Abstract

In view of the high prevalence of biochemical vitamin D deficiency and low calcium intake in pregnancy, the Government of India evolved National Guidelines for "Calcium Supplementation During Pregnancy and Lactation". The guidelines recommend calcium 500mg (as calcium carbonate salt) and 250 IU of vitamin D to be taken twice daily just after meal, starting from 2nd trimester till six months post-partum. The calcium and vitamin D supplementation to pregnant women is being implemented in Delhi.

In government hospitals, a wide variety of calcium and vitamin D preparations are being provided; but regularity of the intake of the supplement is not monitored. There is therefore a paucity of data on the regularity of calcium and vitamin D intake in pregnant women and the effect of calcium and vitamin D supplementation on the course and outcome of pregnancy.

The objective of the present study is to assess the availability of supplements, coverage, acceptance, compliance rates of ongoing Calcium and Vitamin D supplementation in three settings:

- Primary health care institution (PHCI) as part of the research study ensuring continuous supply and careful monitoring of the intake along with nutrition education (Group 1)
- Primary health care institution providing antenatal care under existing service conditions (Group 2)
- Urban community setting under existing conditions (Group 3)

In all three settings apparently healthy pregnant women without any systemic and obstetric problems who were willing to participate in the study were enrolled.

At the initial visit detailed information on the socio-demographic profile and obstetric profile was recorded. In a subset of the pregnant women household food security information was collected using a food frequency questionnaire, food purchase questionnaire and 24-hour dietary recall. Dietary intake of pregnant women was assessed in a sub-sample of women using 24-hour dietary recall.

In view of the high prevalence of anaemia in pregnant women, many physicians prioritized supplementation with 2 IFA tables (following NIPI) and gave one tablet of calcium and vitamin D to pregnant women attending the antenatal clinic in Govt. hospitals.

The research group (Group 1) of the present study in Delhi hospital followed the hospital protocol and provided the pregnant women with a month's supply of calcium and vitamin D supplements, with instruction to take one tablet per day after food. Pregnant women were requested to bring the completed empty tablet strip when women came for follow up. The completed empty tablet strips were collected and compliance with the supplementation and side effects if any were recorded by the research team.

In Group 2 the PHCI supplied calcium and vitamin D supplements to the pregnant women as per the availability. In Group 3 i.e. in the community setting, some pregnant women attended antenatal clinics in govt hospitals others went to private clinics and some to both government and private antenatal clinics. In Group 2 and 3 when the supplements were not available, the health functionaries provided pregnant women with a prescription and requested them to purchase and take the supplements. The composition of the tablets provided by the PHCI or the health functionaries in the community and the composition of the tablets purchased and taken by the pregnant women varied. Pregnant women were requested to bring the completed empty tablet strip which were collected during the next follow-up visit and data on composition of the supplements was ascertained and entered by the research staff and compliance when tablets were available was computed and side effects if any were recorded.

In all three settings weight and BP were measured, during the follow-up visits; information on mode of delivery and birthweight was collected.

Majority of the pregnant women were from low/ low-middle-income group families in their twenties and having their first or second pregnancies. There were no statistically significant differences in the socio-demographic profile of the women among the three groups. The Group 1 pregnant women attended the antenatal clinic in a PHCI with better infrastructure and facilities and better supply of supplements and drugs as compared to the PHCI attended by women in Group 2. Though it is not obvious from the data of SDP, it is possible that the women in Group 1 were from a slightly better-off population as compared to the pregnant women of Group 2.

Information on food security status of the family and dietary intake of the pregnant women were collected in 34, 71 and 100 pregnant women in Group 1, 2 and 3 respectively. Food security was assessed by comparing the calorie intake/day/CU with the EAR for energy (ICMR 2020) both

from the food purchased and food consumed in the last 24 hours. Energy intake as assessed by food purchase data was 2040.9±468.52 Kcal/CU/day; energy intake assessed from actual food cooked and consumed on the previous day was 1807.0±544.33 Kcal/CU/day. These data indicate that the households were food secure. Both data from food frequency and dietary intake collected using 24-hour dietary recall showed that quantity of milk and milk products, pulses/legumes, GLV and other vegetables consumed was below the requirements for a balanced diet. Data from 24-hour dietary recall showed that the energy and the fat intake of pregnant women was higher but iron intake was lower than the EAR calculated for the Delhi pregnant women.

The mean height of the pregnant women was 151.5±5.20 cm (387), 150.1±5.51cm (391) and 152.1±5.53 (448) in Group 1, 2 and 3 respectively; and the initial mean weights were 50.3±8.44 kg (373), 50.1±8.54kgs (400) and 53.9±10.08 (448) in Group 1, 2 and 3 respectively. The mean height of women from Group 2 was lower than the mean height of women from the other two groups, and the difference was statistically significant; however, there were no statistically significant differences in the initial weight between Group 1 and 2 but as enrolment continued across the second and third trimesters in Group 3 the initial weight was significantly higher than the other two groups.

Hb estimation at enrolment confirmed that more than 80% of the pregnant women were anaemic (<11g/dL).

The follow-up rate of Group 1, 2 and 3 were 77.3%, 62% and 92.6% respectively. The follow-up rate was highest in Group 3 because the follow-up was carried out by the research team by home-visits.

In Group 1, the research team ensured continuous supply of the supplements; between the enrollment and the second blood sample collection after 12 weeks of supplementation, the pregnant women received 87±10.8 tablets and consumed 80±11.8 tablets; between enrolment and delivery the pregnant women received a mean of 134±26.2 tablets and consumed 124±25.9 tablets.

In Group 2, the PHCI provided the pregnant women the calcium and vitamin D tablets as and when available or provided a prescription for purchasing the tablets. Unlike IFA tablets calcium and vitamin D tablets are expensive; many women were unable to purchase the tablets due to economic constraints. One tablet of calcium and vitamin D/ day was consumed by 199 pregnant women; out

of them 150 women had to purchase it from outside. The PHCI provided 82±30.7 calcium and vitamin D tablets to 33 pregnant women; out of these 74±27.8 tablets were consumed. Women purchased 62±34.1 tablets and 58±32.1 out of these were consumed. Sixteen women sometimes received the supplement from the PHCI and sometimes bought it from outside; out of the 92±30.9 tablets available 84±29.2 tablets were consumed. Two tablets of calcium and vitamin D/day were consumed by 15 pregnant women. A mean of 156±70.3 tablets were available, out of which the pregnant women consumed 147±71.1tablets.

In Group 3, 19.5% of pregnant women out of the continued cases did not consume any calcium and vitamin D tablets. Despite the national guidelines that calcium and vitamin D should be given as supplements, a substantial proportion of pregnant women attending Government PHCIs and/ or private practitioners were given/ prescribed only calcium tablets. From the Government PHCIs 189 pregnant women received 138±82.7 calcium tablets and 51 received 120±64.3 calcium and vitamin D tablets; out of these the women took 126±79.8 and 111±66.2 tablets respectively. Private practitioners provided prescriptions to pregnant women and they bought them from the pharmacy. Seventy-eight pregnant women bought 116±71.6 calcium and vitamin D tablets and 11 pregnant women bought 114±64.1 calcium tablets; out of which 114±70.3 and 112±63.3 tablets were consumed by them respectively.

In all three groups, the majority of the pregnant women consumed most of the available tablets. This high consumption rate might be attributable to the fact that calcium and vitamin D supplements were not associated with any troublesome side effects.

The mean weight gain in the second trimester and third trimester was 11.8 kg in Group 1, 7.4 kg in Group 2 and 7.6 kg in Group 3. The pregnant women of Group 1 and 2 with obstetric problems, anaemia, PIH or oedema, were referred to tertiary care hospitals and they attended the hospital they were referred to; Group 3, pregnant women were not routinely checked for PIH in clinic settings and their attendance to the ANC was poor. Thus, information on the course of pregnancy and PIH was not available.

Mean birthweight and preterm birth rate were 2.8±0.41, 2.6±0.51 & 2.8±0.49 and 16.4%, 21.4% & 18.1% in Group 1, 2 and 3 respectively. The differences in LBW rate were statistically significant but the differences in the pre-term rate were not statistically significant.

In Group 3, records of pre- and post-pregnancy weight were available in 145 pregnant women which showed even when weight gain during pregnancy was less than 8 kg, there was a significant residual weight gain of 1.9 kg in the post-pregnancy period.

Diet survey had shown that energy intake of non-pregnant women was about 100-150 kcal more than their requirements; energy intake was adequate in pregnant women. This might have resulted in post-pregnancy weight retention of 1.9 kg.

India has entered into dual nutrition burden era. Assessing nutritional status of the women prior to pregnancy and during pregnancy and providing personalized counselling regarding dietary intake and physical activity will enable them to attain optimal pregnancy weight gain, optimal birth weight and reduce post-pregnancy weight gain.

Prevalence of Vitamin D deficiency in India is high. Biochemical estimation of vitamin D is expensive; it will not be possible to screen pregnant women for vitamin D deficiency as a part of routine antenatal check-up, identify deficient pregnant women and provide calcium and Vitamin D supplementation to them. Therefore, all pregnant women will have to be supplemented with calcium and vitamin D to reduce the prevalence of vitamin D deficiency in pregnancy.

The Intensified National Iron Plus Initiative (I-NIPI, MOHFW, 2018) has recommended that anaemic pregnant women should be provided with two tablets of IFA each containing 60 mg elemental iron and 500 µg of folic acid after one meal. This modification makes it feasible to provide two tablets of calcium and vitamin D after two meals to all pregnant women. The impact of supplementing two tablets of IFA together after one meal and two tablets of calcium and vitamin D after two remaining meals on haemoglobin status along with biomarkers for assessing iron status and plasma vitamin D levels will have to be investigated and documented.

Data from the present study indicated that if supply of the calcium and vitamin D tablets is regular with nutrition education and supportive supervision of the supplementation, it will be possible to improve coverage and achieve over 90% compliance with supplementation.

Ensuring uninterrupted supply of calcium and vitamin D supplements to pregnant women is likely to improve the vitamin D status of pregnant women.