IAMJ

INTERNATIONAL AYURVEDIC MEDICAL JOURNAL

Research Article ISSN: 2320-5091 Impact Factor: 6.719

AN OPEN LABEL CLINICAL TRIAL OF KANCHNAR SYRUP IN TUNDIKERI (TONSILLITIS)

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https://doi.org/10.46607/iamj0311082023

(Published Online: August 2023)

Article Received: 03/07/2023 - **Peer Reviewed:** 25/07/2023 - **Accepted for Publication:** 10/08/2023.

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ABSTRACT

AIM: To determine the efficacy of *Kanchnar syrup* in *Tundikeri roga* (tonsillitis) in children. **OBJECTIVE** To determine the efficacy of *Kanchnar* syrup on graded subjective and objective parameters of *Tundikeri roga* (tonsillitis) in children. **Study Design**: Open label, Single arm clinical trial. **Material and Methods**: The study was conducted on 40 children of *Tundikeri* for a period of 45 days. Subjective parameters *Toda* (Pricking pain), *Daah* (Burning sensation), *Galoprodha* (Dysphagia), *Mukha daurgandhya* (Halitosis), Sore throat, *Jwara* (Fever), *Swara bheda* (Hoarseness of voice), *Kasa* (Cough), *Kathin shopha* (Inflammation), *Lasika granthi vriddhi* (Enlarged jugulodigastric lymph nodes) and lab parameters Hb%, TLC, DLC, ESR were documented before and after the completion of treatment. **Statistical Analysis used**: Observations of the study were analysed, and findings were evaluated using Statistical technique. The tests adopted were-Wilcoxon Signed Rank test, Paired t-test using SPSS software. **Results:** Overall assessment of drug was done for subjective and objective parameters based on the significance of statistical test. Marked improvement was observed in 40% patients, moderate improvement in 22.5% patients, mild improvement in 30% patients and no change was seen in 7.5% patients. Maximum effect was seen in *Toda* and least effect was seen in *Kasa* and *Lasika granthi vriddhi*. **Conclusion:** It can be concluded that there is significant effect of *Kanchnar* syrup on sign and symptoms of *Tundikeri* with no side effects observed.

Keywords: *Kanchnar* syrup, *Tundikeri roga*, management of *Tundikeri* by *Ayurveda*, tonsillitis

INTRODUCTION

Any infection in a growing child usually hampers the immune system, growth and development. Childhood phase is prone to have various infections especially upper respiratory tract infections. One such big enemy endangering especially children is Tonsillitis. Tonsils are the immune system's first line of defence against bacteria and viruses that enter our mouth. This function makes the tonsils particularly vulnerable to infection and inflammation. Tonsillitis is one of the most prevalent infectious diseases in the paediatric age group. It is amongst the recurrent infections of upper respiratory tract. According to WHO, infectious diseases are caused by pathogenic microorganisms such as bacteria, viruses, parasites or fungi. These diseases spread directly or indirectly, from one person to another. Tonsillitis is very common in developing countries like India because of low economic status, lack of awareness, poor hygiene, faulty dietary habits like cold beverages or spicy food, poor immunity and sanitary conditions. These factors grouped together result in recurrent episodes of the disease. Tonsillitis is a commonly occurring infectious disease in the paediatric age group which exerts an untoward effect on the entire growth, development and psychology of the child. In *Ayurveda* clinical presentation of *Tundikeri* is similar to tonsillitis. It is described under *Mukha Roga*. Description of *Tundikeri* is found in *Sushrut Samhita*,[1] *Ashtang Hridya*, *Yogratnakar*, *Madhav nidan* and *Bhavprakash*. *Acharya Sushrut* first described *Tundikeri* disease under *Mukh rogas*. Dealing with the treatment modern medicine provides symptomatic relief but does not check the recurrence as well as chronicity of the disease and also has side effects. Moreover, chronic conditions are often treated by tonsillectomy when child stops responding to medicine and in obligatory conditions, which puts a straightforward attack on respiratory and gastrointestinal tract. So, we suggested a safe and effective remedy which not only relieve the symptoms but also increase wellbeing. *Kanchnar* is best suitable for children suffering from tonsillitis due to its *Shotha har, Lekhan, Gandmalanashak, Lasika Granthi Vriddhi har* properties.[2] The present study was carried out to evaluate the efficacy of an *Ayurvedic* formulation *Kanchnar* syrup by assessing subjective and objective parameters.

MATERIAL AND METHODS

Study design- open-label, single arm clinical trial, **Sampling Criterion**- patients having clinical features like *Toda* (Pricking pain), *Daah* (Burning sensation), *Galoprodha* (Dysphagia), *Mukha daurgandhya* (Halitosis), Sore throat, *Jwara* (Fever), *Swara bheda* (Hoarseness of voice), *Kasa* (Cough), *Kathin shopha* (Inflammation), *Lasika granthi vriddhi* (Enlarged jugulodigastric lymph nodes) were selected and lab parameters were Hb%, TLC, DLC, and ESR.

(A) Inclusion Criteria -Patients between the age group of 3-12 years irrespective of gender, Primarily the patients were selected on the basis of the presence of classical symptomatology of *Tundikeri roga*, only chronic tonsillitis was included with 3-4 recurrent attacks in a year.

(B) Exclusion Criteria- Acute tonsillitis**,** children below 3 years or above 12 years**,** Patients having breathing problems, fever more than 102º F, known cases of associated cardiac complaints, malignancy, TB, diabetes, otitis media, peritonsillar abscess, para pharyngeal abscess, tonsillar cyst, tonsilloliths, choking spells, infection that spreads deep into surrounding tissues**,** Patients wo were not willing to be registered for the trial.

(C) Discontinuation Criteria- Adverse drug reaction, patient not willing to continue, appearance of any severe complication, any other severe acute illness, leave against medical advice. The study was done with single drug "*Kanchnar twak*" due to its *Shothahar, Vranashodhaka, Vrana ropaka, Kapha Pitta nashak, Lasika granthi shotha nashak* properties. The drug was modified into syrup form to make administration easy for children. *Kanchnar* syrup was taken as a trial drug for the research study.

Ethical Clearance- Ethical clearance was obtained from Institutional Ethics Committee prior to patient's enrolment vide letter no. UAU/GC/IEC/2021/5.

CTRI- The trial was registered in the clinical trial registry of India before commencement of patient enrolment. Registration number for the trial was CTRI/2021/05/033386.

Procurement of the Drug- Trial drug was manufactured from a GMP Certified Ayurveda pharmacy (Han's pharmacy Sidcul, Haridwar) Ref. no.- 02/HHPL/2022. It was prepared in syrup form in order to enhance its palatability for children.

Method of Treatment /Intervention-

Kanchnar syrup was prepared from *Kanchnar Twak* and *Guda*

Preparation medicine- 16 Kg of *Kanchnar twak* was pounded to coarse powder (*Yavkuta*) form and then soaked overnight in eight parts of water (128 litre). On next day, this mixture was heated on medium flame in stainless steel vessel till the quantity of liquid was reduced to one fourth (32litre) of the total and then filtered. To this filtered *Kwatha* (32 litre), 40 kg of powdered jaggery was added and stirred till it got dissolved completely, then the whole mixture was heated again on low flame until the solution became thick and attained one thread consistency. Then for better shelf-life class II preservative i.e., KMS (Potassium metabisulfite)

was added to the syrup at the rate of 0.3% w/v. In this way a total amount of 54 litre syrup was obtained.

Storage of medicine- After cooling, the syrup was packed in 200 ml and 100 ml sterile airtight bottles, cap sealed and labelled.

Dose of Medicine: For 3-5 years 5 ml, for 6-9 years 7.5ml and for 10-12 years 10 ml thrice daily.

Route of Administration- Oral

Standardization of *Kanchnar* Syrup- The drug was manufactured from a GMP Certified Ayurveda pharmacy (Han's pharmacy Sidcul, Haridwar). Ref. no.- 02/HHPL/2022 on Date- 27/5/2021.

(J) **PRIMARY ENDPOINT**-Improvement in signs and symptoms of *Tundikeri* as mentioned in *Ayurvedic* classical texts.

(K) **SECONDARY ENDPOINT** -Improvement in the haematological parameters Hb%, TLC, DLC, ESR.

Level of Study -OPD / IPD level

Period of Study-2 years

Duration of trial- 45 days

Follow-Up- The assessment of patients was done at-

At registration (R)

At 15th day, 30th day and 45th day

Two Follow up were taken-

15th day after completion of study

45th day after completion of the study

Assessment Criteria- The assessment of trial was done on the basis of following parameters: - 1. Subjective parameters 2. Objective parameters.

Subjective parameters– It included assessment of clinical features of *Tundikeri roga* as described in *Ayurveda* and modern texts as- *Toda* (Pricking pain), *Daah* (Burning sensation), *Galoprodha* (Dysphagia), *Mukha daurgandhya* (Halitosis), Sore throat, *Jwara* (Fever), *Swara bheda* (Hoarseness of voice), *Kasa* (Cough), *Kathin shopha* (Inflammation), *Lasika granthi vriddhi* (Enlarged Jugulo digastric lymph nodes) Grading and scoring system was adopted for assessing each clinical feature before the commencement of trial and after completion of the trial.

TABLE.1

Assessment criteria	0	1	2	3
***Toda* (Pricking pain)**	Absent	Pain during talking	Continuous pain	Severe pain- can't open the mouth
***Daah* (Burning sensation)**	No burning sensation	Occasional localized burning sensation	Burning sensation throughout the day but tolerable	Intolerable generalized burning sensation throughout the day
Galoprodh[3]	No difficulty in	Difficulty in	Unable to swal-	Unable to open mouth completely due to

(Dysphagia)	swallowing	swallowing solid matters	low even saliva	severe pain
***Mukhdaurgandhya* (Halitosis)**	Halitosis absent	Halitosis presents only when mouth is open completely	Halitosis present during yawning	Halitosis presents even during talking
Sore throat	No sore throat	Sore throat without pain	Sore throat with intermittent pain	Sore throat with continuous pain
***Jwara* (Fever)**	Normal body temperature	98.6-100 ºF	100-101 ºF	101-102 ºF
Hoarseness of voice (Swara bheda)	No hoarseness	Hoarseness after long and loud talk	Hoarseness throughout the day but no difficulty in speech	Hoarseness throughout the day with difficulty in speech
***Kasa* (Cough)**	No cough	Cough while talking	Cough more frequently	Cough Present all time
***Kathin shofa*[4] (Inflammation)**	Located within tonsillasr fossa	Tonsillar hypertrophy till the brim of tonsillar fossa	Tonsillar hypertrophies extend beyond the pillars but not touching each other	Tonsils in contact with each other
***Lasika granthi vriddhi* (Enlarged jugulo digastric lymph nodes)**	No palpable lymph nodes	Palpable lymph nodes	Palpable tender lymph nodes	Enlargement bilateral, visible, tender and prominent

(2) Objective parameters: The objective assessment was done on the basis of haematological parameters. - Hb%, TLC, DLC, ESR **Investigations-** Hb% TLC, DLC, ESR

ADR: no ADR was reported during the entire trial period.

Analysis of data and use of statistical methods

Observations documented during the study were analysed and findings were evaluated with the help of the following statistical methods to establish the efficacy by using SPSS software.

1. Wilcoxon Signed Rank test was applied to test the significance difference between the median of subjective parameters within the group.
2. Paired t-Test was applied to test the significance difference between the median of objective parameters within the group.

Level of Significance- Not significant - ($p>0.05$), Significant - ($p<0.001$- >0.05), Highly Significant -($p<0.001$).

The overall effect of therapy was calculated on the basis of percentage. If patients were relieved 100% then they were considered as cured, if there was 75-99% relief it was considered as marked improvement, 50-75% relief was considered as moderate improvement, 25-50% relief mild improvement and less than 25% relief was considered as no improvement.

OBSERVTION AND RESULTS Total 42 patients between 3-12 years of age having clinical features *Tundikeri* were enrolled in this research study out of which two patients left against medical advice and 40 patients completed the trial period of 45 days. Considering the inclusion and exclusion criteria, the whole study is divided under the following headings: 1. Demographic profile 2. Clinical profile **Demographic profile-** Out of 42 cases 20 patients (48%)

were between the age group of 6-9 years, 13 patients (31%) were between 3-5 years and 9 (21%) patients between 10-12 years. 23 (55%) patients were male and 19 (45%) of them were females. 28 (67%) patients belonged to Hindu community while 14 (33%) were from Muslim community. Most of the patients i.e., 31 (74%) belonged to Middle class while 11 patients (26%) were from lower class of the society. 32 (76%) patients were from urban areas and the remaining 10 (24%) were from rural areas. All the patients were immunized appropriately up to their age. Maximum number of patients i.e., 21 (50%) had reduced appetite, 17 (40%) patients had average appetite while 4 (10%) patients had good appetite. Mixed dietary habits were found in 24 (57%) patients and 18 (43%) patients had vegetarian dietary habits. 39 patients (93%) were full term normal vaginal delivered at hospital, 2 (5%) patients were delivered at home and 1 (2%) patient was born through LSCS. 23 (55%) patients had regular bowel habits while 9 patients (21%) had irregular bowel and 10 (24%) had constipated bowel habits. 32 patients had sound sleep (76%) and 10 (24%) had disturbed sleep. **Clinical Profile-** Among 42 cases of *Tundikeri*, the symptoms of *Toda* (Pricking pain) and *Kathin Shofa* were present in all 42 patients (100%), followed by *Galaoprodha* (Dysphagia) in 40 (95.23%) patients, sore throat in 40 (95.23%), *Kasa* (Cough) in 22 (52.38%), *Lasika granthi vriddhi* (Enlarged jugulo diagastric lymph nodes) was seen in 21 (50%) patients, *Daaha* (Burning sensation) in 14 patients (33.3%), *Mukhadaurgandhya* (Halitosis) was found in 5 patients (11.9%) and *Swarabheda* (Hoareseness of voice) in 5 (11.9%) patients. Out of 42 patients, ESR was found elevated in 33 (78.57%) patients while normal in 9 patients i.e., 21.42%. Out of 42 patients 35 patients (83.3%) had Hb between 11-12gm/dl, 5 patients (11.9%) had Hb% between 12-14gm/dl and 2 patients (4.76%) had Hb between 8-10gm/dl. TLC was found normal (4000-11000/cumm) in all 42 (100%) patients. Among 42 patients, only Eosinophils were elevated in 5 (11.9%) patients while rest were normal.

RESULTS

Statistically highly significant results were found in subjective parameters like *Toda*, *Galoprodha*, Sore throat as value of p was <0.001. Statistically significant result was found in subjective parameters like *Daha*, *Kasa* and *Swarabheda* as P-value was <0.05. The P-Value for *Mukhadaurgandhya* and *Jwara* is more than 0.05, hence we can conclude that, effect observed was not significant.

Effect on clinical features-

TABLE. 2.

Signs and Symptoms	Mean		Median		SD		Wilcoxon W	P-Value	% Effect	Result
	BT	AT	BT	AT	BT	AT				
Toda	2.20	0.63	2.00	0.00	0.46	0.87	-5.214[b]	0.0000002	71.59	Sig
Daha	0.53	0.05	0.00	0.00	0.82	0.32	-3.153[b]	0.0016162	90.48	Sig
Galoprodh	1.73	0.53	2.00	0.00	0.60	0.68	-5.090[b]	0.0000004	69.57	Sig
Kasa	1.13	0.65	1.00	0.00	1.16	0.86	-3.002[b]	0.0026861	42.22	Sig
Sore Throat	2.45	0.73	3.00	0.00	0.85	0.88	-5.083[b]	0.0000004	70.41	Sig
Jwara	0.00	0.00	0.00	0.00	0.00	0.00	.000[c]	1.0000000	0.00	NS
Mukhdaurgandhya	0.28	0.18	0.00	0.00	0.82	0.59	-1.633[b]	0.1024704	36.36	NS
Swarabheda	0.28	0.03	0.00	0.00	0.85	0.16	-3.002[b]	0.0033178	90.91	Sig
Kathin Shofa	1.60	0.70	2.00	1.00	0.55	0.65	-4.976[b]	0.0000006	56.25	Sig
Lasika Granthi Vriddhi	0.98	0.58	0.50	0.00	1.03	0.71	-3.358[b]	0.0007859	41.03	Sig

Percentage effect of therapy

The percentage relief in all subjective parameters is as follows: *Toda* (pricking pain) 71.59 %, *Daha* (Burning sensation) 90.48%, *Galoprodh* (Dysphagia) 69.57%, *Kasa* (Cough) 42.22%, Sore Throat 70.41%, *Jwara* (Fever)0.00%, *Mukhdaurgandhya* (Halitosis) 36.36%, *Swarabheda* (Hoarseness of voice) 90.91%, *Kathin Shofa* (Inflammation) 56.25%, *Lasika Granthi Vriddhi* (Enlarged jugulodiagastric lymph nodes) 41.03%, average percentage effect of drug was 63.20%.

Effect of therapy on Lab parameters

Statistically highly significant result was found in objective parameters like *Kathin Shofa, Lasika granthi vriddhi* as value of p was <0.001, significant result was found in Hb, TLC, Neutrophils, Monocytes, Eosinophils and ESR, non-significant result was found in Lymphocytes and Basophils. The percentage relief in all objective parameters is as follows: Hb% (1.02%), T.L.C (6.77%), Eosinophil (33.73%), Monocyte (13.64%), Lymphocyte (2.04%), Neutrophil (1.02%), ESR (18.29%). In objective parameters, statistically significant results were found in Hb, TLC, Neutrophils, Monocytes, Eosinophils and ESR.

Overall effect of the therapy- Marked improvement was seen in 16 (40%) patients, moderate improvement in 9 (22.5%) patients, mild improvement was seen in 12 (30%) patients and no improvement was seen in 3 (7.5%) patients**.**

DISCUSSION

Tonsillitis exerts an untoward effect on the entire growth, development and psychology of the child. These factors grouped together result in recurrent episodes of tonsillitis. The study was conducted on 40 patients after initial screening (based on classical features of *Tundikeri roga* and lab parameters). Patients were recruited and administered with *Kanchnar* syrup according to set dosage thrice daily for 45 days. The assessment of patients was done on the 15th, 30th and 45th day. Two follow up were taken on the 15th day and 45th day after completion of the trial. The drug has shown a significant role in reducing symptoms of *Tundikeri* roga. The average percent effect of trial drug was 63.20%. The drug has shown a highly significant role in reducing symptoms like *Toda, Galoprodha,* sore throat. Statistically significant results were found in subjective parameters like *Daha, Kasa* and *Swarabheda*. No change was seen in parameters like *Mukhadaurgandhya* and *Jwara*. Statistically highly significant results were found in objective parameters like *Kathin Shofa, Lasika granthi vriddhi*. Significant results were found in Hb, TLC, Neutrophils, Monocytes, Eosinophils and ESR. Statistically nonsignificant results were found in Lymphocytes and Basophils.

Tundikeri occurs due to vitiation of *Kapha* and *Rakta* dosha and *Kanchnar* has *Kapha* and *Pitta shamak* properties due to its *Kashaya rasa, Laghu Ruksha guna, Sheeta veerya, Katu vipaka.*[5]

Properties like *Lekhan, Vrana ropak, Dosha shodhak, Kaphahara* and *Kled shoshak* decrease inflammation and size of tonsil and hence relieves symptoms like *Toda, Galoprodh,* sore throat, *Lasika granthi vriddhi, Daha, Kasa* and *Swarabheda*. *Kanchnar* has *Shothhar, Gandmala Nashak, Lasikagranthi Vriddhi har, Kasa har, Lekhan, Medohar, Kapha Pitta shamak, Vranashodhak* and *Vrana ropaka* properties. *Kashaya Rasa* has *Sangrahi, Vrana ropak, Stambhak, Dosha shodhak, Lekhak, Kled shoshak* properties which subsides the vitiated *Pitta, Kapha Dosha* and acts as *Daaha Shamak*. *Laghu* and *Ruksha Guna* absorbs *Kleda* and regulates *Jatharagni, Ruksha Guna* has *Lekhan, Kaphahara* and *Stambhana* properties thereby reducing the size of the tonsil. *Sheeta Virya* is dominated by *Jala, Prithvi Mahabhuta* so acts as *Daha shamak, Katu vipaka* subsides vitiated *Kapha dosha* hence, it is responsible for *Agni deepana* and *Amapachana*.

CONCLUSION

Kanchnar syrup showed statistically significant results on most of the subjective parameters. The syrup is found to be 63.20% effective in management of *Tundikeri*. During the trial period no ADR was observed. No side effects were observed in patients during and after the course of treatment. So, it can be concluded that the patients of *Tundiekri* (Tonsillitis)

can be effectively managed through *Ayurveda* without fear of side effects. Hence, the clinical study clearly indicates that the herbal formulation *Kanchnar* syrup is an effective, well-tolerated, and clinically safe formulation for the treatment of *Tundikeri roga* in children.

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Source of Support: Nil
Conflict of Interest: None Declared

How to cite this URL: Nandini Shah et al: An open label clinical trial of kanchnar syrup in tundikeri (tonsillitis). International Ayurvedic Medical Journal {online} 2023 {cited August 2023} Available from: http://www.iamj.in/posts/images/upload/1820_1826.pdf