INTRODUCTION

The FAO/WHO Expert consultation[1] stated that in most locations in the world in broadband around the equator (between latitude 42°N and 42°S), the most physiologically relevant and efficient way of acquiring vitamin D is to synthesize it endogenously in the skin from 7-dehydrocholestrol by 30 minutes of skin exposure of the arms and face to the sun. By this criterion, vitamin D deficiency is unexpected in India which lies within the defined broad band. However, several factors may interfere with skin exposure to sun's rays and can contribute to vitamin D deficiency in India such as traditional lifestyle, clothing, pollution, geographical location, seasons of the year, skin types (Indian skin type is V) etc. All these factors reduce exposure to sunlight and, hence, can result in vitamin D deficiency.

Osteomalacia in *purda*-wearing north Indian Women in the early part of the last century was a well-recognized clinical entity[2]. However, by the mid twentieth century, it looked as if osteomalacia in women, and babies with congenital rickets were no longer clinical problems and interest in vitamin D status in pregnant women and children waned. In the seventies neonatal hypocalcemia among Asian immigrants in the UK was attributed to poor maternal exposure to sunlight among the immigrants and vitamin D supplementation during pregnancy to the 'at risk' Asian mothers in the UK was suggested as the remedy[3]. As obstetricians in India did not see osteomalacia and paediatricians did not report hypocalcemia in neonates, it was assumed that Indians in India did not face these problems.

The availability of technology for vitamin D estimation in terms of 25(OH)D assay, enabled several investigators to estimate the prevalence of asymptomatic Vitamin D deficiency in population Groups[4,5]. Data from some epidemiological studies indicate that biochemical deficiency is common in both south and north India[5,6]. Studies carried

out in Lucknow have shown very high levels of vitamin D deficiency in pregnant women[7;] vitamin D deficiency as defined by low circulating 25(OH)D concentrations is common during infancy and childhood[6]. During the last two decades, there have been increased reports of neonatal hypocalcaemia and rickets from different parts of the world[8]. There are also an increasing number of reports from India on neonatal hypocalcemia, hypocalcemic symptoms in young infants, vitamin D deficiency in breastfed infants, and clinical and radiological rickets in children of all ages[9].

In view of the high prevalence of biochemical vitamin D deficiency, low calcium intake, and known adverse consequences of poor vitamin D status on the mother-child dyad, calcium and vitamin D supplementation during pregnancy has been advocated. Studies from the UK had reported a reduction in neonatal tetany following calcium and vitamin D supplementation during pregnancy[3].

National Guidelines for "Calcium Supplementation During Pregnancy and Lactation" have been drawn up by the Maternal Health Division, Ministry of Health & Family Welfare (Government of India) in December 2014[10]. The guidelines envisage calcium 500mg (as calcium carbonate salt) and 250 IU vitamin D are to be taken twice daily just after meal; calcium and vitamin D supplementation should begin from the second trimester of pregnancy and continue till six months postpartum. IFA tablets are not to be taken simultaneously with calcium tablets.

The supplementation is to be carried out in all settings – hospital antenatal clinics, antenatal clinics in MCH centres and primary health centres. In community settings, ANMs are to distribute these supplements to pregnant women attending Village Health and Nutrition Day (VHND). In case of pregnant women not coming to VHND, ASHA has the responsibility to deliver the supplements to the pregnant women. In Government hospitals, a wide variety of calcium and vitamin D preparations have been used. The

tablets are provided to all pregnant women attending the antenatal clinic when available.

Regularity of intake of supplementation is not monitored in these women. All women do not come for regular follow up; it is not possible for the hospital to ensure that they do come back to the same hospital for follow-up visits.

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 majority of pregnant women attending the antenatal clinics are anaemic. The National Iron Plus Initiative (NIPI)[11] envisages that anaemic pregnant women should receive 2 tablets of IFA (100mg of elemental iron and 500 µg of folic acid) daily. The majority of families have a three-meal pattern and it will not be possible for them to take 2 tablets each of IFA and calcium & vitamin D separately after different meals. In view of the well-documented adverse consequences of anaemia on the mother-child dyad, many physicians prioritized supplementation with 2 IFA tables and gave one tablet of calcium and vitamin D to pregnant women attending the antenatal clinic in Govt. hospitals. The present study in Delhi hospital followed the hospital protocol for IFA and calcium and vitamin D supplementation. So far there have been no publications on the impact of providing one tablet of calcium and vitamin D to pregnant women on the vitamin D status of pregnant women. So, a study was taken up in research mode where the calcium and vitamin D tablets were provided by our institution, the regularity of intake was carefully monitored and the impact of the supplementation was assessed by comparing the pre and post supplementation Vitamin D levels of providing one tablet of calcium and vitamin D to pregnant women.

Under service conditions Government hospitals are supplied with different brands of calcium and vitamin D tablets; there are gaps in supply of the calcium and vitamin D

supplements to the hospitals. Pregnant women attending antenatal clinics are given calcium and vitamin D tablets of available brands as and when they are available. The antenatal clinics do not document the regularity of supply or pregnant women's compliance in intake of supplements. There is therefore a paucity of data on coverage and compliance with calcium and vitamin D supplementation in pregnant women.

In the community settings, many women do not attend antenatal clinic; women attending the health and nutrition days in Anganwadi or when home visits are done by ANM /ASHA pregnant women who do not attend the antenatal clinic are to be provided with calcium and vitamin D supplementation. There is no data on the coverage, compliance and continuation of use of calcium and vitamin D supplementation in community settings.

The National guidelines on calcium and vitamin D supplementation were laid by GOI in the year of 2014. Till date, there are no published data on coverage, compliance (the number of supplements the pregnant women received and, consumed) or the impact of calcium and vitamin D supplements in hospitals or community settings.

It is essential to obtain data on coverage and compliance with calcium and vitamin D supplementation in in the hospital under research and service conditions and in the community settings, so that problems in the implementation of the supplementation programme can be identified and appropriate mid-course corrections can be done.

HYPOTHESIS

- Regular supply of calcium and vitamin D supplements to pregnant women, along with appropriate nutrition education, will improve acceptance and compliance with calcium and vitamin D supplementation in pregnancy.
- Irregular or inadequate supply of calcium and vitamin D supplements, to pregnant women, will reduce both coverage and continuation rates with calcium and vitamin D supplementation in pregnancy.

OBJECTIVES

To assess the availability of supplements, coverage, acceptance, compliance rates of ongoing Calcium and Vitamin D supplementation in three settings-

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

REVIEW OF LITERATURE

This chapter will focus on the available literature under following heads:

- Introduction
- Requirements for Calcium and Vitamin D in Indian pregnant women
- Nutrition transition and Nutritional status of pregnant women in India
- Dietary intake of calcium by Indian population
- Dietary consumption of calcium by pregnant women in India
- Vitamin D status of adult Indian population
- Vitamin D status of pregnant women and neonates in different parts of India
- Importance/ role of calcium and vitamin D (on mother-child dyad)
- Impact of calcium and vitamin D deficiency on mother-child dyad
- Vitamin D and/ or calcium supplementation during pregnancy
- National Guideline laid by Government of India

METHODOLOGY

Ethical clearance

The Institutional Ethics Committee of the Nutrition Foundation of India (NFI) has approved the proposal of NFI providing calcium (500mg) and vitamin D (250 IU) supplementation to pregnant women attending primary health care institutions under research and service conditions and in community setting where subjects may be attending different ANC clinics (Government and private) and/ or ANM, ASHA are providing antenatal care and calcium and vitamin D supplementation. IEC recommended that the study team will observe, record and report the availability, acceptance, compliance and continuation rates of calcium and vitamin D supplementation in pregnant women in each of these three settings.

Permission to conduct the study

Nutrition Foundation of India had taken permission from Medical Officers and Chief Administrative Medical Officer (CAMO) of the Primary Health Care institutions to work in the Primary Health Care institutions; permission was obtained from the Union Ministry of Women and Child Development (MWCD), State Women and Child Development (WCD) and Integrated Child Development Scheme (ICDS) coordinator to conduct the study in the urban low-income Groups in three ICDS blocks in New Delhi, namely Neb Sarai, Lado Sarai and Andheria mod.

Study design

Currently in Delhi antenatal care is being provided both in hospital and community settings.

The study design envisaged that apparently healthy pregnant women with no known systemic or obstetric problems would be enrolled for the study in three settings:

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

Supplementation regimen finalization

At the end of 2014, when the study commenced, the Government protocol for IFA supplementation (NIPI) recommended that all the anaemic pregnant women were to be supplied with IFA supplements (containing 100mg elemental iron and 500 mcg Folic acid), twice daily. The adverse consequences of anaemia on mother-child dyad is well known. In the traditional Indian three-meal pattern, there was only one slot left for the calcium and vitamin D supplements, after leaving two slots for IFA supplementation. Therefore, many physicians prescribed 2 IFA and 1 calcium and vitamin D to be taken by pregnant women.

Nutrition Foundation of India carried out a short-term research study on the side effects of IFA (containing 60 mg elemental iron and 500 mcg) and calcium and vitamin D (containing 500mg elemental calcium and 250 IU vitamin D) supplementation to fit two tablets of IFA and two tablets of calcium and vitamin D within the usual three meal pattern and found out that there were no significant increase in the side effects between single tablet of IFA and two tablets of IFA consumed together; whereas there was a statistically significant increase in the side effects between single tablet of calcium and vitamin D and two tablets of calcium and vitamin D consumed together[12].

Therefore, for the research component of the study, it was decided to provide one tablet of IFA each with breakfast and dinner (provided by the PHC) and provide 1 tablet of calcium and vitamin D provided by our institution with lunch.

According to the study design, pregnant women were enrolled for the study in three settings:

1. **Primary health care institution as part of the research study ensuring continuous supply and careful monitoring of the intake along with nutrition education (**This setting will be referred as **"Group 1"** henceforth in the synopsis and thesis**):**

Vitamin D status is known to vary with season. Therefore, it was envisaged to enroll 100 pregnant women during the second trimester in each of the four seasons.

Enrolment of pregnant women in Group 1

Women who were living in the nearby areas and attending the antenatal clinic during the second trimester were informed about the proposed calcium and vitamin D supplementation study. Those who were willing to take calcium and vitamin D supplements daily and were willing to come once every month for the supply of the tablets and regular follow-up were enrolled and provided calcium and vitamin D supplementation monthly till delivery.

All the enrolled pregnant women were provided supplements from one brand containing 500mg elemental calcium (in calcium carbonate form) and 250 IU vitamin D3; and monitored for regularity of supplement intake. They were advised to take one tablet daily after lunch. They were advised to take one tablet of IFA after breakfast and one after dinner at night and were told never to take the IFA supplements and calcium supplements together.

Inclusion criteria

- Apparently healthy women in the second trimester of pregnancy.
- Women willing to participate in the study take supplements daily and come for follow up once a month.

- Willing to allow blood samples to be collected at enrollment and 12 weeks after supplementation.
- Willing to come to the hospital for delivery; even when referred to other hospitals continue to take calcium and vitamin D supplements and provide follow-up data on course and outcome of pregnancy.

Exclusion criteria

- Women in the first and third trimesters of pregnancy
- Women not willing to participate in the study and take supplements daily.
- Women with systemic diseases
- Women with bad obstetric history or current obstetric problems

2. **Primary health care institution providing antenatal care under existing service conditions (**This setting will be referred as **"Group 2"** henceforth in the synopsis and thesis**):**

It was envisaged to enroll 100 pregnant women during the second trimester attending the antenatal clinic in four seasons and receiving calcium and vitamin D supplementation under existing services from the hospital.

Enrolment of pregnant women in Group 2

Pregnant women attending another Delhi primary health centre who were from the vicinity and planned to come to antenatal care in the hospital, come to the hospital for antenatal checkups during the second trimester and were willing to come regularly for antenatal checkups and take the supplements provided by the hospital, were enrolled in Group 2.

They were receiving the standard antenatal care provided under the Delhi PHCs and received supplements as provided in the hospital. Regularity of intake with which calcium and vitamin D supplements were provided by the health centre and purchased from outside when supplies were not there were recorded. Records were maintained to show what proportion of pregnant women who came to the hospital were taking the

calcium and vitamin D supplementation provided by the hospital or when a prescription for the same was provided to them, and how many did not receive or bought calcium and vitamin D supplementation were noted. Information on the composition of the tablets supplied in the hospital during the period of this study and also when women took the tablets prescribed from outside were collected. Information on the course and outcome of pregnancy were collected as and when they came to the antenatal clinic. Efforts were made to telephonically contact those who did not come regularly and obtain information on supplement intake, course and outcome of pregnancy.

3. **Urban community setting under existing conditions (**This setting will be referred as **"Group 3"** henceforth in the synopsis and thesis**):**

The Anganwadi worker (AWW), ASHA and ANM identify the pregnant women and provide care under existing conditions; women may access dispensaries or private practitioners for antenatal care; they get iron folic acid and calcium and vitamin D supplementation according to the availability and practice in the clinic. Some pregnant women do not attend any antenatal clinic and some may have irregular visits to the antenatal clinic; AWW, ASHA and ANMs are responsible for providing the recommended supplements to these pregnant women. The study in the community setup would provide data on the availability and coverage under the supplementation when Govt. and private practitioners, AWW, ASHA and ANMs provide the calcium and vitamin D supplements to the pregnant women who did not regularly attend antenatal clinics. Pregnant women identified residing in 30 Anganwadies in 3 areas of South Delhi namely Neb Sarai, Lado Sarai and Andheria Mod were recruited throughout the year. Data on antenatal care from all providers, supplementation prescribed/provided, regularity of intake and course and outcome of pregnancy were collected through home visits.

Follow-up in all the three Group settings:

Follow-up procedures in all three settings were similar. In all three settings, data on the type and regularity of supplement provided, compliance rates and course and outcome of pregnancy were recorded.

- Women were given the tablets required for the month either by the research team in Group 1 or by the existing service providers in Group 2 and Group 3. In Group 2 and 3 i.e. in PHCs when they came to collect the tablets for the next month the compliance was checked and recorded by the research team. The pregnant women were requested to bring the completed tablet strips; using this compliance was checked and recorded. In all women the address and mobile phone numbers of the husband/ neighbour of the woman were collected; the mobile phones were used to contact them as and when necessary especially if they did not come for follow-up to the centre on the expected date. In the community setting, research staff went to the homes of the enrolled willing subjects and collected information on whether they were attending any ANC clinic or private clinic, they were getting the required supplements from the ANM/ ASHA workers. The compositions of the supplements were recorded along with the compliance and continuation of the same.
- In all three Groups, efforts were made to follow-up with the enrolled women through pregnancy and delivery, to document the course (weight and BP) and outcome (birth weight) of pregnancy**.** Weight and BP in Group 1 were measured by the ANM from the antenatal clinic, and in Group 2 and 3 it was measured by the research team.
- In all three settings food frequency questionnaire were administered to a subset of enrolled women to assess the food security status of the household and variations if any in the food consumption patterns.

- In a subsample, diet survey were done using 24-hour dietary recall.

Tools and techniques used:

Pretested proformas were used to collect information on:

- Sociodemographic profile
- Compliance of the calcium and vitamin D supplements
- Food frequency data
- 24-hour diet recall data

The following tools were standardized and used to collect information:

- Stature meter to measure height
- Digital weighing balance to measure weight
- Electronic sphygmomanometer for measuring blood pressure
- Colorimeter to estimate haemoglobin by cyanmethaemoglobin method
- Set of utensils to collect data on dietary consumption

Sample size

There has not been any study documenting the availability, coverage, acceptance and continuation rates of calcium and vitamin D supplementation in primary health care and community settings. It was therefore not possible to compute the sample size required. However, in view of the known seasonal variations in vitamin D levels, an attempt was made to enroll about 100 women in each of the four seasons and follow them up.

RESULT

The data collected from the three different settings has been collected and analysed compared amongst the three different settings.

Socio-demographic profile:

A total of 387 women were enrolled in Group 1 and 400 pregnant women were enrolled in Group 2.

In both settings majority of women belonged to low or low-middle-income Groups, had school education and were homemakers. 2/3rd of husbands had schooling and 1/4th was college educated. Similarly, 2/3rd of husbands had a semiskilled job and 1/4th had worked in clerical jobs or had small businesses.

There was no such significant difference in socio-demographic profile of the women enrolled under these two settings.

A total of 448 women were enrolled in Group 3. The majority of women were from low or low-middle-income Group families, had school education (61.6%) and were homemakers (95.8%). More than 2/3rd of husbands had schooling and 1/5th were college educated. Similarly, 65.4% of husbands had a semiskilled or unskilled job and 1/3rd had worked in clerical jobs or had small business.

The family income was sufficient to meet the basic requirements of food, shelter, health care and education for their children. Due to urban space constraints majority of them lived in one or two-room tenements in overcrowded and unhygienic surroundings.

Obstetric profiles:

In all three settings majority of the women were in their twenties and having their first or second pregnancies. None had any obstetric problems because those with previous obstetric problems were not enrolled for the study. There were no differences in the socio-demographic, obstetric and nutrition profiles of women who continued the supplements and those who discontinued.

In both in Group 1 and 2 nearly 2/3rd of the women were enrolled at 14 to 19 weeks of pregnancy. Only around 5.0% were enrolled late in the second trimester. There was no significant difference in the period of pregnancy at the time of enrolment between these two settings.

In Group 3 pregnant women were enrolled throughout the year as and when they were identified to be pregnant.

The majority (87.3%) were enrolled in their first and second trimester and only 12.7% of the pregnant women were enrolled in their third trimester.

Dietary data of all the three settings together:

Several studies have reported very low intake of calcium in pregnant women. Efforts were made to assess the dietary calcium intake in the study population. Food frequency data provided information on the frequency of calcium-rich food e.g. Milk and milk products consumption by the pregnant women and 24-hour diet recall data provided the amount of calcium consumed in the previous day.

Dietary data of the pregnant women as well as the households were collected using food frequency and 24-hour diet recall method in all three settings. Food frequency was recorded for the family. Food security is computed using the calorie intake /day/CU. The majority of the pregnant women from the families used to stay at home and consume homecooked food. From the 24-hour diet recall data food and nutrient intake was calculated for the pregnant women and compared with the EAR recommended by the ICMR-NIN-2020.

Food security: The food security status of the household energy intake /CU /day was computed from the diet survey using the 24-hour dietary recall method. The mean energy intake of the family /CU/day computed based on the foods cooked and consumed by the family in the previous 24 hours from the diet survey was 1807.0±544.33 (n=205).

Food frequency: Food frequency data was collected for pregnant women as well as for the household., Data on consumption of all foodstuffs belonging to major food Groups were collected. Cereals and roots are consumed daily; wheat being the predominant cereals consumed in the region where data has been collected around 95% of the households consumed wheat and roots daily, 50% of the households consumed rice daily and other cereals were consumed rarely/ never. Approximately 3/4th of the households consumed tubers daily. The frequency of consumption of pulses and legumes was low, around 39% of households consumed pulses daily; and around 50% of households consumed legumes weekly. Around 98% of the households consumed other vegetable daily; this can be attributed to the fact that tomatoes were used to prepare varieties of dishes in the region where the data has been collected and tomatoes were collected in the other vegetable segments in the proforma used by the NFI research team. The frequency of consumption of green leafy vegetables and fruits was low, the majority (39%) of households were consuming GLV weekly and around 50% of the households consumed fruits (mostly bananas) daily. Nov-veg items like eggs, flesh food and fish were consumed weekly by the households. There is not much difference between the food consumption patterns of the pregnant women and their families. The major contributors of dietary calcium are milk and milk products; around 89% of the subjects were consuming milk daily; curd, buttermilk and other milk products were predominantly consumed weekly.

Food consumption: Foodstuffs cooked and consumed in the last 24 hours by the family (including the pregnant women) was collected using 24 hour diet recall method. Foodstuffs other than cereals were not consumed every day. Potato was consumed almost daily and was a source of energy.

In pregnant women

- milk and milk products consumption were below the appropriate quantity of foodstuffs needed for the balanced diet (AQFBD)
- intake of roots and tuber and fat intake were higher than requirements for Delhi women
- pulse, GLV and other vegetables consumption was below the appropriate quantity of foodstuffs needed for the balanced diet (AQFBD)
- fat consumption was way more than the appropriate quantity of foodstuffs needed for the balanced diet (AQFBD)
- animal foods were consumed only once or twice a month but, on the day, they were cooked, they were consumed in adequate quantities.

Nutrient intake: Energy and fat intake of pregnant women was higher than the EAR for sedentary Delhi women (height 151.7cm and optimal bodyweight (BMI of 21 in the nonpregnant state) of 48kg and 8kg pregnancy weight gain). Fats contributed nearly 30% of the energy in the diets consumed by pregnant women. The difference between the EAR for energy for Delhi pregnant women with 8kg pregnancy weight gain and actual intake was only about 65 Kcal/day.

In pregnant women dietary intake of calcium and vitamin A met the EAR; whereas iron intakes were lower as compared to EAR.

Nutritional profile:

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 weight was 50.3±8.44 kg (373), 50.1±8.54kgs (400) and 53.9±10.08 (448) in Group 1, 2 and 3 respectively.

There was a small but statistically significant difference in the height of the pregnant women of Group 2 with both, Group 1 and 3 (Student's T-test p value 0.00012382 and 1.36099E-07 respectively). There were no differences in the height between Group 1 and 3 (Student's T-test p-value 0.140097752).

There is no statistically significant difference in initial weight at enrollment between Group 1 and Group 2 (Student's T-test p-value 0.786521694).

As enrollment continued across the second and third trimesters in Group 3; the initial weight was taken for comparison.

Weight gain during pregnancy

The current study recorded the weight of the pregnant women in the follow-up visits and from that weight gain during pregnancy was calculated.

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 primary health care centre, where the study was undertaken, referred subjects with a rise in blood pressure and/ or oedema. These women continued to attend antenatal clinics in the referral hospital; so, we do not have any data on PIH.

In the community i.e. Group 3, much better follow-up of the women was possible; as the research team was physically checking, the research team had better access thus outcome-wise the data available in the community setting. But in the community setting, we have no data regarding PIH as they were not routinely checked for PIH in clinic settings and their attendance to the ANC was poor. Thus, in the community setting also, information on PIH was not available. In community settings there was excellent data on pregnancy weight gain and also some data on pre- and post-pregnancy weight and weight retention after pregnancy.

Maternal anthropometric indicators and Birth Weight: To assess the impact of maternal height on weight in the early second and late third trimesters of pregnancy and

birthweight, the mean height, weight at 16 weeks and 36 weeks and birthweight were computed in three tertiles of maternal height taking all three settings together to get a substantial number of pregnant women when divided into sub-groups. Women whose height was in the lowest tertile had the lowest mean height, lowest mean weight both at 16 (40.7kg) and 36 weeks of pregnancy(50.0kg) and lower mean birth weights (2.7kg). In contrast, women in the highest height tertiles had the highest mean weight at 16 weeks (60.4kg) and 36 weeks (69.7kg) and the highest mean birthweights (3.0kg). The differences in each of these parameters between tertiles were statistically significant ($p<0.01$). These data suggest that maternal height is a major determinant of maternal weight during pregnancy and birth weight. However, the differences in the weight gain during pregnancy between women in the three height tertiles were small and not statistically significant. In the present study, women were from food-secure families and were eating to appetite; given these conditions, it is possible that optimal weight gain in these short-statured women delivering neonates with mean birthweight of 2.7 kg is below 8 kg.

Post-pregnancy weight retention: In the community setting women, records of prepregnant weight were available in 145 pregnant women. Efforts were made to collect weight in these women three to six months after delivery. The mean post-pregnancy weight (55.8±10.33) was higher as compared to the mean pre-pregnancy weight (53.9±10.06 kg). The mean post-pregnancy BMI (24.0±4.10) was higher as compared to the pre-pregnancy BMI (23.2±4.10). Even when weight gain during pregnancy was less than 8 kg, there was a significant residual weight gain of 2 kg in the post-pregnancy period. Both the residual weight retention (<0.001 ESS (1.09E-07) and gain in BMI (<0.001 ESS (1.73E-07) were statistically significant (paired t-test). Residual weight retention after pregnancy was seen across all maternal weight Groups. Weight retention

improved the nutritional status of under-nourished women but aggravated over-nutrition in overweight women.

Haemoglobin status:

At the time of their initial visit to the antenatal clinic, all pregnant women have the blood drawn from the blood Grouping and VDRL test. In those who agreed to participate in the study an additional 20 µl blood was pipetted and put on a filter paper for haemoglobin estimation by indirect cyanmethaemoglobin method.

In Group 1 haemoglobin status was available for 383 women. Mean Hb at recruitment was 9.6±1.44 g/dL. Nearly ¾th of the women had mild anaemia; 10% had Hb levels below 8 g/dL. Only 18% were not anaemic at recruitment.

In Group 2 mean Hb at recruitment was 9.4±1.53 g/dL. More than 2/3rd of the women had mild anaemia; 15.8% had Hb levels below 8 g/dL. Only 16% were not anaemic at recruitment.

The hospital policy was to provide 60mg elemental iron and 5mg folic acid to all pregnant women irrespective of their Hb levels. The supply of iron and folic acid tablets was sometimes erratic.

Haemoglobin was measured in the indirect cyanmethaemoglobin method by the research team at NFI. In Group 1 mean haemoglobin level at enrollment was 9.6±1.44 g/dL (n=383) and 12 weeks after supplementation was 10.1±1.41g/dL (n=213).

In Group 2 mean haemoglobin level was 9.4±1.53g/dL (n=400) at enrollment and 9.6±1.54g/dL (n=221) at 12 weeks after supplementation.

There was a rise of 0.7 g/dL and 0.2 g/dL in the mean Hb levels of Group 1 and Group 2 respectively (comparing the paired samples). The increase in the hemoglobin is

statistically significantly higher in the primary healthcare institution in which the supplementation study was undertaken.

Compliance with the supplementation:

Group 1: Calcium and vitamin D supplements were made available to the enrolled pregnant women by the research team in Group 1. IFA tablets were provided by the hospital as per their protocol. Nutrition education was provided by the research team as a part of the research study. In Group 1, mean number of tablets given was 107±28.1, out of which 98±25.8 mean number of tablets was consumed and 9±8.5 mean number of tablets were not consumed. These data suggest that these women did consume the tablets regularly. This fact indicates that when the calcium and vitamin D supplements are made available to pregnant women with nutrition and health education and counselling for the need of the supplements, the pregnant women accept and consume the supplements regularly.

Group 2: In Group 2, when the calcium and vitamin D tablets were provided to them from the hospital more than 80% of the tablets provided were consumed. There were 32 pregnant women who did not consume calcium and vitamin D supplements at all, as they did not get hospital supplies and were not able to buy the same; many women were unable to buy all the tablets needed for taking the supplements regularly from the time of enrolment till delivery.

Regularity of attendance even in the routine antenatal clinic, was lower as compared to Group 1.

These data suggest that when the supplements were regularly provided and intake was monitored compliance rate was higher; when the supply gaps occurred and women were requested to buy and consume the tablets consumption rate was lower. But in all the cases the available supplements (provided by the hospital or purchased) were consumed regularly by the pregnant women. This indicates that they are aware of the importance

of taking the supplements but because lack of hospital supply and inability to buy supplements due to cost were unable to take them regularly.

Group 3: In Group 3, 448 pregnant women were enrolled 415 (92.6%) pregnant women continued participating in the study and 33 (7.4%) pregnant women discontinued. Efforts were made to undertake home visits at least once a month and obtain details regarding the ANC visit as and when they went for antenatal checkups (PHC/ Government hospital or private practitioner) were collected along with the source of supplements (received/ bought from outside). Out of 415 continued cases 350 (84.3%) pregnant women received medicines after ANC either in Government or in private settings; 3 (0.7%) pregnant women received supplements from family members working in PHC without any antenatal checkup. Out of the continued cases, 60 (14.5%) pregnant women had not attended any ANC and 2 (0.5%) pregnant women attended ANC but did not receive or buy any supplements (neither IFA/ iron nor Calcium and Vitamin D). Therefore, a total of 62 pregnant women out of 415 continued cases did not consume any supplements.

A total of 352 women attended ANC for antenatal checkups though 2 of them did not receive any supplements. The average number of ANC visits was 4±2.1 (352). Out of these 352 pregnant women who went for antenatal care, the majority went to a Government ANC clinic [256 (72.7%)], ¼th pregnant women [91 (25.9%)] went to private settings and the remaining 5 (1.4%) went to both i.e. few visits in Government settings and few visits in private settings for antenatal checkup as per their convenience and affordability.

Out of the continuous cases 345 pregnant women received or bought calcium and vitamin D/ calcium tablets. The mean of calcium and vitamin D/ calcium tablets available was 129±77.5 (345). Compliance was 93.8% in terms of the available tablets

with a mean consumption of 121±75.9 (334) tablets. Eleven pregnant women didn't consume calcium and vitamin D/ calcium supplements even after receiving them.

Government ANC was attended by 256 pregnant women; different women attended different PHCs/ hospitals. One subject didn't receive either IFA/ iron or calcium and vitamin D/ calcium supplements even after attending. One subject received only calcium and vitamin D/ calcium supplements but not IFA/ iron as there was some problem with the supply of the particular supplement and the clinic was out of stock for the same. Four pregnant women didn't receive calcium and vitamin D/ calcium supplements. The compliance rate in terms of the available supplements was 91.7%. Eleven pregnant women didn't consume the calcium and vitamin D/ calcium though the supplements were made available to them by the Government ANC clinic they attended. The research team tried to convince these pregnant women about the importance of the supplements and reassured them regarding the fear of side effects.

Private ANC clinic was attended by 91 pregnant women; out of them 1 pregnant woman didn't buy either IFA/ iron or calcium and vitamin D/ calcium supplements and another pregnant woman was prescribed IFA/ iron supplements and not calcium and vitamin D/ supplements. The compliance of the available tablets was 98.3%. All the pregnant women who bought the supplements consumed most of the available supplements, as the supplements were bought with their hard-earned money, they took the supplements regularly.

The 3 pregnant women who did not attend any ANC for antenatal checkups but procured the supplements from ASHA/ Anganwadi/ family members working in PHC got only IFA/ iron supplements. They understood the well-known importance and benefits of IFA/ iron supplements during pregnancy and thus they procured the supplements even when they didn't attend any Government or private ANC clinic for

antenatal care; the fact that IFA supplements were relatively inexpensive and affordable also contributed.

Five women who attended ANC, both in Government settings for a few visits and private settings for a few visits as per their convenience and affordability, consumed 94.9% of the available supplements.

The number of supplements available and consumed were compared (Chi-square test) amongst the three Groups and it came out to be statistically non-significant; P-values were Group 1 vs 2-0.9495, Group 2 vs 3-0.9902 and Group1 vs 3-0.9525. Thus, it may be inferred that if the supplements are made available to pregnant women, most of the supplements will be consumed by most pregnant women.

Pregnancy outcome:

In Group 1 and 2, more than 90.0% and in Group 3, 87.3%. had institutional deliveries. Mean birth weight in Group 1 was 2.8±0.41kg (285), in Group 2 was 2.6±0.51kg (223) and in Group 3 was 2.8±0.49kg (345). These differences were statistically significant (Student's T-test p values for Group 1 vs. 2 and Group 2 vs 3 were 0.00026 and 0.00088 respectively) except between Group 1 and Group 3 (Student's T-test P value 0.803).

Preterm rates were 16.4%, 21.4% & 18.1% and low birth weight rates were 13.0%, 31.8% & 21.4% in the primary healthcare institution in Group 1, 2 and 3 respectively. Differences in low birth weight rates were statistically significant, but preterm births were not significant.

DISCUSSION

Pregnant women have been recognized as the most vulnerable Group from the nutritional point of view. Nutrients requirement increase during pregnancy as the woman has to provide not only for herself but also for the growing foetus. In view of the high prevalence of biochemical vitamin D deficiency, low calcium intake, and

known adverse consequences of poor vitamin D status on the mother-child dyad, calcium and vitamin D supplementation during pregnancy has been advocated. National Guidelines for "Calcium Supplementation During Pregnancy and Lactation" recommended two tablets of calcium (as calcium carbonate containing 500 mg elemental calcium) and vitamin D (250 IU vitamin D) twice daily just after meals from the second trimester of pregnancy till six months of lactation. There are no published data on coverage, compliance and impact of calcium and vitamin D supplements in hospital or community settings. The present study was undertaken to assess the acceptance, coverage and compliance of Calcium and Vitamin D supplementation during pregnancy in three Groups (hospital research, hospital service conditions and community settings. The study may provide information regarding mid-course correction needed to improve the programme.

The study was undertaken on pregnant women from urban low-middle-income Groups attending the antenatal clinics in govt primary health centre or residing in the community. These families were food secure. The data on dietary intake by the 24-hour dietary recall method showed that energy intake was either adequate or exceeded EAR in short-statured sedentary pregnant women; calcium intake of the pregnant women met the EAR recommended by the NIN-ICMR. Weight gain in the second and third trimesters in these women was 7.6kg. The higher-than-required intake of energy during pregnancy appears to have resulted in post-pregnancy weight retention of 1.9kg post-pregnancy weight retention.)

A comparison of the data on the consumption of the tablets showed that consumption of calcium and vitamin D supplementation is better when the supplements are regularly given and women receive nutrition and health education. In Group 2 and 3 women consumed the available tablets whether provided or purchased by them but did not do so when they did not have the supply. This indicates that they are aware of the

importance of taking the supplements but the erratic supply of the supplements in the Government healthcare system and the high cost of purchasing calcium and vitamin D supplements reduces the consumption of calcium and vitamin D supplements.

CONCLUSION

It can be concluded from the present study that whenever the supplements were made available to pregnant women or they purchased them (prescriptions were given by private practitioners) majority consumed the supplements. Data from the study indicate that if the supply of the tablets are regular and there was nutrition education and supportive supervision of the supplementation, it will be possible to improve coverage and compliance with calcium and vitamin D supplementation. Nutrition and health education are needed to achieve optimal maternal nutrition and birth weight.

STRENGTH

→ The data from Group 1 provides information on what can happen under continuous and assured supply of calcium and vitamin D supplementation in antenatal clinics in urban primary health institutions.

→ The data from Group 2 depicts the situation of calcium and vitamin D supplements under service conditions in the antenatal clinic in urban primary health institutions.

→ The data from Group 3 provides a clear idea of the current situation of calcium and vitamin D supplements and antenatal care in the low/ low-middle income community.

LIMITATION

→ The standard practice of antenatal clinics in the Delhi Government hospitals provided only a single tablet of calcium (500mg) and vitamin D (250 IU) to pregnant women. This dosage is half that of the recommended dose in the Guidelines.

→ The study could not assess the impact of providing two tablets of the calcium and vitamin D supplements as recommended in the programme guidelines.

→ Impact assessment was not done using pre- and post-supplementation of calcium and vitamin D in pregnant women on vitamin D levels and course and outcome of pregnancy.

WAY FORWARD

→ Undertake studies on feasibility, acceptance, coverage, and compliance of supplementation with two tablets of calcium (500mg) and vitamin D (250IU).

→ Assess the impact of the supplementation (one and two tablets) on plasma vitamin D levels (pre-supplementation and after 12 weeks of supplementation) in pregnant women.

→ Assess the impact of the supplementation (one and two tablets) on course (especially PIH) and outcome of pregnancy.

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