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Clinical trial of an anti-diarrheal diet : Novalac AD

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INTRODUCTION

The treatment of infant's acute diarrhoea is essentially nutritional. After a first period of rehydration that may last 24 to 48 hours to allow re-establishing the solutes balance, a second refeeding period should permit a caloric intake covering the energy requirements of the infant.

The intestinal mucosa damages in association with diarrhoea induce a transient lactase deficiency inside the enterocytes that restrains the ability of some infants to uptake energy from formulas. For these infants, a lactose-free formula is useful to achieve a high caloric intake avoiding hyperosmolar diarrhoea, as feeding starts again.

NOVALAC AD is formulated to allow an early refeeding after the beginning of a diarrhoea. Its energy content is of 61 Kcal/100 ml for a 13% dilution. Its protein content is high (18g/100g of powder) and almost exclusively made of casein.

NOVALAC AD is rich in Medium-Chain Triglycerides (18% of total fat intake) that favour an increased absorption and faster utilisation of lipids supplies.

Its carbohydrates profile is lactose-free, with maltodextrins and starch as main constituents to allow a low osmolarity (197 mosm/l for a 13% dilution).

AIM OF THE STUDY

The aim of this study is to evaluate the tolerance and efficiency of NOVALAC AD (in terms of weight recovery and diarrhoea duration) during the early refeeding stage when infants still suffer of acute diarrhoea.

STUDIED CASES

28 infants (9 girls and 19 boys) suffering from diarrhoea for less than 5 days and aged 10.1 +/- 4.1 months (extreme values : 4 to 20 months) were selected for the clinical study after their hospital admission.

None was treated with an intestinal antispasmodic or antiseptic medication during the study. The first day of inclusion into the experiment, the mean number of liquid stools was 5.6 +/- 3.6 per day and the mean value of the consecutive dehydration was of 6.8 +/- 3.4%.

Faeces analysis allowed the identification of a rotavirus in 4 cases. No pathogenic bacteria was identified in faeces cultures.

METHODS

After a period of oral or parenteral rehydration, NOVALAC AD (at a 13% dilution) was given alone or in association with other food to meet the energy requirements adapted to the age of each infant. During hospitalisation, infant weight, stools number and aspect as well as product acceptability was monitored on a daily basis.

After infants left the hospital, NOVALAC AD was provided to the parents who had to re-utilise usual formulas only 6 days after the appearance of normal stools. Infants were re-examined a short time after the usual formula was reintroduced.

RESULTS

■ **Rehydration** : the mean period of rehydration was 22.6 +/- 9.8 hours within an interval of minimum 12 to maximum 48 hours.

For 7 infants, rehydration was only oral, but for 21 infants rehydration was oral and parenteral. This parenteral rehydration was indicated in 10 cases because of a dehydration of 10% or more and in 11 other cases because of a food intolerance but without a severe dehydration.

■ **Refeeding** : After rehydration, NOVALAC AD was given exclusively to 4 infants of 5 months old, and for 24 older infants was associated with other food.
Intake variations were related to the age of the infants. The average values were : 454.4 +/- 168.1 ml/ day, the first day and 520.4 +/- 132.2 ml/day, the second day.
These intakes correspond to a caloric supply of 93.8 +/- 9.2 kcal/kg / day (extreme values : 80 to 106 kcal / kg/ day), the first day and 95.5 +/- 10.0 kcal/ kg/day (extreme values : 85 to 118 kcal /kg /day), the second day.
The average period of feeding infants with NOVALAC AD was of 10.6 +/- 3.7 days until the reintroduction of the usual formula.

■ **Duration of diarrhoea:** The total diarrhoea duration including the rehydration period was of 50 +/- 16 hours.
The diarrhoea duration while NOVALAC AD was being used to feed the infants was of 28 +/- 13 hours. Diarrhoea did not recur for any infant while fed with NOVALAC AD.
Re-feeding with the usual formula caused a diarrhoea relapse for an infant that lead to the prescription of a lactose free formula. The later evolution of this infant was perfect.

■ **Weight evolution** : The weight evolution during the first 48 hours of refeeding could not be analysed because of the important individual variabilities associated to the different methods of rehydration.
Later on, the infants were re-examined after they left the hospital; this re-examination occurred on average 17+/- 9 days after they were selected for the clinical study, and 11 +/- 4 days after the usual formula was re-introduced. During this examination, the mean weight gain was of 45.3 +/- 34.3 g/day (that is 5.2 +/- 4.6 g/kg/day) compared to their weight on the day they left the hospital and of 40.5 +/- 38.7 g/day (that is 4.7 +/- 4.6 g/kg/day) compared to their weight on the day oral refeeding was re-established.

■ **Tolerance** : No clinical intolerance was observed to NOVALAC AD. The few vomitings observed were due to the digestive pathology and quickly disappeared from the beginning of re-feeding.

NOVALAC AD's acceptability by the infants was good during the hospitalisation as well as after the infants returned home.

CONCLUSION

The refeeding with NOVALAC AD (at a 13 % dilution) of 28 hospitalised infants for an acute diarrhoea :

- allowed from the first days satisfactory calorie intakes,
- demonstrated a good digestive tolerance,
- cured the diarrhoea in an average of less than 51 hours,
- permitted no relapse of the diarrhoea while infants were fed with NOVALAC AD.

THE CHIEF EDITOR'S POINT OF VIEW

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A survey concerning the habits of paediatricians' prescription on an artificial case of 6-month-old child, presenting a diarrhea evolving for 3 days and moderately dehydrated, was sent to 8690 paediatricians in Europe (1). 2997 questionnaires were filled : 80 % of the paediatricians declared using rehydration solutions, but only 16 % used it according to the recommended duration (3-4 hours) and 21 % restarted the food quickly. 54 % used a lactose free formula with or without bovine protein.
The reason for the differences observed between the recommandations of the ESPGHAN (2) and AAP (3) (i.e. to use solutions of rehydration, hypotonic solutions - Na 60 mmol / L, glucose 74-111 mmol / L-, to re-hydrate quickly over 3-4 hours and to re-feed quickly with usual food, including solid without resorting to the specific formulae or to the dilution; in case of breast feeding, it should be maintained, in every case, oral rehydration solutions should be pursued and the use of medical treatment should be avoided) should be looked for.
Some medical justifications can be advanced. Some studies suggest the existence of a secondary and transitory lactase deficiency (4) in case of rotavirus diarrhea, the main etiology of viral diarrheas (5). Numerous studies showed that using a lactose-free formula (soy based) decreased the duration and the importance of the diarrhea (6-7). A recent meta-analysis, including 29 randomised trials including 2215 patients using formulae with or without lactose during re feeding of acute diarrhea, has been published (8). Twice more failures were noticed in the group receiving the lactose containing formula (22 % against 12 %; $p < 0,001$). However, these failures arise in a considerable way in the dehydrated children. So, the relative risk is 2,4 (reliable interval RI 1,8-7,4), indicating a high risk of failures in case of severe dehydration, while this risk is of only 1 (RI 0,5-1,9), not signi-

ficant, in case of mild dehydration. However, it seems of significance that the stools' frequency and quantity, as well as the duration of the diarrhea are decreased, even if the medical importance of these data is moderate.

Other reasons may be related to the parents' behaviour : they want results quickly on the basis of the criteria they are able to evaluate : the duration and the importance of the diarrhea. It should be noticed that the total duration of the diarrhea under Novalac AD, including rehydration period, was 50 ± 16 hours. This could be compared with the duration found by Santosham and coll. in their randomised trial : 54 ± 28 hours in the group of children receiving a soy based formula against 93 ± 56 hours in the one of those receiving a traditional medical treatment (7).

The continuation of the diarrhea is a source of concern for parents and arouses new consultations, contributing to increase the cost of its treatment . To this direct cost, related to the purchase of medicines and to medical services, must be added related loss of productivity due to the duration of parental medical certificates and related travelling expenses.

Finally, recommendation of a specific lactose free formula, enriched in sodium and in chloride, and ensuring a satisfactory caloric intake should be considered. Because of its good tolerance and of its excellent acceptability, it allows an appropriate feeding from the third hour by reaching two purposes: re-hydration and feeding simultaneously (10).

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