Research Article

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Herbal Medicine: Open Access
ISSN 2472-0151

2017
Vol. 3 No. 1: 3

DOI: 10.21767/2472-0151.100023

Effect of Oat Forthe Treatment of Hypertriglyceridemia; Randomized Controlled Trial

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Citation: Hernández-Pérez F, Tlatelpa EC, Cazares EBM. Effect of Oat Forthe Treatment of Hypertriglyceridemia; Randomized Controlled Trial. Herb Med. 2017, 3:1.

Abstract

Introduction: In Mexico, the cardiovascular diseases constitute the first cause of death, from which 56% are from Coronary artery disease, having a very stretch relation with Dyslipidemia.

Objective: To determine if the oat extract is effective, safe, and well tolerated for the treatment of hypertriglyceridemia.

Material and methods: Randomized clinical trial, in volunteers with serum triglyceride levels of 200 mg/dL or more. Two treatments were distributed; 40 gr. of oat, compared to 40 gr. of flaxseed in the morning fasting in both groups, with a follow-up of four weeks with baseline measurements and final lipid profile with diet control and exercise.

Analysis of the results: Student's t-test, was used for the comparison of means, the Wilcoxon signed-rank test was used for skewed populations. Fisher's exact test was used to compare percentages. It was considered a statistical significance of $p<0.05$.

Results: Thirty volunteers were studied, 15 for the oat group and 15 for the flaxseed group; two individuals from the oat group were eliminated due to the presence of minor adverse effects, leaving only 13 volunteers.

No significant differences were found when comparing the oat group against the flaxseed group in the serum triglyceride levels ($p=0.247$ and 0.436 at the beginning and the end, respectively), no significant difference was found in the serum triglyceride levels in the oat group (initial 298.80 ± 114.60 against 307.20 ± 126.95 at the end, $p=0.798$), similar results were found in the flaxseed group (initial 351.61 ± 155.17 against 303.23 ± 117.40 at the end, $p=0.152$). I t was found that in both groups there was significant reduction in weight.

Conclusions: the use of oats and flaxseeds were ineffective in lowering the serum triglyceride levels.

Keywords: Oats; Flaxseeds; Hypertriglyceridaemia; Hypercholesterolaemia

Received: March 01, 2017; **Accepted:** March 13, 2017; **Published:** March 18, 2017

Introduction

Dyslipidemia has become a growing public health problem. The overall prevalence of hypercholesterolemia in Mexico is high (23.6%), however there are studies in health institutions in which the prevalence is higher —between 35 and 48%. Where we can see part of the magnitude of the problem, which increases if other factors associated with overweight, hypertension, diabetes and smoking are added [1-3].

As a general rule, it is considered that hyperlipoproteinemia exists when plasma cholesterol is > 5.2 mmol/L (200 mg/dL) or the level of triglycerides exceeds 2.2 mmol/L (150 mg/dL). It has been found that controlling the levels of serum lipid stabilizes the atheromatous plaque inducing regression of the lesion and slowing down the development of vascular obstruction, with beneficial effects in reducing vascular events as well as related mortality; namely, persistent vascular lesions match with sustained high triglycerides levels [4-8].

It is not yet entirely clear whether hypertriglyceridemia causes heart disease or is merely a marker of it. The fact is that hypertriglyceridemia is closely correlated with the presence of two atherogenic elements which are: the presence of small, dense c-LDL particles and the reduction of the component HDL2 of cholesterol-HDL [9].

There are three interconnected pathways of metabolism of lipoproteins: one is the transportation of diet or exogenous fat; the second is the hepatic transport or endogenous fat; and the last one is the transport of cholesterol. These pathways are separate but the alteration of one affects the function of the other. A diet low in total fat and saturated fat in patients with coronary heart disease decreases the amount of exogenous lipoproteins and chylomicron particles, but both may be altering the liver metabolism as well as its transport, which require more than diet to modify the mortality [10-12].

Within the dietary management of the disease dietary fiber is included as a major component and within these the oatmeal stands out, which is a very common and inexpensive cereal. This cereal is high in soluble fiber and produces decreased levels of total cholesterol with a cardiovascular benefit, with an improved digestion and metabolism as well [13]. The hypocholesterolemic effect of soluble fibers appears to be related to its viscosity; thus, the fibers that form low viscosity aqueous solutions have demonstrated their ability to reduce cholesterol levels. Apparently, the compound to which is attributed the effect of decreasing serum levels of triglycerides are the beta-glucans [14-21].

The main mechanism of action of beta-glucan is due to its ability to bind bile acids, which not only increases the removal of cholesterol via feces, but its concentration in the blood is reduced, because the liver has to use it to make more bile salts that are essential for digestion. Further, by forming a physical barrier and cover the walls of the intestine it also reduces the absorption of dietary cholesterol. It also decreases hepatic synthesis of cholesterol, which contributes to lower the levels of (cholesterol) in the blood. Others suggest that the mechanism is due to increased viscosity of the bolus in the small intestine because the fiber leads to the formation of an impenetrable layer together with water in the mucosa which can act as a mechanical barrier that reduces absorption of nutrients including glucose and fatty acids [22].

In 2010 a study was conducted by Ruiz et al. where the use of oats in rats decreased cholesterol by 52.47% and triglycerides by 50.20%; however, human trails with oats have shown a decrease in cholesterol levels but so far, its effect on triglycerides is doubtful, although well tolerated without significant adverse reactions [23-30].

Materials and Methods

A randomized clinical trial was conducted, using nonprobabilistic sampling to test the efficacy, safety and tolerability of oats. Two groups were integrated: group 1 which received 40 grams of oats* and group 2 received 40 grams of flaxseed**; both groups received it milled, in fasting, dissolved in 250 ml of water, for 30 days in the mornings.

Both treatments were prepared by nutrition staff and administered to the volunteers who came to the consulting room of nutrition and weight control of the General Hospital of Zone no. 47 (HGZ 47, in Spanish) during the period from August 1 to November 30, 2014.

In all volunteers, basal serum levels of triglycerides, total cholesterol, HDL and LDL were measured at baseline and 30 days to assess efficacy of both treatments. Serum transaminases, bilirubin, urea and creatinine levels were also measured to assess the safety of both treatments.

The selection criteria were: both sexes aged between 18 and 50 years, with serum triglyceride levels equal to or greater than 200 mg/dl, which were not under professional medical or dietary treatment to lower lipid levels. All signed informed consent.

It was considered effective if serum triglyceride levels fell 16% or more of their baseline, success was also considered if cholesterol and LDL levels decreased 16% or more.

* Oats: Oat flakes, Kosland brand; manually crushed, 50% dietary fiber.

** Flaxseed: flaxseed flakes, Flax seed brand; manually crushed, 50% dietary fiber.

It was accepted as safe for both treatments if basal liver function had a maximum increase of 20% from the high levels considered normal. Confounding variables were controlled as is the diet and the intensity of physical activity.

Statistical Analysis

To calculate the sample size and for the randomization method, EPIDAT 3.1 statistical software was used.

The variable categories were compared using Fisher's exact test, given the sample size. Student t test was used to compare means between groups but to compare the effectiveness of treatments it was found that both groups had a skewed distribution so the Wilcoxon rank test was used for related tests. It was considered at $p \leq 0.05$ as statistically significant.

Results

Thirty volunteers were studied, 15 in group 1 (oats) and 15 in group 2 (flaxseed), the predominant gender was male with a total of 21 patients and 9 female patients, with an average age of 34 years: 19 (63%) had a history of smoking, 17 (56.6%) with a history of hypertriglyceridemia, and only 8 (26.6%) with hypercholesterolemia as background. The 63% of volunteers were overweight or obese in some degree.

The average of serum triglyceride levels was 326.8 mg/dL at baseline and 283.10 mg/dL at the end, while the levels of cholesterol were 209.00 mg/dL at baseline and 194.07 mg/dL at the end.

Of the initial 30 volunteers, 2 patients in group 2 (flaxseed) had an adverse reaction characterized by abdominal pain, bowel sounds and mild diarrhea persisting for more than three days so the withdrawal of both patients from the study was necessary **(Figure 1).**

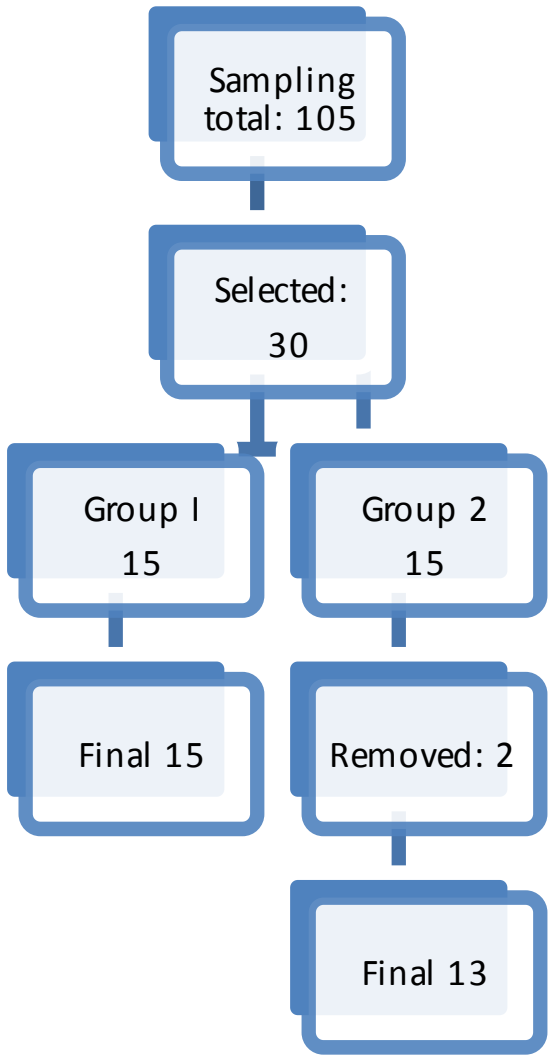

Figure 1 Sample selection.

In the inferential analysis group 1 to group 2 were compared, no significant differences between the two groups in terms of general features were found. Age and gender were similar, as well as background; only patients in group 1 (oats) had more years of being hypertensive patients (p=0.040) **(Tables 1 and 2).**

Efficiency

When comparing the averages of initial and end lipids among the oat group of against the flaxseed group no significant differences were found; also, when treatment alone was compared, no significant difference between before and after treatment with oats nor flaxseed, considering that they were not effective **(Tables 3 and 4).**

Security

Both treatments were very safe as the liver and kidney constants were unchanged at the beginning or end of the study **(Tables 5 and 6)**. It was only found that the final urea levels in the oat group was significantly higher (p=0.041) but in all cases without clinical significance since despite the differences, these remained within normal parameters.

Table 1 Comparison of general characteristics among the group of oats and flaxseed group.

Background	Oats	Flaxseed	p*
Age (years)	36.76 +/- 8.54	36.60 +/- 5.88	0.064
Weight (kg)	85.20 +/- 18.40	89.76 +/- 13.80	0.113
SBP (mmHg)	110.00 +/- 8.45	110.67 +/- 7.03	0.864
DBP (mmHg)	74.00 +/- 7.35	72.67 +/- 4.57	0.019
BMI	31.42 +/- 5.47	32.26 +/- 5.13	0.352
Years of diabetes	0.27 +/-1.03	0.53 +/-2.06	0.344
Years of hypertension	0.77 +/-0.25	0.0 +/-000	0.040

Table 2 Comparison of history among the group of oats and flaxseed group.

Background	Oats (n)	Flaxseed (n)	p*
Gender			
Male	9	12	0.213
Female	6	3	
History of hypercholesterolemia			
Yes	3	5	0.341
NO	12	10	
History of hypertriglyceridaemia			
Yes	8	9	0.500
NO	7	6	
History of Smoking			
Yes	7	13	0.064
NO	8	3	
Degree of obesity			
Normal	3	1	0.362
Overweight	4	3	
Obesity	8	9	
Severe obesity	0	2	

* Fisher's exact test

Confounding variables diet and exercise were monitored. In the case of the exercises there were no significant differences since in both cases it was low-impact exercise, unchanged during the study. For the degree of obesity both groups were similar, with no significant difference (p = 0.362) **(Table 7)**, likewise the average Kcal amount consumed by the volunteer was similar (2786.20 ± 970.01 Kcal from group 1 (oats) against 2762.00 ± 1052.64 kcal of group 2 (flaxseed) with p = 0.948). However, it was found that in both groups there was a significantly reduction in weight **(Tables 8 and 9)**.

Discussion

In the present study, the use of oats and flaxseeds to lower triglyceride levels were not effective, so you should accept the null hypothesis. It is likely that the sample size is influenced decisively, since triglyceride levels of the flaxseed group fell by almost 15% from their original levels, and if this trend continued -with an increase of volunteers. We would have obtained more encouraging results.

On the other hand, it's worth pointing out that in both groups there was significant reduction in weight, without a strict diet or exercise routine. Also, both treatments were well tolerated and

Table 3 Comparison of lipid levels at the beginning and end of treatment oatmeal.

Profile	Before Mean (SD) medium	After Mean (SD) medium	p*
Triglycerides mg/dL	298.80 +/-114.60269	307.20 +/-126.95304	0.798
Cholesterol mg/dL	205.20 +/-37.28209.00	204.27 +/-28.40209.00	0.798
LDL mg/dL	104.08 +/-24.82111.00	110.00 +/-26.83105.00	0.712
HDL mg/dL	44.80 +/-9.0943.00	43.80 +/-8.2742.00	0.674

* Test for paired samples ranges of Wilcoxon

Table 4 Comparison of lipid levels at the beginning and end with the treatment of flaxseed.

Profile	Before Mean (SD) medium	After Mean (SD) medium	P*
Triglycerides mg/dL	351.62 +/- 155.17282.00	303.23 +/-117.40289.00	0.152
Cholesterol mg/dL	215.85 +/-39.85204.00	200.62 +/- 32.87193.00	0.234
LDL mg/dL	101.23 +/-34.2393.00	106.62 +/-27.47103.00	0.944
HDL mg/dL	37.86 +/-6.4637.50	39.92 +/-5.5642.00	0.588

* Test for paired samples ranges of Wilcoxon

Table 5 Comparison of levels of renal and liver function at the beginning and end, with oat.

Profile	Before Mean (SD) medium	After Mean (SD) medium	p*
Direct bilirubin mg/dl	0.16 +/- 0.08 0.16	0.15 +/-0.070.14	0.281
ALT mU/ml	21.40 +/-6.820	21.40 +/-7.122	0.907
Urea mg/dL	28.46 +/-4.6627.80	28.66 +/-5.1130	0.925
Glucose mg/dl	123.53 +/-76.69100	143.47 +/-157.35108	0.865

*Test for paired samples ranges of Wilcoxon

Table 6 Comparison of levels of liver and kidney function at the beginning and end with flaxseed.

Profile	Before Mean (SD) medium	After Mean (SD) medium	p*
Direct bilirubin mg/dl	0.17 +/- 0.06 0.18	0.23 +/-0.20 0.19	0.460
ALT mU/ml	29.31 +/-10.04 26	25.08 +/-6.9 23	0.154
Urea mg/dL	28.98 +/-6.61 30	30.01 +/-8.78 27.90	0.657
Glucose mg/dl	117.69 +/-59.20 95	117.92 +/-57.83 100	0.674

* Test for paired samples ranges of Wilcoxon

Table 7 Distribution of patients according to their weight.

		Treatment		Total
		Treatment with oat	Treatment with flaxseed	
Degree of Obesity	Normal	3	1	4
	Over weight	4	3	7
	Obesity	8	9	17
	Severe obesity	0	2	2
Total		15	15	30

Table 8 Effect on weight with oats.

	Antes Media +/- DE Mediana	Después Media +/- DE Mediana	p*
Weight (kg)	85.29 +/-18.40 83.20	84.42 +/-17.86 83.7	0.007
BMI	31.42 +/-5.47 31.49	31.15 +/-5.32 31.56	0.006

* Test for paired samples combined ranges of Wilcoxon

Table 9 Effect on weight with flaxseed.

	Before Mean +/- SD Medium	After Mean +/- SD Medium	p*
Weight (kg)	89.76 +/-13.80 90.50	89.46 +/-13.60 90.00	**0.043**
BMI	32.26 +/-5.1 32.31	31.37 +/-5.74 31.73	**0.020**

* Test for paired samples combined ranges of Wilcoxon

safe so that only 2 volunteer's flaxseed group had to suspend the treatment for less serious gastrointestinal complaints in which there were no complications following their suspension. They were safe as no any alteration of the liver or renal function so they can be administered without substantial risk found.

So far, the results of other studies on the use of oatmeal in reducing serum triglyceride levels have been poor; while studies in rats were promising, they were, however, frankly disappointing in humans. Nevertheless, natural fibers both oats and flaxseed should continue being recommended as part of the management strategy for patients with risk factors and to a healthy diet without forgetting its effect on weight and the bowel habits.

Despite the results and explanations, we believe that we must continue with more research on the use of oats and other natural fibers in different doses and times, as with a larger sample size because compared to drugs already established for management of dyslipidemia, the natural fibers are much cheaper and with poor side effects and also can be used even in the absence of cardiovascular risk factors.

Conclusions

The oral use of oats is safe and well tolerated but was ineffective for lowering serum triglyceride levels; similarly, the use of flaxseed in volunteers with hypertriglyceridaemia wasn't effective either. However, it was found that in both treatments there was a significantly weight loss.

Acknowledgements

We appreciate the participation of relevant form to:

- Maria Margarita Flores Castillo, Nutritionist, General Hospital No. 47
- Francisco Hernández Balderas, Translation Assistant.

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