

International Journal of Clinical Obstetrics and Gynaecology

ISSN (P): 2522-6614
ISSN (E): 2522-6622
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www.gynaecologyjournal.com
2019; 3(2): 21-25
Received: 15-01-2019
Accepted: 19-02-2019

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Ferric carboxymaltose an alternate to blood

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DOI: <https://doi.org/10.33545/gynae.2019.v3.i2a.07>

Abstract

Background: Anemia is defined as low hemoglobin concentration resulting in a decrease in oxygen carrying capacity of blood according to WHO Hb level of 11gms/dl if consider as anemia. This study is compare the safety and efficacy of FCM injection and blood transfusion in anemic pregnant woman after 20 weeks of gestation.

Method: It is a descriptive study 50 pregnant woman with Hb of 7.5 to 9gms as infused with inj. FCM (500mg/10ml) consider as Group A, Group B 50 Anemic pregnant woman with hemoglobin of 7.5 to 9gms was transfused with blood. Hb, ferritin, PCV, WBC; peripheral smear was monitored in both groups after 3 weeks of infusion, after delivery, 6 weeks after delivery.

Result: FCM infusion significantly increase HB, PCV, Ferritin, peripheral smear LEVELS ($P < 0.01$) from pre infusion Hb, PCV ferritin, peripheral smear and the same investigation was measured after 3 weeks after infusion, immediately after delivery, 6wks after delivery the significant improvement in Hb, ferritin PCV, peripheral there is no significant systemic and local reaction occurred in following FCM infusion. But there is no improvement in WBC level. In blood transfusion groups there is no much significant increase in HB, PCV, Peripheral smear. But there is significant improvement in WBC level as compared to FCM injection.

Conclusion: Our study statically concluded that FCM improve Hb Ferritin PCV Peripheral smear value in anemic pregnant woman. Blood Transfusion also increase Hb, Ferritin, PCV, Peripheral smear levels but not as significant as FCM.

Keywords: FCM Ferriccarboxy maltose, PCV, Packed cell volume, WBC white blood cell count, HB hemoglobin

Introduction

Anemia is the most common hematological disorder in pregnancy. The severe form of anemia are as common as toxemia and they contribute to major prevalence of maternal death in India^[2] One of the primary aims of antenatal care to prevent and treat anemia during pregnancy since the safety of labour and the puerperal health^[3]

The prevalence of anemia in Indian mothers between 80% to 90%. Complication of severe anemia in pregnancy

Maternal complications during pregnancy

- Cardiac Failure
- increase in risk of mis carriage
- Increase in risk of infection
- Preterm Labor
- Incidence of pre eclampsia

During Labor

- Cardiac Failure
- Postpartum Hemorrhage
- Shock

Puerperal

- Infection
- Sub involution
- Lactation failure
- Poor wound healing

Treatment of Anemia depend on

1. Clinical and laboratory assessment of the severity of anemia
2. Typing of Anemia
3. Identifications of Etiology of Anemia
4. Determine the predisposing and precipitating factors

FCM is a newer drug used for the treatment of Anemia in pregnancy it is a better alternative blood transfusions and patient with negative blood groups. It is efficient in II & III trimesters. The primary aim of the study if to compare the safety and efficacy of FCM with VS Blood transfusion anemic pregnant woman after 20 weeks of gestation. Blood transfusion is associated with risk of viral infection volume overload.

FCM is a new drug which is the third generation preparation of intravenous iron. This don't require any test dose since the risk of serious anaphylaxis is remote. It is well tolerated in pregnancy compare and has a comparable safety profile to iron sucrose and no need of repeated infusions [5]. However patient with moderate to severe anemia parenteral therapy should be started as the first live compliance is better and it decrease the need of blood transfusion

Method

It is a Descriptive study was done in between February 2017 to may 2018 in Raja Muthiah Medical Collage and Hospital consent was obtained from patient and patient relatives.

Blood pressure, Pulse rate, Temperature of the antenatal mother was monitored and also for systemic reaction.

FHR was also monitor during transfusion and two hours after transfusion in both group A and B.

Blood sample was collected from both the groups after 3 weeks of infusion immediately after delivery and 6 weeks after delivery. Raise in Hb, ferritin, PCV and WBC, peripheral smear level was analyzed.

Discussion

Since Anemia is a leading cause for maternal mortality in

developing countries like India treating Anemia is a mile stone in obstetric practice since blood transfusion, iron sucrose infusion place a major role in treating anemia for the past few decades we tried an alternative source for anemia correction a third Generation IV iron preparation ferric carboxy maltose in view of eliminating major compliance like allergic and anaphylactic reaction, risk of viral transfusion iron over load.

FCM plays a major role avoid in this complication.

In the present work, ferric carboxymaltose is compared with blood transfusion in the outcomes such as Hb, Ferritin, PCV and WBC. A total of 100 antenatal women were studied. They were randomly assigned into either group 'A' or group 'B'. In group 'A', ferric carboxymaltose was administered whereas in group 'B', blood transfusion was performed. The outcomes are studied at 4 different times viz baseline, 3 weeks after treatment, after delivery and 6 weeks after delivery. Within group A (case) and group B(control) at various measurements is carried by repeated measures ANOVA. Between group comparison is analysed by independent sample 't' test. For between group analyses, the difference in the improvement between two groups was compared at various study times. The entire statistical procedure is carried out by statistical packages of social sciences (spss-21)

The mean Hb at baseline for group 'A' was 8.19 ± 0.48 and it was 8.52 ± 0.43 for group 'B'. The mean Hb was highest at 3rd week for both the groups. The ANOVA is statistically significant for both groups. Therefore, the Hb values are significantly different at various times of study period. The post-HOC analysis shows that there is significant difference in Hb levels at various times when compared between all possible combination of period of measurements in both the groups.

The between group analysis shows that the mean improvement of Hb was higher in group 'A' at 3rd week, after delivery and 6 weeks after delivery. The independent sample 't' test is also statistically significant at all three levels. Hence, Hb improvement is comparatively higher in group 'A' than in group 'B'

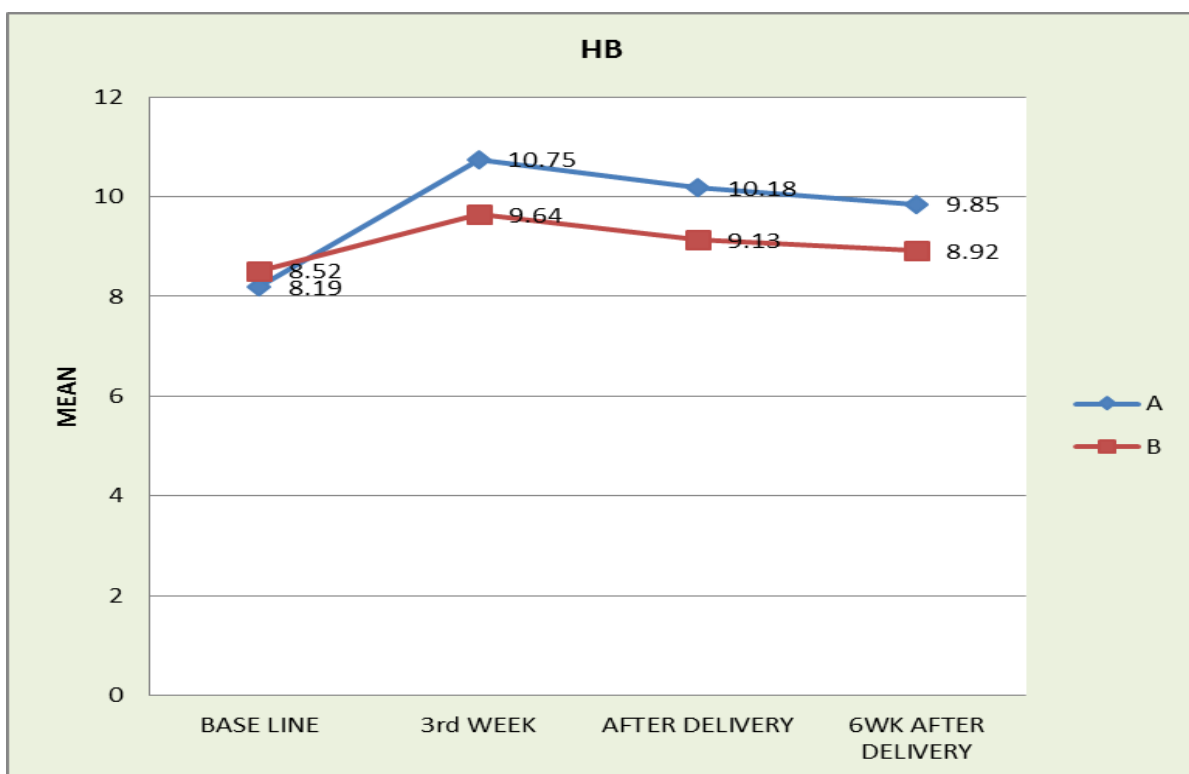


Fig 1: Comparison of HB between Group A and Group B

The mean ferritin values are presented in table 2(a). The repeated measures ANOVA shows that ferritin values are significantly different at various study periods in both groups. The ferritin values are significantly different in group 'A' at all possible combination of pairs of comparisons but in group 'B' the difference is insignificant between baseline and 6 weeks after delivery, whereas in all other combination, the difference is

statistically significant.

Between group analysis shows that the improvement in ferritin is comparatively greater after 3 weeks of treatment, after delivery and 6 weeks after delivery when compared to baseline in group 'A' than in group 'B'. The 't' value is statistically significant at all the three levels of measurements.

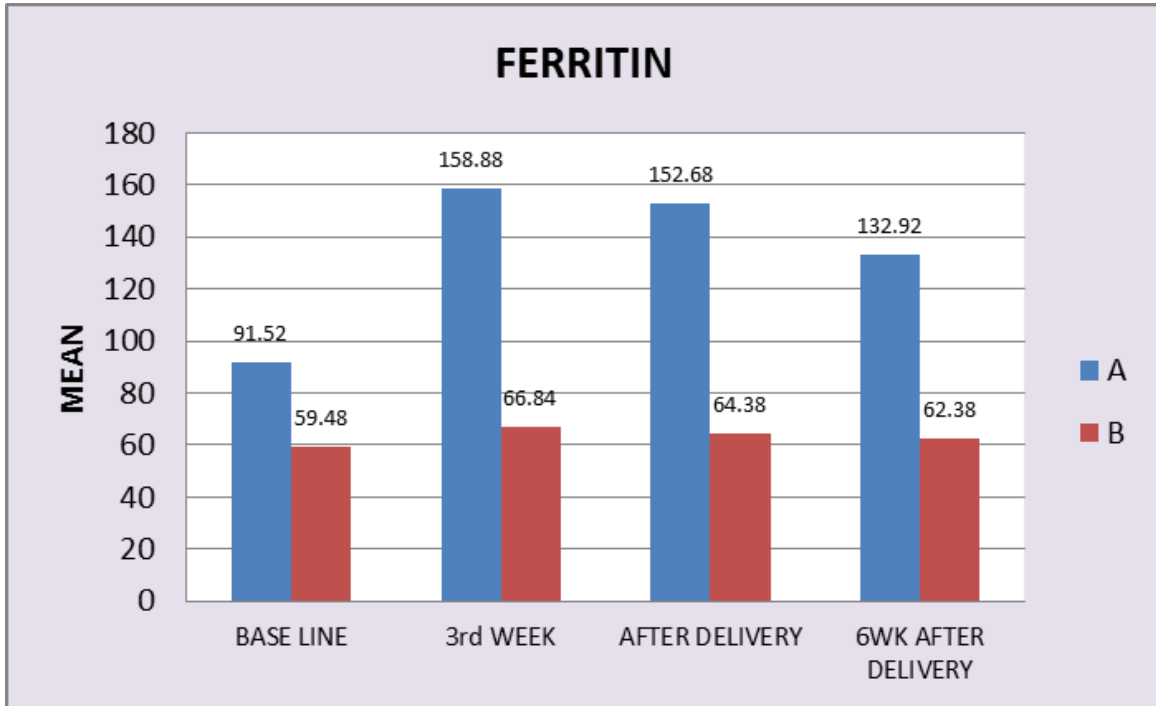


Fig 2: Comparison of FERRITIN between Group A and Group B

The PCV values are highest at 3rd week after treatment in both the groups. The PCV values are significantly different at various times of study period in both the groups. Pair wise comparison shows that PCV values differ significantly at various possible combination of study periods in group 'A'. But in group 'B', between baseline and 6 weeks after delivery, the value is

statistically insignificant. Between group analysis shows that the mean difference in improvement is comparatively higher in group 'A' when compared to baseline at different times of study period. The difference is statistically significant at all the three study periods

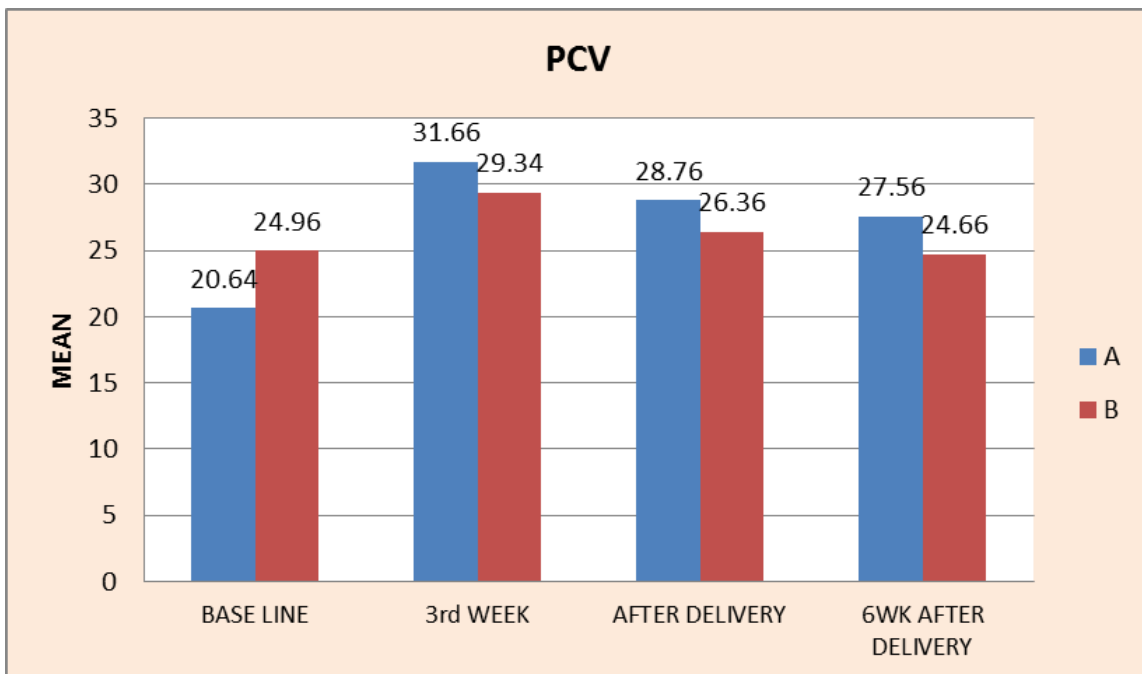


Fig 3: Comparison of PCV between Group A and Group B

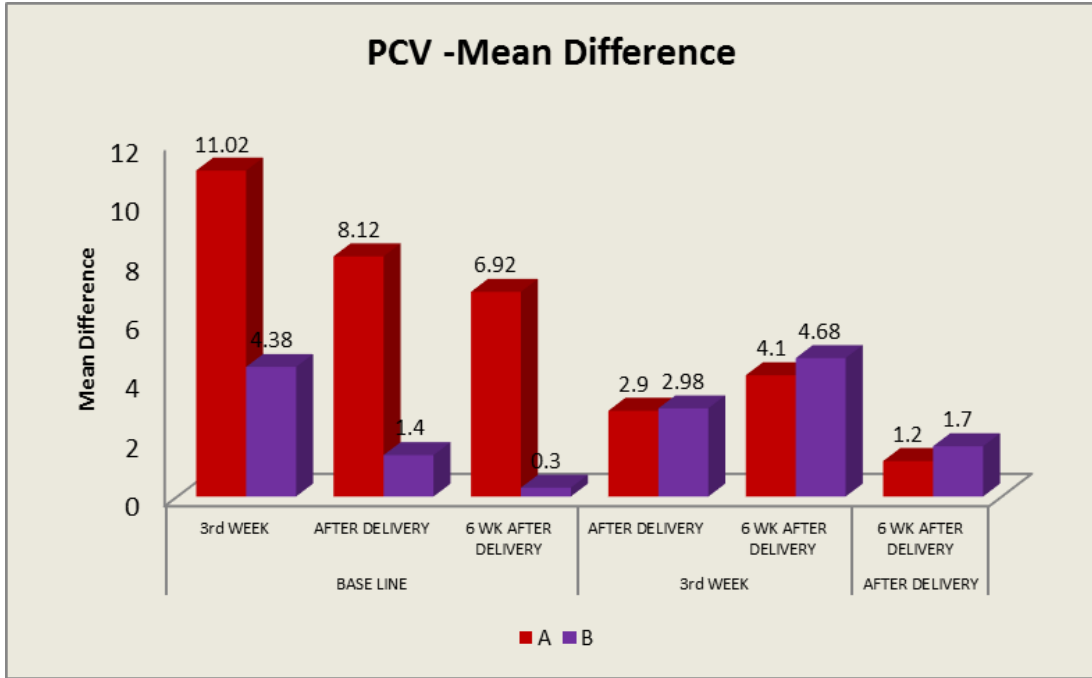


Fig 4: Mean Difference in PCV between Group A and Group B

Table 1: Mean Difference in PCV in study population

PCV		A		B	
		Mean Difference	'p' value	Mean Difference	'p' value
Baseline	3 rd Week	11.02	0.001	4.38	0.001
	After Delivery	8.12	0.001	1.40	0.037
	6 Weeks After Delivery	6.92	0.001	0.30	1.000
3 rd Week	After Delivery	2.90	0.001	2.98	0.001
	6 Weeks After Delivery	4.10	0.001	4.68	0.001
After Delivery	6 Weeks After Delivery	1.20	0.536	1.74	0.001

The WBC is not significantly different at different study periods in group 'A' whereas it is significantly different in group 'B'. In group 'B' apart from after delivery and 6 weeks after delivery, all other combination of measurements show statistical

significance. The mean difference of WBC is comparatively higher in group 'B' from baseline to 3rd week, after delivery and 6 weeks after delivery. The differences are statistically significant.

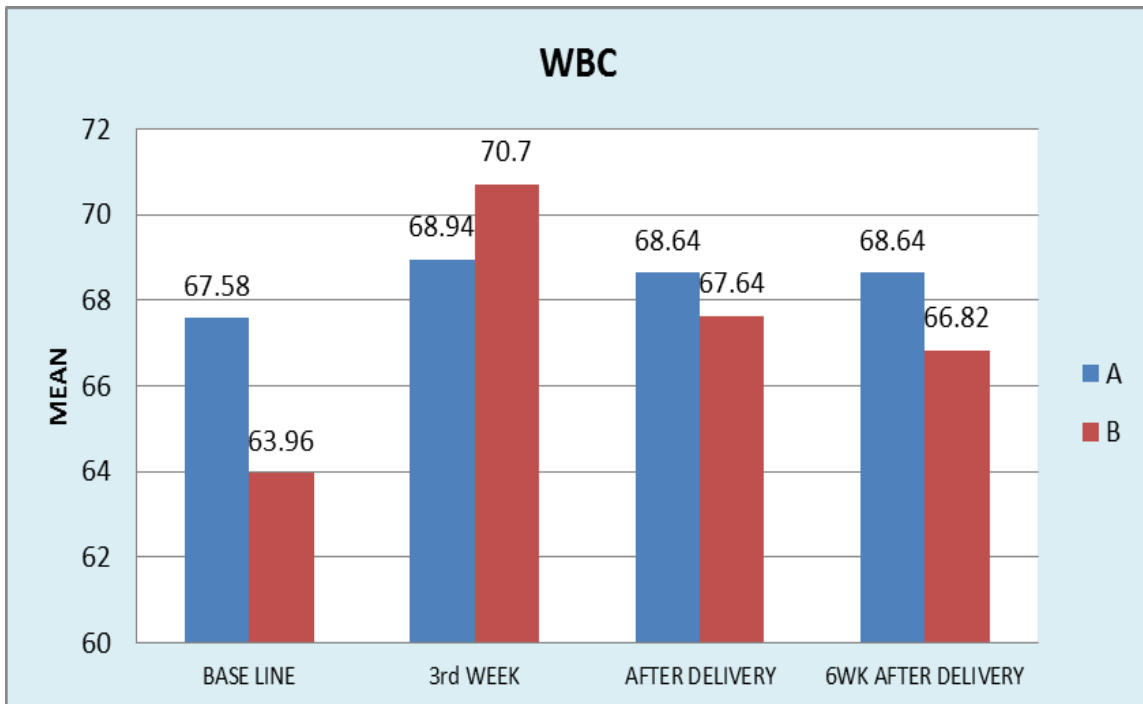


Fig 5: Comparison of WBC between Group A and Group B

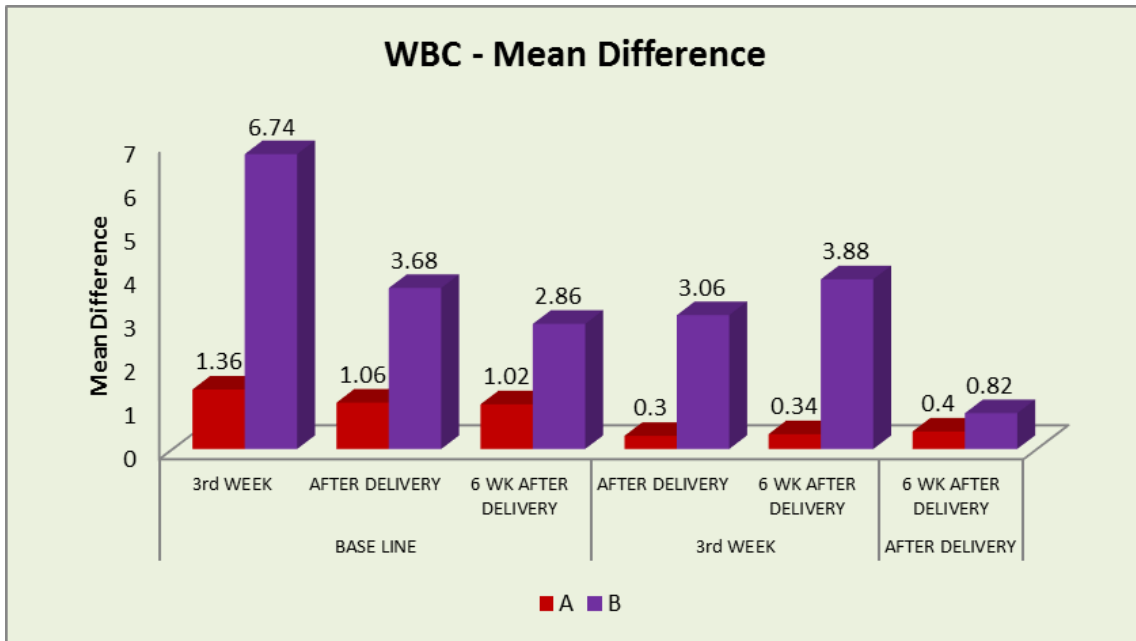


Fig 6: Mean Difference in WBC between Group A and Group B

Peripheral smear report was improved at 3rd week after treatment in both group A and B. In group A 85% improvement in Peripheral smear from microcytic hypochromic to normocytic normochromic after 3 weeks of infusion and the same percentage was maintained after delivery, 65% after 6 weeks after delivery. The difference is statistically significant.

In group B 65% improvement in Peripheral smear from the difference from microcytic hypochromic to normocytic normochromic and remained the same after delivery, the same percentage was maintained after delivery, 45% after 6 weeks after delivery.

Summary of Results

The mean improvement in Hb at 3rd week in group ‘A’ was 2.56 whereas it was only 1.12 in group ‘B’. The difference is statistically significant. The mean improvement in Hb after delivery from baseline in group ‘A’ were 1.99 whereas it were only 0.61 in group ‘B’. The difference is statistically significant. The mean difference in improvement of Hb at 6 weeks after delivery from baseline in group ‘A’ was 1.66 whereas it is only 0.41 in group ‘B’ and again the difference is statistically significant.

The mean improvement in ferritin from baseline to 3rd week, after deliver and 6 weeks after delivery were 67.36, 61.16 and 41.40 respectively for group ‘A’ whereas the mean improvement was only 7.36, 4.90 and 2.90 at 3rd week, after deliver and 6 weeks after delivery respectively for group ‘B’. The differences are statistically significant.

The mean improvement in PCV at 3rd week, after delivery and 6 weeks after delivery in group ‘A’ were 11.02, 8.12 and 6.92 respectively. The mean improvement in PCV for group ‘B’ were 4.38, 1.40 and 0.30 at 3rd week, after delivery and 6 weeks after delivery respectively. The differences are statistically significant.

The mean increase in WBC in group ‘A’ from baseline to 3rd week were only 1.36 whereas it were 6.74 in group ‘B’. The difference is statistically significant. The mean increase in WBC were only 1.06 after delivery in group ‘A’ whereas it were 3.68 in group ‘B’. The mean difference was 1.02 from baseline at 6 weeks after delivery in group ‘A’ and it were 2.88 for group ‘B’. The difference is statistically significant.

Peripheral smear report was improved at 3rd week after treatment in both group A and B. In group A 85% improvement in Peripheral smear from microcytic hypochromic to normocytic normochromic after 3 weeks of infusion and the same percentage was maintained after delivery, 65% after 6 weeks after delivery. The difference is statistically significant.

In group B 65% improvement in Peripheral smear from the difference from microcytic hypochromic to normocytic normochromic and remained the same after delivery, the same percentage was maintained after delivery, 45% after 6 weeks after delivery.

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