



Nutraceuticals Food Supplements and Cholesterol Level Control

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Short Communication

It should be made a clear distinguisho between dietary supplements and nutraceuticals. There is lack of information on the definition and use of food matrices, functional foods, probiotics, herbal products, and food derived products which claim beneficial health effect but is often not supported by scientific data. On the opposite, nutraceuticals efficacy must be supported by clinical evidences. Increasing interest in nutraceuticals, dietary supplements, functional foods, etc., it is related to the growing awareness that the use of drugs may have undesirable side effects that may compromise or limit a long-term use [1].

A nutraceuticals is a food or part of a food, concentrated and administered in the appropriate pharmaceutical form, which provides clinically verified health benefits. Unfortunately, there is not yet a shared regulation defining the nutraceuticals as a new category within the area of food derived products. The requirement of safety and the presence of reliable scientific clinical data therefore reinforce the efficacy of a nutraceuticals and guarantee its effect on a particular pathological condition. A dietary supplement does not necessarily fulfill this last criterion even if, in some cases, it may have a beneficial effect on health and provide the necessary micro or macro nutrient in concentrated form to the organism, where necessary. In this last case, dietary supplements may be able to offset some micronutrients temporary deficiency in absorption and/or inefficient use by the body also when due to pathological conditions in place. Nutraceutical studies the composition, formulation, safety, use in support of therapies of nutraceuticals and their administration in addition to the study of their mechanism of action, and to the assessment of their clinical efficacy.

This new established and multidisciplinary science defines a new frontier between drugs and foods since a nutraceuticals, to be defined as such, must have a clinically proven health benefit, which makes it similar to a drug, at least as it is present in the collective imagination. Nutraceuticals offer a number of solutions that are compatible both with the essential requirement of safety and cost-effectiveness [2], while also taking into account properly the principle of eco-sustainability. Many nutraceuticals are obtained from vegetable matrices, e.g. their phytocomplexes, which can be extracted or recovered from vegetable fractions which are normally considered a "waste" or a by-product of the agriculture industry.

The area of use for nutraceuticals is wide, and lies in the range "beyond the diet, before the drug", and therefore within the scope of the Initiative Medicine, which is able to prevent the onset of chronic pathological conditions by providing active principles that can prevent or delay the onset of a specific chronic pathological conditions.

The term "nutraceuticals" is a neologism: Stephen De Felice coined it first in 1989 from two terms: "nutrition" and "pharmaceutical." The Merriam-Webster dictionary defines nutraceuticals as "a foodstuff (such as a fortified food or dietary supplement) that provides health benefits in addition to its basic nutritional value".

This definitions is suggesting that nutraceuticals, which are extracted from vegetable sources (phytochemical) or are the active metabolite complex (if of animal origin), should be understood as a set of pharmacologically effective substances which have inherent therapeutic properties due to the natural active principles of recognized effectiveness which they contain. They may be administered in the appropriate pharmaceutical form, such as a capsule, a tablet, a drink, etc., which coincide with those used for both drugs and dietary supplements [3,4].

The use of active ingredients of vegetal or animal origin as therapeutic agents has proven to have an efficacy at least comparable to that of drugs in the treatment of many pathological conditions including high blood pressure, depression, Alzheimer's disease, and metabolic

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syndrome, which includes multiple pathologic health conditions, in general asymptomatic, like hypercholesterolemia, hypertension, hypertriglyceridemia, obesity. All of these are often related to wrong lifestyle and diet. Among the benefits of using nutraceuticals can be mentioned: i) their higher bioavailability; ii) their hypoallergenicity; iii) an high digestibility; iv) the lack of undesired side-effects [5-7].

Cardiovascular prevention is one of the areas of nutraceuticals greatest use. Atherosclerosis, due to the deposition of cholesterol crystals in the arteries, is also considered a "per oxidative/inflammatory" disease. A recent study found that polyphenolic compounds, e.g. quercetin, epicatechin, catechin, procyanidine, anthocyanins, chlorohydrins, and phenolic acids contained in apples play an important role in the beneficial properties of this food, and have a significant effect on the cholesterol metabolism. Annurca apple, in particular, the only cultivar originally from the Campania region in Italy, has the highest polyphenolic concentration, and this corresponds to an higher effect on cholesterol metabolism compared to the other commercially available apples varieties.

The polyphenolic fraction of the Annurca variety is the richest one in procyanidines, in particular dimers and oligomers. In vitro experiments have shown that the polyphenolic extract of Annurca apple has great ability to increase Apo-AI levels (2 times) and decrease low density cholesterol (LDL) concentration up to - 48% on HepG2 cell lines.

The dimers are easily absorbed into the intestine, rapidly reaching the liver where they act indirectly by increasing the number of LDL receptors. Oligomers, instead, act locally with a beta-cyclodextrinlike mechanism, capturing cholesterol molecules, and thus reducing their absorption. To test these properties of Annurca apple *in vivo*, a 12-week clinical trial has been conducted. Results indicated that Annurca apples (200 g/day) fed to patients with mild hypercholesterolemia (ranging from 210 to 250 mg/dL) have the highest hypocholesterolemic effect, documented by a total cholesterol (TC) reduction of -8.3%, a reduction of low density cholesterol (LDL) of -14.5% and an increase of high density cholesterol (HDL) of +15.2%. Based on these evidences, a nutraceuticals formulation containing the polyphenolic extract of Annurca apple has been formulated in our Laboratories and has been tested in a clinical trial on two hundreds and fifty healthy subjects affected by mild hypercholesterolemia.

Clinical tests have shown that the administration of two 400 mg/day capsules resulted in a TC reduction of 25%, an HDL increase of 49%, and a LDL lowering of 37%. It is worth to remark that a human intake of maximum 1000 mg/day of procyanidine is considered to be generally safe, without any significant consequences for hematologic, clinical, chemical, histopathological or urinary effects [7-10].

This result is way higher to that obtained with other vegetable matrices and comparable with the results on hypercholesterolemia obtained by using the statins, the first line treatment pharmaceuticals for the treatment of this health condition.

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