

Original Research Article

Impact of the use of iron-fortified iodized salt on hemoglobin levels: a community based open randomized trial

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ABSTRACT

Background: In India prevalence of iron deficiency and anemia is high across all age, sex and physiological groups because of inadequate iron intake and poor bioavailability of iron from habitual Indian diets. Research studies in school-age children have shown that use of iron-fortified iodized salt (DFS) resulted in small improvement in Hb level; there are very few studies reporting impact of DFS use in women and men.

Methods: A community-based open three arm randomised study was carried out to assess the impact of DFS use on Hb in women, men and children. The control group received iodised salt and two intervention groups received two formulations of DFS.

Results: Socio-demographic and nutrition profile of the families, mean Hb, ferritin and C reactive protein levels of women, men and children at enrolment were comparable in all three groups. The DFS use for 12 months resulted in improvement in mean Hb in children (0.8 gm/dl) women (0.4 gm/dl) and men (0.3 gm/dl). Improvement in Hb was higher in anemic women, men and children. There was no change in mean Hb in non-anemic persons. There was a small improvement in ferritin in women who have low ferritin but no change in ferritin in women and men with normal ferritin.

Conclusions: DFS may be a safe, feasible, affordable, and sustainable method for improving the iron intake and Hb status and accelerating India's progress towards the SDG goal of 50% reduction in prevalence of anemia.

Keywords: Anemia, CRP, DFS, Ferritin, Hemoglobin, Impact, Iron fortification, Use of iron-fortified iodized salt

INTRODUCTION

India had and continues to have the highest prevalence of anaemia and the largest number of anaemic persons in the world.¹⁻³ Inadequate intake of micro-nutrient-rich vegetables and poor bioavailability of iron from phytate and fibre-rich Indian diets are two major factors responsible for the high prevalence of anaemia across all age groups.⁴ In an attempt to accelerate reduction in anaemia, India has intensified National Iron Plus Initiative (INIPI) with focus on nutrition education to increase consumption of micronutrient-rich vegetables, use of iron-fortified foodstuffs and improving coverage of iron-folic acid supplementation for vulnerable groups.⁵

India has been a pioneer in the development and evaluation of iron fortified iodised salt.⁶⁻⁸ Two formulations of iron-fortified iodised salt [double fortified salt (DFS)] had been approved by Food Safety and Standards Authority of India (FSSAI).⁹ Several studies and reviews have assessed organoleptic properties and documented acceptability and impact of formulations of DFS.¹⁰⁻¹⁶ Government of India (GoI) guidelines recommend use of DFS in preparing hot cooked meals for children under the school midday meal (MDM) programme and Integrated Child Development Services (ICDS).¹⁷⁻¹⁹ Some states have provided DFS through public distribution system (PDS) and through open market, but reported offtake was low and impact on Hb seen only in adolescents.^{20,21}

DFS is supplied to families and is consumed by all the family members. It is essential to document impact of DFS use on: Hb in women, children and men; Hb in anaemic and non-anaemic persons, and; ferritin levels in persons with low and normal ferritin.

A community-based open randomized study in urban low middle-income families was initiated to assess the impact of use of iodised salt (group 1 IS), and two formulations of DFS, [one fortified with ferrous sulphate (group 2 DFS-FS) and the other fortified with ferrous fumarate (group 3 DFS-FF)], on Hb and ferritin in women, men and children in the family. Results from the study can provide the evidence-base for making decisions regarding

scaling up of DFS use to improve Hb status and achieve the sustainable development goals (SDG) target of a 50% reduction in the prevalence of anaemia in women in the reproductive age group by 2030.²²

METHODS

The community-based open randomized study was conducted in three purposively chosen blocks in South Delhi where our institution has been working for the past decade and has built up rapport with the people, and health and nutrition service providers. The study design is given in Figure 1.

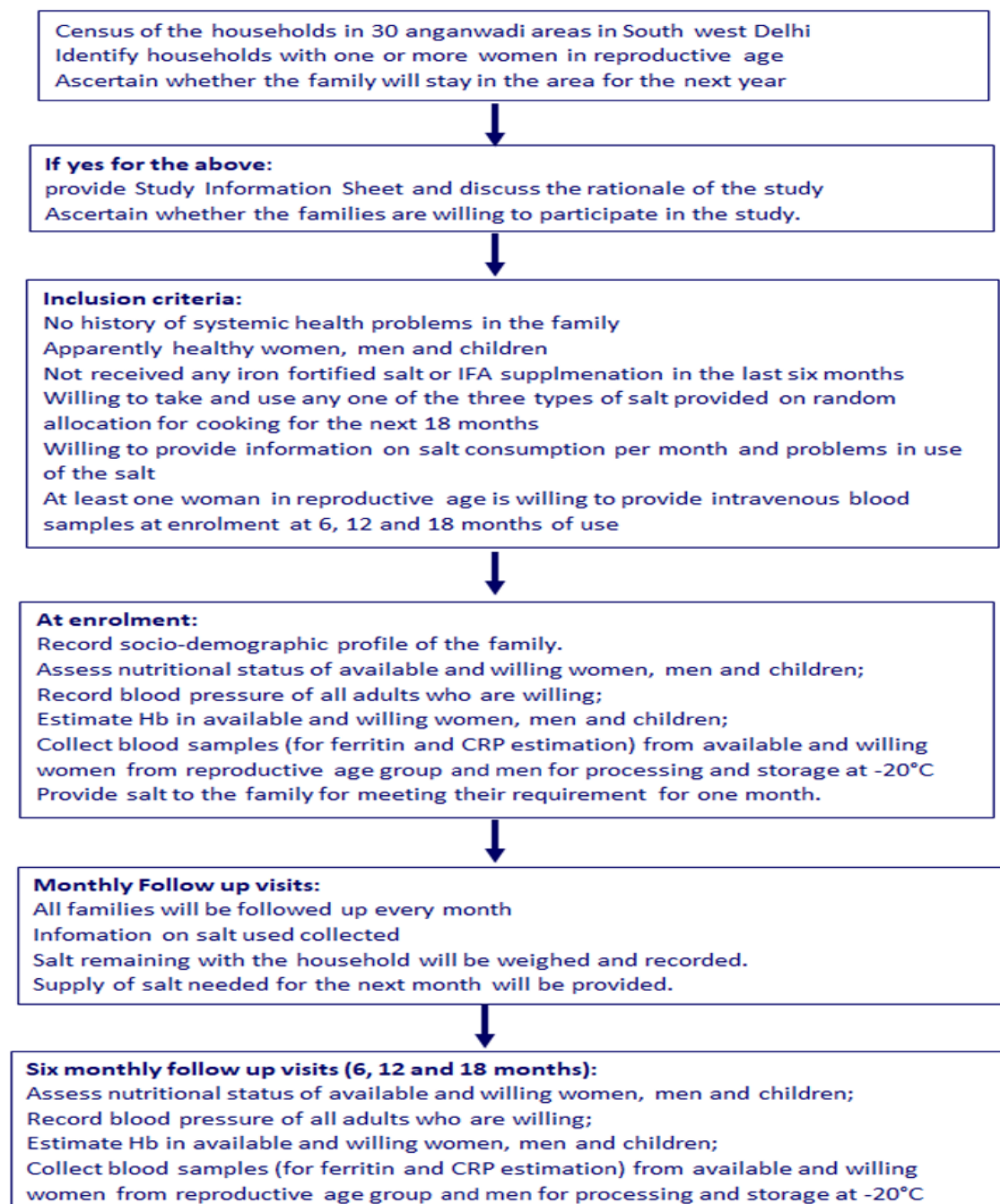


Figure 1: Study design.

Four consignments of all three fortified salts (iodized salt and two formulations of DFS) manufactured simultaneously were purchased from a single manufacturer. From the census of households in the area the first 750 families who fulfilled the inclusion criteria and consented to participate in the study were allocated to one of the three groups [250 each in group 1 (IS), group 2 (DFS-FS), and group 3 (DFS-FF)] using a computer-generated random allocation (Table 1). Blood samples were collected by venepuncture for Hb, ferritin and CRP estimation from available men and women from these families who had given informed consent; blood for Hb estimation was collected from finger prick in available and willing 7-18-year children, whose parent had given informed consent and children had given their assent.

Table 1: Enrolment and follow up.

Group 1	Group 2	Group 3
Random allocation: number of families in each group		
250	250	250
Not willing to accept the salt provided		
20	30	36
Number of families enrolled for the study		
230	220	214
Families continuing upto 6 months		
186	152	163
Families continuing upto 12 months		
96	84	92

Earlier organoleptic studies on these formulations had shown that some families did not accept salt provided through random allocation. Therefore, each of the 750 families who had consented to participate in the study, was given 250 gm of the salt which was to be provided to the family under the random allocation and were requested to use it for cooking for the next few days. These families were revisited after they had used the salt provided. About 10% of the families did not want to use the salt allocated to the family, because one or more family members did not: want to use iodized salt when DFS was being provided to other families; want to consume a salt that had black spots; like the colour of the salt, taste (not salty enough), or oily smell of salt solution in warm water when used for gargling.

As a result, the number of families who were enrolled for the study was 230 in group 1, 220 in group 2, and 214 in group 3 (Table 1). Enrolment was completed between January 2019 and March 2019. Intensive efforts were made to provide nutrition education to all the enrolled households to ensure that: the salt was kept in a screw-topped plastic container; salt container was not kept near the oven; and a plastic spoon was used to take the salt from the container.

Almost all families complied with these requests most of the time.

Socio-demographic details of the families were obtained at enrolment. Height (measured using wall-mounted stature-meter; accuracy of 0.1 cm) and weight (measured using digital weighing machine accuracy of 100 gm) were measured in all available and willing women, men and children in the family. Blood pressure was measured using a digital blood pressure monitor in all available and willing women and men.

Families were followed up every month, to confirm that they had used only the salt provided; problems if any in the continued use of salt were ascertained and appropriate nutrition and health education were provided. At the end of the month, the research team weighed the container with the remaining salt, estimated the salt used during the month, ascertained the amount of salt needed for next month and provided the same. The research team took a small amount of salt from the salt container in the houses and tested the same for iodine and iron using the qualitative 'on the spot' testing kit. In the first month the testing was done in 5% of the households; the results were satisfactory. Thereafter, testing was done in randomly chosen five houses once a month for six months. Subsequently, testing was done once in three months in randomly selected 5 households or when a new consignment of salt was received. This practice was continued till the end of the study. The results of testing showed that both iodine and iron levels in the salt were satisfactory.

At 6 and 12 months follow up, weight (women and men), BP (women and men) were checked and blood samples were collected in available and willing women, men and children. Very few men and school-age children were at home when the research team visited the house. Therefore, number of blood samples collected from them were low.

Hb estimation by cyanmethemoglobin method were carried out at our institution. Ferritin assay was done by electrochemiluminescence immunoassay (ECLIA) and CRP estimation was done using enhanced immunoturbidimetry assay using COBAS 6000 in a laboratory certified by the National Accreditation Board for Testing and Calibrating of Laboratories (NABL), India. All samples were coded and the technicians who undertook Hb estimation and the laboratory which undertook the ferritin and CRP assays were blinded to the group from which the samples were drawn or whether they were the initial or follow-up samples.

Ethical approval

The study was approved by the Institutional Ethics Committee. Permission to carry out the study was obtained from the Department of Women and Child Development of the National Capital Territory Region, Delhi, India. The study was registered with the Indian Council of Medical Research (ICMR) Clinical Trial Registry (registration number CTRI/2019/08/020508).

Sample size

Available data on DFS use in school-age children showed that the improvement in Hb may range between 0.2 to 0.3 g/dL after 6-12 months of use. Earlier studies have shown that the mean Hb in women in these localities was about 10.5 gm/dl. Sample size was calculated assuming that the improvement in mean Hb at 18 months in the DFS groups as compared to the iodized salt users were about 0.3 gm/dl, α of 0.05 and β of 0.80, design effect of 2.

Previous longitudinal studies in this community indicated that the dropout/lost for follow-up rate at 12 months was about 20-25%; at 18 months it may be as high as 30%. Assuming a dropout rate of 30% the sample size was computed to be 250 families for each of the three groups; with every family having at least one woman in the reproductive age group.

The study was planned for follow-up for 18 months. However, in March 24 2020, when majority of families had completed only 12 months of use, India initiated a stringent lockdown to delay the spread of COVID-19 pandemic. Therefore, study was terminated and data collected upto twelve months of use were analysed.

Data entry, data cleaning and data analysis

Data entry was done in MS excel; data cleaning was done using MS excel and SPSS. Data analysis was done with SPSS version 27 and Stata version 15.

The primary unit for providing the intervention (salt) was the family. The primary outcome to assess the impact of

the use of DFS was Hb levels in women in reproductive age group; in addition, the effect, if any, of the use of DFS on Hb in men and children and ferritin levels at 0, 6, and 12, months in women and men were assessed.

Impact of the use of the three types of salt at six and twelve months on mean Hb and ferritin: in women, men and children; in women, men and children who were anemic and not anemic at enrolment, and in women who had low ferritin and those who had normal ferritin at the time of enrolment were assessed by using single-tailed paired t test.

Inter-group comparisons were made using student t test; p values >0.05 were considered as not statistically significant.

RESULTS

The number of families who consented to participate in the study, and the number who actually were enrolled in the study, followed up till six and 12 months is given in Table 1. The follow-up rates were lower than anticipated both at 6 and 12 months.

There were no differences in any of the socio-demographic parameters between the three groups (Table 2). These families stated that they were food secure and had adequate income to meet the essential requirements of household, education of children and health care for minor ailments; but because of urban housing constraints, they lived in one or two-room tenements in over-crowded unhygienic localities.

Table 2: Socio-demographic profile.

Groups	Gr 1 IS (230)	Gr 2 DFS FS (220)	Gr 3 DFS FF (214)
Figures in parenthesis indicate the number of families.			
Number of rooms			
1	40.9	39.5	38.3
2	22.2	25.5	28.0
≥ 3	37.0	35.0	33.6
Ownership of house			
Own	55.7	60.0	57.5
Rented	44.3	40.0	42.5
Standard of living index (SLI)			
Low	2.2	0.9	0.0
Low middle	30.4	32.7	27.1
Middle	67.4	66.4	72.9
Working status (men)			
Semiskilled	49.7	51.0	47.6
Skilled	27.8	23.6	25.4
Clerical/business	4.5	7.8	4.8
Others	17.9	17.6	22.2
Working status (women)			
Home maker	86.1	79.1	80.3
Work outside home	13.9	20.9	19.7

Continued.

Groups	Gr 1 IS (230)	Gr 2 DFS FS (220)	Gr 3 DFS FF (214)
Education (men)			
Primary school	10.1	15.9	16.8
Secondary school	57.1	48.4	53.8
College	26.0	25.1	21.6
Others	6.8	10.7	8.0
Education (women)			
Primary school	12.6	14.3	16.3
Secondary school	43.3	40.4	42.9
College	20.2	25.1	21.4
Others	23.9	24.7	23.2
Family size (%)	5.4±2.51	5.2±2.07	5.4±2.35
Family composition			
Men	396	374	351
Women	381	364	375
Children	451	438	441

Anova Chi-square and T test: There were no statistically significant differences in the sociodemographic profile between the three groups.

At the time of enrolment, mean height was 152.1±5.98 cm in women and 164.2±8.30 cm in men; mean weight 58.4±12.47 kg in women and 66.3±13.49 kg in men; and mean BMI 25.2±5.05 in women and 24.6±4.87 in men. Prevalence of under-nutrition (BMI<18.5) was 6.9% in women and 8.2% in men; 50.3% of women and 44% of men were over-nourished (BMI≥25). There were no differences in the mean height, weight and BMI or prevalence of under- and over-nutrition in men and women between the three groups. All persons who were enrolled for the study had normal blood pressure, because

families in which any member had hypertension were excluded. There were no significant differences in mean blood pressure in men or women between the three groups.

Mean Hb in children and women were lower than the mean Hb in men. Prevalence of anemia in women (<12 gm/dl) and children (<11.5 gm/dl) were higher as compared to men (<13 gm/dl). There were no differences in the mean Hb or prevalence of anemia in men, women and children between group 1, 2 and 3 at the time of enrolment (Table 3).

Table 3: Hb, ferritin and CRP levels at enrolment.

Group	Gr I IS	Gr II DFS FS	Gr III DFS FF
Hb (gm/dl)			
Men	13.2±1.42 (122)	13.4±1.29 (101)	13.1±1.30 (100)
Women	10.7±1.56 (319)	10.9±1.44 (298)	10.7±1.52 (297)
Children	10.4±1.40 (85)	10.6±1.64 (60)	10.8±1.48 (63)
Prevalence of anaemia (%)			
Men	39.3	31.7	46
Women	79.6	74.5	79.1
Children	75.3	68.3	65.1
Ferritin (ng/ml)			
Men	95.0±65.0 (106)	97.7±51.76 (94)	114.3±62.78 (88)
Women	32.8±32.57 (300)	33.5±33.30 (286)	37.4±41.31 (285)
Ferritin <12 ng/ml (%)			
Women	44.5	44	48.9
CRP mg/l			
Men	2.4_2.9 (107)	2.2±2.57 (94)	3.9±4.25 (88)
Women	2.9_3.62 (300)	3.2±3.68 (286)	3.2±3.65 (284)
CRP ≥5 mg/l (%)			
Men	10.7	8.9	28
Women	17.6	21.8	19.3

Anova t test and chi square test: None of the differences between the three groups were statistically significant.

Table 4: Changes in Hb, ferritin and CRP in relation to type of salt and duration of use.

Group	Period of use	Gr 1	Gr 2	Gr 3
Hb	0 months	11.2±1.85 (526)	11.4±1.79 (459)	11.2±1.76 (460)
	6 months	11.3±1.63 (374)	11.4±1.54 (345)	11.4±1.58 (356)
	12 months	11.3±1.70 (243)	11.6±1.70 (200)	11.6±1.63 (216)
Ferritin	0 months	49.0±51.25 (406)	49.2±47.54 (380)	55.6±57.39 (373)
	6 months	54.8±51.30 (302)	57.1±51.76 (239)	62.7±57.01 (273)
	12 months	55.2±54.28 (155)	52.9±46.55 (135)	65.6±60.63 (150)
CRP	0 months	2.8±3.45 (407)	2.9±3.46 (380)	3.4±3.80 (372)
	6 months	2.8±3.27 (302)	3.3±4.01 (239)	3.2±3.44 (273)
	12 months	2.3±4.19 (155)	2.8±3.35 (135)	3.3±3.49 (150)

Comparison across period of use student t test p value: Hb 0 and 12 months Gr 3-0.002; Ferritin 0 and 6 months Gr 2-0.03; 0 and 12 months Gr 3-0.04. Inter-group comparison student t test p value: Hb at 12 months between Gr 1 and Gr 2-0.03; between Gr 1 and Gr 3-0.03; ferritin at 6 months between Gr 1 and Gr 3-0.04.

Mean ferritin levels in men were substantially higher as compared to the mean ferritin levels in women in all the three groups. Nearly half of the women but none of the men had ferritin levels below 12 ng/ml. There were no differences in the mean ferritin and CRP levels between the three groups at enrolment either in women or men (Table 3). These data indicate that the randomization carried out resulted in the three groups having similar and comparable socio-demographic and nutrition profiles at the time of enrolment.

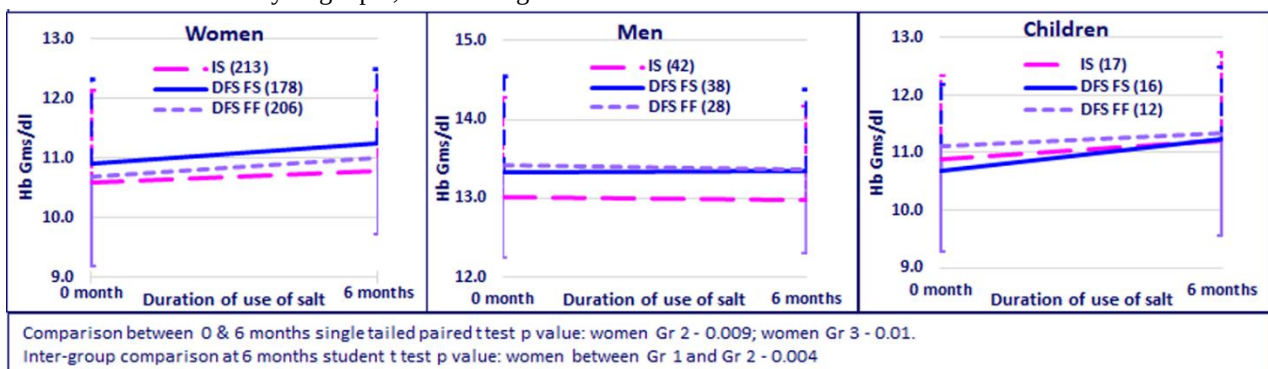
There were no differences in acceptability and continuation rates between the three groups using different salts. Dropout rate was high (Table 1) because of: higher out migration due to unemployment during the study period; women and children from families of migrant workers went to their villages for 4-6 weeks during school vacation; this resulted in discontinuation of salt use.

Families dropping out of the study at 12 months were similar in all the three groups (41.7%, 38.2% and 42.9% in groups 1, 2 and 3); there were no differences in the profile of the families who had dropped out and those who continued using the salt in any of the three groups.

Mean Hb, ferritin and CRP at enrolment, 6 and 12 months in all members of the family in group 1, 2 and 3 is given in

Table 4. There was a small but statistically significant improvement in Hb in group 3 between 0 and 12 months and ferritin in group 2 between 0 and 6 months. Inter-group comparison between control group (group 1) and DFS (group 2 and group 3) groups showed that the mean Hb in group 2 and group 3 were significantly higher as compared to group 1 (p value 0.03); mean ferritin in group 2 at six months was higher as compared to group 1 (p value 0.04). There were no significant changes in the mean CRP in any of the three groups at any of the time points (Table 4).

Paired t test showed that between 0 and 6 and 0 and 12 months of salt use, there was a small but statistically significant increase in mean Hb in women in group 2 and 3; there was a significant increase in Hb between 0 and 12 months in children in group 2 (Figure 2 and Figure 3). Paired T test between 0-6 or 0-12 months of salt use did not result in any significant changes in mean Hb in men in any of the three groups. Men and children in group 1 did not show any change in mean Hb between 0-6 or 0-12 months of use. Inter-group comparison showed that Hb values in women at six months in group 2 were higher as compared to group 1; at 12 months Hb values in group 2 were higher in women, men and children as compared to the control (group 1), and Hb values in children in group 3 were higher as compared to group 1.

**Figure 2: Changes in mean Hb in women, men and children at 6 months.**

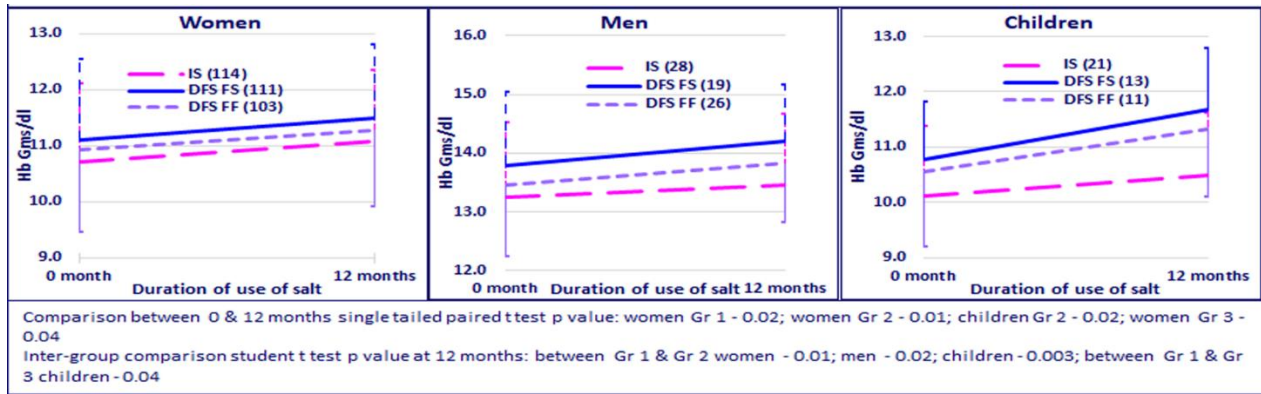


Figure 3: Changes in mean Hb in women, men and children at 12 months.

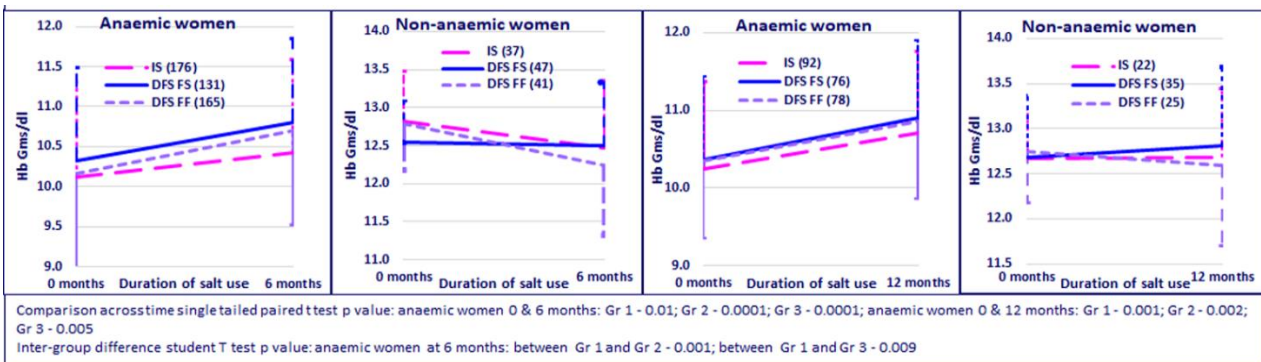


Figure 4: Changes in mean Hb in anemic and non-anemic women at 6 and 12 months.

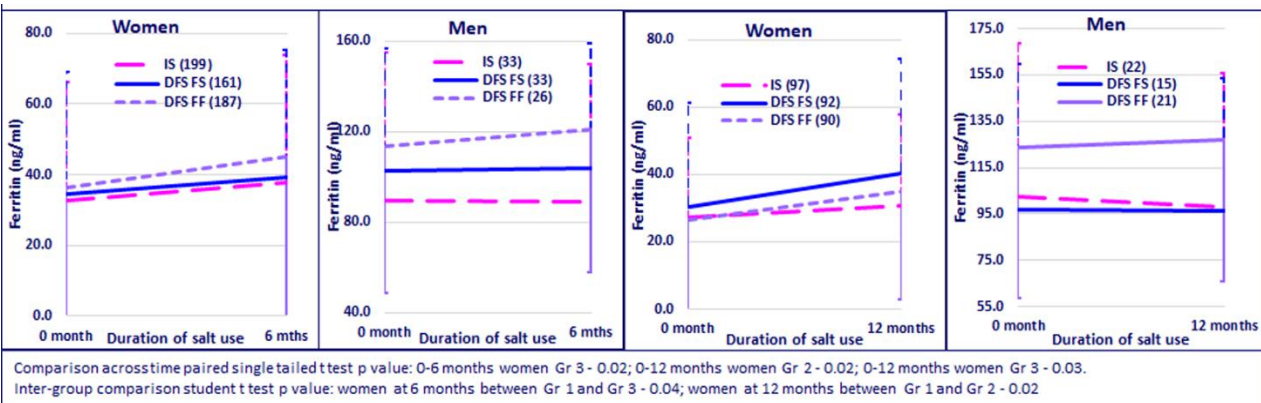


Figure 5: Changes in mean ferritin in women and men at 6 and 12 months.

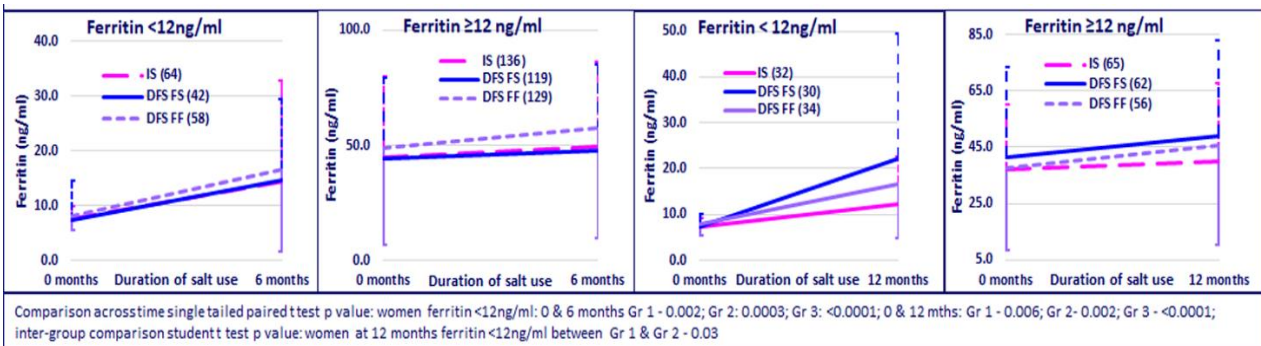


Figure 6: Changes in mean ferritin in women with ferritin <12 ng/ml and ≥12 ng/ml at 6 and 12 months.

To assess whether baseline Hb had any impact on Hb response to DFS use, women were classified into anemic (<12 gm/dl) and non-anemic (≥ 12 gm/dl) on the basis of Hb at enrolment. Improvement in Hb in both the DFS groups (group 2 and 3) was higher in anemic as compared to non-anemic women both at 6 and at 12 months (Figure 4) and these differences were statistically significant. Improvement in mean Hb was higher in anemic men and children as compared to non-anemic persons, but this was not statistically significant because of the small number of men and children in whom blood samples were available.

There was a statistically significant increase in ferritin levels in group 3 women between 0 and 6 months and women in both group 2 and 3 between 0 and 12 months (Figure 5). There were no significant changes in the mean ferritin levels in men belonging to group 1, 2 and 3 and women belonging to group 1 either at 6 months or 12 months. As compared to the control (group 1) the ferritin level at 6 months was higher in women in Gr 3 and ferritin levels in women at 12 months were higher in group 2. The increase in ferritin levels in DFS users persisted even after all samples with CRP ≥ 5 mg/l were excluded from analysis.

To assess whether baseline ferritin had any impact on response to DFS use, women were classified into those with low ferritin (<12 ng/ml) and normal (≥ 12 ng/ml) ferritin at enrolment. None of the men in the paired groups had ferritin levels below 12 ng/ml. The ferritin rise was higher in women with low ferritin as compared to normal ferritin in group 2 and 3 both between 0 and 6 months and 0 and 12 months (Figure 6).

DISCUSSION

Iron deficiency and anaemia are associated with adverse health consequences and are major public health problems.¹⁻⁴ In the present study one-third of the men and three-fourths of women and children were anaemic and over 40% of women were iron deficient at enrolment. National surveys have shown a similar high prevalence of anaemia.^{23,24} Low iron intake and poor iron bioavailability are the major factors responsible for nutritional anaemia.

To improve micronutrient intake and accelerate the pace of decline in anaemia, the Intensified National Iron Plus Initiative (I-NIPI) envisages the effective implementation of a three-pronged strategy: increase in consumption of micronutrient-rich vegetables; use of iron-fortified foodstuffs to improve iron intake of the population; and iron-folic acid supplementation to vulnerable groups.⁵

Despite the country being global number 1 in vegetable production, per capita consumption of micronutrient-rich vegetables in India is low partly because of high cost.⁴ The coverage and compliance under national programmes of iron-folic acid supplementation to women and children

have been low.^{4,24} Global and Indian data indicate that it is difficult to sustain long-term micronutrient supplementation programmes for large population groups.^{4,25,26} Given these constraints, food fortification may be an effective, inexpensive and sustainable method of improving iron intake, especially, among the poorer segments of the population.^{27,28}

India had invested in the development and evaluation of iron-fortified iodised salt for increasing iron intake of the population because: salt is used by all segments of the population and is relatively inexpensive; risk of excessive as well as low consumption of salt is small, and centralized production of salt and the pre-existing programs for the iodine fortification of salt, offers a very ready platform to scale up the production and distribution of DFS.

Iron requirements vary with age, sex and physiological status. Iron absorption from diet is modulated to meet requirements because absorbed iron does not get excreted. Surveys conducted by National Nutrition Monitoring Bureau had shown that the average consumption of salt was about 10 gm/day.²³ Data from the present study also showed that the average salt consumption in the study population was 10 gm/day. Both the formulations of iron fortified iodised salt approved by FSSAI had 1mg of iron/gram of salt. Use of either formulation of DFS will increase the iron intake in adults by 10 mg/day. This may be adequate to bridge the gap between current intake and requirements in vulnerable groups.²⁸

Data from the present study showed that 6-12 months of DFS use related increase in iron intake in families resulted in a small improvement in mean Hb in children and women but not in men. The improvement in Hb was more in anaemic women, men and children. There was a small improvement in ferritin in women who have low ferritin. Cochrane review of 18 studies (13 from India), on impact of DFS concluded that there was a small but significant improvement in Hb and ferritin levels.¹⁶ Use of DFS for 12 months did not result in any change in Hb or ferritin levels in women, men and children with normal Hb and normal ferritin respectively. These data suggest that DFS is a safe, effective, feasible, affordable and sustainable method to bridge gap in iron intake in vulnerable groups.

It is now well documented that excess intake of iron can lead to iron overload and associated adverse health consequences.²⁸ The gap between iron requirements for growing children and pregnant women and the tolerable upper limit (TUL) is narrow. Currently in selected districts ICDS and MDM programmes supply hot cooked meal using both cereals fortified with iron and DFS. However, these fortified foods are used for only one of the three or four meals that children consume per day. Therefore, the risk of crossing TUL for iron by consuming MDM/ICDS hot cooked meal is unlikely even

when both iron fortified wheat flour/rice and DFS are used for preparing the meals.

Chhattisgarh, Tamil Nadu, Bihar, Madhya Pradesh and Uttar Pradesh had provided DFS through PDS; and in Delhi, Tamil Nadu DFS has been sold in open market at some time. The reported offtake in open market was low perhaps due to interruptions in supply and high cost. The poor supply might be largely due salt industries' hesitation to invest in increasing production and improving availability of DFS when consumer demand was low. This vicious cycle of low demand leading to low supply and poor supply resulting in low demand has to be broken. The poor demand might be due to the fact that neither the sellers nor the buyers were aware of the benefits of use of DFS. It is difficult to mount an effective IEC campaign on benefits of DFS use because: anemia and iron deficiency are not associated with any specific symptoms; it takes months of use of DFS to bring about small improvement in Hb, and such small improvement in Hb is not associated with any perceptible improvement in the quality of life.

Unlike the situation in the earlier decades, the population is now aware that many diseases (e.g., hypertension, diabetes) are asymptomatic in the early stage and can be diagnosed only by tests. If screening of vulnerable groups using accurate Hb estimation is made available at all levels of care, it might be possible to improve awareness about the high prevalence of anaemia and undertake nutrition education that use of DFS is a safe and sustainable method of combating anaemia.

In addition to iron fortified iodised salt, FSSAI has approved voluntary fortification of rice and wheat flour with iron, folic acid and vitamin B₁₂.⁹ Review of available global data suggest that cereal fortification with iron is expensive, may not be effective in terms of improvement in Hb levels and is difficult to sustain in large countries with diverse dietary habits.^{31,32} Salt is universally consumed and excess intake is unlikely. Cost of fortifying 10 grams of salt/person/day is far lower than the cost of fortifying 250-300 grams of wheat flour or rice/person/day. India has nearly achieved universal salt iodisation.²⁴ Centralized production of salt and the pre-existing program for iodine fortification of salt offers a very ready platform to launch DFS as a feasible, acceptable, affordable, and sustainable method for improving the iron intake and Hb status of Indians.

Concerns have been raised about the potential problem that iron consumed from multiple fortified food stuffs may cross the TUL especially if the consumers were not iron deficient.^{29,30} Currently, the availability and consumption of multiple food stuffs fortified with iron is low. As and when the country moves towards universal access to DFS, concurrent steps have to be taken to ensure that no other foodstuff fortified with iron is available, so that the potential adverse consequences of iron overload are avoided.

CONCLUSION

The present study showed that use of either of FSSAI approved formulations of DFS for 12 months resulted in a small but statistically significant increase in mean Hb in women and children. Increase in mean Hb was more in anaemic persons and increase in mean ferritin was higher in women with low ferritin. There was no change in mean Hb in non-anaemic persons and no change in mean ferritin levels in persons with normal ferritin. These data suggest that the absorption of iron is well modulated to cope with varying iron status in DFS users. If DFS is the only food fortified with iron, the risk of crossing TUL and incurring the risk of iron overload in iron replete segments of population is minimal. With scaling up of production, distribution and sustained use, DFS can bring substantial reduction in prevalence of anaemia and iron deficiency in India and enable the country to achieve the SDG target of 50% reduction in prevalence of anaemia in reproductive age by 2030.

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