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Research Article

Inulin Effect on Weight Loss and Associated Parameters with the Development of Cardiovascular Disease in Obese Dyslipidemic Subjects

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Abstract

Obesity is one of the most concerning public health problems and it has been associated with the development of cardiovascular diseases (CVD). A healthy diet has demonstrated to improve weight loss and blood lipids but also the inclusion of functional foods could be used. Inulin, a non-digestible carbohydrate, has been shown that can promote weight loss and improve the lipid profile associated with CVD. The aim of the present study was to examine the effect of the addition of inulin to a moderate carbohydrate diet on weight loss and parameters associated with CVD. Sixteen obese dyslipidemic subjects were distributed in a double-blind, crossover trial for 18 weeks with two eight-week treatment periods (9gr of inulin/day or 9gr of dextrose/day as placebo), separated by a two-week washout period. Anthropometric and lipid profile were collected at the beginning and at the end of each treatment. Both treatments significantly improve weight loss and others anthropometric parameters (BMI, body fat and waist and hip circumferences) without statistical difference between them. Inulin significantly increased HDL cholesterol and tend to reduce triglycerides. Non-significant changes were observed on total and LDL cholesterol. In conclusion, we can suggest that the addition to inulin and a moderate carbohydrate diet tend to reduce cardiovascular risk by improving anthropometrics parameters and increasing HDL cholesterol.

Keywords: Inulin; Moderate carbohydrate diet; Obesity; Cardiovascular diseases

Abbreviations

OB: Obesity; MCD: Moderate Carbohydrate Diet; TC: Total Cholesterol; HDL-C: High Density Lipoprotein Cholesterol; LDL-C: Low Density Lipoprotein Cholesterol; TAG: Triglycerides; BMI: Body Mass Index.

Introduction

Obesity (OB) is a chronic disease that has been defined as abnormal or excessive fat accumulation that may impair health [1]. OB is strongly related with dyslipidemia and high blood pressure, which represents important risk factors to develop cardiovascular diseases (CVD), the first cause of registered deaths in Mexico [2]. The increase on the OB rates that has been reported in the late years and itsstrongly relation with CVD and others *chronic non-communicable diseases* are the reason why OB has been recognized as one of the biggest challenges of public health [3].

CVDs are the result of the sum of multiple risk factors, that include non-modifiable risk factors such sex or age and some modifiable risk factors like obesity, dyslipidemia, high blood pleasure, diabetes mellitus, smoking or alcoholism which are susceptible to therapeutic intervention. Particularly in dyslipidemia, increases in TAG, TC and LDL-C or decreases in HDL-C are the lipid profile associated with CVD [4].

Even if dietary interventions have proved to have some beneficial effects on weight loss and cardiovascular risk factors [5], nowadays, the interest has been focus in new strategies, like the inclusion of some functional foods [6].

Inulin is a non-digestible carbohydrate, which belongs to a class of carbohydrates known as fructans. Because of its chemical structure, these molecules cannot be hydrolyzed by human digestive enzymes, due to this characteristic, inulin can be recognized as a functional food that act like fiber and prebiotic [7]. Particularly in obese dyslipidemic subjects with cardiovascular risk factors, inulin appears to be useful. Some studies have suggested that inulin can promote weight loss [8,9] and improve blood lipids [10,11], important medical targets in this population.

The aim of the present study was to evaluate the effect of the addition of inulin to a moderate carbohydrate diet (MCD) on weight loss and some parameters associated with the development of CVD in obese dyslipidemic subjects.

Materials and Methods

The study was designed as a double blind, crossover trial to analyze inulin effect. Each participant was followed by 18 weeks with two eight-week treatment periods separated by a two-week washout period. Participants consumed 9gr of inulin during 8 weeks and 9gr of dextrose as placebo during other 8 weeks as a control phase. Dextrose was chosen as the placebo because of it similar characteristics to inulin

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like similar taste and ability to dissolve in water. Dextrosehas similar energy value to inulin and is fully digestible which mean that is not available for fermentation. Some participants started with inulin and some of them with placebo, the sequence of treatments was randomly assigned. Inulin and placebo were supplied to the participants in the form of white powder in individual sachets with 3 gr each one with the same organoleptic characteristics and they were instructed to add 1 sachet into a glass of water with their breakfast, lunch and dinner.

The inclusion criteria for participants of this study were being obese, determined by BMI >30 kg/m^2, between 20-60 years old that had an altered lipid profile but not being under drug therapy. The exclusion criteria were subjects that modified their diet or lose weight in the last 3 months, subjects under an alternative treatment or women that were pregnant during the study.

Anthropometric measurements were taken at the begging and at the end of each period using standard methodologies. Height was measured with a Stadiometer model 214, Seca (Germany). Weight and body fat percentage were measured using a BC-418 Body Composition Analyzer, Tanita (Japan). Waist and hip circumferences were measured using a flexible-metal tape measure model W606PM, Lufkin (EEUU).

Blood samples were taken at the beginning and at the end of each period. Samples were collected after 12 hours overnight fast into blood collection tubes with polymer gel to separate serum from clot after centrifuging the samples. Lipid profile (CT, HDL-C and TAG) was measured in serum using enzymatic colorimetric methods with RANDOX reagents (United Kingdom) and LDL-C was calculated using Friedewald equation (c-LDL-C=TC-TAG/5-HDL-C) [12].

Cardiovascular risk was evaluated at the beginning and at the end of each period with the cardiovascular disease (10-year risk) equation from the Framingham heart study methodology, specifically the one that uses lipid profile. This value is expressed in the probability of suffering a cardiovascular event in the next 10 years, there are no references value for population, vary about subject condition but it is useful to analyze general cardiovascular health improvement [13,14].

The double-blind was revealed at the end of the study. The study was approved by the ethics committee of the Academic Unit of Nutrition and Gastronomy Sciences of the Autonomous University of Sinaloa (Mexico) and all volunteers gave informed consent at the beginning of the study.

Diet

To evaluate inulin effect, participants use the same diet during control and experimental phase. A hypocaloric MCD was designed by a nutritionists group with a 40% of energy from carbohydrates, 30% from fat and 30% from protein; diets also had fiber content in a range between 25-30 g/day, and the glycemic index was controlled, Preference was given to low and moderate glycemic index food. Energy was calculated in an individualized way using Mifflin St Jeor equation with adjusted body weight to promote weight loss.

Statistical analysis

Statistical analysis was performed using SPSS 2013, version 22. Data are presented as mean and standard deviation (mean±SD). To analyze placebo and inulin effect were compared baseline and final values of each treatment. The differences of baseline and final values of both treatments were used to analyze if there were differences between placebo and inulin effect. The normality of the variables was analyzed by Shapiro Wilk test, those variables that demonstrated normal distribution was analyzed with student t-test (TC, HDL-C, LDL-C, TAG and cardiovascular risk)and those with abnormal distributionwith the Wilcoxon test (Body weight, BMI, waist and hip circumferences). A p value < 0.05 was considered statistically significant for all analyses.

Results and Discussion

The present study was designed to analyze inulin effect on weight loss and some parameters associated with the development of CDV when subjects wereon a MCD, with the aim of proposing an effective non-pharmacological treatment that improves cardiovascular health of the vulnerable population. A total of 16 participants completed the present trial and were considered in the statistical analysis of the results. Only 25 volunteers met the inclusion criteria and started the protocol, 6 of them did not complete the study for personal reasons not related with the protocol and 3 subjects did not follow the protocol indications, therefore there were not considered in the statistical analysis. Sample size was not calculated prior to study but several studies were reviewed and since this was a double-blind crossover trial, a sample size of 16 subjects were considered adequate to conduct this protocol, that is very similar to trials that have been reported in the literature with 15 or fewer subjects.

Anthropometrics variables

After 8 weeks, there were significant reductions in anthropometrics variables with both treatments. MCD demonstrated to have a significant effect in body weight, BMI, body fat, waist and hip circumferences, but when we analyzed differences between inulin and placebo periods significant differences were not observed between treatments (Table 1). Parnell and Reimer in 2009 analyzed inulin effect on weight loss, they designed a study with healthy subjects consuming 21 g of inulin/day/12 weeks and they found that subjects

Table 1: Inulin effect on anthropometrics variables.

	Inulin			Placebo		
	Baseline	Week 8	difference	Baseline	Week 8	difference
Weight (kg)	99.3±18.4	95.7±18.8*	-3.6	98.9±19.4	95.2±18.8*	-3.7
BMI (Kg/m^2)	36.01±5.4	34.66±5.5*	-1.35	35.85±6	34.5±5.5*	-1.35
BF (%)	41.1±6.9	39.4±8.2*	-1.7	40.45±8.5	39.4±8.2*	-1.05
Waist(cm)	112.2±13.7	107.9±15.6*	-4.3	112±15.53	107.8±15.49*	-4.2
Hip (cm)	118.4±11.8	115.46±12.6*	-2.94	118±12	114.5±12.8*	-3.5

Data are presented as the mean±SD. Significantly different from baseline. *Significantly different from placebo effect. BMI: Body mass index; BF: Body fat.

Table 2: Inulin effect on lipid profile.

	Inulin			Placebo		
	Baseline	**Week 8**	**Difference**	**Baseline**	**Week 8**	**difference**
TC	216.4±52.5	216±42	-0.4	205.4±44.85	196.5±42*	-8.9
LDL-C	141.1±47.3	143.8±45.2	2.7	136.3±43.4	122.3±43.2*	-14
HDL-C	44.16±16.11	46.3±12.3*	+2.14**	45.3±12.1	44.1±12.3	-1.25
TAG	156.1±67	129.8±42*	-26.3	150.6±45.5	149.9±45.3	-0.7

Data are presented as the mean±SD. Significantly different from baseline. *Significantly different from placebo effect. **TC: Total Cholesterol; LDL-C: Low Density Lipoprotein Cholesterol; HDL-C: High Density Lipoprotein Cholesterol; TAG: Triglycerides.

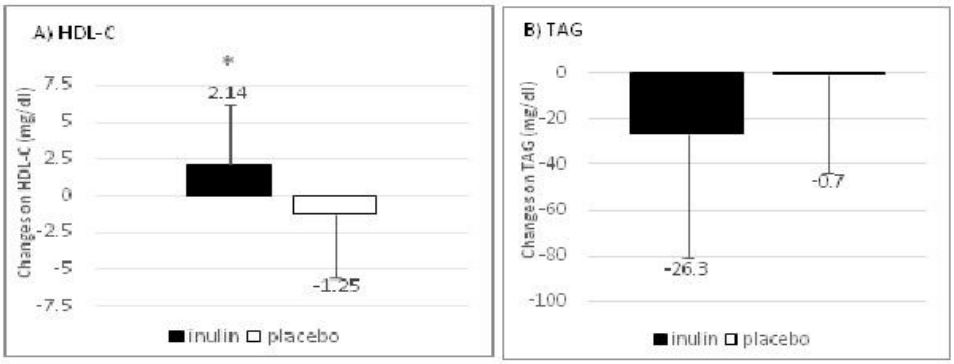

Figure 1: Mean changes from baseline after 8 weeks of treatments on HDL-C and TAG.
Data are presented as the mean of changes after 8 weeks of treatment. Significantly different from placebo changes (*). HDL-C: High Density Lipoprotein Cholesterol; TAG: Triglycerides.

that consumed inulin lost weight significantly compared with subjects with placebo, whom even gained some weight [15]. In the present study weight loss was observed in both periods with similar behavior and this could be explained because our subjects were on a controlled hypocaloric diet, in contrast with Parnell and Reimer trial, that let their subjects without any dietary intervention. Inulin can promote weight loss in a long term when subjects are in a not controlled diet by increasing satiety and consequently decreasing energy intake like it has been reported [9,16], but in a hypocaloric diet that control energy intake, not additional effect on weight loss has been observed with inulin consumption, in fact, a recent study analyzed this behavior and support our results, 44 subjects were randomly assigned in a 18 weeks trial with 30 gr of inulin or 30gr of cellulose per day, in the first 9 weeks subjects were in a dietary intervention to lose weight, and the last 9 weeks they were asked to maintain the weight they had lost without any further dietary support. In the first 9 weeks, a 5% weight loss was observed in both groups but in the next 9 weeks with just supplementation, weight loss was significantly higher in inulin group compared to the cellulose group (2.3±0.1% *vs.* 0.6±0.4%) [17].

Parnell and Reimerstudy demonstrated that by using 21 gr of inulin per day, body weight significantly changed compared to their control, however, in our study we used 9 gr per day, therefore we can assume that the dose matters in terms of body weight loss and inulin consumption. In the same study, Parnell and Reimer reported that 21 gr of inulin consumption per day presented some gastrointestinal negative side effects. Considering that, our research group decided to use a dose that could have a positive change in the lipid profile associated with the prevention of CVD and to avoid discomforting side effects [15,18,19].

Lipid profile

Biochemical parameters were also an important element in the present study since some studies have suggested that inulin improve blood lipids, nevertheless, results are still conflicting due to heterogeneity in studies design, diet and amount of inulin used [11].

In dyslipidemic subjects some trials have shown promising conclusions, but not all the published literature has been consistent and is necessary to discuss some results. Jackson, et al. designed a trial using 10 gr of inulin/day/8 weeks that showed the ability of inulin to decrease TAG concentrations [20] one of its most consistent results [21]. All the studies that do not get a significant result in lipid profile suggest that increasing the amount of inulin used and the time of the intervention, better results could be obtained, but this is not what has been really published. In a trial with 16 gr of inulin/day/12 weeks (higher dose and larger intervention) not changes were observed in lipid profile [22] but surprisingly trials with a lower amount of inulin during a shorter trial (compared with Jackson, et al. trial) better results were obtained, decreasing TC, LDL-C and TAG [11]. This evidence shows why the results about inulin potential to improve lipid profile cannot be conclusive.

The results of inulin effect on lipid profile of the present trial are shown in Table 2. In our study, during inulin period a significant increase in HDL-C was observed after 8 weeks but not in the placebo period. Inulin increased HDL-C a 4.8% while placebo decreased a 2.6%. When differences between the effect of placebo and inulin in HDL-C were compared, a statistically significant different was observed ($p<0.05$) (Figure 1A). HDL-C also increased during inulin period but decreased in placebo period no matter the sequence of treatments assigned, reason why the effect can be attributed to inulin

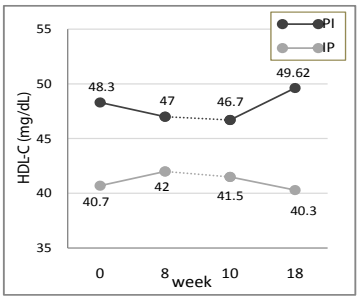

Figure 2: HDL-C behavior by treatments sequences.
Data are presented as the mean. PI: first placebo then inulin. IP: first inulin then placebo. Dotted lines: Wash-out period.

supplementation and not to diet changes (Figure 2). Despite of there are a lot of studies that include HDL-C in its analyzed parameters just a few of them have reported similar results in healthy [23] and dyslipidemic subjects [24].

The most consistent results in the published literature are the ability of inulin to decrease TAG concentrations [21]. In the present study, during placebo period, changes in TAG concentrations were not observed but in inulin period TAG decreased a 17% (Table 2), even if this results were not statistically significant comparing inulin and placebo effect (Figure 1B), clinically, the changes observed with inulin could represent an important non-pharmacological tool in subjects with hypertriglyceridemia. In previous literature more significant results have been obtained, but diet that we used could be the factor that explains this result. Previous trials did not modify the diet of the participants [20] or even used high carbohydrate diets [25], condition that have been considered a factor that increase endogenous synthesis of TAG and inulin potential to decrease blood lipids it have been attributed a by blocking endogenous synthesis via short chain fatty acids by gut microbiota fermentation of inulin [20,25]. The composition of our diet that was moderated in carbohydrates and with low glycemic index foods, due to this, when using a diet that does not stimulate the endogenous synthesis of triglycerides the same results cannot been observed.

Even if some trials have reported inulin ability to decrease TC and LDL-C [10,11], not changes were observed in inulin period, in fact, both were significantly reduced with placebo but not with inulin, although the differences between treatments were not statistically significant. These are unexpected results because even it have been proposed some theoretical mechanisms of how inulin could improve these parameters , like its ability to act like soluble fiber and prebiotic [26], however this results were consistent with previous studies [22].

Cardiovascular risk

Cardiovascular risk was analyzed with the Framingham hearth study's methodology and showed a non-statistically significant reduction.Cardiovascular disease risk decreases from 7.32±5.1 to 6.23±3 and from 6.79±4.4 to 5.98±3.5 after 8 weeks with inulin and placebo, respectively. No significant changes were observed neither comparing baseline and final measurements of treatments nor comparing differences between them. This could be explained because some of the variables used to this methodology are non-modifiable risk factors like age, sex or drug therapy for hypertension [13]. The modifiable variables that are considerate are TC, HDL-C and systolic blood pressure, in which little improvements was observed in our subjects. However, weight loss and waist circumference reduction are not considered in this methodology, and these variables have demonstrated to be important targets to reduce CVD risk [27]. Success in obesity and cardiovascular diseases treatment is not easily reached and any metabolic improvement should be positively considered, no matter how small it was, because it has been proved that could represents a big impact for health [28].

Conclusion

For all the above we can conclude that a MCD represents an able nutritional intervention to reduce anthropometrics parameters related with CVD, but inulin supplementation does not generate additional effects to it. Inulin does not change LDL-C and TC but improves HDL-C and TAG concentration, important therapeutic goals on this population, nevertheless cardiovascular risk equally decreases with inulin and placebo.

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