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Efficacy of Eladi Choorna Lozenges in Management of Tundikeri, Chronic Tonsillitis in Children Aged 5-15 Years: An Open Labelled Randomized Controlled Trial

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ABSTRACT

Introduction: *Tundikeri*, described under *Talukantagata Roga* in *Ayurveda*, is characterized by inflammatory swelling at the base of *Hanusandhi* and is clinically comparable to tonsillitis. Tonsillitis is a prevalent childhood disorder in India and contributes substantially to recurrent morbidity and healthcare burden. Conventional management relies on antibiotics and surgical intervention, both of which raise concerns regarding immune modulation and long-term outcomes. *Ayurveda* describes multiple therapeutic approaches for *Mukha Roga*, including local and systemic interventions. *Eladi Choorna*, a classical formulation indicated in *Kantagata Roga*, was modified into a lozenge form to improve palatability and ease of administration in children, with the objective of evaluating its role as a safe and effective palliative management in *Tundikeri.*

Methods: The study is open labelled randomized clinical trial, which will be carried out at the tertiary *Ayurveda* hospital, Shri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital, Bengaluru, recruiting 39 children with *Tundikeri,* Chronic Tonsillitis. Group A will be administered *Eladi choorna* lozenges and Group B will be administered *Pippali choorna* lozenges at age specific dose for period of 21 days. The overall improvement will be assessed in both groups based on Brodsky grading scale and subjective grading parameters.

Results: Data will be collected using a specially designed Case Report Form (CRF) with standardised assessment scales and analysed using MS Excel and SPSS version 26. The results will be kept confidential and disseminated through peer-reviewed journal publications.

Discussion: Considering the high prevalence and recurrent nature of tonsillitis in children, along with concerns related to antibiotic overuse and surgical management, there is a need for safe, acceptable, and sustainable therapeutic options. *Ayurveda* describes several local and systemic interventions for *Tundikeri*. Modifying *Eladi Choorna*, a classical formulation indicated in *Kantagata Roga*, into a lozenge form aims to improve palatability, compliance, and localized drug action in pediatric patients. The present study was undertaken to evaluate this modified formulation in the management of Tundikeri.

Keywords: *Ayurveda, Balaroga*, Chronic tonsillitis*, Shamana chikitsa, Tundikeri*

BACKGROUND AND RATIONALE

Tundikeri is described under *Talukantagata Roga*,[1,2] characterized by *Shotha* resembling a cotton fruit (*Vanakarpasa Phala*) at the base of *Hanusandhi* (temporomandibular joint).[1] It often aggravates by poor dietary and lifestyle habits, leading to *Kapha Prakopa* and *Rakta Dushti.*[2] Based on presenting symptoms, it can be correlated with tonsillitis in contemporary science, which involves inflammation of the palatine tonsils and may extend to the adenoids and lingual tonsils.[3]

Tonsilitis is one of the most common encountered childhood disorders[4] with approximate 15% of family doctor visits, about 1 in 10 paediatricians visit per year.[5] It occurs rarely below 2 years and has high incidence in India accounting 4.2% to 13.7%, 12% [6] in southern India and around 2,00,000 tonsillectomies performed annually, increasing healthcare burden.[7]

The treatment of tonsillitis primarily involves antibiotics and supportive care to reduce inflammation and infection. However, if potential complications arises, tonsillectomy is considered as gold standard treatment.[3] Both treatments can impact immune system. Studies shows that tonsillectomy increases the risk of allergy, respiratory and infectious diseases later in life, highlighting the need for alternative treatment.[8] Thus, *Ayurveda* offers a wide range of treatment as explained in *Mukha Roga,* such as *Shodhana, Shamana, Kavala, Gandusha, Pratisarana, Nasya, Dhoomapana,* and *Mukhaprakshalana Chikitsa.*[9]

Despite numerous studies documenting the efficacy of Ayurvedic treatments for *Tundikeri* with classical formulations, the magnitude of the problem persists. To address this, the present study aims to develop a more sustainable, standardized, and palatable treatment approach for children suffering from tonsillitis.

Pippali Choorna lozenges has been already studied and proven effective but minimal improvements in episodes of cough and halitosis.[10] Thus, *Eladi Choorna,* a classical formulation indicated in *Kantagata Roga*, is modified to lozenges to enhance palatability and ease administration in children. *Eladi Choorna* has *Tridosha Hara, Vedanasthapana*, *Lekhana*, *Kaphanisarana* and *Mukhashodhana* properties. Volatile oil in Ela, pipperine in *Pippali,* and cinnamaldehyde in *Twak* possess anti-inflammatory, anti-bacterial properties and immunomodulatory effects.[11,12,13] Cineol offers mucolytic, anti-inflammatory properties.[13] Given the therapeutic properties of its ingredients, *Eladi Choorna* is expected to be a safe and effective palliative approach for managing *Tundikeri.* If proven effective, it could significantly contribute to the medical management of tonsillitis in children.

STUDY OBJECTIVES

PRIMARY OBJECTIVE:

To evaluate the efficacy of oral administration of *Eladi Choorna* lozenges in reduction of signs and symptoms of *Tundikeri*, chronic tonsillitis using a subjective graded parameter.[10]

To assess the reduction in the tonsillar enlargement based on the Brodsky grading scale.[14]

SECONDARY OBJECTIVE:

To compare the efficacy of oral administration of *Eladi Choorna* lozenges and *Pippali Choorna* Lozenges in management of *Tundikeri* using Brodsky grading scale[14] and subjective graded parameter.[10]

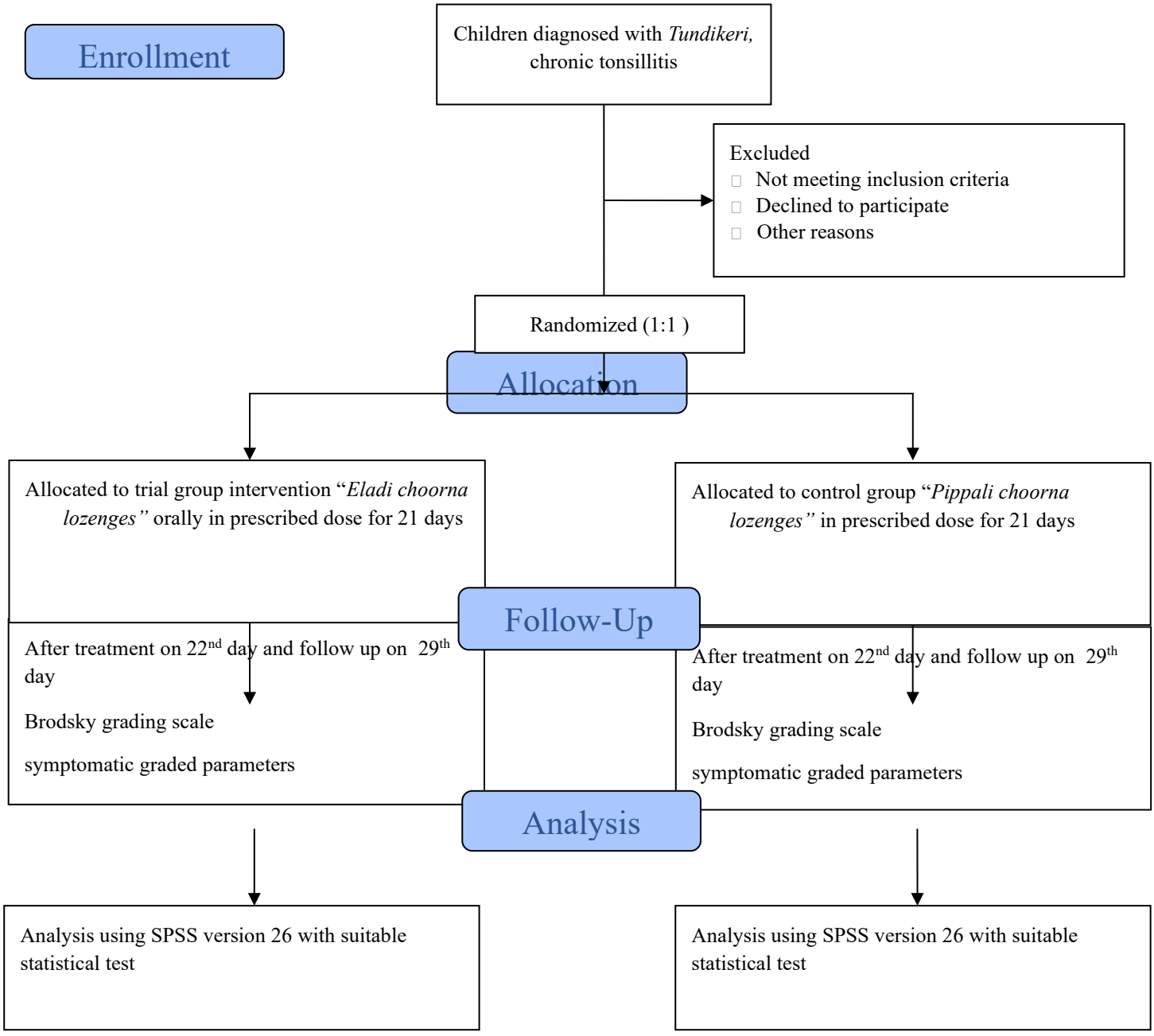
TRIAL DESIGN AND CLINICAL SOURCE

Study Design: Prospective, monocentric, double arm, open label clinical study

Study setting: Children will be recruited from the Outpatient department and Inpatient department of

Kaumarabhritya at Tertiary care Ayurvedic hospital - Shri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital, Bengaluru.
Study Duration: 29 Days
Intervention Period: 21 Days
Follow Up: 7 days

Figure No. 1: Consort flow diagram of the study



ELIGIBILITY CRITERIA: ICD-11 CODE: CA0F
NAMC CODE: GE-3
ELIGIBILITY CRITERIA: Eligible children will be enrolled for the study after screening in the study site.

INCLUSION CRITERIA:

1. Children of either gender aged 5-15 years fulfilling the diagnostic criteria.
2. Willingness and ability of the parents to comply with the study protocol.
3. Who are willing to participate in the study with signed informed consent.

EXCLUSION CRITERIA

1. Children with acute tonsilitis, acute pharyngitis, pneumonia, bronchitis, tuberculosis, otitis media requiring immediate systemic antibiotic therapy.
2. Suffering from complications like peritonsillar abscess, parapharyngeal abscess or any other systemic illness.
3. Children showing signs and symptoms of *Tundikeri* for a duration of less than 3 months.
4. With Grade IV tonsilitis as per the Brodsky Grading scale.

STUDY SETTING AND PARTICIPANTS

Minimum 38 children attaining outpatient department and inpatient Department of *Kaumarabhritya* of Shri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital (SDMIAH), Bengaluru who are fulfilling the inclusion criteria and willing to participate in the study under the parental assent or consent will be recruited for study for a period of 28 days. 38 children will be randomly divided into 2 groups namely Group A (19 children) and Group B (19 children).

Group A (trial group) will be administered with *Eladi Choorna* lozenges in a dose of 2 gm TID for 5-10 years and 4gm TID for 11-15 years after food thrice daily. Group B (control drug) will be administered with *Pippali Choorna* lozenges in a dose of 2 gm TID for 5-10 years and 4 gm TID for 11-15 years after food thrice daily. The overall improvement will be assessed in both groups based on Brodsky grading scale and subjective grading on the day of recruitment (BT), 22nd day(AT) and 29th day (FU). Statistical analysis will be done by considering the data of day 0(BT), day 22 (AT),and day 29 (FU) by suitable statistical tests.

DIAGNOSTIC CRITERIA

The children will be diagnosed with *Tundikeri,* chronic tonsillitis based on the presence of atleast 3 or more clinical signs and symptoms for a duration of 3 months. .

- *Gala shopha*(Enlargement of tonsils)
- *Gala prapaka* (Hyperemia)
- *Gala daha* (sore throat)
- *Jwara* (Fever)
- *Gala toda* (Pain in the throat)
- Halitosis
- Jugulodigastric Lymph Node Enlargement
- Cough (productive/non productive)

INTERVENTIONS:

Upon enrollment, children will receive either the intervention medicine or control group medicine based on allocation.

Table No. 2 TRIAL DRUG – ELADI CHOORNA LOZENGES

AGE	DOSE	TIME OF ADMINISTRATION	ANUPANA	DURATION	ASSESSMENT
5-10 years	2 gm TID orally in lozenges form	Thrice a day, after food	-	Intervention- 21 days Follow up – 7 days	0th day- before treatment 14th Day- monitoring day 22nd day – After treatment 29th day- Follow up
11-15 years	4 gm TID orally in lozenges form				

Table No. 3 CONTROL DRUG – PIPPALI CHOORNA LOZENGES

AGE	DOSE	TIME OF ADMINISTRATION	ANUPANA	DURATION	ASSESSMENT
5-10 years	2 gm TID orally in lozenges form	Thrice a day, after food	-	Intervention- 21 days Follow up – 7 days	0th day- before treatment 14th Day- monitoring day 22nd day – After treatment 29th day- Follow up
11-15 years	4 gm TID orally in lozenges form				

CONCOMITTANT CARE:

1. Standard dietary advice.
2. Avoidance of allergen food, cold, junk, oily foods.

WITHDRAWL CRITERIA

The participants will be allowed to withdraw from the trial if there is any major ailment necessitating the institution of new modalities of treatment. The decision to withdraw a participant from the trial will be taken

by the principal investigator with proper justification and a formal information to the Ethics committee within two working days.

OUTCOMES

PRIMARY OUTCOME MEASURES:

- Clinically significant improvement in the signs and symptoms of Tundikeri, chronic tonsillitis using symptomatic graded parameter.[10]
- Reduction in tonsillar enlargement using Brodsky grading scale.[14]

SECONDARY OUTCOME MEASURES:

To compare the efficacy of oral administration of *Eladi choorna* lozenges and *Pippali choorna* lozenges in management of *Tundikeri,* chronic tonsillitis in children using Brodsky grading scale[14] and symptomatic graded parameter.[10]

Participant timeline: The schedule of clinical assessment performed at each visit is exhibited in table

Study phase	**Screening**	**Baseline BT**	**Interim analysis 14th day**	**After treatment**	**Follow up**
consent/Assent	✓				
clinical Assessment		✓		✓	✓
Intervention		✓	✓	✓	
outcome Assessment				✓	✓
follow up Analysis					✓

SAMPLE SIZE

The sample size was calculated using Standard Deviation from previous study using formula N = 2 (SD)2 x (Z (1-α) + Zβ)2 / d2

This generates the minimum sample of 17 children in each arm.

Considering 10% dropout rate, sample size is taken as 19 in each arm.

A total of 38 participants will be recruited based on feasibility and previous study[15] standard deviation.

Trial group	Group A – Eladi choorna lozenges	19 children
Control group	Group B – Pippali choorna lozenges	19 children

RECRUITMENT

The study will recruit children between 5-15 years of age, of either gender, presenting with signs and symptoms of Tundikeri (chronic tonsillitis from the outpatient department and inpatient department of Kaumarabhritya at Shri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital, Bengaluru. Both the trial group and control group will be recruited from the same population using the same inclusion and exclusion criteria.

ASSIGNMENT OF INTERVENTION

ALLOCATION

Sequence generation: Computer generated random allocation will be used to assign participants to either the trial group or control group.

Allocation concealment mechanism: Random allocation using computer generated random tickets which will be kept labeled in a sealed cover.

Implementation : The sealed covers containing the random tickets will be opened in front of guide at the start of the intervention.

Blinding : Open labelled study where parents/children will be informed about group assignment with treatment, additionally researcher will also be aware of group allocation with treatment allotted.

DATA COLLECTION AND MANAGEMENT

Data will be collected using a specially designed Case Report Form (CRF) that incorporates assessment scales. The researcher will enter the collected data into the CRF, which will then be transferred to MS office excel and SPSS version 26 for statistical analysis.

For statistical analysis, the data will be obtained using Case Report Form (CRF) designed by incorporating all aspects for the study and will be compiled on to a MS Office Excel Sheet. Data will be tabulated and analysed using SPSS (Statistical package for social sciences) version 26.

STATISTICAL ANALYSIS

Both descriptive and inferential statistics will be used to analyze the collected data. Descriptive Statistics will be used to summarize the demographic data and other relevant information, expressed in frequency (f), percentile (%), range and Median. Ordinal data will be expressed in mean, standard deviation and standard error. The Shapiro Wilk test will be used to assess normality, and based on the results, either parametric test or non-parametric test will be employed. For inferential statistics, the study will analyze both qualitative and quantitative data. A significance level of $p < 0.05$ will be used. Non-parametric tests, including Wilcoxon- signed rank test, will be used for within-group comparisons, while the Mann-Whitney U test will be used for between-group comparisons. Parametric tests, such as paired t-tests and unpaired t-tests, will also be employed. The magnitude of the tests will be evaluated using Cohen's D effect size. All statistical analyses will be performed using SPSS version 26

DATA MANAGEMENT

The researcher and guide will monitor the study data and it will be collected, recorded, stored and managed systematically to ensure accuracy, confidentiality and integrity throughout study period. They will also conduct audits, perform interim analysis and report any ADR or changes in study protocol to the Ethical Review Board via principal investigator. The investigator may terminate the participant from the study if their continued participation poses a risk to their safety or wellbeing. Specifically, withdrawal may occur if adverse effects require immediate attention or if the investigator determines that remaining in the study could cause harm to the participant. All study data will be preserved for a minimum period as per IEC policy.

SAFETY MEASURES AND MANAGING ADVERSE EFFECTS

Although the study protocol is expected to be safe for children, the monitoring team will closely track any

unexpected occurrences during the intervention period. In the event of an adverse reaction, the relevant authority will be promptly informed. Parents / guardians will record any issues in their log and notify the principal investigator. All significant adverse events will be documented and published in final record.

ETHICS AND DISSEMINATION

Research ethics approval

On July 16 2025, the Institutional Ethics Committee of Shri Dharmasthala Manjunatheshwara Institute of Ayurveda and Hospital (SDMIAH) granted the trial ethical approval (SDMIAH/IEC/18/2025). On 09/02/2026, the trial has been registered prospectively with the Clinical Trial Registry India (CTRI) (CTRI/2026/02/103396). Confidentiality and anonymity will be maintained throughout the study. Upon completion of the trial, the anonymized data will be made accessible to the primary investigator, data auditors ensuring transparency and accountability.

Protocol amendments

Any modifications to the study protocol will be communicated to relevant authority inclusive of investigator, guide, Institutional ethics committee (IEC), participant and their family and trial registry (CTRI) as per protocol amendement. All proposed changes will be documented, justified and will be submitted to IEC for review and approval prior to implementation.

Study recruitment status

Recruitment for the study is currently open and underway. As of now, subjects have successfully enrolled in the study.

Informed consent, Confidentiality and Access to data

Prior to enrolment, written informed consent/assent will be obtained from parents by designated investigator. The consent will be taken abiding the protocol and will ensure participant understanding of the study purpose, procedures, risk and benefits. Personal and medical information gathered during the study will be strictly confidential. Access to the information will be limited to authorised personnel, who may review records for specific purpose, including result analysis, ensuring study integrity by IEC members and rare court proceedings. Identity of child will remain anonymous and name will not be disclosed.

Ancillary care: Any illness during study period, whether related or unrelated to the present condition will be managed by standard appropriate medical care as per institution policy.

Post-trial care

In the event of any adverse event resulted from the trial participation, the researcher will ensure appropriate treatment or referral to guarantee necessary care. After study completion, participants were advised to follow dietary recommendations. However, no formal post-trial care was advised.

Dissemination policy

The study data will be published in indexed scientific journal and if feasible, may be presented at seminars / conference.

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