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Original article

Informing primi and elderly pregnant women about iron sucrose administration for moderate anemia can improve treatment compliance in public health facilities, Kancheepuram health district, Tamil Nadu, India, 2017: A cross-sectional study

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ABSTRACT

Introduction: Tamil Nadu administers intravenous iron sucrose for correcting moderate anaemia among pregnant women (Haemoglobin level 7–8.9 g/dl) based on preliminary studies. We did a cross-sectional study to estimate compliance level and that of factors associated with intravenous iron sucrose treatment for moderate anaemia among pregnant women attending health facilities of Kancheepuram health district, Tamil Nadu, India, 2017.
Methods: We needed five pregnant women of 20–30 weeks from 70 clusters (health subcentres) for the assumptions of 64% compliance, 7% absolute precision, 95% Confidence Interval (CI) and a design effect of two. We collected data on knowledge and experience with iron sucrose treatment and reasons for non-compliance. We abstracted haemoglobin levels and administered doses from records. We computed compliance level (%) with 95% CI and estimated adjusted odds ratio (AOR) for non-compliance through logistic regression analysis.
Results: The median age of 350 women was 24 years (Range = 22 to 26). Compliance level to intravenous iron sucrose was 79% (95% CI: 73 to 84). Non-compliance was more likely among women aged 25–35 years (AOR: 2.1, 95% CI: 1.2 to 3.7), primi (AOR: 2.2' 95% CI: 1.2 to 3.8) and not received treatment information (AOR: 3.1, 95% CI: 1.1 to 8.8). Major reasons for non-compliance were lack of information about treatment, belief that food was better than injections and that injections could harm the baby.
Conclusions: The compliance to intravenous iron sucrose was insufficient. Providing clear information about intravenous iron sucrose to moderately anaemic pregnant women could increase the compliance to intravenous iron sucrose.

1. Introduction

Anemia is the most common nutritional deficiency disorder of pregnancy. The World Health Organization (WHO) estimated global prevalence of anaemia among pregnant women of 15–45 years as 38% in 2011.[1] Prevalence of anaemia among pregnant women in South East Asian region (as defined by WHO Regions) is 49%, which is the highest among all the regions in the world.[1] In India, the prevalence of anaemia among pregnant women is 54%, which is the highest prevalence in the South East Asian region.[1] Prevalence of anaemia among pregnant women in Tamil Nadu is 44%.[2]

Anaemia during pregnancy will lead to poor maternal and perinatal outcomes. Anaemic pregnant women have a two-fold increase of preterm deliveries, higher incidences of low birth weight, postpartum haemorrhage and puerperal sepsis.[3] The babies born to anaemic women have a higher incidence of intensive care unit (NICU) admissions, hyperbilirubinemia, respiratory distress syndrome, neonatal seizures, birth asphyxia and neonatal sepsis.[3] According to the ministry of women and child development under Government of India, 20% of maternal deaths in India are due to anaemia and India contributes to half of the global maternal deaths due to anaemia.[4]

Various studies showed that iron sucrose injection is safe and

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effective for the treatment of moderate anaemia[5] (WHO definition: Haemoglobin level 7–9.9 g/dl) during pregnancy and three to four weeks of iron sucrose treatment results in an increase of mean haemoglobin of about 2–3 g/dl.[6–12]

The Government of Tamil Nadu has done a pilot study on treatment with iron sucrose for gestational anemia in 2007. The results of the pilot study showed a better increase of haemoglobin level with intravenous iron sucrose than oral iron tablets.[13] In 2009, National Rural Health Mission Tamil Nadu branch have issued revised guidelines that included treatment for moderate anaemia (Hb 7–8.9 g/dl) during 20–30 weeks of pregnancy with intravenous iron sucrose administration.[14] As per this guideline, these moderately anaemic pregnant women have to be given four doses of 100 mg iron sucrose in 100 ml of normal saline intravenously over 20–30 min once a day with two to four days interval between each infusion within two weeks. For antenatal mothers infused with iron sucrose, haemoglobin estimation must be done after one month. If the haemoglobin level is still between the 7–8.9 g/dl and the duration of pregnancy is less than 30 weeks, two top-up doses of 100 mg of iron sucrose infusion have to be given with two to four days interval between each infusion.

Kancheepuram health unit district is located on the southwest of Chennai, the capital city of Tamil Nadu. Our programme evaluation of high-risk pregnancy in this district in 2016 suggested that among the 250 pregnant women surveyed, 93% of pregnant women who utilized the public health facilities had anaemia and 19% had moderate anemia. Our findings suggested that only 64% of these moderately anaemic pregnant women have completed iron sucrose treatment.[15]

In this context, we conducted a survey to estimate the level of compliance to intravenous iron sucrose for the treatment of moderate anemia and to determine the factors associated with non-compliance to intravenous iron sucrose for the treatment of moderate anemia among pregnant women in 20–30 weeks of pregnancy attending public health facilities of Kancheepuram health unit district, Tamil Nadu, India, 2017.

2. Methods

2.1. Study design

We did a community-based cross-sectional study.

2.2. Study participants

We included the pregnant women who had completed 30 weeks of pregnancy but were moderately anaemic (Haemoglobin level of 7–8.9 g/dl) during 20–30 weeks of pregnancy and attending public health facilities for antenatal care as study participants. We excluded the pregnant women who were initiated on iron sucrose injection before 30 weeks but currently on treatment, those who were not the resident of Kancheepuram health unit district and the pregnant women less than 18 years.

2.3. Operational definition

2.3.1. Anaemia complicating pregnancy

We defined “anaemia complicating pregnancy” as haemoglobin level less than 11 g/dl in venous blood sample during pregnancy as irrespective of weeks of pregnancy.

2.3.2. Moderate anaemia

We defined “moderate anaemia of pregnancy” as haemoglobin level between 7 and 8.9 g/dl in venous blood sample during pregnancy irrespective of weeks of pregnancy.

2.4. Treatment for moderate anemia

Treatment for moderate anemia during pregnancy was based on the duration of pregnancy. Treatment for the pregnant woman less than 20 weeks of pregnancy was oral iron and folic acid tablets, for the pregnant woman of 20–30 weeks of pregnancy is intravenous iron sucrose injection, and for the pregnant woman more than 30 weeks of pregnancy is blood transfusion.

2.5. Intravenous iron sucrose treatment

Intravenous iron sucrose treatment refers to the intravenous infusion of 100 mg Iron sucrose in 100 ml of normal saline for 20–30 min once a day for four days with 2–4 days of interval between each infusion within a period of two weeks.

2.6. Compliance to intravenous iron sucrose treatment

A moderately anaemic pregnant woman who has completed four of iron sucrose injections as per guidelines is said to be compliant to treatment.

2.7. Non-compliance to intravenous iron sucrose treatment

A moderately anaemic pregnant woman who has not completed four doses of iron sucrose injections is said to be non-compliant, regardless of the number of doses received from zero to three.

2.8. Sampling procedure

We used cluster sampling method. The primary sampling unit was the health sub-centres (HSC). We used probability proportionate to the population size of pregnant women (more than 30 weeks) of each HSC through linear systematic sampling for cluster selection. In the HSCs, a line-list of pregnant women with anemia status was not available. Hence, a trained village health nurse serially selected the required number of study participants from each HSC.

2.9. Sample size

We needed to select five pregnant women each from 70 clusters (HSCs) based on the assumptions of 64% compliance to iron sucrose treatment among moderately anaemic pregnant women (n = 3373) in the district from 192 HSCs, with 7% absolute precision, design effect of two and 95% confidence interval (CI). There were no line lists maintained for pregnant women with anaemia along with severity grade. Thus, we trained village health nurses to select five study participants, using the operation definition for moderate anaemia, consecutively among the pregnant women visiting their respective health facility.

2.10. Data collection methods and tools

The principal investigator and trained investigators interviewed pregnant women with a structured questionnaire in the local language Tamil at the community level. We collected data on socio-demographic-economic, past experience with iron sucrose, accessibility-related details such as easy access to primary health centres and availability of transport facilities, pregnancy details, awareness about anaemia, health care provider’s interactions with anaemic women regarding their anaemia status, plan of treatment and the reasons for non-compliance. We reviewed records available with the pregnant women (mother and child protection card). From the record, we collected data on last menstrual period (LMP), expected date of delivery (EDD), haemoglobin level for three-time periods (14–16 weeks, 20–24 weeks, 26–30 weeks), height, weight and treatment with iron sucrose and the number of doses received. The principal investigator cross-verified five percent of the interviews for quality assurance.

Table 1
Socio-demographic characteristics of the study participants in the survey of non-compliance to intravenous iron sucrose administration for moderate anemia among pregnant women (N = 350), Kancheepuram health district, Tamil Nadu, India, 2016-17.

Socio-demographic characteristics	n	%
Median age (in years) [Interquartile range]	24 [22,26]	
Multigravida	204	58
Hindu religion	325	93
Scheduled caste and tribal community	155	44
Illiterate	15	4
House wife	288	82

2.11. Data analysis

We calculated descriptive statistics to describe the characteristics of the study participants. We estimated the level of compliance to intravenous level with 95% CI. We compared the frequency of exposures among non-compliant and compliant for intravenous iron sucrose administration and calculated crude prevalence odds ratios (POR) and 95% CI using binary logistic regression analysis. We examined the exposures for third factors. We computed adjusted ORs (AOR) and 95% CI after adjusting for confounders using multivariable logistic regression to identify variables independently associated with non-compliance to intravenous iron sucrose administration. We calculated the fraction of non-compliance attributable to the identified risk factors in the population [Population attributable risk (PAR)] using the classical formula: the proportion of particular risk factor in the population multiplied by the attributable fraction among exposed (1–1/odds ratio). We entered and analysed the data using Epi Info software (version 7.2).

2.12. Human participant protection

We obtained approval from the Institutional Ethics Committee of ICMR School of Public Health, ICMR-National Institute of Epidemiology, Chennai and permission from the Tamil Nadu State Directorate of Public Health and Preventive Medicine and District Director of Health Services. We obtained informed written consent from all the participants in the local language. We maintained the confidentiality of the collected data by removing identifiers.

Table 2
Factors associated with non-compliance to administration of intravenous iron sucrose for moderately anemic pregnant women attending public health facilities (N = 350) in Kancheepuram health district, Tamil Nadu, India, 2016-17.

Factors	Among non-compliant (n = 74)		Among compliant (n = 276)		Crude Odds Ratio	
	#	%	#	%	Estimate	95% CI
Aged 25–35 years	39	53	115	42	1.6	0.9–2.6
Belonging to schedule caste and tribal community	36	49	119	43	1.3	0.7–2.1
Illiterate or educated up to middle school	21	28	92	33	1.3	0.7–2.2
Employed	16	22	46	17	1.4	0.7–2.6
Did not have iron sucrose in the previous pregnancies	29[a]	81	130[b]	77	1.2	0.5–3
Had reactions during treatment	14[c]	40	27[d]	10	6.1	2.8–13.8
Primigravida	38	51	108	39	1.6	1–2.8
Health facility located beyond 5 km from home	39	53	139	50	1.1	0.7–1.8
Waiting time for transport more than 2 h	18	24	44	16	1.7	0.9–3.2
Medical officer not present during visit to health facility	1	1	2	1	1.9	0.2–20.1
Non-availability of iron sucrose injection	6	8	2	1	12.1	2.4–61.2
Waiting time to get injection more than 1 h	5	14	24	9	1.8	0.6–4.9
Unaware of anaemia	10	14	8	3	5.2	2–13.8
Unaware of iron sucrose treatment	26	35	11	4	13.1	6–28.2

[a] n = 36; pregnant women whose current pregnancy is 2nd or more.
[b] n = 168; pregnant women whose current pregnancy is 2nd or more.
[c] n = 21; pregnant women who stopped with one to three doses of iron sucrose.
[d] n = 276; pregnant women who completed four doses of iron sucrose.

3. Results

3.1. Profile of study participants

We interviewed 350 moderately anaemic pregnant women [Median age (range): 24 years (22–26) years]. Most of them (93%) belonged to the Hindu religion, and 44% belonged to scheduled caste and tribal community. Four percent were illiterate, and 82% were housewives (Table 1).

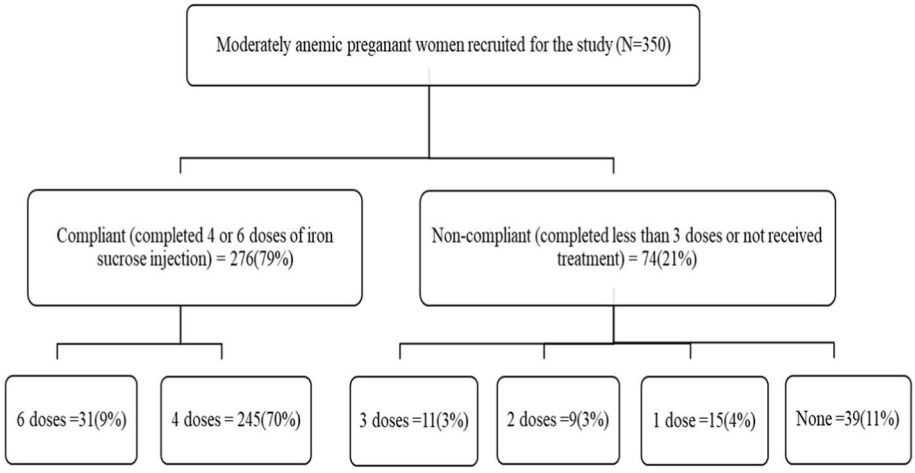

Fig. 1. Compliance level among the moderately anaemic pregnant women (N = 350) to intravenous iron sucrose treatment, Kancheepuram health unit district, Tamil Nadu, India, 2016–17.

Table 3
Factors associated with non-compliance to administration of intravenous iron sucrose for moderately anemic pregnant women attending public health facilities of Kancheepuram health district, Tamil Nadu, India, 2016-17.

Factors	Crude OR	Adjusted OR	
		Estimate	95% CI
Aged 25–35 years[a]	1.6	2.1	1.2–3.7
Primigravida[b]	1.6	2.2	1.2–3.8
Not informed about iron sucrose treatment[c]	13.1	11.5	5.2–25.1

[a] Adjusted with gravida.
[b] Adjusted with age.
[c] Adjusted with non-availability of iron sucrose.

Slightly more than half of these women (51%) resided 5 km away from the health facilities, and the frequency of transport facility from their residence to the health facility and vice versa was less than 1 h. Fifty-eight percent of them were multigravida, and among them, one fourth have received iron sucrose in their previous pregnancies. Among the 350 study participants who were prescribed with iron sucrose injection, 89% (311 pregnant women) had received at least one dose of the injection during the current pregnancy. Among these 311 women, 41 (13.2%) had drug reactions during treatment. Majority (95%) of the participants were aware that they were suffering from anaemia and were informed about four doses of iron sucrose treatment (89%). Most of these women reported that medical officer was available (99.1%) and iron sucrose was in stock (98.9%) when they had visited the facility for iron sucrose treatment. The waiting period was less than 1 h for the majority (91%) of women who received the injection.

3.2. Compliance to iron sucrose treatment

Of the 350 women surveyed, 276 (79%) complied with iron sucrose treatment (95% CI: 73–84) (Design effect = 1.9). Of these 276 women, 31 (8.9%) received six doses. Among the 74 (21%) women who were non-compliant, 39 (11.1%) did not receive even one dose (Fig. 1).

Factors associated with non-compliance to intravenous iron sucrose treatment among the moderately anaemic pregnant women:

We identified that primigravida (OR 1.6, 95% CI: 1–2.8, PAR%: 15.6%), pregnant women who had drug reactions during treatment (OR: 6.1, 95% CI: 2.8–13.5, PAR%: 11.5%), non-availability of iron sucrose during their visit to the facility (OR: 12.1, 95% CI: 2.4–61.2, PAR%: 0.02%), unaware of their moderate anaemia status (OR: 5.2, 95% CI: 2–13.8, PAR%: 0.04%) and not informed about intravenous iron sucrose treatment (OR: 13.1, 95% CI: 6–28.2, PAR%: 0.1%) were factors associated with non-compliance to intravenous iron sucrose treatment (Table 2). We selected, "primigravida", "unaware of anaemia", and "not informed about intravenous iron sucrose injection" as parameters for multivariable analysis. In the multivariable analysis, we identified that primigravida [vs. Multigravida] (AOR: 2.2, 95% CI: 1.2–3.8, PAR%: 22.7%) and not informed about the iron sucrose treatment (AOR: 11.5, 95% CI: 5.2–25.1, PAR%: 0.1%) were independently associated with non-compliance to iron sucrose treatment (Table 3).

Self-reported reasons for non-compliance to iron sucrose treatment:

The primary reasons for non-compliance reported by those women who received one to three doses of intravenous iron sucrose injections were drug reactions (37%), followed by completion of treatment in private facilities (26%) and the belief that diet was better to improve the blood haemoglobin level than injections (26%). The major reasons among those who did not undergo the treatment were, not informed about iron sucrose treatment by the health providers (44%), followed by completion in private facilities (31%) and the belief that diet was better to improve the blood haemoglobin level than injections (23%) (Fig. 2).

4. Discussion

We surveyed moderately anaemic women attending public health facilities in Kancheepuram health district, Tamil Nadu. Over three-fourth women were compliant to the treatment of moderate anemia with iron sucrose injection. We identified that primigravida, drug reactions during treatment, non-availability of iron sucrose injections and not informed about treatment were significantly associated with non-compliance to iron sucrose treatment.

Compliance to intravenous iron sucrose in our study was 79%. It was higher than that found in other studies conducted in various parts of

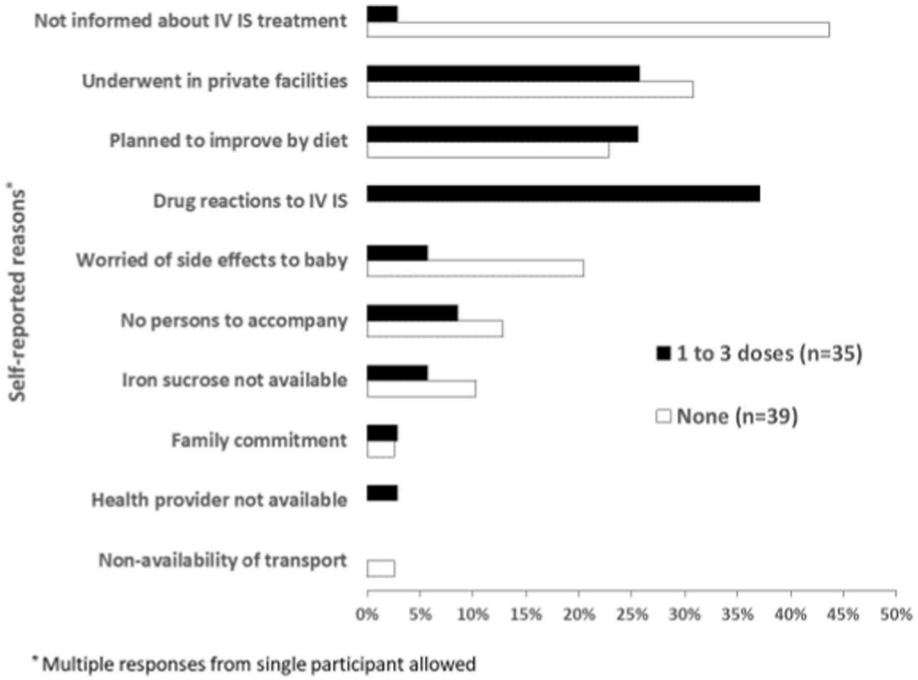

Fig. 2. Self-reported reasons for non-compliance to administration of intravenous iron sucrose for moderately anemic pregnant women (N = 350) attending public health facilities of Kancheepuram health district, Tamil Nadu, India, 2016–17.

India, where the compliance to oral tablets was between 62% and 65%.[16,17] The reason for this difference could be that our study participants were moderately anaemic. Hence they may be more symptomatic than participants in other studies which included mild anaemic pregnant women as well. Compliance to oral iron tablets was 66% according to a survey in Nigeria, which was lesser than what we estimated in our study.[18] This could be because our study participants were provided with the drugs free of cost. Primigravida women were more likely to be non-compliant, which is similar to a study done in South India with similar socio-demographic conditions.[17] In our study, when pregnant women were not informed about intravenous iron sucrose, they were more likely to be non-compliant. This finding was similar to that reported in studies from India and Africa.[16,19] We have compared the compliance of oral iron supplements with intravenous iron supplements, so the comparison may not be viable. Further studies are needed to increase the generalizability of these findings.

Our study has few limitations. Firstly, we anticipate that selection bias could have operated in two ways. We trained health workers to identify the anaemic status of pregnant women and then select the study participants. There is a possibility that the health workers might have enrolled study participant whom they thought would be more compliant to the injection. Hence, this could have led to an over-estimation of compliance. Secondly, we had assumed that women who had reported having treatment in private facilities as non-compliant (n = 21; 6%). However, we believe that this could have compensated for the over-estimate from the previous bias introduced by health workers to a certain extent. Despite these limitations, our study findings can be generalizable in the context of women seeking antenatal care in the district. The key strength of the study is that within a district health system context, we could answer the question that emerged from an earlier evaluation of high-risk pregnancy.[15] Through the evaluation, we did identify that poor compliance to iron sucrose treatment among moderately anemic pregnant women was an important problem. In the present study, we could pursue the reasons for non-compliance and generate evidence for the health system to target specific groups to improve compliance levels.

Based on our findings, we concluded that over three-fourth of the moderately anaemic pregnant women were compliant to intravenous iron sucrose treatment in public health facilities of Kancheepuram health unit district. Primi women of 25–35 years who received no information about the intravenous iron sucrose treatment were non-compliant.

To improve compliance to intravenous iron sucrose treatment for managing moderate anemia among pregnant women attending public health facilities, we recommend providing clear information with counselling about the intravenous iron sucrose treatment mainly targeting primi aged 25–35 years.

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