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CLINICAL STUDY OF HEMADRI RASA IN TAMAKA SHWASA – A UNIQUE FORMULATION

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ABSTRACT

Ayurveda offers treatment for all disorders known to men. One of the ancient diseases that often troubles humankind is Tamaka Shwasa or Bronchial Asthma. Hemadri rasa is a formulation postulated by Rasendra Chinthamani containing Shuddha Parada, Shuddha Gandhaka, Shuddha Tamra and Shuddha Manashila, with a unique preparation method. **Inclusion Criteria** - Symptoms of Shwasa Krichratha, Kasa, Kanta ghurghuratha, Asino Labhate Soukhyam, and Ura Shula were considered. **Objective criteria** – ESR, AEC, DEC, FEV ratio and Chest X-ray. **Results** - Shwasa Kruchratha – 100%, Kanta ghurghuratha – 82.2%, Kasa – 56.59%, Asino Labhate shoukhyam – 100%, Ura Shula – 100%, ESR – 40.47%, AEC – 60.93%, DEC – 53.57%, FEV ratio - 2.7%. **Overall effect of therapy** – No improvement – 0%, Mild improvement – 07%, Moderate improvement – 03%, Marked improvement – 60%, Significant improvement – 30%.

INTRODUCTION

Ayurveda is not merely a science of diseases and drugs, where it has every aspect of life in its sphere. This system's main aim is maintaining good health and enhancing the bright & healthy life span.

Rasashastra and Bhaishajya Kalpana, known as the art of *Vedic* alchemy, is a fusion between mineral and organic compounds. It is a branch of *Ayurveda* that has given great emphasis to the comprehensive

knowledge of both mineral and herbal drugs and the preparation, preservation, and dispensing of the preserved drugs. *Tamaka shwasa*[2,3,4,5,6] is a dreadful disease mentioned in all Ayurvedic classics as a *Vata Kaphaja* disorder with *sanga* pathology. The patients suffering from *Tamaka shwasa roga* will have symptoms like *shwasa kruchrutha, kasa, gurgurutha, asino labhathe soukhyam and urashoola*. It can be equated to Bronchial Asthma and COPD in modern medical science. Incidence rates of these diseases have increased multifold, vowing to altercations in air quality in urban areas, lifestyle modifications, and inappropriate cuisine patterns.

Rasa dravyas have been familiar to humanity for a long time, but their appropriate therapeutic utility started around the 8th century. Since then, revered vaidyas used many herbomineral and mineral preparations, but there was a notable hiatus in comprehensive data regarding analytical parameters and clinical data. *Hemadri Rasa*[1] is a unique formulation found in *Rasendra Chinthamani*, with ingredients in *Shuddha Parada, Shuddha Gandhaka, Shuddha Tamra, and Shuddha Manashila*. *Tamra* having *Kashaya* and *Madhura rasa* mitigates *Vata* and *Kapha dosha* and possesses *Lekhana* property, which is beneficial in *Kapha nissarana* and *srotho vivarana*. *Manashila* also exhibits the same properties as *Tamra* and plays an essential role in subduing *Shwasa roga*. *Hemadri rasa* has *Kajjali* as a prime ingredient which acts as a vehicle for the drug to reach the target site and plays a vital role in the treatment of *Shwasa roga*. So due to these beneficial properties, *Hemadri rasa* becomes the preferable choice in treating *Tamaka Shwasa* and has a cutting edge over presently marketed formulations prescribed for respiratory diseases.

Materials & Methods:

A. Selection of Patients:
For the present study, patients fulfilling the clinical criteria for diagnosing Tamaka Shwasa were randomly selected from the OPD and IPD sections of Taranath Govt Ayurvedic Hospital, Bellary, irrespective of their sex, religion, occupation, etc.

B. Criteria for Inclusion and Exclusion:

INCLUSION CRITERIA
1. Patients between the age groups of 16-60 years
2. Patient with the following diagnostic symptoms of Tamaka shwasa
3. Shwasa krucchrata
4. Ghurgurata
5. Kaasa
6. Asino labhate soukhyam
7. Urashoola

EXCLUSION CRITERIA:
1. Patients aged below 16 years & above 60 years.
2. Patients suffering from multiorgan failure, undergoing dialysis and other
Systemic complications.
3. Lactating & Pregnant women.

C. End staged disorders, Tuberculosis, Ca lungs
   Criteria for Diagnosis:
   - Classical signs & symptoms of Tamaka Shwasa roga according to textual basis.
   - A special proforma was prepared with all the signs and symptoms of Tamaka Shwasa roga.

D. Drug, Dose & Duration of Therapy:
   Drug –Hemadri Rasa internal administration of 125mg in 8 divided doses.
   Duration – 24 days.
   A single group of 30 patients, for which 34 patients were selected, out of which four dropped out.

E. Pathyapathya:
   During the treatment, the patients were asked to follow the pathya apathya prescribed for Tamaka Shwasa in classics.

F. Assessment Criteria:
   All the patients were examined on the 24th day of treatment. The assessment criteria were based on relief in the disease's signs and symptoms. For this purpose, cardinal signs and symptoms were scored according to their severity before and after treatment.

Table no 1:Grading for Parameters:

SI.No.	SYMPTOMS	GRADINGS
1	**Shwasa krucchrata**	0-No shwasa krucchrata. 1-Mild, Shwasa krucchrata after heavy work, relieved by rest. 2-Moderate, Shwasa krucchrata on slight exertion. Patients carry out daily activities with difficulty. 3-Severe, Shwasa krucchrata even at rest. Patients are unable to carry out daily activities.
2	**Kasa**	0-No kasa. 1-Mild, Kasa sometimes but it is not troublesome. 2- Moderate, Kasa is troublesome but does not disturb sleep. Patients carry out daily activities with difficulty. 3- Severe, very troublesome kasa, does not even allow you to sleep. Patients are unable to carry out daily activities.
3	**Ghurghurata**	0-No wheezing. 1- Mild, Wheezing only at night. 2- Moderate, Wheezing at night and occasionally during daytime. Patients carry out daily activities with difficulty. 3- Severe, Wheezing throughout the day. Patients are unable to carry out daily activities.
4	**Asino labhate Soukhyam**	0-Relief on lying position. 1- Mild, temporarily feels better in sitting posture. 2- Moderate, sitting posture gives relief. Patients carry out daily activities with difficulty. 3- Severe, Spontaneous Sitting posture, cannot sleep. Patients are unable to carry out daily activities.
5	**Urashoola / parshwashoola**	0-No urashoola. 1- Mild, Urashoola along with shvasa. 2- Moderate,Often Urashoola even without shvasa. Patients carry out daily activities with difficulty. 3- Severe, always urashoola. Patients are unable to carry out daily activities.
6	**Absolute Eosinophil Count**	
7	**Erythrocyte Sedimentation Rate**	
8	**Diffrential Eosinophil Count**	
9	**FEV1/FEC ratio**	
10	**X – ray**	

G. Criteria for the total effect of the therapy:
- Cured – Patients who show more than 75% improvement in signs & symptoms have been cured.
- Markedly Improved—Patients who show an average improvement of 50-75% in their signs and symptoms have improved significantly.

- Partially Improved – Patients showing improvement in between 25-50% in signs& symptoms have been considered as partially improved.
- Unchanged – No change or less than 25% improvements in signs & symptoms have been considered unchanged.

H. Follow-up study:

All the patients were advised to attend the OPD for another seven days after completing their treatment as a follow-up study.

Observations

Each patient was observed thoroughly and noted neatly. The observations were recorded, and necessary charts and graphs were made.

Table no 2:Showing Effect on *Shwasa kruchruta*

Symptom	Mean score								
Shwasa kruchruta	Bt	At	Bt-at	%	Sd	Se	WSRT value	P value	Remarks
	2.867	0	2.867	100	0.3457	0.063	465.0	0.001	HS

Effect on *Shwasa Kruchruta*

This work of 30 subjects studied in *Tamaka Shwasa* Roga ***Shwasa kruchruta*** is revealed and given in detail. Statistical analysis showed that the mean score, 2.867 before the treatment, was reduced to 0 after the treatment with 100% improvement. Statistical analysis showed that the change that occurred with the treatment is more significant than would be expected by chance; there is a statistically significant result with ($p < 0.001$).
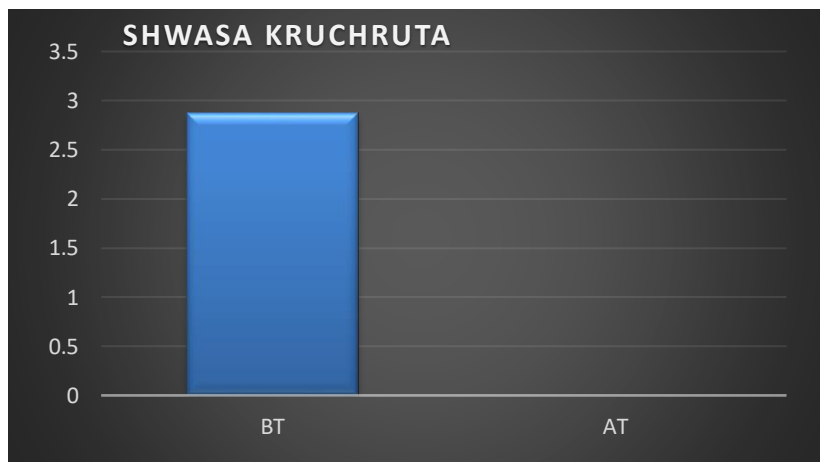

Graph no 1:Showing effects on Shwasa kruchruta

Table no 3:Showing Effect on *gurgurutha*

Symptom	Mean score								
	Bt	**At**	**Bt-at**	**%**	**Sd**	**Se**	**WSRT value**	**P value**	**Remarks**
Gurgurta	1.500	0.2667	**1.233**	**82.2**	**0.9353**	**0.1708**	**276**	**0.001**	**HS**

Effect on *Gurgurutha*

This work of 30 subjects studied in *Tamaka Shwasa* Roga with **Gurgurutha** is revealed and given in detail. Statistical analysis showed that the mean score, 1.5 before the treatment, was reduced to 0.267 after the treatment with 82.2% improvement. Statistical analysis showed that the change that occurred with the treatment is more significant than would be expected by chance; there is a statistically significant result with ($p<0.001$).
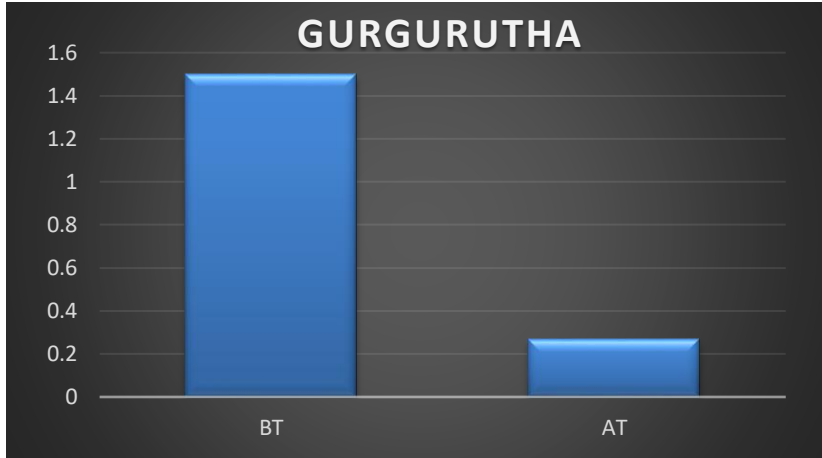

Graph no 2: Showing Effect on *Gurgurutha*

Table no 4:Showing Effect on *Kasa*

Symptom	Mean score								
	Bt	At	Bt-at	%	Sd	se	WSRT value	P value	Remarks
Kasa	1.767	0.7667	1.00	56.593	0.7878	0.1438	276.0	0.001	HS

Effect on *Kasa*

In this work 30 subjects studied in *Tamaka Shwasa* Roga with **Kasa** revealed are given in detail. Statistical analysis showed that the mean score, which was 1.767 before the treatment, was reduced to 0.7667 after the therapy with 56.593% improvement. Statistical analysis showed that the change that occurred with the treatment is more significant than would be expected by chance; there is a statistically significant result with ($p<0.001$).
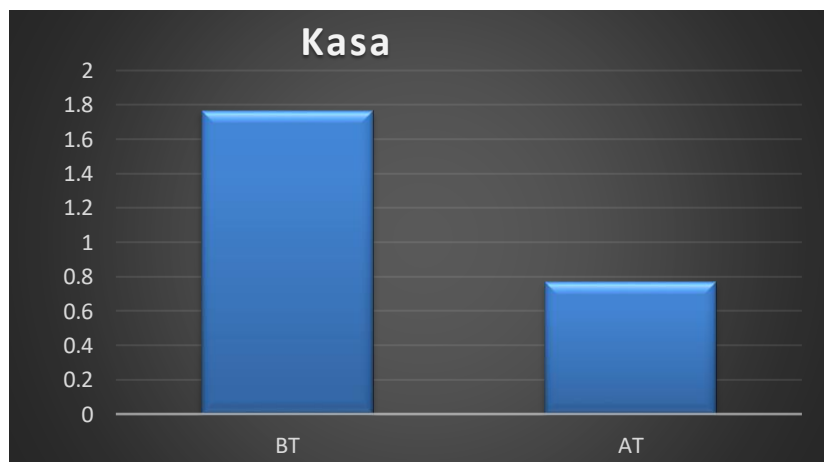
Graph no 3:Showing Effect on *Kasa*

Table no 5:Showing Effect on *Asino labhate soukhyam*

Symptom	Mean score						WSRT value	P value	Remarks
	Bt	At	Bt-at	%	Sd	Se			
Kasa	1.733	0.00	1.733	100	0.8683	0.1585	231	0.0001	HS

Effect on *Asino labiate soukhyam*

In this work of 30 subjects studied in *Tamaka Shwasa* Roga with ***Asino labhate soukhyam*** revealed in detail Statistical analysis showed that the mean score, which was 1.733 before the treatment, was reduced to 0.0 after the treatment, with 100% improvement. Statistical analysis showed that the change that occurred with the treatment is more significant than would be expected by chance; there is a statistically significant result with ($p<0.001$).


Graph no 4: Showing Effect on *Asino labhate soukhyam*

Table no 6:Showing Effect on *Urashoola*

Symptom	Mean score						WSRT value	P value	Remarks
	Bt	At	Bt-at	%	Sd	Se			
Kasa	0.6333	0.00	0.6333	100	0.8503	0.1552	78	0.0001	HS

Effect on *Urashoola*

This work of 30 subjects studied in *Tamaka Shwasa* Roga with ***Urashoola*** revealed are given in detail. Statistical analysis showed that the mean score, which was 0.6333 before the treatment, was reduced to 0.0 after the treatment with 100% improvement. Statistical analysis showed that the change that occurred with the treatment is more significant than would be expected by chance; there is a statistically significant result with ($p<0.001$).
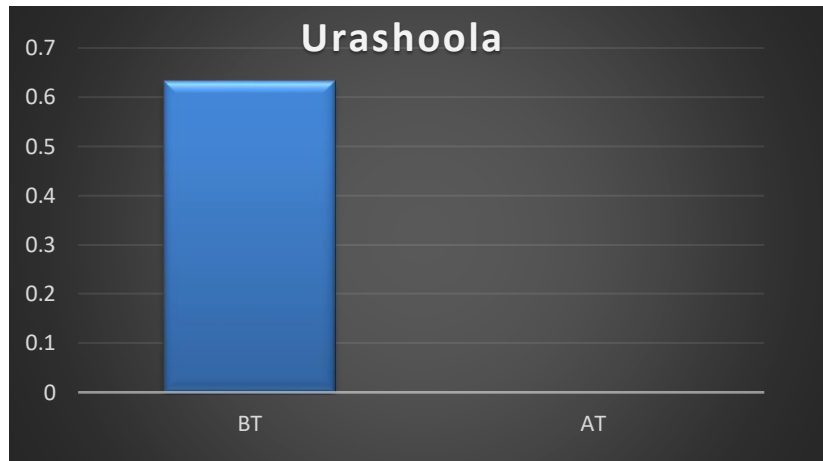
Graph no 5:Showing Effect on *Urashoola*

Table no 7:Showing Effect on Absolute Eosinophil count

Symptom	Mean score								
	Bt	At	Bt-at	%	Sd	Se	T value	P value	Remarks
AEC	318.8	180.1	138.6	43.47	115.1	21.01	6.53	0.0001	HS

Effect on AEC

In this work, 30 subjects studied in *Tamaka Shwasa* Roga with **AEC** revealed are given in detail. Statistical analysis showed that the mean score, which was 318.8 before the treatment, was reduced to 180.1 after the therapy with 43.47% improvement.
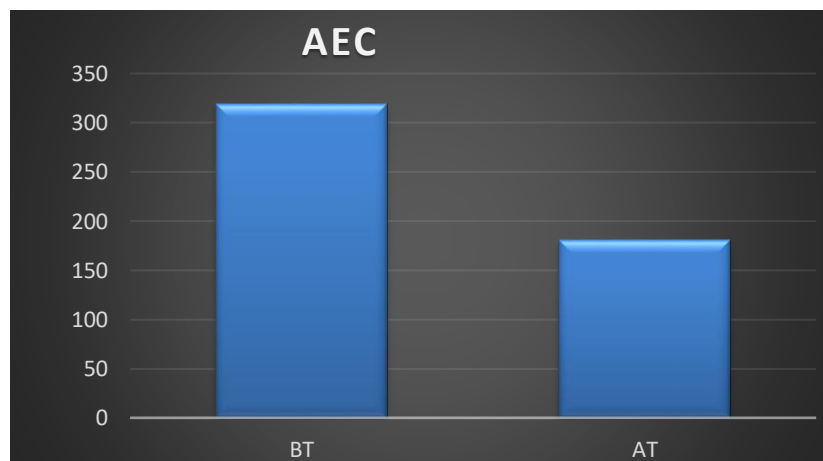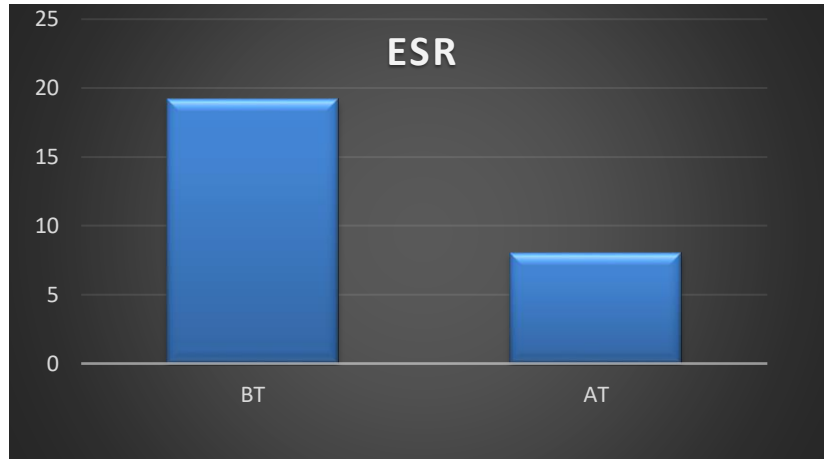

Graph no 6: Showing effects on Absolute Eosinophil Count.

Table no 8:Showing Effect on Erythrocyte Sedimentation Rate

Symptom	Mean score								
	Bt	At	Bt-at	%	Sd	Se	T value	P value	Remarks
ESR	19.20	8.033	11.7	60.93	11.17	2.253	4.956	0.0001	HS

Effect on ESR

In this work, 30 subjects studied in *Tamaka Shwasa* Roga with **ESR are revealed** and given in detail. Statistical analysis showed that the mean score, 19.20 before the treatment, was reduced to 8.033 after the treatment with 77% improvement. Statistical analysis showed that the change with the treatment is more significant than expected by chance; there is a statistically significant result with (p<0.001)


Graph no 7: Showing effects on Erythrocyte Sedimentation Rate

Table no 9:Showing Effect on Differential Eosinophil count

Symptom	Mean score								
	Bt	At	Bt-at	%	Sd	Se	T value	P value	Remarks
DEC	9.233	4.233	4.9	53.07	3.458	0.63	7.762	0.0001	HS

Effect on DEC

In this work, 30 subjects studied in *Tamaka Shwasa* Roga with **DEC are revealed** and given in detail. Statistical analysis showed that the mean score, 9.233 before the treatment, was reduced to 4.233 after the treatment, with a 77% improvement. Statistical analysis showed that the change with the treatment is more significant than expected by chance; there is a statistically significant result with (p<0.001).
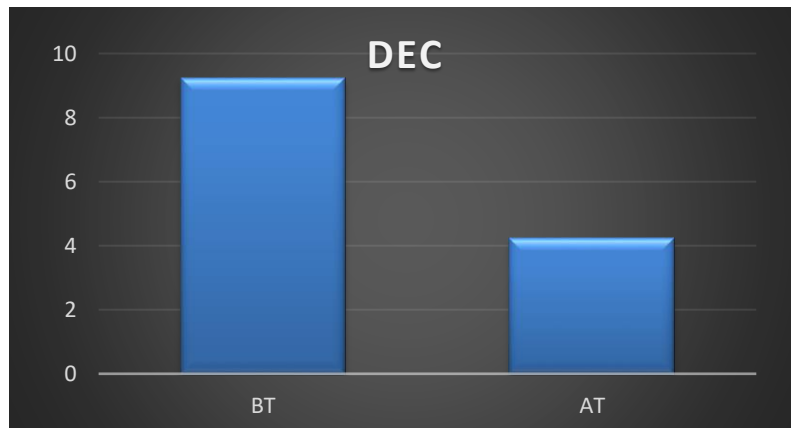
**Graph no 8: Showing effect on Differential Eosinophil Count**

Table no 10:Showing Effect on FEV1/FEC ratio

Symptom	Mean score			%	Sd	Se	T value	P value	Remarks
	Bt	At	Bt-at						
FEV1/FEC	69.77	71.43	-1.667	2.3	1.709	0.312	5.343	0.0001	HS

Effect on FEV1/FEC

This work of 30 subjects studied in *Tamaka Shwasa* Roga with **FEV1/FEC** revealed in detail Statistical analysis that the mean score, 69.77 before the treatment, was reduced to 71.43 after the treatment with a 2.3% improvement. Statistical analysis showed that the change with the treatment is more excellent than expected by chance; there is a statistically significant result with (p<0.001).
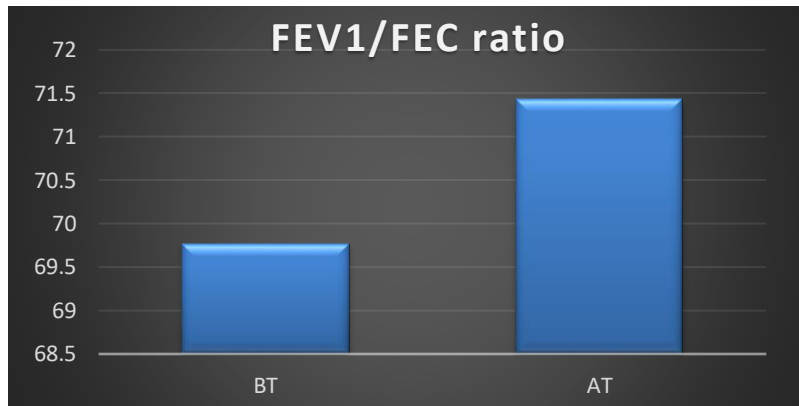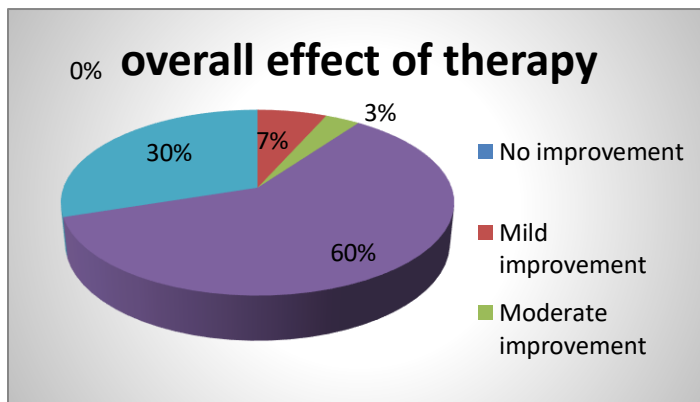

Graph no 9: Showing effect on FEV1/FEC ratio

ASSESSMENT OF TOTAL EFFECT OF THERAPY

Table no 11:Showing Overall Effect

EFFECT OF TREATMENT		
Class	**Grading**	**No. of subjects**
0%	No improvement	0
1–25 %	Mild improvement	02
26 – 50%	Moderate improvement	01
51 – 75 %	Marked improvement	18
76 – 100%	Significant Improvement	09

Graph no 10:Showing Overall Effect of therapy

Comparative statistical analysis was conducted using a Wilcoxon signed rank test on subjective parameters and a paired t-test on objective parameters. All parameters were found to be statistically significant. In percentage terms, Shwasa kruchrutha, Asino labhathe soukhyam, and Urashoola were found to be more effective, followed by Gurgurutha, Kasa, ESR, AEC, DEC, and the FEV1/FEC ratio.

1. Formulated hypothesis of the study:
2. H_0: *Hemadri Rasa* has yet to have significant results in *Tamaka Shwasa*.
3. H_1: *Hemadri Rasa* has substantial results in *Tamaka Shwasa*.
4. Hence, in this study, H_1 is valid and has been proven, which means there is a significant difference in the effect of *Hemadri Rasa* in the management of *Tamaka Shwasa* Roga.

DISCUSSION

Discussion on Sample Size Estimation:

- A total of 34 patients were enrolled for the study, out of which four dropped out.
- The reasons for dropping out are
- Not able to attend regular follow-up due to transportation problems
- Less awareness in patients regarding the seriousness of the disease results in ignorance towards treatment
- The highest number of patients was found in the 44 to 55 age group, probably because of chronic disease, prolonged exposure to etiological factors, and increased awareness regarding the clinical trial.
- No male patients were more in no, probably because of more exposure to dust and other etiological factors.
- No patients belonging to the Hindu religion were more likely due to increased awareness.
- Urban patients were enrolled more due to increased exposure to etiological factors, transportation ease, and awareness.
- Homemakers and farmers were more in no because they were exposed to dust and pollen grains.

- Tamaka shwasa is predominantly a Vata Kaphaja roga; hence, no number of patients belonged to vata pitta prakruthi, followed by kapha pitta prakruthi.
- **Discussion on clinical study**
- **Shwasa kruchrutha:**
- Out of 30 patients considered for therapy, all the patients had shwasa kruchrutha or dyspnoea as symptoms.
- All the patients were cured of dyspnoea symptoms, and the mean score after treatment of shwasa kruchrutha was 0.
- This shows Hemadri Rasa's bronchodilatory action. Bronchoconstriction is mainly caused by the erratic state of the smooth muscles in the bronchi and bronchioles and inflammation of the middle layers of the bronchi and bronchioles.
- According to Ayurveda, pravruddha vata gets occluded by kapha, thereby inducing shwasa kruchruta. Tamra is said to have vata pitta hara properties. By these characteristics and having teekshna guna, the avarana is dissolved, and vata is subsided, thus regulating the proper movement of vata.
- **Kasa**:

Kasa symptoms are due to kapha and vata dushti. Cough in bronchial asthma and COPD are usually due to mucolytic secretion or a sympathetic trigger by foreign particles. Snigdha, Tikshna, and Lekhana Guna help reduce this symptom.

- **Gurgurutha:**
- When increased Kapha is situated in srotas (Kanta) and obstructs the airway, this sound is produced. This type of sound is created during the attack as the patient breathes. This is equivalent to the wheezing sound described in modern science.
- Gurgurtha is a symptom of aggravated vata and kapha. The snigdha, ushna, and lekhana gunas of Tamra, along with the ushna and teekshna gunas of Manashila, help subside vata and kapha dosha.
- **Asino labhate soukhyam:**

- During the attack, the patient feels better sitting than in any other position. In the sitting position, the diaphragm is lowered, and airway secretions do not completely obstruct the airways. There is more space for gas exchange. Hence, the patient gets relief while sitting.
- The diaphragm functions through Prana Vata, which is impeded by Kapha and causes breathing difficulties. Once this avarana is resolved, the normal gati of Vata will be attained.
- As mentioned before, 100% remission implies the avarana resolving attributes of Hemadri rasa. This improves the gati of Vata, thereby improving patients' quality of life.
- Kajjali and Manashila have anulomaka guna, which aids in the proper movement of prana vayu.
- **Urashoola:**
- When a patient is in a recumbent position, a raised diaphragm may cause sudden lung pressure. Air in the lungs cannot pass easily through the airways because secretions in the bronchioles obstruct them. This trapped air inside the lungs exerts pressure on the plea and chest wall, resulting in mild, moderate, or severe pain.
- When vitae Vata enters in urah pradesa, some painful conditions will occur.
- Tamra and Manashila exhibit shulagna and anulomaka properties, which play a key role in pain management.
- Tamra's Lekhana property helps scrape pollen and dust particles, increasing lung capacity and tidal volume. The increased FEV1/FEC ratio validates this.
- **Erythrocyte Sedimentation Rate:**
- The ESR is governed by the balance between pro-sedimentation factors, mainly fibrinogen, and those factors resisting sedimentation, namely the negative charge of the erythrocytes. When an inflammatory process occurs, the high proportion of fibrinogen in the blood causes red blood cells to stick to each other. The red cells form rouleaux stacks, which settle faster due to their increased density.

- A highly significant result was noted in the ESR parameter, probably due to Tamra acting on rakthavaha srotomula, i.e. yakrith and pleeha, from where the fibrinogen and other factors are secreted, which play a prominent role in erythrocyte sedimentation. Also, the Shothahara guna of Tamra reduces inflammation of muscle layers of bronchioles.
- **Absolute Eosinophil Count**:
- Eosinophils, sometimes called eosinophils or, less commonly, acidophils, are a variety of white blood cells (WBCs) and one of the immune system components responsible for combating multicellular parasites and certain infections in vertebrates. Along with mast cells and basophils, they also control mechanisms associated with allergies and asthma. Granulocytes develop during hematopoiesis in the bone marrow before migrating into blood, after which they are terminally differentiated and do not multiply. They form about 2 to 3% of WBCs.
- It gives the total no of eosinophil cells present in the blood, while Differential Eosinophil Count gives the percentage of eosinophil cells in white blood cells. Tamra may help significantly reduce eosinophil cells by inhibiting cytokine and interleukin factors.
- **FEV1/FEC ratio**:
It gives the lung capacity, the more the bronchoconstriction, the less the ratio. A highly significant result in this parameter implies broncho dilatory action by Hemadri Rasa
- The X-ray showed no changes as the therapy takes longer for anatomical changes.
- Formulated hypothesis of the study: H_0: Hemadri Rasa has no significant result in Tamaka Shwasa. H_1: Hemadri Rasa has substantial results in Tamaka Shwasa. Hence, in this study, H_1 is valid and has been proven, which means there is a significant difference in the effect of Hemadri Rasa in the management of Tamaka Shwasa Roga.
- **Probable mode of action**

- Tamra having ushna, teekshna, and lekhana properties dissolves avarana caused by kapha on vata.
- Ushna and teekshna gunas of Manashila and Tamra help in mitigating Vata.
- Manashila and Kajjali have anuloma karma, which helps in restoring the normal gati of Vata.
- All the ingredients have Rasayana properties. Specifically, Manashila is Rasayana agrya, and Tamra is Ati rasyana. These properties help detoxify toxic chemicals released in the inflammatory responses and eliminate pollen and dust particles.
- Also, Tamra has vishagna guna, which helps detoxify and improve their quality of life.

CONCLUSION

- *Hemadri Rasa* is very effective in *Tamaka shwasa* because of its *Kapha nissarana* and *Vata anulomaka* properties.
- It was found that it is very effective in *Shwasa kruchratha* and *Urashoola*
- It was also found very effective in lowering ESR and AEC levels.
- Further it was found that there was no relapse of any symptoms after 15 days of treatment, elucidating its *Rasayana* properties.

SCOPE FOR FURTHER STUDY

- The preparation of Hemadri Rasa can be carried out in aseptic conditions using sophisticated instruments.
- A comparative study of Hemadri rasa with other yogas and different anupanas prescribed for Tamaka shwasa can be done.
- A comparative study of Hemadri Rasa with a Standard drug can be done.

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