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To Compare the Efficacy of Intravenous Ferrous Sucrose with Oral Ferrous Sulphate in Iron Deficiency Anemia During Postpartum Period

KEYWORDS: anemia, postpartum, iron sucrose, ferritin

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ABSTRACT ***Introduction-*** *Postpartum anemia is very common. Present study was a prospective randomized comparison between intravenous iron sucrose and oral iron in treatment of postpartum anemia*

Aims and objectives- *1)To compare the efficacy of oral ferrous sulphate vs intravenous ferrous sucrose on iron deficiency anemia during postpartum period. 2)To note the untoward reactions and complications of intravenous iron sucrose therapy*

Material and method- *women with Hemoglobin of less than 10 g/dl but more than 6g/dl at 24 to 48 hours after delivery and Serum ferritin level less than 15µg/l were randomly divided into two groups. One study group received two doses intravenous iron sucrose 200 mg and other group received oral ferrous sulphate 200 mg twice daily for 6 weeks.. The post therapy evaluation was compared.*

Result- *At the end of 45 days, there was significant rise in Hb level in study as well as control group.Rise in ser ferritin level in iv sucrose group was significantly higher.*
Conclusion- *Iv sucrose in postpartum period is safe and reliable*

1. Introduction

India is a country with diversity. On one hand it has progressed technologically so much that it has its own identity in global scenario and on the other hand even today women are dying because of childbirth related problems .What is more important is majority of these deaths are preventable! Anemia is one of the most important contributing factor for maternal mortality in india and according to the WHO,contributes to 20% maternal deaths. Incidence of anemia in pregnancy varies from 14% in developed and 51% in developing countries[1]. Incidenceof anemia is 65% -75% in India [2].Prevalence of anaemia in an ICMR study covering 11 states was87.65%. According to WHO 56% women suffer postpartum anaemia..

Anaemia is prevalent even before marriage in most of the women and majority of the women start their pregnancy without correction of anemia. High prevalence of iron deficiency is attributable to faulty dietetic habit, faulty absorption mechanism because of high prevalence of intestinal infestation and increased iron loss as consequence of repeated pregnancies at short intervals, excessive blood loss during menstruation, hookworm infestation and chronic malaria[3] . Superimposed pregnancy leads to deterioration of anaemic status.As a result, those who are not anemic in the beginning but whose iron stores are depleted before conception ,develop anemia fast and those who start pregnancy with mild or moderate anemia show deterioration of anemia fast. In developing countries, with non availability of proper antenatal supervision,undercorrection of anemia and pregnancy complications like post partum haemorrhage, post partum patients remain anemic in post partum period.

Mothers are at increased risk of postpartum anaemia if they have less spacing during pregnancies, antepartum anemia and lack of iron supplementation and loss of large amount of blood during childbirth [3] . Postpartum anemia is associated with longer hospital stays,depression, anxiety, and delayed infant development.Today,.women are prescribed therapeutic oral iron therapy for correction of anemia but problems of oral iron therapy are many fold. Parental iron administration with ferrous sucrose is now available and can be used for treatment of iron deficiency anemia in postpartum period. Present study was a prospective randomized comparison between intravenous iron sucrose and oral iron in treatment of postpartum anemia taking advantage of hospital stay and removing the compliance factor.

Aims and objectives-

1)To compare the efficacy of oral ferrous sulphate vs intravenous ferrous sucrose on iron deficiency anemia during postpartum period.

2)To note the untoward reactions and complications of intravenous iron sucrose therapy

Material and methods

The present study was a hospital based prospective randomized controlled trial, conducted from April 2015 to Nov 2015 at a hospital attached to medical college in rural area. All postpartum women belonging to investigators unit admitted in postpartum ward from April 2015 to November 2015 who fulfilled the inclusion and exclusion criteria and who were willing to participate in the study were included in the study.inclusion criteria was Postpartum women following vaginal delivery, above 18 years of age with iron deficiency anemia (IDA),with Hemoglobin of less than 10 g/dl but more than 6g/dl at 24 to 48 hours after delivery and Serum ferritin level less than 15µg/l and who were willing for follow up were included in the study. Women having anemia other than iron deficiency anemia or any genetic anemia and those who were intolerant to oral iron and who had history of any transfusion reaction or allergy to it were excluded from the study. Women with signs of infection were also excluded from the study

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After careful history taking, clinical examination and minimal investigations other causes of anemia were ruled out. The initial iron status of the woman was assessed by the clinical and laboratory examinations.(complete blood picture and serum ferritin levels). Women having Hb levels less than 10 gm/dl and serum ferritin level less than 15 ng/ml at 24-48 hours post delivery were included in the study. They were randomly divided into two groups. One study group [Group A] received two doses intravenous iron sucrose 200 mg on day 2 and day 4 following recruitment in study and the other group [Group B] received oral ferrous sulphate 200 mg twice daily for 6 weeks.Iron sucrose was administered as an infusion in 250ml of 0.9% sodium chloride over a period of more than 30 minutes. Patients were monitored for 30 minutes for signs of intolerance such as anaphylactic reactions, skin rash, dyspnoea, facial flushing, metallic taste, urticaria, hypotension, headache, chest-pain, tachycardia, breathlessness etc. The treatment was stopped after the administration of total dose of 400 mg and received no further iron supplementation. The other group receiving oral treatment received two tablets of Ferrous sulphate 200 mg twice daily for 6weeks.

Side effects of both oral & intravenous iron were recorded. Complaince in oral group was assured by asking colour of stools and checking the empty packets of iron tablets given at time of discharge. Adverse effects of treatment, if any were noted. The post therapy evaluation was done with the estimation of Haemoglobin and serum ferritin levels for both the treatment groups after 6 weeks.The statistical analysis was performed using Z test.

Result-

in the present study total 200 women were included. 100 women received iv iron sucrose and 100 women received oral ferrous sulphate tablets. As is evident from table 1 and 2 ,baseline Hb in iv sucrose group was 8.3658+/-0.630gm% and in oral ferrous sulphate group it was . 8.3398+/-0.63657 gm% and mean ser ferritin levels in the two groups were 11.595+/-1.5646 and 10.7890+/-1.36876 respectively.The difference was not statistically significant. At the end of 45 days, there was significant rise in Hb level in study grp 11.377+/-0.4962gm% as well as control group, 10.7890+/-0.1368 gm%..The rise with iv sucrose was slightly more which was statistically significant similarly, ser ferritin level in iv sucrose group was . 40.120 +/-.7.8756 and in oral iron group was .15.87+/-2.577.At the end of the study as is seen in table on comparative group statistics difference in serum ferritin level as well as hb% was was significant in iv iron sucrose group.Rise in serum ferritin levels were higher in iv iron group as compared to oral iron group..(table 3)

There were no major side effects in both the groups .Side effects observed in oral group were nausea and vomiting in 10%, abdominal pain,5%, constipation, 3% and diarrhoea,4%...In iv sucrose group, there was development of rash in 3% patients and rigors in 5% patients(.table 4)

Discussion-

Because of high prevalence of anemia in our country, it was decided to test the feasibility and efficacy of administering 400 mg of parental iron to patients during hospital stay and compare its efficacy In improving anemia and iron stores with oral therapy with ferrous sulphate 400mg twice a day for 6 weeks.. in the present study baseline Hb in iv sucrose group was 8.3658+/-0.630gm% and in oral ferrous suplphate group it was . 8.3398+/-0.63657 gm%.and ser ferritin levels in the two groups were 11.595+/-1.5646 and 10.7890+/-1.36876 respectively.The difference was not statistically significant. At the end of 45 days, there was significant rise in Hb level in study grp 11.377+/-0.4962gm% as well as control group, 10.7890+/-0.1368 gm%..the rise with iv sucrose was slightly more which was statistically significant. At the end of the study period, ser ferritin level in study group was . 40.120 +/-.7.8756 and in control group it was .15.87+/-2.577 and the difference was highly significant. In the study by Prashant S.Kharde and Bangal[4],the baseline mean Hb level in the oral iron therapy group was7.76+0.7137 g/dl and in the injectable iron-therapy group it was 7.47+0.7678 g/dl.after completion of iron therapy on day 40, it was observed that the rise in Hb levels in oral group was significant.(increase of Hb from 7.76+0.7137 g/dl to 10.78+0.7679 g/dl ,p value < 0.01) . Ininjectable iron therapy group, the mean rise of Hb was noted from 7.47+0.7678 g/dl on day 0 to 11.41+0.7908 g/dl on day 40, which was statistically significant. (p value < 0.01)

The mean level of serum ferritin level was more than 50 µg/l in intravenous group as compared to v little rise in oral group. study by Bayoumeu *et al* [5] reported rise in haemoglobin from 9.6+.79gm/dl to 11.11+1.3 in IV group and from9.7+.5to11.0+1.25 in oral **.**Bhandal N and Russell R et a[6] noted improvement in anemia in both the grops where throughout their study, ferritin levels rose rapidly in those treated with intravenous iron than in those treated with oral iron (p<0.01).The present study had similar findings comparable to the above study.

Thus our results are similar to all the above studies where hemoglobin rise was observed in both the groups,serum ferritin levels were higher in iv sucrose group and there were no major complications in both the groups

conclusion-

Post partum management of anemia and restoration of iron stores is important to to minimise incidence of anemia in future pregnancy. In the two groups with oral ferrous sulphate 200mg twice daily and two doses of intravenous iron sucrose on day 2 and 4 respectively postpartum hemoglobin level had And serum ferritin levels had risen in both groups.with iv iron sucrose serum feriitin level was significantly higher than oral iron group,Thus this study recommends use of iv sucrose administration of two doses as it is feasible and safe in correcting anemia and improving iron stores of a post partum woman.

Tables

Table 1- haemoglobin and serum ferritin levels in iv sucrose group on day 1 and 45

Paired Samples Statistics(IV iron sucrose)							
		Mean	N	Std. Deviation	Std. Error Mean	T value	P value
HB	Day 1 Hb	8.3658	100	0.63056	0.06306	-45.46	<0.001
	Day 45 Hb	11.377	100	0.4962	0.0496		
Serum Fer	Day 1 Fer	11.595	100	1.5646	0.1565	-38.15	<0.001
	Day 45 Fer	40.120	100	7.8756	0.7876		

Table2- haemoglobin and serum ferritin levels in oral

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iron sulaphate group on day 1 and 45

Paired Samples Statistics(Oral iron)							
		Mean	N	Std. Deviation	Std. Error Mean	T value	P value
HB	Day 1 Hb	8.3398	100	0.63657	0.0636	-17.89	<0.001
	Day 45 Hb	10.7890	100	1.36876	0.1368		
Serum Fer	Day 1 Fer	11.595	100	1.5646	0.1565	-15.37	<0.001
	Day 45 Fer	15.87	100	2.577	0.258		

Table 3- comparison of the iv and oral iron group on day 1 and day 45

Group Statistics							
	Group	N	Mean	Std. Deviation	Std. Error Mean	T value	P value
Day 1 Hb	IV	100	8.365800	0.6305636	0.0630564	0.290	0.772
	ORAL	100	8.339800	0.6365786	0.0636579		
Day 45 Hb	IV	100	11.377000	0.4962190	0.0496219	4.03	<0.001
	ORAL	100	10.789000	1.3687637	0.1368764		
Day 1 Fer	IV	100	11.595	1.5646	0.1565	0.000	1
	ORAL	100	11.595	1.5646	0.1565		
Day 45 Fer	IV	100	40.12	7.876	0.788	29.265	<0.001
	ORAL	100	15.87	2.577	0.258		

Table 4 -Comparison of complications

complication	Iv sucrose	Oral
Nausea and vomiting	nil	10
Abdominal pain	nil	5
Constipation	nil	3
Diarrhoea	nil	3
Rash	3	nil
Rigors	5	nil
Restlessness	3	nil
Anaphylaxis	0	0

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