Treatment of Raynaud's Phenomenon with Acupuncture and Chinese Herbal Medicine: Two Case Studies

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Abstract

Objective: This clinical trial of two case studies aims to evaluate the intervention of acupuncture and Chinese herbs on the quantity, quality, and duration of painful episodes associated with Raynaud's Phenomenon. **Hypothesis**: The intervention of properly derived protocols of acupuncture and herbal medicine will decrease pain and increase quality of life for the recipients of these treatments. **Methods:** Two study participants with diagnoses of Raynaud's Phenomenon by a Western-trained licensed doctor, were subjected to 8 weeks of once-per-week acupuncture treatments and daily doses of Chinese Herbs. Both subjects had painful episodes in the hands daily. **Measuring outcomes:** Patients used a Raynaud's Condition Score based on a Numerical Rating Scale of the following -- specific number of painful episodes per day; the duration of these painful episodes, the intensity & quality of the pain/discomfort (scale of 0 -10), and an overall daily condition score based upon the subjective disruption in their daily well-being that the episodes caused them.

Results: Patient overall Condition Scores went from 1.1 - 3.14 pre-treatment to 0 - 1 at one week post treatment and a reduction in intensity of pain of any episodes of average 1.7 - 3.3 to 0 - 1. Additionally, the number of weekly painful episodes, decreased gradually for both and went from an average of 11.5 per week, to 1.5 per week. The physician also noted palpable and visual signs of coldness in the hands during the first 3 treatment sessions (due to temperature of the clinic, both subjects explained), but, no coldness was felt after that. **Conclusion:** This study

shows that acupuncture and Chinese herbs are possibly suitable effective interventions of the painful symptoms of Raynaud's Phenomenon. These results could suggest the validity of an exploration with a large patient cohort, long-term monitoring, and treatment program as the focus of future investigations of this type of treatment for Raynaud's patients.

Keywords: Raynaud's Acupuncture, Acupuncture herbal medicine Raynaud's, Chinese herbs Raynaud's Phenomenon, Raynaud's Disease Syndrome, Chinese Medicine Raynaud's

Introduction

Raynaud's Phenomenon, also known as Raynaud's Disease or Syndrome [3,4], is a painful and, unfortunately, fairly common condition in which the body extremities, most often the fingers/hands or toes/feet, get unusually and extremely cold (so cold that there is pain that is sometimes extreme) and lack the ability to warm back up in a normal timeframe. It has been defined in the Western vernacular as intermittent vasospastic attacks of the acra, mainly of the hands, that can be triggered by cold, fear, or other emotions that trigger the sympathetic nervous system. [1] The body parts can turn white or blue in response to a slight decrease in air temperature or reaching into a refrigerator without or even with gloves (see figure 1). These normal everyday events, for those afflicted, can turn into an "episode" of severe pain that can last for minutes or hours until the blood vessels (presumed spastic) can open and resume normal or near normal blood flow again to warm the tissue. [2,3]

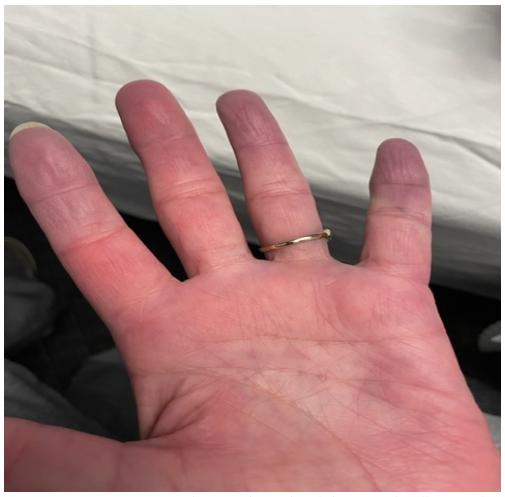

Figure 1. Case #2 shows hand with purple fingertips after being exposed to the waiting room temperature of approximately 73 degrees Fahrenheit for 2-3 minutes.

Prior to conducting this clinical trial, I happened upon two patients who exhibited conventional Raynaud's Phenomenon symptoms of either the hands or feet with daily painful episodes of cold. One had been triggered by a first episode of damp feet out in the cold for several hours. The

other, had a combination of possible damage to hands by consistent usage of machinery along with exposure to cold without proper gloves or gear. Both had insurance for acupuncture treatment, however, both were denied coverage because of lack of American research studies that warranted the efficacy of acupuncture for their conditions – even with a Western diagnosis of Raynaud's and referral from a DO or MD for acupuncture treatment, later, there continued to be no willingness to pay for the treatments.

Insurance commonly pays for addictive opioids or nifedipine – which warms the hands and can lessen the pain of episodes by 70-90%. [1] However, it commonly causes bloating, swelling of the face, rapid weight gain, tremors in feet and hands, and painful muscle spasms elsewhere in the body. [1,4]

It is estimated that anywhere from 5-20% of the adult population suffers from some type of Raynaud's Phenomenon. [3,4,7] Hence, if Traditional Chinese Medicine (TCM) could help many sufferers of Raynaud's get back to work, lead more normal lives, and get their insurance claims paid for, that was ample motivation for the study.

Literature Review

History

A French physician, Maurice Raynaud, first described this ailment in the Western Medical literature in 1862 in his doctoral thesis. He described it as a spasm of the small arterioles and presented 25 patients with cold and discolored digits. He explained that in most with this vascular problem, the oxygen rich pathways of the blood are closed down in response to cold or other types of physical stress (simple fatigue is a strong enough stressor and commonly causes many to suffer painful episodes at the end of every day) [3]. It was also noted that, though, not as commonly, people suffer from PEs in their feet, nipples, ears, and even tongue. [3,4]

In the Eastern Medical literature Raynaud's symptoms, "frigid" extremities with other commonly accompanying GI symptoms, was described at least as early as one of the oldest of the Chinese Medical texts, the Shang Han Lun or Treatise on Cold Damage Disorders, published at the end of the Han Dynasty around 220 AD. Bensky cites the Shang Han Lun's indications for use of Si Ni San (Frigid Extremities Powder) as, "extremely cold fingers and toes while the body and head are relatively warm and can be accompanied by irritability, fullness in the chest and epigastrium, and abdominal discomfort". Many of the additional correlating symptoms, mentioned in the Bensky text, are found in the Raynaud's patients presented here. [5] This "pattern" of disease is distinguished clearly from the entire limb being cold or the body being cold. In fact, the body is most definitely warmer than the hands, with trapped yang qi (warmth) in the body [6]. Using the word "frigid" in the name of the formula suggests an extreme and unusual type of cold in the digits – an abnormal type. Interestingly, the Western medical texts do not mention GI symptoms associated with Raynaud's as the Eastern texts do. In this physician's limited experience, 4 of 4

Raynaud's patients presented with GI symptoms accompanying their conventional Raynaud's hands or feet symptoms.

Commonly, the resolution of these painful episodes happens within 15 – 90 minutes when the affected tissue warms up and the capillaries open allowing normal blood flow to resume.

The Western perspective

Raynaud's Phenomenon (RP) has two distinct types in the Western medical vernacular: Primary Raynaud's, which often occurs first in a person's 20s or 30s or even late teens, affects women more frequently than men [4] and has no correlation with another medical condition or trauma. In other words, the cause is deemed idiopathic. This is thought, by some, to be the most common type (which depends on the varying definitions of the primary and secondary definitions, as well). It can be mild enough that the patient never seeks treatment and can be resolved on its own or it can be so severe as to completely debilitate the patient, keeping them from the majority of normal activities. [2,4]

Secondary Raynaud's is caused by an underlying medical condition, or by a trigger of sorts. Some consider this a less common form of RP and a more serious condition, while others contend it has similar intensity and triggers to PEs as that of Primary RP. It is reported to first appear later in life at around the age of 40. [2,7].

According to the John Hopkins Medical University, experts do not know why some have such severe reactions to cold and call it a medical mystery. However, there are some correlations observed that are helping to form a picture [3].

Some of the causes of secondary RP are thought to be:

- **Connective tissue diseases** – e.g., rare diseases that harden the skin and other organs of the body like scleroderma have secondary RP as a symptom of their primary disease.
- **Diseases of the arteries** – plaque in the blood vessels can cause the hands and feet to become inflamed such as atherosclerosis and Buerger's disease.

- **Carpal tunnel syndrome** – which induces pressure on the major medial nerve to the hand that causes numbness and pain making the hand much more susceptible to cold temperatures.
- **Repetitive action** or repeating exposure to vibration (repeating small traumas) – typing, operating vibrating tools like jackhammers, piano playing, and the like can cause injuries of overuse rendering the functioning of the small blood vessels of the hands compromised.
- **Injuries/trauma** to hands or feet (or other extremities) such as frostbite or fractures and even many surgeries can be a trigger to RP.
- **Medications** – these can include beta blockers, migraine medications with ergotamine or sumatriptan, certain chemotherapy, ADHD, and other drugs that cause blood vessels to narrow like nicotine (smoking) and OTC cold medicines. {2,4] Please see "Discussion" for other medications that this author posits may contribute to secondary Raynaud's via the GI tract. [2,4]

Some Risk Factors for Primary and Secondary RP are thought to be:

- **Gender**. It is stated that RP affects more women than men. (It may be clearer to state that more women than men *report* the symptoms of Raynaud's to their doctors. Two of the three men the author has treated had never reported their symptoms to their Western doctors. When asked why, one said it was because they read up on the disease and realized there was nothing that could be done for it besides pain pills. The other stated he was embarrassed to complain of cold feet, regardless of having endured painful episodes each evening).

- **Climate**. The disorder is more common in people who live in colder climates. (Some people report enduring severe cold without proper protection as the trigger for the onset of RP).
- **Family history**. A parent, child, or sibling having the disease appears to increase the risk of Primary Raynaud's
- **Smoking/nicotine and other medications** / chemicals (appearing in the causation list)
- The **occupations** that include exposure to substances or activities as mentioned above [2,4,7]
- **Associated diseases** that include
    - Connective tissue medical conditions e.g., scleroderma
    - Lupus
    - Rheumatoid arthritis
    - Sjögren's syndrome
    - Atherosclerosis
    - Carpel Tunnel [4]

Western Diagnosis: RP is generally diagnosed by a Western doctor's observation of color changes and patient history and description of difficulties. A cold challenge test may be given wherein the hands are dipped in ice water or otherwise exposed to cold in order for the color changes to be observed. Because of its painful consequences, and the fact that often just an air-conditioned office is enough to observe color changes, this is not often done anymore. If your Western doctor is convinced you have RP, then tests for underlying associated diseases, if not done already, will likely be ordered e.g., lupus or other connective tissue disorders.[3,4]

Western Treatment: According to John Hopkins Medical Center, there is no cure for Raynaud's, but, managing it is crucial. Treatment may include the aforementioned and/or winter month blood pressure medication to encourage the arterioles in the fingers to stay dilated [4]. Additionally, Viagra or Sildenafil (generic) is being utilized as a therapy for some [8]. The complications of Sildenafil for men are obvious and daily ingestion of the drug and its long-term effects have not yet been thoroughly studied. Along with prolonged erections and priapism, acute side effects, already known, that can severely disrupt daily life, are heartburn, body flushes, and vision changes (temporary blindness). These make it difficult for many Raynaud's patients to utilize Sildenafil's benefits. Moreover, it is already known that permanent erectile dysfunction and permanent ocular dysfunction can occur from daily use [8,9].

Furthermore, a Western physician may also advise patients to –

- Avoid cold
- Quit smoking
- Keep warm with gloves, socks, scarf, and hat (even wearing these to bed)
- Keep home temperature higher
- Avoid trauma or vibrations of the hand (e.g., typing or using vibrating tools)
- Some people report PEs being triggered by daily stresses, and for those, relaxation techniques will be recommended [4,6]

It should be noted that complications of Raynaud's Phenomenon are very rare, but, diminished blood circulation to any body part can result in tissue damage. A completely blocked artery can lead to skin ulcers or necrotic tissue resulting in gangrene. Untreated persons could require amputation of the affected body part [3].

The TCM or Eastern Perspective

General Symptoms and Theory. TCM diagnosis is made, traditionally, by four methods: Observation (in skin, eyes, tongue), Smell, Touch (temperature, changes in tissue, pulse), and in the asking of questions or Interrogation [10]. In TCM, there are "patterns" of illness rather than "diseases". There may be many patterns that cause cold hands in TCM, but, there is only one diagnostic pattern that accounts for all of the major symptoms of RP and the majority of the minor symptoms in the two case subjects discussed here. [10,11] This pattern is mentioned in "Discussion of Cold Damage", by Zhang Zhong-Jing (c. 220 AD) as "Frigid extremities due to yang qi constrained in the interior" [6].

The condition is further described as the patient having cold fingers (and/or toes) while the body is warm (not necessarily warmer than is normal, subjectively or observationally, but, not cold and painful like the fingers and/or toes). This pattern may be accompanied by the symptoms of irritableness, fullness in the chest and/or epigastrium, cough, urinary difficulty, abdominal pain, a red tongue (showing the heat in the interior) with possible yellow coating (intense heat) and a wiry pulse at the level of the liver (in Oriental medicine practice, there are many pulse positions that correspond to organs of the body) indicating a disharmony of the liver [5].

Yang is equivalent to warmth and Qi construed as breath/energy/life-force – thus, when the literature speaks of yang qi constrained, it is stating that the body is having trouble distributing the warmth in the torso as far as the extremities [5]. So, interestingly, while the Western perspective might focus on the hands' or fingers' malfunctioning arterioles, the Eastern perspective belays the 'disharmony' to the body's internal mechanism that regulates the qi and

moves the body's heat to all of its parts. In TCM, the liver dominates the largest influence over Qi distribution and a wiry characteristic to the pulse indicates that the liver is in disharmony or constrained. Furthermore, TCM theory holds that when the spleen/stomach are strong (not dampened by certain foods and lifestyle habits), the liver is "soothed", so to speak, and no longer prone to stagnating qi that can form trapped heat in the middle of the body – thus, keeping it from getting it to the extremities [11].

Diagnosis: Therefore, the diagnosis of "Frigid Extremities due to Yang Qi Constrained in the Interior" would rely upon the confirming following -- if it were observed that the patient had discolored fingers or toes from temperatures that do not cause such in other people; if they expressed that they had pain and cold in the extremities only, on a regular basis, from temperatures considered normal by most others; they had a red tongue, and a wiry pulse; subjectively and observationally their extremities were cold, but, their torso felt warm, this would be enough for a diagnosis of this pattern. If additionally, there were GI or other symptoms as described above, this would further confirm the pattern. [5]

Treatment: It follows that, it is important to choose the TCM methods in acupuncture and herbology that will treat this pattern by focusing on the following treatment goals –

The treatment must -- *vent pathogenic qi, release the constraint holding the yang qi captive, spread the liver qi and regulate (strengthen) the spleen.*

Therefore, careful selection of acupuncture points that accomplish these treatment goals should be chosen. The American lifestyle is conducive to weekly treatments, so we conducted acupuncture treatments once per week. Additionally, herbs that complement the mechanisms of the acupuncture treatment that also vent, release the warmth/yang, move liver qi and fortify the digestion with spleen enhancing herbs are chosen for daily consumption, morning, noon, and

evening. The correct formula for accomplishing the treatment goals here is Si Ni San or Frigid Extremities Powder. For convenience, we chose prepared granules, offering a 5:1 ratio for making an instant type of tea for ingestion of the herbal medicine. Raw herbs, boiled daily to make a decoction for sipping throughout the day are the inconvenient, traditional way to prepare medicinal herbs. If there is time, the freshness could enhance the medicinal qualities.

Two Case Studies –

Case Study 1

Age & Gender: 71 years old male 1st treatment: January 31, 2022

Chief Complaint: Painful episodes (PEs) of frigid hands at least once per day and limiting of daily activities because of triggers.

Medical History: He reported that over the past 20 + years, approximately since the year 2000, he was having an average of two painful episodes daily, running from 45 – 120 minutes in duration before subsiding, with a subjective pain/numbing/tingling score of 3 - 5 out of 10 (0 - 10 with 10 being the worst). He could not remember what happened immediately previously to the painful episodes, nor any trauma, medication, or stress that could have been a trigger to the condition's onset.

Exam findings/Additional symptoms: His hands were cool to the touch, but, his arms warm. He did not desire a blanket during treatment, but, did request to put his hands next to his body under the sheet. He was pale with very pale fingers. He reported his body was warm and his stomach did feel warm to the touch. He showed signs of irritability during the question-and-answer period and when it was mentioned, he explained that he did not sleep well the night before, though, normally he slept "ok". His diagnosis of Raynaud's came in a report from a previous doctor with a list of other diagnoses – chronic fatigue, chronic allergic rhinitis, hypothyroidism, and diverticulosis with a prediabetic state. When asked about the diverticulosis, he explained colonics and a high-fiber diet mostly kept the constipation and bloating at bay, but, admitted intermittent constipation still. The patient reported his energy was not great and was observationally with low energy and slept quickly and soundly upon treatment. His secondary complaint was the chronic rhinitis, and it could be heard in the voice and the breathing. He had a

slight non-productive cough throughout the exam. The patient slept during treatment with his mouth open and upon re-entering the room, a smell like that of undigested food and alcohol was perceived. The patient states that he mostly eats a strictly vegan diet.

His tongue: red and deeper red on the sides with purple spots on the sides. The tongue had cracks in the middle and a thin white coat with a slight tinge of yellow in the middle.
His pulse: liver pulse was simultaneously wiry and choppy, and his heart pulse was irregularly irregular. The spleen position was soggy and soft. The pulse, overall, was forceful.
After his first treatment his hands were noticeably warmer to the touch. He stated he felt like something had changed.
Week 2 – During this second week of treatment he stated that he was taking very cold showers, daily, as was his custom, and always seemed to have a PE afterward, but, noticed that they didn't hurt as much, his pain scores were down.
Week 3 – Pain scores still lowering, but, duration times are about the same. Patient notes, "It's hard to explain, but, it feels like there is improvement". He explains that he may not be paying enough attention to when an episode ends, because it is so much less intense. The duration scores may have been lower than noted, he stated.
Week 4 – Pain intensity scores drop significantly from 1.65 to just a value of 1
Week 5 – Slight improvement in pain, duration, but, number of episodes increased. He offered that his house seemed colder than usual that week.
Week 6 – Pain level scores dropped almost by a full point, the number of episodes per week dropped by 5 – almost by 1 per day and his weekly average of overall disruption diminishes to

0.1 (he started using fractions to indicate pain levels of episodes). He states on his notes, "having trouble recognizing if I am even having an episode".

Week 7 – He rates his overall condition/disruption score so low that his weekly average is 0 and has only 3 episodes that week, with low to 0 pain. I asked him if he is still taking cold showers and he answers in the affirmative.

Week 8 – The patient is remaining low on pain, overall condition numbers (0.5 or less), and lowest of all in duration – 12.2 minutes down from a 25-minute average the week prior, but, jumped up to 9 episodes. He explains in his notes that he turned the AC in his house down. He was asked to keep it at the same temperature it had been all of the last 7 weeks at least until the two post-treatment weeks were up.

Post treatment week 1 – the patient scored a 0 in all categories. This was despite the fact that he plunged his hands in ice water on April 3, 2022, for one minute. He explained that after having no episodes for several days he wanted to test it

During our completion interview, the following week, he stated that he felt, still, significantly better, even though episodes came back after turning his AC down to 72 degrees Fahrenheit. He did jump from 0 back up to 30 minutes in his average duration for the 3 PEs he had, but, still, he reported, the pain was at a minute level.

Case Study 2

Age & Gender: 79 year old female 1st treatment: March 15, 2022

Main Complaint: Cold and painful episodes in the hands at least one time per day.

Medical History: The patient reported that since approximately the age of 55 (24 years), immediately following an upper GI side effect from a drug used in the treatment of osteoporosis, (a biophosphonate causing irritation of the esophagus) she began having an average of two painful episodes of Raynaud's symptoms daily. These ran from 5 – 90 minutes in duration before subsiding. She said the pain was always at pain level scores of 1-4. Her hands were pink, with the exception of the center of her palms – white – and the tips of her fingers were blue/purple. She stated that they looked like this 100% of the time (see figure 1).

She restricted her diet to the small list of foods that didn't cause almost immediate gas, reflux symptoms (GERDS), and/or vomiting and was also a strict vegan. She stated that when her hands got "very bad" they often went completely numb and she could experience no feeling at all. She said it was hard at first to fill out the Raynaud's Condition Score [12] as her hands were cold 24/7, but, realized that they were not always painful, especially when she stayed home all day in her a warm house and did not need to go into her freezer for any foods. Gloves went on before opening the refrigerator, too. Her worst event in the two weeks prior to treatment was March 13, 2022, which had a daytime temperature range from 60 – 73 degrees Fahrenheit and she had to be outside several times. When the subject had been diagnosed with Osteoporosis and put on Biophosphonates she remembered her simple all over feeling of cold (she ran cold since she could remember) abruptly went to her hands and began to cause her PEs. She was diagnosed with Raynaud's and then, scleroderma, several years later. However, after a decade of no other symptoms of Scleroderma (besides RP) and tests of the internal organs showing signs of

sclerosis all being negative for over a decade, (and absence of sclerotic dermal tissue) the diagnosis of scleroderma was questionable. [13]

Exam: In the treatment room on the first day, she expressed that the cool temperature of the clinic was enough to trigger a PE and her hands were beginning to hurt.

As the treatment commenced, I put a sheet over her hands -- they were icy cold to the touch, though her arms felt warm. I offered a blanket for over her hands and entire body that she accepted. She reported feeling bloated wondering aloud if it was due to the oatmeal she had eaten earlier. Other than her symptoms of cold fingers/hands and digestion issues, she reported nothing notable, and this physician found nothing else remarkable. The patient claimed an otherwise very healthy 79 years of life.

Her tongue: red with deeper red on the sides, slightly medium to thin white coat.

Her pulse: Wiry in the Liver position, but, overall normal.

Post 1st Treatment -- She claimed to have warm hands for the first time in a very long time. Her hands were warm to the touch as I pulled the needles out (she said the following week in her notes that they remained warm through the night).

Week 2 – Though much remained the same, the duration of her PEs dropped slightly from over 22 minutes to 16.9 minutes

Week 3 – Her pain level average dropped below 1.0 and her notes stated, “I don’t need the extra blanket that I normally use [at night] and I don’t even have to put my hands under the covers anymore since the first treatment”. Additionally, she reported that one of her PEs, for the first time, was “tingling only”.

Week 4 – all numbers have decreased, and her overall condition/disruption score is under 0.5 for the first time since her PEs began.

Week 5 – She had 3 days in a row with no episodes while her pain level average jumped back up to 1.0.

Week 6 – most numbers remain stable, but, her overall condition score and number of episodes rose slightly. She explained that she'd had an unusually difficult day -- she had gone to a theatre for over 2 hours and had not prepared for the unusually cold temperature.

Week 7 – She ventured to a museum one day and a very cold lecture hall, another day with no significant increase in numbers from the previous week and noted that her hands stayed a normal pink color.

Week 8 – She had 5 days with no episodes and only when she ventured to a cold mall did she suffer a pain level of over 1.0.

Week 1 Post Treatment – Her number of episodes remained low at 3.0. Her duration average of the PEs is 8.3 minutes (formerly, an average of over 22 minutes) and overall condition score remained below 0.5.

During our completion interview, one week later and 2 weeks post treatment, subject #2 handed me a hand-written list of items comparing her life before and after treatment -- she thought these should be included in this discussion – they could be important measurements, she felt, that are, perhaps, not quantifiable by the Raynaud's Condition Score alone – [12]

- When she used to go to a museum, market, theatre, mall or any venue with typically cold air-conditioning, her fingers were blue and white the entire time. Since treatment, the fingers stay pink/normal in color.

- Before treatment, handling cold and frozen foods would cause her fingers to turn white, right away, and since then it is significantly less. They often remain pink/normal
- At bedtime, now, her thermostat is set at 74 – 76 degrees Fahrenheit for comfort, whereas previous to treatment, it was never set below 81 F.
- Daytime thermostat: Now she sets it at 75-76 F to keep her hands comfortable and prior to treatment, for over 20 years, she set it to at least 78 F or higher.
- Playing Mah-Jongg at a friend's house every week, she noticed that before treatment she required a sweater and gloves every afternoon. Now, she states that she never needs the gloves and uses her sweater less than ½ the time she is there. She claims to have needed the gloves in order to play – her fingers were too numb to feel the tiles and couldn't pick them up or hold them securely.

Materials and Methods of Treatment

Inclusions/Exclusions:

- We included ages 18 – no upper age limit, both male and female, as well as, both primary and secondary type Raynaud's.
- We excluded only smokers (because of the vascular effects of nicotine), as well as those on any type of vascular medication, bedridden or otherwise seriously ill, and those without a Western medical diagnosis of Raynaud's, Raynaud's Phenomenon, Raynaud's Disease or Syndrome.

- Materials for treatments used were identical for both patients:
    - 13 mm x .18 mm , 25 mm x .22 mm, and 40 mm x .25 sterile, single use, stainless steel acupuncture needles w/silicone coating (Millennia brand)
    - Si Ni San (Frigid Extremities Powder) by Evergreen, 3 grams as tea in 8 oz of warm water, 3 x per day (total of 9 grams per day) ingredients:
        - Gan Cao (radix and rhizome of Glycyrrhizae) 25%
        - Zhi Shi (fructus aurantia immaturus) 25%
        - Chai Hu (radix bupleuri) 25%
        - Bai Shao (Radix Paeoniae Alba) 25% [5]

- Methods used for treatments were identical for both patients:
    - Acupuncture – 8 weeks of weekly treatments lasting a total of 45-50 minutes with 10-15 minutes of talking and inputting needles and 30 minutes of retaining

needles in the following Acupuncture Points (see details of selection in Discussion):

- Ba Xie
- Heart 1
- Large Intestine 4, and 11
- Liver 3
- Lung 9
- San Jiao 5
- Stomach 36
- Kidney 3
- Pericardium 6
- Spleen 6
- Auricular points: Shen Men and Liver [14]

- The Medicinal Herbal Formula was taken daily, instructed to take 3 grams of the powder, 3x per day in an 8 oz glass of warm water, during the treatment period of 8 weeks. It is important to note here that Subject 2 misunderstood instructions (or forgot) and took only 1 gram, three times per day with a total of just 3 grams per day.
- Daily Recording – Raynaud's Condition Score Assessment.[12] The participants of this study recorded their symptoms in detail at the end of each day during the 8-week treatment period, and two weeks prior to treatment and 2 weeks after treatment, in the following manner:
  - Their daily number of PEs

- The duration of each of those PEs
- Their 0 - 10 intensity scores (pain, numbness, or tingling)
- And their daily overall Condition Score as a culmination of the above – e.g., if they had 1 short 5-minute episode with a pain intensity of 1, their condition score would be assessed at 1/10 – a minor inconvenience or disruption of their life and detractor for their overall well-being that day. If they had 3 long episodes that were very painful – 4/10, they may assess their daily condition score at a 3-5.

Results

Table 1. Assessment before and after treatment

	Pre-Treatment		*TREATMENT PERIOD (8 weeks)*								*Post Treatment*	
Weeks	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Number of Painful Episodes, Weekly												
Case 1	**10**	**13**	**10**	**9**	**11**	**6**	**9**	**4**	**3**	**9**	**0**	**3**
Case 2	**10**	**10**	**10**	**6**	**7**	**6**	**3**	**5**	**5**	**2**	**3**	**4**
Average Duration of Weekly Painful Episodes in Minutes												
Case 1	**70**	**58.1**	**45.5**	**32.8**	**29.5**	**28.3**	**26.1**	**28.75**	**25**	**12.2**	**0**	**30**
Case 2	**19.2**	**22.4**	**16.9**	**18.5**	**15.1**	**16**	**16**	**14**	**16**	**17.2**	**8.3**	**24**
Pain/Discomfort Levels on Scale of 0 -10 for each Painful Episode, Weekly Average												
Case 1	**3.3**	**2.85**	**2.2**	**1.8**	**1.65**	**1**	**0.94**	**0.14**	**0.4**	**0.51**	**0**	**0.5**
Case 2	**2.6**	**1.7**	**2.2**	**1.3**	**0.9**	**0.8**	**1**	**1**	**1**	**1.5**	**1**	**1**
Condition/Disruption of Life Score, Weekly Average												
Case 1	**3.3**	**3.14**	**2.29**	**2.29**	**2.29**	**0.79**	**0.39**	**0.1**	**0**	**0.45**	**0**	**0.21**
Case 2	**2.5**	**1.1**	**2.2**	**0.9**	**0.7**	**0.43**	**0.29**	**0.7**	**0.7**	**0.4**	**0.4**	**1**

Table 1. Data was collected per the Raynaud's Condition Score [12]

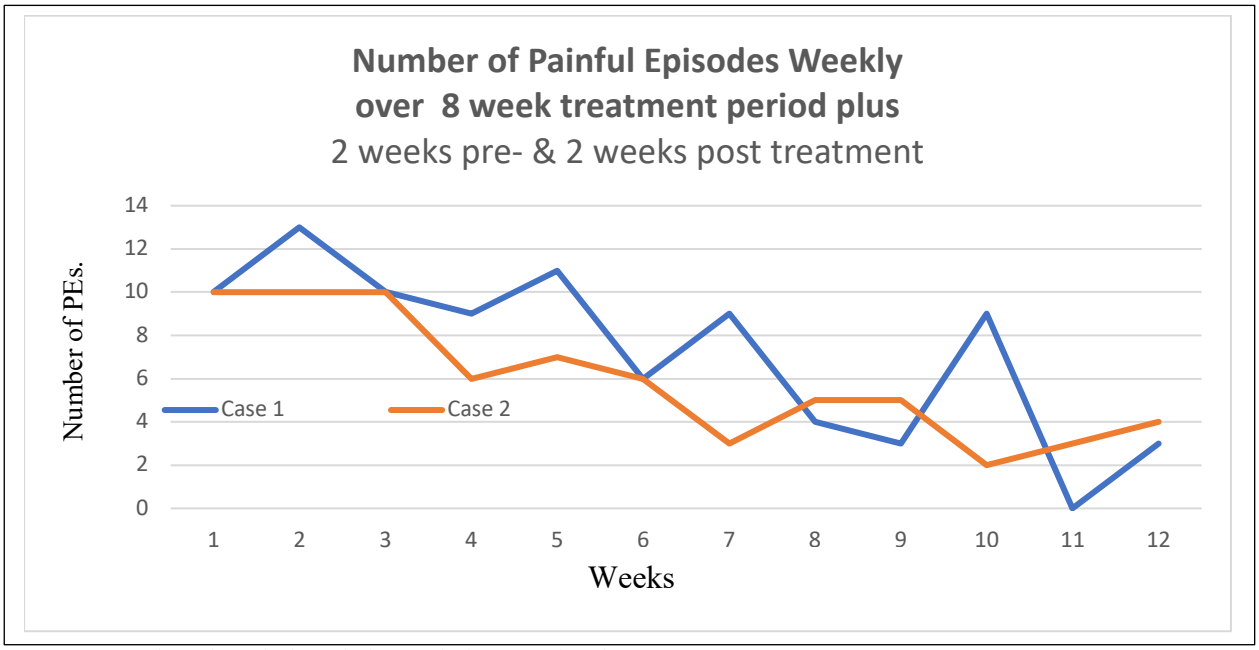

Figure 2. Number of PEs before, during, and after 8 weeks of treatments

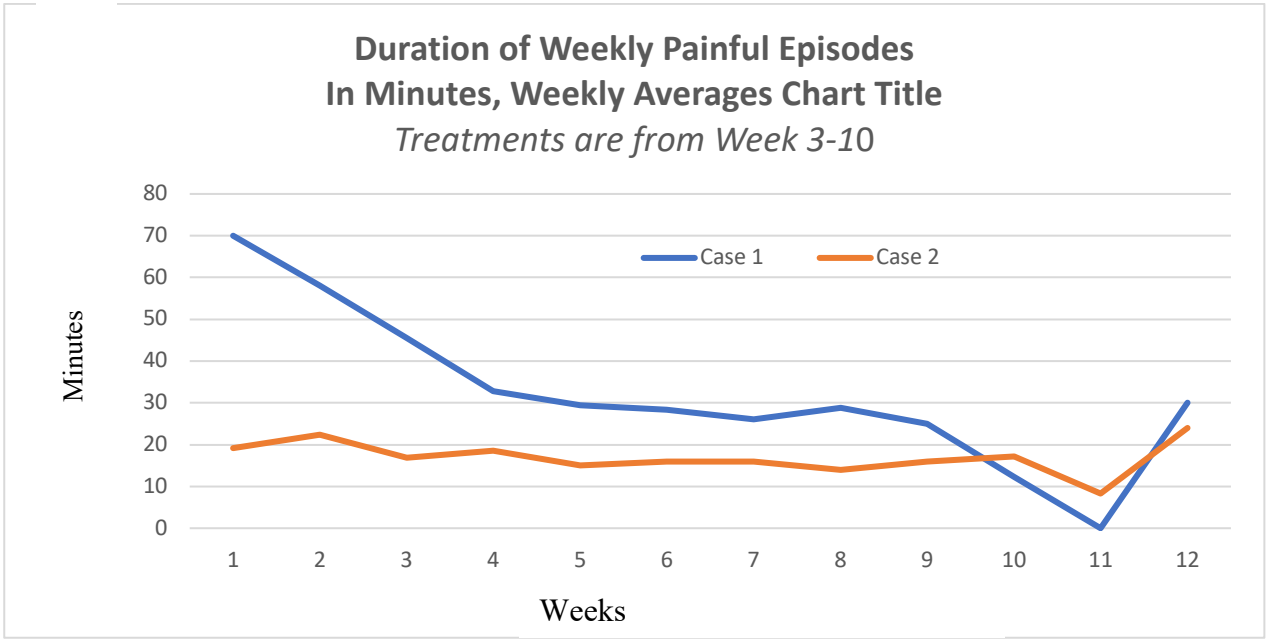

Figure 3. Duration of PEs before, during, and after 8 weeks of treatments

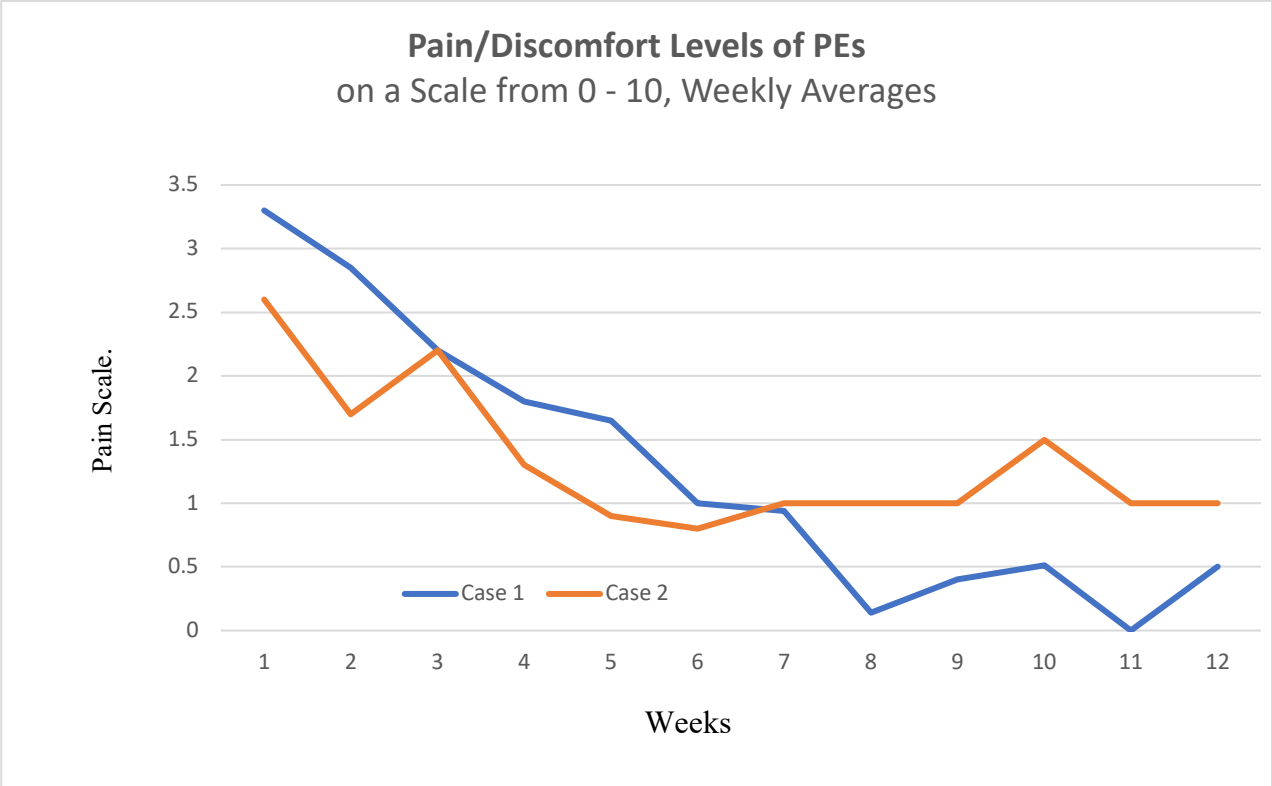

Figure 4. Pain level of PEs before, during and after 8 weeks of treatments

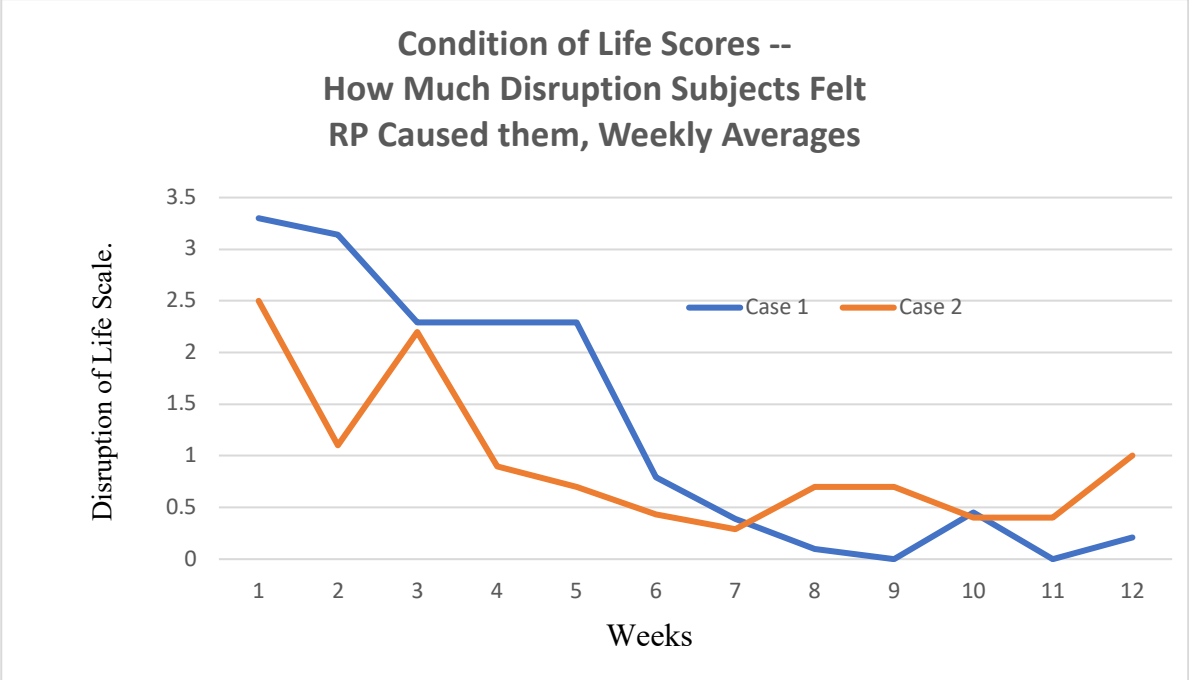

Figure 5. Daily Disruption of Life before, during and after 8 weeks of treatments

The charts in figures 2-5 were created by plotting the data found in table 1. The downward trends of all criteria of the Raynaud's Condition Score [12] are readily perceived in the 1) pain intensity, 2) the number of painful events and 3) the duration of those events each day and then the 4) overall disruption of their lives that RP causes them.

Figure 2 shows both subjects recording, prior to treatment, an average of 10 or more PEs each week or approximately well over 1 episode per day. Gradually, both patients found that during the course of their treatments the number of times per day that they were spending in pain decreased.

In figure 3 it is evident that Case #1 also had a significant gradual decrease in the average number of minutes each of those PEs lasted, along with the lowering number of PEs experienced. Case #2 did not respond in the same manner – while experiencing less daily/weekly PEs, the duration of those PEs was a very gentle if not slight curve downward, but, not as significant as that of Case #1.

Figure 4 reveals a steep downward trend for both subjects, during the course of treatment, in their pain level averages of the PEs. It is important to note that the lines on this chart from week 7 on may be misleading due to misinterpretation of instructions or lack of thoroughly thought-out detail on the part of the designer of the instructions for data entry. Though it appears that at week 7 Case #2 plateaued at approximately level 1 on the pain scale– while Case #1 continued his downward trend at and after week 7 -- Case #1 had taken it upon himself to begin recording fractions of the pain level #1 (e.g., 0.5, 0.25 and even 0.15) while Case #2 explained that she felt

0 was the only number she could write that would be lower than a number one. Thus, if she experienced any pain or tingling/numbness at all, whether it was less than her previous PEs with notations of "1", even if closer to a "0", she would write a number one in her daily record scores rather than a zero, she explained.

In figure 5 we see a significant trend toward the decrease of the perceived disruption that RP has on their lives as the treatment commenced and concluded.

Discussion

In this small study, significant pain reduction and a decrease in the number of painful episodes were observed. The study's hypothesis, that the intervention of properly derived protocols of acupuncture and Chinese herbal medicine would subjectively decrease pain and disruption of life scores of the subjects with RP, has been confirmed.

The significance of this study and its achievements are most likely due, not only to the important compliance of the subjects, but, to the strict adherence to the principals of diagnosing with traditional Chinese medical theory. Additionally, following through with a carefully designed protocol of acupuncture points and herbs that adhere to those same principals in treatment goals completes the successful intervention. Thus, it is important to examine the theory behind the selection of those points and herbs --

- **Acupuncture Point selections explained –** all points were selected for either their local proximity for assistance to the hands/fingers or their ability to fulfill the treatment goals *of venting pathogenic qi, releasing the constraint, spreading the liver qi and regulating (strengthening) the spleen***:**
    - Ba Xie or 8 Pathogens – this is a set of 8 points in the web of the fingers for any kind of numbness, spasm or pathology that has an effect on the fingers
    - Ji Quan or Highest Spring (aka Heart 1) – this is used for any kind of blockage/ pain in the arm. From a Western perspective, the location, the center of the axilla on the medial side of the axillary artery, is home to the brachial plexus which is responsible for sending signals from the spinal cord through the arm to the hand.

This point was chosen for that specific reason – strengthening that nerve tract and removing blockages from this area is of the utmost importance.

- Qu Chi or Pool at the bend (Large Intestine 11) is employed for its ability to move heat (constrained yang/qi) from anywhere in the body. It is also for specific motor impairment of the fingers or upper extremities and a bonus is that it helps to harmonize the intestines for any abdominal or intestinal blockages.
- He Gu or Junction Valley (Large Intestine 4) is on the dorsum of the hand between the 1st and 2nd metacarpal bones, on the radial side, approximately in the middle of the 2nd metacarpal. Among its many uses, any weakness, blockage or motor impairment of the entire limb, abdominal disharmony or constipation, and just about any spasm or stiffness in the arm/hand/fingers can be relieved by He Gu.
- Tai Chong or Supreme Surge (Liver 3) – It is located between the first and second metatarsals in the hollow and the main function of this point is to spread liver qi. It is touted as the main point to sedate liver yang meaning that it gets the free flow of energy back to the middle body and releases any constraint. In fact, its 'surge' was often be felt by the subjects as a swift movement up the anterior portion of the lower leg. In combination with He Gu, it is called the "4 gates" used for accelerating the free flow of qi throughout the body.
- Tai Yuan or Great Abyss (Lung 9) – the main function this point was used for its ability to promote blood circulation to the extremities and its secondary indirect function of governing the blood vessels via the heart.

- Wai Guan or Outer Pass (San Jiao 5) – the location is approximately 2 inches proximal to the dorsal crease of the wrist between the radius and ulna. This point dissipates inflammation, pain, and any type of motor problem from the elbow to the tips of the fingers.
- Zu San Li or Leg 3 Li (Stomach 36) – This is the premiere point for strengthening stomach, spleen, and the entire digestive tract while harmonizing the intestine and dispersing stagnation in particular. It is located approximately 2.5 – 4 inches in the hollow medial to the tibia.
- Tai Xi or Great Canyon (Kidney 3) is located in the depression between the tip of the malleolus on the medial side of the leg and the Achilles tendon. This is a master point of the body for overall strengthening and endurance. The intention is that if the body isn't strong enough to push through the stagnation getting the warm yang to the extremities, this will assist with its power.
- Nei Guan or Inner Pass (Pericardium 6) Located approximately two inches above the transverse crease of the wrist between the tendons of m. palmaris longus and m. flexor carpi radialis, this point, well-known by coastal persons for its placement on seasick bracelets, not only harmonizes the stomach and strengthens all things digestive, it calms irritability and removes blockages causing contracture and/or pain from the elbow to the fingertips.
- San Yin Jiao or Three Yin (organs) Intersection (Spleen 6) – located approximately 3 inches above the tip of the medial malleolus, this is located on a point that intersects the Spleen and Liver and Kidney meridians. It is used for strengthening the spleen/stomach, spreading Liver qi and harmonizing all three

with the additional benefit of strengthening the kidney for further enhancement of the liver and digestive systems.

  - Auricular points: Shen Men for calming the nervous system and liver for stimulating the vagus nerve, as well as, strengthening and soothing the liver qi mechanism.[14]

- **The actions of the herbs in the medicinal herbal formula explained:**
  - **The condition** for which this formula is indicated is due primarily to stagnation and constraint of the qi mechanism, so, its focus is to regulate the qi by venting the yang/heat that the constraint has caused and releasing the constraint at the same time.
  - Chai Hu (radix bupleuri) 25% of the formula, is considered the chief herb because it both vents the heat and releases constraint as its main functions. According to the "Explanation of the Classic Materia Medica", this herb ascends and spreads out the gallbladder and liver qi and when this happens, the other 12 organs follow its lead and do likewise. So, in this way it is able to disperse any kind of stagnated qi in the epigastrium, abdomen, stomach and intestines.
  - Zhi Shi (fructus aurantia immaturus) 25% of the formula, is considered the deputy in this medicinal formula. Its main function is to break up and drain stagnant qi and reduce accumulation in the middle of the body. In this way it restores the transportive and transformative function of the stomach and spleen thereby resulting in a healthier qi-regulating function and smooth dispersion of heat due to the constraint.

- Bai Shao (Paeoniae Radix alba) is the assistant and is also 25% of the formula. It nourishes the liver and preserves the yin (yin can be thought of as cool water in opposition to the harsh heat and dryness of yang).
- Gan Cao (radix and rhizome of Glycyrrhizae), the last 25% of the formula is known as a harmonizer of the other herbs in a formula, as well as, a strengthener of spleen which naturally curbs the liver's pathologies. As the formula's envoy, especially in combination with Bai Shao, it moderates any pain or spasm in the body. [5,15]

Thus, if the diagnosis was indeed correct, then choosing the above carefully selected protocol and administering it properly, the treatment would remove the constraint responsible for the pattern of disharmony. The reduction of the constraint and disharmony, as described, would naturally result in the diminishing of pain in both occurrence and intensity. Only a larger cohort study and one of longer duration can tell us if the decrease would continue until a total remission might be possible.

This study may have also warranted a new look at this pattern, with its GI symptoms, noted as far back as 2000 years ago. Western-trained medical eye, as well. This study was, of course, much too small to know what percentage of Raynaud's patients may have digestive issues matching the TCM pattern treated, herein.

Additionally, there may be no coincidence that two of the 4 herbs of this formula, together craft a classic formula: Shao Yao Gan Cao Tang (Radix Paeoniae Alba – Bai Shao/Shao Yao, and Glycyrrizae – Gan Cao). Cao Tang. This medicinal formula is

prescribed in order to 'soften the liver' (removing constraint), nourish the blood and move blood, and to remove cramping and pain -- spasm. [15] Hence, the base of this formula is also treating the Western mechanistic theory of circulatory difficulties existing with spasm (of the arterioles). We are left to wonder if this treatment would work on those with no GI symptoms, if there are, indeed, RP patients without such. Or, perhaps, this formula and some of the acupuncture points selected simply increased the circulation – affording additional oxygen-carrying blood to the nerves/muscles of the arterioles – thereby improving performance of the small, peripheral blood vessels of the fingers.

It is, as we explored, significant to the TCM texts that this history of digestive issues exists in both subjects. The participants are on very restrictive whole food-type diets – diets that, to a large degree, would follow the prescription from a TCM point of view (with the exception of excluding animal protein) because of the lack of dampening foods: dairy, processed sugary foods, and deep-fried foods. TCM theory holds that dampening the digestion weakens the very mechanism that keeps the liver in check and bolsters its qi delivery system (which includes circulation and kinetic/thermal energy). [11] It would seem they were following some lifestyle choices with food that, from a TCM theory base, would quell their symptoms to some degree. However, it appears from the results, they needed the intervention of acupuncture and/or herbs (in addition to food therapy) to go further to decrease their pattern and thus, pain, further.

While Case #1 states that any antagonist to the onset of his RP symptoms is unknown and presumptively had "idiopathic Raynaud's", there have been digestive issues, possibly as

enduring as the Raynaud's symptoms which causes him to, at least, presently, follow the TCM pattern of disharmony [5]. Additionally, he has a mild hypothyroid case that presently, he claims, comes and goes and was not correlated with the onset of the Raynaud's symptoms. His Western Physician was not specific in the type of Raynaud's he presented with when it was documented. He could not remember if he had ever taken any medication for his thyroid condition, including any immunosuppressant drugs.

Subject #2 had always been aware that the occurrence of her consumption of biophosphonates and their esophageal side effects concurred with the onset of Raynaud's, but, never knew there was any possible explanation to the connection to make it more than a likely coincidence. Only in the Chinese medical theory is there a correlation to and explanation of this Western drug and her "frigid extremities" – which came first, however, is another mystery. It could be that the Liver Qi constraint and disharmony of liver/stomach/spleen left her vulnerable to the esophageal irritation from the bisphosphonates or, perhaps, the drugs caused the liver/digestive organ disharmony, causing the GERDS like "rebellious qi" symptoms, irritating her esophagus, and left her predisposed to Raynaud's. The second most common side effect of the biophosphonates is another one experienced by subject #2 and that is osteonecrosis of the jaw [16]. In TCM, healthy bones are mainly sustained by healthy kidneys [10,11). Utilizing Chinese theory, this group of drugs, then, may damage the liver and kidney qi – this equates to the Western perspective that advises prudent, continual, monitoring of liver and kidney function for many of its oft otherwise, helpful, drugs [17,18].

Case #2 did state that her digestive issues, GERDS-type symptoms and bloating, did seem to be quelled whilst taking the Si Ni San. She has since, requested, as a private patient, to go back on the herbal medicine for a time.

Another observation begging the fusion of Western and Eastern perspectives was also brought to light during this study:

In Oriental medical theory, the force of the body that fights off our pathogens, our external immune system, is considered to be Wei Qi in the Oriental medical system. This is a type of active, superficial, Yang Qi that circulates externally to protect the invasion of pathogens. If one were to 'suppress' the activity of this (thus, suppressing a great deal of yang qi), as immunosuppressant drugs do – and many are utilized in the Raynaud's correlating auto-immune diseases – it could result in RP/TCM's "frigid extremities". It is logical to posit that the treatment/the immunosuppressants, rather than the disease, is perhaps responsible for the correlating pathology of RP.

Moreover, a look at the major role the gastrointestinal tract plays in the human immune system, and the mechanism of action in the common immunosuppressant drug, begs the uniting of East and West perspective into this sub-group of Raynaud's patients taking immunosuppressant drugs. In addition to bacterial overgrowth commonly causing vomiting and diarrhea, immunosuppressed patients suffer other major digestive disturbances as their most common side effect. According to an article in the British Journal of Medicine, multiple are the effects of immunosuppression drugs on the GI tract and include: enteritis, reduced mucosal integrity and mucosal regeneration, and

suppression or complete loss of gastric acid secretion. [19] Clearly, these patients, having multiple digestive disharmonies, also fall into the ancient (Shang Han Lun's) pattern of Raynaud's.

Hopefully, studying these relationships in diseases and patterns, Western and Eastern medical theory, can open a wider window to look from -- from an integrative East-West viewpoint, evaluating pharmaceuticals, medicinal herbal formulas, lifestyle therapies, surgeries with adjunctive or alternative acupuncture, might result in a remission for some, better remediation for all, or even prevention of RP altogether.

Limitations of this study are many and some are obvious, e.g., the short period of time and small number of participants of the study. It is also important to note that nobody can live in a constant temperature which would give the most standardized baseline and certainly make researching a pathology founded upon subjective responses to temperature more accurate. Results may have been different if the subjects had not continually ventured out to museums, restaurants, friends' homes (to live t, and other places where air-conditioned spaces, all, much colder than their own homes. This is why the author chose weekly averages for data and instructed patients to attempt not to live in any way differently – no changing habits of lifestyle – during the 12-week period of the trial. Along this line, it is important to mention that outdoor temperatures increased during their 12-week periods. Southeast Florida is not known for its seasonal extremes like other parts of the country, but, still, the outdoor temperatures do increase with more mid-

80 averages vs mid-to high 70s averages during the time that the data was being taken. On the other hand, it is worthy of noting that 1) neither of the subjects spend a significant time outside their own homes, nor outdoors, and 2) public air-conditioned spaces tend to run cooler as the temperatures warm up outside, in Southeast Florida.

Another limitation of the study is that it leaves us with a big unknown: how much of any positive effect was due to the acupuncture intervention and how much due to the intervention of the herbal medicine? As we saw in the earlier part of this discussion, herbs and acupuncture points are chosen for their parallel mechanisms. It is through clinical practice that we, TCM physicians, may take for granted that the two approaches magnify positive results. But, separating the two modes of treatment may shed light on new information that could benefit the patient further.

Certainly, additionally, the subjectivity of the data is not considered the most reliable. Though we could objectively see the purple fingertips of Case #2's hands when triggered by a 72 F lobby, and objectively feel the temperature of the hands before and after treatments, the data collected from patients was 100% subjective. Of course, one needs to also note that one would think most people would not subject themselves to the effort of treatment, dozens of needles inserted into them weekly, and less than tasteful herbal medicine if it weren't benefitting them.

This author is aware that a pain level dropping from around a 3 down to between 0-1 and a weekly average of approximately 10 down to 2.5 may not seem significant enough, but,

subjectivity seems to be everything when it comes to any individual's reporting of their quality of life. Both subjects, when asked in a completion interview to quantify their level of benefit on a scale of 0 -10 with a 10 being "cured" and 0 being no change, stated 8 was their score and both would recommend the treatment to others with Raynaud's.

While the participants report being pleased with the results of their efforts and TCM's approach to their ailment, it is possible that they may have had even better outcomes had they been of less mature ages – if we had started treatment immediately after the onset -- and had had this treatment prior to several decades of these symptoms. It is also very possible that had the design been one that utilized the gamut of Chinese medicine with its mandates for individualizing and customizing treatments for each individual, it would have resulted in even better results for both subjects.

It is indeed the belief of this Physician that the individualized, along with the multi-modal approach, may prove to be the zenith of medicine. So, while utilizing the best and least invasive, when possible, of Western medicine, Eastern medicine, and *all* other evidence-based complementary and alternative methods, we may, indeed, be closer to the goal of providing a wholistic (whole meaning not *just* Eastern and not *just* Western but, all of medicine) for the very best outcomes for the modern patient of Raynaud's Phenomenon.

Conclusion

The treatment methods in this study were well tolerated with 0 side effects, and the pain intensity, quality and quantity of the episodes were decreased to a significant enough degree to cause the patients to state that their quality of life, subjectively, was much better than before treatment. The use of Chinese medicine could be an effective alternative to pain medication and vascular dilating drugs in the treatment of primary and secondary Raynaud's Phenomenon. With the use of acupuncture and medicinal herbal medicine, this treatment style utilizes a noninvasive and natural route for remedying the painful episodes (PEs) that occur with this disease.

Subsequent follow-up studies with larger patient groups and with longer-term follow-ups are necessary and warranted. Of course, then, these results on pain relief must be replicated and evaluated to determine their true effectiveness.

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Appendix

Appendix A – IRB application approval page

Appendix B -- Consent and Acknowledgement forms Case 1

Appendix C – Consent and Acknowledgement forms Case 2

Appendix D – Instructions for collection of data and raw data