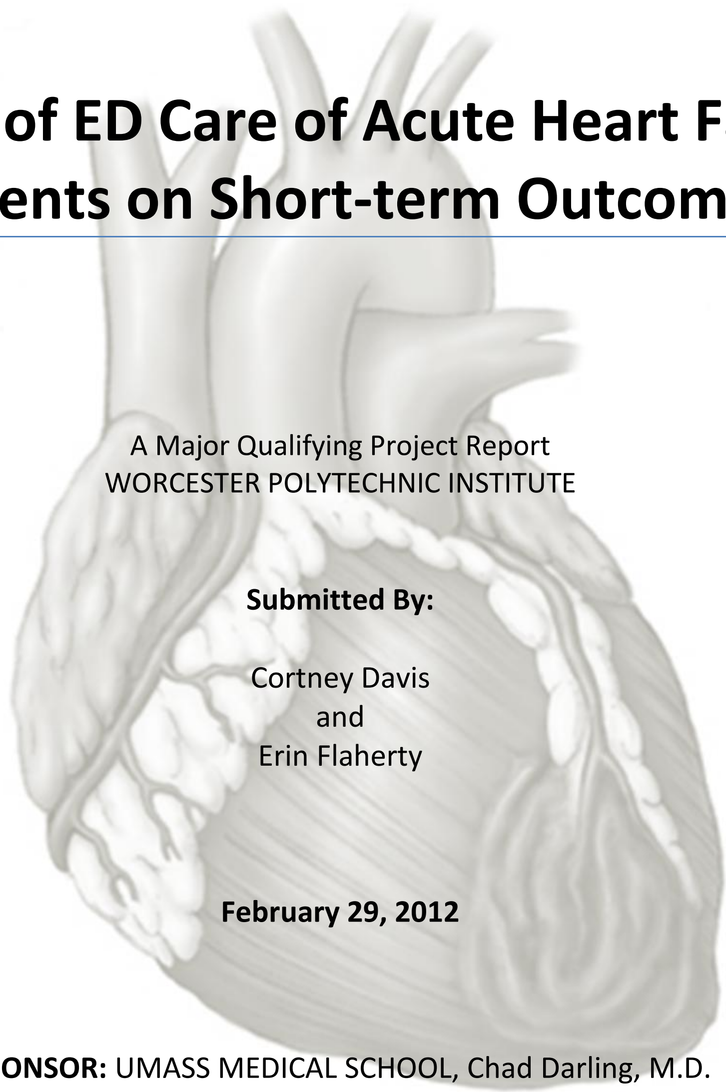

Impact of ED Care of Acute Heart Failure Patients on Short-term Outcomes

A Major Qualifying Project Report
WORCESTER POLYTECHNIC INSTITUTE

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1. Introduction

The purpose of this project is to determine how the treatment of Acute Heart Failure (AHF) patients within the Emergency Department affects short term outcomes such as hospital admission, the total length of hospitalization and the symptomatology. “Approximately three-quarters of all patients who are admitted for AHF are initially cared for in the Emergency Department” (Rodgers, 2006). Although Emergency Department treatment plays a major role in the diagnosis of AHF patients, the optimal treatment for these patients is not defined. Further research into the impact that Emergency Department treatment has on the short term outcomes of AHF patients can define how to provide better care for these patients and how to manage hospital resources appropriately by administrating the optimal care.

1.1 MQP Objectives

The primary hypothesis of this investigation was the early (<1hour) use of vasodilators, and diuretics in acute heart failure patients will result in improved short term outcomes compared to patients given these medications later in their ED stay or not at all. This study was purely observational and all data collection was obtained through enrollment and observation of the care within the ED as well as from chart review. The first goal of this project was to enroll potential heart failure patients based upon the study criteria. After patients were enrolled, the goal was to collect pertinent information about their ED care and relate that information to their short term outcomes.

2. Background

2.1 The Heart

The heart is an organ within the circulatory system whose function is to distribute blood to the tissues and cells of the body. The heart consists of four chambers including the left atrium and ventricle and the right atrium and ventricle. The heart pumps oxygenated blood out of the left ventricle through the aorta and into the arteries. The left ventricle is the main pumping chamber and must have enough force to provide blood to all of the tissues in the body; therefore it is stronger than the other chambers. The arteries, which carry the blood out from the left ventricle, break into smaller vessels called arterioles which eventually meet up with venuoles (the smaller branches of veins). The areas in which these two vessels meet and connect are called capillaries. The walls of the capillaries are very thin and allow for diffusion and exchange of deoxygenated and oxygenated blood (Texas Heart Institute Heart Information Center, 2011).

The once the blood has been deoxygenated within the capillaries, if flows back to the heart through veins. The veins carry the blood through the vena cava and back into the right atrium of the heart. The blood then passes through the tricuspid valve and into the right ventricle. The right ventricle pumps the blood through the pulmonary artery and through the lungs where the blood is oxygenated. After oxygenation, the blood returns through the pulmonary vein, into the left atrium to the left ventricle where the process is repeated once again (Texas Heart Institute Heart Information Center, 2011). The anatomy of the heart is shown in Figure 1. Understanding the anatomy of the heart allows for a more educated approach in the study of heart failure.

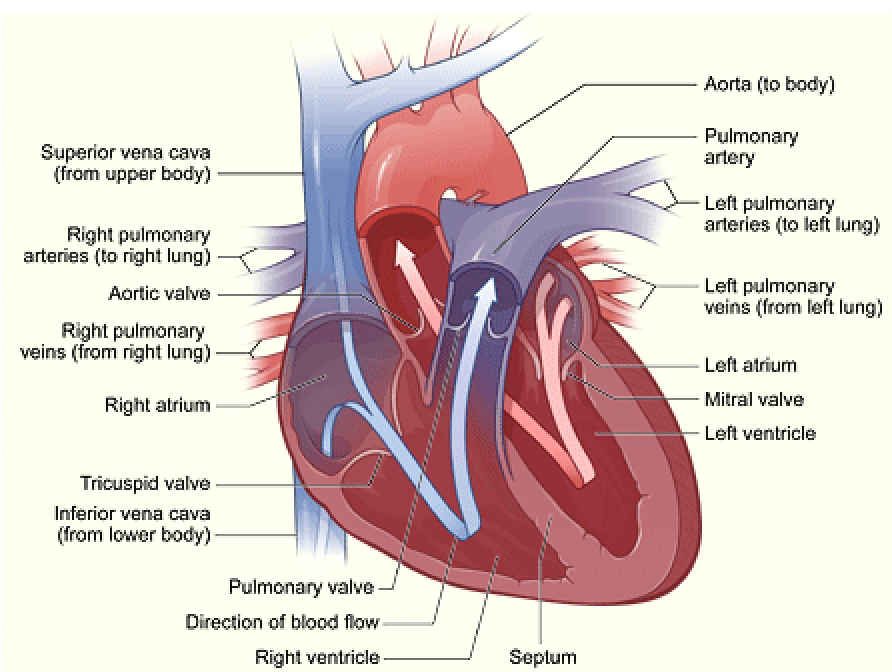


Figure 1: Anatomy of the Heart (What is the Heart, 2009)

The pumping of blood throughout the body is based open the contraction of the heart. However, the contraction of the heart could not occur without electrical signaling. The heart receives an electrical signal which begins in the sinoatrial (SA) node which is located in the right atrium. The signal travels across the cells in the right atrium and then into the left atrium. This electrical signal causes the atria to contract and the blood is pushed into the ventricles. As this is happening, the electrical signal reaches the atriventricular (AV) node in the septum near the tricuspid valve. From here the signal moves along the Purkinje fibers, which are fibers that stretch across the left and right ventricles. This causes the ventricles to contract, forcing the blood into the next chamber or out of the heart and into the body (Bryg, 2009).

2.2 Heart Failure

2.2.1 Introduction

Heart failure is a condition in which the heart has lost the ability to provide an adequate amount of blood to the rest of the body. As a result the organs throughout the body are not receiving enough oxygen to properly function. Heart failure symptoms have been described in ancient texts (Katz, 2012), even though they were not understood. Today, heart failure is the leading cause of hospital admission in people over the age of 65 with 1 million admissions per year (Centers for Disease Control and Prevention, 2011). In the United States there are more than 5 million individuals diagnosed with heart failure and that number is consistently rising with about a half million new cases each year. Heart failure becomes increasingly more common with ages affecting 1% of people age 50 and over, 5% of people 75 years and older and 25% of people aged 85 years or older (Centers for Disease Control and Prevention, 2011). Similar trends can be seen in Figure 2 which shows the increasing rate of heart failure as age increases.

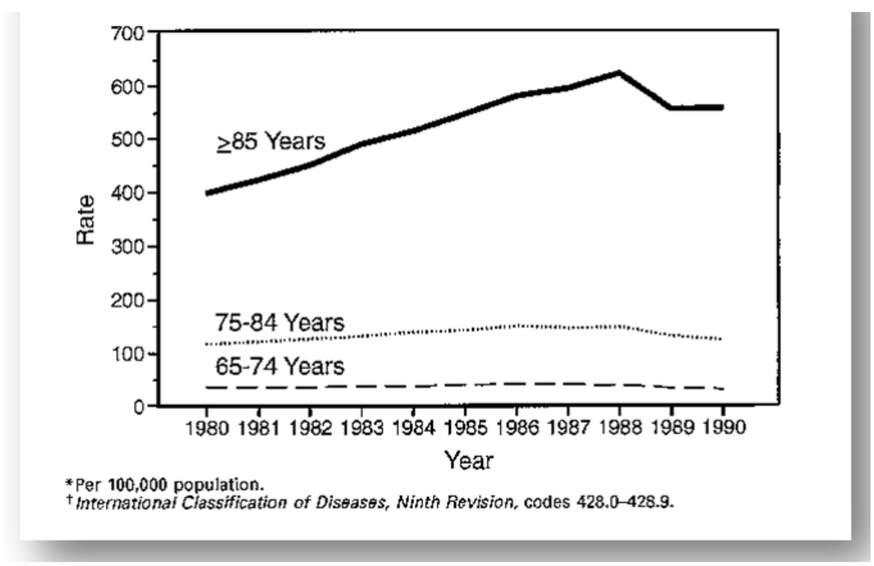


Figure 2: Age specific death rate for CHF (Centers for Disease Control and Prevention, 1994)

There are many different classifications of heart failure which stem from the type of malfunction within the heart. This project is specifically interested in congestive heart failure, which is characterized by a buildup of fluid within the body's tissues. Congestive heart failure is a condition where the pumping action of the heart becomes less and less powerful over time (American Heart Association, 2011). Therefore, the blood cannot move properly throughout the circulatory system and begins to back up into the tissues of the body. This back up causes an increase in blood pressure which also forces the fluid within the vessels into the surrounding tissue.

Although heart failure is extremely common, the symptoms can easily be mistaken for other diseases or disorders making the condition difficult to diagnose. Because the symptoms are broad and overlap with other diseases heart failure is commonly misdiagnosed initially. Therefore, the treatment given to heart failure patients tends to vary from patient to patient. However, the initial treatments given to these patients can have strong consequences on their short term outcomes and overall prognosis.

2.2.2. Heart Failure Classification

There are a variety of reasons for the development of heart failure, allowing the condition to be classified in a number of ways. The first classification of heart failure is into congestive and non-congestive categories. Congestive heart failure, as described above, is when fluid builds up in the body's tissues. The buildup of fluid is called edema and it is the main factor in determining whether a patient has congestive vs. non-congestive heart failure (Darling, 2011). When the left side of the heart is the main cause of failure, the fluid will back up into the lungs causing a condition called pulmonary edema. When the right side of the heart is the main cause of failure the fluid backs up into the body's tissues, most commonly in the legs and feet. As this condition worsens, the fluid backup will move up the legs and can even begin to build up within the abdomen (Darling, 2011).

Congestive heart failure can also be classified as systolic heart failure and diastolic heart failure. Systolic heart failure is characterized by the weakening of the pumping action of the heart. Classification of systolic heart failure is based upon measurement of the hearts ejection fraction, which is the portion of blood that is pumped out of a filled ventricle as a result of a heartbeat. A normal ejection fraction is usually within the range of 55%- 70% and values less than these usually represent a patient with systolic heart failure. Diastolic heart failure can be characterized by a stiff heart which is less compliant when it is filling with blood. In diastolic heart failure the pumping action of the heart is not affected, however, the stiffness prevents blood from reentering the heart and causes fluid to back up into the lungs (Mayo Clinic, 2011).

2.2.3 Symptoms

Heart failure patients can present with a variety of different symptoms, many of which will overlap with other diseases. However, there are three main categories of heart failure symptoms consisting of exercise intolerance, shortness of breath and fluid retention and swelling. During the early stages of heart failure, individuals will begin to experience difficultly exercising or even performing normal physical activity that they had been comfortable with in the past. The heart is not able to pump enough blood to provide the oxygen and other nutrients necessary for the body to function properly.

When this is true, individuals will become short of breath while doing these activities and rest is needed to return the body to its comfortable state (Mayo Clinic, 2011).

As a patient's heart failure becomes more advanced, shortness of breath will become more regular and more severe. Dyspnea (shortness of breath) most commonly occurs in heart failure patients while they are active throughout the day or while they are lying down. If there is fluid buildup into the lungs, the fluid will primarily stay at the base of the lung while an individual is standing due to gravity. However, when a person lays down the fluid will disperse and interfere with oxygen getting into the blood making breathing more difficult. Patients will also experience paroxysmal nocturnal dyspnea meaning they will awaken at night with shortness of breath. Most often this symptom can be relieved by sitting upright or standing (A.D.A.M Medical Encyclopedia, 2011).

Heart failure patients will often experience fluid retention and swelling. As noted previously, the heart's inefficiency can cause fluid to back up into the lungs, known as pulmonary edema, or to black up into the extremities causing peripheral edema. Peripheral edema is most common among heart failure patients at the end of the day after prolonged periods of sitting and standing. Heart failure will cause a specific type of edema called pitting edema. Pitting edema is recognized by pressing a finger to the swollen area. If a fingerprint remains on the skin this is pitting edema. Non-pitting edema is not caused by heart failure and should not be considered a symptom. Patients diagnosed with heart failure typically undergo daily weight checks because the amount of fluid retention correlates with shortness of breath (Darling, 2011).

Other symptoms of heart failure include: fatigue, weakness, irregular heartbeat, persistent cough, swelling in the abdomen, lack of appetite, nausea and difficulty concentrating. These symptoms often are not all present and can be attributed to many causes other that heart failure, making it difficult to diagnose (Mayo Clinic, 2011).

2.2.4 Causes of Heart Failure

Congestive heart failure is a condition which is caused by an underlying heart or blood vessel problem. Heart failure patients typically have numerous underlying problems which cause the heart to weaken over time. Reduction in the heart's pumping efficiency can be due to damage or overloading of the heart muscle. Causes of damage or overloading include coronary artery disease, damaged heart valves, high blood pressure, arrhythmias and heart muscle damage (What is the Heart, 2009).

Coronary artery disease is a result of the narrowing of small blood vessels that supply blood and oxygen to the heart. Decreasing the amount of blood flow to the heart muscle deprives it of blood which in turn, weakens the heart. Narrowed arteries are often caused by atherosclerosis, which is the buildup of plaque. If the plaque in these arteries ruptures or releases from the wall it can cause a clot and block blood flow causing a heart attack. Patients with coronary artery disease are at a much greater risk for heart failure.

Another common cause of heart failure is damaged heart valves. Specific heart valve conditions include valvular stenosis which is when the valve opening is smaller than normal due to fused leaflets. This causes the heart to be overworked because it must pump harder to push the blood through this valve. Leaky valves occur when the valves do not close tightly and therefore allow blood to leak backwards and as this condition worsens the heart must work harder to overcome this blood loss or the body will receive less blood. Both of these valve conditions put patients at a greater risk for heart failure and if the heart becomes overworked, it will typically result in decreased efficiency (What is the Heart, 2009)

High blood pressure is not typically a cause heart failure; however it can be a contributing factor when experienced along with other risk factors. Blood pressure is the force of blood pumped by the heart through the arteries. When the blood pressure is high the heart is working harder to contract more quickly and more forcefully. The heart muscle can become thicker due to the extra work resulting in the heart pumping less efficiently.

Prolonged arrhythmias eventually lead to heart damage and therefore they present a risk factor. An arrhythmia is an abnormal heart beat (The San Diego Cardiac Center, 2010). Certain arrhythmias can cause the heart muscle to work harder and can lead to less production. Overtime the heart will weaken creating the potential for failure. Along with arrhythmias, muscle damage can cause the heart to weaken. The blockage of blood vessels that supply the heart muscle can lead to a heart attack. Heart attacks cause damage to the tissue within the heart muscle and can also cause scar tissue formation. As a result of a heart attack the heart is weakened and may not be capable of pumping enough blood to support the body. Diseased heart muscle that results from an unknown cause is known as idiopathic cardiomyopathy, another risk factor for heart failure due to muscle weakening (Mayo Clinic, 2011).

2.2.5 Diagnosis of Heart Failure

Investigation into a patient's medical history is an important step in diagnosing heart failure. Doctors will look for these different underlying diseases and risk factors in combination with the patient's present symptoms to develop a diagnosis. However, it is still very difficult to distinguish heart failure from similar illnesses that cause breathing difficulties such as bronchitis, pneumonia, emphysema and asthma. A typical differential of a potential heart failure patient can be seen below.

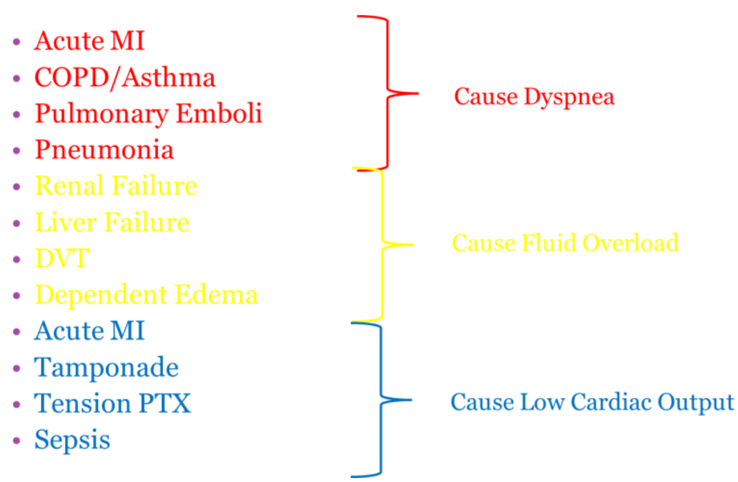


Figure 3: Typical Differential of Patients Presenting with Possible Heart Failure (Darling, 2011)

To help doctors diagnose heart failure, clinical tests can be performed on the patient. Common tests may range from minimally invasive chest x-rays, electrocardiograms blood tests, stress tests and observation to more invasive echocardiograms and (Mayo Clinic, 2011).

Patients with suspected heart failure usually undergo a chest x-ray to help determine the presence of fluid in the lungs. The presence of fluid hints towards a heart failure diagnosis. Doctors will also examine the chest x-ray for heart size. The heart is usually enlarged in CHF patients and this may be visible on the chest x-ray. Close examination of the x-ray may also unveil abnormalities in the patient's heart valves or other structures.

Along with a chest x-ray, blood tests can be performed to assist in diagnosing heart failure. Blood tests are only minimally invasive and therefore they are frequently used in diagnosis. Common blood tests measure kidney function, thyroid function and the level of brain natriuretic peptide (BNP). The most commonly used result for the diagnosis of heart failure is the BNP level. Brain natriuretic peptide is an endogenous hormone released into the blood from stretched ventricles. When the heart is overworked over a long period of time, it will cause an increased level of BNP, and usually a level >400pg/mL is suggestive of heart failure. The BNP level is a good screening test and the levels usually correlate with the severity of the patient's heart failure (Rodgers, 2006).

A stress test and observation of the patient is sometimes helpful in determining if heart failure is an appropriate diagnosis. A stress test can show the way in which the patient's body responds to exertion. Because heart failure patients experience shortness of breath during physical exertion, this can be a very simple but significant test. In addition, many heart failure patients will present with a third beat called an S3 beat. This is a dull and low-pitched sound heard when examining the chest. This sound is caused by the oscillation of blood in the ventricles or by tensing of the chordae tendineae during rapid ventricular filling. By listening to the patient's heart rhythm, the doctor can determine if the patient has this additional beat. Along with listening to their heart rhythm, doctors will conduct a JVP measurement which is seen in Figure 4.

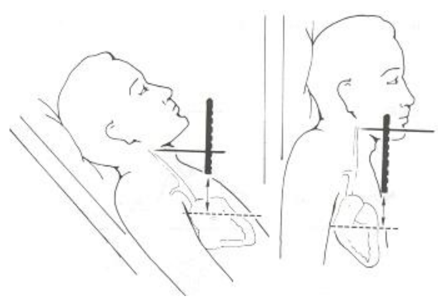


Figure 4: Diagram of a JVP measurement

This measurement is obtained by sitting patients up to 45 degrees and measuring the elevation of neck veins above the sternal angle. Once the elevation is measure 5cm are added because the right atrium is 5cm below the sternal angle (Rodgers, 2006).The normal measurement is around 8cm however in patients with CHF their pressure is much higher and therefore they cannot raise their neck as much.

Although these minimally invasive tests can be helpful in the diagnosis of heart failure, additional tests including echocardiograms and electrocardiograms may be performed. An echocardiogram is a type of ultrasound test that bounces sound waves off different parts of the heart which allow a moving picture of the heart. In heart failure diagnosis the main result of an echocardiogram is the ejection fraction, which shows the fraction of blood pumped out of the ventricles with each heartbeat. A normal ejection fraction is usually between 50-70% and values lower than the normal may suggest heart failure. Electrocardiograms (EKG's) are also minimally invasive and can be used to test the electrical activity of the heart. This may show an underlying condition that presents a risk for future heart failure. Typically an accurate diagnosis of heart failure cannot be made without a combination of these strategies (Rodgers, 2006).

2.2.6 Heart Failure Treatment

Once heart failure has been diagnosed, there are many different treatments to alleviate the symptoms and surgeries to correct the damage caused by this condition. Many medications including diuretics, vasodilators, nitrates, inotropes, digitalis, beta- blockers, natriuretic peptides and nitroglycerin can all be used to treat patients diagnosed with heart failure.

Diuretics are given to about 90% of heart failure patients to keep fluid from building up in the body (Darling, 2011). Diuretics cause the kidneys to remove excess salt and accompanying water from the blood stream. This results in a decreased amount of blood volume (blood pressure) in circulation making it easier for blood to be pumped throughout the body. There are three types of diuretics commonly used to treat heart failure. Thiazides are used to treat high blood pressure by reducing the amount of sodium and water and dilating the blood vessels to lower the patient's blood pressure. Potassium-sparing diuretics reduce the amount of water in the body; however, they do not cause the potassium levels in the body to drop. The third type of diuretic used is loop-acting diuretics which cause the kidneys to output an increased amount of urine. By doing so the amount of water in the body is decreased and blood pressure is lower. Although they are commonly administered and do improve symptoms, their efficacy in improving the short term outcomes in CHF patients has not been established. The main concerns in administering diuretics exist around their potential to activate the renin-angiotensin aldosterone system and the sympathetic nervous system. The activations of these systems may raise the ventricular filling pressures and can lead to reduced renal function (Mayo Clinic, 2011).

A more specific category of medication used to treat heart failure is vasodilators. Common vasodilators include ACE inhibitors, angiotensin II receptor blockers, beta-blockers and nitrates. Overall the goal of vasodilators is to enlarge the arterioles, which helps to relieve the systolic work that must be performed by the left ventricle. By reducing the work load of the left ventricle the heart can more easily pump blood throughout the body (Darling, 2011).

The most common type of vasodilator used to treat heart failure is ACE inhibitors. These medications block the production of angiotensin II which is a vasoconstrictor molecule. Angiotensin II acts as an endocrine and autocrine hormone and it increases blood pressure by stimulating Gq protein in smooth muscle cells. Angiotensin II causes an increased workload for the left ventricle and it is increased in heart failure patients. ACE inhibitors work by blocking the conversion of angiotensin I to angiotensin II causing reduced production of angiotensin II. This type of medication improves the immediate symptoms of heart failure patients but they also help to prolong the lives of heart failure patients by slowing the progression of heart damage. A similar type of medication is an Angiotensin II receptor blocker (ARB). ARBs work by preventing the effect of angiotensin by preventing the molecule from binding to its receptor. These are only prescribed when the patient is unable to tolerate the ACE inhibitor side effects (Rodgers, 2006).

ACE inhibitors and ARBs are arterial vasodilators, while nitrates are venous vasodilators. However, these vasodilators are not as strong or effective as the arterial vasodilators. They are often used in combination with the arterial vasodilators for increased symptom relief. Nitrates are also commonly used in conjunction with Hydralazine which is a smooth muscle arterial vasodilator. This type of medication is prescribed most often in African Americans or patients with poor kidney function (A.D.A.M Medical Encyclopedia, 2011).

Beta- blockers can be given to heart failure patients and their long term use may help in gradually improving the systolic function of the left ventricle. Beta-blockers work to slow down the heart rate, lower the blood pressure and therefore lessen the workload of the left ventricle. These drugs work by blocking the action of norepinephrine and epinephrine on the heart muscle. Norepinephrine and epinephrine are produced by the sympathetic nervous system however; they can be toxic to the heart at high doses over a long period of time. Overall the consistent use of beta blockers can help prolong the life of heart failure patients.

A drug, B- type natriuretic peptide (BNP) is a molecule that is produced by the heart muscle and is produced in excess in heart failure patients. However, it has been determined that giving additional BNP intravenously can lower the pressure in the lung and can function as a mild diuretic. This causes the water within the lungs to be removed and excreted through the kidneys, resulting in the pulmonary congestion relief. This usually prescribed to patients who experience a sudden onset of heart failure symptoms or their condition worsens very quickly. Therefore it is an important drug in the emergency room treatment of heart failure (Mayo Clinic, 2011).

Similar to natriuretic peptides, nitroglycerin is commonly used to treat heart failure patients who experience chest pain. This drug can also be used as a preventative measure for heart failure patients who are about to undergo physical activity. This drug works by relaxing the blood vessels so that the heard does not need to work as hard and therefore it can use less oxygen. Nitroglycerin is different from the other drugs in that the capsules are long acting, however they cannot be used to relieve chest pain once it has begun. Therefore it is a strictly preventative medication.

If the treatment of heart failure symptoms is not successful, surgery may be an option. There are numerous surgeries that can alleviate the effects of heart failure. Coronary bypass surgery is used to bypass a blockage that could be created from the narrowed arteries and arthrosclerosis. Heart valve repair or replacement is another common surgery. Implantable cardioverter-defibrillators and pacemakers monitor the heart beat and will send an electric shock if the device detects an irregular heartbeat. If the heart failure becomes severe enough a left ventricular assist device (LVAD) can be implanted to pump the heart and relieve the work of the heart. The last most serious treatment is a heart transplant which is only done in the most severe cases (Mayo Clinic, 2011).

Doctors will prescribe the appropriate type of treatment needed after their assessment of the patient's symptoms and the underlying cause of their condition. Some of these medications are used in conjunction to improve their effectiveness. There is not set treatment plan for a patient presenting with heart failure, but many algorithms for treatment have been proposed. Figure 5 displays a proposed algorithm for the treatment of a patient who potentially has heart failure. (Collins, 2007) This algorithm is used as a reference for the residents and doctors within the emergency room, however they are not official guidelines that they must follow.

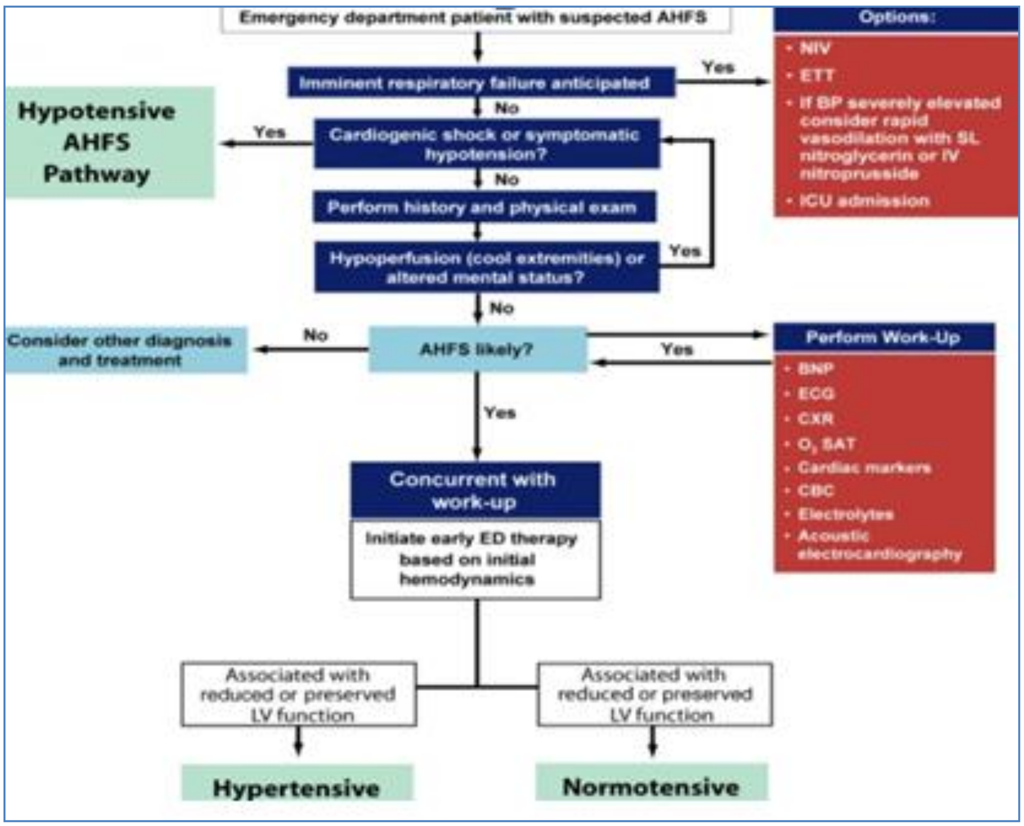


Figure 5: Proposed treatment algorithm for a patient presenting with suspected heart failure (Collins, 2007)

A similar algorithm is shown in Figure 6 except this algorithm begins with patients who enter the emergency room with shortness of breath as their chief complaint.

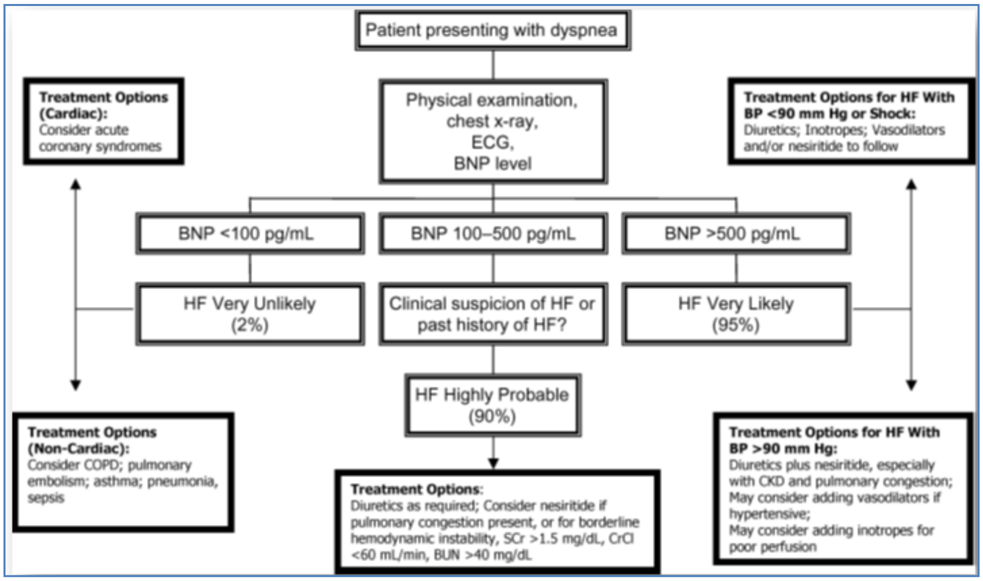


Figure 6: Proposed treatment algorithm for patient presenting with dyspnea (Collins, 2007)

These algorithms serve as treatment guidelines; however they have not been studied in relationship to the short term outcomes of patients. These algorithms become even more specific if they are related to the presenting blood pressure which is classified as normotensive (100-140mm Hg) hypertensive (>140mm Hg) and hypotensive (<90mm Hg). Figure 7 shows the proposed algorithm for patients diagnosed with heart failure and presenting with a hypotensive blood pressure.

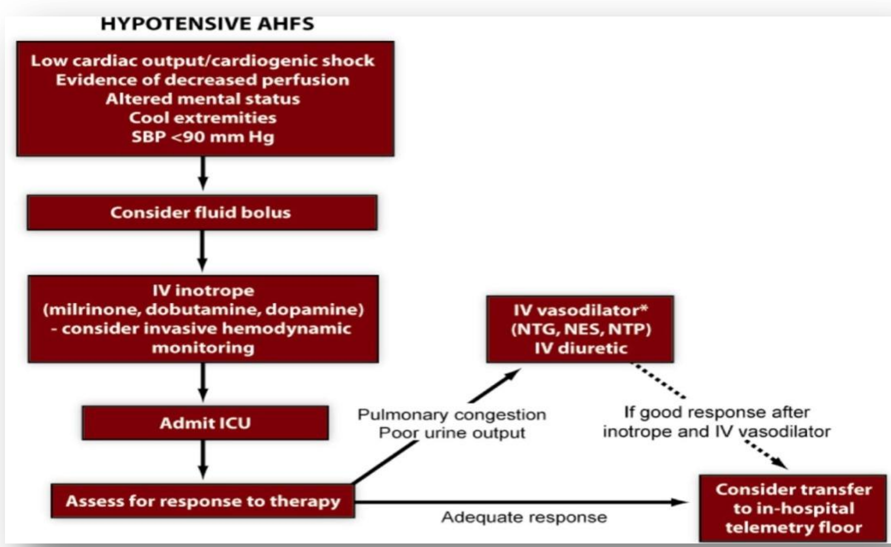


Figure 7: Proposed treatment algorithm with patients diagnosed with hypotensive heart failure (Collins, 2007)

As you can see from Figure 7, the treatment of heart failure is much more specific when the plan is based upon the presenting blood pressure. In this plan, there are fewer decisions to be made than when blood pressure is not integrated into the algorithm from the beginning. The proposed treatment algorithm for hypertensive patients can be seen in Figure 8.

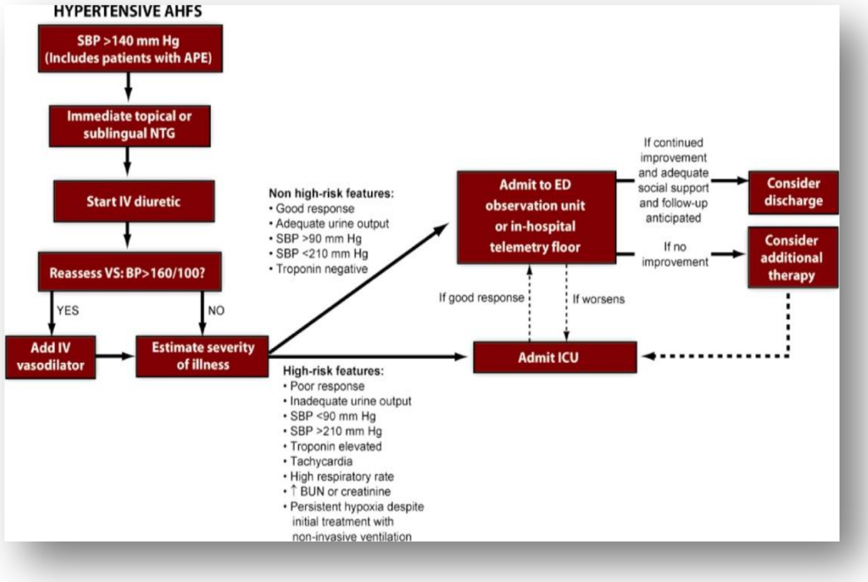


Figure 8: Proposed treatment algorithm for patients diagnosed with hypertensive heart failure (Collins, 2007)

In Figure 8 there are more considerations to be made than in the proposed algorithm for a hypotensive patient, which was presented in Figure 8. The same trend is seen below with even more decisions being necessary when the patient presents with a normotensive blood pressure as seen in Figure 9.

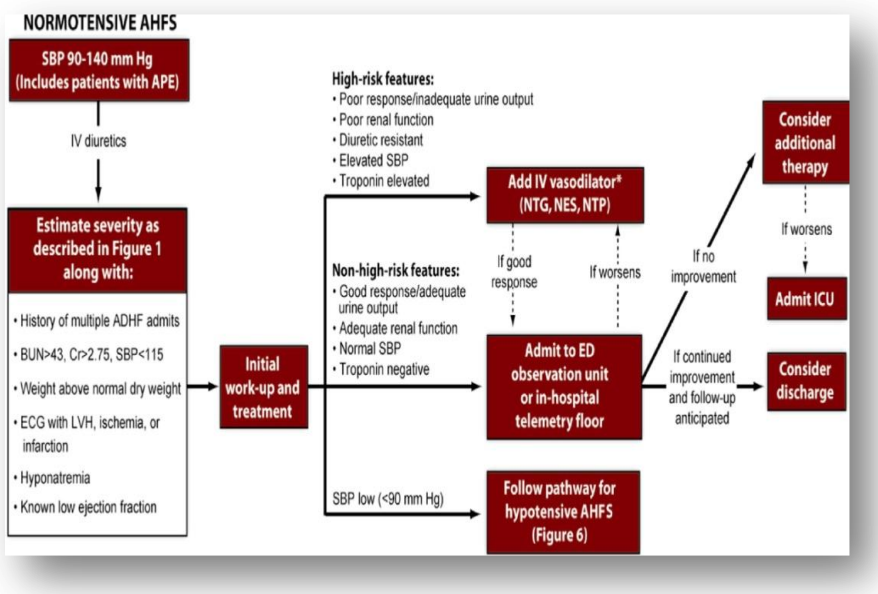


Figure 9: Proposed treatment algorithm for patients diagnosed with normotensive heart failure (Collins, 2007)

Overall these algorithms provide insight into the decision making process that a doctor establishes when a patient presents with heart failure. As shown in these figures, the course of action becomes more specific when the presenting blood pressure is used to customize the treatment. Although these are good methods for deciding upon the treatment of a heart failure patients there is still a great deal of change from one patient to another with many treatment possibilities available. If these algorithms can be improved based on outcome data, patients may have a more streamlined course of treatment which could result in an improved prognosis for heart failure patients.

2.2.7 Prognosis

The prognosis for patients with heart failure patients is fairly poor. Patients with severe heart failure symptoms have the worst prognosis with 50% of patients dying within a year of diagnosis. This statistic decreases in patients with less severe symptoms with 50% of patients dying within 3 to 4 years of diagnosis (American Heart Association, 2011). The main determination in the prognosis of a patient is the function of their left ventricle which can be determined by their ejection fraction. The lower that the ejection fraction becomes in a patient, the worse prognosis becomes (American Heart Association, 2011).

Many patients with heart failure die suddenly from ventricular arrhythmias; however the medications used to treat heart failure have been consistently improving providing a better outlook for heart failure patients. The uses of beta-blocker and ACE inhibitors have now been shown to cause a decrease in mortality rates among heart failure patients. With this being said, 10% of heart failure patients die per year (Centers of Disease Control and Prevention, 1994). It is important that the treatment of these patients improve so that their lifespans can be prolonged and the condition of life can improve for heart failure patients as well. Improved treatment plans are also important to relieve the burden that these patients place upon the hospital system.

2.3 Heart Failure's Burden on Hospitals

Along with improving the overall prognosis of heart failure patients, extended research into the treatment of heart failure can relieve some of the burden placed on hospital by this condition. Heart failure has a very high mortality rate and is the end stage of cardiac disease. Eighty percent of men seventy percent of women above the age of 65 who have heart failure will die within 8 years. Along with the severity of the disease, heart failure was the cause of 3,390,000 hospital visits in 2006. The number of emergency room visits due to heart failure places a severe economic burden upon hospitals. These patients are often admitted into the ICU or inpatient care, utilizing even more hospital resources. In 2009 it is estimated that 37.2 billion dollars was spent on heart failure (Centers for Disease Control and Prevention, 2011). Of the total 37.3 billion approximately 20.1 billion relates to hospital costs alone. These costs are only going to rise in the future with a growing percent of the population entering the above 65 age range (Peacock, 2004).To better utilize the hospitals resources, investigation on how to optimize emergency room treatment of heart failure is essential. Optimal emergency room treatment will result in a shortened length of stays and fewer admissions. To optimize the care given to heart failure patients a clinic trial was proposed and initiated.

2.4 Clinical Trials

A clinical trial is a biomedical or health-related research study that uses human beings as the test subjects. The trial must follow a pre-defined protocol. There are two types of trials that can be done, interventional and observational. Interventional studies involve assigning subjects to a treatment or some other intervention, and then the outcomes are measured. Observational studies are when the subjects are observed and the outcomes are merely observed and analyzed by the investigators. An observational study does not involve changing the treatment of the patient in anyway (Clinicaltrials.gov, 2011). Since observational studies are not randomized they can have certain biases that alter the results of the study.

2.4.1 Purpose of clinical trials

The purpose of clinical trials is to better the health care field. Different aspects of health are studied which can help doctors and other health professionals know how to best treat individuals with these problems. These studies can also help a hospital or health care facility run more effectively.

2.4.2 Clinical Trial Procedures

Once the trial has been approved, by the hospitals institutional review board, the next step is recruiting patients. In order for the subject to be admitted to the trial they must provide informed consent. This is done by explaining the study to the patients in plain English and ensuring that they fully understand the study. IF the patient does not speak English, an attempt can be made to obtain consent from a family member. However, if consent cannot be obtained from a family member, no translator can be provided so that patient was not enrolled. They must be informed of any risk or benefit to them. They also need to be informed that at any time they may withdraw from the study. Then the subject can be asked if they would be willing to be a part of the study. From here the patient gives their consent and signs a consent form as well as whatever other forms are needed for the hospital. Often a HIPPA (Health Insurance Portability and Accountability Act) form also needs to be signed to obtain the patients clinical records (Clinicaltrials.gov, 2011).

2.4.3 History and Ethical Considerations

The term clinical trials may be relatively new but the idea has been around for hundreds of years. Starting in the 1700's there were experiments that used untreated control groups to study the effects of certain drugs. Dating back to the 1800s the United States completed clinical trials relating to smallpox. However, Germany experiments that occurred in Nuremberg brought forward many changes to the ways clinical trials were done (Meinert, 2012). The Nazis performed medical trials and procedures on their prisoners that were extremely unethical. Because of these extremely unethical acts at Nuremberg there was a code termed the Nuremburg code that is essentially what medical ethics were built on. The code set the boundaries for what is acceptable and what is not in the medical world. It dictates that clinical trials are conducted in a manner that can only benefit people rather than harming them (Nuremberg).

The Nuremberg code adopted in the 1950's brought several other advances for clinical trials. In 1966 Institutional Review Boards (IRBs) were mandated, that would be responsible for approving all trials before they could be started. To this day before clinical trials can be initiated they must be reviewed and approved by an Institutional Review Board (IRB). Approval is based on review of information provided by the researcher and describing the details of the study and exactly how the patients will be involved in the trial (Meinert, 2012).

2.5 Previous Clinical Trials on Heart Failure: The Framingham Study

Previous studies investigating heart failure have been done. One such study, The Framingham Heart Study was conducted to identify the common factors that contribute to cardiovascular disease by following its development over a long period of time following a large group of participants who had not yet developed overt symptoms. Overall the original study enrolled 5,209 men and women who fell into the 30-62 age range and it collected data about their lifestyle and medical history (Arruda, 2011). Eventually the study began enrolling patients outside of the original Framingham resident participants.

The study enrolled patients from three generations beginning with the original Framingham residents, and two generations of participants recruited outside of Framingham. The study reviews the patients' medical history, conducts a physical examination and conducts laboratory tests every two years. The collection of this information has allowed for the identification of the risk factors for cardiovascular disease. These risk factors have been compiled into The Framingham Criteria. The criteria are shown in Figure 10 and will serve as the guideline for this project's inclusion and exclusion criteria.

Table 1. Framingham Criteria for CHF
Major criteria
Paroxysmal nocturnal dyspnea or orthopnea
Neck-vein distention
Rales
Cardiomegaly
Acute pulmonary edema
S_3 gallop
Increased venous pressure N16 cm of water
Circulation time z 25 s
Hepatojugular reflux
Minor criteria
Ankle edema
Night cough
Dyspnea on exertion
Hepatomegaly
Pleural effusion
Vital capacity A 1/3 from maximum
Tachycardia (range of z 120/min)
Major or minor criteria
Weight loss z 4.5 kg in 5 days in response to treatment

Figure 10: Criteria developed based upon the conclusions from the Framingham study (Arruda, 2011)

The Framingham criteria are the most accepted way of diagnosing heart failure. The diagnosis incorporates major criteria and minor criteria. If a patient has two or more major criteria or one major and 2 or more minor criteria, they are considered highly likely to have heart failure. The major and minor criteria are both shown in Figure 10.

Heart failure does not have a definitive way of being diagnosed at this point in time. Because of this Dr. Chad Darling has embarked on an observational study to determine the best method of treatment that will lead to short hospitals stays for individuals with heart failure. This study is important because of the positive implications for the patients as well as the hospital. With shorter hospital stays the patients can live their lives more outside of the hospital and spend less money on medical bills. The shorter hospital stays will open up more rooms for other patients, and will take some of the stress off of the nurses and doctors. To complete this study there is a certain methodology that must be followed.

3. Methodology

3.1 Clinical methods

During this investigation protocol outlined in the IRB form, completed by Chad Darling, was followed. Patients presenting to the Emergency Department with a primary complaint that included any of the symptoms of heart failure (shortness of breath, chest pain, edema, and sometimes congestive heart failure) were considered potential candidates for the study. Their medical records were accessed to determine if they had a history of heart failure. If they had a history of heart failure or if they did not have a history but the symptoms could still indicate heart failure they continued to be considered for enrollment. The final inclusion and exclusion criteria that were used to ensure the integrity of the trial were:

Inclusion Criteria:

- Male or female 18 years of age or older
- Presenting to ED with dyspnea concerning for acute heart failure

Exclusion Criteria

- Final (hospital determined) primary or secondary diagnosis that is not heart failure as determined by the Framingham Criteria for HF
- AHF occurring in the setting of acute myocardial infarction
- Dyspnea clearly due to alternative diagnoses (Asthma)
- Inability to provide informed consent (e.g. mentally incapacitated)
- Pregnancy

Once a patient that met these criteria and had been examined by a doctor the next step was to ask the doctor what he/she believed the patient was suffering from. If the doctor believed it was heart failure the patient was approached. If the doctor did not believe it was heart failure but the medical history and symptoms all supported heart failure as a probable diagnosis the patient was still approached.

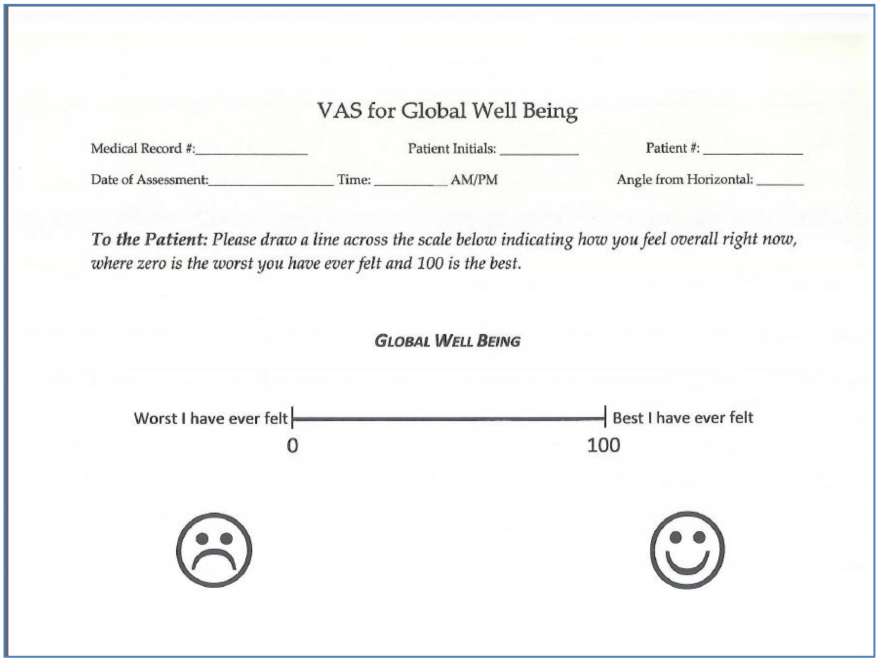
Approaching the patient was done in a way as to not scare or overwhelm them. The patient was told about the study ensuring that they understand that it was strictly observational and that there was no harm or benefit to them, only the potential to help future patients. The patients were told it was a study involving heart failure but that did not necessarily mean that they would be diagnosed with heart failure that day. Researchers are not doctors so giving a diagnosis to the patients was not appropriate. Once the patient had received all the necessary information they were asked if they would be willing to participate in the trial. They were then required to sign a consent form and a medical records release form.

Once a patient had signed all the appropriate forms they were asked to complete a series of wellness scales. The first scale was the global well-being scale. This scale was from zero to 100; with zero being the worst you've ever felt and 100 being the best you've ever felt. The patient was asked orally to compare how they feel at that moment with how they feel on a normal day (before the onset of symptoms). The patient was then asked to draw a line through the scale at the appropriate location corresponding to how they felt. The next two scales involve shortness of breath. The first of the two was similar to the global well-being scale using the same scoring system; with zero being the worst you've ever felt and 100 being the best you've ever felt. Again the patient was asked to compare how they felt at that instance to their normal day and then asked to draw a line through the scale at the corresponding location. The last scale was a shortness of breath scale with several markers and faces for markedly better, mildly better, mildly worse and markedly worse. The patient was asked to score their shortness of breath based on when they came in to the emergency room. The patient was asked to check the box that best describes their state.

After all the scales were filled out the patient was asked for their height and weight. They were then thanked and the researcher left the room. In an hour or two the researcher returned to the room to ask the patient to fill out the three scales again. During this second visit the patient was asked if they have taken in any fluids as well as if they have urinated. If the patient was admitted they were visited the next day and asked to fill out the same three scales for the last time. In addition to the scales at the third hour the patient is also asked to speak about how satisfied they are with the care they received in the emergency room. The patient was asked two multiple choice questions about the quality of care and then the patient was asked open-endedly what they liked or what they would improve.

While the patient was still in the emergency department their nursing and doctor's notes were copied to keep in the record. If there were any electrocardiograms (EKG's) these were also copied. The patient's medicine list was also obtained from either the patient or the nurse while the patients were in the emergency room. Using this information a sheet with all the pertinent information was filled out. This information consists of: blood pressure, heart rate, respiratory rate and percent of oxygen saturation. These are taken every hour for three hours as well as the initial reading, the triage reading. The form used for the data collection can be seen in Appendix E.

The chart review process was the last step of the methodology. The first step was to measure the patient scales with a ruler. Figure 11 shows an example of the global well-being scale.


VAS for Global Well Being

Medical Record #:__________ Patient Initials: ________ Patient #: __________

Date of Assessment:__________ Time: _______ AM/PM Angle from Horizontal: _____

To the Patient: Please draw a line across the scale below indicating how you feel overall right now, where zero is the worst you have ever felt and 100 is the best.

GLOBAL WELL BEING

Worst I have ever felt 0 — 100 Best I have ever felt

Figure 11: Global Well Being Scale

(U.S. National Institutes of Health, 2007) (Centers for Disease Control and Prevention, 2011) (Katz, 2008; Mayo Foundation for Medication Education adn Research, 2011; Peacick, 2002; Collins, 2005)The entire scale was set to equal 100mm. The patients were asked to draw a line through the scale that relates to their well-being. The distance from the 0 point of the scale to the line marked by the patients was measured and recorded in millimeters. The doctor's final diagnosis was determined and with this it is decided if the patient is ruled in or ruled out. The doctor's final primary, secondary or tertiary diagnosis must have been heart failure in order to use the patient's data. Once this was done all the information gathered while the patient was in the emergency room was compiled in the RedCap system online. Redcap is a website which allows projects to be established. All of the information gathered from enrolling patients and reviewing charts was entered into this online system. Once completed, the results were exported from this website into excel and statistical analysis was performed on the data.

3.2 Methods of Analysis

The main source of analysis for the experiments was graphical representations of data as well as analysis of variances (ANOVA). The ANOVAs were used to see if the data had any sort of statistical relevance. The ANOVAs showed if there was a significant difference between patient groups given medicine and those not given medicine. In many cases the sample size is too small to see any statistical significance, because the study had only been in progress for a few months. With a small sample size it was not expected that the data would have any sort of statistical significance. The graphs were used to show trends where the statistics did not support the hypothesis. These graphs were generated using the

GraphPad program bar graphs. The graphs allowed for comparison between different groups that the ANOVA could not be as specific with, and allowed for the visualization of trends.

Other statistics that were done with the data was means, medians and standard deviations. These allowed for a general overview of the average heart failure patient, as well as an understanding of how much heart failure patients can vary from one another (Standard Deviation). Medians were done as well because the standard deviations were often very large, and the medians provided a better view of the average heart failure patient.

4. Results and Discussion

Specifically, the goal of this study was to determine whether the early use of vasodilators and diuretics in acute heart failure patients would results in improved short term outcomes. Data was collected on 38 patients who fit the Framingham criteria. This data was analyzed to see if the hypotheses were validated.

4.1 Trial Demographics

Based upon the enrollment criteria, 38 patients were enrolled into this clinical trial. These patients were then determined to be "rule in" or "rule outs" based upon the Framingham Criteria during the chart review process.

Table 1: Patient Demographics and Clinical Characteristics

Number of Patients		Clinical Characteristics					
Total	41	Triage Systolic BP		Triage HR		Triage RR	
Enrolled	30	Mean	134.8378	Mean	84.081	Mean	21.7027
Male Enrolled	21	STD	25.18654	STD	22.447	STD	4.624001
Female Enrolled	9	Median	135.5	Median	80	Median	21

The total number of enrolled patients was 41, with 11 patients that were ultimately determined to be ruled out of the trial. .This information shows that the inclusion and exclusion criteria for the study are effective. This information can be useful for future doctors who wish to enroll patients presenting with heart failure.

The patients sex was recorded and it was determined that 21 were males and 9 were females. More males presenting with heart failure is consistent with national averages. This is useful information for the principal investigator because it may change future decisions about enrollment. For example, it may be decided to only include male patients because they are much more prevalent and therefore the study would be more efficient in seeking out potential heart failure patients. This study is interested in more than just males though, so this would not be necessary.

The demographic table also demonstrates the clinical characteristics of the heart failure patients. The average triage systolic blood pressure was about 135mg of mercury; this is slightly above the normal 120. The average heart rate of enrolled heart failure patients was about 84 beats per minute, this within the normal range of 60-100 beats per minute. The average triage respiratory rate was about 22 breaths per minute, this is very high with the normal being approximately 12 breaths per minute. This information is important in understanding the normal heart failure patient. From this we can see a trend that heart failure patients may present with an increase in respiratory rate and perhaps a slightly elevated systolic blood pressure. This is congruent with previous knowledge of how heart failure patients present. Tachycardia is typically also a symptom so the small sample size could be skewing the data down out of the tachycardia state.

Another method of improving the efficiency of potential heart failure enrollment is to look at trends in the chief complaint of enrolled patients. Figure 12 shows the chief complaint of the 30 patients ruled into this clinical trial.

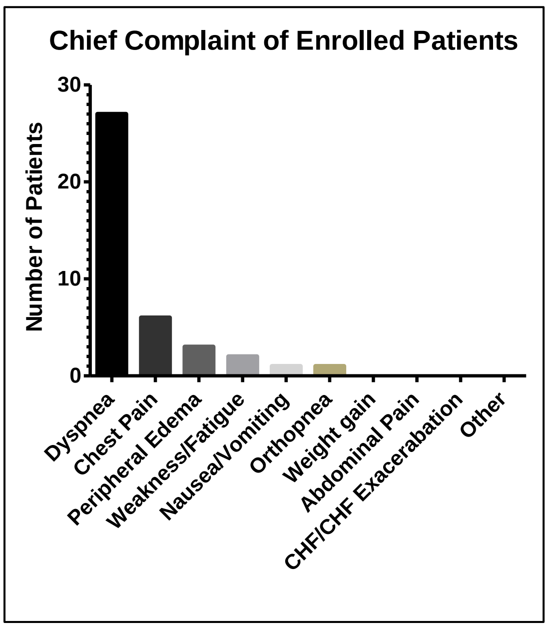


Figure 12: Chief complaint of enrolled patients

As seen in Figure 12, twenty seven of the enrolled patients presented to the ED with dyspnea, which is shortness of breath, a common symptom of hear heart failure. This is congruent with the previous data showing that on average patients presented with an increased respiratory rate. There were a few patients who were enrolled with chest pain, peripheral edema and weakness and fatigue. As the study progresses the chief complaint of enrolled patients should be further investigated. It may be beneficial to enroll only patients who present with dyspnea or to at least limit enrollment to only include dyspnea, chest pain, peripheral edema and weakness. By limiting the symptoms of interest less time will be used investigating patient’s medical history before enrollment.

When conducting this clinical trial doctors and residents were asked for their diagnostic impression of the patient before enrollment. Heart failure is a very difficult disease to diagnosis because the symptoms overlap with many other diseases. The accuracy of the doctor's initial diagnostic impression within the emergency department is examined in Figure 13.

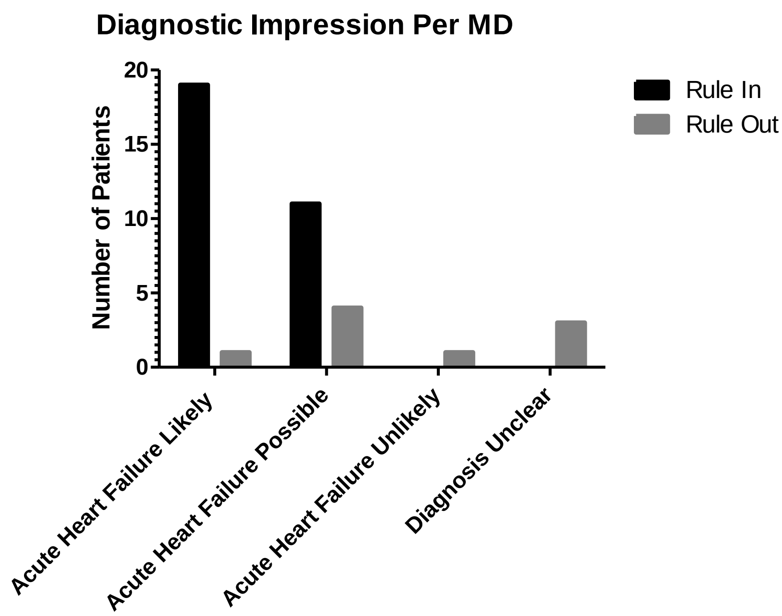


Figure 13: Diagnostic impression of patients within the ED

Figure 13 shows the diagnostic impression of the ED physician for all enrolled patients. The graph is further broken down into patients who were ruled into the study based upon the Framingham criteria. These data indicate that the doctors have been fairly accurate with their initial impression up until this point in the study. Only one patient who was initially considered to be "likely" for heart failure was ruled out of the study. All patients who were enrolled that were considered to be unlikely or unclear for heart failure were ultimately ruled out by the Framingham criteria. Because heart failure is difficult to diagnosis there is some uncertainty when the initial diagnosis is considered to be possible. These data shows that investigators should respect the initial diagnosis of the emergency room doctor and only enroll patients who are considered to be likely or possible.

4.2 Pre-Hospital Care

The treatment the patient undergoes before entering the emergency room can help with the overall analysis of the patients' treatment while in the hospital. Table 2 shows the mode of transportation to the ED and from there how many people received each type of medicine before entering the ED. There are 50 patients shown in the table but only 38 patients were enrolled during chart review. Many patients received some form of pre-hospital medicine. This will be looked at later to see if there was any effect on the administration of these drugs.

Table 2: Pre-Hospital Care Demographics

Mode of Transportation		Pre-Hospital Meds				Length of Stay	
Walk in	EMS	Home		Ambulance		Average	95.47
21	29	Aspirin	10	Aspirin	3	Standard Deviation	84.11
		Diuretics	8	Diuretics	2	Median	75.5
		Nitrates	2	Nitrates	2		

During the course of treatment patients may be moved from the emergency department and admitted onto the floor or into the ICU. Typically patients who will be staying overnight are admitted onto the floor. Once on the floor, patients are given a room and are also reevaluated the next day by a specialist within cardiology. Patients who are very ill and need direct and immediate care are admitted into the ICU. This is less frequent and represents the heart failure patients who had the most severe symptoms. Figure 14 presents the number of enrolled patients admitted in the ED, Floor and ICU during their visit.

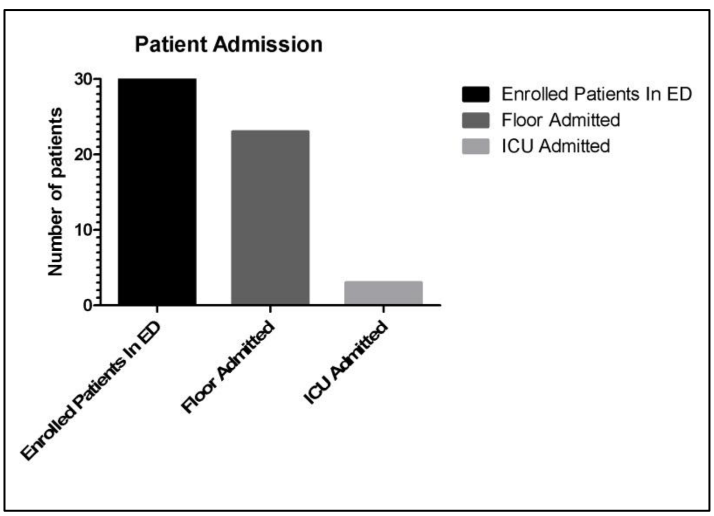


Figure 14: Patient admission data for enrolled patients

The graph in Figure 14 shows that of the 32 patients enrolled into the study 25 of the patients were admitted on the floor while only 3 were admitted into the ICU. Patients who were admitted into the ICU had the most severe symptoms, which may skew the results of this study. These data also demonstrate the level of hospital resources that are being used by heart failure patients. Many patients who visit the emergency department receive treatment and are then discharged a few hours later. However, all of the heart failure patients enrolled into this study had been admitted onto the floor or

ICU which is much more expensive for the hospital. These resources might be saved if optimally effective and immediate care is given to heart failure patients within the emergency department.

4.3 Symptom Improvement: Assessment of Common Medications

To assess what the optimal car for these patients would be, the types of medications given within the emergency department were investigated. There are no set guidelines for the treatment of heart failure patients and therefore numerous types of medications are administered to these patients. Also, due to its overlap with other diseases, treatment for another disease may be given within the emergency room before the patient is diagnosed with heart failure. Figure 15 shows the different types of medications that enrolled patients received during their emergency room visit.

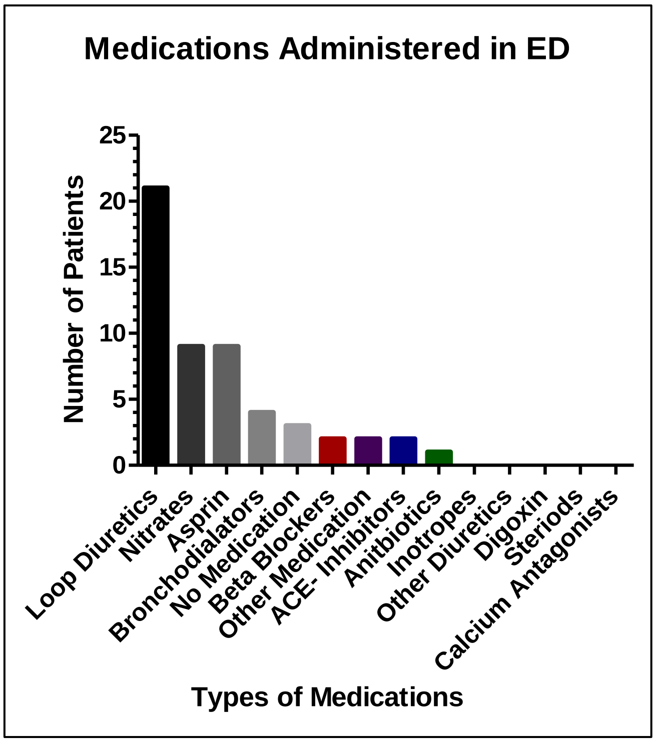


Figure 15: Medications administered in the ED

Figure 15 shows the variety of medications given to the enrolled heart failure patients. The most common three medications included loop diuretics, nitrates and aspirin. The effectiveness of these three medications was assessed during this clinical trail through the comparison of the short term outcomes among enrolled patients. Although this type of comparison will help determine which medication is the most effective, there are many confounding factors involved during a human study. Some patients will have less room for improvement due to mild initial symptoms, while others will present with severe symptoms initially. Also, some heart failure patients receive a panel of home medications. Due to these types of factors it will be difficult to see a significant correlation between any of these medications and short term outcomes with only a small sample size.

4.4 Symptom Improvement: Assessment of blood pressure changes

Blood pressure changes are usually important characteristics for doctors to determine patient progress. In this study patient blood pressure is collected every hour for the first three hours of their emergency room visit. As patients progress during their stay their blood pressure should drop to within normal levels. Figure 16 shows a box and whisker plot of the change in systolic and diastolic blood pressure at each hour.

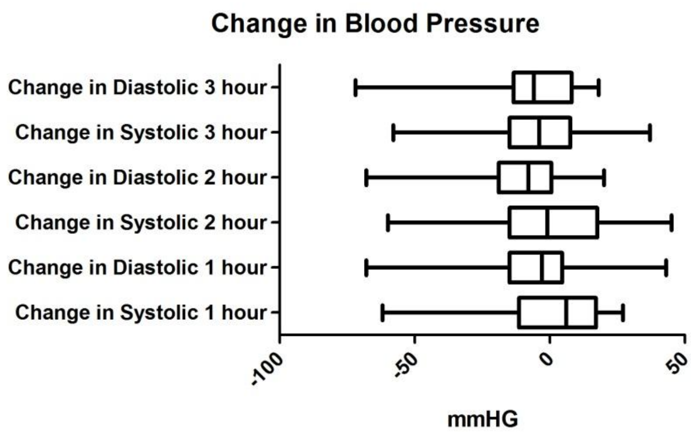


Figure 16: Change in blood pressure after each hour of emergency room stay

Figure 16 shows that there was a slight decrease in the average blood pressure throughout the emergency department visit of a patient. In this graph a decrease in blood pressure is marked as negative change while an increase in blood pressure is marked as positive change. After the first hour in the emergency room both there were only small positive changes in systolic and diastolic blood pressure. After two hours the median change in blood pressure had moved into the negative region. This shows that patients were showing a decrease in blood pressure which is an indicator of symptom improvement. After the third hour the median change in blood pressure was similar to the 2 hour data showing that the hospital may be stabilizing the patients once their blood pressure is slightly decreased. This graph also shows that there is a very large range for the change in blood pressures. Some patients may have begun at much greater extremes and therefore they would have had more room for improvement. This data suggests that on average patients are improving throughout their stay within the emergency room. Blood pressure is an objective measure of symptom improvement and is more accurate than the overall well-being scales which rely on the opinion of the patient at a given time.

4.5 Symptom Improvement: Assessment of length of Stay

The length of stay associated with heart failure patients is a strong indicator of how the patient is doing. If patients stay longer, the hospital believes that they need to be in the hospital. Shortening length of stay could mean an increase in the patients' health, as well as minimizing the cost to the hospital.

The average length of hospital stay associated with heart failure patients was found to be 95.47 hours with a standard deviation of 84.11. The median was found to be 75.5 showing that there were quite a few patients who stayed in the Emergency Department for an extended time which has the effect of increasing the average.

Different medications are given for heart failure, so the question was does the timing of administration of these medicines reduce the length of stay. For this the medications were split into three categories, Aspirin, Diuretics and Nitrates. Each was examined based on the time that they were given, for example pre-hospital means given at home or in the ambulance. Whereas less than 1 hour means within an hour of arriving in the Emergency Department. Both refer to the patient having been given medicine both before arriving at the hospital and once in the Emergency Department. This is shown in Figure 17.

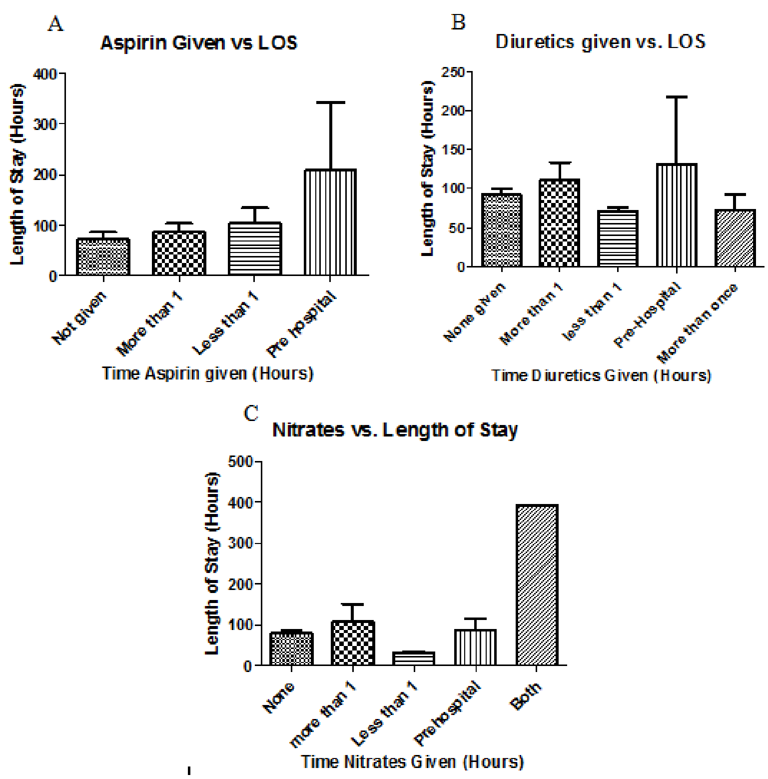


Figure 17: Medications effects on length of stay

In addition to the graphs an Analysis of Variance (ANOVA) was done for each medication. The ANOVA was done to see if there was significant difference in length of stay if medication was given versus if medication was not given. Table 3 shows the P values comparing weather each medication was given or not, for aspirin, diuretics and nitrates.

Table 3: P values for the ANOVA of difference between medication given and medication not given on length of stay

Medication	P Value
Aspirin	0.363
Diuretics	0.723
Nitrates	0.235

Figure 17a displays the data for length of stay based on when the patients received Aspirin. There is not an obvious trend affecting the length of stay, other than the people who were given pre-hospital aspirin had the longest length of stay. However, the ANOVA gave a P value of 0.36 where 0.05 is significant. When generated this graph had extremely large error bars, which could attribute to the high P value. The error bars make the large p value much less significant because it shows that the data was fairly inaccurate. This shows that the time Aspirin is given or if it is given at all does not have a statistically significant affect the length of stay in patients presenting with heart failure. This is congruent with the knowledge that aspirin is typically used as a long term treatment for heart failure patients as well as for heart attacks.

Figure 17B displays the data for length of stay for patients receiving diuretics. While the patients who were given diuretics prior to entering the emergency room appearing to have had a longer length of stay. This is possibly because the patients who are taking home medicines or who are given medication by EMS are the patients who are the most severe. In general, these patients likely have been diagnosed with heart failure before and know to take medicine before coming to the hospital. The other larger bar is the more than 3 hours, suggesting that the diuretic should be administered early in the emergency room stay.

However, the ANOVA gave a P value of 0.72 where 0.05 is significant. This shows that there is no statistically significant difference if diuretic is given in the emergency department or not. This could mean that doctors are good at determining if a patient needs diuretics or not while in the emergency department. It is also possible that this is not correct since there was a very small sample of heart failure patients who did not receive diuretics. This small sample of patients may have been outliers and a larger sample size is needed to fully understand the effect of diuretics.

Figure 17C demonstrates the trend in length of stay for patients receiving nitrates. The nitrates show a similar trend to the diuretics. Giving the patient nitrates in less than an hour after arriving in the emergency department may result in the shortest length of stay. The patients who were given nitrates both before entering the hospital and in the hospital appear to have had the longest length of stay. This may be the case because the patients who are given nitrates more than once are the patients who have the most severe symptoms and likely have been diagnosed with heart failure prior to this hospital stay.

However, the ANOVA for nitrates given affecting length of stay gave a P value of 0.235. This is again; not significant meaning that statistically there is no difference in the length of stay for patients given nitrates compared to people not given nitrates. However, this is the closest to a significant P value out of the three medicines. This may be because there was more data for patients not given medication.

The number of patients given nitrates was about equal to the amount of patients not given nitrates. This provides a much more accurate ANOVA than the other two medicines that had very small number of patients not given medicine.

Overall we were unable to demonstrate that the medicines given in the emergency room affect the length of stay for patients with heart failure. Due to the small sample size it is hard to accept this as final conclusion. There are trends that one can see for diuretics and for nitrates that show giving the patient these medicines early may help to decrease the length of stay. There are also many other factors that play into the patient receiving these medications. Additionally some of these patients may be feeling better because they also receive other medications along with those examined here.

4.6 Symptom Improvement: Assessment of patient Improvement

In addition to studying the length of stay of the patients, the patient improvement was also examined based on how the patients say they feel. Understanding how the patient responds to different medications depending on when they are given is important to understand the effects of medications. This is done by studying the 1 hour and the 3 hour global well being scale and comparing the difference between the two and the time medications was given. In the following graphs, the higher the bar the better the patient is feeling, or the most improvement was reported by the patient. The hypothesis is that the earlier the medication is given the better the patient will feel. This is shown in figure 18.

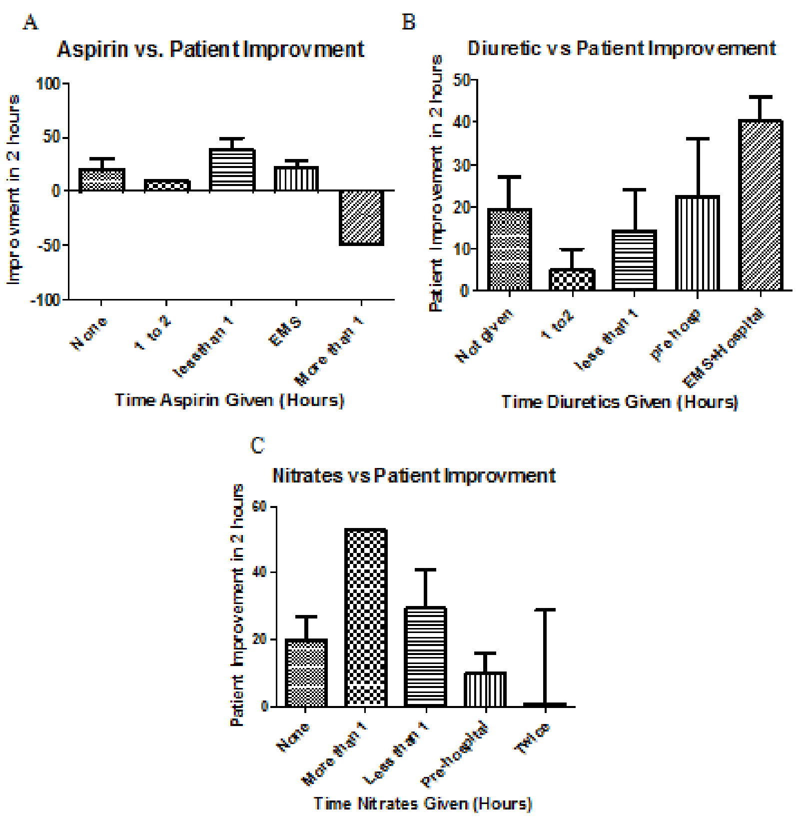


Figure 18: Time medicine administered affecting patient improvement within 2 hours

As well as examining the graphs of times that the medications were given ANOVAs were done to see if there was a significant difference in patient perceived improvement between if medication was given compared to if medication was not given, the P values from here are shown in Table 4.

Table 4: P values for the ANOVA of difference between medication given and medication not given on patient improvement

Medication	P Value
Aspirin	0.572
Diuretics	0.813
Nitrates	0.2098

The first medication examined was aspirin. The graphical representation shown in Figure 18A shows that the largest improvement was when aspirin is given in less than 1 hour. Aspirin could help the patient so that they are not in as much pain thus they believe they are doing better. The patients who were administered aspirin pre-hospital and the patients who were given medicine more than once could be those with the worst symptoms and, thus they were not feeling better in a short period of time. The P value for this was 0.84, indicating that whether the patient receive aspirin or not does not affect the patient improvement.

Figure 18B shows patient improvement based on the time that diuretics were given. The figure shows a trend that the more diuretics that are given as well as the earlier the diuretics are given the greater the patient perceived improvement was. This makes sense because the patient could have been feeling awful and the diuretics gave them a release of fluid. The more that is given and the more time it had to work would make the patient feel considerably better. However, the P value obtained was 0.80, indicating there was no demonstrable difference in patient improvement with patients receiving diuretics and patients not receiving diuretics.

Figure 18C examines patient improvement and time nitrates were administered. The figure shows the exact opposite of what was expected with the best patient improvement following administration more than 1 hour after arrival, and the least patient improvement being those receiving more than one dose of nitrates. The patients who received more than one dose of nitrates could be those with the worst pain resulting in their not feeling well regardless of medicine administered. The P value was found to be 0.80, again demonstrating no demonstrable difference in patient improvement when patients received nitrates compared to when patients did not receive nitrates.

Overall the data does not support the hypotheses. This is possibly because of the small sample size as well as the fact that the data is based on patient's opinion. The patient often does not know what they marked previously so often times they are feeling much better but they mark the same spot as the 1 hour mark or lower. There are also no hash marks defining 10, 20 and so on so it is hard for them to understand where they are placing their mark. Because of all of this the results need to be reassessed when more patients have been enrolled. However, the visual analysis did show specific trends that the earlier the diuretics and nitrates were given the better the outcome for the patients. The aspirin had little effect because it is more of a long term treatment for heart failure patients and would not provide immediate relief. Knowing this in the short term the researchers should continue to do as before while paying close attention to the diuretics and the nitrates, and the time they were administered.

The P values compared patient improvement in regards to if medicine was administered or not so it is not surprising that they did not result in a significant difference. This could simply mean the doctors are good at determining when it is important to give these medications and when they are really not needed. This helps the patient and also saves the hospital time and money.

4.7 Diuretic Use of Heart Failure Patients

To gain a better understanding of why diuretics showed the strongest trend in length of stay and especially patient improvement within 2 hours the urine output that diuretics created was analyzed. The patients who were not given diuretics did not have recorded urine outputs. It was determined that the patients who received diuretics more than once had the greatest urine output, up to 1,525ml with a median of 1266. The other two patients approximately the same median of about 850ml. This shows that the use of diuretics helps to produce urine output which can alleviate the fluid that is built up in the body. This also shows that the more diuretic that is administered the more urine is produced. When comparing this to the patient improvement it appears that the greater the output of urine the more the patient feels improvement.

4.8 Quality of Care

Hospitals success depends on the care that they provide patients as well as the efficiency of the emergency room. If patients are unsatisfied with their care, their dissatisfaction can reflect poorly on the hospital. Many patients become irritated if they perceive their stay in the emergency room was too long or they did not receive quality care.

To assess the quality of care, the patients were asked how they would rate the quality of care as well as how satisfied they were with the care. Overall, the patients stated that the care they received in the emergency room was good, with 39% of patients indicating that the care was excellent, 33% very good and 28% good. The patients were generally satisfied, with 94% either very satisfied or satisfied and the rest unsure. Overall the patients reported that they received good care and were satisfied with that care.

5. Major Conclusions and Recommendations

The enrollment criteria are the Framingham criteria. These criteria do have limitations, since it is not 100% accurate. It is possible that a patient does not have heart failure and then meet the requirements and it is also possible for a person with heart failure not to fit the criteria. The issue is that this criteria is known and accepted so despite the fact that it is not 100% accurate it is the best option to accurately identify heart failure patients.

The process of enrolling patients is important for the study, because enrolling the correct patients is crucial. Patients who aren't in heart failure are not necessarily just thrown away they can be compared to the patients who did actually have heart failure. This can be useful to see how sometimes patients can be incorrectly identified and possibly why. This study showed that with the small sample size the patients are predominantly female, have dyspnea, and that the doctor is typically correct. At this time there is not a better way to enroll patients. Patients who are male or who do not present with one of the main chief complaints should not be overlooked. There are numerous ways that heart failure can present and to have the most accurate outcomes for the study all of these patients need to be studied.

There was a trend with nitrates and diuretics that show giving the patient these two medications early can decrease the length of stay; however, aspirin did not show that it mattered when it was administered. These trends hopefully will turn into actual concrete results when the sample size increases. The patient improvement was seen mostly for diuretics when they were given a larger amount as well as when they were administered early. Aspirin also appeared to alleviate some of the patient's distress resulting in an improvement in 2 hours. Nitrates, however, did not appear to have an effect on patient improvement.

The P values were all not significant showing that if the patient received medicine or not did not affect their length of stay or as well as patient improvement. This could mean that the doctors in the emergency room are good at determining when they should and should not give medicine effectively saving the hospital time and money. The trends seem to show that it is important to the length of stay and patient improvement to give nitrates and diuretics early in the patients stay. Hopefully with further research it can be proven statistically.

As the study progresses the major recommendations are that the research assistants continue to pay close attention to the Framingham criteria to enroll the patients. It is also recommended that the research assistants enroll as many patients who present with shortness of breath who are female. These patients should most defiantly be enrolled if a doctor finds it likely or highly likely that they have heart failure, since it was shown that the doctors are often correct with their diagnostic impressions. The scales should also he altered. This could be something as simple as putting hash marks to identify a few numerical identifiers. This would help the patient understand a little better where they are marking the line on a scale of zero to 100. Another suggestion for the scales is that the patient is able to see their previous scales to allow them to remember what they had said as well as relate it to how they feel then to mark the appropriate value.

These findings will hopefully allow for better patient care as well as save the hospital money by decreasing length of stay. The results as they are now do not necessarily have an effect on these things, but hopefully with a larger sample size the trends that were seen to reduce length of stay will turn into concrete results. The trend of administering medications within the first hour of treatment could really help to decrease the length of stay and help to make the patient feel batter quicker.

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