

Value of a Low Lactose Special Formula in the Management of Acute Infantile Gastroenteritis

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Abstract

Seventy five children with acute diarrhoea were randomly allocated to three groups of 25 each to evaluate the effectivity of a newly introduced low lactose, low fat and high protein nutritional supplement for children suffering from acute infantile gastroenteritis. The special formula was statistically significantly better than cow's milk based formula and Soya based lactose free formula in the period of normalisation of stools, number who had normal stools, weight gain during stay in hospital, recurrence of diarrhoea and weight gain after discharge from hospital.

Introduction

Infantile gastroenteritis is the commonest cause of death in children in Pakistan. Mortality from diarrhoea is especially high in the undernourished child population. The important current concepts in the management of diarrhoea are therefore oral rehydration therapy (ORT) and maintenance of nutrition. A special formula for feeding during acute diarrhoea, which has a high protein content, is low in fats, and with lactose present in traces only, has recently been introduced. The very low lactose content is not sufficient to exacerbate the diarrhoea due to lactose intolerance but helps restore lactose activity early. Clinical trials of this product elsewhere have shown statistically significant better results in the time of normalisation of stools and weight gain in children as compared with cow's milk based formula^{1,2,3,4}.

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A clinical trial of this special formula was undertaken in Peshawar to see whether children in this area, who suffer from frequent episodes of diarrhoea and are undernourished, would respond identically or otherwise to children in the developed countries where majority of the previous clinical trials were conducted.

Material and Methods

75 Children with acute diarrhoea admitted to the Paediatric ward, Khyber Hospital, Peshawar were randomly allocated to three groups of 25 patients each. After initial rehydration, group A was given a cow milk based infant formula, Group B was started on the special formula and group C on a Soya based lactose free formula. All information was recorded on a standardised proforma supplied by the manufacturers, by the Paediatric registrar involved in the study. The children were kept in the ward under observation for 5 days. Investigations required were done in the laboratories of Research Centre, Khyber Medical College, Peshawar. Virological studies were done at the National Institute of Health, Islamabad.

Results

The average age of the children was 7 months for group A, 9 months for group B and 11 months for groups C. Males and females were equally distributed in the 3 groups with group A and B having a male/female ratio of 1.7:1, and group C 1.5:1. The average duration of diarrhoea was 8 days in group A, 9 days in group B and 7 days in group C. Average number of stools passed per day was 9 in groups A and B, and 10 in group C. In group A, 56% had taken drugs before admission while in groups B and C, the proportion was 60 and 68 percent respectively. All the children were artificially fed. Less than 5% dehydration was present in 12% of groups A & B cases and 16% of group C children. Over 10% dehydration was present in 8% group B and C patients. In these groups 44 and 48 percent respectively were malnourished with frank marasmus present in 12% of group A and 18% each of group B and C cases. Table I compares the above data in the three groups. The biochemical, virological and bacteriological findings of the three groups at admission are given in Table II. No significant differences were found.

The clinical effectivity of the special formula is compared with the other two formulas in Table III. Stools became formed in 80% of group B, 68% of group A and 60% of group C patients. The average number of days in which stools became formed was 2.5 for group B and 3.75 & 3.5

for group A and C respectively. The difference is statistically significant ($P < 0.05$). Vomiting stopped within an average of 1.5 days in group B, and 1.7 and 1.9 days respectively in groups A and C. The mean admission weight in the three groups was 5.22, 5.80 and 5.64 kg for group A, B and C respectively. On discharge on the 5th day the weights were 5.16 for group A, 5.92 for group B and 5.55 for group C. The difference is significant ($P < 0.05$). When the mothers' opinion was taken regarding response in their children, 76% of group A, 84% of group B and 72% of group C mothers were satisfied. Nurses were happy with the response in 76% of group A, 84% of group B and 72% of group C children.

On follow up of the children, the mean weights recorded were 5.43 kg in group A, 6.10 kg in group B and 5.74 kg in group C. The difference is significant ($P < 0.05$). The increase in weight was 10-20 gm per day in group A, 15-30 gm per day in group B and 10-15 gm in group C ($P < 0.05$). The increase in weight was recorded in 58% of group A, 78% of group B and 52% of group C children. The difference is again statistically significant ($P < 0.05$). Diarrhoea did not recur in 29% of group A, 35% of B and 26% of group C children. Mild diarrhoea with stools less than 5 per day was present in 58% of group A, 52% of group B and 61% of group C. Five to ten stools were being passed by 12.5% of group A, 13% of group B and 13% of group C. Mothers were satisfied in 79% of group A, 87% of group B and 52% of group C children (Table IV).

Discussion and Conclusion

The study has shown clearly that the special formula is better for the alimentation of children suffering from acute diarrhoea as compared to traditional cows milk based or Soya formulae. In this study almost half the children were undernourished, therefore, the increase in weight in the special formula group during the hospital stay and while diarrhoea was still not completely controlled has special significance. The vicious cycle of diarrhoea-malnutrition-diarrhoea is well known and is responsible for deaths of millions of children in the developing countries. Any product which helps break this cycle is a welcome addition to the limited number of interventions available to doctors to fight diarrhoea in the developing world. However, cost of the product would be a limiting factor in the promotion of this product. Majority of the children who are in need of such nutritional help are in the low socio-economic group and for them any additional cost of treatment, no matter how low by the standard of the rich, is a burden. The special formula could logically be substituted for the many anti-diarrhoeals being used for the treatment of diarrhoea and which are known to

have no proven benefit. However, the traditional dependence on medicine for treatment of any illness in our society will be a constraint since food is not considered medicine. First the doctors need to be convinced that this product could be substituted for drugs in majority of the diarrhoea cases and then it is hoped that they would convince their patient, although it will take a lot of convincing.

TABLE I
COMPARISON OF THE GENERAL CHARACTERISTICS OF THE THREE STUDY
GROUPS AT START OF CLINICAL TRIAL

Group	No. of patients	Average Sex Ratio		Average duration of diarrhoea days	Average No. of stools per day	Number given drugs %	Malnutrition (marasmus)	Nil	Dehydration (%)		
		Age (Months)	M : F						<5%	5-10%	>10%
A	25	7	1.7::1	8	9	56	11(3)	12	48	40	-
B	25	9	1.7::1	9	9	60	12(6)	12	60	20	8
C	25	11	1.5::7	10	10	68	12(6)	16	52	24	8

Note: Figure in parentheses shows the number with marasmus.

TABLE II
LABORATORY DATA OF THE THREE STUDY GROUPS
AT START OF CLINICAL TRIAL

Group	Blood Electrolytes			Bacteria (+)		Virus (+)		Parasites (+)			
	Na	K	Cl	Nos.	%	Nos.	%	Nos.	%		
A	Normal (%)	62	75	75	1. E.Coli	1	(4)	1 Rota	2	(8)	Nil
	Abnormal (%)	38	24	24	2. Proteus Mirabilis	1	(4)	1 Adeno	1	(4)	
					3. Proteus Vulgaris	1	(4)				
B	Normal (%)	62	76	81	1. E. Coli	1	(4)	1 Rota	1	(4)	Nil
	Abnormal (%)	38	24	19	2. Providence	1	(4)				
					3. Pseudomonas Acruginosa	1	(4)	1 Adeno	1	(4)	
C	Normal (%)	57	78	68	1. E. Coli	2	(8)	1 Rota	2	(8)	Giardia Lamblia
	Abnormal (%)	43	22	32	2. Klebsiella	1	(4)	1 Adeno	1	(4)	Cyst (4)

TABLE III
 CLINICAL EFFECTIVITY OF SPECIAL FORMULA
 COMPARED WITH OTHER TWO FORMULAE

Group	Average No. of days stool became formed	Nos. in which stool became formed (%)	Mothers satisfied (%)	Nurse satisfied (%)	Weight (kg) on admission	Weight (kg) on discharge
A	3.75	68	76	76	5.22	5.16
B	2.50	80	84	84	5.80	5.92 P < 0.05
C	3.50	60	72	72	5.64	5.55

TABLE IV
FOLLOW UP DATA OF THE THREE STUDY GROUPS

Group	Diarrhoea since discharge - (%)			Proportion of patients showing increase in weight (%)	Average weight on follow up (kg)	Increase in weight per day (Gms)	P*
	Number of stools per day Nil	<5	5-10				
A	29	38	13	58	5.43	10-20	
B	35	52	13	78	6.10	15-30	P* < 0.05
C	26	61	13	52	5.74	10-15	

Note: The test used for significance student t - distribution.

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