A randomized clinical study to evaluate the effect of Tagaradi yoga in the management of insomnia

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Sleep which is described in Ayurveda as co-pillar of life is a periodic state of rest accompanied by varying degrees of conscious and relative inactivity. Derangement of sleep either qualitatively or quantitatively may terminate into medical illness. Insomnia is a highly prevalent common sleep disorder which adversely affects the health and quality of life of a person causing irritability, fatigue, disorientation, lack of concentration and poor performance at work. Present study was planned to evaluate the efficacy of certain indigenous drugs in the management of insomnia. In present open labeled, randomized clinical trial, 24 patients of insomnia were given hydroalcoholic extract derived from roots of Tagara (Valeriana jatamansi Jones syn. Valeriana wallichi DC.), rhizome of Jatamansi [Nardostachys jatamansi (D.Don) DC.] and rhizome of Vacha (Acorus calamus L.) in capsule form in the ratio of 2:1:1, respectively for 15 days. The drug was administered with water at bed time. Present trial drug showed statistically significant increase in duration of sleep with reduction in time taken for initiating sleep after the therapy. Effect of Tagaradi yoga on other parameters like quality of sleep, feeling of low performance in work, day time headache, time of awakening, post sleep state and irritability during waking hours also showed statistically significant improvement.

Keywords: Ayurveda, Insomnia, Herbal drugs, Tagar, Jatamansi, Vacha

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Ayurveda is one of the most ancient systems of medicine in the world. Its antiquity goes back to Vedas, the oldest recorded wisdom on the earth. Ayurveda describes Aahar (diet), Nidra (sleep) and Brahmacharya as Trayopstambha, i.e., three co-pillars of life which are individually essential under a physiological condition¹. Any sort of derangement of these factors either qualitatively or quantitatively leads to the beginning of pathological cascade terminating into a medical illness. Among these three factors, sleep is considered as the fundamental requirement of every human being. Sleep is defined as a periodic state of rest accompanied by varying degrees of unconsciousness and relative inactivity². It has been mentioned in Ashtanga hridaya that happiness and sorrow, growth and wasting, strength and weakness, virility and impotence, knowledge and ignorance as well as existence of life and its cessation depends on the sleep³. Sleep is considered as nourishing to body tissues and sleep disorders are held responsible for emaciation and other physical and mental ailments. Untimely sleep, excessive sleep and prolonged vigil have ill effects on health and can affect happiness and longevity⁴. Importance of sleep is well accepted by modern science also because of its restorative, recuperative and resting actions. Sleep deprivation is associated with considerable social, financial, and health-related costs, in large measure because it produces impaired cognitive performance due to increasing sleep propensity and instability of waking neurobehavioral functions. Cognitive functions particularly affected by sleep loss include psychomotor and cognitive speed, vigilant and executive attention, working memory, and higher cognitive abilities⁵. Insomnia, a sleep disorder is most commonly reported yet frequently overlooked health problem. It is a highly prevalent disorder that often goes unrecognized and untreated despite its adverse impact on health and quality of life. Insomnia is subdivided into different types on the basis of

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difficulty falling asleep, maintaining sleep, or by short sleep duration, despite adequate opportunity for a full night’s sleep. Insomnia has been associated with concurrent physical and psychiatric problems and may be a risk factor for the onset of depressive or anxiety related illnesses. In Ayurveda Charaka has mentioned insomnia under eighty types of Nanatmaja Vata Vyadhis whereas Shusruta held aggravated Vata & Pitta dosha responsible for insomnia. Apart from these, insomnia has also been described as a premonitory symptom, symptom and as complication of many pathological conditions. Different classes of sedatives and hypnotics are used in modern medicine for the management of sleep related disorders. Constant use of these drugs for a long time has issues like drug dependence, drug abuse, etc. Initially patient responds adequately to these agents, but with the passage of time develops drug dependence and the therapeutic doses of these drugs have to be increased to get optimum response. Keeping in mind the Nidana, Dosha-Dushya and Srotas involved in the pathogenesis of insomnia, Ayurvedic texts were reviewed and the drugs mentioned under the headings of Manaprasadak, Nirajananaka, Medhya, Bhutaghana, Vednasthapaka and Manasrogagahana were found to have properties which can check the pathogenesis of Anidra. Three drugs with these properties named Tagara (Valeriana wallichi), Jatamansi (Nordostachys jatamansi) and Vacha (Acorus calamus) were selected for the present trial to evaluate their efficacy in the management of insomnia.

Objectives of the research work
To clinically evaluate the efficacy of hydroalcoholic extract derived from roots of Tagara (Valeriana wallichi), rhizome of Jatamansi (Nordostachys jatamansi) and rhizome of Vacha (Acorus calamus) in the management of insomnia.

Place of study
The study was conducted as a part of post graduate thesis research work in the department of Kayachikitsa of Rajiv Gandhi Government Post Graduate Ayurvedic College Paprola, district Kangra, Himachal Pradesh.

Material and methods
Selection of patients and place of research
It was open labeled, randomized clinical study carried out in a single group. Study was conducted on 27 patients of insomnia selected from OPD and IPD of department of Kayachikitsa, Rajiv Gandhi Government Post Graduate Ayurvedic Hospital, Paprola, HP. Patients of insomnia in the age group of 18-75 yrs were selected irrespective of caste, sex, race and religion after obtaining their written informed consent. Three patients did not turn up for follow up hence were considered drop out from the study and remaining 24 patients completed the trial.

Diagnostic criteria
Patients were diagnosed according to diagnostic criteria given for insomnia in DSM-IV.

Inclusion criteria
- Patients in 18-75 yrs of age group.
- Patients suffering from primary insomnia or insomnia due to psychic or somatic illness.

Exclusion criteria
- Patients below 18 and above 75 yrs of age.
- Abuse of drugs or alcohol.
- Patients with terminal sickness.

Protocol of research
Written informed consent of every selected patient was taken before inclusion in the trial. After registration patients were given trial drug and were followed up on day zero, 8th day and finally on 15th day, i.e., at the end of trial.

Clinical research form
Demographic data of every patient including chief complaints with duration, present and past history, family history, personal history, socioeconomic history, general physical examination, systemic examination along with Ashtavidha pariksha, Dashvidha pariksha and Srotas examination was recorded in clinical research form.

Trial drug and its ingredients
Drug selected for the clinical trial was Tagaradi Yoga. Trial drug was prepared in the form of capsule comprising hydroalcoholic extract derived from roots of Tagara (Valeriana wallichi), rhizome of Jatamansi (Nordostachys jatamansi) and rhizome of Vacha (Acorus calamus) Each capsule contained hydroalcoholic extract of 2 parts of Tagara, 1 part of Jatamansi and 1 part of Vacha. Isolation of the extract was done at Ayush herbs private limited which is a GMP certified pharmacy.
Dose and administration

Dose of the trial drug was decided according to the body weight of the patients. Patients with body weight below 40 kg were given capsule of 500 mg, patients with body weight between 40-50 kg were given capsule of 750 mg and patients with body weight above 50 kg were given capsule of 1 gm at bed time with water.

Investigations: Following investigations were carried out to rule out any other concomitant disease and to see any untoward effect of the trial drugs both before and after the therapy.

Blood – Hb %, TLC, DLC, ESR, Blood Urea, Serum Creatinine, FBS, SGOT, SGPT

Criteria for assessment

Assessment of effect of therapy was done on the basis of relief in signs and symptoms. Total 10 criterias were selected for assessment. Scoring system adopted for assessment was depending upon the severity, and various symptoms were assigned to four grades ranging from 0-3. Criteria selected for the assessment of effects of therapy were duration of sleep, time taken for initiating sleep, quality of sleep, post sleep state, status of dreams, irritability during waking hours, feeling of low performance at work, day time headache, time of going to bed and time of awakening.

Overall assessment of therapy

For overall assessment of effects of therapy following criterias was adopted:
- Excellent response : > 75 %
- Marked response : 50-75 %
- Mild response : 25-50 %
- No response : < 25 %

Data collection and statistical analysis

Data generated from clinical study was collected and analyzed statistically. The improvement in the status of patients was assessed on the grades of various variables compared between pre-trial and post-trial values in terms of percentage (based on mathematical mean and its difference) and the student ‘t’ tests was applied wherever it was felt necessary by using degree of freedom value. The results were interpreted at the level of p < 0.001 as highly significant, p < 0.01 as moderately significant, p < 0.05 as significant and p > 0.05 as insignificant.

Observations

Every patient coming to the OPD of department of Kayachikitsa was screened for the trial. In the present study total 27 patients meeting the criterias were registered out of which three patients did not turn up for follow up and were considered dropout, hence results were calculated on 24 patients. It was observed that maximum number of patients, i.e., 10 (37.04 %) were in the age group of 51-60 yrs. Maximum 21(77.78 %) were female, all were of Hindu religion, maximum 11(40.74 %) patients were educated up to primary level, 19 (70.37 %) were from middle class, 24 (88.89 %) patients were belonging to rural area, 22 (81.48 %) were married, 16 (59.26 %) were having active life style, 18 (66.67 %) were taking mixed diet, 15 (55.56 %) were addicted to tea/coffee. Maximum number of patients, i.e., 14 (51.85 %) were having weight between 40-50 kg, 8 (29.63 %) patients were having complaint of disturbed sleep since 1-3 months whereas 6 (22.22 %) patients were having disturbed sleep since more than 12 months, 14 (51.85 %) patients were of Vata-Pittaj Prakriti, 18 (66.67 %) were under psychic stress, 10 (37.04 %) patients were having regular bowel habits and maximum number of patients, i.e., 11(40.74 %) were having frequency of micturition 2 - 4 times during night.

Results

Effect of trial drug showed statistically highly significant increase in duration of sleep with p < 0.001. A statistically highly significant reduction in time taken for initiating sleep was observed after the therapy (p < 0.001). Effect of Tagaradi yoga on other parameters like quality of sleep and status of dreams also showed statistically significant improvement with p < 0.001. Irritability during waking hours was decreased significantly with p value < 0.001. Features like feeling of low performance in work, day time headache, time of awakening and post sleep state also showed statistically highly significant improvement with p < 0.001(Table 1).

Effect of therapy on haematological parameters

No statistical significant change was observed in haematological parameters and they remained within physiological range both before and after completion of the therapy which indicates the safety of trial drug in short term use (Table 2).

Overall effect of therapy

Overall effect of therapy revealed that out of total 24 patients who completed the therapy, 14 patients, i.e., 58.33 % showed excellent response, 8 patients, i.e., 33.33 % showed marked response and 2 patients, i.e., 8.33 % showed mild response. None of the registered patient remained unimproved.
Discussion

Out of 27 registered patients in this trial it was observed that maximum patients were of age group 51-60 yrs followed by age group of 31-40 yrs. Vata & Pitta tend to be dominant in the age group of 51-60 yrs and both play a key role in the pathogenesis of insomnia. In this age group Pitta is already dominant whereas Vata starts increasing in body due to transition from madhyama to vridhavastha. Increased incidence of insomnia in age group of 31-40 yrs could be attributed to more stressful life in working age group\(^{11,12}\). Increased incidence in females can be attributed to higher perception of stress in females\(^{11,12}\). Maximum number of patients having Vata-Pitta Prakriti reflects proneness of this Prakriti to sleep related disorders. Increased frequency of micturition during night can be a cause or effect of insomnia. Tea and coffee has a stimulant action on CNS\(^{13}\) which increases mental activity and aggravates the disease condition further. Effect of trial drug showed a statistically highly significant increase in duration of sleep and highly significant reduction in time taken for initiating sleep after the therapy. Effect of Tagaradi yoga on other parameters like quality of sleep, status of dreams, feeling of low performance in work, day time headache, time of awakening, post sleep state and irritability during waking hours also showed statistically highly significant improvement.

Drugs having Vatapitta Shamak, Vednashamaka, Nidrajanaka and Manaprasadaka effects are used in anidra (Insomnia). Keeping this in view, three different indigenous drugs in combination have been used in trial formulation. Tagara has been described under Vednashapna gana. It possesses Snigdha guna and is ushna in nature which alleviates vata\(^{14}\). Due to its vata shanak properties Tagar is medhya and has relaxing effect on brain by which it helps in inducing sleep. Tagara contains a large proportion of volatile oils (ethereal valerianic oil) containing esters of valerianic acid. It is described as nerve sedative, hypnotic, stimulant and calmative\(^{15}\). Valerian acts as a centrally acting sedative and has been described as principal remedy of insomnia especially when it is due to nervous exhaustion and mental fatigue\(^{16}\).

<table>
<thead>
<tr>
<th>S.No</th>
<th>Criteria of assessment</th>
<th>Mean BT</th>
<th>Mean AT</th>
<th>Df (BT-AT)</th>
<th>% relief</th>
<th>±SD</th>
<th>±SE</th>
<th>‘t’</th>
<th>‘p’</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Duration of Sleep</td>
<td>3</td>
<td>0.58</td>
<td>2.42</td>
<td>80.67</td>
<td>0.65</td>
<td>0.13</td>
<td>18.17</td>
<td>&lt;0.001</td>
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<td>2</td>
<td>Time taken for Initiating Sleep</td>
<td>2.92</td>
<td>1.54</td>
<td>1.38</td>
<td>47.26</td>
<td>0.82</td>
<td>0.17</td>
<td>8.18</td>
<td>&lt;0.001</td>
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<td>3</td>
<td>Quality of Sleep</td>
<td>2.83</td>
<td>1.17</td>
<td>1.66</td>
<td>58.66</td>
<td>0.48</td>
<td>0.1</td>
<td>16.97</td>
<td>&lt;0.001</td>
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<tr>
<td>4</td>
<td>Post Sleep State</td>
<td>2.88</td>
<td>0.92</td>
<td>1.96</td>
<td>68.06</td>
<td>0.69</td>
<td>0.14</td>
<td>13.99</td>
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<td>5</td>
<td>Status of Dreams</td>
<td>1.92</td>
<td>0.63</td>
<td>1.29</td>
<td>67.19</td>
<td>0.62</td>
<td>0.13</td>
<td>10.17</td>
<td>&lt;0.001</td>
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<td>Irritability during Waking Hours</td>
<td>2.42</td>
<td>0.71</td>
<td>1.71</td>
<td>70.66</td>
<td>0.46</td>
<td>0.09</td>
<td>18.98</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>7</td>
<td>Feeling of Low Performance in Work</td>
<td>2.13</td>
<td>0.54</td>
<td>1.59</td>
<td>74.64</td>
<td>0.65</td>
<td>0.11</td>
<td>19.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>8</td>
<td>Day Time Headache</td>
<td>2.04</td>
<td>0.54</td>
<td>1.5</td>
<td>73.53</td>
<td>0.72</td>
<td>0.15</td>
<td>10.2</td>
<td>&lt;0.001</td>
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<tr>
<td>9</td>
<td>Time of Going to Bed</td>
<td>2.71</td>
<td>0.96</td>
<td>1.75</td>
<td>64.58</td>
<td>0.74</td>
<td>0.15</td>
<td>11.67</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>10</td>
<td>Time of Awakening</td>
<td>2.67</td>
<td>0.29</td>
<td>2.38</td>
<td>89.14</td>
<td>0.58</td>
<td>0.12</td>
<td>20.21</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Table 1 — Effect of Tagaradi Yoga on criteria of assessment**

<table>
<thead>
<tr>
<th>S.No</th>
<th>Variables</th>
<th>Mean BT</th>
<th>Mean AT</th>
<th>% age Deviation</th>
<th>±SD</th>
<th>±SE</th>
<th>‘t’</th>
<th>‘p’</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Hemoglobin</td>
<td>10.79</td>
<td>11.31</td>
<td>4.82</td>
<td>0.68</td>
<td>0.14</td>
<td>3.66</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>2</td>
<td>TLC</td>
<td>7470.83</td>
<td>7233.33</td>
<td>3.17</td>
<td>601.31</td>
<td>122.72</td>
<td>1.94</td>
<td>&gt;0.01</td>
</tr>
<tr>
<td>3</td>
<td>ESR</td>
<td>18.21</td>
<td>17.46</td>
<td>4.12</td>
<td>7.57</td>
<td>1.55</td>
<td>0.49</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>4</td>
<td>Polymorphs</td>
<td>63.54</td>
<td>63.83</td>
<td>0.46</td>
<td>3.41</td>
<td>0.7</td>
<td>0.42</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>5</td>
<td>Lymphocytes</td>
<td>32.04</td>
<td>31.67</td>
<td>1.15</td>
<td>2.68</td>
<td>0.55</td>
<td>0.68</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>6</td>
<td>Monocytes</td>
<td>1.38</td>
<td>1.83</td>
<td>32.61</td>
<td>0.83</td>
<td>0.17</td>
<td>2.7</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>7</td>
<td>Eosinophils</td>
<td>3.04</td>
<td>2.67</td>
<td>12.17</td>
<td>1.77</td>
<td>0.36</td>
<td>1.04</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>8</td>
<td>FBS</td>
<td>88.13</td>
<td>87.46</td>
<td>0.76</td>
<td>11.03</td>
<td>2.25</td>
<td>0.3</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>9</td>
<td>B. Urea</td>
<td>28.86</td>
<td>27.08</td>
<td>6.17</td>
<td>3.23</td>
<td>0.7</td>
<td>2.17</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>10</td>
<td>S. Creatinine</td>
<td>0.91</td>
<td>0.84</td>
<td>7.78</td>
<td>0.14</td>
<td>0.03</td>
<td>2.63</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

**Table 2 — Effect of Tagaradi Yoga on haematological parameters**

BT= Before treatment, AT= After treatment, Df= Difference, SD= Standard deviation, SE= Standard error, TLC= Total leucocyte count, ESR= Erythrocyte sedimentation rate
Valerian has been shown to encourage sleep, and improve quality of sleep. 17. *Jatamansi* has been said to have *bhutaghnā* or *manasarogagnhā prabhava*. *Jatamansi* causes alleviation of *vata dosha* due to *madhur rasa* and *snigdha guna*, it alleviates *pitta dosha* due to *madhur, tikta, kshaya rasa* and *sheet veerya* nature. It is *vedna sthapak*, *sangyasthapak* and *vatanadi shamaka*18, all these properties helps in pacifying *vata & pitta doshas*, the pathognomic factors responsible for difficulty in inducing and maintaining sleep. *Jatamansi* has shown significant results clinically in sleep disorders as well as on other neuropsychiatric disorders like anxiety, schizophrenia, etc. *Jatamansi* has tranquilizing, CNS depressant, anti-epileptic, anti-anxiety, anticonvulsant and other pharmacological activities.19 *Vacha* possesses properties like *aakshepshamana, vedna sthapaka, manas doshahar* and *medhya*. It alleviates *vata dosha* being *ushna virya* in nature.20 Steam volatile fractions of the roots and rhizomes of *Vacha* have shown prolongation of sleeping time with penobarbital, hexobarbital and ethanol.21 *Vacha* has shown significant effect clinically in management of anxiety related disorders and memory and learning enhancing effects in rats.22 It is helpful in relieving stress induced disorders and has pharmacological activities like sedative, CNS depressants, behaviour modifying, memory enhancing, anti-oxygenant and antiepileptic, etc.22 α- *asarone & β-asarone*, the main constituents of rhizome showed many pharmacodynamic actions similar to some well established tranquillizers. It was found that the sedative effect of α-asarone was dependent on the depression of the etropic division of the hypothalamus. α-asarone reduced spontaneous motor activity and caused reduction in anxiety without suppressing the perceptions in rats. It produced prolonged calming effect in monkeys.24 All these properties help in inducing sleep.

**Conclusion**

On the basis of the clinical trial it is evident that trial drug *Tagarādi Yoga* is effective in the management of insomnia. No untoward effect was observed during the period of study. However, further long term multicentric trials are required to establish the efficacy and safety of these drugs.

**Acknowledgement**

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**Conflict of interest**

None

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