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QUALITY OF LIFE FOR MEN AND WOMEN WITH CONGESTIVE HEART FAILURE

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## QUALITY OF LIFE FOR MEN AND WOMEN WITH CONGESTIVE HEART FAILURE

By

Norma J. VanTol

Submitted to Michigan State University in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE IN NURSING

College of Nursing

### ABSTRACT

## QUALITY OF LIFE FOR MEN AND WOMEN WITH CONGESTIVE HEART FAILURE

By

Norma J. VanTol

Congestive heart failure (CHF) impacts the quality of life (QOL) for men and women. Representative samples of men and women are needed to assess potential gender dependent OOL issues. Statement of Purpose: To compare the perceived OOL of men and women with CHF. OOL across the level of disease severity, and to determine if OOL is different for CHF men and women based on their New York Heart Association (NYHA) functional classification. *Methodology:* A retrospective design with a comparison of 92 men and 92 women from a community heart failure clinic was used. Medical records were reviewed to determine the disease severity and patient demographics. Disease severity was measured with the NYHA, and QOL was measured with the Living with Heart Failure Questionnaire (LHFQ). Results: As disease severity worsened, there was a significant decrease in OOL (p = < 0.0001), but no significant interaction was found between men and women across disease severity (p=0.2870). Significant differences were found between the men and women on the emotional subscale of the LHFQ, with both NYHA class (p=0.0002), and with gender (p=0.0175), but failed to show an interaction on the emotional subscale across the NYHA and gender (p=0.5074). As a secondary analysis, ejection fraction (EF) was found to have little correlation with OOL (p=0.309) or with NYHA classification (p>0.05).

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## DEDICATION

This thesis is dedicated to my husband, Paul. He has helped make my dream a reality with his continuous support as my cheering section and offered support on every level of this research journey.

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I would like to express my extreme appreciation to my committee chairperson, Audrey Gift, and committee members, Valerie DiVecchio and Brigidanne Warren for their time, guidance, and continual encouragement of nursing scholarship. They are exemplary role models and helped facilitate my growth in nursing research, creating future opportunities and possibilities for my career as an advanced practice nurse.

I would also like to thank all of those individuals with CHF who were included in my study and the dedicated health care professionals who work at the Spectrum Health Heart Failure Clinic. It is my hope, that through future study of CHF, that the quality of life for those with CHF will be maximized.

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## CHAPTER I INTRODUCTION

#### Definition, Incidence, and Prevalence

Congestive heart failure (CHF) is a significant global public health care problem. In this country alone, it is estimated to affect 2 to 3 million individuals (Konstam et al., 1994; Buchanan & Tan, 1997; Moser, 1997), with some estimates as high as 4.7 million individuals (Stull, Starling, Haas, & Young, 1999). There are approximately 400,000 new cases of CHF diagnosed each year (Funk, 1993; Stull et al., 1999).

CHF is defined by the Agency for Health Care Policy and Research, now the Agency for Healthcare Research and Quality, as "a clinical syndrome or condition characterized by 1) signs and symptoms of intravascular and interstitial volume overload, including shortness of breath, rales, and edema, or 2) manifestations of inadequate tissue perfusion, such as fatigue or poor exercise tolerance" (Konstom et al., 1994, p. iii). These symptoms result when the heart is unable to meet the metabolic needs of the body (Konstom et al., 1994; McCloskey, 1998) and is the end result of numerous diseases including hypertension, ischemic coronary artery disease, congenital heart disease, idiopathic dilated heart disease, rheumatic fever, valvular dysfunction, cardiomyopathies, pericardial disease, medications, and alcohol abuse (English & Mastrean, 1995; McCloskey, 1998).

The incidence of CHF, based on the Framingham Heart Study, doubles with each decade of life, rising sharply after the age of 75, with onset in women surpassing onset in men after this age (Funk, 1993; Buchanan & Tan, 1997). It is the most common cause of

hospitalization in the elderly and it is the most common diagnostic category at the time of discharge (Stull et al., 1999; Candlish, Watts, Redman, Whyte, & Lowe, 1998; English & Mastrean, 1995), with women hospitalized more frequently than men (Moser, 1997).

The incidence of CHF appears to be greater in men than women, increasing with age in both groups, however women tend to have a later onset of diagnosis than men (72 +/- 11 years, verses 68 +/- 11 years for men). Prevalence is similar for men and women ages 25 to 74, but is higher in women ages 80 and older (Moser, 1997). A significant difference however, exists in the longevity between men and women. For reasons still unknown, women have a longer survival rate with CHF than men (Moser, 1997).

The mortality from heart failure is astonishing, and increases with age (English & Mastrean, 1995). The Framingham study reported a five year mortality rate for CHF as 75% in men and 62% in women, six year mortality rate as 82% for men and 67% for women, ten year mortality as 89% and 79% (Berry & McMurray, 1999; Funk, 1993; Massie & Shah, 1997; Kannel & Belanger, 1991). However, the National Health and Nutrition Examination Survey (NHANES-I) revealed conflicting information when they report the 15 year mortality rate for those older than 55 years as 39.1% for women and 71.8% for men (Funk, 1993).

Not only is there a high prevalence and mortality rate associated with CHF, but the care of this patient population places a tremendous economic burden on our society. Total treatment costs for CHF are estimated at more than \$10 billion dollars and hospitalizations for CHF have tripled since the 1970's (Konstam et al., 1994; English & Mastrean, 1995). With the aging of the population, decreased mortality from coronary heart disease, and the decrease in premature deaths, the prevalence of CHF is expected to

increase (Funk, 1993). In our economic obsessed culture these projections should be viewed as a magnet for expenditure of research, time, and money.

Poor quality of life (OOL) is regularly described by patients with heart failure. Common symptoms include fatigue, shortness of breath, problems with physical activity, loss of energy, fluid retention, and sexual dysfunction (English & Mastrean, 1995). CHF impacts the OOL for both men and women, but may affect women differently than men (Bennett, Baker, & Huster, 1998; Murberg, Bru, Aarsland, & Svebak, 1998; Friedman, 1993: Chin & Goldman, 1998: Moser, 1997: Berry & McMurray, 1999). The majority of research studying QOL with heart failure has been done on male subjects. Research involving women with CHF is minimal. Women have either been represented in small proportions, not included in major clinical trials, or not compared with men (Moser, 1997; Friedman, 1993; Martensson, Karlsson, & Fridlund, 1998). CHF studies with representative samples of both men and women are needed to assess OOL issues that may be dependent on gender. As cited by Chin and Goldman (1998), women have been found to have a poorer OOL than men with other diseases. Therefore, gender specific inquiry may offer insight necessary for the development of practical interventions tailored to women and men.

Gender specific inquiry on QOL of individuals with coronary artery disease (CAD) have had similar findings. Men and women differ in their QOL. In a prospective, cross sectional survey of 280 patients with CAD in Finland, women with CAD scored significantly poorer in the health related quality of life (HR-QOL), than their male counterparts (Lukkarinen & Hentinen, 1998).

Similar results were also found in two separate studies of patients with CAD enrolled in a cardiac rehabilitation program. The results of both of these comparative research designed studies showed the QOL of women with CAD was significantly poorer than men (Deshotels et al., 1995; Loose & Fernhall, 1995).

Lack of representative sampling of women is also observed in the research of CAD. Historically, women have been left out of major medical trials involving CAD. Because of the lack of representation of women in CAD research, the male model has been made the standard for treatment of heart disease. Women with health problems generally experience their conditions differently than men and therefore gender specific health inquiry is necessary (Gijsbers Van Wijk, Van Vliet, & Kolk, 1996).

## CHAPTER II Quality of Life

As people are living longer with heart failure, it is the subject of intense research, with recent investigation shifting from an emphasis on mortality, to maximizing the QOL of those with CHF. Costs have been estimated to be 10 to 38 billion dollars per year for inpatient and outpatient care combined, with the incidence of CHF doubling with each decade of life and CHF being the most common reason for hospital admission for those over age 65 (Smith, Fabbri, Pai, Ferry, & Heywood, 1997; English & Mastrean, 1995; Wenger, 1989), it is no wonder QOL with CHF is a topic of much discussion.

Difficulty lies in the lack of a common standard definition for QOL (Grady, 1993; Linden, 1995). QOL is a highly subjective and multidimensional term which cannot be directly measured, but can be examined by using self-administered questionnaires regarding QOL domains, such as the physical and emotional domains of an individual, yielding reliable information (Martin & Stockler, 1998). Living longer with CHF means living with increased symptoms greatly affecting the QOL in those with heart failure. Persons with CHF experience an impaired QOL secondary to physical symptoms, psychological distress, limitations of social activity, and side effects of treatments (Berry & McMurray, 1999).

A recent attempt to delineate what constitutes general QOL lead to the emergence of the term, health-related quality of life (HR-QOL). This term is considered more specific to disease conditions than general QOL and is used to assess the impact of the disease on the daily lives of individuals with heart failure (Nanda & Andresen, 1998;

Schron, Gorkin, & Gary, 1994; Bennett, Baker, & Huster, 1998). HR-QOL is a multidimensional concept involving the measurement of several domains of the patient's life. These domains include physical symptoms and their consequences, functional ability, and perceptions about their general health, well-being, and life satisfaction (Bennett et al., 1998; Wenger, 1989; English & Mastrean, 1995). Measuring HR-QOL is an important assessment because it includes the patient's perception of their health and well-being (Berry & McMurray, 1999) in addition to their symptoms and functioning. Measuring QOL has been known to guide health-related public policies (Wenger, 1992), such as clinical pathways and specialty care clinics. Increase in knowledge of gender specific HR-QOL in persons with CHF will impact not only delivery of individual care, but also may affect public policy on health promotion and disease prevention.

#### Quality of Life-Drug Studies

QOL has been used as the outcome for testing the effectiveness of experimental medical interventions such as trials comparing drugs verses placebos. Although these clinical trials have demonstrated the relationships of CHF to QOL, the purpose of many of these trials was focused on physiological parameters altered by the medication, with only a secondary analysis on quality of life.

With the Studies of Left Ventricular Dysfunction (SOLVD) QOL substudy trial, the affects of an angiotension-converting enzyme inhibitor was examined in the context of QOL measurement. A battery approach was used with outcome measurement tools that included QOL measures. Generalizability however, of this non-representative sample, consisting primarily of men, is questionable. This experimentally designed drug intervention study with 27 out of 308 recruited subjects women, did not allow comparison of men and women's perceived QOL, and focused only on quality of life in general (Gorkin et al., 1993). The results however, did show a correlation between the patient's NYHA classification and their perceived QOL. Others have found, as would be expected, those with worse NYHA classification showed poorer QOL (Schron et al., 1994).

The exclusion of women in clinical drug trials measuring QOL is all too common as demonstrated in an analysis of HR-QOL studies by Shively, Fox, and Brass-Mynderse (1996). They reviewed a large number of studies involving HR-QOL measures in congestive heart failure patients and found that in the majority of cases the primary study objective was the physiological changes affected by the medication interventions with QOL only as a secondary analysis. The subjects in most of the studies were a majority cohort of men, or gender was not recorded as being measured.

The lack of comparison between men and women, and exclusion of women with heart failure in clinical drug trials is also supported through an analysis by Moser (1997). Women are grossly underrepresented in the major clinical drug trials on heart failure patients. There are multiple studies examining the QOL of CHF patients while participating in clinical drug trials, but few women were included, or not compared with men in these studies (VASODILATORS, the CONSENSUS Trial Study, V-HeFT II, SOLVD, BETA-BLOCKERS CIBIS, US Carvedilol Heart Failure Study, and DIGITALIS).

In a randomized double-blind parallel group-controlled trial of 51 patients Sanderson et al., (1999) compared the effects of carvedilol and metoprolol on QOL. Using the Minnesota Living with Heart Failure Questionnaire (LHFQ), quality of life was measured, showing improvement with both the study groups. However, there were no

comparisons made between men and women, only 11 patients were women, and the majority of the heart failure patients were in NYHA classification of III.

Hjalmarson et al. (2000) also used a randomized, double-blind controlled trial to study the effects of controlled-released metoprolol and its effects on QOL. However, in this sample size of 3991 patients, only 23% of the metoprolol group and only 22% of the placebo group was female. No comparisons were made between the women and men in regards to QOL.

Using the calcium channel blocker amlodipine in a randomized, double-blind, placebo-controlled prospective design, Udelson et al. (2000) studied the effects of exercise tolerance and QOL. However, in this sample of 874 patients with CHF, only 204 were women, and the majority of the sample size was in NYHA classification of II and III. Again, there were no comparisons between men and women.

This lack of comparison between men and women and exclusion of women subjects has also been carried over to recent inotropic intravenous studies with heart failure (Cesario, Clark, & Maisel, 1998; Oliva et al., 1999). In a quasi-experimental study of the effects of a positive inotropic drug by Casario, Clark, and Maisel (1998), 10 subjects were studied, one of which was female. And in an experimental study by Oliva et al. (1999), only 7 women out of the 38 heart failure patients in NYHA classification of III or IV, were in the study.

## Quality of Life-Transplant Candidates

A significant amount of research measuring QOL has been conducted on heart transplant candidates, but gender comparisons have also been excluded from these studies of heart failure patients. Gender was reported as not being a significant contributor to QOL, but only a small representation of women were included in the studies (Dracup, Walden, Stevenson, & Brecht, 1992; Grady et al., 1995; Walden et al., 1989).

Dracup, Walden, Stevenson, and Brecht (1992), used a descriptive nonexperimental design to measure QOL in possible heart transplant patients, but only 17% of the subjects were female. In a study by Grady et al. (1995), a descriptive nonexperimental design was also used to study patients awaiting heart transplantation, but again, only 17% of the subjects were women. And the majority of the 44 patients studied by Walden et al. (1989) in a quasi-experimental, between-subjects design of patients being evaluated for heart transplantation, were men. The actual number of men and women in the study was not recorded.

## Quality of Life - Women with CHF

Studies of women with CHF are underrepresented in the literature. There are only a few studies specifically addressing the population of women with congestive heart failure. This is an important population of study, since recent research has shown heart failure may impact women's QOL differently than men (Bennett et al., 1998; Moser, 1997; Murberg et al., 1998).

Only three studies found in the review of literature specifically studied specifically women with congestive heart failure (Riedinger et al., 2000; Bennett et al., 1998; Friedman & King, 1995). Their findings demonstrated that the symptoms of fatigue and dyspnea were particularly prevalent in this population (Riedinger et al., 2000; Bennett et al., 1998; Friedman & King, 1995). However, caution needs to be used with the interpretation of these results, based on the relatively small sample size used in the studies of Bennett et al., and Friedman and King; 30 women in Bennett, et al. (1998), and 57 women in Friedman and King (1995).

In a secondary analysis of the SOLVD trials, Riedinger et al. (2000) studied predictors of QOL of 691 women with CHF. The mean NYHA functional classification for this cohort was 1.99. Since only 1.3% of the women were in NYHA class IV, classes III and IV were combined for analysis. These results concurred with previous findings that as the NYHA classification increased in severity, QOL scores decreased. However, discretion needs to be used with the interpretation of these results since this was a secondary analysis of this cohort, and was not a representative sample of all NYHA classes.

These results demonstrate the need to perform gender specific comparison studies of the responses of men and women with congestive heart failure in relation to their perceived QOL (Moser, 1997).

## Quality of Life - Men and Women Comparison

QOL research involving both men and women without connection to clinical drug intervention trials or heart transplant candidates, have recently been reported. However, studies specifically measuring gender differences with QOL are few (Chin & Goldman, 1998; Murberg et al., 1998), and can be divided into three categories: those that are hospital based, those not including comparison analyses of men and women, and those specifically looking at gender differences with QOL as their primary measurement of study.

Candlish, Watts, Redman, Whyte, and Lowe (1998) examined QOL in men and women aged 60 years and older in a prospective cohort study of hospitalized patients. Measurement tools were used to measure the patient's satisfaction with care and their QOL. However, even with this equal representative sample of 75 elderly men and 73 elderly women with heart failure, no comparisons between these two cohorts were performed.

A descriptive study by Wiklund, Lindvall, Swedberg, and Zupkis, (1987) was done to assess the QOL of a sample of men and women with heart failure. A newly developed self-assessment questionnaire measuring HR-QOL was used. Although 33 men and 18 women were both included in this study, no gender comparison was done in this study.

In only three studies were gender differences specifically studied, with results revealing men and women responding differently to congestive heart failure, women recording consistently a lower QOL than men (Steptoe et al., 2000; Chin & Goldman, 1998; Murberg et al., 1998). In a study of dilated cardiomyopathy patients, Steptoe et al. (2000) measured HR-QOL on 99 patients. However, in this sample of 99 patients, only 20 were female and 92 of the subjects were in NYHA classification of I and II. And of the 22 women in Murberg et al.'s (1998) study, had heart failure an average of 29.7 months longer than the 59 men, which may be one contributing factors for the differences in recorded QOL between men and women (Murberg et al., 1998). Although length of disease was not controlled in the analysis by Chin and Goldman (1998), the 90 women completing the surveys were an older cohort than the 89 men in the study. The extraneous

variables of length of condition and age of cohort may explain the differences in the QOL recorded by men and women of these studies.

A significant amount of research measuring QOL has been conducted on heart transplant candidates. Findings have shown that the NYHA classification and selfreported functional status was significantly correlated with patient's psychosocial adjustment. Those with a higher NYHA functional classification (class IV) had a poorer life satisfaction than those with less symptom distress and better health perception (Grady et al., 1995; Bennett et al., 1998). However, this exclusive population of persons with heart failure may not be representative of the population of congestive heart failure patients at large, secondary to the meticulous selection criteria of transplant candidates (Bennett, Pressler, Hays, Firestine, & Huster, 1997).

## Level of Severity

The New York Heart Association (NYHA) functional scale is a widely used system to classify the severity of CHF. The grading system divides CHF into four classes as follows: Class I - patients have impaired cardiac function, but do not display symptoms and have no limitations with their activity. Class II - patients are classified at this level if they become fatigued, short of breath, have anginal pain, or palpitations after moderate activity. They are without symptoms at rest. Class III- patients display significant limitations in activity. Slight to moderate activities create symptoms of fatigue, shortness of breath, anginal pain, or palpitations. Class IV - results when patients are unable to do any physical activity without symptoms or discomfort. They display shortness of breath and fatigue at rest (Konstam et al., 1994; Martensson, Karlsson, & Fridlund, 1997; Murberg et al., 1998).

Ejection fraction (EF) is another widely used measurement tool for evaluation of the severity of CHF. The EF is used in clinical practice for the evaluation of left ventricular performance and is defined as the proportion of blood that is ejected during each ventricular contraction compared with the total ventricular volume. Approximately two-thirds of the end diastolic volume is ejected with each cardiac contraction, and is considered a normal value in percentages of approximately 55%. However, this measurement tool is very sensitive to the loading conditions present at the time of measurement, and varies in values depending on the technique used for measurement. Thus, the value can fluctuate based on the afterload present at the time of measurement. Even with these known technical limitations, because of the clarity and ease of measurement, the EF is widely used in practice to measure left ventricular performance (Bellenger et al., 2000; Vera, Gardin, & Bok, 1995; Chatterjee et al., 1991).

The lack of representative studies including equal numbers of men and women with heart failure, demonstrates the need for future studies measuring their QOL. Comparison studies are needed between men and women to assess their perceived symptoms. If men and women respond to heart failure differently, and if women with CHF do indeed have a poorer QOL than men, then measuring their QOL is crucial to testing therapeutic interventions designed specifically to meet their needs and improve their QOL.

Generalization to women in the heart failure population needs careful attention, and not extrapolated without further research. Representative samples of men and women are needed to compare and contrast men and women's perceived QOL.

#### **Theoretical Framework**

The framework used to guide the development of this study and to define QOL is the Wenger model (Wenger, 1989). The Wenger model is part of the framework used in the development of the LHFQ (Rector, Kubo, & Cohn, 1987). In this model, Wenger outlines three domains which should be examined when evaluating the HR-QOL of patients with CHF. These domains include functional capacity, perceptions, and symptoms and their consequences (Wenger, 1989). Figure 1 is a representation of the impact of CHF on QOL across the NYHA classification for this study.

Wenger (1989) describes the first domain of HR-QOL, the functional capacity, as "the patient's ability to carry out the usual activities of day-to-day life" (p. 392). These physical activities involve such things as self-care, intellectual, emotional functioning and interactions with family, work and interpersonal actions (Wenger, 1989). Wenger further describes the functional domain as involving activities which are necessary to perform the activities of daily living which are essential to partake in both occupational and recreational activities, as well as social and family relationships. The intellectual activities are also a part of this domain and are described as the functions necessary to make decisions, such as judgment, confidence, memory, alertness and the ability to communicate (Wenger, 1989).

A second domain necessary to assess the HR-QOL of patients with CHF is the patient's perceptions (Wenger, 1989). This domain includes the patient's perception of their life satisfaction and health-related well-being and gives insight to the patient's beliefs, value systems and perceptions, including the patients' assessment of their disease and how it impacts their ability to function on a daily basis (Wenger, 1989). Perceptions





are included as a domain because research has shown that measuring perceived health is a better indicator of work performance than actual functional measures of health (Wenger, 1989).

Symptoms are outlined as the third domain in assessing the QOL of patients with CHF. According to Wenger (1989), symptoms may relate not only to the disease or disorder, but also to the iatrogenic problems caused by treatment or comorbidities. Wenger describes these symptoms as including but not limited to, dyspnea, exhaustion, fatigue, insomnia, pain, dizziness, and side effects of medications. These symptoms may in turn affect the other domains of functional capacity and perceptions as well (Wenger, 1989).

Examining these three domains when assessing QOL of patients with CHF may be of added value over global or generic QOL measures (Wenger, 1989). Conservation of patient's functional capacity, autonomy, and self-care, are major goals of therapy for patients with CHF (Wenger, 1989; Wenger, 1992). Therefore using these three domains to assess QOL of men and women with CHF will help evaluate their perceived QOL with CHF.

The research questions are as follows. Is there a difference between men and women's perceived QOL with CHF? Is there a difference in QOL across the NYHA functional classifications without differentiation by gender? Is the QOL different for men with CHF than women with CHF based on their NYHA functional classification?

Based on the research questions, it is hypothesized that the scores between men and women with heart failure will be different based on their functional classification, with women scoring lower in their perceived quality of life with CHF than men.

## CHAPTER III Methods and Procedures

A retrospective, non-experimental design using a between-subject comparison was used in this study. Institutional review board (IRB) approval was applied for prior to the retrospective study. Approval from Michigan State University Committee on Research Involving Human Subjects (UCRIHS) and the Spectrum Health Research and Human Rights Committee was granted. Confidentiality was insured to the fullest extent as permitted by law.

The sample was drawn from a population followed by the outpatient Spectrum Health Congestive Heart Failure Clinic, located in Grand Rapids, Michigan. Equal numbers of men and women with each classification delineation were included until at least 20 participants were in each cell. In order to increase the generalizability of the sample, all subjects who were diagnosed with CHF and those who completed the questionnaires during their routine clinical assessment were included in study. Persons with CHF who were potential heart transplant candidates were excluded from this study when known.

Review of the medical records by the investigator was done to collect demographic data and to determine the NYHA functional classification. NYHA classification was compared with their symptoms to ensure interrater reliability. Patient demographics such as gender, age, employment status, socioeconomic factors, race, comorbidities, number of medications, and marital status were collected from the patient's medical records. Ejection fraction (EF) was recorded as a percentage based on

echocardiogram reports done at the time of admission into the heart failure clinic. When there were ranges for EF's recorded in the chart, the data collector consistently recorded the lower of the two numbers. For instance, if an EF was recorded as 25-30%, the collector recorded 25% as their EF.

Participants currently are given the LHFQ upon the initial visit to the heart failure clinic. Analysis of this previously collected data was done in this study. QOL scores were derived from the LHFQ. The total score as well as the physical and the emotional subscales were recorded for each subject. Mean scores and standard deviations were recorded for the entire sample, and for each gender specific cohort, both with and without the independent variable of the NYHA level of disease severity. These descriptive statistics were done for the total LHFQ score and the physical and emotional subscales. Questions that the subjects left blank on the questionnaires were recoded with the mean scores. The highest possible score on the LHFQ was 105.

#### Measures

The disease specific Minnesota Living with Heart Failure Questionnaire (LHFQ) was selected for use in this study to assess patient's QOL with CHF. The LHFQ is a self-administered questionnaire, which measures the patient's perception of how CHF symptoms have impacted their lives during the past month. The questionnaire is a 21-item instrument in which patients rate items on a 6-point response scale (0 = no, 1 = very little, 6 = very much). The items on the questionnaire ask patients to rate how CHF has prevented them from living as they wanted during the past month (Rector & Cohn, 1992).

The LHFQ has two subscales which measure the physical (8 items) and emotional (5 items) symptoms of CHF. The physical subscale consists of items related to the degree

of dyspnea and fatigue of CHF. The emotional subscale consists of items related to feeling burdensome, feeling a loss of self-control, worry, difficulty concentrating, and feeling depressed. The remaining 8 items do not fit in a specific subscale, but include questions about the affects of CHF including earning a living, sexual activity, ankle edema, diet, hospitalizations, medical costs, and side effects (Rector & Cohn, 1992).

Scoring of the LHFQ was computed by summating the responses of all 21 questions. A higher score indicates greater symptom impact, interfering with the person's ability to live the way they wanted during the past month. A lower score indicates better HR-QOL. The physical and emotional subscales were computed by summating their responses to the items to further examine the effect of CHF on a patient's life (Rector & Cohn, 1992).

Internal consistency reliability of the LHFQ has been well established in the use with persons with CHF with a Chronbach's alpha of at least 0.9 (Rector & Cohn, 1992; Bennett et al., 1997; Gorkin et al., 1993; Bass, Fontana, & Bhat, 1997), and Chronbach's alpha of 0.87 (Bennett, Baker, & Huster, 1998) for the total LHFQ score. For this study, a Chronbach's alpha of 0.93 was found with the whole questionnaire, 0.95 for the physical subscale, and 0.88 for the emotional subscale.

Content validity of the LHFQ has been established with the initial version of the questionnaire. Patients were asked if there were any other emotional, physical, or social issues which prevented them from living the way they desired, and no new limitations were identified (Rector et al., 1987). Content validity has also been validated both in a randomized, double-blind, placebo-controlled trial of pimobendan (Rector & Cohn,

1992), as well as in the SOLVD Prevention Trial with enalapril verses placebo (Rector, Kubo, & Cohn, 1993).

Construct validity has been established in a placebo-controlled trial with enalapril, with patient's baseline LHFQ scores significantly different at p<0.001 between asymptomatic and symptomatic CHF patients (Rector et al., 1993). The LHFQ is a well established instrument designed for specific use with CHF patients (Berry & McMurray, 1999; Ni et al., 2000). This questionnaire was developed using a cohort of men (Rector, Kubo, & Cohn, 1987), but validated on women (Bennett et al., 1998). The scale, however, has not been used to compare men and women in the same study.

A factor analysis was done for the LHFQ in this study to validate the items on the subscales. An orthogonal transformation yielded two factors in this study, which contained similar items to the physical and emotional subscales of the LHFQ.

The NYHA functional classification system was used as the criteria for classifying heart failure patients into their level of severity. The New York Heart Association (NYHA) functional scale is a widely used system to classify the severity of CHF. The grading system divides CHF into four classes as follows: Class I - patients have impaired cardiac function, but do not display symptoms and have no limitations with their activity. Class II - patients are classified at this level if they become fatigued, short of breath, have anginal pain, or palpitations after moderate activity. They are without symptoms at rest. Class III- patients display significant limitations in activity. Slight to moderate activities create symptoms of fatigue, shortness of breath, anginal pain, or palpitations. Class IV results when patients are unable to do any physical activity without symptoms or discomfort. They display shortness of breath and fatigue at rest (Konstam et al., 1994; Martensson, Karlsson, & Fridlund, 1997; Murberg et al., 1998).

Although the NYHA classification system is the most widely used system of classification for CHF, it has received criticism for its lack of reliability, especially interobserver reliability (Konstam et al., 1994; Wenger, 1989; Bowling, 1995; Murberg et al., 1998). While further clarity of this classification tool is desired to allow health care providers to communicate CHF status more objectively, it is the most commonly used and understood tool, and the criteria described above was used in this study to classify CHF status.

#### Analysis

The descriptive statistics of means, standard deviations, and ranges for the scores of the questionnaire were provided for gender differences, the physical subscale, the emotional subscale, and level of disease severity. Extraneous demographic variables were reported for men and women and by NYHA functional classification and analyzed for differences using t-test or chi-square as appropriate.

Comparisons between men and women and across level of disease severity on QOL were analyzed using factorial ANOVA with gender and NYHA classification as the independent variable and QOL as the dependent variable. An alpha of .05 was used in this study to determine statistical significance.

## CHAPTER IV Results

The sample size consisted of 184 subjects from the Spectrum Health Congestive Heart Failure Clinic in Grand Rapids, Michigan. Data were analyzed using the SPSS and SAS statistical software. Of these 184 subjects, 168 were Downtown Campus patients and 16 were East Campus patients. The original intent was to collect data on subjects only from the Downtown campus, however in order to have an equal number of men and women in each NYHA classification, data on subjects from the East Campus was also collected.

## Subjects

The study sample consisted of 92 men and 92 women for a total of 184 subjects. All attempts were made to include equal numbers of men and women in each NYHA classification. However, since the heart failure clinic had so few patients in NYHA class I, subjects in NYHA class I and II were grouped together for this analysis. Demographic characteristics of the sample are presented in Tables 1 - 4.

Race was categorized into the following categories: White, African American, Hispanic, Asian, other, and unknown. Most of the subjects in this study were Caucasian. Of the 184 subjects, 140 (76.1%) were white, 21 (11.4%) were African American, 2 (1.1%) were Hispanic, 1 (0.5%) were Asian, 1 (0.5%) were other, and 19 (10.3%) were unknown. For the breakdown by gender, see Table 1.

NYHA functional classification was recorded as being either labeled in the chart or assigned by the data collector based on their symptoms recorded in the chart at the time

## Table 1.

## <u>Race</u>

	Me	n n=92	Womer	n n=92
	<u>n</u>	<u>%</u>	<u>n</u>	<u>%</u>
Caucasian	73	79.30	67	72.80
African American	11	12.00	10	10.90
Asian	1	1.10	0	0.00
Hispanic	0	0.00	2	2.20
Other	0	0.00	1	1.10
Unknown	7	7.60	12	13.00

## Table 2.

## Age

		Men n=9	2 <u>Standard</u>		Women	n=92 <u>Standard</u>
	<u>n</u>	<u>Mean</u>	Deviation	<u>n</u>	<u>Mean</u>	Deviation
Age	92	63.14	14.73	92	65.01	15.82
NYHA I and II	40	61.03	15.50	40	59.68	16.76
NYHA III	32	64.94	14.59	21	69.28	14.00
NYHA IV	20	64.50	13.49	20	68.85	14.03

## Table 3.

## Medications (#'s)

	<u>n</u>	Men n=9 <u>Mode</u>	2 <u>Range</u>	n	Women <u>Mode</u>	n=92 <u>Range</u>
Medications	92	7	3-21	92	7	0-19
NYHA I and II	40	7	3-13	40	7	0-15
NYHA III	32	7	3-21	32	7	4-15
NYHA IV	20	11	3-14	20	13	5-19
NYHA III NYHA IV	32 20	7 11	3-21 3-14	32 20	7 13	4-15 5-19

Table 4.

## **Ejection Fraction**

	<u>n</u>	Men n=9 <u>Mean</u>	2 <u>Standard</u> Deviation	<u>n</u>	Women i <u>Mean</u>	n=92 <u>Standard</u> <u>Deviation</u>
Ejection Fraction	91	26.31	14.02	90	29.43	16.37
NYHA I and II	40	26.25	12.30	39	28.26	14.08
NYHA III	32	25.91	14.38	31	31.16	16.40
NYHA IV	19	27.11	17.27	20	29.05	20.65

of admission. Of the 184 subjects, 56 had NYHA class labeled in the medical record, and the data collector assigned 128. The 92 men in this study ranged from 17 to 92 years of age with a mean age of 63 years and a standard deviation of 14.73. There were 8 men in NYHA class I, 32 in class II, 32 in class III, and 20 in class IV. The 92 women in this study ranged in age from 20 to 97 years with a mean age of 65 years and a standard deviation of 15.82. There were 3 women in NYHA class I, 37 in class II, 32 in class III, and 20 in class I, 37 in class III, and 20 in class IV. Table 2 lists the mean ages and standard deviations for these groups across the NYHA classification.

Medications were recorded by the number of pills taken daily and the drug family classification. The number of medications taken by each individual ranged from 0 to 21 with the mode being 7. There were no statistically significant differences between men and women with the number of medications taken. As disease severity increased, the mean number of medications increased, but there was no statistically significant differences with the QOL scores. Table 3 shows the medication numbers for the men and women across the NYHA classifications. The most frequently prescribed medication was diuretics followed by angiotensin converting enzyme inhibitors.

Medications were examined across NYHA classes and QOL scores. ANOVA did not detect individual drug type differences or numbers between the men and women across the NYHA. Having few subjects take a specific drug in each NYHA class, may account for the lack of findings.

Comorbidities were recorded as hypertension (N= 93), diabetes (N= 64), chronic obstructive pulmonary disease (N= 41), atrial fibrillation (N= 40), cancer (N= 22), arthritis (N= 21), and none (N= 2). There were no significant differences recorded

between the groups in this study, due to the small numbers of subjects with each disease category in each NYHA classification.

However, when analyzing the 64 subjects with diabetes and their QOL scores across the NYHA classification, there were statistically significant differences (F  $_{(2.183)}$ = 3.42, p = 0.0349) noted with NYHA classification and diabetes. Table 5 presents the descriptive statistics for the QOL scores for those with diabetes and for those with other comorbidities. Thus, showing that those with diabetes had lower QOL scores than the subjects with other comorbidities.

Ejection fraction (EF) was recorded as a percentage based on echocardiogram reports done at the time of admission into the heart failure clinic. The mean EF for the subjects in NYHA class I and II combined was 27.24% with a standard deviation of 13.16. The mean EF for the subjects in NYHA class III was 28.49% with a standard deviation of 15.51. The mean EF for the subjects in NYHA class IV was 28.10% with a standard deviation of 18.85.

The mean ejection fraction for the men in this study was 26.31% with a standard deviation of 14.02. One male subject did not have a recorded ejection fraction. The mean EF for the men in NYHA class I and II combined was 26.25% with a standard deviation of 12.30. The mean EF for the men in NYHA class III was 25.91% with a standard deviation of 14.38. The mean EF for the men in NYHA class IV was 27.11% with a standard deviation of 17.27.

The mean ejection fraction of the women in this study was 29.43% with a standard deviation of 16.37. Two female subjects had medical records without a

## Table 5.

## Symptoms Reported as Most Severe

Symptoms Reported as Most Severe by Subjects (n=184), as Measured by the LHFQ									
Symptom	Range Frequency								Mean
		0	1	2	3	4	4.5	5	
Tiredness	0-5	13	7	20	27	35	1	81	3.68
Short of Breath	0-5	18	19	15	30	32	1	69	3.35
Difficulty Walking	0-5	27	12	17	26	30	2	70	3.28
Difficulty Working around Home	0-5	27	16	13	31	24	1	72	3.24
Eating Less	0-5	31	20	13	26	25		69	3.09
Resting Frequently	0-5	39	14	15	30	29		57	2.94
Difficulty w/ Recreational Activities	0-5	32	18	12	43	25	1	53	2.90
Difficulty Going Places	0-5	41	13	16	38	29	2	45	2.77
Worry	0-5	34	26	18	31	27		48	2.73
Difficulty Relating to Family & Friends	0-5	36	20	17	41	30	1	39	2.70

# Symptoms Reported as Most Severe by Men (n=92), as Measured by the LHFQ

Symptom	Range Frequency							Mean	
			0	1	2	3	4	4.5	5
Tiredness	0-5	11	4	9	11	19		38	3.48
Shortness of Breath	0-5	11	9	9	15	18	1	29	3.19
Difficulty Walking	0-5	19	7	7	12	15	1	31	3.01
Difficulty w/ Recreational Activities	0-5	18	6	9	17	14		28	2.94
Difficulty Working Around Home	0-5	19	8	8	16	8		33	2.92
Eating Less	0-5	18	13	5	16	8		32	2.86
Difficulty Sleeping	0-5	20	8	8	15	18		23	2.78
Resting Frequently	0-5	22	9	8	19	9	1	24	2.64
Difficulty Relating to Family & Friends	0-5	20	11	9	20	13		19	2.56
Difficulty Going Places	0-5	26	6	7	19	11	1	22	2.56

Symptoms Reported as Most Severe by Women (n=92), as Measured by the LHFQ

Symptom	<u>kange</u> <u>rrequency</u>								<u>Mean</u>
			0	1	2	3	4	4.5	5
Tiredness	0-5	2	3	11	16	16	1	43	3.88
Difficulty Working Around Home	0-5	8	8	5	15	16	1	39	3.55
Difficulty Walking	0-5	8	5	10	14	15	1	39	3.55
Shortness of Breath	0-5	7	10	6	15	14		40	3.51
Eating Less	0-5	13	7	8	10	17		37	3.33
Resting Frequently	0-5	10	9	4	24	16		29	3.24
Worry	0-5	12	14	5	16	11		34	3.11
Difficulty Going Places	0-5	15	7	9	19	18	1	23	2.97
Difficulty Relating to Family & Friends	0-5	16	9	8	21	17	1	20	2.83
Feelings of Depression	0-5	16	13	13	15	12		23	2.69

documented ejection fraction measurement. The mean EF for the women in NYHA class I and II combined was 28.26% with a standard deviation of 14.08. The mean EF for the women in NYHA class III was 31.16% with a standard deviation of 16.40. The mean EF for the women in NYHA class IV was 29.05% with a standard deviation of 20.65.

When analyzing EF and the NYHA classification, with EF as the dependent variable, there was no statistical significance between the means (F  $_{(2, 180)} = 0.13$ , p = 0.8819). There also was no statistical significance with EF and gender (F  $_{(1, 180)} = 1.65$ , p = 0.2002). And, there was no interaction found with EF across NYHA class and gender (F  $_{(2, 180)} = 0.23$ , p = 0.7932).

## Quality of Life and Gender

The entire sample of men and women together yielded a total mean LHFQ score of 53.81 and a standard deviation of 25.83. The mean LHFQ score for the 92 men in this study was 50.34 with a standard deviation of 26.32. And for the 92 women in the study, the mean LHFQ score was 57.28 with a standard deviation of 25.00. Analyzing the men and women's LHFQ mean scores using ANOVA showed no statistically significant differences between the genders ( $F_{(1, 183)} = 2.24$ , p = 0.1363).

Looking at the two subscales in the LHFQ, the mean score for the physical subscale (items 2, 3, 4, 5, 6, 7, 12, and 13) of the whole sample was 24.54 with a standard deviation of 12.28. The mean score for the emotional subscale (items 17, 18, 19, 20, and 21) of the entire sample was 11.57 with a standard deviation of 7.58. Table 5 reports the subscale scores for men and women in each NYHA class.

Examining the physical subscale scores between men and women yielded no statistically significant difference (F  $_{(1,183)}$  = 1.16, p = 0.2824). However, when examining

the emotional subscale scores between the men and the women, the results showed statistically significant results (F  $_{(1,183)}$  = 5.75, p = 0.0175). Using Tukey's post hoc to test for statistical significance, resulted in difference between the men and women.

The ten items most frequently reported by both genders to impact QOL as measured with the LHFQ are shown in Table 6. Table 6 also shows the ten items reported most frequently as impacting the QOL of each gender. The minimum score for each question in the subscales is 0 with a maximum score of 5.

Interestingly, when examining the relationship between EF and QOL for the entire sample group no relationship was found (r = 0.076, p = 0.309). Similar gender specific analysis also did not yield statistically significant relationships. Furthermore, when the relationship between EF and QOL was examined for each NYHA classification separately, no significant correlation was found [NYHA I & II (r = 0.0794, p = 0.4887); NYHA III (r = 0.0772, p = 0.5475); NYHA IV (r = 0.0639, p = 0.6994)]. Analysis of QOL and EF relationships for each of the subscales separately also did not find a relationship. Even when a natural log linear transformation was used to correct for the skewness in the data, no relationships were found in the results. Thus, there was no relationship found between EF and QOL.

## Quality of Life and NYHA Classification

#### Total scores

LHFQ scores were analyzed across the NYHA classifications to assess QOL for the sample as a whole. Looking at the entire study group of NYHA classes I and II combined, the mean LHFQ score was 45.57 with a standard deviation of 28.28. For NYHA class III the mean LHFQ was 55.24 with a standard deviation of 22.83. The entire

## Table 6.

### LHFQ Scores

	Tota	Total Sample		en	Women	
		Standard		Standard		Standard
	Mean	<u>Deviation</u>	Mean	Deviation	<u>Mean</u>	Deviation
OOL Score						
NYHA I and II	45.57	28.28	38.93	27.69	52.22	27.61
NYHA III	55.24	22.83	53.65	22.87	56.83	23.04
NYHA IV	68.00	17.83	67.87	16.53	68.12	19.59
Physical Subscale						
NYHA I and II	20.60	23.21	17.09	13.22	24.12	12.39
NYHA III	24.89	10.92	24.84	10.27	24.94	11.71
NYHA IV	31.83	8.67	32.55	8.68	31.10	8.83
Emotional Subscale						
NYHA I and II	9.37	7.66	7.21	7.04	11.53	7.73
NYHA III	12.04	7.53	10.95	7.34	13.12	7.67
NYHA IV	15.22	5.97	14.50	5.61	15.94	6.37
QOL Score with CHF and Diabetes						
NYHA I and II	52.21	27.95	47.20	32.19	56.84	23.75
NYHA III	48.65	19.28	52.77	20.79	42.66	15.87
NYHA IV	73.04	16.60	72.67	15.76	73.41	18.92
QOL Score with CHF and Diabetes Excluded						
NYHA I and II	42.56	28.16	35.38	25.34	50.00	29.45
NYHA III	60.05	24.23	54.53	25.43	64.26	22.98
NYHA IV	65.84	18.27	65.81	14.00	65.86	20.12

NYHA class IV yielded a mean LHFQ score of 68.00 with a standard deviation of 17.89. Examining the classes using factorial ANOVA with NYHA as the independent variable and QOL as the dependent variable, and controlling for the size differences in the classes, a significant difference was noted (F  $_{(2, 183)} = 11.35$ , p = < 0.0001). Using Tukey's post hoc test to test for statistical significance between the NYHA classes, while controlling for the differences in class size, resulted in statistically significant differences between the NYHA classes I and II combined with class IV, and between NYHA class III and IV, with a p value of < 0.0001. As disease severity increased there was a conversely significant decrease in QOL.

#### Physical subscale scores

The LHFQ physical subscale mean score for the whole sample was 24.54 with a standard deviation of 12.28. For the entire NYHA class I and II combined the mean score was 20.60 with a standard deviation of 23.21. The physical subscale mean score for the NYHA class III was 24.89 with a standard deviation of 10.92. The physical subscale mean score for the entire NYHA class IV was 31.83 with a standard deviation of 8.67.

Analysis of both subscales was done to assess differences with NYHA class and subscale scores. When analyzing the physical subscale as the dependent variable, and NYHA class as the independent variable, there was statistically significant difference found (F  $_{(2, 183)} = 12.91$ , p = < .0001). Using Tukey's post hoc test showed statistically significant differences between NYHA classes I and II combined, with NYHA class IV, and between NYHA class III and NYHA class IV.

#### Emotional subscale scores

The emotional subscale mean score for the whole sample was 11.57 with a standard deviation of 7.58. For the NYHA class I and II combined, the emotional subscale mean score was 9.37 with a standard deviation of 7.66. The emotional subscale mean score for the NYHA class III was 12.04 with a standard deviation of 7.53. The emotional subscale mean score for the NYHA class IV was 15.22 with a standard deviation of 5.97.

Analysis of the emotional subscale produced similar results. Like the physical subscale, the emotional subscale showed statistically a significant difference with the NYHA classes ( $F_{(2, 183)} = 9.11$ , p = 0.0002). Using Tukey's post hoc test to test for statistically significance between the NYHA classes, while controlling for the differences in class size, resulted in statistically significant differences between the NYHA classes I and II combined and NYHA class IV.

## Quality of Life - NYHA and Gender

Table 2 shows the descriptive statistics for the LHFQ scores of men and women. For the men in the NYHA classes I and II combined, the mean LHFQ scores were 38.93 with a standard deviation of 27.69. The men in NYHA class III had mean LHFQ score was 53.65 with a standard deviation of 22.87. For the men in NYHA class IV, the mean LHFQ score was 67.87 with a standard deviation of 16.53.

The women in NYHA classes I and II combined yielded a mean LHFQ score of 52.22 with a standard deviation of 27.61. Women in NYHA class III had a mean LHFQ score of 56.83 with a standard deviation of 23.04. For the women in NYHA class IV, the mean LHFQ score was 68.12 with a standard deviation of 19.59.

While the mean scores for women with CHF appear lower than the men's mean scores for each NYHA class, analyzing this data did not find statistical significance. Using factorial ANOVA and controlling for class size differences, there was no significant interaction between gender with their LHFQ scores across the level of disease severity (F  $_{(2, 183)} = 1.26$ , p= 0.2870).

## Physical subscale scores

The men in this study in NYHA classes I and II combined scored a mean physical subscale score of 17.09 with a standard deviation of 13.22. For the men in NYHA class III, the mean physical subscale score was 24.84 with a standard deviation of 10.27. Examining the men in NYHA class IV, the mean physical subscale score was 32.55 with a standard deviation of 8.68.

The women in this study in NYHA classes I and II combined had a mean physical subscale score of 24.12 with a standard deviation of 12.39. For the women in NYHA class III, the physical subscale mean score was 24.94 with a standard deviation of 11.71. The women in NYHA class IV had a mean physical subscale score of 31.10 with a standard deviation of 8.83.

Gender specific inquiry with a two way ANOVA yielded no statistically significant interactions between the men and women with their physical subscale scores across the NYHA classes (F  $_{(2, 183)} = 2.51$ , p = 0.0842).

## Emotional subscale scores

The emotional subscale for the men in classes I and II combined had a mean score of 7.21 with a standard deviation of 7.04. The emotional subscale for the men in NYHA class III yielded a mean score of 10.95 with a standard deviation of 7.34. The mean emotional subscale for the NYHA class IV men, were 14.50 with a standard deviation of 5.61.

The emotional subscale for the women of NYHA classes I and II combined had a mean emotional subscale score of 11.53 with a standard deviation of 7.73. The mean emotional subscale for the women in class III was 13.12 with a standard deviation of

7.67. The mean emotional subscale score for the women in NYHA class IV were 15.94 with a standard deviation of 6.37.

Again gender specific inquiry with a two way ANOVA yielded no statistically significant interactions between the men and women with their emotional subscale scores across the NYHA classes (F  $_{(2, 183)} = 0.68$ , p= 0.5074).

## CHAPTER V Discussion

## Summary of Results

The results of this study showed there were no differences in the total QOL scores or their physical subscale scores between men and women. However, there were statistically significant differences found between the men and women in their emotional subscale scores. There were statistically significant differences found between the NYHA classes with the overall QOL score and also with the physical and emotional subscale scores across the NYHA classes. But when evaluating the NYHA across gender, there were no statistically significant interactions found between the men and women across the overall QOL score, or the physical and emotional subscales.

The results of this study support previous work in this area, that as the level of disease severity with CHF progresses as measured by the NYHA classification, there is a statistically significant decrease in the QOL (Riedinger et al., 2000; Bennett et al., 1998; Grady et al., 1995; Schron et al., 1994; Gorkin et al., 1993). However, the results of this study failed to support the hypothesis of the study, which stated that the QOL scores between men and women with CHF would be different based on their functional classification with women scoring lower than men in their perceived QOL.

Despite the fact that the mean scores for the men and women in each NYHA classification varied, with women having a lower overall mean QOL score than the men in this study, there were no statistically significant differences found. One possible explanation for the differences in these findings might be the large standard deviations of

the mean scores for the LHFQ of both men and women. These study findings are in contrast to the findings of others who reported women having a statistically significant lower recorded QOL than men with CHF across the level of disease severity (Steptoe et al., 2000; Chin & Goldman, 1998; Murberg et al., 1998).

However, care must be taken in the interpretation and comparison of this study's results with prior findings. The present findings may likely differ from prior research due to differences in study designs. In the study of Steptoe et al., (2000) only 20 of the 99 subjects were women and 92 of the total sample were in the NYHA classifications I and II. Because of the small number of women in an unequal disease severity distribution, the Steptoe et al., (2000) study may have been sensitive to outliers which may explain the differences with the results of this study.

Length of disease can potentially influence QOL with CHF, especially in light of the high mortality rate of 62-75% within 5 years of diagnosis (Berry & McMurray, 1999; Funk, 1993; Massie & Shah, 1997; Kannel & Belanger, 1991). Although length of disease was unobtainable in the present study secondary to inconsistent recordings in the medical records, Murberg et al. (1998) measured disease length in a study with 22 women and 59 men. The women, who were found to have a lower QOL, had CHF 29.7 months longer than the men. The present study's sampling which obtained equal numbers of men and women in each NYHA class, is likely to have resulted in similar lengths of disease in the men and women and may explain the finding of similar QOL scores for men and women.

The age of the persons in study may also explain the differences in this study's results from prior study findings. In the study by Chin and Goldman (1998) an older cohort of women was studied than the men. In the present study, the mean age for the 92

men was 63.4 years with a standard deviation of 17.73. The mean age for the 92 women in this study was 65.01 years with a standard deviation of 15.82. This mainly Caucasian study group in this study consisted of comparably matched groups of men and women with both ages and range of age. The age difference between the men and women in the study by Chin and Goldman (1998) could potentially explain the lower QOL for the women in their study.

These study results support prior findings of women with CHF and their reported symptoms. The symptoms of fatigue and dyspnea were also particularly prevalent in this study which is consistent with previous research findings for patients with CHF (Riedinger et al., 2000; Bennett et al., 1998; Friedman & King, 1995).

The overall mean QOL score for this entire study group as measured by the LHFQ was 53.81, with a standard deviation of 25.83. Measured on a scale of 0-105 with a lower score indicating a better HR-QOL, this study cohort appeared to report QOL scores compared with other studies. The studies reporting worse QOL had patients primarily in NYHA classes III and IV. Studies reporting better QOL had patients primarily in NYHA classes I and II.

One particular issue with this study of patients with CHF was the scarcity of those in NYHA class I found in this congestive heart failure clinic setting. The logical explanation of this phenomenon may be due to their lack of symptoms, their undiagnosed condition, lack of follow up with their care, or their treatment in the primary care setting by their primary care provider. It can be difficult to fully compare the NYHA classifications across all levels of disease severity due to the potential problem of access to those with the diagnosis of NYHA class I.

Interestingly, there was a statistically significant difference found between the men and women with the emotional subscale of the LHFQ. However, this was not found with the physical subscale. Perhaps women and men differ in these subscales with their symptom complaints, as listed in Table 5. A couple of the symptoms that women recorded more severe than men were that of worry and feelings of depression, which are found solely in the emotional subscale. The symptoms that men recorded more severe than women were that of difficulty with recreational activities and difficulty sleeping, which are items found on the physical subscale. These findings suggest attention to emotional and physical symptoms based on gender may be appropriate and important in the care of patients with CHF.

Evaluating the theoretical framework as depicted in Figure 1, modifications need to be made. With the representation of the staircase approach to CHF and QOL as modified from Wenger's (1989) model for this study, NYHA classes I and II need to be combined onto one stair. This study did not differentiate between NYHA class I and II and therefore inference as to QOL status cannot be extrapolated. Assessing the QOL of patients with CHF as measured by the LHFQ, within the context of the three domains of Wenger's model, helps to evaluate the perceived HR-QOL of patients with CHF as demonstrated in this study.

## **Discussion of Unexpected Findings**

Interesting findings were discovered with this study between those with CHF and diabetes, and those with CHF without diabetes. In this study, those with diabetes and CHF had a statistically significant lower QOL than those subjects with other comorbidities. However these results need to be interpreted with care. The number of

individuals with diabetes in this study was small (n=64), and there were a few extreme outliers which skewed the results within this cohort of subjects. Extrapolation of these finding must be with caution and must be done within this studies context. However, these findings bear note of significance for future study. Perhaps this is a unique group of patients that behave differently or experiences a different QOL than those without diabetes.

Several medications have been touted to improve specific symptoms of CHF. Analyzing the results of medications and QOL have shown some interesting secondary results in this study. There were no individual drug interactions recorded between the men and women across the NYHA classification. These findings may be related to the variety of medications in each classification that were prescribed for this study group. Having few subjects take a specific drug in each NYHA class, may account for the lack of significant findings. Whether the negative side effects of certain medications outweigh the benefits, or whether they impact the subject's QOL, bears further investigation.

As a secondary analysis with this study, ejection fraction was found to have little correlation with QOL or with the physical and emotional subscales. This is an interesting finding and one that deserves additional exploration. Perhaps QOL cannot be measured nor predicted by the functioning of the myocardium.

Ejection fraction and NYHA classification are different and separate ways to characterize disease severity. NYHA classification relates to QOL, while EF did not relate to QOL. The NYHA classification and the QOL measurements both use symptoms in their classifications, while EF is based on physiological functioning of the heart. These results question the significance of using EF to quantify the QOL in people with CHF.

#### **Study Limitations**

A major limitation in this study was the retrospective analysis design. The retrospective examination was limited by the data available for analysis. Data was collected from the information available in the medical charts, but cannot be construed as inclusively allowing insight into the subject's QOL with CHF. Incomplete LHFQ questionnaires by study subjects also presented a limitation. Blank answers on the LHFQ were recoded with the mean score of each question for the analysis. Mean scores were used to replace blank questions to avoid an inadvertently false lowering of the total LHFQ scores for those with missing items.

This study sample predominately consisted of a Caucasian representation. The retrospective design limited the ability to control for ethnic representation consistent with the community. Perhaps this congestive heart failure clinic, due to its location in the community, caters to a primarily Caucasian ethnicity. Perhaps other ethnicities in the community are more equally represented at other heart failure clinics or in the primary care setting.

Although not a part of the study design, the underrepresentation of other ethnic groups in this heart failure clinic may signify the need to address minority barriers to healthcare access. Results of this study can not be extrapolated to the general population or to other race categories, based on the exclusive Caucasian representation of this study.

Because of the retrospective design of this study, the measurement of QOL was limited by the use of only one questionnaire. Using an additional tool to measure QOL in conjunction with the LHFQ might add additional information for future research. A prospective, longitudinal design using a representative sample of equal numbers of men

and women in each NYHA class would also yield more sensitive information to change over time with QOL. Use of time as an additional variable may yield results in how QOL is affected for men and women with CHF over time.

## Implications for Education and Research

Future research should be aimed at a prospective longitudinal design with representative samples of men and women in each NYHA functional classification, including separation of NYHA classes I and II. Women historically have been excluded from many studies with CHF, until recently. Future research must include representative study of both men and women with an ethnic mixture, across all levels of socioeconomic status. Use of a longitudinal design might uncover gender or ethnic interactions over time between CHF and QOL.

Additional studies should be designed to control for length of disease. Differing length of diagnosis with CHF may show interactions between men and women in how they perceive their QOL over time.

Highly reliable and valid measurement tools must be used for this population in study which show subtle differences and which measure all aspects of QOL. Use of multiple standardized measurements would facilitate comparisons among subjects in different population groups. Measurement of QOL should be attempted with a battery approach of questionnaires without undue burden on the respondents. Perhaps using a battery approach study design including the LHFQ, subtle differences between men and women may be discovered. Then interventions tailored to the needs of those with CHF may continue to be developed to increase their QOL. Perhaps measuring QOL with more than one measurement tool may further delineate previous findings that there are gender

differences in QOL with CHF. This would be consistent with other research findings showing gender differences in QOL with CAD.

Another area, which bears further investigation, is the cohort of persons with both CHF and diabetes. Perhaps this is a unique group of patients that behave differently or experience a different QOL than those without diabetes. Future research should also analyze this cohort to see if other study yields similar results. Using multiple standardized measurements would facilitate and support other diabetic studies and comparisons across comorbities.

An additional issue in need of investigation is the impact of caregivers on QOL. This study did not show significant differences between the married and unmarried individuals. Perhaps marital status is not a sensitive measurement as it does not include significant others, other family members, or paid caregivers. A more inclusive inquiry into caregiver status may uncover gender interactions related to CHF and should be built in to future study designs.

## Implications for Primary Care Practice

Future studies should be done using the primary care setting for the study sample. Studying the population of patients with CHF in the primary care setting may yield important information regarding practice patterns and treatment between those treated in a heart failure clinic setting and those treated in primary care. Perhaps inquiry into the primary care setting might yield crisis points of trajectory into care of the patient with CHF.

QOL is a measurement based on a person's perception of their condition and symptoms. It is a highly subjective and multidimensional term, which cannot be directly

quantified. It can be indirectly measured with validated questionnaires to yield highly reliable information (Martin & Stockler, 1998). With this study's results of EF not correlating with QOL, perhaps treatment should continue to be tailored towards symptom alleviation with the CHF population, since QOL is a measurement of the patient's perceptions.

Studying men and women with CHF in the primary care setting might also help further evaluate the reliability of the NYHA functional classification system. Further clarity of this classification tool is desired to allow health care providers to communicate CHF status more objectively. Perhaps studying this group of patients in the primary care setting will stimulate inquiry into the classification of disease severity that is currently used with CHF management.

Gender specific inquiry will further identify treatment aimed specifically at men and women with CHF. Studying men and women in the primary care setting will further test the use of the Wenger theoretical framework with this population. Perhaps due to the methodological constraints of this study, the Wenger model had difficulty tapping into the constructs with this sample. Perhaps further study within the primary care setting will reveal clarity.

Patients with CHF regularly describe poor QOL, and the mortality from this disease is staggering (Konstam et al., 1994; English & Mastrean, 1995). Increased knowledge of gender specific QOL issues related to CHF impacts direct patient care. It is imperative that as the number of people with CHF increase with our aging population, continued inquiry into CHF is encouraged in order to mold our public policy of health promotion and disease prevention to maximize the individuals QOL.

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