

Safety, Tolerability, Efficacy and Logistics of Administration of Three Types of Therapeutic Feeds to Children with Severe Acute Malnutrition (SAM)

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Abstract

Objective: To analyse safety, tolerability, efficacy and logistic issues related to administration of 3 types of therapeutic feeds to children with severe acute malnutrition (SAM) from tribal district of Nandurbar, Maharashtra.

Design: A three arm open label, block randomized trial using 3 therapeutic feeds i.e. commercially available ready to use therapeutic feed (C-RUTF), locally prepared ready to use therapeutic feed (L-RUTF) & amylase rich food (ARF) was given to 1092 tribal children of SAM in Nandurbar District, Maharashtra, India during 2014-2015.

Setting: Tribal district of Nandurbar, Maharashtra.

Participants: 1092 children of SAM, 766 on C-RUTF, 184 on L-RUTF & 143 on ARF followed on treatment for 8 weeks.

Outcomes: The recovery rates in the three groups, any untoward effects during treatment and logistic aspects of procurement, delivery, storage & administration of therapeutic feeds.

Results: Total number of children with SAM were 1092.

Gr 1 – Out of 765 children of SAM,

404 (52.8%) recovered on C-RUTF.

Gr 2 – 80 (43.5%) recovered out of 184 on L-RUTF.

Gr 3 – 64 (44.8%) recovered on ARF at the end of 8 weeks of treatment, the difference being statistically significant between C-RUTF & others.

Out of 38 children on C-RUTF, it was observed that 1 had diarrhoea, 1 had vomiting, 1 had fever, 4 children reported more activity in terms of playfulness, more speaking & smiling. 31 children had nothing specific to report.

Out of 34 children on L-RUTF, 6 children reported diarrhoea, 1 had vomiting & 4 children reported fever. 3 children reported more activity. 23 children had nothing specific to report.

Out of 19 children on ARF, 1 had diarrhoea, 1 had vomiting, 1 had fever, 3 reported more activity. 13 had nothing specific to report.

Untoward effects were noted in 3 out of 38 (7.89%) in C-RUTF group, 11 out of 34 (32.35%) in L-RUTF

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Introduction

A study undertaken on children with severe acute malnutrition from tribal areas of Nandurbar, Maharashtra, India, using three types of therapeutic feeds i.e. commercially prepared ready to use therapeutic food(C-RUTF), locally prepared ready to use therapeutic food(L-RUTF) and amylase rich food(ARF) showed that C-RUTF was superior to all the others in terms of recovery rates, untoward effects, safety, tolerability and logistic issues.

Strengths and Limitations

- This is a real life study in remote tribal inaccessible vulnerable children with malnutrition.
- It is a registered clinical trial.
- Statistically significant
- Probably the first one
- Sample size is a little small for study of untoward effects .However, the total number is large.

Severe acute malnutrition in children under 5 years increases their risk of death 11 times compared to normal children. Treatment of these children is a national priority and should be considered as an emergency. However, these children cannot be admitted in a facility for therapeutic feeding programs as it may overburden the public health systems. It is now an established fact that children of severe acute malnutrition without oedema, medical complications &

with good appetite can be managed in the community under the CMAM (community management of acute malnutrition) program .

Severe acute malnutrition in children aged 6 – 59 months is defined as mid upper arm circumference (MUAC) <115 mm or a weight for height Z score <-3 of the median on WHO growth charts. As per NFHS 4, 26% of the Indian children are wasted (< - 2SD) and 9.4% are severely wasted (<-3SD weight for ht). Various countries have successfully managed CMAM programs using different types of therapeutic feeds. Our present study was designed to study therapeutic efficacy, safety, tolerability and logistics of administration of three types of therapeutic feeds.

Methods

Study Design

A total of 1092 children suffering from SAM were the study patients. Tribal district of Nandurbar, Maharashtra was selected due to high prevalence of wasting (39.8%) in children of 5 years. Children were selected on the basis of MUAC <11.5 cms. and/or weight for height < -3 SD from median on WHO growth charts. Screening was done by front line health workers (ASHA, AWW, and ANM) actively as house to house or passively during immunization or other health services. Children between 6 months to 5 years were selected during study period of 2014-15. Those SAM children who had edema or medical complications or no appetite were referred to the Nutrition rehabilitation center of the

district hospital of Nandurbar. The remaining children comprised of SAM without complications. They formed the study group and were recruited. They belonged to 6 blocks of the district of Nandurbar which were randomized to form 3 groups of 2 blocks each. First group of children received commercial ready to eat therapeutic food (C-RUTF), the second group received locally prepared RUTF (L-RUTF) and the third group received amylase rich food (ARF) prepared by grinding sprouted dried, powdered wheat, green gram and made into porridge. ARF has been the feed available under Govt. run schemes in Anganwadis. C-RUTF is tried worldwide and recommended by WHO for treatment of uncomplicated SAM. L-RUTF was prepared in anganwadi with nearly the same composition as C-RUTF. Children were monitored for appetite, tolerability and palatability along with weekly weight gain /loss. Any untoward symptoms like diarrhoea, vomiting, abdominal pain, refusal to eat the food, fever; activity, playfulness & smile were also observed as well as informed by caregivers. Weekly follow up was done for eight weeks. Recovery was defined as MUAC >12.5 cms or wt. for ht. >-2SD at the end of eight weeks of treatment. Outcome measures were noted and disseminated to the community after completion of the study

Patient and Public Involvement

The clinical trial was registered under clinical trial registry of India No. CTRI/2014/09/004958 and approved by Ethics Committee of Haffkine Research Institute, Mumbai. Data safety monitoring board was formed that reviewed the data periodically. Hospital admission or death was reported to ethics committee & DSMB. Community advisory board was formed to obtain feedback from parents to have patient and public involvement and oversee conduct of the trial.

Observations

Table 1 gives the composition of 3 therapeutic feeds.

Table 2 gives base line characteristics of 1092 children of SAM.

Table 3 gives the number of untoward events in each group.

Total number of 91 children were studied for untoward effects from among 2 villages each from the 6 blocks.

Table 4 gives the recovery rates on therapeutic feeds.

The recovery rates were highest in C-RUTF group 52.8%, 44.8% in ARF group & 43.5% in L-RUTF group.

Discussion

Prevalence of malnutrition in children under 5 is very high in India. It is estimated that 3% of world's children suffer from severe acute malnutrition & the figure for South Central Asia is 5.1%¹. The NFHS (National Family Health Survey, India) 4 survey conducted in 2015-16 has shown an increase in SAM from 6.4% to 7.5% in a decade².

Treatment of children of SAM is a national priority. As per WHO & UNICEF, the management of children with SAM is broadly divided in two categories for ease of medical care. Children who have medical complications like diarrhoea, dehydration, pneumonia, hypoglycemia, electrolyte imbalance, hypothermia or others, oedema or loss of appetite would generally need hospitalization. Stabilization & nutrition rehabilitations is done for children admitted to NRCs (Nutrition rehabilitation centers). These comprise of around 10-15% patients of SAM. However, majority i.e. the remaining 85-90% of the patients can be managed at home in the communities and such patients can be given therapeutic feeding along with antibiotics deworming and other ambulatory care. For these children various therapeutic regimes are tried by various workers.

In our study, we compared 3 therapeutic feeding options in terms of their efficacy, tolerability, palatability and logistic issues.

These three therapeutic feeds were C-RUTF, L-RUTF & ARF which were randomly given to SAM children from 6 tribal blocks of Nandurbar from Maharashtra State, India during 2014-15.

1) C-RUTF - Commercially available ready to use therapeutic food was available in sachets which had a shelf life of 18 months was easy to store, moisture free, sterile. It did not require any preparation. It is in the form of paste of ground nuts, milk powder, sugar and oil in proportions as given in Table 1. Micronutrients are added to the paste. The particle size is less than 200 μ . Taste is sweet and is highly palatable. The cost was around Rs.4,140/- approx. per child's treatment for 2 months.

TABLE 1. Composition of feeding options tested in CMAM effectiveness trial in Nandurbar, Maharashtra (2014-15)

	ARF		L-RUTF		C-RUTF	
Amylase rich flour (g/100 g)		29		na		na
Peanut paste (g/100 g)	na		20		30	
Sugar (g/100 g)	24		28		29	
Milk powder (g/100 g)		24		30		20
Vegetable oil (g/100 g)		19		30		20
Sesame seeds (g/100 g)	5		absent		absent	
Micronutrients approx.		1.6		1.6		1.6
Energy (kcal/100 g)		420		513		550

L-RUTF & ARF were prepared in the Anganwadi by health workers while C-RUTF was obtained in the form of packets that were ready to be consumed. ARF required cooking by boiling. Since the terrain of the villages was hard to reach, food ingredients, packets had to be carried by vehicles, through the river and even on donkey's back.

TABLE 2. Baseline characteristics of the children admitted to the CMAM effectiveness trial in Nandurbar, Maharashtra (2014-15)

	ARF		L-RUTF		C-RUTF		All	
	n	%	n	%	n	%	n	%
Girls	67	46.9	74	40.2	385	50.4	526	48.2
Boys	76	53.1	110	59.8	380	49.6	566	51.8
Total	143	100	184	100	766	100	1,092	100
MUAC <115 mm	55	38.5	86	46.7	387	50.5	528	48.4
WHZ <-3	88	61.5	98	53.3	378	49.5	564	51.6
Total	143	100	184	100	766	100	1,092	100.0

It is seen that 51.8% boys and 48.2% girls were enrolled under the CMAM program. 48.4% were detected by MUAC while 51.6% were detected by using wt for ht. < -3SD.

Table 3.

Untoward event (Unsolicited)	Therapeutic Feeds		
	C-RUTF n = 38	L-RUTF n = 34	ARF n = 19
1) Diarrhoea	1	6	1
2) Vomiting	1	1	1
3) Fever	1	4	1
4) Abdominal distention	0	0	0
5) Any other like excessive sleep, drowsiness, convulsion	0	0	0
6) No report of anything specific	31	23	13
Total	3/38 = 7.89%	11/34 = 32.35%	3/19 = 15.7%

4 children in C-RUTF group, 3 children in L-RUTF group & 3 in ARF group respectively reported increased activity, playfulness, speaking & smiling which were signs of recovery.

TABLE 4. Programme outcomes among children admitted to the CMAM effectiveness trial in Nandurbar, Maharashtra (2014-15)

	ARF		L-RUTF		C-RUTF		All		P-value
	n	%	n	%	n	%	n	%	%
At Exit									
Recovered (MUAC \geq 125/ WHZ \geq -2) ¹	64	44.8	80	43.5	404	52.8	548	50.2	0
Non recovered (MUAC <125/ WHZ < -2) ²	79	55.2	104	56.5	361	47.2	544	49.8	0
Total	143	100	184	100	765	100	1092	100	0

¹MUAC \geq 125 mm for children admitted on the basis of MUAC <115 mm; WHZ \geq -2 for children admitted on the basis of WHZ <-3.

²MUAC < 125 mm for children admitted on the basis of MUAC <115 mm; WHZ < -2 for children admitted on the basis of WHZ <-3.

- 2) L-RUTF - Locally prepared ready to use therapeutic food. This was prepared locally in the village anganwadi center using the same ingredients as C-RUTF. The paste was made in a mixer. It had more bulk, was voluminous and had to be prepared afresh. Storage, safety and contamination (especially bacterial) are major issues in anganwadis that are ill equipped. Even moisture is likely to spoil ground nuts and milk powder. The particle size of the powder is much larger than 200 μ and grinding of paste depended on availability of electricity at the village anganwadi center. The number of calories provided by L-RUTF are nearly similar to those provided by C-RUTF. Cost of treatment was Rs.3,848/- per child for 8 weeks.
- 3) ARF - Amylase rich food was prepared in anganwadi by sprouting wheat, green gram, then drying it and grinding into powder. Sugar, oil & milk powders are added separately while preparing porridge like 'sheera' or 'upma'. It is not as calorie dense as C-RUTF or L-RUTF. Large amount is required to give calories like RUTF. It requires cooking, boiling every day like a hot cooked meal. Constituents may vary from day to day and from person to person while cooking. Multivitamin syrup is given to the child separately to provide micronutrients. Cost per child was Rs.2400/- for 8 weeks. From this, it was observed that C-RUTF has extreme ease of administration, ease of transport, storage and is least contaminated, hence safe. It is finely ground; hence, easily absorbed compared to L-RUTF & ARF which are difficult to prepare, though is economically a bit cheaper.

As is seen from table 3, the number of untoward events were maximum for L-RUTF 32.35% as compared to 15.7% for ARF and were seen to be the least i.e. 7.89% in C-RUTF. Thus the safety of C-RUTF has been obvious in this study. No. of episodes of diarrhoea were highest in L-RUTF group. The main reason could be bacterial contamination.

As seen from Table 4, 52.8% of children on C-RUTF recovered at the end of 8 weeks, the same figures were 44.8% with ARF & 43.5% with L-RUTF. This difference was found to be statistically significant.

There are few published reports on the use of

therapeutic food in treatment of uncomplicated SAM. N. Bhandari found L-RUTF to show 57% recovery while C-RUTF showed 47% recovery³. In African setting C-RUTF has been seen to show 60.8% recovery.

Our study has also analysed untoward effects that are the least with C-RUTF. Indian studies on this qualitative aspect are not published so far.

Considering all these facts, it appears that C-RUTF will definitely form the pillar of community management of SAM in Indian children and should be tried in SAM children by scaling up CMAM program in all States of India where malnutrition is prevalent.

The C-RUTF used was from Amul, Gujarat. There are 22 manufacturers of RUTF approved by UNICEF. Three important ones from India are Bal-Amul by Kaira District co-operative milk producers union Ltd. (AMUL), Compact India pvt Ltd. and Proactiva by Hexagon Ltd. Other common brands are Plumpy nut paste manufactured by Nutriset, Mana nutritive aid products, Diva nutritional products, Nuflower foods, Nutrivita foods, Meds and foods, Power food industries, Edesia USA and Vitaset.

Conflicts of Interest

The authors declare no conflict of interest.

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