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Efficacy of Tonsenorm Compound in the management of *Tundikeri* with special reference to Chronic Tonsillitis in Children

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ABSTRACT

Introduction: Tonsillitis is one of the most common infectious conditions in the paediatric age group. Symptoms such as pain or tenderness in the throat, fever, tonsillar swelling with a white or yellow coating, painful blisters or ulcers on the throat, headache, loss of appetite, ear pain, trouble swallowing, bad breath, a scratchy or muffled voice, and a stiff neck mentioned in this disease. *Ayurveda* addresses the problem of *Tundikeri*, similar to chronic tonsillitis with internal medicines and external therapies. Tonsenorm compound is such a herbomineral formulation formulated with extract a set of nine drugs. **Aim** of the proposed study is to evaluate the efficacy of the Tonsenorm compound in *Tundikeri*. **Material and Methods:** The present study is planned to be conducted under the strict protocol of an open-label clinical trial, in 40 patients. Tonsenorm compound will be given for 60 days at 250 mg thrice a day. Assessment of the patients will be done on the basis of subjective parameters with a grading/scoring system on every 15th day during the study, with a post-intervention follow-up after 1 month. **Results:** The result will show the effectiveness of the trial drugs, which will be economical and safe for long-term use in the patients of *Tundikeri*. **Discussion & Conclusion:** The outcome of this herbomineral drug change in scoring/ grading of symptoms of *Tundikeri* /chronic tonsillitis (will be assess after the completion of the trial work).

Key words: Tonsenorm compound, Tundikeri, Chronic tonsillitis.

INTRODUCTION

Tonsillitis is an inflammation of the pharyngeal tonsils. The name "*Tundikeri*" in *Ayurveda* refers to a condition

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that affects the oral cavity, which is described as swelling at the base of the temporomandibular joint that resembles a cotton fruit. [1] The inflammation may affect other areas of the back of the throat, including the adenoids and the lingual tonsils.[2] In children, chronic tonsillitis is a very common problem that peaks between the ages of 3 and 10 and then subsides. [3],[4] Tonsillitis is categorized into acute, chronic, recurrent and severe. Recurrent tonsillitis is defined by arbitrary criteria that have recently been adopted as a measure of severity. Severe tonsillitis is defined as five or more episodes of tonsillitis in a year, symptoms lasting at least a year, and episodes that are incapacitating and interfere with daily activities. [5] Chronic tonsillitis has a global frequency of 4 to 15%; according to various authors, accounts for 23.7 percent of all pharyngeal

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disorders. [6] In one of the studies on morbidity patterns in rural areas of Jaipur district, Rajasthan, it was found that patients with URTI and tonsillitis attending the OPD during 2013 were 21.06%.^[7] The causative factors of tonsillitis are both viral and bacterial. Viral infection is more common in younger children, and bacterial tonsillitis is mainly caused by group-A beta hemolytic Streptococcus pyogenes (GABHS). Streptococcus species usually affect children aged 5-15 years.[8] Symptoms include pain or tenderness in the throat, fever, swollen tonsils with a white or yellow coating, painful blisters or ulcers on the throat, headache, and loss of appetite, ear pain, trouble swallowing, bad breath, a scratchy or muffled voice, and a stiff neck. [9] Tundikeri mentioned in Ayurveda classics is a similar disease condition in origin, sign, and symptoms to chronic Tonsillitis. Tundikeri is described in Sushruta Samhita's Mukharoaa Nidanasthan.[10] Mukharoga Chikitsasthan^[11] under chapters 16th and 22nd, respectively. According to *Madhava Nidan*, [12] Ashtang Samgraha^[13] and Ashtang Hridaya,^[14] Tundikeri is a large swelling caused by Kapha and Rakta with pricking pain, burning sensation, and suppuration. According to Acharya Sushruta, swelling in the throat located at the meeting place of the lower jaw, resembling the fruit of a Karpasa (cotton), slimy, with mild pain, and hard to touch, is known as *Tundikeri*.[15] Its signs and symptoms are Toda (pricking pain), Shopha (Tonsillar enlargement), Daha (burning sensation), and Prapaka (Inflammation).

Modern treatment options for tonsillitis have several limitations that hinder its effectiveness in providing comprehensive and long-term solutions. One major concern is the development of antibiotic resistance, resulting from the overuse of antibiotics to treat tonsillitis. This makes certain bacterial infections more challenging to treat, posing a significant problem for healthcare providers. Moreover, even after receiving treatment, patients may experience recurring episodes of tonsillitis, leading to a cycle of relief and relapse. The medications used to alleviate symptoms can also have adverse side effects, causing additional discomfort and health issues for patients. Otorhinolaryngologists generally recommend tonsillectomy for recurrent

attacks, but tonsillectomy has a profound detrimental effect on the local IgA response in preventing infection. To overcome these limitations, it is crucial for individuals experiencing tonsillitis to collaborate closely with their healthcare providers. By exploring alternative treatment options and adopting preventive measures, patients can work towards a more personalized approach to managing their condition effectively

Ayurveda offers sufficient references for treating Tundikeri based on Doshika predominance, symptoms, and indicators. [16] One of its treatments includes Bhedana**and Chedana*** by the help of Mandalagra instrument. Although there are lots of formulations available to manage and treat the disease tonsillitis in Ayurveda, it is always needed to develop such formulations that will be economical and safe for long-term use in the patients of Tundikeri. To overcome such clinical problems, limitations, and side effects, it becomes necessary to elucidate another safe and cost-effective drug therapy within the reach of the general population to treat tonsillitis (Tundikeri) and give better results. Thus, the prescribed medicine should be economical and easily available, so anyone can use it for a longer period of time to get rid of the disease. So, the Tonsenorm compound is proposed to evaluate its efficacy and utility in the treatment of Tundikeri (Tonsillitis).

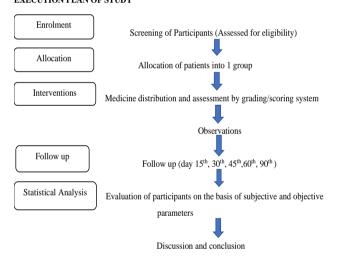
Tonsenorm Compound

S N	Name of Drug	Properties of drug		
N	ыц	Properties as per modern science	As per Ayurveda	
1.	Shirish	Antihistaminic ^[17] Immunomodulatory, ^{[18} []] Anti-microbial, ^[19]	Kasahar, ^[20] Shwasahar ^[21]	
2.	Guduchi	Immunomodulatory, ^{[22} []] Anti-inflammatory, Antimicrobial, Antiviral ^[23]	Tridoshashamak ^[24]	
3.	Ativisha	Analgesic, Anti- inflammatory ^[25]	Tridoshahar, Specially Kaphapittashamak, Shothahar ^[26]	

4.	Trikatu	Anti-inflammatory ^[27] Anti-allergic, ^[28] Antiviral, Expectorant, Carminative ^[29]	Shwasa Har ^[30] Deepan, Kphahar, Medohar ^[31]
5.	Gandha k	Antibacterial, Antifungal ^[32]	Kapha-vatashamak [33]
6.	Tankan	Anti-inflammatory, Healing properties ^[34]	Kasahar, Shwasahar, Kaphanissarak, Lekhana, Jatharagnideepak ^{[35}]
7.	Yashad	Anti-asthmatic ^{[36],[37]} Immunomodulatory ^[38]	Kasa-Shwasahar ^[39] Kaphapittanashak, Shleshmakala Sankochak ^[40]

Fig no. 1

EXECUTION PLAN OF STUDY



METHODOLOGY

The Following materials and methods will be adopted for conducting the present clinical trial:

Source: For the proposed clinical study, the patients will be selected from OPD and IPD of the Kaumarbhritya and Shalakya Tantra departments of the National Institute of Ayurveda, deemed to be The University (de-novo), Jaipur.

Sample Size: 40 Patients

Study Type: Open-label Clinical Trial.

Total Duration of Clinical Trial: 60 Days with a follow-

up period

Inclusion Criteria

- Children of either sex in the age group of 5 to 10 years.
- Patients presenting with symptoms of Tundikeri and/or Chronic tonsillitis.
- 3. Patients clinically having symptoms of chronic tonsillitis from grades 1 to 3.

Exclusion Criteria

- 1. Patients clinically having symptoms of chronic tonsillitis of grade 4.
- 2. Patients presenting with Acute pharyngotonsillitis.

Discontinuation Criteria: Parents/attendants are not willing to participate in or continue the treatment. Appearance of any additional acute sickness during the therapy. Patient develops severe complications during the course.

Administration of Drug

The subjects satisfying inclusion criteria will be given Tonsenorm compound.

Dose and Duration

- Dose Tonsenorm compound 250 mg- TID
- Time and Anupan / Sahapan Medicine will be given three times a day with Honey.
- Total Duration of Clinical trial 60 days. Patient will be assessed on every 15th day during the course of the trial.
- Follow-Up Period 1 month after completion of the clinical trial.

Trial Drug - Hypothetical Tonsenorm compound

SN	Name	Latin name	Part used	Volume in each Capsule
1.	Shirish	Albizia lebbeck	Stem bark	60 mg
2.	Guduchi	Tinospora cordifolia	Stem	50 mg
3.	Ativisha	Aconitum heterophyllum	Tuber	50 mg

Trikatu Zingiber officinale Rhizome 25 mg Piper longum Fruit Piper nigrum Fruit Shuddha 5. Sulphur 25 mg Gandhak 6. Tankan Na2B401lOH20 Bhasama 25 mg Yashad ZnO Bhasma 15 mg

Assessment criteria

The primary outcome will be assessed on the basis of the change in scoring/grading of symptoms of *Tundikeri* /chronic tonsillitis, and the secondary outcome will be assessed on the basis of the change in scoring/ grading of the size of the tonsillar mass. Objective Criteria will be used for the assessment of the tonsil's size (as per standard grading), CBC, ESR, LFT, and RFT.

Table 1: Dysphagia

Symptoms	Grading
No difficulty in swallowing	0
Patient feels difficulty in swallowing of solid diet	1
Difficult during taking semi solid diet	2
Difficulty during taking liquid diet	3

Table 2: Enlarged Lymph nodes

Symptoms	Grading
No palpable lymph nodes	0
Palpable lymph node unilateral	1
Palpable lymph node bilateral	2
Enlargement bilateral, visible and prominent	3

Table 3: Sore throat

Symptoms	Grade
No pain in throat	0

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Mild pain on swallowing the saliva

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Painful and moderate difficulty in swallowing the saliva	2
Patient cannot swallow the saliva	3

Table 4: Halitosis

Symptoms	Grade
Halitosis absent	0
Halitosis observed by others/ observer/ examiner	1
Halitosis observed by patient and observer	2

Table 5: Toda (pricking pain)

Symptoms	Grade
No pain	0
Mild tolerable pain	1
Moderate tolerable pain even during rest	2
Severe intolerable pain affecting routine work	3

Table 6: Daha (Burning sensation in throat)

Symptoms	Grade
No burning in throat	0
Mild burning after taking spicy food	1
Burning sensation after taking any food	2
Continuous burning throughout the day	3

Table 7: Congestion

Symptoms	Grade
No colour change	0
Congestion present only over peritonsillar surface	1
Congestion present on peritonsillar surface and both anterior and posterior pillars	2
Congestion present completely over oropharynx including palate	3

Table 8: Cough

Sign	Grade
Absent	0
Some time	1
Present occasionally	2
All time	3

Table 9: Follicles over the tonsils

Sign	Grade
Absent	0
1-5 Follicles	1
5-10 Follicles	2
More than 10 follicles	3

Table 10: Congestion over tonsils and pillars

Sign	Grade
Normal colour	0
Pinkish tonsils and pillars	1
Between 1 and 3rd	2
Reddened whole tonsil and pillar	3

Table 11: Debris over tonsils crypts

Sign	Grade
Absent	0
1-2 mm	1
3-5 mm	2
More than 5 mm	3

Table 12: Shopha (Tonsillar enlargement)

Sign	Grade
Tonsils are entirely within the tonsillar pillar or previously removed by surgery.	0
Tonsils occupy less than 25% of the lateral dimension of the oropharynx, as measured between the anterior tonsillar pillars (solid yellow arrow).	1

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Tonsils occupy 26 to 50% of the lateral dimension of the oropharynx.	2
Tonsils occupy 51 to 75% of the lateral dimension of the oropharynx.	3
Tonsils occupy more than 75% of the lateral dimension of the oropharynx.	4

RESULT

Enrolling of the subject in current study will start from the August 2023 and the study will be completed within 6 months of the commencement of the trial. The assessment of the subjective criteria for signs and symptoms of *Tundikeri* (Chronic Tonsillitis) *Ayurveda* and modern parameters will be adopted. The results will be obtained through the grading and scoring system of the parameters. To determine efficacy, observations recorded throughout the study will be reviewed, and findings will be assessed using statistical analysis for Objective criteria using a paired T test and a Wilcoxon paired Rank test for Subjective criteria. The expected result of this study: the Tonsenorm compound might be effective in relieving the signs and symptoms of *Tundikeri* (chronic tonsillitis).

DISCUSSION

Tonsillitis, characterized by inflammation of the tonsils due to a bacterial infection known as chronic tonsillitis, is often linked to the common cold. While the symptoms are typically mild, patients may experience swollen tonsils coated with a sore throat following a streptococcal infection, accompanied by feelings of unwellness, fever, and bad breath. The conventional approach to treating chronic tonsillitis involves the use medications with anti-inflammatory immunomodulatory properties, but these medications have their own limitations. Ayurveda describes it under Tundikeri disease which is Shopha, Ruja, Daha, Prapak Yukta. There is predominance of Kapha – Rakta Dosha. The management of *Tundikeri in Ayurveda* includes various formulations for oral intake and different procedures like Pratisarsan, Chedan, Bhedana etc. In this context, recent experimental findings and the principles of Ayurveda have shed light on the potential benefits of Tonsenorm, a compound that boasts

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various ingredients with anti-inflammatory, antimicrobial, antiviral, and immunomodulatory properties.

The Properties of Tonsenorm's Ingredients:

- Shirish and Guduchi: Both possess Tridosha-Shamaka^{[22],[25]} properties, helping to balance the three Doshas - Vata, Pitta, and Kapha. These herbs may play a crucial role in alleviating inflammation associated with chronic tonsillitis.
- Ativisha: Known for its Kapha-Pitta-Shamaka and Shothahar^[27] properties, Ativisha might aid in reducing the swelling of the tonsils and providing relief from discomfort.
- Trikatu: With anti-inflammatory, expectorant, and carminative properties, Trikatu acts as a Deepana and Pachana, [32] stimulating digestion and aiding in the elimination of toxins. Additionally, its Shothahara (Anti-inflammatory) [28] effect in Tundikeri may contribute to alleviating tonsillar inflammation.
- Gandhaka: This ingredient exhibits antibacterial, antifungal, and Kapha-Vata-Shamaka^[34] properties, making it a potential candidate for reducing the size and pain associated with tonsillar masses.
- Tankan Bhasma: Renowned for its Kasahara, Shwashara, Kaphanissaraka, Lekhana, and Jatharagnideepaka^[36] properties, Tankan Bhasma possesses healing and anti-inflammatory^[35] characteristics that could aid in reducing tonsillar swelling.
- Yashad Bhasma: Known for its Kaphapittanashaka and Shleshmakala Sankochaka^[41] effects, Yashad Bhasma may further contribute to managing inflammation and toning down the symptoms of chronic tonsillitis.

The Potential Benefits of Tonsenorm for Chronic Tonsillitis: Drawing from *Ayurvedic* principles and recent experimental findings, Tonsenorm emerges as a promising solution for chronic tonsillitis. Its combination of ingredients with anti-inflammatory,

antimicrobial, antiviral, and immunomodulatory ^{[23],[24]} properties present a comprehensive approach to tackle the infection and associated symptoms effectively.

- Anti-inflammatory Action: The presence of various anti-inflammatory agents in Tonsenorm may help alleviate the swelling and discomfort experienced during chronic tonsillitis, providing relief to patients.
- Immunomodulatory effect: By influencing the immune response, Tonsenorm could potentially enhance the body's ability to fight off the bacterial infection, promoting a faster recovery.
- Antimicrobial and Antiviral Properties: The antimicrobial and antiviral properties of Tonsenorm's components may contribute to combatting the underlying bacterial infection, which is often triggered by streptococcal bacteria.

CONCLUSION

Tonsenorm, with its unique blend of Ayurvedic Tridosha-Shamak, ingredients possessing antiinflammatory, antimicrobial, antiviral, and immunomodulatory properties, presents a promising alternative for managing chronic tonsillitis. While further research and clinical studies are warranted to establish its efficacy and safety definitively, the compound holds the potential to offer relief and aid in the recovery of individuals suffering from this condition. As always, it is advisable for patients to consult with a healthcare professional before considering any new treatment approach.

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