Efficacy and Safety of a New Formulation of Ferric Sodium EDTA Associated with Vitamin C, Folic Acid, Copper Gluconate, Zinc Gluconate and Selenomethionine Administration in Patients with Secondary Anaemia

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Abstract

Anemia is a global problem since two billion people are affected by blood cells disorders. Anemia may reduce the quality of life of affected patients and may also to get worse the outcome and quality of life of patients with comorbidities as kidney failure, heart failure, arrhythmia, coronary heart disease and so on. In patients with coronary heart disease, anginal episodes may increase in frequency and severity, and patients with kidney failure may have an increased number of re-hospitalizations.

Here we report the effectiveness of the therapy with Ferric Sodium EDTA, in combination with vitamin C, folic acid, copper gluconate, zinc gluconate and selenomethionine (FERACHEL FORTE®) that has shown several advantages in daily clinical practice.

Keywords: Anaemia; Ferric sodium EDTA; Cardiovascular risk

Background

Anemia is a global problem since two billion people are affected by blood cells disorders.

According to WHO criteria, anemia is defined as blood hemoglobin (Hb) concentration <13 g/dL or hematocrit (Hct) <39% in adult males or Hb concentration <12 g/dL or Hct <37% in adult females.

Iron-deficiency anemia is the most common type of anemia in young adults in particular in premenopausal women. Iron-deficiency anemia is divided in three different clinical forms from a pathophysiological point of view: increased iron requirement, increased iron loss, reduced iron intake from diet or due to gastrointestinal abnormalities. Furthermore, in daily clinical practice, the most common cause of iron deficiency anemia is clinically related to increased blood loss as metrorrhagia or gastrointestinal bleeding [1].

Iron deficiency anemia can be also linked to a chronic disease as kidney failure, heart failure, coronary heart disease. The anaemia may induce a worsening of clinical conditions that need to be improved [2].

There are two different types of iron supplements: ferric iron supplements (containing Fe³⁺) and ferrous iron supplements (containing Fe²⁺) [3-4].

An important source of ferric iron (Fe³⁺) is Ferric Sodium EDTA which consists in Fe³⁺ chelated with ethylenediaminotetraacetic acid (EDTA).

The iron from ferric sodium EDTA is highly soluble, as it remains bound to EDTA in the acid milieu of the stomach, and becomes released only in the more alkaline medium of the duodenum and of the small intestine, where it is subsequently absorbed in the bloodstream.

Ferric sodium EDTA represents a new iron source in order to treat iron deficiency with interesting features: it is taste-less, it does not interact with foods, it is completely water soluble, and without metallic taste; furthermore, it does not cause teeth and stools staining (especially relevant in case of gastrointestinal diagnostic investigations) and its absorption is complete also in presence of inhibitors of iron absorption as phytates [5].

In last years literature offered many evidences about the advantages of Ferric Sodium EDTA, in particular if it is associated with other components and trace elements as folic acid, vitamin C, copper, zinc and selenium and here we report all clinical improvements obtained with this iron source administered orally (FERACHEL FORTE®) in different clinical conditions in which it has been tested.

Secondary Iron-deficiency Anemia

A multicenter and observational registry enrolled patients with different stages of iron-deficiency anaemia. The study evaluated the effects of the oral Ferric sodium EDTA associated with folic acid, vitamin C, copper, zinc and selenium (FERACHEL FORTE®) on blood parameters and on clinical outcomes (unpublished data).

The study enrolled 111 patients with iron-deficiency anemia: 31 patients with mild iron deficiency anaemia, 62 patients with moderate iron deficiency anaemia and 18 patients with severe iron-deficiency...
anemia. All patients were treated with 1 tablet a day of Ferric sodium EDTA for 72 days. The patients were evaluated at three steps: a) time 0 (before the treatment), b) time 1 (after 24 days of treatment) and c) time 2 (after 72 days of treatment) (unpublished data).

Blood parameters, clinical symptoms and side effects were recorded in all steps of the study.

A progressive increase of iron in the blood was recorded at time 1 and 2 of the study with a respective increase of 13 mcg/dL and 33 mcg/dL in the ferritin levels; also haemoglobin levels increased of 1,2 (g/dL) Hb at time 1 and 2,2 (g/dL) Hb at time 2 (unpublished data).

Nearly 78% of patients at time 2 reported a reduction of clinical symptoms associated with iron deficiency and its related anemia; in particular the treated patients referred a decrease of symptoms as tiredness, fatigue, weakness, and tachycardia.

The 96% of patients did not refer side effects during the treatment with Ferric sodium EDTA in association (FERACHEL FORTE®). The remaining 4% of patients referred aspecific symptoms as side effects that could be related also to their further chronic pathologies (unpublished data).

Cardiovascular Diseases and Iron-deficiency Anemia

Several physicians recently underlined that administration of oral ferric iron (Fe3+) is associated with improvements of cardiovascular outcomes and quality of life [6].

Anemia is a common comorbidity of chronic cardiovascular disease as heart failure, chronic coronary artery disease, atrial fibrillation [7-9]. It is a common disorder of the elderly and its prevalence in al remains the most common type of secondary anemia in these clinical settings.

A common trouble of oral iron-based food supplements is the significant number of side effects on gastrointestinal functions in addition to the time of treatment of about three months with the first signs of effectiveness after at least 40 day of treatment.

The therapy with a new oral source of iron (i.e., Ferric Sodium EDTA, in combination with vitamin C, folic acid, copper gluconate, zinc gluconate and selenomethionine, FERACHEL FORTE®) revealed a good effectiveness in blood iron increase and a significant safety with a reduced percentage of side effects in several chronic diseases showing efficacy evidence already after 24 days of treatment allowing a cycle therapy of about 72 days compared to standard therapies.

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Efficacia e sicurezza della nuova formulazione di ferro sodico edta associato a vitamina c, acido folico, zinco gluconato e selenometionina in pazienti con anemia secondari

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Abstract

L’anemia è un problema globale in quanto due miliardi di persone sono affette da patologie ematiche. L’anemia può peggiorare la qualità della vita dei pazienti affetti e può anche compromettere l’outcome e la qualità della vita dei pazienti con comorbidità quali insufficienza renale, insufficienza cardiaca, aritmia, malattia coronarica etc. Nei pazienti con malattia coronarica, gli episodi possono aumentare in frequenza e in gravità, mentre i pazienti con insufficienza renale possono avere un incremento del numero di re-ricoveri.

Di seguito riportiamo l’efficacia della terapia con Ferro Sodico EDTA, in combinazione con vitamina C, acido folico, rame gluconato, zinco gluconato e selenometionina (FERACHEL FORTE®) che ha mostrato diversi vantaggi nella pratica clinica quotidiana.

Keywords: Anemia; Ferric sodium EDTA; Cardiovascular risk

Background

L’anemia è un problema globale in quanto due miliardi di persone sono affette da patologie ematiche. Secondo i criteri dell’OMS, un individuo adulto di sesso maschile se la propria livello di emoglobina (Hb) sono <13 g / dl o ematocrito (Hct) <39%. Il valore limite per la stessa definizione è pari a 12 g/dl per una donna adulta o Hct <37% nelle femmine adulte. L’anemia da carenza di ferro è una delle forme di anemia più diffuse negli adulti, in particolare nelle donne in premenopausa. Dal punto di vista fisiopatologico, l’anemia sideropenica è divisa in tre diverse forme: aumento del fabbisogno di ferro, aumento della perdita di ferro, riduzione dell’apporto di ferro dalla dieta o dovuto ad anomalie gastrointestinali. Inoltre, nella pratica clinica quotidiana, la causa più comune di anemia sideropenica è clinicamente correlata ad un aumento della perdita ematica come metrorragia o sanguinamento gastrointestinal [1].

L’anemia da carenza di ferro può essere anche collegata ad una malattia cronica come l’insufficienza renale, l’insufficienza cardiaca e malattia coronarica. L’anemia può indurre un peggioramento delle condizioni cliniche che necessitano un miglioramento [2].

Ci sono due diversi tipi di integratori di ferro: integratori a base di ferro in forma trivalente (contenenti Fe3+) e integratori di ferro sottoforma di ione ferroso (contenente Fe2+) [3–4].

Un’importante fonte di ferro Fe3+ è il Ferro Sodico EDTA che è composto da Fe3+ e chelato con acido etilendiamminotetraetacetico (EDTA).

Il ferro da sodico EDTA è altamente solubile, infatti resta legato all’EDTA nell’ambiente acido dello stomaco e viene rilasciato solo in ambienti più alcalini quali il duodeno e l’intestino tenue, dove successivamente è assorbito nel flusso sanguigno.

Il sodio ferrico EDTA rappresenta una nuova fonte di ferro per il trattamento della carenza di ferro con interessanti novità: è insapore, non interagisce con gli alimenti, è completamente solubile in acqua senza la presenza di sapore metallico; inoltre, non provoca la colorazione di denti e feci (particolarmente rilevante in caso di indagini diagnostiche gastrointestinali) e il suo assorbimento è completo anche in presenza di inibitori di ferro come i fitati [5].

Negli ultimi anni la letteratura ha fornito diverse evidenze sui vantaggi del Ferro Sodico EDTA, in particolare se associato ad altri componenti e oligoelementi come acido folico, vitamina C, rame, zinco e selenio e, qui di seguito, riportiamo tutti i miglioramenti clinici ottenuti con FERACHEL FORTE® somministrato per via orale per le diverse condizioni cliniche per cui è stato testato.

Anemia da carenza di ferro

Uno studio multicentrico ed osservazionale ha arruolato pazienti anemici a diversi stadi di carenza di ferro. Lo studio ha valutato gli effetti del ferro sodico EDTA associato all’acido folico, vitamina C, rame, zinco e selenio (FERACHEL FORTE®) sui parametri ematici e i successivi risultati clinici (dati non pubblicati).

Lo studio ha arruolato 111 pazienti con anemia sideropenica: 31 pazienti con anemia ferro carenzziale lieve, 62 pazienti con anemia moderata e 18 pazienti con anemia grave.
Tutti i pazienti sono stati trattati con 1 compressa al giorno di ferro sodico EDTA per 72 giorni. I pazienti sono stati valutati in tre fasi: a) tempo 0 (prima del trattamento), b) tempo 1 (dopo 24 giorni di trattamento) e c) tempo 2 (dopo 72 giorni di trattamento) (dati non pubblicati).

Sono stati registrati i parametri del sangue, la sintomatologia clinica e gli effetti collaterali in tutte le fasi dello studio.

Un progressivo aumento di ferro nel sangue è stato registrato al tempo 1 e 2 dello studio con un rispettivo aumento di 1,2 (g / dL) Hb al tempo 1 e 2,2 (g / dL) Hb al tempo 2 (dati non pubblicati).

Circa il 78% dei pazienti al tempo 2 ha riportato una riduzione dei sintomi associati alla carenza di ferro e all’anemia associata; in particolare i pazienti trattati hanno riportato una diminuzione dei sintomi quali stanchezza, affaticamento, debolezza e tachicardia.

Negli ultimi anni, la buona pratica clinica delle malattie croniche negli adulti e nei pazienti anziani ha rilevato un aumento del numero di pazienti affetti da anemia secondaria. Tuttavia, l’anemia da carenza di ferro resta il tipo più diffuso di anemia secondaria registrata.

La terapia con una nuova fonte orale di ferro (cioè, ferro sodico EDTA, in combinazione con vitamina C, acido folico, gluconato di rame, gluconato di zinco e selenometionina, FERACHEL FORTE®) ha rivelato una buona efficacia nell’aumento del ferro plasmatico e una significativa sicurezza, con una ridotta percentuale di effetti collaterali in diverse patologie croniche, mostrando efficacia già dopo 24 giorni di trattamento e consentendo un ciclo terapeutico di circa 72 giorni rispetto alle terapie standard.

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