \frac{(1.96)^2 \times (66.98)^2}{(6.698)^2}$$

$$= 384.16$$

The sample size was determined to be 384 persons. Secondly, in keeping with stringent sample estimates, the minimum sample size in this study was set to be 384. In addition, Hair, Anderson, Thatham and Black (1998) suggested missing data was a common problem in multivariate analysis. The researcher should consider an estimate of the sample survey and add 10 % to arrive at a true population value. Thus, 38 cases were added, bringing the total sample size to 422.

According to Joreskog and Sorbom (2001), there is no definite formula for calculating sample size for structural equation modeling (SEM). However, Hair, Anderson, Tathum and Black (1998) suggested that the most appropriate ratio of respondents for each estimated parameter is 10:1. Nunnally (1978) suggested 10-20 subjects per item for performing confirmatory factor analysis. The other suggestions exist as well. For example, a good general rule of thumb for factor analysis is 300 cases (Tabachnick & Fidell, 1996) or 50 participants per factor (Pedhazur & Schmelkin, 1991). Furthermore, Comrey and Lee (1992) gave the following guide for samples sizes: 50 as very poor, 100 as poor, 200 as fair, 300 as good, 500 as very good, and 1,000 as excellent. Guadagnoli and Velicer (1988) have shown that solutions with several high-loading marker variables (> .80) do not require as many cases. In addition, if the dependent variable was skewed and the effect size expected was small, substantial measurement error could occur; thus, larger samples were needed (Tabachnick & Fidell, 1996).

In this study, the hypothesized model contained 15 free estimated parameters, thus a sample size of 150 to 300 was the minimum requirement. However, the measurement model of HRQOL had 21 free parameters, thus sample size confirmatory factor analysis should be at least 210 to 420. Therefore, a sample of 422 heart failure patients was appropriate for this study

3.2.2 Sampling technique

A multi-stage random sampling procedure was used to yield a probability sample of heart failure patients as illustrated in Figure 3

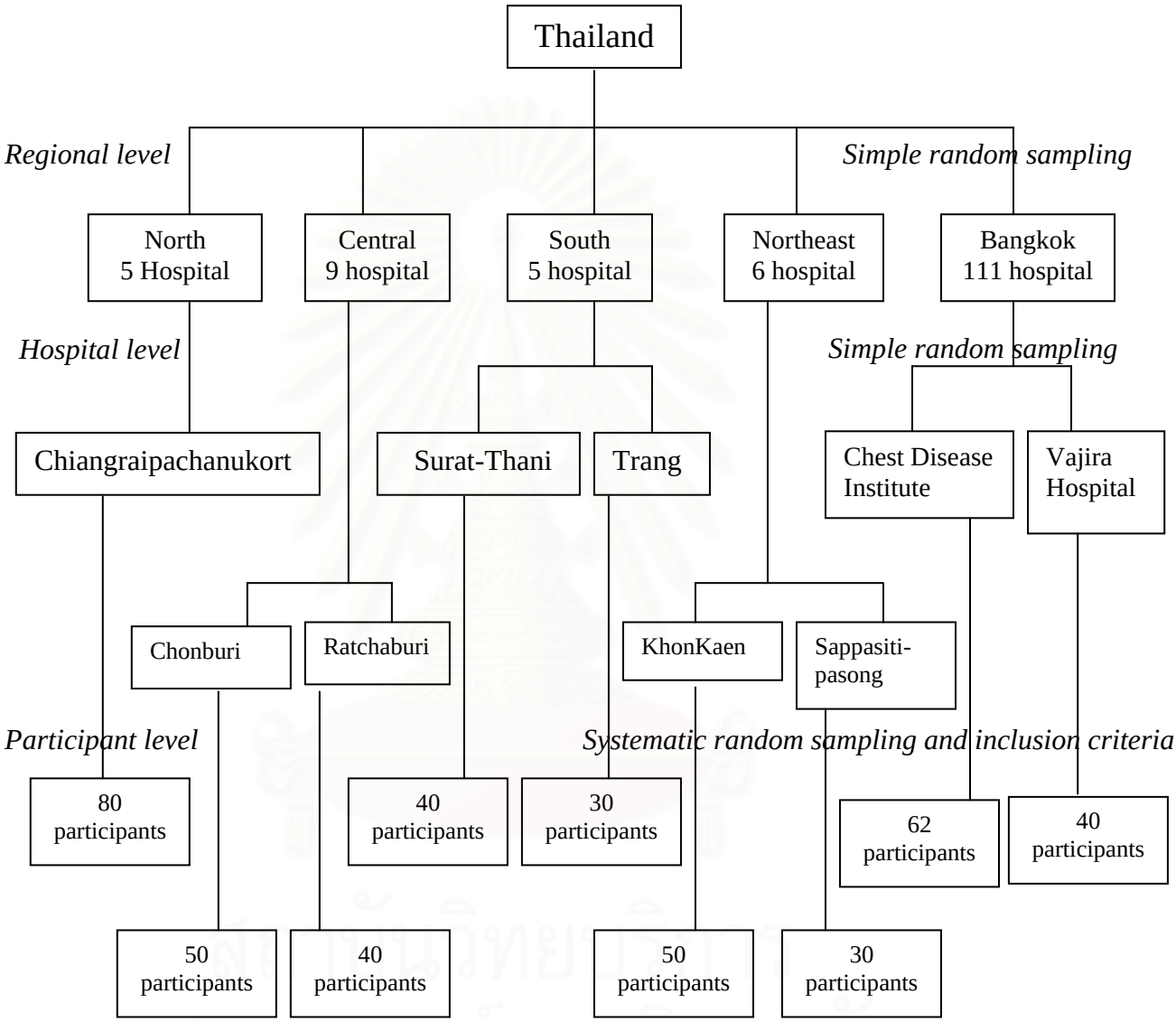

Figure 3 Multi-stage random sampling

The first step (The region level): According to the Ministry of Public Health Thailand, (2005) the number of hospitals, the number of hospital beds and establishment of health facilities were separated by jurisdiction region and province. Thus, there are 5 regions: the Northern, Southern, Central, Northeastern, and Bangkok. There are 1278 hospitals in Thailand: Ministry of Public Health hospitals (875), other ministry hospitals

(85), enterprise and independent public agencies (7), public agencies (13), and private hospitals (289) (MOPH, 2006). Heart failure requires complex and high technological support for patient treatment and diagnostic needs. Except for facilities in Bangkok, community hospitals or some general hospitals in four parts of Thailand can not provide effective care. Thus, regional hospitals in each part of Thailand and a government hospital in Bangkok were randomly selected as study sites.

The second step (The hospital level): Based on information reported by The Office of the Permanent Secretary for Public Health (2006), there were many cardiac patients receiving treatment at out patients units and in patients units of regional hospitals. In the Central Region of Thailand, there are 5 regional hospitals which reported that approximately 4,210,602 cardiac patients required treatment at out patient units and 128,131 as in patients. In addition, there were 105,972 in patients and 3,017,764 out patients in six regional hospitals in the northeastern part. Moreover, about 94,472 in patients and 3,677,475 out patients were treated in five regional hospitals in the Northern Region. Finally, there were 1,690,569 out patients and 65,061 in patients treated in five regional hospitals in the Southern Region.

Because the number of cardiac patients in each regional hospital was not equal, more than one hospital in some parts of Thailand was randomly selected to meet the criteria of sample size. Sappasitipasong Hospital and Trang Hospital reported the number of cardiac patients as fewer than 2,000. Thus, additional sites, KhonKaen Hospital and Surat-Thani Hospital were selected. Furthermore, the central part of Thailand reported more cardiac patients than the other parts, except Bangkok. Thus two regional hospitals, Chonburi Hospital and Ratchaburi Hospital were randomly selected for inclusion. In the Bangkok area, there are 111 government and non-government hospitals which have sufficient high

technology for heart failure management. The number of heart failure patients from each site could not be clarified, Thus two hospitals, Chest Disease Institute and Bangkok Metropolitan and Vajira Hospital were randomly selected to represent this area.

The third step (The participant level): In each hospital, participants were select by systematic sampling technique using their hospital number together with inclusion criteria. The number of participants in each hospital present on Table 3.1 and Figure 3.

Table 3.1 A number of regional hospitals, the number of cardiac patients receiving treatment at out-patient and in-patient units in each part of Thailand and Bangkok in 2006 (MOPH, 2007), number of heart failure patients in each selected hospitals, and number of the participants from each site

Parts of Thailand	Number of Regional hospitals/research setting	Number of cardiac patients		Number of in patients with heart failure/year	Number of participants
		Out-patients (per-year)	In-patients (per-year)		
The Northern Region	All 5 hospitals Chiangraipachanukort hospital	3,677,475	94,472	606	80
The Northeastern Region	All 6 hospitals Sappasiti-pasong hospital KhonKaen hospital	3,017,764	105,972	229 315	30 50
The Southern Region	All 5 hospitals Trang hospital Surat-Thani hospital	1,690,569	65,061	198 290	30 40
The Central Region	All 9 hospitals Chonburi hospital Ratchaburi hospital	4,210,602	128,131	780 551	50 40
Bangkok	All 111 hospitals -Chest Disease Institute - Medical College of Bangkok Metropolitan and Vajira Hospital		-	- 4,480 2,512	62 40

3.2.3 Sample criteria

Participants were recruited into the study based on feasibility of recruitment criteria as follow:

1) Diagnosed with heart failure alone or diagnosed with their baseline diseases (etiology) and reported symptoms of heart failure from hospital records. (Many patients came to the hospital with signs and symptoms of heart failure, but had been diagnosed with specific etiology such as myocardial infarction, disease of heart value (e.g., Aortic, Mitral stenosis) or congenital heart disease and were not enrolled in this study.

2) Age equal or more than 18 years old (adult in law).

3) Having no symptoms of dyspnea, severe fatigue, and/or chest pain

4) Having medical record of LVEF within 1 month before data collection.

5) Able to communicate in Thai with researcher

6) Willing to participate in this study

Exclusion criteria; patients were excluded from the study if they had the following criteria.

1) A large myocardial infarction during the preceding 8 weeks (including a (sudden cardiac arrest).

2) Patients diagnosed with cancer, HIV/AIDs, renal failure, or hyperthyroidism.

There were 422 heart failure patients who participated in this study. More than half of the subjects were female (65.6 %), married (66.6 %) and had a monthly income of less than 1000 bath (69.0%). Their ages ranged between 60-69 and 45-59 years of age (36.3% and 28.7%, respectively, with a mean of 58.47 years of age (SD= 15.67). Most of the participants were Buddhist (95.7%), and 47.9% worked in the home or did not work. About 64.7 % had a primary education and about 10.2 % graduated high school, while 4.5 % had completed a bachelor degree. The demographic characteristics of the subjects are summarized in table 3.2

Table 3.2 Demographic characteristics of the subjects

Characteristics	Frequency	Percentage
Sex		
Male	145	34.4
Female	277	65.6
Age (years)		
18-24	10	2.4
25-44	68	16.1
45-59	121	28.7
60-69	153	36.3
70 and over	70	16.6
Marital status		
Marriage	281	66.6
Single	26	6.2
Window	101	23.9
Divorce	5	1.2
Separate	9	2.1
Religion		
Buddhism	404	95.7
Islam	15	3.6
Christian	3	0.7
Education		
None	74	17.5
Primary	278	64.7
Secondary	43	10.2
Diploma	12	2.8
Bachelor	19	4.5
Master	1	0.2
Occupation		
House work/ not work	202	47.9
Employee	86	20.4
Trade	33	7.8
Government official/ Government enterprise	20	4.7
Own business	5	1.2
Farmer	76	18
Incomes/month		
Less than 5,000 Bath	291	69.0
5,000-10,000 Bath	85	20.1
10,001-20,000 Bath	24	5.7
20,001-30,000 Bath	18	4.3
More than 30,000 Bath	4	0.9

Approximately half of the subjects (54.3 %) had no co-morbidities, while 20.4 % and 7.8 % also had hypertension or diabetes mellitus. About 11.8 % had both hypertension

and DM. About two-third of the subjects (32.7%) were diagnosed with heart failure within the past one year, while 26.5 % were diagnosed more than 1 year to 3 years ago, and only 2.4 % had been diagnosed more than 20 years. The most common etiologies of heart failure were coronary artery disease (24.2%), valvular heart disease (22.5%), and in 28.9% of subjects, the etiology was not defined. . The characteristics and comorbidities of heart failure patients are summarized in table 3.3

Table 3.3 Comorbidity, duration of heart failure, and etiology of heart failure.

Characteristics	Frequency	Percentage
Comorbidity		
None	230	54.5
DM	33	7.8
Hypertension	88	20.9
DM and Hypertension	50	11.9
COPD/Asthma	9	2.1
Peptic ulcer	7	1.7
Gouty arthritis	5	1.2
Duration of heart failure		
> 1 month to 1 year	138	32.7
> 1 year to 3 years	112	26.5
> 3 years to 5 years	56	13.3
> 5 years to 10 years	74	17.5
> 10 years	42	9.9
Etiology		
No defined etiology	101	28.9
Coronary artery disease (CAD)	102	24.2
CAD with arrhythmia	11	2.6
Valvular heart disease	95	22.5
Valvular heart disease & CAD	10	2.4
Arrhythmia	25	5.9
Congenital heart disease	18	4.3
Rheumatic heart disease	1	0.2
Valvular heart disease with arrhythmia	29	6.9
Valvular and congenital heart disease	11	2.6
Myocardial dysfunction (DCM)	9	2.1
Arrhythmia & CAD & Valvular disease	1	0.2
CAD & DCM	5	1.2
Valvular disease & DCM	2	0.5
Congenital & Arrhythmia	2	0.5

3.3 Instruments

A number of questionnaires were used to collect the data addressing the research proposes. The first was the Personal Information Questionnaire included demographic question for collecting the subject's age, marital status, occupation, education, income, and time since diagnosed with heart failure. The second was the personal medical information recorded of LVEF and NYHA. The others were the ENRICHD Social Support Instrument (ESSI), the Cardiac Symptom Survey (CSS), the NYHA functional classification, a 100-mm horizontal Visual Analogue Scale of General Health Perception, and the Minnesota Living with Heart Failure Questionnaire (MLHFQ). The study variables and their indicator or instruments are presented in Table 3.4

Table 3.4 Variables and their indicators or instrument.

Variable	Indicators or Instruments
Social support	ENRICHD Social Support Instrument (ESSI) Thai version
Biological/ physiological	Left ventricular ejection fraction (LVEF)
Symptom status	Cardiac Symptom Survey (CSS) Thai version
Functional status	The subjective NYHA functional classification
General Health Perception	A 100-mm horizontal Visual Analogue Scale of General Health Perception
HRQOL	Minnesota Living with Heart Failure Questionnaire (MLHFQ)

3.3.1 ENRICHD Social Support Instrument (ESSI), Thai Version

The ENRICHD Social Support Instrument (ESSI) original version was derived from questions on the Medical Outcomes Survey and earlier work examining the influences of social support (Gorkin et al., 1993; Berkman et al., 1992; and Williams et al.,

1993 cited in Vaglio et al., 2004). The majority of questions on the ESSI consider general feelings about being loved and valued rather than instrumental types of support (Vaglio et al., 2004). As social support is not totally a function of actual services supporting the patient, but also includes a patient's belief that others care about them and are available if needed (Langford, Bowsher, Maloney, & Lillis, 1997).

The ENRICHD Social Support Instrument proposed only one dimension and does not define sources of different support (i.e., family, friend and other significant person). It is a seven-item self report survey that measures the self-perceived adequacy of social support. However, question 7 (patient's marital status) consistently has the lowest correlation with the other ESSI items and total score. Thus, it was collected as baseline characteristic of individuals. All six items are rated from 1 (none of the time) to 5 (all of the time). Individual items (except item seven) are summed for a total raw score (raw scale scores), then raw scale scores are transformed to a 0-100 scale (transformed scale score) using the formula below (Ware et al., 1993).

$$\text{Transformed scale} = \left[\frac{(\text{Actual raw score} - \text{lowest possible raw score})}{\text{Possible raw score range}}\right] * 100$$

Lowest possible raw score = 6

Highest possible raw score = 30

Possible raw score range = Highest possible raw score - Lowest possible raw score

= 30 - 6 = 24

This transformation converts the lowest and the highest possible score to 0 and 100, respectively. Scores between these values represent the percentage of the total possible score achieved. The level of the transformed scale score was determined by dividing the sum score into five categories, using a proportional method as follows.

Low = below one-fifth of the sum scores of the

individual scores (0-20).

Rather low = between one-fifth and two-fifths of the sum scores of the individual scores (21-40).

Moderate = between two-fifths and three-fifths of the sum scores of the individual scores (41-60).

Rather high = between three-fifths and four-fifths of the sum scores of the individual scores (61-80).

High = above four-fifths of the sum scores of the individual scores (81-100).

Validity and reliability:

Vaglio et al. (2004) tested the psychometric properties of the ESSI in coronary heart patients. Their analyses were undertaken to support the use of the ESSI when examining the relationship between social support and outcomes in cardiovascular disease. The internal consistency reliability for ESSI by using Cronbach's alpha was 0.88. The inter-item correlations were examined with significant association being found between all items and items-total score. Furthermore, the intra-class correlation coefficient was 0.94, reflecting excellent reproducibility.

Concurrent and predictive validity was also assessed by Vaglio et al. (2004). It correlated with symptom improvement and better general health perception and disease-specific quality of life at both baseline and 6-months. According to the only one dimension of social support, they also indicted that the ESSI assesses the four defining attributes of social support: emotional, instrumental, informational, and appraisal.

The modified ENRICHD Social Support Instrument (ESSI) Thai version using a translation and back translation process, from English version to Thai version, was first

done by Lortajakul (2006). Thus, this version met the minimum required standard to determine equivalence of an instrument across different language (Maneesriwonggul & Dixon, 2004). Furthermore, ENRICHD Social Support Instrument (ESSI) Thai version was validated for conceptual equivalence, clarity, and suitable language by experts (Lortajakul, 2006). Reliability of Thai version of ESSI questionnaire was tested with 526 patients with post myocardial infarction, and was reported as 0.875 (Lortajakul, 2006).

With regard to this study, reliability of the Thai version of ESSI questionnaire was tested by 30 patients with heart failure. The Chronbach's alpha coefficient was 0.90. When tested with 422 patients with heart failure, the Chronbach's alpha was 0.86. Confirmatory factor analysis was used to confirm validity of the instrument (results are presented as a subtopic of measurement model assessment in Chapter 4).

3.3.2 Left ventricular ejection fraction (LVEF)

Left ventricular ejection fraction (LVEF) was used for objectively measuring the heart's ability to pump blood to meet the requirement of the body's organs. It was collected from patients' hospital records of heart ultrasound or echocardiogram. Echocardiogram is a standard medical diagnostic instrument used for measuring LVEF. High LVEF indicates higher cardiac functional ability than lower LVEF. All of the participants had been assessed for cardiac function (LVEF) with echocardiogram in during 1 month before data collection. According to the type of heart failure, an LVEF of 40 % and below indicated heart failure with systolic dysfunction, while an LVEF more than 40% indicted heart failure with diastolic dysfunction (AHA, 2006; Bonow et al., 2005).

3.3.3 The Cardiac Symptom Survey (CSS)

The original Cardiac Symptom Survey (CSS) is a 40-item scale developed by the research team of Barnason, Zimmerman, Brey, Catlin, and Nieveen (2006). It measures

10 specific cardiac symptoms: angina, shortness of breath, fatigue, depression, sleeping difficulty, puncture or surgery site pain (e.g. percutaneous coronary intervention site pain), swelling in the legs, fluttering/rapid heart beats (palpitations), anxiety, and poor appetite. This instrument is omprised of two components, evaluation of cardiac symptoms and response to cardiac symptoms. Evaluation of symptoms includes two items: the frequency and severity of each symptom. The frequency and severity of the symptoms are evaluated on a scale of 0–10, with 0 indicating absence of the symptom, 1 indicating very minimal, and 10 indicating very frequent or very severe. For each of the 10 symptoms, the mean of the two items (frequency and severity) was computed to provide a mean symptom evaluation score. The response to symptoms is the second component of the CSS, with two items for each of the 10 symptoms (the impact each symptom has on physical functioning and the impact each symptom has on enjoyment of life). These are also rated on a scale of 0–10, with 0 indicating no impact and 10 indicating a great deal of impact. Each item, impact on physical activity and impact on enjoyment of life, is treated as a separate single-item variable. Nieveen, Zimmerman, Barnason, & Yates, (2006) illustrated that each dimension of the CSS, symptom evaluation and symptom response are independent and can be used separately.

The modified Cardiac Symptom Survey (CSS) Thai version and back translation process, from English version to Thai version, was first done by Lortajakul (2006). Pain of puncture or surgery site was deleted from the CSS Thai version. This was determined as appropriate for cardiac patients who had no surgery or puncture site pain.

According to Wilson and Cleary (1995), symptom status was defined as a patients' subjective perception of the frequency and severity of abnormal physical, mental, and cognitive conditions. Thus symptom status was measured with the symptom evaluation

dimension of the modified Cardiac Symptom Survey (CSS) Thai version (Lortajakul, 2006). The symptom evaluation dimension was measured through frequency and severity ratings of 9 symptoms. All symptoms were theoretically separated into two sub-dimensions, physical symptom (chestpain, dyspnea, fatigue, swelling in the legs, and palpitations) and psychological symptom (depression, sleeping difficulty, anxiety, and poor appetite). According to Barnason et al. (2006) ; Nieveen, Zimmerman, Barnason, and Yates (2007), symptom frequency and severity ratings were evaluated on 1 - 10 scales, with 1 indicating absence of the symptom, and 10 indicating very frequent or very severe. The raw scores for the two items (frequency and severity) were summed and divided by two. This resulted in a raw score of symptom evaluation, which was defined as symptom status in this study. Raw symptom evaluation of each symptom were summed for total raw score (raw scale scores), then raw scale scores were transformed to a 0-100 scale (transformed scale score) using the formula to each scale below (Ware et al., 1993).

$$\text{Transformed scale} = \left[\frac{(\text{Actual raw score} - \text{lowest possible raw score})}{\text{Possible raw score range}} \right] * 100$$

For total symptom status score:

Lowest possible raw score = 9

Highest possible raw score = 90

Possible raw score range = Highest possible raw score - Lowest possible raw score

= 90 - 9 = 81

The level of symptom status score was determined by dividing the sum score into five categories, using a proportional method as follows.

Low = below one-fifth of the sum scores of the individual scores (0-20).

Rather low = between one-fifth and two-fifths of the sum scores of the individual scores (21-40).

Moderate = between two-fifths and three-fifths of the sum scores of the individual scores (41-60).

Rather high = between three-fifths and four-fifths of the sum scores of the individual scores (61-80).

High = above four-fifths of the sum scores of the individual scores (81-100).

Validity and reliability:

Content validity of the original CSS has been supported by an expert panel of clinicians and literature confirming that those symptoms are common in heart failure (Barnason, Zimmerman, Brey, Catlin, & Nieveen, 2006). Internal consistency tests reported alphas ranged from 0.76 to 0.97 at 2 weeks, 0.83 to 0.99 at 4 weeks, and 0.72 to 0.98 at 6 weeks. Test–retest using the same sub-sample of cardiac patients revealed acceptable correlations ranging from 0.92 to 1.00.

The Cardiac Symptom Survey (CSS) Thai version was validated for conceptual equivalence, clarity, and suitable language by experts (Lortajakul, 2006). Internal consistency reliability ranged from .87 to .99. Furthermore, reliability of Thai version of CSS questionnaire was tested with 26 patients with post myocardial infarction and Cronbach's alpha coefficient were .96 (Lortakul, 2006).

In this study, reliability of the Thai version of CSS questionnaire reported Cronbach's alpha coefficient 0.97 in 30 and 422 heart failure patients. These exceed the desired criterion of .70 for new scales and .80 for mature scales (Nunnally, 1978). Confirmatory factor analysis was used for confirming validity of instrument (results are presented in the subtopic of measurement model assessment in Chapter 4).

3.3.4 The New York Heart Association (NYHA) functional classification

The NYHA functional classification system was originally developed in 1928, using NYHA class I, II, III or IV. It was designed for clinical assessment of patients by physicians on the basis of the patient's limitations in physical activities caused by cardiac symptoms. The NYHA functional classification is a highly valid instrument for measuring functional status in heart failure. It is the most commonly used method for quantifying the functional status of patients with heart failure by classifying the extent of patients' ability to perform their daily activity (AHA, 2006). The NYHA functional classification is a 4-point semi-quantitative index of functional status of patients with heart failure (Kubo et al., 2004). It is a patient's perspective of four classes of heart failure symptoms: where patients may have symptoms of heart failure at rest (class IV), on less-than-ordinary exertion (class III), on ordinary exertion (class II), or only at levels of exertion that would limit normal individuals activity (class I) (AHA 2006). The NYHA Classes are used in various ways, from clinician judgment to patient self-report, and yet there are few guidelines for its use. According to the patients' subjective perception of their functional ability, the modified NYHA questionnaire (Criteria Committee of the New York Heart Association, 1973) was used for determining participants' functional status. There is one question that asked patients to determine their over all functional status limitations caused by heart failure.

Validity and reliability:

To further evaluate the validity of NYHA, Miller-Davis et al., (2006) compared the NYHA to many commonly used instruments to quantify each dimension of function status in heart failure patients. They found that the NYHA functional classification classes captured the dimensions of functional capacity limitation (physiologic limitations), functional performance (limitations in physical activity), and reserve (symptoms of fatigue,

palpitations, and chest pain). In addition, NYHA class was correlated with peak exercise oxygen consumption and 6-minute walk distances. It also has good inter- and intra-grader reproducibility (Kubo et al., 2004).

3.3.5 A 100-mm horizontal Visual Analogue Scale of General Health Perception.

The visual analogue scale is a commonly used method to measure health perception in clinical research (Dion et al 2002; Kannisto et al., 1998; Nicholas 1993 cited in Yu et al., 2004), and in heart failure (Havranek et al., 2004). The participants were invited to put a cross on the line to indicate how healthy they perceived they were. The scale ranged from 0 to 100, with higher scale indicating better health perception. The level of general health perception score was determined by dividing the scale into five categories, using a proportional method. A general health perception scale from 0-20 indicted poor general health perception, above 20 to 40 was fair, above 40 to 60 was moderate, above 60 to 80 indicated good, and more than 80 to 100 indicated very good health perception.

Validity and reliability:

Construct validity of this instrument was reported through a study conducted by Havranek et al. (2004). Their study used many survey instruments, a time trade-off questionnaire, a visual analog scale (VAS) score of overall health perception, and the Duke Activity Status Index (DASI) for measuring overall health perception in heart failure patient. They found that there was a significant relationship between the relatively easily obtainable health perception score by VAS with the more complex utility by time tradeoff for a subset of patients in a multi-center randomized clinical trial.

This measurement was evaluated with a single question, thus Cronbach's alpha coefficient reliability could not be estimated. However, Guyatt (2000); Guyatt,

Osoba, Wu, Wyrwich, and Norman (2000) indicated that it could detect the change of health perception over time in chronic illness patients.

3.3.6 The Minnesota Living with Heart Failure Questionnaire (MLHFQ)

This instrument is one of the most commonly used instruments to assess HRQOL in heart failure research (Rector & Cohn, 1992; Rector, Kubo, & Cohn, 1987; Reddy & Dunn, 2000). The MLHFQ was designed in 1984 to measure the effects of heart failure and treatments for heart failure on an individual's quality of life. The content of the questionnaire was selected to be representative of the ways heart failure can affect the key physical, emotional, social and mental dimensions of quality of life without being too long to administer during clinical trials or practice. Furthermore, the MLHFQ is sensitive enough to detect clinically important changes over time (Bennett et al., 2003).

The questionnaire assesses the impact of frequent physical symptoms such as shortness of breath, fatigue, peripheral edema, and difficulty sleeping and psychological symptoms of anxiety and depression. In addition, the effects of heart failure on physical and social functioning are incorporated into the measure. Since treatments might have side effects in addition to ameliorating symptoms and functional limitations produced by heart failure, questions about side effects of medications, hospital stays and costs of care are also included to help measure the overall impact of a treatment on quality of life.

The MLHFQ was developed in the West, thus a back translation process was used in this study. The process was done as follow:

1) The English version of MLHFQ was translated to Thai by non health professional bilingual translators.

2) The first Thai version of MLHFQ validated for conceptual equivalence, clarity, and suitable language by seven experts. This panel of experts included two

physician experts in heart failure, a professor in nursing, a nurse instructor, a clinical nurse, an expert in quality of life in chronic illness care, and experts in instrument development.

3) The English version of MLHFQ was translated to Thai by non health professional bilingual translators. It was comparable to the original version.

There are three dimensions in the original MLHFQ: a physical dimension score (items 2, 3, 4, 5, 6, 7, 12, 13 on the version sent with these instructions); an. emotional dimension score (items 17, 18, 19, 20, 21); and eight additional items (items 1, 8, 9, 10, 11, 14, 15, 16) that are part of the total MLHFQ score, but not part of a subscale score. Because of the socio-economical focus of these additional eight items, it had been called the socio-economical dimension in the MLHFQ Thai version.

Although all items had been identified by factor analysis, it may be scored by simple summation to further characterize the effect of heart failure on a patient's life (Bennett et al., 2003). The MLHFQ asks each person to indicate effects using a 6-point Likert scale from 1 (no impact on HRQOL) to 6 (most severe impact on HRQOL). Individual items were summed for total raw score (raw scale scores), then raw scale scores are transformed to a 0-100 scale (transformed scale score) using the formula below (Ware, et al., 1993).

$$\text{Transformed scale} = \left[\frac{(\text{Actual raw score} - \text{lowest possible raw score})}{\text{Possible raw score range}} \right] * 100$$

For total HRQOL score:

Lowest possible raw score = 21

Highest possible raw score = 126

Possible raw score range = Highest possible raw score - Lowest possible raw score

= 126 -21 = 105

This transformation converts the lowest and the highest possible scores to 0 and 100, respectively. Scores between these values represent the percentage of the total possible score achieved. As consider to the negative phrasing of all items, the items were recoded before transformation. The transformed score of the HRQOL were determined by dividing the sum score into five categories, using a proportional method as follows.

Low HRQOL = below one-fifth of the sum scores of the individual scores (0-20).

Rather low HRQOL = between one-fifth and two-fifths of the sum scores of the individual scores (21-40).

Moderate HRQOL = between two-fifths and three-fifths of the sum scores of the individual scores (41-60).

Rather high HRQOL = between three-fifths and four-fifths of the sum scores of the individual scores (61-80).

High HRQOL = above four-fifths of the sum scores of the individual scores (81-100).

Validity and reliability:

A reliability and validity of this instrument had been reported in many studies (Middel et al., 2001; Rector et al., 1987; Rector & Cohn, 1992). Although the MLHFQ incorporates relevant aspects of the key dimensions of quality of life, the questionnaire was not designed to measure any particular dimension separately. The homogeneity of items had been tested using item–total correlations in one study, and the result was acceptable (Rector et al., 1987). Heo et al (2005) conducted a study to test psychometric properties of the MLVFQ in heart failure patients. Construct validity was demonstrated with factor analysis. The reliability of the MLHFQ was demonstrated as the Cronbach's alpha ranged

from .85 to .91, indicating adequate internal consistency reliability. The measure has acceptable reliability, internal consistency and test–retest and construct validity (Midde et al., 2001; Quittan et al., 2001; Gorkin et al., 1993 cited in Heo et al., 2007).

For purposes of this study, the content validity of the MLHFQ Thai version was evaluated by seven experts. The index of item-objective congruence (IOC) was used to indicate content validity (Rovinelli & Hambleton, 1977 cited in Turner & Carlson, 2003). The IOC of each item was reported between 0.78-0.83. It met the criteria of an acceptable level of internal consistency, a value of .70 (Nunnally & Berbstein, 1994).

Confirmatory factor analysis was done for confirming construct validity of the MLHFQ Thai version. According to the MLHFQ original version, the questionnaire was not designed to measure any particular dimension separately, thus we also found that there were many items that reported high error correlation with each other. After model modification by the correlation between items error suggested by modification index and theoretical support, the hypothesized second order factor analysis indicated fit with existing data (measurement model testing is proposed in chapter IV). Reliability of the Thai version of MLHFQ questionnaire was tested in 30 and 422 heart failure patients and Cronbach's alpha coefficient was equal to 0.94.

3.4 Protection of Human Subjects

This study was conducted with the approval of the Chulalongkorn University Institutional Review Board (IRB) and the Human Research Board of the potential settings. Both written and verbal informed consents were obtained in Thai on the same date as the data collection. The informed consent form explained the purpose of the study, benefits, risks, types of questionnaires, time and tasks to be completed.

Permission was obtained from participants before the start of data collection. At the clinic, the participants were informed about the purpose of the study and their right to refuse participation. If the participants did not want to answer the questionnaires, they could withdraw from the study at any time without penalty. Their names were not used in the data, rather a code number was used to ensure confidentiality. There was no harm to the participants in this study. There was neither cost nor any payment to participants in the study.

3.5 Data collection

3.5.1 A letter asking for the permission to collect the data from the Faculty of Nursing, Chulalongkorn University was sent to the directors and the Institutional Review Board (IRB) committee of nine hospitals (research settings).

3.5.2 After permission from the IRB was approved, the researcher made appointments with doctors and nurses of outpatient departments in each hospital and informed them about the objectives, process of the study and asked for cooperation.

3.5.3 Research assistants were cardiovascular nurses who work at cardiac out patients clinic. They were trained to completed patients medical records for LVEF, NYHA classification and, comorbidity of heart failure patients who met criteria. They had been examined to confirm their understanding of sample criteria, clearly defined definition and concept based of each instruments and over all questionnaire.

3.5.4 The researcher and research assistants studied personal records of heart failure patients, who had appointments with physicians at cardiac out patient clinics each day. There were about 5 to 20 heart failure patients each day in each setting. Then, the researcher and research assistants studied patients' medical diagnosis and medical record

for comobidity, NYHA classification, LVEF results, and duration of diagnosis with heart failure.

3.5.5 The researcher and research assistants selected participants by systematic random sampling and congruence with the inclusion criteria. Patients who met the study criteria were given one of a continuous set of numbers, such as 1,2,3 … , when they arrived at the cardiac out patient clinic. The patients who had odd numbers (i.e., 1, 3 , 5 …) were asked for their permission to participate in this study. All selected participants were willing to be sampled of this study.

3.5.6 The participants were given clear explanation about the study objectives, process of the study and the right to participate in the study.

3.5.7 The participants were asked to sign the informed consent form before data collection.

3.5.8 The participants were asked to complete the questionnaires. It took about 15-20 minutes for participants to complete all the questionnaires. For older participants, the researcher sometimes had to read the questionnaires and asked them for their responses.

3.5.9. The researcher and research assistants examined the questionnaires for completeness of the data. Participants were asked to answer any missing items. Thus, there was no missing data in this study.

3.6 Data analysis

The data were analyzed using descriptive statistics and reliability with the Statistical Package for the Social Science Program version 11.5 (SPSS 11.5). Confirmatory factor analysis of all instruments and the structural equation model analysis were analyzed

by using the Analysis of Moment Structures (AMOS) version 7. The data analysis procedures are described in the following discussion.

3.6.1 Descriptive statistics including frequency, percentage, range, mean and standard deviation were used to describe the characteristics of the sample and to examine the distribution of demographic and other major variables in the study.

3.6.2 The reliability of all instruments was tested in 30 heart failure patients, who parallel subjects in this study. The reliability was tested and reported by Cronbach's Alpha Coefficient.

3.6.3 The measurement models were tested against the data (item responses) with first order confirmatory factor analysis (social support) and second-order confirmatory factor analysis (MLHFQ and CSS) for construct validity using Analysis of Moment Structures (AMOS) version 7 (Byrne, 2001). According to guidelines of factor analysis using AMOS, the factor score loading was to be standardized regression weights, while thecritical ratio (CR) or Z-test was used as statistical test for significance (> + 1.96 and - 1.96) with p value <0.05. In addition, the squared multiple correlation coefficients (R^2) was used to indicate items reliability for each of the observed variables of latent constructs.

3.6.4 The assumptions underlying structural equation model analysis was determine, and included normality of distribution, linearity of relationship, homogeneity of variance, and multicollinearity. Pearson Product Moment correlations were used to test for bivariate relationships among pairs of variables and to assess multicollinearity among the independent variables. Multiple regression analyses were used to compute variance inflation factor and tolerance to examine multicollinearity among the key variables.

3.6.5 The hypothesized causal model was test and modified for best fit and parsimony. Structural Equation Modeling (SEM) was used to test the hypotheses associated

with the study's specific aims. SEM is a multivariate statistical methodology that allows for a confirmatory or hypothesis-testing approach for analyzing theoretically linked relationships between constructs relative to a certain phenomenon (Byrne, 1998). Thus a SEM approach was used to estimate the direct and indirect effects of biological/physical status, social support, symptom status, functional status, and heath perception on HRQOL. This analysis was conducted using Analysis of Moment Structures (AMOS) version 7 (Byrne, 2001). The key for data analysis and results interpretation were as follow:

1) Maximum Likelihood was used as method of parameter estimation. The key parameters were estimated with regression coefficients (factor loading), factor and error variances, and factor covariance. The test statistic significance of parameters estimates is critical ratio (CR), which represents the parameter estimate divided by its standard error. It operates as a Z-statistic in testing that the estimate is statistically difference from zero. Based on a level of .05, the test statistic needs to be more than -1.96 and +1.96 (Byrne, 2001).

2) The overall model-fit-index was examined to determine how well the hypothesized model fits the existing data. Assessment of model fit was determined with Goodness of fit statistics, including Chi-square (χ^2), Goodness-of-fit index (GFI), Adjusted goodness of fit index (AGFI), and Root mean square error of approximation (RMSEA) (Byrne, 2001).

The first set of goodness of fit statistics is the Chi-square (χ^2) value (Wheaton, Muthen, Alwin, & Summers, 1997 cited in Byrne, 2001). According to AMOS out put data, CNIN is suggested as Chi-square statistic (Byrne, 2001). Thus to reduce the confusion, this study was indicated CMIN as χ^2. The results in which the Chi-square (χ^2) is non-significant of a level with a corresponding p- value >.05 and preferably close to 1.00 is

recommended for hypothesized model fitted with the data. Because the chi-square test is sensitive to sample size, the relative chi-square (χ^2 /*df)* has been developed in order to enable a pragmatic evaluation process for large sample sizes (Joreskog & Sorbom, 1986; and Carmines & Melver, 1983 cited in Byrne, 2001). A resulting ratio of the χ^2/df 2.0 or less than 2.0 indicates an acceptable fit between the hypothesized model and sample data.

The goodness-of-fit index (GFI) is a measure of the proportion of all variance and covariance accounted for by the model and compared the squared residuals from prediction with the actual data. It represents the overall degree of fit ranging from 0 (poor fit) to 1 (perfect fit) (Byrne, 2001). High values of GFI indicated better fit. GFI values are 0.9 or above indicated this model fit (Bentler, 1990)

The adjusted goodness of fit index (AGFI) is an extension of GFI that is adjusted by the degree of freedom for the proposed model to the degree of freedom for the null model. AGFI ranged from 0 to 1.00, with closed to 1.00 indicating a good fit.

The last goodness of fit statistics used in this study was the root mean square error of approximation (RMSEA). RMSEA was the discrepancy, which was expressed per degree of freedom in terms of the population. Browne and Cudeck cited in Byrne (2001) suggested that RMSEA values less than 0.05 indicated a good fit and values as high as .08 represent reasonable error of approximation in the population. MacCallum et al. (1996) recently elaborated on these cut-points and noted that RMSEA values ranging from .08 to .10 indicted mediocre fit, and those greater than .10 indicated poor fit. Hu and Bentler (1999) suggested a value of .06 to be indicative of good fit between the hypothesized model and the observed data in adequately sample size (MacCallum et al., 1996 ; Browne & Cudeck, 1993 cited in Byrne, 2001). Furthermore, Joreskog and Sorborm (1996a) cited in Byrne, 2001 suggested that the p-value for that test should be > 0.05. In the

current study, the RMSEA at the 90% confidence intervals and values ranged 0.05 or less and p-value > 0.05 was used as indictor for a good fit.

3) A modification index was used for model modification. Modification indices may suggest that one or more factors share considerable variance with an observed variable other than one already included in the initial factor model or that pairs of residual variance are correlated (Byrne, 2001). In addition, the determination of whether to add a path to a model was based on a combination of theoretical, logical, and empirical indications. Empirically, the examination of modification indices guided path additions to the model. Modification indices are suggestions made by AMOS for paths that can be entered into the model to improve the goodness-of-fit (Kline, 1998; Byrne, 2001). Thus, a modification index between two items was high in relation to other modification index. However, paths suggested with high modification indices, but are not supported by theoretical or not logical meaningful, this path should not be included. In the current study, the initial model was adjusted under the modification index and theoretical meaning until goodness-of-fit was achieved.

4) Based on concepts of theory trimming or model revision (Heise, 1969 cited in Pedhazur, 1997), and suggestion by Duncan (1975) and Heise (1969) cited in Pedhazur, 1997), having estimated parameters of a just-identified model, path coefficients that do not meet the criteria of statistical significance and/or meaningfulness would be deleted from the model. If the model had been tested by a valid Chi-square test or other goodness of fit indices and found to fit the data, it should be interpretable in a meaningful way (McPherson, 1976 cited in Pedhazur, 1997). It should be interpreted as when a hypothesis is supported or unsupported, when a priori grounds exist for testing it. Based on this information, some parameter estimates which reported statistical non-significance in

the current study were not deleted from the hypothesized causal model of health related quality of life in heart failure. These findings were interpreted with the theoretical and substantive meaningful.

Summary

A descriptive correlation, cross-sectional research design was used to test a causal relationship of HRQOL in Thai heart failure patients. A multi-stage random sampling and systematic sampling technique was used. There were 422 heart failure patients willing to be in the research sample. Questionnaires and a data collection form were used to collect the data addressing the research proposes. All of instruments and questionnaires reported appropriate validity and reliability. Descriptive statistics, confirmatory factor analysis and structural equation modeling analysis were conducted using the computer program AMOS version7 and SPSS. Finally, criteria for model testing and model modification were also explained.

CHAPTER IV

RESULTS

The results of this study are presented in this chapter. The results include descriptive statistics of variables, the preliminary analysis, confirmatory factor analysis of the measurement model, and the structural equation modeling analysis of the hypothesized model.

1. Descriptive statistics of the variables

The variables examined in this study included: social support, bio-physiological status (LVEF), symptom status, functional status (NYHA), general health perception (GHP), and HRQOL.

1.1 Social support

The total sum score of social support ranged from 0 to 100 with a mean of 76.71 (SD = 20.65). The mean of social support was not different between men (78.10, p>.05) and women (77.55, p > .05). More than half of subjects were married (66.6%) and live with their spouses (67.5%). Social support was negatively skewed (-0.85) indicating that most of the participants had moderate to high scores for social support. Furthermore, the kurtosis indicated a good variance of scores as seen in a normal curve distribution (0.34) (Table 4.2, Appendix F: Table 5)

1.2 Bioliogical/ physiological status (Left ventricular ejection faction: LVEF)

Most participants (80.6%) had a reported LVEF of more than 40%, which represented heart failure with diastolic dysfunction. In addition, subjects with systolic dysfunction, or LVEF less than 40%, were about 19.4%. (Table 4.1) LVEF was not

different between participants in their first year of living with heart failure and those participants heart failure for a longer time (F= p >.05).

LVEF ranged from 10% to 84 % with a mean of 55.08 % (SD = 15.25). The skewness coefficient of LVEF was -0.54 which indicated that most participants had higher scores of LVEF. Furthermore, the kurtosis of LVEF was -0.27 which also indicated a normal curve of distribution (Table 4.2).

1.3 Symptom status

According to the complex and progressive nature of symptoms experienced by heart failure patients, most subjects presented with more than one symptom. More than half of the subjects had chest pain (55.2%), shortness of breath (64.5%), depression or felt down and blue (50.7%), trouble sleeping (64.5%), arrhythmia (69.2%), anxiety (65.9%) and poor appetite (51.9%). Fatigue or feeling overly tried was the most presenting symptom in this study (78.4%). In contrast, only 29.1% of participants had swelling. Furthermore, some participants experienced related symptoms of nausea/ vomiting (3.1%) and headache (2.4 %) (Table 4.1)

Symptom status of heart failure patients was determined by two sub dimensions of the cardiac symptom survey. These were participants' subjective perceptions of the frequency and severity of five physical symptoms and four psychological symptoms. Total symptom status scores ranged from 0 to 85.50 with a mean of 23.84 (SD = 19.41). The skewness coefficient of total symptom status was 0.99 indicating that most of participants had low scores of symptom status. According to Jacobsen (1997), a skewness value above 0.2 or below -0.2 indicated severe skewness. Additionally, if the skewness was negative this indicated most of the participants had a high score. If the skewness was positive this indicated that most of the participants had a low score. Regarding kurtosis, Jacobsen (1997)

also suggested that if the value is between + 1.96 and -1.96, the distribution has a normal curve. Therefore, the kurtosis of symptom status was 0.60 and indicative of normality (Table 4.2 Appendic F: Table 6).

1.4 Functional status

Functional status as defined with the NYHA, indicted that most of subjects were classified as NYHA functional class II and III (37.4% and 33.6%). A smaller number of participants were classified as NYHA functional class I (6.2%), while 22.7 % presented with NYHA functional class IV (Table 4.1). The mean score of functional status in males ($\overline{X}$ = 2.68, SD = .849) and females ($\overline{X}$ = 2.76, SD = .898) was not different (F= .828, p >.05), and between the first year and those living longer with heart failure (F= .020, P >.05).

NYHA classifications ranged from 1- 4, where low (NYHA functional class I or II) indicated better scores of functional status than higher scores (NYHA functional class III, IV). The skewness coefficient of NYHA was 0.01 and the kurtosis of NYHA was -0.91, which also indicated a normal distribution (Table 4.2).

1.5 General health perception (GHP)

The score of GHP ranged from 1 to 100 with a mean of 53.31 (SD =18.12). In addition, the skewness coefficient of GHP was negative (-0.48) and indicated that most participants had higher scores of GHP. Furthermore, the kurtosis of GHP was 0.95, which indicated a normal curve of distribution. (Table 4.2)

1.6 Health-related quality of life (HRQOL)

The total score of recoded HRQOL ranged from 7.72 to 100, where higher scores represented better HRQOL than lower scores. The mean total score on HRQOL was 55.13 (SD = 20.63). Most subjects perceived their HRQOL was moderate. Mean scores of subscales were as follows: physical dimension ($\overline{X}$ = 52.95, SD = 23.04), psychological

dimension ($\overline{X}$ = 54.74, SD = 23.65), and socio-economic dimension ($\overline{X}$ = 57.71, SD = 22.32). The skewness coefficient of total scores of HRQOL was 0.12 and indicated that most of participants had lower scores of HRQOL. Furthermore, the kurtosis of HRQOL was -0.75, which indicated a normal curve of distribution. (Table 4.2, Appendix F: Table 7) Furthermore, the study found that HRQOL was not different between duration of living with heart failure (F= .485, p >.05), age (F=1.052, p >.05) gender (F= 1.102, p >.05), monthly income (F=1.818, p >.05), and education level (F= .659, p >.05). While HRQOL was significant different between marital status (F=2.284, p <.05), and occupation (F=4.868, p <.05).

Table 4.1 Descriptive statistics of cardiac symptoms and related symptoms, functional status, and left ventricular ejection fraction (LVEF) (n = 422)

	Frequency	Percentage
Cardiac symptoms and related symptoms		
Chest pain	233	55.2
Shortness of breath	272	64.5
Fatigue or felt overly tired	331	78.4
Swelling	123	29.1
Arrhythmia	292	69.2
Depression or down and blue	214	50.7
Trouble sleeping	277	64.5
Anxiety	278	65.9
Poor appetite	219	51.9
Nausea/vomiting	13	3.1
Headache	10	2.4
Functional status		
NYHA functional class I	26	6.2
NYHA functional class II	158	37.4
NYHA functional class III	142	33.6
NYHA functional class IV	96	22.7
LVEF < 40	82	19.4
40 and above	340	80.6

Note: NYHA = New York Heart Association functional classification

Table 4.2 Descriptive statistic of all variables (N = 422)

	Actual range	Possible range	mean	SD	Skewness	Kurtosis
Symptom status	0-85.50	0-100	23.84	19.41	.99	.60
Physical symptom	0-100	0-100	24.43	19.79	.91	.44
Psychological symptom	0-95	0-100	23.24	22.01	1.12	.78
LVEF	10-84	0-100	55.08	15.25	-.54	-.27
NYHA	1-4	1- 4	2.73	.88	.01	-.91
Social support	0-100	0-100	76.71	20.65	-.85	.34
GHP	1-100	1-100	53.31	18.12	-.48	.95
HRQOL	7.72-100	0-100	55.13	20.63	.12	-.75
Physical	0-100	0-100	52.95	23.04	.08	-.73
Psychological	0-100	0-100	54.74	23.65	.11	-.88
Socio-economic	0-100	0-100	57.71	22.32	-.06	-.82

Note: SD = Standard deviation, LVEF = Left ventricular ejection fraction, NYHA = New York Heart Association functional classification, GHP = general health perception, HRQOL = Health-related quality of life.

2. Preliminary Analysis: Assumption Testing

Assumptions underlying multivariate approaches for structure equation modeling were tested to ensure that the assumptions were not violated and the results of this study were not distorted. According to Pedhazur (1997), the assumptions underlying multivariate analysis included normality, homoscedasticity, linearity, and multicollinearity. All of these assumptions were tested.

2.1 Normality

Multivariate normality was tested in all variables by statistical and graphical methods. Two components of normality, skewness and kurtosis, were explored. The normal

value of skeweness ranged from -0.02 to 0.02, and -1.96 to +1.96 for kurtosis. The skewness values of all variables in this study ranged from -0.85 to 1.12 and the kurtosis of all variables ranged from -0.91 to 0.95. According to West, Finch and Curran, (1995), the high of non-normal are 3.00 for skewness and 21.00 for kurtosis, which would underestimate the standard error and result in untrustworthy data output. Thus, the value of skewness and kurtosis of this study were not “highly non normal”. Furthermore, normal probability data plot indicated the normal distribution. Therefore, it was acceptable for SEM analysis.

2.2 Homoscedasticity

Residual scatter plots were examined to assess homoscedasticity. The spread of residual variables around the zero axes within a -2 to +2 standard deviation indicated this assumption was not violated (Appendix F)

2.3 Linearity

The linearity relationships among pairs of measured variables were assessed through bivariate scatter plots. The scatter plots between all independent variables and dependent variable showed no evidence of nonlinearity between pairs of variables (Appendix F)

2.4 Multicollinearity

There are four indicators used for detecting multicollinearity: the simple correlation among the predictors, the tolerance value, the variance inflation factors (VIF) and condition index. A simple correlation coefficient between variables above 0.6 means two independent variables highly related. Furthermore, the low tolerance value (nearly 0) and high variance inflation factor (VIF) (more than 10) indicated a multicollinearity

problem, or two variables are perfectly correlated (Pedhazur, 1997). Condition indexes above 30 and variance proportions greater than .90 are evidence of multicollinearity (Hair et al., 1998) (Table 4.3)

In this study, data indicated no evidence of multicollinearity. The correlation coefficients for all independent variables ranged from -.-.58 to 0.80, which means no extreme value correlations were present. In addition, tolerance values were 0.27 to 0.90, all VIF values were 1.12 to 3.77 and only the Condition Index of the Socio-economic dimension was more than 30 (31.58) (Table 4.3).

In summary, the evaluation of assumptions (normality, homoscedasticity, linearity and multicollinearity) in this study did not violate the criteria of Structural Equation Modeling (SEM).

Table 4.3 Collinearity statistics among variables (n=422)

Variable	Tolerance Value	Variance Inflation Factor(VIF)	Condition Index
1. Physical symptom	0.43	2.34	2.93
2. Psychological symptom	0.38	2.64	7.87
3. Social support	0.90	1.12	8.26
4. LVEF	0.85	1.17	9.72
5. NYHA	0.59	1.69	11.03
6. General perception	0.67	1.50	12.32
7. Physical dimension of HRQOL	0.27	3.77	13.55
8. Psychological dimension of HRQOL	0.46	2.17	18.19
9. Socio-economic dimension of HRQOL	0.30	3.33	31.39

Note: LVEF = Left ventricular ejection fraction, NYHA = New York Heart Association functional classification

3. Model testing

The general SEM model can be decomposed into two sub models, a measurement model and a structural model. The structural model defines relations between the unobserved (latent or construct) variables. There were two exogenous latent variables and four endogenous latent variables proposed in this study. The exogenous latent variables were biological/ physiological status and social support, while symptom status, functional status, general health perception, and health-related quality of life (HRQOL) served as endogenous latent variables.

3.1 Assessment of measurement models

The measurement model defines relations between the observed indicator variables and the underlying constructs they are designed to measure or the unobserved latent variables. There were three measurement models in this study, social support, symptom status, and HRQOL.

3.1.1 Measurement model of symptom status

The measurement model of symptom status was composed of two constructs, physical symptom and psychological symptom. The scores for the measurement model of symptom status showed that the CMIN or chi-square (χ^2)was equal to 155.92, degrees of freedom were 27, the relative chi-square (CMIN/*df* or χ^2 / *df)* = 5.77, GFI = 0.92, AGFI = 0.87, RMSEA = 0.11, and significant (*p* = 0.00). This finding showed that the initial model did not fit with the data so the model was modified. The modification index was used to adjust model fit. The measurement model of symptom status after modification resulted in non significance (*p* = 0.96), χ^2 =6.09**,** *df* = 14, χ^2 /*df* = .44, GFI = 1.00, AGFI = 0.99, and RMSEA = 0.00 (Table 4.4 and Appendix G: Figure 7).

3.1.2 Measurement model of social support

The measurement model of social support was composed of 6 observed variables. The initial scores for the measurement model of symptom experience showed that the chi-square was equal to 75.72, with 9 degrees of freedom, χ^2 /*df* = 8.413, GFI = 0.94, AGFI = 0.87, RMSEA = 0.13, and *p* = 0.000. This finding showed that the initial model did not fit with the data so the model was modified. The modification index was used to adjust the model fit. After modification, the social support measurement model was not significant (*p* = 0.19). χ^2 = 0.04**,** *df* = 7, χ^2 /*df* = 1.43, GFI = 0.99, AGFI = 0.98, and RMSEA = 0.03. (Table 4.4 and Appendix G: Figure 8)

3.1.3 Measurement model of HRQOL

The measurement model of HRQOL was composed of three unobserved constructs, physical dimension, emotional dimension, and socio-economic dimension. The physical dimension and socio-economic dimension each were composed of eight items, while the emotional dimension had five items. The initial scores for the measurement model of HRQOL showed that the chi-square was equal to 1123.54, degree of freedom was 186, χ^2 /*df* = 6.04, GFI = 0.78, AGFI = 0.73, RMR = 0.15, RMSEA = 0.11,and *p* = 0.00. This finding also indicated that the initial model did not fit with the data so the model was modified. After modifying the model, the model fit with the data. The χ^2 values equal 153.22**,** *df* = 133, χ^2/df = 1.15, *p* = 0.11, GFI = 0.97, AGFI = 0.94, and RMSEA = 0.02. (Table 4.4, Appendix G: Figure 9)

In summary, all measurement models were indicated to have overall fit. Chi-square tests had low values and reached non-significant levels. Both GFI and AGFI values were close to or equal to 1.00, and RMSEA values were less than .05. All indices of measurement models were acceptable.

Table 4.4 Statistic Overall Fitted Index of measurement models (N = 422)

Variables	Chi-square	*df*	*p*	GFI	AGFI	RMSEA
Symptom status	6.09	14	0.96	1	0.99	0.00
Social support	10.04	7	0.19	0.99	0.98	0.03
HRQOL	153.22	133	0.11	0.97	0.94	0.02

Note: *df* = degree of freedom, GFI = Goodness of fit index, AGFI = Adjusted goodness of fit index, RMR = Root mean square residual, RMSEA = Root mean square error of approximation

According to factor analysis using AMOS 7, factor score loading is to be standardized using regression weights, while critical ratio(CR) or Z-test is used as a statistical test for significance (> + 1.96 and -1.96) with p value <.05. In addition, the squared multiple correlation coefficients (R^2) is used to indicate items reliability for each observed variable of the latent constructs.

Most indicators loading were statistically significant at level p <.05 (Table 4.5, Table 4.6, and Table 4.7). The reliability of indictors or the proportion of variance between indicators on a factor (R^2) for all measurement models ranged from 0.04 to 0.79 (Table 4.5, 4.6 and 4.7). The R^2 from each item of social support were low (0.19) to moderate (0.69). In addition, the R^2 for symptom status was low (0.04 to 0.20) in each item, although it was high in two sub-constructs (physical symptom and psychological symptom) (Table 4.5). Furthermore, R^2 from each item of HRQOL were low (0.13) to high (0.79). According to Munro (2001), R^2 should not be less than 0.40. The R^2 of some items were less than 0.40 and some were negative, which indicated the construct was not well represented. However, these items were not deleted because it was a standard instrument that was widely used and

with the purpose for comparing the current study result with future studies in heart failure. Furthermore, overall modified measurement models fitted the data (Table 4.4)

Table 4.5 Confirmatory factor analysis of measurement model of social support (ESSI) (N = 422)

Indicators	Estimate (standardized)	SE	CR	Factor score	R^2
ESSI 1	.68	-	-	.02	.46
ESSI 2	.69	.07	16.19	.07	.48
ESSI 3	.84	.06	16.91	.19	.70
ESSI 4	.70	.09	13.00	.08	.50
ESSI 5	.89	.08	15.78	.27	.80
ESSI 6	.82	.09	14.82	.14	.67

Note: SE = standard error, CR = critical ratio, R^2 = Square multiple correlation

Table 4.6 Confirmatory factor analysis of measurement model of symptom status

Indicators	Estimate (standardized)	SE	CR	Factor score	R^2
1. Physical symptom	.93	-	-	.87	
Chest pain	.60	.13	11.34	.36	.08
Dyspnea	.76	.12	15.51	.58	.06
Fatigue	.83	.13	16.95	.68	.10
Sweeling	.50	.11	9.83	.25	.05
Palpitation	.74	.13	14.40	.55	.08
2.Psychological symptom	1.00	.12	14.47	1.00	
Sleep disturbance	.78	.10	12.95	.61	.20
Depression	.67	-	-	.45	.07
Anxiety	.66	.07	13.71	.44	.08
Poor appitites	.67	.08	12.32	.45	.04

Note: SE = standard error, CR = critical ratio, R^2 = Square multiple correlation

Table 4.7 Confirmatory factor analysis of measurement model of HRQOL (N =422)

Indicators (MLHF items)	Estimate (standardized)	SE	CR	Factor score	R^2
Physical dimension	.995	-	-		
(MLHF 1)	.79	.29	4.56	.02	.18
MLHF 2	.67	-	-	.04	.46
MLHF 3	.73	.09	14.01	.03	.53
MLHF 4	.78	.09	14.81	.04	.61
MLHF 5	.88	.09	15.25	.06	.65
MLHF 6	.75	.09	14.26	.07	.56
MLHF 7	.88	.09	16.46	.14	.78
MLHF 12	.74	.08	14.12	.01	.55
MLHF 13	.84	.08	15.70	.16	.71
Emotional dimension	.77	.09	10.73		
MLHF 17	.75	-	-	.16	.56
MLHF 18	.87	.06	17.36	.29	.76
MLHF 19	.79	.05	17.66	.12	.62
MLHF 20	.64	.07	11.60	.08	.41
MLHF 21	.73	.06	14.64	.06	.53
(MLHF 16)	.38	.08	5.68	.06	.35
Socio-economic dimension	.96	.095	6.84		
MLHF 1	-.43	.43	-2.43	-.02	.18
MLHF 8	.88	.31	7.19	.12	.77
MLHF 9	.89	.27	7.43	.15	.79
MLHF 10	.44	.22	6.04	.01	.20
MLHF 11	.68	.24	7.02	.06	.47
MLHF 14	.71	.23	8.35	.12	.50
MLHF 15	.89	-	-	-.32	.13
MLHF 16	.26	.17	3.59	.02	.35

Note: SE = standard error, CR = critical ratio, R^2 = Square multiple correlation,

3.2 Structural model assessment

The hypothesized model was composed of nine observed variables, six latent variables which separated into two exogenous variables and four endogenous variables. The two exogenous variables were bio-physiological status and social support, while the four endogenous variables were symptom status, functional status, general health perception, and HRQOL. All variables were entered into a structure equation model based on the hypothesized model. The correlation matrix of observe variables (Appendix H: Table 8)

were enter to the graphic hypothesized causal model developed by AMOS. One construct of each latent variable was set to 1.0 as a loading factor. The result of the hypothesized model was shown in table 4.10. Parameter estimates or path coefficients were standardized in order to easily compare the model coefficients (Hair et al., 1998).

According to model evaluation guidelines, the goodness of fit statistics were reported. The first, Chi-square was 76.52, *p*-value 0.00, *df* = 17 with χ^2/df = 4.50. The goodness of fit index (GFI) was equal to 0.96, adjusted goodness of fit index (AGFI) was equal to 0.89, and the root mean square error of approximation (RMSEA) was equal to 0.09 (Table 4.8). These indicated that this model did not fit with the data. Thus, model modification was required.

Table 4.8 Statistic overall fitted index of structural model of HRQOL in heart failure patients (N=422)

Structural model	Chi-square	df	χ^2/df	*p*-value	GFI	AGFI	RMSEA
Hypothesized model	76.52	17	4.50	0.00	0.96	0.89	0.09
Modified model	19.87	13	1.53	0.10	0.99	0.97	0.04

Note: *df* = degree of freedom, GFI = Goodness of fit index, AGFI = Adjusted goodness of fit index, RMSEA = Root mean square error of approximation

The tested hypothesized model indicated that most of the proposed parameter estimates and their direction were significant at p value < .05. There were parameter estimates from social support to symptom status (β = -0.24, *p* < .05) and general health perception (β = 0.21, *p* < .05). However, the parameter estimate from social support to HRQOL was significant but in a negative direction (β = - 0.14, *p* < .05). The path from bio-physiological status to functional status was β = - 0.36 *p* < .05. The paths from symptom status to functional status was β = 0.48, *p* <.05, general health perception was β = - 0.26, *p* < .05, and HRQOL was β = -0.52 *p* <.05. The parameter estimate from functional status to

general health perception was β = -0.30, p <.05 and to HRQOL β = -0.27, p <.05. The path from general health perception to HRQOL was β = 0.21, p <.05. However, there was evidence of misspecified parameters between endogenous variables and exogenous variables for the hypothesized model. The path coefficient from social support to functional status was β = 0.03. p >.05 and path coefficient from bio-physiological to symptom status was β = - 0.08. p > .05. (Table 4.9, Figure 4).

Table 4.9 Regression weights, Standard Errors (SE) , Critical ratio (CR) , p-values of Parameter Estimates of the hypothesized causal model of HRQOL in heart failure patients (N = 422)

Path	Estimate	Standard Error	CR	p-Values
Biological				
→ LVEF	1.000			
→ Symptom status	-0.08	.054	-1.51	.132
→ Functional status	-0.36	.002	-7.99	***
Social support				
→ Functional status	0.03	.003	0.47	.637
→ Symptom status	-0.24	.077	-3.20	.001
→ General health perception	0.21	.075	3.25	.001
→ HRQOL	-0.14	.064	-2.44	.015
Symptom status				
→ Physical symptom	0.80			
→ Psychological symptom	0.90	.077	16.22	***
→ Functional status	0.48	.003	8.97	***
→ General health perception	-0.27	.080	-3.77	***
→ HRQOL	-0.52	.071	-7.92	***
Functional status				
→ NYHA	1.000			
→ General health perception	-0.30	2.07	-3.21	.001
→ HRQOL	-0.27	1.85	-3.06	.002
General health perception				
→ GHP	1.000			
→ HRQOL	0.21	.050	3.91	***
Health-related quality of life				
→ Physical dimension	0.91	.065	17.51	***
→ Psychological dimension	0.73	-	-	-
→ Other dimension	0.88	.061	17.94	***

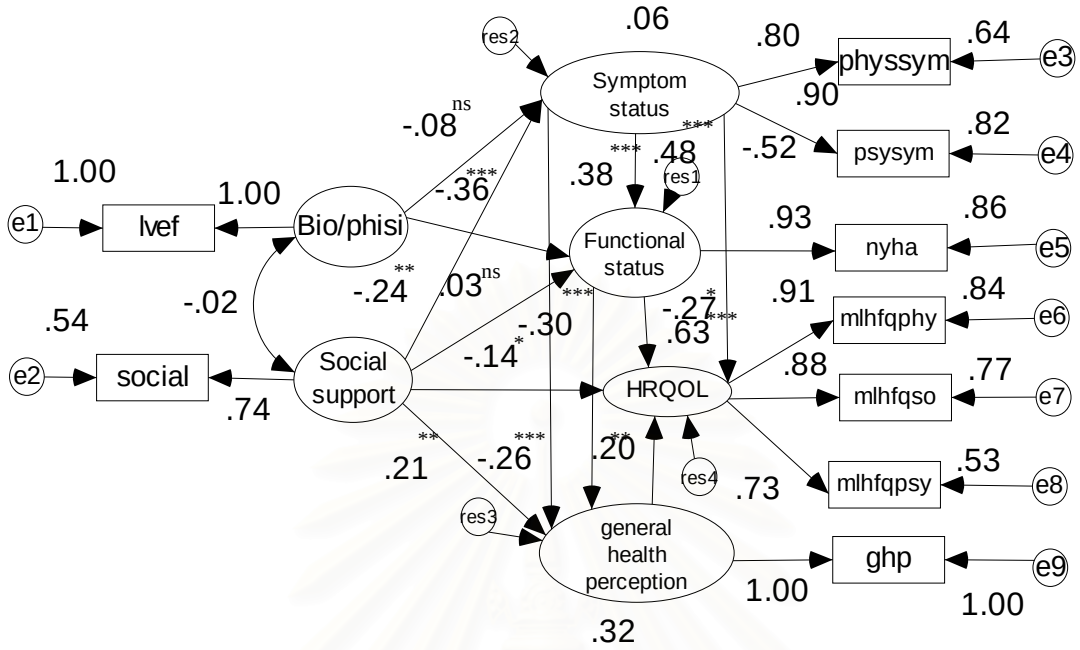

Figure 4 Hypothesized causal model of HRQOL in heart failure patients (N = 422)
Note: ns = non- significant, * $p < .05$, ** $p < .001$, *** $p < .0001$,

Table 4.10 Total effects, indirect effects, direct effects of causal variables on influenced variables of the hypothesized model (N=422)

Causal Variables	Symptom			FS			GHP			HRQOL		
	DE	IE	TE	DE	IE	TE	DE	IE	TE	DE	IE	TE
Social support	-.24**	.00	-.24**	.03NS	-.11NS	-.08NS	.20**	.09**	.29**	-.14*	.21*	.07*
Bio/physiological	-.08NS	.00NS	-.08NS	-.36***	-.03**	-.39***	.00	.14***	.14***	.00	.18***	.18***
Symptom status	-	-	-	.48***	.00	.48***	-.27***	-.14***	-.41***	-.52***	-.21***	-.73***
Functional status	-	-	-	-	-	-	-.30**	.00	-.30**	-.27*	-.06*	-.33*
General health perception	-	-	-	-	-	-	-	-	-	.21***	.00	.21***
	R^2 = .06			R^2 = 0.38			R^2 = 0.32			R^2 =0.63		

$\lambda^2 = 76.52$, $df = 17$, $\lambda^2/df = 4.50$, p-value = 0.00, GFI = 0.96, AGFI = 0.89, RMSEA = 0.09

Note: ns = non- significant, * $p < .05$, ** $p < .001$, *** $p < .0001$, TE = Total effect, IE = Indirect effect, DE = Direct effect, FS = functional status, GHP = general health perception, HRQOL = health related quality of life, R^2 = Squared multiple correlation

4. Model modification

Because, the hypothesized model did not fit with the sample data, model modification was done. The model was modified using modification indices as well as substantive reasoning. Some correlated errors were added to the model for the expected drop in chi-square. In addition, the non-significant parameter estimates had a low factor loading and were not excluded from the model because of their meaningfulness. They were the path from social support to functional status and the path from biological/ physiological to symptom status.

Results of the modification resulted in a decrease in chi-square (19.87), degrees of freedom (13), the RMSEA (0.04) and an increase in the GFI (0.99), the AGFI (0.97), and a decrease in χ^2 /df (1.53), p >.05, which are shown in table 4.8. The modified model fit well with the data (Figure 5; Appendix I)

In the modified model, all parameter estimates were statistically significant. These were the parameter estimates from social support to symptom status (β = - 0.25, p < .05) and general health perception (β = 0.19, p < .05). However, the parameter estimate from social support to HRQOL was also significant but in a negative direction (β = -0.17, p < .05). The parameter estimate from bio-physiological status to functional status was β = - 0.34, p < .05. The parameter estimate from symptom status to functional status was β = 0.45, p <.05, general health perception was β = -0.27, p <.05, and HRQOL was β = -0.48, p <.05. The parameter estimates from functional status to general health perception was β = -0.28, p <.05 and to HRQOL was β = -0.25, p <.05. However, the path coefficients from bio-physiological to symptom status was β = -0.08, p >.05 and the path from social support to functional status was β = 0.02, p >.05 which were statistically not significant. (Table 4.11, figure 5).

Table 4.11 Regression weights, Standard Errors (SE) , Critical ratio (CR) , p-values of Parameter Estimates of the modified causal model of HRQOL in heart failure patients (N = 422)

Path	Estimate	Standard Error	CR	p-values
Biological				
→ LVEF	1.00			
→ Functional status	0.34	.002	-7.99	***
→ Symptom status	0.08	.053	-1.51	.132
Social support				
→ Functional status	0.02	.003	0.33	.738
→ Symptom status	-0.25	.075	-3.33	***
→ General health perception	0.19	.074	3.05	.002
→ HRQOL	-0.17	.069	-2.99	.003
Symptom status				
→ Physical symptom	0.92			
→ Psychological symptom	0.78	.088	14.79	***
→ Functional status	0.45	.003	8.91	***
→General health perception	-0.27	.079	-3.97	***
→ HRQOL	-0.48	.074	-7.78	***
Functional status				
→ NYHA	1.000			
→ General health perception	-0.28	1.99	-2.98	.003
→ HRQOL	-0.25	1.86	-2.94	.003
General health perception				
→ GHP	1.000			
→ HRQOL	0.24	.052	4.73	***
Health-related quality of life				
→ Physical dimension	0.95	.065	18.02	***
→ Psychological dimension	0.78	-	-	-
→ Other dimension	0.85	.061	16.72	***

For the over all model, when the model fits well, the absolute standardized residuals should be less than 2.0 (Jöreskog & Sörbom, 1984). All of the standardized residual covariance of the modified model were between -0.92 to.096. Therefore, these findings indicated that covariance was quite well explained by the model. (Appendix H: Table 9)

In summary, the modified model was accepted and fit with the empirical data rather than the initially hypothesized model. The overall model explained approximately 58% of the variance in overall health-related quality of life. The schematic presentation of the modified structural equation model is presented in Figure 5.

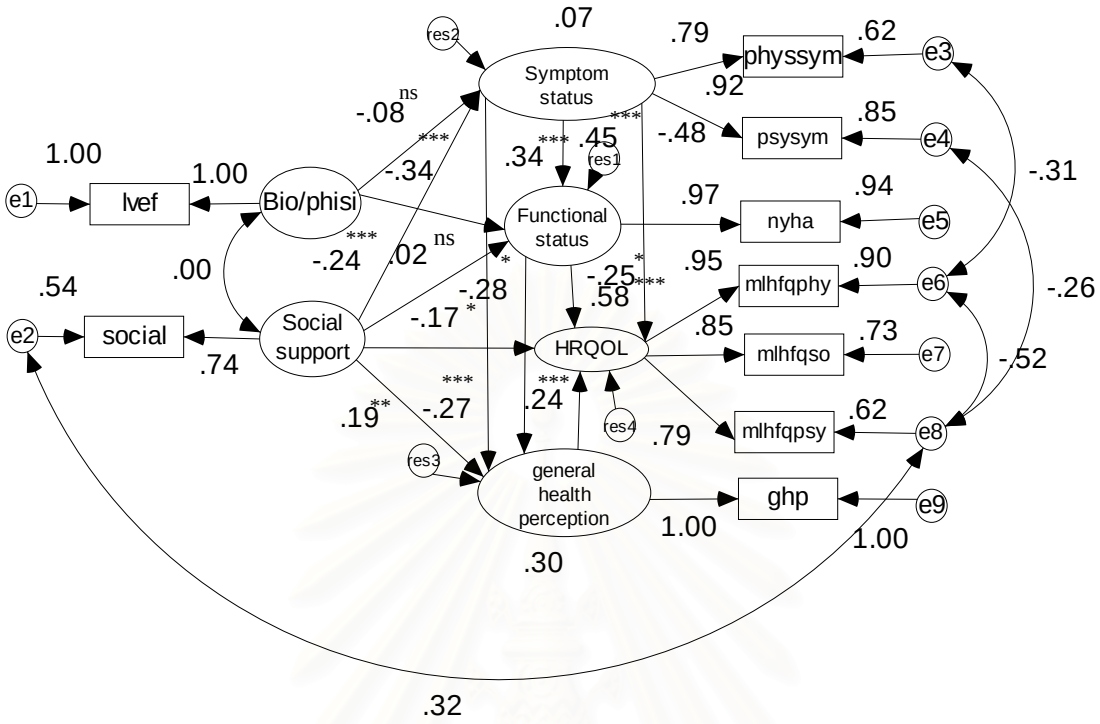

Figure 5 Modified causal model of HRQOL in heart failure patients (N = 422)
Note: ns = non- significant, * $p < .05$, ** $p < .001$, *** $p < .0001$,

Table 4.12 Total effects, Indirect effects, Direct effects of Causal Variables on Influenced variables of the modified hypothesized model (N=422)

Causal Variables	Symptom			FS			GHP			HRQOL		
	DE	IE	TE	DE	IE	TE	DE	IE	TE	DE	IE	TE
Social support	-.25**	.00	-.25**	.02 ns	-.11 ns	-.09 ns	.19*	.09*	.28*	-.17*	.21*	.04*
Bio/physiological	-.08 ns	.00	-.08 ns	-.34***	-.03***	-.37***	.00	.13***	.13***	.00	16***	.16***
Symptom status	-	-	-	.45***	.00	.45***	-.27***	-.13***	-.40***	-.48***	-.21***	-.69***
Functional status	-	-	-	-	-	-	-.28*	.00	-.28*	-.25*	-.07*	-.32*
General health perception	-	-	-	-	-	-	-	-	-	.24***	.00	. 24***
	$R^2 = 0.07$			$R^2 = 0.34$			$R^2 = 0.30$			$R^2 = 0.58$		

$\lambda^2 = 19.87$, $df = 13$, $\lambda^2/df = 1.53$, p-value = 0.10, GFI = 0.99, AGFI = 0.97, RMSEA = 0.04

Note: ns = non- significant, * $p < .05$, ** $p < .001$, *** $p < .0001$

TE = Total effect, IE = Indirect effect, DE = Direct effect, FS = functional status, GHP = general health perception, HRQOL = health related quality of life

5. Hypotheses testing

The hypotheses of the initially proposed causal model of HRQOL in heart failure patients were tested and the results were as follows.

5.1 Hypothesis one: *biological and physiological status (left ventricle ejection fraction: LVEF) would have a negative direct effect on symptom status, functional status (NYHA), and a positive indirect effect on HRQOL through symptoms status, functional status, and general health perception.*

Biological /physiological status was defined by LVEF. The higher the LVEF, the lower symptom distress presents in heart failure. Functional status was indicated using the NYHA functional classification. Participants with NYHA class IV and III reported functional status lower than those with NYHA functional class II and I. Thus, the parameter estimates in table 4.10 and figure 4 indicate that biological /physiological status using LVEF had a significantly negative direct effect on functional status ($\beta = -0.36$, $p < .05$). However, it was statistically not significant and had a negative direct effect on symptom status ($\beta = -0.08$, $p > .05$). It had a significant negative indirect effect on functional status through symptom status ($\beta = -0.03$, $p < .05$). It had a positive indirect effect on general health perception ($\beta = 0.14$, $p < .05$) and HRQOL ($\beta = 0.18$, $p < .05$).

According to the modified model, some value of parameter estimates were little changed (Table 4.12, Figure 5). Bio-physiological status still had a statistically significant negative direct effect ($\beta = -0.34$, $p < .05$) and indirect effect ($\beta = -0.03$, $p < .05$) on functional status. In addition, the total effect of bio- physiological status on functional status was in a negative direction ($\beta = -0.37$, $p < .05$). It had a positive indirect effect on general health

perception (β = 0.13, $p < .05$) and HRQOL (β =0.16, $p < .05$). However, bio-physiological status continued to have a statistically non-significant negative direct effect on symptom status (β = -0.08, $p > .05$). Therefore, hypothesis one partially supported the causal relationships as proposed in the hypothesized model of HRQOL in heart failure patients.

5.2 Hypothesis two: C*haracteristics of the environment (social support) would have a negative direct effect on symptom status and functional status (NYHA), but would have a positive direct effect on general health perception and HRQOL. Further, it would have a positive indirect effect on HRQOL through symptom status, functional status and general health perception.*

The parameter estimates in table 4.10 and figure 4 indicated that social support had a statistically significant negative direct effect on symptom status (β = - 0.24, $p < .05$), while, it had a statistically positive direct effect (β = 0.20, $p < .05$) and indirect effect (β = 0.09, $p < .05$) on general health perception. The direct effect of social support on HRQOL was statistically significant in a negative direction (β = -0.14, $p < .05$), while the indirect effect was significantly positive (β = 0.21, $p < .05$). Thus, the total effect of social support on HRQOL was both significant and positive (β = 0.07, $p < .05$). However, the path coefficients from social support to functional status was not significant (β = 0.03, $p > .05$).

After the model was modified, the parameter estimates as shown in table 4.12 and Figure 5 indicated that social support still reported statistically significance as a negative direct effect on symptom status (β = - 0.25, p .05). At the same time, it had a positively significant direct effect (β = 0.19, $p < .05$) and indirect effect (β = 0.09, $p < .05$) on general health perception. In addition, social support also had a statistically significant negative direct effect (β = -.17, $p < .05$), and a positive indirect effect on HRQOL (β = 0.21, $p < .05$).

Therefore, the total effect of social support on HRQOL was statistically significant in a positive direction (β = 0.04, $p < .05$). Social support had a non-statistically significant positive direct effect on functional status (β = 0.02, $p > .05$). However, social support had an indirect effect on functional status through symptom status (β = -.11, $p < .05$). Thus, the total effect of social support on functional status was negative (β = - 0.09, $p < .05$). Therefore, hypothesis two was partially supported, as were the causal relationships as proposed in the hypothesized model of HRQOL in heart failure patients.

5.3 Hypothesis three: S*ymptom status would have a positive direct effect on functional status and a negative direct effect on general health perception. It would have both direct and indirect effects on HRQOL through functional status and general health perception.*

Based on the hypothesized causal model, symptom status had a significant positive direct effect on functional status (β = 0.48, $p < .05$), while it had a significant negative direct effect on general health perception (β = - 0.27, $p < .05$) and HRQOL (β = -0.52, $p < .05$). It also had a significant negative indirect effect on general health perception (β = -0.14, $p < .05$) and HRQOL (β = -0.21, $p < .05$). Therefore, the total effect of symptom status on HRQOL was statistically significant and negative (β = -0.73, $p < .05$) (Table 4.10, Figure 4).

Although, the hypothesized five was fully supported, as were the causal relationships as proposed in the hypothesized model of HRQOL in heart failure patients, the large modification index was suggested to add some parameters estimated between errors of some observed variables. According to the modified model, symptom status continued to have a statistically significant and positive direct effect on functional status

(β = 0.45, $p < .05$). It had a statistically significantly negative direct effect on general health perception (β = -0.27, $p < .05$) and HRQOL (β = -0.48, $p < .05$). Further, it had a statistically significantly indirect effect on general health perception (β = -0.13, $p < .05$), and HRQOL (β = -0.21, $p < .05$). The total effect of symptom status on functional status was positive direction (β=0.45, $p < .05$), while had negative direction on general health perception (β = -0.40, $p < .05$) and HRQOL (β = - 0.69, $p < .05$). (Table 4.12, Figure 5). Thus, this hypothesis was supported as were the causal relationships as proposed in the hypothesized model of HRQOL in heart failure patients.

5.4 Hypothesized four: *Functional status would have a negative direct effect on general health perception and HRQOL. It would have a negative indirect effect on HRQOL through general health perception.*

The estimate path coefficient indicated that functional status had a significantly negative direct effect on general health perception (β = - 0.30, $p < .05$), and HRQOL (β = -0.27, $p < .05$). It also had a negative indirect effect on HRQOL (β = - 0.06, $p < .05$). Thus, the total effect of functional status on HRQOL was statistically significantly and negative (β = -0.33, $p < .05$). (Table 4.10, Figure 4).

After the model was modified, the effect of functional status on general health perception and HRQOL was statistically significantly in a negative direction (β = - 0.28, β= -0.25, $p < .05$). It also had a significant negative indirect effect on HRQOL (β = - 0.07, $p < .05$). Therefore, the total effect of functional status on HRQOL was significantly negative (β = -0.32, $p < .05$). Therefore, hypothesis four was supported, as were the causal relationships as proposed in the hypothesized model of HRQOL in heart failure patients (Table 4.12, Figure 5)

5.5 **Hypothesis five**: *General health perception would have a positive direct effect on HRQOL.*

Regarding the overall hypothesized model, the findings revealed that general health perception had a statistically significant positive direct effect on HRQOL ($\beta = 0.21$, $p < .05$) (Table 4.10, figure 4). After the model was modified, it still had a significant positive direct effect on HRQOL ($\beta = 0.24$, $p < .05$) (Table 4.12, figure 5). Therefore, hypothesis five was supported, as were the causal relationships as proposed in the hypothesized model of HRQOL in heart failure patients.

In conclusion, the descriptive statistic characteristics of variables studied in this study have been explained. The preliminary analysis reported did not violate assumption for structural equation modeling. The measurement model was tested and confirmed the construct validity of each instrument. The hypothesized causal model of health related quality of life in heart failure patients was tested and modified. The modified causal model fit well with the empirical data of HRQOL in Thai heart failure patients. Although, some research hypotheses were only partially supported, the model is still meaningful and useful for explaining factors affecting HRQOL in heart failure patients. Finally, the all variable in the model explained approximately 58% of the variance in overall health-related quality of life.

CHAPTER V

DISCUSSION

This chapter provides the discussion of the study results. It includes discussion of the characteristics of the subjects, characteristics of the variables, hypothesis testing, and also theoretical and methodological relevance.

5.1 Characteristics of the subjects

The subjects in this study were both male and female who were diagnosis with heart failure. More than half of the subjects were female (65.6 %). They were between 60-69 years of age (36.3%) and 45-59 years of age (28.7%), with a mean of age of 58.47 years (SD = 15.67). Most of the subjects (64.7%) graduated with elementary education, which was consistent with the studies of Piyakul (1999); Kompalaew (2002); and Samranbua (2001). Thus, they graduated with lower than the standard compulsory education in Thailand. As such, they had little chance for competition in the labor market which affected their income. Most of the subjects in the current study were not working because of their health problems or aging, thus most of the subjects' (69 %) home monthly income ranged from 1,000 to 5,000 baht. This finding was similar to that of Chaimati (2001) who reported that 47.5% of cardiac patients had inadequate incomes, and 60% finished primary school with most of those (57.5%) received less education that primary school.

The most common etiology of heart failure in our subjects was coronary artery disease. This finding was congruent with the report of the Ministry of Public Health: MOP (2006) which indicated that ischemic heart disease was reported as the major etiological underlying heart failure. The Ministry of Public Health (2006) also presented that there was

little difference between males (76.6%) and females (84.9%) who suffer with coronary heart disease and heart failure. These characteristics and etiology of heart failure were similar to previous studies conducted on 470 Thai heart failure patients, which found that the mean age of heart failure patients was 59.32 years, most of them were elderly, and reported myocardial infarction as underline etiology of heart failure (Yongkasem, 2006). Furthermore, the related illness of participants in this study included hypertension, diabetic mellitus, or both, which was also congruent with previous studies (Yongkasem, 2006; Chollatda, 2003). In addition, the Ministry of Public Health and Thai Heart Association suggested that hypertension and diabetic mellitus are the major causes of heart diseases, especially coronary heart disease which frequently develops into heart failure (MOP, 2006).

5.2 Characteristics of variables

The variables examined in this study included: social support, LVEF, symptom status, functional status (NYHA), general health perception (GHP), and HRQOL.

5.2.1 Social support

The total sum score of social support ranged from 0 to 100 with a mean of 76.71 (SD = 20.65). The result showed that the subjects perceived social support as moderate to high. More than half of the subjects were married (66.6%) and lived with their spouses (67.5%). Support from family members helped them to problems in daily living and supported them as they coped with the disease. Support from non family members rather than family members had a lower positive effect and resulted in less satisfaction with life (Davidson, 2003). Individuals who were widowed, divorced, or never married were more likely to die from heart disease than married individuals (Lynch, 1990). Moreover in Thailand, the health financial support comes from the health policy of the Thai government

and allows them not to worry about medication cost. Samranbua (2001) illustrated that social support shows significant positive correlation with holistic health (r = 0.28). Social support was greater for women than for men in reducing psychological distress, as indicated by either depressive symptoms or anxiety (Taylor, 2005). In the current study it had statistically significant different between men and women (F =1.813, p <.05), and marital status (F =1.88, p <.05) in perceive social support. Thus, the effect of social support on HRQOL was influenced by gender and marital status.

5.2.2 Biological/physiological status (LVEF)

Left ventricular ejection fraction (LVEF) was used to determine the level of biological/physiological function in heart failure. The range of LVEF for our subjects was 10% to 84 %, with a mean of 55.08 % (SD = 15.25).Most of the participants (80.6%) reported LVEF of more than 40%. In this study, the mean score of symptom status in heart failure with LVEF more than 40% ($\overline{X}$ = 23.23, SD = 19.79) and participants with LVEF less than 40% ($\overline{X}$ = 26.30, SD = 17.63) were not statistically different between groups (F = 1.652, p>.05). Mandinov et al (2000) indicated that individuals with heart failure and normal LVEF consistently demonstrate diastolic dysfunction. They report symptoms of heart failure, even in the presence of normal or slightly reduced LVEF. In addition, subjects with systolic dysfunction or LVEF less than 40 % will result in patients having symptoms of heart failure (Bonow et al., 2005). Therefore, most of participants in this study had clinical=diastolic dysfunction. Furthermore, the level of LVEF did not explain the severity of heart failure symptoms in our participants.

5.2.3 Symptom status

The symptom status scores of the participants ranged from 0 to 85.56

with a mean of 23.90 (SD = 19.29). Following our study design, we could not collect data at the time of heart failure occurred. For example, we were not able to ask heart failure patients if they had dyspnea, chest pain, exhaustion or fatigue at the time of their heart failure. For instance, Chatvichai (2003) revealed dyspnea was most severe at 2-3 hours after admission. However, this study was conducted with heart failure patients in the cardiac out patient clinic and asked them to recall about heart failure symptoms over the past month. Thus, some participants reported no symptoms when they came to the cardiac out patient clinic after being discharged 1 month.

Similar to previous studies showing the complex and progressive nature of symptoms in heart failure patients, (Hunt et al., 2005; Zambroski et al., 2005; Phonphet, 2001) and as indicated by The American Heritage Stedman's Medical Dictionary (2004), most of the subjects presented with more than one symptom.

The common physical symptoms of heart failure were reported by our participants. Shortness of breath or dyspnea was reported in more than half of the participants (64.5%) in this study. However, fatigue or feeling overly tired was the most common presenting symptom in the current study (78.4%). This finding was similar to results from many previous studies in heart failure (Friedman et al., 1997; Wilson et al., 1995; Parshall, 1999; Friedman, 1997; Welsh et al., 2002; Caroci & Lareau, 2004; Friedman & King, 1995; Ekman & Ehrenberg, 2002). Furthermore, it was consistent with studies conducted by Maneesilp (1999) and Sammranbua (2001) which illustrated that dyspnea was commonly reported in patients with cardiac disease and especially when it developed into heart failure. In addition, Chiraporn (1999) reported that fatigue was usually found in Thai heart failure patients.

More than half of these participants (64.5 %) had sleep disorders, which was also consistent with studies conducted by Riedinger et al (2001) and Lainscak and Keber (2003). In addition, Brostrom et al (2004) indicted that, heart failure patients with a New York Heart Association classification II-IV reported difficulties maintaining sleep, initiating sleep, and early morning awakenings. It was also consistent with Johansson, Dahlström, and Broström (2005) who illustrated that sleep disturbances in patients with heart failure were related to sleep disorders, occurring in about 50% of the heart failure population, and/or depression, as well as from heart failure symptoms such as dyspnea and arrhythmia.

Although, only 5.9 % of these participants reported cardiac arrhythmia (e g. atrium fibrillation: AF, bundle branch block: RBBB or LBBB) as the etiology of their heart failure, more than half of the participants reported arrhythmia (69.2%). Arrhythmia has been reported as a symptom of other heart defects, such as valvular heart disease or coronary heart disease (Phonphet, 2001). Arrhythmia also had been reported to correlate with sleep disturbance and dyspnea (Maneesilp, 1999).

Chest pain was a frequent finding in this study. In our participants, 24.2 % reported myocardial infarction as the etiology of their heart failure, and the failure of the heart to pump blood to meet the requirement of body cells and cardiac muscle. In these participants, 55.2 % reported chest pain. In addition, 29.1% of them had swelling, a major symptom of right side heart failure which resulted in systemic venous congestion and peripheral edema (Thelan et al., 1996).

The participants in this study also reported psychological symptoms. More than half of the participants reported anxiety (65.9%) and depression (50.7%). This finding was consistent with previous studies in heart failure; for example studies conducted by

Jiang et al (2004); Januzzi, Stern, Paternak and DeSanctis (2000); Murberg et al (1999); Artinian (2003); MacMahon and Lip (2002); and Nabb et al (2006). Furthermore, psychological problems including both anxiety and depression (Dracup et al., 2003; Jiang et al., 2001; Moser, 2002; Gottlieb et al., 2004, and Lennie et al., 2006), and physical symptoms such as fatigue, nausea, and dyspnea (Lennie et al., 2006) were reported to reduce food intake in heart failure. In addition, sodium restriction was the most common factor affecting food intake by patients with heart failure. Thus, about half of the participants (51.9 %) reported a poor appetite. This also was supported by studies conducted by Aquilani, Opasich, and Verri (2003) who reported the incidence of protein-calorie malnutrition in patients with heart failure was estimated to be as high.

5.2.4 Functional status

The NYHA functional classification was the most commonly used means of quantifying the functional status of patients with heart failure. It is based on classification of the extent of patients' ability to perform their daily activity (AHA, 2006). Using functional status as defined with NYHA, most of subjects in this study were NYHA functional class II and III (37.4% and 33.6%), and 6.2% of them were NYHA functional class I and 22.7 % presented as NYHA functional class IV. NYHA classification ranged from I to IV, and lower scores (NYHA functional class I or II) indicated better scores of functional status than higher scores (NYHA functional class III, IV). Majani et al (1999) indicated that patients in NYHA class III and IV had more frequent problems in daily life than patients in NYHA classes I and II. More than half of the subjects in the current study were in NYHA class II (37.4%) and III (33.6%), while less of them were NYHA class IV (22.7%). Thus the participants' subjective perception of their functional status was moderate to high. Furthermore, current study reported no difference in the mean of

functional status between males and females (F = .828, p >.05) or between participants recently diagnosed with heart failure and those with longer histories of heart failure (F = .020, p >.05). However, age different in perception of functional status (F = 4.467, p <.05). Thus, functional status may be limited with old age, gender and heart failure symptom.

5.2.5 General health perception

GHP scores ranged from 1 to 100 with a mean of 53.31 (SD =18.12). Stewart et al (2004) indicated that heart failure patients always had a poorer health perception because of symptom distress and functional limitations. The result of this current study was similar as the mean of the participants' general health perception was moderate. General health perception was the perception of heart failure patients about their overall health situation. Participants in this study reported low symptom distress, moderate to high functional limitations, and moderate to high social support. Thus, their general health perception was rated as moderate.

5.2.6 Health-related quality of life

The mean score of HRQOL for these participants was 55.13 (SD = 20.63), which ranged from 7.72 to100. This result indicated that subjects perceived their HRQOL as moderate. With regard to the dimensions of HRQOL, the mean of physical well being was less than the mean of emotional well being, social and economic well being. However, Hobbs et al (2002); Johansson, Agnebrink, Dahlstrom, and Brostrom (2004) illustrated that HRQOL in heart failure patients was impaired of all dimensions. The largest impact of heart failure on HRQOL occurred in the younger age group (Calvert et al., 2005; Masoudi et al., 2004; Hou et al., 2004 and Gottlieb et al., 2004). Thus, the level of HRQOL in heart failure in this study was moderate because most of the subjects were older (aged 60 and

above). In addition, studies in Thailand illustrated that not only age and gender, but also occupation, education, and income were also related to HRQOL in cardiac disease, which usually develops into heart failure (Phonphet, 2001; Yamsakul, 1999). The current study indicated consistence with previous studies that HRQOL was significantly different between marital status ($F = 2.284$, $p < .05$), religion ($F = 2.142$, $p < .05$), and occupation ($F = 1.982$, $p < .05$). However, the current study found HRQOL was not different between duration of living with heart failure ($F = .485$, $p > .05$), age ($F = 1.052$, $p > .05$) gender ($F = 1.102$, $p > .05$), monthly income ($F = 1.818$, $p > .05$), and education level ($F = .659$, $p > .05$). Although, most of the participants had a low income, health insurance supported through the Thai government was made them not worry about the cost of medical treatments. Furthermore, most of the participants were not worried about working or studying because of their old age, thus rated their HRQOL was not reduced.

5.3 The overall Model and Causal Relationship

The overall model explained approximately 58% of the variance in overall health-related quality of life. The study's finding also support the application of structural equation modeling in investigation of HRQOL. The causal relationship was explained in each hypothesis testing as follow:

5.3.1 Hypothesis one: Biological/physiological status (left ventricle ejection fraction) would have a negative direct effect on symptom status, functional status, and also would have a positive indirect effect on HRQOL through symptom status, functional status, and general health perception.

1) *Biological/physiological status (Left ventricle ejection fraction) affected symptom status:* The parameter estimate presented in the hypothesized causal model of

HRQOL in Thai heart failure indicated that biological /physiological status, which investigated by LVEF, had a non-significant negative direct effect on symptom status ($\beta = -0.08$, $p > .05$). AHA (2006) indicated that LVEF less than 40% was generally considered to indicate systolic dysfunction. A previous study indicated that LVEF less than 40 % would result in patients having symptoms of heart failure (Bonow et al., 2005). LVEF has been shown to impact mental health with signs of depression (Bhaskaran et al., 2004; Lu et al., 2005; Elatre, Aria, Cayasoo, Huiskes, Beckwith and Heywood, 2003). However, Mandinov et al (2000) documented that individuals with heart failure and normal LVEF consistently demonstrated heart failure with diastolic dysfunction. Diastolic heart failure patients report symptoms of heart failure even in the presence of normal or slightly reduced LVEF. Primary diastolic failure is typically seen in patients with hypertensive or valvular heart disease, as well as in hypertrophic or restrictive cardiomyopathy (AHA, 2006). It can also occur in a variety of clinical disorders, especially tachycardia and ischemia. The etiology of the heart failure patients in the current study was supports diastolic heart failure.

In addition, diastolic dysfunction has a particularly high prevalence in elderly patients. Considering the characteristics of participants in the current study, more than half of them were more than 60 years old and most of them (80.6%) reported their LVEF to be more than 40 %. Further, there was no difference between the mean symptom status in patients who had LVEF less than 40% and those who reported higher than 40%. Thus, LVEF as reported by participants in this current study did not predict symptom status in heart failure. This finding supported that LVEF alone can not used to determined severity of symptoms in the complex presentation and diagnosis of heart failure.

2) Biological/physiological status affected functional status: Biological and physiological status as defined by LVEF had a significant negative direct effect on

functional status in heart failure patients (β = -0.34, $p < 0.05$). This finding supported the results of many previous studies. For example, Bhaskaran et al. (2004) and Lu et al. (2005) indicated that LVEF in NYHA functional class III and class IV are usually less than class I and class II. If blood flow does not meet the requirements of body cells and organs, it also limits the ability of that organ to function. Physical function, psychological function and cognition are limited by low LVEF. The results of the current study supported this hypothesis in that biological/physiological status (LVEF) affected functional status.

3) Biological/physiological status affected HRQOL: Biological and physiological status (left ventricle ejection fraction) had a positive indirect effect on HRQOL through functional status and general health perception. Although LVEF did not have a statistically significant direct effect on symptom status, it had a significant direct effect on functional status of heart failure patients (β = - 0.34, $p < 0.05$). It also had a positive indirect effect on general health perception (β = 0.13, $p < 0.05$) and HRQOL (β = 0.16, $p < 0.05$). This finding was consistent with previous studies where LVEF had been reported to have a weak to no significant direct effect on HRQOL (Clark et al., 2003; Juenger et al., 2002; Riegel et al., 2002; De Jong et al., 2004; Carels et al., 2004). The current study is explained in that the blood flow that meets the requirement of body organs was decreased as LVEF decreased. Decreasing LVEF was associated with increased functional limitations which in turn reduces general health perception and HRQOL.

5.3.2 Hypothesis two: Characteristics of the environment (social support) had a negative direct effect on symptom status and functional status (NYHA) but had a positive direct effect on general health perception and HRQOL. It also had a positive indirect effect on HRQOL through symptom status, functional status and general health perception. This finding was particularly supportive of this hypothesis. The effect of social support on

functional status was not statistically significant, and the direct effect of social support on HRQOL was significant but in a negative direction. The detail of each direction is explained as follow.

1) *Social support affected symptom status:* The estimate parameter showed that social support had a significantly negative direct effect on symptom status ($\beta = -0.25$, $p < 0.05$). Better social support indicted less symptom distress. Although, the path coefficient value was not strong, it supported this hypothesis and was consistent with results from previous studies. For example, Bennett (1998) illustrated that social support was significantly, though not strongly, correlated with physical symptom impact. Social support can reduce psychological distress, symptoms and anxiety (Taylor 2005). Tongin (1999) found that if social status cannot be maintained, these patients have to depend on other people while having to face more financial difficulties from being out of a job. This causes them anxiety and depression. Bennett, Baker, and Huster (1998) reported a modest negative relationship between perception of social support and the impact of physical symptoms among recently hospitalized participants. Therefore, social support can help reduce severity and frequency in heart failure patients.

2) *Social support affects functional status*: The estimate parameter showed that social support was not statistically significant negative direct effect on functional status which defined as NYHA. Although social support could not predict functional status, many previous studies explained it was much influencing factor related to functional status. This finding will encourage healthcare provider to reconsider in this situation. According to inconsistent finding from most previous studies that some have found no relationship, while others have reported a positive relationship between social support and symptom status (Bennett, Baker, & Huster, 1998; Bennett, Perkins, Lane, Deer, Brater, & Murray, 2001;

Murberg, 2004). In addition, Rayond et al (1997) illustrated that social support was positively correlated with physical functioning, for example support from the family will help patients to perform activities of daily living. Sriprasong (2000) and Rayond et al. (1997) illustrated that social support was associated with functional status in cardiac patients. However, a study conducted by Buarapha (2004) indicated that social support had a significant negative effect related with physical activity of Thai heart failure patients. From above previous studies, increasing social support was not consistent with increasing or decreasing functional status.

In this study, functional limitations caused by heart failure were measured using functional status as described by the NYHA functional classification. In considering, more than 50 % of the participants in this study were NYHA functional class III and IV. Heart failure patients with NYHA functional classification class III cannot perform some of their normal daily activity, while heart failure patients with NYHA functional classification class IV have to stop all their activity and absolute bed rest. They always get dyspnea and severe fatigue which will also limit their daily activity and their self-care ability. Even though, social support can help reduce their normal activity and make them feel more comfortable, but not improve their functional class as defined by NYHA. Social support can only maintain or not deteriorated their function status.

In considering how bio-psycho-social factors affected HRQOL, NYHA functional classification class measures focus on biological and physiological limit functional status in heart failure. Heart failure patients with NYHA functional classification III and IV reported high scores on functional limitation from symptoms of heart failure (AHA, 2006). Social support affected symptom status, increasing social support will decreasing physical symptom and psychological symptom of heart failure as described

above. In addition, Frasure-Smit et al (2000) and Koenig (1998) indicated that social support could reduce depression in heart failure. Poor intimate network support (spouse support) was directly and negatively associated with depression in heart failure patients (Murberg et al., 1998). Therefore, support from others may increase participant ability to reduce their symptom, such as reduce their anxiety by help them to cope with stressors through receiving informational and emotional support. Thus, social support could not effect on functional status, but did have a low indirect effect on functional status through symptom status. Current study indicated that gender and marital status were different in perceive social support, thus mediator or covariate variables (e.g. gender and marital status) influencing the effected of social support on functional status should be in concern.

3) Social support affected general health perception: The estimate parameter showed that social support had a statistically significant positive direct and indirect effect ($\beta = 0.19, 0.09, p < 0.05$) on general health perception. The total effect of social support on general health perception was significant and in a positive direction ($\beta = 0.28, p < 0.05$). This finding was consistent with previous studies. For example, Riedinger et al., (2002) illustrated that the correlation between social and general health perception was moderately positive (0.63). In addition, Samranbua (2001) indicated that social support shows significant positive ($r = 0.28$) correlation with perceived overall health. Heart failure patients who reported higher social support also perceived a better general health. Social support provided less symptom distress which also increased functional status and health perception (Rayond et al., 1997).

4) Social support affected HRQOL: The parameter estimate of social support to HRQOL was statistically significant but in a negative direction ($\beta = -.17, p < .05$). Social support also had a statistically significant but positive indirect effect on HRQOL ($\beta = 0.21,$

p <.05). However, total effect of social support on HRQOL also had a statistically significant positive effect ($\beta = 0.04$, p <.05). This hypothesis was partially supported, as were the causal relationships as proposed in this hypothesis.

In consistent found from previous studies, such as Bennett e t a l (2001) indicated that changes in social support was the significant predictor of changes in HRQOL; increase of social support increased HRQOL, but Westlake (2002) found that there was no significant relationship between social status, social network, social support, and HRQOL in heart failure patients. Current study reported that social support had a significant negative direct effect on HRQOL. In considering, the concept of social support is broadly used, different definitions exist, various theoretical views, and as a result many different approaches were used to examine this concept (Luttik et al., 2005). This study used ESSI which determined the perception of heart failure in received adequate social support from others. In other previous studies, health burden in heart failure was significantly greater than that suffered in other serious common chronic disorders (Hobbs et al., 2002). Individual feelings of being a burden to others, and feeling imprisoned by the illness was increased when heart failure patients received support from the others (Martensson, Karlsson, & Fridlund; 1998; Mahoney 2001). Although the item of between ESSI and MLHFQ was not redundant, it was useful when considering some emotional dimensions of the MLHFQ, such as feeling a loss of self control and being a burden to others were incorporated into the measure of HRQOL in heart failure patients. Thus, the negative effect of social support on HRQOL may be influence with the interaction between content of some items of ESSI and HRQOL. Heart failure patients who received more support from others would indicate a lower HRQOL with increased feelings of being a burden. In the Thai culture, economics affects family members. Heart failure patients who

are out of work because of their health problems and older heart failure patients who received support from others who frequently had to miss work to take the heart failure patient to hospital will feel burdened and worry about their economic status. Thus, they will rate their HRQOL as poor while having high social support.

Although, the direct effect of social support was in a negative direction, it was not stronger than the positive indirect effect. Thus, the total effect of social support on HRQOL was statistically significant in a positive direction. This study indicated that changes in social support significantly predicted few changes in health-related quality of life. In considering, current study found that social support can help reduce physical and psychological symptom which turn to increase their general health perception and HRQOL. Social support reduce physical symptom (Bennett et al., 1998) and psychological of heart failure (Frasure-Smith et al., 2000, Murberg et al., 1998). In addition, social support can reduce psychological distress, symptoms and anxiety (Taylor, 2005). It was positively correlated with general life satisfaction (0.63) (Riedinger et al., 2001), which in turn increased HRQOL.

In considering there were most female than male participated in this study, and the gender different in perceived social support. The negative effect of social support on HRQOL may be influenced by covariate variable, gender. Many previous studies reported that women always received less social support than men (Jensen& King, 1997; Stanley, 1999, Chin & Goldman, 1998). The absence of social support and increased fatal cardiovascular events was restricted to women (Krumholz el al., 1998). Thus, future study should consider the covariate variables, such as gender influencing the effect of social support on HRQOL.

5.3.3 Hypothesis three: Symptom status had a positive direct effect on functional status (NYHA), but had a negative direct effect on HRQOL. Further, it had a negative indirect effect on HRQOL through functional status and general health perception.

1) *Symptom status affected functional status*: The estimate parameter showed that symptom status had a statistically significant positive direct effect on functional status (NYHA) ($\beta = 0.45$, $p < 0.05$). The total effect of symptom status on functional status was 0.45 ($p < 0.05$). Therefore, symptom status had a moderate effect on functional status. Increase symptom status will decrease functional status. This finding was consistent with previous studies. For example, functional status of heart failure patients was limited by symptoms (Konstam et al., 1996; Maneesilp, 2000). In addition, Phonphet (2001) indicted that chest pain, dyspnea, and palpitation were mainly related to limited heavy levels of activity. As dyspnea and life stresses increased, the NYHA class was also increased (Murberg et al., 1998). NYHA functional class was impacted with signs of depression (Bhaskaran et al., 2004; Lu et al., 2005; Murberg et al., 1998) and anxiety (Januzzi, Stern, Paternak & DeSanctis, 2000). In addition, Skala et al (1995); Elatre, Aria, Cayasoo, Huiskes, Beckwith and Heywood (2003) reported that depression was a strong predictor of NYHA functional class. Thus, increase symptom frequency and severity will decrease functional limitation in heart failure patients.

2) *Symptom status affected general health perception:* Symptom status had a statistically negative direct effect on general health perception ($\beta = -0.27$, $p < 0.05$). This finding was consistent with previous studies. For example, Sullivan et al. (2004) found that depression symptoms were prospectively associated with poorer health perception in patients with heart failure. Bennett (1998) illustrated that the physical symptoms impact was moderately correlated with perceived health in heart failure patients. De Jong et al.

(2004) illustrated that symptom status strongly related to general health perception. In additional, high levels of emotional distress were associated with low levels of perceived health (Rayond, Rosen, Contrada, Gorkin & Kostis, 1997).

In this study, there was an indirect effect of symptom status on general health perception through functional status, where in this study of a causal model of health-related quality of life in Thai heart failure we found that symptom status had a statistically significant indirect effect on general health perception through functional status (β = -0.13, $p < 0.05$). Interestingly, this finding was inconsistent with a study conducted by Heo et al (2005) which indicted that functional status was not a mediator of the effect of symptom status on health perception. Heart failure patients, who reported high symptom distress also reported high functional limitations and also rated their perception of their over all health as poorer than those who had low symptom distress and no functional limitations.

3) *Symptom status affected HRQOL:* Symptom status had a statistically negative direct effect (β = -0.48, $p < 0.05$) and indirect effect (β = -0.21, $p < 0.05$) on HRQOL. The total effect of symptom status on HRQOL had a significantly moderate negative effect (β = - 0.69, $p < 0.05$). This finding was consistent with previous studies. For example, high depression symptoms were associated with reduced HRQOL scores (Gottlieb et al., 2004). Physical and role function and symptom severity had a statistically significant effect on HRQOL (Sullivan et al., 2004). Yu et al (2004) reported that four variables, including psychological distress, health perception, NYHA classification, and educational level, explained 51.8% of the variance in HRQOL in heart failure patients. In addition, Jong et al (2004) found that the three strongest predictors of health status were anxiety, NYHA class, and depression. As dyspnea, life stresses, and NYHA class increased HRQOL decreased (Murberg et al., 1998). This finding was also supported by Heo et al (2005), who used a

secondary analysis to test Wilson and Cleary's HRQOL Model (WCM). They found that health perception and symptom status predicted the total quality of life. The emotional scale, health perception, symptom status, and New York Heart Association classification predicted the physical scale in HRQOL. Health perception was a mediator of the effect of symptom status on HRQOL. In all of above, the findings showed that functional status and general health perception were mediators between symptom status and HRQOL in the current study.

In the hypothesized causal model of health-related quality of life in Thai heart failure, there was no parameter estimate from the biological/ physiological (LVEF) to HRQOL. Furthermore, previous studies reported that left ventricular ejection fraction (LVEF) and comorbidity were not associated with any dimension or with overall HRQOL (Clark et al., 2003, Mitemi et al., 2003). While, Juenger, Schellberg & Kraemer et al (2002) illustrated that, LVEF showed no clear association with HRQOL. However, the current study found that biological/physiological status (LVEF) had a statistically significant positive indirect effect on HRQOL ($\beta = 0.16$, $p < 0.05$). Thus, heart failure patients who had a high level of LVEF should have a high level of HRQOL. The indirect effect of LVEF on HRQOL should be through functional status and general health perception.

5.3.4 Hypothesis four: Functional status (NYHA) had a negative direct effect on general health perception and a negative indirect effect on HRQOL through general health perception.

1) *Functional status affected general health perception*: The estimated path coefficient indicated that functional status had a statistically significantly negative direct effect on general health perception ($\beta = - 0.28$, $p < 0.05$). Therefore, hypothesis four was

supported, as were the causal relationships as proposed in the hypothesized model of HRQOL in heart failure patients. This finding was consistent with previous studies. For example, Samranbua (2001) indicated that NYHA functional class had a positive moderate correlation with perceived overall health (r = 0.40). Functional status limitations would make heart failure patients unable to perform their normal activities, resulting in them rating their general health perception as poor (Stewart et al, 2004).

2) *Functional status affected HRQOL:* The estimate parameter showed that functional status (NYHA) had a statistically significantly negative direct effect on HRQOL ($\beta = -0.25$, $p < 0.05$), and a negative indirect effect on HRQOL through general health perception. ($\beta = -0.07$, $p < 0.05$). This finding supports the existing literature regarding how subjective NYHA functional class affected HRQOL (Juenger et al., 2002; Parajon et al., 2004; Samranbua, 2001; Maneeslip, 1999). Lu et al (2005) reported that higher NYHA functional class was significantly associated with poorer HRQOL. There was a significant correlation between NYHA classification and the physical and mental health components of HRQOL (Grady, et al., 1998; Beck, et al., 2001; Westlake, et al., 2002; Hofer, et al., 2005). Individuals with lower functional status also perceived their health to be worse and then rated their HRQOL as poor. Although, the subjective NYHA functional class was associated with all HRQOL scales (Juenger, Schellberg & Kraemer et al., 2002), a study conducted by Carels (2004) suggested that functional impairment had a much weaker direct association with HRQOL. The current study found that functional status did not have a strong direct effect on HRQOL ($\beta = -0.25$, $p < 0.05$), and had a very weak indirect effect on HRQOL through general health perception ($\beta = -0.07$, $p < 0.05$). In addition, the total effect of functional status on HRQOL was also not strong ($\beta = -0.32$, $p < 0.05$).

5.3.5 Hypothesis five: General health perception had a positive direct effect on HRQOL.

Regarding the overall hypothesized model, the findings revealed that general health perception had a significant positive direct effect on HRQOL ($\beta = 0.24$, $p < 0.05$). This finding was consistent with previous studies. For example, Lu et al (2005) and Beckie & Hayduk, (2003) and De Jong et al (2004) indicated that general health perception in heart failure patients was a significant factor associated with HRQOL. Heart failure patients who assessed their general health as well also perceived their HRQOL as increased. However, general health perception was reported as a mediator of the effect of symptom status on HRQOL in heart failure (Hoe et al., 2005). Heart failure patients who reported low symptom distress and high functional status had an increased general health perception. In addition, heart failure patients who assessed their general health as well also perceived their HRQOL as increased.

5.4 Summary

There is reliable evidence indicating that a significant number of heart failure patients have a moderate heath related quality of life (HRQOL). The decline of HRQOL in heart failure patients was not different between gender, age, educational level, occupations, and family monthly income or duration of living with heart failure. However, HRQOL of heart failure patients was different between marital status and religion. Although, most of heart failure patients reported their biological/ physiological status as LVEF more than 40%, the symptom status of heart failure patients was not different from heart failure patients who have LVEF less than 40%. Thus the combined clinical evidence of heart failure is

importance to determine effective diagnosis and intervention for improving this clinical condition and increasing HRQOL in heart failure patients.

The findings partially supported the prediction of a causal model of HRQOL in Thai heart failure. Biological/physiological (LVEF), symptom status, functional status (NYHA), social support, and general health perception (GHP) were significant factors in explaining and predicting HRQOL in Thai heart failure patients. The causal relationship indicated that biological/ physiological status as defined by LVEF had a significant negative direct effect on functional status, but did not have a significant effect on symptom status. LVEF had a significant positive indirect effect on HRQOL through functional status and general health perception. Social support had a significant negative direct effect on symptom status and HRQOL, but had a positive direct effect on general health perception. Social support also had a positive indirect effect on HRQOL. However social support had no statistically significant effect on functional status. Symptoms status had a significant positive effect on functional status (NYHA), but had a negative direct effect on general perception and HRQOL. It also had an indirect effect on HRQOL through functional status and general health perception. Functional status (defined as NYHA) had a significant negative direct effect on general health perception and HRQOL. It also had a statistically significant negative indirect effect on HRQOL through general health perception. Finally, general health perception had a significant positive direct effect on HRQOL.

5.5 Comparison of Wilson and Cleary HRQOL conceptual framework (WCM) and a causal model of HRQOL in Thai heart failure patients

A causal model of HRQOL in Thai heart failure patients was derived from WCM. The selected variable and its directional effect on HRQOL were determined by significant

variable related to HRQOL in heart failure from previous studies. Wilson and Cleary HRQOL conceptual model explained a broad view of concepts and propose only linear relationship between concepts (figure 1). According to a causal model of health-related quality of life in Thai heart failure patients, it was developed to determine how factors affected HRQOL. This new model (figure 2) can more explained causal relationship and interrelationship with both direct and indirect effect of selected factors on HRQOL than WCM. A tested causal model of HRQOL in Thai heart failure patients was more valid in explaining HRQOL specific in heart failure patients than linear relationship presented in WCM. The direction and the magnitude of factors effect on HRQOL was presented and guided intervention for enhance HRQOL in heart failure patients.

5.6 Contribution to Nursing Science

The causal model of health-related quality of life in Thai heart failure patients in this study was derived from Wilson and Cleary's Health-Related Quality of Life Conceptual Model (WCM) and supporting literature. Bio- physiological (LVEF), symptom status, functional status (NYHA), social support, and general health perception (GHP) affected HRQOL in testing the causal model of HRQOL in Thai heart failure patients. This current study can be classified as an explanatory theory or factor – relating theory. It provided the specificity needed for usefulness in research and practice. The model was designed to predict HRQOL using bio-physiological status, clinical and socioeconomic outcome factors. Accordingly, the model was tested so that it could contribute to knowledge development. The level of theory was a situation- relating theory or predictive theory. Thus, this current study contributed new knowledge useful in explaining health-related quality of life in Thai Heart failure patients.

CHAPTER VI

CONCLUSION

Summary of the study

The purpose of this study was to examine the causal relationship among bio-physiological status, social support, symptom status, functional status, general health perception, and health-related quality of life (HRQOL) in Thai heart failure patients. Wilson and Cleary's Health-Related Quality of Life Conceptual Model (Reprinted with permission by the Journal of the American Medical Association, 1995) was used as the conceptual framework in this study.

The Sample and Data collection

A descriptive correlation, cross-sectional research design was used to test a causal relationship of HRQOL in Thai heart failure patients. Simple random sampling was used to identify the subjects. The subjects consisted of 422 Thai heart failure patients from nine government hospitals across all parts of Thailand. The data collection was performed between March 2007 and August 2007.

Instruments used in this study were the Personal Information Questionnaire, the personal medical record sheet for LVEF, the ENRICHD Social Support Instrument (ESSI) Thai version (Lortajakul, 2006), the Cardiac Symptom Survey (CSS) Thai version (Lortajakul, 2006), the NYHA functional classification, a 100-mm horizontal Visual Analogue Scale of General Health Perception, and the Minnesota Living with Heart Failure Questionnaire (MLHFQ). The back-translation technique was used to assure the accuracy of the translation for the ENRICHD Social Support Instrument (ESSI) Thai version and the

Cardiac Symptom Survey (CSS) Thai version by Lortajakul (2006). The MLVHF was granted by The Regent of the University of Minnesota, (2006) and the back translation technique was developed by the researchers. The validity and reliability of the instruments were tested. A confirmatory factor analysis was conducted to determine construct validity and to test hypothesized measurement model of the instruments. Finally, AMOS version 7 was used to examine the causal model.

Research Findings

1. Sample characteristics

The subjects consisted of 145 males (34.4 %) and 277 females (65.6%). The age of the subjects ranged from 18 to 92 years, and the mean age was 58.47 years. Most of the subjects (64.7 %) had graduated from elementary education and 17.5% did not go to school. More than half of the subjects were married (66.6%), and had monthly earnings of 1,000 – 5,000 baht (69 %). Nearly half of the subjects (47.9 %) reported they did not work or only did house work. Approximately all of the subjects (95.7 %) were Buddhists.

Approximately half of the subjects (54.3 %) had no other health problems, while 20.4 % had hypertension and 7.8 % reported diabetes mellitus. About 11.8 % had both hypertension and DM. About two-third of the subjects (32.7%) were diagnosed with heart failure within the past 1 year, while 26.5 % had been diagnosed between 1 year to 3 years previously, and only 2.4 % were diagnosed more than 20 years ago. The two most common etiologies of heart failure were coronary artery disease (24.2%) and valvular heart disease (22.5%). However, 28.9 % of participants had no defined etiology. Fatigue or feeling overly tired was the most frequent presenting symptom in this study (78.4%).

Participants in this study reported low symptom distress, moderate to high social support and moderated general health perception. Most of the participants (80.6%) reported LVEF of more than 40%. While 56.3 % were NYHA functional class III and IV. It had statistically significant different between men and women (F =1.813, p <.05), and marital status (F =1.88, p <.05) in perceive social support. In addition, current study also indicated that HRQOL was significantly different between marital status (F = 2.284, p <.05), religion (F = 2.142, p <.05), and occupation (F = 1.982, p <.05). However, it was inconsistence with previous studies that gender and age was not different in perceive HRQOL.

2. Causal model of health-related quality of life in heart failure patients

The overall model of health-related quality of life in Thai heart failure patients was fitted to the sample data. The overall goodness of fit indices were χ^2 = 19.87, df = 13, χ^2 /df (1.53), p = 0.10, GFI = 0.99, AGFI = 0.97, and RMSEA = 0.04. Bio-physiological status, social support, symptom status, functional status, and general health perception explained approximately 58% of the variance in overall health-related quality of life. The findings of causal relationship testing of the overall model were as follows:

2.1 Bio-physiological status (LVEF) had a positive indirect effect on HRQOL through functional status and general health perception (β = 0.16, p > .0001). It had a statistically significant negative direct effect on functional status (β = -0.34, p < 0.05). It also had a negative indirect effect on functional status through symptom status (β = - 0.03, p < 0.05), while it had a positive indirect effect on general health perception (β = 0.13, p < 0.05). However, bio-physiological status (LVEF) had not statistically significant effect on symptom status (β = - 0.08, p > 0.05).

2.2 Social support had a negative direct effect on symptom status (β = - 0.25,

$p < 0.05$), but had a significantly positive direct effect (β = 0.19, $p < 0.05$) and indirect effect (β = 0.09, $p < 0.05$) on general health perception. While Social support had a negative direct effect on HRQOL (β = -.17, $p = 0.05$), it also had a positive indirect effect on HRQOL (β = 0.21, $p= 0.05$). However, total effect of social support on HRQOL was a significant positive effect (β = 0.04, $p = 0.05$). At the same time, social support had a statistically non significant direct effect on functional status (β = -0.02, $p> 0.05$).

2.3 Symptom status had a positive direct effect on functional status (β = 0.45, $p < 0.05$), but it had a negative direct effect on general health perception (β = - 0.27, $p < 0.05$) and HRQOL (β = -0.48, $p < 0.05$). It also had a negative indirect effect on general health perception (β = -0.13, $p < 0.05$) and HRQOL (β = -0.21, $p < 0.05$). The total effect of symptom status on functional status was 0.45 ($p < 0.05$), on general health perception was -0.40 ($p < 0.05$), and - 0.69 for total effect of symptom status on HRQOL.

2.4 Functional status (NYHA classification) had a negative direct effect on general health perception (β = - 0.28 $p < 0.05$) and HRQOL (β = -0.25, $p < 0.05$). It had a negative indirect effect on HRQOL (β = - 0.07, $p < 0.05$). The total effect of functional status on HRQOL was in a negative direction (β = -0.32, $p < 0.05$).

2.5 General health perception had a positive direct effect on HRQOL (β = 0.24, $p < 0.05$)

Implications and Recommendations

The implications and recommendations of this study focused on the implications for nursing practice, nursing education, nursing research, health policy and recommendations for further studies.

1. Implications of research findings

1.1 Implications for practice. The findings of this study indicate the following:

1.1.1 Symptoms of heart failure were found to have the strongest effect on health related quality of life in heart failure patients. Nurses should encourage heart failure patients to evaluate their abnormal symptoms regularly, monitoring side effects of drugs, and identify early signs and symptoms of heart failure. Medication adherence, life style modification (e.g. consuming a low salt diet, and limiting fluid intake) can prevent exacerbation of heart failure. If symptoms of heart failure occurred, intervention should be targeted to reduce the frequency and severity of the symptom. Effective interventions should be emphasized to improve heart failure patients' HRQOL. With regard to the long term care of heart failure patients, a multidisciplinary health care team would be appropriate for heart failure management. Cardiac rehabilitation programs for heart failure patients may be most useful in symptom prevention. Nurses should support and facilitate heart failure patients to address their symptom status which will turn to improve functional status and also improved their HRQOL.

1.1.2 To maintain functional status or improve functional ability of heart failure is important. Heart failure can perform their normal activity and/or self-care activity will reduce heart failure symptom, improve their general health perception and also turn to in crease their HRQOL. Although, social support was not affected functional status (NYHA) directly, it could help reduce frequency and severity of physical and psychological symptom in heart failure patients. In additional decrease symptom distress will also improve functional status in heart failure patients. Thus, the indirect effect of social support on functional status through symptom status should be reconsidered when developing nursing interventions. Nursing intervention should be conducted by add appropriated social support to reduce

symptom or prevent symptom of heart failure rather than developed social support intervention for improving functional status directly. Most of cardiac rehabilitation program supported by health care provider always include physical exercise which also reported its effectiveness if heart failure patients can regular done it. In considering, symptoms of heart failure always take heart failure from this appropriated intervention.

Although social support could not predicted functional status, it may be influencing by some mediator or/and mediator variable. Current study also found that gender and marital status was significant deferent in perception of social support. Therefore, nursing intervention should be more concern about these factors before develop effective social support intervention to enhance functional status in heart failure patients. Furthermore, functional status was not limited with symptom of heart failure but also with the old age. Therefore, support heart failure to restore their functional ability should be reconsidered with age limitation. Support that assists heart failure patients to continue working will be more important in younger heart failure patients than in older.

1.1.3 Functional status has both a direct and indirect effect on HRQOL. Although, the NYHA classification is commonly used to define the functional status of heart failure patients, nurses should carefully determine the level of NYHA functional class of heart failure. NYHA classification as determined from the perspective of the nurse may be different from the patient's perspective. This study used patients perspective to determine heart failure functional status, thus interventions for improvement of functional ability of heart failure patients will be most effective if it has been determined by heart failure patients. For example, physical exercise is recommended to improve physical function and improve health in cardiac patients, but it important to advise only the appropriate kind of exercise in heart failure patients. Furthermore, this kind of exercise should be accepted by patients.

Considering functional status was limited by heart failure symptom. Some heart failure patients do not want to do any thing, not only because of physical limitations, but because of psychological problems such as depression, anxiety, feeling a loss of control over their lives or not confident to do anything. Some cannot perform their functional ability (e.g. normal activity, working role, social role) because of their physical limitation from symptom of heart failure, medical side effect or other treatments effect. Finally, functional status decreased from heart failure make them feel of burden. Thus intervention to improve HRQOL in heart failure patients which focus on increase functional status should be developed by integrated activity to reduce symptom status and increase positive perceive health perception increase or confident in their ability.

2. **Implications for education**

The findings in this study suggest bio-physiological status (LVEF), social support, symptom status, functional status (NYHA), and general health perception influence health-related quality of life (HRQOL) in heart failure patients. Nursing curricula in the field of adult nursing should include the causal model of health related quality of life for heart failure patients based on Wilson and Cleary's Health-Related Quality of Life Conceptual Model. This will strong support the holistic approach in nursing. All bio-psycho-social concepts affected HRQOL in heart failure have to integrate in nursing process.

3. Implications for further research

Based on the results of this study, suggestions for future research are as follows:

3.1 Selecting variables for study as proposed in the causal model of HRQOL in Thai heart failure patients is recommended to further develop nursing science. The variables include bio- physiological status, clinical status, and socio-economic. The causal model of health related quality of life could use for guiding further study in other health problem.

3.2 In order for the causal model to be generalizable, replication studies should be conducted in diverse settings and with diverse populations. Suggesting from results of this study, some demographic characteristic of heart failure patients such as gender, age, and marital status should be incorporated in further study of HRQOL in heart failure patients. Model testing in sub group of heart failure and compare the tested model between, men: women; younger adult: older adult should be developed.

3.3 An intervention study to promote HRQOL in heart failure should be developed. The new intervention should be incorporated all bio-psycho-social factors effect on HRQOL which proposed in a causal model of HRQOL in heart failure. The magnitude and directional of their effect on HRQOL should be reconsidered to improve some current intervention and also in new intervention.

3.4 In considering, the perception of social support was different in age, gender, marital status. Thus further study, the causal model of HRQOL should develop to compare between mediator variable between duration of age (e g. younger adult, adult, and older adult), gender (male and female), and different marital status.

3.5 The interaction of some items in MLHFQ which asked about the perception of normal physical activity limited by heart failure symptom such as sexual ability. The limitation of sexual activity will be caused by old age and also by symptom of heart failure. Thus, the items interaction in MLHFQ should be reconsideration in further study used MLHFQ to determine HRQOL in heart failure patients.

4. **Implications for health care policy**

Health policy in Thailand focuses on health promotion and prevention of chronic health problems, especially cardiovascular disease. In addition, an enhanced Health-Related Quality of Life is a desired outcome for patients with chronic health problems. The findings

of this study showed that symptom status, biological/ physiological, functional status, and general health perception effected HRQOL in heart failure patients. Thus, health care policies should support health related quality of life in heart failure patients by promoting nurse specialists in cardiology for their increased abilities in investigational methodologies, clinical management skills and ability to prevent patients with cardiac disease from going on to develop heart failure. From this knowledge, a health promotion program supported by the Ministry of Public Health should be developed to enhance functional ability in not only normal populations, but also people with chronic illnesses such as heart failure. In considering, functional status in heart failure patients was limited not only with their symptom distress but also with old age, thus health promotion programs should be tailored to fit specific chronic illnesses.

According to higher social support provide directly lower HRQOL found in this study, health policy maker should be reconsider not only sources, kind, and time for supporting but also concern with mediator variables such as gender and marital status in perceive social support. Public policy to enhance good family relationship, decrease rate of divorce and separate. Furthermore, the socio-economic and cultural effect the perception of heart failure patients in receive appropriated social support should be explore in both current and new health promotion project which aim to enhance HRQOL.

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APPENDICES

APPENDIX A

HUMAN SUBJECT APPROVEAL

ที่ ชร 0027.102/ 6047

เอกสารรับรองโครงการวิจัย

โดย

คณะกรรมการพิจารณาด้านจริยธรรมในการศึกษาวิจัยทางชีวเวชศาสตร์

โรงพยาบาลเชียงรายประชานุเคราะห์

คณะกรรมการพิจารณาด้านจริยธรรมในการศึกษาวิจัยทางชีวเวชศาสตร์ โรงพยาบาลเชียงรายประชานุเคราะห์ ขอรับรองว่า

โครงการวิจัย : โมเดลเชิงสาเหตุของคุณภาพชีวิตผู้ป่วยภาวะหัวใจวาย
(A Causal Model of Health-Related Quality of Life in Thai Heart Failure Patients)

ของ : นางสาวพวงผกา กรีทอง

สังกัด : คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

ได้รับการพิจารณาแล้ว เห็นว่าไม่มีการล่วงละเมิดสิทธิ สวัสดิภาพ และไม่ก่อให้เกิดภยันตรายแก่อาสาสมัครที่ยินยอมเข้าร่วมในโครงการวิจัย

จึงเห็นสมควรให้ดำเนินการวิจัยในขอบข่ายของโครงการวิจัยที่เสนอได้ ตั้งแต่วันที่ 19 กุมภาพันธ์ 2550 จนถึงวันที่ 20 กุมภาพันธ์ 2551

ลงนาม.....
(แพทย์หญิงสายสุนี ภูมิวิชชุเวช)
ประธานกรรมการพิจารณาด้านจริยธรรม
ในการศึกษาวิจัยทางชีวเวชศาสตร์

ลงนาม.....
(นายแพทย์สมบูรณ์ศักดิ์ ญาณไพศาล)
ผู้อำนวยการ
โรงพยาบาลเชียงรายประชานุเคราะห์

เอกสารรับรองจริยธรรมทางการวิจัย

เอกสารฉบับนี้ เพื่อแสดงว่า โครงการวิจัย

เรื่อง โมเดลเชิงสาเหตุของคุณภาพชีวิตผู้ป่วยที่มีภาวะหัวใจวาย

ผู้วิจัย คือ นางสาวพวงผกา กรีทอง

สถาบัน/หน่วยงาน นิสิตชั้นปริญญาดุษฎีบัณฑิต คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

ได้ผ่านการพิจารณาจากคณะกรรมการจริยธรรมทางการวิจัย โรงพยาบาลขอนแก่น แล้ว และเห็นว่าผู้วิจัยต้องดำเนินการตามโครงการวิจัยที่ได้กำหนดไว้แล้ว หากจะมีการปรับเปลี่ยนหรือแก้ไขใด ๆ ควรผ่านความเห็นชอบหรือแจ้งต่อคณะกรรมการจริยธรรมทางการวิจัยอีกครั้ง

ออกให้ ณ วันที่ 6 **เดือน** มีนาคม **พ.ศ.** 2550

ลงชื่อ .....

(นายสมศักดิ์ ประฏิภาณวัตร)

นายแพทย์ 8

ประธานกรรมการจริยธรรมทางการวิจัย

โรงพยาบาลขอนแก่น

ลงชื่อ .....

(นายวิทยา จารุพูนผล)

ผู้อำนวยการโรงพยาบาลขอนแก่น

คณะกรรมการจริยธรรมวิจัยในมนุษย์ รพ.ขอนแก่น

ลำดับที่ 13/02 /2550

คณะกรรมการจริยธรรมทางการวิจัย โรงพยาบาลขอนแก่น

สำนักงาน: งานวิจัยและพัฒนาระบบสุขภาพ กลุ่มพัฒนาระบบบริการสุขภาพ โรงพยาบาลขอนแก่น

ถนนศรีจันทร์ อำเภอเมือง จังหวัดขอนแก่น 40000

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คณะกรรมการจริยธรรมเพื่อการวิจัยสถาบันโรคทรวงอก

กรมการแพทย์

กระทรวงสาธารณสุข

โครงการวิจัย : โมเดลเชิงสาเหตุของคุณภาพชีวิตผู้ป่วยที่มีภาวะหัวใจวาย

ผู้ดำเนินการวิจัย : นางสาวพวงผกา กรีทอง

สถานที่ทำการวิจัย : สถาบันโรคทรวงอก

คณะกรรมการจริยธรรมเพื่อการวิจัยสถาบันโรคทรวงอก กรมการแพทย์ กระทรวงสาธารณสุข อนุมัติในแง่จริยธรรมให้ดำเนินการศึกษาวิจัยเรื่องข้างต้นได้

..... ประธานกรรมการ

(นายแพทย์ชูศักดิ์ เกษมศานต์)

..... เลขานุการ

(นายแพทย์ธรรมรัฐ ฉันทแดนสุวรรณ)

รับรองวันที่ 16 มีนาคม 2550

บันทึกข้อความ

ส่วนราชการ โรงพยาบาลชลบุรี กลุ่มงานฝึกอบรมพัฒนาบุคลากรและการวิจัย โทร. 1049

ที่ ชบ. 0027.102/ 074 **วันที่** ๒๙ มีนาคม 2550

เรื่อง อนุมัติให้ดำเนินการวิจัย

....

เรียน หัวหน้ากลุ่มงาน หัวหน้ากลุ่มการพยาบาล

ตามที่ นางสาวพวงผกา กรีทอง นิสิตชั้นปริญญาดุษฎีบัณฑิต คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย มีความประสงค์เก็บรวบรวมข้อมูลเพื่อทำวิจัย เรื่อง "โมเดลเชิงสาเหตุของคุณภาพชีวิตผู้ป่วยที่มีภาวะหัวใจวาย" (A Causal Model of Health-Related Quality of life in Thai Heart Failure Patients) นั้น

โรงพยาบาลชลบุรี พิจารณาแล้วเห็นควรสนับสนุนให้ดำเนินการวิจัยตามขอบเขตที่กำหนดได้ โดยมีข้อเสนอแนะ คือ

1. ประสานงานกับหน่วยงานที่เกี่ยวข้องในการเก็บข้อมูล
2. ส่งสำเนางานวิจัยจำนวน 1 เล่ม ให้กับโรงพยาบาลชลบุรี

จึงเรียนมาเพื่อโปรดทราบ

(นายแพทย์ชาตรี ตันติยวรงค์)
ผู้อำนวยการ โรงพยาบาลชลบุรี

เลขที่ใบรับรอง **064/2550**

คณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์และการใช้สัตว์ทดลองในการวิจัย
กลุ่มวิทยาศาสตร์สุขภาพ จุฬาลงกรณ์มหาวิทยาลัย

โครงการวิจัย : โมเดลเชิงสาเหตุของคุณภาพชีวิตผู้ป่วยที่มีภาวะหัวใจวาย
(A CAUSAL MODEL OF HEALTH-RELATED QUALITY OF LIFE IN HEART FAILURE PATIENTS)

ผู้วิจัยหลัก : นางสาวพวงผกา กรีทอง นิสิตระดับศูนย์บัณฑิต

หน่วยงาน : คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

คณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์และการใช้สัตว์ทดลองในการวิจัย กลุ่มวิทยาศาสตร์สุขภาพ จุฬาลงกรณ์มหาวิทยาลัย

☐ อนุมัติในแง่จริยธรรมให้ดำเนินการศึกษาวิจัยเรื่องข้างต้นได้

.....ประธาน
(รองศาสตราจารย์ นายแพทย์ปรีดา ทัศนประดิษฐ์)

.....เลขานุการ
(ศาสตราจารย์ นายแพทย์สุรศักดิ์ ฐานีพานิชสกุล)

รับรองวันที่ 1 พฤษภาคม 2550 วันหมดอายุ 6 ตุลาคม 2550

No.ท.85

Ethics Committee

For

Researches Involving Human Subjects, the Bangkok Metropolitan Administration

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Title of Project	:	A Causal Model of Health-Related Quality of Life in Heart Failure Patients
Registered Number	:	0036.50
Principal Investigator	:	Miss Phuangphaka Krethong
Name of Institution	:	Kuakarun College of Nursing

The aforementioned project has been reviewed and approved by Ethics Committee for Researches Involving Human Subjects, based on the Declaration of Helsinki.

.....Chairman

(Mr. Manoj Leethochawalit)

Deputy Permanent Secretary for BMA

DATE OF APPROVAL 20 JUN 2007

APPENDIX B

CONSENT FORM AND THE PARTICIPANT

ใบยินยอมของผู้มีส่วนร่วมในการวิจัย

(Informed Consent Form)

ชื่อโครงการ โมเดลเชิงสาเหตุของคุณภาพชีวิตผู้ป่วยที่มีภาวะหัวใจวาย
เลขที่ผู้มีส่วนร่วมในการวิจัย……..

ข้าพเจ้าได้รับทราบข้อมูลจากผู้วิจัย ชื่อ นางสาวพวงผกา กรีทอง นิสิตปริญญาเอก หลักสูตรพยาบาลศาสตรดุษฎีบัณฑิต คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ถึงวัตถุประสงค์ ลักษณะ และแนวทางการวิจัย รวมทั้งรับทราบถึงผลดีและความเสี่ยงที่อาจจะเกิดขึ้น โดยข้าพเจ้าได้ซักถาม ทำความเข้าใจเกี่ยวกับการศึกษาดังกล่าว เป็นที่เรียบร้อยแล้ว

ข้าพเจ้ายินดีเข้าร่วมการศึกษาครั้งนี้โดยสมัครใจ และมีสิทธิที่จะขอออกจากการเข้าร่วมการวิจัยนี้ได้ทุกเวลาโดยไม่จำเป็นต้องแจ้งเหตุผล ซึ่งไม่เกิดผลเสียใดๆต่อข้าพเจ้าและครอบครัวโดยผู้วิจัยรับรองว่าจะเก็บข้อมูลที่ได้จากการถอดเทปและลงรหัสไว้เป็นความลับ เก็บรักษาไว้ในที่ปลอดภัยและจะทำลายข้อมูลดังกล่าวเมื่อเสร็จสิ้นการใช้ข้อมูลตามวัตถุประสงค์ของการวิจัยและจะเปิดเผยเพียงผลการวิจัยโดยไม่มีข้อมูลส่วนบุคคลแต่อย่างใด

หากข้าพเจ้ามีข้อคำถามใดๆที่เกี่ยวข้องในการวิจัยดังกล่าว ข้าพเจ้าสามารถติดต่อสอบถามผู้วิจัยซึ่งอาศัยอยู่ ณ บ้านเลขที่ 245/1 หมู่ 2 ซอยพุทธบูชา 39 ถนนพุทธบูชา แขวงบางมด เขตทุ่งครุ กรุงเทพมหานคร 10140 โทรศัพท์ 02-870-7247 โทรศัพท์เคลื่อนที่ 08-9921-3646 ข้าพเจ้ายินดีเข้าร่วมการศึกษานี้ภายใต้เงื่อนไขที่ได้ระบุไว้แล้วในข้างต้น

.....……	…….....
สถานที่ / วันที่	( )
	ลงนามผู้มีส่วนร่วมในการวิจัย
……..	.....
สถานที่ / วันที่	(นางสาวพวงผกา กรีทอง)
	ลงนามผู้วิจัยหลัก
…….	.....
สถานที่ / วันที่	( )
	ลงนามพยาน

Informed Consent Form

Title: A Causal Model of Health-Related Quality of Life in Heart Failure Patients
Code number: Participant…….

I was informed by the researcher, Phuangphaka Krethong, Ph.D. student, Doctor of Philosophy in Nursing Science Program, Faculty of Nursing, and Chulalongkorn University about the research objectives, characteristics, procedures, as well as benefits, risks or harm that may occur in this study. I already ask questions regarding the study until I thoroughly understand it.

I am willing to participate in this study. I know that I have a right to withdraw from the study at any time without providing reasons to the researcher. This will cause no negative effect on me or my family. The researcher will keep all copies of the transcript and coding in a locked cabinet and erased them after the data is no longer used for the purpose of the study, and will present only the findings of the study and no personal information.

If I have any question regarding the study, I can contact the researcher at 245/1 M. 2 Budabucha 39 Budabucha Road, Bangmod, Thongkru, Bangkok Thailand 10140, home phone 02-870-7247, Mobile phone 08-9921-3646.

I am willing to participate in this study under the above conditions.

---------- ----------
( )
Place / Time Participant signature

---------- ----------
(Miss. Phuangphaka Krethong)
Place / Time Main researcher signature

---------- ----------
(……)
Place / Time Witness signature

ข้อมูลสำหรับประชากรตัวอย่างหรือผู้มีส่วนร่วมในการวิจัย

(Participant information sheet)

1. ชื่อโครงการวิจัย โมเดลเชิงสาเหตุของคุณภาพชีวิตผู้ป่วยที่มีภาวะหัวใจวาย

2. ชื่อผู้วิจัย นางสาวพวงผกา กรีทอง นิสิตคณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

3. สถานที่ปฏิบัติงาน วิทยาลัยพยาบาลเกื้อการุณย์ 131/5 ถนนขาว แขวงสามเสน เขตดุสิต กทม. 10300

โทรศัพท์ที่ทำงาน 02-241-6500

สถานที่อยู่ 245/1 หมู่ 2 พุทธบูชา 39 แขวงบางมด เขตทุ่งครุ กทม. 10140

โทรศัพท์ที่บ้าน 02-870-7247 โทรศัพท์เคลื่อนที่ 089-921-3646

E-mail: phaka47@yahoo.com

4. คำชี้แจงของผู้วิจัย ข้าพเจ้าชื่อนางสาวพวงผกา กรีทอง นักศึกษาปริญญาเอก สาขาพยาบาลศาสตร์ คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย กำลังสนใจและทำการวิจัยเกี่ยวกับคุณภาพชีวิตของผู้ป่วยภาวะหัวใจวาย อนึ่ง วัตถุประสงค์ของเอกสารฉบับนี้จัดทำเพื่อบอกเล่าเกี่ยวกับข้อมูลของผู้ทำวิจัยและการดำเนินการวิจัย ซึ่งท่านจะสามารถเข้าใจและตัดสินใจแสดงความประสงค์ในการเข้าร่วมหรือไม่เข้าร่วมในการวิจัยครั้งนี้ได้

4.1 โครงการวิจัยนี้มุ่งค้นหาและอธิบายเกี่ยวกับคุณภาพชีวิตของผู้ป่วยที่มีภาวะหัวใจวาย โดยมี วัตถุประสงค์ของการวิจัย เพื่ออธิบายปัจจัยที่เป็นสาเหตุที่ส่งผลต่อคุณภาพชีวิตของผู้ป่วยที่มีภาวะหัวใจวายและเพื่อพัฒนาความรู้และแบบจำลองเชิงสาเหตุของคุณภาพชีวิตของผู้ป่วยที่มีภาวะหัวใจวาย

4.2. ประโยชน์ของการวิจัยนี้จะช่วยให้พยาบาลและบุคลากรด้านสุขภาพเข้าใจถึงปัจจัยทั้งทางตรงและทางอ้อมที่มีผลต่อคุณภาพชีวิตของผู้ป่วยที่มีภาวะหัวใจวาย และผลการวิจัยช่วยเป็นพื้นฐานและแนวทาง สำหรับบุคลากรทางด้านสุขภาพ,ทีมการรักษาพยาบาล และผู้ที่มีบทบาทในการตัดสินใจวางแผนในการให้การสนับสนุน ช่วยเหลือ และยกระดับคุณภาพชีวิตของผู้ป่วยที่มีภาวะหัวใจวาย โดยนำไปเป็นแนวทางในการพัฒนางานวิจัย และจัดรูปแบบกิจกรรมทางการพยาบาลที่เหมาะสมเพื่อเพิ่มระดับคุณภาพชีวิตให้ผู้ป่วยที่มีภาวะหัวใจวาย

4.3 .การวิจัยนี้เป็นการวิจัยเชิงปริมาณ ดำเนินการเก็บข้อมูลจากผู้ป่วยที่ได้รับการวินิจฉัยจากแพทย์ว่าเป็นโรคหัวใจและเคยมีภาวะหัวใจวาย มีอายุตั้งแต่ 18 ปีขึ้นไป สามารถสื่อสารด้วยภาษาไทยได้ และ ยินดีให้ความร่วมมือในการศึกษาวิจัยครั้งนี้ จะไม่ทำการเก็บรวบรวมข้อมูลในผู้ป่วยที่ได้รับการวินิจฉัยว่าเป็นโรคกล้ามเนื้อหัวใจตายในบริเวณกว้างภายใน 2 เดือนที่ผ่านมา (เพราะอาจเกิดหัวใจหยุดเต้นอย่างเฉียบพลันได้) เป็นผู้ที่กำลังมีอาการหอบเหนื่อย หายใจลำบาก เจ็บหน้าอก อ่อนเพลียมาก ได้รับการวินิจฉัยว่าเป็นโรคมะเร็ง โรคไตวาย โรคภูมิคุ้มกันบกพร่อง(เอดส์) และผู้ที่มีสติสัมปชัญญะไม่สมประกอบ หรือการรับรู้ผิดปกติ

4.4 สถานที่เก็บรวบรวมข้อมูล คือแผนกผู้ป่วยนอกโรคหัวใจ ของโรงพยาบาลเชียงรายประชานุเคราะห์ โรงพยาบาลสรรพสิทธิประสงค์ โรงพยาบาลศูนย์ขอนแก่น โรงพยาบาลชลบุรี โรงพยาบาลราชบุรี โรงพยาบาลศูนย์สุราษฎร์ธานี โรงพยาบาลศูนย์ตรัง สถาบันโรคทรวงอก และวิทยาลัยแพทยศาสตร์กรุงเทพมหานครและวชิรพยาบาล

4.5 หลังได้รับอนุมัติให้เก็บรวบรวมข้อมูลจากโรงพยาบาลและสถาบันต่าง ๆ แล้ว ข้าพเจ้าจะขออนุญาติหัวหน้าหอผู้ป่วยนอกโรคหัวใจ เพื่อตรวจสอบเวชระเบียนของผู้ป่วยที่มารับการตรวจติดตามผลการรักษาตามนัด เพื่อศึกษาและบันทึกผลการวินิจฉัยโรค โรคร่วมอื่น ๆ การรักษาที่ได้รับในขณะนั้น และผลการตรวจพิเศษต่าง ๆ และคัดเลือกผู้ป่วยที่มีคุณสมบัติตามเกณฑ์มาเป็นผู้มีส่วนร่วมในการวิจัย และข้าพเจ้าจะสอบถามความสมัครใจก่อนให้ผู้มีส่วนร่วมใน

การวิจัยตอบแบบสอบถามอีกครั้ง

4.6 ผู้มีส่วนร่วมในการวิจัยจะต้องตอบแบบสอบถามเกี่ยวกับ ข้อมูลส่วนบุคคล แบบวัดการสนับสนุนทางสังคม แบบสำรวจอาการโรคหัวใจ แบบประเมินความสามารถในการปฏิบัติกิจกรรม แบบวัดการรับรู้ภาวะสุขภาพโดยรวม และแบบวัดคุณภาพชีวิต โดยใช้เวลาในการตอบแบบสอบถามประมาณ 15-30 นาที

4.7 การรักษาความลับของผู้มีส่วนร่วมในการวิจัย โดยจะไม่ระบุชื่อผู้มีส่วนร่วมฯ ในแบบสอบถาม ข้อมูลที่ได้จากแบบสอบถามจะนำไปวิเคราะห์โดยการลงรหัส และวิเคราะห์ในภาพรวมไม่แยกเฉพาะราย แบบสอบถามจะถูกจัดเก็บไว้ในที่ปลอดภัยและเป็นความลับ ผลการวิจัยจะนำเสนอในภาพรวม

4.8 ผู้มีส่วนร่วมในการวิจัยสามารถปฏิเสธหรือถอนตัวจากโครงการวิจัยนี้ได้ตลอดเวลา โดยจะไม่มี ผลเสียใดๆ ต่อผู้มีส่วนร่วม ฯ

4.9 การวิจัยครั้งนี้ไม่มีการจ่ายค่าตอบแทนแก่ผู้มีส่วนร่วมในการวิจัย

4.10 ท่านสามารถซักถามเพิ่มเติมได้ก่อนลงนามในใบยินยอม โดยข้าพเจ้ายินดีตอบคำถามในสิ่งที่ท่านสนใจและเกี่ยวข้องในการวิจัยครั้งนี้ ลายมือชื่อของท่านจะแสดงให้ทราบว่าท่านได้อ่านข้อความในเอกสาร รับทราบและตัดสินใจเข้าร่วมในการวิจัยครั้งนี้แล้ว หากท่านมีคำถามหรือ ข้อสงสัย รวมถึงประสงค์ที่จะถอนตัวจากการวิจัยครั้งนี้ ท่านสามารถซักถามหรือแจ้งความต้องการของท่านแก่ผู้วิจัยได้ตลอดเวลา โดยติดต่อได้ทางหมายเลขโทรศัพท์เคลื่อนที่ 08-9921-3646

Participant Information Sheet

1. Title: A Causal Model of Health-Related Quality of Life in Heart Failure Patients

2. Researcher name: Miss. Phuangphaka Krethong

3. Workplace: Kuakaroon Collect of Nursing, 131/5 Khao Road, Samsen, Dusit, Bangkok

Tel. 02-241-6500

Home: 245/1 Mo. 2 Bangmod, Thongkru, Bangkok, 10140

Tel. 02-870-7247 Mobile phone: 089-921-3646 E-mail: phaka47@yahoo.com

4. Researcher's statement

I am a graduate student in nursing science at Chulalongkorn University, doing a doctoral dissertation on health-related quality of life in heart failure patients. The purpose of this information is to tell you about the researcher and to allow you to make a clear decision about whether you would like to participate or not.

4.1 This study focuses on the examination the causal relationships of factors related to health related quality of life in Thai heart failure. The objectives of the study are to examine the causal relationships among biological and physiological variable (LVEF), social support, symptom status, functional status (NYHA), general health perception, and HRQOL in Thai heart failure patients. And to develop and test a causal model of health related quality of life derived from Wilson and Cleary's Health-Related Quality of Life Conceptual Model in Thai heart failure patients.

4.2. The benefits of this study will help nurse and health care provides to understand the direct and indirect effect of the predictors factors on HRQOL in Thai heart failure patients. The finding will provide a scientifically-based guideline for health care providers, multidisciplinary teams and policy makers to provide suitable support and guidance to enhance HRQOL in Thai heart failure patients. Nurse will be able to use the finding of this study to develop research and nursing intervention to help heart failure patients to improve their HRQOL

4.3 Quantitative approach will be employed in this study. The participants are Thai patients who are diagnosed with heart failure. Age equal or more than 18 years old, and has no dyspnea

and/or severe fatigue. Able to communicate in Thai with researcher and willing to participate in this study. The patients will be excluded from the study if they have a large myocardial infarction during the preceding 8 weeks. (They may be have sudden cardiac arrest.) and patients who has others life-threatening disease, such as cancer, renal failure, HIV/AIDs.

4.4 Research setting are cardiac out patient Chiangraipachanukot Hospital, Suratarni Hospital, Trung Hospital, Rajbury Hospital, Khonkan Hospital, Cholbury Hospital, Chest disease institution, and Medical College of Bangkok Metropolitan and Vajira Hospital.

4.5 After get permission from research settings, researcher looking for heart failure patients who meet criteria from patients' data record. Researcher also record patients' diagnosis, medication used, cardiac examination (LVEF)

4.6. Participants will be asked to complete the questionnaires about personal data, social support, cardiac symptom survey, functional status, general health perception and living with heart failure questionnaire. It will take 15-30 minute for this process.

4.7 It will be no the participant's name on each questionnaire. There coded data and questionnaires will be kept in the locked cabinet. Publication will not contain information that identified name of the participants.

4.8 The participants can withdraw from the study at any point of time without negative effect on the participants and their families.

4.9 Each participant has not received any payment.

4.10 The researcher will be available for all participants 24 hours when they have some questions regarding the study. They can contact the researcher by mobile phone: 08-9921-3646.

APPENDIX C

LIST OF EXPERTS

LIST OF EXPERTS

1. Professor Dr. Somchit Hanucharurnkul Department of Nursing,
   Faculty of Medicine Ramathibodi Hospital, Mahidol University
2. Assistant Professor Dr. Wantana Maneesriwongul, Department of Nursing,
   Faculty of Medicine Ramathibodi Hospital Mahidol University
3. Associate ProfessorDr. Saipin Kasemkitwatana,
   Faculty of nursing, Mahidol University
4. Assistant Professor Dr. Saovalug Jirathumkul
   Faculty of Nursing, Mahidol University
5. Associate Professor Atchara Tacharitpitak
   Thai Cardio-Thoracic Nurses Association.
6. Assistant Professor Dr. Usavadee Asadornwised
   Faculty of nursing, Mahidol University
7. Navin Surapakdee, MD, Medical college of Bangkok Metropolitan and
   Vajira Hospital
8. Kanogporn Jamsomboon, Chest Disease Institute
9. Kriengkrai Hengrussamee, MD. Chest Disease Institute
10. Susan J. Pressler, DNS, RN, FAAN, FAHA (Bennett), Professor
    Indiana University School of Nursing, Indianapolis, USA
11. Associate Professor Dr. Punchanlee Vasanasomsithi.
    Language Institute, Chulalong University
12. Assistant Professor Dr. Reongrudee Soonthornmanee.
    Language Institute, Chulalong University

APPENDIX D

INSTRUMENTS

แบบสอบถามในการวิจัย

แบบสอบถามฉบับนี้ ประกอบด้วยแบบสอบถาม 6 ส่วน คือ ข้อมูลส่วนบุคคล แบบสอบถามการได้รับการสนับสนุนทางสังคม แบบสอบถามเกี่ยวกับความถี่และความรุนแรงของอาการแสดงของโรคหัวใจ แบบสอบถามความสามารถในการปฏิบัติกิจกรรมต่าง ๆ แบบสอบถามการรับรู้ภาวะสุขภาพโดยรวม และแบบสอบถามเกี่ยวกับคุณภาพชีวิตของผู้ป่วยภาวะหัวใจวาย

ส่วนที่ 1 แบบสอบถามข้อมูลส่วนบุคคล

คำชี้แจง : โปรดเติมคำลงในช่องว่าง หรือทำเครื่องหมาย / หน้าข้อที่ตรงกับข้อมูลส่วนบุคคลของท่าน

1. อายุ ..... ปี
2. เพศ ☐ ชาย ☐ หญิง
3. สถานภาพสมรส ☐ แต่งงาน ☐ โสด ☐ หม้าย ☐ หย่า ☐ แยกกันอยู่ ☐ อื่น ๆ
4. ศาสนา ☐ พุทธ ☐ อิสลาม ☐ คริสต์ ☐ อื่น ๆ
5. ระดับการศึกษาสูงสุด
   - ☐ ประถมศึกษา
   - ☐ มัธยมศึกษา
   - ☐ อาชีวศึกษา/ประกาศนียบัตร
   - ☐ ปริญญาตรี
   - ☐ ปริญญาโท
   - ☐ ปริญญาเอก
   - ☐ ไม่ได้รับการศึกษา
6. อาชีพ
   - ☐ ไม่ได้ประกอบอาชีพ
   - ☐ นักศึกษา
   - ☐ รับจ้าง
   - ☐ ธุรกิจส่วนตัว
   - ☐ ค้าขาย
   - ☐ เกษตรกร/ทำสวน/ทำไร่
   - ☐ รับราชการ/รัฐวิสาหกิจ/พนักงานของรัฐ
   - ☐ อื่น ๆ ระบุ.....
7. รายได้ต่อเดือน
   - ☐ น้อยกว่า 5,000 บาท
   - ☐ 5,001-10,000 บาท
   - ☐ 10,001-20,000 บาท
   - ☐ 20,001- 30,000 บาท
   - ☐ มากกว่า30,000 บาท
8. ระยะเวลาของการเจ็บป่วยด้วยภาวะหัวใจวาย.....ปี.....เดือน.....วัน
9. โรคประจำตัวอื่น ๆ ☐ ไม่มี ☐ มี ระบุ.....

ส่วนที่ 2 แบบสำรวจอาการโรคหัวใจ

คำชี้แจง: กรุณาใส่เครื่องหมาย √ ลงในช่อง ☐ ที่ตรงกับความรู้สึกเกี่ยวกับอาการโรคหัวใจของท่าน ในช่วง 1 เดือน ที่ผ่านมา ท่านมีอาการดังกล่าวข้างล่างต่อไปนี้หรือไม่

ถ้าไม่มีอาการในข้อนั้นให้ตอบ 0 = ไม่มี ท่านไม่ต้องตอบในช่องการประเมินระดับความถี่และความรุนแรงของอาการ

แต่ถ้ามีอาการนั้นให้ตอบ 1 = มี และขอให้ท่านตอบระดับของความถี่และความรุนแรงของอาการนั้น ๆ ตามความรู้สึกของท่าน โดยทำครื่องหมาย X บนตัวเลขที่แสดงระดับตั้งแต่ 1 ถึง 10 โดย 1= น้อยที่สุด, จนถึง 10 = มากที่สุด

1. ในช่วง 1 เดือน ที่ผ่านมา ท่านมีอาการเจ็บหน้าอกหรือไม่ ☐ 0 = ไม่มี ☐ 1 = มี
   ถ้ามี โปรด X บนตัวเลขที่แสดงระดับจาก มีน้อยที่สุด(1)..... จนถึงมีมากที่สุด (10)
   ความถี่ 1___2___3___4___5___6___7___8___9___10
   ความรุนแรง 1___2___3___4___5___6___7___8___9___10
2. ในช่วง 1 เดือน ที่ ผ่านมา ท่านมีอาการหายใจขัดบ้างหรือไม่? ☐ 0 = ไม่มี ☐ 1 = มี
   ถ้ามี โปรด **X** บนตัวเลขที่แสดงระดับจาก มีน้อยที่สุด(1)..... จนถึงมีมากที่สุด (10)
   ความถี่ 1___2___3___4___5___6___7___8___9___10
   ความรุนแรง 1___2___3___4___5___6___7___8___9___10
3. ในช่วง 1 เดือนที่ผ่านมา ท่านรู้สึกอ่อนล้าหรือเหนื่อยมาก บ้างหรือไม่? ☐ 0 = ไม่มี ☐ 1 = มี
   ถ้ามี โปรด X บนตัวเลขที่แสดงระดับจาก มีน้อยที่สุด(1)..... จนถึงมีมากที่สุด (10)
   ความถี่ 1___2___3___4___5___6___7___8___9___10
   ความรุนแรง 1___2___3___4___5___6___7___8___9___10
4. ในช่วง 1 เดือนที่ผ่านมา ท่านรู้สึกหดหู่หรือเศร้าหมองอย่างมากหรือไม่? ☐ 0 = ไม่มี ☐ 1 = มี
   ถ้ามี โปรด X บนตัวเลขที่แสดงระดับจากไม่มี (0) มีน้อยที่สุด(1)..... จนถึงมีมากที่สุด (10)
   ความถี่ 1___2___3___4___5___6___7___8___9___10
   ความรุนแรง 1___2___3___4___5___6___7___8___9___10
5. ในช่วง 1 เดือนที่ผ่านมา ท่านมีปัญหาในการนอนหลับบ้างหรือไม่? ☐ 0 = ไม่มี ☐ 1 = มี
   ถ้ามี โปรด X บนตัวเลขที่แสดงระดับจาก มีน้อยที่สุด(1)..... จนถึงมีมากที่สุด (10)
   ความถี่ 1___2___3___4___5___6___7___8___9___10
   ความรุนแรง 1___2___3___4___5___6___7___8___9___10
6. ในช่วง 1 เดือนที่ผ่านมา ท่านมีอาการบวมที่ขาบ้างหรือไม่? ☐ 0 = ไม่มี ☐ 1 = มี
   ถ้ามี โปรด X บนตัวเลขที่แสดงระดับจาก มีน้อยที่สุด(1)..... จนถึงมีมากที่สุด (10)
   ความถี่ 1___2___3___4___5___6___7___8___9___10
   ความรุนแรง 1___2___3___4___5___6___7___8___9___10

7.ในช่วง 1 เดือน ที่ผ่านมา ท่านรู้สึกมีอาการใจสั่นหรือมีหัวใจเต้นเร็วมากหรือไม่? ☐ 0 = ไม่มี ☐ 1 = มี

ถ้ามี โปรด X บนตัวเลขที่แสดงระดับจาก มีน้อยที่สุด(1)..... จนถึงมีมากที่สุด (10)

ความถี่ 1___2___3___4___5___6___7___8___9___10

ความรุนแรง 1___2___3___4___5___6___7___8___9___10

8. ในช่วง 1 เดือน ที่ผ่านมา ท่านรู้สึกกังวลหรือเครียดไหม? ☐ 0 = ไม่มี ☐ 1 = มี

ถ้ามี โปรด X บนตัวเลขที่แสดงระดับจาก มีน้อยที่สุด(1)..... จนถึงมีมากที่สุด (10)

ความถี่ 1___2___3___4___5___6___7___8___9___10

ความรุนแรง 1___2___3___4___5___6___7___8___9___10

9. ในช่วง 1 เดือน ที่ผ่านมา ท่านมีอาการเบื่ออาหารบ้างหรือไม่? ☐ 0 = ไม่มี ☐ 1 = มี

ถ้ามี โปรด X บนตัวเลขที่แสดงระดับจาก มีน้อยที่สุด(1)..... จนถึงมีมากที่สุด (10)

ความถี่ 1___2___3___4___5___6___7___8___9___10

ความรุนแรง 1___2___3___4___5___6___7___8___9___10

10 ท่านยังมีอาการอื่นนอกเหนือจากที่ถามบ้างหรือไม่ ? ถ้ามี กรุณาท่านช่วยบอกให้ทราบด้วยว่าคือ

……..

……

ส่วนที่ 3 แบบสอบถาม การได้รับการสนับสนุนทางสังคม

คำชี้แจง โปรดอ่านข้อความแต่ละข้อ และ **X** ในช่องที่ตรงกับความรู้สึกของท่านมากที่สุด

ไม่มีเลย หมายถึง ท่านไม่เคยได้รับการสนับสนุนตามข้อความนั้นๆ เลยในความรู้สึกของท่าน

มีบ้างเล็กกน้อย หมายถึง ท่านเคยได้รับการสนับสนุนตามข้อความนั้นๆ บ้างเล็กน้อย

ปานกลาง หมายถึง ท่านเคยได้รับการสนับสนุนตามข้อความนั้นๆ เป็นบางครั้ง

เกือบตลอดเวลา หมายถึง ท่านเคยได้รับการสนับสนุนตามข้อความนั้นๆ บ่อยครั้งแต่ไม่ทุกครั้ง

ตลอดเวลา หมายถึง ท่านเคยได้รับการสนับสนุนตามข้อความนั้นๆ ทุกครั้งในความรู้สึกของท่าน

ข้อความ	ไม่มีเลย	เล็กน้อย	ปานกลาง	เกือบตลอดเวลา	ตลอดเวลา
1. คุณมีคนที่พร้อมจะรับฟังคุณในเวลาที่คุณต้องการหรือไม่ ?					
2. คุณมีคนที่พร้อมจะให้คำแนะนำที่ดีเวลาคุณมีปัญหาหรือไม่ ?					
3. คุณมีคนที่พร้อมจะให้ความรักคุณ และห่วงใยคุณหรือไม่ ?					
4. . คุณมีคนที่พร้อมจะช่วยคุณทำงานบ้านประจำวันหรือไม่ ?					
5. คุณสามารถวางใจใครสักคนที่จะพูดคุยเรื่องปัญหาต่าง ๆ หรือช่วยคุณตัดสินใจในเรื่องยาก ๆ หรือไม่ ?					
6. คุณมีการติดต่อกับคนที่คุณรู้สึกว่าใกล้ชิดเชื่อใจและไว้วางใจได้มากเท่าที่คุณต้องการหรือไม่?					
7. ปัจจุบันคุณแต่งงานแล้ว หรืออาศัยอยู่กับคู่ของคุณใช่หรือไม่ ?	☐ ใช่			☐ ไม่ใช่	

ส่วนที่ 4 แบบสอบถามเกี่ยวกับความสามารถในการปฏิบัติกิจกรรม

(New York Heart Association Classification :NYHA)

คำชี้แจง แบบสอบถามนี้เป็นแบบบันทึกความคิดเห็นของท่าน เกี่ยวกับข้อจำกัดในการปฏิบัติกิจกรรมต่าง ๆ ในระยะ 1 เดือนที่ผ่านมา

ให้ท่านขีดเครื่องหมาย X ลงในช่องหน้าข้อที่ท่านคิดว่าการปฏิบัติกิจกรรมต่าง ๆ ในระยะเวลา 1 เดือนที่ผ่านมา กิจกรรมในข้อใดที่ทำให้ท่านมีอาการอย่างใดอย่างหนึ่งหรือมากกว่า 1 อาการ เช่น ทำให้ท่านรู้สึกเหนื่อย หรือ หายใจไม่เต็มอิ่ม หรือ หมดแรง หรือ รู้สึกใจสั่น หรือ เจ็บหน้าอก โปรดเลือกเพียง 1ข้อ

- ☐ 1. ขณะปฏิบัติกิจกรรมตามปกติ เช่น ทำความสะอาดบ้าน ล้างรถด้วยมือ ตัดหญ้า เดินขึ้นบันไดบ้าน 1-2 ชั้น หรือเดินบนพื้นราบในระยะ 50-100 เมตร
- ☐ 2. ขณะปฏิบัติกิจกรรมตามปกติ เพียงเล็กน้อย ทำงานเบา ๆ เช่น ประกอบอาหาร ปูที่นอน ล้างจาน อาบน้ำ หรือเดินขึ้นบันไดได้แค่ครึ่งชั้น หรือเดินบนพื้นราบได้ไม่ถึง 10 เมตร
- ☐ 3. ขณะเปลี่ยนเสื้อผ้า โกนหนวด เดินจากห้องหนึ่งไปยังอีกห้องหนึ่งภายในบ้าน ขณะรับประทานอาหาร หรือขณะพูดคุย
- ☐ 4. ขณะอยู่เฉย ๆ และไม่สามารถนอนราบหรือหนุมหมอน 1 ใบได้ตามปกติ ต้องนอนศีรษะสูง ใช้จำนวนหมอนหนุนศีรษะเพิ่มจากปกติ หรือต้องอยู่ในท่านั่งตลอดเวลา

ส่วนที่ 5 แบบวัดการรับรู้ภาวะสุขภาพโดยทั่วไป

คำชี้แจง : แบบสอบถามนี้ ถามความคิดเห็นของคุณเกี่ยวกับการรับรู้ภาวะสุขภาพโดยทั่ว ๆ ไป ของท่าน ข้อมูลนี้จะช่วยในการบันทึกว่าท่านรู้สึกว่าภาวะสุขภาพโดยทั่วไปของท่านว่าอยู่ในระดับใด จากไม่ดีเลย (0) จนถึงดีที่สุด (100)

ให้ท่านขีดเครื่องหมาย X ลงบนเส้นตรงข้างล่างตรงบริเวณที่ตรงกับความรู้สึกของท่านมากที่สุด เส้นนี้แทนความรู้สึกของท่านว่า “ท่านคิดว่าสุขภาพของท่านโดยรวมเป็นอย่างไรในระยะเวลา 1 เดือนที่ผ่านมา จากไม่ดีเลย (0 คะแนน) จนถึงดีที่สุด(100 คะแนน)

ไม่ดีเลย ดีที่สุด

I----------I----------I

0 50 100

ส่วนที่ 6 แบบวัดคุณภาพชีวิตผู้ป่วยภาวะหัวใจวาย

คำชี้แจง : คำถามต่อไปนี้เป็นคำถามที่ต้องการทราบว่าภาวะหัวใจวาย มีผลต่อการดำเนินชีวิตและความผาสุกของท่านในช่วง 1 เดือนที่ผ่านมา มากน้อยเพียงใด

โปรด ทำเครื่องหมาย X ลงในช่องที่ตรงกับความรู้สึกหรือความเป็นจริงในชีวิตท่านมากที่สุด

0 = ไม่มี หมายถึง ข้อคำถามนั้นไม่เกี่ยวกับท่าน หรือไม่มีเรื่องนี้เกิดขึ้นกับท่านเลย

1 = แทบจะไม่มีเลย หรือ 1-2 ครั้งใน 1 เดือน

2= มีเล็กน้อย หรือ มากกว่า 2- 5 ครั้งใน 1 เดือน

3 = มีปานกลาง หรือ มากกว่า 2 ครั้ง ถึง 3 ครั้ง ต่อสัปดาห์

4 = มีมาก หรือมากกว่า 4 ครั้งถึง 6 ต่อสัปดาห์

5 = มากที่สุด หมายถึง ทุกวันหรือทุกครั้ง

ท่านคิดว่า ในช่วง 1 เดือนที่ผ่านมา ภาวะหัวใจวาย มีผลกระทบต่อท่านในด้านต่าง ๆ เหล่านี้ มีมากน้อยเพียงใด	ไม่มี	แทบจะไม่มีเลย	มีเล็กน้อย	มีปานกลาง	มีมาก	มีมากที่สุด
1. เกิดการบวมที่ข้อเท้า/ ขา/แข้ง หรือที่อื่น ๆ	0	1	2	3	4	5
2. ต้องนั่งพักหรือนอนพักในช่วงกลางวัน	0	1	2	3	4	5
3. ทำให้การเดินขึ้นบันไดได้ลำบาก	0	1	2	3	4	5
4.ทำให้การทำงานในบ้านหรือรอบ ๆ บ้านได้อย่างลำบาก	0	1	2	3	4	5
5. ทำให้ท่านเดินทางออกนอกบ้านได้อย่างลำบาก	0	1	2	3	4	5
6. ทำให้ท่านนอนหลับในเวลากลางคืนอย่างลำบาก	0	1	2	3	4	5
7. ทำให้ท่านมีความยากลำบากในการทำกิจกรรมร่วมกับบุคคลในครอบครัวและเพื่อน ๆ	0	1	2	3	4	5
8. ทำให้ท่านทำงานหรือประกอบอาชีพได้อย่างลำบาก	0	1	2	3	4	5
9. ทำให้ท่านทำงานอดิเรก ออกกำลังกาย หรือทำงานนอกเวลาอื่น ๆ ได้อย่างลำบาก	0	1	2	3	4	5
10.ทำให้ท่านมีกิจกรรมทางเพศได้อย่างลำบาก	0	1	2	3	4	5
11. ทำให้ท่านรับประทานอาหารที่ชอบได้น้อยลง	0	1	2	3	4	5

ท่านคิดว่า ในช่วง 1 เดือนที่ผ่านมา ภาวะหัวใจวาย มีผลกระทบต่อท่านในด้านต่าง ๆ เหล่านี้ มีมากน้อยเพียงใด	ไม่มี	แทบจะไม่มีเลย	มีเล็กน้อย	มีปานกลาง	มีมาก	มีมากที่สุด
12. ทำให้ท่านหายใจหอบ หรือหายใจไม่เต็มอิ่ม	0	1	2	3	4	5
13. ทำให้ท่านรู้สึกอ่อนเพลีย อ่อนแรง หรือพลังลดลง	0	1	2	3	4	5
14. ทำให้ท่านไปนอนพักรักษาตัวในโรงพยาบาล	0	1	2	3	4	5
15. ทำให้ท่านเสียค่าใช้จ่ายในการรักษาพยาบาล	0	1	2	3	4	5
16. ทำให้ท่านมีอาการคลื่นไส้อาเจียน เวียนศีรษะ ปัสสาวะบ่อย หรืออาการไม่สุขสบายอื่น ๆ ซึ่งเป็นผลจากฤทธิ์ข้างเคียงของยาโรคหัวใจ	0	1	2	3	4	5
17. ทำให้ท่านรู้สึกว่าตนเองเป็นภาระของครอบครัวหรือเพื่อน	0	1	2	3	4	5
18. ทำให้ท่านรู้สึกว่าสูญเสียการควบคุมตนเอง	0	1	2	3	4	5
19. ทำให้ท่านรู้สึกวิตกกังวล	0	1	2	3	4	5
20. ทำให้ท่านรู้สึกหลงลืมง่าย หรือไม่มีสมาธิ	0	1	2	3	4	5
21. ทำให้ท่านรู้สึกซึมเศร้า	0	1	2	3	4	5

APPENDIX E

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2. The Minnesota Living with Heart Failure Questionnaire (MLHFQ)

August 8, 2006

Phuangphaka Krethong
Chulalongkorn University Thailand

Journal Name	Year	Citation	Item(s) used
JAMA	1995	273; 59-65	Selected Text

Intended Material will be used PhD dissertation and a future manuscirpt for publication based on the disseration.

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Miss PHUANGPHAKA KRETHONG
(print name and title)

Date: 07/28/2006

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APPENDIX F

TEST ASSUMPTION

Descriptive statistic of social support

Table 5 Descriptive statistic of social support in heart failure patients

Items	Mean	SD.	Skewness	Kurtosis
1. คุณมีคนที่พร้อมจะรับฟังคุณในเวลาที่คุณต้องการหรือไม่ ?	4.04	.998	-.825	.039
2. คุณมีคนที่พร้อมจะให้คำแนะนำที่ดีเวลาคุณมีปัญหาหรือไม่ ?	3.87	1.064	-.696	-.183
3. คุณมีคนที่พร้อมจะให้ความรักคุณ และห่วงใยคุณหรือไม่ ?	4.31	.836	-1.194	1.163
4. คุณมีคนที่พร้อมจะช่วยคุณทำงานบ้านประจำวันหรือไม่ ?	4.06	1.117	-1.031	.131
5. คุณสามารถวางใจใครสักคนที่จะพูดคุยเรื่องปัญหาต่าง ๆ หรือช่วยคุณตัดสินใจในเรื่องยาก ๆ หรือไม่ ?	4.09	.985	-1.046	.691
6. คุณมีการติดต่อกับคนที่คุณรู้สึกว่าใกล้ชิดเชื่อใจและไว้วางใจได้มากเท่าที่คุณต้องการหรือไม่?	4.04	1.051	-1.059	.595

Descriptive statistic of symptom status in heart failure patients

Table 6 Descriptive statistic of symptom status in heart failure patients

Items	Mean	SD.	Skewness	Kurtosis
1. Chest pain	2.162	2.628	1.066	.179
2. trouble breathing or shortness of breath or dyspnea	2.706	2.685	.665	-.543
3. Fatigue	3.460	2.801	.397	-.820
4. Depressed or down & blue?	2.037	2.648	1.169	.348
5. trouble sleeping	2.680	2.892	.914	-.226
6. Swelling in your legs	1.190	2.337	2.122	3.727
7.Felt an irregular or fluttering feeling in your chest or a rapid heart beat	2.695	2.713	.859	-2.3
8. Felt anxious or stressed	2.527	2.657	.871	-2.43
9. Poor appetite	2.049	2.709	1.250	.516

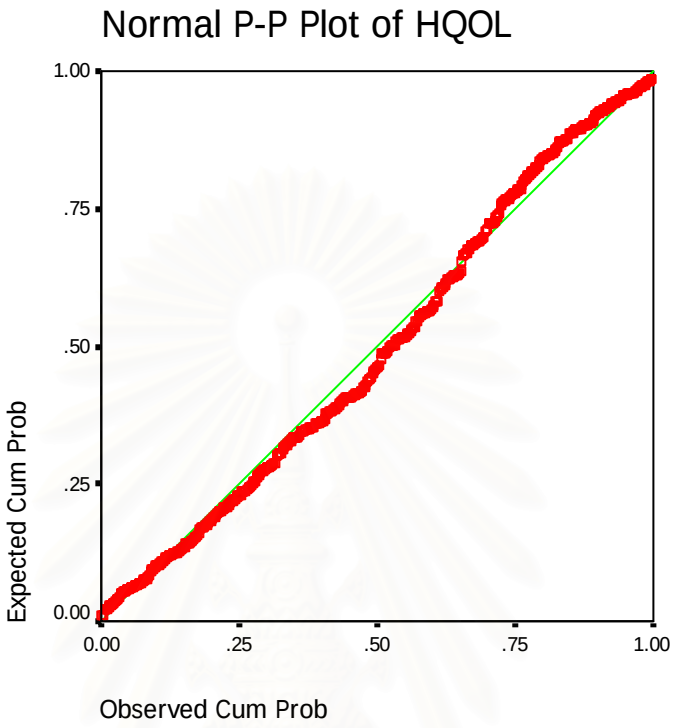
Descriptive statistic of health-related quality of life in heart failure patients

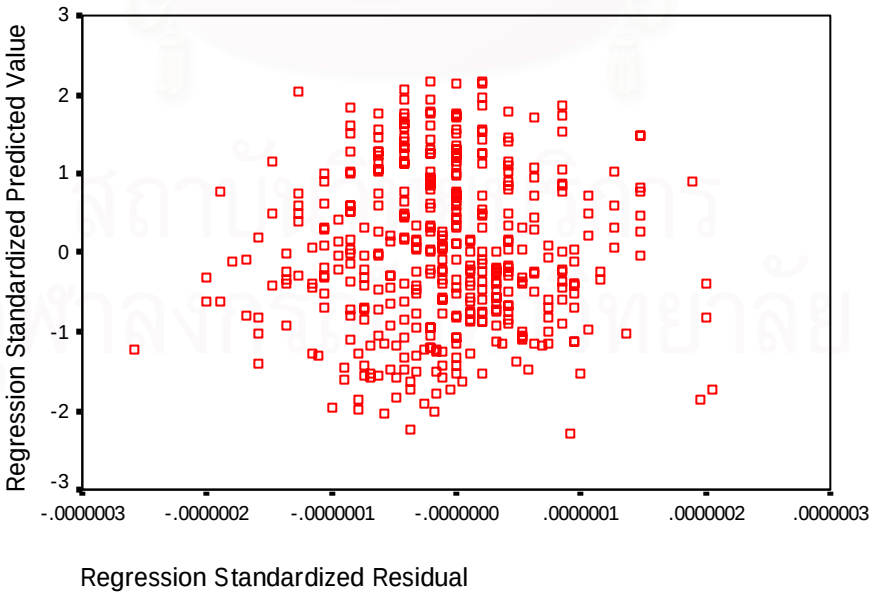
Table 7 Descriptive statistic of health-related quality of life in heart failure patients

Items	Mean	SD.	Skewness	Kurtosis	IOC
1. causing swelling in your ankles, legs, etc.?	4.85	1.516	-.975	-.359	.78
2. making you sit or lie down to rest during the day?	3.40	1.323	-.363	-.446	.81
3. making your walking about or climbing stairs difficult?	3.44	1.591	.195	-1.051	.83
4. making your working around the house or yard difficult?	3.71	1.509	.029	-.927	.81
5. making your going places away from home difficult?	3.42	1.534	.140	-.915	.83
6. making your sleeping well at night difficult?	3.75	1.548	-.018	-1.035	.78
7. making your relating to or doing other things with your friends or family difficult?	3.59	1.526	.029	-.983	.81
8. making your working to earn a living difficult?	3.10	1.597	.381	-.969	.81
9. making your recreational pastimes, sports, or hobbies difficult?	3.32	1.427	.261	-.730	.78
10. making your sexual activities difficult?	4.41	1.859	-.662	-1.113	.78
11. making you eat less of the food you like?	3.86	1.541	-.018	-1.140	.81
12. making you short of breath?	3.40	1.385	.318	-.735	.78
13. making you tired, fatigued, or low on energy?	3.27	1.324	.409	-.541	.81
14. making you stay in a hospital?	3.89	1.707	-.109	-1.312	.81
15. costing you money for medical care?	4.55	1.734	-.767	-.862	.81
16. giving you side effects from medications?	4.07	1.488	-.188	-1.082	.72
17. making you feel you are a burden to your family or friends?	3.49	1.580	.273	-1.062	.78
18. making you feel a loss of self-control in your life?	3.88	1.458	.059	-1.162	.78
19. making you worry?	3.47	1.415	.283	-.812	.78
20. making it difficult for you to concentrate or remember things?	3.73	1.399	.139	-.915	.78
21. making you feel depressed?	4.11	1.362	-.167	-.716	.81

Note: SD = Standard deviation

IOC = Index of item objective congruence


Normal P-P Plot of HQOL
Expected Cum Prob
Observed Cum Prob
0.00
.25
.50
.75
1.00


Scatterplot
Dependent Variable: HQOL
Regression Standardized Predicted Value
Regression Standardized Residual
3
2
1
0
-1
-2
-3
-.0000003
-.0000002
-.0000001
-.0000000
.0000001
.0000002
.0000003

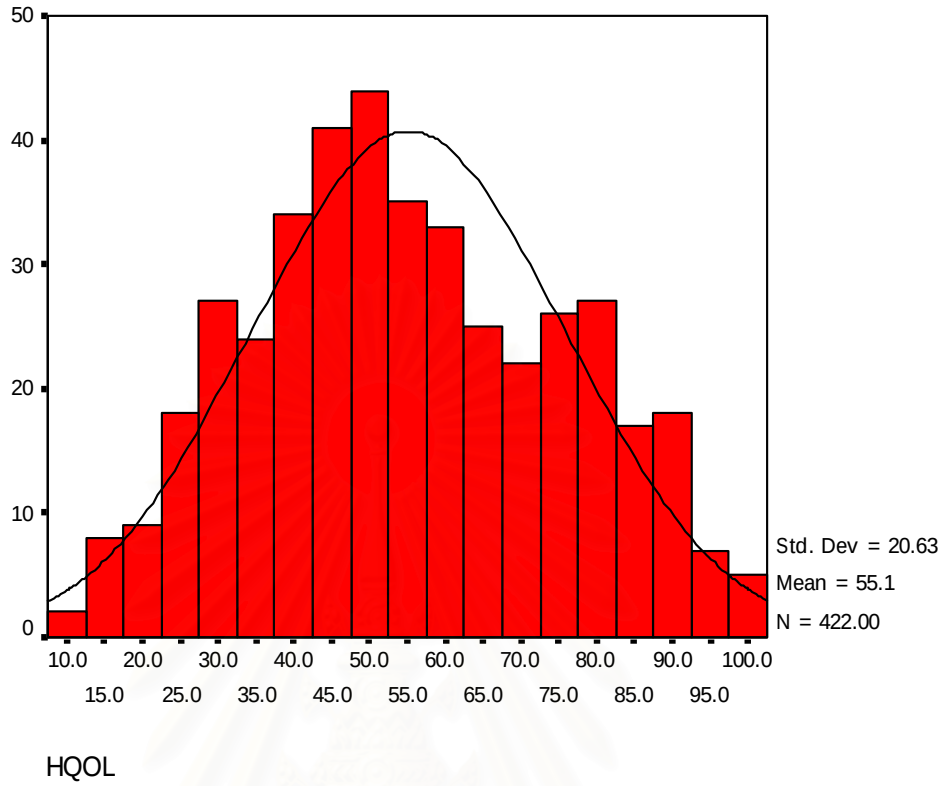
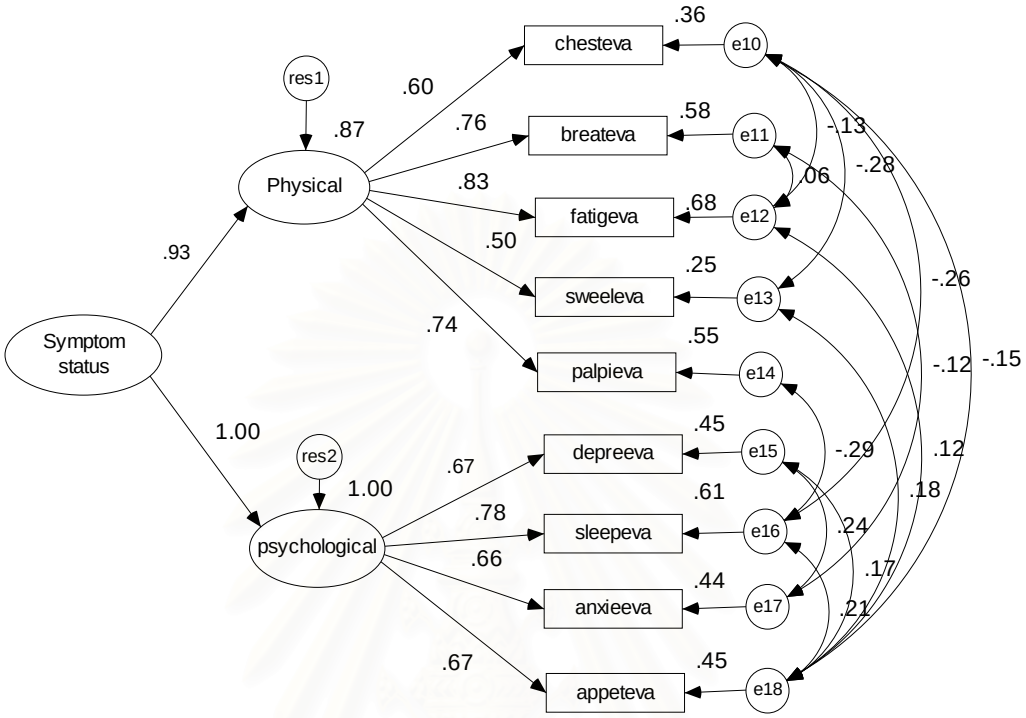


Figure 6 Normal distribution of dependent variable

APPENDIX G

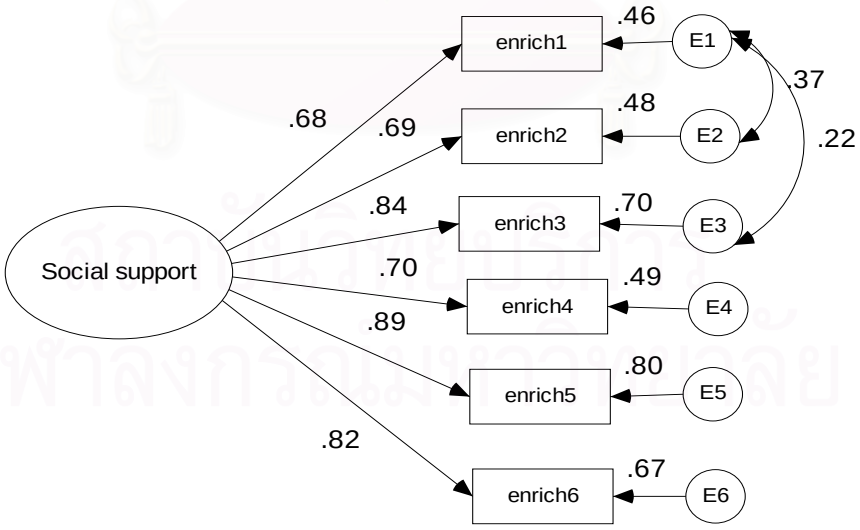
MEASUREMENT MODEL OF THE VARIABLES

Measurement Model of variables



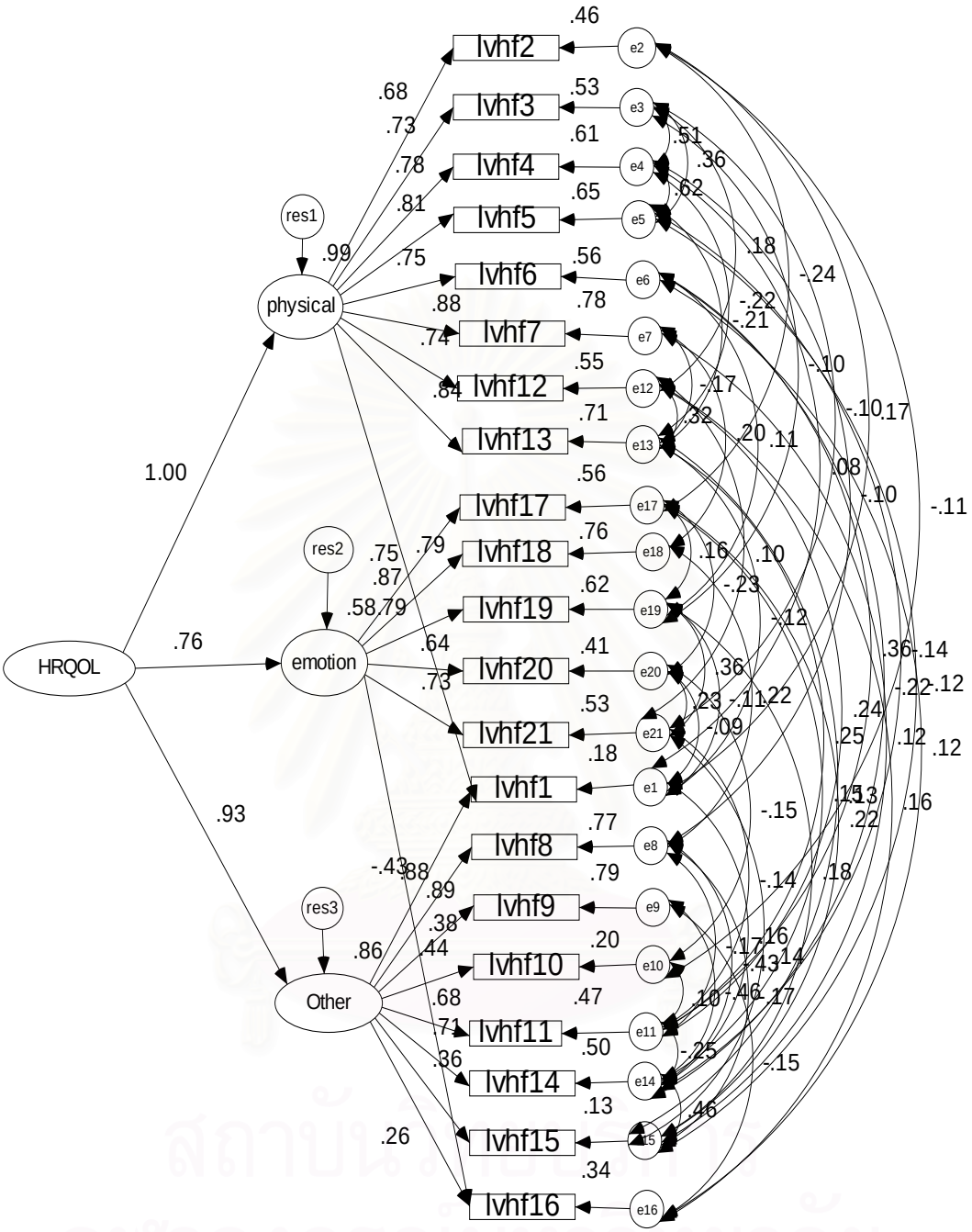
χ^2 =6.09**,** *df* = 14, *p* = 0.96, χ^2 /*df* = .44, GFI = 1.00, AGFI = 0.99, and RMSEA = 0.00

Figure 7 Hypothesized model of modified CSS (evaluation dimension)



χ^2 = 0.04**,** *df* = 7, *p* = 0.19. χ^2 /*df* = 1.43, GFI = 0.99, AGFI = 0.98, and RMSEA = 0.03

Figure 8 First order hypothesized model of ENRICH social support



χ^2 =153.22**,** *df* = 133, *p* =0.11,χ^2/df = 1.15, GFI = 0.97, AGFI = 0.94, and RMSEA = 0.02.

Figure 9 Hypothesized model of The Minnesota Living with Heart Failure Questionnaire (MLHFQ)

APPENDIX H

CORRELATION MATRIX OF OBSERVE VARIABLES

AND

STANDARDIZED RESIDUAL COVARIENCE OF VARIABLES

Table 8 Correlation matrix of observe variables

MEAN	2.73	53.31	55.08	24.43	23.24	52.95	54.74	57.71	76.71
STDDEV	.88	18.12	15.25	19.79	22.01	23.05	23.66	22.32	20.65
NYHA		1.00							
GHP		-.413	1.00						
LVEF		-.363	.140	1.00					
PHYSSYM		.371	-.405	-.064	1.00				
PSYSYM		.419	-.401	-.066	.723	1.00			
MLHFQPHY		-.544	.494	.158	-.566	-.585	1.00		
MLHFQPSY		-.382	.413	.082	-.385	-.538	.638	1.00	
MLHFQSO		-.464	.423	.160	-.454	-.542	.804	.682	1.00
SOCIAL		-.053	.214	-.016	-.107	-.176	.022	.160	.024	1.00

NYHA = New York Heart Association functional classification
GHP = General health perception
LVEF = Left ventricular injection fraction
PHYSSYM = Physical symptom
PHYSSYM = Psychological symptom
MLHFQPHY = Physical dimension of health related quality of life
MLHFQSO = The other dimension of health related quality of life
MLHFQPSY = Psychological dimension of health related quality of life
SOCIAL = The modified ENRICHD Social Support Instrument

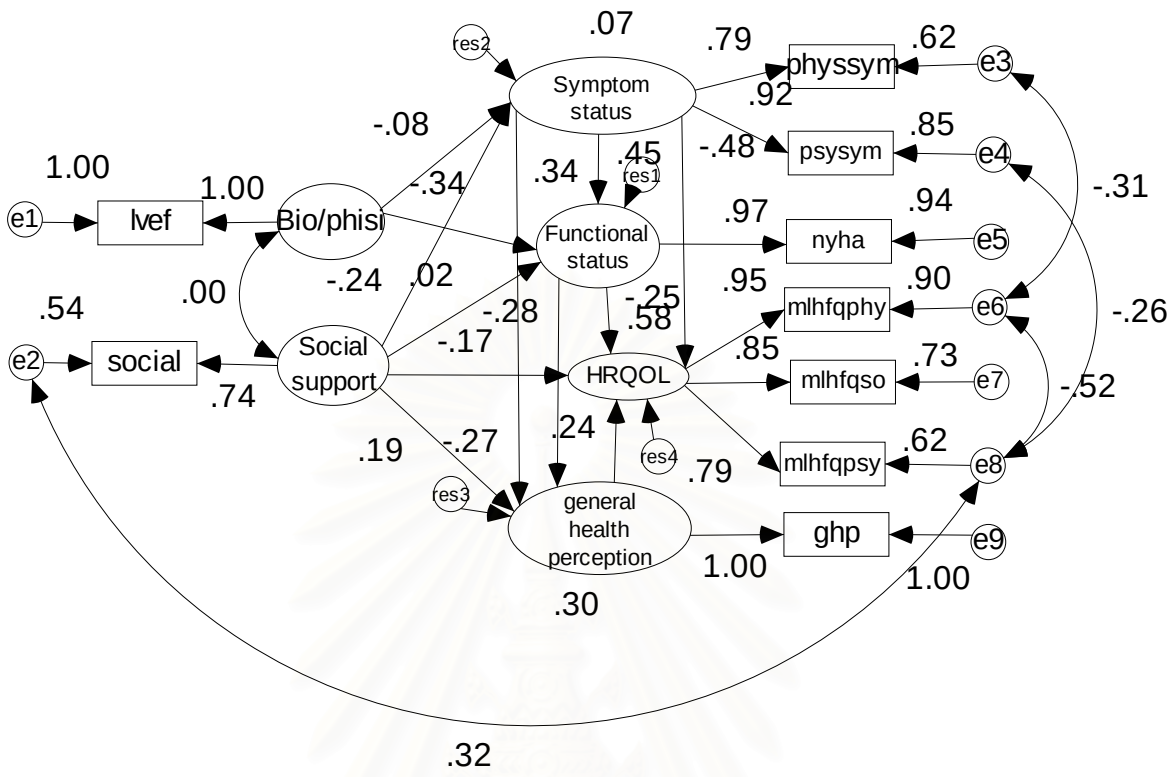
Table 9 Standardized residual covariance of variables

	social	LVEF	physsym	GHP	psysym	NYHA	mlhfqpsy	mlhfqso	mlhfqphy
social	.00								
LVEF	-.39	.00							
physsym	.88	-.08	-.01						
GHP	-.08	.26	-.02	-.01					
psysym	-.11	.14	-.07	-.04	-.05				
NYHA	.28	.00	.36	-.03	-.17	.00			
mlhfqpsy	.06	-.92	.32	.09	.17	.96	.01		
mlhfqso	-.03	.47	-.36	-.36	-.25	.09	.20	.00	
mlhfqphy	-.12	.11	-.20	.06	.02	-.42	-.05	-.04	.05

Note: NYHA = New York Heart Association functional classification, GHP = General health perception, LVEF = Left ventricular injection fraction, physsym = Physical symptom, psysym = psychological symptom, mlhfqphy = physical dimension of health related quality of life, mlhfqso =other dimension of health related quality of life, mlhfqpsy = psychological dimension of health related quality of life, social= social support

APPENDIX I

AMOS PRINTOUT OF STRUCTURAL EQUATION MODEL



Notes for Model (Default model)

Computation of degrees of freedom (Default model)

Number of distinct sample moments:	45
Number of distinct parameters to be estimated:	32
Degrees of freedom (45 - 32):	13

Minimum was achieved
Chi-square = 19.87
Degrees of freedom = 13
Probability level = .10

The model is recursive.
Sample size = 422

Variable Summary (Group number 1)

Your model contains the following variables (Group number 1)

Observed, endogenous variables:
Mlhfqphy, mlhfqso, mlhfqpsy, nyha, psysym, ghp, physsym, lvef, social

Unobserved, endogenous variables:
Symptom_status, HRQOL, general_health_perception, Functional_status

Unobserved, exogenous variables:
e6, e7, e8, Bio/phisi, Social_support, e5, e4, e9, e3, res2, e1, e2, res1, res4, res3

Variable counts (Group number 1)

Number of variables in your model:	28
Number of observed variables:	9
Number of unobserved variables:	19
Number of exogenous variables:	15
Number of endogenous variables:	13

Minimization History (Default model)

Iteration		Negative eigenvalues	Condition #	Smallest eigenvalue	Diameter	F	NTries	Ratio
0	e	9		-.72	9999.00	1984.74	0	9999.00
1	e	8		-.29	1.92	1120.74	21	.45
2	e*	3		-.11	.90	510.23	5	.92
3	e	2		-.04	.35	324.77	5	.89
4	e	0	325.95		.46	151.62	5	.91
5	e	0	281.22		.62	73.86	4	.00
6	e	1		-.02	.62	44.20	1	.51
7	e	1		.00	.23	21.76	8	.97
8	e	0	456.33		.22	19.92	7	.92
9	e	0	530.33		.02	19.87	1	1.03
10	e	0	516.79		.00	19.87	1	1.00
11	e	0	517.41		.00	19.87	1	1.00

Execution time summary

Minimization:	.02
Miscellaneous:	.22
Bootstrap:	.00
Total:	.23

Model Fit Summary

CMIN

Model	NPAR	CMIN	DF	P	CMIN/DF
Default model	32	19.87	13	.10	1.53
Saturated model	45	.00	0		
Independence model	9	1701.32	36	.00	47.26

RMR, GFI

Model	RMR	GFI	AGFI	PGFI
Default model	5.81	.99	.96	.29
Saturated model	.00	1.00		
Independence model	154.80	.43	.28	.34

Baseline Comparisons

Model	NFI Delta1	RFI rho1	IFI Delta2	TLI rho2	CFI
Default model	.99	.97	1.00	.99	1.00
Saturated model	1.00		1.00		1.00
Independence model	.00	.00	.00	.00	.00

Parsimony-Adjusted Measures

Model	PRATIO	PNFI	PCFI
Default model	.36	.36	.36
Saturated model	.00	.00	.00
Independence model	1.00	.00	.00

NCP

Model	NCP	LO 90	HI 90
Default model	6.87	.00	23.02
Saturated model	.00	.00	.00
Independence model	1665.32	1533.98	1804.01

FMIN

Model	FMIN	F0	LO 90	HI 90
Default model	.05	.02	.00	.05
Saturated model	.00	.00	.00	.00
Independence model	4.04	3.96	3.64	4.29

RMSEA

Model	RMSEA	LO 90	HI 90	PCLOSE
Default model	.04	.00	.06	.76
Independence model	.33	.32	.35	.00

AIC

Model	AIC	BCC	BIC	CAIC
Default model	83.87	85.42	213.31	245.31
Saturated model	90.00	92.19	272.03	317.03
Independence model	1719.32	1719.75	1755.72	1764.72

ECVI

Model	ECVI	LO 90	HI 90	MECVI
Default model	.20	.18	.24	.20
Saturated model	.21	.21	.21	.22
Independence model	4.08	3.77	4.41	4.08

HOELTER

Model	HOELTER .05	HOELTER .01
Default model	474	587
Independence model	13	15

Regression Weights: (Group number 1 - Default model)

			Estimate	S.E.	C.R.	P	Label
Symptom_status	<---	Social_support	-.25	.08	-3.33	***	par_7
Symptom_status	<---	Bio/phisi	-.08	.05	-1.51	.13	par_14
Functional_status	<---	Bio/phisi	-.02	.00	-7.97	***	par_6
Functional_status	<---	Symptom_status	.02	.00	8.91	***	par_13
Functional_status	<---	Social_support	.00	.00	.33	.74	par_20
general_health_perception	<---	Social_support	.23	.07	3.05	.00	par_8
general_health_perception	<---	Symptom_status	-.31	.08	-3.97	***	par_15
general_health_perception	<---	Functional_status	-5.93	1.99	-2.98	.00	par_21
HRQOL	<---	general_health_perception	.25	.05	4.73	***	par_4
HRQOL	<---	Social_support	-.21	.07	-2.99	.00	par_9
HRQOL	<---	Functional_status	-5.46	1.86	-2.94	.00	par_10
HRQOL	<---	Symptom_status	-.57	.07	-7.78	***	par_11
lvef	<---	Bio/phisi	1.00				
social	<---	Social_support	1.00				
psysym	<---	Symptom_status	1.30	.09	14.79	***	par_3
physsym	<---	Symptom_status	1.00				
ghp	<---	general_health_perception	1.00				
mlhfqso	<---	HRQOL	1.03	.06	16.72	***	par_5
mlhfqphy	<---	HRQOL	1.18	.07	18.02	***	par_12
nyha	<---	Functional_status	1.00				
mlhfqpsy	<---	HRQOL	1.00				

Standardized Regression Weights: (Group number 1 - Default model)

			Estimate
Symptom_status	<---	Social_support	-.24
Symptom_status	<---	Bio/phisi	-.08
Functional_status	<---	Bio/phisi	-.34
Functional_status	<---	Symptom_status	.45
Functional_status	<---	Social_support	.02
general_health_perception	<---	Social_support	.19
general_health_perception	<---	Symptom_status	-.27
general_health_perception	<---	Functional_status	-.28
HRQOL	<---	general_health_perception	.24
HRQOL	<---	Social_support	-.17
HRQOL	<---	Functional_status	-.25
HRQOL	<---	Symptom_status	-.48
lvef	<---	Bio/phisi	1.00
social	<---	Social_support	.74
psysym	<---	Symptom_status	.92
physsym	<---	Symptom_status	.79
ghp	<---	general_health_perception	1.00
mlhfqso	<---	HRQOL	.85
mlhfqphy	<---	HRQOL	.95
nyha	<---	Functional_status	.97
mlhfqpsy	<---	HRQOL	.79

Covariances: (Group number 1 - Default model)

			Estimate	S.E.	C.R.	P	Label
Bio/phisi	<-->	Social_support	.86	14.85	.06	.95	par_2
e6	<-->	e3	-27.66	9.16	-3.02	.00	par_16
e8	<-->	e4	-32.89	12.20	-2.70	.01	par_17
e6	<-->	e8	-55.50	14.19	-3.91	***	par_18
e8	<-->	e2	64.42	17.34	3.72	***	par_19

Correlations: (Group number 1 - Default model)

			Estimate
Bio/phisi	<-->	Social_support	.00
e6	<-->	e3	-.31
e8	<-->	e4	-.26
e6	<-->	e8	-.52
e8	<-->	e2	.32

Squared Multiple Correlations: (Group number 1 - Default model)

	Estimate
Symptom_status	.07
Functional_status	.34
general_health_perception	.30
HRQOL	.58
social	.54
lvef	1.00
physsym	.62
ghp	1.00
psysym	.85
nyha	.94
mlhfqpsy	.62
mlhfqso	.73
mlhfqphy	.90

Residual Covariances (Group number 1 - Default model)

	social	lvef	physsym	ghp	psysym	nyha	mlhfqpsy	mlhfqso	mlhfqphy
social	.33								
lvef	-5.96	-.02							
physsym	18.50	-.44	-.15						
ghp	2.25	3.68	-18.13	.00					
psysym	-4.11	2.36	-1.86	5.47	-1.94				
nyha	.24	.00	.13	.01	-.13	.00			
mlhfqpsy	2.47	-16.45	13.02	3.57	4.73	1.05	1.08		
mlhfqso	-.58	7.54	-2.17	-6.94	-7.73	.12	6.79	.00	
mlhfqphy	-2.75	1.48	-3.21	2.22	-.58	-.44	-1.79	-2.41	.78

Standardized Residual Covariances (Group number 1 - Default model)

	social	lvef	physsym	ghp	psysym	nyha	mlhfqpsy	mlhfqso	mlhfqphy
social	.01								
lvef	-.39	.00							
physsym	.92	-.03	-.01						
ghp	.12	.27	-.98	.00					
psysym	-.18	.14	-.07	.26	-.06				
nyha	.27	.00	.15	.01	-.13	.00			
mlhfqpsy	.10	-.93	.53	.16	.16	.95	.03		
mlhfqso	-.03	.45	-.09	-.32	-.29	.11	.22	.00	
mlhfqphy	-.12	.09	-.13	.10	-.02	-.39	-.06	-.07	.02

Factor Score Weights (Group number 1 - Default model)

	social	lvef	physsym	ghp	psysym	nyha	mlhfqpsy	mlhfqso	mlhfqphy
Social_support	.52	.00	-.02	.13	-.11	-.22	-.16	.04	-.04
Bio/phisi	.00	1.00	.00	.00	.00	-.03	.00	.00	.00
Symptom_status	-.02	.02	.17	-.03	.49	.77	.04	-.06	-.03
Functional_status	.00	.00	.00	.00	.00	.90	.00	.00	.00
general_health_perception	.00	.00	.00	1.00	.00	-.02	.00	.00	.00
HRQOL	-.04	.00	.05	.03	-.04	-.60	.20	.10	.53

Total Effects (Group number 1 - Default model)

	Social_support	Bio/phisi	Symptom_status	Functional_status	general_health_perception	HRQOL
Symptom_status	-.25	-.08	.00	.00	.00	.00
Functional_status	-.01	-.02	.02	.00	.00	.00
general_health_perception	.34	.15	-.46	-5.93	.00	.00
HRQOL	.05	.20	-.82	-6.92	.25	.00
social	1.00	.00	.00	.00	.00	.00
lvef	.00	1.00	.00	.00	.00	.00
physsym	-.25	-.08	1.00	.00	.00	.00
ghp	.34	.15	-.46	-5.93	1.00	.00
psysym	-.33	-.10	1.30	.00	.00	.00
nyha	-.01	-.02	.02	1.00	.00	.00
mlhfqpsy	.05	.20	-.82	-6.92	.25	1.00
mlhfqso	.05	.20	-.85	-7.11	.25	1.03
mlhfqphy	.06	.23	-.97	-8.14	.29	1.18

Standardized Total Effects (Group number 1 - Default model)

	Social_support	Bio/phisi	Symptom_status	Functional_status	general_health_perception	HRQOL
Symptom_status	-.24	-.08	.00	.00	.00	.00
Functional_status	-.09	-.37	.45	.00	.00	.00
general_health_perception	.28	.13	-.40	-.28	.00	.00
HRQOL	.04	.16	-.69	-.32	.24	.00
social	.74	.00	.00	.00	.00	.00
lvef	.00	1.00	.00	.00	.00	.00
physsym	-.19	-.06	.79	.00	.00	.00
ghp	.28	.13	-.40	-.28	1.00	.00
psysym	-.23	-.07	.92	.00	.00	.00
nyha	-.09	-.36	.44	.97	.00	.00
mlhfqpsy	.03	.13	-.54	-.25	.19	.79
mlhfqso	.03	.14	-.59	-.27	.21	.85
mlhfqphy	.04	.15	-.66	-.30	.23	.95

Direct Effects (Group number 1 - Default model)

	Social_support	Bio/phisi	Symptom_status	Functional_status	general_health_perception	HRQOL
Symptom_status	-.25	-.08	.00	.00	.00	.00
Functional_status	.00	-.02	.02	.00	.00	.00
general_health_perception	.23	.00	-.31	-5.93	.00	.00
HRQOL	-.21	.00	-.57	-5.46	.25	.00
social	1.00	.00	.00	.00	.00	.00
lvef	.00	1.00	.00	.00	.00	.00
physsym	.00	.00	1.00	.00	.00	.00
ghp	.00	.00	.00	.00	1.00	.00
psysym	.00	.00	1.30	.00	.00	.00
nyha	.00	.00	.00	1.00	.00	.00
mlhfqpsy	.00	.00	.00	.00	.00	1.00
mlhfqso	.00	.00	.00	.00	.00	1.03
mlhfqphy	.00	.00	.00	.00	.00	1.18

Standardized Direct Effects (Group number 1 - Default model)

	Social_support	Bio/phisi	Symptom_status	Functional_status	general_health_perception	HRQOL
Symptom_status	-.24	-.08	.00	.00	.00	.00
Functional_status	.02	-.34	.45	.00	.00	.00
general_health_perception	.19	.00	-.27	-.28	.00	.00
HRQOL	-.17	.00	-.48	-.25	.24	.00
social	.74	.00	.00	.00	.00	.00
lvef	.00	1.00	.00	.00	.00	.00
physsym	.00	.00	.79	.00	.00	.00
ghp	.00	.00	.00	.00	1.00	.00
psysym	.00	.00	.92	.00	.00	.00
nyha	.00	.00	.00	.97	.00	.00
mlhfqpsy	.00	.00	.00	.00	.00	.79
mlhfqso	.00	.00	.00	.00	.00	.85
mlhfqphy	.00	.00	.00	.00	.00	.95

Indirect Effects (Group number 1 - Default model)

	Social_support	Bio/phisi	Symptom_status	Functional_status	general_health_perception	HRQOL
Symptom_status	.00	.00	.00	.00	.00	.00
Functional_status	-.01	.00	.00	.00	.00	.00
general_health_perception	.11	.15	-.15	.00	.00	.00
HRQOL	.25	.20	-.25	-1.46	.00	.00
social	.00	.00	.00	.00	.00	.00
lvef	.00	.00	.00	.00	.00	.00
physsym	-.25	-.08	.00	.00	.00	.00
ghp	.34	.15	-.46	-5.93	.00	.00
psysym	-.33	-.10	.00	.00	.00	.00
nyha	-.01	-.02	.02	.00	.00	.00
mlhfqpsy	.05	.20	-.82	-6.92	.25	.00
mlhfqso	.05	.20	-.85	-7.11	.25	.00
mlhfqphy	.06	.23	-.97	-8.14	.29	.00

Standardized Indirect Effects (Group number 1 - Default model)

	Social_support	Bio/phisi	Symptom_status	Functional_status	general_health_perception	HRQOL
Symptom_status	.00	.00	.00	.00	.00	.00
Functional_status	-.11	-.04	.00	.00	.00	.00
general_health_perception	.09	.13	-.13	.00	.00	.00
HRQOL	.21	.16	-.21	-.07	.00	.00
social	.00	.00	.00	.00	.00	.00
lvef	.00	.00	.00	.00	.00	.00
physsym	-.19	-.06	.00	.00	.00	.00
ghp	.28	.13	-.40	-.28	.00	.00
psysym	-.23	-.07	.00	.00	.00	.00
nyha	-.09	-.36	.44	.00	.00	.00
mlhfqpsy	.03	.13	-.54	-.25	.19	.00
mlhfqso	.03	.14	-.59	-.27	.21	.00
mlhfqphy	.04	.15	-.66	-.30	.23	.00

Pairwise Parameter Comparisons (Default model)

Variance-covariance Matrix of Estimates (Default model)

	var_a	par_2	par_3	par_4	par_5	par_6	par_7	par_8	par_9	par_10	par_11	par_12	par_13	par_14	par_15	par_16	par_17	par_18	par_19	par_20
var_a	257.13																			
par_2	-2.42	220.43																		
par_3	.00	.00	.01																	
par_4	-.05	.00	.00	.00																
par_5	.00	-.04	.00	.00	.00															
par_6	.00	.00	.00	.00	.00	.00														
par_7	.28	-.03	.00	.00	.00	.00	.01													
par_8	-.27	.02	.00	.00	.00	.00	.00	.01												
par_9	.26	-.05	.00	.00	.00	.00	.00	.00	.00											
par_10	-.40	-2.24	.00	.05	.01	.00	.00	.00	-.02	3.45										
par_11	.05	.02	.00	.00	.00	.00	.00	.00	.00	-.06	.01									
par_12	.00	-.04	.00	.00	.00	.00	.00	.00	.00	.01	.00	.00								
par_13	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00							
par_14	.00	.11	.00	.00	.00	.00	.00	.00	.00	-.01	.00	.00	.00	.00						
par_15	-.07	.02	.00	.00	.00	.00	.00	.00	.00	-.07	.00	.00	.00	.00	.01					
par_16	-.01	.46	-.26	-.02	-.01	.00	-.03	-.01	-.03	.51	.01	.06	.00	-.01	-.02	83.93				
par_17	.01	1.02	.15	-.02	-.09	.00	.07	.04	.02	-.61	-.12	-.10	.00	.03	.01	-18.09	148.74			
par_18	.03	-7.65	.02	-.12	.45	.00	.06	-.01	.12	-.96	.06	.14	.00	-.01	.03	-5.55	-13.78	201.28		
par_19	-.28	20.91	.03	.07	-.06	.00	-.11	-.10	-.40	.38	-.12	-.04	.00	.02	-.01	5.82	-3.80	-30.07	300.53	
par_20	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00

BIOGRAPHY

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3. Education

3.1 Certificate of Nursing, Public Health and Midwifery 1982

3.2 Bachelor in Nursing 1987

3.3 Master of Science (Nursing) 1992

3.4 Attend study Ph.D. of Nursing Science, Faculty of Nursing Chulalongkorn University, 2004 to 2007

3.5 Scholar visiting at Indiana University School of Nursing, Indiana University-Purdue University Indianapolis (IUPUI), Indiana September, 2005 to August, 2006.

4. Position and experiences

4.1. Staff nurse at Intensive Care Unit of Post Cardiac Surgery,
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4.2. Instructor at the Department of Medical-Surgical Nursing,
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