ORIGINAL ARTICLE

Two Lactobacilli strains as adjuvant therapy in the management of irritable bowel syndrome: a randomized control trial

Dva kmeny laktobacilů jako pomocná terapie při léčbě syndromu dráždivého tračníku: randomizovaná kontrolní studie

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Summary

Alleviating the symptoms of irritable bowel syndrome (IBS) through the addition of probiotics to the treatment of IBS patients appears to be promising. The present randomized clinical trial seeks to assess the efficacy of a multi-strain probiotic product combining two Lactobacillus (L.) strains: *L. acidophilus* and *L. plantarum,* in diarrhea-predominant IBS (IBS-D) patients. A randomized, single-blinded clinical trial design was adopted to randomly assign 100 patients into two groups. Patients in group A received standard IBS treatment, whereas Group B patients were treated with probiotics besides the standard treatment. Both groups were treated for up to 12 weeks. The patients were assessed clinically by using IBS – Symptom Severity Scale (IBS-SSS) before starting the treatment and then at the end of the treatment period to evaluate the actual effect of probiotic intervention in treating IBS-D. Both treatments resulted in significant reductions in the total IBS-SSS score, but the reduction in Group B was significantly higher than in Group A. The reduction was significant in the number of days with pain, the severity of abdominal distension, satisfaction with bowel symptoms, and the effect of IBS on patients' life. The standard treatment showed a reduction of 241 points in the overall IBS-SSS score, while adding the probiotic resulted in 307 points reduction. Before treatment, all patients had severe IBS symptoms, but after treatment, 100% of patients in group B either achieved complete remission or had mild symptoms, while 14.3% of patients in group A still had moderate IBS. The patients on probiotics exhibited higher reductions in IBS-SSS overall scores as well as scores of individual sections. The probiotics also improved the severity of the disease and its symptoms when added to standard treatment. The results of this trial could support the addition of probiotics to the guidelines for managing IBS.

Key words: microbiota dysbiosis • irritable bowel syndrome • nutraceuticals • clinical trials • microbiome • probiotic

Souhrn

Zmírnění příznaků syndromu dráždivého tračníku (IBS) zahrnutím probiotik do léčby pacientů trpící tímto onemocněním se ukazuje jako slibná metoda. Cílem této randomizované klinické studie bylo posoudit účinnost probiotického přípravku kombinujícího dva kmeny Lactobacillus (L.): *L. acidophilus* a *L. plantarum* u pacientů s IBS s převahou průjmu (IBS-D). Do randomizované zaslepené studie bylo zahrnuto 100 pacientů, kteří byli rozděleni do dvou skupin. Pacientům ve skupině A byla podávána standardní léčbu IBS, zatímco pacienti ve skupině B dostávali kromě standardní léčby také probiotika. Obě skupiny byly léčeny po dobu až 12 týdnů. Pacienti byli klinicky hodnoceni pomocí škály závažnosti příznaků IBS (IBS-SSS) před zahájením léčby a poté na jejím konci tak, aby bylo možné zhodnotit skutečný účinek probiotické intervence při léčbě IBS-D. Oba typy léčby vedly k významnému snížení celkového

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skóre IBS-SSS, ve skupině B však bylo snížení výraznější ve srovnání se skupinou A. Snížení celkového skóre bylo významné v počtu dní s bolestmi, závažnosti břišní distenze, spokojenosti se střevními příznaky a vlivu IBS na život pacientů. Při standardní léčbě došlo ke snížení celkového skóre IBS-SSS o 241 bodů, zatímco přidání probiotika vedlo ke snížení o 307 bodů. Před léčbou měli všichni pacienti závažné příznaky IBS, zatímco po léčbě dosáhlo 100 % pacientů ve skupině B buď úplné remise, nebo měli mírné příznaky, zatímco 14,3 % pacientů ve skupině B mělo stále středně závažné příznaky IBS. Celkově lze konstatovat, že u pacientů užívajících probiotika došlo k většímu snížení celkového skóre IBS-SSS i skóre jednotlivých oddílů. Přidání probiotik ke standardní léčbě zlepšilo také závažnost onemocnění a jeho příznaků. Výsledky této studie by mohly podpořit zařazení probiotik do pokynů pro léčbu IBS.

Klíčová slova: microbiota dysbiosis • syndrom dráždivého tračníku • nutraceutika • klinické studie • mikrobiom • probiotika

Introduction

One of the most common functional gastrointestinal diseases is irritable bowel syndrome or IBS for short, which is characterised by recurrent abdominal pain and changes in the frequency and shape of the stool without a documented medical or biological cause[1]. The IBS prevalence is greatly diverse based on nations and areas[2]. A meta-analysis from 2012 found that the overall prevalence of IBS across different countries was 11.2%[3]. Because there are no specific biomarkers for IBS and clinical criteria are the only basis for diagnosis, the reported prevalence of IBS may vary as epidemiological data is collected[4]. In a relatively new study which utilized the Rome IV criteria, the prevalence of IBS was found to be 4.1% in the general population worldwide, while the prevalence increased to 10.1% when the Rome III criteria were applied[5]. Rome IV criteria divide IBS into three categories: diarrhea-predominant IBS, constipation-predominant IBS, and IBS with mixed bowel habits. Diarrhea-predominant IBS or IBS-D is the most common type, accounting for around a third of all IBS cases, but it tends to have more severe effects[3].

The cause of IBS is not well understood and likely involves multiple factors. Some possible causes include issues with intestinal muscle contractions, increased sensitivity to pain in the gut, changes in the immune system in the gut lining, changes in the gut microbiome, and changes in how the nervous system processes signals from the gut[6, 7]. There has been growing attention to the potential connections between these conditions[8, 9]. It is believed that imbalances in the gut microbiome may play a significant role in many of the conditions that have been described[10]. Intestinal dysbiosis, or gut microbiota dysbiosis, refers to a state in which there is an imbalance in the types and activities of microorganisms present in the intestines[10].

In the human body, the gut microflora can be regarded as a "super organ" as it influences how the nutrients are digested and absorbed. Also, it holds the responsibility for the training and functioning of immunity, inducing responses to inflammation, and for shaping the epithelial barrier of the intestines, besides the prominent role of the microbiota-gut-brain axis[11, 12]. It is important to note that the relationship between gut microorganisms, the gut, and the brain is mutual and interdependent. Dysbiosis can lead to changes in intestinal movement, abdominal pain, and overall health, while at the same time, stress can affect the intensity of pain perception in addition to its effect on the structure and function of the gut microbiome[13, 14]. For instance, multiple studies[15–17] have found substantial changes in the gut bacteria that may contribute to the onset and severity of IBS. A recent meta-analysis that focused on the molecular characteristics of gut microorganisms found that *Lactobacillus* strains were significantly less abundant in patients with IBS compared to healthy controls[17]. Moreover, subtype analysis revealed that IBS-D patients had a reduction in the colonization of *Lactobacillus* srtains, showing that these specific bacteria may play a role in maintaining a balance in the gut for individuals with diarrhea-predominant IBS (IBS-D). As a result, altering the microbiota makeup becomes especially critical in managing IBS[18, 19].

Hence, probiotic supplementation for IBS patients appears to be quite promising in this regard. Probiotics are described as living microorganisms that give considerable health benefits to the host when supplied at the appropriate dose[20]. They can ameliorate dysbiosis of the gut microbiota and decrease harmful bacterial colonization. Furthermore, while some probiotics generate an anti-inflammatory activity, others can adjust hypersensitivity of the gut or considerably increase intestinal epithelial integrity and reduce the permeability of the gut barrier[21–23]. Probiotics have been shown to improve patients' quality of life by reducing the IBS symptoms (such as abdominal discomfort or flatulence)[24, 25]. Although specialists believe that probiotics help IBS and are safe for patients, there is no single general consensus about the makeup, dose, and duration of probiotic administration[26]. A recent meta-analysis of more than thirty randomized clinical trials found that supplementing with multi-probiotic strains is superior to single-strain formulations regarding IBS symptom relief[24]. However, specialists feel that further study into the effect of probiotics is needed before probiotic supplements may be used to treat IBS. The current randomized clinical trial is aimed at evaluating the effectiveness of a probiotic product containing two Lactobacillus (L.) strains (2 billion colony-forming units (CFU) per capsule): *L. acidophilus* and *L. plantarum*, in IBS-D patients.

Methods

A randomized, single-blinded monocentric clinical trial design was adopted in this study. The study

was registered in the clinical trial registry of the US National Library of Medicine and followed the CONSORT guidelines. A total of 100 patients clinically diagnosed with IBS-D were included in this study. The randomization was performed using a web-based program, GraphPad (https://www.graphpad.com/quickcalcs/randomize1/), randomly assigning subjects into two groups. Each patient was given a sequence number starting from 1 to 100, and by using the GraphPad website, those patients were randomly assigned into two groups: either "Group A" or "Group B". A minimum sample of 90 patients (45 in each group) was considered to be necessary to detect an effect size of (0.6) with a power of 80% at a significance level of 5% using GPower 3.1.7[27].

The inclusion criteria for this study were patients clinically diagnosed with IBS by fulfilling Rome's IV criteria and aged between 16 and 55 years old. Suffering from IBS-D with pain and distension and having symptoms for at least 6 months were additional inclusion criteria. Diarrhea-predominant IBS was confirmed by asking the patients about their stool consistency at the time of diagnosis. On the other hand, patients older than 55 years old and those suffering from celiac disease, inflammatory bowel disease, thyroid disease, colonic cancer, and other systemic diseases were excluded from the study. The presence of alarming features such as anemia, blood in stool, weight loss, dysphagia, abdominal masses, and a family history of gastrointestinal cancers was also within the exclusion criteria. Lactulose intolerance and a recent history of antibiotic usage within the last three months were additional reasons to exclude patients diagnosed with IBS from being recruited in this study. Finally, a history of anxiety, depression, or other psychological disorders or using antidepressants or anxiolytics were criteria for excluding patients from participating in this trial.

Each patient was given a sequence number starting from 1 to 100, and by using the GraphPad website, those patients were randomly assigned into two groups: either "Group A" or "Group B". Patients in Group A received standard IBS treatment only (mebeverine 135 mg, sulpiride 25 mg and simethicone 200 mg, administered in a single capsule, three times daily before meals). Group B patients were treated with probiotics (two probiotic strains, *L. plantarum,* and *L. acidophilus,* were included in a capsule to be administered twice daily), each capsule contains 2 billion CFU), besides the standard treatment given to group A. In group B, standard treatment and the probiotics were started simultaneously. Both groups were treated for 12 weeks. The patients were assessed before starting the treatment and then at the end of the treatment period to evaluate the actual effect of probiotic intervention in treating IBS-D. Patient recruitment, assessment, assigning to the study groups, and prescribing treatment was carried out in an outpatient clinic for gastroenterology in Ibn Sina Teaching Hospital in Mosul in Iraq.

Patient assessment in this study was carried out using a questionnaire adapted from a study conducted in the United Kingdom[28]. The questionnaire consisted of 3 parts; Part I was to collect data about the demographic characteristics of patients, Part II comprised the IBS severity scoring system (IBS-SSS), and Part III consisted of questions to collect other IBS-related data. The collected demographic characteristics included age, gender, body mass index (BMI), marital status, educational level, employment status, monthly income, and life habits (smoking, alcohol consumption). IBS-SSS consisted of 5 main questions (severity of abdominal pain, number of days having abdominal pain in 10 days, the severity of abdominal distension, patient satisfaction with their bowel habits, and how IBS affects patient life). Each of the 5 questions of the IBS-SSS was given a score from 0 to 100 points. The questions for the severity of abdominal pain and abdominal distension had five possible options: a score of zero was assigned to no pain and no distension, respectively, and a score of 100 was for very severe pain and distension, respectively. The number of days with abdominal pain in the 10-day period was multiplied by 10 to get a 100-point score for the question. For the questions of satisfaction with bowel habits and the effect of IBS on the patient's life, there were 4 possible answers, with the answers of very happy and not at all interfering with life scoring zero and being very unhappy and completely affecting life scoring 100, respectively. The highest possible total score for the IBS-SSS was 500 points. Based on the total score, IBS can be classified into mild IBS (75–174 points), moderate IBS (175–299 points), and severe IBS (300-500 points). Those scoring less than 75 are considered healthy individuals or in remission[28]. The IBS-related information collected in Part III involved asking the patients about the consistency of the stool and if it contains blood or mucus, about the main site of their IBS-related pain, and if IBS is affecting the patient's ability to work. The questionnaire was filled out by one of the researchers while interviewing the patients. The entire questionnaire is available as a supplementary file.

Statistical analysis was performed by using SPSS (Statistical Package for the Social Sciences) version 28. Mean ± SD (standard deviation), frequency, and percentages were used for descriptive analysis, and independent samples-t-test and Chi-square test were used in the inferential analysis. A *P*-value of less than 0.05 was considered an indicator of the results' significance. Before conducting this study, ethical approval was obtained from the Collegiate Committee for Medical Research Ethics at the University of Mosul with its certificate coded CCMRE-ph-A-22-11 on 18/7/2022 and registered at the US Clinical Trials Registry (NCT05523427). Additionally, each patient in the two groups was asked to sign an informed consent and a consent to publish after explaining the aim of the study to them and before allowing them to participate. A copy of the consent is available as a supplementary file.

Results

Two patients were dropped from the study, and a final sample of 98 patients who fit the inclusion criteria participated in the study. The final sample was equally divided between the two study groups (49 patients in each group). The patients in Group A who received standard IBS treatment only were matched to those in Group B who were additionally given probiotics in terms of age, BMI, gender, marital status, education, employment, monthly income, and smoking, as indicated by the lack of significant differences in these demographic characteristics which are presented in Table 1. This matching between the two study groups was also evident in the number of weeks from last year in which the patients were absent from work due to IBS and the number of weeks when they worked despite suffering from IBS. For the 10 patients in group A and the 11 patients in group B who were unemployed, being absent from work or suffered while working meant the domestic chores that they were supposed to do.

The average overall IBS-SSS score and the scores of its individual sections for the two study groups are given in Table 2, along with the statistical differences within each group before and after treatment and between

Table 1. Patients basic demographics characteristic

Variables	Group A (Standard treatment) (n = 49)	Group B (Standard treatment + Probiotics) (n = 49)	*P*-value
Age Mean ± SD Range	 41.55 ± 8.29 22–55	 39.18 ± 10.21 17–54	0.211[1]
BMI Mean ± SD Range	 28.41 ± 3.37 17.63–37.46	 28.63 ± 3.40 22.49–35.16	0.746[1]
Gender (n (%)) Male Female	 29 (59.2) 20 (40.8)	 24 (49.0) 25 (51.0)	0.311[2]
Marital Status (n (%)) Married Single	 44 (89.8) 5 (10.2)	 39 (79.6) 10 (20.4)	0.161[2]
Education (n (%)) No Formal Education Primary Secondary University	 5 (10.2) 8 (16.3) 16 (32.7) 20 (40.8)	 6 (12.2) 4 (8.2) 12 (24.5) 27 (55.1)	0.386[2]
Employment (n (%)) Not Employed Government Private	 10 (20.4) 20 (40.8) 19 (38.8)	 11 (22.4) 23 (46.9) 15 (30.7)	0.695[2]
Monthly income (n (%)) Low (< 500 $) Medium (500–1,000 $) High (> 1,000 $)	 4 (8.2) 37 (75.5) 8 (16.3)	 6 (12.2) 34 (69.4) 9 (18.4)	0.746[2]
Smoking [n (%)] Yes No	 16 (32.7) 33 (67.3)	 17 (34.7) 32 (65.3)	0.831[2]
Absent from work (n (%)) Less than week 1 – 3 weeks More than 3 weeks	 43 (87.8) 5 (10.2) 1 (2)	 44 (89.8) 4 (8.2) 1 (2)	0.941[2]
Suffering at work (n (%)) Less than week 1–3 weeks More than 3 weeks	 13 (26.5) 31 (63.3) 5 (10.2)	 10 (20.4) 33 (67.3) 6 (12.3)	0.762[2]

[1]Independent samples-t-test
[2]Chi-square test

Table 2. IBS-SSS scores between groups

Variables	Group A (Standard treatment) (n = 49)		Group B (Standard treatment + Probiotics) (n = 49)		*P*-value[2]
	Mean ± SD	*P*-value[1]	Mean ± SD	*P*-value[1]	
Overall IBS-SSS scores		**< 0.001**		**< 0.001**	
Before treatment	369.06 ± 24.22		393.80 ± 43.93		**< 0.001**
After treatment	128.02 ± 49.07		86.41 ± 43.28		**< 0.001**
IBS-SSS: Severity score of abdominal pain		**< 0.001**		**< 0.001**	
Before treatment	75 ± 7.21		78.06 ± 10.98		0.106
After treatment	18.88 ± 12.00		17.86 ± 11.41		0.667
IBS-SSS: Number of days in the last 10 days with pain		**< 0.001**		**< 0.001**	
Before treatment	8.84 ± 1.47		8.88 ± 1.60		0.896
After treatment	3.82 ± 1.39		3.20 ± 1.00		**0.014**
"IBS-SSS: Severity score of abdominal distension"		**< 0.001**		**< 0.001**	
Before treatment	70.92 ± 10.64		85.20 ± 13.42		**< 0.001**
After treatment	26.53 ± 9.42		14.29 ± 12.50		**< 0.001**
"IBS-SSS: Satisfaction score for bowel symptoms"		**< 0.001**		**< 0.001**	
Before treatment	68.78 ± 9.40		72.98 ± 18.16		0.154
After treatment	24.24 ± 14.72		14.14 ± 16.50		**0.002**
IBS-SSS: Score of IBS affecting or interfering with life		**< 0.001**		**< 0.001**	
Before treatment	66.00 ± 0.00		68.78 ± 9.40		**0.042**
After treatment	20.20 ± 16.24		8.08 ± 14.33		< 0.001

[1]Within same group
[2]Between groups
Independent samples-t-test

Table 3. Prevalence of IBS severity and IBS symptoms

Variables	Group A (Standard treatment) (n = 49)		Group B (Standard treatment + Probiotics) (n = 49)	
	Before treatment	After treatment	Before treatment	After treatment
IBS severity (n (%))				
Remission	0 (0)	7 (14.3)	0 (0)	20 (40.8)
Mild	0 (0)	35 (71.4)	0 (0)	29 (59.2)
Moderate	0 (0)	7 (14.3)	0 (0)	0 (0)
Severe	49 (100)	0 (0)	49 (100)	0 (0)
Frequency of bowel movement (n (%))				
Once every 2–3 days	0 (0)	1 (2.0)	0 (0)	16 (32.7)
Once a day	1 (2.0)	26 (53.1)	0 (0)	32 (65.3)
2–3 times a day	44 (89.8)	22 (44.9)	34 (69.4)	1 (2.0)
4–6 times a day	4 (8.2)	0 (0)	15 (30.6)	0 (0)
Passing mucus (n (%))				
Yes	49 (100)	49 (100)	49 (100)	8 (16.3)
No	0 (0)	0 (0)	0 (0)	41 (83.7)
Having a hurry (n (%))				
Yes	29 (59.2)	23 (46.9)	41 (83.7)	10 (20.4)
No	20 (40.8)	26 (53.1)	8 (16.3)	39 (79.6)

the groups. Both treatments resulted in significant reductions in the total score, but the reduction in Group B was significantly higher than in Group A. The same level of significance in reducing the scores was also observed in the number of days with pain in a 10-day period, the severity of abdominal distension, satisfaction with bowel symptoms, and the effect of IBS on patients' life. Table 2 shows that although the two treatments were significantly able to reduce the IBS-SSS scores, but the addition of probiotics would result in a more profound positive effect on these scores. The standard treatment showed a reduction of 241 points in the overall IBS-SSS score, while adding the probiotic resulted in 307 points reduction.

Based on the overall IBS-SSS groups, all 98 patients in the two groups had severe IBS before starting the treatments. After 8 weeks of standard IBS treatment in Group A and the addition of probiotics to the standard treatment in Group B, none of the patients had a score for severe IBS. Moreover, patients in Group B had scored only for remission and mild IBS following treatment. Most patients in the two groups (89.8% in Group A and 69.4% in Group B) had 2–3 bowel movements per day before treatment. Following treatment, the majority in the two groups admitted having one bowel movement each day (53.1% in Group A and 65.3% in Group B). All the patients in the two groups admitted passing mucus with stool before treatment. This has not changed after standard treatment in Group A, but 83.7% of patients in Group B stopped passing mucus following treatment. These results are summarized in Table 3.

Discussion

The changes in the gastrointestinal function of patients suffering from IBS are mainly linked to the alteration in gut microbiota[29–32]. Additionally, the ability of probiotics to modulate gut microbiota is documented to relieve IBS symptoms, and different probiotic strains have proven their effectiveness in IBS treatment[30–33]. Therefore, this clinical trial aimed to assess the efficacy of two probiotic strains: L. plantarum and L. acidophilus in alleviating IBS symptoms.

Two strains of Lactobacilli were used in the current trial as in other studies[34, 35]. Whereas many studies around the world were conducted using a single strain of bacteria[30,36–40], probiotics of multiple- strains were also used; in the USA using three strains[41], in the Republic of Korea used six strains[42] and in Bangladesh, fourteen different bacterial strains[43] were used. The literature had contradictory results regarding the superiority of single-strain versus multi-strain probiotic treatment in IBS. Some studies, such as[44], state that a single probiotic strain is superior, while others studies have shown that multi-strain probiotic supplementation is more effective than giving a single strain[24]. However, the evidence seems to favor the multi-strain, as the mentioned article was a meta-analysis of more than 30 studies[24].

In this study, the participants were randomly assigned to either group A (receiving standard treatment only) or group B (receiving standard treatment plus the probiotics). In other studies[30, 37, 38, 41, 43, 45], the patients were assigned to either probiotic or placebo group. The use of standard treatment in the two groups in this study was based on our belief that probiotics are more of an adjuvant therapy rather than standard treatment for IBS. The two groups enrolled in this trial were comparable as no significant differences were found in all the demographic characteristics between the participants in groups A and B. Similar results were found in a Bangladeshi study[43].

IBS severity scoring system (IBS-SSS) was used in the current study to assess patients' symptoms, and it was also used in many other studies[40, 43, 46]. This scoring index appears to be the best available system for the assessment of symptom severity in IBS patients when compared to other available options[47]. Although the patients in the two groups were matched for their socio-demographic attributes, significant differences were found in the overall IBS-SSS score, severity score of abdominal distension, and score of IBS affecting or interfering with life between the two groups before treatment with higher scores in Group B. We would like to highlight that even with these significant differences in the scores before treatment, patients in Group B achieved lower after-treatment scores than those in Group A, further confirming the positive effect of probiotics on IBS.

The duration of therapy was continued for 12 weeks in studies conducted in Finland[40], France[48], and the UK[46]. The same duration was adopted in our trial. While Sun et al.[37] and Kim et al.[38] adopted only 4 weeks, and Preston et al.[41] assessed patients for 6 weeks. On the other hand, the duration of therapy was 6 months in a study by Khodadoostan et al. in Iran[45]. An analysis of the literature regarding the duration of probiotic treatment showed inconsistent findings; for example, the meta-analysis by Zhang et al.[26] concluded that a therapy duration with probiotics of less than 8 weeks is more effective than if the duration was longer than 8 weeks. However, it has been suggested that patient dropouts from studies with longer duration may be responsible for the superiority of shorter durations[49]. One study could not find significant differences between the group taking the probiotics and the placebo group until after 10 or 11 weeks of therapy[49]. Therefore, if patient's adherence could be controlled, then longer durations are probably better.

The current trial demonstrated a significant reduction in the overall IBS-SSS score and its individual sections in both groups of study, although a greater reduction was observed in the group using supplemental probiotics compared to the group using standard treatment only. This gives an indication of the potential benefits gained from adding probiotics to the treatment of IBS patients. Despite the finding that standard treatment alone was sufficient to produce significant improvement in IBS-

SSS, the benefit gained from adding probiotics was much greater. This comes in agreement with all of the evidence mentioned above on the effectiveness of probiotics in alleviating the symptoms of IBS.

Reduction of greater than 50 points in IBS-SSS scoring was considered an indication of patient improvement clinically[28]. However, a decrease of at least 95 points in the IBS-SSS score was necessary to show noticeable clinical changes in symptoms[50]. In our trial, the addition of probiotics to standard treatment resulted in 307-point reduction in the overall IBS-SSS score after 12 weeks of treatment whereas standard treatment alone reduced the score by 241 points only, and the difference between the two reductions was statistically significant. This reduction is greater than that achieved by Ishaque et al. (reduction of 145 points after 4 weeks of treatment, increased to 200 points after 16 weeks)[43]. Lyra et al. found that using a single probiotic strain resulted in only 50 points decrease in IBS-SSS after 12 weeks of treatment[40], and Sisson et al. declared a 63 points reduction in IBS-SSS scores[46].

The prevalence of IBS severity was greatly improved by using standard treatment alone or by adding probiotics with superiority to probiotics; before treatment, all patients were categorized as severe cases, and after using standard treatment alone, about 70% of patients were experiencing mild IBS and only 14% were suffering from moderate IBS. On the other hand, adding probiotics to standard treatment resulted in potential improvement of patients as about 59% had mild IBS, and 41% were in the remission stage. This gives additional support for the privilege of adding probiotics in treating IBS patients.

Before starting the treatment, approximately all patients showed either 2 to 3 or 4 to 6 bowel movements per day, and after receiving standard treatment, bowel movements ranged between 1 and 3 times per day. However, by adding probiotics, 65% of patients had one bowel movement per day, and about 33% moved their bowel once every 2 to 3 days. Thus, regarding bowel movement, both treatments were effective with a favor to probiotics. The standard treatment showed no effect on mucus passing as all patients in group A were still suffering from mucus at the end of 12 weeks of treatment. This contrasted with group B as 84% of patients showed the disappearance of mucus.

Limitations

The study has some limitations, among which the absence of microbial biomarker profile of patients. However, all the participating patients were from the same city and may have a similar microbial composition. Moreover, the sample size was relatively small, and replication with a larger sample size and a longer follow-up may be needed to make a clearer clinical conclusion. Regarding bias context, the study was single-blinded; allowing participant blinding was not possible because the two groups were treated with medications, and the effects of report bias could not be eliminated. All the data collection forms were filled by one researcher; however, efforts were made to lessen patients burden and interpretation of their symptoms. The study was well strengthened by not leaving the control patients untreated or providing them with a placebo treatment as it took into account the ethical consideration of treating a patient suffering from symptoms. As a result, abdominal pain improved significantly in both groups, with a higher rate among the investigated intervention.

Conclusions

Irritable bowel syndrome is a troublesome disorder whose pathogenesis involves a disturbance in gut microbiota. For this reason, probiotics can effectively alleviate IBS symptoms. This trial has shown the correctness of the later statement when the patients treated with probiotics alongside standard treatment experienced better responses than those given standard treatment alone. The patients on probiotics exhibited higher reductions in IBS-SSS overall scores as well as scores of individual sections. The probiotics also improved the severity of the disease and its symptoms when added to standard treatment. Therefore, the guidelines for managing IBS may need to be reviewed to include probiotics as a therapeutic rather than a supplement option. In this study, the effect of probiotics on the clinical picture of IBS was investigated. A stool analysis could be performed in the future to observe the potential of probiotics to improve dysbiosis.

This trial is conducted in accordance with the ethical principles of the Declaration of Helsinki.

Conflict of interest: none.

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