

Randomized Trial of Harp Therapy in In Vitro Fertilization – Embryo Transfer (IVF-ET)

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Introduction

Since the first successful birth resulting from in vitro fertilization – embryo transfer (IVF-ET) in 1978 there have been numerous advances in IVF-ET.¹ These advances have occurred in almost every aspect of the IVF process. Current ovarian stimulation regimens now include the use of gonadotropin releasing hormone agonist as well as antagonists which prevents premature hormone surges and unexpected ovulation.² There have also been changes in the medications used to stimulate multifollicular oocyte development from urinary derived products to now highly purified recombinant derived products.² The in vitro culture environment has been modified from media originally borrowed from the growth of somatic cells to the current media that contains nutritional requirements specific for the growing human embryo.³ In 1991, the introduction of microsurgical fertilization (intracytoplasmic sperm injection – ICSI) revolutionized the treatment of male factor infertility.⁴ These important changes have been critical to the steady increase in “take home babies” from IVF-ET. Despite these advances the overall success rate for IVF-ET still remains less than 50%. One important aspect that has been neglected is the utilization of complimentary alternative medical therapies to enhance IVF-ET success. This is what led to the exploration of Harp Therapy (HT) as an adjunctive therapy in the IVF process in an attempt to reduce patient anxiety and hopefully improve IVF success. The objective of this study was to determine if Harp Therapy (HT) reduces levels of stress (psychological and physiological) and improves clinical outcomes in patients undergoing IVF-ET.

Materials/Methods

This was a prospective randomized trial conducted at a community hospital based reproductive medicine office. The patients were subfertile women undergoing IVF-ET excluding women who are already enrolled in other IVF-ET clinical trials or undergoing preimplantation genetic diagnosis prior to IVF-ET. The women were randomized to either receive HT for 20 minutes with ET or not, this randomization took place after oocyte retrieval. All patients underwent standard IVF-ET procedures. Harp Therapy was performed by Gloria Galante, Certified Music Practitioner. Both the psychological and the physiologic levels of stress in the peri-embryo transfer period as well as the IVF-ET clinical outcomes were assessed. During transfer the patients randomized to the HT group were exposed to 20 minutes of HT. All of the patients filled out a State-Trait Anxiety Inventory (STAI) questionnaire pre- and post- ET. This questionnaire differentiates between temporary or event based “state” anxiety and long standing “trait” anxiety. Higher scores indicate greater levels of anxiety. All patients had physiologic parameters monitored pre- and post- ET including blood pressure (BP), respiratory rate (RR), and heart rate (HR). In addition, implantation and clinical pregnancy rates were compared between the two groups.

Results

There were 101 treated and 101 non treated women. There were 11 treated and 10 non treated that were excluded, for a final sample size of 90 women that received HT and 91 women who did not. The demographic and clinical characteristics of the patients were compared and there were no statistically significant differences between the groups. Women in the control group had higher blood pressure at the pre- ET as compared to the women who received HT (systolic 131 vs. 125 p = 0.004 and diastolic 84 vs. 79 p = 0.002, control vs. HT respectively) and they also demonstrated statistically significant higher systolic BP post-ET (systolic 124 vs. 119 p = 0.007). No statistical difference found in heart rate, respiratory rate, or changes from baseline.

For the STAI questionnaire, no significant difference was found between the groups at baseline for the state score. However, women in the control group had statistically significant higher state scores post transfer ($p = 0.002$). Women receiving HT had a significantly larger decrease in STAI state scores from pre- to post-ET compared to the control ($p = <0.0001$). For STAI trait scores, women in HT had statistically significant higher pre-transfer scores ($p = 0.032$) but not post transfer ($p = 0.3779$). There was no difference in the change in trait score pre- and post-transfer when comparing the two groups ($p = 0.14$). The clinical pregnancy rate was 53% (48/90) in the HT group and 48% (44/91) in the control group. The odds of clinical pregnancy were not statistically significant between groups.

Discussion/Conclusion

This trial was an attempt to merge the current advanced state of the art medical therapies like IVF-ET with alternative complimentary medicine such as HT. The goal was to reduce the anxiety associated with the IVF-ET process and ultimately improve clinical outcomes. This study demonstrated that HT decreases patients "state" or event-based anxiety and women in the control group had significantly higher state scores post transfer; thus demonstrating that HT has an effect on acute levels of stress as assessed by psychological measures. Clinical pregnancy rate with IVF-ET is typically less than 50% as was demonstrated in our control group and although not statistically significant the clinical pregnancy rate was 53% in women receiving HT. Even the smallest increases in odds of pregnancy give infertile couples hope. The psychological reduction in stress as shown with the STAI also may play a large role because stress can change hormone levels within the body making it more difficult to get pregnant. With a larger sample size this may become significant.

Physiologic markers of stress such as blood pressure, heart rate, and respiratory rate did not have a statistically significant change over the course of treatment in either group. It was shown that the control group did have pre-ET blood pressure that was significantly higher than the HT group as well as higher systolic BP post-ET. This indicates that HT creates a more relaxing environment that may reduce physiologic levels of stress.

Strengths of this study include that it was a prospective randomized trial and the first of its kind. This study has ease of reproducibility in other clinical settings. Unfortunately no evaluation of drop out rate/how many patients returned for treatment. Also, besides the STAI trait score the patients were not questioned on prior history of psychiatric diagnosis or treatment. A larger sample size would be ideal to better assess if harp therapy truly has a significant effect on in vitro fertilization-embryo transfer.

This study demonstrated that advanced medical therapies can easily be integrated with complimentary alternative treatment. This opens the door for many more studies in complimentary medicine.

References

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