Effect of iron-fortified candies on the iron status of children aged 4–6 y in East Jakarta, Indonesia[1–3]

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ABSTRACT
Background: Iron deficiency anemia is the most prevalent nutrition problem in young children. One possible strategy to prevent iron deficiency anemia in this population group is the fortification of affordable food.
Objective: This study was designed to assess whether iron-fortified candies can improve iron status and are acceptable to children aged 4–6 y.
Design: A double-blind, placebo-controlled intervention study was conducted in Jakarta, Indonesia. The children were randomly assigned to 1 of 2 treatment groups: a fortified group (n = 57) and a placebo group (n = 60). Every week for 12 wk, 30 g (10 pieces) candy was given to the children. The candy given to the fortified group contained 1 mg elemental Fe/g and very small amounts of other vitamins and minerals.
Results: The hemoglobin concentration of the fortified group increased by 10.2 g/L (95% CI: 8.3, 12 g/L) whereas that of the placebo group increased by 4.0 g/L (2.0, 6.0 g/L; $P < 0.001$). Anemia prevalence decreased from 50.9% at the start of the intervention to 8.8% after 12 wk of intervention in the fortified group ($P < 0.001$) and from 43.3% to 26.7% in the placebo group ($P < 0.05$). After 12 wk of intervention, the serum ferritin concentration was 71% higher than at baseline in the fortified group and 28% higher in the placebo group ($P < 0.001$). Acceptability of the iron-fortified candies was good. The per capita cost of the supplement was approximately US$0.96–1.20 for the 12 wk of intervention.
Conclusion: Iron-fortified candies were effective for improving the iron status of young children and might be an affordable way to combat iron deficiency in children of low-to-middle income groups. *Am J Clin Nutr* 2001;73:1034–9.

KEY WORDS Anemia, iron deficiency, iron fortification, preschool children, candies, East Jakarta, Indonesia

INTRODUCTION

Iron deficiency anemia is still the most prevalent nutrition problem worldwide (1). Young children are a particularly vulnerable group and the prevalence of anemia in this population category in Southeast Asia is 50–70% (2). One of the causes of nutritional anemia is that the amount of iron absorbed is insufficient to meet the body's requirements. This insufficiency may be due to both inadequate iron intake from food and to low bioavailability (3). Children consume less food than do adults and their diet often consists of foods with a low iron content and in which the bioavailability of iron is poor (4).

Anemia during childhood may lead to impaired motor development, decreased growth and appetite, reduced learning capacity, and reduced cognitive performance, and is also associated with poorer performance of the immune system (5–11). Therefore, an adequate supply of iron to all tissues during this critical period of development is essential (4). In the relatively short term, an improvement in the situation can be expected only through interventions such as food fortification or medicinal iron tablets or syrup. Although the Indonesian Ministry of Health supports iron fortification of food as one of the main strategies to prevent iron deficiency anemia, with young children being among the priority target groups (12), studies on the fortification of food with iron are scarce in Indonesia.

The identification of a suitable vehicle is an important consideration in any attempt to fortify foods. Cereal products have traditionally been used as vehicles for fortificant iron in many countries (13). Other vehicles used include sugar (14, 15), fish sauce (16), common salt (17), and cookies (18). Sweets are attractive foods to children and are therefore suitable as a carrier of fortificants for this reason and others. First, the fortification of a staple food is difficult to control, the variation in intake between individuals is large, and the consumption is not limited to specific at-risk groups. Second, in Indonesia, sweets are also eaten by the poorer segments of the population, especially by children.

This study was designed to investigate whether iron-fortified candies could improve the iron status of children aged 4–6 y and whether they would be acceptable to them. Both the fortified and placebo candies used in this study were candies specifically

[1] From Helen Keller International, Jakarta, Indonesia; the Regional Southeast Asian Ministries of Education Organization (SEAMO), the Center for Community Nutrition at the University of Indonesia, Jakarta; and Deutsche Gesellschaft fuer Technische Zusammenarbeit (GTZ) GmbH, Eschborn, Germany.

[2] Supported by the Southeast Asian Ministries of Education Organization, Center for Community Nutrition at the University of Indonesia, Jakarta, and Deutsche Gesellschaft fuer Technische Zusammenarbeit (GTZ) GmbH, Eschborn, Germany. PT Van Melle (Bogor, West Java, Indonesia) donated the fortified and unfortified candies.

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prepared by PT Van Melle (Bogor, West Java, Indonesia). In fact, the same unfortified candies had already been produced and marketed by the same company.

SUBJECTS AND METHODS

Subjects

The study was carried out between early March and early June 1996 in 4 kindergartens in the Pulo Gadung subdistrict, East Jakarta, Indonesia. Subjects were children aged 4–6 y from low-to-middle income groups who were apparently healthy and had a hemoglobin concentration ≥80 g/L. With a sample size of 50 children/group, a difference in the change in hemoglobin concentration of 5 g/L between groups would be detectable at an α level of 0.05 and a power of 80%. The details of the study were explained to 205 mothers, who were also informed that the fortified product mainly contained iron, but also other vitamins and minerals; 132 of the mothers gave informed consent. The research proposal was approved by the Ethical Review Committee of the Regional SEAMEO-TROPMED Center for Community Nutrition (University of Indonesia, Jakarta).

Methods

The study was double-blinded and placebo-controlled with random allocation of children to treatment groups. A hemoglobin concentration <110 g/L was used as a cutoff for defining anemia, whereas a serum ferritin concentration <20 mg/L was used as the cutoff for defining iron deficiency. To minimize the effect of parasitic infestation as a confounding factor, a single dose of 400 mg Albendazole (Smith-Kline & Beecham, Jakarta, Indonesia) was taken by the subjects before the intervention (19, 20).

The 132 subjects enrolled initially were randomly assigned to 1 of 2 groups: a placebo group (n = 67) and a fortified group (n = 65). For 12 wk, the placebo group received nonfortified candies and the fortified group received iron-fortified candies, which provided a total of 30 mg elemental Fe/wk (48% of the recommended dietary allowance for children aged 4–6 y; 21). This amount of iron was shown to improve the iron status of preschoolers (21).The iron-fortified and placebo candies were individually packed in a transparent wrapper that was labeled as either A or B. The coding was known only to the manufacturer and was revealed only after the study and the analyses were completed.

The candies were distributed 3 times/wk, on Monday (3 pieces), Wednesday (3 pieces), and Friday (4 pieces). The distribution and consumption of the candies were supervised directly by one of the authors and the teachers. The subjects who were absent on the days the candy was distributed received candies the next day. At the end of the study, the attendance of the children during the intervention was cross-checked by using the list of attendance in every kindergarten.

Both at baseline and after 12 wk of intervention, the weight and height of the subjects were determined and their hemoglobin and serum ferritin concentrations were assessed. Weight was determined with an electronic bathroom model scale (model 890; Seca, Hamburg, Germany) and was recorded to the nearest 0.1 kg. Height was measured by using a microtoise with an accuracy of 0.1 cm while the subjects were shoeless. Blood samples (2.5 mL) were collected from apparently healthy subjects twice—at baseline and after 12 wk of intervention—by venipuncture by a trained technician. Immediately after collection, part of the sample was removed for measurement of hemoglobin concentrations by the cyanomethemoglobin method (Merck-test 3317; Merck, Darmstadt, Germany) (22). Subjects with initial hemoglobin concentrations <80 g/L were excluded from the study and were treated with medicinal iron syrup (60 mg/d for 12 wk). The remaining blood was placed on ice, protected from light, and centrifuged (750 × g, 10 min, room temperature) at the laboratory of SEAMEO-TROPMED within a few hours. The serum obtained was frozen at −20°C for later measurement of ferritin concentrations. Serum ferritin concentrations were measured within 1 mo after blood collection by using the enzyme immunoassay method (IMx System; Abbott, Abbott Park, IL). Both assessments were performed at the laboratory of SEAMEO-TROPMED and 15% of the blood samples were analyzed twice. CVs based on these duplicate measurements were 3.9% for hemoglobin and 5.5% for serum ferritin.

In the first week of the intervention, all mothers were invited to come to school for an interview about their socioeconomic background, the health of their children, and the acceptability of the iron-fortified candies. The interview was conducted by trained nutritionists using a structured questionnaire. Every child was also interviewed about the acceptability of the candies he or she consumed.

Supplement

The supplement used in this study, Vitaletta, was fruit-flavored, chewy, and sweet and both the fortified and nonfortified candies were prepared by the same factory (PT Van Melle). One fortified candy (3 g) contained 1000 mg elemental Fe/kg candy and insignificant amounts of other minerals and vitamins (**Table 1**). The placebo candy was not fortified and therefore did not contain a significant amount of any vitamins or minerals. The macronutrient content of 1000 g candy, as declared by the manufacturer, was 91 g fat, 363 g starch, 56 g glucose, 54 g fructose, 327 g saccharose, and 77 g protein. To ensure a weekly dose of 30 mg Fe, 10 candies were provided per week, divided over 3 d. Both the fortified and placebo candies had an orange flavor, which had

TABLE 1
Micronutrient content of 30 g (weekly dose) iron-fortified candy[1]

Nutrient	Value	Percentage of RDA[2]
	mg	*%*
Iron	30	48
Vitamin A[3]	1101 [330]	7.6
Thiamine	0.4	7
Riboflavin	0.9	18
Vitamin B-6	0.56	Trace
Vitamin B-12	2	1.0
Vitamin C	9	2.9
Folic acid	0.7	Trace
Vitamin E	4.8	Trace
Niacin	3.9	7
Iodine	0.03	Trace

[1] The composition of the unfortified candy was not analyzed, but because the fortified supplement, which was fortified with a vitamin-mineral premix, contained only a substantial amount of iron, the vitamin and mineral content of the unfortified supplement would have been negligible.

[2] Based on consumption of 10 candies/wk (eg, 30 mg Fe/7 d = 4.3 mg/d = 48% of the recommended dietary allowance).

[3] IU; retinol equivalents in parentheses.

TABLE 2
Age and anthropometric measures of subjects at baseline and after 12 wk of intervention by treatment group[1]

Characteristic	Fortified group (n = 57)		Placebo group (n = 60)	
	Baseline	After 12 wk	Baseline	After 12 wk
Age (mo)[2,3]	65.7 ± 5.7	68.7 ± 5.7	67.8 ± 4.3	70.8 ± 4.3
Weight (kg)[3]	17.5 ± 2.6	17.8 ± 2.7	16.9 ± 2.3	17.2 ± 2.7
Height (cm)[3]	108.2 ± 5.2	109.9 ± 5.4	108.0 ± 5.1	109.7 ± 5.2
Weight-for-age z score[2]	−0.73 ± 1.18	−0.82 ± 1.11	−1.16 ± 0.95	−1.21 ± 1.06
Height-for-age z score[3]	−0.82 ± 0.97	−0.77 ± 0.97	−1.07 ± 1.02	−1.02 ± 1.01
Weight-for-height z score[2,3]	−0.30 ± 1.10	−0.48 ± 0.98	−0.70 ± 0.81	−0.84 ± 0.93

[1] $\bar{x}$ ± SD.
[2] Significant difference between treatment groups at baseline, $P < 0.05$ (Student's t test).
[3] Significant difference between baseline and after 12 wk of intervention for both treatment groups combined, $P < 0.05$ (paired t test). Multivariate analysis with the value after 12 wk of intervention as the independent variable and the value at baseline and treatment group as covariates showed that there was no treatment effect.

been chosen by the manufacturer because of large overall acceptance and preference.

Statistical analysis

Data entry and z score calculations for the anthropometric data were done by using EPI-INFO (version 6.0; Centers for Disease Control and Prevention, Atlanta), whereas other data were entered by using SPSS for WINDOWS (version 6.1; SPSS Inc, Chicago). Serum ferritin concentrations were not normally distributed; therefore, values are reported as medians and percentiles and a logarithmic transformation was used for the statistical analyses.

Differences between treatment groups at baseline were examined by using Student's t test. Differences after 12 wk of intervention were examined by using multiple analysis of variance; the value after 12 wk of intervention was the dependent variable and treatment group, age, sex, anthropometric indexes, and the value at baseline were independent variables. When a treatment effect was found, paired t tests were conducted per treatment group to examine whether the change from baseline after 12 wk of intervention was significant. When no treatment effect was found, a paired t test was performed for the 2 treatment groups combined. Differences in the prevalence of anemia and of low serum ferritin concentrations between the 2 groups were tested for by using chi-square tests. The difference in prevalence of anemia between baseline and after 12 wk of intervention within a treatment group was tested by using McNemar's test.

RESULTS

A complete set of data was obtained for 57 of the 65 children assigned to the fortified group and for 60 of the 67 children assigned to the placebo group. Fifteen children dropped out of the study: 4 because they were absent during the first week of supplementation, 4 (2 in the fortified and 2 in the placebo group) because they refused to continue taking the supplements after the first 6 wk, 4 because they were absent during the second blood collection, 1 because of a very low initial hemoglobin concentration, 1 because the serum ferritin analysis failed, and 1 because the family moved during the intervention. The age, weight, height, and z scores of the subjects in both treatment groups at baseline and after 12 wk of intervention are shown in **Table 2**. Fewer than 2% of the subjects used iron supplements (data not shown); therefore, this information was not taken into account in the analysis.

Effect of iron-fortified candies on iron status

The effects of the treatment on the children's iron status are shown in **Tables 3** and **4**. Weekly consumption of iron-fortified candies significantly improved iron status. After the 12-wk intervention, the hemoglobin concentration, corrected for baseline, was significantly higher in the fortified group than in the placebo group. The same was found among the anemic subjects. Analysis of the total group showed that the serum ferritin concentration after 12 wk of intervention, and corrected for baseline, was also significantly higher in the fortified group than in the placebo group. Of the anemic subjects, the difference in serum ferritin

TABLE 3
Hemoglobin and serum ferritin concentrations before and after 12 wk of consumption of iron-fortified or placebo candies

Characteristic	Fortified group (n = 57)			Placebo group (n = 60)		
	Baseline	After 12 wk	Change[1]	Baseline	After 12 wk	Change[1]
Hemoglobin (g/L)[2,3]	110.6 ± 9.7	120.8 ± 7.8	10.2 ± 7.0[4]	111.3 ± 8.7	115.3 ± 7.9	4.0 ± 7.9[4]
	(108.0, 113.2)	(118.7, 122.9)	(8.3, 12.0)	(109.0, 113.5)	(113.3, 117.3)	(2.0, 6.0)
Serum ferritin (μg/L)[3,5]	19	32	71[4]	25	30	28[4]
	(12, 28)	(23, 46)	(41, 135)	(16, 31)	(20, 43)	(−5, 76)

[1] For serum ferritin, the change is expressed as a proportional change [100% × (value after 12 wk − baseline value)/baseline value]. Log-transformed data were used in the statistical analyses.
[2] $\bar{x}$ ± SD; 95% CI in parentheses.
[3] Significant difference after 12 wk of intervention between treatment groups with control for baseline value (multivariate analysis with the value after 12 wk of intervention as the independent variable and the value at baseline, treatment group, age, sex, and baseline value of anthropometric indexes as covariates). There was a significant treatment effect, $P < 0.001$.
[4] Significant difference, $P < 0.05$ (paired t test).
[5] Median; 25th and 75th percentiles in parentheses.

TABLE 4
Hemoglobin and serum ferritin concentrations before and after 12 wk of consumption of iron-fortified or placebo candies in subjects with a baseline hemoglobin concentration <110 g/L

	Fortified group (n = 29)			Placebo group (n = 26)		
Characteristic	Baseline	After 12 wk	Change[1]	Baseline	After 12 wk	Change[1]
Hemoglobin (g/L)[2,3]	103.5 ± 6.1 (101.2, 105.8)	116.5 ± 6.2 (114.1, 118.8)	12.9 ± 6.8[4] (10.3, 15.5)	102.9 ± 4.9 (100.9, 104.9)	111.3 ± 7.9 (108.1, 114.5)	8.3 ± 8.7[4] (4.8, 11.8)
Serum ferritin (μg/L)[5,6]	17 (10, 27)	29 (22, 39)	85 (43, 132)	18 (9, 27)	24 (16, 40)	33 (8, 91)

[1] For serum ferritin, the change is expressed as a proportional change [100% × (value after 12 wk − baseline value)/baseline value]. Log-transformed data were used in the statistical analyses.

[2] $\bar{x}$ ± SD; 95% CI in parentheses.

[3] Significant difference after 12 wk of intervention between treatment groups with control for baseline value (multivariate analysis with the value after 12 wk of intervention as the independent variable and the value at baseline, treatment group, age, sex, and baseline value of anthropometric indexes as covariates). There was a significant treatment effect, $P < 0.05$.

[4] Significant difference, $P < 0.05$ (paired t test).

[5] Median; 25th and 75th percentiles in parentheses.

[6] Significant difference between baseline and after 12 wk of intervention for both treatment groups combined, $P < 0.05$ (paired t test). Groups were combined because there was no treatment effect.

concentrations after 12 wk of intervention, corrected for baseline, was nearly significant ($P < 0.06$). The prevalences of anemia and iron deficiency, at the beginning of the study and after 12 wk of intervention, per treatment group, are shown in **Table 5**. Although the prevalences of anemia and iron deficiency decreased significantly in both treatment groups after 12 wk of intervention, the prevalence of anemia was significantly lower in the fortified group.

Acceptability of iron-fortified candies

The opinions of the mothers about the iron-fortified candies are shown in **Table 6**. (Possible answers were phrased similarly to the results reported.) Of the 89.9% of mothers who answered that fortified candies were good for their children, 38.1% said that they were good for child growth, 32.0% that they contained additional nutrients, and 14.4% that they increased appetite. Of the 116 mothers, 93.1% said that they would choose fortified candies instead of nonfortified ones for their children and 95.7% said that they would ensure that their children consumed 3–4 pieces of fortified candies 3 times/wk if it were recommended.

The children's answers to the questions about the acceptability of the fortified or unfortified candies indicated that almost 90% of the children liked them (data not shown). When the codes of fortified and placebo candies were disclosed after completion of the trial and analyses, it was found that there were no significant differences in the acceptability of the candies between the treatment groups. The children in the fortified group gave the following reasons for liking the candy: it had a nice taste (48.2%), it was sweet (37.5%), or it had an orange taste (8.9%).

There was no relation between family income and intent to purchase the sweet snacks if they became available in the market (data not shown); 80% of the mothers indicated that they would buy the fortified candies for a price of Rp (rupiah) 300–400 (US$0.04–0.05) per sachet (5 pieces).

DISCUSSION

The results of the present study indicate that the iron-fortified candies, which provided 48% of the recommended dietary allowance of iron per week, were acceptable to children aged 4–6 y and improved their iron status. The willingness of the mothers to provide iron-fortified candies to their children was also good.

Iron deficiency is common in developing countries, where the diet is largely cereal-based and contains little animal protein (23), and it will take a long time for dietary changes to result in improvements in iron status. One way to ensure the adequate iron nutrition of a population is to fortify commonly consumed foods with iron and provide the foods in relatively predictable amounts (24). Food fortification and supplementation are generally considered the best approaches for combating iron deficiency in a population. However, fortified foods do not always reach the intended target groups. Therefore, we studied the effect of the consumption of fortified candies that are mainly consumed by young children, including those of low-to-middle income groups.

The increase in hemoglobin concentrations in the anemic subjects, 12.9 g/L, is similar to the 12-g/L increase observed in a study of children aged <5 y supplemented biweekly with 30 mg elemental Fe/wk (21, 25). The increase in serum ferritin concentrations in anemic subjects of 15 μg/L [calculated from results reported in Table 4: median value at baseline (17 μg/L) × the proportional change (85%)] is comparable with the results of a study in which anemic children were supplemented with both vitamin A and iron, and in which serum ferritin increased by

TABLE 5
Prevalence of anemia and iron deficiency in the 2 groups at baseline and after 12 wk of intervention

	Fortified group (n = 57)		Placebo group (n = 60)	
	Baseline	After 12 wk	Baseline	After 12 wk
Anemia (%)[1]	50.9	8.8[2]	43.3	26.7[3,4]
Iron deficiency (%)[5]	52.6	17.5[2]	36.7	23.3[4]

[1] Defined as a hemoglobin concentration <110 g/L.

[2,4] Significantly different from prevalence at baseline (McNemar's test): [2] $P < 0.001$, [4] $P < 0.05$.

[3] Significantly different from after 12-wk value of fortified group, $P < 0.05$ (chi-square test).

[5] Defined as a serum ferritin concentration <20 μg/L.

TABLE 6
Mothers' opinions about the iron-fortified candies[1]

Variable	Value
Opinion about fortified Vitaletta candies (n = 109)	%
Good	89.9
Bad	0.9
Does not know	9.2
Reasons Vitaletta is good (n = 97)	
It contains additional nutrients	32.0
Increases appetite	14.4
Stimulates child's growth	38.1
Other reasons	9.3
Does not know	6.2
Would the mother choose fortified Viteletta candies instead of unfortified candies (n = 116)	
Yes	93.1
No	6.9
Reasons for choosing fortified Vitaletta (n = 108)	
It contains vitamins and minerals	41.7
It makes the child healthy	45.4
Other reasons	6.5
If results of trial are good	4.6
If the child likes it	1.9
Would the mother buy a sachet (5 pieces) of fortified Vitaletta candies regularly at this price (n = 116)[2]	
Rp 300	98.3
Rp 350	90.5
Rp 400	81.9
If suggested, would the mother supervise the children's consumption of 3–4 pieces of fortified Vitaletta candies 3 times/wk (n = 116)	
Yes	95.7
No	4.3
Reasons for supervising children's consumption of 3–4 pieces of fortified Vitaletta candies 3 times/wk (n = 110)	
Good for the child's health	45.5
It contains vitamins and minerals	18.2
Other reasons	16.4
If there are no side effects	10.9
If the child likes it	9.1

[1] Vitaletta (PT Van Melle, Bogor, West Java, Indonesia).
[2] Rp, rupiah. US$1.00 = Rp 7500.

16.4 μg/L (26). These values are slightly higher than those observed in studies of the effects of iron-fortified soup (27) and of iron-fortified curry powder (28).

The improvement in iron status after consumption of iron-fortified candies was most likely due to the iron content of the candies. Although the candies also contained other micronutrients, such as vitamins C and A [which are known to improve iron absorption and utilization, respectively (6, 15, 29–31)], and other hematopoietic nutrients such as vitamin B-12, vitamin B-6, and folic acid (which are known to increase hemoglobin concentrations), the content of these micronutrients was so small that it is unlikely that they contributed to the improvement in iron status.

The fact that the children finished the candies given to them confirmed their acceptance. During the intervention study, many mothers asked for additional iron-fortified candies to give to their other children. Although this may have been because the candies were provided at no cost, it also indicated that the candies were acceptable to both the children and their mothers. The data on candy-purchasing practices indicated that candies would also be affordable to this low-to-middle income population.

In summary, we conclude that consumption of 10 pieces of iron-fortified candy that provided 30 mg elemental Fe/wk was acceptable to the target group and is a feasible and effective way to improve the iron status of children aged 4–6 y. However, because of the current economic situation in Indonesia, introduction of this strategy to improve the iron status of young children is less likely than it was at the time that the study was conducted. The purchasing power of most of the population has decreased enormously since then and the lower value of the Indonesian rupiah against most foreign currency has markedly increased the cost of fortificants and would thus markedly increase the price of the fortified candies.

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