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A clinical study to evaluate the effect of *Dashamoola Hareetaki Avaleha* in *Tundikeri* w.s.r to Chronic Tonsillitis

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ABSTRACT

Recurrent tonsillitis is commonly seen in children and this has many adverse effects on the normal growth and development of the child, missing of school days, economic burden of treatment etc. are few to name. About 30 million children develop tonsillitis with frequent exposure to bacterial and viral infections. The chronic tonsillitis wherein the tonsil gland gets inflamed and enlarged repeatedly, after treatment the size remains same though the inflammation subsides. This leads to obstruction in the throat both to airways as well as digestive tract. According to *Ayurvedic* classics, various internal medicines and procedures are advocated in the management of *Mukharogas*. In general, the drugs selected for treatment should have *Lekhana*, *Shothahara*, *Pachana*, *Ropana*, *Rakthashambana* and *Vedanasthapana* properties. One such polyherbal preparation is *Dashamoolaharitaki Avaleha* mentioned in *Svayathu Chikitsa* by *Acharya Vagbhata*, which is widely used in clinics for management of *Tundikeri*. In the present scenario scientific validation about the success of these treatments is required. Therefore an open label clinical study was designed to prove the effect of *Dashamoolaharitaki Avaleha* in *Tundikeri*. **Materials and Methods:** An open trial single group clinical study with minimum of 30 patients between the age group of 5 to 15 years with *Tundikeri* over a period of 30 days. **Result:** The clinical study showed highly significant results in relieving the clinical signs and symptoms of *Tundikeri*. **Discussion:** The *Dashamoolaharitaki Avaleha* was found therapeutically effective and safe to be administered in children and the mode of action was elaborated to substantiate the results.

Key words: Ayurveda, Chronic tonsillitis, Dashamoola Haritaki Avaleha, Mukharoga, Shothahara, Tundikeri.

INTRODUCTION

Nature is the supreme mother; endlessly forgiving, endlessly resourceful and for those who acknowledge and work with her, endlessly accessible. We can work with her to maintain health and rejuvenate ourselves. As Nehru rightly said, "the children of today will make

the India of tomorrow", it is our responsibility to provide them with best care.

Ayurveda is the oldest scientific and time related rich medical science, which has been protecting the health of people from centuries. *Kaumarabhritya*, one among the *Ashtangas* of *Ayurveda* exclusively deals with care of children.

The human body is actually a social order of about 100 trillion cells organized into different functional structures, some of which are called organs; some organs combinedly form a system.^[1] The lymphatic vasculature is not considered a formal part of the immune system, but it is critical to immunity. Even though memory CD8⁺ T lymphocytes outside of secondary lymphoid organs outnumber their counterparts in secondary lymphoid organs, secondary lymphoid organs remain the critical meeting point for the initiation of immune responses to antigens

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previously not encountered.^[2] The lymphatic system consists of a fluid called lymph flowing within lymphatic vessels, several structures and organs that contain lymphatic tissue, and red bone marrow, which houses stem cells that develop into lymphocytes. Lymphatic nodules are oval shaped concentrations of lymphatic tissue. Some lymphatic nodules occur in multiple, large aggregations in specific parts of the body and one among these are the tonsils in the pharyngeal region. Usually there are five tonsils, which form a ring at the junction of the oral cavity and oropharynx and at the junction of the nasal cavity and nasopharynx. Structurally being the part of upper respiratory tract, they are strategically positioned to participate in immune responses against foreign bodies that are inhaled or ingested. Whereas their T cells destroy foreign intruders directly, B cells develop into antibody-secreting plasma cells and the antibodies dispose of foreign substances.^[3] So, whenever there is an infection in the oral cavity or respiratory tract, the tonsils play first role in defense mechanism to prevent the infection.

Hypertrophied tonsils and adenoids are the major cause of upper airway obstruction in children.^[4] Sore throat has an annual incidence of 100 in 1000 with tonsillitis accounting for approximately 32 in 1000 subjects per year.^[5] It is also estimated that 35 million work and school days are lost per year because of sore throat. Tonsillitis is one among the disease entity that makes a child to miss his school days. About 30 million children develop tonsillitis with frequent exposure to bacterial and viral infection.^[6]

Chronic tonsillitis that mostly occurs due to improper management of acute condition affects the normal routine of child. If not treated it can have many complications like Peritonsillar abscess, Parapharyngeal abscess, Intratonsillar abscess, Tonsilloliths, Tonsillar cysts, focus of infection in Rheumatic fever, acute glomerulonephritis, etc. The treatment modalities for chronic tonsillitis include conservative management as well as tonsillectomy.^[7]

Shalaky Tantra, one among *Astangas* of *Ayurveda* has given second most important place by *Acharya*

Sushruta. It is that branch which is meant for alleviation of diseases of ear, eye, mouth, nose etc situated in *Urdwajatru*. *Acharya Charaka* has quoted that in a living being, head is the seat for life and all the sense facilities and therefore it is considered as *Uttamanga*.^[8] *Mukharoga* is one among the diseases explained under *Uttamanga*. Tonsillitis can be correlated *Tundikeri* which is one among the *Mukharogas* sub classified under *Talugata* as well as *Kantagata Rogas* by *Acharyas*. Lot of *Ayurvedic* formulations are widely used in the management of chronic tonsillitis and most of them are herbal in origin. However, many of them are yet to be clinically proved and analysed statistically which is a part of present research methodology. By considering the *Lakshanas* of *Tundikeri*, *Pradhanyatha* of *Kapha* and *Rakta* in disease is ascertained and hence, for the *Samprapti Vighatana Kapharaktahara* and *Shophahara* treatment has to be adopted. With this intension *Dashamoola Haritaki* mentioned under *Svayathu Chikitsa* of *Vagbhata* is taken in view of providing symptomatic relief and reducing the recurrence of the disease.^[9] The therapeutic effect of *Dashamoola Haritaki* in chronic tonsillitis is yet to be explored. This drug is considered for the study to avoid the surgical intervention, parental fear and permanent loss of primary defence. Thus, this clinical study is intended to explore the efficacy of *Dashamoola Haritaki* in children suffering from chronic tonsillitis.

AIMS AND OBJECTIVES

To study the efficacy of *Dashamoola Haritaki Avaleha* in the management of *Tundikeri* (Chronic Tonsillitis) in children

MATERIALS AND METHODS

Source of Data

Diagnosed cases of *Tundikeri* (chronic tonsillitis) are selected from OPD & IPD of SDM College of Ayurveda & Hospital, Kuthpady, Udupi.

a) Literary source

Classical textbooks of *Ayurveda*, text book of contemporary science are referred.

b) Clinical source

A minimum of 30 patients suffering from *Tundikeri* in an age group of 5 to 15 years of either sex is selected and subjected to clinical trial.

c) Drug source

All the ingredients for the preparation of trial drug *Dashamoola Hareetaki*, is collected and prepared from GMP certified SDM Pharmacy, Udipi.

Diagnostic Criteria

The subjects will be diagnosed on the basis of clinical signs and symptoms^[18,19]

- Enlarged tonsils (*Hanusandhiashrita Kathina Shopha*)
- Recurrent or persistent sore throat
- Difficulty in swallowing and breathing
- Irritation in throat
- Cough
- Halitosis
- Jugulodigastric lymphadenopathy

Study design

- Study type : Interventional
- Design : Pre-test and post-test
- Allocation : Non random
- Endpoint classification : Efficacy study
- Intervention model : Single group
- Primary purpose : Treatment
- Masking : Open label

Intervention period

30 days, subjects will be reviewed on 15th and 30th day (After completion of treatment)

Follow-Up

Follow up will be done 15 days after the completion of study

Inclusion criteria

1. Children aged between 5 to 15 years presenting with enlarged tonsils with 2 or more symptoms mentioned under the diagnostic criteria.

Exclusion criteria

1. Children suffering from acute tonsillitis.
2. Children presenting with tonsils enlarged in such a way that they are about to touch each other.
3. Children presenting with Peritonsillar abscess, Parapharyngeal abscess, Intratonsillar abscess, Tonsilloliths, Tonsillar cysts, Rheumatic fever, acute glomerulonephritis, and eye and skin disorders.
4. Children suffering from other acute & chronic systemic illness and undergoing other interventions.

Dosage form (Kalpana)	<i>Avaleha</i>
Dose	5-10 years = 5g bd 11-15 years = 7g bd
Dosage form (Kalpana)	<i>Avaleha</i>
Dose	5-10 years = 5g bd 11-15 years = 7g bd
Time of administration	<i>Adhobhakta</i> (After food)
Anupana	Hot water
Route	Oral
Duration of treatment	30 days

Assessment criteria

Subjects are assessed before and after study by observing grades of clinical signs and symptoms

Subjective parameters

1. Recurrent attacks of sore throat
2. Irritation of throat
3. Difficulty in swallowing
4. Difficulty in breathing

5. Cough
6. Halitosis
7. Hoarseness of voice

Objective parameters

1. Size of tonsil
2. Lymph node enlargement

OBSERVATIONS AND RESULTS

No. of patients registered for the study	32
No. of patients completed the study	30
No. of dropout	2

As per the proforma, observations were made regarding the incidence of Age, sex, occupation, religion, socio-economic status, diet, nutritional status etc.

Table 1: Distribution of 30 patients according to different criteria

Parameters	Observations	Maximum number of patients	%
Age group	5-10 yrs	16	53.3
Gender	Male	16	53.3
Socioeconomic class	Lower class	12	40
Domicile	Rural	21	70
Education status	Primary school	17	56.7
Diet	Mixed	21	70
Appetite	Moderate	20	66.7
Bowel habit	Regular	19	63.3
Sleep	Sound	18	60
Prakriti	Pitta Kaphaja	13	43.3

Table 2: Disease related observations

Parameters	Observations	Maximum number of patients	%
Mode of onset	Episodic	21	70.0
Duration of chronicity	1-2 year	10	33.3
Symmetry of enlarged tonsils	Bilateral enlargement	30	100.0
Yellowish beads of pus on the medial side of the tonsil	Present	21	70.0
Membranes, ulcers, mass	Absent	30	100.0
Palpation of tonsils	Palpable	26	86.7

Table 3: Signs and symptoms

Parameters	Observations	Maximum number of patients	%
Recurrent attack of sore throat	Present	30	100.0
Irritation of throat	Present	29	96.7
Difficulty in swallowing	Present	20	66.7
Mouth breathing / difficulty of breathing	Present	17	56.7
Cough	Present	25	83.3
Halitosis	Absent	20	66.7
Hoarseness of voice	Absent	20	66.7

RESULTS

Clinical study was conducted at SDM Ayurveda Hospital, Udupi. Among 32 patients registered for the study, 30 patients who completed the study were assessed before the treatment (BT), on 30th day (AT)

and after 15 days of follow up on the 45th day (AF). Different parameters were assessed based on the grading given to those symptoms. They were recorded in the case proforma. Then finally, relevant statistical tests were applied to check the significance. Wilcoxon signed rank test is used to assess BT, AT and AF values of the individual group as the data is categorical (ordinal). The numerical data was tested using paired ‘t’ test. The analysis is done statistically using Statistical Package for Social Science (SPSS) version 2.0.

Different symptoms, investigations assessed in the patients and their results are as follows;

Table 4: Effect of treatment on objective parameters.

Parameter	Negative ranks			Positive ranks			Tie	Z value	P value	Interpretation
	N	M	SR	N	M	SR				
Size of tonsils										
BT-AT	30	15.50	465.00	0	.00	.00	0	-5.305	.000	HS
BT-FU	30	15.50	465.00	0	.00	.00	0	-4.983	.000	HS
Jugulodigastric lymphadenopathy										
BT-AT	29	15.50	43.00	0	.00	.00	0	-5.231	.000	HS
BT-FU	29	15.50	43.00	0	.00	.00	0	-5.231	.000	HS

Table 5: Effect of treatment on subjective parameters.

Parameter	Negative ranks			Positive ranks			Tie	Z value	P value	Interpretation
	N	M	SR	N	M	SR				
Recurrent attacks of sore throat										
BT-AT	30	15.50	465.00	0	.00	.00	0	-4.983	.000	HS

BT-FU	30	15.50	465.00	0	.00	.00	0	-4.983	.000	HS
Irritation of throat										
BT-AT	27	14.00	378.00	0	.00	.00	0	-4.786	.000	HS
BT-FU	28	14.50	406.00	0	.00	.00	0	-4.774	.000	HS
Difficulty in swallowing										
BT-AT	22	11.50	253.00	0	.00	.00	0	-4.523	.000	HS
BT-FU	22	11.50	253.00	0	.00	.00	0	-4.456	.000	HS
Halitosis										
BT-AT	12	6.50	78.00	0	.00	.00	0	-3.276	.001	HS
BT-FU	12	6.50	78.00	0	.00	.00	0	-3.276	.001	HS
Mouth breathing/difficulty of breathing										
BT-AT	15	8.00	120.00	0	.00	.00	1	-3.873	.000	HS
BT-FU	16	8.50	136.00	0	.00	.00	0	-3.900	.000	HS
Cough										
BT-AT	25	13.00	325.00	0	.00	.00	1	-4.507	.000	HS
BT-FU	25	13.00	325.00	0	.00	.00	0	-4.490	.000	HS
Hoarseness of voice										
BT-AT	11	6.00	66.00	0	.00	.00	0	-3.317	.001	HS
BT-FU	11	6.00	66.00	0	.00	.00	0	-3.317	.001	HS

All the subjective and objective parameters showed highly significant results which discloses that the study drug is effective in reducing the signs and symptoms of chronic tonsillitis.

DISCUSSION

Discussion on the probable mode of action of drug

The major drugs used in the preparation of the *Dashamoola Haritaki Leha* are primarily *Ushna Veerya*, alongside a few *Sheeta Veerya* drugs. In the formulation of the *Dashamoola Haritaki Rasayana*, *Tikta Katu Madhura* and *Kashaya* is the dominant *Rasa*, *Laghu Ruksha* and *Tikshna Gunas* are the major *Gunas*, with only a few *Guru*, *Picchila* and *Snigdha* of the individual herbs.

Laghu Guna does *Lekhana* and *Ropana*.^[10] *Tikshna Guna* does *Sodhana* & *Kaphavatahara Karma*^[11] acts as antagonists to *Kapha Gunas* thereby normalizing *Kapha*. *Ruksha Guna* does *Soshana*^[12] and is *Kaphahara* in action.^[13]

Kashaya Rasa relieves *Pitta* and *Kapha* disorders along with the effects of *Sodhana*^[14] while *Katu Rasa* combats the *Kapha*, clears the obstruction in the *Srotas*, and accomplishes *Sodhana*.^[15] *Tikta Rasa* owns the *Kanta-Sodhana* and *Lekhana* property.^[16] The majority of the *Dravyas* in *Dashamoola Haritaki Leha* are *Tridosha Samakas* and *Pittakapha* pacifying in nature.

So, all these factors helps in reversing the pathophysiology of *Tundikeri*.

Discussion on results

Effect of *Dashamoola Haritaki Avaleha* on size of tonsils

When size of tonsils was compared before treatment to after treatment, z value was -5.305 and p value was 0.000, thus results are statistically highly significant. When compared before treatment to after follows up, z value was -4.983 and p value was 0.000 showing statistically highly significant. It shows progressive reduction in size of enlarged tonsils.

Most of the drugs in the study drug is *Shothahara* in action and the *Dashamoola Haritaki Avaleha* is the

specific formulation told by *Acharya Vagbhata* for *Pravriitha Shophha*.^[17] The main ingredients *Dashamoola* and *Haritaki*, known for its anti-inflammatory properties helps in reducing the inflammation in the tonsillar tissues. This implies that the trial drug was very effective in reducing the size of tonsils and further retained the effect during the follow-up period.

Effect of *Dashamoola Haritaki Avaleha* on Jugulodigastric lymphadenopathy

When Jugulodigastric lymphadenopathy compared before treatment (mean 1.13) to after treatment (mean 0.06) with Wilcoxon signed rank test, z value was -5.231 and p value was 0.000 which is statistically highly significant. When size of tonsils compared before treatment (mean 1.13) to after follow-up (mean 0.06) with Wilcoxon signed rank test, z value was -5.231 and p value was 0.000 which is statistically highly significant.

By checking the phyto-constituents *Dashamoola Haritaki Avaleha* is best analgesic and anti-inflammatory. *Dashamoola*, one among the main ingredient of study drug has consistently shown efficacy in models of inflammation hinted at the possibility of prostaglandin synthesis inhibition as the probable mechanism of action.^[18] Thus reduction in the inflammatory changes of tonsillar tissues in turn facilitates reduction in the local lymphadenopathy.

Effect of *Dashamoola Haritaki Avaleha* on recurrent attack of sore throat

When recurrent attacks of sore throat compared before treatment (mean 1.36) to after treatment (mean 0.03) with Wilcoxon signed rank test, z value was -4.983 and p value was 0.000 which is statistically highly significant. When recurrent attacks of sore throat compared before treatment (mean 1.36) to after follow-up (mean 0.03) with Wilcoxon signed rank test, z value was -4.983 and p value was 0.000 which is statistically highly significant.

The main ingredient, *Haritaki* is known for its wide range of pharmacological action mainly antioxidant and immunomodulatory^[19] and a potent *Rasayana* drug along with other antimicrobial drugs might have

increased the immune status thereby preventing further attacks of infections.

Effect of Dashamoola Haritaki Avaleha on irritation of throat

When irritation of throat compared before treatment (mean 1.57) to after treatment (mean 0.35) with Wilcoxon signed rank test, z value was -4.786 and p value was 0.000 which is statistically highly significant. When irritation of throat compared before treatment (mean 1.57) to after follow-up (mean 0.14) with Wilcoxon signed rank test, z value was -4.786 and p value was 0.000 which is statistically highly significant.

Most of the drugs in the trial drug is *Shothahara*, *Vedanasthapana* and *Lekhana* property helps to clear the *Srotas* and thereby relieving irritation of throat.

Effect of Dashamoola Haritaki Avaleha on difficulty in swallowing

When difficulty of swallowing compared before treatment (mean 1.13) to after treatment (mean 0.04) with Wilcoxon signed rank test, z value was -4.523 and p value was 0.000 which is statistically highly significant. When difficulty of swallowing compared before treatment (mean 1.13) to after treatment (mean 0.00) with Wilcoxon signed rank test, z value was -4.456 and p value was 0.000 which is statistically highly significant.

Difficulty in swallowing is due to enlarged and inflamed tonsillar tissues. The anti-inflammatory action of trial drug might have helped in reduction of difficulty in swallowing.

Effect of Dashamoola Haritaki Avaleha on halitosis

When halitosis compared before treatment (mean 1.25) to after treatment (mean 0.08) with Wilcoxon signed rank test, z value was -3.276 and p value was 0.001 which is statistically highly significant. When halitosis compared before treatment (mean 1.25) to after follow-up (mean 0.08) with Wilcoxon signed rank test, z value was -3.276 and p value was 0.001 which is statistically highly significant.

The antimicrobial^[20] and antibacterial^[21] properties of drugs helps to reduce the breeds of microbes in oral

cavity and the *Kaphahara* and *Srotoshodhana* action of drugs helps in removing accumulated *Doshas* in oral cavity and thereby providing *Vaktrashodhana*.

Effect of Dashamoola Haritaki Avaleha on difficulty of breathing

When mouth breathing/difficulty of breathing compared before treatment (mean 1.12) to after treatment (mean 0.18) with Wilcoxon signed rank test, with z value was -3.873 and p value was 0.000 which is statistically highly significant. When mouth breathing/difficulty of breathing compared before treatment (mean 1.12) to after follow up (mean 0.06) with Wilcoxon signed rank test, z value was -3.900 and p value was 0.000 which is statistically highly significant.

Difficulty in the breathing is due to the narrowing and obstruction of upper airway due to enlarged tonsils. The *Shothahara*, *Vedanasthapana*, *Srotoshodhana* action of drug has helped in reduction of size of enlarged tonsils which in turn reduced the difficulty of breathing by clearing the airway.

Effect of Dashamoola Haritaki Avaleha on cough

When cough compared before treatment (mean 1.56) to after treatment (mean 0.08) with Wilcoxon signed rank test, z value was -4.507 and p value was 0.000 which is statistically highly significant. When cough compared before treatment (mean 1.56) to after follow up (mean 0.00) with Wilcoxon signed rank test, z value -4.490 and p value 0.000 which is statistically highly significant.

The drugs such as *Kantakari*, *Brihati*, *Haritaki*, *Ela*, *Pippali* have action on *Pranavaha Srotas*^[22] and *Kasahara* effect of *Yoga* might have reduced the bouts of cough.

Effect of Dashamoola Haritaki Avaleha on hoarseness of voice

When cough compared before treatment (mean 1.00) to after treatment (mean 0.00) with Wilcoxon signed rank test, z value was -3.317 and p value was 0.001 which is statistically highly significant. When cough compared before treatment (mean 1.00) to after

follow-up (mean 0.00) with Wilcoxon signed rank test, z value was -3.317 and p value was 0.001 which is statistically highly significant.

The ingredients of this *Yoga* have action on *Pranavaha Srotas* and also on *Udanavayu* which in turn bring *Vakshuddi*^[23] thereby resulting in improving hoarseness of voice.

Effect of Dashamoola Haritaki Avaleha on weight

The mean score of weight before treatment is 30.85 and mean score after treatment is 30.90, the mean difference among the two being 0.04kg which shows that there is a 0.12 % improvement seen in weight, which is statistically highly significant with p value 0.000.

The *Deepana Pachana* effect of *Yoga* might have increased *Agni* and on relief from difficulties of deglutition combinedly enhanced the dietary intake resulting in the increase of weight.

CONCLUSION

Tonsillitis is a most common ailment in school going children coming about from Pharyngitis. Considering the paediatric age group, the most probable type of tonsillitis is chronic tonsillitis due to recurrent respiratory tract infections and pharyngitis. The clinical features of chronic tonsillitis can be potentially correlated to *Tundikeri Lakshanas* explained by *Vagbhata*. Most of the *Aharaja Nidanas* like *Guru*, *Abhishyandi Aharas* and *Viharas* like *Avakshayya* and exposure to *Raja-dhuma Atapa* etc. leads to *Kapha Pitta prakopa* and does *Sthanasamshraya* in *Kanta Pradesha* giving rise to disease *Tundikeri*. Factors like poor oral hygiene, excessive intake of cold items etc. can be considered as predisposing factors for tonsillitis. Out of 30 subjects, all subjects had recurrent attacks of sore throat and enlarged tonsils. Majority of subjects had irritation of throat, difficulty in swallowing, difficulty in breathing, cough, where a smaller number of patients had halitosis and hoarseness of voice. Classics have mentioned both surgical and nonsurgical treatment for *Tundikeri*. By looking into treatment modalities, we can say that the drugs which are *having Lekhana, Shothahara, Shulahara, Deepana, Pachana*

properties should be administered in Tonsillitis. The present study revealed that *Dashamoola Haritaki Avaleha* having *Dashamoola* and *Haritaki* as main ingredient along with *Yavakshara* and other drugs, with its anti-inflammatory, analgesic and antimicrobial action helps in reducing the inflammation of tonsillar tissue resulting in reduction of signs and symptoms. Clinically study drug is more effective in reducing the symptoms like cough, irritation of throat and reduction in attacks of sore throat. No adverse reactions were observed in the study; therefore, it is found to be safe for pediatric age group.

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