Real world clinical data on the use of a natural molecular complex for the treatment of Irritable Bowel Syndrome in specialist daily practice

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INTRODUCTION

Irritable Bowel Syndrome (IBS) is a functional bowel disorder characterized by the presence of chronic/recurrent abdominal pain or discomfort, with altered bowel habits and consequent anomalies in stool frequency and form. The current therapeutics to treat visceral pain offer little benefit for abdominal symptoms and can produce undesired and serious side effects. In this context, the pain management remains unsatisfactory, so there is a growing demand for the development of effective treatments[1]. For this reason, we evaluated the benefit of a substance-based medical device (MD) to treat symptoms of IBS.

OBJECTIVES

To investigate the effectiveness and safety of the natural molecular complex ActiMucin in patients with IBS (all IBS types).

METHODS

This was a Real World Evidence (RWE) research using data collected through an electronic questionnaire completed by hospital gastroenterologists uniformly distributed throughout Italy, in the period between the 18th March and the 6th October 2021.
A total of 77 gastroenterology centers representative of the Italian situation were involved in the study. Physicians were asked to evaluate their medical experience in treating patients with IBS using a substance-based medical device through a series of 21 questions. The questionnaires were collected through scientific informants using an electronic tool.

RESULTS

In this survey, 77 gastroenterologists who had at least one year experience with the use of the MD were interviewed. On average, gastroenterologists reported that nearly half of the patients treated with the MD are aged 31 to 50 years while around 27% are aged 51 to 64 years (*Table 1*).
For the majority of physicians, overall effectiveness was evaluated as good (n=51; 66.2%) or excellent (n=19; 24.7%, *Figure 1)*. Similarly, impact on the quality of life was rated as good (n=51; 66.2%) or excellent (n=14; 18.2%), while tolerability was considered excellent for n=54 (70.1%) of the respondents (*Figure 1*).
More than half of gastroenterologists (n=44; 57.1%) reported that patients experienced an improvement in their symptoms within the first month of use (*Figure 2*); in particular, they were very satisfied about the benefits of the MD on the conditions listed in *Figure 3*.
Furthermore, n=56 (72.7%) of gastroenterologists considered the treatment effective for all types of IBS (*Figure 4*). **Moreover, it allowed to reduce the use of other symptomatic therapies in 66.2% of the cases.** As for safety evaluation, no adverse events were reported by the gastroenterologists interviewed.

CONCLUSIONS

RW data obtained through surveys allow to properly deal with post-market monitoring and confirmation of relevant general safety and performance requirements, throughout the product lifespan, as per EU Regulation 2017/745 on MDs. The MD benefit-to-risk assessment on larger and less selected populations than intervention studies, can be complemented by that from these latter studies. Results of this survey showed that, overall, specialists were satisfied with the use of this MD for IBS treatment, as it helps improving symptoms and reduce co-treatments.

Table 1. Age group of patients prescribed with the MD

	Frequency*	% (n=130)
8-11 years	0	0.0%
12-17 years	1	0.8%
18-30 years	26	20.0%
31-50 years	64	49.2%
51-64 years	35	26.9%
>64 years	4	3.1%
Total	**130**	**100.0%**

*Not mutually exclusive

Figure 1. Evaluation of overall effectiveness, impact on quality of life, safety and tolerability

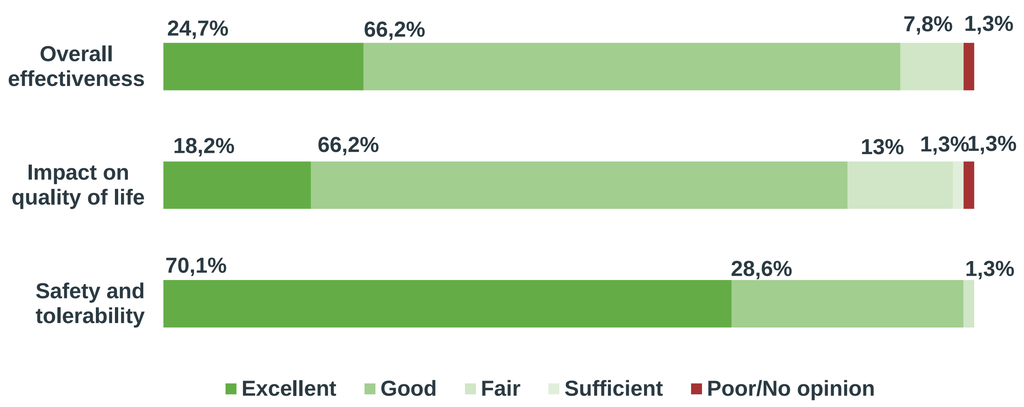
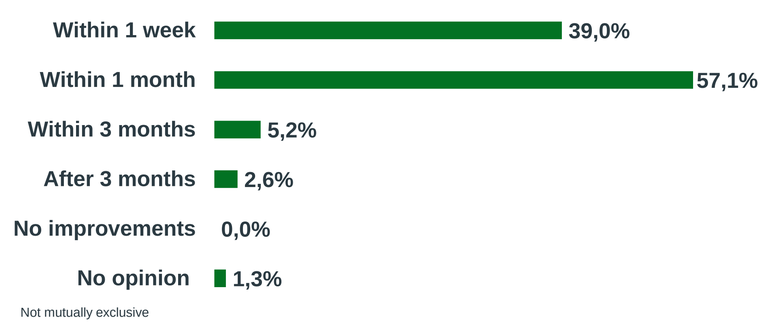
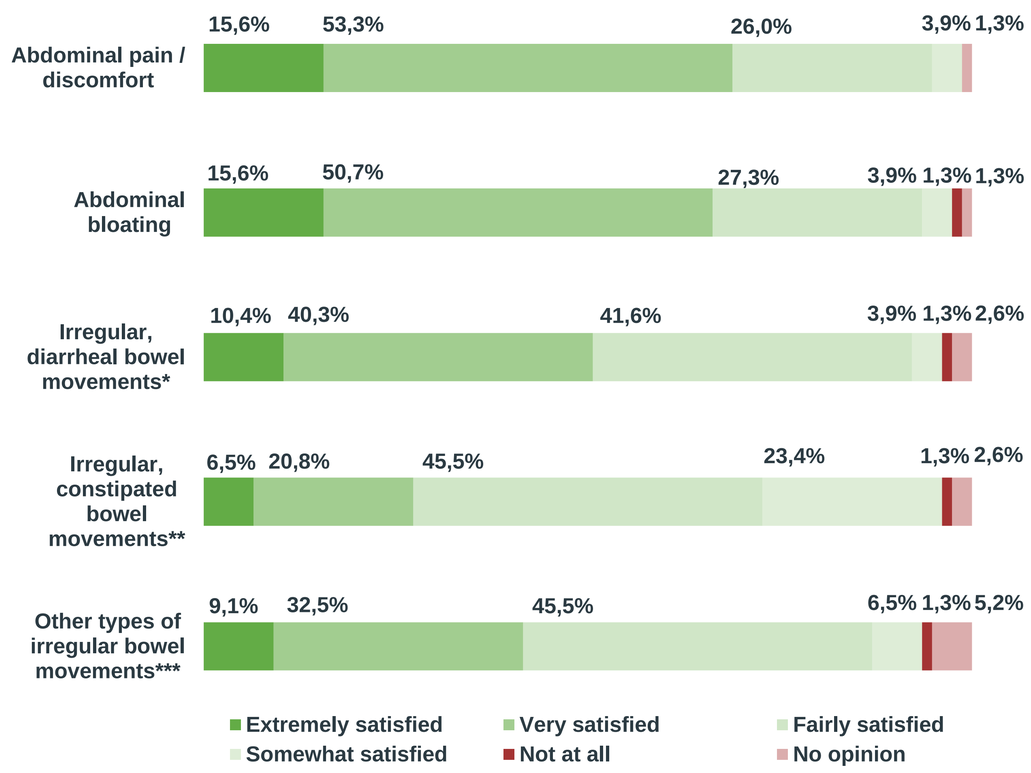


Figure 2. Length of time between treatment start and improvement of symptoms



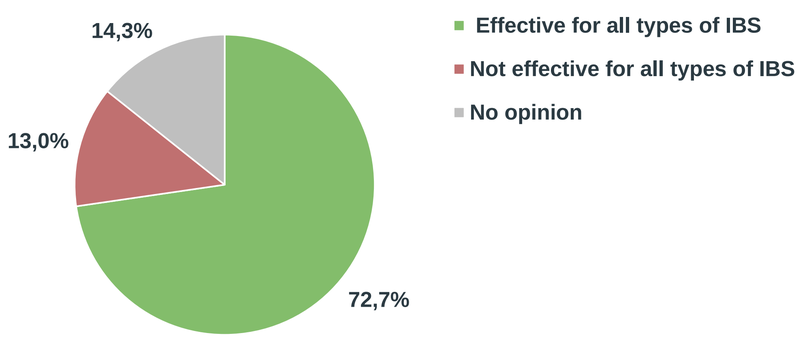
Not mutually exclusive

Figure 3. Evaluation of satisfaction with symptoms improvement



* (i.e. predominantly watery or loose stools)
** (i.e. predominantly hard or nut-like stools)
*** (e.g. alternating diarrhea and constipation)

Figure 4. Evaluation of the effectiveness of MD on all types of IBS



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