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Original Article

Comparison of Oral Iron Therapy with Intravenous Iron Sucrose in Anemic Pregnant Women

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Abstract

Introduction: Anemia is the most common medical problem in pregnancy. Parenteral iron is a new useful agent, used in the treatment of pregnancy/iron deficiency anemia. Oral iron (OI) supplements were associated with more side effects and anaphylactic reactions and IV iron sucrose can overcome the shortcomings of OI therapy.

Aim: The aim of the study was to compare the efficacy and tolerance of intravenous iron sucrose (IVIS) therapy with OI therapy in anemic pregnant women.

Materials and Methods: Fifty pregnant women with mean gestational age 28.26 weeks with Hb <7.0–9.0 g/dL and peripheral smear features suggestive of iron deficiency anemia were included in the study and randomized in two groups of 25 each. Group I received 100 mg ferrous fumarate daily for 4 weeks orally and Group II received IV iron sucrose, dose calculated according to Ganzoni's formula. Target Hb level was 10 mg/dL, hematocrit values were measured at baseline and at day 28, and data were statistically analyzed.

Results: The mean age of the women was 26.85 years and the mean weight was 57.55 kg. The rise in hemoglobin as well as serum ferritin was more in IV iron sucrose group than in OI group at each point of measurement with statistically significant difference ($P < 0.0001$).

Conclusion: IVIS treated iron deficiency anemia of pregnancy more effectively than OI therapy, with no serious adverse drug reactions.

Key words: Intravenous iron sucrose, Iron deficiency anemia, Oral iron therapy, Pregnancy anemia, Serum ferritin

INTRODUCTION

Iron deficiency anemia (IDA) is the most common and widespread problem among all pregnancy related nutritional deficiencies. The World Health Organization (WHO) estimates that 35%–75% of pregnant women in developing countries are anemic.[1] Pregnant women are most vulnerable to anemia and 40–60% of maternal death in non-industrialized countries is caused by pregnancy related anemia.[2] Around 500,000 maternal deaths and 20,000,000 maternal morbidity cases annually are related to iron deficiency anemia according to a WHO data presented at the Federation of International Obstetrics and Gynaecology meeting in 2003 in Chile.[3] About 64.4% of the women who die have a Hb count <8 g/dL and 21.6% had Hb <5 g/dL. The prevalence rate is 57.9% in India.

The fetal consequences of anemia include risk of growth retardation, premature birth, intra-uterine death, infection, and prelabor rupture of membranes. One of the widely practiced treatment methods is the provision of iron supplements to pregnant women that include oral/parenteral iron therapy and blood transfusion.[4] Oral iron (OI) therapy is associated with increased side effects, non-compliance, and delayed treatment response. Blood transfusion is reserved for emergency situations and is also associated with increased risk of cross viral infections. A safe and effective for method for correcting IDA are IV iron sucrose infusion which has reduced risk of infections and anaphylaxis. Many recent studies on IV iron sucrose therapy states that the therapy has a low incidence of side

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effects, anaphylaxis, and tissue toxicity. It is also known to have a high availability for erythropoiesis.[5]

OI therapy requires several weeks to raise the hemoglobin levels and months to replenish the iron stores in the body and many women fail to comply with such prolonged therapy. IV iron sucrose complex has the advantage of replenishing the iron reserves in a short time and also improves the absorption and resistance when compared with OI.[6] This study compares the efficacy of OI therapy and IV iron sucrose therapy in correcting IDA in pregnant women.

Aim

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MATERIALS AND METHODS

This prospective comparative study was conducted at the Department of Gynecology, Government Headquarters Hospital, Dindigul. Fifty pregnant women with gestational age >24 weeks who had established IDA, with confirmed Hb 7.0–9.0 g/dL and peripheral smear features suggestive of iron deficiency anemia were included in the study. Women with any chronic infection, chronic lung, liver, renal, or cardiac diseases were excluded from the study. The study began after obtaining approval from the institutional ethical committee and informed consent was obtained from all the women before the start of the study. Baseline laboratory investigations such as hemoglobin, packed cell volume, mean corpuscular volume, mean corpuscular hemoglobin (MCH), MCH concentration, peripheral smear, serum ferritin, urine routine and culture sensitivity, and stool for ova/cyst were carried out before enrolment. Patients fulfilling the criteria were divided into two groups of 25 each, Group I: OI tablet group (100 mg ferrous fumarate daily for 4 weeks) and Group II: IV iron sucrose group (total iron dose (TID) was calculated according to the Ganzoni's formula: TID (mg) = weight (Kg) × ([ideal Hb - actual Hb] g/dL) × 0.24 + 500 mg (depot iron), rounded up to the nearest multiple of 100 mg. The target hemoglobin was 10 g/dL and treatment was stopped earlier in patients who reached Hb concentration >10.0 g/dL or SF level >300 ng/mL before the administration of the total IV iron. Follow-up evaluation of hematological parameters was done at baseline and at the 28th day. Measurement of serum ferritin was repeated on day 28 after baseline study and clinical improvement in symptoms was assessed. Gastro-intestinal side effects such as nausea, vomiting, constipation and diarrhea, pruritus, fever, myalgia, hypotension, local extravasation, thrombophlebitis, metallic taste, and anaphylactic reactions were noted. Data were analyzed using Independent sample *t*-test and Pearson Chi-square test in SPSS version 21. Value of <0.05 was considered significant and <0.001 was considered highly significant.

RESULTS

Twenty-five cases from each group those who completed the treatment were included in the study. The mean age of the women was 26.85 years and the mean weight was 57.55 kg. Out of the 50 study participants, 28 women had primiparity and 22 women had multiparity. The mean gestational age was 28.26 weeks. No difference in age, weight, gestational age, and parity of the patients between groups was observed. All the pregnant women in IV sucrose iron group completed the full calculated required dose of iron. The two groups were similar in demographic and clinical characteristics. Hb and serum ferritin levels were measured at baseline and at day 28 Figures 1 and 2. The baseline Hb level was 8.64 and 8.28 in the OI group and IVIS group, respectively, and at day 28, the levels were 9.61 and 10.54 in Group I and Group II, respectively. Rise in Hb and serum ferritin was observed in both the groups and the serum ferritin levels at day 28 were 52.64 in the

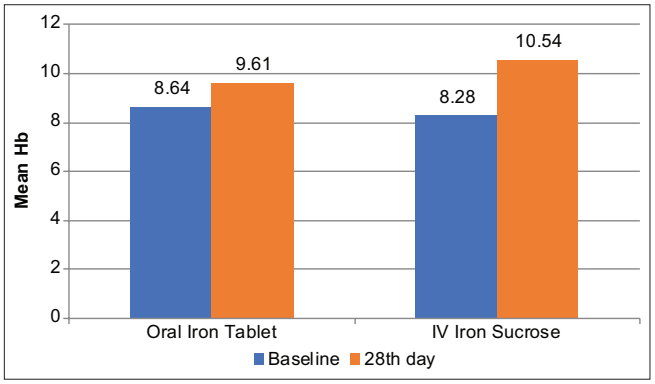

Figure 1: Comparison of mean Hb levels at base line and day 28

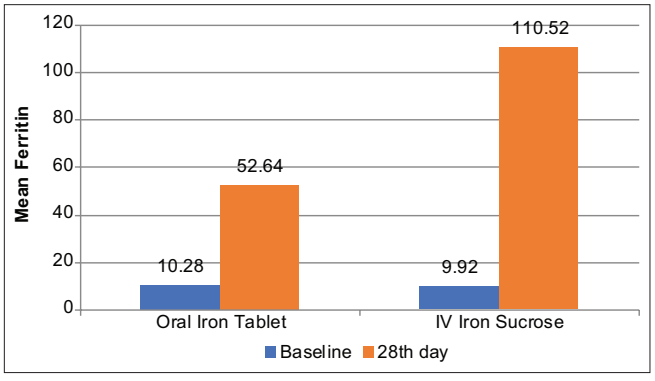

Figure 2: Comparison of mean ferritin levels at baseline and day 22

OI group (baseline – 10.28) and 110.52 in the IVIS group (baseline – 9.92). The rise in hemoglobin as well as serum ferritin was more in IV iron sucrose group than in OI group at each point of measurement with statistically significant difference ($P < 0.05$).

DISCUSSION

OI therapy has been widely used in the treatment of IDA in pregnancy but the patients do not respond adequately. IV iron use was previously underutilized due to the undesirable and sometimes serious side effects. Recent studies have led to the development of the Types II and III iron complexes that offer improved tolerance and efficacy along with a good safety profile.[7] In our study, the efficacy and tolerability of OI were compared with that of IVIS. The study results showed that the mean Hb levels at day 28 were significantly increased ($P < 0.0.12$) in the IVIS group (10.54 g/dL) than in the OI group (9.61 g/dL). There was a significant difference in the mean serum ferritin levels on day 28 between both the groups (52.64 in OI group and 110.52 in IVIS group).

IVIS is safe in pregnancy and corrects anemia at short duration and replenishes iron stores better than OI. Our study findings were similar to the other studies in literature. A case series by Govan and Scott early in 1949 reported the benefits of IV iron.[8] Subsequently, many small observational studies, quasi-experimental studies, and small randomized clinical trials showed improvement in hematological indices with IVIS in pregnant women. Iron sucrose is a type II Fe complex that releases iron to endogenous iron binding protein. It has a half-life of 6 h, and carry a minimum risk of allergic accident or toxic reactions.[9,10] IV administration increases the bioavailability and is directly delivered to the hemopoeitic system.

A randomized open label study by Unlubilgin *et al.* comparing the efficacy of intravenous iron to OI in treatment of anemia in pregnancy concluded that IV iron, treated iron deficiency anemia of pregnancy and restored iron stores faster and more effectively than OI, with no serious adverse reactions.[11] As the rate of increase in hemoglobin is faster, IVIS is suitable for treatment of IDA with lower hemoglobin in the third trimester. Bayoumeu *et al.* observed that a highly significant difference in the ferritin level was observed in the IVIS group than in OI group in his study. Increase in ferritin is because the IVIS complex releases iron rapidly to endogenous iron binding proteins with no deposition in the parenchymal tissue which is an advantage of IVIS over iron dextran or iron gluconate.[12]

Gastrointestinal side effects were reported in 20% in the OI group which included three cases of nausea and vomiting, one case of gastritis, and one case of loose motion. Mild adverse events such as burning sensation and swelling and pain in the injection site were noted one case each in the iron sucrose group. Other studies reported unpleasant taste and fever, which were not observed in our study. The reduced adverse drug reactions and no episodes of anaphylaxis make IVIS safe for anemia in pregnancy. The only disadvantage of IVIS therapy is that it is more expensive than OI and requires admission to hospital. The limitations of the study are that serum ferritin levels were not measured in the post-natal period and also if the hemoglobin levels were maintained in the similar range during the lactation period.

CONCLUSION

OI increases hemoglobin comparably with IVIS, but does not replenish iron stores as much as IVIS. IVIS therapy is better and efficient than OI in improving the Hb levels and serum ferritin levels. The side effects of IVIS are also minimal when compared to that of OI. It is also safe to administer in pregnancy. IVIS is expensive than OI and requires a hospital setting for administration. It can be used as an effective alternative for treating IDA in pregnant women. However, many aspects still require to be studied and many to be re-endorsed before IVIS are used as a routine in management of IDA.

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