

BioAlberic: an alternative for hypercholesterolemia?

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Competing interests

The authors L. Castelo, C. Guardado and J. A. Ramírez are members of the research group that develops the BioAlberic program in Cuba

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ABSTRACT

Introduction: Despite the progress made in the diagnosis and treatment of dyslipidemias, therapeutic goals are often not reached due to noncompliance of medical indications by some patients or to the presence of adverse reactions to lipid lowering drugs. The use of the BioAlberic method can be another therapeutic alternative.

Objective: To assess the effectiveness of the method in the treatment of hypercholesterolemia.

Method: A controlled, randomized, open-label pilot study was designed. The sample was composed of 60 patients with hypercholesterolemia. Patients were divided into three groups of 20 each: group I treated with coltrice 1, Group II treated with coltrice 2 and group III to whom 20 mg of atorvastatin were administered. Treatment consisted of the oral administration of the BioAlberic product, used in drinking water over a period of 90 days, with a monthly monitoring. At the beginning of the research the serum levels of cholesterol, triglycerides, glutamic pyruvic transaminase and oxaloacetic, uric acid, creatinine, and glucose were determined. Total plasma cholesterol and triglycerides were assessed monthly for three months, and levels at the beginning and end of the research were compared.

Results: Cholesterol was normalized in 12 patients with the use of coltrice (between 9.6 and 6.02 mmol / L), 11 reached borderline levels (from 10.43 to 5.9 mmol / L) and there was no response in 17.

Conclusions: Administration of coltrice could be another therapeutic option in the treatment of hypercholesterolemia.

Key words: BioAlberic, Coltrice, Dyslipidemia, Hypercholesterolemia

BioAlberic ¿Una alternativa para la hipercolesterolemia?

RESUMEN

Introducción: A pesar de los avances alcanzados en el diagnóstico y tratamiento de las dislipidemias, en muchas ocasiones no se consiguen las metas terapéuticas por incumplimiento de las indicaciones médicas en algunos de los pacientes o por la presencia de reacciones adversas a los fármacos hipolipemiantes. El empleo del método BioAlberic puede ser otra alternativa terapéutica.

Objetivo: Evaluar la eficacia del método en el tratamiento de la hipercolesterolemia.

Método: Se diseñó un estudio piloto controlado, aleatorizado y abierto. La muestra quedó integrada por 60 pacientes con hipercolesterolemia. Los pacientes se dividieron en tres grupos de 20 cada uno: grupo I tratados con coltríce 1, grupo II tratados con coltríce 2 y un grupo III a los que se les administró 20 mg de atorvastatina. El tratamiento consistió en la administración del producto BioAlberic por vía oral, usada en el agua de beber en un período de 90 días, con un seguimiento mensual. Al inicio de la investigación se determinaron los niveles séricos de colesterol, triglicéridos, transaminasas glutámico-pirúvica y oxalacética, ácido úrico, creatinina y glucemia. El colesterol total plasmático y los triglicéridos se evaluaron mensualmente durante los tres meses, y se compararon los niveles del inicio y el final del estudio.

Resultados: Se normalizó el colesterol en 12 pacientes con el uso del coltríce (desde 9,6 hasta 6,02 mmol/L), 11 alcanzaron niveles limítrofes (desde 10,43 hasta 5,9 mmol/L) y en 17 no hubo respuesta.

Conclusiones: La administración de coltríce podría ser otra opción terapéutica en el tratamiento de la hipercolesterolemia.

Palabras clave: BioAlberic, Coltríce, Dislipidemias, Hipercolesterolemia

INTRODUCTION

Dyslipidemias constitute a health problem worldwide. They are characterized by changes in the concentration of plasma lipids¹. Cumulative researches –basic, epidemiological and clinical– have established a close relationship between increased cholesterol levels and increased risk of presentation of cardio and cerebrovascular disease^{1,2}.

Atherosclerosis is an inevitable process with age, but appropriate measures and interventions that allow us to avoid or at least delay its deleterious consequences¹⁻³ can be taken. Treatment of dyslipidemia includes pharmacological and non-pharmacological measures. Statins are considered the first line of treatment because they produce a marked reduction of cholesterol by inhibiting the enzyme HMG-CoA reductase (hydroxymethylglutaryl-coenzyme A)²⁻³. These drugs also have pleiotropic effects as they improve endothelial function, independently of their effects on plasma lipids^{3,4}.

Research shows that the risk of hepatotoxicity with statins is low. However, adverse effects such as: abdominal pain, flatulence, constipation, diarrhea, nausea, vomiting, dyspepsia, elevated transaminases, toxic hepatitis and cholestatic jaundice, paresthesias, hypoesthesia, headache, myopathies characterized by arthralgia, pain and muscle weakness associated with increased creatine phosphokinase, among others^{3,4} are described. In clinical practice, many patients using statins report symptoms and interrupt treatment.

In the search for solutions to the aforementioned

problems the application of an economic and environmentally friendly, non-invasive, easy to apply and available alternative with no adverse effects was considered. The BioAlberic method, in constant development, is based on the vibratory nature of living organisms, and chemical and natural substances that are manifested in the form of ultraweak electromagnetic waves existing in nature. This method allows to capture, process and record these oscillations in different vehicles, such as water and other liquids, oils, paper and fabrics that are therapeutically used in the control, recovery or eradication of several diseases^{5,6}.

The mechanism of action of the products made by the BioAlberic method lies in the interaction of the electromagnetic spectrum existing in the electromagnetic fields of all living organisms. A physiological response as a result of this interaction enables the therapeutic action⁵⁻⁷.

In our country, BioAlberic® is a registered trademark⁵ with different products being tested, among which is coltrice that is prepared in water medium. The objective of this research was to assess the effectiveness of this therapeutic modality in the treatment of patients with hypercholesterolemia, given the demonstrated effectiveness in research with domestic dogs⁷.

METHOD

A controlled, randomized, open-label pilot study was performed in patients with primary hypercholesterolemia, who visited the Lipid Department of the

Diabetes Care Center, at the National Institute of Endocrinology.

Patients who met the inclusion criteria (high cholesterol levels) in the period between September 2010 and September 2011 were selected. A medical history for data collection was made. The sample was divided, by the simple random method, into three groups: 20 patients in the groups I and II, and 17 in the third. Group I was treated with the product coltrice 1; group II, with coltrice 2; and group III, with atorvastatin, 20 mg daily.

The variables studied were age, sex, skin color, body mass index, smoking, habitual alcohol consumption, and personal medical history of diabetes mellitus, hypertension, ischemic heart disease, cerebrovascular disease, obesity and dyslipidemia.

Laboratory tests

Complementary tests were indicated at the clinical biochemistry laboratory and determinations of cholesterol, triglycerides, glucose, creatinine, uric acid, glutamic oxaloacetic and pyruvic transaminase were performed at baseline. Subsequently, cholesterol and triglycerides levels were monthly checked, and at the end of the research (90 days of treatment) transaminases were repeated. Determination of total cholesterol was carried out by use of the cholesterol oxidase/peroxidase enzymatic method⁸ and triglycerides by an enzymatic method, according to Schettler and Nüssel⁹.

The following physiological levels of total cholesterol were established: desired value < 5.2 mmol/L (< 200 mg /dL), limit value between 5.2 - 6.1 mmol/L (200 - 239 mg /dL), elevated \geq 6.2 mmol/L (\geq 240 mg/dL). As secondary endpoint, triglycerides that are considered normal were determined in figures < 1.7 mmol/L (< 150 mg / dL)¹.

Treatment

Once diagnosis of hypercholesterolemia is confirmed, treatment with coltrice product in water medium (5 ml ampoules) was initiated. The content of the ampoule was diluted in a bottle of drinking water of 1.5 liters and a liter per day was administered for a period of 90 days.

Statistical Analysis

For the analysis of results the statistical package SPSS version 11.5 was used, simple statistics were calculated and a significance level of p 0.05 was used.

RESULTS

When evaluating the results of cholesterol at the beginning and end of the study (**Table**), 12 patients [6 (30.0 %) in groups I and II], normalized figures of this parameter with coltrice product, 12 who had high levels [5 (25.0 %) in group I and 7 (35.0 %) in group II] modified them to borderline values, and in 16 patients, values did not change, and even values above the initial figures were detected. In group III or control, consisting of 17 patients, 12 (70.6%) normalized cholesterol, one (5.9%) presented borderline values and 4 (23.5%) did not change cholesterol levels in blood despite treatment with atorvastatin.

Triglyceride levels were not taken into account because they were considered as secondary endpoint. Furthermore not all patients included in the study had high triglycerides at the beginning of the research. It is worth noting that some patients, who did not normalize cholesterol, did normalized triglyceride levels. In this case we can cite 25 patients with hypertriglyceridemia at the beginning of the research, of which 17 normalized triglyceride levels (from 22.0 to 2.30 mmol/L) after 90 days of treatment ended.

DISCUSSION

The results of this research show that the use of coltrice in the population studied allowed 12 patients to normalize plasma cholesterol levels. In 12, high figures were reduced to borderline values for a total of 24 patients (42.1%). We should note that some patients who at the beginning of the study also had high

Tabla. Result of the behavior of cholesterol levels at the end of the research.

Cholesterol behavior	Group I (n=20)		Group II (n=20)		Group III (n=17)	
	Nº	%	Nº	%	Nº	%
Normal	6	30,0	6	30,0	12	70,6
Borderline	5	25,0	7	35,0	1	5,9
No changes	9	45,0	7	35,0	4	23,5
Total	20	100	20	100	17	100

triglycerides levels could eventually normalize them. This is one of the first studies in patients with hypercholesterolemia in which the BioAlberic method is used. There are no other publications with which to compare our results.

Coltrice is considered a promising method for the treatment of patients with hypercholesterolemia, as it is affordable, easy to use and adverse reactions were not observed. These preliminary results are encouraging and open new horizons in the study of the theme and in the therapeutic options for lipid disorders

CONCLUSIONS

Although the use of coltrice, a BioAlberic product, was effective in a low percentage of patients with hypercholesterolemia, it could be a therapeutic option for those who present adverse reactions to statins.

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RECOMMENDATIONS

The research provided us with data to elaborate new hypotheses and further enhance the efficacy of coltrice product obtained from BioAlberic by uniting several electromagnetic information of drugs and natural products for the treatment of dyslipidemias, which should hypothetically improve the effectiveness of a new product.

LIMITATIONS

In dyslipidemias research it is important to determine the complete lipid profile, which was not possible due to lack of resources and only total cholesterol was determined.

REFERENCES

1. Nasiff Hadad A, Pérez Pérez LM. Primer Consenso Nacional de Dislipoproteinemias: Guía para la prevención, detección, diagnóstico y tratamiento. Rev Cubana Endocrinol [Internet]. 2006 [citado 2013 May 12];17(Supl Especial):[aprox. 41 p.]. Disponible en: http://www.bvs.sld.cu/revistas/end/vol17_4_06/END01406.htm
2. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. Circulation. 2002;106(25):3143-421.
3. Girotra S, Murarka S, Migrino RQ. Plaque regression and improved clinical outcomes following statin treatment in atherosclerosis. Panminerva Med. 2012;54(2):71-81.
4. Vasudevan AR, Hamirani YS, Jones PH. Safety of statins: effects on muscle and the liver. Cleve Clin J Med. 2005;72(11):990-3, 996-1001.
5. Ramírez JA. El método BioAlberic: origen, desarrollo y aplicación en el control de los factores de riesgo cardiovascular. CorSalud [Internet]. 2013 [citado 2013 May 10];5(2):150-4. Disponible en: <http://bvs.sld.cu/revistas/cors/pdf/2013/v5n2a13/es/bioalberic-des.pdf>
6. Ramírez JA, Velázquez H. Empleo de la acupuntura y la auriculopuntura en la recuperación funcional de paciente intervenido por gonartrosis bilateral. XII Congreso Cubano de Reumatología; 12-15 Dic 2007. La Habana: CIMEQ; 2007.
7. Hugues B, González D, Ramírez JA, Álvarez A, Olano R, Pérez L, et al. Utilidad del método BioAlberic en el tratamiento de las hiperlipidemias y la obesidad en caninos domésticos. CorSalud [Internet]. 2013 [citado 2013 May 10];5(2):212-6. Disponible en: <http://bvs.sld.cu/revistas/cors/pdf/2013/v5n2a13/es/bioalberic-lipidos.pdf>
8. Sandoval MH, Barrón HJ, Loli RA, Salazar YV. Precisión en la determinación de glucosa, colesterol y triglicéridos séricos, en laboratorios clínicos de Lima, Perú. An Fac Med. 2012;73(3):233-8.
9. Schettler G, Nüssel E. Triglycerides liquicolor GPO-PAP. Arb Med Loz Med Präy Med. 1975;10:25.