

Unorthodox Alternative Therapies Marketed to Treat Lyme Disease

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(See the Editorial Commentary by Steere and Arvikar on pages 1783–5.)

Background. Some patients with medically unexplained symptoms or alternative medical diagnoses suspect that they chronically suffer from the tick-borne infection Lyme disease. These patients are commonly targeted by providers of alternative therapies. This study was designed to identify and characterize the range of unorthodox alternative therapies advertised to patients with a diagnosis of Lyme disease.

Methods. Internet searches using the Google search engine were performed to identify the websites of clinics and services that marketed nonantimicrobial therapies for Lyme disease. We subsequently used the PubMed search engine to identify any scientific studies evaluating such treatments for Lyme disease. Websites were included in our review so long as they advertised a commercial, nonantimicrobial product or service that specifically mentioned utility for Lyme disease. Websites with patient testimonials (such as discussion groups) were excluded unless the testimonial appeared as marketing on a commercial site.

Results. More than 30 alternative treatments were identified, which fell into several broad categories: these included oxygen and reactive oxygen therapy; energy and radiation-based therapies; nutritional therapy; chelation and heavy metal therapy; and biological and pharmacological therapies ranging from certain medications without recognized therapeutic effects on *Borrelia burgdorferi* to stem cell transplantation. Review of the medical literature did not substantiate efficacy or, in most cases, any rationale for the advertised treatments.

Conclusions. Providers of alternative therapies commonly target patients who believe they have Lyme disease. The efficacy of these unconventional treatments for Lyme disease is not supported by scientific evidence, and in many cases they are potentially harmful.

Keywords. Lyme disease; *Borrelia burgdorferi*; alternative; complementary; unorthodox.

Some individuals with chronic illnesses or with medically unexplained symptoms attribute their condition to chronic infection with the tick-borne bacterium *Borrelia burgdorferi*, the cause of Lyme disease. In many cases such individuals, regardless of whether

they have evidence of the infection, seek treatments that depart from mainstream medical practices. The most publicized example of this is the use of prolonged and unorthodox antibiotic regimens. There is, however, a variety of nonantimicrobial alternative treatments that are marketed to patients for Lyme disease. In this study we report the results of internet searches performed to catalog unorthodox and potentially hazardous treatments that are currently advertised to patients who believe they have Lyme disease. In this discussion, references to patients with “Lyme disease” refer to individuals who have been diagnosed with or *who have come to believe* they have this infection, regardless of whether this is true.

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METHODS

We searched the internet using the Google search engine for nonantimicrobial alternative therapies promoted for the treatment of Lyme disease. In some cases, the advertised therapies were found after reading testimonials posted by patients in online support groups. We then used PubMed searches to assess whether a scientific basis had been established for the effectiveness of any of the cited therapies.

RESULTS

Several broad categories of therapies were identified: (1) oxygen and reactive oxygen species; (2) energy and radiation; (3) heavy metals and chelation; (4) nutrients; (5) biological and pharmacological therapies (Table 1).

Oxygen and Reactive Oxygen Species

Oxygen therapy was marketed to patients for treatment of Lyme disease primarily in 3 forms: **hyperbaric oxygen, ozone, and hydrogen peroxide**. Hyperbaric oxygen is administered using hyperbaric oxygen chambers and was promoted as having salutary effects on the immune response to *B. burgdorferi* infection [1–3]. Alternatively, some practices promoted using chemically reactive oxygen species, including ozone therapy and/or intravenous infusion of hydrogen peroxide. Ozone can be generated from atmospheric oxygen and administered in several forms. These include intravenous administration of an ozonated solution, ingestion of ozonated water, ozonation and reinfusion of blood, administration of ozonated oils, and rectal or vaginal insufflation with gaseous ozone [4, 5].

Energy and Radiation

This broad category of therapies included light, lasers, heat, and magnets. Among the examples, ultraviolet light is administered by irradiating blood *ex vivo*, followed by reinfusion [6]. Low intensity (also referred to as “cold”) laser therapy is either directed at symptomatic body parts or at acupuncture points [7, 8]. “Photon” therapy can be performed at home with the purchase of a device such as the \$13 000 Bionic 880, which reportedly has a 96% cure rate for Lyme disease [9, 10]. A light-emitting device is applied to the skin, and according to promotional literature, “its light is injected into cells, it forces pathogens out of the cells, where they are then mopped up by a now-stronger immune system” [11]. Less expensive is the \$1600 Photonic Energetics PE-1, which uses light emitting diodes [12]. A magnet therapy protocol recommended sleep and rest on a bed containing an array of 70 magnets [13]. “Rife” therapy consists of a device that delivers electromagnetic energy at prespecified therapeutic frequencies [14, 15]. Several sites sold rife machines for home use with prices generally in the range of \$1000 [16–21]. Finally,

Table 1. Examples of Alternative Medical Therapies Marketed to Patients for the Treatment of Lyme Disease

Categories of Therapy	Examples
Oxygen	Hyperbaric oxygen Hydrogen peroxide Ozone
Energy and radiation	Ultraviolet light Photon therapy “Cold” lasers Saunas and steam rooms “Rife” therapy (electromagnetic frequency treatments) Magnets
Metal/chelation	Mercury chelation and removal Dimercaptosuccinic acid (DMSA) 2,3-Dimercapto-1-propanesulfonic acid (DMPS) Alpha lipoic acid (ALA) Ethylene diamine tetraacetic acid (EDTA) Removal of dental amalgam Colloidal silver Bismuth
Nutritional supplements	Vitamins C and B12 Herbs Garlic, cilantro, Chlorella, Sarsaparilla, Andrographis, Turmeric, Olive leaf, Cat’s claw Burnt mugwort (moxibustion) Glutathione Fish oil Magnesium Salt
Biological and pharmacologic	Urotherapy (urine ingestion) Enemas Bee venom Hormonal therapy Dihydroepiandrosterone, Pregnenolone, Cortisone, Hydrocortisone Synthetic thyroid hormone Lithium orotate Olmesartan Cholestyramine Naltrexone Sodium chlorite (bleach) Intravenous immune globulin (IVIG) Apheresis Stem cell transplantation

thermal energy treatments using steam rooms and infrared saunas are also marketed to patients with Lyme disease [22–24].

Heavy Metals and Chelation

Some sites discussed heavy metal toxicity, particularly due to mercury, as copathogenic with Lyme disease [25]. Specifically, Lyme disease was said to predispose to symptomatic mercury toxicity; consequently, mercury chelation was a recommended adjunct to other treatments for Lyme disease. The interventions marketed for mercury toxicity included chemical chelators such as dimercaptosuccinic acid, 2,3-dimercapto-1-propanesulfonic acid, alpha lipoic acid, and ethylene diamine tetraacetic acid (EDTA) [25, 26]. Some herbal therapies such as garlic, cilantro, or chlorella were also said to be beneficial for heavy metal

intoxication. In addition to chelation, some sources recommended the removal of all mercury-containing amalgam dental fillings and root canals as part of Lyme disease therapy [27]. Some have suggested receiving future dental care only from “biological dentists” [28].

Bismuth and silver, in contrast to mercury, were heralded for their therapeutic rather than toxic properties. Silver is said to “support(s) the immune system as it attempts to kill off these bacterium [*sic*].” [29] “Silver kills lyme [*sic*] (and other infections) through oxidation first, then alkylation.” [30] Usually sold in “colloidal” form, silver particles are administered both orally and parenterally [29, 30]. Bismuth compounds were promoted for killing “cyst” forms of *B. burgdorferi* and are sometimes combined with EDTA to sequester additional substances [31, 32].

Nutritional and Herbal Therapy

A wide variety of dietary and nutritional interventions were marketed including conventional nutrients such as **vitamin C and vitamin B₁₂**, commonly used supplements such as **garlic and fish oil**, as well as other herbal products such as **turmeric, olive leaf, teasel root, cilantro, chlorella, sarsaparilla, andrographis, marijuana, cannabis oil, and cat’s claw** [26, 33–35]. One combination, a salt/vitamin C protocol was marketed as a “miracle cure” for Lyme disease [36]. A website advocated high dose methyl B₁₂ and glutathione, given as self-administered injections for “detoxification” [26]. The traditional East Asian remedy moxibustion (application of burning mugwort root to a patient’s skin) was also advertised [37]. Some sites marketed modified diets such as gluten restriction or high protein diets [34, 38]. One protocol recommended magnesium and water supplementation with oral serrapeptase, a protease derived from *Serratia* bacteria [39]. In addition to serrapeptase, other enzymes have been advertised to treat patients with Lyme disease including the soybean-derived nattokinase and the earthworm-derived lumbrokinase [40].

Biological and Miscellaneous Pharmacological Therapy

This category included a large variety of treatments. Ingestion of one’s own urine was said to have a variety of salubrious effects for Lyme disease and other medical conditions [41]. Enema therapy, involving coffee and herbal products, was marketed largely for “detoxification” [42]. Some protocols promoted the use of drugs not normally used for either infectious or inflammatory conditions such as the angiotensin receptor blocker olmesartan [43], the opioid antagonist naltrexone [44], lithium orotate salts [45], and the rarely used anti-inflammatory agent dimethyl sulfoxide [46]. In order to treat “adrenal fatigue,” some patients are presumptively given the anabolic steroid dihydroepiandrosterone, the steroid precursor pregnenolone, or the glucocorticoids cortisol or hydrocortisone [47–49]. Some

patients are given thyroid hormone replacement to combat fatigue [47, 48]. The bile acid binding resin cholestyramine is said to remove “toxins” from Lyme disease patients [50, 51]. A 28% sodium chlorite solution (ie, bleach), termed “miracle mineral solution,” has also been marketed for both oral and transdermal use to treat a variety of medical conditions including Lyme disease [52]. Bee venom preparations are also used to treat Lyme disease with the rationale that its constituent compounds have both potent antimicrobial and anti-inflammatory properties [32]. Intravenous immune globulin and subcutaneously administered immune globulin were marketed for the treatment of Lyme disease as well as other tick-borne diseases [53]. Apheresis, the extracorporeal filtration and reinfusion of a patient’s blood, was promoted as a means of toxin removal [54]. Finally, some clinics offer patients stem cell transplantation for Lyme disease [55, 56]. Testimonials in online patient networks referenced having received stem cell transplantation for Lyme disease at clinics in India, Panama, Bermuda, Costa Rica, and the United States.

Review of the Medical Literature

Scientific studies supporting the efficacy of any of the treatments discussed above could not be found on review of the medical literature. Most of the cited treatments were never evaluated with any scientific study, although we did find that a few treatments were evaluated in studies that either were poorly designed or had unclear relevance to human disease.

Two studies are worth mentioning in more detail. A study of combination therapy with cholestyramine-atovaquone enrolled 25 patients with persistent symptoms after being diagnosed with and treated for babesiosis-Lyme disease coinfection [57]. In this study, however, all patients received cholestyramine for the entirety of the trial, so no inferences could be made about its therapeutic efficacy.

The effect of hyperbaric oxygen on strains of *B. burgdorferi* was assessed both in vitro and in experimentally infected mice in one study [58]. The investigators found that growth of the organism in vitro was inhibited by hyperbaric oxygen in 14 of 17 cultures. In addition, the organism was cultivable from the bladders of only 20% of mice treated with hyperbaric oxygen, compared with 90% of untreated mice. No study of this therapy in humans with Lyme disease has ever been published.

DISCUSSION

Our study illustrates that many “alternative” therapies are marketed to patients who either have persisting problems after initial antibiotic therapy for Lyme disease or who are suspected to harbor the pathogen. None of the examples cited above include treatments with demonstrated or even, in almost all cases, biologically plausible efficacy for *B. burgdorferi*

infection. The exception to this is hyperbaric oxygen, for which a single study suggests in vitro and in a murine model that hyperbaric oxygen inhibits the growth of certain strains of *B. burgdorferi* [58]. On the other hand, there has never been a trial in humans showing that hyperbaric oxygen therapy is clinically effective for Lyme disease or in any way improves outcomes compared with conventional antibiotic therapy alone. Moreover, hyperbaric oxygen therapy is time-consuming, expensive, and has complications including middle ear barotrauma and myopia [59]. Several other treatments cited in this study such as exposure to reactive oxygen species in the forms of ozone or peroxide, chelation therapy, intravenous silver infusion, and stem cell transplantation pose significant risks to patients. Bismuth therapy has been fatal, leading to an explicit warning against its use for Lyme disease by the US Food and Drug Administration [60].

Two common themes characterized the websites referenced in this study. One was the reliance on anecdotes and testimonials from patients. The second was the veneer of scientific credibility, ranging from the medical credentials of the service providers to the use of seemingly technical terminology. In virtually all cases, these testimonials and scientific expositions were used promotionally to sell therapeutic services and products. Our review of the medical literature did not yield evidence to support these health claims. Few of the cited examples explained contraindications to the promoted treatment or possible adverse effects on the web sites.

Although not all practices explicitly advertised their services as treatment for “chronic” Lyme disease, this is the subset of patients with a diagnosis of Lyme disease that is most likely to seek treatments outside of mainstream allopathic medicine, specifically because patients with this diagnosis often suffer from persistent, medically unexplained pain, or fatigue. A diagnosis of chronic Lyme disease provokes considerable confusion, however, as the apparent specificity of the term is not supported by a clinical or microbiologic definition [61]. Although some patients with Lyme disease may have ongoing symptoms following antibiotic treatment, numerous studies of patients referred for evaluation of chronic symptoms attributed to Lyme disease have demonstrated that few have evidence of active or even of prior infection with *B. burgdorferi* [61]. Patients who come to believe they have chronic Lyme disease generally can be divided into those with other medical diagnoses, those with chronic medically unexplained symptoms, and a wide variety of patients who have a coincidentally positive test result for antibodies to *B. burgdorferi* [61, 62]. The presence of psychiatric comorbidities in some cases can exacerbate the experience of fatigue and pain [63–65]. There is often a great discordance between patients’ belief about the cause of their symptoms and the conventional medical understanding of Lyme disease; this can prove exceptionally frustrating to

individuals and families who have experienced prolonged suffering and who are desperate for a solution. This frustration is often worsened by long clinical evaluations that can include multiple office visits, referrals, and diagnostic tests that in many cases fail to yield a satisfactory diagnosis or treatment. The resulting disaffection can alienate patients from conventional medical practice and stimulate them to pursue care outside of mainstream medicine.

Seeking help from alternative care providers is associated with skepticism about conventional medicine, negative perceptions of health status, and negative opinion about locus of control over one’s health [66]. A number of factors make patients susceptible to practitioners’ claims about alternative therapies, even when there is neither scientific evidence nor even a basis in logic to support their efficacy or safety. These include psychological factors (such as hope, or wishful thinking), distaste for conventional authority figures (such as physicians) or for conventional science, and vigorous marketing on the part of proponents [67]. As this study illustrates, practitioners of unorthodox alternative therapies specifically target their marketing to the group of patients who believe they have Lyme disease.

The easy accessibility to testimonials from patients, particularly in the forms of online blogs, discussion boards, and promotional materials by alternative therapy providers, can be persuasive to vulnerable populations. The internet has democratized access to reliable health information; not until the internet era has accurate information for lay-readers, not to mention the scientific literature itself, been so accessible to the public. On the other hand, there is also a large volume of inaccurate information about Lyme disease on the internet, and this may impede some patients from making well-informed decisions about their health [68, 69].

It may indeed be true that patients feel better while taking some of the treatment regimens described in this study. In the largest clinical trial of extended antibiotics for the treatment of persistent symptoms following treatment of Lyme disease, 38% of placebo-treated patients improved—a proportion not significantly different than among those who received antibiotics [70]. This underscores the importance of the potential placebo effect in the assessment of any treatment’s efficacy.

Over the past few decades, patients with chronic unexplained fatigue, often accompanied by other unexplained symptoms, have been incorrectly identified as having chronic brucellosis (1930s–1950s), chronic Epstein-Barr virus infection (1960s–1980s), chronic candidiasis (1970s–1990s), toxic mold exposure (1980s–present), chronic xenotropic murine leukemia virus-related virus infection (2009–2011), and chronic *B. burgdorferi* infection (Lyme disease) (1980s–present) [71]. The term chronic Lyme disease has been applied to patients with a great diversity of symptoms that go well beyond fatigue and has been the most resistant to change because it is supported by a sizable and vocal

constituency of patient advocates, as well as by healthcare practitioners who espouse similar viewpoints. The use of antibiotics for such patients has been justified by using the label of Lyme disease (or Lyme disease with coinfections) for patients with such symptoms [72]. For the subset of chronically suffering patients who have a verifiable history of conventionally treated Lyme disease, several prospective, placebo controlled treatment trials have shown that extended parenteral antibiotic therapy frequently results in harm without convincing evidence of benefit [70, 73–75]. One alternative therapy site openly cited and discussed these trials to justify its promotion of nonantimicrobial treatments [43].

The types of alternative therapies we discuss have not been validated using the standards by which the scientific community accepts or rejects new therapies. In some cases they are potentially dangerous. Aside from direct adverse effects, pursuing such therapy may delay the identification and treatment of other important diagnoses. They may also come at significant financial cost to the patient. These costs are difficult to measure as few alternative care providers make their prices publically available. That said, in the authors' collective experience many patients have reported spending thousands of dollars on office-based purchases of nutritional therapies alone. We have discussed some devices such as rife machines and photon/laser therapy devices that cost thousands of dollars.

This study does not, nor was it intended to, present a comprehensive catalogue of the unorthodox therapies offered to patients who believe they have Lyme disease. The list of these offerings will certainly change over time. Furthermore, this study cannot measure how popular or appealing these therapies are among such patients. Part of the difficulty in such an assessment is that a diagnosis of "Lyme disease" is not always made using scientifically accepted criteria, and the population of persons who have either been told or suspect they have Lyme disease is quite diverse. Nonetheless, it is clear that patients with this diagnosis are seen as an important market for providers of alternative medicine. Many such patients are without doubt suffering from chronic, often disabling symptoms, regardless of whether their diagnosis of Lyme disease is accurate. Whether calling attention to these unconventional treatments will serve to discourage their use remains to be determined, but their usage has only grown in the past decades despite little evidence of benefit in many disorders [63]. In the meantime, physicians evaluating patients who attribute chronic symptoms to Lyme disease would be wise to provide counseling about the risks and costs of unconventional therapies.

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