Abstract

A randomised iron supplementation trial with different dose levels of iron was carried out in pregnant women with the following major objectives;

1. To study the efficacy of decentralized home-based delivery of iron supplements at different dose levels on coverage, compliance, side effects and beneficial effects.

2. To study longitudinally the effect of different dose levels of iron i.e. 60 mg, 120 mg and 180 mg and 1.5 mg of folic acid per day given during pregnancy for 12-16 weeks, on selected parameters of maternal and infant outcome.

One hundred and seventy one pregnant women, 20-24 weeks of gestation were enrolled from 15 ICDS centres and randomly allotted to the three iron treatment groups as specified above. At enrollment data were obtained on socio-economic characteristics, obstetric history, health services utilization, morbidity profile, anthropometry and hemoglobin. Iron tablets packed in autoseal polythene covers were provided every month through decentralized home-based delivery for a period of 12-16 weeks during pregnancy. Follow-up visits were conducted every month till delivery and data on health services utilization, compliance, anthropometry, morbidity profile and Hb were obtained from

the pregnant women. Birth weight of infants was also recorded. After delivery, the mother-child pair was followed up for six months. Maternal weight and hemogloin were obtained at six month post-partum on all available subjects.

At third and sixth month of age data on infant's feeding pattern, anthropometry, hemoglobin and morbidity profile were collected on all available subjects.

Highlights of the findings demonstrated that a decentralised system for iron supplement distribution achieved extensive coverage as 70% of the pregnant women could be provided iron supplementation as against only 19.4% reported for a centre based distribution. The remarkable compliance with the iron supplement consumption reflected by a tablet consumption of 100 doses of 60 mg iron by 90% of the women only in the 120 mg and 180 mg group highlighted the need to increase the level of iron in the anemia control programme in India.

An inexpensive mother retained card (calendar) which was tested as a compliance measure and a memory device was utilized by approximately 50% of the women. A highly significant positive correlation ($r = 0.7785$) was found between mean tablet consumption by counting the remaining tablets in the autoseal covers and the calendar estimates, for those who marked the calendar, establishing the efficacy of the calendar as a compliance measure.

Pregnant women consuming 120/180 mg iron per day exhibited the highest reduction in the prevalence of anemia, and the highest rise in mean Hb per month compared to those receiving only 60 mg iron per day. Higher rise in mean Hb was found with higher levels of tablet consumption in all the treatment groups. Duration of stay in the study influenced the level of tablet consumption as mean tablet consumption was found to be the highest when the women stayed in the study for a period of four months.

Morbidity profile of the women indicated that higher levels of iron did not exacerbate the incidence of infectious morbidity, but on the contrary showed a trend of decreased incidence with higher levels of iron supplementation during pregnancy. There were no significant differences in the weight gain, gestational duration and incidence of premature delivery in the three treatment groups. However the birthweight of the infants in the group supplemented with 180 mg iron, was higher than the ones supplemented with 60 or 120 mg iron. Similarly the incidence of low birthweight was found to be the lowest in the 180 mg group.

Mean Hb and mean weight of the women at 6 months postpartum who belonged to the 120 and 180 mg group were found to be higher than those in the 60 mg group. Infants in the 120 and 180 mg group exhibited higher heights and weights than the 60 mg group. Mean Hb levels were also found to be higher in infants in the 120 and 180 mg group compared

to the 60 mg group. Morbidity profile of these infants at third and sixth month showed a trend towards reduced incidence in terms of mean episodes and mean number of days compared to the 60 mg group. The diet pattern of these infants in all the three groups was found to be similar.

These maternal and infant outcomes showed that 120 mg dose level of iron was as effective as 180 mg dose level except with reference to birth weight and incidence of low birth weight but the former was associated with much lower unpleasant side effects in the initial period of supplementation. The 60 mg dose level group was found to be consistently poorer with regard to most of the outcome effects.

Thus considering the feasibility, recommendations that emerge from the present study are that iron supplementation during pregnancy with 120 mg iron and 1.5 mg folic acid per day through home delivery with improved packaging can reduce the prevalence of anemia to one-third the current level in accordance with the goals of ACC/SCN (1991), ICN (1992a) and National Nutritional Policy of India (1991) and confer many other beneficial effects in terms of maternal and infant outcome.