

RESEARCH STUDIES

Evaluation of the effectiveness of Ferzymb administration in digestive diseases

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Abstract

Background: Assessing effectiveness of the next generation probiotic Ferzymb in conjunction with other probiotics for correction of the microbiocenotic status in different digestive disorders.

Material and methods: 120 children aged between 6 months and 17 years, with the mean age of 9.3 ± 0.61 years, were included in the study, being admitted to Gastroenterology Department of Institute of Mother and Child. The research methods included: thorough anamnesis of the disease and comprehensive clinical examination. The clinical testing procedure included a clinical monitoring during the 10-day inpatient treatment and 1 month after the outpatient treatment.

Results: A more favorable clinical and progressive improvement curve was observed in children who received Ferzymb. Both the stool consistency and frequency improved faster. It has been recorded a gradual and continuous remission of the abdominal pain and decrease of the discomfort up to the 10th day of treatment. The final segment of the "treatment with probiotics" curve confirms the assumption that treatment effectiveness is maintained for about 10 days, so that it can cover the acute period of disturbances.

Conclusions: Ferzymb is practically the only solution in the intestinal microbiocenosis control in children with intestinal malabsorption and Coeliac disease, as the capsule does not contain dismutate gluten. Efficacy of Ferzymb indicated to children with digestive disorders is a priority over the biological non-sorbit preparations and monocompetent ones because Ferzymb regulates the microbiocenotic status of the small intestine and colon.

Key words: Ferzymb, intestinal microflora, digestive disorders.

Introduction

Intestinal microflora plays an indispensable role in restoring the vitamin and fermentation balance, in building unspecific resistance, as well as in other important functions such as trophic and energetic functions, functions of stimulating intestinal peristalsis, of detoxification, endotoxin and exotoxin evacuation, mutagen elimination etc. [1, 2, 3]. A wide variety of biological preparations can be used for restoring the balance of the intestinal flora, but their recommendation should be based upon a well-balanced decision and the clinical benefit for the patient, especially in case of children [1, 3, 5, 6]. Probiotics, remedies that contain live bacteria ready to colonise the intestinal tract, represent the most significant group of biological preparations [2, 4, 7, 8, 13].

In 2001, the World Health Organization defined probiotics as "live microorganisms which when administered in adequate amounts confer a health benefit to the host." Despite their beneficial effect in the host, these preparations require special storage conditions, otherwise they can turn unstable and, eventually, ineffective [10, 13]. Moreover, in order to be able to colonise the intestinal tract, several conditions should be met (for example, intestinal pH etc.), which frequently lack in children with digestive disorders [2, 12, 13]. The majority of biological remedies available today are monocomponent preparations, i.e. they contain only one microorganism – a situation which cannot restore the state of microbiocenosis neither of the large intestine nor of the small one [9, 10, 11].

Having considered the advantages of the probiotic preparations for the correction of the microbiocenosis state in various digestive disorders, we have selected Ferzymb.

Ferzymb is a polycomponent supplement that contains strains of *Bifidobacterium* microorganism subsp. *Lactis* BLC1, *Lactobacillus acidophilus* LA3, *Bacillus coagulans* BC513 and a number of vitamins indispensable for the human body (vitamin B1, B2, niacine, panthothenic acid, vitamin B6, folic acid, vitamin B12), thus having the mechanism of redressing the microbiocenosis state of the small intestine and colon. Ferzymb is available in enteric-coated capsules, which are freed intact in the intestine where they dissolve in pH 6.8. Ferzymb is an oral preparation from a new group of probiotics which, besides live bacteria, also contains in its capsule the culture environment of the microorganisms, which increases the bacteria survival rate and optimum colonisation of the intestinal tract.

In comparison with other probiotic preparations, Ferzymb capsule is gluten free, which represents an advantage for children who suffer from intestinal malabsorption, especially children with Coeliac disease.

The purpose of the study was to evaluate the effectiveness of Ferzymb administration in the treatment of digestive diseases in children with gluten and lactose intolerance, coeliac disease, intestinal malabsorption and pathogenic microflora growth, bacterial contamination of the colon, irritable bowel syndrome, as well as antibiotic-associated diarrhoea.

Material and methods

The study was a prospective case-control one. Object of study: 120 children aged between 6 months and 17 years, from the Gastroenterology unit, Public Medical-Sanitary Institution: Institute for Mother and Child Health Care. The average age of the children included in the study constituted 9.3 ± 0.61 years, among them 23.4% (28 patients) children under the age of 2, 50% (60 patients) – children aged between 2 and 12 years, and 26.7% (32 patients) – children older than 12 years (fig. 1).

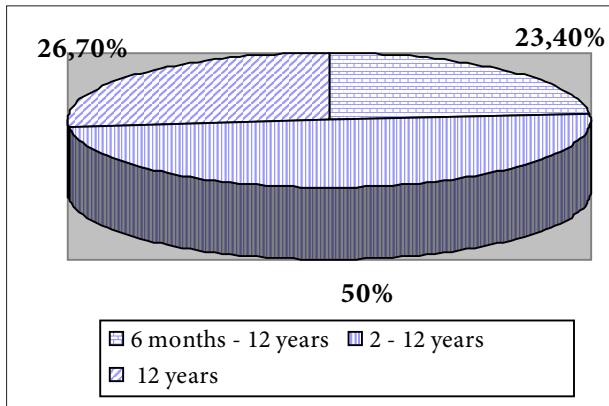


Fig. 1. Distribution of children by age group.

The patients were selected based on the assessment of their complaints, anamnesis data of their life and health condition, as well as parents' (guardians') informed consent to the aim and the methodology of preparation administration.

Children with allergic reactions as well as children whose parents did not give their consent were excluded from the study.

The methods of research included: detailed anamnestic method in studying morbidity and thorough clinical examination. The clinical trial included a 10-day inpatient monitoring as well as one month outpatient monitoring, namely the monitoring of patient's general condition, evaluation of the abdominal pains, frequency and consistency of the stool, meteorism.

The Instrumental and Laboratory Examinations included blood count test, urine test; stool ova and parasite examination; examination of the intestinal microbiocenosis; biochemical tests (total and indirect bilirubin levels, ALT, AST, urea, creatine, amylase, glycemic index, calcemia, phosphatemia, sideremy), ultrasound examination, radiological examination, endoscopy and histology.

Children with intestinal malabsorption from the control group did not receive probiotics, because these preparations contain (dismulate) gluten.

The clinical test of the preparation was conducted by comparison with the curative care programs recommended for children with the same diagnosis.

Considering that gastric acidity is relatively low in children under the age of 2, the patients from this group received un-

encapsulated Ferzymb. Thus, children aged between 6 months and 5 years received 0.5 capsules twice a day, children aged between 6 and 14 years received 1 capsule twice a day, while children older than 14 years received 1-3 capsules twice a day.

All the children included in the study (from both groups) followed a gluten and lactose free diet. They have also received all the necessary medication recommended for digestive disorders.

The statistical analysis applied the χ^2 criterion, the Fisher criterion, Student t-criterion and the correlation coefficient for parametric and nonparametric indices. The statistical veracity was performed for each result and the p-value beyond 0.05 level was considered as significant one.

Results

The clinical monitoring of the general health condition of the children included in the study helped determine comparatively the stool frequency and consistency, the type and period of reduction of the meteorism and abdominal pains, microbiocenosis deviations.

One of the aims of the study was to observe the regression of the stool frequency in children who received Ferzymb, compared to the indices of the children who received a non-sorbed monocompetent probiotic (fig. 2). It is necessary to mention that the absolute number shows the improvement of the stool but not its reduction or the reduction of its frequency and, respectively, it shows the presence of daily stools in constipated children or the reduction of the stool frequency in children with diarrhoea, during the 10-day treatment.

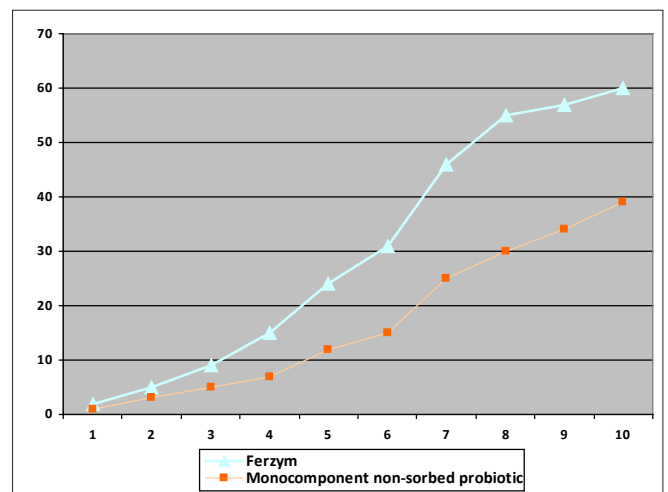


Fig. 2. Comparative evolution of stool frequency after Ferzymb administration, compared to stool frequency in children who received a non-sorbed monocomponent probiotic.

The findings show that children who received Ferzymb showed a better improvement of the stool frequency. Moreover, the curve is a progressive one, showing increased improvement in the stool of children who received Ferzymb ($p = 0.0487$) in comparison with children who received probiotics from other groups. The same progressive direction is seen in the curve showing the stool consistency in children following the curative care supplemented by Ferzymb (fig. 3), in com-

parison with the reference value ($p = 0.05$). All the children who received Ferzym showed considerable improvements.

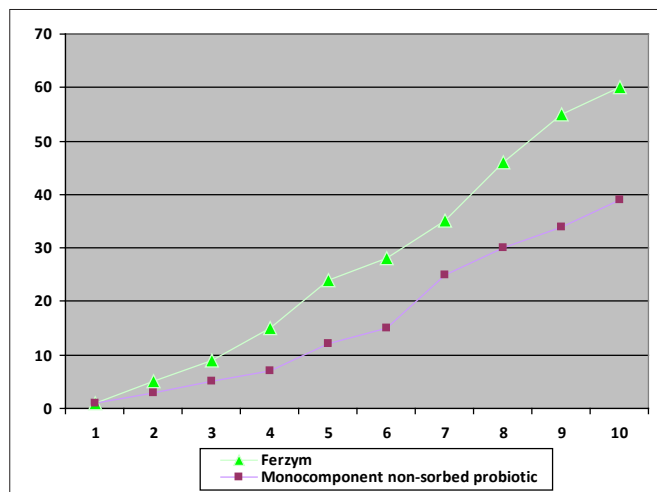


Fig. 3. Comparative evolution of stool consistency after Ferzym administration, compared to stool consistency in children who received a non-sorbed monocomponent probiotic.

The improvement curves representing meteorism show a definite effectiveness of Ferzym administration in the treatment of digestive disorders (fig. 4), in comparison with the administration of non-sorbit monocomponent probiotics. In conclusion, the deviation between the improvement value in the group of children with malabsorption and Coeliac disease, who received Ferzym, and those who followed the gluten-free diet, was due exclusively to Ferzym administration. Thus, if comparing the outcomes of all children under study, where the rate of children with intestinal malabsorption, Coeliac disease and lactose intolerance constituted approximately 63% (29 children), then the improvement deviation between the control groups constituted approximately 26% (12 children), showing better results in children who received Ferzym.

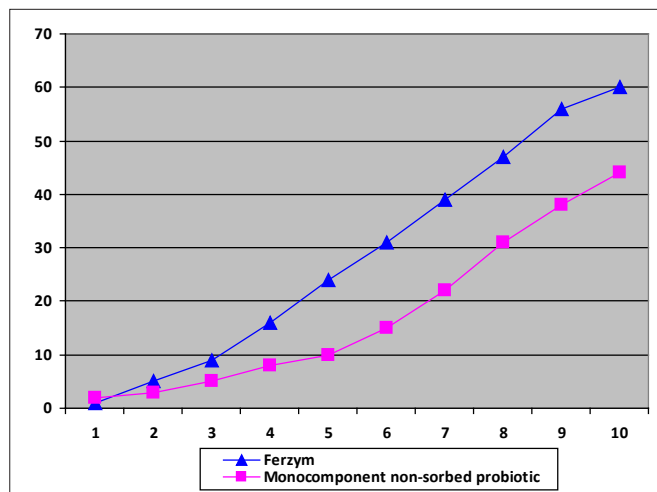


Fig. 4. Comparative evolution of abdominal meteorism after Ferzym administration.

The general condition improvement and abdominal pains reduction were progressively recorded until the 10th day of the

treatment (fig. 5). The last segment of the curve “treatment with probiotics” confirms the supposition that the effectiveness of the treatment is maintained for 10 days, thus it can cover the acute period of the disorder.

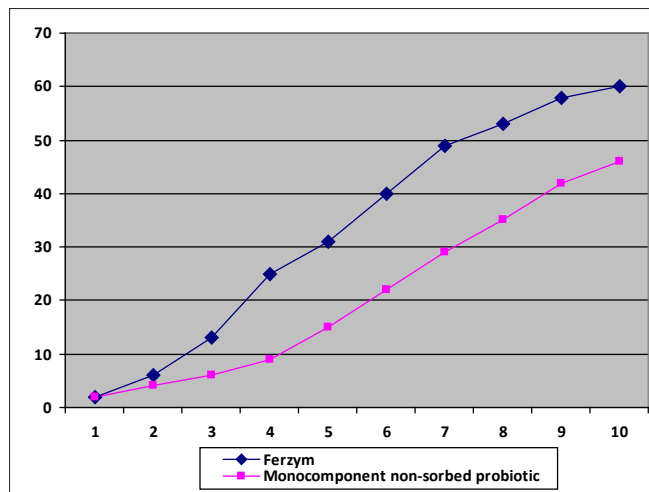


Fig. 5. Comparative evolution of discomfort or abdominal pain after Ferzym administration.

Including Ferzym in the treatment of children with digestive disorders, especially children with intestinal malabsorption, Coeliac disease, certainly improves the general health condition of the patients. Ferzym is practically the only solution to restore the intestinal microbiocenosis in children suffering from intestinal malabsorption and Coeliac disease, due to the fact that its capsule does not contain gluten. The improvements recorded in children with intestinal malabsorption from the control group were attributed to the strict following of the gluten-free regimen. The values of the Ferzym curve show the real contribution of the probiotics administration in the improvement of the clinical condition in the above mentioned diseases, especially in the case of intestinal malabsorption and lactose intolerance.

Accordingly, we can draw the conclusion that from all the clinical symptoms the most responsive proved to be the abdominal meteorism, a condition that considerably improves the quality of children’s life, especially of children suffering from intestinal malabsorption, Coeliac disease, and lactose intolerance. This condition is followed by the reduction of abdominal pains, the significance of which is evident in children suffering from any disease. After Ferzym administration clear improvements were recorded in other symptoms and signs as well: in the stool consistency and frequency, symptoms which actually represent the criteria for evaluation of the clinical condition in the diseases under study.

We consider that reduction of the abdominal pains in children with irritable bowel syndrome was recorded not because of the analgesic or spasmolytic effect of the preparation, but mainly because of the meteorism reduction. This is because children with irritable bowel syndrome have an increased intestinal sensitivity, which means that excitations, which are considered physiological (such as intestinal meteorism, in this case), represent a negative factor for them. The improvement

of the clinical condition of children with this diagnosis, including abdominalgia, is a timely and important finding, because a single remedy can cure a series of essential clinical signs.

After having processed the indices of the microbiocenosis state in children before and after the treatment, the findings showed that of 32 children with 3rd degree disorder before the treatment, only 9 still had it after the treatment with Ferzym (fig. 6), which accounts for a 70% reduction ($p < 0.08$; $\chi^2 = 3.0$). This is an encouraging result which leads us to the conclusion that the administration of gluten-free capsules can be recommended to children with Coeliac disease, intestinal malabsorption, ulcerative colitis and other digestive diseases.

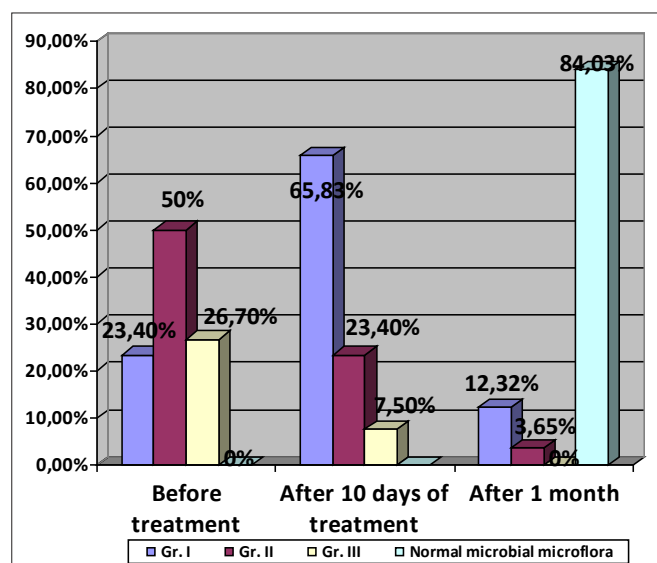


Fig. 6. Level of modification of the intestinal microbiocenosis state in children before and after the treatment with Ferzym.

It is worth mentioning that during the 10-day inpatient treatment, the daily monitoring of the clinical condition of children under study did not record any cases of immediate or late-phase allergic reactions.

Concomitant administration of Ferzym with Amoxicillin, Ampicillin, Clarithromycin, Metronidazole, Cefazolin, Ceftriaxon does not modify the effectiveness of the probiotic. The improvement of the condition in cases of increased growth of the pathogenic bacteria in intestinal microflora and colon colonisation by bacteria is evident, especially in comparison with children whose treatment was not supplemented with probiotics. Moreover, we have also observed that the shorter the interval between the antibiotic therapy and the initiation of the treatment with Ferzym, the more evident its effectiveness. The treatment with Ferzym should be extended for at least 3 weeks, in case there was a longer period of time after the interruption of the antibiotic therapy, irrespective of the reasons of the time lag.

Conclusions

1. The effectiveness of Ferzym administration in children with digestive diseases proved to be higher compared to non-sorbed biological preparations or monocompetent ones, because Ferzym restores the microbiocenosis of the small intestine and colon.

2. The administration of Ferzym in children with intestinal malabsorption, including children with Coeliac disease, has recorded a favourable evolution of the health condition, due to the fact that its capsule does not contain gluten.

3. Including Ferzym at an early stage of the treatment has a direct relation with its effectiveness. Thus, a long time lag after the interruption of the antibiotic therapy and Ferzym administration leads to the extension of the treatment for at least 3 weeks.

4. Ferzym proved to be efficient in the treatment of functional disorders of the intestine, accompanied by constipation and diarrhoea, due to the fact that it eliminates one of the pathogenic causes of these disorders – microbiocenosis disbalance.

5. The administration of un-encapsulated form of Ferzym in children under the age of 2 does not reduce the effectiveness of the remedy and does not generate adverse effects.

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