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REVIEW ON RASAYANA DRUGS USED IN GERIATRIC CONDITIONS W.S.R. TO MADANPALA NIGHANTU

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ABSTRACT

Rasayana is one among the eight branches of Ayurveda. *Rasayana* drugs are those which destroys *Jara* and *Vyadhi*. *Achary Charaka* enlist the benefit of *Rasayana* longevity of life, retaining youth for longer with maintaining strength of all organs optimally, enhanced intelligence, improve complexion, voice, and allied positive health attributes etc. Proper use of *rasayana* helps body to strengthen in its physiological, anatomical and psychological perspective. This leads to increase and maintenance in the physical and functional capability of the individual for longer period of time. The present review concluded that some *rasayana* drugs given in *Madanpalnighatu* act by general tonic properties to all the systems of body increasing their functional capacity e.g. *Shatavari*, *Ashwagandha* ect. Total 33 drugs are compiled from *Madanpalanighantu* which are quoted for *rasayana chikitsa*. Among them 14 drugs act by *Madhura rasa* while 8 act by *Katu,Tikta rasa pradhanya*, 18 drugs act by *Madhur Vipaka* while 13 drugs act by *Katu Vipaka*. 15 drugs by *Ushna virya* and 16 drugs by *Sheeta virya*.

KEYWORD: *Rasayana, Madanpalnighantu, Virya, Vipaka.*

INTRODUCTION

Jara is a term which indicates the declining phase of life or ageing process. The purpose of Ayurveda is maintenance of *Swasthya* (health) and treatment of the *Aatura* (diseased person).[1]

Practical application of *Rasayana* at both the levels help in serving the purpose. Classification of *Rasayana* in different ways help in understanding its use in different indications. As age progresses we suffer from some loss from time to time. Replenishment of these losses needs use of different rejuvenating agents at different age groups. Use of *Rasayana* also means escalation of *Satva Guna* of mind and that can only be achieved by simultaneous use of *Achara Rasayana*. With advancement in modern sciences, the age old concept is also studied using newer techniques and parameters and is proven to be effective rejuvenator and has added a lot of information. Hence, use of *Rasayana* is for all. It is equally important in treatment of diseases as well as in maintaining health. Use of different medicines as per disease is useful in correcting *Dhatu Vaishamya* and attaining *Dhatu Samya*. *Acharya Sushrut* has described that *Jara* is a natural phenomenon of human body. It is classified as *kalaj Jara* and *akalaj Jara*[2]. *Acharya* By implementing proper lifestyle along with use of *Rasayan chikitsa*, *kalaj jara* can be delayed and *akalaj jara* can be avoided. *Charaka* says properly administered *Rasayana* can bestow the human being with several benefits like longevity, memory, intelligence, freedom from diseases, youthful age, excellence of luster, complexion and voice, optimum strength of physique and sense organs, respectability and brilliance.[3] The average life span of a modern era man is 60 years so the ideal age for administration of *Rasayana* is from 16 to 40 years of life. During *Madhyama vaya* when the metabolic and physio-anatomical changes in the body are at its peak.

OBSERVATION AND DISCUSSION

Classification

(A) Acharya Charaka has been mentioned two types.[4]

- *Kutipravesika* - In such therapy, person will be admitted in *Kuti* and *Rasayana* therapy applied with strict precautions and close monitoring.
- *Vatatapika* - *Rasayana* therapy is administered without strict rules and regulations and exposure of *Vata (*air) and *Atapa*(sun light) are allowed.

(B) Acharya Sushruta has classified into four types.

- *Sarvopaghata Samaniya*[5]- counteracts the disease process.
- *Medhayuskamiya*[6]- increases intellect and prolongs life.

- *Svabhavavaydhi Pratisedhaniya*[7]- delays the onset of *Svabhavika Vyadhi*like *Kshudha, Jara, Pipasa, Mrityu*, etc.
- *Nivritta Santapiya*[8] - rebuilds the physical and mental faculties following their disturbance due to disease process.

1. (C)Three types as per ***Dalhana's*** opinion probably based on the utility of *Rasayana*.[9]

- *Kamya* : which further divided into two:
  - *Pranakamiya* - which increases the life span.
  - *Medhakamya*- which increases the cognitive abilities of mind and
  - *Shreekamya*-which increases the wealth of life.
- *Naimittika – Rasayana* drugs specially indicated for a various diseases like *Shilajatu, Bhallataka, Tuvaraka* etc.,
- *Ajasrika*- particular diets to promote the health and to increase the strength such as daily intake of milk, ghee, etc.

(D) Two types as mentioned by Dalhana based on their mode of action.[10]

- *Samsodhana* – Cure by expelling the aggravated *Dosha*.
- *Samsamana*- Cure by pacifying the accumulated *Dosha*.

For this *rasayana* therapy 33 drugs are noted from *Madanapalanighantu.*[11] They are specifically quoted with the *rasayana* activity. They are as follows:

No.	***Drug***	***Botanical Source***	***Rasa***	***Vipaka***	***Virya***	***Guna***
1	*Haritaki*	*Terminalia chebula Retz.*	*Kashaya Madhura, Amla, Katu, Tikta*	*Madhura*	*Ushna*	*Laghu, Ruksha*
2	*Guduchi*	*Tinospora cordifolia (Willd.) Miers ex Hook.f.&Jhoms.*	*Katu, Kashaya*	*Madhura*	*Ushna*	*Laghu*
3	*Kashmari phala*	*Gmelina arborea Linn.*	*Katu,Tikta,Kashay*	*Madhura*	*Sheeta*	*Guru*
4	*Shalaparni*	*Desmodium gageticum DC.*	*Tikta, Madhur*	*Madhur*	*Ushna*	*Guru*
5	*Jivanti*	*Leptadenia reticulata W.&A.*	*Madhura*	*Madhura*	*Sheeta*	*Snigdha, Laghu*
6	*Rakta Punarnava*	*Boerhavia diffusa L.*	*Tikata*	*Katu*	*Sheeta*	*Laghu*
7	*Ashwagandha*	*Withania somnifera Dunal.*	*Tikta, Kashaya*	*Madhura*	*Ushna*	
8	*Shatavari*	*Asparagus racemosa Willd.*	*Madhura*	*Madhura*	*Sheeta*	*Guru, Snigdha*
9	*Mahashtavari*	*Asparagus sarmentosus Linn.*	*Madhur, Tikta*	*Madhura*	*Sheeta*	*Guru, Snigdha*
10	***Bala Chtushtay*** *Bala Atibala Nagbala Mahabala*	*Sida cordifolia Linn. Abutilon indicum Linn. Grevia hirsuta Sida rhombifolia*	*Madhura*	*Madhura*	*Sheeta*	*Guru*
11	*Vidari*	*Peuraria tuberosa DC.*	*Madhura*	*Madhura*	*Sheeta*	*Snigdha, Guru*
12	*Bakuchi*	*Psoralea corylifolia Linn.*	*Madhura,Katu, Tikta*	*Katu*	*Sheeta*	*Ruksha*
13	*Bringraj*	*Eclipta alba Hassk.*	*Katu,Tikta*	*Katu*	*Ushna*	*Ruksha*
14	*Ativisha*	*Aconitum heterophyllum Wall.*	*Tikta*	*Katu*	*Ushna*	-
15	*Kakamachi*	*Solanum nigrum Linn.*	*Tikta, Katu*	*Katu*	*Ushna*	*Snigdha*
16	*Vriddhadaru*	*Argyreia speciosa Sweet.*	*Kashaya, Tikta*		*Ushna*	

17	*Somvalli*	*Ephedra gerardiana Wall.*	*Katu,Tikta*	*Katu*	*Ushna*	-
18	*Mushli*	*Curculigo orchioides Gaertn.*	*Madhur, Tikta*	*Madhra*	*Ushna*	*Guru*
19	*Shankhapushpi*	*Convolvulus pluricaulis Chois.*	*Kashaya*	*Katu*	*Ushna*	-
20	*Brahmi*	*Bacopa monnieri Linn.*	*Tikta, Madhur*	*Madhura*	*Sheeta*	*Sara, Laghu*
21	*Mandukparni*	*Centella asiatica Linn.*	*Tikta, Madhur*	*Madhura*	*Sheeta*	*Laghu, Sara*
22	*Kumari*	*Aloe vera Linn.*	*Tikta, Madhura*	*Katu*	*Sheeta*	
23	*Pippali*	*Piper longum Linn.*	*Katu*	*Madhura*	*Atyushna*	*Laghu, Snigdha*
24	*Guggula*	*Commiphora mukul Engl.*	*Madhra, Tikta*	*Katu*	*Ushna*	*Sukshma, pichhila, Sara*
25	*Tilaka*	*Wendlandia exerta DC.*	*Katu*	*Katu*	*Atyushna*	-
26	*Pilu*	*Salvadora persica Linn.*	*Madhur, Tikta*		*Ushna*	*Laghu*
27	*Bijaka (Vijaya sara)*	*Pterocarpus marsupium Roxb.*	*Katu*	*Katu*	*Sheet*	-
28	*Shalmali*	*Bombax malabaricum DC.*	*Madhura*	*Madhura*	*Sheeta*	*Snigdha*
29	*Rasona*	*Alium sativum Linn.*	*Katu,Tikta,Kashay, Lavana, Madhura*	*Katu*	*Ushna*	*Tikshna, Snigdha, Guru, Sara*
30	*Varahi*	*Tacca aspera Roxb.*	*Madhura, Tikta*	*Katu*	*Ushna*	-

Among these categorization is done according to Rasa, Virya and Vipaka as follows:

No.	Categories	Observations found
1	*Rasa*	14 drugs with *Madhura rasa pradhanya* 8 drugs with *Katu Rasa pradhanya* 8 drugs with *Tikta Rasa pradhanya* 3 drugs with *Kashaya Rasa pradhanya*
2	*Virya*	16 drugs with *Sheeta virya* 15 drugs with *Ushna virya* 2 drug with *Atyushna virya*
3	*Vipaka*	15 drugs with *Madhura vipaka* 13 drugs with *Katu vipaka* 2 drugs *Vipaka* is not mention

Dashemani which can be correlated with *rasayana* therapy is coated below and drugs from above list which are included in these *dashemani* are as follows

No.	***Dashemani***	**Drugs from *Madanpalanighantu* for *Rasayana* therapy**
1	*Jeevaniya*[12]	*Jivanti*
2	*Balya*[13]	*Ashwagandha*
3	*Virechnopaga*[14]	*Haritaki*
4	*Sangyasthapana*[15]	*Brahmi, Guggula*
5	*Vayasthapana*[16]	*Guduchi, Haritaki, Jivanti, Shalaparni*
6	*Shoolaprashamana*[17]	*Pippali*

According to *Agrya aushadhi* quoted in Brihatrayi

No.	Drugs from *Madanpalanighantu* for *Rasayana* therapy	*Agrya* (*Charaka Sanhita sutrasthana*)[18]
1	Haritaki	*Pathyanama*
2	Shalaparni	*Vrishya Sarvadoshaharanama*

Few drugs are *Rasayana* by acting on particular system/organ which decreases the symptoms of *Jara* reported in classics are such as

No.		Drugs	Mode of action
1	*Medhya*	*Shankhapushpi* *Guduchi* *Brahmi* *Haritaki* *Shatavari* *Vidari*	*Medhya* action is considered as *Prabhava*. These drugs increase power of acquisition, retention and recollection.
2	*Sangyasthapana*	*Brahmi*	The drug which will restore the lost conciousness. *Brahmi* by its *Madhura rasa*, *sheeta virya* helps in development of *dhatus* and mainly nourishes *Majja dhatu* ultimately resulting in *sangysthapana*.
3	*Vedanasthapana*	*Guggulu*	The drug which is used to remove the pain of a particular part of the body and which restores normal state. Vitiation of *Vata Dosha* is main factor for *Vedana* so for relieving pain drug should poses *vata doshaghna* property. Here *guggula* acts *vataghna* by its *ushna virya*.
4	*Chakshushya*	Shatavari Jivanti	Drugs which keep the eyes in natural state. Shatavari with its *Madhura rasa*, *sheeta* and *snighdha guna* acts as *chakshushya*.
5	*Vrishya*	Shatavari Ashwagandha Pippali Rasona Gambhari phala Vidari Varahi Mushali Kakamachi Shankhapushpi	Drugs with Madhura rasa, Sheeta virya acts as Vrishya. According to Sharangdhara Ashwagandha, Shatavari, Mushali are ***Shukrala*** which acts on spermatogenesis. Brihati phala is ***shukra rechaka*** helps in emission and ejaculatiory disorders.

Few drugs acts *Rasayana* by *Dhatukara* action as follows

No.	***Dhatus***	Drugs	Mode of action
1	*Rasa*	Shatavari Guduchi Jivanti	Drugs having *Madhura rasa, sheeta virya* tend to be *rasa dhatu vardhaka.*
2	*Rakta*	Guduchi, Bakuchi	Acts *rakta-prasadana* by *Pitta dosha shamana* with the help of *Tikta,Madhura rasa*
3	*Mamsa*	Ashwagandha Rasona	Drugs by *snigdha, guru gunas* and more *parthiva ansha* acts as *mansa vardhaka.*
4	*Meda*	Naveena Guggulu	Diminishes the vitiated *Kapha dosha* and *Kleda*, improves proper *dhatu* production.
5	*Asthi*	Rasona Guggulu	Acts as *Bhagna-sandhaneeya.*
6	*Majja*	Bramhi Shalmali	By its *Madhura rasas* and *snigdha guna* with *jaleeya* properties acts as *majja vardhaka.*
7	*Shukra*	Ashwagandha	Acts as *vajikara*.

*Prakriti*wise Suitable *Rasayana:*

- ***Vataja*** *-- Bala, Nagbala*
- ***Pittaja*** *-- Shatavari*
- ***Kaphaja****-- Guggulu, Pippali*
- ***Manasa*** *--Ashwagandha, Shankhapushpi, Brahmi*

Research activities of these drugs

	Immunomodyulators	**Antioxidant**	**adaptogenic**	**Antistress**
1	Guduchi	Guduchi	Ashwgandha	Brahmi
2	Jivanti	Jivanti	Mandukparni	Mandhkparni
3	Ashwgandha	Gambhari	Guduchi	Ashwgandha
4	Shtavari	Ashwgandha	Shtavari	Punarnava
5	Kumari	Punarnava	Pippali	Shankhpushpi
6	Pippali	Shtavari	Haritaki	
7	Bhrigraja	Shankhpushpi		
8		Guggulu		

In this way *rasayana* can be considered as:

- *"Medhya rasayana*"(e.g.Shankhapushpi, Brahmi etc.)
- "*Doshaghna rasayanas*(e.g. Haritaki, guduchi etc.)
- "*Dhatu rasayanas*"(e.g. Ashwagandha, rasona etc.). Which can be further categorised as:
- Rasayana for system.
- Rasayana for Dhatus.

These 33 drugs quoted as *'rasayana'* from *Madanpalanighantu* are repeated in *Dashemani* and *Agrya aushadhi* relating to the *rasayana* therapy. Also research works reveals that some drugs i.e. Shatavari and Bramhi pocesess the anti-ageing properties.

CONCLUSION

- *Jara* is an inevitable phenomenon of life characterized by decreased functional capability of all the systems of the body.
- *Rasayana* is a therapy which establishes the age (*Vayasthapana*), increases the life span (*Ayushkara*), intellegence (*Medha*) and Strength (*Bala*) as well as it enables the person to get rid of the diseases
- *Akalaja jara* can be prevented by application of *rasayana chikitsa* and following *dinacharya* and *rutucharya* mentioned in Ayurveda.
- Total number of 33 drugs are mentioned in *Madanpala Nighantu* having *Rasayana* properties.
- Most of the *rasayana* drugs are of *madhura rasa* and *sheeta veerya* having *guru, snigdha gunas*.
- *Rasayana* drugs acts on *Agni*, *Doshas* and *Dhatus* to exhibit its pharmacological properties. For e.g. *Pippali* acts on *agni*, *Haritaki* acts on *doshas* and *Shatavari* on *dhatu*.

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CLINICAL EVALUATION OF *NIDRAJANANA KARMA*(SEDATIVE ACTIVITY) OF *BIJAPURADI*YOGA W.S.R. TO *ANIDRA*(INSOMNIA)

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ABSTRACT

Introduction: *Anidra* is very comman disease in present era. Today's man has become a part of tired and chronically sleep-deprived generation. Clinical study on *individual Bijapura, Ashawagandha, Pippalimula* and *Jatamansi* has been done and these drugs have proved to have effect on *Anidra*(insomnia), thus present study has been carried out to evaluation the combination of these drugs i.e. *Bijapuradi Yoga* and *Bhavita Bijapuradi Yoga*(three *Bhavanas* of *Bijapura Patra Swarasa*) these are *Anubhuta Yoga* **Aim:** Patients suffering from *Anidra*(Primary Insomnia) were selected to clinically evaluate the efficacy of the test drugs i.e. *Bijapuradi Yoga(BY)* and *Bhavita Bijapuradi Yoga(BBY)*. **Materials and Methodos:** In this present clinical study, total 40 patients were registered and randomised in to two groups A and B. 5g of powder of *Bijapuradi Yoga*(*BY)* and *Bhavita Bijapuradi Yoga*(*BBY)* with Lukewarm water (*Sahapana*/vehicle) was administered orally at half an hour before bed time once at night for 4 weeks in group A and Group B respectively In **Result:** There was statistically significant improvement in all main symptoms in both group. Excellent improvement was found in group A i.e.72.22% and Group B 78.94%. **Conclusion:** *Bijapuradi* and *Bhavita Bijapuradi Yoga* is safe and effective formulation in the management of Anidra(insomnia).

KEYWORD: Anidra, *Bijapuradi Yoga*, *Bhavitabijapuradi Yoga.*

INTRODUCTION

Ayurveda is one of the most ancient medical sciences of the world; advocates a complete promotive, preventive, and curative system of medicine. Ayurveda treats the patient as a whole rather than treating his ailment as separate entity. *Ahara* (diet), *Nidra* (sleep) and

Brahmacharya (celibacy), are mentioned as three *Upastambhas* (sub-supporting pillars) which play an important role in maintaining the health.[1]

The inclusion of *Nidra* in three *Upastambha* proves its importance. While discussing about *Nidra*, it is stated that happiness & sorrow, growth & wasting, strength & weakness, virility & impotence and knowledge & ignorance as well as the existence of life and its cessation depend on the sleep. *Aswapna* is one of *vata nanatmja vikara.*[2]

The modern medical science is still not having a definite treatment for insomnia. Although hypnotics, sedative, anxiolytic, psychotropics are evolved they have got their own limitations because of their hazardous adverse effects. Such modern anxiolytic drugs have limited application due to their addiction, resistance and producing variety of neuro- endocrine and hepatic side effects. Therefore, such agents cannot be safe for a long period[3]. Hence, it becomes imperative to search out the drugs which are safe and effective from natural systems of medicine like Ayurveda which can help patients of insomnia.

This clinical study is to evaluate the role of *Bijapuradi Yoga* and *Bhavita Bijapuradi Yoga* in the management of *Anidra* with special reference to Primary Insomnia. Till now no work has been carried out to evaluate the action of *Bijapuradi* and *Bhavita Bijapuradi Yoga* in the management of *Anidra*. The individual work of the ingredient of these Yoga was done, so this study is done for evaluate the efficacy of combination of *Bijapura* (*Citrus medica* Linn.), *Ashwagandha* (*Withania somnifera*Dunal.), *Pippalimula*(*Piper longum* Linn.) and *Jatamansi*(*Nardostachys jatamansi* DC.)

According to *Charak* samhita, *Sanskar* means imparting other properties in natural product. This properties are infused by several process and *Bhavna* is one of them. In this study three Bhavanas were given to Bijapuradi Yoga by *Bijapoora parta Swarasa* to evaluat the efficacy of *Yoga*.

MATERIAL AND METHODS

For this clinical trial, patients fulfilling the inclusion criteria of Insomnia and willing to participate from Out-patient and In-patient of *Dravyaguna* Department and referred from other Department, IPGT&RA hospital, GAU, Jamnagar were registered. The research protocol was approved by Institutional Ethics Committee (No.- PGT/7/-A/Ethics/2015-16/1470.) and registered in Clinical Trial Registry of India with No. CTRI/2016/03/006740.

An informed consent form each enrolled patient was obtained before commencement of the treatment.

Inclusion criteria

1. Age between 18 -70 years, of either gender.
2. Primary Insomnia like Insomnia without Identifiable Cause and Psycho-physiologic Insomnia.
3. Fresh patients of Insomnia who are not addicted to drugs were included.

Exclusion criteria

1. Patients below 18 and 70 years of age.
2. Patients suffering from chronic Insomnia who were addicted to sedative medications and taking any drugs possessing sedative effect were excluded. Patients of *Rajyakshma, Unmada* or *Apsmara*,
3. Secondary Insomnia like Transient Situational Insomnia, Insomnia Associated with Neurological Disorders, Mental Disorders, Drug or Alcohol-Dependent Insomnia.
4. Patient with systemic uncontrolled disease – like type I or II diabetes, hypertension etc were also excluded.

Grouping and Posology

The 20 patients were included in each group of study based on a special Performa.40 patients randomized into 2 groups with flipping coin randomization method. Group A and B label where A label represents the patients treated by *Bijapuradi Yoga* and B label includes patients treated by *Bhavita Bijapuradi Yoga*. During the intervention, Patients of Group A were given 5g. *Bijapuradi Yoga Churna* form mixed with *Anupana* lukewarm water and patients of group B were treated by *Bhavita Bijapuradi Yoga Churna* with same dose and *Anupana* for four week.

Investigations

Following investigations will be carried out to rule out any other pathology and to rule out the adverse effects of drug.

- Complete blood count
- Urine: Routine and microscopic examinations.

These investigations were done (BT&AT)

Criteria for assessment

Improvement in condition was assessed on the basis of changes in scoring pattern developed for grading these clinical factors.

1	Sleep induction (time it takes you to fall asleep after turning-off the lights)	
	– No problem – Slightly delayed (1/2 to 1 hour) – Markedly delayed (1 to 2 hours) – Very delayed (more than 2 hours) or did not sleep at all	0 1 2 3
2	Awakenings during the night	
	– No problem (Not at all) – Minor problem (Total hour of awaking is in between ½ to 1 hours) – Considerable problem (Total hour of awaking is in between 1to 2 hours) – Serious problem(Total hour of awaking is more than 2 hoursor did not sleep at all	0 1 2 3
3	Final awakening earlier than desired	
	– Not earlier – A little earlier (1/2 to 1 hour) – Markedly earlier (1 to 2 hours) – Much earlier (more than 2 hours) or did not sleep at all	0 1 2 3
4	Total sleep duration	
	– Sufficient (more than 6 hours) – Slightly insufficient (5 to 6 hours) – Markedly insufficient (3 to 5 hours) – Very insufficient (less than 3 hours) or did not sleep at all	0 1 2 3
5	Overall quality of sleep (no matter how long you slept)	
	– Satisfactory – Slightly unsatisfactory – Markedly unsatisfactory – Very unsatisfactory or did not sleep at all	0 1 2 3
6	reduced motivation	
	– None or mild – Moderate or severe difficulty	0 1
7	making errors or having accidents	
	– None or mild – Moderate or severe difficulty	0 1
8	Irritability or mood disturbance	
	– None or mild – Moderate or severe difficulty	0 1
9	Tandra (daytime attention, concentration, or memory problems)	
	– None or mild – Moderate or severe difficulty	0 1
10	Jadya (daytime fatigue)	
	– None or mild	0

	– Moderate or severe difficulty	1
11	Shirogourava (tension headaches)	
	– None or mild – Moderate or severe difficulty	0 1
12	Apakti(digestive problems)	
	– None or mild – Moderate or severe difficulty	0 1
13	Angamarda (Body ache)	
	– None or mild – Moderate or severe difficulty	0 1
14	Jrumbha (Yawning)	
	– None or mild – Moderate or severe difficulty	0 1
15	Bhrama (Giddiness)	
	– None or mild – Moderate or severe difficulty	0 1
16	Glani (Nervousness)	
	– None or mild – Moderate or severe difficulty	0 1
17	worried or distressed about sleep problems – None or mild – Moderate or severe difficulty	 0 1
18	sleep problems interfered with home management	
	– None or mild – Moderate or severe difficulty	0 1
19	sleep problems interfered with ability to work	
	– None or mild – Moderate or severe difficulty	0 1
20	sleep problems interfered with social life	
	– None or mild – Moderate or severe difficulty	0 1
21	sleep problems interfered with close relationships	
	– None or mild – Moderate or severe difficulty	0 1
22	No. of days 0 1 2 3 4 5 6 7	
23	No. of days 0 1 2 3 4 5 6 7	

Special clinical proforma was designed to record the demographic data, history of present illness, personal history, examination of *Dashavidh-bhava* and change in assessment parameters.

Overall percentage of improvement

After the completion of treatment the total effect of therapy was assessed in following

categories.

- <10 % - No improvement.
- >10-<40 % - Mild improvement.
- >40-<70 % - Moderate improvement.
- >70-100 % - Excellent improvement.

Presentation of data and Statistical analysis

The epidemiological data of patients and information about primary Insomnia collected and compiled from clinical trial were presented with tabular form in terms of Mean, Standard Deviation (±SD) and Standard Error (±SE).

To find out individual effect of therapy, paired non-parametric data of before and after treatment was analysed by Wilcoxon singed rank test and for comparison of the effect between the therapies, unpaired non-parametric data was analysed by Mann Whitney rank sum test. Test was performed by using SigmaStat 3.1software.

The obtained results were interpreted as:

Insignificant $p > 0.05$

Significant $p \leq 0.05$

Highly significant $p \leq 0.01$

Highly significant $p \leq 0.001$

OBSERVATION

Total 60 patients were screened, among them, 40 were registered and randomlyallocated into group A (n=20) and B (n=20). Among totally excluded patients, 25% of patients were excluded due to transient situational insomnia, 15% due to insomnia associated with mental disorders 20% insomnia associated with medical disorders and 25% due to systemic uncontrolled diseases. 2 patients were dropped out in group A and 1 in group B. personal problem, family problem and concomitant other sedative drugs during trial were the reasons for drop out.

25% patients were belonged to 41-50 years age group and 22.5% patients were belonged to 51-60 years age group which indicates that incidence of primary insomnia is a high in middle-aged and older adults. Maximum patient (70%) were female, 95% were Hindus, 85% patients were married, , 27.5% patients had only primary and secondary education, 50%

patients belonged to lower-middle socio-economical status and 52.5% were house wives. In maximum patients (77.5% and 82.5) disease developed gradually and progressively respectivly. *Vata* aggravating life style and middle-old age (25%) and menopause (30%) were found as causative factor. 50 % patients had taken any kind of treatment for current problem. Maximum (62.12%) patients had *Madhyama Jatharagni*. 60% had *Madyama Kostha,* 80% patients were preferring *Katu* taste in food.

RESULTS

Result of *Bijapuradi Yoga* (group A)

Bijapuradi Yoga administered for 4 weeks, reduce three of the major symptoms of insomnia highly significantly (P <0.001) i.e. sleep induction(P <0.001), awakening during the night and final awakening earlier than desired(P<0.001), resulting in highly significant improvement of total sleep duration and overall quality of sleep. This result indicates that *Bijapuradi Yoga* may be used both for early insomnia in which sleep induction is a prominent complaint and also in chronic insomnia with complaint of poor sleep quality.

Associated symptoms like reduced motivation(P=0.002), irritability or mood disturbance(P<0.001), *Tandra*(P=0.004), *Shirogaurava*(P<0.001), *Apakti*(P<0.001) , worryor distress due to sleep problems(P=0.002), sleep problems interfered with home management(P=0.008), disturbed nights per week(P<0.001), sleep problems affecting their private life(P<0.001) relief was provided by *Bijapuradi Yoga* which was statistically highly significant(P<0.001). other associated symptoms like making errors or having accidents(P=0.016) and Jadya(P=0.016) was observed statistically significant. Test drug did not improve *Angamarda*, *Jrumbha*, *Bhrama* and *Glani*, sleep problems interfered with ability to work, sleep problems interfered with social life and close relationship these associated symptoms was statistically insignificant

Result of *Bhavita Bijapuradi Yoga* (group B)

In *Bhavita Bijapuradi Yoga* group significant result was observed in symptoms such as late sleep induction (P<0.001), awakenings during the night (P<0.001) and thereby total sleep duration (P<0.001) and overall quality of sleep (P<0.001) improved highly significantly. Early awakening in morning (P=0.016), Associated symptoms like reduced motivation (P<0.001), making errors or having accidents (P<0.001), irritability (P<0.001), *Tandra* (P=0.002), *Jadya* (p=0.002), *Shirogourava* (P=0.002), *Apakti* (P<0.001), *Bhrama*(P<0.001), *Glani*(P<0.001)have also improved highly significantly. But drug was unsuccessful to

improve sleep problems interfered with home management, sleep problems interfered with ability to work, close relationship.

Comparison

Comparing the effect of treatments on the individual symptoms and associated symptoms of insomnia, the difference was found statistically insignificant between both the groups. By this, we can state that *Bijapuradi Yoga* exhibits result similar to *Bhavita Bijapuradi Yoga.*

Overall effect of therapies

In *Beejapuradi Yoga* group, Excelent improvement was found in 72.22% of patients, moderate improvement and mild improvement was observed in 11.11% of patients. 5.55% of patients have remained unchanged after completion of treatment.

In *Bhavita Bijapuradi yoga* group, 78.94%, 10.52% and 5.26% of the patients experienced excelent, moderate and mild improvement respectively. 5.26% of Patients have remained unchanged after completion of treatment.

DISCUSSION

Diagnostic criteria

The Diagnostic and Statistical Manual of Mental Disorders (DSM), published by the American Psychiatric Association, offers a common language and standard criteria for the classification of mental disorders. It describes a few global Insomnia diagnoses and relies primarily on clinical interview. The DSM-IV is the only diagnostic manual that uses the term 'Primary Insomnia', and this disorder requires three characteristics: (1) poor sleep for at least 1 month, (2) the sleep disturbance causes clinically significant daytime impairment, and (3) this problem cannot be better explained by another mental or physical condition, or substance use.[4] DSM is the official diagnostic system for mental disorders in the US.[5] DSM has been praised for standardizing psychiatric diagnostic categories and criteria. Reliability and validity of these criteria is high.[6] Therefore, for the present study, these criteria were selected to diagnose the patient of primary Insomnia for clinical study.

Insomnia and age

Observations of some previous studies stated that Insomnia becomes more chronic with increasing age.[7] A high rate of Insomnia is seen in middle-aged and older adults.[8,9] Progressive inactivity, dissatisfaction with social life, and presence of medical and

psychiatric illness can be most prognostics of Insomnia in old age. Data in present study also substantiate that the prevalence of Insomnia gradually increased with advancing age, from 15% in younger adults (18–30 years), up to 25% among the middle age (41-50 years).

Old age is *Vata* predominant age and *Rajas* is mainly related with *Vata*. These mental and physical factors play important role in the pathogenesis of *Anidra.* Changes in sleep physiology associated with old-age play a significant role in the marked increase of prevalence of Insomnia in old-age. Observations of this study also support this view.

Insomnia and gender

In present study maximum patient were female(70%) and male patients were (30%).Recent 2005 NSF *Sleep in America* poll of all adults revealed that women are more likely than men to have difficulty falling and staying asleep. Biological conditions unique to women, like the menstrual cycle, pregnancy and menopause, can affect how well a woman sleeps. This is because the changing levels of hormones that a woman experiences throughout the month and over her lifetime, like estrogen and progesterone, have an impact on sleep.[10] Although there are different researchers proved that women have the higher rate of Insomnia compare to male while Insomnia is correlated with both stress and depression, most of the samples are focused on western countries only.

Insomnia and menopause

In the present study, it is observed that among the female patients suffering from Insomnia majority of patients belonged to menopausal age(46.42%). In elder women, sleep can be affected by many factors, such as hormonal and lifestyle changes. During the course of peri-menopause, ovaries gradually decrease production of estrogen and progesterone, a sleep-promoting hormone[11]. Many previous studies showed that the prevalence of Insomnia increased with menopause. Because, during menopause, waning levels of estrogen may make more susceptible to environmental and other stressors which disrupt sleep.

Insomnia and Religion

Maximum patients registered for the present study (95%) were Hindus, which is due to the dominancy of Hindu population in this area and has nothing to do with the prevalence of Insomnia in this particular group of reported people.

Insomnia and Education and Occupation

Data of present study illustrates that maximum number of the patients (27.5%) had primary education or secondary school education.17.5% were graduate. The present study reveals that maximum numbers (52.5%) of the patients were housewives, followed by 15% businessmen and 12.5% serviceman. This reflects that high level of physical or mental stress, strain with responsibilities which causes stress and thus Insomnia has become more common in housewives. It is reported that stress is also one of the major causative factors ofInsomnia. Especially when family had a negative attitude toward the patient it may act as a stressor and enhance the psychic symptoms found in Insomnia.

Insomnia and Marital status

The data in the present study indicates that the majority of the patients i.e. 75% were married. Among the patients, 13.33% were unmarried and 11.67% were widow/widower. This may be because of maximum patients were from middle and old aged group. The relationship between sleep complaints and marital status has not received much scientific attention.

Insomnia and Socio-economic status

The present study shows that maximum number of patients i.e. 50 % were from lower middle class, while 40% from middle class. The middle class people may have more struggles in life, hence Insomnia dominates.[12] The data of present study also suggest that lower socioeconomicstatus was associated with higher rate of sleep disturbance.

Insomnia and *Agni* & *Koshtha*

Majority of the patients of the present clinical trial were having *Mandagni*(45.5%) or *Vishamagni*(45.5%) and *Madhyama*(60%) or *Krura Koshtha*(35%), and thus suffered from poor appetite and unsatisfactory bowel habit. *Vishamagni* and *Krurakoshtha* are associated with increase or vitiation of *Vata* which further make the individual prone to *Anidra*. Proper sleep helps for normal digestion and excretion.

Some studies supported classical opinion that poor state of *Agni* is associated with sleep complains. A study has reported that irritable bowel syndrome, indigestion, and heart burn are top co-existing conditions seen among people with Insomnia.[13]

Insomnia and Exercise & Sedentary life style

Maximum, 62.5% patients were not performing any kind of physical exercise, and were

leading a sedentary life. Doing no physical exertion results in the feel that there is no need for rest, and thus may lead to sleeping difficulties which can later result into Insomnia. Further, sedentary lifestyle leads to obesity and as the degree of obesity increases the incidence of sleep disturbances also rises. This association might be a by-product of sleep apnea, which is related to obesity and is also a risk factor for Insomnia.

Insomnia and Addiction

Sleep may be negatively affected by a number of specific behaviors, including drinking caffeinated beverages, smoking, drinking alcoholic beverages.[14,15] Maximum number of patients (100%) studied were having addiction of tea, followed by tobacco (15%), Pan (7.5% each), Beedi(2.5%) and and coffee (2.5%). Tea contains caffeine and small amounts of theobromine and theophylline, which are stimulants[16]. Excessive caffeine can cause Insomnia. A 2005 National Sleep Foundation poll found that people who drank four or more cups/cans of caffeinated drinks a day were more likely than those who drank zero to one cups/cans daily to experience at least one symptom of Insomnia and at least a few nights each week.[17]

Insomnia and *Prakriti*

Data showed that *Vatapradhana-Pitta Prakriti* was observed in maximum (60%) patients. Generally person who has *Vata Prakriti* gets poor quality of sleep due to *Chala Guna* of *Vata Dosha,* hence this *Prakriti* individuals are more prone to Insomnia.[18] *Vatadosha* reflects *Rajasaguna* and various emotional factors related with *Rajoguna* keep the *Manas* in over active condition which cause either delayed or lesser sleep duration. This gives evidence that *Vata* dominant *Prakriti* persons are at risk to suffer Insomnia.

Dasha Viddha Pariksha

Data of present study shows that majority of the patients (82.5 %) had *Madhyama Sara*, *Madhyama Samhanana* (90%), and *Madhyama Pramana* 70%. *Sara, Samhanana* and *Pramana* reflect the nourishment and constitution. Role of sleep in growth and nourishment is very important. Majority of patients having *Madhyama Sara* and *Samhana,* indicates disturbed status of nourishment, which may have indirectly resulted due to *Mandagni or Vishamagni* status causing poor status of appetite. Maximum patients (68.33%) had *Madhyama Satmya* followed by *Avara Satmya* (25%). Maximum number of patients had *Avara Sattva* (52.5%) followed by 47.5 % patients who had *Madyama Sattva*. *Charaka* has mentioned that a person having *Madhyama* and *Avara Satva* are more vulnerable to diseases

which is supported in this study. *Avara Sattva* persons will have unsteady mind and they are unable to control *Manovikaras* like *Kama, Kroda etc.* These *Vikaras* further vitiate the mind and provokes *Rajas* and *Tamas* which leads to psychological disorders. Insomnia may be due to this psychological disorders or direct vitiation of *Rajas* and *Tamas.* Maximum patients (82.5%) had *Madhyama Abhyavaharana Shakti* followed by (17.5%) *Avara Abhyavaharana Shakti.* Whereas 75% patients had *Madhyama Jarana Shakti* followed by (25%) *Avara Jarana Shakti.* This shows that Insomnia also effects on *Annavaha Srotas* and cause either poor appetite or indigestion. The 72.5% patients had *Madhyama Vyayama Shakti*, while 27.5% had *Avara Vyayama Shakti*. Due to abnormal sleep, working capacity and performance decreases resulting into poor physical work.

Mode of action

Ingredients of this drug formulations are *Bijapura, Ashwagandha, Jatamamsi* and *Pippalimula.* As a Ayurvedic view vitiation of *Vata and Pitta* is the most important factors of *Anidra*, where these drugs might help in the *Samprapti Vighatana* by its *Vatapittahara* property as the *Bijapura* has *Deepana, Pachana and Vatakaphashamaka* properties, *Ashwagandha* has *Balya, Brihamana, Mastishkshamak* property due to its *Snigdha Ushna Guna* and *Vatashamak* properties, *Pippalimula is Dipana, Pachana, Anaha Prasamanana and Vatanulomana* and *Jatamansi* has *Pittashamaka* properties. All over these formulation is *Vata-pitta shamaka*. Is also clear the digestive problem like *Adhmana, Apachana* because the site of action of *Bijapura* and *Pippalimula* is *Amashaya* and *Pakvashya,* one of the cause of insomnia is also indigestion so *Bijapura* and *Pippalimula* have resolved thus, the site of action of *Ashwagandha* and *Jatamansi* is *Manovaha Srotasa*. Thus these drugs regulates *Prana-Apana Gati* and *Manovah Shrotasa* Hence these were found effective in management of *Anidra* (Insomnia). Thus, according *Ayurvedic* principles, mode of action of drug can be concluded that *Bijapuradi Yoga and Bhavita Bijapuradi Yoga* acts on *Anidra* by specific potency of sleep induction (*Nidrajanaka Prabhava*), when administrated by oral route (*Aushadhmarga*) during night time (*Ratri-kala*).

In the modern pharmacology the drug action is quite often correlated with its chemical structure or active principle. Approved hypnotic drugs have clearly shown to improve subjective and objective sleep measures in various Insomnia situations.[19]

Probable mode of action of *Bijapura* leaves is alkaloids and essential oils might be responsible of sedative and CNS depressant activities of *Citrus medica* leaves by acting on

the $GABA_A$ receptor complex. *Ashwagandha* is proved sedative, anxiolytic, antidepressant, and antistress, adaptogen. *Ashwagandha* produces gamma-aminobutyric acid (GABA)-like activity, which may account for the herb's antianxiety effects. GABA is an inhibitory neurotransmitter in the brain. Its function is to decrease neuron activity and inhibit nerve cells from over firing. This action produces a calming effect. Excessive neuronal activity can lead to restlessness and Insomnia, but GABA inhibits the number of nerve cells that fire in the brain, and helps to induce sleep, uplift mood, and reduce anxiety.[20] The standardized extract of *Ashwagandha* was proved effective on the negative effects of stress; it increases energy, reduced fatigue, better sleep, enhanced sense of well-being, and reduction of cortisol levels up to 26%. *Ashwagandha* can address many of the health and psychological issues that plague today's society.[21] By considering these facts only *Ashwagandha* was selected as a trial drug in the present study formulation. Jatamansone (Valeranone), active ingredient of *Jatamansi* rhizome, was reported to have sedative and tranquilizing activities by Arora *et al* in 1963.[22] Its administration has a similar behavioural effect to that of benzodiazepine. Jatamansone may enhance the effect of the neurotransmitter gamma-aminobutyric acid (GABA) at the $GABA_A$ receptor.[23] *Pippalimula* has piperine and piplartin which are knownto have sedative effects. Probable mode of action of *Pippalimula* is that alkaloids like piperine and essential oils might be responsible of sedative and CNS depressant activities of *Piper longum* Linn root by acting on the $GABA_A$ receptor complex.

Mode of action of *Bijapuradi Yoga*

Bijapura, Ashwagandha, Jatamansi and *Pippalimula* is well proven for its chemical constituents which have sedative activity and *Prabhava* on *Anidra* as a *Ayurvedic* view mention as above, thus the combination of these drugs is useful to manage the *Anidra* due to its *Nidrajnana Karma.*

Mode of action of *Bhavita Bijapuradi Yoga*

The ingredients are same but three *Bhavanas* were given by *Bijapura Patra Swarasa*. So mode of action of this *Yoga* is same as *Bijapuradi Yoga* but *Bhavana* with *Bijapura Patra Swarasa* improves the bioavailability of drugs thereby enhances their rate of absorpation.

But statistically there are no difference in both group because of the patients enrolled in Group-B is more chronic and second cause *Bijapura Patra* is may be effective in patients who are suffering from digestive problem but not in psychological problem.

CONCLUSION

Clinical study suggested that *Bijapuradi Yoga and Bhavita Bijapuradi yoga* highly significantly decreased the all major symptoms on patients of primary insomnia. Associate symptoms like *Angamarda*, *Jrumbha*, *Bhrama* and *Glani*, sleep problems interfered with ability to work, sleep problems interfered with social life and close relationship these associated symptoms was statistically insignificant in Group-A(BY) and Group-B(BBY) was unsuccessful to improve sleep problems interfered with home management, sleep problems interfered with ability to work, close relationship. In a nut shell, excellent improvement (72.22%) was exhibited by *BY* in comparison to excellent improvement (78.94%) exhibited by *BBY* which indicates that *Bhavita Bijapuradi Yoga* is relatively effective to *Bijapuradi Yoga* in the management of primary insomnia.

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