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TREATMENT CORRELATION OF SIDEROPENIC ANEMIA WITH IRON (III) PROTEIN SUCCINYLATE (IPS) AND SUCROSOMIAL IRON (SI)

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Abstract

Introduction: Anaemia denotes a reduced number of erythrocytes or reduced amount of Hgb, or one and the other at the simultaneously, below the reference values for the appropriate age. Iron is a metal taken-in by ingestion and it is crucial for haemoglobin synthesis, and saturation of its storage. During the different ages of life, and in infants also, the daily iron needs increases, and if this need is not compensated, hypochromic anaemia develops.
Purpose: This paper aims to determine the time ratio and the results of the treatment of iron-deficiency anaemia with IronProteinSuccinylate and Sucrosomial Iron.
Materials and Methods: The prospective study was performed during the screening of anaemia in infants at the PHI – PEDIATRIKA in Tetovo and the clinical laboratory at the Clinical Hospital of Tetovo; 76 infants aged 1-12 months were screened, diagnosed with anaemia and treated during the period of January – June 2018. At the average age of 7.4 months, the gender composition was as follows: 47 infants are females, and 29 are males.
Results: The results obtained at the beginning and after treatment with anti-anaemia therapy in both groups were analysed. The group that had been treated with Sucrosomial Iron has shown significant improvement of some parameters such as Hgb, HTC, MCV and Fe^{++} after using therapy for 1 month, while the group of patients treated with Iron Protein Succinylate has had a significantly weaker improvement compared to the first group.
Conclusion: Sucrosomial Irontreatment has been shown to be most effective in the largest percentage of patients with Iron-deficiency anaemia, with parameters such as Hgb, HCT, MCV and Fe^{++} having higher growth in the group treated with Sucrosomial Iron for a period of 1 month.
Discussion: The infant's feeding habits are very important and affect the results of the treatment of anaemia; iron-rich food products and the use of supplementary therapy that is known of not having side effects, and that shortens the treatment period are recommended.

Keywords: anaemia, treatment

INTRODUCTION

Anaemia denotes a reduced number of erythrocytes or reduced amount of Hgb, or one and the other at the simultaneously, below the reference values for the appropriate age.
Anaemia can be caused by various factors and is the most frequent childhood blood disease. Prevalent in 30% of the world's population, it is one of the major health problems, characterized by changes in size and colour of the erythrocytes; it is a disease that reduces blood oxyphoricity. Due to the reduced oxyphoricity, tissue hypoxia ensues.
Iron is a metal taken-in by ingestion and it is crucial for haemoglobin synthesis, and saturation of its storage. Iron is absorbed from iron-rich foods and iron-rich supplementary preparations takes place in the duodenum and the upper small intestine. Iron can be found in two forms: two- and three-valent iron, but only the two-valent form of iron can be absorbed in the intestine.

The three-valent form of iron is converted to two-valent iron under the influence of hydrochloric acid.
In normal person, only 5-10% of the iron present in food can be absorbed, while in hypochromic anaemic persons this value is higher and it may be as high as 20%.In the organism around 2/3 of the total iron quantity can be found within haemoglobin, and ¼ within the iron storages (bone marrow/ liver, spleen, and in the form of ferritin, and hemosiderin), and approximately 3% can be found in myoglobin. During the different stages of life, and in infants also, the daily iron needs increase, and if this need is not compensated, hypochromic anaemia develops.
Iron is an oligoelement involved in many metabolic processes, such as: oxygen transport, electron transport, catecholamines' metabolism, RNA synthesis, gene regulator, etc.(Azemi et al., 2010).
The need for iron increases during the child's development, and the needs for proper supply of this mineral is very important in order to encourage a healthier growth. (Gjuric 2000, Borancic 2000) It is determined that anaemia is less incidental in breast-fed children, and more incidental in children nourished with infant formula milk, and significantly more in children nourished with cows' milk.
Iron in Sucrosomial Iron, can be found within the phospholipidic Sucrosomial® membrane, which means, it is very bio-soluble, and this technologyprevents entirely the side effects related to iron. Diagnosis is determined based on clinical manifestations and laboratory analysis. Erythrocytes are very small (microcytic), haemoglobin concentration is persistently decreased thus erythrocytes are vaguely coloured (hypochromia), the haematocrit is decreased, the mean corpuscular volume is decreased under 60 fL, iron-concentration in serum is decreased, while the iron-binding capacity is increased, and the ferritin concentration in serum is decreased. Clinical manifestations of anaemia may be minor, or major, and they are proportional to the decreased quantity of Hgb. The clinical manifestations are a consequence of tissue hypoxia, skin and mucosae paleness, headache, food rejection, slow increase of body mass, lack of appetite, irritability, etc (Janic 2000, Stojcevski 1995, Boranic 2000)
The treatment principles of sideropenic anaemia are: administration of iron preparations, managed gradually: by beginning with small doses and until reaching the necessary therapeutic dose; it is best absorbed as three-valent iron which is ionised and absorbed as ferro-sulphate, or ferro-gluconate. The iron preparations should be taken jointly with ascorbic acid, which helps its absorption and prevents di-valent iron's oxygenation into three-valent iron, and it also facilitates iron's absorption from the digestive tract into the blood. The treatment continues for 3 months.

PURPOSE

This paper aims to determine the time ratio and the results of the treatment of iron-deficiency anaemia with Iron Protein Succinylate and Sucrosomial Iron.

MATERIALS AND METHODS

The prospective study was conducted during the screening of anaemia in infants at the PHI – PEDIATRIKA in Tetovo and the clinical laboratory at the Clinical Hospital of Tetovo; 76 infants aged 1-12 months were screened, diagnosed with anaemia and treated during the period of January – June 2018.
The group of infants were divided into two groups based on the treatment:

1. Group 1 – 38 patients treated with anti-anaemic therapy esp. with Iron Protein Succinylate;

2. Group 2 – 38 patients treated with Sucrosomial Iron

Every patient was treated for a month.

Anamnesis obtained from every patient, focused mainly on their eating habits Anaemia is determined pursuant to the criteria for anaemia diagnosis. Venous blood was obtained from the children at the time of the treatment, and again one-month after treatment with anti-anaemic therapy. According to the criteria of having Hgb < 11 g/dl, and the haematocrit < 33%, MVC < 70 fl, Fe^{++}< 7 µmol/l, the average age was: 7,4 months, and the division according to gender grouping was as follows: 47 female infants and 29 male infants.

RESULTS

The results, obtained from the patients, during the initial stages of treatment, were analysed and compared to the results obtained after finishing the treatment with anti-anaemic therapy; the group for a month with Sucrosomial Iron have shown significant improvement of the following parameters: Hgb, HCT, MCV, and Fe^{++}, whereas the patients treated with Iron Protein Succinylate have had less noticeable improvement of the said values (Table 1).

From the analysis of the average values in both study groups, it results that the group treated with Sucrosomial Iron has had a higher increase in the values of haemoglobin from 7.1 mmol/l to 11 mmol/l, in relation to the group treated with Iron Protein Succinylate, for a period of one month. (Figure 1).

From the analysis of the average values in both study groups, it results that the group treated with Sucrosomial Iron has had a higher increase of the value of haematocrit, from 0.30 % to 0.33 %,in relation to the group treated with Iron Protein Succinylate, for a period of one month (Figure 2).

From the analysis of the average values in both study groups it results that the group treated with Sucrosomial Iron has had a higher increase of the value of MCV, from 60 to 75 fl in relation to the group treated with Iron Protein Succinylate, for a period of one month (Figure 3).

From the analysis of the average values in both study groups it results that the group treated with Sucrosomial Iron has had a higher increase of the value of $Fe^{++}$from 2.5 µmol/l to 6.5 µmol/l in relation to the group treated with Iron Protein Succinylate, for a period of one month (Figure 4).

Several side effects of the anti-anaemic therapies have been reported, such as: vomiting, in three cases of patients treated with Iron Protein Succinylate, whereas patients treated with Sucrosomial Iron have not been shown to have any side effect (Table 2).

In both study groups a clear distinction exists concerning the side effects; Of note in the group treated with Iron Protein Succinylate there are three cases of side effects reacting to the therapy and it is manifested with vomiting, whereas the group treated with Sucrosomial Iron showed no signs of side effects (Figure 5).

Table 1. Average values of the laboratory results after a one-month treatment with anti-anaemic therapy

		Treated with Iron Protein Succinylate		**Treated Sucrosomial Iron**	
		Before therapy	After therapy	Before therapy	After therapy
Hgb	*mmol/l*	7.1	10	7.1	11
HCT	*%*	0.30 %	0.31 %	0.30%	0.33 %
MCV	*fl*	59	71	60	75
Fe^{++}	*µmol/l*	2.5	3.5	2.5	6.5

From the analysis of the average values in both study groups, it results that the group treated with Sucrosomial Iron has had a higher increase in the values of haemoglobin from 7.1 mmol/l to 11 mmol/l, in relation to the group treated with Iron Protein Succinylate, for a period of one month. (Figure 1).

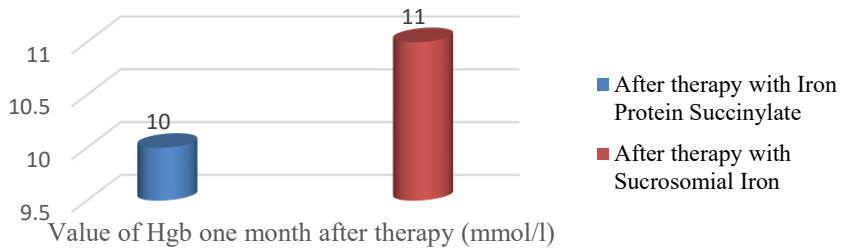

Figure 1. Average values of haemoglobin in both groups

From the analysis of the average values in both study groups, it results that the group treated with Sucrosomial Iron has had a higher increase of the value of haematocrit, from 0.30 % to 0.33 %, in relation to the group treated with Iron Protein Succinylate, for a period of one month (Figure 2).

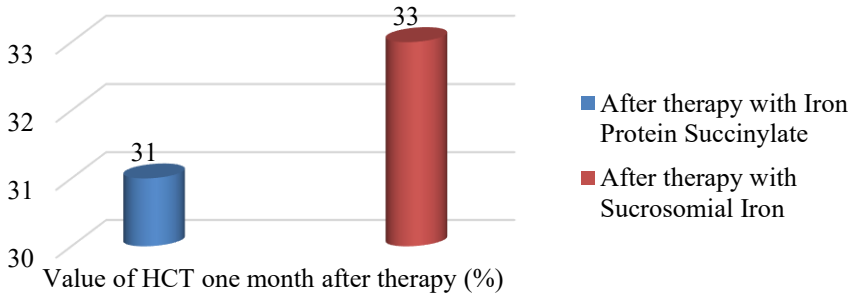

Figure 2. Average values of haematocrit, in both groups

From the analysis of the average values in both study groups it results that the group treated with Sucrosomial Iron has had a higher increase of the value of MCV, from 60 to 75 fl in relation to the group treated with Iron Protein Succinylate, for a period of one month (Figure 3).

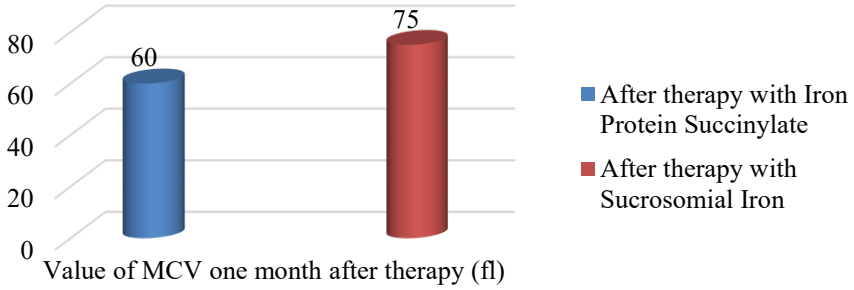

Figure 3. Average values of mean corpuscular volume, in both groups

From the analysis of the average values in both study groups it results that the group treated with Sucrosomial Iron has had a higher increase of the value of Fe^{++} from 2.5 µmol/l to 6.5

μmol/l in relation to the group treated with Iron Protein Succinylate, for a period of one month (Figure 4).

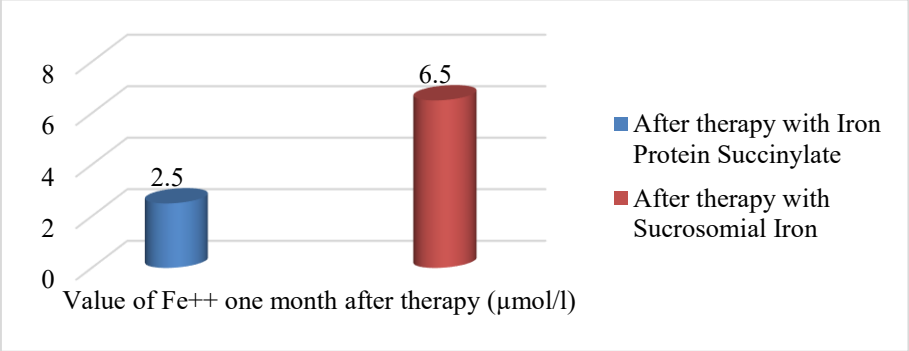

Figure 4. Average values of Iron in both groups

Several side effects of the anti-anaemic therapies have been reported, such as: vomiting, in three cases of patients treated with Iron Protein Succinylate, whereas patients treated with Sucrosomial Iron have not been shown to have any side effect (Table 2).

Table 2. Side effects in both groups

	Patients treated with Iron Protein Succinylate	**Patients treated with Sucrosomial Iron**
	After therapy	After therapy
Side effects	3	n/a

In both study groups a clear distinction exists concerning the side effects; Of note in the group treated with Iron Protein Succinylate there are three cases of side effects reacting to the therapy and it is manifested with vomiting, whereas the group treated with Sucrosomial Iron showed no signs of side effects (**Figure 5**).

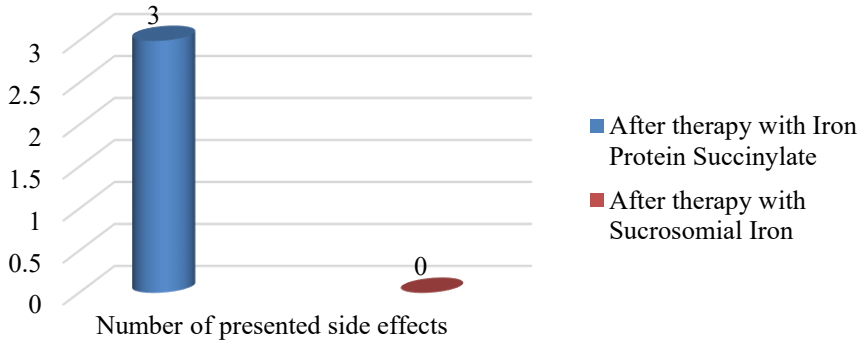

Figure 5. Representation of side effects in both groups

CONCLUSION

Treatment of anaemia remains a problem of health practices with children. Normally, treatment of iron-deficiency anaemia lasts 3 months.
From the obtained results we can conclude that:

1. Treatment with Sucrosomial Iron has shown to be more effective for a period of one month, in most patients with iron-deficiency anaemia;

2. Haematologic parameters: haemoglobin, haematocrit, mean corpuscular volume, iron (II), have a greater increase in the group treated with Sucrosomial Iron;
3. The group treated with Sucrosomial Iron has shown a better improvement compared to the group treated with Iron Protein Succinylate, for a period of 1 month of treatment;
4. The group treated with Sucrosomial Iron has not presented any side effects, in relation to the group treated with Iron Protein Succinylate, for which three cases of vomiting as a side effect to treatment have been reported.

DISCUSSION

Nutrition habits of infants are very important and affect the results of treatment of iron-deficiency anaemia.
Nutrition products rich-in-iron are recommended because therapy, unsupported by adequate nutrition is not sufficient to maintain the necessary levels of haematologic parameters, and it doesn't guarantee normal growth and development, especially in the phase of infancy, during which development is very intensive.
Sucrosomial Irontherapy has a special composition which has positive effects on the facilitating re-absorption of iron from the intestine, so supplementary ascorbic acid (vitamin C) is not necessary.
Anti-anaemic therapy that shortens the treatment period and does not have any side effects should be recommended.
Prevention of iron-deficiency anaemia by recommendation of iron preparations administrated *per os* is indicated for:

- Children with a low concentration of Hgb,
- Children nourished only with cow's milk since birth,
- Premature born children,
- Children with chronic hypoxemia,
- Children with tendencies for infections,
- Children living in poor economic conditions.

Authors: Gómez-Ramirez S., Brilli E., Tarantino G., Muňoz M., on their scientific paper: "*Sucrosomial ® Iron: A New Generation Iron for Improving Oral Supplementation*" recommend that Sucrosomial, as an iron supplementary preparationemerges as a most valuable first option for treating iron-deficiency anaemia, even more for subjects with intolerance to or inefficacy of iron salts.
Lopez A., Cacoub P., Macdougall IC., Peyrin-Biroulet L., in their studies contest the thesis for treatment of anaemia with hepcidin, in children and adults, whichhas a key role in iron homoeostasis and could be a future diagnostic and therapeutic target
Gwetu TP., Chhagan MK., Taylor M., Kauchali S., Craib M., in their scientific paper for "*Anaemia control and the interpretation of biochemical tests for iron status in children*" recommend regular screening of anaemia in school-aged children from disadvantaged communities is recommended, in order to prevent the detrimental consequences of anaemia upon their growth and development.
Mafodda A., Giuffrida D., Prestifilippo A., Azzarello D., Giannicola R., Mare M., Maisano R., in their scientific work "*Oral sucrosomial iron versus intravenous iron in anemic cancer patients without iron deficiency receiving darbepoetin alfa*" recommend that oral Sucrosomial Iron offers a similar increase of Hgb levels, but with a higher tolerance, in relation to intravenous iron supplements.
Elli L., Ferretti F., Branchi F., Tomba C., Lombardo V., Scricciolo A., Doneda L., Roncorni L., in their scientific work "*Sucrosomial Iron Supplementation in Anemic Patients with Celiac Disease Not Tolerating Oral Ferrous Sulfate*" recommend Sucrosomial Iron can be effective

in providing iron supplementation in difficult-to-treat populations, such as patients with coeliac disease, iron-deficiency anaemia, and patients with known intolerance to iron sulfate.
Fabiano A., Brilli E., Fogli S., Beconcini D., Carpi S., Tarantino G., Sfera Y., in their scientific work "*Sucrosomial® iron absorption studied by in vitro and ex-vivo models*", concluded that Sideral ® RM, retains iron in simulated gastric fluid (SGF) and it is the most suitable for internalisation of Fe^{3+} from Caco-2 cells, Fe^{3+} protection from enzymatic reduction and promotion of Fe^{3+}absorption across intestinal epithelium.

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