

LASER ACUPUNCTURE BEFORE AND AFTER EMBRYO TRANSFER IMPROVES ART DELIVERY RATES: RESULTS OF A PROSPECTIVE RANDOMIZED DOUBLE-BLINDED PLACEBO CONTROLLED FIVE-ARMED TRIAL INVOLVING 1000 PATIENTS.

J.L. Fratterelli, M.R. Leondires, K. Fong, A. Theall, S. Locatelli, R.T.

Scott, Reproductive Medicine Associates of New Jersey, Morristown, NJ

OBJECTIVE: Acupuncture has been advocated for the treatment of infertility, including immediately prior to and after transfer. Unfortunately, data are conflicting and adequate studies with appropriate controls are lacking. This study evaluates 2 forms of acupuncture on outcomes in ART patients.

DESIGN: Prospect randomized double blind and placebo controlled.

MATERIALS AND METHODS: On the day of transfer, participants were randomly assigned to a study group; needle acupuncture (AC), laser acupuncture (LZ AC), sham laser acupuncture (LZ sham), relaxation (RX), or no treatment (NT). The AC and LZ AC puncture groups were considered treatment groups, the RX controls for the additional rest before and after transfer, and NT is the non-intervention group. Most significantly, the LZ Sham group provided an important control group. The laser acupuncture device was randomly preprogrammed per case to either fire (and provide LZ AC) or to not fire and thus provide a true double blind control group (LZ sham). It was not possible for the patient or acupuncturist to know if the laser fired. No contact occurs with the patient in laser acupuncture so there is no acupressure effect or contact with the wrong meridians. All treatments were administered for 25 minutes before and after embryo transfer. Outcomes were compared by Chi-square and multiple logistic regression analysis to control for the potential confounders including female age, embryo quality, and day of transfer (Table 1).

RESULTS: All treatments were well tolerated. No differences in terms of patient demographics, cycle type, stimulation outcomes, embryo number and quality, day of embryo transfer, transferring physician, or acupuncturist were found between the 5 study groups. Implantation rates were significantly improved with laser acupuncture. Traditional needle acupuncture had outcomes equivalent to the 3 control groups. Subanalyses of patient age and embryo transfer day produced similar findings with laser acupuncture enhancing outcome rates.

CONCLUSIONS: This large prospective randomized and well controlled study consistently demonstrated benefit to LZ AC. Treatment was well tolerated and significantly improved implantation rates.

TABLE 1. Clinical Outcomes (%)

| Rates | AC (n=200) | LZ AC (n=202) | LZ Sham (n=198) | RX (n=203) | NT (n=197) | P Values |
|-------------------------------|---------------|------------------|--------------------|---------------|---------------|-------------|
| Implantation | 28.9 | 33.7 | 26.8 | 24.9 | 30.2 | <0.05 |
| Chemical Pregnancy | 61.5 | 60.9 | 53.0 | 53.7 | 60.4 | 0.22 |
| Clinical Pregnancy | 51.5 | 54.5 | 43.9 | 45.3 | 50.3 | 0.19 |
| Ongoing Pregnancy/Delivery | 39.0 | 42.1 | 35.4 | 37.4 | 39.6 | 0.71 |

*Supported by: EMD Serono
Reproduced from: Fertility and Sterility*