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Short Communication

Individual component analysis of gastrointestinal symptom rating scale for irritable bowel syndrome in irritable bowel syndrome patients treated with *Bacillus coagulans* SNZ 1969: additional findings from a randomized, double-blind, placebo-controlled study

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ABSTRACT

This study evaluated the therapeutic efficacy of *Bacillus coagulans* SNZ 1969 (*B. coagulans* SNZ 1969) in patients with constipation-predominant irritable bowel syndrome (IBS-C) and diarrhea-predominant IBS (IBS-D). We conducted a randomized, double-blind, placebo-controlled trial in 80 patients (40 IBS-C, 40 IBS-D) who received either *B. coagulans* SNZ 1969 (500 million CFU) or placebo twice daily for 60 days. Assessments were performed at baseline and on days 30, 60, and 75. Here we present the additional findings of the individual components of Gastrointestinal Symptom Rating Scale for IBS (GSRS-IBS). Results demonstrated significant reductions in all individual components of GSRS-IBS (abdominal pain, bloating, constipation, diarrhea, and satiety) in both IBS-C and IBS-D patients treated with *B. coagulans* SNZ 1969 compared to placebo. In conclusion, *B. coagulans* SNZ 1969 found to be an effective therapeutic option for IBS, demonstrating broad efficacy across multiple symptom domains.

Keywords: *Bacillus coagulans* SNZ 1969, Gastrointestinal symptom rating scale for irritable bowel syndrome, Irritable bowel syndrome, Probiotics

INTRODUCTION

Irritable bowel syndrome (IBS) affects approximately 11% of the global population and significantly impacts patients' quality of life.[1] IBS manifests as recurrent abdominal pain associated with altered bowel habits, primarily classified as constipation-predominant (IBS-C) or diarrhea-predominant (IBS-D). While the pathogenesis is complex, growing evidence suggests altered gut microbiota plays a crucial role, leading to increased interest in probiotic interventions.[2]

Current pharmacological treatments for IBS often provide limited efficacy and associated with adverse events.[3] Probiotics, particularly *Bacillus* species, have emerged as a promising therapeutic alternative due to their ability to modulate gut microbiota and enhance barrier function.[3] Previous studies have demonstrated the benefits of various *B. coagulans* strains in IBS management. However, most studies in India have focused on either IBS-C or IBS-D exclusively, despite the known tendency of IBS symptoms to alternate between subtypes.[3]

We have previously demonstrated the overall efficacy and safety of *B. coagulans* SNZ 1969 (*B. coagulans* SNZ 1969) in patients with IBS-C and IBS-D.[2] While these findings established the broad therapeutic potential of this probiotic strain, a detailed analysis of individual symptom components from the gastrointestinal symptom rating scale for IBS (GSRS-IBS) can provide deeper insights into its specific therapeutic benefits.[2] In this communication, we present a detailed analysis of GSRS-IBS individual symptom components to better understand how *B. coagulans* SNZ 1969 specifically targets and manages IBS symptoms.

METHODS

This randomized, double-blind, placebo-controlled study was conducted at the medical gastroenterology department, Apollo hospitals, Hyderabad, India, from June 2021 to April 2022. Adult patients aged between 18 and 50 years of either sex were included in the study if they fulfilled the inclusion criteria.[2] The study included 80 patients (40 IBS-C, 40 IBS-D) who received either *B. coagulans* SNZ 1969 (500 million CFU) or placebo twice daily for 60 days. The GSRS-IBS scores were analysed across five domains: abdominal pain, bloating, constipation, diarrhea, and satiety. Assessments were conducted at baseline, day 30, 60, and 75. The study was approved by the institutional ethics committee, and informed consent was obtained from all participants. The trial was prospectively registered with the clinical trial registry of India (CTRI/2021/04/032513). Statistical analysis was performed using ANOVA and the paired t tests.

DEMOGRAPHICS

A total of 80 patients (40 IBS-C and 40 IBS-D) completed the study. The demographics of the study participants are summarized in Table 1. The mean age across groups ranges from 40.95 to 44.75 years. The majority of participants in all groups are male, with percentages varying from 60% to 75%, while females comprise the 25% to 40% of each group.

INDIVIDUAL COMPONENT ANALYSIS OF GSRS-IBS

Abdominal pain

B. coagulans SNZ 1969 demonstrated statistically significant reduction in the individual component of abdominal pain in the GSRS-IBS score compared to placebo in both IBS subtypes (Table 2). By day 75, the probiotic group showed a 39.1% reduction in patients with IBS-C (p<0.0001) and 36.8% reduction in patients with IBS-D (p<0.0001), compared to minimal changes in the placebo groups (-10.1% and -6.7% respectively).

Bloating

B. coagulans SNZ 1969 demonstrated statistically significant reduction in individual component of bloating in the GSRS-IBS score compared to placebo in both IBS subtypes (Table 2).

Probiotic group achieved 53.1% reduction in patients with IBS-C and 46.8% in patients with IBS-D by day 75 (both p<0.0001), while placebo groups showed minimal reduction (-9.9% and -8.4% respectively).

Table 1: Demographic characteristics of the study population.

Variables	IBS-C treatment group	IBS-C placebo group	IBS-D treatment group	IBS-D placebo group
Age (in years)	42.65±5.05	42.1±4.66	44.75±4.28	40.95±5.28
Sex, N (%)				
Male	14 (70.00)	15 (75.00)	15 (75.00)	12 (60.00)
Female	6 (30.00)	5 (25.00)	5 (25.00)	8 (40.00)

Table 2: Changes in individual component scores in the GSRS-IBS following the *Bacillus coagulans* SNZ 1969 treatment.

Variables		BC SNZ-1969	Placebo	BC SNZ-1969	Placebo
Abdominal pain	Baseline	11.50±1.00	11.35±0.93	10.60±0.60	11.15±0.75
	Day 30	9.40±0.82	11.30±1.03	9.90±0.85	10.70±0.57
	Δ from baseline	-2.10±0.85	-1.15±0.88	-0.90±0.50	-0.75±0.55
	% change	-18.3	-10.1	-8.5	-6.7
	P value	0.017*	-	0.402	-
	Day 60	11.10±0.64	11.35±0.99	7.20±0.77	11.10±0.64
	Δ from baseline	-4.15±0.88	-1.10±0.79	-3.40±0.75	-0.75±0.55
	% change	-36.1	-9.7	-32.1	-6.7
	P value	<0.0001***	-	<0.0001***	-
	Day 75	7.00±0.00	11.20±0.70	6.70±0.73	10.70±0.57
	Δ from baseline	-4.50±1.00	-1.15±0.81	-3.90±0.72	-0.75±0.55
	% change	-39.1	-10.1	-36.8	-6.7
	P value	<0.0001***	-	<0.0001***	-

Continued.

Variables		BC SNZ-1969	Placebo	BC SNZ-1969	Placebo
Bloating	Baseline	16.75±1.55	16.65±1.57	16.25±1.25	15.40±1.54
	Day 30	13.20±0.62	16.10±1.62	15.30±0.98	16.15±0.88
	Δ from baseline	-3.55±1.15	-2.15±1.66	-1.05±1.10	-1.25±1.12
	% change	-21.2	-12.9	-6.5	-8.1
	P value	0.0046**	-	0.5288	-
	Day 60	9.75±1.48	16.20±1.51	9.30±1.26	15.40±1.43
	Δ from baseline	-7.00±1.49	-1.35±1.39	-6.95±1.70	-1.10±0.79
	% change	-41.8	-8.1	-42.8	-7.1
	P value	<0.0001***	-	<0.0001***	-
	Day 75	7.85±0.93	15.90±1.25	8.65±1.04	15.70±1.03
	Δ from baseline	-8.90±1.45	-1.65±1.63	-7.60±1.60	-1.30±1.38
	% change	-53.1	-9.9	-46.8	-8.4
	P value	<0.0001 ***	-	<0.0001***	-
Constipation	Baseline	12.40±0.50	12.45±0.51	2.00±0.00	2.00±0.00
	Day 30	9.75±0.64	12.20±0.70	2.00±0.00	2.00±0.00
	Δ from baseline	-2.65±0.67	-0.75±0.64	0.00±0.00	0.00±0.00
	% change	-21.4	-6.0	0.0	0.0
	P value	<0.0001***	-	1.000	-
	Day 60	7.90±1.02	12.20±0.70	2.00±0.00	2.00±0.00
	Δ from baseline	-4.50±1.05	-0.75±0.55	0.00±0.00	0.00±0.00
	% change	-36.3	-6.0	0.0	0.0
	P value	<0.0001***	-	1.000	-
	Day 75	6.70±0.98	12.20±0.62	2.00±0.00	2.00±0.00
	Δ from baseline	-5.70±1.08	-0.75±0.62	0.00±0.00	0.00±0.00
	% change	-46.0	-6.0	0.0%	0.0
	P value	<0.0001***	-	1.000	-
Diarrhea	Baseline	4.50±0.69	4.35±0.67	22.85±1.69	22.90±1.62
	Day 30	4.65±0.49	4.55±0.76	19.45±2.54	23.15±2.11
	Δ from baseline	0.65±0.67	0.90±0.72	-3.40±1.50	-1.45±1.00
	% change	+14.4	+20.7	-14.9	-6.3
	P value	0.268	-	0.0002***	-
	Day 60	4.65±0.49	4.45±0.83	12.35±1.69	23.20±1.67
	Δ from baseline	0.55±0.60	0.90±0.64	-10.50±1.73	-1.60±1.39
	% change	+12.2	+20.7	-45.9	-7.0
	P value	0.085	-	<0.0001 ***	-
	Day 75	5.00±0.00	4.35±0.75	11.05±1.79	23.15±2.11
	Δ from baseline	0.60±0.60	0.70±0.66	-11.80±2.12	-1.45±1.00
	% change	+13.3	+16.1	-51.6	-6.3
	P value	0.661	-	<0.0001***	-
Satiety	Baseline	11.20±1.32	11.30±1.30	10.80±1.40	10.80±1.15
	Day 30	9.80±0.83	10.90±1.29	8.80±1.70	10.80±1.54
	Δ from baseline	-1.50±0.76	-1.80±1.20	-2.30±0.98	-0.90±0.91
	% change	-13.4	-15.9	-21.3	-8.3
	P value	0.329	-	0.0002***	-
	Day 60	7.55±0.51	10.90±1.37	6.25±0.44	11.00±1.38
	Δ from baseline	-3.65±1.27	-1.40±1.57	-4.55±1.32	-1.30±1.08
	% change	-32.6	-12.4	-42.1	-12.0
	P value	0.0001***	-	<0.0001 ***	-
	Day 75	7.35±0.49	10.90±1.52	6.05±0.22	10.80±1.54
	Δ from baseline	-3.85±1.18	-1.80±1.24	-4.75±1.45	-0.90±0.91
	% change	-34.4	-15.9	-44.0	-8.3
	P value	<0.0001***	-	<0.0001***	-

*Data presented as mean±SD. Δ from baseline represents absolute change from baseline and % change represents percentage change from baseline. Statistical significance versus placebo: *p<0.05, **p<0.01, ***p<0.001. *BC SNZ-1969=Bacillus coagulans* SNZ 1969*;* GSRS-IBD=gastrointestinal symptom rating scale for irritable bowel syndrome; SD=standard deviation.

Subtype-specific symptoms (constipation and diarrhea)

In patients with IBS-C, constipation scores decreased by 46% in treatment group versus 6% in placebo (p<0.0001). For patients with IBS-D, diarrhea scores decreased by 51.6% with treatment compared to 6.3% with placebo (p<0.0001). Reduction in subtype-specific symptoms began as early as day 30 and continued through day 75 (Table 2).

Satiety

B. coagulans SNZ 1969 demonstrated statistically significant reduction in the individual component of satiety in the GSRS-IBS score compared to placebo in both IBS subtypes (Table 2). The probiotic group showed reductions of 34.4% in IBS-C and 44.0% in patients with IBS-D (both p<0.0001).

DISCUSSION

Our detailed component analysis of GSRS-IBS scores reinforces the therapeutic potential of *B. coagulans* SNZ 1969 in IBS management, aligning with emerging evidence on probiotics as a viable option for IBS symptom modulation.[3-5] The consistent reductions observed across all GSRS-IBS domains-abdominal pain, bloating, constipation, diarrhea, and satiety-underscore the broad-spectrum efficacy of *Bacillus* species. Additionally, the significant improvements in subtype-specific symptoms (constipation in IBS-C and diarrhea in IBS-D) suggest that *B. coagulans SNZ* 1969 may act through mechanisms that normalize gut motility and secretory functions, a finding consistent with prior studies on Bacillus species demonstrating their ability to modulate intestinal transit and visceral hypersensitivity.[6,7]

The sustained symptom relief observed through day 75 post-treatment is clinically noteworthy. While short-term efficacy of probiotics in IBS is well-documented, the durability of effects beyond the intervention period remains understudied (Ford et al). Our results mirror those of Majeed et al, who reported prolonged benefits of *B. coagulans* MTCC 5856 in IBS-D patients.[8] The spore-forming nature of *B. coagulans* SNZ 1969 may similarly enhance its survival through the gastrointestinal tract, enabling sustained microbial modulation and metabolite production (e.g., short-chain fatty acids), which are critical for maintaining gut barrier integrity and reducing inflammation.[3,9]

The pronounced reduction in bloating (53.1% in IBS-C, 46.8% in IBS-D) aligns with mechanistic studies linking *Bacillus* strains to decreased gas production via inhibition of hydrogen sulfide-producing bacteria and enhanced carbohydrate fermentation.[10-12] Furthermore, the comparable efficacy in both IBS subtypes challenge the conventional approach of subtype-specific therapies, suggesting *B. coagulans SNZ* 1969 could serve as a universal probiotic for IBS, irrespective of bowel habit predominance. This adaptability may stem from its bifunctional impact on gut motility-ameliorating constipation through butyrate-mediated stimulation of peristalsis and alleviating diarrhea via tightening of epithelial junctions.[9,13,14]

Our findings are also consistent with the Rome IV guidelines, which emphasize the need for therapies targeting multiple IBS symptoms.[15] The significant improvements in satiety (34.4-44.0%) further highlight the strain's potential to address extra-intestinal symptoms, possibly by modulating gut-brain axis signalling pathways.[16]

While our study provides compelling evidence, there are a few limitations as well. The sample size, though adequate for detecting treatment effects, may limit generalizability.[2] Additionally, the absence of microbiome or metabolomic data precludes mechanistic insights into how *B. coagulans SNZ* 1969 alters gut ecology. Future studies should incorporate multi-omics analyses to elucidate strain-specific interactions and validate its effects in diverse populations. Long-term trials lasting more than six months can help establish durability and safety.

CONCLUSION

In conclusion, B. *coagulans* SNZ 1969 demonstrates comprehensive efficacy across IBS symptom domains, supported by sustained and subtype-agnostic benefits. These findings position it as a promising candidate for integrative IBS management, bridging the gap between symptom-specific therapies and holistic gut microbiota modulation.

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