

A CLINICAL STUDY OF PANCHSHARA RASA IN THE MANAGEMENT OF SHUKRAKSHAYA

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ABSTRACT

Ayurveda, the Indian system of medicine uses drugs from three main sources i.e. plant, animal and mineral. *Rasa Shastra* is a branch of Medicine, which deals with preparation of the drugs with metals and minerals having wide range of therapeutic efficacy, possessing innate qualities like quick action, less dose, tastelessness, prolonged shelf life and better palatability. According to Ayurvedic classics *Sukradoshas* are eight in number. *Shukrakshaya* is one among them eventually leading to infertility. *Vajikarana*, a special branch of *Ashtanga Ayurveda* is aimed at the superlative fertility, potency and healthy progeny. *Panchshara Rasa* is one important *Rasoushadhi* mentioned in *Bhaishajya Ratnavali* indicated in *Shukrakshaya*. The chief ingredients of *Panchshara Rasa* are *Suddha Parada*, *Suddha Gandhaka*, and *Shalmali moola swarasa*. *Panchshara Rasa* is a blend of *Kharaliya* and *Parpati* preparations. A Randomized Open- Label Clinical trial has been done to evaluate the efficacy of *Panchshara Rasa* in *Shukrakshaya*. The details of the clinical study will be discussed in the full paper.

Keywords: *Rasoushadhi*, *Shukrakshaya*, *Panchshara Rasa*

INTRODUCTION

Clinical study is a planned and disciplined work to establish the efficacy of a drug, to evaluate various aspects regarding posology in context to contemporary scenario, in the light of principles laid down in our classical texts. *Rasa Shastra* offers vast treasure of remedies for all the ailments of mankind. However, they have to be brought to light through scientific clinical study. The ultimate aim of any medical research is to assess the efficacy of formulation in the

management of the particular disease without causing any side effect. According to *Acharya Charka*, one who knows the principles governing the correct application of drugs in consonance with the place, time and individual variation should be regarded as best physician¹. The evaluation of drug is considered incomplete until it is tried clinically. Further, clinical trial helps in understanding the mechanism of action of the drug and successful clinical trials form basis

for laying down parameters of standard pharmaceutical process. In this study, a clinical trial of *Panchshara Rasa* has been carried out to evaluate its efficacy in *Shukrakshaya*.

AIMS AND OBJECTIVES

The present clinical study has been planned to evaluate the therapeutic efficacy of *Panchshara Rasa* in *Shukrakshaya*.

MATERIAL AND METHODS

- a) Patients attending the O.P.D. of P.G. Department of *Rasa Shastra* and Department of *Prasuti* and *Stree roga* of S.V. *Ayurvedic* Hospital, Tirupati were selected.
- b) The drug *Panchshara Rasa* was prepared in the Department of *Rasa Shashtra*, S.V. *Ayurvedic* College, Tirupati.
- c) Total 32 patients with signs and symptoms of *Shukrakshaya* were registered. Out of them 30 patients completed the course of treatment.
- d) **Study design:** A Randomized Open-Label Clinical study

CRITERIA FOR SELECTION OF PATIENTS

Inclusive criteria

- Infertile male subjects of age between 21 years to 45 years.
- Male subjects with Sperm count below 20 million/ml.
- Asthenospermia (Reduced motility of spermatozoa)
- Teratospermia (High number of abnormal spermatozoa)

Exclusive criteria

- Subjects categorized under Azospermia.
- Subjects with history of Tuberculosis, Testicular maldescents, Hydrocele, Carcinoma-Testes, Varicocele, Epididymo-orchitis, S.T.Ds. and AIDS.

- Subjects with renal diseases and other malignant metabolic disorders.

INTERVENTION

Internal Therapy: *Panchshara Rasa*

Dose: 125 mg

Kala: Thrice a day after meals

Sahapana: *Tambula patra*

Anupana: *Mahisha dugdha*

Duration of study: 90 days

Preparation of *PanchsharaRasa*

Panchshara Rasa is mentioned in *Bhaishjaya Ratnavali*. The main ingredients of *Panchshara Rasa* are *Suddha Parada*, *Suddha Gandhaka* and *Shalmali moola swarasa*. *Shuddha Parada* was taken in *khalwa yantra* and *mardana* with *Shalmali moola swarasa* was done for 21 days. *Shuddha Gandhaka* was taken in *khalwa yantra* and triturated with *Shalmali moola swarasa* for 21 days. After trituration, *Mardita Parada* and *Bhavita Gandhaka* were taken in *khalwa yantra* and *mardana* was done to obtain black, fine and lusterless powder i.e. *Kajjali*. *Kajjali* was taken in a ghee smeared *darvi* and melted in *mandagni*. The molted *kajjali* was poured on banana leaf and covered with another banana leaf and compressed by a steel plate to prepare *Parpati*. *Parpati churna* was subjected to *bhavana* for 21 days with *Shalmali moola swarasa*. The obtained final product was compressed to 125 mg tablets of *Panchshara Rasa*.

CRITERIA FOR ASSESSMENT AND GRADING

The patients were assessed before and after treatment for subjective and objective parameters.

Subjective parameters

Assessment was totally based on the changes in the clinical features of *Shukrakshaya* and improvement in Scoring index of *Dourbalya*, *Mukhashosa*, *Pandu*, *Sadana* and

Shrama. For all these symptoms, the following symptom scores were given depending upon the changes seen before and after the treatment.

Table No.1: Showing grading of subjective parameters

S.No.	Criteria	G ₀	G ₁	G ₂	G ₃
1.	<i>Dourbalya</i>	No weakness	Slight weakness	Weakness and work affected	Can't do any work
2.	<i>Mukhashosa</i>	No dryness of mouth	Slightly dryness of mouth	Dryness relieved by anything putting in mouth	Dryness not relieved by anything
3.	<i>Pandu</i>	(Pallor of lips, conjunctiva, tongue, nails; corresponding to Hb) 12.5%	10-12.4%	7-10%	<7%
4.	<i>Sadana</i>	None	Mild / doing regular work	Moderate / not performing his work sometimes	Severe / not doing his work most of the time
5.	<i>Shrama</i>	No fatigue	Increased fatigue over baseline, but not altering normal activities	Moderate / difficulty in performing some activities	Severe / loss of ability to perform activity

Objective parameters

Objective parameters were based on semen Analysis i.e. Volume of Semen, Sperm Count, Sperm motility and morphology.

Table No.2: Showing grading of objective parameters

S.No	Criteria	G ₀	G ₁	G ₂	G ₃
1.	Volume of Semen	<1 ml	1.5-1 ml	2-1.6 ml	>2 ml
2.	Sperm count	<5 million / ml	>5 and <10 million / ml	>10 and <20 million / ml	>20 million / ml
3.	Sperm motility	<10% motile sperms	>10% and <30% motile sperms	>30% and <50% motile sperms	>50% motile sperms
4.	Sperm morphology	<10% normal form	>10% and <20% normal form	>20% and <30% normal form	>30% normal form

Statistical evaluation of results

The obtained information was analyzed statistically in terms of mean score(x), Standard Deviation (S.D.), Standard Error (S.E.). Paired t-Test was carried out at the level of 0.05, 0.01, and 0.001 of P levels.

For the more effectiveness of therapy paired t-Test is carried out. The results were interpreted as

- Insignificant : $p > 0.05$
- Significant : $p < 0.05$

- Highly significant : $p < 0.01, p < 0.001$

OBSERVATIONS AND RESULTS

Maximum number of patients i.e. 10 (33.33%) were between the age group of 35-40 years; 9 patients (30%) were between 30-35 years of age; 06 patients (20%) were between 40-45 years of age; 05 patients (16.66%) were between 25-30 years of age. Maximum number of patients i.e. 28 (93.33%) were Hindus, 02 patients (6.66%) were Muslims. Maximum number of patients i.e. 22 (73.33%) were from *jangala desha*; while 04 patients (13.33%) were from *anupa desha* and rest of the 04 patients (13.33%) were from *sadharana desha*. Maximum number of patients i.e. 27 (90%) were educated and the remaining 03 patients (10%) were uneducated. Maximum numbers of patients, i.e.14 (46.66%) were belonging to middle class; 10 patients (33.33%) were poor and rests of the 06 patients (20%) were rich. Maximum number of patients i.e. 15 (50%) were doing labour work, 05 patients (16.66%) were engaged with moderate work, 05 patients (16.66%) were sedentary workers and 05 patients (16.66%) were stressful workers. Maximum number of patients i.e. 18 (60%) were having bath with *ushna jala* while rest of the 12 patients (40%) were having *snana* with *sheeta jala*. Maximum number of patients i.e. 22 (73.33%) were consuming mixed diet and 08 patients (26.66%) were taking vegetarian diet only. Maximum number of patients i.e. 16 (53.33%) were having *vishama agni*;

whereas 08 patients (26.66%) were having *manda agni*, 03 patients (10%) were having *sama agni* and 03 patients (10%) were having *tikshna agni*. Maximum number of patients i.e. 12 (40%) were having *Vishama nidra*; 10 patients (33.33%) were having *Alpa nidra*, 06 patients (26.66%) were having *Sukha nidra*, remaining 02 patients (6.66%) were having *Ati nidra*. Maximum number of patients i.e. 14 (46.66%) were having *krura koshtha*, 12 patients (40%) were having *madhyama koshtha* and only 04 patients (13.33%) were having *mridu koshtha*. Maximum number of patients i.e. 14 (46.66%) were of *vata- pitta prakruti*, 12 patients (40%) were of *vata-kapha prakruti* and rest of the 04 patients (13.33%) were of *kapha-pitta prakruti*. Maximum number of patients i.e. 16 (53.33%) were wearing synthetic under garments while 14 patients (46.66%) were wearing cotton under garments. 18 patients (60%) were wearing tight underwear while 12 patients (40%) were wearing loose underwear. Nocturnal emission was present in 12 patients (40%) and absent in 18 patients (60%). 20 patients (66.66%) were having the habit of masturbation and 10 patients (33.33%) were not having it. 24 patients (80%) took medication and only 06 patients (20%) had not taken any medicine.

RESULTS

Table No. 3: Showing effect of Panchshara Rasa on Subjective parameters in 30 patients

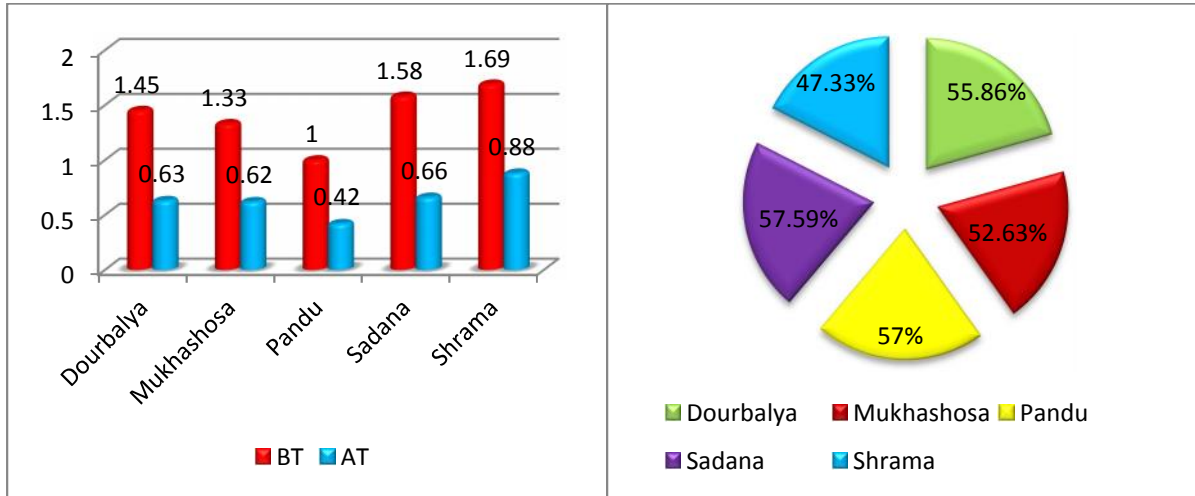
Symptoms	-n-	Mean		Mean dif-ference	Relief %	S.D.	S.E.	‘t’	P
		B.T.	A.T.						
<i>Dourbalya</i>	22	1.45	0.63	0.81	55.86	0.50	0.10	7.65	<0.0001
<i>Mukhashosa</i>	24	1.33	0.62	0.70	52.63	0.46	0.09	7.47	<0.0001
<i>Pandu</i>	7	1.00	0.42	0.57	57.00	0.53	0.20	2.82	0.03

Sadana	24	1.58	0.66	0.91	57.59	0.40	0.08	11.00	<0.0001
Shrama	26	1.69	0.88	0.80	47.33	0.40	0.07	10.25	<0.0001

Note: -n- No. of patients suffering with symptom, **B.T.:** Arithmetic mean of scoring Before Treatment, **A.T.:** Arithmetic mean of scoring After Treatment, **S.D.:** Standard Deviation, **S.E.:** Standard Error, **P-value:** Indicates significance of treatment on specific symptom. S.D, S.E, t and p-value are calculated substituting 'n' value as

actual number of patients suffering from that specific symptom (But not the total number of patients)

Graph No. 1: Showing effect of Panchshara Rasa on Subjective parameters in 30 patients



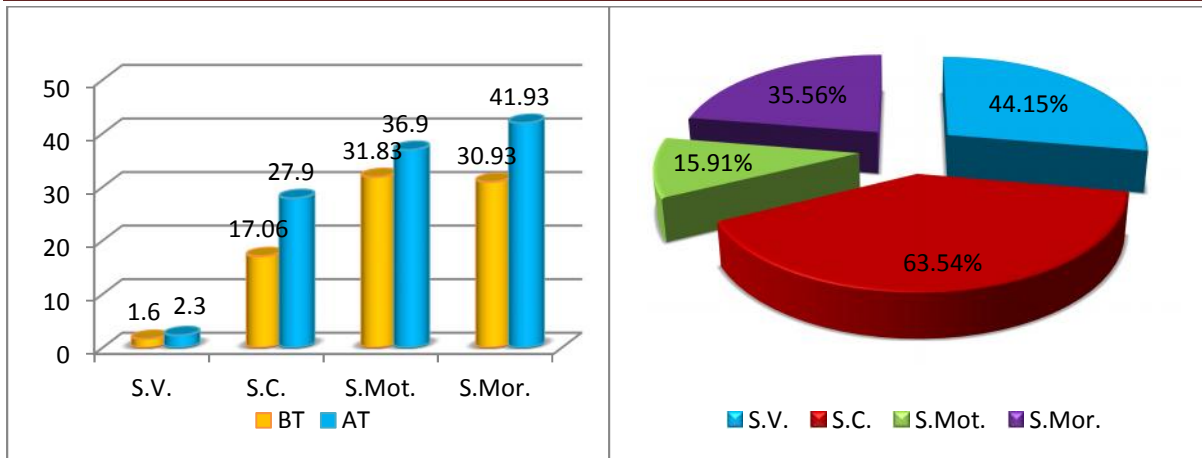
➤ Above data clearly shows that Panchshara Rasa has statistically highly significant relief in Dourbalya, Mukhashosa, Sadana and

Shrama(p<0.0001) and statistically significant relief in Pandu (p<0.03).

Table No. 4: Showing effect of Panchshara Rasa on Objective parameters in 30 patients

Parameters	-n-	Mean		Mean difference	Relief %	S.D.	S.E.	't'	P
		B.T.	A.T.						
Semen Volume	30	1.62	2.34	0.71	44.15	0.62	0.11	6.25	<0.0001
Sperm Count	30	17.06	27.90	10.84	63.54	5.84	1.06	10.16	<0.0001
Sperm Motility	30	31.83	36.90	5.067	15.91	9.97	1.82	2.78	0.0094
Sperm Morphology	30	30.93	41.93	11.00	35.56	9.27	1.69	6.49	<0.0001

Graph No.2: Showing effect of Panchshara Rasa on Objective parameters in 30 patients



Note: S.V: Semen Volume, S.C: Sperm Count, S.mot: Sperm Motility, S.mor: Sperm morphology:

Above data clearly shows that *Panchshara Rasa* has statistically highly significant relief in Semen Volume, Sperm Count and Sperm Morphology ($p < 0.0001$) and statistically significant relief in Sperm Motility ($p = 0.0094$).

DISCUSSION

Maximum number of patients belonged to 35-40 years age group (33.33%). Factors like fast and hectic life style, availability of contraceptive methods, late marriages and late planning of pregnancy are responsible for this observation. Maximum number of patients (93.33%) belonged to Hindu religion. As the study was conducted in Hindu predominant area, this finding was observed. Maximum number of patients belonged to *Jangala desha* (73.33%). *Jangala desha* is a *Vata-Pitta* predominant *desha*. *Shukrakshaya* is a *Vata* and *Pitta* predominant disorder. Maximum numbers of patients were educated (90%). This reflects the increased awareness among the educated to take *Ayurvedic* treatment. But education possibly does not have direct relationship with *Shukrakshaya*. Maximum number of patients belonged to middle class (46.66%), followed by poor class (33.33%). Middle

& poor class patients cannot afford the cost of laboratory investigations and medicines in private hospitals. Hence they select government institution for treatment. In middle and poor class, undernourishment is there due to financial crisis and illiteracy. According to *Charaka Alpasana* is believed to be responsible for *Shukrakshaya*². It is also noted that malnutrition causes hypogonadism and decreased function of Leydig cells due to reduced response of the male accessory organs to testosterone stimulation³. Vitamin A deficiency also causes testicular atrophy and reduces spermatogenic activity⁴. Maximum number of patients belonged to labour group (50%), Excess work i.e. *ativyayama* which is a cause for *Vata prakopa*, might have led the patient to suffer from this condition. In the remaining patients lack of exercise or stress might be the aggravating factors in developing this condition. Maximum numbers of patients were using *ushna jala* (60%) followed by 40% patients were using *sheeta jala*. Spermatogenesis is impaired with increased heat. So bath with *ushna jala* can be taken as an aggravating factor for *Shukrakshaya*. Maximum numbers of patients were found to be taking mixed diet (73.33%) while 26.66% patients were taking vegetarian diet. It is difficult to establish the relation between these

dietary habits and the disease. Maximum numbers of patients were having *Vishamagni* (53.33%), *Mandagni* was reported in 26.66% patients and 10% patients each were reported to have *Tikshnagni* and *Samagni* respectively. *Tikshnagni* is due to *pitta*, *Mandagni* due to *Kapha* and *Vishamagni* is due to *Vata* dominance⁵. *Sukrakshaya* is a *Vatapitta janya vyadhi*. Maximum numbers of patients had *Vishama nidra* (40%) while 33.33% had *Alpa nidra* and 20% patients had *Sukhapurvaka nidra*. According to *Acharya Charaka*, disturbed or poor quality sleep leads to impotency as well as various disease conditions in the body⁶. Maximum numbers of patients were having *Krura Koshtha* (46.66%), 40% had *Madhyama Koshtha* and only 13.33% of patients had *Mridu Koshtha*. *Krura Koshtha* is the indication of aggravated *Vata*. According to *Acharya Sushruta* all the *Shukradusti* are the outcome of vitiation of *Apana* and *Vyana Vayu*. *Krura Koshtha* itself is a vitiation of *Apana Vayu*. Maximum number of patients (46.66%) belonged to *Vata-Pitta Prakruti*. *Vata Prakruti Purusha* will have *Alpa Santana*. *Pitta Prakruti Purusha* will have *Alpa Shukra*, *Alpa Vyavaya Shakti* & will have *Alpa Santana* by virtue of *Katu-Amla Rasa* of *Pitta Dosh*⁷. Hence it may be inferred that either *Vata* or *Pitta* association in *Sharira Prakruti* may make the person more susceptible for *Shukrakshaya*. *Shukrakshaya* is also *Vata* and *Pitta Janya Vyadhi*. Maximum numbers of patients (60%) were used to wear tight under wears where as 53.33% used synthetic under wears. Tight trousers and synthetic under wears hamper sweating mechanism, raises scrotal temperature which results in impaired sperm production⁸. Maximum number of patients (66.66%) reported about practicing mastur-

bation. Excessive indulgence in masturbation can be considered under *Ayoni Maithuna*, which is one of important causes of *Shukravaha Srotodushti*. So here habit of masturbation in majority of patients might be a predisposing cause of *Shukrakshaya*. If we observe the treatment history, 80% of patients had taken treatment. This shows the severity of the disease.

Randomized selection of patients for clinical study improves accuracy of results by preventing possibility of bias. According to actual reference the dose of *Panchshara Rasa* is *Valla*. So basing on this the dose of drug is 375mg per day in divided dose. The *sahapana* is *Tambula patra*. *Vibandha* is a common symptom encountered while taking *Rasa yogas*. According to *Ayurveda prakasha*, *Rasayogas* when administered along with *Tambula patra* will not create *Vibandha*⁹. The *anupana* is *Mahisha dugdha*. *Mahisha dugdha* has *Madhura rasa*, *Snigdha*, *Guru guna* and *Vrishya* property¹⁰. Hence it is used as *anupana dravya*. *Panchshara Rasa* has given statistically highly significant relief in *Dourbalya*, *Mukhashosa*, *Sadana* and *Shrama* and statistically significant relief in *Pandu* due to its *Rasayana*, *Balya* and *Vata-Pittahara* properties. *Panchshara Rasa* has given statistically highly significant improvement in Volume of Semen, Sperm count and Sperm morphology and statistically significant improvement in Sperm motility due to its *Vata-Pittahara* and *Vrishya* properties.

CONCLUSION

Panchshara Rasa is one of the important formulations of *Ayurveda* useful in the management of *Shukra* related problems. *Panchshara Rasa* has shown statistically significant relief in subjective parameters like *Dourbalya*, *Mukhashosa*, *Pandu*,

Sadana and *Shrama*. The statistical analysis of the clinical study shows that this drug is effective as a stimulant to increase the Spermatozoa count by promoting the production quantitatively as well as qualitatively. Apart from increasing the Sperm count, Panchshara Rasa has also shown significant improvement in Semen volume, Sperm morphology and Sperm motility.

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