70 - STUDY OF ADVERSE REACTIONS FROM THE USE OF MOLASSES OF SACCHARINE SORGHUM (SORGHUM BICOLOR L. MOENCH)

MARIA DO SOCORRO ROCHA MELO PEIXOTO[1]
DANIELE IDALINO JANEBRO[2]
BRUNA CAROLINA DA SILVA BATISTA[2]
ALUÍSIO DE MOURA FERREIRA[2]
VERA LÚCIA ANTUNES DE LIMA[3]
1. Universidade Estadual da Paraíba
2. Faculdade Maurício de Nassau
3. Universidade Federal de Campina Grande, Paraíba
1e.mail:Socorrorocha.1@hotmail.com

INTRODUCTION

The role of dietary constituents in the genesis and prevention of diseases and their mechanisms of action have been studied for decades. There is a worldwide growing interest in the role played by health foods that contain components that influence metabolic or physiological activities. The ancient Chinese cultures, Indian, Egyptian and Greek in particular, worked hard with the concepts of therapeutic foods, assigning preventive properties and / or curative almost all foods, as well as recognizing the right conditions for preparation and consumption.

Among the culteres of large energy potential, the one of the most prominent are the sugar cane, sugar beet and saccharine sorghum. The saccharine sorghum (Sorghum bicolor L. Moench) is one of the world's leading agricultural cultures, although it is still little known in America and Europe. It is the fifth most planted cereal in the world, coming soon after wheat, rice, corn and barley. In Brazil, sorghum has emerged as an excellent alternative to the various regions of Brazil, with annual production of 242,745 tons in 1995. In the Brazilian Northeast, the application of sorghum in in the human feeding has great potentialities for use and could be considerable economy of exchange value with the decrease of the import of the wheat (SOUZA et al., 2005).

In this light, the study aimed to identify possible adverse reactions presented by the co-product obtained from the stem sorghum juice in study.

METHODOLOGY

The tested botanical product of vegetable origin was the saccharine sorghum (Sorghum bicolor L. Moench) Variety IPA 467-4-2, registered in the Ministry of Agriculture, Livestock and Supply under No. 01325, in 30/09/1998.

The Volunteers took a sachet containing 21g of the of the sorghum molasses, once a day, for 8 weeks (56 days) orally. This amount and frequency of administration of the sorghum molasses were based on recommendations of the Dietary Reference Intake (DRI) published in 1997 by the National Academy of Sciences (USA).

During the whole course of the research, the Volunteers were well educated to communicate any sign or symptom that appeared by chance, telling through the questionnaire, once the ingestion of products of vegetable origin can cause adverse effects. A research foi hair approved Research Ethics Committee of Universidade Estadual da da Paraíba (CAAE-0595.0.133.000-09)

RESULTS AND DISCUSSION

Several studies through clinical rehearsals are being accomplished with the intention of discovering new medicinal properties that the natural products can present, as well as the safe use of those products (PAULO et al., 2009).

Starting from the questionnaires answered by the volunteers, were identified some adverse reactions, that occured sporadically and didn't justify the interruption of the research. The more common adverse effects are described in the Illustrations 1, 2 and 3.

In relation to the effects gastrointestinal reported by the volunteers in the basal evaluation, six (13%) reported having an accelerated appetite. However, until the third week of the experiment, eleven volunteers (23,9%) showed an increase in the appetite (Illustration a1).

According to Kamath & Belavady (1980) that fact possibly this tied the insoluble fraction contained in the sorghum, that is the cellulose, because that stimulates the movements peristaltic accelerating the intestinal transit, however, after to 3rd week there was a significant reduction of the appetite.

In relation to the reaction adverse heartburn, eight of the volunteers (17,3%) complained about that symptom during whole the experiment (Illustration 1). That fact could be related to the acid pH (5,3) found in the molasses. Another factor that may contribute to this symptom is the soluble fiber content, those act mainly in the superior part of the gastrointestinal tract increased the secretion of the digestive enzymes (MOTA & BIANCHI, 2005; MEDEIROS et al., 2009; PAULO et al., 2009).

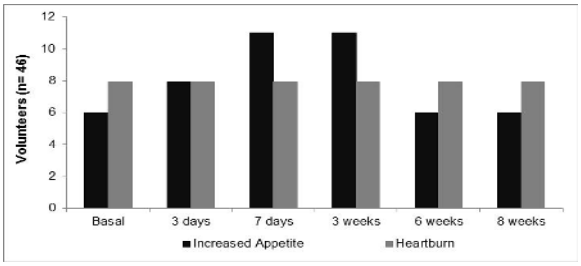

ILLUSTRATION 1. Adverse reactions in the gastrointestinal system reported by the 46 volunteers before, during and after the use of the sorghum molasses saccharine.

In the evaluation basal fifteen volunteers (32%) reported suffered of intestinal constipation (Illustration 2), however that symptom went reducing along the experiment, in the 8th week two (4,3%) patients are still reported this symptom. These data is in agreement with the findings of Medeiros et al (2007), that accomplishing toxicity rehearsals with the flour of the peel of the

yellow passion fruit applied in thirty six volunteers, seven (16,6%) had these symptoms. In pré-clinical study accomplished by Paulo et al (2009) using 15mL of a fitoterapic composed of Schinus terebinthifolius, Plectranthus amboinicius Lour and Eucalyptus globulus Labill in twenty eight healthy volunteers, two (7,1%) have presented intestinal constipation.

That fact can have correlation with the content of insoluble fibers found in products of vegetable origin that stay practically intact through the entire gastrointestinal tract, decreasing intestinal transit time, thus increasing the stool and making the stool softer, reducing constipation and having thus, positive effect on some evils (THIMOTHY et al., 2005; MOTA & BIANCHI, 2005; MEDEIROS et al., 2009; PAULO et al., 2009).

Another factor that may have contributed to minimize the intestinal constipation is the presence of citric acids, malic and tartaric, found in products of vegetable origin, these present laxative effect when provoking a physiological activity of the secretions of the mucous secretions of the digestive tract, promoting a gradual and healthy intestinal regulation (TAVARES et al., 2006).

Observing the Illustration 2, of the 46 volunteers rated 17,3% complained of abdominal cramps and diarrhea simultaneously, fact that justifiable because some people when subjected to treatment with iron salts may occasionally experience disturbances gastrointestinal such as: nauseas, vomits, abdominal pains, diarrheas and/or intestinal constipation (ASSUNÇÂO et al., 2007). In these volunteers the administration immediately after the meals minimized these effects.

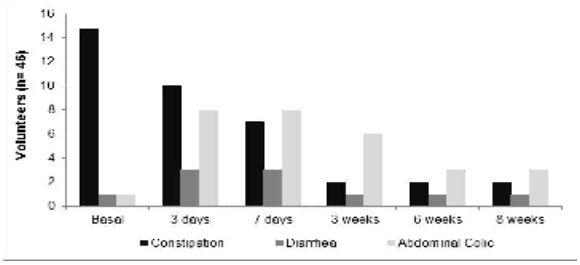

ILLUSTRATION 2. Adverse reactions reported by volunteers during the use of the nutritional supplement.

Another complaint indicated until the 7th day of the evaluation in 10,8% of the volunteers were headache (Illustration 3), this symptom was reduced to 2,1% of the volunteers to the end of the experiment.

This reaction was not shown associated to the use of the alimentary supplement, because all the search participated made it since the beginning of the experiment.

The report of somnolence in 17,3% of the volunteers was also observed until the 7th day of the administration of the molasses, corresponding to the acute phase of the toxicological evaluation, however the symptoms persisted until the 8th week in 8,6% of the volunteers (Illustration 3). According to Tavares et al. (2006), an universal scale doesn't exist to describe or to measure the gravity of an adverse reaction to certain products of vegetable origin, the evaluation, however it is largely subjective. Considering that the majority of products of vegetable origin with nutritional ends and medicinal purposes is administered orally, the possible disturbances gastrointestinal such as appetite loss, nausea, flatulence sensation, constipation or diarrhea are responsible for high percentage of all of the described reactions (TAVARES et.al, 2006).

On the other hand, was indicated by 23,9% of the volunteers a considerable increase of the disposition for the work and decrease of pains in the legs during the use of the molasses of the saccharine sorghum (Illustration 3). This fact can be justified according to Thimothy et al. (2005) and Brandt and collaborators (2009) that do references to rich products in composed phenolics, which are also found in the sorghum. According to Brandt et al (2009) these compounds present antioxidant activity, cholagogic, hepatic microssomal inductors, ciclooxygenase inhibitor and lipoxygenase, suggesting, respectively, the decrease of the oxidation of LDL-CI, increase of the lipidic excretion of the organism, because they present capacity to reduce the inflammation improving the endothelial function and inhibiting the platelet aggregation.

Bastos et al. (1980) analyzed the concentration of fatty acids, verified that the same presented 52% of linoleic acid and 1% of linolenic acid.These acids are essential for the synthesis of the prostaglandins that cause a larger capillary permeability and also has power to attract macrophages to phagocytosis of cellular remains during the inflammatory process, fact this that might have contributed to a better disposition and minimization of pains in the volunteers during the eight weeks of administration of the sorghum molasses.

Those adverse reactions evidenced along the experiment were also reported in several studies of clinical toxicology using fitoterapics products (MOTA & BIANCHI, 2005; MEDEIROS et al., 2009; PAULO et al., 2009), however the number of volunteers affected with adverse reactions in relation to the total number was small, demonstrating like this, that these registered reactions are reversible and of light nature, because are easily tolerated and for not interfering in daily activities, so, not being necessary to suspend the use of molasses.

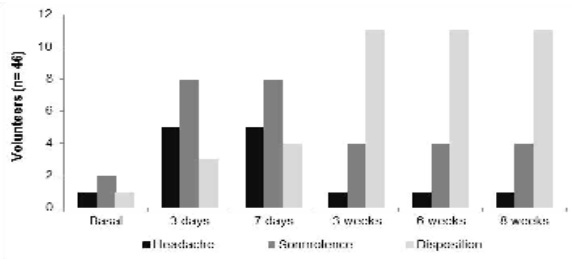

ILLUSTRATION 3. Diverse effects reported by the volunteers during the use of nutritional supplement.

The adverse events told by volunteers seemed not to have casualty relationship with the tested products.

The data obtained in this study by the oral ingestion of the molasses of the sorghum saccharine in the dose from 21g a day for 56 days, showed a good tolerance, not presenting significant adverse reactions.These results complement those obtained with preclinical toxicological tests carried out by Medeiros (2004) suggest that there was no toxicity with use of the product and they indicate that this can be used by the population, in the dose and way of tested administration.

With these data, can be made viable Trial study, Phase II, in according to Resolution No. 251 of August 7, 1997 of the

National Council of Health, in registration at ANVISA. However, these results don't guarantee absence of adverse reactions, especially those of low incidence, which would only be observed after use for hundreds or thousands of patients. Thus, it is important to maintain a pharmacovigilance program during the use of the product (MEDEIROS, 2009).

CONCLUSION

The use of the product was well tolerated by the volunteers, not adverse reactions being reported during the study in the appraised period that could commit the use, in the ingested amount, could suggest consumption as dietary supplement.

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MARIA DO SOCORRO ROCHA MELO PEIXOTO
Endereço: Manoel Elias de Araújo, 453
Bairro: Jardim TavaresE-mail:
Campina Grande-PB
CEP: 58402022
socorrorocha.1@hotmail.com

STUDY OF ADVERSE REACTIONS FROM THE USE OF MOLASSES OF SACCHARINE SORGHUM (SORGHUM BICOLOR L. MOENCH)

ABSTRACT

Natural products may contain a variety of substances that can cause adverse physiological effects or decrease the bioavailability of some nutrients. This work aimed to evaluate the presence of possible adverse reactions with the use of co-product of the juice of the stem of the saccharine sorghum (Sorghum bicolor L. Moench). For this purpose we used sorghum molasses 21g once daily for 8 weeks and orally and during the study volunteers were instructed to report any signs or symptoms that may present. It was seen that the product in study was well tolerated with no reported adverse reactions during the study period that could commit its use, amount ingested, suggesting its use as a dietary supplement. it is needed larger studies regarding the use as food with property of health.

KEYWORD-: quality; Bicolor Sorghum, adverse reactions

ETUDE DES EFFETS INDÉSIRABLES DE L'UTILISATION DE SIROP DE SORGHO SACCHARINE (SORGHUM BICOLOR L. MOENCH)

SOMMAIRE

Les produits naturels peuvent contenir une variété de substances qui peuvent causer des effets physiologiques défavorables ou diminue la biodisponibilité de certains nutriments. Ce travail visait à évaluer la présence de possibles réactions indésirables à l'utilisation de la co-produit du jus du culm du sorgho saccharine [(Sorghum bicolor L. Moench). À cette fin, nous avons utilisé 21g de mélasse de sorgho oralement un fois par jour pendant 8 semaines et Tout au long de l'étude les volontaires ont été avertis de signaler tout signe ou symptôme qui pourrait présenter. Il a été constaté que le produit à l'étude a été bien toléré sans effets indésirables rapportés au cours de la période d'étude qui pourrait nuire à son utilisation, la quantité ingérée, ce qui suggère son utilisation comme complément alimentaire. Pourtant, il est nécessaire de poursuivre les études concernant son utilisation comme aliment aux propriétés santé.

MOTS-CLÉS: la qualité du sorgho, bicolor, les réactions indésirables

ESTUDIO DE LAS REACCIONES ADVERSAS POR EL USO DE JARABE DE SORGO SACARINO (SORGHUM BICOLOR L. MOENCH)

RESUMEN

Los productos naturales pueden contener una variedad de sustancias que pueden causar efectos fisiológicos adversos o disminuir la biodisponibilidade de algunos nutrientes. Este trabajo tuvo como objetivo evaluar la presencia de posibles reacciones adversas con el uso de co-producto del jugo del tallo del sorgo sacarino (Sorghum bicolor L. Moench). Para ello se utiliza la melaza de sorgo 21 g una vez al día durante 8 semanas y por vía oral a través de los voluntarios del estudio fueron instruidos a reportar cualquier signo o síntoma que pueda presentar. Se encontró que el producto en estudio fue bien tolerado sin reacciones adversas durante el período de estudio que podrían afectar a su uso, la cantidad ingerida, lo que sugiere su uso como suplemento dietético. Todavía no hay necesidad de más estudios sobre su uso como alimento con propiedades para la salud.

PALABRAS CLAVE: calidad, Sorghum bicolor, las reacciones adversas

ESTUDO DAS REAÇÕES ADVERSAS DO USO DO MELADO DO SORGO GRANÍFERO SACARINO (SORGHUM BICOLOR L. MOENCH)

RESUMO

Os produtos naturais podem conter uma variedade de substâncias que podem provocar efeitos fisiológicos adversos ou diminuir a biodisponibilidade de alguns nutrientes. Este trabalho teve como objetivo avaliar a presença de possíveis reações adversas com o uso do co-produto obtido do caldo do colmo do sorgo granífero sacarino [(Sorghum bicolor L. Moench). Para tanto foi utilizado 21g do melado do sorgo, uma vez ao dia, durante 8 semanas por via oral e durante toda a pesquisa os voluntários foram instruídos a comunicarem qualquer sinal ou sintoma que porventura apresentassem. Foi visto que o produto em estudo foi bem tolerado não sendo relatadas reações adversas durante o período avaliado que pudessem comprometer sua utilização, na quantidade ingerida, podendo sugerir seu consumo como suplemento dietético. Ainda assim, necessita-se de maiores estudos com relação ao seu uso como alimento com propriedade de saúde.

PALAVRAS-CHAVES: qualidade; Sorghum bicolor, reações adversas.