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Dextroamphetamine Sulfate Therapy Markedly Improves the Chronic Fatigue Syndrome

Diane L Check[1], Jerome H Check[1, 2*] and Brittney Katsoff[3]

*[*1]Cooper Institute for Reproductive Hormonal Disorders, P.C., Mt. Laurel, NJ, USA.*

[2]Department of Obstetrics and Gynecology, Division of Reproductive Endocrinology & Infertility, School of Rowan University, Camden, NJ, USA.

[3]Vitas Healthcare Miami, Fl, USA

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ABSTRACT

Purpose: To evaluate the efficacy of treatment of chronic fatigue syndrome in women with dextroamphetamine sulfate.
Methods: Dextroamphetamine sulfate, in the form of amphetamine salts 15 mg extended release capsules (equivalent to 9.4 mg dextroamphetamine sulfate), was given to women complaining of severe chronic fatigue. The dosage could be increased up to 60 mg. A questionnaire was administered 6 months after initiation of therapy – Has the chronic fatigue: 1) increased, 2) remained stable but not improved, 3) slightly improved, 4) moderately improved, 5) markedly improved?
Results: Forty-eight of 50 reported markedly improved (96%) and 2 of 50 (4%) reported moderately improved.
Conclusions: There is no other alternative effective pharmacologic agent for chronic fatigue than dextroamphetamine sulfate. Besides treating the chronic fatigue other co-morbidities will be corrected also.

Keywords: Chronic fatigue syndrome, Endometriosis, Sympathomimetic amines, Dextroamphetamine sulfate, Increased cellular permeability syndrome

INTRODUCTION

Anecdotally, dextroamphetamine sulfate has been found to markedly improve long standing treatment refractory chronic fatigue syndrome [1]. Dextroamphetamine sulfate is included in a group of pharmacologic agents known as psychostimulants. These drugs, besides dextroamphetamine sulfate, includes methylphenidate, pemoline, modafinil and armodafinil.

There have been 7 randomized clinical controlled studies evaluating methylphenidate and modafinil for fatigue in patients with cancer [2-4]. Only one study showed some benefit in women who completed chemotherapy for breast or ovarian cancer [2]. Subsequently, another large randomized controlled studies did not find any improvement over placebo using a long acting methylphenidate preparation [5]. A randomized controlled study of 850 patients failed to show a significant difference compared to placebo [4].

In all these controlled studies there were some patients who did seem to improve their fatigue which seemed more than a placebo effect. However, they were such a small minority that despite large studies there was insufficient power to show a significant difference [2-5]. For some reason, these studies preferred other psychostimulants than dextroamphetamine sulfate.

The tremendous response to dextroamphetamine sulfate therapy in the published case report of severe chronic fatigue warranted a larger prospective study to determine if dextroamphetamine sulfate can improve chronic fatigue in some cases, but only a minority, as seen with the other psychostimulants, or could dextroamphetamine sulfate be a much better type of treatment for the chronic fatigue syndrome?

MATERIALS & METHODS

Fifty women were enlisted who had unexplained chronic fatigue syndrome. Patients with a known history of cancer and multiple sclerosis were excluded, as were women diagnosed with autoimmune disorders, confirmed by laboratory testing.

Patients were excluded with anemia, hypothyroidism, uncorrected thyrotoxicosis, or adrenal insufficiency, by appropriate laboratory testing. Patients were not excluded if

Corresponding author: Jerome H Check, M.D., Ph.D., Old York Road Melrose Park, PA, 19027, USA, Tel: 215-635-4400; Fax: 215-635-2304 7447; E-mail: laurie@ccivf.com

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only a positive antinuclear antibody test was found, without confirmation by further testing for autoimmune disorders, e.g., lupus erythematosus, rheumatoid arthritis, scleroderma, or Sjogren's syndrome.

Amphetamine salts 15 mg extended release capsules, containing 9.4 mg dextroamphetamine sulfate, was the initial therapy. They were evaluated on a monthly basis where the dosage could be 1) reduced, 2) increased, or remained stable based on response vs. side effects. The maximum dosage allowed was 60mg extended release capsules in 2 divided dosages.

After 6 months after initial of therapy, the patients filled out a questionnaire as follows: The chronic fatigue syndrome was (please check one): 1) worse, 2) stable but no better, 3) slightly better, 4) moderately better, 5) markedly better.

RESULTS

After 6 months, 48 of 50 (96%) reported that they were markedly better, whereas 2 of 50 (4%) reported they were moderately better.

The median dosage of amphetamine salts at the completion of the study was 30 mg per day (18.8 mg dextroamphetamine sulfate).

DISCUSSION

This study showed that treatment with dextroamphetamine sulfate will markedly improve chronic fatigue syndrome in the large majority of women with unexplained chronic fatigue syndrome. These results are consistent with the hypothesis that dextroamphetamine sulfate works by a different mechanism than the other psychostimulants, and that is the reason for its apparent superiority.

The majority of these patients did not report depression, so that it does not seem likely that the efficacy of this drug was related to its effect on the psyche. The authors favor the hypothesized mechanism that the drug improves fatigue by releasing more dopamine from sympathetic nerve fibers and thus inhibits unwanted elements from entering mitochondria resulting in muscle dysfunction and fatigue [6-8]. This hypothesis contends that increased cellular permeability in various tissues related to genetic factors or tissue damage from trauma or infection may lead to increased cellular permeability which leads to either inflammation which may result in pain, or muscle dysfunction [9]. Dextroamphetamine sulfate releases dopamine from sympathetic nerve fibers which in turn leads to decreased cellular permeability and improvement of symptoms according to the hypothesis [9].

In fact, many of these 50 patients had other co-morbidities, e.g., pelvic pain, headaches, joint pain and other conditions that similarly showed marked improvement following dextroamphetamine sulfate therapy [10-16].

One woman, not part of this study, was referred by another patient who had marked chronic fatigue that was improved by dextroamphetamine sulfate. The woman who was referred was unable to walk for 25 years related to a mitochondrial defect known as the mitochondrial encephalopathy lactic acid stroke-like syndrome. Shockingly, within 2 months of taking dextroamphetamine sulfate she was able to walk normally, and this complete reversal of paresis has persisted for 10 years [17].

Dextroamphetamine sulfate has also been demonstrated to relieve a whole potpourri of symptoms related to smooth muscle dysfunction including achalasia, gastroparesis, pseudo intestinal obstruction and severe urinary incontinence related to a neurogenic bladder [18-22].

There is the possibility that the mechanism for chronic fatigue syndrome in patients with cancer differs from the mechanism in patients with unexplained chronic fatigue syndrome. Thus, perhaps dextroamphetamine sulfate would not prove as effective for this group. However, anecdotally, these authors have seen this drug markedly reverse severe chronic fatigue in patients with cancer, and these case reports are being prepared for submission for publication. Nevertheless, it is hoped that this study will stimulate interest in other clinicians who see a larger population of patients with cancer to test its efficacy in this group with a large prospective study possibly comparing dextroamphetamine sulfate to one of the other psychostimulants that had shown at least mild benefits to some patients. We will also try to convince our own oncology department to collaborate with our reproductive and medical endocrine group to perform a randomized control trial for patients with cancer suffering from severe fatigue either related to their cancer, per se, or from chemo or radiotherapy.

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