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Can A Vegetarian Diet Improve Quality of Life in Type 2 Diabetics, Compared to Other Diabetic Diets?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine if a vegetarian diet is more effective in improving quality of life in Type 2 Diabetics compared to other diabetic diets.

STUDY DESIGN: Review of two randomized control trials published in 2011 and 2013, and one prospective clinical intervention study published in 2010.

DATA SOURCES: Data sources were articles published in peer review journals found using PubMed and Cochrane Databases.

OUTCOMES MEASURED: Quality of life was measured by amount of weight loss from baseline and Obesity and Weight-Loss Quality of Life (OWLQOL) questionnaires.

RESULTS: Ferdowsian et al (2010) reported that the vegetarian group lost an average of 5.1 kg during the 22 week trial, compared to the control group which gained an average of 0.1 kg. Kahleova et al (2011) reported that on average people in the vegetarian group lost 3 kg more body weight than the control group. Kahleova (2013) demonstrated that the vegetarian group reported higher scores for weight-loss related quality of life on the OWLQOL questionnaire.

CONCLUSIONS: The results of the two randomized control trials and prospective clinical intervention study demonstrate that a vegetarian diet did lead to improved quality of life when compared to other diabetic diets. Future study is warranted to evaluate quality of life over a long term period. The trials were not double blind studies and had a relatively small sample size, which may have limited the data formulated.

KEY WORDS: Diabetes, Vegetarian Diet.

INTRODUCTION

Type 2 Diabetes (T2DM) is a progressive metabolic disease of insulin resistance, impaired insulin secretion, or elevated hepatic production resulting in hyperglycemia. The cause of Type 2 diabetes is idiopathic, with strong contributing factors such as obesity, diet, lifestyle choices, and genetics. Classically, patients exhibit signs of central obesity, hypertension, and retinopathy. Patients may be asymptomatic or present with weakness, nausea, vomiting, anorexia, altered mental status, blurred vision, paresthesias, polydipsia, or polyuria. Often, the disease is found incidentally on general screenings. Blood glucose levels on Random Plasma Glucose Tests, Fasting Plasma Glucose Tests, or HbA1c may confirm diagnosis[3].

Type 2 Diabetes affects about 22 million Americans[2]. It is most common in minorities and the obese. T2DM was previously rare in adults over 40 years old, but recently prevalence has been increasing in overweight children as well. [3] First step of treatment is to improve insulin resistance/secretion through exercise and weight loss. If conservative treatment fails to improve hyperglycemia, oral medications are added. Mainstays include insulin sensitizers (i.e. Metformin) and insulin secreatagouges (i.e. Glyburide and Nateglinide). Insulin is added only when hyperglycemia proves refractory to exercise, dietary changes, and oral hypoglycemic treatments[3].

Complications of T2DM are numerous and can be disabling. Commonly seen complications include diabetic retinopathy, cataracts, glaucoma, cardiovascular disease, nephropathy, ESRD, and peripheral neuropathies[2]. Patients may also experience increased risk of infections due to decreased immunity and foot ulcers secondary to

peripheral neuropathy. Gastrointestinal and genitourinary dysfunction include diarrhea, constipation, gastroparesis, and sexual dysfunction[2].

The total estimated cost of diabetes in the U.S. in 2012 was $245 billion, including $176 billion in direct medical costs and $69 billion in reduced productivity[1]. The largest components of medical expenditures were hospital inpatient care (43%), prescription medications to treat complications (18%), anti-diabetic agents and diabetic supplies (12%), physician office visits (9%), and nursing/residential facility stays (8%)[1]. There are approximately 37.3 million healthcare visits and about 635,000 inpatient stays with diabetes as primary diagnosis per year[1].

In general, a well-balanced vegetarian diet has lower intakes of saturated fat, cholesterol and animal protein than meat based diets. They are also reported to have higher intakes of complex carbohydrates, dietary fiber, magnesium, folic acid, vitamin C and E, carotenoids and other phytochemicals that benefit weight loss[7]. The intervention being analyzed in this study is if implementing a vegetarian diet as adjunctive treatment can improve quality of life in Type 2 diabetics[7].

OBJECTIVE

The objective of this selective EBM review is to determine “Can a vegetarian diet improve quality of life in Type 2 Diabetic patients, compared to other diabetic diets?”

METHODS

Specific selection criteria of the 2 randomized control trials and 1 prospective clinical intervention study were used in this review. Although each of the trials had specific criteria, a common trend as seen in all three. The populations of all trials included type 2 diabetic patients >21 years old with a BMI >25 kg/m2 and an HbA1c >6.

Candidates selected were required to show willingness to change dietary habits and follow a prescribed exercise plan. All studies compared Type 2 diabetics on a conventional diabetic diet to those on a strictly vegetarian diet. Though many outcomes were measured in each study, the one outcome of concern was improved quality of life for patients, measured by weight-loss from baseline or OWLQOL questionnaires. Statistical data analysis included confidence intervals (CI) set at 95% and p-value significance set at 5%.

All three of the RCTs were written in English and discovered in published peer review journals. Key words used to acquire literature were “diabetes” and “vegetarian diet”. The author searched articles through PubMed and Cochrane databases and were selected based on the relativity to the question proposed. Inclusion criteria included articles from 1997 to the present, RCTs or prospective intervention studies, implementation of vegetarian diet, and if the resulting data could be expressed as a POEM. Exclusion criteria included articles before 1997, articles that were not RCTs/prospective intervention studies, and studies that did not use a vegetarian diet as an intervention. The statistics used in the articles were p-values, paired t-tests, CI’s, and standard deviations. Table 1 expresses the specific demographics, inclusion, and exclusion criteria of each trial used in this review.

Table 1. - Demographics and Characteristics of included studies. [4,5,6]

Study	Type	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Ferdowsian 2010 [4]	Prospective clinical intervention study	113	21-65 y/o	Male and female employees of the Government Employees Insurance Company (Geico) 21-65 y/o with BMI > or = 25 and/or a previous dx of Type 2 diabetes	History of unresolved alcohol or drug abuse or dependency, pregnancy, history of severe mental illness, unstable medical status, current use of a low-fat, vegetarian diet, or an A1c >10.5%.	12	Low-fat vegetarian (vegan) diet: Fat intake <25% of energy, saturated fat <5% of energy, and cholesterol <50 mg per day.
Kahleova 2013	Randomized, open, parallel, controlled trial	74	30-70 y/o	Type 2 diabetes, age 30–70 years, HbA1c between 6 and 11% (42–97 mmol/mol), BMI between 25 and 53 kg/m2, and willingness to change dietary habits and follow a prescribed exercise program.	HbA1c < 6% (< 42 mmol/mol) or > 11% (> 97 mmol/mol), use of insulin, abuse of alcohol or drugs, pregnancy, lactation, or current use of a vegetarian diet	0	Vegetarian diet with ~60% of energy from carbohydrates, 15% protein and 25% fat
Kahleova 2011	Randomized, open, parallel, controlled trial	74	30-70 y/o	Type 2 diabetes, age 30–70 years, HbA1c between 6 and 11% (42–97 mmol/mol), BMI between 25 and 53 kg/m2, and willingness to change dietary habits and follow a prescribed exercise program.	HbA1c < 6% (< 42 mmol/mol) or > 11% (> 97 mmol/mol), use of insulin, abuse of alcohol or drugs, pregnancy, lactation, or current use of a vegetarian diet	6	Low calorie vegetarian diet with energy values of ~60% carbohydrates, 15% protein and 25% fat x 24 weeks.

OUTCOMES MEASURED

The outcome measured by this systematic review was improved quality of life. Each of the studies compared individuals who ate a strictly vegetarian diet to those who consumed meat as part of their regimen. One RCT and one prospective clinical study quantified quality of life by weight loss from base line. The other RCT measured the outcome by scores on the OWLQOL questionnaire.

RESULTS

In Kahleova 2011 et al. seventy-four patients ages 30-70 with Type 2 diabetes chosen by their endocrinologists were randomly assigned to either the experimental group receiving a vegetarian diet, or the control group receiving a conventional diabetic diet. Both diets were isocaloric and calorie restricted. All participants had no clinically significant differences at baseline with regards to demographic characteristics, BP, or HbA1c[6]. This study excluded patients using insulin as part of their daily regimen. Both groups were followed over a period of 24 weeks. Weight was measured at 0, 12, and 24 weeks. Both groups started with 37 participants and ended with 31, however all data was carried forward in intention to treat analysis. “High” compliance was defined by exceeding calorie limit by <100 kcal/day, and was met by 55% of the experimental group and 32% of the control group[6]. Weight loss was clinically significant in both groups, but the experimental group experienced higher success rates than in the control group [–6.2 kg (95% CI –6.6 to –5.3) vs. –3.2 kg (95% CI –3.7 to –2.5); group x· time P = 0.001] [6]. All statistical analysis was performed with a confidence interval (CI) of 95%. The results are summarized in Table 2.

Table 2. BMI change from baseline (kg/m^{-2}) of experimental vs control group at 12 and 24 weeks of treatment.

Duration	Vegetarian Group	Control Group	P-values
12 weeks	- 2.15 (SD 1.42)	- 1.12 (SD 1.46)	0.001
24 weeks	- 2.18 (SD 2.06)	- 0.-98 (SD 1.57)	0.001

Ferdowsian 2010 et al studied one-hundred and thirteen GEICO employees ages 21-65 with Type 2 DM who volunteered to participate in the prospective clinical intervention. The trial excluded participants with a BMI <25 kg/m^2. The intervention group (n=68) was assigned a vegan diet restricting fat intake <25% of energy, saturated fat <5% of energy, and cholesterol <50 mg per day. The control group (n= 45) was asked to continue their habitual diet. There were no significant differences found between groups for any clinical measures at study initiation, but there were differences for gender (p=.003) and race (p= .03) [4]. At the end of the study, the intervention group participants experienced greater weight loss than the control-group (mean -5.1 [SE, .6] kg vs. + .1 [SE, .6] kg, p < .0001) [4]. Weight loss of 5% of body weight was more frequently observed in the intervention group (48.5%) compared with the control group (11.1%)[4].

Table 3. Average weight loss from baseline of vegetarian vs control group at the end of the trial.

Weight (kg)	**Vegetarian group**	**Control group**
At baseline	98.7 kg (SD 2.8)	100.1 kg (SD 3.5)
At 22 weeks	93.6 kg (SD 2.7)	100.3 kg (SD 3.7)
Average weight loss from baseline	-5.1 kg (SD 0.6), P<0.0001	+ 0.1 kg (SD 0.6)

Kahleova 2013 et al. studied 74 subjects with Type 2 diabetics between the ages of 30- 70 years old being treated with oral hypoglycemic agents. The intervention group was

assigned a vegetarian diet composed of ~60% daily calories from carbohydrates, 15% protein, and 25% fat with animal products limited to 1 carton of low fat yogurt a day. The control group followed a conventional diabetic diet. Quality of life was assessed using the Obesity and Weight Loss related Quality of Life Questionnaire (OWLQOL). Confidence Intervals were >95%. Participants in the experimental group reported greater improvement in quality of life. Significant changes from 0-12 weeks and 12-24 weeks for within-group changes assessed by paired comparison t-tests were $p < 000.1$[5]. Results are detailed in Table 4.

Table 4. OWLQOL mean scores at baseline, 12, and 24 weeks of treatment.

OWLQOL score	Baseline score	12 weeks	24 weeks	p-value (24 wk)
Vegetarian Group	45 (SD 2)	50 (SD 1)	56 (SD 0.6)	$p < 0.001$
Control Group	40 (SD 1)	45 (SD 1)	46 (SD 1)	$p > 0.05$

None of the trials reported any adverse effects secondary to the implemented intervention. All participants who left the studies reported personal reasons or lack of motivation. All trials described a vegetarian diet to be a safe and effective intervention.

DISCUSSION

This selective EBM review investigated two randomized controlled trials and a prospective clinical intervention. All trials compared quality of life related to weight loss in diabetics placed on vegetarian diets to those on diabetic diets that did not restrict meat. Eliminating meat from participants diet was beneficial: all three trials indicated that the intervention groups experienced greater changes in quality of life than the control groups. This data was statistically significant in the RCT by Kahleova 2011 et al. in which the intervention group lost more weight from baseline then the control group. In Ferdowsian

2010, those adhering to a vegetarian diet also lost more weight from baseline than the control group. In Kahleova H. 2013, the vegetarian group reported higher scores on Obesity and Weight Loss Quality of Life questionnaires.

There were several limitations among the trials presented in this selective EBM review. None of the trials were double blind studies. Limitations in Kahleova et al. include the small sample size, variability, and relatively short time period. The 24 week trial period was an adequate time to compare weight reduction within groups, it was not a sufficient time to determine long term compliance and tolerability of diet. In Ferdowsian et al, the trial was only 22 weeks long, did not supply data on physical activity, and participants were self-selected. For all three trials, the results may have been influenced by these limitations.

Vegetarian diets have been demonstrated to be advantageous in other disease states as well. This lifestyle has been used in prevention and treatment of cardiovascular disease, hypertension, cancer, osteoporosis, renal disease and dementia, diverticular disease, gallstones and rheumatoid arthritis[7]. Many of these conditions are known complications of T2DM. Contraindications for implementing a vegetarian diet may include malabsorptive diseases requiring high fat and protein intake such as Crohn's disease, B12 deficiency/pernicious anemia, or hypersensitivity diseases (i.e. Celiacs disease) in which intake is already limited. Some adverse effects may include deficiencies in protein, iron, zinc, calcium, vitamin B12 and A, n-3 fatty acids and iodine[7]. Supplementation of these nutrients may be necessary for certain individuals and should be considered with treatment.

Diabetes is not yet curable and can lead to complications of multiple organ systems if not properly managed. The numerous complications and associated disease states have a significant impact on a patient's quality of life. For this reason, abundant funding and research has been accomplished. Oral medications, such as Metformin, have made a significant impact on improving hyperglycemia and managing the disease. Major foundations like the American Diabetes Association continue to explore different research topics and new medications in the hope of better treatments[1]. Until a cure is possible, maintaining blood glucose levels, improving nutrition and exercise, and preventing complications are the symptomatic mainstay treatment regimens.

CONCLUSION

In conclusion, this systematic review demonstrates that a vegetarian diet is more effective than a conventional diabetic diet to improve quality of life in Type 2 diabetics. Not only is it effective, it is also a safe and conservative treatment option. The data collected in all of the studies showed statistical significance of improved weight related quality of life with no reported unwanted side effects. Based on the results of the studies reviewed in this analysis, a vegetarian diet should be strongly considered for implementation early in the disease process.

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