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DETERMINING THE MOST EFFECTIVE WAY IN WHICH TO MANAGE
CONGESTIVE HEART FAILURE PATIENTS

By
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A Thesis
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DETERMINING THE MOST EFFECTIVE WAY IN WHICH TO MANAGE
CONGESTIVE HEART FAILURE PATIENTS

By

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A Thesis Approve on

November 22, 2010

By the following Thesis Committee:

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Dr. John Myers (Thesis Director)

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Dr. Steven McCabe

DEDICATION

This thesis is dedicated to my wonderful family:

My Husband Thacien Ntihinyurwa for his continued support

My daughters Benita Bwiza Ntihinyurwa and Elisa Hora Ntihinyurwa for the inspiration I
get from their eyes every morning

My sister Pacifique Munezero, my brothers Desire Isidore Munyeshuli
and Romeo Irere Kwihangana for their invaluable encouragement

My beloved mother Annonciata Nyiramahoro for the strength she put in me, for making
me who I am today and without whom all this could not have happened

My late father Valere Munyakazi whom I love very much and miss every day for
teaching me at a very young age that the most important things in life are to obey God's
commandments and respect people

ACKNOWLEDGMENT

ABSTRACT

DETERMINING THE MOST EFFECTIVE WAY IN WHICH TO MANAGE

CONGESTIVE HEART FAILURE PATIENTS

Beatrice Ugiliweneza

November 22, 2010

Background: CHF is a chronic disease that affects nearly five million people each year; in which at least 500,000 are newly diagnosed cases. Patients diagnosed with this disease will be under a physician's care for the remainder of their life. It is of great importance that the strategy, used to manage these patients, maximizes their health outcomes in a cost effective manner.

Objective: The objective of the current analysis is to compare the health outcomes with the available CHF management methods: the 'Case Management' (CM), the 'Self Management' (SM) and the current 'Standard of Care' (SC). Also, this study aims to identify the optimal management programs for CHF patients.

Data: Data used are from a multicenter clinical trial funded by the AHRQ. The trial enrolled 134 patients randomized to three study arms representing the three management methods. These participants were followed for 12 months.

Statistical methods: To describe the distributions of the outcome variables, summary statistics were used. For the inferential statistics, comparisons of means across the study

arms were performed using *ANOVA* techniques and comparisons of proportions were performed using *Logistic Regression* models. Survival analysis techniques, *Kaplan Meier* curves and *Cox Regression,* were used to compare the group effect in delaying the timing until the first hospitalization.

Results: Throughout the trial, the SC arm was represented with better outcomes for all the outcomes of interest. On average, patients in the SC arm had more hospital free days (335 ± 72), shorter in-hospital length of stay (4 ± 13), fewer hospitalizations (1 ± 2) and a longer time delay for first hospitalization (139 ± 118) in comparison to the patients in the CM and SM arms. However, the differences were not statistically significant (p-value > 0.05).

Conclusion: The results from the current study did not establish if one management program had significantly better outcomes when compared to the other two.

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CHAPTER I

INTRODUCTION

Background

Congestive Heart Failure (CHF) is a clinical condition characterized by lack of perfuse systematic circulation due to the heart's damaged pumping capabilities [1, 2]. CHF affects nearly 5 million people each year; in which at least 500,000 are newly diagnosed cases [3]. While it is estimated that 1.5 to 2.0% of all Americans suffer from CHF, CHF disproportionately affects individuals older than 65 years of age in which the prevalence is estimated to be 6-10% [3]. In addition, men and African Americans are more likely to suffer from CHF, when compared to women and whites. Annually, CHF directly causes 39,000 deaths and is a contributing factor in another 225,000 deaths [4].

CHF is traditionally viewed as a chronic condition that is the result of silent killers such as hypertension and unmanaged diabetes. However, more recently, clinical research has focused on CHF cases that occurs suddenly [1]. CHF has always been a fruitful area of research due to its high rate of mortality and morbidity as well as being the leading cause of hospitalization in the elderly [5]. As a result, not only does CHF cause extensive medical burdens for society, CHF also carries a tremendous financialburden as well. It is estimated that $10 billion are spent annually for the management of CHF patients[4].

Fortunately, some cases of CHF are curable; such as cases of heart failure that are most likely caused by either an excessive workload like anemia or thyrotoxicosis (in which clinicians treat as a primary disease) or those caused by anatomical problems like valve defect (which require surgical corrections). Although, unfortunately, most forms of heart failure (those due to damaged heart muscle) have no known cure. The treatments available, aim to improve the patient's quality of life as well as their length of survival [1]. These treatments comprise drug therapy and, more importantly, lifestyle changes by the patient. The recommended lifestyle changes consist of: quitting smoking (if applicable), losing weight (if necessary), abstaining from alcoholic beverages, reducing salt and fat intake, and staying physically active [1]. To manage CHF patients' physician monitors them closely and routinely follows-up with the patients with appointments scheduled each 3 to 6 months. This management strategy is the current standard of care for CHF patients. In addition, patients should monitor their weight by weighing themselves daily; since weight gain can be a sign that the patient's body is retaining fluid, which may indicate that their heart failure is worsening.

To assist both patients in their self monitoring as well as clinicians in the monitoring of the patient, two more contemporary management strategies have recently been proposed. These two forms of management have been entitled 'Case Management' and "Self Management'. When Case Management is advocated for a patient, the patients are given a special scale and transmission machine that allow them to measure and record their weight and other important parameters specific to them daily in their home. This system is connected and transmits the data to a call center that is staffed by trained nurses that monitor the values. If there is a significant change in any measurement's value, then,

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the nurse either in agreement with the physician's office, contacts the patient makes an appointment for them with their doctor or the nurse advises them to go to the nearest Emergency Department(ED). When Self Management is advocated for a patient, the patient is given the same scale as in the Case Management and a 'Smart Box'. The scale takes the same measurements as those measured in Case Management; however, these are transmitted to the 'Smart Box' itself (which is not connected to a nurse staffed call center) advises the patient to call the doctor for an appointment or visit the ED when warranted. Hence, self management does not require any additional personnel. As such, in order to determine the most optimal way in which to manage CHF patients the effects of each management strategy must be evaluated simultaneously. Therefore, the study aim of the current project was to determine the health benefits of using Case Management and/or Self Management, when compared to the current standard of care.

Congestive Heart Failure (CHF)

Overview

Heart failure is clinically defined when the cardiac pump function is impaired losing its ability (and elasticity) to meet the body's metabolic[2]. While congestion, (the buildup of fluid in one's body) is common in CHF patients, it is not present in all CHF patients. The term heart failure does not mean that the heart has stopped working; it signifies that the heart is failing. That the heart's ability to pump adequate amounts of blood to fully oxygenate the body is weakened and that the heart is working less effectively. Regrettably, in most cases this is incurable without surgical repairs or a

transplant. When surgery or transplantation is unreasonable, prolonging life is the goal of management.

The severity of the disease is defined by the level of the pumping capacity loss and indicates the impact the disease will have on the patient's quality and quantity of life. Usually, treatment helps patients live complete and fulfilling lives and extends the time between two critical conditions: the mild form that has little impact on the patient's life and the severe form that can interfere with even very simple activities [1].

Types of CHF

Classically, CHF is classified in two main categories of CHF according to the elasticity condition of the heart:

- *Systolic heart failure*: In this condition, the heart has a problem to contract and forcing the blood out of the heart. The heart loses its ability to push a sufficient amount of blood into the circulation. Therefore, the cells of the body are not fully oxygenated and will begin to die.

- *Diastolic heart failure*: In this condition, the heart has a problem relaxing. The heart loses its ability to fill with blood because the muscle has become stiff [1]. Therefore even if the heart could contract properly, there would not be enough blood to force out of the heart.

More recently, the types of CHF heart failure are determined by the Ejection Fraction (EF) of the left ventricle. The EF is the fraction of blood (in percentage) ejected by the left ventricle during the contraction phase of the cardiac cycle. This EF qualifies the

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functionality of the left ventricle. The normal value is 58% and when it found to be less than 35% then, the left ventricle function (LVF) is said to be depressed. Thus, there are two main types of heart failure (HF):

- *HF without preserved LVF:* In this case, the ventricle is depressed; it cannot contract to eject enough blood.

- *HF with preserved LVF:* The ejection fraction is good (EF > 35) but, the ventricle has difficulties to expand and relax to receive enough blood.

Treatment of CHF

Since most forms of CHF forms are incurable, treatment is routinely focused on prolonging life and increasing a patient's quality of life. Patients must carefully monitor themselves to minimize the effect of CHF by controlling their risk factors for general heart disease. This potentially can be achieved by the patient incorporating an appropriate lifestyle. In addition to this, the patient must be closely monitored by a doctor through follow-up appointments. Furthermore, a majority of heart failure patients have to take medications to help the heart in its ability to pump.

The most common medications taken by CHF patients are:

- ACE (angiotensin converting enzyme) inhibitors to help open up vessels and help the heart not work very hard.

- Diuretics to help the body get rid of fluid and salt.

- Digitalis glycosides to help the heart contract.

- Angiotensin receptor blockers (ARBs) to reduce the workload of the heart.

- Beta-blockers which is particularly useful for those who have had a coronary artery disease.

Some patients who suffer from the more severe forms of CHF require the implantation of devices such as IABPs (Intra-aortic balloon pumps) or LVADs (Left Ventricular assist devices) to assist with their management. These devices are usually a temporary solution that bridges the patient to a heart transplant [1].

Target population

It is well established that the risk of CHF increases with age. Thus, the condition is mostly prevalent in older individuals. It affects about 1% of people age 50, but about 5% people age 75 [1]. The disease affects more men than women and is twice prevalent in African Americans than in whites [1].

The problem

CHF is a chronic disease that affects a considerable proportion of the population in the US, especially older individuals. The incidence of the CHF disease is positively correlated with age increasing dramatically for each year of age over 50. The inpatient and outpatient costs associated with CHF are estimated to be in the tens of billions of dollars each year in the US. Similarly, the prevalence of CHF continues to increase as the baby boomers continues to age. As a result, CHF will continue to increase as a burden for society [6]; therefore there is an urgent need to establish effective ways in which to manage CHF patients. That is, there is a need to address the management of CHF in a way that considers the medical effectiveness for the patient.

Purpose of the current study

The main goal of this study was to compare the three management methods, the smart-box self monitoring (Self Management), the tele-monitoring with a nurse-staffed call center (Case Management) and the current standard of care; in terms of hospital free days, hospital admission rates and in delaying the timing until the first hospitalization managing CHF patients with either.

Data used are from a multi-center clinical trial, funded by the Agency of Healthcare Research and Quality (AHRQ), which enrolled 134 congestive heart failure patients. These participants were randomly assigned to the three management strategy: Standard Care was the first arm, Case Management was the second arm and Self Management was the third arm. All the physicians following the participants in this clinical trial were given the American Heart Association/American College of Cardiology (AHA/ACC) guidelines. Patients were followed for 12 months and the primary endpoints were Emergency Department (ED) visits and hospital readmissions.

Description of study arms

Standard Care

For patients who were enrolled in the standard care management arm, they remained under the care of their usual physician, who could be a cardiologist or a regular family doctor, with regular appointments scheduled every 3 to 6 months to monitor their health [1]. In addition to these visits, the patients were encouraged to develop a healthier and more appropriate lifestyle, track their weight and comply with prescribed medications.

Case Management

For patients in the case management arm, they were also followed by a doctor similarly as those in the standard management arm. Additionally, these individuals were provided with a scale and modem machine connected to a nurse staffed call center through the email via the phone. For each patient, this scale was programmed to ask the individual, once on the scale every morning, questions related to their condition. These questions were prepared by the physician in charge of the participant and they were tailored to their specific type and level of CHF disease. The patients' weights as well as their responses were immediately sent via the internet to the nurse staffed center. This center had a list of normal parameters, tailored the physician to each patient, to which they compared the responses. If there was an alert, the nurse would contact the physician's office or recommend seeking an immediate medical treatment at the nearest Emergency Department (ED).

Self Management

For patients in the self management arm, they are followed by a doctor regularly (similar as above). However, instead of a machine connected to a nurse staffed call center, the patients were provided with an automated smart box, connected through a modem and the internet, immediately to the physician's office. This smart box was programmed and tailored to each patient with a list of normal ranges of important CHF parameters. Just like in the Case Management arm, patients were given a scale with a set of questions adapted and specific to them. But, here, the responses were transmitted to the smart box which would then, perform the necessary comparisons. If there was a

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significant change, an alert was sent to the physician's office or the box would advice the patient to go to the nearest ED.

Study overview

The current study investigated the effectiveness of each one of the management strategies considered for managing CHF patients. Initially a descriptive statistical analysis was performed to look at the population involved. Then, an inferential analysis was performed to test for differences in the outcomes studied between the three management strategies.

In addition to the traditional statistical analyses, a survival analysis was done to evaluate the difference in the time until the first hospital admission.

Implications from the Study

The current analysis will permit health care providers and their patients to see the advantages and disadvantages of each strategy and will assist them when deciding how to optimally manage their CHF.

Summary of the whole study

Congestive Heart Failure is a chronic disease which has an increasing incidence in the United States. The health outcomes of its management are important issues that must be addressed in order to provide care for CHF patients effectively. Three management strategies currently being evaluated for their medical soundness were considered in the current study: the standard care, the case management and the self management strategy. The objective of this study was to estimate the health benefits of managing CHF patients

with either self management or case management when compared to the current standard

of care.

CHAPTER II

LITTERATURE REVIEW

Overview

Congestive Heart Failure (CHF) also referred to simply as Heart Failure (HF) is a condition in which the heart cannot pump enough blood to adequately supply the rest of the body [1]. Most of the time, CHF is the result of the myocardial failure that has affected either the left or the right ventricle or sometimes both ventricles [1, 3]. CHF is an irreversible condition that often causes symptoms that make everyday life very difficult. In addition, unfortunately, currently, there is no cure for the disease. Patients diagnosed with CHF can only improve their lives by adhering to appropriate healthy life changes and by complying with medications.

The incidence and prevalence of CHF are high in the United States, especially in the population age 65 and over. The incidence and prevalence of CHF are most likely to continue to increase due to the increase in baby-boomers reaching 65 years of age. Patients with CHF have a very high rate of hospitalizations and readmissions to the hospital, which translates to high costs, associating CHF with high health expenditure. The fact that it is an incurable disease implies that the condition of CHF patients worsen over time. Although treatments and management strategies have improved considerably

in the past years, CHF is still associated with a high mortality rates and many detriment morbidities.

Most of the time, CHF causes significant reduction of physical health which is linked to a very poor quality of life for the patients. Thus, family and social support play an important role in the patients' lives.

Many efforts have been made to help improve not only the patients' conditions but also to and reduce the burden on society. To help patients cope with their condition, reduce hospitalizations and prolong survival (life expectancy), a new management strategy has been proposed; the nurse management program. These nurse management strategies traditionally assign a patient to a nurse for regular tailored communication and contact -thru personal, telephonic and even advanced technology contacts. The medical effectiveness as well as and the cost effectiveness of these methods have been widely discussed in the medical literature. However, the conclusions are variable and are contrast with one another. Some results are favorable, while others are unfavorable.

History of Congestive Heart Failure

As early as the 16th-18th century, from the connoisseurs' writings such as William Harvey (1578-1657) and Lazare Riviere (1989-1655) and others , recognize and describe anomalies and diseases people died of very similar to heart failure. At that time, these disorders were referred to as 'abnormal physiology'. Around the end of the 18th century and in the 19th century, texts of the time described conditions analogous to heart failure as 'concentric and eccentric hypertrophy (architectural anatomy)'. In the early 20th century, the diseases with symptoms like heart failure were viewed as 'rheumatic heart disease'

and they represented approximately 60 to 80% of all adult heart diseases. It was not until the 1950's that the condition was named the 'failing heart' condition which eventually evolved to be called 'Heart Failure' as it is known today.

For many years, the advocated treatment of Heart Failure had been prolonged bed rest. Half a century ago, some specific medications such as diuretics were introduced for the treatment of congestive heart failure. Later, in the 1970s, β-adrenergic agonists and phosphodiesterase inhibitors started to be used to combat symptoms of CHF. In the 1990s, new drugs known as vasodilators as well as β-adrenergic were added to the advocated list of medications for congestive heart failure [7]. Other treatment options that have been developed in the last couple of decades include surgery and use of medical devices.

Epidemiology

Incidence

There are more than 500,000 cases of heart failure diagnosed each year [8, 9], which is disproportionately diagnosed in elderly populations (65 and older) with an incidence of about 10/1000 [10]. According to recent studies, for the last 30 years, the increase in the incidence of Heart Failure has not been dramatic [8]. While the famous longitudinal Framingham Heart Study showed that there was a significant decrease from 1950 to 1969: no significant change was observed from 1970 [8].

Prevalence

The stability of the Heart Failure incidence is well established, and since DHF is significantly positive correlated with age, as the aging population increases, the prevalence of the disease continues and has become very high. Currently more than 5 million, or 2% of the current population, live with a heart failure [8, 9]. This is a dramatic increase compared to the 1971 where the estimate population with heart failure was only one to two million or 0.5%-1% of the population. An estimated 100%-300% increase in the prevalence of CHF. Similar to the incidence of CHF, Congestive Heart Failure disproportionately affects is mainly present in the elderly populations. CHF is the only major cardiovascular disorder that is increasing in prevalence [9].

Congestive Heart Failure in special populations

While Congestive Heart Failure affects both men and women and the symptoms are similar; the incidence is greater among men [8].

Older people, 65 years of age and older are affected more by this condition [8]. It is well established that Congestive heart failure incidence increases with age. The Rotterdham study showed that the incidence is less than 1% in people ages 55 to 64 but it is more than 17% in the people aged 85 and older [9].

Some population-based studies have shown that Congestive Heart Failure mortality rate is higher among African American patients compared with white patients under the age of 65 [8].

Hospitalizations and hospital readmissions

The Congestive Heart Failure condition is characterized by frequent hospitalizations. From the U.S. National Hospital Discharge Survey, there has been a relative increase of 289% from 1979 to 1999 [8] of Heart Failure-related hospitalizations and the numbers continued to rise during the 1990s [9] and it is anticipated that these numbers will continue to rise. In 1995, of the 9.4 million Medicare beneficiaries (65 +) hospitalized, more than 605,000 had Heart Failure [11].

For CHF patients hospitalized, readmission rates are very high. The 30-day readmission rates are up to 14% and the 60-day readmission rates are greater than 40%. A study done with the National Medicare data showed that there was an increase in the odds of hospital readmission at 30-day form 1993 to 1999. In 1995, in the population age 65 and over, the two-day readmission rates were 21.4 per 1000 and the 30-day readmission rate was a high 208.4 per 1000 [11].

Mortality

The American Heart Association (AHA) has estimated that about 50,000 patients die of Heart Failure annually. The mortality rate of this condition is high; the one-year mortality rate is estimated to be about 20% [10]. Regrettably, it is estimated that more than one half of the patients diagnosed today with CHF will die within the next five years [12].

Impact of Congestive Heart Failure on the society

Congestive Heart Failure has enormous consequences on the patients' health as well as the associated costs [8]. As a result, CHF is considered one of the important public health problems in the United States [9] not only because of its medical burden but

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also for its economic burden. The total health care expenditure associated with Heart Failure was $26.7 in 2004[12] and in 2005. The National Heart, Lung, and Blood institute estimates that the total Heart Failure-related hospitalization costs will be close to $15 billion[8]. In 2006, the Heart Failure related total costs were estimated to be 29.6 billion [13]. The expenses related to Heart Failure were estimated to reach $33.2 billion in 2007 [12]. As clearly seen, these costs have an increasing trend over time and are estimated to continue to rise.

Risk factors and prevention

Heart Failure is a final pathway of many cardiovascular disorders [8, 14]. The main risk factors are Coronary Artery Disease (CAD) and hypertension [8].

Since Congestive Heart Failure is a non-curable disease, the emphasis must put on the prevention. In general, prevention of CHF includes prevention of the main risk factors (CAD and hypertension), diabetes and ischemic heart diseases [8]. Folsom et al. showed in their study that having at least one of the four risk factors (blood pressure, plasma cholesterol, diabetes, and smoking) accounted for 77.1% of all heart failure events seen. Therefore, it is important for clinicians to promote the maintenance of a life which avoids the development of these risk factors [10].

Treatment of Congestive Heart Failure

CHF is a chronic disease that imposes on the patient to adhere to therapeutic treatment for the remainder of life [15]. In the recent decades, promising new therapies have been developed. In general, treatment options are aimed to improve symptoms, help

the heart to pump and in overall, improve the quality of life. These options include drugs, surgery and medical devices.

Medications developed to treat Heart Failure have the ability to help the patient function more effectively and attempt to maintain their normal daily living. Therefore, adherence and compliance to medication can lead to better health outcomes for many CHF patients. Wu et al. in their study found that Heart Failure patients whose adherence to medication is less than 88%, had a Hazard Ratio (HR) to first event (ED visit for HF exacerbation, cardiac hospital readmission, or all-cause mortality) of 2.2 by dose count (p=0.021) and 3.2 by dose-day (p=0.002) [16]. Also, they showed that about one half to two thirds of Heart Failure related hospitalizations could be prevented by better adherence medication regiment.

Surgery treatment is administered to patients who are candidates for heart transplantation. However, there is an issue with of the limited availability of the donor hearts [12] and many patients die while waiting for a heart. In this perspective, new therapies that attempt to try repair the heart such as stem cells for the heart, also known as cardiac cell therapy, have been developed and are being researched for their effectiveness.

Many medical devices have developed and are being used to assist the heart to be more effective and supply the body with enough blood for functioning. They have been proven to decrease the risk of Heart Failure related events [17] such as hospitalizations, hospital readmissions and all cause mortality [14].

Exercise training has been associated with improved outcomes in CHF patients. Although, rest was routinely the golden rule for Heart Failure patients, many recent studies have shown that physical training is linked to improved survival and decreased hospitalizations and that the absence of exercise may lead to worsening of the symptoms [14].

Despite all these existing treatment options, the primary emphasis remains to be disease management. Patients diagnosed with CHF have to follow a healthy lifestyle that mostly comprises of reducing salt intake, eating more fruits and vegetables, exercising regularly, reducing their weight, quitting smoking and more steps that are tailored to the individual patient [8]. They have to self monitor themselves through frequent weigh measurement and comply with medication (on time and with the right dose). Disease Management is a strategy by which the patients may be assisted in these everyday Heart Failure-related routines.

Nurse-Administered Disease Management of Congestive Heart Failure

Nurse-Administered strategies were developed to provide Congestive Heart Failure patients with a nurse, who will help with daily self-monitoring, make a connection between the patient and the primary care provider, promote compliance to medication and sometimes provide additional disease management education to the patient. In these programs, nurses can assist the patient in various ways: they can do regular visitations; they can communicate with patients by telephone [18] and even by more advanced technologies where the patient contacts the nurse through a screen connected to the nurse center 24/7.

There have been several controlled clinical trials conducted to examine the effectiveness of the Nurse-Administered disease management in different settings.

In most of the trials, patients were assigned to different arms where the control arm would receive the usual care without any enhancement and the treatment arm would be appointed a nurse to supplement their usual care.

In a considerable randomized clinical trial the treatment group was assigned scheduled telephone calls and/or home visits by trained nurses; Dunagan et al. found that this management program, in a population selected from Barnes Jewish Hospital, St Louis, MO; delayed hospitalizations, hospital readmissions and Heart Failure-specific readmission in patients in the treatment group compared to the control. The Hazard Ratio (HR) and the 95% confidence interval (CI) for the three health care outcomes were HR=0.67 95% CI = (0.47, 0.96) and p-value=.045, HR= 0.67 95% CI= (0.46, 0.99) and p-value=.045; and a HR=0.62 95% CI = (0.38, 1.03) and p-value=.063, respectively [18]. Smith et al. showed that, in community-dwelling patients 18 and older in South Texas, on the treatment arm, this intervention has a positive effect (improvement) on self-reported health at 6 months (p-value=.04) and 12 months (p-value=.004) [19]. Both these studies reported a positive impact of the nurse enhance strategy on the management of Heart Failure. Sisk et al., in a minority community of Harlem, NY; found that at 12 months, compared to the control arm, the patients in the intervention arm had fewer hospitalizations (adjusted difference, -13 hospitalizations/person year; 95% Confidence interval, (-0.25, -0.001) and better functioning [20].

However, not all clinical trials coincided with these findings. Weinberger et al., in patients hospitalized with diagnosis of Congestive Heart Failure in nine Veterans Affairs medical centers, concluded a contrary result in his research. In his study, not only did this strategy not improve self-reported health status but it also increased the number of hospitalizations. At the six months follow-up, patients in the treatment group were hospitalized on average 1.5 ± 2.0 when the patient in the same trial as Weinberger et al., resulted in this line. The patients in the treatment group, compared to the control group, had higher rates of hospital readmissions (0.19 vs.0.14 per month, p-value=0.005), longer hospital length of stay (10.2 vs. 8.8, p-value=0.041); although the quality of life scores did not differ (p-value=0.53) [21].

Some researchers could not conclude that the strategy has any impact on the outcomes. DeBusk et al. [22], in five northern California hospitals, found similar rate of hospitalization (Proportional hazard= 0.85, 95% confidence interval = (0.45, 1.57)) as well as similar rate of hospital readmission in both groups (Proportional hazard= 0.98, 95% confidence interval = (0.76, 1.27)). Also, Laramee et al., in a more heterogeneous setting, found that the 90-day readmissions rates were the same in both groups (37%) [23].

Different types of settings of clinical trials have been conducted. Feldman et al. conducted a clinical trial in which instead of assigning patients the two arms, nurses were randomly assigned to control or to treatment groups. Nurses were supplied information of different degree. Patients were then assigned to these nurses (not randomly though). There was also the usual care group: patients with no nurse. The study concluded that both intervention groups had better mean KCCQ (Kansas City Cardiomyopathy

Questionnaire) score (15.3 and 12.9% respectively) compared to usual care (p-value ≤ 0.05). Riegel et al. conducted a different type of trial where the primary physicians were the ones to be randomly assigned to intervention or control. Then, patients were assigned to physicians (in a non random manner). This research found that at 3 months, Heart Failure-related hospitalizations in the intervention group were lowered 45.7%. At 6 months, the Heart Failure-related hospitalizations were lowered 47.8%, Heart Failure days were lowered (p-value=.03) as well as multiple readmissions (p-value=.01).

CHAPTER III

METHODS

Overview

Individuals with CHF are subject to continuous management once they receive a diagnosis of CHF. The treatment therapies available are to control the symptoms, reduce the negative effects encountered and in general help the patient live as normal a life as possible. These treatments comprise of medications and regular surveillance by a physician thru routinely scheduled appointments. Primarily, CHF patients have to adhere to healthier lifestyles and monitor themselves daily for any change, especially weight change; since a weight gain may indicate water retention which is associated with a deterioration of their CHF disease. This type of monitoring is the usual care for CHF patients and was represented by the 'Standard care' arm in this analysis. Recently, there have been proposed new strategies for managing CHF patients, which introduce a link between the patients and their physician during the time between their routinely scheduled appointments. It is hypothesized that this link will help the patients in their daily routine of self check up and medication compliance, and will help the doctor to detect early signs of sickness aggravation/progression. The first form of connection was to provide a nurse who would regularly interact with the patient and report to the supervision of the patient's doctor. This was represented by the 'Case Management' in the current study. The other type of connection, relatively new with respect to the nurse

management is the use of a 'smart box' which replaces the nurse and hence, reduces the expenditures related to a nurse's services. This was defined as the 'Self Management' arm in this analysis.

The goal of this thesis was to identify the most optimal management strategy in which to manage patients suffering from CHF. To realize this goal, initially differences between the three groups discussed above (self-management, case management, and current standard of care) were tested using traditional ANOVA and logistic regression techniques. Then differences in the time until a patient's first hospitalization were investigated using survival analysis techniques. In addition, a cost effectiveness analysis was performed to evaluate the incremental cost effectiveness of the smart-box self monitoring (Self Management) and the tele-monitoring with a nurse-staffed call center (Case Management), when compared to the current standard of care. Data and information used were collected from a randomized clinical trial, funded by the Agency of Healthcare Research and Quality (AHRQ), which aimed to evaluate the medical soundness of self management and case management in terms of decreasing emergency department visits and inpatient hospital readmissions for CHF patients. The trial used a prospective, experimental design and followed individuals for 12 months.

The database developed subsequent to the clinical trial was stored as an ACCESS file and exported to SAS for data management and statistical analysis. Data in the final database included demographics and traditional risk factors, emergency department and hospital visits, medications, and type of Congestive Heart Failure. A more detailed description of these data is given below. Only patients with CHF were recruited and enrolled in the study. The trial was conducted as a multicenter clinical trial with the

following contributing sites enrolling patients: Billings, MT; Philadelphia, PA; Louisville, KY; Indianapolis, IN; Lancaster, and New York, NY. The data were de-identified. That is, each patient was assigned a unique, random study identification number. As a result, the analyst was blinded to patient identification. An independent data and safety monitoring board monitored the trial for abnormal rates of adverse events and whether the trail could be terminated early. The trial received approval from all contributing sites Institutional Review Boards (IRBs) to ensure patient safety. Informed consent was obtained for all participants enrolled in the study prior to participation in the study and collection of data.

Database Description

The original data sets were developed as a result of the multicenter randomized clinical trial discussed above. The study enrolled a total number of 134 people. During the trial each patient was randomly assigned to one of three arms: Standard Care, Case Management and Self Management. All the participating physicians were given the AHA/ACC guidelines of CHF.

In *the Standard Care arm*, patients received the recommended standard of care, which included regularly scheduled appointments with their Primary Care Provider (PCP). The PCP was the patient's usual physician who was not restricted to be a cardiologist. In addition, patients receiving the standard of care monitored themselves through a defined protocol (e.g., daily weight measurement, routine blood pressure and pulse assessment) and if these measurements were abnormal they were advised to schedule an appointment with their PCP or visit an emergency department if warranted.

In the *Case Management arm*, in addition to their regularly scheduled appointments with their PCP, their routine self monitoring was enhanced by a special scale that was connected directly to a nurse staffed call center with trained nurses through the internet. After measuring the weight, the scale was programmed to ask the patients a list of questions tailored to their condition. At, the nurse staffed center, the weight and the responses were compared to a set of normal parameters defined by the physician for the patient. If there was a significant change in the weight or an alert from the responses, the nurse notified their PCP and a decision for the patient to schedule an appointment or to go the hospital was made by the PCP or the nurse advised the patient to go to an Emergency Department.

In the *Self Management arm*, the patients were given a scale and a automate smart-box to use for self-monitoring of their measurements (weight and specific CHF parameters). The scale recorded the weight and the responses and compared them to the in-programmed normal ranges. If the physician needed to be notified an automated message was sent to the physician's office. If the patient needed to go to an Emergency Department, the patient received an alert to seek treatment at the nearest Emergency Department.

Data was collected on each patient for a total period of 12 months follow-up. The first nine months were considered to be the active clinical study period and the last three months were considered a wash out period.

The complete merged data set available for analysis comprised of 15 subsets of data. However, for the current analysis, four subsets of data were considered: the

Hospitalization set [admission dates, length of stay in hospital, physical measurements while in the hospital], the Heart Failure history set [study ID number, NYHA class type, type of insurance, CHF related diseases and co-morbidities], the Patient Identifiers set [date of birth, demographics, clinical trial related information such as date the Inform Consent was signed, the date of enrollment in the study, study arm], and the Visits set [date of visit, reason of visit, whether the visit is a routine or not, physical measurements at the time of visit]. The unique subject ID for each patient was consistent across each subset of data allowing for easy merging of the subsets of data. The final database used for all analysis, described below, was comprised of these four data sets.

Descriptive Statistical Analysis

To evaluate the distribution of the outcome variables, continuous variables were summarized as means and standard deviations, while categorical data were summarized as frequencies. Continuous variables analyzed included age and BMI. Categorical variables included study arm, age group, race, gender, marital status, living situation (i.e. alone, not alone), education level, whether the patient was obese, had hypertension, diabetes type I or type II, hypercholesterolemia, hyperlipidemia, medication type (ACE [Angiotensin-converting enzyme] inhibitors, Beta Blocker, β1-Adrenoreceptor (AR) Blocker, ACE inhibitor or AR Blocker), type of CHF (systolic or diastolic CHF, the NYHA class, whether the patient is NYHA class III or IV, smoking status (current smoker, not a current smoker), whether the individual was loss to follow up and mortality.

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Software: Both the descriptive analysis as well as the inferential analyses were performed in SAS (Statistical Analysis Software) version 9.2.

Inferential statistical analysis

ANOVA and Logistic regression analysis

Comparisons of means across the study arms were performed using ANOVA techniques and comparisons of proportions were performed using logistic regression. One-way ANOVA was used to simultaneously compare the three group means from the independent samples from each study arm. This method assumes that the samples are independent and have equal variances. For this reason, tests to validate these assumptions were carried out with the Kernel Density estimation graphs.

Logistic regression models were developed to simultaneously compare the three group proportions and effect from the independent samples from each study arm.

Variables: For the inferential statistical analysis, the following outcome variables were considered: *1) In-hospital days, 2) Hospital free days, 3) Length of stay, 4) Number of hospitalizations, and 5) Whether a patient was hospitalized at least once or not and.*

In hospital days: Concurrent with the clinical trial, details about an individual's hospital length of stay were recorded. As such, the total number of days each patient spent at the hospital during the 365 days of the trail was summed.

Hospital free days: Hospital free days were computed by taking the difference of the number of days a patient spent in the study and subtracting the number of days they were in the hospital.

Length of stay: The length of stay was computed as the difference of the discharge date and the admission date at the each visit. The average length of stay was used as the analysis variable.

Number of hospitalizations: The actual numbers of times each patient was hospitalized or went to the ER were counted using admissions data.

Whether a patient was hospitalized at least once or not: This variable was defined to take the value 1 if a patient had been hospitalized at least once and 0 if the patient had not been hospitalized during the 365 days of study.

Study arm: The study arm had three values. It was 1 if the patient was randomized in the 'Standard care" arm, 2 if the patient was randomized to the 'Case management' arm and 3 if the patient was randomized to 'Self management' arm.

The adjusted variables: Since there was a considerable amount of data missing due to loss of follow up, for the first three variables we created adjusted variables (adjusted in hospital days adjusted hospital free days and adjusted number of times hospitalized). That is, we let X represent the outcome of interest, the corresponding adjusted variable was computed the following way: Adjusted X = X * (365/ in study days), where 365 represented the total length of the study and in study days represented the total number of days a patient actually stayed in the study. Here, an exit to the study before the end (365 days) was either death or considered to be a loss to follow up.

Survival analysis

Survival analysis techniques were used to determine and compare the group effect in delaying the timing until the first hospitalization. The Kaplan Meier curves were graphed to evaluate the any presence of differences across arms in delaying the first hospitalization, while the Log rank test was performed to formally test for differences. Then, Cox regression analysis was used to test the differences and measure the arm effect on time delay to first hospitalization.

The event of interest: The event of interest in this analysis was the first hospitalization or ER visit (an ER visit was considered to be a one day hospitalization). If a patient had been hospitalized at least once, then the first admission to the hospital established the time the event of interest occurred. If a patient had not been hospitalized then he/she was considered right censored either due to loss to follow up, to death or the end of the study.

The variables- time and censoring : The time was measured as: (1) the number of days between enrollment day and the first hospitalization if the patient had been hospitalized at least once in the study, (2) if the patient had not been hospitalized and was lost to follow up, then the time was the difference in days of the lost-to-follow-up date and the enrollment date, and (3) if a patient had not been hospitalized and was in the study until the last day, the time was the total number of days patients were followed in the clinical trial.

The censoring variable was represented by delta (1 or 0); delta = 1 if the person had experienced the event and 0 if not. Thus, if a person had been hospitalized at least once, delta=1. If the patient had not been hospitalized, then delta=0.

Software: For the survival analysis, the SAS package version 9.2 was used.

Research questions and methods

The research questions and the methods are summarized used in this study are summarized in the table below.

Table 3.1: Research questions and methods

Research question	Outcome	Independent variable	Statistical analysis
Do the hospital free days differ in the 3 study arms?	Number of hospital free days	Study arm	ANOVA
Do the hospital free days differ in the 3 study arms considering the number of days in the study?	Adjusted number of hospital free days	Study arm	ANOVA
Does the in hospital days differ in the 3 study arms?	Number of in-hospital days	Study arm	ANOVA
Does the in hospital days differ in the 3 study arms considering the number of days in the study?	Adjusted number of in-hospital days	Study arm	ANOVA
Does the average length of stay differ in the 3 study?	Average length of stay during hospitalization	Study arm	ANOVA
Does the number of times hospitalized differ in the 3 study arms?	Number of times hospitalized	Study arm	ANOVA
Does the number of times hospitalized differ in the 3 study arms considering the number of days in the study?	Adjusted number of times hospitalized	Study arm	ANOVA
Does the study arm have an effect on the hospitalization usage?	Whether a patient was hospitalized at least once or not	Study arm	Logistic regression
Are the hazards of being hospitalized the same in the 3 study arms?	Time delay before first hospitalization		Life test and Kaplan Meier
Does Case Management or Self Management have a different effect than Standard Care?	Time delay before first hospitalization	Study arm	Cox (Proportional Hazards) Regression
Is any management system other than Standard Care has a different effect?	Time delay before first hospitalization	Study arm	Cox Regression

CHAPTER IV

RESULTS

Overview

Congestive Heart Failure is a medical condition characterized by the inability of the heart to pump enough blood to the rest of the body. Most of its forms are not curable and when patients are diagnosed with an incurable form of CHF, they are must combat the disease for the remainder of their life. Available treatments can help these patients cope with their conditions and live fulfilling lives. These treatments comprise drug therapies, lifestyle changes, daily weight traction and regular monitoring by a doctor.

The doctor's monitoring and the patient self observation are what define the management strategy for following the patient. The traditional management method consists of the patients watching themselves on a daily basis and meeting with their physician every three to six months. This is the 'Standard or Usual Care'. In the perspective to assist the patients in their daily self monitoring and aid the doctors thus providing more effective help to the patients, two relatively new methods have been suggested: 'Case Management' and "Self Management'. In the current study, in the 'Case Management' strategy, the patient was given a scale which helped them tract their weight and other important tailored CHF parameters. This scale was connected to a nurse staffed center via a modem connected to the internet through the phone. The center

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monitored these values and compared them, daily, to a set of normal parameters ranges defined by the principal physician. In case of a significant change, these nurses informed the physician for an action or, if necessary, sent the patient to the emergency department. In the 'Self Management' system, the patient was also given a scale which, just like in the 'Case Management' case, helped the patients in the daily self follow up. However here, the patient was given a 'smart box', connected to the physician' office, which performed the tasks of the nurse center in the 'Case Management'. If there was a significant change, it was the automated machine that sent an alert to the physician's office to take action or told the patient to seek medical help to the nearest emergency department.

Therefore, this study aimed to compare these three managements considering their cost as well as the benefits to the patients. Particularly, the focus was on evaluating the feasibility of using Case Management and/or Self Management when compared to the current standard of care. The main objective was to determine the optimal choice of follow-up management, for CHF patients, that would benefit the patients without having a high financial impact.

Description of the sample data

Data used in this study are from a multi-center clinical trial that enrolled a total of 134 participants. These patients were randomized to three arms: 28 patients (21%) were assigned to the 'Standard Care' (SC) arm, 56 patients (42%) were assigned to the 'Case Management' (CM) arm and 50 participants (31%) were assigned to the 'Self Management' (SM) arm (see Table 4.1).

The mean age in the clinical trial was 66 with a standard deviation of 13. About 54% of the participants were above 65 years old. Most of the participants were female (59%) and a majority were white (78%). Thirteen percent (13%) of patients were current smokers, 32% were smokers in the past but had quit at the time of enrollment and 34% had never smoked. Marital status was taken at the enrollment: 70 enrollees were married (52%), 31 were divorced (23%) and 33 were widowed (25%). Among all participants 48 lived alone (36%). The education level was available for sixty seven participants (50%), of whom 36 attended and/or graduated from high school (27%) and 29 attended and/or graduated from college (22%). Patients had different types and characteristics of CHF, 56% had Systolic Heart Failure (SHF), 53% had Diastolic Heart Failure (DHF) and the majority of them (51%) had a depressed left ventricular function with a left ventricular ejection fraction (LVEF) less or equal to 35%. The patients were stratified into class II, III and IV (43% were class II, 46% were class III and 11% were class IV). Additionally, class was divided into two class factors (class II versus class III or IV). The CHF related medications taken by patients while on the study were available for all participants: 114 patients were on Beta blockers (85%), 77 were on ACE inhibitors (57%) and 47 were on AR Blockers (35%). The important co-morbidities of CHF were recorded at the beginning of the study. The average BMI (Body Mass Index) for the patients enrolled in the study is 30 with a standard deviation of 11. About half of the patients were obese (51%). For the patients for whom the hypertension status was documented, 108 had hypertension (81%). Diabetes I was present in only 6% of the patients while Diabetes II was present in 38% of the patients. Among the patients for whom the

hypercholesterolemia status was available, 37 had high cholesterol (28%). The

hyperlipidemia status was also taken: 49 patients were positive (38%) (See Table 4.1)

During the 12 month study, about 17% of the patients enrolled were lost to follow

up and 2% died (see Table 4.1).

Table 4.1: Characteristics of the data

Type	Variable	SC (28) N (%)	CM (56) N (%)	SM (50) N (%)	Total (134) N (%)
Demographics	Mean Age (SD)	68 (14)	65 (13)	67 (13)	66 (13)
	Age $\geq$ 65	20 (71)	23 (41)	30 (60)	73 (54)
	Gender				
	Male	10 (36)	22 (39)	23 (46)	55 (41)
	Ethnicity				
	White	24 (86)	41 (73)	40 (80)	105 (78)
	Black	3 (11)	13 (23)	6 (12)	22 (16)
	Hispanic	0 (0)	0 (0)	2 (4)	2 (1)
	Marital Status				
	Married	17 (61)	30 (54)	23 (46)	70 (52)
	Divorced	4 (14)	13 (23)	14 (28)	31 (23)
	Widowed	7 (25)	13 (23)	13 (26)	33 (25)
	Lives alone	9 (32)	20 (36)	19 (38)	48 (36)
	Education level				
	High School	6 (21)	18 (32)	12 (24)	36 (27)
	College	9 (32)	8 (18)	12 (24)	29 (22)
	Smoker				
	Current	4 (14)	5 (9)	9 (18)	18 (13)
	Quit	6 (21)	22 (39)	15 (30)	43 (32)
	Never	13 (46)	18 (32)	14 (28)	45 (34)
CHF types And characteristics	Systolic	13 (54)	35 (63)	27 (54)	75 (56)
	Diastolic	20 (71)	26 (54)	25 (50)	71 (53)
	LVEF $\leq$ 35%	14 (46)	36 (64)	20 (40)	69 (51)
	NYHA class				
	Class II	16 (56)	24 (43)	17 (34)	57 (43)
	Class III	10 (36)	26 (46)	25 (50)	61 (46)
	Class IV	2 (7)	5 (9)	8 (16)	15 (11)
	NYHA class				
	Class III or IV	12 (43)	31 (55)	33 (66)	76 (57)
CHF medications taken	ACE inhibitors	17 (61)	36 (64)	24 (48)	77 (57)
	Beta-blockers	22 (79)	50 (89)	42 (84)	114 (85)
	AR Blocker	7 (25)	18 (32)	22 (44)	47 (35)
	ACE or ARB	23 (82)	49 (88)	43 (86)	115 (86)

Type	Variable	SC (28) N (%)	CM (56) N (%)	SM (50) N (%)	Total (134) N (%)
CHF co-morbidities	Mean BMI (SD)	32 (14)	31 (11)	29 (8)	30 (11)
	Obese (BMI≥30)	18 (64)	30 (54)	20 (40)	68 (51)
	Hypertension	26 (93)	45 (80)	37 (74)	108 (81)
	Diabetes I	1 (4)	6 (11)	1 (2)	8 (6)
	Diabetes II	11 (39)	21 (38)	19 (38)	51 (38)
	Hypercholesterol	9 (32)	21 (38)	19 (38)	49 (37)
	Hyperlipidemia	12 (43)	16 (29)	12 (24)	37 (28)
Loss to follow up		3 (11)	12 (22)	8 (16)	23 (17)
Death		0 (0)	2 (4)	1 (2)	3 (2)

Descriptive statistics: Distribution of the outcome variables of interest

CHF is mostly characterized by the frequent hospitalization of the patients. The treatments and the management strategies used have one important objective, to reduce and prevent these hospitalizations. In this study, the three study groups were compared in hospital free days, total number of in-hospital days during the study period, average length of stay per hospitalization, number of hospitalizations and having been hospitalized at least once, and time until first hospitalization. Since some patients died or were lost to follow up, all the patients do not have the same length in the study. Thus, in order to put the outcome variable on a comparative level, for each patient, the adjusted variables corresponding to the response variables were calculated and were also used for a comparison of the three arms.

Throughout the trial, the 'Standard Care' arm was represented with better outcomes for all variables (see table 4.2). For example, 24 patients (86%) in this arm had more than 300 hospital free days compared to 42 (75%) in 'Case Management' and 40 (80%) in 'Self Management'. This finding remained consistent even when using the adjusted variables. Half of the participants assigned to the 'Standard Care' arm were not

hospitalized at all during the study and only 4% spent more than 30 days in the hospital in total. In the 'Case Management' arm, about 5% of the patients spent more than 30 days in the hospital and the percentage of people in this category from the 'Self Management' arm was 6%. After adjusting the in-hospital stay variable to consider the loss to follow-up and the death, the percentages changed slightly. The in-hospital stay of more than 30 days was about 7% for the 'Standard Care' arm, 7% for the 'Case Management' arm and 8% for the 'Self Management' arm. At each hospitalization, 39% of the participants in the 'Standard Care' arm stayed for zero to five days on average while only 32% of each of the other management strategies stayed this long. Only in the 'Case Management' arm, patients were hospitalized more than five times. In the 'Self Management' group, 24% were hospitalized between once and five times compared to only 7% in 'Standard Care' arm. After adjusting for this variable, no patient from the 'Self Management' arm was found to be hospitalized more than five times while about 4% of the patients in the 'Standard care' arm and 9% of the patients in the 'Self Management' arm were found in this category.

Overall, 67% of the participants were hospitalized at least once in the 12 month study. Stratified by study arms, the percentages of the patients who were hospitalized at least once were as follow: 57% in the 'Standard Care', 61% in the 'Case Management' and 80% in the 'Self Management' arm. (See table 4.2).

In this study, the three arms were also compared considering the cost and the effect of the management strategies. The fixed and the variable costs as well as effectiveness were used to evaluate the most cost effective follow up method. The clinical trial study did not collect data on the cost, thus, a third party data set and expert

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collaboration were used to estimate the needed costs for analysis. The fixed costs comprised the estimated total expenditure to the physician visits, the nurse training in the 'Case Management' arm' and the 'smart box' in the 'Self management' arm. The variable costs included home medications, one night hospital stay and nurse daily pay. The effectiveness in this study was considered to be the number of hospital free days. Since this variable may be biased by the loss to follow up and death, the effectiveness was counted as the adjusted number of hospital free days. The fixed effectiveness was obtained by taking the mean of the variable adjusted hospital free days. In the analysis, it was considered that a day at home would be valued a one incremental unit. If the patient spent a day at the hospital, then the effectiveness was '-1' (which means one hospital free day lost). Death had an incremental value of zero (see table 4.3).

Table 4.2: Distribution of the response variables

Outcome variable	Levels	SC (N=28)	CM (N=56)	SM (N=50)	p-value	Total (N=134)
Number of hospital free days	[1,200]	3 (11)	12 (21)	6 (12)		21 (16)
	[201,300]	1 (4)	2 (4)	4 (8)	0.4765	7 (5)
	>300	24 (86)	42 (75)	40 (80)		106 (79)
Adjusted hospital free days	[201,300]	1 (4)	2 (4)	3 (6)	0.8057	6 (4)
	>300	27 (96)	54 (96)	47 (94)		128 (96)
In-hospital days	[1,10]	11 (39)	17 (30)	22 (44)		50 (37)
	[11, 30]	2 (7)	8 (14)	1 (2)	0.4638	11 (8)
	>30	1 (4)	3 (5)	2 (6)		7 (5)
Adjusted in-hospital days	[1, 10]	11 (39)	15 (27)	21 (42)		47 (35)
	(10,30]	1 (4)	9 (16)	1 (2)	0.3774	11 (8)
	>30	2 (7)	4 (7)	4 (8)		10 (7)
Average length of stay	[1, 5]	11 (39)	18 (32)	17 (32)		46 (34)
	(5,10]	2 (7)	6 (11)	6 (12)	0.9939	14 (10)
	>10	1 (4)	4 (7)	3 (6)		8 (5)
Number of hospitalizations	[1, 5]	2 (7)	3 (5)	2 (4)	0.1861	7 (5)
	>5	0 (0)	3 (5)	0 (0)		3 (2)
Adjusted number of hospitalizations	[1,5]	1 (4)	5 (9)	7 (14)	0.0724	13 (10)
	>5	1 (4)	5 (9)	0 (0)		6 (4)
Hospitalized at least once	No	12 (43)	22 (39)	10 (20)	0.0482*	44 (33)
	Yes	16 (57)	34 (61)	40 (80)		90 (67)

In summary, the variable hospital free days was skewed to the left (see figure 4.1) which represents the fact that a majority had many hospital free days. After adjusting this variable, it became normally distributed (see figure 4.2). The variable in-hospital days (figure 4.3) and its adjusted correspondent (figure 4.4) were skewed to the right. Many patients had few in-hospital days and only few patients had many days in the hospital in total. The average number of days spent at the hospital per hospitalization was skewed to the right. This shows that many people had relatively shorter stays. The number of hospitalizations (figure 4.5) as well as the adjusted number of hospitalizations (figure 4.6) was also skewed to the right. In the trial, only few patients were hospitalized many times.
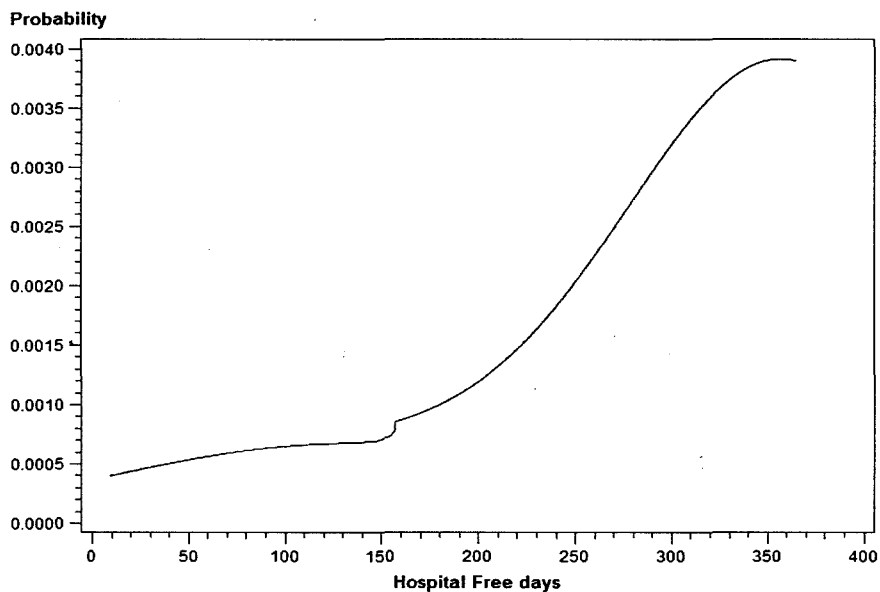
Probability

Figure 4.1: Density distribution of the hospital free days for all the participants
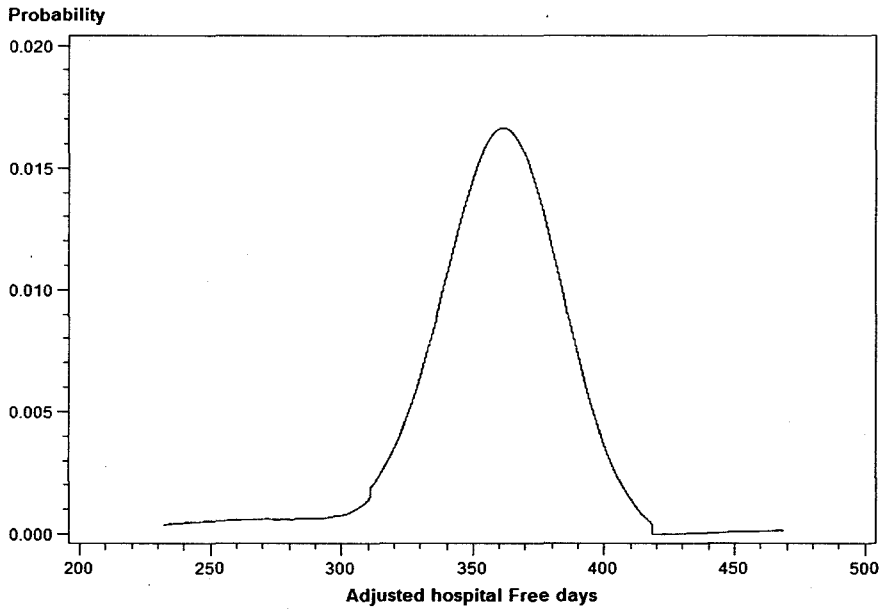
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Figure 4.2: Density distribution of the adjusted hospital free days for all the participants
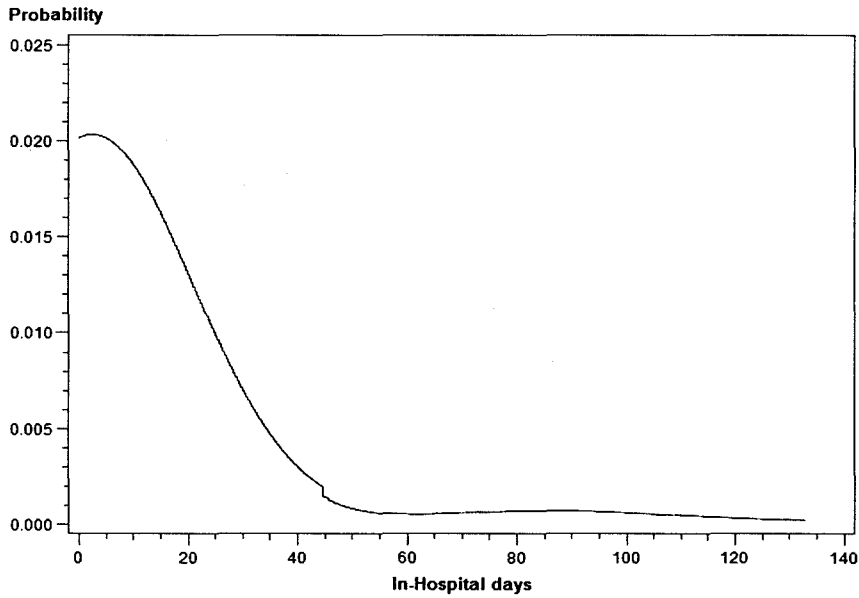
Figure 4.3: Density distribution of the in-hospital days for all the participants

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Figure 4.4: Density distribution of the adjusted in-hospital days for all the participants

Figure 4.5: Density distribution of the average length of hospital stay for all participants

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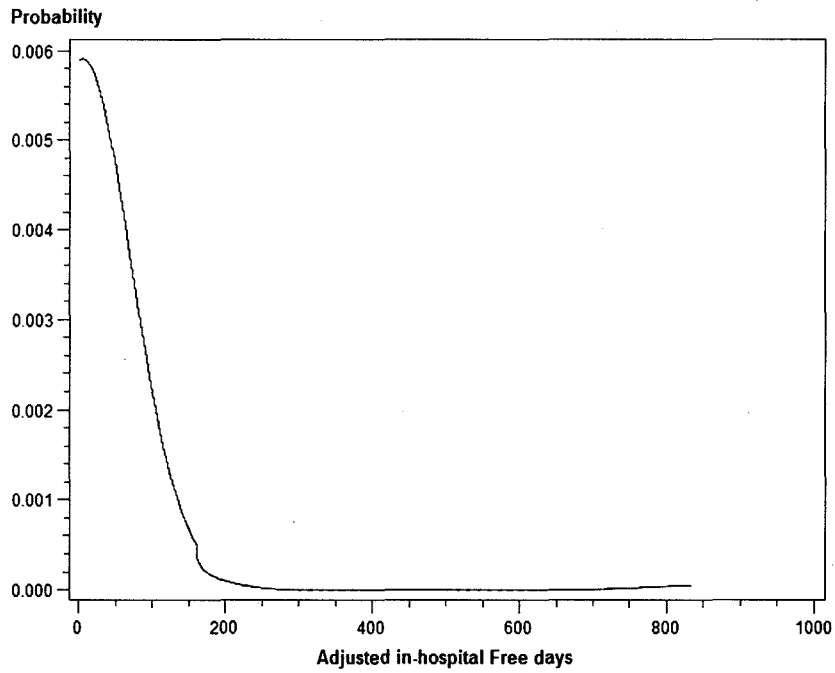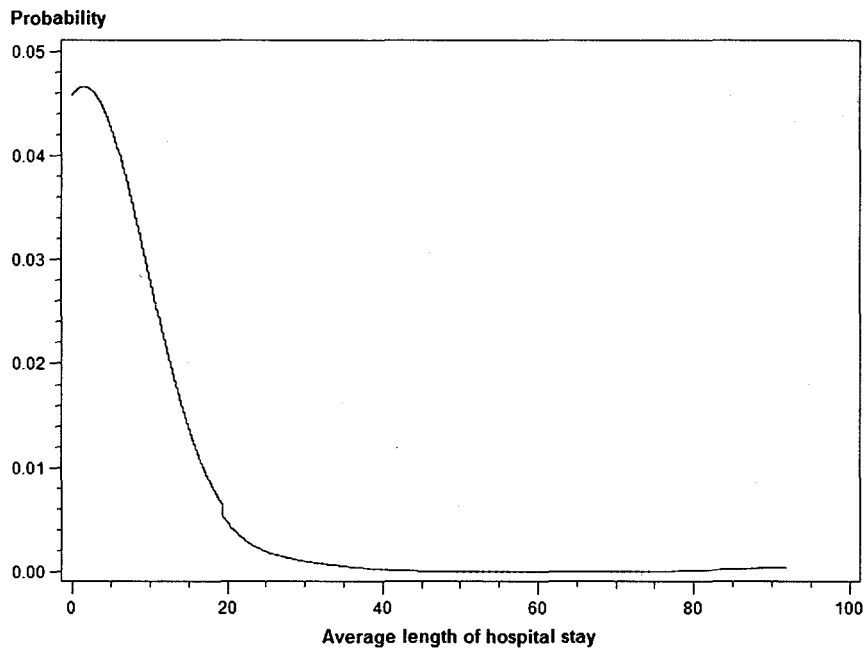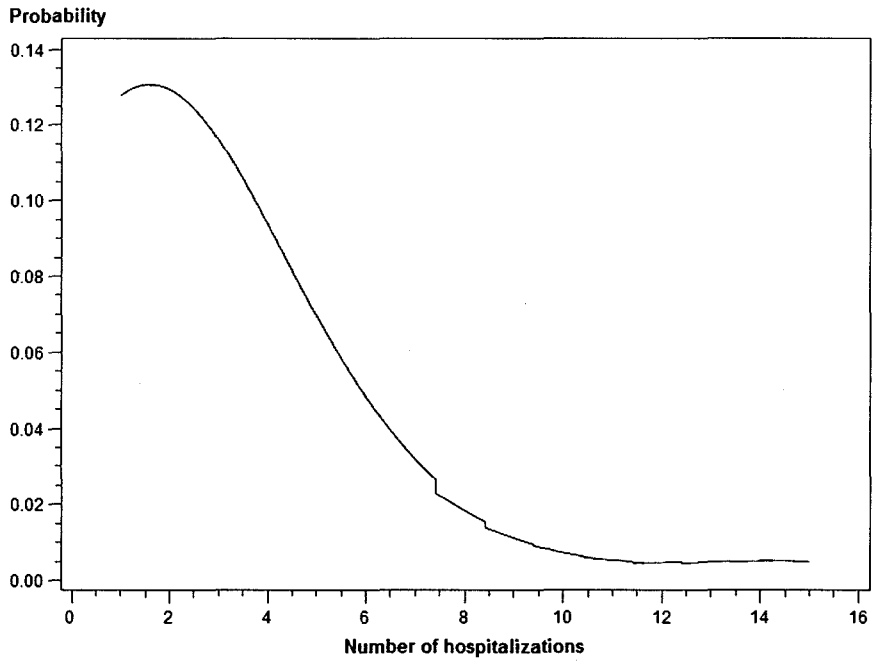**Figure 4.6: Density distribution of the Number of hospitalizations for all participants**
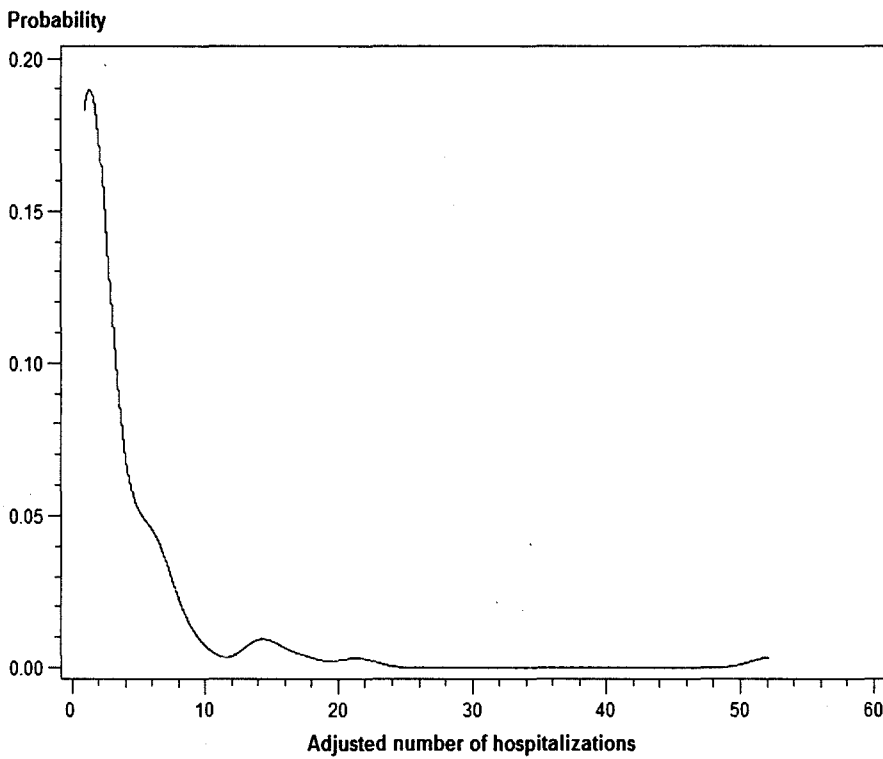

Figure 4.7: Distribution of the adjusted number of hospitalizations for all participants

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Inferential statistics: Comparison of the effects of the three CHF management methods

The main objective of this study was to compare the three management strategies used in monitoring patients diagnosed by incurable versions of CHF. The three management strategies are: the 'Standard Care', the 'Case Management' and the 'Self Management'. These consequences of most interest are hospitalizations, Emergency Department (ED) visits and increased length of stay during a hospitalization. In this analysis, these three management strategies were evaluated bases on hospital free days, total number of in-hospital stays, average length of stay per hospitalization, total number of all- cause hospitalizations, the proportions of the patients who were hospitalized at least once, and the delay to first hospitalization. In addition, cost effectiveness ratios for the two experimental arms, which not only considered the effectiveness as hospital free days but also the cost that implementing them would require was calculated. The hypothesis was that, in terms of outcomes, the 'Case Management' would be superior or at worst similar to the 'Self Management' strategy and that both would be superior to the 'Standard Care'. In terms of cost, the hypothesis was that the 'Standard Care' would be the least expensive, followed by 'Self Management' and that 'Case management would be the most costly. The ultimate goal of this study was to indicate to patients and their physician, as well as any financial responsible party involved, the most cost effective management strategy. The descriptive statistics above suggested some differences in outcomes; however, it was of great necessity to evaluate the statistical significance of these differences.

To compare the hospital free days, the in-hospital days, the average length of stay and the number of hospitalization, the *ANOVA models discussed above* were used. The evaluation of the significance in the proportions of patients hospitalized at least once was performed using the *Logistic Regression above* and the comparison of the time delay to first hospitalization was done by using *Kaplan Meier methods* and *Cox Regression (Proportional Hazard Regression) techniques.* All the statistical tests performed were two sided with a 0.05 significance level. Also, for continuous variables, the means and standard deviations were calculated. For the categorical variables, the counts and the corresponding percentages were presented.

Hospital free days comparisons: The average number of hospital free days was different across study arms. 'Standard Care' had the highest hospital free days (335 ± 72), followed by 'Case management' (298 ± 114) and 'Self Management' had the lowest number of hospital free days (325 ± 86). The average hospital free days seem to suggest that 'Case Management' had the worst outcome. However, the F-test of the three group comparison revealed no statistical difference (p-value=0.1850) (see table 4.4). The pair-wise comparisons of this variables also showed that the differences were not statistically significant (see table 4.5). This result held also for the adjusted hospital free days. Adjusted hospital free days are the regular hospital free days with a weight representing the actual number of days the individual spent into the study. For this variable, the three group difference were not significant (p-value=0.9579, see table 4.4) and the pair-wise comparisons of the study arms were not significant either (see table 4.5).

In-hospital days comparisons: The variable 'in-hospital days' measured the total number of days the patient spent in the hospital during the study period of 12 months. The

'adjusted in-hospital days' are the 'in-hospital days' taking into consideration the loss to follow up and death. The study analysis results yielded 6 ± 17 in-hospital days in average for the 'Standard Care', 9 ± 24 in-hospital days for the 'Case Management' and 7 ± 19 in-hospital days for the 'Self Management'. In this study, a hospitalization was measured as a failure hence, the arm with the least number of in-hospital days, had a better outcome than the other arms. Thus, considering the mean values, the 'Standard Care' had better results, followed by 'Self Management' and the worst results were associated with the 'Case Management' arm. These results suggested a difference in 'in-hospital days', to conclude about its statistical significance, the three groups were first compare simultaneously and the difference was found not statistically significant (p-value=0.7708, see table 4.4). The analysis of the 'adjusted in-hospital days' led to an analogous conclusion. The average number of days was 7 ± 19 days for 'Standard Care', 25 ± 113 days for 'Case Management' and 9 ± 24 days for 'Self Management'. Even though these numbers show some difference, suggesting that 'Case Management' had the worst outcomes, the test of differences showed no statistical significance (p-value=0.4493, see table 4.5). For these two corresponding variables, the pair wise comparisons also showed no significant differences (see table 4.5). Thus, from this study, it cannot be concluded that neither 'Self Management' nor 'Case Management' had different 'in-hospital days' for the CHF.

Length of stay comparisons: The variable 'Length of stay' measured the average number of days the patient stayed at the hospital each hospitalization. The average 'length of stay' was about the same in mean values for 'Standard Care' and 'Case Management': 3 ± 6 and 3 ± 4 respectively. In the 'Self Management' arm, the patients spent an average

of 4 $\pm$ 13 days per hospitalization. These results seemed to suggest that the 'Standard Care' and the 'Case Management' had similar lengths of stays during treatment and 'Self Management' had a different outcome. However, the test of these differences showed no statistical difference (p-value=0.6012, see table 4.4). Again there was not enough evidence from this study to conclude that 'Self Management' or 'Case Management' had a different outcome than 'Standard Care'.

Number of hospitalizations comparisons: On average, a patient in the 'Case Management' arm was hospitalized 2 $\pm$ 3 times while a patient in the 'Standard care' and in 'Self Management' arms stayed at the hospital 1 $\pm$ 2 times. The difference is of about one day. The F test comparing the three groups yielded no statistical difference (p-value=0.4792, see table 4.4). Taking into consideration the loss to follow up and the death, if all patients had stayed into the study ended alive then a patient in the 'Standard Care' arm would have been hospitalized 2 $\pm$ 4, a patient in the 'Case Management' arm would have been hospitalized 3 $\pm$ 8 times and a patient in the 'Self Management' arm would have stayed at the hospital 2 $\pm$ 3 times. The greatest frequency of hospitalization is found in the 'Case Management' arm. However, statistically, the differences were not significant (p-value=0.2644).

Comparison of the proportions of patients hospitalized at least once (Comparison of the risks of hospitalization): The variable considered, in this analysis, measured being hospitalized at least once in the study. The difference in proportions was not statistically significant (p-value=0.6986, see table 4.4). The objective of this part of analysis was to look at the odds of being hospitalization (or the odds of hospitalization) in the 'Case Management' arm or the 'Self Management' arm compared to the 'Standard Care' arm.

The odds of being hospitalized for 'Case Management' versus 'Standard Care' were 1.000 (95% confidence interval = (0.403, 2.483)). The risk of hospitalization was non-significantly was about the same in the 'Standard Care' arm and in the 'Case management'. The odds ratio estimate for being hospitalized for 'Self Management' versus 'Standard Care' were 0.738 (95% confidence interval = (0.292, 1.867)). The Self Management strategy reduced the risk of hospitalization for about 30%, but was not significant. The odds ratio estimate for being hospitalized for 'Case Management' versus 'Self Management' were 1.355 (95% confidence interval = (0.63, 2.911)). The 'Case Management' method increased the risk of hospitalization by a little bit over 30% (see table 4.5), but not significantly.

Comparison of the times to first hospitalization: A better 'time delay' strategy would mean a better outcome in terms of risk of hospitalization. The Kaplan Meier curve (Figure 4.7) showed a difference in time delay in the three management systems during the study illustrating the 'Standard Care' to have a longer delay. On average, the time delay to first hospitalization was of 139 ± 118 in the 'Standard Care' patients, 98 ± 100 in the 'Case Management' group and about 139 ± 104 in the 'Self Management' group. However, the log-rank testing equality over group revealed that the three arms did not have statistically significant different time delays to first hospitalization (p-value=0.4343, see table 4.4). Further analysis consisted of evaluating the hazards of hospitalizations in pair-wise comparisons. The hazard ratio estimate of 'Case Management' compared to 'Standard Care' was of 1.462 (95% confidence interval = (0.813, 2.631)) and the hazard ratio estimate of 'Self Management' in comparison to the 'Standard Care' was of 1.427 (95% confidence interval = (0.686, 2.266)). This showed that the patients in the 'Case

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Management' or in the 'Self Management' groups had a non-significant 40% chance

increase of being hospitalized earlier, than their peers in the 'Standard Care' group. The

hazard ratio of 'Case Management' versus 'Self Management' was found to be 1.173

(95% confidence interval = (0.733, 1.877)) which showed that the risk of an earlier

hospitalization was about 17% higher in the 'Case Management arm than in the 'Self

Management' arm in a non-significant manner (Table 4.5).

Table 4.3: Study arms comparisons

Type of analysis	Outcome variable	Value format	SC (N=28)	CM (n=56)	SM (n=50)	p-value
Group means comparisons	HFD	Mean (std)	335 (72)	298 (114)	325 (86)	0.1850
	A*HFD		358 (19)	357 (28)	356 (24)	0.9579
	IHD		6 (17)	9 (24)	7 (19)	0.7708
	A*IHD		7 (19)	25 (113)	9 (24)	0.4493
	ALOS		3 (6)	3 (4)	4 (13)	0.6012
	H		1 (2)	2 (3)	1 (2)	0.4792
	A*H		2 (4)	3 (8)	2 (3)	0.2644
Group proportions comparisons	Hosp.** at least once	N (%)	16 (57)	34 (61)	40 (80)	0.6986
Time to failure comparisons	Time to 1st hospital encounter	Mean (std)	139 (118)	98 (100)	139 (104)	0.4343

HFD = Hospital Free days, IHD = In-Hospital Days, ALOS = Average Length Of Stay, H=Number of hospitalizations, *A=Adjusted, ** Hosp. = Patients hospitalized at least once

Table 4.4: Post-hocs study arms comparisons

Type of analysis	Outcome variable	Test measure	CM vs. SC	SM vs. SC	CM vs. SM
Group means comparisons	HFD	p-value	0.1	0.6449	0.1608
	A*HFD		0.8678	0.7709	0.8766
	IHD		0.5101	0.8334	0.5969
	A*IHD		0.3090	0.9222	0.2750
	ALOS		0.9857	0.4389	0.3590
	H		0.4140	0.8852	0.2521
	A*H		0.2796	0.8263	0.1216

Type of analysis	Outcome variable	Test measure	CM vs. SC	SM vs. SC	CM vs. SM
Group proportions comparisons	Hosp.** at least once	OR (95% CI)	1.000 (0.40, 2.48)	0.738 (0.29, 1.87)	1.355 (0.63, 2.91)
Time to failure comparisons	Time to 1st hospital encounter	HR (95% CI)	1.462 (0.81, 2.63)	1.247 (0.67, 2.27)	1.173 (0.73, 1.88)

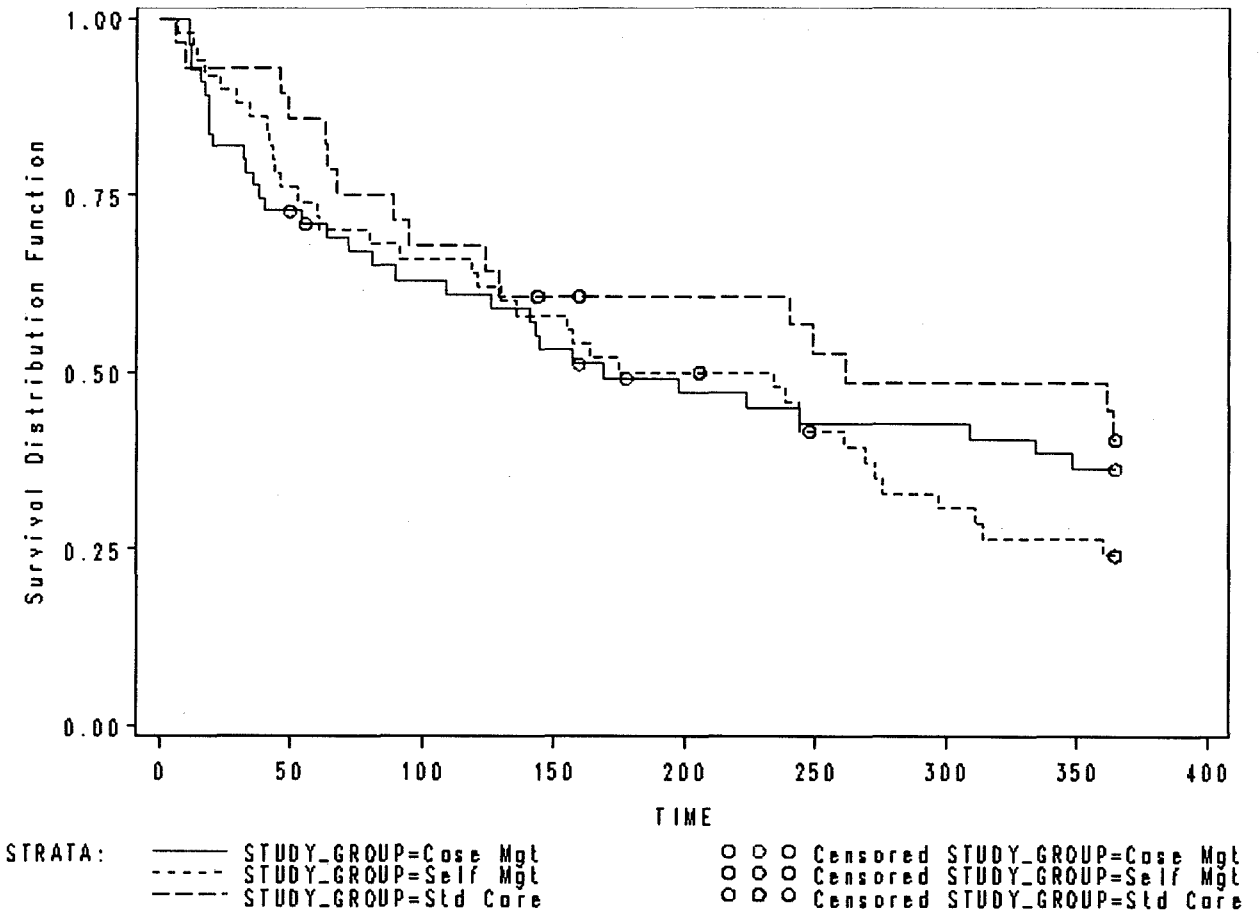OR = Unadjusted Odds Ratio, HR = Unadjusted Hazard Ratio, CI = Confidence Interval

Figure 4.8: Kaplan Meier distribution of the survival time to first hospitalization

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CHAPTER V

DISCUSSION

Overview

In the current study, clinical trial data was used to analyze seven primary outcome measures (traditionally used) to determine whether differences exist between three management strategies 'Standard Care', 'Case Management' and 'Self Management' used in monitoring Congestive Heart Failure (CHF) patients. Traditional statistical analyses were used to test for differences among the three groups of individuals. The seven outcome measures evaluated in the current study were: (1) hospital free days, (2) in hospital days, (3) average length of stay per hospitalization, (4) number of hospitalizations, (5) proportions of patients hospitalized at least once during the study period and (6) time until the first hospitalization. These variables were examined to answer the following research questions:

1) Does the number of hospital free days differ in the three strategies?

2) Does the number of in hospital days differ in the three strategies?

3) Does the average length of hospital stay differ in the three strategies?

4) Does the management strategy have an effect on hospitalization usage?

5) Is the time until the first hospitalization the same in the three strategies?

As a result, primary and secondary research questions were addressed using the in trial clinical data.

Description of findings

In this clinical trial, the 'Case Management' and the 'Self Management' arms had more patients who experienced bad outcomes for almost all outcome variables considered, when compared to the traditional 'Standard Care' arm. Although the 'Case Management' arm did have patients who experienced better outcomes on some variables when compared to the 'Self Management' (see table 4.2). However, differences observed were not found to be statistically significant. Therefore, the results from the current study did not establish if one management strategy had significantly better outcomes when compared to the other two strategies. As result, the current study cannot advocate one management strategy for monitoring CHF patients. That is, the test statistics calculated revealed no significant difference between the arms in terms of hospital free days, in-hospital days, length of stay, number of hospitalizations, risk of hospitalization (proportion of patients hospitalized at least once) and time delay to first hospitalization. The pair-wise comparisons also did not indicate any statistical differences. The results obtained in this study were consistent with published studies in the literature. Previous researchers have found that there were no difference in health outcomes between patients who were followed with the usual care and those who were monitored with special disease managements [22, 23]. In a randomized, controlled clinical trial study comparing the usual care to the enhancement of care with a nurse management, DeBusk et al [22] found that the rate of first re-hospitalization and all cause re-hospitalizations were similar in both study groups. Also, from a clinical trial where participants were randomized to

either a control group or a case management group, Laramee et al [23] reported that the 90-day readmission rates were the same in both groups. The disease management groups (intervention group) in these two reports correspond directly to the 'Case Management' group in the current study. The current study concluded that the 'Case Management' group and the 'Standard Care' group did not significantly differ based on hospital usage (hospital free days, in-hospital days, number of hospitalizations, time to first hospitalization, and length of hospital stay). Therefore, the findings in the current study coincide with those found in DeBusk et al and Laramee et al.

Similar to the published literature, in which there are observed disagreement, the current study's results differ from some published reports. Many results and conclusions studying case management strategies have been controversial and in disagreement. Some analyses have reported a positive effect for some outcomes [19, 20], while being associated with negative effects [21] for others. Smith and colleagues [19] found that the assignment of a registered nurse as a disease manager resulted in improvements in the qualitative outcome self-reported improvement in health at 6-months and 12-months after discharge in a community dwelling population. In agreement with Smith et al, Sisk et al [20] showed that a nurse management improved functioning and lowered hospitalizations in a diversified population in Harlem, NY. In contrast, Weinberger et al [21] demonstrated that in a population of discharged veterans from nine Veterans Affairs Medical Centers, though a close follow up by a nurse increased patient satisfaction, the rate of hospitalization was rather increased.

To this investigator knowledge, the current study is novel in reporting the comparison of the 'smart box' management approach to usual care and to the nurse

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management approach. Therefore, this thesis is pushing knowledge forward and filling a gap in the knowledge base concerning management of CHF patients.

Limitation of the study

The current study did not consider the cost of implementing the 'Self Management' or the 'Case Management' strategies in comparison to the standard of care. A cost effectiveness analysis would provide a complete comparison of the three management methods by providing the incremental cost effectiveness when using either of the newer management strategies in comparison to using the standard strategy. Also, the analysis considered all cause hospital usage; a more sophisticated analysis may wish to adjust the cause of the hospital usage and compare the three methods with respect to these causes.

Implications

CHF is a chronic unfortunate condition that diagnosed patients will have to manage for the rest of their lives. Patients should change their life styles, comply with medications and adhere to daily self -monitoring. To avoid a preventable deterioration of their condition, it is imperative to evaluate all management strategies that can assist them with their disease. It is for this reason the current comparison was performed.

The new management strategies bring an additional interconnection between the physician and the patient to usual care that can be of great importance. With this bridge, the patients are encouraged and acquire effective means to self-follow their daily changes and earlier detection of any significant deterioration in their condition which can be taken

care of earlier. This may result in a decrease in hospital usage and in an overall better health status for CHF patients.

In this study, comparing the management strategies 'Usual Care', 'Case Management', and Self Management' did not yield any statistical significant differences in terms of health outcomes measured. Nevertheless, the input of a management strategy is of necessity because of its characteristics to bring the patients closer to their physicians. Even though the health outcomes were found to be similar, prior published reports have reported patient satisfaction and quality of life in association to the implementation of management programs [18, 21]. In the current study, the 'Self Management' strategy was found to be comparable to the 'Case Management' strategy for which patient satisfaction has been proven [18, 21]. Hence, with a cost comparison of the management programs, either 'Self Management' or 'Case Management' may be found to be financially feasible and very beneficial to the patients.

Further research

Further research regarding the management of CHF will warrant a deeper analysis of these management strategies. To accomplish this, all the sets of the clinical trial records should be analyzed and the management arms should be compared adjusting for important characteristics of the CHF condition. Moreover, a cost effectiveness analysis should be conducted in order to ensure a management choice that considers both the costs incurred by health care purchasers (i.e., Humana, United, Aetna) as well was the medical effectiveness for the patient. Also, a qualitative research design could be considered with the patients participating during the trial in qualitative surveys, focus groups or in one-on-

one interviews. This not only would allow participants to provide an input regarding their satisfaction about the strategy they were assigned to but also it would help in determining the optimal choice of management strategy for them using a more comprehensive approach. In addition, a cost effectiveness analysis should be undertaken to estimate the incremental cost effectiveness of managing congestive heart failure patients with either Self Management or Case Management in comparison to the standard care.

Summary and conclusions

Patients diagnosed with Congestive Heart Failure will be under a physician care for the remainder of their life. It is of great importance that the strategy used to manage these patients maximizes their health care outcome (days out of the hospital, patient satisfaction and quality of life) in an effective manner. The purpose of this study was to determine which of the three management strategies ('Standard care', 'Case Management' and 'Self Management') would provide better health outcome. 'Case Management' has been proposed to enhance patient self-daily monitoring, encourage patient compliance to medication and create a professional and knowledgeable connection between the patient and the physician, in order to detect earlier any sign of CHF condition deterioration. 'Self Management' was introduced to achieve the same benefits as the 'Case Management' while eliminating the cost of an intermediate nurse. Thus, the particular objective of the current study was to analyze whether 'Case Management' or 'Self Management' was beneficial when compared to 'Standard Care', and whether 'Self Management' may be comparable to 'Case Management'. This goal was realized by evaluating the differences in these strategies and testing these differences for statistical significance. In overall, the study found no evidence from this clinical trial

that either 'Case Management' or 'Self Management' have different outcomes when compared to 'Standard Care'; in terms of hospital free days, average length of hospital stay, number of hospitalizations, risk of hospitalization and time delay to first hospitalization.

Nevertheless, considering the fact that an enhanced follow up strategy constitutes a bridge between the patients and the doctors, a management program with a nurse or with a 'smart box' may be a useful tool that warrants consideration. A cost effectiveness comparison of the two approaches may provide a financially acceptable and reasonable choice leading to better patient health outcomes. This study encountered limitations due to the complete lack of cost comparison. The comparison of the management methods was performed considering patient health outcomes. Despite these limitations, this analysis provided important and additional information to address the existing controversy of the effect of disease management programs on CHF health outcomes. A more in depth analysis considering all the subsets of this clinical trial data would lead to a better understanding of the complete effect of these management strategies. Further data collection through interviews and surveys of all the patients alive who participated to the clinical trial would assist as well by providing a better individual choice of an optimal management choice.

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Oct. 2009   **MWSUG2009,** Cleveland, OH
Analysis of breast cancer and surgery as treatment option

Oct. 2008   **MWSUG2008,** Indianapolis, IN
Mastectomy versus Lumpectomy in breast cancer treatment

Mar. 2008   **SAS Global Forum 2008,** San Antonio, TX
Analysis of breast cancer cost and treatment using SAS

Nov. 2007   **SESUG2007,** Hilton Head Island, SC
*Use of ARIMA Time Series and Regressors to Forecast the
sale of electricity*

Poster presentation

Oct. 2010   **M2010,** Las Vegas, NV
*Best Data Mining model for commercial health insurance
companies to detect and profitably retain unsatisfied
customers*

Oct. 2009   **M2009,** Las Vegas, NV
*Analysis of Medications used by Mastectomy-Lumpectomy
patients using SAS*

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*Breast Cancer summary statistics from the MarketScan
data- A preprocessing analysis*

May 2008   **ISPOR2008,** SC
Analysis of Mastectomy in breast cancer treatment

Nov. 2007   **INFORMS2007,** Seattle, WA
Analysis of breast cancer cost and treatment using SAS