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A Pilot Study: Observations of Patients Participating in Heart Failure Shared Medical Appointments while Receiving Nutrition Education

Hannah Hugo
Central Washington University, hugoh@cwu.edu

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A PILOT STUDY: OBSERVATIONS OF PATIENTS PARTICIPATING IN HEART
FAILURE SHARED MEDICAL APPOINTMENTS WHILE RECEIVING NUTRITION
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Graduate Studies

We hereby approve the thesis of

Hannah Hugo

Candidate for the degree of Master of Science

APPROVED FOR THE GRADUATE FACULTY

Professor Dana Ogan, Committee Chair

Dr. Tim Englund

Megan Hodges, PharmD

Dean of Graduate Studies

ABSTRACT

A PILOT STUDY: OBSERVATIONS OF PATIENTS PARTICIPATING IN HEART FAILURE SHARED MEDICAL APPOINTMENTS RECEIVING NUTRITION EDUCATION

by

Hannah Hugo

May 2020

The purpose of this pilot project was to examine descriptive statistics from patients who participated in heart failure (HF) shared medical appointments (SMAs) at a mid-sized heart center in the Northwest, in which nutrition education was provided by an RD. Information collected included blood pressure (BP), heart rate (HR), weight, scores from the Minnesota Living with Heart Failure (MLHF) Survey, and the Atlanta Heart Failure Knowledge (AHFK) questionnaire. Due to small sample size and lack of control group, simple descriptive statistics, such as mean and median were used to examine the data. Three of the participants were female and 4 were male. Five patients in this group had a diagnosis of HF with reduced ejection fraction (HFrEF), and two patients had a diagnosis of HF with preserved ejection fraction (HFpEF). Average weights of the participants ranged from 171.4 lbs to 339.6lbs. Quality of life (QOL) for this group of patients was diverse, average MLHF scores ranging from 0.4-78.3. The 3 lowest scores on the MLHF questionnaire and the 3 lowest average HRs were observed in the 3 patients (21, 22 & 32) who had the lowest recorded weights in the group (<200lbs). The

2 highest average BPs were observed in the 2 patients (20 & 25) with HFpEF. One limited potential trend that was detected within this data was that the 3 patients with average weights <200lbs appeared to have lower MLHF scores (indicating higher QOL), as well as lower HRs, than the 4 patients with weights >200lbs.

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CHAPTER 1

A PILOT STUDY: OBSERVATIONS OF PATIENTS PARTICIPATING IN HEART FAILURE SHARED MEDICAL APPOINTMENTS WHILE RECEIVING NUTRITION EDUCATION

Introduction

Heart Failure (HF) contributes about \$30.7 billion to healthcare costs annually, and impacts approximately 5.7 million Americans (Centers for Disease Control and Prevention [CDC], 2019). HF is a type of heart disease, which falls under the umbrella term: cardiovascular disease (CVD), which includes any disease or condition impacting the cardiovascular system (“What is Heart Failure,” 2017). The heart is the driving force of the circulatory system, and is responsible for pumping blood sufficiently to support the rest of the body (Heart Failure, n.d). When its ability is restricted, it can result in HF (“What is Heart Failure,” 2017). HF can be divided into 3 types: left sided HF, right sided HF, and congestive HF (CHF), often referred to as just HF. Once a HF diagnosis is made, the severity of HF (class I - class IV) is determined, based on the symptoms that an individual displays, as well lab tests/imaging (“Classes of Heart Failure”, n.d). Risk factors that can contribute to the development of HF include: coronary artery disease (CAD), high blood pressure/hypertension (HTN), diabetes (DM), smoking, a high sodium, high cholesterol, and high saturated fat diet, lack of physical activity, as well as obesity (CDC, 2019).

Treatment for HF includes a combination of medical and lifestyle approaches. Medications are used to help control underlying diseases, such as HTN, CAD, and DM, to decrease overall stress on the heart. Lifestyle changes, such as increasing physical

activity and changing dietary patterns, are also recommended. The 2015-2020 Dietary Guidelines recommend that a person consuming a 2,000 calorie diet should have: 2 ½ cups of vegetables, 2 cups of fruits, 6oz of grains (half of which are whole grain), 3 cups of low fat or fat free dairy, 5 ½ oz. protein, 5 tsp of non-tropical oils, and sugar and saturated fats should be limited (A Closer Look Inside, n.d). The American Heart Association (AHA) also emphasizes those same foods, as well as incorporating nuts and legumes, reducing added sugars, and limiting sodium consumption to 1,500-2,300mg/day. The AHA recommends the DASH (Dietary Approaches to Stop Hypertension) diet as a suitable diet for Americans to follow, as it includes all of the recommended components (The American Heart Association Diet and Lifestyle Recommendations, 2017).

In 2016, the American Heart Association reported that, despite survival rates increasing, about half of those diagnosed with HF will not live past 5 years (Mozaffarian et al., 2016). Therefore, it is evident that additional interventions should be assessed regarding the maintenance of this disease. One proposed method is through shared medical appointments (SMAs). An SMA is typically a small group of approximately 10-15 patients, all with the same or related medical diagnosis/condition. These patients are seen by a multi-disciplinary medical team consisting of a nurse, a doctor, a pharmacist, and sometimes a dietitian. Together the patients share their experiences, concerns, questions, and discuss past stories with the SMA group (Shared Medical Appointments, n.d). SMAs are considered to be most beneficial for patients with chronic conditions, such as diabetes, HTN, asthma and heart disease/ HF (Shared Medical Appointments, n.d). In their 2016 article, Smith et al. found that a group of 92 patients involved in a HF

SMA rated the appointments highly and reported that the discussions and sharing stories and points of view was one of the most beneficial ways to help with the management of HF. Additionally, it was found that there was a decrease of 33% in re-hospitalizations due to HF compared to the control group (Smith, 2015). Shared medical appointments are a newer concept for the maintenance of chronic health conditions, and while there is research supporting the use SMAs, there is limited research available regarding the potential benefits of adding a Registered Dietitian (RD) to the SMA team. When considering the research regarding SMAs and nutrition education, there are a few gaps in the literature that future research can shed some light on. The mode that nutrition education is provided, either by an RD or other healthcare provider, is one gap that has not been extensively studied. Further research is warranted to determine if RD provided nutrition education might provide additional benefits to patients. Another area for further research is the influence of the consistency and duration of nutrition education provided.

In a 2014 study, Smith et al. followed an intervention and a control group for 1 year. The SMA group received self-management education, which covered a variety of topics, for 4 weeks, and then once more at the 6 month mark. For the standard care group, the participants received education after discharge, a phone call, and then one more follow up within 1 month. Some promising results were observed, such as the SMAC-HF (Self- Management & Care of Heart Failure) group rated the meetings very positively. However, the researchers also noted that more research is needed regarding the benefits of “additional booster sessions,” or consistency of education provided over a 12-month period of time (Smith et al., 2014). In 2016, Smith et al., reported outcomes after 72 appointments between the intervention group and the control group, finding similar

results as the 2014 study. They also found decreases in hospitalizations in the group clinic patients group versus the group that received standard care (Smith et al., 2015). While this study looked at the effects of consistent education over a 12 month period, the education was varied, and did not provide extensive nutrition education, beyond following a low sodium diet, managing fluids, and providing a recipe book (Smith et al., 2015).

As the number of HF diagnoses continues to rise, and dietary intake remains one of the main lifestyle focuses for controlling risk factors (cholesterol, HTN, type two diabetes, CAD) that impact HF outcomes, it is important that extensive nutrition education is incorporated into group medical appointments. Therefore, the purpose of this pilot project is to collect and report descriptive statistics from participants who participated in HF SMAs, in which nutrition education was provided by an RD.

CHAPTER II

LITERATURE REVIEW

Anatomy/ how heart works

In order to better understand the etiology, diagnosis, treatment and prevention of HF, the anatomy and physiology of the heart must first be discussed. The circulatory system consists of the heart, the arteries, the capillaries, the veins, the blood vessels, and the blood (“How the Heart Works,” n.d.). The driving force of the circulatory system is the heart, which is made up of 4 chambers. Within those chambers lies the right and left atriums, the pulmonary, aortic, tricuspid, and the mitral valves, along with the right and left ventricles. The main function of the heart is to pump blood throughout the body, delivering nutrients and oxygen to the organs. The heart is connected to the circulatory system by association to veins and to arteries (“How the Heart Works,” n.d.) and the direction of blood flow is managed by the opening and closing of valves (“How the Healthy Heart Works, n.d). De-oxygenated blood flows from the body to the heart’s right atrium, and from the right atrium, it travels down to the right ventricle, by the opening of the tricuspid valve (“How the Healthy Heart Works, n.d).When the pulmonary valve opens, blood travels from the right ventricle to the pulmonary artery, where it can be sent to the lungs for oxygenation. After oxygenation, blood travels back to the heart’s left atrium via the pulmonary veins. The blood is sent to the left ventricle via the mitral valve, and from there the blood can be sent to the aorta and back into circulation (“How the Healthy Heart Works, n.d).The flow of blood through the heart (the cardiac cycle) can be divided into 2 categories, systole and diastole (Fukuta & Little, 2009). Systole occurs when the heart contracts and ejects, and diastole occurs when the heart goes through “isovolumetric relaxation, early diastolic filling, diastasis, and atrial filling” (Fukuta &

Little, 2009). In an individual with no heart complications, the heart is able to fill, empty and contract adequately (Fukuta & Little, 2009), and is strong enough to pump blood at a sufficient rate to support the body (“How the Heart Works,” n.d). HF occurs, not when the heart ceases to pump blood, but when the ventricles of the heart are unable to pump enough blood to maintain the function of the body’s organs (Nelms, 2011, p. 326).

Heart Failure & Diagnosis

Heart Failure, along with myocardial infarction, dilated cardiomyopathy, mitral valve regurgitation and prolapse, and congenital heart failure, is a type of heart disease, which falls under the overarching term: cardiovascular disease (Felman, 2020). HF occurs when the heart becomes weak and is not able to pump sufficient amounts of blood, containing oxygen and nutrients, to support and sustain proper functioning of the body (CDC, 2019). There are three types of HF, left-sided HF, right-sided heart failure, and congestive HF (which is often referred to as just heart failure) (“Types of Heart Failure, n.d). There are two types of left-sided HF, systolic and diastolic HF. Right sided HF is generally a consequence to left-sided HF, which results in fluid and pressure build-up, leading to damage of the right ventricle. When the right ventricle is unable to pump adequately, it leads to blood building up in the veins, and thus swelling occurs.

Congestive HF (CHF) occurs when blood flow is decreased, which results in slow return of blood back to the heart; this leads to congestion in the tissues, and fluid build-up in the lungs, resulting on shortness of breath (SOB) and edema (“Types of Heart Failure, n.d).

As HF cannot be diagnosed by labs values alone, a physician must acquire a physical examination, past medical history, chest radiography, blood labs, signs, symptoms, and especially, an echocardiogram (King et al., 2012). The signs and

symptoms of HF can include stomach, foot, leg, or ankle edema, along with weight gain. Individuals with HF may also experience difficulty breathing while performing every-day tasks or if lying down (CDC, 2019). When classifying HF, the New York Heart Association Functional Classification is generally used to classify an individual's symptoms. There are four classes of patient symptoms and four classes of objective assessment, as displayed in Table 1. Therefore, the HF classification is based on symptoms that the patient experiences, and "objective evidence" observed by the practitioner ("Classes of Heart Failure", n.d)

TABLE 1: New York Heart Association Functional Classification	
Class	Symptoms
I	Physical activity is not limited, and does not result in fatigue, dyspnea, or palpitation.
II	Physical activity is slightly limited, but the individual is comfortable when resting. Regular physical activity results in fatigue
III	Physical activity is limited, but resting is comfortable.
IV	Inability to participate in physical activity, without feeling discomfort. At rest, HF symptoms are present.
Class	Objective Assessment
A	CVD objective evidence is not present. The individual has no symptoms or physical activity limitations
B	CVD evidence is limited. Individual experiences symptoms which are mild and slightly decrease exercise ability
C	Objective assessment shows moderately severe evidence of CVD. Physical activity is decreased due to symptoms.
D	CVD evidence is severe, and the individual experiences excessive limitations, even when resting.

Note: Reprinted from "Classes of Heart Failure," <https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure>, 2020 By AHA.

Ejection Fraction/Systolic & Diastolic Function.

The main force behind the heart's pumping action, is the left ventricle. The heart's level of function can be evaluated by its ejection fraction (EF) percentage ("Understanding Heart Failure," n.d). Ejection fraction is a ratio, comparing the heart's stroke volume to its end-diastolic volume, which depicts how well the left ventricle is emptying (Fukuta & Little, 2009). In a 2013 article, Komaura discusses support for the hypothesis that HF is a "single syndrome" and that diastolic HF and systolic HF are two "phenotypes" at each end of a spectrum (Komaura, 2013). HF with preserved ejection fraction (HFpEF) is considered diastolic HF, and HF with reduced ejection fraction (HFrEF) is considered systolic HF (Komaura, 2013). In the case of systolic HF, inadequate amounts of oxygenated blood is delivered to the body, as the heart lacks sufficient pumping strength (Cleveland clinic). In the case of diastolic HF, the heart is able to pump and contract with the right amount of strength, but both ventricles are inflexible, dense ("Understanding Heart Failure," n.d) and unable to relax (King et al., 2012). This results in inadequate amounts of blood filling the ventricle, and a lack of "end-diastolic pressure," (King et al., 2012) which leads to a lack of blood being delivered to the body ("Understanding Heart Failure," n.d).

Causes/Risk factors for Heart Failure

The results of diastolic and systolic HF occur when the heart has to compensate in response to stressors. The heart adapts to the stress when the angiotensin-aldosterone system and the sympathetic nervous system are recruited, which initiate an increase in: blood volume, blood pressure, stroke volume, as well as cardiac output. (King et al., 2012). The stressors can include a number of underlying causes, many of which are

impacted by dietary choices. Underlying causes that put stress on the heart include coronary artery disease (CAD), high blood pressure (HTN), diabetes mellitus (DM), valvular heart disease, lack of physical activity, smoking, as well as obesity (King et al., 2012).

Coronary Artery Disease

Coronary artery disease is the contributing factor to more than half of people diagnosed with systolic HF (King et al., 2012). Coronary artery disease develops when the endothelial layer of the artery becomes damaged, resulting in lesions. Damage to the endothelial layer can be caused/agitated by excess lipids, cytokines, advanced glycation end products (AGEs) caused from uncontrolled diabetes, and from the release of hormones associated with vasoconstriction, in relation to HTN. Plaque develops when the adhesions fill with leukocytes (Libby & Theroux, 2005), cholesterol, calcium, fat, and other molecules (“Atherosclerosis,” n.d). As the plaque builds up, it results in the artery becoming narrower, which decreases the radius in which blood is able to flow through and thus, less blood flow to the body’s organs (“Atherosclerosis,” n.d).

Hypertension

One of the biggest risk factors for cardiovascular complications and HF is HTN. In The Framingham Heart Study, “Lifetime Risk for Developing Congestive Heart Failure,”—which followed 3,757 women and 4,472 men— Lloyd-Jones et al. reported that for women, HTN can be attributed to 59% of congestive HF (CHF) risk, and for men, the number is 39% (Lloyd-Jones et al., 2002). High blood pressure puts an individual at risk because it can cause damage to the blood vessels, the arteries and to the heart (“High Blood Pressure,” n.d). When the heart is exposed to too much pressure or

volume for a long period of time, it changes and damages the heart, leading to the development of HF (Messerli, et al., 2017). The “overload” of pressure results in an increase in size of the left ventricle, as that is the compensatory mechanism used to accommodate the higher pressure of blood. This results in worsened diastolic function, and thus leads to diastolic HF (HFpEF) (Messerli et al., 2017). Consequently, when blood volume has exceeded its normal level, the left ventricle has to stretch further, resulting in left ventricle deterioration, therefore, leading to systolic HF (HFrEF) (Messerli et al., 2017). HTN is diagnosed when systolic blood pressure is ≥ 140 mm Hg or when diastolic blood pressure is 80-89 at two different doctor’s visits (“High Blood Pressure,” n.d). There are two types of HTN, primary HTN and secondary HTN. Primary HTN progresses over an extended period of time, such as part of the aging process, and secondary HTN can be a result of certain medication or a consequence following another medical diagnosis (“High Blood Pressure,” n.d). HTN can be classified into 4 different stages, as displayed in Table 2 (New acc/aha, 2017).

Table 2: Stages of HTN	
Blood Pressure	Reading
Normal	$\leq 120/80$ mm Hg
Elevated	120-129/ ≤ 80 mm Hg
Stage 1	130-139/80-89 mm Hg
Stage 2	$\geq 140/ \geq 90$ mm Hg
Hypertensive Crisis	$> 180/ >120$ mm Hg

Note: reprinted from New ACC/AHA High Blood Pressure Guidelines Lower Definition of Hypertension <https://www.acc.org/latest-in-cardiology/articles/2017/11/08/11/47/mon-5pm-bp-guideline-aha-2017>, 2020 American College of Cardiology Foundation.

Table 3 displays the 4 stages of damage or dysfunction that the heart can endure resulting from high blood pressure (Messerli et al., 2017).

Table 3: Stages of Heart Dysfunction	
Stage 1	Impairment of the left ventricle functioning, but no presence of heart enlargement
Stage 2	The left ventricle becomes enlarged, in addition to impairment of left ventricle functioning.
Stage 3	Occurs when the person is diagnosed with diastolic HF (HFpEF).
Stage 4	Occurs when there is unusual enlargement of the left ventricle along with systolic dysfunction (HFrEF)

Note: reprinted from The Transition From Hypertension to Heart Failure: Contemporary Update By Messerli et al 2017 By Elsevier
<https://www.sciencedirect.com/science/article/pii/S2213177917303177?via%3Dihub>

While there are some non-controllable risk factors, such as family history, age, sex, race and genetics, HTN can often be prevented, or nonetheless partially controlled through lifestyle changes. Lifestyle changes include following a diet rich in fruits and vegetables, participating in regular exercise, smoking cessation, and weight control (“High Blood Pressure,” n.d). Medication may also be used to relieve some of the volume overload, and thus reduce pressure.

Diabetes

Another underlying factor that can contribute to the development of HF is uncontrolled diabetes (DM). There are several types of diabetes, the main two being type 1 and type 2 diabetes. Type 1 DM makes up about 10% of the cases and usually develops early on in life. Type 1 DM is an autoimmune disease where the pancreas stops producing insulin as a result of β -cells destruction (Palicka, 2002). Type 2 DM makes up the other 90% of DM cases, and is characterized by insulin resistance, which can arise as a consequence of certain lifestyle choices and other factors (Palicka, 2002). When the body is not able to produce insulin, or adequate amounts of insulin, the body does not

recognize that there is glucose available to use; this results in excess glucose in the blood (hyperglycemia). In the article “Diabetes and Advanced Glycation End Products,” Vlassara and Palace discuss the negative consequences that long term hyperglycemia can have, and how it can lead to the development of heart disease. When DM is uncontrolled and hyperglycemia is present over an extended period of time, it leads to the development of advanced glycosylated end products (AGEs), which are believed to be a principal factor in the progression of complications associated with diabetes (Vlassara & Palace, 2002). When glucose concentrations are high in the blood, there is an increased risk that molecules, such as lipids and protein, will bond with the glucose (glycosylation). When those molecules become glycosylated, it can interfere with how the body recognizes and manages those molecules (Vlassara & Palace, 2002). One example of this is when apoprotein B (ApoB) is glycosylated. In the article “Glycosylation End Products Blocking Uptake by the Low Density Lipoprotein Receptor,” Bucala et al. (1995) found that when apoB is glycosylated, its functioning becomes modified, and the “ability of LDL to undergo receptor-mediated uptake and degradation” is altered. As the disposal of LDL becomes reduced, and the amount of LDL circulating in the blood is elevated, it puts the individual at risk for atherosclerosis (CAD), as excess lipids can contribute to the development and progression of plaque build-up, and thus a narrowing of the artery (Bucala et al., 1995).

Treatment of Heart Failure

Treatment of HF includes a combination of both medical approaches and lifestyle changes. As HF is a chronic condition, the goals of therapy are to help the patient manage his or her symptoms, which generally stem from underlying medical diagnoses such as

diabetes, CAD, and high blood pressure, which all cause the heart to work harder (“Treatment Options For Heart Failure,” n.d). Management for HF includes the use of medications, along with a set of dietary and lifestyle recommendations, which can vary depending on underlying medical diagnoses, class of HF the patient is diagnosed with, and the clinical signs and symptoms present (Yancy et.al., 2013). For example, Yancy et al. state that sodium recommendations for different stages of HF may differ, and that while heavily restricted sodium for some stages of HF may be beneficial, there is limited research as to how much of a sodium restriction is beneficial for other stages of HF (Yancy, et.al, 2013). While in patients with a diagnosis of diabetes, the goal is to control blood glucose levels and prevent hyperglycemia, which includes its own medication and dietary protocol (Yancy et al, 2013).

Some of the most common medications used for managing HF include diuretics, (CDC, 2019) ace inhibitors, aldosterone antagonists, angiotensin receptor blockers, beta blockers, digoxin, and isosorbide dinitrate/hydralazine hydrochloride (“Heart Failure,” n.d). Diuretics help the body eliminate excess build-up of fluid in the body. Ace inhibitors are utilized to help decrease high blood pressure, which causes the heart to work harder. Aldosterone antagonists help the body to get rid of extra sodium, which can be passed through the urine. (“Heart Failure,” n.d).As the blood’s volume lessens, so does the amount of work the heart has to do to, in order to pump blood through the body. Angiotensin receptor blockers reduce blood pressure by helping blood vessels to relax. Beta blockers also help reduce blood pressure, by decreasing the rate at which the heart beats. Digoxin is used to strengthen the heart’s beat, allowing it to pump a larger amount

of blood throughout the body. Isosorbide dinitrate/hydralazine hydrochloride helps blood vessels to relax, decreasing the heart's work ("Heart Failure," n.d).

If patients still experience difficulty with managing their HF symptoms, additional medical treatment options include a pacemaker or an implantable cardioverter defibrillator (ICD). A biventricular pace maker is used to help both sides of the heart pump at the same time and an implantable cardioverter defibrillator (ICD) is used when the heart beats are fast and irregular, which if not treated, can result in cardiac arrest ("Heart Failure," n.d). If those treatment options do not work, a mechanical heart pump may be utilized, which aids the heart with its task of pumping blood throughout the body. If all interventions do not suffice, a heart transplant may be a final mode of treatment ("Heart Failure," n.d).

Lifestyle recommendations for HF often include incorporating physical activity, depending on what the patient can handle, (CDC, 2019), and adhering to the AHA dietary recommendations. The AHA recommends limiting dietary sodium intake 1,500-2,300mg/day, limiting saturated fat, alcohol consumption, and sugar, and increasing fruit and vegetable consumption for increased fiber intake (CDC, 2019), (The American Heart Association Diet and Lifestyle Recommendations, n.d). As lifestyle changes can be overwhelming and difficult to adhere to, meeting with a Registered Dietitian (RD), or participating in a support group or a shared medical appointment (SMA) can be helpful and encouraging when making those changes (Heart disease-CDC). In fact, many studies have reported that number of hospitalizations rise when HF patients do not have adequate support from others (Yancy et.al., 2013). Therefore, group appointments such as SMAs can be a practical for patients with HF.

Impacts of Diet

While the physiological impacts of certain medical diagnoses, such as CAD, HTN and diabetes, can induce inflammation, putting stress on the heart, one significant risk factor that cannot be overlooked is the association between dietary habits and HF. There are different perspectives as to how diet can impact the heart's function. Research has been done to determine the impacts of consuming specific food groups, such as meat, fruits and vegetables, as well as the impacts of consuming specific macro or micronutrients such as fat, cholesterol and sodium. Some research has also observed the effects of when a specific diet regimen is followed, such as a vegetarian, Mediterranean, or the DASH diet and past literature show trends that a diet, high in fat, cholesterol, and sodium, and low in fruits and vegetables, can increase an individual's risk for HD and HF, and can negatively impact the outcomes of those already diagnosed with HD and HF. Nutrition related research regarding HF outcomes has examined the effects of single nutrients, such as saturated fat and sodium intake, as well as dietary regimens such as the DASH and Mediterranean diets. While the research may be inconsistent, and highly debated, the AHA dietary guidelines remain as such: eat a diet that includes a variety of fruits and vegetables, whole grains, low-fat dairy products, lean meat, nuts and legumes, non-tropical vegetable oils, and limit the amount of trans fat, saturated fat, red meat, sweets, and sodium (AHA). While some components of the recommendations are still debated (saturated fat, red meat, and sodium intake), currently enough quality evidence exists to influence the recommendations. Therefore, when providing extensive nutrition education to HF patients, an educator must be knowledgeable regarding the literature that has influenced the current recommendations.

Saturated Fat & Cholesterol

The correlation of saturated fat and heart disease dates back as early as 1957, when Keys et. al reported a positive influence of saturated fat intake on cholesterol levels and the risks and outcomes of heart disease (Dietschy, 1998). As research has progressed, high dietary intake of saturated fats has continued to show negative health consequences regarding heart disease and HF outcomes. For the last 25 years, epidemiologic studies have indicated that dietary fat intake has a positive correlation with cholesterol and coronary heart disease (CHD) mortality (Dietschy, 1998). The 2015-2020 Dietary Guidelines recommend to limit saturated fat to <10% of total calories (“A Closer Look Inside, n.d), and the American Heart Association recommends that saturated fat should only make up only 5-6% of total daily calories (“The American Heart, n.d). However, despite the recommendations that saturated fat intake should be limited, and the body of evidence that supports it, there is still conflicting research, making the impacts of saturated fat on heart disease a controversial issue. For example, Ascherio et al. discuss the relationship between coronary heart disease incidence and dietary fat & saturated fat intake. After observing the effects, it is reported that a diet high in cholesterol and saturated fat is linked to coronary disease and increases that risk. However, they also state that those effects may be partially explained by a diet that is also low in fiber. The findings conclude that although the positive benefits of decreasing saturated fat and cholesterol intake decreases heart disease risk, it may not have quite as big of an impact as when those changes are followed by increasing the consumption of fiber rich foods. Ascherio et al. emphasize that prevention for coronary disease should consist of a variety of dietary components, including decreasing saturated/trans fats, decreasing cholesterol,

as well as increasing foods that are high in fiber, such as fruits and vegetables (Ascherio et al., 1996).

In the article “The Role of Lipids and Lipoproteins in Atherosclerosis,” Linton et al. (2019) discussed how cholesterol contributes to plaque build-up in the arteries and how it can be directly related to atherosclerosis (CAD) development. When there are high levels of LDL-cholesterol (LDL-C), as well as the main LDL protein, apolipoprotein B (apoB) 100, it increases the risk of cardiovascular problems that are related to atherosclerosis. For example, lipoproteins that contain apoB can penetrate and reside inside the wall of the artery, and can initiate the “inflammatory response that promotes the development of atherosclerosis” (Linton et al., 2019). When high levels of inflammation are not resolved, it can lead to the build-up of plaque (Linton et al., 2019). As LDL-C is a major impactor for the development of CAD, and CAD is a critical underlying risk factor for HD and HF, it is important that health professionals remind these patients of the importance of monitoring LDL-C concentrations in the body. However, the overall effect of total cholesterol (TC) concentrations and the impact on HD & HF continues to be controversial.

As some studies have reported that low cholesterol levels may result in worse CHF outcomes, and greater risk of mortality, this has been an area for research (Sakatani et al, 2005). Sakatani et al. investigated the effects of cholesterol levels on CHF patients. They divided the patients into 2 groups; one group included the patients diagnosed with CAD, and the other group included those without a CAD diagnosis (Sakatani etval., 2005). In this study, they reported that total cholesterol (TC) concentrations were not significantly different between those who survived and those who didn’t survive at the

time of follow up, when considering the patients in both groups. However, when each group was analyzed separately, they found some differences. For example, in the CAD group of patients, LDL and TC were lower in those who survived vs those who didn't (Sakatani et al., 2005). As for the patients without CAD, they reported that when TC was low, it was linked to a poorer outcome. They concluded, that while TC is important for forecasting CHF outcomes, patients with a diagnosis of CAD should be assessed differently than if CAD is not an underlying risk factor (Sakatani et al., 2005). In addition to the fact that underlying diseases, such as CAD, can impact cholesterol and fat recommendations for patients, some studies have looked at how types of LDL cholesterol may impact outcomes.

In the article, "The Evidence for Saturated Fat and for Sugar Related to Coronary Heart Disease," DiNicolantonio, Lucan, and O'Keefe (2015) discuss how the size of LDL cholesterol particles, such as small dense ones as opposed to ones that are larger and more buoyant, may be something to consider with regards to CHD outcomes (DiNicolantonio et al., 2015). They state that LDL that is smaller and denser is more vulnerable when it comes to oxidation, and that those types of particles are more likely to produce inflammation than more buoyant/large LDL (DiNicolantonio et al., 2015). In addition, St-Pierre et al. found, that LDL that was smaller and denser indicated an increased Ischemic Heart Disease (IHD) risk during a follow up, after a short period of time of about 7 years. They also noted that larger LDL particles were not indicative of an increased IHD risk in men (St-Pierre et al., 2004). As there has been some fascinating research illustrating the complexity to this issue, it is generally not knowledge that patients have the time and energy for. While some foods may produce cholesterol that is

denser or more buoyant, it is much simpler to just focus on reducing cholesterol containing foods.

Sodium

In addition to saturated fat and cholesterol, sodium is a key nutrient of interest when it comes to HF lifestyle recommendations. Sodium is a necessary mineral/electrolyte for the body; it helps manage fluid balance, and aids in proper function of muscles and nerves (Lewis, 2018). However, when too much sodium is consumed in the diet, it can lead to increased blood volume, which makes it harder for the kidneys to filter. When the kidneys are challenged to filter excess blood, it can decrease their ability to eliminate toxins and excess fluid that resides inside of cells, and the excess blood volume then puts pressure on the heart (“How salt can impact your blood pressure, heart and kidneys,” 2017). While the AHA recommendations still hold that sodium should be restricted to 1,500-2,300mg per day (The American Heart Association Diet and Lifestyle Recommendations, n.d) there continues to be conflicting evidence as to how large an impact sodium consumption has on cardiovascular outcomes. It has been noted that some of the controversial results regarding sodium’s impact on the development of high blood pressure may be due to the fact that some people are considered “salt-sensitive” and others “salt –resistant” (Morris et al., 2016). While some studies have found that there is no significant association regarding negative cardiovascular outcomes and sodium intake, there is enough compelling evidence that has influenced the recommendations to remain as they are. Reduced sodium consumption continues to be a major controllable risk factor for the development of HTN and to prevent poorer cardiovascular outcomes. According to the World Health Organization (WHO), about

13% of deaths around the world are a result of HTN, which is strongly impacted by sodium intake (“Global Health Risks, 2009). Therefore, as HTN is considered a major risk factor for HF & negative outcomes, it is important to understand the research that has influenced sodium recommendations.

In 2013, Aburto et.al performed a meta-analysis using “36 randomized controlled trials,” and concluded that systolic and diastolic blood pressure is significantly decreased when dietary sodium intake is reduced (Aburto et al., 2013). They found that systolic blood pressure was reduced by 3.39mmHg, and diastolic blood pressure was reduced by 1.54mmHg (Aburto et al., 2013). The results of this study mirrored those from previous systematic reviews, which also have concluded that lower sodium consumption decreases blood pressure in both individuals with and without HTN. In one of the first prospective studies, He, et.al discovered a “strong and independent relationship between dietary intake of sodium and increased risk of CHF in overweight persons” (He et al, 2002). This study included 5,233 non-overweight individuals and 5,129 overweight individuals. After a 5-10 year follow up, the researchers found that as quartile of sodium intake went up, so did the risk of CHF, but the percent of risk for each quartile was higher in the overweight group. They concluded that sodium intake in overweight individuals was significantly associated with CHF risk, but not in non-overweight individuals (He et al., 2002). In addition to leading to negative CHF and CVD health outcomes, studies have also reported that higher sodium intake can lead to higher risks of stroke and stroke mortality. In 2018 a meta-analysis of 16 prospective cohort studies was conducted and the researchers reported the outcomes of sodium consumption and CVD outcomes (Zhu et al., 2018). The individuals in the study were followed up between 3.5 and 19 years. After

the follow up, researchers found that the results regarding sodium intake and CVD outcomes are mixed. They also saw a trend: increased sodium intake is associated with an increased risk of stroke and stroke mortality. As with the previous studies, Zhu et al. also reported that there was a trend regarding high sodium intake and CVD, but that this was only observed in the overweight individuals, not the non-overweight individuals (Zhu et al., 2018). It is evident that there is still controversy regarding this topic. But, as there is a continued strong association between high sodium intake and negative health outcomes, the recommendations have not changed and healthcare professionals continue to encourage reducing dietary sodium intake.

The effects of single nutrients such as saturated fat, cholesterol, and sodium can contribute to adverse cardiovascular health outcomes, but those effects are not so black and white. Managing cardiovascular health, and overall health depends on more than single nutrients or single lifestyle habits. The AHA recommendations for managing HF include a variety of dietary changes for a reason, and many studies, such as one done by Mente et al., suggest that the total dietary composition should be focused on, not just single foods or nutrients (Mente et al., 2009). Therefore, many different types of dietary regimens have been studied, such as vegetarian type diets, Mediterranean diets, and the DASH diet.

DASH diet

The DASH diet began in the 1990's, with an objective to determine how diet impacts the outcome of HTN (Challa et al., 2019). The DASH diet was inspired by studies that discovered an association between vegetarian type diets and a reduction in blood pressure (Kerley, 2018). Following the DASH diet includes reducing the

consumption of animal proteins, sugar, fat and highly processed foods. The diet emphasizes consumption of wholegrain carbohydrates, a variety of fruits and vegetables, nuts, seeds, as well as fish and lower fat dairy products (Kerley, 2018). The diet recommends 5 servings of vegetables, 5 servings of fruit, 7 servings of carbohydrates, 2 servings of low-fat dairy products, ≤ 2 servings of lean meat daily, and incorporating seeds and nuts 2-3 times throughout the week (Challa et al., 2019). In one of the earlier studies, “A Clinical Trial of the Effects of Dietary Patterns on Blood Pressure,” Appel et al. studied 459 adults that were assigned to one of three diet groups. The groups consisted of a control diet, a diet with increased amounts of vegetables and fruits, and a “combination diet” which was low in fat and saturated fat, contained low-fat dairy products, and incorporated lots of vegetables and fruits. All participants began the study consuming a control diet for a 3 week period, and then had blood pressure measurements taken. Then, the participants were appointed to one of the three diets, and continued with that diet assignment for a total of 8 weeks, with periodic blood pressure (BP) measurements taken. The amount of sodium for each diet was around 3,000mg/day. After study completion, the researchers found that the group with increased fruits and vegetables had BP reductions of -2.8mmHg for systolic and -1.1mmHg for diastolic BP. The combination diet showed the greatest improvements, of -5.5mmHg and -3.0mmHg for systolic & diastolic BP, when compared to the control group. It is also noted that the participants in this study, whom were diagnosed with HTN, had comparable reductions in blood pressure to other trials using “drug monotherapy” to treat HTN (Appel et al., 1997). In another study, researchers reported results that linked adherence to the DASH diet to a reduction in HF incidence (Levitan et al., 2009). The study looked at 36,019

women from ages 48-83, who had no history of heart disease or diabetes. The participants filled out food diaries, which were then scored based on how each food item compared to the DASH diet, and how close the person's intake was to 2 specified food/nutrient guidelines. The participants with higher scores had diets that were more similar to the DASH diet than the participants who had lower scores. After confounding factors were controlled for, the researchers found that the individuals whose diets were closer to the DASH recommendations had a "37% lower incidence of HF," in comparison to participants who had lower scores (Levitan et al., 2009).

Heart Failure and Shared Medical Appointments (SMAs)

When considering the numerous potential medical diagnoses, and various lifestyle habits that can lead to the development or worsening of HF, it is no wonder this issue has continued to grow. The AHA dietary recommendations for managing HF are extensive. The recommendations include variety because the literature has indicated that the management of this disease does not solely depend on a few specific food choices or avoidances, but that the best outcomes arise when individuals include a variety of changes. As uncontrolled HTN, DM, and CAD, can all contribute to HF, and all have recommended dietary and lifestyle recommendations, it is understandable how individuals can have difficulty with dietary adherence. Not to mention, many of these patients have more than one underlying disease risk, and often take multiple medications. Therefore, due to the complexity of this disease, one method that is increasing popularity regarding treatment regimens is the concept of shared medical appointments (SMAs).

What are SMAs?

The concept of group visits was created in Northern California at Kaiser, in 1996, by a doctor named Edward Noffsinger, PhD, who started what was known as “the drop-in group medical appointment model” (Stein, 2011). As time has progressed, increasingly more medical organizations have implemented group visits for patients, as it can help to not only reduce costs, but also increases productivity (Stein, 2011). The difference between SMAs and support groups, is that SMAs have a medical and educational component. An SMA can have a wide range of patients, anywhere between 5 patients to 20 patients, and includes a combination of methods to help with patient success. (Stein, 2011). The duration of SMAs is typically 1-2 hours, depending on what is being covered in the appointment (Edlemen et al., 2012). SMAs are run by a multi-disciplinary medical team (Shared medical appointments, n.d), and are generally considered for the management of chronic conditions, such as DM, HTN, asthma, and cardiovascular diseases, such as HF (Shared Medical Appointments, n.d). The multi-disciplinary team can consist of all or some of the following healthcare professionals: a doctor, a nurse, a pharmacist, a dietitian (Shared medical appointments, n.d) and sometimes a social worker (Smith et al., 2014)

While SMAs have been around since 1990s, the research is still limited and controversial. In 2012 it was stated that there is not “enough evidence to make a strictly evidence-driven decision about implementation of SMAs in any context except diabetes,” (Edlemen et al., 2012). That trend continued in 2017 articles, as authors’ commented that the published literature for HF SMA outcomes remains limited (Cohen et al., 2017). In the article, “A Heart Failure Management Program Using Shared Medical

Appointments,” the hypothesis was not supported, and patients who were in the HF SMA group did “not have lower 12-month hospitalization or mortality rates, shorter hospital stays, or longer time to hospitalization compared to the HF clinic only” group (Carroll et al., 2017). However, the current literature that exists can provide a platform for future research, such as gaps to be addressed, and the types of outcomes to be assessed. As the prevalence of HF continues to dramatically rise, and studies have reported that about 70% of the readmissions related to HF could have been prevented if self-management skills in patients were improved, it is pertinent to research the benefits of SMAs regarding outcomes of this disease (Smith et al., 2016).

The use of SMAs regarding the management of HF has started to gain some traction, and there are a few studies that have shown promise and can help direct the future research. For example, some of the current research regarding HF SMAs has looked at how attendance to SMAs affects hospitalization rates, self-care skills, HF related discouragement, quality of life (QOL) (Smith et al., 2015) as well as mortality, (Carroll et al., 2017). Two key articles regarding SMAs include the 2014 & 2015 articles by Smith, et al. In the 2014 study, 2 groups were compared, one received standard care (n=106), and the other group participated in SMAs (n=92). They reported that vasodilator and beta blocker adherence was poorer in the standard care group versus the SMA group, and that the SMAs were well accepted by the patients (Smith et al., 2014). In 2015, the researchers looked back at the previous study and this time focused on the methods, materials, and outcomes. They found that the patients who were in the SMA group used checklists and calendars to manage daily weights, to a higher degree than the patients in the standard care group. They also reported that the SMA group had greater

improvements for HF self-care skills, decreasing salt intake, taking medications, incorporating exercise, and had less hospitalizations than the standard care group (Smith et al., 2015). In another article, researchers observed how dietitian consultation effected the reduction of cardiovascular disease risk factors in individuals who were considered “high risk” (Ross, et.al, 2019). They found that for HDL, lipid levels, triglycerides, LDL, and total cholesterol, dietetic consultation was “at least as effective as usual minimal care,” and that that 4 studies indicated a “superior effect” with the use of a dietitian. (Ross et al., 2019).

While there is some positive research showing improvements in HF patients who participate in SMAs (Ross, et.al, 2019), (Smith et al., 2014), (Smith et al., 2015), there is also controversy (Carrol et al., 2017), which is why it is important that more research is conducted. The current, limited literature has reported on some of the impacts that SMAs have on patient outcomes, such as medication adherence, dietary adherence, laboratory values, as well as compared control groups to intervention groups over short and long periods of time. Some of the research has included the addition of an RD to the interdisciplinary team. However, the impact that RD provided nutrition education has on HF related outcomes is limited. As dietary composition is a major factor for underlying risk factors (cholesterol, HTN, type 2 diabetes, CAD) to HF, it is essential that more research is conducted with the addition of an RD, and with a greater focus on nutrition education.

In conclusion, HF is a complex chronic condition. The management of HF requires a team of healthcare professionals and a delicate balance of managing underlying medical conditions, medications, and dietary management. As heart disease remains the

number one cause of death in the United States, it is evident that changes to patient care such as SMAs and a greater focus on dietary education are crucial. The gaps in the literature previously discussed along with the increasing prevalence of heart disease support the purpose of this pilot project: to collect and report descriptive statistics from participants who participated in HF SMAs, in which nutrition education was provided by an RD.

CHAPTER III

JOURNAL ARTICLE

A Pilot Study: Observations of Patients Participating In Heart Failure Shared Medical Appointments Receiving Nutrition Education

Authors:

Hannah Hugo, Dana Ogan, Megan Hodges, Tim Englund

Author's Affiliation: Central Washington University

Corresponding Author: Dana Ogan, Central Washington University

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Abbreviations:

AHFK: Atlanta Heart Failure Knowledge Questionnaire

MLHF: Minnesota Living With Heart Failure Survey

HFrEF: Heart Failure with Reduced Ejection Fraction

HFPEF: Heart Failure with Preserved Ejection Fraction

BP: Blood pressure

HR: Heart Rate

HTN: Hypertension

HF: Heart Failure

Abstract:

The purpose of this pilot project was to examine descriptive statistics from 7 patients who participated in HF SMAs at a mid-sized heart center in the northwest, in which nutrition education was provided by an RD. Information collected included blood pressure (BP), heart rate (HR), weight, scores from the Minnesota Living with Heart Failure

(MLHF) Survey, and the Atlanta Heart Failure Knowledge (AHFK) questionnaire. Due to small sample size and lack of control group, simple descriptive statistics, such as mean and median were used to examine the data. Three of the participants were female and 4 were male. Five patients in this group had a diagnosis of HF with reduced ejection fraction (HFrEF), and two patients had a diagnosis of HF with preserved ejection fraction (HFpEF). Average weights of the participants ranged from 171.4 lbs to 339.6lbs. Quality of life (QOL) for this group of patients was diverse, average MLHF scores ranging from 0.4-78.3. The 3 lowest scores on the MLHF questionnaire and the 3 lowest average HRs were observed in the 3 patients (21, 22 & 32) who had the lowest recorded weights in the group (<200lbs). The 2 highest average BPs were observed in the 2 patients (20 & 25) with HFpEF. One limited potential trend that was detected within this data was that *the 3 patients with average weights <200lbs appeared to have lower MLHF scores (indicating higher QOL), as well as lower HRs, than the 4 patients with weights >200lbs.*

Introduction:

Heart Failure (HF) contributes about \$30.7 billion to healthcare costs annually, and impacts approximately 5.7 million Americans (Centers for Disease Control and Prevention [CDC], 2019). Risk factors that can contribute to the development of HF include: coronary artery disease (CAD), high blood pressure/hypertension (HTN), diabetes (DM), smoking, a high sodium, high cholesterol, and high saturated fat diet, lack of physical activity, as well as obesity (CDC, 2019).

Treatment for HF includes a combination of medical and lifestyle approaches. Medications are used to help control underlying diseases, such as HTN, CAD, and DM, to decrease overall stress on the heart. Lifestyle changes such as increasing physical activity and changing dietary patterns are also recommended. The American Heart Association (AHA) emphasizes consumption of a variety of fruits & vegetables, low fat/fat free dairy, lean meats, as well as incorporating nuts and legumes, reducing added sugars, and limiting sodium consumption to 1,500-2,300mg/day.

In 2016, the AHA reported that, despite survival rates increasing, about half of those diagnosed with HF will not live past 5 years (Mozaffarian et al., 2016). Therefore, it is evident that additional interventions should be assessed regarding the maintenance of this disease. One proposed method is through shared medical appointments (SMAs). An SMA is typically a small group of approximately 10-15 patients, all with the same or related medical diagnosis/condition. These patients are seen by a multi-disciplinary medical team, consisting of a nurse, a doctor, a pharmacist, and sometimes a registered dietitian (RD). Together the patients share their experiences, concerns, questions, and discuss past stories with the SMA group (Shared Medical Appointments, n.d). SMAs are considered to be most beneficial for patients with chronic conditions, such as diabetes, HTN, asthma and heart disease/ HF (Shared Medical Appointments, n.d). In their 2015 article, Smith et al found that a group of 92 patients involved in HF SMAs had a decrease of 33% in re-hospitalizations due to HF, compared to a control group who did not participate in an SMA (Smith, 2015). Current research has also observed the effects that SMAs have on other patient outcomes such as medication adherence, dietary adherence, and laboratory values. However, the impact that extensive RD provided nutrition

education has on HF related outcomes is limited. As the number of HF diagnoses continues to rise and dietary intake remains a major factor for underlying risk factors (cholesterol, HTN, type 2 diabetes, CAD) to HF, it is essential that more research is conducted with a greater focus on nutrition education. Therefore, the purpose of this pilot project is to examine descriptive statistics from patients who participated in HF SMAs, in which nutrition education was provided by an RD.

Methods:

Subjects:

This retrospective pilot study examined 7 HF patients that participated in a SMA at a mid-sized heart center in the northwest, between April 2018 and January 2020. De-identified data from the 7 HF patients was retrieved from an electronic health record database at a mid-sized heart center in the northwest. Demographics for the SMA participants were collected, such as gender, age, and ethnicity. Inclusion criteria for this group included the following: >18 years old, heart failure diagnosis, patient attendance of ≥ 3 visits, and enrolled in HF SMA program. This study was approved by Central Washington University's Human Subject Review Board.

Data Collection:

Dependent Variables:

Information collected from the de-identified patients included blood pressure (BP), heart rate (HR), weight, scores from the Minnesota Living with HF (MLHF) Survey, which was given at each visit, as well as the Atlanta Heart Failure Knowledge (AHFK)

questionnaire, which was given at 3 different times over the course of the study. For the purpose of this study, the MLHF and the AHFK questionnaires were utilized to determine if patient responses improved over time. Patient attendance, HR, BP and weight were also observed.

Data Analysis:

Due to small sample size and lack of control group, simple descriptive statistics, such as mean and median were used to examine the data.

Results:

The results to this pilot project are mixed. Although there are not adequate amounts of data to draw any firm conclusions, the results do help generate some questions that could direct future research studies. Most of the data over the course of the SMAs fluctuated, and there were not many common trends among all patients. Some minor trends were present, including lower MLHF scores at the last visit compared to the first visit. However, even those trend lines fluctuated and did not show any clear patterns. This group of patients was diverse and ages ranged from 45-83 years old. Three of the participants were female and 4 were male. Five patients in this group had a diagnosis of HF with reduced ejection fraction (HF_rEF), and two patients had a diagnosis of HF with preserved ejection fraction (HF_pEF).

Weights

When looking at the weights displayed on a line graph, 7 of the patients maintained their weight, with insignificant fluctuations throughout the course of the SMAs. See graph 1. Average weights of the participants ranged from 171.4 lbs to 339.6lbs. The weights of 3 patients (20, 21, & 22), despite some fluctuations, were lower at the last appointment than the first appointment, indicating some potential weight loss.

over time. The graph for patient 21, showed a slight downward trend in weight over time. Since most patients were on diuretic medications, weight changes were likely influenced in part, by those medications and/or associated changes to the regimen. Patients 24 & 32 had good weight maintenance, with weight only fluctuating a total of 7lbs for patient 24 and 5 pounds for patient 32. Patient 25 had the most significant weight change around visit 9, gaining about 47 lbs and then losing 52 lbs.

MLHF/AHFK Questionnaires

At each visit, patients filled out the MLHF questionnaire, which measures quality of life (QOL) with HF. The scores range from 0 to 105. A score of, or near 0 indicates QOL is not significantly impacted by HF; and a score of, or around 105 indicates HF does impact QOL to a great degree. Results to the MLHF questionnaire show that the QOL for this group of patients was diverse, average scores ranging from 0.4-78.3. The 3 lowest scores on the MLHF questionnaire were seen in the 3 patients with the lowest recorded weight averages (<200lbs). The highest scores were seen in the 4 patients with the highest average weights recorded (>200lbs). Patient 25 had the most significant weight change, but when observing the MLHF score at that visit, it did not seem to significantly increase in correspondence. However, patient 25 did have the highest MLHF average score of all the patients; the average score being 78.3 and the next highest average score only reaching 56.4. While all the scores fluctuated over the course of the SMA visits, the scores at the last visit for each patient was either the same, or lower than the first score. See graph 2.

The amount of data available for the AHFK questionnaire was not optimal, and therefore, it was difficult to draw any clear conclusions. The scores of the AHFK

questionnaire were not widespread, as the average score range was 22.7-26.3, being the number of questions answered correctly out of a possible 30

Blood Pressure/HR

The average BPs for this group of patients ranged from normal to stage 2. The 2 highest average BPs were observed in the 2 patients (20 & 25) with HFpEF. The rest of the patients were diagnosed with HFrEF. Other than the highest BPs being found in the 2 patients with HFpEF, BP did not appear to be related to weight and there did not appear to be any consistencies with regards to average MLHF scores.

The 3 lowest average HRs were observed in the 3 patients (21, 22 & 32) who had the lowest recorded weights in the group (<200lbs). As previously stated, patients 21, 22 & 32 also had the lowest average scores to the MLHF questionnaire. Therefore, this seems to be one of the limited potential trends that was detected within this data: *the 3 patients with average weights <200lbs appeared to have lower MLHF scores, as well as lower HRs, than the 4 patients with weights >200lbs.*

Discussion:

The purpose of this pilot project was to examine improvements in HF related outcomes in 7 patients who participated in HF SMAs over the course of 21 months. An RD was present for 12 months of visits, however, there was not adequate amounts of data to make any inferences regarding this as a unique variable. Despite the limited and inconclusive results to this pilot project, some potential trends were observed and could be elaborated on in future SMA studies. One potential relationship that could be expanded upon is between weight, HR and the scores to the MLHF questionnaire. Results from this project showed that the four participants whose weights were >200lbs had the

highest HRs and MLHF scores. However, this trend is reported with caution for several reasons; the correlation is inconsistent, as the patient with the highest average weight did not have the highest average MLHF score and furthermore, height/BMI was not factored into this observation. This observation therefore, warrants further research. If consistencies with this trend are present in future studies with better validity, it could help support the need for greater weight management education to be included in HF SMAs. See graph 3.

It was also observed that patients with weights >200lbs seemed to have a more volatile QOL, as indicated by the MLHF scores. Patients 25 (average weight 259lbs) and 23 (average weight 253lbs) appeared to have the most variations in their MLHF scores. This observation may help support the fact that future SMAs should include weight management as a part of nutrition education. This observation of course, does not represent causality, but helps support why extensive nutrition education is crucial to the overall management of this disease. When considering an exacerbation of HF, a higher weight may lead to a more negative impact on QOL (high MLHF score). Furthermore, while the MLHF scores fluctuated over the course of the SMA visits, the scores at the last visit for each patient was either the same, or lower than the first score, suggesting a trending improvement in QOL in some of the patients. For future studies looking at QOL of HF patients, an important factor to consider when interpreting the results is the time of year. Many individuals experience seasonal depression in the winter months, which could be a variable that could skew the data and cause variation that is not necessarily due to HF symptoms or attitude towards HF. Due to the small sample size of this study, and the inconsistent attendances among the patients, this variable was not able to be extensively

explored. Although many patients seemed to have an upward spike in their MLHF score (lower QOL) at visit 8, this visit did not fall on the same month for each patient. The months included in visit 8 were June, May, November, February, and March. When looking at the patients with their 8th visit occurring in fall/winter months, their scores on the MLHF questionnaire were higher, than patients with their 8th visit falling in June and May. Although patient 22's 8th visit fell in June, this patient did not have a MLHF score, so this patient was not included in this observation. Furthermore, patient 22's 3 highest MLHF scores fell during the months of May, June, and October, and therefore, contradicts the potential correlation that MLHF scores will be higher in fall/winter months vs spring/summer months. Regarding BP and the MLHF questionnaire, no clear conclusions could be drawn, as most patients were likely on BP medications. For example, patient 25 had the highest average BPs, as well as the highest average MLHF score, but patient 20, with the second highest BP, had the second lowest score on the MLHF questionnaire.

Although the ability to make connections with this data is limited, it was observed that the 2 patients (20 & 32) with the lowest average weights had the highest average AHFK scores. It cannot be concluded that a higher score is related to a lower body weight, however further studies could explore this potential connection. It is also interesting to note that patients 20 & 32 had the lowest recorded SMA attendance. It's plausible that these patients already had better control & knowledge regarding their HF, and thus did not need to attend as many visits as other patients. Nonetheless, with the small study sample, no clear conclusions can be made with this data.

Although the outcomes to this project unveiled more questions than answers, the variation among the data help illustrate the complexities of this disease and elicit more research regarding the effects of SMAs on HR, BP, weight, and QOL.

Current Research/ Trends in SMAs

Although shared medical appointments have been around for a while, the evidence and support for them is still limited. In a 2012 systematic review, Eddlemen and colleagues stated that there was not an adequate amount of research available to implement SMAs for any diseases besides diabetes (Eddlemen et al 2012). Since then, research in HF SMAs has progressed, and some studies have even observed the impacts of nutrition education on HF related outcomes (Ross et al., 2019). A few trends on the literature are important to note, such as patients who participate in SMA's are accepting of this method of health care delivery (Smith et al. 2014), and some research has reported that SMA patients have reductions in HF related hospitalizations compared to a control group (Smith et al. 2016). In a 2019 systematic review and meta-analysis, Ross et al reported outcomes between patients who participated in traditional medical care, which may or may not have included nutrition education, to patients who received a minimum of 1 face to face visit with an RD. Ross et al found that in some studies RD provided nutrition education was "at least as effective as usual minimal care," and in others they reported a significant difference between the intervention and control group (Ross et al., 2019).

The length of SMAs have ranged from 3 months (Ross et al, 2019) to 4 years (Delichatsios et al, 2015), and beyond, as well as the frequency of visits. There is a wide span of methods used, health care professionals included, and objective measures

observed. Regardless, there are still many gaps in the literature. For example, there is a limited amount of research observing the effects of consistent nutrition focused education for more than 12 months. Many studies have observed the results when an SMA group (including an RD) is compared to a control group (i.e a standard care group) but there are many uncontrolled variables in this flawed study design, as SMAs can differ widely from standard care. In the current literature, there was no research found that has compared 2 SMA groups to one another with variables such as nutrition education content (extensive vs basic) and nutrition educator (a doctor, a nurse, a pharmacist, or an RD). Lastly, while some research has looked at laboratory tests, such as lipid panels (Ross, et.al, 2019), more research is needed to observe the effects that SMAs have on other measures, such as weight, HR, BP, as well as patient knowledge.

The results and questions that have been generated from this project could help guide future SMA research that includes measures of weight, HR, BP, and patient knowledge. By comparing 2 SMA groups to one another, this would help limit the amount of confounding variables present when comparing an SMA group to standard care. In addition, this method could help isolate certain aspects of the SMAs, such as nutrition education and help answer some of the following research questions: How significant is the role of nutrition education with regards to HF related outcomes? How extensive does nutrition education correlate with positive outcomes for weight, BP, HR and quality of life? How does patient knowledge, HR, BP and weight impact quality of life?

Limitations

There are limitations regarding the results to this pilot project. Two main

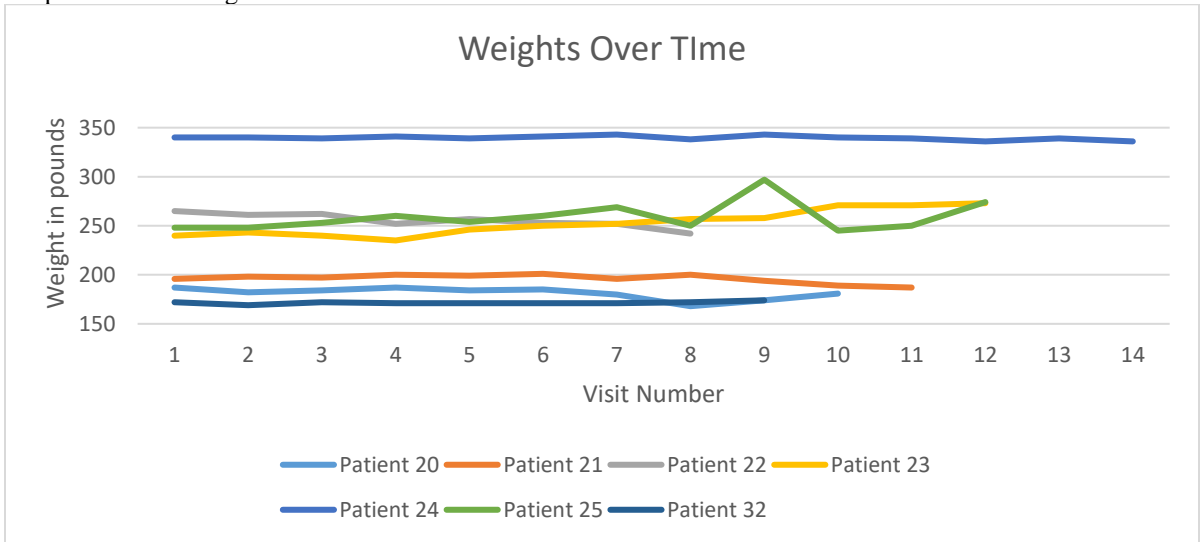
limitations were the sample size and the lack of data from a control group. Although the data from the 7 patients spans 21 months, some patients missed visits, resulting in a fewer data points for those patients. While, the patients were exposed to RD provided nutrition education for 1 year, it was only once per month and inconsistent amongst the participants. Therefore, more frequent education sessions or follow-ups during the rest of the month may be warranted in future studies.

Conclusions

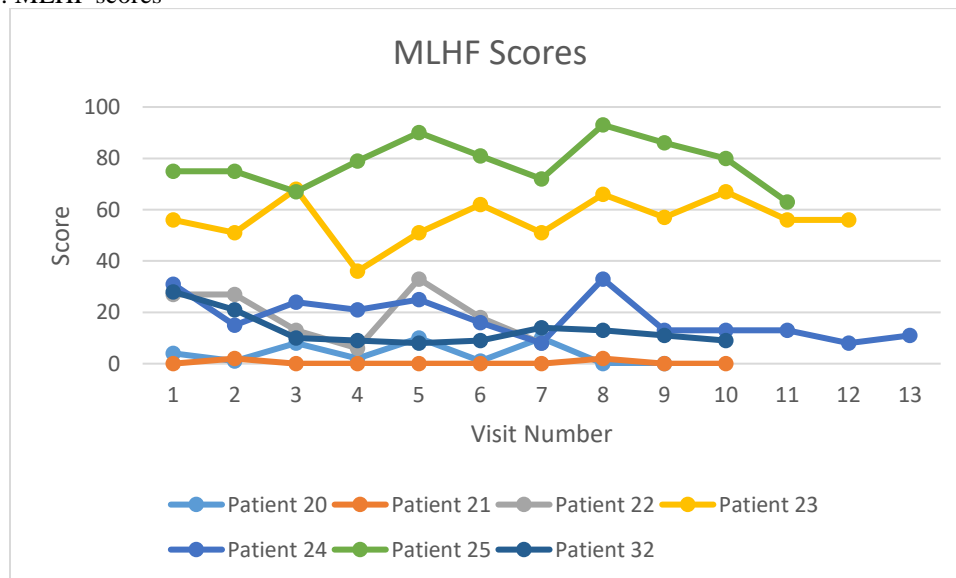
Due to data limitations, no clear conclusions were identified. Some potential relationships were observed, such as between weight, HR and MLHF questionnaire scores, and therefore, one potential trend that was detected within this data was that the 3 patients with average weights <200lbs appeared to have lower MLHF scores (indicating higher QOL), as well as lower HRs, than the 4 patients with weights >200lbs. As there were inconsistencies within the correlations of this data, the results should be observed with caution. Although the results generated more questions than answers, those questions may elicit more research regarding the relationship between HR, BP weight, and QOL in future HF SMA research.

Graphs

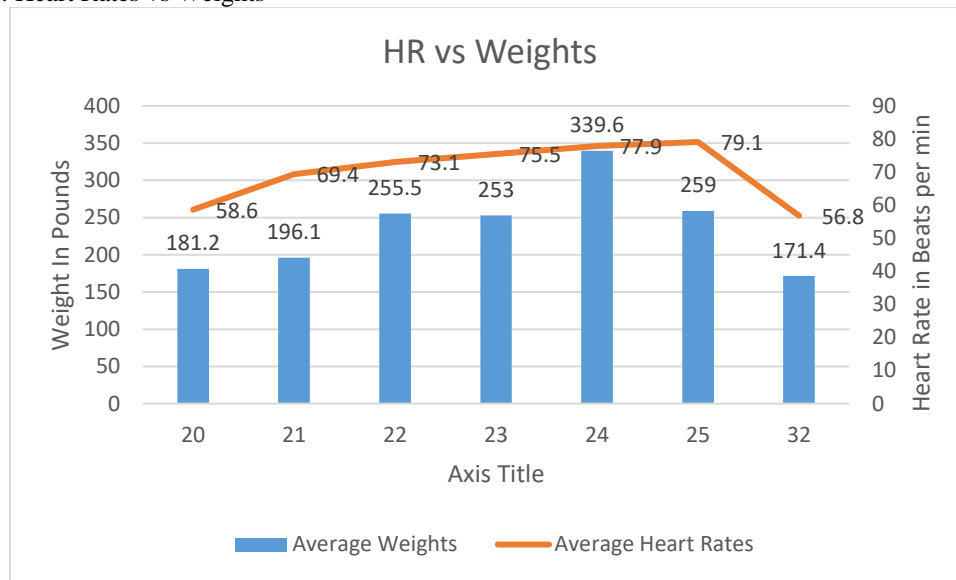
Graph 1: Patient weights over time



Graph 2: MLHF scores



Graph 3: Heart Rates vs Weights



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