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Short Communication

Nutraceutical Therapy for Patients Suffering from Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), Post-Covid Syndrome (PCoS), or Alzheimer Disease (AD)

Comhaire F[1]*, Pen J[2], and Deslypere JP[1]

[1]*Consulting Specialist for Internal Medicine, Endocrinology and Metabolic Diseases, Fertility-Belgium Clinic, Belgium*

[2]*Specialist Internal Medicine and Ultrasonography, Belgium*

***Corresponding author**

Frank Comhaire, Consulting Specialist for Internal Medicine, Endocrinology and Metabolic Diseases, Fertility-Belgium Clinic, Weststraat, 16, 9880 Aalter, Belgium, Tel: 32 475618555; Email: frank.comhaire@telenet.be

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- Myalgic encephalomyelitis, Chronic fatigue syndrome, post-COVID syndrome, Long-COVID, Nutraceutical treatment, infusion therapy, Alzheimer's disease, stem cell therapy

Abstract

In the present observational prospective open-label study the effect was evaluated of treating 113 patients suffering from myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) or from post-COVID syndrome (PCoS, also called long-COVID) with either the nutraceutical QALY® plus sodium-dichloroacetate and meldonium, or with infusions containing magnesium-sulphate plus multivitamins, or with glutathione plus stem cells. Overall 86% of patients reported a variable degree of decreased fatigue after 4 to 6 weeks, with no significant difference between the two modes of treatment. In addition, in 2 patients with evolutive age-related Alzheimer's disease (AD) receiving oral therapy together with the extract of Hericium echinaceus, mental deterioration could be halted for 48 and 72 months respectively.

Taking into account the limitations of the present preliminary study it is suggested that complementary treatment may be considered as add-on to conventional therapy in ME/CFS or PCoS patients, as well as in patients suffering from age-related AD.

INTRODUCTION

Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CVS) and post (acute)-COVID syndrome (PCoS), also called long-COVID, present many similar clinical manifestations. External factors may induce these chronic diseases in persons with certain genetic or acquired characteristics, like a great sense of responsibility. Infection, either bacterial or viral [1], physical or emotional trauma, surgery, or long-term stress may induce systemic immune disorder [2,3]. With activation of inflammatory mechanisms, including elevated cytokine levels. These may persist due to epigenetic hypermethylation of genes involved with inflammation [4]. Evidence suggests that inflammation and oxidative overload can impair mitochondrial aerobic metabolism by increased phosphorylation of pyruvate dehydrogenase, resulting in lowered generation of adenosine triphosphate (ATP), and shifting glucose-pyruvate to anaerobic metabolism through the Cori cycle with excessive production of lactate [1]. This may explain post-exertion fatigue and poor recovery, as well as cerebral complaints such as brain fog, cognitive impairment, memory malfunction, and sleep disturbance. The regular intake of sodium-dichloroacetate (DCA-laboratory, Vilnius, Lithuania) and of meldonium (Mildronate®, Grindex, Riga, Latvia), counteracting these metabolic alterations, were found to be effective in treating many patients with ME/CFS [5].

Mechanisms activating neurodegenerative diseases and early development of dementia were found to be stimulated post-COVID [6]. However, cardio-vascular disease like atherosclerosis, and metabolic diseases such as insulin resistance and diabetes, as well as unhealthy life style equally increase the risk of Parkinson's and Alzheimer's diseases (AD), probably also because of inflammatory and oxidative overload [7]. In contrast, high flavonoid intake is associated with significantly reduced risk of AD [8,9].

Based on these considerations we have given particular natural substances to patients with the diseases mentioned above, either orally or in intravenous infusions, and we have

registered their reaction in terms of improving fatigue and general well-being.

MATERIALS AND METHODS

All 113 patients had been diagnosed to suffer from ME/CFS or PCoS either by university reference centres for these diseases or after clinical investigation by one of the authors.

Oral treatment consisted of the combination of the nutraceutical QALY® (Jona Pharma, Elversele, Belgium; ingredients in appendix) with a formulation containing sodium-dichloroacetate (CDA-lab, Vilnius, Lihuania; ingredients in appendix) and meldonium (Mildronate®, Grindex, Riga, Latvia). This was given to 85 patients.

Of the 28 patients treated by *infusion therapy* 20 received 2 or 3 gr of Magnesium-sulphate together with multivitamins (SoluVit®, Sterop, Brussels, Belgium). Eight patients were given Magnesium-sulphate together with a mixture of glutathione and stem cells (Completté®, Kuhra Vitae Derma Pharma, Lucerne, Switzerland; ingredients in appendix).

Before initiation of treatment 105 patients completed the Fatigue Severity Score (FSS) [10] and this was repeated at the end of treatment after 4 to 6 weeks.

All data were collected in the spreadsheet of the MedCalc statistical program [11], and parametric statistical tests were applied as required.

Two patients with progressive deterioration of Alzheimer disease (AD) were given oral therapy together with the extract Hericium echinaceus. In addition, insulin resistance was treated with the extract of Momordica charantia in one of them, and methylprednisolone IV was given intermittently in the other case presenting immune disorder with elevated IgA [12]. The evolution of the disease, as recorded by their care takers, was followed-up during 72 and 48 months respectively.

RESULTS

There was no statistical difference in the epidemiologic characteristics between patients included in the different treatment groups, nor between the cases with ME/CFS or PCoS. Only the duration of the disease was much longer in the patients belonging to the first group (mean 9.4 yrs; SD: 5.4 yrs) as compared to that of patients in the second group (mean 10.3 mths, SD: 4.7 mths). Overall 83 % were female and the mean age was 43.9 yrs (SD11.4 yrs). Of the 113 patients, 86 % reported improvement, defined as FSS after treatment being lower than that before treatment. The FSS decreased with an average of 23 % among the successful cases. The success rate among the patients treated by infusion therapy (89.3%) was similar to that of oral treatment (84.7%).

None of the patients reported adverse effects and all cases on oral therapy continued treatment. Five out of the 28 cases on infusion therapy abandoned treatment because of the relatively high cost, or because of technical problems at venepuncture. In one of the latter cases the Compette® was alternatively given by slow intramuscular injection, on the explicit request of the patient who experienced major therapeutic benefit.

Among the patients with AD no significant improvement of the mental state was recorded, but the diseases could be stabilized and progression of dementia could be halted during respectively 72 and 48 months of follow-up so far.

DISCUSSION

Signs and symptoms of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) are similar to those seen in many patients with so-called Long-COVID or Post (acute)-COVID Syndrome (PCoS). Both conditions are probably related to persistent inflammation and immune deregulation, both at the somatic and at the cerebral level. In addition, patients who suffered severe COVID have been found to run a greater risk of developing neurodegenerative diseases, Alzheimer disease (AD) in particular [6].

Conventional treatment of these diseases has focussed on promoting physical recovery, memory training and adaptation of the working and living environment. Though certainly indicated and helpful [13], the effectiveness of this approach is moderate, leaving the need for complementary therapy.

Recently we have published the results of pragmatic, real life studies of nutraceutical treatment using the combination of vitamins, mineral salts and plant extracts with antioxidant, anti-inflammatory and adaptogen capacity. There is evidence that this nutraceutical does reduce epigenetic hypermethylation [14], which has been shown to play an important role in COVID-19 infection [4]. The nutraceutical was combined with substances optimizing mitochondrial metabolic function. As an alternative to, or in combination with the oral treatment, intravenous infusion therapy was given using magnesium-sulphate, multivitamins, essential amino acids [15], and – more recently – stem cells.

The present paper summarizes the preliminary results of these therapeutic approaches based on observational, open-label prospective registration in a total of 113 cases in two different outpatient clinics. Overall 86% of patients reported a variable degree of reduced fatigue and improvement of general wellbeing within 4 to 6 weeks of treatment.

Since several biological mechanisms leading to AD may be activated by COVID infection, and since chronic inflammation and oxidative overload are also involved in the development of age-related AD, oral therapy was given to 2 patients with evolutive AD. Treatment could not improve their condition, but it prevented further deterioration.

The present finding should be interpreted with great caution because the number of observations is small and there is no comparison with a control group. However, the preliminary results should justify the initiation of a randomized placebo-controlled double-blind trial, using either oral or infusion therapy as add-on in patient who respond poorly to conventional treatment.

The results of pragmatic real-life study suggest a significant, though variable degree of improvement of fatigue and of general well-being and quality of life can be obtained in the majority of patients. Most of the patients wished to continue their therapy,

since improvement seemed to be maintained or even continued to increase in the majority of them.

APPENDIX

Ingredients of QALY®: Astaxanthin (biomass of Haematococcus pluvialis); Oxido-reductase Ubiquinol Q10; Pine bark extract (Pinus maritima); Extract of roseroot (Rhodiola rosea); Vitamin B9 (folic acid); Vitamin B12 (methylcobalamine), Selenomethionine; Zinc- bisglycinate; Krill oil.

Ingredients of DCA formula: Sodium-dichloroacetate; Vitamin B1 (Thiamine); Alpha lipoic acid; Ubiquinol Q10.

Ingredients of Completté®: Bio-glutathione; Hesperidin; Ascorbic acid; Hyaluronic acid; m-tranexamic acid; Argan stem-cell, Bio-stem cell.

CONFLICT OF INTEREST

The first author owns the Belgian patent of some of the ingredients of QALY®. The study did not benefit from any financial support.

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