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Impact of whole systems traditional Chinese medicine on in-vitro fertilization outcomes

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Abstract Patients undergoing IVF may receive either acupuncture or whole-systems traditional Chinese medicine (WS-TCM) as an adjuvant IVF treatment. WS-TCM is a complex intervention that can include acupuncture, Chinese herbal medicine, dietary, life-style recommendations. In this retrospective cohort study, 1231 IVF patient records were reviewed to assess the effect of adjuvant WS-TCM on IVF outcomes compared among three groups: IVF with no additional treatment; IVF and elective acupuncture on day of embryo transfer; or IVF and elective WS-TCM. The primary outcome was live birth. Of 1069 non-donor cycles, WS-TCM was associated with greater odds of live birth compared with IVF alone (adjusted odds ratio [AOR] 2.09; 95% confidence interval [CI] 1.36 to 3.21), or embryo transfer with acupuncture only (AOR 1.62; 95% CI 1.04 to 2.52). Of 162 donor cycles, WS-TCM was associated with increased live births compared with all groups (odds Ratio [OR] 3.72; 95% CI 1.05 to 13.24, unadjusted) or embryo transfer with acupuncture only (OR 4.09; 95% CI: 1.02 to 16.38, unadjusted). Overall, IVF with adjuvant WS-TCM was associated with greater odds of live birth in donor and non-donor cycles. These results should be taken cautiously as more rigorous research is needed.

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KEYWORDS: acupuncture, Chinese herbal medicine, embryo transfer, in-vitro fertilization, live births, traditional Chinese medicine

Introduction

Women undergoing IVF commonly pursue adjuvant complementary and alternative health approaches to support their cycles. Given that early studies have found that acupuncture significantly improves IVF pregnancy rates, patients increasingly choose adjuvant acupuncture to optimize their chances of pregnancy and live birth (De Lacey et al., 2009). Utilization rates are unclear. In a survey of 428 Northern Californian couples, 22% reported using acupuncture (Smith et al., 2010), but of 118 Boston-area women surveyed, 47% women reported using acupuncture and 17% used herbs during their assisted reproduction technique cycle (Domar et al., 2012). Another survey of 77 patients found that 92% reported using acupuncture to support their IVF cycle (Aelion et al., 2009). A patient may seek an acupuncturist's support by self-referral, or her IVF physician may refer her, but it is also possible that IVF physicians may not be aware of patient use of these additional therapies (Boivin and Schmidt, 2009).

Investigations into the effect of acupuncture on IVF outcomes largely focus on a limited number of standardized treatments, usually two, on or around embryo transfer compared with no acupuncture, sham acupuncture or a placebo needle. Initial studies suggested that acupuncture on or around embryo transfer improved IVF outcomes (Dieterle et al., 2006; Paulus et al., 2002; Smith et al., 2006; Westergaard et al., 2006), and, in a meta-analysis of seven trials, acupuncture increased the odds of clinical pregnancy by 65% (Manheimer et al., 2008). As more trials were completed, the equivocal effects were found when this narrow dose of only two or three acupuncture sessions were compared to controls. In a review of 14 trials, two to three acupuncture treatments administered around embryo transfer did not improve clinical pregnancy rates compared with controls (Cheong et al., 2013b). Another review of 16 trials confirmed these findings, but the covariate of baseline pregnancy rate was found to be a significant mediator of acupuncture's effect (Manheimer et al., 2013). Additionally, a clear need exists for an adequate acupuncture control, as penetrating or non-penetrating 'sham or placebo' acupuncture controls are likely to be impractical and may have physiological effects (Manheimer, 2011; Vickers et al., 2012).

With the advent of two standardized acupuncture sessions as a complete investigational intervention, acupuncture providers thereby question whether it is a sufficient dose (Craig et al., 2014; Shen et al., 2015). In clinical practice, acupuncture treatment is not standardized and instead considers the patient singularly; treatment is individualised. A course of treatment can range from six to 24 treatments depending on the complexity of the case. Furthermore, if an IVF patient seeks adjuvant acupuncture treatment in the period before the day of embryo transfer, it is possible that the patient, her partner, or both, will receive a complex intervention at the acupuncturist's office, such as whole-systems traditional Chinese medicine (WS-TCM). This is a multi-dimensional intervention that can include any combination of modalities classified under the system of traditional Chinese medicine. These include any combination of acupuncture (the insertion of sterile, filiform needles in the body) (Cochrane et al., 2014), moxibustion (the burning of processed herb, artemesia argyi, on or near the body) (Nedeljkovic et al., 2013), Chinese herbal medicine (Cao et al., 2013; Ried and

Stuart, 2011; Tan et al., 2012), Chinese medical massage with a tool (guasha) or without (tuina), Chinese medicine-based dietary recommendations, breathing exercises (Qi Gong), or movement exercises (Tai Chi) (Noll and Wilm, 2009). It may also include recommendations for vitamins, supplements, or both, depending on the training and licensure of the provider. Beyond a published case study (Hullender Rubin, 2010) and expert texts (Liang, 2003; Lyttleton, 2004; Noll and Wilm, 2009), the effectiveness of the multi-dimensional WS-TCM approach on IVF outcomes is unclear.

Given this background, we sought to compare the reproductive outcomes of women who elected WS-TCM treatment in addition to their usual IVF care, and compared them with those who received the usual IVF care alone and to those who received two standardized acupuncture treatments on the day of embryo transfer acupuncture only. Our main objective was to compare the three groups on the primary outcome of live birth.

Materials and methods

Study design

This was a retrospective cohort study of WS-TCM effects on IVF reproductive outcomes compared with two groups: those who received acupuncture treatments only on the day of embryo transfer (ACU); and those who received IVF usual care alone. The Oregon College of Oriental Medicine Institutional Review Board approved this study on 11 January 2011 (IRB reference number 09-028). Reproductive outcomes data were obtained from a single, private IVF centre, the Northwest Center for Reproductive Sciences (NCRS), Kirkland, Washington.

Patient criteria

Of 1509 patient charts, only NCRS patients who underwent IVF with fresh donor or non-donor embryos transferred between August 2005 and December 2010 were included, regardless of embryo quality. Additionally, women who underwent pre-implantation genetic screening testing or intracytoplasmic sperm injection cycles were also included. To further reduce selection bias, all biomedical diagnoses were included. Diminished ovarian reserve was diagnosed if FSH was 12 mIU/ml or more, antral follicle count total less than 10, and anti-Müllerian hormone less than 1.0 ng/ml, or any combination of these measures. Since the mean age of the WS-TCM was higher than the other groups, this most likely accounted for the increased incidence of diminished ovarian reserve diagnosis. All patients who underwent transfers with frozen embryos ($n = 251$) or embryos from frozen oocytes ($n = 27$, research cycles) were excluded.

All included patient data ($n = 1231$) were reviewed to identify patients who received ACU, and then reviewed a second time to identify and tabulate patients who received WS-TCM, as all WS-TCM patients received ACU as part of their treatment plans. The data were de-identified and assigned unique identifiers. The key was only available to the primary investigator. Visit data were then independently abstracted

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