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Original Research Article

Locally prepared ready to use therapeutic food for the treatment of children with severe acute malnutrition: a randomized controlled trial

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ABSTRACT

Background: Severe acute malnutrition (SAM) remains as one of the major killers of children under five years of age. As per WHO are guidelines, dietary management plays a big role in the longer rehabilitation phase of management of SAM. RUTFs are now being used as a substitute to F-100 diet in the management of SAM around the globe. The objective of the study was to compare the efficacy of locally-prepared ready-to-use therapeutic food (LRUTF) and F-100 diet in promoting weight-gain in children with SAM.
Methods: A total of 120 children were included in the study. The control cohort received F-100 while the study cohort received LRUTF diet. Both the groups received a total of 6 feeds per day which included 3 feeds of either LRUTF or F100 and 3 feeds from family pot. Outcome was measured in terms of Rate of weight gain/kg/day, duration of hospital stays and recovery rates.
Results: There were 60 subjects in each group. Rate of weight gain was found to be (9.15±3.39 gm/kg/day) in LRUTF group and (6.72±1.05 gm/kg/day) in F-100 group. Significant difference in rate of weight gain was observed in LRUTF group. Duration of hospital stay was lesser in LRUTF group than F-100 group... Recovery rates in LRUTF group were better than F-100 group.
Conclusions: LRUTF promotes more rapid weight-gain when compared with F100 in patients with SAM during rehabilitation phase. Duration of hospital stay is lesser in LRUTF group than that of F-100 group.

Keywords: Dietary management, Locally prepared ready-to-use therapeutic food, SAM

INTRODUCTION

Severe acute malnutrition or severe wasting as defined by WHO criteria includes

- Very low weight for height (<70% of expected or below -3 SD scores for the median WHO standards) and /or
- Visible wasting and / or
- By the presence of nutritional oedema and / or
- Mid upper arm circumference less than 115mm.[1]

It is estimated that 13 million children under five years of age are severely acutely malnourished.[2] Most of them live in south Asia and sub Saharan Africa. India alone is home to approximately 8,105,000 children with severe acute malnutrition.[3]

As per the WHO 's guidelines for the inpatient management of Severe acute malnutrition children, after initial stabilization phase where the acute medical conditions like hypoglycaemia, hypothermia, dehydration, electrolyte imbalance, infections are managed, there after Dietary management plays a big role in the longer rehabilitation phase of management of severe acute malnutrition.[4] Guidelines provided by WHO for management of children with severe acute malnutrition has advised two formula diets, F-75 and F-

100. F-75 (75 kcal/100mL) diet is used during initial phase of treatment while F-100 (100kcal/100mL) is used during rehabilitation phase after appetite has returned. These diets can be prepared at locally using cow milk, sugar, vegetable oil, and water.[5]

F-100 diet needs to be prepared just before consumption; cow milk used sometimes can act as growth medium for pathogenic bacteria if proper hygienic conditions are not maintained during diet preparation. Milk is also liable to get adulterated easily. Shelf-life of F-100 depends on its constituents like milk which has a very short shelf-life of few hours in tropical climates.[4]

To deal with these problems there was a need to develop a therapeutic feed which had prolonged shelf-life, was a poor growth media for pathogens, could be prepared locally with available resources, and was cheap and locally acceptable. In the present study, a local ready to use therapeutic food (LRUTF) was prepared from groundnut, milk powder, sugar and vegetable oil.

The objective of the study was to compare the efficacy of LRUTF with that of F-100 diet in promoting weight gain among children with severe acute malnutrition during rehabilitation phase. To assess the effectiveness of LRUTF diet in the recovery of children with severe acute malnutrition.

METHODS

Study design

It is a randomized controlled trial.

Inclusion criteria

Children aged 6 months to 5 years diagnosed with severe acute malnutrition as per the WHO criteria and in rehabilitation phase after finishing the initial stabilization phase.

Exclusion criteria

- Children with chronic illness like tuberculosis, congenital heart disease, asthma, diabetes mellitus and other serious illnesses
- Children affected with primary immunodeficiency's and HIV
- Children who develop primary failure during hospital stay

All children aged 6 to 60 months, diagnosed as severe acute malnutrition according to WHO criteria and hospitalized in our institution during the study period were included in study.

Initial stabilization phase was begun after hospitalization, life-threatening problems were identified and treated, specific deficiencies were corrected, metabolic abnormalities were reversed and feeding was begun. During this initial stabilization phase, cautious feeding was begun with F-75. Feeding was begun with 80 kcal/kg/day and gradually increased to 100 kcal/kg/day. The volume of feeds was increased gradually while decreasing the frequency of administration. This phase was similar in both cohorts.

On completing stabilization phase, Children were given a test feeding of the LRTUF and standard F-100 to screen for food allergy and ensure acceptability. These children were randomly assigned into one of the two groups by using a manual method. The subjects with odd serial number at the time of enrolment were given LRUTF diet (study group) and the subjects with even number at the time of enrolment are given F-100 diet (control group).

During rehabilitation phase, children in study group received 3 meals of LRUTF daily in addition to 3 meals of food from family pot. All Children in study group received a measured quantity of 15 g/kg/day of LRUTF daily. This therapeutic food provides approximately 75 kcal/kg/day. Patients also received approximately 75 kcal/kg/day from family pot. Thus, a total of 6 feeds per day and around 150 kcal/kg/day with 1.5- 2 gm/kg of protein were given to every child in study group.

Children under control group received 3 meals of F-100 daily in addition to 3 meals of food from family pot. All Children in control group received a total of 75 ml/kg/day of F-100 daily which provided approximately 75 calories/kg/day. Patients also received approximately 75 kcal/kg/day from family pot. Thus, a total of 6 feeds per day and around 150 kcal/kg/day with 1.5-2 gm/kg of protein were given to every child in control group. LRUTF was prepared every Sunday in hospital kitchen under all aseptic precautions and stored in air tight containers of 1kg each. Mother or caregiver was advised with the amount of F-100 or LRUTF to be given per feed. Food from family pot was consumed at 11am, 5pm and 11pm. F-100 was prepared daily as per the number of children at 8am, 2pm and 8pm.

The children's clinical parameters were checked daily including vitals and anthropometry. Children's weight was measured to the nearest 5gm with an electronic weighing machine daily. Height was measured with a stadiometer to the nearest millimetre and in children less than 2 years; length was measured using an infantometer daily. Mid upper arm circumference was measured with a tape to the nearest millimetre daily. Children were examined daily for the presence of oedema.

Before discharge from hospital, caregiver of each child was taught to prepare LRUTF and F-100. They were advised to give LRUTF and F-100 at home in same quantity as in hospital and report every 15 days. Weight gain was calculated before discharge and on each follow-up. At each follow up visit child's weight, height/length, mid upper arm circumference was noted. Patients were

followed till they achieve weight of 1 S.D. below the median for height.

Outcome

Primary outcome variable was rate of weight gain (gm)/kg bodyweight/day. This was calculated as follows:

$$\frac{(W2 - W1) \times 1000}{(W1 \times N)}$$

Where, W2 – Weight at the time of discharge (kg) or follow up; W1 – Minimum weight during study period (kg); and N – Number of days from minimum weight to discharge or follow up; gm = gram.

Recovery - Children from both groups were considered to have recovered when she/he attained a weight for height Z score of 1SD below the median of the WHO reference population and had lost all edema for those with edematous acute malnutrition.

RESULTS

In the LRUTF 55% children were in age group of 13 to 24 months and 21.67% children were in 6 to 12 months. In the F-100 group 51.67% children were in 13 to 24 months and 25% in the age group of 6 to 12 months. The age distribution among two groups was comparable.

Table 1: Composition of LRUTF and F-100 used in the present study.

Ingredient	LRUTF(1kg)	F-100 (1ltr.)
Fresh cow's milk	-	900ml
Sugar	350g	75g
Vegetable oil	120g	20g
Peanut butter	280g	-
Milk powder	250g	-
Water	nil	to make 1000ml
Calories	5140kcal/kg	1000 kcal/l
Proteins	136 g/kg	27.2 g/l

In the LRUTF group, 33.3% children were still breastfed, 53.3% of them were from rural residence, 66.7% were from lower socioeconomic status and 71.7% mothers were illiterates. In F-100 group 40% children were breast fed, 46.7% of them were from rural residence, 58.3% from lower socioeconomic status and 66.7% mothers were illiterates.

In the LRUTF, Fever was the most common symptom (26.7%) followed by cough and diarrhoea. Oedema was present in 33.3% and 6.7% children had stunting at admission. In F-100 group cough was present in 25% cases followed by fever and diarrhoea. Oedema was present in 36.6% cases and stunting was noted in 6.7% children at admission. LRUTF group had a weight gain of 9.15gm/kg/day and F-100 group had a weight gain of 6.72gm/kg/day at the time of discharge. Secondary failures in LRUTF and F-100 groups were 6.67% and 13.3% respectively. Weight gain in LRUTF and F-100 among children with oedema was 9.62gm/kg/day and 7.97 gm/kg/day respectively. In children without oedema it was 6.94 gm/kg/day and 5.92gm/kg/day respectively.

Table 2: Age and sex distribution of the study and control groups.

Age in months	Study group	Male (%)	Female (%)
6-12	LRUTF, N=60	8(13.33)	5(8.33)
	F-100, N=60	9(15)	6(10)
13-24	LRUTF	19(31.6)	14(23.33)
	F-100	17(28.33)	14(23.33)
25-48	LRUTF	4(6.67)	4(6.67)
	F-100	4(6.67)	4(6.67)
49-60	LRUTF	4(6.67)	2(3.33)
	F-100	4(6.67)	2(3.33)

In LRUTF group weight gain was highest (9.15gm/kg/day) in the age of 13 to 24 months. In F-100 group weight gain was highest (7.19gm/kg/day) in the age of 25 to 48 months.

However, there was no significant intra group variation in weight gain among different ages in both groups (p value >0.05). L-RUTF group had a height and MUAC gain of 0.56mm and 0.42mm respectively. F-100 group had a height and weight gain of 0.42mm and 0.35mm respectively.

Table 3: Outcome in both groups at the time of discharge.

Outcome	LRUTF N=60	F-100 N = 60
Average weight gain gm/kg/day, mean (SD)*	8.85(1.90)	6.43(1.04)
Average weight gain gm/kg/day among failures mean (SD)	4.58(0.89)	4.53 (0.63)
Average weight gain gm/kg/day among improved *mean (SD)	9.15(1.56)	6.72 (0.77)
Secondary failures	4(6.67%)	8 (13.3%)
Death	4	5
LAMA	5	5

*p value <0.0001

Duration of hospital stay in LRUTF group was 17.07days. In F-100 group average hospital stay was for 23 days. (P value <0.0001).

Average duration for recovery in LRUTF was 41.96 days. In F-100 group average duration of hospital stay was 48.66 days. (P value <0.05).

Table 4: Average weight gain in male and female sex in both groups at discharge.

Determinant	Sex	Weight gain gm/kg/day, mean (sd)	
		LRUTF	F-100
Overall Average	Male*	8.13 (1.58)	6.41 (1.13)
	Female*	9.76 (1.95)	6.45 (0.92)
Without oedema at admission	Male*	8.87 (0.92)	6.99 (0.99)
	Female*	10.32(1.75)	6.58 (0.85)
With oedema at admission	Male*	7.28 (1.84)	5.59 (0.77)
	Female*	7.52 (0.77)	6.16 (1.07)

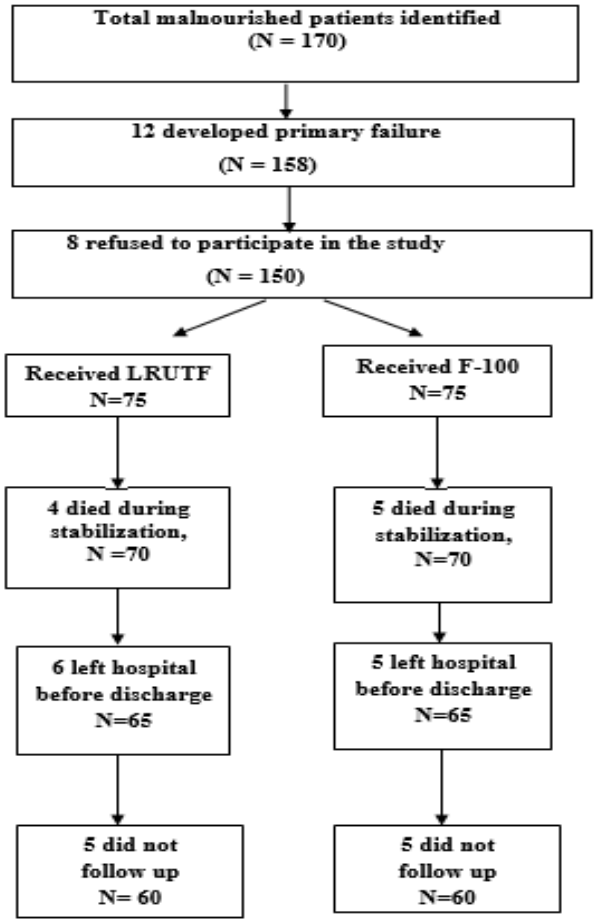

Figure 1: Flow chart of group allocation.

DISCUSSION

The mean age of present study was not significantly different between the two groups. Similar distribution of cases was noted in a study conducted by Diop, et al. with a mean age of 17.8 months in F-100 and 15.8 months in LRUTF group respectively.[6]

In the present study 100% children had weight for height less than 3 SD and 71.6% had MUAC less than 115mm including both groups. This was comparable to the study of Singh, et al. where the incidence of Weight for height less than 3 SD was 89.7% and 80.7% children had MUAC less than 115mm among children with severe acute malnutrition who got admitted to nutritional rehabilitation centres in Uttar Pradesh, India.[7]

In the present study weight gain in LRUTF group was significantly better than F-100 group (p value <0.0001). A similar study in hospitalized patients done by Diop, et al. Reported average weight-gains of 15.6 and 10.1 g/kg/d in the RTUF and F-100 groups respectively.[7] In another similar study conducted by Thakur, et al. the average weight gain was 9.59g/kg/day and 5.41 g/kg/day. (P value < 0.0001).[8] In our study, the average weight gain was 9.15gm/kg/day and 6.72gm/kg/day respectively.

A systematic review also suggested that use of therapeutic nutrition products like RUTF for home-based management of uncomplicated SAM appears to be safe and efficacious.[9]

In the present study children without oedema had a better weight gain than with oedema at admission (p value <0.0001) in both groups. This was in unison with the study of Thakur, et al. where LRUTF group had better weight gain in children with and without oedema at admission (p value < 0.0001). This was in contrast to the study of Diop, et al. where weight gain in the children who initially had oedema was not different from them who did not have oedema.[7]

In the present study, the average duration of hospitalization in LRUTF group was 17 days and in F-100 group it was 23 days. This was similar to the study of Thakur et al where the duration of stay in LRUTF group was 13 days and 16 days in F-100 group. (P value < 0.0001).[8]

In the present study LRUTF had better weight gain than F-100 group during follow up period and the difference was statistically significant. (P value <0.0001). This was in unison with the study of Thakur, et al. Which also showed that LRUTF had a better weight gain during follow up period than F-100 group.[9] However weight gain was lesser in follow up period at home (8.75 gm/kg/day) than at hospital. This may be due to intra household sharing of LRUTF among family members. Duration for recovery was significantly less in LRUTF group than F100 group (p value <0.0001). Peanut butter used in LRUTF preparations contains potent allergens, which may be enhanced further during cooking.[10] Clinical allergy is rare in developing countries, especially in severely malnourished children with suppressed immune reaction.[11] In other areas, the development and field testing of a peanut-free spread might be warranted.

CONCLUSION

LRUTF diet is found to be superior to F-100 in the promotion of weight gain during the rehabilitation phase of the management of severe acute malnutrition. Acceptability of LRUTF is good in both urban and rural

population. With no adverse reactions and better weight gain, LRUTF is of great help in the management of SAM. LRUTF also has lesser duration of hospital stay which has a great relevance in treatment of SAM at national level as it can decrease the cost of treatment to a greater extent and can give psychological satisfaction to caregivers. Hence, LRUTF diet can be recommended as a substitute for F-100 to be used by National Health Mission in Nutritional Rehabilitation programs to promote the weight gain of SAM children both at Nutrition Rehabilitation Centers and as well as at community level. However Further studies with large sample size should be conducted at grass root level in community level among the socioeconomically disabled groups to assess the feasibility, acceptance and efficacy of LRUTF diets.

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