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Treatment of Severe Anemia with Oral Supplements and Methylcobalamine Injection

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ABSTRACT

Nutritional anemia is most prevalent in the Indian population which may predispose to many health ailments. To observe the effects of oral ferrous sulphate 100 mg tablets with folic acid 100 mcg twice daily and injection vitamin B12 (cobalamin) 1000 mcg weekly in patients with severe anemia. A prospective interventional study was conducted in Vels Medical College and Hospital for the period of one year from May 2022 to April 2023 on 50 patients, attending outpatient clinic of Vels Medical College and Hospital, Tiruvallur District, Tamil Nadu. A thorough history followed by clinical examination were carried out and patients were given oral ferrous sulphate 100 mg with folic acid 100 mcg tablets twice daily with injection B12 weekly was given after estimation of baseline hemoglobin level. Estimation of hemoglobin level was done at 4 weeks time interval. All adverse events following the study was noted and asked for compliance, tolerance and side effects. Improvement in the hemoglobin levels from 6.2 g dL⁻¹ from enrollment level to 8.7 g dL⁻¹ after one month of treatment was noted which was statistically significant with minor adverse effects. The combination of oral ferrous sulphate 100 mg parenteral Vitamin B12 and folic acid may provide an efficient, effective, safe and practical option to treat severely anemic patients, especially in resource-poor settings.

INTRODUCTION

With 30% of the population being affected with iron deficiency anemia (IDA)^[1], the WHO has recognized iron deficiency anemia as the most common nutritional deficiency in the world.

Iron Deficiency Anemia is more prevalent in children and women, adult men are also susceptible depending on their socioeconomic status and health conditions^[2].

The decreased dietary iron intake and absorption are also culpable causes^[3], although, the most common causes of IDA are gastrointestinal (GI) bleeding and menstruation in women.

Iron is required for various cellular functions not limited to enzymatic processes but also DNA synthesis, oxygen transport and mitochondrial energy generation.

It is well known that iron deficiency anemia significantly affects quality of life (QoL) with recent evidence demonstrating that treating iron deficiency anemia improves Quality of Life, regardless of the underlying cause for anemia.

Vitamin B12 (also known as cobalamin) deficiency can cause reversible bone marrow failure and demyelinating disease due to its inherent function in erythropoiesis and myelination of the central nervous system. Any conditions that cause malabsorption of vitamin B12 as well as dietary deficiency can lead to cobalamin deficiency.

In our study, we observe the effects of oral ferrous sulphate 100 mg with folic acid 100 mcg twice daily and injection vitamin B12 1000 mcg weekly in patients with severe anemia for the period of one month.

Aims and objectives: The aims and objectives of this research was to observe the effects of oral ferrous sulphate 100 mg tablets with folic acid 100 mcg twice daily and injection vitamin B12 1000 mcg weekly in patients with severe anemia.

MATERIALS AND METHODS

A prospective interventional study was conducted in Vels Medical College and Hospital for the period of one year from May 2022 to April 2023.

Study was conducted on 50 patients, attending outpatient clinic of Vels Medical College and Hospital, Tiruvallur District, Tamil Nadu.

Inclusion criteria:

- Patients with hemoglobin of 5-7 g dL⁻¹
- Patients with age of 18-65 years
- Patients with no signs of congestive cardiac failure

Exclusion criteria:

- Patients with hemoglobin less than 5 g dL⁻¹ and above 7 g dL⁻¹.
- Patients with congestive cardiac failure
- Any medical disorder like tuberculosis, thyroid disease, diabetes, liver or kidney disease, coagulation and bleeding disorders
- Pregnant women
- Patient with age less than 18 years of age and more than 65 years of age

A prospective interventional study was carried out at a tertiary care hospital between May 2022 to April 2023 for a period of one year. Ethical committee clearance was obtained before the commencement of the study. All the study patients were enrolled after a duly signed informed consent about the study. Fifty patients coming to OPD aged between 18 and 65 years of age were taken based on inclusion and exclusion criteria. Medical disorders like thyroid disease, diabetes, liver or kidney disease, bleeding and coagulation disorders, tuberculosis were excluded.

A thorough history followed by clinical examination were carried out and patients were given oral ferrous sulphate 100 mg with folic acid 100 mcg tablets twice daily with injection B12 weekly was given after estimation of baseline hemoglobin level.

Estimation of hemoglobin level was done at 4 weeks time interval. All adverse events following the study was noted and asked for compliance, tolerance and side effects.

Statistical analysis: Tables were generated with the help of Microsoft office version 2021. Results were tabulated and statistically analysed using SPSS version 15.

RESULTS

In our study, 50 participants were present. Out of 50 patients, 35 patients were female and 15 patients were male. The mean hemoglobin level in our study group at enrollment was 6.2 g dL⁻¹ with standard deviation of 1.2 g dL⁻¹. The mean hemoglobin improvement in our study group at one month was 2.5 g dL⁻¹ with the standard deviation of 0.9 g dL⁻¹.

Table 1 show that 40% of the participants are belongs in the age group 25-40 years and 30% of the participants is in the age group of 18-25 years, where only 10% of the participants are belongs to the age group 50-65 years. Table 2 clear shows that majority of the patients (56%) hemoglobin is 6-7 g dL⁻¹. Table 3 shows that Mean hemoglobin improvement in our study group (Fig. 1 and 2).

Minor side effects such as nausea and vomiting is seen in 4 patients (8%) of the individuals and constipation was found in 5 patients (10%).

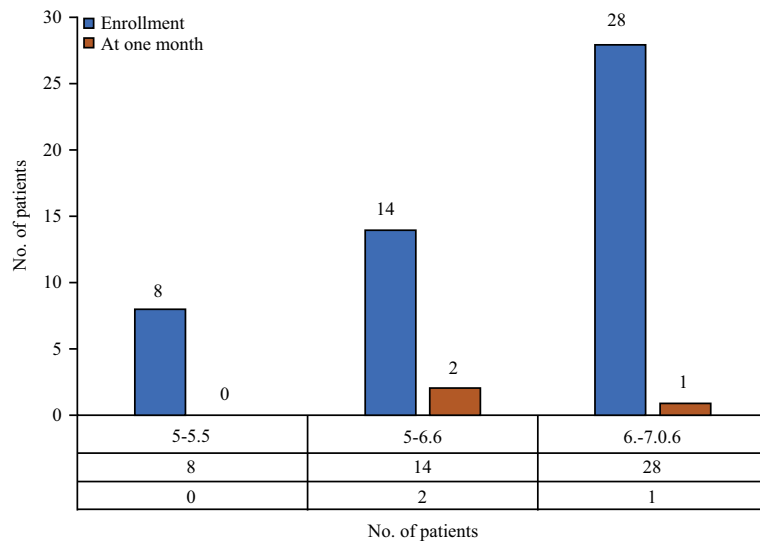


Fig. 1: Hemoglobin improvement in our study group

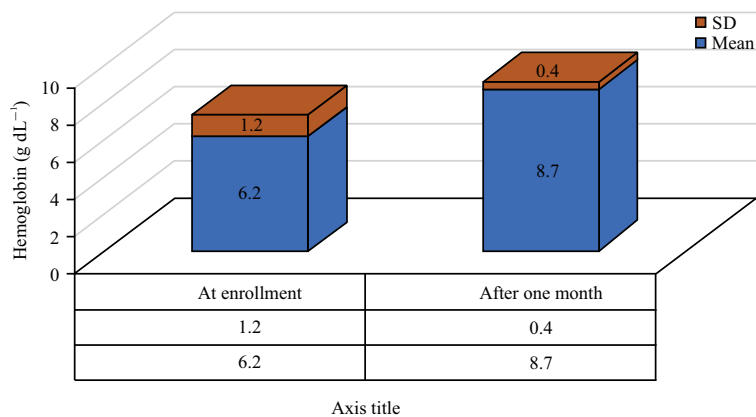


Fig. 2: Hemoglobin levels in our study group

Table 1: Study participants characteristics during enrollment

Age group of the population	Frequency
18-25 years of age	15 (30%)
25-40 years of age	20 (40%)
40-50 years of age	10 (20%)
50-65 years of age	5 (10%)

Table 2: Hemoglobin at enrollment

Hemoglobin levels	No. of patients (frequency)
5-5.5 g dL ⁻¹	8 (16%)
5.6-6 g dL ⁻¹	14 (28%)
6-7 g dL ⁻¹	28 (56%)

Table 3: Improvement in hemoglobin in the defined time interval

Mean hemoglobin during enrollment (SD)	Mean hemoglobin after one month (SD)	Mean difference in hemoglobin (SD)	95% CI of the difference	Significance
6.2 g dL ⁻¹ (1.2 g dL ⁻¹)	8.7 g dL ⁻¹ (0.4 g dL ⁻¹)	2.5 g dL ⁻¹ (0.9 g dL ⁻¹)	2.4-3.2	<0.001

DISCUSSIONS

Our study suggested that the combination of ferrous sulphate, Vitamin B12 and folic acid might be an effective and pragmatic approach for severely anemic patients and where the compliance to multiple

doses of iron sucrose is challenging. It showed significant improvement in hemoglobin levels with minimal side effects^[4].

Froessler *et al.*^[5], Pels *et al.*^[6], Rodriguez *et al.*^[7] and Mohiuddin *et al.*^[8] showed that intravenous ferric carboxymaltose (FCM) was effective and safe in the

treatment of iron deficiency anemia during pregnancy. Our study showed that persistently higher rise in Hemoglobin levels with no patients remained severely anemic and no serious side effects during the study period. Risk of anaphylaxis is very less in our study regimen.

Christoph *et al.*^[9] had compared intravenous ferric carboxymaltose (FCM) with iron sucrose for treating severe anemia in pregnancy and concluded that the ferric carboxymaltose (FCM) was better tolerated. Although, FCM has a comparable safety profile as iron sucrose, a much higher single dosage of FCM reduces the need for repeated administration.

Studies from India by Patel *et al.*^[4] and Mohinuddin *et al.*^[8] reported very few mild side effects as it was seen in our study regimen.

Our study showed that the combination of oral ferrous sulphate 100 mg with folic acid 100 mcg twice daily with weekly vitamin B12 (cobalamin) injection has statistically significant difference in the hemoglobin levels after a period of one month.

CONCLUSION

The combination of ORAL FERROUS SULPHATE 100MG parenteral Vitamin B12 and folic acid may provide an efficient, effective, safe and practical option to treat severely anemic patients, especially in resource-poor settings. However, more studies with robust study design are required to compare effectiveness of this combination regimen.

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