HOSPITAL PROTOCOL FOR EVALUATING EFFECTIVENESS AND SPEED OF USE OF THE SUCROSOMIAL® IRON IN CARDIAC REHABILITATION DEPARTMENTS.

• Authors name:

Denas Gentian MD[1], Leopoldo Pagliani MD PhD[2], Mario Gregori[1], Nicolosi Elisa[1], Di Naro Agnese MD[1],

• Authors' affiliation:

[1]Cardiovascular Prevention Unit and Cardiology Department Motta di Livenza High Specialization Rehabilitation Hospital

[2] Veneto Oncology Institute-IOV- IRCCS Padova

• Background

In modern cardiology, rehabilitation plays an important role and is an integral part of the therapeutic strategy in cardiac patient for favourable effects have been documented, since the quality of life, on cardiovascular risk profile and, ultimately, incidence of sudden death and global mortality after the acute event [1-3]

 In this patients the finding of the moderate anemia it is frequent, particularly in patients female or little size structures or low body surfaces. It is mostly caused by blood loss secondary to recent interventional cardiology procedures or cardiac surgery [4] or multifactorial causes, as occurs in heart failure patients. In the Cardiac Rehabilitation Unit of the percentage of hospitalized patients have anemia is equal to 20-30% of the observed population if as a criterion for the diagnosis considering a red cells number <3500000 / mm [3] the entrance to it, and if you consider a hemoglobin level <11 g / 100 ml is equal to about 50%. Supplementation terapy with iron, vitamin B12 and folate are useful to correcting the status of anemia, although it is not uncommon the need to resort to therapies favoring erythropoiesis and of course to blood transfusions.

In this scenario the need for therapies with rapid effect and well tolerated, becomes crucial in this setting of patients, considering also to stabilize patients who are hospitalized in 2nd or 3rd post-operative days and where we have available about 12-16 days to complete the first cycle of rehabilitation.

• Objectives

Evaluate effectiveness and speed of action in using Sucrosomial® iron than iron-based constituents to be taken orally and entered into the hospital formulary available in a cohort of patients referred to rehabilitation and population preventive cardiology

• Methods

The study design provides randomization of the total 100 patients divided into two consecutive arms by random selection. Each patient pertaining to cardiac rehabilitation and preventive with hemoglobin of between 8.5 (to the exclusion of ischemic patients whose limit values was 9 mg) and 11.9 mg / dl (Not including patients with active peptic ulcer, erosive gastritis note, ulcerative colitis and other inflammatory bowel disease or malabsorption diagnosed) was sent to therapy ferrous sulfate to the usual dose planned in hospital protocols and Sucrosomial® iron dosage in accordance with the data sheet.

The study began 30 days ago with the goal to evaluate the patients with Blood count controls, Serum Iron, Ferritin, Transferrin, and Percentage of Reticulocytes to the hospital entrance time (basal) to 15 days at the end of the first rehabilitation cycle (mid-term) and 30 days after initiation of oral therapy or before the second rehabilitation cycle (late term) provided at discharge.

 • Preliminary Results

They are evaluated as a preliminary result of 16 patients data with a comparable age (TAB.1) and with a comparable baseline hemoglobin (9.5 vs 9.2 g / dL) (TAB. 2).
As shown in the diagrams in the appendix the mid-term results did not show a significant difference (10.1 vs 9.9 g / dl) (TAB. 2) in the recovery of hemoglobin. So they also present the results of transferrin despite the baseline in the arm of ferrous sulphate were significantly higher (174 vs. 194 mg / dl) (TAB. 3) even though they are not pathological. They were high instead of Ferritin values but with greater stability in the 14-day treatment of patients treated with Sucrosomial® iron (503-408 vs 603-875 ng / mL) (TAB. 4) . It is reported as 2 patients (33%) have left the treatment arm with oral ferrous sulfate after about a week of treatment for Gastro-Intestinal disorders.
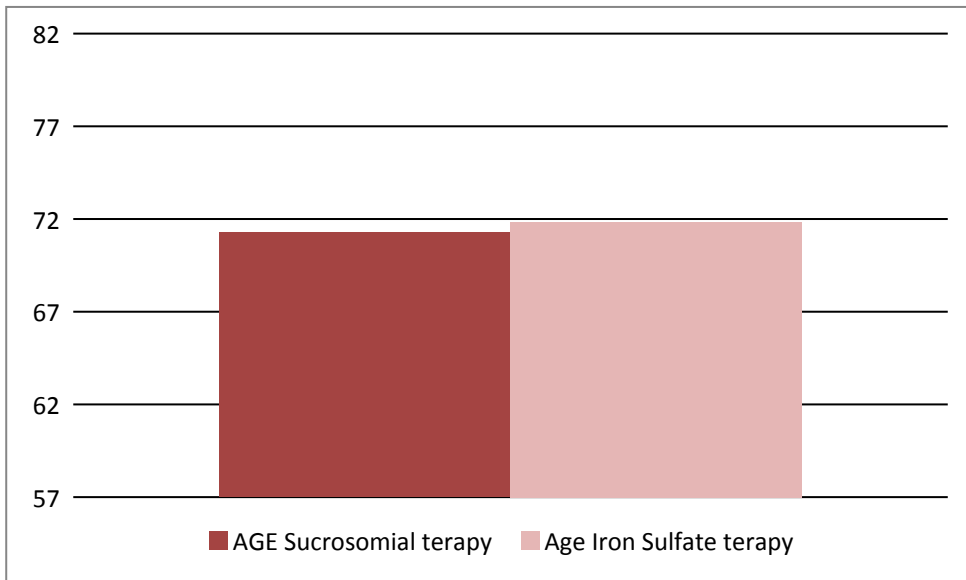
• Conclusions

Even more so after the realization of the study design, it will be important to understand how to approach the anemic patient in the departments of Rehabilitative and Preventive Cardiology. It will be necessary that we complete the study with expected numbers to have a significant statistical power and to understand in the time period of 30 days of treatment as other ferrous preparations are better adapted to the clinical reality of cardiac patients. It remains solid the assumption of how the Sucrosomial® iron are better tolerated without loss of effectiveness. Long distance assessment also of Serum iron values, Transferrin, Ferritin and Percentage of Reticulocytes will complete the analysis giving fundamental inspiration also to understand the real homeostatic mechanisms changed by different molecules.
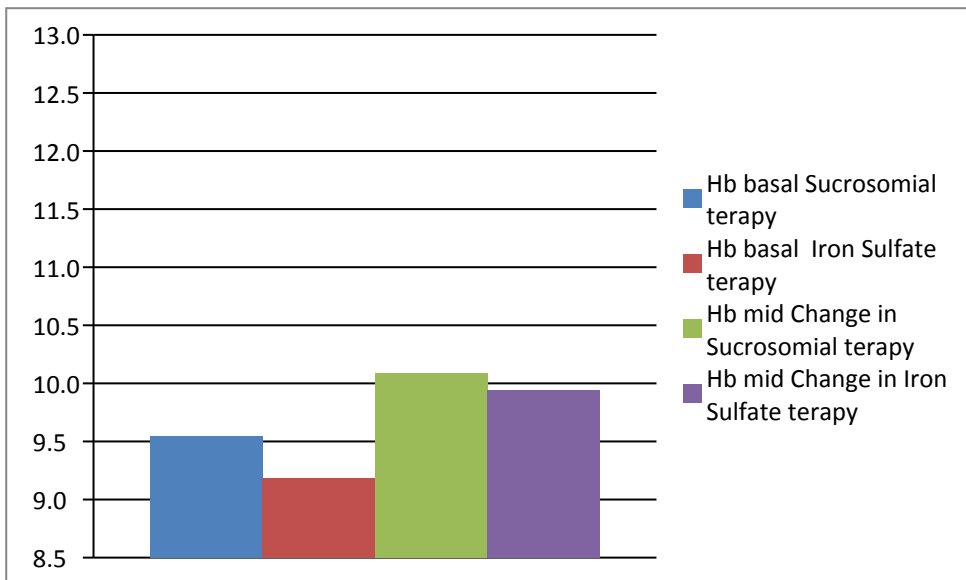
• Bibliography

1.   Rehabilitation after cardiovascular diseases, with special emphasis on developing countries. Report of a WHO Expert Committee. World Health Organ Tech Rep Ser 1993; 831: 1-122.
2.   Guidelines ANMCO-SIC-GIVFRC on rehabilitation cardiology. G Ital Cardiol 1999; 29: 1057-91
3.   Long-term comprehensive care of cardiac patients. Recommendations by the Working Group on Rehabilitation of the European Society of Cardiology. Eur Heart J 1992; 13 (Suppl C): 1-45
4.   De Foe GR, CS Ross, O lmstead EM, et al. Lowest hemat ocrit on bypass and adverse outcomes associated with choir-nary artery bypass grafting. Northern New England Cardiovascular Disease Study Group. Ann Thorac Surg 2001; 71: 769-76
5.   Inamura J et al. Upregulation of hepcidin by interleukin-1 in human hepatoma cell lines. Hepatology Research 33 2005 198-205
6.   Jade Pistons, Massimiliano Di Martino, Elisa Veziano, Stefano Saffioti: abstract 57 ° SIN Congress, Rome, October 2016, as published on the Italian Journal of Nephrology (Year 33 - Vol. S67).
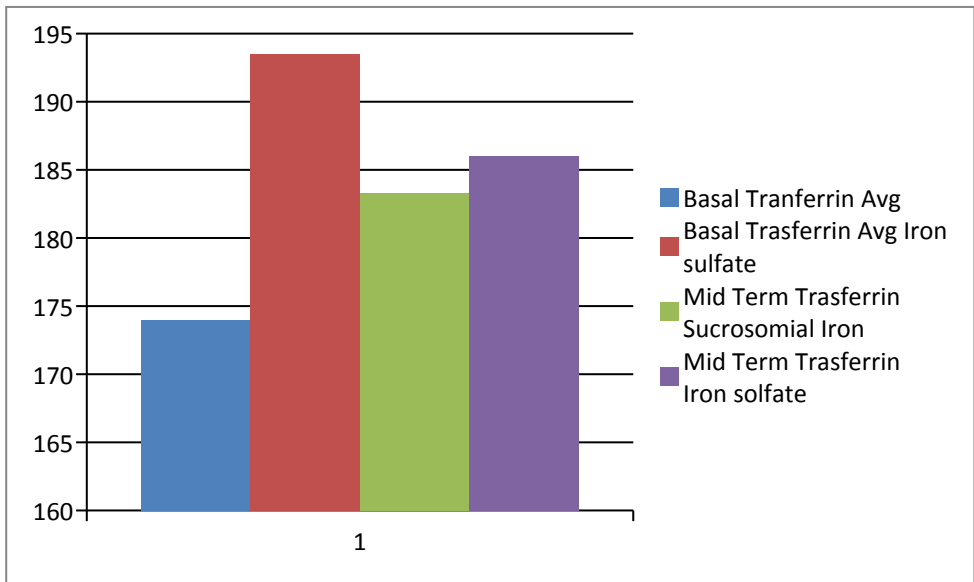
APPENDIX Table

(TAB.1)

(TAB.2)

(TAB.3)

- Basal Tranferrin Avg
- Basal Trasferrin Avg Iron sulfate
- Mid Term Trasferrin Sucrosomial Iron
- Mid Term Trasferrin Iron solfate

(TAB.4)

- Basal Ferritin Avg Sucrosomial Iron
- Basal Ferritin Avg Iron sulfate
- Mid Term Ferritin Sucrosomial Iron
- Mid Term Ferritin Iron solfate