LactoSpore®

For the management of irritable bowel syndrome

Sabinsa

Probiotics have long been employed by cultures and traditions, consumed in food, and used as medicine, and are considered to be an integral part of nutritional supplements. Knowledge of the human microbiome has greatly improved, with researchers focusing on the role of microbiota in our health. Microorganisms living in our gut are thought to affect not only our gut health but also other parts of the body. Studies are now investigating the gut–brain axis, which is best understood as a bi-directional pathway of communication between the gut microbiota and the brain, particularly with regard to its cognitive and emotional functions [1].

Stress plays an important role in gut physiology, and in irritable bowel syndrome (IBS) affects motility, visceral perceptions, gastrointestinal (GI) tract permeability and secretion with consequent negative impacts on microbiota [2].

Here we consider how gut health in IBS, a health condition greatly influenced by gut–brain communication, may be improved by probiotic supplementation with LactoSpore®.

Composition and technical specifications

Bacillus coagulans MTCC5856 is an FDA GRAS probiotic strain [3] which has been studied for its possible health benefits including in patients with IBS-D (IBS related to diarrhoea). LactoSpore® is a patented and trademarked probiotic strain containing spores of *B. coagulans* MTCC5856 and is produced by Sabinsa Corporation at its dedicated biotech facility in India.

As a spore-forming strain, *B. coagulans* MTCC5856 is stable at room temperature for 3 years. It is available in strengths of 6 billion CFU/g and 15 billion CFU/g, and is GMO free, dairy free, gluten free and antibiotic free.

Table 1 gives the technical specifications of LactoSpore®.

Efficacy and safety

A double-blind placebo controlled multi-centre study was conducted to evaluate the safety and efficacy of *B. coagulans* MTCC 5856 in IBS-D [4].

A total of 36 patients newly diagnosed with IBS-D were randomized into two groups and administered a single daily dose of 2 billion CFU/g LactoSpore® in tablet form or placebo, along with standard care for 90 days. The primary end points in both groups were clinical symptoms of IBS-D such as bloating, vomiting, abdominal pain, diarrhoea and stool frequency. The safety of LactoSpore® as a supplement was also assessed by physical examinations and measuring vital

Organoleptic properties	
Appearance	Powder
Colour	White to off-white
Odour	Mild characteristic
Physical properties	
Solubility	Slightly soluble in water, insoluble in methanol
Lactic acid-producing capacity	>10 ml of 0.05 N NaOH is consumed
Loss on drying (% w/w)	<8.0%
Sieve test	
20 mesh	>100%
40 mesh	>95%
80 mesh	>90%
Microbiological properties	
Other aerobic microorganisms (CFU/g)	<0.1 million
Total yeasts and moulds (CFU/g)	<100
Escherichia coli	Negative/10 g
Salmonella	Negative/10 g
Staphylococcus aureus	Negative/10 g
Pseudomonas aeruginosa	Negative/10 g
Bile-tolerant gram-negative bacteria (CFU/g)	<100
Coliforms (CFU/g)	>10
Assay	
Bacillus coagulans viable spore count	>15,000 million spores/g
Shelf life	3 Years
Storage	Room temperature

Table 1 - Technical specification for LactoSpore® (15 billion CFU/g)

signs. The secondary outcomes or end points were evaluated using physician assessment of disease severity and a 34-item IBS quality-of-life (QOL) questionnaire.

The results of the clinical study showed that supplementation with LactoSpore® at a dose of 2 billion CFU/day in a single serving administered for 90 days resulted in significant improvement in the symptoms associated with IBS-D (Figs. 1 and 2) such as bloating, diarrhoea, stool frequency, abdominal pain and vomiting as compared to the placebo group. The physician global assessment scale and the QOL questionnaire also showed that LactoSpore® supplementation mitigated the clinical symptoms of IBS. No significant adverse events were recorded and supplementation with LactoSpore® was found to be safe in both groups. Biochemical and histological examination before and after treatment showed no significant changes, suggesting LactoSpore® supplementation was safe in IBS-D patients.

The study concluded that LactoSpore® supplementation resulted in a positive outcome in patients with IBS-D and receiving standard care.

This clinical study also opens the door for assessment of the role of *B. coagulans* in the management of gut–brain axis disregulation such as in IBS. Further findings accepted for publication support its role in IBS and its positive health effects.

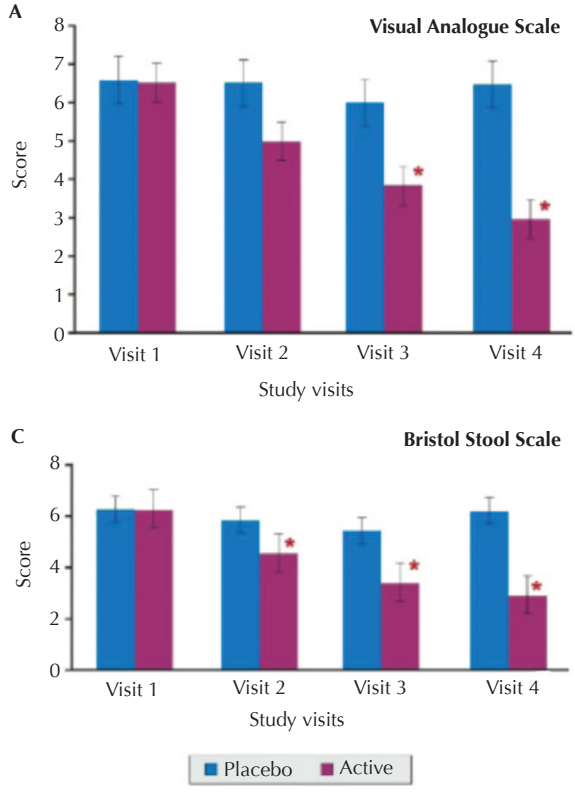

Figure 1 - Visual analogue scale (mean ± S.E) for abdominal pain and Bristol stool score for stool frequency in patients with irritable bowel syndrome and supplemented with either LactoSpore® or placebo and receiving standard care.
*$p < 0.01$ between placebo and active groups

Applications and use

LactoSpore® at a dosage of 2 billion CFU/serving/day was found to be safe and effective in the management of IBS-D [4].

As an FDA GRAS ingredient, it can be formulated in a variety of functional foods, while in Canada it is has been accepted as a Natural Health Product (NHP) ingredient.

The MTCC5856 strain has shown remarkable resistance against the processing required to produce some foods and supplementation formulations and so can be used in various processed foods [5] such as juices, gummy sweets, coffee, tea, confectionery and vegetable oils.

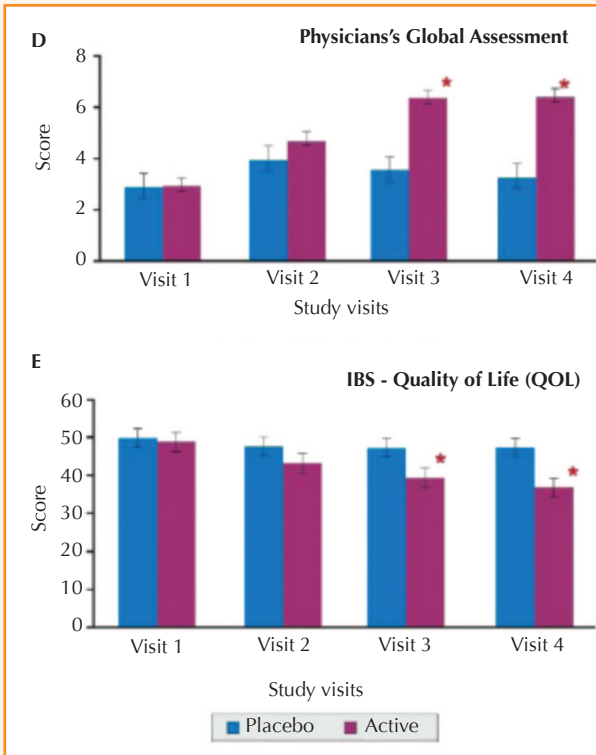

Figure 2 - Physician's global assessment and IBS quality-of-life score (mean ± S.E) in patients with irritable bowel syndrome (IBS) and supplemented with either LactoSpore® or placebo and receiving standard care.
*$p < 0.01$ between placebo and active groups

LactoSpore® Health Claims

Several published studies on *B. coagulans* have supported a variety of structure/function claims for the GI tract and microflora. The clinical study discussed above supported the health claim in Canada that the *B. coagulans* MTCC5856 strain as an NHP related to IBS 'helps relieve the abdominal pain associated with IBD at a dosage of 2 billion CFU/day'.

REFERENCES

1. Carabotti M *et al* (2015) The gut-brain axis: interactions between enteric microbiota, central and enteric nervous systems. Ann Gastroenterol 28:203–209
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3. FDA (2015) GRAS Notice (GRN) No. 601. https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM476927.pdf
4. Majeed M *et al* (2016) *Bacillus coagulans* MTCC5856 supplementation in the management of diarrhea predominant irritable bowel syndrome: a double blind randomized placebo controlled pilot clinical study. Nutr J 15:21
5. Majeed M *et al* (2016) Evaluation of stability of *Bacillus coagulans* MTCC 5856 during processing and storage of functional foods. Food Sci Technol 51(4):894–901

Sabinsa in a nutshell

Sabinsa's mission is to provide alternative and complementary natural products for human nutrition and well-being. Since 1988, Sabinsa has brought to market more than 100 standardized botanical extracts, and privately funded clinical studies in conjunction with prestigious institutions in support of these products. With more than 120 full-time scientists conducting ongoing research in India and the United States, Sabinsa continues to develop and patent phytonutrients for world markets. Products intended for human consumption are certified kosher and halal.

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