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Nutrition and Metabolism: An Open Access

Volpe R, et al. Nutr Metab Open Acc: NMOA-103.

DOI:10.29011/NMOA-103.100003

Case Report

Hypercholesterolemia: Nutraceutical Treatment, an Alternative to No-Therapy

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Citation: Volpe R, Patti MC, Tommasino R, Vellucci A (2018) Hypercholesterolemia: Nutraceutical treatment, an Alternative to No Therapy. Nutr Metab Open Acc: NMOA-103. DOI:10.29011/NMOA-103.100003

Received Date: 19 June, 2018; **Accepted Date:** 11 July, 2018; **Published Date:** 16 July, 2018

Case Report

Atherosclerotic cardiovascular diseases can be largely prevented, and since Low-density Lipoprotein Cholesterol (LDL-C) is the lipid component with the greatest atherogenic effect, treatment of hypercholesterolemia is essential for effective cardiovascular prevention [1].

Case Description

MC, woman, aged 58 years, postal clerk, leading a sedentary life style, never-smoker. Menopause at age 53.

Family History

Father with hypercholesterolemia, non-smoker, died of Myocardial Infarction (MI) at the age of 69, (first MI at the age of 52). One sister, aged 56 years, overweight, and with high levels of Total Cholesterol (TC) (about 280mg/dL) and triglycerides (about 300mg/dL). Two sons, aged 31 and 28 years old; the younger always having high cholesterol, with a current lipid profile showing a TC of 243mg/dL and a LDL-C of 169mg/dL. Hence, positive family history of hypercholesterolemia and combined hyper-lipidaemia, as well as premature cardiovascular disease.

Personal History

Hypercholesterolemia was identified during the first pregnancy. In 2015, due to a significant increase in TC levels (from 241 to 273 mg/dL) and a LDL-C of 185mg/dL, the patient was referred by her primary care physician to the Lipid Clinic of the "Umberto I" Hospital of Rome "La Sapienza" University, for a suspected diagnosis of Familial Hypercholesterolemia (FH) (Achilles tendon xanthomas and corneal arcus on physical examination).

Diagnosis was confirmed using the Dutch Lipid Score with the patient reporting a score of 9 [1]. In addition, a color Doppler ultrasound of the carotids vessels revealed an Intima-Media Thickness (IMT) of 1.5mm in the right carotid bifurcation. This imaging finding confirmed the cumulative damage associated with elevated LDL-C levels, which is typical of individuals with FH [1,2].

The patient was also post-menopausal, overweight (having height of 166cm and weight of 76kg; calculated Body Mass Index (BMI) 27.5). The liver was palpable one finger's breadth below the right costal margin, with evidence of hepatic steatosis (fatty liver) at hepatobiliary ultrasonography. In addition, the patient had been diagnosed with reflux esophagitis.

Discussion

Despite a low-fat, low-calorie diet, accompanied by moderate regular exercise (brisk walking, stationary cycling) monitored through the S-Health app, which resulted in a modest weight loss (72.3kg; BMI 26.3), hypercholesterolemia was still present: TC 256mg/dL, LDL-C 178mg/dL. Although the treatment of hypercholesterolemia cannot be separated from a low-fat diet (including reduced saturated fat intake), it is not always possible to achieve the recommended LDL-C treatment goals with the diet alone [1].

The patient was started on atorvastatin 10mg daily (in accordance with Note 13 of the Italian Medicines Agency (AIFA)), resulting in a moderate reduction in TC (189mg/dL) and LDL-C

(109mg/dL) levels. Since the patient was not at-goal, the dose of atorvastatin was up-titrated to 20mg. This resulted in a further decrease in TC and LDL-C levels (161mg/dL and 84mg/dL, respectively), so the treatment goal was achieved!

In the following months, however, there was a minor increase in Creatine Kinase (CK) (324mg/dL versus upper normal limit of 190mg/dL), which slightly improved at the follow-up visit (287mg/dL), although the patient reported a (variable) sensation of tightening in the calves. Afterwards, she spontaneously stopped the treatment, but a subsequent lipid profile showed elevated TC and LDL-C levels (251mg/dL and 169mg/dL, respectively). Despite this, she did not want to restart statin therapy, not even in combination with ezetimibe, because of concerns about side effects.

Statins are the standard of care for lowering cholesterol, and serum cholesterol can be reduced by up to 50% depending on the type and dose of statin used [3]. The reduction of cholesterol levels over time (obviously with a continuous, long-term treatment) [4] is associated with a significant decrease in cardiovascular events and mortality and also in all-cause mortality, as well as a slower progression, or even regression, of atherosclerotic lesions [5]. However, these drugs can occasionally cause elevations in transaminase levels and, more importantly, in CK levels with the potential for side effects such as myalgia and muscle weakness that may rarely lead to true myopathy or rhabdomyolysis; these reactions can often result in interruption or discontinuation of cholesterol-lowering therapy [6]. This contributes to the fact that, in Italy, the current status of diagnosis and control of hypercholesterolemia, although improved over time, is still insufficient and inadequate (Table 1) [7].

	Men	Women
Not aware	39.2	42.1
Aware, not treated	32.8	37.3
Not well treated	4	3.4
Well treated	24	17.2

Table 1: Control status (%) of hypercholesterolemia in Italy. Men and women, aged 35-74 years [7].

	TC	LDL-C	HDL-C	Triglycerides
Baseline	273	185	53	177
Low-fat, Low-calorie Diet	256	178	49	143
Atorvastatin 10mg/day	189	109	54	131
Atorvastatin 20mg/day	161	84	51	128
Treatment Discontinuation	251	169	51	156
Colesia Oral Gel	192	108	54	148

Table 2: Serum lipid measurements at baseline and after different cholesterol-lowering treatments (all values are expressed in mg/dL).

Hypercholesterolemic adults with medium-to-low Cardiovascular (CV) risk
Hypercholesterolemic children-adolescents with family history of premature CV disease
Hypercholesterolemic adults intolerant to drugs (or who are afraid of the side effects of drugs)

Table 3: Potential indications for non-pharmacological treatment of hypercholesterolemia in primary prevention [9].

The patient was referred to a Lipidologist who started a treatment with a nutraceutical ("Colesia oral gel", 1 stick daily), with the following components: Phytosterols (400mg), Monacolin K derived by the mycotic fermentation of yeast rice from Monascus purpureus (5mg), and Annurcomplex (800mg) containing the antioxidant procyanidins, with this formulation, has been obtained a reduction in TC and LDL-C: 192mg/dL and 108mg/dL, respectively (Table 2). Moreover, transaminases, CK, and blood glucose were normal.

Conclusion

Therefore, in primary prevention patients with moderately elevated lipid levels and/or those with side effects of statins, it is possible to implement a nutraceutical-based treatment with substances that have been shown to lower blood cholesterol levels in several clinical trials, as phytosterols or dietary fibers (both acting by reducing intestinal absorption of cholesterol), or fermented red rice, which contains Monacolin K (equivalent to lovastatin), an agent that inhibits hepatic cholesterol synthesis [8]. Overall, the cholesterol-lowering efficacy of nutraceuticals ranges from 10% for phytosterols and dietary fibber's up to more than 20-25 % for monacolin K [9]. Accordingly, these substances, used separately, or better in combination, can be an effective strategy to help reduce cardiovascular risk in hypercholesterolemic patients who, having discontinued or abandoned statin therapy, are no longer adequately protected [9]. Furthermore, the rationale of treatment with nutraceuticals is also to provide effective preventive coverage even to those individuals who, although not at high risk, are nevertheless at risk (Table 3) [9].

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