



## Research Article

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### NASYA WITH VILWĀDI GULIKA VS HINGVĀDI YOGA IN MILD TO MODERATE DEPRESSIVE DISORDER: A RANDOMIZED CONTROLLED TRIAL

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#### ABSTRACT

Depression is a state of low mood and aversion to activity that can affect a person's thoughts, behavior, feelings and sense of well-being. Globally depression is a common illness with an estimated 350 million people affected. Kaphajonmāda, viṣāda and cittavasada are similar conditions narrated in Ayurvedic parlance. Previous studies on Hingvādi Yoga nasya had proven its effect in depressive disorder. Efficacy of Vilwādi Gulika as nasya was observed from the clinical practice in depression, but no scientifically validated data available. 32 patients fulfilling the inclusion criteria were selected from OPD and IPD of VPSV Ayurveda college hospital and GARIM, Kottakkal, Malappuram, Kerala, India satisfying ICD-10 diagnostic criteria for mild to moderate depression. They were administered marsa nasya with Vilwādi gulika as trial drug and Hingvādi yoga gulika as control for 7 days, at the dosage of 2 ml for each nostril during morning hours (7-9 am). The effect of therapy was assessed with Hamilton's depression rating scale and Quality of Life Satisfaction and Enjoyment scale, before the procedure and on the 4<sup>th</sup>, 7<sup>th</sup> and on 10<sup>th</sup> day after nasya. Vilwādi gulika was found to be statistically significant at the level of  $p < 0.001$  in mild to moderate depression. Hingvādi yoga was also found to be statistically significant at the level of  $P < 0.001$ . On comparison of Vilwādi gulika with Hingvādi yoga it was significant at  $p < 0.05$ .

**Keywords:** Depression, Kaphajonmāda, Vilwādi Gulika, Hingvādi Yoga, HAM-D

#### INTRODUCTION

Everyone at various times in their life feels sad or blue at some occasions. Sometimes this sadness comes from things that happen in our lives; by our reflex we want to rectify them. But normal feeling of ups and downs experienced, and the feelings caused by clinical depression are entirely different. When a person has a depressive disorder, it interferes his daily life. Our mind and body are in inseparable coexistence. The mind is responsible for perception, thinking, understanding and taking the right decision at the right time<sup>1</sup>. If the mind is afflicted, then the body mind apparatus is in menace. When the mind is healthy, it contains positive feelings such as love, affection, sharing and caring. If the natural state of mind is disturbed and these positive feeling are driven out then negative feelings such as sad, anxious, empty, hopeless, worried, helpless, worthless, guilty, irritable, hurt or restless go through.<sup>2</sup>

A wide range of psychiatric conditions have been described in the Āyurvedic parlance. Primary psychological conditions caused purely by mānasadoṣa i.e. rajas and tamas includes Kāma (Lust), Krodha (Anger), Lobha (Greed), Moha (Delusion), Īrshya (Jealousy), Māna (Pride), Śokam (Grief), Cinta (Anxiety), Bhaya (Fear), Harṣa (Happiness). Psychological factors are involved in almost all the disease processes along with the physical disturbance. An imbalance at the mental level is usually reflected and re-enforced at the physical level and vice versa. The vitiation of the manovaha srotas results in diseases such as unmāda, atatvābhiniveśa, viṣāda etc. As per the Āyurvedic pathogenesis, depression is to be explained as an imbalance of rajas and

aggravation of *tamas* at the psychic level, alteration of vāta doṣa and vitiation of kapha doṣa manifested at the physical level.<sup>3</sup>

Depression is a state of low mood and aversion to activity that can affect a person's thoughts, behavior, feelings and sense of well-being<sup>4</sup>. Globally depression is a common illness with an estimated 350 million people affected, according to WHO it has a major contribution to the global burden of disease.<sup>5</sup> Depression is a disorder of major public health importance, in terms of its prevalence and the suffering, dysfunction, morbidity and economic burden. Women are more affected by depression than men<sup>6</sup>. It is estimated that one million deaths per year occur due to on and off causes of depression<sup>7</sup>. Considering the grave nature of this disease, WHO designed the mental health action plan to work towards depression.<sup>8</sup> If current trend for demographic and epidemiological transition continue, it is estimated that by the year 2020, depression be the second leading cause of disability-adjusted life years (DALYs).<sup>9</sup>

In view of the morbidity, depression as a disorder has always been a focus of attention in India and most prevalent among the reported psychiatric disorders.<sup>10</sup> There is an alarming rise in the suicide rates among women in Kerala, India in which depression accounts nearly its half<sup>11</sup>. The increasing rate of depression points to the inadequacy of the effective management. Current approaches in the management of depression have its own limitations as per published studies.

The procedure Nasya is capable of providing solution to the problem by tackling the disturbed Kapha and Vāta physically and by attaining clarity to the mental faculties. It also helps in

maintaining the balance of psychological status of the individual. Studies also evaluate the cost-effective models of procedure which can be easily used in the primary care setting in depression. Vilwādi gulika is conventionally practiced in Ayurveda especially in the context of mānasika rogās. The drugs in Vilwādi gulika possess the properties of Kapha vāta hara, laghu, rūkṣa, uṣṇa vīrya, katu vipāka as well as medhya.

As it regulates both the Vatha and Kapha; is of srotośodhaka and clarifies the obstructed manovaha srotas, thus by accomplishing reversal of the pathogenesis of depression. Hingvādi avapīda nasya is a combination conventionally in use in Government Ayurveda Research Institute for Mental disorders (GARIM), Kottakkal, India for years in depression with efficacy and was kept as control in the study.

The drugs consisting of Hingvādi avapīda nasya yoga are Hingu, Vacā and Dāruharidra.<sup>13</sup> Both the control and trial drugs are predominantly of katu-tikta rasa, katu vipāka, uṣṇa vīrya, laghu, rūkṣa guna and Kapha vāta samana in action. Almost all ingredients of Vilwādi gulika are of tīkṣṇa and Kaphagna property.

### Need and Significance

Depression has no doubt augmented the curiosity of the medical world due its prevalence and wide varied presentations. Unfortunately, the available management is unable to find an expected solution even though many advances are there in pharmaceutical interventions. Also increased studies on adverse effects of anti-depressants have demanded assistance from the other medical systems. Efficacy of Vilwādi gulika was observed from the clinical practice since a few years. Though studies were conducted regarding Hingvādi as nasya, there is no scientifically validated data available on the efficacy of Vilwādi gulika nasya in depression. In addition to this availability, feasibility and cost effectiveness of this medicine favors the study.

### Methodology

#### Aim

To provide an enhanced as well as cost effective management for mild to moderate depressive disorder

#### Objectives

- To assess the efficacy of Vilwādi gulika nasya in mild to moderate depressive disorder.
- To compare the efficacy of Vilwādi gulika with Hingvādi yoga as nasya in mild to moderate depressive disorder.

#### Diagnostic criteria

ICD 10 diagnostic criteria of depressive disorders<sup>12</sup>

#### Inclusion criteria

Diagnosed cases of mild to moderate depression, as per ICD-10, between 20 - 50 years, irrespective of gender, religion and economic status and with informed consent were included.

#### Exclusion criteria

Those with any other psychiatric disorders, on ongoing antidepressants, Pregnant women and lactating mothers, Subjects with Coronary artery disease, Thyroid dysfunction, Hypertension etc and also those unfit for Nasya karma were excluded

#### Materials

- Medicines (Vilwādi gulika, Hingvādi yoga gulika)
- Hamilton's depression rating scale
- Q-LES-Q-SF
- Case record form
- Consent form

#### Assessment tools

- Hamilton's depression rating scale
- Quality of Life Enjoyment and satisfaction Questionnaire - short form

#### Method

- Study design: Comparative clinical trial
- Period of study: 18 months
- Sample size: 16
- Sampling method: Simple random sampling
- Settings: Manaśśānti OPD, V P S V Ayurveda College and GARIM, Kottakkal, India

Protocol was approved by Institutional Review Board - No. IEC/CI/13/17, dtd 27/04/2017.

32 subjects satisfying the inclusion criteria were selected from the Manaśśānti OPD of V P S V Ayurveda College and GARIM and randomized into two groups as per random number table.

#### Intervention

- Dose: 2 ml (each)
- Time: Morning (7- 9 am)
- Duration: 7 days
- Assessment was done on 0<sup>th</sup>, 4<sup>th</sup>, 7<sup>th</sup> and follows up on 10<sup>th</sup> day.

No adverse effect was noticed and reported by the patient for the drugs during the study period. There were no dropouts in the study.

#### Observation and Result

The data obtained were statistically analyzed in each assessment scales separately by using Friedman's two way ANOVA to test the effect of intervention for each assessments, Wilcoxon signed rank test for pairwise comparison within the group, and to compare the effects in between the groups, Mann-Whitney U test was done.

**Total Score of Ham-D Scale**

**Table 1: Effect on the Total score of HAM-D scale – trial and control groups**

Group	Comparison	Mean	S.D	Mean Rank	Chi-Square	P
Trial	BT	14.42	2.90	43.89	318.76	< 0.001
	AT1	12.85	3.23	43.11		
	AT2	9.14	2.38	41.96		
	AT3	6.14	2.14	41.04		
Control	BT	13.87	2.47	39.84	316.58	< 0.001
	AT1	12.56	2.30	39.16		
	AT2	9.75	2.17	37.94		
	AT3	7.25	1.73	37.06		

**Table 2: Multiple comparison within group, Total score HAM-D scale - trial and control**

	Comparison	Negative rank	Positive rank	Mean rank	Sum rank	P
Trial	BT vs AT1	13	0	7	91	< 0.001
	BT vs AT2	16	0	8.5	136	< 0.001
	BT vs AT3	16	0	8.5	136	< 0.001
Control	BT vs AT1	11	0	6	66	< 0.01
	BT vs AT2	16	0	8.50	136	< 0.001
	BT vs AT3	16	0	8.50	136	< 0.001

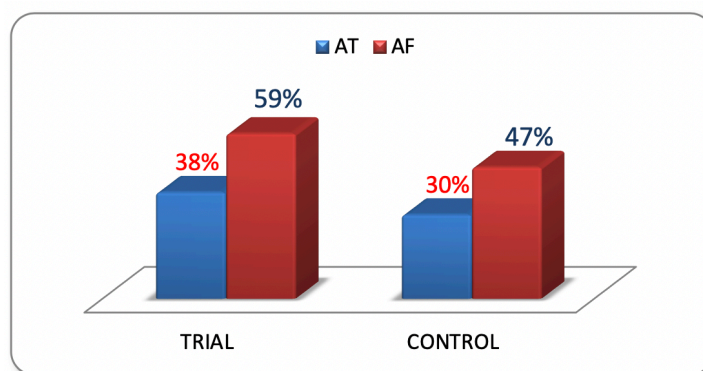
**Table 3: Total score, efficacy between trial and control groups**

	Group	Mean Rank	Sum of Ranks	Mann-Whitney U	P
BT vs AT	Trial	19.81	317	75	< 0.05
	Control	13.19	211		
BT vs AF	Trial	20.25	324	8	< 0.05
	Control	12.75	204		

While assessing with HAM-D scale, Vilwādi gulika nasya was found to be statistically significant at  $p < 0.001$ . Hingvādi yoga nasya was also found to be statistically significant at  $p < 0.001$ . While comparing the effect of nasya with Vilwādi nasya with that of Hingvādi yoga, showed significant difference in total score of HAM-D scale and found to be statistically significant at  $p < 0.05$  with increase in mean rank in trial group. While assessing with Quality of Life Enjoyment and satisfaction Questionnaire, in trial group, quality of life was found improved in all the domains except Sexual interest / performance, economic status and living/ housing situations. While assessing with Quality of Life

Enjoyment and satisfaction Questionnaire, in control group, the quality of life was found improved in all the domains except sexual interest / performance, economic status, living/ housing situations and ability to get around physically without feeling dizzy / unsteady / falling.

While comparing the effect of Vilwādi nasya with Hingvādi nasya in Quality of Life Enjoyment and satisfaction Questionnaire, the domains work and family relationship was found to be significant at the level of  $p < 0.05$ , with increase in mean rank in trial group.



**Graph 1: Percentage of relief in total score after intervention and follow up- trial and control**

**DISCUSSION**

**Effect of intervention on Hamilton’s depression rating scale**

**Depressed mood**

Depressed mood includes sadness, anhedonia can be compared with sāda and aprahaṣa. Both groups showed significant result in the symptom, the effect may be due to indriya laghutva and

indriya prasāda of nasya karma and also the tīkṣhṇa guna and vāta kapha hara property of the drugs. This might have acted on the kapha vāta vitiated condition of depressed mood.

**Feeling of guilt**

Guilt is a consequence of worthlessness in depression. In this domain the effect of vilwādi gulika nasya as well as the hingvādi yoga nasya was insignificant.

### **Suicide**

Suicidality is always associated with depression, at its worst depression can lead to suicide. The lowering of melatonin level in depression results in suicidal tendency. In trial group the effect of drug was significant with 34% of relief, where as in control group it was insignificant. Nasya karma leads to manassudhi and is kaphavātahara. Medhya guna of vilwādi gulika might have helped to decrease the suicidal thoughts<sup>14</sup>.

### **Insomnia early, middle and late**

Insomnia early includes difficulty in falling sleep probably due to vitiation of Vatha; both groups were statistically significant in this domain. Trial group provided 31% improvement and in control group it was 25%. Vātanulomana property of the drugs and sukhasvapna prabodhana of samyak nasya<sup>15</sup> have helped in improving the symptom. In insomnia middle patient complains of being restless, disturbed and waking during night. Both group showed significant result in this domain. Trial group provided (38%) relief as compared to the control group (22%) and trial drug provided better relief in insomnia middle.

Waking in early hours of the morning and unable to fall asleep again if gets out were the features found in insomnia late. Vilwādi nasya got significant result with (20%) relief, where as in control group the effect was insignificant. Clinically some of the patients were complaining of early morning waking than their usual time after administrating the medicines. Kapha hara property of the drug and tīkṣṇa guna may be the reason of waking up in the kapha kala. Lesser time of sleep, longer sleep latency and frequent awakening are complained in depression of mild and moderate in nature<sup>16</sup>.

### **Work and activities**

Apravrithi can be incorporated with this symptom. Trial group provided (19%) relief as compared to the control group (14%) and both were statistically significant. Indriyaprasāda guna of avapīḍa nasya and kaphagna, tīkṣṇa guna of the drugs have helped to improve the fatigue or loss of interest in activities, work or hobbies. Studies shows that work and activities are reduced along with depressed mood.<sup>17</sup>

### **Retardation**

Decreased motor activity, slowness of thought and speech was observed in this domain. Mandaceṣṭha and alpavāktvam can be incorporated with this symptom. Changes in both trial and control group were statistically significant; trial group provided (22%) relief as compared to the control group (16%). Here aggregation of kapha doṣa and tamas was observed. Better relief in sadana is due to the tīkṣṇa and kaphahara properties of drugs and might have stimulated with the medhya property to reduce the symptom. The serotonin and melatonin levels determine the psychomotor activity and its decrease will result in the symptom.<sup>18</sup>

### **Agitation**

Agitation is a condition of inability to relax or feeling of restlessness. In trial group the result was significant with (28%) of relief, and also in control group with (19%) of relief. Vitiation of vāta and rajo doṣa was observed here, so vātaśamana property of the drugs have reduced agitation and the trial drug showed better result.

### **Anxiety (psychic and somatic)**

Both drugs showed significant change in anxiety. Percentage reduction in trial group was 42% and in control was 28%. Tension and irritability, worrying about minor matters etc can be understood with augmentation of vāta and rajās. Vātahara, anulomana and medhya properties of drugs and manassudhi guna of nasya karma have helped. Physiological components of anxiety such as dry mouth, indigestion, palpitation, sweating, headache etc. was observed in all patients. Here control group provided (31%) relief as compared to trial (18%) which were statistically significant. Here vāta pitta vitiation was observed and the better relief in control due to the vātapitta śamana property of the drugs in the hingvādi yoga.

### **Somatic symptoms gastrointestinal**

Control group provides (28%) of relief with statistically significant result, where as in trial group it was found as insignificant. This shows the effect of hingvādi nasya in somatic symptoms in GIT of depression. The dīpana-pacana and kaphahara drugs in hingvādi yoga helped to improve the gastrointestinal abnormalities such as aruci, agnimāndya etc. There is direct relationship between agni and mind. The serotonin which is mostly secreted in the GIT is directly related to mood disorders.

### **Somatic symptoms general**

General debilities such as heaviness in head, extremities, loss of energy, fatigability etc. reduced significantly in both the groups. Somatic symptoms are more common manifestation in India. Trial group provided (47%) of relief as compared to control (38%). The effect is expected due to the śīrolaghutva of nasya, kaphagna and tīkṣṇa properties of the drug. The subjects felt "lightness" after the procedure.

### **Genital symptoms**

Genital symptoms include loss of libido and menstrual disturbances were observed as reduced significantly in both groups.

### **Hypochondriasis**

No significant result was procured on the symptom in trial group, where as in control group it was significant.

### **Loss of weight**

Correction of agni along with restoration of bala was needed to improve the condition. No significant result was found in both groups; hence both groups have no effect on the loss of weight

### **Insight**

Insight was present in all the patients. As the subjects selected were mild and moderately depressed no one had psychotic features and absence of insight.

### **Total score of HAM-D**

Both trial and control groups were effective in reducing the total score and significant after 7 days of treatment at  $p < 0.001$ , it was also significant at follow up period also at  $p < 0.001$ . Trial group provided (38%) improvement and in control group improvement was (30%) after treatment, after follow up period relief in trial was (59%) and (47%) in control. The result may be by the overall

effect of the drugs. While considering the mean scores it was found that trial group showed more significant effect than control group.

#### Mode of action of Nasya karma

While explaining the pharmacodynamics of nasya karma, the medicine administered as nasya consists of lipid soluble substances that have greater affinity for passive absorption through the cell walls of nasal mucosa. Cilia of the olfactory cells and the portions of the body of the olfactory cells contain relatively large quantities of lipid materials.<sup>19</sup> Primary action of nasya is on stimulation of receptor cells of nasal mucosa. The peripheral olfactory nerves are chemoreceptor in nature. Olfactory nerves are connected with the higher centers of the brain i.e. limbic system, so the drugs administered here stimulate the higher centers of brain. Experimental stimulation of olfactory nerves causes stimulation in hypothalamus and amygdaloidal complex.<sup>20</sup> Thus hypothalamus regulates control of autonomic nervous system, regulation of hormone synthesis, regulation of emotional and behavioral patterns and states of consciousness.

The drug enters to the systemic circulation and also pools into the intracranial region by vascular path. Such a pooling of blood from nasal veins to venous sinuses of brain is more likely to occur in head lowering position due to gravity. Further drug administration can also be enhanced by local massage and fomentation.<sup>21</sup> It is proved from a study that stimulation from nasya dravya can influence over – mood, sexual behavior, memory and endocrinal function. As depression is a mood disorder nasya may influence in this way<sup>22</sup>. Regarding avapīḍa nasya, Achārya Sharṅgadhara opined that it has a special indication in mānasika vikāra<sup>23</sup>, as it is tīkṣhṇa, it possesses quick and fast absorption and action of the drugs. Most of the drugs used in avapīḍa nasya are of uṣṇa, tīkṣhṇa and lekṣhṇa nature, which helps to clear the channels and enhances the perception thus the person will get laghutva, manaprasada, śīrasudhi and vyadhisamkṣaya.

#### Mode of action of the drug – Vilwadi gulika

The combined effect of vilwādi gulika is predominantly of katu tikta rasa, uṣṇavīrya, katu vipāka, laghu, ruṅka guna and kapha vāta śamana in action. Trikatu is an immune modulator.<sup>24</sup> Katu rasa increases endorphin and is a serotonin modulator.<sup>25</sup> Piperine extracted from pippali and marica is known to have anti-depressant activity and MAO inhibitor activity.<sup>26</sup> Pippali increases bio availability and thus enhances the absorption of all other drugs, it also increases the serotonin production.<sup>27</sup> Proved anxiolytic and antidepressant activity of individual drugs vilwa, surasa, nata, sundi, haridra, amalaki, vibhitaki in vilwādigulika also enhances the result. With all these properties, vilwādigulika pacifies kaphavāta and cleans the obstructed manovaha srotas and overcomes the samprapti of depression. Hence it is justifiable to attribute an antidepressant activity to Vilwādi gulika.

#### CONCLUSION

Efficacy of Vilwādi gulika nasya was found significant in reducing the symptoms of mild to moderate depressive disorder on Hamilton's depression rating scale. The comparison between the efficacies of Vilwādi gulika nasya with Hingvādi yoga nasya in mild to moderate depressive disorder was statistically significant.

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