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Review

Herbal products containing *Hibiscus sabdariffa* L., *Crataegus* spp., and *Panax* spp.: Labeling and safety concerns

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ABSTRACT

Herbs have been used from ancient times for infusion preparation based on their potential health effects. In particular, the consumption of *Hibiscus sabdariffa* L., *Crataegus* spp. and *Panax* spp. has been largely associated to cardiovascular benefits. In this work, the label information of 52 herbal products for infusion preparation containing the referred herbs was analyzed and discussed, taking into consideration the European Union regulation for herbal products, which intends to protect public health and harmonize the legal framework in Member States. Details about the cardiovascular-related statements and warning notifications about consumption were considered. Also, regulatory issues and possible herb-drug interactions were explored and discussed. A total of 14 of the 52 herbal products selected presented health claims/statements on the label. Hibiscus was present in the majority of the products and, in some cases, it was mentioned only in the ingredients list and not on the product front-of-pack. Despite the promising outcomes of these plants to modulate cardiovascular risk markers, consumers with some sort of cardiovascular dysfunction and/or under medication treatments should be aware to carefully analyze the labels and consult additional information related to these herbal products. Manufacturers have also a huge responsibility to inform consumers by presenting awareness statements. Lastly, health professionals must advise and alert their patients about possible interactions that could occur between the concomitant consumption of drugs and herbs. Overall, there is still a real need of additional studies and clinical trials to better understand herbs effects and establish a science-based guidance to assess their safety.

1. Introduction

Cardiovascular diseases (CVD) are a health and economic burden and a main concern (Lee & Kim, 2014). In the last century, CVD became epidemic in low and middle-income countries as a consequence of globalization (Mozaffarian et al., 2015). Several studies reported that plant polyphenols have cardio protective effects by acting on the antioxidant system, affecting signaling and transcription pathways, and regulating inflammation, lipid metabolism, endothelial function, and platelet function (Dauchet et al., 2010; Habauzit & Morand, 2012). Fruits, vegetables, grains, and herbs are common sources of these bioactive compounds. Indeed, an extensive variety of plants has been traditionally used over the centuries to prevent and/or treat CVD (Dufresne & Farnworth, 2001; Hooper et al., 2008; Hussain, Panjagari, Singh, & Patil, 2015). The term "herbs" refers mainly to herbaceous plants and includes crude plant parts such as rhizomes, roots, bark, wood, stems, seeds, flowers, and leaves, which can be intact, fragmented or powdered (WHO, 2007; Kogiannou, Kalogeropoulos, Kefalas, Polissiou, & Kaliora, 2013). These products can be consumed in many different forms, however, infusion, decoction and percolation with water are the easiest and most common methods to consume their bioactive compounds (Chen & Long, 2014).

The Regulation (EU) No 1169/2011 on the provision of food information to consumers, establishes the general principles, requirements and responsibilities considering food information and, specifically, food labeling. Herbal and fruit infusions, tea, decaffeinated tea, instant/soluble tea or tea extract (decaffeinated or not) are under this scope despite being exempted from the requirement of the mandatory nutrition declaration (*Reg. 1169/2011*, 2011).

The commercialization of herbal products has to fulfill the general principles and requirements of European Union (EU) food legislation. Nonetheless, some herbs are considered medicinal plants. In this case, the European Medicines Agency (EMA) is responsible for assessing the safety and the efficacy of the herbal products. The Directive 2004/24/EC established that an herbal medicinal product is "*any medicinal product, exclusively containing as active ingredients one or more herbal substances, or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations*". The

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same Directive describes herbal substances as "*all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh*". According to Directive 2004/24/EC, it is mandatory that products authorized as medicinal products, before commercialization, undergo an evaluation procedure and a submission for registration. The Herbal Medicinal Products Committee (HMPC) is responsible to establish Community herbal monographs for herbal medicinal products (*Directive 2004/24/EC*, 2004). The monographs include the HMPC scientific opinion about individual herbs including safety and efficacy data (Miroddi, Mannucci, Mancari, Navarra, & Calapai, 2013).

Plants as hibiscus (*Hibiscus sabdariffa* L.), hawthorn (*Crataegus* spp.) and ginseng (*Panax* spp.) have been extensively studied as cardiovascular health modulators. These particular herbs were selected for this study based on their role in traditional medicine and wide presence in common herbal infusions. Indeed, there is a great variety of herbal and herbal/fruit products directly available to consumers in which these plants are a main part of the ingredients. Some of these labels contain statements/claims associated to CVD risk factors, such as hypertension or dyslipidemia that can lead consumers with some sort of cardiovascular dysfunction to acquire them. However, these products may not be noticed by consumers as drug-interfering agents, and the concomitant use of medicines and herbal products can represent a potential risk for some patients (*e.g.* medicated with certain drugs such as warfarin or digoxin) (Suroowan & Mahomoodally, 2015).

In this work, a screening of herbal and herbal/fruit products, available in the Portuguese market, containing hibiscus (*Hibiscus sabdariffa* L.), hawthorn (*Crataegus* spp.) and ginseng (*Panax* spp.) was performed. The labels were critically analyzed, mainly regarding product composition, lack of information, the presence of statements/claims associated to CVD, and warning notifications about consumption. Safety and toxicological concerns were also highlighted and discussed. Along with a legal critical analysis and a cardiovascular effect assessment of the referred herbs, this work also intended to analyze the current market situation on these herbal products.

2. Materials and methods

2.1. Sampling and data collection

The herbal products selected for this study were available through different distribution channels and sold as food and food supplements. Samples were randomly selected from 6 local supermarkets and 3 herbalist shops in Porto (Portugal) in April and May of 2016. Previously to the *in loco* market screening, manufacturer websites were explored to overview the commercial existing products.

The selection included the available brands not taking into account the different price categories. A total of 52 herbal products for infusion preparation were found, from 22 commercial brands. The selection criteria included the plant individually present in the product or in mixtures. The products were coded and assembled into three groups: (1) products containing hibiscus, (2) products containing hawthorn, and (3) products containing ginseng. Mixtures containing more than one of these three herbs were not found in the market.

The scientific works about food labeling suggest three major data: nutritional composition, ingredients list and claims (Miller & Cassady, 2015). In order to develop this survey, the data extracted from the labels was systematized. In a first step, for each sample, different information was collected, namely the ingredients list, plant part(s) present in the product, presentation form (*e.g.* dried plant, infusion bags, soluble preparation…), and recommendations to prepare the beverage. Secondly, the presence of any statement/claim that referred health condition properties and warnings for specific health or wellbeing disorders were evaluated. The obtained information is summarized in Table 1.

3. Results and discussion

3.1. Label analysis

Herbal infusions are among the most widely consumed beverages. They are used from ancient times due to their medicinal and organoleptic properties (Xanthopoulou et al., 2016). The plant species used and the preparation method will influence the bioactive compounds content of the beverage, which will be directly related to its functional properties (Fotakis et al., 2016).

From all the 52 selected samples (Table 1), 30 presented hibiscus as ingredient, 16 contained hawthorn, and 6 contained ginseng (Table 1). Herbal products (or extracts) should be accompanied by relevant information (*e.g.* scientific botanical name, geographical origin, identification of the plant part used…) in order to guarantee total and easy access to the product identification. Moreover, a confusing terminology should be avoided. Nevertheless, not all the products presented the plant scientific name. Instead, in some cases ($n = 33$) only the common name was used. In some products ($n = 5$), the front-of-pack name refers to a unique plant, while in the ingredients list several plants are described. In other situations ($n = 10$), the main ingredient is not referred in the front-of-pack.

Samples were presented in different forms, namely bags, dried part of plants and instant/soluble preparations. The plant proportion within the total ingredients varied significantly from 1% (in mixtures) to 100%. Hibiscus extracts were present in some products ($n = 4$). Nevertheless, in this research, preparations containing hawthorn or ginseng extracts were not found.

In several products ($n = 19$), the plant amount was not described in the ingredients list, neither which part of plant was used.

It is known that the nutritional composition and bioactive compounds content differ among plant species (including in their different parts) mainly due to metabolic pathways, environmental, soil, and harvest conditions (Da-Costa-Rocha, Bonnlaender, Sievers, Pischel, & Heinrich, 2014). For example, in hawthorn, differences between leaves, flowers, and fruits, regarding the levels of sugars (sucrose, glucose, xylose, and fructose), terpenes, organic acids and phenolics have been reported (Edwards, Brown, Talent, Dickinson, & Shipley, 2012). In accordance, infusions prepared with different parts of the same plant will present different chemical compositions.

Table 2 compiles information about the most representative chemical constituents of *Hibiscus sabdariffa* L., *Crataegus* spp. and *Panax* spp., as well as their major effects on cardiovascular outcomes. A wide range of bioactive compounds content was expected to be found in literature for the different plants and respective parts (leaves, flowers…). The variations depicted in Table 2 are probably a result of several combined factors as (1) edaphoclimatic conditions, (2) plant genetics and metabolic pathways, (3) harvesting practices, and (4) method of analysis. In fact, different sample preparation methods (*i.e.* grinding degree), solvents, sample/solvent ratio, time and temperature of extraction, type of analytical method (*e.g.* spectrophotometry, chromatographic technique) can easily lead to different results, making difficult the comparison between studies (Edwards et al., 2012; Da-Costa-Rocha et al., 2014).

The purification, identification, and quantification of plant bioactive compounds are also important steps to explore potential health benefits. Phenolic compounds, saponins, alkaloids, anthraquinones, cardiac glycosides, and cyanogenic glycosides are among the secondary metabolites that mostly occur in plants. Phenolic compounds, in particular, are the most abundant group of antioxidants in the human diet. They are classified according to its structure being the phenolic hydroxyl groups the common structural feature. These natural compounds can be simple molecules such as phenolic acids, flavonoids, and phenylpropanoids or highly polymerized compounds like lignins and tannins. Based on their chemical structure, the majority of dietary polyphenols could be divided in four classes: phenolic acids, flavonoids,