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Original Article

A quantitative, retrospective inquiry of the impact of a provider-guided low-carbohydrate, high-fat diet on adults in a wellness clinic setting

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ABSTRACT

Aims: Despite the critical status of obesity as an epidemic chronic illness in the United States contributing toward diabetic and cardiovascular disease as well as early preventable death, treatment approaches in primary care remain in conflict; providers lack evidence-based guidelines toward impactful disease management, particularly from dietary approaches. This study aimed to evaluate the impact of initiation of a 5–10% low-carbohydrate, 75–85% high-fat diet on specific clinical indicators of obesity, a metabolic disease associated with increased morbidity and mortality, at baseline and six months in an adult population.

Materials and methods: Utilizing a retrospective electronic medical record data collection protocol, one hundred patients with obesity in a wellness clinic in the Southwestern United States between 2017 and 2018 prescribed a low-carbohydrate, high-fat diet were selected via simple random sampling. Measurements of body mass index, hemoglobin A1C, and lipid levels were extracted at baseline and six months after initiation.

Results: Mean differences of each biomarker at baseline and six months were analyzed utilizing paired samples t-testing in SPSS and demonstrated statistically-significant improvement across each category. Body mass index decreased, hemoglobin A1C decreased, and each of three clinically-relevant lipid level measurements moved numerically toward normal-value ranges.

Conclusion: Data from this sample of 100 patients with obesity suggest body weight, diabetic, and cardiovascular status improvement from a low-carbohydrate, high-fat diet over six months, affording a prescriptive nutrition option for primary care providers to consider prior to or as a complement to pharmacologic management.

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1. Introduction

According to the Centers for Disease Control and Prevention (CDC) in 2018, 39.8% or 93.3 million of American adults suffer from obesity [1]. Consequentially, two of the leading obesity-related

comorbidities contributing toward, “preventable, premature death” in the nation include heart disease and type 2 diabetes [1]. Despite being on the front line in the fight against obesity, it is documented that primary care providers lack both a foundational knowledge of obesity diagnosis as a chronic illness as well as an evidence-based approach to manage it [2]. There is wide debate as to the best approach for obesity management in the primary care setting. This wellness clinic-based study sought to identify the impact of initiation of a low-carbohydrate, high-fat diet with provider counseling on adult patients with obesity and obesity-related diseases of diabetes and hyperlipidemia.

The researchers took a retrospective look at a population of adults with obesity in a wellness clinic setting in Southern New

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Mexico. The utilization of a low-carbohydrate, high-fat diet is mainstay. Each patient receives provider-guided one-on-one nutritional counseling and monthly follow-up visits, and specific clinical indicators are measured at the initial visit and at six months. The study's ultimate aim was to provide guidance in the primary care setting for dietary recommendations which are evidence-based and can help providers manage and positively impact clinical indicators of obesity.

A research question was established, as follows: In an adult outpatient wellness clinic setting, how does initiation of a low-carbohydrate, high-fat diet with provider counseling impact clinical indicators, including body mass index (BMI), hemoglobin A1C (HgA1C), and lipid level (HDL or high-density lipoprotein, triglycerides, and LDL or low-density lipoprotein) measurements at six months after initiation when compared to baseline?

2. Background

Obesity is a complex and under-diagnosed disease. It is often accompanied by comorbidities, including diabetes mellitus and hyperlipidemia (each typically managed in the primary care setting from a pharmacologic approach). Not only is hyperlipidemia named among the ten most costly diagnoses in the United States, it is directly correlated to cardiovascular disease [3]. A systematic review of the literature by Abdelaal, le Roux & Docherty (2017) revealed an association between obesity and increased morbidity and mortality [4]. The life span for individuals suffering from severe obesity with a BMI greater than 35, for example, is reduced by approximately five to 20 years [4]. The pathophysiology of obesity is still being mapped out and an understanding of this complex metabolic disease is lacking.

The recent institution of the Affordable Care Act (ACA) affected American primary care with an influx of patients seeking newly-covered and cost-free obesity screening and counseling services [5]. A gap exists in the literature, however, in an agreed-upon, evidence-based approach to obesity management, particularly when it comes to dietary approaches.

2.1. A low-carbohydrate, high-fat diet

A controversial topic in healthcare and among the public at large is the approach to treat overweight and obesity with a low-carbohydrate, high-fat diet, commonly referred to as a ketogenic diet. Foundational principles of such a diet routinely include energy consumption in the form of carbohydrates at less than 20%, fat energy intake of 50% or more, and varying energy requirements from protein [6].

Waldman, Krings, Smith, and McAllister (2017) address the conflict in presenting a common misconception of a low-carbohydrate and high-fat diet as just another way to restrict overall caloric intake [7]. Rather, there is recent evidence that supports the diet as contributing toward favorable changes which take place relative to hormone, enzyme, and mitochondrial systems [7].

2.2. Primary care nutritional counseling

Fitzpatrick and Stevens (2017) highlight weight management counseling as the preferred first-line intervention for obesity with supportive statistics of an average initial decrease in weight by eight to ten percent [5]. This change alone corresponds with significant improvement in both diabetic and cardiovascular risk [5].

It is not surprising that patients report a preference to receive obesity counseling from a primary care provider over a specialist or adjunctive team member for multiple reasons, including cost, rapport, and access [8]. The role is vital to the approach and

management of overweight and obesity [9].

3. Methodology

3.1. Setting and sample

Setting. The study took place in an outpatient clinic in the Southwestern United States which provides both non-surgical as well as surgical evaluation and treatment of adults with obesity and associated comorbidities including, but not limited to, diabetes mellitus, hypertension, high cholesterol, polycystic ovarian syndrome (PCOS) and fatigue. This study was limited to the wellness specialty and did not seek to research any aspect of the surgical approach. Treating providers included a physician board-certified in both internal and obesity medicine who serves as the medical director of the program and a nurse practitioner with greater than 15 years of experience who now focuses on wellness medicine.

Sample. The study population from which to identify participants meeting inclusion criteria existed as previously-established patients of the clinic who ranged in age between 18 and 65 years with a BMI of 30 or greater. Patients must have participated in a minimum of two visits: initial and six-month follow-up, regardless of results. Within 30 days of both the initial and six-month follow-up visits, measurements must have been obtained for BMI, HgA1C, HDL, triglycerides, and LDL values. The same lab panel was drawn on each subject, fasting, at initial and six-month follow-up visits.

Exclusion criteria were subjects 1) on anti-diabetic medication(s), 2) on cholesterol-lowering medication(s), 3) on weight-lowering medications (see Appendix A for comprehensive list of exclusion medications), 4) outside of the age range of 18–65 years, and/or 5) subjects who had undergone bariatric surgery.

3.2. Intervention: the Wellness Diet

Initial visit. Adult patients at this outpatient wellness and weight loss clinic participated in an initial provider-guided nutritional counseling visit lasting approximately 60 min in total, of which 45 min were spent in education and counseling. At this initial visit, the patient was given a 17-page nutritional guide with encouragement to bring the guide back to each monthly follow-up visit thereafter for additional education and reinforcement of topics.

The initial visit patient education focused on obesity history, an explanation of insulin resistance, introduction of a low-carbohydrate and high-fat diet food guide pyramid (See Fig. 1), the importance of hydration, the concept of tracking food and water intake, and meanings and significance of *carbohydrates*, *fats*, and *protein*. Prescription of the low-carbohydrate, high-fat diet (namely, *The Wellness Diet*, in the clinic) consisted of the following: limiting of carbohydrates to between 30 and 50 g per day, instruction to eat plenty of healthy fats, and to consume a serving of protein every four hours during waking hours.

This particular low-carb, high-fat diet or Wellness Diet. Each patient was instructed according to the following:

1. Drink one-half of body weight (in pounds) in ounces of water daily.
2. Keep total carbohydrates less than 50 g per day.
3. Eat plenty of healthy fats.
4. Consume a moderate amount of protein.
5. Avoid white foods (examples: potatoes, breads, cereals, tortillas, and grain products).
6. Avoid processed foods, fast food, and sugar-containing drinks and sodas.

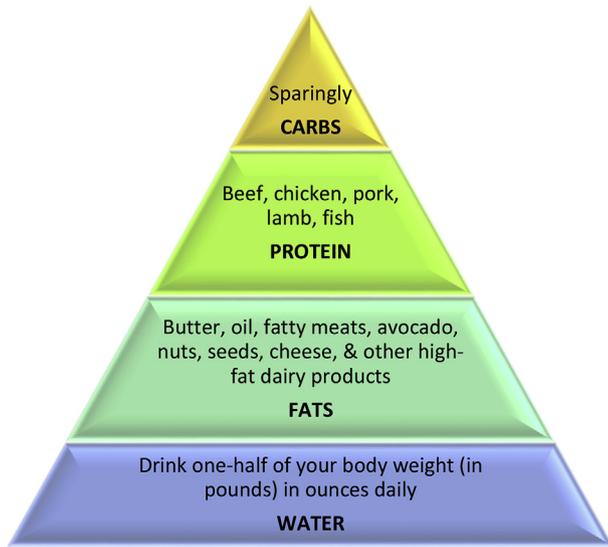


Fig. 1. Wellness diet food guide pyramid.

7. Eliminate artificial sweeteners, including sugar-free drinks and diet soda.

Patients were instructed to either track all food intake on a

device (cellular phones were highly recommended for convenience) or on paper and to be sure to bring tracking to each follow-up visit for provider-patient review. The free application, *MyFitnessPal* (myfitnesspal.com), was encouraged for ease of macronutrient tracking, particularly of and limited to carbohydrates. Providers educated patients as needed related to application download and intake entry.

Patients were encouraged to eat plentifully and often. Carbohydrates were restricted. Calories were not restricted. Recommendations were made to select foods with less than 5 g of carbohydrates per serving and focus on vegetables for this category, eliminating fruit intake. Fats in the forms of saturated and mono-unsaturated, as well as liberal use of olive and coconut oils, avocados and nuts were recommended. See [Table 1](#) for additional specific recommendations related to the prescribed diet.

Follow-up visits. Routine monthly visits were also patient-to-provider, one-on-one interactions with the majority of a 20-to-40-min visit comprised of nutritional review, further guidance and counseling. Tracking was reviewed and patients were counseled based upon intake choices. Recipes were provided to patients interested in creative options and meal planning.

3.3. Quantitative data collection

Ethical clearance. Institutional review board (IRB) as well as research site approval were attained for this study prior to any data

Table 1
The wellness diet.

Macronutrient or Dietary Requirement	Daily Quantity	Options and Recommendations
Water	Drink ½ of body weight (in lb) in oz	
Additional Beverage Options	Extra and not counted toward water intake	<ul style="list-style-type: none"> • Unsweetened almond milk • Caffeinated beverages: Limit to 1–2 servings (No flavored creamer, sugar, or artificial sweeteners) • AVOID: Milk, alcohol, sugar-free drinks, diet sodas
Healthy Fats	Eat in abundance	<ul style="list-style-type: none"> • Butter • Oils: olive, coconut, flaxseed, grape seed, hemp, walnut, avocado • Fatty meats • Avocado • Nuts & seeds (sunflower, pumpkin, flaxseed, sesame) • Olives: black, green, kalamata, Greek • Cheese and other high-fat dairy products such as heavy whipping cream, full-fat yogurt, full-fat cheese • Animal fats: real butter, ghee, beef tallow, lard, heavy cream, chicken thighs, fatty beef cuts such as rib eye or 70/30 ground beef, bacon, sausage • Other: coconut, fatty salad dressings like ranch, Caesar, and bleu cheese • AVOID: Canola or vegetable oil, margarine, shortening or Morrell lard • One serving must have <5 g of carbohydrates • Meats: beef, bison, pork, chicken, turkey, lamb, duck, fish, shellfish, eggs, nitrate-free lunch meats and sausages • Dairy: soft and hard cheeses, full-fat cottage and cream cheese, plain Greek yogurt, heavy cream • Other: natural peanut and almond butter • AVOID: Breaded foods or foods with sweet sauces such as barbeque, ketchup, or teriyaki
Protein	One serving every 4 h (waking hours only)	<ul style="list-style-type: none"> • High quality • Vegetables: Crucial & principle carbohydrate for vitamins, minerals and fiber • Minimum 3 servings per day (Example: ½ cup cooked or raw vegetables, 1 cup leafy green vegetables) • Any crunchy green vegetable can be eaten without restriction • RECOMMENDED: Fresh or frozen vegetables, such as asparagus, cabbage, green beans, lettuce, artichokes, cauliflower, chile peppers, spinach, bell peppers, cucumber, hearts of palm, squash, broccoli, celery, mushroom, kale, brussels sprouts, eggplant, onions, zucchini • AVOID: Potatoes, carrots, beets, corn, legumes (beans), root vegetables, peas
Carbohydrates	Eat sparingly, except vegetables (particularly green & leafy) 30–50 g/day	<ul style="list-style-type: none"> • HIGH FIBER • Recommended sweeteners include stevia, erythritol, monk fruit • Recommended to bake with: almond flour, coconut flour, xanthum gum • Cakes, cookies, candies, bread, pasta, rice, tortillas and cereal (including oatmeal) • High-carbohydrate foods such as fruits, some vegetables, some dairy products, processed meat products, flavored drinks, alcohol, condiments and processed foods • Artificial sweeteners • Agave nectar, honey, maple syrup
Other	RESTRICT	

collection.

Data Collection Process. The study's research data were obtained from existing medical records within the site's electronic medical record (EMR) system. A retrospective data extraction protocol was performed on-site by research team members only.

The protocol was implemented by 1) pulling of queries from the EMR database between the years of 2017 and 2018 according to aforementioned inclusion and exclusion criteria, 2) extracting of query results in order to produce a CSV (comma separated values) file of a de-identified, limited data point set which was then input into a Microsoft Excel 2010 spreadsheet file, 3) application of algorithms within Microsoft Excel 2010 in order to produce a simple random sampling and limit the resultant limited data set to a goal patient sample size of between 100 and 200 non-identifiable subjects, and finally, 4) performance of analysis of data utilizing SPSS (see Table 2).

4. Results

Mean BMI of the sample population decreased by 3.36 kg/m². Mean HgA1C decreased by 0.69%. HDL mean increased by 4.31 mg/dL. Triglycerides demonstrated the most dramatic change, a decrease in mean of 24.450 mg/dL. Finally, mean LDL levels decreased by 8 mg/dL. See Table 2: SPSS Paired Samples Statistics as well as Fig. 2 through 6.

The mean differences of each biomarker for this sample ($n = 100$) at baseline and six months after initiation of the prescribed diet were analyzed utilizing paired samples t-testing in SPSS and demonstrated statistically-significant improvement across each category. A null hypothesis of biomarker equivalence at pre- and post-intervention intervals was rejected for each of the five key health measurements with $p < 0.01$.

5. Discussion

A clear association between obesity and increased morbidity and mortality exists, therefore necessitating effective interventions in healthcare [4]. Data from this sample demonstrate body-weight-, diabetic-, and cardiovascular-status improvement from a low-carbohydrate, high-fat diet over six months. One hundred people with obesity were followed and demonstrated improvements in cardiometabolic health as evidenced by improvement in each of five key clinical markers. Body mass index trended toward a healthy value of less than 25 [10]. The change in HgA1C signifies a baseline level (6.75%) indicative of diabetes mellitus type 2 diagnosis and post-intervention level of 6.06% as a pre-diabetic state [11]. Specific to cardiovascular risk, each of three lipid level measurements improved. Evidence shows statistically-significant improvement in five key measurements of health.

The biomarkers chosen for this study are key for assessing health. BMI is a measurement of body size and takes into account one's height and weight (kg/m²). A person with a BMI >30 is considered obese and is at higher risk for hypertension, hyperlipidemia, coronary artery disease, diabetes mellitus type 2, and cardiovascular disease. Increased BMI additionally conveys risk for

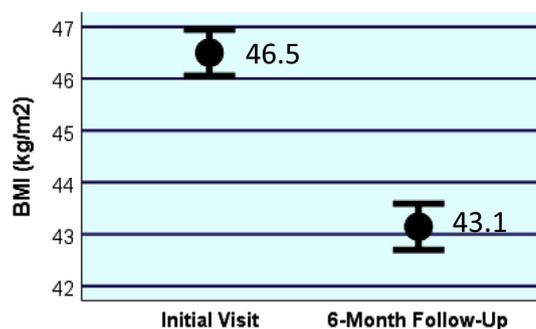


Fig. 2. BMI at baseline & 6 months.

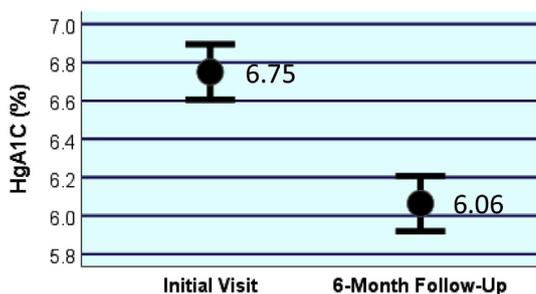


Fig. 3. HgA1C at baseline & 6 months.

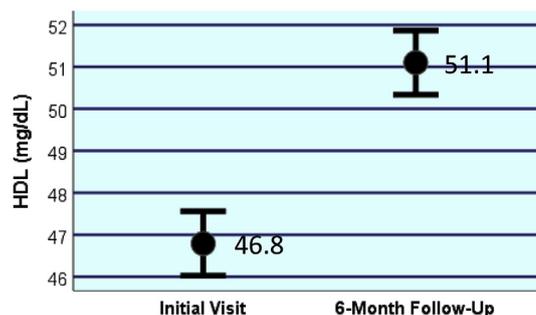


Fig. 4. HDL at baseline & 6 months.

decreased quality of life related to pain and mobility impairment [12]. Hemoglobin A1C is a measurement of the percentage of hemoglobin in the blood that has attached glucose and is a determinant of the average blood glucose level over the past three months. A healthy percentage is less than 5.7 whereas a higher value indicates a pre-diabetic or diabetic state [11].

Finally, lipid levels are broken down into subgroups, three of which were chosen for inclusion in this study as those most frequently used in medicine to predict cardiovascular risk: HDL, LDL and triglycerides. The American Heart Association recommends evaluation of triglycerides and lipoproteins to determine

Table 2

SPSS paired samples T-Tests (paired differences).

		Mean Difference	Std. Deviation	t score	p value
Pair 1	Baseline BMI 6-Month BMI	3.35600	4.49753	7.462	.000
Pair 2	Baseline A1C 6-Month A1C	0.68700%	1.45600%	4.718	.000
Pair 3	Baseline HDL 6-Month HDL	-4.310	7.735	-5.572	.000
Pair 4	Baseline Trig 6-Month Trig	24.450	36.149	6.764	.000
Pair 5	Baseline LDL 6-Month LDL	8.000	15.001	5.333	.000

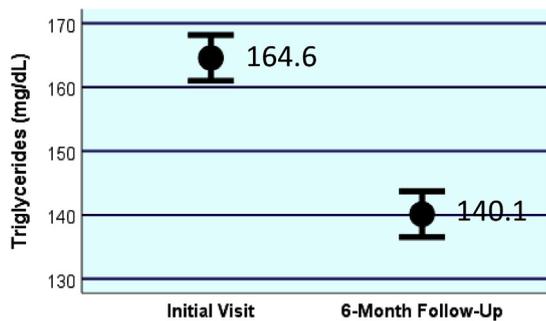


Fig. 5. Triglycerides, baseline & 6 months.

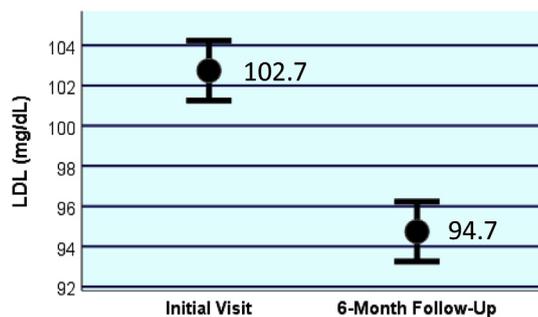


Fig. 6. LDL at baseline & 6 months.

atherosclerotic cardiovascular disease risk [13]. Measurement of these five indicators of health provides an accurate way to measure overall adult health and wellness.

This study shows a clear correlation between adherence to a low-carbohydrate, high-fat diet and a positive change in health status. The diet, combined with individual counseling and guidance, has shown statistically-significant results in treating obesity and related cardiometabolic risk factors. The diet is a suitable tool for use in the primary care setting because of its simplicity and effectiveness.

5.1. Limitations and future research considerations

Although the research conducted revealed positive outcomes for all measures, limitations did exist. Subjects on antidiabetic, cholesterol-lowering, and weight-lowering medications were excluded from the study in order to reduce potential for confounding variables toward measurement of the five clinical indicators. In the future, inclusion of populations already on pharmacologic therapy for cardiovascular disease and diabetes would be more reflective of the average primary care patient population.

This study was retrospective in nature, and therefore limited to extraction of certain data points. Future controlled and randomized prospective clinical trials may provide impactful, useful data on the effect of a low-carbohydrate, high-fat diet in higher-risk groups, including those suffering from uncontrolled diabetes and hyperlipidemia.

The sample was limited to 100 subjects studied over a six-month timeframe. A study design incorporating a larger sample size of participants and extended over a longer timeframe may lend insight into longer-term benefits as well as risks and sustainability of the diet. Ideally, researchers might afford comparison of male-to-female subjects, monitor and measure exercise habit modifications over time, and control for other concomitant measures subjects may utilize to accelerate or complement nutritional management

of obesity.

Lastly, it was clear that the amount of time patients spent one-on-one with providers was longer in duration than a typical primary care provider visit. Fiscella and McDaniel (2018) report that primary care visits average less than 20 min in duration with just five minutes spent in discussion of the chief complaint [14]. Providers must not only be consumers of research but also astute in reimbursement opportunities related to obesity management. Medicare, one of the only payers of intensive behavioral therapy for obesity, calls for ten to 15 min per visit spent in nutritional counseling to substantiate reimbursement, though the majority of primary care providers are entirely unaware of any such reimbursement [5].

6. Conclusions and recommendations

Primary care providers seek evidence-based research for the effective treatment of obesity and its comorbidities [2]. Already-“over-burdened primary care,” clinics require structured and sound, evidence-based guidelines in order to be effective [15].

In this study, a specific low-carbohydrate, high-fat diet affords a prescriptive nutrition option for primary care providers who seek to guide their patients in achieving healthy weight and improvement in both diabetes mellitus and cardiovascular clinical indicators. The diet is a teachable, uncomplicated intervention for an adult patient population looking for an alternative, non-pharmacological, non-surgical approach to obesity; the low-carbohydrate, high-fat or *Wellness Diet* is ideal for the primary care clinic setting.

Finally, there is a need for further research, particularly prospective clinical trials to determine long-term impact on such clinical indicators as measured herein and specifically in patients with uncontrolled diabetes and cardiovascular disease who remain primarily treated from a pharmacotherapeutic approach. Fitzpatrick and Stevens (2017) point to a re-inventing of US primary care in order to support true evidence-based obesity practice implementation in primary care [5].

For interested providers, the Obesity Medicine Association (OMA, 2019) and the American Board of Obesity Medicine (ABOM, 2019) maintain standards in the management of obesity [16,17]. Both entities offer obesity management certification for providers, recognizing not only clinical expertise but also a commitment to bridge the gap between its epidemic prevalence and the lacking in evidence-based approaches toward effective treatment. Physicians may sit for the diplomate exam with the American Board of Obesity Medicine (2019), and OMA (2019) offers a certificate of advanced education to nurse practitioners and physician assistants [16,17]. It is this research team's recommendation that primary care providers attain obesity management certification in order to enhance their treatment options and understanding of this complex metabolic disease.

Conflicts of interest

The authors declare no conflict of interest.

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Appendix A

The diabetic medication list for exclusion purposes according to Epocrates (2019) is the following: acarbose, Glyset, miglitol, Precose, acarbose, Symlin, pramlintide, ACTOplus met, ACTOplus met XR, pioglitazone, metformin, alogliptin, Avandamet, rosiglitazone, Fortamet, glipizide, Glucophage, Glucophage XR, Glucovance, glyburide, Glumetza, Invokamet, canagliflozin, Invokamet XR, Janumet, Janumet XR, sitagliptin, Jentadueto, linagliptin, Jentadueto XR, Kazano, alogliptin, Kombiglyze XR, saxagliptin, Metaglip, Prandi-Met, repaglinide, Riomet, Segluromet, ertugliflozin, Synjardy, empagliflozin, Synjardy XR, Xigduo XR, dapagliflozin, colesevelam, Welchol, Cycloset, bromocriptine, Glyxambi, Januvia, Juvisync, Nesina, Onglyza, Oseni, Qtern, Steglujan, Tradjenta, Adlyxin, lixisenatide, Bydureon, exenatide, Bydureon BCise, Byetta, Ozempic, semaglutide, Soliqua, insulin, insulin glargine, Tanzeum, albiglutide, Trulicity, dulaglutide, Victoza, liraglutide, Xultophy, insulin degludec, Admelog, insulin lispro, Afrezza, Apidra, insulin glulisine, Basaglar, Fiasp, insulin aspart, Humalog, insulin lispro protamine, insulin NPH, insulin regular, Humulin, Lantus, Levemir, insulin detemir, Novolin, NovoLog, insulin aspart protamine, Toujeo Max Solostar, Toujeo Solostar, Tresiba, nateglinide, Prandin, Starlix, Farxiga, Invokana, Jardiance, Steglatrol, Amaryl, glimepiride, Avandaryl, chlorpropamide, DiaBeta, Diabinese, Duetact, Glucotrol, Glucotrol XL, glyburide micronized, Glynase PresTab, Micronase, tolazamide, tolbutamide, Actos, and Avandia [18].

The dyslipidemia medication list for exclusion purposes according to Epocrates (2019) is the following (there is some cross-over between diabetic and dyslipidemia medication lists): Kynamro, mipomersen, cholestyramine, colesevelam, Colestid, colestipol, Prevalite, Questran, Questran Light, Welchol, ezetimibe, simvastatin, Liptruzet, atorvastatin, Vytorin, Zetia, Antara, fenofibrate micronized, fenofibrate, fenofibric acid, Fenoglide, Fibricor, gemfibrozil, Lipofen, Lofibra, Lipid, Tricor, Triglide, Trilipix, Advicor, niacin, lovastatin, Altoprev, Caduet, Crestor, rosuvastatin, fluvastatin, Juvisync, Lescol, Lescol XL, Lipitor, Liptruzet, Livalo, pitavastatin, Mevacor, Pravachol, pravastatin, Simcor, Zocor, Zypitamag, Juxtapid, lomitapide, vitamin B3, Niacor, Niaspan, Slo-Niacin, Lovaza, omega-3-acid ethyl esters, Vascepa, icosapent ethyl, Praluent, alirocumab, Repatha, and evolucumab [18].

Finally, two medications were identified by the Athena EMR database as anti-obesity in classification: phentermine and Contrace, and were also included in exclusion criteria.

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