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**Comparative Study**

# A comparative study of brahmi taila and anutaila pratimarsha nasya in management of Generalized Anxiety Disorder (GAD)

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## ABSTRACT

Treatment administered in the form of any charya, especially Dinacharya, will ensure a continuous dose of the drug in a safe long-term way that will not harm the patient with side effects, hence an attempt was made to incorporate the Nasya charya as a part of treatment. The study involved 108 patients identified with symptoms of GAD, of which 54 subjects were classified as group A and received Pratimarsha Nasya drops with Brahmi Taila drug. 54 subjects were classified in group B and received Pratimarsha Nasya drops with Anu Taila drug. Research Design taken up was randomized comparative clinical trial conducted in two groups, each group consisting of 50+ patients. The patients were selected from OPD of Sri Sri College of Ayurvedic Sciences and Research, Bengaluru on the basis of judgmental sampling and then were randomly distributed in each group through lottery method. A clinical and social history was taken. The patients were assessed on the basis of Hamilton's anxiety rating scale (HAM-A), and Clinical Global impression (CGI) scale. The difference between CGI –S & CGI –I of group A and Group B was found to be highly significant with significance level of 0.000. It can be said that the pratimarsha nasya procedure may be useful not only to control progression of disease, but it can also pave the way for effective and non-invasive techniques in the treatment of GAD, when implemented at an early stage.

***Keywords:*** *Brahmi taila, Anutaila, Pratimarsha Nasya, Generalized anxiety disorder.*

Even though one becomes familiar with the concept of health, the maintenance part is specially the difficult one. One of the major reasons among the hindrances to health, which is easily overlooked, is the 'Stress'. 'Stress' has become inevitable in the day to day scenario of man. One can either take it positively and overcome, or succumb to it. Our Acharyas recommended following of *Dinacharya* (Daily routine), *Sadvrutta* (virtuous conduct) and *Dharaneeya vegas* (Urges which should be withheld), so as to avoid the negative effect of stress. These rules were formed to maintain the balance between man and his environment (social aspect), and the internal balance of man himself (mental aspect). *The environment plays an important part in forming a link between the agent of the disease and the host. Dinacharya* (Daily routine) plays an important role in controlling the environment (external and internal). As its definition goes – ***Dine dine charya dinacharya I***[1] i.e, it refers

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to the activities carried out on a regular basis. *Pratimarsha* nasya (trans-nasal medication) is one such procedure in *dinacharya* (Daily routine), which should be practiced regularly.

**Generalized anxiety disorder** (**GAD**)[2] is an excessive anxiety and worry about several events or activities for a majority of days during at least a 6-month period. This excessive worry often interferes with daily functioning, as individuals suffering GAD typically anticipate disaster, and are overly concerned about everyday matters such as health issues, money, death, family problems, Friendship problems, Interpersonal relationship problems or work difficulties.

Anxiety is prolonged by uncertainty, and therefore it is important to set out a clear plan of treatment. Patients with recent onset anxiety need no more than counselling, but the more severe and persistent cases usually require additional cognitive or behavioral or drug treatment. ***Pratimarsha Nasya*** (trans-nasal medication) not only ensures the continued medication, but provides strength to Shiras. Hence the topic is taken up for study.

## REVIEW OF LITERATURE

**Nasya** (trans-nasal medication) is one of the *dinacharya* (Daily routine) procedures, which can be explained in simple terms as follows – *Nasayam praneeyamanam aushadham nasyam II* [3] i.e. the medicine administered through nasal route is known as Nasya.

Nasya, and specifically ***Pratimarsha*** nasya is considered as '*Aajanma satmya*'[4] meaning, which is suitable by birth.

Sushruta states that Nasya relives one from urdwa jatru gata rogas and brings about *vimalata* (freshness) *in Indriyas*(sense organs).[5]

Pratimarsha nasya when given in *pratah kala* (early morning) is considered as *Manah prasadakara* (refreshes the mind). [6,7]

**Generalized anxiety disorder**[8] is defined as- *'The anxiety disorder that is characterized by excessive, uncontrollable and often irrational worries about everyday things that is disproportionate to the actual source of worry.'* worry is associated with somatic symptoms such as muscle tension, etc. The anxiety is difficult to control and is subjectively distressing and produces impairment in important areas of a person's life.

***Chittodwega*** (anxious state of mind) can be correlated with **generalized anxiety disorder** on the basis of following considerations. The etymology of *Chittodvega* clearly highlights the anxious status of mind.
The term *Chittodvega*[9] is taken to be a construction of two terms – *Chitta* (mind) + *Udvega* (anxiousness), meaning 'The anxious state of mind', depicting the condition of anxiety.

*Ayurvedic* herbs like *Brahmi*, fulfill the requirements of a safe drug in the treatment of *Chittodwega*. Here a clinical trial is planned to evaluate their efficacy in GAD.

***Brahmi Taila*** [10] is considered to be *Saumya* (mild) and *Sheetala* (cooling), It is *Buddhi vardhaka* (increases intelligence) and *Kesha vardhaka* (favours hair growth). It is known to increase the strength of mind and the power of eyes.

***Anutaila*** is one of the best medicines advocated for Pratimarsha nasya.

## MATERIALS AND METHODS

The symptoms of GAD in its *poorvaroopavastha* (early stage of the disease manifestation) are not much severe and do not require continuous monitoring and stay in the hospital. Therefore, the study was undertaken on OPD basis.

The grouping was made on based on the fact that efficacy of *Nasya karma* (trans-nasal medication) was to be studied as a part of *dinacharya* (Daily routine), the well-established medicine explained for *pratimarsha nasya* (trans-nasal medication). Also, the medicine explained in the same context, - '*anu taila*' was selected.

As the condition was related to mental health, the well - known drug of choice which is also a *rasayana* (nutritional supplement) and hence fit to be administered on daily basis, - *brahmi taila* was selected.

Therefore, subjects of group A were administered *brahmi taila* and subjects of group B were administered *anutaila*.

Both groups had common procedure of *pratimarsha nasya* (trans-nasal medication), but only the medicine administered varied for each group viz., *Anu-taila* and *Brahmi taila*.

Duration of the study was restricted to 3 months. As the research was for a procedure of *dinacharya* (Daily routine), the patients were followed till three months for procedure of *Pratimarsha Nasya* (trans-nasal medication). Currently majority of patients are continuing the process of *Pratimarsha Nasya* (trans-nasal medication) till date. The follow up was fixed once every month so as to keep the patient's condition under observation and also to keep the patient motivated.

### *Study Designs*

Research Design taken up was randomized comparative clinical trial conducted in two groups, each group consisting of 50+ patients. The patients were selected from OPD of Sri Sri College of Ayurvedic Sciences and Research, Bengaluru on the basis of judgmental sampling and then were randomly distributed in each group through lottery method. (Picked serial numbers were assigned to the respective groups)

The follow-up was kept during the treatment after every month so as to ensure the continuity of administration of *nasya* (trans-nasal medication).

Diagnostic and Assessment criteria was taken up through two scales - Hamilton's rating scale for Anxiety neurosis and Clinical Global impression (CGI) scale for severity and improvement, along with general examination to ensure proper fulfillment of inclusion criteria.

### *Hamilton's rating scale for Anxiety neurosis:*[11]

The HAM-A was one of the first rating scales developed to measure the severity of anxiety symptoms and is still widely used today in both clinical and research settings. The scale consists of 14 items, each defined by a series of symptoms, and measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety).

***Scoring***
Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0–56, where <17 indicates mild severity, 18–24 mild to moderate severity and 25–30 moderate to severe.279

***Clinical Global impression (CGI): [12]***
Amongst the most widely used of extant brief assessment tools in psychiatry, the CGI is a 3-item observer-rated scale that measures illness severity (CGIS), global improvement or change (CGIC) and therapeutic response. The illness severity and improvement sections of the instrument are used more frequently than the therapeutic response section in both clinical and research settings.

***Inclusion Criteria***
The age between 18-50 years of either sex were considered as this is the age group which has multiple reasons for stress induction, and are in need of a preventive modality.

Newly diagnosed cases (3 months) were taken up for study as this is a preventive modality and aims at primary prevention rather than curative. Ambulatory and co-operative patients were included because the treatment duration extended for 3 months and the patient's continuity for procedure had to be ensured.

***Exclusion Criteria***
Severe cases having interference with concentration and communication was excluded as it was difficult to convey the motive of the research and also the patients required established medication and therapies.

Patients depending on any other medicines for GAD were also excluded as the intended research was on prevention of GAD rather than treatment.

Patients with systemic diseases like Hypertension, Diabetes and Hyperthyroidism were also excluded to avoid the influence of the disease or its medication on the research topic and also to maintain uniformity in research population.

***Observations and Results***
In this study 108 patients identified with symptoms of GAD and fulfilling the inclusion criteria were selected for the clinical trial by judgmental sampling method. The patients were then randomly divided in 2 groups, comprising of 54 patients each.
The data recorded are presented under the following headings:

***Demographic data***
Demographic data suggest that the majority of patients were in the 30-40 age group and were female. *VataPitta prakruti* seemed more common than others. The patients also suggested that stress related to work or family was more common in them.
Among the specific symptoms of GAD, restlessness and irritability were more common in most patients.

***Table No. 1. Specific data related to disease of individual group***

| HAM-A scale: HAM-A | Mild | | | | Moderate | | | | Severe | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Group A | % | Group B | % | Group A | % | Group B | % | Group A | % | Group B | % |
| **BT** | 35 | 65 | 46 | 85 | 16 | 30 | 5 | 9 | 3 | 5 | 3 | 5 |
| **AF1** | 42 | 78 | 46 | 85 | 9 | 17 | 5 | 9 | 3 | 5 | 3 | 5 |
| **AF2** | 53 | 98 | 53 | 98 | 1 | 2 | 1 | 2 | 0 | 0 | 0 | 0 |
| **AT** | 53 | 98 | 53 | 98 | 1 | 2 | 1 | 2 | 0 | 0 | 0 | 0 |

In Group A,

- It was observed that 35 (65%) Patients had mild symptoms, 16 (30%) had moderate symptoms and 3 (5%) had severe symptoms before commencement of treatment. 42 (78%) Patients had mild symptoms, 9 (17%) had moderate symptoms and 3 (5%) had severe symptoms at the end of day 30.
- 53 (98%) Patients had mild symptoms, 1 (2%) had moderate symptoms and none (0 %) had severe symptoms at the end of day 60.
- 53 (98%) Patients had mild symptoms, 1 (2%) had moderate symptoms and none (0 %) had severe symptoms after the completion of the treatment on day 90.

In Group B,

- 46 (85%) Patients had mild symptoms, 5 (9%) had moderate symptoms and 3 (5%) had severe symptoms before commencement of treatment.
- 46 (85%) Patients had mild symptoms, 5 (9%) had moderate symptoms and 3 (5%) had severe symptoms severe symptoms at the end of day 30.
- 53 (98%) Patients had mild symptoms, 1 (2%) had moderate symptoms and none (0 %) had severe symptoms at the end of day 60.
- 53(98%) Patients had mild symptoms, 1 (2%) had moderate symptoms and none (0 %) had severe symptoms after the completion of the treatment on day 90.

## RESULTS RELATED DATA FOR INDIVIDUAL GROUP

***CGI wilcoxan***

There is not much difference between the Clinical Global Impression- Severity score and Improvement score between group A & group B.

***Table No. 2 - Group A***

**Hypothesis Test Summary**

| | Null Hypothesis | Test | Sig. | Decision |
|---|---|---|---|---|
| 1 | The median of differences between HAM-A before treatment and HAM-A after treatment equals 0. | Related-Samples Wilcoxon Signed Rank Test | .000 | Reject the null hypothesis. |

Asymptotic significances are displayed. The significance level is .05.

The difference between CGI –S & CGI –I of group A is found to be highly significant with the significance level of 0.000. Hence, the $H_0$ is rejected and $H_1$ is accepted.

***Table No. 3 - Group B***

**Hypothesis Test Summary**

| | Null Hypothesis | Test | Sig. | Decision |
|---|---|---|---|---|
| 1 | The median of differences between HAM-A before treatment and HAM-A after treatment equals 0. | Related-Samples Wilcoxon Signed Rank Test | .000 | Reject the null hypothesis. |

Asymptotic significances are displayed. The significance level is .05.

The difference between CGI –S & CGI –I of group B is found to be highly significant with the significance level of 0.000. Hence, the $H_0$ is rejected and $H_1$ is accepted.

***Fredman test***

***Table No. 4 - Group A***

**Ranks[a]**

| | Mean Rank |
|---|---|
| HAM-A after day 30 | 2.99 |
| HAM-A after day 60 | 1.94 |
| HAM-A after treatment | 1.06 |
| a. group = group brahmi tail | |

| Test Statistics[a,b] | |
|---|---|
| N | 54 |
| Chi-Square | 102.292 |
| Df | 2 |
| Asymp. Sig. | .000 |
| a. group = group brahmi tail | |
| b. Friedman Test | |

Here the mean ranks are reducing from day 30 to day 60 to day 90 as – 2.99, 1.94, & 1.06 respectively. It can be inferred that there is improvement in symptoms associated with HAM-A scale. Hance Freadman test is considered to be highly significant with the level of significance being 0.000

***Table No. 5 - Group B***

**Ranks[a]**

| | Mean Rank |
|---|---|
| HAM-A after day 30 | 2.92 |
| HAM-A after day 60 | 2.05 |
| HAM-A after treatment | 1.04 |
| a. group = group Anu taila | |

| **Test Statistics[a,b]** | |
|---|---|
| N | 54 |
| Chi-Square | 101.685 |
| Df | 2 |
| Asymp. Sig. | .000 |
| a. group = group Anu taila | |
| b. Friedman Test | |

Here the mean ranks are reducing from day 30 to day 60 to day 90 as – 2.92, 2.05, & 1.04 respectively. It can be inferred that there is improvement in symptoms associated with HAM-A scale. Hence Freadman test is considered to be highly significant with the level of significance being 0.000

***Table No. 6 - Man Whitney test***

**Hypothesis Test Summary**

| | Null Hypothesis | Test | Sig. | Decision |
|---|---|---|---|---|
| 1 | The medians of HAM-A after treatment are the same across categories of group. | Independent-Samples Median Test | 1.000 | Retain the null hypothesis. |

Asymptotic significances are displayed. The significance level is .05.

If we consider HAM – A score of out-come of day 90 of two groups, there is no much difference between the groups. Hence $H_0$ (no difference between the groups) is accepted.

***Table No. 7 - Wilkoxen for HAM- A***

**Hypothesis Test Summary**

| | Null Hypothesis | Test | Sig. | Decision |
|---|---|---|---|---|
| 1 | The median of differences between HAM-A before treatment and HAM-A after treatment equals 0. | Related-Samples Wilcoxon Signed Rank Test | .000 | Reject the null hypothesis. |

Asymptotic significances are displayed. The significance level is .05.

There is significant difference found in the scores of before treatment and after treatment of HAM-A of group A, with the significance level of 0.000 hence, $H_0$ is rejected and $H_1$ is accepted.

**Hypothesis Test Summary**

| | Null Hypothesis | Test | Sig. | Decision |
|---|---|---|---|---|
| 1 | The median of differences between HAM-A before treatment and HAM-A after treatment equals 0. | Related-Samples Wilcoxon Signed Rank Test | .000 | Reject the null hypothesis. |

Asymptotic significances are displayed. The significance level is .05.

There is significant difference found in the scores of before treatment and after treatment of HAM-A of group B, with the significance level of 0.000 hence, $H_0$ is rejected and $H_1$ is accepted.

## DISCUSSION

In this study 108 patients identified with symptoms of GAD and fulfilling the inclusion criteria were selected for the clinical trial by judgmental sampling method.

The patients were then randomly divided in 2 groups, comprising of 54 patients each.
The data recorded are presented under the following headings:

1. Demographic data
2. Specific data related to disease of individual group
3. Results obtained for individual group

**1. Demographic data Age**:
The observations showed that maximum patients were from the age group of 30-40 years of age which may be due to increased stress level of work, family, finance, etc., and decreased coping ability.

- **Gender**: In this study group, females were found to be more affected than males. This may be the result of balancing the work and family life.
- **Occupation:** Maximum number of the patients were either in some kind of service, they undergo more mental strain rather than physical strain which may be key factors in precipitating the *Cittodvega* (anxious mind).
- **Prakruti** (innate nature): Maximum i.e. 47.7% patients were of *Vata – Pitta*, and *Vata Prakruti*. Mainly *Vata* along with Pitta are main provocative *Doshas* (active principle of body) which help in *samprapti* (disease development) of *Cittodvega* (anxious mind). Thus, it can be said that *Vata* and *Vata– Pitta Prakruti* people are more prone to *Cittodvega* (anxious mind). In the same way, it can be said that *Sama* (equal) *prakruti* (innate nature) patients are less prone to *chittodvega* (anxious mind).
- **Hetu** (Cause)**:** The *hetu* (Cause) was targeted on identifying the stress inducing factors and were grossly classified in to work, family, and finance stress. It was observed that work and family stress gained upper hand which might depend on the fact that man is a social animal and he depends on his companions for fulfillment of his emotional needs. When these needs are not met with, the mental balance gets disturbed, which may lead to conditions like *chittodvega* (anxious mind).

**2. Specific data related to disease of individual group Symptoms:**
In the study group Irritability and restlessness symptoms were found to be more common than other symptoms. These two symptoms actually contribute towards the core meaning of *chitodvega* (anxious mind).

The next highest number of patients suffered from natural consequence of sleep disturbance due to increased mental activity and inability to relax which later results in to increased muscle tension and body pain, which intern results in to fatigue. In addition to these symptoms there's reduced concentrating power. Thus, we can actually see the development of the condition into a full-fledged disease.

- **HAM-A scale:** The scale shows a positive impact of treatment through reduction in number of severe cases from 3 to zero, and reduction of moderate cases from 16 to 1 and as a corollary mild case increased from 35 to 53 patients in group A i.e. *Brahmi taila pratimarsha nasya*. also 3 severe cases to 0 and 5 moderate cases to 1 and also increase in number of mild cases from 46 to 53 in group B i.e. *Anu taila pratimarsha nasya*.

**3. Results related data for individual group**
***CGI wilcoxan***
The test used here is Wilcoxon's signed rank test. It is a non-parametric test. It is usually used when comparing two related samples (also paired samples, or repeated measures on a single sample) to assess whether the mean ranges of the given population differ. (that is, it is a test of paired differences).

In both groups there was significant difference between CGI-S and CGI- I, which showed that there was much improvement after administering PN for three months. Between the groups.

It was observed that there is not much difference between the Clinical Global Impression-Severity score and Improvement score between group A & group B.

Even though there was good difference between before and after treatment in each of the groups, there was not much difference between the two groups. This information actually indicates that there are other factors playing.

***Fredman test***
It is one way Anova for non-parametric data. It will find the variation within the group, between the group and total variation.

Here the mean ranks are reducing from day 30 to day 60 to day 90 in both groups. It can be inferred that there is improvement in symptoms associated with HAM-A scale.

***Man Whitney U- test***
We used the Mann Whitney test to - Determine whether the population medians of two groups differ. When we considered HAM – A score of out-come of day 90 of two groups, there was not much difference between the groups. Hence it can be said that both populations show similar changes. Although group A showed slightly better result than group B, but there is no significant difference.

***Wilkoxen for HAM- A***

As explained above, the Wilcoxon's signed rank test is a non-parametric test. When compared difference in the scores of before treatment and after treatment of HAM-A of group A and group B, there is difference with the significance level of 0.000 indicating positive changes in the score.

## CONCLUSION

It was observed that there is significant difference found in the scores of before treatment and after treatment in HAM-A of group A and also in group B with significance level of 0.000.

The difference between CGI –S & CGI –I of group A and Group B was found to be highly significant with significance level of 0.000. Hence, the Null Hypothesis (H0) was rejected and Research Hypothesis (H1) was accepted.

However, it was noticed that there was no much difference between the Clinical Global Impression- Severity score and Improvement score between group A & group B.

It is evident from the study that *Pratimarsha Nasya* (trans-nasal medication) as a procedure of *Dinacharya* (Daily routine) is highly effective in the management of Generalized anxiety disorder.

Though, *Brahmi Taila* was seen to be more effective as *Mana prasadakara* (refreshing the mind) by the virtue of its properties, it was not reflected statistically to be effective in GAD.

Therefore, the Role of *Taila Pratimarsha Nasya* (trans-nasal medication) in management of GAD is established.

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***Conflict of Interest***
The author declared no conflict of interest.

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