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Original Research Article

Observational study to assess efficacy and safety of *Bifidobacterium longum* W11 + fructo-oligosaccharide combination in patients with irritable bowel syndrome

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ABSTRACT

Background: Irritable bowel syndrome (IBS) is a prevalent functional gastrointestinal disorder. Synbiotics, combinations of probiotics and prebiotics offer a promising therapeutic approach, particularly formulations involving *Bifidobacterium longum* W11 and fructo-oligosaccharides (FOS). To assess the improvement in global IBS symptoms compared to baseline.
Methods: A prospective, single-arm, open-label observational study was conducted involving 50 patients with IBS (predominantly IBS-D and IBS-M subtypes). Participants received a daily oral dose of *Bifidobacterium longum* W11 (5 billion CFU) and FOS (2.5 gm) for 30 days. Clinical outcomes were assessed using the irritable bowel syndrome symptom severity scale (IBS-SSS), and patient-reported stool frequency and consistency verbal feedback. Evaluations were performed at baseline, day 15, and day 30. Continuous variables are summarized using N, mean, SD, median, minimum, and maximum/range. Categorical variables were presented as number of patients and N (%) based on exposed participants.
Results: The study showed significant symptom relief; IBS-SSS scores dropped 75.6% (362.6 to 90.4, $p<0.001$) by day 30, with major improvements in abdominal pain (−93-94%), distension (−74%), bowel habit dissatisfaction (−65%), and QoL interference (−63%). Severity shifted from predominantly severe to mild/normal. Stool normalized in all patients, frequency reduced from 5 to 2 per day ($p<0.001$), and no adverse events occurred.
Conclusions: The synbiotic combination of Bifidobacterium longum W11 and FOS demonstrated significant clinical benefits by helping to reduce IBS symptoms, normalizing stool patterns, and improving quality of life over a 30-day period.

Keywords: Bifidobacterium longum W11, Fructo-oligosaccharide, IBS-SSS, Irritable bowel syndrome

INTRODUCTION

Irritable bowel syndrome (IBS) represents one of the most prevalent functional gastrointestinal disorders (FGIDs), emerging as a quintessential example of disrupted gut-brain axis communication.[1] Clinically, it is characterized by chronic or recurrent abdominal pain or discomfort in conjunction with alterations in bowel habits, encompassing diarrhea, constipation, or a combination of both. Globally, IBS is recognized as a common disorder of gut-brain interaction, with a reported prevalence approximating 10% of the population.[1,2] In an expansive epidemiological survey led by the Indian Society of Gastroenterology, nearly 3,000 individuals diagnosed with IBS and over 4,500 community participants were assessed across 18 medical centers. Notably, this investigation employed a purely symptom-based diagnostic approach, diverging from conventional use of the Rome or Manning criteria. The study reported an estimated IBS prevalence of 4.2% within the Indian population.[3]

In accordance with the Rome III criteria for bowel habit subclassification, IBS is stratified into four distinct subtypes, determined solely by stool form: IBS with constipation (IBS-C), IBS with diarrhea (IBS-D), mixed-type IBS (IBS-M), and unsubtyped IBS (IBS-U). Among these, IBS-M has emerged as the most frequently encountered clinical variant, with reported prevalence ranging from 30% to 63% across various populations.[4-6] Emerging evidence implicates several pathophysiological triggers in the onset of IBS, including small intestinal bacterial overgrowth (SIBO), post-infectious alterations within the gastrointestinal tract, and low-grade mucosal inflammation, all of which contribute to the disruption of normal gut function.[7]

The irritable bowel severity scoring system (IBS-SSS) offers a straightforward and practical tool for the clinical evaluation and longitudinal monitoring of IBS. Designed for ease of use, this scoring system facilitates standardized assessment of symptom severity, thereby streamlining both diagnosis and therapeutic follow-up. The findings to date underscore its potential utility as a valuable clinical instrument, capable of addressing the multifaceted challenges associated with managing irritable bowel syndrome.[8]

Pharmacological agents such as antispasmodics, antidiarrheals, and laxatives are frequently employed in the management of IBS; however, their long-term use is often limited by adverse effects and safety concerns.[9] Lactobacillus strains have demonstrated efficacy in reducing flatulence and improving both abdominal discomfort and global symptom scores, while Bifidobacterium species have shown anti-inflammatory effects in intestinal epithelial cells. A 12-week clinical study reported statistically and clinically significant improvements across multiple IBS-related outcomes, including IBS-SSS, IBS-QoL, abdominal pain severity, and anxiety scores.[10] Fructooligosaccharides (FOS), a well-studied class of prebiotics, are increasingly incorporated into dietary supplements and infant formulas due to their capacity to selectively stimulate the growth of Bifidobacterium species, suppress pathogenic microorganisms, and support immune function.[11] Although FOS have been proposed as a potential therapeutic for IBS, current clinical findings remain inconsistent, warranting further investigation.[12] In light of the aforementioned context, the present study was undertaken to evaluate the efficacy and safety of a synbiotic formulation comprising *Bifidobacterium longum* W11 and fructo-oligosaccharides FOS in individuals diagnosed with IBS.

METHODS

Study design

This was a prospective, single-arm, open-labelled, observational study involving patients with IBS to assess the efficacy and safety of *Bifidobacterium longum* W11 + FOS combination in patients with IBS, conducted at Liver Gastro Clinic, Shalimar Bagh, Delhi, India, from 22nd October 2024 to 24th February 2025. A written consent form was signed by all the patients. *Bifidobacterium longum* W11 and fructooligosaccharides used in the study was manufactured by Abbott Healthcare Pvt. Ltd.

Study method

The patients were orally administered with one sachet of *Bifidobacterium longum* W11 (5bn cells) and fructo-oligosaccharides (2.5 gm) for a month. At baseline (day 0), medical history, demographic details, a complete physical examination, vital signs, the IBS-SSS questionnaire, subject verbal feedback (to assess stool form and frequency), and concomitant medication usage were recorded. On day 15 (±1 day) (visit 2), assessments included vital signs, a symptom-directed physical examination, the IBS-SSS questionnaire, a subject verbal feedback (to assess stool form and frequency), study medication compliance, concomitant medication usage, and adverse events (AEs). On day 30 (±1 day), at the end-of-treatment visit, the following were assessed; study medication compliance, vital signs, a symptom-directed physical examination, the IBS-SSS questionnaire, a subject verbal feedback (to assess stool form and frequency), global tolerability (evaluated by both the patient and investigator), concomitant medication usage, and adverse events (AEs).

Ethical considerations

This study was conducted in accordance with the guidelines of good clinical practice (GCP) including archiving of essential documents, and as per the Health Authority of India. The study was approved by an ethics committee and was registered in clinical trials registry (CTRI/2024/07/070510).

Eligibility criteria

Patients aged 18-60 years, either sex, with confirmed diagnosis of IBS (IBS-D/IBS-C/IBS-M), and with no improvement in the IBS symptoms despite treatment with antispasmodics were included in this study.

Patients with severe respiratory insufficiency, organic brain damage, sleep apnea syndrome, severe, acute, or chronic hepatic insufficiency (risk of occurrence of encephalopathy), myasthenia gravis, chronic psychosis, major depressive episodes, phobic or obsessional states, or dementia, other pre-existing GI disorders, GI surgery, abnormal upper, and lower GI endoscopy finding; family history of colon cancer or inflammatory bowel disease; symptoms that discriminate lower GI organic diseases from IBS such as blood in stool, night-time symptoms that cause sleep disturbance, unintentional weight loss or change in typical IBS symptoms such as new and/or different pain; and alcohol or drug-dependency were excluded from this study.

Endpoints

The primary endpoint was to assess the improvement in global IBS symptoms compared to baseline.

The secondary endpoint was to evaluate the improvement in abdominal pain compared to baseline, proportion of patients showing improvement in abdominal distension, and proportion of patients showing normalization of stool form and frequency.

Definitions

Irritable bowel syndrome symptom severity scale (IBS-SSS)

IBS-SSS is a composite score of abdominal pain, number of days with abdominal pain, bloating/distension, satisfaction with bowel habits, and IBS-related quality of life (QoL). Each measure is rated from 0 to 100, with total scores ranging from 0 to 500. Mild, moderate and severe cases were indicated by scores of 75 to 175, 176 to 300 and >300 respectively.

Subject verbal feedback for stool form and frequency

Verbal feedback of the subjects to check the stool form and frequency.

Sample size calculation

The sample size was calculated based on detecting a clinically significant mean reduction in the IBS symptom severity scale (IBS-SSS) score from baseline to the end of treatment (day 30).

Previous studies using the IBS-SSS have reported a mean reduction of approximately 90 points as clinically meaningful, with a standard deviation (SD) of about 120 points.[8,13] Assuming a two-sided significance level (α) of 0.05 and 80% power ($1-\beta=0.80$) to detect this difference, the sample size for a paired t-test was estimated using the formula:

The sample size was calculated using the formula for comparison of paired means (paired t-test):

$$n=[\Delta(Z_{1-\alpha/2}+Z_{1-\beta})\sigma]^2$$

Where: n = required sample size

$Z_{1-\alpha/2}$ = standard normal deviate corresponding to two-sided significance level

(for $\alpha=0.05$, $Z=1.96$)

$Z_{1-\beta}$ = standard normal deviate corresponding to study power (for 80% power, $Z=0.84$)

σ = standard deviation of change from baseline (assumed 70 based on previous study)

Δ = expected mean difference to be detected

(30-point reduction in IBS-SSS score)

Calculation:

$$n = [(1.96 + 0.84)/(30/70)]^2$$

$$n = [(2.8 \times 70)/30]^2$$

$$n \approx 45$$

Accounting for dropouts, 50 subjects were planned and enrolled.

To account for potential dropouts (≈20%) and to improve statistical robustness, the final planned sample size was increased to 50 patients, which provides >95% power to detect a ≥90-point reduction in IBS-SSS scores.

Statistical analysis

The descriptive statistics for continuous variables were presented with number (N) of non-missing observations, mean, SD, median, minimum, and maximum or range. For categorical data, the descriptive statistics are presented with number of exposed patients and number (N) with percentage of observations in the various categories of the endpoint, where percentage are based on the exposed participants. All efficacy and safety endpoints will be summarized using appropriate measures. The significance of the mean changes in IBS-SSS from baseline at day 30 will be calculated by paired sample t-test. The statistical analysis included the use of a paired sample t-test to evaluate changes in IBS-SSS scores from baseline. Repeated measures comparison for stool frequency was performed using the Friedman test, followed by Wilcoxon signed-rank test for post-hoc pairwise comparisons. Descriptive statistics were also applied and summarized as mean, standard deviation (SD), median, range, and percentages. All statistical analyses were performed using IBM SPSS statistics software (version 26).

RESULTS

Demographic characteristics of the patients

A total of 50 patients were included in this study. The mean age of the patients was 40.1 years. Of these, 80% were male and 20% were female. The mean height was 167.7 cm, and mean weight was 72.1 kg, resulting in a mean BMI of 25.7 kg/m^2. The distribution of IBS types at baseline confirmed that 90% had IBS-D and 10% had IBS-M. At baseline, no patients were on concomitant medications. However, by day 15 and day 30, 90% of the patients had been prescribed concomitant medications. These results are summarized in Table 1.

Table 1: Demographic characteristics of the patients.

Parameters	No. of patients
Age (years), mean (SD)	40.1 (11.4)
Sex	
Male	40 (80.0)
Female	10 (20.0)
Height (cm), mean (SD)	167.7 (8.2)
Weight (kg), mean (SD)	72.1 (13.9)
BMI (kg/m^2), mean (SD)	25.7 (5.0)
Medical history	
IBS-D	42 (84.0)
IBS-M	5 (10.0)
Piles	2 (4.0)
Ulcer	1 (2.0)
IBS type	
IBS-D	45 (90.0)
IBS-M	5 (10.0)
Concomitant medications	
Baseline	0
Day 15	45 (90.0)
Day 30	45 (90.0)

Data given as N (%), unless otherwise specified.

Change in IBS-SSS score for each parameter from baseline to day 15 and day 30

Table 2 summarizes the irritable bowel syndrome symptom severity scale (IBS-SSS) total score significantly decreased from a baseline mean of 362.6 to 239.4 at day 15 and 90.4 at day 30, showing a 34.06% and 75.56% reduction respectively ($p<0.001$). At day 30, mean IBS-SSS score reduced more significantly when compared with baseline (362.6 versus 90.4, $p<0.001$). The mean difference was significantly higher at day 30 (-272.2) when compared to day 15 (-123.1), $p<0.001$. The percent reduction in IBS-SSS total score from baseline to day 15 was 34% and even higher at day 30 (75.5%). This depicts that *Bifidobacterium longum* W11 + fructo-oligosaccharide was effective in reducing the IBS-SSS total score within 30 days of treatment.

Table 2 also presents the analysis of the IBS-SSS scores for each parameter, showing a significant reduction in abdominal pain (68.6 versus 38.8, $p<0.001$) from baseline to day 15. At day 30, mean abdominal pain score reduced more significantly when compared with baseline (68.6 versus 5.0 $p<0.001$). The mean difference was significantly higher at day 30 (-63.6) when compared to day 15 (-29.8), $p<0.001$. The percent reduction in abdominal pain from baseline to day 15 was 44.5% and even higher at day 30 (93.2%).

Table 2: Mean change in IBS-SSS score for each parameter from baseline to day 15 and day 30.

Visit (s)	Mean	SD	LS of mean	Percent reduction	P value
IBS-SSS total score (0-500)					
Baseline	362.6	34.0	-	-	-
Day 15	239.4	37.4	-123.2	34.06	<0.001
Day 30	90.4	62.1	-272.2	75.56	<0.001
Abdominal pain intensity (0-100)					
Baseline	68.6	9.7	-	-	-
Day 15	38.8	13.2	-29.8	44.58	<0.001
Day 30	5.0	9.7	-63.6	93.29	<0.001
Abdominal pain frequency (0-100)					
Baseline	46.4	12.1	-	-	-
Day 15	20.4	7.5	-26.0	55.82	<0.001
Day 30	3.0	6.1	-43.4	94.36	<0.001
Abdominal distension/ tightness (0-100)					
Baseline	73.8	8.3	-	-	-
Day 15	49.0	11.8	-24.8	33.70	<0.001
Day 30	19.2	15.2	-54.6	74.28	<0.001
Dissatisfaction of bowel habit (0-100)					
Baseline	84.8	6.5	-	-	-
Day 15	62.8	8.8	-22.0	25.80	<0.001
Day 30	30.0	18.3	-54.8	64.91	<0.001
Interference on life in general (0-100)					
Baseline	89.0	6.8	-	-	-
Day 15	68.4	7.9	-20.6	22.97	<0.001
Day 30	33.2	19.2	-55.8	62.98	<0.001

Table 3: Changes in IBS symptoms, stool form, and stool frequency from baseline to day 30 in IBS-D and IBS-M patients.

Parameters	Group	Baseline	Day 15	Change from baseline to day 15	P value	Day 30	Change from baseline to day 30	P value
IBS-SSS Total Score (0-500)	IBS-D	365.8 (30.5)	242.4 (34.9)	−123.33	<0.001	90.7 (63.5)	−275.1	<0.001
	IBS-M	334 (53.2)	212 (51.7)	−122.00	<0.001	88 (52.6)	−246.0	<0.001
Abdominal pain intensity (0-100)	IBS-D	70 (7.7)	40 (11.1)	−30.00	<0.001	4.9 (9.4)	−65.1	<0.001
	IBS-M	56 (16.7)	28 (24.9)	−28.00	0.005*	6 (13.4)	−50.0	<0.001
Abdominal pain frequency (0-100)	IBS-D	47.1 (12)	20.7 (7.5)	−26.44	<0.001	3.1 (6.3)	−44.0	<0.001
	IBS-M	40 (12.2)	18 (8.4)	−22.00	<0.001	2 (4.5)	−38.0	0.001
Abdominal distension (0-100)	IBS-D	74.2 (7.8)	49.6 (12.1)	−24.67	<0.001	19.1 (15.6)	−55.1	<0.001
	IBS-M	70 (12.2)	44 (8.9)	−26.00	<0.001	20 (12.2)	NA	NA
Dissatisfaction of bowel habit (0-100)	IBS-D	85.1 (6.6)	63.1 (8.7)	−22.00	<0.001	30.2 (18.9)	−54.9	<0.001
	IBS-M	82 (4.5)	60 (10)	−22.00	0.004*	28 (13)	−54.0	<0.001
Interference on life in general (0-100)	IBS-D	89.3 (6.5)	69.1 (7.6)	−20.22	<0.001	33.3 (20)	−56.0	<0.001
	IBS-M	86 (8.9)	62 (8.4)	−24.00	<0.001	32 (11)	−54.0	<0.001
Stool form [n=50]	Hard and lumpy	5 (10)	1 (2)	—	—	0	—	—
	Smooth and Soft	19 (38)	45 (90)	—	—	50 (100)	—	—
	Watery	26 (52)	4 (8)	—	—	0	—	—
Stool frequency	1 time	0 (0)	0 (0)	—	—	8 (16)	—	—
	2 times	2 (4)	15 (30)	—	—	32 (64)	—	—
	3 times	8 (16)	26 (52)	—	—	10 (20)	—	—
	4 times	12 (24)	9 (18)	—	—	0 (0)	—	—
	5 times	16 (32)	0 (0)	—	—	0 (0)	—	—
	6 times	6 (12)	0 (0)	—	—	0 (0)	—	—
	7 times	5 (10)	0 (0)	—	—	0 (0)	—	—
	8 times	1 (2)	0 (0)	—	—	0 (0)	—	—
	Median (IQR)	5 (1.25)	3 (1.0)	—	—	2 (0)	—	—
	Z statistic	—	−5.810	—	<0.001	−6.133	—	<0.001

Abbreviations: IBS- irritable bowel syndrome; IBS-D- diarrhea-predominant irritable bowel syndrome; IBS-M- mixed-type irritable bowel syndrome; IBS-SSS- irritable bowel syndrome severity scoring system; M- mean; SD- standard deviation; LS- least-squares; IQR- interquartile range; NA- not available.

Abdominal pain frequency which reduced significantly (46.4 versus 20.4, p<0.001) from baseline to day 15. At day 30, mean Abdominal pain frequency score reduced more significantly when compared with baseline (46.4 versus 3.0 p<0.001). The mean difference was significantly higher at day 30 (-43.4) when compared to day 15 (-26.0), p<0.001. The percent reduction in abdominal pain frequency from baseline to day 15 was 55.8% and 94.3% at day 30.

Abdominal distension/tightness score decreased significantly (73.8 versus 49.0 p<0.001) from baseline to day 15. At day 30, mean abdominal distension/tightness score reduced more significantly when compared with baseline (73.8 versus 19.2, p<0.001). The mean difference was significantly greater at day 30 (-54.6) when compared to day 15 (-24.8), p<0.001. The percent change in abdominal distension/tightness from baseline to day 15 was 33.7% which further decreased to 74.2% at day 30.

Dissatisfaction of bowel habit score reduced significantly (84.8 versus 62.8, p<0.001) from baseline to day 15. At day 30, mean dissatisfaction of bowel habit score decreased significantly when compared with baseline (84.8 versus 30.0 p<0.001). The mean difference was significantly higher at day 30 (-54.8) when compared to day 15 (-22.0), p<0.001. The percent reduction in dissatisfaction of bowel habit reduced from baseline to day 15 (25.8%) and further decreased to 64.9% at day 30.

Interference on QoL score reduced significantly (89.0 versus 68.4 p<0.001) from baseline to day 15. At day 30,

mean interference on life in general score reduced more significantly when compared with baseline (89.0 versus 33.2 p<0.001). The mean difference was significantly higher at day 30 (-50.8) when compared to day 15 (-20.6), p<0.001. The percent reduction in interference in QoL score reduced by 22.9% at day 15 and 62.9% at day 30, from baseline. *Bifidobacterium longum* W11 + fructo-oligosaccharide significantly reduces individual IBS-SSS parameters within 30 days.

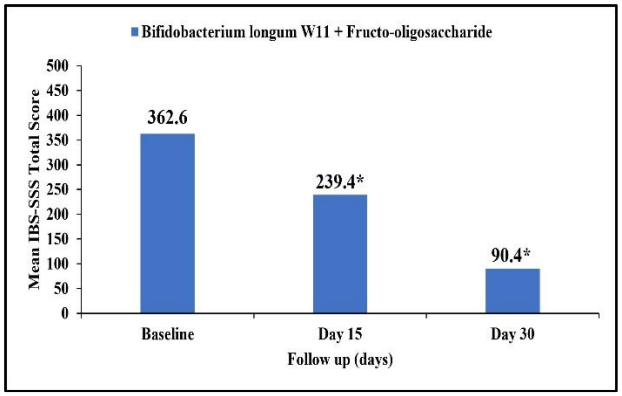

Figure 1: Mean total irritable bowel syndrome severity scoring system (IBS-SSS) score at baseline, day 15, and day 30 following treatment with *Bifidobacterium longum* W11 + fructo-oligosaccharide.

P<0.05 versus baseline.

Figure 1 depicts the mean change in IBS-SSS score between all visits which reduced significantly (362.6 versus 239.4 p<0.001) from baseline to day 15. At day 30, mean IBS-SSS score reduced more significantly when compared with baseline (362.6 versus 90.4 p<0.001).

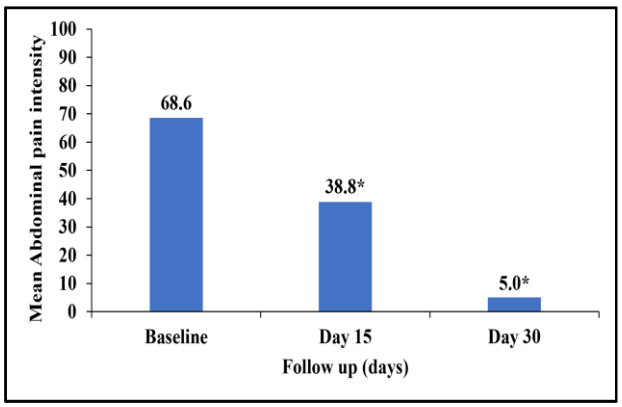

Figure 2: Mean abdominal pain intensity component of the irritable bowel syndrome severity scoring system (IBS-SSS) at baseline, day 15, and day 30 following treatment with *Bifidobacterium longum* W11 + fructo-oligosaccharide.

P<0.05 versus baseline.

Figure 2 shows the abdominal pain intensity which reduced significantly (68.6 versus 38.8, p<0.001) from baseline to day 15. At day 30, mean abdominal pain score decreased more significantly when compared with baseline (68.6 versus 5.0, p<0.001).

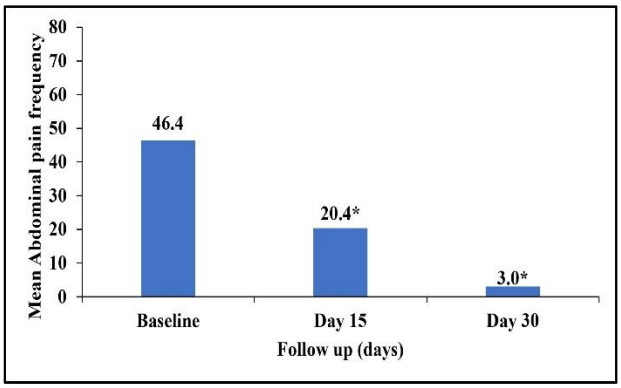

Figure 3: Mean abdominal pain frequency component of the irritable bowel syndrome severity scoring system (IBS-SSS) at baseline, day 15, and day 30 following treatment with *Bifidobacterium longum* W11 + fructo-oligosaccharide.

P<0.05 versus baseline.

Figure 3 depicts abdominal pain frequency which reduced significantly (46.4 versus 20.4, p<0.001) from baseline to day 15. At day 30, mean abdominal pain frequency reduced more significantly when compared with baseline (46.4 versus 3.0, p<0.001).

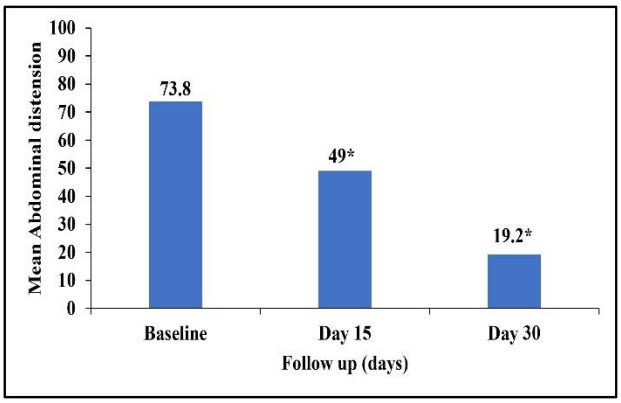

Figure 4: Mean abdominal distension component of the irritable bowel syndrome severity scoring system (IBS-SSS) at baseline, Day 15, and Day 30 following treatment with *Bifidobacterium longum* W11 + fructo-oligosaccharide.

P<0.05 versus baseline.

Figure 4 depicts mean abdominal distension which decreased significantly (73.8 versus 49.0, p<0.001) from baseline to day 15. At day 30, mean abdominal pain frequency reduced more significantly when compared with baseline (73.8 versus 19.2 p<0.001). The proportion of patients showing improvement was higher at day 30 with percent reduction of 74.2% than 33.7% reported at day 15.

Figure 5 depicts mean dissatisfaction which reduced significantly (84.8 versus 62.8, p<0.001) from baseline to

day 15. At day 30, mean abdominal pain frequency reduced significantly when compared with baseline (84.8 versus 30.0, p<0.001).

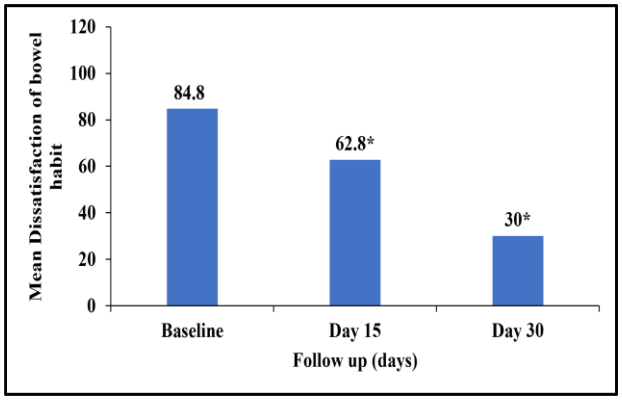

Figure 5: Mean dissatisfaction with bowel habits component of the irritable bowel syndrome severity scoring system (IBS-SSS) at baseline, day 15, and day 30 following treatment with *Bifidobacterium longum* W11 + fructo-oligosaccharide.

P<0.05 versus baseline.

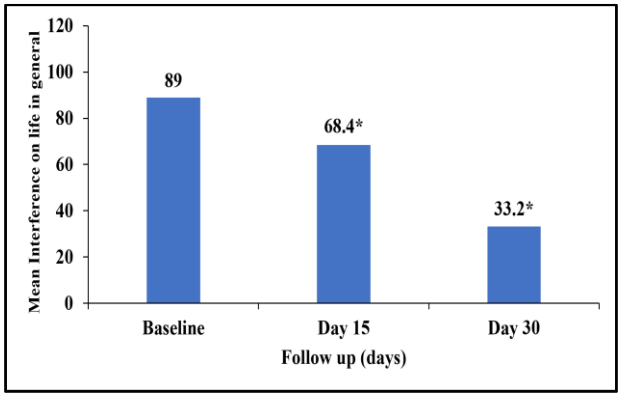

Figure 6: Mean interference with quality of life (life in general) component of the irritable bowel syndrome severity scoring system (IBS-SSS) at baseline, day 15, and day 30 following treatment with *Bifidobacterium longum* W11 + fructo-oligosaccharide.

P<0.05 versus baseline.

Figure 6 depicts mean interference on life in general which reduced significantly (89.0 versus 68.4, p<0.001) from baseline to day 15. At day 30, mean abdominal pain frequency reduced more significantly when compared with baseline (89.0 versus 33.2, p<0.001).

Symptom improvement at day 15 and day 30 in IBS M and IBS D patients

Table 3 summarizes the symptomatic improvement at day 15 and day 30. In IBS M, the abdominal pain intensity decreased from 56 at baseline to 28 at day 15 (p=0.005) and further to 6 at day 30 (p<0.001). In IBS-D, the abdominal pain intensity score reduced from 70 to 40 at day 15 (p<0.001) and to 4.9 at day 30 (p<0.001). In IBS-D, the abdominal pain frequency score reduced from 47.1 to 20.7 at day 15 (p<0.001), and further to 3.1 at day 30 (p<0.001). In IBS-M, it reduced from 40 to 18 at day 15, and further to 2 at day 30 (p<0.001). The abdominal distension reduced from 74.2 to 49.6 (p<0.001) to 19.1 at day 30 (p<0.001) in IBS-D group and in IBS-M group, the score reduced from 70 to 44 at day 15 from baseline and further decreased to 20 at day 30 in patients with IBS-M. Upon considering the dissatisfaction of bowel habits, the score reduced from 85.1 to 63.1 (p<0.001) and further to 30.2 at day 30 (p<0.001), in IBS-D group, whereas the score reduced from 82 to 60 at day 15 and further to 30.2 at day 30 (p<0.001), in group IBS-M. This showcases that this combination was effective in both IBS-M and IBM-D.

Change in IBS-SSS severity categories from baseline to day 15 and day 30

Figure 7 shows that at baseline, 96% patients reported severe IBS symptoms, which decreased to moderate (94%) followed by 4% severe and 2% mild, at day 15. At day 30, 58% patients reported normal IBS-SSS score followed by 24% mild and 18% moderate. None of the patients reported severe IBS-SSS at day 30. The *Bifidobacterium longum* W11 + fructo-oligosaccharide significantly reduced IBS severity, with no patients reporting severe symptoms by day 30 and a shift toward normal, mild and moderate symptom categories.

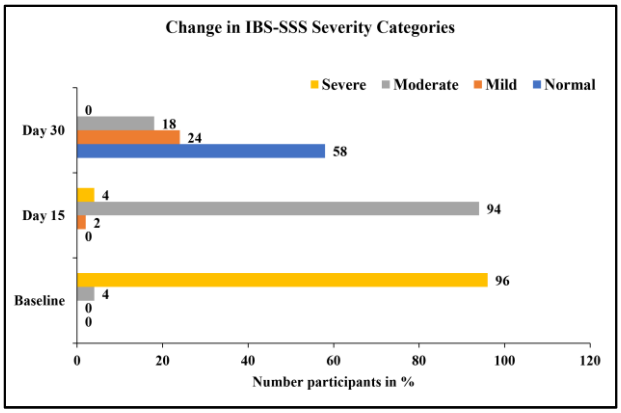

Figure 7: Distribution of participants according to IBS-SSS severity categories (normal, mild, moderate, and severe) at baseline, day 15, and day 30.

The proportion of participants with severe IBS decreased progressively over the study period, with a corresponding increase in the proportion of participants achieving normal or mild symptom severity following treatment with *Bifidobacterium longum* W11 + fructo-oligosaccharide.

Analysis of patient's stool form and frequency

Table 4 shows the analysis of patients' stool form and frequency upon verbal feedback. The majority of patients (52%) reported watery stools followed by 10% of patients reporting hard and lumpy stools at baseline, however, at day 15 and 30, around 90% and 100% of patients reported smooth and soft stools, respectively. This shows that the

gradual improvement in the stool form from baseline to day 15 and day 30 on administration of *Bifidobacterium longum* W11 + FOS.

Upon comparing the stool frequency from baseline to day 15 and day 30, it was observed that the majority of patients (32%) reported the frequency to be 5 times per day, however, at day 15 the frequency gradually reduced to thrice per day (52%) and at day 30, the frequency reduced to twice a day (64%), $p<0.001$. This shows that *Bifidobacterium longum* W11 + FOS reduced the stool frequency significantly.

No AEs or OPRIs were reported in this study.

DISCUSSION

The present prospective study evaluated the efficacy and safety of *Bifidobacterium longum* W11 + fructo-oligosaccharide combination in patients with IBS. Significant symptom relief was observed with *Bifidobacterium longum* W11 + FOS, showing an impressive reduction in IBS symptom severity, with over a 75.6% decrease in the IBS-SSS score within just 30 days. Additionally, normalization of stool consistency with smooth and soft stools was achieved in 100% of patients by Day 30, marking a major clinical improvement.

Probiotics show considerable promise in treating functional bowel disorders like IBS; however, debates continue regarding their optimal formulation, dosage, and therapeutic effectiveness.[12] A meta-analysis by Ford et al supported the effectiveness of multi-strain probiotic combinations in improving overall IBS symptoms and reducing abdominal pain.[13]

The IBS-SSS is a validated tool for quantifying symptom severity in IBS and is particularly sensitive to detecting clinically meaningful changes in moderate cases.[14] In this study, *Bifidobacterium longum* W11 + FOS reduced IBS-SSS scores by 75.6% by day 30, indicating rapid and substantial symptom relief. This improvement notably exceeds that of other probiotic studies, such as Skrzydło-Radomanska et al, where *Bifidobacterium* reduced IBS-SSS by 43.8% over 16 weeks. These findings suggest that *B. longum* W11 + FOS is a highly effective synbiotic for managing moderate-to-severe IBS, particularly in patients unresponsive to standard therapies.[12]

Abdominal pain is the main symptom used to assess IBS severity, as it closely correlates with patient-reported outcomes and healthcare use. Although symptoms like diarrhea, constipation, and bloating vary by IBS subtype, abdominal pain remains a consistent and significant marker across all types.[15-17] In this study, *Bifidobacterium longum* W11 + FOS reduced abdominal pain intensity by 93.2% and frequency by 94.3% by day 30, with improvements in distension, bowel satisfaction, and quality of life. IBS severity shifted from 96% severe at baseline to 58% normal and none severe by day 30, with benefits seen in both IBS-M and IBS-D patients and no adverse events reported. These findings align with Toporowski et al, who showed FOS improved constipation and pain, and O'Mahony et al, who reported *Bifidobacterium* reduced pain, bloating, and discomfort in IBS.[18,19]

By day 30, all patients passed soft, smooth stools with complete resolution of watery stools, and stool frequency reduced from a median of five to two times per day. Similarly, a placebo-controlled study by Okada et al showed that 25 billion CFUs of heat-killed *Bifidobacterium longum* significantly improved defecation frequency and stool consistency in constipation-prone individuals by increasing water secretion in the intestines, thus softening stools, reducing pain, and improving constipation-related quality of life.[20]

There was no placebo or comparative treatment arm, making it impossible to definitively attribute improvements to the intervention rather than placebo effect. Only 50 patients were included, limiting the generalizability and statistical power. Follow-up was only for 30 days, which may not capture long-term efficacy or safety.

Scope of the study

Future research should aim to validate these preliminary findings through larger, randomized, placebo-controlled trials with longer follow-up periods to assess the sustained efficacy and safety of the *Bifidobacterium longum* W11 and FOS synbiotic formulation.

CONCLUSION

This observational study demonstrated that the combination of *Bifidobacterium longum* W11 and fructo-oligosaccharides (FOS) is effective and well-tolerated in helping to improve symptoms in patients with irritable bowel syndrome (IBS), particularly in those with diarrhea-predominant (IBS-D) and mixed-type IBS (IBS-M). Significant and consistent reductions were observed in irritable bowel syndrome symptom severity scale (IBS-SSS) total scores, abdominal pain intensity and frequency, abdominal distension, dissatisfaction with bowel habits, and interference with daily life activities. By day 30, both IBS-M and IBS-D patients experienced notable symptom improvement, with a marked shift in IBS severity from predominantly severe to normal, mild and moderate categories. No adverse events were reported during the study.

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