

**Patterns of Infertility and Prior Treatment for Women Who Seek Treatment
at a Traditional Chinese Medical University Fertility Clinic**

by

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A Capstone Project

**Presented in partial fulfillment of the requirements for the
Doctor of Acupuncture and Oriental Medicine Degree**

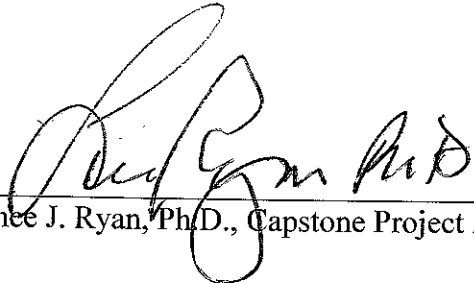
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Abstract

This study engaged retrospective chart review to discern patterns of prior diagnosis and treatment of women who were seen at a Traditional Chinese Medicine (TCM) university based fertility clinic. The data that emerged from this study were analyzed in three age categories—women under 35, 35-39 and over 40 years of age. A surprising finding of this study was that of the 50 charts reviewed, 42 (84%) were of women who were 35 years of age or older and therefore within the definition of advanced maternal age. It was the youngest group, women under 35 years of age, who were observed to have had the highest incidence of treatment for fertility prior to consultation at the TCM University based fertility clinic. The data also showed that the most common TCM diagnoses on intake at the fertility clinic were those of Spleen qi deficiency and Liver qi stagnation. Given the observed data, additional questions arose regarding the economic and geographic nature of the sample studied. Recommendations for further research were generated.

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Chapter One: Introduction

Statement of the Problem

Infertility affects approximately 7.3 million Americans between the ages of 15 and 44, or 10-15% of couples, with up to 1 in 8 couples failing to conceive a child. (Resolve, n.d.; Puscheck, E. 2010). With 20% of the women in the United States having children after the age of 35, infertility rates are climbing as an estimated 1/3 of these women have fertility problems (Center for Disease Control and Prevention, 2009). Terminology includes infertility, which the Center for disease Control and Prevention (CDC) defines as problems becoming pregnant among married couples, and impaired fecundity, which includes all women who have difficulty becoming or staying pregnant (CDC, 2010). For the purposes of this study the term infertility will refer to the broader terms described by the CDC as impaired fecundity. Two general categories of infertility are typically used for diagnoses; primary infertility in which the woman (couple) has have never had a child and secondary infertility, which is the failure to conceive following a previous pregnancy.

The common criterion in establishing infertility is 6 months of unprotected intercourse if over the age of 35, due to the aging and depleting eggs, and 1 year of unprotected intercourse if under the age of 35, with no pregnancies resulting. Male factor has been identified in various studies as an infertility causation factor in 30% to 50% of infertility cases. The remaining 50% to 70% of infertility cases are attributed to the women and various conditions that may be straight forward in nature or complex and as the result of several or multiple factors (US Department of Health and Human Services, n.d.)

Etiologies of Female Infertility

The classification of the etiologies of female infertility include advanced maternal age, medical conditions, lifestyle choices, environmental factors, stress and the category of unexplained infertility.

Women of advanced maternal are over the age of 35 and have a decreasing chance of pregnancy as the few eggs that remain are typically of poor quality and the ovaries may not function effectively, if at all, in releasing the eggs. Health factors such as age and hormonal imbalances can also affect the ability to conceive (Center for Disease Control and Prevention, 2009).

Medical conditions include autoimmune disorders, clotting disorders, hormonal and ovarian disorders, uterine factors such as a malformed uterus, Polycystic Ovarian Syndrome (PCOS), Pelvic Inflammatory Disease (PID), endometriosis, defects of the fallopian tubes or cervix, luteal phase defect, premature ovarian failure, tumors, infections and sexually transmitted diseases (Puscheck, 2010; Lobo, 2007; Speroff & Fitz, 2005).

Lifestyle choices include poor diet, smoking, alcohol and illicit or prescription drug use as well as excess weight loss or gain, athletic rigorous training and exposure to environmental hazards such as heavy metals and pesticides (Center for Disease Control and Prevention, n.d.; Puscheck, 2010).

In the past women who were did not conceive naturally remained barren or adopted children. Today with the establishment of Assisted Reproductive Technologies (ART), women thought to be barren are now successfully having children. In 1978, Louise Brown was born in England because of the first successful In Vitro Fertilization (IVF), which is a method of ART.

A new era was born where researchers and clinicians advanced IVF and established new procedures such as gamete intrafallopian transfer, zygote intrafallopian transfer, cryo-preserved embryos and frozen embryo transfer (FET). As these procedures are becoming more mainstream, women are seeking these and other infertility treatments. In 2006 approximately 127,000 ART procedures were performed, with the number climbing to approximately 150,000 in 2008 (Center for Disease Control and Prevention, n.d.; Puscheck, 2010). It has been estimated that over 1,000,000 IVF cycles are performed around the world each year; but the live birth rates, from the procedures listed above, have flat lined at rates near those of 2006, which ranged between 28.6% and 35.7%, depending upon the type of procedure (Magarelli, Cridennda, & Cohen, 2010; Puscheck, 2010).

Many organizations such as Resolve: The National Infertility Association, along with The American Fertility Association, The Worldwide Fertility Network, The National Infertility Network Exchange, and The American Society for Reproductive Medicine have been established to address the trends for assisted reproductive technology procedures and thus the ability to conceive in situations that would have been impossible prior to 1978. Numerous allopathic and Complementary and Alternative Medicine (CAM) facilities, groups and organizations are specializing in fertility treatments and support ranging from the ART procedures themselves to the supporting practices of acupuncture, yoga, massage, psychological support groups and legal firms. Traditional Chinese Medicine organizations such as the American Board of Oriental Reproductive Medicine and specialized individual and group practices have been established to provide support for couples dealing with infertility.

Acupuncture began to gain some prominence in the world of fertility treatments when in 1996, the Stener-Victorin paper was published which reported that electro-stimulation acupuncture increased the uterine artery blood flow in IVF patients. Following in 2002, was the Palus, et. al. paper that reported that acupuncture before and immediately following embryo transfer, enhanced pregnancy rates. These reported findings opened the door for acupuncture and Traditional Chinese Medicine (TCM) and began to establish a more visible role with infertility patients and the beginning of a working relationship with western physicians. Traditional Chinese Medicine includes acupuncture, electro-stimulation acupuncture, Chinese herbology, nutrition and tuina, a method of Chinese massage (Stener-Victorin, Waldenstrom, Anderson, & Wikland, 1996; Paulus, Zhang, Strehler, El-Danasouri & Sterzik, 2002).

Today, many Los Angeles fertility practices combine fertility services such as ART with in-house or on-call acupuncturists to enhance ART procedures. Study results suggest that acupuncture is a valuable complementary method to assist infertile couples. However, few studies identify the western infertility diagnosis, the TCM diagnosis or prior western medicine treatments received by these women. This study will seek to provide such information. Completion of research regarding this topic is important since the fertility clinic, especially the fertility clinic associated with a Traditional Chinese Medicine university, is a very new phenomenon in the United States. While Traditional Chinese Medicine is perceived by most as an “alternative” approach to healthcare, it is becoming more and more within the mainstream as consumers have become more aware of the limitations, expense and occasional hazards associated with Western Medicine. It is important to discern the factors that motivate women with infertility problems to seek assistance at a fertility clinic associated with a Traditional Chinese Medicine university. It is expected that research regarding this topic will help to guide

the further development for fertility clinics in the United States by providing valuable information regarding the factors that led patients to seek their help.

Glossary of Relevant Terms

ART: Includes techniques involving direct manipulation of oocytes outside of the uterus (Speroff & Fitz, 2005).

CAM: The collection of diverse medical and health care systems, practices, and products that are not considered part of conventional Western medicine. Complementary medicine refers to use of CAM together with conventional medicine, such as using acupuncture in addition to western medicine disciplines to help lessen pain. Alternative medicine refers to use of CAM in place of allopathic or conventional medicine (National Institutes of Health, n.d.).

Cryo-preservation: The freezing and thawing of oocytes or embryos (Speroff & Fitz, 2005)

Gamete intrafallopian transfer: The tubal transfer of oocytes and sperm (Speroff & Fitz, 2005).

Infertility: One year of unprotected intercourse with no resulting conception (Speroff & Fitz, 2005).

IVF: A sequence of steps including controlled ovarian hyper-stimulation, retrieval of oocytes from the ovaries, laboratory fertilization and transfer of embryo's into the uterus (Speroff & Fitz, 2005).

Zygote Intrafallopian Transfer: The tubal transfer of zygotes (Speroff & Fitz, 2005).

Chapter Two: Literature Review

This literature review chapter will provide the scholarly foundation for the current study. This chapter will review the most current literature regarding the use of acupuncture/TCM for general health conditions and for treating infertility. It will also review published work regarding why women seek acupuncture or Complementary and Alternative Medicine (CAM) for treatment of infertility. The literature review section will be followed by a brief integration section that summarizes the status of the literature and leads directly to the rationale for the current study. In conducting this literature review, the researcher engaged key word searches through the US National Library of Medicine National Institutes of Health (PubMed.gov), National Center for Biotechnology Information (NCBI) and several other databases that include the consideration of Traditional Chinese Medicine and alternative/complementary theory and procedures. For all searches the key words used included “infertility”, “TCM”, “CAM”, “female infertility”, “acupuncture”, “community acupuncture clinics”, “why women seek acupuncture/CAM/TCM for fertility/infertility.” Many of the sources reflected in this chapter were accessed through the Yo San University Library on-line journals and research based web sites.

Acupuncture

Acupuncture is a treatment method which encourages the body to heal naturally and to improve overall body functioning. Acupuncture treats many health conditions by stimulating "acu-points" found at specific locations on the body via the insertion of fine needles that aid in the circulation of qi and nutrients throughout the body, which restores health and balance while relieving pain and various other symptoms (California Acupuncture Board, n.d.; Bovey, 2001).

The world health organization (WHO) lists many conditions that acupuncture has proven to be effective in treating through controlled trials. These medical conditions include: adverse reactions to radiotherapy and or chemotherapy, allergic rhinitis, biliary colic, depression, dysentery, epigastralgia, facial pain, headaches, hypertension, hypotension, knee pain, leukopenia, low back pain, nausea and vomiting, neck pain, pain in dentistry, periarthritis of the shoulder, postoperative pain, renal colic, rheumatoid arthritis, sciatica, sprain, stroke and tennis elbow. Although in their 2003 report, infertility was placed in the category of “further proof needed but therapeutic effects were shown”, many areas involved with fertility, gynecology and obstetrics were included. These areas included primary dysmenorrhea, premenstrual syndrome, induction of labor, mal-position of fetus and morning sickness. Due to preliminary experimental studies that reported Acupuncture’s effect of regulating abnormal functioning of the hypothalamic-pituitary-ovarian axis, acupuncture was recommended for hormonal imbalances such as luteinizing hormone, estradiol and gonadotropin- releasing hormone. Acupuncture was also suggested for female infertility due to inflammatory obstruction of the fallopian tubes (World Health Organization, 2003).

The American Hospital Association reported in 2007 that 20.8% of community hospitals offered some method of treatment that did not fit into traditional western medicine care, an increase from the 8.6% reported in 1998. This increase is due to a rapid growth in the 1990’s of integrative medicine centers at major research institutions, particularly oncology centers. The Health Forum/AHA Complementary and Alternative Medicine Survey of Hospitals reported in 2007, that complementary programs were more common in urban than rural hospitals and acupuncture is listed as one of the top six CAM services offered (Henkel, 2010).

A 1997 survey compared survey results with those from a previous study in a 1997. The results showed an increase from 36.3% to 46.3% ($P=.002$) in the probability of users visiting an alternative medicine practitioners, and an estimated increase of 45.2% in expenditures for alternative medicine services. The data also identified an increase of visits to alternative medical providers from 427 million in 1990 to 629 million in 1997, which exceeded all visits made to primary care physicians (Eisenberg, Davis, Ettner, Appel, Wilkey, Van Rompay, & Kessler, 1998).

A 1998 study identified that Chinese medicine was a growing phenomenon but that little was known about why, or the demographics of those who sought Chinese medicine services. An anonymous mixed quantitative qualitative survey questionnaire was used in five US states, at six general service clinics, with a total number of 575 participants. The questionnaire rendered information regarding the type of Chinese medicine modalities used, participant demographics, participant health complaints, response to care received, satisfaction with the received care and other health care modalities utilized. The results showed that CAM services were used most often for musculoskeletal dysfunction, mood care, and overall wellness care, with a large majority of users reporting a disappearance or improvement of symptoms, improved quality of life and a reduction in prescription drug use and surgeries. The participants were well-educated, employed, middle aged and in the middle-income bracket. Varieties of other types of services were used in conjunction with Chinese medicine, with Chinese medicine showing an extremely high satisfaction rate. A follow up article analyzed hand-written stories gathered from 460 of the participants, at the time of the above mentioned study, in which participants reported enjoying a close relationship with their Chinese medicine practitioner, enjoying learning new things, and enjoying the feeling of being more able to guide their own lives and to care for themselves.

Their vocabulary in the letters and the description of their experiences indicated familiarity with a holistic model of healthcare and they appeared to have found that Chinese medicine and their experiences with it using it as a treatment modality fit their view of holistic care. Cassidy, the author, summarized that this was a significant finding as participants are utilizing a homegrown, if nonmainstream, model of healthcare and that it shows that a holistic health delivery model is not only feasible, but currently exists in the United States. She further commented that how Chinese medicine practitioners are trained, and how they deliver medical care to their patients, could serve as a model for American healthcare reform (Cassidy, 1998).

A 2005 study evaluated the completed surveys from 9408 consecutive acupuncture patients. The two most significant short-term reactions reported by the patients were the feeling of relaxation (79.1%) and feeling energized (32.7%). Although “negative” reactions such as drowsiness, bruising and tiredness were frequently reported, the majority of patients were willing to experience these reactions again (MacPherson & Thomas, 2005).

Acupuncture and ART/IVF

Since 2003 many studies have been published regarding acupuncture and infertility. The results are varied with some reporting that acupuncture does enhance IVF treatments and increase live births, while others dispute the claim, and many suggest that more research is needed. Statistically significant higher pregnancy rates were reported in many studies completed prior to 2006 (Bovey, M., 2001). Since 2006, more western, controlled studies are being conducted, and the data suggest that more scientific data is need from larger, better defined studies. The World Health Organization’s review and analysis of reports of controlled clinical trials lists several categories where further studies are needed. Included are the areas of female infertility, reduction of labor pain and many non-fertility related conditions. A 2008 systematic

review and meta-analysis of acupuncture in in-vitro fertilization analyzed thirteen trials that included 2500 women in randomized trials. The study concluded that the literature reviewed did not provide enough evidence to show that acupuncture in conjunction with in-vitro fertilization improves clinical pregnancy rates. The Stener-Victorin study, which found that acupuncture increased blood flow to the uterus as well as enhancing endometrium thickness, also identified that further studies were needed to verify these results (World Health Organization n.d.; El-Toukhy, Sunkara, Khairy, Dyer, Khalaf & Coomarasamy, 2008; Stener-Victorin, et al., 1996).

Stress is a key factor in infertility and acupuncture has a significant role to play in helping women relax on both a physical and emotional level. Research linking psychological stress and poorer pregnancy outcome suggests reducing levels of stress may be a key factor in infertility treatments. A study that examined psychological stress and ovarian norepinephrine levels with respect to the outcome of in vitro fertilization included one hundred and seven women with infertility due to tubal factors. The subjects were assessed before and during their first IVF treatments to evaluate stress levels. The study concluded that psychological stress, which included both anxiety and depression, might negatively affect the clinical pregnancy rate of IVF procedures in women with tubal factor infertility (Li, Ma, Geng, Qin, Hu & Li, 2010).

An additional study that evaluated the stress levels of both pregnant and non-pregnant women throughout the stages of in-vitro fertilization found that the differences between the pregnant and non-pregnant groups regarding stress and biological factors indicated that stress is directly related to the pregnancy rate of in-vitro fertilization. (Boivin & Takefman, 1995).

The results of an additional study which focused on the effect of acupuncture on psychosocial outcomes for women experiencing infertility, examined the efficacy of acupuncture on reducing infertility related stress with a wait-list control group. Thirty-two women between 20

and 45 years of age received six acupuncture treatments over an eight-week period. The primary outcome measures were infertility-related stress, anxiety and infertility self-efficacy. Infertility self-efficacy is determined by assessing perceived stress, current levels of distress due to fertility problems and coping styles (Cousineau, Green, Corsini, Barnard, Seibring, & Domar, 2006). The results of the study indicated that the women who received acupuncture showed reduced anxiety and a trend towards improved self-efficacy as well as less social and relationship concerns. The women who received acupuncture also reported relaxation and calmness on both a physical and psychological level. The researchers concluded that further research is justified, as acupuncture may be a useful modality useful to assist with the reduction of infertility related stress (Smith, Ussher, Perz, Carmady, & de Lacey, 2011).

A 2009 pilot study was conducted that evaluated acupuncture and IVF with specific reference to the relationship between perceived stress, acupuncture, and pregnancy rates among IVF patients. The researchers found that the group who did not receive acupuncture achieved a 42.5% pregnancy rate, while those who received acupuncture along with IVF or IVF/ICIS achieved a 64.7% pregnancy rate. The study concluded that acupuncture may have an important role in pregnancy rates (Balk, Catov, Horn, GeCSI, & Wakim, 2009).

Patient Self Reports

Acupuncture has been demonstrated in some studies to assist women in becoming healthier, to lower stress and to have enhanced fertility and increased pregnancy rates. As the number of women seeking infertility treatments and CAM practices increases, it is important to understand why women seek treatments from CAM providers. It is estimated that 22,000,000 people sought CAM practices in England in 1998, and that Americans spent an estimated \$13,000,000 in out of pocket funds on a variety of CAM services. According to the 2007

National Health Interview Survey, which included a comprehensive survey of CAM use by Americans, an estimated 3.1 million U.S. adults and 150,000 children had used acupuncture in the previous year. Between 2002 and 2007 acupuncture use among adults increased by approximately 1 million people (Thomas, Nicholl & Coleman, 2001).

Self-reporting from patients in various surveys identifies the major factors that motivate patients to seek CAM-oriented treatments. Among the factors revealed are the quality of the relationship with the CAM practitioner, the presence of a holistic treatment plan, and the increased overall feeling of well-being(Cassidy, 1998).

A 2010 study regarding the demographics of CAM users was conducted via a systematic literature search of computerized databases and research papers. Although the researchers determined that future research is needed to address methodological limitations in existing studies, the results suggest that CAM users are educated women of middle age who tend to have more than one health concern (Bishop, & Lewith, 2001).

A further study provided an international comparison of attitudes toward traditional and modern medicine in both Chinese and American clinic settings. The study sought to provide insight regarding several factors including both patient characteristics and universal characteristics associated with the use of Traditional Eastern Asian Medicine (TM). One rationale for the study was the lack of studies examining why individuals seek CAM or TM therapies. The study pointed out the lack of data regarding correlations between attitudes, beliefs and psychosocial or socio-cultural status and the use of TM. The results showed that the majority of patients in both China and The United States initially sought allopathic medicine services, while the patients in the United States had a higher rate of stopping allopathic treatments after beginning TM treatments. Patients in China received TM for a variety of

conditions while the US patients presented most commonly with musculoskeletal issues. Patients in China were significantly more satisfied with allopathic treatments while US patients were significantly more satisfied with TM. Patients in both countries were significantly more satisfied with TM than allopathic medicine. Included in the study were demographic data collected from 570 recent patients from the US clinic. The data yielded the following patient information: 61% female, average of 40.2 years of age, 62% Caucasian, 15% Asian, college level 59% and 32% graduate school levels. Full data were not available regarding the Chinese sample, but estimates of the typical patients manifest the China sample as individuals in their mid-40s with a higher percent being females. The researchers concluded that although treatment often originated with allopathic providers, many patients sought other types of treatments, presumably to find the best solution to the patient's problems. The tendency toward self-directed health care suggests that a dual or pluralistic health care system may provide the greatest satisfaction due to improved outcomes and patient involvement in choosing the modality of medical care (Burke, Kuo, Harvey & Wang, 2008).

As infertility treatments increase and acupuncture gains more visibility, women are deciding to incorporate Chinese medicine with their western infertility procedures. In Australia women are using CAM to enhance fertility and researchers have identified that little is known about why women use CAM services for fertility (Rayner, McLachlan, Forster & Rhian, 2009). Although the study included only seven women, the results showed that the women valued the support, information and sensitive communication provided by the practitioners. This finding supports the conclusion of Sirois (2008) that the motivation for CAM use is its holistic approach to healthcare.

A study that focused on the use of CAM modalities with infertility patients showed that 90% of the subjects reported stress reduction, improved mood, empowerment and perceived cycle response improvement as the benefits of CAM treatments. Infertility diagnosis included unexplained infertility (32%), age related (18%) and male factor (18%) with the mean age of the participants at 36.7 years of age (Aeilon, Barbieri, Shastri, Grill, Chung, & Rosenwaks, 2009).

What is lacking in the vast majority of current studies, is data about the medical history of these women, their diagnosis of infertility in both allopathic and Traditional Chinese Medicine and previous infertility treatments. Many of the available studies are generalized to assess overall CAM use, with few studies available that discuss the reason for the use of acupuncture or TCM treatments for infertility or fertility enhancement. The one study that did look at the relationship between TCM and western medical diagnoses was a randomized control trial of 180 women with a mean age of 35.7, undergoing ART, who were recruited prior to egg retrieval. Participants were assigned one or more TCM diagnoses, primarily by one practitioner who was not blinded to the western diagnosis, based upon signs, symptoms, and tongue and pulse qualities. The outcome revealed that 53.9% of the women had kidney yang deficiency, 53.3% had kidney yin deficiency, 38.9% had qi stagnation, 36.1% had blood deficiency, 33.9% had blood stagnation and 19.4% had a damp pathology. Additional diagnoses included 8.3% with heat in the blood, 5.6% with cold in the uterus and 3.3% with spleen blood and qi deficiency as well as several that did not measure as statistically important in this trial. The western diagnosis for these women revealed that 24.4% had unexplained infertility, 24.4% had endometriosis, 15.6% had tubal factors, 4% had proximal disease, 1% had luteal insufficiency, and a large percentage (35.6%) were listed under "other." The researchers reported correlations between the TCM and western diagnoses. Women with unexplained infertility had a high rate of having a

diagnosis of qi stagnation while women with endometriosis were most commonly seen to have a diagnosis of blood or qi stagnation. Many single or multiple factors such as advanced maternal age, hormonal, ovarian and uterine factors could be at play with these patients. In order to focus treatments and further research on acupuncture and infertility it is necessary to provide more studies to analyze patterns in infertility diagnosis and treatments in the women choosing acupuncture in place of, or in conjunction with, western treatments (Coyle, & Smith, 2005).

Literature Review Integration

There have been a number of studies that have established the effectiveness of complementary and alternative medicine (CAM) techniques in assisting individuals who are dealing with the condition of Fertility (Aeilon, et al., 2009; Magarelli, et al., 2011; Chang, et al., 2002). While these studies have been helpful in understanding the theory, technology and procedures involved, they provide little information regarding the background of patients who seek fertility treatment. As a result, there is a gap or blind spot in the current literature. It will be the objective of the current project to begin to fill that gap by completing a preliminary study of the medical history, prior fertility treatments TCM diagnosis and other factors of women patients who seek treatment at a Traditional Chinese Medicine University Fertility Clinic.

Chapter Three: Method

Method Designation and Rationale

The use of existing health records is a recognized and frequently used qualitative research procedure. It is identified as a method that has the potential to make effective use of meaningful existing data to fulfill research objectives and to respond to research questions. Chart review as a research method involves a number of steps that include the systematic gathering and organizing of existing data through the use of protocols carefully and specifically designed for abstracting information from patient charts. While the method of retrospective chart review has been used effectively in mental health/behavioral science studies (Gearing, Mian, Barber & Ickowicz, 2006), it has also been used in studies that involve medications, drugs and other medical issues (Gandhi, Seder & Bates, 2000; Hess, 2004). Moreover, as a qualitative method, retrospective chart review is a method that is easily adapted for use in the discipline of Traditional Chinese Medicine.

Retrospective chart review research method includes a number of steps that assure that the data gathering process is engaged systematically and with minimal opportunity for bias. The process starts with a clear conception of the research objective that is supported by a sound literature review. A research proposal stipulates the processes to be engaged in the data gathering including the specification of a data abstraction instrument that is supported by both clearly detailed sampling criteria and data gathering guidelines (Gearing, Mian, Barber, & Ickowicz, 2006).

The method of retrospective chart review is especially appropriate in the current study. The current study is considered to be preliminary study dealing with a relatively new and unique

phenomenon of the TCM University based fertility clinic. Chart Review is the most appropriate method for achieving the research objective of the current study. The archived charts of patients who have been treated in a TCM Fertility clinic are rich with demographic and other data that have the potential to provide a clearer picture regarding the background, motivation and prior treatment of patients. By “mining” charts of a representative number of patients, it is likely that patterns and themes will provide a clearer picture of the female patients who seek service from fertility clinics based at TCM universities. The emergence of that information may also pave the way to future studies of a more controlled nature.

Procedures

All data engaged in the current study were extracted from the charts of patients were seen at the Yo San University Fertility Clinic in Los Angeles, California. All patients had completed the new patient intake form prior to extraction of data. The patient charts that were reviewed to gather data for this study were those of patients who were seen at the Yo San University Fertility Clinic between May 2010 and June 30, 2011. The sections below specify how the charts were chosen for review.

Inclusion Criteria

For the current study, patient charts were chosen that fit the following criteria:

- Female patients
- Non-pregnant
- Seen in the Yo San University Fertility Clinic between May 1, 2010 and June 30, 2011.

Exclusion Criteria

For the current study there were two exclusion criteria. They are listed below:

- Male patients
- Current pregnancy

Data Collection Instrument

A data collection instrument was developed specifically for the current study.

The chart extraction form was developed to be consistent with the questions listed on the Yo San Fertility Clinic “New Patient Intake Form.” The instrument included eight areas of content which sought to discern prior patterns of diagnosis and treatments of infertility. The form included eight areas of data as follows:

1. Allopathic Diagnosis related to infertility: This section identified if the patient had been given a diagnosis of infertility and if so what it was.
2. How long trying to conceive: This section determined if the patient fits the standard diagnosis of infertility—12 months of unprotected sex if under 35, and 6 months if over 35, resulting in no pregnancies.
3. Hormone laboratory work and results: This section determined if hormone lab tests were conducted to assess hormonal factors influencing fertility, and what the outcome of these tests were.
4. Fallopian tubes evaluated medically and procedures if noted. This section determined if fallopian tubes had been evaluated for fertility.
5. Medications to assist ovulation: This section determines if medication was taken to assist ovulation and if so, which medications.

6. Male Factor Evaluation: This factor discerned whether the partners of the patients had undergone semen analysis.
7. Any prior fertility treatments: The section identified any IVF procedures, acupuncture or TCM treatment as well as when and with whom they occurred.
8. Patterns of TCM diagnosis: This section will determine the single or multiple TCM diagnosis rendered during the initial intake at the fertility clinic.

A copy of the data collection instrument is included in Appendix B.

Data were collected from the new patient intake forms completed by the patients prior to their first treatment at Yo San University's community fertility clinic. The files of all non-pregnant females, seeking treatment in the fertility clinic between May 2010 and June 2011 were designated as the sample for the current study. The data extraction process took place during July of 2011.

Patient responses to the questions described above were entered into the data collection form and then entered into an Excel spreadsheet. On the spreadsheet the data was sorted and viewed in various categories. All data entered on the research instrument were extracted from the chart forms and reflect responses to specific questions that each patient responded to prior to discussions with the practitioner. All questions with no response were coded as "NR" on the data collection form.

Data were extracted from the charts of all non-pregnant women who had attended the Yo San University fertility clinic. The patients were coded on a separate spreadsheet as they were reviewed to avoid duplication. On the spreadsheet the patients were listed with initials only. Patient names and identifying data were not added to the data collection sheet or the spreadsheet, to ensure patient confidentiality. In addition to being entered into a password-

protected file on the researcher's laptop computer. The spreadsheet data files were saved on an external flash drive and stored in a locked filing cabinet.

The charts of all non-pregnant female patients who attended the university fertility clinic for fertility treatments were included in this chart review. Pregnancy and gender were the only exclusion criteria. As the fertility clinic first opened and treated patients in May of 2010, charts were only available for a 14-month period. Data were extracted from 50 patient charts.

Data Analysis

As this research project constituted a preliminary study, the researcher did not designate any specific hypotheses. As the data were collected and summarized, factors that emerged as worthy of further consideration were identified and engaged in further analysis. Due to the nature of the data that emerged, the analysis process in the current study falls primarily into the arena of descriptive analysis. The data generated from this chart review study were discerned to fall into three general areas:

- Interval data from items where there were tallies or counts.
- Categorical data from the demographics terms including prior diagnosis and treatment modes.
- Narrative data where the patient describes her condition or status.

Additionally, the researcher carefully analyzed the data to discern factors in the data collection instrument that need to be added, eliminated or refined in the event that it is used in a future research.

Human Subjects Research Ethical Considerations

Since the research process involved no gathering of new data, and all data used were pre-existing and extracted from archived patient charts, the current study is exempt from Institutional

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Review Board (IRB) consideration. Nonetheless, the proposal for the current study was submitted to and reviewed by the Yo San University IRB Director in February of 2011.

Subsequent to that submission the researcher received a letter from the IRB Director affirming the exempt status of the study. A copy of the IRB letter is included in Appendix A.

Chapter Four: Results

The objective of this project was to examine patterns of previous treatment and diagnosis in women seeing infertility treatment at a teaching university fertility clinic. Retrospective chart review method was engaged to accomplish the research objective. The data for this project came from the chart files of 50 female patients treated at a university fertility clinic between May of 2010 and July of 2011. Data were extracted from the new patient intake forms completed by patients prior to their initial visit at the fertility clinic. The data from the women patients were organized and tallied in three age groups: under 35, 35 through 39 and 40 years of age and older.

This chapter presents a summary of the data gathered beginning with a summary of eight critical factors that emerged from the chart review. For each of the designated age groups the researcher gleaned from the charts data regarding the Allopathic infertility diagnosis. This factor is vital since treatments are likely to be rendered consistent with this diagnosis. The second factor was the indication of how long the patient has been trying to conceive. This factor is very important as it may also be viewed as an indication of the motivation of the patient. Is the condition at the level that it might be considered acute, or is it already at the chronic level? Hormone lab work data constituted the third factor. The fourth factor was the status of the Fallopian tube as per any prior evaluations, and the fifth factor was the record of any medications taken to assist ovulation. The status of male infertility workups for spouses/partners constituted the sixth factor. The seventh factor included indications of prior or concurrent fertility treatments. The eighth and final factor examined across the age groups was the TCM diagnosis.

The data that emerged from the three designated groups are summarized in the sections that follow. The sections that follow the presentation of the data for the three groups include observations that compare the data for the eight factors across the three groups. Those

subsequent sections are sub-headed as “intergroup comparisons and observations.”

Discrepancies in the data below are due to the fact that for some of the charts reviewed the patients did not include responses to every item.

Women Under Thirty-Five

This group included eight women with the mean age observed to be 33.0 years.

Even though the number in this group is the smallest for all three groups, the data emerging from this group should be considered carefully since, because of their younger age, and because of the fact that they are in the midst of their fertility years, the women in this group represent the most unlikely among the three groups to be seeking fertility treatment.

1. Allopathic Infertility Diagnosis: 4 of 8 (50%) responded yes to the question with the results being: unexplained and Endometriosis, unexplained and PCOS, Methylene tetrahydrofolate reductase (MTHFR) and slightly high FSH.
2. How long trying to conceive: The observed range was 4 months to 3 years. For the 7 respondents in this age group the average time trying to conceive was 16.87 months.
3. Hormone Lab work and results: 5 of 8 (62%) had a recent workup. Two reported “ok” results, 2 had high FSH, 1 had high testosterone, 1 had low T-cells, and 1 had high T3 and T4.
4. Fallopian tube evaluation: 5 of 8 (62%) responded yes. Two reported no significant findings, 1 had one twisted tube, and 2 had inconclusive results.
5. Medications to assist ovulation: 4 of 8 (50%) confirmed that they had taken medication to assist ovulation.

6. Male fertility workup: 6 of 8 (75%) reported yes, with 2 reporting low sperm count.
7. Previous or concurrent fertility treatments: 5 of 8 (62%) responded yes, with 1 receiving TCM treatments. Four of the five yes respondents had undergone IUI, and or IVF procedures.
8. Patterns of TCM Diagnosis: 6 of 8 (75%) were diagnosed with both spleen qi deficiency and liver qi stagnation. Four of 8 (50%) were diagnosed with kidney deficiency, 2 of 8 (25%) were diagnosed with excess heat, and 2 of 8 (25%) with blood stasis.

Women Thirty-Five Through Thirty-Nine

This group included 19 women with the mean age of 36.89. Like the group of women whose age is under 35 years and also like the group that is over 40 years, this group deserves careful consideration as they are likely representative of two differing expectations—women who expect to be fertile as well as women who are approaching the age when the expectation is that fertility will be diminished.

1. Allopathic Infertility Diagnosis: 10 of 19 (53%) responded yes to the question—with the results being: MTHFR, PCOS, low Inhibin B, tubal factor, and 1 listed advanced maternal age.
2. How long trying to conceive: The respondent range was 5 months thru 5 years. Of the 14 respondents the average was 24.5 months.
3. Hormone Lab work and results: 10 of 19 (53%) had recent workups while 7 of 19 (36%) had not had any recent workups. Two of 19 (10%) did not respond with 1 listed the results as low Inhibin B.

4. Fallopian tube evaluation: 9 of 19 (47%) responded yes. Seven of 19 (37%) responded no and 3 of 19 (16%) did not respond. Results of the fallopian tube evaluation indicated 1 with a misaligned tube and 1 with a damaged tube.
5. Medications to assist ovulation: 7 of 19 (37%) responded yes, 8 of 19 (42%) responded no, and 5 of 19 (26%) did not respond.
6. Male fertility workup: 9 of 19 (47%) responded yes, 9 of 19 (47%) responded no and 1 did not respond. Eight of 9 (89%) reported that semen analysis identified no problems, with 1 reporting results of low motility and concentration.
7. Previous or concurrent fertility treatments: 8 of 19 (42%) responded yes, 5 of 19 (26%) responded no and 6 of 19 (31%) did not respond. One of the 8 who responded yes to this item had received TCM treatments, and 7 had undergone FET, IUI and or IVF treatments.
8. Patterns of TCM Diagnosis: 11 of 19 (58%) were diagnosed with spleen qi deficiency and liver qi stagnation, 8 of 19 (42%) with kidney deficiency, 7 of 19 (37%) with excess heat, 4 of 19 (21%) with blood stasis, 3 of 19 (16%) with shen disharmony, 3 of 19 (16%) with deficiency heat and 2 of 19 (10%) with dampness.

Women Over Forty

This group included 23 women with the mean age of 42.78. With the largest number of patients, this group represents the mode for patients seeking fertility treatment, and is thus likely the most representative of patients seeking fertility treatment at a university community clinic.

1. Allopathic Infertility Diagnosis: 10 of 23 (43%) responded yes, 12 of 23 (52%) responded no, and 1 responded with a question mark. Diagnostic results were as follows:

- 1 listed missing an ovary and advanced maternal age; 1 listed high FSH and early menopause; 3 listed unexplained infertility; 1 listed recurrent pregnancy loss with anti-nuclear antibodies and advanced maternal age; and 4 listed advanced maternal age.
2. How long trying to conceive: 8 months thru 5 years was the observed range. For the 18 who responded the average time trying to conceive was 25.7 months.
 3. Hormone Lab results: 15 of 23 (65%) had recent workups, 6 of 23 (26%) responded no and 2 of 23 (8.7%) did not respond. Six of 15 reported high FSH, 1 reported anti-nuclear antibodies, and 8 reported that their hormone levels were “fine.”
 4. Fallopian tube evaluation: 10 of 23 (43%) responded yes they had a prior fallopian tube evaluation, 9 of 23 (39%) responded no and 4 of 23 (17%) did not respond. One reported inconclusive results, with 8 reporting that their fallopian tubes were “fine”.
 5. Medications to assist ovulation: 9 of 23 (39%) responded yes, 10 of 23 (43%) responded no, with 4 of 23 (17%) not responding.
 6. Male fertility workup: 11 of 23 (49%) responded that their partner did have a male fertility workup. Two of 23 (9%) responded with “non-applicable” as they were using sperm and embryo donors. Eight of 23 (35%) responded no, and 2 of 23 (9%) did not respond. Results of the male fertility workup include 1 male diagnosed as infertile. 1 listed poor morphology; 7 of 11 (64%) reported that semen analysis identified no problems. One had surgery to correct a varicocele, and 1 had surgery to reverse a vasectomy.

7. Previous or concurrent fertility treatments: 11 of 23 (49%) responded yes. Six of 23 (26%) responded no, and 8 of 23 (27%) did not respond.
8. Patterns of TCM Diagnosis: 19 of 23 (83%) were diagnosed with spleen qi deficiency. 18 of 23 (78%) were diagnosed with liver qi stagnation; 15 of 23 (65%) kidney deficiency; 7 of 23 (30%) blood deficiency; 6 of 23 (26%) damp or phlegm retention; 5 of 23 (22%) yin deficiency; 4 of 23 (17%) blood stasis; 4 of 23, (17%) qi deficiency; 3 of 23 (13%) excess heat, 2 of 23 (9%) deficient heat, and 1 of 23 (4%) Lung deficiency.

Intergroup Comparisons and Observations

In this section, comparisons and observations will be made regarding the eight identified factors across the three designated age groups. The observations and comments in this section resulted from either simple tallying or other descriptive statistical measurements regarding the factor under consideration.

1. Allopathic infertility diagnosis: Of the 50 files reviewed, only 24 (48%) of the charts reviewed indicated having an allopathic diagnosis of infertility. Only 7 of 42 (22%) reported advanced maternal age as a prior allopathic diagnosis. Nonetheless, all 42 are actually at the stage of advanced maternal age. This factor indicates a lack of awareness of the factor of advanced maternal age. Of the 50 charts, 26 (52%) of the women responded that they had not received an allopathic diagnosis of infertility. Of those who listed a diagnosis (48%), 5 had a diagnosis of unexplained infertility, 2 had a diagnosis of MTHFR, 2 had a diagnosis of PCOS, 2 had a diagnosis of high FSH, 1 had a diagnosis of low Inhibin B, 1 had a diagnosis of endometriosis, 1 had a tubal factor diagnosis, 1 woman was missing an ovary, 1 was in early menopause, 1 had

- undergone recurrent pregnancy loss, and 1 woman was diagnosed with Antinuclear Antibodies.
2. Length of time trying to conceive: The group under 35 identified fertility concerns with a range of 4 months to 3 years, and an average of 16.87 months of trying to conceive with no viable pregnancies. Progressively the mid-group (35 thru 39 years of age) tried for 5 months thru 5 years, with an average of 24.5 months. The age group over 40 was 8 months thru 5 years trying to conceive, with an average of 25.7 months.
 3. Hormone lab work and results: 30 of the 50 charts reviewed (60%) reported having blood lab work done with high FSH being reported as the most frequent diagnosis. Eight of 15 (53%), and 9 of 15 (60%) reported that their hormone levels were “fine.” One reported anti-nuclear antibodies, 1 listed the results as low Inhibin B. One had high testosterone, 1 had low T-cells, and 1 had high T3 and T4. The charts of four patients included “no response” (left blank), and 16 (32%) of the charts indicated that they did not have hormonal blood work done. The findings per age category for having had prior hormone lab work were: under 35 years of age 5 of 8 (63%); 35-39 years of age 10 of 19 (53%); over 39 years of age 15 of 23 (65%).
 4. Fallopian tube evaluation: 24 of 50 (48%) had their fallopian tubes evaluated, with 7 (14%) with indication of no response, and 19 (38%) who have not had their fallopian tubes evaluated. Three of the 24 who did have a fallopian tube evaluation, reported inconclusive results; 4 reported a misalignment, damaged or twisted fallopian tube, and 8 reported that their tubes were “fine”.

5. Medications to assist ovulation: Of the 50 women, 20 (40%) had received medication to assist ovulation with the largest percentage being in the below 35 age group in which 50% had taken ovulation medication. Twenty of the 50 (40%) women reported having taken medication to assist ovulation. The majority of respondents did not identify which medications were taken, and therefore no data is reported.
6. Male fertility workup: Two patient charts indicated a response of “non- applicable” to the male fertility workup question. Of the remaining 48, 26 (54%) reported that their partners had undergone semen analysis. The highest affirmative rate was in the under 35 age group, with 6 of 8 (75%) having had the analysis; with 9 of 19 (47%) of the 35-39 age; and 11 of 23 (48%) in the over 40 years of age group. Results indicated 3 problem areas and 2 resolutions via varicocele surgery and vasectomy reversal.
7. Previous or concurrent fertility treatments: Responses to the fertility treatments question was inconsistent with many non-responders. Minimally, 24 women (48%) have received TCM or allopathic treatments. The under 35 age group had the highest percentage with 5 of 8 (63%) of the women having undergone allopathic procedures such as IUI or IVF.
8. TCM diagnosis: Regarding the TCM diagnoses, it needs to be pointed out that generally practitioners assign more than one diagnosis to each case. For some cases, practitioners may assign as many as three or four diagnoses. As a result the number of diagnoses rendered exceeds the number of cases. The researcher also wants to remind the reader of the fact that the diagnoses in this sample were rendered by at least 12 different doctoral level practitioners/interns who are all licensed acupuncturists. Across all three groups, the most frequently rendered diagnosis was

spleen qi deficiency, with the diagnosis being designated in 36 of the 124 diagnoses rendered for the 50 cases (29%). The next most frequent diagnosis was liver qi stagnation, which was rendered in 35 of the 124 diagnoses (28%). In the middle of the diagnosis spectrum were the diagnoses of kidney deficiency which included kidney qi, yang and yin deficiencies due to a generalized “kidney deficiency” diagnosis by the practitioners, rendered in 27 of the 124 diagnoses (21%). The diagnosis of excess heat, was rendered in 12 of the 124 diagnoses (9.6%) while at the lower end of the diagnosis spectrum, the diagnosis of blood stasis was observed to be rendered 10 times of the total of 124 diagnoses (8%). Table 1 (See Appendix C) summarizes this data. Diagnoses which occurred less than 5 times such as shen disharmony or deficient heat were not included in the 124 diagnoses found in the 5 primary diagnostic categories listed above or seen in the appendix C, Table 1- raw data chart. In the raw data chart, because of the low numbers, some of the diagnoses were consolidated, such as dampness being included in the spleen qi deficiency category. Qi stagnation was included in the liver qi stagnation category.

Chapter Five: Discussion

From 1970 to 2006 the proportion of first births to women aged 35 years and older increased nearly 8 times, equating to 1 out of every 8 births being to a women over 35. With this trend, it is not surprising to see such a high percentage of women over 35 seeking treatment from a TCM university fertility clinic. Consistent with this observation 42 of the 50 charts reviewed in the current study were those of women, seeking fertility treatments at Yo San University Fertility Clinic. The women over 35 years of age did not appear to identify with being of advanced maternal age, nor did they see the need for tests and interventions. It appears that the age group under 35 years of age is more proactive and perhaps more knowledgeable about infertility, as they began treatments sooner than the older women. In this younger age group, there were also a larger percentage of charts with indication of prior hormonal blood lab work having been completed, fallopian tube evaluations, allopathic interventions and sperm analyses.

Spleen deficiency, which is related to digestive functions, nutrition absorption, creation of energy, quality and quantity of blood, and of holding the abdominal organs in place, had the highest diagnosis with 36 of the 124 diagnosis (Liang, 2010).

Liver qi stagnation, which can be equated to stress in western terms, and relates to the timing of the menstrual cycle, was the second highest diagnosed condition across all age groups with 35 of 124 diagnoses. Kidney deficiency, which is linked with issues of heredity, growth, development, reproduction and fertility, had the 3rd highest diagnosis (Liang, 2010).

Fertility in Traditional Chinese Medicine can be viewed from the perspective of the *Huang Di Nei Jing*, which states that women begin to decline after the age of 35 when the Yang Ming (stomach) channel gradually weakens. The stomach has an internal partnership with the spleen, so inherent to the weakening of the stomach is the weakening of the spleen and therefore

digestion and the various spleen functions, which suggests this study's finding of the prevalence of spleen qi deficiency in this population of women, the majority of whom were over the age of 35. (Wang, 2002).

Implications for Theory

Numerous TCM books, articles as well as the survey conducted by Coyle and Smith (2005) discussed in Chapter Two, identify kidney deficiencies as the primary diagnosis of infertility. The results from the current study identified spleen deficiency (29% of all diagnoses) closely followed by liver qi stagnation with 28% as the highest categories of diagnoses, with one 21% receiving a diagnosis of kidney deficiency. Factors such as life style and diet in Australia where the Coyle and Smith (2005) study was conducted may differ from those in west Los Angeles. The training of the practitioners can affect the diagnostic outcome, particularly when their training has occurred at different Universities or Colleges. The diagnoses rendered, in both studies, may have been based upon the patient's chief complaints, the underlying constitutional condition or a combination of both, which could play a major role is the assignment of diagnosis. Future studies with diagnostic guidelines to address these variables, may provide additional information to support the findings in this or the Coyle and Smith (2005) study.

Implications for Practice

Education of students and practitioners regarding advanced maternal age and the subsequent fertility challenges inherent to treating women of advanced maternal age is extremely important. Women under 35 may be more aware of fertility issues due to the availability of information on the internet and the tendency of younger generations to use the internet as well as portable technology applications for information, suggestions and treatments. Many younger women are using phone applications to discern menstrual cycles. They also consult ovulation

calendars and fertility charts to document and predict their menstrual cycles and ovulation. There is observed to be a gap for the advanced maternal age patient group regarding their knowledge of fertility as well as perhaps a denial of age-associated factors that relate to fertility. The value of lab work with many patients is very helpful as are tubal evaluations, HSG's and ultrasounds. Students and patients should be educated regarding the value of these tools.

With approximately 50% of the women who sought TCM treatment in this study who have not seen a reproductive endocrinologist (RE) or undergone allopathic treatments, it would suggest that the Yo San University Fertility Clinic, where this study was conducted, is not receiving referrals from the local RE and fertility practices. Marketing to these groups would potentially increase new patients including patients who had undergone many of the possible medical tests for infertility.

Limitations

Since this study was based upon only 50 patient charts, ideally, a study of this nature would have benefited from the inclusion of a larger number of participants. Having a larger pool of charts would provide data that are more conclusive across a wider spectrum of participants. Analysis of a larger pool of charts might include extracting data after more patients have been seen, or extracting data from the charts of all Yo San University Community Clinic patients and not just those attending the Fertility Clinic. Conducting this study over a longer period of time would also allow the researcher to view the data over a wider range of economic and societal conditions. A longer period for conducting the study would allow for the review of charts during prosperous times as well during the time period of May 2010 to June 2011 that included economic recession, high rates of depression in men and women, the country being at war, high unemployment and the occurrence of many natural disasters throughout the world.

A study which incorporates broader demographics regarding age and locations may provide additional information and assist in discerning if the economic or geographic factors are significant. Another factor is the fact that the charts reviewed at the Yo San University Fertility Clinic are organized in a manner that separates the clinical information from the demographic information. The only demographic factor that was considered was the age of the patient. Other factors such as ethnicity, education and socioeconomic data were not considered. As a result, in the current study, the bulk of the demographic was not incorporated into the study design. This limitation is one that should be considered when designing future research.

An additional factor may be considered a limitation is the fact that the study was conducted in West Los Angeles where there is an abundance of products and treatments aimed at retaining youthfulness. Spas, dental offices, gyms and medical groups offer “age defying” programs, diets, cosmetics and surgeries to assist women in looking and feeling younger. The current study included 42 of the 50 charts reviewed of women over thirty-five years of age—all within the definition of advanced maternal age (Center for Disease Control and Prevention, 2009). Further study needs to be conducted over a wider geographic area to discern whether the above-named factors are indeed local to West Los Angeles or whether they are more national in nature.

A prospective, rather than retrospective study would enable the researcher to clearly identify and report on specific questions and responses. Consideration should be given to doing a study that includes disclosure to the patients that their data is being collected at least in part for research purposes. Under those conditions patients may be more forthcoming on their intake forms as they will be more aware of the value and importance of their responses.

Recommendations for Future Research

A larger prospective study rather than a retrospective study with patient awareness of the value in completing all questions would assist greatly in determining the previous and concurrent allopathic diagnosis and treatments. A prospective, rather than retrospective study with strict evaluation criterion for the practitioners in diagnosing the patients during the first visit would provide a more consistent database of information. Having a limited number of practitioners would also assist in tightening up the research process, since up to 12 doctoral interns and three supervisors were involved in diagnosing the various patients in the current study.

As discerned from the literature study review of this study, little research has been conducted to provide a cross view of both allopathic and Traditional Chinese Medicine diagnoses. Further studies should develop more refined treatment protocols and could result in a deeper understanding of integrated fertility medicine. Data from such studies would greatly support and assist university based fertility clinics in the process of providing quality and efficient service. Such data would also contribute greatly to the education of Traditional Chinese Medicine practitioners and students who specialize in reproductive medicine.

Conclusions

University based fertility and community clinics treating fertility must continue to educate not only their students and interns but also the community regarding the challenges, limitations and associated dangers of women waiting to have children until well after their prime fertility age. Patient education materials, seminars and treatments geared toward fertility at a younger age may be beneficial particularly with those early in the advanced maternal age

Murchison Capstone

category, since they appeared in the current study to be lacking in education and or acceptance of their reduced fertility potential.

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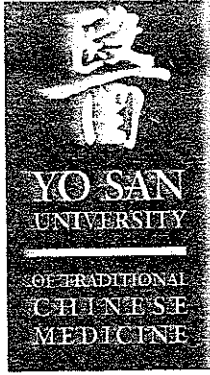
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Appendix A: IRB Approval Letter



January 24, 2011

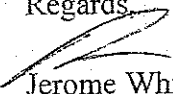
Andrea Murchison\
1621 Venice Blvd., Apt. 107
Los Angeles, CA 90291

Dear Andrea,

Your Claim for Exemption from the Institutional Review Board (IRB) has been reviewed. Your research proposal has been approved, with no recommendations effective February 11, 2011 through February 11, 2012.

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.

Regards,


Jerome White

Appendix B: Data Collection Instrument

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Medical history factors of women who utilize Traditional Chinese Medicine for Infertility

Data Extraction Instrument

Chart	1	2	3	4	5	6	7
Patient Chart Indicators							
Age							
Alopathic Infertility Diagnosis							
If yes, what was it							
Length of time trying to conceive							
Hormone laboratory tests performed							
If Yes, What were the results							
Fallopian tubes evaluated medically							
If yes, what were the results							
Medications to assist ovulation							
Male fertility workup							
If yes, what were the results							
Any fertility treatments							
If yes, what were they							
TCM Diagnosis							

Appendix C: Table 1—Raw Data Summary

Table 1 Raw Data Summary

	n=8 Women Under 35	n=19 Women 35-39	n=23 Women 40+	Total Diagnosis	% of 124 Diagnosis
Spleen Qi Deficiency	6 (75%)	11 (58%)	19 (82%)	36	29%
Liver Qi Stagnation	6 (75%)	11 (58%)	18 (78%)	35	28%
Kidney Deficiency	4 (50%)	8 (42%)	15 (65%)	27	21%
Excess Heat	2 (25%)	7 (37%)	3 (13%)	12	10%
Blood Stasis	2 (25%)	4 (21%)	4 (17%)	10	8%