Recovery pattern in severely malnourished children fed with World Health Organization F-75 diet and homogenized toned milk

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Received – 22 August 2018 Initial Review – 21 September 2018 Accepted – 08 October 2018

ABSTRACT

Background: An average 8 million Indian children younger than 5 years (under-fives) are severely wasted. Each year approximately 2.3 million deaths among 6–60 months aged children in developing countries are associated with malnutrition, which is about 41% of the total deaths in this age group. **Objective:** The objective of the study was to compare the efficacy of cereal-based the World Health Organization (WHO) F-75 diet and homogenized toned milk with added sugar in the recovery of presenting complaints and weight gain in severe acute malnutrition (SAM) children in the stabilization phase. **Materials and Methods:** This clinical effectiveness trial was conducted between March 2016 and August 2017 in the Department of Pediatrics, in a Medical University, Saifai, Uttar Pradesh. A total of 77 children aged 6–59 months with SAM who were admitted in the pediatric ward for various reasons were included in the study. Patients were randomly allocated to receive either cereal-based F-75 diet (Group I) or homogenized toned milk (Group II). Each child was monitored during the early stabilization phase for improvement in terms of the return of appetite, the start of edema reduction as well as the complete disappearance of edema, vomiting, loose stool, weight gain, clinical duration of hospital stay, and mortality. Data collected from each group were analyzed. **Results:** No statistically significant difference was found in the onset of edema reduction, complete disappearance of edema and return of appetite in both groups. Number of vomiting and loose stools per day, on day 4 and day 10, was significantly lower in children fed with homogenized toned milk (Group II). Mean weight gain among patients fed with the WHO F-75 diet (Group I) was higher (8.29±2.77 g/kg/day) as compared to that of Group II (7.31±2.87 g/kg/day) but difference in weight gain among patients of Group I and Group II on day 10 was not statistically significant (p=0.133). **Conclusions:** As homogenized toned milk avoids problems of quality control and microbial contamination, it may be considered for evaluation in difficult circumstances where standard protocols are not feasible for management of severe malnutrition, especially in developing countries.

Key words: *Appetite, Edema, F-75 diet, Homogenized toned milk, Severe acute malnutrition, Weight gain*

Childhood undernutrition is an underlying cause of an estimated 35% of all deaths among children under five and 21% of total disability-adjusted life years lost among under-five children [1]. Severe acute malnutrition (SAM) remains a major killer of children as mortality rates in children with severe wasting are 9 times more than those in normal children. A civil society collective appealed to policymakers (in a press release) on July 23, 2015, to "declare malnutrition as a medical emergency to save India's children dying of hunger Express Health News Bureau [2]." In India, the National Family Health Survey-4 in 2015–16 indicated that 36% of Indian children under the age of five are underweight, 38% are stunted, and 21% are wasted [3]. Therefore, despite an economy growing often at nearly 10% annually [4], an average 8 million Indian children younger than 5 years (under-fives) are severely wasted [5]. Each year approximately 2.3 million deaths among 6–60 months aged children in developing countries are associated with malnutrition, which is about 41% of the total deaths in this age group [6].

Children with SAM observe slowing down of organ systems and undergo physiological and metabolic changes in orderly sequence to allow survival on limited calories; this phenomenon is called as a reductive adaptation. Due to this reductive adaptation, they cannot tolerate usual amounts of protein, sodium, or high amounts of fat initially. So they must be given a diet that is low in protein and sodium and high in carbohydrates. The starter (F-75) diet is designed to fulfill these requirements.

Milk and milk products are widely used for rehabilitation of the malnourished patients. The WHO recommends F-75 formula feed for the stabilization phase of SAM. As milk has higher protein content and immunoglobulin level, it can be used easily and more hygienically in the stabilization phase. Homogenized toned milk has an energy density that is almost similar to F-75

feed and can be consumed directly by the child with added sugar but, without the addition of water, which eliminates the risk of bacterial contamination from the added water. Yet, the efficacy of homogenized toned milk has never been tested in a trial; therefore, its recommendation for extensive use in the community might be premature. We, therefore, carried out a randomized trial to compare the efficacy of F-75 diet and homogenized toned milk, which is considered to be the reference diet during the stabilization phase.

MATERIALS AND METHODS

This randomized single-blind study was carried out at the department of pediatrics, in a medical university, Etawah, Uttar Pradesh. All severely malnourished children between 6 months and 59 months of age were admitted in the pediatric ward from March 2016 to August 2017, for various reason, who fulfilled the criteria for SAM were included in the study. SAM among children 6–59 months is defined by the World Health Organization (WHO) as any of the following: (i) Weight-for-height z scores) of <−3 standard deviation (SD), (ii) clinical criteria (presence of "visible severe wasting" or "bipedal edema)," and (iii) mid-upper arm circumference (MUAC) of <11.5 cm [7].

Children who were born either premature or small for gestational age or known case of lactose intolerance or having clinical evidence of any chronic disease (e.g., cerebral palsy, congenital heart diseases, hemolytic anemia, malignancies, known metabolic disorders, known malabsorption syndromes, chromosomal malformations, and chronic renal disorders), as a cause of severe malnutrition, were excluded from the study. Children who failed to stabilize hemodynamically within 48 h of admission or died within 10 days of admission were also excluded.

For quantitative data, the basic parameters required are SD and mean for that parameter. The sample size was calculated as $4\times(SD)^2/E^2$ where, E was decided by the size and mean. In previous studies, the SD for average weight gain in SAM children during stabilization phase was 8.28 and mean weight gain was 9.23 g/kg/day. Allowable error can be kept as ±2 g/kg/day [8]. Sample size calculated by above formula was 68 so, we had taken minimum 68 subjects as a sample size with each group including minimum of 34 subjects.

All the patients with SAM admitted in the pediatric ward were evaluated regarding their eligibility to be included or excluded in the study. First, the parents were interviewed regarding the antenatal history, drug history, family history of TB, HIV/AIDS, or any chronic illness, etc. Every patient was examined for any major congenital malformations, cardiac disease, or renal disease, etc. Then, the parents of the eligible patients were briefed regarding the purpose of the study. Informed written consent was obtained from caregiver regarding participation in this study. A standardized clinical form was used to collect sociodemographic information, clinical symptoms and their duration, immunization history, anthropometric measurements, physical signs, results of laboratory investigations, and the patient's final outcome.

All the children were managed as per the standard protocol. Dehydration was managed using low osmolality oral rehydration salts with added potassium supplements (20 meq/L). All admitted children received age-appropriate dose of Vitamin A (preventive/therapeutic), twice recommended dietary allowance of multivitamin supplements, folic acid (5 mg on day 1, then 1 mg/d), zinc (2 mg/kg/d), potassium (3–4 meq/kg/d), and magnesium (Injection magnesium sulfate [50%] at 0.3 ml/kg up to a maximum of 2 ml intramuscular once, thereafter orally 0.2–0.3 ml/kg mixed with feeds) during the entire period of stay.

On initial presentation, every child was assessed for edema and had his/her weight, length or standing height, and MUAC measured. Length was measured through infantometer for children <2 y of age (±1 mm), and weight was measured through stadiometer for children >2 y of age (±1 mm). Weight was measured using an electronic scale (brand Phoenix ±10 g). Left MUAC was measured with measuring tape (±1 mm). Children were assessed once per day in the morning.

Intervention and Outcome Measures

After hospitalization, initial stabilization phase begins, life-threatening problems were identified and treated, specific deficiencies and metabolic abnormalities were corrected, and cautious feeding was started as soon as possible. Before starting the feed, each participant was randomly assigned with equal probability to either Group I or Group II. This was done through computer-generated randomization table. The patients in Group I were fed with WHO F-75 diet and patients in Group II were fed with homogenized toned milk with added sugar during the stabilization phase of management this feed was given by the trained staff. Children participated in the study for a minimum of 10 days or until they were stabilized. Once patient showed signs of improvement (disappearance of fever and other signs of infection, regaining of appetite, and started losing edema) he/she was shifted to the rehabilitation phase. The child was being monitored during the early stabilization phase for weight gain, clinical improvement in terms of return of appetite, disappearance of edema, decrease in number of loose stool and vomiting, and duration of hospital stay and mortality.

Data Analysis

Data were cross-checked for completeness before being entered into Microsoft Access database and analyzed using International Business Machines Statistics is a software package version 22.0 software. Descriptive statistics including proportions and means were calculated. Comparison of means was done using paired t-test and Chi-square test was performed to compare categorical variables. Statistical significance was set at $p<0.05$.

RESULTS

The present study was conducted to compare the efficacy of the WHO F-75 diet and homogenized toned milk in the recovery of presenting complaints and weight gain in SAM children. Among

the patients aged 6–59 months with SAM, who were admitted, only 77 fulfilled the inclusion criteria were enrolled in the study and were randomly divided into two groups. Out of 77 patients enrolled in the study, 39 (50.6%) were fed with WHO F-75 diet classified as Group I and rest 38 (49.4%) were fed with homogenized toned milk classified as Group II. (Figure-1)

The difference in age of patients of the above two groups was not statistically significant. Although the proportion of male patients was higher in Group I (56.4%) as compared to Group II (39.5%), this difference was not statistically significant. Most of the patients presented with one or more comorbidities which were almost equally distributed in both the groups (Table 1).

Onset of edema reduction and its complete reduction among the patients of Group II was earlier as compared to those of Group I, but these differences were not statistically significant. Mean duration of appetite gain among patients of both the groups was almost equal and was not statistically significant (Table 2).

On day 1, mean body weight of patients of Group I (7024.36±1466.91 kg) was found to be higher as compared to Group II (6445.05±1370.61 kg) but difference in body weight of patients of both the groups was not found to be statistically significant (p = 0.078). On day 4 and day 10 too, mean body weight of patients of Group I was found to be higher as compared to Group II but difference in body weight of patients of both the groups was again not found to be statistically significant. (Figure-2)

As shown in Table 3, the mean frequency of vomiting in Group II was significantly lower than that in Group I both on day 4 and day 10. In both, the groups, subsequent decline in the frequency of baseline was observed, and change in frequency of vomiting was statistically significant at day 4 and day 10 in both the groups. Similarly, on day 4 and day 10, the mean number of stools passed/day by patients of Group II was significantly higher than that in Group I. In both the groups, subsequent decline in number of stools was observed and change in frequency of stools was statistically significant at day 4 and day 10 in both the groups.

Table 1: Baseline characteristics and anthropometry of study subjects at presentation

Characteristics	Group I (n=39) mean±SD	Group II (n=38) mean±SD	Total (n=77) mean±SD
Age (mo)	18.56±12.63	15.08±11.49	16.8±12.1
Males (%)	22 (56.4)	15 (39.5)	37 (48.1)
Weight (kg)	7024±1466.9	6739	6738±1440.55
Height/Length (cm)	74.82 (9.14)	71.42 (8.40)	73.18±8.88
Edema present	8	9	17
Disturbed Appetite present	26	24	50
Vomiting	19	19	38
Loose stools	25	25	50
Mid-arm circumference (cm)	9.49 (0.79)	9.32 (0.88)	9.41±0.83
Length/Height for age (Z score)	1.85±1.31	1.50±1.13	1.68±1.23
Weight for length/height (Z Score)	2.87±0.66	2.79±0.67	2.86±0.66

SD: Standard deviation

Table 2: Comparison of duration of relief in symptoms

Variables	Group I		Group II		Student t-test	
	n	Mean±SD	n	Mean±SD	t	p
Onset of edema reduction (days)	8	3.50±0.54	9	3.11±0.60	1.402	0.181
Complete reduction of edema (days)	8	9.50±0.54	9	9.11±1.05	0.939	0.362
Duration of appetite gain (days)	13	4.00±0.71	14	3.71±0.73	1.034	0.311

SD: Standard deviation

Table 3: Change in baseline frequency of vomiting, frequency of stool and weight

Time interval	Group I					Group II				
	Mean Ch.	SD	% Ch.	t	p	Mean Ch.	SD	% Ch.	t	p
Vomiting day 4	−1.95	0.71	−37.00	−12.04	<0.001	−3.00	0.58	−60.00	−22.65	<0.001
Vomiting day 10	−3.95	1.08	−75.00	−15.95	<0.001	−4.42	0.84	−88.42	−23.00	<0.001
Loose stools day 4	−2.92	0.86	−48.67	−16.93	<0.001	−1.92	0.95	−32.65	−10.06	<0.001
Loose stools day 10	−4.32	1.03	−72.00	−20.98	<0.001	−3.60	1.19	−61.22	−15.12	<0.001
Weight day 4	226.92	95.43	3.23	14.851	<0.001	199.74	103.13	3.10	11.939	<0.001
Weight day 10	583.33	254.28	8.30	14.326	<0.001	490.00	282.21	7.60	10.703	<0.001

SD: Standard deviation

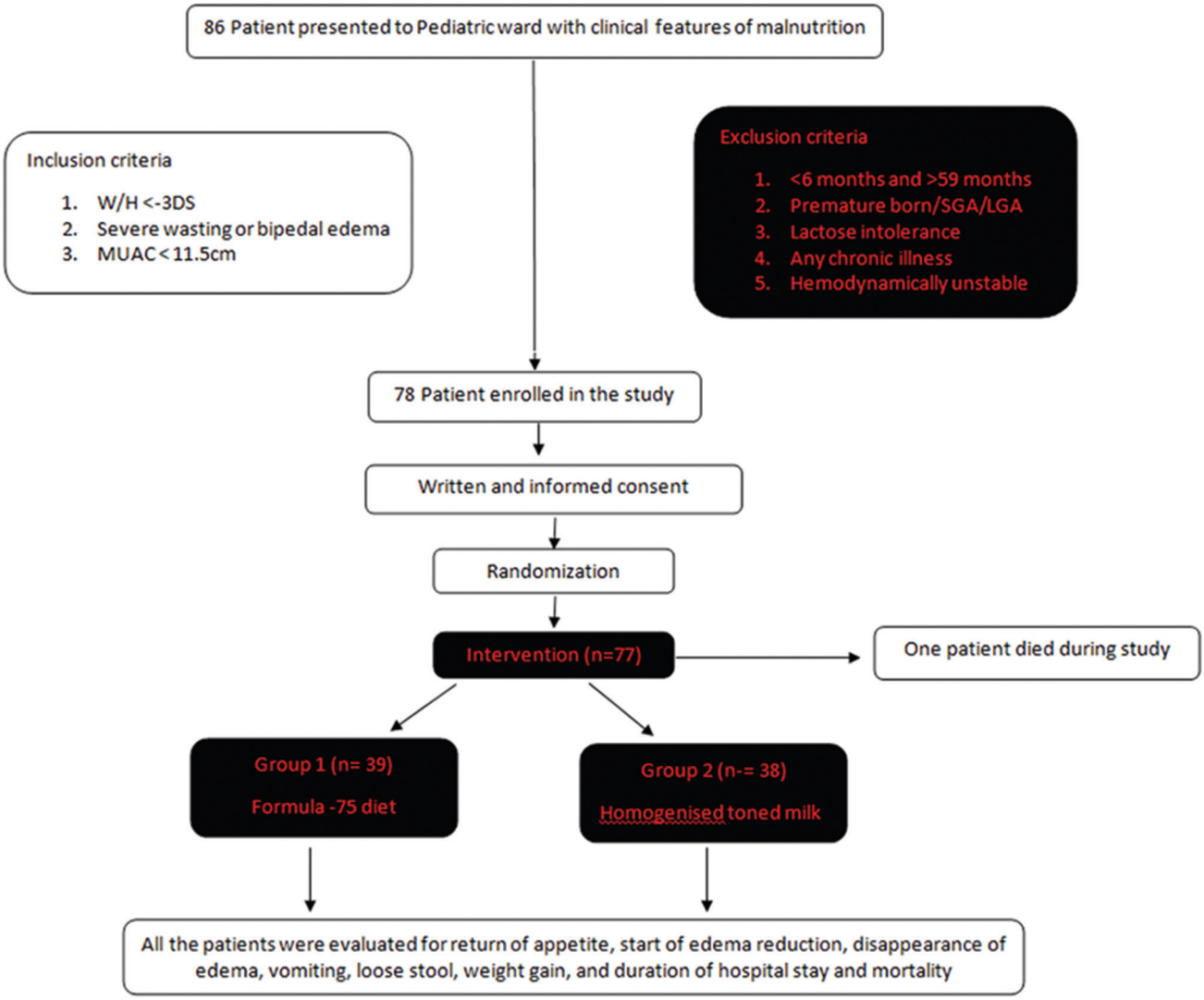

Figure 1: Study chart

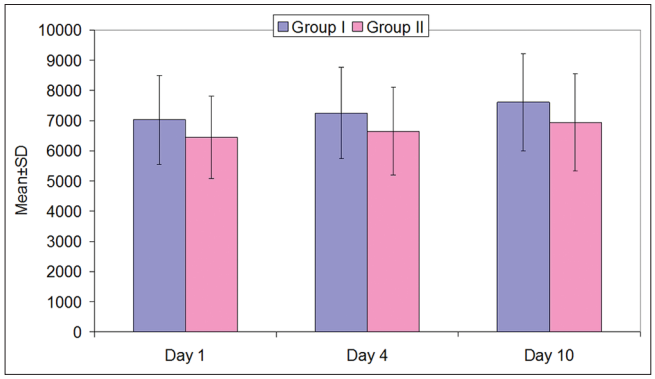

Figure 2: Body weight at different time intervals in both groups

DISCUSSION

The results of our study suggest that homogenized toned milk, facilitated under supervised setting is almost equally effective in recovery of presenting complaints during the management of the stabilization phase of SAM. In this single-blind trial, while both F-75 diet and homogenized toned milk were accepted well by young children, the acceptability of homogenized toned milk was somewhat better.

In our study, the mean age of patients was 16.84±12.13 months, and there was no significant difference in the distribution of the age group in both the groups (p=0.061). Similar observation was seen by Suman *et al*. [9] and Sharma [10]. Similarly, Mamidi *et al*. [11] in their study on hospital-based treatment of SAM reported that 71.1% of children were below 24 months of age. In initial 2–3 years of life, rapid growth occurs, and requirement of substrates for energy and building of tissue also increases; thus a deficiency of protein, energy, and other micronutrients in these year results in malnutrition.

In this study, there were 37 (48.1%) male and 40 (51.9 %.) female with no significant difference in sex distribution in both the groups (p=0.137). Ashraf *et al*. [12] and Aneja *et al*. [13] reported that malnutrition is relatively more common in males as compared to that of females. However, Joshi and Walgankar [14] and Rao *et al*. [15] reported that the extent of the malnutrition was significantly higher in girls than boys. This difference might be due to the fact that these two were field studies conducted in the general population where malnutrition is more common in female

counterpart as compared to male whereas Ashraf *et al*. [12] and Aneja *et al*. [13] and present studies were hospital based where, male patients were more than female which might be due to the fact that in northern part of India, male children are bought to hospital early and are given more importance. Ritual and social norms are also considered as a contributing factor to it.

Out of 27 patients with poor appetite, mean duration of appetite gain among patients of Group II was less than that in Group I but with no significant difference. There are some studies suggesting that different foods have different effects on appetite, apart from the effect of the energy content. Some studies suggest that high protein content in a diet will have a negative effect on energy intake [16], which could be an important reason, apart from cost, not to have too high a protein content in diets for malnourished children. On day 4, the mean frequency of vomiting/day in patients of Group II was significantly lesser than that in Group I ($p<0.001$). On day 10 also, mean frequency of vomiting in Group II was significantly lesser than that in Group I ($p=0.005$). This can be explained by more palatability of homogenized toned milk.

Range of weight gain of patients in Group I and Group II was 3.30–13.6 and 3.00–12.7 g/kg/day. Although mean weight gain among patients of Group I was higher than that in Group II, the difference was not significant ($p=0.133$). These findings are consistent with the previous reports. Oakley *et al*. [17] found that treating children with SAM with 10% milk ready-to-use-therapeutic-food (RUTF) resulted in a lower rate of recovery compared with the standard 25% milk RUTF. This signifies that milk-based products are helpful in good recovery of malnourished patients. Michaelsen *et al*. [18] studied that milk also has a specific effect on linear growth. Milk protein has a high-quality score and contains many peptides and other bioactive factors, which might have special effects on recovery from undernutrition. Hossain *et al*. [19] also compared locally prepared food prepared from cow milk and the WHO protocol in the treatment of SAM and found mean weight related to gain in the WHO protocol and locally prepared food was 11.2±4.1 and 11.1±3.9 g/kg/day, respectively.

Limitation of the study was that it was done at the rural center which may not reflect overall picture in India. Furthermore, the other comorbid conditions were not studied which may affect the outcomes. Although the cost involved in managing severely malnourished children was not calculated methodically, it is presumed that because homogenized toned milk is locally available product and weight gain achieved was same, the cost would be lower in case of homogenized toned milk.

CONCLUSION

The result obtained in this study has important implications in introducing protocol-based management of severely malnourished children in hospitals with limited resources. As it avoids problems of quality control and microbial contamination, homogenized toned milk may be considered for evaluation in difficult circumstances where standard protocols are not feasible for the management of severe malnutrition, especially in developing countries.

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Funding: Nil; Conflict of Interest: Nil.

How to cite this article: Singh DK, Kumar D, Singh S, Yadav RK, Singh M. Recovery pattern in severely malnourished children fed with World Health Organization F-75 diet and Homogenized toned milk. Indian J Child Health. 2018; 5(10):611-615.

Doi: 10.32677/IJCH.2018.v05.i10.002