



**Research Article**

**EFFECT OF VYAGHRI HARITAKI LEHYA IN CHRONIC TONSILLITIS IN CHILDREN OF THE AGE GROUP 3-12 YEARS**

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**ABSTRACT**

Tonsillitis is the inflammation of the tonsils. The tonsils are two small glands on either side of the throat. The tonsils play a key role in helping the body to protect against infection. This is especially in young children, whose immune system is still developing. The tonsils act as a barrier, trapping an infection and stopping it spreading to other parts of the body. In Ayurveda tonsillitis is correlated with *Tundikeri*, the disease of *Talu* (palate) and *Kantha* (throat), both of which are the *Avaranas* (establishment) of *Mukharoga* (diseases of mouth). Although no specific formulation for *Tundikeri* is given and surgical treatment is described for the disease, many formulations for *Mukharogas* (mouth disorders) are effective in *Tundikeri*. *Vyaghri haritaki lehya* is described by *Bhaishajya Ratnavali* and *Chakrvadatta*. It is also included in *Bhava Prakasha*, *Yoga Ratnakara*, *Gada Nigraha*, *Vanga Sena samhita* and *Bharat Bhaishajya Ratnakar*. A case study of 20 children on chronic tonsillitis done using Ayurveda medicine to improve general health. Internal administration of *Vyaghri haritaki lehya*, the dose was 5gm for children between 3 to 6 years and 10gm for children between 7 to 12 years with lukewarm water as adjuvant, for a period of 60 days given. Follow up done after a period of 30 days.

**INTRODUCTION**

Respiratory disorders are the leading causes of morbidity and mortality that induces an economic and social burden worldwide. In today's world, finding preventive methods and cures for these enormous challenges should be one of the priorities in the global health sector. Among many respiratory disorders affecting the health of human beings, one of the most common diseases is tonsillitis.<sup>[1-4]</sup> The worldwide prevalence of tonsillitis is not completely known. In India, approximately 77% of females are affected with tonsillitis compared to 22.9% of males. Gram A beta-Hemolytic streptococcus (GABHS) accounts for acts for causative factor in 5% to 15% of adults with pharyngitis and 15% to 30% of patients between the ages of five and fifteen.

Viral etiologies are more common in patients under five. GABHS is rare in children under two years of age.<sup>[2,4,5]</sup>

Ayurveda is the most established ancient medical science dependent on interminable laws of nature. The utilization of natural prescriptions is expanding step by step as there is no incidental effect or poisonousness, and are likewise practical. A disease that is similar to tonsillitis in clinical presentation in Ayurveda is *Tundikeri* which is described under *Mukharoga*. *Tundikeri* is caused by *Kapha prakopa* (aggravation) and *Raktadusti* (vitiation), and *Doshas* are located in *Talu* and *Kantha Pradesh*.<sup>[6,7]</sup> Medications having *Lekhana*, *Shothahara*, *Sandhaniya*, *Ropana*, *Raktastambhaka*, *Vedanasthapaka*, and *Pitta-kapha shamana* properties should be ideal for the treatment of Tonsillitis.<sup>[8-10]</sup> Dealing with the treatment of the disease *Tundikeri* particularly, *Acharya Sushruta* mentions that *Tundikeri* is the *Bhedya Roga* and it should be treated as per the line of treatment of the disease *Galashundika*. *Tundikeri* is the upper respiratory tract infection which can affect everyone anytime after getting certain exposure. *Tundikeri* is

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referenced under *Talugata roga* in *Sushruta Samhita*. *Acharya Vagbhata* has referenced the illness "*Tundikerika*" as happens in the *Hanu-sandhi Pradesh* (temporo-mandibular joint).<sup>[11,12]</sup>

Ayurvedic texts describe many herbal formulations for respiratory disorder, *Vyaghri haritaki lehya* is one of the most common formulations mentioned by Acharyas for respiratory disorders.<sup>[13-15]</sup> *Avaleha* is the semi-solid dosage formula of Ayurvedic medicines having a long shelf-life. *Vyaghri haritaki lehya* is described in the treatise *Bhaisajya Ratnavali Kasa roga dhikar* and *Chakradutta*. It is also included in *Bhava Prakasha*, *Yoga Ratnakara*, *Gada Nigraha*, *Vanga Sena*, *Bharat Bhaisajya Ratnakara* and *API*. It is indicated in *Swasa*, *Kasa*, *Kshaya*, *Kshata*, *Peenasa*, and *Rajyakshma*.<sup>[15,16]</sup>

Prevention, control, cure of these diseases, and promotion of respiratory health must be a top priority in global decision-making in the health sector. Ayurveda is a repository of innumerable formulations that have potential action on respiratory disorders. Ayurveda emphasizes prevention first and hence many *Rasayana* formulations are mentioned in various classical texts of Ayurveda.<sup>[16]</sup> *Rasayana* formulations prevent chronicity of diseases and also accelerate recovery. It enhances tissue strength by improving its functions and protects from diseases. Internal administration of *Rasayana* along with the one which improves *Vyadhikshamatva* (immunity) in children helps in preventing the recurrence of the diseases like *Tundikeri*.

This formulation consists of two main ingredients *Kantakari* (*Solanum xanthocarpum*) and *Haritaki* (*Terminalia chebula*). *Kantakari* is known for its anti-inflammatory, immuno-stimulatory, and cough relieving properties and found to be very effective in controlling mild to moderate bronchial asthma. *Haritaki* is known for its anti-oxidant, free radical scavenging, cytoprotective, immuno-modulatory, anti-inflammatory, and anti-allergic activity. *Trikatu* and *Chaturjata* are the *Prakshepa dravya* that helps in the bioavailability of the formulation and improves appetite, digestion, and palatability of herbal formulations and also correct respiratory and renal disorders. *Trikatu* is also used during the current outbreak of pandemic COVID 19 and for other pre-existing respiratory disorders which are causing devastation to the respiratory health of the entire mankind across the globe. *Gudam* (jaggery) has *Shwasahara*, and *Kasahara* properties whereas

*Madhu* has *Swasahara*, *Kasahara*, and *Dahahara* properties, and both increase the palatability of the formulation.<sup>[16,17]</sup>

## AIM

The study aims to validate the use of this formulation in the treatment of chronic tonsillitis in children of the age group 3-12 years.

## OBJECTIVES

1. To determine the effect of *Vyaghri haritaki lehya* in reducing frequency, severity, and associated features of chronic tonsillitis in children of the age group 3-12 years.
2. To determine the upcoming dangerous consequences after administration of *Vyaghri haritaki lehya* in chronic tonsillitis of the age group 3-12 years
3. To determine the changes in the recurrent attack of chronic tonsillitis after administration of *Vyaghri haritaki lehya* of the age group 3-12 years
4. To determine whether the disease is completely curable after administration of *Vyaghri haritaki lehya* in chronic tonsillitis of the age group 3-12 years.

## METHODOLOGY

Research is a systematic search for information and new knowledge. It covers topics in every field of science and the perception of its scope and activities are unlimited. Research methodology is a way to systematically solve the research problem. The present clinical study entitled "Effect of *Vyaghri haritaki lehya* in chronic tonsillitis in children age group 3 to 12 years" was carried out through different systematically designed steps to get unbiased results. The followed steps were adopted to complete the study.

**Study type:** Quasi-experimental, interventional pre and post-study

**Research design:** Interventional model: single group assignment, Pre and post-study design

**Study setting:** OPD of Dept. of Kaumarabhrithya, Government Ayurveda College Hospital women and children, Poojappura, Thiruvananthapuram, Kerala.

**Study duration:** 90 days

**Interventional period:** 60days

**Follow up:** 30days

**Study period:** 18 month

**Study population:** Children of 3 to 12 years affected with the chronic tonsillitis

**Sample size:** 20

**Inclusion criteria:** Children of age group 3 to 12 years presenting with clinical manifestations of chronic tonsillitis attending OPD of Kaumarabhrithya, Govt. Ayurveda College Hospital for Women and Children, Poojappura, Thiruvananthapuram, Kerala.

**Exclusion Criteria:** Children suffering from acute, tonsillitis complication, peri-tonsillar abscess,

malignancy, TB, presenting as tonsillitis or other somatic or mental disorders requiring treatment.

#### Details of Intervention (Drug Details)

Ayurveda, the science of life gives prime importance to rationality in treatment of diseases. Use of congenial diet and regimen is equally important. The condition of the disease, place, climate and strength of the patients has to be analysed carefully before

treatment. Selection of drugs plays a major role in disease. The trial drug selected is *Vyaghriharitaki lehya* which is mentioned in *Bhaishajya Ratnavali Kasarogadhikar*. *Lehya* consists of the following drugs which are given below in the table, most of the drugs are *Deepana* and *Pachana* along with *Tridoshahara* property.

S.No.	Drug name	Botanical name	Family	Part
1.	<i>Haritaki</i>	<i>Terminalia chebula</i>	Combretaceae	Fruit
2.	<i>Sunti</i>	<i>Zingiber officinale</i>	Zingiberaceae	Rhizome
3.	<i>Pippali</i>	<i>Piper longum</i>	Piperaceae	Fruit
4.	<i>Kantakari</i>	<i>Solanum xanthocarpus</i>	Solanaceae	Fruit
5.	<i>Ela</i>	<i>Eletarria cardammomum</i>	Zingiberaceae	Seed
6.	<i>Twak</i>	<i>Cinnamomum Zeylanicum</i>	Lauraceae	Stem bark
7.	<i>Nagkesar</i>	<i>Mesua ferrea</i>	Guttiferae	Stamen
8.	<i>Twakpatra</i>	<i>Cinnamomum tamala</i>	Lauraceae	Leaf
9.	<i>Maricha</i>	<i>Piper nigrum</i>	Piperaceae	Fruit
10.	<i>Jala- water</i> For decoction <i>Gudam - Jaggery</i>			

#### Preparation of *Vyaghri haritaki avaleha*

For the decoction, water is taken in a clean vessel into which *Kantkari panchang* and *Potali* containing seedless *Haritaki* is added and heated till it reduces to 1/8<sup>th</sup> of the decoction. The *Potali* containing *Haritaki* is removed from the decoction and then strained. *Gudam* is added to the decoction and is heated till *Pakalakshana* attains. After the *Pakalakshana*, *Haritaki* is added and mixed well. The mixture is allowed to cool followed by which *Prakshepadravayas*; *Sunthi*, *Maricha*, *Pippali*, *Twak*, *Twakpatra*, *Nagkesar*, *Ela* and honey are added and mixed homogeneously. Store the *Avaleha* in a clean airtight glass container. This *Lehya* is given to the patient in prescribed quantity and advised to take twice daily after food.

#### Dose and dosage schedule

Medicated *Lehya* made into airtight packet 200gm

**Dose:** 5gm for 3 to 6 years 10gm for 6 to 12 years

**Dosing schedule:** After food, twice daily morning and evening

**Vehicle:** Warm water

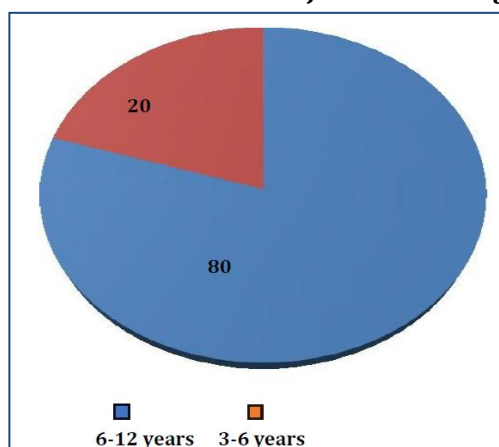
**Route of administration:** oral

#### Observational Data

**Table 1: Distribution of subjects according to age**

Age (in years)	Number	%
3-6	4	20
6-12	16	80
Total	20	100

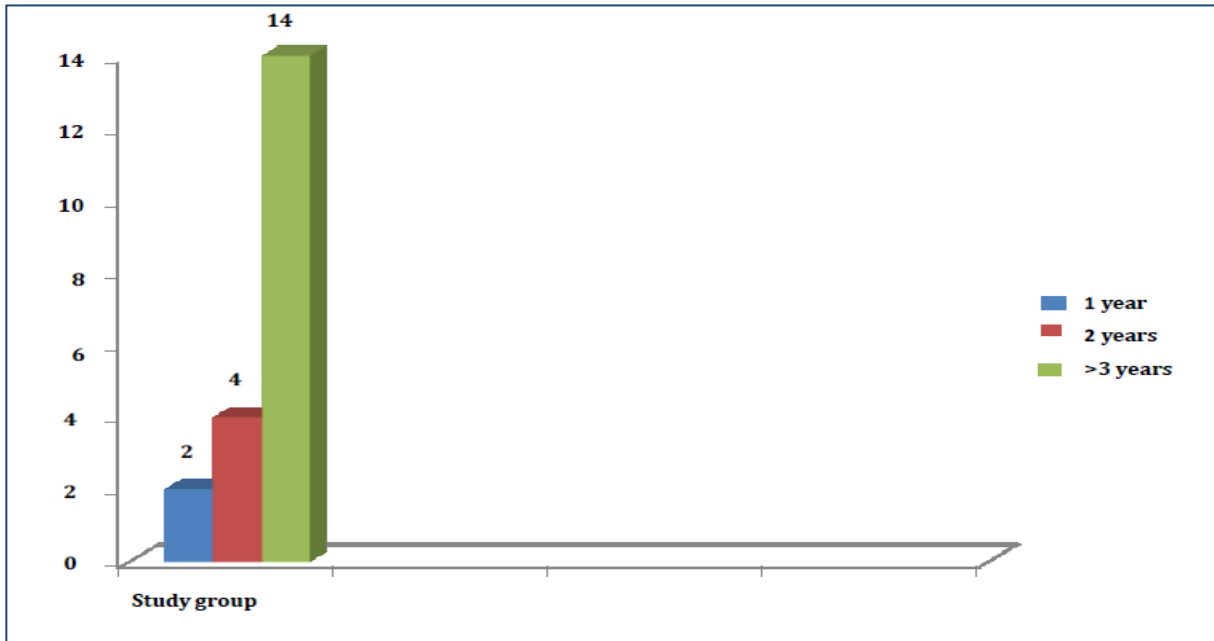
**Figure 1: Distribution of subjects according to age**



**Table 2: Distribution of children according to duration of onset**

Duration of onset (in year)	Number	%
1	2	10
2	4	20
>3	14	70
Total	20	100

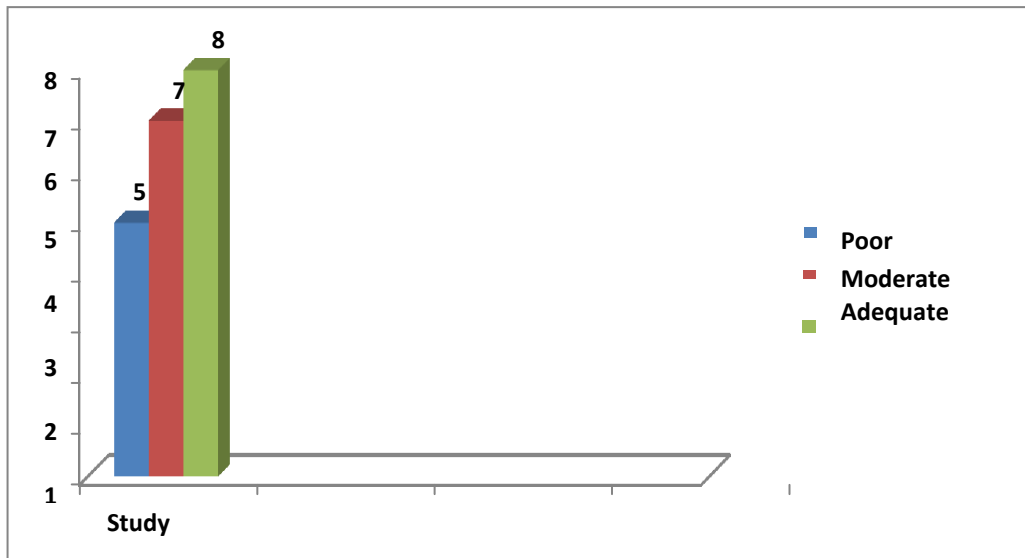
**Figure 2: Distribution of children according to duration of onset**



**Table 3: Distribution of subjects according to the type of chronic tonsillitis**

Types of chronic tonsillitis	Number	%
Chronic follicular T	04	20
Chronic parenchymatous T	07	35
Chronic fibroid T	09	45
Total	20	100

**Figure 3: Distribution of subjects according to the type of chronic tonsillitis**



**RESULTS****Table 4: Description of data related to response to treatment**

<b>Signs &amp; Symptoms</b>	<b>Data related to response to treatment</b>	
1.Sore throat	<b>Paired Comparison</b>	<b>Wilcoxon signed rank test</b>
		<b>Z</b>
		<b>P</b>
	BT vs AT	4.099
AT vs FU	2.828	0.005
BT vs FU	4.177	<0.001
2. Irritation in the throat	<b>Paired Comparison</b>	<b>Wilcoxon signed rank test</b>
		<b>Z</b>
		<b>P</b>
	BT vs AT	4.072
AT vs FU	3.606	<0.001
BT vs FU	4.099	<0.001
3. Pain in throat	<b>Paired Comparison</b>	<b>Wilcoxon signed rank test</b>
		<b>Z</b>
		<b>P</b>
	BT vs AT	4.177
AT vs FU	3	0.003
BT vs FU	4.072	<0.001
4. Pain during swallowing	<b>Paired Comparison</b>	<b>Wilcoxon signed rank test</b>
		<b>Z</b>
		<b>P</b>
	BT vs AT	4.089
AT vs FU	2.828	0.005
BT vs FU	4.099	<0.001
5. Difficulty in swallowing	<b>Paired Comparison</b>	<b>Wilcoxon signed rank test</b>
		<b>Z</b>
		<b>P</b>
	BT vs AT	4.089
AT vs FU	2.828	0.005
BT vs FU	4.099	<0.001
6.Foul breath	<b>Paired Comparison</b>	<b>Wilcoxon signed rank test</b>
		<b>Z</b>
		<b>P</b>
	BT vs AT	4.233
AT vs FU	2.333	0.02
BT vs FU	4.042	<0.001
7. Malaise	<b>Paired Comparison</b>	<b>Wilcoxon signed rank test</b>
		<b>Z</b>
		<b>P</b>
	BT vs AT	4.3
AT vs FU	2.646	0.008
BT vs FU	4.134	<0.001
8. Mouth breathing	<b>Paired Comparison</b>	<b>Wilcoxon signed rank test</b>
		<b>Z</b>
		<b>P</b>
	BT vs AT	4.035
AT vs FU	3.051	0.002
BT vs FU	4.028	<0.001

9. Cough	<b>Paired Comparison</b>	<b>Wilcoxon signed rank test</b>	
		<b>Z</b>	<b>P</b>
	BT vs AT	4.472	<0.001
	AT vs FU	2.236	0.025
	BT vs FU	4.134	<0.001
11. Hoarseness of voice	<b>Paired Comparison</b>	<b>Wilcoxon signed rank test</b>	
		<b>Z</b>	<b>P</b>
	BT vs AT	4.3	<0.001
	AT vs FU	2.236	0.025
	BT vs FU	4.234	<0.001
12. Choking spells at night	<b>Paired Comparison</b>	<b>Wilcoxon signed rank test</b>	
		<b>Z</b>	<b>P</b>
	BT vs AT	4.042	<0.001
	AT vs FU	2.236	0.025
	BT vs FU	4.128	<0.001
13. Size of tonsils	<b>Paired Comparison</b>	<b>Wilcoxon signed rank test</b>	
		<b>Z</b>	<b>P</b>
	BT vs AT	4.041	<0.001
	AT vs FU	.000 <sup>c</sup>	1
	BT vs FU	4.041	<0.001
14. Yellowish beads of the pus from crepts	<b>Paired Comparison</b>	<b>Wilcoxon signed rank test</b>	
		<b>Z</b>	<b>P</b>
	BT vs AT	4.093	<0.001
	AT vs FU	3	0.003
	BT vs FU	4.134	<0.001
15. Redness of soft palate	<b>Paired Comparison</b>	<b>Wilcoxon signed rank test</b>	
		<b>Z</b>	<b>P</b>
	BT vs AT	4.128	<0.001
	AT vs FU	2.449	0.014
	BT vs FU	4.134	<0.001
16. Edema of Uvula	<b>Paired Comparison</b>	<b>Wilcoxon signed rank test</b>	
		<b>Z</b>	<b>P</b>
	BT vs AT	4.053	<0.001
	AT vs FU	2.449	0.014
	BT vs FU	4.177	<0.001
17. Deviation of Uvula	<b>Paired Comparison</b>	<b>Wilcoxon signed rank test</b>	
		<b>Z</b>	<b>P</b>
	BT vs AT	4.3	<0.001
	AT vs FU	2	0.046
	BT vs FU	4.3	<0.001

18. Lymph node enlargement	Paired Comparison	Wilcoxon signed rank test	
		Z	P
	BT vs AT	4.134	<0.001
	AT vs FU	2.828	0.005
	BT vs FU	4.234	<0.001

### Laboratory Investigations

Haemoglobin, WBC, Platelet count, and MCV investigated before, after and after follow up which are; average haemoglobin level before treatment, after treatment and after follow up was  $11.28 \pm 0.68$ ,  $11.96 \pm 0.60$  and  $12.02 \pm 0.58$  respectively. The change in Haemoglobin% from before treatment to after treatment and after follow-up were statistically significant ( $p < 0.05$ ).

Average WBC count before treatment, after treatment and after follow up was  $14827.5 + 479.1$ ,  $13056.0 + 503.6$  and  $12560.0 + 786.3$  respectively. The change in platelet from before treatment to after treatment and after follow-up were statistically significant ( $p < 0.05$ ).

Average platelet level before treatment, after treatment and after follow up was  $218455.2 + 35220.1$ ,  $279276.0 + 46327$  and  $342118.5 + 40658.0$  respectively. The change in platelet from before treatment to after treatment and after follow-up were statistically significant ( $p < 0.05$ ).

Average MCV level before treatment, after treatment and after follow up was  $73.8 + 4.3$ ,  $85.7 + 4.9$  and  $90.6 + 3.7$  respectively. The change in MCV from before treatment to after treatment and after follow-up were statistically significant ( $p < 0.05$ ).

### DISCUSSION

The discussion aims to state the interpretations and opinions, explains the implication of the findings and gives a suggestion for future research. Its main function is to answer the questions posed in the introduction, explain how the results support the answer and how the answers fit in with existing knowledge on the topic. Tonsils are the sentinels of the oral cavity. Repetitive assaults of infection in the body like tonsillitis influence the typical development and advancement of youngsters. In chronic and recurrent condition, tonsillectomy is necessary to conduct for prevention of other respiratory disorders. In order to avoid the disadvantage of surgery, the recurrence and chronicity of disease should be controlled by the application of many conventional drugs which are mentioned by Acharyas. These drugs are more effective compared to modern management. After assessing the chronicity of the condition Ayurvedic treatment is adopted.

Ayurveda is a science of life, it is very useful in daily life that has changed the experiences of innumerable individuals over millennia. Acharyas

compared the human body with the tree whereas *Srotas* (passages) of the body is correlated to the roots of that tree. How the healthy, strong, and deep roots are essential for a tree to remain firm likewise a healthy *Srotas* is essential for the body. As *Mukha* is the beginning of the gastrointestinal system,

*Mukhaswashtha* (oral hygiene) is very essential to remain healthy. Since poor oral hygiene is also a major cause of oral diseases it will give a great impact on the quality of life. If oral diseases persist for a long time would become a major health issue. *Sthanika chikitsa* (localized treatment) is an essential part of treatment of *Mukhroga* (oral cavity). *Mukhaswashtha rakshana* (oral hygiene), which can be easily implemented in daily life like *Kavala* (medicated liquid for gargling), *Gandusha* (medicated liquid for gargling), and *Pratisarana* (rubbing) which are the main *Mukha sodhana* (purification of mouth) procedures explained in the Ayurvedic classics, can be adopted as well as *Nidanaparivarjana* (avoidance of causes) as per the basic principles of Ayurveda. In *Tundikeri*, *Shleshma (Kapha)* and *Pitta* vitiation are present. *Shleshma (Kapha)* vitiation can be understood by the presence of *Kathina shopha* (hard swelling) and *Gala uprodha* (obstruction of throat). *Pitta* vitiation can be understood by the presence of *Dourgandhya* (foul breath) and *Ragatva* (redness) here indicating *Rakta dushti* also. *Dourgandhya* (foul breath) and *Sthivan* (sputum) of *Shleshma (Kapha)* represent the *Sama Avastha* of *Shleshma (Kapha)* and *Pitta dosha* in *Mukha*. *Koshta gata ama* is understood by the presence of irregular bowel habits and reduced appetite. Hence the condition was diagnosed as *Sama kapha pitta avastha* of *Tundikeri*.

Thus *Ama pachana*, *Deepana* line of management was adopted for breakdown of the *Samprapti* of *Tundikeri*. In Ayurvedic context, there are many drugs for respiratory disorders. *Vyaghri haritaki lehya* is selected for *Tundikeri chikitsa* because most of the ingredients are having *Deepana*, *Pachana*, *Kaphavatahara*, *Raktashodhana* and *Anulomana*. *Vyaghri haritakilehya* is mentioned in the context of the treatment of *Kasa* and *Shwasa* in *Bhaisajya Ratnavali Kasa Rogadhikar*. *Vyaghri haritaki lehya* is also mentioned in various treatises of Ayurveda. It is prepared in the dosage form of *Avaleha*, a semisolid drug form that can be licked.

**Mode of action of the drug**

*Vyaghri haritaki avaleha* is very effective in upper respiratory infection mainly in chronic tonsillitis. Due to *Nidanas* like *Ahitha ahara vihara* (uncongenial diet and regimens), *Vegdharana* (suppression of natural urge), etc. *Agnimandhya* and *Kaphadosha prakopa* occurs and *Ama* leads to *Raktadushti*. Chronicity of the disease results *Dhatu kshaya* which leads to *Vata prakopa*. So the disease is *Kapha* and *Rakta* predominant. The manifestation of the disease can be summarized as the end product of all *Doshas* along with *Rakta*. *Agnidushti* (improper digestive fire), and *Srotodushti* (unclear passages) are caused by *Vishamashana*, *Vegdharana*, and *Dhatukshaya*. The *Dosha prakopa* is corrected by the *Doshashamana* property of *Vyaghri haritaki lehya*. Here *Agnidushti* is corrected by *Srotosodhana* and *Agnivardhaka* property of *Vyaghri haritaki lehya*. *Haritaki* is having mainly *Vatanulomana* property and also *Rasayana* property. *Madhu* is having *Chedana*, *Lekhana*, *Raktasodhana* and *Kaphahara* properties. The *Deepana-pachana* (appetizer- digestive) properties of *Vyaghri haritaki avaleha* digest the *Sama kapha* by enhancing the *Jatharagni* as well as *Rasa dhatvagni* and *Bhutagni*, which neutralize the *Srotorodha* (blockage in channels) in *Annavaha* and *Pranavaha srotas* due to *Sama kapha* and *Vata*. *Dhatukshaya* is corrected by *Bramhana* property of the *Avaleha*.

**CONCLUSION**

To clinical study aimed to evaluate the combined effect of *Vyaghri haritaki lehya* in chronic tonsillitis in children of the age group 3-12 years.

The assessment concluded that:

1. *Vyaghri haritaki lehya* is effective in reducing the majority of sign and symptoms of chronic tonsillitis
2. *Vyaghri haritaki lehya* is effective in reducing the number of attack of chronic tonsillitis.
3. The action of *Vyaghri haritaki lehya* was sustained even after the treatment period.
4. *Vyaghriharitai lehya* seems to be effective in improving the general health and immune status thus preventing the recurrence.
5. The alternate hypothesis "*Vyaghri haritaki lehya* is effective in reducing the signs and symptoms of chronic tonsillitis (*Tundikerika*) in children" of the study proved.

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