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Original Research Article

COMPARISON OF INTRAVENOUS IRON SUCROSE INFUSION AND INTRAMUSCULAR VITAMIN B12 INJECTION VS INTRAVENOUS IRON SUCROSE IN MANAGEMENT OF IRON DEFICIENCY ANAEMIA IN PREGNANT WOMEN

[1]Dr. Neha Shakya, [2]Dr. Anmol Wadhwani, [3]Professor, Dr. Neelam Rajput, [4]Dr Neelu Rajput

[1]PG Resident Department of Obstetrics and Gynaecology GRMC Gwalior.
[2]PG Resident Department of Obstetrics and Gynaecology GRMC Gwalior.
[3]MBBS, MS Obstetrics And Gynaecology, Professor Department of Obstetrics And Gynaecology, GRMC Gwalior.
[4]MBBS, MS Obstetrics and Gynaecology , assistant Professor, Department of Obstetrics and Gynaecology, GRMC Gwalior

Corresponding Author*: Dr. Neelam Rajput

ABSTRACT

Background-Anemia is defined by World Health Organization as Hb level < 11gm/dl. It is one of the most serious global public health problem affects 52%of pregnant women in developing and 23% in developed countries. The objective of this study was to determine the effectiveness of IV iron sucrose and IM vitamin B12 vs IV iron sucrose in IDA during pregnancy and to determine the safety of IV iron sucrose and vitamin B12 in the treatment of IDA during pregnancy and comparison of side effects in both groups

Material and Method – A comparative prospective study, where 200 anemic antenatal women with hemoglobin level of 6.5-8.5 g/dl with microcytic hypochromic anemia having s. ferritin <15 ng/ml were randomized in two groups. This study was carried out in the Department of Obstetrics and Gynaecology, Kamla Raja Hospital, G.R.M.C, Gwalior, M.P. The study was conducted with data collection for a period of November 2020 to October 2022.

Results-The mean baseline s.ferritin is 12.40 ±2.09 and 13.16 ±1.57 in groupA and groups B respectively. Post treatment average rise of s.ferritin is 129.8 and 13.16 in group A and group B respectively (p value 0.0001), which is significant. In our study Hb rise by 3.34gm% ingroup A and 3.11 gm% in group B which is significant.In our study most of the patients were muligravida.In our study Hb, s ferritin and mcv rises more in group A which receives vitamin B12 as compared to group B[Hb 3.34gm%,mcv-7fl, s.ferritin 129.8mg/l in group A and in group B Hb3.11gm%,mcv4.74fl,s.ferritin 101.8mg/l

Conclusion- This study concluded that intravenous iron sucrose and intramuscular vitamin B12 is safe, highly efficacious with better compliance for the treatment of iron deficiency anemia in pregnancy. Iron sucrose with vitamin B12 therapy is more effective in achieving the optimum results, an increase in hemoglobin concentration, mean corpuscular volume levels and an increase in s.ferritin.

Keywords: -IDA-Iron Deficiency anemia, iron sucrose,vitamin B12,Pregnant Women.

1. Introduction

Anemia is defined by World Health Organization as Hb level < 11gm/dl. It is one of the most serious global public health problem affects 52%of pregnant women in developing and 23% in developed countries(Cochrane Data Review).(1)In under developed countries anemia is

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major contributing factor to higher maternal and perinatal morbidity, mortality rate.Anemia in pregnancy is associated with an increased risk of preterm delivery, low birth weight, asphyxia, prolonged labour, PROM, PIH, APH,PPH and maternal mortality (Harvey LJ –

	GroupA	Group B	P-value

Dainty JR, Hollands WJ, et al)(.2)Iron is an essential component of Hb (i.e. oxygen carrying pigment in blood). The pregnant women need 1000 mg of iron all through i.e. 3-5mg/day to maintain iron balance. This demand increases to 6-6.7 mg/day during later half pregnancy and for several weeks after delivery.Iron is essential to life because of its unique ability to serve as both an electron donor and acceptor. This is the study comparing the effectiveness, tolerability and safety of the two drugs IV iron sucrose and IM vitamin B12 in the treatment of iron deficiency anemia in pregnant women.

2. Material and Methods

This study was a Prospective CASE CONTROL comparative study. The study was carried out in the Department of Obstetrics and Gynaecology, Kamla Raja Hospital, G.R.M.C, Gwalior, M.P. The study was conducted with data collection for a period ofNovember 2020 to October 2022. Total 200 cases were taken in this study (100Cases in group A and 100 cases in group B

Inclusion criteria: Peripheral smear – Microcytic hypochromic anemia Hb level between 6.5 to 8.5 g/dl Gestational age between 13 wk – 30 wk Singleton pregnancy Serum ferritine < 15 ng / ml

Exclusion criteria: Refusal of consent for study Gestational age < 13 weeks and >30 weeks Multiple pregnancy Placenta previa/abruption placenta S. anaemia Hb <6.5 gm/dl Any associated medical disorder Hypersensitivity reaction to Iron sucrose

Method

This prospective study, where 200 anemic antenatal women with hemoglobin level of 6.5-8.5 g/dl with microcytic hypochromic anemia having s. ferritin <15 ng/ml were randomized in two groups. Prior to the study tablet albendazole 400 mg given in both groups.In group A (n=100) the women received IV iron sucrose infusion (200mg in 100 ml normal saline) and vitamin B12 (IM) 2 ml daily for 5 days aIn group B (n=100) only IV iron sucrose is given.

Formula for calculation of Iron requirement :(2.4 x (target Hb-actual Hb) x pre pregnancy weight (kg)) + 1000 mg.Primary outcome is measured as treatment efficacy associated by measurement of Hb ,s.ferritin,cbc ,peripheral smear

3. Observation and Results

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	Frequency	Percent	Frequency	percent	
General weakness	88	88.0	80	80.0	
General weakness loss of apetite	12	12.0	20	20.0	0.238
Total	100	100.0	100	100.0	

Table 1: Symptoms wise distribution of participants

Table 2 : Age wise distribution of study participan

	GroupA		Group B	
	Frequency	Percent	Frequency	Percent
≤ 20 years	25	25.0	20	20.0
21-25years	54	54.0	48	48.0
26-30years	16	16.0	25	25.0
>30years	5	5.0	7	7.0
Total	100	100.0	100	100.0

According to our study population, Highest number of percentage observed in the age group of 21-25 years of both the groups A (54%) and B (48%).

Table 3 : Distribution of cases according to booking status

	GroupA		Group B		P-value
	Frequency	Percent	Frequency	Percent	0.368
Booked	36	36.0	30	30.0	
Unbooked	64	64.0	70	70.0	
Total	100	100.0	100	100.0	

	GroupA		Group B		P-value
	Frequency	Percent	Frequency	Percent	
Chills	1	1.0	4	4.0	0.175

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Pain	3	3.0	2	2.0	0.651
Thrombophlebitis	3	3.0	2	2.0	0.651
Gastritis	0	0	0	0	-
Nausea	0	0	0	0	-
None	93	93.0	92	92.0	0.788
Total	100	100.0	100	100.0	

Table 4 : Distribution of cases according to side effects status

Table 5 : Distribution of cases on the basis of diet

	GroupA		Group B		P-value
	Frequency	Percent	Frequency	Percent	0.451
Non-Vegetarian	30	30.0	35	35.0	
Vegetarian	70	70.0	65	65.0	
Total	100	100.0	100	100.0	

Table 6 : Distribution of cases on the basis of signs

	GroupA		Group B		P-value
	Frequency	Percent	Frequency	Percent	
Pallor	89	89.0	80	80.0	0.079
Pallor,Edema	9	9.0	18	18.0	0.042
Pallor,Spherocytosis	2	2.0	2	2.0	1.000
Koilonychia	0	0	0	0	-
Total	100	100.0	100	100.0	

Table 7 : Distribution of cases on the basis of education

	GroupA		Group B		P-value
	Frequency	Percent	Frequency	Percent	0.254

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Illiterate	61	61.0	53	53.0	
Literate	39	39.0	47	47.0	
Total	100	100.0	100	100.0	

In our study majority of women were in the age group of 21 - 25 years and maximum number of patients were multigravida(In group A 66.% were multigravidas and in group b were 60%). In this study the most of the patients are gestational age of between 25 to 30 in both groups. Most of the pts were unbooked 64% in group A and 70% in group B as there is no history of antenatal checkup in 1st trimester. In our study 70% patients were vegetarian in group A and 65% in group B this is explained by that iron and vitamin B12 deficiency is more common in vegetarians as compared to non- vegetarians. Present study shows that shorter interpregnancy interval increases risk of anemia in pregnancy There are no serious adverse effects in the study, however some pt complains of chills, pain, thrombophlebitis which were insignificant.

Table 8: Comparison pre and post values of hemoglobin, MCV and serum ferritin Group –A (Paired t-test)

	Pre	Post	p-value
Hemoglobin	8.02 ± 0.40	11.36± 0.49	<0.0001
MCV	80.55 ± 4.30	87.55± 2.59	<0.0001
Ferritin	12.40± 2.09	142± 100.2	<0.0001

Among group-A cases, Hemoglobin (p=<0.0001), MCV (p=<0.0001) and Ferritin (p=<0.0001) were significantly increased in post treatment period observation.

Table 9: Comparison pre and post values of hemoglobin, MCV and serum ferritin Group –B (Paired t-test)

	Pre	Post	p-value
Hemoglobin	8.0 ± 0.50	10.81± 0.68	<0.0001
MCV	79.74 ± 4.79	84.58± 8.05	<0.0001
Ferritin	13.16± 1.57	114.9± 19.9	<0.0001

Among group-B cases, Hemoglobin (p=<0.0001), MCV (p=<0.0001) and Ferritin (p=<0.0001) were significantly increased during pre to post treatment period observation.

Table 10 : Comparison of pre and post mean values In group A and group B (Independent t-test)

	Group A	**Group B**	**p-value**
Age	23.14 ± 3.41	23.94 ± 3.75	0.1160
Pre Hb	8.02± 0.40	8.0 ± 0.50	<0.0001

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Pre MCV	80.55± 4.30	79.7 ± 4.79	0.2101
Pre Ferritin	12.40 ± 2.09	13.1± 1.57	0.0040
Post Hb	11.36 ± 0.49	10.8 ± 0.68	<0.0001
Post MCV	87.55 ± 2.59	84.5 ± 8.05	<0.0001
Post ferritin	142.2 ± 100.2	114 ± 19.9	0.0080

According to our data analysis, Age and MCV(Pre treatment) were no significant difference observed in both the groups. However, During post treatment period of MCV were observed significant difference in Group-A compared to Group-B(p=<0.0001).
It was observed that During post treatment period Group-A patients Hemoglobin highly significant difference observed compared to Group-B(p=<0.0001)..During post treatment period Group-A patients of ferritin highly significant difference observed compared to Group-B(p=0.0080).

Table 11 : Comparison of hemoglobin percent pre treatment vs post treatment in group A and group B

	Pre	**Post**
Hb(Group A)	8.02± 0.40	11.36± 0.49
Hb(GroupB)	8.00 ± 0.50	10.81 ± 0.68

Table 11 shows mean hemoglobin 8.02 g% pretreatment and 11.36g% post treatment in Group-A and therefore a rise by 3.34 g% in 6 weeks.The mean hemoglobin 8.0 g% pretreatment and 10.81 g% post treatment inGroup-B and therefore a rise by 3.11 g% in 6 weeks. This is statistically Significant

Table 12 : Comparison of MCV percent pre treatment vs post treatment in group A and group B

	Pre	**Post**
MCV(GroupA)	80.55 ± 4.30	87.55± 2.59
MCV(GroupB)	79.74 ± 4.79	84.58 ± 8.05

Table 12 shows mean MCV 80.55 fl pretreatment and 87.55 fl posttreatment in Group-A and therefore a rise by 7 fl in 6 weeks. The meanMCV 79.74 fl pretreatment and 84.58 fl post treatment in Group-B and therefore a rise by 4.74 fl in 6 weeks. This is statistically significant

Table 13 : Comparison of serum ferritin percent pre treatment vs post treatment in group A and group B

	Pre	**Post**
Ferritin(GroupA)	12.40± 2.09	142.2± 100.2
Ferritin(GroupB)	13.16± 1.57	114.9 ± 19.97

Table13 shows mean ferritin 12.40 mg/l pretreatment and 142.20mg/l % post treatment in Group-A and therefore a rise by 129.8 mg/l in 6weeks. The mean ferritin 13.16 mg/l

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pretreatment and 114.99 mg/l posttreatment in Group-B and therefore a rise by 101.83 mg/l in 6 weeks. This is statistically significant.

4. Discussion

This prospective case control study was conducted in Obstetrics & Gynaecology Department, Kamla Raja Hospital, GRMC Gwalior. The aimof the study was to determine the effectiveness of IV iron sucrose and IM vitamin B12 vs intravenous iron sucrose in iron deficiency anemia during pregnancy and to determine the safety of intravenous iron sucrose and vitamin B12 in the treatment of iron deficiency anemia in pregnancy .The characteristics of patients in group A and in group B were statistically comparable in relation to age. In the study majority of women were in the age group of 21 - 25 years. Prevalence of anemia is more in reproductive years.

In our study maximum number of patients were multigravida. This is explained by high prevalence of iron deficiency anemia in multigravida due to less spacing between pregnancy, less calorie intake, more number of children (In our study in group A 66.% were multigravidas and in group b were 60%). When these anemic women become pregnant their anemia will be aggravated by increased need of iron during pregnancy.

In the present study the most of the patients are gestational age of between 25 to 30 in both groups this is explained by the increase demand from the second trimester in pregnant women because more number of patients reported to hospital in 2nd and 3rd trimester and increased demand of iron in diet as pregnancy advances.

Most of the pts were unbooked 64% in group A and 70% in group B as there is no history of antenatal checkup in 1st trimester. In our study 70% patients were vegetarian in group A and 65% in group B this is explained by that iron and vitamin B12 deficiency is more common in vegetarians as compared to non- vegetarians. Present study shows that shorter interpregnancy interval increases risk of anemia in pregnancy as women enters pregnancy in iron deficient state which is aggravated due to increased demand.44% pts in group A and 40% in group B have shorter interpregnancy interval[less than 3yrs].

There are no serious adverse effects in the study, however some pt complains of chills, pain, thrombophlebitis which were insignificant. In our study all pts give history of general weakness .Among 200 patients studied 89% in group A and 80% in group B showing presence of pallor on general physical examination in either groups respectively, and pallor with edema.in 9% in group A and 18% in group B,pallor with sperocytosis 2% in both groups.In our study, the mean baseline hemoglobin was 8.02 ±0.40 and 8.0g/dl ±0.50 in group A and group B respectively. Post treatment hemoglobin after 6 weeks showed a mean value of 11.36 ± 0.49 gm/dl and 10.81 ± 0.68gm/dl in group A and group B respectively (p value <0.0001),which is statistically significant. The average rise of hemoglobin is 3.34gm% and 3.11 gm% in group A and group B respectively[p value<0.0001 which is significant.The mean baseline s.ferritin is 12.40 ±2.09 and 13.16 ±1.57 in groupA and groups B respectively. Post treatment s.ferritin 142.2 ± 100.2 and 114.99 ± 19.97 group A and group B respectively after 6 weeks showed, an average rise of s.ferritin is 129.8 and 13.16 in group A and group B respectively (p value 0.0001), which is statistically significant.The mean baseline MCV is 80.55 ± 4.30fl and 79.74 ± 4.79fl in group A and group B respectively. Post treatment MCV after 6 weeks showed an average rise of 7fl and 4.74fl ± in group A and group B respectively (p value 0.0001), which is statistically significant.Most of the pts were of lower socio economic standards[70% were of class 5in group A ,64% in group B] and illiterate[61% in group A and 53%in group B .our study is also comparable with other studies. Mirza Zec at al reported that giving vitamin B12 in addition to folic acid and iron improves haematogical

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markers(15), In our study Hb, s ferritin and mcv rises more in group A which receives vitamin B12 as compared to group B[Hb 3.34gm%, mcv-7fl, s.ferritin 129.8mg/l in group A and in group B Hb3.11gm%,mcv4.74fl,s.ferritin 101.8mg/l. PG Bansal et al reported better s.ferritin status in adolescent girls receiving vitamin B12 with weekly iron folic acid as compared to those who receives only iron folic acid,in our study s.ferritin improves more in group A as compared to group B[s.ferritin 129.8mg/l in group A and s.ferritin 101.8mg/l in group B after 6 weeks](16) Shruti B et al reported a significant rise in Hb value in IV iron sucrose group(8), Milman N et al also reported rise in Hb more rapidly in intravenous iron group as compared to oral iron. In our study Hb rise by 3.34gm% in group A and 3.11 gm% in group B which is significant.Armond Ugon et al reported by giving iron sucrose in treatment of postpartum anemia Hb rises by 2.1gm% and s. ferritin value also improves in our study hb ,s ferritin and mcv rises which were significant [Hb3.34gm%,mcv-7fl,s.ferritin 129.8mg/l in group A and in group B Hb3.11gm%,mcv4.74fl,s.ferritin 101.8mg.Gi Annouli.C Danillidis(9) et al reported IV iron sucrose in treatment of iron deficiency anemia increases mean Hb by 3.3gm% after 6 weeks . In our study Hb rise by 3.34gm% in group A and 3.11 gm% in group B which is significant.

5. Conclusion

This study concluded that intravenous iron sucrose and intramuscular vitamin B12 is safe, highly efficacious with better compliance for the treatment of iron deficiency anemia in pregnancy. Iron sucrose with vitamin B12 therapy is more effective in achieving the optimum results, an increase in hemoglobin concentration, mean corpuscular volume levels and an increase in s.ferritin. Therefore it is a suitable alternative to iron sucrose alone in treatment of iron deficiency anemia.

Approval from Ethical Committee

Ethical approval was obtained from the institutional Ethical Committee of GAJRA RAJA MEDICAL COLLEGE AND JAYA AROGYA GROUP OF HOSPITALS,KAMLARAJA HOSPITAL veer sawarkar marg GWALIOR Our Ethical Committee certificate number is 21/IEC-GRMC/2020 .Consent was obtained from participants.data analysis and interpretation was done by paired and independent t test(Software:SPSS26.0version,IBM)

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