Hospital Management of Severely Malnourished Children: Comparison of Locally Adapted Protocol with WHO Protocol

MM Hossain, MQ Hassan, MH Rahman, ARML Kabir, AH Hannan and AKMF Rahman

From the Faculty of Pediatrics, Institute of Child and Mother Health, Matuail, Dhaka, Bangladesh.
Correspondence to: Dr Mohammad Monir Hossain, Sadar Hospital, Brahmanbaria, Bangladesh.
E-mail: monir91@yahoo.com

Objectives: To compare the effectiveness of locally adapted Institute of Child and Mother Health (ICMH) protocol with the WHO protocol for the management of severely malnourished children in Bangladesh.

Design: Quasi-experimental non-randomized clinical trial.

Setting: Hospital based.

Participants: Severely malnourished children (2-59 mo) with weight for height <70% (*n*=60).

Intervention: Children treated with either WHO protocol (Group I, *n*=30) or ICMH protocol (Group II, *n*=30).

Outcome variables: Clinical improvement, weight gain, time taken to achieve target weight gain, and mortality among the study subjects.

Results: Mean (SD) weight related to gain in Group I and Group II was 11.2 (4.1) and 11.1 (3.9) g/kg/day, respectively. The weight gain was not related to the age group or type of malnutrition. The time taken for edema to subside (7.3 d vs 8 d) and for improvement of appetite (6.5 d to 7.3 d vs 6.7 d to 8.4 d) was similar between the groups. The target weight gain was achieved in 28.3 (11.5) days in Group I against 27.9 (6.2) days in Group II (*P*=0.88). The mortality rate was 6.7% in each group.

Conclusion: Treatment of severe malnutrition with locally adapted ICMH protocol using locally available foods is as efficacious as the WHO protocol.

Key words: Bangladesh, Child, Malnutrition, Management

Severely malnourished children have a high mortality rate. Even in the 1990s, mortality rates as high as 49% have been reported for malnourished children in hospitals(1). Optimum management of these acutely ill children and a good outcome depends on an evidence based prescriptive regimen of care(2). High case fatality rate in hospitals has been attributed to faulty case management due to lack of knowledgeable staff and absence of prescriptive guidelines. To address this issue, WHO has advocated a protocol and various agencies have adapted it according to their need and available facilities. In Bangladesh, Institute of Child and Mother Health (ICMH) has been following its own protocol for the management of severe malnutrition. A study conducted by Talukder, *et al.*(3) using ICMH protocol showed a mortality rate of 4.5% among severely malnourished children.

The WHO protocol for the management of severe malnutrition has some limitations. In this protocol, there are phases of feeding from low to high calorie density. Treatment includes dose of a combined mineral and vitamin mix (CMV), which is difficult to procure locally. Whereas, ICMH protocol is locally adapted and easy to follow. The calorie density is same through-out and micronutrient deficiency is corrected using locally available minerals and vitamins.

This study was conducted to compare the outcome of management of severe malnutrition in children by ICMH protocol with the WHO protocol.

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Our study was based on the hypothesis that a similar outcome can be achieved by modifying the WHO

protocol, by providing fixed calorie diet and replacing CMV with locally available vitamins and minerals.

METHODS

This quasi-experimental clinical trial was conducted in two hospitals for six months from June to December 2003. One hospital each used the WHO protocol and ICMH protocol for treating severely malnourished children(4,5). The sample size for equivalence was calculated assuming that the mean time taken for targeted weight gain is 25 days in each group with SD of 6 days. Minimum acceptable difference in the two groups was 4.5 days with alpha error 0.05, and power 80%.

Severely malnourished children, aged 2 months to 59 months, whose weight for height was below 70% of the expected (NCHS/WHO references)(6), with or without bilateral pitting edema were included in the study. Children with major congenital abnormalities or disabilities and having feeding difficulty were excluded. All children belonged to the urban and periurban areas of Dhaka. Children at Ad-din Hospital, Dhaka (Group I, *n*=30) were managed according to WHO Protocol(4). Children at ICMH, Dhaka (Group II, *n*=30) were managed by ICMH Protocol(5). Senior staff nurses and doctors of each hospital were trained on the specific management protocol. Senior staff nurses were involved for supervised feeding and monitoring of children, and in helping the physician during anthropometric measurements. Study children were assessed by history, anthropometry, clinical examination and laboratory investigations and managed as per specified protocols. Permission from the ethical committee was obtained and, an informed consent was obtained from the child's guardian before including the child in the study.

Management

Group I: WHO protocol: The management of children with severe malnutrition was divided into 2 phases; initial, and rehabilitation phase and managed as per the protocol(4).

Group II: ICMH protocol(6): In this protocol, there was no phasing in the management. Identification of

life-threatening problems, and management of unconsciousness, convulsion, hypothermia, and hypoglycaemia were done as for Group I. Correction of electrolyte imbalance and micronutrients deficiencies were done by giving locally available minerals and trace elements like Potassium chloride (5 mmol/kg/day), Magnesium sulphate (10 mg/kg/day), Zinc sulphate (2 mg/kg/day), Folic acid (2.5 mg/day), and multivitamins 0.6 mL/day (composition per 0.6 mL of multivitamin: vitamin D1, 200 i.u., thiamine 1 mg, riboflavin 1 mg, pyridoxine 1mg, panthenol 2mg, nicotinamide 5mg, vitamin C 60 mg) orally. Copper was not available in the local market for use. Iron supplementation (6 mg/kg/day) was started on the 15th day. In case of severe anemia with or without heart failure, blood transfusion was given. Every child was given vitamin A supplement. Antibiotics used in this protocol were the same as recommended by WHO. Feeds were made using whole cow's milk, sugar, soya oil and water to provide 100 kcal in 100 mL/kg/day administered every 2 hours during day and night. If the child wanted more than the prescribed diet, extra family food was given *ad-libitum* and breastfeeding was encouraged. Play therapy, nutrition education, and discharge criteria were similar to those for children in Group I.

Outcome measures

(*a*) *Clinical*: improved appetite, disappearance of edema, improvement of other associated medical conditions.

(*b*) *Catch-up growth*: weight gain in gram per kg per day.

(*c*) *Time taken for gaining target weight* (weight for height reaching 1SD (90%) of NCHS/WHO median reference values) calculated from admission weight using NCHS/WHO reference growth chart.

(*d*) *Mortality rate.*

Statistical analysis: All the clinical parameters, appetite, weight, edema etc. were collected daily. Data were collected through structured questionnaire and checked manually at collection period and prior to entry into computer program. MS

Access was used for data entry and SPSS/PC+ for analysis. For comparing the continuous variables like mean weight gain, mean duration of gaining target weight among two groups, student's *t* test was used, and for comparing the mortality rate, chi-square test was used.

RESULTS

The baseline characteristics of the two groups were similar (*Table* I). Two third children were marasmic and one third had edematous malnutrition. *Table* II compares outcome variables between the two groups, which were found to be comparable.

The growth rate varied depending upon the age of the child. In Group I, mean weight gain (SD) was 11.6 (6.8), 12.3 (4.7), 11.4 (3.1) and 11.1 (2.4) gram per kg per day for the 0-6 months, 7-12 months, 13-24 months and above 2 years patients, respectively. On the other hand, it was 17.5 (7.5), 11.8 (2.4), 11.2 (11.2) and 8.1 (2.6) gram per kg per day for the 0-6 months, 7-12 months, 13-24 months and above 2 years patients, respectively in Group II. The difference between two groups were not statistically significant. The average time for improvement of appetite was 7.3 (2.7) days and 7.9 (2.2) days in Group I and Group II, respectively, the difference was not statistically significant.

DISCUSSION

For the management of severe malnutrition in the hospital setting using the WHO protocol, the gradation of hypo-to isocaloric feeds and the use of specific vitamin mineral mix may not be feasible, especially in developing countries. For the management of malnourished children, the protocol developed by ICMH differs from that of WHO. In the ICMH protocol; (*i*) the child was fed with fixed caloric diet, 100 Kcal/kg per day from the beginning of management and continued throughout hospitalization; (*ii*) vitamins and minerals were not mixed with the diet; and (*iii*) potassium, zinc, magnesium and multivitamins were given separately. The present study result has shown that local adaptation of the protocol can yield comparable result.

The study is unique in the sense that it has documented comparisons of treatment outcome in

TABLE I SOCIODEMOGRAPHIC CHARACTERISTICS AND NUTRITIONAL STATUS OF CHILDREN BY STUDY GROUP

Characteristics	Group I WHO group (n = 30)	Group II ICMH group (n = 30)	P value
* Age (mo)	18.33 (13.76)	17.90 (14.17)	0.90
Sex Ratio	1:1	1:1	
Father's education	*n* (%)	*n* (%)	
Illiterate	10 (33.5%)	6 (20%)	
Primary	13 (43.3%)	18 (60%)	0.39
Secondary	7 (23.3%)	6 (20%)	
Mother's education	*n* (%)	*n* (%)	
Illiterate	14 (46.7%)	16 (53.3%)	
Primary	11 (36.7%)	11 (36.7%)	0.73
Secondary	5 (16.7%)	3 (10%)	
Father's profession	*n* (%)	*n* (%)	
Day laborers/ rickshaw pullers	16 (53.3%)	16 (53.3%)	
Service	8 (26.7%)	8 (26.7%)	1.0
Small traders/ cultivator	6 (20%)	6 (20%)	
Mother's profession			
Housewives	18 (60%)	23 (76.7%)	0.37
Day laborers/ Maid servants	8 (26.7%)	5 (16.7%)	
Garment worker	4 (13.3%)	2 (6.7%)	
* Monthly income ($)	40.2 (14.2)	48.7 (36.7)	0.24
Nutritional status	*n* (%)	*n* (%)	
Marasmus	20 (66.8%)	20 (66.8%)	
Marasmic kwashiorkor	4 (13.3%)	5 (16.7%)	0.9
Kwashiorkor	6 (20%)	5 (16.7%)	

* Values in mean (SD)

terms of specific indicators like time needed for gaining target weight, weight gain in grams per kg per day and mortality. Though the sample size seems small, the power calculation is enough for the time to achieve target weight gain. For mortality, this sample size may not be adequate. Again the study groups were not taken from same hospital. This could lead to some selection bias.

Time to reach target weight in our study (28.3 days and 27.9 days in two groups) is similar to that reported

TABLE II COMPARISON OF THE OUTCOME VARIABLES BETWEEN THE TWO GROUPS

Outcome parameters	WHO Group $n=30$	ICMH Group $n=30$	P value
Outcome, No.(%)			
Discharge with target weight gain	25 (83.3)	25 (83.3)	0.72
Discharge on request	2 (6.7)	3 (10)	0.99
Death	2 (6.7)	2 (6.7)	0.6
Absconded	1 (3.3)	0 (0)	
Time taken, Mean (SD)			
For edema to subside in days*	7.3 (2.7)	8.00 (1.8)	0.53
For gaining target weight in days**	28.3 (11.5)	27.9 (6.2)	0.88
Weight gain in g/kg/day, mean (SD)			
in marasmus ($n1 = 16, n2=16$)[+]	11.8 (3.4)	10.5 (3.3)	0.28
in kwashiorkor ($n1 = 6, n2=4$)[+]	8.7 (3.7)	11.5 (4.1)	0.29
in marasmic kwashiorkor ($n1 = 3, n2=5$)[+]	16.3 (5.8)	15 (6.6)	0.79

* Children with edema in each group=9; **Excluding 5 children with death, discharge on request and absconding;
[+]n1= number of children in WHO group belonging to the category, n2=number of children in ICMH group belonging to the
category.

earlier(7). Two children in each group expired within 48 hours of hospitalization. These children had hypoglycemia, septicemia, severe dehydration, heart failure and shock. The mortality was 6.7% in both the protocols, which indicates moderate case fatality(4). Similar mortality rate was also observed by Kabir, *et al.*(8). One third (33.3%) of children in each protocol had edematous malnutrition. It took 7.3 (2.7) days in WHO protocol and 8 (1.8) days in ICMH protocol for edema to subside. The edema of most of the children began to subside on the 4th day of initial management similar to that observed with WHO protocol(4). The average duration of improvement of appetite of most of the children was 7.6 days and it was higher than that observed with WHO protocol. The weight gain of the recovered children showed similar result in both groups. The rate of weight gain in marasmic kwashiorkor children was higher than that in marasmus and kwashiorkor in both the protocols. Catch-up growth rate in 0-6 month old children was slightly higher in ICMH protocol group than that in WHO protocol group (17.5 vs 11.6 gram/kg/day), though this difference was not statistically significant (*P*=0.21). Catch-up growth rate was almost same in sub groups with or without pedal edema in both the protocols.

If the feasibility of implementation of local protocols is considered, there was no change of diet from F-75 to F-100 in ICMH protocol; rather, same calorie-dense food (100 kcal/100mL) was provided throughout the whole length of stay in hospital. Locally available cow's milk, zinc, potassium, magnesium sulphate and multivitamins were used in ICMH protocol instead of imported skimmed milk and CMV. Standard ORS was used instead of CMV based ReSoMal to correct dehydration. Though acceptance was not specifically studied, the service providers appreciated the simplicity of ICMH protocol. Although the cost involved in managing severely malnourished children was not calculated methodically, it is presumed that because ICMH protocol depended on locally available products and duration of hospital stay was almost same, the cost would be lower in case of ICMH protocol.

The result obtained in this study has important implications in introducing protocol based manage-ment of severely malnourished children in hospitals with limited resources. ICMH protocol appears to be a feasible alternative in district hospitals of developing countries for management of severe malnutrition.

What is Already Known?

- WHO protocol adequately manages severely malnourished children in hospital setting.

What This Study Adds?

- A modified protocol using fixed calorie diet and low cost locally available vitamins and minerals achieves comparable outcome.

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