

**TREATMENT OF IRRITABLE BOWEL SYNDROME
DOUBLE BLIND TRIAL OF *SACCHAROMYCES BOULARDII****

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Irritable bowel syndrome, «spastic colon», «functional colitis» are the terms most widely used to describe a polymorphous symptomatology which runs a chronic course and where no specific lesional etiology can be incriminated. The most common symptoms, present in various combinations, are poorly defined abdominal pain, disturbed intestinal transit, diarrhoea or constipation, dyspepsia, distension, etc. Amongst the multiple factors responsible for such problems, imbalance in the digestive micro-flora and more widely, the whole of the «intestinal ecosystem» has often been discussed (1, 2).

Amongst the large number of treatments most frequently used, sometimes empirically, *Saccharomyces boulardii* is widely prescribed, providing valuable therapeutic benefit in such patients. The active principle of *Saccharomyces boulardii* consists of living cells of a special strain of *Saccharomyces boulardii*. Free of toxicity, this preparation has been found experimentally to have a stabilizing effect on the intestinal flora (3, 4), an action which has been confirmed in human clinical use (5, 6).

The present study was thus aimed at confirming by a double-blind control trial the efficacy of *Saccharomyces boulardii* in this pathology.

MATERIAL AND METHODS

This clinical trial was carried out in three centers, using the double-blind method against placebo, with prior randomization.

Criteria for selection of patients

Patients of both sexes and aged over the age of 18, suffering from an irritable bowel syndrome symptomatology, with abdominal pain, distension and episodes of diarrhoea, were included in the trial. All patients with a diagnosed organic disorder were obviously excluded.

Randomization and treatment

A randomization table was drawn up before the trial was started. Batches of treatment were then attributed according to this table as the patients were included in the trial after their initial assessment. Batches of active preparation of placebo were identical, indistinguishable by either physician or patient.

The duration of treatment was one month at a dose of three capsules morning, noon and evening, taken with meals.

No associated treatment with an influence on the intestinal flora, secretions or motility of the digestive tract was allowed with the exception of mebeverine hydrochloride. Diet was unrestricted and was noted on the case report.

Criteria of assessment

• Opinion of the physician and of the patient

This study involving a disorder rich, in subjective symptoms, the overall opinion of the physician and of the patient were selected as principal criteria and were scored from 0 (nil) to 4 (excellent).

• Number and consistency of stools

The number of stools was noted before and after treatment. In addition, the consistency was noted as follows:

- 0: normal stools,
- 1: soft stools,
- 2: liquid stools.

• Other criteria

Three subjective criteria were analyzed:

- Abdominal pains,
- Distension,
- Dyspepsia.

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RESULTS

Retrospective analyses

Amongst the 24 patients included in the trial, after decoding it was found that 16 were treated with *Saccharomyces boulardii* active preparation and 18 with the placebo.

In order to confirm their homogeneity, two groups were compared before treatment by different statistical tests in relation to the criterion studied (Woolf G test or Chi2 test, Student t).

No difference was seen before treatment between the groups with regard to sex (20 males and 14 females), age (42 years average), digestive or other past histories, digestive function studies, stool culture, nor in any of the criteria of assessment:

- number of stools per day and their consistency,
- abdominal pain,
- distension,
- dyspepsia.

In the same way, during treatment patients of both groups on average received the same number of tablets of mebeverine hydrochloride.

Results of treatment

• Opinion of the physician and the patient

The opinion of the physician (Fig. 1) and that of the patient (2) were remarkably similar, taking the cases as a whole. For each of these two criteria, the difference between the active group and the placebo group was highly significant ($p < 0.05$) in favour of *Saccharomyces boulardii*.

• Digestive transit

Comparison of the two groups with regard to a decrease in the number of stools in the patients with a tendency to decrease and in terms of the improvement in the consistency of the stools once again revealed a statistically significant difference ($p < 0.05$).

• Other criteria

The other three criteria, scored using a linear estimation scale, failed to reveal any statistical difference. However, it is of interest to analyze the results in detail, since whilst the improvement in the symptoms (distension) was absolutely identical in both groups, improvement with regard to pain and dyspepsia difference was nevertheless not statistically significant (even though at the limit for pain) because of the wide variability in the parameters and the small number of cases. It would appear most likely to become significant with a larger number of cases.

• **Tolerance**

No signs of intolerance were noted during the course of this trial.

Table 1 - Results of treatment

Criteria	Mean		Student t	
	<i>Saccharomyces boulardii</i>	Placebo		
Physician opinion	2.63	1.33	2.80	p < 0.05
Patient opinion	2.44	1.28	2.40	p < 0.05
Decrease in number of stools	2.19	0.50	2.79	p < 0.05
Improvement in consistency	1.00	0.44	2.59	p < 0.05
Decrease in pain	40.44	19.67	1.85	NS
Decrease in distension	22.25	19.61	0.24	NS
Decrease in dyspepsia	25.94	9.83	1.48	NS

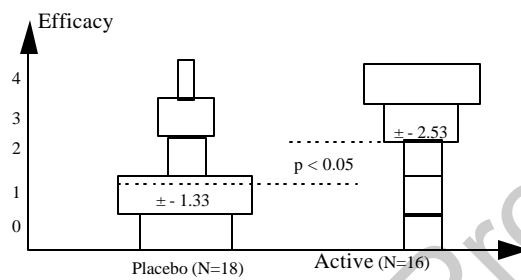


Fig. 1 - Opinion of physician

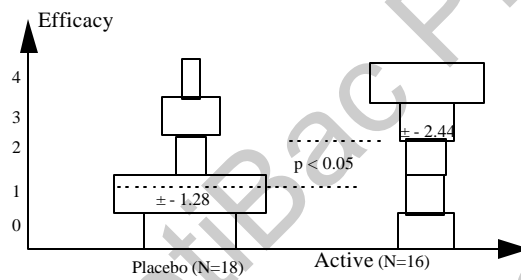


Fig. 2 - Opinion of patient

CONCLUSION

In the context of irritable bowel syndrome, the aim of this trial was to confirm by an appropriate method (randomized double-blind against placebo) the clinical activity of a type of treatment capable of restoring equilibrium to the intestinal ecosystem. The trial results led to a conclusion of the statistically significant efficacy of *Saccharomyces boulardii* with regard to the majority of items studied (opinion of physician, opinion of patient, number and consistency of stools). These results, combined with the perfect tolerance of the medication, confirmed that the use of *Saccharomyces boulardii* in the treatment of irritable bowel syndrome with diarrhoea is a well-founded practice.

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