

REDUCTION OF FIBROMYALGIA SYMPTOMS THROUGH INTRAVENOUS NUTRIENT THERAPY: RESULTS OF A PILOT CLINICAL TRIAL

Patrick B. Massey, MD, PhD

Objective • To evaluate the effectiveness of a modified Myers' formula of intravenous nutrient therapy (IVNT) on the symptoms of fibromyalgia (FM) in therapy-resistant FM patients.

Methods: In this pilot clinical trial, 7 participants with therapy-resistant FM were given IVNT once per week for 8 weeks. Patient's pain levels, fatigue, and activities of daily living were evaluated weekly.

Results • All participants reported decreased pain levels, decreased fatigue, and increased activities of daily living. Participants noted increased energy levels within 24-48 hours of the initial infusion. At the end of the study, all participants reported increased energy and activities of daily living as well as a 60% reduction in pain ($P=.005$) and an 80% decrease in fatigue ($P=.005$). No participants, however, reported complete or lasting

resolution of pain or fatigue. No side effects were reported.

Discussion • Anecdotal reports have indicated benefit for IVNT for patients with chronic pain, including FM. However, except for 2 reports, the medical literature is devoid of any studies of IVNT for the treatment of FM. In this pilot study, 7 participants received IVNT once a week for 8 weeks. All participants had long-standing FM (at least 8 years) and had tried conventional therapies, such as antidepressants, nonsteroidal anti-inflammatory drugs, and exercise, without significant or lasting relief. All had improvement in symptoms and increases in their activities of daily living, although no participant reported complete resolution of symptoms. IVNT appears to be safe to reduce FM symptoms. (*Altern Ther Health Med.* 2007;13(3):32-34.)

Patrick B. Massey MD, PhD, is the medical director of Complementary and Alternative Medicine at Alexian Brothers Hospital Network, Elk Grove Village, Ill.

Fibromyalgia (FM) is a chronic medical condition characterized by widespread pain, specific tender points, fatigue, and sleep disturbances primarily affecting women between 20 and 65 years old.^{1,2} Prevalence increases with age until after 65 and then rapidly declines. FM is 3 times more common in women than in men, and risk factors include trauma, middle age, lower education level and household income, divorce, and disability.^{3,4}

Conventional medical therapies for FM include antidepressants, nonsteroidal anti-inflammatory drugs (NSAIDs), and other pain medications.^{2,4,6} Exercise, nutrition, acupuncture, and stress reduction also may be effective at reducing the symptoms of FM.^{7,9} However, no one therapy seems to be universally effective.⁹

There is anecdotal evidence that a specific combination of both intravenous vitamins and minerals (modified Myers' formula) may reduce pain and increase energy in patients with FM.¹⁰ However, documentation of any benefit of this specific intravenous nutrient combination, for any medical condition, is limited to a clinical report of intravenous nutrient therapy

(IVNT) alleviating hot flashes in men with prostate cancer undergoing androgen deprivation therapy.¹¹

In this clinical trial, we explored the effect of weekly IVNT on a small cohort of patients with chronic and severe FM. All participants had failed numerous medical therapies and had very poor quality of life secondary to pain and fatigue. During therapy, all participants reported decreases in pain and increases in energy and activities of daily living. None of the participants, however, reported complete resolution of pain within the 8-week period.

MATERIALS AND METHODS

Seven women between the ages of 38 and 65 with a diagnosis of therapy-resistant FM were recruited from the ALT-MED medical and physical therapy program (private clinical practice of the author) and enrolled in this open-label, clinical trial. The diagnosis of FM was made and/or confirmed by a rheumatologist, using the American College of Rheumatology criteria of at least 11 of 18 tender points being painful upon palpation. Therapy resistance was defined as persistence of pain significantly affecting activities of daily living in spite of appropriate medical intervention. All participants had been diagnosed with FM at least 5 years before.

At the time of the study, the participants were not taking antidepressants but were using NSAIDs and occasional opioid

medications for pain control. Participants also were occasionally taking multivitamins, omega-3 oils, and calcium supplements. Neither medications nor dietary supplements were changed during the clinical trial. The participants did not have other serious medical conditions such as heart disease, high blood pressure, cancer, renal or hepatic disease, or allergies to thiamine.

Initial and weekly pain levels were measured using a numeric analog pain scale (0=no pain; 10=severe pain). Subjective initial and weekly fatigue levels also were measured on a simple numeric scale (5=high energy/ability to complete all activities of daily living; 0=low energy/difficult to do any activities of daily living).

Participants received IVNT once per week for 8 weeks, using the modified Myers' formula (see Table) diluted in 100 mL of normal saline. The infusion was given in a peripheral vein over 20-30 minutes. There were no complications or reported side effects. Pain levels (initial and final) and fatigue levels (initial and final) were analyzed using the Student's *t* test ($n=7$, $P<.005$).

TABLE Modified Myers' Intravenous Nutrient Formula

Vitamin/Mineral	Dose
Magnesium chloride hexahydrate	400 mg
Calcium gluconate	40 mg
Vitamin C	3000 mg
Hydroxocobalamin (B ₁₂)	1,000 µg
Pyridoxine hydrochloride (B ₆)	100 mg
Dexpanthenol (B ₅)	250 mg
Riboflavin (B ₂)	2 mg
Thiamine (B ₁)	100 mg
Niacinamide	100 mg

RESULTS

Averaged initial and weekly pain and fatigue levels were assessed. By the second administration of IVNT, all participants reported a decrease in both pain (Figure 1) and fatigue (Figure 2). Although there was variation in reported pain levels from week to week, over the course of the 8-week clinical trial, pain levels and fatigue significantly improved ($P=.005$). None of the participants achieved a pain-free or fatigue-free state, but all participants consistently reported increased energy 24-48 hours post-IVNT. One participant improved to the point that she was able to return to work part-time.

DISCUSSION

It has been estimated that FM affects 3-6 million Americans, the overwhelming majority being women between 30 and 60 years old.^{2,4} FM seems to be precipitated by trauma, virally mediated illnesses, and autoimmune disease.¹² For many, FM causes significant alterations in lifestyle. Studies show that 25%-31% of people diagnosed with FM are completely disabled.¹³ Disability is persistent and, over time, may progress. Although the research is far from conclusive, changes in regulation of the inflammatory process appear to play a role.

FM patients have higher levels of substance P, and this may amplify the central pain message.¹⁴ In addition, inadequate levels of natural anti-inflammatory compounds, such as alpha-antitrypsin (AAT), also may contribute to the pain and disability.¹⁵ However, the mechanism(s) by which FM manifests itself is still undetermined.

Pain is the primary symptom of FM. Allopathic medical approaches, such as antidepressants, exercise, and pain medications, are beneficial to some degree.^{2,5-7} Early research suggests that acupuncture, mind-body-based stress reduction, and tai

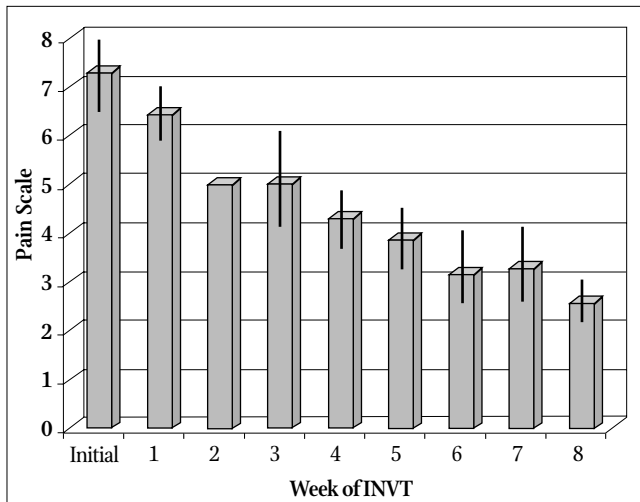


FIGURE 1 Pain Levels Initially and During Intravenous Nutrient Therapy

Weekly averaged pain levels of participants initially and during IVNT. Pain levels were measured using a numeric analog pain scale (0=no pain, 10=severe pain). Significant improvement in pain from initial assessment to week 8 ($P=.005$; *t* test).

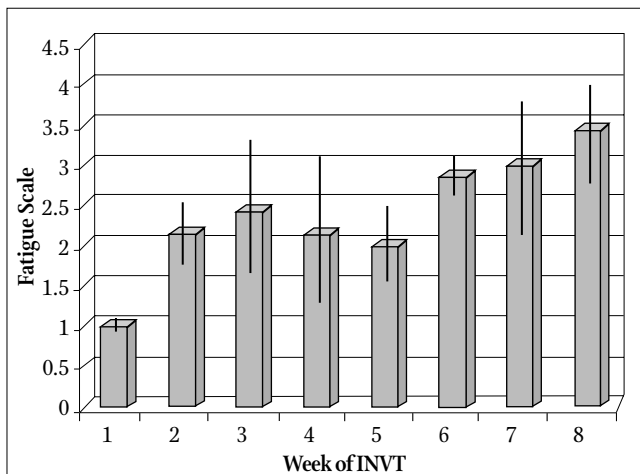


FIGURE 2 Fatigue Levels Initially and During Intravenous Nutrient Therapy

Weekly averaged fatigue levels of participants initially and during IVNT. Fatigue levels were measured using a numeric analog pain scale (0=low energy/difficult to do any activities of daily living, 5=high energy/ability to complete all activities of daily living). Significant improvement in fatigue from initial assessment to week 8 ($P=.005$; *t* test).

chi may be helpful therapeutic options.^{2,16} There is anecdotal evidence that the Myers' formula IVNT may help with a number of chronic pain conditions, including FM.¹⁰ To the author's knowledge, however, this article is the first reported clinical trial of Myers' formula IVNT and FM.

In this study, all participants had considerable reductions of reported pain, but no participant reported a pain-free state during the 8-week session. There also was an increase in self-reported energy levels. Increases in energy resulted in anecdotal reports of an increase in the activities of daily living, such as housework and interactions with family and friends (data not shown). Although there was some variability in pain levels and energy over the 8 weeks, the overall trend for each participant was toward improvement.

None of the patients reported any serious side effects. If the IVNT was infusing too quickly, an occasional burning feeling was reported at the needle site, but this sensation disappeared when the infusion rate was reduced.

Given the myriad number of biochemical reactions in all organ systems involving the B vitamins, magnesium, calcium, and vitamin C in the IVNT, there is not enough data to speculate on specific mechanism(s) of action. Nevertheless, the nutritional role of the IVNT and the anti-inflammatory effects of vitamin C and magnesium cannot be excluded as possible mechanism(s) of action.

There seem to be measurable nutritional deficiencies in FM, and these deficiencies may contribute to the symptoms of FM.¹⁷ Improved nutrition may reverse some of these, as adoption of a vegetarian or vegan diet can significantly reduce pain, stiffness, and sleep disturbances, possibly as a result of increased amounts of vitamins and nutrients.^{8,18}

There is also ample evidence that increased B vitamins and vitamin C levels amplify the production of neurotransmitters in the central nervous system.¹⁹ Vitamin-induced changes in specific neurotransmitters may alter the perception of pain in FM. For example, in a small study, reduction of dietary excitoneurotoxins such as monosodium glutamate and aspartame greatly improved pain and function in patients with FM.²⁰

Magnesium has been shown to be beneficial in the treatment of pain in FM. In this study, however, it is unlikely that magnesium is the sole "active" anti-inflammatory. The amount of magnesium used is much lower than the amount of magnesium reported to benefit FM,²¹ and B vitamins also have direct anti-inflammatory potential.²²

Though the results of this clinical trial are positive, there are a number of questions that cannot be answered without larger, randomized, placebo-controlled clinical trials, including the following: the role of the placebo effect; the optimal combination of specific nutrients for FM; the best interval and duration of therapy; and whether the benefits are enduring after discontinuation of IVNT. Nevertheless, given the improvements in pain level and activities of daily living resulting from IVNT, as well as the lack of any side effects, these data strongly suggest that further research into IVNT as a therapy for FM is indicated.

REFERENCES

1. Wolfe F, Smythe HA, Yunus MB, et al. The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia. Report of the Multicenter Criteria Committee. *Arthritis Rheum.* 1990;33(2):160-172.
2. Mease P. Fibromyalgia syndrome: review of clinical presentation, pathogenesis, outcome measures, and treatment. *J Rheumatol Suppl.* 2005;75:6-21.
3. Wolfe F, Ross K, Anderson J, Russell IJ, Hebert L. The prevalence and characteristics of fibromyalgia in the general population. *Arthritis Rheum.* 1995;38(1):19-28.
4. White KP, Speechley M, Harth M, Ostbye T. The London Fibromyalgia Epidemiology Study: the prevalence of fibromyalgia syndrome in London, Ontario. *J Rheumatol.* 1999;26(7):1570-1576.
5. Rao SG, Bennett RM. Pharmacological therapies in fibromyalgia. *Best Pract Res Clin Rheumatol.* 2003;17(4):611-627.
6. Bennett RM, Kamin M, Kamin R, Rosenthal N. Tramadol and acetaminophen combination tablets in the treatment of fibromyalgia pain: a double-blind, randomized, placebo-controlled study. *Am J Med.* 2003;114(7):537-545.
7. Adams N, Sim J. Rehabilitation approaches in fibromyalgia. *Disabil Rehabil.* 2005;27(12):711-723.
8. Donaldson MS, Speight N, Loomis S. Fibromyalgia syndrome improved using a mostly raw vegetarian diet: an observational study. *BMC Complement Altern Med.* 2001;1:7. Epub 2001 Sep 26.
9. Morris CR, Bowen L, Morris AJ. Integrative therapy for fibromyalgia: possible strategies for an individualized treatment program. *South Med J.* 2005;98(2):177-184.
10. Gaby AR. Intravenous nutrient therapy: the "Myers' cocktail." *Altern Med Rev.* 2002;7(5):389-403.
11. Massey PB. Intravenous nutrient therapy eliminated androgen deprivation therapy-induced hot flashes in two men with prostate cancer. *J Soc Integr Oncol.* 2006;4(4):153-156.
12. Yunus MB, Khan MA, Rawlings KK, Green JR, Olson JM, Shah S. Genetic linkage analysis of multicausal families with fibromyalgia syndrome. *J Rheumatol.* 1999;26(2):408-412.
13. Wolfe F, Anderson J, Harkness D, et al. Work and disability status of persons with fibromyalgia. *J Rheumatol.* 1997;24(6):1171-1178.
14. Russell IJ. The promise of substance P inhibitors in fibromyalgia. *Rheum Dis Clin North Am.* 2002;28(2):329-342.
15. Blanco LE, de Serres FJ, Fernandez-Bustillo E, et al. Alpha1-Antitrypsin and fibromyalgia: new data in favour of the inflammatory hypothesis of fibromyalgia. *Med Hypotheses.* 2005;64(4):759-769.
16. Taggart HM, Arslanian CL, Bae S, Singh K. Effects of T'ai Chi exercise on fibromyalgia symptoms and health-related quality of life. *Orthop Nurs.* 2003;22(5):353-360.
17. Werbach MR. Nutritional strategies for treating chronic fatigue syndrome. *Altern Med Rev.* 2000;5(2):93-108.
18. Kaartinen K, Lammi K, Hypen M, Nenonen M, Hanninen O, Rauma AL. Vegan diet alleviates fibromyalgia symptoms. *Scand J Rheumatol.* 2000;29(5):308-313.
19. Lee L, Kang SA, Lee HO, et al. Effect of supplementation of vitamin E and vitamin C on brain acetylcholinesterase activity and neurotransmitter levels in rats treated with scopolamine, an inducer of dementia. *J Nutr Sci Vitaminol (Tokyo).* 2001;47(5):323-328.
20. Smith JD, Terpening CM, Schmidt SO, Gums JG. Relief of fibromyalgia symptoms following discontinuation of dietary excitotoxins. *Ann Pharmacother.* 2001;35(6):702-706.
21. Russell IJ, Michalek JE, Flechas JD, Abraham GE. Treatment of fibromyalgia syndrome with Super Malic: a randomized, double blind, placebo controlled, crossover pilot study. *J Rheumatol.* 1995;22(5):953-958.
22. Palmas W. Effects of short-term supplementation with ascorbate, folate, and vitamins B6 and B12 on inflammatory factors and estrogen levels in obese postmenopausal women. *Int J Vitam Nutr Res.* 2006;76(1):34-38.