

Comparative Effects of a Very Low-Calorie Ketogenic Low-Fat Diet vs. a Standard Hypocaloric Diet on Lipid Profiles in Adults with Dyslipidemia: A Randomized Controlled Trial

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ABSTRACT

Background: Dyslipidemia is known as abnormalities in the concentration of lipids in the blood. The most important are hypercholesterolemia and hypertriglyceridemia, there are other alterations, such as the decrease in HDL cholesterol. In Mexico, a study of more than 1,700 patients showed that 16.4% had cholesterol levels ≥ 240 mg/dl, 34.1% of those studied reported values between 200 – 240 mg/dl, and 32.5% had elevated triglyceride and they had not been previously diagnosed.

Objective: To compare the effect of two nutritional interventions in the regulation of blood lipid levels.

Methodology: A prospective, randomized, double-blind study, lasting 12 weeks. 88 patients were recruited, 56 assigned to VLCKLFD group and 32 to LCD group. We evaluated total weight, visceral body fat, cholesterol levels, HDL, LDL, VLDL and triglycerides.

Results: The mean weight loss for the VLCKLFD reported 12.39 ± 2.8 , while for the LCD it was 6.95 ± 1.9 kg. ($p < 0.001$). The total cholesterol in VLCKLFD group at baseline was 192.6 ± 35.7 mg/dl and at the end 170.0 ± 34.3 mg/dl., patients assigned to LCD baseline was 184.6 ± 36.1 mg/dl and at the end of the study was 166.46 ± 34.3 mg/dl. The Triglycerides in the VLCKLFD group at baseline was 161.5 ± 68.7 mg/dl and in the final determination was 94.1 ± 42.1 mg/dl., the LCD group at baseline reported 165.5 ± 100.74 mg/dl and the final 106.5 ± 57.22 mg/dl.

Conclusion: VLCKLFD is more effective at 12 weeks in reducing blood lipid levels when compared with LCD.

KEYWORDS

VLCKLFD, Dyslipidemia, Hypercholesterolemia, Hypertriglyceridemia.

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Highlights

A VLCKLFD is more effective for weight loss than LCD

VLCKLFD improves the lipid profile with a VLCKLFD, total cholesterol, LDL and VLDL are reduced but HDL levels are preserved.

(Abstract accepted for presentation at the 7th Heart in Diabetes [HID] 2023 Congress poster session in Philadelphia)

Introduction

Dyslipidemia is a term used to describe a disorder in metabolism because of an increase in blood concentration of lipids and decrease of HDL cholesterol (High Density Lipoprotein) or the increase of chylomicrons in blood [1]. The risk factors most frequently associated with the development of coronary heart disease are dyslipidemia, systemic arterial hypertension, diabetes mellitus, obesity, smoking, sedentary lifestyle and inadequate diet [2]. Clinical research done in adult population in Mexico have shown that 50.5% of the evaluated population had cholesterol values >200 mg/dl and 32.5% presented high triglyceride levels [3]. If obesity and dyslipidemia are correlated 60 to 70% of patients with obesity are patients suffering from dyslipidemia [4]

Implementing a nutritional intervention in the treatment of obesity and dyslipidemia has two relevant aspects; the first is the effect of loss weight on serum lipids and the second is the effect of different nutrients in levels of lipids. Dattilo and collaborators have published a meta-analysis evaluating the effect of loss weight with a low-calorie diet, in which the low-calorie diet showed a triglyceride low level, and the different subtypes of cholesterol began to normalize at the same time of lost weight [5]. It is a fact that in most studies on the effects of nutritional interventions on cardiovascular risk factors, they bet in the long term, however the highest weight loss is obtained during the first months, and unfortunately a large number of patients recover the lost weight, resulting that the final weight loss is relatively modest [6]. The study of different types of nutritional interventions in which the contents of macronutrients and their effect on the lipids were evaluated allow us to see that when low carbohydrate diets were compared with low fat diets, in both cases there is a reduction in triglycerides, LDL cholesterol and elevation of HDL cholesterol, and the most important is the reduction of the C-LDL with the low fat diet [7]. In another way, comparing high-fat versus low-fat diet, this originated an important lost in C- LDL, though an increase in C-HDL and decrease in triglycerides was most important with the diet rich in fat [8]. Finally, when comparing a ketogenic diet with a low-fat diet, the result showed a greater reduction in triglyceride and increase in C-HDL level. In another way with the standard ketogenic diet the level of C-LDL Increase [9].

A ketogenic diet is a nutritional intervention in which body fat has transformed as energy through the formation of ketone bodies [10]. Diverse types of ketogenic diets have been described

[11], such as the standard ketogenic diet characterized by a contribution with carbohydrates 20 to 50 g, protein 40 to 60 mg, without a limit fat established. An extremely low carbohydrates ketogenic diet (VLCKD) will indicate as a standard ketogenic diet. An adequate ketogenic diet (WFKD) means that macronutrients are fats, proteins and carbohydrates meet the proportions of the standard ketogenic diet. Therefore, provide the best opportunity for ketosis. The ketogenic diet (KD) includes a standard ketogenic diet scheme, and the principal fat content are the medium chain triglycerides (MCT) on the diet. Caloric restricted ketogenic diet is like a standard ketogenic diet, except, calories limited to a certain amount. Cyclic ketogenic diet (ERC) also known as carbohydrate recharge, implies days with a mayor ingested of carbohydrates, such as five ketogenic days followed by two days with mayor consume of carbohydrates. Directed ketogenic diet (TKD) is similar to standard ketogenic diet, except that carbohydrates are consumed around training hours. High protein ketogenic diet, this diet includes more protein than a standard ketogenic diet, with a 35 % protein proportion, 60 % fat and 5 % carbohydrates [11]. Diet line Latin America through the Zélé method, proposes one more type in which a maximum of 60 gr. of carbohydrates, 0.8 to 1.5 g of protein per kilogram of ideal weight and a maximum of 20 g of fat, which has been called normo-protein ketogenic diet low in fats or very low calories ketogenic low-fat diet (VLCKLFD).

This clinical research is based on although weight loss in a first time and then there is recovery from the lost weight, the reduction of risk factors will be evident, and the unexpected cardiovascular event rate could decrease. There are no studies in which the effect of a LCD with a VLCKLFD where blood lipid levels are measured, this double -blinding clinical trial was decided to conduct in the short term, in the Mexican population of patients with type I obesity.

Material and Methods

A double -blind randomized clinical trial was performed for 12 weeks in which the effect of a low calorie diet (LCD) and the Zélé method, which consists of a low-fat normo-protein ketogenic diet (VLCKLFD) on body weight, Visceral fat, plasma levels of total cholesterol, C-HDL, C-LDL, C-VLDL and triglycerides. (This paper is part of the trial code NCT06275347).

Eighty-eight patients from Mexico City were included who responded to an open invitation on social networks and who accepted through an informed consent signature to participate in the study (Ethics Committee on Combioetic Research-30-CEI-001-20170221).

Inclusion criteria: adults between 18 and 60 years of age, men, and women, with an BMI between 30 and 34.9 kg/m², without a history of endocrine diseases related to lipid metabolism or who were under treatment with Hypolipemians.

Randomization and blinding: Patients were randomized blindly, to one of the study groups, the feeding scheme was directly

distributed by the food production plant, the segment broke until all patients finished week twelve of study. The distribution was following fifty-six patients to the VLCKLFD group and thirty-two patients to the LCD group.

Interventions

The VLCKD was divided into three stages according to stipulated in the Z     method, with a duration of 4 weeks per stage. The first stage, the frank ketosis that consisted of a very low caloric ketogenic diet (between 650 and 730 kcal /day) in 5 times of feeding during the day, with average protein contribution of 0.8 to 1.2 g /kg of weight Ideal per day, 20 g/day of lipids based on essential fatty acids and less than 60 g/day of absorbable carbohydrates complemented with low glycemic index vegetables. Patients received throughout the nutritional intervention vitamin and oligoelements (sodium chloride, magnesium oxide, calcium carbonate) to complete the daily nutritional requirements recommended for this type of diet. The second stage or mixed ketosis: make a substitution of commercial preparations by proteins of animal origin (meat, fish, eggs, etc.), which increased from 100 to 150 kcal/day, without the patient abandoning the state of ketosis, and finally the integral and metabolic stabilization phase: during this stage the patient followed a hypocaloric diet adapted to its measured energy expenditure, which varied between 1300 and 2250 kcal/day, with a distribution of macronutrients of 50% carbohydrates, 25 % proteins and 25% fat, according to the study of Diogenes [12].

In the LCD group were treated with a 25% nutritional caloric was below the basal metabolic expense, this was measured by multifrequency or calculated bioelectric impedance according to FAO/WHO/ONU formula [13]. The caloric contribution was between 1,200 and 1,500 kcal per day with a macronutrient distribution of 50 % carbohydrate, 25 % protein and 25 % fat, according to the study of Diogenes [12] contributed by products that will simulate those of the frank and mixed ketosis stage were the same as those of the integral phase.

Both groups received nutritional, psycho-emotional advice and physical activity weekly, as well as clinical evaluation, in addition to measurement of body composition through multifrequency bioelectric impers. At the beginning of the project, at week 6 and at the end of the project, plasma cholesterol, triglycerides, LDL, HDL and VLDL levels were determined.

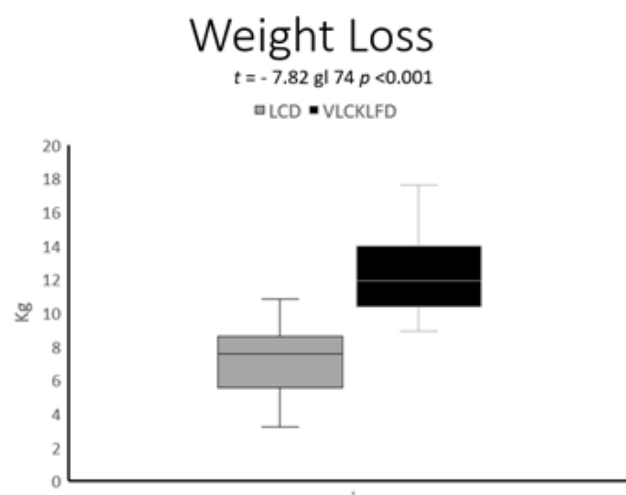
The statistics data collected to Excel program, then those were analyzed with SPSS V 21.0, descriptive statistics performed in percentages and frequencies, T student test was used for comparison of means in quantitative variables, the Pearson X2 test, Haenszel or Kruskal-Walli's test for qualitative variables comparison. Multivariable logistic regression was performed to determine independent predictors and effect of the VLCKD diet.

Results

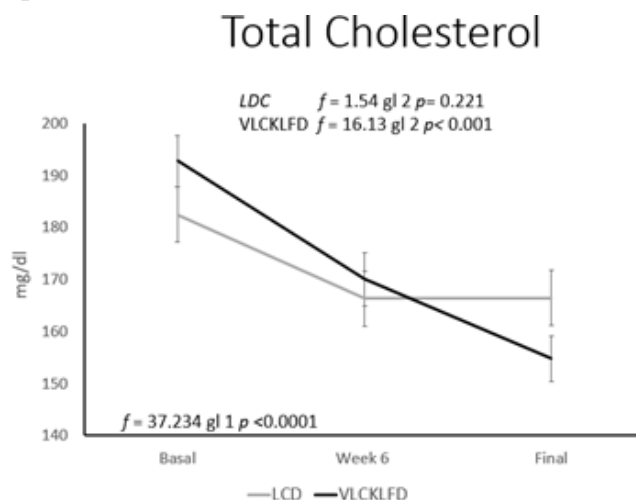
A total of eighty-eight patients were recruited, only seventy-six

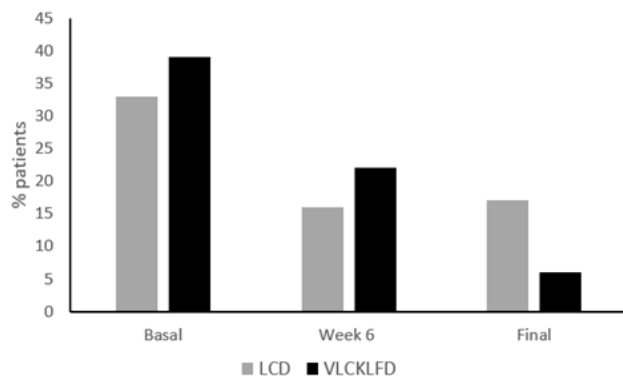
patients concluded the 12 weeks of treatment, fifty-two patients included to VLCKLFD group and twenty-four were assigned to LCD group. Patients who received LCD diet the mean basal weigh was 81.9 ± 8.0 kg, and for VLCKLFD were 86.9 ± 8.8 kg. A weight loss 12.39 ± 2.8 kg in the VLCKLFD group and 6.95 ± 1.9 kg to patients LCD group ($t = -7.82$ gl 74 $p < 0.001$) (Graph 1). 8 patients included in LCD group and 18 VLCKLFD group began the study a cholesterol >200 mg/dl. The mean cholesterol for the LDC group was basal 182.44 ± 7.1 mg/dl, at 6 weeks 166.46 ± 8.53 mg/dl and at 12 weeks 166.32 ± 7.55 mg/dl ($f = 1.54$ gl 2 $p = 0.221$). The mean cholesterol for the VLCKLFD group was basal 192.71 ± 4.93 mg/dl, at 6 weeks 170.04 ± 5.12 mg/dl and at 12 weeks 154.78 ± 4.39 mg/dl ($f = 16.13$ gl 2 $p < 0.001$) (Graph 2). Taking this analysis to the percentage of patients with cholesterol levels above 200 mg. The LCD group started with a rate of 33.3% of patients with cholesterol >200 mg/dl and ended 16.7%, while patients who received VLCKLFD started 33.8% with a cholesterol >200 mg/dl and ended with 6.1% of patients with levels with levels with levels of total cholesterol >200 mg/dl ($X^2 = 13.05$ gl 1 $p < 0.0001$) (Graph 3).

Graph 1



Graph 2

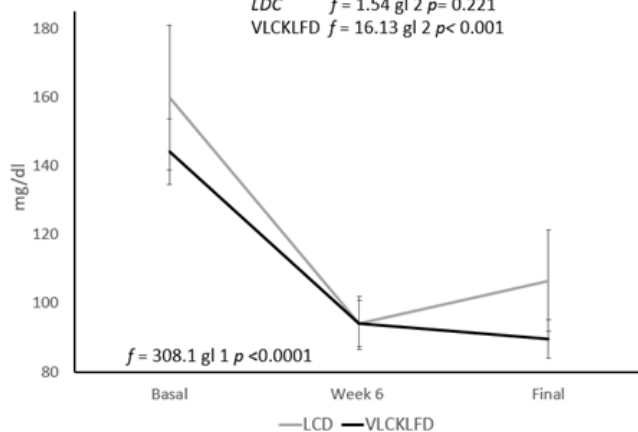


Graph 3**Clinical Evolution of Hypercholesterolemia** $\chi^2 = 13.05$ gl 1 $p < 0.0001$ 

Regarding the triglycerides >150mg/dl the LCD group at the beginning of the study found in 40 % of the patients, with a mean value 165.5 ± 96.6 mg/dl. Patients in the VLCKLFD group triglycerides >150mg was in 45% of patients with a mean value 161.5 ± 68.7 mg/dl (χ^2 0.109 gl 1 $p = 0.741$). The behavior of triglyceride measurements in mg/dl for patients in LCD group were mean basal 165.5 ± 96.6 , at 6 weeks 94.9 ± 38.1 and in the end 106.5 ± 57.2 mg/dl. Patients with VLCKLFD group have a mean basal level 161.5 ± 68.7 , 90.7 ± 40.9 and 94.1 ± 42.1 respectively ($f = 308.1$ gl 1 $p < 0.0001$) (Graph 4).

Graph 4**Triglycerides**

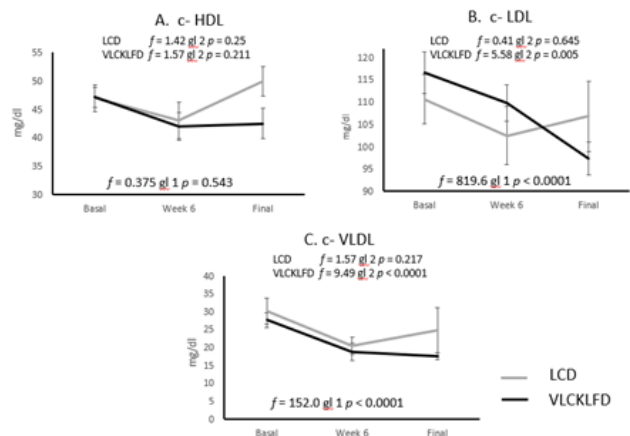
LCD $f = 1.54$ gl 2 $p = 0.221$
 VLCKLFD $f = 16.13$ gl 2 $p < 0.001$



In relation to c-HDL, patients treated with LCD presented non-significant modifications of the levels always, with a mean basal c-HDL 46.9 ± 10.9 , decreased to 43.1 ± 15.0 and subsequently increase to 49.8 ± 10.4 ($f = 1.42$ gl 2 $p = 0.25$). Patients in VLCKLFD group with a mean basal level 47.14 ± 12.3 , at 6 weeks 41.99 ± 16.9 and at 12 weeks 42.46 ± 17.83 mg/dl. ($f = 1.57$ gl 2 $p = 0.211$) (Graph 5 Panel A).

The comparative analysis of low density cholesterol behavior

(c-LDL) show similar behavior the general pattern of cholesterol, in patients who received a low-caloric diet the basal mean was 110.64 ± 26.3 mg/dl, which to the 6 weeks of treatment descended to 102.42 ± 31.2 mg/dl to finish the 12 -week period in 106.79 ± 30.7 ($f = 0.41$ gl 2 $P = 0.645$); Patients who received the VLCKLFD started with 116.53 ± 32.6 mg/dl, at 6 weeks 109.81 ± 27.7 and ended at 97.36 ± 25.4 which showed an intragroup difference $f = 5.58$ gl 2 $p = 0.005$, Intra tests - Group also showed a highly significant difference $f = 819.6$ gl 1 $P < 0.0001$ (Graph 5 Panel B). Finally, in patients with LCD group C-VLDL mean 30.08 ± 16.89 mg/dl, at 6 weeks 20.52 ± 10.44 and at the end 24.75 ± 23.46 mg/dl ($f = 1.57$ gl 2 $p = 0.217$), in the VLCKLFD group the mean level 27.59 ± 13.18 , at 6 weeks 18.72 ± 14.13 and at 12 weeks 17.50 ± 6.87 mg/dl ($f = 9.49$ gl 2 $p < 0.0001$), difference between both groups of $f = 152.0$ gl 1 $p < 0.0001$ (Graph 5 Panel C).

Graph 5**High, Low and Very Low Density Lipoproteins****Discussion**

The weight loss in patients treated with the Zél  method (VLCKLFD with clinical, nutritional, psychological and physical activity supervision) was almost double that subject to a LCD group treated (nutritional, psychological and physical activity supervision). The patients of the VLCKLFD group presented a progressive and continuous decrease and cholesterol mean was 192.7 to 154.7 mg/dl and lost 30.3 mg/dl below the initial value. Cholesterol in the patients from the LCD total mean cholesterol decrease 182.4 to 166.46 mg/dl in the middle of the study without continuing the decrease in the last 6 weeks, mean decrease of 15.8 mg/dl. The decrease occurred eminently due to the influence of treatment on LDL and VLDL levels, which in patients with a low -calorie diet was modified from 110.6 to 106.5 mg/dl and for VLCKLFD of 116.53 to 97.36 that is 19.17 mg/dl. And the VLDL in the LCD group of 30.08 to 24.75, 5.33 mg/dl, and in the VLCKLFD group it was 27.59 to 17.5 or 10 mg/dl.

Regarding, patients with the LCD started with a mean C-HDL 46.9 and ended in 49.8mg/dl presenting an increase of 3.1 mg/dl and while patients treated with VLCKLFD started with a HDL mean

47.14 and at 12 weeks 42.4 mg/dl, no significant decrease of 4.7 mg/dl. In relation to triglyceride levels, patients treated with LCD have a decrease of 59 mg/dl versus patients with VLCKLFD of 161.5 to 94.1 mg/dl a loss of 67.4 mg/dl. About loss weight there is a decrease in triglycerides, c-LDL, and ideally an increase in c-HDL levels, even though we must recognize that the response can vary individually in patients according to the nutrients consumed. In a recent meta-analysis of thirty randomized control trial with 2434 participants, reported a weight loss with a decrease of 4 mg/dl in triglycerides, a decrease of 1.28 mg/dl in c-LDL, and increase 0.46 mg/dl in c-HDL per 1 kg of weight loss [14]. In this clinical research patients treated with a VLCKLFD had a decrease in total cholesterol of 2.44 mg/dl per 1 kg of weight loss, in LCD 2.27 mg/kg group c-LDL decreased 0.59 mg/dl per 1 kg with LCD and 1.58 mg/dl per 1 kg of weight loss. In relation to c-VLDL Patients in LCD presented a decrease of 0.76 mg/dl for each kg of lost weight and patients with VLCKLFD 0.80 mg/dl per lost kg.

The decrease in triglycerides was 8.01 mg/dl in patients LCD group and 5.43 in patients with VLCKLFD group. In existing studies, refer the classical ketogenic diet is more efficient than the hypocaloric diets in the control of triglycerides with a moderate elevation of HDL levels, with a moderate elevation of total cholesterol and c-LDL [15] and in obese patients without dyslipidemias or other metabolic anomalies, a low-calorie diet still produces a decrease in triglycerides without changes in c-HDL levels [16]. In this study in which the nutritional intervention evaluated a diet with 0.8 to 1.2 g protein per kg of ideal weight with a content of 50 g carbohydrates and 20g. The c-HDL decrease by the fat consumed in all supplements in vitamins and mineral.

Conclusion

Conclude that there are no other studies related to a low ketogenic diet in fat, that this type of diet allows us C-HDL. In patients who used the Zélé method, there were reduction in absolute figures twice the mg/dl of total cholesterol, LDL and VLDL versus patients treated with a low -calorie diet. Lipid profile correction can be in relationship to efficiency in a VLCKLFD in weight loss.

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