

III. PEDIATRICS

ENTERIC COATED MINIMICROSPHERE IN THE TREATMENT OF PANCREATIC FAILURE FROM CYSTIC FIBROSIS

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Abstract

Paper aim consists of a comparative retrospective evaluation of the pancreatic enzyme therapy with microsphere versus minimicrosphere. 25 children with mucoviscidosis, followed-up by the cystic fibrosis (CF) Centre Timisoara who benefit from both categories of enzymes represented study material. As a conclusion, using of enteric coated pancreatic minimicrosphere implies lower daily doses, decreases the risk for fibrosing colonopathy and reduces the therapy costs.

Key words: pancreatic enzyme therapy, microsphere, minimicrosphere, cystic fibrosis

Background

The pancreatic failure (PF) represents a major and characteristic aspect in cystic fibrosis (CF). More than 85-87% of the patients have varying degrees of PF. In fact the histological abnormalities started in utero (1).

Clinical manifestations connected to the deficiency of PF have a very large spectrum: meconial ileus or distal intestinal obstruction syndrome (DIOS), chronic diarrhoea with steathoreea and failure to thrive, liposolubil vitamins deficiency, hemolitic anemia, hypoproteic edema, rectal prolapse (2, 3).

The most important treatment of PF consist of replacement with animal origin enzymes (3). During history, the main question was: how to produce replacement enzymes that in a small volume, could ensure both a sufficient enzymatic supply and a large digestive surface and to be protected by the gastric acids in the same time. The answer to these problems came after the introduction of the enteric coated pancreatic microsphere in '80. However, there were frequent clinical situations, when no improvement in steathoreea has been observed, and, as a result, higher doses of enzymes have been used because: medical recommendation were more or less documented, the patients were familiar to take large amount of drugs, commercial products with up to 50 000 IU lipase were offered by pharmaceutical industry representatives, irrational interpretation of therapeutic scheme. Because of these problems, in the latest years had appeared a new complication of CF – fibrosing colonopathy (4,5). Fibrosing colonopathy consist of severe fibrosis at the submucosal

level in the upper colon, with secondary obstruction (6). In this context, the lower dosis of enzyme could be compensated by ensuring a larger digestive surface. This problem was resolved after the introduction of the minimicospheres in the treatment of CF.

Aim of the study

The aim of this study was a comparative retrospective evaluation of the pancreatic enzyme therapy with microsphere versus minimicosphere.

Material and method

The studied lot: 25 children with CF, followed-up by the CF Centre Timisoara, who benefit from both categories of pancreatic enzymes.

Criteria for including patients in the study were: stable clinical status; digested stools, the absence of other clinical aspects related to PF (rectal prolapse, DIOS); minimal doses of enzyme in microspheres, at least 2000 IU lipase /Kg body/lunch, respectively 800IU/Kg body/snack (drugs with 25 000 IU lipase /ampoule).

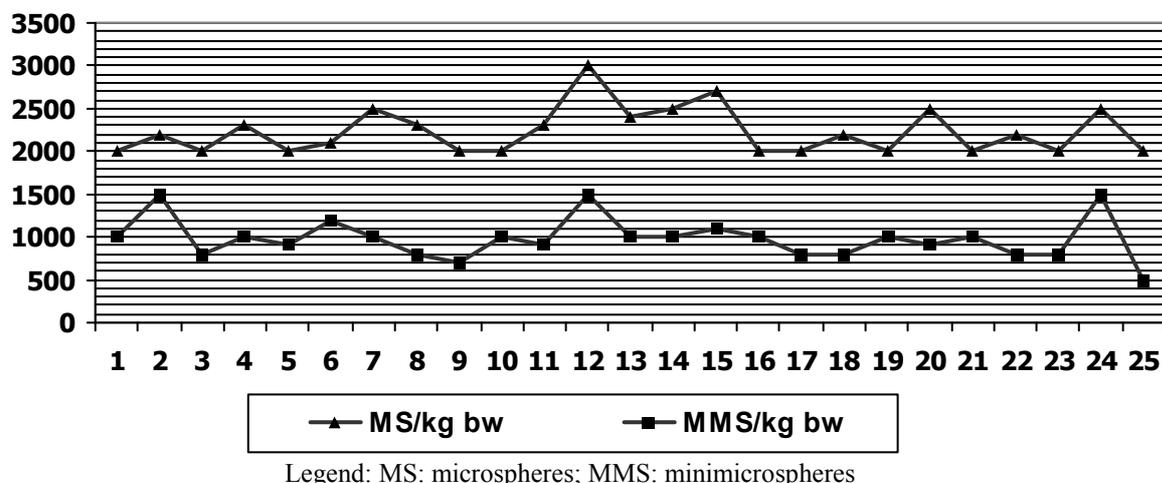
We have administered minimicospheres in varying doses, between 800-2000 IU lipase /Kg body/lunch, respectively 500-800 IU lipase /Kg body/ snack, so that the initial parameters remain similar with those for included criterias. We used minimicospheres of 10 000 IU lipase /ampoule.

Results and discussions

Replacement therapy with minimicospheres was introduced in our services more than 10 years ago (red cross helping) and it was generalised approximately 5 years ago when the specific types of drugs were available in Romania(7) . Present recommendation for the dosage of pancreatic enzymes are (8):

- infant: 2000 – 4000 IU lipase /120 ml milk;
- 1-4 years: 1000 IU lipase /Kg bw/lunch, respectively 500 IU lipase /Kg bw/ snack;
- 4-15 years: 500 IU lipase /Kg bw/lunch, respectively 250 IU lipase /Kg bw/snack;
- teenager-adult: lower doses because of a lower lipid intake.

The comparative evaluation of the two type of pancreatic enzymes revealed a lower average amount for minimicospheres comparatively with standard microspheres. (see diagram).



The average amount for microspheres was 2128 IU lipase/Kg bw/lunch and for minimicrospheres the average amount was 916 IU lipase/Kg bw only. Results revealed that the enzyme average ratio/kg was lower with 12% in the case of minimicrosphere than for microsphere. At the same time there were no cases with the fibrosing colonopathy observed in the study.

Conclusions

1. Using of enteric coated pancreatic minimicrospheres implies lower daily doses, decreases the risk for fibrosing colonopathy

2. The therapeutic regimens elaborated by the CF Centre Timisoara as a coordinative institution at national level presents recommendations for such a treatment.

3. Using of enteric coated pancreatic minimicrospheres implies at the same time the reduces of therapy costs.

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