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Dietary Interventions to Reduce Metabolic Syndrome in an Uninsured Population: An Evidence-Based Approach

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DIETARY INTERVENTIONS TO REDUCE METABOLIC SYNDROME IN AN UNINSURED POPULATION: AN EVIDENCED-BASED APPROACH

by

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Abstract

Recent studies show that more than one-third of U.S. adults (over 72 million people) were obese in 2005–2006. This includes 33.3% of men and 35.3% of women. Obesity is a primary factor in the development of metabolic syndrome, a condition that places individuals at high absolute risk of mortality and morbidity. The use of a nutritionally balanced diet aimed at weight reduction has the potential to decrease the prevalence of obesity, therefore reducing the incidence of metabolic syndrome and its consequences.

The purpose of this project was to investigate whether individual nutrition counseling would improve the outcomes of patients with metabolic syndrome. A trans-disciplinary team of faculty and graduate students from nutrition and nursing served as consultants and educators at a clinic for the uninsured in a southeastern city in the United States. This study was a one-group before-and-after design, with baseline data obtained on patients prior to the practice change. The study ran for six months. The intervention was an evidence-based practice change incorporating intensive dietary program for 19 patients with metabolic syndrome and an evaluation of the effect of that change on lipoproteins, glucose, blood pressure, weight, and waist circumference.

Although there were no positive changes in weight or waist circumference, the participants did enjoy a significant decrease in blood pressure, fasting glucose and plasma lipids. None of these changes were significantly associated with the dietary intervention. Based on the most current evidence, the most effective way to reduce risks associated with metabolic syndrome is weight reduction, adequate nutrition, and exercise.

Chapter One: Introduction

Cardiovascular disease is a major cause of morbidity and mortality in the U.S. (Rosamond, 2007) and prevention, and treatment has been at the center of scientific research for many years. As risk factors for cardiovascular disease were identified, it became clear that more than one risk factor tended to occur in individuals. Obesity, type 2 diabetes, dyslipidemia, and hypertension-are often present in individuals with cardiovascular disease. This cluster of risk factors became known as "syndrome X," "insulin resistance syndrome," and, the most widely and currently accepted term, "metabolic syndrome" (Reaven, 1988).

In 1997, the World Health Organization (WHO) published a landmark document recognizing obesity as a worldwide disease that poses a serious threat to public health (Mokdad et al., 1999). Persons who are overweight or obese have a substantially increased risk for morbidity from numerous chronic disorders, such as diabetes, hypertension and cardiovascular disease. "Adults aged 40–59 had the highest obesity prevalence compared with other age groups. Approximately 40 percent of men in this age group were obese, compared with 28 percent of men aged 20–39, and 32 percent of men aged 60 and older. Among women, 41 percent of those aged 40–59 were obese compared with 30.5 percent of women aged 20–39" (Ogden, Carroll, McDowell, & Flegal, 2007, p. 2). The latest data from the Centers' for Disease Control (CDC) (2008) indicate that nearly 36% of black Americans, about 29% of Hispanics, and 24% of whites are obese.

According to the National Cholesterol Education Program (NCEP) panel, metabolic syndrome will soon have a greater impact on premature coronary artery disease than tobacco (Third Report, 2001). However, traditional risk factors, including metabolic syndrome, cannot explain the greater health burden of disease seen in obese African Americans. Thus, it is imperative to identify additional risk factors that may contribute to disease development or identify early indication of disease and examine the effect of lifestyle and dietary management programs on these risk factors.

Metabolic syndrome is a grouping of risk factors that, when three or more are present, increase a person's risk for developing diabetes and heart disease. These risk factors include insulin resistance, obesity, hyperlipidemia, hyperglycemia, and hypertension (Grundy, Brewer, Cleeman, Smith & Lenfant, 2004). However, further examination of the criteria by which the metabolic syndrome is diagnosed revealed that these criteria differ depending on who established them (Grundy et al., 2005).

In 1998, the World Health Organization (WHO) developed a consensus definition of metabolic syndrome. This was followed by definitions by the European Group for the Study of Insulin Resistance (EGIR) in 1999, the third Adult Treatment Panel of the National Cholesterol Education Program (NCEP-ATP III) in 2001 and the American Association of Clinical Endocrinologists (ACCE) in 2003.

The International Diabetes Federation (IDF), in a global consensus statement, presented a new, clinically accessible definition of the metabolic syndrome, representing the views of experts in the fields of diabetes, cardiology, lipidology, public health, epidemiology, genetics, metabolism, and nutrition from six continents (Grundy, Brewer et al. (2004). According to the IDF 2005 definition, for a person to be defined as having

the metabolic syndrome the person must have central obesity (defined as waist circumference ≥ 94 cm for men and ≥ 80 cm for women) plus any two other risk factors. The NCEP-ATP III definition from 2001 was revised in 2005 and is based on any three risk factors. Similarly, the American Heart Association (AHA) and the National Heart, Lung, and Blood Institute (NHLBI) base their definition on the presence of three risk factors. Table 1.1 presents the evolution of the various definitions.

Evidence-based obesity treatment and medical nutrition therapy for obesity related chronic diseases such as metabolic syndrome includes individualized counseling. This is designed to increase knowledge and skills to improve adherence to healthy behaviors including the adoption of a diet rich in whole grains, fruits and vegetables, and a physically active lifestyle (Emili, Abushomar, & Nair, 2007).

The Extent of the Problem

It is difficult to determine the prevalence of metabolic syndrome worldwide because of the differing criteria used to identify the condition (Ford, 2004). The IDF suggests that the data presented from the third National Health and Nutrition Examination Survey (NHANES III) surveys are a good estimation of the worldwide prevalence (IDF, 2007). Findings from NHANES III suggest that 24% of American men and 23% of American women, or about 47 million people, have metabolic syndrome (see Table 1.2). These data were compiled in 2002, but recent statistics may be even higher. It has been reported that the prevalence of metabolic syndrome increases with age and its prevalence among Americans over the age of 60 is 42–43.5%. Mexican Americans were found to have the highest prevalence of metabolic syndrome at 31.9%. White Americans and African Americans had the lowest prevalence at 23.8% and 21.6%, respectively.

Table 1.1 Criteria Proposed for Clinical Diagnosis of Metabolic Syndrome

Clinical measure	WHO (1998)	EGIR (1999)	ATP III (2001)	AACE (2003)	ATP III (2004)	IDF (2005)	AHA/NHLBI (2005)
Insulin resistance	IGT, IFG, T2DM, or lowered insulin sensitivity plus any two of the following:	Plasma insulin > 75th percentile plus any two of the following:	None, but any three of the following five features:	IGT or IFG plus any of the following based on clinical judgment:	None, but any three of the following five features:	None	None, but any three of following five features:
Body weight	Men waist to hip ratio > 0.90 Women waist to hip ratio > 0.85, or BMI > 30 kg/m^2	Waist circumference (WC) ≥ 94 cm	WC Men ≥ 102 cm Women ≥ 88 cm	BMI ≥ 25 kg/m2	WC Men ≥ 102 cm Women ≥ 88 cm	Increased WC Men > 94 cm Women > 80 cm plus any two of the following:	WC Men ≥ 102 cm Women ≥ 88 cm
Lipids	TG ≥ 1.7 mmol/L and/or HDL-C < 0.91 mmol/L	TG ≥ 2.0 mmol/L and/or HDL-C <1.01 mmol/L or treated for dyslipidemia	TG ≥ 1.69 mmol/L, HDL-C < 1.03 mmol/L	TG ≥ 1.69 mmol/L and HDL-C < 1.03 mmol/L	TG ≥ 1.69 mmol/L, HDL-C < 1.03 mmol/L	TG ≥ 1.7 mmol/L or on TG Rx, HDL-C < 1.03 mmol/L or on HDL-C Rx	TG ≥ 1.69 mmol/L or on TG Rx, HDL-C < 1.03 mmol/L or on HDL-C Rx
BP	≥ 160/90 mm Hg	≥ 140/90 mm Hg or on hypertension Rx	≥ 130/85 mm Hg	≥ 130/85 mm Hg	≥ 130/85 mm Hg	≥ 130 mm Hg systolic or ≥ 85 mm Hg diastolic or on hypertension Rx	≥ 130 mm Hg systolic or ≥ 85 mm Hg diastolic or on hypertension Rx
Glucose	IGT, IFG, or T2DM	IGT or IFG (but not diabetes)	> 6.11 mmol/L (includes diabetes)	IGT or IFG (but not diabetes)	> 5.6 mmol/L (includes diabetes)	≥ 5.6 mmol/L (includes diabetes)	≥ 5.6 mmol/L or on hypoglycemic
Other	mALB > 30 mg creatinine						

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African American and Mexican American women had a greater prevalence of metabolic syndrome than the men of the same ethnicity (Gami et al., 2007).

Currently there are no data for the prevalence of metabolic syndrome in the state of Florida or Duval County. According to self-reported Behavioral Risk Factor Surveillance System (BRFSS) data, 55.8% of Florida adults are overweight or obese, which approximates to 7 million residents (Florida Department of Health [DOH], 2001). Of these, 18.8% or nearly 2.5 million people are obese, with a body mass index (BMI) ≥ 30. The 2001 BRFSS survey reported that the prevalence of being overweight among adult men and women in Florida has increased by 58% since 1986, and the prevalence of obesity has increased by 93% since 1986 (CDC, 2002) .

Treatment

The primary goal of clinical management of metabolic syndrome is to reduce risk for clinical atherosclerotic disease. Weight reduction and increased physical activity are first-line therapies for metabolic syndrome. Drug therapy is recommended when low-density lipoprotein cholesterol (LDL-C) is not lowered sufficiently by lifestyle modifications.

Purpose

The purpose of this project was to investigate whether an intensive dietary program including individual nutrition counseling would improve the outcomes of patients with metabolic syndrome in an uninsured population.

Definition of Terms

Metabolic syndrome. For the purposes of this study, the NCEP-ATP III (2002) criteria will be used (see Table 1.3).

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Intensive dietary program. The individualized diet program will be based on the Therapeutic Lifestyle Changes (TLC) diet. It is targeted to people whose LDL cholesterol is above the goal level for their category of risk for heart disease. These are the essential components of TLC diet (see Table 1.4).

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Dietary intake was assessed using the single 24-hour recall method by graduate nutrition interns. Before testing, all subjects were instructed to maintain their usual dietary habits. In this study, the daily energy intake and percentages of the ADA food pyramid groups.

Chapter Two: Literature Review

This chapter presents an overview of the search strategies used for identification and retrieval of the evidence. This is followed by a brief overview of cardiovascular disease and a review of the evidence with respect to the effects of metabolic syndrome on cardiovascular disease. A discussion of the relationship between socioeconomic position and metabolic syndrome is followed by a synthesis of the evidence for the use of the Mediterranean and TLC diet. Evidence for non-pharmacologic measures for the treatment of metabolic syndrome is also addressed.

Search Strategies

For this review, the following databases were searched: The Cochrane Library, (inception to March, 2008), MEDLINE (inception to March, 2008), OVID (inception to April, 2008), CINAHL (March, 2008), and MD Consult (inception to April, 2008). There were no language restrictions for either searching or trial inclusion. The search strategy below was used and adapted to suit the individual databases. Specific journals cited most frequently included *Annals of Internal Medicine, Circulation, Heart, Diabetic Medicine*, and *The Journal of the American Dietetic Association*. Keywords used included: *metabolic syndrome, obesity,* and *dietary factors.* Searches were limited to randomized, controlled trials (RCT) and meta-analyses conducted with human subjects investigating the treatment of metabolic syndrome. In addition, a manual search of citations from relevant original studies and review articles was performed. The final search produced one recent Cochrane Review, three recent meta-analyses, one Agency for Healthcare

Research and Quality *(*AHRQ*)* guideline and six randomized controlled trials (RCTs). The search was then updated through examining references from meta-analyses and review articles.

Metabolic Syndrome and Cardiovascular Disease

According to the AHA, (2007), more than 1 million Americans would suffer a first or recurrent coronary event and nearly 500,000 of these would result in death. Cardiovascular disease is the leading cause of death for both men and women, and its prevalence increases with age. Despite known lifestyle changes and risk-factor modification with pharmacologic and non-pharmacologic therapies, many patients are still at risk for a cardiac occurrence.

There is strong evidence to suggest that metabolic syndrome doubles the risk for cardiovascular disease and raises the risk for diabetes and mortality fivefold over a 5- to 10-year period (Greenstone, 2008). The data supporting this relationship are outlined in Table 2.1.

Data from NHANES III (2006) were used to examine the frequency and clustering of the risk factors that make up the metabolic syndrome. From the 12,332 subjects aged 30–74 years in the NHANES sample, this study identified 1,513 who were free of diabetes and met the definition of the metabolic syndrome. When compared to the U.S. population, this represents a sample of 16.5 million persons with metabolic syndrome. This study demonstrated that the most common components of the metabolic syndrome (present in more than 75% of subjects) were increased waist circumference (> 40 inches in men and > 35 inches in women), high BP (≥ 130/85 mm Hg), high

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triglycerides (≥ 150 mg/dL), and low HDL-C (≤ 40 mg/dL in men and ≤ 50 mg/dL in women). Impaired fasting glucose (≥ 110 mg/dL), the least common risk factor, was evident in 22% of men and 17% of women (Grundy et al., 2005).

Gami et al. (2007) performed a meta-analysis of longitudinal studies that assessed any cardiovascular event outcomes or mortality in people with three or more coronary risk factors (regardless of whether this was termed the metabolic syndrome) compared with people without the diagnosis of metabolic syndrome. A total of 37 cohort studies from 1971 to 1997 including 172,573 individuals were included. This meta-analysis showed patients with metabolic syndrome had a relative risk (RR) of cardiovascular events and death of 1.78 (95% confidence interval [CI] 1.58, 2.00). The association was stronger in women (RR 2.63 vs. 1.98, $p = 0.09$), in studies enrolling lower risk individuals (RR 1.96vs. 1.43, $p = 0.04$), and in studies using the WHO definition (RR 2.68 and 2.06 vs. 1.67 for National Cholesterol Education Program definition and 1.35 for other definitions; $p = 0.005$). The association remained after adjusting for traditional cardiovascular risk factors (RR 1.54, 95% CI, 1.32, 1.79). The population of patients in this trial was probably heterogeneous in that the review included studies of overweight patients aged over 18 years. There was little description of the patients in the individual studies.

Gami et al. (2007) found that (a) definitions of metabolic syndrome based on factor analysis were far more predictive of cardiovascular events and death than were other definitions; (b) the WHO-based criteria were better than NCEP-based criteria in predicting cardiovascular events and death; and (c) the substitution of BMI for waist circumference or waist-to-hip ratio in these criteria did not appear to affect their

outcomes. Inclusion and reporting biases in the RCTs may have limited the assessment of the efficacy of lowering LDL concentration in diabetic patients without coronary heart disease. Most trials of lipid lowering interventions for primary prevention of coronary heart disease excluded diabetic patients by varied and ambiguous criteria.

A meta-analysis by Galassi, Reynolds, and He (2006) included a total of 21 prospective cohort studies. Among the 21 studies, 11 were conducted in the U.S. and 10 in Europe. The number of subjects ranged from 318 to 19,223. The ATP III criteria were used in 16 studies, and the WHO criteria were used in 5. Two studies used both criteria. The RR of cardiovascular disease associated with the metabolic syndrome in each study and overall is > 1.0 and all but five were statistically significant. Individuals with the metabolic syndrome had an overall RR of cardiovascular disease of 1.61 (95% CI, 1.42, 1.83) compared with individuals without the metabolic syndrome, Prevalence of the metabolic syndrome varied from 8.8% to 92.3%. However, the highest prevalence of the metabolic syndrome (75.6–92.3%) was observed in the three studies in which all study participants had type 2 Diabetes.

A significant increase in the risk of cardiovascular disease associated with the metabolic syndrome was found when data were analyzed according to sex, length of follow-up, study country, and history of cardiovascular disease at baseline (Galassi et al., 2006). The RR was higher among women compared with men and those studies with follow-up that was longer than five years. Compared with the overall analysis, the RR was slightly reduced in studies that were conducted on non diabetic patients. The meta-analysis indicated that individuals with metabolic syndrome have a 61% increased risk of

cardiovascular disease compared with individuals without the metabolic syndrome (Galassi et al., 2006).

Many experts believe that early and efficient identification of patients with metabolic syndrome is important and that it is essential to use more advanced short-term risk assessments such as those used in the Framingham Study. Grundy et al. (2005) clearly states that these are the tools that should be used for short-term risk assessment. The Framingham Risk Score (FRS) was derived from the Framingham Heart Study, and is the most commonly recommended tool in the U.S. for global risk assessment in the primary prevention setting (Ingelsson et al., 2007). Short-term absolute risk, defined as the probability of a person developing a hard CHD endpoint (myocardial infarction or cardiac death) in the next 10 years, can be estimated by calculating the number of Framingham points assigned to each graded risk (see Table 2.2). At least three recent studies have compared the short-term predictive value of the metabolic syndrome criteria with that of the FRS (Obunai, Jani & Dangas, 2007).

There is evidence to suggest that abdominal obesity is an independent risk factor for the development of diabetes, hypertension, hyperlipidemia and cardiovascular disease in individuals with BMI < 35 (Carr & Brunzell, 2004). Abdominal obesity is also associated with the metabolic syndrome. Measurement of waist circumference is the simplest clinical method to detect abdominal obesity.

Katzmarzyk, Janssen, Ross, Church & Blair (2006) compared the predictive ability of the NCEP-R and IDF metabolic syndrome criteria for mortality risk, and examined the effects of waist circumference on mortality within the context of these

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criteria. Their sample included 20,789 White, non-Hispanic men aged 20–83 from the Aerobics Center Longitudinal Study. "The study concluded that waist circumference is a valuable component of metabolic syndrome. However, the change in the IDF definition of metabolic syndrome of an elevated waist circumference warrants caution given that a large proportion of men with normal waist circumference have multiple risk factors and an increased risk of mortality" (p. 406).

General Treatment Strategies for Metabolic Syndrome

The primary goal of clinical management of metabolic syndrome is to reduce risk for clinical atherosclerotic disease. The NCEP guidelines recommend a two-pronged approach to clinical management of the metabolic syndrome: (a) reversing underlying lifestyle causes, such as obesity, atherogenic diet, and physical inactivity; and (b) treating associated non-lipid and lipid risk factors (NCEP Expert Panel, 2002). Weight reduction and increased physical activity are first-line therapies for metabolic syndrome. Obesity, hypertension, hyperlipidemia and type 2 Diabetes may mask underlying metabolic syndrome, which is characterized by atherogenic dyslipidemia, elevated blood pressure, insulin resistance, proinflammatory cytokines and a prothrombotic state. Treatment of the metabolic syndrome involves appropriate risk assessment for potential future cardiac events. The use of the Framingham risk assessment tool is helpful in predicting 10-year risk of coronary heart disease and stratifying patients as to their need for intensive treatment (Ingelsson, et al., 2007). According to the NCEP, measurements of adiposity and lipid levels are reliable identifiers for those with insulin resistance, and they describe what another group has termed "hypertriglyceridemic waist," or a combination of

elevated measurements of waist circumference and triglycerides that is associated with increased cardiovascular risk (Tankó, Bagger, & Qin, 2005).

Metabolic syndrome has been linked to insulin resistance, abdominal obesity and an unhealthy lifestyle. It has been estimated that if left untreated, those with metabolic syndrome will experience complications such as insulin resistance and atherosclerosis within 15 years, which presents time for intervention. Treatment of early symptoms may help to alleviate poor health outcomes and perhaps lessen the burden on health care costs. The most common treatments for metabolic syndrome are therapeutic lifestyle changes (TLC) (i.e. diet and exercise), weight loss, and medication (Grundy et al., 2005).

Individuals with hyperlipidemia require initiation of therapeutic lifestyle changes including weight reduction, reductions in saturated fat and cholesterol in the diet, increased intake of soluble fiber (10–25 g/day) and plant stanols/sterols (2 g/day) and increased physical activity. First-line treatment for obesity is behavior modification, including a low-calorie, low-fat diet with calorie reduction of 500–1000 kcal/day, increased activity to 30 minutes per day most days of the week and behavioral counseling to improve stimulus control, reward positive lifestyle changes, and provide social support.

Pharmacologic therapy for obesity is warranted after an adequate trial of behavioral modifications including diet, exercise, and behavioral therapy have failed to yield appropriate weight loss goals (Levy, Finch, Crowell, Talley, & Jeffery, 2007). Both orlistat and sibutramine are effective in inducing modest weight losses in conjunction with behavioral therapies. Surgical procedures for obesity may be considered for individuals with a BMI $\geq$ 40 who have obesity-related co-morbid conditions such as

hypertension, impaired glucose tolerance, diabetes, hyperlipidemia or obstructive sleep apnea, and where other options for weight loss have failed (Orchard et al., 2005).

Cholesterol management is a cornerstone of therapy for patients at risk for heart-related events, with the focus of interventions aimed at reducing LDL-C concentrations. The reduction of LDL-C has been proven to have a significant impact in reducing the morbidity and mortality associated with cardiac disease. In addition to LDL-C reduction, results from the Framingham Heart Study and other trials have demonstrated that event risk is also independently associated with varying concentrations of HDL-C (Obunai et al., 2007). With this in mind, the initial treatment protocol for cardiovascular disease centers on TLC, guidelines that prompt the patient to assess and modify eating and exercise habits. The goal of treatment is to reach and maintain ideal body weight, bring blood pressure to within normal limits, and reduce the impact that lifestyle choices have on total and LDL-C (Emili et al., 2007).

Pharmacologic Measures for Treatment of Metabolic Syndrome. Drug therapy, typically a statin, is recommended when low-density lipoprotein cholesterol (LDL-C) is not lowered sufficiently by lifestyle modifications. Treating non-lipid risk factors includes treating hypertension and using aspirin to reduce the prothrombotic state in patients with chronic heart disease (CHD). Insulin resistance, which is usually indicated by an impaired fasting glucose, is best improved by weight loss, a heart-healthy diet, and regular physical activity (Grundy et al., 2005).

The ATP III (2005) recommends medication therapy for LDL levels > 160 mg/dL, and patients at moderately high risk may consider a treatment goal of LDL < 100 mg/dL. Statins are usually first-line treatment for hyperlipidemia, although individuals

with metabolic syndrome frequently have low high-density lipoprotein cholesterol (HDL-C) and hypertriglyceridemia that may require additional medication with niacin or fibrates if statin therapy is unable to reduce their lipoprotein profile adequately.

Nonpharmacologic Measures for Treatment of Metabolic Syndrome. Lifestyle intervention, inducing a modest BMI and waist reduction, can substantially affect the prevalence of metabolic syndrome and its components (Bo et al., 2007). Lifestyle modification is a primary treatment modality for all of the parameters that make up metabolic syndrome. Such modifications include changes in both dietary and exercise behaviors**.** These lifestyle interventions appear to be most effective in reducing waist circumference and blood pressure with relatively little effect on HDL-C and lipid abnormalities (Katzmarzyk et al., 2006). The Diabetes Prevention Program (DPP) showed that intensive lifestyle changes resulting in losing 5–7% of weight through increased physical activity and a reduced calorie diet prevented or delayed the onset of type 2 diabetes by 58% in people at high risk for the disease. The DPP also showed that metformin, an oral diabetes drug, reduced the onset of type 2 diabetes by 31% (Diabetes Prevention Program Research Group [DPPRG], 2002).

Therapeutic Lifestyle Changes (TLC) Diet. Originally outlined in the American Heart Association's Step 1 and Step 2 diets (Lichtenstein et al., 2002), the TLC diet consolidates the key elements into one set of guidelines. The primary diet message has remained basically unchanged over several decades: choose a diet rich in fruits, vegetables, whole grains, poultry, fish, and non-fat dairy foods, and limit intake of red meat, full-fat dairy foods and other high-fat animal products. The updated guidelines expand on what types and how much fat should be included in a "heart healthy" diet and

propose adding fiber and plant sterols to the diet as additional cholesterol-lowering strategies. “Thus, a comprehensive strategy to decrease cardiovascular morbidity and mortality should include primarily a cardioprotective diet” (de Lorgeri, M. et al, 1999, p. 785). It should also be associated with other means aimed at reducing modifiable risk factors.

Nutrition that leads to at least a 7–10% decrease in weight or BMI of hopefully < 25 kg/m2, which includes at least five servings of fruits and vegetables daily, and has a negative energy balance on average of 500 calories per day is sufficient to have a significant impact on the components of the syndrome and the prevention of development of diabetes (DPPRG, 2002). TLC diet guidelines limit the intake of saturated fat (found in animal fats and tropical oils) and trans fat (hydrogenated or hardened), vegetable fat found in margarine and many types of cookies, crackers, and other snack foods. Both types of fat have been shown to raise LDL-C. On the other hand, liquid or soft polyunsaturated fats (vegetable oil, soft margarine) and monounsaturated fats are associated with lower LDL-C levels. The most common sources of monounsaturated fats in the U.S. diet are olive oil, canola oil, and nuts. In addition, the TLC guidelines advise consumers to consider using a stanol- or sterol-containing spread to further lower LDL-C. Patients are also advised to increase their intake of soluble fiber, either from supplements such as Metamucil or fiber-rich foods like oatmeal, beans, and apples (Lichtenstein et al., 2002) (see Table 2.3).

Mediterranean diet: Inspired by the low incidence of cardiovascular disease in Mediterranean countries, proponents of the Mediterranean diet recommend high intakes

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of unsaturated fats (olive oil, nuts, fatty fish), fruits, vegetables, legumes, and whole grains (Estruch et al., 2006).

Dairy products, eggs, poultry, and fish are eaten a few times per week, while red meat and sweets are eaten sparingly. Many small studies suggest the Mediterranean diet can reduce both cardiovascular risk and overall mortality. A 2005 cohort study of more than 74,000 healthy Europeans over 60 years of age revealed that those eating a Mediterranean-style diet had a significantly longer life expectancy than those following other dietary patterns. A three-month trial comparing two versions of the Mediterranean diet (one with olive oil, the other with nuts) with a low-fat AHA diet reported reductions in CVD risk with the Mediterranean diet (Trichopoulou, 2005). Both Mediterranean groups showed significant improvements in blood pressure, blood glucose, cholesterol:

HDL ratio, and HDL levels, compared with the low-fat group. The Mediterranean diet with nuts also showed decreases in total cholesterol and triglycerides (McMillan-Price, Petocez, & Atkinson, 2006).

The TLC diet and Mediterranean-type diets have been recommended for the treatment of metabolic syndrome as they seem to be effective in promoting long-term adherence. Since patients with metabolic syndrome may differ in their clinical picture, their responses to different dietary approaches, treatments are best individualized (Melanson, 2008). While some of the factors that predict heart disease risk (including age, gender, and family history) are not variable, progression of most types of heart diseases can be modified by lifestyle choices.

Diet counseling. A Cochrane Review was revised in 2007 on the effects of dietary advice given by a dietitian compared with another health professional or the use of self-help resources in reducing blood cholesterol in adults (Thompson et al., 2003). This study assessed the effects of providing dietary advice to healthy adults in order to produce improvement in their diets over a sustained period of time and examined whether dietary improvement would reduce the risk factors associated with heart disease. They studied 38 trials in which 17,871 healthy adults were randomly assigned to receive dietary advice or no dietary advice.

The dietary improvements recommended to the people in the intervention groups centered largely on the reduction of salt and fat intake and an increase in the intake of fruit, vegetables, and fiber (Thompson et al., 2003). Advice was delivered in a variety of ways, including one-to-one contact, group sessions, and written materials. There were variations in intensity of intervention, ranging from one contact per study participant to

50 hours of counseling over 4 years. The duration of the trials ranged from 3 months to 4 years, with a median follow-up period of 10 months. Participants receiving advice from dietitians experienced a greater reduction in blood cholesterol than those receiving advice only from doctors (-0.25 mmol/L [95% CI, -0.37, -0.12 mmol/L]). There was no statistically significant difference in change in blood cholesterol between dietitians and self-help resources (-0.10 mmol/L [95% CI, -0.22, 0.03 mmol/L]). No statistically significant differences were detected for secondary outcome measures between any of the comparisons with the exception of dietitian versus nurse for HDL-C, where the dietitian group showed a greater reduction (-0.06 mmol/L [95% CI, -0.11, -0.01]) and dietitian versus counselor for body weight, where the dietitian group showed a greater reduction (-5.80 kg [95% CI, -8.91, -2.69 kg]) (see Figure 2.1).

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There were some problems with this dietary review. First, according to the inclusion/exclusion criteria, studies were not examined for medical nutritional therapy versus other types of counseling. Medical nutritional counseling by a dietician includes an individualized approach with at least one follow-up visit. Second, studies of nutritionists were included, addressing the effectiveness of counseling given by a registered dietitian who has received education via an American Dietetic Association (ADA) accredited program and internship. Studies included in the Cochrane Review were of a variety of individuals, including those with normal cholesterol values and not specifically metabolic syndrome. Finally, the analysis was based on a limited number of studies, some of which were of dubious quality, and some that may not have met the inclusion criteria on a drop-out of approximately 20%.

Gami et al (2007) found 37 eligible studies that included 43 cohorts (from 1971 to 1997) and 172,573 individuals. Meta-analysis showed metabolic syndrome had a relative risk (RR) of cardiovascular events and death of 1.78 (95% confidence interval [CI] 1.58 to 2.00). The association was stronger in women (RR 2.63 vs. 1.98, $p = 0.09$) and in studies using factor analysis or the World Health Organization definition (RR 2.68 and 2.06 vs. 1.67 for National Cholesterol Education Program definition and 1.35 for other definitions; $p = 0.005$). Cardiovascular events were about 33% higher for women than men, according to seven studies that provided separate risk analyses for both sexes. As part of the study, investigators did a separate meta-analysis of studies that simultaneously adjusted for metabolic syndrome and its components. The relative risk was 1.54 (95% CI 1.32-1.79). Women should be aware that they are at higher risk. “We

generally think of men having a higher risk of CVD, but with the metabolic syndrome, it appears women have a higher risk relative to men," Gami et al. stated (2007, p. 412).

Dansinger (2007) in a meta analysis of 46 trials of dietary counseling revealed a maximum net treatment effect of -1.9 (95% CI, -2.3 to -1.5) BMI units (approximately -6%) at 12 months. These studies were identified through a previously published systematic review: MEDLINE and the Cochrane Central Register of Controlled Trials from 1997 through July 2006. The authors included only weight loss studies with a dietary component. Different analyses suggested that calorie recommendations, frequency of support meetings, inclusion of exercise, and diabetes may be independent predictors of weight change. Studies were generally of moderate to poor methodological quality. They had high rates of missing data and failed to explain these losses.

Franz (2008) identified randomized controlled trials (RCTs) that evaluated weight loss interventions in overweight or obese adults and had >1 year follow-up. Eighty RCTs (n=26 455, mean age 23–69 y, 0–100% men) met the selection criteria. At baseline, mean weight was 77–131 kg and mean body mass index was 29–43 kg/m2. The interventions included advice only (28 RCTs), exercise (6 RCTs), diet (51 RCTs), diet plus exercise (17 RCTs), meal replacements (7 RCTs), very-low-energy diet (11 RCTs), orlistat (13 RCTs), and ibutramine (7 RCTs). No RCT on bariatric surgery was found. Study duration ranged from 12 to 60 months. Overall patient follow-up was 69%. For most interventions, maximum weight loss occurred early in the study (pooled mean weight loss at 6 mo was 0.7 kg for advice only, 2.4 kg for exercise, 4.9 kg for diet, 7.9 kg for diet plus exercise, 8.2 kg for sibutramine, 8.3 kg for orlistat, 8.6 kg for meal replacements, and 18 kg for very-low-energy diet), with some re-gain over time. Except for advice only,

mean weight did not completely return to baseline level by study end. Meta-analysis showed that reduced-energy diets, with or without exercise, resulted in more weight loss than advice alone. The results of the comprehensive review by Franz et al. (2007) support guidelines for weight loss: a multifaceted approach of diet, exercise, and behavioral therapy, with the addition of medication if the initial approach is not effective after 6 months. As expected from clinical experience, early weight loss was followed by a plateau. Weight re-gain occurred with all interventions, including after discontinuing the weight loss medications. It is important to note that the long-term safety of these medications is unknown. On average, participants in diet and exercise, medication, or meal replacement interventions maintained a 4–8% weight loss at >1 year, approximating the 5–10% weight loss advised for health benefits.

Reviews of the significant meta-analyses identified in this project are listed in Table 2.4. While all of these findings are applicable to clinical practice, clinicians can use this evidence to motivate patients when counseling them to reduce risk factors associated with metabolic syndrome. Medications and meal replacements, although more effective than diet alone, are not recommended or accessible for all patients, especially in the uninsured population. They also must be accompanied by diet, exercise, and behavioral therapy. The evidence demonstrating the effectiveness of specific interventions in preventing cardiovascular disease in this population with metabolic syndrome is limited. This project examines the evidence for the use of nutritional interventions in addressing the modifiable risk factors.

Table 2.4 Meta-Analysis Evaluation

Question	Cochrane Review 2007	Gami et al., 2007	Dansinger et al., 2007	Franz et al. 2007
Will the answer if true, have a direct bearing on the health of patients?	Yes	Yes	Yes	Yes
Is the outcome or topic something that patients/clients/population groups would care about?	Yes	Yes	Yes	Yes
Is the problem addressed in the review one that is relevant to practice?	Yes	Yes	Yes	Yes
Will the information, if true, require a change in practice?	Yes	Yes	Yes	Yes
Was the question for the review clearly focused and appropriate?	Yes	Yes	Yes	Yes
Was the search strategy used to locate relevant studies comprehensive? Were the databases searched and the search terms used described?	Yes	Yes	Yes	Yes
Were explicit methods used to select studies to include in the review? Were inclusion/exclusion criteria specified and appropriate? Were selection methods unbiased?	Yes	Yes	Yes	Yes
Was there an appraisal of the quality and validity of studies included in the review? Were appraisal methods specified, appropriate, and reproducible?	Yes	Yes	Yes	Yes
Were specific treatments/interventions/exposures described? Were treatments similar enough to be combined?	No	Yes	No	No
Was the outcome of interest clearly indicated? Were other potential harms and benefits considered?	Yes	Yes	Yes	Yes
Were processes for data abstraction, synthesis, and analysis described? Were they applied consistently across studies and groups? Was there appropriate use of qualitative and/or quantitative synthesis? Was variation in findings among studies analyzed? Were heterogeneity issued considered? If data from studies were aggregated for meta-analysis, was the procedure described?	???	Yes	No	No
Are the results clearly presented in narrative and/or quantitative terms? If summary statistics are used, are levels of significance and/or confidence intervals included?	Yes	Yes	Yes	Yes
Are conclusions supported by results with biases and limitations taken into consideration? Are limitations of the review identified and discussed?	No	Yes	No	No
Was bias due to the review's funding or sponsorship unlikely?	Yes	Yes	Yes	Yes

"The time has come to apply to diet research the same level of evidence required for other interventions. We believe that indications or claims made for weight loss or health improvement via diet—whether made by authors, the government, or associations—must be supported by 3 types of evidence: proof that the diet provides essential nutrients in actual patients, efficacy studies, and randomized, controlled trials with clinical events as end points....Until then, the public will continue to be subject to speculation and potentially hazardous extrapolation from putative biological surrogates to clinical outcomes" (Yancy, Westman, French, & Califf, 2003, p. 14).

Chapter Three: Methodology

This chapter includes a description of the design, setting and sample for the project. This is followed by a discussion of the methods and procedures for the study, including the protection of human subjects.

Study Design

This project was the implementation of an evidence-based practice change incorporating an intensive dietary program for patients with metabolic syndrome and an evaluation of the effect of that change on lipoproteins, glucose, blood pressure, weight, and waist circumference. This study was a one-group before-and-after design, with baseline data obtained on patients prior to the practice change. The study ran for six months.

Setting

The setting for the study was a medical practice in a large city in the southeastern U.S. The practice had both physicians and nurse practitioners providing primary care services. The clinic serves uninsured residents of the county who have an income level of not more than 150% of federal poverty criteria. The clinic patient demographics were as follows: Caucasian (44%), African American (30%), Asian American (11%), Latino/Hispanic (9%), and 5% classified as other. The demographics for the county include: Caucasian (64.4%), African American (29.8%), Latino/Hispanic (6.3%) and 1.8% classified as other (VIM-JAX, 2008 Data). There were approximately 5,000 patients in this practice, approximately 22% of whom have metabolic syndrome.

Sample

This project was offered to all new patients of the practice who met the criteria for metabolic syndrome. The subjects were eligible for participation in this study if they met three or more of the five NCEP-ATP III criteria for identifying metabolic syndrome (Grundy et al., 2005):

1. Waist circumference > 35 in. for women and > 40 in. for men.
2. Blood pressure with either diastolic > 134 or systolic > 84 mm HG.
3. Fasting triglycerides > 150 mg/dL.
4. HDL-C < 50 mg/dL for women and < 40 mg/dL for men.
5. Fasting blood glucose ≥ 100 mg/dL or the presence of type 2 diabetes.

Patients who already had type 2 diabetes or hypertension were able to be included in this study. Exclusion: Participants who were younger than 21 years of age were excluded from this project. If a person had a history of medical noncompliance documented in the medical record, they were excluded.

Methods

Data collection for this study took place over a period of six months, beginning in early July 2008 and ending in December 2008. Subjects were identified by the clinic medical director and clinical director as potential participants. The subjects were new to the practice with the diagnosis of metabolic syndrome based on the ATP III guidelines. Once the diagnosis was verified by chart review, the researcher spoke to the participants to thoroughly explain the research and they were told they could terminate the interview at any time if they so desired. After the explanation was completed, the participant was given the opportunity to ask questions. Once written consent to participate was obtained,

participants were counseled by the researcher or the clinic director regarding the diet program. The patients were told it would take approximately three one-hour sessions with the graduate dietary intern over a six-month period.

Data Collection

Blood pressure, weight, waist circumference, and exercise participation were measured on entry into the study. A dietary assessment was performed using a 24 hour dietary recall. Fasting blood levels were determined for lipoproteins and blood glucose. These parameters were assessed again at 3 months and 6 months.

Blood pressure. Blood pressure was measured by the graduate dietary intern who had been individually trained following the guidelines published by the American Heart Association (Pickering et al., 2005). Blood pressure was recorded in the sitting position using the right arm to the nearest 2 mmHg with a sphygmomanometer. Two readings were taken 5 min apart, and the mean of the two was taken as the blood pressure.

Weight. Weight was evaluated in pounds using the same Detecto^{TM} office scale. Weight was measured by the graduate dietary intern with the patient fully dressed and without shoes. Although the standard is that calibration of the scale within the last year resulted in scales with significantly more precise readings ($p \leq 0.001$) (Stein, Haddock, Poston, Catanase, & Spertus, 2005), for the purposes of this study, monthly calibration was done

Waist circumference. Waist girth was measured as the narrowest circumference between the bottom of the rib cage and the iliac crest by using an unstretched tape measure (Katzmarzyk et al, 2006). Waist circumference was measured by the graduate

dietary intern using the same tape measure for each patient. Waist circumference was measured at the level of the umbilicus with clothing from around the waist removed.

Lipoproteins and fasting glucose. Blood samples from all individuals were obtained after a 12-hour fasting period. Samples were analyzed by Consolidated Laboratories. Consolidated Laboratory Services is a comprehensive laboratory that services medical facilities throughout northeast Florida and southeast Georgia. The laboratory is subject to stringent internal and external quality control programs. They have a planned systematic process for monitoring, evaluating, and continually improving the quality of laboratory services.

Intervention

Participants continued to receive the usual primary care at the clinic. Additionally they received dietary counseling strategies designed to prevent Type 2 diabetes and cardiovascular disease by the achievement and maintenance of normal body weight and reduction of abdominal obesity, blood lipid values, fasting blood glucose levels, and blood pressure. Each participant was counseled by a graduate nutrition intern from the University of North Florida regarding the Mediterranean and TLC diets. The best dietary pattern contains elements from each of the diets described here: an emphasis on whole-grain carbohydrates, unsaturated fats, fruits, vegetables, legumes, and lean protein, with reductions in saturated and trans fats and refined carbohydrates. Participants were counseled and assisted to choose foods from the two diets that would fit in with their personal likes and lifestyles because the most important process is finding a diet the person can adopt for the long term in combination with regular exercise (Zivkovic, German, & Sanyal, 2007).

Participants took part in three individualized nutrition counseling sessions scheduled at 4-6 weeks intervals (see Appendix C). The initial session was used to obtain a 24-hour diet recall, occupation, living situation and current life situation. The session topic, "10 Steps to a Healthy Lifestyle," reviewed the importance of fiber, reading food labels, importance of exercise, pedometer use, proper portion sizes, low-fat food choices and how to complete a food journal.

The second session included information on eating out, healthy snacking, and omega-3 fatty acids. Examples of healthy entrees and snacks were given. Subjects were given samples of whole grain cereal.

Session three focused on Internet resources. The websites provided were for healthy recipes, motivation, exercise, healthy living tips, and nutrition databases. To encourage intake of water and calorie-free fluids subjects were given a water bottle. Each subject was given lab order form and instructed to get the blood drawn (fasting) at the beginning of the week of their next appointment. During the third session a final 24-hour food recall was obtained. Results of new lab work were discussed and comparisons were made from the initial visit.

Protection of Human Subjects

Permission to conduct this study was obtained from the investigator's project committee, the Institutional Review Board for The University of North Florida, and the executive board of the clinic. Subjects were provided essential information for informed consent and signed a consent form. The benefit-risk ratio was assessed for this study, indicating important benefits and minimal risk.

Chapter Four: Results

This chapter describes the study population using mean scores and frequency of the variables. Analyses were executed using SPSS statistical software (version 16.0, 2007, Chicago, IL) with statistical significance determined at $p \leq .05$. Data were analyzed using descriptive statistics and non-parametric t-tests to determine changes in metabolic syndrome indicators from pretest to posttest. Pearson correlation coefficients were calculated to quantify the associations among variables.

Demographic Data

Twenty-three individuals signed consent to participate in the study, but only 19 completed the study. There were no significant differences in either demographic or study variables at the initial data collection point between those who completed the study and those who did not. Data analysis is based on the 19 who completed the study. Subjects were between 29 and 58 years-of-age (M=45.21, SD=8.68); predominately female (n=16, 84.21%); and predominately Caucasian (n=13, 68.42%) with 4 (21.05%) African-Americans and 2 (10.53%) Hispanics. Fifteen (78.95%) of the participants smoked cigarettes. Demographic variables of the sample were not significantly different from the demographics of patients in the clinic. Table 4.1 presents the baseline measures related to body measurements.

Dietary Adherence

Examination of the 24-hour diet recalls at baseline and six months revealed no significant difference in any of the dietary variables (see Table 4.2)

Table 4.1

Baseline Measures of Sample (n = 19)

	Participants	
	Mean	SD
Waist Circumference	46.43	±6.95
Body Weight	252.22	±58.07
BMI	40.9	±9.76

Table 4.2

24- hour Diet Recall (n=13)

Food Group (recommended # of servings)	Average # Servings at Baseline	Average # Servings After 6 Months	Change
Bread, Cereal, Rice, and Pasta (6-11 servings)	4.0	3.31	-0.69
Vegetables (3-5 servings)	1.54	1.31	-0.23
Fruits (2-4 servings)	1.46	1.46	0.0
Milk, Yogurt, and Cheese (2-3 servings)	1.85	2.31	+0.46
Meat, Poultry, Fish, Dry Beans, Eggs, and Nuts (2-3 servings)	3.62	3.23	-0.39
Fats, Oils, and Sweets (use sparingly)	2.85	2.69	-0.16

The data from the participants who completed the 24 hour diet recall was only thirteen of the nineteen patients in the study. We relied on self-reported dietary intake, but we validated the dietary assessment individually to minimize the amount of missing data. Finally, one might argue that the unique nature of the clinic in this study makes it difficult to generalize the results to clinic setting. However, we believe that similar strategies to maintain adherence could be applied elsewhere.

Comparison of Metabolic Syndrome Indicators Before and After Dietary Intervention

Because not all participants returned to the clinic for data collection at the 3-month session, only baseline and 6-month data were consistently available for 19 participants. Changes were measured and calculated by subtracting the baseline value from the 6-month value. The mean change in metabolic syndrome indicators for each variable indicates that the study group had significantly improved systolic and diastolic blood pressure, total cholesterol, fasting glucose, triglycerides, HDL and LDL levels compared to the group from baseline to post-intervention as illustrated in Table 4.3.

Table 4.3

Study Group Mean Diagnostic Indicators from Baseline to Post-Intervention (n=19)

	Data (Mean)		
	Initial	6 Months	Change
Weight (pounds)	252.2	261.78	9.58
Body mass index (kg/m^2)	40.9	42.37	1.47
Waist Circumference (in)	46.43	46.7	0.27
Fasting Glucose (mmol/L)	98.87	95.92	-5.08
Systolic blood pressure (mm Hg)	136.74	127.11	-13.89
Diastolic blood pressure (mm Hg)	93.22	81.67	-12.11
Triglycerides* (mmol/L)	147.57	129.47	-5.07
High-density lipoprotein(mmol/L)	39.30	43.67	3.47
Low-density lipoprotein (mmol/L)	121.00	113.47	-6.13

Pearson correlation analyses revealed no significant association between the demographic variables of age, race, gender, and smoking with any of the outcome variables themselves, or with the post-intervention change. Participants varied in the number of dietary counseling sessions they attended. While 14 of the 19 participants

(73.68%) had one or more visits, only 5 (26.32%) had more than three total visits. There was no discernable pattern of association between the dose of the dietary intervention (that is, the number of visits) and metabolic syndrome indicators.

Although the intent at the outset of the study was to hold medications constant, in fact, three individuals (15.79%) had cholesterol-lowering medication changes and two individuals (10.53%) had antihypertensive medication changes during the course of the study. There was no significant association between the medication changes and the metabolic syndrome indicators.

Chapter Five: Conclusion

This chapter provides a discussion of the study findings relevant to the dietary intervention and lessons learned in the process. Implications for evidence-based practice and future research are also presented.

Discussion

The aim of this project was to determine whether dietary changes related to nutrition counseling can improve the outcomes of patients with metabolic syndrome at the Volunteer in Medicine Jacksonville Clinic (VIM-JAX) in Jacksonville, FL. Additionally, age, gender, and baseline laboratory studies as predictors of weight loss were explored. Diet has been shown to be a major contributor to metabolic syndrome in susceptible individuals (Grundy et al., 2005). Among adults, the prevalence of obesity and overweight has increased rapidly over the last 15 years to 65% and parallels the increase in diabetes. The prevalence of metabolic syndrome increases with age and varies by ethnicity, with Hispanics having the highest age-adjusted prevalence compared with other ethnic groups. Hispanics currently represent over 14% of the total U.S. population and have a projected growth to 25% of the total population by 2050 (Noel, S., Newby, P., Odrovas, J., & Tucker, K., 2009). Even though only 9% of the population at VIM-JAX is Hispanic, 21% of the participants were in this group.

Results of the study showed marked improvement in all of the variables for hypertension and dyslipidemia (blood pressure, FBS, HDL, LDL and triglycerides). On the other hand, both BMI and weight increased overall in this study group. Multiple

attempts to identify correlation between these variables and dietary intervention were unsuccessful. Also, most of the patients (94%) were either on a lipid lowering agent and/or antihypertensive throughout the study which may have affected the outcomes. This study failed to support the hypothesis that TLC dietary intervention will improve metabolic syndrome parameters in an uninsured population. Most of the individuals affected by metabolic syndrome are overweight, therefore dietary treatment should be primarily focused on weight reduction. Therefore a diet to treat individuals with metabolic syndrome will have some general characteristics, but will have specific properties to take into account the abnormalities present in that individual patient (i.e. hypertension and dyslipidemia). "In the absence of clear scientific evidence, individuals with metabolic syndrome will continue to be treated with multiple drug prescriptions that mitigate the symptoms, but are inadequate to treat the disease" (Riccaradi & Reveilles, 2000, p. S147).

Limitations

Lack of uniform definition. There were many limitations to this study that should be noted. First, the lack of a uniform definition of the Metabolic Syndrome was a limitation for this study. Although the Metabolic Syndrome is a well recognized clinical phenomenon, there is no accepted definition, and the physiological changes in childhood make the definition particularly difficult to classify. Johnson and Weinstock (2006) have shown the NCEP ATP III criteria to have definite flaws. "First, the 5 criteria and the cutoffs appear to be arbitrary and not evidence based. Second, the risk factor values are continuous and must be considered as such, not just as present or absent. The fact that CVD risk increases with increasing blood glucose levels, systolic blood pressure, and

LDL cholesterol values has been well documented. Third, important risk factors such as LDL cholesterol, cigarette smoking, family history, and age are not included, limiting the usefulness of the metabolic syndrome in predicting CVD risk" (p. 1616). The metabolic syndrome has been defined in several ways and thus cannot be considered a precise diagnosis.

Recently (2009), five major scientific organizations – the International Diabetes Federation (IDF), the (NHLBI), the AHA, the World Heart Federation (WHF), the International Atherosclerosis Society (IAS), and the International Association of the Study of Obesity (IASO) – have just released a joint interim statement that represents a giant leap toward a unified definition of the metabolic syndrome. Individuals who meet at least 3 of 5 clinical criteria will be diagnosed as having the condition; presence of none of these criteria is mandatory. Specific cut points are defined for all criteria, except elevated waist circumference, which must rely on population and country-specific definitions (Alberti et al., 2009).

Weight loss limitations. The weight loss of the subjects may not reflect fat mass loss. Obesity was measured by BMI and weight. This measure was used because of its simplicity, economical and ease of use for the clinician, however, true fat mass was not assessed. Weight loss generally involves the loss of both fat and lean mass and it is anticipated that fat mass loss contributes to improvements in Metabolic Syndrome markers.

Multiple providers. Second, study participants were seen by different graduate dietary interns who rotated throughout the semester. Based on scheduling conflicts, the study participant would not see the same intern for follow-up appointments. In addition,

VIM-JAX uses multiple primary care providers who followed these patients. Rapport with the patient may be better with consistent providers. Beutow (2003) cautioned "provider continuity will not happen if there is a lack of consistency in who attends with or for the patient during successive visits" (p. 509). He also described how continuity of care can be weakened because the clinician may be hindered from providing a "sustained partnership" and having an ongoing sense of responsibility to the patient.

Use of graduate nutrition students. Because graduate nutrition practitioners are educated in a wide range of practice settings, it is difficult to differentiate the varying levels of expertise. There may be a lack of systematic instruction, counseling and coaching system caused by the use of multiple interns at VIM-Jax that impacted on the ability to promote effective diet change. There is a need for more consistent training of the graduate nutrition interns along with the primary care providers for use of specific and consistent messaging via counseling or motivational interviewing and coaching.

Lack of computer support. Originally, the study was designed to use a dietary analysis computer program. The Self-Efficacy for Healthy Eating Scale (Baughman et al., 2003) measures healthy eating self-efficacy. The instrument consists of a 20-item likert scale with a reliability α coefficient of 0.95 and was designed to measure participant ability to eat a healthy diet including eating more fruits and vegetables, eating less dietary fat, and eating smaller portions. Food records of weekly intake were to be analyzed using the Food Processor ™ computer program to provide mean dietary energy intake, daily grams of fiber, percentage of calories from fat, saturated fat, protein, and carbohydrates; and daily servings of fruits and vegetables. The Food Processor instantly compares patient dietary intake against recommended nutrient standards, analyzing as

many as 164 nutritional components. It includes a database of over 32,000 foods, recipes and exercises and users can add an unlimited number of foods and modify existing foods (ESHA research). Because of outdated and limited computer support at VIM-JAX, this program was unavailable for use.

Scheduling conflicts. Finally, individuals who were recruited for the current study had to attend the nutrition appointments within a specified time frame. Therefore, the sample was limited to those who made and attended the appointments at VIM-JAX. Because the study used UNF graduate nutrition interns, the students' schedule was an obstacle to providing choices in appointment times and dates for the study participants. All of the nutrition classes were only offered on Fridays when classes were in session. National data suggests that 12 million appointments in the primary care setting are not attended each year, approximately 6.5% of the appointments made (Martin, Perfect, & Mantle, 2005). This "no show" rate is likely to be higher in a primary care setting serving predominantly indigent patients who have more barriers to attending appointments (i.e., transportation, work schedule, daycare).

Conclusion

Those with metabolic syndrome have significantly higher risks for developing diabetes and cardiovascular disease. Public health experts estimate that billions of dollars in medical costs are spent managing patients with metabolic syndrome each year in the United States. Morbidity and mortality stemming from obesity and metabolic syndrome has reached epidemic proportions. Aggressive treatment of metabolic syndrome is critical for the health of the world's population. More research is necessary to identify the components that are most effective for weight loss especially in the primary care setting.

Specifically, evidence based studies are needed with this population comparing medical and pharmacotherapy versus more general dietary/exercise interventions. The issue of the confounding variables related to medication vs. diet and different outcomes based on adherence to one or the other and subsequent outcomes needs more research. Twenty eight percent of the participants in the study were either on an antihypertensive or lipid lowering agent or both.

The optimal management of patients at high risk for cardiovascular disease requires both assessment and treatment of the modifiable cardiometabolic risk factors established by evidence-based guidelines. "The ultimate utility of even considering metabolic syndrome may simply be to provide patients and clinicians a framework in which to discuss the importance of multiple risk factors and interventions, especially if the patient has no symptoms and therefore is likely to be unmotivated and more likely to choose pharmacotherapy when ill than lifestyle changes before irreversible illness occurs" (Stolar, 2007, p. 207).

Lifestyle changes are the most important element in helping patients stop the progression of metabolic syndrome to cardiovascular disease. These are often the most difficult patients for health care providers to manage. "Motivational interviewing" is another useful strategy that can aid the provider when resistance is met or the challenge to change seems burdensome. Motivational interviewing is a 3-step, therapeutic approach that can assist providers in encouraging behavior change in their patients with metabolic syndrome (West, DiLillo, Bursac, Gore, & Greene, 2007). Numerous studies have shown that trust between a health care provider and a patient is one of the most important elements contributing to a patient's success (Beutow, 2003). Yet patients find

it difficult to undertake the recommendations we ask of them. If we could identify metabolic syndrome patients who are at risk of developing diabetes or cardiovascular disease, we might be able to intervene earlier. By gaining skills to help motivate, encourage, and support patients in successfully implementing lifestyle changes to improve their health status, clinicians can enhance their patients' wellness and begin reducing the burden of cardiovascular disease in the U.S.

"The time has come to apply to diet research the same level of evidence required for other interventions. We believe that indications or claims made for weight loss or health improvement via diet—whether made by authors, the government, or associations—must be supported by 3 types of evidence: proof that the diet provides essential nutrients in actual patients, efficacy studies, and randomized, controlled trials with clinical events as end points" (Yancy, et al., 2003, p. 14).

As clinicians, "if we could identify patient subgroups truly at risk of developing diabetes or cardiovascular disease, we might be able to intervene earlier and more cost-effectively, rather than screening and treating the general population" (Stolar, 2007, p. 206). The ultimate reason to identify metabolic syndrome may simply be to provide patients and clinicians a framework in which to discuss the importance of multiple risk factors and interventions. This is especially important if the patient has no symptoms and therefore is likely to be unmotivated and more likely to choose pharmacotherapy than lifestyle changes.

Appendix A: Critical Analysis Table: Review of the Evidence

Author (Dates)	Title	Type	N	Comments
Brunner et al. (2007)	Dietary advice	Cochrane Review	17,871 subjects	Dietary advice appears to be effective in bringing about modest beneficial changes in diet and cardiovascular risk factors over approximately 10 months but longer-term effects are not known.
Gami et al. (2007)	Metabolic syndrome	Meta-analysis and systematic review of metabolic syndrome and incidence of cardiovascular events	37 studies, 172,573 subjects	Evidence suggested metabolic syndrome increases risk of cardiovascular events.
Dansinger et al. (2007)	Meta-analysis: The effects of dietary counseling	Meta-analysis of the effects of dietary counseling compared with usual care in adults	46 clinical trials, 11, 853 subjects	Compared with usual care, dietary counseling interventions produce modest weight losses that diminish over time.
Franz et al. (2007)	Weight-loss outcomes: A systematic review and meta-analysis	Systematic review to determine types of weight-loss interventions that contribute to successful outcomes and to define expected weight-loss outcomes from the interventions	80 RCT studies, 26,455 subjects	Reduced-energy diets, with or without exercise, promote weight loss more than advice alone. Meal replacement and weight-management drugs promote weight loss more than diet alone. Regardless of intervention type, most weight loss occurs in the first six months, with some weight re-gain

Author (Dates)	Title	Type	N	Comments
Nordmann et al. (2006)	Effects of low-carbohydrate vs. low-fat diets on weight loss	Meta-analysis comparing the effects of low carbohydrate diets without restriction of energy intake vs. low-fat diets in individuals with a BMI of at least 25	5 RCT studies, 447 subjects	Low-carbohydrate, non-energy-restricted diets appear to be at least as effective as low-fat, energy restricted diets in inducing weight loss for up to one year
Galassi et al. (2006)	Metabolic syndrome and risk of cardiovascular disease: A meta-analysis	Meta-analysis examining the association between the metabolic syndrome and risk of cardiovascular disease	21 Prospective cohort studies, 78,769 subjects	This meta-analysis indicated that individuals with the metabolic syndrome have a 61% increased risk of cardiovascular disease compared to individuals without the metabolic syndrome
Yamaoka & Tango (2005)	Efficacy of lifestyle education	Meta-analysis evaluating the efficacy of lifestyle education for preventing type 2 diabetes in individuals at high risk by meta-analysis of RCTs	9 RCT studies, 10,461 subjects	Lifestyle education interventions of the studies varied widely. This meta-analysis provided evidence of a relationship between lifestyle education in high risk subjects and the prevention of type 2 diabetes

Author (Dates)	Title	Type	N	Comments
AHRQ (2005)	Screening for metabolic syndrome	Guideline using a review of published meta-analyses, systematic reviews, and systematic reviews with evidence tables.	N/A	The recommendations were based primarily on sources such as national guidelines and consensus statements written on hyperlipidemia, hypertension, and diabetes mellitus by the National Cholesterol Education Program Expert Panel, the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, and Workgroup of the American Diabetes Association. Guidelines and statements were synthesized to make them applicable to the screening and treatment of metabolic syndrome
Groeneveld et al. (2008)	Evaluating the cost- effectiveness of a lifestyle intervention	RCT	692 subjects	By improving lifestyle, CVD risk may be lowered, yielding benefits for both employee and employer. By improving lifestyle, CVD risk may be lowered, yielding benefits for both employee and employer. If proven effective, this lifestyle intervention will be implemented on a larger scale within the Occupational Health Services in construction industry
Ilanne-Parikka et al. (2008)	Effect of lifestyle intervention on the occurrence of metabolic syndrome	RCT	522 subjects	There is a significant reduction in the prevalence of metabolic syndrome in the intervention group compared with the control group, suggesting that lifestyle intervention may also reduce risk of cardiovascular disease
Bo et al. (2007)	Effectiveness of a lifestyle intervention on metabolic syndrome	RCT	375 subjects	A lifestyle intervention based on general recommendations was effective in reducing multiple metabolic abnormalities

Author (Dates)	Title	Type	N	Comments
Orchard et al. (2005)	The effect of metformin and intensive lifestyle intervention	RCT	1,711 subjects	Metabolic syndrome affected approximately 50% of the participants in the Diabetes Prevention Program at baseline. Both lifestyle intervention and metformin therapy reduced the development of the syndrome in the remaining participants in the study
Esposito et al. (2004)	Effect of a Mediterranean-style diet	RCT	180 subjects	A Mediterranean-style diet might be effective in reducing the prevalence of the metabolic syndrome and its associated cardiovascular risk
de Lorgeril et al. (1999)	Mediterranean diet, traditional risk factors	RCT	605 subjects	There is reduced risk of CHD mortality due to Mediterranean diet
Lutsey et al. (2008)	Dietary intake and the development of metabolic syndrome	Prospective multicenter cohort study	9,514 subjects	The consumption of a Western dietary pattern, meat, and fried foods promotes the incidence of metabolic syndrome, whereas dairy consumption provides some protection
Seidel et al., (2008)	Translating the diabetes prevention program into an urban medically underserved community	Prospective intervention study	573 subjects	Adults in an urban medically underserved community can decrease their risk for type 2 diabetes and CVD through participation in a group lifestyle intervention, and short-term sustainability is feasible

Author (Dates)	Title	Type	N	Comments
Katzmarzyk et al. (2006)	The importance of waist circumference in the definition of metabolic syndrome	Prospective cohort study	20,789 subjects	Waist circumference is an important component of metabolic syndrome; however, the IDF requirement of an elevated waist circumference warrants caution given that a large proportion of men with normal waist circumference have multiple risk factors and an increased risk of mortality
Bonora et al. (2003)	Carotid atherosclerosis and coronary heart disease in the metabolic syndrome	Prospective population-based survey	888 subjects	Subjects with the metabolic syndrome by WHO criteria had an increased five-year incidence and progression of carotid atherosclerosis
Osei et al. (2008)	Is glycosylated Hemoglobin A1C a surrogate for metabolic syndrome	Cross sectional	219 subjects	Measuring random HbA1c levels in African American patients serves as a surrogate of metabolic syndrome
Dilley et al. (2007)	Association of A1C with cardiovascular disease and metabolic syndrome	Cross sectional	1,620 subjects	In Asian Indians with normal glucose tolerance, A1C showed an association with most CVD risk factors, the metabolic syndrome, and CAD
Mendoza et al. (2007)	Dietary energy density is associated with obesity and the metabolic syndrome	Cross sectional	9,688 subjects	Dietary energy density is an independent predictor of obesity, elevated fasting insulin levels, and the metabolic syndrome in U.S. adults

Author (Dates)	Title	Type	N	Comments
Panagiotakos et al. (2004)	The impact of lifestyle habits on the prevalence of the metabolic syndrome	Cross sectional	3,042 subjects	Decreased risk of having the metabolic syndrome due to Mediterranean diet
Vaidya et al. (2007)	Defining the metabolic syndrome	Cross sectional	6,781 subjects	Metabolic syndrome was associated with greater insulin resistance and was compatible with two of three "syndrome" constructs tested
Strazzullo et al. (2008)	Diagnostic criteria for metabolic syndrome	Comparative	933 subjects	A five-fold difference in the prevalence of MS resulted from the use of different diagnostic criteria
Dallongeville et al. (2005)	Household income is associated with the risk of metabolic syndrome	Comparative	1,695 subjects	Limited household income, which reflects a complex unfavorable social and economic environment, may increase the risk of metabolic syndrome in a sex-specific manner

Abbreviations: A1C = ; BMI = body mass index; CAD = ; CHD = ; CVD = cardiovascular disease; RCT = randomized controlled trials.

Appendix B: Data Collection Sheet

NCEP-ATP III Definition	Data		
	Initial	3 Months	6 Months
n			
Age (years)			
Men (%)			
Body mass index (kg/m^2)			
Waist, men (cm)			
Waist, women (cm)			
Glucose (mmol/L)			
Systolic blood pressure (mm Hg)			
Diastolic blood pressure (mm Hg)			
Triglycerides* (mmol/L)			
High-density lipoprotein(mmol/L)			
Low-density lipoprotein (mmol/L)			
Smokers			

Appendix C: Dietary Counseling Sessions

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Curriculum Vitae

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