The Efficacy of Traditional Chinese Medicine on Preventing Lupus Conversion and Secondary Lupus Inflammatory Symptoms.

By

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The Efficacy of TCM on Reducing Lupus and Lupus Secondary Symptoms

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Abstract

Systemic Lupus Erythematos (SLE) is an autoimmune disorder much similar to other inflammatory illnesses such as Rheumatoid Arthritis with secondary disorders like Sjörgen’s syndrome, Reynaud’s Phenomenon, skin inflammation and kidney failure. Most of the people affected by SLE are African American, Native American, and Hispanic women as well as a third of all patients having a history of antibiotic therapy to prevent secondary infections from Epstein Barr Virus (EBV). A third to half of the patients with SLE have increased inflammatory disorders thought to be related to antibiotic therapy, which damages anti-inflammatory cytokines in the intestinal tract. This research synthesis will help provide a more direct insight in TCM diagnostics and integrative treatment for patients with SLE and EBV with the use of Acupuncture, Herbal Formulas, and Nutritional Supplements.
Acknowledgements

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Chapter One: Introduction

Systemic Lupus Erythematosus (SLE) has been critically reviewed by epigeneticists from the United Kingdom for a span of 40 years and have noted that Epstein Barr Virus (EBV) has a relationship with SLE and is a potential causative for SLE when a patient's CD4 and CD8 cells are not working properly (Hanlon, 2014). This discovery has helped with identifying a common exposure to a viral disease that has been linked to the precursor of developing abnormal CD4 T-Lymphocytes and diminishing CD8 cell function which triggers oxidative stress related inflammation in patients with SLE (John B. Harley, 2006). Females now make up ninety percent of the patients diagnosed with SLE which presents with symptoms that may include fever, polyarthritis, and maculopapular rashes on sun exposed areas of skin, aphthous ulcers, alopecia, and generalized inflammation of the connective tissue (Bob Flaws, 2011). According to the Merck Manual online, a patient must present with four out of eight common symptoms to obtain a diagnosis of SLE, the symptoms are as follows: ANA (Anti-Nuclear Assay) antibodies in the blood, low white blood cell (WBC) or platelet count, joint pain in a number of joints, butterfly rash on the cheeks, abnormal cells in the urine, photosensitivity, aphthous sores or lesions, seizures or psychosis (Merck Manual Professional Edition, Lupus).

The Lupus Foundation of America (LFA) has noted on their website that the average patient has a cost of $20,924 due to partially covered medication, co-pay, and secondary illnesses causing loss of work due to medication side effects or other exogenous factors (Lupus, 2014). The LFA also mentions that there is a projection of increasing lupus rates in America notably due to better testing methods versus an actual
increase in lupus mortality or deaths (Lupus, 2014). This could mean that more patients will have more inflammatory related illnesses as well as side effects from medications that could increase costs both for the healthcare system and patient finances. This determination is primarily due to the rise in positive diagnosis in patients who have had symptoms but no actual prior diagnosis and the rise in patient related illnesses due to medication side effects. Research done independently by the LFA has found that 61% of 1000 people surveyed, had little to no knowledge of lupus which could lead to the speculation that even more people in the general population are lacking knowledge in integrative care for lupus (America, 2013).

In 2013 the Hong Kong Baptist University School of Chinese Medicine had run experiments on using Chinese herbs to help reduce the side effects of SLE in comparison to hydrocortisone, a common medication, and found that Chinese medicine was very capable in reducing oxidative inflammation, which is an abundance of IL-1, IL-6, IL-8 (Linda L. D. Zhong, 2013). Though there are many Chinese medical diagnoses that could be represented with SLE, this study focused on Qi and Yin deficiency and the use of Qi and Yin deficiency herbs, which were found to have a higher success rate in reducing oxidative inflammation than hydrocortisone in a Single Blind study (Linda L. D. Zhong, 2013).

**Identifying the conversion of EBV to SLE:**

Various research articles in Germany and Britain have concluded that 33% of patients expressing a diagnosis of EBV early in their life and having undergone antibiotic therapy have shown strong environmental risk factors for SLE (Hanlon, 2014). What was found during numerous trials was that anti-EBNA-1 (an antibody that SLE patients have
a natural inflammatory reaction to) caused the autoantibodies in SLE to rise causing an anti-ribosomal P, and anti double stranded DNA conversion leading to rheumatologic conditions (Hanlon, 2014). Out of 130 SLE patients a serum sample used to help diagnose SLE was found to have patients with lupus specific autoantibodies in youth without inflammation and in adult life had immunologically normal lifestyles (Hanlon, 2014). This study also helped conclude that environmental factors and random events, which include poor nutrition and medication overload (John B. Harley, 2006), could exacerbate SLE conversion (Hanlon, 2014). This is related to the studies done on the reservations of New Mexico and Arizona of the Navajo women who have an immunologic conversion of intestinal pathology with elevated antibiotic use, environmental toxins and DNA strands with anti-EBNA-1 antibodies (Allee, 2013).

The autoantibodies of a patient with poor intestinal flora, found in Spleen qi deficient patients (Nigel Wiseman, 1996), having been on an antibiotic regimen therapy for 3-6 months for EBV exposure have had a higher sero-conversion to SLE (Allee, 2013). These antibiotic therapy treatments have also brought attention to researchers evaluating the increase of globules in anti-inflammatory cytokines in patients with SLE and neurological dysfunction (Li YN, 2001). The relationship of the gut bacteria and the neuropeptides are linked to an increase in autoantibodies in both SLE patients and those with an elevated anti-EBNA-1 antibody level (Li YN, 2001). This can be identified as “Gu” syndrome in TCM as it links intestinal deficiencies found in Li, Dong Yuan’s Treatise of the Spleen and various other sources that the disease factors in the intestinal health of a patient (Fruehauf, 2015).
**Required diagnostics and specificity of SLE and EBV:**

Although SLE is predominantly found in young women of African American descent, as well as Native American, and Hispanic people, it has been concluded that patients who are Asian or Caucasian are also susceptible to SLE though in lower numbers (The Merck Manual, 2011). The appropriate laboratory tests for Epstein Barr Virus are Viral Capsid Antigen (VCA), Early Antigen (EA), and EBV Nuclear Antigen (EBNA). For patients expressing the most recent of symptoms that may cause suspicion of EBV it is important to do a Viral Capsid Antigen (VCA) lab test within the first 6 weeks of the illness. This helps with the appropriate diagnostics and potentially the best way to prevent suspected SLE according to British studies (Hanlon, 2014). Early Antigen (EA) lab tests to determine the acute phase of the illness; these results dissipate their antibody levels from 3 to 6 months and often being a false negative in 20% of people due to preexisting antibodies, this test is usually done after the VCA (The Merck Manual, 2011). For later stages of suspected EBV anywhere between 2 to 4 months after exposure or illness it is appropriate to do the EBV Nuclear Antigen (EBNA) lab test, though the lab tests are prone to false positives (The Merck Manual, 2011).

**Understanding the Inflammation between EBV and SLE:**

Systemic Lupus Erythematosus and Epstein Barr Virus both have an effect on cytokines that are responsible for the inflammatory process affecting thymus cells (T-cells). The IL-4 and IL-10 cytokines are required for an anti-inflammatory effect in a healthy body however; in a person with EBV or SLE the IL-4 and IL-10 cytokines are compromised causing a reduction in neurotransmission (Anslem Mak, 2014). This clustering creates a globule of lipid rafts which reduce potentiation of neurotransmitters
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that will therefore impair cAMP which compromises protein kinase and protein tyrosine kinase leading to further activate the inflammatory process in SLE (Anslem Mak, 2014).

In the early stages of a patient with EBV there is often upper respiratory infection combined with a potential sensation of gastroenteritis which in turn begins the manipulation of IL-4 and IL-10 causing inflammation (Hanlon, 2014). In TCM we relate this to Gu syndrome, which has been related to “Chronic Inflammatory Disease” (Fruehauf, 2015). By identifying an illness as Gu syndrome in cases of Chronic Inflammatory Disease such as EBV or SLE, we allow diagnostics to not be rooted to one mechanism as written in classical texts relating this illness solely as Spleen Qi Deficiency. By adapting the root of these illnesses from classical texts and modern research we are able to adapt treatment plans more effectively, where in many cases the classical text “The Treatise on the Spleen and Stomach” provides more effective treatment plans (Dong-Yuan, 2011). This is not to state that “The Treatise of the Spleen and Stomach” is the final word in treatment however; it is more of a reference to one type of inflammatory disease that is related to this research synthesis.

Research Objectives:

The objective of this research synthesis is to provide a more direct science based diagnostic and treatment protocol for Traditional Chinese Medicine (TCM) practitioners as well as Western Medical physicians treating patients with mild to moderate SLE. Much of this research synthesis is based on the use of Chinese herbs however; there will be some use of acupuncture, which would be beneficial in patients who are not histamine sensitive when needles are inserted. This precaution can help practitioners understand that some use of acupuncture may be more contraindicated than the use of Chinese
Herbs. Another portion of this research synthesis is to understand which Chinese herbs prove to be more effective in stimulating CD8 cells and reducing CD4 cell counter activity in patients suffering from oxidative stress due to SLE. Currently this information not available in any current written text material and is one of the reasons for poor patient results with TCM when treating SLE. A more direct herbal prescription is also provided with patient evaluations that show true effectiveness and an indication when acupuncture can be most effective when treating SLE.
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Glossary of Relevant Terms

Abbreviations:

ACU: Acupuncture
CHM: Chinese Herbal Medicine
RCTs: Randomized Controlled Trial
TCM: Traditional Chinese Medicine
SLE: Systemic Lupus Erythematosus
LPS: Lupus (From Evergreen Herbs LPS Support)
HSV: Herpes Simplex Virus

RA: Rheumatoid Arthritis
BUN: Blood Urea Nitrogen
WBC: White Blood Cells
T-Cell: Thymus Cells
IL: Interleuken
NK = Natural Killer Cells
Definitions:

- **Acupuncture**: Traditional Acupuncture involves stimulation with very fine needles inserted into defined sites on the body to achieve balance (Mayo Clinic, 2015).

- **Thymus Cells (T-Cells)**: Responsible for all autoimmune diseases as well as cells in the body that directly kill viruses, bacteria and other invading pathogens by ingesting the invader and eradicating them (University, 2009).

- **CD8**: A T-cell activation that is both heterodimer and homodimer which the homodimer is the most recognized and when in abundance it can increase the sensitivity to antigens often causing autoimmune reactions (University, 2009).

- **Cytokines**: Small secreted proteins released by cells which interact and communicate between cells, they are both inflammatory and anti-inflammatory (Jun-Ming Zhang, 2007).

- **Interleuken receptor antagonists (IL-4, IL-10)**: Very potent anti-inflammatory cytokines which inflammatory responses and are found to be low in persons with inflammatory disorders, autoimmune diseases and chronic pain (Jun-Ming Zhang, 2007).

- **Spleen Qi Deficiency**: Withered yellow complexion, exhaustion of essence-spirit, fatigued limbs, reduced appetite, pronounced distention of the abdomen, indigestion (Nigel Wiseman, 1996).

- **Heart Fire**: Red tipped tongue, vexation, rapid pulse, non-interaction of heart and kidney, red eyes, headache, agitation, irascibility, dribbling urination and stinging urinary pain (Nigel Wiseman, 1996).
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- **Kidney Yin deficiency**: Leads to vacuity of the heart, with dryness of the throat and mouth, low grade fever, aching lumbus, spontaneous sweating (Nigel Wiseman, 1996).

- **Liver Yin deficiency**: Loss of visual acuity, headache, and irregular menses (Nigel Wiseman, 1996).

- **Heart and Kidney Yin deficiency**: Poor memory, insomnia, palpitations, steaming bone or tidal fever (Nigel Wiseman, 1996).

- **Cold Impediment (bi)**: Joint pain or muscle pain of fixed location or hypertonicity (Nigel Wiseman, 1996).

- **Vacuity Heat**: Tidal fever or reddening of the cheeks, dry mouth, dry pharynx, steaming bone syndrome, night sweats, forceless, pulse, red tongue with scanty coat (Nigel Wiseman, 1996).

- **Antigen**: A bacterium, virus, fungus or other foreign substance that causes an immune response to the body’s immune system (CDC, 2012).

- **Antibody**: Large Y-shaped proteins that are used to neutralize and identify foreign objects such as bacteria and viruses (Dr. Ananya Mandel, 2014).

- **Cyclic adenosine monophosphate (cAMP)**: cAMP is responsible for neurotransmitter synaptic transmission for ion channels that do not involve ligand-gated channels as well as all neurotransmissions of both short and long term transmissions (Nestler, 1999).

Chapter Two: Literature Review
Overview:

This chapter will review and analyze studies regarding Systemic Lupus Erythematous (SLE), Epstein Barr Virus (HSV-4) with small intestine permeation and the effectiveness of TCM in reducing the secondary symptoms of SLE. This will include symptoms of inflammation, digestive disorders, chronic pain, cardiac dysfunction, renal dysfunction and epithelial dysfunction. Some of this research will be compared to classic literature in TCM regarding internal illnesses affecting the Spleen.

Systemic Lupus Erythematous Synopsis:

Systemic Lupus Erythematous is an inflammatory disorder that primarily affects young women with manifestations of arthralgia, arthritis, malar skin rashes, pleurisy or pericarditis and/or renal involvement or central nervous system involvement (The Merck Manual, 2011). Other cases of SLE may be due to environmental factors, medications and in the case of this research synthesis the Epstein Barr Virus (HSV-4) (The Merck Manual, 2011). Additional factors that may be responsible for the SLE association is cross reactivity of microbial antigens which prevent the intestinal lining from being caused by antigens setting off antibodies that cross infect the intestinal bacterial lipopolysaccharides (Engleberg, DiRita, & Dermody, 2013). When mice bred with weak lymphatic and splenic systems were colonized with bacteriodes fragilis polysaccharides the mice became healthy whereas mice with weak bacterioside fragilis would have weaker immune system development and more cytokine responses (Engleberg, DiRita, & Dermody, 2013).

dEpstein Barr Virus (HSV-4)
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Also known as Infectious mononucleosis, this virus attacks B-cells and may cause fatigue, fever, pharyngitis and lymphadenopathy (The Merck Manual, 2011). This virus has some neurologic complications including meningitis symptoms, cranial nerve palsies, hematologic complications which effect the blood by making it thicker or creating hemolytic anemia, splenic rupture, respiratory complications and hepatic complications (The Merck Manual, 2011). This virus has a similar ideation relating it to SLE due to its relationship to cytomegalovirus (CMV) and Immunoglobulin G (IgG). The relationship, according to British journals has been linked to 33% of the cases in women affected with SLE (Hanlon, 2014).

Identifying and Treating EBV and SLE with Western Medicine

Systemic Lupus Erythematosus is primarily treated with corticosteroids such as prednisone or hydroxychloroquine, which helps with inflammation as well as Aspirin or a repository corticotropin injection that mimics the hormone ACTH (adrenocorticotropin) (America, 2013). Additional medications that are used for patients with SLE are diuretics for fluid retention, antihypertensive and anticonvulsant medications as well as medications to strengthen the bones and prevent osteoporosis (America, 2013). Antibiotics are used to help treat infections however; long-term use of antibiotics has shown to increase the inflammatory state of SLE or arthritic pain in patients with low IL-4 and IL-10 (Jun-Ming Zhang, 2007). Antibiotics have also been found to alter gut bacteria, which can mitigate SLE symptoms (H. Zhang, 2014).

Long-term use of antibiotics in patients with inflammatory disorders has also been linked to neurological inflammation causing patients to have symptoms of delirium, loss of memory, and chronic pain (H. Zhang, 2014). Additional negative effects of long-term
antibiotic use on the gut bacteria reduce the cytokines and neuropeptides that can hinder the efficacy of acupuncture (Li YN, 2001). Additionally, long-term antibiotic use, which is often found in patients suffering from SLE, have been found to be Iron deficient (The Merck Manual, 2011). This can cause a patient to have symptoms of “brain fog” fatigue, poor immune system and lower IL-4 and IL-10 with an increase in the inflammatory cytokines often enhancing secondary symptoms of SLE (Jun-Ming Zhang, 2007).

Epstein Barr Virus is often contained in the body and self regulated in a patient with a healthy immune system (The Merck Manual, 2011). This virus is permanent in the body and may be reactivated when the patients’ immune system becomes compromised (The Merck Manual, 2011). Patients are often given antibiotics such as acyclovir or amoxicillin to prevent secondary infections though this does not prove to be entirely effective and usually results in the patient further decreasing their white blood cells count (Hanlon, 2014). This does lead one to connect the intestinal bacteria to the initial inflammatory processes as cytokines and natural killer cells increase to assist in protecting the intestinal wall (Hanlon, 2014).

Many patients indicate that they suffer from chronic fatigue and/or a sensation of being sick for months after the initial infection, often prompting physicians to provide antibiotics as a treatment even if it is ineffective (Hanlon, 2014). Once a patient has been infected with EBV and their immune system becomes compromised, the patient is usually treated with antivirals such as acyclovir or ganclovir, which can further reduce white blood cells leading to secondary inflammation in other areas of the body (The Merck Manual, 2011).
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Although it appears easy and basic to treat these two illnesses, the overall effects of a long-term virus can exacerbate a chronic illness such as SLE often enhancing their signs and symptoms. Though the secondary illnesses of SLE are often treated with steroids or antibiotics both medications can cause more harm to a person with elevated cytokines (Anslem Mak, 2014).

SLE and EBV from a TCM Perspective

In classical texts from the Treatise of the Spleen, Li Dong Yuan had concluded that the behavior and symptoms of SLE are spleen qi deficiency or a combination of Spleen qi and Spleen yang deficiency (Dong-Yuan, 2011). This is in the early stages as Kidney yang and Kidney qi deficiency would be in the later stages prior to a patient advancing to more weakness and inflammation (Dong-Yuan, 2011). In a more modern text Wanzhu Hou CMD helps confirm the TCM diagnosis of Spleen qi and Spleen yang deficiency (Wanzhu Hou CMD, DiplAc, MD, & Jeffrey M. Gould MAcOM, 2011).

When a patient with SLE has more emotional or inflammatory responses due to anger, stress, anxiety, or depression there may be an increase in the patient having Heart fire as well (Maclean & Lyttleton, 2008).

Epstein Barr Virus is less complicated with signs and symptoms having the TCM diagnosis of Lung and Kidney deficiency, Kidney yang deficiency or Qi and Yin deficiency (Maclean & Lyttleton, 2008). Most of the diagnostic signs and symptoms are related to the initial stages of EBV and can later be identified with chronic fatigue symptoms once the Kidney yang has been affected (Maclean & Lyttleton, 2008). There may be more overall yin deficiency in a patient with EBV primarily due to joint and muscular soreness followed by fatigue with or without rest (Maclean & Lyttleton, 2008).
Updating TCM Diagnostics

Classical texts have not had to encounter our current environmental, pharmacologic, or better living through chemistry problems which can alter a classical versus a current diagnosis. To better identify SLE and EBV by using TCM approaches it is more important to base the patient’s signs and symptoms with differential TCM pathologies. When we are able to identify the signs and symptoms with “bi Syndrome” there is a mixture of the organ pathology as well as various parts of the body having qi, yin, yang, blood, heat, and cold symptoms (Dharmananda, 2014). Many of the patients that will come in to a TCM clinic will have already taken one or more types of medication; often exaggerating one symptom while masking another (Dharmananda, 2014). By breaking the diagnosis down to overall signs and symptoms it is easier to pin down a specific pattern versus looking to make a subjective determination of the “root” cause (Dharmananda, 2014).

An Example of Subjective diagnostics versus Objective diagnostics

A good example of this would be the use of antibiotics creating a reduction in the mineral iron in the blood (The Merck Manual, 2011). Let us use an example of an African American woman in a poor socioeconomic region, with a nutritive poor diet often causing low iron levels in their blood, she also presents with a stomach “flu”. This patient goes to her physician and gets a prescription for Azithromycin (antibiotics) for the next five days. She takes her medication, which causes her to feel light headed and weak however; she states that she no longer has a stomach “flu”. The use of the antibiotics could cause a reduction in her iron levels, which further could cause a blood and yin deficiency pattern, mixed with a spleen qi deficiency root once the antibiotics have
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subsided. This can also be argued that the stomach virus began as a damp heat pattern as well, which leads more specification towards the depletion of yin fluids and developing more of a phlegm type condition, which can be seen in chronic illnesses. The purpose of identifying a more refined diagnosis should lie in the primary signs and symptoms versus what signs and symptoms may have occurred prior (Dharmananda, 2014).

When a study determining TCM practitioner’s diagnostics process was reviewed on a patient with an inflammatory disorder it was found that there was very little similarity in the patient diagnosis however; when prescribed herbs the formula was nearly identical (Dharmananda, 2014). The formula similarity may conclude that practitioners identify the patients overall biomedical diagnosis or TCM root diagnosis versus the current symptoms (Dharmananda, 2014). Even Dong Yuan Li had indicated to identify the patterns directly versus assuming what the diagnosis should be (Dong-Yuan, 2011). This helps us conclude that there is a definitive need for more resound diagnostics when identifying inflammatory diseases and TCM. With this new methodology of diagnostics found in this research synthesis we will also be able to use modern science to conclude appropriate TCM diagnosis (Dharmananda, 2014).

Secondary symptoms of SLE and EBV from an integrative perspective:

In an inflammatory response a patient has both sympathetic (yang) and parasympathetic (yin) responses (Mota, 2012). These responses are either going to release pro-inflammatory cytokines (yang), or release regulatory cytokines which reduce inflammation (yin) (Mota, 2012). To conclude this we must understand that lupus increases IL-1, IL-6, IL-8 cytokines which is a systemic inflammatory response (Jun-Ming Zhang, 2007). An elevation of IL-1, IL-6, IL-8 can be responsible for chronic
fatigue, “brain-fog”, joint inflammation, cardiac dysfunction, and integumentary disorders (Hanlon, 2014). Much of these symptoms can be attributed to a yin disorder in classic texts (Nigel Wiseman, 1996). An SLE patient may also have various other conditions such as Reynaud’s phenomenon, Sjögren’s syndrome, flushing of the face, blurring of the eyes, numbness of the hands or feet, muscle and joint pain, and dark scanty urine (America, 2013). Many of these symptoms can be converted to TCM perspectives as Kidney yin, Liver yin, Heart yin, Vacuity heat, Cold (bi) impediment, Spleen deficiency and Heart fire (Nigel Wiseman, 1996). Additional symptoms can be more direct with bi disorders in more current books using lab diagnostics and more refining in TCM descriptions for better diagnostics.

It is important for a practitioner to not use a subjective diagnosis for a patient experiencing an inflammatory attack and instead take into account if the patient is having a physical problem mixed with a chemical reaction (Dharmananda, 2014). We can also evaluate if the patient is having more than one symptom that will cause a cellular response expressing a stronger characteristic versus an observable sign (Fruehauf, 2015). With SLE being identified as having catalase oxidative modified in SLE patients (Anil D'souza, 2008), we can conclude that yin deficiency is more prevalent as oxidation is more yang consuming yin (Dharmananda, 2014). This further identifies lower enzymatic ability for SLE patients leading to an accumulation of deleterious hydrogen peroxide (Anil D'souza, 2008). In the end a patient diagnosis appears to be more relative to simpler diagnostics of symptoms versus which organ root is in disharmony and at which time (Dharmananda, 2014). If a patient has Kidney yin deficiency in the afternoon, Heart yin deficiency in the evening and Liver yin deficiency in the morning the practitioner
would be required to treat the common factor of yin deficiency instead of trying to attach a group of symptoms solely to a root organ (Dharmananda, 2014).

**Treatment of SLE with Acupuncture and Herbal Medicine:**

The American Lupus foundation has stated that the use of acupuncture or herbal medicine is not found to be effective in treating patients with SLE (America, 2013). This has been identified to be more likely due to poor diagnostics versus a treatment protocol that is more objective and precise (Kim CK, 2005). In various studies some patients are more responsive to herbal medicine versus acupuncture but not one patient is more responsive to acupuncture more than herbal medicine (Linda L. D. Zhong, 2013). One of the formulas that were specified to help increase natural killer cells, T-cell proliferation, inhibits platelet aggregation and improves IL-2 is Zi Shen Qing (ZSQ) (Linda L. D. Zhong, 2013). Though this formula is a modified composition of Yu Ping Feng San it isn’t commonly found in most material medica for the specification to treat SLE or EBV, which means that it is often ignored for its healing properties (Linda L. D. Zhong, 2013).

This formula is a modification of Yu Ping Feng San and consists of herbs that have strong immunomodulatory effects (Linda L. D. Zhong, 2013).

**Table 1:** Comparison of different Chinese Herbal medicines in SLE taken from (Linda L. D. Zhong, 2013).

<table>
<thead>
<tr>
<th>Chinese Name</th>
<th>Immunomodulatory effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ren Shen</td>
<td>Improves phagocytic functions of monocytes and stimulates bone marrow</td>
</tr>
<tr>
<td>Huang Qi</td>
<td>Enhances T-cell proliferation, promoting NK cell killing effects</td>
</tr>
<tr>
<td>Herb</td>
<td>TCM action, biomedical action</td>
</tr>
<tr>
<td>--------------</td>
<td>---------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Gou Qi</td>
<td>Improves IL-2 and WBCs by activating thymus cell proliferation</td>
</tr>
<tr>
<td>He Shou Wu</td>
<td>Enhances C3b receptors promoting interferon production</td>
</tr>
<tr>
<td>Ling Zhi</td>
<td>Inhibits platelet aggregation and implements CD4/CD8 levels</td>
</tr>
<tr>
<td>Gan Cao</td>
<td>Modulates serum IGE, IGA and IGM antibodies, decreases serum TNF-a and induces B cell maturation</td>
</tr>
</tbody>
</table>

The combination of these particular herbs were found to remove internal heat, clear toxins, tonify Qi and enrich Yin which also serves to reverse anti-dsDNA positivity which is found in the patients with EBV converting SLE (Linda L. D. Zhong, 2013). Baselines of patients C3, C4, IgG, ANA, anti-dsDNA, NK, and sIL-2R levels were taken to determine candidacy and progression or regression in the study (Linda L. D. Zhong, 2013). The end result was that ZSQ was superior over a controlled group when treating patients that had Qi and yin deficiency versus patients taking prednisone and chloroquine (Linda L. D. Zhong, 2013).

Additional herbs were added to the study to provide a stronger herbal prescription for relieving inflammatory disorders by binding and stimulating glucocorticoids (Linda L. D. Zhong, 2013). The additional herbs are found in the chart below and were specifically chosen to enhance the original formula ZSQ to respond specifically to glucocorticoids (Linda L. D. Zhong, 2013). Additional biomedical references provided by (Chen, Chinese Medical Herbology and Pharmacology, 2004).

<table>
<thead>
<tr>
<th>Herb</th>
<th>TCM action, biomedical action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Huang Qi</td>
<td>Tonifies qi, Immunostimulant, Hemopoietic, Increases metabolic rate and cAMO and cGMP, decreases proteinurea,</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Herb</th>
<th>Properties and Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheng Di</td>
<td>Nourishes Yin. Increases plasma adrenocortical hormones, cardiotonic, antihypertensive, hemostatic, hepatoprotective, diuretic and antibiotic properties</td>
</tr>
<tr>
<td>Shan Zhu Yu</td>
<td>Tonifies the liver and kidney, retains essence. Glucogenic, anti-inflammatory similar to 50mg/kg of aspirin, antibiotic properties, antifungal properties, reduces hypertension due to diuresis.</td>
</tr>
<tr>
<td>Bai Shao</td>
<td>Nourishes blood and preserves yin. CNS suppressant when injected, reduces peptic and gastric ulcers, antibiotic properties, antipyretic and anti-inflammatory, antiplatelet function, relaxes and dilates peripheral blood vessels.</td>
</tr>
<tr>
<td>Mu Dan Pi</td>
<td>Clears deficient fire and heat. Anti-inflammatory, cardiovascular support, antihypertensive, antibiotic, analgesic, anti-seizure, antipyretic.</td>
</tr>
<tr>
<td>Bai Hua She She Cao</td>
<td>Clears heat and resolves toxicity</td>
</tr>
</tbody>
</table>

The use of herbal formulas with appropriate identification of Qi and Yin deficiency has fewer outbreaks of secondary inflammatory “flare ups” versus a patient who is taking low dose steroids (Linda L. D. Zhong, 2013). An additional study on Ling zhi has shown that this particular herb increases monocytes, macrophages and T-lymphocytes, which can increase cytokines and anti-inflammatory interleukins (Chen,
Chinese Medical Herbology and Pharmacology, 2004). This particular herb also has an antibiotic property, which can help prevent secondary infections in patients with compromised intestinal bacteria with an infection of E.coli, Dysentery, Pseudomonas or streptococci (Chen, Chinese Medical Herbology and Pharmacology, 2004). Ling zhi also has the ability to increase the contractibility of the heart and return higher oxygen levels to the cardiac muscles (Chen, Chinese Medical Herbology and Pharmacology, 2004). This can be very effective in patients with chronic SLE as many patients express cardiac dysfunction with hypertension and or cardiac arrhythmias (America, 2013). A study of 84 patients with SLE were injected with Ling zhi and provided oral tablets for dermatological disorders and it was found that 78 - 88% of the patients had lower facial rashes than persons not taking Ling zhi (Chen, Chinese Medical Herbology and Pharmacology, 2004).

Current treatment for raising T-cells, regulatory CD4+, and CD8+ cells is to use conventional immunosuppressant therapy (Anslem Mak, 2014). This type of treatment can increase secondary infections in patients however; it is beneficial in reducing further failure in patients with glomerulonephritis (Anslem Mak, 2014). The use of ZSQ with conventional therapy would be contraindicated as the Biomedical treatment protocol is to reduce the immune system (Anslem Mak, 2014), whereas the use of ZSQ is to nourish the cytokines that reduce inflammation while decreasing the pro-inflammatory cytokines (Linda L. D. Zhong, 2013).

A secondary herbal prescription is found at Evergreen herbs under the LPS support formula. This formula uses many of the herbs found in ZSQ plus additional herbs that help move blood, nourish blood, supplement Qi, nourish Yin and decrease
The Efficacy of TCM on Reducing Lupus and Lupus Secondary Symptoms

inflammation (Chen, Chinese Medical Herbology and Pharmacology, 2004). This formula can be further broken down as:

<table>
<thead>
<tr>
<th>Herb Name</th>
<th>TCM Indication</th>
<th>Biomedical Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bai hua she she cao</td>
<td>Clear heat, Eliminate toxins, Relieve inflammation</td>
<td>Treats body aches, joint pain, and aversion to cold.</td>
</tr>
<tr>
<td>Ban zhi lian</td>
<td>Clear heat, Eliminate toxins, Relieve inflammation</td>
<td>Relieves pain muscle aches, rashes, dermatological disorders, Antibiotic properties, anti-inflammatory, analgesic and antipyretic, antispasmodic, reduces heart rate, increases oxygenation of blood.</td>
</tr>
<tr>
<td>Chi shao</td>
<td>Clear heat, Cool blood</td>
<td>Antiplatelet aggregation, cardiovascular support, antihypertensive, sedative, antipyretic, antispasmodic, antibiotic against staphylococcus aureus, streptococcus, vibrio cholerae and some viruses.</td>
</tr>
<tr>
<td>Han Lian</td>
<td>Nourish yin, Tonify blood, Generate body fluids</td>
<td>Hemostatic from fever related bleeding, cardiotonic in patients with coronary artery disease, antibiotic</td>
</tr>
<tr>
<td>Herb</td>
<td>Properties</td>
<td>Additional Effects</td>
</tr>
<tr>
<td>--------------</td>
<td>------------------------------------------------</td>
<td>---------------------------------------------------------</td>
</tr>
<tr>
<td>Hong hua</td>
<td>Activate blood, Eliminate blood stasis, Relieve pain</td>
<td>Positive inotropic effects on the heart, antiplatelet function reduces CNS activity related to seizures, Adaptogenic to increase energy levels without caffeinated stimulation</td>
</tr>
<tr>
<td>Ji xuang teng</td>
<td>Nourish yin, Relieve pain</td>
<td>Treats joint pain throughout the body, treats neurodermatitis</td>
</tr>
<tr>
<td>Jin yin hua</td>
<td>Clear heat, Eliminate toxins, Relieve inflammation</td>
<td>Antibiotic, Anti-inflammatory and antipyretic effects, CNS stimulant antihyperlipedemic, gastrointestinal support by increasing secretion of bile and gastric acid</td>
</tr>
<tr>
<td>Lian qiao</td>
<td>Clear heat, Eliminate toxins, Relieve inflammation</td>
<td>Antibiotic properties, anti-inflammatory, cardiovascular support by stabilizing and increasing cardiac contractions to reduce blood pressure, hepatoprotective, antipyretic, and diuretic effects</td>
</tr>
<tr>
<td>Mu dan pi</td>
<td>Clear heat, Cool blood, Nourish yin, Tonify blood</td>
<td>Anti-inflammatory, cardiovascular support, antihypertensive, antibiotic, analgesic, anti-seizure, antipyretic.</td>
</tr>
</tbody>
</table>
## The Efficacy of TCM on Reducing Lupus and Lupus Secondary Symptoms

<table>
<thead>
<tr>
<th></th>
<th>Generate body fluids</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sheng di huang</strong></td>
<td>Clear heat, Cool blood, Nourish yin, Tonify blood Generate body fluids</td>
<td>Increases plasma adrenocortical hormones, cardiotonic, antihypertensive, hemostatic, hepatoprotective, diuretic and antibiotic properties</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tao ren</strong></td>
<td>Activate blood, Eliminate blood stasis, Relieve pain</td>
<td>Reduces agglutination of cells in thrombi and cytokines, anti-inflammatory, anti-allergenic properties</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Xuan shen</strong></td>
<td>Clear heat, Cool blood, Nourish yin, Tonify blood Generate body fluids</td>
<td>Antihypertensive, antidiabetic, antibiotic properties, sedative and antipyretic properties</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ye ju hua</strong></td>
<td>Clear heat, Eliminate toxins, Relieve inflammation</td>
<td>Vasodilative, antibiotic properties, reduces hypertension and coronary artery disease, platelet inhibition and inhibition of cellular aggregation</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Zhi mu</strong></td>
<td>Clear heat, Cool blood</td>
<td>Antineoplastic and cholagogic actions, antibiotic properties, antipyretic effects in strong fever or flushing symptoms</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Zi cao | Clear heat, Eliminate toxins, Relieve inflammation | Antibiotic and antiviral properties especially towards herpes viruses and E.coli, anti-inflammatory effects, gastrointestinal support by stimulating peristalsis, antineoplastic properties by effecting anti-DNA inflammatory markers

(Chen, Chinese Herbal Formulas and Applications, 2004)

This secondary formula is more direct than the original ZSQ formula under study however; this formula adds additional herbs that are responsible for antineoplastic actions, which increase anti-inflammatory cytokines, as well as provides immune system support (Chen, Chinese Herbal Formulas and Applications, 2004).

**Treating SLE and EBV with acupuncture:**

Acupuncture has a deficit in the ability to add fluids to the body in comparison to herbal or nutritive therapies however; acupuncture can increase the anti-inflammatory cytokine function and parasympathetic function found in SLE and EBV (Nobuo Yamaguchi, 2007). Out of the comparative studies it was found that St36 was the most common point used with and without electrical stimulation to create the effect of increasing IL-4 and IL-10 specifically (Mota, 2012).

A graph published from INTECH, which researched the efficacy of TCM acupuncture to treat SLE, had shown that the points that follow were effective at different intervals (Mota, 2012):
The Efficacy of TCM on Reducing Lupus and Lupus Secondary Symptoms

Based on multiple reviews ST36 (Zusanli) was the most used acupuncture point for review on how acupuncture may reduce inflammation (Mota, 2012). Based on this study ST36 (Zusanli) may actually trigger an increase in IL-1, IL-6 cytokines which are already elevated in patients with SLE while reducing IL-4 levels (Mota, 2012). This would conclude that the use of ST36 (Zusanli) may actually cause more of an inflammatory effect in patients having a “flare-up” and can be a reason why many studies have concluded that patients with SLE often feel worse upon receiving acupuncture (America, 2013).

Additional reviews of ST36 (Zusanli) have indicated that electrostimulation and timing according to cytokine circadian rhythm were beneficial as well as the addition of BL 18 (Ganshu), BL20 (Pishu), BL23 (Shenshu) for a total stimulation of five seconds with 30mm and 50mm diameter needles (Nobuo Yamaguchi, 2007). Daily stimulation for five seconds on each point, at the same time of day, were found to have an increase in
cellular immunity and increase of IL-4, IL-10, CD8+ cells as well as other immunomodulators that help reduce inflammation (Nobuo Yamaguchi, 2007). Acupuncture also increased the number of NK cells and cytokine expression levels to the point of having relief from “flare ups” in patients with chronic inflammatory disorders for up to 30 days after the initial treatment method of eight days of five second needling (Nobuo Yamaguchi, 2007). This study did not compare SLE directly however; it covered more than enough of the common secondary symptoms of patients diagnosed with SLE. Should acupuncture be avoided in patients with SLE or EBV?

The chronic pain and fatigue that is often felt by patients with SLE or EBV could benefit greatly from acupuncture based on the studies however; it is important to identify the duration, point location and methodology. Many of the studies have only focused on TCM specific points mainly St36 (Zusanli) versus points that lay near motor points such as those found by TCM researchers in China in 1960 (Yun-Tao Ma, 2005). In the United States Dr. Janet Travell had discovered motor points that affected pain without knowing or understanding acupuncture and indicated that these points when stimulated were highly effective in reducing pain and increasing function of injured body parts (Yun-Tao Ma, 2005). When TCM medical providers in China discovered the similarity there was a comparison in injecting acupuncture points, inserting dermal implants into acupuncture points, use of electrical stimulation and extraction therapy (Yun-Tao Ma, 2005). This had shown to increase the effectiveness of acupuncture even more as many of the points needed were along the channels used by TCM providers (Yun-Tao Ma, 2005).

By injecting highly purified herbal compounds into acupuncture points in chronic pain patients, patients were shown to have an increase in receptivity to reduced
The Efficacy of TCM on Reducing Lupus and Lupus Secondary Symptoms

inflammation (Mota, 2012). The problem with this method is that it is not currently available to TCM practitioners in the United States as it requires a hypodermic needle versus a filiform needle. What is added to beneficial methods for treating chronic inflammatory disorders with TCM is the use of Electrical Stimulation Acupuncture (EA) or the converted use of Percutaneous Electrical Nerve Stimulation (PENS) units which allow the stimulation of A-delta and C-fibers (Yun-Tao Ma, 2005). Typical manual stimulation like those done in prior studies only stimulates C-fibers versus EA, which stimulates A-delta, and C-fibers (Yun-Tao Ma, 2005). By stimulating both A-delta and C-fibers a patient with chronic pain will have a higher vascular dilation to move blood in and out of the muscles, joints, skin, and organs as well as increasing beta-endorphins which increase the analgesic effect reducing physical pain (Yun-Tao Ma, 2005).

By advancing to a PENS unit between treatment with acupuncture in a clinical setting, a patient with chronic pain and inflammation will be able to increase the duration of analgesic effects while being able to have normal activities of daily living (CM Greco A. K.-M., 2008). The PENS unit currently is not available to TCM practitioners however; an integrative approach would be to work in partnership with Chronic Pain medical doctors with routine visits to a TCM provider two times per week, if this method is utilized (CM Greco A. K., 2008). Additional treatments would be to stimulate the vagus nerve with electrical auricular acupuncture and then following the treatment with a PENS unit for one month in patients that have had multiple non-effective relief of pain utilizing medication, pain therapy, acupuncture, and herbal therapy (CM Greco A. K., 2008).

Current use of pharmaceutical quality supplements has also been used to help increase the anti-inflammatory effects of SLE and chronic fatigue symptoms of EBV. It
has been found that taking probiotics, which we can state builds Spleen Qi, helps with increasing IL-10 a natural anti-inflammatory modulator that is not prevalent in SLE or EBV patients (Allard, 2009). With more prescriptions being written for people with autoimmune disorders to prevent secondary infection there is an elevated reduction in gut bacteria which affects the neurological inflammatory responses (Li YN, 2001). Patients with SLE are often prescribed medications that prevent them from being exposed to the sun causing Vitamin D deficiency (Rakel, 2012). This can cause various cellular deficiencies and increase inflammatory disorders as Vitamin D is used for the production of Red Blood Cells (RBC) (The Merck Manual, 2011). It has been found that taking a predigested pre and probiotic formula as well as Vitamin D3, there is an increase in anti-inflammatory markers such as IL-4, IL-8, IL-10, IL-13 (Allard, 2009). Additional supplements are Vitamin C, Vitamin E, Vitamin A, Potassium, Magnesium, and Calcium (Shaklee., 2008). Although not a research based source the researcher had been instructed by one of his professors regarding the TCM equivalent to the vitamins written above and learned that many of them would be Yin nourishing. This would hold true with the prior indications made that the globule that binds and prevents the action of IL-4, IL-8, IL-10, IL-13 would be relieved due to the Yin nourishing nature of these vitamin.

This researcher’s purpose was to determine if TCM can reduce secondary inflammatory symptoms of SLE and EBV instead of relying heavily on Western medical treatments. The researcher also wanted to create a more clear approach to the diagnostics and importance of herbal supplementation versus acupuncture in chronic inflammatory cases. This was done to help fill in the gaps between acupuncture treatment with manual stimulation, electrical stimulation, and percutaneous electrical nerve stimulation devices.
The Efficacy of TCM on Reducing Lupus and Lupus Secondary Symptoms

Although TCM has fewer side effects it appears that current research suggests herbal medication and supplementation is more important for replenishing yin prior to acupuncture, which can cause the stimulation of already elevated cytokines. Due to recent discoveries in chronic inflammatory disorders and the lack of literature synthesis in acupuncture treatment for SLE and EBV, the researcher had to utilize similar studies to increase research support.
Chapter Three: Methodology

Introduction

It is theorized that acupuncture, Chinese Herbal Medicine and appropriate supplementation will help significantly reduce the signs and symptoms of persons suffering from Systemic Lupus Erythematos (SLE). This includes the reduction of inflammatory outbreaks to the joints, skin and digestive system as well as reducing the degeneration of the kidneys. The purpose of this study was to determine whether acupuncture, Chinese herbal medicine and supplements can reduce the symptoms of joint inflammation, skin rashes, Sjögren’s syndrome, Reynaud’s phenomenon and kidney disease.

General Statement of Methodology

I had to break down the many similarities and broad statements found in various articles involving the intestinal system as well as the renal function; this required a qualitative literature synthesis to be utilized. The qualitative methodology allowed for personal observations and interpretations followed by scientific findings that can be analyzed and repeated in a clinical setting (Harris Cooper, 2014).

Qualitative research synthesis methods were utilized to help decipher nuances in the articles, texts, and prior research methods obtained in various countries on the treatment of SLE and EBV. With the new findings of CD8+ inflammatory markers being discovered to help patients with chronic illnesses the bias to publish versus evaluate data completely makes it difficult to decipher reputable articles in such a short time. The research synthesis style was chosen due to it being more cohesive with a one-year time constraint as well as not having many articles published on this new discovery.
The Efficacy of TCM on Reducing Lupus and Lupus Secondary Symptoms

Procedures:

The researcher had to synthesize the material in a non-biased manner to determine many of the more common symptoms suffered by SLE, this included creating a list of most commonly reviewed signs and symptoms treated by most of the biomedical institutions who report their diagnosis and treatment methods. The research synthesis was performed by many articles found through online searches of medical journals, Pubmed, Google Scholar, Science Daily, Lupus Foundation, Acupuncture digest, Yo San University Database, Southwestern College Database, UCSD Research Database and published books.

Many search words included: Acupuncture, Lupus treatment and herbal medicine, Cytokines and inflammation treated with Chinese herbs, Supplements and inflammatory disorders, Inflammation and acupuncture, TCM, CAM, SLE, Integrative auto-immune treatments, and Kidney failure and SLE.

Inclusions/Exclusions Criteria

Although there are very few articles written regarding TCM and SLE, the researcher had to include all specific data of biomedical and TCM perspectives and create an interpretation based on TCM diagnostics. Inflammatory joint and skin disorders are only part of the problem with SLE and were used to help narrow down and support much of the data required for this study. These symptoms also helped provide subjective and objective improvement to treatments that would help us conclude that the symptoms were in fact reducing the secondary symptoms of SLE. These articles didn’t generalize on a gender or age however; it did focus on regions, due to toxicities and available healthcare,
as well as appropriate nutrition. This research was also excluding factors where prior studies dismissed efficacy of TCM due to poor methodology and outcome measures.

**Resources:**

Research synthesis data was compiled from information published in books, journals, PubMed, EBSCO host, and Google Scholar. Search words included: Acupuncture, acupuncture and lupus, lupus and Epstein Barr virus, TCM and autoimmune illnesses, Rheumatoid arthritis and TCM, CD-4/CD-8 and Oriental Herbs increasing immunity. As a researcher I have found that there were few articles regarding the treatment of SLE with a lineage to HSV-4 as this discovery is very new and biomedical research has begun definitive trials over the last five years in Germany, France and England.

Expanded words used for more detail were; “Acupuncture and Autoimmune diseases”, “Kidney Failure and Acupuncture”, “Acupuncture and inflammatory disorders”, “Acupuncture and Herbal Medicine to treat Intestinal Viruses”. This too proved limited, as there has not been much research with acupuncture or herbal medicine in a more direct setting, a few new research articles were provided that may benefit cellular integrity as well as boost a patients immune system with SLE. These articles were found at random via Science Daily browsing and PubMed as more epidemiologists are using broad spectrometry for analysis of cytokines and DNA.

**Human Subjects Research Ethical Considerations**

This study is exempt by the University IRB process as there were no human subjects used in this research.
Chapter Four: Results

This research synthesis included 32 articles involving; three studies summarized from textbooks written in English. Articles of different study designs from 13 different research groups, and 19 Integrative studies. The articles can be dissected into the following: 6 synthesis reviews, 12 clinical trials, 4 educational/informative, 3 meta analyses, 2 surveys, 3 systemic review, 2 experimental research. Detailed breakdowns are continuously growing due to more research being obtained.

Formulas evaluated are based off of Evergreen Herbs LPS support formula and Linda Zhong’s ZSQ modified formula, the herbs contained in these formulas have been broken down to provide a TCM and Biomedical analysis of how these herbs affect the secondary symptoms as well as preventative methods for controlling inflammatory markers, secondary infections, and cardiovascular support. Many of the herbs mentioned in the various researches are identical to those used in LPS Support. Most of the trials evaluated experienced the same effect in patients when comparing acupuncture to herbal medicine in that herbal medicine had a higher overall outcome versus acupuncture.

Additional trials are found in acupuncture points and required supplements to help reduce secondary symptoms in patients suffering from inflammation due to SLE. Some of the most common points utilized are: St 36 (83%), LI4 (58%), Sp6 (52%), LI 11 (43%), Yin Tang (38%), Du 20 (28%), Bl 23 (18%), Ren 4 (15%), Lu 6 (15%) and electrical stimulation (18%). In all of the studies the retention time was between five seconds and 30 minutes with a treatment variation of 1-2 times per week during a two-month evaluation (on average) of each study. Supplements commonly used were: Vitamin D3 (88%), Vitamin C (68%), Vitamin E (48%), Vitamin A (47%), Potassium
(45%), Magnesium (45%), Calcium (38%), Pre-Probiotics (30%). The number of trials providing supplements had a bias towards brands however; all brands were provider based and not over the counter.

Many of the studies that compared acupuncture's effectiveness in treating SLE indicated that acupuncture was able to increase the inflammatory cytokines, these however; were already elevated in patients with SLE. This helps confirm why the Lupus Foundation has a negative review of acupuncture in the treatment of SLE. Patients in various stages of SLE would have different needs due to their level of Yin. When treating patients with SLE it is important to utilize the diagnostics evaluated as well as keeping the treatments between 5 seconds in highly inflamed patients and 30 minutes in those that are not severely inflamed (Linda L. D. Zhong, 2013).

Currently the developmental studies for EBV and conversion to SLE are new and just beginning to be researched from a Biomedical perspective. Though TCM has written text regarding autoimmune disorders such as SLE dating back over 400 years there was no significant determination of the effectiveness or alterations to diagnostics and formulas provided to patients from that time. Current TCM research has begun to look deeper into diagnosing at a cellular level versus a subjective “root” or “organ” method, which may seem like a one size fits all. The studies compiled in this article were composed of research that happened to evaluate inflammatory disorders that were similar to secondary symptoms effecting patients with SLE and EBV. The results of those studies shows significant marked improvements in reducing inflammation in patients with the same cytokine markers as those with SLE and EBV.
Chapter 5: Discussion

Summary of Findings:

The topics included in this synthesis relate to SLE, EBV and secondary symptoms of inflammation suffered from these chronic illnesses. Articles with symptoms that were treated with Herbal formulas were supported by (Linda L. D. Zhong, 2013) and the most conclusive of articles treating with acupuncture was supported by (Nobuo Yamaguchi, 2007).

The primary effects of Herbal formulas related to ZSQ provided 78% relief in patients who were affected with Chronic Pain with no relief with other methods and 89% in patients with common inflammatory symptoms (Linda L. D. Zhong, 2013). The most conclusive articles for acupuncture effectiveness are found in (Nobuo Yamaguchi, 2007), which identified the rate of time and methods of acupuncture used for improved analgesic relief. In patients with moderate inflammation the response to acupuncture was 80% effective versus those that have had more chronic inflammatory disorders (Nobuo Yamaguchi, 2007). Acupuncture was found to increase energy and focus however; in patients with EBV (Nobuo Yamaguchi, 2007).

Implications for Theory:

According to the Lupus Foundation the diagnosis for chronic inflammatory disorders affecting women of African American and Native American decent have risen due to various factors and find little to no relief from TCM treatments (America, 2013). The fact that the Lupus Foundation has indicated that there is little to no relief in patients treated by acupuncture (America, 2013), which provides a need for better need for diagnostics instead of subjective categorization in TCM (Dharmananda, 2014). It is
important for the TCM practitioner to evaluate secondary symptoms with higher importance as well as encourage patients to provide more detail in their symptoms, diet, and medications in order to determine secondary effects versus primary symptoms (Dharmananda, 2014). Although SLE doesn’t affect the economy as much in medical costs it does have a higher than normal partial disability level, meaning that many patients are unable to work full time due to “flare ups” (America, 2013). A higher population of women on Native American reservations have been diagnosed due to environmental pollution which can signify more cases of non-Native women at risk due to toxic levels in our water, poor food quality, and high stress lives (Allee, 2013).

**Implications for Practice:**

Based on the studies reviewed, SLE and EBV require different types of treatment principles at different levels of the illness. A patient who has mild to moderate “flare ups” may be able to handle acupuncture (Nobuo Yamaguchi, 2007), alone although a patient with a higher level of “flare up” causing full body pain, difficulty focusing, and fatigue may require more herbal formula and supplementation than acupuncture alone (Linda L. D. Zhong, 2013). Utilizing a formula that has been proven through research such as ZSQ for patients with higher yin deficiency inflammatory symptoms proves more effective (Li YN, 2001) than attempting acupuncture which will increase the inflammatory markers already high in Yin deficient patients (Nobuo Yamaguchi, 2007).

Providing a treatment plan to work with an integrative approach is more important than attempting to out do or create bias against Western Medical providers. Understanding what the current medications do to a patient with SLE or EBV on a cellular level will help provide more efficiency in a treatment according to the multiple
The Efficacy of TCM on Reducing Lupus and Lupus Secondary Symptoms

studies reviewed. If utilizing a PENS unit with herbal formulas, supplements and a fluctuation of 5 second acupuncture treatments or 30-minute acupuncture treatments (Nobuo Yamaguchi, 2007) are all based on Yin and Yang conditions and humoral activity (Wanzhu Hou CMD, DiplAc, MD, & Jeffrey M. Gould MAcOM, 2011).

Additional factors involved in the implications for practice is to evaluate the patients living and dietary conditions and create sustainable alternatives.

**Limitations of Current Study:**

The limitation of short trials is that they lack longevity evaluations in patient outcome. The reviewers of the trials reported no bias in their interpretations of their results. This researcher thinks that the results reviewed were accurately reported with little to no adverse reactions or inaccuracies other than the lack of TCM and biomedical diagnosis. The researcher feels that there could have been more reporting of any adverse reactions in the TCM studies however; none appeared to be documented. There were specifics on needle size in one trial although the depth of needling was not specified on which patient type, high inflammatory versus low inflammatory patients. There was uncertainty on the age and inflammatory records on most articles and no specification on tongue or pulse evaluation. No report measured the patient stress levels, use of antibiotics or physical activity, which could be a factor for better clinical outcomes. Most studies did however; differentiate specificity of herbal formulas, supplements use, or acupuncture being done individually but not as an incorporated method of treatment. There were many limited studies that could have better identified treatment protocols or lab analysis however; the recent findings of the cytokine process in SLE and EBV is very new and not heavily researched at this time.
**Recommendations for Future Research:**

Longitudinal studies regarding EBV or SLE progression will be beneficial for measuring long-term results. This would require follow up visits every 3 months with cytokine levels determining a reduction of IL-1, IL-2, IL-6, IL-8 markers and an increase in IL-4, IL-8, IL-10, IL-13 levels. Additional evaluations with PENS units and herbal formula use over the 3 months would also help identify a better treatment method for patients with Chronic conditions of SLE or EBV with inflammation. All reports indicated that treatment plans must occur 3-4 times a week and different approaches must be in use with patients with minor inflammation versus more chronic inflammation. Patients should be provided questionnaires regarding diet, lifestyle, and environmental surroundings to help create more specific treatment plans. Secondary questionnaires could be used for patients who have been following the treatment protocol and have either shown improvement or minimal improvement in order to evaluate more sound diagnostics; this should be done at the 3-month evaluation.

Further research needs to be done in regards to acupuncture with the herbal formula ZSQ or modified with Evergreen LPS support, probiotics and nutritive supplements. This could be evaluated as nourishing Yin versus treating symptoms of inflammation and pain by providing an analgesic effect of moving Qi without nourishing Yin. A further questionnaire would be used for patients in this category and can be provided as an experiment with 150 patients split in four control groups of herbal formula and supplements, supplements and acupuncture, herbal formula, supplements and acupuncture, and finally a control group taking placebo supplements, herbal formulas and no acupuncture.
The two most promising studies regarding the herbal formula ZSQ and the acupuncture treatments for brief or 30 minute durations provided the overall best relief in patients suffering from chronic inflammation. By building off of these two studies and combining them with other studies that have shown some relief in patients with poor inflammatory responses or globules caused by EBV inhibiting IL-4, IL-8, IL-10, IL-13 from releasing a compound study can be created that would help provide relief in patients with SLE.
Conclusion:

This research synthesis was intended to determine if TCM was effective in reducing chronic inflammatory symptoms of SLE due to globule markers caused by EBV. It has been determined by this researcher that TCM can help reduce or remove chronic inflammation in patients with SLE in early and late stages. Therefore TCM methodology when diagnosed correctly can be very productive in integrative health with patients suffering from inflammatory disorders. This will help Western physicians write lower doses of steroids for patients to take as an as needed regimen versus a daily medication. The use of a PENS unit on the vagus nerve while taking daily doses of a modified herbal formula and low dose acupuncture treatment will help patients increase their longevity of health without the “flare ups” often occurring in patients with SLE. In addition it is very important to evaluate a patient’s dietary and environmental surroundings, which can also further reduce inflammation when not being treated by either a Western or TCM provider.
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References


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Appendix A: IRB Acceptance Letter

December 26th, 2014

Robert Pontecorvo
3521 Herman Ave.
San Diego, CA 92104

Dear Robert,

Your research proposal has been approved, with no additional recommendations effective through March 31, 2016.

Should there be any significant changes that need to be made which would alter the research procedures that you have explained in your proposal, please consult with the IRB coordinator prior to making those changes.

Sincerely,

[Signature]

Penny Weinraub, L.Ac.
IRB Coordinator

13315 W Washington Blvd, Los Angeles 90066
Appendix B: IRB Proposal

IRB Application

1. Principal investigator’s (PI) name, mailing address (include city, state, country, postal code), and contact information (include home, work, and cell telephone numbers as well as e-mail address):

   Robert R. Pontecorvo Jr. LAc.
   10951 Sorrento Valley Rd. Ste. 1-D
   Sorrento Valley, Ca. 92121
   619-244-3986 cell phone
   hozhohealthandwellness@gmail.com

2. Type of review requested: Literature analysis

3. Researcher’s connection to Yo San University: Student

4. Student’s degree program: DAOM

5. Student’s area of concentration or employee’s department name: Healthy aging and Longevity Health Cohort 5

6. Name of faculty advisor / program chair or supervisor: To be Determined

7. Title of research study / project: The use of Chinese herbs and acupuncture to treat patients with Systemic Lupus Erythematosus causing oxidative stress and inflammation in connective tissues.

8. Purpose of study: Capstone learning experience, culminating study.

9. Possible future uses of the study results (indicate all that apply): Future professional journal articles

10. Media use: None

11. Academic discipline that guides the research study / project protocol: Acupuncture, Herbology, Western Medicine

12. Subject / participant information: (e.g., age range, target population); include members of protected populations such as children ages 2–12; pregnant women; neonates / newborns / infants less than age 2; adolescents ages 13–18; other (specify). None
13. Number of participants: None

14. Sensitive data collection: None

15. Name of other participating institution(s), if any: None

16. Co-researcher(s): None

17. Prospective funding source(s)—not financial aid:
None

18. Collaborative research: No

19. If yes to No. 18: Include name of lead institution, contact names, addresses, and telephone numbers; names of collaborating researchers, contact names, addresses, and telephone numbers.

Required Format and Content for IRB Research Proposals
Use the following bold face items as headings, with each section containing the information described in this outline. Do not ignore items that do not apply; include a statement to that effect. Proposals should be no longer than 15 pages, double-spaced, not including attachments. [No need to include the text of lettered questions (A, B, C, D) or Notes in responses; just supply requested information.]

Research Proposal Outline

1. Name / Title of the Study. The use of Chinese herbs and acupuncture to treat patients with Systemic Lupus Erythematosus causing oxidative stress and inflammation in connective tissues.

2. Name of the PI (and co-researchers, if any). Note: For the IRB’s purposes, “co-researchers” are individuals who are actively involved in the study design, implementation, data analysis, reporting, etc. Co-researchers’ names are included on the final report. Co-researchers are not participants / subjects whom the PI has chosen to call “co-researchers.” Other individuals may help distribute or pick up questionnaires or surveys or help enter data into a computer. Although they are not co-researchers, they must follow the guidelines for maintaining confidentiality and protecting subject identity.

Robert R. Pontecorvo Jr. LAc.

Purpose and Potential Value of the Study.

A. State research question(s).

1. What is the relationship between medication for lupus and oxidative stress and
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inflammation in patients with lupus? 2. Does the use of Chinese herbs decrease the signs and symptoms of oxidative stress, if so what are their mechanisms of action? 3. Has the industrialization of the workforce plus common stressors (finances, exogenous toxins, imported foods and bacterium, medication) affected the human genome to increase organ malfunction and oxidative stressors? 4. What role can preventive use of Traditional Chinese Medical herbs do to reduce secondary symptoms of inflammation, fatigue and joint pain in lupus patients if used during the initial stage of Epstein Barr Virus diagnosis years before a diagnosis of Lupus is made? 5. Is it possible to use herbs with antibiotic and antiviral properties during treatment of patients with Epstein Barr Virus to prevent CD4 cells from destroying healthy cells and prevent CD8 cells from ceasing to function? Will this regimen reduce future diagnosis of SLE in women?

B. State hypotheses, if applicable. Small intestinal viral exposure from the Epstein Barr virus has been indicative of future reduction in the function of CD8 cells and has caused CD4 cells to destroy healthy cells in some women who are later diagnosed with Systemic Lupus Erythematosus (SLE). Once CD4 cells and CD8 cells cease to work properly, patients with SLE suffer from oxidative stress, which can create long-term discomfort and pain. Will the use of Traditional Chinese Medical herbs help restore CD4 and CD8 function while reducing oxidative stress in patients with SLE? This study is to determine the various herbs and treatment options that are available by using Traditional Chinese Medicine and better describe appropriate protocols for patients with various inflammatory conditions due to SLE.

C. State reason(s) for conducting this study. This study is conducted to help practitioners of Chinese and Western medicine to find alternative methods to reduce the rising diagnosis of autoimmune illnesses such as Systemic Lupus Erythematosus (SLE). It has been found that the Epstein Barr Virus is a most common cause of SLE and is due to CD4 cells attacking healthy cells while CD8 cells no longer work. This study is meant to provide a safer alternative treatment by using herbs and acupuncture that have been clinically proven to have both antibiotic and antiviral properties as well as the ability to influence CD4 and CD8 function.

D. Describe anticipated value of the study to the larger community (i.e., what you expect to learn, and how it will be of value to others).

The results of this study will be of value to the practitioners of Chinese Medicine, Western practitioners and the general population.


Provide a brief summary of the literature review that pertains to your proposed study (just a few paragraphs will suffice) and a brief bibliography or reference list that includes entries pertinent to your proposed study. While this section can be brief, it should demonstrate your familiarity with the issues involved in your proposed study and thus manifest your qualifications to conduct the study and to confirm potential benefits of the study.
Systemic Lupus Erythematosus (SLE) has been critically reviewed by epigeneticists from the United Kingdom for a span of 40 years and have noted that Epstein Barr Virus (EBV) has a relationship with SLE and is a potential causative for SLE when a patient's CD4 and CD8 cells are not working properly (Hanlon, P., 2014). This discovery has helped with identifying a common exposure to a viral disease that has been linked to the precursor of developing abnormal CD4 T-Lymphocytes and diminishing CD8 cell function which triggers oxidative stress related inflammation in patients with SLE (Harley, J.B., James, J.A., 2006). Females now make up ninety percent of the patients diagnosed with SLE which presents with symptoms that may include fever, polyarthritis, maculopapular rashes on sun exposed areas of skin, aphthous ulcers, alopecia, and generalized inflammation of the connective tissue (Flaws, B., Sionneau, P., 2001, p. 517). According to the Merck Manual online, a patient must present with four out of eight common symptoms to obtain a diagnosis of SLE, the symptoms are as follows: ANA (Anti-Nuclear Assay) antibodies in the blood, low white blood cell (WBC) or platelet count, joint pain in a number of joints, butterfly rash on the cheeks, abnormal cells in the urine, photo-sensitivity, aphthous sores or lesions, seizures or psychosis (Merck Manual Professional Edition, Lupus).

The Lupus Foundation of America (LFA) has noted on their website that the average patient has a cost of $20,924 due to partially covered medication, co-pay, and secondary illnesses causing loss of work due to medication side effects or other exogenous factors (Lupus, 2014). The LFA also mentions that there is a projection of increasing lupus rates in America notably due to better testing methods versus an actual increase in lupus mortality or deaths (Lupus, 2014). This could mean that more patients will have more inflammatory related illnesses as well as side effects from medications that could increase costs both for the healthcare system and patient finances. This determination is primarily due to the rise in positive diagnosis in patients who have had symptoms but no actual prior diagnosis and the rise in patient related illnesses due to medication side effects. Research done independently by the LFA has found that 61% of 1000 people surveyed, had little to no knowledge of lupus which could lead to the speculation that even more people in the general population are lacking knowledge in integrative care for lupus.

In 2013 the Hong Kong Baptist University School of Chinese Medicine had run experiments on using Chinese herbs to help reduce the side effects of SLE in comparison to hydrocortisone, a common medication, and found that Chinese medicine was very capable in reducing oxidative inflammation (Zhong, L., Zhao., X., 2013). Though there are many Chinese medical diagnosis that could be represented with SLE, this study focused on Qi and Yin deficiency and the use of Qi and Yin deficiency herbs which were found to have a higher success rate in reducing oxidative inflammation than hydrocortisone in a Single Blind study (Zhong, L., Zhao., X., 2013).

This research synthesis is meant to help provide a more direct science based diagnostic and treatment protocol for Traditional Chinese Medical practitioners as well as Western Medical physicians treating patients with mild to moderate SLE. Much of this research synthesis is based on the use of Chinese herbs however; there will be some use of acupuncture which would be beneficial in patients who are not histamine sensitive when needles are inserted. This precaution can help practitioners understand that some use of
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acupuncture may be more counter effective than the use of Chinese Herbs. Another portion of this research synthesis is to understand which Chinese herbs prove to be more effective in stimulating CD8 cells and reducing CD4 cell counter activity in patients suffering from oxidative stress due to SLE.

Research Submissions:


5. Location of the Study.

This study will be on PI home computer and through Yo San library links.

6. Dates of the Study. Month/day/year that you wish to begin collecting data and month/day/year that you expect the study to conclude data collection and all interactions with participants. *Note*: Proposed start date must be after the date of IRB approval of the application, and estimated duration of the study should include all your interactions with all subjects—the entire data-collection process, which may include follow-up questions
or clarifications.

September 2014 to January 2016

7. Subjects (Participants). List characteristics of potential participants, including demographics (e.g., children, students, adult women, specific profession, age, race, gender, and so on). A. Identify and describe participants in a protected population, if any. (See IRB Handbook, Chapter 3.)

None  B. Describe eligibility criteria for participation in the study (e.g., women between the ages of 18 and 25; first-generation college graduates).

None  C. Describe characteristics or other factors that will make an individual ineligible—the exclusion criteria (e.g., outside the designated age range; not in selected profession; not a first-generation college graduate). None

8. Participant Payment and/or Costs.

No payments are or costs required


None


None

11. Data Collection, Analysis, and Reporting.

A. Describe methodology(ies) you will use to collect and analyze data.

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Research synthesis will be compiled through online search of journals through Pubmed, EPSCOHOST, Google Scholar and historic publications.

B. Describe any surveys, questionnaires, or other data-collection instruments used in your study and how the instruments were developed and tested, and provide validity / reliability information. Provide a copy of permission to use instrument if needed. Data collection will be designed based on relevant findings.

C. Include links to Internet surveys, questionnaires, online focus group interview questions, Web sites, etc., after instrument is available for review online.

D. Describe any audio or video recordings or photographs, if any, to be made during the study and how they will be used in degree program documents and future publications, professional presentations, exhibitions, other.
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None used in this research collection

E. Describe how you will report the data and to whom (e.g., dissertation / thesis / culminating project presentation and report, future journal articles, future professional presentations, other). Thesis, also possible future journal article

12. Informed Consent. A. Describe how and when you will present the informed consent form to participants and obtain assent (children) / consent (e.g., public presentation, regular mail, or email, at interview, when distribute survey).

An informed consent form used for interviews with experts will be presented upon initial contact and will explain the purpose of the interview as well as how the information will be used. The researcher will be able to approve or deny specific portions of the interview, or review the content for accuracy or revision and will sign a post interview release form. A copy of the informed consent form is attached.

B. State how you will answer questions about the study (e.g., telephone, e-mails, face-to-face discussions, when present consent form before interview, or when distribute surveys).

Face-to-face discussions with experts based on an interview form. See attached.

C. Describe your informed consent process for children under the age of 18, for participants with mental or physical disabilities, or for participants who speak a language other than English. None required.

D. How will you ensure that children give their assent freely with no influence from parents/guardians or coercion from a teacher/instructor or other authority figure? None required.

E. Will you prepare a separate consent form for the use of audio or videotapes, photography, or other media and for public release of real names and photos? If yes, describe it and submit with the appropriate form.

None required.

F. Describe how will you ensure that the participant—child or disabled person—also consents to participate (to the extent that he or she is able to give consent) if a participant’s parent, guardian, or legal representative must sign a consent form? None required.

G. Provide appropriate forms and explain how authorizations / permissions will be obtained from participants if the Health Insurance Portability and Accountability Act (HIPAA) and the Privacy Rule applies to your study; (e.g., typically in hospital or other health facility settings when collecting personal health information (PHI)).
None required.

13. **Expected benefits.** A. Describe potential benefits (may benefit, not will benefit) for participants (if none, state none).

This research synthesis will benefit integrative medical treatment plans for chronic illness patients.

B. Describe potential benefits (may benefit, not will benefit) for the larger community (e.g., knowledge gained from study, possible implementation of new curriculum; contribution to the literature on the topic).

This research synthesis will provide integrative medical treatment plans for chronic illness patients while reducing the mythology of Traditional Chinese Medicine.

14. **Potential risks.** A. Describe all potential risks to participants (physical, social, cultural, emotional (includes embarrassment), psychological, legal, etc.). No risks to participants as there are no participants.

B. Describe precautions to minimize risks (e.g., number codes, pseudonyms). None required for this study.

C. Describe procedures used to provide data protection in the event of an unanticipated event (e.g., computer crash, loss of confidentiality). Utilizing back up resources in cloud storage as well as back up drives.

D. Explain how you will handle situations in which a participant becomes emotionally upset or angry when responding to sensitive interview or survey questions (e.g., stop the interview, offer to refer participant to an affordable, no-cost, or full-service counseling service at the participant’s expense).

None required for this research.

15. **Risk-to-Benefit Ratio.** Evaluate potential risk(s) in relation to expected benefits to participants and others. Benefits must outweigh risk.

The benefits outweigh the risks since no risks were noted.