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Influence of drinking a probiotic fermented milk beverage containing *Bifidobacterium animalis* on the symptoms of constipation

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ABSTRACT – Background – Constipation is a chronic problem in many patients all over the world. **Objective** – To evaluate the effect of consumption of a probiotic fermented milk beverage containing *Bifidobacterium animalis* on the symptoms of constipation. **Methods** – This randomized, double-blind controlled trial included 49 female patients aged 20 to 50 years and diagnosed with constipation according to the ROME III criteria (Diagnostic Criteria for Functional Gastrointestinal Disorders) and the Bristol Stool Form Scale. The patients were randomized into two groups: the intervention group received the probiotic fermented milk beverage and the control group received non-probiotic milk. Participants were instructed to ingest 150 mL of the beverages during 60 days. At the end of this period, patients were assessed again by the ROME III criteria and Bristol scale. The Wilcoxon test was used to evaluate pre and post-intervention results of the ROME III criteria and Bristol scale. The statistical significance level was considered as 5% ($P \leq 0.05$). **Results** – The intervention group showed improvement in the following criteria: straining during a bowel movement ($P<0.001$), feeling of incomplete evacuation ($P<0.001$) and difficulty in passing stool ($P<0.014$), in addition to Bristol scale results ($P<0.001$). In the control group, improvements were observed in the following criteria: straining during a bowel movement ($P<0.001$), feeling of incomplete evacuation ($P<0.001$) and difficulty in passing stool ($P<0.025$), in addition to Bristol scale results ($P<0.001$). No statistically significant post-intervention differences were observed between the two groups for the Rome III criteria and Bristol scale. **Conclusion** – The results show that the consumption of milk resulted in the improvement of constipation symptoms, regardless of the probiotic culture.

HEADINGS – Probiotics. Constipation. Cultured milk products. Functional food.

INTRODUCTION

Constipation is a chronic problem in many patients all over the world[11]. In most cases it causes great discomfort and may result in loss life quality[5]. According to the most recent set of Rome III diagnostic criteria, which are the most widely accepted criteria functional constipation is characterized by straining during defecations; lumpy or hard stools; sensation of incomplete evacuation; sensation of anorectal obstruction/blockage; manual maneuvers to facilitate defecations; and fewer than three defecations per week[6].

Changes in dietary and behavioral habits are usually sufficient for the treatment of constipation. The consumption of food with probiotics is one of the therapeutic approaches[8]. The intestine is the natural habitat of an immense and diverse population of microorganisms that adapt to mucosal surfaces. The symbiotic relationship between intestinal bacteria and their host is beneficial for both parts, since the host offers a habitat rich in nutrients, while bacteria offer important benefits, such as fermentation, which results in the production of short chain fatty acids, amino acids, and vitamins[9]. Bacteria also protect the host against pathogens, acting in the intestinal epithelium and the immune system[12].

Probiotics are defined as live microorganisms that, when administered in adequate amounts, confer health benefits to the host[16]. Lactobacilli and Bifidobacteria are the most studied probiotics for use as functional ingredients[18]. Microorganisms are considered as probiotics when they have humans as host species, are resistant to gastric juices, bile and lysozyme, can adhere to the epithelium, can aggregate, are resistant to processing and storage conditions and have proper concentration at the time of consumption[21].

Considering that consumers are already familiar with the fact that fermented milk have microorganisms beneficial to health, probiotics were inserted on the market mainly as dairy products. Besides others probiotics mentioned previously also stand out a few Streptococcus and Escherichia coli species for treatment of constipation[3].

According to the Technical Regulation of Identity and Quality of the Brazilian Ministry of Agriculture, Pecuary and Food Supply, a dairy product is defined as milk product resulting from the mixture of milk (fresh, pasteurized, sterilized, ultra-pasteurized – UHT, reconstituted, concentrated, powdered, integral, semi-skimmed and skimmed milk) and whey (liquid, concentrated or powdered), added or not of products or food substances such as: vegetable oil, fermented milk, lactic ferments and other dairy products, but with at least 50% of the total ingredients constituted by dairy products[1].

The present study is justified by the need of scientific investigations on the beneficial relationship between the daily consumption

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of dairy product with probiotic culture and well-being, health and nutrition. This work aimed to evaluate the effect of consumption of a probiotic cultured milk drink with *Bifidobacterium animalis* on the symptoms of constipation.

METHODS

This randomized, double blind and controlled clinical trial included 49 women aged 20 to 50 years old and diagnosed with constipation, from the city of Teutônia/Brazil. Exclusion criteria were: diabetes, pregnancy, nursing, gastrointestinal symptoms, previous gastrointestinal pathologies, current or recent consumption of antibiotics, anti-inflammatory drugs, laxatives or other drugs; diseases that alter bowel habits, such as allergies and food intolerances, ulcerative rectocolitis, Chron's disease and irritable bowel syndrome; lactose intolerance or dislike of milk; or use of other types of probiotic, prebiotic and symbiotic products.

The participants were diagnosed with constipation according to the recommendations established by the ROME III criteria[6] and the Bristol Scale[13]. The included women responded to a questionnaire of general data, with questions related to the consumption of fruits and vegetables, meat, dairy products, water intake, alcohol intake, smoking, and physical activity. In addition, a nutritional evaluation was conducted with anthropometric measurements before intervention. The weight was mensured with a digital scale (Tanita®) with capacity of up to 300 kg. Height, waist and hip circumference were measured with 1.5-m inelastic measuring tape, with participants wearing light clothing and barefoot. The body mass index (BMI), waist-hip ratio (WHR) for risk of cardiovascular diseases, classified according to the criteria established by the World Health Organization, were calculated[22].

The participants were randomized into two groups. One group received probiotic cultured milk drink (intervention group), containing 3.2x107 colony-forming *Bifidobacteruim animalis*, and the other group received milky drink without probiotic culture (control group). The patients were oriented to consume one daily glass (150 mL) of the milk beverage, preferably before or during breakfast, during 60 days. The dairy products were donated by a company, and produced especially for this study as 1-liter bottles, transported in thermal boxes and distributed in three stages, each twenty days at the residence of the participants. After the 60 days of consumption of the drink beverage, the participants were evaluated again according to the ROME III criteria and Bristol Scale.

The study was approved by the Research Ethics Committee of the Univates University Center, under Protocol n° 246,012. It has also been approved and registered in Clinical trials NCT02091115. All participants signed an informed consent. Before the start of the distribution of the dairy products, the participants were oriented about the storage and consumption of the beverage. The milky beverage should be consumed every day preferably in the morning, be shaken before consuming, should not be warmed and should be stored in a refrigerated place. During the study, the participants were also oriented not to modify their eating habits, physical activity practice, fluid intake and not to use other products with probiotic culture.

For statistical analyses, quantitative variables were described by mean and standard deviation or median and interquartile range. Categorical variables were described as absolute and relative frequencies. Group averages were compared with the Student's *t*-test for independent samples. In case of asymmetry, the Mann-Whitney test was used. The Chi-square test of Pearson was used to compare proportions, and the Wilcoxon test was applied to evaluate the pre-and post-intervention ROME III and Bristol Scale results. Data were analyzed with the Statistical Package for the Social Sciences (SPSS) version 18.0. The results were considered statistically significant if $P \leq 0.05$.

RESULTS

Table 1 presents the characteristics of the sample, composed entirely by women. Age, height, BMI, physical activity practice, water intake, alcohol intake and smoking were similar between the groups. A significant difference was observed in weight, with an average weight of 72.2±16.5 kg in the control group and 63.4±10.9 kg in the intervention group. The average waist circumference was 84.5±13.4 cm in the control group and 76.6±9.7 cm in the intervention group (P=0.023), showing a relationship with WHR mean values which were 0.77±0.07 and 0.72±0.05 in the control an intervention group, respectively (P=0.004).

TABLE 1. Characterization of the pre-intervention sample

Parameters	Control (n=24)	Intervention (n=25)	*P*
Age (years) – mean ± SD	29.0 ± 7.98	30.84 ± 10.07	0.483*
Weight (kg) – mean ± SD	72.2 ± 16.5	63.4 ± 10.9	0.033*
Height (m) – mean ± SD	1.63 ± 0.07	1.62 ± 0.04	0.295*
BMI (kg/m^2) – mean ± SD	26.94 ± 6.0	24.22 ± 4.4	0.076*
Waist circumference (cm) – mean ± SD	84.5 ± 13.4	76.6 ± 9.7	0.023*
WHR (cm) – mean ± SD	0.77 ± 0.07	0.72 ± 0.05	0.004*
Physical activity – n(%)			0.769#
Yes	8 (33.3)	10 (40.0)	
No	16 (66.7)	15 (60.0)	
Water Ingestion – n(%)			0.280#
Up to 1 liter/day	13 (54.2)	9 (36.0)	
Between 1 and 2 liters/day	8 (33.3)	14 (56.0)	
Over 2 liters/day	3 (12.5)	2 (8.0)	
Alcohol ingestion – n(%)			0.725#
Yes	5 (20.8)	4 (16.0)	
No	19 (79.2)	21 (84.0)	
Smoking – n(%)			0.656#
Yes	2 (8.30)	1 (4.0)	
No	22 (91.7)	24 (96.0)	

* Student's *t*-test - data presented as mean values and standard deviation. # Chi-square test. SD: standard deviation; BMI: body mass index; WHR: waist-hip ratio.

As shown in Table 2, the groups were similar regarding the consumption of fruits and vegetables, dairy products and meat. A borderline difference was observed considering the consumption of cereals, which was 100% in the control group and 80% in the intervention group (P=0.050).

TABLE 2. Food consumption per group

Variables	Control (n=24)	Intervention (n=25)	*P**
Consumption of fruits and vegetables – n (%)			0.609
Yes	23 (95.8)	22 (88.0)	
No	1 (4.20)	3 (12.0)	
Frequency – fruits and vegetables – n (%)			0.699
No daily consumption	1 (4.20)	3 (12.0)	
1 to 2 portions/day	6 (25.0)	6 (24.0)	
3 portions/day	6 (25.0)	6 (24.0)	
4 portions/day	4 (16.7)	6 (24.0)	
5 portions/day	7 (29.1)	4 (16.0)	
Consumption of canned food – n (%)			1.000
Yes	24 (100.0)	25 (100.0)	
No	0 (0)	0 (0)	
Frequency – canned food – n (%)			0.644
1 to 2 portions/week	4 (16.7)	7 (28.0)	
3 to 4 portions/week	2 (8.30)	1 (4.0)	
5 to 6 portions/week	5 (20.8)	3 (12.0)	
Daily	13 (54.2)	14 (56.0)	
Consumption of meat – n (%)			1.000
Yes	24 (100.0)	25 (100.0)	
No	0 (0)	0 (0)	
Frequency – meat – n (%)			0.130
1 to 2 portions/week	0 (0)	0 (0)	
3 to 4 portions/week	1 (4.20)	3 (12.0)	
5 to 6 portions/week	3 (12.5)	0 (0)	
Daily	20 (83.3)	22 (88.0)	
Consumption of cereals – n (%)			0.050
Yes	24 (100.0)	20 (80.0)	
No	0 (0)	5 (20.0)	

* Chi-square test.

In both groups, three of the six ROME III criteria for the symptoms of constipation showed significant modifications after the intervention (Table 3): straining during defecations; sensation of incomplete evacuation; and sensation of anorectal obstruction/blockage. Considering the Bristol Scale, both groups reported modifications in the shape and consistency of stools (*P*=<0.001), but no statistically significant differences were observed between the groups (*P*=0.666).

The analysis of the onset of constipation showed that in 8.3% of participants in the control group (n=2) the symptoms had initiated two years earlier, in 54.2% (n=13) for over 2 years and 27.5% (n=9) had the symptoms since childhood. In the intervention group, 56% (n=14) of the participants presented the symptoms for over 2 years and 44% (n=11) since childhood. The frequency of bowel movements before and after the intervention was modified in similar proportion in the two groups, with no significant differences (*P*=0.343).

DISCUSSION

The results of the present study, which evaluated the effect of consumption of probiotic cultured milk drink, showed that the daily consumption of milky beverage, regardless of probiotic culture, had a positive effect in three of the six ROME III criteria for constipation. Weight, waist circumference and WHR were significantly higher in the control group the pre-intervention. Concerning the Bristol Scale, the type and consistency of feces improved in both groups, without a significant difference between them.

It is known that cereals, mainly integral, are a good source of fiber, and are widely used for prevention and treatment of constipation[2]. Mello et al. evaluated the consumption of fiber in children with chronic constipation, observing insufficient dietary fiber intake in most patients (89.5%; n=38)[14]. In a study conducted with preschool children, encouragement to consumption of two servings of whole-wheat cereal daily during four weeks resulted in increase in the weight of fecal mass and frequency of bowel movements[20]. The present study showed a borderline statistic difference between the two group in cereal consumption, with a higher consumption of cereals in the control group than in the intervention group.

The frequency of bowel movements increased after the consumption of dairy products. Corroborating with results were observed by Yang and colleagues in the investigation of 135 Chinese women with constipation, with a significant increase in the frequency of bowel movements after consumption of dairy products[23]. Furthermore, the consumption of a milk product containing probiotics and prebiotics resulted in increased frequency of bowel movements and modification in the consistency of feces, which became less hardened[8]. In Japan, a study conducted with 50 healthy women who consumed 170 g/day of yoghurt containing *Bifidobacterium lactis* DN 173010 showed a reduction in bowel transit time, in addition to increased frequency of bowel movements[15]. A similar study conducted by

TABLE 3. ROME III criteria and Bristol Scale pre-and post-intervention with dairy products

Criteria	Control			Intervention			Between groups	
	Pre	Post		Pre	Post		Pre- and post-variation	
	Md (P25-P75)	Md (P25-P75)	*P*	Md (P25-P75)	Md (P25-P75)	*P*	Md (P25-P75)	*P*
Straining during defecations	1 (0 – 1)	3 (1 – 4)	<0.001	1 (0 – 1)	3 (1 – 4)	<0.001	-3 (-3 a 0)	0.292
Lumpy or hard stools	4 (3 – 4)	4 (1 – 4)	0.296	4 (3 – 4)	4 (1 – 4)	0.114	2 (-1 a 3)	0.645
Sensation of incomplete evacuation	4 (1 – 4)	0 (0 – 1)	<0.001	4 (1 – 4)	2 (0 – 3)	<0.001	3 (0 a 4)	0.155
Sensation of anorectal obstruction/blockage	1 (0 – 1)	0 (0 – 0)	0.025	1 (0 – 1)	0 (0 – 0)	0.014	1 (0 a 1)	0.793
Manual maneuvers to facilitate defecations	0 (0 – 0)	0 (0 – 0)	1.000	0 (0 – 0)	0 (0 – 0)	1.000	0 (0 a 0)	1.000
Bristol Scale	3 (1 – 3)	5 (3 – 5)	<0.001	3 (1 – 3)	5 (2 – 5)	<0.001	-2 (-4 a 0)	0.666

Md: median; P25=25th percentile; P75=75th percentile.

Tabbers et al. with 159 constipated children (Netherlands and Poland) showed that consumption of a fermented dairy product, containing *Bifidobacterium lactis*, resulted in increase in stool frequency, but this increase was comparable in the control group[17].

These results show that the consumption of dairy products improve constipation symptoms, with no significant differences between the groups. This result was also found in a double-blind randomized study, with 179 constipated individuals who consumed yoghurt with or without probiotic culture. A significant improvement of symptoms of constipation was observed, but no significant difference between the groups[20]. Different results were found in a study in which Brazilian women participants in the intervention group consumed cheese enriched with probiotic *Bifidobacteruim lactis* for 30 days[7]. A positive effect was observed in five of the six ROME III criteria in the intervention group, while the control group showed improvement in three of these criteria. Another study showed beneficial effects of goat yoghurt containing *Bifidobacterium longum* in 59 individuals diagnosed with constipation, also by the ROME III criteria. Three symptoms showed significant improvement with the use of probiotic product: abdominal pain, pain on evacuation and increased frequency of bowel movements[10].

According to Vitetta and colleagues, the consumption of yoghurt may be beneficial for facilitating the action of digestive enzymes and proteins. Dairy products are similarly recommended for consumption for their probiotic and nutritional characteristics[19]. One of the beneficial effects observed in the present study concerned the type and consistency of feces, which became less fragmented, segmented and hardened. Paula et al. evaluated the effect of a symbiotic food on the bowel habit in constipated women, with methods similar to the present study, and observed that the consumption of this food improved the quality/aspect of the feces[4]. A similar result was observed in this study, with a significant difference between the groups relative to the Bristol Scale evaluation.

Considering the results, it may be observed that the time of intervention and the amount of dairy product consumed were the main limitations of this study, since the products were delivered every 20 days, and depended on the participants remembering to ingest the daily recommended portion. Furthermore, the number of colony-forming bacteria found in probiotic cultured milk drink may have been insufficient to achieve significant differences in the intervention group, since studies have shown the effectiveness of dairy products in the treatment of constipation. In addition, the small number of studies relating the consumption of probiotic cultured milk product with the improvement of symptoms of constipation must be stressed.

CONCLUSION

The results found in the present study lead to the conclusion that the consumption of dairy products improved three of the six ROME III criteria, in addition to improvement in the type of feces, which became less hardened and fragmented, as evaluated by the Bristol Scale. This improvement was observed in both groups assessed, showing that the consumption of dairy products with or without probiotic culture assisted in the treatment of constipation.

Authors' contributions

Moreira TR: study design, writing of the scientific article and review. Leonhardt: study design and writing of the scientific article. Conde SR: review of article.

Moreira TR, Leonhardt D, Conde SR. A influência de bebida láctea com cultura probiótica (*Bifidobacterium animalis*) no tratamento dos sintomas de constipação. Arq Gastroenterol. 2017;54(3):206-10.

RESUMO – Contexto – Constipação é um sintoma crônico que acomete grande parte da população mundial. **Objetivo** – Avaliar o efeito do consumo de bebida láctea com cultura probiótica (*Bifidobacterium animalis*) nos sintomas de constipação intestinal. **Métodos** – Ensaio clínico randomizado, duplo cego e controlado. A amostra foi de 49 pacientes, do gênero feminino, com idade entre 20 a 50 anos e com diagnóstico de constipação intestinal conforme os critérios de ROMA III (*Diagnostic Criteria for Functional Gastrointestinal Disorders*) e escala de Bristol. As pacientes foram divididas em dois grupos através de randomização, o grupo intervenção recebeu bebida láctea com cultura probiótica e o grupo controle recebeu bebida láctea. Estas foram orientadas a consumir 150 mL diariamente durante 60 dias. Ao final deste período, aplicaram-se novamente os critérios de ROMA III e escala de Bristol. Para avaliação dos critérios de ROMA III e escala de Bristol pré e pós-intervenção, o teste de Wilcoxon foi aplicado. O nível de significância estatística considerado foi de 5% ($P \leq 0,05$). **Resultados** – No grupo intervenção houve melhora nos seguintes critérios: esforço para evacuar ($P<0,001$), sensação de evacuação incompleta ($P<0,001$) e dificuldade na passagem das fezes ($P=0,014$), além da escala de Bristol ($P=<0,001$). No grupo controle houve melhora nos seguintes critérios: esforço para evacuar ($P<0,001$), sensação de evacuação incompleta ($P<0,001$) e dificuldade na passagem das fezes ($P=0,025$), além da escala de Bristol ($P=<0,001$). Verificou-se que os critérios de Roma III e escala de Bristol não houve diferenças estatisticamente significativas entre os grupos pós-intervenção. **Conclusão** – Concluiu-se que o consumo de bebida láctea auxiliou na melhora dos sintomas de constipação intestinal, independentemente da cultura probiótica.

DESCRITORES – Probióticos. Constipação intestinal. Produtos fermentados do leite. Alimentos funcionais.

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