Original Research Article

Comparative study of outcome between IAP versus WHO guideline for initial fluid bolus therapy in severely malnourished children with shock

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ABSTRACT

Background: Severe acute malnutrition is a major cause of mortality in children under 5 years of age in developing countries. Dehydration and Shock are the common serious complications of SAM and require cautious treatment. We carried out this study to compare 2 different guidelines given by WHO and IAP in patient of SAM with shock to compare their outcome and complications.

Methods: A randomized controlled trial was conducted during January 2019 to October 2019 at tertiary care centre of central Gujarat. Total 40 patients were enrolled according to inclusion criteria and randomized into two groups equally, Group A (following WHO guidelines) and Group B (following IAP guidelines). Rehydration therapy was given accordingly and patients were assessed for improvement in shock, developing complications and outcome as discharge or death.

Results: Out of 20 patients in each group, after bolus, not a single patient in group A showed improvement after 1 hour while in Group B 3/20 (15%) patients were improved. In Group A 8/20 (40%) and in Group B 12/20 (60%) patients showed improvement within 12 hours of bolus. In Group A 7/20 (35%) patients and in Group B 6/20 (30%) patients developed complication of fluid overload. In Group A 12/20 (60%) while in Group B 8/20 (40%) patients expired during the treatment.

Conclusions: Rehydration therapy according to IAP guidelines showed better improvement in shock, less incidence of complications and better outcome as compared to WHO Guidelines in SAM patients, however no significant difference was achieved due to smaller sample size.

Keywords: SAM, Shock, WHO, IAP

INTRODUCTION

Severe acute malnutrition (SAM) is a major public health problem as it contributes to childhood morbidity, mortality, impaired intellectual development, suboptimal adult work capacity and increased risk of disease in adulthood and a major cause of mortality in children under 5 years of age in developing countries.[1] It is estimated that 19 million children under 5 years of age are affected with SAM worldwide and is estimated to account for approximately 4,00,000 child deaths each year.[2] Dehydration and shock are two major and serious complications in patients with SAM as correction with intravenous fluids in SAM patient is like two-edged sword. It should proceed more slowly and cautiously or it may land up with fluid overload, pulmonary oedema, congestive cardiac failure and even death. There are no ideal guidelines for management of SAM with shock as the two major guidelines followed worldwide given by WHO and IAP also differs in their recommendations in this

regard. Fluid volume to be infused during the first hour in WHO guideline is 15 ml/kg, On the other hand IAP guideline recommend 10 ml/kg infused over 20-30 min up to 3 times making a total of 30 ml/kg infused over the first hour almost double the amount recommended by WHO. Similarly, recommendation regarding the blood transfusion and inotropes is also different in both the guidelines. Thus, this study was conducted to compare these 2 guidelines in terms of improvement, complication of fluid overload and outcome.[1,3]

METHODS

This randomized controlled study was conducted over 10 months from January 2019 to October 2019 at department of paediatrics, S. S. G. Hospital and Medical College and S.S.G. Hospital, Vadodara and was approved by the institutional ethics committee on human research of medical college and S. S. G. Hospital Medical College and S.S.G. Hospital, Vadodara, Baroda. Sample size was calculated using statistical data available from monthly statistics of paediatric intensive care unit and wards. Total sample size of 40 (20 in each arm) was calculated.

Inclusion criteria

All the admitted patients fulfilling WHO criteria of SAM (Weight-for-height Z score (WHZ) ≤3, mid-upper arm circumference (MUAC) <115mm, bilateral pedal oedema, visible wasting) in age group of 6 months to 5 years with lethargy or unconsciousness; slow capillary refill; weak or fast pulse; cold extremities were included.[1]

Exclusion criteria

Patients with major congenital anomaly or major morbidities like renal failure or congenital heart disease or meningitis and relatives not willing to give consent were excluded.

All the enrolled patients were divided in 2 groups by randomised envelop method by on duty resident doctor. Patients in Group A were treated according to WHO guidelines and in Group B were treated according to IAP guidelines. Patients in Group A received intravenous 0.9% NaCl bolus @15ml/kg over 1 hour. Those who improved after 1st bolus were given 2nd bolus similarly and then switched over to oral or nasogastric ReSoMal @ 10ml/kg/hour for up to 10 hours, in alternate hours with starter F-75. Those not showing signs of improvement, were considered in septic shock and started with inotropes along with maintenance fluids.[1] Patients in Group B received intravenous 0.9% NaCl bolus @10ml/kg over 20-30 min. in patients not showing signs of improvement, same bolus repeated for 2 more times. So, patients received total 30ml/kg bolus over 1 hour according to IAP guidelines. Even after not improving with 3 boluses, patients were given inotropic support along with maintenance fluid considering fluid refractory shock and Packed cell transfusion given if Hb was ≤10 gm%. While

those patients who improved after 1 bolus were started with maintenance fluid considering fluid responsive shock.[3] Standard of care was maintained in both the groups such as management of other co-morbidities like hypoglycaemia, hypothermia, electrolytes imbalance and to control sepsis by use of broad-spectrum antibiotics. Patients in both the groups were monitored for vitals, signs of shock improvement at 1 hour and at 12 hour, signs of fluid overload and for their outcome in the forms of death/ discharged and noted in the proforma. Data collected were analysed by applying appropriate statistical tests like CHI SQUARE test and entered by using MS Office Excel and analysis done by using Med CalC version 19.6.1, p value <0.05 was considered significant.

RESULTS

Total 220 patients with signs of shock were admitted in paediatric emergency during the study period, out of which 60 were fulfilling criteria for severe acute malnutrition. Out of 60, total 40 patients fulfilling the inclusion criteria were enrolled and randomised into 2 groups (Figure 1).
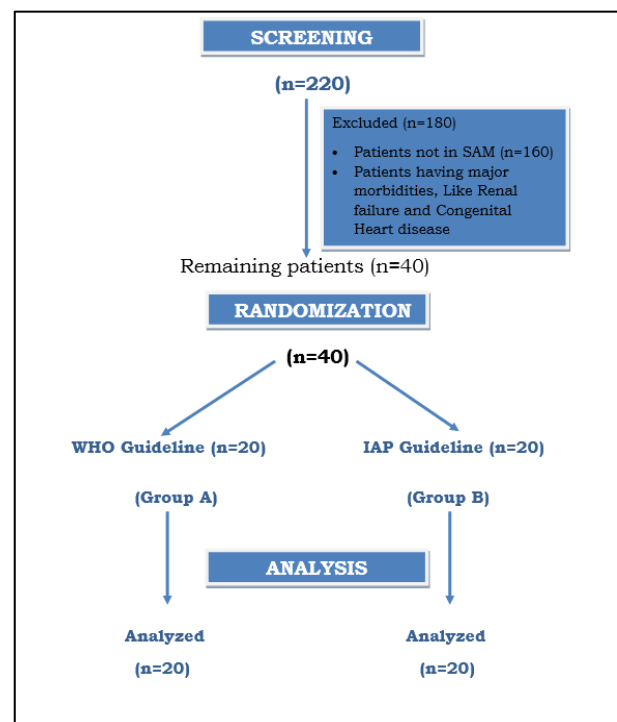

Figure 1: Randomization of subjects in 2 groups.

Group A: WHO guidelines, Group B: IAP guidelines Demographic details of both the groups are shown in (Table 1). Both the groups were comparable in terms of age, gender, severity of malnutrition and associated comorbidities. Both the groups were compared in the terms of improvement in signs of shock after 1st hour, improvement in signs of shock after 12 hours, patients developing signs of fluid overload and final outcome. Not a single patient in Group A showed any improvement at the end of 1st hour. While 3 patients in Group B showed

improvement at the end of 1st hour, p value was 0.021 which is statistically significant difference in both groups.

Table 1: Age distribution in both the groups.

Age distribution (N=20)		
Age group	WHO, N (%)	IAP, N (%)
6 months-1 year	7 (35)	9 (45)
1 year-2 year	6 (30)	5 (25)
2 year-3 year	6 (30)	4 (20)
3 year-4 year	1 (5)	1 (5)
4 year-5 year	0 (0)	1 (5)
Total (n=40)	20	20
Mean age (months)	15.89	15.43

Table 2: Gender distribution in both the groups.

Gender distribution (N=20)		
Sex	WHO N (%)	IAP N (%)
Male	12 (60)	10 (50)
Female	8 (40)	10 (50)

Table 3: Comparison of improvement in signs of shock at 1st hour.

Variables	WHO (N=20) Frequency (%)	IAP (N=20) Frequency (%)	P value
Yes	0 (0)	3 (15)	0.021043
No	20 (100)	17 (85)	

Table 4: Comparison of improvement in sign of shock at 12 hours.

Variables	WHO (N=20) Frequency (%)	IAP (N=20) Frequency (%)	P value
Yes	8 (40)	12 (60)	0.107055
No	12 (60)	8 (40)	

Total 8/20 (40%) patients in Group A and 12/20 (60%) patients in Group B showed improvement in signs of shock at 12 hours after starting treatment (Table 4). The data reveals that improvement in signs of shock in IAP groups was better (60%) compared to the WHO groups (40%). But statistically this difference is not significant as p value is 0.10 and this may be due to smaller sample size. Development of complications like pulmonary oedema, congestive cardiac failure in both groups is depicted in (Figure 2). In Group A, 4/20(20%) patients developed pulmonary oedema and 4/20(20%) patients developed congestive cardiac failure. In Group B, 5/20(25%) patients developed pulmonary oedema and 3/20(15%) patients developed congestive cardiac failure. So, in our study, occurrence of fluid overload was more or less same in both groups and the difference is statistically not significant (p=value 0.3578). Comparison of outcome between 2

groups is depicted in (Figure 3). 12/20(60%) patients in Group A and 8/20(40%) patients in Group B were expired during the treatment, while rest got discharged. Though difference of 20% is considerable, statistically it is not significant as p value is 0.0812.
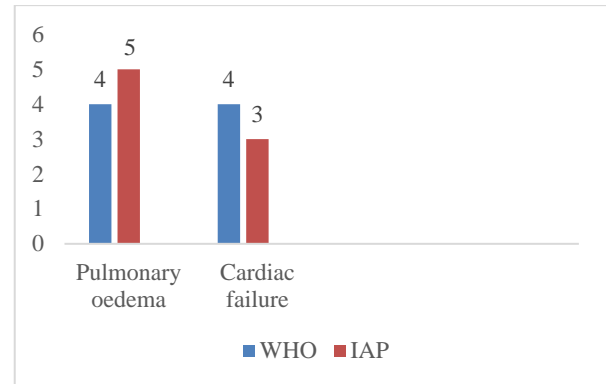

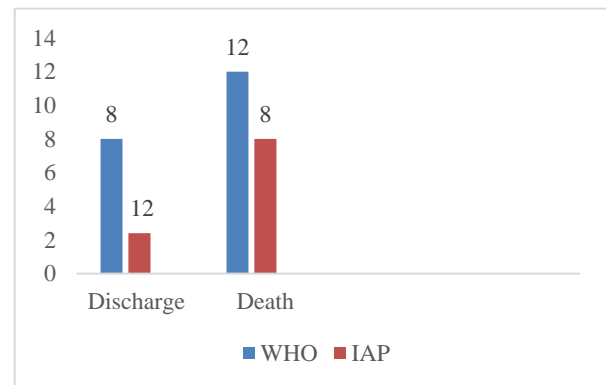**Figure 2: Comparison of number of patients developing complications of fluid overload.**

Figure 3: Comparison of outcome.

DISCUSSION

It is universally accepted that rehydration therapy in patients with malnutrition should proceed more slowly and cautiously but there it is not known at what rate and what amount of fluid to be given to improve shock and avoid other complications. Ann Ashworth et al wrote the editorial to IAP stating that high volume in malnutrition patient with low potassium level can lead to congestive cardiac failure. As in many setups IAP guidelines has been following, it is important to verify the apprehension expressed by WHO.[4]

Akech et al conducted a randomised phase 2 trial in Kenya with severe malnutrition and shock to compare effectiveness of low dose of hypotonic fluid resuscitation (2 boluses of 5% dextrose over 2 hours in one group) v/s Ringer's lactate (10 ml/kg bolus every 30min upto 2 hours i.e., 40 ml/kg over 2 hours). The study concluded that modest volume and rate of infusion were not effective for improvement of shock. Persistence of shock and mortality were higher in previous group as compared to second one

and deaths were not related to fluid overload.[5] Obonyo et al also conducted a similar study in 2017 in Africa to compare WHO protocol with other protocol where patients with SAM with Shock received 10 ml/kg/hour RL for max 5 hours and mortality data was compared at 48 hours and 28 days. Results showed that deaths in both the groups were 36% and 44% in respected groups at 48 hours and 81.8% and 55.6% in respected groups at 28 days from admission and most of the deaths were not related to fluid overload.[6] Both the above study and our study also suggested that very slow and conservative approach to volume expansion advocated by WHO leads to inadequate volume expansion in vascular compartment and may be responsible for not achieving expected improvement in shock following fluid bolus. This also causes suboptimal response to inotropes and also leads to unfavourable outcome. On the other hand, though IAP guideline recommends higher volume as compared to WHO, it shows better improvement in shock and better outcomes. And previous studies also support that death in patients with SAM with shock in both the groups are not always associated with fluid overload.[5,6]

Limitations

The major limitation of study was the smaller sample size and due to this we failed to prove that though there were considerable differences between 2 groups, it was not statistically significant.

CONCLUSION

From our study we concluded that volume expansion with greater Intravenous fluid volumes that is recommended by WHO protocol does not seem to increase the incidence of fluid overload, while response to volume expansion according to IAP guidelines showed better outcome compared to WHO group. Similarly, less patient died (40%) in IAP group compared to WHO group (60%). However statistically significant difference was not achieved due to smaller sample size. A multicentric study with large sample size is required on the urgent basis to prepare a useful guideline related to type, amount and rate of fluids in patients with SAM with shock for better outcome.

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