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CLINICAL STUDY OF ATIBALA MOOL CHURNA (ABUTILON INDICUM) IN SHUKRA-KSHAYA W.S.R. TO OLIGOSPERMIA. DR.SANJEEV L ATHANI¹ DR.YOGESH KHAMBHAYAT²

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ABSTRACT

Basackground- Oligospermia is one among the prime factor in the male infertility and it is defined as a subnormal concentration of spermatozoa in the penile ejaculate i.e. less than 20 million/ml. The condition Oligospermia can be well matched with Ksheena Shukra in Ayurveda. The quantity and quality of sperms are decreasing day by day, which may be due to altered life styles, rapid industrialization etc. However, till date no satisfactory medical management has been developed for this problem. Although a number of research studies have been carried out, still an effective and safe formulation is needed for the management of Ksheena Shukra. The inspiration behind to take "Atibala Moola Churna" for the clinical study is based on the hypothesis that it is useful for combating the Ksheena Shukra. **Key Words:** Ksheena Shukra; Oligospermia; Atibala Moola Churna

INTRODUCTION

Achievement of Scientific integrity and credibility of the concepts can only be with well designed and conducted research studies. To create a Healthy Progeny is one of the foremost Dharma of an individual. So infertility is an existential necessity since the time immemorial. Infertility, defined as the inability to conceive after at least one year of unprotected intercourse, affecting about 18 - 20% of all married couples. In about 60% of these couples Male factor is the primary problem. Except some physical defects low sperm count (oligospermia) and poor sperm quality is responsible for male infertility in more than 90 % of cases. In approximately 40% of cases pathology found in male alone and another 20% both males and females contribute to the infertility. Male Infertility can be defined as an inability to induce conception due to defect in spermatic functions. The male partner carrying pathological semen reports including low sperm count, poor motility, abnormal forms in sperm functional tests and whose female partners have been ruled out for the possible etiological factors of infertility may be diagnosed under male infertility rates in this industrialized world. Ayurvedic classics, Acharyaas In

mentioned regarding four Purushaarthaas i.e. Dharma, Artha, Kaama and Moksha. Kaama, the desire, is also related with sexual gratification, which is one of the happiness in the life and to create a healthy progeny. So fertility is an existential necessity from the time immemorial. The essential factors of conception are Ritu (reproductive age and ovulation period), Kshetra (female reproductive tract), Ambu (nutritional factors) and Beeja (sperm and ovum). Any malfunction of these factors may lead to infertility. Charaka compares the man who is incapable of procreation as shadow less, single branched, foul smelling tree devoid of fruits that has no purpose or plays no role in the world. The ambition or aim of a person is that to propagate his legacy through his progenies. Infertility makes the man incapable Main function of Shukra Dhatu is reproduction. Ksheen Shukra is a disease in which both quality and quantity of Shukra is reduced and may lead to infertility. In this context quality of Shukra refers to the motility of sperm and the Quantity refers to the decreased sperm count. So Ksheenshukra can also be correlated with Oligospermia. According to Ayurveda, Shukra should possess such a potency so as to conceive a lady. The impact of defective Shukra is Infertility. KsheenShukra is Dosha Bala Pravrutta, Khruccha Sadhya Roga of Shukravaha

Strotas. It is understood that Dushita Vata and Pitta Dosha are responsible for this condition. So for the management of KsheenShukra, Vrishya Dravyas or Shukra Vardhaka or Shukrala drugs enriched with Madhura Rasa, Sheeta Veerya and Guru -Snigdha Guna and highly potentiated with Balya, Vrishya and Rasayana properties should be used. Ayurveda, the holistic medicine describes potent drugs and efficient therapeutic procedures to face the problem of infertility. Vaajikarana, the eighth branch of Ayurveda mainly deals with the drugs and therapeutics which are aphrodisiacs in nature. It provides progeny to infertile couple, potency to the impotent, at the same time excellence of progeny with suitable therapeutic measures. ATIBALA (ABUTILON INDICUM) is the drug having the properties like Madhura Rasa, Madhura Vipaka, Sheeta Virya. It has Laghu, Snigdha, Pichihl Guna all of which Shamak are Vata-Pitta and Shukra Vardhaka (Bhavaprakasha), so it can be effectively used in KsheenShukra. The present clinical study is conducted to compare the efficacy of ATIBALA (ABUTILON INDICUM) drugs in the management of KsheenShukra w.s.r. to Oligospermia

OBJECTIVES:

1. To study the clinical efficacy of ATIBALA MOOL CHURNA

(ABUTILON INDICUM) with its Shukrala Details property in and 2. То study Ksheen Shukra Oligospermia in Details. 3. To bring in parlance with Oligospermia in the modern and Ksheena Shukra in Ayurveda

MATERIALS AND METHODS

Patients of Male sex attending OPD and IPD of Shri J. G. C. H. S. Ayurvedic medical college, Ghataprabha and its associated Hospitals, who are diagnosed as Ksheena Sukra (Oligospermia) were selected for study.

STUDY DESIGN: Standard single blind clinical study.

It is a clinical study consisting of 30 patients of inclusive criteria. Inclusion and exclusion criteria for selecting subjects for the study, were as follows: Diagnostic Criteria: Mainly based on the signs and symptoms of KsheenShukra and Semen Analysis.

Inclusion Criteria –

 1. Male subjects of age group between 21

 to 45 year

2. Subjects with features of Ksheen Shukra (Oligospermia)

3. Subjects with total sperm count below15 million/ml

Exlusion Criteria –

 Subjects categorized under Azoospermia
 Individuals with HIV, HBsAg +ve will be excluded from the study 3. Varicocele, Accesory sex gland infection, Testicular maldescent, previous reproductive organ

surgery, congenital reproductive organ defects and sexually transmitted diseases will be excluded.

4. Past history of Mumps, Orchitis, Trauma, Addictions and Acute Febrile illness will be excluded from study.

5. Diabetes, Thyroid disorders, Tuberculosis, Vascular Diseases, Alcoholic, Tobacco addict and any longstanding infection cases will be excluded from study.

Methods of collection of data (including sampling procedures)

30 patients diagnosed as Ksheena Shukra (Oligospermia), from OPD and IPD of Shri J. G. C. H. S. Ayurvedic medical college, Ghataprabha and its associated hospitals were selected for the study after following the inclusion and exclusion criteria.. The trial group had been given "Atibala Moola Churna", 3 gm twice a day with Ushnodaka, after meals. The duration of the treatment was 90 days. The subjective and objective parameters of the patients were assessed before scheduled treatment. The symptomatic relief and changes were observed for every 30 days of treatment and it was documented. Further follow up study done for 30 days and assessment of result has been done. Information regarding the

Pathya, Ahaara and Vihaara had been given. Apathyas were restricted during the treatment period.

Collection of semen for Analysis

Abstinence : Before collection of the ejaculate minimum of 3 days and maximum of 5 days abstinence was followed.

Method : Masturbation method was preferred for the sample collection.

Container : The Laboratory supplied a dried and wide mounted bottle was used.

Place : A private room adjacent to the laboratory was used for semen collection

Time : Semen collection time was restricted between 9.30 am to 11.30 am

Inclusion criteria:

1. Patient diagnosed as Ksheena Shukra (Oligospermia)

2. Male patients of age ranging from 21 to

45 years were included.

Exlusion Criteria –

1. Subjects categorized under Azoospermia

2. Individuals with HIV, HBsAg +v were excluded from the study.

3. Varicocele, Accesory sex gland infection, Testicular maldescent, previous reproductive organ

surgery, congenital reproductive organ defects and sexually transmitted diseases were excluded.

4 Past history of Mumps, Orchitis, Trauma,Addictions and Acute Febrile illness were excluded from study.

5. Diabetes, Thyroid disorders, Tuberculosis, Vascular Diseases, Alcoholic, Tobacco addict and any longstanding infection cases were excluded from study.

Laboratory investigations

1.Semen analysis which includes - Sperm count - Motility - pH - Liquification time -Sperm morphology, etc.

- 2. ESR to rule out the infections
- 3. Hb% to rule out Anemia
- 4. RBS to rule out Diabetes

Treatment schedule:

Table No. 1 showing : Sample size, medicine, dose, Sahapana and duration

Sample size	30 patients
Medicine	Atibala Moola Churna
Dose	3 gm, Twice a day, after meals
Sahapana/ Anupaana	Lukewarm Water
Duration	90 days

Follow up study

Follow up study were undertaken for 30 days after the treatment to assess the

result.

Assessment response:

The improvements of patients were

assessed on the basis of relief in Subjective and objective parameters. According to severity, the grading for the parameters was given as below;

1. Grading for Symptoms of Ksheena Shukra

- a) Normal (No symptoms) -
 - 0
- b) Mild (Presence of any of the Saarvadaihika Lakshanaas) -

- c) Moderate (Presence of Level 1 Severity Pratyaatma (Sthaanika) Lakshanaas with or without Saarvadaihika 2 Lakshanaas)
- d) Severe (Presence of Level 2 Severity Pratyaatma Lakshanaas with or without Sarvadaihika Lakshanaas and Level 1 Severity of Pratyaatma Lakshanaas) 3

Level 1 severity symptoms	Level 2 severity symptoms
Medhra Dhumayana	Maithuna Ashakti
Medra Vedana	Klaibya
Vrishana Vedana	Shukra Avisarga
Chirat Praseka	Sarakta Shukra Darshana
\sim	
	symptoms Medhra Dhumayana Medra Vedana Vrishana Vedana

Table No. 2 : Saarvadaihika Lakshanas, Level 1 and Level 2 severity symptoms

2 Decire

3.

2. Desire		till the end of the act) 0	
a) Normal (Desire without any	0	b) Mild (unable to maintain– 1	
initiation from the partner)		erection during the act)	
Mild (Desire after the-	1	c) Moderate (Failure to do the- 2	
involvement of the partner)		insertion even though having	
Moderate (Desire after the		erection)	
involvement of the partner		d) (No erection) – 3	
and cannot maintain the-	2		
desire further)	4.	Ejaculation	
d) Severe (Lack of desire) –	3	a) Normal (Without any type of discomfort)-	0
Erection		b) Mild (Pain and burning after ejaculation)-	1
a) Normal (Maintain the erection-		c) Moderate (Less ejaculation at the end of-	2

the act)

d) Severe (No ejaculation or blood mixed– 3less ejaculate or premature ejaculation)

5. Orgasm

a) Normal (Orgasm attains at the end of– the act with full satisfaction)

b) Mild (Attains orgasm just before thecompletion of the act)

c) Moderate (Attains the orgasm in themiddle of the act)

d) Severe (Lack of orgasm)

GRADING FOR OBJECTIVE

PARAMETER

1. Sperm coun

- a) Normal (20 million / ml or more)- 0
 - b) Mild (>14 <20 million / ml) 1
 - c) Moderate (7 14 million / ml) 2
 - d) Severe (>0 7 million / ml)-3

2. Sperm motility

- a) Normal (motility Above 75 %)
- b) Mild (motility 50% 75%)
- c) Moderate (motility 25% 50%)
- d) Severe (motility Below 25%)

Statistical Analysis:

Descriptive data that included Mean, Standard Deviation (S.D), Standard Error (S.E), 't value' and 'p value' were calculated for all the variables in trial group. Post treatment changes were assessed by paired "t test".

Assessment of the overall effect:

To assess the overall effect of the therapies net result obtained on various parameters of assessment both before and after treatment were taken in to consideration. Then it was graded in terms of percentage of relief in 0symptoms.

Grading of Remarks or Criteria for lassessment of overall effects of the therapy

a2Complete cure - 100% relief

- b) Marked improvement ->66% to <100%
- c3Moderate improvement>33 to <66% of relief
- d) Mild Improvement ->1 to <33 % Of relief
- e) Unchanged -0% of relief

OBSERVATION

In the present study 30 patients having Ksheena Shukra fulfilling the inclusion criteria were selected and put under the trial group. Following pages contains the descriptive statistical analysis of the 30 patients studied along with the observations and results.

Data are mentioned here under the following headings :

- 1. Data related to demography.
- 2. Data related to disease (Patient's clinical findings).

3. Data related to results (Statistical analysis of the assessment of the patient before and after the treatment in the single group by following Paired't' test).

1. DATA RELATED TO DEMOGRAPHY

Table No.	3 showing	distribution of	f patients acc	ording to age

AGE	NUMBER OF PATIENTS	0⁄0
21 - 25	4	14%
26 - 30	6	20%
31 - 35	12	40%
36 - 40	8	26%
Total	30	100%

Table No. 4 Showing distribution according to socio-economic status

SOCIO-ECONOMIC	NO. OF PATIENTS	PERCENTAGE
UPPE <mark>R CL</mark> ASS	3	1 %
MIDDLE CLASS	23	76.66 %
LOWER CLASS	4	13.33 %

Table No 5. showing distribution of patients according to nature of work

Nature of work	No. of patients	Percentage
Hard Manual	0	0 %
Moderate Manual	4	13.33 %
Mild Manual	13	43.33 %
Sedentary Manual	13	43.33 %
Total	30	100 %

Table No. 6 showing distribution of patient according to diet

Diet	No. of patients	Percentage
Mixed diet	19	63.33 %
Vegetarian diet	11	36.66 %
Total	30	100 %

Table No. 7 showing distribution of patients according to Agni

Agni	No. of Patients	Percentage	
Samanagni	12	40 %	
Mandagni	4	13.33 %	
Tikshanagni	1	3.33 %	
Vishamagni	13	43.33 %	
Total	30	100 %	

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VYASANA	NO. OF PATIENTS	PERCENTAGE
ALCOHOL	1	3.33 %
TOBACCO	3	10 %
TEA	19	66.33 %
COFFEE	3	10 %
NONE	4	13.33 %
TOTAL	30	100 %

Table No. 8 showing distribution of patients according to Vyasana.

1. DATA RELATED TO DISEASE (Patient's clinical findings).

a) Incidence based on Sperm count

Table No. 9 Distribution of 30 patients based on Sperm Count

Gr <mark>ade</mark> of sperm count in Oligospermia	No. of patients	%
$\frac{\text{Mild}(>14 - <20 \text{ million/ml})}{1000}$	40 2 100	15%
Moderate (>7 - < 14 million/ml)	14	45%
Severe (>0 - < 7 million/ml)	12	40%

Table No.10 showing complaints of Shukra-Kshaya

Complaints	No. of patients	%
Klaibya	20	66%
Medra Vedana	08	26%
Vr <mark>ushana Ve</mark> dana	10	33%
Asakta Mithuna	16	53%
Chirat Praseka	08	26%
Chinta		50%
Shrama	12	40%
Daurbalya	10	33%
Pandutwa	9	30%
Mukhashosha	18	60%
Sadana	10	33%

RESULTS

30 patients were registered in this study, whose results are presented here. In this study 3 gms

of Atibala Moola Churna administered two times a day before meals for 90 days with warm

water.

The results obtained on various parameters are as follows

S.No	Parameters	BT(Mean <u>+</u> S.D)	AT(Mean + S.D)	P Value
1	Liquification time (in minutes)	<u>26+</u> 6.39	<u>19.6 +</u> 6.32	0.001
2	Semen volume(In ML)	1.55 <u>+</u> 0.51	<u>2.025 + 0.46</u>	0.001
3	Sperm count (In millions)	18.215 <u>+</u> 5.12	<u>23.067 + 4</u> .96	0.001
4	Rapid linear progression	12.75 <u>+</u> 8.7	17.25 <u>+ 8.5</u>	0.05
5	Slow linear progression (SLP) motility	<u>32.2 + 10.62</u>	37 <u>+</u> 10.55	0.01
6	Non-progressive (NP) motility	23 <u>+</u> 6.8	28 <u>+</u> 6.5	0.01
7	Immobile sperm(In millions)	27 <u>+ 15.34</u>	13.75 <u>+</u> 15.28	0.001
8	Abnormal sperm forms (In millions)	65.75 <u>+ </u> 7.11	55.5 <u>+</u> 7.08	0.001

The mean liquification time decreased with the treatment by 25.4% time on completion of the treatment. On statistical analysis the value is significant at the level of P (0.001) The mean Semen Volume was increased with the treatment by 30.65% ml on completion of the treatment. On Statistical analysis the value is significant at the level of P (0.001)

The mean sperm count increased with the treatment by 26.63% on completion of the treatment. On statistical analysis the value is significant at the level of P (0.001) The mean RLP sperm motility increased with the treatment by 35.29% on completion of the treatment. On statistical analysis the value is significant at the level of P (0.05) The mean SLP increased with the treatment by 14.90% on completion of the treatment. On statistical analysis the value is significant at the level of P (0.01)

The mean NP increased with the treatment by 21.73% on completion of the treatment. On statistical analysis the value is significant at the level of P (0.01

The immobile sperms were decreased with the treatment by 49.09% on completion of the treatment. On statistical analysis the value is significant at the level of P (0.01). The mean total abnormal sperms were increased with the treatment by 17.48% on completion of the treatment. On statistical analysis the value is significant at the level of P (0.001).

No. of patients	Percent relief	
0	0	
5	16.66%	
18	60%	
7	24.34%	
	0	0 0 5 16.66% 18 60%

Table No. 12 showing overall effect of Atibala Moola Churna in Ksheena shukra.

After full course of treatment with Atibala Moola Churna, 16.66% showed marked improvement, 60% showed mild improvement, while 24.34% did not show any change and none of them conceived.

DISCUSSION

It is observed in the clinical study that maximum number of patients were from the age group of 31 - 35 years ie 40% followed by the group of 36 - 40 years ie. 26%. In the age group 21 - 25 years, 14% patients and 26 - 30 there were patients 20%.

It is observed in this clinical study most of the patients are from the Hindu religion ie. 97% and only one person was from the Muslim religion i.e., 3%

It is observed in this clinical study that 50% of the patients has completed SSLC, followed by the 25% of the patients who were completed the Degree and just 20% studied below SSLC. There was no patient who has completed the Post graduation. Maximum patients were from the middle class group i.e 76.66%, followed by lower class group about 13.33% while very less from the upper class i.e. 1%

Maximum patients belonged to sedentary manual and mild manual work catergory of about 43.33% each; whereas only 13.33% belonged to moderate manual work group and none from the hard manual work group.

As per the study maximum number of patients were observed taking mixed diet 63.33% where as 36.66% were taking vegetarian diet As per study maximum patients belonged to Vishamagni about 43.33%, Samanagni 40%, Mandagni 13.33% and only 3.33% had tikshna agni.

In case of prakruti 50% were of vatapitta prakruti, 20% were of Pitta-kapha and 10% were of vata-kapha prakruti.

Atibala decreased the liquification time by 25.4% on completion of the treatment. On statistical analysis the value is significant at the level of P (0.001). So, Atibala Moola Churna is effective in reducing Liquification time of semen.

The mean Semen Volume was increased with the treatment by 30.65% ml on completion of the treatment. On Statistical analysis the value is significant at the level of P (0.001). It may be said that the Atibala Moola Churna is effective in increasing the semen volume to some extent. The mean sperm count increased with the treatment by 26.63% on completion of the treatment. On statistical analysis the value is significant at the level of P (0.001). So, Atibala Moola Churna has good action on increasing the sperm count a.Rapid Linear Progression : The mean RLP sperm motility increased with the treatment by 35.29% on completion of the treatment. On statistical analysis the value is significant at the level of P (0.05).

b.Slow linear progression : The mean SLP increased with the treatment by 14.90% on completion of the treatment. On statistical analysis the value is significant at the level of P (0.01).

c.Non- progressive motility: The mean NP increased with the treatment by 21.73% on completion of the treatment. On statistical analysis the value is significant at the level of P (0.01).

d.Immotile Sperms : The immotile sperms were decreased with the treatment by 49.09% on completion of the treatment. On

statistical analysis the value is significant at the level of P (0.01).

Among the motility grade RLP and SLP play vital role in fertility. So, Atibala Moola Churna has good result on RLP and SLP. At the same time, it also increased the non-progressive and reduced the immotile sperms.

Atibala Moola Churna increase the total abnormal sperms from mean 55.75 to 65.5, it is statistically significant at the level of P (0.001)

The other parameters like viscosity, pH and pus cells were also considered for the study but these parameters wer within the normal limit before the treatment was given and at the same time after administration of the treatment showed no significant changes in their normal parameters.

After full course of treatment with Atibala Moola Churna, 16.66% showed marked improvement, 60% showed mild improvement, while 24.34% did not show any change and none of them conceived.

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