Original article

Diet and chronic constipation. Benefits of oral supplementation with symbiotic zir fos (*Bifidobacterium longum* W11 + FOS Actilight)

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Abstract. *Background and aim*: Constipation is one of the most common disorders in Western countries and it is known that dietary factors such as a low fiber diet and low caloric intake are associated with this condition. Weight loss can disrupt the intestinal ecosystem resulting in intestinal dysbiosis that worsens constipation. The aim of this study was to evaluate he effects of treatment with symbiotic zir fos (*Bifidobacterium longum* W11 + FOS Actilight) on chronic constipation in patients undergoing a weight loss diet. *Methods:* Our evaluation included the recording of age, gender, weight, height, BMI, physical activity, constipation, diet, therapy compliance and laxative supplies. A hypocaloric diet (1,200/1,400 cal.) was prescribed to all patients, and they were submitted to a physical activity program and received 1 bag of symbiotic zir fos per day for the entire duration of the study. Patients' follow-up was available for up to 60 days. *Results:* Two hundred and ninety seven patients (79.4% women and 18.2% men, mean age 32.2) were included in the study. The mean baseline BMI was 33.4±5.6 (range 22.8-56.3 Kg). The improvement of constipation turned out to be associated to age ($p<0.01$). Patients with a mean age of 35±12 showed an improvement of constipation. BMI values were not significantly different among the groups of patients with improved, worsened or unchanged constipation. No significative difference was observed among groups due to physical activity. At the follow-up, after 20 days from the beginning of the study, patients that assumed at least 17/20 of the zir fos bags showed a greater improvement of constipation ($p<0.01$) than the remaining patients who assumed less than 17/20 of the zir fos bags or that didn't assumed any at all. Patients that assumed laxatives (at least once a week) showedn to be more frequently associated with a worsening of constipation ($p<0.001$). Diet compliance does not seem to influence the course of constipation. *Conclusion:* Our data demonstrate the utility of symbiotics in improving constipation during hypocaloric diet in the treatment of obesity. (www.actabiomedica.it)

Key words: Constipation, *Bifidobacterium longum* W11 + FOS Actilight, hypocaloric diet

Introduction

Constipation is defined as a bowel condition in which faeces are dry and hard, and evacuation is difficult and infrequent (1). Constipation is defined in different ways by different people. Most often the criterion is the infrequency of evacuation, which would be less than three bowel movements per week, based on studies in normal subjects (type A constipation) (2, 3). For other patients, abnormally hard stool or defecation that requires excessive straining (dyschezia) defines constipation (type B constipation).

Two pathophysiologic mechanisms are used to explain constipation (4). The first of these is colonic inertia (slow-transit constipation), in which a failure of peristalsis that moves luminal contents through the colon prolongs the time for bacterial degradation of solids and more time for salt and water absorption, thus dramati-

cally reducing stool frequency and stool weight. Interestingly, water and solids appear to be reduced proportionally in the stool of patients with constipation (2).

The second mechanism is the outlet functional obstruction, in which an abnormal function of the pelvic floor or of rectum and anus results in transient obstruction and dyschezia.

It is known that dietary factors such as a low fiber diet and low caloric intake are associated with constipation (5, 6). Weight loss typically means a loss of both fat and lean tissue and can disrupt the intestinal ecosystem resulting in a condition called intestinal dysbiosis (7).

The gastrointestinal tract is filled with trillions of microorganisms. While some bacteria, such as *Salmonella*, *E. coli* and *Helicobacter pylori*, are disease-causing microbes, probiotic bacteria, such as *Lactobacillus acidophilus* and *Bifidobacterium*, are health promoters (8). Preserving those good microorganisms consuming foods rich in FOS (fructo-oligosaccharides) and inulin, an undigestible food ingredient, known as prebiotics, beneficially affects the host by selectively stimulating the growth and/or the activity of a limited number of bacteria in the colon (9).

In this study we aimed to evaluate the effects of treatment with symbiotic zir fos (*Bifidobacterium longum* W11 + FOS Actilight) on chronic constipation in patients undergoing a weight loss diet.

Methods

Constipation was defined as showing two or more of the following symptoms for more than 25% of the time for over 3 months: hard or pellet-like stool, infrequent passages (less than 3 per week), straining and painful defecation, or sense of incomplete evacuation.

Our evaluation included recording of age, gender, weight, height, BMI, physical activity, constipation, diet, therapy compliance and laxative supplies.

We used zir fos (*Bifidobacterium longum* W11 + FOS Actilight) as symbiotic supplementation in order to treat constipation. A moderately hypocaloric diet (1,200/1,400 cal.) was prescribed to all the patients according to a protocol that included the consumption of 5 portions of fruit and vegetables every day, a simple physical activity consisting in a 30 minute walk every day that was to be carried out in slowly accelerating steps and 1 bag of zir fos per day for the whole duration of the study.

Patients' period of observation was defined as the period including and between the date of the first record and the date of the final record. Hence, a 60 day follow-up was available.

The study was performed according to the principles outlined in the Declaration of Helsinki and approved by the Ethics Committee. All participants gave their informed consent.

Data are expressed as mean values ± SD, as numbers of the subjects studied and as percent values of the total cases (%). Univariate associations involving each of the stratification measures (BMI, sex, symptoms, use of symbiotics, use of laxatives and diet compliance) were assessed using Pearson's $\chi 2$ test and Friedman's test. Differences were considered to be statistically significative at $p<0.05$.

Results

Two hundred and ninety seven patients, mean age 32.2 years (range 8-78 years), were included in the study; 18.2% (54 pts) were men and 79.4% (236 pts) were women. Each patient's nutritional status was assessed anthropometrically by measuring his/her weight (Kg) and body mass index (BMI) at baseline and during follow-up. The mean BMI was 33.4±5.6 (range 22.8-56.3 Kg). Weight and height were used to calculate BMI: weight in kilograms divided by height in square meters (Kg/m^2). Participants were also categorized on the basis of BMI as underweight (<18.5), normal weight (≥18.5 and <25), overweight (≥25 and <30), obese class I (≥30 and <35), obese class II (≥35 and <40) and obese class III (≥40) (10, 11).

Anthropometrical measurements and demographic and clinical characteristics of the patients enrolled in the study are reported in Table 1. Defecation characteristics, constipation onset, and the use of laxatives and symbiotics of the patients enrolled are reported in Table 2, while data relative to patients that completed the follow-up are reported in Table 3.

At the follow-up, 20 days after the beginning of the study, patients that assumed at least 17/20 of the zir fos bag showed a greater improvement of constipation ($p<0.01$) in comparison with the remaining patients that assumed less than 17/20 of the zir fos bag or didn't assume any at all (Table 4 and Figure 1).

Moreover our data demonstrated that: after 60 days of therapy the improvement of constipation turned out to be associated with age ($p<0.01$); patients with a medium age of 35±12 years showed an improvement of constipation in comparison with the other groups; BMI values were not significantly different among the groups of patients with improved, worsened or unchanged constipation; physical activity didn't show a significative difference among the groups (Table 5).

At every follow-up, patients that assumed laxatives (at least once a week) showed to be more frequently associated twith a worsening of constipation ($p<0.001$). In particular, after 20 days of therapy, 110 patients were taking laxatives and 91 of them (78,4%) showed a worsening of constipation. At the second control (40 days of therapy) 153 patients were assuming laxatives and 134 of them (87,6%) indicated a worsening of con-

Table 1. Demographic and clinical characteristics of the enrolled patients

Demographic and clinical charateristics		
		[range]
Age (years)	32.2±4.7	[8-78]
Weight (Kg)	83±16	[45-156]
BMI	33.4±5.6	[22.8-56.3]
Patients	297	(%)
men	54	(18,2%)
women	236	(79,4%)
lacking data	7	(2,4%)
lacking data	7	(2,4%)
Degree of obesity		
overweight	67	(22,6%)
type I	86	(29,0%)
type II	61	(20,5%)
type III	33	(11,1%)
lacking data	50	(16,8%)
Physical activity		
light	230	(77,4%)
moderate	24	(8,1%)
heavy	0	(0%)
lacking data	43	(14,5%)
Major co-morbidity		
hypercholesterolemia	62	(20,9%)
steatosis	37	(12,5%)
anemia	27	(9,1%)
hypertension	25	(8,4%)
hypertrigliceridemia	18	(6,1%)
hyperuricemia	17	(5,7%)
diabetes	14	(4,7%)
dislipidemia	14	(4,7%)
thyroiditis	5	(1,7%)
chronic renal failure	5	(1,7%)
cholecystolithiasis	3	(1,0%)
cardiac unbalance	4	(1,3%)
diverticulitis	3	(1,0%)

Table 2. Defecation characteristics

Patients	N = 297	%
Before diet		
regular	200	(67,3%)
tendentially constipation	86	(29,0%)
Number of evacuations/ week	2.7±1.1	(1-7)
Months of constipation	119±81	(3-300)
difficulty in evacuation	6	(2,0%)
lacking data	5	(1,7%)
Onset of the constipation		
before the diet	80	(26,9%)
at the beginning of the diet	10	(3,4%)
after the beginning of the diet	207	(69,7%)
after some days (from the beginning of the diet)	31±20	(6-210)
Laxatives (used on an as-needed basis)	203	(68,3%)
senna	197	(66,4%)
lactulose	1	(0,3%)
Mechanic laxatives (glycerin, clysters)	1	(0,3%)
others	4	(1,3%)
none	94	(31,7%)
Zir fos		
associated to the beginning of the diet	86	(28,8%)
associated later on	211	(71,2%)
after some days (from the beginning of the diet)	58±102	(7-1246)

Table 3. Number of patients at the follow-up

Enrolment and follow-up	N. of patients	(%)
Baseline	297	(100%)
20 days	289	(97,3%)
40 days	275	(92,6%)
60 days	221	(74,4%)

Table 4. Assumption of zir fos and stipsis after 20 days of therapy

	Constipation		p [(1)]
	Improved	Unchanged/worsened	
Assumption of zir fos			
more than 16 bags	30 (27.0%)	81 (73.0%)	<0.01
less than 17 bags	11 (11.3%)	86 (88.7%)	

[(1)] χ^2 test with correction of continuity

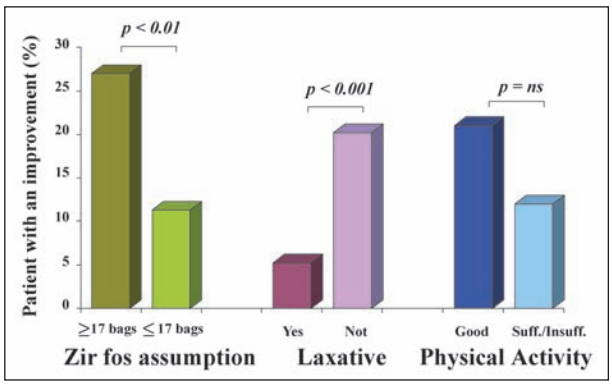

Figure 1. Patients with improved constipation after 20 days of zir fos supplementation

stipation. At the third control (60 days), 9.3% of all the patients showed a worsening of constipation. Even if the adhesion to the balanced diet (good/sufficient) was always ≥80%, diet didn't seem to influence the course of constipation as shown in Figure 2.

Discussion

Obesity has reached epidemic proportions and the Western world is experiencing an obesity epidemic (12-14) which has a substantial impact on morbidity (15-20) and has been categorized by the World Health Organization as one of the top 10 health problems (13).

The goal of weight loss therapy is to improve or eliminate obesity comorbidities and to decrease the risk of future obesity-related medical complications. If an one hand physical activity alone is not an effective method for achieving weight loss, it is known that dietary factors such as low fiber diets and low caloric intake are associated with constipation (5, 6). Weight loss typically means a loss of both fat and lean tissue and can disrupt the intestinal ecosystem resulting in a condition called intestinal dysbiosis (7). The dysbiosis hypothesis states that the modern diet and lifestyle, as well as food restrictions, have led to the disruption of the normal intestinal microflora. These factors result in alterations in the bacterial metabolism, as well as in the overgrowth of potentially pathogenic microorga-

Table 5. Clinical characteristics of the patients in relation to the constipation at the end of the study (60 days of follow-up)

	Constipation			p
	Improved	Unchanged	Worsened	
Age (years)	35±12	40±16	44±16	p<0.001
Weight (Kg)	86±16	81±11	83±17	p=ns
BMI	33.8±5.2	33.9±6.5	34.7±5.9	p=ns
Degree of obesity				
overweight	5 (11.9%)	2 (4.8%)	35 (83.3%)	
Type I	11 (16.7%)	6 (9.1%)	49 (74.2%)	p<0.05
Type II	9 (16.7%)	8 (14.8%)	37 (68.5%)	
Type III	10 (38.5%)	1 (3.8%)	15 (57.7%)	
Physical activity				
mild	43 (24.9%)	13 (7.5%)	117 (67.6%)	p=ns
moderate	0 (0%)	2 (14.3%)	12 (85.7%)	
Laxatives assumption				
yes	8 (6.6%)	5 (4.1%)	109 (89.3%)	p<0.001
no	46 (46.9%)	14 (14.3%)	38 (38.8%)	

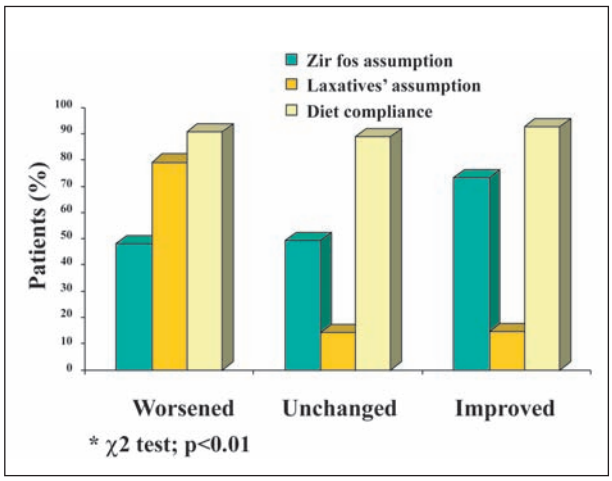

Figure 2. Variation of constipation after 20 days from the beginning of the diet and of zir fos assumption

nisms (21). A probiotic is classically defined as a viable microbial dietary supplement that beneficially affects the host through its effects in the intestinal tract (22-25). A prebiotic is defined as "functional foods, an undigestible food ingredient that beneficially affects the host by selectively stimulating the growth and/or the activity of one or of a limited number of potentially health-promoting bacteria variety" (26). Among the most promising targets of functional foods are the gastrointestinal functions, including those that control transit time, bowel habits, and mucosal motility, as well as those that modulate epithelial cell proliferation and gastrointestinal functions.

The only prebiotics for which sufficient data have been generated that allow foran evaluation of their possible classification as functional food ingredients are the inulin-type fructans (27-29).

The combination of probiotics and prebiotics in what has been called a symbiotic effect, beneficial affects the host by improving survival and implantation of live microbial dietary supplements in the gastrointestinal flora, by selectively stimulating the growth or activating the catabolism of one or of a limited number of potentially health-promoting bacteria variety in the intestinal tract, and by improving the gastrointestinal tract microbial balance.

Our data demonstrate utility of symbiotics in the improvement of constipation during a hypocaloric diet is the treatment of obesity after 20 days of supplementation with zir fos.

Physical activity as well as balanced diet did not seem to affect constipation in patients that took part in the study.

The dose that is necessary to obtain an improvement of constipation is at least 1 symbiotic bag per day for at least 20 days.

From our experience, we can conclude that symbiotic zir fos which regulates dysbiosis, frequently present during a hypocaloric diet, is a useful therapeutic drug for constipation. Zir fos, acting on the migration motor complexes, regulates the internal transit and improves constipation; moreover it increases the intestinal water content making the stool more voluminous and soft and facilitating the evacuation in type B constipation.

New and future studies are necessary in order to confirm and estimate the changes in the intestinal flora after 20 days of uninterrupted therapy and to evaluate the usefullness of symbiotics in constipation therapy in these particular patients undergoing a hypocaloric diet.

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