

## 5th International multidisciplinary course on iron anemia, 31st March–1 April 2017, Florence, Italy

### SIDERAL® FORTE – THE FIRST EXPERIENCE OF 3 MONTH THERAPY OF ANEMIA IN INFLAMMATORY BOWEL DISEASES

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**Introduction:** The article describes the modern view on the etiology and treatment approaches of anemia in inflammatory bowel diseases (IBD). Standard iron drugs' low efficacy and poor tolerability due to malabsorption and chronic inflammation of the intestinal wall are discussed.

**Objective:** The aim of this work is to determine the pathogenetic validity, efficacy and tolerability of the novel oral Sucrosomial® iron (Sideral® Forte) in IBD patients with anemia.

**Methods:** We have currently analyzed the results of 6 anemic patients treated with oral Sucrosomial® iron, Sideral® Forte. The therapy was prescribed after hospital discharge under the supervision of a hematologist. The drug was given as one capsule (30 mg of elemental iron) two times a day when the serum ferritin level was less than 100 µg/L. The result was evaluated before and after 1 and 3 months of treatment. We used erythrocyte indices and routine parameters for iron metabolism as laboratory markers of the treatment effectiveness. Clinical efficacy and tolerability of Sideral® Forte was determined according to the severity of anemia, sideropenic symptoms, complaints associated with the manifestation of IBD before and after 3 months of treatment. With this purpose a special questionnaire was developed and filled out by patients. It included three main groups of anemia and IBD symptoms with point ranging from 1 to 5 depending on the severity of the symptoms. The questionnaire was assessed by calculating mean value for each item, then the average value for three groups of complaints.

**Results:** Laboratory efficacy of Sideral® Forte was demonstrated by an increase in hemoglobin (Hb, from 11.1±1.4 g/dL to 12.4±1.6 g/dL), mean corpuscular hemoglobin (MCH, from 26.3±2.6 to 29.4±3.0 pg), serum iron (SI, from 4.6±1.6 mkmol/L to 8.1±4.1 mkmol/L) and serum ferritin (SF, from 12.4±13.3 mkg/L to 20.2±33.9 mkg/L) levels and by a decrease in erythrocyte sedimentation rate (ESR, from 30.8±1.2 to 20.8±7.4 mm/h) and total iron binding capacity of serum iron (TIBC, from 56.4±10.9 to 51.7±4.9 mkmol/L), thus, showing normalization of Hb, MCH and SF levels after 3 months of treatment. Mean Hb increase leads us to conclude that Sucrosomial® iron is an effective drug for anemia in IBD patients. MCH increase was significant, which is explained by the quick increase of iron availability, needed for erythropoiesis, and it proves the normalization in hemoglobin formation with Sideral® Forte treatment. Despite the sharp increase of exogenous iron utilization, SF increase, during therapy, is an efficacy criterion for the treatment of iron deficiency anemia (IDA).

Questionnaire results for the five patients receiving Sideral® Forte demonstrates, after 3 months of treatment, a decrease in the average scores (average manifestations) for anemic symptoms (from 3.0±1.2 to 1.7±0.6), sideropenic symptoms (from 2.4±1.6 to 1.6±0.3) and IBD gastrointestinal manifestations (from 2.5±0.8 to 1.8±0.3). The most significant changes were seen in the reduction of anemic (to 2.1±0.5) and sideropenic (to 1.6±0.4) manifestations already after 1 month of treatment.

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**Conclusions:** Clinical symptoms of IBD had also positive dynamics and none of the patients abandoned the treatment. The findings suggest that Sideral® Forte is an effective (by laboratory and clinical data) and safe treatment of anemia in patients with IBD. This preparation is adequate for the treatment of anemia and helps changing the paradigm of relatively poor tolerable iron supplements. Further research is to allow recommending Sideral® Forte as the main drug for the treatment of anemia associated with IBD.

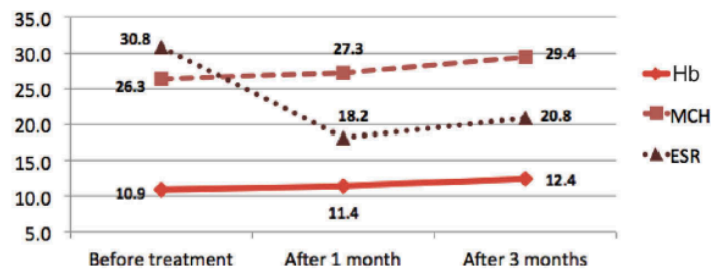


Figure 1. Hemoglobin (Hb, g/dL), mean corpuscular hemoglobin (MCH, pg), erythrocyte sedimentation rate (ESR, mm/h) in patients treated with Sideral® Forte.

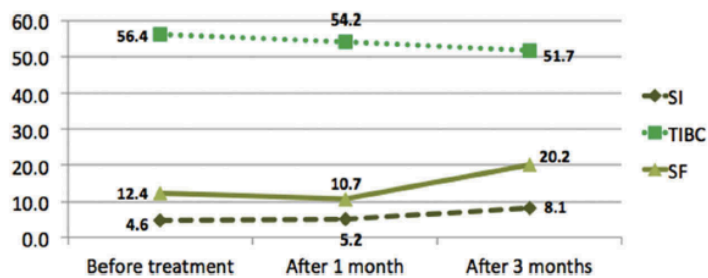


Figure 2. Serum ferritin (SF, mkg/l), Serum iron (SI, mkmol/l), total iron-binding capacity of serum (TIBC, mkmol/l) in patients treated with Sideral® Forte.

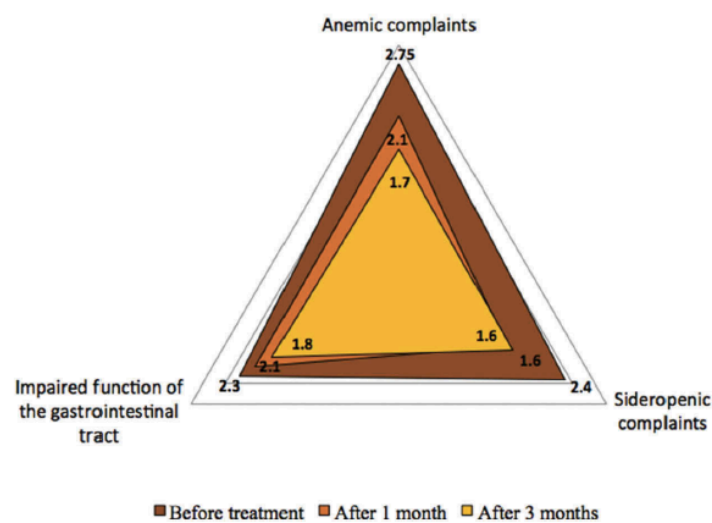


Figure 3. Clinical efficacy and tolerability of Sideral® Forte.