LYMESTOP TREATMENT EFFICACY FOR CHRONIC LYME DISEASE

This text is used with permission and has been taken from a manuscript style project submitted in partial fulfillment of the requirements for the degree of Master of Science in Applied Statistics in May, 2021.

By Bradley Rechtzigel and Dr. David M. Reineke

INTRODUCTION

There are fourteen vector-borne illnesses that are of national public health concern in the United States, with Lyme disease being the most common (CDC, 2019). A vector-borne illness is passed by vectors such as ticks and mosquitos. The vectors can hold infectious agents like bacteria and viruses that can be transmitted from one another (Beard, 2016). The focus of this study will be on Lyme disease, which according to the CDC, is a bacterial infection caused by Borrelia, that humans generally contract from deer ticks or black legged ticks (CDC, 2019). According to the CDC, an early diagnosis and proper use of antibiotics can help prevent Lyme from worsening (CDC, 2020). However, when Lyme is left untreated in the early stages, a person can develop a plethora of symptoms that can be difficult to treat ("Chronic Lyme", 2020). This is where an alternative treatment to antibiotics known as LymeStop can be implemented. According to Dr. Tony Smith, the developer of LymeStop, this technique can be effective at treating Lyme at all stages, however many patients try antibiotic treatments before trying LymeStop.

LITERATURE REVIEW

In the United States, the amount of Lyme cases each year are estimated to be over 300,000, however, the number of chronic cases in unknown (Ilads, n.d.). Lyme can be classified generally in three stages; early localized disease, early disseminated Lyme, and late disseminated Lyme (GLA, 2019). The first stage begins within a few hours or days following an insect bite and is the easiest to cure because the infection has not spread throughout the body. The symptoms are generally mild flu-like symptoms and may also include a "bull's eye" rash (GLA, 2019). Stage two may arise either several weeks or even months after the initial bite. This is when bacteria have begun to spread throughout the body and the symptoms become more serious (GLA, 2019). Lastly, stage three is when a patient may be classified as having late disseminated Lyme or chronic Lyme disease (CLD) and the symptoms become severe enough to debilitate many patients (GLA, 2019). Thus, someone with Lyme disease can show less serious measurable symptoms, such as a fever and swollen lymph nodes, or more severe symptoms such as inflammation of the brain or an irregular heartbeat depending on the stage (CDC, 2020). When drugs such as Amoxicillin, Cefuroxime axetil, and Doxycycline are unsuccessful in treating the disease, the more severe symptoms may develop (CDC, 2020). Even when patients have been treated early for Lyme, more than 10% remain sick after the antibiotic treatment (Ilads, n.d.). In addition, because the plethora of symptoms associated with Lyme, it can be misdiagnosed or left untreated, which can lead to a patient developing chronic Lyme disease ("Chronic Lyme Disease can", 2020). Misdiagnosis happens because the symptoms linked with Lyme are similar to chronic fatigue syndrome, fibromyalgia, and other multi-system illnesses (Ilads, n.d.). Many patients with CLD are

debilitated, and therefore in a state where drugs are not effective. In this study, the treatment to cure CLD is an alternative to antibiotics known as LymeStop (Smith, 2020). This technique was first developed in 2010 by Dr. Tony Smith. Before understanding LymeStop, one must first discuss the CranioBiotic Technique (CBT) which was developed in 2002 by Dr. Smith (Health, n.d.).

When infected with CLD, a patient's brain struggles to identify and correct the resulting problems within the body (Health n.d.). "CBT uses gentle and effective Muscle Response Testing (MRT) to obtain feedback from your body concerning the presence of any hidden 'health stressors' that may be causing your problem(s)" (Health n.d.). The pressure points associated with MRT were discovered to be therapeutic rather than strictly diagnostic, thus allowing for the body's own immune system to fight off the microbes instead of using antibiotics (Scott, 2018). When a stressor such as an allergy or infectious organisms have been revealed, the doctor will help to stimulate specific neurovascular "reflex points" on both the cranium and upper body to pass the information to the brain. This allows the brain to acknowledge the stressor and the body's own immune system can start correcting itself (Health, n.d.). This technique has been modified to help cure CLD in a treatment known as LymeStop.

Dr. Smith found there were many points on the body that were Lyme-specific (Smith, n.a.). "He found that each of these sensitive points was uniquely relevant for each form of Borrelia, and for most Lyme co-infections" (Smith, n.a.). It is important to note that there are many different infections, not just Borrelia, that all need to be treated during the technique. The main differences between CBT and LymeStop are that CBT was developed first and does not have the Lyme specific infection points. In addition,

both techniques can involve magnets, although in LymeStop, the magnetic stimulation would be done on what Dr. Smith classifies as Lyme specific points called BioMagnetic Lyme Points (Smith, n.a.). Even though this technique was first put into place in 2010, and it is anecdotally seen to be effective in practice, this is the first statistical study of its efficacy (Smith, n.a).

METHODS

Subjects/Procedures

The purpose of this study was to determine the effectiveness of LymeStop in treating chronic Lyme disease. Participation involved five initial LymeStop treatments within a week, and then a follow up in three to four months following the standard LymeStop protocols. However, many patients can take longer than this three-to-four-month period to heal. This study began on August 1st, 2020 and ended April 1st, 2021. The data was collected using all the patients from both Dr. Ben Erlandson and Dr. Tony Smith during this listed time interval. Dr. Erlandson is based out of Wisconsin at Erlandson Family Chiropractic and Dr. Smith is based out of Idaho at Dynamic Health. Dr. Smith and Dr. Erlandson are currently the only two practitioners to use LymeStop in the world. The study contained 146 patients with 46 males and 100 females ranging in age from 3 to 77 years old. There was no control group in this study because of limited time and patients. In addition, this treatment had already been used on over 5,000 patients and anecdotally demonstrated to be safe and effective by both doctors, thus avoiding what could be deemed as an unethical use of the placebo. Lastly, no informed consent was needed because the data was de-identified (*i.e.* removing the patient's names).

Variables

The variable at the forefront was called Percent Better which was a self-reported number for how the patient felt post treatment. Post-treatment reporting came three to four months after the initial week with five treatments given within five days. Other variables of focus were the total number of symptoms out of the total 77 listed on the patient form (pre and post), and total number of infections detected using BioMagnetic

Lyme Points out of 43 listed on the treatment form (pre and post). From the total number of symptoms, the number of severe or constant symptoms was also recorded. Each symptom had both a level of severity and a frequency level. The severity levels were mild, moderate, and severe and the frequency levels were occasional, often, and constant. Thus, a symptom that was in moderate or severe condition or was in often or constant frequency was recorded as constant/severe. In other words, a symptom was not recorded as constant/severe if the symptom was both mild in severity and occasional in frequency. The infections that were tracked individually were Borrelia, Babesia, Bartonella, Lyme Virus, Epstein-Barr virus, protomyxzoa, and mold. Those were coded as binary (0 or 1) where 1 was the patient having the infection and 0 was the patient not having infection. In addition, the number of infections within certain body areas were also tracked. The specific locations that were grouped into different areas throughout the body can be seen in Table 1.

Table 1. The specific locations that were grouped together for different areas within the body.

Area of Body	**Specific Locations**
Neurologic	Brain, Pituitary, Hypothalamus, Cerebral Spinal Fluid
Joint/ Muscle	Joint and Muscle
Respiratory	Sinus/Eustachian/Ears, Throat, Bronchi, Lungs
GI Infections	Small Int., Large Int., Descending Colon
Heart	Heart
Body	Blood, Spleen, Lymph, Liver, Bladder, Pancreas
Teeth	Tooth Canals

RESULTS

The median Percent Better was 57.5 with the population median for all Lyme patients estimated to be between 52.5 and 62.5 percent better at the three to four-month follow-up visit with 95% confidence. To better understand where the patients would be classified with respect to improvement, they were grouped into 25% increments and grouped into 5 groups as shown in Table 2 below.

Table 2. Example categorical grouping of Percent Better.

Percent Better	Improvement
0	None
1-24.99%	Mild
25.-49.99%	Moderate
50-74.99%	Good
75 % and up	Great

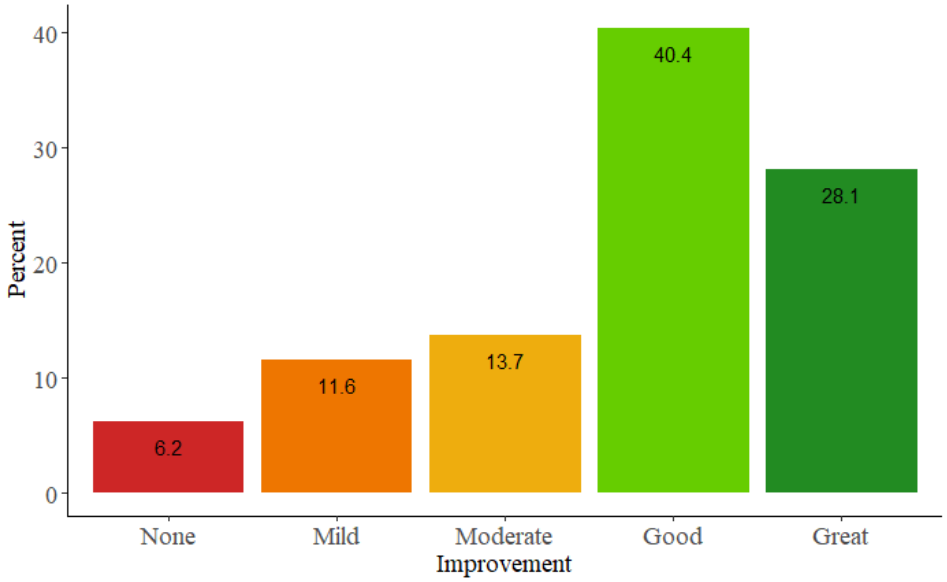

Figure 1. Grouping the response variable Percent Better based on Dr. Erlandson's way of grouping.

As shown in Figure 1, the percentage of patients that saw a good or great improvement in just three months is 68.5%. According Dr. Erlandson, most people who are 50% or better at three months, will most likely be full healthy at 12 to 18 months based on previous experience. Thus, patients in the groups who had no or mild improvement are part of the "gray area" and it is hard to say how much better they will be within a certain time period. An important thing to note is many of the patients in the no or mild improvement groups had CIRS (Chronic Inflammatory Response Syndrome). CIRS also known as mold illness, generally occurs after significant exposure to a water-damaged building (Mitchell, 2021). Unfortunately, CIRS was on the treatment form but was not tracked in this data set, otherwise the percent effect of CIRS on Percent Better would have been included in the study. This could be a possible explanation for why they did not feel any better even though their Lyme infections were no longer present. According to Dr. Erlandson, mold illness and Lyme disease cause very similar clinical symptoms. Therefore, if a patient has both Lyme and mold illness both typically have to be successfully resolved for full symptomatic improvement.

Table 3. Summary of the total number of symptoms, total number of severe or constant symptoms and total number of infections.

Variable	Time	Min	Q1	Median	Q3	Max	95% CI for the Difference Pre - Post
Total Symptoms	Pre	0.0	19.0	34.5	47.5	75.0	(8.0 , 11.5)
	Post	0.0	9.3	20.0	33.0	75.0	
Total Severe or Constant	Pre	0.0	10.0	21.0	34.0	69.0	(7.0 , 10.5)
	Post	0.0	5.0	10.0	20.8	66.0	
Total Infections	Pre	12.0	16.0	19.0	23.0	29.0	(17.0 , 18.5)
	Post	0.0	1.0	2.0	2.0	5.0	

From Table 3 the 95% confidence interval for the difference was significantly greater than 0 for all three of the response variables given there. This means there were

statistically significantly fewer symptoms and infections for all patients who receive the LymeStop treatment. One important distinction is that even though the total number of symptoms are clearly less after LymeStop treatment, they are still showing up with a median of 20 as compared to the prior median of 34.5.

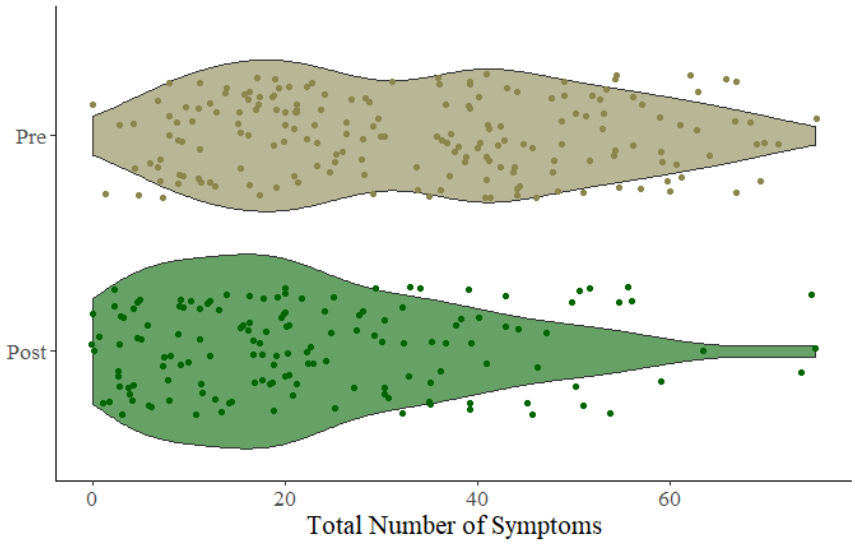

Figure 2. Violin plot with jittered points of the difference in the total number of symptoms before and after LymeStop.

However, there was a much larger decrease in the number of infections with a median of 19 before the treatment to only 2 after the treatment. As stated by Dr. Erlandson, this is attributed to the fact that the body's first step in healing is to eliminate the infections within the first few months. As a result of this, the body then has to heal from all of the chronic stress on the system and rebuild its nutrient status. Thus, because the follow ups for LymeStop are only three to four months after the initial treatment, the full impact of LymeStop on the symptoms cannot be seen. According to Dr Erlandson, the length of time to heal is related to how long the patient has been sick. The longer they have had symptoms, the longer they generally take to recover. To better visualize the

distinction between the symptoms and infections, refer to Figure 2 above and Figure 3 below.

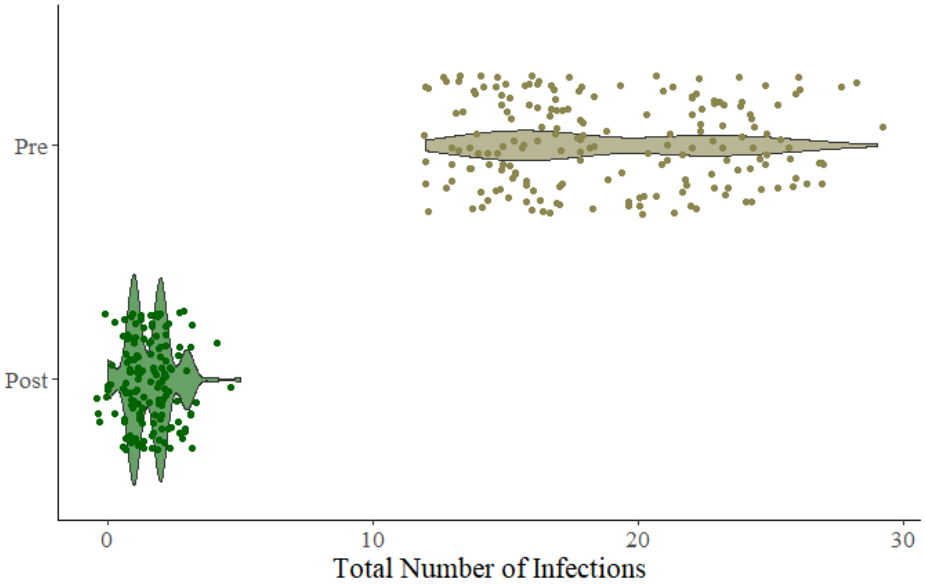

Figure 3. Violin plot with jittered points of the difference in the total number of infections before and after LymeStop.

Limitations and Recommendations

The first limitation was not having a control group which removes this study's ability to compare the efficacy of LymeStop to that of a placebo. It would have been good to have compared LymeStop to an inert treatment. Another limitation was that our main response variable, which was the Percent Better the patient felt, was a subjective, self-reported measure of the patient's recovery at that moment. In addition to this, the reality of this treatment is to have patients fully healthy 12 to 18 months after the initial treatment, but the doctors typically only do follow-ups after three to four months. The doctors choose to reevaluate after three to four months because they want to be able to

retreat any infections still present in the follow-up. If the patient responds well, they will usually eliminate infections within a few months of initial treatment.

Although additional follow-ups are done for patients who need further treatment to eliminate any remaining infections, they usually do not have contact with the patients after dismissed from the follow-up if they are clear of infections. After the infections are eliminated from the body there is no need for additional follow-ups because the remaining healing is not dependent on treatments, but rather on time, diet, stress management, supplementation, etc. Consequently, knowing exactly how much a patient will heal is hard to judge. As mentioned earlier, according to Dr Erlandson, the length of time to heal is related to how long the patient has been sick. The longer they have had symptoms, the longer they generally take to recover. Tracking roughly how long someone has had symptoms could be an important variable added to future studies.

Another limitation is that a patient's symptoms could be from other ailments. For example, an older patient having blurry vision may be due to age and not an infection but they would still check the box for that symptom. Lastly, one variable that was part of the treatment sheet but was not tracked for this study but should be included in future studies was the CIRS infection. It seemed to be common in follow-ups and could be an important explanatory variable when looking at Percent Better.

CONCLUSION

Based on the nonparametric 95% confidence intervals for the quantitative variables, patients after LymeStop treatment saw significant decreases in their total number of symptoms, severe or constant symptoms, and especially infections. In

addition, patients also saw significant decreases in the total number of infections at all the different locations measured throughout the body. Similarly, there were also significant decreases in the presence of specific infections. While all seven specific infections had significant decreases, 52.7% of patients had to be retreated for the Borrelia infection at the first follow up in some capacity. Even though an infection needs to be retreated, the severity may not be nearly as high as the initial visit. Lastly, the Percent Better a patient felt just three to four months after the treatment was significantly above 50 with a median between 52.5 and 62.5 with 95% confidence.

REFERENCES

Beard, C.B., R.J. Eisen, C.M. Barker, J.F. Garofalo, M. Hahn, M. Hayden, A.J. Monaghan, N.H. Ogden, and P.J. Schramm, 2016: Ch. 5: Vectorborne Diseases. The Impacts of Climate Change on Human Health in the United States: A Scientific Assessment. U.S. Global Change Research Program, Washington, DC, 129-156.http://dx.doi.org/10.7930/J0765C7V

CDC. (2020, September 29). Lyme Disease. Retrieved October 30, 2020, from https://medlineplus.gov/lymedisease.html

CDC. (2020, October 26). Treatment for Lyme. Retrieved from https://www.cdc.gov/lyme/treatment/index.html

CDC. (2019, December 16). Lyme Disease. Retrieved October 30, 2020, from https://www.cdc.gov/lyme/index.html

Chronic Lyme Disease can make patients profoundly debilitated. (2020). Retrieved from https://www.lymedisease.org/lyme-basics/lyme-disease/chronic-lyme-disease/

GLA. (2019). Stages of Lyme Disease. Retrieved from https://globallymealliance.org/about- lyme/diagnosis/stages/

Health, D. (n.d.). How Does CBT Work? Retrieved October 30, 2020, from https://craniobiotic.com/about-cbt-details/

Ilads. (2020, February 18). Lyme Disease Basics for Providers. Retrieved from https://www.ilads.org/research-literature/lyme-disease-basics-for-providers/

Lyme Disease Data Tables: Historical Data. (2019, November 22). Retrieved from https://www.cdc.gov/lyme/stats/tables.html

Mitchell, D. (2021, February 19). CIRS - Toxic Mold Illness Treatment: Dr. Dean Mitchell. Retrieved from https://www.mitchellmedicalgroup.com/services/cirs-toxic-mold-illness/

Smith, T., Dr. (n.d.). About LymeStop and Dr. Tony Smith. Retrieved October 30, 2020, from http://lymestop.com/about/

Scott, [BetterHealthGuy]. (March 17,2018). Episode #64: LymeStop with Dr. Tony Smith, DC. Retrieved from https://www.youtube.com/watch?v=ik7Y7mQq-ck

PACKAGES/SOFTWARE

A. Liaw and M. Wiener (2002). Classification and Regression by randomForest. R News 2(3), 18--22.

Burnham KP, Anderson DR (2002) Model selection and multimodel inference, 2nd edn. Springer, New York.

H. Wickham. ggplot2: Elegant Graphics for Data Analysis. Springer-Verlag New York, 2016.

R Core Team (2021). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/.

R. Pruim, D. T. Kaplan and N. J. Horton. The mosaic Package: Helping Students to 'Think with Data' Using R (2017). The R Journal, 9(1):77-102.

Stefan Fritsch, Frauke Guenther and Marvin N. Wright (2019). neuralnet: Training of Neural Networks. R package version 1.44.2. https://CRAN.Rproject.org/package=neuralnet

Vincent Calcagno (2020). glmulti: Model Selection and Multimodel Inference Made Easy. R package version 1.0.8. https://CRAN.R-project.org/package=glmulti