LIPOSOMIAL IRON IMPROVES FATIGUE IN PATIENTS WITH MYELODYSPLASTIC SYNDROMES AS REFRACTORY ANEMIA. A MULTICENTER STUDY.

Berardi Donata 2, D’ Amico Fabio 3, Commatteo Antonio 1, Traficante Divina 4, Carabellese Bruno 5, Licianci Antonietta 6, Di Marizio Luigi 6, Berardi Giuseppe 7, Gigli Rosanna 8, Magri Marilù 8, Niro Giovanna 8, Di Lullo Liberato 1, Giordano Giulio 1.

1. Oncology – Cardarelli Hospital – Campobasso, Italy; 2. University “La Sapienza” – Rome, Italy; 3. Foundation “John Paul II” – Campobasso, Italy; 4. Oncology – Venezia Hospital – Isernia, Italy; 5. Nuclear medicine – Cardarelli Hospital – Campobasso, Italy; 6. Hospital management – Cardarelli Hospital – Campobasso, Italy; 7. Family medicine, Campobasso, Italy; 8. Laboratory medicine – Cardarelli Hospital – Campobasso, Italy.

Objectives of the study:

The aim of this study is to verify whether sucrosomial iron support in myelodysplastic syndromes as refractory anemia improves fatigue perception in patients with a saturation of total iron binding capacity < 20%.

Materials and Methods:

Between June 2011 and December 2014, 20 patients affected by refractory anemia were studied. Median follow-up was 12 months (R10-24). Patients were randomized 1:1 and in group A median age was 60 years (R65-70), M/F: 8/2. In group B median age was 66 years (R60-75), M/F: 6/4. Karyotype was normal in group A and B patients. Median level of haemoglobin was 9 g/dL in group A (R8.5-11) and 8.8 g/dL (R8.5-11.5) in group B. To Group A received alpha erythropoietin 40000 IU sc/week + calcium levofolinate 7.5 mg/day orally + Vitamin B12: 400 mg/day orally. Group B received sucrosomial iron 14 mg (Sideral®), 1 capsule orally/day + alpha erythropoietin 40000 IU sc/week + calcium levofolinate 7.5 mg/day orally + Vitamin B12: 400 mg/day orally. Fatigue was measured using the Modified Fatigue Impact Scale (FISC - Fisk 1994).

Results:

Patients in group A reached a median hemoglobin level of 11.5 g/dL and after 3 month of therapy referred a median FISC score of 74 (R65-80). Patients in group B reached a median hemoglobin level of 12.5 g/dL and after 3 month of therapy referred a median FISC score of 54 (R42-68).

Conclusion:

Sucrosomial iron support improves fatigue perception in patients with refractory anemia. This study needs confirmation on a larger cohort of patients.