ALBION®
HUMAN NUTRITION

RESEARCH NOTES

A COMPILATION OF VITAL RESEARCH UPDATES ON HUMAN NUTRITION

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Ferrochel® Continues to Prove Itself

The importance of iron to health has been shown over and over. It is still the mineral of greatest overall deficiency worldwide. According to the World Health Organization, it affects nearly 2 billion people globally. According to the Mayo Clinic (on-line patient care and health information), the symptoms of iron deficiency anemia can include: (See Figure 1)

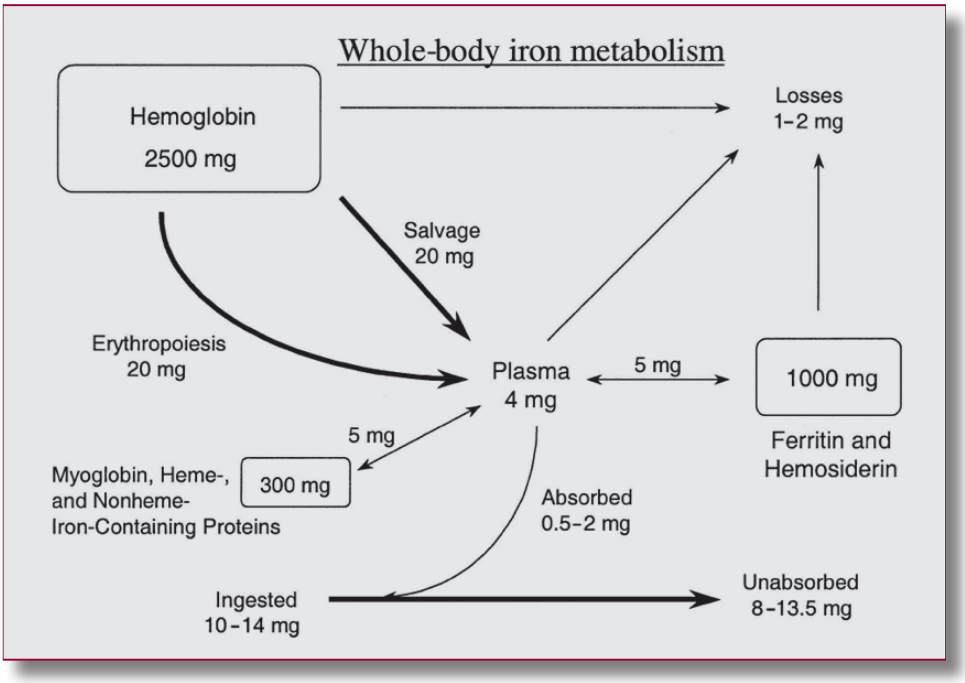
Iron deficiency is a little different from iron deficiency anemia. Iron deficiency is a condition in which there is a decrease in total body iron stores to below normal established levels, while iron deficiency anemia occurs when the iron deficiency is sufficient to cause a reduction in erythropoiesis or red blood cell production. Iron deficiency anemia can cause a reduced work capacity in adults, and impair motor and mental development in children and adolescents.

Neurocognitive Development & Perinatal Iron Deficiency

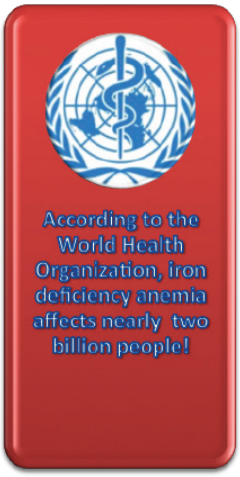
The concept of nutrition and cognitive function is one that has received much attention the last few years. A lot of that attention has resulted from the loss of short-term memory and so on, as one ages. Since people are living longer today, the concern over aging and a decline in cognitive function has become more acute. In an earlier edition of Albion Research Notes (Vol 21, No 2, September 2012), we talked about the roles that magnesium and creatine play in maintaining or improving cognitive function, helping even in the recovery of cognition following closed head injuries and strokes. The importance of iron and neurocognitive development of the fetus and newborns cannot be underestimated. Two recent published articles point this out quite clearly: Radlowski EC and Johnson RW; Frontiers in Human Neuroscience 2013;7:585 and Lachowicz JL, et al; Curr

Figure 1.

Extreme fatigue	Pale skin	Poor appetite, expecially in infants and children
Headaches	Dizziness or lightheadedness	Weakness
Brittle nails	Cold hands & feet	Shortness of breath
Unusual cravings for non-nutritive substances	Frequent infections	Inflammation or soreness of tongue
Fast Heartbeat	Chest pain	Uncomfortable tingling or crawling feeling in legs-Restless Leg Syndrome



Med Chem 2014 Jul 6(epub ahead of print). They point out again that the most common form of nutrient deficiency globally is iron deficiency. The incidence of iron deficiency is due to the limited availability of quality food in developing nations and poor dietary habits in industrialized countries. According to the National Hematologic Disease Information Services on-line website (USDHHS), anemia associated with inflammatory and other chronic diseases is the second most common form of anemia. This is not, strictly speaking, just an iron deficiency, and could be a topic unto itself. Rates of anemia in non-pregnant women of childbearing age hit about 40% in developing nations and 20% in the industrialized countries. The incidence of iron deficiency anemia increases during pregnancy, reaching 59% in developing countries and 25% in the industrialized nations. According to the World Health Organization, iron deficiency anemia affects nearly 2 billion people. The high incidence of maternal iron deficiency anemia observed during pregnancy has severe implications [Radlawski ED & Jolinson RW, Hum Neuro Sci; 2013:(7):p585].



For the fetus, the lack of maternal iron has a negative impact on neurodevelopment, because iron is needed for proper neurogenesis, development, and myelination. Iron deficiency during pregnancy increases the risk of low birth weight, due either to premature birth or fetal growth restriction, which is associated with delayed neurocognitive development and oft times psychiatric illness. Infants that receive adequate iron in utero will experience rapid neurodevelopment, but if they receive low iron in their diets after 6 months of age, they will show decline in neurocognitive development, including impairments in learning and memory. The prevention of iron deficiency during the critical pre and postnatal periods of brain development must be of utmost concern. Iron deficiency during these periods results in complications that persist into adulthood. It should also be noted that 40% of perinatal maternal deaths are associated with anemia.

Iron Deficiency Leads To Other Health Consequences

In addition to the symptoms of iron deficiency stated earlier, Iron deficiency anemia can have other consequences, some quite severe. According to

Aspuru, K., et al (Int J Gen Med 2011, 4; 741-750) iron deficiency anemia can lead to: (See Figure 2)

Research into Iron Therapy is a Continuous Need

Research has continued to be conducted over the last 20+ years, on Albion's Ferrochel® (ferrous bisglycinate chelate). Ferrochel® has been shown to be a very effective form of iron. Studies have shown its effectiveness in various fortification studies and programs in Guatemala, Costa Rica, Brazil, South Africa, Saudi Arabia, and Tanzania. It has been used to fortify milk, UHT milk, bread, yogurt, cookies, margarine, and more. Clinical studies have demonstrated Ferrochel's effectiveness in prenatal supplementation, as well as in hematinic products around the globe. Currently, there are two new clinical studies on Ferrochel® being conducted. In the last 2 years, there were a couple of very interesting published clinical studies centered on Ferrochel®. These studies were conducted independently from Albion.

Ferrous Bisglycinate 25 mg Iron Is As Effective As Ferrous Sulfate 50 mg Iron in the Prophylaxis of Iron Deficiency and Anemia During Pregnancy in a Randomized Trial

Milman N, Jønsson L, Dyre P, Pedersen PL, Larsen LG. J Perinat Med. 2014 Mar;42(2):197-206.

Figure 2.

Alopecai	Lingual papillary atrophy	Dry mouth due to decreased salivation	Spoon nails	Chlorosis	Plummer-Vinson Syndrome with dysphagia due to esophageal membranes and atrophic glossitis	Impaired immunity, increasing morbidity due to infectious diseases	Altered thyroid function	Congestive Heart Failure

Abstract

OBJECTIVE:

(AA) To compare the effects of oral ferrous bisglycinate 25 mg iron/day vs. ferrous sulfate 50 mg iron/day in the prevention of iron deficiency (ID) and iron deficiency anemia (IDA) in pregnant women. Design: Randomized, double-blind, intention-to-treat study. Setting: Antenatal care clinic. Sample: 80 healthy ethnic Danish pregnant women.

METHODS:

Women were allocated to ferrous bisglycinate 25 mg elemental iron (Aminojern®) (n=40) or ferrous sulfate 50 mg elemental iron (n=40) from 15 to 19 weeks of gestation to delivery. Hematological status (hemoglobin, red blood cell indices) and iron status (plasma iron, plasma transferrin, plasma transferrin saturation, plasma ferritin) were measured at 15-19 weeks (baseline), 27-28 weeks and 36-37 weeks of gestation. Main outcome measures: Occurrence of ID (ferritin <15 ↔g/L) and IDA (ferritin <12 ↔g/L and hemoglobin <110 g/L).

RESULTS:

At inclusion, there were no significant differences between the bisglycinate and sulfate group concerning hematological status and iron status. The frequencies of ID and IDA were low and not significantly different in the two iron groups. The frequency of gastrointestinal complaints was lower in the bisglycinate than in the sulfate group (P=0.001). Newborns weight was slightly higher in the bisglycinate vs. the sulfate group (3601+517 g vs. 3395+426 g, P=0.09).

CONCLUSIONS:

In the prevention of ID and IDA, ferrous bisglycinate was not inferior to ferrous sulfate. Ferrous bisglycinate in a low dose of 25 mg iron/day appears to be adequate to prevent IDA in more than 95% of Danish women during pregnancy and postpartum.

COMMENT

It should be noted that in the Danish study, Ferrochel® was given at half the dose of ferrous sulfate, and was equally effective - more evidence of Ferrochel® exhibiting greater utilization. The finding that Ferrochel® has equal or better efficacy versus ferrous sulfate at lower does has been seen in other published studies.

Treatment of Mild Non-Chemotherapy-Induced Iron Deficiency Anemia in Cancer Patients: Comparison Between Oral Ferrous Bisglycinate Chelate and Ferrous Sulfate.

Ferrari P, Nicolini A, Manca ML, Rossi G, Anselmi L, Conte M, Carpi A, Bonino F.
Biomed Pharmacother. 2012 Sep;66(6):414-8. Epub 2012 Jun 29.

Abstract

(AA) In cancer patients mild-moderate non-chemotherapy-induced iron deficiency anemia (IDA) is usually treated with oral iron salts, mostly ferrous sulfate. In this study, we compare efficacy and toxicity of oral ferrous bisglycinate chelate and ferrous sulfate in cancer patients with mild IDA. Twenty-four patients operated on for solid tumors (10 breast, 12 colorectal, 2 gastric), aged 61+10 years (range 45-75), with non-chemotherapy-induced hemoglobin (Hb) values between 10 and 12 g/dL and ferritin lower than 30 ng/mL were randomized to receive oral ferrous bisglycinate chelate, 28 mg per day for 20 days, and then 14 mg per day for 40 days (12 patients) (A group) or oral ferrous sulphate, 105 mg per day for 60 days (12 patients) (B group). Values of hemoglobin and ferritin obtained at diagnosis, 1 and 2 months from the beginning of treatment were compared. Adverse events (AEs) related to the two treatments were recorded. In the 12 patients treated with ferrous bisglycinate chelate, basal hemoglobin and ferritin values (mean+SD) were 11.6+0.8 g/dL and 16.1+8.0 ng/mL. After 2 months of treatment, they were 13.0+1.4 g/dL and 33.8+22.0 ng/mL, respectively (P=0.0003 and P=0.020). In the group treated with ferrous sulphate, hemoglobin and ferritin mean values were 11.3+0.6 g/dL and 19.0+6.4 ng/mL basally, and 12.7+0.70 g/dL and 40.8+28.1 ng/mL (P<0.0001 and P=0.017) after 2 months of treatment. AEs occurred in six cases. In all these six cases, two (17%) treated with ferrous bisglycinate chelate and four (33%) with ferrous sulphate, toxicity was grade 1. In conclusion, these data suggest that ferrous bisglycinate chelate has similar efficacy and likely lower GI toxicity than ferrous sulphate given at the conventional dose of 105 mg per day for the same time.

In a more recent animal study (Biol Trace Elem Res. 2014 May;158(2):197-202) by Zhuo Z, et al, looked into the absorption kinetics of ferrous bisglycinate and its impact on relevant transport protein in Sprague –Dawley rats, as compared to ferrous sulfate. According to the researcher, the ferrous bisglycinate, as an iron source can be absorbed more and utilized faster than FeSO4, and they had different effects on the expression of intestinal transport protein.

FERROCHEL®

Ferrochel® (ferrous bisglycinate chelate) is Albion's finest form of iron. It has been the subject of at least 60 published articles or studies. It is GRAS in the USA and EFSA approved, and has been approved for certain applications in China, which is a rarity. The EFSA approval is broad based, allowing Ferrochel® as an iron source in foods intended for the general public, food supplements, and foods for particular nutritional use, including foods intended for infants and young children. It is EFSA approved for infant formulas, as well as follow-on formulas (toddler formulas).

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