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ORIGINAL CONTRIBUTIONS

Effects of Probiotics Supplementation on Gastrointestinal Symptoms and SIBO after Roux-en-Y Gastric Bypass: a Prospective, Randomized, Double-Blind, Placebo-Controlled Trial

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Abstract

Bariatric surgery may cause undesirable gastrointestinal symptoms due to anatomical, functional and intestinal microbiota changes.

Purpose

The aim of this study was to evaluate the effect of probiotic supplementation on gastrointestinal symptoms and small intestine bacterial overgrowth (SIBO) in patients after Roux-en-Y gastric bypass (RYGB).

Materials and Methods

This is a prospective, randomized, double-blind, placebo-controlled trial. The patients were randomized into Control Group (CG) ($n = 39$) and Probiotic Group (PG) ($n = 34$). The PG received tablets containing *Lactobacillus acidophilus* and *Bifidobaterium lactis* (5 billion CFU/strain) for 90 days, and the CG received tablets with starch. Both the Gastric Symptom Rating Scale (GSRS) questionnaire and 3-day food record were answered before surgery (T0) and after 45 days (T1) and 90 days of surgery (T2). At T0 and T2, hydrogen breath test was used to verify the presence of SIBO.

Results

The prevalence of SIBO was similar among times, and the mean score of GSRS responses did not differ between groups at any time. However, PG patients reported less bloating compared to CG, more abdominal pain at T1 (which reduced at T2), more

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episodes of soft stools and nausea and less hunger pain after surgery, with no reports of urgent episodes to evacuate, even though they consumed more fat than the CG.

Conclusions
The supplementation of *L. acidophilus* and *B. lactis* is effective in reducing bloating, but without influencing the development of SIBO in the early postoperative period.

Keywords Bariatric surgery · Probiotics · Gastrointestinal symptoms

Introduction

Roux-en-Y gastric bypass (RYGB) is the most commonly performed bariatric surgery technique in Brazil. It promotes loss of approximately 65–70% of excess weight and contributes to a significant reduction in obesity-associated comorbidities [1–4].

Despite improving the overall quality of life of individuals, RYGB has risks and some unwanted side effects. One of the unwanted side effects of surgery is the development of gastrointestinal (GI) symptoms arising from anatomical changes in the gastrointestinal tract, which causes inadequate secretion of enzymes, reduces production of hydrochloric acid by the stomach, and alters intestinal peristalsis, which changes the amount and type of bacteria intestine residents and favors the development of small intestine bacterial overgrowth (SIBO) that can trigger non-specific GI symptoms [5–7].

Previous studies have found that the use of probiotics has the potential to reduce SIBO and to improve GI symptoms after bariatric surgery [6, 7]. *Lactobacillus acidophilus* and *Bifidobacterium lactis* are strains that act on digestive functions and favor host eubiosis [8, 9]; however, their supplementation effects after RYGB have not yet been investigated.

Thus, the aim of this study was to evaluate the effect of *L. acidophilus* and *B. lactis* supplementation on the GI symptoms and SIBO in patients subjected to RYGB in the early postoperative period.

Materials and Methods

Participants

This is a prospective, randomized, double-blind, placebo-controlled trial conducted with patients undergoing RYGB in a public hospital. This study is registered in the Brazilian Clinical Trials Registry—REBEC under the RBR-4x3gqp protocol.

In this study, the power test obtained in the sample calculation based on large effect size and bilateral hypothesis was 0.9.

The inclusion criteria were adults (18–59 years old), with body mass index (BMI) ≥35 kg/m2, without immediate surgical complications, and who signed the free and informed consent form. The exclusion criteria were patients who underwent other surgical techniques or reoperation, those who used antibiotics 4 weeks before the T0, and pregnant women. Those who took antibiotics during the probiotic/placebo supplementation or who did not use the tablets for 5 days or more during the study period were withdrawn from the study.

Randomization and Treatment

Patient randomization was performed by sequencing with treatment allocation by group. Probiotics and placebo were identified as A or B, both being chewable tablets. The probiotic was FloraVantage® (5 billion *Lactobacillus acidophilus* NCFM® and 5 billion *Bifidobacterium lactis* Bi-07) from Bariatric Advantage (Aliso Viejo, CA, USA), and the placebo was an inert manipulated tablet consisting of starch and 190 mg of lactose. The tablets were requested to be taken for 90 days, once a day, starting on the seventh postoperative day, and adherence was monitored weekly by the researchers.

Clinical and Dietary Intake Assessment

The dietary orientation was the same for all patients, according to the protocol of the institution. However, as a way of controlling this variable, patients were instructed to fill out the randomized 3-day food record during the week preceding the interview of each phase. All records were carefully reviewed by a registered dietitian. The home measurements were standardized and converted to grams or milliliters according to the Food Survey Criticism Manual [10]. Data were entered into the ERICA software (Studies of Cardiovascular Risks in Adolescents) [11], and the information entered in the software was associated with the Table of Nutritional Composition of Food of the Brazilian Institute of Geography and Statistics—IBGE 2008–2009 [12] through the SPSS version 22® statistical program.

For the SIBO evaluation, the H_2 breath test was done using the H_2 Check Monitor (MD Diagnostics Ltd., Kent, UK). After 12 h of fasting, 25 g of glucose diluted in 240 ml of water was given orally to each patient [13]. SIBO was diagnosed when at the first fasting measurement, ≥20 ppm of

expired H_2 was found, or when after offering glucose substrate, in two consecutive measurements, an increase of ≥10 ppm occurred as compared to baseline [14].

To evaluate GI symptoms, the Gastric Symptom Rating Scale (GSRS) questionnaire was applied using the Likert scale (1 = no discomfort to 7 = severe discomfort) [15, 16].

Follow-up Assessments

Data collection took place in three moments: at the first meeting (T0) about 10 days before surgery, the second meeting (T1) approximately 6 weeks after surgery, and the third meeting (T2) approximately 12 weeks post-operatory. At all times, anthropometric data were collected, GSRS questionnaire was applied, and the patients were instructed to fill the food record. The H_2 breath test was performed only at T0 and T2 due to the risk of dumping symptoms in the early post-operatory period.

Statistical Analysis

For the analysis of differences between groups and at different times, the Student's t test was used for data with normal distribution, and the Mann Whitney's test was used for non-normal data. For frequency evaluation, the chi-square test was used.

In order to evaluate the association among groups, time, and the presence of SIBO, a generalized linear mixed effects model was fitted. Since the outcome is dichotomous (presence or absence of SIBO), we opted for the model with binomial response and logit link function.

A p value <0.05 was considered significant. All analyses were performed using the IBM SPSS Statistics version 22.0 software (SPSS, Chicago, IL) and R software version 3.6.1 (GLP, Auckland, New Zealand).

Results

Fifty patients were randomized to each group, of which 39 CG and 34 PG patients finished the study. The reasons for drop off are shown in Fig. 1.

Regarding baseline characteristics, age was significantly higher in the CG. All other variables analyzed were similar in both groups (Table 1).

All available 392 food records were considered for analysis: 195 from the CG and 197 from the PG. The distribution of nutrient consumption was similar in both groups, except for fiber (at T1) and lipid intake (at T2), which was respectively lower and higher in the PG (Table 1).

The presence of SIBO was similar in both groups and evolved equally during the analyzed times. At T0, 33 CG and 29 PG individuals were evaluated, and 3 patients from each group presented SIBO (9% and 10.3%, respectively). At T2, 33 CG and 27 PG individuals were evaluated, and 4 patients from each group presented SIBO (12.1% and 14.8%, respectively); however, these were different patients than the ones from T0. As a result of the likelihood ratio test, $p = 0.938$ was found associated with no interaction effect. Thus, there is no statistical evidence of a combined effect of group and time. Likewise, in the case of the interaction effect, there was no statistical significance for both the time effect ($p = 0.524$) and the group effect ($p = 0.735$).

The mean GSRS score did not differ statistically among the groups in the three analyzed periods. However, the use of *L. acidophilus* and *B. lactis* strains was associated with a change in the frequency and/or intensity of 5 of the 15 GI symptoms evaluated in PG (Table 2). At T1, the presence of abdominal pain and hunger pain was more intense and/or frequent in the PG, and at T2, bloating was less intense and/or frequent when compared with the CG (Graph 1).

Since heartburn and reflux symptoms can be difficult for patients to distinguish, both symptoms were grouped in the analysis and were named heartburn syndrome. In both groups, the incidence of this syndrome reduced after surgery.

CG patients from T1 to T2 reported fewer episodes of hard stools but more urgency to evacuate. In contrast, at T1, PG patients reported more abdominal pain as compared with T0, and from T1 to T2, the abdominal pain decreased significantly, as well as bloating symptoms. Patients from both groups also had more episodes of loose stools at all stages after surgery. At the end of 12 weeks of intervention, PG patients reported less hunger pain but more nausea when compared with T0.

Discussion

In this study, the supplementation of *L. acidophilus* and *B. lactis* after RYGB was associated with reduced bloating, without influencing the development of SIBO.

Besides altering the anatomy of the GI tract and the secretion of intestinal hormones, bariatric surgery also changes the intestinal microbiota by increasing the ratio between Bacteroidetes/Firmicutes phyla [17] and facilitating the development of SIBO [7, 18]. The use of probiotics for intestinal microbiota modulation and treatment of GI symptoms has been considered an alternative to improve the results of bariatric surgery and to minimize its adverse effects [6, 7].

SIBO has been observed as one of the causes of the development of undesirable GI symptoms after RYGB [18]. Its prevalence after RYGB has been reported to vary from 40% in asymptomatic patients and reaching up to 80–90% in symptomatic patients [13, 18, 19]. In the present study, SIBO occurred in 13.33% of the patients. This is due to changes in acidity and peristalsis of the GI tract, which favors the overgrowth of bacteria in the upper portion of the digestive system.

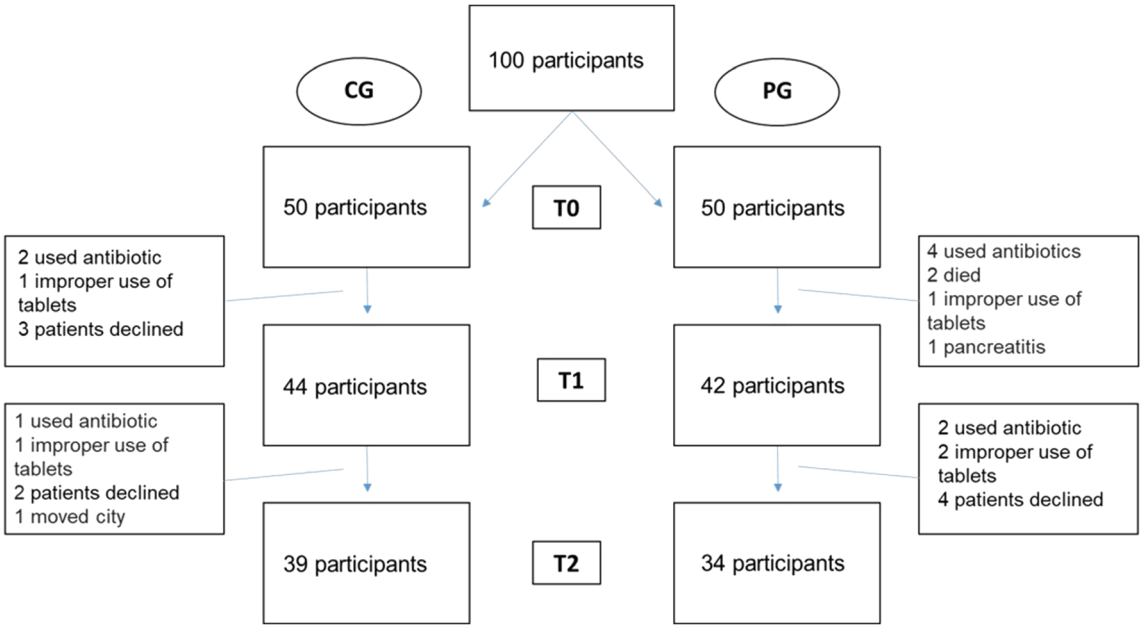


Fig. 1 Randomization and monitoring diagram of research participants. Legend: *CG* control group, *PG* probiotic group

The high fermentation of substrates by these bacteria results in gastric and intestinal discomfort and increases the patients' symptoms, as bloating, abdominal pain, nausea, or diarrhea [18]. Theoretically, *L. acidophilus* and *B. lactis* have good adhesion to the intestinal mucosa and improve intestinal motility and acidity, inhibiting the growth of pathogenic bacteria. Therefore, their supplementation could reduce SIBO as well as improve GI symptoms in patients after RYGB [8, 9]. However, the statistical similarity in the remission of cases of SIBO after surgery and the emergence of new cases in T2 in this study suggest that this might be due to the surgical procedure and not the probiotic use.

Although the protocol by Gasbarrini et al. (2009) suggests offering 50 g of glucose for SIBO verification by H_2 breath test in patients undergoing RYGB [20], it was decided to reduce the amount of glucose offered in order to avoid the development of dumping symptoms. It was known that such a change could influence the sensitivity of the test, but would not compromise its specificity [14]. This is because, in a pilot study made for this research, when offering patients 50 g doses of glucose, high rates of abdominal pain and discomfort were observed, indicating the presence of adverse effects of high-dose glucose administration in patients at risk of developing dumping syndrome—as also shown in previous studies [14, 21]. Despite the presence of 190 mg of lactose in the tablet offered to the control group, it has been shown that amounts of less than 400 mg/day of lactose in the medication do not interfere with the amount of expired H_2 or gastrointestinal symptoms [22].

Regarding the use of the GSRS questionnaire, this instrument has been developed to evaluate the effectiveness of treatments for peptic ulcer and irritable bowel syndrome, but in recent years, it has also been used as an instrument to assess GI symptoms in patients undergoing bariatric surgery [16, 23–25].

It was observed that although the intensity and/or frequency of abdominal and hunger pains were higher in PG patients at T1 when compared to CG, the use of probiotics significantly reduced hunger pain in PG patients at T2, as well as the sensation of bloated air. Bloating is considered the most common symptom related to SIBO [26]. This symptom worsens during the first year after surgery and may affect 57% of individuals after RYGB [19, 27]. Although the percentage of patients with SIBO in our study was lower than described in the literature, possibly due to the reduced sensitivity of the test with lower glucose supply, the improvement of bloating indicates the role of probiotics as agents of important changes in the local microbiota.

Similar to our findings, another study conducted with GI symptomatic patients after RYGB supplemented with *Clostridium butyricum* or *Bifidobacterium longum* has reported a reduction of bloating. However, in that study, improvements in abdominal pain, rumbling, heartburn, and burping were also observed [7]. A study with adults undergoing mechanical intestinal preparation for colonoscopy, reported improvement in abdominal pain ($p = 0.049$) among patients supplemented during 14 days with the same strains of our study [28].

The lower consumption of dietary fiber by PG at T1 may justify the presence of higher frequency/intensity of hunger pain since some types of dietary fiber may favor satiety [29].

The presence of loose stools and nausea was increased in the PG at the end of the treatment period when compared to the CG. Alteration of stool consistency with *L. acidophilus*

Table 1 Characteristics of all individual participants included in the study

Data	CG ($n = 39$)	PG ($n = 34$)	p value
Age (years)	43.3 (±10.54)	37.3 (±10.8)	0.01*
BMI T0 (kg/m^2)	42.8 (34.9–66.6)	40.6 (35.8–59.2)	0.37
T0 Weight (kg)	109.7 (80.7–160)	105.3 (±81.7–180)	0.52
% EWL T1	32.7 (±9.7)	31.3 (±9.1)	0.51
% EWL T2	49.9 (±11.8)	48.1 (±10.8)	0.51
Women (%)	89.7	88.2	0.84
T0 DM2 (%)	17.9	17.6	0.97
T0 Pre DM2 (%)	17.9	17.6	0.97
T0 Dyslipidemia (%)	59	73.5	0.24
T0 CVD (%)	5.1	5.9	0.90
T0 SAH (%)	56.4	35.3	0.06
Use of PPI T0 (%)	15.8	5.9	0.18
Use of PPI T1 (%)	36.1	38.7	0.83
Use of PPI T2 (%)	12.8	14.7	0.82
Dietary Composition at T0[a]			
Energy (Kcal)	1304.83 (1060–1686)	1444.00 (1114–2094)	0.11
Protein (g)	61.37 (43.59–8659)	70.71 (54.03–96.54)	0.11
Lipids(g)	45.60 (36.64–63.07)	51.49 (32.37–80.02)	0.25
Carbohydrates (g)	171.24 (121.7–221.7)	199.70 (125.0–241.2)	0.16
Fibers(g)	14.02 (9.37–21.87)	15.73 (11.39–20.00)	0.36
Dietary Composition at T1[a]			
Energy (Kcal)	636.62 (411.8–845.6)	572.48 (446.5–787.4)	0.87
Protein (g)	41.64 (20.91–59.54)	34.42 (24.44–52.57)	0.73
Lipids(g)	13.90 (8.63–20.27)	17.89 (10.82–22.76)	0.07
Carbohydrates (g)	80.89 (55.5–116.4)	71.77 (46.3–92.7)	0.16
Fibers(g)	6.81 (5.00–8.69)	5.55 (3.57–7.98)	0.03*
Dietary Composition at T2[a]			
Energy (Kcal)	728.48 (591.7–952.9)	793.9 (619.2–1021.6)	0.41
Protein (g)	51.92 (30.47–66.72)	57.37 (37.92–73.92)	0.15
Lipids(g)	21.06 (12.49–30.89)	26.89 (16.79–39.81)	0.02*
Carbohydrates (g)	93.08 (64.8–115.4)	72.27 (58.5–103.0)	0.08
Fibers(g)	7.79 (5.82–12.85)	7.05 (4.66–9.93)	0.12

CG control group, *PG* probiotic group, *BMI* body mass index, *EWL* excess weight loss, *DM2* type 2 diabetes mellitus, *CVD* cardiovascular disease, *SAH* systemic arterial hypertension, *PPI* proton pump inhibitor, % percentage in relation to the sample, (*n*) number of patients

*$p \leq 0.05$

[a] Values are presented in median and IQR; CG ($n = 34$), PG ($n = 30$)

and *B. lactis* supplementation has been reported in some studies, revealing their potential action to reduce constipation, prevent antibiotic diarrhea, and reduce intestinal transit time [30–34].

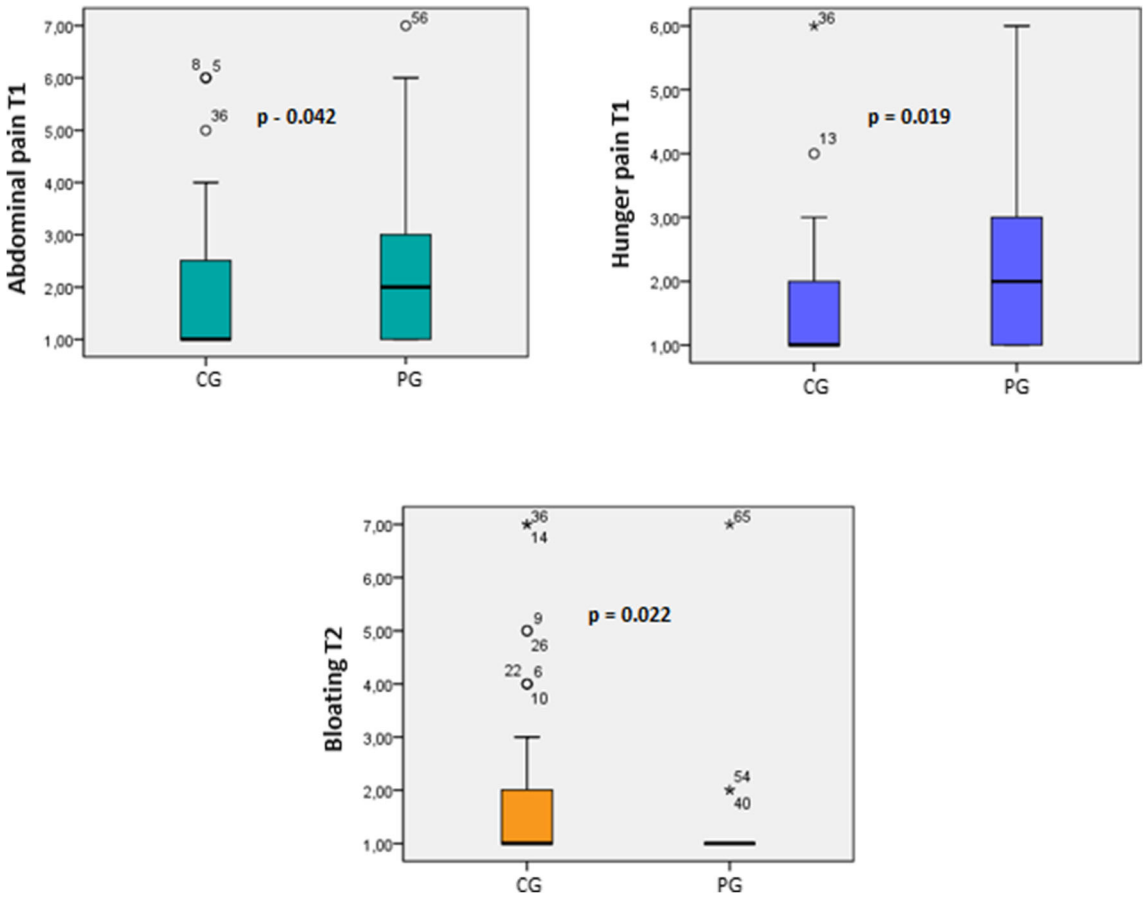
During this period, higher lipid consumption was observed in PG patients, which may also have contributed to the change in stool consistency. There was an increase in the number of episodes of urgency to evacuate between T1 and T2 in the CG, which was not significant in the PG, although there was a higher lipid consumption in the PG during this period. After surgery, the metabolism of fat is affected and may trigger episodes of steatorrhea with greater frequency and intensity [35]. The absence of reports of these episodes in the PG may be justified due to bacterial enzymatic hydrolysis, which favors the bioavailability of nutrients such as proteins and lipids, reducing GI symptoms related to malabsorption [36].

In the present study, patients already reported GI discomfort in the preoperative evaluation, statistically similar to the postoperative scores. The same was observed in another study in which patients with obesity experience more GI symptoms

Table 2 Evolution of gastrointestinal symptoms scores

Symptoms	CG			PG		
	T0	**T1**	**T2**	**T0**	**T1**	**T2**
Abdominal pain	1 (1–4)^{Aa}	1 (1–3)^{Aa}	1 (1–3)^{Aa}	1 (1–3)^{Aa}	2 (1–3)^{Bb}	1 (1–2.25)^{Aa}
Heartburn syndrome	2 (1–3)^{Aa}	1 (1–1)^{Ab}	1 (1–1)^{Ab}	2 (1–4)^{Aa}	1 (1–1)^{Ab}	1 (1–1)^{Ab}
Hunger pains	1 (1–3)^{Aa}	1 (1–2)^{Aa}	1 (1–1)^{Aa}	2 (1–4)^{Aa}	2 (1–3)^{Bac}	1 (1–2.25)^{Abc}
Nausea	1 (1–2)^{Aa}	1 (1–3)^{Aa}	1 (1–2)^{Aa}	1 (1–1)^{Aa}	1 (1–4)^{Aac}	1 (1–3)^{Abc}
Rumbling	2 (1–4)^{Aa}	3 (1–6)^{Aa}	3 (1–5)^{Aa}	2 (1–4)^{Aa}	4 (1–6)^{Aa}	2 (1–5)^{Aa}
Bloated	1 (1–3)^{Aa}	1 (1–2)^{Aa}	1 (1–2.25)^{Aa}	1 (1–4)^{Aa}	2 (1–3.5)^{Aa}	1 (1–1)^{Bb}
Burping	2 (1–4.25)^{Aa}	3 (2–6)^{Aa}	3 (1–5)^{Aa}	3 (2–5)^{Aa}	4 (2–6)^{Aa}	3 (1.7–5)^{Aa}
Flatulence	4 (3–5)^{Aa}	4 (3–6)^{Aa}	4 (2–5)^{Aa}	4 (2–6)^{Aa}	5 (3–6)^{Aa}	4 (3–6)^{Aa}
Constipation	1 (1–2)^{Aa}	1 (1–5)^{Aa}	1 (1–3.25)^{Aa}	1 (1–3)^{Aa}	1 (1–4)^{Aa}	1 (1–2.25)^{Aa}
Diarrhea	1 (1–2.25)^{Aa}	1 (1–2)^{Aa}	1 (1–2)^{Aa}	1 (1–2.5)^{Aa}	1 (1–2)^{Aa}	1 (1–3)^{Aa}
Loose stools	2 (1–4)^{Aa}	1 (1–3)^{Aa}	2 (1–3.25)^{Aa}	2 (1–3)^{Aa}	2 (1–3)^{Aa}	3 (1–5)^{Ab}
Hard stools	1 (1–2.25)^{Aab}	2 (1–5)^{Aa}	1 (1–3)^{Ab}	1 (1–3)^{Aa}	2 (1–4.25)^{Aa}	1 (1–3)^{Aa}
Urgency to evacuate	1 (1–3)^{Aab}	1 (1–2)^{Aa}	2 (1–4)^{Ab}	1 (1–4)^{Aa}	1.5 (1–4)^{Aa}	2.5 (1–5)^{Aa}
Incomplete evacuation	1 (1–3)^{Aa}	2 (1–4)^{Aa}	1 (1–4)^{Aa}	2 (1–4.5)^{Aa}	3 (1–5.25)^{Aa}	2.5 (1–4)^{Aa}
Total average of scores	2.17 (1.67–2.70)^{Aa}	2.33 (1.80–2.73)^{Aa}	2.37 (1.70–2.70)^{Aa}	2.40 (1.87–2.87)^{Aa}	2.63 (1.93–2.73)^{Aa}	2.10 (1.67–2.73)^{Aa}

Capital letters: comparison between groups at the same time. Lowercase: comparison of times in the same group. Values are presented in median and IQR. The conclusions were based on a significance level of 5%



Graph 1 Comparison of groups by dispersion of symptoms scores with significant difference. Abbreviations: *CG* control group, *PG* probiotic group. The results indicate that the PG presented less bloating in T2 and more abdominal pain and hunger pain in T1, when compared with CG

than eutrophic patients, and many of these symptoms improved after 6 months of RYGB, resembling the severity of symptoms reported by individuals without obesity [37].

In a meta-analysis of GI symptoms in individuals with obesity, symptoms such as abdominal pain, gastroesophageal reflux, diarrhea, heartburn, nausea, vomiting, and incomplete bowel movement were strongly associated with BMI, being more frequent and intense in individuals with higher BMI [38]. The etiology of such preoperative symptoms in patients with obesity has been associated with increased intra-abdominal pressure leading to chronic abdominal compartmental syndrome that can lead to symptoms similar to irritable bowel syndrome [37].

To the best of our knowledge, this is the only known study in which food intake data were evaluated, to avoid bias in patients supplemented with probiotics after RYGB, which reinforces the importance of the present study.

The absence of GI symptoms or their low frequency before and after the surgery may have contributed to the relatively low statistical difference between the groups, and this is the main limitation of this study. Because the study was performed in the early postoperative period, the greater adherence to dietary treatment observed in this period may have contributed to the low presence of GI symptoms among patients. This is because the consumption of foods that can precipitate GI symptoms and SIBO, such as excessive sugar and fat, is still prohibited at this stage [39, 40].

The use of probiotics in the treatment of SIBO and GI symptoms has shown to be effective; however, there is only a very limited amount of randomized, double-blind, placebo-controlled studies with significant number of participants that were followed since the preoperative period [41]. Conducting a similar study in a later postoperative phase, including only GI symptomatic patients, shall provide further clarifications about the effects of probiotics in GI symptoms and SIBO after RYGB.

Conclusion

The administration of *L. acidophilus* and *B. lactis* for 90 days in patients subjected to RYGB is a promising alternative for the treatment of specific GI symptoms such as bloating, but without influencing SIBO development in the early postoperative period. Further studies including symptomatic patients are needed to evaluate the effects of probiotics in GI symptoms and SIBO in a later post-operatory phase.

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Compliance with Ethical Standards

This study was approved by the Research Ethics Committee of the Pontifical Catholic University of Paraná (PUCPR) under the number 2.810.276.

Conflict of Interest The authors declare that they have no conflict of interest. The probiotics were donated by Bariatric Advantage (Aliso Viejo, CA, USA) and placebo and glucose by Dermatologica Pharmacy (Curitiba, Paraná, Brazil). The authors report non-financial support from Bariatric Advantage or Dermatologica Pharmacy. They had no influence on writing or interpreting the data.

Statement of Informed Consent The authors declare that informed written consent was obtained from all individual participants included in the study.

Statement of Human Rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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