Effects of an Overall Heart Healthy Diet on Outcomes of Heart Failure

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Background: Despite inconsistent research findings, the recommended 2,000 mg sodium restricted diet has become standard practice for medical nutrition therapy for people with heart failure. This systematic review set out to analyze the effects of an overall dietary pattern approach of a heart healthy diet on outcomes of heart failure including mortality, re-hospitalization rate and symptom improvement, and quality of life.

Methods: This project used the Academy of Nutrition and Dietetics Evidence Analysis Library methodology. The five steps include: Formulate an Evidence Analysis Question, Gather and Classify Evidence, Critically Appraise Each Article, Summarize the Evidence, and Write and Grade the Conclusion Statement.

Results: Five primary research articles were included in the analysis. For the outcome of mortality, Spaderna et al., (2013) identified that consumption of foods rich in polyunsaturated fatty acids (PUFA) and monounsaturated fatty acids (MUFA) was positively associated with reduced Hazard Ratios for death/deterioration. A 1-unit increase in consumption frequency of foods rich in these was associated with a 50% risk reduction for this outcome. (HR 0.49, 95% CI 0.26-0.92; P=0.028). Levitan et al., (2013) found that women with a higher DASH diet score had a lower hazard rate of death. In the fully adjusted models, the HR associated with 1-unit higher DASH diet score was 0.98 (95% CI 0.97-0.99, p=0.003). Miró et al., (2018) found that the cumulative mortality at the end of their study was lower in patients adherent to the Mediterranean diet than in those who were not adherent, although the difference did not reach statistical significance (HR: 0.86; 95% CI: 0.73 to 1.02; p=0.08). For the outcome of re-hospitalizations and symptom improvement, Spaderna et al. (2013) concluded that more frequent consumption of fruits/vegetables/legumes increased chances for delisting from the cardiac transplant list due to improvement in symptoms after additional adjustment for cardiac index (HR 3.89, 95% CI 1.14- 13.29; P= 0.03). Miró et al., (2018) concluded that patients adherent to the Mediterranean diet showed a significantly lower re-hospitalization rate than non-adherent patients (HR: 0.74; 95% CI: 0.61 to 0.90; P= 0.003). Hummel et al., (2018) studied changes in symptoms/ symptom improvement using the Kansas City Cardiomyopathy Questionnaire (KCCQ). The summary score increased in both groups from hospital discharge to week 4 (DASH: 46±23-59±20, change 13±19; usual care: 43±19-53±24, change 10±16 ($p < 0.001$). The mean increase of the score was 3 points greater in the DASH group, but this difference was not statistically significant (p=0.37). Rafai et al., (2015) measured quality of life using the Minnesota Living with Heart Failure Questionnaire (MLHFQ). MLHFQ scores at baseline were similar between groups (p=0.056); however, patients in the DASH group reported improved scores at 3-month follow-up (p= 0.006).

Conclusion: A heart healthy dietary pattern (DASH/Mediterranean diet) in adult patients with HF trends towards an association with decreased mortality rates, decreased re-hospitalization rates, and improvement in quality of life.

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CHAPTER 1: INTRODUCTION

Heart failure (HF) has become one of the most common causes of hospitalization, hospital readmissions and death (Horwitz, L., Krumholz, H., 2016). There are greater than 900,000 new HF cases diagnosed annually in the United States, an increase from 650,000 per year in 2013. Nearly 6 million persons living in the United States have been diagnosed with HF with the lifetime risk for development of 20% for Americans age 40 and older (American Heart Association, 2015). With the continuing rise in prevalence, along with the fact that 1 in 5 Americans will be older than age 65 years by 2050, the number of Americans with HF is expected to continue to increase significantly. HF is considered a complex disease that results from any structural or functional impairment of our heart's ventricular filling or ejection of blood (Yancy et al., 2013). This impairment can lead HF decompensation with symptoms of dyspnea, fatigue and fluid retention and can greatly affect a person's quality of life.

Poor health related quality of life (HRQoL) has been shown to predict cardiac mortality and morbidity in HF patients. Research has indicated most patients express a preference for better HRQoL when compared to a longer life. Medical nutrition therapy has become an important part in the treatment of HF symptoms and there has been continuing research investigating the specific role dietary sodium intake plays in regards to symptom management and overall benefit to people living with HF. An association has also been found relating malnutrition with higher rates of cardiac mortality. With approximately half of patients with HF suffering from malnutrition, as indicated by progressive weight loss, the question arises if an alternative approach to a sodium restriction is necessary. Additionally, worsening HF symptoms may be aggravated by poor nutrition. Loss of appetite, age-related changes in taste and smell,

and the recommended sodium restriction can affect food intake and therefore result in a poor nutrition status (Son, YJ., & Song, EK, 2012).

Rationale

Multiple organizations, including the Heart Failure Society of America and The American Heart Association, have differing recommendations for a daily sodium intake amount that would benefit HF patients in greatly reducing their symptoms and hospitalizations. The inconsistency of guidelines emphasizes the weak database of research that supports this cornerstone treatment for such a serious condition (Yancy et al., 2013). Studies also exist that show detrimental outcomes of a sodium restriction to a patient's health (Paterna et al., 2008).

Gaining a better understanding of how overall heart healthy nutrition plays a role in HF symptoms is important because the singular approach in the form of a sodium restriction has become the primary nutrition recommendation and common practice despite these inconsistent findings. The purpose of this evidence analysis project is to critically analyze the current research and explore the relationship between the DASH/Mediterranean style diet and HF management, specifically if it is comparable or superior to a sodium restriction alone. Although primary prevention of cardiovascular disease (CVD) is the keystone to facing the challenge of heart failure occurrences, secondary prevention once the diagnosis has been made has similar importance. Evidence has been clear in recent decades that interventions using the Mediterranean diet have been useful in CVD prevention so recommending this dietary pattern could potentially benefit those who are already diagnosed with CVD, specifically CHF. This diet allows for intake of nutritious foods that could potentially combat common nutrient deficiencies identified in people with HF such as calcium, folate, magnesium, vitamin D, vitamin E and zinc (Lennie et al., 2013).

Potential Significance

Patients with diverse medical histories as well as differing stages of HF may respond differently to dietary intervention treatments. They also have varied symptoms that can include lack of appetite as well as unique preferences and lifestyles, making personalizing recommendations as much as possible vital to their health and wellbeing. Keeping patients at home and out of the hospital is one way to improve their quality of life. After reviewing the literature, it is hopeful that improved and consistent nutrition recommendations can be made for patients who have HF to improve their quality of life.

Research Question

Is a heart healthy, DASH or Mediterranean, diet more effective at reducing hospitalizations and improving quality of life than a singular focus on a sodium restriction for patients diagnosed with heart failure? Should a low sodium diet, defined as less than or equal to 2,000 mg per day, be recommended for patients with HF or should an overall dietary pattern be recommended?

Sub-problems

Does restricting sodium intake decrease the amount of other nutrients a person consumes? Is quality of life affected when a low sodium diet is followed?

Limitations

Limitations would include the availability of research conducted involving people with HF who are instructed to follow a heart healthy diet. It will also be limited to studies that look at outcomes pertaining to quality of life and symptom management as well as number of hospitalizations. Patients with HF can have multiple comorbidities and are prescribed different

medications and doses making it difficult to find a population in a study that is always similar to a patient that is in need of these recommendations.

Delimitations

Delimitations will be set on the evidence analysis. The evidence analysis will only investigate studies that include sodium intake as well as a heart healthy pattern of intake DASH or Mediterranean diet. For this population, the concentration will be studies that focus on outcomes regarding quality of life, symptom management, number of re-hospitalizations, and mortality. Studies can focus on quality of life factors, symptom management, number of re-hospitalizations, mortality or all four.

Assumptions

It will be assumed that all studies included in the literature review contain accurate information. It will also be assumed that all patients are honest and as accurate as possible, with assistance from dietitians and other members of the research team, in any food diaries or surveys regarding symptoms and/or quality of life data.

Definition of Terms

-**Edema or Oedema:** an abnormal accumulation of fluid in the interstitium, located beneath the skin and in the cavities of the body, which can cause severe pain.

-**Ejection Fraction (EF):** Aids in determining how well a heart is pumping out blood and a measurement under 40 may be evidence of HF.

-**Health Related Quality of Life (HRQoL):** an individual's or a group's perceived physical and mental health over time.

-**New York Heart Association Functional Classification (NYHA):** the most commonly used classification system that places patients in one of four categories (I to IV) based on how much they are limited during physical activity.

-**Palliative Care:** An approach that improves the quality of life of patients and their families facing the problems associated with a life-threatening illness. This is accomplished through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.

-**DASH Diet:** The DASH diet is based on the research studies: Dietary Approaches to Stop Hypertension, and has been proven to lower blood pressure, reduce cholesterol, and improve insulin sensitivity. Blood pressure control with the DASH diet involves more than just the traditional low salt or low sodium diet advice. It is based on an eating plan proven to lower blood pressure, a plan rich in fruits, vegetables, and low-fat or nonfat dairy. It emphasizes whole grains and contains less refined grains compared with a typical diet. It is rich in potassium, magnesium, calcium, and fiber.

-**Mediterranean Diet:** The Mediterranean diet (MedDiet) was first defined by Ancel Keys as being low in saturated fat and high in vegetable oils, observed in Greece and Southern Italy during the 1960s [1]. In the Seven Countries Study this dietary pattern was associated with reduced risk of coronary heart disease (CHD) compared to northern European countries and the United States after 25 years follow-up [2,3]. Over the past several decades the study of the MedDiet has advanced, and the definition originally introduced by Keys has evolved and varied. The definitions include guidelines for high intake of extra virgin (cold pressed) olive oil, vegetables including leafy green vegetables, fruits, cereals, nuts and pulses/legumes, moderate intakes of fish and other meat, dairy products and red wine, and low intakes of eggs and sweets.

CHAPTER 2: REVIEW OF LITERATURE

Heart failure (HF) is a complex clinical disease that results from any structural or functional impairment of one's heart's ventricular filling or ejection of blood. The main symptoms are dyspnea and fatigue, which in turn, may limit exercise tolerance and can cause fluid retention that may lead to pulmonary and/or splanchnic congestion and/or peripheral edema. There is no single diagnostic test for HF because it is a clinical diagnosis based on careful history and a physical examination by a physician. There are many different reasons for the outcome of HF, but the majority of patients who experience these symptoms have an impaired left ventricular myocardial function (Yancy et al., 2013). HF is more likely to happen with age and most people who develop HF have (or had) another heart condition. The most common conditions that lead to HF are coronary artery disease, hypertension and previous heart attacks (American Heart Association, 2015a). Obesity has also been found to be independently associated with HF and can also contribute to the development of additional HF risk factors. These independent risks include hypertension, left ventricle hypertrophy and diastolic filling abnormalities. Obesity is also linked to insulin resistance and glucose intolerance, hyperaldosteronism, salt sensitivity and plasma volume expansion, creating both pressure and volume overload stressors for the heart. The metabolic demand of excessive adipose tissue increases cardiac output requirements, making cardiomyopathy with HF the leading cause of death in patients with severe obesity (Heart Failure Society of America, 2006).

Heart failure has become one of the most common causes of hospitalization, hospital readmission and death (Horwitz, L., & Krumholz, H., 2016). There are greater than 900,000 new HF cases diagnosed annually in the United States, an increase from 650,000 per year in 2013. Nearly 6 million persons living in the United States have been diagnosed with HF

(American Heart Association, 2015a). Currently, the lifetime risk of developing HF is 20% for Americans age 40 years and above. With HF prevalence continuing to rise, along with the fact that one in five Americans will be older than 65 years by 2050, the number of Americans with HF is expected to significantly increase (Yancy et al., 2013). In the developed countries around the world, approximately 1-2% of the adult population has HF with the prevalence rising to 10% or more among persons aged 70 years or older. Despite advances in detection and treatment, HF carries a 5-year mortality rate of approximately 50% after diagnosis and between 20%-30% of these patients are using the emergency department or are hospitalized each year (Colin-Ramirez, E et al, 2014).

Although advances have been made in the treatment for HF, hospital admissions due to HF have increased by 175% over the past two decades. In fact, 59% of patients with HF are readmitted to hospitals within 19 months of their previous admission (Heo, S et al, 2009). HF caused by damage to the heart over a period of time cannot be cured, but it can be treated. Quite often the goal of treatment is to improve the main symptoms. These treatment options for HF include lifestyle changes, medications, device implantations and surgical procedures. Nutrition, as one of the lifestyle change options, includes eating a heart healthy diet as well as weight maintenance or weight loss to achieve a healthy weight. Guidelines for a heart healthy diet provided by the American Heart Association emphasize a variety of fruit and vegetables, whole grains, low-fat dairy products, skinless poultry and fish, nuts and legumes, non-tropical vegetable oils and limited amounts of saturated fat, sodium and sugar-sweetened beverages (American Heart Association, 2015d) Some approaches for nutrition, though, have specifically observed sodium reduction alone as a treatment (Gupta et al. 2012). Palliative care can play an important role in difficult decisions regarding treatment in advanced HF. Specialists can help patients live

improved lives by providing assistance in relieving symptoms and improving quality of life as well as supporting patients in whatever treatment plan they choose (American Heart Association, 2015c) The purpose of this literature review is to critically analyze the evidence of nutrition strategies that are effective in assisting with the treatment of HF.

Background

Classifying Heart Failure

Patients with HF vary with respect to demographics, comorbid conditions, prognosis and response to therapies; however, a common factor in classifying HF is by using the ejection fraction (EF) (Yancy et al., 2013). An EF helps in determining how well a heart is pumping out blood and a measurement under 40 may be evidence of HF (American Heart Association 2015a). It is common in clinical trials to select patients based on their EF but HF stages are also commonly used. The main organizations that provide information on stages of HF are the American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) and the New York Heart Association (NYHA). The ACCF/AHA stages emphasize the development and progression of disease and the NYHA classes focus on exercise capacity and the status of a patient's symptoms (Yancy et al., 2013).

Physicians will usually classify a patient's HF according to the most commonly used classification system, which is the NYHA, described in Table 1 below. These classes are broken down into two categories based on functional capacity (patient's symptoms) and an objective assessment. The symptom class ranges from I to IV, starting with: I) no limitation of physical activity; II) the inability to carry on any physical activity without discomfort; III) having symptoms of HF at rest and; IV) if any physical activity is undertaken, discomfort increases. The objective assessment ranges from A to D, with A, having no objective evidence of

cardiovascular disease and no symptoms or limitations in ordinary activity to D, having evidence of severe cardiovascular disease and severe limitations, experiencing symptoms even while at rest (American Heart Association, 2015b).

Table 1: NYHA Heart Failure Class (American Heart Association, 2015b)

Class	Patient Symptoms
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.
Class	**Objective Assessment**
A	No objective evidence of cardiovascular disease. No symptoms and no limitation in ordinary physical activity.
B	Objective evidence of minimal cardiovascular disease. Mild symptoms and slight limitation during ordinary activity. Comfortable at rest.
C	Objective evidence of moderately severe cardiovascular disease. Marked limitation in activity due to symptoms, even during less-than-ordinary activity. Comfortable only at rest.
D	Objective evidence of severe cardiovascular disease. Severe limitations. Experiences symptoms even while at rest.

There is an even larger range of risk factors for the development of HF other than the ones previously discussed. These range from lifestyle factors to comorbidities. The risk increases with age and men have a higher risk than women. Lower physical activity, coffee consumption, increased salt intake and lower socioeconomic status have all been associated with increased risk. Comorbidities such as hypertension, diabetes, obesity and coronary disease all increase the risk. In fact, half of the patients admitted for HF, regardless of EF, have coronary artery disease. Additional risk factors include valvular heart disease, excessive alcohol intake, smoking,

dyslipidemia and renal dysfunction. Multiple risk factor prediction schemes, for example, the Framingham Risk Score that uses information like age, sex, tobacco status, cholesterol and blood pressure have been developed to predict coronary events. Despite these predictions, HF syndrome represents a large spectrum ranging from ischemic to non-ischemic etiologies and normal to depressed EF. Some elderly subjects may develop HF due to age-related cardiovascular changes in the absence of traditional risk factors. High-risk subjects, therefore, may not be detected using coronary risk schemes (Buter, J., 2012).

Nutrition Status of People Living with Heart Failure

Malnutrition is a prevalent disorder that affects at least 25% (other studies reporting higher based on criteria used) of patients hospitalized with heart failure. These patients show a worse prognosis than those with an adequate nutritional status, leading to higher mortality rates and more frequent hospitalizations (Bonilla, J.L, 2016). Diminished appetite and inadequate food intake may occur in HF as a consequence of clinical symptoms like fatigue and dyspnea or intestinal edema causing nausea, diminished absorption and protein-losing enteropathy. Decreased intake may also be a result of imposed dietary restrictions such as a lower sodium diet or medication side-effects. An additional aspect is a significantly higher resting metabolic rate, which increases with HF severity. For these reasons, people with heart failure are at risk for developing malnutrition (Kamya K-Z., 2008).

Prevention and Treatment

There is a large number and range of risk factors for the onset of HF. Prevention of these risk factors relies on lifestyle change. Several studies have reported reduced risk for HF with a healthy lifestyle. Healthy weight, avoiding tobacco use, engaging in regular exercise, and a healthy diet have been shown to reduce many HF risk factors including coronary disease,

diabetes mellitus, and hypertension. The Physicians' Health Study's investigators reported that healthy lifestyle habits, that is, normal body weight, not smoking, regular exercise, moderate alcohol intake, consumption of breakfast cereals, and consumption of fruits and vegetables were associated with a lower risk of HF, with the highest risk of 21.3% in men adhering to none of these habits and the lowest risk of 10.1% in men adhering to 4 or more (Butler, Javed, 2012).

There are many different approaches to treating HF with the main objective to control a patient's symptoms. Other goals for all stages of HF include treating the condition's underlying cause such as coronary artery disease, hypertension or diabetes as well as preventing the further development of HF, increasing lifespan, and improving quality of life. Common medications include ACE inhibitors, Aldosterone Antagonists, Angiotensin Receptor Blockers, Beta Blockers, Digoxin, Diuretics and Isosorbide Dinitrate. These are prescribed based on the type of HF, how severe it is, and a patient's overall medication response. Other treatments include a discussion regarding heart healthy intake which includes a dietary sodium restriction, aiming for a healthy weight, physical activity and to quit smoking, if needed (National Heart, Lung, and Blood Institute, 2015). Dietary sodium indiscretion is considered a common and potentially modifiable cause of HF decompensation. As a result, a dietary sodium restriction is the most commonly recommended self-care behavior recommended to patients with HF (Hummel et al, 2016). As HF advances, lifestyle changes and medications may no longer be effective in controlling symptoms. Therefore, a medical procedure or surgery to implant a resynchronization therapy device, implantable cardioverter defibrillator or heart transplant become the next options (National Heart, Lung, and Blood Institute, 2015).

Dietary Sodium Recommendations

The ACCF/AHA Task Force's executive summary on guidelines for management of HF identifies many A and B levels of evidence for management of HF through medications

including ACE inhibitors, Angiotensin-Receptor Blockers, Beta Blockers, and Digoxin. After a review of selected literature through October of 2011, with some additional selected references through April 2013, their comment regarding sodium restriction is “even the widely embraced dictum of sodium restriction in HF is not well supported by current evidence” (Yancy et al., 2013). The Academy of Nutrition and Dietetics (AND) also reported a conclusion statement from 2006-2008 regarding sodium intake and HF as, “the limited available evidence supports a 2,000 mg-per-day and 1.5L per day fluid restriction”. During the AND evidence review, they found studies to support this 2,000 mg sodium, 1.5 L/day intake to benefit quality of life, NYHA functional class, sleep disturbance, physical activity, edema, BNP and blood pressure. This recommendation by AND was recently updated to include their new 2016 recommendations. This updated conclusion statement is as follows: Research reported that sodium intake of less than 3,000 mg per day resulted in reduced symptom burden (in terms of frequency and severity of shortness of breath, difficulty breathing when lying flat, swelling of legs or ankles, lack of energy and lack of appetite), when compared to sodium intake levels above 3,000 mg per day, but fluid intake was not reported. This new statement received a grade of III- Limited/Weak, downgraded from a grade II -fair rating for their previous recommendation. Further research is needed regarding the effect of sodium or fluid intake on quality of life, signs and symptoms (Academy of Nutrition and Dietetics, 2016).

Although the above entities report limited evidence to support a sodium restriction, sodium restriction continues to be recommended by the American College of Cardiology (ACC) and the AHA. Excessive sodium intake has been associated with fluid retention and, therefore, all HF management guidelines recommend sodium restriction. In 2005, the ACC and the AHA HF guidelines recommended 3g to 4g daily sodium intake; but, for patients with acute volume

overload, the recommendation is 2g per day. The Heart Failure Society of America recommends 2g to 3g daily sodium intake and less than 2g for patients with moderate to severe HF symptoms (NYHA class III-IV). Multiple other organizations have their recommendations that are shown in Table 2 and expert opinion or level of evidence C has been largely the basis for these recommendations. The inconsistency of guidelines highlights the weak research database that supports this cornerstone treatment for such a serious condition (Yancy et al., 2013). Results from several studies have raised concern that restricting dietary sodium to less than 2 grams per day may not be beneficial and may even be harmful for patients with HF (Nakasato et al., 2010, Paterna et al., 2008).

Current Dietary Sodium intake in the United States

To examine the current prevalence of excess sodium intake among Americans, the Center for Disease Control (CDC) analyzed data from 14,728 participants older than 2 years from the 2009-2012 National Health and Nutrition Examination Survey (NHANES). This NHANES study included an in-person examination with 24-hour dietary recall and a second 24-hour dietary recall administered by telephone 3-10 days later (excluding pregnant women as well as respondents with unreliable dietary recalls). Estimated mean usual daily sodium intake was 3,500 mg for individuals 19 years of age or older. Sodium intake estimates excluded salt added at the table and from dietary supplements and antacids, which account for about 5%-6% of sodium intake. It was found that frequently consumed foods that are high in sodium included breads, rolls, deli meats, pizzas, poultry, soups, sandwiches, cheese, pasta dishes, mixed meat dishes and savory snacks (Center for Disease Control, 2016).

Table 2.

Guideline Recommendations for Dietary Sodium and Fluid Restriction in Heart Failure **(**Gupta et al. 2012)

Guideline	**Year**	**Recommendation Sodium Restriction Recommendation Fluid Restriction Recommendation**	**Level of Evidence**
National Heart Foundation of Australia/Cardiac Society of Australia and New Zealand	2006	<3g/day for NYHA Class II without peripheral edema/<2g/d for NYHA class II and IV <2L/d for all patients and <1/5 L/d during fluid retention episodes	C
Heart Failure Society, India	2007	<2g/d <2L/d	Not stated
European Society of Cardiology	2008	Moderate restriction 1.5-2 L/d in patients with severe symptoms and especially with hyponatremia	C
Canadian Cardiovascular Society	2008	<2g/d	Not stated
American College of Cardiology/American Heart Association	2009	Moderate restriction (≤2 g/d, if volume overload, followed by fluid intake restriction to 2L/d if fluid retention persists)	C
Royal College of Physicians	2010	Salt reduction Fluid restriction	Limited; further research required
Heart Failure Society of America	2010	2-3 g/d, <2g/d may be considered in moderate to severe heart failure <2 L/d, if fluid retention persists and if severe hyponatremia (serum Na <130 mEq/L) is present	C
Scottish Intercollegiate Guidelines Network	2010	<2.4 g/d tailored fluid restriction	1+
American Dietetic Association	2011	<2g/d 1.4-1.9 L/d depending on clinical symptoms (updated 2016- see text)	Fair

*Level of Evidence: C=Limited populations evaluated. Only consensus opinion of experts, case studies, or standard of care; Fair=Benefits exceed the harms but quality of evidence is not as strong; 1+ = well-conducted meta-analysis, systemic reviews, or randomized controlled trials with low risk of bias. NYHA indicates New York Heart Association.

Current Literature

It is important to review current research in order to provide patients with proper treatment advice. The majority of nutrition related research in the treatment of HF investigates the association between sodium intake and symptoms, hospitalization rates and mortality, while others also include quality of life factors. The research article by Youn-Jung Son et al. (2011), mentioned many past studies that examined the possible cause for many typical HF exacerbation symptoms. Most of these symptoms have been associated with fluid retention or volume overload secondary to non-compliance to prescribed medication, excessive volume intake, or excessive dietary sodium intake. It has been suggested in multiple studies that one of the primary reasons patients with HF seek medical treatment for their symptoms is the non-adherence to the dietary sodium restriction (Youn-Joung et al., 2011). The articles reviewed were published within the last 10 years to help critically analyze the evidence of how sodium consumption affects HF along with other current treatment practices.

Sodium and Fluid Restrictions

A prospective study conducted by Song et al. (2014), compared differences in event-free survival with HF patients consuming differing intakes of daily sodium (< 2g, 2-3g, or >3g). Outcomes of the study were based on the patients' class of HF using the NYHA classification. Prior experimental studies that have raised concern for a sodium restriction have shown that intravascular volume depletion induced by less than 2g of daily sodium intake can compromise renal function especially in patients who are well compensated by treatment with ACE inhibitors and diuretics (Damgaard et al., 2006, Parrinello et al., 2009, and Paterna et al., 2008). Serum aldosterone and rennin levels were reported to be significantly higher among patients with approximately 1.8 g of daily sodium intake, compared to patients with 2.8 g of daily sodium intake. Using this previous data, they hypothesized that patients identified as NYHA Class I/II

with sodium intake less than 2g would be independently associated with higher risk for hospitalization or death compared to patients with sodium intake between 2g-3g, but not with patients identified as NYHA Class III/IV.

During the study, 244 HF patients were followed for a median of 365 days. Patients were recruited from outpatient clinics located in Kentucky, Indiana and Georgia. The patients needed to have a confirmed diagnosis of chronic HF with either non-preserved systolic function, left ventricular ejection fraction (LVEF) of less than 40%, no recent changes in prescribed doses of medications during the prior 3 months and also having the ability to read and speak English. Participants were excluded if they were referred for a heart transplantation, had a primary etiology of HF from valvular heart disease, peripartum HF or myocarditis, had a history of cerebrovascular accident or recent myocardial infarction within the previous 3 months and were also excluded if having a co-existing terminal illness such as cancer, liver or renal failure. Also excluded were patients with an average energy intake calculated at less than 1,000 Kcal per day because this level is associated with suppressed appetite or inadequate food intake to meet required energy (using the Harris-Benedict equation).

Baseline nutrition intake was measured for each participant using a 4-day food diary. Patients were visited in their homes by trained research assistants and were provided digital scales with detailed oral and written instructions for measuring the weight of each food item. Food models were also provided for estimating serving sizes when a food could not be measured. To assure accurate and complete diaries, patients were asked to demonstrate food measurement and recordings. A dietitian was also involved upon completion of the diaries to verify serving sizes, obtain any missing information and clarify food preparation techniques. Nutritional Data

System for Research (NDSR, Minneapolis MN) software was used to analyze food diaries and determine the daily sodium intake.

To compare outcomes among patients with different sodium intakes, patients were divided into three groups based on current sodium recommendations: those with dietary sodium intakes less than 2g, those with intakes of 2 to 3g, and those with greater than 3g of daily intake. These groups were then examined and the study's primary outcome looked at was the composite end-point of time to first event of all-cause hospitalization or death. Over a median follow-up of 365 days, 2 patients passed away and 86 were hospitalized. Independent t-test or Chi-square tests were used to compare differences in sample characteristics between patients in NYHA class I/II and those in NYHA class III/IV. Hierarchical Cox proportional hazard regression with survival curves was used to compare differences in adjusted event-free survival among patients with less than 2g, 2g to 3 g, and greater than 3 g of daily sodium intake stratified into NYHA class I/II and class III/IV while controlling for age, gender, HF etiology, BMI, LVEF, total co-morbidity score, total caloric intake, the presences of lower leg or ankle edema and use of ACE inhibitors and diuretics.

The data demonstrated that in NYHA class I/II, patients with less than 2 g of daily sodium intake had shorter event-free survival (HR= 3.68, 95% CI = 1.18-11.50), while patients with greater than 3 g daily sodium intake had longer event-free survival (HR = 0.39, 95% CI = 0.16-0.98), compared to those with 2 to 3 g of daily sodium intake. In NYHA class III/IV, patients with greater than 3 g of daily sodium intake had a 2.1 times higher risk for hospitalization or death than those with 2 to 3 g of daily sodium intake ($p = .044$). No significant difference in adjusted survival curves were found between patients with less than 2 g and those with 2 to 3 g of daily sodium intake ($p = .418$). Results suggest that recommendations for sodium

restriction may need to vary by severity of HF; having a highly restrictive low sodium diet may not be advantageous for patients with class I and II, while greater than 3g may not be beneficial for patient in class III and IV.

Limitations of the study include the 4-day food diary which may not reflect long-term sodium intake in comparison to a urinary sodium excretion lab test. It was also not an interventional study, limiting the ability to fully draw a causal relationship between sodium intake and even-free survival. In addition, only 12% in class I/II and 15% in class III/IV had less than 2g of daily sodium intake, making the sample size of those groups small. Strengths of this study include significant tools to help patients create an accurate food diary as well as focusing on results between different NYHA classes. Also, patients with HF are already so different so determining outcomes based on their different NYHA stages helps with creating clear groups between this large, diverse population.

Evaluating a 3,000 mg Sodium Restriction

The study performed by Lennie et al. (2011) also investigated different outcomes with sodium intake dependent on NYHA HF class. The researchers discussed the limited evidence that is likely responsible for the lack of consensus among HF guidelines and the trend toward providing only non-specific recommendations for sodium restriction. The purpose of the study was to compare differences in cardiac event-free survival between patients with sodium intake above and below 3g/day. The 3 g/day sodium restriction was chosen based on the Heart Failure Society Association's specific guidelines.

This was a prospective observational study of participants recruited from six large community hospitals or academic medical centers in Kentucky, Georgia, Indiana, and Ohio. Three hundred and two patients were included in this study with eligibility criteria including a

confirmed diagnosis of chronic HF with either reduced or preserved LVEF, on stable medication doses for at least three months or the ability to read and speak English. Exclusion criteria included if they were referred for heart transplantation, history of acute myocardial infarction or cerebrovascular accident within the prior three months, valvular heart disease, peripartum HF, myocarditis as primary HF etiology, other known inflammatory processes, end-stage renal failure, or co-existing terminal illness such as cancer.

For this study, the level of dietary sodium intake was estimated by measurement of a 24-hour urine (UNa). This measurement is considered an objective indicator of dietary sodium intake. In individuals who do not perspire heavily, 24-hour UNa accounts for approximately 95%to 98% of dietary sodium intake measured by food diaries. UNa was collected from eligible patients and they were divided into two groups using a 3g/day UNa cut point and further divided by NYHA class I/II and III/IV. After 12 months, event-free survival was determined by interviews and medical record review and a Cox regression hazard ratio. Patients in NYHA class I/II with a UNa greater than 3 g had longer event-free survival than patients with UNa less than 3 g (HR = 0.44, 95% CI = 0.20- 0.97). In contrast, patients with NYHA class III/IV with UNa greater than 3 g had shorter event-free survival than patients with UNa less than 3 g (HR = 2.54, 95% CI = 1.10-5.84). These results were not expected for patients with NYHA class I/II with UNa less than 3g to have a shorter event-free survival than class I/II patients with higher UNa. Patients classified as NYHA class III/IV with UNa above 3g had shorter event-free survival than NYHA class III/IV with lower UNa, again suggesting that recommendations for sodium intake may depend on the NYHA class.

Limitations discussed regarding this study include UNa data functioning best in stable patients who have normal fluid and sodium retention, possibly making UNa an unreliable

indicator of dietary sodium intake. Researchers did recruit patients who were weight stable and had no change in medications for the past 3 months which indicates stable fluid and sodium balances and may have helped adjust for this. Although this may have helped with UNa results, it also does not represent many hospitalized HF patients who experience fluid imbalances and medication changes frequently. Also, one 24-hour UNa measurement may not reflect long-term sodium intake. Strengths include again separating groups out into NYHA class in order to try and provide more specific recommendations for these HF patients.

To determine whether adherence to a sodium-restricted diet affects symptom burden and cardiac-free survival in patients with HF, Youn-Jun Son et al. (2011) performed a prospective cohort study involving 232 patients from several outpatient HF clinics in two large university hospitals in Seoul, South Korea. At the clinic, patients received instructions on how to follow a sodium restricted diet, determined to be <3 g/day, and how to monitor their daily symptoms as part of a standard care provided by their clinicians. Eligibility criteria included confirmed diagnosis of HF within the last 2 years, having non-preserved left ventricular systolic function with LVEF of less than 40%, and stable prescription of medications for at least 3 months prior. Exclusions included an acute myocardial infarction or cerebrovascular attack within the previous 6 months, an obvious cognitive impairment defined as a diagnosis of stroke, dementia or head trauma, and a history of cancer, severe thyroid disease, liver or renal failure.

Daily sodium intake was determined by measuring a 24-hour UNa and symptom burden was assessed by using the modified Memorial Symptom Assessment Scale-Heart Failure (MSAS-HF) previously established as reliable (Beich, KR., and Yancy C, 2008). The frequency and severity of seven symptoms specific to HF were measured with a four-point Likert scale (1 rarely- 4 almost always or constantly) describing how the patients had experienced the HF

symptoms over the previous 2 weeks. The primary outcome of this study was the composite end-point of time to first event of a cardiac-related ER visit, cardiac-related hospitalization, or death due to cardiac events during the 12 month follow-up period. Two groups were formed and the above was assessed based on adherence to a <3 g/ day sodium intake or > 3 g/day sodium intake.

An independent t test was used to compare the frequency and severity of each symptom between patients who had a 24-hr UNa of < 3 g and those with > 3g. Hierarchical multiple linear regression was used to determine whether non-adherence to the sodium restriction was associated with a greater symptom burden after controlling for other factors. The Hierarchical Cox proportional hazards regression with survival curves was also performed to predict cardiac event-free survival. It was found that over half of the participants were overweight and obese according to the obesity cut-off points for East Asians by WHO and the majority of the patients were in the NYHA class III or IV. Thirty-five percent had a 24-hr UNa of 3 g or less and the majority were prescribed diuretics, beta-blockers, and ACE inhibitors. When divided into two groups based on 24-hr UNa, patient characteristics were similar except those with >3g UNa had a significantly higher mean BMI.

During the 12-month follow-up, 13 patients (5.6%) passed away, 69 (29.7%) were hospitalized, and 19 (8.2%) had ER visits due to decompensated HF and other cardiac-related causes. After controlling for the same risk factors, patients who had a 24-hr UNa >3g had a shorter event-free survival when compared to patients with < 3 g. There were also significant differences in the frequency and severity of HF symptoms other than frequency of waking up breathless at night and difficulty in sleeping showing an independent associated with greater symptom burden in patients with HF and non-adherence to sodium restricted diet. These findings, overall, indicate that patients who do not adhere to recommended sodium limit of <3

g/day were approximately twice as likely to experience ER visits, hospitalizations, or death due to cardiac-related causes, even after controlling for other risk factors.

The above study's strengths include a previously validated measure to determine symptom burden as well as an adequate-sized sample populations and follow-up time. Limitations discussed include the common 24-hr UNa possibly not being accurate for people experiencing fluid overload or sodium imbalance, as well as the measurement occurring only once during the entire 12 month time. This study was performed in South Korea, making it difficult to fully apply information to a different country's population of HF patients.

Investigating a Combined Sodium and Fluid Restriction

In many HF-related studies, both a sodium and fluid restriction were investigated simultaneously. The purpose of a 12-week prospective, randomized intervention trial study, by Henriette et al. (2013) was to develop recommendations for sodium and fluid intake. The study's aim was to evaluate the effects of a sodium and fluid restriction on composite endpoint, consisting of HF class, hospitalizations, body weight, peripheral edema, quality of life, thirst, and diuretics. Data from this study was used to develop recommendations for its use in HF patients.

Patients with a history of HF, in NYHA class II-IV were enrolled from the Sahlgrenska University Hospital, Gothenburg and Södra Älvsborg, Hospital Borås in Sweden. Inclusion criteria include patients to be considered in stable condition, documentation of LV dysfunction and history of hospitalization, history of signs of fluid retention, on a maximum tolerated dose of ACE inhibitors and beta-blockers with no change in medication for at least 2 weeks prior to enrollment as well as $\geq$80 mg of furosemide or equivalent doses of other diuretics for patients who had NYHA II or $\geq$40 mg of furosemide for patients in NYHA III-IV. Patients were excluded from the study if they had liver or renal disease causing fluid retention, present fluid

retention requiring adjustment of diuretics; other disease limiting the patients' physical capacity; and lack of ability, determined by the study's physician, to follow instructions for example patients with dementia or language problems. From this criteria, it was determined that 97 participants would be included in the study with a mean age of 75 (+/- 8) years.

For the patients randomly placed into the intervention group, recommendations were individualized keeping in mind the patient's cultural, economic and social habits, and were provided advice to reduce sodium intake to 2-3g/day and to limit fluid to 1.5L. The control group was given only the generalized advice of "be aware not to drink too much and use salt with caution". Patients were contacted by telephone, unannounced by a dietitian, after 10-12 months. A 24 hour dietary recall interview was performed and patients completed a questionnaire about adherence to the salt and fluid advice given during the study period, all participants in the intervention group reported they had modified their diet during the study period. Forty-nine patients were randomized into the intervention group (45 completed the study) and there were significant reductions in urine volumes of sodium in this group compared to the control group of 45 patients.

The overall measurement was whether a patient deteriorated, improved or had no change in the above composite endpoints. Deterioration was considered as (a) deterioration of at least one NYHA class; (b) hospitalization for heart failure; (c) weight gain $\geq$ 2 kg; (d) increased leg edema (e) increased thirst or (f) reduced Quality of Life (QoL). Even if a patient improved in all other criteria, the patient was classified as deterioration if only one of the criteria had deteriorated. Patients were considered to have improved if none of the above criteria were met and they met at least one of the following (a) improved at least on NYHA class; (b) weight loss $\geq$ 2 kg (c) decreased leg edema; (d) improved QoL or (e) decreased dose of diuretics. Patients were

considered deteriorated if no change occurred since the intervention was aimed to show improvement. Comparisons of the groups were made using the two-tailed, independent sample t-test for continuous, normally distributed data, and Mann-Whitney for skewed, continuous variables.

Individualized sodium and fluid restrictions were associated with significant improvement in composite endpoint. Improvement was seen among 51% of the patients in the intervention group and only 16% of patients in the control group, P> 0.001, mostly due to an improved NYHA class and reduced edema. Another promising outcome found was that weight, thirst, and QoL were not affected by the salt and fluid restrictions. Researchers concluded that the effects of the intervention were due to efforts were to meet the nutritional needs of the individual and to promote good nutrition status with an individualized dietary plan.

Strengths of this study include the personalized approach to nutrition education, although difficult to replicate, as well as the amount of composite endpoints they observed. Physicians were blinded to the randomization and typically examined the same patient at baseline and follow-up. Limitations include that for most of the patients, both groups had already received dietary instructions in accordance with HF guidelines prior to inclusion making it conceivable that the observed effects of salt and fluid restriction would have been greater if the patients had not received prior dietary advice. The study could have also strengthened with a longer follow-up period of more than one year.

Poor Nutritional Status, Poor Health-related Quality of Life

When HF occurs, lack of appetite can become a symptom that could in turn lead to malnourishment. Quality of life is also an important aspect to look at with a patient experiencing HF symptoms. Some experts may even suggest the most desirable outcome in HF management

is to improve health-related quality of life. Approximately half of patients with HF suffer from malnutrition as seen in progressive weight loss, which in turn is associated with higher rates of cardiac death. Additionally, worsening HF symptoms may become more aggravated by poor nutrition. Loss of appetite, age-related changes in taste and smell, dietary sodium restrictions, social isolation and use of diuretics were identified to cause inadequate food intake, resulting in poor nutritional status and multiple nutrient deficiencies. Despite raising concerns about the poor nutrition status of HF patients, recommendations in management have focused mostly on a sodium-restricted diet (Son, YJ et al., 2012).

As an alternative to evaluating the sodium intake of HF patients, Son, Young-Jung & Song, Eun Kyeung (2012) performed a prospective study on the relationships between poor nutritional status and total comorbidity and health-related quality of life (HRQoL). This study was used to determine the impact of nutritional risk on HRQoL beyond sodium intake among community-dwelling patients with HF recruited from clinics in tow regional medical centers located in Seoul, South Korea. In order to participate, patients had to have a cardiologist confirmed diagnosis of HF for at least 2 years, on stable medication regimen for at least 6 months, have impaired LV systolic function with LVEF of less than 50% and able to read and writer in Korean. Participants were excluded from the study if they had a contraindication for a low sodium diet, an acute myocardial infarction 6 months before enrollment, any hospitalizations or emergency room visits in the 3 months prior, obvious cognitive impairment, history of terminal illness such as cancer, severe hyperthyroidism or hepatic or renal failure, or were undergoing cardiac transplant evaluation. One hundred thirty-four patients participated in this study with 70% being normal or overweight in accordance with the obesity cut-off points for

East Asians established by the World Health Organization, and the majority were also in the NYHA class of II or III.

Each patient's nutritional risk was evaluated using the Nutrition Screening Initiative (NSI) checklist that was developed through a collaboration of AND, the American Academy of Family Physicians and the National Council on the Aging, with scores ranging from 0 to 21 (Rector TS & Cohn JN, 1992). HRQoL was measured using The Minnesota Living with Heart Failure Questionnaire (LHFQ), (Posner et al., 1993), at baseline and 6 months later. This instrument was developed specifically to measure HF patients' perception of how much their illness and its treatment affects perceived HRQoL with a score ranging from 0 to 105 with higher scores reflecting worse HRQoL. Dietary sodium intake per day was determined, as well, by measuring a 24 hour urinary excretion.

This data, along with other risk factors including age, gender, presence of spouse, BMI, NYHA class, etiology of HF and LVEF were collected and statistical analysis was used. The independent t-test and chi-squared tests were used to compare differences in sample characteristics between patients with higher and lower nutritional intake. Hierarchical multiple linear regression was used to determine if nutritional risk was independently associated with worse HRQoL at baseline as well as 6 months later considering the other risk factors mentioned were related to impaired HRQoL in previously studies.

Their findings demonstrated that HF patients with higher nutrition risk, which ended up being approximately 60% of their patients, were independently at greater risk (about 9%-10%) for having worse HRQoL after adjusting for other risk factors and daily sodium intake. Furthermore, patients with higher nutritional risk had a higher total comorbidity score than those with lower nutrition risk (P=0.038). The authors felt this study reinforced knowledge that patient

with HF are suffering from poor overall nutrition and the main or even only focus should not be on sodium intake.

A continuing theme for limitations with HF studies continues with having only a 24 hour sample being taken which may not represent long-term intake of sodium. The NSI checklist used in this study is reported as a non-diagnostic instrument that measures actual nutrient intake, therefore nutritional risk cannot be connected to being malnourished. Six months is also a small amount of time for follow-up considering a patient may live with HF for many years. The main strength of the study is the use of validated instruments in order to assess nutrition risk and HRQoL which is an important factor to consider in patients with chronic disease.

Assessing Whether a Sodium Restriction is Appropriate

Nakasato et al. (2008) sought to investigate whether the recommendation for a 2g/day sodium restriction was appropriate for all patients with HF. They hypothesized that a low-sodium diet may not be beneficial to all patients with this condition. Patients were eligible for this study if they had a HF diagnosis and were in a stable compensated phase and in NYHA stage I, II or III. Patients also needed an EF <40% in the last 6 months, were 18 years of age or older, willing to adhere to the low sodium diet and likely to return to the hospital. Exclusions included alcoholism, acute 30-day infection, creatinine concentration >2.5 mg/dl, hypertension, BMI > 40, hypertrophic cardiomyopathy, valvular heart disease requiring surgical correction, steroid or immunosuppression, recent surgery, medication changes in the last 15 days, restrictive disease, and significant co-morbid conditions including malignancies or severe obstructive lung disease.

The 50 participants eligible for this randomized crossover study began with an average intake of 6.6g sodium/day and were randomly divided in two subgroups, both advised to follow a 2g/day sodium diet. After a week, the first group was advised to increase intake to 6g

sodium/day for 7 days and the second group was to continue with 2g sodium/day. Both groups had weekly meetings with a dietitian, who provided dietary counseling on how to decrease the intake of sodium to 2g/day or 6g/day. They were advised to avoid sodium-rich foods, but to otherwise keep their dietary habits. Over the course of the study, participants were also advised to maintain fluid intake of approximately 1,000 ml/day.

Statistics used were the Student's t-test to analyze the comparison between groups with normal distribution, the Mann-Whitney test for non-parametric variables as well as the ANOVA for repeated measures considering the participants were placed under multiple sets of conditions. Significance was set at a p-value of 0.05. Under further statistics review, the researchers looked at BMI as it appeared to interfere with the patients' response to the low sodium diet. They found that having a lower BMI (26.2 +/- 0.7 kg/m²) and consuming the 2g/day diet reduced their weight and serum sodium while increasing plasma norepinephrine, plasma renin, serum aldosterone, serum urea, serum calcium and plasma nitrate. In the higher BMI participants (28 +/- 0.6 kg/m²), the 2 g/day intake reduced urinary sodium, plasma IL-6, serum total cholesterol and HDL-C. The researchers further explained that the mechanisms behind reduction in serum sodium could include the actual intake restriction, loss of sodium due to use of diuretics or hemodilution. The consequence of hyponatremia could have potential deleterious effects as it has been identified in several studies as a risk factor for increased morbidity and mortality in patients with HF as these patients have poorer prognosis, significantly higher rates of major complications and mortality when compared to normonatremic patients with HF.

During this study, it was observed that a sodium restricted diet led to a lower consumption of protein, phosphorus, iron, zinc, selenium, and vitamin B12. The group of researchers felt this prospective study overall exposed that the 2g/day restriction diet for patients

with HF increased neurohormonal activation associated with progression of HF, reduced food consumption, lowered BMI and did not change BNP levels when switching from a higher sodium intake to a lower sodium intake. In contrary to Son, Young-Jung & Song, Eun Kyeung (2012), they did find a sodium restriction to improve QoL which was calculated using a QoL questionnaire (no further details were provided). The authors concluded that following a 2 g sodium diet for someone with HF increased the neurohormonal activation associated with HF progression.

A weakness of this study is the low number of participants involved and although the randomized cross-over study design was strong, there was a short-trial period of only 3 to 4 weeks. Eligibility criteria seemed strict compared to other research studies and seemed to limit "real-world" examples of HF patients. The inclusion of a weekly meeting with a dietitian improved confidence of the participants' knowledge of how to follow what was advised. Although they did realize this was a short trail period, the researchers determined this study suggested the need for an individualized sodium plan per patient due to different responses; possibly dependent on BMI.

Another study with findings that suggest recommending a normal sodium diet (NS) vs. a low sodium diet (LS) is Paterna et al (2008). They wanted to look at a second-line treatment as diuretics have long been accepted as the first-line treatment of patients with severe HF though a lack of response to diuretic therapy is common, particularly in elderly patients with advanced disease. The aim of the study was to evaluate the effects of a NS diet compared with a LS diet in combination with high-dose furosemide and fluid restriction of 1,000 mL/day in patients compensated after recently having decompensated HF. They wanted to focus on readmission for

worsening HF but in addition, morality, plasma BNP and aldosterone levels and plasma renin activity (PRA) during a 180 day follow-up.

Patient population eligibility criteria included needing to have been hospitalized for decompensated HF within the last 30 days who are now considered having compensated HF. They also were considered to be unresponsive to treatment with high doses of oral furosemide (up to 250-500 mg/day and/or combinations of diuretics. Additionally, patients had to have a left ventricular EF of < 35% as well as serum creatinine < 2 mg/dl, BUN of <60 mg/dl and decreased urinary volume of < 500 mg/24 hour and low natriuretic despite receiving established treatments. All patients received high-dose furosemide, a NS diet and decreased fluid intake during the recent hospitalization and when the compensated state was achieved, the treatment was continued after discharge. Criteria defining patients who were no eligible included patients with cerebral vascular disease, dementia, cancer, uncompensated diabetes, severe hepatic disease, patients requiring pacemaker implantation and those with an alcoholic habit. Other exclusions occurred if they were unable to follow the assigned treatment or if they had side effects to ACE-inhibitor treatment. After discharge from the hospital, patients were controlled with clinical and laboratory evaluations as outpatients every week for the first 30 days (if necessary treatments were corrected due to evaluation) and those at 30 days after the discharge who met the eligibility criteria were included in the study.

Randomization of which patients were to follow a LS (1,840 mg/day) and NS (2,760 mg/day) diet was carried out using a preliminary computer algorithm and assigned at 30 days post discharge. A total of 232 patients were randomized and evaluated every week for the first month, every 2 weeks for the next 2 months and then every month for the remainder of the study period. All patients received multiple written standard diets containing 1,840 mg of sodium

prepared by dietitians and the group with the NS diet received the same diets but with an extra 920 mg of sodium/day. Therefore, all patients received the same amount of saturated fat, fruit, vegetables etc. In addition, they were contacted every week during follow-up by physicians and dietitians for a telephone interview to determine the adherence to the reduced fluid intake as well as the prescribed diet. Both groups continued to restrict fluids to 1,000 mL/day and continue with prescribed medication.

Statistical analysis of the data was performed using a two-tailed Student's t-test to identify differences between groups and ANOVA for repeated measures with Bonferroni post-hoc test correction for intra-group data. Nominal data was analyzed by the X^2 test. $P < 0.05$ was assumed as statistically significant. Findings included significant readmission rate reduction for the group receiving the NS diet ($P < 0.05$) when compared with the LS diet group as well as a significant reduction ($P< 0.001$) in combined mortality and readmissions. During the follow-up period, 9 patients from the NS diet group were readmitted for worsening HF and 6 patients diet and 30 patients were readmitted to the hospital and 15 died in the LS diet group. Other results found, included no significant change in the renal function parameters after 90 and 180 days from the baseline values in the group receiving the NS diet but in contrast, the creatinine and BUN values increased in the LS diet group. A significant ($P < 0.001$) inter-group difference was observed in plasma BNP levels at the end of the study with the group receiving the NS diet had significantly lower BNP levels at 90 ($P<0.001$) and 180 days ($P<0.0001$) compared with the group receiving the LS diet. Overall, the authors feel their findings suggest that a NS diet with limited fluid intake when associated with loop diuretic is able to reduce both hospital readmissions for worsening of HF and neurohormonal activation after 180 days of follow up. They also suggest that a LS diet and free water intake, usually recommended in clinical practice,

might not be the best treatment for these patients and merits further investigation. They suggest further studies as well to determine whether the detrimental renal and neurohormonal effects were due to high dose of diuretic used or the LS diet.

Limitations to the study included the lack of a double blinded study as patients were able to perceive the difference in the amount of salt in the two diets making it an unblended design. The follow up period of 180 days was brief but the significant decrease in readmission rate recommended the discontinuation of the study. A third limitation (not discussed by the authors) is that the patient's treatment of diuretics was based upon a NS diet and the diet was then changed to a LS diet for half of the participants. If the diuretics were originally dosed/adjusted when following a LS diet, it leaves the question to whether the same results would be found. Also not discussed was whether they adjusted the meal plan provided for sex, age and calorie need. The authors realize that the intensive follow up received by patients in this study could have affected the overall outcome.

Sodium Restriction combined with a nutrient dense, heart healthy diet

Hummel et al (2018) wanted to create a more effective strategy to improve outcomes for patients with HF during the particularly vulnerable post discharge period and beyond when they may experience dyspnea, nausea, anxiety, depression and fatigue. United States' hospitals have instituted formal programs to reduce preventable re-hospitalizations in patients with HF but the decline in 30-day readmissions have plateaued as well as seeing an increase in the 30-day mortality rate. Dietary factors are believed to be an important cause of hospitalization in this population but few dietary interventions, other than a sodium restriction, have been performed. Therefore, the purpose for this study was to assess the outcome of providing sodium restricted DASH compliant meals to older adults with hypertension after discharge from the hospital for

acute decompensated HF (ADHF). They hypothesized that this strategy would improve disease-specific quality of life at 4 weeks post discharge. Important additional goals were to assess safety of intervention, including effects on cardiac biomarkers and re-hospitalization burden.

The GOURMET-HF study was a randomized, single-blind, controlled trial of 12 weeks. Sixty six patients were randomized in a 1:1 stratified fashion by gender and left ventricular EF (<50% vs >50%) included with inclusion criteria consisting of age of 55 of older, history of systemic hypertension and having an admission for ADHF and being discharged home. Exclusion criteria included hypotension, hyperkalemia or severe anemia during admission, length of stay less than 24 hours or greater than 14 days, expected survival less than 12 months, active alcohol or substance abuse, dementia or history of nonadherence to treatment.

Each week, post discharge, participants assigned to the study diet could choose their preferred menu items from a variety of options tailored to the low sodium DASH specifications. Three daily meals, snacks, and some beverages were provided for a daily calorie intake of 2,100 and 1,500 mg of sodium. Both groups received a standardized educational pamphlet at hospital discharge with information on how to follow a sodium-restricted diet. Baseline dietary patterns and nutrient intake were assessed at hospital discharge using the 110-item Block Food Frequency questionnaire. Adherence to the diet was assessed by meal delivery records and review of 3-day food diaries recorded during weeks 1 and 4 post discharge. Overall adherence was defined as the proportion of the total meals consumed from the home-delivered study food. Cardiac biomarkers, prealbumin, and C-reactive protein were measured at hospital discharge and at week 4. Twenty-four-hour urine collection was also performed for sodium and potassium excretion at discharge and week 4. KCCQ, a self-administered, 23-item instrument was used to assess HF-related physical limitation, symptoms, self-efficacy and social interference.

Statistical analysis was performed for between group differences using X^2 tests for dichotomous variables and 2-sample tests for continuous variables. With-in group discharge to week 4 changes in KCCQ summary scores were evaluated using paired t-tests. Between-group comparisons were made using linear regression with week 4 KCCQ as the outcome and with treatment group and discharge KCCQ as covariates. The probabilities over time since discharge of all-cause re-hospitalization and HF re-hospitalization were visualized using Kaplan-Meir curves, with between-group comparisons made using log-rank tests.

Data obtained from the food frequency questionnaire during admission to the hospital showed estimated energy intake was 1602 (1192-2154) kcal per day and sodium intake was 2557 (1911-3561) mg/day. There were no significant between-group differences in estimated calories, sodium or potassium intake. Energy and sodium intake were highly correlated ($P<0.001$). For participants assigned meal delivery, 77% of all meals consumed consisted of complete or partial home-delivered study meals. They were received for an average of 27 +/- 1 days. The baseline KCCQ summary score was not statistically different between groups but it increased in both groups from hospital discharge to week 4. The mean increase in KCCQ summary score was 3 points greater in the DASH group, but this difference was not statistically significant. At 30 days post-discharge, there were 4 all-cause re-hospitalizations in 4 participants compared to 12 total all-cause hospitalizations in 9 participants in the usual care group $P= 0.12$ (3 patients had 3 HF re-hospitalizations in the DASH group, 9 patients with a total of 11 HF re-hospitalizations in the usual care group $P= 0.055$). The DASH group spent 17 cumulative days re-hospitalized compared to 55 days usual care group ($P=0.06$). At 12 weeks, there were 11 DASH patients had 15 total all-cause re-hospitalizations, whereas 14 usual care patients had a total of 22 all-cause hospitalizations and 1 death $P=0.45$ for comparison (8 re-hospitalizations in 7 DASH patients, as

compared to 18 HF re-hospitalizations in 13 usual care patients (P= 0.11). This study overall demonstrated trends for improvement in symptoms and physical limitations related to HF as well as re-hospitalization burden.

Limitations include the smaller amount of participants at 66. Also, they reported that in most cases food diary records were sufficient to gauge the proportion of home-delivered meals consumed by participants assigned to the DASH group but they could not definitively analyze the nutrients consumed during participation as some 3-day food records had inadequate detail despite prompting from study personnel. Because of this large limitation, direct comparison between the provided meals and diet consumed by usual care group could not be provided. This group of participants also needed to have a history of hypertension to be included in the study, making results less generalized to all HF patients.

Summary

HF is a chronic disease associated with high prevalence of hospitalizations and death. Persons living with HF can experience many undesirable symptoms including dyspnea, fatigue, and edema as well as depression and anxiety that can greatly affect their quality of life. It is widely perceived that HF management to avoid symptoms includes a dietary sodium restriction, a recommendation that is endorsed by many national and international guidelines. Multiple research studies, discussed above, investigated this recommendation further.

All studies mentioned chose to consider either a 2g or 3g sodium intake as a restriction presumably based on current recommendations. Song et al. (2014) and Lennie et al. (2011) decided to focus on how sodium intake affects a patient depending on their NYHA stage and looked at an end-point of length of event-free survival. Both studies suggest that having a highly restrictive low sodium diet may not be advantageous for patients with class I and II, while

greater than 3g may not be beneficial for patient in class III and IV. Paterna et al. (2008) found that sodium depletion had detrimental renal and neurohormonal effects with worse clinical outcome in compensated HF patients with NYHA II-IV when following a low sodium diet.

Quality of life was an important end-point in both Henriette et al. (2013) and Youn-Jung Son et al. (2012) and suggested a change of focus from a simple sodium restriction to a more involved process of individualizing recommendations to promote good nutrition status with an individualized nutrition plan. Both studies discuss findings of patients with HF having high nutrition risk as well as Nakasato et al. (2010) found a decreased intake of many important nutrients with a sodium restriction recommendation. While Henriette et al. (2013) concluded weight, thirst, and QoL were not affected by the salt and fluid restrictions and Nakasato et al. (2010) found a sodium restriction to improve QoL, Son, YJ. and Song, EK (2012) looked beyond the sodium restriction and found QoL to decline as nutrition risk increases. A new approach considered by Hummel et al. (2018) was to provide HF patients with lower sodium DASH meals during their most vulnerable time, post discharge. They observed whether overall quality of diet, not just a sodium focus, affected outcomes of QoL and re-hospitalizations.

Gaps in Current Research

Each patient with HF is unique due to different comorbidities, NYHA class and dosage of medications; therefore, it is difficult to perform studies to generalize a good nutrition plan for all cases. HF is a syndrome with a high prevalence of comorbidities and multiple chronic conditions, but most guidelines are developed for patients with a single disease. Many of the above studies excluded patients based on additional comorbidities and even decompensated HF, limiting the ability to generalize recommendations to real-world patients. The coexistence of additional diseases such as diabetes, renal insufficiency, and chronic lung disease for example

should most likely call for a modification to treatment. Many studies compensated patients for participation, increasing the adherence to diet prescription. In the real world, recommendations might be made to a patient in a hospital and follow-up with adherence to diet prescription is not consistent. Few data exists with regards to research based on an overall dietary approach of a heart healthy diet as the sodium restriction has become the main research topic for treatment of HF. Considering the majority of HF patients are considered to have poor nutritional health, it would be beneficial to look at research that investigate outcomes with consumption of nutritious foods instead of a sole focus on limitation of sodium. Evidence suggests that the beneficial effects of polyunsaturated fatty acids on cardiovascular health may extend to patients with heart failure and fruit and vegetable intake has been associated with reduced incidence of heart failure (Spaderna et al., 2013). Overall, studies performed include medications as part of the treatment and this can be very different from patient to patient, making it difficult to assess whether sodium intake is the cause of poor or favorable results, although many of the studies mentioned they did prevent changes in a patient's medication regimen for a time period before and during the study.

There are multiple current studies adequately addressing sodium intake, although recommendations remain controversial. Also, when looking for recent research, controlled studies that specifically placed patients into groups and provided meals with known amounts of sodium were difficult to find. In fact, only one pilot study, published this year, was found to have attempted this. Increased control of a participant's actual intake would increase confidence in results. The majority of current studies found had participants weighing food items and recording data into a journal or measuring their daily UNa usually only once, adherence to diet was also not controlled for. Stronger evidence would be made, although more expensive, if patients were

provided meals with known amounts of sodium grams daily and if careful monitoring of actual intake of these meals was accomplished. Differences in protocols including ones dealing with medications, addition of fluid intake recommendations, the method of sodium intake measurement and how often, and clinical and therapeutic characteristics among these studies make it challenging to compare data and draw definitive conclusions in the research.

SUMMARY

The prevalence of HF continues to rise in the United States, increasing the need and importance for the effective dietary intervention. From the current recommendations, a sodium restriction of 2g/day may be beneficial for some HF patients. Typically, the current protocol is to have decompensated heart failure patients follow a 2g/day sodium diet restriction to prevent further hospitalizations and multiple studies investigate if better outcomes are found based on a more lenient sodium restriction. These studies include Song et al. (2014) and Lennie et al. (2011) and suggest that benefits of the restriction amount may be dependent on many factors including their NYHA class finding better outcomes for NYHA stage I and II with an intake > 2 g per day and stage III and IV patients with a < 3 g/day intake. Youn-Jun Son et al. (2011) also determined that with patient's in NYHA classes III and IV, a sodium restriction < 3g/day made it less likely to experience ER visits, hospitalizations or death due to heart related causes.

Another overall finding from current research is whether the current treatment plan is for quality of life and symptom relief versus hospitalization and mortality. Son, Young-Jung & Song, Eun Kyeung (2012) conducted a study to determine the impact of nutritional risk on HRQoL beyond sodium intake among community-dwelling patients with HF. Their findings demonstrated that HF patients with higher nutrition risk, which ended up being approximately 60% of their patients, were independently at greater risk (about 9%-10%) for having worse

HRQoL after adjusting for other risk factors and daily sodium intake. This shows that clinicians caring for patients need to be aware of the importance of nutrition self-care beyond daily sodium intake. Palliative care is starting to become a more involved entity, especially in hospital settings and this may be beneficial in determining the treatment plan and overall goals of the patients.

Nakasato et al., (2010) discovered HF patients had poor nutrition status as well, especially with patients who were solely advised to limit high sodium foods and continue their other current habits. They found this decreased consumption of protein, phosphorus, iron, zinc, selenium and B12 as well as increased neurohormonal activation associated with progression of HF. Paterna et al., (2008) also looked at neurohormonal activation with a sodium restricted diet and reported their findings to suggest that a normal sodium diet with limited fluid intake when associated with loop diuretic is able to reduce both hospital readmissions for worsening of HF and neurohormonal activation after 180 days of follow up. They also suggest that a low sodium diet and free water intake, usually recommended in clinical practice, might not be the best treatment for these patients and merits further investigation.

Starting to look at overall nutrient quality of the diet versus sodium intake only is an idea that reflects prevention of heart disease potentially being the same as the treatment. Hummel et al. (2018) wanted to provide patients with a nutrient dense, DASH compliant and 1,500 mg sodium/day, diet during their most vulnerable time, post hospitalization. The study overall demonstrated trends for improvement in symptoms and physical limitations related to HF as well as re-hospitalization burden with patients who were provided these nutrient dense meals. This study also shows that a nutrient dense diet with > 2,000 calories per day can be possible even when following a lower sodium diet.

There is a definite need for more investigation to provide better understanding of the role of nutrition and HF symptoms, quality of life, hospitalizations and mortality. Current dietary recommendations for HF patients are largely based on data from populations without HF, and much of the focus in on sodium. Dietary patterns rich in fruits, vegetables, whole grains nut and legumes and low in processed foods and red meats, such as the Mediterranean and DASH dietary patters, can be palatable, relatively easy to adhere to, have demonstrated beneficial cardiovascular effects, and are consistent with many dietary recommendations. Although data is scarce, these patterns may also reduce the rate of mortality in HF patients (Levitan EB et al., 2013). In the future, it would be ideal to find a definite plan for nutrition based on HF class as well as paying attention to quality of life and overall nutrition status, keeping HF patients out of the hospital and enjoying their lives.

CHAPTER 3: METHODOLOGY

The Academy of Nutrition and Dietetics' Evidence Analysis Library (EAL) was launched online in 2004 and is a user friendly resource that provides a summary of the best available research on numerous relevant nutrition topics. For each topic, expert workgroup members evaluate, synthesize and grade the strength of the available evidence to support conclusions that answer a precise series of questions. The EAL has many benefits that include minimizing possible bias, use of the highest quality research studies to answer relevant food and nutrition questions, and it overall aids in the development of evidence-based nutrition practice guidelines to ensure patient care. To guarantee a critical analysis of multiple research studies and papers for the evaluation of a food and nutrition question, there is a rigorous 5-step process: 1) Formulate the Evidence Analysis Questions, 2) Gather and Classify the Evidence, 3) Critically Appraise

Each Article, 4) Summarize the Evidence, 5) Write and Grade the Conclusion Statement (The Academy of Nutrition and Dietetics, 2017).

Step One: Formulate the Evidence Analysis Questions

In order to specify a focused, quality question in a defined area of practice, three key items are utilized. These items include an analytical framework to identify links between factors and outcomes, a PICO format to write the question, and the nutrition care process to serve as a framework (The Academy of Nutrition and Dietetics, 2017). The focus of this particular EAL is to review the evidence and determine whether following a Heart Healthy, defined as DASH or Mediterranean diet improves HF patient's outcomes instead of having the sole focus of a nutrition intervention be on a sodium restriction only. To formulate a specific research question, a PICO format was utilized. For population with a specific problem, people with HF were chosen. For the intervention, procedure or approach, a DASH or Mediterranean diet was chosen. Assessed clinical improvements and/or symptom management, re-hospitalizations, mortality rate and HRQoL will be the outcomes of interest.

Step Two: Gather and Classify the Evidence

The process of finding the best, most appropriate research involves several actions: developing a search plan with inclusion and exclusion criteria, conducting a search using various sources, reviewing citations and abstracts, gathering articles that meet criteria, and constructing a search plan and results through detailed examination of included and excluded articles.

Search Plan and Results

Question:

Should an overall diet approach recommending the DASH or Mediterranean diet, regardless of exact sodium intake, be recommended for a nutrition intervention for patients with HF?

Date of Literature Review: 2016-2018

Inclusion Criteria:

- Nutrition-Related Problem/Condition: Heart Failure
- Age of participants: at least 18 years old
- Setting: Acute care, clinic or home environment
- Study Design: Include all study designs
- Size of Study Groups: The sample size must equal at least 10 individuals for each study group
- Outcomes looking at mortality, re-hospitalization rate, quality of life and/or symptom management
- Year Range: 2008-2018
- Languages: English

Exclusion Criteria:

- Participant Age: Less than 18 years of age
- Languages: Languages other than English
- Year Range: Prior to 2008
- Does not meet inclusion criteria

Search Terms: "heart failure and diet", "heart failure and heart healthy diet", "heart failure and DASH diet", "heart failure and Mediterranean diet", "heart failure and dietary approaches to stop hypertension", "heart failure and nutrition"

Electronic Databases: EBSCOhost, Google Scholar

List of Included Articles:

- Hummel, SL., Karmally, W., Gillespie, B., Helmke, S., Teruya, S., Wells, J., Trumble, E., ... Maurer, M. (2018). Home Delivered Meals Post discharge From Heart Failure Hospitalization: The GOURMET-HF Pilot Study. *Circ Heart Fail*. 11. doi: 10.1161/circheartfailure.117.004886.
- Levitan EB., et al. (2013). Mediterranean and DASH Diet Scores and Mortality in Women with Heart Failure: The Women's Health Initiative. *Circ Heart Fail.* doi: 10.1161/CIRCHEARTFAILURE.113.000495
- Miró Ó., Estruch, R., Martin-Sánchez, FJ., Gil, V., Jacob, J., Herrero-Puente, P., . . . Llorens, P. (2018). Adherence to Mediterranean Diet and All-Cause Mortality after an Episode of Acute Heart Failure. *JACC: Heart Failure* 2018 January (6)1 52-62. doi: 10.1016/j.jchf.2017.09.020
- Rifai, L., Pisano, C., Hayden, J., Sulo, S., & Silver, MA. (2015). Impact of the DASH diet on endothelial function, exercise capacity, and quality of life in patients with heart failure. *Proc (Bayl Univ Med Cent):* April; 28 (2): 151-156.
- Spaderna H., Zahn, D., Pretsch, J., Connor, SL., Zittermann, A., Schleithoff, SS., . . Weidner, G. (2013). Dietary Habits are Related to Outcomes in Patients With Advanced Heart Failure Awaiting Heart Transplantation. *Journal of Cardiac Failure* 19(4). doi: 10.1016/j.cardfail.2013.02.004

List of Articles Included from Handsearch or Other Means: n/a

List of Excluded Articles with Reason:

- Hummel, SL., Seymour, EM., Brook, RD., Kolias, TJ., Sheth, SS., Resenblum, HR., . Weder, AB. (2012). Low-Sodium Dietary Approaches to Stop Hypertension Diet Reduces Blood Pressure, Arterial Stiffness, and Oxidative Stress in Hypertensive Heart Failure with Preserved Ejection Fraction. *Hypertension.* 60:1200-1206. doi: 10.1161/HYPERTENSIONAHA.112.202705
    - Reasons for exclusion: size of study groups < 10, Outcomes looked at were not mortality, re-hospitalization rate, quality of life and/or symptom management
- Matthew, AV., Seymour, EM., Byun, J., Pennathur, S., & Hummel, SL. (2015). Altered Metabolic Profile with Sodium-restricted Dietary Approaches to Stop Hypertension Diet in Hypertensive Heart Failure with Preserved Ejection Fraction. *J Card Fail.* 21(12): 963-967. doi: 10.1016/j.cardfail.2015.10.003
    - Reasons for exclusion: size of study groups < 10, Outcomes looked at were not mortality, re-hospitalization rate, quality of life and/or symptom management
- Chrysohoou, C., Pitsavos, C., Metallinos, G., Antoniou, C., Oikonomou, E., Kotroylannis, I., ... Stefanadis, C. (2012). *Heart Vessels*. 27:576-584, doi: 10.1007/s00380-011-0190-9
    - Reason for exclusion: Outcomes looked at were not mortality, re-hospitalization rate, quality of life and/or symptom management

Summary of Articles Identified to Review: 8 primary research articles were identified and 5 were included

Step Three: Critically Appraise Each Article

Step three involves critically assessing each included article for methodological quality. Each of the studies is evaluated based on appropriateness of study design and the quality of how the study was conducted. This is accomplished by using the Academy's risk of bias tool called the Quality Criteria Checklist (Appendix A). Information from each research study is placed into this worksheet to assist with answering clear questions to determine the strength of the evidence. The study is then considered negative, neutral or positive through these questions and answers.

Step Four: Summarize the Evidence

There are two major tasks achieved during step four. Key data from the included articles is extracted by using the Academy's extraction template as well as developing an easy-to-read summary through summarizing the evidence extracted from each study. An evidence summary is then established and typically includes the type of studies, population studies, number of subjects, methods used, main findings and study limitations.

Step Five: Write and Grade the Conclusion Statement

A concise conclusion statement for the research question is developed during this step by pulling together all information achieved through this entire process. The conclusion statement is then assigned a grade that reflects the overall strength and weakness of evidence in forming the conclusion statement. The grading scale used by the Academy is: Grade I (good/strong), II (fair), III (limited/weak), IV (expert opinion only), or V (not assignable). A grade is given to each element including quality, consistency, quantity, clinical impact and generalizability giving an overall strength evaluation of studies included on the nutrition topic.

Specific Considerations

When establishing the research question, the primary purpose was to focus on the population of HF patients that may be in question of whether a sodium restriction is beneficial for them. This population is a further subset of the unique variety of a HF patient that can be seen while hospitalized. In order to focus recommendations on sodium, studies that utilized a fluid restriction as an intervention were not considered in this analysis. Investigating this role with patients at least 18 years of age also helps clarify results for this specific population. An additional consideration was determining the type of setting for research. Although acute care patients are typically seen in a clinical setting, recommendations from this analysis are intended to also extend into the community setting.

Results

Author, Year, Study, Design, Class, Rating	**Study Purpose**	**Study Population**	**Intervention**	**Outcomes**	**Limitations**
Author: Spaderna et al. Year: 2013 Study Design: Prospective observational Class: D Rating: Neutral (Ø)	Evaluated the role of dietary habits on outcomes of HF patients on transplant list: death, delisting due to deterioration, high-urgency transplantation, delisting due to clinical improving and elective transplantation	318 with advanced heart failure, waiting for a heart transplant candidates (82% male, age 53±11 years)	Examined associations between consumption frequencies of salt foods, foods high in PUFA + MUFA, foods high in saturated fat, fruits/vegetable/legumes	A more frequent salty food intake was associated with shortened time to transplantation in high-urgency status, clinical deterioration. A 1-unit increase in consumption frequency of salty food intake was associated with an almost 3-fold Hazard Ratio for this outcome (HR 2.88, 95% CI 1.54-5.37; P< 0.001). (Remained independently associated with an increased for high urgency transplantation when all dietary habits entered together HR 2.91, 95% CI 1.29-6.60; P=0.11). Consumption of foods rich in PUFA+MUFA was positively associated with reduced Hazard Ratios for death/deterioration. A 1-unit increase in consumption frequency of foods rich in these was associated with a 50% risk reduction for this outcome. (HR 0.49, 95% CI 0.26-0.92; P=0.028). (Remained independently associated with an increased for high urgency transplantation when all dietary habits	Food frequency questionnaire was used, which does not allow for any conclusions about actual nutrient intakes or total amount of calories consumed. Prospective observational study design limits drawing conclusions about cause and effect relationships. It is possible that other variables not measured could have affected clinical

				entered together HR 0.48, 95% CI 0.24-0.95; P= 0.34). More frequent consumption of fruits/vegetables/legumes increased chance for delisting due to improvement (CI 1.14- 13.29; P= 0.03).	outcomes (such as cachexia) Low number of women in study.
Author: Levitan et al. Year: 2013 Study Design: Prospective observational Class: D Rating: Neutral (Ø)	To explore the relationship of dietary patterns with mortality among women with HF, evaluating Mediterranean and DASH diet scores.	3,215 postmenopausal women ages 50-79 recruited for Women's Health Initiative later diagnosed with HF.	Measured dietary intake using a Food Frequency Questionnaire at baseline visit and again at 1 year or 3 years. (completed median of 2.3 years prior to HF hospitalization)	Women with a higher DASH diet score had a lower hazard rate of death. With 1-unit higher DASH diet score HR was 0.98 (95% CI 0.97-0.99, P=0.003) Higher intake of vegetables, nuts and legumes, and whole grains were associated with lower mortality rates, but other dietary components including sodium and alcohol were not.	Women only study. Food frequency questionnaire was used, which does not allow for any conclusions about actual nutrient intakes or total amount of calories consumed.
Author: Rafai et al. Year: 2015 Study Design: Randomized controlled Class: A Rating: Positive (+)	Examined the effects of the DASH diet on endothelial function, exercise capacity, and quality of life in patients with HF.	48 stable HF patients with chronic symptomatic (stage C, NYHA I-III) heart failure. (DASH – 12 men, 11 women and Comparison – 16 men, 8 women)	General HF diet information vs. DASH diet educational packet with eating plan guidebook, DASH shopping list. Daily and weekly food diary filled out. Multiple meetings/phone calls to dietitian for both groups reinforcing their respective diets.	Quality of life measured with Minnesota Living with Heart Failure Questionnaire (MLHFQ) scores at baseline were similar between groups (P=0.056); patients in DASH group reported improved MLHFQ scores at 3 months follow-up (21 vs. 39; P=0.006) No statistically significant changes in estimated sodium intake were found in the groups during the study.	No blinding techniques were used. Adherence was self-reported rather than confirmed via objective tests Short term results of 3 months.
Author: Miró et al. Year: 2018 Study Design: prospective observational Class: D Rating: Neutral (Ø)	To Evaluate clinical outcomes of patients after an episode of acute HF according to their adherence to the Mediterranean diet	991 patients (mean age 80±10 years, 57.8% women. 523 (52.9%) adherent to Mediterranean diet.	Utilized 14-point questionnaire of adhesion to MedDiet to ask about dietary habits followed by patients during the year before the index episode (asked 1 month post episode) and at end of follow-up period to see if changes occurred. No diet instructions (except salt	After a mean follow-up period of 2.1±1.3 years, no differences were observed in survival between adherent and non-adherent patients (HR 0.86; 95% CI: 0.73-1.02). Patients adherent to the MedDiet showed a significantly lower hospitalization rate than non-adherent patients (HR: 0.74; 95% CI: 0.61 to 0.90; P= 0.003)	Limited generalizability: High comorbidities and elderly cohort (some diagnosed with CVD years earlier). Salt intake and dietary energy intake were not recorded. Non-interventional study: potential

			intake) were given to the patients during stay.		benefits of increasing adherence to MedDiet were not evaluated. 15% of patients changed dietary habits during duration of study; did not explore the effects of changes in diet.
Author: Hummel et al. Year:2018 Study Design: randomized, controlled trial Class: A Rating: Positive (+)	To examine the effects of direct dietary support in patients with HF after hospital discharge	66 (age, 71 ± 8 years, 30% female; ejection fraction, 39±18%	4 weeks of home-delivered nutritiously completed meals meeting DASH-low sodium guidelines vs. usual care post discharge	KCCQ summary score increased in both groups from hospital discharge to week 4 (DASH: 46±23-59±20, change 13±19;usual care: 43±19-53±24, change 10±16 ($p < 0.001$) 3 points greater in the DASH group, but this difference was not statistically significant 30 day post discharge, 4 all-cause (3 HF) hospitalizations had occurred in DASH group compared to 12 (11HF) in usual care group ($p=0.005$) DASH spent 17 cumulative days re-hospitalized compared to 55 days for usual care group ($P=0.06$) At 12 weeks, 15 all cause re-hospitalizations (8HF), 22 all cause (18HF) in usual care group ($p=0.45$) No significant between-group differences in calories, sodium or potassium intake	Unable to definitively analyze the nutrients consumed as some 3-day food records had inadequate detail. Limited generalizability due to all patients having hypertension to participate.

CHAPTER 4: RESULTS

A total of five articles were included in the evidence analysis by meeting the established inclusion criteria and providing evidence for the research question, "Should an overall diet approach recommending the DASH or Mediterranean diet, regardless of exact sodium intake, be recommended for a nutrition intervention for patients with HF?" The following results were recognized from the analysis.

Mortality

Spaderna et al (2013) designed an observational study to evaluate the role of dietary habits on outcomes of HF patients on the cardiac transplant list. The study received a neutral rating. Previous evidence suggested that the beneficial effects of MUFA and PUFA on cardiovascular health may extend to patients with heart failure and in addition, fruit and vegetable intake has been associated with reduced incidence of HF (Spaderna et al., 2013). Furthermore, the clinical benefits of restricting salt and fluid intake remain unclear. Therefore, investigators examined associations between consumption frequency of high salt foods, foods high in PUFA and MUFA, foods high in saturated fatty acids, fruits/vegetables/legumes by using a food frequency questionnaire adapted from the *Fragebogen zur Erfassung des Gesundheitsverhaltens* (FEG; Questionnaire for the Assessment of Health Behavior). Participants were recruited starting April 1, 2005, to December 31, 2006 and were followed until January 2009. Results showed that consumption of foods rich in PUFA and MUFA was positively associated with reduced Hazard Ratios for death/deterioration. A 1-unit increase in consumption frequency of foods rich in these was associated with a 50% risk reduction for this outcome. (HR 0.49, 95% CI 0.26-0.92; P=0.028).

In another observational study by Levitan et al. (2013), the effects of overall dietary patterns on mortality for people with HF were examined. The study received a neutral rating. Investigators wanted to change from a sole focus on sodium intake to an overall dietary pattern of the DASH or Mediterranean diet that have been found to be palatable, relatively easy to adhere to, have demonstrated beneficial cardiovascular effects, and are consistent with many dietary recommendations. Dietary intake of 3,215 postmenopausal women was assessed using a modified Block FFQ prior to their first HF hospitalization. A standard portion size and 9 possible

frequency-of-consumption responses, ranging from “never or less than once per month” to “6 or more times per day” was given for each food item and DASH and Mediterranean diet score was calculated. They constructed the DASH score based on food and nutrients emphasized or minimized in the DASH diet focusing on 8 components: high intake of fruits, vegetables, nuts and legumes, low-fat dairy products, and whole grains and low intake of sodium, sweetened beverages, and red and processed meats. The components of the Mediterranean diet included vegetables (excluding potatoes), fruits, nuts, whole grains, legumes, fish, ratio of monounsaturated to saturated fat, red and processed meats, and alcohol. Participants with intake above the median intake received 1 point for these categories; otherwise, they received 0 points. Red and processed meat consumption below the median received 1 point. Over a median of 4.6 years of follow-up, a higher Mediterranean diet score was associated with a lower hazard rate of death among women with HF in age-and energy adjusted model but after adjustment for demographics, health behaviors, comorbidities and medications, women with Mediterranean diet scores in the top quartile had a 15% lower hazard rate of death than those in the bottom quartile, though this was not statistically significant (p=0.08). Women with a higher DASH diet score had a lower hazard rate of death in models adjusted for age and energy intake. In the multivariable adjusted models, women with HF who had DASH diet score in the top quartile had a 16% lower hazard rate of death than women with scores in the bottom quartile (p for linear trend = 0.01). In the fully adjusted models, the HR associated with 1-unit higher DASH diet score was 0.98 (95% CI 0.97-0.99, p=0.003).

Miró et al. (2018) developed a prospective cohort observational study to evaluate clinical outcomes of patients after an episode of acute heart failure, according to their adherence to the Mediterranean diet. It received a neutral rating. A 14-point score of adherence was calculated for

991 patients using a food questionnaire to assess the intake 1 year prior to hospitalization. Adherence was determined if patients achieved ≥ 9 points. No diet instructions, except for salt intake, were given to patients during their stay in the ED. An attempt was made to contact non-deceased patients at the end of follow-up to investigate if any changes in diet had occurred since baseline. After a mean follow-up period of 2.1±1.3 years, 569 patients died with no differences between both groups in the follow up time (p=0.41). The cumulative mortality at the end of the study was lower in patients adherent to the Mediterranean diet than in those who were not adherent, although the difference did not reach statistical significance (HR: 0.86; 95% CI: 0.73 to 1.02; p=0.08).

Re-hospitalization rate & Symptom Improvement

Spaderna et al. (2013) as well as Miró et al. (2018) found additional results other than mortality; they assessed outcomes of symptom improvement and re-hospitalization rates. Spaderna et al. (2013) concluded that more frequent consumption of fruits/vegetables/legumes increased chances for delisting from the cardiac transplant list due to improvement in symptoms after additional adjustment for cardiac index (HR 3.89, 95% CI 1.14- 13.29; P= 0.03). Miró et al. (2018) concluded that patients adherent to the Mediterranean diet showed a significantly lower re-hospitalization rate than non-adherent patients (HR: 0.74; 95% CI: 0.61 to 0.90; P= 0.003).

Hummel et al. (2018) designed a randomized, single-blind controlled trial aiming to examine outcomes after providing nutritionally complete, DASH diet compliant, meals to patients for 12 weeks after experiencing a HF hospitalization. It received a positive rating. Although only one group received meals, both groups did receive a standardized educational pamphlet at hospital discharge with information on how to follow a sodium-restricted diet. Both groups also provided 3-day food diaries during weeks 1 and 4 post-discharge from the hospital.

The study's main objective was to look at changes in symptoms/ symptom improvement using the Kansas City Cardiomyopathy Questionnaire (KCCQ). The summary score increased in both groups from hospital discharge to week 4 (DASH: 46±23-59±20, change 13±19; usual care: 43±19-53±24, change 10±16 ($p < 0.001$). The mean increase of the score was 3 points greater in the DASH group, but this difference was not statistically significant ($p=0.37$). The KCCQ clinical summary score also increased in both groups from discharge to week 4 with the mean increase in the clinical score of 9 points greater in the DASH group, nearing but not achieving statistical significance ($p=0.053$). At 30 day post discharge, 3 patients with 3HF re-hospitalizations occurred in the DASH group, as compared to 9 patients with a total of 11 HF re-hospitalizations in the usual care group ($p=0.055$). At 12 weeks, 15 all cause re-hospitalizations (8HF), 22 all cause (18HF) in usual care group ($p=0.11$). There was no significant difference between-group difference in estimated calorie, sodium, or potassium intake. Although the study did not provide any statistically significant results, the authors determined that home delivery meals were feasible, participants largely adhered to the study diet, and diet-related adverse events were uncommon and overall it demonstrated trends for efficacy in several domains including symptoms and physical limitations related to HF as well as re-hospitalization burden.

Quality of life

Rafai et al. (2015) is a single-center randomized controlled study, examining the effects of the DASH diet on outcomes including quality of life in patients with chronic symptomatic (stage C) HF. The study received a positive rating. Forty-eight patients were randomized to follow the DASH or general HF dietary recommendations. To accurately assess the degree of concordance with the DASH diet, patients were assessed monthly using a DASH diet index. During a monthly interview with a registered dietitian, the reported intake of sodium was

estimated from the patients' corresponding food diaries and included in a food frequency questionnaire. Although more patients in the comparison group had sodium intake levels >1500 mg/day at baseline, groups were comparable regarding the changes in sodium intake levels at 1,2 and 3 months (p values > 0.05). Quality of life was measured using the Minnesota Living with Heart Failure Questionnaire (MLHFQ) at baseline and 3 months following either diet plan. MLHFQ scores at baseline were similar between groups ($p=0.056$); however, patients in the DASH group reported improved scores at 3-month follow-up ($p= 0.006$).

CHAPTER 5: DISCUSSION

An overall healthy dietary pattern rich in fruit, vegetables, whole grains, nuts, and legumes and also low in processed foods and red meats has been increasingly studied in HF patients. A reason for this increasing interest is the demonstrated benefits of this dietary pattern on prevention of heart disease as well as the inconsistent data on the common sodium restriction recommendation. Malnutrition is also common in HF and the standard recommendation to restrict sodium could contribute to further dietary nutritional deficiencies. As HF rates continue to rise, the nutrition factors that may influence this disease will continue to be explored.

Evidence from the five studies, found a heart healthy (DASH/Mediterranean) intake is associated with significant beneficial effects on patients with HF, including decreased mortality rate, decreased re-admission rates, increased symptom management, and improved quality of life ratings. The results of the studies analyzed, however, were weakened by the study design flaws, many being observational studies using food diaries and food frequencies questionnaires that can be flawed due to a participant's lack of understanding of what is being asked as well as truthfulness of the responses. The prospective observational design of the majority of the studies

in this analysis limits drawing conclusions about cause and effect relationships. Two of the five studies, Hummel et al. (2018) and Rifai et al. (2015) were randomized, controlled studies but Hummel et al. (2018) did not find any significant results for outcomes being assessed and Rifai et al. (2015) had less than 50 participants. Unfortunately, although all five studies examined HF and heart healthy intake, they also focused on different outcomes, meaning some of the outcomes mentioned were assessed in only one available study.

Mortality

Three observational, non- controlled trials, examined the outcome of mortality. The study design allowed for each study to have large samples, Spaderna et al. (2013) having the lowest at 318 subjects. This study looked at the specific parts of a heart healthy dietary pattern instead of providing a points-system for an overall adherence and found the increase in MUFA and PUFA intake significantly reduced the risk of death/deterioration independently from other dietary habits. Both Levitan et al. (2013) and Miró et al. (2018) examined whole dietary patterns. Levitan et al. (2013) evaluated participants' diets and provided both a DASH and Mediterranean diet score finding only an association with lower mortality and a higher Mediterranean score but also found that patients with a higher DASH diet score had a significant lower hazard rate of death in models adjusted for age and energy intake. Miró et al. (2018) assessed adherence to the Mediterranean diet and found that cumulative mortality at the end of the study was decreased in patients who were adherent to the diet but there was no significance found. Overall, Levitan et al. (2013) was the only study to find that an overall DASH dietary pattern is associated with lower mortality rates in patients with HF. Study participants were all women, making it difficult to generalize to the general population.

Re-hospitalization rate & Symptom Improvement

Three of the analyzed studies examined the outcome of reduced re-hospitalizations and symptom improvement. The two observational, non-controlled trials, were Spaderna et al. (2013) and Miró et al. (2018). Spaderna et al. (2013) did not look at overall dietary pattern and concluded that an increase intake of fruit/vegetables/legumes significantly improved symptoms. Miró et al. (2018) found that adherence to the Mediterranean diet pattern reduced re-hospitalizations rates compared to non-adherence to it. The last study that examined re-hospitalization rates was Hummel et al. (2018), a randomized single-blinded controlled trial with only 66 participants. Although there were less re-hospitalizations overall for the patients who received DASH diet delivered meals, no significance was found. Overall, one study found the Mediterranean dietary pattern was effective in decreased re-hospitalizations and the one study focusing on symptom improvement was focused on only one aspect of a heart healthy diet.

Quality of Life

Unlike the previous outcomes, an increased quality of life only had one study dedicated to this outcome. Rafai et al. (2015) was a randomized control trial with only 48 participants. This study chose to analyze the DASH diet's adherence, providing education to participants on how to follow this diet as well as frequent contact with a registered dietitian. Quality of life was measured using the MLHFQ at baseline and 3 months. Patients in the DASH group reported improved scores at 3-month follow-up from hospitalization. This study did limit its generalizability due to enlisting patients who were considered in stage C of HF with chronic symptoms. Again, one of the five studies provided results for the Mediterranean diet increasing reported quality of life.

Research Design Summary and Limitations

A randomized controlled trial (RCT) is typically the ideal study design in order to appropriately assess an intervention compared to a control group. Out of the five studies, two chose to use this study design and the other three were observational, non-controlled trials. One RCT was not able to determine significant differences following statistical analysis. Limitations exist with the dietary assessment protocol of self-administered questionnaires. Although dietary assessment tools were used, dietary recall remains a subjective and biased measurement, especially when having family members in one study fill it out for the participant. Each study preferred a different food frequency questionnaire, some using a 14-point system and others using a 9-point system for adherence, making standardization difficult. Specific nutrient intake was also not assessed due to limitations of these questionnaires, making it difficult to conclude if specific nutrients or lack of nutrients, such as magnesium, potassium or sodium, led to outcomes. Other limitations to the studies of this analysis included limited diversity of participants including one study with all women, another study with 82% men and another study having only patients considered in Stage C HF. This lack of diversity makes it difficult to generalize results to the HF population.

Conclusion Statement

A heart healthy dietary pattern (DASH/Mediterranean diet) in adult patients with HF trends towards an association with decreased mortality rates, decreased re-hospitalization rates, and improvement in quality of life.

This is a Grade III-*Limited* conclusion due to the limited number of studies, lack of generalizability and weak study designs. Results were limited due to inconsistent findings

between studies, having only one study per outcome find significant results. Also, the fact that sodium intake was typically not calculated is concerning as this could be the leading determinant in the outcomes.

Applications to Practice

Patients with HF are at greater risk for malnutrition because of malabsorption from gut edema and anorexia from cytokine production. Limitations in eating and food preparation from fatigue due to an increased work of breathing also can contribute to malnutrition (Academy of Nutrition and Dietetics, 2018).

Dietary recommendations and sodium restriction education for HF patients are primary interventions for registered dietitian nutritionists. The EAL for HF currently focuses on sodium and fluid intake reporting research suggests that sodium intake of less than 3 g daily resulted in reduced symptom burden, when compared to sodium intake levels above 3 g daily, fluid intake was not recorded. It is acknowledged that further research is needed (Academy of Nutrition and Dietetics, 2016). The Nutrition Care Manual from the Academy of Nutrition and Dietetics recommends nutrition education to help minimize HF symptoms by using targeted nutrition interventions that provide adequate calories, proteins, and nutrients while limiting fluid (2L/day) and sodium (2-3 g/day*) as needed* to control HF symptoms (Academy of Nutrition and Dietetics, 2018).

A low sodium intake may be associated with further dietary micronutrient deficiencies and lower overall energy intake, especially in elderly HF patients. In the research, restriction of salt intake has uncertain efficacy. Observations studies have shown some benefits and harms, possibly depending on NYHA HF stage, whereas some RCTs have suggested harms. This makes

it difficult for the registered dietitian nutritionist to confidently provide education regarding a sodium restriction to their patients. Hummel et al. (2018) did show that a low sodium, nutrient complete diet is possible. The preparation of these meals may not be feasible for many fatigued, elderly HF patients to prepare on their own though and palatability is a potential deterrent when anorexia is a potential symptom. Conclusions from these studies are more specific regarding which types of foods to recommend to patients with HF to meet nutrient needs, heart healthy ones including fruit, vegetables, nuts/legumes, whole grains and foods high in MUFA and PUFA including olive oil and fish. A focus on this pattern of intake also appears to improve patients' quality of life, possibly due to a focus on foods they can eat instead of a focus on limiting sodium. Ultimately, patients with HF who are counseled to follow a heart healthy dietary pattern may have the potential to positively affect re-hospitalization rates, decrease mortality rates and improve their quality of life.

Recommendations for Future Research

Despite this EAL project's a Grade III –*Limited* conclusion for a heart healthy dietary pattern for HF patients, more research is needed. Further RCT studies with larger, diverse sample sizes would provide strength to outcomes. Examining patients who are non-adherent to a heart healthy diet and then educating the intervention groups on the heart healthy (DASH or Mediterranean diet) and the control group on a low sodium diet would set up a scenario for possible change in the commonly practiced dietary education on a sole sodium reduction. Also, continuing with Hummel et al.'s (2018) idea, providing lower sodium yet nutrient dense meals to participants and having the control group follow a nutrient dense, no sodium restriction diet would be beneficial to explore. Providing meals, although costly, would solve the problem of subjective food frequency questionnaires. Outcomes examined should be ones patients and

physicians care about; mortality, symptom management, re-hospitalization rate and quality of life all having large impacts on HF patients' lives. Overall, there does appear to be promising outcomes when patients with HF follow a heart healthy dietary pattern.

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APPENDIX A: EVIDENCE ANALYSIS WORKSHEETS

Academy of Nutrition and Dietetics Evidence Analysis Library Worksheet for Primary Research Article

Citation:	Spaderna H., Zahn, D., Pretsch, J., Connor, SL., Zittermann, A., Schleithoff, SS., . . Weidner, G. (2013). Dietary Habits are Related to Outcomes in Patients With Advanced Heart Failure Awaiting Heart Transplantation. Journal of Cardiac Failure 19(4). doi: 10.1016/j.cardfail.2013.02.004
Study Design:	Prospective Observational
Class:	D
Quality Rating:	Neutral (Ø)
Research Purpose:	To evaluate the role of dietary habits, consumption frequency of salty foods, foods high in PUFA + MUFA, foods high in saturated fatty acids, fruits/vegetables/legumes on outcomes of HF patients on the cardiac transplant list
Inclusion Criteria:	No inclusion criteria was described
Exclusion Criteria:	• Age < 19 years • Listed for combined heart-lung transplantation • Re-transplantation • Not fluent in German • Too severely ill to participate (rated by physician)
Description of Study Protocol :	Recruitment: Patients were recruited from 17 hospitals after being newly placed on cardiac transplantation list. Recruitment took place from April 1, 2005 – December 31, 2006 and subjects were followed until January 2009. Study Protocol: A food frequency questionnaire was administered within a median of 15 days since being placed on listing to assess consumption frequencies of 33 food items and 5 alcoholic beverages. Participants were asked to specify how often they consumed the listed foods and drinks (4=daily, 3=several times a week, 2= occasionally, 1=never. Based on these ratings, 4 scores were calculated to measure frequency of (1) salty foods, (2) foods high in saturated fat, (3) foods high in PUFA + MUFA and (4) fruits/vegetables/legumes. Statistical Analysis: • To compare frequency data between groups (e.g., patients with and without hyponatremia) chi-square tests were used. • The Cox proportional hazards regression was used to evaluate if dietary habits were associated with time until outcomes. Multivariate analyses were conducted, adjusted for age, sex, disease duration, BMI, and heart failure severity.
Data Collection Summary:	Dietary intake was assessed and patient characteristics were collected at baseline. Dependent Variables: Outcomes observed were death on the waiting list, need for high urgency transplant, elective transplant, delisting due to clinical deterioration or delisting due to clinical improvement.
Description of Actual Data Sample:	Initial n = 380 met inclusion criteria, 340 consented, 318 completed the questionnaire. Final n = 318 (82% male, age 53 ± 11 years). Ethnicity not described.

	Multi-center study in Germany and Austria
Summary of Results:	A more frequent salty food intake was associated with shortened time to transplantation in high-urgency status, clinical deterioration. A 1-unit increase in consumption frequency of salty food intake was associated with an almost 3-fold Hazard Ratio for this outcome (HR 2.88, 95% CI 1.54-5.37; P< 0.001). (Remained independently associated with an increased for high urgency transplantation when all dietary habits entered together HR 2.91, 95% CI 1.29-6.60; P=0.11). Consumption of foods rich in PUFA+MUFA was positively associated with reduced Hazard Ratios for death/deterioration. A 1-unit increase in consumption frequency of foods rich in these was associated with a 50% risk reduction for this outcome. (HR 0.49, 95% CI 0.26-0.92; P=0.028). (Remained independently associated with an increased for high urgency transplantation when all dietary habits entered together HR 0.48, 95% CI 0.24-0.95; P= 0.34). More frequent consumption of fruits/vegetables/legumes increased chance for delisting due to improvement (CI 1.14- 13.29; P= 0.03).
Author Conclusions:	This study indicates that dietary habits are related to the prognosis of patients with advanced HF awaiting transplantation. Specifically, patients who reported consumption of salty foods at time of listing had an increased risk for deterioration of health status. More frequent consumption of foods rich in PUFA + MUFA was independently associated with decreased risk for death/deterioration. These effects were independent of other factors including severity of HF, inpatient status, age, sex, disease duration, BMI and other dietary habits and health behaviors. There was some indication that frequent intake of fruit/vegetables/legumes increased the chance for clinical improvement and subsequent delisting, but only with additional adjustment for cardiac index.
Reviewer Comments:	*<u>Strengths</u>:* • *Many covariates and variables were controlled for during the multivariate analysis* • *Follow-up time was > 1 year* *<u>Limitations</u>:* • *It is unknown whether changes in dietary intake occurred throughout the years of follow up. No further assessment of intake was taken other than at baseline.* • *Self-reported or family -reported data was collected at home without assistance* • *Limited diversity of Sample as 82% were men, making it difficult to generalize results to women with HF as well.* • *Observational design of study limits drawing conclusions about cause and effect relationships.*
Funding Source:	None listed

Citation:	Levitan EB., et al. (2013). Mediterranean and DASH Diet Scores and Mortality in Women with Heart Failure: The Women's Health Initiative. *Circ Heart Fail.* doi: 10.1161/CIRCHEARTFAILURE.113.000495
Study Design:	Prospective Observational
Class:	D
Quality Rating:	Neutral (Ø)
Research Purpose:	To explore the relationship of dietary patterns with mortality among women with HF
Inclusion Criteria:	Adjudication of HF hospitalization was based on at least one of the following criteria: • Diagnosis by a physician and receipt of medical treatment for HF during admission • HF diagnosed by a physician and receipt of medical treatment for HF during admission plus documented impaired systolic or diastolic left ventricular function • Pulmonary edema or congestion by chest x-ray on admission • Dilated ventricles or poor left or right-side ventricular function by echocardiography, radionuclide ventriculogram/multigated acquisition, or other contrast ventriculography or evidence of left ventricular diastolic dysfunction
Exclusion Criteria:	• Survive at least 1 day past HF hospitalization • Missing Information on dietary intake or covariates • Implausible energy intake (<600 kcal/d or > 5,000 kcal/d)
Description of Study Protocol :	Recruitment: Patients were recruited from 1993-1998 at 40 United States' clinical centers through the Women's Health Initiative Clinical Trial. There were different portions of the trial including the Clinical Trial (CT) component, Hormone Therapy (HT), Dietary Modification (DM) and Calcium Plus Vitamin (CaD) and the Observational Study (OS) component. The CT and OS ended in 2004-2005; participants were invited to continue the Extension Study 2005-2010 and 2010-2015. This study included participants that were hospitalized for HF from 1993-2005. Study Protocol: Dietary intake was assessed using a modified Block FFQ. This was administered during baseline screening visit for all participants. Subsequently all participants in the DM portion of the trial completed FFQs at year 1, a portion DM participants completed FFQs yearly thereafter and OS participants completed FFQs at 3 years. The most recent completed FFQ prior to HF hospitalization was selected for each participant. A Mediterranean and DASH diet score was calculated. The most recent assessment prior to HF hospitalization of covariates including pill-bottle reviews, blood pressure, height and weight were selected as well. Follow-up for mortality began on the date of HF hospitalization and continued through the date of death or the last contact with the participant prior to August 2009. Statistical Analysis: • Linear regression for continuous variables and chi-squared tests for categorical variables. • Spearman correlation coefficient was used between the Mediterranean and DASH diet scores.

	• Cox proportional hazards models were used to estimate hazard ratios of mortality associated with quartiles of the DASH and Mediterranean diet scores. Two-sided p-values < 0.05 were considered statistically significant. No adjustments were made for multiple comparisons.
Data Collection Summary:	Dietary intake was assessed and patient characteristics were collected at baseline an again either every year or every 3 years. The most recent data prior to HF hospitalization was utilized. Deaths were determined through direct reports to the WHI participants' family, friends, or health care providers, response to WHI mailings by family, friends or US Postal Service, internet searches. Dependent Variables: Outcome observed was mortality classified as definite CHD, possible CHD, cerebrovascular, other cardiovascular, and unknown cardiovascular were considered CVD deaths.
Description of Actual Data Sample:	Initial n = 4,043 met inclusion criteria, 29 excluded who did not survive at least 1 day past HF hospitalization, 605 excluded due to missing information on dietary intake or covariates and 194 excluded due to implausible energy intake calculated used FFQ.. Final n = 3,215 (100% women, age 50-79) <u>Race/Ethnicity</u> (listed from highest % to lowest) White not of Hispanic origin, Black, Hispanic, Asian/Pacific Islander, American Indian/Alaskan Multi-center study in the United States
Summary of Results:	Over a median of 4.6 years of follow-up, 43.1% participants died. Sodium intake was positively associated with the Mediterranean diet score and inversely correlated with the DASH diet score. Women with a higher DASH diet score had a lower hazard rate of death. With 1-unit higher DASH diet score HR was 0.98 (95% CI 0.97-0.99, P=0.003) Higher intake of vegetables, nuts and legumes, and whole grains were associated with lower mortality rates, but other dietary components including sodium and alcohol were not. Sodium intake was positively associated with the Mediterranean diet score and inversely associated with the DASH diet score. After adjustment for demographics, health behaviors, comorbidities, and medications, women with Mediterranean diet scores in the top quartile had a 15% lower hazard rate of death than those in the bottom quartile, though not statistically significant (P=0.08)
Author Conclusions:	Results suggest that dietary patterns recommended for the general population and those with other cardiovascular conditions may also be beneficial in people with HF. Higher DASH diet scores were modestly associated with lower mortality in women with HF; there was a trend toward an association with the Mediterranean diet score that did not reach significant difference.

Reviewer Comments:	*Strengths:* • *Large population* • *Follow-up seemed an appropriate amount of time* *Limitations:* • *This is a women-only study making it difficult to generalize to all HF patients* • *It would have been nice to see sodium adjusted for to see if lower sodium intake was the only reason for lower mortality or if the DASH diet was the reason.* • *It is unknown whether changes in dietary intake occurred throughout the years of follow up. No further assessment of intake was taken other than at baseline* • *Observational design of study limits drawing conclusions about cause and effect relationships.*
Funding Source:	• The National Heart, Lung, and Blood Institute, • National Institutes of Health • U.S Department of Health and Human Services

Citation:	Rifai, L., Pisano, C., Hayden, J., Sulo, S., & Silver, MA. (2015). Impact of the DASH diet on endothelial function, exercise capacity, and quality of life in patients with heart failure. *Proc (Bayl Univ Med Cent):* April; 28 (2): 151-156.
Study Design:	Randomized Control Study
Class:	A
Quality Rating:	PLUS/POSITIVE (+)
Research Purpose:	To examine the effects of the DASH diet on endothelial function, exercise capacity, and quality of life in patients with chronic symptomatic (stage C) HF.
Inclusion Criteria:	• Adults > 18 years of age • Stage C/NYHA functional class I-III • Systolic or diastolic HF for at least 6 months
Exclusion Criteria:	• Serum creatinine > 3 mg/dL • Allergy or intolerance to components of the DASH diet • Chronic inflammatory bowel disease affecting gastrointestinal absorption, inability to perform the 6-minute walk test due to severe musculoskeletal disease • Dependency on using a walker or cane for ambulation
Description of Study Protocol :	Recruitment: Patients were recruited from the outpatient adult clinic at Advocate Christ Medical Center between February and July 2013. Study Protocol: Patients were randomized, using a block-randomization algorithm, to be in the DASH group or comparison group for 3 months in addition to receiving their standard HF medical therapy. DASH group were provided with an educational packet consisting of a copy of the US Department of Health and Human Services DASH eating plan guidebook; a DASH shopping list and a daily and weekly food diary. Comparison group had no changes suggested to their dietary habits other than the current general cautions for diet in HF. All patients received further education

	regarding their diet from a dietitian with the same dietitian conducting monthly, in-person sessions and weekly or biweekly phone calls to further reinforce respective diets. Statistical Analysis: Baseline characteristics and secondary outcomes of interest were compared using: • Student's t test • chi-square or Fisher's exact test • Mann-Whiney U test or Wilcoxon signed rank test depending on variable type and distribution. Two-sided p-values 0.05 was defined as statistically significant
Data Collection Summary:	Intake was assessed monthly (1, 2, and 3), using a DASH diet index, sodium intake was estimated by the dietitian from food diaries and food frequency questionnaire. Quality of life was measured using Minnesota Living with Heart Failure Questionnaire (MLHFQ) at baseline and 3 months follow-up. Other measured data includes baseline demographics and characteristics, a 6-minute walk test, measured at 1 and 3 months, pressure pulse contour analysis was used to assess endothelial function and hemodynamic parameters at baseline and at 1, 2 and 3 months follow-up. Independent Variables: Instructed regarding DASH diet or "cautionary" diet for HF. Dependent Variables: Outcomes observed were endothelial function, exercise capacity, and quality of life
Description of Actual Data Sample:	Initial n = not mentioned. Final n = 48 (60 % men) Race/Ethnicity (listed from highest % to lowest) Black, White Single-center study in the United States
Summary of Results:	Quality of life measured with Minnesota Living with Heart Failure Questionnaire (MLHFQ) scores at baseline were similar between groups (P=0.056); patients in DASH group reported improved MLHFQ scores at 3 months follow-up (21 vs. 39; P=0.006) No statistically significant changes in estimated sodium intake were found in the groups during the study. No statically significant differences between the DASH and comparison groups were found in weight, BMI, BNP, or for hemodynamic parameters. No statistically significant differences found in other outcomes measured over time.
Author Conclusions:	In patients with HF, the DASH diet was associated with favorable changes in LAE, exercise capacity, and quality of life scores. Integrating the DASH diet into the dietary patterns of patients with HF could hold potential beneficial effects in decreasing the progression of endothelial dysfunction.
Reviewer Comments:	*Strengths:* • *Randomized, control study* • *Diverse and generalizable population*

	Limitations: • *Short duration of study, data collected < 6 months after intervention* • *Adherence to diet was self-reported* • *Less than 50 participants in study* • *No blinding technique was used*
Funding Source:	• None Listed

Citation:	Miró Ó., Estruch, R., Martin-Sánchez, FJ., Gil, V., Jacob, J., Herrero-Puente, P., . . . Llorens, P. (2018). Adherence to Mediterranean Diet and All-Cause Mortality after an Episode of Acute Heart Failure. *JACC: Heart Failure* 2018 January (6)1 52-62. doi: 10.1016/j.jchf.2017.09.020
Study Design:	Prospective Cohort Observational
Class:	D
Quality Rating:	Neutral (Ø)
Research Purpose:	To evaluate clinical outcomes of patients after an episode of acute heart failure (AHF) according to their adherence to the Mediterranean diet.
Inclusion Criteria:	• Met inclusion into the Epidemiology of Acute Heart Failure in Emergency departments registry • Patient or relative able to answer questions about their regular diet
Exclusion Criteria:	• None specifically described
Description of Study Protocol :	Recruitment: Patients were recruited from the Epidemiology of Acute Heart Failure in Emergency departments registry between February 1, 2014 and March 31, 2014. Study Protocol: Questionnaire, administered via telephone, asked about dietary habits followed by patients during the year before the index episode. Adherence to MedDiet was estimated by using the 14-point questionnaire of adhesion to the MedDiet used and validated in the PREDIMED trial. Patients were divided into 2 groups depending on adherence (9 or more points) or non-adherence (8 or fewer points). No diet instructions (except salt intake were given to the patients included during their stay in the ED). Statistical Analysis: • Mann-Whitney nonparametric test • Chi-square test (with Yate's correction when needed) • Survival tables obtain by the Kaplan-Meier method • Comparisons of primary and secondary outcomes were performed following the Cox model Statistical significance was accepted if 95% CI of HRs excluded the value 1 or the p value was < 0.05.
Data Collection Summary:	Intake was assessed at baseline and they report "tried" to contact patients who were alive at the end of the follow-up period to investigate if any changes to diet had occurred. Dependent Variables: Primary end-point was all-cause mortality at the end of follow-up. Secondary end-points were ED revisits due to HF (without need for hospitalization), need for re-hospitalization due to HF.

Description of Actual Data Sample:	Initial n = 1,120 (11 excluded due to inability to answer questionnaire) Final n = 1,109 (57.8% female, 80 ±10) Race/Ethnicity : Not described Multi-Center study in 7 Spanish Hospitals' Emergency Departments
Summary of Results:	After a mean follow-up period of 2.1±1.3 years, no differences were observed in survival between adherent and non-adherent patients (HR 0.86; 95% CI: 0.73-1.02). Patients adherent to the MedDiet showed a significantly lower hospitalization rate than non-adherent patients (HR: 0.74; 95% CI: 0.61 to 0.90; P= 0.003) 85% of patients' dietary habits went unchanged from baseline for duration of study.
Author Conclusions:	The study did not show any association of the MedDiet with mortality of patients. In a group with such poor health status, effects on long-term outcomes may be beyond the influence of the adherence to the MedDiet pattern.
Reviewer Comments:	*Strengths:* • *Very little exclusions, making it a more generalizable cohort* • *Large n value, > 1,000* • *Re-assessed intake after baseline* *Limitations:* • *Adherence to diet was self/family-reported* • *Older cohort, may not apply to younger population* • *No intervention, potential increase in adherence to MedDiet was not evaluated* • *Participants had a very high number of comorbidities as well as functional limitations* • *Observational design of study limits drawing conclusions about cause and effect relationships.*
Funding Source:	None listed

Citation:	Hummel, SL., Karmally, W., Gillespie, B., Helmke, S., Teruya, S., Wells, J., Trumble, E., ... Maurer, M. (2018). Home Delivered Meals Post discharge From Heart Failure Hospitalization: The GOURMET-HF Pilot Study. *Circ Heart Fail*. 11. doi: 10.1161/circheartfailure.117.004886.
Study Design:	Randomized Controlled Trial
Class:	A
Quality Rating:	PLUS/POSITIVE (+)
Research Purpose:	To test the effects of home-delivered meals in patients after discharge from HF hospitalization.
Inclusion Criteria:	• ≥ 55 years of age (started at ≤65 but lowered due to slow recruitment) • Primary hospitalization for acute decompensated HF

	• Discharged to home
Exclusion Criteria:	• Hypotension during hospitalization • Hyperkalemia • Severe anemia • Length of stay < 48 h or > 14 d • Expected survival < 12 mo • Active alcohol or substance abuse • Dementia or history of nonadherence to treatment • At discharge: blood pressure systolic > 180 mmHg or diastolic > 100 mmHg, hypotension, need for intravenous inotropic therapy, severe renal insufficiency
Description of Study Protocol :	Recruitment: Recruited from 3 hospitals, post HF hospitalization Study Protocol: At hospital discharge, patients were randomized to usual care vs. receiving 4 weeks of home-delivered meals following a DASH diet plan (3 daily meals, snacks and some beverages) having 1,500 mg sodium and 2,100 calories daily. Both groups received a standardized educational pamphlet with information on how to follow a sodium-restricted diet. Meal delivery was paused for re-hospitalization and resumed at hospital discharge. Investigators were blinded to treatment assignment. Statistical Analysis: • All study outcomes were evaluated in an intent-to treat-analysis. • Between group differences in baseline characteristics were assessed using chi-squared tests for dichotomous variables and 2-sample t tests for continuous variables. • Within-group discharge to week 4 changes in Kansas City Cardiomyopathy Questionnaire (KCCQ) summary scores were evaluated using paired t tests and between-group comparison was made using linear regression • Probabilities over time since discharge of all-cause re-hospitalization and HF re-hospitalization were visualized using Kaplan-Meir curves.
Data Collection Summary:	Baseline population characteristics and cardiac biomarkers were taken. Baseline dietary patterns and nutrient intake were assessed at hospital discharge using 110-item Block FFQ for all participants. Adherence was assessed by meal delivery records and review of 3-day food diaries recorded during weeks 1 and 4 post-discharge for DASH group and 3-day food diaries for comparison group. Twenty-four hour urine collection was also performed at 1 and 4 weeks. KKCQ was taken at baseline and at 4 weeks post-discharge Dependent Variables: Change in KKCQ summary score, death, all-cause readmission
Description of Actual Data Sample:	Initial n = 107 • 23 met exclusion criteria before discharge • 8 were not discharged home • 12 declined to participate/other Final n = 66 (1/3 female)

	Race/Ethnicity : (listed from highest % to lowest) White, Black, Other 36% Hispanic, 64% non-Hispanic Multi-Site study, 3 hospitals in the United States
Summary of Results:	KCCQ summary score increased in both groups from hospital discharge to week 4 (DASH: 46±23-59±20, change 13±19;usual care: 43±19-53±24, change 10±16 ($p < 0.001$). 3 points greater in the DASH group, but this difference was not statistically significant At 30 day post discharge, 4 all-cause (3 HF) hospitalizations had occurred in DASH group compared to 12 (11HF) in usual care group. DASH spent 17 cumulative days re-hospitalized compared to 55 days for usual care group (P=0.06) At 12 weeks, 15 all cause re-hospitalizations (8HF), 22 all cause (18HF) in usual care group. No significant between-group differences in calories, sodium or potassium intake
Author Conclusions:	Home delivery meals were feasible, participants largely adhered to the study diet, and diet-related adverse events were uncommon. It did not meet its primary outcome (KKCQ changes) but it demonstrated trends for efficacy in several domains including symptoms and physical limitations related to HF as well as re-hospitalization burden.
Reviewer Comments:	*Strengths:* • *Single blinded, randomized control trial* • *For intervention subjects, actual intake is well known due to actual meals being provided* *Limitations:* • *They were unable to provide direct comparison between the provided meals and the diet consumed post-discharge by comparison group due to some 3-day food records having inadequate detail.* • *Short-duration to study* • *No significant results*
Funding Source:	• National Institutes of Health/National Institute of Aging • PurFoods, LLC

APPENDIX B: VALIDITY WORKSHEETS

Relevance Questions					
Citation: Spaderna H., Zahn, D., Pretsch, J., Connor, SL., Zittermann, A., Schleithoff, SS., . . Weidner, G. (2013). Dietary Habits are Related to Outcomes in Patients With Advanced Heart Failure Awaiting Heart Transplantation. Journal of Cardiac Failure 19(4). doi: 10.1016/j.cardfail.2013.02.004		**Yes**	**No**	**Unclear**	**N/A**

1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)		X			
2. Did the authors study an outcome (dependent variable) or topic that the patients / clients / population group would care about?		X			
3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?		X			
4. Is the intervention or procedure feasible (NA for some epidemiological studies)?		X			
If the answers to all of the above relevance questions are "yes", the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.					
VALIDITY QUESTIONS					
		Yes	**No**	**Unclear**	**N/A**
1. Was the research question clearly stated?		X			
1.1 Was the specific intervention(s) or procedure (independent variable(s)) identified?					X
1.2 Was the outcome(s) (dependent variable(s)) clearly indicated?		X			
1.3 Were the target population and setting specified?		X			
2. Was the selection of study subjects / patients free from bias?		X			
2.1 Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?		X			
2.2 Were criteria applied equally to all study groups?					X
2.3 Were health, demographics, and other characteristics of subjects described?		X			
2.4 Were the subjects /patients in a representative sample of the relevant population?		X			
3. Were study groups comparable?					X

3.1Was the method of assigning subjects / patients to groups described and unbiased? (Method of randomization identified if RCT)					X
3.2 Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?					X
3.3 Were concurrent controls used? (Concurrent preferred over historical controls.)					X
3.4 If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?					X
3.5 If case control study, were potential confounding factors comparable for cases and controls? If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.					X
3.6 If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g. "gold standard")?					X
4. Was method of handling <u>withdrawals</u> described?		X			
4.1 Were follow up methods described and the same for all groups?		X			
4.2 Was the number, characteristics of withdrawals (i.e. dropouts, lost to follow up, attrition rate) and/or response rate (cross -sectional studies) described for each group? (Follow up goal for a strong study is 80 %.)					X
4.3 Were all enrolled subjects/patients (in the original sample) accounted for?		X			
4.4 Were reasons for withdrawals similar across groups?					X
4.5 If diagnostic test, was decision to perform reference test not dependent on results of test under study?					X
5. Was <u>blinding</u> used to prevent introduction of bias?			X		
5.1 In intervention study, were subjects, clinicians / practitioners and investigators blinded to treatment group, as appropriate?					X
5.2 Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)				X	
5.3 In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?					X

5.4 In case control study, was case definition explicit and case ascertainment not influenced by exposure status?					X
5.5 In diagnostic study, were test results blinded to patient history and other test results?					X
6. Were intervention / therapeutic regimens / exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?		X			
6.1 In RCT or other intervention trial, were protocols described for all regimens studied?					X
6.2 In observational study, were interventions, study settings, and clinicians / provider described?		X			
6.3 Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?		X			
6.4 Was the amount of exposure and, if relevant, subject / patient compliance measured?			X		
6.5 Were co-interventions (e.g., ancillary treatments other therapies) described?					X
6.6 Were extra or unplanned treatments described?					X
6.7 Was the information for 6.4, 6.5, 6.6 and 6.7 assessed the same way for all groups?		X			
6.8 In diagnostic study, were details of test administration and replication sufficient?					X
7. Were outcomes clearly defined and the measurements valid and reliable?		X			
7.1 Were primary and secondary endpoints described and relevant to the question?		X			
7.2 Were nutrition measures appropriate to question and outcomes of concern?		X			
7.3 Was the period of follow-up long enough for important outcome(s) to occur?		X			
7.4 Were the observations and measurements based on standard, valid, and reliable data collection instruments / tests / procedures?		X			
7.5 Was the measurement of effect at an appropriate level of precision?		X			

7.6 Were other factors accounted for (measured) that could affect outcomes?		X			
7.7 Were the measurements conducted consistently across groups?		X			
8. Was the statistical analysis appropriate for the study design and type of outcome indicators?		X			
8.1 Were statistical analyses adequately described and the results reported appropriately?		X			
8.2 Were correct statistical tests used and assumptions of test not violated?		X			
8.3 Were statistics reported with levels of significance and/or confidence intervals?		X			
8.4 Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?				X	
8.5 Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g. multivariate analyses)?		X			
8.6 Was clinical significance as well as statistical significance reported?		X			
8.7 If negative findings, was a power calculation reported to address type 2 error?					X
9. Are conclusions supported by results with biases and limitations taken into consideration?		X			
9.1 Is there a discussion of findings?		X			
9.2 Are biases and study limitations identified and discussed?		X			
10. Is bias due to study's funding or sponsorship unlikely?				X	
10.1 Were sources of funding and investigators' affiliations described?			X		
10.2 Was there no apparent conflict of interest?		X			
SYMBOL NEUTRAL (ø)					
NEUTRAL (ø) If the answers to validity criteria questions 2, 3, 6, and 7do not indicate that the study is exceptionally strong, the report should be designated with a neutral (ø) symbol on the Evidence Quality Worksheet.					

Relevance Questions

Citation: Levitan EB., et al. (2013). Mediterranean and DASH Diet Scores and Mortality in Women with Heart Failure: The Women's Health Initiative. *Circ Heart Fail.* doi: 10.1161/CIRCHEARTFAILURE.113.000495		**Yes**	**No**	**Unclear**	**N/A**
1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)		X			
2. Did the authors study an outcome (dependent variable) or topic that the patients / clients / population group would care about?		X			
3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?		X			
4. Is the intervention or procedure feasible (NA for some epidemiological studies)?		X			
If the answers to all of the above relevance questions are "yes", the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.					
VALIDITY QUESTIONS					
		Yes	**No**	**Unclear**	**N/A**
1. Was the <u>research question</u> clearly stated?		X			
1.1 Was the specific intervention(s) or procedure (independent variable(s)) identified?					X
1.2 Was the outcome(s) (dependent variable(s)) clearly indicated?		X			
1.3 Were the target population and setting specified?		X			
2. Was the <u>selection</u> of study subjects / patients free from bias?		X			
2.1 Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?		X			
2.2 Were criteria applied equally to all study groups?					X

2.3 Were health, demographics, and other characteristics of subjects described?		X			
2.4 Were the subjects /patients in a representative sample of the relevant population?			X		
3. Were study groups comparable?					X
3.1Was the method of assigning subjects / patients to groups described and unbiased? (Method of randomization identified if RCT)					X
3.2 Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?					X
3.3 Were concurrent controls used? (Concurrent preferred over historical controls.)					X
3.4 If cohort study or cross-sectional study ,were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?					X
3.5 If case control study, were potential confounding factors comparable for cases and controls? If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.					X
3.6 If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g. "gold standard")?					X
4. Was method of handling withdrawals described?		X			
4.1 Were follow up methods described and the same for all groups?					X
4.2 Was the number, characteristics of withdrawals (i.e. dropouts, lost to follow up, attrition rate) and/or response rate (cross -sectional studies) described for each group? (Follow up goal for a strong study is 80 %.)		X			
4.3 Were all enrolled subjects/patients (in the original sample) accounted for?		X			
4.4 Were reasons for withdrawals similar across groups?					X
4.5 If diagnostic test, was decision to perform reference test not dependent on results of test under study?					X
5. Was blinding used to prevent introduction of bias?			X		
5.1 In intervention study, were subjects, clinicians / practitioners and investigators blinded to treatment group, as appropriate?					X

5.2 Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)				X	
5.3 In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?					X
5.4 In case control study, was case definition explicit and case ascertainment not influenced by exposure status?					X
5.5 In diagnostic study, were test results blinded to patient history and other test results?					X
6. Were intervention / therapeutic regimens / exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?		X			
6.1 In RCT or other intervention trial, were protocols described for all regimens studied?					X
6.2 In observational study, were interventions, study settings, and clinicians / provider described?		X			
6.3 Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?		X			
6.4 Was the amount of exposure and, if relevant, subject / patient compliance measured?		X			
6.5 Were co-interventions (e.g., ancillary treatments other therapies) described?				X	
6.6 Were extra or unplanned treatments described?			X		
6.7 Was the information for 6.4, 6.5, 6.6 and 6.7 assessed the same way for all groups?					X
6.8 In diagnostic study, were details of test administration and replication sufficient?					X
7. Were outcomes clearly defined and the measurements valid and reliable?		X			
7.1 Were primary and secondary endpoints described and relevant to the question?		X			
7.2 Were nutrition measures appropriate to question and outcomes of concern?		X			
7.3 Was the period of follow-up long enough for important outcome(s) to occur?		X			

7.4 Were the observations and measurements based on standard, valid, and reliable data collection instruments / tests / procedures?		X			
7.5 Was the measurement of effect at an appropriate level of precision?		X			
7.6 Were other factors accounted for (measured) that could affect outcomes?		X			
7.7 Were the measurements conducted consistently across groups?					X
8. Was the statistical analysis appropriate for the study design and type of outcome indicators?		X			
8.1 Were statistical analyses adequately described and the results reported appropriately?		X			
8.2 Were correct statistical tests used and assumptions of test not violated?		X			
8.3 Were statistics reported with levels of significance and/or confidence intervals?		X			
8.4 Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?				X	
8.5 Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g. multivariate analyses)?		X			
8.6 Was clinical significance as well as statistical significance reported?		X			
8.7 If negative findings, was a power calculation reported to address type 2 error?					X
9. Are conclusions supported by results with biases and limitations taken into consideration?		X			
9.1 Is there a discussion of findings?		X			
9.2 Are biases and study limitations identified and discussed?		X			
10. Is bias due to study's funding or sponsorship unlikely?		X			
10.1 Were sources of funding and investigators' affiliations described?		X			
10.2 Was there no apparent conflict of interest?		X			
SYMBOL NEUTRAL (ø)					
NEUTRAL (ø)					

If the answers to validity criteria questions 2, 3, 6, and 7do not indicate that the study is exceptionally strong, the report should be designated with a neutral (ø) symbol on the Evidence Quality Worksheet.

Relevance Questions					
Citation: Rifai, L., Pisano, C., Hayden, J., Sulo, S., & Silver, MA. (2015). Impact of the DASH diet on endothelial function, exercise capacity, and quality of life in patients with heart failure. *Proc (Bayl Univ Med Cent):* April; 28 (2): 151-156.		**Yes**	**No**	**Unclear**	**N/A**
1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)		X			
2. Did the authors study an outcome (dependent variable) or topic that the patients / clients / population group would care about?		X			
3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?		X			
4. Is the intervention or procedure feasible (NA for some epidemiological studies)?		X			
If the answers to all of the above relevance questions are "yes", the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.					
VALIDITY QUESTIONS					
		Yes	**No**	**Unclear**	**N/A**
1. Was the <u>research question</u> clearly stated?		X			
1.1 Was the specific intervention(s) or procedure (independent variable(s)) identified?		X			
1.2 Was the outcome(s) (dependent variable(s)) clearly indicated?		X			
1.3 Were the target population and setting specified?		X			

2. Was the selection of study subjects / patients free from bias?		X			
2.1 Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?		X			
2.2 Were criteria applied equally to all study groups?		X			
2.3 Were health, demographics, and other characteristics of subjects described?		X			
2.4 Were the subjects /patients in a representative sample of the relevant population?		X			
3. Were study groups comparable?		X			
3.1Was the method of assigning subjects / patients to groups described and unbiased? (Method of randomization identified if RCT)		X			
3.2 Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?		X			
3.3 Were concurrent controls used? (Concurrent preferred over historical controls.)		X			
3.4 If cohort study or cross-sectional study ,were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?					X
3.5 If case control study, were potential confounding factors comparable for cases and controls? If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.		X			
3.6 If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g. "gold standard")?					X
4. Was method of handling withdrawals described?			X		
4.1 Were follow up methods described and the same for all groups?		X			
4.2 Was the number, characteristics of withdrawals (i.e. dropouts, lost to follow up, attrition rate) and/or response rate (cross -sectional studies) described for each group? (Follow up goal for a strong study is 80 %.)		X			
4.3 Were all enrolled subjects/patients (in the original sample) accounted for?		X			
4.4 Were reasons for withdrawals similar across groups?					X

4.5 If diagnostic test, was decision to perform reference test not dependent on results of test under study?					X
5. Was <u>blinding</u> used to prevent introduction of bias?			X		
5.1 In intervention study, were subjects, clinicians / practitioners and investigators blinded to treatment group, as appropriate?			X		
5.2 Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)			X		
5.3 In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?					X
5.4 In case control study, was case definition explicit and case ascertainment not influenced by exposure status?					X
5.5 In diagnostic study, were test results blinded to patient history and other test results?					X
6. Were intervention / therapeutic regimens / exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?		X			
6.1 In RCT or other intervention trial, were protocols described for all regimens studied?		X			
6.2 In observational study, were interventions, study settings, and clinicians / provider described?					X
6.3 Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?		X			
6.4 Was the amount of exposure and, if relevant, subject / patient compliance measured?		X			
6.5 Were co-interventions (e.g., ancillary treatments other therapies) described?				X	
6.6 Were extra or unplanned treatments described?			X		
6.7 Was the information for 6.4, 6.5, 6.6 and 6.7 assessed the same way for all groups?		X			
6.8 In diagnostic study, were details of test administration and replication sufficient?					X
7. Were outcomes clearly defined and the measurements valid and reliable?		X			

7.1 Were primary and secondary endpoints described and relevant to the question?		X			
7.2 Were nutrition measures appropriate to question and outcomes of concern?		X			
7.3 Was the period of follow-up long enough for important outcome(s) to occur?		X			
7.4 Were the observations and measurements based on standard, valid, and reliable data collection instruments / tests / procedures?		X			
7.5 Was the measurement of effect at an appropriate level of precision?		X			
7.6 Were other factors accounted for (measured) that could affect outcomes?		X			
7.7 Were the measurements conducted consistently across groups?		X			
8. Was the statistical analysis appropriate for the study design and type of outcome indicators?		X			
8.1 Were statistical analyses adequately described and the results reported appropriately?		X			
8.2 Were correct statistical tests used and assumptions of test not violated?		X			
8.3 Were statistics reported with levels of significance and/or confidence intervals?		X			
8.4 Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?				X	
8.5 Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g. multivariate analyses)?		X			
8.6 Was clinical significance as well as statistical significance reported?		X			
8.7 If negative findings, was a power calculation reported to address type 2 error?					X
9. Are conclusions supported by results with biases and limitations taken into consideration?		X			
9.1 Is there a discussion of findings?		X			
9.2 Are biases and study limitations identified and discussed?		X			
10. Is bias due to study's funding or sponsorship unlikely?				X	

10.1 Were sources of funding and investigators' affiliations described?			X		
10.2 Was there no apparent conflict of interest?				X	
SYMBOL PLUS/POSITIVE (+)					
PLUS/POSITIVE (+) If most of the answers to the above validity questions are "Yes" including criteria 2, 3, 6, and 7 and at least one additional "yes",(the report should be designated with a plus symbol (+) on the Evidence Quality Worksheet.					

Relevance Questions					
Citation: Miró Ó., Estruch, R., Martin-Sánchez, FJ., Gil, V., Jacob, J., Herrero-Puente, P., . . . Llorens, P. (2018). Adherence to Mediterranean Diet and All-Cause Mortality after an Episode of Acute Heart Failure. *JACC: Heart Failure* 2018 January (6)1 52-62. doi: 10.1016/j.jchf.2017.09.020		**Yes**	**No**	**Unclear**	**N/A**
1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)		X			
2. Did the authors study an outcome (dependent variable) or topic that the patients / clients / population group would care about?		X			
3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?		X			
4. Is the intervention or procedure feasible (NA for some epidemiological studies)?		X			
If the answers to all of the above relevance questions are "yes", the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.					
VALIDITY QUESTIONS					
		Yes	**No**	**Unclear**	**N/A**
1. Was the <u>research question</u> clearly stated?		X			

1.1 Was the specific intervention(s) or procedure (independent variable(s)) identified?					X
1.2 Was the outcome(s) (dependent variable(s)) clearly indicated?		X			
1.3 Were the target population and setting specified?		X			
2. Was the selection of study subjects / patients free from bias?		X			
2.1 Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?		X			
2.2 Were criteria applied equally to all study groups?					X
2.3 Were health, demographics, and other characteristics of subjects described?		X			
2.4 Were the subjects /patients in a representative sample of the relevant population?		X			
3. Were study groups comparable?					X
3.1Was the method of assigning subjects / patients to groups described and unbiased? (Method of randomization identified if RCT)					X
3.2 Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?					X
3.3 Were concurrent controls used? (Concurrent preferred over historical controls.)					X
3.4 If cohort study or cross-sectional study ,were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?		X			
3.5 If case control study, were potential confounding factors comparable for cases and controls? If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.					X
3.6 If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g. “gold standard”)?					X
4. Was method of handling withdrawals described?		X			
4.1 Were follow up methods described and the same for all groups?		X			
4.2 Was the number, characteristics of withdrawals (i.e. dropouts, lost to follow up, attrition rate) and/or response rate (cross		X			

-sectional studies) described for each group? (Follow up goal for a strong study is 80 %.)					
4.3 Were all enrolled subjects/patients (in the original sample) accounted for?		X			
4.4 Were reasons for withdrawals similar across groups?		X			
4.5 If diagnostic test, was decision to perform reference test not dependent on results of test under study?					X
5. Was <u>blinding</u> used to prevent introduction of bias?			X		
5.1 In intervention study, were subjects, clinicians / practitioners and investigators blinded to treatment group, as appropriate?					X
5.2 Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)				X	
5.3 In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?				X	
5.4 In case control study, was case definition explicit and case ascertainment not influenced by exposure status?					X
5.5 In diagnostic study, were test results blinded to patient history and other test results?					X
6. Were intervention / therapeutic regimens / exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?		X			
6.1 In RCT or other intervention trial, were protocols described for all regimens studied?					X
6.2 In observational study, were interventions, study settings, and clinicians / provider described?		X			
6.3 Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?		X			
6.4 Was the amount of exposure and, if relevant, subject / patient compliance measured?		X			
6.5 Were co-interventions (e.g., ancillary treatments other therapies) described?				X	
6.6 Were extra or unplanned treatments described?			X		

6.7 Was the information for 6.4, 6.5, 6.6 and 6.7 assessed the same way for all groups?		X			
6.8 In diagnostic study, were details of test administration and replication sufficient?					X
7. Were outcomes clearly defined and the measurements valid and reliable?		X			
7.1 Were primary and secondary endpoints described and relevant to the question?		X			
7.2 Were nutrition measures appropriate to question and outcomes of concern?		X			
7.3 Was the period of follow-up long enough for important outcome(s) to occur?		X			
7.4 Were the observations and measurements based on standard, valid, and reliable data collection instruments / tests / procedures?		X			
7.5 Was the measurement of effect at an appropriate level of precision?		X			
7.6 Were other factors accounted for (measured) that could affect outcomes?		X			
7.7 Were the measurements conducted consistently across groups?		X			
8. Was the statistical analysis appropriate for the study design and type of outcome indicators?		X			
8.1 Were statistical analyses adequately described and the results reported appropriately?		X			
8.2 Were correct statistical tests used and assumptions of test not violated?		X			
8.3 Were statistics reported with levels of significance and/or confidence intervals?		X			
8.4 Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?				X	
8.5 Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g. multivariate analyses)?		X			
8.6 Was clinical significance as well as statistical significance reported?		X			

8.7 If negative findings, was a power calculation reported to address type 2 error?					X
9. Are <u>conclusions</u> supported by results with biases and limitations taken into consideration?		X			
9.1 Is there a discussion of findings?		X			
9.2 Are biases and study limitations identified and discussed?		X			
10. Is bias due to study's <u>funding or sponsorship</u> unlikely?				X	
10.1 Were sources of funding and investigators' affiliations described?			X		
10.2 Was there no apparent conflict of interest?				X	
SYMBOL NEUTRAL (ø)					
NEUTRAL (ø) If the answers to validity criteria questions 2, 3, 6, and 7do not indicate that the study is exceptionally strong, the report should be designated with a neutral (ø) symbol on the Evidence Quality Worksheet.					

Citation: Hummel, SL., Karmally, W., Gillespie, B., Helmke, S., Teruya, S., Wells, J., Trumble, E., ... Maurer, M. (2018). Home Delivered Meals Post discharge From Heart Failure Hospitalization: The GOURMET-HF Pilot Study. *Circ Heart Fail*. 11. doi: 10.1161/circheartfailure.117.004886.		**Yes**	**No**	**Unclear**	**N/A**
1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)		X			
2. Did the authors study an outcome (dependent variable) or topic that the patients / clients / population group would care about?		X			
3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?		X			
4. Is the intervention or procedure feasible (NA for some epidemiological studies)?		X			
If the answers to all of the above relevance questions are "yes", the report is eligible for designation with a plus (+) on					

the Evidence Quality Worksheet, depending on answers to the following validity questions.					
VALIDITY QUESTIONS					
		Yes	**No**	**Unclear**	**N/A**
1. Was the research question clearly stated?		X			
1.1 Was the specific intervention(s) or procedure (independent variable(s)) identified?		X			
1.2 Was the outcome(s) (dependent variable(s)) clearly indicated?		X			
1.3 Were the target population and setting specified?		X			
2. Was the selection of study subjects / patients free from bias?		X			
2.1 Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?		X			
2.2 Were criteria applied equally to all study groups?		X			
2.3 Were health, demographics, and other characteristics of subjects described?		X			
2.4 Were the subjects /patients in a representative sample of the relevant population?		X			
3. Were study groups comparable?		X			
3.1Was the method of assigning subjects / patients to groups described and unbiased? (Method of randomization identified if RCT)		X			
3.2 Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?		X			
3.3 Were concurrent controls used? (Concurrent preferred over historical controls.)		X			
3.4 If cohort study or cross-sectional study ,were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?					X
3.5 If case control study, were potential confounding factors comparable for cases and controls? If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.		X			

3.6 If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g. "gold standard")?					X
4. Was method of handling <u>withdrawals</u> described?		X			
4.1 Were follow up methods described and the same for all groups?		X			
4.2 Was the number, characteristics of withdrawals (i.e. dropouts, lost to follow up, attrition rate) and/or response rate (cross -sectional studies) described for each group? (Follow up goal for a strong study is 80 %.)		X			
4.3 Were all enrolled subjects/patients (in the original sample) accounted for?		X			
4.4 Were reasons for withdrawals similar across groups?		X			
4.5 If diagnostic test, was decision to perform reference test not dependent on results of test under study?					X
5. Was <u>blinding</u> used to prevent introduction of bias?		X			
5.1 In intervention study, were subjects, clinicians / practitioners and investigators blinded to treatment group, as appropriate?			X		
5.2 Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)		X			
5.3 In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?					X
5.4 In case control study, was case definition explicit and case ascertainment not influenced by exposure status?					X
5.5 In diagnostic study, were test results blinded to patient history and other test results?					X
6. Were intervention / therapeutic regimens / exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?		X			
6.1 In RCT or other intervention trial, were protocols described for all regimens studied?		X			
6.2 In observational study, were interventions, study settings, and clinicians / provider described?					X
6.3 Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?			X		

6.4 Was the amount of exposure and, if relevant, subject / patient compliance measured?		X			
6.5 Were co-interventions (e.g., ancillary treatments other therapies) described?				X	
6.6 Were extra or unplanned treatments described?			X		
6.7 Was the information for 6.4, 6.5, 6.6 and 6.7 assessed the same way for all groups?		X			
6.8 In diagnostic study, were details of test administration and replication sufficient?					X
7. Were outcomes clearly defined and the measurements valid and reliable?		X			
7.1 Were primary and secondary endpoints described and relevant to the question?		X			
7.2 Were nutrition measures appropriate to question and outcomes of concern?		X			
7.3 Was the period of follow-up long enough for important outcome(s) to occur?		X			
7.4 Were the observations and measurements based on standard, valid, and reliable data collection instruments / tests / procedures?		X			
7.5 Was the measurement of effect at an appropriate level of precision?		X			
7.6 Were other factors accounted for (measured) that could affect outcomes?		X			
7.7 Were the measurements conducted consistently across groups?		X			
8. Was the statistical analysis appropriate for the study design and type of outcome indicators?		X			
8.1 Were statistical analyses adequately described and the results reported appropriately?		X			
8.2 Were correct statistical tests used and assumptions of test not violated?		X			
8.3 Were statistics reported with levels of significance and/or confidence intervals?		X			

8.4 Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?		X			
8.5 Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g. multivariate analyses)?		X			
8.6 Was clinical significance as well as statistical significance reported?		X			
8.7 If negative findings, was a power calculation reported to address type 2 error?					X
9. Are <u>conclusions</u> supported by results with biases and limitations taken into consideration?		X			
9.1 Is there a of findings?		X			
9.2 Are biases and study limitations identified and discussed?		X			
10. Is bias due to study's <u>funding or sponsorship</u> unlikely?		X			
10.1 Were sources of funding and investigators' affiliations described?		X			
10.2 Was there no apparent conflict of interest?		X			
SYMBOL PLUS/POSITIVE (+)					
PLUS/POSITIVE (+) If most of the answers to the above validity questions are "Yes" including criteria 2, 3, 6, and 7 and at least one additional "yes",(the report should be designated with a plus symbol (+) on the Evidence Quality Worksheet.					