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Research Article

Iron Supplementation in Gastrointestinal Diseases: Effectiveness and Safety of Emoglofer® Oral Administration

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Abstract

Anaemia is the most common complication of Inflammatory Bowel Disease (IBD), it's estimated that the prevalence of anaemia in patients with Crohn disease (CD) was 27% and 21% in patients with Ulcerative Colitis (UC). The conventional oral treatments for anaemia in IBD patients are often associated with poor iron absorption and consequently a high proportion of non-absorbed ingested iron remains in the gut, and so oral iron supplementation is associated with gastrointestinal side effects such as nausea, vomiting, diarrhoea, abdominal pain, and constipation in up to 20% of patients. The aim of the present study was to evaluate the efficacy and safety of Emoglofer® oral administration in patients with anaemia deriving from IBD or other gastro-intestinal inflammations considering a chronic administration regimen with two control time points (after three and six months of administration) monitoring the most simple and standard parameters related to iron anaemia (ferritin, sideremia, haemoglobin and haematocrit). The present study suggests that Emoglofer® oral administration is safe and is able to increase haemoglobin, ferritin, sideremia and haematocrit after three and six months from oral administration; more consistent controlled clinical trials should be conducted in order to deeply investigate the effect on anaemia correlated to Gastro-intestinal Inflammatory conditions GIIC.

Keywords: Iron supplementation, Gastro-intestinal inflammatory conditions (GIIC), Haemoglobin, Erritin

Introduction

Anaemia is conventionally described as a reduction in the proportion of red blood cells or haemoglobin or haematocrit. The presence of a symptomatology depends on the aetiology of anaemia and is correlated also to the presence of different comorbidities. It's a very common disease that affects up to one-third of the global population and its prevalence increases with age, in women in reproductive age, pregnant women and elderly patients [1]. Anaemia is the most common complication of Inflammatory Bowel Disease (IBD) that includes also extraintestinal manifestations such as rheumatic, dermatologic, and ophthalmologic [2-3]. It's estimated that the prevalence of anaemia in patients with Crohn Disease (CD) was 27% and 21% in patients with Ulcerative Colitis (UC). Anaemia in IBD is mostly multifactorial, resulting, from chronic intestinal blood loss from inflamed intestinal mucosa combined with impaired iron absorption mainly as a consequence of inflammation but also in association with intake of proton pump inhibitors, persisting H. pylori infection or reduced food and thus impaired dietary iron uptake [4]. The conventional oral treatments for anaemia in IBD patients are often associated with poor iron absorption and consequently a high proportion of non-absorbed ingested iron remains in the gut, and so oral iron supplementation is associated with gastrointestinal side effects such as nausea, vomiting, diarrhoea, abdominal pain, and constipation in up to 20% of patients [4-5]. Also, in case of Celiac Disease, anaemia is one of the most common clinical man-

ifestations and it is estimated that is present in over half of patients at the diagnosis stage with chronic intestinal inflammation playing an important role in the development of anaemia [6-8].

Many other conditions related to gastro intestinal inflammation and bleeding are also associated with iron deficiency such as diverticular bleeding, gastro-intestinal ulcers, angiodysplasia [9]. Therefore, the scientific research is globally oriented to novel therapeutic approach in different fields with the aim to maximise the efficacy and patients' compliance reducing side effects [10-13]. Emoglofer® is an innovative nutraceutical specifically formulated with a new iron based patented technology called Phosphosome® iron. Particularly, Phosphosome® iron is a vehiculated formulation of iron pyrophosphate able to enhance the iron bioavailability and the therapeutic efficacy reducing side effects with a tested clinical effect in other therapeutic areas [14]. The aim of the present study was to evaluate the efficacy and safety of Emoglofer® oral administration in patients with anaemia deriving from IBD or other gastro-intestinal inflammations considering a chronic administration regimen with two control time points (after three and six months of administration) monitoring the most simple and standard parameters related to iron anaemia (ferritin, sideremia, haemoglobin and haematocrit).

Materials and Methods

Settings

The clinical survey has been conducted by an Italian medical doctor and is based on its clinical experience in patients taking Emoglofer®. The retrospective observational survey was conducted in accordance with the Standards of Good Clinical Practice of the European Union and the ethical principles expressed in the Declaration of Helsinki. Data were retrospectively collected in the period December 2022 – June 2023 by the medical specialist. Ethical approval was not necessary according to National Code on Clinical Trials declaration because this data derives from a real-life retrospective study [15]. The aim of the present study was to evaluate the effect of Emoglofer® oral administration at T0 (enrolment phase), after three months (T3) and six months (T6) of treatment.

Study Population, Treatment and Evaluated Parameters

An Italian medical doctor enrolled participants in the period December 2022 – June 2023 evaluating their clinical manifestations during medical examination. In particular, the participants were selected according to defined inclusion criteria that were related to anaemia correlated with GIIC such as: Crohn disease, ulcerative colitis, diverticular disease, jejunal angiodysplasia, peptic disease, Celiac disease. Considering these clinical conditions, a total of 28 patients with a mean age of 50 years were enrolled in the present survey; at the first medical examination, the doctor reported for each patient its age, comorbidity and use of pharmacological treatments. Regarding pharmacological treatments, about 82% of the patients took specific drugs: mesalazine, Monoclonal Antibodies (MAB), azathioprine, insulin, aspirin and ACE inhibitor, rifaximin, omeprazole. At the enrolling time (T0) serum values for ferritin, haemoglobin, sideremia and haematocrit were registered. Then, each participant administered Emoglofer® with a posology of one tablet/day and repeated the sub mentioned hematic parameters that were registered from the doctor after the follow-up visit at 3 months (T3) and at six months (T6).

Results and Discussion

Anaemia in patients with IBD is multifactorial and the two most frequent etiological forms by far are Iron Deficiency Anaemia (IDA), resulting from iron deficiency secondary to blood loss through the ulcerations of the intestinal mucosa, reduced iron absorption and reduced intake and Anaemia of Chronic Disease (ACD). ACD is characterized by normal or reduced Mean Corpuscular Volume (MCV), reduced serum iron, reduced Total Iron Binding Capacity (TIBC), normal to elevated serum ferritin level, and Reticulo Endothelial System (RES) stores that are elevated relative to total body iron [16]. Oral iron is conventionally the therapy of choice in case of anemia related to GIIC, in fact the use of intravenous iron preparations is often associated with side effects and so it is widely considered as a second choice if not necessary [16-17]. Specifically, for IBD patients with mild anemia (Hb >10 g/dL) oral therapy can be used but it is widely known that more than 90% of ingested iron, in traditional formulations, is unabsorbed, and consequenlty oral iron supplementation is associated with many gastro-intestinal side effects and low therapeutic adherence [16]. Haemoglobin (Hb) normal levels according to World Health Organization are different with respect to the specific population investigated, with a cutoff of 130 g/L for men, 110 g/L for pregnant women and 120 g/L for non-pregnant; while in children between 12-14 years the cutoff is 120 g/L, 115 g/L in children between 5- 11 years and 110 g/L in children between 6 and 59 months [18]. In the present retrospective clinical survey, all the selected patients showed at T0 a mean Hb value of about 10 g/dL that could be considered as a sure indication of anaemia regardless of the specific target population, gender and age. As reported in Figure 1, after three months of oral treatment with Emoglofer®, the mean Hb level raised up to 11.4 g/dL and after six months this value reached 12.4 g/dL with a 24% enhancement with respect to T0.

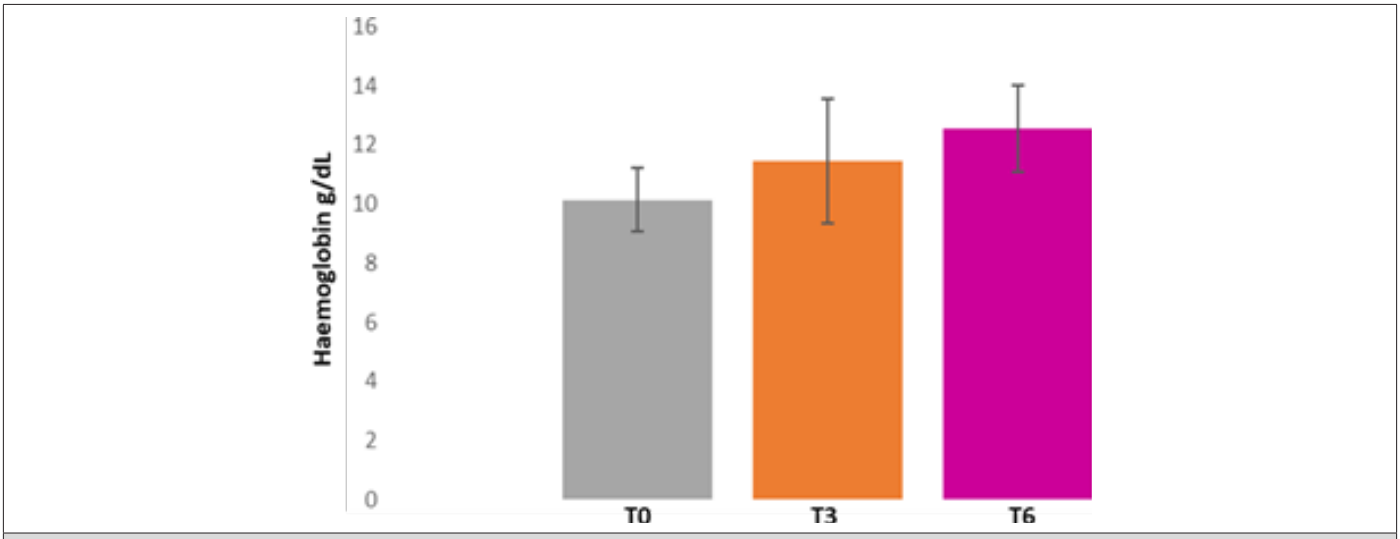

Figure 1: Haemoglobin levels at T0 (grey) and after 3 months (orange) and 6 months (purple) of treatment with Emoglofer ®. Data are expressed as mean ± standard deviation.

In addition, other important parameters were monitored after the treatment with Emoglofer® as reported in Figure 2. Particularly, levels of sideremia, as marker of circulating iron, were strongly improved after the administration of Emoglofer® with an overall enhancement of about 178% at T6 and about 92% at T3. In order to evaluate also iron storage, ferritin levels were evaluated and all patients at T0 showed very low levels with a mean value of about 19 ng/mL. Surprisingly, at T3 an increase of ferritin of about 105% was detected and after six months of treatment there was an overall increase of about 137%. The haematocrit, is the volume percentage of red blood cells in blood, it is normally 40 –54% for males and 36 – 48% for females, and it is a simple hematic parameter conventionally examined with haemoglobin, ferritin in order to have a complete idea of iron status into the body [18]. In all enrolled patients' haematocrit level, as detected for haemoglobin, sideremia and ferritin, was lower than guideline indications with a mean value of about 33%; after six months of treatment with Emoglofer® also haematocrit value increased of about 15% raising the value in the normal condition range.

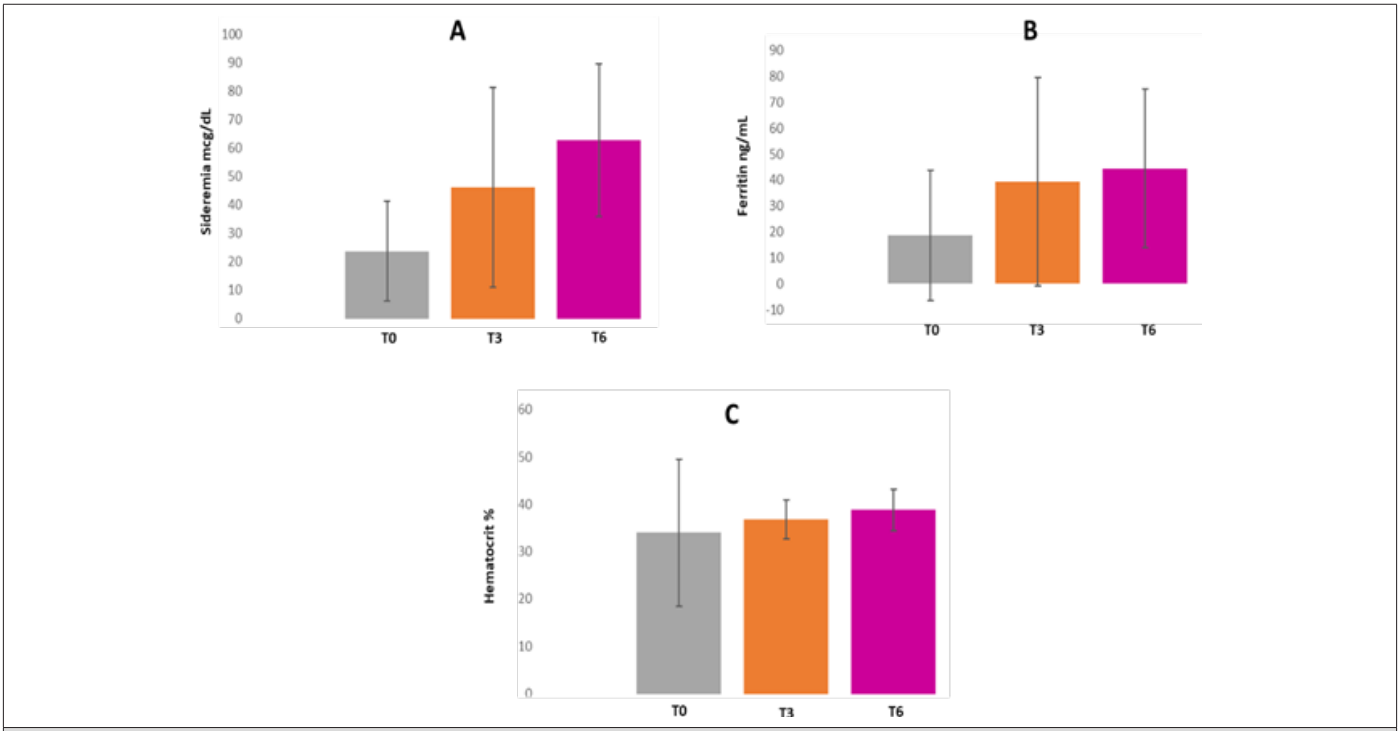

Figure 2: Sideremia levels at T0 (grey) and after 3 months (orange) and 6 months (purple) of treatment with Emoglofer ® (A); ferritin levels at T0 (grey) and after 3 months (orange) and 6 months (purple) of treatment with Emoglofer ® (B); haematocrit percentage at T0 (grey) and after 3 months (orange) and 6 months (purple) of treatment with Emoglofer ® (C). Data are expressed as mean ± standard deviation.

This is the first study regarding the oral administration of Phoshposome® iron in gastroenterology, demonstrating a good efficacy to restore the main hematic parameters correlated with iron metabolism after three months of treatment with a subsequent further improvement of these parameters six months after the start of treatment (T6). No side effect correlated to the use of Emoglofer® up to six months was detected in the present study confirming its high compliance. These interesting results are strictly correlated to the patented technology, Phosphosome® iron in the formulation of Emoglofer®. In fact, as reported in previous bibliographic data, Phosphosome® iron showed an improved resistance to gastric digestion and higher intestinal absorption than conventional ferric pyrophosphate used as control. In the Follicle-Associated Intestinal Epithelium Model (FAE), Phosphosome® iron induced larger iron absorption than in the Caco-2 monolayer, most likely due to the transcytosis ability of M cells. The larger iron absorption in the Phosphosome® iron treated FAE model corresponds to higher ferritin level, proving physiological iron handling that was once delivered by the patented formulation. Finally, the formulation did not induce any alterations in viability and barrier integrity. The in vitro study concluded that, Phosphosome® iron enhanced iron absorption and ferritin expression, while preserving any adverse effects [19]. The present retrospective clinical survey, could be considered as a starting point for the validation of Emoglofer® as therapeutic tool in the treatment of anaemia in patients with gastro-intestinal inflammatory conditions; more specific clinical trials including hematic parameters of inflammation (C reactive protein, erythrocyte sedimentation rate) and a more deep characterization of iron hematic parameters (such as transferrin saturation) are needed to confirm the potentially clinical application.

Conclusion

The treatment of anaemia in patients with gastro-intestinal inflammatory conditions is very difficult and often result in poor therapeutic efficacy and patients' compliance. A total of 28 patients with diagnosed anaemia correlated to GIIC were enrolled in the present retrospective clinical survey and were orally treated with Emoglofer® monitoring the main parameters of iron metabolism: haemoglobin, sideremia, ferritin and haematocrit after three and six months from the administration miming a chronic dosage regimen. All the parameters were already improved at T3 and after six months of Emoglofer® administration a further increase in serum levels of hemoglobin, ferritin and sideremia was observed as well as the haematocrit was found to be within the recommended values. The high therapeutic efficacy and the absence of typical gastro-intestinal side effects of Emoglofer® are due to the patented iron formulation (Phosphosome® iron) able to guarantee gastro-resistence and an optimum absorption profile in the intestine trough different mechanisms. The present study suggests that Emoglofer® oral administration is safe and is able to increase haemoglobin, ferritin, sideremia and haematocrit after three and six months from oral administration; more consistent controlled clinical trials should be conducted in order to deeply investigate the effect on anaemia correlated to GIIC.

Acknowledgement

None.

Conflicts of Interest

We declare that Umberto Di Maio is a Shedir Pharma Group S.p.A. member and Antonino Bagnulo is Neilos S.rl. member.

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Authors' Contributions

All authors contributed equally to the manuscript and read and approved the final version of the manuscript.

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