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Lipo-structured Hematinic Formulation: A Novel Approach

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Abstract

Iron deficiency Anemia, a reduction in the hemoglobin concentration of oxygen-carrying capacity of blood. Anemia is characterized by loss of appetite, abdominal pains, tiredness, shortness of breath and headaches. Iron deficiency may result from lack of iron in the diet, inadequate absorption from the gut, or losses, usually through bleeding. The iron products that are currently available in the market are totally traditional, based on conventional concepts and do not employ any innovative technology. Artificial iron salts containing formulation are not as efficient as formulation containing biological background (RBC concentrate). Thus there is a need of incorporation of newer innovative technologies to enhance the efficiency of Hematinics.

Introduction

Despite the fact that iron is the second most abundant metal in the earth's crust, iron deficiency is the world's most common cause of anemia. When it comes to life, iron is more precious than gold[4]. Iron deficiency is the most common form of malnutrition in the world, affecting more than 2 billion people globally. Iron deficiency anemia (inadequate amount of red blood cells caused by lack of iron) is highly prevalent in less-developed countries but also remains a problem in developed countries where other forms of malnutrition have already been virtually eliminated. Iron deficiency is not the only cause of anemia, but where anemia is prevalent; iron deficiency is usually the most common cause. The prevalence of anemia, defined by low hemoglobin or hematocrit, is commonly used to assess the severity of iron deficiency in a population[3].

Iron deficiency is the most common nutritional cause of anemia in humans. It can result from inadequate iron intake, malabsorption, blood loss, or an increased requirement, as with pregnancy. When severe, it results in a characteristic microcytic, hypochromic anemia. Iron is an essential component of myoglobin, heme enzymes such as the cytochromes, catalase, and peroxidase; and the metalloflavoprotein enzymes, including xanthine oxidase and the mitochondrial enzyme *a*-glycerophosphate oxidase. Iron deficiency can affect metabolism in muscle independent of the effect of anemia on O_2 delivery, possibly due to a reduction in the activity of iron-dependent mitochondrial enzymes. Iron deficiency also has been associated with behavioral and learning problems in children, abnormalities in catecholamine metabolism, and impaired heat production[5]**.** Iron deficiency Anemia, a reduction in the hemoglobin concentration of oxygen-carrying capacity of blood. Anemia is characterized by loss of appetite, abdominal pains, tiredness, shortness of breath and headaches. Iron deficiency may result from lack of iron in the diet, inadequate absorption from the gut, or losses, usually through bleeding. For example: Iron deficiency Anemia affects 10-15 percent of women of menstruating age because the iron they lose in menstrual blood exceeds the iron obtained from food. Therefore, women with high menstrual losses may need higher iron intakes. Too much iron is toxic. An excess can damage the heart, liver, and pancreas, and irritate the gut causing constipation or diarrhoea[1].

During adulthood, iron stores gradually increase in men; in women, stores start to increase after menopause. Total body iron averages about 3.8 g in men and 2.3 g in women. The extraordinary capacity of the human body to retain iron (15–40 g) is exhibited in individuals with hemochromatosis. About one third of the total body iron is bound to storage proteins, primarily ferritin or hemosiderin in the liver, spleen, and bone marrow. About two thirds of the total body iron serves metabolic or enzymatic functions[2]. In modern society, the oral iron supplements are clearly needed in the treatment and prevention of iron deficiency in humans. In fact, the diet of most of the world's population is deficient in iron and so iron deficiency has been a worldwide problem. A new oral supplement is needed. Presently available oral supplements are ferrous salts whose side effects can include epigastric pain, diarrhea and constipation, which can often be severe enough to cause the termination of treatment[6]. Iron is required

for a number of vital functions which include: oxidative metabolism, reproduction, cellular growth, wound healing, execution of various metabolic processes. The main role of Iron is to carry oxygen to the tissue where it is needed. It is also essential for the proper functioning of numerous enzymes involve in DNA synthesis, energy me-tabolism, and protection against microbes and free radicals, because free radical produced in the body can promote the development of heart diseases and can damage cholesterol in the blood[1].

There are two forms of dietary iron: heme and non-heme. The heme is derived from hemoglobin, heme iron is found originally in animal food that originally contains hemoglobin such as fish and poultry. Iron in plant foods such as lentils and beans is arranged in a chemical structure called non-heme iron. This is the form of iron added to iron-enriched and iron-fortified foods. Heme iron is absorbed better than non-heme iron, but most dietary iron is non-heme iron[1].

Blood:

Blood is a connective tissue. It provides one of the means of communication between the cells of different parts of the body and the external environment, e.g. it carries:

- Oxygen from the lungs to the tissues and carbon dioxide from the tissues to the lungs for excretion
- Nutrients from the alimentary tract to the tissues and cell wastes to the excretory organs, principally the kidneys
- Hormones secreted by endocrine glands to their target glands and tissues
- Heat produced in active tissues to other less active tissues
- Protective substances, e.g. antibodies, to areas of infection
- Clotting factors that coagulate blood, minimizing its loss from ruptured blood vessels.

Blood makes up about 7% of body weight (about 5.6 litres in a 70 kg man). This proportion is less in women and considerably greater in children, gradually decreasing until the adult level is reached. Blood in the blood vessels is always in motion. The continual flow maintains a fairly constant environment for the body cells. Blood volume and the concentration of its many constituents are kept within narrow limits by homeostatic mechanisms[7].

Hematinic formulation:

The brand, Dexorange and others, with biological background (RBC concentrate) was a very popular iron-tonic but it was to be substituted by the artificial iron source because of some regulatory reasons. The product was top-selling and unquestioning for its super-efficacy. Now, in its new version with artificially added iron-source, is unlikely to produce the same impact due to loss of very important biological components and henceforth patient is at loss. In the light of above problems, it is worth looking for the alternative after identification of the real problem, to help restore the glorious performance of biological-iron-product such as Dexorange. Fortunately, there has been a substantial progress in the field of formulation development with the emergence of newer technologies. The right delivery of the molecules and synergism with other components has revolutionalised the field of pharmaceutics. Our experience over the period of years gives us a feeling to venture into this product to help regain its unambiguous status. First is the identification of the problem related to the absence of biological components, which are responsible in the augmentation of iron-metabolism and transport and thereafter working on relevant formulation strategies. Therefore, we put forward a developmental proposal to bring transformation of iron-tonics trying to mimic the biological one, of course by means of non-biological approach in compliance with the regulatory bodies. The strategies of the proposal are briefly summarized here.

Current Research Scenario and the Need:

The iron products that are currently available in the market are totally traditional, based on conventional concepts and do not employ any innovative technology. The effort so far rests upon the inclusion of vitamins like Vit.C to improve the absorption of iron. No attention is paid on the delivery aspects, such as using novel excipients and the transport facilitation across the bio-membranes and into compartments.

Phospholipid Encapsulated Iron-supplement

Phospholipids are the unique, bio-friendly molecules which represent bio-membranes. These molecules on interaction with water in conjunction with other lipids, proteins and other components give rise to self-assembled nano-range supramolecular structures. Within these structures, if iron salts are encapsulated, while optimizing the composition and technique with respect to desired physicochemical properties such as size, shape, surface, charge etc., and then the iron within will find the synergism and the improved transport and distribution. The iron encapsulated within these phospholipid membrane systems (similar to cell-membranes), in all probability, supposed to match the performance of the RBC concentrate. This similarity in the structural aspects of the product is the strong support for the project hypothesis.

Following Iron salts could be considered for developing the proposed product:

1. Ferric ammonium citrate
2. Ferrous sulphate
3. Ferrous fumarate
4. Ferrous succinate
5. Ferrous glycine sulphate

Conclusion

A novel lipo-structured Hematinic formulation can match up the quality of the Hematinic formulation containing biological background. Thus, there is wide scope for development of a research based Hematinic product with improved properties that would help the mass sufferers of iron deficiency.

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