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TCM and Male Infertility – A Research Update

by by Ray Rubio, DAOM, L.Ac., FABORM

Dieterle et al. recently published in *Fertility and Sterility* (October, 2009) a prospective, randomized, single-blind, placebo controlled trial of acupuncture in infertile men with severe oligoasthenozoospermia (low sperm count/concentration + low sperm motility). The acupuncture points used were: *Zusanli* (ST 36), *Sanyinjiao* (SP 6), *Taixi* (KI 3), *Taichong* (LR 3), *Guilai* (ST 29), *Ciliao* (BL 32), *Xuehai* (SP 10), and *Guanyuan* (CV 4).

The strengths of this study were that it was prospective and randomized, and that there was some attempt at a control. Another strong point of the study was that, although there was no improvement in the count/concentration, or semen volume (both of which were secondary outcome measures), there was a slight improvement in the percentage of motile sperm (which was a primary outcome measure).

The total course of treatment for this particular study was 6 weeks, with acupuncture given twice weekly. Based on different books and studies in the past, it is given that spermatogenesis takes roughly 72-74 days; however, this trial was completed in just 42 days. It is therefore possible that there would have been an even more significant impact on sperm motility, and perhaps also on the concentration and volume, had the investigators allowed for the complete cycle of spermatogenesis.

Another positive aspect of this trial was that these western-trained investigators followed STRICTA, which is the Standards for Reporting Interventions in Controlled Trials of Acupuncture. STRICTA is a checklist of standards that should be reported in any acupuncture trial to allow for homogeneity of these studies for meta-analysis, and for consistency of reporting. It inquires about a complete spectrum of considerations, including:

- Rational for the acupuncture points chosen
- Style of acupuncture
- Depths of needle insertion
- Number of needles used and their stimulation
- Retention time of needles
- Treatment regimen (how many treatments over what length of time at what interval)
- Any co-interventions such as moxibustion, cupping, etc.
- Practitioner's background, training and experience
- Type of control used, if any

This particular trial addresses each of these standards, and they used trained and licensed professional acupuncturists to conduct the acupuncture and placebo acupuncture:

Intervention	Description of Item
1) Acupuncture rationale	1a) Style of acupuncture 1b) Rationale for treatment (e.g. syndrome patterns, segmental levels, trigger points) 1c) Literature sources to justify rationale
2) Needling details	2a) Points used (unilateral/bilateral) 2b) Numbers of needles inserted 2c) Depths of insertion (e.g. <i>cun</i> or tissue level) 2d) Responses elicited (e.g. <i>de qi</i> or twitch response) 2e) Needle stimulation (e.g. manual or electrical) 2f) Needle retention time 2g) Needle type (gauge, length, and manufacturer or material)
3) Treatment regimen	3a) Number of treatment sessions 3b) Frequency of treatment
4) Co-interventions	4a) Other interventions (e.g. moxibustion, cupping, herbs, exercises, life-style advice)
5) Practitioner background	5a) Duration of relevant training 5b) Length of clinical experience 5c) Expertise in specific condition
6) Control intervention(s)	6a) Intended effect of control intervention and its appropriateness to research question and, if appropriate, blinding of participants (e.g. active comparison, minimally active penetrating or non-penetrating sham, inert) 6b) Explanations given to patients of treatment and control interventions 6c) Details of control intervention (precise description, as for Item 2 above, and other items if different) 6d) Sources that justify choice of control

The primary weakness of this trial was that they chose a patient group with inclusion criteria that were essentially useless for outcome measures in any real world clinical decision-making. They selected male patients with sperm concentrations of <1 million sperm/ml, which means that even if the acupuncture had doubled the sperm concentrations in just 42 days, these patients would still require IVF/ICSI to achieve pregnancy with their partners.

Another weakness of this trial, albeit an inherent weakness in most placebo-controlled or sham-controlled acupuncture trials, is that the placebo needles (in this case non-penetrating needles by Asia Med affixed to the skin with a band-aid) are probably not inert. Placebo needles are acupuncture needles that disappear into the insertion tube without penetrating the skin, and they are used on real acupuncture points where both the treatment group and the control group use the same acupuncture points.

Also, this trial, like most acupuncture trials, fails to reflect how TCM is applied, i.e. according to pattern differentiation, pulse diagnosis, abdominal and channel palpation, and so on.

Another potential confounding outcome of this particular trial is that there was an actual decrease in semen volume after acupuncture, but not placebo acupuncture, and there was a small, but significant increase in sperm concentration after the placebo acupuncture, but not the real acupuncture. Again, the placebo is probably not inert in the same way that some of the minimally invasive acupuncture techniques like Toyo Hari are not inert.

There have been several previously reported uncontrolled case reports and non-randomized case studies by Zhang et al., Siterman et al., Gurfinkel et al., and Pei et al., all of which showed improvements in percentages of rapidly motile sperm, morphologically normal sperm, total motile sperm per ejaculate, and sperm concentration. None of these trials met the rigor of a randomized controlled trial (RCT). The relative small number of published studies on male factor infertility, as well as the heterogeneity of these studies resulted in the one published meta-analysis on male infertility, showing no statistical benefit from acupuncture.

Herbal Studies on Male Infertility

In 2003, Suziki et al. published a prospective, randomized trial in the *Journal of Reproductive Medicine*, comparing 16 “normozoospermic” males to 47 “non-normozoospermic” males (measured by semen analysis, serum hormone levels, and superoxide dismutase (SOD) in both the serum and seminal plasma). Both groups were given the Kampo Formula Sairei-To/*Chai Ling Tang* (Bupleurum and Poria Decoction) [a combination of *Xiao Chai Hu Tang* (Minor Bupleurum Decoction) and *Wu Ling San* (Five-Ingredient Powder with Poria)] at 9 grams daily for 3 months, then re-evaluated. Interestingly, the “normozoospermic” males showed no change, but the “non-normozoospermic” males showed statistically significant improvement in sperm concentration and motility. The pulsatility index for the testicular artery was also significantly decreased, demonstrating improved testicular blood flow. There was no change however for either group in the serum hormone levels or SOD levels.

This particular trial did not use blinding for the participants and the investigators, nor was a placebo control used. This is unfortunate because it is so easy to control with placebo in herbal trials. There is also no mention of patient consent or IRB (Institutional Review Board) approval in this trial.

The strength of this trial is that it was conducted for the appropriate length of time (3 months is adequate for a complete cycle of spermatogenesis), and the dose of herbs used is fairly conservative for such a positive outcome. They also utilized other outcomes measures of male fertility (testicular artery pulsatility index, serum hormone levels, and SOD, etc.) instead simply looking at basic semen analysis.

Another interesting fact about Saire-To/*Chai Ling Tang* (Bupleurum and Poria Decoction) is that Fujii et al. published an article in the journal *Vitamin and Hormone* in 2002, which showed decreased rates of recurrent pregnancy loss resulting from antiphospholipid syndrome when using this formula. Saire-To has been studied extensively in Japan for the treatment of autoimmune conditions.

There have been other studies from Hong Kong showing that Chinese Herbs from the categories of tonifying yin and tonifying yang have the ability to stimulate mitochondrial ATP generation, and may also suppress an over-reactive immune system. Examples of herbs studied included *Rou Cong Rong* (Herba Cistanches), *Dong Chong Xia Cao* (Cordyceps), and *Ling Zhi* (Ganoderma).

There have also been a few reported trials from China that pointed to Chinese Herbal Medicines showing greater improvements in decreasing the levels of antisperm antibodies. One of these trials involved male patients using a TCM herbal formula compared with those men using prednisone alone. The strength of this study is that the treatment is compared against the typical medical intervention for antisperm antibodies (i.e. prednisone). The weakness of this trial is that it was not blinded. This trial also chose to study a condition in male infertility that is typically bypassed with IUI (intra-uterine insemination) in most of Europe, Canada and the US. Another study evaluated mice induced to have antisperm antibodies, and they showed significant improvements after treatment with the formula Tai-Bao.

A 1998 study published in a Japanese journal by Yamanaka et al. looked at the use of the Kampo medicine Hochuekkito/*Bu Zhong Yi Qi Tang* (Tonify the Middle and Augment the Qi Decoction) for its protective effects on sperm with antisperm antibodies. This study was particularly interesting in that it looked at the effect of adding Hochuekkito/*Bu Zhong Yi Qi Tang* (Tonify the Middle and Augment the Qi Decoction) directly to the semen sample after the swim-up wash, and then evaluating the motility. The direct addition of this formula to the post-wash semen sample showed improvements in motility.

About the Author

Dr. Ray Rubio has been in private practice at Westlake Complementary Medicine in Los Angeles for over a decade, and was on the clinical staff at the Toluca Lake Health Center – a multidisciplinary outpatient medical clinic – for half of that time. Dr. Rubio's specialty is Women's Health, with an emphasis in Reproductive Medicine and the treatment of infertility. He works both with patients who would prefer to conceive naturally, and those who will be utilizing Assisted Reproductive Techniques (ART). He speaks to infertility support groups on a regular basis and is a member of the American Board of Oriental Reproductive Medicine (ABORM). He is currently in the process of conducting a clinical trial on the treatment of diminished ovarian reserve with Chinese Herbal Medicine in patient undergoing IVF.

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