PSYCHOLOGICAL DISTRESS, WELL-BEING, AND CARDIAC-SPECIFIC QUALITY OF LIFE AMONG PATIENTS WITH HYPERTROPHIC OBSTRUCTIVE CARDIOMYOPATHY UNDERGOING NONSURGICAL SEPTAL REDUCTION THERAPY

By

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“Consider it pure joy, my brothers, whenever you face trials of many kinds,
because you know that the testing of your faith develops perseverance.
Perseverance must finish its work so that you may be mature and complete,
not lacking anything.” –James 1:2-4

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Patients with hypertrophic obstructive cardiomyopathy (HOCM) are presumed to have poor quality of life (QOL) and distress related to their cardiac symptoms and functional limitations. Nonsurgical septal reduction therapy (NSRT) is a rapidly emerging treatment for HOCM, designed to improve heart function and reduce cardiac symptoms. The purpose of this study was to evaluate psychological distress, well-being, and cardiac-specific QOL among HOCM patients pre- and post-NSRT. There were 45 adult participants (*M* age = 54.3, *SD* = 15.62; 59.1% female; 97.6% Caucasian; 65.9% married) who were recruited during their initial evaluation or index hospitalization for NSRT. Psychological and medical measures were collected pre- and 3-month post-NSRT, including the Center for Epidemiological Studies–Depression (CES-D) Scale and the Minnesota Living with Heart Failure Questionnaire (MLHFQ) to assess depression and cardiac-specific QOL, respectively. Results indicated that prior to NSRT, 55.8% reported

clinically relevant levels of depression (CES-D > 16), a higher prevalence than cardiac disease and general populations. Pre-NSRT HOCM patients also reported poor cardiac-specific QOL (*M* MLHFQ = 49.86, *SD* = 29.83) and satisfaction with life (*M* = 21.02, *SD* = 8.42). Repeated measures analyses of variance (*n* = 20) revealed that NSRT is an effective procedure in reducing resting left ventricular outflow tract (R-LVOT) gradient (*M* = 59.26 vs. 20.79, $p < .001$), depression (*M* = 23.95 vs. 14.37, $p = .005$), and cardiac-specific QOL (*M* MLHFQ = 58.16 vs. 30.32, $p < .001$). However, when including R-LVOT gradient as a covariate, change in depression and cardiac-specific QOL were dependent on disease severity pre-NSRT. Contrary to the hypothesis, baseline depression did not predict 3-month post-NSRT cardiac-specific QOL. Notably, post-hoc analyses revealed that baseline R-LVOT gradient and cardiac-specific QOL predicted 3-month post-NSRT depression, explaining 62.7% of the variance (F [3,15] = 11.093, $p < .001$). This study was the first comprehensive, longitudinal outcome study examining HOCM patients and NSRT from a biopsychosocial model. Findings suggest that before intervention, patients may benefit from multidisciplinary care. Greater precision in depressive symptom identification independent of cardiac symptoms and QOL may point to a subset of depressed HOCM patients whose depression does not improve over time.

CHAPTER 1
INTRODUCTION

Cardiovascular disease (CVD) has been the number one killer in the United States every year since 1900, with the exception of 1918 (World War I). Nearly 2,600 Americans die of CVD every day, claiming more lives each year than the next five leading causes of death combined (American Heart Association, 2003). One in five adult males and females have some form of CVD. One type of CVD is cardiomyopathy (CM), which is defined as a structural abnormality limited to the myocardium. The computed mortality rate (actual confirmed occurrence) for cardiomyopathy in the year 2001 was 26,863, while the total mention mortality (predicted or assumed) for 2000 was 55,300 (American Heart Association, 2003). Further, hypertrophic cardiomyopathy (HCM) is the leading cause of sudden cardiac death in young athletes, estimated at about 36% of cases (American Heart Association, 2003). Mortality rates of HCM in the general population are between 1 to 6% annually (Cannan, Reeder, Bailey, Melton, & Gersh, 1995; Maron et al., 1999). With the high prevalence and mortality rates of CVD in general and specific types of disease (e.g., HCM), it is critical to examine its risk factors, resilience factors, and treatments from both a biomedical and a psychological standpoint.

The incidence of CVD has climbed due to poor health behaviors and individuals living longer lives. Now is an era of expanding therapies for these disease states, which further leads to an increase in an aging population living with CVD and other comorbid conditions. With advances in treatment regimens (e.g., polypharmacy, interventional

procedures, devices), there is a need for robust mechanisms to quantify the impact of new treatment on patients, their survival, their symptoms, and their quality of life (QOL). In addition to the patients, payers, practitioners and regulatory agencies are increasingly relying upon patient-centered outcomes to monitor and improve quality of care (Green, Porter, Bresnahan, & Spertus, 2000). There are several ways researchers may examine quality of care and QOL with the goal of improvement. The examination of predictors of QOL, physical well-being, psychological well-being, and most recently spiritual well-being provide information for potential intervention targets.

The current study examined physical and psychological functioning among patients diagnosed with hypertrophic obstructive cardiomyopathy (HOCM), using biomedical and self-report data. Further, this study examined the biopsychosocial status of HOCM patients before and after a cutting edge treatment procedure (Nonsurgical Septal Reduction Therapy; NSRT), which was designed to relieve the obstruction of the left ventricular outflow tract (LVOT), and, in turn, alleviate cardiovascular symptoms.

CHAPTER 2
LITERATURE REVIEW

This paper begins by briefly describing HOCM and its treatment. However, the focus is on the anticipated QOL and psychosocial implications that correspond with this disease and its ensuing treatment. Due to the paucity of psychosocial literature regarding HOCM, the majority of our knowledge stems from general cardiac populations.

Medical Background

Cardiomyopathies

The cardiomyopathies are a group of heart disorders in which there is a structural abnormality limited to the myocardium. This group of disorders often results in symptoms of heart failure with the underlying cause sometimes identifiable; however, the etiology is often unknown (Chen, Dec, & Lilly, 2003). There are three broad classifications of cardiomyopathy: dilated, restrictive, and hypertrophic, with the latter being the focus of this study.

Hypertrophic Cardiomyopathy

Hypertrophic cardiomyopathy (HCM) is a primary, often familial disorder of heart muscle caused by mutation of one or more of the genes coding for sarcomeric proteins (Marian & Roberts, 2001). It is characterized by heterogeneous expression between genotypes and within the same family, unique pathophysiology and clinical course (Yoerger & Weyman, 2003). It results in an abnormally thickened ventricular wall with an abnormal diastolic relaxation but usually normal systolic (contraction) function.

The septal or left ventricular (LV) thickening is not due to chronic pressure overload; that is, it is not associated with hypertension or aortic stenosis, which are the most frequent antecedents to congestive heart failure (CHF). Severity of symptoms can vary greatly, with some patients having minimal or no symptoms, and other patients experiencing severe symptoms including sudden cardiac arrest and/or death. Signs and symptoms include fatigue, exercise intolerance, shortness of breath (dyspnea) at rest and with exertion, chest pain (angina), dizziness, pre-syncope or syncope, palpitations, and arrhythmias. The most frequent symptom is dyspnea due to elevated diastolic LV pressures, which is further exacerbated by high systolic LV pressure and mitral regurgitation (Chen et al., 2003). Arrhythmias occurring with HCM, which may be due to the disarray of myocardial fibers, are the most concerning because they exacerbate symptoms. For example, atrial fibrillation further impairs diastolic filling and can worsen pulmonary congestion. Ventricular fibrillation is of greatest concern, and sometimes is the first clinical manifestation of HCM, resulting in sudden cardiac death (Chen et al., 2003).

In some patients, a diagnosis is made only after they, or an affected family member, experience(s) sudden cardiac death. HCM affects approximately 0.2% (1:500) of the adult general population and is the most common genetic (familial) cardiovascular disease (Maron, 2002). Although HOCM affects individuals of all ages, sudden death in young people is its most devastating effect and is the most common cause of sudden cardiac death in young people (Chen et al., 2003; Maron, 2002; Roberts & Sigwart, 2001).

Hypertrophic obstructive cardiomyopathy (HOCM) is considered a more severe condition in terms of anatomical and functional impairments compared to other

nonobstructive conditions in the HCM disease classification (Chen et al., 2003). It is characterized by abnormal enlargement of the cardiac interventricular septum (asymmetric hypertrophy) which interferes with mitral valve function and creates an obstruction to outflow of blood from the left ventricle (LVOT obstruction) into the aorta. LVOT obstruction contributes to and may result in systolic anterior motion (SAM), commonly present with HOCM. SAM is the abnormal movement of the anterior mitral valve leaflet into the LVOT, due to the turbulence of the blood flow through the obstructed LVOT (Venturi Effect) (Yoerger & Weyman, 2003). This then causes greater obstruction because the anterior mitral valve leaflet makes contact with the septum during systole (Chen et al., 2003).

Medical Management of HOCM

The aim of medical therapy for HOCM is to decrease LVOT obstruction, improve diastolic function, and improve symptoms (Nielsen, Killip, & Spencer, 2002). Historically, there have been three types of treatment available for HOCM: medications, pacemaker, and surgery (Maron, 2002). Surgery is the only treatment designed to be curative in focus rather than to just reduce symptom burden. Medications (i.e., beta-blockers, calcium channel blockers, other negative inotropic medications) are used in attempts to “relax” the heart, decrease left ventricular wall tension, reduce obstruction, and alleviate symptoms. However, they frequently have limited effectiveness even in high doses. Implantation of a permanent pacemaker is thought to change the pattern of the contraction of the heart and may help improve left ventricular outflow, but there is considerable debate regarding the effectiveness of this treatment (Nishimura et al., 1997). Surgical excision of the thickened interventricular septal muscle (myectomy, myomectomy) and/or mitral valve replacement has been the gold standard of treatment of

drug-refractory HOCM, although operative cases represent only 5% of the overall HOCM population (Maron, 2002).

The newest treatment for HOCM is nonsurgical septal reduction therapy (NSRT; also termed alcohol septal ablation), in which absolute ethanol is injected into the area of hypertrophied muscle to induce infarction in the targeted area. As healing occurs, the thickened muscle is replaced with thinner, noncontractile scar tissue and the mechanical obstruction of the left ventricular outflow tract (LVOT) is relieved. NSRT has been shown to improve diastolic function, decrease left ventricular hypertrophy and mass, and cause changes at the cellular and molecular level, thereby improving myocardial function (Nielsen & Spencer, 2002).

Maron (2002; Maron et al., 2003) has repeatedly criticized NSRT for lack of direct comparison to surgical therapy in randomized, controlled, clinical trials. However, studies have compared the two procedures in nonrandomized trials, and researchers have made comparisons through literature reviews. NSRT compares favorably to surgical myectomy in terms of LVOT gradient reduction, septal wall thickness, symptomatic improvements, and QOL improvements (Firoozi et al., 2002; Ruzyllo et al., 2000). Improvement in exercise capacity (i.e., peak oxygen consumption, exercise time) has been inconsistent, with some research demonstrating that NSRT is inferior to myectomy (Firoozi et al., 2002); yet, the majority of research demonstrates equivalent benefit between the two procedures (Ruzyllo et al., 2000), as well as analogous improvements in exercise blood pressure (Kim et al., 1999).

In general, NSRT compares favorably to other treatments for HOCM and appears to provide greater symptom reduction (Lakkis, Nagueh, Dunn, Killip, & Spencer, 2000; Nagueh et al., 2001). While it is equally as effective as myectomy in regards to

symptomatic improvements, NSRT has demonstrated superiority over surgery with respect to complications (Kuhn et al., 2000). NSRT is less invasive than open-heart surgery, therefore reducing surgical risk (Ruzyllo et al., 2000). For example pre- and post-operative mortality rates of myectomy range from 1-10% (Mayes et al., 2002). Because the procedure is less invasive, recovery time and rehabilitation are substantially shorter in patients undergoing NSRT than myectomy, and improvements continue status post procedure up to six months (Nielsen et al., 2002).

Nonsurgical Septal Reduction Therapy

Patients evaluated for NSRT are symptomatic despite medical treatment. To be considered an appropriate candidate for NSRT, patients must have asymmetrical septal hypertrophy (ASH) with septal wall thickness $\geq$ 1.6 cm or a septal to posterior wall ratio of 1.3; SAM of the mitral valve contributing to the obstruction; and a resting LVOT gradient of $\geq$ 30 mmHg or a provoked gradient of $\geq$ 50 mmHg (Nielsen et al., 2002). In addition, many investigational studies include a criteria of NYHA $\geq$ 3 functional classification (Chang, Lakkis, Franklin, Spencer, & Nagueh, 2004).

Similar to myectomy and other interventional procedures, such as coronary artery bypass graft (CABG) surgery, the goals of NSRT are to bring symptom relief to the patients and to improve QOL. The procedure continues to be refined and perfected as more procedures are performed and the specialized interventional cardiologists determine the most effective strategies and approaches (Nagueh et al., 2001; Ruzyllo et al., 2000). Two-dimensional, Doppler, and contrast echocardiography are used throughout the NSRT procedure, as well as x-ray fluoroscopy (Mayes et al., 2002). Resting LVOT gradient is determined at rest and sometimes with provocative maneuvers such as during and after Valsalva and after extrasystole. Other methods that may reveal an LVOT

gradient include exercise, administration of intravenous Dobutamine, and inhalation of amyl nitrite (Ommen & Nishimura, 2000).

The ostium of the left coronary artery is cannulated with a guiding catheter and radiographic contrast is injected into the coronary artery under fluoroscopic observation. Septal perforator branches of the left anterior descending (LAD) coronary artery are identified on the coronary angiogram, determining the appropriate septal branch(es) that supply the hypertrophied septum, and allow for angioplasty techniques to administer the ethanol (Mayes et al., 2002). A small angioplasty balloon catheter is introduced over the guidewire into the proximal portion of the target artery. The balloon is inflated and appropriate positioning is confirmed by angiography. Radiographic contrast injected through the balloon is used to confirm that there is no leak of contrast (and therefore, alcohol) retrograde around the balloon into the LAD artery; and that there is no communication of this septal perforator with other arteries or cardiac structures (Karen Smith, M.D., personal communication, July 19, 2004; Mayes et al., 2002). Then, echocardiographic contrast medium is injected through the lumen of the balloon catheter and the septum is observed under echocardiography. This contrast “lights up” the area of the septum supplied by the artery, confirming that the selected septal perforator supplies the area of the hypertrophied septum responsible for the LVOT obstruction. Confident of anatomy and positioning, the interventional cardiologist then infuses absolute ethanol through this septal perforator artery into the basal septal myocardium. Depending on the size of the vascular territory, 1 to 4 mL of ethanol is instilled through the inflated balloon catheter over five to ten minutes at a slow injection rate of approximately 0.25-0.5 mL/minute (Karen Smith, M.D., personal communication, July 19, 2004). The ethanol also gives the basal septum a white or bright appearance under echocardiographic

observation, allowing the area of infusion to be visible to the cardiologist. The total amount of ethanol infused is judged by the interventional cardiologist based on area of brightness of the septum, contractility of the septum, resolution of the gradient, electrocardiographic and hemodynamic changes, and experience (Karen Smith, M.D., personal communication, July 19, 2004). Upon completion of the ethanol infusion, the balloon is deflated and removed. Morphological results of the NSRT are examined by coronary angiography and the LVOT gradient measurements are repeated.

The alcohol injected into the septum is directly toxic to the myocardium and kills the cells. Immediately, the effected septum becomes akinetic and therefore no longer bulges into the LVOT during systole, thus producing an immediate reduction in gradient (Ommen & Nishimura, 2000). Over ensuing weeks and months, the injured myocardial tissue is replaced, through the normal healing process, by much thinner scar tissue; thus reducing the obstruction, enlarging the effective LV chamber, improving blood flow out of the LV, reducing the turbulence of the ejected blood, and reducing the LV pressure gradient. Through improvement in flow characteristics, SAM and mitral regurgitation are also improved or completely alleviated (Karen Smith, M.D., personal communication, July 19, 2004).

Following the procedure, patients are hospitalized for three to five days for close cardiac monitoring. Most patients notice improvement in symptoms such as shortness of breath, chest discomfort, paroxysmal nocturnal dyspnea, and orthopnea almost immediately. As healing occurs and the septum thins over the next several weeks and months, they report further improvements especially in fatigue and exercise tolerance (Karen Smith, M.D., personal communication, January 7, 2004). Interventional cardiologists and primary care providers follow patients for the next several years.

Generally, echocardiograms are performed three months post-NSRT and then yearly to evaluate septal thickness and contractility, LV gradient, and the mitral valve (Karen Smith, M.D., personal communication, January 7, 2004).

The most common side effect of NSRT is an arrhythmia (irregular heart beat) called complete heart block (also called atrioventricular block). This occurs because the site of the ablation is located near the conduction system. Damage to this conduction system causes interruption of the electrical communication and synchronization between the atria and ventricles resulting in (sometimes profound) bradycardia, which may require implantation of a permanent cardiac pacemaker (Gietzen et al., 1999). The incidence of complete heart block is steadily declining with experience of the interventional cardiologists (Kuhn et al., 2000). Neither surgical myomectomy nor NSRT appears to significantly alter the risk of sudden cardiac death in patients with HCM. Some cardiologists have postulated that the scar tissue created by the alcohol ablation procedure might become a focus for development of arrhythmias, but this has not been confirmed (Kuhn et al., 2000; Ommen & Nishimura, 2000). Other noted complications include requirement of a second NSRT procedure to further relieve the obstruction, and death (< 1%) (Seggewiss, 2000).

NSRT may be considered analogous to implantable cardioverter defibrillators (ICD) in the 1980s. For the past three decades, ICD implantation has increased exponentially. For example, approximately 20,000 devices were implanted in 1995 and as many as 125,000 were implanted in 2002 (Medtronic, Inc., personal communication, June 2, 2004). Today, ICDs are considered the first line of treatment for ventricular tachycardia/fibrillation, sudden death, ejection fraction (EF) < 30%, and it is even used prophylactically in many other cardiac conditions (Sears & Conti, 2003). With further

refinement, modifications, better technology, and more experience, NSRT may prove to be the “gold standard” of treatment for HOCM. Currently, only a select few interventional cardiologists are trained in the procedure, but with increased patient demand and more refined procedures, better outcomes are expected. For example, Nagueh and colleagues (2001) modified their NSRT technique with the addition of contrast echocardiography after 7 procedures and demonstrated dramatic improvement in outcomes (heart block requiring permanent pacing in 22% vs. 8.6%) after the modification. In just a few years, outcomes of NSRT have improved substantially with the use of echocardiographic contrast agents, thereby enabling the precision of the delivered alcohol into the septum (Firoozi et al., 2002). NSRT procedures will never be as common as ICD implantation rates due to the fewer numbers of candidate patients, but it is reasonable to project that their rates will continue to rise as it establishes itself as an effective intervention for HOCM. Therefore, the examination of QOL and psychosocial factors along with biomedical indices of the condition and of the procedure are now indicated.

Quality of Life

At its heart, QOL is a nebulous subjective construct that may be assessed and determined in a number of ways. QOL implicitly focuses on the quality, value, meaning, or worth of life beyond that of number of years alive. The QOL construct strives to describe the components of “living” including emotional well-being or distress, social relationships or functioning, financial concerns, physical functioning or limitations, health status, and/or spiritual well-being (Swenson & Clinch, 2000).

Health-Related Quality of Life

Health-related QOL, irrespective of disease specificity or generality, combines physical, cognitive, emotional, and social functioning experienced and reported by the

patient. It can be considered the appreciation of the pervasive and adverse effects of illness on the patient as perceived by the patient (Swenson & Clinch, 2000). In other words, it is the "*illness experience* as opposed to the *disease*" (Swenson & Clinch, 2000, p. 406). Aligned with that definition, Wenger, Mattson, Furgerg, and Elinson (1984) depict health-related QOL as comprised of three aspects: functional capacity, perceptions or patients' personal judgments, and symptoms and their consequences.

Health-related QOL instruments may either be generic measures of health status or disease-specific measures. Generic measures of health-related QOL incorporate a broad spectrum of function, health perceptions, and symptoms, which can be used in different patient populations including those without disease. This enables direct comparison of QOL across different disease states and conditions. The inherent limitation of generic measures is that they may overlook important aspects or changes that are of particular value for a specific medical condition (Swenson & Clinch, 2000). Disease-specific measures quantify more clinically relevant domains for a specific disease state than a generic measure. They are often more responsive to changes in health-related QOL and are more sensitive in discriminating the range of impairment in health-related QOL because their focus is on the most relevant aspects for the problem or condition assessed (Guyatt, Feeny, & Patrick, 1993; Swenson & Clinch, 2000). Given the breadth and complexity of QOL, it is important to include and assess multiple domains of QOL from a variety of perspectives usually incorporating both generic and disease-specific measures. It is these reasons as to why the proposed study utilizes cardiac-specific QOL as the primary outcome and generic health-related QOL as the secondary outcome.

Quality of Life Among Patients with Cardiac Disease

The Medical Outcomes Study demonstrated that across nine chronic medical conditions, cardiac disease (e.g., myocardial infarction [MI], CHF) had the greatest adverse impact on broad domains of functioning and well-being (Stewart et al., 1989). Stewart and colleagues (1989) found that QOL is more severely impaired in heart failure patients compared to other common chronic conditions, such as angina, diabetes, arthritis, and lung disease. Since then, investigators have consistently demonstrated that QOL is impacted in a variety of cardiac conditions, ranging from patients with CHF, angina, coronary artery disease (CAD), to arrhythmias and electrical desychronization (Dougherty, Dewhurst, Nichol, & Spertus, 1998; Dracup, Walden, Stevenson, & Brecht, 1992; Kamphuis, De Leeuw, Derksen, Hauer, & Winnubst, 2002). In addition, QOL is impacted among patients who have undergone treatment and/or procedures such as percutaneous transluminal coronary angioplasty (PTCA) and CABG (Konstam et al., 1996; Majani et al., 1999). Not only are a variety of QOL domains influenced, but also they, in turn, can lead to declining health and/or death. For example, QOL components including emotional distress, social functioning, physical functioning, perceived health, and life satisfaction were predictors of all-cause mortality in a sample of CHF patients (Konstam et al., 1996). Impairments in QOL are frequently evidenced in sleep disturbance, financial difficulties, dysfunctional eating patterns, and decreased sexual activity and sexual dysfunction (Majani et al., 1999).

Quality of Life Among Patients with Cardiomyopathy

QOL among patients with cardiomyopathy (CM) has received minimal empirical investigation, thus the value of the proposed study. There are two studies that provide some QOL information specific to HCM and dilated CM (DCM) (Cox, O'Donoghue,

McKenna, & Steptoe, 1997; Steptoe, Mohabir, Mahon, & McKenna, 2000). Both studies were identical in procedure to enable comparison between samples of CM. Each study was a cross-sectional design with two aims: (1) to evaluate the level of health-related QOL and psychological well-being among CM patients, and to compare them to the general population and patients with other serious cardiac conditions, and (2) to identify the clinical, demographic, and psychosocial factors that predicted limitations in QOL in patients. The researchers used standardized measures: Health Survey Short Form (SF-36), Hospital Anxiety and Depression Scale (HADS), MOS sleep quality, questions on adjustment, and biomedical data to answer their questions.

Examining QOL in HCM patients, Cox and colleagues (1997) found that these patients had significant impairments on all 8 scales of the SF-36 (i.e., physical functioning, physical role limitations, emotional role limitations, social functioning, mental well-being, general health perceptions, vitality, and bodily pain). The sample consisted of 171 patients diagnosed within the broad HCM disease spectrum (Cox et al., 1997). In other words, not all patients had an obstructed LVOT, but were rather characterized because of their enlarged heart muscle, which typically occurs in the left ventricle and the interventricular septum. Patients were divided into three groups: no known family history of HCM, those with family history, and those with family history and one or more with premature sudden death. There were no significant differences among family history groups on demographic or clinical data, QOL, psychological well-being, or adjustment. As a whole, HCM patients reported impairments similar to patients with CHF, hypertension with CHF, complicated diabetes, MI, regular angina, and severe autonomic neuropathy ($p < .01$). They also found that HCM patients reported significantly poorer QOL in terms of role limitations attributable to emotional problems,

social functioning, and mental health compared to the general and cardiac populations. This suggests that QOL is severely affected among patients with HCM, particularly in mental health functioning, and even in comparison to known severe disease.

Similarly, Steptoe, Mohabir, Mahon, and McKenna (2000) demonstrated that patients with DCM (N = 99) reported poor QOL in areas of physical functioning, activities of daily living, emotional and social functioning, vitality, and general perceptions of health, and sleep quality compared to the general population ($p < .025$). However, DCM patients reported greater restrictions in social functioning and pain compared to HCM patients ($p < .003$). DCM patients reported similar depression rates but greater anxiety levels and social functioning restrictions, compared to other cardiac disease populations. In addition to describing poor QOL among these patients, predictive relationships were also shown between physical role limitations and depression. Those who reported poorer QOL among the HCM patients were associated with experiencing chest pain and dyspnea (Cox et al., 1997). This finding suggests that physical symptoms lead to functional limitations and therefore reduced QOL, which may in turn lead to psychological distress.

These two studies also examined predictors of QOL among CM patients. Adjustment to HCM was the most consistent correlate of QOL and psychological well-being dimensions, predicting a range of difficulties across physical, social, and emotional domains, independent of demographic and clinical variables (Cox et al., 1997). The researchers hypothesized that patients with familial cardiomyopathy (e.g., DCM, HCM) might experience greater psychological distress since they have knowledge that their cardiac condition can be inherited or passed on to offspring. While this potential origin of distress would not be impacted by medical treatment, it is an area that may be addressed

with psychosocial treatment, and currently, these patients are often neglected in terms of psychosocial care. Other significant relationships seen in these CM studies were between physical functioning and patients with comorbid CHF, lower left ventricular shortening fractions, and higher left ventricular end diastolic diameters. Poor social functioning was seen in CM patients with moderate to severe mitral regurgitation. The most notable finding was that poor adjustment to CM predicted poor physical function, mental health, and emotional distress.

Summary and Implications of Quality of Life Literature

The familial origin of HCM and its potential reason for distress may be one of the main differences in the development of psychological distress when comparing HCM patients to other cardiac populations. While QOL may be impacted in all cardiac populations, development and progression of disease and/or psychological problems may be vastly different. For example, HOCM is a structural abnormality caused by mutations on the genes encoding proteins of the muscle fibers (Marian & Roberts, 2001; Mayes et al., 2002). In other words, patients with HOCM did nothing themselves to cause the disease, whereas a significant proportion of CHD (i.e., CAD) develops from poor lifestyle and health behaviors (e.g., diet, physical activity) and is the leading preventable disease. Therefore, reported QOL and rates of psychological distress may be similar across cardiac disease; yet, worse than the general population, but emerging from different factors. These QOL impairments may then lead to further physical and emotional problems, including death.

These CM studies provide rationale for the current study. They indicate the need for an increased understanding of psychosocial concerns and QOL, of which is pervasive and poorly understood. These studies also emphasize the importance of further

examination of QOL among CM patients. Gaining this knowledge, we can better optimize both emotional and physical outcomes with CM patients. These specific CM studies also emphasize weaknesses and/or gaps in the literature. For example, these studies were only cross-sectional, and only longitudinal studies can attempt to determine how impairments in QOL develop and progress. While there is ample QOL research in other areas, it is extremely sparse among HCM patients, particularly HOCM patients. Further, psychosocial examination of treatments for HOCM is even more limited. Researchers not only need to study HOCM, but also its treatments from a physiological perspective, but also from a psychosocial perspective, the latter being the focus of this study.

Psychological Distress

Related to and independent of QOL, negative emotions play a role in psychological and physical health, particularly in cardiac disease. The experience of negative emotions such as anger, anxiety, and depression are probable risk factors for coronary heart disease (CHD) and may substantially account for poor cardiac disease outcomes (Kubzansky & Kawachi, 2000). Emotions may influence cardiovascular health through a number of pathways, including excessive activation of the sympathetic nervous system or the hypothalamus-pituitary-adrenal (HPA) axis, or altered autonomic regulation of the heart (Kubzansky & Kawachi, 2000). For example, anxiety may provoke electrical instability in the heart, promote increased atherosclerotic processes, and trigger myocardial infarction (Kubzansky, Kawachi, Weiss, & Sparrow, 1998). Depression may impact cardiac outcomes by altering neuroendocrine functioning, increasing sympathetic tone and decreasing vagal tone, and by increasing platelet aggregation (Carney, Freedland, Rich, & Jaffe, 1995).

In addition to the influence of emotions on physiology, psychological distress can impact social and behavioral components of health. Anxiety and depression experienced before and during a recovery period from a procedure (e.g., CABG, PTCA) are as important as physical limitations and comorbidities in influencing outcomes such as length of hospital stay, ability to function, and QOL (Pirraglia, Peterson, Williams-Russo, Gorkin, & Charlson, 1999). Negative emotional states have also been associated with reduced adherence to prescribed medical regimens (i.e., increasing self-care and decreasing health compromising behaviors) known to be important in cardiac rehabilitation (Januzzi, Stern, Pasternak, & DeSanctis, 2000; Ziegelstein et al., 2000).

Mood and affective disorders appear to be common in cardiac patients, ranging from diagnoses of panic disorder, agoraphobia, generalized anxiety disorder, and social phobia, to dysthymia, major depressive disorder, and alcohol abuse (Griez et al., 2000). Panic disorder is evident in patients with CAD, mitral valve prolapse, and it is also suggested in those with idiopathic cardiomyopathy (Kahn et al., 1987). See Table 1 for prevalence rates of depression and anxiety among cardiac samples.

Depression Among Patients with Cardiac Disease

Emotional distress and depression have been suggested as new risk factors for CAD (Rozanski, Blumenthal, & Kaplan, 1999). Rates of depression among cardiac patients range from 14% to 87%, among patients with CAD, ischemic heart disease, nonischemic heart disease, arrhythmias, and patients with ICDs (Blumenthal et al., 2003; Musselman, Evans, & Nemeroff, 1998; Sears, Todaro, Saia, Sotile, & Conti, 1999). Higher rates are more often seen in patients awaiting CABG, those with unstable angina, and those with ICDs (Blumenthal et al., 2003; Sears et al., 1999). Clearly, the wide range in depression rates depends, in part, on the method of measurement used as well as the

specific condition examined. Despite the variation of rates, it is evident that depression is highly prevalent in cardiac populations and may predict psychosocial and physical health status, and therefore, warrants examination and treatment.

Table 1. Prevalence rates of depression and anxiety in the published cardiac literature

Sample/Population	Depression	Anxiety	Investigator
General population	2-9%	1-3%	American Psychiatric Association, 1994
CAD	14-47%		Blumenthal et al., 2003
		6-34%	Jeejeebhoy et al., 2000
CHF	30.2%		Rumsfeld et al., 2003
	36.5%		Koenig, 1998
Idiopathic CM		51%	Kahn et al., 1987
Idiopathic DCM[a]	19%	19%	Griez et al., 2000
DCM[a]	22%	52%	Steptoe et al., 2000
HCM[a,b]			Cox et al., 1997
Possible	13.1%	21.2%	
Probable	9.5%	28.5%	
ICD	24-87%	13-38%	Sears et al., 1999
CABG	12-76%		Blumenthal et al., 2003
Pre	32%	55%	Rymaszewska et al., 2003
3-months post	26%	32%	
Angioplasty	15%	26%	Lenzen et al., 2002
Heart transplant			Fisher et al., 1995
0-4 months pre	>49%		
5 year post	11%		

Note. [a] Comparable to other cardiac populations, but greater than the general population.
[b] Greater than a cancer sample ($p < .0001$).

In addition to the high prevalence, depression holds predictive value. For example, among coronary revascularization studies, preoperative depression affects postoperative QOL and psychosocial functioning (Duits, Boeke, Taams, Passachier, & Erdman, 1997). Depression also influences morbidity and mortality, independent of

cardiac disease severity, including left ventricular dysfunction (Burg, Benedetto, Rosenberg, & Soufer, 2003). It is associated with elevated cardiac mortality risk, similar to its impact on patients' prognosis with unstable angina and post MI (Frasure-Smith & Lesperance, 2003; Zellweger, Osterwalder, Langewitz, & Pfisterer, 2004).

Depressive symptoms are common in patients with CHF, which subsequently may be an important determinant of health status (Vaccarino, Kasl, Abramson, & Krumholz, 2001). Patients with CHF suffer with moderate to severe depression and moderate anxiety and appear to have higher levels of depressive disorders (36.5% vs. 17.0%, $p = .002$) compared to other cardiac patients, but no significant differences with Major Depression, specifically (Dracup, Walden, Stevenson, & Brecht, 1992; Koenig, 1998). Rumsfeld and colleagues (2003) found that depressed CHF patients reported markedly worse baseline health status compared to nondepressed patients ($p < .001$). Further, after adjusting for baseline health status, demographic, cardiac, and treatment variables, depressive symptoms were a strong predictor of worsening heart failure symptoms, functional status, and QOL over a 6-week period. Not only were depressive symptoms a predictor, but also seen in multivariable models of change in QOL scores, symptoms scores, and social functioning scores, depressive symptoms had the largest magnitude of association with the outcome. Rumsfeld and colleagues' (2003) study was the first to demonstrate the unique impact of depressive symptoms on heart failure specific health status and indicate that patient-centered outcomes for heart failure patients may be improved with the recognition and treatment of depression.

A large body of research provides evidence for a strong relationship between depression and cardiac disease, particularly after a MI. While, there is inconsistent evidence regarding the causative role of depression in CHD, the bulk of the evidence

supports depression's causal role in CHD. In the National Health Examination Follow-Up Study, self-reported depression was associated with an increased risk of fatal and nonfatal ischemic heart disease (RR = 1.5 and 1.6, respectively) (Anda et al., 1993). A prospective, longitudinal study found that men with psychiatric diagnoses of clinical depression were at a significant risk of subsequent CHD (RR = 2.12) (Ford et al., 1998). Other follow-up studies have failed to show a relationship between depression and increased risk of CHD (e.g., ischemic heart disease, MI) (Vogt, Pope, Mullooly, & Hollis, 1994; Wassertheil-Smoller et al., 1996). Regardless of the unknown or unproven direction of the relationship between depression and CHD, there is notably a strong relationship between the two and that the relationship has critical clinical relevance and implications for outcomes and QOL in all examinations of cardiac disease, including HOCM.

Anxiety Among Patients with Cardiac Disease

Anxiety is another negative emotional state that is experienced in a large number of cardiac patients, and is more strongly associated with CHD than depression or anger (Kubzansky & Kawachi, 2000). Symptoms of anxiety and symptoms of cardiac disease can often times mimic each other. For example, chest pain, shortness of breath, heart palpitations, and racing heart are all symptoms of both anxiety disorders and heart disease (including HOCM) (Jeejeebhoy, Dorian, & Newman, 2000). Patients with known heart disease, may be more susceptible to hypervigilance in monitoring their symptoms, have an increased somatic concern and body awareness, fear and worry about chest and heart sensations, along with avoiding activities that may elicit cardiac symptoms or activity (Jeejeebhoy et al., 2000; Lebovitz, Shekelle, Ostfeld, & Paul, 1967; Zvolensky, Eifert, Feldner, & Feldner, 2003). According to Zvolensky and colleagues (2003) heart-

focused anxiety is the fear of cardiac-related stimuli and sensations grounded in their perceived negative meaning. Therefore, cardiac symptoms and anxiety may perpetuate each other in a constant cycle. Further, the experience of health-related anxiety during the course of illness may occur as the patient engages in persistent worry about their condition, and not just their manifest symptoms (Zvolensky et al., 2003). Therefore, anxiety is not an uncommon condition among cardiac patients.

The majority of researchers have reported associations between anxiety and CHD. For example, the Northwick Park Heart Study as well as the Health Professionals Follow-Up Study found that phobic anxiety had relative risks of fatal CHD of 3.77 and 2.45, respectively, compared to men reporting low or no anxiety (Haines, Imeson, & Meade, 1987; Kawachi, Colditz, et al., 1994). In the Normative Aging Study, men reporting symptoms of anxiety had elevated risks of fatal CHD, particularly that of sudden cardiac death (Kawachi, Sparrow, Vokonas, & Weiss, 1994). In the Framingham Heart Study, anxiety symptoms were significantly related with MI and coronary death among homemakers but not among employed women (Eaker, Pinsky, & Castelli, 1992). Further, anxiety may cause acute cardiac events such as MI by stimulating the release of catecholamines that increase the heart rate, blood pressure, and cardiac output (Mittleman et al., 1995). Therefore, it may cause myocardial ischemia and electrocardiogram changes in those with already established heart disease (Tofler et al., 1990).

Summary and Implications of Psychological Distress Literature

This review has highlighted that not only do cardiac patients experience significant psychological distress, but also their distress can predict outcomes both psychologically and medically. Symptoms of cardiac disease (e.g., shortness of breath, fatigue, dizziness, chest pain) tend to lead to functional limitations in those who

experience them, with greater limitations the more severe the symptoms. Along with the distressing symptoms, patients may be even more distressed by the limitations and impairments that are caused by these symptoms. Patients with HOCM who are evaluated for NSRT are usually at their last line of defense in terms of treatment, and consequently have been suffering for years with unrelenting symptoms of increasing severity. In addition, they report significant functional limitations in a variety of areas, and thus, report poor QOL.

The current study evaluated these emotional states because it was assumed that symptoms of depression and anxiety would occur in HOCM patients due to their physical symptoms and functional limitations; however, it has not been evaluated in a systematic fashion. Further, congruent with the literature, it was expected that the symptoms of depression and anxiety would impact these patients' QOL, physical health, and the effectiveness of and/or recovery from NSRT.

Psychological Well-Being

With psychological distress now an accepted risk factor for poor overall health, it is worthwhile to also examine positive emotions, resilience factors, and their relationship with cardiac conditions. Resilience factors are those that enhance one's ability to recover quickly from distress or illness. Research indicates that positive emotions such as optimism, positive expectations, satisfaction, and spirituality may enhance one's ability to cope with illness, treatment, and other related stressors.

Optimism Among Patients with Cardiac Disease

In the general population, optimism and satisfaction with life has been shown to be a mental health factor that positively influences both psychological and physical well-being (Taylor, Kemeny, Reed, Bower, & Gruenewald, 2000). Optimism may allow

individuals to mobilize effective coping strategies and resources when faced with stress or adversity (Scheier et al., 1999). Optimistic individuals may believe that their attitudes or actions will positively influence their health outcomes.

Initial optimism research among cardiac patients has yielded promising results. Positive expectations and an optimistic disposition predict fewer symptoms, lower levels of cardiovascular reactivity, and better health outcomes in CABG and cardiac patients (Cohen, de Moor, & Amato, 2001; Leedham, Meyerowitz, Muirhead, & Frist, 1995; Scheier & Carver, 1987, 1992). The prospective Veterans Affairs Normative Aging Study examined optimistic versus pessimistic explanatory style, revealing that a more optimistic explanatory style lowered the risk of CHD in that particular sample of older men, independent of health behaviors (i.e., tobacco or alcohol consumption) (Kubzansky, Sparrow, Vokonas, & Kawachi, 2001).

A recent study supported the existence of resilience factors in a prospective study of ICD patients (Sears et al., 2004). Results suggested that optimism and positive health expectations differentially relate to specific health outcomes from baseline to a 14-month follow-up. Positive health expectations were more closely associated with general physical health, while optimism was more closely associated with mental health outcomes. Collectively, these resilience factors appear to hold some value in promoting future intervention studies in terms of QOL for the ICD patient (Sears et al., 2004). Positive health expectations and/or optimism may be beneficial by facilitating healthy behavioral practices, enhancing treatment adherence, and increasing motivation to engage in appropriate health behaviors such as exercise and healthy dietary choices (Salovey, Rothman, Detwieler, & Steward, 2000).

Spiritual Well-Being Among Patients with Cardiac Disease

Along with optimism, spirituality or spiritual well-being has been seen as a resilience factor. In health promotion literature, spiritual health has been defined as, “a high level of faith, hope, and commitment in relation to a well-defined worldview or belief system that provides a sense of meaning and purpose to existence in general and that offers an ethical path to personal connectedness with self, others, and a higher power or larger reality” (Hawks et al., 1995, p. 373). Accordingly, overall wellness may be conceived to include not only emotional and physical health, but also spiritual health.

Researchers have begun to focus on the relationship between spirituality and health, providing ample data to suggest that there is a relationship between spirituality and physical and psychological health (Brady, Peterson, Fitchett, Mo, & Cella, 1999; Mytko & Knight, 1999). The relationship between spirituality and enhanced quality of life has been demonstrated in many populations, such as healthy individuals (Kaye & Robinson, 1994), HIV patients (Ironson et al., 2002), cancer patients (Brady et al., 1999; Cotton, Levine, Fitzpatrick, Dold, & Targ, 1999), and cardiac patients (Morris, 2001; Sears, Rodrigue, Greene, Fauerbach, Mills, 1997). Individuals with a strong sense of spirituality tend to have less symptomatology compared to those without a sense of spiritual well-being. They are also found to have less pain, anxiety, and isolation, as well as higher life satisfaction, better psychological adjustment, and lower mortality rates (Brady et al., 1999; Cotton et al., 1999; Levin & Schiller, 1987).

In the Lifestyle Heart Trial, researchers assessed sense of spiritual well-being four-years after the completion of an intervention to promote heart healthy behaviors (Morris, 2001). The intervention compared a group following a vegetarian diet, regular aerobic exercise, and practiced meditation daily for one hour to a group provided with

standard medical care. The primary endpoint was computerized cardiac catheterization data, measuring disease progression or regression of coronary obstruction. The experimental group scored higher on spiritual well-being than the control group and spirituality was correlated with disease progression or regression. Participants with low spirituality scores tended to have progression of their disease, and participants with high spirituality scores tended to have regression of their coronary obstruction. In addition to demonstrating a significant relationship between spirituality and health, this study indicates that sense of spirituality influences objective health. It is the first to suggest a definable relationship between spirituality and documented physical data (Morris, 2001).

A small amount of research exists examining relationships between spirituality and/or religiousness with both physical and psychological health among cardiac patients. Researchers have studied patients in the coronary care unit, awaiting cardiac surgery, and those with cardiac arrest and near death experiences. Among these studies, researchers have operationalized spirituality by measuring different components of spirituality such as, prayer, spirituality as a coping strategy, optimism, meaning of life, and love and acceptance of others (Ai, Peterson, Bolling, & Koenig, 2002; Byrd, 1988; Harris et al., 1999; van Lommel, van Wees, Meyers, & Elfferich, 2001). In studies examining intercessory prayer (someone praying on another's behalf) and patients on the coronary care unit, using a severity-adjusted outcome score, they found a trend of lower overall adverse outcomes for coronary care unit patients randomized to a prayer group compared to those in a usual care group; however, results were not statistically significant (Byrd, 1988; Harris et al., 1999). Optimistic patients awaiting cardiac surgery tended to be individuals who used private prayer for coping, and were less depressed and less anxious than those who were not considered optimistic (Ai et al., 2002). van Lommel and

colleagues (2001) concluded that medical factors could not account for near death experiences. Instead, they reported that patients with near death experiences had significantly decreased fear of death, increased belief in an afterlife, and rated themselves higher on spiritual items, such as meaning of life, love, and acceptance of others, and were more religious than before their near death experience.

Summary and Implications of Psychological Well-being Literature

Collectively, research on optimism and spirituality indicate that patients reporting higher levels of these traits report less symptomatology in both medical and psychological indices. Also, QOL appears to be enhanced in patients with an optimistic disposition, positive expectations, or spiritual well-being. It may be that these resilience factors lead individuals to engage in better health behaviors. While it is important to examine risk factors and disease, it is equally important to examine resilience factors and disease. Positive psychology has only recently been receiving a great deal of attention, and the promising research and outcomes explain why (Seligman & Csikszentmihalyi, 2000). Evaluating QOL cannot be complete unless examining both risk factors and resilience factors together. Thus, psychological well-being was incorporated in the current study of HOCM patients. This study's overarching aim was to capture the essence of HOCM patients, which includes negative and positive characteristics, QOL, and health.

Psychosocial Evaluation of Medical Treatment

Assessing QOL and other psychosocial components in cardiac patients can be especially useful in comparing differential treatment options, considering adverse treatment effects, and comparing mild mood symptom change (Wenger et al., 1984). First, QOL measurement is beneficial when examining a treatment that has the potential

of showing a major improvement in survival over another clinical investigation or treatment option (e.g., NSRT in HOCM). Second, if a treatment is effective in reducing mortality but may have toxic or unacceptable side effects for some patients, including QOL measurement can help patients and physicians weigh out costs and benefits (e.g., ICD shocks, chemotherapy). Third, QOL measurement is helpful when a mildly symptomatic or asymptomatic patient is on long-term treatment to ensure QOL is not diminished, thereby creating a risk of poor compliance to treatment (e.g., antihypertensive medication). A particular application of psychosocial evaluation is to be able to provide information about the patients to the medical team or vice versa to the patients from the medical team in order to optimize treatment outcome.

CABG and PTCA are the two most common cardiac procedures and the most well known in the general population. CABG surgery has been described as the *most thoroughly studied operation in the history of surgery*, with angina relief and QOL improvement as the primary goals of CABG (American College of Cardiology/American Heart Association Task Force, 1991; Burg et al., 2003). Studies demonstrate that changes in emotional functioning and satisfaction following CABG and PTCA are generally favorable for most patients relative to their preoperative emotional status. However, patients reporting high levels of anxiety and depression prior to interventional procedures often do not feel satisfied with their life, have more complaints about their health, disregard positive effects of surgery, and are less apt to return to work after procedure; thus, impacting social functioning and occupational functioning, and may lead to continued and worse anxiety and depression (Duits et al., 1999; Rymaszewska et al., 2003; Swenson & Clinch, 2000; Timberlake et al., 1997).

Advances have been made in the medical management of CABG; however, attention to the psychological management is warranted because of its prognostic importance. Blumenthal and colleagues (2003) examined the relationship between depression and mortality among 817 patients pre- and six-months post CABG. Participants were also followed for up to 12 years following data collection (mean follow-up time = 5.2 years). Results indicated that moderate to severe depression before CABG, or persistent depression ($\geq$ 6 months) predicted increased risk of death over the course of 12 years. Patients with moderate to severe depression had a greater than two-fold higher risk of death compared to nondepressed patients during the follow-up period. Further, depression was significantly associated with mortality after controlling for other risk factors, such as age, sex, number of grafts, smoking history, diabetes, ejection fraction, and previous MI (Blumenthal et al., 2003).

Anxiety has also been seen among patients undergoing CABG and PTCA (Lenzen et al., 2002; McCrone, Lenz, Tarzian, & Perkins, 2001; Sirois, Sears, & Bertolet, 2003). Preoperative anxiety has been well documented in CABG patients, such that high, moderate, and even low anticipatory anxiety levels at baseline were maintained up to six months postoperatively (Fitzsimons, Parahoo, Richardson, & Stringer, 2003; Vingerhoets, 1998). In addition, preoperative trait anxiety has shown significant contribution to patient's postoperative state anxiety in patients undergoing CABG or PTCA (Lenzen, Gamel, & Immink, 2002; McCrone et al., 2001; Vingerhoets, 1998). Five impacts of anxiety emerged from the data analyzed by Fitzsimons and colleagues (2003): (a) chest pain, (b) procedure uncertainty, (c) forthcoming operation, (d) physical incapacity, and (e) dissatisfaction with health service. Both the quantitative and

qualitative analyses of anxiety revealed that anxiety is a pervasive feature of the experience of waiting for CABG (Fitzsimons et al., 2003).

In addition to predicting future anxiety, baseline levels have been used to predict cardiac symptoms and clinical outcomes. Fitzsimons and colleagues (2003) found significant differences in both state and trait anxiety levels by angina severity (grades 1-4). Among patients undergoing PTCA, a factor of negative emotions (i.e., depression and anxiety) predicted anginal frequency at 6-months and 1-year post-PTCA, more than demographic and biomedical variables (Sirois et al., 2003). Negative emotions were also the strongest predictor of anginal frequency at 6-months and 1-year post-PTCA, evidenced by the standardized beta weight (-0.35 and –0.42, respectively). Baseline symptom report was also found to be a significant predictor at all time periods (6-weeks, 6-months, and 1-year post PTCA). These studies suggest that not only is anxiety prevalent in cardiac patients with differing diagnoses and awaiting different procedures, but that it should be included in interventions to help allay distress and promote physical health.

In contrast to risk factors in cardiac procedures, such as preoperative anxiety or depression, resilience factors such as higher preoperative levels of positive expectations demonstrate a faster recovery rate after CABG (Scheier et al., 1989). In a similar study, patients with positive expectations undergoing CABG were half as likely to be rehospitalized six months later for complications or other cardiac symptoms (Scheier et al., 1999). Spirituality has also been associated with enhanced quality of life, as well as promoting adjustment to trauma, treatments, and recovery (Brady et al., 1999; Cotton et al., 1999; Morris, 2001).

Summary and Implications of Psychosocial Management of Medical Treatment

Research demonstrates that physical symptoms, medical procedures, and outcomes can impact psychological distress and well-being and likewise, distress and well-being can impact symptoms, procedures, and outcomes. NSRT is a new treatment of HOCM, and therefore, evaluating the procedure from a biopsychosocial perspective is beneficial and aids in determining whether NSRT is an effective treatment, not only from a medical standpoint, but also from the patients' views. The current study took a biopsychosocial approach in examining this new medical procedure, which has already been shown to have good biomedical outcomes.

Statement of Purpose

The current study combined the cardiac psychosocial literature, and of particular relevance, are the two studies of CM patients and the use of psychological variables when studying CABG and PTCA. Findings demonstrate the critical importance of the inclusion of psychosocial components of QOL in the treatment of cardiac disease. Building upon the CM studies, this study also addressed limitations in this area. It focused on patients with HOCM, and was longitudinal in design to enable examination of progression and/or changes of QOL. Further, the current study took an additional step, not only examining patients longitudinally, but also evaluating the QOL impact for a specific treatment of HOCM (i.e., NSRT). The study aimed to provide descriptive information about HOCM patients and NSRT, but also to provide longitudinal and clinically relevant data, which may aid in future biomedical and psychological treatments. Therefore, the purpose was threefold:

1. *Descriptive*: To describe HOCM patient characteristics, including the rates of psychological distress, well-being, and cardiac-specific QOL pre-NSRT.

2. *Change Over Time:* To determine if there were changes in distress, well-being, and cardiac-specific QOL in HOCM patients pre- and post-NSRT.

3. *Predictive:* To determine if psychological distress and well-being pre-NSRT predicted post-NSRT cardiac-specific QOL.

CHAPTER 3
METHODS

Participants

There were 45 adult participants with HOCM from two sites: the Shands Teaching Hospital at the University of Florida (UF) (*n* = 25) and the Medical University of South Carolina (MUSC) (*n* = 20). Participants were recruited during their initial outpatient clinic evaluation or index hospitalization for NSRT. Patients were excluded from the study if they were younger than 18 years of age, or not able to read and write English.

Procedure

After checking into their outpatient medical clinic and completing their standard medical forms, a member of the medical team approached the patient with informed consent for the current study. The patient was informed that his/her responses to research questionnaires would not influence psychological or medical care that is part of standard clinical care, and vice versa. The physician, or a member from the cardiac psychology team, was available to answer any of the patient's questions. After providing signed informed consent, the participants completed the packet of research questionnaires examining QOL and psychological factors (baseline). At the time of standard clinical care, the same research questionnaires were re-administered three-months post-NSRT. The battery of questionnaires took approximately 30 to 45 minutes to complete. In addition to self-report questionnaires, information was obtained from medical and/or

psychological records available through their residing institution of care (i.e., University of Florida/Shands Teaching Hospital or MUSC). During standard clinical care or the research protocol, if a patient needed or requested psychological services, an appropriate referral was made. Completed questionnaire packets were returned to a member of the medical or cardiac psychology team, which were then given to the project coordinator (ERS). To control for treatment effects, throughout the study, participants were asked if they have or are currently receiving psychotherapy or other forms of psychiatric treatment.

Measures

Demographic Information

The *Background Information Questionnaire* was included at each of the patients' assessments. This measure is a brief self-report tool to facilitate collection of demographic information. It includes information such as, age, gender, education, work status, income, marital status, religion, and use of past and/or present psychological treatment.

Biomedical Information

Resting left ventricular outflow tract (R-LVOT) Gradient is the biomedical marker that was used as an outcome measure, collected at baseline and the 3-month follow-up, obtained from the patient's echocardiogram. The gradient is the difference between the left ventricle (LV) systolic pressure and the aortic systolic pressure due to obstruction of the LVOT. Normal values for both resting and provoked gradient are less than 30 mm Hg.

General Health-Related Quality of Life

The *SF-12 Health Survey* (SF-12; Ware, Kosinski, & Keller, 1995) is a generic measure of health status and was used to measure general QOL. The 12 items that comprise this measure are a subset from the SF-36. The scale measures eight components: physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality (energy/fatigue), social functioning, role limitations due to emotional problems, and mental health (psychological distress and well being) (Ware et al., 1995). The SF-12 can be separated into two components: physical component summary (PCS-12) and mental component summary (MCS-12). All scores of the SF-12 are comparable and highly correlated with SF-36 scores (ranging from .63-.97) (Ware et al., 1995; Ware, Kosinski, & Keller, 1996). The SF-12 reproduced 90% of the variance in the SF-36 PCS and MCS measures in the United States and on cross-validation in the MOS (Ware et al., 1996). Test-retest reliability for the PCS-12 scale in the United States was .89, and for the MCS-12 scale was .77 (Ware et al., 1996). Internal consistency has been demonstrated for the PCS-12 (.77) and the MSC-12 (.80) (Luo et al., 2003). In the current study, the PCS-12 demonstrated poor three-month test-retest reliability (r_p = -.018), and therefore results were interpreted cautiously. This may be because our sample reported improvements over time.

Cardiac-Specific Quality of Life

The *Left Ventricular Dysfunction Questionnaire* (LVD-36; O'Leary & Jones, 2000) was designed to measure the impact of left ventricular dysfunction on daily life and well-being. This 36-item questionnaire measured cardiac-specific QOL. Responses are dichotomous (true or false). True responses are summed, which are then calculated as

a percentage; higher scores indicate worse functioning (i.e., 0 = best possible score). Analyses have also revealed that for this measure significant differences were found between all NYHA classes, except between classes III and IV (O'Leary & Jones, 2000). The measure demonstrated high internal consistency in a sample with chronic left ventricular dysfunction (Kuder-Richardson coefficient = .95) (O'Leary & Jones, 2000). In the current sample, high internal consistency was found (Cronbach's α = .95). Test-retest reliability in this sample was moderate (r_p = .594).

The *Minnesota Living with Heart Failure Questionnaire* (MLHFQ; Rector, Kubo, & Cohn, 1987) was used to measure cardiac-specific QOL, including components of symptom distress and function (Harrison et al., 2002). The 21 items that comprise the MLHFQ originate from the Sickness Impact Profile. Patients with congestive heart failure were asked to select items that they experienced and attributed to their CHF. Items are rated on a 6-point Likert-type scale from 0 to 5; scores range from 0-105. Lower scores indicate less disability from symptoms, or in other words, better QOL. A physical dimension and an emotional dimension can also be calculated from this scale. In this study, the primary variable used was the total score. Research demonstrates that the MLHFQ is more sensitive to changes across a six and twelve week period among CHF patients (Harrison et al., 2002). Analyses have also revealed that for this measure significant differences were found between all NYHA classes, except between classes III and IV (O'Leary & Jones, 2000). The scale has demonstrated strong internal consistency, yielding a Kuder-Richardson coefficient of .95 among patients with chronic left ventricular dysfunction (O'Leary & Jones, 2000). Internal consistency in the present sample was established (Cronbach's α = .96), and moderate three month test-retest reliability was found (r_p = .537).

Depression

The *Center for Epidemiological Studies-Depression Scale* (CES-D; Radloff, 1977) is a 20-item self-report measure that assesses depressive symptomatology. Respondents indicate how frequently they have experienced each symptom in the past week. Responses range from 0 (less than one day) to 3 (5-7 days). The total score can range from 0 to 60 and reflects both the number of depressive symptoms and their duration. In the general population, a standard cut-off score of 16 can be used to indicate clinically significant symptoms of depression (Radloff, 1977). Heart disease and primary care literature has demonstrated that CES-D scores can be grouped into three depression classifications: mild/ subclinical symptoms (0-15), moderate symptoms (16-26), and severe symptoms (>26) (Blumenthal et al., 2003; Zich, Attkinsson, & Greenfield, 1990). Previous research has demonstrated that the CES-D is highly sensitive and specific and exhibits a high internal reliability coefficient of .85. It has been reported as a more generally useful self-report measure of depression than the Beck Depression Inventory, the MMPI Depression Scale, and the Zung Self Rating Scale of Depression (Turk & Okifuji, 1994). In the current sample of HOCM patients, the CES-D demonstrated to have strong internal consistency (Cronbach's α = .87) and moderate three month test-retest reliability (r_p = .530).

Anxiety

The *Revised State Trait Personality Inventory-Trait Scale* (STPI; Spielberger et al., 1979) is a 40-item self-report measure used to assess dispositional anxiety. The full trait scale is comprised of 4 subscales (10 items each): anxiety, anger, depression, and curiosity. In the current study, only the first three subscales (anxiety, anger, and

depression) were used; therefore the current measure consists of 30 items. Respondents rate how strongly they agree with each item on a 4-point Likert-type scale ranging from 1 to 4, with total scores ranging from 30-120. The scoring procedure for the STPI is the same as that used in the STAI and STAXI, with higher scores indicating greater presence of dispositional anxiety, anger, and depression (Spielberger & Reheiser, 2003). The current study utilized a total score only, which is a summation of the 30 items. In the current HOCM sample, strong internal consistency was seen (Cronbach's α = .77) and strong three month test-retest reliability (r_p = .777).

Well-Being

The *Satisfaction with Life Scale* (SWLS; Diener, Emmons, Larson, & Griffin, 1985) was designed to assess overall satisfaction with life. It is a 5 item measure that respondents are asked to rate their agreement with each item using a 7-point Likert-type scale, ranging from 1 ("strongly disagree) to 7 ("strongly agree"). Possible scores range from 5 to 35, with higher scores indicating higher satisfaction with life. Strong reliability has been demonstrated, yielding a Cronbach's alpha of .87 and a two-month test-retest reliability of .82. Adequate levels of convergent validity with the Life Satisfaction Index were also seen (Diener et al., 1985). The SWLS did not correlate with the Marlowe-Crowne measure (r = .02), indicating that it is not evoking a social desirability response pattern. In addition, it appears that individuals who are satisfied with their lives are generally well adjusted and free from emotional distress or psychopathology (Diener et al., 1985). The scale demonstrated high internal consistency (Cronbach's α = .91) and strong three month test-retest reliability (r_p = .818) in the current sample of HOCM patients.

The *Life Orientation Test-Revised* (LOT-R; Scheier, Carver, & Bridges, 1994) is a 6-item, self-report questionnaire (with 4 additional filler items) that assesses generalized expectancies for positive versus negative outcomes. Respondents rate the items on a 5-point Likert-type scale from 0 (“strongly disagree”) to 4 (“strongly agree”). Half of the items are phrased in the positive direction (items 1, 4, 10). The scores for the negative items (items 3, 7, 9) are reversed, and then all items are summed to yield an overall dispositional optimism score. Range of scores is 0-24, with higher scores indicating a more positive disposition. The LOT-R has an acceptable reported reliability alpha of 0.78. Test-retest reliability of the LOT-R has been shown across 4 to 28 months to range between .56 and .79 (Scheier et al., 1994). The authors conclude that overall, the LOT-R has good predictive validity, and dispositional optimism (as measured by the LOT) is quite distinguishable as an independent construct, as compared to the constructs of neuroticism and negative affectivity (Scheier et al., 1994). In the current sample, internal consistency was poor (Cronbach’s α = .26), but three month test-retest reliability was excellent (r_p = .769).

The *Spiritual Well-Being Scale* (SWBS; Paloutzian & Ellison, 1982) is a self-report measure comprised of 20 items assessing sense of well-being in the relationship with God and sense of purpose in and satisfaction with life (Paloutzian & Ellison, 1982). Ten items assess existential well-being (EWB) and 10 items assess religious well-being (RWB). Half of the items from each subscale are positively-valenced, and the other half are negatively-valenced. Responses to items are on a 6-point scale from 1 (strongly agree) to 6 (strongly disagree). The SWBS yields three scores: (1) a total score; (2) a summed score for religious well-being items; and (3) a summed score for existential

well-being items. Higher scores indicate greater well-being. The subscales have demonstrated both high reliability and internal consistency. Test-retest reliabilities were 0.93 (SWB), 0.96 (RWB), and 0.86 (EWB) (Paloutzian & Ellison, 1982). Internal consistency has been demonstrated for the three scores: 0.89 (SWB), 0.87 (RWB), and 0.78 (EWB) (Paloutzian & Ellison, 1982).

This study intended to use the total score for spiritual well-being. However, in the current sample, the total score demonstrated poor internal consistency (Cronbach's α = .38) and low three-month test-retest reliability (r_p = .432). Due to the scale's demonstration of poor consistency, reliability, and validity, it was dropped from all analyses in the current project.

CHAPTER 4
STATISTICAL ANALYSES

Analyses were conducted to evaluate psychological distress, well-being, and health related QOL among HOCM patients pre- and post-NSRT, with cardiac-specific QOL as the primary outcome. See Figure 1 for a diagram of constructs tested. General QOL (SF-12) was also examined as a secondary outcome, but only for normative comparisons to other general and cardiac populations. The Bonferroni alpha correction procedure was used to control familywise error (Tabachnick & Fidell, 2001). This procedure was used to reduce the probability of making a Type 1 error due to the multiple analyses conducted.

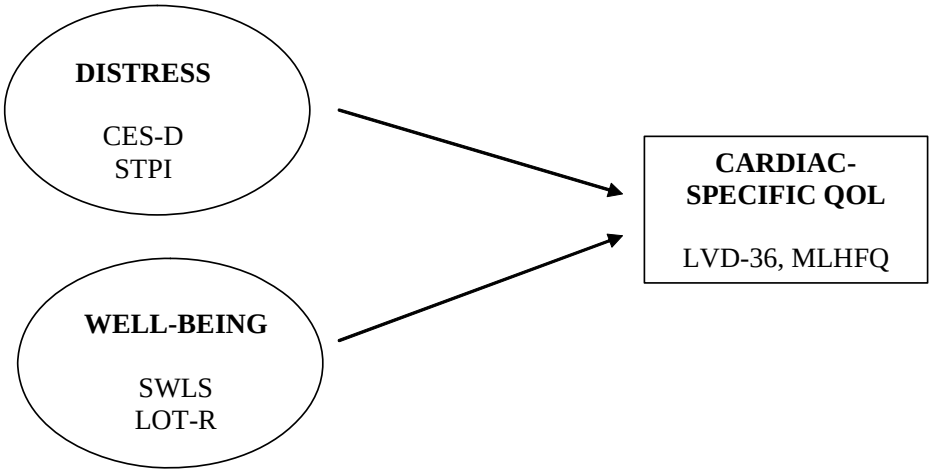

Figure 1. Diagram of constructs tested

Power and Sample Size Calculations

In the original proposal, a rationale for a sample size of 30 participants for pre- and 3-month post-NSRT was presented. Significant challenges in patient recruitment were encountered indicating the need to review progress with n = 20 pairs of pre- post-

NSRT data. There were two notable findings with the current data related to sample size. First, the data on which power analyses were calculated (i.e., pre- post- LVOT gradient, QOL) demonstrated very large effect sizes (Cohen's $d > 1.00$) and more than satisfactory power (> .85). These findings supported the decision of sufficient data to stop data collection. Secondly, to examine other psychosocial constructs (e.g., distress, well-being) while controlling for disease severity, it would take more than 4 years and be cost prohibitive to recruit a sample size ($N > 150$) that would yield adequate power and effect sizes. For example, in the repeated measures analysis, controlling for disease severity, depression yielded a $\eta_p^2 = .020$, with observed power = .086.

Aim 1: Describe HOCM Patients Pre-NSRT

The first aim of the study was to describe HOCM patient characteristics, including the rates of psychological distress, well-being, and cardiac-specific QOL, pre-NSRT. Descriptive analyses (i.e., means, one-sample t tests) were used to describe HOCM patients at baseline, examining pre-NSRT HOCM patients on demographic, medical, and psychosocial variables. It was predicted that pre-NSRT HOCM patients would be comparable to other cardiac populations, but worse than the general population on measures of distress (CES-D, STPI), well-being (SWLS, LOT-R) and QOL (LVD-36, MLHFQ, SF-12). To correct familywise error, Bonferroni alpha corrections were applied to the descriptive analyses based on the eight psychosocial variables of interest (CES-D, STPI, SWLS, LOT-R, LVD-36, MLHFQ, PCS-12, MCS-12), yielding significance at alpha = .006 (.05/8).

Patient Characteristics Pre-NSRT

Descriptive analyses were conducted on the 45 participants (*M* age = 54.3, *SD* = 15.62) who completed questionnaires during their evaluation for NSRT or at index

hospitalization at time of NSRT. Patients also received an echocardiogram as part of standard medical evaluation.

Participants were predominantly female (59.1%), Caucasian (97.6%), and married (65.9%). Fifty percent reported that they were retired or receiving disability or other financial assistance and 38.1% were working full-time. Majority of the sample reported having spiritual beliefs of a Judeo-Christian religious background (78.9%). Based on self-report, 8.6% reported that they were currently receiving psychotherapy and 17.1% reported currently taking psychotropic medications. Combining antidepressant or anxiolytic prescriptions from their medical record, 36.4% of the sample was taking a psychotropic medication. The percentage of HOCM patients who were receiving some kind of psychiatric treatment (i.e., self-report or medical chart review) was 45.9%.

Patients' biomedical parameters were comparable to the NSRT research (Chang et al., 2004; Ralph-Edwards et al., 2005). Average R-LVOT gradient was 60.36 mm Hg (*SD* = 35.74), and average provoked LVOT gradient was 101.12 mm Hg (*SD* = 52.57). See Table 2 for complete descriptive data of demographic, medical, and psychosocial variables at pre-NSRT. All variables, except demographic variables, were normally distributed and reflected the full ranges of scores, without ceiling or floor effects.

Comparisons for differences between sites

There were no significant differences in demographic variables between UF and MUSC participants. There were significant differences between sites on both pre-NSRT resting (p = .001) and provoked (p = .002) LVOT gradient, with MUSC scores being worse. However, the differences did not exist at 3-month post-NSRT (p = .213, and p = .348, respectively). It is assumed that MUSC may have initiated the procedure on sicker patients; but, procedurally, the sites did not differ, evidenced by comparable outcomes.

Table 2. Descriptive statistics on demographic, medical, and psychosocial variables in pre-NSRT HOCM patients

Variable	*n*	Mean/ %	*SD*	Minimum	Maximum
Demographic variables					
Age	44	54.3	15.62	18	77
Sex (male)	44	40.9%	0.50	0	1
Race	42		0.62	1	5
Caucasian		97.6%			
African-American		2.4%			
Marital status	41		1.14	1	5
Single		12.2%			
Separated/Divorced		9.8%			
Widowed		7.3%			
Married/Remarried		65.9%			
Living with partner		4.9%			
Have children (Yes)	42	81.0%	0.40	0	1
Number of children	33	2.58	1.48	1	7
Religion	38		1.06	0	4
Not religious/None		2.6%			
Catholic		23.7%			
Protestant		52.6%			
Jewish		2.6%			
Other		18.4%			
Employment status	42		2.19	1	6
Full-time		38.1%			
Homemaker		7.1%			
Unemployed		4.8%			
Disability/ Financial asst.		21.4%			
Retired		28.6%			
Income	36		1.68	1	7
< $14,000		2.8%			
$15,000 – 29,999		38.9%			
$30,000 – 44,999		13.9%			
$45,000 – 59,999		13.9%			
$60,000 – 74,999		19.4%			
$75,000 – 89,999		2.8%			
> $90,000		8.3%			
Medical Variables					
Heart rate	44	70.70	13.63	49	110
Normal range:				60	100
Systolic blood pressure	45	131.20	24.12	79	200
Normal range:				90	140

Table 2. Continued

Variable	*n*	Mean/ %	*SD*	Minimum	Maximum
Diastolic blood pressure	45	66.84	11.45	44	94
Normal range:				50	90
Ejection fraction (%)	42	70.95	7.05	55	85
Normal range:				>55	
Ventricular septal thickness	42	19.21	6.21	7	36
Normal range:				8	10
Ventricular posterior wall thickness	42	13.12	3.89	7	24
Normal range:				7	9
Resting LVOT gradient	44	60.36	35.74	0	150
Normal range:				<30	
Provoked LVOT gradient	33	101.12	52.57	10	210
Normal range:				<30	
Psychosocial variables					
Depression	43	20.53	14.01	1	54
Anxiety	43	57.05	19.34	31	107
Satisfaction with life	42	21.02	8.42	6	34
Optimism	41	14.82	6.20	0	24
Cardiac-specific QOL (LVD)	43	59.50	27.06	0	94.44
Cardiac-specific QOL (MLHFQ)	43	49.86	29.83	0	104
Median score = 50.00					
Physical health (SF-12)	28	31.47	8.68	19.29	53.78
Mental health (SF-12)	28	45.00	12.72	24.23	66.76

Comparisons for differences between completers and noncompleters

Examining participants, at baseline, who completed 3-month post-NSRT vs. those who did not, revealed no significant differences in demographic variables. There were also no differences between completers and noncompleters on medical variables. Significant differences were found between completers and noncompleters on QOL measures, with completers reporting worse QOL. Differences were seen in MLHFQ scores (M = 62.70 [SD = 19.81] vs. M = 32.71 [SD = 32.74], respectively); higher scores indicate worse QOL (F [1, 25] = 8.122, p = .009). Differences were also seen in the PCS-12 scores, completers (M = 28.07 [SD = 5.02]) vs. noncompleters (M = 35.05 [SD =

10.24]), with lower scores indicating worse QOL (F [1, 25] = 4.923, p = .036). However, after Bonferroni alpha correction (α = .006) was taken into account, neither of these differences maintained significance.

Normative Comparisons Pre-NSRT

Examining HOCM patients at evaluation for NSRT, patients reported significant psychological distress, and poor QOL. Comparisons were made between the current HOCM sample pre-NSRT and other populations with previously published norms. It was predicted that scores would be comparable to other cardiac populations but worse than the general population.

Psychosocial normative comparisons

Depression scores were comparable to other cardiac populations. Notably, more than half the HOCM sample expressed, at minimum, mild levels of depression (M CES-D = 20.53, SD = 14.01). This sample was not statistically different from CHF patients (M CES-D = 16.9, SD = 11.9) (Koenig, 1998) (t score [42] = 1.701, p = .096). But scores were significantly worse compared to a sample of patients with other types of heart disease (M CES-D = 12.2, SD = 11.9) (t score [42] = 3.901, p < .001), and from other medical diseases (M CES-D = 15.8, SD = 12.2) (t score [42] = 2.216, p = .034) (Koenig, 1998).

While ratings of depression may be similar to other cardiac populations, the point prevalence rate of depression in this sample of HOCM patients appears to be higher than other cardiac populations. Based on the three-group severity classification system (Table 3), 44.2% of pre-NSRT HOCM patients reported mild (subclinical) symptoms of depression, 20.9% reported moderate symptoms, and 34.9% reported severe symptoms of depression. Among patients pre-CABG, Blumenthal and colleagues' (2003) found 26%

scored moderate symptoms and 12% scored severe symptoms; thus, prevalence rates for meeting criteria for depression were 55.8% (HOCM) vs. 38% (CABG). Of the 55.8% of HOCM patients reporting clinically significant depression (CES-D score > 16), 47.6% were receiving some sort of psychiatric care (i.e., psychotherapy or psychotropic medication).

Normative comparisons for other psychosocial constructs that could be made with this sample were with the SWLS and the LOT-R. These pre-NSRT HOCM patients reported significantly less satisfaction with life compared to a general elderly population referenced in the scale's validation analyses (M = 21.02 vs. M = 25.8) (t score [41] = -3.675, p = .001). Regarding optimism scores, there were not significant differences between these HOCM patients compared to patients awaiting CABG surgery (M = 14.83 vs. M = 15.16) (t score [40] = -.341, p = .735) or to college students (M = 14.33) (t score [40] = .515, p = .609).

Table 3. CES-D depression severity cut-off scores and HOCM prevalence rates

CES-D score	Depression severity	HOCM prevalence rates pre-NSRT	HOCM prevalence rates post-NSRT
0 – 15	Mild/subclinical symptoms	44.2%	65.0%
16 – 26	Moderate symptoms	20.9%	25.0%
> 26	Severe symptoms	34.9%	10.0%

Note. Blumenthal et al., 2003; Zich, Attkinsson, & Greenfield, 1990

Quality of life normative comparisons

Results of comparisons depended on normative data and measure used. QOL scores were commensurate to other cardiac populations with NYHA class III heart failure (Rector et al., 1987). However, when compared to a population with chronic left ventricular dysfunction (validation sample of the LVD-36), the current sample of pre-NSRT HOCM patients reported significantly worse cardiac-specific QOL on both the LVD-36 and the MLHFQ (O'Leary & Jones, 2000). On both the LVD-36 and the

MLHFQ, lower scores indicate better QOL. HOCM patients scored a *M* LVD-36 = 59.50 (*SD* = 27.06) compared to a normative sample *M* = 39.0 (*SD* = 28.9) (*t* score [42] = 4.968, $p < .001$). Using the MLHFQ, HOCM patients' *M* = 49.86 (*SD* = 29.83) compared to the same normative sample for the LVD-36, *M* MLHFQ = 29.7 (*SD* = 22.7) (*t* score [42] = 4.432, $p < .001$).

While the cardiac-specific QOL scales did not indicate differences with CHF patients, the SF-12, measuring generic QOL did capture significant differences between the current HOCM sample and a CHF population on physical health (PCS-12) (*M* = 31.47 vs. *M* = 40.02) (*t* score [27] = -5.217, $p < .001$) and on mental health (MCS-12) (*M* = 45.00 vs. *M* = 51.12) (*t* score [27] = -2.548, $p = .017$). HOCM SF-12 scores were also significantly worse than scores from a population of minor medical conditions for both PCS-12 and MCS-12 ($p \leq .001$) (Ware et al., 1995). Collectively, these results indicate that QOL in these pre-NSRT HOCM patients is worse than the general population and worse than other cardiac populations.

Relationships pre-NSRT

Zero-order correlations with pre-NSRT data were examined to evaluate relationships of interest. Seen in Table 4, age, sex, and R-LVOT gradient were not significantly related to any of the psychological distress, well-being, or QOL variables, except for the relationship between sex and the MLHFQ ($p < .05$). Depression was highly correlated with all the psychological and QOL variables, and exceeded the collinearity cutoff of $r = .70$ (Kleinbaum, Kupper, Muller, & Nizam, 1998) in its relationship with the STPI ($r = .856$) and all QOL scales: LVD-36 ($r = .746$), MLHFQ ($r = .762$), and the PCS-12 ($r = -.779$). All depression and QOL correlations indicated inverse relationships, such that as depression increased, QOL decreased. However, in this sample, depression and QOL were seemingly too highly related or confounded at pre-NSRT. The measures used

Table 4. Zero-order correlations of relevant pre-NSRT variables

	Variable	2	3	4	5	6	7	8	9	10	11
1	Age	.166	.043	.014	-.137	.213	.180	-.031	-.115	-.093	.211
2	Sex		.297	.142	.034	.043	-.057	.213	.319*	-.146	.242
3	R-LVOT gradient			.171	.098	.107	.066	.201	.264	-.218	.031
4	Depression				.856**	-.489**	-.519**	.746**	.762**	-.287	-.779**
5	Anxiety					-.593**	-.585**	.597**	.600**	-.130	-.750**
6	Life satisfaction						.710**	-.433**	-.246	.088	.496**
7	Optimism							-.338	-.197	.019	.451*
8	Cardiac-specific QOL (LVD-36)								.727**	-.586**	-.700**
9	Cardiac-specific QOL (MLHFQ)									-.424**	-.643**
10	Mental health (SF-12)										-.002
11	Physical health (SF-12)										---

Note. * $p < .05$; ** $p < .001$. Sample size for all correlations ranged 41-43, except correlations with SF-12, $n = 28$.

to assess these constructs appear to be tapping into shared components of the indices, and thus, may not be independent or unique when evaluated at the same point in time in this study.

In addition to showing problematic collinear relationships, the correlation analyses also demonstrated good convergent validity between measures. Satisfaction with life and optimism were collinear (r = .710), but also demonstrated convergent validity between the two well-being measures. The QOL measures also demonstrated good convergent validity. For example, the LVD-36 and MLHFQ (r = .727) were highly related, as were the LVD-36 and the PCS-12 (r = -.700), and the MLHFQ and the PCS-12 (r = -.643).

Aim 2: Change Pre- Post-NSRT

The second aim of the study was to determine if there were changes in psychological distress (CES-D, STPI), well-being (SWLS, LOT-R), and cardiac-specific QOL (LVD-36, MLHFQ) in HOCM patients across time, from pre- to post-NSRT. First, descriptive analyses (e.g., means, one-sample t tests) were conducted to compare 3-month post-NSRT HOCM patients to other cardiac populations as well as the general population (α = .006). This was performed so that both (a) change and (b) how post-NSRT patients compared to cardiac and general populations were evaluated over time. Repeated measure analyses of variance (RM-ANOVA) were conducted to evaluate change from pre- to 3-month post-NSRT.

Patient Characteristics at 3-Months Post-NSRT

Of the 45 participants pre-NSRT, there were 20 participants (44.4%) who completed 3-month post-NSRT data (UF, n = 9; MUSC, n = 11). The average follow-up time was 3.55 months (SD = .880), congruent with the design of the study, corresponding to standard clinical care. Participants (n = 25) were lost to follow-up because they did not

return to the clinic for their standard cardiology clinic follow-up appointment, and therefore did not receive and complete the packet of questionnaires nor did they have an echocardiogram taken. As seen by the completers vs. noncompleters analysis, those who completed 3-month post-NSRT data reported worse QOL at baseline. It is unknown if completers would still report worse QOL 3-months post compared to noncompleters, because data was not collected. It is presumed that the noncompleters did not attend their follow-up appointment because their health status had improved dramatically, and therefore, felt no need to see the cardiologist. See Table 5 for prevalence of past and current history of psychiatric treatment at baseline and post-NSRT.

Table 5. Summary of psychiatric history of patients pre- and 3-months post-NSRT

	Pre-NSRT		3-month post-NSRT	
Variable (no/yes)	*n*	%	*n*	%
Past psychotherapy (SR)	34	11.8%	18	16.7%
Past psychotropic medications (SR)	33	27.3%	18	6.3%
Current psychotherapy (SR)	35	8.6%	18	5.6%
Current psychotropic medications (SR)	35	17.1%	18	22.2%
Antidepressant prescription (CR)	44	27.3%	20	30.0%
Anxiolytic prescription (CR)	44	15.9%	20	25.0%
Total currently treated (SR)	35	17.1%	18	22.2%
Total with prescription (CR)[a]	44	36.4%	20	35.4%
Overall treatment (SR or CR)	37	45.9%	18	55.6%
CES-D > 16, overall treatment (SR or CR)	21	45.7%	7	57.1%

Notes. SR = Self-Report, CR = Chart Review. There were no significant changes over time (*p* values ranged .082 – 1.000).
[a] Prescription includes only antidepressant or anxiolytic medication.

Normative Comparisons Post-NSRT

Normative comparisons of psychosocial status at 3-months post-NSRT, along with pre-NSRT findings are seen in Table 6. Notable findings were that scores had significantly changed over time, such that at pre-NSRT, HOCM patients reported worse scores (e.g., more depression, lower life satisfaction, poorer QOL) on a majority of the

Table 6. Normative comparisons (t tests) with pre-NSRT and 3-month post-NSRT scores

Measure	Norm *M*	Comparison population	Pre-NSRT HOCM *M*	*p*	Post-NSRT HOCM *M*	*p*
CES-D	16.9	CHF	20.53	.096	14.1	.277
	12.2	Other heart diseases	20.53	< .001	14.1	.457
	15.8	Other medical diseases	20.53	.032	14.1	.505
SWLS	25.8	Elderly	21.02	.001	21.4	.030
LOT-R	15.16	Awaiting CABG	14.83	.735	16.3	.411
	14.33	College students	14.83	.609	16.3	.163
LVD-36	39.0	Chronic left ventricular dysfunction	59.50	< .001	35.83	.622
MLHFQ	29.7	Chronic left ventricular dysfunction	49.86	< .001	30.1	.943
PCS-12	40.02	CHF	31.47	< .001	38.03	.540
	47.10	Minor medical conditions	31.47	< .001	38.03	.012
MCS-12	51.12	CHF	45.00	.017	47.61	.325
	53.62	Minor medical conditions	45.00	.001	47.61	.102

measures than the normative samples (i.e., both cardiac populations and the general population), and later, post-NSRT, HOCM patients report comparable scores to the normative samples. Similarly to depression findings pre-NSRT, scores of depression post-NSRT were not significantly different from normative samples; however, prevalence rate of depression (CES-D scores > 16) continued to be noteworthy (35%). Thus, while these patients reported dramatic improvements, three-months post-NSRT, they were still comparable to other sick cardiac populations. Three-month post-NSRT, the only significant findings when comparing HOCM to other populations were in satisfaction with life (p = .030) and the PCS-12 (p = .012). Thus, HOCM patients, post-NSRT, reported worse life satisfaction compared to an elderly population. They also reported worse QOL compared to a population of minor medical conditions; however, they report equivalent scores to a CHF population. After Bonferroni correction (α = .006, based on the 8 measures for normative comparisons), these significant differences disappear.

Repeated Measures Results

It was predicted that HOCM patients would rate improvements on post-NSRT scores of distress, well-being, and cardiac-specific QOL compared to their ratings pre-NSRT. Several significant time effects were found from pre-NSRT to 3-month post-NSRT (See Table 7 for means and standard deviations across time). Bonferroni alpha corrections were applied to the repeated measures analyses based on the six psychosocial variables of interest (CES-D, STPI, SWLS, LOT-R, LVD-36, MLHFQ), yielding significance at alpha = .008 (.05/6).

Table 7. Mean scores across time from pre- to 3-month post-NSRT (n = 20)

	Pre-NSRT		3-month post-NSRT	
Variable	Mean	*SD*	Mean	*SD*
R-LVOT gradient**	59.26	41.45	20.79	23.7
P-LVOT gradient**	100.21	56.31	30.71	28.09
Depression**	23.95	14.81	14.37	11.44
Anxiety*	62.21	21.93	54.95	16.94
Life satisfaction	21.68	8.83	21.63	8.53
Optimism	15.61	5.96	16.67	6.07
Cardiac-specific QOL (LVD-36)*	67.11	23.72	34.80	28.63
Cardiac-specific QOL (MLHFQ)*	58.16	25.03	30.32	25.38

Note. * $p < .05$; ** $p < .01$.

Biomedical variables

As expected, the medical outcome of both resting and provoked LVOT gradient decreased dramatically and demonstrated a large effect size (Cohen's *d*, adjusted with Hedges' g = 1.12 and 1.52, respectively). R-LVOT gradient improved from M = 59.26 (SD = 41.45) to M = 20.79 (SD = 23.70) ($p < .001$, n = 19). Provoked gradient improved from M = 100.21 (SD = 56.31) to M = 30.71 (SD = 28.09) ($p < .001$, n = 14). Calculating power from differences in pre- to post-NSRT, R-LVOT gradient yielded power of .92, and provoked LVOT gradient yielded power of .99.

Psychosocial variables

Among the psychosocial variables, there were significant time effects for depression (Pillai's Trace F [1, 18] = 10.226, p = .005) and anxiety (Pillai's Trace F [1,18] = 5.251, p = .034). Depression demonstrated a strong medium effect size (Cohen's *d*, adjusted with Hedges' g = .71) and power = .58. Anxiety demonstrated a small but strong effect size (Cohen's *d*, adjusted with Hedges' g = .36). After Bonferroni corrections, the time effect for anxiety was no longer significant. There were no significant time effects for the constructs of satisfaction with life, and optimism.

Quality of life variables

Similarly to medical outcome, cardiac-specific QOL demonstrated highly significant improvements from pre-NSRT to 3-month post-NSRT, as well as very large effect sizes. Examining scores on the LVD-36, Cohen's *d*, adjusted with Hedges' *g* = 1.20 (Pillai's Trace F [1,18] = 34.468, $p < .001$). Power for the LVD-36 was .96. Additionally, examining scores on the MLHFQ, Cohen's *d*, adjusted with Hedges' *g* = 1.08 (Pillai's Trace F [1,18] = 25.05, $p < .001$), and power was .85.

Repeated Measures Results: Controlling for Disease Severity

Repeated measures analyses of covariance (RM-ANCOVA) were conducted using pre-NSRT R-LVOT gradient as a covariate, to control for disease severity. It was predicted that HOCM patients would report improvements across time on scores of distress, well-being, and cardiac-specific QOL and would maintain significance, even after controlling for disease severity at baseline.

Psychosocial variables

There was no significant change in depression after controlling for disease severity, contrary to the hypothesis. However, the analysis revealed a negligible effect size indicated by $\eta_p^2 = .020$ and poor observed power (.086). There was a significant depression by covariate (pre-NSRT R-LVOT gradient) interaction effect (Pillai's Trace F [1,17] = 7.613, $p = .013$, $\eta_p^2 = .31$, observed power = .74), indicating that change in depression was dependent on disease severity at baseline. There were no significant effects for anxiety (main effect $p = .809$, $\eta_p^2 = .004$; interaction effect $p = .124$, $\eta_p^2 = .133$). Similar to previous RM-ANOVAs, the addition of the covariate did not yield significant results with satisfaction with life and optimism.

Quality of life variables

Similar to the findings for depression, examining cardiac-specific QOL revealed no significant main effects of time. Both cardiac-specific QOL measures significantly interacted with the covariate. Scores on the LVD-36 significantly varied by pre-NSRT R-LVOT gradient (Pillai's Trace F [1,17] = 7.668, p = .013, η_p^2 = .311, observed power = .742). In addition, scores on the MLHFQ significantly varied by gradient (Pillai's Trace F [1,17] = 25.719, p < .001, η_p^2 = .602, observed power = .998). Thus, change in cardiac-specific QOL was dependent on disease severity at baseline, and therefore, the hypothesis was not supported. After Bonferroni alpha corrections were made, the only significant time effect with gradient as the covariate was cardiac-specific QOL using the MLHFQ.

Aim 3: Prediction Model

To determine whether psychological distress and well-being pre-NSRT predicted 3-month post-NSRT cardiac specific QOL two hierarchical multiple regression analyses were conducted with the LVD-36 and MLHFQ at 3-month follow-up as the dependent variables. Disease severity (R-LVOT gradient) was entered on the first step. Depression (CES-D) was entered on the second step and satisfaction with life (SWLS) was entered on the third step. It was predicted that after controlling for pre-NSRT disease severity, patient's baseline level of clinical distress and well-being would uniquely predict post-NSRT cardiac-specific QOL.

Initially, it was planned that both the CES-D and the STPI would be used to measure distress and SWLS and LOT-R would be used to measure well-being. After examining the zero-order correlations at baseline, both the STPI and LOT-R were eliminated from the hierarchical regression analyses because of their collinearity with CES-D and SWLS, respectively. The CES-D and SWLS were retained in the analyses

because, in the current sample, they demonstrated not only good but also stronger reliability (Cronbach's α = .87 and .91, respectively) than the STPI (Cronbach's α = .77) and the LOT-R (Cronbach's α = .26) (Pedhazur, 1997).

Results for the LVD-36

With the LVD-36 as the dependent variable, gradient, distress, or well-being factors did not significantly account for unique change in variance. However, the full model significantly predicted cardiac-specific QOL using the LVD-36 (F [3,15] = 3.333, p = .048), without taking into account the Bonferroni alpha corrections (p = .008). The full model explained 40.0% (Adjusted R^2 = .280) of the variance in the LVD-36. Unique significant predictors of the LVD-36 were R-LVOT gradient (β = -.612, t = -2.601, p = .020) and depression (β = .695, t = 2.387, p = .031), indicating that higher gradient (more severe disease) and less depression pre-NSRT predicted better cardiac-specific QOL (lower scores indicate better QOL) at 3-month post-NSRT. However, these results were nonsignificant after Bonferroni correction. See Table 8 for summary of regression analysis.

Table 8. Summary of hierarchical multiple regression analysis for predictors of CS-QOL using the LVD-36

	b	*SE b*	β	*t*	*p*
Step One					
R-LVOT gradient	-.311	.169	-.409	-1.846	.082
Step Two					
R-LVOT gradient	-.326	.158	-.428	-2.061	.056
Depression	.736	.402	.381	1.832	.086
Step Three					
R-LVOT gradient	-.466	.179	-.612	-2.601	.020
Depression	1.343	.563	.695	2.387	.031
Life satisfaction	1.504	1.011	.464	1.488	.157

Notes. Step one: R^2 = .167, Adjusted R^2 = .118, F (1, 17) = 3.408, p = .082.
Step two: R^2 change = .144, F change (1, 16) = 3.356, p = .086.
Step three: R^2 change = .152, F change (1, 15) = 2.214, p = .157.
Total R^2 = .400, Adjusted R^2 = .280, F (3, 15) = 3.333, p = .048.

Results for the MLHFQ

Results were similar using scores on the MLHFQ as the dependent variable. R-LVOT was significantly related to the MLHFQ, accounting for 22.1% (Adjusted R^2 = .175) of the variance (F [1, 17] = 4.827, p = .042). Entering depression into the model did not explain uniquely significant variance, but the overall model including R-LVOT gradient and CES-D was significant (F [2, 16] = 4.070, p = .037). Satisfaction with life was not a significant addition to the model predicting MLHFQ. The full model was not significant (F [3, 15] = 2.960, p = .066), explaining 37.2% (Adjusted R^2 = .246) of the variance in the MLHFQ, but R-LVOT gradient at baseline was demonstrated as the only unique significant predictor of cardiac-specific QOL using the MLHFQ (β = -.603, t = -2.504, p = .024), suggesting that higher gradient (more severe disease) was associated with better cardiac-specific QOL post-NSRT (lower scores indicate better QOL) using the MLHFQ. See Table 9 for summary of multiple regression analysis. Taken together, these two analyses do not support the hypothesis. Baseline distress and well-being did not predict cardiac-specific QOL at 3-months post-NSRT.

Table 9. Summary of hierarchical multiple regression analysis for predictors of cardiac-specific QOL using the MLHFQ

	b	*SE b*	β	*t*	*p*
Step one					
R-LVOT gradient	-.317	.144	-.470	-2.197	.042
Step Two					
R-LVOT gradient	-.329	.138	-.488	-2.393	.029
Depression	.584	.349	.341	1.674	.114
Step three					
R-LVOT gradient	-.407	.163	-.603	-2.504	.024
Depression	.921	.510	.538	1.806	.091
Life satisfaction	.834	.917	.290	.910	.377

Notes. Step one: R^2 = .221, Adjusted R^2 = .175, F (1, 17) = 4.827, p = .042.
Step two: R^2 change = .116, F change (1, 16) = 2.801, p = .114.
Step three: R^2 change = .035, F change (1, 15) = .829, p = .377.
Total R^2 = .372, Adjusted R^2 = .246, F (3, 15) = 2.960, p = .066.

Exploring the Relationship between Depression and Quality of Life

Depression and QOL (both generic and cardiac-specific) were highly confounded in this study and demonstrated collinearity at pre-NSRT and at 3-months post-NSRT ($r >$ .70). However, across time these variables were not related to each other in either direction. In other words, depression at pre-NSRT was not significantly related to QOL at 3-months post-NSRT. Two out of three QOL measures (MLHFQ, PCS-12) at pre-NSRT were not significantly related to the CES-D at 3-months post-NSRT, but the LVD-36 pre-NSRT (r = .545, p = .016) was significantly related to CES-D post NSRT.

Depression Components

Due to the confounded relationships between depression and QOL, the CES-D was divided into previously published factors to determine if there was a specific factor driving the relationship. Four factors were calculated: depressed affect (7 items), somatic activity (7 items), interpersonal problems (2 items), and positive affect (4 items) (Dikmen et al., 2004). Item 9, “I thought my life had been a failure” is an example of a depressed affect scale item. Item 7, “I felt that everything I did was an effort” is an example of a somatic activity scale item. Along with the CES-D factors, the MLHFQ physical dimension and emotional dimension were examined (Rector et al., 1987). Depressed affect of the CES-D and emotional scale of the MLHFQ were collinear pre- and post-NSRT, as were somatic activity of the CES-D and the physical dimension of the MLHFQ were. An important relationship that evolved from these analyses was the significant, but non-collinear relationship between the CES-D depressed affect scale and the MLHFQ physical dimension at both pre-NSRT (r = .590, p = < .001) and post-NSRT (r = .654, p = .002). This relationship was not significant over time, in either direction. An

additional notable finding was the significant, but non-collinear relationship between the CES-D depressed affect scale and the LVD-36 pre-NSRT (r = .664, p < .001), suggesting that separating out “depressed affect” may be the most applicable for measuring depression in this sample, especially in relation to cardiac-specific QOL. See Table 10 for correlations between subscales of the CES-D and the QOL measures pre-NSRT.

Along with attempts to separate out important components of depression and QOL, prevalence of depression was examined more closely. Prevalence of clinical depression (CES-D > 16) pre-NSRT was remarkably high, with overall prevalence rates reducing over time (55.8% to 35%), as did CES-D scores. Notably, despite the improvements over time, of those who reported significant levels of depression at baseline, 58.4% continued to report clinically significant depression.

New Prediction Model

Despite the significant relationships between depression and QOL, the hypothesized model did not capture their relationship. Changing the direction of the hypothesized model, depression at 3-month post-NSRT was significantly predicted by cardiac-specific QOL at baseline in a two-step hierarchical multiple regression analysis, performed post-hoc. The LVD-36 was used as the measure for cardiac-specific QOL because throughout the analyses of the study, it appeared to be a cleaner and more valid measure compared to the MLHFQ. Age and R-LVOT gradient at baseline were entered in step one, significantly explaining 37.7% (Adjusted R^2 = .299) of the variance in the LVD-36 (F [2, 16] = 4.848, p = .023), with worse disease severity pre-NSRT was associated with less depression at 3-months post-NSRT. The LVD-36 was entered on the second step and explained significant unique variance (32.5%) in 3-months post-NSRT

Table 10. Zero-order correlations between depression subscales and QOL measures pre-NSRT

	Variable	2	3	4	5	6	7	8	9	10	11
1	CES-D total	.969**	.912**	.645**	-.660**	.762**	.646**	.821**	.746**	-.287	-.779**
2	CES-D depressed affect		.865**	.619**	-.571**	.737**	.590**	.813**	.664**	-.229	-.752**
3	CES-D somatic activity				-.411**	.873**	.780**	.880**	.784**	-.458*	-.720**
4	CES-D interpersonal problems				-.460**	.318*	.267	.456**	.363*	-.033	-.455*
5	CES-D positive affect					-.269	-.318*	-.378*	-.505**	.049	.563**
6	MLHFQ total						.948**	.924**	.727**	-.424*	-.643**
7	MLHFQ physical							.800**	.808**	-.703**	-.522**
8	MLHFQ emotional								.766**	-.409*	-.714**
9	LVD total									-.586**	-.700**
10	SF-12 physical health										-.002
11	SF-12 mental health										---

depression scores. The full model significantly predicted depression at 3-months post-NSRT, accounting for a total of 83.8% (Adjusted R^2 = .702) in depression scores (F [3, 15] = 11.772, p < .001). Worse disease severity (β = -.598, t = -4.221, p = .001) and better cardiac-specific QOL (lower scores indicate better QOL) (β = .573, t = 4.041, p = .001) pre-NSRT predicted less depression at 3-months post-NSRT. This post-hoc analysis seems to explain the relationship between depression and cardiac-specific QOL better than the previous hypothesized model.

CHAPTER 5
DISCUSSION

This study is the first comprehensive outcome study examining the relationships between psychological distress, well-being, and biomedical outcomes among HOCM patients. Further, while many have examined NSRT from a biomedical perspective, evaluating symptoms, outcome, and precision of the procedure in short and long-term studies (Firoozi et al., 2002; Lakkis et al., 2000; Nielsen et al., 2002; Nielsen & Spencer, 2002), this is the first evaluation of NSRT from the patient's perspective and how psychosocial parameters change over time. There were three main overall findings. First, there was a high prevalence of clinical levels of depression in these pre-NSRT HOCM patients. Second, HOCM patients' disease severity, depression, and QOL improved over time and that disease severity at baseline was the primary determinant of change amongst the psychosocial variables. Thirdly, in the hypothesized prediction model, psychosocial variables tested here did not significantly impact health outcomes.

Patient Pre-NSRT Characteristics

Examining HOCM patients' characteristics pre-NSRT, scores demonstrated that this group of patients is similar to other cardiac populations with NYHA class III or IV symptoms in demographic characteristics and in quality of life measures. Most notable in this study was the prevalence rate of depression appears to be higher than other heart disease groups, exemplifying the need for psychological attention in this group. Depression scores were comparable to other cardiac populations, but the proportion of

patients reporting significant depression was higher than in other cardiac populations reported in the literature (Blumenthal et al., 2003). Patients in this study often suffered from cardiac symptoms and functional impairments of significant duration before proper diagnosis and before presenting to the HOCM clinic for NSRT evaluation. NSRT has typically been the last line of defense in treating HOCM and patients are generally managed with medications prior to considering this procedure. Continuing to be symptomatic, patients present for NSRT evaluation, expressing frustration with symptoms (e.g., shortness of breath, fatigue, chest pain), medical treatment, and functional limitations (e.g., unable to walk a flight of stairs, care for children). Related to symptoms of depression that were expressed, patients' noted poor satisfaction with life, which was significantly related to not only depression, but also QOL.

This study included three separate measures of QOL, two cardiac specific, and one generic measure. All three demonstrated strong convergent validity amongst each other and indicated poor QOL in this sample of HOCM patients. Depending on comparison group and type of measure used, these HOCM patients reported comparable cardiac-specific QOL in some studies including those with NYHA class III or IV heart failure patients (Rector et al., 1987). Yet, compared to other cardiac populations (e.g., chronic left ventricular dysfunction), medical populations, and the general population, cardiac-specific QOL was worse in this sample of HOCM (Koenig, 1998; O'Leary & Jones, 2000). Using a generic measure of QOL (SF-12), this sample of HOCM patients reported worse QOL than CHF patients and other medical conditions, and therefore, was also worse than Cox and colleagues' (1997) sample whose scores were akin to CHF patients. Cox and colleagues' (1997) patient sample was comprised of HCM patients with or without obstruction; therefore, it is probable that the current sample was

comprised of patients with more severe disease, and subsequently reported more/worse symptoms and more limitations.

Depression and Quality of Life

When examined cross-sectionally, depression and QOL were highly significantly related to each other both at baseline and at 3-month post-NSRT. Their relationship was so strong, that they could be considered collinear, measuring almost identical information when measured simultaneously. Findings suggest that depressive symptoms may be the main component of QOL in this sample of HOCM patients, rather than one of several components that comprise QOL, and therefore, they are highly confounded. When the CES-D was divided into four factors from previous research, collinear relationships between the four factors and QOL still existed in many of the correlations. The key relationship that was highlighted in these analyses was the relationships between the CES-D depressed affect scale, MLHFQ physical dimension scale, and the LVD-36 scale. Separating out depressed affect from other components of depression allowed the relationship to be significant while maintaining uniqueness, suggesting greater validity for measuring depression in this sample. This was also seen when separating the physical and emotional components of QOL.

It is well known that depression and illness are often comorbid, and that depression includes somatic symptoms that can be misinterpreted as medical symptoms and vice versa. The findings with the subscales of the CES-D (particularly the depressed affect and somatic activity scales) support the intermingled relationship. The confounded relationship is difficult not only in terms of research measurement, but also in terms of clinical diagnosis and treatment. Patients and medical providers may misinterpret their depressive symptoms as cardiac symptoms or the opposite way around. This may result

in either under or over reporting of cardiac symptoms and likewise with depressive symptoms, and subsequently patients may be misdiagnosed or mistreated, undermining outcome or treatment response.

Patient Characteristic Conclusions

Overall, the reported levels of depression, poor satisfaction with life, and QOL were worse than other cardiac and the general populations. Therefore, patients' experience of physical and emotional symptoms was worse than hypothesized, highlighting the need for routine psychological assessment and intervention. Attention to the patients' experience of disease and its impact can play a critical role in medical and psychological treatment of the patient and its outcome.

A key treatment element for these patients is focus on enhancing QOL pre-NSRT, which may then subsequently reduce depression. Psychosocial treatments that are developed from a cognitive-behavioral approach can help patients cope with current symptoms, prepare for NSRT, and may also help with recovery. Changing perceptions (i.e., cognitive restructuring) of symptoms, disease, treatment would likely enhance QOL and decrease depression. Areas that cognitive-behavioral therapy can target are patients' fear and worry of the procedure that involves creating a controlled heart attack. Another target area for therapy is expectations of the procedure, making sure they are realistic and that the patient is prepared for symptom reduction that may not meet expectations.

Efficacy of Nonsurgical Septal Reduction Therapy

Based on the repeated measures analyses, it appears that NSRT is an effective medical procedure in not only reducing LVOT gradient, consistent with the literature (Lakkis et al., 2000; Nielsen et al., 2002; Ralph-Edwards et al., 2005), but also in reducing levels of depression, anxiety, and improving cardiac-specific QOL in patients

with HOCM. The latter findings are much needed additions to the current literature. It appears that even without a change in psychiatric treatment (i.e., psychotherapy, psychotropic medications), depression and QOL improved from pre- to post-NSRT. This suggests that favorable improvement in HOCM symptoms is associated with improvement in depressive symptoms and overall QOL or that they are highly confounded.

While depression and QOL improved greatly over time, scores 3-month post-NSRT were still only comparable to other cardiac populations, rather than reporting as good or as healthy as the general population. These patients were a highly select, highly symptomatic sample of cardiac disease. Therefore, while they made dramatic improvements, statistically and clinically, they are moving from outlier status to closer to the mean of the greater heart disease distribution. Importantly, while depression scores decreased from pre- to post-NSRT, prevalence rate was still considerable. Further, those who reported clinically significant depression pre-NSRT, a majority of them continued to report elevated levels of depression 3-months post-NSRT. Therefore, it is critical to recognize and treat these patients for depression beyond the NSRT procedure.

Similar patterns of change emerged with the addition of baseline R-LVOT gradient as a covariate. There were improvements in depression and cardiac-specific QOL from pre-NSRT to 3-month post-NSRT, but they were dictated by disease severity pre-NSRT linearly. The findings are interesting by themselves; however, it was hypothesized that significant change in psychosocial and QOL variables would occur even after controlling for disease severity. Thus, the findings did not support the hypothesis. This relationship between disease severity, QOL and depression is also seen in previous studies (Ford et al., 1998; Rumsfeld et al., 2003; Vaccarino et al., 2001).

Increasing disease severity, impacts physical, social, emotional functioning, which can also be associated with depression and epitomizes the biopsychosocial model of health and wellness. Change across time, contingent on disease severity was shown, and the next step was to determine a model of prediction, or direction of these relationships. Thus, the biopsychosocial model was tested to examine direction over time.

Biopsychosocial Model and Prediction

Literature has shown that patients who are more distressed report greater physical symptoms and/or disease and worse QOL (Carels, 2004; Duits et al., 1997; Rector, 2005; Zvolensky et al., 2003). It was predicted that pre-NSRT psychological distress and well-being would be related to post-NSRT cardiac-specific QOL. This was not found in the current study. Using the LVD-36 as the measure for cardiac-specific QOL, depression pre-NSRT was associated with LVD-36 scores at 3-months post-NSRT. But the results with the MLHFQ indicated that baseline psychosocial characteristics did not predict cardiac-specific QOL 3-months following NSRT procedure. Further evaluating the hypothesis with the subscales of the CES-D and the MLHFQ also did not lead to a significant prediction model. In the present analyses, pre-NSRT reported psychological health did not predict future patient-reported symptom experience (cardiac-specific QOL).

While the model was theoretically sound, it was not statistically significant. This could be due to several reasons. It may be that in this sample, the relationships exist and were not able to be captured due to sample size. Had the study only used the LVD-36 to measure cardiac-specific QOL, the data would have supported the hypothesis; however, two measures were used to increase sensitivity of cardiac-specific QOL and to compare validity amongst the two. It also may be that the relationships exist, but in the opposite

direction. Seen in the post-hoc analyses, cardiac-specific QOL pre-NSRT was associated with future psychological distress and well-being. It is highly probable that clinically the relationship is bi-directional, but cannot be seen statistically in this sample.

Extending the Findings

The mechanism yielding a change in depression needs to be considered. Over time, from pre- to post-NSRT, disease severity, depression, and QOL improve. Among pre-NSRT variables, R-LVOT gradient was not significantly related to either depression or QOL at baseline. Yet, according to the findings, it appears that disease severity has a strong impact on these two constructs over time. In fact, pre-NSRT R-LVOT gradient was inversely related to depression and QOL at 3-months follow-up.

There are several possible reasons for the improvements in depression and QOL, as well as the inverse relationship between baseline disease severity and the patients' reported experience over time. It may be that patients who start out with worse disease severity have more room for improvement over time. Their condition may have been so severe and disruptive that any reduction in symptoms is perceived as an improvement, and subsequently QOL and depression improved as well. Patients experiencing a reduction in symptoms are able to engage in more activities, have less limitations or impairments, and enjoy their life more fully, at least relative to before NSRT. Another plausible explanation is that patients accept their condition and symptoms over time, and therefore, were less negatively impacted as they continue to live their lives. Finally, applying cognitive dissonance theory (Festinger, 1957), patients experiencing severe disease pre-NSRT, and then choosing to undergo a relatively new and controversial procedure will perceive their post-NSRT health status favorably so that it is congruent with all that they have suffered through (i.e., disease severity, procedure). All these

mechanisms would likely lead to improved depression and QOL. Furthermore, the relationship between symptoms and depression may be moderated by QOL and/or cognitive appraisals.

The model of QOL moderating the relationship between symptoms and future depression was seen in the post-hoc multiple regression analysis, and it appeared to fit the relationship better than the hypothesized model. Baseline disease severity and cardiac-specific QOL predicted depression at 3-months post-NSRT, which is still consistent with current literature among medical illness populations, including CHF (Rumsfeld et al., 2003). Based on this last analysis, it appears that HOCM patients who are doing poorly pre-NSRT have more opportunity for improvement, and thus, when symptoms improve drastically, they report improved mood 3-months post-NSRT. Thus, intervening with psychosocial treatment targeted at improving cardiac-specific QOL pre-NSRT may improve later depression after NSRT.

Limitations

While this study is groundbreaking in the HOCM and NSRT literature, there are also areas for improvement in design, acquisition of data, and in statistical analyses. This study was simple in its quasi-experimental design and limited in scope of size and follow-up durations, which limits study conclusions. As with any longitudinal study, attrition can be a problem, and was the most significant limitation to the study. This study had a 55.6% attrition rate, mostly due to patients not returning to their cardiology clinic follow-up appointment. Because of the high attrition rate, the sample size was smaller than anticipated, and therefore, constrained planned statistical analyses. Future studies should consider design revisions. For example, mailing questionnaire packets to participants or having questionnaires on a secure Internet website may resolve some

attrition issues, at least in terms of psychosocial data. Another solution would be to add additional centers for participant recruitment.

In terms of statistical analyses, sample size was determined, during study development, based on medical variables (i.e., R-LVOT gradient) and QOL as a guideline for power analyses. Examining the current data, analyses with these variables, with the current sample size, have large effect sizes and more than sufficient power to detect true change. In contrast, examining psychosocial constructs (e.g., depression, anxiety, optimism), the current sample size did not allow for adequate power to detect change and indicated that the study would need hundreds of more participants (i.e., $N > 150$) to reach an adequate power of .80. Critical variables were confounded in this study, and variables that may contribute information to this population and treatment were not included because of the project's simplicity.

Lastly, it is believed that this sample is representative of HOCM patients undergoing NSRT because patients were recruited from two independent institutions. However, the sample may not be representative of all HOCM patients, or HOCM patients choosing other treatment options. All patients in this study were severely ill and symptomatic, seeking out a relatively new treatment done by a few interventionalists. More research is needed in this area, with larger sample sizes and with patients utilizing different treatments and with a range of disease severity.

Clinical and Research Implications

This study has positive implications for the fields of cardiac psychology and interventional cardiology. The study provided a well-rounded description of HOCM patients, medically, symptomatically, and psychologically, incorporating both objective and subjective indices. These findings can be used in development and implementation of

psychosocial treatments, particularly those based in a cognitive-behavioral framework. HOCM patients present to the cardiology clinics with cardiac and psychologic symptoms that are difficult to distinguish and would likely be better addressed by the inclusion of a health psychologist as part of the treatment team. Collectively, findings indicate the need for multidisciplinary care of HOCM patients, regardless of NSRT as a treatment choice.

The prevalence rate of depression, along with a majority of those whose depression did not improve, was a compelling finding, one that needs utmost attention. Knowing that these patients pre-NSRT may be at particularly high risk for depression and its maintenance, members of the medical team can be trained to discern symptoms of depression from cardiac symptoms and then request appropriate consult from and referral to a health psychologist. A key treatment element for these patients is focus on both cognitive and behavioral techniques, enhancing QOL and cognitive appraisals, both pre- and post-NSRT, which may then subsequently reduce depression.

Psychosocial and QOL outcomes were overshadowed by disease severity, as measured by a biomedical marker. Baseline disease severity was inversely related to outcomes at 3-months post-NSRT, such that starting with worse severity and symptoms was associated with less depression and better QOL after NSRT. These data provide preliminary, short-term data, and are the starting point of development of clinical outcome trials, multidisciplinary care, and highly specialized treatment aimed at symptom reduction and QOL enhancement. To fully understand the relationship between these three constructs more powerful studies are needed and evaluating outcomes over a longer period of time. Taking this study one more step would be to develop identification methods of depression, enabling prediction of those who are depressed prior to intervention and does not improve over time. Examining psychological distress, well-

being, and QOL in patients receiving myectomy vs. NSRT, and in patients who may have undergone both procedures, would also be beneficial to the literature and in patients' treatment and outcomes. Other beneficial studies would be evaluating patients recently diagnosed with HOCM, as well as patients who choose not to undergo NSRT. Critical to NSRT efficacy trials are longer-term studies evaluating outcomes from a biopsychosocial perspective.

Conclusions

There are two critical conclusions from this project. The first is the psychosocial status of these HOCM patients pre-NSRT. They reported clinically significant levels of depression and depression was more prevalent compared to patients with other cardiac diseases and to the general population. These patients also reported poor QOL compared to other medical populations, including those with cardiac disease. Literature has established that baseline psychosocial status can impact treatment outcomes and recovery; therefore, these patients are prime candidates for psychological intervention pre-NSRT.

The second conclusion from this study is that NSRT is an effective procedure in reducing R-LVOT gradient, depression and QOL, over the first three months after NSRT. Despite no changes in psychiatric treatment, patients reported dramatic improvements in mood and QOL. These improvements appeared to be dictated by disease severity at baseline. It is hypothesized that the relationship between medical health and depression is moderated by QOL. Future research is needed to test this model and to look at long-term effectiveness of NSRT on depression and QOL.

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BIOGRAPHICAL SKETCH

Eva R. Serber was born December 15, 1975, to Mary Lynn Serber and Russell Paul Serber. She was born and raised in Newport Beach, California, with her older sister Carolyn. She graduated from Corona Del Mar high school in 1994, after which she moved to San Diego, California. Eva earned a bachelor's degree in psychology, with a minor in speech communications, from the University of San Diego in 1998. She earned a master's degree in preclinical psychology from San Diego State University in 2001.

Since 2001, Eva has been a doctoral student at University of Florida in the Department of Clinical and Health Psychology, specializing in clinical health psychology. Eva's predoctoral internship will be at the Medical University of South Carolina, in Charleston, from 2005-2006, after which she will have fulfilled all requirements for her doctorate. Eva's career goals are to continue integration of patient care and research. Her ultimate goal is to be a psychologist in a heart center or other medical institution, providing consultative, assessment, and treatment services to cardiac patients, alongside conducting research on treatment outcomes and quality of life.