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Clinical Study To Evaluate The Efficacy Of *Ashwagandadi Leha* In *Ksheena Shukra* With Special Reference To Oligospermia.

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ABSTRACT: - Male infertility can be defined as an inability to induce conception due to defect in Spermatic functions. It is multifactorial condition in more than 90% of cases , except some physical sperm defects low sperm count and poor sperm quality are the responsible for the male infertility more than 90% of cases. Sperm count less than 20mill/ml is considered as oligospermia. It is one among prime factor in the male infertility. It is defined as a subnormal concentration of spermatozoa in the penile ejaculate. It is correlated with *ksheena shukra* condition. It is pathological condition of *shukra* in which there may be reduced sperm count. In classics many *shukra janaka* drugs are explained in *ksheena shukra* condition. As *Ashwagandadi leha* having *Vrishya* property thus helps in increasing the production of spermatozoa which ultimately causes increases in sperm count useful for combating the *ksheena shukra*. This research work is clinical study with pre-test and post-test design, 30 patients suffering from *Ksheena shukra* (Oligospermia) were selected randomly for study from OPD of SDM' Trust Ayurvedic Medical college, Terdal. Selected patients were treated with *Ashwagandadi leha* for 60 days 10 gms BD with milk. Follow up study was under taken for 30 days after 60 days of treatment. It was found that *Ashwagandadi leha* showed significant improvement in various parameters like *Dorbalya* (Weakness), *Maithuna ashakti* (Loss of interest in Coitus), *Shukra Avisraga*, Desire, Ejaculation, Erection, Orgasm, Sperm count and Sperm motility.

Keywords: *Ksheena shukra*, *Ashwagandadi leha*, *Anupana*, *Oligospermia*.



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INTRODUCTION

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. which is one of main factor for male infertility and it is an important clinical condition. In more than 90% of cases [4], according to WHO criteria <20mill/ml [5] is considered as low sperm count. and *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 srotodusti*. Prevalence in *madhyama vayas* being a disease from *apana vataj* province, in which decreased quality and quantity of *Shukra Dhatu* is observed.

Infertility is defined as a failure to conceive within one or more years of unprotected coitus [7]. Oligospermia is prime one among the male infertility and is defined as subnormal

concentration of spermatozoa in the penile ejaculate [8].

As the sperm count decreases, there is a corresponding decrease in likelihood of conception. Modern medical science has reached to its peak in MART (Medically assisted reproductive technology). Artificial insemination, in-vitro fertilization, intra cytoplasm injection. are considered as advanced technologies. India being poor country, due to their exuberant cost, these techniques are not widely accepted. The rate of their success is also not very assuring despite their high cost.

Ayurveda describes potent drugs and efficient therapeutic procedures mentioned in *vajikarana* to treat the *ksheena shukra* and infertility. In classics there are number of formulations mentioned for the *Vajikarana*. Although a number of research studies have been carried out, still an effective and safe formulation is needed for the the management of *ksheena shukra*. The inspiration behind to take a herbal formulation "*Ashwagandadi leha*" [9]. Mentioned in *Sahasra yoga avaleha prakarana*, for the clinical study is cost effective and based on the hypothesis that its ingredients *ashwagand*, *tila*, *maasha*, *pippali*, having *madhur rasa shita virya snigdha guna* of *ashwagandadi leha* cause pacification of *vata* and *pitta* which are the main *doshas* involved in the pathogenesis of *ksheena shukra* thereby leading to *shukra gata vata pitta shaman*.

In addition *Ashwagandadi leha* possess *Vrishya*

effect thus increasing the production of spermatozoa which ultimately causes increases in sperm count is useful for combating the *Ksheena shukra*.

AIMS & OBJECTIVES

1. To carry out the comprehensive literary work covering *Ayurvedic* classics, contemporary medical systems of medicine on *Ksheena shukra*.
2. To evaluate the efficacy of *Ashwagandadi leha* is effective in the management of *Ksheena Shukra*.

MATERIALS & METHODOLOGY

The clinical study entitled “ Clinical study to evaluate the efficacy of *Ashwagandadi leha* in *Ksheena shukra* with special reference to Oligospermia” was carried out on 30 patients who attended the OPD sections of *Prasooti Tantra and Stree Roga* Department, SDMT’S Ayurvedic medical College, Danigond Post Graduation Centre, Terdal , Bagalkot.

Study Design:

- 1- Single group Open clinical study.
- 2- It is a clinical study with a Pre – test and Post-test design, where 30 Patients suffering from *Ksheena shukra* were selected.
- 3- The duration of treatment was for 60 days
- 4- The parameters of signs and symptoms were scored on the basis of standard method of Statistical Analysis.

DIAGNOSTIC CRITERIA

Diagnosis will be done on the basis of the classical signs and symptoms of *Ksheena shukra*.

- Dourbalya*
- Shukra avisarga*
- Medra – Vrshna vedana*
- Maithuna shakti*

Inclusion Criteria:

Patients presenting with *Pratyatmaka Lakshana* of *Ksheena shukra* i.e *Dourbalya, Shukrav avisarga, Medra – Vrshna vedana, Maithuna ashakti*

1. Sperm count < 20 million / milliliter
2. Male patients of age ranging from 21-45 years

Exclusion Criteria:

1. Patients with Azoospermia.
2. Genetic defects like Klinefelter syndrome.
3. Patients with diseases like Varicocele, Accessory sex gland infection, STD and systemic diseases like DM etc.

Investigations

Detailed semen Analysis will be carried out for diagnosis and assessment.

1. Semen analysis
 - i. Volume
 - ii. Total sperm count
 - iii. Motility
 - iv. Liquefaction
 - v. Viscosity
 - vi. pH
 - vii. Total abnormal forms
2. Complete blood count
3. Urine routine

Interventions

The Subjects fulfilling above criteria are selected and assigned in a group for administration of *Ashwagandadi leha* , 10 gms twice a day with Milk.

Duration of Treatment-60 days.

Follow Up After 30th and 60thdays.

I. Subjective parameters

- 1- Relief in the symptoms of *Ksheena shukra Dourbalya, Shukra avisarga, Medra – Vrshna vedana, Maithuna ashakti* etc.

2. Sexual health parameters – Desire, Erection, Ejaculation and Orgasm will be graded and assessed.

2- Objective parameters

Semen analysis i.e Total Sperm count and Motility.

Subjective and Objective parameters will be assessed before, during and after treatment. The data obtained will be subjected to statistical analysis by using appropriate test.

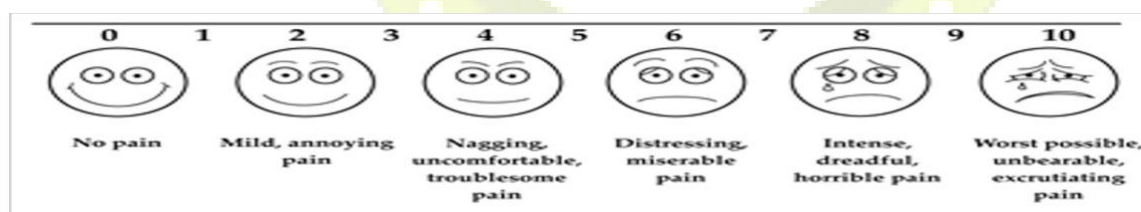
ASSESSMENT SCORING

SUBJECTIVE PARAMETRES

1. Dourbalya (Weakness or Debility)

- No weakness he can perform routine work effectively - 0
- Slight weakness but he can do routine work normally - 1
- Slight weakness and feel difficulty in performing routine work - 2
- Marked weakness and can not perform his routine work – 3

Will be assessed as per VAS scale



VAS scale (visual analogue scale) has been used for pain gradation. Pain intensity 0= No pain, 1-3=Mild pain (pain present but does not disturb the routine), 4-6=Moderate pain (pain present which disturbs the routine), 7-10=Severe pain (patients roll on the bed due to pain).

- Marked weakness and can not do any type of work - 4

2. Shukra avisarga (Delayed or blood mixed or no ejaculation)

- Timely ejaculation in all sexual encounters - 0
- Delayed ejaculation in 25% of sexual encounters - 1
- Delayed ejaculation 50% of sexual encounters - 2
- Delayed and blood mixed ejaculation – 3
- No ejaculation - 4

3. Medra – Vrishana vedana (Pain in scrotum and penis)

- No pain - 0
- Occasional mild pain during coitus and lasts after coitus - 1
- Frequent mild pain during coitus and lasts after coitus – 2
- Persistent mild pain during coitus and long lasting - 3
- Persistent severe pain during coitus and long lasting - 4

4. Maithuna ashakti (Problematic or not satisfactory coitus)

- No problem - 0
- Able to perform satisfactory coitus once in a day - 1

- Able to perform satisfactory coitus at the interval of 1 week – 2
 - Able to perform satisfactory coitus at the interval of 2 week – 3
 - Not able to perform a satisfactory coitus – 4
4. Desire
- Normal (Desire without any initiation of the partner) - 0
 - Mild (Desire after the involvement of the partner) - 1
 - Moderate (Desire after the involvement of the partner and can't maintain the desire further) - 2
 - Severe (Lack of desire) – 3
5. Erection
- Normal (Maintain the erection till the end of the act) - 0
 - Mild (Unable to maintain erection during the act) - 1
 - Moderate (Failure to do the insertion even though having erection) - 2
 - Severe (No erection) – 3
6. Ejaculation
- Normal (Without any type of discomfort) - 0
 - Mild (Pain and burning after ejaculation) - 1
 - Moderate (Less ejaculation at the end of the act) - 2
 - Severe (No ejaculation / Premature ejaculation) – 3
7. Orgasm
- Normal (Orgasm attains at the end of the act with full satisfaction) -0
 - Mild (Attains orgasm just before the completion of the act) - 1
 - Moderate (Attains the orgasm in the middle of the act) - 2
 - Severe (Lack of orgasm) – 3

OBJECTIVE PARAMETERS

1. Sperm count
- Normal (20 million / ml or more) – 0
 - Mild (> 14 - <20 million /ml) - 1
 - Moderate (7 – 14 million / ml) - 2
 - Severe (> 0 – 7 million / ml) – 3
2. Sperm motility
- Normal (Motility above 75%) – 0
 - Mild (Motility 50% - 75%) – 1
 - Moderate (Motility 25%-50%) – 2
 - Severe (Motility below 25%) – 3

Overall effect of the Therapy

Table No - 01

Overall Effect	Grading
Marked improvement	>75 % relief in signs and symptoms
Moderate improvement	>50 % to 75 % relief in signs & symptoms
Mild improvement	>25% & 50% relief in signs & symptoms
Unchanged	Up to 25% relief in signs & symptoms

OBSERVATIONS

1. Showing Results Of Wilcoxon Signed Rank Test On The Symptom *Dourbalya*

Table No - 1

<i>Dourblya</i>	Mean score	Median score	Median difference	n	Wilcoxon signed rank test (T ⁺)	P- Value
Before treatment	2.73	3	2.00	30	465	0.0033
After treatment	0.56	1				

Table No - 02

<i>Dourblya</i>		0	1	2	3	4	Total
Before treatment	Count	0	0	13	12	5	30
	%	0.00%	0.00%	43.33%	40.00%	16.67%	100.00%
After treatment	Count	15	13	2	0	0	30
	%	50.00%	43.33%	6.67%	0.00%	0.00%	100.00%

2. Showing Results Of Wilcoxon Signed Rank Test On The Symptom *Shukra – Avisarga*

Table No - 03

<i>Shukra avisarga</i>	Mean score	Median score	Median difference	n	Wilcoxon signed rank test (T ⁺)	P- Value
Before treatment	2.67	2	2.00	30	435	0.0060

Table No - 04

<i>Shukra-avisarga</i>		0	1	2	3	4	Total
Before treatment	Count	0	0	18	4	8	30
	%	0.00%	0.00%	60.00%	13.33%	26.67%	100.00%
After treatment	Count	21	6	3	0	0	30
	%	70.00%	20.00%	10.00%	0.00%	0.00%	100.00%

3. Showing Results Of Wilcoxon Signed Rank Test On The Symptom *Medra –Vrishana Vedana* Table No - 05

<i>Medra_vrushana vedana</i>	Mean score	Median score	Median difference	N	Wilcoxon signed rank test (T ⁺)	P- Value
Before treatment	2.60	2	2.00	30	435	0.00598
After treatment	0.67	0				

Table No - 06

<i>Medra_vrushana vedana</i>		0	1	2	3	4	Total
Before treatment	Count	0	0	16	10	4	30
	%	0.00%	0.00%	53.33%	33.33%	13.33%	100.00%
After treatment	Count	15	10	5	0	0	30
	%	50.00%	33.33%	16.67%	0.00%	0.00%	100.00%

3. Showing Results Of Wilcoxon Signed Rank Test On The Symptom *Maithuna Ashakti* Table No - 7

<i>Maithuna ashakti</i>	Mean score	Median score	Median difference	N	Wilcoxon signed rank test (T ⁺)	P- Value
Before treatment	2.47	2	2.00	30	465	0.00279
After treatment	0.60	0				

Table No - 8

<i>Maithuna ashakti</i>		0	1	2	3	4	Total
Before treatment	Count	0	1	16	11	2	30
	%	0.00%	3.33%	53.33%	36.67%	6.67%	100.00%
After treatment	Count	15	12	3	0	0	30
	%	50.00%	40.00%	10.00%	0.00%	0.00%	100.00%

4. Showing Results Of Wilcoxon Signed Rank Test On The Symptom Desire

Table No - 9

Desire	Mean score	Median score	Median difference	N	Wilcoxon signed rank test (T ⁺)	P- Value
Before treatment	2.06	2	2.00	30	435	0.0073
After treatment	0.43	0				

Table No - 10

Desire		0	1	2	3	Total
Before treatment	Count	1	4	17	8	30
	%	3.33%	13.33%	56.67%	26.67%	100.00%
After treatment	Count	18	11	1	0	30
	%	60.00%	36.67%	3.33%	0.00%	100.00%

5. Showing Results Of Wilcoxon Signed Rank Test On The Symptom Erection

Table No - 11

Erection	Mean score	Median score	Median difference	N	Wilcoxon signed rank test (T ⁺)	P- Value
Before treatment	1.53	2	2.00	30	300	0.0094
After treatment	0.17	0				

Table No - 12

Erection		0	1	2	3	Total
Before treatment	Count	4	6	20	0	30
	%	13.33%	20.00%	66.67%	0.00%	100.00%
After treatment	Count	26	3	1	0	30
	%	60.00%	36.67%	3.33%	0.00%	100.00%

6. Showing Results Of Wilcoxon Signed Rank Test On The Symptom Ejaculation

Table No - 13

Ejaculation	Mean score	Median score	Median difference	N	Wilcoxon signed rank test (T ⁺)	P- Value
Before treatment	2.06	2	2.00	30	435	0.00495
After treatment	0.40	0				

Table No - 14

Ejaculation	Mean score	Median score	Median difference	N	Wilcoxon signed rank test (T ⁺)	P- Value
Before treatment	2.06	2	2.00	30	435	0.00495
After treatment	0.40	0				

7. Showing Results Of Wilcoxon Signed Rank Test On The Symptom Orgasm

Table No - 15

Orgasm	Mean score	Median score	Median difference	N	Wilcoxon signed rank test (T ⁺)	P- Value
Before treatment	2.2	2	2.00	30	435	0.0071
After treatment	0.37	0				

Table No - 16

Orgasm		0	1	2	3	Total
Before treatment	Count	1	2	17	10	30
	%	3.33%	6.67%	56.67%	33.33%	100.00%
After treatment	Count	20	9	1	0	30
	%					

8. Showing Results Of Wilcoxon Signed Rank Test On The Symptom Sperm Count

Table No - 17

Sperm Count	Mean score	Median score	Median difference	N	Wilcoxon signed rank test (T ⁺)	P- Value
Before treatment	2.06	2	2.00	30	406	0.0042
After treatment	0.40	0				

Table No - 18

Sperm Count		0	1	2	3	Total
Before treatment	Count	0	3	22	5	30
	%	0.00%	10.00%	73.33%	16.67%	100.00%
After treatment	Count	19	10	1	0	30
	%	63.34%	33.33%	3.33%	0.00%	100.00%

9. Showing Results Of Wilcoxon Signed Rank Test On The Symptom Sperm Motility

Table No - 19

Sperm Motility	Mean score	Median score	Median difference	N	Wilcoxon signed rank test (T ⁺)	P-Value
Before treatment	1.9	2	2.00	30	458.5	0.0087
After treatment	0.3	0				

Table No - 20

Sperm Motility		0	1	2	3	Total
Before treatment	Count	1	5	20	4	30
	%	3.33%	16.67%	66.67%	13.33%	100.00%
After treatment	Count	21	9	0	0	30

Mean percent improvement in various Assessment parameters:-

Table No - 21

Parameters	Mean Improvement %	Remark
<i>Dourblya</i>	81.38%	Significant
<i>Shukra -Avisarga</i>	85.27%	Significant
<i>Medra_vrushna Vedana</i>	76.38%	Significant
<i>Maithuna ashakti</i>	78.61%	Significant
Desire	78.33%	Significant
Erection	76.67%	Significant
Ejaculation	83.33%	Significant
Orgasm	81.66%	Significant
Sperm Count	81.11%	Significant
Sperm Motility	84.44%	Significant
Average Mean % improvement	80.718%	

Distribution of patients according to relief:**Table No - 22**

For assessment, all the assessment parameters were used.

Overall Effect (patient wise)	Criteria
Marked improvement	>75 % relief in signs and symptoms
Moderate improvement	>50 % to 75 % relief in sings & symptoms
Mild improvement	>25% & 50% relief in sings & symptoms
Unchanged	Up to 25% relief in sings & symptoms

Distribution of patients according to relief:**Table No - 23**

Overall Effect (patient wise)	Count	%
Marked improvement	20	66.67%
Moderate improvement	10	33.33%
Mild improvement	0	0.00%
Unchanged	0	0.00%
Total	30	100.00%

DISCUSSION**Probable mode of action of Ashwagandadi leha:**

The trial drug *Ashwagandadi leha* contains *Ashwagand*, *Pippali*, *Masha*, *Tila* mainly having *Madhur rasa* so the resultant product gets *Madhur rasa*. *Susruta* and *Charaka acharya* mentioned that the *madhur rasa* is having the *shukra vardhaka* property, there by it is helped in *shukra vriddhi*. All the drugs having *Snigdha* and

Guru guna all these *gunas* also helps in the production of *Shukra*, based on the *Samanya vishesh siddanta*.

All the drugs in the trial drug has got *Vata anulomana*, *Bhrimhana*, *Balya* and *Vrishya* properties. By all these properties of the drugs, might have helped for the *Shukra Vriddhi*. *Vata* and *pitta* are the *doshas* which are involved in the production of *ksheena shukra*. The fallowing way the trial drug rules over the *dosha*. Due to

the *madhur rasa*, *Snigdha guna* it pacifies *vata* and does the *Vataanuloman* and end product of *avaleha* pacifies having properties like Madhur, snigdha so reduces the *pitta*.

Mode of Action of the Anupana i.e *Dugdha* :

Godugdha has got *Madhura rasa*, *Sheeta Virya*, *Snigdha guna* and *Madhura vipaka*. It is known as *sadyo vrishya*. It is *Ajanma Satmya* and it has got all the properties that which increase the *shukra*. There by the *Anupan*, *Godugdha* is going to help in the action of the drug by acting as a catalyst or by supporting the trial drug in the vitiated *pitta* is going to be removed or pacified and its properties also helps in the *Vataanulomana*.

CONCLUSION

After a thorough study of all the observations and the results obtained the following conclusions can be drawn.

The Description of *Ksheena Shukra* is found in *Brihatrayees* of *Ayurveda*, but scattered information regarding the disease is seen later treaties, the review of Literature of Oligospermia was scattered in modern texts.

In this Clinical study majority of the patients complaints of premature ejaculation, for which performance anxiety is the main cause, couples counseled.

The drug *Ashwagandadi leha* did not shown any intolerance, reactions during the course of treatment in any taking the milk after intake of medicine. The drug was proved to be safe and effective oral formulation, which helps in the management of *Ksheena Shukra* when the disease is not too advanced and when correctly used by the patient as per instructions.

This Clinical study supported the alternative hypothesis after the management i.e the trial drug *Ashwagandadi leha* was found to be effective in

the management of the *Ksheena Shukra* (Oligospermia). Proper sex education and Counseling were also needed for effective treatment.

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Conflict of Interest: Nil

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