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"A CONTROLLED COMPARATIVE CLINICAL TRIAL TO STUDY THE EFFECT OF GUDUCHI-SHALMALYADI YOGA IN KSHEENA SHUKRA W.S.R. TO OLIGOSPERMIA"

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ABSTRACT

Infertility is the problem of global proportions, affecting on average 8-12% of couples worldwide Annual incidence of male infertility is at least 2 million Cases (based on NWHIC). Recent studies have indicated that the prevalence of Oligospermia is extremely high in metropolis as well as in smaller towns of India.

Infertility is defined as the inability to achieve pregnancy after 1 year of unprotected cotitus. Male infertility is considerable less complicated than female infertility but can account for 30-40% of infertility Except some physical defect. Low sperm count (Acc. to WHO criteria <15mill/ml) it's called Oligospermia and poor sperm quality are responsible for male infertility is more than 90% of cases. Out of these in about 30% to 40% the cause is unexplained and in the rest of the cases critical illness, malnutrition, genetic abnormalities, side effect of some medicines, hormones and chemicals play the major role.

The term Oligospermia may be correlated with ksheena shukra. Acharya Sushruta has included ksheena shukra under 8 varieties of shukra dushti. Here vata and pitta undergo vitiation and does disturbance in the normal qualities of the shukra dhatu. Hence the main line of treatment for Oligospermia is Upachya & Janana of shukra dhatu. The shukrala dravyas, which have properties like madhura, snighda, guru should be administered".

Therefore to explore this research area an attempt is made to study the effect of Guduchi-shalmalyadi yoga over Shatavaryadi churna in the management of ksheena shukra.

Key Words:
Ksheena shukra, Guduchi- Shalmalyadi yoga, Shatavaryadi churna, Oligospermia.

Introduction:
Ayurveda asserts four objectives of life that is Dharma, Artha, Kaam and Moksha.[1] Amongst it the first three objectives has great importance during the life period attained which should be harmonious and productive.

Ayurveda states that righteousness, wealth, affection and good repute are dependent on begetting a son[2]. This is possible only with reproduction. Reproduction is an important phenomenon for the continuation of species. Since the beginning of recorded history, the human race has placed a great emphasis on fertility. Fertility or being fertile itself is a necessity for existence. Being infertile or unable to bring forth a progeny itself is a worrying situation for a couple which makes them approach for a medical advice. Reproductive Medicine is a branch of medical science which deals with infertility cases in males and females and associated disorders.

Male infertility to the inability of a male to achieve a pregnancy in a fertile female. In human it accounts for 40-50% of infertility[1]. Male infertility is due to deficiencies in the semen and semen quality is used as surrogate measure of male fecundity[2]. Some of the known responsibility of male infertility are poor semen quality, endocrine inter relationship, testicular function, and genetic factors etc.[3] except some physical defects, low sperm count, and poor sperm quality are responsible for the male infertility. In more than 90% of cases[4]. Low sperm count (according to WHO criteria <20mill/ml). Is called Oligospermia and which is one of main factor for male

infertility and it is an important clinical condition.

Ayurveda classics have mentioned that, the function of shukra Dhatu is reproduction. There are eight types of shukrsa dusti according to classics[6] .A person having shukra dusti is unable to fulfill his Chaturvidha Purusharta Ksheena shukra dusti is one among the shukra dusti. It is vataja vyadhi, manifested as a result of shukravaha sroto dusti. Prevalence in madhyama vayas being a disease from apana vataj province, in which decreased quality and quantity of Shukra Dhatu is observed.

Ksheena Shukra or Shukrakshaya[4] is the type of Shukra dusti resulting in infertility in which Oligospermia is one of the presentations. 'The diagnosis of Oligospermia is based on one low count in a semen analysis performed on two occasions. For many decades sperm concentrations of less than 20 million sperm/ml were considered low or oligospermic, recently, however the WHO[5] reassessed sperm criteria and established a lower reference point, less than 15 million sperm/ml, consistent with the 5th percentile for fertile men.' Sperm concentrations fluctuate and oligospermia may be temporary or permanent. Out of these some cases remain unexplained whereas rest of the cases are caused due to malnutrition, genetic abnormalities, side effects of some medicines, hormones and chemicals play the major role.

The problem of oligospermia is observed quite common in male infertility cases. Hence it is important to find a remedy which is effective, affordable and having less complications. Nevertheless to say nature has answers for all. Many herbal plants are used since ages for infertility issues.

Vajikarana is one of the branch of Ayurveda that deals with the preservation and amplification of sexual potency of a healthy man and conception of healthy progeny as well as management of defective semen, disturbed sexual potency and spermatogenesis along with treatment of seminal related disorders in man[6]. Vajikarana promotes the sexual capacity and performance as well as improves the physical, psychological, and social health of an individual[7].

The term Oligospermia may be correlated with ksheena shukra. Acharya Sushruta has included ksheena shukra under 8 varieties of shukra dushti[8]. Here vata and pitta undergo vitiation and does disturbance in the normal qualities of the shukra dhatu[9]. Hence the main line of treatment for Oligospermia is Upachya & Janana of shukra dhatu[10]. The shukrala dravyas which have properties like madhura, snighda, guru should be administered[11]. Therefore to explore this research area an attempt is made to study the effect of Guduchi-shalmalyadi yoga over Shatavaryadi churna in the management of ksheena shukra. Due to these medicine Vata and Pitta shaman takes place which are the Dosha involved in the pathogenesis of ksheena shukra it leads to shukra gata vata pitta shaman.

AIMS AND OBJECTIVES:

To compare the effect of Guduchi-Shalmalyadi yoga and Shatavaryadi churna in ksheena shukra

DIAGNOSTIC CRITERIA:

The diagnosis is purely based on the clinical sign and symptoms of Ksheena Shukra (Oligospermia).
Sperm count less than 15 mill/ml.

INCLUSION CRITERIA

1. Married Male patients of age 21-60years

2. Patients with clinical presentation of ksheena shukra (Oligospermia)
3. Sperm count less than 15mill/ml.
4. Patient willing to sign the consent form.

EXCLUSION CRITERIA

1. Patients with Azoospermia, Aspermia.
2. K/C/O Primary testicular failure
3. K/C/O Male Congenital abnormalities
4. K/C/O Genetic defect like Klinfelter syndrome and Reifenstein syndrome
5. Patients with disease like varicocele in scrotum, Benign prostatic hyperplasia.
6. Accessory sex gland infection, Sexually Transmitted Diseases.
7. systemic diseases like Diabetes Mellitus, Obesity, Liver disease, Renal disease, Pyrexia.
8.

RESEARCH DESIGN: Randomized Controlled Clinical Trial

STUDY DESIGN

40 patients of *Ksheena shukra* screened, randomly selected and grouped in two, in which group A were received *Guduchi-Shalmalyadi yoga* group B were received *Shatavaryadi churna* for clinical trial study for duration of 90 days. Who were fulfilling the inclusion criteria and willing to participate in the study was selected. The details about the clinical features and recurrence of *Ksheena shukra* were recorded on a structured clinical proforma by personal interaction and clinical examination.

SAMPLE SIZE: 40 screened patients of *Ksheena shukra.*

INTERVENTION

(A)	(B)
Sample size - 40	Sample size - 40
Group - A	Group - B
Medicine - *Guduchi-Shalmalyadi yoga*	Medicine - *Shatavaryadi Churna*
Dose - 6gm	Dose - 6gm
Anupana - Warm milk	*Anupana* -Warm milk
Route - Orally	Route - Orally
Timing - Morning, Evening	Timing - Morning, Evening
Duration of treatment - 90 days	Duration of treatment - 90 days
Assessment - Before, during and after treatment	Assessment - Before, during and after treatment
Follow up - 3 Follow-ups viz.	Follow up - 3 Follow-ups viz.
1 during treatment	1 during treatment
2 after treatment	2 after treatment

Investigation: Semen Analysis (sperm count)

ASSESSMENT CRITERIA:

SUBJECTIVE PARAMETERS:

Symptoms	Grade	Scale
Daurbalya	No weakness Slight weakness Weakness but routine work not affected Weakness and work affected Can't do any work.	0 1 2 3 4
Shukra Avisarga (Delayed or blood mixed or no ejaculation)	Timely ejaculation in all encounters Delayed ejaculation in 25% encounters Delayed ejaculation in 50% encounters Delayed ejaculation in 75% encounters Delayed and blood mixed ejaculation	0 1 2 3 4

	No ejaculation	5
Medra-Vrushanavedana (Pain in scortum and penis)	No pain. Occasional mild pain during coitus mild pain during coitus moderate pain during coitus severe pain during coitus	0 1 2 3 4
Maithunashakti (Problematic or not satisfactory coitus)	Able to perform satisfactory coitus once in a day Able to perform satisfactory coitus at interval of 1 wk Able to perform satisfactory coitus at interval of 2 wk Not able to perform a satisfactory coitus	0 1 2 3

OBJECTIVE PARAMETERS:

Sperm Count	Normal(20mill/ml) Mild(>14-<20mill/ml) Moderate(7-14mill/ml) Severe(>0-7mill/ml)	0 1 2 3

OBSERVATION AND RESULT

Table: Showing percentage wise reduction of treatment in Group A and Group B

Parameters	% Reduction			
	Group A	N	Group B	N
Daurbalya	80.95%	17	68.42%	13
Shukra Avisarga	80.95%	17	78.94%	15
Medhra Vrushana Vedana	85.71%	18	68.42%	13
Maithuna Aasakti	85.71%	18	57.89%	11
Sperm Count	85.71%	18	78.94%	15

Discussion:

Age : Maximum **47.61%** patients belonged to the **Age group of 31-40 years.** This is due to the fact that most men have sensitive crises related to their physical, mental, and sexual health during their middle years of life. Pitta predominance, stress, and restless nights may be the cause, but evidence must be proven in appropriate circumstances.

Agni: Maximum patients of this study were having ***Tikshnagni* (45.00%).** *Tikshnagni* is due to *Vata Pitta*. It act as a trigger factor for *Ksheena shukra.* This relates to hampering the agni as well as the nutritional needs for the body, leads to *dhatu Kshaya* causes to *ksheena shukra.*

Ahara: 57.50% patients were found **Vegetarians** while 42.50% patients were reported mixed diet. The diet which causes *apatarpana*, *dhatu Kshaya, vata prakopa*, might lead to oligospermia in both diet, that's why exact conclusion can not be drawn.

Koshta: 45.00% of the total patients were with **Mrudu Koshta**. Tikshnagni leads to Amotpati which further resulted to metamorphosis of Dhatu and ultimately resulted into Ksheena-Śukra. Change in life style and dietary habits is responsible for the reduction of Koshta capacities.

Locality: In this study, majority of patients (60.00%) were residing in **urban area**. Urban life is associated with lots of mental stress, psychological insecurities; and exposure to many type of pollutions. All these are known to cause Vata prakopa, which may lead to impairment of Śukra.

Nidra: Majority of the patients (65%)having **disturbed sleep**. Indirectly disturbed sleep causes vitiation of vata and pitta, which directly affects the sperm count and results into *ksheena shukra*.

Occupation: In this study maximum numbers of patient i.e. 22.50% in **IT and Sedentary work**. This shows that men serving the family & lack of concentration towards thier health. As well as stressful life, altered sleep habits, stress of desire for child and hectic duty hours and peer pressure succumb work load contributes towards *Nidana's* of *Ksheena shukra.*

Religion: In the study maximum numbers of patient i.e. 42.85% were **Hindu**. This may be due to the predominance of Hindu at this geographical area. No relation can be drawn between the *Ksheena- Śukra* and Religion of patients in present study.

Prakruti: Majority of patients (25.00%) were **Vata-pitta Prakruti**, Vata Prakruti Purusha will be having Alpa Santana, Pitta Prakruti Purusha will be having Alpa shukra, Alpa Vyavaya shakti & Alpa Santana by the virtue of Katu Amla Rasa of Pitta Dosha. Hence it may be inferred that either Vata or Pitta association in Prakruti may make more susceptible the person for Ksheena shukra. Ksheena shukra is also Vata and Pitta Janya Vyadhi. So on consumption of Apathya, it easily leads to formation of pathologies in that person.

Socio- Economical status: Among 40 patients in group A and group B maximum 13(32.50%) patients belongs to **upper middle class**. In this study group size is small so, exact conclusion can not be drawn.

DISCUSSION ON RESULTS

This may be due to *madhura Tikta rasa*, *madhura Vipaka* and *guru gunatmaka* action of Guduchi-Shalmalyadi yoga, which had addition *Tikta rasa* which Will cause *srotovishodana* in *Ksheena shukra* and Balya, Bṁhaṉiya, Vṁshya, Rasayana properties of drugs are collectively resulted into improve at the level of nutrition, immunity and metamorphoses of Dhatu. It was effective in managing daurbalya.

Guduchi- Shalmalyadi yoga having *shukra vardhaka* and *shukra Janana* properties, which leads to increase *shukra* qualitatively and quantitatively and also works on *vyana* and *apana* which helps for proper ejaculation *(shukra Avisarga).*

In *shukra Vegavrodha* it is told that there will be *Medhra- Vrishana- Vedana* due to vitiation of *Apana vata* i.e. pain in the genitals. *Guduchi- Shalmalyadi yoga* having *madhura-tikta rasa, madhura vipaka, Sheeta Virya, Vrusha guna* which helps in *dhatu vridhi* and *vata shamana*. It helps in proper ejaculation and simultaneously helps in *Medhra Vrishana vedana*.

Guduchi- Shalmalyadi yoga contains shatavari, Musali, Gokshura increases testosterone, serotonin, dopamine level which works on Maithuna ashakti and increases sperm count.

Properties of drugs like Balya, Bṁhaṉiya, Vājeekara, Rasayana etc. are lead to the process of spermatogenesis. Increase testosterone level. Presence of high local concentrations of testosterone within the seminiferous tubules is thought to play an important role in both the initiation & maintenance of sperm production.

CONCLUSION

The research study prevailed -

- GUDUCHI- SHALMALYADI YOGA and SHATAVARYADI YOGA had significant results in improving the seminal parameters as well as improving subjective parameters like Daurbalya, Shukra Avisarga, Maithun Ashakti, Medhra Vrishana Vedana etc.
- The predominance of the doshas specific to the disease origin of Ksheena Shukra i.e. Vata pitta doshas was observed in maximum number of patients as well as the Aharaja (dietic) and Viharaja (behavorial) pattern were suggestive of vitiating Vata and Pitta doshas.
- GUDUCHI- SHALMALYADI YOGA and SHATAVARYADI YOGA have similar guna of that of shukra, hence the effect seen was improving the shukra dhatu quantitatively and qualitatively. But GUDUCHI- SHALMALYADI YOGA results are more effective than SHATAVARYADI YOGA.
- There was no any untoward effects associated with the trial drug GUDUCHI- SHALMALYADI YOGA and the comparable control drug SHATAVARYADI YOGA with the dosage pattern of 3 gm twice a day for 30 days during the treatment. Both the drugs had good acceptability and tolerance.
- Proper sex education with counselling to both the couples simultaneously can play an important role in cases of infertility.

- Mental status like depression and feeling of inferiority or fear to face the society should be eliminated with proper counselling and correction of their diet to healthy and nutritious diet with necessary behavorial conducts can improve the seminal parameters.