To clinical study evaluate the therapeutic effect of Agastya Haritaki of Sharangdhar Samhita

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Abstract

Rasayana is a specialized section of *Ayurveda*, which mainly deals with the prevention of disease and promotion of the health; as we know it is also the aim of *Ayurveda*. *Agastya Haritaki Rasayana* is a popular *Avaleha kalpana*, used in the *Pranavaha Sroto Vikaras* like *Kasa, Swasa, Hikka, Kshaya*, etc. The study was taken with a view to enlist the ingredients of *Agastya Haritaki Rasayana* from *Sharangdhar Samhita* and critical analysis was done with help of clinical trial.

Introduction

Vata and Kapha are the two key pathological factors involved in the Samprapthi of Tamaka Swasa which demands distinct remedy and hence writing a prescription in such a situation is wheels in wheels. Thus, more and more research work will be needed in bringing an effective control. Rasayana is a specialized section of Ayurveda, which mainly deals with the prevention of disease and promotion of the health; as we know it is also the aim of Ayurveda. Agastya Haritaki Rasayana is a popular Avaleha kalpana, used in the Pranavaha Sroto Vikaras like Kasa, Swasa, Hikka, Kshaya, etc. Most of the ingredients of Agastya Haritaki Rasayana are having -Tikta, Kashyaya, Madhura Rasa, Laghu, Ruksha, Tikshna Guna, Katu Vipaka, Ushna Veerya and having Kaphavata Shamaka properties. Thus, Agastya Haritaki Rasayana is used in the management of diseases which are mainly Vatakapha Pradhana. Agastya Haritaki Rasayana is indicated as main line of treatment in Swasa, Kasa Roga as well as used as the Naimittika Rasayana in various other diseases like Grahani, Aruchi, Arsha etc. The study was taken with a view to enlist the ingredients of Agastya Haritaki Rasayana from Sharangdhar Samhita and critical analysis was done with help of clinical trial.

Need of the study

To check the clinical efficacy of the Agastya Haritaki of Sharangdhar Samhita.

Objective of study

To evaluate the Therapeutic effect of Agastya Haritaki in patients suffering from Tamaka Swasa.

Materials and Methods

Source of data:

The study will be conducted in 41 patients suffering from Tamaka Swasa.

Method of collection of data:

A special proforma will be prepared with details of History taking, Physical signs, Symptoms and Lab-Investigations as mentioned in Ayurvedic classics and allied Sciences. Patients will be analysed and selected accordingly. The parameter of assessment of signs and symptoms will be scored based on standard method and will be analysed statistically.

Research Methodology

- > Pharmaceutical Research Preparation of Agastya Haritiki as mentioned in Sharangdhar Samhita.
- > Analytical study-Analytical Study is subdivided into two types:
 - **1.** Physical tests.
 - 2. Chemical tests.
- > Physical tests-
 - **1.** Organoleptic Analysis
 - 2. Colour
 - 3. Smell
 - 4. Consistency
- > Chemical Analysis-
 - 1. Particle Size
 - 2. Quantitative & Qualitative Assay
 - 3. Moisture content

Design of the study:

A single blind clinical study with pre-test and post-test design where in a minimum 30 patients suffering from *Tamaka Swasa* of either sex between the age group of 16 & 60 yrs. will be selected for the study.

INTERVENTION:

> Dosage:

These patients will be treated with oral administration of Agastya Haritaki Rasayana in a dose of 12gms bd along with warm water on the stomach.

> Duration of study:

28 days, patients will be examined for the change in the signs and symptoms on 14th and 28th day of treatment and then results will be analysed by using paired 't' test.

Inclusion criteria:

- 1) Patients presenting with Prathyatma Lakshanas of Tamaka Swasa.
- 2) Patients between the age group pg. 16 yrs.- 60 yrs.
- 3) Patients having the history of more than 6 months.

Exclusion criteria:

- 1) Patients with severe attacks of Tamaka Swasa.
- 2) Patients of Tamaka Swasa also suffering from other systemic disorders.
- 3) The Bronchial asthma, associated with complications like emphysema and corpulmonale.
- 4) Patients on steroid.

Assessment criteria: Subjective symptoms like cough, breathlessness, sputum, speech, respiratory, rate, expansion of chest, breath sounds, heart rate will be scored by following the standard methods and will be compared before and after the treatment.

• Objective clinical signs, including peak-flow meter pulmonary function test.

Research design: Exploratory blind fold clinical Research trial.

Karma & Doshagnata/ Actions & Therapeutic Indications of Agastya Haritaki Rasayana according to different classical texts [Table No.1]

	e No.1]									
S.N.	Name of the disease	C.S ¹	$S.S^2$	A.H ³	B.B ⁴	B.R ⁵	S.Y ⁶	$\mathbf{C}.\mathbf{D}^7$	V.S ⁸	G.N. ⁹
1.	Vali	+	-	+	+	+	+	-	+	-
2.	Palitya	+	-	+	+	+	+	-	+	-
3.	Varna-Ayu-Bala Vardhana	and the second	+	+	+	+	+	+	+	+
4.	Kasa	+	+	+	+	+	+	+	+	+
5.	Kshaya	+	+	+	+	+	+	+	+	-
6.	Swasa	+	+	+	+	+	+	+	+	+
7.	Hikka	+	+	+	+	+	+	+	-	+
8.	Vishamajwara	+	+	+	+	+	+	+	+	+
9.	Gulma	-	+	-		+		+	-	-
10.	Meha	-7/	+			+	-	-	-	-
11.	Grahani	+	+	+	+	+	+	+	+	+
12.	Arsha	+	+	+	+	+	+	+	-	+
13.	Hridroga	+	+	+	+	+	+	-	+	+
14.	Aruchi	+	+	+	+	+	+	+	-	+
15.	Pinasa	+	+	+	+	+	+	+	-	+
16.	Pleeha	-	-	-	5 -	-	-	+	-	-
17.	Swarabhanga		-	-	-	-	-	+	-	-
18.	Agnijanana	-	-	1-1-1	-	-	-	+	-	-
19.	Pandu		- L	<mark>/ -</mark>	-	-	-	-	+	+
20.	Rajayakshma	-		-	-	-	-	1-72	+	+
21.	Shiroroga	-	+	-	-	-		- 2	-	+
22.	Netraroga	-	-	-	-	-	- 1	4	-	+

Methods of preparation of Agastya Haritaki Rasayana¹⁰

The drugs from the 1 to 20 (from *Rasapanchaka* table) (2 *Pala* = 96 gm each; *Dashmoola* 96gm each individual) are coarsely powdered and kept in a vessel.

Pancha Adhaka (5*3.072 ltrs=15.360 ltrs) of water is added and Kwatha is prepared reducing it to 1/4th (4.8 ltrs)

Yava (1 Adhaka=3.072kg) and Haritaki (100 in number) are bundled in a piece of cloth which is immersed by suspension, as in *Dolayantra*. Mixture of *Yava* and *Haritaki* is boiled till *Yava* becomes soft.

Bundle is opened and Yava is discarded

Jaggery (1 tula=4.2 kg) and Haritaki is added to the decoction and boiled to the required Paka.

After *Paka Ghrita & Taila* (4 *Pala*=192 g each) is added along with the *Pippali Churna* (4 *Pala*=192gm). Allowed to cool and finally honey (4 *Pala*=192gm) is added.

Agastya Haritaki Rasayana is ready.

Rasa Panchaka of Individual components of Agastya Haritaki Rasayana¹¹

[Table	No.2]
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S.N.	Drug Name	Botanical Name	Rasa	Guna	Virya	Vipaka	Doshagnata
1.	Bilva	Aegle marmelos	Madhura	Laghu	Sita	Madhura	Tridoshagna
	(Rt/st.Bk)	Linn.					
2.	Syonaka	Oroxylum indicum	Madhura, Tikta,	Laghu,	Ushna	Katu	Kapha-

	(Rt/st.Bk)	(L)Benth ex Kurz.	Kashaya	Ruksha			Vatashamaka
3.	Gambhari (Rt/st.Bk)	Gmelina arborea Roxb.	Tikta, Kashaya, Madhura	Guru	Ushna	Katu	Tridoshasamaka
4.	Patala (Rt/st.Bk)	Stereospermumsuav eolens (Roxb) DC.	Tikta, Kashaya	Lagu, Ruksha	Ushna	Katu	Tridoshasamaka
5.	Agnimantha (Rt/st.Bk)	Premna mucronta Roxb.	Tikta, Katu, Kashaya, Madhura	Lagu, Ruksha	Ushna	Katu	Kapha- Vatashamaka
6.	Salaparni (pl)	Desmodium gangeticum DC	Madhura Tikta	Guru, Snigdha	Sita	Madhura	Tridoshasamaka
7.	Prisniparni (pl)	Uraria picta Desv	Madhura Tikta	Laghu Snigdha	Ushna	Madhura	Tridoshasamaka
8.	Brhati (pl)	Solanumindicum linn	Katu, Tikta	Lagu, Ruksha, Tikshna	Ushna	Katu	Kapha- Vatasamaka
9.	Kantakari (pl)	Solanum surattense Burm	Tikta Katu	Lagu, Ruksha, Tikshna	Ushna	Katu	Kapha- Vatasamaka
10.	Gokshura (pl)	Tribulus terrestis Linn.	Madhura	Guru, Snigdha	Sita	Madhura	Vata-Pittasamaka
11.	Atmagupta (sd)	Mucuna prurita Wight	Madhura Tikta	Guru, Snigdha	Ushna	Madhura	Tridoshasamaka
12.	Shankapusphi pl)	Convolvulus pluricaulis Choisy	Kashaya, Katu	Snigdh, Picchila	Sita	Madhura	Tridoshahara
13.	Sati (Rz)	Hedychium spicatum Sm in A Rees	Katu, Tikta, Kashaya	Laghu, Tikshna	Ushna	Katu	Vata- Kaphashamaka
14.	Bala (Rt)	Sida cordifolia Linn	Madhura	<mark>S</mark> nigdha, Guru	Sita	Madhura	Vata- Pittashamaka
15.	Hastipippali (Fr)	Piper chaba Trel&Yunck	Katu	Ruksha	Ushna	Katu	Vatahara
16.	Apamarga (Rt)	Achyranthes aspera Linn	Tikta Katu	Sara, Tikshna	Sita	Madhura	Kapha- Vatashamaka
17.	Pippalimula (Rt)	Piper longum Linn	Katu	Tikshna, Lagu, Snigdha	Anusna	Madhura	Kapha- Vatashamaka
18.	Chitraka (Rt)	Plumbago zeylanica Linn	Katu	Tikshna	Ushna	Katu	Kapha- Vatashamaka
19.	Bharangi (Rt)	Clerodendron serratum Linn	Katu, Tikta	Ruksha, Laghu	Sita	Madhura	Kapha- Vatashamaka
20.	Puskaramula (Rt)	Inula racemosa Hook	Katu, Tikta	Tikshna, Lagu	Usna	Katu	Vata- Kaphashamaka
21.	Yava (Sd)	Hordeum vulgare Linn	Kashaya, Madhura	Ruksha, Guru, Picchila	Ushna	Katu	Kaphahara
22.	Haritaki (P)	Terminalia chebula Retz.	Kashaya Pradhana Lavana Varjita	Lagu, Ruksha	Usna	Madhura	Tridoshahara

Selection of patients

The study was conducted on 30 clinically diagnosed & confirmed cases of Bronchial Asthma from OPD & IPD section of Desh Bhagat Ayurvedic College & Hospital, Amloh-Mandi Gobindgarh Road, Village Shonti, District Fatehgarh Sahib, Punjab.

Materials & Methods:

> Type of Study: Open uncontrolled (Single- Arm) Clinical Study

Criteria for Selection of Patients

A) Inclusion Criteria

- i. Age group between 20 to 60 years of age
- ii. Sex- Both males and females
- iii. Patients having signs and symptoms of *Tamak-shwas* (Bronchial Asthma) in *Awegawastha* (non-acute phase)

B) Exclusion Criteria

- i. Patients having age below 20 years and more than 60 years.
- ii. Patients having asthma or breathlessness due to renal or cardiac problems
- iii. Patients having acute attacks or status asthmatics stage
- iv. Patients having other systemic disorders like Diabetes mellitus, Carcinoma, Pulmonary T. B., hepatitis
- v. Patients having HIV, AIDS & other STDS

Ethical Clearance & Consent: The study design was approved by the institutional ethical committee, and signed informed consent was obtained from all the patients.

Plan of Clinical Trial:

- > Number of Patients: Total number of patients included in this study was 30.
- Drug: Agastya Haritaki Avaleha was prepared with the help of Rasashastra & Bhaishajya Kalpana Department.
- **Dose:** 01 Pala (4 tola = 40gms) in two divided dosages, with empty stomach
- Duration of Treatment: 28 days
- **Follow up:** Was taken after every one week.
- **Diet**: Patient's regular diet

Criteria for the Assessment of Patients & Results of the Treatment:

The efficacy of the therapy was assessed on the basis of subjective as well as objective criteria. Most of the symptoms & signs of *Tamak Swasa* (Bronchial asthma) described in Ayurveda are subjective in nature. Hence multidimensional scoring system was adapted for statistical analysis and to give results on subjective parameters. Score was given according to the severity of symptoms as follows:

- ✓ Shwas Kashtata (Dyspnoea)
- ✓ Kasa (Coughing)
- ✓ *Aasino Labhate Saukhyam* (Relief in sitting posture)
- ✓ *Peenas* (Nasal discharge)
- ✓ Anidra (Sleeplessness)
- ✓ Sweda Pravritti (Perspiration)
- ✓ *Ghurghurakam* (Rhonchi)

Investigations:

Following investigations were done for every patient before starting the treatment & after completion of the treatment.

- Blood Investigations: Haemoglobin, R.B.Cs., ESR, TLC and DLC
- Lung Function Tests (LFT)
- Respiratory Rate (R/R)
- Expansion of chest (EOC)
- Breath Holding Time (BHT)
- Peak Expiratory Flow Rate (PEFR) -FEV1-
- Inspiration Time
- Expiration Time
- X-Ray Chest PA View and ECG was done to exclude any other pathology.

Patients undergoing trial were examined clinically at every follow up to maintain a record of the same. Record and follow up of all the patients included in the trial was documented and maintained in the case record form.

Organoleptic characters

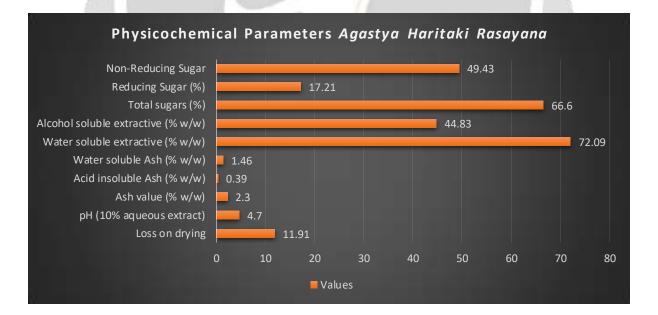
- Sparsha (Texture) Soft
- Rupa (Colour) Dark Reddish Brown
- *Rasa* (Taste) Sweetish Astringent
- Gandha (Odour) Characteristic Sweet
- **Consistency** Semisolid

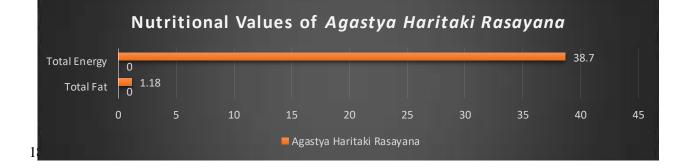
[Table No. 3] Organoleptic characters

S. N.	Parameters	Agastya Haritaki Rasayana
1.	Sparsha (Texture)	Soft
2.	Rupa (Colour)	Dark Reddish Brown
3.	Rasa (Taste)	Sweetish Astringent
4.	Gandha (Odour)	Characteristic Sweet
5.	Consistency	Semisolid

[Table No. 4] Values of physicochemical parameters

S. N.	Parameters	Agastya Haritaki Rasayana
1.	Loss on drying	11.91
2.	pH (10% aqueous extract)	4.7
3.	Ash value (% w/w)	2.3
4.	Acid insoluble Ash (% w/w)	0.39
5.	Water soluble Ash (% w/w)	1.46
6.	Water soluble extractive (% w/w)	72.09
7.	Alcohol soluble extractive (% w/w)	44.83
8.	Total sugars (%)	66.6
9.	Reducing Sugar (%)	17.21
10.	Non-Reducing Sugar	49.43
11.	Total Tannins (%)	3.33



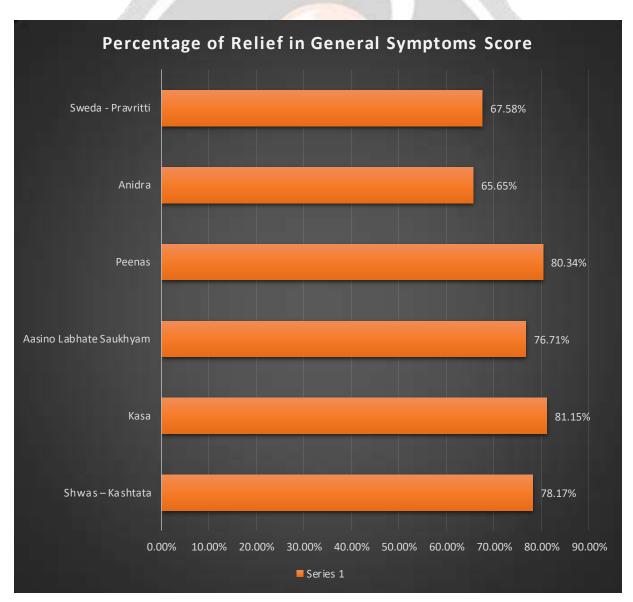


[Table No. 5] Nutritional Values of Agastya Haritaki Rasayana

S. N.	Parameters	Unit	Agastya Rasayana	Haritaki			
		1.			Total Fat	%	1.18
		2.			Total Energy	Cal/gm	38.70

Table No. 6] Percentage of Relief in General Symptoms Score

S. N.	General Symptoms	Relief Score
1.	Swasa – Kashtata	78.17%
2.	Kasa	81.15%
3.	Aasino Labhate Saukhyam	76.71%
4.	Peenas	80.34%
5.	Anidra	65.65%
6.	Sweda - Pravritti	67.58%
7.	Rhonchi	69.71%



S. N.	Physical Parameters in their respective units	Mean of Difference = SD	S.E.	T ₂₉	Р
1.	Respiratory Rate (R/R)	4.20 ± 1.43	0.26	16.1	<0.001 Highly significant
2.	Expansion of Chest (EOC)	1.50 ± 0.69	0.13	11.54	<0.001 Highly significant
3.	Breath Holding Time (BHT)	2.70 ± 1.26	0.23	11.74	<0.001 Highly significant
4.	PEFR- FEV1	28.00 ± 12.15	2.22	12.61	<0.001 Highly significant
5.	Inspiration Time	0.93 ± 0.36	0.07	13.29	<0.001 Highly significant
6.	Expiration Time	1.03 ± 0.41	0.07	14.71	<0.001 Highly significant

[Table No. 7] Showing Effect on Physical Parameters of Patients of Tamak-Swasa

[Table	No.	8] E	ffect	on	Haematological	Investigations	of Patients	of	Tamak- Swasa	
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S. N.	Haematological Investigations in their respective units	Mean of Difference ± SD	S.E.	T ₂₉	Р
1.	Haemoglobin (Hb gm %)	0.44 ±0.54	0.10	4.40	<0.001 Highly significant
2.	Total R.B. Cs (TRC)	0.11 ± 0.14	0.03	3.67	<0.001 Highly significant
3.	Total Leucocyte Count (TLC)	200 ± 954.12	174.11	1.15	>0.05 Not significant
4.	Eosinophil Count	1.43 ± 1.77	0.32	4.47	<0.001 Highly significant
5.	Neutrophil Count	0.47 ± 6.38	1.16	0.41	>0.05 Not significant
6.	Lymphocyte Count	1.67 ± 8.07	1.74	1.14	>0.05 Not significant

[Table No. 9] Statistical Analysis	of Symptoms	of Patients	of Tamak-Swasa	Wilcoxon-matched-pairs
signed-ranks Test				

S. N.	Symptoms		Mean	SD	SE	Sum of all Signed Ranks	No. of Pairs	Value of 'Z'	р
1.	Swasa-	BT	2.23	0.43	0.08	465.0	30	4.78	<0.001
	<i>Kashtata</i>	AT	0.53	0.51	0.09				Highly Significant
	(Dyspnoea)	Dif	1.70	0.54	0.097				
2.	Kasa (Coughing)	BT	2.33	0.48	0.09	465.0	30	4.78	<0.001 Highly Significant
		AT	0.53	0.51	0.09				
		Dif	1.80	0.48	0.09				
3.	Aasino Labhate Saukhyam	BT	1.90	0.40	0.073	378.0	27	6.42	<0.001
		AT	0.57	0.50	0.092				Highly Significant
		Dif	1.33	0.66	0.12				

4.	Peenas	BT	1.70	0.88	0.16	378.0	27	6.42	< 0.001
		AT	0.36	0.49	0.089				Highly
		Dif	1.33	0.71	0.13				Significant
5.	Anidra	BT	1.50	0.51	0.09	325.0	25	4.37	< 0.001
		AT	0.67	0.66	0.12				Highly
		Dif	0.83	0.37	0.07				Significant
6.	Sweda-	BT	1.07	0.58	0.11	210.0	20	3.92	< 0.001
	Pravritti	AT	0.40	0.50	0.09				Highly
		Dif	0.67	0.48	0.09				Significant
7.	Rhonchi	BT	2.13	0.57	0.104	465.0	30	4.78	< 0.001
		AT	0.73	0.64	0.12				Highly
		Dif	1.40	0.50	0.09				Significant

	Table	No.	101 Sho	wing	Total	Effect	of Therapy	on 30 Patients	of Tamak- Swasa
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S. N.	Total Effect of Therapy	No. of Patients	Percentage
1.	Cured (100%)	00	0%
2.	Markedly Improved (50-100%)	21	70%
3.	Improved (25-50%)	09	30%
4.	Unchanged (0-25%)	00	0%
	Total	30	100%

Observation of Recurrences of Swasa- Vega within period of 6 months

Recurrence of *Swasa* was observed in all 30 patients on follow up study of six months.22 patients (73.3%) had no attack of *Swasa* up to six months while 08 patients (26.67%) had attack once or twice with in the period of 6 months.

Discussion

The basic method of the preparation of Agastya Haritaki Rasayana includes major 4 components; Drava-dravya (containing Kwatha of Dashmula, Atmagupta, Shankapusphi etc.,) Madhura Dravya (with Guda & Makshika;) Sneha Dravyas (Ghrita & Taila), Prakeshapa Dravya (Pippali). Drava form helps in the extraction of active principles in the form of Kwatha; sugar medium is responsible for palatability & also acts as preservatives; Sneha to keep the Avaleha soft & also helps in preservation; Prakeshapaka Dravyas enhances the taste as well as increases the bioavailability of the drugs.¹² The methods of preparation of Agastya Haritaki Rasayana are similar in all the texts. Pharmaceutical Principle regarding the preparation was first described by Shrangadhara in Sarangadhara Samhita.¹³ A modified form is now adopted to facilitate the preservation over the longer period of time by removing the seeds from the boiled *Haritaki* are removed and pulp is dried well and powdered. After the required Paka, the powdered Haritaki along with Pippali Choorna is added.¹⁴ Pharmacognostical and Phytochemical evaluation of Agastya Haritaki Rasayana is a step towards standardization of polyherbal formulations in Avaleha form.1⁵ Haritaki as the main ingredients(100 in number); along with Dashamoola, Kapikacchu, Shankapusphi, Shati, Bala, Gajapippali, Apamarga, Chitraka, Bharangi, Pippalimoola, & Puskarmula is mentioned in Charaka Samhita which is common in most of the classical references. Acharya Sushruta has added Rasna, Guduchi, Patha, Nagara, Yavasa and Pippali & omitted Apamarga and Pippali mula. Vangasena has added Devadaru, Madhulika, Punarnava, Panchakola, Pashanbheda, and omitted Apamarga, Pippalimoola and Chitraka. Agastya Haritaki Rasayana Avaleha is one of the Rasayana Kalpa explained by Charakacharya especially for the diseases of Pranavaha Strotas. It performs both functions-Rasayana as well as Vyadhihara. It was easy to prepare, affordable & well tolerated to the patients with no undesired effects. Swasa Kashtata, Ghurghurakam (Rhonchi), Peenas & Kasa were the most prominent symptoms present in the patients included in this study. Agastya Haritaki Rasayana Avaleha was given to the patients mostly in the Awegwastha (non-acute phase) for 28 days which showed significant subside of symptoms which were shown by percentage of relief in symptoms & by statistical analysis which was highly significant. The onset of action of this drug could be in the very first week, symptoms started to fall from the first week & improvement was noticed in the further weeks of treatment. Hence it should be continued to furthermore, to reduce the risk of relapse & severity of Tamak-Swasa. Out of the 30 patients included in the study, none patient showed total relief in symptoms, 21 patients were markedly improved (50-100% relief) while 09 patients showed improvement (25-50% relief). No one patient remained unchanged. On Follow Up study of six months in all 30 patients for observation of recurrence of Swasa - Vega showed that 22 patients (73.33%) had no attack of shwas while 08 patients (26.67%) had attack once in the period of 6 months. It was done to prove the sustainability of effects of Rasayana. In this study, drug is given only for 28 days. As Tamak -Swasa is a Yapya Vyadhi (palliable disease) as mentioned by Acharya Charaka, if this drug given over a long

period of time, relapse would not be there & results would be more significant. Thus, by taking all these facts into consideration it can be said that there is major advantage of this classical formulation for the patient as it prolonged the duration between two attacks & decreased period of attack allow the patients to continue their day-to-day activities & saves improvement time of people & renders the patients better Quality of Life. (Table No. 6)

Conclusion

There are many treatment modalities for Swasa Roga. Here an effort was made to show the effect of Agastaya Haritaki Rasayana on Swasa Roga. Now the day modern science is showing its limitations towards some diseases, here Rasayana can be best option for upgrading the treatment schedule for any patient. Shodhana followed by Rasayana is good line of treatment proved in this case. Regular intake of Shodhana and Rasyana can be adopted, also Nitya Shodhana helps effectively in reducing the severity of attack of Tamakswasa. Rituanusara Shodhana followed by Rasayana therapy can be opted for several such conditions. For the better functioning of cardiovascular and respiratory systems Pranayama proved as a better intervention compared to Agastya Haritaki Rasayana. Though Agastya Haritaki Rasayana has been used for various pathological conditions viz Kasa (cough), Swasa (Dyspnoea) of respiratory system still it could not produce any significant effect on cardio vascular parameters. Based on the obtained results on chronic bronchitis, Agastya Haritaki Rasayana proves its positive effect on reduction of symptoms of chronic bronchitis.

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