

## Original Research Article

# Comparison study on efficacy of UNICEF specified therapeutic food (F-75/F-100) with traditionally used home based food in management of severe acute malnutrition

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**Received:** 03 April 2018

**Accepted:** 02 May 2018

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### ABSTRACT

**Background:** The management of malnutrition depends on its severity. While mild to moderate malnutrition can be managed on ambulatory basis, severe malnutrition is preferably managed in hospital settings. This study was undertaken to find the magnitude of SAM in children (6 months to 60 months) and to compare the UNICEF specified therapeutic food (F-75/F-100) with traditionally used home based food in treatment of severe acute malnutrition.

**Methods:** This prospective and observational study was conducted in the Department of Pediatrics of G.S.V.M. Medical College, L.L.R. and Associated Hospitals, Kanpur. Logarithmic transformation was achieved by SPSS 20.

**Results:** The prevalence of SAM in children between 6 months to 60 months of age to be 18%. Clinical spectrum of SAM showed 95.24% of marasmus 3.57% of Kwashiorkor and 1.19% of marasmic kwashiorkor. There was significant increase in weight of hospitalized patient receiving F75/F100 at 28 days of follow up. Weight gain was not statistically significant in patients treated at home.

**Conclusions:** SAM should preferably be treated in hospital with appropriate therapy rather than home based management.

**Keywords:** Home based food, Severe acute malnutrition, UNICEF specified therapeutic food

### INTRODUCTION

Malnutrition may be mild, moderate or severe. At one end of spectrum, mild PEM manifests itself mainly as poor physical growth in children and at the other end of spectrum, kwashiorkor (characterised by the presence of edema) and nutritional marasmus (characterised by severe wasting) have high case fatality rates.<sup>1</sup>

The management of malnutrition depends on its severity. While mild to moderate malnutrition can be managed on ambulatory basis, severe malnutrition is preferably managed in hospital settings. Up to 15% under-5 children with SAM require inpatient management because of medical complications. The remaining 85% (without

medical complications) can be managed through a community-and/or home based care approach.

The move to community-based treatment of SAM has made it possible to address SAM as a public health problem treating millions of children across 35 countries in the past few years. This change has addressed key capacity constraints especially those of trained staff and hospital inpatient capacity that previously limited both the numbers of children treated and the quality of treatment for those who managed to gain access.

The diet (F-100) used in emergency by agency Action Contra le Faim was found to promote rapid recovery of the children. This protocol was offered to the WHO for

their consideration in 1992 which was formally adopted in the same year and since then given rise to several derivative works.

This study was undertaken to find the magnitude of SAM in children (6 months to 60 months) attending paediatric OPD and IPD of Medical college and to compare the Unicef specified therapeutic food (F-75/F-100) with traditionally used home based food in treatment of severe acute malnutrition.

**METHODS**

This prospective and observational study was conducted in the Department of Pediatrics of G.S.V.M. Medical College, L.L.R. and Associated Hospitals, Kanpur, UP, India.

**Inclusion criteria**

- Patient between ages 6 to 60 months with SAM
- Weight for height below,3 standard deviation(SD or Z scores) of median WHO growth reference(2006).
- Visible severe wasting
- Presence of bipedal edema
- Mid upper arm circumference below 11.5 cm

**Exclusion criteria**

- Children having other chronic systemic diseases incriminated as a cause of severe malnutrition, including cerebral palsy, congenital heart disorders, chronic haemolytic anaemias, malignancies, known metabolic disorders, known malabsorption syndromes, chromosomal malformations, or chronic renal and hepatic disorders.
- Patient identified to be HIV Positive.

The cases of SAM were identified and selected from Pediatric O.P.D. and I.P.D. following the WHO guidelines. SAM patients with complications need hospitalization and those without complication can be treated either at hospital or at home. Patients were assigned for treatment to either hospital based treatment with F75/F100 or home based management with locally available food. Those patients who were stable and not willing for admission in the hospital were assigned for home based therapy. Majority of such patients enrolled in study were between March 2011 to July 2011. Hospitalized patients received F75/F100 for 4-8 weeks, while other group received management of SAM with traditionally home based food. Home based food was advised to provide 150kcal/kg/day and 2-3 gm /kg/day of proteins. A diet chart was provided using energy dense foods like khicdi, paratha, curd-ricedalia, banana enriching them with oil, jaggery. Energy dense feeding was gradually increased so as to provide approximately 150-220 kcal/kg/day and proteins 4-5 gm/kg/day.Mother was given advice about the type of food, quantity of food, and feeding frequency. No external support for procuring

or making food for families were provided. Multivitamin supplements were continued for 8 weeks. Mother was counselled to give cheerful stimulating environment and to engage the child in playful activity. The hospitalized patients were fed under continuous supervision and regularly monitored whereas patients undergoing home based rehabilitation were called for regular follow up. Frequency of follow up visits were one visit every 7 days or earlier if required due to any arising complication. At each visit dietary intake was recorded by recall-method, and detailed general physical and systemic examination was done. Mother was re-counselled about type, quantity and frequency of food to be given. Any medical problem identified during follow up visits were treated. Weight assessment was repeated at follow up visits. A weight gain of >5gm/kg/day was defined as an acceptable weight gain. To compare whether there is any statistically significant difference in weight, analysis of Variance technique was used. It was observed that basic assumption of ANOVA that parent population is normally distributed was not satisfied. In order to counter this we used the technique of transformation of variable of interest. Logarithmic transformation was achieved by SPSS 20. The ANOVA was applied on thus transformed variable for cases of home and hospital therapy. For multiple comparison Tukeys’s Post Hoc test was applied.

**RESULTS**

This study comprised of 84 children who met the WHO criteria for SAM from the paediatric OPD and IPD of L.L.R. Children Hospital, Kanpur. Of these 38 children were assigned to receive traditional home based therapy and 46 to receive Hospital based therapy with F-75/F-100. Out of 84 cases of severe PEM, 80 (95.24%) cases were of marasmus, 3 (3.57%) were of Kwashiorkor and 1 (1.19%) cases were of marasmic kwashiorkor.

**Table 1: Age and sex distribution of patients.**

Age groups (months)	Males		Females		Total	
	No.	%	No.	%	No.	%
6-12	19	48.72	24	53.34	43	51.2
> 12-24	11	28.20	12	26.67	23	27.4
> 24-36	7	17.95	6	13.33	13	15.5
> 36-48	0	0	2	4.44	2	2.4
> 48-60	2	5.13	1	2.22	3	3.5
Total	39	100	45	100	84	100

The Table 1 shows that incidence of severe malnutrition is more common under 3 years of age and maximum in less than 1 year. Females were more affected than males in all age groups except those above 4 years of age.

Common presenting symptom in study group were fever 76.19%, loose stools 61.9%, loss of appetite 45.23% and abdominal pain 23.81%. Nearly 21.43% had altered sensoriumand 13.1% had even tremors. Pallor was present in all of the cases (Table 2).

**Table 2: Clinical signs and symptoms present in 84 patients of SAM at initial visit (n=84).**

Symptoms and signs	No. of cases	Percentage
Pallor	84	100
Fever	64	76.19
Loose stools	52	61.9
Cough	46	54.76
Loss of appetite	38	45.23
Respiratory distress	24	33.33
Vomiting	26	30.95
Abdominal pain	20	23.81
Altered sensorium	18	21.43
Tremor	11	13.1

**Table 4: Mean weight (wt.) of hospitalized patients at various follow up.**

Patient (hospital)	Range (kg)	Mean±SD	95% confidence interval
Wt. at first visit	2.55-10.72	5.57±2	4.97-6.16
Wt. at 7 days	2.62-10.86	5.675±2.01	4.63-5.82
Wt. at 14 days	2.84-10.95	5.81±1.99	5.22-6.41
Wt. at 21 days	3.27-10.54	6.276±1.873	5.76-6.88
Wt. at 28 days	3.72-10.9	6.546±1.9	5.98-7.11

**Table 3: Incidence of complications in cases of SAM (n=84).**

Complication	No. of cases	Percentage
Infection	31	36.9
Electrolyte imbalance	23	27.38
Hyponatremia	11	13.5
Hypertatremia	2	2.4
Hypokalemia	20	23.8
Hypocalcemia	3	3.57
Hypoglycemia	12	14.3
Severe anemia with congestive heart failure	10	11.9
Hypothermia	9	10.7

**Table 5: ANOVA table for weight gain in different follow ups of hospitalized patient weight of hospitalized patient.**

Weight	Sum of squares	df	Mean square	F	P value
Between groups	1.119	4	0.280	2.862	0.024
Within groups	22.001	225	0.098		
Total	23.120	229			

**Table 6: Post hoc analysis.**

(I) different follow up	(J) different follow up.	Mean difference (I-J)	Std. error	p value	95% Confidence Interval	
					Lower bound	Upper bound
0.00	1.00	0.04479	0.06520	0.959	-0.1345	0.2241
	2.00	0.13269	0.06520	0.253	-0.0466	0.3120
	3.00	0.16124	0.06520	0.101	-0.0181	0.3406
	4.00	0.18089*	0.06520	0.047	0.0016	0.3602
1.00	0.00	-0.04479	0.06520	0.959	-0.2241	0.1345
	2.00	0.08790	0.06520	0.661	-0.0914	0.2672
	3.00	0.11645	0.06520	0.384	-0.0629	0.2958
	4.00	0.13610	0.06520	0.229	-0.0432	0.3154
2.00	0.00	-0.13269	0.06520	0.253	-0.3120	0.0466
	1.00	-0.08790	0.06520	0.661	-0.2672	0.0914
	3.00	0.02855	0.06520	0.992	-0.1508	0.2079
	4.00	0.04820	0.06520	0.947	-0.1311	0.2275
3.00	0.00	-0.16124	0.06520	0.101	-0.3406	0.0181
	1.00	-0.11645	0.06520	0.384	-0.2958	0.0629
	2.00	-0.02855	0.06520	0.992	-0.2079	0.1508
	4.00	0.01965	0.06520	0.998	-0.1597	0.1990
4.00	0.00	-0.18089*	0.06520	0.047	-0.3602	-0.0016
	1.00	-0.13610	0.06520	0.229	-0.3154	0.0432
	2.00	-0.04820	0.06520	0.947	-0.2275	0.1311
	3.00	-0.01965	0.06520	0.998	-0.1990	0.1597

\*. The mean difference is significant at the 0.05 level.

The Table 3 shows that infections were most common (36.9%) followed by electrolyte imbalance (27.8%). Hypoglycemia, severe anemia with congestive heart failure and hypothermia were present in 14.3%, 11.9% and 10.7% respectively. Hypokalemia (23.8%) was the most common electrolyte abnormality followed by hyponatremia (13.5%). The mean wt ±SD at first visit was found to be 5.57±2 kg which increased consistently every week on follow up and was 6.546±1.9 kg at 28 days (Table 4).

The Table 5 shows that weight gain at different follow ups is statistically significant (P=0.024). For further analysis to know about inter follow up differences Post Hoc Test (Tukey’s test) was used.

Significant weight gain from basal weight was evident on 28th day of follow up with a P value of 0.047. Rest differences in weight gain are statistically not significant (Table 6).

The Mean ±Sd weight was 6.04±2.2 kg at first visit which increased gradually to 6.17±2.24 kg at 28 days. The above graph shows that though there is increase in mean weight of home treated patients however increment was small as compared to those treated at hospital (Table 7).

The Table 8 shows that statistically significant weight gain was not evident in patient receiving home based

therapy with P value of 0.999. For further analysis to know about inter follow up differences Post Hoc Test was used.

**Table 7: Mean Wt. of patients treated at home.**

Patient (home)	Range (kg)	Mean±Sd	95% confidence interval
Wt. At first visit	2.4-10	6.04±2.2	5.32-6.8
Wt. at 7 days	2.46-10.06	6.12±2.2	5.4-6.9
Wt. at 14 days	2.5-10.3	6.14±2.21	5.41-6.87
Wt. at 21 days	2.5-10.31	6.16±2.23	5.43-6.9
Wt at 28 days	2.55-10.35	6.17±2.24	5.44-6.9

**Table 8: ANOVA table for weight gain in different follow ups of patients treated at home.**

Weight	Sum of squares	df	Mean square	F	P value
Between groups	0.015	4	0.004	0.025	0.999
Within groups	28.691	185	0.155		
Total	28.706	189			

**Table 9: Post hoc test.**

(I) Different follow up	(J) Different follow up	Mean difference (I-J)	Std. error	Sig.	95% Confidence interval	
					Lower bound	Upper bound
0.00	1.00	0.00360	0.09035	1.000	-0.2453	0.2525
	2.00	0.00627	0.09035	1.000	-0.2426	0.2552
	3.00	0.01126	0.09035	1.000	-0.2376	0.2602
	4.00	0.02577	0.09035	0.999	-0.2231	0.2747
1.00	0.00	-0.00360	0.09035	1.000	-0.2525	0.2453
	2.00	0.00267	0.09035	1.000	-0.2462	0.2516
	3.00	0.00766	0.09035	1.000	-0.2412	0.2566
	4.00	0.02217	0.09035	0.999	-0.2267	0.2711
2.00	0.00	-0.00627	0.09035	1.000	-0.2552	0.2426
	1.00	-0.00267	0.09035	1.000	-0.2516	0.2462
	3.00	0.00499	0.09035	1.000	-0.2439	0.2539
	4.00	0.01950	0.09035	1.000	-0.2294	0.2684
3.00	0.00	-0.01126	0.09035	1.000	-0.2602	0.2376
	1.00	-0.00766	0.09035	1.000	-0.2566	0.2412
	2.00	-0.00499	0.09035	1.000	-0.2539	0.2439
	4.00	0.01451	0.09035	1.000	-0.2344	0.2634
4.00	0.00	-0.02577	0.09035	0.999	-0.2747	0.2231
	1.00	-0.02217	0.09035	0.999	-0.2711	0.2267
	2.00	-0.01950	0.09035	1.000	-0.2684	0.2294
	3.00	-0.01451	0.09035	1.000	-0.2634	0.2344

Results were statistically not significant suggesting that weight gain was not adequate ( $P>0.05$ ) in patients treated at home (Table 9).

## DISCUSSION

633 children from 6 months to 60 months of age attended pediatric OPD and were admitted in LLRM children hospital. Out of these 633 children 114 children were found to be suffering from severe acute malnutrition. Hence, the prevalence of severe acute malnutrition in children between 6-60 months of age in present study is 18%.

In the present study, 84 children of severe acute malnutrition were studied. Out of 84 children, 80 (95.24%) cases were of marasmus, 3 (3.57%) were of Kwashiorkor and 1 (1.19%) case was of Marasmic kwashiorkor. The prevalence of severe acute malnutrition in children under 5 varies between 2-5% as shown by Beaton et al.<sup>2</sup>

This study being hospital based study where only sick children were studied, the prevalence of severe acute malnutrition was higher i.e 18% as compared to a recent field based study.<sup>3</sup>

Maximum numbers of cases were in 6 months to 12 months age group. Hence, 6-12 month of age emerged as the most vulnerable period in which factors such as complimentary feeding, parental care, immunization and hygiene come into play.

As per the National Family Health Survey the most common age of PEM is between 6 month and 2 years and around 50-60% of children are malnourished by 2 years.<sup>4</sup> Malnutrition increased significantly with the increase in age and was slightly more prevalent among the boys.

In present study fever was the predominant symptom which brought the patient to hospital followed by diarrhoea/dysentery which was followed by respiratory complaints.

Present findings are comparable to observations made by other co worker Shimles D et al who studied the pattern of infection in children with severe PEM under 5. They concluded that 80% were infected and lungs were the commonest site of infection. 63% had pneumonia, 49% had diarrhea, 37 had UTI, CNS infection was seen in 12% children and septicemia in 14% children.<sup>5</sup>

In this study hypothermia was seen in 10.17% hypoglycemia in 14.3% and CHF in 11.9% cases. Electrolyte imbalance in the form hypokalemia was seen in 23.8%, hyponatremia in 13.5% cases, hypernatremia in 2.4% cases, hypocalcemia in 3.57% cases. But at the top of list was an infection which was present in 31% of patients. Present findings are close to many co workers. Kerr et al found hypoglycemia in 10% cases of

kwashiorkor while the corresponding number in Uganda was 18.23% in children with Kwashiorkor (Whitehead and Karland).<sup>6,7</sup> According to Brooke, hypothermia occurred in 20% cases of severe PEM.<sup>8</sup>

### Weight

Mean weight gain in patients treated at hospital was more than those treated at home. When weight gain of patients treated at hospital was statistically analysed using ANOVA technique, weight gain was found to be statistically significant ( $P=0.024$ , F ratio=2.862).

When comparisons were made using Tuckeys Post Hoc test it was found that weight gain from basal weight to weight at 28 days was statistically significant ( $P=0.047$ ).

On similar analysis of patients treated at home using ANOVA technique of statistical analysis, it was found that there was no significant weight gain ( $P=.999$ ,  $F=0.025$ )

Average weight gain in hospitalized patient was found to be  $7.525\text{gm/kg/day} \pm 6.09$  (SD), whereas those receiving home therapy had average weight gain of  $1.013\text{gm/kg/day} \pm 2.43$ (SD).

The findings were consistent with findings of Raja S Mamidi et al who had average weight gain of  $5\text{g/kg/day}$  in patients with morbidity and  $7\text{gm/kg/day}$  in those without morbidity.<sup>9</sup> In a randomized controlled trial by Malik et al, children (6 month to 5 years) having severe acute malnutrition were divided into Group A ( $n=74$  children) given WHO recommended therapeutic food and group B ( $n=75$  children) given home based therapeutic food.<sup>10</sup> The mean rate of weight gain was significantly higher ( $p<0.05$ ) in the group received home based therapeutic food.

Weight gain in patients receiving home therapy was significantly lower probably due to lack of professional caregivers, lack of appetite and non adherence to dietary advice.

A prospective study was done by Shazia et al in nutrition rehabilitation center of Government District hospital, Madikeri among 72 severe acute malnourished children.<sup>11</sup> Children attaining weight gain of 10% of admission weight at discharge were only 20% ( $n=7/34$ ) in group 1 (WHO Protocol) as compared to 63.5% ( $n=20/32$ ) in group 2 (WHO Protocol Versus Davangere Mix), the difference being statistically significant ( $p$  value  $<0.001$ ).

Approaches to identifying, referring, and treating SAM cases have been evolving, and a mix of programmatic approaches can be found globally. The WHO endorses community-based management of uncomplicated SAM and recommends that children with poor appetite, severe edema (Grade III), and any of the Integrated Management of Childhood Illness danger signs or medical

complications be treated in inpatient facilities in accordance with their 10-step model (WHO 2013).<sup>12</sup>

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Shukla A, Rao YK. Comparison study on efficacy of UNICEF specified therapeutic food (F-75/F-100) with traditionally used home based food in management of severe acute malnutrition. Int J Contemp Pediatr 2018;5:1674-9.