Bahwere P, Banda T, Sadler K, Nyirenda G, Owino V, Shaba B, Dibari F, Collins S. (2014) **Effectiveness of milk whey protein-based ready-to-use therapeutic food in treatment of severe acute malnutrition in Malawian under-5 children: a randomised, double-blind, controlled non-inferiority clinical trial.** Maternal and Child Nutrition, Feb 13 [e-pub ahead of print]; doi: 10.1111/mcn.12112.

Introduction

Ready-to-use therapeutic foods (RUTF) are now used widely to treat severe acute malnutrition (SAM), primarily in community-based and out-patient programs. The current standard recipe for RUTF is prepared from peanut paste, vegetable oil, milk powder, sugar, and minerals and vitamins [1], and it is recommended that at least half of the proteins contained in the food should come from milk products [2]. To scale up community-based management of acute malnutrition (CMAM) services, appropriately formulated, effective, safe, low-cost and readily available RUTF are needed. However, the cost of milk protein is often raised as a concern in the production of RUTF. Replacing dried skimmed milk with whey protein concentrate may be a good strategy to reduce the costs of RUTF. Whey is a by-product of cheese making, and it contains high levels of proteins and milk lactose and is rich in minerals. The quality of whey protein concentrate is similar to that of dried skimmed milk, and based on an analysis published in 2008, whey protein concentrate was found to cost approximately 25-33% less at that time [3].

This issue of NNA summarizes the findings of a study recently published in *Maternal & Child Nutrition* which investigated the effectiveness of milk whey protein-based RUTF compared with standard RUTF in the treatment of severe acute malnutrition (SAM) in young children in Malawi.

Methods

In a randomized, double-blind, controlled clinical trial 600 children 6 – 59 months of age with SAM were randomly assigned to receive peanut-based RUTF containing dried skimmed milk (P-RUTF) or RUTF containing whey protein concentrate (WPC-RUTF) as its primary protein source. An additional difference between the two study products was that the WPC-RUTF contained soybean, maize and sorghum and no peanut. Both products were packaged in 250 g pots and were similar in consistency and color. The daily ration of both RUTF products provided approximately 175 kcal per kg body weight.

Children in both groups were treated according to the Malawi national guidelines for the management of SAM. SAM was diagnosed as mid-upper arm circumference (MUAC) <11.0 cm or pitting edema of grade 1(+) or 2(+). In case of medical complications, dehydration or absence of appetite children were referred to the hospital for treatment and were only eligible for study participation when they were referred back to one of the 17 outpatient treatment programs in the study area.

After admission into the study, all children received a 5-day course of amoxicillin, a single 100 mg dose of mebendazole, and a 1-week ration of their respective RUTF, along with health and nutrition advice. All children were asked to return to the outpatient treatment site one week later, where they received another 1-week ration of RUTF and if indicated, medical treatment according to the guidelines of the national policy and the Integrated Management of Childhood Illness (IMCI) by the World Health Organization. The primary outcomes of interest were average recovery rate and mean daily weight gain. The length of stay in treatment was a secondary outcome of interest in the present study.

Results and conclusions

At enrollment, the mean age of the 600 enrolled children was 25 months. Edematous malnutrition was the dominant form of SAM as >80% of children were admitted to the study due to the presence of edema. The recovery rate was 84.8% for children receiving WPC-RUTF and 84.2% for children receiving P-RUTF, which was not significantly different. The intention-to-treat and per-protocol analyses showed that the recovery rate in the WPC-RUTF group was not inferior to the recovery rate in the P-RUTF group. Average weight gain did not differ between groups and was 3.1 g per kg per day for the children in the WPC-RUTF group and 2.9 g per kg per day for those in the P-RUTF group. The intention-to-treat and per-protocol analyses showed that weight gain among children in the WPC-RUTF group was not inferior to the average weight gain of the P-RUTF group. There was no difference in recovery rate or weight gain by age group or type of malnutrition (edematous vs. non-edematous). The length of stay in treatment was also not inferior in the WPC-RUTF compared to P-RUTF. There was no significant difference between the two groups, whether the outcome was analyzed by intention-to-treat or per-protocol analyses, for all children or only children who were discharged as recovered.

This study demonstrated that an RUTF containing whey protein as its primary source of protein is as effective in treating SAM as an RUTF containing dried skimmed milk. Moreover, in the acceptability trial, the two products were well accepted and both products were ranked as excellent or very good for color, aroma and texture. Although the weight gain observed in both groups was lower than the recommended 5 g per kg per day, it was comparable to other studies carried out in Malawi. Thus, the authors considered the observed weight gain as satisfactory.

Policy Implications

The present study demonstrates that RUTF containing whey-protein was as effective in treating children with SAM as RUTF containing dried skimmed milk. These results provide governments and humanitarian communities with a potential alternative to peanut-based RUTF containing milk. However, further research is needed to confirm these findings in other populations groups, particularly among non-edematous children with SAM.

NNA Editor's Comments *

Inclusion of milk products in RUTF and other lipid-based nutrient supplements (LNS) is based on the hypothesis that milk has a positive impact on linear growth. Because cost has been raised as a concern in the production of LNS – whether produced at large scale internationally or in smaller quantities locally – and because the cost of dried skimmed milk can substantially contribute to the overall cost of LNS, further research is needed on more affordable RUTF compositions. These may include different quantities or types of milk proteins or sources of protein other than milk. Calculations of cost are also required for the production of different RUTF formulations, since the price of milk and other ingredients not only vary greatly over time, but also depend on availability and transportation costs.

It is important that new recipes of RUTF are tested for their efficacy before introduction into SAM treatment programs and the present study showed that a soybean-maize-sorghum-based RUTF containing whey protein was as effective in treating young children with SAM as standard peanut-based RUTF. However, the two study products varied by more than just the protein source and it can thus not be concluded that the findings were related to the type of milk protein used.

***** These comments have been added by the editorial team and are not part of the cited publication.

References

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Announcement of new publication:

World Health Organization. **Guideline: Updates on the management of severe acute malnutrition in infants and children**. Geneva: World Health Organization, 2013. Available at: http://apps.who.int/iris/bitstream/10665/95584/1/9789241506328_eng.pdf?ua=1

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