Evaluation of Sucrosomial® Iron efficacy in paediatric patients with iron deficiency anaemia in an outpatient setting

By Junia Pharma

In childhood, iron deficiency anaemia is usually associated with malnutrition, malabsorption often linked to coeliac disease, inflammatory bowel disease (IBD) or obesity [1, 2]. In industrialized countries, there are high percentages of overweight children with iron deficiency, which may be due to low iron intake and/or increased iron requirements in this population. Moreover, obese patients are characterized by chronic inflammation which increases the level of hepcidin produced in the liver [1]. Hepcidin is an important hormone secreted by hepatocytes in response to inflammatory markers, such as IL-6, which once it is released into the bloodstream, binds and degrades ferroportin proteins, causing sequestration of iron into the deposit. The major consequence of iron deficiency is impaired cognitive development in children, who may also show fatigue and asthenia.

Conventional iron preparations often have gastrointestinal side effects and can be ineffective in some patients with malabsorption due to coeliac disease or inflammatory conditions such as IBD or obesity. Normal iron salts are absorbed in the duodenum by receptors in the apical membrane of enterocytes. In coeliac disease, the microvilli of enterocytes are disrupted, causing a decrease in the absorption of several vitamins and minerals, including iron. In other diseases such as IBD or obesity, inflammation decreases the ability of the body to absorb iron. Indeed, a high prevalence and higher risk of iron deficiency has been demonstrated in obese and overweight patients, which is mainly caused by the excess adipose tissue that produces pro-inflammatory markers [1]. Consequently, this population of patients shows a reduced response to conventional iron salts [1]. As reported in the literature, obese populations usually show a high rate of oral iron therapy failure due to side effects or treatment ineffectiveness. Here we report that Sucrosomial® Iron was effective and safe in supporting paediatric patients with iron deficiency anaemia.

<h1>COMPOSITION AND TECHNICAL DETAILS</h1>

Sucrosomial® Iron (one of the ingredients in Sideral® Oro, Junia Pharma S.r.l., Italy) is a unique and patented iron formulation featuring an extremely high level of bioavailability. The pyrophosphate iron in the formulation is carried within a double layer of phospholipids plus sucrose esters of fatty acids. This allows higher absorption of iron compared to other iron formulations, including ferrous sulfate, and avoids gastrointestinal side effects such as abdominal pain, constipation, vomiting and diarrhoea, and oxidative reactions, caused by traditional oral iron formulations [3, 4]. Its high tolerability and the improvement in patient serum iron, haemoglobin and
ferritin levels have been confirmed by several studies [3-7]. Oral Sucrosomial® Iron has also been demonstrated to have similar effects to intravenous iron therapy [5, 7].

**Efficacy and Safety**

The purpose of the study was (i) to determine the efficacy of Sucrosomial® Iron in mainly overweight paediatric patients with iron deficiency anaemia and (ii) to evaluate all reported side effects. The study was conducted at ASL Caserta (Italy) by Drs M Sticco, M Ferraiuolo, A Argenziano, D Longo, G Galzerano, D Stabile, M Tedesco and F Napolano, in collaboration with Drs E Pera and G Tarantino (Junia Pharma S.r.l).

Forty-nine paediatric patients (24 male, 25 female) with a median age of 10 years (range 4–16) were enrolled in an outpatient setting. Five of these patients had coeliac disease, 35 were obese, and 9 showed iron deficiency anaemia. Patients were supplemented with a formulation (Sideral® Oro) containing Sucrosomial® Iron, corresponding to 12 mg of elemental iron per day, plus vitamin B complex, for a median of 60 days (range 45–90). Blood haemoglobin values and side effects were evaluated.

Patients' haemoglobin increased from a median of 10.8 g/dL (range 9–12.3) to 11.50 g/dL (9.3–13.1) (Fig. 1, left panel). Additionally, the 35 obese patients, who were supplemented for a median of 80 days (75–90), had a median increase of 1 g/dL (0.4–2.10) of haemoglobin (Fig. 1, right panel). The increase in haemoglobin was dependent on the duration of supplementation. Thus, patients treated for less than 60 days had a median increase of 0.4 g/dL, which value increased to 0.55 g/dL with 60 days of supplementation, to 0.95 g/dL with 70 days of supplementation, and to 1 g/dL with 75–90 days of supplementation (Fig. 2). High compliance was reported and no side effects related to the formulation were seen.

**Applications and Dosage**

Sucrosomial® Iron allows for safe and effective supplementation with a highly bioavailable source of iron with no side effects. To ensure recovery of iron stores along with improvement in haemoglobin values, supplementation for at least 75 days is recommended. The presence of vitamin B complex in the formulation (Sideral® Oro) while having a positive effect on erythropoiesis, also provides relief from asthenia and fatigue by supplying macronutrients which may be deficient in these patients.
Figure 1  Haemoglobin values in paediatric patients with iron deficiency anaemia before and after Sideral® Oro supplementation. Left panel: all patients (n=49); right panel: obese patients (n=35). Data are mean values±SD. ***p<0.01

Figure 2  Effect of Sideral® Oro supplementation over time on increase in haemoglobin values in paediatric patients with iron deficiency anaemia. Data are the mean±SD increase over basal blood haemoglobin values.
REFERENCES


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Junia Pharma in a nutshell

Junia Pharma, established in 2010, is a pharmaceutical company offering a range of medicines, and over-the-counter and nutraceutical products aimed mainly at children and teenagers. Junia Pharma is renowned for its high-quality products that meet the medical needs of infants, children and adolescents.