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Research Article

THE COMBINED EFFECT OF *VARABHRIHATYADI KASHAYA* AND *SARAPUNKHA LEPA* IN CHRONIC TONSILLITIS IN CHILDREN

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ABSTRACT

Children with the clinical features of Chronic Tonsillitis coming under the age group 3-12 years were included in the study. The patients were randomly allocated in to the study group and control group using simple random sampling technique. In the study group the dose of *Varabrihatyadi Kashaya* was fixed as follows, in the age group 3-6 years: 10ml bd before food, in the age group 6-9 years: 20ml bd before food, in the age group 9-12 years: 30ml bd before food. *Sarapunkha lepa* was applied around the neck where enlarged lymph nodes were found. Frequency of paste was fixed as two times daily and at each time, it is kept until it becomes dry. At the same time those in the control group were subjected to external application of *Sarapunkha lepa* only. Both the groups were followed for a period of 1 month after the scheduled course of intervention. Routine blood investigations were also carried out before and after the study. The data were analyzed using the most appropriate statistical tests. Significant changes were obtained in the clinical parameters in the study group used for assessment such as recurrent attacks of sore throat, pain in the throat, pain on swallowing, difficulty in swallowing, halitosis, mouth breathing, hoarseness of voice, chocking spells at night, size of the tonsil, congestion of pillars, oedema of the uvula, deviation of the uvula and lymph node enlargement. There was a significant change in the routine blood investigations also. Moreover the trial drug sustained its potential action even during the follow up period. The effect of control drug was insignificant. The final evaluation proved that combination of *Varabhrihathyadi Kashaya* and *Sarapunkha lepa* was effective in reducing the signs and symptoms of Chronic Tonsillitis in children of 3-12 yrs age group.

KEYWORDS: Chronic Tonsillitis, *Tundikerika. Varabrihatyadi Kashaya, Sarapunkha lepa.*

INTRODUCTION

Ayurveda an ancient traditional system of medicine is considered the oldest system of health care, with literature going back 5000 years and an oral tradition that is much older. Ayurveda helps the healthy person to maintain health and the diseased person to regain health. *Kaumarabhrithya* is one among the most important branches of Ayurveda dealing with child care. The knowledge attitude and practice of this childcare system have to be uplifted for the welfare of entire child population. The researchers are to be done in this field to ensure the development of Ayurvedic Paediatric Department.

Sore throat is a common condition in primary care. As many as 1 in 10 people suffer recurrent episodes of tonsillitis. The cost per year to the NHS for primary care consultations, before investigation and treatment, for sore throats is estimated at 60 million pounds. It is also estimated that 35 million work and school days are lost per year because of sore throats. Tonsillitis most often occurs in children; however, the condition rarely occurs in children younger than 2 years. Acute tonsillitis is a common condition often seen in children aged 5–10 and young adults aged 15–25. Chronic Tonsillitis is usually due to the complication of improperly managed tonsillitis that affects child's day-to-day performances. If not managed properly it may lead to systemic disorders namely rheumatic fever, acute glomerulo-nephritis and even interferes with normal growth and development of child.

Chronic tonsillitis can be simulated with different diseases mentioned in Ayurvedic classics. It can be compared with different diseases like *Apachi, Kanda Salookam, Kapha Pitta Sopham, Galavidradi, Tundikerika,* etc. Precise comparison cannot be possible in any of these disorders. It also gives an inference that in that ancient era tonsillitis was not as prevalent and serious problem as it is now.

Apachi is described as generalized chronic lymphadenitis due to various etiologies. Specific sites

of *Apachi* include *Kaksha* (axilla) and *Vamkshana* (groin) that gives an inference that it is not a simple oral disease. Other clinical features like suppuration, oozing and synonym like *Gandamala* (cervical lymphadenitis) of *Apachi* points out it into a clinical condition similar to Scrofuloderma found with tuberculosis.[1] The *Kanda Salukam*, an oral disease mentioned in *Astanga Hridaya* and Susrutha Samhitha, cannot be compared with chronic tonsillitis, because size and shape of *Salukam* which is explained as *Kolaphala* is not matching with size and shape of tonsils and *Saluka's* specific site other than throat is not mentioned.[2]

Kapha Raktha Sopha, *Kapha Pitta Sopha, Gala Vidradi* are all umbrella terms which do not have any specificity and is applicable to diseases manifesting in any part of the body.

Even though exact correlation is not possible, chronic tonsillitis can be simulated with *Tundikerika*, a *Mukha roga* (oral disease) explained in various classics. Susrutha considered *Tundikerika* under *Talugata roga*[3] (according to Susrutha, *Talu* is one among seven basic units of oral cavity) while Vagbhata described it under *Kantagata roga* (according to Vagbhata *Kanta* is one among eight basic units of oral cavity).[4]

Lot of Ayurvedic formulations are widely used in Kerala in the management of Chronic Tonsillitis; most of them are herbal in origin. However many of them are yet be clinically proved and analysed statistically which is a part of present research methodology.

In the present study it was planned to evaluate the combined effect of *Varabhrihathyadi Kashaya* and *Sarapunkha Lepa* in chronic tonsillitis. The reference of above mentioned formulations are given in *Arogyakalpadrumam*[5], a traditional Ayurvedic paediatric textbook. The combination of decoction and paste is mentioned in the treatment of *Apachi*[6] (a clinical condition similar to chronic lymphadenitis). Since tonsil is a lymphoid tissue, the above combination is taken in this clinical trial to assess its efficacy in chronic tonsillitis.

In the present scenario, well-established clinical trials like Randomized Controlled Trial have highest level of significance to prove the efficacy. Therefore, a therapeutic single blinded, randomized controlled trial was designed to prove the combined effect of *Varabhrihathyadi Kashayam* and *Sarapunkha Lepam* in chronic tonsillitis.

MATERIALS AND METHODS

Aims and objectives

The aim of the study was to evaluate the combined effect of *Varabhrihatyadi kashayam* (decoction) and *Sarapunkha lepam* (paste) in Chronic Tonsillitis in children of age group 3 - 12 years and to evaluate its sustained effect for a period of one month.

Ethical considerations

Ethics are principles of right conduct. Ethical principles always represent basic human values. Efforts were made to maximize the benefits to the subjects (beneficence) and subject should suffer no harm (non-malfeasance) in the present study.

Hypothesis

The research hypothesis is a tentative statement that can be tested by a scientific research design. Since this clinical research is concerned with relationships between observations or variables, a research hypothesis was developed.

Null hypothesis

Combination of *Varabhrihatyadi kashayam* and *Sarapunkha lepam* is not effective in chronic tonsillitis in children in the age group between 3 years and 12 years.

Alternate Hypothesis

Combination of *Varabhrihatyadi kashayam and Sarapunkha lepam* is very effective in chronic tonsillitis in children in the age group between 3 years and 12 years.

Variables

The experimental variable was the combination of *Varabhrihatyadi* decoction and *Sarapunkha* paste. Change noted in the condition of Chronic Tonsillitis in children was the dependent variable. A number of intervening variables such as diet, age, sex, seasonal change, constitution etc. kept constant by keeping a control.

Drug selection

The combination of *Varabhrihatyadi kashayam* and *Sarapunkha* paste is explained in the context of Treatment of *Apachi* (a clinical condition similar to chronic lymphadenitis). Even though the combination is not directly mentioned for chronic tonsillitis, the drugs in the decoction possess anti inflammatory, antibacterial, antipyretic, diuretic, analgesic and immunomodulatory properties. The paste of *Sarapunkha*, which is processed in *Thriphala* decoction, supposed to possess anti-inflammatory properties. Thus, the combination becomes an ideal drug for chronic tonsillitis.

Raw materials for the preparation of the trial drugs were procured from a reputed raw drug shop, at Thiruvananthapuram. The drugs were powdered in a micro pulverizer by maintaining the standards for an infusion. The care takers of patients were requested to prepare the infusion with prescribed quantities of powder. The root of *Sarapunkha* was

powdered and provided to care takers to prepare the paste in *Thriphala* infusion.

Control drug

External application of *Sarapunkha* paste over the neck (where enlarged tonsils can be palpated) was taken as the intervention in the Control Group**.** *Thriphala* decoction was the liquid base for preparing the paste**.** Care takers of patients were requested to prepare *Thriphala* infusion with powdered *Thriphala*. They were requested to soak *Sarapunkha* powder in *Thriphala* decoction overnight and grind well to prepare a paste. They were asked to apply the paste over the neck (where enlarged tonsil can be palpated) of the patients.

Research Population

The children affected with *Tundikerika* (Chronic tonsillitis) with age limit of 3 to 12 years attending the outpatient unit of department of *Kaumarabhrithya*, Govt. Ayurveda College Hospital for Women and Children Poojappura, Thiruvananthapuram was the research population of the study. Patients from throughout Trivandrum district are attending the OPD section of department of *Kaumarabhrithya*.

Inclusion Criteria

Children of 3 to 12 years presenting with clinical manifestations of chronic tonsillitis were included in the study**.** As tonsillitis is infrequently occurs in children younger than 2 years children from 3 years were included in the study. Since the children only up to 12 years attend the OPD unit, the maximum age limit kept was twelve years.

Exclusion Criteria

Children suffering from acute tonsillitis, complications like peritonsillar abscess and other systemic illness were excluded from the study.

Time and Duration of the Study

Study was started on October 2011 and completed by March 2013 with the duration of 18 months.

Technique of Data Collection

As per the inclusion criteria, the children suffering from chronic tonsillitis (*Tundikerika*) were thoroughly interrogated; history and facts were noted in a specially designed clinical proforma. It included past illness, physical findings, clinical manifestations, and treatment history.

To ensure sufficient accuracy relevant data were collected by personal observation of salient features and relevant history that included environmental conditions of individuals, their characteristics such as age, sex, dietary habits, treatment or therapeutic procedures and responses of these individuals. The clinical qualitative parameters were graded and their variations were recorded by researcher itself. Quantitative data relating to the routine haematological study were collected from the Laboratory of Govt. Ayurveda College Hospital for women and children Poojappura. Periodical assessment was done at an interval of 10 days.

Treatment Schedule

Children of age group of 3 - 12yrs attending the outpatient unit of *Kaumara-bhritya* department were screened for Chronic Tonsillitis using clinical and laboratory parameters.

An informed consent of parents was obtained before recruiting child into the trial. The subjects were recruited randomly in to two groups for the trial, the Study Group and Control Group; were made identical in all aspects except for the intervention. Both the groups were followed for a period of 1 month after the scheduled course of intervention. Duration of the treatment was 60 days. In the study group as per the recommendations of Acharya Sargadhara the dose of *Varabrihatyadi* decoction was fixed as follows, in the age group 3-6 years: 10ml bd before food**,** in the age group 6-9 years: 20ml bd before food, in the age group 9-12 years: 30ml bd before food. *Sarapunkha Churna* was made into paste by adding *Thriphala* decoction and applied around the neck where enlarged lymph nodes can be palpated. Duration of paste was fixed as two times daily and at each time, it is kept until it becomes dry. At the same time, those in the control group were subjected to external application of *Sarapunkha* paste only. Both the groups were followed for a period of 1 month after the scheduled course of intervention.

Assessment Criteria

Both the groups were assessed before and after the study by observing

1. Graded clinical signs and symptoms
2. Routine blood investigations Hb, T.C, D.C and E.S.R.

Data Analysis

Data were consolidated by using statistical methods. The efficacy of the intervention was evaluated and conclusions were drawn by using statistical tests such as Wilcoxon Signed Ranks Test and Mann Whitney Rank Sum Test.

Trial drug

The combination of *Varabhrihatyadi kashayam* (decoction) for internal use and *Sarapunkha lepam* (paste) was administered in the Study Group. The reference of above mentioned formulations from *Arogyakalpadrumam*, a traditional Ayurvedic Paediatric Textbook. The combination of decoction and paste is mentioned in the treatment of *Apachi*. (a clinical condition similar to chronic

lymphadenitis). Since tonsil is a lymphoid tissue, the above combination is taken in this clinical trial to assess its efficacy in chronic tonsillitis

Collection of Raw Materials

The ingredients of *Varabhrihatyadi* decoction include following drugs.

Amalaki (Emblica officinale), Hareethaki (Terminalia chebula), Vibeethaki (Terminalia bellerica), Bhrihati (Solanum indicum), Nimba (Azadirachta indica), Rajani (Curcuma longa), Vrisha (Adathoda vasica), Daru (Cedrus deodar), Patola (Trichosanthes dioica) and *Sarapunkha (Tephrosa purpurea).*

The root of *Sarapunkha* (*Tephrosia purpurea*) is used for the preparation of paste for the topical application. For making *Sarapunkha* (*Tephrosia purpurea*) paste, the decoction of *Thriphala* is used as the liquid base for soaking and grinding *Sarapunkha* (*Tephrosia purpurea*) powder. *Thriphala* decoction is made by using powder of *Emblica officinale*, *Terminalia chebula* and *Terminalia bellerica* in equal quantity.

The required amount of raw drug is collected from a reputed Ayurvedic raw drug shop at Thiruvananthapuram. The authenticity of these drugs is then approved by the Department of Dravyaguna at Govt. Ayurveda College, Thiruvananthapuram.

Quantity of drugs in Study Group

The below mentioned amount of drugs were used for preparing the medicines in the study group.

Table 1: Drugs for *Varabhrihatyadi* decoction

Sl.No	Drug	Parts used	Quantity
1	*Amalaki* (*Emblica officinale*)	Fruit	2 kg
2	*Hareethaki* (*Terminalia chebula*)	Fruit	2 kg
3	*Vibeethaki* (*Terminalia bellerica*)	Fruit	2 kg
4	*Bhrihati* (*Solanum indicum*)	Root	2 kg
5	*Nimba* (*Azadirachta indica*)	Bark	2 kg
6	*Rajani* (*Curcuma longa*)	Stem	2 kg
7	*Vrisha* (*Adathoda vasica*)	Root	2 kg
8	*Devadaru* (*Cedrus deodar*)	Heart wood	2 kg
9	*Patola* (*Trichosanthes dioica*)	Root	2 kg
10	*Sarapunkha* (*Tephrosa purpurea*)	Root	2 kg

Table 2: Drugs for *Sarapunkha* (*Tephrosia purpurea*) paste

SL No	Drug	Part used	Quantity
1	*Sarapunkha*	Root	3 kg

Table 3: Preparing *Thriphala* decoction (liquid base) for soaking and grinding of *Sarapunkha*

Sl.No	Drug	Part used	Quantity
1.	*Amalaki* (*Emblica officinale*)	Fruit	1 kg
2.	*Hareethaki* (*Terminalia chebula*)	Fruit	1 kg
3.	*Vibeethaki* (*Terminalia bellerica*)	Fruit	1 kg

Method of Preparation of Drugs in Study Group

Preparation of *Varabhrihatyadi* Decoction

The *Varabhrihatyadi* decoction was administered in the form of infusion *(Phanta kashayam).* In order to prepare an infusion, coarse powder of ingredients is required. So all drugs were washed, cleaned and dried in sunlight and then powdered well in a micro pulverizer. Powder was packed in airtight containers. Care takers of patients were requested to prepare an infusion with prescribed quantity of powder and advised to take twice daily before food.

Preparation of *Sarapunkha* Paste

Thriphala decoction was the liquid base for preparing the paste**.** Care takers of patients were requested to prepare *Thriphala* infusion with powdered *Thriphala*. They were requested to soak *Sarapunkha* powder in *Thriphala* decoction overnight and grind well to prepare a paste. They were asked to apply the paste over the neck (where enlarged tonsil can be palpated) of the patients.

The Control Group

The use of placebo may not be always possible due to ethical consideration, so external application of *Sarapunkha* paste over the neck (where enlarged tonsils can be palpated) was taken as the intervention in the control group. The paste is supposed to possess anti-inflammatory property. The paste is mentioned in *Arogyakalpadrumam* in the context of the treatment of *Apachi* for the reduction of enlarged lymph glands.

Method of preparation of drug in Control Group

Care takers of patients were requested to prepare *Thriphala* infusion with powdered *Thriphala*. They were requested to soak *Sarapunkha* powder in

Thriphala decoction overnight and grind well to prepare a paste. They were asked to apply the paste over the neck (where enlarged tonsil can be palpated) of the patients.

Research design

Therapeutic, single blinded, Randomized Controlled Trial.

Sampling

Simple Random sampling was followed in the study. Selected subjects were randomly divided into two groups, Study Group and Control Group by using Table of Random Number.

Sampling Element

Sampling element was children of 3 to 12 years affected with Chronic Tonsillitis.

Sampling Fraction

Children in the age groups 3 to 6 years, 6 to 9 years and 7 to 12 years with clinical features of Chronic Tonsillitis attending the outpatient section of Department of *Kaumarabhritya*, Govt. Ayurveda College, Thiruvananthapuram were the sampling fraction.

Observation Interpretation and Analysis

Demographic data

1. From the above table it is evident that 60% of the subjects were from the age group 7-12 years and 40% were in the age group 3-6 years.
2. Sex wise Distributions showed that among the subjects, 58% were males and 42% were females.
3. The distribution of the subject's religious status was shown in the above table. 80% of the subjects were from Hindu community and the remaining 17% from other two communities
4. The socio economic status of the subjects was shown in the above table. From the above table it is clear that 78% of the subjects were from the middle socio economic status group and 12% from poor socio economics status and 10% from the upper socio economic status.
5. The domicile status of the study revealed that 58% of the subjects were from the urban area and 42% of the subjects were from the rural area. The status of the food consumption is concerned; all subjects were consuming mixed diet.
6. According to the educational status 73% of the subjects were attending above the primary school level and 27% were below primary school level

Clinical picture

1. Over all 65% of the subjects were more than or equal to 3 years duration of the onset of disease, 28% were more than or equal to 2 years of onset of disease and rest of them were having an onset of 1 year or less.
2. Maximum children (48%) were of *Vata kapha prakrithi,* followed by *Pitha kapha prakrithi* (42%) and *Vata pitha prakrithi* (10%).
3. Majority of subjects (48%) had *Mandangi* (poor digestive capacity) rest 37% had *Vishamagni* (inconsistent digestive capacity), 10% had *Teekshana agni* and 5% had *Sama agni.*
4. Distribution according to nutritional status showed that 32% had poor nutritional status, 25% had moderate nutritional status, 43% had adequate nutrition.
5. Distribution according to the type of Chronic Tonsillitis showed that 10% had chronic follicular tonsillitis, 38% had chronic parenchymatous tonsillitis and 52% had chronic fibroid tonsillitis.

Data related to response to treatment

Table 4: Comparison of change in frequency of recurrent attacks of sore throat in subsequent follow-up within the group

Recurring attacks of sore throat	Group	No. of patients	Wilcoxon W value	P value
BT - AT	Study	20	- 124	0.001
	Control	20	-12	0.135
AT - AFU	Study	20	-140	0.001
	Control	20	-12	0.125

The remarkable improvement is statistically significant (p=0.001). However, in the control group there was no significant improvement. From this data, it is clear that the drug was effective in reducing the recurring attack of sore throat and there was sustained action even during follow up.

Table 5: Comparison of change in the frequency of recurrent attacks of sore throat between study and control group

Recurring attacks of sore throat	Group	No. of patients	Median	Mann Whitney T value	P value
AT	Study	20	1	440	0.001
	Control	20	2		
AFU	Study	20	1	470	0.001
	Control	20	3		

In the study group the recurrent attack of the sore throat is showing statistically significant difference (p=0.001) after treatment as well as follow-up period. This implies that the trial drug was very effective in reducing the recurring attack of sore throat than that of the control group and further retained the effect during the follow-up period.

Table 6: Comparison of change in irritation in the throat within the group and subsequent follow-up period

Irritation in the throat	Group	No. of patients	Wilcoxon W value	P value
BT – AT	Study	20	110	0.001
	Control	20	130	0.001
AT – AFU	Study	20	110	0.001
	Control	20	130	0.001

The comparison of the irritation in the throat within the study and control group of patients revealed high significant improvement (p=0.001) after treatment and subsequent follow-up. This indicates that both trial drug and control drug were equally effective in reducing the irritation of throat.

Table 7: Comparison of change in irritation in the throat between study and control groups

Irritation in the throat	Group	No. of patients	Median	Mann Whitney U test	P value
AT	Study	20	1	360	0.569
	Control	20	2		
AFU	Study	20	1	365	0.557
	Control	20	2		

The difference in the median value between the two groups is not great enough to exclude the possibility that the difference is due to random sampling variability. There is no statistical significant difference after treatment as well as after follow-up. This shows that both the treatments were equally effective in reducing irritation of throat.

Table 8: Comparison of change in pain in the throat in subsequent follow-up within the group

Pain in the throat	Group	No. of patients	Wilcoxon W value	P value
BT-AT	Study	20	- 184	0.001
	Control	20	-25	0.115
AT-AFU	Study	20	-184	0.001
	Control	20	-29	0.089

The comparison of the pain in throat in the study group showed that there was significant effect (p=0.001) after the treatment as well as after follow-up. In the control group, this effect was not statistically significant. Thus, it showed that trial drug was very effective in reducing pain

Table 9: Comparison of change in the pain in throat between study and control group

Pain in the throat	Group	No. of patients	Median	Mann Whitney U test	P value
AT	Study	20	0	480	0.001
	Control	20	2		
AFU	Study	20	0	483	0.001
	Control	20	3		

The symptom, pain in the throat is significantly (p=0.001) reducing after treatment as well as follow-up period. This implies that the trial drug was very effective in reducing the pain in the throat than that of the control group and further retained the effect during the follow-up period.

Table 10: Comparison of change in the pain on swallowing in subsequent follow-up within the group

Pain on swallowing	Group	No. of patients	Wilcoxon W value	P value
BT-AT	Study	20	- 110	0.001
	Control	20	-20	0.075
AT-AFU	Study	20	-110	0.001
	Control	20	-20	0.075

Wilcoxon Signed Rank test showed that there is highly significant change in the pain on swallowing in the study group (p<0.001) whereas in the control group change is not significant. This proved that the efficacy of the trial drug given to the study group is reducing the symptom. This effect was sustained during the follow up period.

Table 11: Comparison of change in the pain on swallowing between study and control group

Pain on swallowing	Group	No. of patients	Median	Mann Whitney U test	P value
AT	Study	20	0	420	0.005
	Control	20	2		
AFU	Study	20	0	431	0.003
	Control	20	1		

The pain on swallowing is significantly reduced (p=0.005) after treatment. In the follow up period this effect was sustained (p=0.003). This implies that the trial drug was very effective in reducing the pain on swallowing than that of the control drug and further the effect was prolonged in the follow-up period.

Table 12: Comparison of change in the difficulty in swallowing on subsequent follow-up within the group

Difficulty in swallowing	Group	No. of patients	Wilcoxon W value	P value
BT-AT	Study	20	- 126	0.001
	Control	20	-15	0.093
AT-AFU	Study	20	-126	0.001
	Control	20	-15	0.076

The comparison of the difficulty in swallowing showed that there was remarkably reducing the difficulty in swallowing in the study group after the treatment as well as after the follow-up. This remarkable improvement is statistically significant (p=0.001). However, in the control group there was no significant improvement. From this data, it is clear that the drug was effective in reducing the difficulty in swallowing and these improvements has sustained effect during follow up.

Table 13: Comparison of change in the difficulty in swallowing between study and control groups

Difficulty in swallowing	Group	No. of patients	Median	Mann Whitney U test	P value
AT	Study	20	0		
	Control	20	2		
AFU	Study	20	0		
	Control	20	3		

The difference in the median values between the groups is greater than would expect by chance; there is a statistically significant difference. Thus, the study drug was too effective in reducing difficulty in swallowing than the control group.

Table 14: Comparison of change in the foul breath within group and on subsequent follow-up

Foul Breath	Group	No. Of patients	Wilcoxon W value	P value
BT-AT	Study	20	- 124	0.001
	Control	20	-12	0.135
AT-AFU	Study	20	-130	0.001
	Control	20	-11	0.125

The comparison of the foul breath before treatment and after the treatment showed that there was remarkable improvement in the study group and it sustained after follow-up. This remarkable improvement is statistically significant (p=0.001). However, in the control group there was no significant improvement. From this data, it is clear that the drug was effective in reducing the foul breath and these improvements have sustained effect during follow up.

Table 15: Comparison of change in the foul breath between study and control group

Foul Breath	Group	No. Of patients	Median	Mann Whitney U test	P value
AT	Study	20	1	405	0.001
	Control	20	2		
AFU	Study	20	1	401	0.001
	Control	20	3		

Between group comparison the foul breath significantly reduced (p=0.001) both after treatment as well as follow-up period. Thus, the study drug was too effective in reducing foul breath in the study group than the control group.

Table 16: Comparison of change in the malaise on subsequent follow-up within group

Malaise	Group	No. Of patients	Wilcoxon W value	P value
BT-AT	Study	20	- 73	0.001
	Control	20	-20	0.108
AT-AFU	Study	20	-73	0.001
	Control	20	-20	0.110

The remarkable improvement is statistically significant (p=0.001).But in the control group there was no significant improvement. From this data it is clear that the drug was effective in reducing the malaise and there was sustained action even during follow up.

Table 17: Comparison of change in the malaise between study and control group

Malaise	Group	No. Of patients	Median	Mann Whitney U test	P value
AT	Study	20	1	405	0.058
	Control	20	1		
AFU	Study	20	1	413	0.043
	Control	20	2		

The malaise is significantly reduced (p=0.043) in the follow-up period but immediately after treatment the difference was not significant, difference was due to random sampling, (p=0.58).

Table 18: Comparison of change in the mouth breathing on subsequent follow-up within group

Mouth breathing	Group	No. of patients	Wilcoxon W value	P value
BT-AT	Study	20	- 30	0.001
	Control	20	-10	0.216
AT-AFU	Study	20	-43	0.001
	Control	20	-11	0.325

This remarkable reduction is statistically significant (p=0.001). However, in the control group there was no significant improvement. This implies that the drug was effective in reducing the mouth breathing and there was sustained action even during follow up.

Table 19: Comparison of mouth breathing between study and control group

Mouth breathing	Group	No. Of patients	Median	Mann Whitney U test	P value
AT	Study	20	2	405	0.002
	Control	20	2		
AFU	Study	20	1	395	0.003
	Control	20	2		

The difference in the median values between the groups is greater than would expected by chance; there is a statistically significant difference implies that the trial drug was very effective in reducing the mouth breathing than that of the control group and further retained the effect during the follow-up period.

Table 20: Comparison of change in the cough on subsequent follow-up within the group

Cough	Group	No. Of patients	Wilcoxon W value	P value
BT-AT	Study	20	- 144	0.001
	Control	20	-120	0.001
AT-AFU	Study	20	-153	0.001
	Control	20	-131	0.001

The remarkable improvement is statistically significant (p=0.001). In the control group there was also statistically significant reduction of cough (p=0.001).

Table 21: Comparison of change in the cough between study and control group

Cough	Group	No. Of patients	Median	Mann Whitney U test	P value
AT	Study	20	1	365	0.101
	Control	20	1		
AFU	Study	20	1	360	0.095
	Control	20	1		

The median value difference between two groups is due to the possibility of random sampling variability. The difference was not statistically significant. This implies that both the treatment were equally effective in reducing the cough.

Table 22: Comparison of change in the hoarseness of voice on subsequent follow-up within group

Hoarseness of voice	Group	No. Of patients	Wilcoxon W value	P value
BT-AT	Study	20	- 68	0.001
	Control	20	-10	0.143
AT-AFU	Study	20	-130	0.001
	Control	20	-18	0.139

The comparison of hoarseness of voice showed that there was remarkable improvement in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.001). However, in the control group there was no significant improvement. From this data, it is clear that the drug was effective in reducing the hoarseness of voice and there was sustained effect in the follow up period.

Table 23: Comparison of change in hoarseness of voice between study and control group

Hoarseness of voice	Group	No. of patients	Median	Mann Whitney U test	P value
AT	Study	20	0	410	0.029
	Control	20	1		
AFU	Study	20	0	398	0.040
	Control	20	1		

The difference in the median values between the groups is greater than would expected by chance; there is a statistically significant difference implies that the trial drug was very effective in reducing the hoarseness of voice than that of the control group and further retained the effect during the follow-up period.

Table 24: Comparison of change in the choking spells at night on subsequent follow-up within group

Choking spells at night	Group	No. of patients	Wilcoxon W value	P value
BT-AT	Study	20	- 52	0.005
	Control	20	-10	0.631
AT-AFU	Study	20	-52	0.005
	Control	20	-10	0.631

The comparison of choking spells at night, which was a major symptom, showed that there was remarkable improvement in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.005). However, in the control group there was no significant improvement. From this data, it is clear that the drug was effective in reducing the choking spells at night and there was sustained action even during follow up.

Table 25: Comparison of choking spells at night between study and control group

Choking spells at night	Group	No. of patients	Median	Mann Whitney U test	P value
AT	Study	20	0	356	0.009
	Control	20	1		
AFU	Study	20	0	356	0.009
	Control	20	1		

The choking spells at night is statistically significant (p=0.009) both after treatment as well as follow-up period. This implies that the trial drug was very effective in reducing the choking spells at night than that of the control group and further retained the effect during the follow-up period.

Table 26: Comparison of change towards reduction in the size of tonsils on subsequent follow-up within group

Size of tonsils	Group	No. of patients	Wilcoxon W value	P value
BT-AT	Study	20	- 25	0.031
	Control	20	-5	0.935
AT-AFU	Study	20	-38	0.006
	Control	20	-5	0.956

The comparison of size of tonsils showed that there was remarkable reduction of the sign in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.031). However, in the control group there was no significant improvement. From this data, it is clear that the drug was effective in reducing the size of tonsils in trial group and there was sustained action even during the follow

Table 27: Comparison of change towards reduction in the size of tonsils between study and control group

Size of tonsils	Group	No. of patients	Median	Mann Whitney U test	P value
AT	Study	20	0	398	0.009
	Control	20	1		
AFU	Study	20	0	425	0.005
	Control	20	2		

The difference in the median values between the groups is greater than would expected by chance; there is a statistically significant difference, this implies that the trial drug was very effective in reducing the size of tonsils than that of the control group and further retained the effect during the follow-up period.

Table 28: Comparison of yellowish beads of pus from crypts on subsequent follow-up within group

Yellowish beads of pus from crypts	Group	No. of patients	Wilcoxon W value	P value
BT-AT	Study	20	- 135	0.003
	Control	20	-143	0.004
AT-AFU	Study	20	-131	0.002
	Control	20	-123	0.005

The comparison of yellowish beads of pus from crypts showed that there was remarkable improvement in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.003). In the control group there was also significant improvement (P=0.004and p=0.005). From this data, it is clear that the drug and control drugs were effective in reducing yellowish beads of pus from crypts.

Table 29: Comparison of yellowish beads of pus from crypts between study and control group

Yellowish beads of pus from crypts	Group	No. of patients	Median	Mann Whitney U test	P value
AT	Study	20	2	410	0.001
	Control	20	2		
AFU	Study	20	2	405	0.002
	Control	20	2		

The difference in the median values between the groups is greater than would expect by chance; there is a statistically significant difference, even though the control drug is effective in reducing the symptom, trial drug was more effective in reducing the yellowish beads of pus from crypts of tonsils than that of the control drug and further retained the effect during the follow-up period.

Table 30: Comparison of change in the congestion of pillars on subsequent follow-up within group

Congestion of pillars	Group	No. of patients	Wilcoxon W value	P value
BT-AT	Study	20	- 139	0.001
	Control	20	-20	0.076
AT-AFU	Study	20	-160	0.001
	Control	20	-20	0.076

The comparison of congestion of pillars showed that there was remarkable reduction of the sign in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.001). However, in the control group there was no significant improvement. From this data, it is clear that the drug was effective in congestion of pillars and there was sustained action even during follow up.

Table 31: Comparison of change in the congestion of pillars between study and control group

Congestion of pillars	Group	No. of patients	Median	Mann Whitney U test	P value
AT	Study	20	0	450	0.001
	Control	20	1		
AFU	Study	20	0	425	0.001
	Control	20	1		

The difference in the median values between the groups is greater than would expect by chance; there is a statistically significant difference. This implies that the trial drug was very effective in reducing the congestion of pillars than that of the control group and further retained the effect during the follow-up period.

Table 32: Comparison of change in the redness of soft palate on subsequent follow-up within group

Redness of soft palate	Group	No. of patients	Wilcoxon W value	P value
BT-AT	Study	20	- 24	0.031
	Control	20	-12	0.235
AT-AFU	Study	20	-24	0.031
	Control	20	-12	0.235

The comparison of redness of soft palate, which was a major clinical sign, showed that there was remarkable reduction of the sign in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.031). However, in the control group there was no significant improvement. From this data, it is clear that the drug was effective in reducing the redness of soft palate and there was sustained action even during follow up.

Table 33: Comparison of change in the redness of soft palate between study and control group

Redness of soft palate	Group	No. of patients	Median	Mann Whitney U test	P value
AT	Study	20	2	342	0.589
	Control	20	3		
AFU	Study	20	2	364	0.613
	Control	20	3		

The difference in the median value between the two groups is not great enough to exclude the possibility that the difference is due to random sampling variability. There is no statistical significant difference after treatment as well as after follow-up.

Table 34: Comparison of change in the oedema of the uvula on subsequent follow-up within group

Oedema of the uvula	Group	No. of patients	Wilcoxon W value	P value
BT-AT	Study	20	- 100	0.001
	Control	20	-12	0.122
AT-AFU	Study	20	-133	0.001
	Control	20	-12	0.135

The comparison of oedema of the uvula, which was a major clinical sign, showed that there was remarkable improvement reduction of the sign in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.001). However, in the control group there was no significant improvement. From this data, it is clear that the drug was effective in reducing the oedema of the uvula and there was sustained action even during follow up.

Table 35: Comparison of change in the oedema of the uvula between study and control group

Oedema of the uvula	Group	No. of patients	Median	Mann Whitney U test	P value
AT	Study	20	0	425	0.001
	Control	20	1		
AFU	Study	20	0	433	0.001
	Control	20	1		

The difference in the median values between the groups is greater than would expect by chance; there is a statistically significant difference. This implies that the trial drug was very effective in reducing the oedema of the uvula attacks than that of the control group and further retained the effect during the follow-up period.

Table 36: Comparison of change in the deviation of the uvula on subsequent follow-up within group

Deviation of the uvula	Group	No. pf patients	Wilcoxon W value	P value
BT-AT	Study	20	- 98	0.001
	Control	20	-14	0.128
AT-AFU	Study	20	-100	0.001
	Control	20	-18	0.105

The comparison of deviation of the uvula, which was a major symptom, showed that there was remarkable improvement in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.001). However, in the control group there was no significant improvement. From this data, it is clear that the drug was effective in reducing the attack of sore throat and there was sustained action even during follow up.

Table 37: Comparison of change in the deviation of the uvula between study and control group

Deviation of the uvula	Group	No. of patients	Median	Mann Whitney U test	P value
AT	Study	20	0	410	0.001
	Control	20	1		
AFU	Study	20	0	415	0.001
	Control	20	1		

The difference in the median values between the groups is greater than would expect by chance; there is a statistically significant difference. This implies that the trial drug was very effective in reducing the deviation of the uvula attacks than that of the control group and further retained the effect during the follow-up period.

Table 38: Comparison of lymph node enlargement on subsequent follow-up within group

Lymph node enlargement	Group	No. of patients	Wilcox on W value	P value
BT-AT	Study	20	- 55	0.005
	Control	20	-5	0.500
AT-AFU	Study	20	-55	0.002
	Control	20	-5	0.500

The comparison of lymph node enlargement, which was a major clinical sign, showed that there was remarkable improvement in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.002). However, in the control group there was no significant improvement. From this data, it is clear that the drug was effective in reducing the lymph node enlargement and there was sustained action even during follow up.

Table 39: Comparison of lymph node enlargement between study and control group

lymph node enlargement	Group	No. of patients	Median	Mann Whitney U test	P value
AT	Study	20	0	410	0.004
	Control	20	1		
AFU	Study	20	0	410	0.004
	Control	20	1		

The difference in the median values between the groups is greater than would expect by chance; there is a statistically significant difference. This implies that the trial drug was very effective in reducing the lymph node enlargement than that of the control group and further retained the effect during the follow-up period.

Table 40: Comparison of mean difference in the haemoglobin concentration between study group and control group

Haemoglobin Concentration	Mean Difference	SD	t-value	P-value
Study Group	1.47	0.65	3.89	0.004
Control Group	0.46	0.35		

From the above table it is clear that the comparison between before and after treatment between two groups, the haemoglobin concentration in study group has remarkably increasing than that of the control group. This mean difference is statistically significant (p=0.004).

Table 41: Comparison of mean difference in the Lymphocytes count between study group and control group

Lymphocyte Count	Mean Difference	SD	t-value	P-value
Study Group	4.63	2.03	3.49	0.014
Control Group	1.85	1.68		

From the above table it is clear that the comparison between before and after treatment between two groups, the lymphocytes count in study group has remarkably decreasing than that of the control group. This mean difference is statistically significant (p=0.014).

Table 42: Comparison of mean difference in the E.S.R between study group and control group

E.S.R	Mean Difference	SD	t-value	P-value
Study Group	8.54	3.21	4.29	0.001
Control Group	0.37	1.07		

From the above table it is clear that the comparison between mean difference in before and after treatment between two groups, the E.S.R level in study group has remarkably decreasing than that of the control group. This mean difference is statistically significant (p=0.001).

DISCUSSION

Tonsillitis is an infection of the tonsils. Tonsillitis is an extremely common in children and young people but it can occur at any age. The pathogenesis of infectious or inflammatory disease in the tonsils most likely has its basis in their anatomic location and their inherent function as organ of immunity, processing infectious material, and other antigens and then becoming, ironically, a focus of infection or inflammation. No single theory of pathogenesis has yet been accepted, however viral infection with secondary bacterial invasion may be one mechanism of the initiation of chronic disease, but the effects of the environment, host factors, and the widespread use of antibiotics, ecological considerations, and diet all may play a role. Tonsillitis most often occurs in children; however, the condition rarely occurs in children younger than 2 years. Acute tonsillitis is a common condition often seen in children aged 5–10 and young adults aged 15–25. As such; a risk factor for tonsillitis is simply being at a young age. In addition, children attend school and while they are at school, they are in close contact with other children. They have frequent exposure to bacterial and viral infections, which can result in tonsillitis.

Combination of *Varabhrihatyadi Kashayam and Sarapunkha lepam* is mentioned in the context of treatment of *Apachi* (a clinical condition similar to chronic lymphadenitis) in *Arogyakalpadrumam,* a traditional Ayurvedic pediatric text book. Though the drug is not directly indicated for *Chronic Tonsillitis,* it is taken as trial drug because tonsils are also in lymphoid origin.

Due to indulging in prescribed aetiological factors *Kapha and Pitha Dosha* will get vitiated and thus vitiated *Doshas* circulates in *Siras* (*Prasara*) and get localised (*Sthanasamshraya*) around throat. This will results in the manifestation of *Tundikeri*. *Agnimandya* (suppression of digestive system) and *Ama* (morbid substances) formation being basic pathology of all diseases, these factors definitely present in the manifestation of *Tundikeri.* The *Varabhrihthyadi Kashaya* having following drugs *Amalaki* (*Emblica officinale*), *Hareethaki* (*Terminalia chebula*), *Vibeethaki* (*Terminalia bellerica*), *Bhrihati* (*Solanum indicum*), *Nimba* (*Azadirachta indica*), *Rajani* (*Curcuma longa*), *Vrisha* (*Adathoda vasica*), *Devadaru* (*Cedrus deodar*), *Patola* (*Trichosanthes dioica*) and *Sarapunkha* (*Tephrosa purpurea*).

Hareetaki Vibhithaki and *Amalaki* are having *Pachana* (digestive), *Deepana* (carminative) and *Anulomana* (laxative) properties. *Vibhithaki and Hareethaki* are having *Kapha* and *Pitha* alleviating properties. *Amalaki* is having the potency to alleviate all *Doshas* with *Kapha* and *Pitha* predominance *Bhrihathi, Sarapunkha* and *Devadaru* are having *Pachana* (digestive) *Muthrala* (diuretic), *Sodhahara (*anti inflammatory) properties. *Amalaki* and *Hareethaki* are having *Rasayana* (rejuvinative) and *Balya* (immunomodulatory) actions. *Nimba, Rajani Patola* and *Vrisha* are having *Pachana* (digestive), *Deepana* (carminative) antimicrobial (*Boothakhna*) and immunomodulory actions *(Balya).* Topical application of *Sarapunkha* provides anti inflammatory effect.

At a glimpse the total potential of the study formulation can be attributed to following headings:

- *Hareetaki Vibhithaki* and *Amalaki, Rajani, Nimba, Patola* and *Vrisha* are having *Pachana* (digestive) and *Deepana* (carminative) properties. Thus they have the potency to promote digestive system and have the capacity to eliminate the morbid substance (*Ama*).
- *Hareetaki Vibhithaki* and *Amalaki, Rajani, Nimba, Sarapunkha* and *Patola* are having a cumulative effect on alleviating the vitiated *Kapha* and *Pitha Doshas*. Thus controlling infection and inflammatory process in chronic tonsillitis.
- *Rajani, Nimba* and *Vrisha Amalaki, Hareethaki* and *Vibeethaki* are having immunomodulatory action. Thus preventing recurrence of infection.
- *Sarapunkha* is having anti-inflammatory property when it is used as a topical application. In this trial *Varabhrihatyadi kashaya* is providing internal purification and immunomodulatory action and *Sarapunkha lepa* is providing supportive local anti inflammatory action.

Overall, this combination has controlled infection, reduced inflammation, and recurrence of chronic tonsillitis.

The comparison of frequency of the recurrent attacks of sore throat, which was a major symptom, showed that there was remarkable improvement in the study group after the treatment as well as after the follow-up. This remarkable improvement is statistically significant (p=0.001). However, in the control group there was no significant improvement.. This implies that the trial drug was very effective in reducing the recurrence of sore throat than that of the control group and further retained the effect during the follow-up period.

The comparison of the irritation in the throat within the study and control group of patients revealed highly significant improvement (p=0.001) after treatment and subsequent follow-up. However, the difference in the median value between the two groups is not great enough to exclude the possibility that the difference is due to random sampling variability. There is no statistical significant difference after treatment as well as after follow-up. This shows that both the treatments were equally effective in reducing irritation of throat.

The comparison of the pain in throat in the study group showed that there was significant effect (p=0.001) after the treatment as well as after follow-up. In the control group, this effect was not statistically significant. Thus, it proved that trial drug was very effective in reducing the pain. There was statistically significant difference in the median values between the groups.

There was significant reduction in the difficulty in swallowing in the study group ($p < 0.001$) whereas in control group there was no change. Comparison of two groups showed that the difference in the median values between the groups is greater than would expected by chance; there is a statistically significant difference. Thus, the study drug was too effective in reducing difficulty in swallowing than the control group.

Comparison of the symptom malaise showed that there was remarkable improvement in the study group after the treatment as well as after the follow-up. This remarkable improvement is statistically significant (p=0.001). But in the control group there was no significant improvement. Between the group analysis highlighted that the malaise is significantly reduced (p=0.043) in the follow-up period but immediate after treatment the difference was not significant, so difference was due to random sampling (p=0.58).

Comparison of the symptom mouth breathing showed that there was a reduction in the symptom in the study group after the treatment as well as after follow-up. This remarkable reduction is statistically significant (p=0.001). However, in the control group there was no significant improvement. Between the two-group analysis, the difference in the median values between the groups is greater than would expected by chance; there is a statistically significant difference implies that the trial drug was very effective in reducing the mouth breathing than that of the control drug and further retained the effect during the follow-up period.

The comparison of change in the cough showed that there was remarkable reduction of the symptom in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.001). In the control group there was also statistically significant reduction of cough (p=0.001). However, the difference in the median value between the two groups is not great enough to exclude the possibility that the difference is due to random sampling variability. There is no statistical significant difference after treatment as well as after follow-up (p=0101, p=0.095). This shows that both the treatments were equally effective in reducing irritation of throat. This effect in the control group may be due to combined effect of interventional drug and general instruction followed by control group.

The comparison of hoarseness of voice showed that there was remarkable improvement in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.001). However, in the control group there was no significant improvement. Between the two group analysis, the difference in the median values between the groups is greater than would expected by chance; there is a statistically significant difference, implies that the trial drug was very effective in reducing the hoarseness of voice than that of the control drug and further retained the effect during the follow-up period.

The comparison of choking spells at night, which was a major symptom, showed that there was remarkable improvement in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.005). However, in the control group there was no significant improvement. Between the two group analysis, the choking spells at night is statistically significant (p=0.009) both after treatment as well as follow-up period. This implies that the trial drug was very effective in reducing the choking spells at night than that of the control group and further retained the effect during the follow-up period.

The comparison of size of tonsils showed that there was remarkable improvement in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.031). But in the control group there was no significant improvement. Between the group analysis clarified that the difference in the median values between the groups is greater than would expected by chance; there is a statistically significant difference, this implies that the trial drug was very effective in reducing the size of tonsils than that of the control group and further retained the effect during the follow-up period.

The comparison of yellowish beads of pus from crypts showed that there was remarkable

improvement in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.003). In the control group there was also significant improvement (P=.004). The difference in the median values between the groups is greater than would expected by chance; there is a statistically significant difference, this implies that even though the control trial is effective in reducing the symptom trial drug was more effective in reducing the yellowish beads from the crypts than that of the control group and further retained the effect during the follow-up period.

The comparison of congestion of pillars showed that there was remarkable improvement in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.001). However, in the control group there was no significant improvement. Between the two groups analysis showed that, there is statistically significant difference between two groups in reducing the symptoms, which implies superiority of the trial drug over the control.

The comparison of redness of soft palate, which was a major clinical sign, showed that there was remarkable improvement in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.031). However, in the control group there was no significant improvement. Between the two-group analyses, the redness of soft palate was not statistically significant between trial drug group and control group. There is no statistical significant difference after treatment as well as after follow-up. (p=0.589and p=0.613). This shows that both the treatments were equally effective in reducing redness of soft palate.

The comparison of oedema of the uvula, which was a major clinical sign, showed that there was remarkable improvement in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.001). Nevertheless, in the control group there was no significant improvement. Between the two-group analyses, the difference in the median values between the groups is greater than would expect by chance; there is a statistically significant difference. This implies that the trial drug was very effective in reducing the oedema of the uvula attacks than that of the control group and further retained the effect during the follow-up period.

The comparison of deviation of the uvula, which was a major sign, showed that there was remarkable improvement in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.001). However, in the control group there was no significant improvement. Between the two-group analyses, the difference in the median values between the groups is greater than would expect by chance; there is a statistically significant difference. This implies that the trial drug was very effective in reducing the deviation of the uvula attacks than that of the control group and further retained the effect during the follow-up period.

The comparison of lymph node enlargement, which was a major clinical sign, showed that there was remarkable improvement in the study group after the treatment as well as after follow-up. This remarkable improvement is statistically significant (p=0.002). However, in the control group there was no significant improvement. Between the two group analysis the difference in the median values between the groups is greater than would expected by chance; there is a statistically significant difference. This implies that the trial drug was very effective in reducing the lymph node enlargement than that of the control group and further retained the effect during the follow-up period.

In total, the trial drug was effective in reducing recurrent attacks of sore throat, irritation in the throat, pain in the throat, pain on swallowing, difficulty in swallowing, malaise, mouth breathing, halitosis, cough, hoarseness of voice, choking spells at night, size of the tonsil, congestion of pillars, oedema of the uvula, deviation of the uvula, redness of soft palate, lymph node enlargement, yellowish pus from crypts.

However, in the control group there was no significant change over the symptoms like recurrent attacks of sore throat, pain in the throat, pain on swallowing, difficulty in swallowing, malaise, mouth breathing, halitosis, hoarseness of voice, choking spells at night, size of the tonsil, congestion of pillars, oedema of the uvula, deviation of the uvula, and lymph node enlargement.

Both study drug and control drug were equally effective in reducing the following symptoms i.e. irritation of the throat, cough and redness in the soft palate. This may be due to the combined effect of interventional drug strict diet restriction and regiments followed by control group. It all can also be attributed to sampling variations.

The control drug was effective in reducing the yellowish beads of pus from crypts but between the group evaluations showed that study drug was much more effective than the control drug. This effect in control group may be due to strict diet restriction and regiments followed by the control group.

The comparison between before and after treatment of haemoglobin between two groups showed that, the haemoglobin concentration in study group has remarkably increased than that of the control group. This mean difference is statistically significant (p=0.004). This effect is maintained during the follow up period also. Control of the infection may have raised the haemoglobin concentration, due to enhanced general health status.

Evaluation of the change in the Lymphocyte count before and after treatment between two groups reveals that, the lymphocytes count in study group has remarkably decreasing than that of the control group. This mean difference is statistically significant (p=0.014). Lymphocyte count is usually elevated in gram-positive pus forming bacterial infections. Statistically significant reduction of lymphocyte count implied the control of the infection. The comparison between before and after treatment between two groups, the lymphocytes count in study group has remarkably decreasing than that of the control group. This mean difference is statistically significant (p=0.014).

The comparison between mean difference of E.S.R before and after treatment between two groups showed that the E.S.R level in study group has remarkably decreased than that of the control group. This mean difference is statistically significant (p=0.001). E.S.R value will be elevated during an infection and reduction of E.S.R indicates control of infection

CONCLUSION

1) Combination of *Varabhrihatyadi Kashaya* and *Sarapunkha Lepa* is effective in reducing the majority of signs and symptoms of Chronic Tonsillitis.
2) Combination of *Varabhrihatyadi Kashaya* and *Sarapunkha Lepa* is effective `in reducing the number of attacks of Chronic Tonsillitis.
3) Topical application of *Sarapunkha* has provided additional anti-inflammatory effect.
4) Combination of *Varabhrihatyadi Kashaya* and *Sarapunkha Lepa* has provided sustained effect.
5) The alternate hypothesis, combination of *Varabhrihatyadi Kashaya* and *Sarapunkha Lepa* is effective in reducing the signs and symptoms of Chronic Tonsillitis in children" was accepted.

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