A multistrain probiotic in patients with irritable bowel syndrome with predominant constipation

AIT ABDELLAH, Samira[1], DAUCHET, Quentin[1], BLONDEAU, Claude[1], HOCHET, Xavier[1], BOCANDE, Emmanuelle[1], PERLEMUTER, Gabriel[2,3]

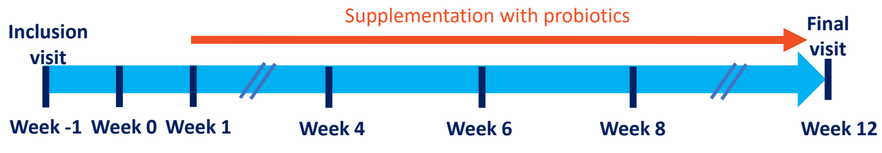
[1] PiLeJe Laboratoire, Paris, France; [2] Antoine-Béclère Univ. Hospital, AP-HP, Hépato-gastroentérologie et Nutrition, Clamart, France; [3] Univ. Paris-Saclay, Inserm U996, Inflammation, Microbiome and Immunosurveillance, Clamart, France; s.aitabdellah@pileje.com

OBJECTIVE

To assess symptom outcome in patients with irritable bowel syndrome with predominant constipation (IBS-C) during a 12-week supplementation with a multistrain probiotic, Lactibiane Référence® (PiLeJe Laboratoire)

Supplementation

- **Lactibiane Référence®** (PiLeJe Laboratoire) comprises 4 strains: *Bifidobacterium longum* LA101, *Lactobacillus helveticus* LA102, *Lactococcus lactis* LA103, and *Streptococcus thermophilus* LA104
- **Regimen:** all patients received 1 capsule of $10x10^9$ CFU per day for 84 days (12 weeks).



Evaluation with IBS-SSS (irritable bowel syndrome-severity scoring system), pain VAS, SF-12 questionnaire (quality of life), Bristol stool scale, stool frequency

Inclusion criteria

- Men and women ≥18 and ≤65 of age with IBS-C according to Rome IV criteria
- IBS-SSS score ≥175 (IBS moderate or severe);
- Abdominal pain score ≥40 on the corresponding IBS-SSS item over the last 10 days
- Significant impact of abdominal pain/discomfort on daily life over the last 10 days (score ≥2 on a 5-point Likert scale from 0: no impact to 5: extreme impact)

Non-inclusion criteria

- Woman pregnant, breast-feeding or planning to become pregnant during the study
- Proven food intolerance or allergy
- BMI < 18.5 kg/m² or BMI > 35 kg/m²
- Diagnosis or known history of IBS-D, IBS-M, or unclassified forms of IBS, or other gastrointestinal pathologies
- With current first- or second-line treatment for IBS-C (including probiotics)
- Use or wishing to use alternative treatments
- Treatment likely to affect visceral sensitivity or intestinal transit
- Intention to change diet or lifestyle
- Excessive alcohol consumption or smoking
- Having undergone or wishing to undergo bariatric surgery
- Have any known pathologies likely to affect intestinal transit or absorption
- Deviant eating habits
- Intake of antibiotics in the 3 months prior to inclusion.

RESULTS

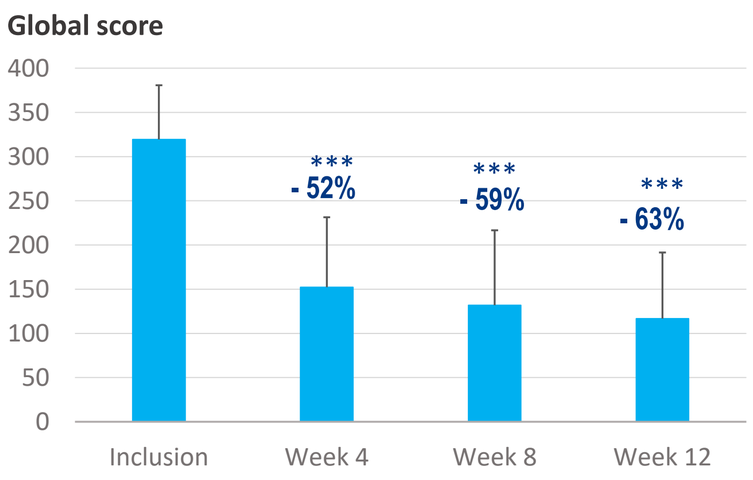
1 Patient characteristics at baseline

- **Intent-to-treat (ITT) population = 73**
- Per-protocol (PP) population = 67

ITT population:
86.3% female; mean age 41.2 ± 11.8 years

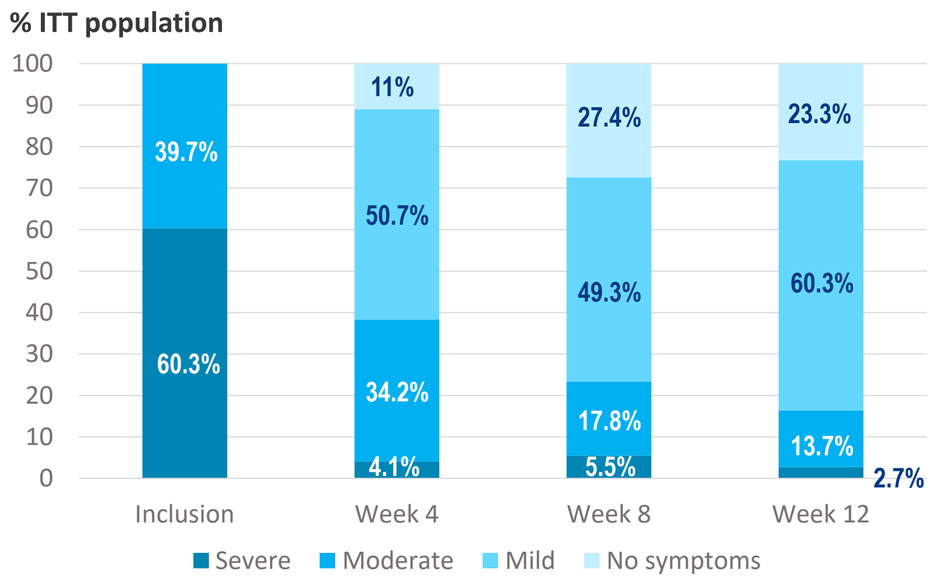
2 Significant decrease in IBS-SSS score

IBS-SSS score was reduced by more than half from Week 4, a reduction that was observed and increased at Weeks 8 and 12 (*** p<0.0001)



Clinically relevant results were: ≥95-point decrease in IBS-SSS score and ≥30% decrease in abdominal pain in 80-90% of patients at all three time points

3 Significant decrease in IBS severity

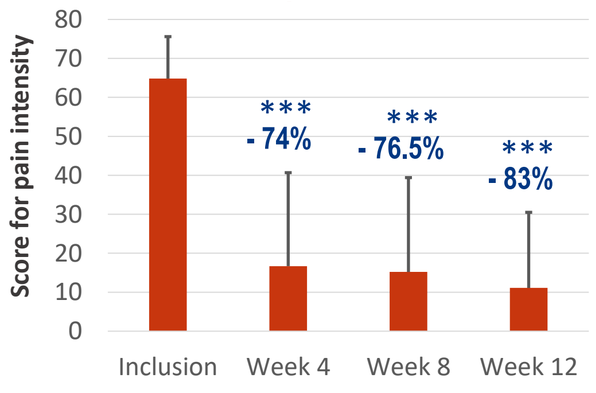


Severity according to IBS-SSS score (points):
- 0-75: no symptoms
- 75-175: mild
- 175-300: moderate
- 300-500: severe

p<0.0001 for Week 4, 8 or 12 versus inclusion

4 Significant decrease in abdominal pain (VAS)

Significant decrease in pain intensity
***** p<0.0001**



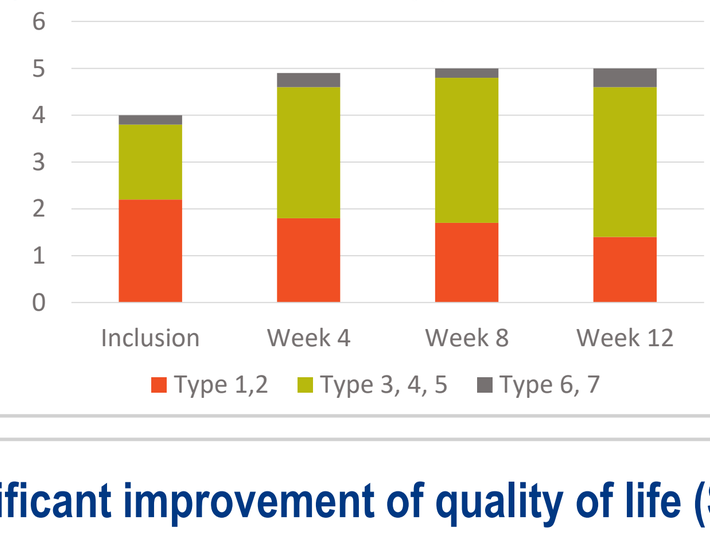
Significant decrease in no. of days with pain over previous 10 days
***** p<0.0001**

And significant decrease in distension intensity (p<0.0001) and in dissatisfaction with bowel function (p<0.01)

5 Significant change in stool frequency and consistency

- Significant increase in the number of stools per week from 5 ± 4 at inclusion to 6.6 ± 4.1, 6.5 ± 3.7, and 6.7 ± 4.1 at Week 4, 8, and 12, respectively (p<0.0001)
- Significant improvement of stool consistency (Bristol stool scale):

Significant decrease in the number of type 1,2 stools (p<0.05 *versus* inclusion)



Significant increase in the number of type 3,4,5 stools (p<0.0001 *versus* inclusion)

6 Significant improvement of quality of life (SF-12)

	Inclusion	Week 4	Week 8	Week 12
Physical condition score	49.3 ± 7	49.8 ± 6.6	52.1 ± 5.2 **	52.4 ± 6.4 **
Mental condition score	41.1 ± 9.2	44 ± 8.9 ***	44.9 ± 8.2 ***	46.4 ± 8.4 ***

** p<0.001, *** p<0.0001 *versus* inclusion

7 Satisfaction and tolerance

- ≥80% patients reported a slight to marked improvement in their intestinal problems at all three time points
- The majority of patients were satisfied to very satisfied with supplementation
- Supplementation was well tolerated

CONCLUSION

Supplementation for one month with the multistrain probiotic in patients with IBS-C produced significant benefits, which were maintained and reinforced over the following two months.