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 scientific validation of a formulation.
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 Shukракшaya.

AIMS AND OBJECTIVES
The present clinical study has been planned to evaluate the therapeutic efficacy of Panchshara Rasa in Shukракшaya.

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 Shastra, S.V. Ayurvedic College, Tirupati.

c) Total 32 patients with signs and symptoms of Shukракшaya 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 Azoo-spermia.
➢ Subjects with history of Tuberculosis, Testicular maldescents, Hydrocele, Carcinoma-Testes, Varicocele, Epididymoorchitis, 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 Panchshara Rasa
Panchshara Rasa is mentioned in Bhaishjya 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 Bhavitaa 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 melted 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 Shukракшaya 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

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Criteria</th>
<th>G₀</th>
<th>G₁</th>
<th>G₂</th>
<th>G₃</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Dourbalya</td>
<td>No weakness</td>
<td>Slight weakness</td>
<td>Weakness and work affected</td>
<td>Can’t do any work</td>
</tr>
<tr>
<td>2.</td>
<td>Mukhashosa</td>
<td>No dryness of mouth</td>
<td>Slightly dryness of mouth</td>
<td>Dryness relieved by anything putting in mouth</td>
<td>Dryness not relieved by anything</td>
</tr>
<tr>
<td>3.</td>
<td>Pandu</td>
<td>(Pallor of lips, conjunctiva, tongue, nails; corresponding to Hb) 12.5%</td>
<td>10-12.4%</td>
<td>7-10%</td>
<td>&lt;7%</td>
</tr>
<tr>
<td>4.</td>
<td>Sadana</td>
<td>None</td>
<td>Mild / doing regular work</td>
<td>Moderate / not performing his work sometimes</td>
<td>Severe / not doing his work most of the time</td>
</tr>
<tr>
<td>5.</td>
<td>Shrama</td>
<td>No fatigue</td>
<td>Increased fatigue over baseline, but not altering normal activities</td>
<td>Moderate / difficulty in performing some activities</td>
<td>Severe / loss of ability to perform activity</td>
</tr>
</tbody>
</table>

### 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

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Criteria</th>
<th>G₀</th>
<th>G₁</th>
<th>G₂</th>
<th>G₃</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Volume of Semen</td>
<td>&lt;1 ml</td>
<td>1.5-1 ml</td>
<td>2-1.6 ml</td>
<td>&gt;2 ml</td>
</tr>
<tr>
<td>2.</td>
<td>Sperm count</td>
<td>&lt;5 million / ml</td>
<td>&gt;5 and &lt;10 million / ml</td>
<td>&gt;10 and &lt;20 million / ml</td>
<td>&gt;20 million / ml</td>
</tr>
<tr>
<td>3.</td>
<td>Sperm motility</td>
<td>&lt;10% motile sperms</td>
<td>&gt;10% and &lt;30% motile sperms</td>
<td>&gt;30% and &lt;50% motile sperms</td>
<td>&gt;50% motile sperms</td>
</tr>
<tr>
<td>4.</td>
<td>Sperm morphology</td>
<td>&lt;10% normal form</td>
<td>&gt;10% and &lt;20% normal form</td>
<td>&gt;20% and &lt;30% normal form</td>
<td>&gt;30% normal form</td>
</tr>
</tbody>
</table>

### 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 : \( p < 0.05 \)
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

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>n-</th>
<th>Mean B.T.</th>
<th>Mean A.T.</th>
<th>Mean difference</th>
<th>Relief %</th>
<th>S.D.</th>
<th>S.E.</th>
<th>‘t’</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dourbalya</td>
<td>22</td>
<td>1.45</td>
<td>0.63</td>
<td>0.81</td>
<td>55.86</td>
<td>0.50</td>
<td>0.10</td>
<td>7.65</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Mukhashosa</td>
<td>24</td>
<td>1.33</td>
<td>0.62</td>
<td>0.70</td>
<td>52.63</td>
<td>0.46</td>
<td>0.09</td>
<td>7.47</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Pandu</td>
<td>7</td>
<td>1.00</td>
<td>0.42</td>
<td>0.57</td>
<td>57.00</td>
<td>0.53</td>
<td>0.20</td>
<td>2.82</td>
<td>0.03</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Parameters</th>
<th>-n-</th>
<th>Mean</th>
<th>Mean difference</th>
<th>Relief %</th>
<th>S.D.</th>
<th>S.E.</th>
<th>‘t’</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Semen Volume</td>
<td>30</td>
<td>1.62</td>
<td>2.34</td>
<td>0.71</td>
<td>44.15</td>
<td>0.62</td>
<td>0.11</td>
<td>6.25</td>
</tr>
<tr>
<td>Sperm Count</td>
<td>30</td>
<td>17.06</td>
<td>27.90</td>
<td>10.84</td>
<td>63.54</td>
<td>5.84</td>
<td>1.06</td>
<td>10.16</td>
</tr>
<tr>
<td>Sperm Motility</td>
<td>30</td>
<td>31.83</td>
<td>36.90</td>
<td>5.067</td>
<td>15.91</td>
<td>9.97</td>
<td>1.82</td>
<td>2.78</td>
</tr>
<tr>
<td>Sperm Morphology</td>
<td>30</td>
<td>30.93</td>
<td>41.93</td>
<td>11.00</td>
<td>35.56</td>
<td>9.27</td>
<td>1.69</td>
<td>6.49</td>
</tr>
</tbody>
</table>

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. 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 stimulation. Vitamin A deficiency also causes testicular atrophy and reduces spermatogenic activity. Maximum number of patients belonged to labour group (50%), Excess work i.e. ativayama 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 dominancy. 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 body. Maximum numbers of patients were having Krura Koshta (46.66%), 40% had Madhyama Koshta and only 13.33% of patients had Mridu Koshta. Krura Koshta is the indication of aggravated Vata. According to Acharya Sushruta all the Shukradusti are the outcome of vitiation of Apana and Vyana Vayu. Krura Koshta 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 Dosha. Hence it may be inferred that either Vata or Pitta association in Shari-ra 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 production. 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. The anupana is Mahisha dugdha. Mahisha dugdha has Madhura rasa, Snigdha, Guru gunaand Vrishya property. 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. PanchsharaRasa 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.

REFERENCES

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