Background: Anemia during pregnancy is very common in India affecting almost 80% women. Despite regular prescription of oral iron to almost all pregnant women, incidence remains high due to poor compliance due to side-effects of oral iron. The aim of present study was to evaluate the effectiveness of ferrous bisglycinate tablet in the control of iron deficiency in pregnant women.

Materials and methods: The study was designed and performed as non-comparative, open labelled clinical trial. Total of 22 pregnant women were with anemia. The women were routinely followed up as per protocol; hemoglobin (Hb) estimation was performed after 4 weeks of therapy. Results: After 4 week of treatment, there were significant increases in hemoglobin levels with mean rise in hemoglobin level is 2.4 g/dL and it showed better compliance and lack of unwanted side-effects. Conclusion: To conclude, ferrous bisglycinate in dose of 2 tablets a day is an effective treatment for anemia during pregnancy without any major side effects and with better compliance.

Keywords: Iron, anemia, hemoglobin, ferrous bisglycinate.

INTRODUCTION
Iron deficiency anemia during pregnancy is associated with increased maternal as well as fetal morbidity, including prematurity, low birth-weight and pre-natal and infant loss. Therefore, routine iron supplementation during the second half of pregnancy has been recommended but iron-supplementation programs, especially among pregnant women is poor, due in part to the side effects associated with other iron salt preparations.

Currently, there are many iron preparations available containing different types of iron salts, including ferrous sulfate, ferrous fumarate, ferrous ascorbate and ferrous bisglycinate (chelated form of iron).

Product resulting from the reaction of a metal ion from a soluble salt with amino acids to form coordinate covalent bonds, the resulting molecule is called as chelate and chemical bonding process is called chelation.[1]

Ferrous bisglycinate is highly stable and totally nutritionally functional chelate. It is an amino acid chelate which is formed by the binding of two molecules of glycine to one Fe²⁺ atom.[1]

Following oral administration, ferrous bisglycinate adds to the intestinal intraluminal pool of inorganic, non-haem iron and is absorbed intact into the mucosal cells of the intestine, and subsequently iron is dissociated from ferrous bisglycinate and then distributed, reversibly bound to transferrin for utilisation in proteins, including storage proteins.[2]

The main advantages of ferrous bisglycinate over other inorganic forms of iron supplements are its high bioavailability in the presence of dietary inhibitors because it is theorized that the chelate prevents iron from binding to inhibitors in food (phytates) or precipitating as insoluble ferric hydroxide in the pH of the small intestine, does not inhibit absorption of other minerals such as zinc and calcium, can be added to multivitamin preparations because it does not affect the stability of vitamins and less likely to have any of the gastrointestinal side-effects associated with commonly used iron salts. [2, 3]

Szarfarc SC et al., study on pregnant women concluded that daily supplementation with ferrous amino acid chelate was significantly more effective, than supplementation with ferrous sulfate. [4]

This study was design to evaluate the effectiveness of ferrous bisglycinate tablet in the control of iron deficiency in pregnant women. The effectiveness of daily supplementation of iron from ferrous bisglycinate was evaluated by measuring hemoglobin levels.

MATERIALS AND METHODS
Study design:
This study was 4 weeks, non-comparative, open labeled, single centre study to evaluate the effectiveness of ferrous bisglycinate (Ferose™) tablet in pregnant women with anemia. Pregnant women, age range of 18-30 years with a Hb level between 8-10 g/dL were included in the study. Patients with associated conditions like megaloblastic anemia or pernicious anemia, thalassemia, sickle cell or aplastic anemia, bleeding peptic ulcer, piles, esophageal varices, helminthiasis were excluded from the study. Also excluded were patients suffering from severe or uncontrolled systemic and metabolic diseases and who were on treatment with other haematinic agents within 24 hours before the start of the study.

Treatment:
Ferrous bisglycinate tablet containing 30 mg elemental iron, 11 mg of elemental zinc, 0.5 mg of folic acid and 7.5 µg of vitamin B12, was given twice daily for 4 weeks.

Clinical evaluation:
Evaluation was done on the basis of Hb estimation. Haemoglobin was measured prior to the administration and repeated after 4 weeks of therapy.

Safety and tolerability analysis:
Patients were monitored for any adverse effects. All adverse effects or unexpected events were recorded in the case report forms.
Stastical analysis:
All values are expressed as Mean±S.D. Hemoglobin analysis was performed by one-way analysis of variance (ANOVA) followed by Bonferonni’s post test.

RESULTS

Patient’s characteristics
A total of 25 pregnant women screened and enrolled in the study at single centre. Two patients were lost to follow-up while 1 woman suffering from hypoplastic anemia and 22 patients completed the 4-weeks treatment period. Statistical analysis was performed on 22 completed patients. The mean age of women was 25.2±2.5 years and were in second or third trimester of pregnancy.

Clinical evaluation
In the ferrous bisglycinate group, the Hb rise was 2.4 g/dL at the end of 4 weeks which was significantly higher (P < 0.05) compared to the baseline value. (Table 1, Figure 1)

Table 1: Effects of ferrous bisglycinate treatment on haemoglobin levels.

<table>
<thead>
<tr>
<th>Group (N=22)</th>
<th>Haemoglobin g/dL (Mean±S.D)</th>
<th>Mean rise in Haemoglobin in g/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferrous bisglycinate tablet</td>
<td>9.2±0.53</td>
<td>11.6±0.65*</td>
</tr>
</tbody>
</table>

By one way ANOVA, *P<0.05 when compared to the corresponding baseline value.

Safety and tolerability analysis
All 22 patients tolerated the drug well. Only two women had mild nausea which settled on changing the time of intake of iron tablets to after meals. As this side effect was not serious enough to withdraw the therapy.

DISCUSSION
To prevent iron deficiency anemia during pregnancy supplemental iron is advisable for all pregnant women. Women not receiving iron during pregnancy had exhausted iron stores at term and serum ferritin values stayed low even at 6 months after delivery. [5]

According to Singh S et al, study on 375 adult female patients, 42-day daily treatment with ferrous bisglycinate or ferrous sulphate resulted in significant increase in hemoglobin (Hb) levels. On day 42, the mean increase in Hb of the group receiving ferrous bisglycinate (22.72%) was significantly higher than that of the group receiving ferrous sulphate (18.66%). [6]

REFERENCES
2. Ferrous bisglycinate as a source of iron for use in the manufacturing of foods and in food supplements: The EFSA Journal 2006; 299: 2-17.

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