

## REGULAR ARTICLE

# High-fibre enteral feeding results in improved anthropometrics and favourable gastrointestinal tolerance in malnourished children with growth failure

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## Keywords

Adverse events, Anthropometrics, Gastrointestinal tolerance, High-fibre enteral feeding, Malnutrition

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## ABSTRACT

**Aim:** The practical value of using fibre-enriched enteral feeding regimens to rehabilitate malnourished children remains inconclusive. This study determined the usage patterns, gastrointestinal tolerance, anthropometrics and safety of high-fibre enteral feeding in malnourished children with growth failure.

**Methods:** This Turkish observational study between February 2013 and June 2015 comprised 345 paediatric patients from 17 centres with malnutrition-related growth failure, with a weight and height of <2 SD percentiles for their age. Changes in anthropometrics, gastrointestinal symptoms, defecation habits and safety data relating to adverse events were analysed during the six-month follow-up period.

**Results:** Most subjects (99.7%) were supplemented with enteral feeding. The absolute difference and 95% confidence interval values for the Z scores of height for age, weight for age, weight for height and body mass index for height increased significantly in four months to six months to 0.21 (0.09–0.32), 0.61 (0.51–0.70), 0.81 (0.56–1.06) and 0.70 (0.53–0.86), respectively ( $p < 0.001$  for each). The percentage of patients with normal defecation frequency significantly increased from 70.3% to 92.8% at the four months to six months visit ( $p = 0.004$ ). Adverse events occurred in 15 (4.3%) of patients.

**Conclusion:** Using a six-month high-fibre enteral feeding was associated with favourable outcomes in anthropometrics, appetite, gastrointestinal tolerance and safety in malnourished children.

## INTRODUCTION

Using an enteral feeding regimen for malnourished children, either as a sole or as a supplementary nutritional source is considered beneficial, because of its association with maintenance of gut function and immunity and the prevention of mucosal atrophy and endotoxin translocation (1–3).

Studies have shown that the beneficial biological effects of fibre and its fermentation products on bowel function have resulted in a shift from traditional use of fibre-free enteral formulas to fibre-enriched enteral formulas in a wide range of clinical settings (2,4,5).

Nutritional supplements are suggested to promote catch-up growth in children with malnutrition, while data on the practical value of fibre-enriched enteral feeding regimens in nutrition rehabilitation remain still inconclusive (2,6–8). This observational study was designed to evaluate the use of high-fibre enteral feeding regimen in children with

malnutrition in terms of usage patterns, gastrointestinal tolerance, anthropometric indices and safety.

## Key notes

- The practical value of using fibre-enriched enteral feeding regimens to rehabilitate malnourished children remains inconclusive.
- This Turkish observational study comprised 345 paediatric patients from 17 centres with malnutrition-related growth failure, with a weight and height of <2 SD percentiles for their age.
- High-fibre enteral feeding over six months was associated with favourable outcomes in anthropometrics, appetite, gastrointestinal tolerance and low adverse events in malnourished children.

## PATIENTS AND METHODS

### Study population

Paediatric outpatients aged one year to 10 years who were diagnosed with malnutrition-related growth failure, defined as a weight and height below two standard deviation (SD) percentiles for their age, were included in this multicentre observational study. All subjects had been prescribed isocaloric or hypercaloric high-fibre oral or tube-fed enteral feeding regimens. The study was conducted between February 2013 and June 2015 at 17 centres across Turkey, including 13 paediatric gastroenterology outpatient clinics and four general paediatric outpatient clinics. The exclusion criteria were the presence of chronic renal failure, decompensated liver disease, any chronic disease not under control, any malignant disease, cystic fibrosis, short bowel syndrome, any type of food allergy or intolerance, growth hormone deficiency and the use of enteral feeding in the last four weeks. Of the 378 patients we initially enrolled, 345 (51.6% girls), with a mean age of 4.8 years and SD of 2.7 years, were eligible to participate in this study, as 33 patients were excluded due to protocol violations detected after enrolment.

Written informed consent was obtained from the children and/or children's parents or legal guardian following a detailed explanation of the objectives and protocol. The study was conducted in accordance with the ethical principles in the Declaration of Helsinki and approved by the institutional ethics committee of the Erciyes University Faculty of Medicine.

### Data collection

After the baseline evaluation, the patients were followed up for six months, and data on various factors were recorded at their baseline and two consecutive follow-up visits performed two months to three months and four months to six months after enrolment. We recorded their demographic characteristics and their anthropometrics, including their height for age Z score, weight for age Z score, weight for height Z score and body mass index for height Z score. The following were also recorded: comorbid diseases; gastrointestinal symptoms including nausea, vomiting and abdominal distension; and appetite scored from zero for reluctance to five for very good and defecation habits, including frequency, stool characteristics such as stool shape, consistency and blood or mucus in stools, pain during defecation, reluctance to defecate and the use of laxatives.

At the baseline visit, detailed information on any high-fibre enteral regimen was collected, including the date and indication of the prescription and the daily amount, type and route of enteral feeding. During the follow-up visits, additional information on the occurrence of any disorders that were likely to interfere with gastrointestinal symptoms, such as respiratory infections, food poisoning and acute febrile illness, was recorded. We also recorded patient adherence to treatment and any adverse events.

### Study parameters

Changes in anthropometric parameters, gastrointestinal symptoms, appetite scores, defecation habits, laxative use and the use of the feeding regimen and taste perception scores were analysed from baseline to each follow-up visit. Safety was evaluated based on any reports of adverse events. Consistent with the noninterventional design, the selection of enteral feeding regimens and timing of follow-up visits were at the physicians' discretion according to the local prescribing information and routine medical practices.

### Gastrointestinal tolerability

Gastrointestinal tolerability was evaluated based on gastrointestinal symptoms of nausea, vomiting and gastrointestinal distension, defecation frequency and/or pain during defecation and/or reluctance to defecate, stool characteristics, the use of laxatives and appetite score. Normal defecation was to define as less than three times a day to at least three times a week, diarrhoea as three or more times a day and constipation as less than three times a week.

### Statistical analysis

Categorical variables were summarised using numbers and percentages; continuous variables were summarised as means and standard deviations, medians, interquartile ranges and minimum and maximum values. Changes over time were evaluated by dependent group t-tests or Wilcoxon tests, depending on distrusting patterns of continuous variables, and by the McNemar test for categorical variables.

Group comparisons were carried out using one-way analysis of variance or the Jonckheere–Terpstra test, depending on distrusting patterns of continuous variables. Analyses were performed using IBM SPSS Statistics for Windows, version 21.0 (IBM Corp., New York, NY, USA).

## RESULTS

### Patient disposition and baseline characteristics

Of the 345 patients evaluated at the baseline visit, 126 and 138 patients attended the follow-up visits two months to three months and four months to six months after baseline, respectively. The rate for anaemia decreased significantly from 18.0% to 5.5% ( $p = 0.002$ ) between baseline and the four months to six months follow-up, and new cases of acute febrile illness and respiratory infection occurred in 9.3% and 10.7% of patients, respectively, during the two follow-up visits.

### High-fibre enteral feeding therapy

Of all patients those were included, 323 of 345 (93.6%) received PediaSure Enteral Formula (Abbott Nutrition, Istanbul, Turkey). In 190 of 345 cases (55.0%), they received the 1.0 Cal with Fibre version, and in 133 of 345 cases (38.5%), they received the 1.5 Cal with Fibre version. These products were made up of the following: protein (11.2%), carbohydrate (43.6%), fat (44.7%) and dietary fibre

and short-chain fructo-oligosaccharides (0.5%). The other 22 (6.4%) patients received the high-fibre Fortini 1.0 Multi Fibre regimen (Nutricia, Istanbul, Turkey), and this contained carbohydrates (10.0%), fat (47%) and dietary fibre (3.0%). The main indication for the high-fibre enteral feeding regimen in these 22 patients was to compensate for their daily fibre needs, and this applied to 70.4% of those cases. Enteral feeding was used as a supplement (99.7%) and provided orally (99.1%) for the majority of patients (Table 1). Irregular use of the feeding regimen and withdrawal were noted in 18.3% and 2.9% of patients, respectively, and were mainly associated with taste problems in 15.9% and 2.0% of cases, respectively (Table 1).

### Anthropometrics

Significant increases were noted from baseline to the follow-ups at months 2–3 and months 4–6 in the Z scores for height for age ( $p = 0.001$  and  $<0.01$ , respectively), weight for age ( $p < 0.001$  for each), weight for height ( $p < 0.001$  for each) and body mass index for height ( $p < 0.001$ ) (Table 2).

**Table 1** Characteristics of clinical nutrition

Prescription indication, n (%) <sup>a</sup>	
To meet daily fibre need	243 (70.4)
Constipation	83 (24.1)
Malnutrition	345 (100.0)
Nutritional support	28 (8.1)
Diarrhoea	7 (2.0)
Used as, n (%)	
A supplement	337 (97.7)
Sole source of nutrition	6 (1.7)
No record	2 (0.6)
Route, n (%)	
Per oral	342 (99.1)
Via tube	3 (0.9)
Package used per day, mean (SD)	2.0 (0.9)
Daily calorie intake (kcal/kg), median (25th/75th quartile)	41.1 (25.7/61.1)
Daily fibre intake (mg/kg), median (25th/75th quartile)	303.0 (186.2/452.4)
Daily water intake (mL/kg), median (25th/75th quartile)	24.6 (15.9/38.5)
Irregular enteric feeding, n (%)	63 (18.3)
Due to	
Taste problem	55 (15.9)
Adverse event	6 (1.7)
Parents do not convince for enteric feeding need	1 (0.3)
Parents do not convince for enteric feeding benefit	1 (0.3)
Enteric feeding withdrawal, n (%)	10 (2.9)
Due to	
Taste problem	7 (2.0)
Unsatisfying weight gain	1 (0.3)
Less weight gain	1 (0.3)
Unknown	1 (0.3)

\*Selection of more than one choice was possible.

### Gastrointestinal symptoms

The percentage of symptom-free patients increased significantly from 85.7% at baseline to 92.8% at four months to six months visit for vomiting ( $p = 0.009$ ), from 82.5% to 91.3% for nausea ( $p = 0.001$ ) and from 90.5% to 93.5% for abdominal distension ( $p < 0.001$ ) (Table 3). Overall, 77.9% of the patients had increased appetite scores in months 4–6 (Table 3).

### Defecation habits and laxative use

The frequency of large hard stools decreased significantly from 29.5% at baseline to 17.3% at the end of follow-up ( $p < 0.001$ ), while the frequency of softer pasty stools increased from 2.2% to 30.6% ( $p < 0.001$ ) (Table 4).

Using nutritional support was associated with lower rates of painful defecation (26.2% versus 12.9%,  $p < 0.001$ ), reluctance to defecate (21.0% versus 10.0%,  $p < 0.001$ ) and lower laxative use (21.7% versus 13.6%,  $p < 0.001$ ) at

**Table 2** Absolute change in anthropometric parameters during the study course

	Month 2–3	Month 4–6
Height for age Z score		
n	124	136
Mean (SD)		
Baseline*	-1.78 (1.04)	-1.65 (0.98)
Current	-1.59 (1.04)	-1.44 (0.89)
Absolute difference <sup>†</sup>	0.18	0.21
95% CI of difference	0.08; 0.28	0.09; 0.32
p Value <sup>‡</sup>	0.001	<0.001
Weight for age Z score		
n	123	136
Mean (SD)		
Baseline*	-2.12 (0.95)	-2.12 (0.88)
Current	-1.71 (1.02)	-1.51 (0.91)
Absolute difference <sup>†</sup>	0.41	0.61
95% CI of difference	0.32; 0.51	0.51; 0.70
p Value <sup>‡</sup>	<0.001	<0.001
Weight for height Z score		
n	68	71
Mean (SD)		
Baseline*	-1.45 (0.87)	-1.53 (0.86)
Current	-0.92 (1.09)	-0.72 (1.13)
Absolute difference <sup>†</sup>	0.53	0.81
95% CI of difference	0.34; 0.72	0.56; 1.06
p Value <sup>‡</sup>	<0.001	<0.001
BMI for height Z score		
n	124	136
Mean (SD)		
Baseline*	-1.51 (1.15)	-1.59 (1.04)
Current	-1.05 (1.13)	-0.89 (1.21)
Absolute difference <sup>†</sup>	0.46	0.70
95% CI of difference	0.29; 0.63	0.53; 0.86
p Value <sup>‡</sup>	<0.001	<0.001

BMI, body mass index; CI, confidence interval; SD, standard deviation.

\*Baseline data specific to patients who attended to that follow-up visit.

<sup>†</sup>Positive value indicates increase in Z score over the time.

<sup>‡</sup>Wilcoxon test.

**Table 3** Gastrointestinal symptom severity and appetite scores from baseline to follow-up

	Baseline*	Month 2–3	Baseline*	Month 4–6
Vomiting, n (%)				
Never	105 (83.3)	108 (85.7)	114 (82.6)	128 (92.8)
Infrequent	18 (14.3)	17 (13.5)	20 (14.5)	9 (6.5)
Frequent but not disturbing	3 (2.4)	1 (0.8)	4 (2.9)	1 (0.7)
Limiting daily activities	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total	126 (100)	126 (100)	138 (100)	138 (100)
p Value†		0.413		<b>0.009</b>
Nausea, n (%)				
Never	92 (73.0)	104 (82.5)	104 (75.4)	126 (91.3)
Infrequent	27 (21.4)	20 (15.9)	28 (20.3)	10 (7.2)
Frequent but not disturbing	7 (5.6)	2 (1.6)	4 (2.9)	2 (1.4)
Limiting daily activities	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)
Total	126 (100)	126 (100)	138 (100)	138 (100)
p Value†		<b>0.026</b>		<b>0.001</b>
Abdominal distention, n (%)				
Never	104 (82.5)	114 (90.5)	113 (81.9)	129 (93.5)
Infrequent	15 (11.9)	10 (7.9)	14 (10.1)	5 (3.6)
Frequent but not disturbing	7 (5.6)	2 (1.6)	10 (7.2)	4 (2.9)
Limiting daily activities	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Total	126 (100)	126 (100)	138 (100)	138 (100)
p Value†		<b>0.035</b>		<b>0.002</b>
Appetite score		n = 123		n = 136
Mean (SD)	2.2 (1.1)	3.0 (1.0)	2.1 (0.9)	3.4 (1.0)
Difference (95% CI)	0.8 (0.6; 1.0)		1.4 (1.2; 1.6)	
p Value†		<b>&lt;0.001</b>		<b>&lt;0.001</b>
Appetite change from baseline, n (%)	Month 2–3	Month 4–6		
Same	33 (26.8)	25 (18.4)		
Increased	78 (63.4)	106 (77.9)		
Decreased	12 (9.8)	5 (3.7)		
Total	123 (100)	136 (100)		
p Value†	<b>&lt;0.001</b>	<b>&lt;0.001</b>		

CI, confidence interval.

\*Refers to baseline data from patients who attended to the specific follow-up visit.

†Wilcoxon test.

Values in bold indicate statistical significance ( $p < 0.05$ ).

the end of the follow-up of four months to six months when rates were compared to the baseline values (Table 4).

A significant increase was noted in the percentage of patients with normal defecation frequency (from 70.3% to 92.8%) and less constipation (from 23.2% to 5.1%) and diarrhoea (6.5% to 2.2%) when the baseline data were compared with the four months to six months follow-up ( $p = 0.004$ ) (Table 5).

### Safety data

Adverse events occurred in 15 (4.3%) of the patients, and these included infections and infestations (2.3%) and gastrointestinal disorders (1.2%) in most cases. None of the patients experienced serious adverse events or death, and none of the adverse events required medical or surgical interventions. Adverse events were only related to the enteral feeding regimen in one (0.3%) patient (Table 6).

### DISCUSSION

Our findings revealed that high-fibre enteral feeding supplements significantly improved weight for age, weight for height, body mass index for height and height for age Z scores. This seems notable given the positive correlation of anthropometric improvement with the duration of enteral feeding (9) and the likelihood of ongoing adequate nutrient intake to enable recovery and catch-up growth via weight gain velocity that exceeded normal rates (10,11).

Enteral nutrition has also been reported to be associated with improved anthropometrics in several studies in hospitalised children as well as in children with chronic diseases (9,12,13).

High-fibre enteral feeding regimens were used as oral supplement based on an average of two packages per day in the majority of patients that provided daily calorie intakes

**Table 4** Defecation habits and laxative use at baseline versus 6-month follow-up

	Baseline n (%)	Follow-up* n (%)	p Value <sup>†</sup>
Large hard stool	80 (29.5)	47 (17.3)	<b>&lt;0.001</b>
Small hard round pellets	35 (12.9)	20 (7.4)	<b>0.020</b>
Semi-solid stool	193 (71.2)	210 (77.5)	0.093
Soft pasty stool	6 (2.2)	83 (30.6)	<b>&lt;0.001</b>
Loose stool	0 (0.0)	11 (4.1)	CNC
Watery stool	1 (0.4)	0 (0.0)	CNC
Blood in stool	3 (1.1)	0 (0.0)	CNC
Mucus in stool	0 (0.0)	0 (0.0)	CNC
Painful defecation	71 (26.2)	35 (12.9)	<b>&lt;0.001</b>
Reluctance to defecate	57 (21.0)	27 (10.0)	<b>&lt;0.001</b>
Use of laxatives	75 (21.7)	47 (13.6)	<b>&lt;0.001</b>

CNC, cannot be calculated.

\*Any time during follow-up.

<sup>†</sup>Baseline versus follow-up; McNemar test.Values in bold indicate statistical significance ( $p < 0.05$ ).**Table 5** Defecation frequency

Defecation frequency	Baseline n (%)	Month 2–3 n (%)	Baseline n (%)	Month 4–6 n (%)
<3 times/week (constipation)	26 (20.6)	7 (5.6)	32 (23.2)	7 (5.1)
≥3 times/week, <3 times/day (normal)	90 (71.4)	118 (93.7)	97 (70.3)	128 (92.8)
≥3 times/day (diarrhoea)	10 (7.9)	1 (0.8)	9 (6.5)	3 (2.2)
Total	126 (100)	126 (100)	138 (100)	138 (100)
p Value*	0.086		<b>0.004</b>	

\*Wilcoxon test.

Values in bold indicate statistical significance ( $p < 0.05$ ).

of at least 40 kcal/kg, daily fibre intake of at least 300 mg/kg and daily water intake of at least 25 mL/kg in half of the patients. On the basis that our study showed that anthropometric indices significantly improved as a result of short-term nutritional provision, our findings emphasise that high-fibre enteral feeding is adequate to provide nutritional support to meet the nutritional needs of malnourished children and to promote catch-up growth or maintain growth (9,13,14).

High-fibre enteral feeding was associated with favourable tolerability in our cohort, ameliorating all gastrointestinal symptoms and increasing the number of symptom-free patients and patients with increased appetite during the entire course of the study. Defecation habits also improved significantly from baseline to the end of follow-up, with increases in the percentage of patients with normal defecation frequency and stool characteristics; reductions in the rates of constipation, diarrhoea and the need for laxative

**Table 6** Adverse events in all patients (n = 345)

By system organ class	n (%)
Gastrointestinal disorders	4 (1.2)
Abdominal pain	1 (0.3)
Gastrointestinal hyper motility	1 (0.3)
Gastroesophageal reflux disease	1 (0.3)
Vomiting	1 (0.3)
Infections and infestations	8 (2.3)
Bronchitis	1 (0.3)
Pneumonia	2 (0.6)
Upper respiratory tract infections	5 (1.4)
Metabolism and nutrition disorders (Food intolerance)	1 (0.3)
Nervous system disorders (Convulsion)	1 (0.3)
Respiratory, thoracic and mediastinal disorders	2 (0.6)
Respiratory tract infections	1 (0.3)
Tonsillitis	1 (0.3)
Total	15 (4.3)
By severity	
Mild	7 (2.0)
Moderate	6 (1.7)
Severe	0 (0.0)
Action taken for adverse events	
None	8 (2.3)
Other (excluding medical or surgical intervention)	5 (1.4)
Missing	2 (0.6)
Relation to study therapy	
Related	1 (0.3)
Probably related	2 (0.6)
Not related	10 (2.9)
Probably not related	1 (0.3)
Missing	1 (0.3)
Serious adverse events requiring hospitalisation	3 (0.9)
Bronchitis	1 (0.3)
Convulsion	1 (0.3)
Pneumonia	1 (0.3)
Outcome	
Continuation of adverse event	1 (0.3)
Life-threatening serious adverse event	0 (0.0)
Prolongation of hospitalisation required for serious adverse event	0 (0.0)
Significant medical event requiring medical or surgical intervention	0 (0.0)
Persistent disability	0 (0.0)
Abortion or miscarriage	0 (0.0)
Death	0 (0.0)

use; and lower incidences of painful defecation and reluctance to defecate.

The past studies showed favourable gastrointestinal tolerance in a range of medical conditions when enteral feeding has been based on formulas containing fibre rather than fibre-free formulas. The improvements noted were a lower incidence of diarrhoea (15,16), improved stool output (6,17–19) and lower rates of laxative use, abdominal pain and bloating (17,19) and vomiting (20).

Major drawbacks of fibre-free enteral formulas that have been reported include poor gastrointestinal tolerance leading to impaired bowel function, characterised by diarrhoea

in hospital settings, and constipation as a result of home enteral nutrition (2,4,21).

In our cohort, high-fibre enteral feeding increased the percentage of patients with normal bowel frequency and decreased constipation and diarrhoea. This seems consistent with accumulating evidence that fibre-enriched enteral formula modulates gut function by reducing bowel frequency and stool consistency at the extreme ends of the continuum (2,5,16,18,22).

Hence, our findings show that high-fibre enteral formulas can be well tolerated, without leading to clinically distinguishable adverse events in the paediatric population, by patients in a wide age range and with a wide range of medical conditions (18). Our findings emphasise that the use of high-fibre enteral nutritional supplements provides a good and safe strategy for paediatric patients with, or at risk of, malnutrition on the basis of improved anthropometrics, increased appetite and favourable gastrointestinal tolerance with normalised bowel frequency.

Certain study limitations need to be considered. First, due to the observational nature of the study, and the nonrandomised allocation, main selection bias and confounding are possible. Second, the lack of intervention with regard to the timing and number of follow-up visits, in accordance with the observational nature, meant that the frequency of patient visits was not uniform. This challenged the analysis of the efficacy variables for each patient, due to subgrouping of the raw data into months 2–3 and 4–6 for analysis purposes. Nonetheless, the lost to follow-up rate was minimal as 283 of 345 patients attended at least one follow-up visit. Third, given that high-fibre enteral feeding regimen was used as a supplement for the majority of the patients, the lack of data on the value provided by calories to the diets of children that were not malnourished was another limitation and these data would have extended the knowledge achieved in the current study. Despite these limitations, our study adds to the data available on fibre-enriched enteral feeding regimens in the nutritional rehabilitation of malnourished children in Turkey, which were limited before this study. Our findings have provided data on real-life clinical practice, using a multicentre design at 17 centres across Turkey, and make a valuable contribution to the literature.

## CONCLUSION

The use of a six-month high-fibre enteral feeding programme for malnourished children with growth failure improved their anthropometrics, increased their appetite, improved their gastrointestinal tolerance, by normalising their bowel frequency, and resulted in favourable patient compliance, good tolerability and a good safety profile that was consistent with high use and taste perception scores. The findings in our cohort suggest that fibre-enriched enteral formulas play a modulatory role on gut function by reducing bowel frequency and stool consistency at the extreme ends of the continuum. High fibre enteral feeding also provides adequate nutritional support to meet the

nutritional needs of malnourished children that promotes catch-up growth or maintains existing. Our findings indicate that high-fibre enteral feeding regimens should be considered as a first-line treatment in the clinical care of malnourished children with faltering growth.

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## FINANCE STATEMENT

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## CONFLICTS OF INTEREST

Aysugul Alptekin Sarioglu is an Abbott employee. The other authors have no conflicts of interest.

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