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Research Article

Oligospermia

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A clinical study to evaluate the efficacy of Mashadi Ghrita in Ksheena Shukra (oligospermia)

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Background: Ksheena Shukra bears resemblance to Oligospermia, a condition where sperm count is below 15 million/ml. In Ksheena Shukra, both the quantity and quality of Shukra Dhatu are impaired, while Oligospermia specifically refers to a reduction in sperm count. Ksheena Shukra is classified as one of the eight types of Shukradushti in classical literature and is identified as a Vata-Pittaja Vyadhi.

Aim: The aim of the study was to evaluate the efficacy of an Ayurvedic formulation named Mashadi Ghrita which was unexplored Aushadha Yoga explained in the text Vaidya Manorama's Rasayana-Vajikaran Adhyaya for the management of Ksheena Shukra (Oligospermia)

Materials and Methods: 30 patients fulfilling the diagnostic and inclusion criteria were selected for an open labelled single arm study. They received the trial drug, Mashadi Ghrita in the dosage of 6ml BD before food with Ushnodaka (lukewarm water) as Anupana for the period of 60 days. The assessment was done on the baseline 0th day, 31st day, 61st day and 76th day.

Results: After the clinical study, the trial group showed effective results in mitigating Ksheena Shukra. On statistical analysis within the group, it showed the significant effect on the objective parameters like Semen Volume, Semen pH, Sperm Count, Liquefaction Time.

Conclusion: On statistical analysis within the group on different intervals, Mashadi Ghrita was beneficial in the management of Ksheena Shukra (Oligospermia). It showed improvement in the Lakshanas of Ksheena Shukra and seminal parameters.

Keywords: Mashadi Ghrita, Ksheena Shukra, Sperm Count, Oligospermia, Male infertility, Shukra Kshaya, Beeja Dushti, Shukra Dhaatu, Vajikarana therapy

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Introduction

Dating back to the Vedic period, the pursuit of having healthy children has been held in high regard and esteemed as a significant ideal.

प्रीतिर्बलंसुखंवृत्तिर्विस्तारोविपुलंकुलम्।।२१।।
यशोलोकाःसुखोदर्कास्तुष्टिश्चापत्यसंश्रिताः। (च. चि २-१:२१)

Fertility has been an essential aspect of existence since ancient times. The key factors involved in conception include *Ritu* (reproductive age and ovulation period), *Kshetra* (female reproductive tract), *Ambu* (nutritional factors), and *Bija* (sperm and ovum). Successful conception relies on the proper functioning of the reproductive system; any dysfunction can lead to infertility. Ayurvedic texts indicate that reproduction is governed by *Shukra dhatu*. *Ksheena Shukra* is one of the eight types of *Shukradushti* outlined in these texts and is classified as a *Vata Pittaja Vyadhi,*[1] predominantly affecting individuals in the *Madhyama Vayas* age group. This condition, stemming from the *Apana Vata* province, renders a person incapable of conceiving with their partner, resulting in infertility. An individual with *Shukra dusti* cannot achieve their *Chaturvidha Purusartha. Ksheena Shukr*a is a specific type of *Shukradusti.*

Ksheena Shukra bears resemblance to Oligozoospermia, a condition where sperm count is below 15 million/ml. Shukra is regarded as the fundamental essence of all seven *Dhatus*, with its primary role being *Garbhotpatti*.[2] The status of *Shukra* significantly influences factors such as *Dhairya, Preeti, Dehabala*, and various psychosomatic elements.[3] In *Ksheena Shukra*, both the quantity and quality of *Shukra Dhatu* are impaired, while Oligozoospermia specifically refers to a reduction in sperm count. *Ksheena Shukra* is classified as one of the eight types of *Shukradushti* in classical literature and is identified as a *Vata Pittaja Vyadhi*,[4] more prevalent in those of *Madhyama Vayas*. This condition originates from the *Apana Vata* region, preventing individuals from conceiving with their partners and resulting in infertility. *Ksheena Shukra* (Oligospermia) has been selected for this study to generate objective and quantitative data, such as sperm count and motility, which will enhance the clarity and scientific acceptance of the findings. Ayurvedic texts highlight the treatment of *Ksheena Shukra* as *Upachaya* of *Shukra Dhatu*,[5]

Which can be addressed using *Shukra* itself or through herbal remedies that possess similar attributes or functions.

Vajikarana is a branch of Ayurveda that focuses on the preservation and enhancement of sexual potency in healthy individuals, the conception of healthy progeny, and the management of defective semen, disturbed sexual potency, and spermatogenesis, along with the treatment of seminal disorders in men. [6] Several *Vajikarana* drugs are mentioned in Ayurvedic classics, with *Mashadi Ghrita* being one of them, mentioned in *Vaidya Manorama*.[7] The aim of the present clinical study is to evaluate the effect of *Mashadi Ghrita* in the management of *Ksheena Shukra*, with a special emphasis on Oligospermia.

Aim and Objective

Aim: To evaluate the efficacy of *Mashadi* Ghrita in the management of *Ksheena Shukra* (Oligospermia).

Objective of the study: To study the effect of *Mashadi Ghrita* on the Sperm Count and other seminal parameters.

Materials and Methods

Sample Source:A minimum of 30 male patients attending the OPD and IPD of Alva's Ayurveda Medical College and Hospital, Moodubidire, Medical camps and other referrals diagnosed as *Ksheena Shukra* and fulfilling the inclusion criteria were selected. Data was collected on a detailed case proforma designed for the study.

Study Design: Open-Label, Single-Arm Clinical Study with pre-test and post-test.

Blinding: None

Sampling: Convenience Sampling

TreatmentPeriod: 60 days

Diagnostic Criteria: Patient diagnosed with -

- Sperm Count Less than 15 million/ml of semen.
- Unable to conceive for at least 1 year of unprotected coitus in married couple.

Inclusion Criteria:

1. Married male patients between the age group of 22-45.

2. Patients who fulfil the diagnostic criteria.
3. Patients from any religion, occupation or any socio-economic class.
4. Patients willing to participate in the study and ready to sign the informed consent form.

Exclusion Criteria:

1. Male patients with absolute Azoospermia and Teratozoospermia.
2. Male patients on certain medications like antineoplastic agents (e.g., Nitrogen mustard, procarbazine, vincristine, methotrexate), cimetidine, oestrogen and methyltestosterone.
3. Patients having chromosomal disorders like Klinefelter's Syndrome.
4. Patients suffering from major systemic disorders like Tuberculosis, AIDS and Sexually Transmitted Diseases (STD) & other gonadal disorders like Testicular Atrophy, Testicular Failure, Orchitis which may interfere with study will be excluded.
5. Patients having any anatomical deformity in gonads (e.g., Cryptorchidism, Monorchidism)

Subjective Parameters:

1. Bhrama
2. Sadana
3. Dourbalya
4. Pandutva

Objective Parameters:

1. Semen Volume
2. Seminal pH
3. Liquefaction Time
4. Sperm Count

Intervention:

Table 1: Intervention

Group	Single
Trial Drug	Mashadi Ghrita
Dosage	6ml BD
Anupana	Ushna Jala (Warm Water)
Aushadha Sevana Kala	Pragbhakta (before food)
Duration	60 days

Investigation: Semen Analysis / Seminogram

Observation Period: The patients were assessed clinically on the baseline 0th day and during the treatment on 31st and after the treatment on 61st day and 76th day.

Follow Up: The follow up of patient was done on 76th day, i.e., 15 days after study duration.

Observation and Results

Table 2: Observation of 30 male patients recruited in the study.

Characteristics	Predominance	Percentage
Age	30-37	46.66 %
Religion	Hindu	60 %
Marital Status	Married	100 %
Education Status	Graduate	76.66 %
Socio-economic Status	Middle	76.66%
Occupation	Business	30 %
Locality	Urban	90 %
Ahara	Mixed	86.66 %
Nidra	Alpa	60 %
Prakriti	Vata-Pitta	56.66 %

Statistics:

On the above observations, descriptive statics were drawn out.

Paired T test was applied for the objective parameters, while Wilcoxon Signed Rank Test was applied for the subjective parameters within the group for the statistical analysis at different intervals.

Results:

Table 3: Effectiveness of trial drug before and after on the subjective parameter.

Symptom	Median Score			W value	P-value	Results
Daurbalya	BT					
	1	DT	1	-30.000	P = 0.266	NS
		AT	1	-54.000	P = 0.057	NS
		FU	1	-75.000	P = 0.017	SS
Bhrama	BT	DT	0	-1.000	P = 1.000	NS
	0	AT	0	-1.000	P=1.000	NS
		FU	0	15.000	P = 0.063	NS
Sadana	BT					
	0	DT	0	-1.000	P = 1.000	NS
		AT	0	-1.000	P = 1.000	NS
		FU	0	15.000	P = 0.063	NS
Panduta	BT					
		DT	1	-18.000	P = 0.465	NS
		AT	1	-33.000	P = 0.105	NS
		FU	1	-33.000	P = 0.105	NS

Table 4: Effectiveness of Trial drug before and after on the Semen Volume

Time Points	Mean	SD	Mean Diff.	SD Diff	P-value	Paired t	Results
BT	3.050	0.201	-0.317	0.605	P < 0.050	-2.866	SS
DT	3.367	0.809					
BT	3.050	0.201	-0.733	0.720	P < 0.050	-5.576	SS
AT	3.783	0.691					
BT	3.050	0.201	-0.233	0.951	P < 0.050	-1.343	SS
FU	3.283	0.611					
DT	3.367	0.809	-0.417	0.617	P <0.001	-3.699	SS
AT	3.783	0.691					
DT	3.367	0.809	0.0833	0.789	P = 0.567	0.579	NS
FU	3.283	0.611					
AT	3.783	0.691	0.500	0.455	P <0.001	6.021	SS
FU	3.283	0.611					

Table 5: Effectiveness of Trial drug before and after on the Liquefaction Time

Time Points	Mean	SD	Mean Diff.	SD Diff	P-value	Paired t	Results
BT	37.167	14.425	7.167	8.875	P <0.001	t = 4.423	SS
DT	30.000	11.064					
BT	37.167	14.425	10.667	10.726	P <0.001	t = 5.447	SS
AT	26.500	10.352					
BT	37.167	14.425	28.500	10.822	P <0.001	t = 4.386	SS
FU	28.500	10.680					
DT	30.000	11.064	3.500	7.560	P = 0.017	t = 2.536	SS
AT	26.500	10.352					
DT	30.000	11.064	1.500	8.003	P = 0.313	t = 1.027	NS
FU	28.500	10.680					
AT	26.500	10.352	-2.000	6.242	P = 0.090	t = -1.755	NS
FU	28.500	10.680					

Table 6: Effectiveness of Trial drug before and after on the Semen pH

Time Points	Mean	SD	Mean Diff.	SD Diff	P-value	Paired t	Results
BT	7.480	0.379	0.163	0.373	P = 0.023	t = 2.400	SS
DT	7.317	0.359					
BT	7.480	0.379	0.297	0.423	P <0.001	t = 3.841	SS
AT	7.183	0.245					
BT	7.480	0.379	0.247	0.409	P = 0.003	t = 3.302	SS
FU	7.233	0.341					
DT	7.317	0.359	0.133	0.320	P = 0.030	t = 2.283	SS
AT	7.183	0.245					
DT	7.317	0.359	0.0833	0.296	P = 0.134	t = 1.542	NS
FU	7.233	0.341					
AT	7.183	0.245	-0.0500	0.304	P = 0.375	P = 0.375	NS
FU	7.233	0.341					

Table 7: Effectiveness of Trial drug before and after on the Sperm Count

Time Points	Mean	SD	Mean Diff.	SD Diff	P-value	Paired t	Results
BT	6.637	5.946	-6.520	5.595	P = <0.001	t = -6.383	SS
DT	13.157	7.783					
BT	6.637	5.946	-12.177	7.376	P = <0.001	t = -9.042	SS
AT	18.813	8.600					
BT	6.637	5.946	-10.170	6.561	P = <0.001	t = -8.491	SS
FU	16.807	7.518					
DT	13.157	7.783	-5.657	5.898	P = <0.001	t = -5.253	SS
AT	18.813	8.600					
DT	13.157	7.783	-3.650	6.945	P = 0.007	t = -2.879	SS
FU	16.807	7.518					
AT	18.813	8.600	2.007	7.184	P = 0.137	t = 1.530	NS
FU	16.807	7.518					

Discussion

On Sperm Count: There was statistically significant difference between Sperm count values before treatment and after treatment with $p < 0.05$ in paired-t test. The lower sperm count is either due to *Shosha* of *Shukra* by *Vata dosha* or *Ushnata* of *Pitta*. The ingredients are *Madhura rasa, Snigdha Guna & Madhura Vipaka* which helps in the *Prinana* of *Dhatus*. The drugs probably mitigates the vitiated Vata and Pitta dosha resulting in the formation of healthy *Shukra*

On Liquefaction Time: There was statistically significant difference between Liquefaction Time values before treatment and after treatment with $p < 0.001$ in paired-t test. The drugs possess *Sheeta* and *Madhura* quality which proves dominance of *Prithvi* and *Jala Mahabhuta*. These possibly have help in nourishing the *Shukra Dhatu* as *Madhura Rasa* is *Dhatuvriddhikara* and *Ajanmya Satmya* in nature. *Tikta Anurasa* of these drugs possesses *Vishyandana* (cleaning) and *Avaranahara* property.

On Semen Volume: There was statistically significant difference between Seminal Volume values before treatment and after treatment with $p < 0.050$ in paired-t test. The increase in Semen volume is due to *Guru, Snigdha* quality and predominance of *Prithvi* and *Jala Mahabhuta*. Semen in dominant in *Prithvi* and *Jala Mahabhuta* as it has *Gandha* and *Dravata*. So, because of *Samana Dravyata* these qualities had probably helped in increasing Semen volume.

Ghrita might have corrected the metabolism at *Dhatvagni* level due to its *Vanhimandyapranashana* property, while the *Medhya* and *Rasayana* property of *Ashwagandha* probably enhanced the hypothalamic-pituitary-testicular axis which further helped in maintaining the physiology of testicular tissues leading to increase of semen volume.

On Semen pH: There was statistically significant difference between Semen pH values before treatment and after treatment with $p < 0.001$ in paired-t test. All the drugs possess antioxidant property and this might be the reason for the reduction of ROS and oxidative stress at testicular level further result in the maintenance of pH.

Probable mode of action of the drug:

Table 8: Ingredients of the trial drug along with their properties.

Drug	Rasa	Karma	Chemical Constituent	Action
Masha	Madhura	Snigdha, Sukrala, Vrushya	Genistein, Glycinl Kievitone, Eugenol, Betasitosterol, Phloretin	Anti-oxidant
Tila	Madhura, Tikta	Vrushya, Deepana, Srotovishodhana	Tri-terpinoids, sterols	Anti-estrogenic and antioxidant properties
Ashwagandha	Katu, Tikta, Kashaya	Vajikara, Vrushya, Ati Shukrala	Steroidal lactones (withanolides, withaferins), saponins, sitoindosides VII-X, withaferin-A, withaferin-D	Inhibits lipid peroxidation, Improves sperm count and motility, Regulates reproductive hormonal levels, Improves blood circulation.
Musali	Madhura, Tikta	Vrushya, Brihmani	Triterpenoids, saponinchloromaloside-A, stigmasterol, hacogenin	Improves in the serum testosterone level
Laja	Madhura, Kashaya	Brihmana	gamma-oryzanol	Neutralize & scavenging activities in minimizing the detrimental effects of ROS.
Ghrita	Madhura	Shukrala	Vitamin E	Increases the thickness of germinal epithelium in seminiferous tubules of testicles.

Conclusion

In this study, *Mashadi Ghrita* was considered as the trial drug for the management of *Ksheena Shukra* (Oligospermia). After the treatment there was statistically significant improvement in the objective parameters, while the subjective parameters didn't show much improvement.

Therefore, *Mashadi Ghrita* was found to be effective in mitigating the symptoms of *Ksheena Shukra.*

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