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AN OPEN LABEL SINGLE ARM CLINICAL STUDY TO EVALUATE THE EFFICACY OF *KALYANAKA GHRITA NASYA* AND *SARASWATHARISHTAM* IN *CHITTODVEGA* VIS-À-VIS GENERALIZED ANXIETY DISORDER

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ABSTRACT

Generalized anxiety disorder is one of the anxiety disorders, it is defined as persistent, excessive, and/or unrealistic worry associated with muscle tension, impaired concentration, autonomic arousal, feeling "on edge" or restless and insomnia. In the Ayurvedic perspective, it can be correlated to *Chittodvega*. *Chittodvega* is defined as *udvignata* of *chitta* or *manas* which is caused because of *Rajo dosha* involving *Vata* & *Pitta dosha prakopa* causing manifestation of *Manasika* and *Sharirika Lakshana*. Patients with anxiety disorders often face difficulty coping with personal, academic and professional life causing hinderance to day-to-day activities. A safer and effective approach in the management of Generalized Anxiety Disorder through Ayurveda is necessary. Hence this study has been undertaken to evaluate the efficacy of *Kalyanaka ghrita nasya* and *Saraswatharishtam* in *Chittodvega* vis-a-vis Generalized anxiety disorder. This is an open label clinical study with 30 subjects who were selected incidentally. All subjects underwent *nasya* procedure with *Kalyanaka ghrita* for 7 days followed by administration of *Saraswatharishtam* after food for next 38 consecutive days. The result of the study revealed a statistically significant result with p value < .001.

KEYWORDS: *Chittodvega,* Generalized Anxiety Disorder, *Nasya, Saraswatharishtam.*

INTRODUCTION

A human being goes through various stages of life dealing with both physical health and mental health challenges. Mental well-being of a person is paramount for a person to lead his life over various spectrums of the daily activities.

The definition of health by WHO has acknowledged not only the well-being of physical body, but also mental well-being, wherein it states, Health as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.[1]

Anxiety Disorders are the most prevalent psychiatric illnesses in the general community. According to National Mental Health Survey 2016, the weighted prevalence of Generalized Anxiety Disorder in adult general population was 0.57%.[2]

Generalized Anxiety disorder is characterized by persistent, excessive, and unrealistic worry about everyday things. This worry could be multifaceted, including financial, family, health, and future concerns. It is excessive, difficult to control, and is often accompanied by many nonspecific psychological and physical symptoms.[3]

Currently, among the pharmacological treatment modalities available for the management of generalized anxiety disorder, the first line agents include Selective serotonin re-uptake inhibitors (SSRIs) or Serotonin-norepinephrine reuptake inhibitors (SNRI) with a response rate of 30% to 50%, Benzodiazepines with a concern for misuse and dependence, Buspirone with a therapeutic lag in the efficacy of 2-3 weeks. Every medication has adverse effects, such as weight gain, hyperlipidemia, and diabetes; thus, the patients need to be monitored.[4]

Considering the above reasons, it is relevant to search for alternative management, which is effective, and which gives long term remission.

In Ayurveda, the term *Chittodvega* can be correlated to Generalized Anxiety Disorder. *Chittodvega* is a mental disorder having its reference in the *Charaka Samhita*.[5]

It is characterized by excitation/agitation of manas. The involvement of both *Mano dosha Rajas* and *Shareerika dosha* i.e., *Vata* and *pitta* are interpreted to be the Pathological factors involved in the development of *Chittodvega*.

In *Chittodvega*, approach with *Nasya* and *Shamana Dravya* having properties of *Medhya*, *Rasayana*, *Vata-pitta shamaka* along with its anxiolytic and nootropic actions are useful. Therefore, to treat *Chittodvega*, *Nasya karma* with *Kalyanaka ghrita* was chosen as *Panchakarma* followed by *Saraswatharishtam* internally. Hence the current study was taken up to assess the clinical efficacy of *Kalyanaka Ghrita Nasya* and *Sarawatharishtam* in *Chittodvega* vis-à-vis Generalized anxiety disorder.

MATERIALS AND METHODS

Subjects were incidentally selected from OPD & IPD of Government Ayurveda Medical College and Hospital, Mysuru and Government Hi-Tech Panchakarma Hospital, Mysuru.

Source of drug

- *Kalyanaka Ghrita* was procured for the study from a GMP certified pharmacy, AVP Pharmacy.
- *Saraswatharishtam* was procured for the study from a GMP certified pharmacy, Doothpapeshwar ltd.

Inclusion criteria

- Subjects with clinical features of Generalized anxiety disorder (Chittodvega) under DSM- V criteria
- Subjects between the age group of 20 to 60 years irrespective of gender, caste, religion were included.
- Both fresh and treated cases were taken for the study.

Exclusion criteria

- Patients diagnosed with Schizophrenia, Bipolar disorder, OCD, PTSD
- Patients with history of chronic drug abuse
- Patients under any psychotropic medication
- Pregnant and lactating women.
- Patients with uncontrolled hypertension (blood pressure levels above the range of 150/100 mmHg) and uncontrolled diabetes (Random blood sugar level above 250mg/Dl)
- Subjects unfit for intervention (*nasya karma*).

Diagnostic criteria

Diagnosis was based on Diagnostic and Statistical Manual Of Mental Disorders, 5th edition (DSM V)

Assessment criteria

To assess the effect of intervention, Hamilton Anxiety Scale was adopted.

	0	1	2	3	4
1**. Anxious Mood** -Worries, anticipation of the worst, fearful anticipation, irritability.					
2. **Tension**-Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax.					
3. **Fears**-Of dark, of strangers, of being left alone, of animals, of traffic, of crowds.					
4. **Insomnia**-Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors.					
5. **Intellectual**-Difficulty in concentration, poor memory.					
6. **Depressed Mood**-Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing.					
7. **Somatic (muscular)**-Pains and aches, twitching, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone.					
8. **Somatic (sensory)**-Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation.					
9. **Cardiovascular Symptoms**-Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, missing beat.					
10. **Respiratory Symptoms**-Pressure or constriction in chest, choking feelings, sighing, dyspnoea.					
11. **Gastrointestinal Symptoms**-Difficulty in swallowing, wind abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation.					
12. **Genitourinary Symptoms**-Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of rigidity, premature ejaculation, loss of libido, impotence.					
13. **Autonomic Symptoms**-Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair.					
14. **Behavior at Interview**-Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc.					

Assessment schedule

- Pre-test assessment- 0th day before the intervention
- Mid-test assessment- 8th day after completion of *nasya*
- Post-test assessment- 46th day after completion of intervention

Statistical methods

Descriptive statistics – Mean, Standard deviation, Frequency, Percentile.

Inferential Statistics

- Chi-square test
- ANOVA repeated measures
- Paired sample t-test

Intervention

The interventions were as follows

All the subjects were administered with *Nasya karma* followed by *Shamanoushadhi*.

Nasya karma was administered as follows.

- *Poorva karma* was done by *Sthanika mukha abhyanga* with *Moorchita tila taila* followed by *sweda*.
- *Pradhana karma* was done through *Nasya* with *Kalyanaka ghrita*- 6 *bindu*(3ml) in each nostril in the morning on empty stomach.
- *Paschat karma* was advised by gargling with lukewarm water.
- *Shamana aushadhi* was started after completion of *Nasya karma*.

Shamana aushadhi: For 38 days.

a) *Saraswatharishtam* 25ml with *Sukhoshna jala* as *anupana*(q.s), twice a day, after food (From 8th day to 45th day).

Total Duration of the Intervention- 45 days

RESULTS

Result on Anxious Mood

The effect of intervention on anxious mood was statistically highly significant with
p value 0.000

Result on Tension

The effect of intervention on tension was statistically highly significant with p value
0.000

Result on Fears

The effect of intervention on fears was statistically highly significant with p value
0.000

Result on Insomnia

The effect of intervention on insomnia was statistically significant with p value .020.

Result on Intellectual Symptoms

The effect of intervention on intellectual symptoms was statistically highly significant with p value 0.000.

Result on Depressed Mood

The effect of intervention on depressed mood was statistically significant with p value 0.014.

Result on Somatic (Muscular) Symptoms

The effect of intervention on somatic(muscular) symptoms was statistically highly significant with p value 0.000.

Result on Somatic (Sensory) Symptoms

The effect of intervention on somatic(sensory) symptoms was statistically significant with p value 0.003.

Result on Cardiovascular Symptoms

The effect of intervention on cardiovascular symptoms was statistically insignificant with p value 0.715.

Result on Respiratory Symptoms

The effect of intervention on respiratory symptoms was statistically highly significant with p value .000.

Result on Gastrointestinal Symptoms

The effect of intervention on gastrointestinal symptoms was highly significant with p value .000.

Result on Genitourinary Symptoms

The effect of intervention on genitourinary symptoms was highly significant with p value .000.

Result on Autonomic Symptoms

The effect of intervention on autonomic symptoms was significant with p value .008.

Result on Behavior at Interview

The effect of intervention on behavior at interview was highly significant with p value .000.

Result on Hamilton Anxiety Scale (Total Score)

The effect of intervention on the total score of Hamilton anxiety scale was highly significant with p value .000

The Paired Samples Test revealed significant symptom improvements at all assessment points:

Timeline	p-value
Before treatment (BT) to after *Nasya* (AN)	$p < .001$
After *Nasya* (AN) to after treatment (AT)	$p < .001$
Before treatment (BT) to after treatment (AT)	$p < .001$

Specifically, the mean difference between BT and AN was 4.10 ($p < .001$), indicating considerable improvement post-*Nasya*. The difference between AN and AT was 4.80 ($p < .001$), reflecting ongoing enhancement following *Shamana Aushadhi*. The most significant improvement was observed from BT to AT, with a mean difference of 8.90 ($p < .001$). Overall, these findings highlight the effectiveness of both treatments,

with the greatest symptom reduction achieved after the complete treatment regimen

DISCUSSION

Probable mode of action of Kalyanaka Ghrita nasya

The *karma* of *kalyanaka ghrita* includes *Medhya, Rakshoghna* and *Tridoshahara*.

Due to the drugs possessing *hrdya guna such as brihati, Talisa patra, Ela, Hima*, it may be useful in *mano vikara as hrudaya is the sthana of manas*. *Hrdya* in the relation to *Mano rogas* can be considered as the drugs which acts on CNS(Brain).[6]

Due to the drugs possessing *Rasayana guna such as Amalaki, Shalaparni*, it may rejuvenate the *manas* and helps in attainment of *smriti, medha* and optimum strength of *deha* and *indriya*. With these benefits of *rasayana*, it may act as a promotive therapy in *Chittodvega*.

Ghrita by virtue of its *snigdha property* it alleviates Vata and due to its *sheeta* property alleviates *Pitta*, it promotes *Medha* and *smriti*. It has '*Samskarasya anuvartanaat'* action and hence it may act as bioenhancer of the drugs present in the formulation.[7] It is Rich in omega-3 fatty acids, which has been studied for its positive effects on symptoms of anxiety.[8]

The *Sneha* administered, *Ghrita* which is a base component in the study drug, facilitates the transport of constituents to the brain through its lipophilic activity. The active constituents of *ghrita* have shown improved blood-brain barrier penetrating properties to help in the easy delivery of drugs, thereby increasing the efficacy of drugs.[9] This mechanism along with the nasal route of administration may be the probable mechanism of action of *Kalayanaka ghrita nasya* in *Chittodvega.*

Probable mode of action of Saraswatharishtam

Among the 23 drugs, *Brahmi, Shatavari, Abhaya, Mishi, Pippali, Vacha* have *Medhya* action. This may help in the improvement of symptoms of psychological and intellectual symptoms of *Chittodvega*.

Brahmi, Shatavari, Vidarika, Abhaya, Renuka, Pippali, Vajigandha, Amruta, Vidanga have *Rasayana Karma*. This helps in the Nourishment of *Manas* thereby helping in the normal functioning of *manas*.

Vacha acts as *Medhya* and *Rasayana dravya* and has the potential to increase the grasping and retention of knowledge and memory.[10]

Brahmi, Vidari, Abhaya, Shunti, Mishi, Kana, Devapushpa, Kushta, Vajigandha, Amruta, Ela, Vidanga, twak have *Anulomana Karma*. This helps in the pacification of *Vata dosha* and *Rajas* (As *Vata dosha* is dominant in *Rajas guna*,[11] with this understanding, both *Vata* and *Rajas* are related to each other).

Probable mode of action

Probable Effect on worry, tension, fear and behavioural symptoms-

- *Brahmi* has 2 major saponins, bacoside A and B, these saponins have been proven in memory-promoting action and anxiolytic action. *Brahmi* has action over the HPA axis causing reduced levels of cortisol as well as decreasing the 5-HT levels in stress conditions.[12]
- *Ashwagandha* Anti-anxiety effects were observed for root extracts, leaf extracts and isolated compounds including withaferin A and a mixture of sitondosides VII-X.[13]
- *Vacha* contains an active component called asarone which has been studied on behaviour, stress and anxiety.[14]

Effect of intellectual symptoms

- *Guduchi* has been shown to enhance cognitive elements with both its alcoholic and aqueous extracts. This may contribute to improvement in the intellectual symptoms such as attention and concentration in Generalized anxiety disorder.[15]

Effect on Insomnia

- *Ashwagandha* with its active ingredient triethylene glycol (TEG), helps in initiation of sleep by increasing the frequency of NREM.[16]
- *Tagara* contains 6-methylapigenin and hesperidin which have sedative and sleep-enhancing properties.[17]

Effect on Gastrointestinal Symptoms

- Drugs like *Abhaya, Usheera, Mishi, Renuka, Guduchi, Shunti, Kana* are carminatives which may help control the gastrointestinal symptoms.[18]

Effect on genitourinary symptoms

- Lyophilized aqueous extracts from Shatavari root have been studied for its aphrodisiac property, this action may be attributed to the presence of steroidal saponins and hence help in loss of libido experienced in anxiety disorders.[19]
- Root extracts of ashwagandha have also been studies for its aphrodisiac property with improvement in serum hormone levels.[20]

Hence as a compound formulation, with the probable modes of action of drugs in it, *Sarawatharishtam* is effective in the management of *Chittodvega* vis-à-vis Generalized anxiety disorder.

CONCLUSION

Chittodvega is a *Vatapitta pradhana Rajasika Vyadhi*. It is characterized by an anxious state of mind. Based on the clinical features, it can be correlated to Generalized anxiety disorder. To manage this condition *Kalyanaka Ghrita Nasya* followed by *Saraswatharishtam* were administered in the present study. After the completion of intervention for 45 days, there was statistically highly

significant result with p value p <.001. The intervention used in the present study was highly effective in relieving the symptoms of Generalized Anxiety Disorder.

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