



Research of the Obstacles in the Treatment of Chronic Lyme Symptoms and the use of the Herbal Formula - Phoenix Rising to Aid in Chronic Fatigue, Pain and Brain Fog in this Population

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Abstract

Lyme Disease affects 475,000 Americans each year (CDC, 2021). It originated in Lyme, Connecticut, and expanded to other parts of the globe (Hout, 2018). In Europe, it is considered one of the top vector-borne diseases (Wijngaard et al., 2017) and is continuing to spread to countries previously not affected (Stone et al., 2017). Many patients present chronic sequelae such as fatigue, pain, neurological impairment, thyroid, and heart problems (Jamal et al., 2017) which are often life-changing and debilitating. The *Borrelia burgdorferi* is proficient at forming biofilms that have a protective matrix (Sapi et al., 2019). It has been shown that doxycycline, cefuroxime, and amoxicillin are effective in treating the growing spirochete but not in treating the biofilms and microcolonies (Feng et al., 2017). Terms used for symptoms that continue after treatment are Chronic Lyme, which is the belief that these symptoms are from an ongoing presence of the bacteria and Post Lyme Disease Syndrome which is considered a destabilizing mechanism in the body from the initial infection. In seeking a greater understanding an autopsy study found *Borrelia burgdorferi* in the brain, heart, liver, and kidney tissues of someone infected 16 years prior (Sapi, et al., 2019). Since it hides in the tissues it may be causing ongoing symptomatology that is undetected. Most agree that early antibiotic treatment is highly effective but a substantial number of those treated experience life-altering changes that can continue for many years or for life (Bobe et al., 2021). Some say 20% of treated Lyme patients continue with symptoms, others state this number is low (Cameron et al., 2014). There are other herbal Lyme protocols that have helped a small percentage of people after one or two years but many still continue to present with symptoms. Clinical histories indicate that Phoenix Rising, an herbal formula that this author created, has the potential to aid in symptoms of pain, fatigue and brain fog in a shorter time period.



Objectives

To research why chronic symptoms exist in those who have been treated for Lyme

To find herbs that can aid in relieving and removing chronic symptoms of Lyme disease and see how Phoenix Rising can help those experiencing life-changing issues from chronic fatigue, pain, and brain fog.

To analyze the efficacy and duration of use

To continue research o analyze herbs used in Phoenix rising for mechanisms of action via High-Performance Liquid Chromatography

Future - To do a clinical trial

Methodology

Research of peer reviewed studies on why chronic symptoms exist and why they are difficult to treat.

Analyze the properties of the herbs used via peer reviewed research

Analyze case histories of 67 people, who were diagnosed with a past Lyme infection who presented with severe chronic symptoms of pain, fatigue and cognitive dysfunction that lost quality of life and were given Phoenix Rising for an average of 40 days. Progress was noted at intervals of 7 days, 14 days, 24 days, and after completion. A follow-up was done periodically for 1 to 9 years.

Analyze case histories of 7 Dogs who had difficulty getting up and climbing stairs that took Phoenix Rising for an average of 21 days (approved by their Veterinarians). Progress was noted at 7 days, 14 days, 24 days and after completion. A follow-up was noted for 1-4 years.

To get the formula lab tested for safety at a food lab and licensed by the Department of Consumer Protection and filed with the FDA

High-Performance Liquid Chromatography HPLC - to analyze herbs and see if a new chemical was created



Results of Research of Continued Lyme Symptoms, reasons and challenges

Borrelia burgdorferi Bb is a gram-negative bacteria. Early-stage infection remains around the site of the bite and later disseminates through the body and moves to distal collagen-rich tissues where it hides (Marques, 2015). Early symptoms are an erythema migrans around the bite which may be accompanied by cellulitis. Shortly after, a fever may present as well as fatigue and headaches (Vrijmoeth et al., 2019). Fatigue is often severe with the patient feeling that doing normal tasks are a burden. If the patient is not treated the disease often gets progressively worse with severe muscle pain, often around the neck area and joints (Vrijmoeth et al., 2019). Lyme can also affect the nervous system and the brain causing an inability to focus and concentrate. It can eventually spread to various organs and the spinal cord (Vrijmoeth et al., 2019). Medical-related costs of \$712M to 1.3 billion are estimated annually for Lyme Disease and Post Lyme Disease Syndrome PLDS (Bobe et al., 2021).

Treatments

According to information from the Center for Disease Control patients recover completely if treated early with antibiotics for 10-14 days. Disseminated Lyme treatment may include intravenous antibiotics or extended oral treatment (CDC). Twenty percent of these patients experience the following sequela, pain, fatigue, and some brain fog for years to life (Cameron et al., 2014). Terms used for symptoms that continue after treatment are Chronic Lyme (Chronic Lyme Disease | NIH, n.d.), which is the belief that these symptoms are from an ongoing presence of the bacteria and Post Lyme Disease Syndrome -PLDS (CDC) which is considered a destabilized mechanism in the body from the initial infection. Studies of patients who were given extended antibiotics (60 days oral, 30 days to 10 weeks IV) for symptoms of fatigue, pain and cognitive dysfunction showed no benefit (Chronic Lyme Disease | NIH, n.d.).

How the spirochete works

The Bb is a spirochetal bacterium that infects a host via a hard-bodied tick (the vector) that gathers disease from rodents, especially the white-footed mouse and other mammals (Wilson, et al., 1985). Once the tick is infected it moves Bb from the midgut tick to the hemolymph, (Hyde 2017), which is an invertebrate fluid akin to blood, that circulates through the insect (Kanst, M, 2009). If Bb is transmitted to the new human host, it can disseminate through the body to invade distal tissues where it hides in immunoprotective areas of the body. This creates inflammation, avoiding the innate immune response. The spirochete's helical shape is due to the structure of its lipid bilayers and space that contains endoflagella and peptidoglycan. They move through the body in the lymphatic system and through tissue with the aid of the flagellum and this movement creates its virulence and aids it in finding its home deep in the distill tissues of the body where they affect, joints, mitochondria, and vital organs (Hyde, 2017).

Manganese

Bb has unique aspects that allow it to avoid the immune system effectively. It acts differently than most other pathogens in that it utilizes manganese instead of iron. Other pathogens circumvent the iron issue with a high-affinity iron uptake mechanism, so they can get iron from transferrin and lactoferrin. There is nothing in the body that sequesters manganese to keep it from the Bb (Aguirre et al., 2013) which also helps it to thrive.

Biofilms

The challenge continues as Bb creates a protective biofilm around itself that is resistant to antibiotics. Biofilms are a colony of microorganisms that gather on various surfaces. They self-produce and are created by microbial cells that adhere to one another forming an architecture that continues to build. (Jamal et al., 2017). In that, over 20% of Lyme disease cases report life-changing disorders long after antibiotic treatment, (Cameron et al., 2014) the role of biofilms in Bb must be addressed (Sapi et al., 2019). Bio-films adhere to cells, interact within cells, have solid-liquid interconnections and hydrophobic surfaces to which microorganisms likely attach. As the attachment becomes more stable it creates micro-colonies that secrete molecules that signal each other for communication (Mukherjee & Bassler, 2019). Many patients present chronic symptoms such as fatigue, pain, neurological impairment, thyroid and heart problems, for which biofilms could be the root cause. Biofilms often surround bacteria or viruses and can cause disease and infections. Most chronic infections are related to biofilms (Kvich et al., 2020). In vivo studies found a surviving strain of Bb that resists, antibiotic treatment and a persistent Bb after antibiotic treatment (Chronic Lyme Disease | NIH, n.d.). Microbial cells enclosed in a biofilm have a resistance to antibiotics that is 10-1000 times greater than other planktonic cells (Sharma et al., 2019) Bb is proficient at forming biofilms that have a protective matrix (Torres et al., 2020). This could be one reason why Chronic Lyme /PLDS symptoms exist and could explain the lingering illness which causes chronic inflammation in cells, including lymphocytes, macrophages, and plasma cells. A study showed brain tissues specimens from autopsies of those with Chronic Lyme had *Borrelia burgdorferi* that were in the form of biofilms (Gadilla et al., 2021).

Evidence Supporting the Existence of Chronic Lyme

Bb was present in the autopsy tissues of a patient who had Lyme disease and was treated with antibiotics for 16 years due to chronic symptoms. Tissue samples from various places of the body, including the brain, liver, kidney, and heart showed borrelial spirochetal and surface biofilm markers. The study showed chronic inflammation in the cranial nerve blood vessels, fibrous scars in the kidney and heart, perivascular inflammatory infiltrates, and lymphocytic inflammation in the liver. (Sapi et al., 2019). The conclusion was that the biofilm was resistant to antibiotics which may be the possible cause of the chronic inflammation, pain, and fatigue found in many patients with Lyme. (Sapi et al., 2019). These symptoms are often life-changing and debilitating and the infection often spreads to the heart, nervous system, and joints (Cameron, Johnson, & Maloney, 2014). It has been shown that doxycycline, cefuroxime, and amoxicillin are effective in treating the growing spirochete but not in treating the biofilms and microcolonies (Feng et al., 2017). Some antibiotics showed to be more effective, but did not totally break through the biofilms. The antibiotics were given intravenously and had many side effects and often did not work (Feng et al., 2017).

Various studies discovered remnants of Bb, post treatment, in mice, and nonhuman primates but could not culture the bacteria to investigate infection (Chronic Lyme Disease | NIH, n.d.). In 2017, a study with rhesus macaques showed evidence of Bb was reported as persistent and metabolically active (Chronic Lyme Disease | NIH, n.d.). More studies of Drug-resistant persisters are ongoing (Chronic Lyme Disease | NIH, n.d.). The herbs in Phoenix Rising have shown in research to break biofilms, have anti-biotic, anti-fungal, anti-microbial and anti-inflammatory properties.

Clinical Histories Results

Participant 1 was a young woman who felt she was no longer functioning. Fatigue, brain fog, and pain were severe as well as depression. She could not walk without feeling extreme fatigue and felt there was no hope. After a month on Phoenix Rising, she said she was walking and felt the sunshine on her face. After two months she said she was living her life again. **Participant 2** - Was a dog who was completely paralyzed with Lyme and the vet said it was the worst case she had ever seen, and Doxycycline must be taken for 60 days. She agreed to 2 days to try the herbs but if she did not see significant improvement the antibiotic should commence. Two days later the dog WALKED into the vet's office, not well, but walked. Three weeks later the dog was completely fine. One year later symptoms arose again that were less serious. A 21 day treatment was immediately administered and the dog was fine again for a year, the second year symptoms appeared and after the 21 day dose, the dog was healthy and had no symptoms ever again. **Participant Group 3** - (23 participants) Severe symptoms that included loss of cognitive function, joint, neck, back pain, and fatigue. All of these participants had one or multiple rounds of Doxycycline and some had taken intravenous antibiotics and other herbal protocols. After 42 days of taking Phoenix Rising all were better and felt all symptoms were gone. Three of these participants had slight fatigue, brain fog, and pain one year later, although felt fine for the rest of the year. A 21-day round was given, and they were fine for another year, then the symptoms came up even less severe one year later and another 21-day round was given, and they were fine. **Participant Group 4** - (42 participants) These participants had joint pain, brain fog, and fatigue which affected their life, but they were functioning. All stated that symptoms were gone after 42 days on the remedy, with no recurring symptoms. One of these participants did not take any antibiotics or herbs prior and felt all symptoms were gone in the 42 days. One participant retested following the remedy and then had a negative test result. **Participant Group 5** - 1 person, also had Hashimoto's, possibly Babesia and other co-infections and felt some changes that they described as a Herx reaction but stated it was hard to tell with all the other issues they were dealing with. **Participants Group 6** - 6 dogs that had pain and lethargy that included trouble walking, getting up, and functioning. Four fully recovered after 42 days of treatment and one was fine for a year then had difficulty getting up and did another 21-day dose and was fine.

Herbal research - mechanisms of action

Research showed that the herbs in Phoenix Rising have the following properties, anti-inflammatory, antibiotic, anti-microbial, anti-fungal and anti-viral. They inhibit 5-lipoxygenase and leukotriene synthesis, properties that modify disease, decrease cell-mediated immunity, break through biofilms, inhibit microbial enzymes, act against Gram-positive bacteria, inhibit GrsZ GTPase activity, are able to activate Nrf2 to clear toxins and misfolded proteins, have anti-cancer effects, are liver protective, and aided in killing *Staphylococcus aureus*.

Lab analysis at Alliant Food Lab showed Phoenix Rising to be safe for Human Consumption. The Process to make the remedy was analyzed at the Lab and overseen by an inspector from the Department of Consumer Protection, approved and licensed. FDA necessary paperwork was filed

HPLC - high-performance liquid chromatography is an analytical technique used give information on pharmaceuticals and herbs to show what compounds are in a sample. It does this through a machine that passes the substance or mixture through a stationary phase so the various constituents, which have different timing traveling through the solvent. The mobile phase is where components are introduced and move at the same rate of travel. Upon completion, a readout of the constituents is created (McPolin, O., 2009).

Goal -Clinical Trial

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