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Evaluation of Clinical Study to Compare Efficacy Between *Mamsyadi Kwath* and *Takradhara* in *Nidranasha* w.s.r to Primary Insomnia

Raviprasad Hegde¹

¹Associate Professor, Department of Manovijnana evum Manasaroga, Alva's Ayurveda medical college, Moodubidire – 574227(India)

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Address for Correspondence:

Dr. Raviprasad Hegde, Associate Professor, Department of Manovijnana evum Manasaroga Alva's Ayurveda medical college, Moodubidire – 574227(India)
Email: raviprasadhegde@gmail.com

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ABSTRACT

Evaluation of clinical study to compare the efficacy between *Mamsyadikwath* and *Takradharain Nidranasha* w.s.r to primary insomnia was applied in 30 patients. Both types of treatments gave a significant result in the patients suffering from primary insomnia, objective parameters like Pulse rate, Respiratory rate, and Blood Pressure, *Nidranasha Lakshana*, and assessment criteria like Insomnia Screening Questionnaire and Visual Analogue Scale. But statistically, *Takradhara* provided more results when compared to the *Mamsyadi Kwatha* in initiating the sleep, increasing the duration of the sleep, reducing the time of disturbed sleep, reducing the Systolic as well as Diastolic Blood Pressure, reducing the *Nidranasha Lakshana* like *Jadya* and assessment criteria Visual Analogue Scale.

Keywords: *Mamsyadi Kwatha*, *Mustasadita Takradhara*, *Nidranasha*.

INTRODUCTION

Nidrakshaya, *nidrabhanga*, *nidrabhramsa*, *vigatanidra*, and *Nashtanidra*¹ are a few of the synonyms of *nidranasha*, shares a lot of similarities with primary insomnia. In *nidranasha*, *shariradosha vata* and *mano dosha rajas* and *thamas* play an important role. According to *Hathayoga Pradeepa*, there is a relationship between *vata* and *manas*². As *vata* and *manas* are interrelated if one is vitiated the other gets adversely affected.

The prevalence of insomnia is approximately 10%, with a 2:1 ratio of women to men. The prevalence of primary insomnia is approximately 1%. The prevalence of primary

insomnia increases with age³. Chronic insomnia leads to a lot of societal consequences and has a history of morbidity associated with chronic insomnia and even a degree of mortality⁴. One of the few research works that are carried out in different institutions using diverse designs of the study is as follows. A Comparative Clinical Study on *nidranasha* resulted in complete remission in 14.3% of patients in the *taila dhara* group while it was 8.3% in the *jala dhara* group⁵. *Takra Dhara*⁶, as an external therapy, and *Mamsyadi Kwatha*⁷ for internal administration were planned in this study, to restore sleep.

Aim and Objectives: 1. To evaluate the therapeutic effect of *Mamsyadi- Kwatha* in *Nidranasha*

2. To evaluate the therapeutic effect of *Takra Dhara* in *Nidranasha*
3. To compare the therapeutic effect of *Mamsyadi Kwatha* and *Takra Dhara* in *Nidranasha*

MATERIAL AND METHODS

Source of data: A minimum of 30 patients was selected for the study from IPD/OPD of SDM College of Ayurveda Hospital Udupi, 15 for each group, irrespective of sex, caste, and creed.

Study design: An open-label comparative clinical study with pre and post-test design.

Intervention: Selected patients were allocated randomly into two groups, and were subjected to the following intervention

Group I (MK Group): *Mamsyadi Kwatha*: 30 ml thrice a day for 7 days

Group II (TD Group): *Shiro Dara* with *Mustasadhita Takra* for 45 minutes, once a day, for 7 days

Duration of the treatment: 7 days

Diagnostic Criteria:

1. *Lakshana* of *Nidranasha*
2. DSM-IV-TR criteria for primary insomnia

Inclusion Criteria:

1. Patients of either sex, age group of 16-60 yrs.
2. Patients fulfilling the diagnostic criteria of *Nidranasha*
3. *Nidranasha* patients with chronicity of minimum of 1 month to maximum of 5 years.

Exclusion Criteria:

1. *Nidranasha* due to *Madatyaya*, *Abhighata*,
2. Any other psychiatric diagnosis where the patient is receiving any medication or drugs that could cause sedation
3. With other conditions like hypertension, diabetics, vertigo, and pregnancy.

Criteria for Assessment:

1. Insomnia Screening Questionnaire (ISQ)⁸
2. Daily Sleep Dairy⁹.
3. Visual Analogue Sleep quality Scale (VAS)¹⁰

Table 1: Mamsyadi Kwatha Contents¹¹

Drug	Botanical Source	Part Used	Total Quantity
Jatamamsi	Nordostachys jatamansi	Moola	5040g
Ashvagandha	Withania somnifera	Moola	1260g
Parasika Yavani	Hyoscyamus niger	Beeja	460g

Table 2: Mustasadhita Takradhara Contents¹²

Drug	Botanical Source	Part Used	Total Quantity
Mustaka	Cyperus rotundus	Kanda	7000g
Amalaki	Emblica Officinalis	Phala	14000g
Takra			21lit

OBSERVATION AND RESULT

Table 3. Effect of Mamsyadi Kwatha on Sleep pattern

Signs and Symptoms	Mean Score				Paired t-test			
	BT (±SE)	AT (±SE)	Difference	%	S.D (±)	S.E.M (±)	't'	'p'
Time to fall asleep (in mts)	85.07 (1.416)	80.53 (1.480)	4.533	5.33	4.941	1.276	3.554	=0.003
No of awakening	2 (0.000)	1.33 (0.215)	0.867	43.35	0.834	0.215	4.026	=0.001
Total time of sleep (Hrs)	3.267 (0.345)	4.867 (0.256)	-1.600	48.97	1.454	0.375	-4.262	<0.001
Total time of disturbed sleep	4.800 (0.424)	3.467 (0.393)	1.333	27.70	1.113	0.287	-4.641	<0.001
Sleep quality	0.000 (0.000)	0.667 (0.126)	-0.667	66.7	0.488	0.126	-5.292	<0.001
Tiredness	2.000 (0.000)	1.133 (0.215)	0.867	43.35	0.834	0.215	4.026	=0.001
Irritability	1.867 (0.133)	0.800 (0.262)	1.067	57.15	1.033	0.267	4.000	=0.001

The therapeutic effect of *Mamsyadi Kwatha*: One week of *Mamsyadi Kwatha* was statistically significant in all patterns of sleep as per table 3

Table 4: Effect of Mamsyadi Kwatha on Pulse, Respiratory Rate, and Blood Pressure

Objective Parameter	Mean Score					Paired t-test		
	BT (±SE)	AT (±SE)	Difference	%	S.D (±)	S.E.M (±)	't'	'p'
Pulse Rate	74.333 (1.485)	71.867 (1.162)	2.467	3.32	2.167	0.559	4.409	<0.001
Respiratory Rate	19.867 (0.689)	18.800 (0.428)	1.067	5.37	1.280	0.330	3.228	=0.006
Systolic Blood Pressure	137.73 (2.572)	132.00 (1.069)	5.733	4.21	8.836	2.281	2.513	=0.025
Diastolic Blood Pressure	85.067 (1.416)	80.533 (1.480)	4.533	5.33	4.941	1.276	3.554	=0.003

As shown in table 4, the therapeutic effect of 7 days of *Mamsyadi Kwatha* was statistically significant on Pulse, Respiratory Rate, and Blood Pressure.

Table 5: Effect of Mamsyadi Kwatha on Nidranasha Lakshana

Nidranasha lakshana	Mean Score				Paired t-test			
	BT (±SE)	AT (±SE)	Difference	%	S.D (±)	S.E.M (±)	't'	'p'
Angamarda	1.000 (0.000)	0.667 (0.126)	0.333	33.3	0.488	0.126	2.646	= 0.019
Shirogaurava	0.933 (0.0667)	0.400 (0.131)	0.533	57.12	0.516	0.133	4.000	= 0.001
Jrambha	0.800 (0.107)	0.333 (0.126)	0.467	58.38	0.516	0.133	3.500	= 0.004
Jadya	1.000 (0.000)	0.733 (0.118)	0.267	26.6	0.458	0.118	2.256	= 0.041
Glani	0.933 (0.0667)	0.667 (0.126)	0.267	28.62	0.458	0.118	2.256	= 0.041
Bhrama	0.0667 (0.0667)	0.000 (0.000)	0.0667	100	0.258	0.0667	1.000	= 0.334
Tandra	0.200()	0.133()	0.0667	33.35	0.258	0.0667	1.000	=0.334
Apakti	0.467 (0.133)	0.133 (0.0909)	0.333	71.30	0.488	0.126	2.646	= 0.019

Effect on Nidranasha Lakshana: As shown in table 5, the therapeutic effect of *Mamsyadi Kwatha* over the *Lakshana* of the *Nidranasha* are statistically significant, except *Bhrama* and *Tandra*, which are statistically insignificant (P=0.334).

Table 6: Effect of Mamsyadi Kwatha on ISQ and VAS

Assessment Criteria	Mean Score				Paired t-test			
	BT (±SE)	AT (±SE)	Difference	%	S.D (±)	S.E.M (±)	't'	'p'
ISQ	28.333 (0.934)	19.267 (1.209)	9.067	32	4.698	1.213	7.475	<0.001
VAS	6.267 (0.547)	3.333 (0.475)	2.933	46.80	2.434	0.628	4.668	<0.001

The therapeutic effect of *Mamsyadi Kwatha* on Insomnia Screening Questionnaire and Visual Analogue Scale of 15 patients of *Nidranasha*

Effect of *Mamsyadi Kwatha* on Insomnia Screening Questionnaire and Visual Analogue Scale of 15 patients of *Nidranasha* are statistically significant (p<0.001) as shown in table 6

Table 7: Effect of Takra Dara Mustasadita Takra on Sleep pattern

Signs and Symptoms	Mean Score				Paired t-test			
	BT (±SE)	AT (±SE)	Difference	%	S.D (±)	S.E.M (±)	't'	'p'
Time to fall asleep(in mts)	81.667 (23.893)	19.000 (3.817)	62.667	76.73	91.03	23.57	2.666	=0.018
No of awakening	2.267 (0.206)	1.333 (0.159)	0.933	41.16	0.799	0.206	4.525	<0.001
Total time of sleep (Hrs)	4.133 (0.236)	6.200 (0.368)	-2.067	33.34	0.961	0.248	8.328	<0.001
Total time of Disturbed sleep	3.997 (0.247)	2.200 (0.340)	1.929	48.26	0.997	0.267	7.236	<0.001
Sleep quality	0.000 (0.000)	0.800 (0.107)	-0.800	100%	0.414	0.107	-7.483	<0.001
Tiredness	1.867 (0.133)	0.867 (0.236)	1.000	53.56	0.926	0.239	4.183	<0.001
Irritability	1.733 (0.182)	0.600 (0.235)	1.333	76.92	0.990	0.256	4.432	<0.001

Therapeutic Effect Of *MustaSadita TakraDhara*: For *Takra Dara Mustasadita Takra* was used at body temperature. The effect on the various parameters was as follows:

Effect on Sleep pattern: As shown in table 7 and, one week of *Takra Dara* on all the aspects of sleep pattern is statistically significant.

Table 8: Effect of *Takra Dara* on Pulse, Respiratory Rate, and Blood Pressure

Objective Parameter	Mean Score				Paired t-test			
	BT (±SE)	AT (±SE)	Difference	%	S.D (±)	S.E.M (±)	't'	'p'
Pulse Rate	79.467 (1.684)	73.067 (1.307)	6.400	8.05	4.290	1.108	5.779	<0.001
Respiratory Rate	22.133 (0.661)	19.867 (0.601)	2.267	10.24	2.120	0.547	4.141	<0.001
Systolic Blood Pressure	122.00 (2.795)	120.000 (3.519)	2.000	1.64	13.732	3.546	0.564	=0.582
Diastolic Blood Pressure	77.333 (2.482)	73.333 (2.323)	4.000	5.17	11.832	3.055	1.309	=0.212

Effect on Pulse, Respiratory Rate, and Blood Pressure: As shown in table 8, the 7 days of *Takra Dara* was statistically significant on Pulse and Respiratory rate. Statistically insignificant on Blood Pressure.

Table 9 Effect of *Takra Dara* on ISQ and VAS

Assessment Criteria	Mean Score				Paired t-test			
	BT (±SE)	AT (±SE)	Difference	%	S.D (±)	S.E.M (±)	't'	'p'
ISQ	28.533 (0.888)	15.533 (1.754)	13.000	45.56	6.141	1.586	8.199	<0.001
VAS	4.333 (0.410)	1.200 (0.355)	3.133	72.30	1.356	0.350	8.951	<0.001

Effect on ISQ and VAS: As shown in table 9, the administration of *Takra Dara* for 7 days reduces the ISQ by 45.56%, and the VAS by 72.30 %, which are statistically significant (P=<0.001).

Table 10: Effect of *Takra Dara* on *Nidranasha Lakshana*

<i>Nidranasha</i>	Mean Score	Paired t-test
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	BT (±SE)	AT (±SE)	Difference	%	S.D (±)	S.E.M (±)	't'	'p'
<i>Angamarda</i>	0.867 (0.0909)	0.333 (0.126)	0.533	61.48	0.516	0.133	4.000	= 0.001
<i>Shirogaurava</i>	0.800 (0.107)	0.200 (0.107)	0.600	75	0.507	0.131	4.583	<0.001
<i>Jrambha</i>	0.667 (0.126)	0.133 (0.0909)	0.533	79.91	0.516	0.133	4.000	=0.001
<i>Jadya</i>	0.867 (0.0909)	0.267 (0.118)	0.600	69.20	0.507	0.131	4.583	<0.001
<i>Glani</i>	0.933 (0.0667)	0.600 (0.131)	0.333	35.69	0.488	0.126	2.646	=0.019
<i>Bhrama</i>	0.458 (0.118)	0.000 (0.000)	0.267	58.30	0.458	0.118	2.256	=0.041
<i>Tandra</i>	0.467 (0.133)	0.0667 (0.0667)	0.400	85.65	0.507	0.131	3.055	=0.009
<i>Apakti</i>	0.533 (0.133)	0.133 (0.0909)	0.400	75.05	0.507	0.131	3.055	=0.009

Effect on Nidranasha Lakshana: As shown in table 10, the effect of *Takra Dara* over the *Lakshana* of the *Nidranasha* is statistically significant.

Table 11: Comparative therapeutic effect of Mamsyadi Kwatha and Mustasadita Takra Dara on sleep pattern

Signs And Symptoms	Mean Score BT-AT		Unpaired 't' Test					
			SD		S.E.M		't'	P
	MK Group	TD Group	MK Group	TD Group	MK Group	TD Group		
Time to fall Asleep (mts)	80.533	19.000	5.730	14.784	1.480	3.817	15.030	<0.001
No of awakening	1.667	1.333	0.617	0.617	0.159	0.159	1.479	=0.150
Total time of sleep (Hrs)	4.867	6.200	5.730	14.784	1.480	3.817	15.030	<0.001
Total time of Disturbed sleep	3.467	2.200	1.642	1.270	0.424	0.340	2.311	=0.029
Sleep quality	0.667	0.800	0.488	0.414	0.126	0.107	-0.133	=0.426
Tiredness	1.133	0.867	0.834	0.915	0.215	0.236	0.834	=0.411
Irritability	0.800	0.600	1.014	0.910	0.262	0.235	0.568	=0.574

Effect on Sleep pattern: As shown in Table No-11, *Takra Dara* gave a maximum result in Time to fall asleep and Total time of the sleep ($p < 0.001$), and also in Total time of disturbed sleep ($p = 0.029$) than the *Mamsyadi Kwatha*.

Table 12: Effect on Pulse, Respiratory Rate, and Blood Pressure

Objective Parameter	Mean Score BT-AT		Unpaired 't' Test					
			SD		S.E.M		't'	P
	MK Group	TD Group	MK Group	TD Group	MK Group	TD Group		
Pulse Rate	71.867	73.067	4.502	5.063	1.162	1.307	-0.686	=0.498
Respiratory Rate	18.800	19.867	1.656	2.326	0.428	0.601	-1.447	=0.159
Systolic Blood Pressure	132.00	120.00	4.140	13.628	1.069	3.519	3.263	=0.003
Diastolic Blood Pressure	80.533	73.333	5.730	8.997	1.480	2.323	2.614	=0.014

Effect on Pulse, Respiratory Rate, and Blood Pressure: As shown in Table No-12, *Takra Dara* gave more reduction in the Systolic Blood Pressure ($p = 0.003$), as well as Diastolic Blood Pressure ($p = 0.014$) than the *Mamsyadi Kwatha*.

Table 13: Effect on Nidranasha Lakshana

Nidranasha	Mean Score	Unpaired 't' Test
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			SD		S.E.M		't'	P
	MK Group	TD Group	MK Group	TD Group	MK Group	TD Group		
<i>Angamarda</i>	0.667	0.333	0.488	0.488	0.126	0.126	1.871	=0.072
<i>Shirogaurava</i>	0.400	0.200	0.507	0.414	0.131	0.107	1.183	=0.247
<i>Jrambha</i>	0.333	0.133	0.488	0.352	0.126	0.0909	1.288	=0.208
<i>Jadya</i>	0.733	0.267	0.458	0.458	0.118	0.118	2.792	=0.009
<i>Glani</i>	0.667	0.600	0.488	0.131	0.126	0.131	0.367	=0.716
<i>Bhrama</i>	0.000	0.000	0.000	0.000	0.000	0.000	0.000	=1.000
<i>Tandra</i>	0.133	0.0667	0.352	0.258	0.0909	0.0667	0.592	=0.559
<i>Apakti</i>	0.133	0.133	0.352	0.352	0.0909	0.0909	0.000	=1.000

Effect on Nidranasha Lakshana: As shown in Table No-13, There was no much difference statistically in *Nidranashalakshana* between the 2 groups except *Jadya*, which is reduced markedly by the administration of the *Takra Dara* in comparison with the *Mamsyadi Kwatha* ($p=0.009$).

Table 14: Effect on ISQ and VAS

Assessment Criteria	Mean Score BT-AT		Unpaired 't' Test					
	MK Group	TD Group	SD		S.E.M		't'	P
			MK Group	TD Group	MK Group	TD Group		
ISQ	19.267	15.533	4.682	6.791	1.209	1.754	1.753	=0.091
VAS	3.333	1.200	1.839	1.373	0.475	0.355	3.600	=0.001

Effect on ISQ and VAS: As shown in Table No-14, the *Takra Dara* has been given more reduction in the scores of the Visual Analog Scale for sleep ($p=0.001$), when compared with the Scores of *Mamsyadi Kwatha*.

DISCUSSION

Mode of Action of Mamsyadi Kwatha:

Mamsyadi Kwatha is prepared by herbal drugs like *Jatamamsi*, *Ashvagandha*, and *ParasikaYavani* and administered orally. According to the Ayurvedic Pharmacopoeia of India, *Jatamamsi* has the properties like *Nidrajanana*. And it is having therapeutic uses in *Anidra*. *Jatamamsi* contains a variety of sesquiterpenes and coumarins. The sedative sesquiterpenevaleranolone induces sleep. Another ingredient of *Mamsyadi Kwatha* is *Ashvagandha*. *Ashvagandha* (*Withania somnifera*) roots contain flavonoids and many active ingredients of the withanolide class. *Withania somnifera* has anti-stress, mind-boosting properties. So, by reducing the stress, relaxing the mind induces sleep. *ParasikaYavani* has the properties like *Madaka*, *Nidrakara*. Hyoscyamine is the principal ingredient of *ParasikaYavani*. It is useful for insomnia.

Mode of Action of Takra Dara:

Takra Dara stimulates the *Sthapani Marma* which is a *Sira Marma*. Mild stimulation of the *Marmas* may provide relief in certain diseases. So, it is possible that during *Shiro Dara* the *Prana Uttejana* takes place in

Sthapani Marma, brings *Tama* and *Kapha* to a normal state and leads to *Nidra Utpatti*. According to Yogic

science among the seven *charkas*, two are located in the head i.e. *Ajnachakra* (Optic Thalami) and *Sahasrarachakra* (Cerebrum). It can be hypothesized that with *Shiro Dara* therapy these two charkas are getting stimulated and are activating the hypothalamus. Thus, the *Takra Dara* influences *Nidra* by solving the causative factors of the *Nidranasha* leading to *Manaprasadana*.

CONCLUSION

Therapeutic Effect of Mamsyadi Kwatha:

- The formulation *Mamsyadi Kwatha* contains *Jatamamsi*, *Aswagandha*, and *ParasikaYavani*. The studies have proved that it gives 5.33% relief in Sleep initiation, Number of awakening is reduced by 43.35 %, The total time of sleep is increased by 48.97 %, The total time of disturbed sleep is reduced by 27.70 %, The sleep quality increased by 66.7 %, The Tiredness and Irritability is reduced by 43.35%, 57.15% respectively.
- Mamsyadi Kwatha* reduces the Pulse rate by 3.32%, Respiratory rate is reduced by 5.37%, The Systolic Blood Pressure is reduced by 4.21%, Whereas the

Diastolic Blood Pressure is reduced by 5.33%.

- *Mamsyadi kwatha* reduces one Lakshana of the Nidranasha i.e. Angamarda by 33.3%, Shirogaurava is reduced by 57.12 %, Jrambha is reduced by 58.38 %, Jadya is reduced by 26.6 %, Glani is reduced by 28.62 %, Bhrama is reduced by 100 %, Tandra is reduced by 33.35 %, Apakti is reduced by 71.30 %.
- The ISQ is reduced by 32%, and the VAS by 46.80%

Effect of Takra Dhara:

- The Takra Dara is done with Musta, Amalaki, and Takra. The studies have proved that there is 76.53% relief in sleep initiation, Number of awakening is reduced by 41.16 %, The total time of sleep is increased by 33.34 %, The total time of disturbed sleep is reduced by 48.26 %, The sleep quality is increased by 100 %, The Tiredness and Irritability is reduced by 53.56%, 76.92% respectively.
- 7 days of Takra Dara reduces the Pulse rate by 8.05%, Respiratory rate is reduced by 10.24%, The Systolic Blood Pressure is reduced by 1.64%, The Diastolic Blood Pressure is reduced by 5.17%.
- The effect of Takra Dara over the Lakshana of the Nidranasha i.e. Angamarda is reduced by 61.48%, Shirogaurava is reduced by 75 %, Jrambha is reduced by 79.91 %, Jadya is reduced by 69.20 %, Glani is reduced by 35.69 %. Bhrama is reduced by 58.30 %, Tandra is reduced by 85.65 %, and Apakti is reduced by 75.05 %.
- The administration of Takra Dara for 7 days reduces the ISQ by 45.56%, and the VAS by 72.30 %.

It is obvious from the foregoing studies that both the oral administration of *Mamsyadi Kwatha* and the external therapy of *Takra Dara* provided significant relief from *Nidranasha*. But on comparing the results of both the therapies it can be stated that *Takra Dara* provided better relief to the patients of *Nidranasha* as the main cause of *Nidranasha* was stress, which could be tackled by *Takra Dara* easily in comparison with *Mamsyadi Kwatha*.

However, this study was on a small scale sample, so further study along with Psychoneuropharmacological study can provide some fruitful conclusions.

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