Journal of Biology and Today's World
ISSN 2322-3308
http://www.journalbio.com

Received: 02 May 2014 • Accepted: 18 June 2014

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doi:10.15412/JBTW.xxxx

Study of the Effect of Probiotic Saccharomyces Boulardii on the Treatment of Irritable Bowel Syndrome

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ABSTRACT

Irritable bowel syndrome is the most common diagnosed gastroenteric disorder incriminated for 12% of cases of referring to gastroenterologists. Various studies have shown that the intestinal microflora of the patients affected with IBS undergoes some changes. So, it seems that the recovery of intestinal flora is a useful therapeutic approach. This study investigated the effect of probiotic Saccharomyces Boulardii on improving the symptoms of IBS. This study was a randomized double-blind clinical trial conducted on 60 IBS patients. The patients were divided into two groups of 30 (case and control groups). The patients in the case group received Yomogi and those in the control group received placebo. Demographic information and symptoms as abdominal pain, flatulence, diarrhea, constipation, gurgling, eructation (belching and burping), urgent defecation, and release of gas from the anus (farting and fizzling) were collected before intervention and three weeks after initiation of treatment, and analyzed. 43.3% of the patients in the case group were male and 56.7% were female. Also, 40% of the patients in the control group were male and 60% were female. A comparison of the mean scores of abdominal symptoms in the case group before and after intervention revealed that there was a statistically significant difference between before and after intervention values for pain severity (P=0.001), flatulence ((P=0.001), diarrhea (P=0.001), gurgling (P=0.001), eructation (P=0.023), and gas release from the anus (P=0.001). Yet, there was no statistically significant difference before and after intervention for symptoms of constipation (P=0.161), and urgent defecation (P=0.09). The consumption of SaccharomycesBoulardii reduces pain severity, flatulence, diarrhea, gurgling, eructation, and gas release from the anus in patients with IBS and improves life quality.

Key words: Probiotic, Saccharomyces Boulardii, Irritable Bowel Syndrome

1. INTRODUCTION

Irritable bowel syndrome is the most common diagnosed gastrointestinal disorder incriminated for 12% of cases of patient presentation to gastroenterologists (1). This syndrome can directly or indirectly lead to increased health care expenses, this figure being estimated to be 30 million US dollars in America (2). Its prevalence is different among different countries. In some research conducted so far, the rate of incidence of IBS is said to be 10-15% on North America and 11.5% in Europe (3). Since there is no definite treatment for IBS, the current treatment modalities are more of a palliative and supportive nature (4, 5). Irritable bowel syndrome is a functional intestinal disturbance which manifests itself with symptoms as abdominal pain or problem, or a change in intestinal habits in the absence of any structural disorder. Risk factors include the female gender (two or three times more prevalent), acute gastrointestinal infections (e.g., campylobacter or salmonella), and psychological factors (5-7). Various studies have demonstrated that enteric microflora in patients with IBS sustain

some changes and the symptoms aggravate after enteric infections (8-11). Hence, it appears that the recovery of enteric microflora is an appropriate therapeutic approach. One strategy for returning normal flora is the use of probiotics (12). Probiotics are useful bacteria or yeasts taken to improve health status(12). They also act as moderators of the immune response and decrease the production of cytokines. There is some strong evidence in favor of the useful role of probiotics in preventing antibiotic-induced diarrhea, traveler's syndrome, and pediatric diarrhea (13, 14). A change in the normal flora of the colon is rendered as the main cause of pathogenesis in irritable bowel syndrome. That is why the use of probiotics for the correction of the normal flora of colon has been considered as a suitable approach and more research has been recently conducted on this issue (15, 16). However, the findings of these studies have been various and relatively contradictory (17). The aim of this study was to investigate the effect of the probiotic SaccharomycesBoulardii (Yomogi) on improving the symptoms of IBS.

2. MATERIALS AND METHODS

This was a randomized double-blind clinical trial carried out on 60 patients with IBS after receiving the approval of the Committee of Ethics at Yazd Shahid Sadoughi University of Medical Sciences and obtaining informed written consent of each patient. The patients were selected randomly using the random numbers table. The patients were divided into two groups of 30 (case group= 30, and control group = 30). The patients in the case group received Yomogi and those in the control group took placebo. Demographic information and symptoms as abdominal pain, flatulence, diarrhea, constipation, gurgling, eructation (belching and burping), urgent defecation, and farting and fizzling were collected before intervention and three weeks after initiation of treatment and analyzed. The diagnosis of IBS was made by a gastroenterologist. Based on clinical signs, symptoms, and examinations, and the required and ordered laboratory hematologic tests and biochemical profile (CBC, ESR, BUN, Cr, Na, K, S/E), the assumedly required assessments including colonoscopy, colon biopsy, Anti TTG, sonography, and stool culture were done. After selecting the patients and receiving the patient inclusion criteria, the patients randomly entered the three-week phase of treatment (SaccharomycesBoulardii vs. placebo) and were assessed at the end of the third week (at the completion of treatment). Any type of previous treatment of IBS was discontinued at the time of arrival into the study. Demographic and clinical information of the patients (age, sex, education level, medical history, pharmacologic history, and duration of affliction with IBS) were collected in a face-to-face interview with the patients. SaccharomycesBoulardii and placebo were taken in the form of capsules. SaccharomycesBoulardii capsules contained freezed yeast powder with a coating which was dissolvable in duodenum in the neutral pH. The placebo capsules were similar to Yomogi capsules except that they did not contain any Saccharomyces powder and had no coating. All the capsules could be kept in room temperature. The recommended dose of saccharomycesBoulardii for reaching the enteric colonization (10 colonies) was 1 cap qd pp (one capsule per day postprandial, i.e., following a meal). The patients were asked to score the severity of their digestive symptoms on a Likert scale containing four subscales of 0-4 points. These symptoms included abdominal pain, flatulence, urgent emptying of the bowel (defecation), diarrhea, constipation (or obstipation) gurgling, eructation (belching and burping), and gas release from the anus (farting and fizzling). The questionnaires were completed in the first and third weeks of intervention. The required data were collected from the patients via interview, recorded in checklists, and analyzed with SPSS version 15. Data were analysed by t-test and Paired samples t-tests.

3. RESULTS AND DISCUSSION

The results of the study showed that 13 (43.3%) patients under investigation in the case group were male and 17 (56.7%) were female. Also, there were 12 (40%) male and 18 (60%) female patients in the control group. There was no statistically significant difference between the two groups in terms of gender (P=0.793). Furthermore, the mean age of the patients was 37.23±16.712 years in the case group and 44.20±13.976 years in the control group which were not significantly different using the T-test (P=0.085). Comparing the mean scores of abdominal symptoms before intervention, there was no significant difference between the two groups regarding pain severity (P=0.398), flatulence (P=0.130), diarrhea (P=0.155), constipation (P=0.171), gurgling (P=0.317), eructation (P=0.599), urgent defecation (P=0.137), and gas release from the anus (P=0.225). Comparing the mean scores of abdominal symptoms after intervention, the results revealed that there was a significant difference between the two groups regarding pain severity (P=0.008), diarrhea (P=0.001), and gurgling (P=0.317). Yet, there was no significant difference between the two groups after intervention regarding flatulence (P=1), constipation (P=0.121), eructation (P=0.197), urgent defecation (P=0.630), and gas release from the anus (P=0.071) (Table 1).

Table 1. Comparison of mean scores of abdominal symptoms between the two groups after intervention

symptoms	case group		control group		F	t	p-value*
	mean	S.D	mean	S.D			
pain	1.3	0.466	1.83	0.95	23.439	-2.761	0.008
flatulence	2	0.263	2	0.455	2.320	0.000	1

diarrhea	1.7	0.466	2	0	152.25	-3.525	0.001
constipation	1.3	0.466	1	0.346	10.807	1.573	0.121
gurgling	1.3	0.466	1	0	152.25	3.525	0.001
belching and burping	1.5	0.509	1.67	0.479	3.625	-1.306	0.197
urgent defecation	1.73	0.45	1.67	0.606	5.159	0.484	0.63
farting and fizzling	1.43	0.504	1.67	0.479	2.174	-1.837	0.071

*: t-test

Comparing the mean scores of abdominal symptoms in the case group before and after intervention, the results revealed that there was a significant difference regarding pain severity (P=0.001), flatulence (P=0.001), diarrhea (P=0.001), gurgling (P=0.000), eructation (P=0.023), and gas release from the anus (P=0.001). Yet, there was no significant difference between before and after intervention regarding constipation (P=0.161), and urgent defecation (P=0.090), (Table 2).

Table 2. Comparison of mean scores of abdominal symptoms in the case group before and after intervention

symptoms	before		after		t	p-value*
	mean	S.D	mean	S.D		
pain	3.13	0.346	1.3	0.466	15/503	0.001
flatulence	2.57	0.679	2	0.263	4/572	0.001
diarrhea	2.07	0.254	1.7	0.466	4/097	0.001
constipation	1.23	0.43	1.3	0.466	-1/439	0.161
gurgling	2.67	0.844	1.3	0.466	8/411	0.001
belching and burping	1.67	0.479	1.5	0.509	2/408	0.023
urgent defecation	1.97	0.718	1.73	0.45	1/756	0.09
farting and fizzling	2.03	0.615	1.43	0.504	4/539	0.001

*: Paired samples t-tests

Additionally, comparing the mean scores of abdominal symptoms in the control group before and after intervention, the results revealed that there was a significant difference regarding pain severity (P=0.001), flatulence (P=0.005), and gurgling (P=0.001). Yet, there was no significant difference between before and after intervention regarding diarrhea (P=1), constipation (P=0.573), eructation (P=0.161), urgent defecation (P=0.662), and gas release from the anus (P=0.231) (Table 3).

Table 3. Comparison of mean scores of abdominal symptoms in the control group before and after intervention

symptoms	before		after		t	p-value*
	mean	S.D	mean	S.D		
pain	3.07	0.254	1.83	0.95	7/526	0.001
flatulence	2.33	0.479	2	0.455	3/01	0.005
diarrhea	2	0	2	0	0	1
constipation	1.1	0.305	1.13	0.346	-0.571	0.573
gurgling	2.47	0.681	1	0	11/789	0.001
belching and burping	1.6	0.498	1.67	0.479	-1/439	0.161
urgent defecation	1.7	0.651	1.67	0.606	0.441	0.662
farting and fizzling	1.83	0.648	1.67	0.479	1/233	0.231

*: Paired samples t-tests

This study investigated the effect of the probiotic Saccharomyces Boulardii on the treatment of irritable bowel syndrome. In our study, there was no significant difference in the mean scores of pain severity between the two groups before intervention while there was a difference in the mean scores of pain severity in the two groups after intervention (P=0.004). Although there was a decrease in pain severity in both groups after intervention compared to before intervention, the rate of decrease in pain severity after intervention was greater in the case group compared to the control group indicating that there was an improvement in abdominal symptoms following the consumption of Saccharomyces Boulardii. The results of improvement of abdominal symptoms are consistent with the findings of Qanaee, Kim, and Edler (18-21). In our study, abdominal pain and diarrhea were the most common IBS-related abdominal symptoms. In Serra J's study, abdominal pain was the patients' most frequent complaint (22), while in the study by Lembo T conducted on 443 patients affected with IBS, the patients' most common complaint was flatulence (60%) and 29% of the patients complained of abdominal pain (22). Comparing the mean score of diarrhea severity, the results demonstrated that there was a statistically significant difference before and after intervention in the case group (P=0.001) while there was no statistically significant difference before and after intervention in the control group comparing the mean score of diarrhea severity (P=1). This indicated that the probiotic SaccharomycesBoulardii reduced the severity of diarrhea. This is consistent with the findings of the systematic review study by McFarland, Kotowasks M, and Villarruel G (23, 24). Moreover, Szajewska H carried out a meta-analysis in 2007 aimed at studying the effect of Saccharomyces Boulardii on the treatment of diarrhea in children finding that the consumption of Saccharomyces Boulardii reduced the length of the episode of diarrhea (25). In the present study, there was a significant difference in the case group (P=0.001) and in the control group (P=0.005) regarding the rate of flatulence before and after intervention, yet, there was no significant difference between the two groups in this regard after intervention. This means that we cannot claim that only Sac-

charomycesBoulardii affected flatulence, this being consistent with the claims made by Kim & Edler. Bozzochi and Hun claimed in their study that probiotics were effective in decreasing flatulence (26, 27). Regarding constipation and urgent defecation, there was no significant difference in the case group before and after intervention. The study by Osullian aiming at investigating the effect of the probiotic lactobacillus on abdominal symptoms of IBS was conducted on 25 patients. It showed that although the symptoms of diarrhea, abdominal pain, and urgent defecation decreased after intervention compared to before intervention, the difference was not statistically significant (28). Osullivan's report on urgentdefecation was consistent with our study, yet, it was not consistent with our findings regarding diarrhea and abdominal pain.

4. CONCLUSION

The findings of this research showed that the use of saccharomycesBoulardii (Yomogi) can be effective in improving the symptoms of IBS, specifically pain severity, diarrhea, eructation, and gas release from the stomach. Considering the high prevalence of IBS and lack of effective treatment, the provision of a therapeutic modality which improves the symptoms of the disease, though to a small degree, is regarded as an important achievement. One of the limitations of our study was that we followed the patients just for three weeks. For future study and obtaining more accurate results, it is recommended that more studies with greater sample volumes and longer follow-up periods be conducted.

ACKNOWLEDGMENT

No mentioned any acknowledgment by authors.

AUTHORS CONTRIBUTION

This work was carried out in collaboration between all authors.

CONFLICT OF INTEREST

The authors declared no potential conflicts of interests with respect to the authorship and/or publication of this article.

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