

The Effects of Traditional Chinese Medicine on Type 2 Diabetes:
A Literature Review Synthesis

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By

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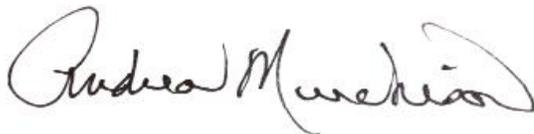
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Abstract

Type 2 diabetes is a chronic metabolic disease that has a significant impact on health, quality of life and life expectancy of patients. It is, by far, the most commonly occurring disorder of the endocrine system in all populations and all age groups. Chinese medicine has been treating diabetes for thousands of years and even though it has been documented in Chinese medical classics, there is a void of documented modern medical studies. The purpose of this study was to gather a consensus on the effectiveness of TCM via recently published scientifically relevant studies. In this research synthesis, 20 studies were reviewed pertaining to the use of Chinese single herbs, Chinese herbal formulas and acupuncture in the treatment of type 2 diabetes. Though there were a number of studies done on the efficacy of single herbs and herbal formulas on blood glucose levels and HgA1c percentages, there is certainly a paucity of studies done on the effects of acupuncture. Further research should be conducted in order to validate the connection between acupuncture and its effect on type 2 diabetes.

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Chapter One: Introduction

Background

Diabetes mellitus type 2 is a metabolic disorder that is characterized by high blood glucose in the context of insulin resistance and relative insulin deficiency. It is by far the most commonly occurring disorder of the endocrine system in all populations and all age groups (Kumar et al., 2005).

In a study published in 2010, the Centers for Disease Control (CDC Journal, 2010), projected that as many as 1 in 3 U.S. adults could have diabetes by 2050 if current trends continue. Type 2 diabetes accounts for 90-95% of diabetes cases. Risk factors include obesity, a sedentary lifestyle, and family history. Diabetes is the 7th leading cause of death in the U.S. (CDC Journal, 2011). Diabetes costs \$174 billion annually, including \$116 billion in direct medical expenses (Eckman et al., 2012).

Once known as 'adult onset' diabetes, type 2 diabetes is increasingly being diagnosed in young people (SEARCH Study Group, August 2004). SEARCH for Diabetes in Youth investigators found that overall the prevalence of type 2 diabetes had increased 21% among American youth from 2000-2009.

Diagnosis and treatment of this common but complex endocrinologic disorder continues to pose a challenge for health care practitioners. Patients treated for type 2 diabetes can encounter additional health complications, especially cardiovascular heart disease and hypertension, eye problems, kidney disease, nervous disease, periodontal disease, amputation, fatigue, depression and complications during pregnancy (Eckman et al., 2012). In order to manage diabetes, it is essential for people to make healthy

lifestyle choices in diet, exercise and other health habits. It is also important to create a support team, which includes the primary care doctor, endocrinologist, dietitian and a licensed acupuncturist.

Acupuncture and Chinese herbal medicine have been used for over 2000 years to treat diabetes (Dharmananda, 2002). Chinese doctors have long recognized the clinical manifestations of diabetes mellitus as a specific disorder under the name *Xiao Ke*, wasting and thirsting disease. References in the *Nei Jing*, the pre-eminent classic of Chinese Medicine, to wasting and thirsting disease are scattered through 14 books of this classic, which discuss its disease causes and mechanisms, clinical manifestations and treatment (Flaws, Kuchinski & Casanas, 2002).

In China, acupuncture is used in conjunction with Western drugs to treat diabetes. The combination helps reduce pharmaceutical medication dosages and reduces the side effects. Acupuncture aims to optimize the body's ability to function normally. Clinical and experimental studies have demonstrated that acupuncture has a beneficial effect on lowering serum glucose levels (Covington, 2001).

Objectives of the Study

The objective of this project was to establish the effects of Traditional Chinese Medicine on type 2 diabetes mellitus (type 2 diabetes) with a focus on the effects of acupuncture. According to TCM, diabetes is caused by an imbalance of the cyclical flow of Qi within the meridians and organ systems (Flaws, Kuchinski & Casanas 2002). This particular imbalance produces heat that depletes the body's fluids and Qi causing symptoms such as fatigue, polydipsia, polyuria, polyphagia, peripheral neuropathy and

poor wound healing. TCM offers a way to address each patient individually, to eliminate the symptoms associated with diabetes and reduce the need for insulin. Working in conjunction with their primary health care provider and their acupuncturist may help diabetic patients to balance not only the side effects of the disease but also those of the medications that they are on. The results of this study will hopefully bring awareness to not only other patients with type 2 diabetes, who may not be aware of the benefits of acupuncture, but to the community and public at large. In the United States, acupuncture is best known as an alternative therapy for pain management. This study will prove to the community that not only is acupuncture effective in treating diabetes, but also in preventing and managing complications of the disease.

This study will proceed with a list of relevant terms and their definitions to close out chapter one. Chapter Two will constitute the literature review, which will establish the theoretical foundation for the current study. Chapter Three will summarize the method engaged in this study, and Chapter Four will present the results. Finally, Chapter Five will include a discussion that will engage the implications of the findings of the current study.

Glossary of Relevant Terms

- **Achathosis Nigricans:** (AN) is a skin condition that causes one or more areas of the skin to darken and thicken in body folds and creases (Habif, T. 2009). AN can be a sign of pre-diabetes, which increases the risk of getting diabetes (Hermanns-Le et al., 2004).
- **Blood sugar concentration or blood glucose levels:** the amount of glucose present in the blood of a human or animal. The normal blood glucose level

(tested while fasting) for non-diabetes, should be between 70 and 100 milligrams per deciliter (mg/dL). The blood glucose target range for diabetics should be 90-130 (mg/dL) before meals and less than 180 (mg/dL) after meals (Davidson et al., 2011).

- **Diabetes:** is a group of metabolic diseases in which a person has high blood sugar, either because the pancreas does not produce enough insulin or because cells do not respond to the insulin that is produced (Shoback, 2011).
- **Diabetic cardiomyopathy:** a disorder of the heart muscle in people with diabetes. It increases the risk of heart failure in individuals with diabetes, independently of co-existing ischemic heart disease, hypertension or other macrovascular complications (Voulgari et al., 2010).
- **Diabetic ketoacidosis:** (DKA) is an acute life-threatening complication of diabetes that occurs mainly in patients with type 1 diabetes, but is not uncommon in patients with type 2 diabetes (Raghavan, V. 2013).
- **Diabetic peripheral neuropathy:** nerve damage caused by chronically high blood sugar levels from diabetes. It leads to numbness, loss of sensation and sometimes pain in the feet, legs or hands. It is the most common complication of diabetes (Dansinger, 2013.)
- **Diabetic retinopathy:** damage to the retina caused by complications of diabetes, which can eventually lead to blindness. It can affect upto 80 percent of all patients who have had diabetes for 10 years or more (Kertes et al., 2007).
- **Gestational Diabetes:** a condition in which women without previously diagnosed diabetes mellitus exhibit high blood glucose levels or any degree of

glucose intolerance that is first recognized during pregnancy. This condition occurs in approximately 4 percent of all pregnancies (Stoppler, M. 2013).

- **HgA1c:** glycosylated hemoglobin, is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over prolonged periods of time. In diabetes mellitus, higher amounts of HgA1c has been associated with cardiovascular disease, nephropathy and retinopathy (Larsen et al., 1990).
- **Hyperosmola nonketotic coma:** a life-threatening complication occurring in people with diabetes (McCoy, K. 2013), in which high blood sugars cause severe dehydration. It affects predominately patients with type 2 diabetes, and is usually precipitated by an infection (Stoner, G. 2005), myocardial infarction, stroke or another acute illness.
- **letrogenesis:** Preventable harm resulting from medical treatment or advice to patients. It refers to “any unintended and untoward consequence of well-intended healthcare interventions” (Francis, D. 2005).
- **Insulin:** a hormone that facilitates the transport of blood sugar (glucose) from the bloodstream into cells throughout the body for use as a fuel (Weil, 2014).
- **Insulin resistance:** a physiological condition in which cells fail to respond to the normal actions of the hormone insulin. The body produces insulin but the usual actions of insulin are not mediated (Mandal. 2014). Insulin resistance can be linked to diabetes, hypertension and cardiovascular disease (Rao, 2001).
- **Polydipsia:** a form of excessive (Porth, C. 1990), or abnormal thirst, characteristically found in diabetics, often as one of the initial symptoms.

- **Polyphagia:** or hyperphagia, refers to excessive hunger or increased appetite (Berthoud et al., 2011). It is one of the main signs of diabetes.
- **Polyuria:** a condition where the body urinates more than usual and passes excessive or abnormally large amounts of urine each time one urinates, more than 3 liters a day in adults (Bhandari, S. 2013). It is one of the main symptoms of diabetes.
- **Type 1 diabetes:** also known as T1DM, formerly insulin dependent diabetes or juvenile diabetes. A form of diabetes mellitus that results from the autoimmune destruction of the insulin producing beta cells in the pancreas. The subsequent lack of insulin leads to increased blood and urine glucose (Cooke, 2008).
- **Type 2 diabetes:** formerly noninsulin-dependent diabetes mellitus (NIDDM) or adult onset diabetes is a metabolic disorder that is characterized by high glucose in the context of insulin resistance and relative insulin deficiency (Kumar et al., 2005).

Chapter Two: Literature Review

Overview

The literature review for the current study was conducted primarily using the on-line data base of the resources of the Yo San University Library. Additional searches were performed at the University of California Library at Los Angeles. Finally, several face-to-face interviews were conducted with seasoned Traditional Chinese and western medicine practitioners who have considerable experience in treating type 2 diabetes.

This literature review chapter will commence by providing perspectives regarding the types of diabetes and tests of diabetes. Those sections will be followed by consideration of the history of diabetes and Chinese medicine perspectives regarding diabetes. The use of acupuncture points, including ear points as well as nutritional factors will also be engaged. The chapter will end with a brief literature review integration section that sums up the prior literature and makes a case for the current study.

Types of Diabetes

There are 3 main forms of diabetes (Stoppler, 2012). Type 1 results from the body's failure to produce insulin, usually referred to as insulin dependent diabetes or juvenile diabetes. Type 2 results from insulin resistance, in which cells fail to use insulin properly. This is known as non-insulin dependent diabetes or adult onset diabetes. Gestational diabetes occurs when pregnant women without a previous diagnosis of diabetes develop a high blood sugar level. It may precede development of Type 2 diabetes.

Untreated diabetes can cause many complications (Tang 2009). Acute complications include diabetic ketoacidosis and nonketotic hyperosmolar coma. Serious long-term complications include cardiovascular disease, chronic renal failure and diabetic retinopathy. Adequate treatment of diabetes is very important, as well as lifestyle changes that include proper diet and exercise, stop smoking and maintain a healthy body weight.

Type 2 Diabetes

Type 2 diabetes is the most common form of diabetes. Ninety percent of all patients diagnosed with diabetes have type 2. As of 2010 there are approximately 285 million people with the disease compared to around 30 million in 1985 (Smyth, Heron 2006). Long-term complications from high blood sugar can include heart disease, strokes, diabetic retinopathy where eyesight is affected, kidney failure that may require dialysis and poor circulation of limbs leading to amputations. The acute complication of ketoacidosis, a feature of type 1 diabetes, is uncommon (Fasanmade, Odeniyi & Ogbera, 2008).

Type 2 diabetes can have a slow onset, and early symptoms can be confused with signs of stress, being overweight or a poor diet. It is known as a silent killer because of its easy - to - miss symptoms (Collazo-Clavell, 2013). The best way to pick up on it is a blood, test but some of the common symptoms are:

- Increased urination and excessive thirst. These two symptoms go hand in hand and are the body's ways of trying to manage high blood sugar.
- Weight loss. Overly high blood sugar levels can cause rapid weight loss, about 10-20 pounds over a two to three month period. Since the insulin hormone is not

able to get insulin to the cells, the body starts breaking down protein from the muscles as an alternate source of fuel. With the kidneys working overtime to eliminate the excess sugar, this then creates a further loss of calories.

- Hunger. This can come from sharp peaks and lows in blood sugar levels.
- Itchy Skin. Perhaps the result of poor circulation. Acanthosis nigricans is also another sign of diabetes.
- Slow healing.
- Yeast infections.
- Fatigue and irritability
- Blurry vision. This symptom is reversible once blood sugar levels are returned to normal or near normal.
- Tingling or numbness in hands and feet. If the symptoms are recent, they are likely to be reversible (Collazo-Clavell, 2013).

Tests for Diabetes

Several blood tests are used to check for diabetes, but a single test result is never enough on its own. According to the World Health Organization (World Health Organization report, 2007) patients should be told they have diabetes if:

- Blood sugar levels as measured by a fasting plasma glucose test are equal to or greater than 126 mg/dL.
- Diabetes symptoms exist and glucose levels measured at random are equal to or greater than 200 mg/dL.
- Glucose is equal to or greater than 200 mg/dL during an oral glucose tolerance test.

The American Diabetes Association (American Diabetes Association, 2010) also suggests that if test results indicate diabetes, testing should be repeated on a different day to confirm the diagnosis. If a random blood test has found glucose equal to 200 mg/dL or above, the confirming test used should be a fasting plasma glucose or an oral glucose tolerance test.

The development of type 2 diabetes is caused by a combination of lifestyle and genetic factors (Riserus, Willett & Hu 2009). While diet and obesity can be controlled, other factors such as increasing age, female gender and genetics are not (Williams textbook of Endocrinology, 12th ed). The effect of sleep on metabolism has also been linked to type 2 diabetes (Touma & Pannian 2011). A poor intrauterine environment can also result in an increased predisposition to obesity and diabetes in offspring that can transfer from daughters to granddaughters across generations (Nathanielsz, 1999).

Treatment for Type 2 diabetes requires a life-long commitment to:

- Blood sugar monitoring
- Healthy diet
- Regular exercise
- Possibly diabetes medication or insulin therapy

According to the Mayo Foundation for Medical Education and Research, the amount of sugar in blood can change unpredictably. They suggest that patients with diabetes enlist the help of a diabetes treatment team that can help teach them the causes of these fluctuations. Some of the causes for blood sugar fluctuations can be:

- Food. What and how much
- Physical activity

- Medications
- Illness
- Alcohol
- Stress
- For women, fluctuations in hormone levels

Some patients with type 2 diabetes can manage their blood sugar with diet and exercise alone, but many need medications. Often patients who are newly diagnosed are prescribed metformin (Glucophage & Glumetza), a medication that improves the body tissues' sensitivity to insulin and lowers glucose production in the liver. When metformin is not enough to control the glucose levels, other oral or injected medications can be added.

History

Diabetes is one of the first diseases described (Ripoli & Leutholtz, 2011) 3000 years ago by the ancient Egyptians (Ahmed 2002), mentioning “too great emptying of the urine” (Poretsky, 2009). Indian physicians around the same time identified the disease and classified it as *madhumeha* or ‘honey urine’ (Poretsky, 2009). The term “diabetes” or “to pass through” was first created by Aretus of Cappadocia, 81-133 AD (Ahmed 2002). Later the word “mellitus” was added by Thomas Willis in England in 1675 after rediscovering the sweetness of urine of patients, first noticed by doctors in India (Ahmed 2002).

In 1776, Matthew Dobson confirmed that the sweet taste of urine of diabetics was due to excess of a kind of sugar in the urine and blood. It was in 1857 in France, that Claude Bernard established the role of the liver in glycogenesis and the concept

that diabetes is due to excess glucose production. The role of the pancreas in pathogenesis of diabetes was discovered by Mering and Minkowski in Austria in 1889 . This discovery then constituted the basis of insulin isolation and clinical use by Banting and Best in Canada in 1921 (Ahmed 2002).

Chinese Medicine and Diabetes

Chinese Medicine has been treating diabetes for thousands of years. Called *Xiao-Ke*, or “wasting and thirsting disease” (Flaws, Kuchinski & Casanas, 2002), it was first described in one of the oldest books about Chinese medical theory. The *Nei Jing* states that diabetes occurs typically among wealthy people: “You ask them to refrain from a rich diet, advice which they may resist.” This description fits Type 2 diabetes (Joswick, 2013).

The studying and understanding of wasting and thirsting spanned a period of 2000 years of recorded medical history in China (Zhang et al., 2010). The process of understanding, identification and naming of wasting and thirsting, as represented by *The Yellow Emperor’s Classic of Internal Medicine (Huang Di Nei Jing)*, 475 B.C. – 8 A.D. (Warring States Period – Western Han Dynasty); the documentation of wasting and thirsting as represented by *Treatise on Febrile and Miscellaneous Disease (Shang Han Za Bing Lun)*, 9 A.D.-280 A.D. (Eastern Han Dynasty-Three Kingdoms); the understanding of “sweet urine” and its documentation in *Ancient and Modern Proved Formulae (Gu Jin Lu Yan Fang)*, 265 A.D.-1368 A.D. (West Jin Dynasty-Yuan Dynasty); and the connection between wasting and thirsting and diabetes as represented in *The Integration of Traditional Chinese Medicine and Western Medicine (Yi Xue Zhong*

Zhong Can Xi Lu), 1368 A.D.- 1949 A.D. (Ming Dynasty – Republic of China) (Zhang et al., 2010).

The Yellow Emperor’s Classic of Internal Medicine records symptoms of “three increases and one decrease,” i.e. polydipsia, polyuria and polyphagia and weight loss (Zhang et al., 2010, pg 42). Around 2000 years ago, upon identifying the onset of primary symptoms, diabetes was then diagnosed as *xiao-ke* (Zhang et al., 2010). After wasting and thirsting was classified as a disease, the development, diagnosis and treatment were elaborated in this book. Twenty-five entries on wasting and thirsting were recorded in this book, which included the name *Xiao-ke*, symptoms (three increases, one decrease and complications), pathogens (obesity, greasy foods), pathologies (yin-yang theory, five elements), therapies (acupuncture, herbs), health-care (diet control), diagnosis (pulse-taking) (Gao, 2002).

In *Shang Han Za Bing Lun*, Zhong Jing Zhang gave a detailed account on wasting and thirsting, *Golden Chamber, Wasting-Thirst (Jin Kui Yao Lue, Xiao Ke)*. Nine sub-sections and nine formulas on wasting-thirst were recorded in this book and in *Treatise on Febrile Diseases (Shang Hun Lun)*, another book by this author (Zhang, et al., 2010). Hence, he has been identified and honored as the innovator of treating wasting and thirsting as a specific disease. His theory focused on relating wasting and thirsting to the upper, middle and lower *jiaos*. It later influenced doctors such as Wansu Liu (1120-1200 A.D.) who created the “theory of three wasting-thirsts”, and Ken Tang Wang (1549 A.D.-1613 A.D.) who presented his theory in *Standards of Diagnosis and Treatments (Zheng Zhi Zhun Sheng)* (Zhang et al., 2010).

In the Sui and Tang dynasties (581-907 A.D.), the diagnosis and treatment focused on markers (sweet urine), treatment, prevention, maintenance and diet (Zhang et al., 2010). “Sweet urine” was considered an important diagnostic symptom of wasting and thirsting in *Ancient and Modern Proved Formulae* written by Li Yan Zeng (545 A.D.-649 A.D.) This method of symptom diagnostics was noted by other doctors like Tao Wang in 752 A.D. in *The Secret Medical Essentials of a Provincial Governor*. In a case report, he identified sweet urine as an essential method of diagnosing diabetes (Dengben, 2004).

Sun Si Miao (581-682 A.D.) wrote two outstanding medical books (Zhang, et al., 2010), *Essential Prescriptions Worth a Thousand Gold* (Qian Jin Yao Fang, published in 652 A.D.) and *The Revision of Essential Prescriptions Worth a Thousand Gold* (Qian Jin Yi Fang, published in 682 A.D.). These books present the herbal and acupuncture treatments, as well as prevention, regulation and maintenance medicine (Zhang, 2006). By 682 A.D., the herbal formulas for wasting and thirsting disease had increased from one formula in *The Yellow Emperor’s Classic of Internal Medicine* to nine in Zhong Jing Zhang’s books and to 73 in Sun Si Miao’s books. The use of herbal remedies had grown from one herb, *Eupatorium Fortunei* (Pei Lan), to dozens of herbs by Zhong Jing Zhang, and to over 100 herbs used by Sun Si Miao, such as *Trichsanthes Radix* (Tian Hua Fen), *Ophiopogonis Radix* (Mai Dong), *Rehmanniae Radix* (Sheng Di Huang), *Coptidis Rhizoma* (Huang Lian), etc. (Zhang et al., 2010, pg 43).

In the Ming and Qing dynasties (1368-1911 A.D.) the development of Traditional Chinese Medicine slowed down (Zhang et al., 2010). However, work done on herbs and herbal formulas, as recorded in medical books, continued. Over 100

comprehensive medical studies were described during that time. Xichun Zhang (1860-1933 A.D.), a famous specialist in the integrative study on TCM and Western medicine wrote a book named *The Integration of Traditional Chinese Medicine and Western Medicine*. A chapter named “Xiao Ke Therapies,” discussed eight aspects correlating wasting and thirsting and diabetes (Zhang, et al., 2010). They are nomenclatures (disease names), theories (pathologies), primary formulas, (Yu Ye Fang and other formulas for diabetes), medications (herbology and pharmacology), nursing (remedy, food therapy and bland diet recommendations), medical cases (discussion with TCM and Western medicine), and integrated analysis (protein and essence, qi and fluids) (Lin, 2008). Yunxiu Yu and associates (1939) (Si, 2008; Hao, 2008) researched the history of diabetes and wasting and thirsting disease and wrote a book named *Discourses On the Name of Ancient Diseases* (Yu, 1953). Yu identified diabetes similar to the TCM concept of wasting and thirsting, because both TCM and Western medicine regarded diuresis as a symptom, “sweet urine” as a diagnosing marker, and greasy foods as pathogens, and their discussed complications were similar (Zhang et al., 2010).

According to TCM, dryness and heat leading to qi and yin vacuity, is the main disease mechanism of diabetes mellitus (Flaws et al., 2002). This dryness and heat may be due to “natural endowment exuberance” (Flaws et al., 2002, p. 24) or insufficiency, dietary irregularity, psycho-emotional stress, unregulated “stirring and stillness” (Flaws et al., 2002, p. 24) and unregulated sexual activity. Iatrogenesis and Gu worms could also be factors (Flaws et al., 2002).

Prof. Zhang Su Qing stresses an original yin depletion and vacuity as the main type of natural endowment insufficiency (Zhao et al., 2001). Some people are born with less yin than others. Bob Flaws in his book “The Treatment of Diabetes Mellitus with Chinese Medicine” says, “The act of living is the transformation of yin into yang and the consumption of yin by yang in the same way a candle’s flame transforms wax into light and also consumes that wax.” (Flaws, et al., p. 23). The *Nei Jing (Inner Classic)* says, “[By] 40 years, yin is automatically half.” (Flaws, et al., p.23). This statement helps explain why diabetes is primarily a condition associated with aging (Flaws et al., 2002). However, diabetes may also be associated with an inherent tendency to yang exuberance, commonly stomach yang exuberance. People with stomach yang exuberance develop large appetites and tend to overeat. If overeating leads to gaining weight and developing adipose tissue, that adipose tissue aggravates internal heat (Flaws et al., 2002). In addition, people with yang exuberance also tend to overwork and over a period of their lives, fail to conserve their qi and yin, thus damaging and consuming both through over-taxation.

Irregular food intake in the form of over consumption of greasy, spicy and sweet foods and over consumption of alcohol, impairs the transportation and transformation functions of the Spleen and Stomach, which in turn generates internal heat. That generated heat consumes fluids thereby creating thirst and hunger. In the *Simple Questions*, (Su Wen), it is explained that “fat causes interior heat while sweetness causes fullness in the middle burner”. The qi therefore rises and overflows and the condition changes into that of wasting and thirsting (Choate, 1999).

Zhang Zi He (Congzheng) 1156-1228 A.D., in his book *Ru Men Shi Qin (A Confucian's Responsibility for One's Parents)*, "Treatise on the Three Wastings", says, "Wasting and thirsting...is produced by excessive consumption and chaos of the essence spirit (or psyche) and dryness, heat, depression and exuberance" (Flaws, et al., p. 22). This observation highlights the role that psycho-emotional stress plays as one of the contributory causes of diabetes.

Prolonged emotional stress and disturbance may contribute to wasting and thirsting by hindering the flow of qi. Over thinking and anxiety damages the Spleen, causing the qi to bind in the middle, while anger, resentment and frustration leads to constrained Liver qi. This constrained Liver qi transforms into fire, which in turn consumes the yin of the Lung and Stomach (Choate, 1999). A passage from the *Spiritual Axis* (Ling Shu) Chapter 2 says, "The five inner (yin) organs are soft and weak and prone to symptoms of wasting heat. When there is something soft and weak, there must be something hard and strong. Frequent anger is hard and strong and the soft and weak are thereby easily injured." (Choate 1999, p. 5).

In Chinese Medicine, "stirring" refers to any movement in the body, whether it is mental-emotional, verbal or physical (Flaws, et al., 2002). Since movement in the body is empowered by Qi, it is easy to over consume and damage the Qi with excessive stirring, thus, in turn, damaging the Spleen. "Stillness" is the absence of stirring (Flaws, et al., 2002 pg 23). As a cause of disease, it can refer to mental-emotional, verbal or physical inactivity. Since excessive sitting damages the Spleen, inactivity can cause or aggravate Spleen vacuity. Physical activity promotes the movement of qi, blood and fluids in the body. Hence, physical inactivity creates depression of qi and blood leading

to damp and phlegm accumulation and poor circulation due to blood stasis. “It is easy to see that, when it comes to stirring and stillness, too much or too little of either may contribute to the causation of diabetes mellitus” (Flaws et al., 2002, p. 23).

Excessive and unregulated sexual activity can lead to kidney qi and jing consumption and hence to heat in the lower *jiao*. This in turn leads to kidney yin deficiency. Wang Tao in his *Wai Tai Mi Yao (Secret Essentials of the External Platform)*, “Wasting and Thirsting and Middle Wasting,” says “Excessive bedroom affairs must result in kidney qi vacuity and consumption and the engenderment of heat in the lower burner. [This] heat leads to kidney dryness and kidney dryness leads to thirst.” (Flaws, et al., p.23). In sexual activity that leads to orgasm, qi and yang are both discharged and yin/ essence is consumed, leading to kidney qi and essence deficiency (Flaws, et al., 2002).

Sun Si Miao and Wang Tao, in their treatises written during the Tang dynasty, laid emphasis on the over use of longevity elixirs and tonics and their effect on the depletion of yin in the body, thus leading to wasting and thirst. In modern Western medicine, certain medications may cause or increase the incidence of diabetes. Certain diuretics and beta-blockers prescribed for lowering blood pressure can cause or aggravate diabetes, as can lithium, generally prescribed for bi-polar disorders, cause or aggravate nephropathy often associated with long term diabetes (Flaws et al., 2002).

Long term use of antibiotics and corticosteroids, such as prednisone, can damage the Spleen, according to the understanding and logic of Chinese medicine. This in turn leads to Spleen deficiency and the various complications associated with Spleen deficiency, such as turbid dampness or damp heat (Flaws et al., 2002).

According to Bob Flaws, “Corticosteroids are very upbearing and out-thrusting,” (Flaws et al., 2002, p. 24), hence their ability to reduce inflammation. Their ability to clear heat in the body works in the same way that exterior releasing herbs work, by releasing heat up and out of the body. However, they are very acrid, and in doing so they consume yin thus leading to yang exuberance. Over a period of time, since yin and yang are “mutually rooted,” (Flaws et al., 2002 p 24), this then leads to yin and yang deficiency accompanied with fire rising.

In this way, according to Chinese medicine, type 2 diabetes is the result of a number of factors, all of which lead to qi and yin deficiency with dryness and heat. When there is considerable dry heat, it consumes Lung fluid, thereby creating a dry mouth and thirst. The tongue is red and the pulse is rapid.

Heat in the Stomach and Spleen creates excessive hunger and appetite. Stomach Fire manifests as excessive hunger, bad breath and constipation. The tongue is red with a yellow coat and the pulse is rapid.

Overworking, prolonged stress or illness, excessive sexual activity and multiple pregnancies deplete essence, which in turn leads to Kidney Yin deficiency. Yin deficiency manifests as weight loss, frequent and copious urination, dizziness, blurred vision, sore back, itching and ulceration of the skin and vaginal itching. The tongue is red with little or no coat and the pulse is thin and rapid. Since, according to the principle that Kidney yin deficiency leads to Kidney yang deficiency, we then observe, in prolonged cases, *Xiao Ke* syndrome occurring when there is Kidney yang deficiency.

The focus of the treatment can be established by analyzing which of the three organs is the most yin deficient, Lung, Spleen or Kidney and by concentrating on

relieving deficiency heat from either the upper, middle or lower burner. The treatment for diabetes focuses on regulating the circulation of blood and Qi and balancing the organ systems to improve pancreatic function and address internal heat and the depletion of fluids (Sonmore, 2006.)

Common symptoms created by the depletion of body fluids and Qi are:

- Fatigue
- Lethargy
- Weight Loss
- Excessive thirst
- Excessive urination
- Excessive hunger
- Poor wound healing
- Infections
- Irritability
- Blurry vision

Scientific studies and clinical tests in international research centers in the past 10 years have shown that acupuncture can help diabetic patients in the following ways:

- Attenuate symptoms of polyphagia, polydipsia and polyuria
- Prevent slowing of motor nerve conduction
- Improve microcirculation and myocardial contractility
- Enhance blood outflow and regulate vascular peripheral resistance
- Induce secretion of endogenous beta-endorphin
- Obliterate atherosclerosis of the legs

Acupuncture Points for Diabetes

Chinese Acupuncture texts, both ancient and contemporary, have formulated over the ages, acupuncture points for the treatment of wasting and thirst. The Ming dynasty saw the publication of a multitude of books dealing with acupuncture and moxibustion formulas, a few of which are *Zhen Jiu Da Cheng (The Great Compendium of Acupuncture and Moxibustion)*, by Yang Ji Zhou, *Zhen Jiu Da Quan (The Great Collection of Acupuncture and Moxibustion)* by Xu Feng, *Pu Ji Fang (Prescriptions of Universal Relief)*, an extensive prescription book with over 60,000 formulas published in 1406, and *Shen Ying Jing (Divinely Responding Classic)*, from Yang Ji Zhou's Great Compendium of Acupuncture and Moxibustion.

Contemporary publications have extensive and detailed formulas dealing with type 2 diabetes. *Jin Zhen Wang Le Ting (Golden Needle Wang Le Ting)* compiled by Dr Yu Hui-chan and Dr Han Fu-ru, Dr Wang's students, was published in Beijing in 1984. Wang (1894-1990) was 89 years old when the Chinese edition from which this book has been created was first compiled in 1983. *Nei Ke Zhen Jiu Pei Xue Xin Bian (A New Compilation of Acupuncture and Moxibustion for Internal Medicine)* by Zhan Xi Wang, published in 1993 and *Zhong Guo Zhen Jiu Chu Fang Xue (A Study of Chinese Acupuncture and Moxibustion Prescriptions)* by Xiao Shao Qing, published in 1986, are some of the outstanding works that give us clear and concise prescriptions for treating upper, middle and lower *jiao* wasting.

Upper Burner/*Jiao*

For injury of body fluids by Lung heat, the treatment principle is to strengthen the function of the Lung, tonify yin and clear heat. Clinical manifestations are excessive thirst, dry throat and mouth, dry cough, hoarse voice, night sweats, emaciation and flushed cheeks.

Points:

- *Fei Shu* BL 13: Clears excess or deficient heat from the Lung and upper *jiao* and tonifies Lung yin.
- *Chi Ze* LU 5: Clears heat from the Lung, alleviates cough and regulates water passages.
- *Yu Ji* LU 10: Clears Lung heat and benefits the throat.
- *Gao Huang Shu* BL 43: Nourishes blood and yin, tonifies deficiency, cools heat and treats night sweats. BL 43 tonifies Lung, Spleen and Kidneys and can be used in any of the three patterns of disharmony, but due to its location in the upper *jiao*, it is recommended for this pattern, especially when the deficiency is accompanied by deficiency heat.
- *Zu San Li* ST 36: Assists BL 13 in strengthening the Lung.
- *Lian Quan* REN 23: Stimulates the production of body fluids.
- *Tai Xi* KID 3: Tonifies the Kidneys, nourishes yin and supports the Lung.

If there is Lung and Kidney qi deficiency, add *Guan Yuan* REN 4, with supplementing method. If Lung and Stomach heat is intense, add *San Yin Jiao*, SP 6 and *Nei Ting* ST 44, using draining method.

Middle Burner/*Jiao*

For injury of yin by Stomach dryness the treatment principle is to clear Stomach dryness and heat and tonify yin. Clinical manifestations are: excessive appetite or propensity to hunger, halitosis, dry lips, painful swelling or bleeding of gums, constipation, burning sensation in the epigastrium.

Points:

- *Zu San Li* ST 36: Clears Stomach dryness and benefits Stomach yin.
- *Nei Ting* ST 44: Clears Stomach heat.
- *Nei Guan* PC 6: Regulates the middle *jiao* and clears heat.
- *San Yin Jiao* SP 6: Benefits the Stomach and tonifies yin and body fluids.
- *Zhong Wan* REN 12: Harmonizes the middle *jiao* and tonifies stomach.
- *Pi Shu* BL 20 and *Wei Shu* BL 21: Both benefit Spleen and Stomach.
- *Wei Guan Xia Shu* (M-BW-12) or *Yi Shu* (Pancreas Shu): Clears heat and generates fluids. First mentioned by Sun Si Miao in the *Thousand Ducat Formulas* in the 7th century for wasting and thirsting disorder.
- *Tai Xi* KID 3: Tonifies Kidneys and nourishes yin. Supports the yin of the whole body.

Lower Burner/*Jiao*

For exhaustion of Kidney essence and Kidney yin, the treatment principle is to strengthen the function of the Kidneys and nourish essence. The clinical manifestations are: excessive urination, lumbar pain, weakness of the legs, constipation, blurred vision, dizziness, poor memory, afternoon fever and nocturnal emission.

Points:

- *Guan Yuan* REN 4: Benefits essence, tonifies and nourishes Kidneys and benefits the Bladder.
- *Qi Hai* REN 6: Tonifies Kidney qi.
- *Tai Xi* KID 3: Tonifies Kidney and nourishes yin
- *Ran Gu* KID 2: Clears deficiency heat and regulates the Kidneys.
- *SanYin Jiao* SP 6: Benefits the Kidneys and nourishes yin.
- *Shen Shu* BL 23: Tonifies the Kidneys, nourishes yin and essence and treats excessive urination.
- *Jing Men* GB 25: (front-mu point of the Kidney) combines with its back-shu point *Shen Shu* BL 23 to tonify the Kidneys, benefit the water passages and control urination.

(Choate, C. 1999; Flaws, et al., 2002).

Further points to supplement Kidney yin are *Zhi Shi* BL 52, *Xin Shen* BL 15, *Shen Men* HT 7, with even-supplementing even-draining method. When there is a pattern of both yin and yang deficiency, add *Zhi Shi* BL 52, *Ming Men* GV 4, with supplementing method and moxa on *Ming Men* (Choate, C. 1999; Flaws, et al., 2002).

According to Li Yong Zhi and Meng Fan Yi, in their book *Xiao Ke (Wasting and Thirsting* 1995), the course of acupuncture treatments must be more than three months. The effects of these treatments, according to them, can be very high (Flaws et al.,2002). If possible, treat as frequently as daily or every other day, with needles retained for 30 minutes (Choate, 1999).

Ear Acupuncture

Ear acupuncture for type 2 diabetes can be done at:

- Pancreas
- Liver
- Endocrine
- Triple Burner
- Kidney
- Vagus Root
- Heart.

The following points can be added according to predominant symptoms:

- For polydipsia: add Lung and Thirst Point.
- For polyphagia: add Spleen and Stomach.
- For polyuria: add Urinary Bladder.

If needling, it is important not to use more than 5-7 needles at a time, retaining needles for 20-30 minutes at a time. Treatments can be done every other day or at least three times a week. Press needles or ear seeds can also be used, taped over the points and stimulated by finger pressure several times a day (Flaws, 2002; Choate, 1999).

Chinese Nutrition and Food Remedies for Diabetes

Chinese nutrition is an extremely important and integral part of Chinese medicine. It differs from modern Western nutrition in that it determines not only the prevention of disease and the maintenance of good health, but also plays a pivotal role in bringing about the remedy and cure for disease. It does that by determining the therapeutic property of foods rather than the effect of the chemical constituents of

individual foods on the body. It is well understood in Chinese nutritional therapy that all foods have a certain temperature, certain organ energies that they tonify and nourish and takes into consideration factors such as the individual's body type, age and vitality, time of year and geographic location and the method of preparation in determining the appropriate diet. Thus, in case of illness, rather than focusing only on the disease, the whole person can be addressed. Understanding and treating each person's personal imbalance and illness and the ability to adapt to the changing needs of an individual, is the basis of Chinese nutritional therapy (Flaws et al., 2002).

The root pattern of diabetes, as understood in Chinese medicine, is qi and yin deficiency with dryness and heat (Flaws et al., 2002). Therefore, when treating diabetes, it is important to tonify qi, nourish yin, moisten dryness and clear heat. It is the sweet flavor within food that is responsible for tonifying and nourishing qi. Grains, legumes, fruits and vegetables all contain, to some extent, some sweet flavor that fortifies the Spleen and hence qi. Unfortunately, the sweeter the food, the more it generates fluids (Flaws et al., 2002). If more fluids are generated than the Spleen can transport and transform, these collect and create damp in the body thus damaging the Spleen and creating a Spleen deficiency. Therefore, it is important to remember that one cannot simply eat sweet foods to tonify qi. In fact, it is the over eating of sweet foods and sugars that has created the disease in a diabetic patient in the first place (Flaws et al., 2002).

Refined white sugars and other simple sugars ultimately convert to fat in the body (Pitchford, 1993). In type 2 diabetes, even though enough insulin is produced, the utilization in the cells of the body is blocked by the effects of a diet rich in fats (Olefsky

et al., 1974). This, in turn, causes Liver stagnation, which then creates a Spleen imbalance, thereby making pancreatic secretions such as insulin less effective (Pitchford,1993).

Foods high in “flavor” nourish yin, blood and essence (Flaws et al., 2002, pg 22), especially animal products such as meat, eggs and milk products. Flavor, according to Flaws, refers to “the clear part of the turbid from which yin is engendered and transformed” (Flaws et al., 2002 p 24). They are, however, difficult to digest and could, if not consumed in moderation, damage the Spleen and thus lead to internal damp. Animal products are essentially high in fats, and though people with yin deficiency need to eat more highly flavored and fatty foods, such as duck, shellfish, beef, butter and milk, in diabetic patients, these foods, being warm and/or hot, will not only create damp but also heat (Flaws et al., 2002).

Diabetes occurring in a person who has overindulged in a diet of meat, fat and refined foods will exhibit not only a few yin deficiency symptoms but also signs of heat and excess, usually manifesting as being overweight and constipated, with red complexion and a thick yellow tongue coating (Pitchford, 1993). In Chinese medicine, every food has a temperature, “the effect the food has on yang heat within the body” (Flaws et al., 2002 p 24). Hence, foods that are cool or cold, and cleansing, should be added to the daily diet of excess type, hyperactive yang patients.

According to Bob Flaws, it is important for patients with diabetes not only to be careful about the harmonization of the five flavors but also to not eat foods that aggravate their condition in terms of their “pattern discrimination”. Patients should not overeat any of the specific flavors of sweet, spicy or salty, since sweet, as has been

mentioned before, damages the Spleen. In the same vein, excess salt damages the kidneys and excess consumption of acrid, spicy foods creates internal heat and damages and consumes yin (Flaws et al., 2002).

The key is to be careful and mindful about consuming less food, especially foods that stress the Liver, weaken the Spleen, damage the Kidneys and consume yin and to eat only moderately sweet foods, limit the intake of greasy and fatty foods (meats, eggs, cheese, butter, excess oil, nuts and seeds), avoid “denatured” foods (refined white flour, hydrogenated, synthetic fats such as margarine and shortening and chemical ingredients). Diabetic patients should also avoid late night eating and complex food combinations. Small, frequent meals help to stimulate insulin production (Pitchford, 1993). See Appendix A for Foods Commonly Used in the Treatment of Diabetes.

Literature Review Integration

Research and theory have been developed regarding the treatment of type 2 diabetes. Modern practitioners of TCM are learning how to integrate the precision of Western medicine with the holistic approach of Chinese medicine. Prior studies have engaged the TCM theories of acupuncture (Choate, 1999; Flaws, 2002; Sonmore, 2006; Zhao et al, 2001; and Zhang, 2006) with some studies including special focus on herbs, formulas and nutrition (Flaws et al, 2002; Pitchford, 1993). If Chinese medicine is to be used by itself or in tandem with modern Western medicine for the benefit of patients suffering from diabetes, a more comprehensive synthesis of current TCM findings pertaining to the treatment of diabetes needs to be generated. At this point, such a synthesis does not exist in the literature. It will be the goal of the current study to begin to fill that gap by providing a synthesis of prior research pertaining to the treatment of

type 2 diabetes with acupuncture, herbs and formulas. The development of that synthesis will facilitate the improvement of the therapeutic effectiveness of Traditional Chinese Medicine in the treatment of diabetes.

Chapter 3: Method

The purpose of this study was to explore the effects of traditional Chinese medicine (TCM) on type 2 diabetes. Western or conventional therapies for diabetes generally work towards regulating blood glucose with a combination of diet modification, insulin and medications. Western medicine and TCM share the same goal in helping patients with Type 2 diabetes reduce their symptoms and prevent complications. However, their approaches to conceptualizing, diagnosing and treating the disease are very different. This study will help redefine the concept of treating Type 2 diabetes with a TCM alternative option.

Designation of Methodology

This study utilized literature review synthesis method with the application of grounded theory method to discern and detail a TCM alternative option for the treatment of Type 2 diabetes. This chapter describes and provides information regarding the methods engaged to achieve the research objective of this project. This chapter describes the procedures engaged in the current study with detailing of search terms, inclusion criteria, sampling procedures, data sources, data collection and grounded theory data analysis.

With its primary focus on the analysis of prior published research and theory, personal communications and observations, this study synthesized existing data to better understand the effective role that TCM plays in controlling blood sugar levels in patients with Type 2 diabetes. The method of qualitative literature review synthesis (Onwuegbuzie, Leech & Collins, 2012) was chosen as the most appropriate method for

integrating data from a variety of sources. The method of literature review synthesis involves six basic specific steps as follows:

- Definition of the research problem
- Examination of relevant primary and secondary sources
- Inclusion of reference works
- Formulation of specific search terms
- Systematic search for resources
- Summary of key points from sources

The method of literature review synthesis was attractive to the current researcher since it allows for the consideration of not just published materials, but also encourages the engagement of personal communications (“talk”), observations (such as experiences from professional practice) as well as other non-narrative documents. The inclusion of diverse resources makes it more possible that multiple levels of meaning and theory will be generated (Onwuegbuzie et al., 2012). Because the method of literature review synthesis does not involve human subjects, when the proposal for the current research was reviewed by the Yo San University IRB, it was deemed as being exempt. (See Appendix D).

Data Analysis Procedures:

The grounded theory procedure of constant comparison analysis (Glaser & Strauss, 1967) was further engaged to provide a means for systematically analyzing the data generated from the many sources of data engaged via literature review synthesis. As a qualitative inductive procedure, constant comparison analyzes each resource as compared to all others in terms of being similar or different with the ultimate goal of

deriving new meaning from the comparisons (Glaser, 1965). Constant comparison analysis does not test existing theory, but more foundationally is instrumental in the construction of new theories. It is a method that boasts openness to the multiple meanings that are likely to be derived from data. Moreover the procedure results in the identification of relationships among factors so that themes can emerge. Rather than beginning with givens or presuppositions, constant comparison analysis allows themes to emerge out of the data (Glaser & Strauss, 1967).

Sampling Procedures

The sources of the data for this research project were derived primarily from various articles from both western and Chinese medicine journals, textbooks and interviews with leading practitioners of Chinese medicine. The online search for published articles was conducted on the principal investigator's home computer and on the computer at the UCLA bio-medical library. The online resources included PubMed, EBSCOhost, Google Scholar, and the Cochrane Library.

Search Terms

The common search words used were TCM, diabetes type 2, acupuncture, blood sugar levels, HgA1c percentages, metformin, effects of Traditional Chinese medicine on type 2 diabetes, Chinese herbs, and qi gong.

Inclusion Criteria

For the current study articles and other resources were chosen that met the following inclusion criteria:

- Journal or text articles published primarily within the past ten years.

- Both Western medicine and traditional Chinese medicine resources are considered.
- Preference for journal articles from peer reviewed journals.
- Articles and resources that relate directly to or are otherwise associated with the search terms listed above.

Chapter 4: Results

Overview

The objective of this study was to determine the effect of the different modalities of Traditional Chinese Medicine (TCM) on type 2 diabetes mellitus (type 2 diabetes). It has become an increasing and severe health problem. TCM has a history of over 2,000 years, and has evolved into a well-developed, coherent system of medicine that uses several modalities to treat and prevent diabetes. They include acupuncture, moxibustion, herbal remedies, diet and Qi Gong.

The reason for doing this research is because the use of TCM by people with diabetes is limited. Furthermore, it is to review available research and results in order to determine what else can be done in this regard. This chapter presents the data that emerged from the literature review synthesis process.

The first section provides a summary of the types of studies that were used in the synthesis. This is followed by a summary of Chinese medicines used and their reported effects. The subject of acupuncture is then reviewed regarding its effect on patients with type 2 diabetes.

The studies reviewed provided data about the effects of using Chinese herbs and Chinese herbal formulas and a synthesis of these findings is included. Finally, a synthesis is provided regarding diabetes associated peripheral neuropathy and the effects of acupuncture regarding the complications arising from this problem. A review of what is out there, what has been done, and what needs to be done to further the use of TCM in the treatment of diabetes is also included.

Findings

Twenty-five studies were reviewed. Using a Data Collection Form, pertinent information from each of the studies was recorded, including data regarding participants, the treatment procedures utilized and outcomes. The following sections summarize the findings that emerged.

Summary of Participants

Three different areas of studies were reviewed. A total of over 6,000 participants were involved with the studies with a range from a high of 4,565 to a low of 21. Studies involved use of single herbs, formulas and acupuncture.

1. Studies with Herbs

(Al-Rowais, 2002) 296 diabetic patients; 51 were using herbs

(Celan-Isik, et al., 2008) Treatment of cardiovascular complications in diabetes.

(Ji, et al., 2013) 800 diabetic patients with unsatisfactory glycemic control

(Yeh, et al., 2003) 4,565 patients with diabetes or impaired glucose tolerance in 108 trials examining 36 herbs

(Xie, et al., 2011) Frequently prescribed herbs in China.

(Li, et al., 2004) Review of 86 medicinals.

2. Studies with formulas

(Ji, et al., 2013) 800 diabetic patients with unsatisfactory glycemic control, using Xiao Ke pill

(Yeh, et al., 2003) 4,565 patients with diabetes or impaired glucose tolerance examining Xiao Ke tea

3. Studies with Acupuncture

(Tong, 2010) 42 diabetic patients treated with acupuncture and 21 cases exposed to sham acupuncture;

(Abuaisha, 1998) 46 patients using acupuncture for diabetic neuropathy

(Liang, 2010) 234 publications examining the effect of acupuncture on insulin resistance.

Chinese Herbal Medicines Researched in the Study and Their Effects

Chinese medicine, relying mainly on herbal formulas, has been utilized extensively in China to treat non-insulin dependent diabetes mellitus, NIDDM. Based on extensive laboratory and clinical evaluations, about 20 herbs have emerged as primary candidates for treatment. (Dharmananda, S. 2003). Five studies were reviewed that focused upon the use of both single herbs and formulas.

Single Herbs

Six studies were reviewed on the use of single herbs. Some studies reviewed one herb, some studies reviewed four herbs, and one study reviewed 49 herbs for treating diabetes, 13 foods in diets, and 18 medicinal plants with outstanding anti-diabetic potential.

The study by Li and associates (2004) reviewed 86 natural medicines used in the traditional Chinese medical system. Eighty-two originated from plants and four from animals or insects. The paper reviewed the 86 natural medicines with regards to their origin, anti-diabetic principles, and/or pharmacological test results, which are commonly used in TCM and have demonstrated experimental and/or clinical diabetic effectiveness (Li et al., 2004). The investigation showed that there are about thirty-three herbs most

frequently used in Chinese traditional prescriptions for the clinical treatment of diabetes and its complications.

In the study done by Li and associates (2004) the five herbs most commonly used were *Radix Astragali seu Hedysari (Huang Qi)*, *Radix Rehmanniae* and *Radix Rehmanniae Praeparata (Shu di Huang)*, *Radix Trichosanthis (Tian Hua Fen)*, *Radix Puerariae (Ge Gen)*, and *Radix Ginseng*. They reported:

- *Radix Astragali seu Hedysari (Huang Qi)* appears in almost every anti-diabetic Chinese formula. Astragalus polysaccharides have an effect on regulating the level of blood glucose, which can increase the blood glucose of hypoglycemic animals or humans to normal level, and significantly lower the level of blood glucose, triglycerides and myocardial calcium (Ye et al., 1000; Zhang et al., 2001). They also inhibit the onset of type 1 diabetes in non obese diabetic mice (Chen et al., 2001), and exert a beneficial effect on experimental diabetic nephropathy by suppressing renal hypertrophy (Xu et al., 1997).
- *Radix Rehmanniae and Radix Rehmanniae Praeparata (Shu di Huang)*. In the research by Li and associates, 2004, they determined that the mechanism of hypoglycemic activity stimulated the secretion of insulin and reduced the glycogen content in the liver of normal mice (Kiho et al., 1992; Zang et al., 1996). Some preparations of this plant have been developed and are clinically used for the treatment of diabetes. 1990).
- *Radix Trichosanthis (Tian Hua Fen)* contains saponins, protein and various amino acids (Wang, et al., 1998). Studies showed that water extract of this

herb had blood sugar lowering activity and an anti-hypoglycemic effect on mice (Hikino et al., 1989).

- *Radix Puerariae (Ge Gen)*. Pueraria flavonoid (PF) is a useful preparation for patients with diabetes complicated by hyperlipidemia (Sun et al., 2002).

Tectorigenin, an isoflavone and kaikasaponin III, a glycoside, isolated from the flowers of *Pueraria thunbergaini* (same genus as *Puraria lobata*), showed potent hypoglycemic and hypolipidemic effects (Lee et al., 2000). Experimental results showed that rat lens protein were effectively inhibited by the ethanol extract of *Radix Puerariae*, which indicated that the extract can be used in treating diabetic complications (Duan et al., 2000).

- *Radix Ginseng*. The extracts of all parts of ginseng (the roots, stems, leaves and fruits) are of anti-hyperglycemic effect (Lei and Wang, 1957; Wang et al., 1990; Yang, 1991; Fang et al., 1998; Chung et al., 2001; Xie et al., 2002; Attele et al., 2002). Saponins are one of the active principles (Bao, 1981; Lee et al., 1997; Jang et al., 2001), and some saponins were isolated and experimentally or clinically confirmed to be bioactive for anti-diabetes or/and anti-diabetic complications. These saponins inhibit renal disorder (Kitamura et al., 1997) and promote insulin secretion (Ng and Yeung, 1985). Ginseng polypeptides were also reported to have an anti-hyperglycemic effect (Wang et al., 1991).

Xie and associates (2011) updated 30 anti-diabetic formulas and the top 10 of the most frequently prescribed herbs approved by the State Food and Drugs Administrator (SFDA) in China in the treatment of type 2 diabetes, in order to conduct a

discussion on how to develop TCM in the treatment of type 2 diabetes. They also maintained that not only was there an increasing need for TCM herbs and formulas for those type 2 diabetes patients that were intolerant of adverse effects of chemical drugs but also for those who could not afford expensive medical treatments in developing countries.

In their results, Xie and associates (2011) concluded that there were only a few reputed single-herb prescriptions found in China. They indicated that:

- *Ginseng* was an emerging alternative therapy for type 2 diabetes (Vuksan et al., 2001, Sotaniemi et al., 1995). Ginseng significantly decreased insulin resistance and fasting blood glucose (FBG) in type 2 diabetes patients (Ma et al., 2008, Vuksan et al., 2008). Ginseng might exert an antihyperglycemic effect by promoting insulin secretion (Vuksan et al., 2001), protecting pancreatic islets (Kim et al., 2010) stimulating glucose uptake (Shang et al., 2008) and enhancing insulin sensitivity (Vuksan et al., 2008). Ginseng had no significant side effects (Vuksan et al., 2008).
- *Golden Thread* is commonly used to treat diabetes in China (Xie et al., 2011). *Berberine* is an isoquinoline alkaloids and the active ingredient of Golden Thread. Berberine had a significant antihyperglycemic effect on both 36 patients newly diagnosed with type 2 diabetes and also on 48 poorly controlled patients with type 2 diabetes (Yin et al., 2008). This effect was comparable to metformin. Berberine increased glucose uptake and stimulated glycolysis (Chen et al., 2010, Yin et al., 2008). Berberine promoted beta cell regeneration (Zhou et al., 2009). In the intestines, berberine inhibited glucose absorption by suppressing

disaccharidase activities (Liu et al., 2010). No significant functional liver or kidney damages were documented (Xie et al., 2011).

- *Bitter Melon* lowered fasting and postprandial serum glucose levels in type 2 diabetes patients (Ahmad et al., 1999). However, adverse effects of bitter melon included hypoglycemic coma, convulsions and headaches in children (Basch et al., 2003). Bitter melon might have additive effects when taken with other glucose-lowering agents (Xie et al., 2011).
- *Fenugreek* improved blood glucose control and insulin resistance in diabetic patients (Gupta et al., 2001, Puri 1999, Madar et al., 1988). The findings of 18 cases of patients showed that FBG, triglycerides and very low-density lipoprotein cholesterol (VLDL-C) decreased significantly after taking fenugreek seed soaked in hot water (Kassaian et al., 2009). Its antihyperglycemic mechanisms were associated with potentiating insulin secretion, increasing insulin sensitivity (Puri et al., 2002) and inhibiting intestinal carbohydrate digestion and absorption (Hannan et al., 2007). Fenugreek was relatively safe (Lu et al., 2008) and also had no genotoxicity (Flammang et al., 2004). However, caution was to be used in combining it with aspirin, in case of the risk of bleeding (Abebe, 2002).
- *Garlic* had antihyperglycemic and antihyperlipidemic effects in type 2 diabetes patients (Sitprija et al., 1987, Ashraf et al., 2005). Garlic improved glycaemic control through increased insulin secretion and enhanced insulin sensitivity (Liu et al., 2005). Garlic had no significant side effects (Xie et al., 2011).
- *Cinnamon*, taken orally every day, reduced serum glucose and lipid levels in patients with type 2 diabetes, suggesting that the inclusion of cinnamon in the

diet of patients with type 2 diabetes would reduce risk factors associated with diabetes and cardiovascular diseases (Khan et al., 2003). Cinnamon reduced A1c (HbA1c) by 0.83% compared with usual care alone lowering HbA1c by 0.37% in patients with type 2 diabetes in a randomized, controlled trial (Crawford, P. 2009). Cinnamon had no significant side effects (Dugoua et al., 2007).

Coptis chinensis is commonly used to treat diabetes in China (Hui et al., 2009).

Berberine is an isoquinoline alkaloids and the active ingredient of *Coptis chinensis* (Hui et al., 2009). Berberine may also relieve some diabetic complications. Studies showed that berberine restored damaged pancreas tissues in diabetic rats (Liu, et. al., 2008). The hypoglycemic effect of berberine was similar to that of metformin in 36 adult patients of recently diagnosed type 2 diabetes (Yin et al., 2008). Berberine also lowered fasting blood glucose and postprandial blood glucose in 48 adult patients of poorly controlled type 2 diabetes during a 3 month period (Yin et al., 2008).

In a randomized, double-blind placebo-controlled study (Zhang et al., 2008), 116 patients with type 2 diabetes and dyslipidemia were randomly allocated to receive *Berberine* (1.0 gm daily or 0.5 gm twice daily) or placebo prepared in indistinguishable tablets. The berberine was extracted from *Coptis chinensis* with acidic water and had a purity of 97% or greater. Berberine had a glucose lowering effect by significantly reducing fasting and postprandial plasma glucose by 1.4 and 3.1 mmol/liter, respectively, at 3 months and HbA1c by 0.9% from the initial levels of 7.5%. The decline of HbA1c achieved with berberine was fully comparable with that of existing pharmacologic products used in treatment of type 2 diabetes (Bloomgarden et al., 2006)

Regarding the treatment of cardiovascular complications in type 2 diabetes, Celan-Isik and associates (2008) summarized in their review, the application of traditional Chinese medicinal therapies. Of the 200 species of herbs that have shown to possess hypoglycemic properties (Jia et al., 2003), they concluded that the herb that stood out was:

- *Panax Ginseng* significantly lowered blood glucose in diabetic individuals with an efficacy similar to the insulin sensitizer phenformin (Cheng, 2000). Data provides evidence that ginseng and its active ingredients may be used as an effective anti-diabetic agent through the prevention of oxidative stress (Cho et al., 2006). This supports the benefit of ginseng radix on cardiac and central nervous system complications in diabetes and obesity (Xie et al., 2006).

Formulas

Yeh and associates (2003), in an electronic literature search of available clinical studies published in English language examined a total of 108 trials examining 36 herbs (25 single herbs, 11 combination herb formulas) and 9 vitamin/mineral supplements involving 4,565 patients with diabetes or impaired glucose tolerance, to review the efficacy and safety of herbal therapies. The best evidence for efficacy from adequately designed randomized controlled trials was available for American ginseng. They determined that the data available for herbal combinations was very limited, and no formula had been studied in more than one trial. Of the three formulas for which evidence was found in each trial, was a formula containing *Coptis Chinensis*, *Astragalus Membranaceus* and *Lonicera Japonica*. These plants were selected for study by the Chinese Academy of Medical Science, based on reports of efficacy and safety. They

maintain that the formula was not effective for influencing the action of insulin, but it did decrease digestive carbohydrate absorption (Yeh, et al., 2003).

Another, much smaller trial ($n=12$) examined a TCM preparation called *Xiao Ke* tea. They determined that very little was written about this formula in English publications. Though the trial did not report details about the constituents of the tea, the investigators reported that it did not affect insulin concentrations and was ineffective in rats that lacked endogenous insulin (Hale, et al., 1998).

The third formula that they found data for was Semen Persical Decoction for Purgation with Addition (SPDPA), a combination of eight different herbs. This trial reported that the decrease in fasting blood glucose was not significantly different from changes seen with glyburide (Xiong, et al., 1995).

Xiao Ke pill was the focus of a study by Ji and associates. 800 patients with diagnosed type 2 diabetes, with unsatisfactory glycemic control (fasting glucose 7-13 mmol/L and HbA1c 7-11%), were randomly administered, in a controlled, double-blind trial, *Xiao Ke* pill for 52 weeks. They found that in China, some medications for diabetes were combinations of Chinese herbs with Western medications such as glibenclamide. One such formulation was *Xiao Ke* pill (Yeh, et al., 2003), which contains 0.25 microgram of glibenclamide per pill (Ye. T, 2006). The herb components include *Radix Astragali*, *Radix Trichosanthis*, *Stylus Zeae Maydis*, *Fructus Schisandrae Sphenantherae* and *Rhizoma Dioscoreae*. These were selected from two ancient TCM formulas for “wasting and thirsting” *Yuquan San* (Zhu, et al., 1993) and *Xiaoke Fang* (Pharmacopoeia Commission, 2010). Patients with type 2 diabetes, aged 21-70 years, who met the following criteria, were recruited for the study: 1) Drug naïve patients with

body mass index (BMI) within 18kg/m²-28 kg/m²; 2) Patients who received treatment with metformin at a stable dose >750 mg/day for at least 3 months before screening, with BMI within 18 kg/m²-35 kg/m²; 3) Stable body weight within at least 3 months before screening; 4) Poor glycemic control with fasting plasma glucose (FPG) between 126-234 mg/dL (7.0-13 mmol/L) and glycated hemoglobin (HbA1c).7.0% at screening.

Eligible patients were separately randomized to receive double blind therapy or add on therapy with Xiao Ke pill or Glibenclamide tablet. The results of the study determined that patients on the Xiao Ke pill were 38% less likely to have any hypoglycemia compared to those on Glibenclamide. The average annual rate of hypoglycemia was 24% lower in patients treated with Xiao Ke pill. Patients on Xiao Ke pill were also 41% less likely to have a mild hypoglycemic episode compared to those on Glibenclamide.

Between 4 and 24 weeks of the study, 52.7% and 51.6% of patients in the treatment naïve group reduced HbA1c to below 6.5% on Xiao Ke Pill and Glibenclamide respectively. During the same period, 70.1% and 67.9% patients reduced FPG to below 7 mmol/L. At 48 weeks, the absolute changes in FPG levels were also similar in both study groups.

In their course of their study, Ji and associates found five studies published in medical journals in China (Zhou, et al., 2003; Zhang, H. 1999; Zhao, et al., 1998; Chen, et al., 2003; Wu, H. 2005) that showed significant improvement in diabetes symptoms in favor of Xiao Ke pill. These studies were mostly for 4-8 week periods and only one study assessed the hypoglycemic events. They, however, questioned the validity of the

design of these studies, which in turn made it difficult for them to draw any conclusion with regard to the safety and efficacy of Xiao Ke pill.

In a randomized controlled pilot study, Tu, and associates demonstrated the effect and benefits of another TCM formula *Wu Mei Wan* on the blood sugar levels of type 2 diabetes patients. The 10 herb components of this formula are: *Wu Mei*, *Xi Xin*, *Gan Jiang*, *Huang Lian*, *Dang Gui*, *Fu Zi*, *Hua Jiao*, *Gui Zhi*, *Ren Shen* and *Huang Bai*. Their pilot study was conducted to evaluate and assess the efficacy of *Wu Mei Wan* on lowering blood glucose levels on patients with type 2 diabetes. All patients included in the study had to have $7.0 \text{ mmol/L (126 mg/dL)} \leq \text{fasting plasma glucose (FGP)} \leq 13.3 \text{ mmol/L (240 mg/dL)}$ or $11.1 \text{ mmol/L (200mg/dL)} \leq 2\text{h postprandial plasma glucose (2hPG)} \leq 22.9 \text{ mmol/L (412mg/dL)}$. Other inclusion criteria included an age range of 18 to 70 years and normal renal function. A total of 85 subjects were randomized to receive either *Wu Mei Wan* or metformin, over a period of 12 weeks. All patients received diet and exercise therapy (Tu, et al., 2013).

The study determined that *Wu Mei Wan* was as effective as metformin in reducing blood glucose levels. By week 12, the fasting plasma glucose concentration had decreased by 1.53 mmol/L to 6.35 mmol/L in the *Wu Mei Wan* group and decreased by 1.44 mmol/L to 6.06 mmol/L in the metformin group. At week 12, the postprandial plasma glucose levels decreased by 5.45 mmol/L to 9.73 mmol/L in the *Wu Mei Wan* group and decreased by 4.29 mmol/L to 9.72 mmol/L in the metformin group.

The levels of HbA1c decreased from 7.66 percent to 6.78 percent in the *Wu Mei Wan* group and decreased from 8.23 percent to 6.76 percent in the metformin group. The fasting insulin concentrations were similar in the *Wu Mei Wan* and metformin

groups and they did not significantly change during the 12 week period (data not shown). The lipid profiles (TC, TG, LDL and HDL) were similar in the Wu Mei Wan and metformin groups and they did not significantly change during the 12 week period (data not shown). For subjects whose body mass index (BMI) was between 23 and 25 and >25, Wu Mei Wan could significantly decrease BMI, with no significant differences compared with metformin. For subjects whose BMI <23, neither metformin nor Wu Mei Wan could decrease BMI (Tu, et al., 2013).

One patient in the Wu Mei Wan group withdrew because of adverse events. The patient had palpitations and diarrhea. These symptoms left after the discontinuation of Wu Mei Wan. The adverse events were classified as moderate in severity and were probably related to Wu Mei Wan (Tu, et al., 2013).

Tu and associates concluded that Wu Mei Wan was as effective as metformin in reducing blood glucose levels. They did, however, express caution in interpreting results. They felt that blood glucose levels could be affected by many factors, since subjects also underwent dietary and exercise therapy, and that in itself could affect blood glucose significantly. They did feel that since both groups received dietary and exercise therapy, the results still had clinical implications.

They also felt that since the trial lasted only a short 12 week period, they could not arrive at any conclusions concerning the long term effect and safety of Wu Mei Wan. They felt that since one subject dropped out because of diarrhea and palpitations, it raised the question of the long term toxicity of Wu Mei Wan, which contains both *Rhizoma Typhonii Gigantei (Fu Zi)*, as well as *Herba Asari (Xi Xin)*.

This study was a randomized controlled pilot study. Tu and associates felt that even though they went to great lengths to make the trial a well designed one, it was difficult to carry out a double blind trial due to the obvious difference between TCM and metformin. The common consensus of these studies was that compared with the established hypoglycemic effects of Western medicine, the blood glucose-lowering effect of TCM herbs and formulas remains controversial, primarily because of the paucity of studies and information.

Acupuncture

Of the studies examined regarding the effects of acupuncture on type 2 diabetes, two discussed the effects of acupuncture on diabetic peripheral neuropathy. In the research done by Tong and associates, they stated that an estimated 12-50 percent of people with diabetes had some degree of diabetic peripheral neuropathy (Nicolucci, et al., 2004). Investigators have demonstrated that the nervous system and neurotransmitters respond to acupuncture needling stimulation and electroacupuncture (Foster, et al., 1987; Qian. X, 1986; Tang, D. 1987). Paul and associates reported that two out of a total of three patients showed increased benefit when a series of six acupuncture sessions was added to the on going nefazodone therapy for the treatment of diabetic peripheral neuropathy (DPN). In a randomized controlled trial, Chen and associates concluded that the point through point method of acupuncture was more effective than mecobalamin for the improvement of motor nerve conduction velocity (MNCV) of the peroneal nerve. Ahn and associates determined that acupuncture lowered the pain caused by DPN. Based on these studies, Tong and associates carried

out a randomized controlled trial to investigate the effects of acupuncture on DPN (Tong, et al., 2010).

Forty-two cases treated with acupuncture were compared with 21 exposed to sham acupuncture over a period of 15 days. The inclusion criteria was patients with DPN with an age range of 35-52 years. These patients were diagnosed with mild DPN based on subjective symptoms and no foot ulcerations. Motor nerve conduction velocity (MNCV) in the tibial nerve of patients ranged between 30m/s and 45m/s. Patients' sensory nerve conduction velocity (SNCV) in the median nerve (distal area) ranged between 35m/s and 55m/s with stable glycemic control (HbA1c \leq 9%, with \pm 0.5% variation in the previous 3 months (Tong, et al., 2010).

Both acupuncture and sham acupuncture groups continued with diet therapy, hypoglycemic agents, insulin and hypotensive agents. However, medication to aid neuropathy control was prohibited. All patients participated in one session per day, lasting 30 minutes, for 15 days. Points used were *Hegu* (LI 4), *Fenglong* (ST 40), *Quchi* (LI 11), *Zusanli* (ST 36) and *San Yin Jiao* (SP 6) (Tong, et al., 2010).

In the acupuncture group, HbA1c at baseline and day 15 was 6.8 ± 1.3 and $6.7 \pm 1.2\%$ respectively. Corresponding values in the sham acupuncture group were $6.6 \pm 1.2\%$ and $6.7 \pm 1.3\%$, respectively. There were no significant differences between the two groups at any time point. Three of the six measures in motor nerves demonstrated significant improvement ($p < 0.05$) over the 15 day treatment period. No electrophysiological measures of motor or sensory function significantly improved in the sham acupuncture group. The two measures of sensory function, forearm and distal SNCV also improved in the acupuncture group. The change of forearm SNCV from

baseline was significant ($p < 0.05$). There were also significant differences in vibration perception threshold (VPT) between groups ($p < 0.05$) when compared to the baseline levels ($p < 0.01$) in the acupuncture group (Tong, et al., 2010).

Numbness in the upper extremities (severity) and sensation of rigidity (extent) were significantly improved in the acupuncture group compared with the sham acupuncture group ($p < 0.05$ and 0.01 , respectively) after 15 days treatment. There was no significant difference between the two groups in the sensation of parasthesia, hypesthesia and weakness of extremities (Tong, et al., 2010).

In another study (Abuaisha, et al., 1997), 46 diabetic patients with chronic peripheral neuropathy were treated with acupuncture over a period of 10 weeks. Patients with clinical features of symptomatic painful peripheral neuropathy were recruited to receive acupuncture treatment. Neuropathy was diagnosed clinically on the basis of a modified neuropathy disability score (NDS) derived from the findings on examination (Young, et al., 1993). All patients were outpatients and the inclusion criteria was 1) painful symptoms in both legs for at least 6 months before the study; 2) NDS score of more than 2; 3) vibrational perception threshold (VPT) greater than the 95th centile for age related reference value. NDS and VPT were repeated after the full course of treatment.

Acupuncture points used were *Tai Chong* (LV 3), *San Yin Jiao* (SP 6), *Yin Ling Quan* (SP 9) and *Zu San Li* (ST 36). The first, second and third treatments were at weekly intervals. The fourth and fifth were fortnightly and the sixth treatment was after a month. Thereafter, subsequent treatments took place when the patient felt the need for

them and according to the patient's symptomatology. There were no changes in diabetic management during the study (Abuaisha, et al., 1997).

After the initial six courses of acupuncture, 77% noted an improvement in their primary and/or secondary symptoms. After the initial full course of acupuncture treatments, 32% were able to stop their medications completely, 32% were able to reduce their medications significantly while 36% continued on their original treatment with their medications. Patients who did respond to acupuncture treatments (34 patients) were followed up to evaluate the long term effect of acupuncture analgesia and only 24% patients needed further acupuncture sessions after their basic standard six courses of treatment. Although 77% noted significant improvement in their symptoms, only 21% experienced complete symptom relief. There were no significant changes in NDS, VPT or HgA1c during the course of the treatment (Abuaisha, et al., 1997).

In a review article (Liang et al., 2010), 234 English publications on the PubMed database between 1979 and 2009 were reviewed to determine the effectiveness of acupuncture as a treatment for insulin resistance diseases, which included obesity, type 2 diabetes, hypertension, polycystic ovary syndrome (PCOS), non-alcohol fatty liver diseases (NAFLD) and metabolic syndrome. The authors determined that those studies concluded that acupuncture was beneficial and effective as a treatment modality for type 2 diabetes, and that patients with type 2 diabetes seemed to respond better to acupuncture than patients with Type 1 diabetes (Hu, H. 1995). Type 2 diabetes patients showed improved clinical manifestations as well as reduction in fasting blood sugar levels and improvement in oral glucose tolerance tests. Other studies indicated that

acupuncture improved both hyperglycemia and insulin resistance (Feng, et al., 1997; Chen, et al., 1994; Chen, et al., 1985).

Results Summary

In summary, the left hand columns of the table below list the acupuncture points, single herbs and formulas that have shown to be effective in the treatment of one or more aspects of type 2 diabetes. The citation of the appropriate author/researcher is included in the right hand column.

Table 1: Summary of Acupuncture Points, Single Herbs and Formulas that Emerged in the Current Study

Acupuncture

<i>Hegu</i> (LI 4)	Tong, et al., 2010
<i>Fenglong</i> (ST 40)	
<i>Quchi</i> (LI 11)	
<i>Zusanli</i> (ST 36)	
<i>San Yin Jiao</i> (SP 6)	
<i>Tai Chong</i> (LV 3)	Abuaisha, et al., 1997
<i>San Yin Jiao</i> (SP 6)	
<i>Yin Ling Quan</i> (SP 9)	
<i>Zu San Li</i> (ST 36)	

Single Herbs

Radix Astragali seu Hedysari (Huang Qi), Radix Rehmanniae and Radix Rehmanniae Praeparata (Shu di Huang)	Li, et al., 2004
Radix Trichosanthis (Tian Hua Fen)	
Radix Puerariae (Ge Gen)	
Radix Ginseng	Li, et al., 2004; Xie, et al., 2011
Golden Thread	Xie, et al., 2011
Bitter Melon	
Fenugreek	
Garlic	
Cinnamon	

Formulas

Coptis Chinensis, Astragalus Membranaceus and Lonicera Japonica	Yeh, et al., 2003
Semen Persical Decoction for Purgation with Addition (SPDPA)	Xiong, et al., 1995
Xiao Ke pill	Yeh, et al., 2003
Wu Mei Wan	Tu, et al., 2013

Chapter 5: Discussion

Summary of Findings

The objective of this project was to establish the effects of Traditional Chinese Medicine on Type 2 Diabetes Mellitus (type 2 diabetes) with a focus on the effects of acupuncture. Acupuncture is widely applied in clinical practice for insulin resistance related diseases such as obesity, diabetes and related complications, PCOS and hypertension (Cho et al., 2009; Wang et al., 2008; Stener-Victorin et al., 2008; Lee et al., 2009).

Using literature review synthesis with grounded theory constant comparison method across twenty-five human and animal studies, systematic analysis yields the observation of a high level of efficacy regarding the use of acupuncture and Chinese herbs in the treatment of Type 2 Diabetes Mellitus. In the analysis of the studies, it was observed that both single and combined herbal formulations were used. It was also observed that acupuncture has been effectively used, though the focus has been more on the effects of acupuncture on peripheral neuropathy as a result of Type 2 Diabetes than on improving glucose tolerance levels and A1c percentages (Al-Rowais, 2001; Qin, 2003; Li, 2013; Yeah, 2003; Tong, 2010; Abuaisha, 1998; Dharmananda, 2003; Li et al., 2004; Zhang et al., 2001; Chen et al., 2001; Xu et al., 1997; Kiho et al., 1992., Miura et al., 1997; Sanae et al., 1996; Kishimura et al., 1990).

Implications for Theory

The research on TCM treatments for type 2 diabetes has been ongoing for several decades, yet remains in the developmental stages due to the complexity of the situation. Even though there is no clinical evidence that Western medications for

diabetes and Chinese herbal therapies are incompatible, there is concern that when combining the two, blood sugar levels may decline too far (Dharmananda, 2003). While Chinese medical literature occasionally mentions the use of Chinese herbs along with Western medications, specific strategies for combining the two are not commonly presented.

Acupuncture is a common approach to treating diabetes in China. However, the efficacy and indications for acupuncture have been controversial because of scientific, historical and philosophical differences. The assumption is that acupuncture is only suitable for pain management, perhaps because the initial introduction to acupuncture in the Western world was mainly for this application. Therefore, relatively few people realize the broad spectrum of diseases and maladies that acupuncture can not only treat but also effectively work in conjunction with Western medications for the health and betterment of patients.

In this research synthesis, twenty studies were reviewed pertaining to the use of Chinese single herbs, Chinese herbal formulas and acupuncture in the treatment of type 2 diabetes. Of these studies, it was concluded that considerable work was done regarding the use of single herbs and their individual effect on type 2 diabetes. Six studies were also reviewed to understand the existing complementary and alternative modalities that are part of and are imbued in the daily culture and dietary regimen of older cultures.

Since diabetes has been regarded as a disease in many Asian countries for centuries, those cultures have imbibed various herbs and plant derivatives to treat the disease. In a study done in Riyadh, Saudi Arabia, of the 296 diabetic patients interviewed, fifty-one

subjects (17.4%) reported using some form of herbs. The most common were myrrh, black seed, helteet, fenugreek and aloe (Al-Rowais, 2002).

In the Chinese and Indian cultures, herbal medicine has long been the foundation in the treatment of diabetes. Approximately 800 plants have been identified in the treatment or prevention of type 2 diabetes (Wang et al., 2013). Many formulations are present as a single herbal extract or in a complex formula. Over 400 extracts have shown to be effective *in vitro* or *in vivo* (Prabhakar et al., 2011). Foods such as bitter gourd/melon, mulberry leaves, and fenugreek have been incorporated in daily diets in China, South America, India, the Carribean and East Africa (Leung et al., 2009; Prabhakar et al., 2011).

It was interesting to note that in a study done in Taiwan regarding the use of complementary and alternative medicine (CAM), which included mind-body medicine, biologically based practices, manipulative and body-based practices and energy medicines, the majority of patients used CAM in conjunction with conventional medicine, not as an alternative (Chang et al., 2010). Of the 195 participants who saw health care professionals and used CAM along with their Western medicines, only 24.6% had disclosed their CAM use to their health care professional. 55.8% of them claimed that they never thought of it, since they considered CAM as a part of their daily lives.

In the studies reviewed for single herbs, the ones that stood out and were common to all were ginseng, cinnamon, bitter melon, golden thread, fenugreek and garlic. The studies proved that the action mechanisms of these herbs were related to improving insulin sensitivity, stimulating insulin secretion, protecting pancreatic islets and even inhibiting intake of intestinal carbohydrates. However, according to Xie and

associates, it is very difficult to determine the antihyperglycemic components of these herbs. They felt that in the future, it required further validation of the phytochemical, pharmacological and clinical natures of these herbs in type 2 diabetes treatments, especially for those herbs with a high prescription frequency (Xie et al., 2011).

Yeh and associates, in an electronic literature search of available clinical studies published in English language examined a total of 108 trials investigating 36 herbs (single or in combination) involving 4,565 patients with diabetes or impaired glucose tolerance, to review the efficacy and safety of herbal therapies. The best evidence for efficacy from adequately designed randomized controlled trials was available for American ginseng. They determined that the data available for herbal combinations was very limited, and no formula had been studied in more than one trial. Of the three formulas for which evidence was found in each trial, was a formula containing *Coptis Chinensis*, *Astragalus Membranaceus* and *Lonicera Japonica*. Another trial examined a TCM preparation called *Xiao Ke* tea. The third formula that they found data for was Semen Persical Decoction for Purgation with Addition (SPDPA), a combination of eight different herbs.

Xiao Ke pill was also the focus of a study by Ji and associates. In a controlled, double-blind trial, 800 patients with diagnosed type 2 diabetes were randomly administered *Xiao Ke* pill for 48 weeks. In a randomized controlled pilot study, Tu, and associates demonstrated the effect and benefits of another TCM formula, *Wu Mei Wan*, on the blood sugar levels of type 2 diabetes patients.

The consensus of these three studies was that compared with the established hypoglycemic effects of Western medicine, the blood glucose-lowering effect of TCM

herbs and formulas remains controversial, primarily because of the paucity of studies and information.

Of the studies examined regarding the efficacy of acupuncture on type 2 diabetes, two discussed the effects of acupuncture on diabetic peripheral neuropathy. In one study (Tong et al., 2010), 42 cases treated with acupuncture were compared with 21 exposed to sham acupuncture over a period of 15 days. In the other study (Abuaisha et al., 1997), 46 diabetic patients with chronic peripheral neuropathy were treated with acupuncture over a period of 10 weeks. Though this particular study reported that there were no significant changes in vibratory perception threshold (VPT) or in HbA1c percentages in patients studied during the course of the treatment, both studies reported evidence that acupuncture may be considered as an effective and safe therapy and modality for the treatment of chronic peripheral diabetic neuropathy. In a review article (Liang et al., 2010) 234 English publications on the PubMed database between 1979 and 2009 were reviewed to determine the effectiveness of acupuncture as a treatment for insulin resistance diseases, which included obesity, type 2 diabetes, hypertension, polycystic ovary syndrome (PCOS), non-alcohol fatty liver diseases (NAFLD) and metabolic syndrome. The review authors determined that those studies concluded that acupuncture was beneficial and effective as a treatment modality for type 2 diabetes, and that patients with type 2 diabetes seemed to respond better to acupuncture than patients with Type 1 diabetes. Type 2 diabetes patients showed improved clinical manifestations as well as reduction in fasting blood sugar levels and improvement in oral glucose tolerance tests.

The common thread, though, was that most of these studies have been of short duration and since type 2 diabetes is a chronic condition, they felt that further studies over a longer period of time involving larger patient numbers, would be necessary to determine whether the results of acupuncture are sustained.

Implications for Practice

The effectiveness and success of traditional Chinese medicine with diabetes has been well documented in Chinese medical texts and books over the centuries. An amazing number of Chinese doctors and practitioners have devoted their attention and careers toward this disease and have tried to formulate treatments, whether with acupuncture or well formulated herbal prescriptions, to help patients with this disease. Currently, type 2 diabetes is rising to epic proportions. This is when Chinese medicine, with its arsenal of not only acupuncture and herbs, but the entire plethora of diet, supplements, moxibustion, and exercises such as Qi Gong and Tai Chi, needs to come into the forefront and work hand in hand with Western medicine to formulate an integrated approach for the well being of patients with type 2 diabetes.

In order to achieve this collaborative effort, it is imperative for TCM practitioners to be aware of the research done regarding the use of specific herbs, whether as single herbs or as herbal formulas, that have proven to be effective in the treatment of this disease. Since integrating Chinese medicine with Western ideology is the goal to combat this disease, it would serve Chinese practitioners well to understand which Chinese herbs work with blood sugar levels, which herbal formulas work with inhibiting inflammation and why the known acupuncture point, Wei Guan Xia Shu, is called the “diabetes” point.

This focus needs to be incorporated in schools for Chinese medicine as well. Focus on the research done on Chinese herbs and acupuncture globally should be an essential part of the TCM educational curriculum. Training in Chinese herbs is presently an important component of the study of Chinese medicine. It is, however, restricted to examining them from the Chinese medicine perspective. The concept of the efficacy of herbs and acupuncture needs to be widened to include research understanding, so that, students as future practitioners can not only work with Western practitioners, but also contribute to further research.

Since it is such a common and increasingly prevalent condition, continuing education sessions for TCM practitioners should include specific focus on the treatment of type 2 diabetes. As of 2010, an estimated 285 million people had diabetes globally, with type 2 making up about 90 percent of the cases. By 2030, this number is estimated to almost double (Wild et al., 2004). Chinese medicine, especially when working hand in hand with Western medicine, is certainly one of the answers to handling this disease. Over the ages, effective acupuncture points have been formulated to treat diabetes. Continuing education sessions can also help to keep practitioners in touch and up to date with these excellent treatments and make other practitioners aware regarding their use.

Blood testing procedures related to glucose levels should be an important and essential factor in the practices of TCM practitioners who treat type 2 diabetes. It is important that all practitioners have a working knowledge of the disease and are able to read and understand the implications of blood testing regarding blood sugar levels. HgA1c percentages should be incorporated as an essential component both in schools

of Chinese medicine and in the treatment procedures of practitioners. This awareness would be beneficial not only when working as a team with endocrinologists, but also when working with patients. TCM practitioners need to help patients understand their blood glucose and HgA1c levels—what are normal, high or low and how practitioners and patients can monitor the effect of the acupuncture and herbal treatments. Such monitoring can provide tangible proof of how the TCM treatments are helping patients to compliment and maximize their health.

It is the responsibility of practitioners of Chinese medicine who have a working knowledge of the efficacy of acupuncture and Chinese herbs, to make Western doctors and the public aware of this alternative/integrative form of medicine. Practitioners of Chinese medicine need to emphasize that once a person has been diagnosed with type 2 diabetes, they need to be reassured that they have a whole team working with them, their Western doctor, endocrinologist, dietician and acupuncturist.

Limitations of the Current Study

The current study was limited to the review of prior research published in or translated to English. It is possible that there are additional studies in other languages which the current researcher could not access or translate. That factor constitutes the primary limitation of the current study.

As suggested earlier, the focus of this study was to determine the effects of TCM on type 2 diabetes, especially regarding acupuncture and its ability to help diabetic patients lower their blood sugar levels and their HgA1c percentages. Of the studies reviewed, only three pertained exclusively to the use of acupuncture for patients with diabetes, of which two dealt with peripheral neuropathy, which was a result of chronic

diabetes. Only one study, which was a review analysis of 234 publications, dealt with the effect of acupuncture on various diseases related to immune resistance and not solely with type 2 diabetes.

Numerous studies declared that certain Chinese herbs had proved, over a period of time, to be efficacious in lowering blood sugar levels in patients with type 2 diabetes. The methodology of some of the published studies was poor and no firm conclusions could be drawn from them. Some trials declared that TCM could provide clinical benefits for diabetic patients with microvascular or macrovascular complications, but most lacked the backing of well-designed controlled research, without which solid demonstration of evidence is lacking. The low methodological quality of trials and the absence of scientific understanding can and has, to an extent, created skepticism and lack of complete understanding of a modality that, over many centuries, has been known to be so effective and successful in the treatment not only of type 2 diabetes but almost all diseases.

Recommendations for Future Research

On the basis of the current study, it is clear to the researcher that additional systematic research is needed regarding the impact of acupuncture on glucose levels and HgA1c percentages. There is enough theory to support the use of acupuncture on diabetes. However, evidence based systematic research is needed to corroborate the theory and to relieve skepticism that currently exists. Most specifically, we need a study that determines that Wei Guan Xia Shu is the important “diabetes” point. We need to discern whether it really works. A clinical trial study needs to be conducted with a sample of 30 individuals who are diagnosed with type 2 diabetes and who are treated

with needling this point. A second sample of 30 type 2 diabetes patients should be given sham acupuncture, and a third sample of 30 patients with type 2 diabetes should be given no treatment. Blood glucose levels should be monitored for the patients in all three groups. Such systematic clinical trials will provide the next step in demonstrating the efficacy of acupuncture in the treatment of type 2 diabetes.

Beyond the study on the Wei Guan Xia Shu point, it would be interesting to conduct a series of studies that examined the impact of acupuncture for the treatment of type 2 diabetes differentiating gender (men vs. women). Studies regarding the effect of exercises such as Qi Gong and Tai Chi on patients with type 2 diabetes would also be beneficial in determining the benefits of traditional Chinese medicine as a whole on this disease that is rapidly on the rise globally.

Conclusion

The effects of Traditional Chinese Medicine on diabetes have been well documented in Chinese Medical classics for centuries. Due to the nature of contemporary medicine, we need concrete Western scientific model data and evidence gathering to demonstrate the efficacy of Chinese medicine in the treatment of diabetes and its affect on blood glucose levels. Western medicine has developed the science and technology to design protocols and investigative treatment programs, while Chinese medicine has developed the treatment methodologies. It would be wonderful for Western and Chinese medical schools, research communities and practitioners to collaborate to work as a team for the benefit and health of diabetic patients.

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Appendix A: Foods Commonly Used in the Treatment of Diabetes

Foods Commonly Used in the Treatment of Diabetes

Vegetables

- Asparagus: Cooling. Clears heat, detoxifies, promotes blood circulation and clears lungs. The underground tubers of asparagus tonify Kidney yin and moisten the Lungs.
- Bamboo Shoots: Cooling. Strengthens the Stomach, resolves mucus, promotes diuresis.
- Bok Choy: Cooling. Clears heat, lubricates intestines, quenches thirst.
- Carrots: Neutral. Benefits Lung, strengthens Spleen, improves Liver function, stimulates the elimination of wastes.
- Celery: Cooling. Tonifies Kidney, strengthens Spleen and Stomach, clears heat, lowers blood pressure.
- Jerusalem Artichoke: Sweet. Nourishes Lungs, treats constipation, stimulates insulin production, contains inulin, thereby reducing insulin needs.
- Kohlrabi: Neutral, Sweet, pungent and bitter. Improves qi circulation, reduces damp, treats blood sugar imbalance.
- Mushroom (Chinese Black or Shitake): Neutral, sweet. Strengthens the Stomach, promotes healing, lowers blood pressure, lowers blood fat levels.
- Pumpkin: Cooling. Dispels damp, particularly beneficial for diabetes.
- Snow Peas: Cold. Strengthens the middle *jiao*, quenches thirst.
- Spinach: Cooling. Strengthens all organs, lubricates intestines, quenches thirst. Particularly useful in the treatment of diabetic dryness and thirst.
- String Beans: Neutral, sweet. Kidney and Spleen tonic.

- Turnip: Cooling. Clears heat removes damp.
- Winter Melon: Cooling. Clears heat, detoxifies, quenches thirst, dispels damp. Particularly effective in treating diabetes.

Fruits

- Avocado: Cooling, sweet. Builds blood and yin, harmonizes Liver, lubricates Lungs and intestines.
- Crab Apple: Neutral, sweet and sour. Quenches thirst, benefits Heart, Liver and Lung.
- Guava: Warm, sweet. Relieves frequent urination.
- Lemon and Lime: Cooling, very sour and astringent. Benefits Liver, improves absorption of minerals, promotes weight loss, cleans blood, treats poor circulation.
- Mulberry: Slightly cold. Quenches thirst, tonifies Kidneys, lubricates Lung, relieves constipation, calms the spirit.
- Pear: Cooling, sweet and slightly sour. Affects the Lung, eliminating heat, moistens Lungs and dryness in general, quenches thirst.
- Plum: Neutral, sweet and sour. Builds body fluids. Used for Liver diseases and diabetes.
- Strawberry: Cooling. Promotes body fluids, strengthens Spleen.

Grains and Legumes

- Millet: Cooling. Benefits the Stomach and intestines, promotes urination.
- Pearl Barley: Cooling. Strengthens Spleen, clears heat.

Sweet Rice: Warm, sweet. Benefits Spleen, Stomach and Lungs.

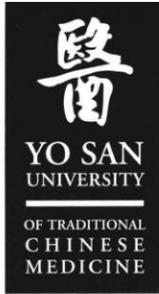
- Mung Beans: Cooling, sweet. Detoxifies the body, beneficial to the Liver, produces yin fluids.
- Garbanzo Beans: Sweet. Benefits the pancreas, stomach and heart.
- Soybeans: Cooling, sweet: Strengthens the Spleen, moistens dryness, supplements the Kidneys, helps restore pancreatic functioning, especially in diabetic conditions.
- Whole wheat: Cooling, salty and sweet. Tonifies the Kidneys, builds yin.

Animal Products

- Clam: Cooling, salty. Moistens dryness, nurtures the yin.
- Chicken: Warming, sweet. Used for conditions resulting from Spleen imbalances, especially diabetes.
- Beef: Warming, sweet. Used in the wasting stage of diabetes, treats insufficient yin.

(Pitchford, P. 1993; Flaws et al., 2002; Choate, C. 1999; Ni and McNease 2009).

Appendix B: IRB Approval Letter



May 28, 2013

Gayatri Chopra Heesen, MAOM, L.Ac.
300 E. Canon Perdido, Ste. E-1
Santa Barbara, CA 93101

Dear Gayatri,

Your revised research proposal has been approved, with no additional recommendations effective through March 31, 2014.

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.

Respectfully,

Shelley Cerny, L.Ac.
IRB Coordinator