

ROLE OF TAGARADI CAPSULE IN THE MANAGEMENT OF ANIDRA (INSONIA) – A CLINICAL STUDY

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ABSTRACT

Anidra (Insomnia) is a type of sleep disorder in which individual feels difficulty in falling asleep, staying asleep or both. In Ayurveda, *Anidra* is indicated as *VataNanatmajaVikara* by *Acharya* Charaka. Insomnia affects most of the people at any stage of life due to today's stressful day to day life. Allopathic hypnotic drugs are used to treat insomnia in acute stage, but long-term use can lead to dependency and withdrawal symptoms along with other side effects. In present study a polyherbal compound *Tagaradi* Capsule consist extracts of *Tagara*, *Jatamansi*, *ParsikaYavani*, *Ashwagandha*, *Brahmi*, *Shankhapushpi*, *Pippalimula* and *Sarpagandha* is used to check its efficacy in the management insomnia. **Aim:** Role of *Tagaradi* capsule in the management of *Anidra* (Insomnia).

Materials and methods: Total 33 newly diagnosed patients of age group 18 to 70 years of insomnia who were not taking any other hypnotic medicine were selected and administered 2 capsules each of 500 mg of *Tagaradi* compound extract along with a cup of warm milk at bedtime for 2 months. Assessment was done considering the overall improvement of sleep quality according to Pittsburgh Insomnia Rating Scale, improvement in associated complains, relieving of anxiety according to Hamilton Anxiety rating Scale and relieving of depression according

to Hamilton Depression Rating Scale. **Observations:** The information gathered on the basis of observations was subjected to statistical analysis. The Paired ‘t’ test was used to check the significance of objective criteria and Wilcoxon Signed Rank Test was used to check the significance to subjective criteria. **Results:** The results showed that the trial drug had highly significant effect on almost all the mentioned parameters of Insomnia.

Keywords: Ayurveda, *Anidra*, *Tagaradi* capsule, Insomnia

INTRODUCTION

Insomnia is one of the burning problems not only in India but all over the world. The modern rapidly developing world, we find stress everywhere in the family, business organization/enterprise or any other social or economic activity. This is the main cause of various psychic and psychosomatic disorders. According to the statistics 20% - 40% adults, encounter insomnia problems during a year time.¹ Especially 15 to 55 years old are more affected. Further, Insomnia is 1.4 times more common in woman than in men and affects 1 in 3 people.²

In Ayurveda, Charaka has described *Anidra* as one of the *VataNanatmaja Vikara*.³ The conditions likephthisis, wasting of muscle, thirst, diarrhoea, dyspnoea, hiccup, cause *Anidra* because of the predominance of *Vatika* activity.⁴ The other conditions responsible for insomnia include: smoke, excessive physical exercise, bloodletting, fast, uncomfortable bed, hunger, pain, noise, happiness, misery, emaciation strength, weakness, virility etc.⁵ Various psychic traits like anger, fear, worry, anxiety etc. are responsible for vitiation of *Doshas* and cause *Anidra* (Insomnia).

Among insomniacs, 28% receive psychotropic drug, 14% receive benzodiazepines and 19% receive antidepressants. Allopathic hypnotic drugs are useful for short term treatment in Insomnia which is due to acute stage.⁶ Long term uses of certain classes of sedatives cause physical dependence, which manifests in withdrawal symptoms if the drug is not carefully tapered down. Further, hypnotic medications also have a number of side effects such as daytime fatigue, motor vehicle crashes, cognitive impairments and falls and fractures. Elderly people are more sensitive to these side-effects.

In the present time, patient prefers readymade, cost effective, palatable drugs with fewer side effects for

their health problems. Hence, it is need of the time to formulate such new herbal formulation which can be a solution for Insomnia and can be prescribed for long term with minimal adverse effects. There are many herbs available in Ayurveda which are useful for initiating sleep. Some of these herbs with established sedative effect were selected and prepared a combination to establish the combine effect of the newly formulated compound *Tagaradicapsule* in the management of insomnia in this clinical trial entitled “Role of *Tagaradi* Capsule in the management of *Anidra* (Insomnia)”.

Tagaradi Capsule is the combination of the extracts of *Tagara*, *Jatamansi*, *Ashwagandha*, *ParsikayavaniShankhpushpi*, *Brahmi*, *Sarpagandha* and *Pippalimoola*. All these herbs have either *Nidrajanana* or *Madaka* or *Medhya* actions.^{7,8} and have also clinically and experimentally proved sedative activity but here in this study all these herbs’ extracts are used in the combination to see the combine effect of all these herbs with best palatability.

Aim and Objectives:

Evaluate the role of *Tagaradi* capsule in the management of *Anidra* (Insomnia).

Materials and Methods:

A total of 35 patients of between the age of 18 to 75 years fulfilling the diagnostic criteria of *Anidra* (Insomnia) were selected and registered in this study from the OPD and IPD of Kayachikitsa Department, IPGT and RA, Jamnagar. The study has been carried out after obtaining ethical clearance of the Institutional Ethics Committee (PGT/7/-A/Ethics/2016-17/3934, Dated – 23/02/2017) and was also registered with Clinical Trial Registry of India (CTRI) vide CTRI/2017/03/008084, Dated – 14/03/2017. Informed written consent of each patient was taken prior to reg-

istration in the study. For the diagnosis a detailed medical history was taken, and physical examination was done in detail according to both modern and Ayurvedic clinical methods and it was noted in specially prepared proforma.

Diagnostic Criteria:

The patients complaining of persistent difficulty in falling asleep or staying asleep despite the opportunity and were suffering from daytime fatigue and impaired concentration and memory and patients fulfilling Pittsburgh Insomnia Rating Scale, were selected for the study.

Inclusion criteria:

- Patients of both sexes in between the age group 18-75 years.
- Patients suffering from following type of disturbed sleep pattern.
 - a) Sleep onset insomnia (Difficulty to taking sleep at the beginning of the night)
 - b) Sleep maintenance insomnia (Difficulty to maintain the sleep)
 - c) Nocturnal awakening (Difficulty to returning to sleep after awakening in the middle of the night or wakening early in the morning)
 - d) Rebound insomnia (Patients who has developed dependence to sedatives)
 - e) Circadian rhythm disorders (Sleeping pattern changes)
 - f) Patients having insomnia more than 2 weeks, less than 6 months
- Patients of insomnia with mild hypertension, mild depression and anxiety disorder without any complains of other major diseases.

Exclusion Criteria:

- Patients less than 18 years and more than 75 years.
- Patients suffering from fatal familial insomnia.
- Insomnia with major psychiatric illness like, Schizophrenia, Depressive psychosis, Epilepsy, etc.
- Patients having advanced chronic illness like Bronchial asthma, Diabetes mellitus, Malignancy, Liver cirrhosis, Chronic renal failure, etc.

- Patients with alcohol or drug dependency will be excluded.
- Patients having acute illness like Cardiovascular accidents, Myocardial infarction, Chronic obstructive pulmonary disease.
- Pregnant woman and planning to be pregnant within six months.

Trial drug details:

Drug and Posology: The details of the trial drug are as given below. (Table no-1) *Tagaradi* capsule in the dose of 2 capsules (each of 500 mg) with Lukewarm milk was administered at bedtime for the period of 8 weeks. *Pathyapathya* was advised to all the patients as per classics. After completion of treatment, patients were asked to follow up for 4 weeks. *Tagaradi* Capsule contained extracts was procured from the Konark Herbals, Daman which were analyzed in the pharmacognosy and pharmaceutical laboratories of IPGT and RA, Gujarat Ayurved University, Jamnagar.

Criteria of assessment: The efficacy of the treatment was assessed on the basis of relief in signs and symptoms and in the Pittsburgh insomnia rating scale, Hamilton's Anxiety Rating Scale and Hamilton's Depression Rating Scale.

Data presentation: General data was subjected to suitable statistical analysis such as Wilcoxon Signed Rank test for non-parametric paired data, unpaired t-test for quantitative unpaired data. After preparing the master chart of all the required data in Microsoft excel work sheet, statistical calculations were made with the help of Sigma stat 3.5 software and in stat 3 software. The results were interpreted as significant $p < 0.05$, highly significant $p < 0.01$, very highly significant $p < 0.001$, insignificant $p > 0.05$. Considering the relief in major symptoms and improvement in the quality of sleep, the subjects were divided into groups 0% - 25% improvement as unchanged, 26% - 50% positive changes as mild improvement, 51%-75% positive changes as moderate improvement, 76 - 99% positive changes as marked improvement and 100% relief as complete remission.

OBSERVATIONS:

A total of 34 patients of *Anidra* (Insomnia) were registered in this trial, out of which 33 patients had completed the course of the treatment. Maximum patients i.e. 26.47% belonged to 41– 50 years of age group, maximum (52.94%) were male and 82.35% patients were married, 85.29% Hindus, 32.35% patients had taken education up to graduation, 70.59% patients belonged to middle socio-economic status, 38.24% were house wives and 79.41% were belonging to urban habitat. Majority of the patients i.e. 64.70% patients had *Vishamagni*, 61.76% had *Madhyama-Koshtha*, 64.70% had moderate appetite and 64.70% patients had *Rajasika* food habit and Maximum patients (50%) had *Vata-pitta Sharirika Prakriti*. (Table no. 2)

While analyzing the data related to chronicity of insomnia, it was revealed that maximum number of patients (44.11%) had chronicity of insomnia from 1 to 3 months. Data of present study reveals that 91.17% patients were having anxiety, 85.29% were having *Tikta Katu Shushka Laghu Bhojana*, 79.41% were taking *Akalabhojana*, 64.70% patients were having history of *Vegadharana* as probable causative factor of insomnia. (Table no. 2).

All the patients i.e. 100% had complaint of sleeplessness, among them 98.10% patients reported difficulty in initiating sleep at bedtime, 93.33% patients had difficulty in maintaining sleep, 96.19% reported that they woke up too early in the morning and could not sleep again. According to Pittsburgh Insomnia rating scale 73.33% patients were having moderately bothered sleep, 28.57% patients were having slightly bothered sleep and 0.95% patients were having severely bothered sleep. 99.05% patients were suffering from *Akshigaurava*, 98.10% patients had the complain of *Shirogaurava*, 97.14% had *Angamarda*, 93.33% had *Alasya*, 92.38% had *Ajirna*, 90.48% had *Vibandha*, 86.67% had *Netradaha*, 84.76% had *Bhaya*, 66.67% had *Jrimbha*, 54.29% had *Kshudhamandhya*, 49.52% had *Krodha* and 45.71% patients had the complain of *Shoka*. (Table no. 2)

All the patients were further analyzed by using Hamilton Anxiety Rating Scale which showed that 70.48 %

patients were having moderate level of anxiety further 29.52% were having mild level of anxiety. According to Hamilton Depression Rating Scale 80.00% patients were having mild level of depression and 16.19% moderate level of depression was found. (Table no. 2)

RESULTS:

Analysis of the results showed that *Tagaradi* capsule has statistically highly significant relief on almost all the chief complains of insomnia, like difficulty getting sleep at bed time (81.40%), awakening after getting sleep (84.51%) waking up too early in the morning (79.07%). When effect of therapy was assessed on insomnia by using Pittsburgh Insomnia Rating Scale it revealed that 61.67% observed and result was statistically highly significant. Anxiety was assessed by Hamilton Anxiety Rating scale and it was found that, statistically highly significant 60.38% effect. Depression was assessed with the help of Hamilton Depression Rating Scale and statistically highly significant effect was observed on depression with 80% reduction. (Table no. 3)

While analyzing the effect on haematological values it was found that change in Eosinophils count (reduced 28%) was Statistically highly significant and Monocytes count (reduced 14.71%) was also significant, FBS value was increased 4.75% and S. Cholesterol was reduced 5.34% which was also statistically significant, Serum cortisol level remained in normal range but reduced 2.90% which was also statistically significant. (Table no. 4)

The overall effect of therapy was assessed considering the overall improvement of sleep according to Pittsburgh Insomnia Rating Scale, relieving of associated complains of insomnia, relieving of level of anxiety according to Hamilton Anxiety Rating Scale, relieving of level of depression according to Hamilton Depression Rating scale. (Table no. 5)

Overall effect of therapy revealed that, marked improvement was found in 48.48% patients, moderate improvement was observed in 45.45% patients, Complete Remission and mild improvement was found in 3.03% patients. (Chart no. 1)

Probable Mode of action of Tagaradi capsule:

Tagaradi capsule acts on Anidra (Insomnia) due to the combine action of its ingredients which act on *Manovahasrotas*. Its most of the ingredients are *Vatashamaka* or *Vatakaphashamaka* with *Snigdha*, *Ushna Guna* and *MadhuraRasa* or *Vipaka* due to that *Vatashamana* occurs. Most of the ingredients have *Nidrajanana Prabhav* due to that it directly acts on the *Manovahasrotasa* and reduce the stress or over thinking and calm the mind which initiate and maintain the sleep with good quality.

According to modern, most of the ingredients of the *Tagaradi* capsule have sedative, anti-anxiety, anti-stress and CNS depressant action due to that it reduces the stress level and calm the mind which help the individual to initiate the sleep and maintain the sleep with improvement in other associated symptoms also. *Tagaradi* capsule also reduces the blood pressure in hypertensive patients due to the ingredients like *Shankhapushpi*, *Sarpagandha*, etc. For better relieving effect, treatment for longer duration is required if Insomnia is chronic.

DISCUSSION

Nidra is very important phenomenon for healthy life where as *Asamyaka Nidra* or *Anidra* causes various health problems. Insomnia is more commonly seen in middle age group especially more in female during menopause age. *Vata –Pitta* predominance and *Rajas* plays an active role in the pathogenesis of *Anidra*. It manifests mostly patients who are in stressful conditions. *Rajasika* or *Ushna*, *Teekshana* type of *Ahara* reduce the sleep and leads to insomnia. Among the cardinal symptoms of *Anidra* maximum encountered symptoms is difficulty getting to sleep at bedtime, awakenings after getting sleep and waking up too early in the morning. Administration of *Tagaradi* capsule provided statistically highly significant effect due to sedative and anti-depression and anti-stress properties on all the parameters of insomnia. During the clinical trial no adverse effects of the *Tagaradi* capsule was reported.

CONCLUSION

It can be concluded that *Tagaradi* capsule has complex Psycho-neuro-pharmacological activities and *Nidrajanana Prabhava* thus is able to break the pathogenesis of insomnia at different levels. *Anupana* of milk may further potentiate the effect of trial drug.

Table 1: Composition of *Tagaradi* capsule (*Anubhuta*):

Drug Name	Botanical Name	Ratio of Extract	Part Used
<i>Tagara</i>	<i>ValerianaWallich</i> DC.	1 part	<i>Moola</i>
<i>Jatamansi</i>	<i>Nardostachysjatamansi</i>	1 part	<i>Kanda</i>
<i>Ashwagandha</i>	<i>Withaniasomnifera</i> Dunal.	1 part	<i>Moola</i>
<i>Parsikayavani</i>	<i>Hyoscyamusniger</i> Linn.	1 part	<i>Beeja</i>
<i>Shankhapushpi</i>	<i>Convolvulus pluricaulis</i> Chois.	1 part	<i>Panchanga</i>
<i>Brahmi</i>	<i>Bacopa Monnieri</i> Linn.	1 part	<i>Panchanga</i>
<i>Sarpagandha</i>	<i>Rouwolfia serpentine</i> Benth ex. Kurz.	1 part	<i>Moola</i>
<i>Pippalimoola</i>	<i>Piper longum</i> Linn.	1 part	<i>Moola</i>

Table 2: General observations of the trial:

Content	Details	No of Patients	Percentage
Age	41-50	9	26.47
	51-60	6	17.65
Gender	Male	18	52.94
	Female	16	47.06

Religion	Hindu	29	85.29
	Muslim	05	14.71
Education	Graduate	11	32.35
	Higher secondary	10	29.41
Occupation	Housewives	13	38.24
	Business	07	20.59
Marital status	Married	28	82.35
	Unmarried	04	11.76
Socio-economic status	Middle class	24	70.59
	Lower middle class	08	23.53
Habitat	Urban	27	79.41
	Rural	07	20.59
Chronicity of Insomnia	0 to 3 months	15	44.12
	3 to 6 months	07	20.59
<i>Divasvapa</i>	No sleep	23	67.65
	30-60 minutes	08	23.53
Chief complains	Difficulty in initiating sleep	33	97.06
	Difficulty in Maintaining sleep	33	97.06
Pitusburgh insomnia rating scale	Moderately bothered	23	67.65
	Slightly bothered	11	32.35
Associated complains	<i>Shirogaurava</i>	34	100
	<i>Akshigaurava</i>	33	97.06
Probable <i>Nidana</i>	Anxiety	31	91.18
	<i>TiktaKatuShushkaShitaLaghuBhojana</i>	29	85.29
<i>Agni</i>	<i>Vishama</i>	22	64.71
	<i>Manda</i>	08	23.53
<i>Koshtha</i>	<i>Madhyama</i>	21	61.76
	<i>Krura</i>	13	38.24
<i>Aahara</i>	Vegetarian	21	61.76
	Mixed	13	38.24
Food Habit	<i>Rajasika</i>	22	64.71
	<i>Tamasika</i>	07	20.59
Appetite	Moderate	22	64.71
	Poor	06	17.65
Addiction	Tea	24	70.59
	Alcohol	03	8.82
Bowel habit	Irregular	19	55.88
	Constipated	12	35.29
<i>Sharira Prakriti</i>	<i>Vata-Pitta</i>	17	50
	<i>Pitta-Kapha</i>	14	41.18
Hamilton Anxiety Rating Scale	Moderate	20	58.82
	Mild	14	41.18
Hamilton Depression Rating Scale	Moderate	28	82.35
	Mild	06	17.65

Table 3: Effect of Therapy:

Parameter		BT	AT	Diff.	% change	P	S
Total hours of sleep		33	2.36	1.03	1.33	56.41	HS
Chief complains	Difficulty in getting sleep	2.61	0.48	2.12	81.40	<0.001	HS
	Awakening at night	2.15	0.33	1.82	84.51	<0.001	HS
	Waking up too early in the morning	2.61	0.55	2.06	79.07	<0.001	HS
Pitusburgh Insomnia Rating Scale		1.82	0.70	1.12	61.67	<0.001	HS
Associated Complains	<i>Akshigaurava</i>	1.88	0.27	1.61	85.48	<0.001	HS
	<i>Shirogaurava</i>	1.82	0.21	1.61	88.33	<0.001	HS
	<i>Alasya</i>	1.33	0.18	1.15	86.36	<0.001	HS
	<i>Jrimbha</i>	0.67	00	0.67	100	<0.001	HS
	<i>Angamarda</i>	2.06	0.64	1.42	69.12	<0.001	HS
	<i>Ajirna</i>	1.33	0.24	1.09	81.22	<0.001	HS
	<i>Krodha</i>	0.42	0.06	0.36	85.71	<0.001	HS
	<i>Bhaya</i>	0.79	0.03	0.76	96.15	<0.001	HS
Hamilton Anxiety Rating Scale		1.61	0.64	0.97	60.38	<0.001	HS
Hamilton Depression Rating Scale		1.21	0.24	0.97	80	<0.001	HS

Table 4: Effect of therapy on Hematological values:

Haematological Parameter	Pa-	Mean		Diff.	% Change	Paired t test				
		BT	AT			SD	SE	t	P	S
Hb		13.08	13.16	-0.09	-0.65	1.097	0.191	-0.447	0.658	IS
RBC count		4.71	4.67	0.04	0.91	0.427	0.074	0.579	0.567	IS
WBC count		7139.39	7203.03	-63.64	-0.89	1681.3	292.7	-0.217	0.829	IS
Neutrophils count		54.15	56.79	-2.64	-4.87	7.553	1.315	-2.005	0.053	IS
Lymphocytes count		37.55	36.12	1.42	3.79	6.629	1.154	1.234	0.226	IS
Eosinophils count		5.30	3.82	1.48	28	2.195	0.382	3.885	<0.001	HS
Monocytes count		3.09	2.64	0.45	14.71	1.277	0.222	2.045	0.049	S

Table 5: Effect of therapy on Biochemical values:

Biochemical Parameter	Pa-	Mean		Diff.	% Change	Paired t test				
		BT	AT			SD	SE	T	P	S
Blood Urea		23.42	22.94	0.48	2.07	6.286	1.094	0.443	0.661	IS
S. Creatinine		1.11	1.04	0.07	6.01	0.245	0.043	1.566	0.127	IS
FBS		91.15	95.48	-4.33	-4.75	11.545	2.010	-2.156	0.039	S
S. Cholesterol		179.88	170.27	9.61	5.34	24.473	4.260	2.255	0.031	S
S. Tryglyceride		160.58	154.91	5.67	3.53	64.00	11.14	0.509	0.615	IS
SGOT		23.42	24.39	-0.97	-4.14	7.431	1.394	-0.750	0.459	IS
SGPT		21.27	23.21	-1.94	-9.12	10.347	1.801	-1.077	0.290	IS

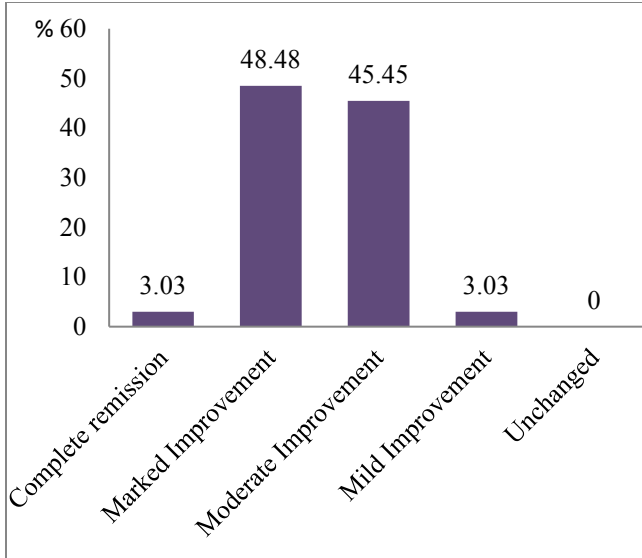


Chart 1: Overall Effect of Therapy

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