Study Protocol

Comparative study of Effectiveness of Yognidra and Antioxidants on semen quality in sub fertile male patients undergoing IVF treatment at Wardha Region, India

ABSTRACT-

Background: There are various reasons of infertility in male which can be managed with pharmacotherapy and psychological methods .Physiological and Psychological factors such as low self esteem , stigma, depression anxiety etc which leads to stress contribute to infertility related causes. Yoga(Asanas, Pranayama and Meditation) shows effects on improving psychological factors but no studies are conducted on yognidra related with male infertility. A comparison between yognidra and antioxidant will be efficient in improving quality of semen and can increase ART success rate and Pregnancy incidence by treating psychological and physiological factor.

Aim and Objectives:

To study the effectiveness of *yognidra* and antioxidant on semen quality in subfertile male patients undergoing IVF cycles
To sensitize all subfertile males about the study
To assess the effect of *yoganidra* in subfertile males
To assess the effect of antioxidant in subfertile males
To compare and analyze the semen quality after giving both types of interventions

Methodology:60 infertile patients visiting Infertility clinic Wardha test tube baby centre ,AVBRH, Sawangi Meghe, Wardha will participate in the study. Consent form will be signed by patient. The patients will be divided in to 2 groups of Group number 1 with (30 subjects) antioxidants and Group number 2 will be given (30 subjects) Yognidra. Comprehensive history of patient will be taken in the prescribed format and external genitalia will be clinically examined at Surgery OPD. Study the semen quality and divide according to WHO criteria .Assessment and comparison of semen quality of both the groups before and after intervention .Data of two groups will be analysed and compared.

Expected Results: The study shows a comparison between yognidra and antioxidant will be efficient in improving quality of semen and can increase ART success rate and Pregnancy incidence by treating psychological and physiological factor..

Conclusion: The current research study will help to understand and explore the utility of yognidra at Infertility clinics and assist practitioner to engage subfertile couples undergoing IVF treatment in the practice of these technique. This study will enhance the quality of support programmes and psychological research. Incorporating psychological intervention provided by yognidra will act as a complementary therapy during infertility treatment.

Keywords- Semen analysis, Infertility, Antioxidants, Yognidra

BACKGROUND:

The most common cause of infertility related to male is abnormal functioning of the sperm. Therefore, evaluation of male infertility should be done for each couple coming for consultation and routinely it is done by examining his semen sample. The aetiology of reduced semen quality is not known fully but environmental, lifestyle and occupational factors have been suggested [1,2]. The harmful hazards of oxidative stress are accountable for 30 – 80 % of subfertility in male cases. [3]. Due to production of excess of reactive oxygen species (ROS) it leads to oxidative stress in sperms as the antioxidant capacity is exhausted. [4]. Apart from oxidative stress, numerous factors may cause male infertility like lifestyle related disorders, obesity, smoking, alcohol consumption, exposure to various environmental metals. These factors result in hampering structural & developmental quality of sperm and also its count and motility.

Recently, various alternative therapies have been employed to improve the quality of sperms and to increase the probability of conception. One of the alternative therapies used in various lifestyle related disorders is the ancient technique of Yoga. Yoga is the best lifestyle ever devised in the history of mankind. There are numerous studies which reflect the positive influence of Yoga on the various physiological systems. Yoga is an ancient science and it consist of a system of spiritual, moral and physical practices. The most common practices of yoga followed today are various postures (asanas) and breathing exercises (pranayamas) that helps to focus the mind, achieve relaxation and enhance wellness.

One of the techniques known to provide relaxation to mind and body is Yoga nidra. Yoga Nidra was developed by Swami Satyananda Saraswati in 1976. It is easy method of meditation to be used by people of various backgrounds and cultures and not having any previous knowledge [5] .The most important in Yoga Nidra meditation is a personal resolution, that addresses a topic to the person and that affects him or her in a positive way. [6] It is a organized form of guided relaxation. The duration of yoga nidra is for 35 to 40 minutes at a time. There are various types of yoga nidras like- for depression, stress, weight loss, insomnia etc. *Yoganidra* is a state in which the mind remains in borderline of sleep and awake state.
By following the verbal commentary, the whole body is made to relax followed by relaxation of mind systematically and then the practitioner becomes aware of the inner world. In yoga nidra the subject maintains the state of light withdrawal of the 5 senses with four senses internalised, that is, withdrawn, and only hearing still connects to any instructions given. [5]
In the current study we inculcated Yoga nidra to subjects where the sperm quality was compromised and then will observe the influence of Yoga technique on the male reproductive systems. Also, antioxidants prescribed is known to improve the sperm quality. So in this study we will compare and analyse the effect of *Yoganidra* and antioxidants on male reproductive systems. So, the aim of this study will be to analyse and compare the effects of both the interventions (Yoganidra and antioxidants) on semen quality of subfertile male patients undergoing IVF cycles .

AIM :

To study the effectiveness of *yognidra* and antioxidant on semen quality in subfertile male patients undergoing IVF cycles.

OBJECTIVES :

1) To sensitize all subfertile males about the study
2) To assess the effect of *yoganidra* in subfertile males
3) To assess the effect of antioxidants in subfertile males
4) To compare and analyze the semen quality after giving both types of interventions.

METHODS

a) Study design: It is a cross section study.

b) **Study setting:** The study will be done in Wardha test tube baby centre AVBRH SWANGI MEGHE WARDHA. .

c) .Period of study will be from July 2021 to September 2021.

d) **Sample size-** 60 sub fertile male patients. (n= 30-antioxidants group and n =30 – yognidra group) visiting Wardha test tube baby centre AVBRH SWANGI MEGHE WARDHA will participate in the study.

It is a prospective interventional study. will be signed by patient. After signing to consent form, comprehensive history of the patients in prescribed format will be taken & examination of external genitalia will be carried out at OPD. After that, the patient will have to observe abstinence for 3 days. On the fourth day semen sample will be collected by masturbation. Semen samples will be tested after the liquefaction at room temperature and the semen analysis will be carried out. Volume of ejaculate, pH, Viscosity & time for liquefaction of semen will be noted before analysing the sample for microscopic analysis. Appearance of semen: done by assessing the colour. Routine Semen Analysis will be done by using Macklers chamber for semen parameters

According to WHO guideline (Fifth Edition) subjects will be divided into four categories as-

(i) **Normozoospermics:**

- Sperm concentration of 15 million/ml or more.
- Motility of Sperm being 40% or more (a+b type motility).
- Normal sperm morphology –lower reference limit for normal forms is 4%

(ii) **Oligoasthenoteratozoospermic:**

- Sperm concentration less than 15 million/ml.
- Motility of sperm below 40 % (a+b type motility).
- Normal sperm morphology lower reference limit for normal forms is less than 4%

(iii) **Asthenoteratozoospemic:**

- Sperm concentration of 15 million/ml or more.
- Sperm Motility below 40%(a+b type motility).
- Normal sperm morphology lower reference limit for normal forms is less than 4%

(iv) **Azoospermics:**

- Total absence of sperms in semen(even after centrifugation)

The above abnormal seminogram subjects (sample size = 60) will be divided in to 2 groups of intervention. Group A (n=30) will consist of participants who will be given *Yoganidra* and

group B (n=30) will consist of participants who will be given antioxidant drug (Coenzyme-Q10) as a treatment.

Intervention in the study:

1) ***Yognidra :***

The pre-recorded stress relaxation Yognidra will be used for the study. The Yoganidra is prepared by Dr. Vishwas Mandlik of Yogavidyagurukul University of Nasik. While practicing Yoga nidra one has to just lie in supine position in *Shavasana* listen to the pre-recorded commentary and follow the instructions. During 'Practice Period'. the use of Prerecorded commentary in English/Hindi or Marathi will be made available. The duration of yoganidra session is for 30 minutes and we will advise the study participant to listen at least for minimum once a day for 3 months (90 days) and will take follow up for it.

2) Antioxidants mainly Coenzyme-Q10 is prescribed for the other group once in a day for 3 months as a treatment.

The duration of intervention will be 3 months (90 days). After the 90 days of intervention semen analysis will be repeated for both groups. Result of pre and post intervention will be compared statistically and analyzed.

Inclusion Criteria :

- Subfertile males attending Wardha test tube baby centre.
- Age group: 25 to 40yrs.
- Cases of primary and secondary infertility
- Normal Female partener
- Subfertile male with Asthenoteratozoospermia and Oligoasthenoteratozoospermia

Exclusion criteria :

- Patient not giving consent for research
- Age >40 yrs.
- Subjects with any structural abnormality like hydrocoele, varicocele, undescended testes will be excluded
- Patients with any history of surgical intervention in genitourinary tract which may interfere with male fertility will be excluded..
- Subjects with any treatment history with drugs like cancer chemotherapy or any hormonal preparation which may directly suppress the spermatogenesis will be excluded from the study.
- Subjects with normozoospermic ,necrozoospermics and Azoospermics will be excluded from the study

STATISTICAL ANALYSIS:-

In this study, effect of Yognidra and Antioxidants on semen quality in sub fertile male patients undergoing IVF treatment will be compared and evaluated . The total sample size in the study project will be **60 patients** by using purposive sampling and as duration of study is small. Accordingly patient will be divided into 2 groups for intervention. The statistical version which will be used is – SPSS 24.0 version, Graph Pad Prism 7V. Statistically significant differences in continuous variables will be determined using appropriate statistical test. *P*-values of <0.05 will be considered as statistically significant.

EXPECTED RESULTS:

The study shows a comparison between yognidra and antioxidant will be efficient in improving quality of semen and can increase ART success rate and Pregnancy incidence by treating psychological and physiological factor..

DISCUSSION:

The current study will help to explore whether Yoganidra is helpful in improvinf reproductive health of male. Also it will help to analyse and compare between *Yoganidra* and antioxidant as which technique is efficient in improving quality of semen and can increase ART success rate and pregnancy incidence by treating psychological and physiological factor.

Various studies have been done in the area of antioxidants and sperm parameters. Rafael *et. Al.* study observed improvement in sperm parameters with use of antioxidant Coenzyme Q10 treated in male infertility patients.[7]

Also, studies were done to observe the impact of *Yoganidra* on various physiological systems.
Rani *et. Al.* investigated the effect of *yoganidra* on psychological well being in female students having irregularities in menstruation. It was concluded that, the practice of *yoganidra* to relieve pain related with menstruation. Researcher also observed reduction in anxiety and depression and increased positive well-being.[8]
Dwivedi *et.al* found the effectiveness of *Yoganidra* in reducing the stress level of the workers at the workplace by mental and emotional relaxation.[9]
Kumar K *et. Al.* investigates the effect of yognidra in curing the psycological disorders like insomnia, anxiety etc and psychosomatic diseases of the students. It was observed that moderate level of stress was decreased after administration of *yoganidra*.[10]

Mandlik et al investigates the effect of yognidra on brain activity by EEG & found that starting EEG shows beta activity and then in progression of yognidra beta activity was replaced by alpha activity Also, *yoganidra* contains a systematic sequence of body awareness and breathing that influences the parasympathetic nervous system and increase the alpha acitivty in the brain. [11]. A number of related studies were reviewed[12-15].

Thus from above mentioned research study it is clear that *yoganidra* is having some psychological impact on physiological well being which improves the abnormal conditions. The current study will be done to explore the utility of *yoganidra* at Infertility clinics and assist practitioner to engage subfertile couples undergoing IVF treatment in the practice of these technique and to enhance the quality of support programmes and psychological research.

Conclusion:

The current research study will help to understand and explore the utility of yognidra at Infertility clinics and assist practitioner to engage subfertile couples undergoing IVF treatment in the practice of these technique. This study will enhance the quality of support programmes and psychological research. Incorporating psychological intervention provided by yognidra will act as a complementary therapy during infertility treatment.

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