Chettinad Health City Medical Journal
Volume 11, Issue 3 - 2022, Pg. No. 43-47
Peer Reviewed & Open Access Journal

Research Article

Study of Compliance, Pattern of Treatment Interruption and Adverse Events Reported by Anaemic Pregnant Women Receiving the Parenteral Iron Sucrose Therapy

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DOI: https://doi.org/10.24321/2278.2044.202228

I N F O

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How to cite this article:
Singh A, Agrawal D, Goel PK. Study of Compliance, Pattern of Treatment Interruption and Adverse Events Reported by Anaemic Pregnant Women Receiving the Parenteral Iron Sucrose Therapy. Chettinad Health City Med J. 2022;11(3):43-47.

Date of Submission: 2022-06-04
Date of Acceptance: 2022-08-20

A B S T R A C T

Background: In spite of many efforts by the government since independence anaemia in pregnant women has shown resistance to improvement.

Aim: The main aim was to study the compliance of parenteral iron sucrose therapy in pregnant woman along with an additional objective which was to study the pattern of treatment interruption and adverse events observed by them.

Methods: This study was conducted by the Department of Community Medicine in the rural and urban field practice area of district Nuh. A list of three hundred and eighty four anaemic pregnant females put on IVIS therapy, fetched from the health centre and relevant details were documented.

Result: Out of total of 384 study participants, 291 (75.8%) were compliant with IVIS therapy i.e., they received all four doses. Out of total 93 either non-compliant or partially compliant subjects, most of them (51.6%, n=48) missed 3 doses whereas 22 participants (23.7%) missed 2 doses of the IVIS therapy. Ten study participants (10.7%) showed non-compliance to the therapy. Multigravida subjects were either non or partial compliant compared to primigravida. The three most common adverse events recorded at the time of infusion of 1st dose of IVIS therapy were swelling at injection site, pruritus, and muscle pain or joint pain experienced by 32 (8.3%), 17 (4.4%) and 16 (4.2%) study participants respectively.

Conclusion: IVIS therapy is relatively safe therapy and well tolerated by anaemic pregnant females when given as slow infusion. Multigravida subjects were either non or partial compliant compared to primigravida females for IVIS therapy.

Keywords: Moderate Anaemia, Parenteral Iron Therapy, Adverse Events, Compliance

Introduction

Anaemia remains a cause of high maternal and infant mortality in our country. During any stage of the pregnancy, 45.7% females in the age group of 15-49 years were diagnosed to have anaemia as per the national level health survey as per recent report.[1] Anaemia has been regarded as all-time risk factor for pregnancy.[2] Important causes for anaemia in typical Indian pregnant females are raising iron demand in the pregnancy, poor dietary intake for multiple reasons, repeated pregnancies without sufficient gap and already existing anaemia.[3] It is an established fact that maternal anaemia is an important risk factor for perinatal and infant mortality.[4] Most cases of anaemia in pregnancy are attributed to Iron deficiency in Indian scenario.

The state of Haryana adopted the Intravenous iron sucrose (IVIS) therapy in year 2014 and released the notification regarding the same in order to combat anaemia in pregnancy. Even after enormous effort by the government since independence this entity has shown resistance to improvement. Though improvement has been noted the results are not up to the expectations. Feedback is very important for any kind of improvement.

IVIS therapy is relatively a newer programme that has been rolled out by the health department to combat anaemia. There exists a scarcity of relevant data like compliance among pregnant females, and a pattern of treatment interruption & reporting of adverse events regarding IVIS therapy. On the other hand, the geographically and socio-culturally distinct area, triggered us to conduct this study. The main objective of this investigation was to study the compliance of parenteral iron sucrose therapy in pregnant woman along with the additional objective which was to study the pattern of treatment interruption along with adverse events observed by anaemic pregnant women receiving the said therapy.

Materials and Methods

This study was by conducted by Department of Community Medicine in the rural and urban field practice area of district Nuh. The study duration was six months from September 2020 to February 2021. The sample size was calculated (n = 384) considering the prevalence of compliance to IVIS therapy as 50% (as no literature available for the area) by applying the standard formula: $N = (Z^{1-a/2})^2 \times p(1-p)/d^2$; where Z = Standard normal variate for level of significance (at 5% Type I error [P <0.05], Z = 1.96, a = level of significance (0.05), d = absolute error (5%).

A multistage sampling technique was adopted. In the first stage, one community health centre was selected randomly. In the second stage, the first day of data collection was chosen randomly. In the third stage, subsequent days of data collection were decided on the basis of systematic random sampling.

A list of three hundred and eighty four anaemic pregnant females put on the IVIS therapy, and the list was fetched from the health centre. A questionnaire was framed for the purpose of capturing relevant details. Section 1 contained personal details and socio-demographic characteristics. Section 2 contained obstetrics history. Section 3 contained details regarding receipt of various doses of iron sucrose infusion and this section also contained adverse events reported by them.

Compliance, non-compliance and partial compliance were defined for the purpose of this study. Compliance to treatment was considered when pregnant women took all the 4 prescribed doses of the iron sucrose. Non- compliance to treatment was considered when pregnant women failed to take all the 4 prescribed doses of the iron sucrose. Partial compliance to treatment was considered when pregnant women failed to take < 4 prescribed doses of the iron sucrose.

Table 1. Distribution of Study Participants according to selected Socio-demographic Characteristics & Obstetrics History

Socio Demographic Variables	Number of Patients	Percentage
Age group		
<21 years	91	23.7
21-30 years	242	63.0
>30 years	51	13.3
Religion		
Muslim	314	81.8
Hindu	68	17.7
Sikh	2	0.5
Literacy status		
Illiterate	186	48.4
Literate	198	51.6
Age at first child birth		
≤ 21 years	237	61.7
> 21 years	147	38.3
Gravida status		
Primi gravida	89	23.2
Multigravida	295	76.8

Ethical clearance for the study was obtained from the Institutional Ethics Committee vide letter number EC/OA-37/2020. Data was entered into Microsoft excel sheet. Later on data was imported to statistical software. Statistical analysis was performed with SPSS software version 22.

ISSN: 2278-2044
DOI: https://doi.org/10.24321/2278.2044.202228

The interpretation of results was done with appropriate statistical tools.

Results

A majority of study participants (63%, n=242) were in the age group of 21-30 years. Religion wise, more than 80% of subjects were Muslim. 48.4% were illiterate. The age of the participants at first child birth was ≤ 21 years in 61.7% (*n*=237) subjects (Table 1).

Of a total of 384 study participants, 291 (75.8%) were compliant to IVIS therapy i.e., and received all four doses. The remaining 93 (24.2%) subjects were either non-compliant or partially compliant (Table 2).

Table 2.Distribution of study Participants according to Compliance to IVIS Therapy

Compliance to IVIS therapy in terms of adherence	Number of Patients	Percentage
Compliant or Adherent	291	75.8
Non/ partial Compliant or Adherent	93	24.2
Total	384	100.0

Out of a total of 93 either non-compliant or partially compliant subjects, most of them (51.6%, n=48) missed 3 doses whereas 22 participants (23.7%) missed 2 doses of the IVIS therapy. Ten study participants (10.7%) showed non-compliance to the therapy. Multigravida subjects were more non/partial compliant compared to primigravida (Table 3).

Table 3.Distribution of study Participants according to Pattern of Treatment Interruption

Pattern of treatment interruption	Primigravida	Multigravida	Total
Missed all 4 doses	3 (3.2%)	7 (7.5%)	10 (10.7%)
Missed 3 doses	14 15.1%)	34 (36.5%)	48 (51.6%)
Missed 2 doses	7 (7.5%)	15 (16.2%)	22 (23.7%)
Missed 1 dose	5 (5.4%)	8 (8.6%)	13 (14.0%)
Total	29 (31.2%)	64 (68.8%)	93 (100%)

The three most common adverse events recorded at the time of infusion of 1st dose of IVIS therapy were swelling at injection site, pruritus, and muscle pain/joint pain experienced by 32 (8.3%), 17 (4.4%) and 16 (4.2%) study participants respectively (Table 4).

Gravida and literacy status of mothers were found to be significantly associated with compliance to IVIS therapy. Multigravida mothers were found to be more compliant as compared to primigravida mothers. Similarly literate mothers were found to be more compliant as compared to illiterate mothers. The difference was found to be statistically significant (p< 0.001) (Table 5).

Table 4.Adverse events Recorded at the time of Infusion of IVIS therapy (n=384)

AdverseEvent	At the time of infusion of 1st dose of IVIS therapy Frequency (%)	At the time of infusion of subsequent dose of IVIS therapy Frequency (%)
Swelling at injection site	32 (8.3%)	25 (6.5%)
Pruritus	17 (4.4%)	12 (3.1%)
Muscle pain/ joint pain	16 (4.2%)	8 (2.1%)
Vertigo	12 (3.1%)	8 (2.1%)
Feeling of Chest compression	4 (1.0%)	2 (0.5%)
Blurred vision	3 (0.8%)	2 (0.5%)
Nausea	1 (0.3%)	1 (0.3%)
Vomiting	1 (0.3%)	0 (0.0%)
Multiple Responses Permitted		

Table 5.Association of Gravida and Literacy Status of Mother with Compliance to IVIS therapy

Variable	Compliant	Non/partial compliant	Total	Test of significance
Gravida status				
Primigravida	36 (9.4)	53 (13.8)	89 (23.2)	χ^2= 78.7984, df=1, p< 0.001
Multigravida	255 (66.4)	40 (10.4)	295 (76.8)	
Total	291 (75.8)	93 (24.2)	384 (100.0)	
Literacy status				
Illiterate	127 (33.1)	59 (15.4)	186 (48.4)	χ^2= 11.0607, df=1, p< 0.001
Literate	164 (42.7)	34 (8.8)	198 (51.6)	
Total	291 (75.8)	93 (24.2)	384 (100.0)	

ISSN: 2278-2044
DOI: https://doi.org/10.24321/2278.2044.202228

Discussion

This investigation was a modest attempt to fetch information about adherence and safety profile of iron sucrose therapy in peripheral the government health care setup with a view to improvise it. In this study we observed that of total 384 study participants, 291 (75.8%) were compliant to IVIS therapy i.e., received all four doses. Authors find it difficult to compare with findings of other studies because of scarcity of literature on the topic. However another study by Jogia AD et al. from Gujarat observed that compliance to four doses was 77.6%. In other words, 22.4% (68/304) subjects were non-compliant or partial-compliant.[5] Another difficulty faced by authors was the use of different operational definitions in various studies. Without uniform operational definition it becomes difficult to compare the findings.

Niveditha D et al. studied the usage of iron sucrose among anaemic pregnant females from two states of India i.e. Uttar Pradesh and Tamil Nadu.[6] We did not find operational definitional used by them however the study observed that in the state of Uttar Pradesh, 46% of study subjects received only one dose of iron sucrose. Similarly 15% of study participants received one dose in the state of Tamil Nadu. In this study we observed that of total 384 study participants, 48 received one dose.

Regarding adverse events, this study observed the three most common adverse events recorded at the time of infusion of 1st dose of IVIS therapy were swelling at injection site, pruritus, and muscle pain/joint pain experienced by 32 (8.3%), 17 (4.4%) and 16 (4.2%) study participants respectively. Gupta U et al. from Lucknow conducted a prospective study among thirty six pregnant women and noted down minor side effects among them. One patient reported headache and pain at injection site. Two patients reported warm tingling sensation whereas three subjects informed about metallic taste.[7] Neeru S et al. conducted a study comparing the oral iron versus intravenous iron sucrose among 100 subjects at KMC hospital at Karnataka. Subjects in iron sucrose group reported minor adverse events like vomiting and rashes.[8] Unpleasant metallic taste has been observed as a side effect in various studies along with flushing during transfusion, cough, vomiting, pruritus and muscle pain.[9-10]

Better tolerance of iron sucrose depends on slower delivery of iron from the iron sucrose complex as well as low allergenicity of sucrose. As per the available literature, only one report of death from IVIS therapy has been documented.[5] As per the guidelines, iron sucrose 100 mg must be given as slow infusion with 100 ml normal saline.

This study observed association of gravida and literacy status of mother with compliance to IVIS therapy. It was found that gravida and literacy status of mothers were found to be significantly associated with compliance to IVIS therapy. Authors did not find any other study compare this finding.

Conclusion

IVIS therapy is a relatively safe therapy and well tolerated by anaemic pregnant females when given as slow infusion. Multigravida subjects were more compliant compared to primigravida females. Targeted counselling activities can improvise compliance among multigravida women.

Conflicts of Interest: None

References

1. International Institute of Population Sciences (IIPS) National Family Health Survey (NFHS) 5 Fact Sheets [Accessed on May 21, 2021]. Available from: http://rchiips.org/nfhs/factsheet_NFHS-5.shtml.
2. Singal N, Setia G, Taneja BK, Singal KK. Factors associated with maternal anaemia among pregnant women in rural India. BJMS. 2018 Sep;17(4):583-92. [Google Scholar]
3. Vindhya J, Nath A, Murthy GV, Metgud C, Sheeba B, Shubhashree V, Srinivas P. Prevalence and risk factors of anemia among pregnant women attending a public- sector hospital in Bangalore, South India. J Family Med Prim Care. 2019 Jan;8(1):37-43. [PubMed] [Google Scholar]
4. Rahman MA, Khan MN, Rahman MM. Maternal anaemia and risk of adverse obstetric and neonatal outcomes in South Asian countries: a systematic review and meta-analysis. Public Health Pract (Oxf). 2020 Jun;1:100021. [PubMed] [Google Scholar]
5. Jogia AD, Kanabar BR, Rathod JB. A prospective study of adverse effects and compliance of intravenous iron sucrose for the treatment of severe anemia in ante-and post-natal women. Int J Med Sci Public Health. 2017 Mar;6(3):489-92. [Google Scholar]
6. Devasenapathy N, Singh R, Moodbidri P, Bhushan H, Gupta S, Zodpey SP, Neogi SB. An observational study on the use of IV iron sucrose among anaemic pregnant women in government healthcare facilities from two states of India. J Obstet Gynaecol India. 2015 Jul;65(4):230-5. [PubMed] [Google Scholar]
7. Uma G, Kumkum S, Aditi D, Ayesha A, Kumar GN. Efficacy and safety of intravenous iron sucrose for treating anemia in pregnancy: a pilot study. J Evol Med Dent Sci. 2013 Jul;2(27):5007-13. [Google Scholar]
8. Neeru S, Nair NS, Rai L. Iron sucrose versus oral iron therapy in pregnancy anemia. Indian J Community Med. 2012 Oct;37(4):214-8. [PubMed] [Google Scholar]
9. Reveiz L, Gyte GM, Cuervo LG, Casasbuenas A.

Treatments for iron-deficiency anaemia in pregnancy. Cochrane Database Syst Rev. 2007;2:CD003094. [PubMed] [Google Scholar]

10. Perewusnyk G, Huch R, Huch A, Breymann C. Parenteral iron therapy in obstetrics: 8 years experience with iron-sucrose complex. Br J Nutr. 2002 Jul;88:3-10. [PubMed] [Google Scholar]
11. Das SN, Devi A, Mohanta BB, Choudhury A, Swain A, Thatoi PK. Oral versus intravenous iron therapy in iron deficiency anaemia: An observational study. J Family Med Prim Care. 2020 Jul;9(7):3619-22. [PubMed] [Google Scholar]

ISSN: 2278-2044
DOI: https://doi.org/10.24321/2278.2044.202228