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RESEARCH ARTICLE

COMPARATIVE STUDY OF INTRAVENOUS IRON SUCROSE AND ORAL IRON FOR THE TREATMENT OF ANEMIA IN PREGNANCY

Dr. B. Manjulatha, Dr. P. Padmasri and *Dr. T. Prathibha Sravanthi

Department of Obstetrics and Gynecology, S.V.Medical College, Tirupati

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ABSTRACT

Anemia is directly or indirectly responsible for 40% of maternal mortality in India. In spite of National anemia control programme the prevalence of Iron deficiency anemia in pregnant women continues to be high in our country. The present study was conducted in Government Maternity Hospital, S.V. Medical College, Tirupati to compare the efficacy of Oral iron and Intravenous iron sucrose. Intravenous iron sucrose administration showed statistically significant improvement in hemoglobin level of 2.95gm/dl and PCV rise of 7.34% within a short time, compared to oral iron. Target level of hemoglobin i.e. 11gm% was achieved in 34% of women given intravenous iron sucrose, compared to none in oral group within a period of six weeks. In view of the failure of oral iron in the correction of anemia to significant extent in pregnant women with moderate anemia intravenous administration of iron under supervision is a better alternative for women with moderate anemia.

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INTRODUCTION

Iron deficiency anemia (IDA) is the most common anemia in pregnant women. According to WHO, the prevalence of IDA is about 18% in developed countries and 35-75% in developing countries, in India the prevalence is between 33-89%.[1] About half of the global maternal deaths due to anemia occur in south Asian countries and India contributes about 80% of this mortality. Anemia occurs at all stages of life cycle but is more prevalent in pregnant women and young children. In 2002 IDA was considered as most important contributing factor to the global burden of diseases. In India, anemia is directly or indirectly responsible for 40% of maternal deaths. There is 8-10 fold increase in maternal mortality when the Hb falls below 5g/dl. Hence, early detection and effective management of anemia in pregnancy is required to reduce maternal mortality. (Kalaivani, 2009)

MATERIALS AND METHODS

The study was conducted at Government Maternity Hospital, S. V. Medical College, Tirupati from January 2014 to November 2014. Pregnant women attending the antenatal clinic, having anemia with Hb 6.5gm/dl to 8.5gm/dl, with gestational age of 20-32wks were included in the study after explaining the procedure and obtaining informed consent.

**Corresponding author: Dr. T. Prathibha Sravanthi*
Department of Obstetrics & Gynecology, S.V.Medical College, Tirupati

Study design: Prospective comparative study.

Sample size: 100 pregnant women (50 in each group)

Inclusion criteria

- Singleton pregnancy.
- Gestational age of 20-32weeks.
- Hemoglobin concentration of 6.5-8.5gm%.
- Willing for enrollment into the study.
- Likely to come for follow up.

Exclusion criteria

- Those known to be allergic to parenteral iron.
- Medical disorders like tuberculosis, diabetes, renal and hepatic failure.
- Patients with Hb<6.5 or >8.5gm%
- Patients with obstetrical complications like PIH, APH, multiple pregnancy etc.
- Patients with acute and chronic infections.

Study method

The study was conducted after obtaining ethical clearance from concerned ethical committee. The data for the study was

collected from subjects fulfilling inclusion criteria, after detailed history and examination of the patient, the women were divided into 2 groups (50 each).

Oral group: Oral ferrous sulfate group.

I.V. group: I.V. iron sucrose group.

Oral group: They received ferrous sulfate 200mg containing 60mg of elemental iron BD orally for 4wks. Patients were instructed to take the tablets with empty stomach and also instructed not to take coffee or tea after taking tablets. Hb and PCV was repeated 1wk, 3wks & 6wks after completion of 4wks of oral treatment.

IV group: They received iron sucrose intravenously .Total dose was calculated by using the following formula.

Body weight (kg) X (target Hb – actual Hb) g/dl X 0.24 + 500mg

Rounded up to the nearest multiples of 100mg. In the formula weight represented the patient's weight before pregnancy in kilograms. Target hemoglobin is 11g/dl.

Calculated dose of iron sucrose was given in divided doses thrice weekly, 200mg of iron sucrose was mixed in 200ml of normal saline, the first 12.5ml was infused intravenously over a period of 15min, if there were no adverse reactions the remaining amount was infused over 30min period. No test dose was given, additional oral iron was not administered during the study. Patients were closely monitored for any adverse reactions and emergency drugs like steroids, antihistamines and antipyretics were kept ready. If there were any reactions drip was stopped immediately and treated accordingly. Hb and PCV was repeated 1wk, 3wks & 6wks after completion of I.V. Iron sucrose treatment.

Visit I: (Base line)

Detailed information was obtained. Thorough general physical examination and detailed obstetric examination was done. Pre investigations done for each patient include the following:

1) Hb by sahlis method
2) PCV
3) Peripheral Smear
4) Urine examination
5) Stool for ova, cyst

All the women were given 500µgm folic acid daily. Deworming was done with mebendazole 100mgBD for 3days. They were explained about repeating the investigations during follow-up visits.

Follow Up Visits: 1st week, 3rd week and 6th week after completion of treatment

1) Patients were enquired about adverse reactions,
2) General physical examination, obstetric examination was done
3) Hb and PCV repeated.

OBSERVATIONS AND RESULTS

In Oral group – age of cases were ranging from 19-30 years with mean age of 23.12 years. And in IV group age of cases were ranging from 19-31 years with mean age of 23.68 years.

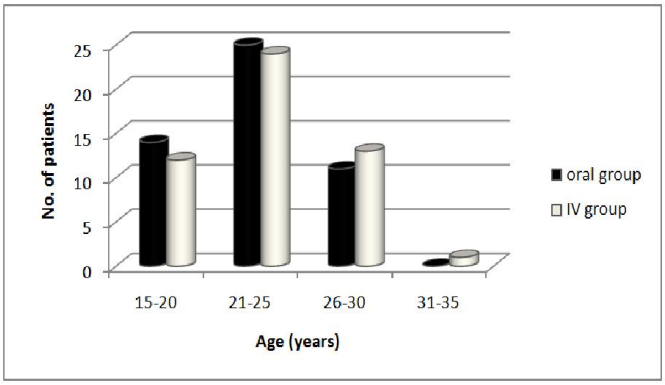

Fig. 1. Age wise distribution of cases

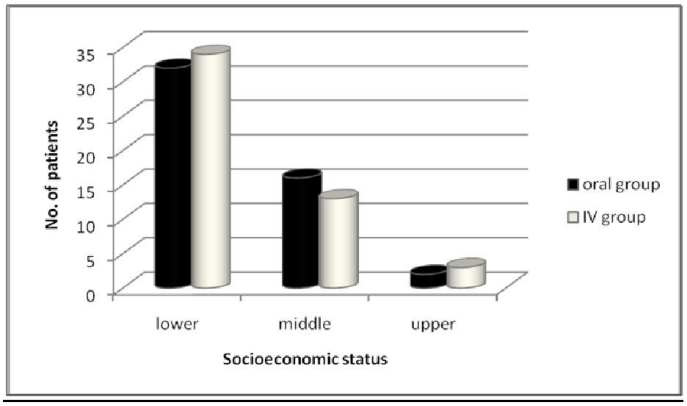

Fig. 2. Distribution of patients according to socioeconomic status

Majority of study group belong to low and middle socioeconomic status.

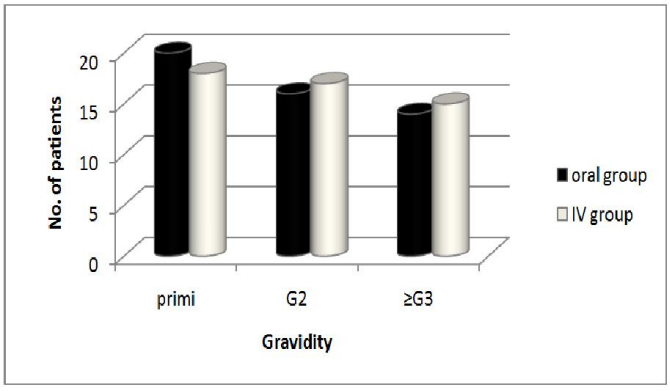

Fig. 3. Distribution of patients according to gravidity

Among the study population in Oral group 40% were Primigravida, 32% were Gravida-2, 28% were Gravida-3 or more. In IV group 36% were Primigravida, 34% were Gravida-2, 30% were

Gravida-3 or more

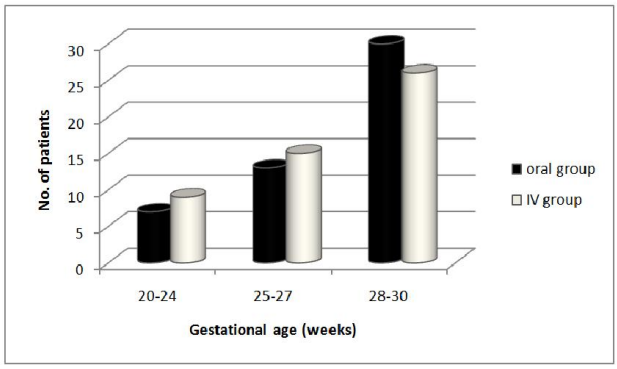

Fig. 4. Distribution of patients according to gestational age

The range of gestational age at the time of inclusion in to the study was 20-32 weeks. In oral group mean gestational age is 27.92 weeks and in IV group mean gestational age 27.42 weeks.

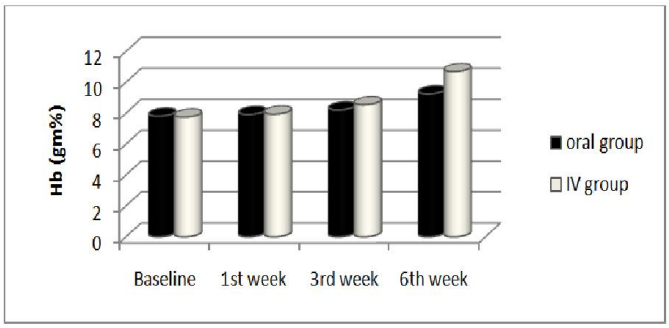

Fig. 5. Comparision of Haemoglobin percentage during different visits in both groups

The mean baseline hemoglobin was 7.82 and 7.75g/dl in Oral and IV group respectively. Post treatment, after 1 week hemoglobin (Hb) showed a mean value of 7.93 and 7.95g/dl in Oral and IV group respectively (p value 0.838), which was statistically not significant. Post treatment, after 3 weeks Hb, showed a mean value of 8.22 and 8.55g/dl in Oral and IV group respectively (p value 0.002), which was statistically significant. Post treatment, after 6 weeks Hb showed a mean value of 9.26 and 10.7g/dl in oral and IV group respectively (p value < 0.001), which was statistically highly significant.

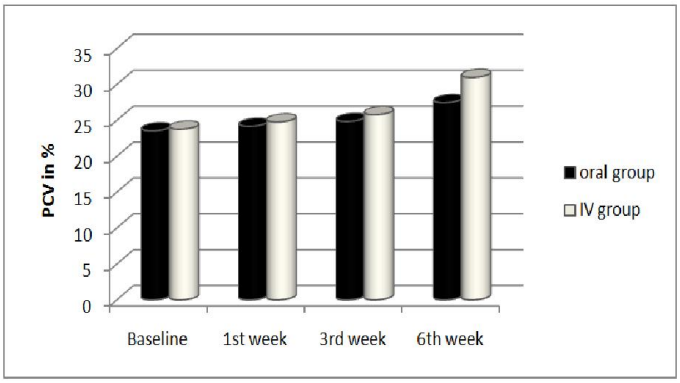

Fig.6. Comparision of PCV percentage during different visits in both groups

The mean baseline PCV was 23.52 and 23.64 in oral and IV group respectively.

Post treatment PCV after 1 week showed a mean value of 24.16 and 24.76 in Oral and I.V. Group respectively (p value 0.076), which was statistically not significant.

Post treatment PCV after 3 weeks showed a mean value of 24.84 and 25.78 in Oral and I.V. Group respectively (p value 0.001), which was statistically significant.

Post treatment PCV after 6 weeks showed a mean value of 27.46 and 30.98 in Oral and I.V. Group respectively (p value <0.001), which was statistically highly significant.

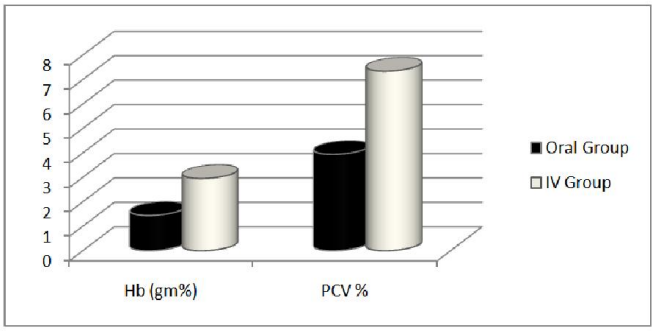

Fig. 7. Comparision rise of Haemoglobin and PCV between oral and iv groups at the end of the study

The rise of Hb from baseline, in Oral group is 1.44gm/dl where as in I.V group it is 2.95gm/dl. The rise of PCV, in Oral group is 3.94% where as in I.V. group it is 7.34%. A significant rise of 1.51gm/dl hemoglobin (more than in oral group) and 3.40% PCV (more than in oral group) was observed in IV group (p value <0.001), which is statistically highly significant.

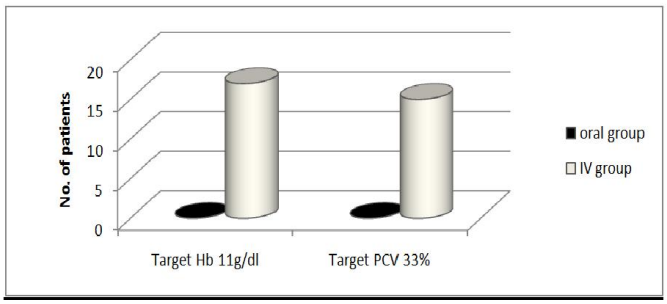

Fig.8. Comparision of target Haemoglobin and PCV between oral and iv groups at the end of the study

17 patients have reached target Hb i.e. 11g/dl and target PCV i.e. 33% in IV group, but none of the patients were reached either target Hb or PCV in Oral group.

Table 1. Adverse reactions

Adverse reactions	Oral group	IV group
Nausea/vomiting	6	0
Epigastric pain	2	0
Constipation	2	0
Thrombophlebitis	0	1
Rashes	0	0
Myalgia	0	1
Fever	0	1
Chills	0	1
Hypotension	0	0
Total	10	4

There were no serious adverse effects in the study, however 10 pregnant women out of 50 in Oral group and 4 out of 50 in IV group had minimal side effects, they continued with the study.

ANALYSIS AND DISCUSSION

It is paradoxical that while iron is one of the least expensive and most readily available medicinal substance, its deficiency particularly in the female population still presents serious problems. Patients often present themselves with severe anemia in pregnancy, this is particularly a problem in the developing countries where nutrition, mass education and availability of blood are far from satisfactory. Low availability and poor absorption of iron and repeated and closely spaced pregnancies place a constant drain on the iron stores of pregnant women resulting in development of IDA. (Kumar *et al*., 2005) Studies have shown that Hb levels <8gm% (moderate to severe anemia) in pregnancy are associated with higher maternal morbidity. Hb <5gm/dl is associated with cardiac decompensation and pulmonary edema. Blood loss of even 200ml in third stage of labor can cause sudden shock and death in these women. (Alka Kriplani *et al*., 2013)

Author	Pre treatment Hb		Post treatment Hb		Average rise of Hb		P value
	Oral	IV	Oral	IV	Oral	IV	
Present study	7.82	7.75	9.26	10.7	1.44	2.95	<0.001 (S)
Ragip *et al*. (2005)	9.8	9.9	10.4	11.10	0.6	1.2	<0.001 (S)
Aggarwal *et al*. (2012)	5.95	10.26	6.27	11.3	4.31	5.03	<0.001 (S)
Syal Neeru *et al*. (2012)	9.75	11.06	9.18	11.24	1.31	2.06	<0.001 (S)
Alka Kriplani *et al*. (2013)		7.63		11.2		3.57	<0.001 (S)
Surriya *et al*. (2011)	9.35	11.2	9.2	12.65	1.85	3.45	<0.001 (S)

In the present study the mean gestational age at the time of inclusion in both the groups was comparable, which is around 27 weeks. The base line hemoglobin was 6.5 to 8.5 gm/dl. The mean baseline Hb was 7.82 and 7.75gm/dl in Oral and IV group respectively, which was statistically insignificant between the groups. Post treatment hemoglobin after 3 weeks showed a mean value of 8.22gm/dl and 8.55gm/dl in oral and IV group respectively (p value 0.002) which was statistically significant. Post treatment haemoglobin after 6 weeks shows that in IV group haemoglobin increase is from 7.75+0.57 to 10.7+ 0.67, where as in oral group haemoglobin increase is from 7.82+0.45 to 9.26+0.54, which was statistically highly significant (p<0.001). At the end of study the average rise of Hb was 2.95gm/dl and 1.44gm/dl in IV and oral group respectively, which was statistically significant.

This study was compared with studies of Ragip *et al*. (2005), Aggarwal Rohina *et al*. (2012), Syal Neeru,N Sreekuman *et al* (2012), Alka Kriplani *et al*. (2013) Surriya Halimi *et al*. (2011) in the following way.

In our study in the IV group 17 patients have reached target hemoglobin of 11g/dl where as in oral group none of the patients have reached the target hemoglobin.

- In the study of Ragip *et al*. (2005) 9 patients in oral group and 43 patients in IV group have reached target Hb of 11gm/dl. This difference with the present study is due to higher base line Hb in Ragip *et al*. (2005) group (9.8 & 9.9gm/dl).
- In the study of Aggarwal Rohina *et al*. (2012) target hemoglobin level of 11.0gm/ dl was reached in 4weeks time in IV iron sucrose but not in oral group.
- In Syal Neeru, Sreekuman *et al*. (2012) study target hemoglobin of 11g/dl was attained by 66% of the patients in the IV iron group as compared with 61% in oral group. This can be explained by the difference in the baseline Hb, which was higher (9.75 & 9.18) in this study group when compared to our study group.

There are no serious adverse effects in the study, however 20% in Oral group and 8% in IV group had minimal side effects, but continued with the study, in other studies like Al-Momen *et al*. (1996), Aggarwal Rohin *et al*. (2012) and Bayoumeu *et al*. (2002) found there were no serious adverse reactions.

Conclusion

In view of the failure of oral iron in the correction of anemia to significant extent in pregnant women with moderate anemia intravenous administration of iron under supervision is a better alternative for women with moderate anemia.

To conclude, intravenous administration of iron sucrose is safe, highly efficacious with better compliance for the treatment of iron deficiency anaemia. Iron sucrose therapy is more effective in achieving the optimum results. Even after constant motivation to improve the compliance, and sufficient time to improve haemoglobin the raise of haemoglobin was not significant in oral group. Where as in IV group the raise in Hb and PCV was significant. The target level of Hb was achieved in 34% of I.V. group patients compared to none in Oral group. Therefore iron sucrose is suitable alternative to ferrous sulfate for treating iron deficiency anaemia in pregnancy with minimal side effects.

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