Treatment of Migraine with Targeted Nutrition Focused on Improved Assimilation and Elimination

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Abstract

This study was undertaken to assess the impact of three months of targeted nutritional therapy for migraine on health-related quality of life. The study is also intended to lend support to a theory that migraine is caused by an underlying dysfunction involving assimilation or elimination mechanisms. Forty people were selected from approximately 120 applications. Fourteen participants were selected from among those applicants within the authors' practices and 26 from applicants solicited via the Internet. Participants were required to complete the Medical Outcomes Trust Migraine Specific Quality of Life (MSQ) Questionnaire. Eighty percent of the study participants experienced significant and sustained improvements in quality of life during the 90 days of the study. The study instrument is specifically designed to measure quality of life improvement and thus does not solicit responses relative to number of migraine attacks or duration of each migraine. However, it should be noted that improvement in quality of life is likely due to a reduction in the duration and frequency of migraine attacks.

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Introduction

Migraine prevalence studies have indicated that the condition is suffered by more than 17 percent of the female and six percent of the male population in the United States.[1] In addition to the debilitating effect of a migraine attack, sufferers report a significant impact on their quality of life between attacks. Many migraine patients report that the fear of getting a headache totally disrupts their ability to plan social events, vacations, and other family activities.[2,3] The debility associated with migraine has substantial economic impact, with estimates of the direct cost of migraine treatment and indirect migraine-associated costs due to lost productivity in the workplace as high as $17.2 billion annually in the United States.[4] Studies have shown that most

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people who have migraine headaches are never diagnosed by a physician or treated with prescription medicine,[1,5] and those who do receive care are often dissatisfied with the results.[6]

Available research on the treatment of migraine is focused in acute treatment and prophylactic medications. Advances in acute treatment are well documented. Sumatriptan, a serotonin-1 agonist, administered subcutaneously, orally, or intranasally, is effective in alleviating the pain and associated symptoms of the acute migraine attack. Moderate or severe pre-dose pain is reduced to mild or no pain within two hours of dosing in approximately 80 percent of patients treated with the subcutaneous form and 63 percent of patients treated with the nasal form, and within four hours of dosing in 65-78 percent of patients treated with the oral form.[7-10] The use of sumatriptan has also been shown to have a positive impact on the quality of life of migraine sufferers.[11]

In contrast there has been limited progress in the prophylactic treatment of migraine. Although current preventive pharmaceuticals can be expected to reduce the duration and frequency of migraine attacks, the treatment guidelines suggest almost all patients will still require symptomatic or acute treatment.[12] Indeed a good response to prophylactic treatment is defined as a 50-percent reduction in the frequency or severity of migraine attacks.[12] Few studies have compared the response to particular migraine preventive drugs, leaving physicians with little guidance for choosing among various agents.[13] The medications used include beta blockers, calcium channel blockers, tricyclic antidepressants, anticonvulsants, serotonin antagonists, NSAIDS, and MAO inhibitors.

Botanical and nutritional approaches to migraine prevention have shown some promise. For example, riboflavin proved superior to placebo in reducing frequency and length of migraines.[14] On average, magnesium levels are lower in people with migraines.[15] It has been shown that intravenous magnesium can relieve some migraines in minutes.[16] Double-blind research indicates daily supplemental magnesium reduces premenstrual migraines.[17] Studies have shown the continuous use of botanicals, including *Tanacetum parthenium* (feverfew)[18-20] and *Petasites hybridus* (butterbur)[21] can result in a reduction in the duration, frequency, and severity of migraine attacks.

The approach utilized in this study is based on classic naturopathic medical philosophy; i.e., disease is the deterioration of normal function in one of two areas – either the body is not getting what it needs due to faulty assimilation or the body is unable to remove wastes and toxins due to poor elimination, or both. Naturopathic philosophy also suggests that genetics determine underlying susceptibility to disease or dysfunction, but not actual disease manifestation. The goal is to remove obstacles to cure by focusing on improving assimilation and elimination, allowing the body's inherent abilities of repair and recovery to function properly.

Subjects

Subjects were solicited via the Internet and from the patient base of the physicians involved. Those selected included five males and 35 females, 18 years and older, who had suffered from migraines for at least one year. Due to the relative short term of the evaluation effort (90 days), only patients who suffered at least two migraines per month on a consistent basis were selected. Applicants with head or neck trauma in their medical histories were eliminated. No consideration relative to inclusion or exclusion from the study was given to the patients' current or previous use of pharmaceutical, over-the-counter, or natural products.

Materials and Methods

Two nutritional formulations were used. The first, Combination A, contained an

enzymatically rendered fish protein with a high level of bioactive peptides and amino acids. Research on the biological activity of peptides has focused on the critical care arena, comparing peptide-based enteral feeding formulas to intact protein or amino acid-based formulas. In a randomized trial of a peptide diet versus an intact protein diet in patients following traumatic injury, diarrhea developed in 40 percent of patients receiving the intact protein formula compared to no diarrhea in those receiving the peptide diet.[22] A peptide diet has also been reported to be better tolerated than an amino acid diet in postoperative patients.[23] Peptide-based diets have also been reported to improve intestinal morphology in patients with radiation-induced gut injury[24] and inflammatory bowel disease.[25]

Combination A also contains a blend of four probiotics (*Lactobacillus acidophilus* (DDS-1 strain), *Lactobacillus bulgaricus*, *Enterococcus faecium*, and *Bifidobacterium bifidum*) and chlorophyll. Probiotics are the beneficial bacteria that inhabit the intestinal lining and assist in the digestion and absorption of nutrients. Lactobacillus and Bifidobacteria maintain a healthy balance of intestinal flora by producing organic compounds such as lactic acid, hydrogen peroxide, and acetic acid that increase the acidity of the intestine and inhibit the reproduction of many harmful bacteria.[26,27] Probiotic bacteria also produce bacteriocins, which act as natural antibiotics to kill undesirable microorganisms.[28] The theory for their use for migraine prevention is that the combination of peptides and probiotics should improve nutrient assimilation in most patients.

The second formulation, Combination B, is a blend of twenty-one different ingredients designed to improve the nutritional status of the liver and kidneys. The ingredients include vitamins (thiamine mononitrate and pyridoxal 5-phosphate), minerals (magnesium aspartate, manganese glycerylphosphate, zinc gluconate, and copper glycinate), micronutrients (malic acid, proanthocyanidins, inositol, N-acetyl-L-cysteine, and super oxide dismutase), glandulars (liver, kidney, and spleen), and herbs (*Silybum marianum* (milk thistle), *Beta vulgaris* (beet root), *Nasturtium officinale* (watercress), *Apium graveolens* (celery seed), *Taraxacum officinale* (dandelion), *Apium petroselinum* (parsley), and *Capsicum frutescens* (cayenne)).

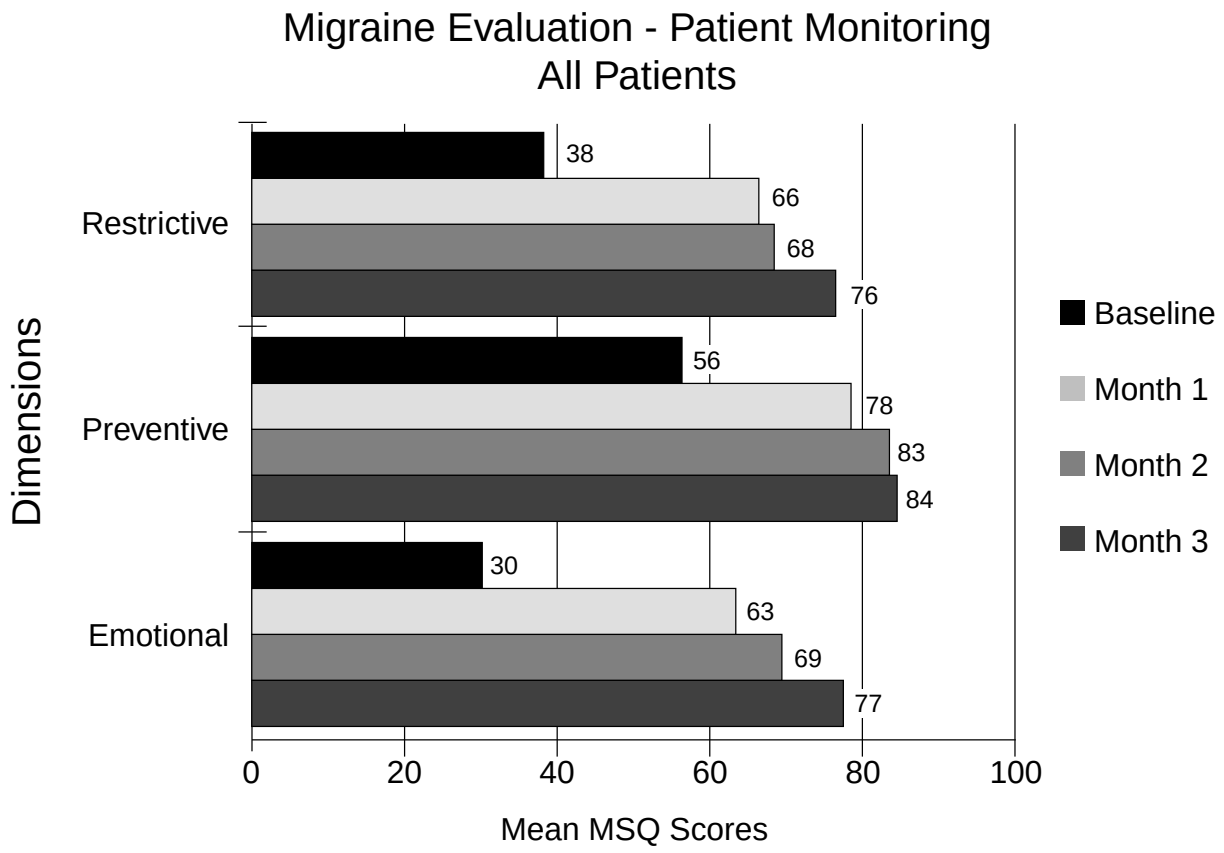
The function of Combination B was to provide direct nutritional support to the organs of elimination, while also providing the nutrient and herbal components that have been shown in practice and/or research to be critical for antioxidant and detoxification function. Some of the ingredients have been shown to have direct impact in these two areas and others are known co-factors for enhancing detoxification and increasing glutathione levels in the liver.

An open label design was chosen to simulate the conditions under which a healthcare provider or migraine patient might introduce a new therapy. Participants were instructed to take three capsules of Combination A and two capsules of Combination B ten minutes before their two largest meals of the day. In anticipation of a limited amount of digestive disturbance that can accompany any dietary adjustment, the participants were instructed to take reduced dosages for the first week: two Combination A capsules and one Combination B capsule once per day for the first three days, two Combination A capsules and one Combination B capsule twice per day for the next three days, and the full dosage for the remainder of the trial. Participants were not required to make any changes in current use of other migraine products, whether pharmaceutical, natural, or over-the-counter, and no lifestyle or dietary changes were required.

Participants were required to complete the Medical Outcomes Trust Migraine Specific Quality of Life (MSQ) Questionnaire (Version 2.1, copyrighted 1992, 1996, 1998 by Glaxo Wellcome Inc., Research Triangle Park, North

Carolina)[29] at baseline (prior to taking any product), and again at 30, 60, and 90 days. The MSQ is a 14-item questionnaire that assesses aspects of health believed to be particularly affected by migraine. Three dimensions were measured: (1) role-function restrictive (the degree to which performance of normal activities is restricted or limited by migraine); (2) role-function preventive (the degree to which performance of normal activities is prevented or interrupted by migraine); and (3) emotional function (the emotional effects of migraine). For example, typical questions address migraine-associated problems in attending social activities (role-function restrictive) or the degree to which migraine patients feel their migraines are a burden on others (emotional function). The MSQ has shown evidence of reliability and validity in migraine sufferers participating in clinical trials.[30,31]

Figure 1. Results of Migraine Specific Quality of Life Questionnaire



0 →100 is a quality of life scale with 0 the lowest and 100 the highest
MSQ = Migraine specific quality of life questionnaire

The MSQ was completed and mailed to the study administrator at 30-day intervals. Data analysis was conducted according to predesigned software provided by Medical Outcomes Trust.

Results

Each of three MSQ dimensions was scored separately and transformed onto a scale ranging from 0 (least favorable score) to 100 (most favorable score). Reviewing each of the three dimensions (restrictive, preventive, and emotional) measured by the MSQ reveals positive results in each. Figure 1 represents a graphical depiction of results.

In the category role-function restrictive, the degree to which performance of normal activity was restricted or limited by migraine, the study participants registered a combined quality of life scale of 38. At the end of 30 days this quality of life dimension had risen to 66 and by the end of 90 days it was at 76.

The role-function preventive dimension quality of life scores also rose from a baseline of 56 to 78 at 30 days and 84 at the conclusion of 90 days.

The emotional function dimension scores rose from a baseline of 30 to a quality of life score of 63 at 30 days and 77 at the conclusion of 90 days.

Eight of the 40 participants experienced no improvement in their migraine frequency or duration and subsequently their quality of life scores remained consistently low. Twenty-four (60%) of the participants experienced almost total relief from migraine attacks and their quality of life scores were in the 80 to 100 range. The remaining eight participants experienced varying degrees of improvement in the duration and frequency of their attacks and their quality of life scores reflected the extent of improvement.

Discussion

Advances in migraine research and knowledge over the last decade have resulted in improvements in the quality of life for migraine sufferers. The most significant of these advances has been in the area of migraine abortive drugs such as sumatriptan. For the first time, migraine patients have the knowledge that they can eliminate the pain of an intense attack. Unfortunately, these abortive advances have little impact on reducing the number of attacks, and side effects associated with the triptans limit the patients' willingness to use them indiscriminately.[13,14,32]

Advances in migraine prevention have been limited. While there are a variety of preventive pharmaceutical approaches available, none has proven to be free of side effects or effective for an extended period of time.[13,14,32]

This study clearly indicates that it is possible to significantly improve the quality of life of migraine sufferers with targeted nutritional therapy. Additionally, the fact that the supplements caused no noticeable side effects resulted in a high level of patient satisfaction and compliance.

These study results support the theory that migraines may be, at least in part, caused by an underlying deterioration of normal body functioning. In this study, by improving assimilation and elimination mechanisms, the manifestation of migraine diminished or ceased for the majority of the participants. Although the study instrument measures specific quality of life markers, it is critical to note that 60 percent of the study participants also reported they were virtually migraine free, including participants who have suffered migraine disease for over 25 years and have tried many available treatments, both natural and pharmaceutical.

Discussions are currently underway to repeat this study with appropriate controls in a major university medical center. Studies to investigate the effects of improved assimilation and elimination in other chronic diseases also seem warranted.

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