

Effectiveness of mind-body intervention on oocyte quality and serum cortisol level in sub-fertile women undergoing IVF treatment in Wardha region: A Study Protocol

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Abstract

The grounds of the contemporaneous examination is to evaluate the association in unite repercussions of mind-body intercession and serum cortisol measures and eggs attributes. The cognizance that psychological stress may avert females from accomplishing and keeping up a gestation has become vastly received. Mind-body intercession incorporates calmness, optimistic make-believe, biofeedback, balm, meditation, rumination, yoga, and more. All these acts work discreetly to help someone alleviate illness. Mind-body interventions (MBIs) may be an efficacious implement to assist females to cope with the ultimatum of infertility pinpointing and ministration Objective of this study is to sensitize all sub fertile females about the study, to investigate serum cortisol level of sub fertile females and to investigate the quality of oocyte of sub fertile females. This non-invasive methodology appends a set down of ministration history and the manifestations. Advice will be given to all the patients for research. Additional convention appends checking of oocytes quality after mind-body intercession in the second cycle of IVF after retrieving poor quality of oocytes in the first cycle and failure of the cycle due to it.

Keywords: IVF, first cycle failure, oocytes quality, mind-body intervention, MBI, ART, IVF, ICSI.

INTRODUCTION

Infertility is a disease that is detected after one year of unprotected sexual intercourse after marriage, according to WHO 2010.(1)

Recently there is relatively more focus on physical causes of infertility. The psychological impact may be overlooked.

Uncertain outcomes, low self-esteem, stigma, depression all contribute to infertility-related stress.(2)

Is there one would expect, many bodily and psychic elements that can bring out infertility. The starting point of this issue can be male or female.(3)(4)

Infertility may be primary or secondary in nature. When not a single gestation has occurred then it is primary infertility and when a minimum of one gestation is attained and then after unable to conceive again is secondary infertility.(5)

Moreover, the grounds of infertility can be answerable and mendable or it may be inexplicable, stress-associated, or amalgamated to supplemental psychosomatic agents.(2)(6)

The notion of stress was instigated in 1926 by Hans Selye to expound the entity feedback mechanism to environmental inducement. In the latest, “Selyan sense”, stress can be expounded as the common reply of the body to each entreaty.(7)(8)

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As per Richard Lazarus's transactional approach which was expounded instigated in 1984, stress is a bilateral affair that entails the making of stressors by the environment and the reply of an solitary lay bare to these stresses or not only the identification of infertility but infertility ministrations have been analogous with uplifted measures of distress. A handful of studies in vitro fertilization ministrations: psychological and neurohormonal assessment.(9)

Psychologically and emotionally ministration of infertility is stressful.(10) Stress prior to, in the course of, and/or in the wake of the treatment is multifaceted. There is the awful fount of stress that has given rise to the ultimatums of enduring infertility and the dropping of hope.(11)

A further source of stress is the threat of the ministration itself, such as quotidian shots, venipuncture, USG, Ovum pick-up, and the odds of non-success at any of the various steps.(12) The another source of stress is the threat of an unbidden termination if conceive in the course of ministrations. The pregnancy test manifested to account for the most stressful instant of the treatment cycle.(13)

The adrenal gland produces steroid hormone namely cortisol which is a primary stress hormone and also helps in raising blood sugar level, intensify the use of sugar by the brain, and works as the finest stress biosignature.(14)(15)

Its measures can be pomp by bodily stress, psychic stress, and ailments. In the event of an elevated level of stress, resulting in an elevation in serum cortisol level, consequently it is a well-founded standard in forbearing encountering stressful circumstances in life.(16)

Bodily and/or psychic stress persuades lessen blood flow attacks in patients with coronary artery disease (CAD). Late studies have bespoken that, mental agents are intricated in the pathogenesis of CAD and that stress could persuade coronary vasospasm and myocardial ischemia.(17)

But along with this, some studies have also be-spoken that increased level of cortisol, that is the stress hormone affects the emission of GnRH from the hypothalamus and directly affects the production or emission of follicle-stimulating hormone (FSH) out of the ventral pituitary gland. FSH is a hormone that is responsible for the development of the follicles in the ovary. So due to stress, the level of the hormone cortisol in the blood will increase which acts on the emission of GnRH (lessens the secretion). And hence, it will act on the emission of FSH and also act on the count and quality of oocytes.(18)

Mind-body intercession are rational in turning down psychic anguish ergo enlarges the ART success rate, fetal upshot by ameliorating the psychic and bodily stress.(19)

The grounds of the contemporaneous examination is to evaluate the association in unite repercussions of mind-body intercession and serum cortisol measure and eggs attributes.(20)

The cognizance that psychical stress may avert females from accomplishing and keeping up a gestation has become vastly

received.

Mind-body intercession incorporates calmness, optimistic make-believe, biofeedback, balm, meditation, rumination, yoga, and more.(21) All these acts work discreetly to help someone alleviate illness.(21) Mind-body intercession (MBIs) might be an efficacious implement to assist female to cope with the ultimatum of infertility pinpointing and ministration.(22)

Research Gap Analysis:

A lot of researches has been done in the field of assisted reproductive techniques used for infertility but still, the success rate of ARTs all around the world sums up to 30% only. Despite all favorable conditions, good-quality oocytes remained an uncertain part.

Recently there is relatively more focus on physical causes of infertility. The psychological impact may be overlooked. Uncertain outcomes, low self-esteem, stigma, depression all contribute to infertility-related stress.

Mind-body intercession are structured in overcasting psychic anguish accordingly expanding success rate of IVF/ICSI ministration, fetal upshots by ameliorating the psychological and physiological stress.

Rationale:

There is one review study published by Luba Sominsky on linking stress and infertility. In which, he relates many psychological factors by which stress is occurring and relates it with the increasing infertility rate and how stress is affecting IVF treatment outcomes. In this endocrine review article, the author also tries to find the link between the role of the gut hormone ghrelin in causing infertility due to stress in both animals and the human model. His studies said that every human has his way to express his anxiety and stress but animals show the same characteristics for expressing their stress and anxiety that's why it becomes much easier to find the relation between stress and infertility in animals than humans.(23)

In 2016, Shilpa Prasad published a review article in which she mention how stress and lifestyle adaptations can affect oocyte quality and hence female reproduction. In her study, she mentioned various factors that are responsible for causing stress in women and how that factors are responsible for rising ROS and OS in the body which is affecting ovaries. She also mentioned the relation between rising serum cortisol and depletion of estradiol due to it.(24-31)

Miok Kim in 2013, published a research article on the positive effect of mind-body intercession on infertile forbearing female in their second round of infertility treatment. In his study he tried to find out the effect of stress, anxiety caused by infertility treatment in infertile women and how it is affecting the implantation rate. the intervention in his study is to carry out mind-body intercession on infertile women in which he considers two groups, one is the experimental group and the second one is the control group. And after carrying out this study he concluded that there is no

difference in implantation rate but there is a decrease in stress in both the groups after mind-body intercession.(32)

In 2013, Yuan An in his prospective study tries to find out the correlation between mental stress and first IVF treatment outcome. The study is about to assess whether mental stress does affect IVF treatment outcome or the changes in the sympathetic nervous system (SNS) and HPA (hypothalamus-pituitary-adrenal) axis influence the first IVF cycle. The study was conducted between 2009 to 2010 in which 264 women were involved in ART treatment and had anxiety and stress due to ongoing infertility treatment, which is examined by a set mental questionnaire and serum cortisol and norepinephrine blood assay. In this study, they deemed to be that infertile women are more anxious at the time of pregnancy test surpassing normal women with no infertility issues.(35)

Aim:

To study the efficacy of mind-body intercession on eggs quality by scrutinizing serum cortisol measures in sub fertile women.

Hypothesis:

We hypothesized that mind body intervention may help in improvement of oocyte quality in ART treatment.

Null hypothesis:

There is no correlation between Mind body intervention and oocyte quality

Methods:

Study design: Interventional Study

Methodology:

PART I :

The study will be conducted in WARDHA TEST TUBE BABY CENTRE, A.V.B.R.H., Sawangi (Meghe), Wardha. Pertinent facts on the headcount and ministration history, as well as the manifestation for IVF/ICSI ministration, will be set down. Patients will be stimulated using a regimental GnRH protocol. The routine protocol in our setup will be continued up to the 14th day of menses. On the day of OPU, serum cortisol levels will be analyzed early morning and oocytes will be retrieved. After OPU, the quality of the oocyte will be monitored. Patients with abnormal oocytes will be included in the study.

PART II :

Before patients undergo for second OPU, the patient has been given mind-body treatment for 8 weeks for everyday in the morning. In this intervention activities like Yoga nidra, Deep breathing, Music therapy (ambient and classical) will be carried out.

The same ovarian stimulation protocol will be followed as the previous cycle. And on the 14th day in the early morning,

serum cortisol levels will be analyzed and OPU will be done. After retrieval of oocytes, quality will be checked. Final oocytes quality will be compared with 1st cycle and will compare the outcomes.

CLINICAL IMPLICATIONS

This portable research may accord commendatory out turned. Time ahead, this wide-reaching specimens, if deliberated, will be a uprising in the field of mind-body ministration & ART will be immensely obliging for the women facing difficulties of less and immature (MI and GV) eggs retrieval and also females will have their own oocytes in spite of donor eggs.

Setting:

Location: WARDHA TEST TUBE BABY CENTRE, A.V.B.R.H, Sawangi (Meghe), Wardha

Participants: Infertile women visiting WARDHA TEST TUBE BABY CENTRE, A.V.B.R.H, Sawangi (Meghe), Wardha

Inclusion criteria

- Partners agonizing from primary and secondary infertility and inscribed for two IVF/ICSI cycle
- Patient from age group 25-35yrs.
- Patient with AMH >1.5.
- Patients with no genetical reproductive abnormality.

Exclusion criteria

- Patients set down for only one IVF cycle.
- Patients with AMH <1.5
- Couples not fit for IVF/ICSI having viral ailment like HIV, Hbs-Ag, HCV etc.

Study duration – September 2021 - March 2023

Study population – Sub fertile female patients attending Wardha Test Tube Baby Centre, A.V.B.R.H., Sawangi (Meghe), Wardha.

Place of Study - Wardha test tube baby centre AVBRH SWANGHI MEGHE WARDHA.

Sample Size- 50 sub fertile female patient.

Sample size formula –

$$N = \frac{\chi^2 * N * p(1-p)}{C^2 (N-1) + \chi^2 p(1-p)}$$

Total population = N=25 during 6 months

χ^2 =Chisquare value for 1 degrees at some desired probability level. This is 3.84 at 5%

level of significance.

P=50% proportion

Q=100-p

=50

C= Confidence interval of the one choice(95% CI)

$$=0.05$$

$$N=3.84*50*0.5*0.5$$

$$(0.05)^2 *40+3.84*(0.5*0.5)$$

$$=48.52 \approx 50$$

Expected Outcomes:

50 women with abnormal eggs retrieved in the first IVF/ICSI cycle will be included in the study. For 8 weeks, mind-body intercession will be carried out after the earliest IVF cycle for 8 weeks and the second OPU will be done in the very next IVF cycle. After oocytes retrieval, the quality of oocytes will be checked and compared with the quality of eggs retrieved in the initial IVF cycle OPU. And it is expected that oocytes retrieved in the second IVF cycle will be of better quality than the first IVF cycle as an impact of mind-body intercession.

Discussion:

The foremost intent of this study is to improve oocytes' quality with the help of mind-body intercession. In women with poor oocytes quality with no genetic anomaly, this intervention will prove to be a boon. As all along with the IVF cycle procedure, stress increases due to less probability of outcomes, and the women with recurrent abortion have more chances of having stress and anxiety which affects oocytes quality and hence directly affects IVF outcomes.

Translatory Component

We can provide option of mind body intervention to women with poor ovarian reserve, immature and poor oocyte retrieval to have their own genetic Baby. It can be a new recommendation in future we can have it for long term and also in larger sample size. It will give consistent positive, It can change whole scenario of IVF treatment.

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