



# AN OPEN LABELLED, NON-COMPARATIVE CLINICAL TRIAL – ON AṄGAMARDA PRAŚAMANA GHANAVAṬI IN THE MANAGEMENT OF CHRONIC FATIGUE SYNDROME.

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## **ABSTRACT:**

**Background:** Chronic fatigue syndrome is a debilitating disorder of unknown aetiology. As per recent studies, it predominately affects adults, with a peak age of onset of between 20-45 years with a female to male ratio of 3:1. Even though disease is having well established clinical features, diagnosis is still of exclusion i.e. mainly from other medical condition. Treatment options include cognitive behavioural therapy & Graded exercise therapy, both are which shown symptomatic relief as per studies. No alternative medicine have been proven efficacy. Aṅgamarda praśamana Mahākaṣāya is one such group of medicine having multidisciplinary action. **Aim:** To evaluate the efficacy of Aṅgamarda praśamana Mahākaṣāya Ghanavaṭi in chronic fatigue syndrome. **Material & Method:** Present study is an open labelled, Non-Comparative clinical study, conducted on 20 subjects with chronic fatigue syndrome, treated with Aṅgamardapraśamana Ghanavaṭi. Subjective assessment was done based on CDC Criteria. **Results:** Subjects responded well for treatment. Significant results were observed on all cardinal symptoms of chronic fatigue syndrome. **Conclusion:** Aṅgamarda praśamana Mahākaṣāya Ghanavaṭi shown significant results in chronic fatigue syndrome.

**Keywords:** Chronic fatigue syndrome, Aṅgamarda praśamana Mahākaśāya Ghanavaṭi, Cognitive behavioural therapy, Graded exercise therapy.

## **INTRODUCTION:**

Chronic fatigue syndrome is a debilitating disorder characterized by persistent & un-explained Fatigue that is not relived by rest lasting for 6 months, resulting in severe impairment in daily functioning. As per the Centres for disease control for chronic fatigue syndrome, along with Fatigue it should be associated with at least four of following symptoms: Post- exertional malaise; unrefreshing sleep; impaired memory or concentration; muscle pain; poly-arthralgia; sore-throat; tender lymph nodes; or new headaches<sup>1</sup>.

The current management for these two conditions in Allied science is mainly by Cognitive behavioural therapy, Graded exercise therapy followed by Analgesics in the form of NSAIDs<sup>2</sup> which provide temporary relief, associated with long term complications. Hence, there is a need to provide an efficient and quality treatment.

By considering the practical challenges in diagnosis & management of chronic fatigue syndrome, it is essential to analyse the pathology involved in this conditions and formulate an effective remedy through Āyurvēda seems to be the best alternative.

Āyurveda is one among ancient science. Even though there is mentioning of few vyadhis (Diseases) in classical texts of Āyurveda, guidelines had been mentioned to understand anukta vyadhi<sup>3</sup> & to treat such conditions. AMP Mahākaśāya is one such formulation mention in charaka saṁhitā sutrasthana, shadvirecanashatashritiya adhyaya<sup>4</sup>. Formulation itself named as Aṅgamardapraśamana, which shows its effect on Aṅgamarda. But analysis of this formulation showed multi-disciplinary action. Hence an attempt had been taken to evaluate its efficacy in chronic fatigue syndrome.

## **AIM & OBJECTIVE:**

To evaluate the efficacy of Aṅgamarda praśamana Mahākaśāya Ghanavaṭi in chronic fatigue syndrome.

## **MATERIALS & METHODS:**

The study got approved by institutional ethical committee (no.: **IRC-EC/SS (1)/2019-20**) & trial was registered in Clinical trial registry of India (Reg.No. **CTRI/2021/02/031222**).

**Study sample:** Aṅgamardapraśamana daśēmāni dravyās as mentioned in Caraka saṁhita i.e., Vidārīgandhā, Pṛśniparṇī, Bṛhatī, Kaṅṭakārika, Eraṅḍa, Kākōlī, Candana, Uśīra, Elā & Madhukā which are

authenticated by Indian pharmacopeia were selected & prepared in the form of ghanavaṭi, from Sanjeevini pharmacy, Kengeri, Bengaluru & the same GMP Certified Medicine was utilized for the study.

**Study design:** The study was a single arm, open-labelled, non-comparative, Pre-post interventional test design.

**Sample size:** 20 subjects [n=20]

**Sampling method:** For present study, 20 Subjects were taken from OPD & IPD of Government Āyurveda Medical College, Mysuru. At the screening visit, all eligible cases willing to participate in the study were given detailed description about the study. Only subjects who met the requirements & signed an informed consent form were included in the study.

At the baseline visit (Day 0), the symptoms of Chronic fatigue syndrome was assessed using Modified CDC Criteria & Aṅgamarda was measured using pain scale. Later subjects were provided with Aṅgamardapraśamana ghanavaṭi (500mg Tablets) & advised to consume 2 vati's Thrice a day, after food with uṣṇajala as anupāna continuously for about 24 days. On 25<sup>th</sup> day patient symptoms were assessed using Modified CDC Criteria.

**Intervention Details:**

TABLE No. 1 DETAILS OF INTERVENTION	
<b>Disease Condition</b>	Chronic fatigue syndrome
<b>Intervention</b>	Aṅgamardapraśamana Mahākaṣāya Ghanavaṭi
<b>Dose</b>	500mg 2 vati's TID
<b>Time of Intervention</b>	After Food
<b>Anupāna</b>	Uṣṇajala
<b>Duration</b>	24 days

**DETAILS OF RASAPANCHAKA OF AṄGAMARDA PRAŚAMANA MAHĀKAŚĀYA****DRAVYAS**

<b>TABLE No.2 OVERVIEW OF AṄGAMARDA PRAŚAMANA MAHĀKAŚĀYA DRAVYĀ'S<sup>7</sup></b>						
<b>SL.No</b>	<b>DRAVYA</b>	<b>RASA</b>	<b>GUᅇA</b>	<b>VĪRYA</b>	<b>VIPĀKA</b>	<b>DŌᅒAGHNATA</b>
1.	<b>Vidārigandhā</b>	Madhura, Tikta	Guru, Snigdha	Uᅒᅇa	Madhura	Tridōᅒaśāmaka
2.	<b>Pᅒᅒniparᅒī</b>	Madhura, Kaᅒu	Laghu, Sara	Uᅒᅇa	Madhura	Tridōᅒaśāmaka
3.	<b>Bᅒhatī</b>	Kaᅒu, Tikta	Laghu, Rooksha	Uᅒᅇa	Kaᅒu	Kapha-Vāta Śāmaka
4.	<b>Kaᅒᅒakārika</b>	Kaᅒu, Tikta	Laghu, Rooksha, Tikᅒᅒᅇa	Uᅒᅇa	Kaᅒu	Kapha-Vāta Śāmaka
5.	<b>Ēraᅒᅒa</b>	Madhura, Anurasa: Kaᅒu, Kashaya	Snigdha, Tikᅒᅒᅇa, sukᅒᅒma	Uᅒᅇa	Madhura	Kapha-Vāta Śāmaka
6.	<b>Kākōlī</b>	Madhura	Guru, Snigdha	Śīta	Madhura	Tridōᅒaśāmaka
7.	<b>Candana</b>	Tikta, Madhura	Laghu, Rukᅒa	Śīta	Kaᅒu	Kapha-Pittahara
8.	<b>Uᅒīra</b>	Tikta, Madhura	Rooksha, Laghu	Śīta	Kaᅒu	Vāta-Pitta Śāmaka
9.	<b>Sūkᅒmailā</b>	Kaᅒu , Madhura	Laghu, Rukᅒa	Śīta	Kaᅒu	Kapha –Vāta Śāmaka
10	<b>Madhukā</b>	Madhura	Guru, Snigdha	Śīta	Madhura	Vāta-Pitta Śāmaka

**DIAGNOSTIC CRITERIA:**

- Routine Lab Investigations to exclude other medical conditions from Chronic fatigue syndrome.
- Standard pain scale to measure aṅgamarda<sup>5</sup>.
- CDC Criteria & Questionnaire for Chronic fatigue syndrome<sup>6</sup>.

**INCLUSION CRITERIA:**

- Subjects of age group 25-45 years.
- Subjects presenting with classical features of Chronic fatigue syndrome & fulfilling diagnostic criteria.

**EXCLUSION CRITERIA:**

- Subjects having any other medical condition explaining fatigue
- Major depressive disorders (psychotic features) or bipolar disorders.
- Schizophrenia, dementia or delusional disorders
- Anorexia nervosa, bulimia nervosa
- Alcohol or substance abuse
- Severe obesity (BMI>40).

**CRITERIA FOR ASSESSMENT:**

Subjects were assessed after the treatment with:

- Standard pain scale for assessment of Aṅgamarda.
- CDC Criteria for Chronic fatigue syndrome. For the present study criteria was modified & given scores for assessment of subjects before & after the intervention.

Pre- assessment will be done on 0th Day & finally Post- assessment on 25<sup>th</sup> Day.

[**Note:** Assessment is mainly based on variation in Pre & Post assessment scorings.]

<b>TABLE No.3 : SHOWING COMPONENTS OF MODIFIED CDC CRITERIA</b>					
<b>Sl.No:</b>	<b>Symptoms</b>	<b>NONE</b>	<b>YES</b>		
			<b>Mild</b>	<b>Moderate</b>	<b>Severe</b>
<b>1.</b>	<b>Fatigue</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>2.</b>	<b>Difficulty with sleep</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Early morning wakening	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Insomnia	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Hypersomnia	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Unrefreshing-sleep	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>3.</b>	<b>Muscles / Joint pain</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Single joint	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Multiple joints	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>4.</b>	<b>Headache</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>5.</b>	<b>Sore throat</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>6.</b>	<b>Cognitive impairment</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Confusion	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Difficulty in thinking	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Inability to concentrate	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Impairment of short term memory	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Word finding difficulty	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Inability to plan / organize thoughts	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Spatial disorientation	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
• Difficulty with information processing	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	
<b>7.</b>	<b>Physical / Mental Exertion make symptom worse</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>

<b>8.</b>	<b>Recurrent flu like symptoms</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>9.</b>	<b>Neuro- endocrine symptoms</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Orthostatic intolerance	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Nausea	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Palpitations	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>10.</b>	<b>Autonomic symptoms</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Loss of thermostatic stability	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
	• Marked weight change	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>

### STATISTIAL ANALYSIS:

<b>TABLE No. 4 STAISTICAL METHODS APPLIED IN THE ANALYSIS OF DATA</b>	
<b>Descriptive Statistics</b>	<b>Inferential Statistics</b>
▪ Frequency	▪ Chi-square test
▪ Percent	▪ Paired Sample 'T' test
▪ Mean	▪ Repeated Measure ANOVA
▪ Standard Deviation	

### OBSERVATIONS:

For present study, total 22 subjects were registered. Around 20 subjects were completed the treatment & 2 subjects due to personal reason didn't came for follow-up. All 20 subjects were assessed properly for CDC Criteria.

Among 20 subjects, Maximum 14 (70%) subjects were Female, 19 (85.0%) subjects were Hindu, 17 (85.0%) subjects were married, 13 (65.0%) subject was from Urban, 19 (95%) subjects were from Middle class family & 12 (60%) subjects were from IT Profession.

Among 20 subjects enrolled for study, Persistent fatigue was present in 15 (75%) subjects, 10 (50%) subjects had disturbed sleep, All 20 (100%) subjects had Multiple joints pain, 13 (65%) subjects had Confusion, 7 (35%) subjects had Difficulty in thinking, 10 (50%) subjects had Inability to concentrate, 4 (20%) subjects had Impairment in short term memory, 3 (15%) subjects had Word finding difficulty, 13

(65%) subjects had Inability to plan or organize thoughts, No subjects had Spatial disorientation & 9 (45%) subjects had Difficulty with information processing. All 20 were presented with aggravation of symptom on physical / mental exertion, 10 (50%) subjects had orthostatic intolerance, 2 (10%) subjects had Nausea & 11 (55%) subjects had Palpitations.

## **RESULTS:**

Aṅgamarda Praśamana Mahākaṣāya Ghanavaṭi results were highly significant on all the components & symptoms of Chronic fatigue syndrome.

<b>TABLE No 5: Q10. OBSERVATION ACCORDING TO c/o FATIGUE &gt;6 MONTHS</b>					
	Category	Before Intervention		After Intervention,	
		Frequency	Percent	Frequency	Percent
<b>Persistent Fatigue</b>	<b>None</b>	<b>5</b>	25.0%	<b>11</b>	40.0%
	<b>Mild</b>	<b>0</b>	0.0%	<b>9</b>	45.0%
	<b>Moderate</b>	<b>2</b>	10.0%	<b>0</b>	0.0%
	<b>Severe</b>	<b>13</b>	65.0%	<b>0</b>	0.0%
<b>Unexplained Fatigue</b>	<b>None</b>	<b>14</b>	70.0%	<b>17</b>	85.0%
	<b>Mild</b>	<b>0</b>	0.0%	<b>3</b>	15.0%
	<b>Moderate</b>	<b>0</b>	0.0%	<b>0</b>	0.0%
	<b>Severe</b>	<b>6</b>	15.0%	<b>0</b>	0.0%
<b>PEARSON CHI-SQUARE SIGNIFICANT VALUE: .001</b>					



<b>TABLE No 6: Q20.0% OBSERVATION ACCORDING TO DISTURBANCE TO SLEEP</b>					
	Category	Before Intervention		After Intervention,	
		Frequency	Percent	Frequency	Percent
<b>Early Morning Wakening</b>	<b>None</b>	<b>13</b>	<b>65.0%</b>	<b>16</b>	<b>80.0%</b>
	<b>Mild</b>	<b>1</b>	<b>5.0%</b>	<b>4</b>	<b>20.0%</b>
	<b>Moderate</b>	<b>3</b>	<b>15.0%</b>	<b>0</b>	<b>0.0%</b>
	<b>Severe</b>	<b>3</b>	<b>15.0%</b>	<b>0</b>	<b>0.0%</b>
<b>Pearson Chi-Square Significant Value: .044</b>					
<b>Insomnia</b>	<b>None</b>	<b>18</b>	<b>90.0%</b>	<b>18</b>	<b>90.0%</b>
	<b>Mild</b>	<b>0</b>	<b>0.0%</b>	<b>2</b>	<b>10.0%</b>
	<b>Moderate</b>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>
	<b>Severe</b>	<b>2</b>	<b>10.0%</b>	<b>0</b>	<b>0.0%</b>
<b>Pearson Chi-Square Significant Value: .135</b>					
<b>Hypersomnia</b>	<b>None</b>	<b>20</b>	<b>100.0%</b>	<b>20</b>	<b>100.0%</b>
<b>Pearson Chi-Square Significant Value: .001</b>					
<b>Unrefreshing Sleep</b>	<b>None</b>	<b>11</b>	<b>55.0%</b>	<b>18</b>	<b>90.0%</b>
	<b>Mild</b>	<b>0</b>	<b>0.0%</b>	<b>2</b>	<b>10.0%</b>
	<b>Moderate</b>	<b>6</b>	<b>30.0%</b>	<b>0</b>	<b>0.0%</b>
	<b>Severe</b>	<b>3</b>	<b>15.0%</b>	<b>0</b>	<b>0.0%</b>
<b>Pearson Chi-Square Significant Value: .005</b>					
<b>Disturbed Sleep</b>	<b>None</b>	<b>11</b>	<b>55.0%</b>	<b>15</b>	<b>75.0%</b>
	<b>Mild</b>	<b>0</b>	<b>0.0%</b>	<b>5</b>	<b>25.0%</b>
	<b>Moderate</b>	<b>6</b>	<b>30.0%</b>	<b>0</b>	<b>0.0%</b>
	<b>Severe</b>	<b>3</b>	<b>15.0%</b>	<b>0</b>	<b>0.0%</b>

Pearson Chi-Square Significant Value: .002

**TABLE No 7: Q3: OBSERVATION ACCORDING TO MUSCLE / JOINT PAIN**

	Category	Before Intervention		After Intervention,	
		Frequency	Percent	Frequency	Percent
Single Joint Pain	None	20	100.0%	20	100.0%
Multiple Joint Pain	None	0	0.0%	12	60.0%
	Mild	0	0.0%	8	40.0%
	Moderate	2	10.0%	0	0.0%
	Severe	18	90.0%	0	0.0%

Pearson Chi-Square Significant Value: .001

**TABLE No 8: Q4: OBSERVATION ACCORDING TO HEADACHE**

Category	Before Intervention		After Intervention	
	Frequency	Percent	Frequency	Percent
None	1	5.0%	17	85.0%
Mild	0	0.0%	3	15.0%
Moderate	16	80.0%	0	0.0%
Severe	3	15.0%	0	0.0%

Pearson Chi-Square Significant Value: .001

**TABLE No 9: Q5: OBSERVATION ACCORDING TO SORE THROAT**

Category	Before Intervention		After Intervention,	
	Frequency	Percent	Frequency	Percent
None	14	70.0%	19	95.0%
Mild	4	20.0%	1	5.0%
Moderate	2	10.0%	0	0.0%
Severe	0	0.0%	0	0.0%

PEARSON CHI-SQUARE SIGNIFICANT VALUE: .102

**TABLE No 10: Q6A: OBSERVATION ACCORDING TO COGNITIVE IMPAIRMENT**

	Category	Before Intervention		After Intervention,	
		Frequency	Percent	Frequency	Percent
Confusion	None	7	35.0%	13	75.0%
	Mild	2	10.0%	7	35.0%
	Moderate	10	50.0%	0	0.0%
	Severe	1	5.0%	0	0.0%
<b>Pearson Chi-Square Significant Value: .001</b>					
Difficulty In Thinking	None	13	65.0%	16	80.0%
	Mild	1	5.0%	4	20.0%
	Moderate	5	25.0%	0	0.0%
	Severe	1	5.0%	0	0.0%
<b>Pearson Chi-Square Significant Value: .044</b>					
To Inability To Concentrate	None	10	50.0%	16	80.0%
	Mild	1	5.0%	4	20.0%
	Moderate	6	30.0%	0	0.0%
	Severe	3	15.0%	0	0.0%
<b>Pearson Chi-Square Significant Value: .007</b>					
Short Term Memory Loss	None	17	85.0%	20	100.0%
	Mild	2	10.0%	0	0.0%
	Moderate	1	5.0%	0	0.0%
	Severe	0	0.0%	0	0.0%
<b>Pearson Chi-Square Significant Value: .198</b>					

<b>TABLE No 11: Q6B: OBSERVATION ACCORDING TO COGNITIVE IMPAIREMENT</b>					
	Category	Before Intervention		After Intervention,	
		Frequency	Percent	Frequency	Percent
<b>Word Finding Difficulty</b>	None	16	80.0%	20	100.0%
	Mild	1	5.0%	0	0.0%
	Moderate	3	15.0%	0	0.0%
	Severe	0	0.0%	0	0.0%
<b>Pearson Chi-Square Significant Value: .108</b>					
<b>Inability To Plan / Organize Thoughts</b>	None	8	40.0%	11	55.0%
	Mild	0	0.0%	8	40.0%
	Moderate	9	45.0%	1	5.0%
	Severe	3	15.0%	0	0.0%
<b>Pearson Chi-Square Significant Value: .001</b>					
<b>Spatial Disorientation</b>	None	20	100.0%	20	100.0%
<b>Pearson Chi-Square Significant Value: .007</b>					
<b>Difficulty With Information Processing</b>	None	11	55.0%	14	70.0%
	Mild	0	0.0%	6	30.0%
	Moderate	8	40.0%	0	0.0%
	Severe	1	5.0%	0	0.0%
<b>Pearson Chi-Square Significant Value: .002</b>					

**TABLE No 12: Q7: OBSERVATION ACCORDING TO PHYSICAL / MENTAL EXERTION**

Category	Before Intervention		After Intervention,	
	Frequency	Percent	Frequency	Percent
None	0	0.0%	4	20.0%
Mild	0	0.0%	16	80.0%
Moderate	0	0.0%	0	0.0%
Severe	20	100.0%	0	0.0%

Pearson Chi-Square Significant Value: .001

**TABLE No 13: Q8: OBSERVATION ACCORDING TO RECURRENT FLU LIKE SYMPTOMS**

Category	Before Intervention		After Intervention,	
	Frequency	Percent	Frequency	Percent
None	17	85.0%	20	100.0%
Mild	3	15.0%	0	0.0%
Moderate	0	0.0%	0	0.0%
Severe	0	0.0%	0	0.0%

Fisher's Exact Test Significant Value: .231

**TABLE No 14: Q9: OBSERVATION ACCORDING TO NEURO0.0%ENDOCRINE SYMPTOMS**

	Category	Before Intervention		After Intervention,	
		Frequency	Percent	Frequency	Percent
Orthostatic Intolerance	None	9	45.0%	15	75.0%
	Mild	4	20.0%	5	25.0%
	Moderate	4	20.0%	0	0.0%

	Severe	3	15.0%	0	0.0%
<b>Pearson Chi-Square Significant Value: .035</b>					
Nausea	18	90.0%	20	100.0%	18
	2	10.0%	0	0.0%	2
	0	0.0%	0	0.0%	0
	0	0.0%	0	0.0%	0
<b>Pearson Chi-Square Significant Value: .487</b>					
Palpitations	None	10	50.0%	18	90.0%
	Mild	2	10.0%	2	10.0%
	Moderate	8	40.0%	0	0.0%
	Severe	0	0.0%	0	0.0%
<b>Pearson Chi-Square Significant Value: .006</b>					

**TABLE No 15: Q10: OBSERVATION ACCORDING TO AUTONOMIC SYMPTOMS**

	Category	Before Intervention		After Intervention,	
		Frequency	Percent	Frequency	Percent
Loss Of Thermostatic Stability	None	19	95.0%	20	100.0%
	Mild	1	5.0%	0	0.0%
	Moderate	0	0.0%	0	0.0%
	Severe	0	0.0%	0	0.0%
<b>Pearson Chi-Square Significant Value: 1.001</b>					
Marked Weight Change	None	14	70.0%	15	75.0%
	Mild	1	5.0%	5	25.0%
	Moderate	5	25.0%	0	0.0%

	<b>Severe</b>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>
<b>Pearson Chi-Square Significant Value: .021</b>					

## EFFICACY ON PAIN

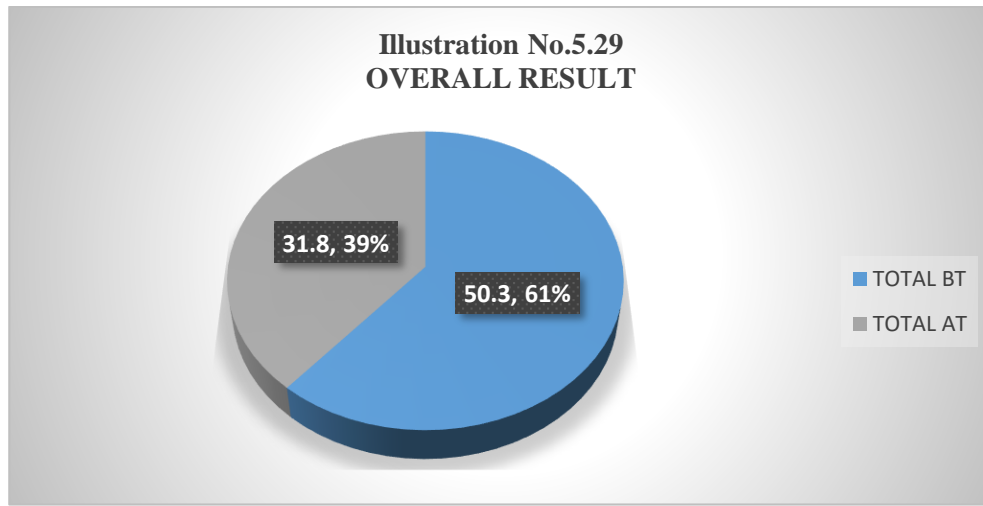
Before the intervention, maximum of 19 (95%) subjects had severe pain & 1 (5%) Subject had Moderate pain. After Intervention, 9 (45%) subjects had No pain & 11 (55%) subjects had only mild pain. Intervention was highly significant with P value .001

<b>TABLE No 16: Q11: OBSERVATION ACCORDING TO PAIN</b>				
Category	Before Intervention		After Intervention,	
	Frequency	Percent	Frequency	Percent
None	<b>0</b>	0.0%	<b>9</b>	45.0%
Mild	<b>0</b>	0.0%	<b>11</b>	55.0%
Moderate	<b>1</b>	5.0%	<b>0</b>	0.0%
Severe	<b>19</b>	95.0%	<b>0</b>	0.0%
<b>Pearson Chi-Square Significant Value: .001</b>				

## OVERALL EFFECT OF INTERVENTION:

The overall effect of the intervention on CFS baseline & after intervention, is given below. The statistical analysis revealed that the mean score of assessment scale, which was 50.30 before intervention, was reduced to 31.80 after the intervention. The change from baseline to after intervention, was statistically highly significant (with P value .001). Further details with Standard deviation, Standard error of Mean, 't' value & 'p' value are given below in table no. 5.29 & is represented in illustration No. 5.29.

<b>TABLE NO 17: PAIRED SAMPLES STATISTICS</b>				
	Mean	N	Std. Deviation	Std. Error Mean
<b>TOTAL BT</b>	<b>50.30</b>	<b>20</b>	<b>2.830</b>	<b>.633</b>
<b>TOTAL AT</b>	<b>31.80</b>	<b>20</b>	<b>1.508</b>	<b>.337</b>



### DISCUSSION:

AMP Mahākaṣāya is one such combination with multidisciplinary action. Analysis of rasadi pancaka of dravya reveals its efficacy in chronic fatigue syndrome as follows.

- **Rasa:** among 10 dravyās, of Mahākaṣāya, 5 dravyās are of madhura rasa pradhāna, 3 dravyās are kaṭu rasa pradhāna & 2 dravyās are tikta rasa pradhāna.
- **Guṇa:** 5 dravyās are having Laghu-Rūkṣa guṇa, 3 are having Guru-Snighdha guṇa
- **Vīrya & Vipāka:** Among 10 dravyās, 5 dravyās are Śīta vīrya & remaining 5 are of Uṣṇa vīrya. Similarly, 5 with Madhura vipāka & Remaining 5 with Kaṭu vipāka.
- **Dōṣagnata:** Among 10 dravyās, 3 dravyās are Tridōṣa śāmaka, 4 are Kapha-vāta śāmaka, 1 with Kapha-Pittahara & 2 with Vāta-Pitta śāmaka.



**Table No. 6.1: KARMUKATA OF AṄGAMARDAPRAŚAMANA DAŚĒMĀNI  
BASED ON PRADHĀNA RASA**

Sl.No.	Rasa	Karma
Rasa	Madhura <sup>8</sup>	<ul style="list-style-type: none"> <li>➤ Āyusyaḥ, Ṣaḍindriya prasādaka, <b>Pitta-viṣa-mārutaghnaḥ</b>, Balyaḥ, Prīṇana, Jīvana, Tarpaṇa, Bṛhmaṇa, Sthairyakara, <b>Mūrchāpraśamanaḥ</b></li> <li>➤ Rasa-Rakta-Māmsa-Mēdō-Asthi-Majja-<b>Ōjaḥ-Śukra-</b>Stanyavardhana</li> </ul>
	Kaṭu <sup>9</sup>	<ul style="list-style-type: none"> <li>➤ Agniṁ Dīpayati, <b>Mārgān Vivṛṇōti</b>, Ślēṣmāṇaṁ Śamayati</li> <li>➤ Dīpana, Pācana, Rōcana, <b>Ālasya Praśamana</b></li> </ul>
	Tikta <sup>10</sup>	<ul style="list-style-type: none"> <li>➤ <b>Mūrchāpraśamanaḥ</b>, Sthirīkaraṇa, Dīpana, Pācana</li> <li>➤ Dīpana, <b>Mūrchāpraśamanaḥ</b></li> </ul>
Guna	Laghu & Rooksha Guṇa	Is beneficial in removing the kapha (In terms of Āma also), which is the reason for Srōtōrodha.
	Guru & snigdha guṇa	Beneficial in alleviating aggravated Vāta dōṣa.
Vīrya	Uṣṇa Vīrya dravyās <sup>11</sup>	Pacifies Vāta-Kapha dōṣa
	Śīta Vīrya dravyās <sup>11</sup>	Pacify Pitta dōṣa.
Vipāka	Madhura vipāka dravyās	Vāta-pitta śāmaka, does the action of Santarpaṇa & Dhatu poshana.
	Kaṭuvipāka dravyās	Act as kapha śāmaka, does the action of Pachana followed by Deepana & anulomana.

Along with this, 3 dravyās are endowed with Tridōṣa śāmaka, 4 with Kapha-vāta śāmaka, 1 with Kapha-Pittahara & 2 with Vāta-Pitta śāmaka karma. With this catagorisation one can infer that Aṅgamardapraśamana daśēmāni dravyās are capable enough to do **tridōṣaśāmaka karma**.

Many of **Aṅgamardapraśamana dravyas** also present in other **Mahākaṣāya varga** mentioned in **Kashaya varga of caraka saṁhitā**. Through which one can infer that Aṅgamardapraśamana also help in doing other Santarpaṇa karmas like Jīvanīya, Bṛhmaṇīya & Balya, addressing other comorbid conditions like Kāśahara, Chardinigrahaṇa etc. Hence through this Multidisciplinary action of Aṅgamardapraśamana can be known. it also helps in repair and re-establishment of the dhātus through its Rāśayana Karma.

**Discussion on Efficacy of Intervention:**

**Nature of the disease** – On general consideration, CFS represent a common pathology i.e., apatarpaṇa. The Apatarpaṇōttha vikāras are Vāta-Pitta dōṣa predominant in nature and occur in Vāta-Pitta prakṛti individuals due to the susceptibility.

**Nature of the Cikitsā** – Thus as discussed above, the Apatarpaṇōttha sārīra, Vāta-Pitta dōṣa, Rasa dhātu all have one common line of management i.e., Santarpaṇa (e.g., Brumhaṇa).

So one can infer that Aṅgamardaprasāmana Mahākaṣāya gaṇa chiefly perform “**Santarpaṇa Karma**”.

**DISCUSSION ON EFFECT OF INTERVENTION ON CFS BASED ON MODIFIED CDC CRITERIA & QUESTIONNAIRE:**

Among the components of assessment criteria,

- ▲ Fatigue & Multiple Joint Pain is due to Vāta pradhāna Tridōṣa duṣṭi.
- ▲ Disturbed Sleep, Head Ache, Sore Throat, Confusion, Inability to concentrate, Inability to plan or organize thoughts, Physical / Mental exertion makes symptom worse are vāta pradhāna lakṣaṇa.
- ▲ Orthostatic Intolerance, Palpitation are vāta-Pitta pradhāna lakṣaṇa.

As mentioned earlier, effect of intervention on CFS is based on following criteria.

**Effect of intervention on Fatigue & Multiple Joint Pain:**

Fatigue can be considered as Śrama & multiple joint pain as Aṅgamarda to some extent in terms of Āyurveda. It is seen due to duṣṭi as Vāta- Pitta vṛddhi, Kapha kṣaya or vāta vṛddhi, pitta sama & Kapha Kṣaya; As Madhura rasa is having balya, prīṇana, tarpaṇa, jīvanīya, sthīrikārana & Vāta hara property & kaṭu rasa is having Ālasya prasāmana property, significant results were observed.

**Effect of intervention on disturbed sleep:**

Disturbed sleep can be considered as Viṣama nidra which is mainly due to Vāta dōṣa duṣṭi. As madhura rasa is having mārutaghna property & through uṣṇa vīrya & madhura vipāka one can infer Vāta prasāmana karma, so improvements were seen in disturbed sleep.

**Effect of intervention on Headache:**

Headache can be considered as Aṅgamarda to some extent, which is mainly due to Vāta pradhāna duṣṭi as explained earlier. As madhura rasa is having Vātāhāra karma, Kaṭu rasa is having Mārgan vivrunoti karma, significant results were observed.

**Effect of intervention on Sore Throat, Confusion, Inability to concentrate, Inability to plan or organize thoughts, Physical / Mental exertion makes symptom Worse:**

All these symptoms can be considered mainly due to Vāta pradhāna duṣṭi. Based on pradhānata of madhura rasa, Guru-sniḡdha guṇa, uṣṇa & madhura vipāka one can infer Vāta Prasāmana karma along with Balya, Jīvanīya & rasāyana karma, significant results were observed.

### **Effect of intervention on Orthostatic Intolerance, Palpitation:**

Symptoms like Orthostatic Intolerance, Palpitation can be considered due to Vāta-Pitta pradhāna duṣṭi. As Madhura rasa is having Pitta viṣama marutaghna, murchaprasamana h & Tikta rasa with murchaprasamana property, significant results were observed.

### **CONCLUSION:**

Chronic fatigue syndrome is one among fast expanding global disease, which needs a complete remedy to act on it. AMP Mahākaṣāya is one such formulation which gives promising result in this debilitating condition. It showed satisfactory results on major components of CFS. i.e., on Fatigue, Muscle / Joint pain, Headache, Physical / Mental exertion, major components of Cognitive impairment & on Pain [P=0.001], Disturbed sleep [P=0.002] & Insignificant on components like Sore-throat [P=0.102], Autonomic symptoms. These insignificant results are mainly because of less prevalence of these symptoms on selected subjects for present study. With this one can understand that AMP Mahākaṣāya is effective in counteracting CFS.

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