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RESEARCH ARTICLE

Adherence, Determinants and Barriers to Calcium Supplementation in Pregnancy: A Mixed Methods Study

R. Krithika Valli*, Priya Pasupathy and V. Damodaran

Institute of Community Medicine, Madras Medical College, Chennai - 600003, Tamil Nadu, India; krithika.ramki@gmail.com

Abstract

Background: Calcium intake of 1gram/day in pregnancy reduces the risk of pre-ecclampsia and preterm birth. Universal free calcium supplementation program was started throughout India at considerable cost to the government. Although coverage is high, this program is only effective if there is good adherence among mothers, and this is unknown. This study was conducted to estimate the prevalence of adherence to calcium tablets among mothers and to identify the determinants and barriers to adherence to calcium supplementation. **Methods:** A cross sectional mixed methods study was conducted among mothers attending antenatal clinic at Kundrathur PHC. Mothers with >20 weeks of gestation were recruited consecutively. They were interviewed using the Morisky Medication Adherence Scale (MMAS-8). Barriers to adherence were elicited by freelisting and analysed using Visual Anthropac 1.0. **Results:** 89 mothers completed the study. The participants had a mean age of 25.29+4.275 years. Majority of mothers were literate and primi gravida. The Mean MMAS score was 4.98+1.79 (95% CI 4.61, 5.36), out of a maximum score of 8. In our study, the majority of mothers (69.66%, 95%CI 59, 78.97) had low adherence, and high adherence was seen only in 6.7% women. (95% CI 2.51, 14.10). Only 3.4% mothers were aware of the role of calcium in hypertension. There was a significant association between adherence and level of education, and having a support person (OR 11.5, 95%CI -2.568, 51.502). Major barriers identified were forgetfulness, big size of the tablet, vomiting, dosing schedule and unavailability of tablets. **Conclusion:** Adherence to Calcium supplementation is low among mothers. Having a designated support partner in pregnancy, who helps in reminding and giving supplements, can help improve adherence. Addressing the major barriers identified can help in improving adherence and reducing hypertension in pregnancy.

Keywords: Adherence, Antenatal, Calcium, Pre-ecclampsia, Support

1. Introduction

Calcium supplementation in pregnancy is said to reduce the risk of pre-ecclampsia and preterm births, and their attendant maternal and neonatal morbidity and mortality. The World Health Organisation strongly recommends 1.5-2 g of daily oral calcium supplementation in pregnancy, in areas where dietary calcium intake is low[1].

Against the Indian setting of high prevalence of hypertension in pregnancy, high complications from hypertension, a strong protective effect of calcium supplementation and a very low dietary calcium consumption, India drafted guidelines to provide 1g of Calcium per day to all pregnant and lactating women from 2nd trimester till 6 months postpartum, in 2 divided doses. One Calcium tablet is to contain 500mg of Calcium in the form of Calcium carbonate and 250IU of Vitamin D.

With each pregnant woman requiring 720 tablets per pregnancy[2] and India having 30 million pregnancies a year[3], this program of Calcium supplementation has been ongoing at considerable cost to the Indian Government since 2014. However,

*Author for correspondence

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calcium supplementation in pregnancy will only have the intended protective effect if there is good adherence among Indian mothers, and literature regarding the same is scarce. To address this gap, assess the adherence to Calcium tablets among Indian mothers, and identify determinants and barriers to calcium tablet adherence, this mixed methods study is undertaken.

2. Review of Literature

Hypertensive disorders of pregnancy are one of the leading causes of maternal deaths, especially in developing countries[4], accounting for about 14% of all maternal mortality worldwide[5] and 11.35% in Southeast Asian regions[6]. Sequelae of hypertension in pregnancy include preterm birth, low birth weight, congenital malformations and perinatal and infant mortality[7]. Complications of preterm and low birth weight are the leading causes of infant and under 5 mortality, and leave many survivors with lifelong morbidity[8]. Apart from being a severe complication of pregnancy, the prevalence of Hypertensive disorders of pregnancy is also high in India -11%, higher than the global average[6].

Calcium supplementation in pregnancy has been shown to reduce the risk of hypertensive disorders in pregnancy and their complications. A Cochrane review of 13 RCTs on the topic[9], in a total of 15730 women, concluded that at least 1g of calcium a day halved the risk of pre-ecclampsia (RR 0.45 95% CI 0.31–0.65), with up to a 78% reduction in high risk women, and a 64% reduction in women with low dietary calcium. There was a 20% reduction in maternal mortality and serious morbidity and a 24% reduction in preterm birth[10].

Dietary calcium consumption in India is also low, with median Calcium consumption of pregnant and lactating women around 330 mg per day against the RDA of 1200g. 80% women consumed less than half the recommended amount of Calcium[11].

As a country with low dietary calcium consumption, India supplements all mothers with 1g of Calcium per day at considerable cost to the government. Calcium can only have its intended protective effects if taken as prescribed, however, the effectiveness of this program in India is unassessed.

Data regarding adherence to calcium tablets among pregnant women is not available from any previous Indian studies. A study in North East India identified that only 61.2% had received the full course of calcium supplements[12]. Comparatively, the NFHS 5 states that though 99% of women had received iron and folic acid tablets, only 63% took them as recommended for 180 days or more. Given that awareness regarding anemia and the importance of iron supplementation is high in India compared to calcium, the adherence to calcium supplementation is likely to be even lower.

Shrestha *et al.*,[13] in a hospital based study in Kathmandu identified 35.6% adherence to calcium medication. Liu *et al.,* identified a 11% adherence in a large scale study from China[14]. In Cameron, it was identified that only 72% women took any calcium at all in pregnancy, and only 12% took calcium tablets as prescribed throughout pregnancy[15].

Factors associated with higher adherence in previous studies were higher education and income, urban residence, regular antenatal care, having reminder materials, adherence partners and family support[14-16].

Barriers to calcium adherence were limited knowledge about pre-ecclampsia, side effects, fear of adverse effects, preferences against tablets, working schedules, being away from home, not receiving free supplements, and pill burden[16.17].

3. Objectives

1. To estimate the prevalence of adherence to calcium tablets among antenatal mothers.
2. To identify the determinants of Calcium tablet adherence among antenatal mothers.
3. To identify the barriers faced by mothers in adherence to calcium tablets.

4. Methodology

4.1 Materials and Methods

A mixed methods study was designed to estimate adherence to calcium supplementation and to identify barriers among antenatal mothers in a rural field practice area in Kanchipuram District, Tamil Nadu. Sample size was calculated based on a previous study done by Shrestha et al in Nepal[13], which reported 64.4% of mothers were non adherent. With a confidence level of 95%, a desired absolute precision

of 10, and a non response rate of 10%, we arrived at a sample size of 97.

Data collection tools: The pre-validated Tamil version of the Morisky Medication Adherence Scale-8 was used to evaluate adherence to Calcium tablets. Barriers to adherence were elicited using the Freelisting technique.

4.1.1 Sampling Methodology

From all the antenatal mothers attending antenatal clinics at Kundrathur PHC in the 1 month study period, those with gestation more than 20 weeks- that is, those who should have been taking Calcium tablets for at least 1 month- were included consecutively into the study.

4.1.2 Data Collection

After obtaining written informed consent, antenatal mothers were interviewed in the local language, Tamil, by the principal investigator. A short semi-structured questionnaire was used to obtain baseline details, and adherence was assessed using the MMAS tool. Barriers to adherence were elicited using Freelisting. Participants were asked to list out the difficulties faced by them in taking the calcium tablets as prescribed, and responses were recorded verbatim. Mothers unwilling to participate or finish the study were taken as non-responders.

4.2 Data Management and Analysis

Responses were entered into a coded Google form. Freelisting responses were recorded as is. This was then imported into MS Excel. Data was cleaned and coded, and imported to SPSS Version 25 for analysis. Means and Standard deviations and frequencies, and percentages were used as needed to describe the data. The MMAS was scored on a scale of 1-8, and participants were categorised as low adherence (<6), medium adherence (score 6-7.9), and high adherence[8]. Chisquare and Odds ratios were used to identify associations between adherence and the factors studied.

Freelisting responses were examined for similarity in language and concept, and recoded accordingly in English. This was then entered as a list into Notepad and analysed using Visual Anthropac 1.0. Salience indices were identified for each barrier, and charted in a Scree plot to identify the most significant barriers. These were then plotted in an Euler diagram to identify the distribution of barriers across adherence categories.

5. Results

5.1 Baseline Information

89 mothers completed the study. Mean age was 25.29+4.275 years, ranging from 19 to 39 years. Majority of the participants were educated, with 51.7% having a graduate degree or higher, and 91% having completed a high school level education (Figure 1). The majority (68%) were not employed. Slightly more than half of the interviewed mothers were primi gravida (57.3%). Mean age of gestation was 7.45 months.

5.2 Adherence to Calcium Supplementation

The Mean MMAS score was 4.98+1.79 (95% CI 4.61, 5.36). This falls in the low adherence category. In our study, the majority of mothers (69.66%, 95%CI 59, 78.97) had low adherence to Calcium supplementation, and 23.6% (95%CI 15.24, 33.78) had medium adherence. Only 6.74% had high adherence (95%CI 2.51, 14.10) (Figure 2).

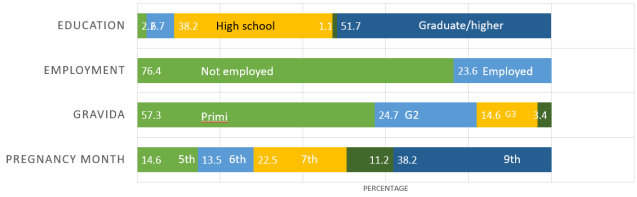

Figure 1. Participant characteristics.

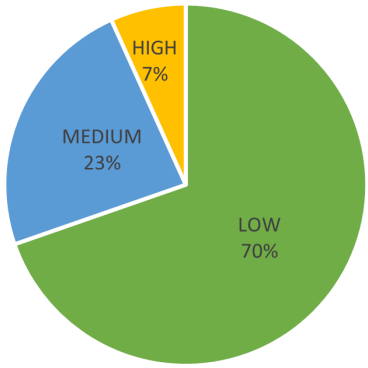

Figure 2. Calcium adherence.

5.3 Determinants of Calcium Adherence

Only 79.8% mothers knew that they were taking calcium tablets by name. Only 3.4% mothers knew that taking calcium tablets could prevent hypertension and complications in pregnancy. The majority (64%) said it was a nutritional supplement, or aided in the development of the baby, and 32.6% did not know why they were taking the Calcium tablets at all. Only 21.3% women said they should take 2 calcium tablets a day as recommended, and 74.2% had been asked to take 1 tablet a day. However, most women (88.8%) had received the calcium tablets from the government (Table 1).

When asked whether they had a support person-someone who helped them in taking the tablets as prescribed- 42.7% said yes, and 33.7% said they had a support person some of the time. Nearly one in 4 women (23.6%) did not report having any such support.

Those mothers with an adherence partner or support person (who helps in reminding and giving supplements) in their home were 11.5 times more likely to have higher adherence compared to those without a support person. This association was statistically significant. (OR 11.65, 95%CI 2.57, 51.50) Those with a support person some of the time were 2.97 times more likely to be in a higher adherence category, however, this association was not statistically significant. (OR 2.967, 95%CI 0.75, 11.74)

There was no significant association with employment status, gravida, or age of gestation. No significant association was seen with knowledge, number of tablets taken or receipt of calcium tablets.

Table 1. Factors related to adherence, n = 89

Factor	Category	Mean MMAS (SD)	Low Adherence n(%)	Medium-High Adherence n(%)	P value
Education	<High school	5.28(2.15)	6(75)	2(25)	0.541*
	Atleast high school education	4.96(1.76)	56(69.1)	25(30.9)	
Employment	Not employed	4.87(1.81)	49(72.1)	19(27.9)	0.376
	Employed	5.34(1.70)	13(61.9)	8(38.1)	
Gravida	1	5.16(1.62)	34(66.7)	17(33.3)	0.582*
	2	4.93(1.71)	17(77.3)	5(22.7)	
	3	4.94(2.35)	8(61.5)	5(38.5)	
	4	2.58(1.37)	3(100)	0 (0)	
Gestational age	2nd trimester	4.87(1.59)	34(75.6)	11(24.4)	0.221
	3rd trimester	5.10(1.98)	28(63.6)	16(36.4)	
Knows taking calcium tablets by name	Yes	5.12(1.72)	47(66.2)	24(33.8)	0.158
	No	4.46(2.01)	15(83.3)	3(16.7)	
Reason for taking Calcium	Nutrition/Baby development	4.91(1.93)	39(68.4)	18(31.6)	0.913*
	Prevents hypertension	4.67(1.61)	2(66.7)	1(33.3)	
	Don't Know	5.16(1.55)	21(72.4)	8(27.6)	
Number of tablets	0	2.87(1.36)	4(100)	0(100)	0.351*
	1	4.97(1.81)	46(69.7)	20(30.3)	
	2	5.47(1.49)	12(63.2)	7(36.8)	
Received tablets	Yes	5.06(1.79)	54(67.5)	26(32.5)	0.267*
	No	4.36(1.71)	8(88.9)	1(11.1)	
Support	Yes	5.92(1.53)	8(40)	12(60)	**0.002**
	Sometimes	4.98(1.82)	31(72.1)	12(27.9)	
	No	4.27(1.64)	23(88.5)	3(11.5)	

Association by Chi square test. *Have expected values<5, Fisher's exact test.

5.4 Barriers to Calcium Tablet Adherence

Table 2 depicts the identified barriers to Calcium tablet adherence. 17 different barriers were identified.

These barriers were arranged by salience on a scree plot (Figure 3).

The barriers on the plot before the 'elbow' point in the plot are taken as significant barriers. Here, the first 6 barriers are significant: Forgetfulness, the big size of the tablet, vomiting and nausea, inconvenient timing of the tablet, dislike of taking tablets and not having tablets at hand.

These barriers were plotted by adherence category to map the distribution of barriers to adherence (Figure 4). Big size of the tablet was a universal barrier, regardless of adherence category. Low and medium adherence women cited forgetfulness as the major barrier, a barrier not cited by high adherence women. Other barriers among low and medium adherence women were the belief that calcium tablets were heat, the belief that alteration in stools caused by calcium tablets, etc. Barriers unique to low adherence women were vomiting, timing of the tablet, not having the tablets, fear of having a big baby and a difficult delivery due to calcium supplementation.

Table 2. Barriers identified by free listing

S. No	Item	Frequency (%)	Average Rank	Salience
1	Forgetfulness	49	1.08	0.471
2	Big size of the tablet	25.5	1.31	0.222
3	Vomiting, nausea	13.7	1.43	0.108
4	Inconvenient timing of the tablet	7.8	1	0.078
5	Don't like taking tablets	5.9	1	0.059
6	Not having tablets at home/with me	3.9	1	0.039
7	Uneasiness on taking	5.9	2	0.036
8	Tiredness after taking	5.9	2	0.036
9	Bad aftertaste of the tablet	3.9	1.5	0.029
10	Altered stools	3.9	2	0.026
11	Belief that Calcium tablet is "heat"	3.9	2	0.023
12	Don't like the smell of the tablet	3.9	2	0.02
13	Fear baby will be too big	2	1	0.02
14	Fear of side effects	2	1	0.02
15	Too many tablets to take	2	2	0.01
16	Hassle to take while going out	2	2	0.01
17	Not told/aware about tablets	2	2	0.01

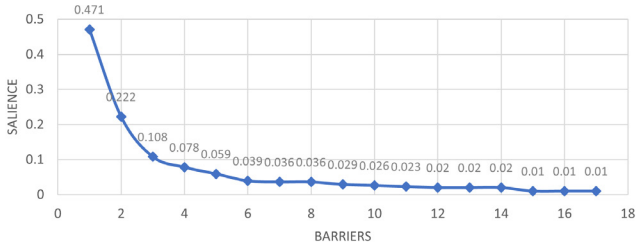

Figure 3. Scree plot of barriers to calcium adherence.

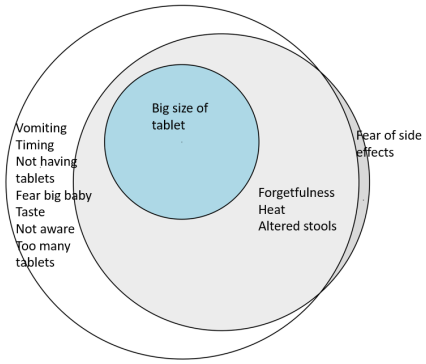

Figure 4. Euler diagram: Distribution of barriers by adherence.

6. Discussion

Our study was conducted among mothers in a rural area. The sample is likely to be representative of mothers availing antenatal care at rural primary health centres, as it included all mothers who visited the centre in one month, with a low non-response rate of 8%. However, the literacy rate in our study was higher than that of Tamil Nadu as per NFHS 5[18].

Adherence to calcium tablets was low in our study, with 70% mothers having low adherence, and only 6.7% with high adherence. This is comparable to previous studies in Nepal[13] which a but higher than that reported from studies in China[14] and Cameron[15]. According

to NFHS 5,[18] the adherence to Iron supplementation was 63%, which is more than twice the adherence rate of Calcium observed in this study. Such low rates of adherence are a cause for concern, and require steps be taken to address this issue.

In our study, though 90% mothers were educated to atleast a high school level, only 80% even knew that they were taking calcium tablets by name. One in three women did not know why they were taking calcium supplements at all. Only 3% knew of Calcium's role in preventing hypertension and its complications. Though in our study, these were not factors associated with higher adherence, this could be due to inadequate power for subfactor analyses as well as the high prevalence of low adherence.

Only 21.3% were prescribed 2 tablets a day as per guidelines, while the majority of mothers were asked to take only 1 calcium tablet a day. This variation in prescribing, even in a single centre, is worrying and requires standardisation of training and prescribing practices. However, there is evidence to suggest low dose calcium supplementation is as effective in preventing hypertension and has higher acceptability[19,20]. However, in our study, there was no association observed with lower dose of calcium supplementation and higher adherence.

In our study, mothers having an adherence partner or someone to support them in taking calcium tablets, was significantly associated with higher adherence. This is similar to findings from previous studies[21], and suggests the need for experimental research into using social support to improve medication adherence.

Our study identified qualitatively the major barriers to calcium tablet adherence. Of 17 barriers identified, the ones identified as significant were forgetfulness, big size of the tablet, nausea and vomiting, tablet schedule, and personal preferences regarding tablets, and not having tablets on hand. Of these, all but one are amenable to modification or intervention.

On assessing these barriers with regard to the adherence status of the women, big size of the tablet was a universal barrier regardless of adherence status. Working with pharmaceutical companies to produce smaller tablets more acceptable to mothers, could help in improving the adherence to calcium tablets.

Forgetfulness was a major barrier not seen in high adherence mothers, and was reported only by low and medium adherence mothers. Ensuring support partners at home would improve adherence, as well as involve the husband and other family members in the pregnancy, and improve outcomes. Other reminder materials and technology could also help in removing this barrier.

Barriers unique to low adherence women were nausea and vomiting, dosing schedule, etc. should be identified and addressed on a case to case basis to correct the cause and improve adherence. Reliable methods to assess and address adherence among pregnant women should be identified and incorporated into all antenatal visits.

7. Conclusions

In our study, adherence to calcium supplementation was low. Having support partners to help in taking medication was associated with higher adherence. Major barriers identified to adherence were forgetfulness, the size of the tablet, vomiting, dosing schedule, availability of tablets and personal preferences. These barriers should be addressed to improve the adherence to calcium supplementation, and effectively prevent hypertensive complications in pregnancy.

8. Limitations

The prevalence of high adherence was very low, and thus, this study was underpowered for subgroup analysis to identify all factors affecting calcium adherence. It was also conducted in a single rural field practice area, and results may not apply to urban women.

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