A randomized double blind comparison of real and placebo acupuncture in IVF treatment

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BACKGROUND: Acupuncture has been used during IVF treatment as it may improve outcome, however, there are concerns about the true efficacy of this approach. This randomized double blind study aimed to compare real acupuncture with placebo acupuncture in patients undergoing IVF treatment. METHODS: On the day of embryo transfer (ET), 370 patients were randomly allocated to either real or placebo acupuncture according to a computer-generated randomization list in sealed opaque envelopes. They received 25 min of real or placebo acupuncture before and after ET. The endometrial and subendometrial vascularity, serum cortisol concentration and the anxiety level were evaluated before and after real and placebo acupuncture. RESULTS: The overall pregnancy rate was significantly higher in the placebo acupuncture group than that in the real acupuncture group (55.1 versus 43.8%, respectively, P = 0.038; Common odds ratio 1.578 95% confidence interval 1.047–2.378). No significant differences were found in rates of ongoing pregnancy and live birth between the two groups. Reduction of endometrial and subendometrial vascularity, serum cortisol concentration and the anxiety level were observed following both real and placebo acupuncture, although there were no significant differences in the changes in all these indices between the two groups. CONCLUSIONS: Placebo acupuncture was associated with a significantly higher overall pregnancy rate when compared with real acupuncture. Placebo acupuncture may not be inert. Trial registered with HKClinical-Trials.com: number HKCTR-236.

Keywords: acupuncture; IVF; pregnancy rate

Introduction

IVF-embryo transfer (IVF-ET) is an effective treatment for various causes of infertility. Despite improvement in ovarian stimulation regimens, culture media conditions and the technique of ET, there has not been a significant increase in the implantation rates of cleaving embryos, which have remained steady at 20–25% for a long time (ESHRE, 2001, 2008).

Acupuncture has been used during IVF treatment, either on the day of transvaginal ultrasound-guided oocyte retrieval (TUGOR) (Stener-Victorin et al., 1999, 2003; Humaidan and Stener-Victorin, 2004; Gejervall et al., 2005; Sator-Katzenschlager et al., 2006) or the day of ET (Paulus et al., 2002, 2003; Dieterle et al., 2006; Smith et al., 2006; Westergaard et al., 2006). A meta-analysis (Ng et al., 2008) of these 10 randomized studies revealed a significant improvement of the pregnancy rate in favour of acupuncture treatment [odds ratio (OR) 1.42, 95% confidence interval (CI) 1.17–1.72]. A subgroup analysis detected a significant improvement of the pregnancy rate for acupuncture treatment when it was administered on the day of ET (OR 1.83, 95% CI 1.40–2.39) but no improvement of the pregnancy rate when acupuncture treatment was administered on the day of TUGOR only (OR 1.07, 95% CI 0.81–1.42). These data suggest that acupuncture improves IVF outcomes only when it is done on the day of ET. The positive effect of acupuncture during IVF treatment may be related to the change in uterine blood flow and uterine contractility, and relaxation of stress (Ng et al., 2008).

Another meta-analysis reveals similar findings (Manheimer et al., 2008). However, there is still concern about the efficacy of acupuncture in IVF (Pinborg et al., 2008) as the improvement in the pregnancy rates of IVF treatment with acupuncture is higher than that for drugs or other procedures given to enhance the success of this treatment and the underlying biological mechanism is difficult to explain. Patients were not blinded in the majority of the above randomized studies because of the difficulty in achieving blindness in the acupuncture treatment. The study of Smith et al. (2006) was single blind and only that of Sator-Katzenschlager et al. (2006) was double blind. Sator-Katzenschlager et al. (2006) found that auricular acupuncture with electric stimulation significantly