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RANDOMIZED CONTROLLED CLINICAL STUDY OF SOMGHRI TA
IN MANAGEMENT OF KSHEENSHUKRA (OLIGOSPERMIA)

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ABSTRACT

Nowadays infertility becomes a burning issue among married couples. Along with female infertility, male infertility incidence also increases day by day. The leading cause of this male infertility is Oligospermia. The drugs used in modern medicine mostly interfere with hormonal conditions and have adverse effects on the body of men, they maybe either early or remote. Other than this, the only option available is Assisted Reproductive Technologies (ART). But this option is very costly. Hence Ayurvedic management seems to be cheaper, non-surgical and has negligible side effects. Ancient *Acharyas* told the term *Ksheenshukra* which is much similar to that of oligospermia. Also, they told very effective management of *Ksheenshukra* to overcome male infertility. *Somghrita* is one of the formulations in that text. Which contains drugs that have *balya*, *medhya*, *Shukra janana* properties. This formulation may find useful on different disorders of males which are leading to infertility. The present study is aimed to observe the efficacy of the Ayurvedic formulation mentioned in *Bhaishajya Ratnavali* (an Ayurvedic text) - “*Somghrita*” in *Ksheenshukra*. The study was conducted on 70 patients, 35 patients each in the Trial group and Control group respectively. The clinical assessment was done on basis of grading criteria with specific symptomology of *Ksheen-shukra*. The results were statistically and clinically significant to give relief from the disease *Ksheenshukra* and improve the reproductive health of male partners.

Keywords: *Ksheenshukra*, Oligospermia, *Somghrita*.

INTRODUCTION

As we know, Ayurveda is a divine Science. The things told by Ayurveda in ancient times exactly resemble things in the modern world. *Dharma, Artha, Kama,* and *Moksha* are four *Purusharthas*, which are told by Ayurveda. Every man aimed to achieve these *Puru- sharthas*. Out of which *Kama* is nothing but sexual de- sire. The ultimate aim of *Kama Purushartha* is to have a Child. *Ashtanga* Ayurveda has 8 branches¹, out of which *Rasayana* and *Vajikarana* are important ones. Infertility is defined as the inability to conceive within one or more years even after unprotected and regular coitus. Males are seen to be solely responsible for about 30% to 40% of infertility cases globally². Oligospermia is the leading cause of male infertility. In India prevalence of male infertility is 23%³. Oligospermia refers to a decrease in sperm count of less than 20 million per ml of semen⁴. *Shukra Kshaya* or *Ksheenshukra* can be correlated with Oligospermia according to Ayurveda. Sushrutacharya mentioned the term *Ksheenshukra*, and he also mentioned that such *shukra* is not able for *prajotpadana*⁵ i.e., for conception. According to Vagbhata and Sushruta in this *shukradushti vata* and *pitta dosha* are mainly vitiated. *Ativyavaya, Chinta,*

Shoka, Ati ushna-laghu-ruksha ahara etc. are the caus- ative factors of *Ksheenshukra* and *Panduta, Daurbalya*⁶, *Shukraprasek, Maithuna ashakti*⁷, *vrushana- medhra vedana*⁸ etc. are the lakshanas of *Ksheenshukra*.

AIM - To study the efficacy of “*Somghrita*” in *Ksheenshukra* with special reference to oligospermia.

OBJECTIVES –

1. To correlate *Ksheenshukra* and *oligospermia*.
2. To study *Somghrita* in detail.
3. To find out an effective ayurvedic treatment modality for the management of *Ksheenshukra*.

MATERIAL AND METHODS-

Materials – All available *Ayurvedic* books and Modern texts, articles, journals, Internet research papers were referred for the study.

1. **Sample size** – 35 in each group
2. **Selection of patient** – from the Infertility O.P.D of Dept. of *Prasuti Tantra* and *Stree Roga*
3. **Drug**: - Drug is readily purchased from a standard ayurvedic pharmacy.

Sr. No.	Drug Name	Sr. No.	Drug Name
1	<i>Siddharthaka</i>	13	<i>Rajani</i>

			(Haridra)
2	Vacha	14	Patha
3	Brahmi	15	Bhrungaraja
4	Shankhapushpi	16	Devadaru
5	Punarnava	17	Suvarchala
			(Beejapuraka)
6	Vayasya (Amalaki)	18	Manjishtha
7	Yashtimadhu	19	Haritaki
8	Katuka	20	Bibhitaka
9	Draksha	21	Shyama (Priyangu)
10	Gambhari	22	Vrushapushpa (Adulsa)
11	Falasa	23	Gairika
12	Sariva	24	Ghrita

Table 1: Contents of Somghrita-⁹

4. Standardisation of drug- It was done in a well-known authentic Laboratory.

Methods –

1. Medium of study- English which is supplemented by Ayurvedic terminology wherever necessary in Sanskrit.

2. Type of study- It was a clinical controlled open randomized study in which Patients were divided randomly into two groups.

Group	Group-A – Trial Group	Group-B- Control Group
Number of	35	35

patients-		
Drug	Somghrita	Tablet Clomiphene Citrate
Dose	10ml OD Orally	25mg OD Orally
Duration of Treatment	3 months	3 months

Table 2: Group of Patients

3. Ethical Clearance– This research study follows the guidelines of the Declaration of Helsinki and Tokyo for humans. Clearance from the Ethical Committee of the concerned Medical College was taken.

4. Consent– A written consent of patients was included in this trial in the language best understood by them before the screening.

5. Diagnostic Criteria-

Clinical features of *Ksheenshukra* (Oligospermia) mentioned in ayurvedic texts as well as the modern text was considered. The clinical sign of *Ksheenshukra* (Oligospermia) based on H/O male infertility and male patient having Sperm count less than or equal to 20 million /ml were kept in consideration. Detailed clinical examinations of male reproductive organs were done. [Reference: Cooper, TG et al. WHO reference values for

human semen characteristics. Hum. Reprod. Update. 2010. 16(5):559]

6. Duration of study- Duration of study - 18 months, Total duration of treatment - 90 days

7. Follow-up- Patients was screened clinically every month i.e., on day 30, day 60 and day 90. Semen Analysis was done before and after treatment.

8. Investigations –

1) Blood- Hb, Blood Sugar Level (Random), HIV, HBsAg before treatment as routine and to exclude complications said in ‘Exclusion Criteria’.

2) Urine- Routine and microscopic.

3) Semen Analysis was done before and after treatment.

9. Inclusion Criteria –

1) All male patients have signs and symptoms of *Ksheenshukra* (oligospermia).

2) Married Patients

3) Age –Between 20 – 50yrs.

4) Male patient having Sperm count less than or equal to 20 million/ml.

10. Exclusion Criteria –

1) Azoospermia.

2) Patients with any major systemic illness such as Diabetes Mellitus, Hypertension, HIV, HbsAg, STD etc.

3) Unmarried patients.

4) Patients having any surgical illness

related to the Inguinal-scrotal region.

11. Criteria of Assessment –

The result was assessed with regards to improvement recorded, in clinical findings and laboratory investigations.

Changes to be observed in signs and symptoms. It was assessed by adopting suitable scoring methods and objective signs by using appropriate clinical tools. Markedly improved – Above 75% but below 100% relief in signs and symptoms.

Moderate Improved- More than 50% to 74% relief in signs and symptoms.

Mild improvement – 25 to 49% relief in signs and symptoms.

Poor improvement- 0 to 24% relief in signs and symptoms.

12. Subjective –

Symptoms of *Ksheenshukra* mentioned in the text or practically observed was assessed at each follow-up and presence or absence of them was registered. All symptoms were graded based on severity to assess the changes.

Gradaation of Subjective Criteria –

1) Daurbalya (Fatigue):

- Grade 0 - No Fatigue.
- Grade I – Moderate Fatigue in doing routine work.
- Grade II – Excessive Fatigue in doing routine work.
- Grade III – Excessive Fatigue even

in doing littlework.

2) **Panduta (Paleness):**

- Grade 0 –Absent.
- Grade I– Only one of the *Nakha, Netra, Jivha Pan-dutva.*

3) Liquefaction Time

4) Sperm Count

5) Viability

6) Motility

7) RESULTS-

- Grade II–Any of the sign one plus.
- Grade III– All the signs.

A) Statistical Analysis: In Group A and Group B

3) **Shukra Prasek:**

Grade 0 – More than 5 Minutes.

- Grade I – Within 2-5 minutes.
- Grade II – Within 2 min
- Grade III – Immediately after penetration.

4) **Medhra Shula:**

- Grade 0– Absent
- Grade I –Present.

5) **Vrushana Vedana:**

- Grade 0 –Absent
- Grade I–Present

6) **Maithun Ashkati:**

- Grade 0 – Never fail to perform the whole sexual activity and good performance every time.
- Grade I – Sometimes fails to perform whole sexualactivity.
- Grade II – Fail to perform whole sexual activity.

13. **Objective Criteria –**

Semen Analysis was done before and after treatment.

1) pH of Semen

2) Semen Volume

RESULTS-

B] Statistical Analysis: In Group A and Group B

Table 3: Subjective Parameters (By Wilcoxon Signed Ranks Test)

	Group	BT/AT	N	Mean	Median	W	P
A) <i>Daurbalya</i>	Group A	BT	35	1.743	2	528	<0.0001
		AT	35	0.428	0		
	Group B	BT	35	1.314	1	194	<0.0001
		AT	35	0.571	0		
B) <i>Panduta</i>	Group A	BT	35	0.228	0	21	0.0313
		AT	35	0.057	0		
	Group B	BT	35	0.171	0	10	0.1250
		AT	35	0.057	0		
C) <i>Shukra praseka</i>	Group A	BT	35	1.629	2	313	<0.0001
		AT	35	0.487	0		
	Group B	BT	35	1.429	1	386	<0.0001
		AT	35	0.428	0		
D) <i>Medhra shula</i>	Group A	BT	35	0.285	0	28	0.0156
		AT	35	0.085	0		
	Group B	BT	35	0.314	0	36	0.0078
		AT	35	0.085	0		
E) <i>Vrushan vedana</i>	Group A	BT	35	0.200	0	15	0.0625
		AT	35	0.057	0		
	Group B	BT	35	0.142	0	6	0.2500
		AT	35	0.057	0		
F) <i>Maithun ashakti</i>	Group A	BT	35	0.800	1	136	<0.0001
		AT	35	0.257	0		
	Group B	BT	35	0.571	0	120	<0.0001
		AT	35	0.142	0		

BT- Before Treatment, AT- After Treatment

Table 4: Objective Parameters (By Student's t Test for Paired data)

	Group	BT/AT	N	Mean	SD	t	P
A) pH of semen	Group A	BT	35	7.500	0.000	NA	NA
		AT	35	7.514	0.084		
	Group B	BT	35	7.500	0.000	NA	NA
		AT	35	7.500	0.000		
B) Semen volume	Group A	BT	35	2.440	0.691	6.810	<0.0001
		AT	35	3.137	0.880		
	Group B	BT	35	2.580	0.688	4.862	<0.0001
		AT	35	2.957	0.796		
C) Liquefaction time	Group A	BT	35	22.85	5.852	1.989	0.0548

D) Sperm count	Group B	AT	35	21.08	7.402	1.827	0.0764
		BT	35	23.42	5.527		
		AT	35	21.71	6.746		
	Group A	BT	35	12.32	5.201	4.681	<0.0001
		AT	35	18.09	10.09		
		BT	35	11.82	5.051		
E) Viability	Group B	AT	35	16.90	9.059	4.357	0.0001
		BT	35	52.25	11.51		
		AT	35	58.17	9.859		
	Group A	BT	35	50.97	11.36	4.871	<0.0001
		AT	35	56.51	9.895		
		BT	35	33.05	11.48		
F) Motility	Group A	AT	35	39.68	15.71	4.037	0.0003
		BT	35	37.45	12.45		
		AT	35	44.40	14.53		
	Group B	BT	35	37.45	12.45	4.281	0.0001
		AT	35	44.40	14.53		
		BT	35	37.45	12.45		

A] Statistical Analysis: Comparison Group A and Group B

Table 5: Subjective Parameters (By Mann Whitney's UTest)

	Group	N	Mean	Mean Rank	U	P
A) <i>Daurbalya</i>	Group A	35	1.314	1498	357	0.0026
	Group B	35	0.749	987		
B) <i>Panduta</i>	Group A	35	0.171	1277.5	577.5	0.6715
	Group B	35	0.114	1207.5		
C) <i>Shukrapraseka</i>	Group A	35	1.143	1320	570	0.4902
	Group B	35	0.972	1236		
D) <i>Medhra shula</i>	Group A	35	0.200	1246	616	0.8723
	Group B	35	0.222	1310		
E) <i>Vrushan vedana</i>	Group A	35	0.142	1297.5	592.5	0.6543
	Group B	35	0.083	1258.5		
F) <i>Maithun ashakti</i>	Group A	35	0.542	1308	582	0.5782
	Group B	35	0.416	1248		

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Table 6: Objective Parameters (By Student's t Test for Unpaired data)

	Group	N	Mean	SD	T	P
A) pH of semen	Group A	35	0.014	0.084	NA	NA
	Group B	35	0.000	0.000		
B) Semen volume	Group A	35	0.697	0.605	2.601	0.0114
	Group B	35	0.366	0.456		
C) Liquefaction time	Group A	35	1.771	5.270	0.082	0.9348
	Group B	35	1.667	5.477		
D) Sperm count	Group A	35	5.771	7.294	0.4923	0.6241
	Group B	35	4.944	6.859		
E) Viability	Group A	35	5.914	5.967	0.348	0.7284
	Group B	35	5.389	6.699		
F) Motility	Group A	35	4.629	6.783	1.078	0.2847
	Group B	35	6.750	9.527		

A] According to % Relief in Symptoms Table 7: % Relief in Symptoms of both groups

Sr. No.	Symptoms	% Relief	
		Group A	Group B
1	<i>Daurbalya</i>	75.41	56.52
2	<i>Panduta</i>	75	66.67
3	<i>Shukra praseka</i>	70.18	70
4	<i>Medhra shula</i>	70	72.73
5	<i>Vrushan vedana</i>	71.43	60
6	<i>Maithun ashakti</i>	67.86	75
7	Avg. % Relief	71.64	66.81

A] According to Avg. Change in Objective parameters Table 8: Avg. Change in Objective parameters of both groups

Sr. No.	Parameters	Avg. Change	
		Group A	Group B
1	pH of semen	0.014	0
2	Semen volume	0.69	0.38
3	Liq. Time	1.77	1.71
4	Sperm count	5.77	5.09
5	Viability	5.91	5.54
6	Motility	4.63	6.94

A] Overall Effect of Therapy- According % Relief Table 9: Overall Effect of Therapy according % Relief

Sr. No.	Criteria	Improvement Grade	No. of patients		No. of symptoms	
			Gr. A	Gr. B	Gr. A	Gr. B
1	75% to 100%	Marked	19	13	02	01

2	50% to 74%	Moderate	14	20	04	05
3	25% to 49%	Mild	02	02	00	00
4	00% to 24%	Poor	00	00	00	00

C] According to statistical analysis

1. Subjective Parameters

Table 10: Overall Effect of Therapy as per Statistical analysis

Sr. No.	Subjective Parameters	Within Groups (Wilcoxon test)		Comparison (Mann-Whitney's test)
		Group A	Group B	
1	<i>Daurbalya</i>	Significant	Significant	Significant (A > B)
2	<i>Panduta</i>	NA	NA	NA
3	<i>Praseka</i>	Significant	Significant	Insignificant (A ≈ B)
4	<i>Medhra shula</i>	NA	NA	NA
5	<i>Vrushana vedana</i>	NA	NA	NA
6	<i>Maithuna ashakti</i>	Significant	Significant	Insignificant (A ≈ B)

(≈ - means statistically equal, not exact equal)

2. Objective Parameters

Table 11: Overall Effect of Therapy as per Statistical analysis

Sr. No.	Objective Parameter	Within Groups (Paired t test)		Comparison (Unpaired t test)
		Group A	Group B	
1	pH	NA	NA	NA
2	Volume	Significant	Significant	Significant (A > B)
3	Liq. Time	Significant	Significant	Insignificant (A ≈ B)
4	Count	Significant	Significant	Insignificant (A ≈ B)
5	Viability	Significant	Significant	Insignificant (A ≈ B)
6	Motility	Significant	Significant	Insignificant (A ≈ B)

(≈ - means statistically equal, not exact equal)

DISCUSSION

Properties and Uses of *Somghrita* as follows-¹⁰ *Somghrita* is a formulation in which different ayurvedic drugs are taken and with these drugs, ghee is medicated. Ghee i.e., *ghrita* is *Yogavahi* in nature which means *ghrita* carries not only its properties but also the properties of every drug by which it is medicated. About 23 drugs are used to prepare *Somghrita*. And many of them have *vajikar karma* with *vrushya prop- erty*. Hence the net effect of *somghrita* is *vajikar*. Also in *phalshruti* of *somghrita acharya* mentioned that is “*pumsm doshahara*” that is, it is useful in different male disorders and “*sarvatram*

janayet putram” that is, it serves the function of conception. According to *Bhaishajya Ratnavali*, *Somaghrita* is useful in all diseases; it cures infertility & gives birth to a baby. It is found useful in different disorders of women such as *Yonidushti* (Disorders related to female genital or- gans). It also cures different seminal disorders in males which leads to infertility in males.

Probable mode of action

Ksheenshukra has a predominance of *vata* and *pitta*. *Somghrita* is the best remedy for *tridosha* treatment according to ayurvedic classic. All contents of *Somghrita* are *vrushya* & *Shukra janana* in action which

probably have improved the process of spermatogenesis. Because of *balya karma*, *vrushya karma*, *shukrastambhana karma* & potent action against *vata* & *pitta*, *Somghrita* has provided relief in symptoms of *Ksheenshukra*. Because of *Shukra janana karma*, there is also an increase in sperm count. The overall quality of semen is also improved because of *Somghrita*.

CONCLUSION

Somghrita provided a significant increase in Sperm count and it is also useful in the improvement of motility, the volume of semen, viability of sperm. It is also useful in decreasing the liquefaction time. It has no significant result on *Panduta*. The analysis of the observation implies that the therapy improves spermatogenesis at the same time it improves the quality of semen, which is indicative of the above conclusion. *Somghrita* has a very significant effect on *Daurbalya*, *Shukrapraseka*, and *Maithunashakti* while it is slightly effective on *Medhrashula* and *Vrushanavedana*. From all the above clinical studies, we can conclude that an ayurvedic formulation-*Somghrita* is found useful in *Ksheenshukra* (Oligospermia).

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