Effect of the ingestion of a symbiotic yogurt on the bowel habits of women with functional constipation

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Summary

Background/aims: *functional constipation is a prevalent problem within the western population. There is evidence supporting the fact that the inclusion of pre and probiotics in the diet can favorably modify the intestinal function. The present study evaluates the effect of the consumption of Activia®, a yogurt containing 10^8 UFC/g of Bifidobacterium animalis (DN-173 010) and fructoligosaccharide, in women between the ages of 18 and 55 with and without functional constipation (Rome II criteria).* ***Methods:*** *after a stabilization and a basal period, women were randomized to receive 2 units/day of Activia or a lacteous dessert without probiotics (control) for a period of 14 days. Afterwards the groups were intercrossed for another 14 days.* ***Results:*** *of the 399 women who started the study, 378 were eligible for study participation. In the group of women with functional constipation (n= 266), the consumption of the symbiotic was associated with a higher bowel evacuation rate (6.1±2.7 depositions/week with Activia vs. 5.0±2.6 dep./week in the control group; P<0.01), an improvement in the quality of the stools according to the Bristol scale (3.6±1.0 vs. 3.4±1.0; P<0.01), a reduced perception of straining effort (1.9±0.8 vs. 2.2±0.9; P<0.01) and a reduced perception of pain associated with defecation (0.1±0.2 vs. 0.2±0.3; P<0.01). In the group of women without constipation (n=112) there were statistically significant variations in equal sense but of smaller magnitude, with the exception of pain which, having a very low value in the basal period, did not experience changes.* ***Conclusion:*** *the consumption of a symbiotic yogurt by women with functional constipation showed a significant improvement in the parameters related with bowel evacuation. The use of this symbiotic food can result in a useful and safe tool for managing constipation.*

Key words: *Constipation, Probiotics, Prebiotics, Intestines, Colon.*

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Efecto de la ingesta de un alimento simbiótico sobre el hábito evacuatorio en mujeres con constipación funcional

Resumen

Introducción/objetivos: *la constipación funcional es un problema prevalente en la población occidental. Existen evidencias de que la toma de alimentos pre y probióticos puede modificar favorablemente el hábito evacuatorio intestinal. En este trabajo se estudió el efecto de la ingesta de Activia®, un yogur conteniendo 10^8 UFC/g de Bifidobacterium animalis (DN-173 010) y un fructoligosacárido en mujeres de 18 a 55 años con y sin constipación funcional (criterios de Roma II).* ***Métodos:*** *luego de sendos períodos de estabilización y basal fueron aleatorizadas a recibir durante 14 días 2 unidades/día de Activia o de un postre lácteo sin probiótico ni prebiótico (control). Luego los grupos fueron entrecruzados durante otros 14 días.* ***Resultados:*** *de las 399 mujeres que iniciaron el estudio, 378 fueron evaluables. En el grupo de constipadas (n= 266) la toma del simbiótico se asoció con una mayor frecuencia evacuatoria (6,1±2,7 dep./semana con Activia vs. 5,0±2,6 dep./semana en controles; P<0,01), mejoría en la escala de Bristol de calidad de las heces (3,6±1,0 vs. 3,4±1,0; P<0,01), menor esfuerzo evacuatorio*

(1,9±0,8 vs. 2,2±0,9; P<0,01) y menor proporción de dolor evacuatorio (0,1±0,2 vs. 0,2±0,3 ; P<0,01). En el grupo sin constipación se observaron variaciones estadísticamente significativas en igual sentido pero de menor magnitud, con excepción del dolor que mostró un valor basal muy bajo. ***Conclusión:*** *la ingesta del yogurt prebiótico en mujeres con constipación funcional mostró una mejoría significativa de los parámetros relacionados con la evacuación intestinal. La utilización de este alimento simbiótico puede resultar una herramienta útil y segura en el manejo de la constipación.*

Palabras claves: *Constipación, Probiótico, Prebiótico, Intestinos, Colon.*

List of abbreviations:
Fructoligosaccharide (FOS)

Constipation is one of the most prevalent complaints referred by the general population.[1] It can be secondary to multiple causes, however, in healthy people it is principally attributed to many of their habits that characterize the current lifestyle. The abundance of refined foods, the poor intake of dietary fiber or non-digestible residues and physical inactivity are probably important factors involved in the genesis of this disorder. Constipation is more frequent in women, probably due to a hormonal effect,[2] many times aggravated during pregnancy[3] and/or secondary to the anatomic and functional changes in the dynamics of the pelvic floor following delivery.

There is no single definition of constipation. Most patients define constipation by one or more symptoms: hard stools, infrequent stools (typically fewer than three per week), the need for excessive straining effort, sensation of incomplete bowel evacuation, an excessive time spent on the toilet or in unsuccessful defecation.[4] The operative definitions of constipation were built from a combination of parameters; such is the case of the Rome II criteria used in the current study.

In a study published in 1987 in the United States carried out presumptively amongst healthy young adults, Sandler and Drossman reported a prevalence of constipation of 7.3%. Subjects most commonly defined constipation as straining effort and hard stools.[5]

Based on the register of the number of depositions per week, constipation affects 10% of the population in our country. However, the unspecific disorders associated with constipation are referred spontaneously by one third of the people. In recent investigations carried out in representative samples of the argentinean urban population, 27% of the respondents spontaneously referred problems related to constipation as being a main motive of preoccupation concerning their health. Of these people, 78% perceived inconveniences associated with constipation at least once a week, 60% of which reported seeking a solution to this affection throughout their diet.[6]

There is evidence supporting the fact that the intake of probiotics can be useful to reduce the affections related with constipation. Three different clinical studies,[7-9] have demonstrated that the consumption of Activia®, on a daily basis improves colonic transit time and that such effect is dose-dependent. Other studies performed in human volunteers have confirmed this benefit.[10] Activia® (Danone Argentina) is a yogurt containing *Bifidobacterium animalis* DN 173010 (10^8 colony forming units -CFU- per gram of product) with the natural yogurt starter bacteria: *Lactobacillus bulgaris and Streptococcus thermophilus* (10^7 CFU/g of product), with the addition of a small proportion (0,5 g%) of inulin. Inulin is a fructoligosaccharide (FOS) which is obtained from a natural fiber of chicory (chicorium intybus), a polymer of fructose containing 1-4 bonds with prebiotic activity, which stimulates the proliferation of bifidobacteria in the intestinal tract.[11] The addition of inulin to an exogenous bifidobacteria substantially increases the proportion of bifidobacteria in the colonic flora.[12] Experimental studies with this combination called Acti regularis have confirmed that it is capable of substantially increasing the concentration of bifidobacteria in both caecum homogenates and colon of mice *in vivo*, of favorably modifying the production of organic acids and of decreasing the formation of colonic enzymes such as nitroreductase which are involved in the transformation of pro-carcinogens into carcinogens.[13]

The main objective of this study was to determine whether the consumption of Activia, a symbiotic yogurt (dairy product) with probiotics and prebiotics, modifies the principal characteristics and the subjective sensations associated with bowel evacuation, evaluated through the stool frequency, stool shape (Bristol stool scale), straining effort and evacuation pain.

Materials and methods

With the intention of recruiting almost 300 constipated women and 100 women without constipation, 456 six women were invited to participate in this open, randomized, controlled study in parallel groups with intercrossing in the city and outskirts of Buenos Aires from November 2005 through April 2006. The mean age of the participants was 33.5 years, ranging from 18 to 55. All participants proceeded from a routine visit to the nutritionist where they were categorized and invited to participate in the study. All participants were categorized according to the Rome II criteria for functional constipation. Those having a BMI > 28, significant chronic pathologies and/or not having had stable dietary habits for at least the last three months were excluded from the study. Patients were also excluded if they met any of the following criteria: chronic pharmacologic treatment that may alter bowel function, dependence on laxatives to complete bowel evacuation, catharsis lesser than one time per week and/or the use of manual maneuvers or mechanic means (enemas, suppositories) to facilitate bowel movements.

Determinations were carried out before and after the study in the office visits to the nutritionist. The participant's personal, nutritional and gastrointestinal history was assessed in these meetings. The determinations carried out in the study included: detailed medical history, assessment of detailed digestive symptoms, a self-reported questionnaire based on the perception of the digestive-related quality of life before and after the first intervention, mean dietary fiber consumption per day (by a self-filling report regarding the food ingested during the study), shape of the stools according to the Bristol scale, excessive straining effort and pain during bowel evacuation.

Participants were randomly assigned to one of the two groups (group 1 and group 2) using a computerized system. Each group received Activia or a control lacteous dessert (see table 1) respectively during the first two weeks of the intervention (interventions A1 and C1 respectively). During the following two weeks the interventions were inverted so that group 1 received the control lacteous dessert and group 2 received Activia (interventions C2 and A2 respectively). Participants had the number of rations necessary for each intervention of the study delivered to their homes. All the people involved in the investigation knew which product was being consumed at all times. Participants were instructed about being able to abandon the study at any time because of their own wish or due to any other unexpected reason such as intolerance or any other secondary effect. The study was carried out with the approval of an independent ethics committee.

Table 1. *Main characteristics of Activia® and the desserts used as a Control.*

	Activia® yogurt	Control "Ser®" dessert	Control "Serenito®" dessert
Carbohydrates	18.1 g	23.1 g	25.3 g
Lipids (g)	4.4 g	0.59 g	4.5 g
Proteins (g)	4.9	5.5 g	3.6 g
Calories (kcal)	131	120 kcal	156 kcal
Weight (g)g	125	130 g	110 g

In order to determine the variations in the subjective sensation of well-being we used a self perception questionnaire to track symptoms of digestive discomfort with a simple questionnaire previously used by the sponsor (Danone UK) in observational studies comparing item by item in a direct way,[1] using a 5 point option multiple choice (*"five point Likert scale"*). The questionnaire was completed at the beginning of the study and after concluding the first intervention, allowing a direct comparison between the subjects that consumed Activia and the subjects that consumed the control product in an independent manner.

We compared the variations presented before and after the interventions between the two groups for each one of the subpopulations. All the emergent variables of the population under study (n=378), divided into participants with functional constipation (n=266) and participants without functional constipation (n=112), were studied by the corresponding method for each type of variable. In order to reduce the residual effect of the previous intervention, the measurements were done during the second week of each interventional period.

For variables such as age, fiber consumption and defecatory characteristics we used the Wilcoxon signed summation test (for paired samples) to compare the Activia® vs. basal intervention, the control vs. basal intervention and the Activia® vs. control intervention. To compare group 1 and group 2 (between

branches) we used the Wilcoxon range summation test (for two independent samples) and calculated the odds ratios for an increase in stool frequency, of at least once a week, and for the improvement in the quality of the stools.

In order to consider a subject as respondent for a determined variable, we defined the ranges of abnormal values for each variable after having analyzed the results obtained in the group of women without constipation. For variables such as frequency, consistency and straining effort we considered a value as abnormal if it lay outside a quartile, either by being beneath the p25 for the variables in which a rise was expected, or by being above the p75 for those in which a downfall was expected after carrying out the intervention. We have also calculated the OR for stool frequency using the current criteria for normality considered as having a minimum of three bowel movements per week. Regarding the pain associated with bowel evacuation, subjects were considered abnormal if they had an initial value higher than "zero" (those who have claimed some type of pain). A subject was operatively defined as respondent for a determined variable when such a variable had a value which was considered abnormal before the intervention and normal after the procedure.

Results

Of the 456 women who were included in the analysis, 399 started the study, 57 were excluded for not meeting protocol requirements, 378 being eligible for study participation (266 constipated and 112 not constipated). Regarding the exclusions carried out during the course of the study (dropouts) we found ourselves with two well differentiated groups: one corresponding to the participants who had to be excluded because of their own causes, and the other conformed by the subjects that were excluded because of poor compliance in recording the characteristics of their bowel habits. The total number of "dropouts" included 21 participants, divided in 7 groups (Table 2). Of those participants who voluntarily retired from the study, only two did not give any explanation concerning the underlying cause.

The age of the constipated women was 34.9±8.9 years (mean and SD), while the age of the women without constipation was 33.5±8.9 years.

The ingestion of fiber calculated according to the participants register of consumed food during the study, shows that constipated women ingested a smaller amount of fiber per day (Table 3); however, this difference was not statistically significant.

Table 2. *Causes for study drop-outs.*

Description	Nº
Loss of daily register material	1
Failure to restrict the consumption of probiotics during the course of the study	2
Failure to fulfill study registers	3
Medical record not related to the consumption of the product	2
Unexpected journey during the course of the study	1
Voluntary withdrawal from the study	2
Retirement because of mistakes in daily study registers	10
Total	21

Table 3. *Daily ingestion of dietary fiber by women with and without constipation during the course of the study.*

	Constipated	Not constipated
N	276	118
Dietary fiber consumption (g/day) (Media ± SD)	8.7±6.4	9.4±6.5
CI 95%	8.2-9.5	8.2-10.5

Regarding the parameters associated with bowel habits we carried out comparisons between the interventions A1 and A2 and the interventions C1 and C2, not being able to demonstrate significant differences, therefore allowing us to unify the results of A1 and A2 and of C1 and C2 under the denominations Activia period and Control period, respectively.

In the group of constipated women stool frequency was significantly higher during the Activia period compared to the one observed during the Control period (6.1±2.7 vs. 5.0±2.6 depositions/week respectively: $P<0.01$). The consumption of Activia was also associated with a significant improvement in the quality of the stools according to the Bristol scale (3.6±1.0 vs. 3.4±1.0 respectively; $P<0.01$). The perception of straining effort was sig-

nificantly reduced during the Activia period compared to the Control (1.9±0.8 vs. 2.2±0.9 respectively; P<0.01). There was also a reduction in the proportion of pain associated with bowel evacuation (0.1±0.2 vs. 0.2±0.3 respectively; P<0.01) (Table 4 and Figure 1).

The differences between the Activia period and the Control period are greater when only the constipated women who presented with pain and straining effort ≥ 3 (moderate to very high) during the basal period are considered in the analysis (Figure 2).

In the group of women without constipation there were statistically significant variations in equal sense but of smaller magnitude, with the exception of pain, which, having a very low value in the basal period, did not undergo changes (Table 5).

Based on the criteria mentioned above we calculated the odds ratios (OR) between the Activia vs. Control interventions for each one of the 4 principal variables. In Table 6 we can clearly see that the OR was significantly in favor of Activia compared

Table 4. *Effect of the ingestion of the control dessert and Activia on the variables related with intestinal evacuatory function in constipated women.*

Constipated women	Control	Activia	p
Bowel movements per week			
Mean ± SD	4.96±2.62	6.09±2.69	<0.0001
CI 95%	4.64-5.28	5.76-6.42	
Stools Shape			
Mean ± SD	3.44±1.02	3.61±0.97	<0.003
CI 95%	3.31-3.56	3.49-3.73	
Straining effort			
Mean ± SD	2.19±0.85	1.94±0.91	<0.0001
CI 95%	2.08-2.30	1.84-2.05	
Pain during bowel evacuation			
Mean ± SD	0.17±0.30	0.08±0.21	<0.0001
CI 95%	0.13-0.21	0.06-0.11	

Figure 1. *Effect of the ingestion of Activia in relation to the control on stool frequency (bowel movements/week), stool shape, pain and straining effort associated with bowel evacuation in constipated women.*

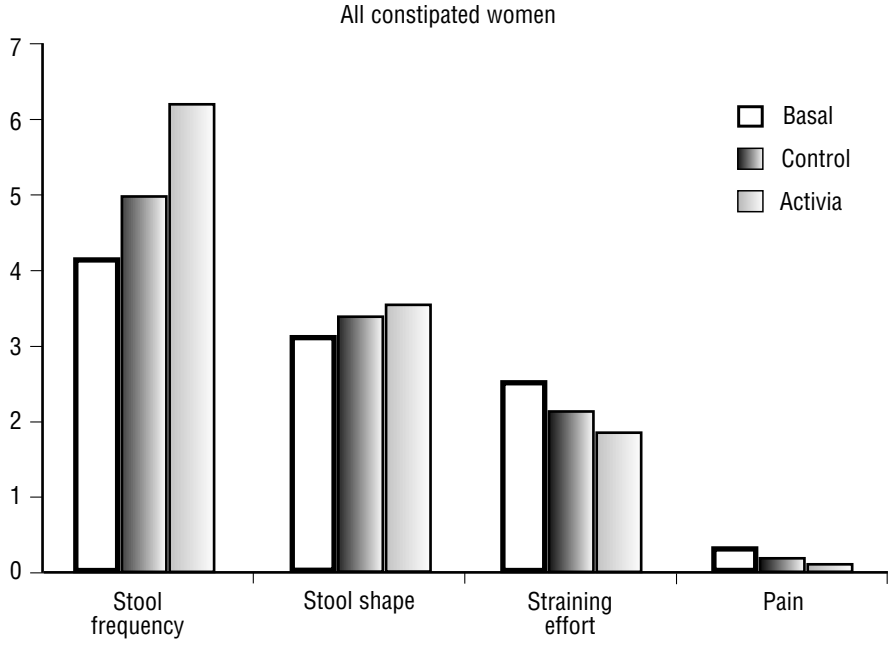

Figure 2. *Effect of the ingestion of Activia in relation to the control regarding stool frequency (bowel movements/week), stool shape, pain and straining effort associated with bowel evacuation in a subgroup of constipated women who presented pain and straining effort during defecation higher or equal to 3 during the basal period.*

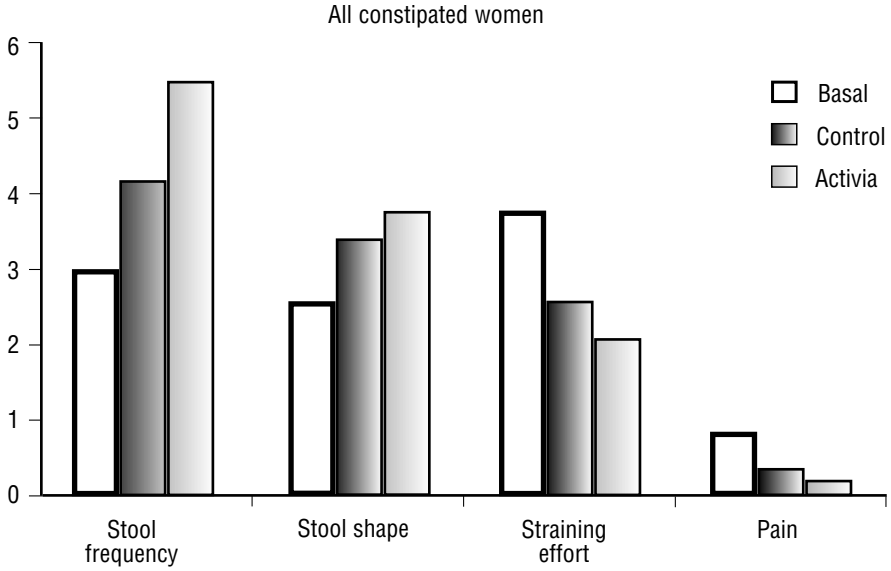

Table 5. *Effect of the ingestion of the control dessert and Activia on the variables related with intestinal evacuatory function in women without constipation.*

Women without constipation	Control	Activia	p
Bowel movements per week			
Mean ± SD	6.67±3.32	7.71±3.60	<0.0001
CI 95%	6.05-7.30	7.03-8.39	
Stool Shape			
Mean ± SD	3.62±0.84	3.89±0.83	<0.0005
CI 95%	2.46-3.78	3.73-4.04	
Straining effort			
Mean ± SD	1.64±0.62	1.50±0.58	<0.019
CI 95%	1.51-1.76	1.38-1.61	
Pain during bowel evacuation			
Mean ± SD	0.06±0.13	0.03±0.13	<0.068
CI 95%	0.03-0.10	0.001-0.05	

to the control group for variables such as stool frequency, straining effort and pain. No difference was found regarding stool consistency.

In relation to the self-reported questionnaire based on the perception of the digestive-related well-being, comparing the differences presented before and after the first intervention in both groups, we observed a significant improvement in the constipated population in the matters concerning: the degree of satisfaction with their digestion and the perception of uncomfortable sensations resulting from constipation or associated with their low transit. In the population of women without constipation we observed statistically significant variations in the matters regarding: discomfort due to excessive flatulence or gas retention, discomfort due to abdominal bloating, sensation of heaviness or lethargy resulting from digestive disorders, discomfort due to digestive problems in general, and the importance assigned to digestive-related pain or complaints. In the present study no adverse effects were seen related to either intervention.

Table 6. *Odds ratio (OR) concerning the Activia and Control interventions in the group of constipated women for each one of the principal variables: stool frequency and consistency, and effort and pain associated with bowel evacuation.*

Criteria of response	Total Nº	Respondents with Control	Respondents with Activia	OR	IC 95%	p
Stool frequency > 5/week	177	66	109	2.70	1.75-4.14	<0,001
Stool frequency > 3/week	76	68	48	4.60	1.75-4.14	<0,001
Stool Shape	54	62	62	1.42	0.79-2.54	<0,238
Straining effort	132	96	87	2.18	1.33-3.59	<0,002
Pain during bowel evacuation	98	48	67	2.25	1.26-4.03	<0,006

Discussion

This study was performed on young women with and without functional constipation.[21] Constipation is most prevalent in women than in men, which we believe is a sufficient reason for only including women in this study, in this way clearing out an important variable such as gender. Constipation was defined according to the Rome II criteria, a validated tool widely used in studies for the selection of individuals with functional disorders. Although the aim of this study was to evaluate the effect of the consumption of Activia® in constipated women, a group of women without constipation was included in this work so as to observe the effect of the intervention in the population lacking this disorder, obtaining data which allowed us to clearly define the parameters for normality, and making the operative definitions regarding the women who were respondent for each variable.

Women who presented severe constipation or referred data suggesting constipation secondary to alterations in the perineum and anorectal area were deliberately excluded from the study. Although there is not a totally convincing argument denying the possibility that the consumption of Activia may result beneficial for women who present these last two conditions, the objective of this work was to asses women who have functional constipation compatible with a relatively normal life and do not have severe alterations in their intestine's physiology; in other words, healthy women with low severity functional constipation. On the other hand, our presumption was that the inclusion of these two groups (severe constipation and alterations in the perineum and anorectal area) would have made the population under study more heterogeneous.

The design of the study[25] consisted in two parallel and intercrossed branches, each intervention lasting two weeks. We must acknowledge the fact that the intercrossing performed two weeks after the first intervention limited the time of each intervention and hindered a more prolonged observation. However, on the other hand, the design with intercrossing enabled all participants to receive both interventions (Activia and dessert control) which, compared to a design without crossing-over, duplicated the number of individuals who received each one of the interventions. The study was carried out in a controlled and open way, using the daily intake of two units of a lacteous dessert of the participant's choice as a control (see list I). This implied that both the investigators and the participants were fully aware of the interventions performed. The fact that the participants knew that they were consuming Activia®, a product that is identified by the public as being a yogurt which has a regulatory effect on the intestinal function, in this way being able to influence the results observed in this study. It is known that the effect of placebo can be important, especially in the case of therapies regarding functional disorders. However, in these circumstances it is not easy to find an ideal placebo. Such ideal

placebo should have: 1) organoleptic qualities undistinguishable from those of Activia®, 2) no identifying label, 3) similar chemical composition (including modifications made by bacteria in the original ingredients and presence of the bacteria's metabolic products), 4) absence of viable bacteria. This last point is particularly complex. If a product which is not fermented had been used, that is without bacteria, the products contained in the placebo would not have been modified by the bacteria, and therefore the presence of viable bacteria not being the only variable. Neither is the use of a radiated probiotic (to kill bacteria) an ideal placebo because, even though it would contain the products of the ingredients modified by the bacteria's metabolism, it would also contain the components liberated by the dead bacteria, which could at the same time have some effect on the physiology of the digestive system. Provided the impossibility to count with an ideal placebo and with the intention to circumscribe the effects of each one of the preparations, it would be necessary to include at least two placebos: a) a non fermented product and b) a fermented product but containing dead bacteria. This resource implies a considerable increase in the number of subjects to be included in the study. On the other hand, the use of new alimentary products also implies having to deal with legal matters related to the use of alimentary products which have not been approved by official regulatory entities. Based on the analysis made, we believe that the decision to carry out this first open study at a national level is justified by the operative complexity and high costs of the aforementioned options. These considerations could eventually be taken into account in the planning of future studies.

This study was not designed to evaluate the mechanisms involved in the observed effects. However, we can speculate that changes in the intestinal flora could accelerate the colonic transit, decrease its capacity to reduce the hydrophilia of the intestinal contents, or moderate the capacity of the colon to absorb water. We also think that it is possible that this type of interventions, which not only modify the flora in its composition and metabolism but also modify the neuroendocrine and immune response of the mucosa and its functional (and perhaps structural) consequences, may have to be observed for a more prolonged period of time in the future. Having obtained the results here presented, it would be interesting to plan the realization of studies with more prolonged intervention and suspension times (with intake of placebo after the yogurt).

A standardized visual scale was used in order to clinically visualize the changes in stool consistency.[14] Visual scales to evaluate stool consistency or characteristics have been widely used over time.[15] It is a simple, replicable procedure which is directly related to colonic transit time[16-18] measured by other methods such as the use of radiopaque markers.

In the group of constipated women we observed a significant increase in stool frequency, a change in the aspect of stools (with an upgrade in the Bristol scale), a significant reduction in the perception of straining effort, and an also significant reduction in the perception of pain associated with defecation. These two last effects are, in our opinion, the most important changes as they imply a significant reduction in the perception of unpleasant sensations. Neither do the increase in stool frequency nor the change in stool characteristics necessarily imply a benefit in themselves. However, both variables are probably intimately attached to the other two and, in addition to this having a low cathartic rate is a frequent motive of complaint amongst the general population. On the other hand, having a high (or daily) evacuation rate has an important value within our culture, although not necessarily always associated with absence of straining effort or pain. The observation that Activia was more active in the subgroup of more constipated women indicates that probably its benefic effect is not restricted to the mildest constipated women.

Even though this protocol was not designed for elucidating the mechanisms involved in the effects observed, there are some considerations which can be made. The increase in stool frequency could be explained either by an increase in the excreted fecal volume or by a reduction in the volume of each deposition. In the present study we have not measured fecal volume and therefore we cannot elucidate which factor was associated with the increase in stool frequency. The upgrade in the Bristol scale suggests an increase in stool humectation, that is, better hydrated feces, and probably a larger total fecal volume. On the other hand, as we have already mentioned, there is evidence which demonstrates that the results obtained using the Bristol scale correlate to colonic transit time measured with radiopaque markers19. If we apply this correlation to the results of our study we can infer that the intake of Activia could have reduced colonic transit

time in the group of constipated women. The mechanisms involved in the reduction of colonic transit time are not clear. Basically, in the absence of significant modifications in the ingestion of nutrients and fiber (variables that were controlled during this study), an increase in colonic transit velocity could be explained either by a change in intestinal motility, or by an increase in the intracolonic volume, or both. Probably both factors influence each other, making it difficult to establish which one was primarily modified. The changes in intestinal motility that could increase transit velocity are: a) an increase in peristaltic contractions, b) a reduction in anti-peristaltic contractions, or c) a reduction in the tonic contractions of the left colon. On the other hand, a primary increase in the intracolonic volume could be secondary to: a) a larger volume contributed by the upper gastrointestinal tract, b) a reduced absorption of the colonic content, either because of a change in the secretory/absorptive function of the mucosa or a reduced degradation by colonic bacteria (and consequent colonic absorption) of osmotic and/or hydrophilic elements, whose absorption depends on previous endoluminal degradation and c) an increase in the amount of endoluminal bacteria (which represents approximately 60% of the fecal volume). Our results do not enable us to speculate which of the mechanisms described is or are involved, but it is possible that the ingestion of Activia could modify one or more of these factors.

It is interesting to point out the fact that a recent study shows that the intake of bifidobacterium infantis significantly reduced symptoms in patients with diarrhea-predominant, constipation-predominant or alternating diarrhea and constipation irritable bowel syndrome.[20-23] Although the mechanisms involved in the genesis of irritable bowel syndrome are not entirely known, it is accepted that changes in gut motility, visceral sensitivity and in immune processes and mood may play an important role in this affection. The intake of probiotics may probably modify the relationship between the intestinal microbiota and the mucosa. The mentioned study shows that the ingestion of bifidobacterium infantis normalized the imbalance of cytokines regulating the inflammatory response[24] which is seen in patients with irritable bowel syndrome. For the first time this observation strongly suggests that the beneficial effects resulting from the intervention with a probiotic in patients with irritable bowel syndrome could be due to a change in the inflammatory/immunologic response of the mucosa. Recently Guyonnet also showed beneficial effects with the ingestion of a probiotic food containing Bifidobacterium animalis DN-173 010 on discomfort HRQoL score and bloating in constipation-predominant IBS, and on stool frequency in subjects with <3 stools/week[26].

The analysis of the results obtained in the group of women without constipation shows that the intake of Activia was associated with significant modifications in the same direction but of lesser magnitude than the ones observed in the constipated group, with the exception of pain, which, having a very low score in the basal period, did not experience changes with the consumption of Activia.

It is important to emphasize the fact that no adverse events were seen related to either intervention, showing the high security of the products under study, both Activia and the desserts used as a control. However, in this point we must consider the fact that one of the exclusion criteria was intolerance to dairy products or yogurt; and therefore this may make this conclusion not applicable to the general population, especially those having antecedents of intolerance to this type of products.

In conclusion, this prospective, randomized and open study shows that the ingestion of Activia can significantly improve the parameters related with bowel evacuation in women with functional constipation. The use of this simbiotic can result in a useful and safe tool for managing constipation.

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