

PediaSure in the Treatment of Severe Malnutrition in Pakistani Children

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Abstract

Objectives: We used “PediaSure” a high-density supplemental high caloric feed, for the purpose of nutrition therapy of malnourished children during the initial 2 weeks of rehabilitation.

Methodology: Thirty-one severely malnourished children between the ages of 1-5 years of age completed the study after management of acute medical complications, they were started on “PediaSure” as their source of calories, for 2 weeks. Their weight gain clinical tolerance, stool output were monitored, as were hematological and biochemical parameters.

Results: The study revealed a significant increase in caloric intake ($p < 0.01$) at the end of 2 weeks. There was also a significant improvement in weight gain of these children, averaging to 7.5 gm/kg/day. The Z score weight or age improved as well, ($p = < 0.01$) over the 2 week period. The biochemical parameters registered an increase in their serum potassium levels, but no untoward chemical imbalance was noted. Tolerance for PediaSure was very high, only one child was excluded from the study due to limited intake. None of the children developed diarrhea.

Conclusion: We conclude that “PediaSure” can be used effectively in the initial stage of nutrition rehabilitation of severely malnourished children (JPMA 50:377,2000).

Introduction

Approximately 10% of children in Pakistan do not survive to their sixth year of life. A primary contributing factor to the high childhood mortality in Pakistan is the prevalence of malnutrition. The immediate cause of such a high mortality rate is the synergistic effect of inadequate dietary intake and recurrent infections¹. UNICEF figures from 1997 show that 50 per cent of Pakistani are stunted, 38 percent are under-weight, while 9 percent demonstrate evidence of wasting². Further complicating the problem is the high incidence of infectious diseases in areas of poverty, where living conditions may be crowded and/or sanitation is substandard. While infections, including infectious diarrhea, may not be caused by malnutrition, the effect of diminished cellular immunity and changes in physiologic function resulting from malnutrition complicate the recovery from such conditions. Rapid replenishing of energy protein, vitamins, minerals, and electrolyte balance is critical in patients hospitalized for malnutrition. Particularly in areas with poor hospital facilities. Ideally, treatment for malnutrition should provide adequate nourishment and at the same time should not aggravate accompanying medical conditions, such as diarrhea. It should also be well tolerated, i.e., not cause diarrhea, vomiting, or water retention, and should be easy to prepare, administer and store.

The present study was undertaken to define the benefits of PediaSure in the short-term treatment of severely malnourished pediatric patients at the Nutritional Rehabilitation Unit (NRL), at the Civil Hospital in Karachi, Pakistan.

Methods

Pediatric patients (1-5 years of age) hospitalized for severe malnutrition (weight—for—age $< 3SD$) were included in the study, after obtaining parental consent. Patients with congenital diseases, neurological disorders, septicemia, severe illness (including pneumonia and meningitis), persistent diarrhea, or fluid intake restrictions sufficient to interfere with PediaSure intake, were excluded from the study. This was done because the study was testing the efficacy of PediaSure and it was essential to minimize possible biases that could be introduced through patients with severe infection.

PediaSure is a balanced nutritional product used for complete or supplement nutritional support supplied as a powder, which when reconstituted with water, is suitable for oral administration. In our study PediaSure was given for a two-week period, as complete nutrition or as a supplement to established breast-feeding.

PediaSure provides 1 calorie per ml, 3.0 grams of protein per calorie, 49.8 grams of total fat per liter (includes linoleic and linoleum fatty- acids). 109.7 grams of carbohydrates per liter (comprised of cornstarch and sucrose, but 110 lactose) and 1.4 mg of iron per liter. The sodium level of PediaSure is sufficiently low to prevent potassium loss, which is important in patients with malnutrition-related potassium depletion. The sodium plus potassium to calcium ratio is 1.5: 1 and that of calcium to phosphorus is 1.2:1. PediaSure is nearly isotonic (310 mOsm/kg), Formulated with a lower renal solute load to prevent osmotic dysfunction and dehydration. PediaSure meets or exceeds the NAS-NRC recommendation of 1.0 mEq/kg/day, as well as allowances for all vitamins and minerals for children 1 - 10 years of age.

PediaSure feedings began on day 1 and continued through day 14. Non breast-fed patients were given solely PediaSure, while breast-fed patients were given a diet of breast milk supplemented with PediaSure. The quantity of PediaSure ingested varied per child according to demand and tolerance. The protocol did not specify the number of feeds and quantity of PediaSure to be given per day, this was dependent on the calorie requirement of the child. The minimum number of calories ingested for each child on day 1 were at least 50 percent of the total requirement. as calculated for expected weight-for-age. The caloric contribution from breast milk was calculated using a standard of 20 calories per ounce of expressed milk. The amount of expressed breast milk per feeding was estimated by asking the mother to express milk at various time points throughout the day (including the first feeding) and averaging the total volume of expressed milk for a per-feed volume.

A day prior to the start of PediaSure feedings, a thorough medical, social, and dietary history was taken. Weight-for-age Z-scores (WAZ), height, body mass index (BMI) defined as weight in kilograms divided by height in meters squared, mid-upper arm circumference, skin fold thickness (triceps and sub scapular measurements), and head circumference were measured on day 1 and day 14. Weight and caloric intake were recorded daily. Changes from baseline and total change were calculated. Clinical chemistry (serum electrolyte, sodium, potassium, chloride, BUN, creatinine, calcium, phosphorus, calcium, total protein, testing glucose, random glucose, albumin, cholesterol, triglyceride, alkaline phosphatase, uric acid, total bilirubin, and HDL) and hematology (WBC, hemoglobin, platelet, hematocrit, neutrophil, lymphocyte, monocyte, and eosinophil) profiles were done on day 1 and 14 as reported. A daily gastrointestinal intolerance record was maintained for stool frequency, Vomiting, and other possible complications. The behavior profile program was completed on day 1, day 7, and day 14 as a measure of how acceptable the formula was to the child, i.e., Whether the child liked or disliked the formula.

Results

Of the 45 patients enrolled in the study, 30 completed the study. After initiation of PediaSure feedings, 2 patients were discounted due to non-compliance (refusal to take PediaSure), 4 due to diarrhea secondary to infection, 1 due to intolerance to PediaSure resulting in diarrhea, 1 due to ineligibility for study participation and 7 were withdrawn due to parental request. The remaining 30 patients completed the 14-day study period and are included in the efficacy analysis.

The patient population was 50% (n = 15) male and 50% (n = 15) female and ranged in age from 12 to 48 months (22 ± 8.6 month). At baseline (day prior to initial of feeding) 80 per cent (n=24) of the total thirty patients were malnourished. 13 per cent (n=4) had malnourished kwashiorkor, and 7 per cent (n=2) had kwashiorkor. Thirty-seven per cent (n=11) patients had a completely insufficient diet and 63 per cent (n=19) had a partially insufficient diet. Nine patients received PediaSure as a supplement to breast feeding, the remaining patients (n = 21) received PediaSure for total nutritional support.

Over the two-week treatment period, the average caloric intake increased from 854 calories/day on day 1 to 1139 calories/day on day 14 ($P < 0.01$). The average weight increased from 6.4 kg to 7.2 kg ($P < 0.001$), an increase that represents an average overall daily weight gain of 8.3 gm/kg/day (Figure 1).

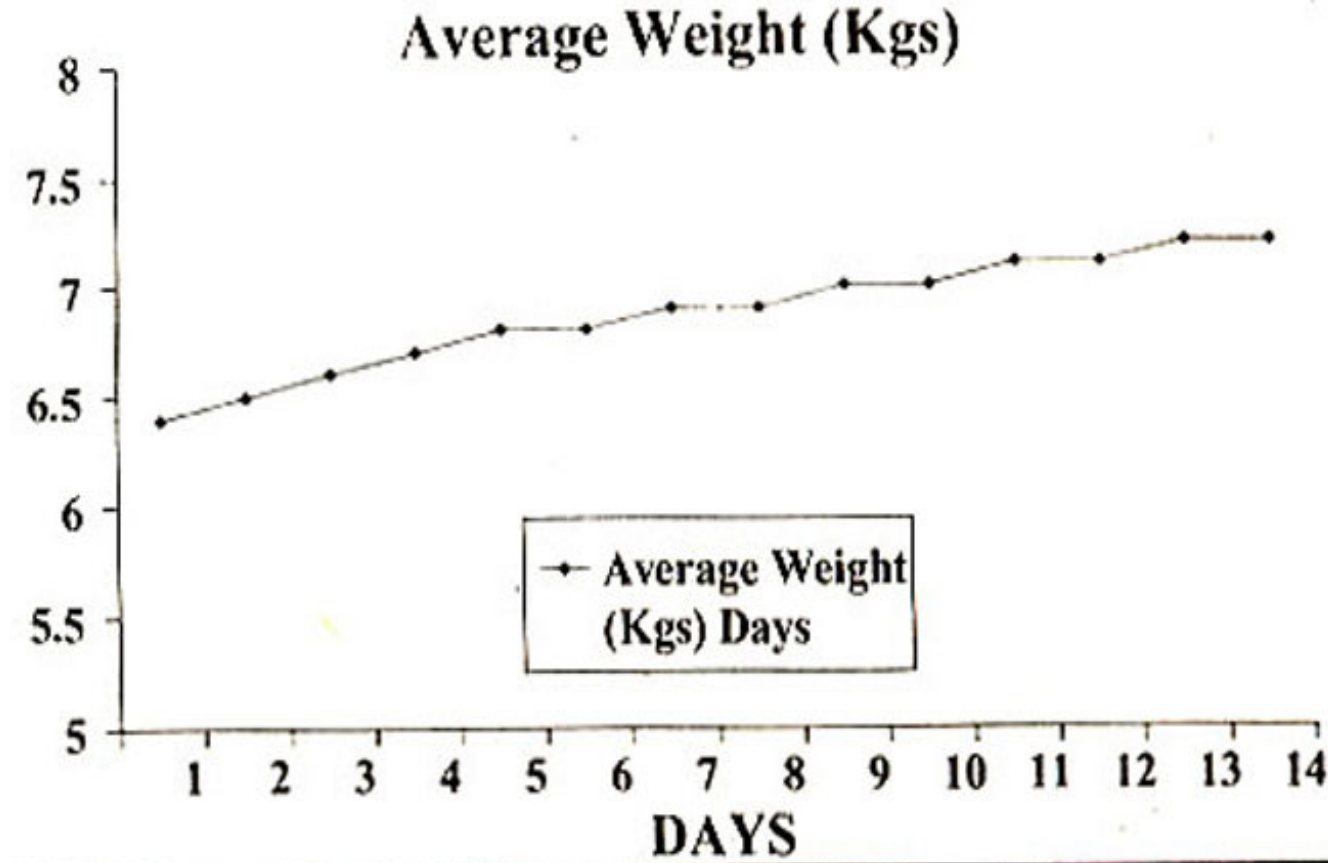


Figure 1. Average daily weight over the 2-week study period.

As data demonstrates, PediaSure treatment resulted in an immediate increase in both caloric intake (Figure 2)

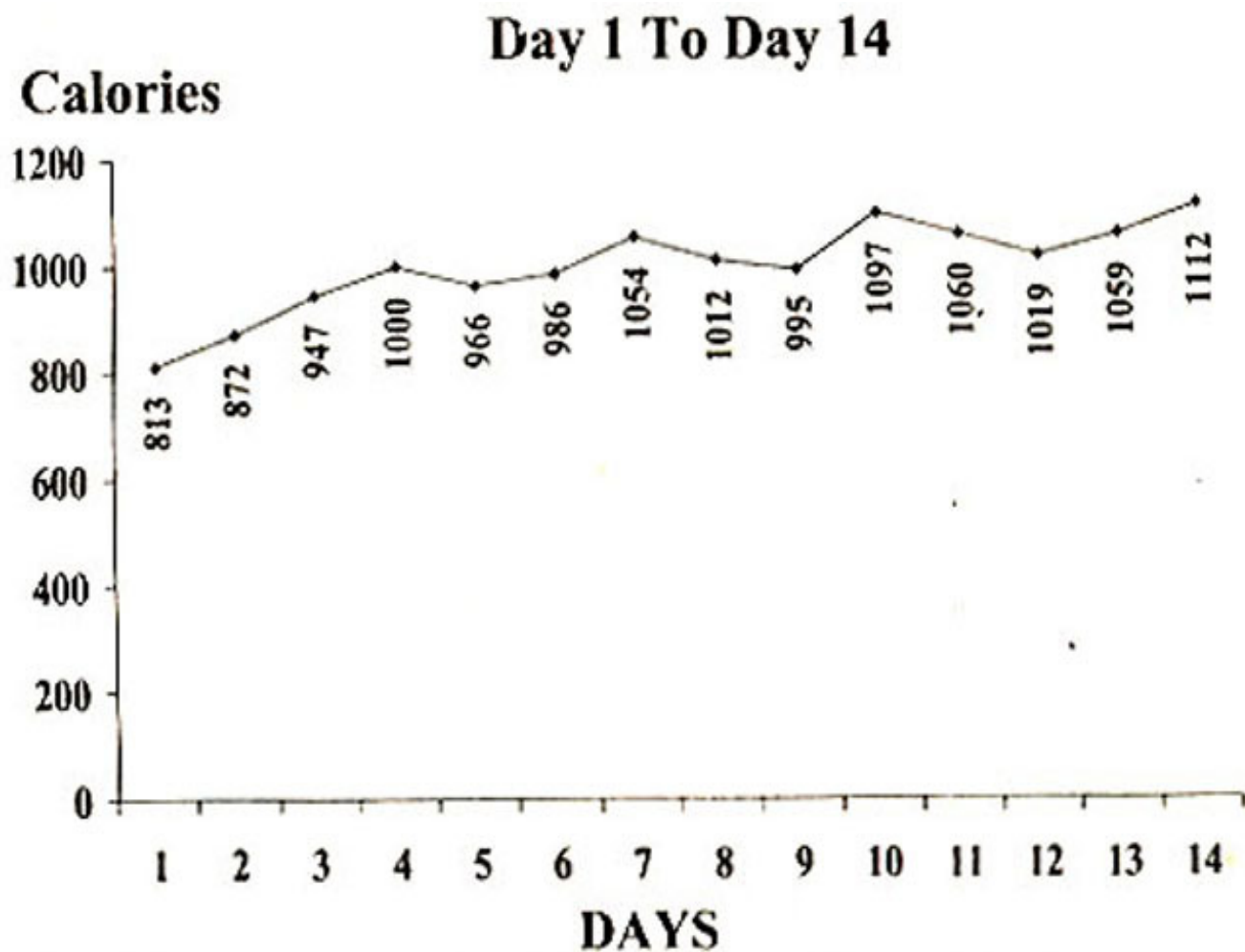


Figure 2. Average daily caloric intake over the 2-week study period.

and associated weight gain (Figure I). With an increase in weight the average MAC, BMI, and skin fold thickness also increased, while the WAZ decreased significantly over the treatment period. Only height and head circumference did not show statistically significant changes over the 14-day study period, both these indicators show change over a long period of time, the mean anthropometric parameters for Day 1 and Day 14 are shown in Table 1.

Table 1. Anthropometric Data at Day 1 and Day 14.

Parameters	Day 1 Mean $\pm$ SD	Day 14 Mean $\pm$ SD	P-value
Weight (kg)	6.4 $\pm$ 0.9	7.2 $\pm$ 0.9	<0.009
WAZ	-4.4 $\pm$ 0.75	-3.8 $\pm$ 0.75	<0.01
Height (cm)	70.7 $\pm$ 3.7	70.8 $\pm$ 3.8	NS
BMI	12.7 $\pm$ 1.4	13.9 $\pm$ 3.0	<0.001
MAC	10.7 $\pm$ 1.0	11.5 $\pm$ 1.0	<0.001
Skin Fold			
Triceps (mm)	4.7 $\pm$ 2.1	6.5 $\pm$ 2.4	<0.01
Subscapular (mm)	3.3 $\pm$ 1.5	4.5 $\pm$ 1.7	<0.001
Head Circumference	43.7 $\pm$ 1.5	43.9 $\pm$ 1.5	NS

NS = Not significant

Formula tolerance was based on how well the patient liked the formula and on stool frequency. As rated by the parents, the formula was extremely well liked by 15 patients, very well liked by 11, moderately liked by 3 and disliked by 1 patient. The average stool frequency over the 14-day period was 1.5 $\pm$ 2.1. This demonstrates that PediaSure was well tolerated.

No significant changes in any hematology parameters were noted. Likewise, there were no statistically significant changes in serum chloride, sugar (fasting or random), albumin, alkaline phosphatase, uric acid, total bilirubin, and HDL. There were, however, statistically significant changes over the two-week treatment period in other clinical chemistry parameters as shown in Table 2.

Table 2. Clinical Chemistry Parameters that had a statistically significant change over the 2-week test period.

Variable	Day 1 (n = 30) Mean SD Range	Day 14 (n = 30) Mean SD Range	P-value
Sodium (M Eq/L)	136.4 ± 3.7 129.1 - 145.	139.2 ± 3.1 130.9 - 142.7	< 0.001
Potassium (M Eq/L)	4.4 ± 0.9 3.2 - 6.5	5.4 ± 0.6 3.9 - 6.6	< 0.001
BUN (mg %)	6.6 ± 2.7 2 - 13	12 ± 3.7 6 - 19	< 0.001
Creatinine (mg %)	0.4 ± 0.1 0.2 - 0.7	0.3 ± 0.1 0.2 - 0.5	< 0.001
Calcium (mg %)	9.4 ± 0.8 7.3 - 10.6	9.8 ± 0.7 8.3 - 11.2	< 0.05
Phosphorus (mg %)	4.1 ± 1.1 2 - 7.1	5.8 ± 1.1 2.5 - 7.7	< 0.001
Total Protein (G %)	6.8 ± 0.9 4.7 - 8.3	7.3 ± 0.8 5.7 - 8.7	< 0.05
Cholesterol (mg %)	111 ± 36 52 - 202	136 ± 38 60 - 226	< 0.05
Triglyceride (mg %)	200 ± 98 47 - 545	188 ± 90 75 - 408	< 0.05

PediaSure intake resulted in the normalization of electrolyte imbalance as evident in the normalization of sodium levels of 21 patients having hyponatremia at baseline. Also low levels of BUN (n=10), calcium (n=2) and phosphorus (n=10) became normal. High alkaline phosphates and triglyceride levels and low HDL levels were unchanged at the end of the study period.

Five cases of diarrhea were reported among the 45 patients admitted to the study, four of which showed evidence of infective diarrhea. These cases were dropped from study on days 1 and 2 of the study. In the patient with non-infective diarrhea, the condition resolved when PediaSure was discontinued. Upon restarting PediaSure, after three days, the patient again developed diarrhea. The complication of

vomiting decreased from an average incidence level of 6.3 on day 1 to 0.7 at the end of the treatment period, for the 30 patients.

Discussion

The figures of the prevalence of malnutrition in Pakistan are as high as 48% for children under 5 years³. The cause of such high incidence of malnutrition is inadequate intake of calories complexes with proper sanitary conditions leading to infections. With poor hospitalization facilities there is a need for diets which will bring about rapid weight gain, so that the child do not need to stay in hospital for a long time. This study was a clinical trail of PediaSure, which fulfills the above requirements. PediaSure has been designed such that it can be used as an central formula, or it can be used for total oral nutritional support or as a supplement to enhance the caloric intake of malnourished children.

The average weight gain of the present study was 8.3g/kg/day. Some studies done previously suggest a weight gain of 7gm/kg/day or more as satisfactory. An assessment of the Kersey Nutrition Rehabilitation Center, Nigeria showed a weight gain average of 7gm/kg/day in miasmas and miasmatic kwashiorkor patients and 6 gm/kg/day in kwashiorkor patients, treated from 1987-1991⁴.

The weight gain and decrease in WAZ of the present study population improved more significantly ($p=0.001$, $p<0.01$) as compared to another study with a similar Pakistani samples⁵. For the study population this increase in average weight represents more than a 10 per cent increase in the average weight, over a 14-day period.

Weight gain was seen in miasmatic children from the first week, In patients with edema, the weight gain occurred from the end of the first week. The acceptability of PediaSure was good; therefore the caloric intake was fairly high from the beginning even in breast-fed infants. Similar findings have been reported From Taiwan. The triceps measurement of children fed on PediaSure increased from 6.1 ± 0.3 to 6.7 ± 0.4 mm, over a period of twelve weeks.

A previous study reported energy intakes of 40-125/Cal/kg/day during the initial treatment of PEM, whereas the final energy intake varied between 100-175 cal/kg/day, when the mean study period was 20 days⁶. The results of the present study were also similar with an average caloric intake of 126.5 cal/kg/day during the first 3 days of treatment and 162.7 cal/kg/day during the last 3 days of treatment. The WHO protocol on Management of Severe Malnutrition states that malnourished children during the rehabilitation phase, i.e. after the initial 7-10 days when the Childs appetite returns, should take between 150–220 cal/kg/day⁷. Therefore we can safely conclude that our sample children were doing well on PediaSure, when judged by the WI-JO protocol.

In the Taiwanese sample of children the caloric intake improved from 882 cal/day to 1424 cal/day over a period of 12 weeks. The results of the present study show an improvement from 854/day to 1139/day in 2 weeks.

The serum albumin increased in the six patients with edema, by approximately 1 gm/dl over the 14-day period. Since this increase was not significant in the miasmatic children, who had normal serum albumin levels on admission. Therefore the overall increase in serum albumin for the 30 patients is not statistically significant.

Nearly 97% of the patients liked the formula diet very much; therefore the acceptance of the product under evaluation (PediaSure) was very well, conversely, the rate of complications was extremely low. Only one patient had osmotic diarrhea, of the 45 enrolled patients.

The average stool frequency in the first 3 days was 4.9 ± 2.4 , which reduced to 3.3 ± 2.0 on the last 3 days. A reduction of 1.6 ± 0.4 stools/day. Out of the 5 patients who were dropped from the study due to diarrhea only 1 showed evidence of osmotic diarrhea. The incidence of vomiting was greatly reduced by the end of the study period. Therefore the tolerance of the patients towards PediaSure was very good.

The present study concluded that the supplementary formula PediaSure is effective in producing a

mean weight gain of 8.3 g/kg/day and normalizing laboratory values (sodium, BUN). It is well accepted and tolerated by severely malnourished children. It is especially effective in the initial stages of treatment of severely malnourished patients.

References

1. UNICEF, The State of the World's Children 1998, UNICEF, Oxford university Press, tiE , 1998: p. 100.
2. UNICEF, Atlas of South Asian Children and Women, UNICEF Regional Office South Asia, 1996, PP 38-42.
3. Government of Pakistan, 1995, Multi Indicator Clastet Survey of Pakistan (MICS). Ministry of H ealth, Governament of Pakistan/CNICEFAGALLOP, Islamabad, 1995, pp. 75-77.
4. Ibekwe V.E Asliwortit A Management of PEM ID Nigeria An Evaluation of' the Regimen at the Kersey Nttiriiiioii Rehabilitation Center, Nigeria, Traiis R Soc. hop. Med Hyg., 1994, 88:594-5.
5. Akrant D. S., Agboatwalla NI., Zakir I. cl al. Use of local cost effective diets in the m iiiagciiiciit of persistent d arrlica rop. Pedi atr I 1997:43 45—49.
6. Morales U. Craig LU. Mclean WC Diethry maiiagcincni of malnourished children whit a new central feeding. J.AM.Diet.Assoc, , 1991:91:10-11.
7. World Ilealtli Organization, Management of Severe Malnutrition WHO Protocol. Geneva WHO 1995, p 10.