

## Comparison of Therapeutic Feed (Different recipes) during Stabilization Phase for the management of Children with Severe Acute Malnutrition (SAM)

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### ABSTRACT

**Objective:** To compare the feeding of sugar based F75, Cooked rice based F75 and Enhanced cooked rice based modified F75 during stabilization phase for the management of children with SAM (Severe Acute Malnutrition) aged 6-60 months presented with diarrhea.

**Study Design:** An open-label randomized controlled trial.

**Place and Duration:** Stabilization center, Children's Hospital and Institute of Child Health Multan from 1<sup>st</sup> January 2018 to 30<sup>th</sup> November 2019.

**Methodology:** The total 270 children, (who were under 5 years of age and admitted to the stabilization center for complicated Severe Acute Malnutrition (SAM) during study duration) were divided into three groups of 90 patients each. Group A was given Standard sugar-based F75, Group B was given Cooked Rice based F75 and Group C was given Enhanced cooked rice based modified F75. Clinical and biochemical parameters of patients were analyzed at day 1, day 3 and day 7 after admission.

**Results:** The age of our patients was  $16.7 \pm 12.2$  months with male to female ratio of 1.2:1. The mid upper arm circumference (MUAC) of cases was  $10.07 \pm 0.86$  cm. More than half of the children had diarrhea at admission. During the initial stabilization phase (day 1 to day 7), number of patients with complains of diarrhea increased from 57.78% to 65.54% in group A while it reduced from 52.22% to 15.54% in group B and from 62.16% to 7.77% in group C.

**Conclusion:** Modified rice base therapeutic feeding is more effective for treatment of SAM with diarrhea as compared to standard sugar based F75 formula.

**Keywords:** Children, Diarrhoea, Severe Acute Malnutrition, Stabilization Phase, Carbohydrate Malabsorption, Diarrhea, F75 Rice Based Therapeutic Feed

### How to Cite This:

Khan S, Iqbal I, Ali I, Batool N, Abbas A, Arshad R. Comparison of Therapeutic feed (different recipes) during Stabilization Phase for the management of Children with Severe Acute Malnutrition (SAM). *Isra Med J.* 2022; 14(3): 108-112. DOI: <https://doi.org/10.55282/imj.0a1140>

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### INTRODUCTION

Early childhood less than five years of age is an important period for child survival, growth and development. Adequate nutritional intake at this time is necessary for normal growth and development of children. Inadequate nutrition during this primary period result in different manifestations of malnutrition (underweight child, stunting and wasting), which are common in children of developing countries including Pakistan<sup>1</sup>.

Severe acute malnutrition contributes to almost half of death of children fewer than five years of age. The mortality in children with SAM is 9 times more as compared to normal children<sup>2</sup>. Severe acute malnutrition affects 20 million children universally and results in elevated death rates toward the death of half a million children of age less than five years every year<sup>1,2</sup>. According to National Nutrition Survey of Pakistan (NNS) 2018, percentage of underweight children was 28.9% (almost one in three children), stunting was seen in 40.2% (almost 4 in 10 children) and wasting in 17.7%<sup>3</sup>.

A child is diagnosed with Severe acute malnutrition (SAM) if he/she has any one of the following three: very low weight for height (below -3z scores of the median WHO growth standards), OR mid upper arm circumference (MUAC) less than 115 mm OR

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Received for Publication: September 19, 2020  
1<sup>st</sup> Revision of Manuscript: December 06, 2021  
2<sup>nd</sup> Revision of Manuscript: February 10, 2022  
3<sup>rd</sup> Revision of Manuscript: August 08, 2022  
4<sup>th</sup> Revision of Manuscript: December 06, 2022  
Accepted for Publication: December 26, 2022

by the presence of nutritional oedema. Severe acute malnutrition (SAM) affects all organ system and functions in the body resulting in physiological and metabolic disturbances which have been called reductive adaptation<sup>4</sup>. Acute, persistent and chronic diarrhea is commonly seen in children with SAM. The relationship between SAM and diarrhea is bidirectional. Malnutrition predisposes children to more frequent and prolonged diarrhea. Due to diarrhea, there is decreased absorption of macro and micro nutrients that contributes to and worsens SAM. Significant water loss in malnourished children with poor energy reserves leads to dehydration, electrolytes imbalance, shock and ultimately death<sup>5</sup>.

World Health Organization (WHO) has recommended protocols for inpatient management of children with complicated SAM in designated areas called SC (stabilization centers). Initial phase of management of sick children in these centers is called Stabilization Phase lasting 3 days. Early feeding of the child is recommended with therapeutic diets. Feeding is started with F-75 formula which is designed to improve metabolic homeostasis and correct hypoglycemia. In the later rehabilitation phase, catch up growth is achieved with F-100 or Ready to use therapeutic food (RUTF). Standard F75 formula is a low protein 0.9g/100ml, carbohydrate dense formula that uses carbohydrate sources of sucrose, and milk-based lactose to treat hypoglycemia in SAM. Malabsorption of carbohydrates especially lactose and a high sucrose load may lead to increased intestinal osmotic load resulting in osmotic diarrhea in children with SAM<sup>6,7</sup>. For the same reason, WHO management protocols give the option of replacing part of sugar with cooked cereal in F-75 diet where cooking facilities and cereals are available<sup>8</sup>.

Rice is an indigenous cereal used for starting complimentary feeding in children. Rice is also well known to reduce the intensity and duration of diarrhea in children and adults. Rice based foods have been successfully given in infants and children for the management of persistent diarrhea<sup>9</sup>. The aim of the present study was to determine whether substitution of two different amounts of rice for sugar in standard sugar-based F-75 diet results in reduction in duration of diarrhea and improved metabolic profile during inpatient management of sick children admitted for management of complicated Severe Acute Malnutrition (SAM) in Stabilization Center (SC) according to WHO recommended protocol of management. So, this study was conducted with an objective to compare the feeding of sugar based F75, Cooked rice based F75 and Enhanced cooked rice based modified F75 during stabilization phase for the management of children with SAM (severe acute malnutrition) aged 6-60 months presented with diarrhea.

## METHODOLOGY

This open-label randomized controlled trial was conducted in Stabilization center, The Children's Hospital and Institute of Child Health (CH&ICH), Multan, Pakistan. After ethical approval and explaining the risks and benefits of this research, written informed consent was taken from the children's parents/guardians. Simple random sampling technique was used and all the children who gave consent and were less than five

years and admitted to the Stabilization center from 1<sup>st</sup> January 2018 to 31<sup>st</sup> October 2019, with a diagnosis of complicated SAM) i.e. weight/height or length <3SD or Mid Upper Arm Circumference (MUAC) < 11.5cm<sup>9</sup> were included in the study. The children whose guardian refused consent, or left against medical advice were excluded from the study. Each child enrolled in the study was followed closely up till initially stabilized which took about 7- 10 days.

WHO guidelines for management of SAM children were followed<sup>9</sup>. After admission, all malnourished children were initially stabilized, vital signs were recorded, random blood glucose level was checked, baselines blood sample was taken for Serum sodium, potassium, magnesium, calcium, phosphate by the staff nurse. Samples were tested at Pathology department of The Children's Hospital and Institute of Child Health (CH-ICH), Multan by the trained lab technician. A container given to mothers to collect a stool sample for pH and reducing substances. Inpatient children included in the study were randomized into three groups, by using labeled cards in closed envelopes: Group A, Group B and Group C. First group was given standard sugar-based F75 formula for initial feeding (Group A), second group was given cooked rice based F75 formula (Group B); and third group was given enhanced cooked rice based modified F75 (Group C). These diets were prepared according to following formulas:

- Standard sugar-based F75: whole milk 300ml + sugar 100gm + oil 20ml + 20 ml of 7.46% Potassium Chloride + up to 1000ml water<sup>7</sup>.
- Cooked Rice based F75: Whole milk 300ml + sugar 70gm + rice 35gm + oil 20ml + 7.46% Potassium Chloride 20 ml + up to 1000ml water<sup>7</sup>.
- Enhanced cooked rice based modified F75: Whole milk 300ml + sugar 25gm + rice 75gm + oil 20ml + 7.46% Potassium Chloride 20 ml + up to 1000ml water

The recipe of Enhanced cooked rice based modified F75 was developed by replacing the carbohydrates source from sugar to rice. The calories, carbohydrates percentage and rest of the ingredients were same. According to WHO guidelines, the feed of each child was calculated as 120-150ml/kg/day and initially 2 hourly feed was given to each child who later transitioned to 3 hourly feed and then 4 hourly feed according to the condition of the patient. The diet preparation was supervised by the doctors of the department and performed by the trained staff nurses.

Clinical signs related to malnutrition were assessed at admission as per WHO critical care pathway chart and recorded daily, using case report forms. Following complications at the time of admission were checked and recorded and child monitored daily for below mentioned complication by the duty doctors of the department.

All children were assessed daily for the following complications. Dehydration as per WHO guidelines, Diarrhea: Passage of more than 3 loose watery stools/day, Increased frequency of stool, more than 10 stools/day, Vomiting: Forceful expulsion of gastric contents through mouth at least 3 episodes/ day, Anemia: Hemoglobin less than 10 gm/dl, Pneumonia: fast breathing or chest in drawing (WHO IMNCI guidelines), Hypoglycemia: blood

glucose < 3mmol/l or 54 mg/dl, Shock: lethargic and unconscious and cold peripheries with capillary refill time 3 second or fast and weak pulse, Hypothermia: Axillary temperature below 36.5C, Heart failure: tachycardia, tachypnea, tender hepatomegaly, Primary outcomes was based on clinical stabilization, after which could switch to high protein density therapeutic formulas to promote catch up growth.

Stabilization was achieved when all above mentioned complications were managed and child was tolerating oral feeds as per WHO guidelines<sup>7</sup>.

Daily assessments included vital signs, anthropometry, hydration status, degree of edema, mode of feeding, and number of stools per day was done by the staff nurses. The child was discharged when they achieved the -2SD weight goal and were referred to OTP for follow-ups at 15 days interval. However, the follow-up was not recorded in this study due to limited resources.

**Operational definition: Clinical Stabilization:** Stabilization was achieved when the child has no vomiting, diarrhea settled or lesser in frequency, return of appetite (finishing 80% of prescribed feed, 4 hourly feed of F75, No or dissolving edema, return of smile.

**Data analysis:** Qualitative data (diarrhea, vomiting, dehydration and edema) was expressed in percentages Quantitative data (age, weight, height mid upper arm circumference) was expressed in mean +SD. Serum blood biochemistry was analyzed and expressed as mean +SD. The data was entered and analyzed using SPSS 21.0 version and p-Value more than 0.05 was considered significant.

## RESULTS

During the study period, 300 children were admitted for treatment of complicated SAM and were enrolled in the study. Eight patients expired within a few hours after admission due to severe complications already present i.e. sepsis , sepsis shock and acute renal failure , and twenty two patients left the hospital due to social issues after their initial management.

These 30 patients were excluded from final data analysis. Data about 270 patients was analyzed. The age of our patients was 16.7 ± 12.2 months. The male to female ratio were 1.23:1. The mid upper arm circumference (MUAC) of cases was 10.07±0.86 cm. There were 90 patients in each of the three groups. Group A patients were given Standard sugar-based F75, Group B patients were given Cooked Rice based F75, and Group C patients were given enhanced cooked rice based modified F75.

Table I compares the baseline characteristics (age, gender), anthropometric measurements, complications and settlement of diarrhea in all three groups .Most of patients were suffering from multiple complications including vomiting, diarrhea, dehydration, anemia, hypoglycemia and pneumonia at the time of admission (day 1). Diarrhea was seen in more than 50% of children at the time of admission almost equally in all the three groups. The median time to stabilization was 5-7 days, similar between all groups However; complications were much less frequent in Group B and Group C (Table I).

**Table – I: Baseline characteristics, anthropometry and complications of SAM children (N=270)**

Characteristics	Group A (n= 90) mean ± SD	Group B (n= 90) mean ± SD	Group C (n= 90) mean ± SD	Total (n= 270) mean ± SD
Age (mo.)	18.78 ± 12.64	15.69 ± 2.02	15.76 ± 11.97	16.7 ± 12.2
Males (%)	56 (62.22)	42 (46.67)	51 (56.67)	149 (54.98)
Females	34 (37.78)	48 (53.33)	39 (43.33)	121 (45.01)
Weight (kg)	7.5 ± 1.46	7.9 ± 2.12	8.14 ± 2.19	7.85 ± 1.9
Height / Length (cm)	78.52 ± 10.21	76.23 ± 9.46	81.43 ± 9.52	78.72 ± 9.73
Edema (%)	18 (20)	19 (21.11)	21 (23.33)	58 (21.48)
Disturbed Appetite	56 (62.22)	62 (68.89)	49 (54.44)	167 (61.85)
MAUC	10.49 ± 0.92	9.52 ± 1.21	10.22 ± 0.89	10.07 ± 0.86
Length/Height for age (Z score)	1.94 ± 1.35	1.76 ± 1.21	2.11 ± 1.46	1.9 ± 1.34
Weight for length/ height (Z score)	3.06 ± 1.01	2.92 ± 0.71	2.89 ± 0.78	2.96 ± 0.83
Fecal pH	5.4 ± 0.4	5.9 ± 1.1	5.7 ± 0.8	5.67 ± 0.76
<b>Complications</b>				
Dehydration	53 (58.89%)	50 (55.56%)	54 (60%)	-
Diarrhea	52(57.78)	47(52.22)	56(62.16)	-
Vomiting	48(53.33)	46 (51.11)	45 (50)	-
Anemia	43 (47.78)	49 (54.44)	39 (43.33)	-
Pneumonia	26 (28.86)	24 (26.64)	27 (29.97)	-
Hypoglycemia	23 (25.56)	29 (32.22)	26 (28.8)	-
Shock	8 (8.89)	11 (12.22)	7 (7.78)	-
Hypothermia	7 (7.78)	8 (8.89)	10 (11.11)	-
Heart failure	4 (4.44)	6 (6.67)	8 (8.89)	-
<b>Complications seen in three patient groups during stabilization (D1-D7).</b>				
Days of Stabilization	5-7 days	5-7 days	5-7 days	-
Vomiting	62 (68.89)	24 (26.67)	37 (41.11)	-
Resomal ORS Treatment	66 (73.33)	55 (61.11)	49 (54.44)	-
Shock	21 (23.33)	18 (20)	13 (14.44)	-
IV therapy	23 (25.56)	27 (30)	19 (21.11)	-
Worsening of general condition	11 (12.22)	9 (10)	4 (4.44)	-
Hypoglycemia	8 (8.89)	4 (4.44)	3 (3.33)	-

SD: Standard Deviation

**Table – II: Serum profile of severely malnourished children at time of Admission (normal values given with each measurement) (N=270)**

Blood profile	Group A (n= 90)	Group B (n= 90)	Group C (n= 90)
Potassium 3.5-5.8mm mol/L	3.063 ± 1.749	3.23 ± 1.49	3.12 ± 1.62
Sodium 136-146mm mol/L	138.94 ± 8.69	139.92 ± 7.64	137.72 ± 8.06
Calcium 8.1-10.4m mol/L	8.513 ± 1.586	8.42 ± 1.63	8.62 ± 1.66
Phosphate1.45-1.78m mol/L	0.98 ± 0.40	1.1 ± 0.45	0.96 ± 0.38
Albumin, 38-54g/L	24.3 ± 8.6	26.4 ± 8.2	25.7 ± 7.9
Hbg/l	7.19 ± 2.387	8.02 ± 2.400	7.88 ± 2.36
Magnesium 1.5-.5mg/ dL	2.238 ± 2.387	2.32 ± 1.97	2.29 ± 1.89

The blood profile including serum biochemistry of children with SAM at the time of admission is given in Table II. Low

Hemoglobin (7-8gm/dl) and low albumin (2.43-2.64 gm/dl) are seen in all groups.

During the period of 7 days, increased frequency of diarrhea (more than 10 stools /day was observed) in Group A (Standard sugar-based F75), while it decreased significantly in Group B (Cooked Rice based F75) and Group C. (Enhanced cooked rice based modified F75).

**Table – III: Burden and settlement of Diarrhea in children on different F75 formulations (N=270)**

Outcomes		Group A (n = 90)	Group B (n = 90)	Group C (n = 90)	P – Value
<b>Days of Stabilization</b>		5-7 days	5-7 days	5-7 days	
<b>Day 1</b>	Diarrhea	52(57.78)	47(52.22)	56(62.16)	>0.05
<b>Day 3</b>	Diarrhea	67(74.44)	35(38.8)	27(29.99)	<0.05
<b>Day 7</b>	Diarrhea	59(65.54)	14(14.54)	7(7.77)	<0.05
Mean duration of diarrhea to Settle		10 ± 2 days	5 ± 1 days	3 ± 1 days	-

At day 7, diarrhea was present in 59(65.54%) children in Group A, in 7 (7.77%) children in Group B and in 14(14.54%) children in Group C. (Table-III). The mean duration of settlement of diarrhea is given in Table III. There is little to no weight gain during stabilization phase and weight gain was not calculated and monitored in this study as it was not the objective. Nor was child monitored at follow-ups. The outcome of three groups is given in Table III, and IV. Only baseline relevant variables were analyzed in this study related to topic.

Analysis of serum biochemistry and stool pH in all patients at the time of admission and after 3 days of admission showed that patients in group B and C were passing less acidic stools as compared to group A. (Table: IV. Acidic stools are frequent cause of nappy rashes in children.

## DISCUSSION

We compared three different F75 diets by increasing amount of rice and replacing sugar in the formula feed during Stabilization

phase for the management of children with SAM (Severe acute malnutrition) while rest of their management were as per WHO guidelines for treatment of SAM. Group A was given Standard sugar- based F75, Group B was given Cooked Rice based F75 and Group C was given Enhanced cooked rice based modified F75. At day 7, diarrhea was present in 59(65.54%) children in Group A, in 7 (7.77%) children in Group B and in 14(14.54%) children in Group C. (Table I). An increase in diarrhea was seen in children given Standard sugar-based F75 while increasing amounts of rice in formula significantly reduced the persistence of diarrhea in these children.

Data suggests strongly that carbohydrate digestion and absorption is impaired in severely malnourished children and leads to osmotic diarrhea. Osmotic diarrhea leads to dehydration and electrolytes disturbances in SAM children and contribute to increase burden of morbidity and mortality in SAM. Similar study was conducted by Bandsma et al and Talbert et al. proved that reduced carbohydrate and lactose content s reduces the diarrheal episodes during hospital stay<sup>10,11</sup>. Another study also concluded that lactose burden in feed leads to low stool pH which is indicator of carbohydrates malabsorption and changing lactose to sucrose may facilitate absorption. Another study also indicates that lactose free formula in malnourished children with diarrhea results in significant reduction in diarrhea and linked directly to low osmolarity<sup>12,13</sup>.

Present study concluded that patients who were taking sugar and lactose containing standard F75 feeds were observed to develop an increase in diarrhea and vomiting leading to dehydration during the initial phase of treatment and patients who were taking low sugar rice based F75 had lower risk of these complications. Similar studies conducted by Talbert et al, Kuissverg et al. and Bandsma et al. revealed that high sugar content leads to poor digestion and malabsorption of carbohydrates in malnourished children<sup>14-17</sup>. Thus, different studies also fortify that replacing rice with sugar content in therapeutic feeds effectively reduces diarrhea and contributes in speedy recovery of SAM children.

**Table – IV: Comparison of Serum biochemistry and stool pH in SAM patients receiving three different forms of F75 at admission and on Day 3 (N=270)**

Characteristics	Day 1 Total patients N=270	Day 1 Group A N=90	Day 1 Group B N=90	Day 1 Group C N=90	Day 3 Total patients N=270	Day 3 Group A N=90	Day 3 Group B N=90	Day 3 Group C N=90	Day 7 Total patients N=270	Day 7 Group A N=90	Day 7 Group B N=90	Day 7 Group C N=90
Low Sodium <135mmol/L	107 (39.63)	32 (35.55)	37 (41.11)	38 (42.22)	112 (41.48)	37 (41.11)	34 (37.78)	41 (45.55)	105 (38.88)	26 (28.88)	32 (35.55)	47 (52.22)
Low Potassium <3.5mmol/L	61 (22.59)	16 (17.78)	21 (23.33)	24 (26.67)	26 (9.63)	08 (8.89)	07 (7.78)	11 (12.22)	21 (7.77)	5 (5.55)	3 (3.33)	13 (14.44)
Low Magnesium <0.7mmol/L	27 (10)	07 (7.78)	11 (12.22)	09 (10)	41 (15.18)	17 (18.89)	13 (14.44)	11 (12.22)	35 (12.96)	12 (13.33)	7 (7.77)	16 (17.77)
Low Phosphate <0.7mmol/L	28 (10.37)	09 (10)	07 (7.78)	12 (13.33)	16 (5.92)	05 (5.55)	04 (4.44)	07 (7.78)	10 (3.70)	3 (3.33)	2 (2.22)	5 (5.55)
High Sodium >145mmol/L	27 (10)	09 (10)	07 (7.78)	11 (12.22)	35 (12.96)	11 (12.22)	09 (10)	15 (16.67)	27 (10.00)	9 (10)	7 (7.77)	13 (14.44)
Stool pH ≤5.5	38 (14.07)	13 (14.44)	11 (12.22)	14 (15.55)	34 (12.59)	19 (21.11)	09 (10)	6 (6.67)	23 (8.51)	15 (16.66)	5 (5.55)	3 (3.33)

The study duration was too short to provide long term results, further longer trials should be conducted to produce more concrete results and therapeutic diets should be modified accordingly for better outcome of malnourished patients.

### CONCLUSION

Modified rice base therapeutic feeding is more effective for treatment of SAM with diarrhea as compared to standard sugar based F75 formula.

### AUTHOR'S CONTRIBUTION

**Khan S:** Conceived idea, Designed methodology, Manuscript writing

**Iqbal I:** Designed Methodology, Manuscript final reading and approval

**Ali I:** Data analysis, Critical review of manuscript

**Batool N:** Data collection and compilation, Literature review

**Abbas A:** Data Interpretation, Statistical Analysis

**Arshad R:** Data collection and compilation, Manuscript writing

**Disclaimer:** None.

**Conflict of Interest:** None.

**Source of Funding:** None.

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